

Operating Instructions

O₂ Monitor



Keep these instructions in a safe place!



DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck, Germany



Tel: (+49) 451 80904-0
Fax: (+49) 451 80904-111
www.DEHAS.de

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1. Explanation of the key abbreviations

NTC	Electrical resistance with negative temperature coefficients
RH	Relative humidity
l/min	Litres per minute
TRGS	Technical Rules for Hazardous Substances
O ₂	Chemical formula for oxygen
N ₂	Chemical formula for nitrogen
CO ₂	Chemical formula for carbon dioxide
N ₂ O	Chemical formula for dinitrogen monoxide (nitrous oxide)

2. Safety information – Warnings, precautions and identification information













General instructions









These operating instructions are considered a part of the O₂ Monitor. It must be kept near the device at all times. If inconsistencies or problems occur during your usage that cannot be clarified by these instructions, please contact the manufacturer for clarification.

Strict adherence to the instructions is required to operate the device as intended. You must also follow these instructions in order to ensure the necessary level of safety.

Warranty claims for damages resulting due to the use of unsuitable third-party accessories and consumption materials are not covered.


Explanation of the symbols

Symbol	Description
	This symbol indicates that the device complies with the regulation 93/42/EEC concerning medical devices and all applicable international standards.
 WARNING	Indicates a potentially hazardous situation which, if not avoided, <i>could</i> result in death or serious injury.
 CAUTION	CAUTION is used to indicate a potentially hazardous situation which, if not avoided, may result in property damage.
 or 	Refers the user to the necessity of consulting the operating instructions.
	DO NOT USE OIL
	Follow the instructions!
	The disposal regulations must be observed! Defective devices and empty batteries should not be put in household waste. They must be disposed of in accordance with the relevant national or regional regulations.
	Notes on batteries
	Unique Device Identifier
	Shows the serial number of the manufacturer so that a certain medical product can be identified.
	Shows the order number of the manufacturer so that the medical product can be identified.

	Show the manufacturer of the medical product according to the EU guidelines 90/385/EEC, 93/42/EEC and 98/79/EC.
	Shows a medical product that should not be used if the packaging is damaged or opened
	Describes a medical product that must be protected against humidity.
	Describes a medical product which can break or be damaged if not handled with care.
	Describes the temperature limit values that the medical product can be safely exposed to.
	Describes the humidity range that the medical product can be safely exposed to.
	Describes the atmospheric pressure range that the medical product can be safely exposed to.
	None sterile

Safety notes

 WARNING
The oxygen monitor is not permitted for use in potentially explosive areas.

 WARNING
This oxygen monitor is not MRI-compatible since its electrical components can be destroyed.

Regarding the oxygen sensor which is used with this device, the following safety instructions of the manufacturer must be followed:

 WARNING
Do not mechanically damage the sensor. Do not use damaged products. Do not

use for purposes other than intended.

Possible dangers

Dangers for humans and the environment:

Lead/ lead compounds: Poisoning will result from ingestion, inhalation of dusts or skin absorption, use protective measures in accordance with TRGS 505 (6/88).

Potassium hydroxide solution GefStoffV (Ordinance on Hazardous Substances) "corrosive", acid burns result from skin and eye contact.

Do not disinfect in liquid.

Remove dirt or impurities with a damp disposable cloth.

Instructions for disposal of the oxygen sensor product

Recommendation: Dispose of in accordance with regulations by incinerating at a hazardous waste incineration facility. Follow all applicable regional regulations.

Do not dispose of in household garbage.

EAK - key 160202 and 160606

Regulations

Marked in accordance with GefStoffV as "corrosive" for the KOH solution component


3 Contents of delivery; Inspection upon receipt

Contents of the delivery:	1 O2 Monitor	D-B-QMon-O2
	1 Sensor cable	D-B-QMon-cable
	1 ENVITEC O2 sensor OOMLF111	D-B-O2-111LF
	1 Flow diverter	01-002171
	1 T- piece	46-006005 (optional)
	1 Blender Buddy	D-B-B-O2 (optional)
	1 Operating instructions	

Spare Parts: The reordering of spare parts is only possible via the manufacturer DEHAS or an authorized DEHAS dealer under the specified article numbers:

Spare Part/ Product	Article No.
Sensor cable	D-B-QMon-Kabel
ENVITEC O2-Sensor OOMLF111	D-B-O2-111LF
Flowdiverter	01-002171
T-Piece	46-00600
or	
Blenderbuddy	D-B-B-O2

Inspection: Take the device out of its packaging and inspect it for damage. Do NOT use the device if you detect any damage. Contact your supplier.

