Operating Instructions

Quality Mix

Air-Oxygen Mixer

Quality Mix High Flow (illustrated with flow meters)
Quality Mix Low Flow

Save these instructions!

CE 0482

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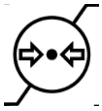
1. Explanation of the key abbreviations

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

2. Safety information – Warnings, precautions and identification information

Symbol	Description
CE 0482	This symbol indicates that the device complies with the regulation 93/42/EEC concerning medical devices and all applicable international standards.
 **WARNING**	Indicates a potentially hazardous situation which, if not avoided, *could* result in death or serious injury.
 **CAUTION**	CAUTION is used to indicate a potentially hazardous situation which, if not avoided, may result in property damage.
 or 	Refers the user to the necessity of consulting the operating instructions.
	Follow the instructions!
	DO NOT USE OIL

SN	Shows the serial number of the manufacturer so that a certain medical product can be identified.
REF	Shows the order number of the manufacturer so that the medical product can be identified.
MD	Medical device
UDI	UDI Barcode
	Non-sterile
	Date of manufacture
	Show the manufacturer of the medical product according to the EU guidelines 90/385/EEC, 93/42/EEC and 98/79/EC.
	Shows a medical product that should not be used if the packaging is damaged or opened
	Describes a medical product that must be protected against humidity.
	Describes a medical product which can break or be damaged if not handled with care.
	Describes the temperature limit values that the medical product can be safely exposed to.
	Describes the humidity range that the medical product can be safely exposed to.
	Describes the atmospheric pressure range that the medical product can be safely exposed to.
EC REP	EU Authorised Representative

3. Contents of delivery; Inspection upon receipt

Contents of the delivery:	1	Base mixer along with any additional components specified for your order
	1	Operating instructions
Inspection:	Take the device out of its packaging and inspect it for damage. Do NOT use the device if you find any damage. Contact your retailer.	

4. Intended usage

The air-oxygen mixer Quality Mix is used to administer a continuous, precise mix of medical air and medical oxygen – through its outlet ports – to infants, children and adults. The exact fractional inspiratory oxygen concentration (F_{IO_2}) corresponds to the selected F_{IO_2} setting on the control knob (dial).

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

Contraindications: This device should not be used for patients who cannot breathe on their own. Do not use for life support or life saving procedures.

5. Before initial usage

Read all instructions before use!

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

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

WARNING

- The air-oxygen mixer should only be operated by trained medical professionals under the direct supervision of a licensed physician.
- Use this air-oxygen mixer only for the purpose described in these instructions.
- Check the prescribed dose before administering to patients. Monitor the flow frequently.
- The air-oxygen mixer may only be serviced by a qualified service technician.
- Always follow the EN and DIN standards pertaining to medical gas products, flow meters and oxygen handling.
- The oxygen concentrations can optionally be confirmed using an oxygen analyser/monitor.
- The accuracy of the oxygen concentration can be affected if the bleed **flow** is not activated at flow settings below 15 l/min for High Flow mixers, and at 3 l/min for Low Flow mixers.
- Do NOT interfere with or disable the alarm.
- Do not use the mixer when the alarm sounds.
- Do NOT use oil in or near the mixer.
- Do NOT obstruct or block the bleed port at the auxiliary outlet of the mixer.
- Do NOT use the mixer near flames, flammable/explosive substances, vapours or gases.
- NEVER smoke in an area where oxygen is being used.
- The rotary dial for the oxygen concentration cannot be rotated 360 degrees. Turning the dial to less than 21% or more than 100% oxygen will damage the mixer.

CAUTION

- Close the gas supply line whenever the air-oxygen mixer is not being used.
- Store the air-oxygen mixer in a clean, dry place when it is not in use.
- The air-oxygen mixer contains NO magnetic, ferrous materials; it can be used with MRIs (max. 3 Tesla). A distance of 2 metres must be adhered to. The O2 monitor cannot be used with MRIs as an accessory part.

CAUTION
• Make sure that all connections are secure and tight. • Avoid excessive pressure surges of more than 6.5 bar whenever the mixer's inlets are pressurized. • Do NOT sterilise. • Do NOT immerse in liquids. • Do NOT sterilise with Ethylene Oxide (EtO). • Do NOT use if dirt or contaminants are found on or near the mixer or its connectors. • Do NOT clean with aromatic hydrocarbons. • The supply's inlet pressure must correspond to the value specified on the mixer. • When using bottled gas or a high-pressure gas source, always use a pressure reducer to maintain the pressure range between 3.2 and 6.5 bar.

