Diadice Médical
Laboratoire biomédical

User Manual

QualityMix N_2O

Oxygen-Nitrous Oxide Mixer

QualityMix N_2O 70
QualityMix N_2O 50
QualityMix N_2O 50 FIX

Keep these instructions!

CE 0482

Contents

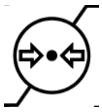
Status: 11/2019

1. Explanation of the most important abbreviations

FIO_2	Fractional concentration of inspiratory oxygen
DISS	Diameter Index Safety System
NIST	Non-interchangeable Screw Thread System
Bar	Unit of measurement for pressure
l/min	Litres per minute

2. Safety information - warnings, safety precautions and labelling information

Symbol	Description
CE 0482	This symbol indicates that the device complies with the requirements of Regulation 93/42/EEC regarding medical devices and all applicable international standards.
 **WARNING**	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 **ATTENTION**	Use of this symbol indicates a potentially hazardous situation which, if not avoided, could result in equipment damage.
 or 	Indicates the need for the user to consult the user manual.
	DO NOT USE OIL
SN	Indicates the serial number of the manufacturer so that a specific medical device can be identified.

	Indicates the manufacturer's order number so that the medical device can be identified.
	Medical device
	Non-sterile
	Date of manufacture
	Indicates the manufacturer of the medical device according to EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Indicates a medical device that should not be used if the packaging is damaged or opened.
	Designates a medical device that must be protected against moisture.
	Designates a medical device that may break or be damaged if handled carelessly.
	Describes the temperature limits to which the medical device can be safely exposed.
	Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

3. Package contents and inspection upon receipt

Package contents: 1 Basic unit consisting of:
1 1 mixer with adjustment unit
1 Nitrous oxide module with flush function
2 Connection hoses (O_2 & N_2O)
2 Pressure reducer 3.8 Bar (O_2 & N_2O)
1 User manual

According to order option

1 Demand System N_2O with connection hose

Or

1 Flow meter with connection block and reservoir bag

Inspection: Remove the device from its packaging and inspect it for damage. If you notice any damage, DO NOT use the device and contact your distributor.

4. Intended application

The QualityMix N_2O oxygen/nitrous oxide mixer is designed for the administration of a continuous and accurate mixture of medical nitrous oxide and medical oxygen to infants, children and adults via the exit port. The exact fractionated inspiratory oxygen nitrous oxide concentration (FIO2/FIN2O) corresponds to the selected FIO2/FIN2O setting on the control knob (rotary selector).

Indication:
This device is to be used by patients under the supervision of trained specialist personnel for pain therapy.

Contraindication:
Do not use with patients who cannot breathe independently. Do not use for life support or life saving.

5. Before first use

Read all instructions before use!

These instructions for use provide qualified personnel with instructions for installing and operating the QualityMix N_2O. The instructions are intended for your safety and to protect the device from damage. If you do not understand any information or instructions in this instruction manual, do not use the device and contact your supplier.

DANGER

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

WARNING

- The QualityMix N_2O oxygen/nitrous oxide mixer should only be operated by medical personnel under the direct supervision of a licensed physician

- The QualityMix N_2O oxygen/nitrous oxide mixer should be used only for the purposes described in these operating instructions.
- Review the prescribed dose before administration to the patient and monitor the administration frequently
- The QualityMix N_2O oxygen/nitrous oxide mixer may **only** be serviced by a qualified technician
- Always comply with EN and DIN standards for the handling of medical gas products, flow meters and oxygen
- The oxygen/nitrous oxide concentration must be confirmed with an oxygen analysis/monitoring device
- **DO NOT** interfere with the alarm
- **DO NOT** use the mixer when the alarm sounds
- **DO NOT** use oil in or near the mixer
- **DO NOT** use the mixer near flames, combustible/explosive materials, vapours or gases
- **NEVER** smoke in an area where oxygen is administered
- When administering O_2/N_2O, personnel may be exposed to N_2O. The applicable national laws specifying exposure limits and safety regulations for handling medical gases in the workplace must be complied with. Possible exposure can be prevented by continuous, effective control of the system, ventilation and working practices
- The oxygen concentration rotary switch cannot be rotated 360 degrees. Turning the switch to less than 30% or more than 100% oxygen will damage the mixer

