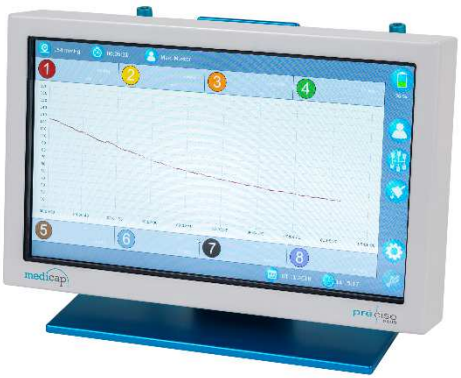
Operating instructions for the measuring unit to determine transcutaneous oxygen partial pressure – $tcpO_2$

Précise 8008



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1 Introduction

1.1 Intended use

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

The sensor parameters, the measurement process, as well as the measurement results can be saved to the internal database. Therefore, you can reliably document every measurement and track it at any time.

Moreover, analysis software can optionally be used, which offers the user another method of graphically displaying the recorded data in addition to the Précise 8008 display. In addition to the expanded display, further functions have been added, all of which are explained in detail in this document.

This results in two versions of the **Précise 8008**:

Version 1:
The computer is connected with the interface on the side of the **Précise 8008** using a USB cable. This connection allows data to be displayed and saved in the analysis software in real time. Furthermore, a detailed $tcpO_2$ measurement report can be saved as a .pdf document or printed. A purely "raw data export" is also possible.

Version 2:
The Précise 8008 is used independently as a "stand-alone device". Using a USB stick, the measurement data can be recorded, retrieved and displayed in a "raw data form". Therefore, you can document every 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 oxygen partial pressure on the surface of the skin. During the procedure, the skin is warmed to 40° - 44°C.

The oxygen measurement is based on the luminescence lifetime measurement. This is dependent on the oxygen partial pressure. Measurement preparations (e.g. changing electrolyte, covering the sensor, etc.) are thus omitted, as is known from the Clark sensor.

The sensors are suited both for the determination as well as for the long-term measurement of oxygen partial pressure.

1.3 Important usage and safety instructions Précise 8008

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 device must be checked and, if need be, repaired by the authorised service technician if it has a damaged plug or cable, is not working properly, has been dropped, damaged or if liquid has got into the device.

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

- Temperature selection
- Measurement site selection
- Patient's age
- Patient's general physical health (e.g. fever)
- Smoking
- Coffee consumption
- Acclimating the patient to the outside temperature

This summary is not complete.

Portable and mobile HF communication equipment can affect medical electrical devices. This can lead to malfunctions in the devices.
For this reason, radiation sources (devices that emit electromagnetic waves) must be kept a minimum distance away from running medical electrical devices, see the below table.

Radiation sources	Minimum distance from a medical electrical device including all connecting cables
Mobile telephone (mobile)	3.3 m
DECT telephone (cordless telephone)	1.2 m
Bluetooth devices (laptops, mobiles)	0.7 m
Remote controls	1.2 m
WLAN devices (e.g. laptops, repeater, access point, print server)	2.3 m

The power cable must not exceed a maximum length of 4m.

The use of other accessories and cables not listed in the operating instructions can lead to an increased emitted interference or a reduced interference immunity of the device.

- The **Précise 8008** is not a blood gas analyser.
- The sensor 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 sensor.
- The device must only be opened by maintenance technicians authorised by medicap homecare GmbH.
- The **Précise 8008** must be tested **annually** by an authorised person from medicap homecare GmbH.
- Remove the wall plug transformer from the socket if the device is not being used for long periods.
- Only original components must be used.
- Protect the **Précise 8008** from moisture and dampness.
- Do **not** place adhesive tape or similar on the sensor surface.
- Do not expose the sensors to **direct sunlight or UV radiation**.

IMPORTANT!

Do not insert or remove the sensor modules except ONLY in the de-energised state.

1.4. Important usage and safety instructions - Analysis software

Please avoid disconnecting the **Précise 8008** from the computer while the live transfer is in progress. It is recommended to stop the transfer first and then remove the USB cable.

