Kröber
MEDIZINTECHNIK

Instructions for Use

Kröber O2

Instruction manual
ALWAYS KEEP
ready to hand on the unit

Read the instructions for use
before working with the unit

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1 Preliminary statement 6
2 General 7
2.1 Information in these instructions for use 7
2.2 Declaration of Manufacturer 8
2.3 Type plate 9
2.4 Liability and warranty 9
2.5 Warranty 9
2.6 Explanation of symbols 10
2.7 Copyright protection 11
2.8 Return and waste disposal 11
2.9 Customer service 11
3 Safety 12
3.1 General 12
3.2 Customer's responsibility 12
3.3 Intended use 13
3.4 Dangers which may arise from the unit 13
3.5 What to do if a hose caught fire 16
4 Design and function 17
4.1 General description 17
4.2 Design 17
5 Technical data 19
6 Transport, packaging and storage 21
6.1 Transport inspection 21
6.2 Storage 21
7 Taking into service 22
7.1 Before assembling 22
7.2 Choosing the location 23
7.3 Assembly 24
7.3.1 Without external humidification 24
7.3.2 With external humidification 26

8 Operation 28
8.1 Taking into service 28
8.2 Adjusting the oxygen volume flow 29
8.3 Alarms 30
8.3.1 Alarm priorities 30
8.3.2 Alarm categories 31
9 Maintenance 35
9.1 Safety 35
9.2 General notes 35
9.2.1 Cleaning 35
9.2.2 Disinfecting 35
9.3 Maintenance plan 36
9.4 Maintenance work 38
10 Spare parts 40
11 Appendix 41
11.1 EMC regulations 41
11.1.1 Electromagnetic compatibility, interference emission 41
11.1.2 Electromagnetic compatibility, interference emission 42
11.1.3 Recommended safety distances 45
11.2 Explanation of symbols on the unit 46
12 Index 48

1 Preliminary statement

Your doctor has found that you require an additional oxygen supply. With the Kröber O2 you received a German brand product for oxygen supply, which has been developed on the basis of the latest knowledge in both medical engineering and electronics. Permanent quality inspections ensure uniform quality on the highest level.

The Kröber O2 is a highly reliable oxygen concentrator , intended for use in homes or at home, as well as for clinical applications.

However, should problems arise with the Kröber O2, you may contact your dealer at any time.

This medical care product from Kröber is labelled with the CE-sign according to MPG (Medical Product Law).

Only use the Kröber O2 after a medical indication and only in compliance with the doctor's orders by following these instructions for use.

If side effects or extreme health restrictions occur during the therapy, you should immediately consult your doctor.

2 General

2.1 Information in these instructions for use

These instructions for use describe the installation, operation and maintenance of the unit. Strict compliance with the stated notes on safety and instructions for use is a prerequisite for safe and proper work with the unit.

Moreover, compliance with the accident prevention instructions valid at the location of use and the general safety regulations is mandatory.

This instruction manual is part of the product and should be kept near the unit so that it is at any time available for personnel involved i installation, operation, maintenance and cleaning.

The graphic illustrations in this manual may perhaps differ slightly from the actual design of the unit.

2.2 Declaration of Manufacturer

Kröber GmbH
Salzheck 4
56332 Dieblich
Tel.: 02607 / 9 40 4 0
Fax: 02607 / 9 40 4 22

Konformitätserklärung
Declaration of Conformity

Produktspezifikation / *product details*:

Produktbezeichnung / *product name*	**Sauerstoff-Konzentrator** ***Oxygen concentrator***
Type / *type*	**Kröber O2**
Systemkomponenten / *Systems Components*	
Klassifizierung nach RL 93/42/EWG, Anhang IX / *Classification according 93/42/EEC, annex IX*	**II a nach Regel 11 /** **II a *per rule 11***

Konformitätsbewertung / *assessment details*:

Benannte Stelle / *notified body*	**TÜV Rheinland Product Service GmbH**
Verfahren nach RL 93/42/EWG / *route of directive 93/42/EEC*	**Vollständiges Qualitätsmanagementsystem gem. Anhang II /** ***Full Quality Assurance System acc. Annex II***
Zertifikate / certificates	**HD 60004429 0001**

Angewandte Normen / *used standards*:

Harmonisierte Normen / *harmonized standards*	**EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996** **IEC 60601-1-2:2001** **EN 60601-1-4:1996** **EN ISO 8359:1997**
Sonstige Normen / *other standards*:	**EN ISO 14971:2000**

Wir erklären in alleiniger Verantwortung, daß die oben beschriebenen Produkte den Anforderungen der Richtlinie 93/42/EWG und des deutschen Medizinproduktegesetzes MPG entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen.
We declare under sole responsibility that the products described above are in compliance with directive 93/42/EEC and the German Medical Device Act MPG. The products are CE marked.

