Operating instructions for measuring unit to determine the transcutaneous partial pressure of Oxygen - $tcpO_2$

Précise 8008

Table of Contents

1 Introduction

1.1 Intended use

The transcutaneous oxygen measurement unit **Précise 8008** is intended for the measurement partial pressure of oxygen, also known as $tcpO_2$, on the surface of the skin. The measurement values may be displayed and saved numerically or graphically.

The probe parameters, the measurement process, as well as the $tcpO_2$ measurement results can be saved onto a SD card. Therefore, you can reliably document every $tcpO_2$ measurement and process it at any time externally on a PC.

1.2 Functional description

The $tcpO_2$ measurement is a non-invasive procedure to determine the $tcpO_2$ of the tissue over the surface of the skin. During the procedure, the skin will be warmed up to from 37° up to 44°C.

The $tcpO_2$ measurement is based on the luminescence lifetime measurement. This is dependent on the oxygen partial pressure. Measurement preparations (e.g. changing electrolyte, covering the probe, etc.) are thus obsolete.

The probes are suited both for the determination as well as for monitoring of $tcpO_2$, as they are also applicable for long-term measurements.

1.3 Important usage and safety instructions

Before using the **Précise 8008**, make sure you have read and understood these operating instructions and observe them at all times.

The **Précise 8008** may only be used in accordance with the general provisions for the installation and operation of medical devices (§22 Medical Device Act). In accordance with §22, Para. 1, the user must be sure of its functional safety and proper condition.

When connecting additional devices, there is the possibility of exceeding permitted leakage currents. External electromagnetic interference poses no risk to the user.

The Précise 8008 must be checked and, if necessary, repaired by the authorised service technician if it has a damaged plug or cable, is not working properly, the device has been dropped, damaged or liquid has penetrated into the unit (see *5 Cleaning and maintenance* section).

The transcutaneous partial pressure of oxygen is dependent on the following conditions, among others:

- Measurement temperature selection
- Measurement site selection
- Age
- General physical health (e.g. fever)
- Smoking
- Coffee consumption
- Acclimatisation of the patient to the ambient temperature

Note that this compilation is not fully consolidated.

The **Précise 8008** is not a blood gas analyser. The probe is protected against defibrillator discharge. Use of the **Précise 8008** together with high frequency surgical devices may result in burns on the patient and damage to the probe. Only original components and spare parts must be used. Protect the **Précise 8008** from moisture and dampness. Authorised maintenance technicians must only open the device.

To ensure reliability and longevity of the **Précise 8008** it is recommended to **maintain the device unit and its probes once a year** by a medicap-authorised staff.

Remove the wall plug-in power supply if the Précise 8008 is not in use for longer periods. **Do not** place adhesive tape or similar on the probe surface.

IMPORTANT!

Insert or remove the probe modules ONLY in the de-energised state – the Précise 8008 must be SWITCHED OFF.

Do not expose the probes to direct sunlight or UV radiation.

1.4 Symbols

ON / OFF:
The device can be switched ON and OFF or the ongoing measurement can be finished

PLAY:
The measurement begins

STOP:
The measurement can be finished

BACK:
One may return to the previous menu without changing anything

SAVE:
The measurement can be saved

SETTINGS:
Various parameters can be set

LOAD DATA:
On the SD card saved data can be loaded

GRAPHIC:
The graphical measurement view can be entered

ZOOM-IN:
The selected image section can be enlarged

ZOOM-OUT:
The enlarged image section is turned off and the original image appears

2 Preparation

2.1 General

Touch screen:

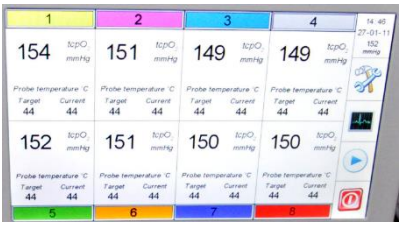
Different items in the menu can be selected or confirmed by pressing the touch screen

Switching on:

Start the Précise 8008 by pressing the touch screen directly to enter the initial screen after the welcome menu.