6. Technical specifications

	High Flow with high flow capacity	**Low Flow** with low flow capacity
Main outlet of flow	15 – 120 l/min	3 – 30 l/min
Auxiliary outlet of flow with bleed	0 – 105 l/min	0 – 27 l/min
Auxiliary outlet of flow without bleed	15 – 120 l/min	3 – 30 l/min
Bleed flow	≤ 13 l/min at 3.4 bar	≤ 3 l/min at 3.4 bar
Maximum combined flow (of all outlets)	≥ 120 l/min	≥ 30 l/min
Emergency flow (malfunction of air or oxygen supply)	> 85 l/min	> 15 l/min

	Applies to both High Flow and Low Flow
Alarm sounds when supply pressure drops	Alarm on at a pressure difference between both gasses of 0.9 – 1.8 bar. Alarm off at a pressure difference between both gasses of > 0.3 bar. E.g.: Inlet pressure 4.2 bar. Alarm on at 3.3 – 2.4 bar. Alarm off at max. 3.9 bar.
Alarm volume	≥ 80 dB at a distance of 30 cm
Setting range of the oxygen concentration	21 – 100%
Gas inlet pressure	3.2 – 6.5 bar: air and oxygen pressure differential should be within max. 0.7 bar
Accuracy of the mixed gases (FIO_2)*	± 3% oxygen
Connection types	DISS outlets for mixed gases and NIST inlets for air and oxygen
Dimensions (LxWxH)	13 x 16.5 x 12.2 cm
Weight	1600 g
Operating temperature	+5°C to +50°C

** The accuracy of the oxygen concentration can be affected if the bleed is not activated in accordance with the specifications.*

This air-oxygen mixer has been degreased before it was delivered to prepare it for use with oxygen. The reverse gas flow of the air-oxygen mixer corresponds to clause 9 of the ISO 11195 standard. The oxygen-analysis device being used must comply with the ISO 80601-2-55 standard and the CE regulations.

7. Pressure drop in the system

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% F_{IO_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% F_{IO_2}

8. Transportation and storage conditions

Temperature range	-20°C to 50°C
Humidity	Max. 95% non-condensing air humidity

9. Dryness and composition of the supply gases

Air:

The medical air supply must meet the requirements of the national standards.

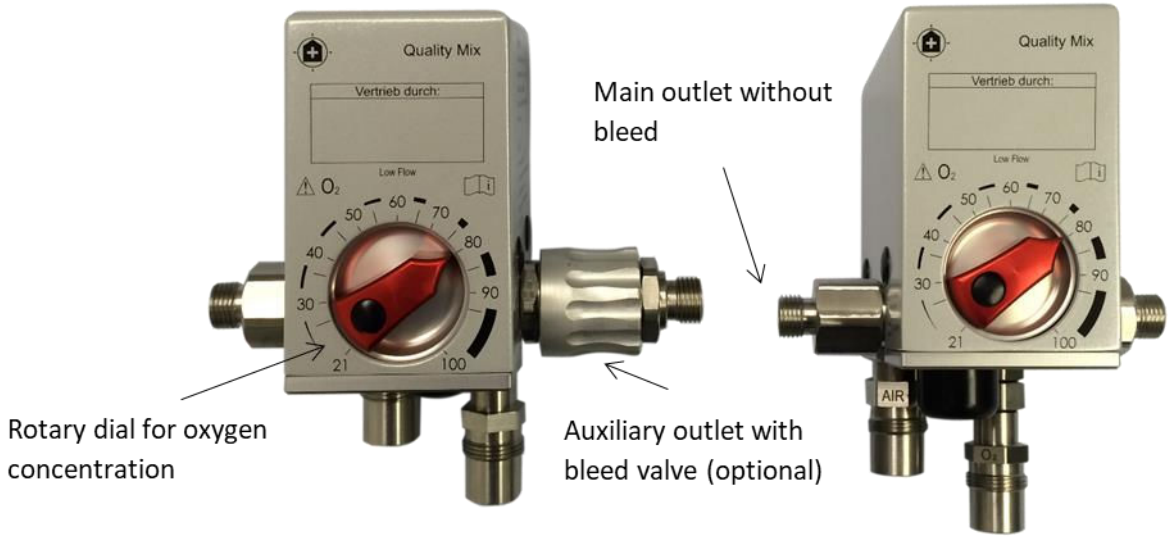
Oxygen:

The oxygen being used must meet all requirements for medical oxygen according to the European Pharmacopoeia.

