

# **OxiQuant MC**



# Oxygen Monitor User Manual / Service Manual

#### User Manual

#### OxiQuant MC<sup>®</sup> Oxygen measuring device

The greatest care has been taken in preparing this manual. However, if you still come across any incorrect information in this manual when using the system, then please contact us. This will allow us to correct any mistakes as soon as possible.

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# 1 General Guidelines

This manual forms part of the device. It should always be kept near to the device.



This symbol means: please consult the manual. Warnings are indicated by the WARNING symbol on the left . Warning symbols inform users about any potentially serious risk for



#### This symbol means: ATTENTION

patients or users.

ATTENTION symbols inform users about how to use the OxiQuant MC in a safe and efficient manner.

# 2 Safety Guidelines

#### 2.1 General Safety Guidelines

Correctly observing this manual will ensure that the device is used in an appropriate manner and for its intended purpose. It will also ensure the health and safety of any users and patients who may depend on it.

The quality assurance system used by EnviteC-Wismar GmbH in all its company facilities complies with standards EN ISO 9001 and EN 13485.

No warranty claims can be made in the event of any damage as a result of using inappropriate accessories and consumable materials.

Faulty devices and empty batteries should not be disposed of as domestic waste, but in accordance with applicable national or local legislation.



#### ATTENTION:

The device is not suitable for use in areas where there is a risk of explosion.

## 2.2 Safety Guidelines for the Oxygen Sensor

#### Do not damage the sensor in any way

Do not use any damaged products. Only use the device for its intended purpose.

#### Potential risks

Potential risks to humans and the environment:

Lead or lead compounds: poisonous if consumed, inhalation of dust or skin resorption, safety measures in accordance with TRGS 505 (6/88).

Potassium hydroxide solution: 'corrosive' (German Ordinance on Hazardous Substances), chemical burns following contact with skin and eyes.

Do not disinfect in liquid.

Any dirt should be removed with a disposable tissue.

#### Guidelines for disposal of the oxygen sensor

Product

Recommended: disposal in accordance with applicable legislation in special waste incineration facilities. Local regulations must be complied with.

Do not dispose of as domestic waste.

EAK waste key numbers 160202 and 160606

#### Regulations

Indicated as 'corrosive' (in accordance with the German Ordinance on Hazardous Substances) due to the potassium hydroxide solution component.

# 3 Introduction

### 3.1 Application Area

The OxiQuant MC oxygen measuring device is designed for measuring and monitoring oxygen concentrations in breathable gas mixtures that are used for medical purposes.

The OxiQuant MC can be used for the functional monitoring of breathable gas mixtures for anaesthetic devices and respiration devices, as well as neonatal incubators.

The device is highly suitable for mobile use, due to its compact design and light weight, as well as user-friendly operation and calibration.

The OxiQuant MC should not be used for personal security. It should not be used for the production of gas mixtures.

The OxiQuant MC should be used exclusively with the ENVITEC oxygen sensor, type OOM111 (art. no.: 01-00-0114), which is very reliable, performs in a stable manner, and has been especially designed for use with the monitor.

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# 4 Operation Controls and Symbols4.1 The Device



No.	Description
1	Alarm buttons (alarm limits) with LED for
	optical display of alarm. By pressing the
	'ALARM' button (for approx. 3 sec.) and then
	the ' $\wedge$ ' or ' $\vee$ ' button, the alarm limits can be
	changed
	ightarrow also see Section 7: Alarm settings
2	Alarm button (alarm Auto Set)
	By pressing the 'AUTO SET' button (for approx.
	3 sec.), the alarm limits are set at their standard
	value
	ightarrow also see Section 7: Alarm settings
3	Alarm button (silence)
	By pressing the ' 麄 ' button, the acoustic

	alarm will be suppressed for approx. 1 minute $\rightarrow$ also see Section 7: Alarm settings
4	Calibration buttons By pressing the 'CAL' button (for approx. 3 sec.) and then '21%' or '100%', the device will be calibrated for air or 100% oxygen
	$\rightarrow$ also see Section 6: Calibration
5	ON/OFF button To turn on the OxiQuant, press down the ON/OFF button for 2 sec. To turn off the OxiQuant, also press down the ON/OFF button for 2 sec.
6	LC display The display directly indicates oxygen concentration in the range 0-100 % O <sub>2</sub> .