Welcome menu screen:

Initial menu screen:

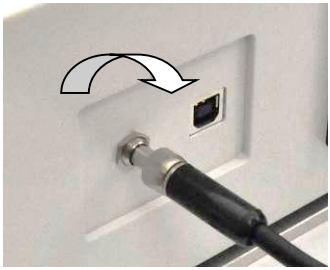


2.2 Probe assignment

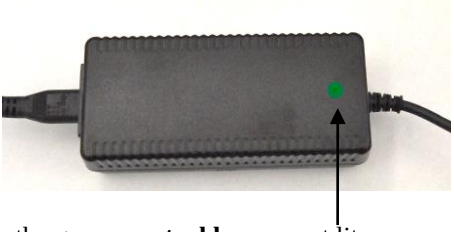
Up to eight probes can be connected simultaneously to the **Précise 8008** (note the probe modules can only be inserted or removed in the de-energised state). The assignment of the probes is graphically represented in the following figure:

2.3 Power supply & SD card

Insert the **power supply plug** into the back of the housing and tighten the locking screw in the clockwise direction.



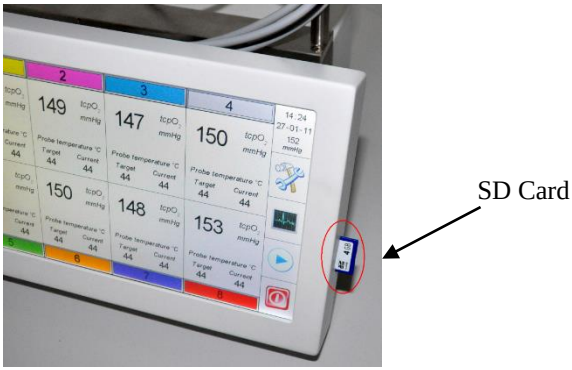
Connect the power supply plug with the wall socket.



↳ the **green control lamp** must lit up

↳ ONLY the original supply plug (FW7405M/12) from medicap must be used

Before starting the measurement, **insert the SD card** into the **SD card slot at the right hand** side of the Précise 8008. During the usage, each measurement can be reliably documented/saved for any further process or analysis externally on any PC. All data can be stored on the SD card as .txt file (separated by tabs).

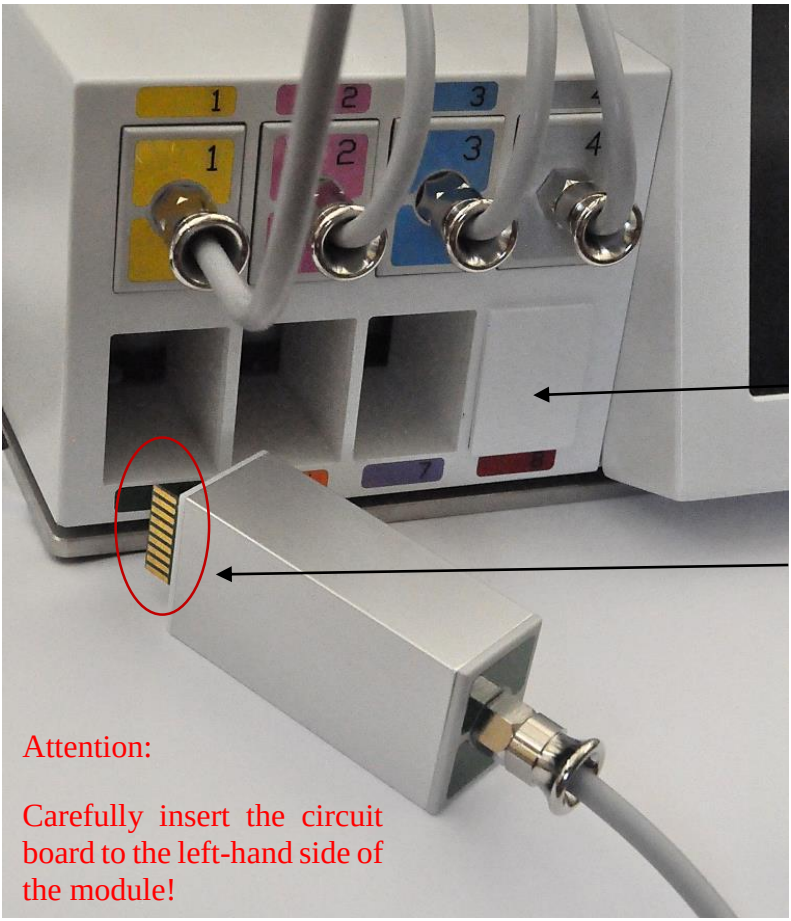


2.4 Connecting the probe modules

Insert or remove the probe modules ONLY in the de-energised state – the Précise 8008 must be SWITCHED OFF.

Do NOT expose the probes to direct sunlight or UV radiation.