2. Preparation

2.1 Connecting the power supply

⇨ Power supply socket on the side of the housing (right)

⇨ Insert the power supply into the contact outlet (100 to 240 VAC).

↳Only the supplied medicap homecare GmbH power supply should be used.

↳The inbuilt battery enables a runtime of approx. 3 hours without any external power supply.

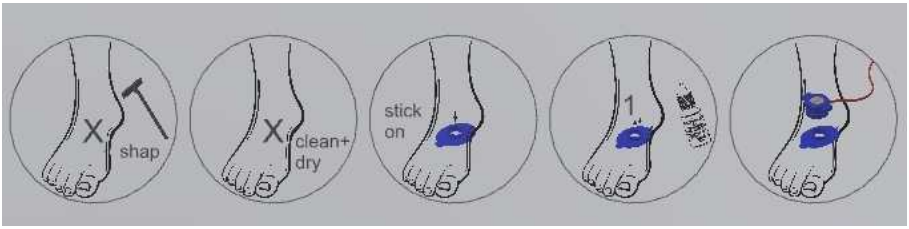
↳The battery must be protected against deep discharge. There is a specially designed deep discharge protection for this purpose. This automatically switches off the load as soon as the battery voltage falls below a set limit. As the battery should not be more than 80% discharged, promptly charging the battery prevents a deep discharge.

2.2 Fixing the sensor and preparing the measurement site

The sensor can be fixed to various body parts, such as the arms, legs, chest area, etc. The fixation site should be determined by a doctor in accordance with each area of application. Fixing the sensor is described in the following example; fixing the sensor to a foot. The sensor surface should be cleaned before **each measurement with a disinfectant**[1] or **alcohol pad**[2]. Do not exert too much pressure.

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

[2] Alcohol Pads B.Braun REF 9160612 / PZN 00629703



If necessary, the section of skin to be measured should be cleaned with an alcohol pad. In addition, any hair should be removed from the desired section of skin and dead epithelial cells should be removed from the skin by repeatedly applying and removing adhesive tape, with a new piece of tape being used each time.

Carefully remove a fixing ring from the backing material. The adhesive surface must not be soiled in the process.

Apply the fixing ring to the skin site to be measured. Let **a drop** of contact fluid drop into the opening of the fixing ring. It must be ensured that the fixing ring is on the skin in an **air-tight** and **secure** manner.

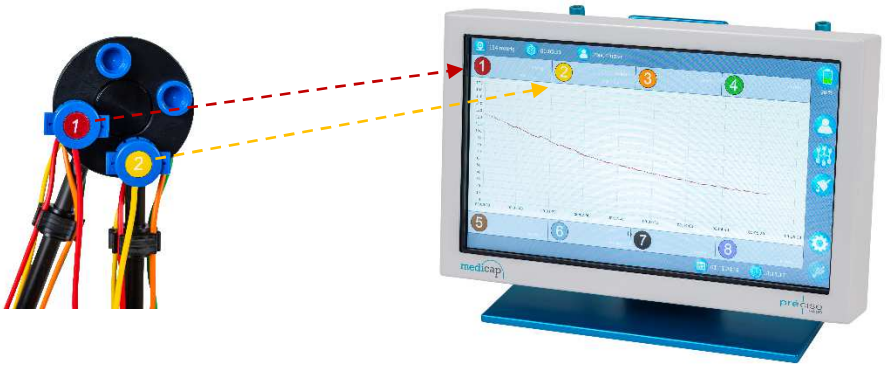
The sensor head can be inserted onto the fixing ring by means of a one-touch click system. To avoid shearing off the sensor, it is important to note that the **cable is not being pulled** during this insertion.

It is optionally recommended to fix the **sensor cable and sensor head** with the highly flexible medicap homecare GmbH disposable fixation tape. It is important to make sure that **no pressure is exerted on the sensor head**. The 5 cm wide, blue fixation tape should be used for the sensor head and the 2.5 cm wide, red fixation tape should be used for the cable routing.

