Operating Instructions

QualityMix Pro

Oxygen-air gas mixer
QualityMix Series

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1. Introduction

1.1 Overview

Table of Contents

This chapter includes

- general information on the operating instructions,
- the specified type of usage for the QualityMix Pro and
- the manufacturer's requirements for the operating personnel.

1.2 Overview

Validity

These operating instructions apply to the QualityMix Pro oxygen-air gas mixer.

Manufacturer

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Retention and completeness

- These operating instructions are an integral part of the QualityMix Pro oxygen-air gas mixer and must always be available to authorized personnel.
- Precise knowledge of the information and warnings contained in these operating instructions is a key requirement in order to safely operate the QualityMix Pro. Nevertheless, it is no substitute for training.
- No chapters may be removed from these operating instructions at any time. A missing manual or missing pages – especially the chapter "Safety" – must be replaced immediately if lost.
- Make sure that you read and understand this manual and the safety instructions it contains before using this product. Failure to do so may result in serious injury or death.
- Follow all instructions. Doing so will prevent fire, explosion or other hazards that could result in property damage and/or serious or fatal injury.
- Keep all safety notes and instructions for future reference and pass them on to subsequent users of this product.

Change service

This documentation is subject to the change management service from DEHAS Medical Systems GmbH.
Changes to this documentation may be made without further notice.

Internet

- Information about the product is available at the following address: http://www.dehas.de.

Request for information

- The operating manual and technical information can be requested from DEHAS Medical Systems GmbH by calling (+49) 451 80 90 4-0.

Feedback

- Suggestions and ideas for improving our products can be sent to the following e-mail address: info@dehas.de.

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1.3 Intended use

Intended use

The air-oxygen gas mixer QualityMix Pro is used to administer a continuous, precise mix of medical air and medical oxygen – through its outlet ports – to infants, children and adults. The precise fractional inspiratory oxygen concentration (FIO2) corresponds to the selected FIO2 setting on the control knob (a rotary switch).

Indication:

This device should be used for patients who find it difficult to get sufficient oxygen from the ambient air.

The use of a medical oxygen mixer may be indicated for the following medical situations.
Typical indications are:
Respiratory diseases: Patients with respiratory diseases such as chronic obstructive pulmonary disease (COPD), asthma, pulmonary fibrosis or respiratory distress syndrome may benefit from oxygen therapy. An oxygen mixer allows the oxygen concentration to be precisely adjusted to support breathing and meet the patient's oxygen requirements.

Anaesthesia: Patients require a controlled supply of oxygen during an operation or sedation. A medical oxygen mixer is used to control the exact concentration of oxygen supplied and to provide the patient with sufficient oxygen during the procedure.

Emergency medicine: For emergency situations, such as a heart attack, a severe asthma attack or acute respiratory distress, the administration of oxygen can be life-saving. An oxygen mixer provides a quick and precise flow of oxygen to remedy the lack of oxygen in the body.

Obstetrics: For newborn babies with breathing difficulties or insufficient oxygen supply, a medical oxygen mixer can be used to increase the oxygen concentration in the breathing air and support breathing.

Contraindications:

There are also certain contraindications where the use of a medical oxygen mixer may not be suitable or should be only used with caution.

Typical contraindications:
This device should not be used for patients who cannot breathe on their own.

Do not use for life support or lifesaving procedures.

Carbon dioxide retention:
Patients with a history of chronic carbon dioxide retention (CO2 retention) may react sensitively to an excessively high oxygen concentration. Excessive oxygen supply can suppress the respiratory stimulus signals and lead to further carbon dioxide retention. In such cases, the oxygen concentration must be closely monitored to avoid overloading with oxygen.

Hyperoxia: For some medical conditions or injuries, an excessive concentration of oxygen may be harmful. For example, an excessive oxygen supply to premature babies can lead to eye damage. This is known as premature retinopathy. Close monitoring of the oxygen concentration and individual adjustments are essential for avoiding hyperoxia.

Sensitivity to high oxygen concentrations:
Some patients may react sensitively to a high oxygen concentration and develop symptoms such as breathing difficulties, coughing, chest pain or dizziness. In such cases, the oxygen concentration must be carefully adjusted to avoid undesirable reactions.

Usage in environments with increased fire risk:
In environments where there is an increased risk of fire or explosion (such as in the vicinity of flammable gases or liquids), the use of a medical oxygen mixer may be contraindicated. In such situations, alternative oxygen supply methods must be considered.

Possible side effects and residual risks:

Incorrectly chosen setting values may endanger the patient. Values which are set too low may result in an insufficient supply of oxygen. On the other hand, prolonged ventilation with a high oxygen concentration can lead to oxygen toxicosis.
The operating personnel must be sufficiently trained in the application of oxygen in order to avoid possible risks in a timely manner. Check the prescribed dose before administering to patients. Monitor the flow frequently.

1.4 Misuse

Any non-intended improper use constitutes misuse.
The following operating conditions are classified as misuse:

- Operating the QualityMix Pro with gases that are not specified on the ratings plate.
- The use of the QualityMix Pro with gases in their liquid phase.
- Operating outside the permissible technical limits.
- Failure to observe the inlet pressures specified for the device.
- Failure to observe and comply with locally applicable legal rules and regulations.
- Failure to carry out required inspection and maintenance work.

1.5 Misuse

All other types of use that are not listed in the intended use section are categorized as misuse of this device.

1.6 Personnel requirements

Definition of an authorized person

A person is deemed to be an authorized person if they have been trained as a medical professional or medical assistant. They must also have been technically instructed and informed about the overall system and the associated hazards associate with the gas supply, compressed gas cylinder, medical gas, gas cylinder valve and pressure regulator.

Tasks of the operating personnel

The operating personnel must recognise faults or irregularities and – as far as possible and permissible – eliminate them.

Requirements for the operating personnel

The operating personnel must meet the following requirements to be able to carry out these tasks:

- The operator must have been trained to operate the QualityMix Pro by an authorized person.
- He or she must have read and understood these operating instructions in full.
- The operator must wear adequate personal protective gear according to the activities or hazards of the environment. The company instructions, the specifications of the employers' liability insurance associations, and the safety data sheets must all be observed.

Maintenance and repair work may only be carried out by specially trained personnel.

1.7 Contents of delivery; Inspection upon receipt

Item	Item number
1 x QualityMix Pro	**D-B-QMP**
1 x rail holder for standard rail	**D-B-SH**
1 x power supply unit with cable, complete	**D-SKN.M04.GLLR**
Two 9V batteries	**D-505408 Rev.0**
1 x O2 sensor OOM111LF	**D-B-O2-111LF**
1 x O2 sensor cable	**D-B-O2-KG**
1 x silencer muffler 9/16	**D-B-DK-22**
1 x pulse oximetry sensor DISPOSABLE ADULT RD SET	**D-RD-SET-ADT**
1 x pulse oximetry sensor DISPOSABLE PAEDIATRIC RD SET	**D-RD-SET-PDT**
1 x pulse oximetry sensor DISPOSABLE NEONATAL RD SET	**D-RD-SET-NEO**
1 x pulse oximetry connection cable, short	**D-4080**

1.8 General conditions of liability

The General Terms and Conditions of DEHAS Medical Systems GmbH are binding. These can be found on the company website.

The following also applies to this device:
DEHAS Medical Systems GmbH accepts no responsibility or liability for the safe operation of the QualityMix Pro whenever servicing or repairs are carried out by persons who have not received appropriate technical training or when the device is handled in a manner that does not correspond to its intended use.

Furthermore, DEHAS Medical Systems GmbH accepts no responsibility or liability for the safe operation of the QualityMix Pro if the specified functional testing and maintenance intervals are not observed. The user is responsible for observing the maintenance and functional testing intervals.

DEHAS Medical Systems GmbH accepts no liability for damages resulting from non-compliance with the above instructions.

2. Safety

2.1 Basic information

The product complies with the accepted rules of engineering and technology. Nevertheless, knowledge of the media used and their dangers as well as basic knowledge of the pressure control panel are required to ensure safe and accident-free work.

The operating instructions must be read and understood by every user. The operator must document their training in writing.

The safety instructions are a supplement to the applicable accident prevention regulations and laws. Existing accident prevention regulations and laws must always be followed!

Notice:

Hazards from the operating environment can cause injuries.

a) No changes may be made to the product that could cause a change in function.

b) All hazards due to the environment or unforeseeable operating conditions cannot be covered and presented within the scope of this manual.

2.2 Overview

Table of Contents

This chapter includes

- An explanation of the symbols used,
- The main notices relevant for the safe handling of the QualityMix Pro and the associated Masimo pulse oximeter

Important note!

The following safety notices are a supplement to the national accident prevention regulations and laws already in force. Existing accident prevention regulations and laws must always be followed.

2.3 Explanation of the key abbreviations

FIO_2	Fractional concentration of inspiratory oxygen
DISS	Diameter Index Safety System
NIST	Non-Interchangeable Screw Thread
Bar	Measurement unit for pressure
l/min	litre per minute
Flow	Flow rate

2.4 Symbols used

WARNING!

This symbol indicates that there is a danger to personal health and life.

Caution!

This indicates that caution is required when handling the device or controller near where this symbol is located, or that the current situation requires the operator's attention or intervention to avoid undesirable consequences.

Notice

This indicates a potentially harmful situation. If not avoided, the product or something in the vicinity may be damaged.

2.5 Basic safety notices

WARNING!

Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
WARNING Do not use the QualityMix Pro or pulse oximeter if it appears to be damaged or is suspected of being damaged.	Be sure to check that the product is complete and whether there is any damage.
WARNING Risk of electric shock and flammability	Before cleaning, always switch off the device and disconnect it from any power source.

WARNING!

Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard
WARNING Do not use the QualityMix Pro during magnetic resonance imaging (MRI) or in an MRI environment.
WARNING Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
WARNING For safety reasons, avoid stacking several devices or placing anything on top of the device during operations.
Warning Read the operating instructions carefully before you install or use this device.
Warning Explosion hazard: Do not use the pulse oximeter in the presence of flammable anaesthetics or other flammable substances in combination with air, an oxygen-enriched environment or nitrous oxide.

Caution!

You must observe the following safety notices in order to avoid undesirable consequences:

Potential hazard
When patients undergo photodynamic therapy, they may react sensitively to light sources. Pulse oximetry should only be used under careful clinical supervision for short periods of time to minimise interference with photodynamic therapy.
Do not place the pulse oximeter on electrical devices that could interfere with the device and cause it to function improperly.
Disposal of the product: Comply with all relevant local laws when disposing of the device and/or its accessories.

To minimize radio interference, other electrical devices that emit high-frequency transmissions should not be located in the vicinity of the QualityMix Pro or the pulse oximeter.

2.6 Explanations of the safety information on the packaging, the product and the instructions for use

Symbol	Title	Description
	CE marking	This product complies with the applicable requirements regulated in the EU harmonization regulation for the affixing of the CE marking.
	Medical device	Indicates that the item is a medical device.
	Manufacturer	Indicates the manufacturer of the medical device.
	Date of manufacture	Indicates the date that medical device was manufactured.
	Refer to the operating instructions.	Indicates that the operating instructions must be read.
	**WARNING!**	Warning indicates a possible imminent danger. If not avoided, death or serious injury could result.
	**CAUTION!**	Caution indicates that caution is required when handling the device or controller near where this symbol is located, or that the current situation requires the operator's attention or intervention to avoid undesirable consequences.
	Notice	Notice indicates a potentially harmful situation. If not avoided, the facility or something in the vicinity may be damaged.
	Non-sterile	Indicates a medical device that has not been sterilized.
	Keep free of oil and grease.	You must keep the device free of oil and grease.
	Not MR compatible	Items marked Not MR compatible are known to pose a hazard in all MR environments. Keep this product away from magnetic resonance imaging (MRI) equipment.

	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that the specific medical device can be identified.
	Unique device identifier	Displays a carrier containing information about a unique device identifier (UDI).
	Do not use if the packaging is damaged	Indicates that the device must not be used if the packaging in which the device is contained is damaged.
	Fragile; handle with care	Indicates that the contents of the transport package are fragile and the package must be handled with care.
	Store dry	Indicates a medical device that must be protected from moisture.
	Temperature limit	Indicates the maximum and minimum temperatures at which the item may be stored, transported or used.
	Atmospheric pressure limits	Indicates the permissible upper and lower atmospheric pressure limits for transport and storage.
	Humidity limits	Indicates the permissible upper and lower limits for relative humidity during transport and storage.
	HF transmitter	Indicates devices that contain high-frequency transmitters or intentionally emit electromagnetic high-frequency energy.
	Do not dispose of in the trash or rubbish.	This device contains batteries and electronic components. It must not be disposed of with household waste.
	Direct current IEC 60417	Indication on the ratings plate that the device is only suitable for operating with direct current.
	"ON"	Device is switched on

	"OFF"	Device is switched off
	USB interface	USB interface: connection option for data
	Notices on battery mode	Display for battery status

3. Surroundings

WARNING!

Be sure to follow these safety instructions to avoid danger to life and health:

WARNING! **Explanation:** If the QualityMix Pro is used outside of the specified permitted ambient temperature range, there is a risk of malfunction, incorrect dosing, fire or damage to the system.	Do **not** use in ambient temperatures below +5°C and above +50°C.
WARNING! The air humidity must be below 95% rel. humidity to prevent condensation.	Do **not** use in an ambient condition with humidity ≥ 95% rel. humidity.

3.1 Degree of cleanliness

- The product should be kept clean (dust-free)
- A suitable gas must be used as the purging gas, taking into account the quality and properties of the process gas.

4. Product description

4.1 Overview

Table of Contents

This chapter includes

- A description of the main features of the QualityMix Pro,
- An overview of the most important parts of the QualityMix Pro,
- A functional description of the QualityMix Pro,
- An overview of the operating controls of the QualityMix Pro, as well as their function and the technical data.

4.2 Key performance characteristics / product features

The main features of the QualityMix Pro product are the delivery of a user-defined oxygen concentration with simultaneous display and measurement of pulse and SpO2, in order to maintain or adjust the flow of oxygen to the patient in response to changes. The measured values correspond to user-defined target values for the O2 concentration, flow rate settings and the pre-specified range thresholds.
The device triggers the corresponding alarms if these target values set by the user are exceeded or not reached.

4.2.1 Key performance characteristics according to IEC 60601-1

- When a set limit is exceeded, a corresponding alarm is generated for the user.
- Controlled and monitored delivery of a volume flow in the range of 0.2 – 60 lpm
- Measurement and display of the current FiO2 concentration
- Display of oxygen concentration, heart rate and perfusion index
- The built-in monitoring system also generates an alarm for the following situations:
  - Failure of the external power supply
  - Discharge of the battery
  - Gas supply outage

4.2.2 Additional product features

There are application and usage advantages provided by the market-proven mechanical gas mixer from the QualityMix series and the use of a user interface that features a modern layout with touch display and intuitive menu navigation.

- Digitalization of the well-known mechanical gas mixer
- Precise flow control of the mixed gas using a motorized valve
- The display enables you to see and regulate the flow rate
- Precise, known setting for the O2/air mixing ratio is referenced at the built-in O2 sensor
- Sub-menus for alarms / alarm limits / language settings / service menu / night screen
- Logging function for all process parameters
- All data can be transferred to a PDMS / HIS / control centre via RJ-45 interface and the HL 7 protocol (V3); communication in accordance with ISO/IEEE 11073 in hospital directory structure.
- Backup battery for power outages and during transport (max. 15 minutes without external power supply)
- The individual components are coordinated and low-maintenance
- Outstanding reliability due to durable components / design
- Ideal for use with ECMO, HFOX-CPAP, HFOX-NIV, and in all intensive care units for adult, paediatric and neonatal applications. (Further gas mixtures such as additional CO2 / N2O are pending)

4.3 Technical specifications

Notice:
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
Notice **Explanation:** Technical data missing	The technical data is listed in the data sheet for the respective product. If not available, it can be requested at info@dehas.de. The maximum inlet and outlet pressures and the type of gas are noted on the ratings plate or the label.

Technical specifications	
Parameter	**Description**
Dimensions (LxWxH)	190 x 130 x 218.9 mm
Weight	1400 g
Display	7 inch TFT, 1024x800 resolution
Power supply for power supply unit	110 – 230 V AC / 50 – 60 Hz
Power supply for device	24 V DC
Internal battery	Two 9-V block batteries / 15 min. running time (not rechargeable)
Gas inlet pressure	2.7 – 6.5 bar: air and oxygen pressure differential should be within max. 0.7 bar
Gas connection type O2	NIST
Gas connection type AIR	NIST
Gas outlet	9/16”
Flow capacity	0.2 – 60 litres / minute
Setting range of the oxygen concentration	21% – 100%
Measuring range of O2 sensor	15% – 100%
Measuring sensor	OOMLF111 (Honeywell Healthcare Solutions GmbH)
Accuracy of the mixed gases (FIO_2)*	± 3 % oxygen (vol.)
Alarm triggers when the supply pressure of a gas drops	Alarm on at a pressure difference between both gasses of ≥ 0.9 bar. Alarm off at a pressure difference between both gasses of ≤ 0.3 bar. For example: Inlet pressure of O2 at 4.2 bar and inlet pressure of AIR at 5.1 bar: alarm on. Alarm off at 4.8 bar inlet pressure of AIR or 4.5 bar inlet pressure of O2 at the latest.
Alarm volume	≥ 80 dB at a distance of 30 cm
Transfer interface	RJ-45
Data transfer protocol	HL7 protocol (V3) according to ISO / IEEE 11073
Operating temperature	+5 °C to +50 °C
Operating time	Continuous operations
IP protection class	IP0X

4.4 Pressure drop in the system

Parameter	**Description**

Low Flow	≤ 0.14 bar at inlet pressures from 3.2 to 6.5 bar, with a flow rate of 10 l/min at 60% FIO_2
High Flow	≤ 0.21 bar at inlet pressures from 3.2 to 6.5 bar, with a flow rate of 30 l/min at 60% FIO_2

4.5 Transportation and storage conditions

Temperature range	0 °C to 50 °C
Humidity	Max. 95% non-condensing air humidity

4.6 Variants

Order code	Variants	GTIN
D-B-QMP	-	4251411702694

4.7 Standards and laws

Law / standard	Designation
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices
93/42/EEC	Directive 93/42/EEC of 14 June 1993 concerning medical devices
2011/65/EU	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
1907/2006/EU	Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
2004/12/EC	Directive 2004/12/EC of the European Parliament and of the Council of 11 February 2004 packaging and packaging waste
MEDDEV 2.7.1:2016	Clinical evaluation: Guide for manufacturers and notified bodies
ISO 18562-1:2017	Assessment of the biocompatibility of the airways in medical applications – Part 1: Assessment and review within a risk management process
ISO 11195:2018	Gas mixers for medical use – individual devices
IEC 60601-1-8:2006/Amd 2:2020	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 780:2015	Packaging – Shipping packaging – Graphical symbols for handling and storage of packages
EN ISO 20417:2021	Medical devices – Requirements for information to be provided by the manufacturer
EN ISO 15223-1:2021	Medical devices – Symbols for use in the information to be provided by the manufacturer – Part 1: General requirements
EN ISO 15002:2008 + A1:2019	Flow measurement equipment for connecting to tapping points of pipework systems for medical gases
EN ISO 15001:2011	Anaesthesia and respiratory equipment – Compatibility with oxygen
EN ISO 14971:2019 + A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 13485:2016 + AC:2018 + A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Assessment and audits within the framework of a risk management system

