

**Operating instructions for the  
measuring unit to determine the  
transcutaneous partial pressure of  
Oxygen - tcpO<sub>2</sub>**

**Précise 8008**



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# 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<sub>2</sub>, 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<sub>2</sub> measurement results can be saved onto a SD card. Therefore, you can reliably document every tcpO<sub>2</sub> measurement and process it at any time externally on a PC.

## 1.2 Functional description

The tcpO<sub>2</sub> measurement is a non-invasive procedure to determine the tcpO<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub>, 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. Only medicap homecare GmbH -authorised technicians are allowed to 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 homecare GmbH -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:



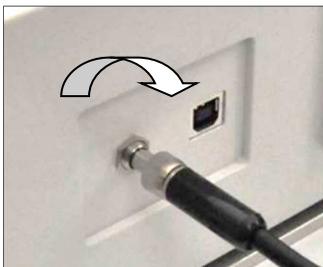
## 2.2 Probe assignment

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.



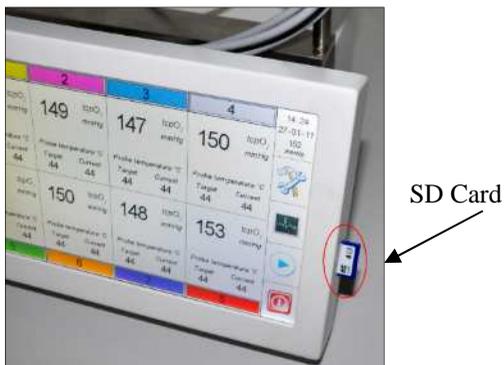
Connect the power supply plug with the wall socket (100 - 240 VAC).



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

↳ **ONLY** the original supply plug (FW7405M/12) from medicap homecare GmbH 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).