 ATTENTION
The operation of the device in the listed configuration for the purpose intended by the manufacturer, is to be used only with the specified original, compatible accessories from DEHAS . Any deviation from this intended combination caused by the user may lead to a failure of the essential performance features of the device.

4 Intended usage

The O2 Monitor is used to identify and monitor oxygen concentrations in breathing gas mixtures in medical applications. The O2 Monitor can be used for function monitoring of breathing gas mixtures from anaesthesia machines and breathing respirators as well as baby incubators.

Indication: The oxygen content of a breathing gas should be monitored.

Contraindications: Not suitable for personal protection. Do not use for monitoring during the production of gaseous mixtures.

5 Before initial use

Read all instructions before use!

These operating instructions are intended to show trained medical professionals how to install and operate the O2 Monitor. They promote safety and protect your device from damage. If you do not understand information or instructions in this document, do not use the device and contact your supplier.



WARNING

This product is not intended for use as a life-sustaining or life-supporting device.

6 Technical specifications

All technical data apply for standard conditions:
an ambient pressure of 1013 hPa and dry ambient air at 25 °C

Characteristic	Specification in connection with the oxygen measuring cell OOMLF111
Measuring range	0-100% oxygen
Display accuracy	0.1% oxygen
Accuracy	<1% vol. O ₂ , when calibrated to 100 % vol. O ₂
Offset voltage	< 200 µV in 100 % nitrogen over 5 min
Response time	< 12 sec. at 90 % of final value
Linearity error	< 3% relative deviation to the characteristic curve
Drift	< 1% vol. O ₂ over 8 hours
Cross-sensitivity	< 0.1% vol. O ₂ in reaction to: 10 % CO ₂ residual N ₂ 80% N ₂ O residual N ₂ 7.5% Halothane residual N ₂ 7.5% Isoflurane residual N ₂ 7.5% Enflurane residual N ₂ 9% Sevoflurane residual N ₂ 20% Desflurane residual N ₂
Influence of moisture	0.03% relative per RH
Pressure influence	Proportional to the change in partial pressure of oxygen
Susceptibility to shocks	< 1% relative accuracy after a fall in height of 1 m
Operating temperature	+5°C to +50°C
Temperature compensation	Built-in NTC compensation
Operating humidity	0-99% non-condensing rel. humidity
Operating pressure range	750-1250 hPa
Storage temperature of monitor	-20°C to +50°C
Recommended storage temp. of measuring cell	+5°C to +15°C

Recommended storage temp. of the battery	+5°C to +50°C
Battery type	Three type AAA / 4.5V
Protection degree	IP 42

7 Electromagnetic compatibility

Precautions:

Electromedical equipment requires special precautions regarding electromagnetic compatibility (EMC). This device may only be used for the purposes described in this document and must be installed, configured and operated in accordance with the EMC directive.



WARNING

Portable RF - communication devices (including peripherals such as antenna cables and external antennas) must not be used closer than 30 cm to any part of the O2 monitor, including cables to be used by the manufacturer. Failure to do so may result in a reduction in the performance of this unit.



WARNING

Do not use the device directly next to or on top of another device. If use adjacent to or on top of other equipment is required, check that normal operation is possible with the particular configuration before using the equipment.

Do not use accessories other than those specified for the device, as this may result in increased emissions or reduced immunity of the device.




ATTENTION

If the essential performance characteristics of the product are impaired or lost due to electromagnetic interference, according to the manufacturer's experience and risk assessment, there is no danger to the patient which could lead to an unacceptable risk. This device is not directly connected to a main device for the application of respiratory gases and is intended only for the use intended by the manufacturer. The essential performance characteristics and basic safety of the main device are not affected by the use of this product.