2.3 Sensor assignment

Between one and eight sensors can be connected to the **Précise 8008** simultaneously.

The assignment of the sensors is visually represented in the following figure:



2.4 Connecting sensors

Do not insert or remove the sensor modules except only in the de-energised state.

Do **not** expose the sensors to direct sunlight or UV radiation.

The desired number of sensors can be connected laterally to the left and right side. A maximum of four sensors can be connected on each side. It is possible to connect a maximum of 8 sensors to the **Précise 8008**.

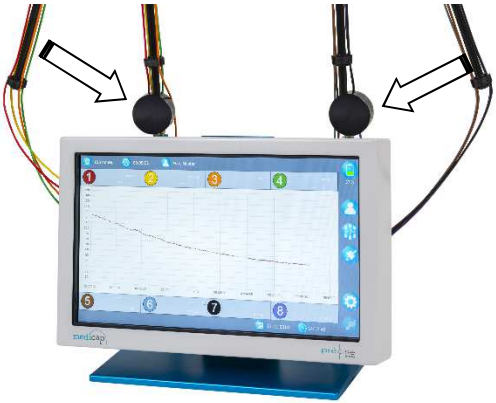
If no sensors are used, **"asterisks"** will appear in the sensor field. Sensors can also be deactivated manually. The deactivated sensors are illustrated by **"hyphens"** in the sensor field.

Asterisks:
No sensor module connected

Hyphens:
Sensor is deactivated

2.5 Fixing & using the supporting frame with a retaining arm

Placement of the 180° double-jointed arms in the **Précise 8008** base unit; these are fixed to the device with a click system.



Carefully insert the optical fibre cable into the guide clips.

Movement options of the double-jointed 180° pivotable cable carrier:

3 Operation

3.1 General

Touching the screen:		To select different items in the menu.
Pressing the symbols:		When the unit is switched on, the software is controlled, retrieved or confirmed by pressing
Back:		To quit the current menu **without** changes
Discard:		Directly back to the initial display, **current data is discarded**
System settings		system menu to set the language and system settings (service menu)

3.2. Switching the unit on

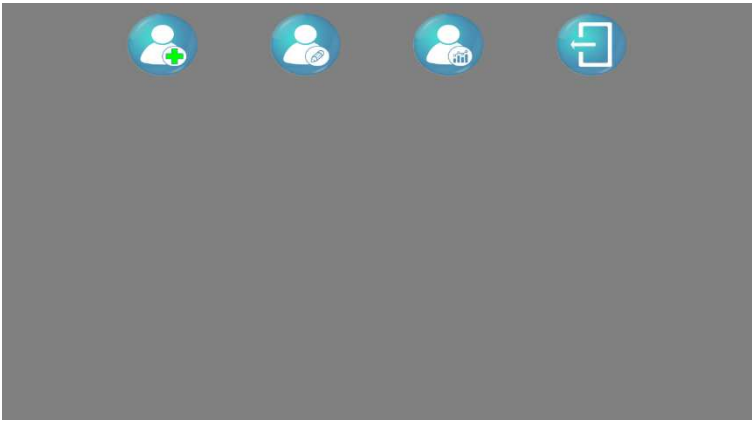
⇨ Switch on with the I/O key (at least 3 sec.), this is located on the right side of the device (an acoustic signal can be heard)

The *initial display* appears directly afterwards. The **Précise 8001** is ready for operation when the **tcpO₂ value of the optical sensors increases to the air tcpO₂ value from the inbuilt control barometer.**

3.3 General operation - start measurement / open database

⇨ Press the patient symbol

⇨ The “patient menu” appears. Select the desired menu item and press the symbol to confirm.



Create patient data

Edit patient data

Open patient database

*Display - **Create** patient data:*

To create a patient, the mandatory fields of first name, last name and date of birth **must** be completed; selecting the patient's gender is optional.

Entering the mandatory fields unlocks the Create Patient symbol. This symbol must be pressed to create and save the data in the database.

*Display - **Edit** patient data:*

To edit a patient, the mandatory fields of first name, last name and date of birth **must** be completed. All of the recorded data can be amended.