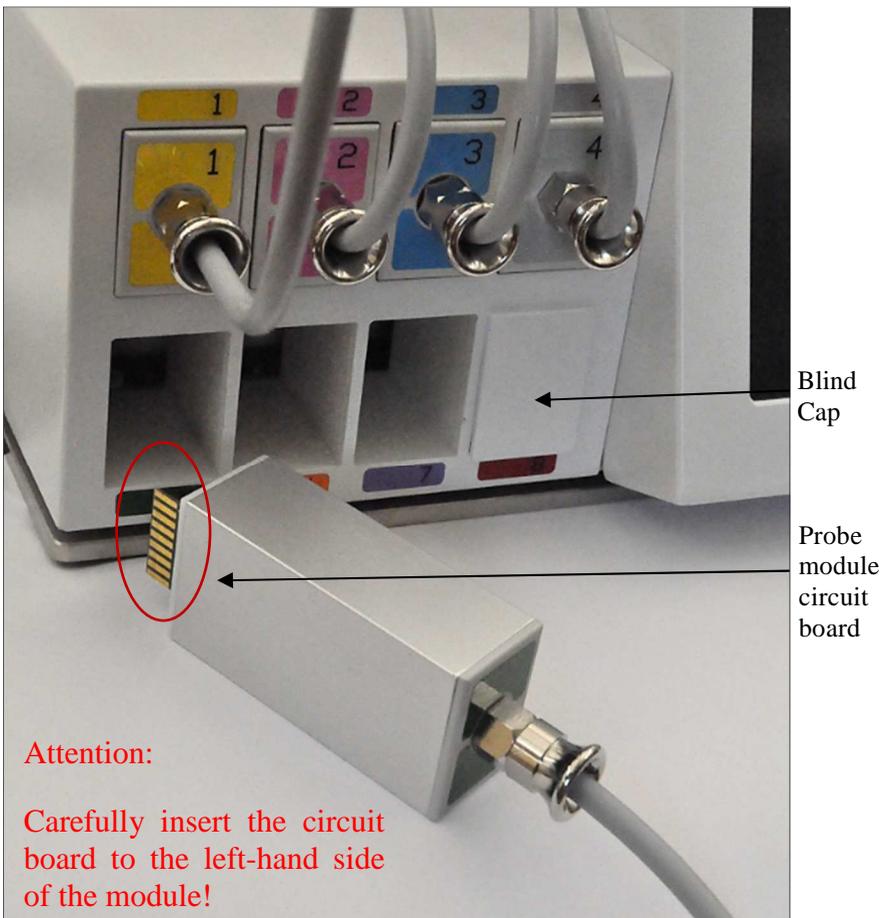


## 2.4 Connecting the probe modules

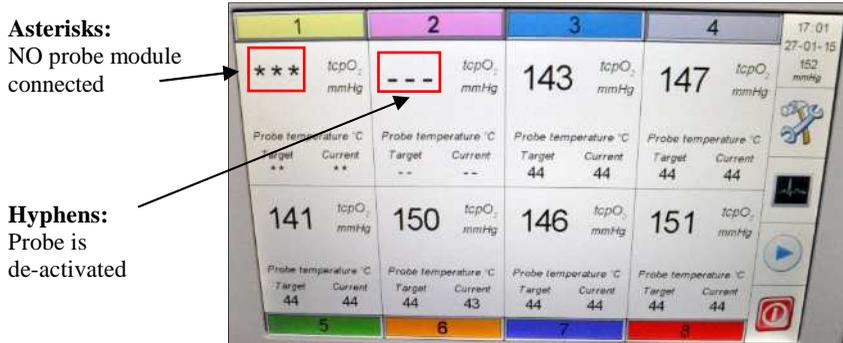
**Insert or remove the probe modules ONLY in the de-energised state – the Précise 8008 must be SWITCHED OFF.**

**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.



### 2.5 Fixation & usage of the carrier handle & cable holders

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



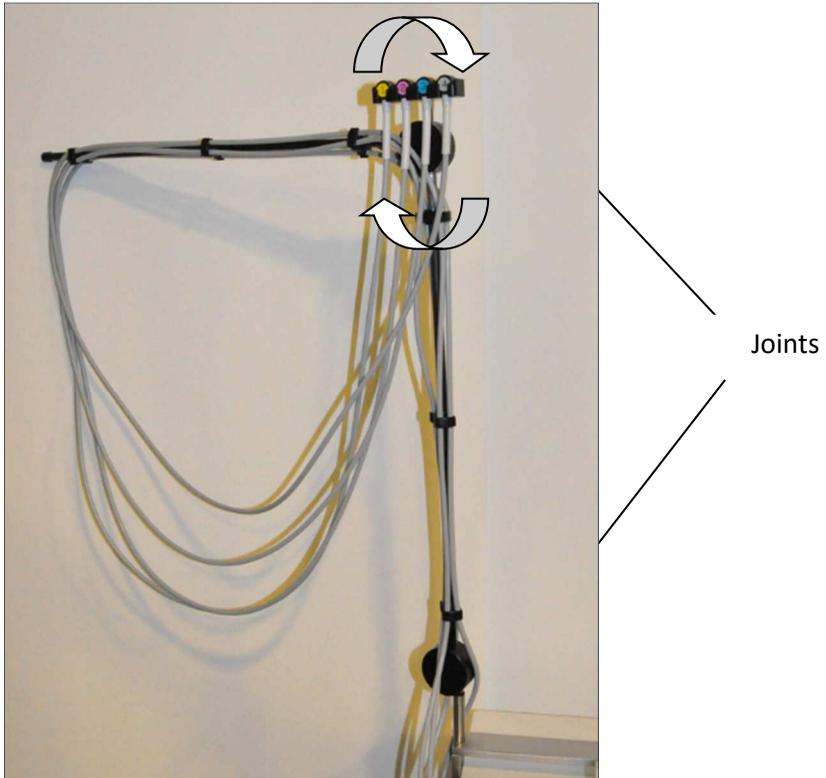
Insert the optical fibres cables carefully into the routing clips



**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.

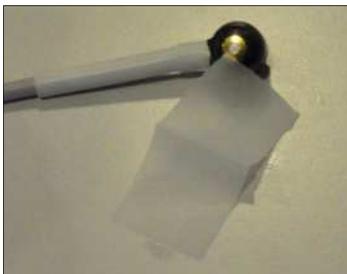


Moving possibilities of the double-jointed 180° flexible cable holders



## 2.6 Fixation of the probe and preparation of the measurement point

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<sup>1</sup> 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.



If necessary, remove hair (shave-off) & the skin epithelium (tape-off) by tearing off 10-15 times each with a new tape.