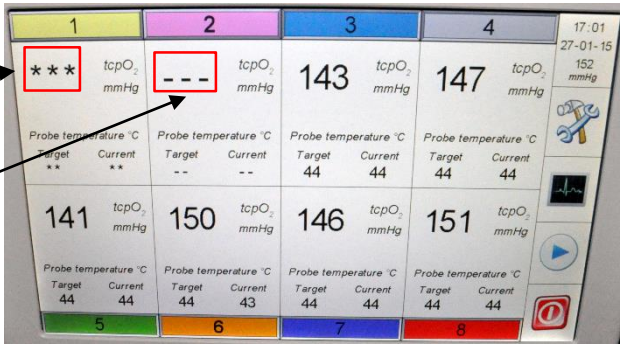
Connect the probe modules which should be used for the measurement. It is possible to connect one or up to eight probes at the same time. (*see 2.2 Probe assignment* section). When using only one of the probes, put a blind cap on the other openings. Be careful with the probe module's circuit board; carefully insert the circuit board to the left-hand side of the module!



The de-activated probes are also illustrated by **"Hyphens"** in the probe field. If no probes are used, **"Asterisks"** will appear in the probe field.

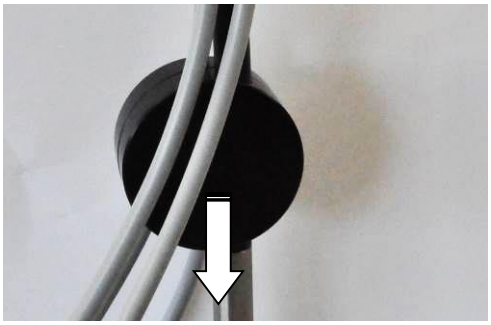
Asterisks:
NO probe module connected

Hyphens:
Probe is de-activated



2.5 Fixating & usage of the carrier handle & cable holders

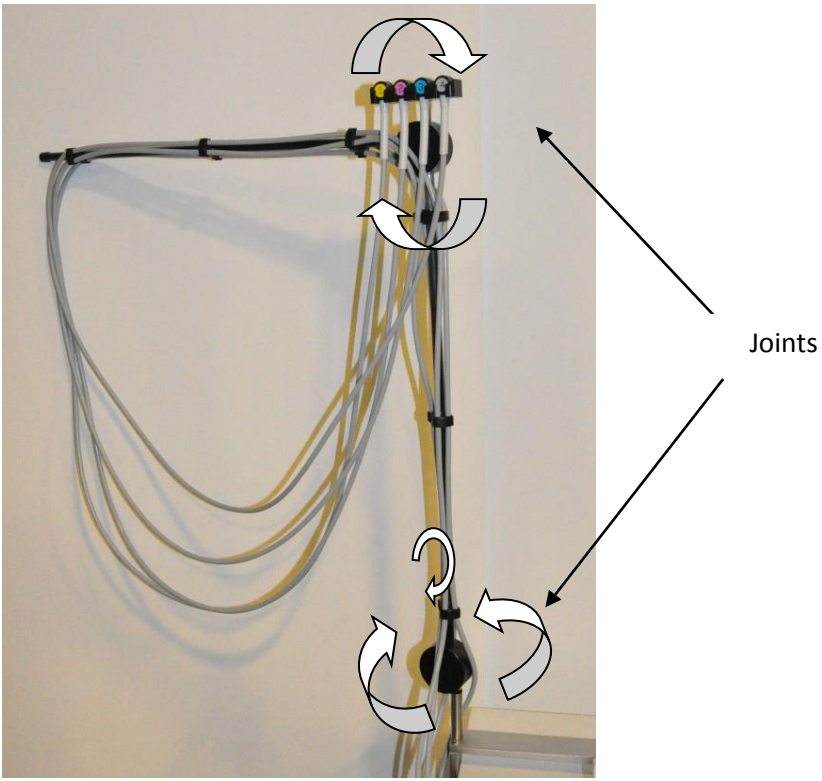
Fixate the double-jointed 180° flexible cable holders into the appropriate Précise 8008 main unit holders



Insert the optical fibres cables carefully into the routing clips

Attention: Do not bend or fold the optical fibres cables around the joints. The optical fibres cables need space when assorting them to avoid cable breaks.