Guidelines and manufacturer's declaration Electromagnetic emissions			
1	The O2 monitor is intended for operation in an environment as specified below. The customer or the user of the O2 monitor should ensure that it is operated in such an environment.		
2	Interference emissions	Compliance	Electromagnetic Environment – Guidance
3	RF emissions CISPR 11	Group 1	The O2 monitor uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely that neighboring electronic devices will be disturbed.
4	HF-emission CISPR 11	Class B	The product is intended for use in all facilities, including residential areas and those areas directly connected to a public utility network that also supplies buildings used for residential purposes.
5	Emissions of harmonics IEC 61000-3-2	Not applicable	Not applicable
6	Emission of voltage fluctuations IEC 61000-3-3	Not applicable	Not applicable

Guidelines and manufacturer's declaration electromagnetic immunity			
The O2 monitor is intended for operation in an environment as specified below. The customer or the user of the O2 monitor should ensure that it is operated in such an environment.			
Interference immunity tests	IEC 60601 Test level	Compliance level	Electro-magnetic environment - Guidelines
Static electricity discharge (ESD) IEC 61000-4-2	±8 kV Kontakt-entladung	±8 kV	Floors should be made of wood or concrete, or have ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
	±2 kV, ±4 kV, ±8 kV, ±15 kV Luftentladung	±2 kV, ±4 kV, ±8 kV, ±15 kV	
Radiated RF - disturbances according to IEC 61000-4-3	3 V/m 80 MHz – 1000 MHz 1,0 – 2,7 GHz	3 V/m 80 Mhz – 2,7 GHz	The field strengths of fixed RF transmitters ^a determined during an electro-magnetic site analysis must be below the over-tuning level ^b in each frequency range. Interference may occur in the vicinity of equipment marked with the following
	27 V/m 385 MHz	27 V/m	
	28 V/m 450 MHz	28 V/m	
	9 V/m 710-780 MHz	9 V/m	
	28 V/m 810-930 MHz	28 V/m	

	28 V/m 1720-1970 MHz	28 V/m	symbol:  Portable and mobile radios should not be used at a distance from the O2 monitor, including lines, less than the recommended protective distance: $d > 0.3\text{m}$
	28 V/m 2450 MHz	28 V/m	
	9 V/m 5240-5785 MHz	9 V/m	
Conducted RF disturbances IEC 61000-4-6	3V 0,15 - 80 MHz	3V 0,15 - 80 MHz	
	6V ISM - frequency bands 0.15-80 MHz	6V ISM - frequency bands 0.15-80 MHz	

Note 1: For 80 MHz and 800 MHz, the higher frequency range applies.
 Note 2: these guidelines may not apply to all situations. The propagation of electromagnetic fields is affected by absorption and reflection from buildings, objects and people.

^a The field strength of stationary transmitters, such as cell phone base stations and mobile land mobile radios, amateur radio stations, and AM and FM radio and television transmitters, is theoretically not 100% predictable. To determine the electromagnetic environment with respect to stationary transmitters, on-site testing is recommended. If the field strength measured at the site of this equipment exceeds the compliance levels listed above, the equipment should be monitored to ensure that it is operating as intended. Additional measures, such as changing the orientation or location of the device, may be required if unusual performance characteristics are observed.

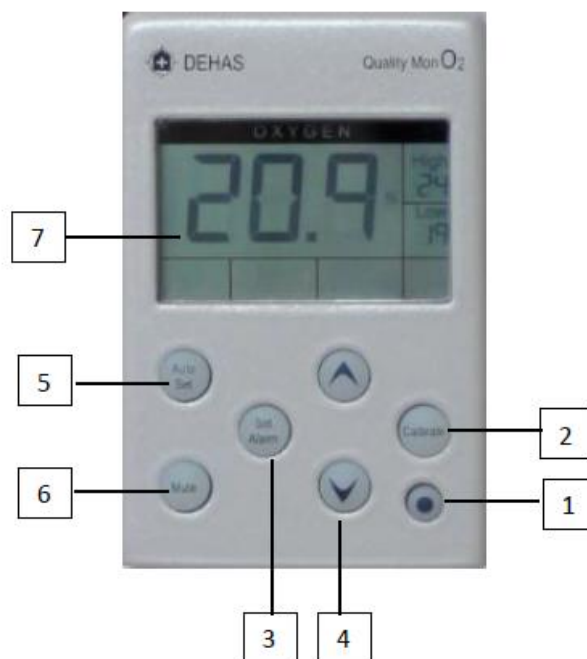
^b In the frequency range 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

<p>Immunity to magnetic fields with power frequencies IEC 61000-4-8</p>	<p>30 A/m 50Hz 60Hz</p>	<p>30 A/m 50Hz 60Hz</p>	<p>Magnetic fields at the mains frequency should correspond to the typical values found in business and hospital environments.</p>
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8 Illustrations and identification of components