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

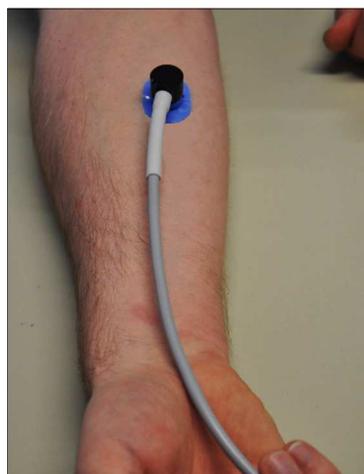
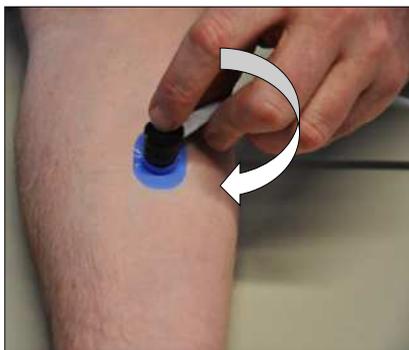
Carefully remove the blue fixation adhesive ring from the tape. In the process, do not soil the adhesive surface.



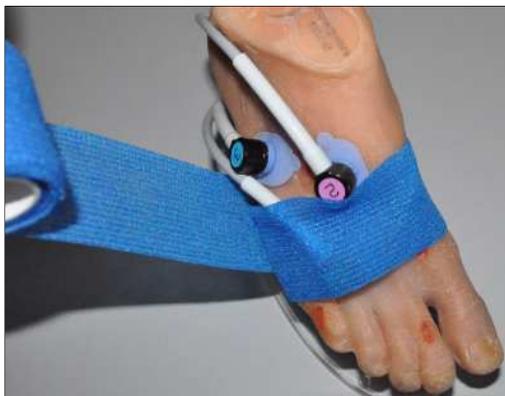
Apply the fixation adhesive ring on the skin site to be measured. Fixation adhesive ring has to be placed **without leakages** onto the skin's surface.



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.  $\frac{1}{2}$  turn. Note that, during this fixation rotation, no pulling tension is caused at the cable.



As an option, it is highly recommended to use the extremely flexible disposable fixation tape for fixation of the **probe head and cable course**. During this process, take care **not to exert any pressure onto the probe head**. The 5 cm tape is recommended for fixation of the probe head and the 2.5 cm for fixation of the cable course.



### 3 Operation

#### 3.1. Switching ON the unit

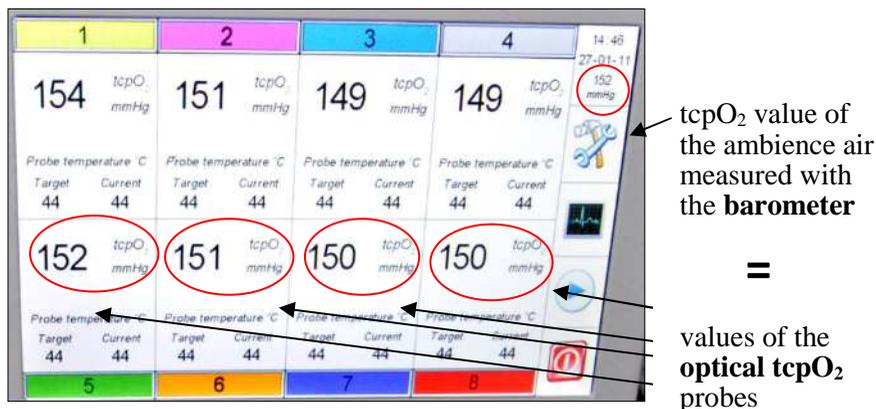
Switch on by pressing the touch screen.



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<sub>2</sub> values reach the value of the air measured with the barometer** by ca. 155 mmHg.



### 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:**

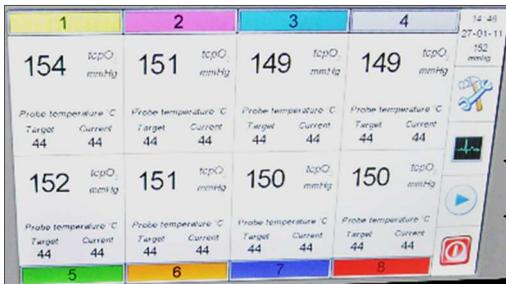
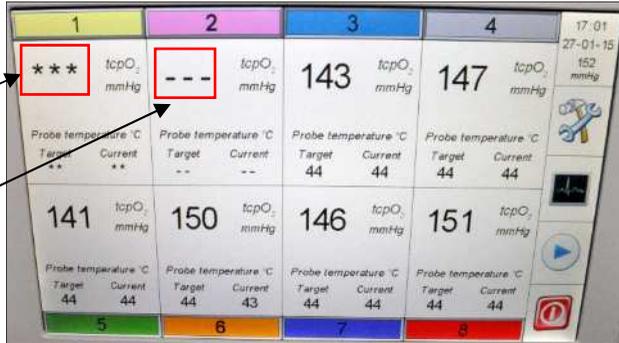