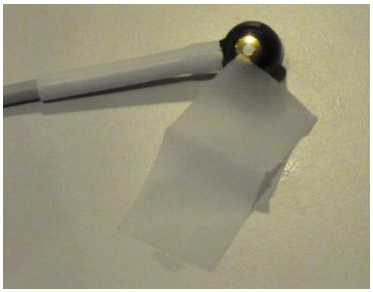
Moving possibilities of the double-jointed 180° flexible cable holders



2.6 Fixating the probe

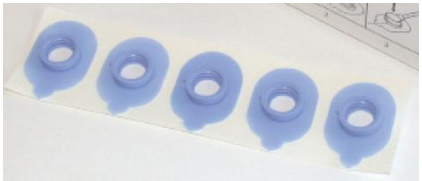
The probe can be fixated on various body parts, such as the arms, legs, chest area, etc. A doctor in accordance with each area of application should determine the fixation site. The fixation of the probe is described in the following example, fixation of the probe on the forearm.

Clean the probe gently with an alcohol pad[1] always before starting any measurement. Do not exert much pressure to avoid damaging the probe layer.



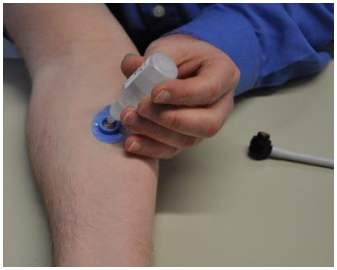
Clean also the measurement skin area with an alcohol pad.

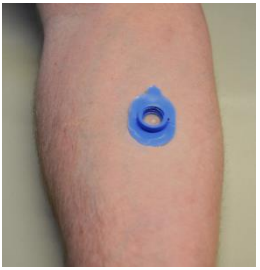
Carefully remove the blue fixation adhesive ring from the tape. In the process, do not soil the adhesive surface.



Apply the fixation adhesive ring on the skin site to be measured.

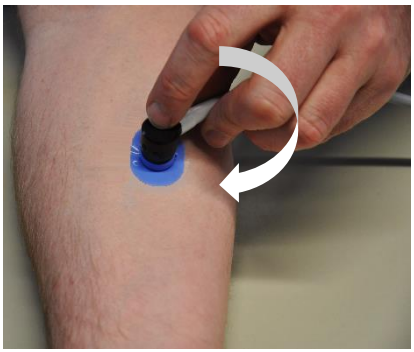
[1] Qualified manufacturers disinfection recommendations: DESCOTON FORTE (conc. max. 4%), SEKUSEPT AKTIV (conc. max. 20g/l)

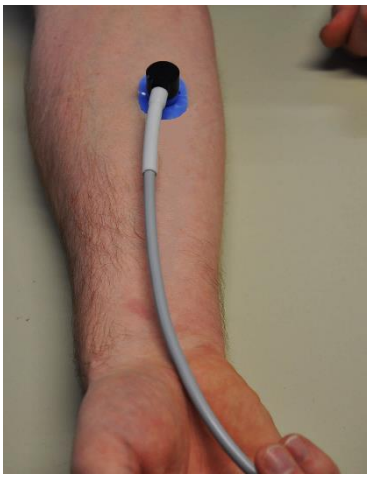




Use only **ONE-TWO drops** of contact fluid into fixation adhesive ring (as large as a pinhead). The probe can be fixated by rotation in clockwise direction using the thread on the fixation adhesive ring – approx. ½ turn.

Note that, during this fixation rotation, no pulling tension is caused at the cable. To avoid tension, we recommend that the cable runs to the palms of the hands. Fixation adhesive ring has to be placed without leakages onto the skin's surface.





As an option it is recommended to use following disposable fixation tape for fixation of the probe head and cable course

- Art.Nr. 802.224
  Disposable Fixation Tape, red, 2,5 cm

- Art.Nr. 802.225
  Disposable Fixation Tape, blue, 5 cm

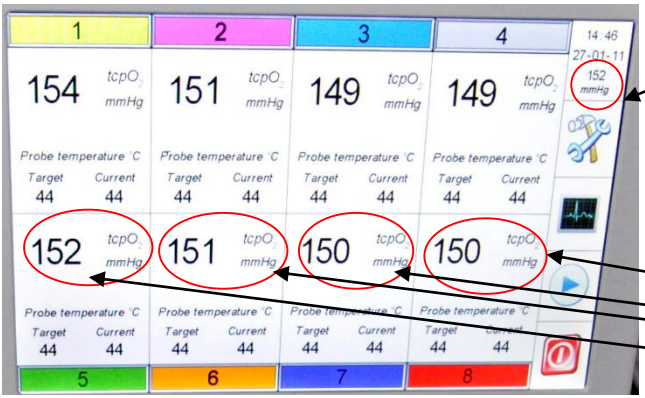
3 Operation

3.1. Switching On the unit

Switch on by pressing the touch screen.

The welcome display appears for a few seconds.