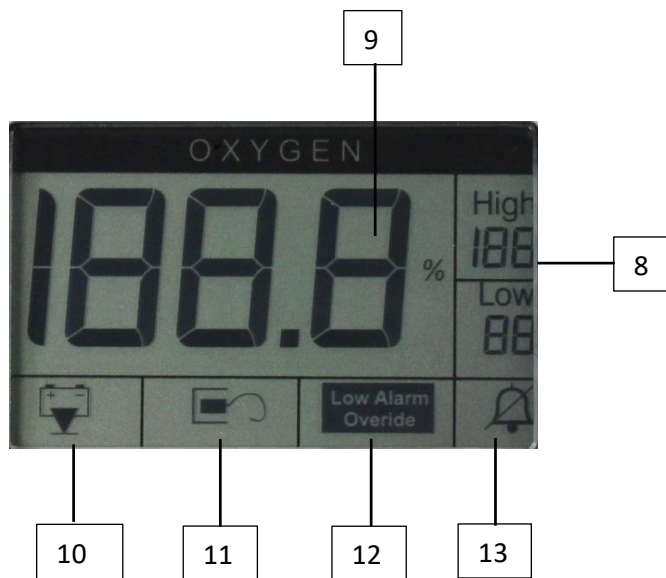
CAUTION

If you follow the cleaning instructions, the labelling on the device should stay readable. Contact your local representative if the labelling becomes unreadable or is missing.



No.	Description
1	On/Off switch – Press for approx. 2 seconds to switch on and off
2	Calibration button – Push the "Cal." button (for approx. 3 seconds) to put the device in calibration mode. Default is 21% (air). Push the Arrow UP button (4) if you would like to calibrate to 100% O ₂ . Push "Cal." again to start the calibrating process. -> Refer to section 10 <i>Calibration and measuring accuracy</i>
3	Alarm setting – Press the "Set Alarm" button (approx. 3 seconds) to set the alarm limits. Press once for lower alarm limit; press again for upper alarm limit. If pressed a third time, the device goes back into measurement mode.
4	Up/down selection button
5	Alarm standard values – Press the "Auto Set" button (approx. 3 seconds) to set the standard alarm limits (lower alarm limit is 2% under default value, upper alarm limit is 3% above default)
6	Mute – Press the Mute button to suppress the acoustic alarm for approx. 1 minute.
7	LCD - The display shows the oxygen concentration in the range of 0 to 100% O ₂ , as well as the upper and lower alarm limits.

