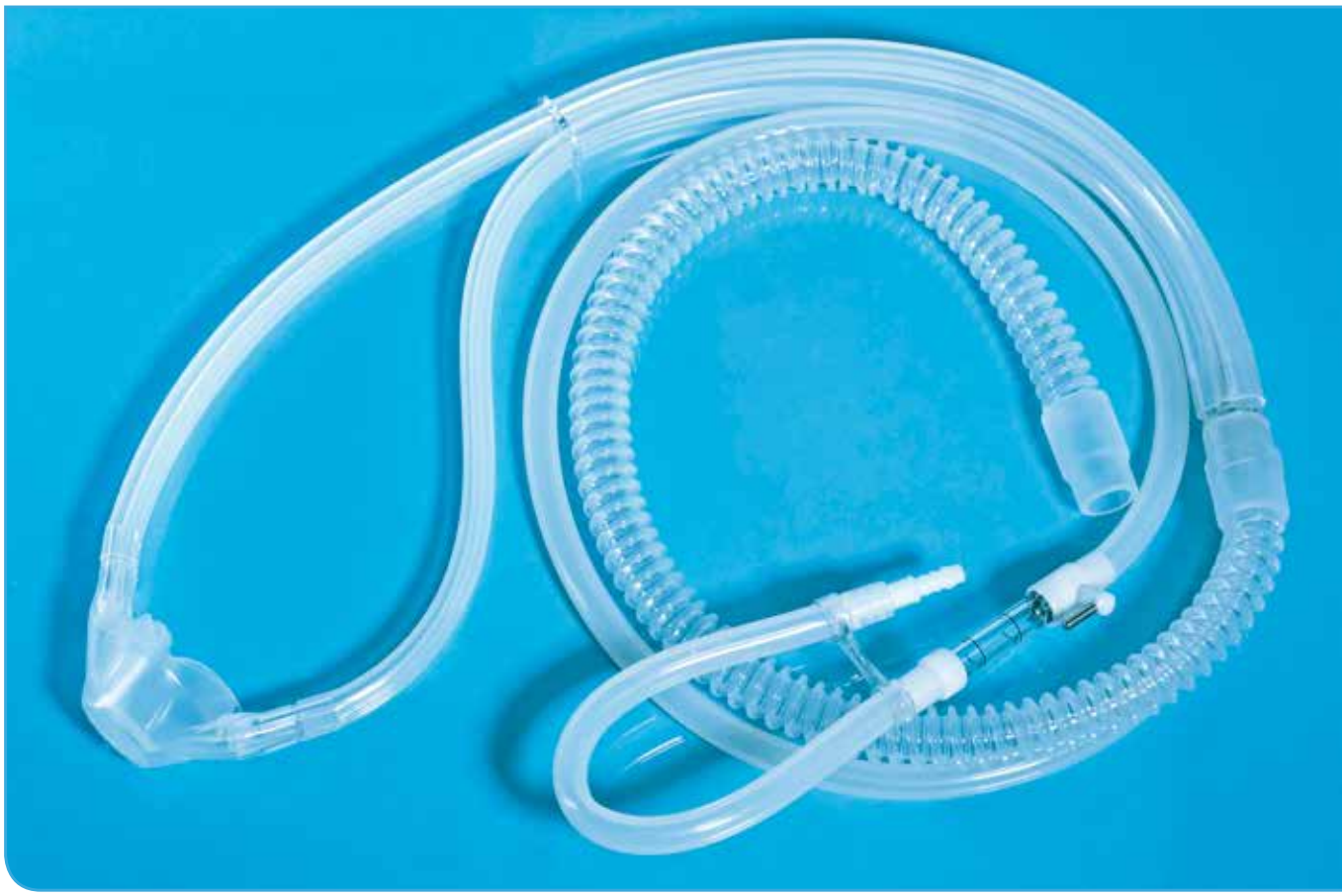
Medizintechnik Baldus

BALDUS®
Scavenger System

» Instructions for use



MADE
IN
GERMANY

WELCOME

to Baldus Medizintechnik GmbH

Your specialist for nitrous oxide sedation and medical gases

Baldus Medizintechnik GmbH
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CONTENTS