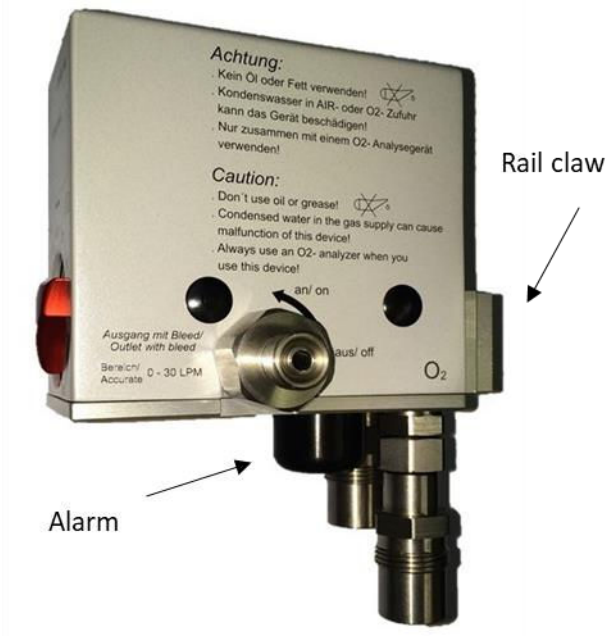
10. Illustrations and identification of components

CAUTION
The labelling on the device will not come off if you follow the preparation instructions properly. Contact the manufacturer or your local representative if the labelling becomes unreadable.

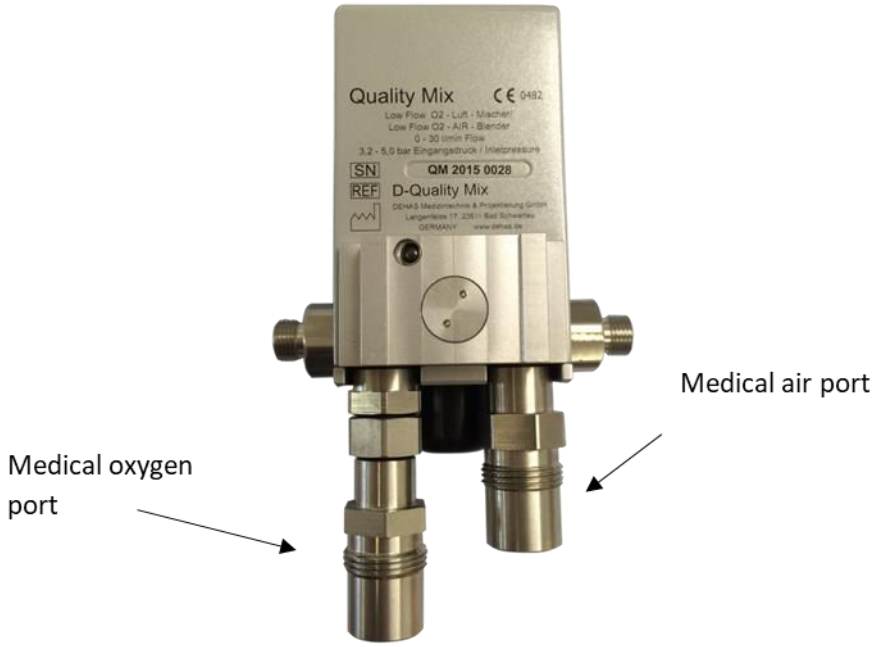
These images show the Quality Mix Low Flow



Left side, without bleed valve



Right side



Rear view

Components	Description
Rotary dial for oxygen concentration	A rotary dial for setting oxygen concentration levels between 21% – 100%. The F_{IO_2} scale is used for reference purposes only. This dial cannot be turned 360°. It starts at 21% and can turn to 100%.
Main outlet without bleed	A DISS fitting with external (male) thread and a check valve. This provides the gas flow when connected to a control mechanism such as a flow meter.
Auxiliary outlet with bleed valve (optional)	A DISS oxygen fitting with external (male) thread and a check valve. This provides the gas flow when connected to a control mechanism such as a flow meter. The outlet can be fitted with a bleed valve that allows the user to activate (ON) or deactivate (OFF) the bleed function. If the bleed is activated (ON), this outlet ensures an accurate oxygen concentration at the following flow rates: Model Flow range High Flow 0 – 105 l/min Low Flow 0 – 27 l/min
Adjustment collar on the bleed valve	This collar is used to activate or deactivate the bleed (venting) function. This bleeding ventilation is necessary to maintain an accurate F_{IO_2} concentration at flows below 15 l/min (for the HF mixer) or below 3 l/min (for the LF mixer). To activate the bleed function, turn the knurled collar ring until the ON position is reached.
Medical oxygen port	A NIST oxygen connection with internal thread and one-way valve: for connecting an oxygen supply hose.
Medical air port	A NIST air connection with external thread and one-way valve: for connecting an air supply hose.
Alarm	An audible alarm that sounds when an excessive pressure drop or stoppage is detected on the air or oxygen supply lines.