# 4.2 Display





No.	Description
7	Upper and lower alarm limits
8	Oxygen concentration in vol. % O <sub>2</sub>
9	Device error
10	Battery display
11	Sensor error

If the battery indicator is displayed continuously, then you must replace the battery, as it is almost empty. If the indicator is flashing, the battery is empty. If the battery indicator only flashes for a short time when you turn on the device, and the device turns off immediately, then the battery is completely empty. The device can then no longer be used ( $\rightarrow$  replace battery!)

### 4.3 Symbols on the OxiQuant MC

Symbol	Description
$\triangle$	Please consult the manual!
Ŕ	The device belongs to type BF. It is not protected against the effects of defibrillators.
	Date of manufacture

# 5 Putting into Operation



#### Connecting the oxygen sensor

Connect the sensor (2) to the OxiQuant MC with the jack (1).

Turn on the OxiQuant MC and check if a measurement value is displayed.

- A measurement value is indicated  $\rightarrow$  the OxiQuant MC is ready for use
- No measurement value is indicated → the OxiQuant MC is not ready for use (see Section 6.3. Calibration and measurement errors)



#### ATTENTION:

Carry out calibration ( $\rightarrow$  see Section 6: Calibration and measuring accuracy)

After successful calibration, the device will be ready for use.

In order to attach the device to a gas-operated system, connect the sensor (1) to the flow diverter (3), and plug it into the T-piece (4).

# 6 Calibration and Measuring Accuracy

## 6.1 Calibration and Ambient Air

- 1. Turn on the OxiQuant MC.
- 2. Keep the sensor away from the body.
- 3. By pressing the 'CAL' button ('CAL' is flashing) and then '21%' ('21%' is flashing), the device will automatically be calibrated for ambient air. The display will alternately show the indications 'CAL' and '21' for approx. 5 sec.
- The device is ready for use! The oxygen concentration of the ambient air is 20.95% O<sub>2</sub>. This results in a calibration value of 20.9% O<sub>2</sub>. Ambient pressure, ambient moisture and ambient temperature can all affect the indicated value (see Section 6.4).

## 6.2 Calibration at 100% O<sub>2</sub>

To measure high oxygen concentrations (50-100%  $O_2$ ), we recommend calibration with calibration gas at 100%  $O_2$ . In such a case, you should ensure during the gas flow that the connection between the oxygen sensor and the inlet is tight enough, so as to prevent any mixing with ambient gases.

Connect the T-piece to the oxygen supply and plug the sensor into the T-piece with the flow diverter.

Set the oxygen supply to a recommended oxygen flow of 2L/min. and initially expose the sensor to the gas for at least 1 min.

By pressing the 'CAL' button ('CAL' is flashing) and then '100%' ('100%' is flashing), the device will automatically be calibrated for pure oxygen. The display will alternately show the indications 'CAL' and '100' for approx. 5 sec. Remove the sensor from the inlet and check by pure ambient air if the device shows a measurement value of approx. 21%  $O_2$  after approx. 60 sec. When checking, hold away

the sensor from the body (no respiratory gases!) and swivel it (also disconnect the flow diverter).  $\rightarrow$  The device is ready for use!



#### ATTENTION:

The calibration process must be carried out or repeated prior to taking any new measurements! If calibration cannot be carried out correctly, then see Section 6.3: Calibration and measurement errors, or contact your supplier.

### 6.3 Calibrating and Measurement Errors

The measurement value varies by more than 1 vol.  $\% O_2$ 

Possible causes:

- The sensor is not at the same temperature as the ambient environment;
- Thermal influence of warm hands on the sensor;
- Incorrect time setting of the sensor (see box label);
- The sensor opening is dirty and/or wet;
- Gas mixes with ambient gases during calibration;
- Internal electric defect in the device  $\rightarrow$  inform your supplier!

The device does not display the expected measurement value  $\rightarrow$  possible causes:

- Faulty calculation of the gas mixture;
- Faulty manometer;
- The device has not been calibrated;
- The sensor is not at the same temperature as the ambient environment;
- The gas is mixed with ambient gases.

After being turned on, the device displays 'ERR'  $\rightarrow$  possible causes:

• Send the device to your supplier or the manufacturer for checking!

