

Operation Manual

Wenoll-System O₂ Demand module



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General Remarks

This product was manufactured with maximum care. Incorrect storage, handling and application can cause failures or disturbance in operation. So exact knowledge and consideration of this operation manual is required.

Please inform the manufacturer immediately if disturbances should occur.

Appendixes on Operation Manual

Following documents are components of this operation manual. Knowledge of all documents is required before using this product:

- Safety data sheet Oxygen
- O₂ Package leaflet / Information for the user

Range of Application

Specified normal operation of this Demand module is the normobar oxygen application at patients (or for personal use) at increased oxygen demand e.g. after a decompression accident, cardiovascular disease, symptoms of poisoning etc.

For indication and contraindication please see enclosed O₂ Package leaflet / Information for the user.

This product may only be used with medical oxygen under normobaric conditions.

A. Safety Instructions

- If there are external damages do not use product or components and contact immediately the manufacturer
- Observe expiration date and service periods of all components - they should not be used after expiration date! Please contact the manufacturer 4-8 weeks prior to expiration date
- Control pressure of cylinder and durability of components every 6 months. Pressure of cylinder has to be 200 bar \pm 15 bar to assure the specified periods of treatment
- Attend to operation manual and all enclosed documentation before use
- Note Package leaflet / Information for the user
- Note Safety data sheet Oxygen
- Maintenance and service just by manufacturer or authorised distributors (e.g. filling of oxygen cylinder, re-test, spare parts, etc.)
- Do not throw or bounce product and components - protect them against slipping or falling down, store clean
- Use product just in combination with spare parts/components of manufacturer
- Never disconnect screw-, plug- or other connections
- Keep product and components free of other gas or fluid
- Store inaccessible for children
- Protect from high temperatures
- Store or use product and components not over +50°C or less than -20°C
- Keep product and components free of grease and oil
- Smoking and open flames are strictly forbidden
- Pay attention to legal or other regulations concerning application of this product

Improper storage, improper use and any application beyond the described application purpose (normobar oxygen application at patients (or for personal use) at increased oxygen demand e.g. after a decompression accident, cardiovascular disease, symptoms of poisoning etc.) result in the expiry of warranty and other claims.

Indication & Contraindication by trained personnel and according O₂ Package leaflet / Information for the user.



B. Operation of the Wenoll Demand module

B.1. Preliminary Note

Use of the Wenoll Demand module allows a treatment duration of up to 40 minutes with 100% oxygen concentration (with a 2 litre cylinder filled with 200 bar, depending on breathing pattern).

Before use it is important to ascertain that all components are in an undamaged condition and that the expiry date of components has not passed.

If using in an emergency, remain calm and carry out and check each step with great care, so that effective treatment of the patient is ensured. The procedure must be carried out according to the steps described in this manual.

B.2. Assembly and Operation

1 Connect the Wenoll Demand module with the pressure regulator by taking the white connection tube with the silver quick connector, DIN or UNF-winding - depending on ordered type of Wenoll Demand module. It must be ensured that the pressure regulator has a medium-pressure outlet with an initial pressure of 5 bar! Otherwise, a proper function of the demand module is not guaranteed!

2 Put the end of the white connecting tube into the silver quick connector of the pressure regulator (ensure correct connection (click sound)) or screw in the DIN- or UNF-winding into the middle pressure outlet of the pressure regulator. Ensure correct position of the O-ring and a solid and tight fit. The cylinder valve should still be closed.

3 Fully open the valve on the oxygen cylinder as far as it will go (in the direction marked "open") so that in the medium pressure outlet, where the demand module is plugged in, a pressure of 5 bar is applied.
Cylinder pressure should show on the pressure gauge as 200 bar +/- 15 bar (a lower pressure will result in shorter duration of use).

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Pull the mask over the head, holding the mask forward with one hand and pulling the mask holder with the other hand, pull downwards over the head. One band must sit above the ears and the other below them. The small mask valve (for adjusting the air cushion) must be at the top. Now pull the mask tight by hooking the four mask bands equally into narrower holes on the mask hooks. Check for air-tightness by closing the large opening with the ball of the thumb. Breathing should not be possible.

If air-tightness cannot be established in the mask seating, try adjusting the mask's air cushion (see 6).

If air-tightness is not possible, use the mouthpiece together with the nose clip (without illustration).