WARNING

- Close the gas supply when the QualityMix N_2O oxygen/ nitrous oxide mixer is not being used
- Always ensure an adequate supply of the gases used. After each use, check the level of the gas source before reuse
- Store the QualityMix N_2O oxygen/nitrous oxide mixer in a clean, dry place when not in use

  The QualityMix N2O oxygen/nitrous oxide mixer does NOT contain magnetic materials containing iron and is MRI compatible (max 3 Tesla). A clearance of 2 meters must be maintained

  The O_2 monitor is not suitable as an accessory for MRT

ATTENTION

- Always ensure that all connections are **secure** and **tight**
- **NOT** suitable for sterilization
- **DO NOT** immerse in liquids
- **DO NOT** sterilize with ethylene trioxide (EtO)
- **DO NOT** use if dirt or impurities are present on or near the mixer or connectors

- **DO NOT** clean with aromatic hydrocarbons
- The inlet pressure of the supply source must correspond with the specifications of the mixer.
- **When using any gas source, always use a pressure reducer within a pressure range of 3.2 to 3.8 bar**

6. Technical Data

Model:	**QualityMix N_2O Variants:** **QualityMix N_2O 50 FIX** **QualityMix N_2O 50** **QualityMix N_2O 70 (Mechanical stop at 50% N2O)**
Main output flow	1-120 l/min
Emergency flow (failure of nitrous oxide or oxygen supply)	>50 l/min
FLUSH Button	100% O_2 ca. 50 Litre/Minute
Alarm activation when supply pressure drops	Alarm on - at a pressure difference between the two gases of approx. 0.9 bar. Alarm off - if the pressure difference between the two gases is > 0.3 bar. Example: Input pressure 3.8 bar. Alarm on at 2.7-2.4 bar. Alarm off at a maximum of 3.5 bar
Alarm volume	≥80 dB at a distance of 1 m.
Adjustment range of N_2O concentration	0 - 70 % N_2O With a mechanical barrier at 50% nitrous oxide concentration. Results in an N_2O value equivalent to an O_2 concentration of between 100% and 30%
Gas inlet pressure with required pressure reducer	3.2 - 3.8 bar nitrous oxide and oxygen within max. 0.7 bar pressure differential

Accuracy of the mixed gas (FIO2)*	± 3 % oxygen
Connection types	1 x DISS output for mixed gas and 1 x NIST input for nitrous oxide N_2O and oxygen O_2 respectively
Dimensions LxBxH	13 x 16.5 x 18.2 cm
Weight	2100 g
Operating temperature	+5°C to +50°C

The QualityMix N_2O oxygen/nitrous oxide mixer has been degreased for oxygen utilization prior to delivery. The reversed gas flow of the oxygen nitrous oxide mixer complies with Clause 9 of ISO 11195:2018. The oxygen analyser used must comply with ISO 80601-2-55 and CE regulations.

7. Pressure drop in the system

Low flow	≤0.14 bar with inlet pressures of 3.2-3.8 bar and a flow rate of 10 l/min at >50% F_{IN_2O}
High flow	≤0.21 bar at inlet pressures of 3.2-3.8 bar and a flow rate of 30 l/min at 50% F_{IN_2O}

8. Transport and storage requirements

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

9. Dryness and composition of gas supplies

Nitrous oxide (N_2O):