EN 60601-1-6:2010 + A1:2015 + A2:2021	Medical electrical devices – Part 1-6: General requirements for safety including essential performance characteristics – supplementary standard: Suitability for use
EN 60601-1-2:2015 + A1:2021	Medical electrical devices – Part 1-2: General requirements for safety including essential performance characteristics – supplementary standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021	Medical electrical devices – Part 1: General specifications for safety including the essential performance characteristics

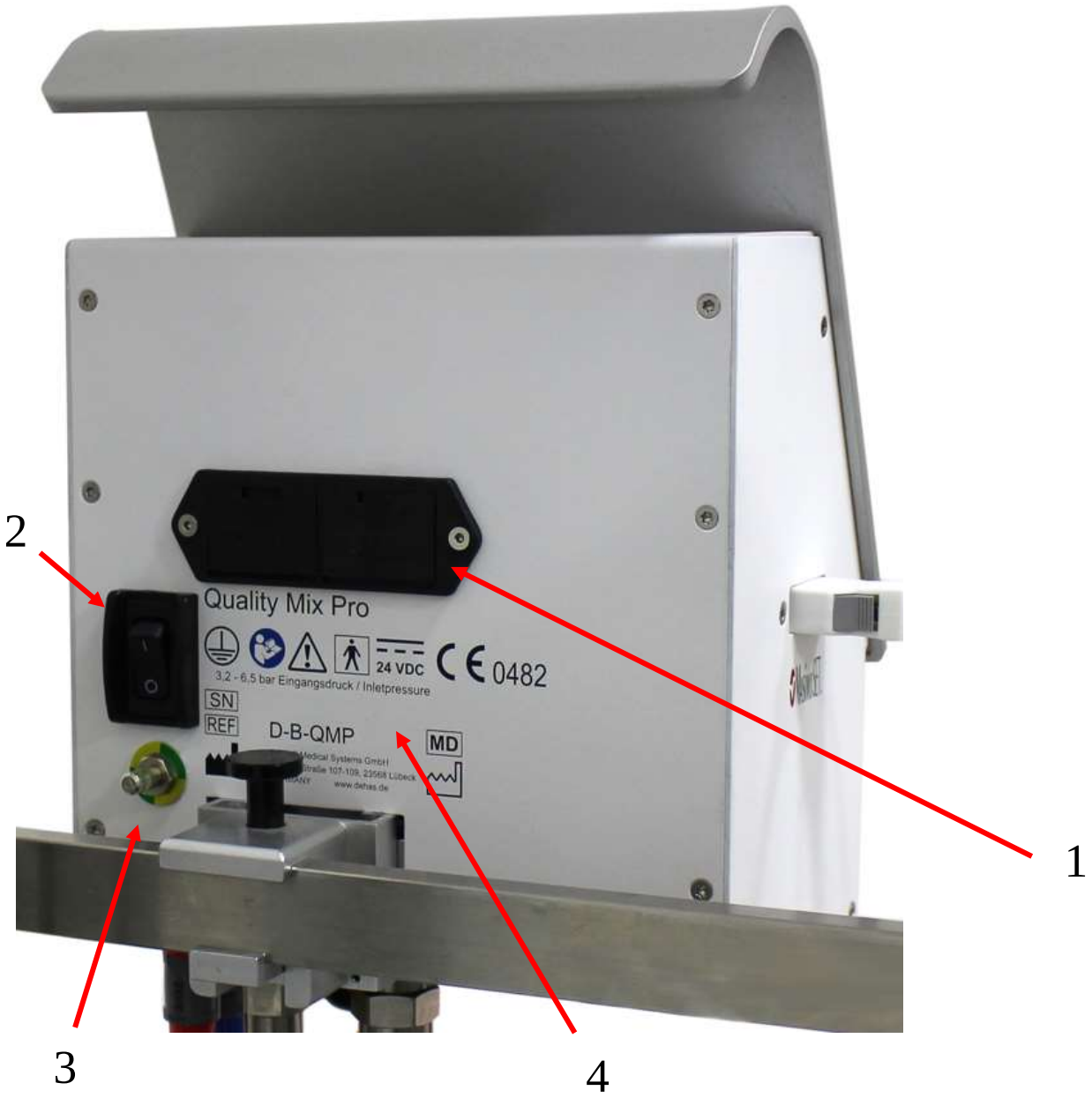
4.8 Description of the product construction and functionality

4.8.1 Overview: front of entire device

Pos.	Component designation	Function
1	Rotary dial for manually adjusting the oxygen concentration for the oxygen-air gas mixer	A rotary dial for setting the oxygen concentration levels between 21% – 100%. The FIO_2 scale is used for reference purposes only. It starts at 21% and can turn to 100%. This dial cannot be turned 360°.
2	Gas outlet	A 9/16" connection for extracting the mixing gas.
3	Medical oxygen port	A NIST oxygen port with external thread and one-way valve for connecting a supply hose for medical oxygen.

4	Medical air port	A NIST air port with external thread and one-way valve for connecting a supply hose for medical air.
5	Alarm bar	The alarm bar flashes briefly when the system is started to indicate that the alarm system is functioning properly If there is an alarm, the alarm bar flashes in the colour corresponding to the alarm priority. For further information refer to: Chapter 7
6	Screen	A touchscreen display for operating the QualityMix Pro's user interface.

4.8.2 Overview: rear of entire device



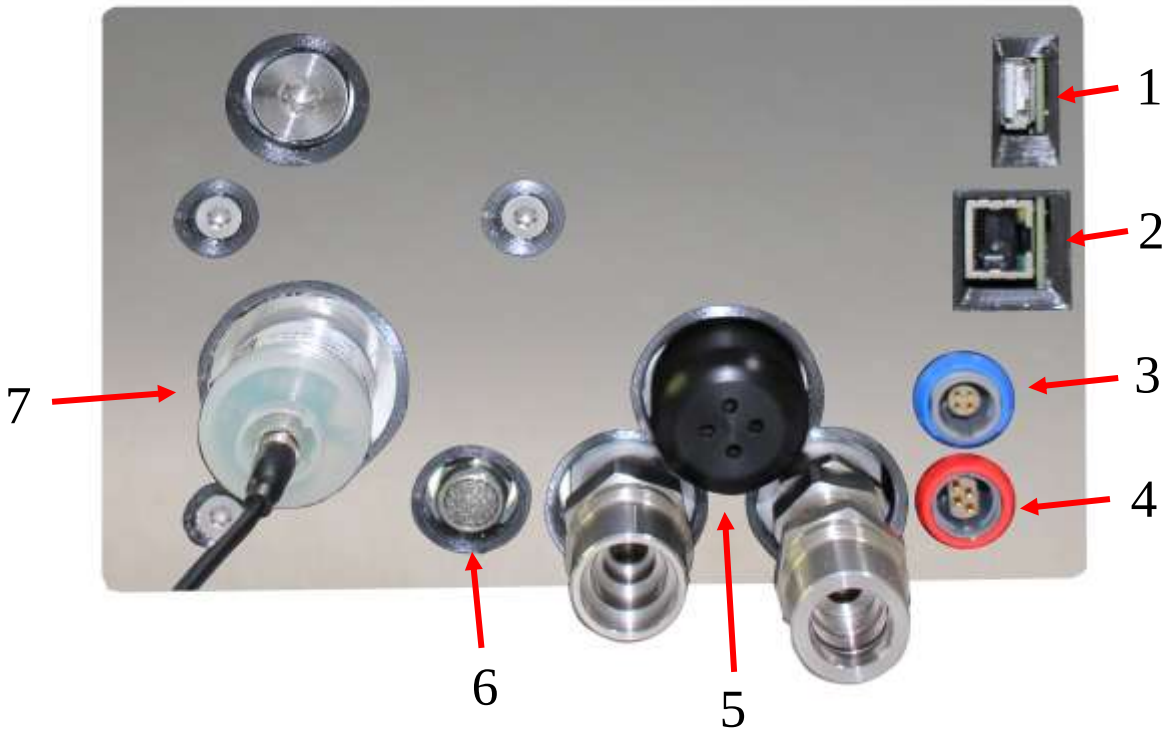
Pos.	Component designation	Function
1	Battery compartment	The battery holder contains two battery compartments which hold one 9-V

		battery each. These can be removed separately.
2	Main switch	Switch that switches the QualityMix Pro on and off
3	Earth pin	-
4	Ratings plate	-

4.8.3 Overview: left side of the entire device

Pos.	Component designation	Function
1	Connection for Masimo Set sensor	Mechanical connection for the Masimo SPO2 sensor including cable

4.8.4 Explanation for the connections on the underside

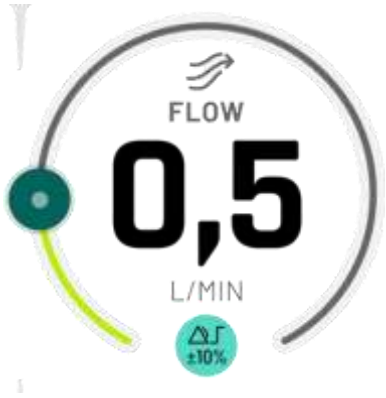


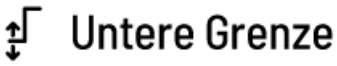
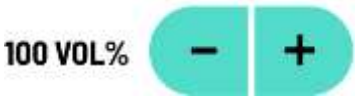
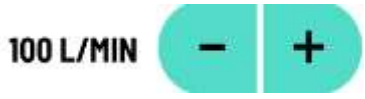
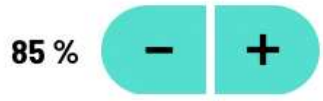
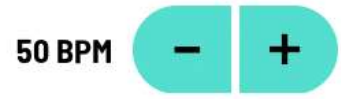
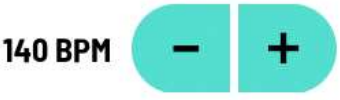
Pos.	Component designation	Function
1	USB interface	USB interface for data exchange
2	RJ-45 interface	RJ-45 interface for connecting to the PDM system
3	Oxygen sensor connection	Connection for 4-pole sensor cable
4	Power supply connection	Connection for the power supply unit
5	Pneumatic alarm unit	Alarm transmitter for gas supply selection. Refer to section 5.6 for description.
6	Output bleed valve	Output bleed valve for FiO2 concentration accuracy at low flows (It is switched on automatically at low flow ≥ 3 LPM to ensure the most accurate FiO2 concentration possible.)
7	Oxygen sensor connection	Connection for attaching the oxygen sensor.

4.8.5 Explanation of the indicators and symbols on the display

Display / symbol	Explanation
Main display symbols	
	**Device status**
	**Battery and mains power supply connection** The current status of the batteries and the connection to the mains power supply are displayed for the user.

	**Date / time** The current date and time are displayed for the user. The data can be changed manually in the settings menu under the heading: Date & Time (refer to section 5.12).
	**Button for Setting Menu** The user can click on this button at the touchscreen to go to the Setting menu (and additional sub-menus).
	**ID of current patient, in normal mode** This symbol shows the current, assigned patient ID for the currently running therapy. This symbol is displayed during normal mode.
	**Emergency mode** This symbol indicates to the user that the device is in emergency mode for patient care. In this mode, no patient ID is specified beforehand. The functions of the device are immediately available to the user for the therapy.
	**Button to auto-set the alarm limits for the flow meter at ±10 % L/min** By pressing this button, the user can set the automatic alarm limits (upper and lower alarm limits) for the specified and measured flow to ±10 %.
	**Button to auto-set alarm limits at ±3% FiO2 or auto-set alarm limits at ±3% SPO2** By pressing this button, the user can set the automatic alarm limits (upper and lower alarm limits) **for the measured oxygen concentration to ±3 %**. **and** By pressing this button, the user can also the set automatic alarm limits (upper and lower alarm limits) **for the SPO2 value measured by the Masimo FingerClip sensor to ±3 %**.
	**Measured oxygen saturation** The currently measured oxygen saturation is displayed here, as a %. The **auto-set alarm limits at ±3%** function is available in the lower symbol.

	**Measured FiO2 vol. %** The current FiO2 vol. percentage value measured by the oxygen sensor is displayed here. The oxygen concentration is set using the mechanical rotary dial at the oxygen-air gas mixer. The **auto-set alarm limits at ±3% FiO2** function is available in the lower symbol.
	**Set flow in L/min** The current flow rate is displayed here **in litres per minute**. The flow setting can be adjusted manually by the user by pressing the virtual dial.
	**Measured heart rate, in BPM** The heart rate currently measured for the user by the Masimo FingerClip sensor is shown here in BPM.
	**Measured perfusion index** The current perfusion index measured by the Masimo SET sensor is displayed here.
	**Pop-up message** This symbol indicates a pop-up message at warning level III for the user. An alarm is present and requires the user's attention. The associated text field and the LED display provide information about the type of alarm. The device prompts the user to react immediately. **The meaning of the warning levels is described in Chapter 7.** 

	**Pop-up message Acknowledge alarm** The "Acknowledge" button can be used to close the text field of the alarm pop-up message. The alarm remains in this mode until the user has cancelled this mode by taking the required action. The alarm message is shown at the top of the display until that point.
Icons in the Alarms sub-menu 	
	**Lower alarm limit / threshold** Displays the lower alarm limits for the FiO2 concentration, volume flow, SpO2 and heart rate
	**Upper alarm limit / threshold** Displays the upper alarm limits for the FiO2 concentration, volume flow, SpO2 and heart rate
	**Lower alarm limit: FiO2 concentration**
	**Upper alarm limit: FiO2 concentration**
	**Lower alarm limit: Flow**
	**Upper alarm limit: Flow**
	**Lower alarm limit: Oxygen saturation**
	**Upper alarm limit: Oxygen saturation**
	**Lower alarm limit: Heart rate**
	**Upper alarm limit: Heart rate**
	**Calibration sub-menu** The oxygen sensor can be calibrated to 21% or 100% here
	**Language sub-menu** You can choose between different languages here.

BENUTZERTYP	**User sub-menu**
DATEN & SERVICE	**Data/ Maintenance sub-menu** Set the device to factory default settings and update the software.
EINSTELLUNGEN	**Settings sub-menu** The SpO2 sensor can be switched on here. The sensitivity of the sensor can also be set here.
DATENTRANSFER	**Data transfer sub-menu** Data can be saved to a USB flash drive and the connection to the hospital network can be configured here.

5. Assembly and preparation

5.1 Safety notices

Caution!
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
Caution **Explanation:** **Injury or damage due to improper installation or dismantling.**	Special steps are required for installation and dismantling of the product. Injuries to persons and damage to the product are possible. Installation and dismantling work may only be carried out by the installer or appropriately qualified specialist companies and persons.
Caution **Risk of injury or damage when the device and accessories are incomplete.**	Check the QualityMix Pro for visible damage before use. Do not use it if it is damaged.

5.2 Installation

The QualityMix Pro must be securely mounted before the initial commissioning. The steps described in the following chapter must be followed.

5.2.1 Mounting onto a standard rail

Proceed as follows to mount the QualityMix Pro onto a standard rail:

Step	Activity / Figure
1	Remove the device and accessories from their packaging.
2	Make sure that • The product is complete upon receipt according to the delivery list (refer to section 1.7). • The product has not been damaged during transport.
3	The QualityMix Pro must always be attached to the standard device rail with the rail bracket before the initial commissioning. To attach it, hang the retaining clip onto a standard rail (cross-section: 10 x 25 mm). Make sure that the pressure relief valve (refer to the illustration) on the underside of the device is not blocked.
4	The QualityMix Pro is now installed onto the standard rail bracket.

5.2.2 Connection to the gas supply

WARNING!

Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard
WARNING The functionality of the QualityMix Pro can be ensured only when both the supplied oxygen and the supplied medical air are free of condensed water, oil and contamination.
WARNING In order to prevent fire, oxygen must not come into contact with oil or grease. Therefore, make sure that all parts of the QualityMix Pro that come into contact with oxygen (e.g. gas supply hoses, O2 inlet, patient outlet, patient hoses) remain free of oil and grease.

For the QualityMix Pro to run properly, it must be supplied with medical air and medical oxygen from an external source.

The following gas type requirements must be met: (Dryness and composition of the supply gases)

Medical air:
The medical air supply must meet the requirements of the national standards.
Oil ≤ 0.1 mg/m3, ideally oil-free
Pressure: 2.7 – 6.5 bar
H2O ≤ 870 ppm (V/V), with no condensate! If, due to the operating temperature, condensate may occur even with a lower concentration of H2O in the air, then the concentration of H2O must be correspondingly lower.

Medical oxygen:
The oxygen being used must meet all requirements for medical oxygen according to the European Pharmacopoeia.
Oxygen content: ≥ 99.5%
H2O ≤ 67 ppm (V/V) (free of condensate)
Pressure: 2.7 – 6.5 bar

To connect the device to the gas supply, take the following steps:

Step	Activity
1	The QualityMix Pro may be configured with gas supply ports in accordance with either NIST or DISS standards. The hose sets used for connecting to the external gas source must also comply with the corresponding standard.
2	Connect an oxygen connection hose (ISO gas type coding: colour white) to the QualityMix Pro (which is already mounted on the standard rail) using the gas supply port NIST (**only hand tight**). **Never use tools to attach the connecting hose!**
3	Connect an air supply hose (ISO gas type coding: colour black/white) to the QualityMix Pro (which is already mounted on the standard rail) using the gas supply port NIST (**only hand tight**). **Never use tools to attach the connecting hose!**
4	Now connect the other end of the oxygen connection hose to the wall outlet for the central gas supply (tapping point socket) using the central gas supply connector. Observe the safety functionality (latching function) provided by the manufacturer of the socket outlet.
5	Now connect the other end of the air connection hose to the wall outlet for the central gas supply (tapping point socket) using the central gas supply connector. Observe the safety functionality (latching function) provided by the manufacturer of the socket outlet.
6	The QualityMix Pro device is now supplied with medical oxygen and medical air.

5.2.3 Connection to the power supply

The QualityMix Pro should be used with a continuous power supply.

5.2.3.1 Operating with a mains power supply

Potential hazard	Ways to avoid
 **Caution** **There is a risk of electric shock**	**The power supply unit must not be opened.**
	Only use the compatible power supply unit [REF SKN.M04.GLLR] that has been approved by the manufacturer. Do not connect other power supply units!

Warning:

If the "Battery empty – plug in power supply" alarm does not disappear despite plugging in the power supply unit and deleting the alarm text (e.g. by triggering a push message / text message or a high priority alarm (red)), then there may be a malfunction or fault. Contact the manufacturer and do not use the device further.