Entering the mandatory fields unlocks the Edit Patient symbol. This must be pressed. Now the changes made to the patient data are saved.

Display - ***Patient database***

⇨ Select the desired patient and confirm by pressing the symbol.

⇨ Note: By entering the first name and/or last name, you can quickly and easily refine the selection and avoid having to manually search through the database.

Record measurement

Open database (analyse saved measurements)

Display - ***Record measurement***

The measurement graphic, temperature and oxygen partial pressure can be read.

- Oxygen partial pressure
- Actual temperature

Measurement duration

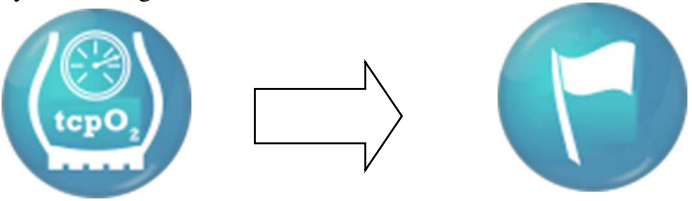
Current patient

➧ **Start measurement:**

Display during the measurement

When the automatically calculated steady state value is reached (this can also be skipped manually by pressing the "Steady state recognition" symbol), an acoustic signal sounds and it is represented visually by a line.

The symbol changes as follows:



The steady state recognition process can be repeated up to a maximum of five times for provocations or location changes. When activating an "event", the time of the steady state recognition is displayed in colour.

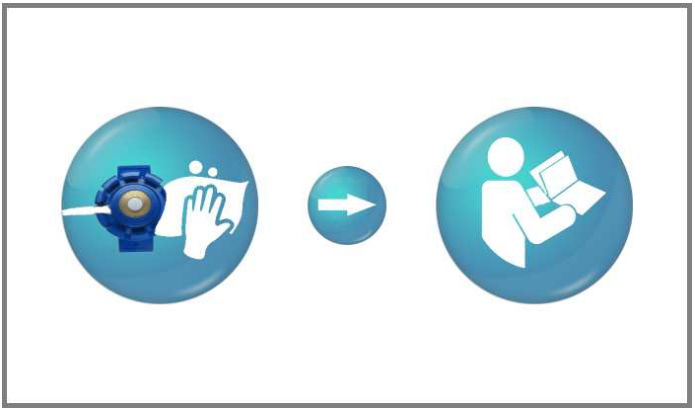
Steady state value line

Event duration - a new steady state value determination has been started

➧ **End measurement:**

⇨ The measurement data is automatically saved in the database when the measurement stops. All data is saved, i.e. the graph and the result. The data can often be retrieved as needed.

⇨ Remove the sensor from the fixing ring and carefully pull the fixing ring off of the skin. The sensor must be cleaned after **each measurement with a disinfectant[1] or an alcohol pad[2]**. Do not exert too much pressure.

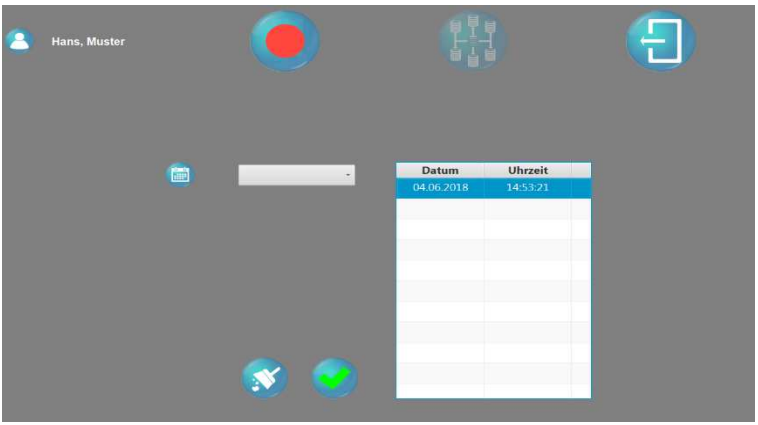


[1] Recommended disinfectant manufacturers: DESCOTON FORTE (max. conc. 4%), SEKUSEPT AKTIV (max. conc. 20g/l)