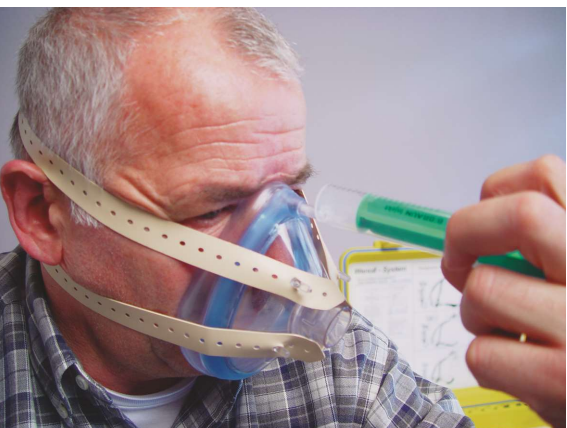
5



Attach the breathing mask (as in illustration) to the connector on the Demand module. The system is now in operation - breath normally!

To prevent irritation of the respiratory tract by the dry oxygen, a HME / bacterial filter can be inserted between the connection of demand module and mask.

6



If air-tightness cannot be established in the mask seating, try adjusting the mask's air cushion. Take the disposable syringe, draw it half way up and insert it firmly into the mask's filler tube. Put air in (cushion becomes firmer) or remove air (cushion becomes softer). Now repeat the air-tightness test (step 4).

If air-tightness is not possible, use the mouthpiece provided together with the nose clip (without illustration).



C. Maintenance / Service Periods

Please be aware of the following service and re-testing periods of the Wenoll Demand module:

The demand module has to be retested every **5 years**
(see label on the demand module with next re-test date)

It can be cleaned by wipe disinfection.

All spare parts or maintenance and service works may only be purchased by manufacturer or authorized distributors. Only original parts may be used.

D. Contact Service, Manufacturer and Purchasing

EMS GmbH

Im Gewerbegebiet 5
91093 Hessdorf
Germany

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www.ems-med.com

**Package Leaflet
Information for the user**date of information:
July 2010
Rev.-Nr.: GIO2_07_10

Oxygen for medical use

100% gaseous medicinal product for inhalation or ventilation

Read all of this leaflet carefully because it contains important information for you. This medicinal product is available without prescription. However, you still need to use OXYGEN FOR MEDICAL USE carefully to get the best results from it. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve. If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What is OXYGEN FOR MEDICAL USE and what is it used for?
2. Before you use OXYGEN FOR MEDICAL USE?
3. How to use OXYGEN FOR MEDICAL USE?
4. Possible side effects
5. How to store OXYGEN FOR MEDICAL USE?
6. Further information

1. What is OXYGEN FOR MEDICAL USE and what is it used for

OXYGEN FOR MEDICAL USE is a medical gas for inhalation and ventilation. OXYGEN FOR MEDICAL USE is used for the treatment and prophylaxis of oxygen deficiency conditions (hypoxia or hypoxemia).

2. Before you use OXYGEN FOR MEDICAL USE

Special care while using OXYGEN FOR MEDICAL USE is necessary in case of disturbances of ventilation or perfusion of the lungs due to pathological alterations of the lung tissue. In this connection OXYGEN FOR MEDICAL USE must not be delivered uncontrolled because of altered respiration drive control as otherwise a life-threatening situation may arise.

If used in premature infants / neonates as oxygen treatment may cause specific eye variations (retrolental fibroplasias). By an appropriate selection of the oxygen concentration, which will be defined by the physician, the risk of this variation can be downsized.

Use of OXYGEN FOR MEDICAL USE with other medicinal products

No interactions with other medicinal products are known.

Please inform your physician or pharmacist if you take / use other medicinal products or you took / used them previously, albeit these were no prescription medicinal products.

Pregnancy and breast-feeding

OXYGEN FOR MEDICAL USE can be used under control and advice respectively by the treating physician.

Driving and using machines

OXYGEN FOR MEDICAL USE has no influence on driving and using machines.

3. How to use OXYGEN FOR MEDICAL USE

Always use OXYGEN FOR MEDICAL USE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is: The treatment with OXYGEN FOR MEDICAL USE will be adjusted individually to your clinical picture. In principle the supply will be adjusted as low as possible. By means of regular controls (blood gas analysis) by the physician or in the hospital the necessary oxygen quantity will be determined. In general an oxygen supply of 2-4 L/min is recommended.

Route of administration

OXYGEN FOR MEDICAL USE is determined as an inhalation gas or for ventilation. Ventilation can ensue by different techniques, for instance through a nasal catheter (nasal tube) or a mask. In case of artificial respiration the oxygen will be administered via resuscitation tube (tubus) inserted into the air tube.