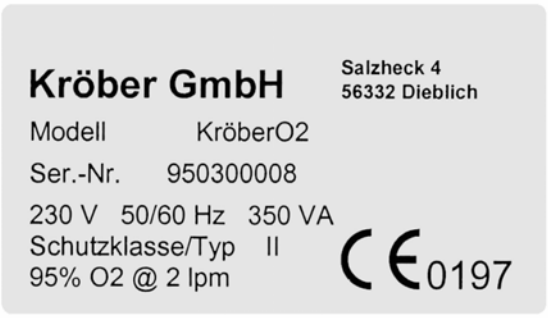
CE 0197

Dieblich, 08.06.2005

Horst Kröber, Geschäftsführer

2.3 Type plate

The type plate of the Kröber O2 is attached to the back of the unit above the coarse dust filter.



2.4 Liability and warranty

All details and notes for the operation, maintenance and cleaning of the unit are made to the best of our knowledge taking into consideration our experience and knowledge gained up to now.

We reserve the right to make technical changes to the machine dealt with in these instructions for use within the context of ongoing development.

Translations are also carried out to the best of knowledge. We do not accept any liability for errors in translation. The German version of the instructions for use, which is also delivered with the unit, is the definitive version.

Texts and illustrations do not necessarily correspond to the scope of delivery. The drawings and graphics are not to scale 1:1.

Read instructions for use carefully before starting operation of the unit!

The manufacturer will not assume liability for damage or disruptions that occur as a result of non-compliance with the instructions for use.

Handing over these instructions for use to third parties is not permitted and results in the obligation for compensation.

2.5 Warranty

Differing from our General Terms of Business we grant an extended warranty of 30.000 operating hours for all functional parts (e.g. compressor, control board, valve technology, etc.) used in our oxygen concentrator Kröber O2 . This extended warranty is valid for maximum 5 years from the date of purchase.

This warranty does not cover filters and zeolites, damage caused by improper handling and mechanical damage of parts (e.g. transport damage).

Our warranty is limited to the free-of-charge replacement delivery for defective parts. The defective components must be returned to us for inspection. Locally arising costs for travel and labour time will not be refunded. If units are returned to us free of charge for warranty repair we will also cover the labour costs for probable warranty repairs.

2.6 Explanation of symbols

Important safety and equipment related notes in these instructions for use are highlighted by symbols. These notes must be strictly adhered to in order to avoid accidents, personal injuries and damage to property.

WARNING!

This symbol warns of dangers that can lead to adverse effects on health, injuries, permanent physical damage or to death.

Strictly comply with all notes regarding work safety, and be particularly careful in these situations.

WARNING! Danger of electric current!

This symbol draws attention to dangerous situations involving electrical currents. There is a danger of serious injury or death if the safety notes are not complied with. The related work may only be carried out by qualified electricians.

ATTENTION!

Information highlighted with this symbol must be strictly complied with in order to avoid damage to the machine, malfunction and/or breakdown.

NOTE!

This symbol highlights hints and information to be observed for efficient and non-disrupted operation of the unit.

2.7 Copyright protection

These instructions for use are to be treated confidentially. They should only be used by persons who have been authorized accordingly. It may only be passed on to third parties with the written consent of the manufacturer.

All documents are protected by copyright protection law.

It is not permissible to pass on or reproduce the documents, either as a whole or excerpts thereof, to evaluate or communicate their content, unless explicitly entitled to do so. Any violations are liable to prosecution and require compensation.

We reserve the right to exercise industrial property rights.

2.8 Return and waste disposal

– If the unit has been delivered through a parcel service and not directly by a dealer you should keep the packaging material for possible service instances.

– If there is no corresponding agreement regarding the return of packing material, then the packing material remains with the customer. He is responsible for environmental waste disposal in accordance with the applicable waste disposal legislation.

– After use the unit may be returned to the dealer, who is then responsible for proper disposal of the unit.

– Non-infectious used accessories (e.g. nasal cannula) can be disposed off as domestic waste

– Infectious accessories (e.g. nasal cannula of an infected user) must be disposed of through a specially approved waste disposal company. Addresses are available from your local municipality.

2.9 Customer service

Service work should normally be carried out by your local authorized dealer.

You can contact Kröber Medizintechnik GmbH as follows:

Office hours:	Mo-Thu from 7.30 a.m. - 4.00 p.m. and Fr. from 7.30 a.m. - 2.00 p.m.
Address:	Kröber Medizintechnik GmbH Salzheck 4 D-56332 Dieblich
Phone:	02607-94040
Fax:	02607-940422
Internet:	www.kroeber.de
eMail:	info@kroeber.de

3 Safety

This section provides an overview over all important safety aspects for safe and trouble-free operation of the unit.

The individual chapter additionally contain actual safety notes highlighted with symbols, which will help to avoid immediate dangers.

3.1 General

The machine is built according to the currently applicable rules of technology and is safe to operate.

However, dangers may still arise from the unit if it is incorrectly operated or used for purposes it is not intended for.

Any persons using this unit must have read and understood these instructions before starting operation. This also applies if the person in question has already worked with just such a unit or similar equipment or was trained by the manufacturer.

Knowing the content of these instructions for use is a prerequisite for the avoidance of mistakes and for safe and trouble-free operation of the unit.

Neither changes nor conversions may be carried out on the equipment, which have not been explicitly authorized by the manufacturer, to avoid dangers and to ensure optimal performance.