[2] Alcohol Pads B.Braun REF 9160612 / PZN 00629703

3.4 Analysing the measurement data

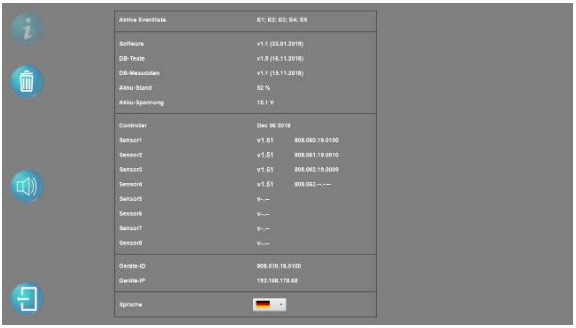
In the initial display, press the Patient symbol in order to open the "patient menu" drop-down menu. You must first select the patient, as described above Select the desired measurement (measurements are saved by date and time) and confirm.



⇨ The measurement curve and associated data are retrieved and displayed graphically.

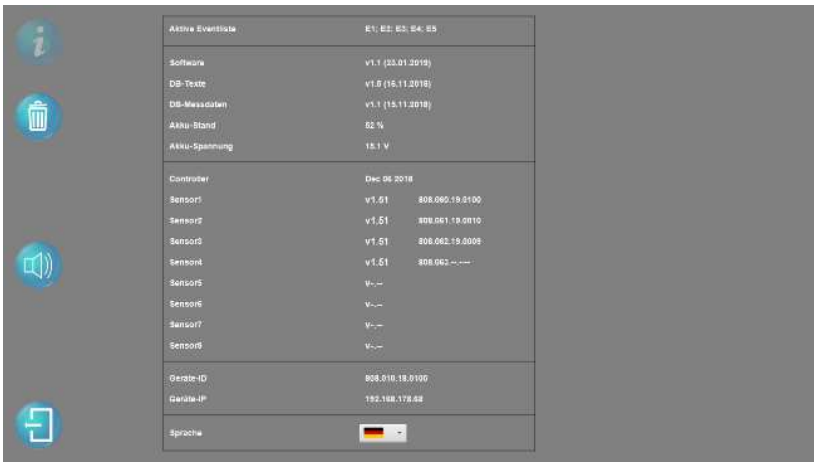
3.5 System menu

Display - System settings:



System information | Database | Sound | Back

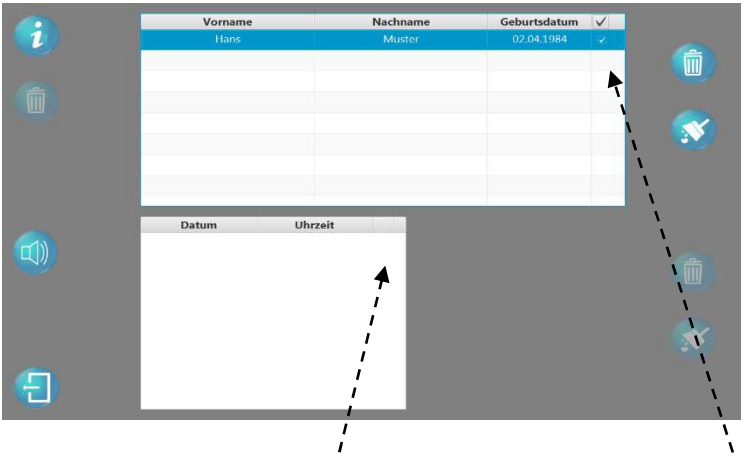
Display - System settings:



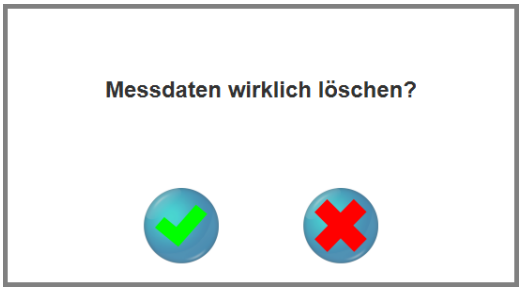
In this menu, the current software version, hardware parameters and serial numbers of the sensors can be read.