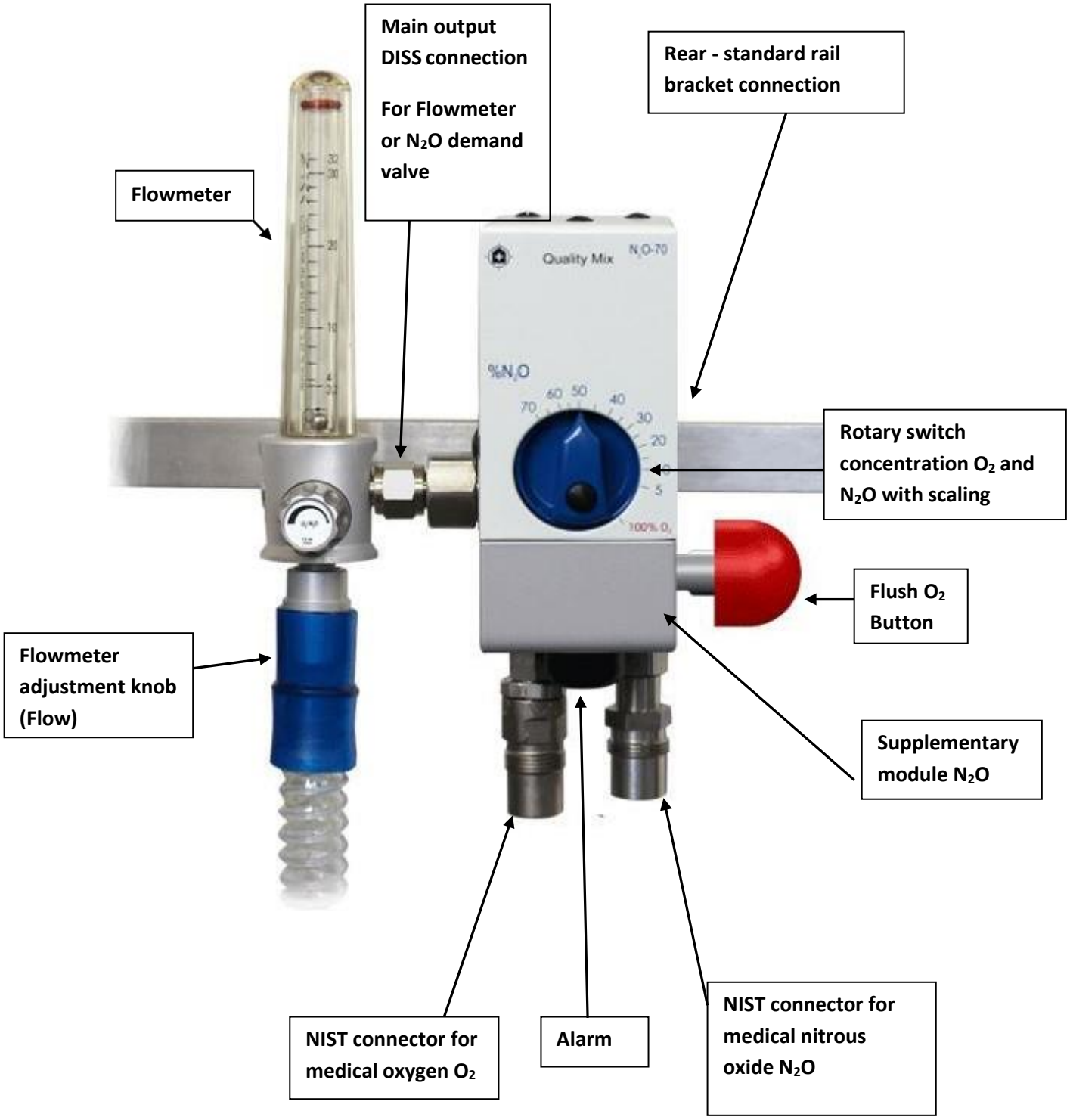
The medical nitrous oxide must meet all of the requirements for medical nitrous oxide (N_2O) according to the European Pharmacopoeia.

Oxygen (O_2):

The oxygen used must meet all of the requirements for medical oxygen (O_2) according to the European Pharmacopoeia..

10. Illustrations and naming of components

ATTENTION
If you follow the instructions regarding processing, the labelling on the devices will remain intact. If the labelling should nevertheless become illegible or missing, please contact the manufacturer or your local contact person.