All safety decals and operating signs on the unit must be kept well legible at all times. Damaged or illegible decals must be replaced immediately.

3.2 Customer’s responsibility

These instructions for use must be kept near the unit, so that it is available for the user at any time.

Apart from the notes on safety mentioned in this manual, all generally valid safety and accident prevention instructions must also be observed and adhered to.

The machine may only be operated in a technically perfect condition and if operationally safe.

The information contained in the instruction manual is complete and must be adhered to without limitation.

3.3 Intended use

The operational safety of the unit is only assured when used for the purpose it is intended for, as specified in the instructions for use.

The Kröber O2 solely intended for use within the scope of a medical therapy for the additional supply of oxygen. The unit may thereby be used in hospitals, homes or at home.

The unit must only be used according to the medical indication and only in accordance with the doctor's prescription by following these instructions for use

The intended use also includes the compliance with the assembly instructions, as well as the notes on cleaning and maintenance of the unit.

Any other use of the unit beyond these limits is prohibited and is not considered as unintended use! Claims of any kind against the manufacturer and/or his authorized representatives resulting from damage caused by unintended use of the unit are excluded. The customer is solely liable for any damage resulting from unintended use.

3.4 Dangers which may arise from the unit

The unit was subjected to a risk analysis. The resultant construction and design of the unit corresponds to the current status of technology.

However, there is still a remaining risk!

The unit requires responsibly minded and cautious operation. Improper operation or operation by unauthorized persons can endanger persons.

WARNING! Risk of health damage!

If an absolutely safe oxygen supply is required, it is strictly necessary to have a second, independent oxygen source available as replacement (e.g. a mobile oxygen economy system with an oxygen cylinder).
If the patient or the operator notices at any time that the available amount of oxygen is not sufficient, you should immediately contact your dealer and/or doctor.

WARNING! Risk of health damage!

Particular supervision is required if the unit is to be used in the vicinity of children or bedfast persons. The unit must under no circumstances be used with children without additional supervision!

WARNING! Danger of side effects!

If side effects or extreme health restrictions occur during the therapy, you should immediately consult your doctor.

WARNING! Fire hazard caused by oxygen!

Oxygen is vital, but in concentrators with only a few percentage points above the normal oxygen content in the air it is a highly dangerous fire accelerant. There are only a few materials which will not burn off like an explosion under a raised concentration of oxygen.

Therefore:

- **Oxygen may only be handled by trained or specially instructed persons!**
- **The misuse of oxygen, e.g. to cool down or improve the ambient air, to cool down and dust or blow off of persons, clothes, furniture etc. is dangerous and therefore prohibited!**
- **Smoking and handling ignition sources and open flames is prohibited when working with oxygen!**
- **Keep a minimum distance of 2 metres from all spark generating equipment and open fire!**
- **After having stayed in a possible oxygen saturated atmosphere you should thoroughly aerate your cloths, because oxygen adheres to the clothes very well! An ignition source, e.g. a burning cigarette, could easily cause burning of your clothes.**
- **Materials that do not burn in air may burn very vigorously and even spontaneously in oxygen or oxygen enriched air. This already applies for an enrichment of only a few percent!**
- **Oil and grease (even creams and gels) can react in an explosion like manner when coming in contact with oxygen. It is therefore mandatory to keep the unit free of oil and grease!**
- **Oxygen considerably increases the temperature of a flame and the speed of combustion!**
- **Do not fill the moisturizer with inflammable fluids!**

WARNING! Danger of electric current!

Electric energies can cause severe injury. Damaged insulation or components cause a danger to life.

Therefore:

- **Work on the equipment must only be performed by trained professionals.**
- **Pull the mains plug out before starting work on the unit!**
- **Check mains leads for damage before every use.**

ATTENTION! Observe high frequency safety!

Medical equipment can be influenced by (mobile) HF communication equipment (e.g. mobile phones).
Do not use mobile radio equipment in the immediate vicinity of the Kröber O2.

ATTENTION! Observe electromagnetic compatibility!

Electrical medical equipment is subjected to stringent protective measures concerning electromagnetic compatibility (EMC) and must be installed and operated in accordance with the EMC information contained in the accompanying documents. The following should be noted in particular:

- **Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.**
- **During operation the unit must therefore not be exposed to extremely strong magnetic fields.**
- **Magnetic fields at mains frequency must comply with the typical values found in business or hospital environments.**

ATTENTION! Keep the minimum distance!

The air intake of the Kröber O2 is located on the back side of the unit, the following is therefore of importance:

- **There should be a minimum distance of 30cm from walls, curtains and other large objects (e.g. cupboards), so that an unrestricted entry of air is assured at the back of the unit.**
- **The Kröber O2 oxygen concentrator must not be used directly beside or even stacked with other equipment.**

ATTENTION! Avoid overheating!

The unit is air cooled, in order to avoid overheating it must not be placed near heaters, etc.

3.5 What to do if a hose caught fire

Should a hose catch fire despite all protective measures, it is not enough to just switch the unit off, because oxygen will continue to flow for a while after the unit has been switched off.