Trust the specialists in

MEDICAL GASES AND INHALATION SEDATION

Our service has been evaluated by doctors who use nitrous oxide as being a grade 1 (1.4), the highest possible grade

INHALT NICHT STERIL / CONTENTS NOT STERILE

CE 0483

Certified Quality System mdc ISO 13485

As at: 01/06/2016

1. IMPORTANT INFORMATION AND INTENDED PURPOSE

Please read the instructions for use carefully and in full before first operating the device in order to protect you and your patients from any incorrect operation. This handbook contains instructions about the control tests which must be carried out by the user at regular intervals. Keep this handbook so you can consult them at a later date.

Purpose

The Baldus® double mask system was developed to reduce the ambient air contamination with nitrous oxide and to protect staff. The oxygen-nitrous oxide mixture is guided into the patient's inner mask via the gas supply hose (spiral hose) and the patient inhales the gas mixture. When exhaling, a membrane opens and the gas is guided via the outer mask and the vacuum hose. The fact that the patient's breathing has been disconnected from the suction system makes it easier for him or her to breathe. The perfect fit and the soft material mean the mask fits any face shape. The outer mask works like a bell jar, in other words it provides efficient protection against the micro-leaks which occur as a result, for example, of a moustache. The vacuum control block is a safety feature and is used to monitor and adjust the suction capacity. If the suction is set too high the nitrous oxide will have a time delayed effect and in the worst case scenario there will be no effect whatsoever. The suction can also be set too low, resulting in the staff inhaling the nitrous oxide.

Important notes

The mask system is only intended to be used in the field of medicine and may only be used by a trained doctor to sedate patients with nitrous oxide and oxygen as necessary. The doctor who is operating the device is responsible for ensuring sufficient ventilation of the room and for complying with the limits for nitrous oxide concentration in the room. Please comply with the technical rules for hazardous substances TRGS 900 (workplace limits) and TRGS 525 (handling hazardous substances in facilities for human medical care). Please take into account the table in Chapter 5 on reducing ambient air contamination with nitrous oxide.

Suction is **compulsory** and should be at a rate of at least 45l/min.
▶ available to order as an accessory, see Chapter 3.
They must be monitored using a **vacuum control block.**