The initial menu screen appears directly afterwards. The Précise 8008 is now ready for operation when the **probe $tcpO_2$ values reach the value of the air measured with the barometer** by ca. 152 mmHg.



value of the ambience air measured with the barometer

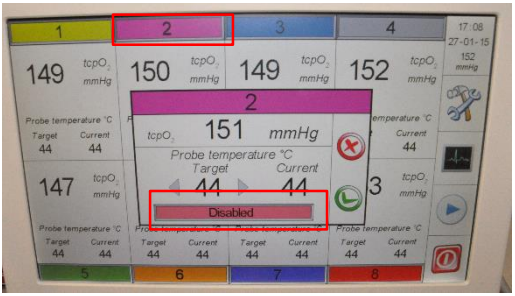
=

values of the optical $tcpO_2$ probes

3.2 Starting measurement

Select the probes you will use for the measurement by pressing the numbered bar (*see 2.2 Probe assignment* section).

The probe selected can be activated or deactivated by pressing the bar.



This current state can be recognised based on the colour intension of the bar:

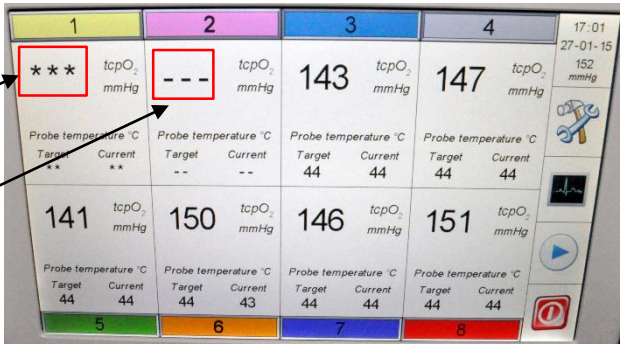
Probe activated / switched on:
→ intensive coloured bar

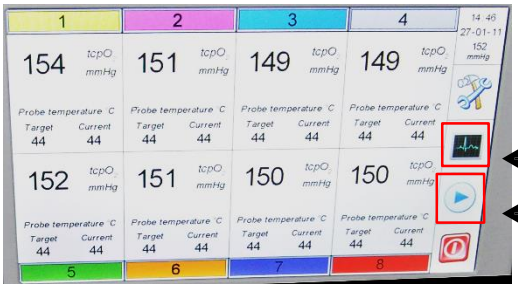
Probe deactivated / switched off:
→ Pale coloured bar

The de-activated probes are also illustrated by "hyphens" in the probe field. If no probes are conncted, "asterisks" will appear in the probe field (use blind caps for the empty probe slots).

Asterisks:
No probe module connected

Hyphens:
Probe is deactivated





After selection of the activated probes, **press the PLAY** key to begin the measurement.

GRAPHIC

PLAY

After **pressing the PLAY** button, a system message appears showing the $tcpO_2$ value storage interval can be adjusted in the settings (*see 3.4. Changing Parameters* section)

The measurement can be displayed as a graphic curve by pressing the **GRAPHIC** key (see above). During the measurement process, the $tcpO_2$ value course of the measurement value can be observed. The **measurement time** can be read from the **X-Axis** and **$tcpO_2$ measurement value can be read** from the **Y-Axis**. The value of the oxygen partial pressure is displayed simultaneously in the probe field.

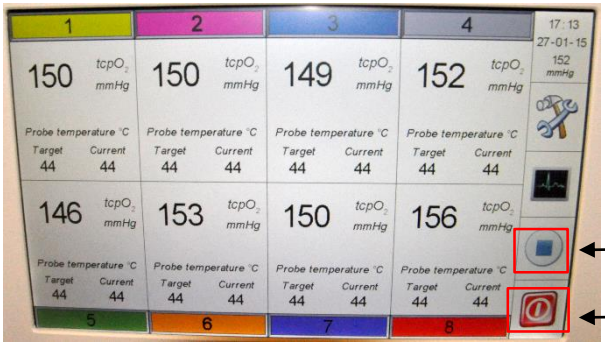
measurement time: X-Axis

$tcpO_2$ value Y-Axis

Return to the initial screen at any time during the measurement by pressing the **BACK** button during the $tcpO_2$ measurement without interruption. Here the measurement values are displayed as values in the probe field.

BACK button for switching from/to $tcpO_2$ graphic or value screen

The measurement can be finished by pressing the **ON/OFF** key or **STOP** button. To really finish the measurement session another dialogue has to be confirmed.



STOP button

ON/OFF button

After the measurement is completed, a question will appear whether the measurement value should be saved or discarded.