Please take care that the oxygen is moistened and potentially warmed up to avoid irritations of the mucous membrane during inhalation. Duration and frequency of administration should be agreed upon with your doctor or pharmacist.

continued from 3. How to use OXYGEN FOR MEDICAL USE

If you used more OXYGEN FOR MEDICAL USE than you should have done:

If you detect abnormalities during intake (cough, respiration problems) check the oxygen supply and / or contact your doctor. If the oxygen supply has been adjusted to a higher flow by error as agreed upon with the treating physician reduce the oxygen supply gradually to the agreed amount.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines OXYGEN FOR MEDICAL USE can cause side effects although not everybody gets them.

The following frequency information was used in the assessment of side effects:

Very frequently	More than 1 of 10 treated
Frequently	Less than 1 of 10, but more than 1 of 100 treated
Occasionally	Less than 1 of 100, but more than 1 of 1,000 treated
Rare	Less than 1 of 1,000, but more than 1 of 10,000 treated
Very rare	Less than 1 of 10,000 or unknown

During simple inhalation via nasal tube / mask oxygen is only administered in such concentrations that no side effects are reported.

Possible side effects in association with anaesthesia:

Diseases of the respiratory system: In case OXYGEN FOR MEDICAL USE is administered for more than 24 hours there may be restrictions regarding the lung function due to pulmonary changes. Exsiccations of the mucous membrane also may occur.

Eye diseases:

Eye alterations may occur in premature infants and neonates (retrolent fibroplasias).

Please report side effects of all kind (also those not listed) to your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store OXYGEN FOR MEDICAL USE

Keep out of the reach and sight of children.

Do not use OXYGEN FOR MEDICAL USE after the expiry date which is stated on the container. The expiry date refers to the last date of that month.

Store in original container. The container must be kept firmly locked.

Protect from heat exposure (<50°C) and store at a well ventilated place. Do not store together with combustible and easily inflammable substances. Prevent from unintended effusion because of an increased fire hazard. Smoking and fire ban!

The pressure container has to be prevented from tilting down. Do not store, use, or operate in stairways, corridors, and passage ways (obey accident protection regulations!).

Safe Use:

Use only registered valves and equipments and keep the whole system free of oil and fat. Take oxygen only via a pressure reducer; before usage all pressurized parts have to be checked for cleanness. In case of contamination clean with a clean cloth. Prior to use the system has to be checked for leak tightness of the connections. Oxygen connections are only to be opened slowly and not jerky. Improper use, fillings by the user or not registered manufacturers are not permissible.

Use only original fillings of the manufacturer.

6. Further information

What OXYGEN FOR MEDICAL USE CONTAINS

The active substance is oxygen.

1 litre contains at least 0.995 litre oxygen as the active pharmaceutical ingredient. No other constituents.

What OXYGEN FOR MEDICAL USE looks like and content of the container:

The gas (OXYGEN FOR MEDICAL USE) is colourless and odourless. The packaging (pressure container) is presented white (according to DIN 1089-3) / coated.

By residual pressure valves a residual pressure of 2 bar will be sustained, even in case of complete deflation.

Marketing Authorization Holder and Manufacturer:

Rießner Gase GmbH & Co KG

Rudolf Diesel Strasse 5

96215 Lichtenfels

Tel: +49-(0)9571 765-0 Fax: +49-(0)9571765-67

gase@riessner.de <http://www.riessner.de>

This package leaflet was last approved 12/2009

Safety Data Sheet

(according TRGS 220 / 91/155/EWG)

Data-S-No.: 02
Version: 1.0
Modified:
19-05-2010
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Oxygen

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Trade name : Oxygen
Chemical formula : O₂
Company identification :
Rießner-Gase GmbH & Co. KG
Rudolf-Diesel-Str. 5, D-96215 Lichtenfels
Tel: +49 9571 / 765-0, Fax: +49 9571 / 765-67
emergency number: +49 9571 / 765-43

2. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Preparation : Substance
CAS No: 7782-44-7
EC No: 231-956-9
Annex No: 008-001-00-8
Classification: OR8
Oxygen : 100 % ;
Contains no other components or impurities which will influence the classification of the product.

3. HAZARDS IDENTIFICATION

Compressed gas. Oxidant. Strongly supports combustion. May react violently with combustible materials.

4. FIRST AID MEASURES

- **Inhalation** : Continuous inhalation of concentrations higher than 75% may cause nausea, dizziness, respiratory difficulty and convulsion. Remove victim to uncontaminated area.