The power supply unit (REF D-SKN.M04.GLLR) for the QualityMix Pro may only be connected to a power connection with the following characteristics:

Characteristic	Value
Input voltage	100 → 240 V AC
Frequency	47 – 63 Hz
Rated output voltage	24 V DC
Output current range	Maximum of 3 A
Rated output power	72 W
Input connection	IEC320-C8
Output connection type	2.1 x 5.5 x 12 mm, with centre contact positive
Number of outputs	1
Plug type	Barrel plug, right angle (2.1 x 5.5)
Medical technology certification	Yes
Holding time	10 s
Cable length	1800 mm
Temperature max.	+50 °C
Operating temperature range	+5 °C to +50 °C
Complied standards	CE, cURus, FCC, Nemko, IEC 60601-1, EN 60601-1, Class II, UL ANSI/AAMI ES60601-1
Energy efficiency class	DoE Level VI / CoC Tier 2
Temperature min.	+5 °C

Step	Activity
1	Connect the power supply unit to the power input port on the QualityMix Pro using the four-pin power plug (refer to the illustration). **WARNING: The QualityMix Pro may only be operated using the power supply unit provided by the manufacturer (REF SKN.M04.GLLR) and with suitable power cables for connecting to the local power supply. Otherwise, the safety of the device and the EMC cannot be guaranteed.**
2	Then connect the other end of the power supply unit to the central power supply.
3	The power supply to the device is now established.

5.2.3.2 Battery operation (emergency operating mode)

The QualityMix Pro has two 9-volt block batteries and can be used for **a maximum of 15 minutes** in battery mode if these **non-rechargeable** batteries are fully charged.

The battery status is displayed at the top left of the QualityMix Pro screen (refer to the illustration).

Warning:

Only use the batteries recommended by the manufacturer (two 9-volt batteries). It is not possible to use rechargeable batteries or to recharge these batteries.

Warning:

A full battery is indicated by the three-bar icon. As soon as only two bars remain, the battery icon is displayed in red; the QualityMix Pro should be connected to the mains power supply as soon as possible. If there is only one bar shown, the battery alarm is triggered and the device must be connected to the mains power supply as soon as possible.

5.2.4 Connection to external data interfaces:

5.2.4.1 USB data interface

The USB data interface of the QualityMix Pro can be used to retrieve the device's internal data and to upload software updates. The USB interface supplies either live data or trend data. This must be downloaded and saved to a computer or data management system. The data is serial data which is converted internally into a USB signal.

To connect the QualityMix Pro to a system for archiving and processing the patient data, use a standard USB cable (USB 2.0 type A to USB 2.0 type B) that is double-wound through a ferrite. We recommend using the article 742-711-32 from the manufacturer Würth Elektronik.

You can also use a USB flash drive to retrieve patient data.

5.2.4.2 Output data / protocols

The QualityMix Pro data includes the set flow, the measured oxygen concentration, all alarms, oxygen saturation, heart rate and the perfusion index from the connected Masimo Set SpO2 sensor. The date, time, device name and software version are also regularly stored. The live data is output automatically and continually during normal operations. However, these data are not saved in the device. If the live data is of interest, it must be recorded and stored by a computer or data system. Otherwise, it will be lost. The data is saved and output in **.xls** format.

5.2.5 Mounting the oxygen sensor

Before switching on the QualityMix Pro, you must connect the supplied **OOM111LF** oxygen sensor to the device.

1. Take the **OOM111LF** oxygen sensor and screw it into the designated position on the underside of the QualityMix Pro.

2. Take the supplied 4-pin sensor cable and connect it to the designated port on the underside of the QualityMix Pro.

3. Then connect the 3.5 mm plug of the sensor cable to the OOM111LF oxygen sensor (use the designated socket on the sensor). The connection is then established.

5.2.6 Connecting the Masimo SpO2 sensor

The QualityMix Pro can be connected to a Masimo SpO2 sensor. The device has an interface for this purpose (refer to section 3.10.3). Connect the cable of the RD SET series MD14-12 to the left side of the QualityMix Pro, as shown in the following illustration. The connection between the QualityMix Pro and the sensor cable is then established.

WARNING!
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
WARNING! Risk of entanglement or strangulation of the patient	As with all medical devices, route the patient cables very carefully to minimize the risk of patient entanglement or strangulation.
WARNING! The pulse oximeter or accessories could fall on the patient	Do not place the pulse oximeter or accessories in a position where they could fall on the patient.
WARNING Electric shock to the patient	To protect against electric shock, always remove the sensors and disconnect the pulse oximeter completely from the mains power supply before bathing the patient.

6. Initial commissioning of the product

Safety notices

Warning:

Training by authorized sales and technical personnel is required after the installation.
The device may only be used by trained specialist personnel.

Oxygen calibration must be carried out after long periods of inactivity. Refer to the menu Settings / Maintenance / Oxygen sensor calibration (section 5.12).

Before starting the system for the first time, the authorized trained specialist personnel must ensure that the installation steps for the device have been carried out in accordance with the manufacturer's instructions.

Ambient temperature
If the device is moved from a cold storage location to a warm environment, condensation may form and disrupt the device functionality. This would result in impaired functioning.
► Do not switch on the device until the condensate has dried off.

6.1 System start

Step	Activity	Description
1	**Switching on the device**	Pressing the "On/Off" switch (refer to section 3.9.2) on the back of the device to start the QualityMix Pro. This automatically triggers the system test. The functions are checked and the device starts up during this test.  Make sure that no patient is connected to the device during the system test. An error messages will be displayed if an error is detected during the system test. Refer to Chapter 7 for the meaning of the individual error messages. After the system test completes without errors, the QualityMix Pro starts in the mode selection menu (emergency or patient ID) and can be used on the patient.

6.2 Operating mode

6.2.1 Start in normal mode / Display

Step 1: Select the "Normal" operating mode:

After you have successfully started the device, you can select the operating mode. The emergency mode is available for situations where things have to happen quickly. The device can be used directly in this mode. The device immediately jumps to the main screen.

The "Normal" operating mode is selected by pressing the "Patient ID" button. The device then prompts you to enter the patient ID.

Step 2: Enter the patient ID

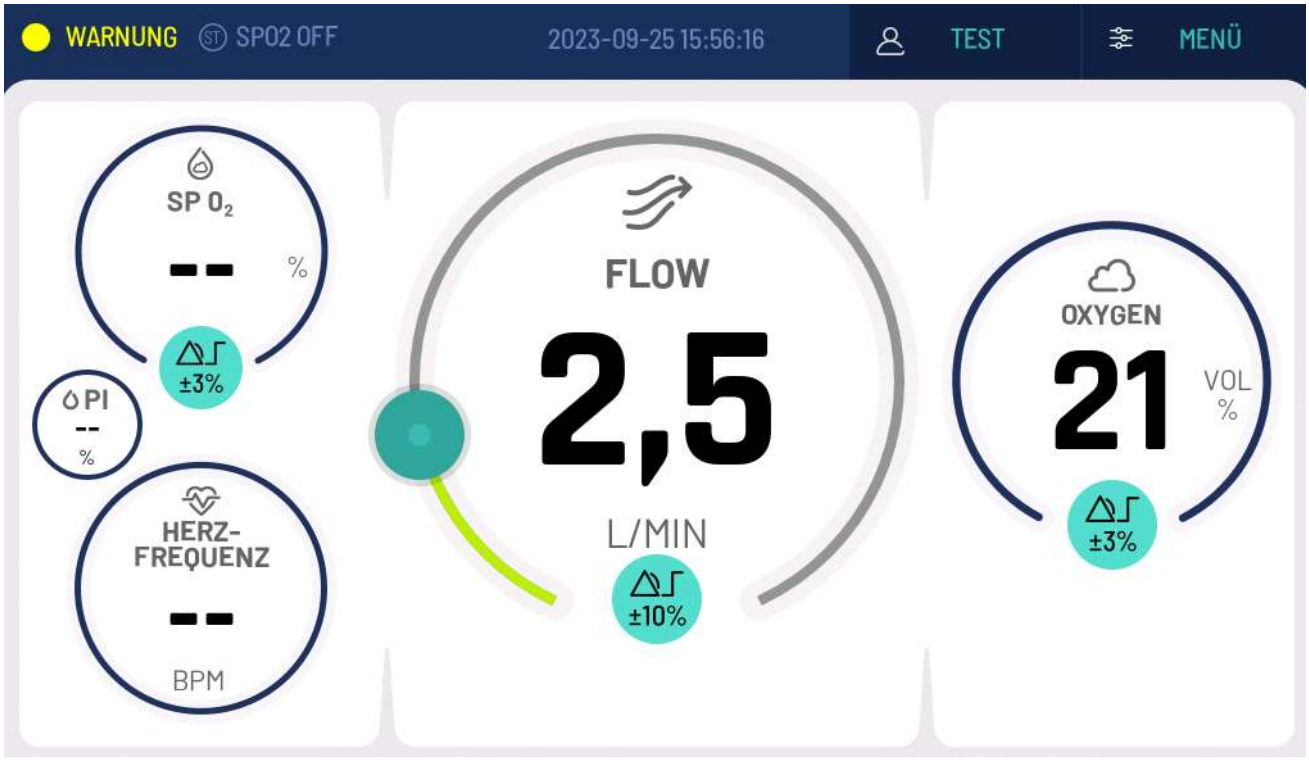
In the next step, enter the ID assigned to the patient.

Step 3: Calibration of the oxygen sensor
After specifying the patient ID, you will be requested to calibrate the oxygen sensor. Depending on the particular application, it is possible to calibrate this to 21% or 100%. Refer to section 6.7 for more information.

Step 4: Display on main screen

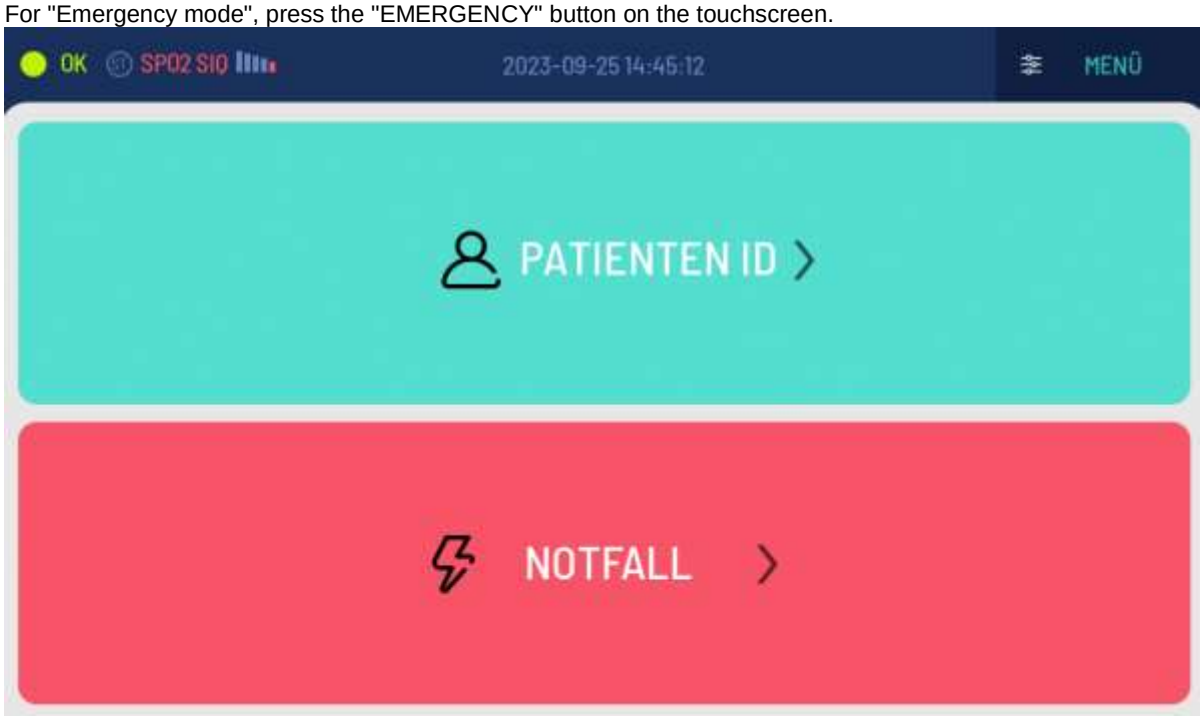
You will now be taken to the main screen. The device is ready for operations. You can now make the appropriate adjustments (such as the volume flow).

Notice: The default setting for the volume flow rate is 2.5 l/min. The connected sensor is switched off. Instructions for activating the pulse oximetry can be found in Chapter 6.



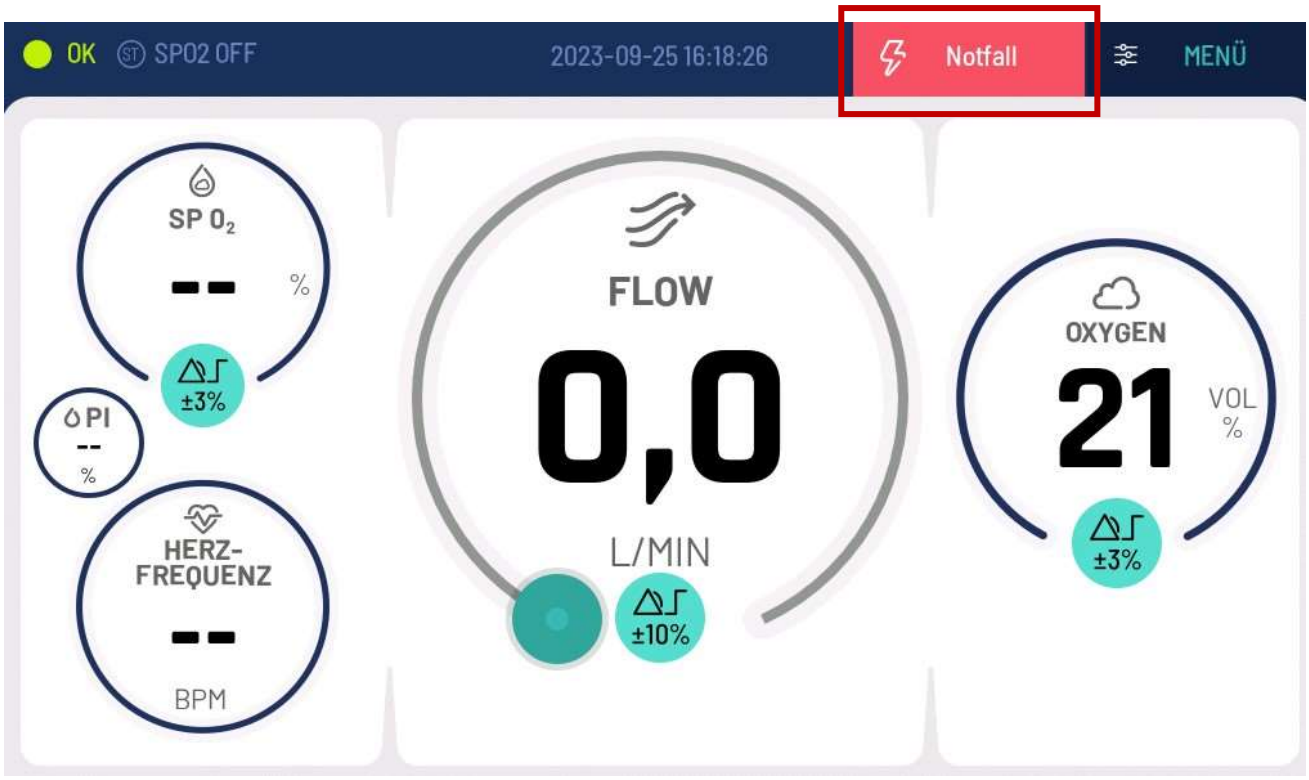
6.2.2 Starting in emergency mode / Display

Step 1: Select the "Emergency" operating mode:
For "Emergency mode", press the "EMERGENCY" button on the touchscreen.



Step 2: Display on main screen

You will now be taken to the main screen without having to enter the patient ID. The medical indication settings can now be set on the device. The emergency operating mode is indicated at the top of the main task bar.



6.3 Changing the mode

The mode can be changed by the user at any time. To switch between the two modes "Normal mode" and "Emergency mode", proceed as follows:

From the main screen, press the Patient ID or Emergency button (highlighted on the top screen, depending on the current operating mode).

After confirmation, you will automatically be taken to the menu for selecting the modes.

6.4 Adjusting

Turn the FiO2 rotary dial at the front of the oxygen-air gas mixer to the right or left to set the prescribed FiO2 concentration.

When the rotary dial of the mixer is turned to the right, the FiO2 value increases. The setting range from 21 % – 100 % oxygen by volume is possible.

The currently set oxygen concentration is shown to the user at the touchscreen.

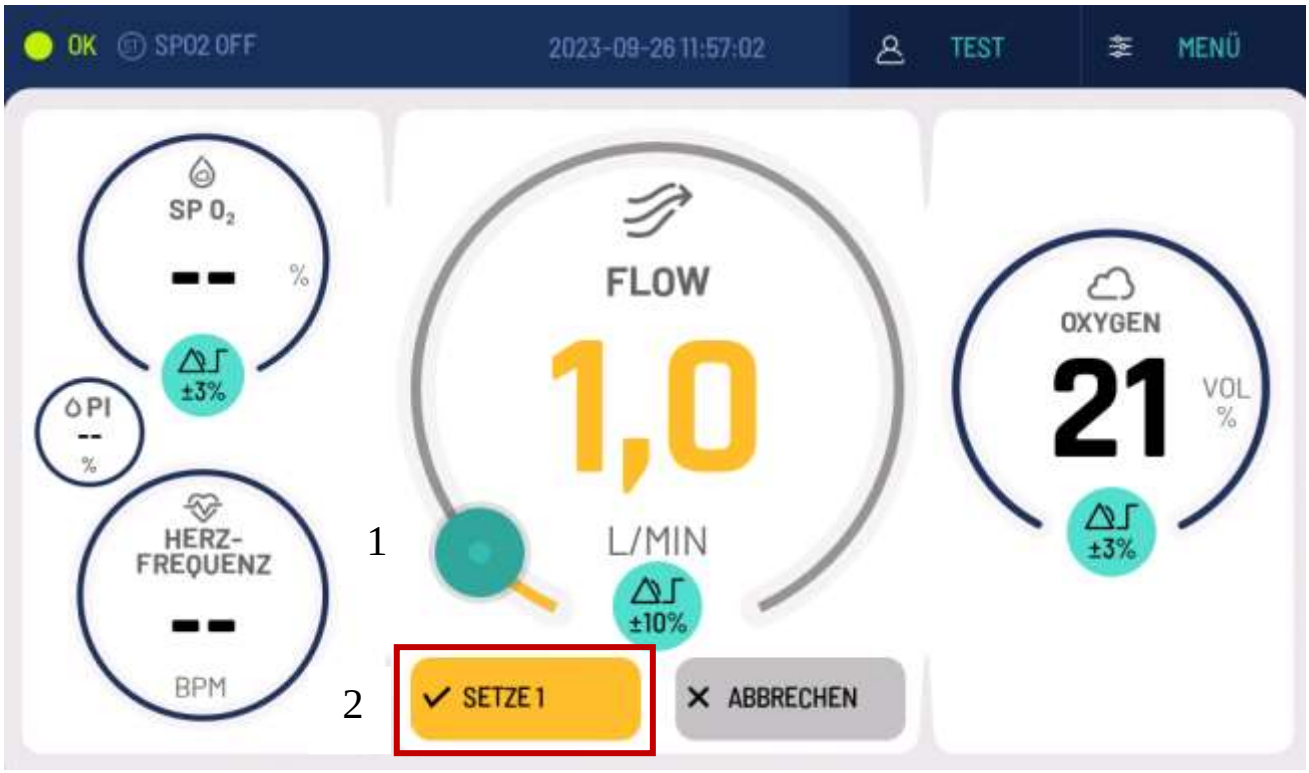
6.5 Setting the flow rate / flow

The volume flow rate can be set using the touchscreen. The volume flow rate can be adjusted in the range from **0.2 to 60** l/min. The flow rate is shown on the main screen and can also be set here.