11. Installation

WARNING
• Read the operating instructions carefully before you install or use this device.
CAUTION
Check the Quality Mix for visible damage before use. Do **not** use it if it is damaged.

Note: Carry out the following tests before you use the device for the first time:

- **Alarm test (see the following section 12)**

Preparation for the alarm test

1. Mount the air-oxygen mixer on a rail or support rod in an upright position.
2. Connect the air and oxygen supply lines to the appropriate inlet ports on the bottom of the mixer.
3. Connect a flow meter or other metering device to one of the outlet ports.

   Flow capacity of the main outlets:

   - HF mixer: 15 – 120 l/min
   - LF mixer: 3 – 30 l/min

   Bleed outlet:

   Some of the air-oxygen mixture is vented at this outlet to maintain an accurate concentration at a low flow setting.

   - HF mixer: 15 l/min or less
   - LF mixer: 3 l/min or less
4. Connect a supply line to the outlet port of the flow meter.

12. Alarm test

1. Connect the air-oxygen mixer to the air and oxygen sources. Put the mixer under pressure and open the flow meter in the direction of the tapered arrow.
2. Set the oxygen concentration dial to 60% (FIO_2).

3. Disconnect or turn off the air supply to the air-oxygen mixer. A loud whistling noise should be emitted from the mixer as an alarm. This whistling noise indicates that the alarm is working properly.

4. Re-connect the air supply to the mixer and activate; the whistling should stop.

5. Disconnect or turn off the oxygen supply to the mixer. This whistling noise indicates that the alarm is working properly.

6. Re-connect the oxygen supply to the mixer and open the line; the whistling should stop.

7. DO NOT USE the device when the alarm is not functioning properly.

13. Initial use

CAUTION
Check the Quality Mix air-oxygen mixer for visible damage before use. **Do not** use it if it is damaged.

1. Mount the mixer to the rail or to a stand holder.

2. Connect the air and oxygen supply lines to the mixer and the supply.

3. Connect the flow meter(s) to each outlet on the mixer.

   The flow meter must be connected to the bleed side for flow rates up to 15 l/min for High Flow and 3 l/min for Low Flow!

   On mixers with the optional built-in bleed shut-off (optional), this must be turned on. Turn the knurled collar ring until it engages in the ON position.

   For flow rates above 15 l/min for High Flow and 3 l/min for Low Flow mixers, this can be deactivated if the devices are fitted with bleed shut-off. Turn the knurled collar ring until it engages in the OFF position.

4. Set the oxygen concentration dial to the prescribed value.

5. Check the flow of air/oxygen mixture to the patient.

6. Use an oxygen analyser/monitor to check the air-oxygen concentration.

7. If the air-oxygen mixer is not used any more, close the gas supply and disconnect the device from the gas supply.

14. Cleaning / disinfection

CAUTION
• **NOT** suitable for sterilisation. • **NEVER** immerse the air-oxygen mixer in liquids. • Do **NOT** use strong solvents or abrasives. • Do **NOT** clean with aromatic hydrocarbons.

The exterior of the device should be disinfected at regular intervals. At a minimum, it should be disinfected after each patient according to the applicable hygiene standards.

1. Disconnect all gas connections and equipment before cleaning.

2. Wipe down the outer surfaces using a cloth moistened with a non-oxidizing disinfectant and water.

3. Wipe dry with a dry cloth.

The manufacturer recommends the use of the disinfectant Dismozon plus®, from Bode Chemie GmbH & Co.

15. Maintenance

The following maintenance and inspection tasks must be carried out:

- The user must test the alarm once per month.
- The safety technical inspection must be carried out each year by a trained operator or a medical technician.
- Have the device serviced at least once every 2 years by a trained professional. The test of the reverse gas flow is part of the service and must therefore be carried out every 2 years.

Test of the reverse gas flow

1. Set the oxygen concentration of the air-oxygen mixer to 60%.

2. Connect the air connecting tube to the mixer and to the gas supply. Then turn on the gas supply.

   Measure the flow at the oxygen inlet using a suitable measuring instrument.