Regular controls

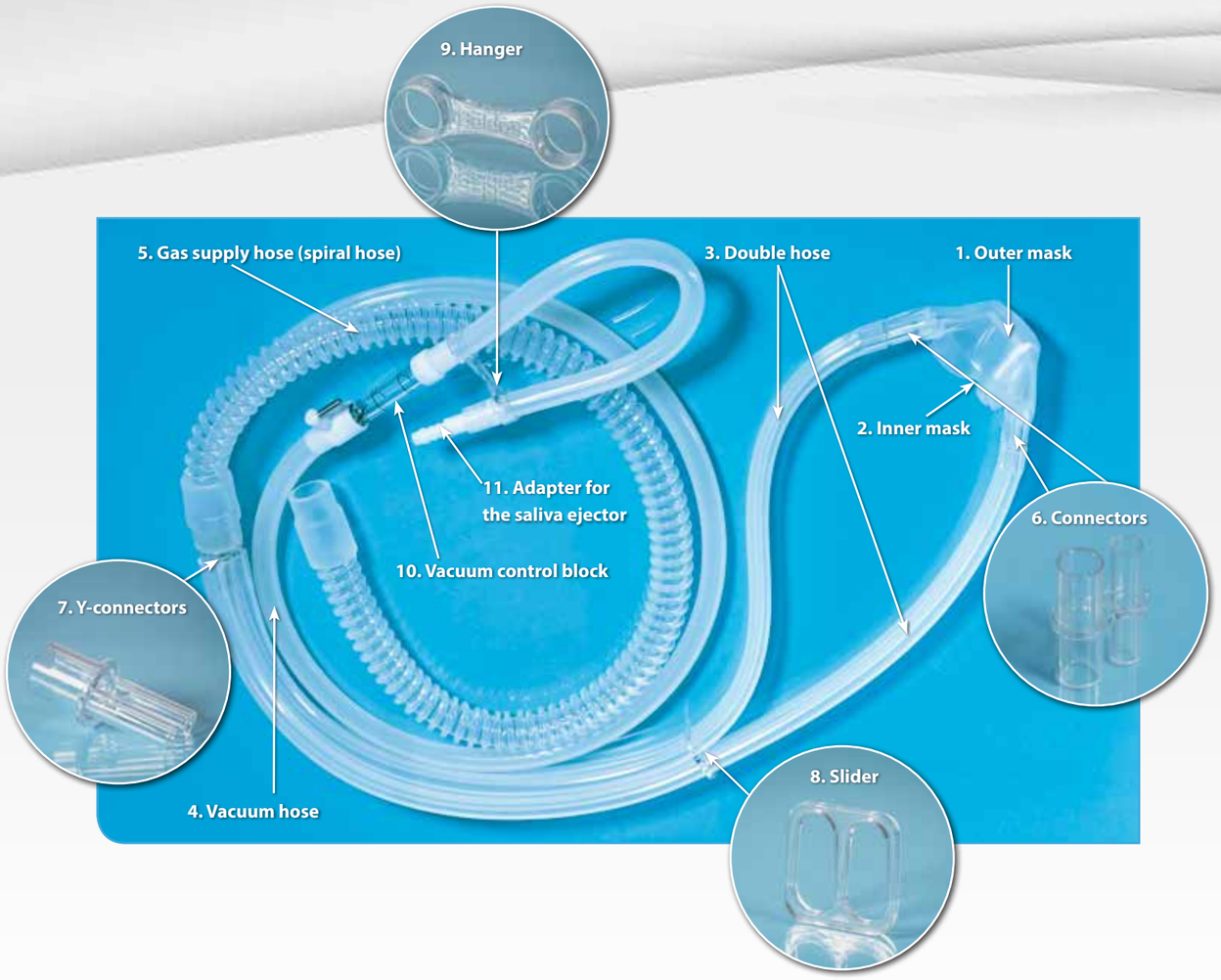
The scavenger system is maintenance-free. In order to protect both the patients and staff, however, you must carry out regular controls.

▶ **Regular controls:** see Chapter 5

Only accessories certified by Baldus® may be used. If you have any problems or leakages, contact **Baldus Medizintechnik** immediately (0049 261/ 96 38 926-0). Do not attempt to repair the device yourself.

Storage and disposal

The pipe system must be stored such that it is protected from damage and contamination. Do not store at temperatures below -10°C or above +35°C. Comply with the standard disposal channels when disposing of the device.