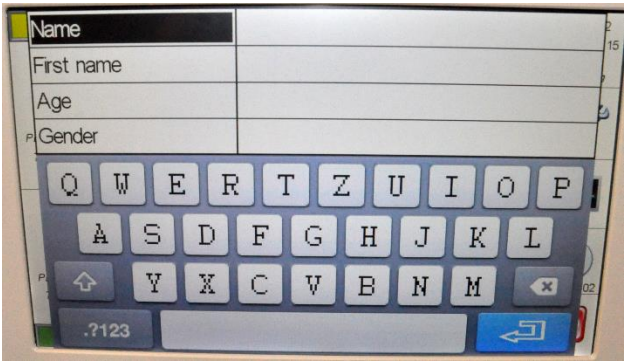
Measurement can be continued, data can be discarded or saved by pressing the confirmation button.

Discard: The data is lost and cannot be recovered.

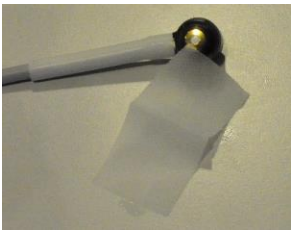
Save: All data is stored on the SD card, i.e. image and measurement values can always be loaded again by pressing the **LOAD DATA** key. The data can be analysed or further processed on an external PC using the SD card!

The measurement session can be personalised on the SD card by entering the following details:

- First name
- Last name
- Age and
-Gender

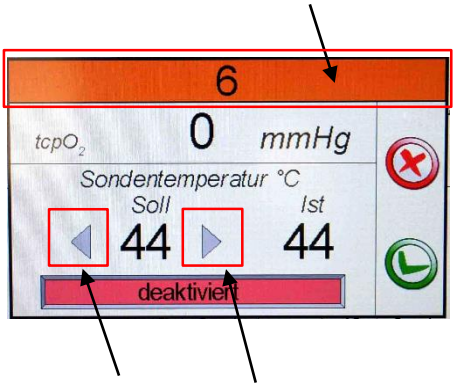


Carefully remove the probes from the skin when the measurement is completed. Remove the adhesive fixation ring. The probe must be cleaned with an alcohol pad **after every** measurement.



3.3 Changing the probe temperature

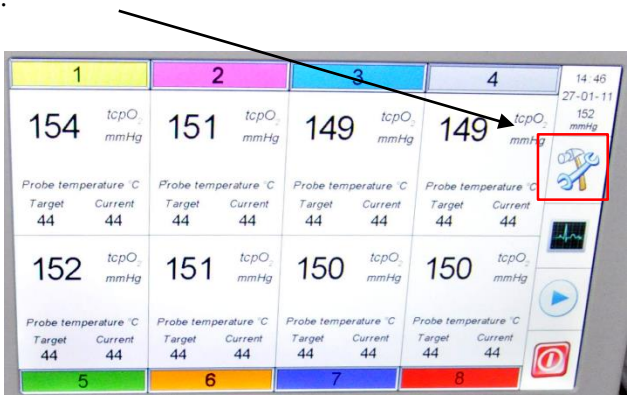
Select the desired probe by **pressing the probe** bar in the main menu display.



The probe target temperature between 37 °C and 44 °C can be selected by pressing the **side arrows**

3.4 Changing parameters

Press the **SETTINGS** key in the main menu display to change or reset the parameters.



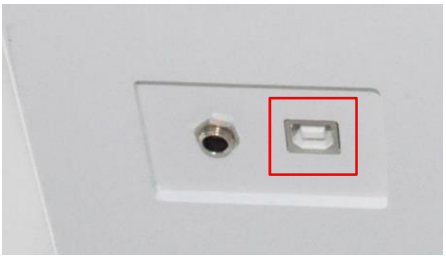
The following parameters can be adjusted:

- Date
- Time
- Storage interval
- System settings

3.5 USB Interface

For a **real time RAW-DATA $tcpO_2$ values export** connect the Précise 8008 with a USB 2.0 standard Plug B printer cable to your PC system. For example with standard terminal software, it is possible to export the live measured $tcpO_2$ values. Also the $tcpO_2$ values are saved in parallel onto the SD card (*see 3.2 Starting measurement* section)

Note: Printing capabilities are not available with this connection!



3.6 Switching off the Précise 8008

Press the **ON/OFF** key to switch the unit off. The message appears:

After confirmation Précise 8008 will shut down!

4 Alarms and monitoring functions

The **Précise 8008** has a microcontroller, which ensures constant monitoring of the most important parameters.

If the probe temperature decreases under 22° C **--.- (Hyphens) will be displayed on the screen**. After reaching a temperature of 22°C, the probe temperature is displayed as a numerical value.