   The flow must not exceed 10 ml/h.

   If the flow is greater than 10 ml/h, the duckbill valve in the oxygen inlet must be replaced in accordance with service instructions and the measurement must be repeated.

3. Connect the connecting tube for oxygen with the mixer and the gas supply and open the supply.

   Measure the flow at the air inlet with a suitable measuring instrument.

   The flow must not exceed 10 ml/h.

   If the flow is greater than 10 ml/h, the duckbill valve in the air inlet must be replaced in accordance with service instructions and the measurement must be repeated.

16. Product returns

Please contact your retailer concerning this. 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 returns must be shipped in sealed containers to prevent damage. The specialist retailer is not responsible for any devices that are damaged during transport.

17. Disposal

This device and its packaging contain no hazardous materials. No special precautions are required when disposing of the device and its packaging.

Please recycle.

18. Troubleshooting

Consult the following section in the event that the 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**
Discrepancy between the oxygen concentration setting at the mixer and the concentration at the analyser/monitor (of more than 3%)	1. Flow requirements for high-flow model: less than 15 l/min. Flow requirements for low-flow model: less than 3 l/min.	1. Use the bleed outlet and activate the vent (bleed) function
	2. The analyser/monitor is not registering or measuring precisely	2. Re-calibrate the monitor or check using another analyser/monitor.
	3. The bleed outlet is blocked at low flow.	3. Remove the blockage.
	4. The gas supply line is contaminated.	4. Check the gas supply using a calibrated oxygen analyser/monitor to ensure that the oxygen content is 100% and the air content is 21%.
	5. Downstream device causing back flow or restricted flow	5. Disconnect the mixer. Check the oxygen concentration at the outlets of the mixer.
No flow at the mixer's outlets	1. The gas supply is switched off.	1. Switch on the gas supply.
	2. The gas supply is not connected.	2. Connect the gas supply.

Problem	Possible cause	Remedy
The alarm sounds	1. The difference between the oxygen pressure and air supply pressure is greater than specified.	1. Adjust this pressure differential until the air/oxygen pressures meet the specifications

19. 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 retailer is not authorised to make oral warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written 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.

20. Part numbers

Designation	Part number
QualityMix High Flow Blender DISS Connection	D-B-G-HF-DISS
QualityMix High Flow Blender NIST Connection	D-B-G-HF-NIST
QualityMix Low Flow Blender DISS Connection	D-B-G-LF-DISS
QualityMix Low Flow Blender NIST Connection	D-B-G-LF-NIST
QualityMix flow meter 0-3L	D-B-FL-3
QualityMix flow meter 0-6L	D-B-FL-6
QualityMix flow meter 0-15L	D-B-FL-15
QualityMix flow meter 0-16L	D-B-FL-16
QualityMix flow meter 3,2-32L	D-B-FL-32
QualityMix flow meter 8,5-85L	D-B-FL-85
QuylityMix O2 Module – Oxygen monitor for direct mouting on the blender	D-B-O2-M
QualityMix pressure reducer module DISS	D-B-PR-DISS
QualityMix pressure reducer module NIST	D-B-PR-NIST
QualityMix rail clamp	D-B-SH
QualityMix rail clamp	D-B-SH-MKIII
QualityMix rail clamp version with safety-pin	D-B-SH-SP
Transport bracket for gas blender - consisting of fastening claw and mounting plate	D-B-G-TH
QualityMix membrane kit, Service	D-EM019294

Designation	Part number
QualityMix service kit	D-EM019284

DECLARATION OF CONFORMITY

DEHAS Medical Systems GmbH
Wesloer Strasse 112
23568 Lübeck,
GERMANY

CE

Quality Mix HF; Quality Mix LF and accessories **0482**

Classification: IIb

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

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

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

Applied standards:

EN 1041	ISO 11195
EN ISO 14971	ISO 18562-1
EN ISO 15001	ISO 18562-2
EN ISO 15002	ISO 18562-3
EN ISO 15223-1	ISO 10993-1
EN ISO 62366-1	

Notified authority: Medcert GmbH / CE 0482

Address: Pilatuspool 2, 20355 Hamburg, GERMANY

Certificate number: 4153DE410200327 Expiration date: 05/2024

Devices already manufactured: Traceable by serial number

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

Manufacturer representative: Quality manager

Position: Quality systems

Date of issue: 03-04-2020

Your contact for sales and service:

EC REP

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