2. DESCRIPTION OF THE COMPONENTS AND HANDLING

1. **Outer mask:** The outer mask surrounds the inner mask, thereby catching nitrous oxide molecules which escape and guiding them through the vacuum hose and the suction system into the open. A connector for the gas supply and a connector for the gas discharge pipe via a suction system are both connected to the two outer sides. The double hose is connected to the outer mask. Item no. E16026 Adult / E16032 Pedo.
2. **Inner mask:** The inner mask is fixed to both sides of the outer mask by means of small, round barbs. Both masks are labelled "L" (left) and "R" (right) to help with the orientation. The patient exhales the oxygen-nitrous oxide mixture and an oval membrane made of silicon opens, thereby guiding the gas mixture into the outer mask. Item no. E16027 Adult / E16033 Pedo.
3. **Double hose:** There is one lumen for the fresh gas and one lumen for the suctioned gas. The vacuum hose is fixed to the double hose by means of the small Y-connector and the gas supply hose (spiral hose) is fixed to the double hose by means of the large Y-connector. Item no. E16004
4. **Vacuum hose:** Connects the double hose to the suction (e.g. small or large suction cup). Item no. E16003
5. **Gas supply hose (spiral hose):** Connects the oxygen-nitrous oxide mixer to the double hose. Item no. E16013-90 (90 cm)/ E16013-180 (180 cm).
6. **Mask connectors:** Used to connect the outer mask to the double hose. Important feature: single, safe bar to prevent confusion. The bar integrated into the broad lumen prevents two connectors being placed one above the other and therefore supply air and exhaust air being mixed up. A confusion of this type is definitely possible in other mask systems. This results in the sedation having no effect. This occurs for example when the person providing the treatment first sedates an adult and then switches the mask for a children's mask which also had adapters connected to it. This is a safety feature. Item no. E16018
7. **Y-connectors:** The Y-connector on the vacuum hose is used to connect the double hose to the vacuum hose. The Y-connector on the gas supply hose (spiral hose) is used to connect the double hose to the gas supply hose (spiral hose). Item no. E16016 Y-connector "large" / E16017 Y-connector "small".
8. **Slider:** The slider is used to draw the double hose inside of it closer to the patient's head so the mask fits the patient's face perfectly. Item no. E16019
9. **Hanger:** The hanger can be used to make a loop with the vacuum hose so the vacuum control block can be hung up and therefore read vertically. Item no. E16015
10. **Vacuum control block for monitoring the suction capacity:** The oxygen-nitrous oxide mixture inhaled through the mask is extracted by means of a vacuum hose. The vacuum control block can be found between this hose. The flow ball in the flow pipe shows whether the suction is too strong or too weak when the block is positioned vertically. The inscriptions "VAC" and "MASK" must be legible when reading the results. There is a marked area in the centre of the flow pipe. If the ball is in the marked area, the suction capacity is optimal. If the ball is in the lower area, approx. 45l/min are being suctioned and if it is in the upper area approx. 60l/min are being suctioned. There is a knob on the left hand side which can then be used to set the suction capacity. Rotating this knob reduces or increases the throughflow. Suction is stopped when the device is in a horizontal position. The suction capacity is strongest when the device is in a vertical position. Item no. E16002
11. **Adapter for the saliva ejector** The adapter is used to connect the vacuum hose to the saliva ejector in the small dental suction cup. Item no. E16014

Assembly instructions

The gas supply hose (spiral hose) is placed on the front 22 mm connection of the oxygen-nitrous oxide mixer and the breathing bag on the rear connection (see Fig. 1).

The other end of the gas supply hose (spiral hose) is connected to the double hose (large Y-connector) by means of a connector. The thin vacuum hose is connected to the double hose by means of the small Y-connector (Fig. 2). Connect the outer mask to the double hose using the connectors (Fig. 3).

Both the inner mask and the outer mask are labelled "L" and "R" (left and right) to ensure that the inner mask is correctly placed in the outer mask (Fig. 4). When using the dental chair suction system, either insert the other end of the vacuum hose into the large extractor without an adapter or use the white adapter to connect it to the saliva ejector on the small extractor. If you require both extractors for treatment, please contact your chair manufacturer and order an additional extractor or a T-piece or order a nitrous evacuator from Baldus Medizintechnik GmbH (see Accessories). Please note that the adapter for the saliva ejector of the small suction cup cannot be autoclaved.

The vacuum control block is assembled between the vacuum hose. It is used to monitor the suction capacity and set the suction strength.

Left: Vacuum control block

Above: White adapter for the saliva ejector of the small suction cup (cannot be autoclaved)

Vacuum control block, vacuum hose with a hanger and an adapter

Fig 1: Connection of the gas supply hose (spiral hose) and mixer

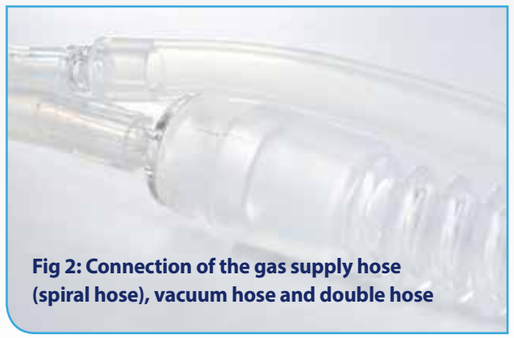


Fig 2: Connection of the gas supply hose (spiral hose), vacuum hose and double hose