Take the following steps:

- Pull the oxygen hose off the unit to interrupt the oxygen supply.
- Choke the flames (e.g. with a blanket).
- Ventilate well after extinguishing the fire, because a burning PVC-hose will emit toxic gases.

The metal connection on the oxygen outlet acts as a fire inhibitor, preventing the flames from spreading into the unit.

4 Design and function

4.1 General description

The Kröber O2 oxygen concentrator for has been optimized for the oxygen supply at home. The electronically controlled oxygen concentrator separates the oxygen from the ambient air and supplies the user through the nasal cannula with highly concentrated oxygen.

4.2 Design

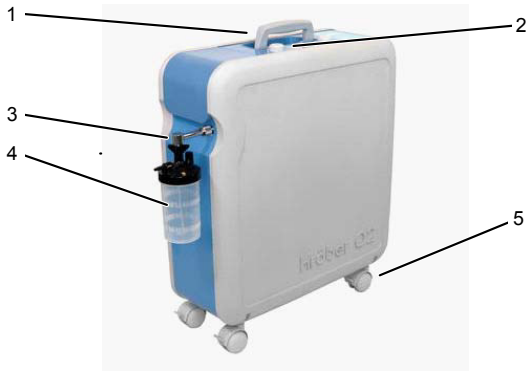


Fig. 1: Front

Design:

1 Carrier handle

2 Control panel

3 Angle connection

4 Humidifier

5 Steerable castors

Fig. 2: Back

6 Mains lead

7 Coarse dust filter

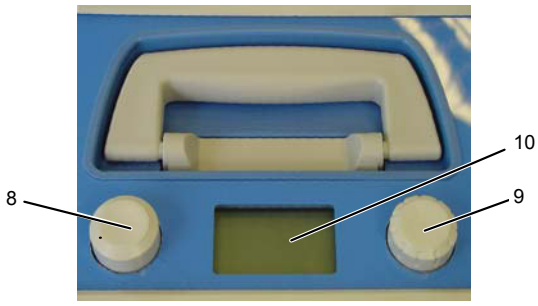


Fig. 3: Control panel

8 On/Off-switch

9 Volume flow regulator

10 LC display

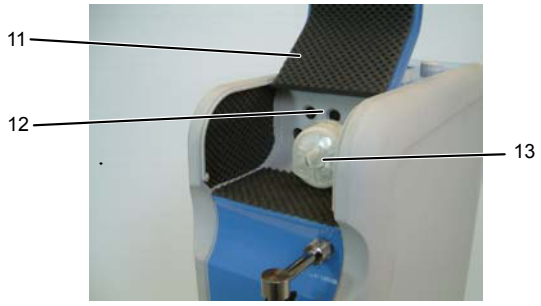


Fig. 4: Service flap

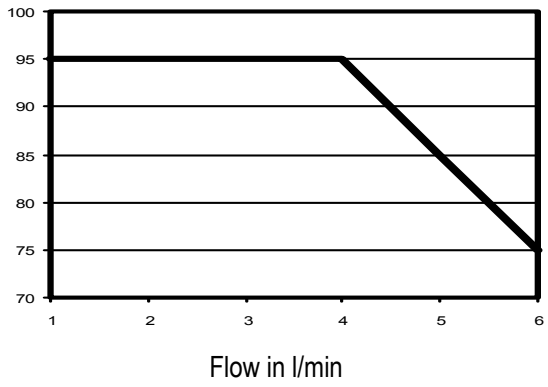
11 Service flap

12 Fuses

13 Air intake filter

5 Technical data

Model	Kröber O2
Classification acc. to MPG	IIa
Operating voltage	230 V, 50 Hz
Ambient operating temperature	Operation: +10 to +40 °C Storage: -20 to +70 °C
Sound pressure level	< 35 dB(A)
Power input	360 W
Coarse dust filter	in back of housing
Bacteria filter	behind service flap
Fuses	mains side: 2 x TT2,5A H 250 V internal: 1 x T1,0A L 250 V
Interface	USB
Temperature range	+10 to +40 °C
Atmospheric pressure range	700 mbar to 1060 mbar
Weight	19.8 kg
Dimensions (HxWxD)	(53.5 x 20.3 x 52) cm without castors
Warranty of manufacturer	30.000 operating hours, max. 5 years (see chapter 2.5)
O2-concentration	1 to 4 l/min. 95 % - 3 % 4 to 5 l/min. 85 % +/- 3 % 5 to 6 l/min. 75 % +/- 3 %
Status display O2-concentration (at operating temperature)	82% status display 60% deficiency display
max. recommended volume flow	6 l/min
Volume flow (at 0 or 7kPa)	1 - 6 l/min acc. to pre-setting
max. output pressure:	70 kPa
Overpressure relief	200 kPa (oxygen reservoir) 250 kPa (compressor)

Characteristic, at a counter pressure of 0 kPa, O2 concentration in %	

6 Transport, packaging and storage

The following should be noted when transporting the Kröber O2:

– The unit should only be shipped and transported in its original packaging.

– For transport, e.g. by car, the unit may stand upright or lay on one of the two large flat sides.

– Open the transport box from the top. Do not stand the transport carton upside down or on one of its narrow sides.