Press the circular marker **(marked as 1, below)** for the FLOW setting on the centre display. Then move it to the desired flow setting.
→Clockwise movement increases the flow up to max. **60 l/min**.
→Anti-clockwise movement reduces the flow down to a minimum flow rate of **0.2 l/min**.

Confirm this setting by pressing the yellow button (icon – **marked as 2, below**). The setting has now been saved by the device.

If you do not want to save this setting, press the button (icon) to cancel the action.



6.6 Alarm system and settings

The QualityMix Pro offers a variety of customizable acoustic alarms for the vital signs. This section provides an overview of the alarms and describes how you can configure the different alarms.

Overview of the alarm system:

Alarm	Description
Pneumatic, acoustic alarm	Alarm for outage of the gases O2 / AIR
Electronic, acoustic alarm	Alarm for the specified oxygen alarm limits (upper and lower alarm limits)
Electronic, acoustic alarm	Alarm for the specified flow alarm limits (upper and lower alarm limits)
Electronic, acoustic alarm	Alarm for the specified oxygen saturation (upper and lower alarm limits)
Electronic, acoustic alarm	Alarm for the specified heart rate (upper and lower alarm limits)
Electronic, acoustic alarm	Alarm for error messages or malfunctions

6.6.1 Pneumatic acoustic alarm for the gas mixer

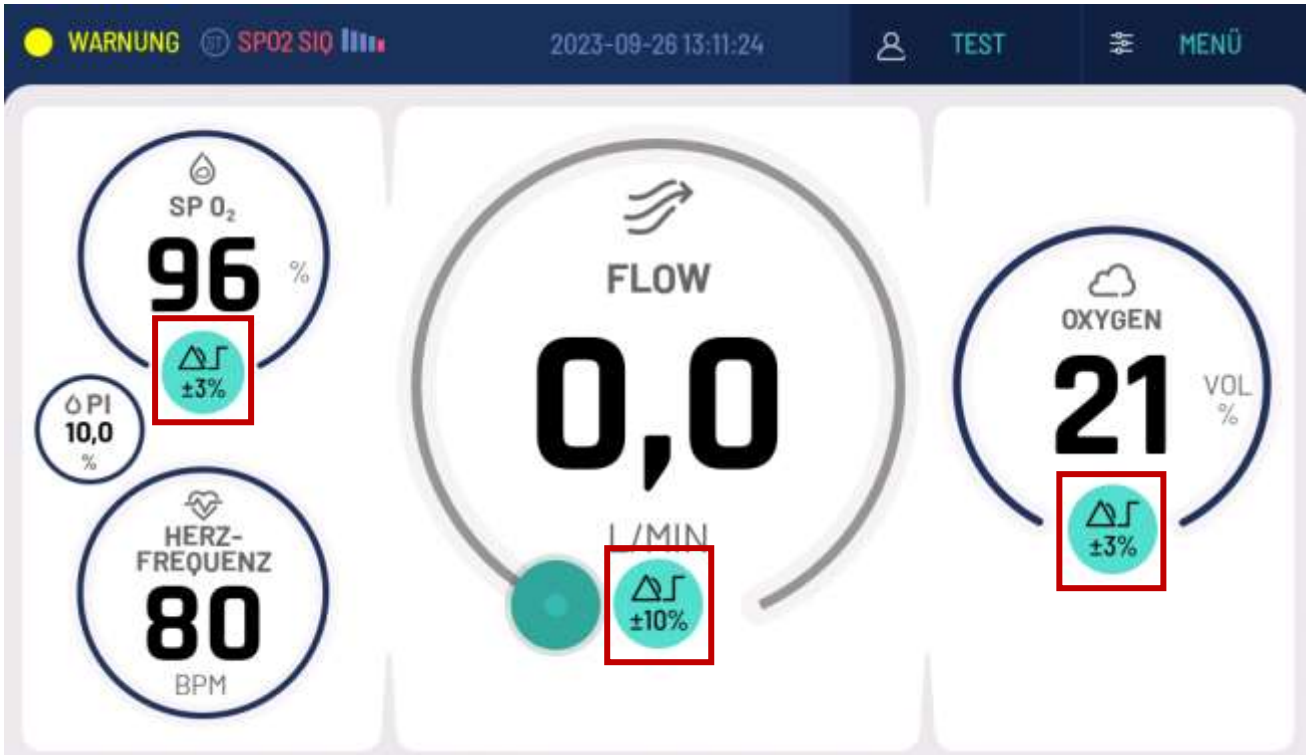
The QualityMix Pro has a pneumatic acoustic alarm. This alarm is triggered independently of the electronics when one of the two supply gases fails (AIR or O2) or when the pressure difference between the supply gases (AIR / O2) is greater than ≥ 0.9 bar.

6.6.2 Setting the electronic alarm limits using the auto-set function.

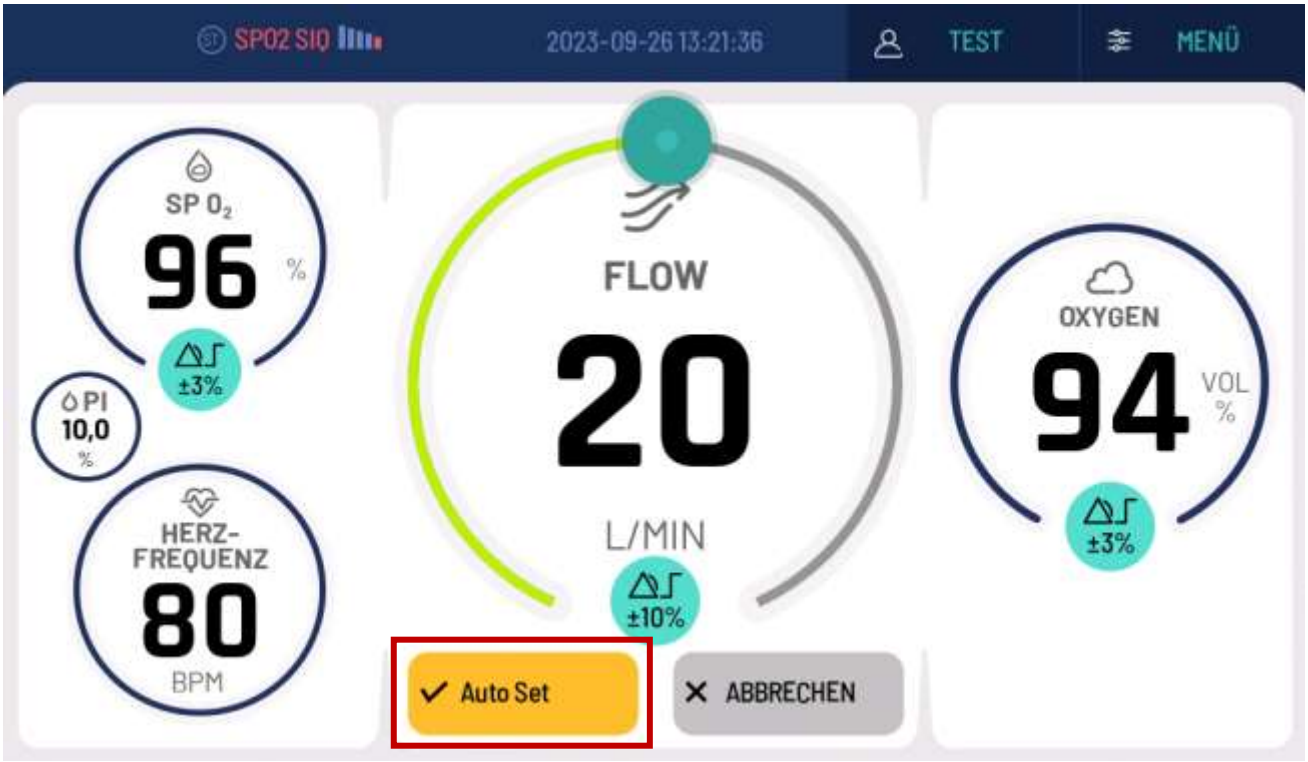
The QualityMix Pro has an electronic alarm function. The alarm limits for flow, oxygen concentration and oxygen saturation can be set using auto-set, depending on the current value. This enables you to adapt the alarm limits to your requirements very quickly.

The corresponding buttons are outlined in red in the illustration. By pressing the corresponding Auto-set button, the alarm limits (lower and upper alarm limit) are set depending on the current value.

- ➔ The alarm limits for the flow are set to ± 10% of the current value.
- ➔ The alarm limits for the current FiO2 concentration are set to ± 3% of the displayed value.
- ➔ The alarm limits for the current oxygen saturation are set to ± 3% of the displayed value.



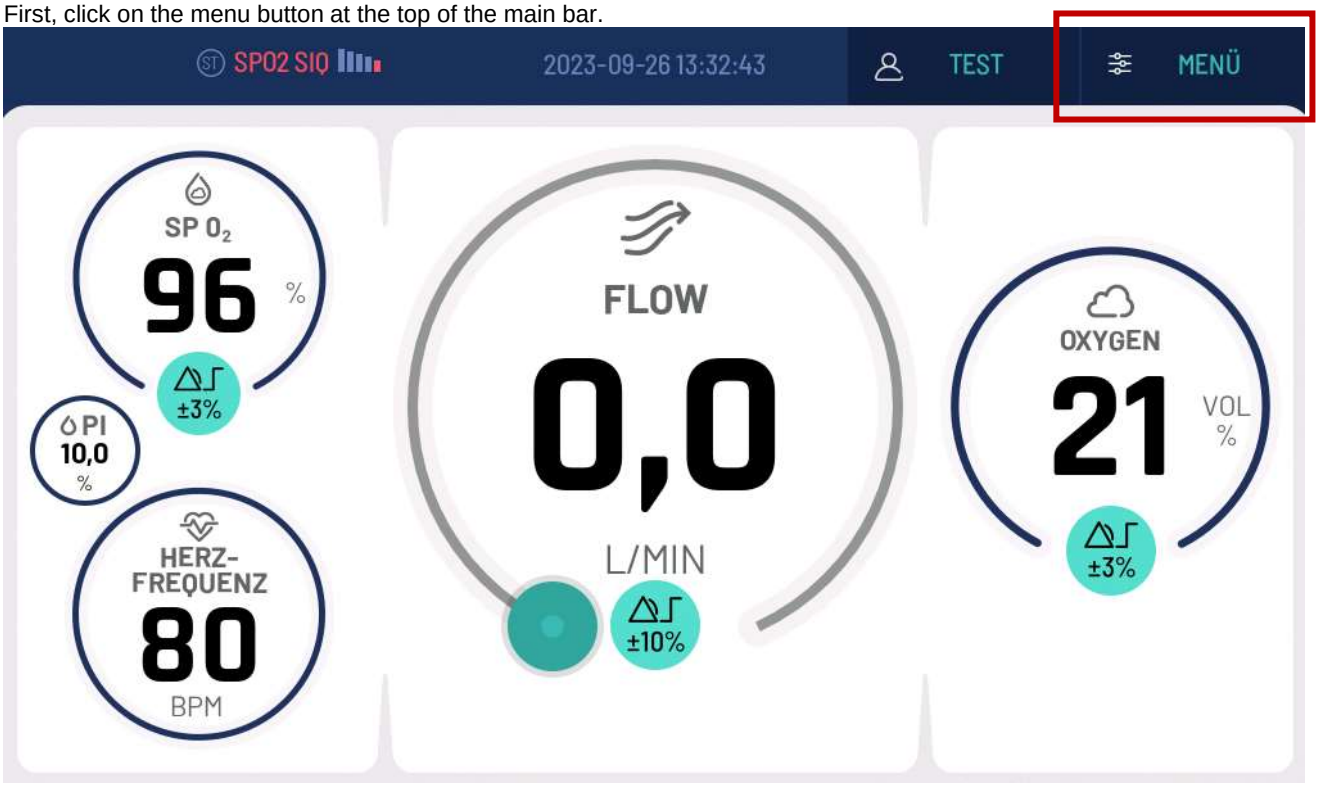
After you have used the Auto-set button to set the respective alarm limits, you must confirm your entry. The alarm limit is then set to the desired value.



6.6.3 Setting the electronic alarm limits manually

In addition to automatically adjusting the alarm limits via the Auto-set function, the QualityMix Pro also has the option of setting the alarm limits manually and individually in the sub-menu (independent of the current operating mode). To do this, proceed as follows:

Step 1: Access the main menu
First, click on the menu button at the top of the main bar.



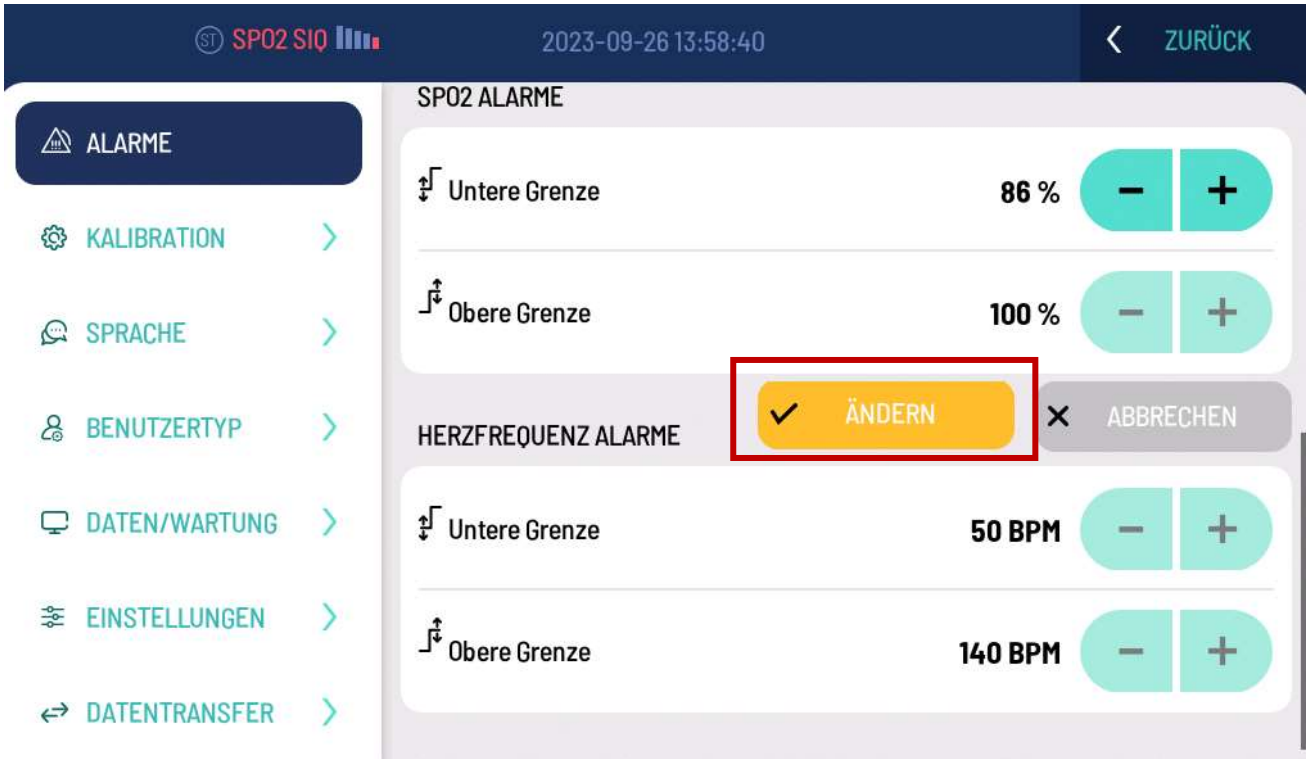
Step 2: Select the sub-menu for the alarm system
From the main menu, there are various selection options. To set the alarm limits, choose the Alarms sub-menu

Step 3: Manually set the lower and upper alarm limits
In this sub-menu, you can manually set the alarm limits for the upper and lower alarm limit. You can set the alarm limits for the following parameters here:

- ➔ FiO2 concentration (15% – 103%)
- ➔ Flow rate (0 l/min – 60 l/min)
- ➔ Oxygen saturation SpO2 (85% – 103%)
- ➔ Heart rate (15 BPM – 200 BPM)

For this, use the buttons labelled plus and minus to increase or reduce the alarm threshold. Press the button until the desired alarm limit is set.

You only need to confirm the entry; the system then accepts the alarm limit. After confirmation, you have successfully accepted the alarm limits.



6.7 Oxygen sensor calibration

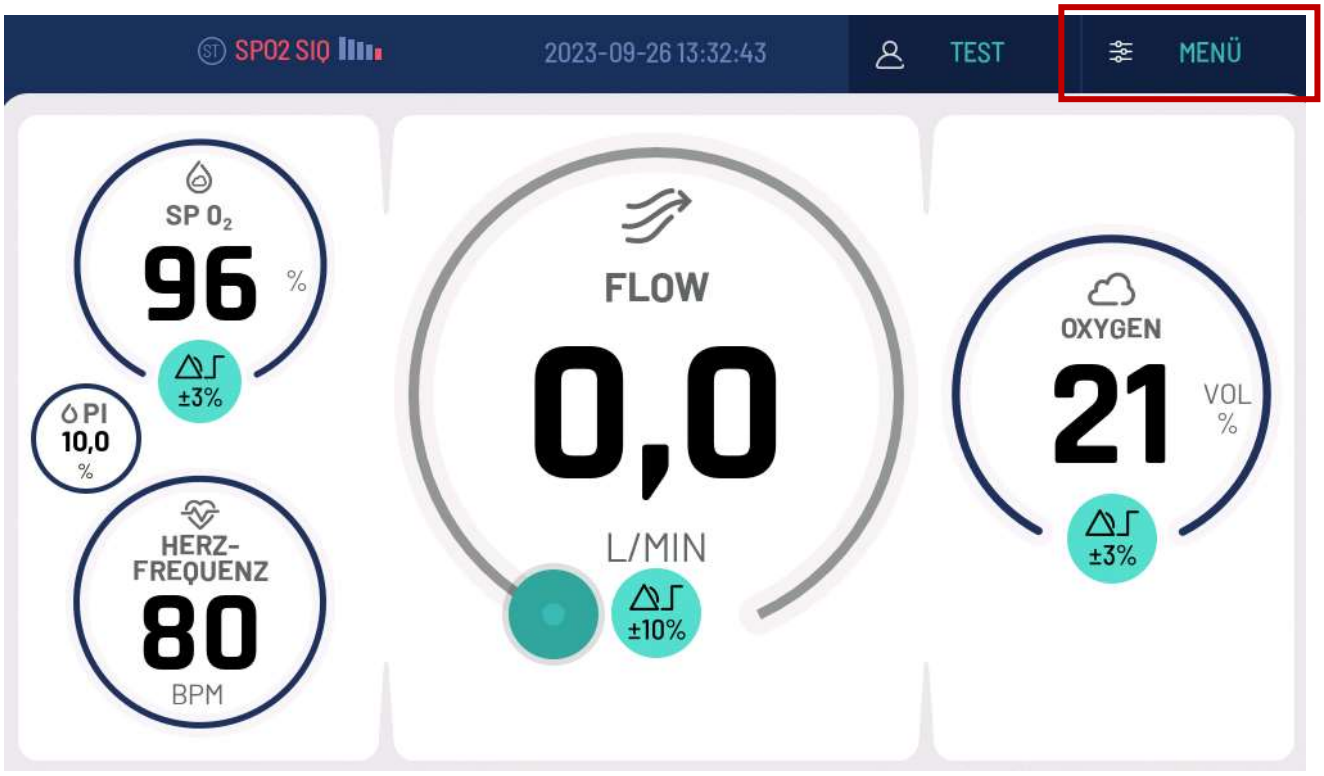
This section describes how to calibrate the connected oxygen sensor.