If the probe temperature rises above 45° C, the heating unit will be turned off and, instead of the temperature, the display shows ::,: (**Colons**) and the **ON/OFF** button blinks.

The **Précise 8008** must be switched off. The device can be switched on again after the probe has cooled down. The service must be informed if the error occurs again.

5 Cleaning and maintenance

Clean the unit occasionally, using only a dry cloth.

The probe **must be cleaned** with an alcohol pad after **every** measurement. Clean the probe surface gently.

Do **not** use any pointed or sharp objects to clean the probes.

Do **not** allow and liquid to penetrate the unit!

To ensure reliability and longevity of the Précise 8008 it is recommended to maintain the device unit and its probes **once a year** by a medicap-authorised staff.

Do not place adhesive tape or similar on the probe surface.

6 Disposal

The Précise 8008 and its packaging can be returned to medicap for disposal free of charge. medicap is taking care of environmentally friendly disposal procedures. Do **not** dispose of used batteries with household waste!

7 Symbols

Attention, see accompanying documents

Device with applied part BF

8 Technical data

Dimensions (without handrails):	approx. 400mm x 250mm x 170mm
Weight (incl. 8 probes):	approx. 3920g
Voltage:	100 to 230 VAC +/- 10%,
max. power consumption:	60 W
Protection class:	II
Type:	BF
MDD 93/42 EEC Classification:	IIa
Unit complies with:	MDD 93/42/EEC
Ambient temperature:	+15 to +35°C
Relative humidity:	non-condensing 10 to 95%
Storage temperature:	-10 to +50°C Oxygen partial
pressure:	0 to 165 mmHg +/- 6mmHg
probes - temperature adjustable:	37 to 44°C

9 Accessories

Name	Article number
User manual **Précise 8008**	808.208
Brochure for **Précise 8008**	808.211
Carrier Handle with 1x double-jointed 180° cable holder left side	802.230
Carrier Handle with 1x double-jointed 180° cable holder left & right side	808.231
Double-jointed 180° cable holder left side	808.232
Double-jointed 180° cable holder right side	808.233
O_2 probe Ø 22mm for **Précise 8008** threaded	802.221
Plug-in power supply for **Précise 8008**	808.201
Contact fluid for **Précise 8008**	802.203
Fixation adhesive rings for probe (1Package = 50 pieces)	802.222
Blind cap for probe plug	802.209
Disposable Fixation Tape 2,5 cm, red, 5m roll	802.224
Disposable Fixation Tape 2,5 cm, red, 5 pcs. Pack	802.226
Disposable Fixation Tape 5 cm, red, 10 pcs. Pack	802.227
Disposable Fixation Tape 5 cm, blue, 5m roll	802.225
Disposable Fixation Tape 5 cm, blue, 5 pcs. Pack	802.228
Disposable Fixation Tape 5 cm, blue, 10 pcs. Pack	802.229

10 User manual's and manufacturer's EMC declaration

User manual's and manufacturer's declaration - electromagnetic radiation		
The **Précise 8008** is intended for use in the electromagnetic environments indicated below. The customer or user of the **Précise 8008** should ensure that the device is used in such environments.		
Irradiation test	Compliance	Electromagnetic environment - user manual
HF radiation CISPR 11/EN55011	Group 1	The **Précise 8008** only uses HF radiation for its internal functioning. The HF radiation of this device is therefore extremely low and the equipment is unlikely to interfere with other electronic devices in its vicinity.
HF radiation CISPR 11/EN55011	Class B	The **Précise 8008** is suitable for use in typical healthcare environments which are directly connected to public low voltage power supply grids.
Harmonic radiation IEC/EN 61000-3-2	Class A	
Voltage fluctuation/ Flicker radiation IEC/EN 61000-3-3	Complies	

User manual's and manufacturer's declaration – electromagnetic insensitivity			
The **Précise 8008** is intended for use in the electromagnetic environments indicated below. The customer or user of the **Précise 8008** should ensure that the device is used in such environments.			
Insensitivity test	IEC/EN 60601- Test level	Agreed level	Electromagnetic environment - user manual
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	+/- 6kV contact +/- 8kV atmosphere	+/- 6kV contact +/- 8kV atmosphere	The ground should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative air humidity should be at least 30%.
Rapid transient electrical interferences / Burts in accordance with IEC 61000-4-4	+/- 2kV for mains cable +/- 1kV for input and output cables	+/- 2kV for mains cable +/- 1kV for input and output cables	The main power supply quality should be equivalent to that of a typical business or hospital environment.
Pulse voltage IEC/EN 61000-4-5	+/-1kV differential mode voltage +/-2kV common mode voltage	+/-1kV differential mode voltage +/-2kV common mode voltage	The main power supply quality should be equivalent to that of a typical business or hospital environment.