6.1 Transport inspection

It is highly recommended to check the complete delivery for completeness and possible transport damage, immediately after receipt.

In case of externally detectable transport damage you should not accept the delivery, or only with reservation. Acknowledge the receipt only with reservation (e.g. on the freight document). Specify the expected damage and inform the manufacturer immediately.

Hidden damage should be claimed immediately after detection, because damage claims can only be lodged within the applicable claims periods.

The packaging material should be saved, it may be needed if the unit has to be returned.

6.2 Storage

If the package is to be stored before it is taken into service, please observe the following instructions:

– Store in a dry environment. Relative humidity: max. 60 %.

– It must be assured that the package is not stored outdoors.
It must also be assured that the floor used for storage is dry over the entire storage period.

– Storage temperature -20 to +70°C.

– Store in a dust-free environment.

– Avoid mechanical shocks and damages.

7 Taking into service

7.1 Before assembling

Check before assembling whether all components needed for correct operation are available.

Fig. 5: Scope of delivery 1

Unit:

- Unit Kröber O2
- User manual

Fig. 6: Scope of delivery 2

Further components:

1 Angle connection for humidifier

2 Humidifier

3 Coarse dust filter

Fig. 7: Scope of delivery 3

4 Nasal cannula for oxygen

5 Safety hose for oxygen 15m

6 Wall bracket for humidifier

7 Set for external humidification (optional)

7.2 Choosing the location

Please consider the following when choosing the location:

– The unit should have 30cm clearance from any walls, curtains and other large objects (e.g. cupboards), to ensure unrestricted entry of air through the back of the unit.

– The unit is air cooled. It must therefore not be placed near heaters, etc. At such a location there is a risk of overheating.

NOTE!

The unit can be safely lifted and moved by the carrier handle on top of the unit.

ATTENTION! Ensure a sufficient air supply!

The Kröber O2 oxygen concentrator must not be operated directly next to or even stacked with other equipment. Ensure a sufficient distance from the walls, etc.!

7.3 Assembly

There are generally two possible ways to use the unit.

1 The unit is standing next to the user during use.

2 The user uses the "Set for external humidification". In this case the unit can stand in another room.

7.3.1 Without external humidification

If the unit is to stand next to the user, it is started up as follows:

Fig. 8: Mains lead

1 Insert the mains lead into a professionally grounded **socket**.

! ATTENTION!

The Kröber O2 is only designed for operation on a 230 Volt, 50Hz mains network.

Fig. 9: Angle connection

2 Screw the angle connection to the oxygen outlet of the Kröber O2.

Fig. 10: Humidifier Max.-mark

3 Fill the humidifier up to the top MAX.-mark **(1)**.

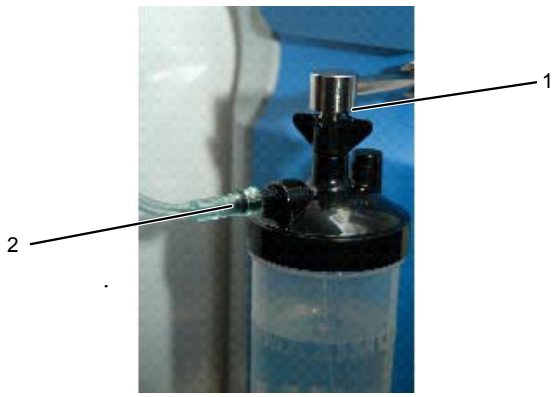


Fig. 11: Humidifier assembly

4 **Fasten the humidifier** on the angle connection **(1)**.

5 **Push the nasal cannula** with its socket end over the **outlet connection** of the Kröber O2 **(2)**.

WARNING! Danger of tripping over!

On the back of the Kröber O2 you will find a winding device for the mains lead. This should be used when the unit is out of use, to avoid any danger of tripping over.

7.3.2 With external humidification

If the unit does not need to stand next to the user, the installation is carried out as follows:

Fig. 12: Mains lead

1 Insert the mains lead into a professionally grounded **socket**.

! ATTENTION!

The Kröber O2 is only designed for operation on a 230 Volt, 50Hz mains network.

Fig. 13: Adapter for ext. humidification

2 Screw the angle connection to the oxygen outlet of the Kröber O2**.**

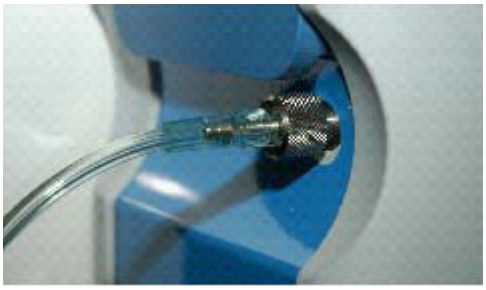


Fig. 14: Safety hose for oxygen

3 Plug the safety hose for oxygen (extension hose) **onto** the **adapter**.

Fig. 15: Humidifier Max.-mark

4 Fill the humidifier up to the top MAX.-mark **(1)**.

Fig. 16: Humidifier assembly

5 **Screw the angle adapter (1)** to the humidifier.