The display

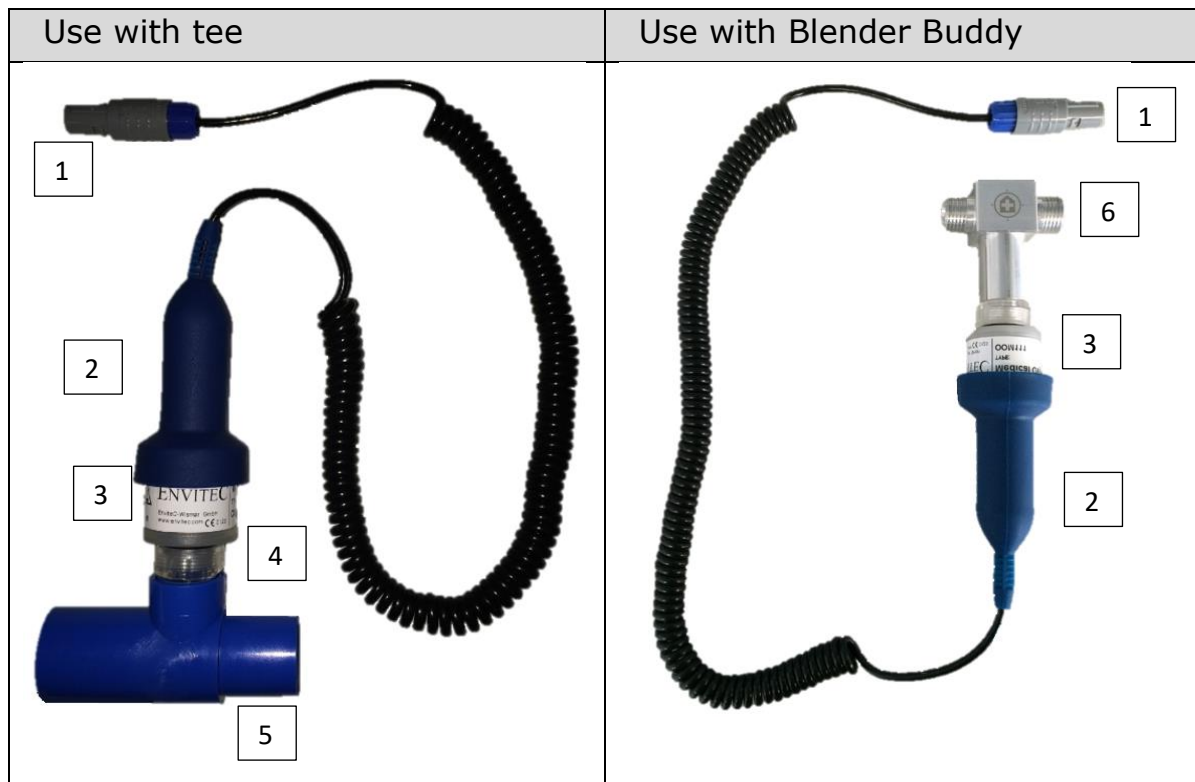


No.	Description
8	Upper and lower alarm limits
9	Oxygen concentration in vol. % O ₂
10	Battery indicator
11	Sensor error: sensor not recognised
12	The lower alarm limit can be lowered to 16% (Can be set with the key combination "Auto Set" + ↓)
13	Muting the alarm

Whenever the battery indicator is continually displayed, the batteries should be replaced because they can only provide the required voltage for a short time more. The battery is empty when the display is flashing. If the battery indicator flashes briefly when you turn on the device and then goes out immediately, this indicates that the batteries are empty and the device cannot be used. The batteries must be replaced.

9 Initial use

1. Connect the oxygen sensor



Both figures show the same sensor cable; the colour differences are caused by the lighting.


The sensor cable is connected to the port (1) on the back of the monitor that is connected to the device.

The flow diverter (4) is screwed onto the sensor (3).

The sensor (3) is connected to the sensor cable via the sensor receptacle (2).

Note: Make sure that you push the sensor all the way into the receptacle until it can go no further.

2. Switching on the monitor

Press and hold the ON/Off button (for more than 2 seconds)  to switch on the O2 Monitor. It then carries out a self-test. A measured value will be displayed when the sensor is properly connected to the device.

→ The measured value is displayed:

The O2 Monitor is working

→ No measured value is displayed or there is an error message:

The O2 Monitor is not functioning properly; refer to Chapter 10, section 3 for troubleshooting.

3. Calibrating the O2 Monitor

Refer to Chapter 10 Calibration and measurement accuracy.

4. The device is ready to take measurements after the calibration has finished successfully.
5. Connecting to the gas-bearing system

Place the sensor with the flow diverter in the tee (5) or the Blender Buddy (6) (depending on your selected version).

10 Calibration and measuring accuracy

1. Calibrating with ambient air

- Switch on the O2 Monitor.
- Hold the sensor away from your body.
- Press the calibration button "Cal." to start the calibration. "Cal." and "21" flash. (If "21 %" does not flash, press "↓").
- The display alternates between "Cal." and "21". Then press the "Cal." button again. The device is now calibrated to the ambient air with 20.9% and displays this.
- The device is ready to take a measurement.

Note: The oxygen concentration in the ambient air is 20.95% O₂. This results in the calibration value of 20.9% O₂. Atmospheric pressure, humidity and temperature all influence the displayed value (*refer to section 4*).

2. Calibrating with 100% oxygen

Note: When measuring high concentrations of oxygen (50 – 100%), we recommend using a calibration gas of 100% oxygen. Make sure that the connection between the oxygen sensor and the receptacle does not leak when gas is reaching the sensor. It must not be possible for ambient air to mix in with the oxygen; this would falsify the calibration.

- Connect the tee with the oxygen supply. Insert the sensor and flow diverter into the tee.
- Adjust the oxygen flow. We recommend using a flow of 2 l/min and gassing the sensor at least 1 minute prior to the calibration.
- Press the calibration button "Cal." ("Cal." flashes). Then, press "↑" ("100%" flashes), so that the device automatically calibrates with the pure oxygen.
- The display alternates between "Cal." and "100". Then press the "Cal." button again. The device is now calibrated to 100% oxygen.
- Remove the sensor from the receptacle. Now check for one minute if a reading of 21% O₂ results from a test measurement in ambient air.