Fig 3: Connection of the outer mask to the double hose

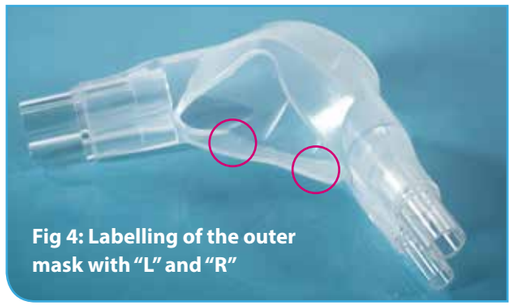


Fig 4: Labelling of the outer mask with "L" and "R"

3. SCOPE OF DELIVERY AND ACCESSORIES

In addition to the gas supply hose (spiral hose), vacuum hose, vacuum control block, double hose, autoclavable outer mask, autoclavable inner mask and the connectors, further accessories are also required for dental sedation. The essentially accessories are available from Baldus Medizintechnik GmbH:

Item No.	Product
E16009	Baldus® Oxygen-nitrous oxide mixer Analog
E15020	Ultraslim bottle pressure reducer O_2
E15021	Ultraslim bottle pressure reducer N_2O
E16038-1 and E16038-2	Baldus® N_2O and O_2 pressure hoses
E15015-3L or E15015-2.3L	Breathing bag for adults 3L or breathing bag for children 2.3L
E15016	Baldus® holder for bottles (bottle trolley)
E16021	Baldus® holder for gas mixers (mobile cart)
E15018	Pulse oximeter with alarm limits (e.g. OxyTrueA)
E15030	Suction (e.g. the Nitrous Evacuator mobile suction pump)

The following accessories are **non-essential**:

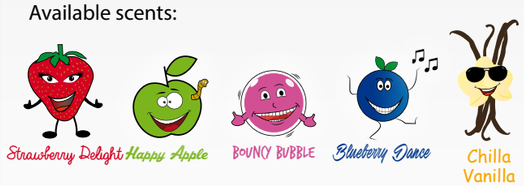
Glass (9) Bag (8) Adult (A) Pedo (P)

E1602___-___A (Happy Apple)
E1602___-___Blue (Blueberry Dance)
E1602___-___Bub (Bouncy Bubble)
E1602___-___E (Strawberry Delight)
E1602___-___V (Chilla Vanilla)

SINGLE USE - CONTENTS CANNOT BE AUTOCLAVED. PLEASE DO NOT USE STEAM AUTOCLAVES, CHEMICAL STEAM STERILISERS, HOT AIR STERILISATION OR CHEMICAL DISINFECTANTS.

Contents: 25 item

Available scents:



4. TECHNICAL DATA

Disposable inner masks

Product variant 1 (Item number E16024-1)**: Baldus® Double nasal mask system for adults**

Double hose:
L 700 x OD 14.0 x OD 10.90 x ID 10.40 x ID 6.90 mm
Vacuum hose: L 1000 x OD 15.0 x ID 9.60 mm
Gas supply hose:: L 900 x OD 26.5 x ID 22.0 mm
Outer mask Adult (H x W x D)**:** 59.62 x 126.15 x 57.59 mm
Inner mask Adult (H x W x D)**:** 45.4 x 89.02 x 49.5 mm
Weight including connectors: 0.7 kg.

Product variant 2 (Item number E16030-1)**: Baldus® Double nasal mask system for children**

Double hose: L 700 x OD 14.0 x OD 10.90 x ID 10.40 x ID 6.90 mm
Vacuum hose: L 1000 x OD 15.0 x ID 9.60 mm
Gas supply hose: : L 900 x OD 26.5 x ID 22.0 mm
Outer mask Pedo (H x W x D)**:** 59.62 x 110.92 x 48.13 mm
Inner mask Pedo (H x W x D)**:** 39.08 x 81.84 x 40.07 mm
Weight including connectors: 0.7 kg.

Product variant 3 (Item number see Chapter 3 "Accessories")**: Disposable masks for adults:**

Disposable inner mask Adult (H x W x D)**:**
45.4 x 89.02 x 49.5 mm
Weight: 10 g.

Product variant 4 (Item number see Chapter 3 "Accessories")**: Disposable masks for children**

Disposable inner mask Pedo (H x W x D)**:**
39.08 x 81.84 x 40.07 mm
Weight: 8 g.