After being turned on, the device displays the sensor symbol  $\rightarrow$  possible causes:

- The original oxygen sensor is not being used  $\rightarrow$  use of an ENVITEC oxygen sensor, type OOM111 (art. no.: 01-00-0114), is recommended;
- The sensor has not been connected correctly to the jack;
- The sensor is defective  $\rightarrow$  replace the sensor!

Shortly after the device has been turned on, the display switches off or does not switch on  $\rightarrow$  possible causes:

• Empty battery  $\rightarrow$  replace the battery!



#### ATTENTION:

The shelf life of the oxygen sensor will also be reduced when the device is turned off. The sensor must be replaced when the values of 20.9%  $O_2$  or 100%  $O_2$  are no longer displayed during calibration, or - after checking for any of the defects outlined above the measurement value appears to be incorrect.

### 6.4 Influential Factors

#### Influence of gas pressure and measuring gas moisture

The oxygen sensor measures the oxygen partial pressure in the gas mixture, but the device indicates the oxygen concentration and therefore needs to be calibrated. During calibration, the oxygen partial pressure will be equalised to a volume concentration of 20.9%  $O_2$  through dry ambient air. Due to the absolute measurement gas moisture, the oxygen percentage (oxygen partial pressure) will vary slightly. The influence of moisture can be discarded, since the margin of error between absolutely dry gas and saturated gas is less than 1%  $O_2$  for the whole operating temperature.



#### ATTENTION:

In general, calibration must be carried out under the same pressure conditions as when measurements are taken, so as to equalise the effect of pressure differences.

Pressure conditions during measurements include the gas mixing pressure and the actual air pressure, which takes into account the extent to which the measurement location is above sea level.

#### Ambient air temperature

The influence of changes in ambient temperature are taken into account by the OxiQuant MC.

However, you should still ensure that the measuring device and oxygen sensor are adjusted to the ambient temperature. Strong and short changes in gas temperature could temporarily affect the accuracy of any measurements.

#### Water

All contact of the sensor wiring and jack connections with water should be avoided. Any water on the gas entry point of the oxygen sensor will affect the measurement.

In the event that the device has become wet, use a cloth to dry the surface. We recommend that you do not turn on the device until the sensor is completely dry.



#### ATTENTION:

The device should only be opened by authorised and qualified technicians!

# 7 Alarm Settings

# 7.1 Setting the Alarm Limits

- $\rightarrow$  Free selection of alarm limits
- By pressing the 'ALARM' button once ('Low' is flashing) and then the '^' or 'v' button, the lower alarm limits will be changed.

Note: The minimum value that can be set is '18'!  $\rightarrow$  Safety standard

• By pressing the 'ALARM' button twice ('High' is flashing) and then the '\alpha' or '\alpha' button, the upper alarm limit will be changed.

Note: The maximum value that can be set is '100'!

- $\rightarrow$  Selection of standard alarm limits
- By pressing the 'AUTO SET' button for 3 sec. ('OFF' is flashing), the lower and upper alarm limits are set at the standard alarm limits (Low 18 / High 23). Preset by the manufacturer.)

## 7.2 Setting the Acoustic Alarm

In the event that the measured and indicated oxygen concentration is outside of the alarm limits set, an acoustic alarm can be heard (beeps at regular interval) and an optical alarm is displayed at the same time (flashing LED).

- $\rightarrow$  Acoustic alarm off
- By pressing the '  $\cancel{\alpha}$  ' button, the acoustic alarm will be suppressed for approx. 1 minute  $\rightarrow$  '  $\cancel{\alpha}$  ' appears on the display.
- After 1 minute, the acoustic alarm can be heard again continuously and ' 🍂 ' appears in the display.
- The optical alarm (flashing LED at the 'ALARM' button) will also continue when the acoustic alarm is suppressed.

# 8 EnviteC Oxygen Sensor

### 8.1 Operating Principle

In short, the oxygen sensor operates in the following way:

- 1. The measuring device diffuses through a synthetic membrane and dissolves into the electrolyte of the oxygen sensor.
- 2. The electrolyte contains two electrodes that are connected via an external resistance network.
- 3. The percentage of oxygen dissolved is reduced at the operational electrode (cathode). The second electrode (anode) is oxidised.
- 4. The resulting internal ion flow causes an external electric current, which is proportional to the amount of oxygen transformed.
- 5. The diffusion of gas molecules depends on temperature. In order to compensate for this dependence, the current is transformed into a temperature-compensated voltage via a thermistor-resistance network.