- Hold the sensor away from your body and swivel it. No breathing exhalations should reach the sensor! If necessary, unscrew the flow diverter.
- The device is ready to take a measurement.

CAUTION
<p>The calibration should be checked before each new measurement by repeating the calibration! If the calibration cannot be performed correctly, refer to section 3 <i>Errors in calibration and recording measured values</i> in this chapter or contact your dealer.</p>

3. Errors in calibrating and recording measured values

Error pattern	Possible cause
<p>The measured value fluctuates by more than 1 vol. % of O₂.</p>	<ul style="list-style-type: none"> ➤ The sensor should be the same temperature (in thermal equilibrium) as the environment. ➤ Avoid thermal transfer from your hands to the sensor. ➤ Observe the sensor's adjustment time. ➤ The sensor's opening must be clean and dry ➤ Gas has mixed with ambient air during calibration. ➤ Internal electrical fault in the device → Contact your dealer!
<p>The device does not display the expected measured value</p>	<ul style="list-style-type: none"> ➤ Calculations of the gas mixture are incorrect ➤ The pressure gauge is defective. ➤ Device is not calibrated ➤ Sensor not in thermal equilibrium with the environment ➤ Ambient gases have mixed in.
<p>After being switched on, the device displays "ERR/lo".</p>	<ul style="list-style-type: none"> ➤ Send in the device to the dealer or manufacturer for inspection!
<p>Device displays symbol or "LO" for sensor after being switched on</p>	<ul style="list-style-type: none"> ➤ The original oxygen sensor is not being used. Use of the ENVITEC oxygen sensor of type OOMLF111 (part no.: D-B-O2-111LF) is mandatory. ➤ The sensor is not connected correctly to the jack plug. ➤ The sensor is defective → Replace the sensor!
<p>The display goes out shortly after the device is switched on, or does not go on at all.</p>	<ul style="list-style-type: none"> ➤ Batteries are empty → Replace the batteries!



CAUTION

The oxygen sensor will wear out over the course of its normal lifespan, even when the power is off. The sensor must be replaced when the proper values are not displayed during the calibration (20.9% or 100% O₂), or when the measured values are not plausible (after the troubleshooting possibilities have been gone through).

4. Influencing factors

Influence of gas pressure and gas moisture:

The oxygen sensor measures the oxygen partial pressure in the gas mixture. However, the device displays the percentage oxygen concentration so that it first needs to be calibrated.

During calibration, the oxygen partial pressure of dry ambient air is equated with a volume concentration of 20.9% O₂. Depending on the absolute humidity of the measured gas, the oxygen content (oxygen partial pressure) in the gas will fluctuate slightly. This moisture influence can be neglected because the error for the entire operating temperature range between absolutely dry and saturated gas is less than 1% O₂.



CAUTION

The calibration should be carried out under the same pressure conditions as the measurements, so that pressure differences are taken into account. The pressure conditions taken into account during the measurement include the gas mixture pressure, the current air pressure, and the height of the measuring location above sea level.

Influence of ambient temperature:

The influence of changes in ambient temperature is compensated for by the O₂ Monitor.

Note: Remember that the monitor's oxygen sensor should be adjusted to the ambient temperature. Strong short-term fluctuations in the gas temperature can temporarily impair the accuracy of the displayed value.

Influence of water:

Do not completely cover the sensor or the jack with water. The measured results are influenced when water is on the gas-inlet surface of the oxygen sensor.

The surface of the device can be dried with a cloth if it gets wet. We recommend that you wait until the sensor is dry before switching on the device.



CAUTION

This device may only be opened by authorised and trained technicians!

11 Setting the alarm

1. Setting the alarm limits:

➤ Configuring the alarm limits

Lower alarm limit:

Press the "Set Alarm" button once ("Low" flashes). Then press "↓" or "↑" to change the lower alarm limit.

Note: According to the safety standard, the smallest configurable value is 18!

Pressing the button "Auto Set" + ↓ enables the lower alarm limit to be set up to 16 % O₂. Turning the device on and off puts the alarm limits back in the adjustable standard range of 18% to 104%.