→ **Pale** coloured bar

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

**Asterisks:**  
No probe module connected

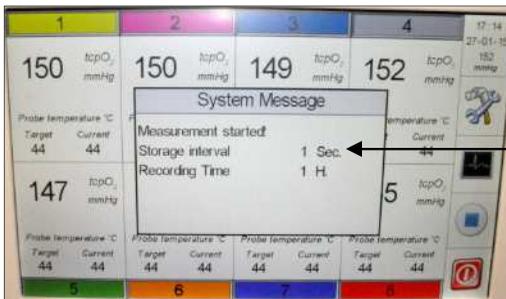
**Hyphens:**  
Probe is deactivated



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

**GRAPHIC View**

**PLAY = Start**



After **pressing the PLAY** button, a system message appears showing the tcpO<sub>2</sub> 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<sub>2</sub> value course of the measurement value can be observed.

The **measurement time** can be read from the **X-Axis** and **tcpO<sub>2</sub> measurement value** can be read from the **Y-Axis**. The value of the oxygen partial pressure is displayed simultaneously in the probe field.

**Value  
Y-Axis**



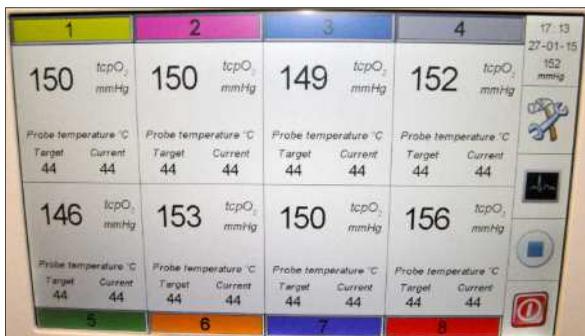
**Time  
X-Axis**

Return initial at any time during the measurement by pressing the **BACK** button during the tcpO<sub>2</sub> measurement without interruption. Here the measurement values are displayed as values in the probe field.



**BACK** button for switching from/to tcpO<sub>2</sub> graphic or value screen

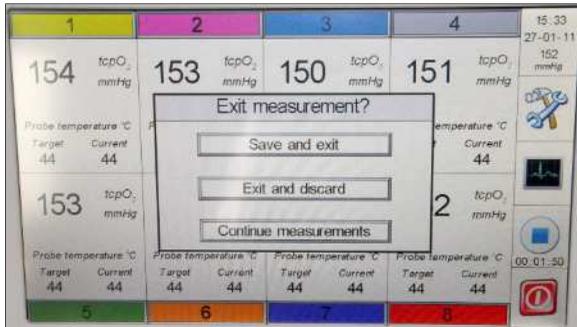
The measurement can be finished by pressing the **ON/OFF** key or **STOP** button. To really finish the measurement session another dialogue has to be confirmed.



**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

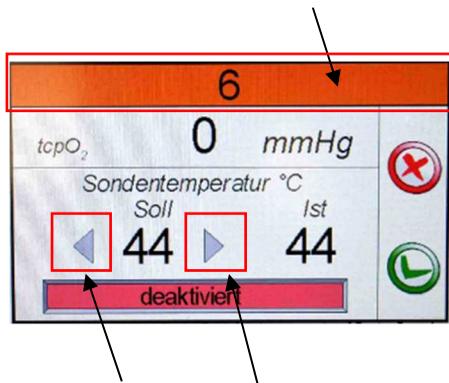


Screw-off the probes from the skin when the measurement is completed. Remove the adhesive fixation ring carefully from the skin. The probe must be cleaned with an alcohol pad **after every** measurement.