Notice: Only use the OOM111LF oxygen sensor approved for the QualityMix Pro.

Notice: 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).

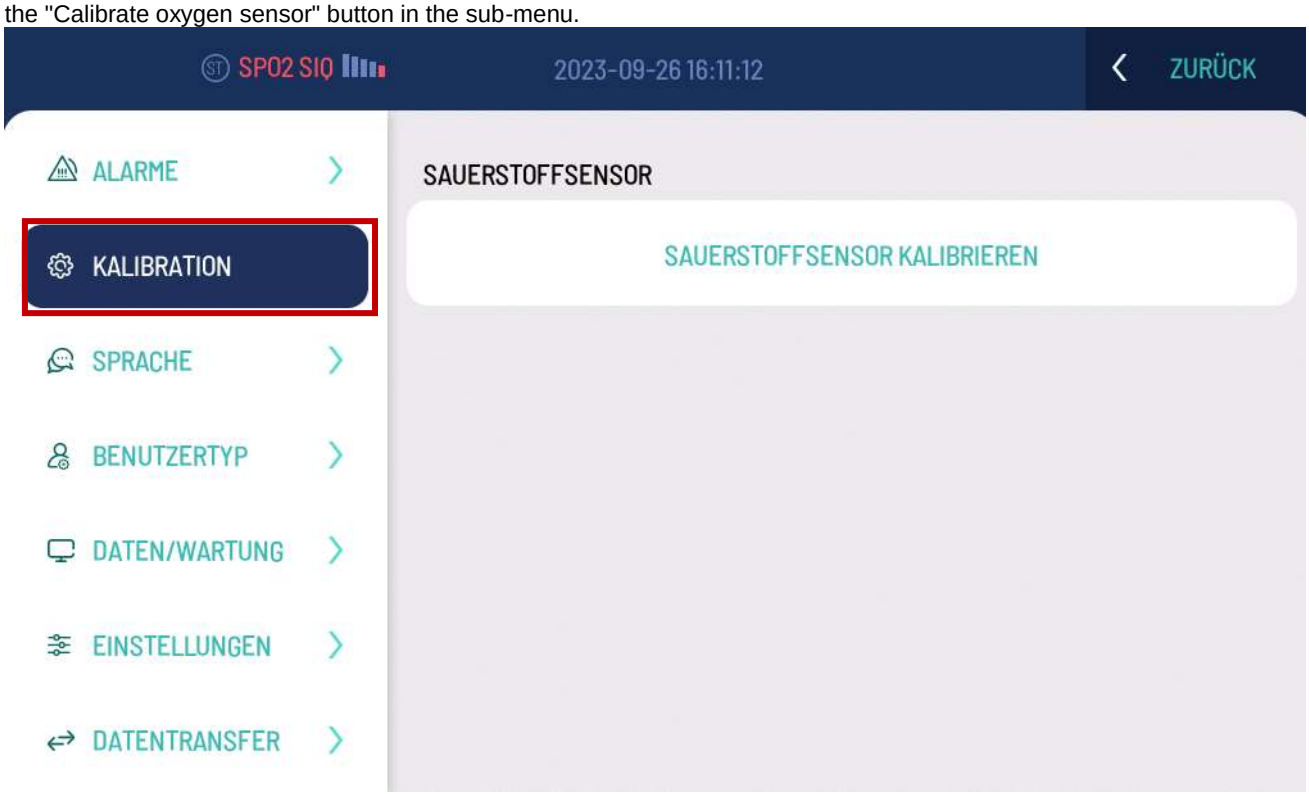
It is possible to calibrate the sensor to either 21% or 100%, depending on the desired application. We recommend calibrating the sensor to 100% when using high oxygen concentrations of ≥ 50% O2.

Step 1: Access the main menu
First, click on the menu button at the top of the main bar.



Step 2: Select the Calibration sub-menu

From the main menu, you can select the sub-menu for calibrating the oxygen sensor at the left side. Then, simply click on the "Calibrate oxygen sensor" button in the sub-menu.

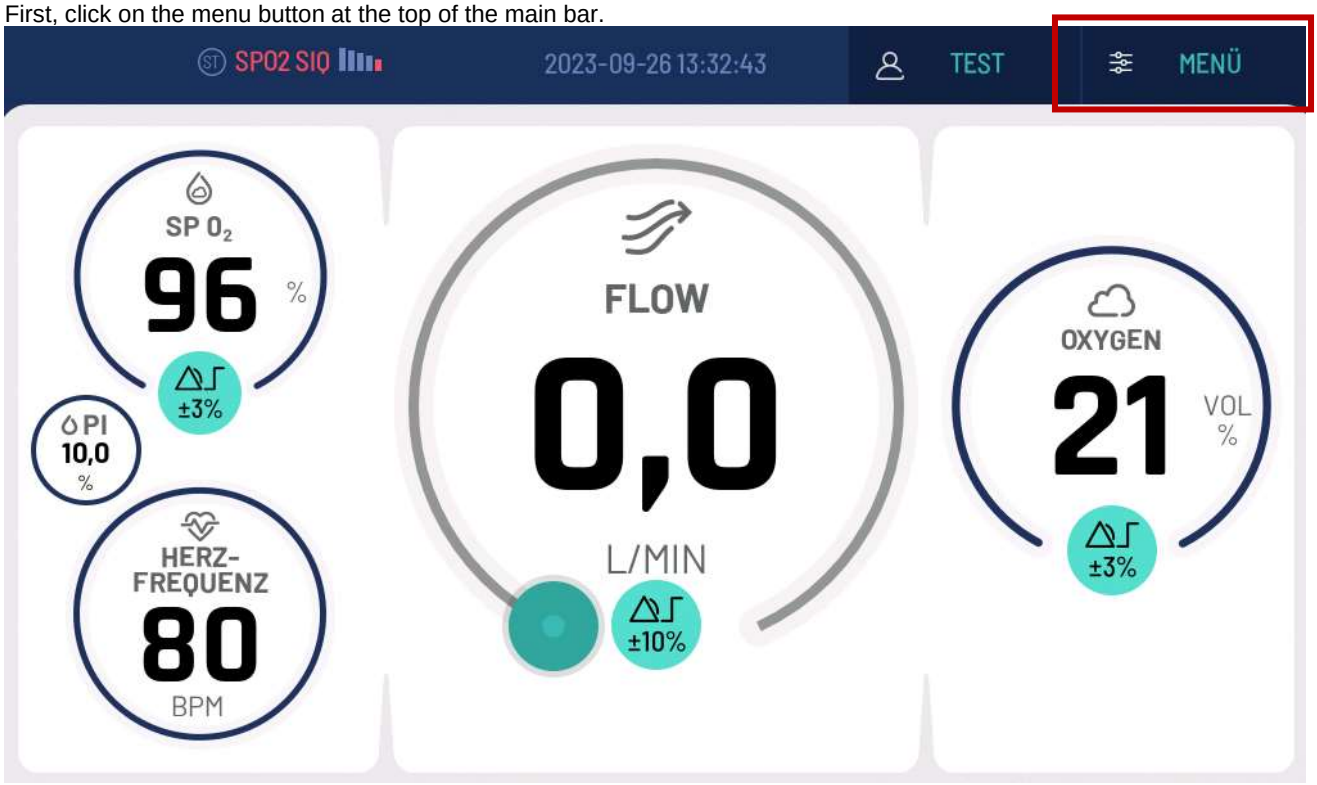


Step 3: Start the calibration
You can now calibrate the sensor to 21% or 100%.
To do this, simply choose the corresponding button and then press the "Start calibration" button. The process takes a few seconds. You can then use the sensor. If the process fails, you will receive a corresponding message.

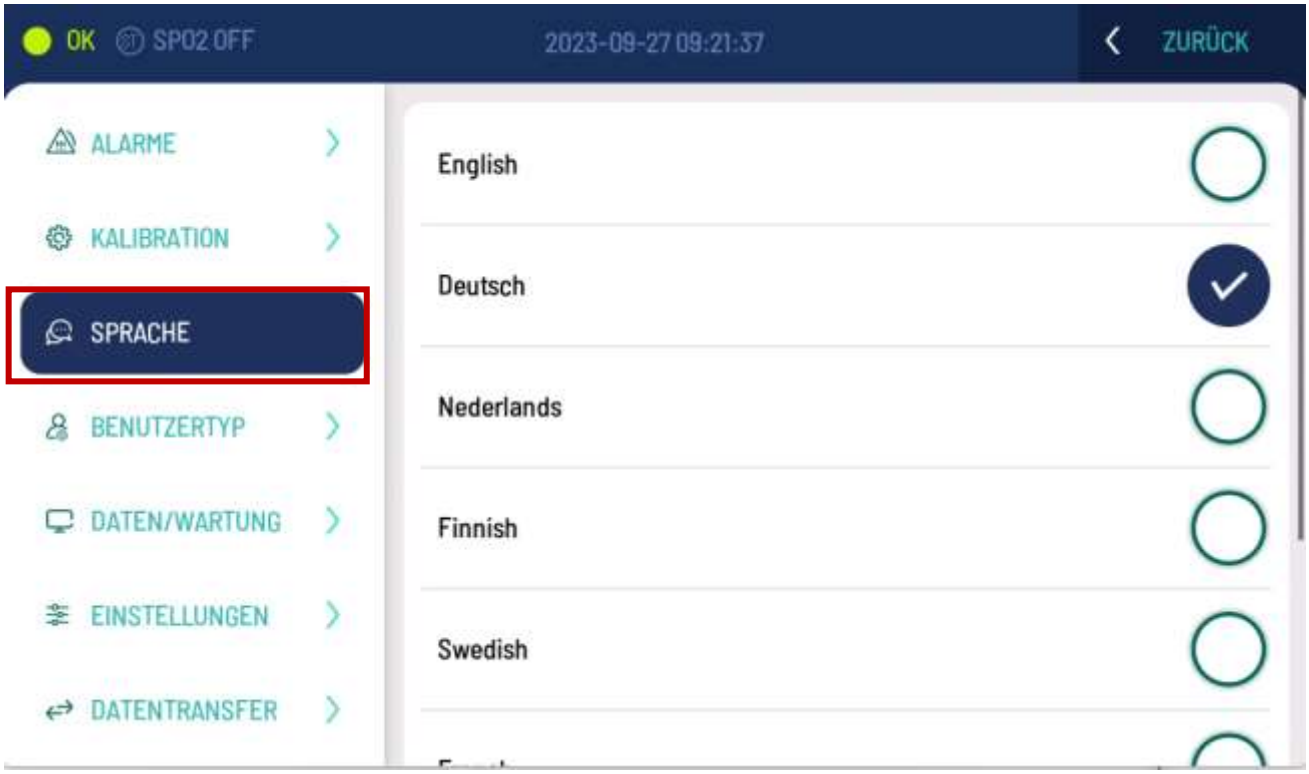
6.8 Setting the language

It is possible to change the language of the QualityMix Pro. You can choose between the different languages in the corresponding sub-menu.

Step 1: Access the main menu
First, click on the menu button at the top of the main bar.



Step 2: Choose the "Language" sub-menu from the main menu. You can now simply click on the desired language and the language will be changed.



6.9 Setting the user type

The QualityMix Pro gives you the option of choosing between three different user types. To do this, simply go to the "User type" sub-menu from the main menu. You can then set the user type.

User type	Authorizations
Standard	• Setting the alarm limits • Calibrating the oxygen sensor • Activating the SpO2 sensor
Power user	• Setting the alarm limits • Calibrating the oxygen sensor • Activating the SpO2 sensor • Setting the language • Updating the firmware • Resetting the device • Downloading log files • Establishing communication with the PDM system, including changing the IP address • Changing the PIN
Service technician	• Setting the alarm limits • Calibrating the oxygen sensor • Activating the SpO2 sensor • Service activities

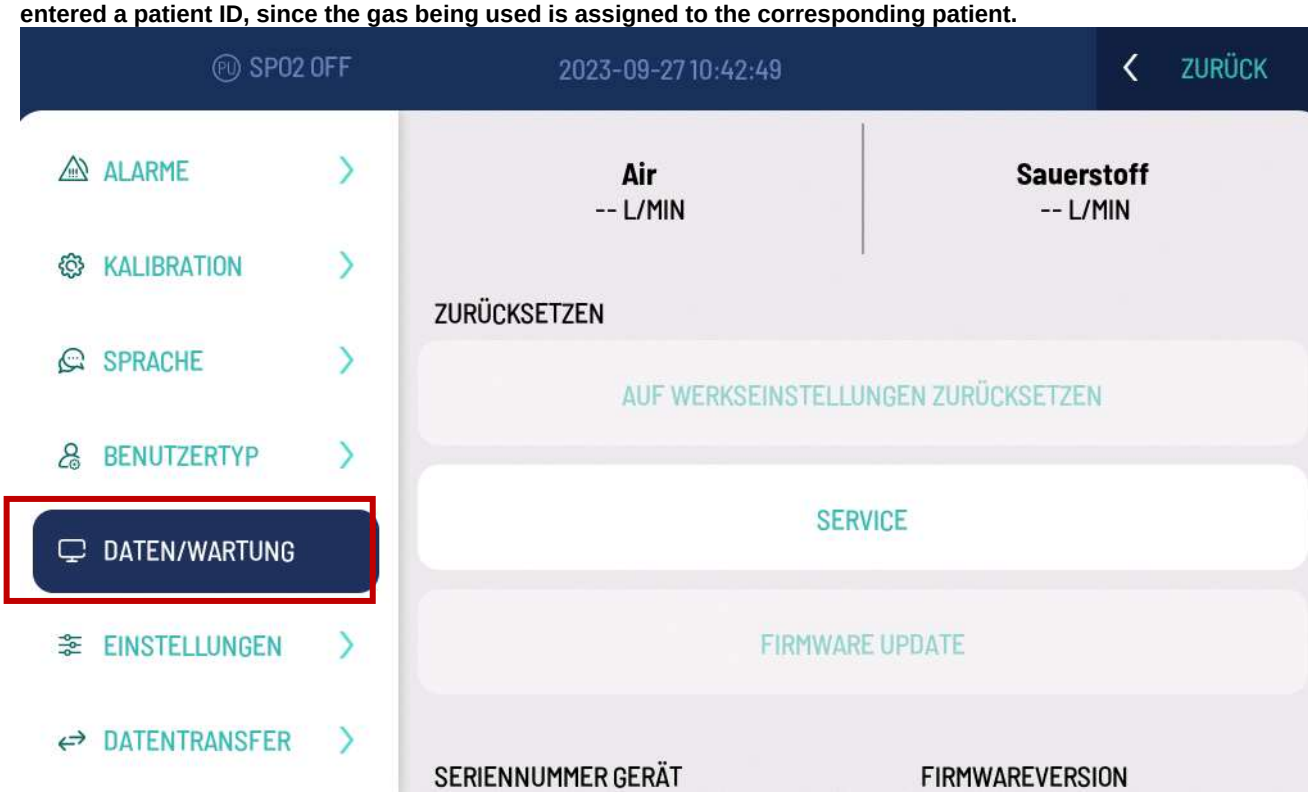
Notice: A PIN must be entered to change the user profile. This PIN can be changed. If you change the PIN, be sure to write it down!

6.10 Data/Maintenance

The QualityMix Pro offers you several service options for maintenance issues. Information about the gas being used (AIR/O2) and the software version is also displayed.

Simply go to the corresponding sub-menu "Data/Maintenance". It can be accessed via the main menu.

Notice: Information about the gas being used is only available if you are in "normal mode" and have entered a patient ID, since the gas being used is assigned to the corresponding patient.



6.11 Data transfer

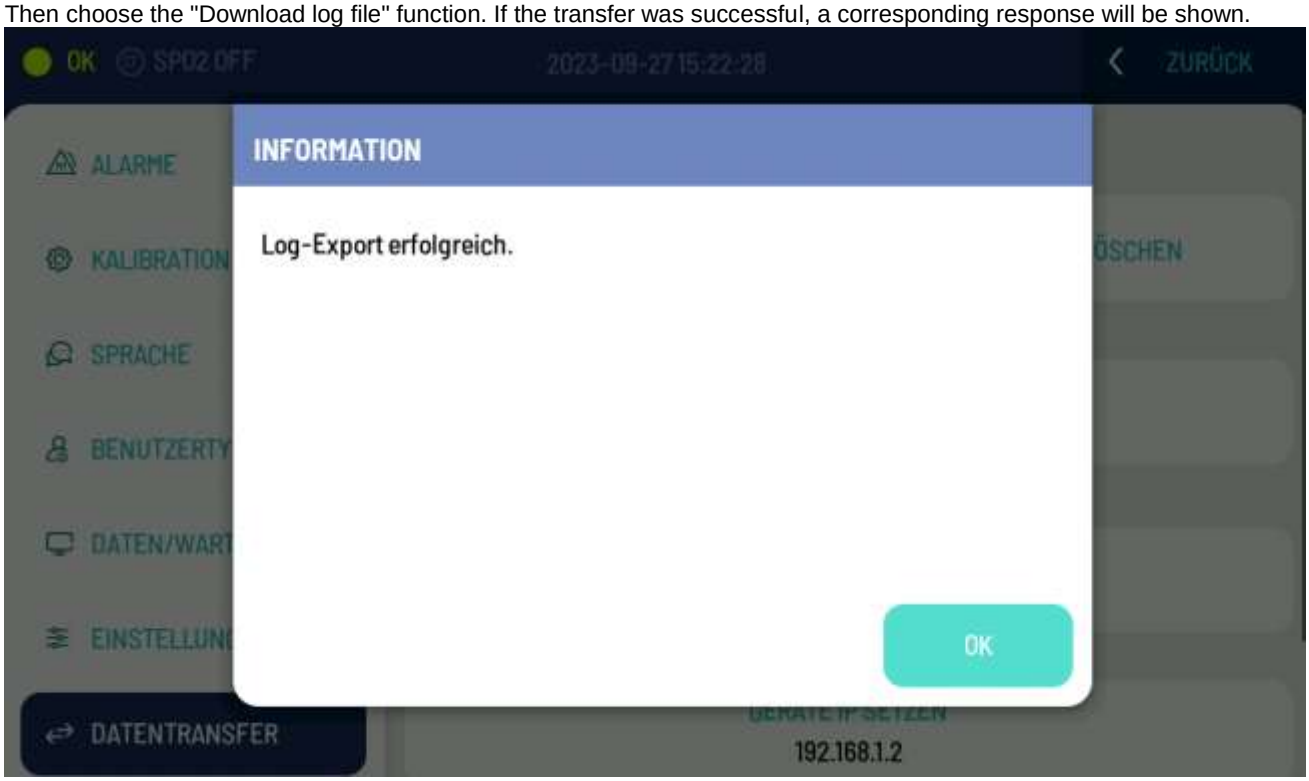
The QualityMix Pro enables you to export the device's saved data. This includes, for example, the vital signs and the associated patient ID. The device has two interfaces for communication: a USB interface and an RJ-45 interface (refer to section 4.2.5).