Upper alarm limit:

Press the "Set Alarm" button twice ("High" flashes). Then press "↑" or "↓" to change the upper alarm limit.

Note: The highest configurable value is 104!

➤ Selecting the default alarm limits


Press the "Auto Set" button for three seconds ("OFF" flashes). This sets the lower and upper alarm limits to their normalised default settings (lower alarm limit: -2 % of the set mixing ratio; upper alarm limit: +3 % of the set mixing ratio).

2. Setting the acoustic alarm


When the measured/displayed oxygen concentration falls below or exceeds the specified alarm limits, an acoustic signal alarm (a periodic peeping tone) is emitted.

➔ Deactivating the acoustic alarm

Press the "Mute" button " " to deactivate the acoustic alarm for 1 minute.

The display will show " ".

After a minute, the acoustic alarm will sound again continuously and the "

 " icon disappears from the display.

12 **EnviteC oxygen sensor OOMLF111**

1. Operating principle

The basic functionality of the oxygen sensor is described below.

1. The gas being measured diffuses through a synthetic membrane and dissolves in the electrolyte of the oxygen sensor.
2. The electrolyte contains two electrodes which are interconnected via an external resistor network.
3. The proportion of the dissolved oxygen is reduced at the working electrode (the cathode). In turn, the second electrode (the anode) is oxidised.
4. The resulting inner ion current causes an outer, electrical current which is proportional to the reaction of the oxygen.
5. The diffusion of gas molecules is dependent on the temperature. To compensate for this dependency, the current is converted by a thermistor/resistor network into a temperature-compensated voltage.

2. Lifespan of the sensor and batteries

The O2 Monitor consists of a measuring device and an oxygen sensor. Since the batteries and sensor are considered wearing parts, they should be replaced when the device no longer provides accurate measurements. The sensor has been designed so that, under normal usage conditions, it should last for about one year. The batteries power the unit for at least 1,100 hours of operation under normal conditions.

The following influences on wearing and ageing should be noted:

The oxygen sensor wears out regardless of whether the device is switched on. This wear depends on the temperature and the oxygen partial pressure at the gas-sensitive surface of the sensor. The minimum lifespan (operating time) of the oxygen sensor, therefore, relates to 1% oxygen times the hours and is > 1,000,000 % O₂h. The sensor therefore wears out more quickly if it is stored or operated under higher oxygen partial pressures. The temperature speeds up the material conversion of the oxygen sensor and therefore influences the ageing. So, put simply, the higher the temperature, the shorter the expected lifespan. Very dry ambient conditions also have a negative impact on the lifespan of the oxygen sensor. This is because evaporation of the electrolytes increases.



CAUTION

Due to these circumstances, you should not store the O₂ Monitor at unnecessarily high ambient temperatures, or in very dry environments, or under increased partial pressure of oxygen.

3. Replacing the sensor

- Loosen and remove the sensor receptacle.
- Dispose of the sensor.
- Connect the new sensor and check the function.
- Carry out a calibration.



CAUTION

Only use the oxygen sensor OOMLF111!



Follow the instructions on the sensor packaging! The sensor contains electrolyte and lead!

4. Packaging and storage

During storage, the sensor consumes the oxygen content of the gas located in the interior of the gas inlet opening. This ageing is reduced when the sensor is stored in its original packaging. After the sensor is removed from its packaging, it needs some time before it is ready to be used for measurements. This time depends on the storage time and the storage temperature. This period can last up to 30 minutes. Therefore, a calibration of the device should be carried out after the sensor has been allowed time to stabilise. Storage at a temperature between 5 – 15 °C is recommended in order to shorten the required stabilisation time.

Storage:

Temperature range: -20 °C to 50 °C / Store in original packaging.

Labelling:

Product name: Oxygen sensor:

Usage: for measuring oxygen concentrations

Type: OOMLF111 – sequential type number

Manufacturer / Supplier information:

Manufacturer:

ENVITEC - Wismar GmbH by Honeywell, Alter Holzhafen 18,
D-23966 Wismar

Telephone / Fax: 49 - 3841 360 1 / 49 - 3841 360 222

Supplier:

DEHAS Medical Systems GmbH

Wesloer Strasse 107-109

23568 Lübeck

Telephone / Fax: 0451 80904 0 / 0451 80904 111

13 Cleaning / disinfection

1. Device surface

Turn the O2 Monitor off.