### 3.3 Changing the probe temperature

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



The probe target temperature between 37 °C and 44 °C can be adjusted by pressing the **side arrows at any time during the measurement.**

### 3.4 Changing parameters

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

1	2	3	4	14-48 27-01-11 152 mmHg
154 $tcpO_2$ mmHg	151 $tcpO_2$ mmHg	149 $tcpO_2$ mmHg	149 $tcpO_2$ mmHg	   
Probe temperature °C Target Current 44 44				
152 $tcpO_2$ mmHg	151 $tcpO_2$ mmHg	150 $tcpO_2$ mmHg	150 $tcpO_2$ mmHg	
Probe temperature °C Target Current 44 44				
5	6	7	8	

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  $36^{\circ}\text{C}$  **--.-(Hyphens) will be displayed on the screen**. After reaching a temperature of  $36^{\circ}\text{C}$ , the probe temperature is displayed as a numerical value.

If the probe temperature rises above  $45^{\circ}\text{C}$ , 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

The housing and the touch display of the Précise 8008 must be cleaned with **Ethanol or Ethanol** containing cleaning and disinfection detergents. In addition, **Isopropyl** alcohol detergents can alternatively be used, too.

Do not wipe the touch display with a dry cloth, as it can may cause scratches. Wipe off the stain on the touch display by using **soft cloth** moistened with ethanol or isopropyl alcohol. Before start cleaning the touch display, the detergents must be distributed evenly onto a cloth. First, wipe off the stain **from the display edge into the centre of the display**. To complete the cleaning wipe off the remaining stain from the centre of the display.

During the cleaning of the device-housing unit, do not allow **to get liquids into the device**.

The tcpO<sub>2</sub> probes **must be cleaned** with an alcohol<sup>1</sup> pad **without pressure** after every measurement. Clean the white probe surface **gently**. Do **not** use any **pointed or sharp objects** to clean the probes. **Do not** place any adhesive tape or similar on the probe surface.

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 homecare GmbH -authorised staff.

## 6 Disposal

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

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

## 7 Symbols



Attention, see attached 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

<b>Name</b>	<b>Article number</b>
User manual <b>Précise 8008</b>	808.208
Brochure for <b>Précise 8008</b>	808.211
Carrier Handle with 1x double-jointed 180° cable holder left side	808.230
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 <sub>2</sub> probe for <b>Précise 8008</b>	802.221
Plug-in power supply for <b>Précise 8008</b>	808.201
Contact fluid for <b>Précise 8008</b>	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 <b>Précise 8008</b> is intended for use in the electromagnetic environments indicated below. The customer or user of the <b>Précise 8008</b> 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 <b>Précise 8008</b> 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 <b>Précise 8008</b> 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 <b>Précise 8008</b> is intended for use in the electromagnetic environments indicated below. The customer or user of the <b>Précise 8008</b> 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 / Bursts 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 <b>Précise 8008</b> needs continued operation even during interruption of the energy supply, powering the <b>Précise 8008</b> 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 <b>Précise 8008</b> is intended for operation in the electromagnetic environment indicated below. The customer or user of the <b>Précise 8008</b> should ensure that the device unit is used in such environments.			
Troubleshooting-tests	IEC 60601-Testing level	Conformance level	Electromagnetic environment - guidelines
Mains-mediated HF interferences in accordance with IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	Portable and mobile radio sets should not be used any closer to the device and cables than the recommended protective distance calculated using the relevant emitter frequency equation.  <b>Recommended protective distance:</b>  $d = 1.2 * \text{root of } P$
Radiation-mediated HF interferences in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 * \text{root of } P$ ; 80 MHz to 800 MHz  $d = 2.3 * \text{root of } P$ ; 800 MHz to 2.5 GHz

			<p>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).</p> <p>The field strength of stationary radio frequency transmitters should be less than the agreed level.<sup>3</sup> for all frequencies according to a test carried out locally<sup>2</sup></p> <p>Interference may occur in the vicinity of devices bearing the following images.</p>
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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.

<sup>2</sup> 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.

<sup>3</sup> 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.

Nominal capacity of the emitter	Protective distance in metres depending on emitter output		
	150 kHz to 80 MHz $d = 1.2 * \text{root of } P$	80 MHz to 800 MHz $d = 1.2 * \text{root of } P$	800 MHz to 2.5 GHz $d = 2.3 * \text{root of } P$
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.**

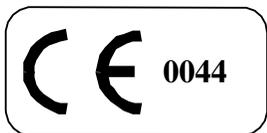
Defects that occur under warranty shall be remedied in accordance with the terms and conditions of our warranty.

However, the medicap homecare GmbH 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 homecare GmbH **does NOT automatically consider that the owner of the device is also authorised to perform maintenance work.**

### Important

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



Complies with:  
MDD93/42/EEC

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