This allows you to retrieve the data via the USB interface and connect the device to the corresponding PDM in order to extract the data directly. Sections 5.12.1 and 5.12.2 below describe how you can connect to the device via the corresponding interface.

6.11.1 Connecting through the USB interface

Step 1: Go to the "Data transfer" sub-menu.

Step 2: Make sure that you are connected to the QualityMix Pro via the USB interface.
Then choose the "Download log file" function. If the transfer was successful, a corresponding response will be shown.



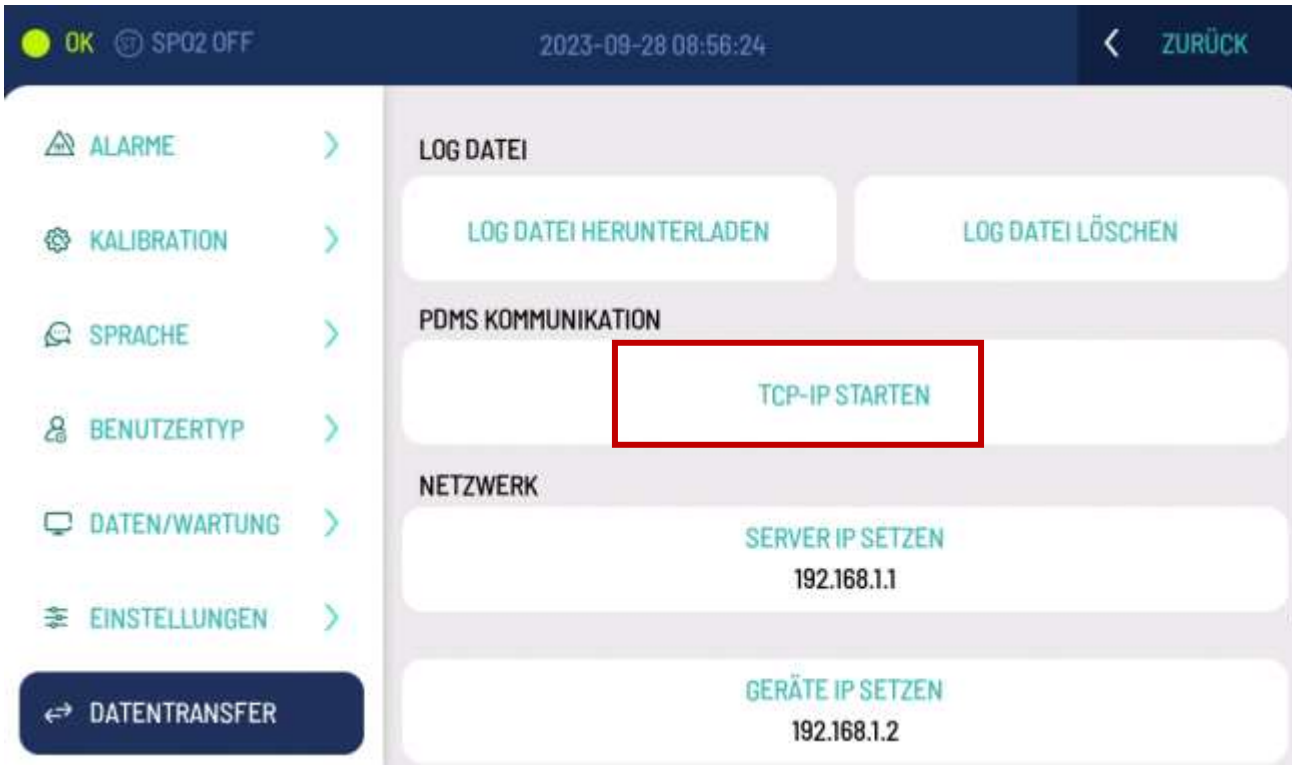
6.11.2 Connecting through the RJ-45 interface

Step 1: Go to the "Data transfer" sub-menu.

Step 2: Set up the network. To establish communication with the corresponding network, you should set the IP address and netmask for the device. Set the IP address of the QualityMix Pro for your network. The QualityMix Pro uses the IPv4 standard.

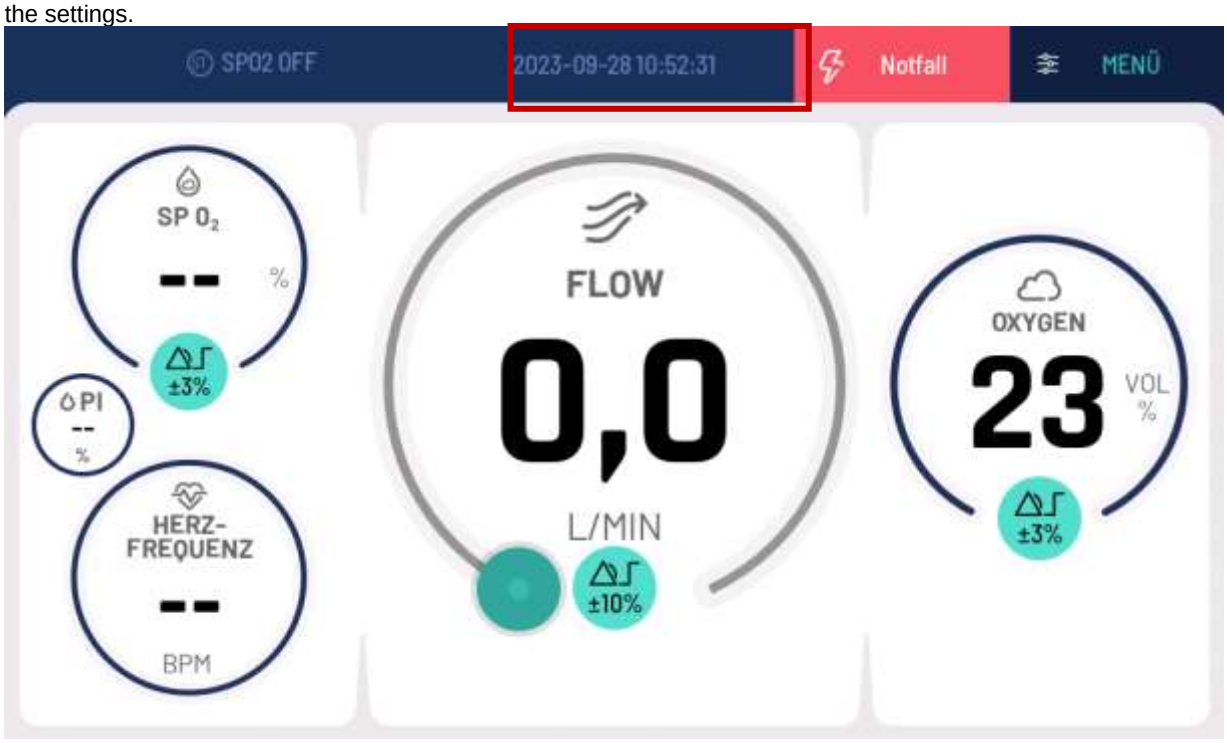
Step 3: Connect the device. Once you have made the network settings, you can connect the QualityMix Pro to the PDM system. Simply choose the corresponding field; the QualityMix Pro should then be successfully connected.

Notice: The HL7 protocol is used for communicating over the RJ-45 interface.



6.12 Setting the date and time

The QualityMix Pro always shows you the current date and time on the main display. You can change this information in the settings.



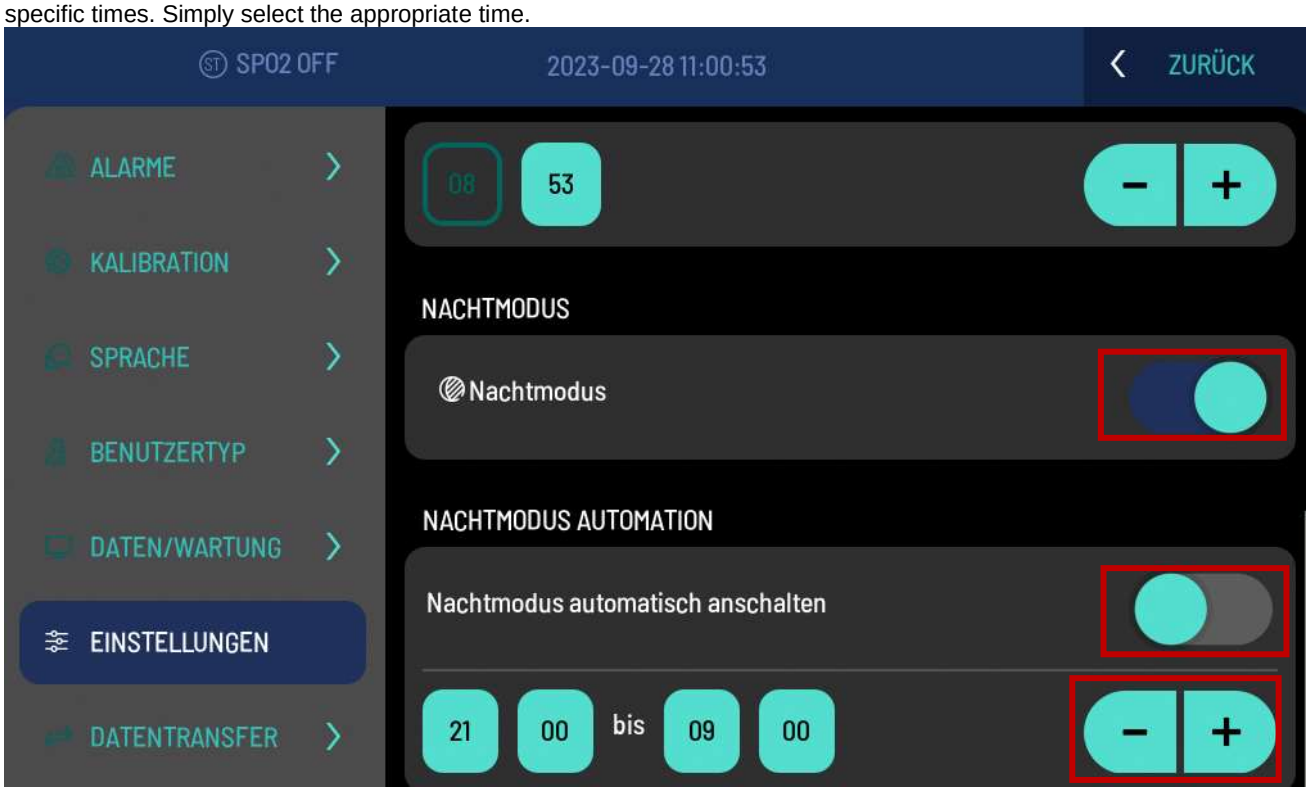
Step 1: Go to the "Settings" sub-menu. You have the option here of setting the date and time.

Step 2: Simply click on the desired value for the date (year, month, day) or the time (hour or minute) and then use the plus and minus symbols to increase or decrease the value, as shown in the example in the following illustration.

6.13 Setting the night mode

The QualityMix Pro enables you to activate night mode for the device so that the screen does not shine so brightly in low ambient light. This makes it easier for users and patients to use the device in the evening or night.

Go to the "Settings" sub-menu. In addition to the settings for the sensor and the time, you have the option of activating night mode here. Simply click on the night mode icon to activate it. You can also automatically activate night mode for specific times. Simply select the appropriate time.



7. SpO2 sensor Masimo

Notice: **The pulse oximeter may only be operated by qualified personnel or under qualified supervision. The manual, accessories, instructions for use, all safety instructions and the technical data should be read before use.**

This chapter describes the Masimo SpO2 technology and how to use it together with the QualityMix Pro.

7.1 Product description

The QualityMix Pro with the integrated Masimo Set SpO2 sensor is intended to be used for non-invasive continuous monitoring of the functional oxygen saturation of arterial haemoglobin (SpO2), the pulse rate/heart rate (PR), and the perfusion index (PI).
The following key functions are available for the QualityMix Pro in conjunction with the Masimo Set Sensor:
• Functionality of the Masimo SET® technology.
• Non-invasive, functional oxygen saturation of arterial haemoglobin (SpO2) and pulse rate (PR), the plethysmography variability index (PVi) and the respiratory rate (Rrp) as determined by a plethysmographic curve.
Areas of application:
The pulse oximeter and accessories are indicated for non-invasive spot-check monitoring or continuous monitoring of functional oxygen saturation of arterial haemoglobin (SpO2) and pulse rate (PR), for use in hospitals, medical facilities, during transport and home environments in adults, children, infants and neonates with or without movement, and in patients with good or poor perfusion.
The pulse oximeter and accessories are indicated for non-invasive spot-check monitoring, or continuous monitoring of respiratory rate via the photoplethysmogram (RRp), for use in hospitals, medical facilities, during transport and domestic environments in adults and children without movement.

7.2 Overview of the Masimo Set technology

The following chapter contains general descriptions of the functional oxygen saturation (SpO2) and Signal IQ parameters that are used by the Masimo products.

Signal Extraction Technology® (SET®)
The signal processing for the Masimo Signal Extraction Technology differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that the arterial blood is the only blood movement (pulsation) at the measuring point. However, as the patient moves, venous blood also moves, causing conventional pulse oximeters to give low readings since they cannot distinguish between arterial and venous blood movement (this is sometimes referred to as noise). Masimo SET® pulse oximetry uses parallel algorithms and adaptive filters. The performance of adaptive filters is dependent on their ability to adapt to changing physiological signals and/or noise and to separate them by breaking down the signal into its basic components. The Masimo SET® signal processing algorithm, Discrete Saturation Transform ® (DST®) in combination with Fast Saturation Transform (FST®), can reliably detect noises, isolate them and suppress them using adaptive filters. The actual arterial oxygen saturation is then reported for display on the monitor.

General description of oxygen saturation (SpO2)
Pulse oximetry is based on the following functional principles:

1. Oxyhaemoglobin (oxygenated blood) and deoxyhaemoglobin (non-oxygenated blood) differ in their ability to absorb red and infrared light (spectrophotometry).

2. The amount of arterial blood in the tissue depends on the pulse (photoplethysmography). Therefore, the amount of light absorbed by the different amounts of arterial blood also varies.

Reliably monitoring the SpO2, PR and Pi
The stability of the SpO2 values is usually a good indication of the validity of the signal. Although stability is a relative term, empirical values create confidence in changes that are artificial or physiological in nature, as well as in the speed, timing and behaviour of these changes. The stability of the measured values is influenced by the averaging time. The longer the averaging time, the more stable the measured values will be. This is due to an attenuated response, since the signal is averaged over a longer period of time than would be the case with shorter averaging times. However, longer averaging times also delay the response of the device and reduce the measured variations in SpO2 and pulse rate.

Functional oxygen saturation (SpO2)
The sensor has been calibrated to measure and display functional oxygen saturation (SpO2): the amount of oxyhaemoglobin expressed as a percentage of haemoglobin available to transport oxygen.
Notice: Dyshaemoglobins cannot transport oxygen, yet are recognized by conventional pulse oximetry devices as oxygen-enriched haemoglobins.

General description of the heart rate/pulse rate (PR)
The pulse rate (PR) is measured in beats per minute (bpm) and is based on the optical detection of the peripheral pulse.
General description of the perfusion index (PI)
The perfusion index (Pi) is the ratio of pulsatile blood flow to non-pulsatile or static blood in the peripheral tissue. Pi is a non-invasive peripheral perfusion value that can be measured continuously and non-invasively with a pulse oximeter.

Signal IQ
Signal IQ enables the signal quality of the displayed SpO2 value to be assessed.

The SpO2 SIQ enables the signal quality of the displayed measured value to be assessed. A fully filled vertical bar indicates a higher signal quality of the measured value. An unfilled vertical bar indicates a lower signal quality of the displayed measured value.
A very low signal IQ suggests that the accuracy of the displayed measured value may be inadequate.

Fully filled bar (very good signal quality) 

Partially filled bar (poor signal quality) 

7.3 Activating the Masimo sensor on the QualityMix Pro

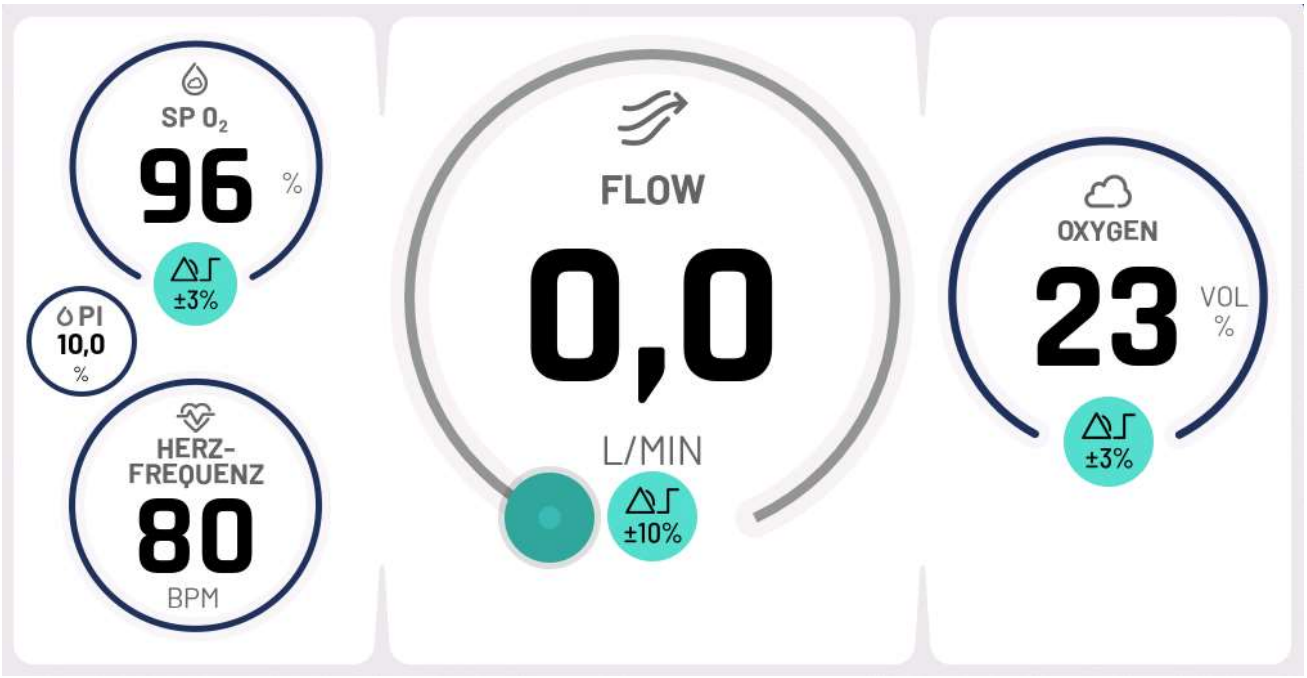
The QualityMix Pro has an option for switching the external sensor on or off. The connection is switched off as delivered, so you must first activate the sensor to set it up. Proceed as follows.