5. FIRE-FIGHTING MEASURES

Specific hazards : Exposure to fire may cause containers to rupture/explode.
Supports combustion.
Hazardous combustion products : None.
Extinguishing media
All known extinguishants can be used.
Specific methods : If possible, stop flow of product.
Move away from the container and cool with water from a protected position.
Special protective equipment for fire fighters: None.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions :

Evacuate area.
Ensure adequate air ventilation.
Eliminate ignition sources.

Environmental precautions :

Try to stop release.
Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous.

Clean up methods : Ventilate area.

7. HANDLING AND STORAGE

Handling

Use no oil or grease.
Open valve slowly to avoid pressure shock.
Suck back of water into the container must be prevented.
Do not allow backfeed into the container.
Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.
Keep away from ignition sources (including static discharges).
Refer to supplier's container handling instructions.

Storage

Segregate from flammable gases and other flammable materials in store.
Keep container below 50°C in a well ventilated place.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

Personal protection :

Do not smoke while handling product.
Wear suitable hand, body and head protection.
Wear goggles with suitable filter lenses when use is cutting/welding.
Avoid oxygen rich (>21%) atmospheres.
Ensure adequate ventilation.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state at 20 °C : Gas.
Colour : Colourless gas.
Odour : No odour warning properties.
Molecular weight : 32
Melting point [°C] : -219
Boiling point [°C] : -183
Critical temperature [°C] : -118
Vapour pressure [20°C] : Not applicable.
Relative density, gas (air=1) : 1.1
Relative density, liquid (water=1) : 1.1
Solubility in water [mg/l] : 39
Flammability range [vol% in air] : Oxidiser.
Auto-ignition temperature [°C] : Not applicable.
Other data : Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.

10 STABILITY AND REACTIVITY

Hazardous decomposition products : None.
Materials to avoid : May react violently with combustible materials.
May react violently with reducing agents.
Violently oxidises organic material.
Keep equipment free from oil and grease.
Conditions to avoid :
Consider the potential toxicity hazard due to the presence of chlorinated or fluorinated polymers in high pressure (> 30 bars) oxygen lines in case of combustion

11 TOXICOLOGICAL INFORMATION

Toxicity information : No known toxicological effects from this product.

12 ECOLOGICAL INFORMATION

Ecological effects information : No ecological damage caused by this product.

13 DISPOSAL CONSIDERATIONS

General : To atmosphere in a well ventilated place.
Do not discharge into any place where its accumulation could be dangerous.
Contact supplier if guidance is required.

14 TRANSPORT INFORMATION

UN No.: 1072
Labelling ADR, IMDG, IATA
Label 5.1 : Oxidizing substances.
Label 2.2 : Non flammable, non toxic gas.

Land transport
ADR/RID
H.I. nr : 25
Proper shipping name : OXYGEN, COMPRESSED
ADR Class : 2
ADR/RID Classification code : 1 O
Packing Instruction(s) - General : P200

Sea transport
IMO-IMDG code
Proper shipping name : OXYGEN COMPRESSED
Class : 2.2
IMO Packing group : P200
Emergency Schedule (EmS) - Fire : F-C
Emergency Schedule (EmS) - Spillage : S-W
Instructions - Packing : P200

Air transport
ICAO/IATA
Proper shipping name : OXYGEN, COMPRESSED
Class : 2.2
Passenger and Cargo Aircraft : Allowed.
Packing instruction : 200
Cargo Aircraft only : Allowed.
Packing instruction : 200

Other transport information : Avoid transport on vehicles where the load space is not separated from the driver's compartment.

Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
Before transporting product containers :
- Ensure that containers are firmly secured.
- Ensure cylinder valve is closed and not leaking.
- Ensure valve outlet cap nut or plug (where provided) is correctly fitted.
- Ensure valve protection device (where provided) is correctly fitted.
- Ensure there is adequate ventilation.
- Compliance with applicable regulations.

15 REGULATORY INFORMATION

EC Classification :
Annex No : 008-001-00-8 O; R8
EC Labelling Symbol(s) :
O: Oxidizing
R Phrase(s) : R8 :
Contact with combustible material may cause fire.
S Phrase(s) : S17 :
Keep away from combustible material.

16 OTHER INFORMATION

Ensure all national/local regulations are observed.
Ensure operators understand the hazard of oxygen enrichment.
This Safety Data Sheet has been established in accordance with the applicable European Directives and applies to all countries that have translated the Directives in their national laws.

DISCLAIMER OF LIABILITY : Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.
Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.

Impressum

Wenoll-System Operating Manual O₂ Demand module

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(1st edition 1990)

Manufacturer and Purchasing

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Modification on product, on interpretation and on documentation as well as errors/mistakes excepted.