This illustration depicts the QualityMix N_2O

Component	Description
Rotary switch for oxygen and nitrous oxide concentrations	A rotary switch for setting the oxygen concentration to between 21 % - 100 %. The FIO_2 scale is for reference purposes only. This rotary switch cannot be rotated 360°. The rotary switch starts at 21% and extends to 100%.
Main outlet	A male threaded DISS connector with shut-off valve that provides gas flow when connected to a control device such as a flow meter with reservoir bag or an N_2O demand system.
Connection for medical oxygen	A NIST oxygen connection with female thread and one-way valve for connecting an oxygen supply hose.
Connection for medical nitrous oxide	A male threaded NIST connector and a one-way valve to connect a nitrous oxide supply hose.
Alarm	An audible alarm that sounds in the event of excessive pressure drop or failure of oxygen and/or nitrous oxide supply.
Flush O_2 button	For administration of 100% O_2, independent of the concentration setting on the rotary switch of the QualityMix N_2O mixer.

11. Installation

Warning
• **Read** the user manual before installing or using the unit. • **Monitor** the oxygen and nitrous oxide concentration with an oxygen analyzer/monitoring device.
Attention
Check the QualityMix N_2O mixer for visible damage before use and do **not** use if it is damaged.

Note: Perform the following test before operating the device for the first time

Alarm test (see section 12)

Preparation for the alarm test

1. Attach the QualityMix N_2O oxygen/nitrous oxide mixer to a rail or support rod in an upright position.

2. Connect the nitrous oxide and oxygen supply lines to the appropriate inlet ports at the bottom of the mixer.

3. Connect a flow meter or N_2O demand valve to one of the output ports.

Flow capacity of the output:

- N_2O mixer, all variants: 0 – 120 l/min

4. Connect an exhaust line to the outlet port of the flow meter or to the intended connection of the N_2O demand valve.

12. Alarm test

1. Connect the QualityMix N_2O mixer to the nitrous oxide and oxygen sources, pressurize the mixer and turn the flow meter anti-clockwise.

2. Set the rotary switch for nitrous oxide concentration to 50% (FIN_2O).

3. Disconnect or switch off the nitrous oxide supply to the QualityMix N_2O oxygen/nitrous oxide mixer. The mixer should make a loud beeping

sound as an alarm. This sound indicates that the alarm is working properly.

4. Reconnect and activate the nitrous oxide supply to the mixer; the beeping should stop.

5. Disconnect or switch off the oxygen supply to the mixer. The beeping sound indicates that the alarm is functioning properly.

6. Reconnect and activate the oxygen supply to the mixer; the beeping sound should stop.

7. If the alarm does not function correctly, **DO NOT USE** the unit.

13. Initial operation

Attention
Before use, check the QualityMix N_2O oxygen/nitrous oxide mixer for visible damage and do not use if it is damaged.

1. Attach the mixer to the rail or stand bracket.
2. Connect the nitrous oxide and oxygen supply lines to the mixer and supply.
3. Connect the flow meter or the N_2O demand system to the output of the mixer.
4. Set the nitrous oxide concentration rotary switch to the prescribed value.
5. Check the flow of the oxygen/nitrous oxide mixture to the patient.
6. Check the oxygen/nitrous oxide concentration with an oxygen analysis/monitoring device.
7. When the oxygen/nitrous oxide mixer is not in use, shut off the gas supply or disconnect the appliance from the gas supply.

14. Cleaning and disinfection

Attention
• **NOT** suitable for sterilization. • **NEVER** immerse the QualityMix N2O oxygen nitrous oxide mixer in any liquid • **DO NOT** use strong solvents or abrasives • **DO NOT** clean with aromatic hydrocarbons

The outside of the device must be disinfected at regular intervals or at least after each patient in accordance with the applicable hygiene standard.

1. Disconnect all gas connections and equipment before cleaning.
2. Wipe the outside with a cloth moistened with non-oxidizing disinfectant and water.
3. Wipe dry with a dry cloth.

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

15. Maintenance

The following maintenance and inspection tasks must be carried out:

- **Monthly** check of the alarm by the user
- A **safety inspection** (SI) must be carried out **every** year by a **trained operator** or medical technician.
- Maintenance should be carried out **at least every 2 years** by trained specialist personnel. Inspection of the reversed gas flow is part of the maintenance and is therefore carried out every 2 years.