Step 1: Once you have set up the device and selected the desired operating mode in accordance with section 5.2, go to the main menu to access the "Settings" sub-menu. You have the option here of activating or deactivating the sensor and setting the sensitivity of the sensor.

Step 2: To activate the sensor, simply choose the corresponding function. The sensor is then activated. The measured values of the sensor are then shown on the main display.

WARNING!
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard
WARNING! Only operate the pulse oximeter after the correct setup has been verified.
WARNING! If a measurement appears questionable, first check the patient's vital signs by other means and then check the pulse oximeter for proper functionality.



7.4 Overview of sensitivity modes

Three sensitivity levels enable the doctor to adapt the response of the QualityMix Pro to the requirements of the individual patient's situation.

Normal sensitivity
Normal sensitivity is recommended as the sensitivity mode for patients with mild impairment of blood flow or circulation. This level is recommended for care sectors where patients are frequently monitored, such as intensive care units.

APOD® (Adaptive Probe Off Detection® sensitivity)

APOD is the recommended sensitivity mode for situations where there is a high probability of the sensor becoming detached. This mode is also recommended for care sectors in which patients are not constantly monitored visually. This mode offers better protection against incorrect pulse rate and arterial oxygen saturation readings if a sensor is unintentionally dislodged due to excessive patient movement.

Maximum sensitivity

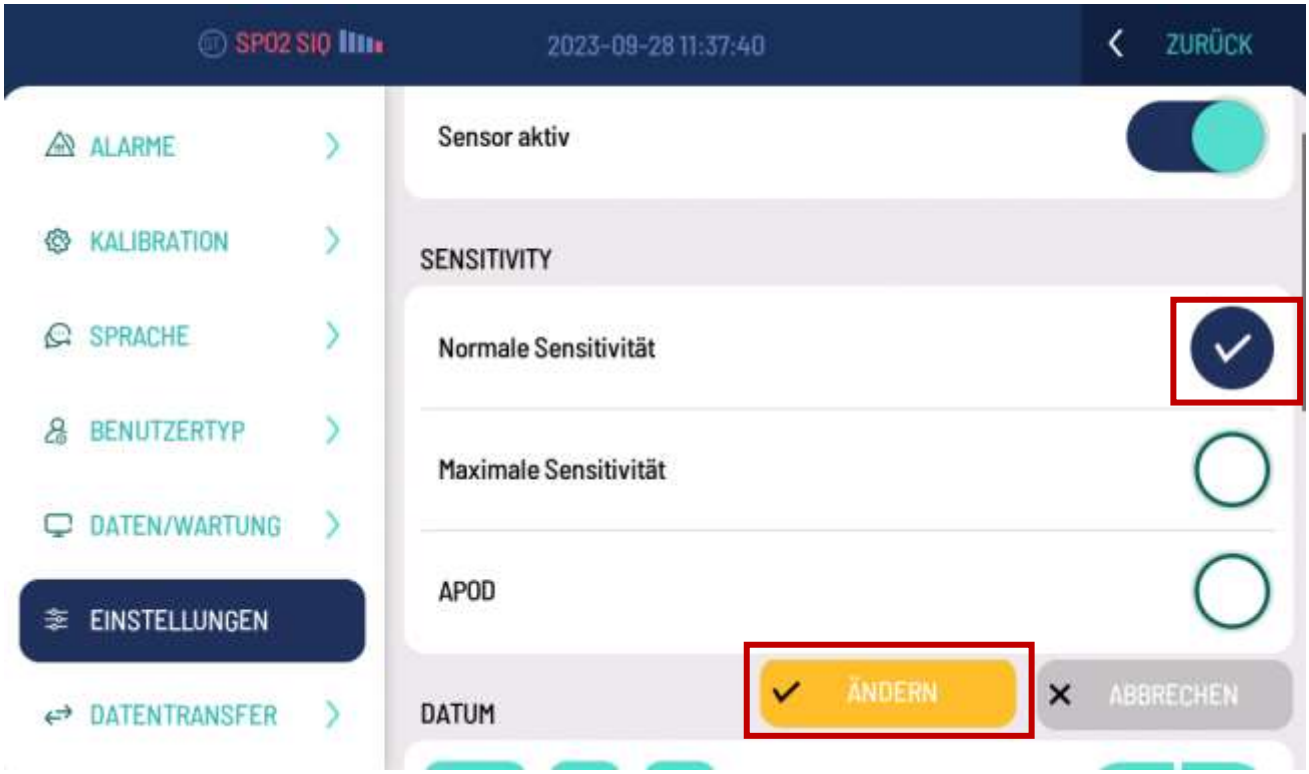
Maximum sensitivity is recommended as a sensitivity mode for patients with low perfusion or when the message for poor perfusion is displayed in APOD mode or in normal mode. Maximum sensitivity is not recommended for care sectors where patients are not frequently checked by nursing staff, such as in medical-surgical wards. This mode was designed in order to display data at the measuring point when the signal is weak due to reduced blood flow. If a sensor becomes detached from the patient, there is no protection against incorrect readings of the pulse rate and arterial oxygen saturation.

7.4.1 Setting the sensitivity modes

You can set the corresponding sensitivity mode on the QualityMix Pro for the sensor as follows:

Step 1: Go to the "Settings" sub-menu. In addition to the option of activating or deactivating the sensor, you can also set the sensitivity of the sensor.

Step 2: You can now switch between the sensor modes described in section 6.3. Click on the appropriate mode and confirm your entry. The mode is successfully changed.



7.5 Troubleshooting

Inaccurate SpO2 measurements can have the following causes:

- Improper usage and placement of the sensor
- Elevated COHb or MetHb values: High COHb or MetHb values can occur with an apparently normal SpO2 value. If elevated COHb or MetHb levels are suspected, a laboratory analysis (CO oximetry) of a blood sample should be carried out.
- Elevated bilirubin levels
- Elevated levels of dyshaemoglobin
- Vasospastic diseases such as Raynaud's disease and peripheral vascular diseases
- Haemoglobinopathies and synthesis disorders such as thalassaemia, Hb s, Hb c, sickle cell anaemia, etc.
- Hypocapnic or hypercapnic conditions
- Severe anaemia
- Very low arterial blood flow
- Extreme movement artefacts
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheter and intra-aortic balloons
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied colourants and textures, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolouration, moisture on the skin, deformed or abnormal fingers, etc.
- Skin colour disorders

Notice:

- Interfering substances: Dyes or substances containing dyes that change the usual blood pigmentation can lead to incorrectly measured values.
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter is not an apnoea monitor.
- The pulse oximeter can be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter can be used during electrocautery, but this may affect the accuracy or availability of parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.
- The SpO2 value was empirically calibrated in healthy adult volunteers with normal levels of carboxyhaemoglobin (COHb) and methaemoglobin (MetHb).
- The pulse oximeter or accessories must not be adjusted, repaired, opened, disassembled or modified. This could cause personal injury or damage to the device. Send the pulse oximeter in for maintenance if necessary.
- A functional test device cannot be used to assess the accuracy of the pulse oximeter.
- Extreme light sources with high intensity (such as pulsating strobe lamps) directed at the sensor can cause the pulse oximeter to not receive vital sign measurements.
- When using the Maximum sensitivity setting, the performance of the "Sensor off" detection may be impaired. If the device is in this setting and the sensor is removed from the patient, ambient noise such as light, vibrations and excessive air movement may result in incorrect readings.
- Do not wind the patient cable into a tight coil or wrap it around the device, since this may damage the patient cable.
- For additional information on the Masimo sensors that are compatible with the pulse oximeter, including information on parameter/measurement performance during motion and low perfusion, please refer to the Directions for Use (DFU) for the corresponding sensor.
- Cables and sensors are equipped with X-Cal™ technology. This minimises the risk of inaccurate readings and unexpected patient monitoring failure. The specified duration of patient monitoring can be found in the instructions for use of the cable or sensor.

Caution!
You must follow the following safety notices in order to avoid undesirable consequences:

Potential hazard
If the message "Low perfusion" is displayed frequently, look for a monitoring site with better perfusion. In the meantime, assess the patient and check the oxygenation status by other means when necessary.
Change the application site or replace the sensor and/or the patient cable if the message "Replace sensor" and/or "Replace patient cable" or a persistent message about poor signal quality (e.g. "Low SIQ") is displayed at the host monitor. These messages may indicate that the monitoring time for the patient cable or the sensor has been exhausted.
If the SpO2 values indicate hypoxaemia, a laboratory blood sample should be taken to confirm the patient's condition.
If you are using pulse oximetry during whole-body irradiation, keep the sensor outside the radiation field. If the sensor is exposed to radiation, the measured value may be inaccurate or the device may display zero for the duration of the active radiation.
To ensure that the alarm limits are appropriate for the patient being monitored, you should check the limits each time the pulse oximeter is used.

The measured values may fluctuate greatly and can be influenced by both the sampling technique and the physiological conditions of the patient. Any results that are not consistent with the patient's clinical condition should be repeated and/or supplemented with additional test data. Blood samples should be analysed with laboratory instruments prior to clinical decision making in order to fully assess the patient's condition.
Do not immerse the pulse oximeter in a cleaning solution and do not attempt to sterilize it by autoclaving, irradiation, steam, gas, ethylene oxide or any other method. This would seriously damage the pulse oximeter.
Replace the cable or sensor if the sensor is replaced, or if a low SIQ message is consistently displayed when monitoring consecutive patients after completing the troubleshooting steps listed in this manual.

7.6 Masimo licence

NO IMPLIED LICENSE: Possession of this device does not convey any express or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device."

"NON-AUTHORIZED ACCESSORIES: Masimo technology is designed to operate together with Masimo cables, sensors and accessories as an integrated system. When any component of the system is compromised, erroneous measurements can occur. Accordingly, the use of unauthorized sensors or accessories, such as third-party reprocessed or copycat sensors can yield unreliable results when used with a Masimo device. The performance of Masimo technology is not validated when used with any unauthorized sensor or accessory.

For more information: https://www.masimo.com/company/masimo/patents/

8. Alarms and error messages:

This chapter gives you an overview of the various alarms and alarm messages of the QualityMix Pro.

The alarm system of the QualityMix Pro distinguishes between three different alarms. There are high, medium and low priority alarms.

This chapter is intended to give you an overview of all alarm messages that may appear while the QualityMix Pro is running.

You can recognize the priority by the different alarm sequence or tone sequence. The volume of the individual alarms also differs as described in chapter 7.5.

You can also see the individual alarm messages with their priority at the LEDs.

There are three LEDs. Each LED is assigned a different priority. High priority alarms light up red, medium and low priority alarms light up yellow.

8.1 Alarms and error messages during system start-up

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
System start	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The device is not ready for operation. Please contact the manufacturer.**	**Warning. The device is not ready for operation.** Please contact the manufacturer.
System start	High priority	High priority	Flashing red	Flashing red	**Warning. The device is not ready for operation. Please contact the manufacturer.**	Device failure (critical self-test)

8.2 Alarms and error messages during operation

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
FLOW alarm limits exceeded	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The upper alarm limit set for the flow value has been exceeded**. Please check the flow and alarm limit settings.	
Falling below the FLOW limits	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The flow value has fallen below the specified lower alarm limit**. Please check the flow and alarm limit settings.	
Oxygen concentration FiO2 alarm limits exceeded	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The upper alarm limit set for the oxygen concentration has been exceeded.** Please check the settings of the alarm limits and oxygen concentration.	
Oxygen concentration FiO2 has fallen below the alarm limits	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The oxygen concentration has fallen below the specified lower alarm limit value.** Please check the settings of the alarm limits and oxygen concentration.	
Oxygen value < 18%	High priority	High priority	Flashing red	Flashing red	**Warning. Oxygen concentration below 18%**. Check the patient's oxygen supply and calibration as well as the OOMLF111 sensor.	
Oxygen sensor not detected (user error / incorrect sensor / connection faulty)	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. No oxygen sensor was detected.** Please check the connection to the oxygen sensor OOMLF111 and replace sensor if necessary.	

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
Oxygen sensor defective	High priority	High priority	Flashing red	Flashing red	**Warning. The oxygen sensor is defective.** Please check the connection to the oxygen sensor and replace if necessary.	
Oxygen sensor not calibrated	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The oxygen sensor is not calibrated or the calibration is faulty.**	
Battery full in battery mode	Low priority	Low priority	Steady yellow	Steady yellow	**Warning. The device is in battery mode and will switch off in approx. 15 minutes.**	
Battery medium in battery mode	Low priority	Low priority	Steady yellow	Steady yellow	**Warning. The device is in battery mode and will switch off soon.** (≤ 2 minutes) Please connect to the mains power supply.	
Battery low in mains operation	Low priority	Low priority	Steady yellow	Steady yellow	**Warning. The battery for battery operation must be replaced.**	
Battery low in battery mode	High priority	High priority	Flashing red	Flashing red	**Warning. The device is in battery mode and will switch off immediately.** Please connect the mains power supply immediately.	
Emergency mode longer than 30 min	Medium priority	Medium priority	Flashing yellow	Flashing yellow	**Warning. The device is in emergency mode.** Please switch to normal mode	

8.3 Alarms and error messages while the Masimo SpO2 sensor is operating.

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
Upper SpO2 alarm limit exceeded. (High limit)	Medium priority	Medium priority	Flashing yellow	Flashing yellow	The upper limit value is the upper threshold value at which an alarm is triggered.	Comment: Factory setting without default. Default value 100
Lower SpO2 alarm limit exceeded. (Low limit)	High priority	High priority	Flashing red	Flashing red	The lower limit value is the lower threshold value at which an alarm is triggered.	Comment: Factory setting is clinically recognized; lower alarm limit must not be less than 85% SpO2! Default value 85 and low values not possible
Upper limit PR (pulse rate) alarm exceeded (high limit)	High priority	High priority	Flashing red	Flashing red	The upper limit value is the upper threshold value at which an alarm is triggered.	Comment: Factory setting is 140 bmp
Lower limit PR (pulse rate) alarm exceeded. (Low limit)	High priority	High priority	Flashing red	Flashing red	The lower limit value is the lower threshold value at which an alarm is triggered.	Comment: Factory setting is 50 bmp
ALARM_TYPE_MASI-MO_NO_CONNECTION	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Internal sensor line SpO2 sensor is defective. Please contact the manufacturer.	
ALARM_TYPE_MASI-	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Connection to SpO2 sensor failed. Please	

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
MO_NO_CABLE_CONNECTED					check the connection to the SpO2 sensor and replace the sensor or sensor cable as necessary.	
ALARM_TYPE_MASI-MO_CABLE_EXPIRED	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Shelf life of patient cable has expired. Please change the patient cable.	
ALARM_TYPE_MASI-MO_INCOMPATIBLE_CABLE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor connection cable is incompatible. Please check the connection to the SpO2 sensor and replace the sensor cable if necessary.	
ALARM_TYPE_MASI-MO_UNRECOGNIZED_CABLE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Connection to SpO2 sensor failed. Please check the connection to the SpO2 sensor and replace the sensor cable if necessary.	
ALARM_TYPE_MASI-MO_DEFECTIVE_CABLE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Connection to SpO2 sensor failed. Please check the connection to the SpO2 sensor and replace the sensor or sensor cable as necessary.	
ALARM_TYPE_MASI-MO_CABLE_NEAR_EXPIRATION	Low priority	Low priority	Flashing yellow	Flashing yellow	Warning! Shelf life of patient cable near expiration. Please change the patient cable.	
ALARM_TYPE_MASI-MO_NO_SENSOR_CONNECTED	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor not connected. Please check the connection to the SpO2 sensor and replace the sensor or sensor cable as necessary.	
ALARM_TYPE_MASI-MO_SENSOR_EXIPIRED	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Shelf life of SpO2 sensor has expired. Please change SpO2 sensor immediately.	
ALARM_TYPE_MASI-MO_INCOMPATIBLE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor is incompatible. Please check SpO2 sensor and replace sensor if necessary.	
ALARM_TYPE_MASI-MO_UNRECOGNIZED_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor is not recognized. Please check SpO2 sensor for compatibility and replace if necessary.	
ALARM_TYPE_MASI-MO_DEFECTIVE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor is defective. Please change the SpO2 sensor.	
ALARM_TYPE_MASI-MO_CHECK_CABLE_AND_SENSOR_FAULT	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Connection to the SpO2 sensor has been interrupted. Please check the connection to the SpO2 sensor and replace the sensor or cable if necessary.	

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
ALARM_TYPE_MASI-MO_SENSOR_NEAR_EXPIRATION	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Shelf life of SpO2 sensor near expiration. Please change the SpO2 sensor.	
ALARM_TYPE_MASI-MO_NO_ADHESIVE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 disposable sensor not connected. Please check the connection to the SpO2 disposable sensor and replace the sensor or sensor cable if necessary.	
ALARM_TYPE_MASI-MO_ADHESIVE_SEN-SOR_EXPIRED	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Shelf life of SpO2 disposable sensor has expired. Please change the disposable SpO2 sensor immediately.	
ALARM_TYPE_MASI-MO_INCOMPATIBLE_ADHESIVE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 disposable sensor is incompatible. Please change immediately to an approved disposable SpO2 sensor.	
ALARM_TYPE_MASI-MO_UNRECOGNIZED_ADHESIVE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 disposable sensor is not recognized. Please check the SpO2 disposable sensor for compatibility and replace if necessary.	
ALARM_TYPE_MASI-MO_DEFECTIVE_ADHE-SIVE_SENSOR	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 disposable sensor is defective. Please change the disposable SpO2 sensor.	
ALARM_TYPE_MASI-MO_SENSOR_INITIALIZING	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor in initialization mode < 30 s. Sensor function check; please wait for a moment.	
ALARM_TYPE_MASI-MO_SENSOR_OFF_PATIENT	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor not properly attached to the patient. Please check the connection.	
ALARM_TYPE_MASI-MO_PULSE_SEARCH	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Pulse – CO-Ox / Pulse search < 30 s. Please wait for a moment.	
ALARM_TYPE_MASI-MO_INTERFERENCE_DETECTED	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Pulse – CO-Ox fault has occurred. Please contact the manufacturer.	
ALARM_TYPE_MASI-MO_LOW_PERFUSION_INDEX	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Pulse – CO-Ox Low perfusion index. Please contact the manufacturer.	
ALARM_TYPE_MASI-MO_DEMO_MODE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor in demo mode. Please contact the manufacturer.	
ALARM_TYPE_MASI-MO_ADHESIVE_SEN-SOR_NEAR_EXPI	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Shelf life SpO2 disposable sensor near expiration. Please change the disposable SpO2 sensor.	

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
RATION						
ALARM_TYPE_MASI-MO_CHECK_SENSOR_CONNECTION	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Connection to SpO2 sensor failed. Please check the connection to the SpO2 sensor and replace the sensor or sensor cable as necessary.	
ALARM_TYPE_MASI-MO_SpO2_ONLY_MODE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Only SpO2 mode is enabled. Sensor initialization/pulse search routine failed. Please change the SpO2 sensor.	
ALARM_TYPE_MASI-MO_TOO_MUCH_AMBIENT_LIGHT	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Excessive ambient light or strobe light. Please check the ambient light.	
ALARM_TYPE_MASI-MO_LOW_SIGNAL_IQ	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 sensor has low signal IQ.	
ALARM_TYPE_MASI-MO_BOARD_FAILURE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 system error, error code xx. Please restart the device or contact the manufacturer.	
ALARM_TYPE_MASI-MO_DIAGNOSTIC_FAILURE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Possible incorrect measured values from SpO2 sensor, error code xx. Please restart the device or contact the manufacturer.	