6 **Plug the safety hose for oxygen** (extension hose) **onto** the **angle adapter (2)**.

7 **Push the nasal cannula** with its socket end over the **outlet connection** of the Kröber O2 **(3)**.

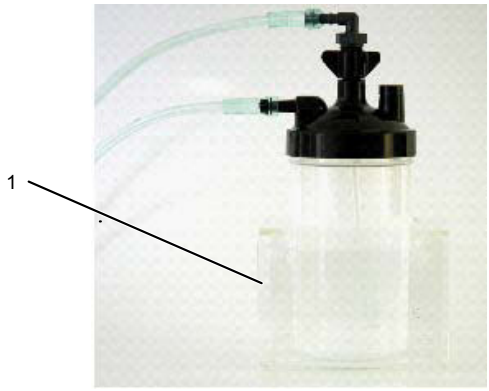


Fig. 17: Humidifier bracket

8 **Stand the humidifier** into the **bracket (1)** .

NOTE!

The bracket has the function of preventing the humidifier from falling over. It is therefore recommended to mount the bracket to a wall, a cupboard, etc.

WARNING! Danger of tripping over!

On the back of the Kröber O2 you will find a winding device for the mains lead. This should be used when the unit is out of use, to avoid any danger of tripping over.

8 Operation

WARNING! Health risk!

Inappropriate use of the Kröber O2 can lead to severe personal and/or material damage.
You should therefore only start up the unit in strict compliance with the instructions for use and the notes on safety.

8.1 Taking into service

Fig. 18: Control panel

1 Start the unit by actuating the **mains switch (1)** on top of the unit.

– The Kröber O2 runs a self-test.

– The oxygen production starts after the self-test.

– The LC-display continuously shows the current oxygen volume flow and the equipment status.

NOTE!

During the start-up phase the oxygen alarm appears for 2 minutes. This alarm should disappear after two minutes. If this does not happen, the unit may be defective.
During the start-up phase the unit also shows the operating hours. This information disappears after 30 seconds.

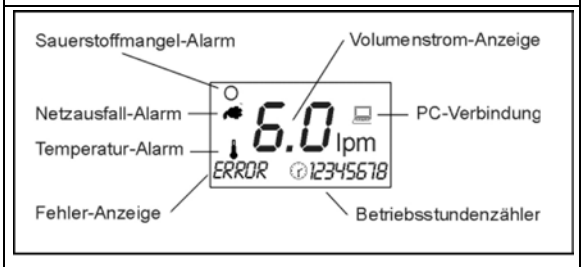


Fig. 19: LC display

– Information concerning the operating status of the unit can be found in the display.

Fig. 20: Nasal cannula

2 **Wear** your **nasal cannula**.
Insert both cannula openings into your nose.
Place both feed hoses over your ears.
Pull the sling with the sliding piece tight under your chin.

WARNING! Risk of health damage!

Do not smoke while operating the Kröber O2! Oxygen must NOT be used near open fire, sparks, glowing objects, etc.!

8.2 Adjusting the oxygen volume flow

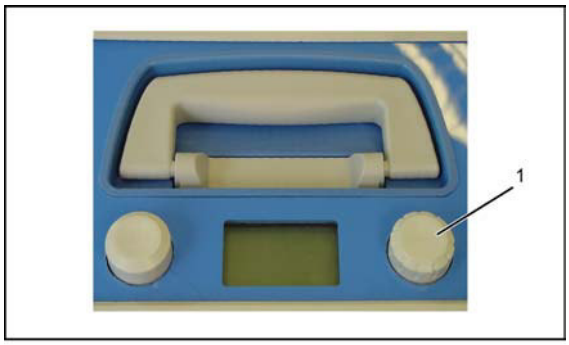


Fig. 21: Adjusting the volume flow

1 **Press the adjustment regulator (1)** for at least **2 seconds**.

– When a signal sounds and the volume flow indication in the LC display flashes the adjustment mode has been activated.

2 **Change the volume flow by turning** the **adjustment regulator**. Turning clockwise increases the volume flow; turning the regulator anti-clockwise reduces the volume flow.

NOTE!

Perform the following steps to adjust:

0 - 2 l/min in steps of 0.1
2 - 4 l/min in steps of 0.2
4 - 6 l/min insteps of 0.5

3 The **settings** are accepted by **pressing** the **adjustment regulator again**. The input is once again acknowledged by an audible signal.

NOTE!

It may take up to 2 minutes until the actual volume flow corresponds with the setting. If the output is closed, the output pressure can increase up to 0.7bar. The maximum gas output temperature is maximum 6 degree higher than the ambient temperature.

ATTENTION!

The unit has been designed for operation at altitudes of up to 2000 m above seal level. If the unit is used beyond this specification, compliance with the specified performance data can no longer be guaranteed.

8.3 Alarms

WARNING! Risk of health damage!

If an alarm cannot be switched off by applying certain countermeasures, you should immediately change over to an alternative oxygen supply (e.g. oxygen cylinder). You should also immediately contact the customer service of the manufacturer.