Reverse gas flow test

1. Set the nitrous oxide concentration of the mixer to 50%.

2. Connect the nitrous oxide supply hose to the mixer and the gas supply and open the supply.

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

   The flow rate should not exceed 10 ml/h.

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

3. Connect the oxygen supply hose to the mixer and the gas supply, and open the supply.

   Measure the flow rate at the nitrous oxide inlet using a suitable measuring instrument.

   The flow rate should not exceed 10 ml/h.

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

16. Return of Goods

Please contact your distributor regarding this matter. They will coordinate the return for you. It is important that you provide a description of the problem so that the return can be processed in a targeted manner. All returns must be sent in sealed containers to avoid damage. The distributor is not responsible for equipment that is damaged during transport.

17. Disposal

This device and its packaging do not contain any hazardous substances. No special precautions are required when disposing of the device and/or its packaging.

Please recycle

18. Troubleshooting

If the oxygen/nitrous oxide mixer fails, refer to the troubleshooting section below. If this does not solve the problem, please contact your local distributor.

Problem	**Possible cause**	**Remedy**
Discrepancy between the setting of the oxygen concentration on the mixer and on the analysis/monitoring device (more than 3 %)	1. Pre-pressure too unequal/too low	Pre-pressure inspection: optimum pre-pressure 3.9 to 6.5 Bar
	2. Analysis/monitoring device does not accurately register	Recalibrate the monitoring device or use a different analysis/calibration monitoring device
	3. Gas supply contaminated	Check gas supply with calibrated oxygen analyser/monitoring device to ensure oxygen content is 100% and nitrous oxide content is 0%
	4. The Flow of downward mounted device causes backflow or restricted flow	Disconnect the mixer. Check the oxygen concentration at the mixer outlet
No flow at the mixer output	1. Gas supply turned off	Turn on gas supply
	2. Gas supply not connected	Connect gas supply
Problem	**Possible cause**	**Remedy**
Alarm sounds	Difference between oxygen and nitrous oxide inlet pressures higher than prescribed	Correct pressure difference until oxygen and nitrous oxide pressures meet specifications

19. Warranty conditions

The distributor guarantees that the mixer is free from defects in workmanship and/or materials for the following period of time:

One (1) year after delivery

The distributor will, with written notice and with evidence that the device has been stored, installed, serviced and operated in accordance with instructions and standard industry practices and that no modifications, substitutions or modifications have been made to the product, will correct such defect by appropriate repair or replacement at the distributor's expense.

VERBAL STATEMENTS DO NOT CONSTITUTE A GUARANTEE.

The distributor is not authorized to provide oral guarantees about the product described in this agreement, and such statements are not binding and are not part of the purchase agreement. Therefore, this second statement is the final, complete and exclusive representation of the terms of this agreement.

The current version of the General Terms and Conditions of the distributor and German law shall apply.

Declaration of Compliance

DEHAS Medizintechnik GmbH
Wesloer Straße 112, Gebäude M
23568 Lübeck
GERMANY

CE 0482

REF

QualityMix N_2O 50 FIX

QualityMix N_2O 50

QualityMix N_2O 70

And the relevant accessories

Classification: IIb

Classification Criteria: Clause 3.2 Rule 11 of Annex IX of the MDD

We hereby declare under our sole responsibility that the products mentioned above comply with the provisions of the following directives and standards of the EC Council. All documents are retained on the premises of the manufacturer and the notified body.

Guidelines: General application guidelines: 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:

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

Notified Body: Medcert GmbH / 0482

Address: Pilatuspool 2, 20355 Hamburg; GERMANY

Certificate number: 4153FR410180612 Expiry date: 11/2021

Already manufactured devices: Traceability via serial number

Valid from/to: 06/ 2018 to expiry date

Manufacturer representative: Jens Mittendorf

Position: CEO /Head of Development

Date of issue: 27 November 2019

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