## 8.2 Sensor and Battery life

The OxiQuant MC consists of a measuring device and an oxygen sensor. As the battery and sensor are liable to run out, they should be replaced when the device can no longer be turned on or the initial display message is no longer shown. The sensor has been designed in such a way that it has an average life of approx. 2 years. The battery provides the device with a minimum of 1,100 operating hours under normal conditions.

# The following wear-and-tear influences should be taken into account:

The shelf life of the oxygen sensor is reduced irrespective of the time that the device is turned on. This shelf life is relative to the temperature and oxygen partial pressure at the gas inlet of the sensor.

The minimal operational use of the oxygen sensor is therefore estimated at 1 oxygen x number of hours and amounts to 1,000,000% O<sub>2</sub>h. The shelf life of the sensor reduces more quickly when it is stored or used in high oxygen partial pressure conditions. The temperature accelerates the material conversion of the oxygen sensor and therefore affects condition. The higher the temperature, the shorter the anticipated shelf life.

Very dry ambient conditions also have a negative effect on the life of the oxygen sensor, since this increases the evaporation level of the electrolyte.



#### ATTENTION:

You should try and avoid storing the OxiQuant MC at high ambient temperatures, in a very dry environment, or at an increased level of oxygen partial pressure.

### 8.3 Changing the Sensor

- Remove the sensor and disconnect the jack.
- Dispose of the sensor
- Connect the new sensor and check if it works
- Carry out calibration



Observe the instructions on the packaging of the sensor! The sensor contains an electrolyte and lead!

### 8.4 Packaging and Storage

When stored, the sensor uses up the amount of oxygen contained in the gas inside the gas inlet. As a result, even if the sensor is stored in its original packaging, its shelf life will still be reduced. The sensor requires some time to stabilise and provide a measurement when removed from its packaging, depending on the length of time it has been stored. This adjustment time can take up to 30 min. We therefore recommend that the measuring device is only calibrated after it has stabilised or recalibrated prior to subsequent use. We recommend a storage temperature between 5–15°C in order to shorten this adjustment time as much as possible.

#### Storage:

Temperature range  $-20^{\circ}$  to  $50^{\circ}$  / Storage in origin al packaging.

Labelling:

Article description: oxygen sensor Use: to measure oxygen concentrations Type: OOMXXX, XXX – continuous type number Manufacturer/supplier information: Manufacturer: **ENVITEC**-Wismar GmbH, Alter Holzhafen 18, D-23966 Wismar, Germany Tel./Fax: 03841 360 1 / 03841 360 222

# 9 Cleaning

### 9.1 Device Surface

Turn off the OxiQuant MC.

Use only a moist cloth to clean the device and ensure that no fluid enters the device.

The most commonly available cleaning and disinfection agents can be used.



#### ATTENTION:

Do NOT use any disinfection agents that contain phenol and/or peroxide to disinfect the surface of the device!

Instead, use disinfectants that have been specifically made for disinfecting surfaces. Based on material tolerance, disinfectants containing the following active compounds are suitable: aldehydes, alcohol or quaternary ammonium compounds.

For users within the German Federal Republic, we recommend that you use disinfectants that are listed in the most up-to-date DGHM list (DGHM: – the German Society for Hygiene and Microbiology).



#### WARNING:

Danger of electric shock, damage to device. If any fluid has entered the device, then it should only be used again after it has been checked and approved by the Service Department.

## 9.2 Accessories

Disinfection of the T-piece and flow diverter by wiping:

- E.g. with Buraton 10 F or Terralin;
- Remove any larger amounts of dirt with a disposable tissue prior to disinfection.

Disinfection of the T-piece and flow diverter by submerging:

- E.g. with Gigasept FF = free of formaldehyde;
- Sufficiently submerge the part into the solution; Do not clean with a hard brush! Thoroughly rinse the part with Aquadest. Let the part dry completely!



ATTENTION: The device and accessories cannot be autoclaved!

# 10 Scope of Delivery and Accessories

Article	P/N
OxiQuant MC	46-00-0027
O <sub>2</sub> -Sensor OOM111	01-00-0114
Flow diverter	01-002171
T-piece	46-006005
Tubing adapter	46-000087 (optional)



#### ATTENTION:

Faulty devices and empty batteries should not be disposed of as domestic waste, but in accordance with the applicable national or local legislation.