8.4 Alarms and error messages while the Masimo SpO2 sensor is operating.

There are two different error messages with different error codes for problems or errors related to the Masimo sensor and the Masimo OEM board.

Process step / incident	Alarm priority	Acoustic alarm	LED display	Display	Text	Remark
ALARM_TYPE_MASI-MO_BOARD_FAILURE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! SpO2 system error, error code xx. Please restart the device or contact the manufacturer.	
ALARM_TYPE_MASI-MO_DIAGNOSTIC_FAILURE	Medium priority	Medium priority	Flashing yellow	Flashing yellow	Warning! Possible incorrect measured values from SpO2 sensor, error code xx. Please restart the device or contact the manufacturer.	

The following error codes are available for errors relating to diagnostics or sensor errors. The xx should be replaced by the relevant error code.

Error message:
Warning! Possible incorrect measured values from SpO2 sensor, error code **xx**. Please restart the device or contact the manufacturer.

Error code	Meaning
0x00	No error
0x01	Sensor defective
0x02	Short-circuited at LEDs (LED on sensor defective, replace sensor and report to manufacturer)
0x03	Short-circuited at detector (detector on sensor defective, replace sensor and report to manufacturer)

0x04	Sensor defect
0x05	Calibration error (restart device, replace sensor if necessary)
0x06	Calibration error (restart device, replace sensor if necessary)

If the following error message appears on the QualityMix Pro, please contact the manufacturer. In this error message, the "xx" stands for 61 different error codes, all of which indicate that the internal sensor board is defective. The corresponding component must be replaced.

Warning! SpO2 system error, error code xx. Please restart the device or contact the manufacturer.

8.5 Alarm volume

Alarm type	Volume in (dB)	At A - weighted background volume (dB)
High priority (red)	**69**	**53**
Medium priority (flashing yellow)	**67**	**52**
Low priority (yellow constantly on)	**67**	**52**

8.6 Alarm reset

Alarm priority	Reset
High priority (red)	All high priority alarms (all red alarms) are self-sustaining. This means that these alarms are only deactivated after confirmation by the user and removal of (or solution for) the alarm condition.
Medium priority (flashing yellow)	Medium priority alarms (yellow) are not self-sustaining. This means that these alarms are automatically cancelled / reset when the alarm condition no longer exists.
Low priority (yellow steady)	Low priority alarms (yellow) are not self-sustaining. This means that these alarms are automatically cancelled / reset when the alarm condition no longer exists.
Text messages	If no other text message is displayed, the text message is displayed here for approx. one minute and then deleted.

9. Device in emergency program mode:

If high-priority alarms occur during operation of the QualityMix Pro due to faults or failures in the supply, the device attempts to maintain operations as long as possible. The normal function of the QualityMix Pro is restricted as follows:

The mode change of the QualityMix Pro is limited: The mode can only be changed if the emergency program has been triggered by a disconnection alarm. Otherwise, the error must be rectified before changing the mode.

If the emergency program is caused by the failure of one of the supply gases, the QualityMix Pro® continues to operate with the remaining gas, resulting in an oxygen concentration of 21% or 100%. The valve continues to emit a flow. It uses the last set value. The motorized control valve remains in this position until the device is reconnected to the power supply and a new value is set. This ensures that patient care is maintained in the event of a fault.

If a serious error occurs in the device, the flow is deactivated and the device must be restarted.

10. Troubleshooting the pneumatic mixer

Consult the following section in the event that the integrated air-oxygen mixer malfunctions. If this information does not help to solve the problem, please contact DEHAS or your nearest retailer.

Problem	Possible cause	Remedy
No flow at the mixer's outlet	The gas supply is switched off.	Check the supply gas. Switch on the gas supply.
	The gas supply is not connected.	Connect the gas supply.
	Downstream device causing back flow or restricted flow	Disconnect the mixer. Check the oxygen concentration at the outlets of the mixer.
Problem	**Possible cause**	**Remedy**
Pneumatic alarm sound activated:	Difference between oxygen and air inlet pressures greater than specified (≥ 0.9 bar)	Adjust this pressure differential until the air/oxygen pressures meet the specifications. Another option: Use a pressure reducer for the central gas supply.
	Outage of a supply gas. Pressure difference between the two supply pressures is outside the specified tolerance.	Check the supply gas pressures. Check the gas connection hoses (AIR / O2).

11. Dismantling

11.1 Hardware shutdown and dismantling

The following steps must be carried out to switch off and dismantle the device.

Step	Activity
1	To switch off the device hardware, the ON/OFF rocker switch on the back of the device must be switched off (refer to the symbol xxx) The central gas supply must be shut off. Otherwise gas will constantly escape through the bleed valve.
2	After switching off the device by moving the rocker switch to the OFF position on the back of the device, the device can be disconnected from the air and oxygen supplies. The power supply unit can also be disconnected from the central power supply.
3	Please ensure that the individual components are not damaged during disassembly and that they are stored cleanly as specified by the manufacturer.
4	The supply hoses must be cleaned and disinfected before storage. Please refer to the hose manufacturer's instructions.
5	The surface of the QualityMix Pro must be cleaned and disinfected as described in Chapter 11.

12. Cleaning:

12.1 Dismantling for cleaning

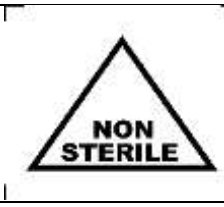
Warning:

- Disconnect the power supply unit from the mains power supply during thunderstorms.
- **Do not** pull the cable to disconnect the power supply unit from the mains socket.
- The power supply unit of the QualityMix Pro must be disconnected from the mains before cleaning!

Notice:
Since the 9-V block batteries discharge even when inactive, we recommend replacing them regularly if the device is stored or used for a long period of time.

12.2 Cleaning / disinfection

12.2.1 Cleaning and disinfection of the QualityMix Pro

Manufacturer: DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Lübeck Germany	**Sterilization process:** **N/A** **This product is not intended for the sterilization process.**	

Described product:
Product:
QualityMix series

WARNING: 	Do not use any disinfectants containing phenol. Do not use strong solvents or abrasives. Do not autoclave! Do not sterilize! Do NOT immerse in a liquid.
The listed instructions have been validated by the manufacturer of the medical device as SUITABLE for the reprocessing of a medical device for reuse. The reprocessing agent is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and staff used in the reprocessing plant achieves the desired results.	

WARNING!

Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
WARNING To protect yourself from injury, follow the instructions below:	- Avoid placing the device on surfaces with visible liquid residues. - Do not soak the device or immerse it in liquid. - Do not attempt to sterilize the device. - Only use cleaning solutions that are described in these operating instructions. - Do not attempt to clean the device while you are monitoring a patient.

Instructions	
Preparation for decontamination:	The exterior of the device should be disinfected at regular intervals. At a minimum, it should be wipe-disinfected after each patient according to the applicable hygiene standards.
Manual cleaning	**For this process:** 1. All connections to the device must be disconnected before starting to clean. 2. Any heavily soiled surfaces of the device must be pre-cleaned! 3. Use a ready-to-use disinfectant wipe to pre-clean the device. 4. Remove coarse soiling/deposits with a ready-to-use disinfectant wipe. 5. Please dispose of the used wet wipe properly. 6. Wipe all surfaces with a clean, dry, lint-free cloth. No impurities should be visible afterwards.
Manual disinfection	7. Take out a ready-to-use disinfectant wipe and wipe the cleaned surface again to visibly wet all surfaces to be disinfected. All surfaces must remain visibly wet. Observe the exposure time specified by the disinfectant manufacturer. 8. Dispose of the used disinfectant wipe properly.
Drying	9. After the exposure time has elapsed, wipe the surfaces with a clean, dry, lint-free cloth until no disinfectant residues, such as streaks, are visible.

Manufacturer recommendation	The manufacturer recommends the use of pre-soaked, ready-to-use disinfectant wipes such as Bode Bacillol 30 Sensitive Tissues from Bode Chemie GmbH & Co. The current product data sheet from the disinfectant manufacturer must be followed.
Maintenance, inspection and testing	A visual and functional check must be carried out after each cleaning and disinfection.
Packaging	The device must be stored in the packaging approved by DEHAS for transport.
Storage	▪ Temperature: +5 °C to +50 °C ▪ Max. 95% non-condensing humidity ▪ Store the device in the original packaging provided by the manufacturer. ▪ Store in a dry, clean place, free from lubricants, oil and other contaminants.
Transport	▪ Temperature: 0 °C to +50 °C ▪ Max. 95% non-condensing humidity
Additional information	N/A
Contact us	DEHAS Medical Systems GmbH, Wesloer Strasse 107-109, 23568 Lübeck, OT Schlutup, Germany Phone: +49 451 80904-0, Fax: +49 451 80904-111, E-mail: info@dehas.de

Important notice: A visual and functional check of the device must be carried out after each cleaning and disinfection.

13. Maintenance

Warning!
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
Warning! **Improper operations** Improper device operations (e.g. due to instruction errors) can lead to injury to persons or damage to the system.	a) Access to the operating instructions by the operating and maintenance personnel must be guaranteed at all times! b) Thus, a copy of the installation documentation including the operating instructions must be kept either at the device or at a suitable accessible place.
Warning! **Working on the device** If an accident occurs while working with this product, there is a considerable risk of injury!	a) Never carry out work on the device unsupervised or unannounced! b) Adhere to the safety rules and permission procedure that is applicable at your site!
Warning! **Maintenance** Incorrect or untimely maintenance work may result in damage to the device or injuries.	a) To avoid static charges, never clean the product with dry cloths. Use damp cotton cloths. b) The maintenance intervals shall be determined by the facility operator within the framework of their risk assessment. c) Observe the maintenance intervals (2 years) and maintenance instructions from the manufacturer and the applicable directives. d) Components may only be replaced using spare parts of identical construction. The specifications from the component manufacturer must be observed during installation.

Caution!
Be sure to follow these safety instructions to avoid danger to life and health:

Potential hazard	Ways to avoid
Caution! **Explanation:** **Injury or damage due to improper installation or dismantling**	Special steps are required for installation and dismantling of the product. Injuries to persons and damage to the product are possible. a) Installation and dismantling work may only be carried out by the installer or appropriately qualified specialist companies and persons. b) The product may not be reused after the dismantling. All components must be disposed of properly!

14. Electromagnetic compatibility

Precautionary measures:

The information in this section provides the operator of the QualityMix Pro with the necessary information to decide whether this device is suitable for their environment from the point of view of electromagnetic compatibility.

Warning:

The QualityMix Pro is a medical electrical device. Thus, in order to ensure the proper device functionality, precautionary measures regarding electromagnetic compatibility must be observed. The device must be set up and put into operation in accordance with the following conditions.

The characteristics of the QualityMix Pro as determined by its emissions permit its use in clinical facilities (CISPR 11, Class A).

This device may not provide adequate protection for radio services when used outside the application range specified by the manufacturer. If necessary, the user must take corrective measures such as relocating or realigning the device.

Portable or mobile RF communications equipment (e.g. mobile phones) should be used no closer than 30 cm to the designated components and lines. Failure to keep this distance may result in a reduction in the performance characteristics of the device.

Notice:

Electromagnetic interference may affect the device, which may be indicated by alarms (refer to Chapter 8 for a detailed description) or restrictions to the normal functionality of the QualityMix Pro (refer to Chapter 9).

Electromedical devices require special precautions with regard to electromagnetic compatibility (EMC). This device may only be used for the purposes described in this document. It must be installed, configured and operated in accordance with the EMC Directive.

Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the QualityMix Pro (including the cables specified by the manufacturer). Failure to maintain this distance may result in a reduction in the performance of this device.

Warning

Do not use the device directly next to or on top of another device. If it is necessary to use the device next to or on top of other devices, you must first verify that normal operation is possible in that particular configuration.

Do not use any accessories other than those specified for the device, since this may lead to increased emissions or reduced immunity for the device.

CAUTION

If the essential performance characteristics of the product are impaired or lost due to electromagnetic interference,

there is no danger to the patient that could lead to an unacceptable risk according to the manufacturer's experience and risk assessment. This device is not directly connected to a main device for the application of breathing gases and shall only be used for the purpose intended by the manufacturer. The essential performance features and basic safety of the main device are not impaired by the use of this product.

Guidelines and manufacturer's declaration for electromagnetic emissions			
1	The QualityMix Pro is intended for use in the electromagnetic environment specified below. The customer or user of the QualityMix Pro or the responsible clinical institution must ensure that this device is only operated in such an environment.		
2	Emissions test	Conformity	Electromagnetic environment – Guidelines/
3	HF emissions CISPR 11	Group 1	The QualityMix Pro uses high-frequency energy only for its internal function. Its high-frequency (HF) emissions are therefore very low and it is unlikely that adjacent electronic equipment is disturbed.
4	HF emissions CISPR 11	Class A	The QualityMix Pro is intended for use in professional healthcare facilities (CISPR11, Group 1, Class A).
5	Harmonic frequency emissions IEC 61000-3-2	Class A	
6	Emissions of voltage fluctuations IEC 61000-3-3	Fulfilled	

Guidelines and manufacturer's declaration for electromagnetic immunity			
The QualityMix Pro is intended for use in the electromagnetic environment specified below. The customer or user of the QualityMix Pro or the responsible clinical institution must ensure that this device is only operated in such an environment.			
Interference immunity tests	IEC 60601 Test level	Compliance level	Electro-magnetic environment – Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge	± 8 kV ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.

Radiated HF – disturbance variables 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 electromagnetic site analysis must be below the over-tuning level[b] in each frequency range. In the vicinity of devices that are labelled with the following symbol, interference may occur:  Portable and mobile radio devices should not be used at a distance from the QualityMix Pro, including its cables, that is less than the recommended protective gap: d > 0.3 m
	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	
	28 V/m 2450 MHz	28 V/m	
	9 V/m 5240 – 5785 MHz	9 V/m	
Conducted RF disturbance variables IEC 61000-4-6	3 V 0.15 – 80 MHz	3 V 0.15 – 80 MHz	
	6 V ISM frequency bands 0.15 – 80 MHz	6 V ISM frequency bands 0.15 – 80 MHz	

Notice 1: The higher frequency range applies at 80 MHz and 800 Mhz.
Notice 2: These guidelines may not apply to all situations. The propagation of electromagnetic fields is influenced by absorption and reflection from buildings, objects and people.

[a] The field strength of stationary transmitters (such as mobile phone base stations and mobile land radios, amateur radio stations and AM/FM radio and television transmitters) cannot theoretically be predicted with complete accuracy.
In order to determine the electromagnetic environment with regard to such stationary transmitters, an on-site test is recommended. If the field strength measured at the location where this device is used exceeds the compliance levels listed above, the device should be monitored to verify that it is operating as intended. Additional measures, such as changing the orientation or location of the device, may be necessary if unusual performance characteristics are observed.

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

Immunity to magnetic fields with energy frequencies IEC 61000-4-8	30 A/m 50 Hz 60 Hz	30 A/m 50 Hz 60 Hz	Magnetic fields at this mains frequency should correspond to the typical values as found in business and hospital environments.

15. Part numbers / accessories:

15.1 Part numbers and accessories

Designation	Part number
Basic units	
QualityMix Pro	D-B-QMP
Accessories	
QualityMix Schienenhalterung / QualityMix rail clamp	D-B-SH
QualityMix Schienenhalterung Version mit Sicherungsstift / QualityMix rail clamp version with safety-pin	D-B-SH-SP
Mischer-Universalhalterung / Blender univ. mounting	D-B-UH
Transport bracket for gas mixer consisting of mounting claw and mounting plate	D-B-G-TH
Chassis with gas cylinder holder for 2 x 10 litre cylinders and the QualityMix Pro and accessories	D-B-FG-QMP
QualityMix Pro power supply unit	D-SKN.M04.GLLR
Spare parts	
O2-Messzelle / Oxygen Cell	D-B-O2-111LF
Sicherungsstift für Schienenhalterung mit Halteseil / Safety pin for rail clamp with retaining rope	D-B-SP
QualityMix Regeleinheit, Service / QualityMix control unit, Service	D-EM019286
QualityMix Verstelleinheit, Service / QualityMix adjust unit, Service	D-EM019285
QualityMix Alarmgeber, Service / QualityMix alarm unit, Service	D-EM019287
QualityMix Membrankit, Service / QualityMix membrane kit, Service	D-EM019294
QualityMix Adapter 9/16" / QualityMix adapter 9/16"	D-EM016583
QualityMix Wartungskit / QualityMix service kit	D-EM019284
QualityMix Werkzeug Regler / QualityMix tool controller	D-EM015518
QualityMix Werkzeug Bleed / QualityMix tool Bleed	D-EM018511
QualityMix Montagelehre / QualityMix assembling template	D-EM021610

16. History of software versions and hardware changes:

The QualityMix Pro's software consists of various packages:

Some of these determine the operating characteristics of the QualityMix Pro, the alarms and the range of functions.
The display macro version defines the available display languages. Each software version is dependent on a specific version of the display macros.

Software version	Hardware changes	Description
SW Version V 1.0	-//-	First version

17. Warranty conditions:

The supplier guarantees that the mixer 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 authorized to make spoken warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written second statement is a final, complete and exclusive statement of the contractual terms.
The current version of the retailer's Terms and Conditions and German law are valid.

18. Return shipments

Warning:

Repairs

Repairs to the QualityMix Pro may only be carried out by trained and expert service personnel in accordance with the instructions and warnings in the service manual. After each maintenance or repair, a complete function test must be carried out and passed before the QualityMix Pro can be used on patients again.

Modifications to the device

The QualityMix Pro must not be modified without the permission of the manufacturer and subsequent suitable tests and inspections to ensure continued safe use.

18.1 Repairs / Returns

Please contact your retailer concerning returns and repairs. They will help to coordinate the return. It is important that you provide a description of the error or malfunction so that the return can be processed effectively. All device returns must be sent in their original containers to avoid any damage. The retailer is not responsible for any devices that are damaged during transport.

If products must be returned to DEHAS for inspection or repair, they must first be purged with inert gas.

Please refer to Chapters 4 and 12 for decommissioning / dismantling information.

An inspection by DEHAS can only be carried out if the return has been agreed upon (declared) and when the return form and the decontamination declaration have been filled out.

Please contact DEHAS Customer Service in advance to request a return form.

DEHAS Medical Systems GmbH
Department: Customer Service
Phone +49 451 80904-0
E-mail: info@dehas.de

19. Reporting serious incidents

If a serious incident occurs with the product, this must be reported to the manufacturer or an authorized representative and to the competent national authority of the country in which the serious incident occurred.

20. Disposal

The dismantling and disposal must be carried out professionally in accordance with the relevant official and legal requirements. Consult your responsible waste disposal company for this.

Please dispose of the device and the associated power supply unit correctly in accordance with WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment).

21. Declaration of Conformity