Product variant 5 (Item number E16002)**: Baldus® Vaccum Control Block**

Dimensions (L x W x D)**:** 50 x 20 x 15 mm
Connection for the vacuum hose: 10 mm
Suction capacity at the lower line: 45l/min
Suction capacity at the upper line: 60l/min
Weight: 30 g.

5. SAFETY AND REGULAR CONTROLS

Control of the membrane:

Please check whether the membrane is still on the inner mask before the start of each treatment. If this is missing, you cannot sedate any patients using the mask.

Weekly control of the vacuum control block:

As soon as any damage is visible or the flow ball can no longer be regulated by the suction capacity to be within the marked range or the flow ball does not show any further movement, the block must be sent in and checked.

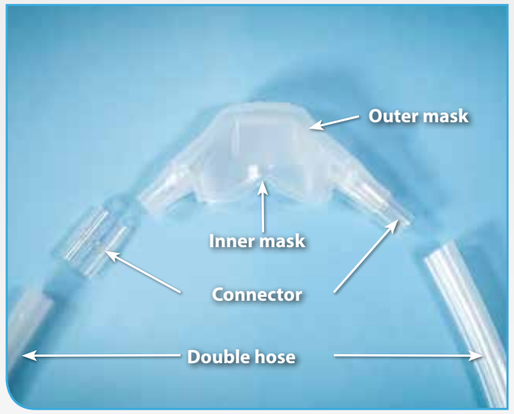
Monthly control: Leaks

Check all parts of the mask system for holes or damage on a monthly basis. Leaks put staff at risk.

Rapid test to check the gas bag and hose system for leaks

1. Remove the nasal mask and one of the two connectors. See Fig. right column.
2. Connect the two double hoses using the other connector. A closed system is created.
3. Increase the flow until the breathing bag fills like a balloon, then set the flow back to zero.
4. Watch the breathing bag for five minutes.
5. The bag should remain inflated. This means the test was successful and there are no leaks. If the bag does not remain filled, the Y-connectors, connectors, hoses or the bag have leaks and have to be replaced.
6. Remove one of the double pipes from the connector again and re-install the nasal mask.

When carrying out nitrous oxide sedation, follow the instructions given to you during the training session, at which you were certified as a user of the device, and the instructions of your service partner. Please comply with the technical rules for hazardous substances TRGS 900 (workplace limits) and TRGS 525 (handling hazardous substances in facilities for human medical care).



Remove the double mask and one connector from the double hoses.

Connect the double hoses to the other connector.

Check for leaks

IMPORTANT: Suction is compulsory and should be at a rate of at least 45l/min.

Single masks are still authorised for nitrous oxide treatment. However, the following risks must be taken into account:

Risks of single masks

- Safe compliance with the workplace nitrous oxide limits (e.g. 100 ppm in Germany, see TRGS 900) is difficult with the single mask. This is why there is no Baldus® single mask.
- In order to protect staff, the single mask system should not longer be used (see Dr Brigitte Mohr, The Use of Nitrous Oxide in Dentistry, 2014).

Advantages of the double mask

- is the latest technology available.
- results in significantly less nitrous oxide in the treatment room than when a single mask is used.
- achieves a high level of suction. The patient exhales the oxygen-nitrous oxide mixture, the membrane in the inner mask opens and the gas mixture is extracted and guided into the open via the external mask, the double hose and the vacuum hose.
- only the double mask should be used in order to protect staff from the nitrous oxide.

By using the double mask you minimise the risk of ambient air contamination. The Baldus® double mask system was developed to reduce the ambient air contamination with nitrous oxide and to protect staff. The oxygen-nitrous oxide mixture is guided into the patient's inner mask via the gas supply hose (spiral hose) and the patient inhales the gas mixture. When exhaling, a membrane opens and the gas is suctioned out via the outer mask and the vacuum hose. The outer mask works like a bell jar, so it provides efficient protection against the micro-leaks which occur as a result, for example, of a moustache. The perfected fit and the soft material mean the double mask fits any face shape. The fact that the patient's breathing has been disconnected from the suction system makes it easier for him or her to breathe compared to other mask systems. The vacuum control block is a further safety feature and is used to monitor and adjust the suction capacity. If the suction is set too high the nitrous oxide will have a time delayed effect and in the worst case scenario there will be no effect whatsoever. The suction can also be set too low, potentially resulting in the staff inhaling the nitrous oxide.