# 11 Specifications and Characteristics

All specifications apply to standard conditions. Ambient pressure 1013 hPa, 25°C dry ambient air.

Measurement range: Display accuracy: Accuracy:	0-100% oxygen 0.1% oxygen < 1% vol. 0 <sub>2</sub> , if calibrated at 100%
<b>Offcet</b> .	vol. $O_2$ < 1% vol. $O_2$ in 100% N <sub>2</sub>
Response time:	< 12 sec. at 90% of final value
Linearity error:	< 3% relative
Drift:	< 1% vol. O <sub>2</sub> for 8 hours
Cross sensitivity:	$< 0.1\%$ vol. $O_2$ in response to:
·	$10\% \text{ CO}_2 \text{ rest N}_2$
	80% N <sub>2</sub> O rest N <sub>2</sub>
	7,5% Halothane rest N <sub>2</sub>
	7,5% Isoflurane rest N <sub>2</sub>
	7,5% Enflurane rest N <sub>2</sub>
	9% Sevoflurane rest N <sub>2</sub>
	20% Desplurane rest N <sub>2</sub>
Moisture sensitivity:	0.03% relative per % RH
Pressure sensitivity:	proportional to amendment of oxygen partial pressure
Shock sensitivity:	< 1% relative to fall from 1m height
Operating	0°C – 50°C
temperature:	
Temperature	built-in NTC compensation
compensation:	·
Operation humidity:	0 - 99% rel. humidity
Storage temperature:	-20°C – 50°C
Recommended storage:	5°C – 15°C
Battery type:	3 x type AA / 1,5V
Protection class:	IP 40

### Manufacturer's Declaration and Electromagnetic Emissions

1	G	uidelines and Manufacture Electromagnetic Emi	r's Declaration ssions
2	The OxiQuant MC is intended for use users of the OxiQuant MC should en	in the electromagnetic enviro sure that the device is only use	onment specified below. Customers or d in such an environment.
3	Emissions test	Compliance	Electromagnetic environment - guidelines
4	RF emissions CISPR 11	Group 1	The OxiQuant MC uses RF energy for its internal function only. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class <b>B</b>	
7	Harmonic emissions IEC 61000-3-2	Not applicable	
8	Flicker voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	
9			The OxiQuant MC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.

#### Guidelines and Manufacturer's Declaration Electromagnetic Emissions

The OxiQuant MC is intended for use in the electromagnetic environment specified below. Customers or users of the OxiQuant MC should ensure that the device is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV	± 6 kV contact ± 8 kV air	Floors should consist of wood, concrete or ceramic tile. If floors are covered with synthetic material, then the relative humidity should be
	air		at least 30%.
Magnetic fields by power frequency (50/60) Hz	3 A/m	3 A/m	Power frequency magnetic fields should at all levels correspond to those for a typical location in a typical commercial or bospital
IEC 61000-4-8			environment.
Conducted RF IEC 61000-4-6	<b>3 V</b> 150 kHz – 80 MHz	3 V	Portable and mobile communications equipment should not be used at any closer distance to any part of the OxiQuant MC, including cables, than the recommended separation distance, which is calculated on the basis of the equation applicable to the frequency of the transmitter. <b>d</b> > <b>0.3m</b>
Radiated RF IEC 61000-4-3	<b>3 V/m</b> 80 MHz – 800 MHz	3 V/m	d > 0.1m
Radiated RF IEC 61000-4-3	<b>3 V/m</b> 800 MHz – 2.5 GHz	3 V/m	d > 0.2m

	ENVI Way about in T
E	U - Conformity Statement
	We declare with sole responsibility, that the product:
	OxiQuant MC
	P-N 46-00-0027
complies with the basi Council on Medical Pro accordin	ic requirements according to appendix 1 of the Regulations of t iducts of 14 <sup>th</sup> June 1993 (93/42/EWG). The product was classi ig to appendix 1X of the Regulation 93/42/EWG as
	Class IIa
	CE mark awarded:
	CEars
Issued by:	ENVITEC - WISMAR GMBH
	Alter Holzhafen 18 D-23966 Wismar Germany
Place, Date:	Wismar, 2005-08-26
Authorised signature:	d.