Voltage drops, temporary interruptions and fluctuations of the supply voltage in accordance with IEC 6100-4-11	>5% Ut (>95% drop in Ut) for ½ period 40% Ut (60% drop in Ut) for 5 periods 70% Ut (30% drop in Ut) for 25 periods >5% Ut (>95% drop in Ut) for 5 s	>5% Ut (>95% drop in Ut) for ½ period 40% Ut (60% drop in Ut) for 5 periods 70% Ut (30% drop in Ut) for 25 periods >5% Ut (>95% drop in Ut) for 5 s	The power supply quality should be equivalent to that of a typical business or hospital environment. If the user of the **Précise 8008** needs continued operation even during interruption of the energy supply, powering the **Précise 8008** from an uninterruptible power supply or a battery is recommended.
Magnetic field of supply frequency (50/60Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field of grid frequency should be equivalent to the typical values found in a business or hospital environment.
Comment: Ut is the mains alternating voltage before using the test level.			

User manual's and manufacturer's declaration – electromagnetic insensitivity			
The **Précise 8008** is intended for operation in the electromagnetic environment indicated below. The customer or user of the **Précise 8008** should ensure that the device unit is used in such environments.			
Troubleshooting-tests	IEC 60601-Testing level	Conformance level	Electromagnetic environment - guidelines
			Portable and mobile radio sets should should not be used any closer to the device and cables than the recommended protective distance calculated using the relevant emitter frequency equation.
Mains-mediated HF interferences in accordance with IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	**Recommended protective distance:** d = 1.2 * root of P
Radiation-mediated HF interferences in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 * root of P; 80 MHz to 800 MHz d = 2.3 * root of P; 800 MHz to 2.5 GHz

			where P is the nominal capacity of the emitter in watts (W) according to the information supplied by the emitter manufacturer and d is the recommended protective distance in metres (m). The field strength of stationary radio frequency transmitters should be less than the agreed level.[3] for all frequencies according to a test carried out locally[2] Interference may occur in the vicinity of devices bearing the following images.

Comment 1 The higher frequency range applies at 80 MHz and 800 MHz.

Comment 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[2] The field strengths of stationary emitters such as the base station of radio telephones and mobile terrestrial radio equipment, amateur radio stations , AM- and FM radio and TV emitters cannot, in theory, be accurately pre-determined. A local study should be considered in order to assess the electromagnetic environment with regard to stationary emitters. If the field strengths measured in the location where the the device is used exceed the aforementioned agreed levels, then the device should be monitored in order to monitor function in accordance with requirements. If unusual output values are recorded, additional measures may be required, e.g. change the direction or select a different location for the device.

[3] The field strength should be below 3 V rms over a frequency range of 150 kHz to 80 MHz.

Recommended protective distances between portable and mobile HF telecommunication appliances and the **Précise 8008**

The **Précise 8008** is intended for use in an electromagnetic environment in which RF interference is controlled. The customer or operator of the device can help to prevent electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication appliances (emitters) and the device – depending on the power output of the communication device, as described below.

	Protective distance in metres depending on emitter output		
Nominal capacity of the emitter	150 kHz to 80 MHz d = 1.2 * root of P	80 MHz to 800 MHz d = 1.2 * root of P	800 MHz to 2.5 GHz d = 2.3 * root of P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For emitters, who maximum nominal capacity is not specified in the above table, the recommended protective distance (d) in metres (m) can be calculated using the equation in the respective column, whereby P is the maximum nominal output of the emitter in watts (W) according to the information supplied by the manufacturer.

Comment 1: The higher frequency range applies at 80 MHz and 800 MHz .

Comment 2: This guideline may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11 Warranty

From the date of delivery, we guarantee the device to be free from defects in material and workmanship **for a period of two years and the probes for one year. If the probe is serviced, the warranty will be renewed for 1 year.**

Defects that occur under warranty shall be remedied in accordance with the terms and conditions of our warranty.

However, the medicap warranty does not cover defects that arise through failure to comply with the instructions for use, incorrect use of The Précise 8008 or third party intervention.

medicap does NOT automatically consider that the owner of the device is also authorised to perform maintenance work.

N.B.
Claims under warranty can only be considered with proof of purchase.

CE 0044

Complies with:
MDD93/42/EEC

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