Workplace nitrous oxide limit in accordance with TRGS 900

German workplace nitrous oxide limit: 100 ppm for nitrous oxide treatments which last 30 minutes or more. In the case of sessions of treatment lasting, for example, 15 minutes, the workplace limit may be exceeded by a factor of 2 (200 ppm).

Duration of exposure (min.)	15	20	25	30
Exceedance factor	2	1.5	1.2	1

The workplace limit indicates the nitrous oxide concentration, acute or chronic, at which it can be assumed that there will be harmful effects on the patient's general health (Section 3 paragraph 6 of the Ordinance on Hazardous Substances. The workplace limits are the time-weighted average values of the generally eight hours of exposure over five days a week during the individual's working life.

The limits vary across the federal states and are currently under discussion. It is the operator's obligation to comply with the ambient air concentration limits for nitrous oxide.

5. SAFETY AND REGULAR CONTROLS

Nitrous oxide exposure should be kept as low as possible in order to protect staff. The following points should be taken into account in order to comply with the workplace limits set out in TRGS 900.

Each practice should create its own risk analysis.

Pay particular attention to	Countermeasure
Leaks in the mask system	Carrying out regular controls
	For each patient: check whether the mask is flush with the skin, select the correct size and model. Watch out for open areas when putting the mask on the patient.
	Above all, use the double mask which has been proven in studies. The double mask minimises ambient air contamination (see studies by the University of Bonn and many more).
Too much nitrous oxide in the treatment room	Set the chair suction before setting the nitrous oxide flow and control this using the vacuum control block (45l/min = marked area).
	Do not sedate patients in one room for more than two hours without a break.
	Ventilate the room between each patient (at least 5 minutes).
	Change rooms between two sessions of treatment with nitrous oxide.
	Keep the dose of nitrous oxide as low as possible.
	Switch on the air conditioning system to circulate the air in the room.
The patient is speaking a lot/breathing through their mouth	Tell the patient to breathe through their nose and to talk as little as possible.
	Stop treatment with nitrous oxide in patients who are not able to consciously breathe through their nose (e.g. young children etc.).
	Leave a saliva dam attached so the patient is forced to breathe through their nose.

6. HYGIENE

Warning	The mask system is not sterile when it is delivered, please clean and autoclave all components which can be autoclaved before used in line with the instructions for use.
Restriction on re-preparation	Frequent reuse has limited effects on the mask system. The end of the product life cycle is normally determined by wear and damage caused by use. Please replace the mask if discolouration or tears occur. Slight discolouration is acceptable. Please comply with the expiry date.
Location of use	Remove surface contamination with a disposable cloth/paper towel.
Storage and transport	No special requirements. We recommend that the mask system be re-prepared as soon as possible after use.
Cleaning preparation	**Disassembly before cleaning:** Remove the inner mask from the outer mask. Remove the two connectors from the outer mask and the double hose. Remove the Y-connectors from the double hose, vacuum hose and gas supply hose (spiral hose). Then remove the slider from the double hose. Then remove the vacuum control block and the hanger from the vacuum hose.
Manual cleaning Vacuum control block	**Please only clean the following accessories manually and do not sterilise them:** **Vacuum control block** Please clean the outside surfaces of the block using a mild cleaning agent which is authorised for cleaning in healthcare facilities. Do not apply the solution directly to the block, put it on a cloth and use this to wipe down the block.
Manual cleaning Outer mask Inner mask Double hose Vacuum hose Gas supply hose Connectors, sliders, Y-connectors and hangers Breathing bag (first clean and then sterilise)	Manual cleaning and disinfection in a cleaning disinfection device in accordance with ISO 15883. • **2 min pre-cleaning** with cold tap water • Empty • **5 min cleaning with 55°C warm tap water** and 0.5% cleaning solution of Neodisher MediClean by Dr. Weigert, Hamburg (used in the preparation validation) • Empty • **3 min rinse with cold demineralised water** • Empty • **2 min rinse with cold demineralised water** • Empty • **Thermal disinfection** taking into account the national requirements in terms of the A0 value (e.g. A_0 value of 3000 at 93°C and with a 3 minute hold time) **Do not use any chemical disinfectants**
Controls and functional tests	**For all cleaned and disinfected components:** Carry out a visual inspection for damage, wear and residual contamination. If any residual contamination can be identified, repeat the cleaning/disinfection process.