This menu is also used to set the language, which can be selected from a drop-down menu.
The desired language can be selected in the form of the country's flag. A restart is not necessary for the change to take effect.

Display - Database:



In the menu, individual measurements of a patient or patients can be deleted. The data **cannot** be recovered after being deleted. To be able to delete the data, in the settings menu click on the patient or the desired measurement and confirm this with  . A window opens to confirm the deletion again:

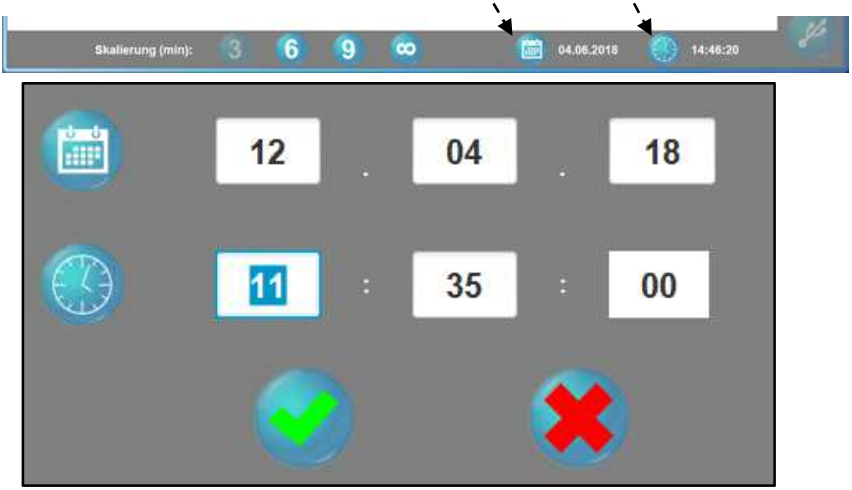


By pressing the *Confirm* symbol, the entered changes are saved and you return to the initial screen.

By pressing the symbol *Cancel*,
you return to the initial screen **without** changing anything.

3.6 Date & time

The menu for changing the date and time is opened by pressing on the symbols in the initial display.



The data can be amended by pressing on the desired field.

By pressing the *Confirm* symbol, the entered changes are saved and you return to the initial screen.

By pressing the symbol *Cancel*,
you return to the initial screen **without** changing anything.

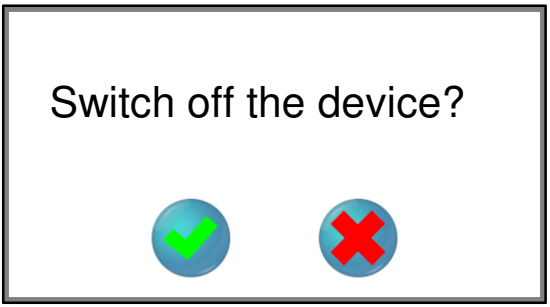
3.7 USB interface

For a **real time $tcpO_2$ value export**, connect the device to a computer using a USB cable. With the standard terminal software it is possible, for example, to export the $tcpO_2$ real time measurement values. The $tcpO_2$ values and patient data are also saved at the same time to the internal database in the **Précise 8008.**

Note: A print function is **not** possible.

3.8 Switching off the device

⇨ Switch off by pressing the I/O key. This is located on the right side of the device (an acoustic signal can be heard)



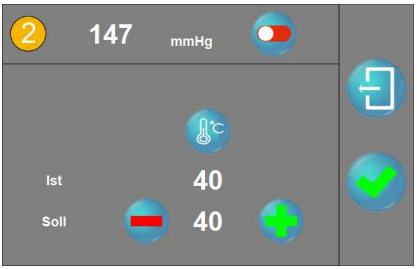
After confirming the query, the **Précise 8008** is switched off.