8.3.1 Alarm priorities

We differentiate between three alarm priorities:

Alarm priority	Description
High priority:	**WARNING! Risk of health damage!** **Immediate countermeasures required to save the patient from any harm.**
Medium priority:	Quick countermeasures by the user are required.
Low priority:	Utmost attention of the user is required.

NOTE!

The alarm priorities can audibly be differentiated by different alarm sound sequences. With a higher priority the number of alarm signals per unit of time increases.

NOTE!

Some acoustical alarms can be permanently inhibited by the setting in the PC service program.

8.3.2 Alarm categories

Alarm category / LC display	Description
Temperature alarm 	**High priority** The operating temperature inside the concentrator is too high. **Countermeasures:** – The unit should be switched off immediately. – Check whether the air flow into the unit is restricted. Also make sure that the unit has a sufficient clearance to other objects (wall, cupboard, etc.). – It may be necessary to replace the coarse dust filter in the back wall of the unit. Further information concerning this matter can be found in the section "Maintenance". *NOTE!* *The oxygen supply is immediately stopped to protect the patient. However, the compressor keeps on running.*

Alarm category / LC display	Description
Mains failure alarm 	**High priority** The power supply for the unit is interrupted. This causes immediate function failure of the Kröber O2! **Countermeasures** The following should be checked: – Is the mains lead properly plugged into the socket? – Has a fuse tripped? Check the fuse, replace if necessary. *NOTE!* *Further information concerning checking the equipment fuse of the Kröber O2 can be found in section "Maintenance".* **Note** If a function test concerning the mains failure alarm is to be performed, you should proceed as follows: – Pull the mains plug out of the socket. – Switch on the unit. The alarm works, if it is activated during the switch-on self-test. *NOTE!* *If the alarm is triggered again after switching on, you should inform the service department.*
Lack of oxygen alarm 	**Medium priority** The oxygen concentrator Kröber O2 is equipped with an innovative multi-function sensor to monitor the oxygen concentration of the oxygen output. If this drops below 60%, the lack of oxygen alarm is triggered. **Countermeasures** – Check humidifier and hoses for leaks – Inform the customer service. *NOTE!* *The **acoustical** oxygen failure alarm can be inhibited by the setting in the PC service program.*

Alarm category / LC display	Description
Oxygen status alarm 	**Low priority** The oxygen concentrator Kröber O2 is equipped with an innovative multi-function sensor to monitor the oxygen concentration of the oxygen output. If this drops below 82%, the oxygen status alarm is triggered. **Countermeasures** – Check humidifier and hoses for leaks – Inform the customer service. *NOTE!* *The **acoustical** oxygen failure alarm can be inhibited by the setting in the PC service program.*
Sensor alarm 	**Medium priority** There is a malfunction of the multi-function sensor, quantity and concentration of oxygen cannot be determined with sufficient accuracy. **Countermeasures** – Inform the customer service. – Check whether the accessories are correctly connected.
System alarm 	**High priority** Micro-processor fault. **Countermeasures** – Switch off the unit immediately and inform the customer service. NOTE! *Output and generation of oxygen is stopped for safety reasons.*

Alarm category / LC display	Description
Volume flow alarm 	**Medium priority** The actual volume flow does not match the setting. **Countermeasures** – Check whether the oxygen hose is buckled or squeezed. – Check whether the accessories are correctly connected. *NOTE!* *If the volume flow output is too high, the output and generation of oxygen is interrupted for safety reasons.* *NOTE!* *The **acoustical** volume flow alarm can be inhibited by the setting in the PC service program.* *A high volume flow alarm will always be activated.*

WARNING! Risk of health damage!

Before resuming operation of the unit make sure that fault and cause of fault have been rectified professionally.

9 Maintenance

9.1 Safety

WARNING! Danger of electric current!

Before starting cleaning the unit must be switched off and disconnected from the mains supply.

9.2 General notes

Cleanliness is a prerequisite for the success of an oxygen therapy at home. The specified cleaning intervals must therefore strictly adhered to!

The following notes on maintenance correspond with the recommendations of the professional association SPECTARIS$^{med.}$

9.2.1 Cleaning

– The unit should be cleaned with a damp (not wet) cloth, so that not fluid can enter.

– You should only use commercial cleansing agents (e.g. washing-up liquid).

– Aggressive cleansers must not be used under any condition!

9.2.2 Disinfecting

– Any commercial disinfectant can be used for disinfecting. An up-to-date list is available from the manufacturer.

– The information for use issued by the disinfectant manufacturer must be strictly complied with.

9.3 Maintenance plan

Maintenance and cleaning work must be performed at regular intervals as specified in the table below.