6. HYGIENE

Packaging: Outer mask Inner mask Double hose Vacuum hose Gas supply hose Connectors, sliders, Y-connectors and hangers	Standard packaging material in accordance with ISO 11607 can be used. The sterile packaging must be large enough for the components to be sterilised so the seal is not under stress.
Sterilisation: Outer mask Inner mask Double hose Vacuum hose Gas supply hose Connectors, sliders, Y-connectors and hangers Breathing bag (after the cleaning described above)	The components can be autoclaved. Steam autoclave: • 3 -re-vacuum phases • Sterilisation temperature: 134°C • Hold time: 5 minutes • Drying time: 20 min Exceeding the sterilisation time of 20 minutes decreases the service life. **Do not use hot air sterilisers.**
Storage after sterilisation	Dry, low-dust environment
Assembly before the next treatment	Please connect the inner mask to the outer mask. Pull the slider over the double hose. Insert the two connectors into the outer mask and the double hose. Now connect the Y-connectors to the double hose, vacuum hose and gas supply hose (spiral hose). Then connect the vacuum control block and the hanger to the vacuum hose.
Contact with the manufacturer	**Baldus Medizintechnik GmbH** Auf dem Schafstall 5 · 56182 Urbar – Germany ✆ +49 (0) 261 / 96 38 926 - 0 · Fax +49 (0) 261 / 96 38 926 - 21 ✉ info@lachgassedierung.de **www.lachgassedierung.de**
Validation:	The instructions above were validated by the medicinal product manufacturer as SUITABLE for the preparation of a medicinal product for reuse. The person carrying out the preparation is responsible for ensuring that the preparation actually carried out achieves the desired results with the equipment, materials and staff in the preparation facility. Validation and routine monitoring of the procedure are normally required for this. Any deviation from the instructions provided should be carefully evaluated by the person carrying out the preparation for possible negative consequences.

Baldus Medizintechnik GmbH does not guarantee that the information is current, correct and complete.
We reserve the right to make changes.

7. DECLARATION OF CONFORMITY

Wir / *We*

Name und Adresse der Firma /
Name and address of manufacturer:

Baldus Medizintechnik GmbH
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✆ +49 (0) 261 / 96 38 926 - 0
🖷 +49 (0) 261 / 96 38 926 - 21
✉ info@lachgassedierung.de

erklären in alleiniger Verantwortung, dass / *declare on our own responsibility that:*

die Medizinprodukte / *the medical devices:*

- **Baldus® Scavenger Breathing System Pedo**
- **Baldus® Scavenger Breathing System Adult**
- **Baldus® Disposable Inner Masks Pedo and Adult**
- **Baldus® Vacuum Control Block**

Chargennummer / *batch-nr.:* *siehe Aufkleber auf dem Medizinprodukt / see label*

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG, Anhang II entspricht. /
meets all applicable requirements of the Directive 93/42/EEC Annex II.

Name, Adresse und Kennnummer der Benannten Stelle /
Name address and identification number of Notified body:

mdc medical device GmbH
Kriegerstraße 6 · 70191 Stuttgart
CE 0483

Konformitätsbewertungsverfahren / *Conformity assessment procedure:*

Annex II.
Class IIa (Medicinal Products Act)

17/12/2020
Gültigkeitsdauer / *validity*

Urbar, 01/06/2016
Ort, Datum / *place, date*

L. Baldus
Rechtsverbindliche Unterschrift / *legally binding signature*

Lisa Baldus, QM Officer
Name und Funktion / *name and function*

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Certified Quality System mdc ISO 13485

Medizintechnik Baldus