4. Sensor menu

Select the desired sensor in the initial display; pressing the “Sensor” symbol takes you into the “sensor menu”.

With you confirm the set changes and return directly to the start screen. To quit the menu without changes, use

4.1 Setting the sensor temperature



In the menu item “Parameters”, the target temperature can be changed by pressing the and symbols.

Target temperature: desired sensor temperature
Actual temperature: current sensor temperature

↳ Temperature range
from 40°C - max. 44°C

3.2 Switching the sensor on/off

You can activate or deactivate the sensor using the on/off symbol.

On

Off

The deactivated sensors are illustrated by **"hyphens"** in the initial display. This setting is **not** possible while a measurement is running.

5. Alarms and monitoring functions

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

If instead of the temperature **--.- (hyphens)** are displayed, the sensor temperature is below 36°C. After reaching a temperature of 36°C, the sensor temperature is displayed as a numerical value.

If the sensor temperature rises above 45°C, the heating is turned off and, instead of the temperature, the display shows ::,: **(colons)**.

The device must be switched off. The device can be switched on again after the sensor has cooled. Service must be informed if the error occurs again.

6. Cleaning and maintenance

The housing of the **Précise 8008** should only be cleaned occasionally with a dry cloth.

To clean the display, the cleaning agent or disinfectant should be evenly distributed on a dry and clean cloth. You can then use this cloth to clean the surface of the touch screen. Please start by cleaning the dirt from the edge of the surface in the direction of the centre of the monitor, and then remove any remaining dirt from the centre itself. The cleaning agents or disinfectants must **not scratch or etch**.

When cleaning or disinfecting the device, make sure that **no liquids** get **inside** the device housing.

When cleaning the $tcpO_2$ sensors, do **not** use any pointed or sharp objects. Do **not** place adhesive tape or similar on the sensor surface.
The sensor **must** be cleaned after **each** measurement with an alcohol pad[1]. Do not put **too much pressure** on the white sensor surface.

The device **and** the sensors must be tested **annually** by authorised personnel from medicap homecare GmbH as part of the safety-related checks.

To prepare the tcp02 sensor we recommend:
- **DESCOTON FORTE** (max. concentration 4%)
- **SEKUSEPT AKTIV** (max. concentration 20g/1 litre)

To prepare the housing we recommend:
- **KORSOLEX FF** concentrate
- **BIGUANID Fläche**

The appropriate operating instructions must be observed.

7. Disposal

The device and its packaging can be returned to medicap homecare GmbH for disposal free of charge. We advocate environmentally friendly disposal procedures.

Do **not** dispose of used batteries with household waste!

8. Pictograms

Attention, see accompanying documents

Device with applied part BF

8.1 Software symbols

Patient menu

Create patient

Edit patient

Patient database

Settings

Date of birth

Note

Discard data

Measurement Data

Date

Database

Event - Set measurement point

Gender

Info

Accept

Cancel

First name

Last name

Record measurement

Clean sensor

Steady state recognition

Temperature

Start measurement

Stop measurement

USB port

Eject USB port

Quit / back

Barometer

Delete

Export data

Measurement duration

Set scaling

Battery empty

Battery very low

Battery defective

Battery full

Battery empty in state of charge

Battery 50% in state of charge

Sound on

Sound off

9 Technical Data

Dimensions (without handrails):	approx. 400mm x 250mm x 170mm
Weight (incl. 8 sensors):	approx. 3920g
Display:	15.1"
Voltage:	100 to 230 VAC ± 10%
Max. power consumption:	35 VA
Protection class:	II
Type:	BF
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 2000 mmHg +/- 10% mmHg
Sensor temperature adjustable:	40 to 44°C

10 Warranty

The device comes with a two-year warranty and the sensors come with a one-year warranty as from the purchase date that covers material or manufacturing defects.

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

The warranty of medicap homecare GmbH does not cover defects that arise through failure to comply with the operating instructions, incorrect use of the device or third party intervention.

Medicap homecare GmbH does not automatically consider the owner of the device to be authorised to perform maintenance work.

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

Complies with: MDD93/42/EEC

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