Wipe the device using a damp cloth. Make sure that no liquid enters the device.

Common cleaning agents and disinfectants are normally suitable for use.



CAUTION

Device damage: Do not use phenol-based disinfectants and peroxide compounds for disinfecting the device surfaces.

Use surface disinfectant cleansers for disinfecting. For reasons of material compatibility, cleaning preparations based on aldehydes, alcohols or quaternary ammonium compounds are suitable for use.

For users in Germany, we recommend using only disinfectants that are registered in the current list maintained by the German Society for Hygiene and Microbiology.

The manufacturer recommends the use of the disinfectant Bacillol ® 30 Foam, Bacillol ® 30 Tissues, Bode Chemie GmbH & Co. The current product data sheet of the disinfectant manufacturer must be observed.



WARNING

Electrical hazards and device damage: If liquid gets inside this device, the monitor may only be used after our customer service has inspected it.

2. Accessories

Disinfection wipes for the tee, the Blender Buddy and the flow diverter:

- Use, for example, Bacillol® 30 Foam.
- Initially, use a disposable cloth to wipe away larger areas of contamination or dirt.

Disinfection bath for the tee, Blender Buddy and flow diverter:

- Use Gigasept FF (formaldehyde-free) or similar.
- Move each part thoroughly around in the bath. Do not clean with a hard brush! Rinse well with distilled water. Allow each part to dry completely!



CAUTION

This device and its accessories are not suitable for sterilisation!

14 Maintenance

Regular maintenance is not required. To rule out any mechanical damage to the device, a visual check of the following housing parts must be carried out:

- Battery cover
- Front cover (buttons)
- Socket

The affected component must be replaced if significant damage (cracks, chipping, etc.) is found.

15 Disposal

Defective devices and empty batteries should not be put in household waste. They must be disposed of in accordance with the relevant national or regional regulations.

16 Warranty conditions

The supplier guarantees that the monitor will be free of material defects or workmanship errors for the following period:

One (1) year from delivery

If, within the applicable period, a device defect should occur, then the dealer shall – after written notification thereof and substantiation that the device has been stored, installed, maintained and operated in accordance with the instructions of the dealer and in accordance with standard industry practice, and that no modifications, substitutions or changes were made to the product – correct such a defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

The dealer is not authorised to make oral warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written statement is a final, complete and exclusive statement of the contractual terms.

The current version of the dealer's Terms and Conditions and German law are valid.

DECLARATION OF CONFORMITY



DEHAS Medical Systems GmbH
Wesloer Strasse 107-109
23568 Lübeck,
GERMANY



O2 Monitor

0482

Classification: IIb

Classification criteria: Clause 3.2, Rule 11 of Annex IX of the MDD

We hereby declare with sole responsibility that the above products comply with the following guidelines and standards of the EC Council. All supporting documents are kept on the premises of the manufacturer and the notified authority.

Directives: Medical Device Directive (MDD), Council Directive 93/42/EEC of 14 June 1993 Annex II, 3 on medical devices of the European Parliament.

Applied standards: ISO 80601-2-55
EN 60601-1-2
EN ISO 14971
EN 1041
DIN EN ISO 15223-1

Notified authority: DNV Medcert GmbH /  0482

Address: Pilatuspool 2, 20355 Hamburg, GERMANY

Certificate number: 4153DE410200327 Expiration date: 05/2024

Devices already manufactured: Traceable by serial number

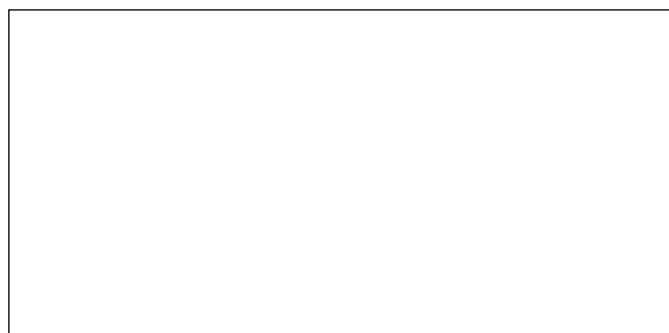
Valid from/to: 27-03-2020 to expiration date

Manufacturer representative: Director of Technology

Position: Production and Development

Date of issue: 27-03-2020

Your contact for sales and service:

A large, empty rectangular box with a thin black border, intended for providing contact information for sales and service.