Interval	Cleaning work
daily	The **humidifier** must be cleaned and disinfected every day.
daily (in case of stationary or ambulant use)	**Nasal cannula** should be disposed of and replaced every day.
daily (when used in homes or for nursing care)	Clean the **nasal cannula**.
weekly	If the "**Set for external humidification**" is used, it must be cleaned and disinfected every week.
every 14 days **earlier if necessary**	The **Kroeber O2** must be cleaned with a damp cloth and disinfected after.
every 4 weeks	Replace the **coarse dust filter**
every 4 weeks (when used in homes or for nursing care)	Replace the **nasal cannula**.
annually / after 5000 operating hours	Replace the **air intake filter** *NOTE!* *With extremely dirty ambient air the filter must be changed earlier.*
with changing patients	The **Kroeber O2** must be cleaned with a damp cloth and disinfected after.
with changing patients	Replace the **humidifier**.
with changing patients	Replace the **coarse dust filter**
with changing patients	Replace the **air intake filter**
with changing patients	If the "**Set for external humidification**" is used, the

Interval	Cleaning work
	bracket must be cleaned and disinfected.
with changing patients	Replace the **nasal cannula**. **WARNING! Health risk!** **In order to avoid cross infection, each user of the Kröber O2 should wear his/her own nasal cannula.**
after infections	After an infection a new **nasal cannula** should be used to prevent re-infection.
after service work	The **Kroeber O2** must be cleaned with a damp cloth and disinfected after.
after service work	**Nasal cannula** should be disposed of and replaced by a new one.
after service work	Replace the **coarse dust filter**
after service work	Replace the **air intake filter**.

Interval	Inspection
annually	Safety inspection

9.4 Maintenance work

Maintenance work	Description
Cleaning the humidifier	**1** Unscrew the humidifier from the angle connection **2** Unscrew the lid from the humidifier and pour out any water residues **3** Clean the humidifier with clear, warm water **4** Disinfect the humidifier as instructed **5** Fill fresh, distilled water into the humidifier **6** Turn the lid back on **7** Fasten the humidifier on the angle connection *NOTE!* *When changing patients the humidifier must be disposed of.* **Sterile water system** If the Kröber O2 is used with a sterile water system, the following must be observed: – Sterile water systems must not be cleaned and refilled. – The old water flask must be disposed of. – The information provided by the sterile water producer (package insert) must be observed!
Cleaning the nasal cannula	**1** Disconnect the hose of the nasal cannula from the Kröber O2. **2** Clean the nasal cannula in warm soapsuds. You may alternatively use a weak acetic solution (10% vinegar, 90% water). **3** Rinse the nasal cannula with lots of clear water. **4** Let the nasal cannula dry in air. The nasal cannula may only be used again for the therapy after it has properly dried.

Maintenance work	Description
Replacing the coarse dust filter	**1** Remove the coarse dust filter cover/bracket from the back of the Kröber O2. **2** Remove the coarse dust filter and place a new filter into the bracket. **3** Reattach the coarse dust filter cover.
Replacing the air intake filter	**1** Open the service flap. **2** Pull the old air intake filter with a slight twist off the filter off the filter holder. **3** Plug the new filter element on. **4** Close the service flap.
Checking the **equipment fuse**	**WARNING! Danger of electric current!** **Before checking the fuse switch off the unit and pull the mains plug out of the socket.** **1** Open the service flap. **2** Apply slight pressure and turn the fuse cover anti-clockwise. **3** Remove the fuse. **4** Inspect the fuse visually. **5** If necessary replace the fuse **6** Reinstall the fuse

10 Spare parts

ATTENTION!

The intended use of the equipment is only possible when using approved accessories. The use of accessories that have not been designed for use with this unit, can severely affect the performance of the unit.

The following article numbers should be used when ordering:

Article number	Designation
KRO2.01	Instructions for use for Kröber O2
KRO2.02	Angle connector for humidifier
KRO2.03	Set for external humidification
KRO2.04	Hose connection with cap nut
KRO2.05	Bracket for humidifier
KRO2.06	Humidifier, for refilling
KRO2.07	Nasal cannula
KRO2.08	Nasal cannula, 5 m
KRO2.09	Coarse dust filter for Kröber O2
KRO2.10	Air intake filter
KRO2.11	Bacteria filter

11 Appendix

11.1 EMC regulations

11.1.1 Electromagnetic compatibility, interference emission

Regulations and declaration of manufacturer - Electromagnetic compatibility, interference emission		
The Kröber O2 is intended for use in an environment as described below. The operator of the Kröber O2 must make sure that the unit is operated in such an environment.		
Measurement of interference emission	**Compatibility**	**Electromagnetic environment - regulations**
HF emissions acc. to CISPR 11	Group 1	The Kröber O2 uses HF energy solely for its own function. The HF emission is therefore very low and any interference with adjacent electronic equipment is very unlikely.
HF emissions acc. to CISPR 11	Class B	The Kröber O2 is intended for use in all facilities, including living quarters and other environments that are connected to the public supply network, which also supplies buildings used for the purpose of living.
Emission of harmonics acc. to IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flickers acc. to IEC 61000-3-3	compatible	

Table 1: Electromagnetic compatibility, interference emission

11.1.2 Electromagnetic compatibility, interference emission

Regulations and declaration of manufacturer - Electromagnetic compatibility, interference emission			
The Kröber O2 is intended for use in an environment as described below. The operator of the Kröber O2 must make sure that the unit is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Compatibility level**	**Electromagnetic environment - regulations**
Discharge of static electricity acc. to IEC 61000-4-2	±6 kV contact discharge ±8 kV Air discharge	±6 kV contact discharge ±8 kV Air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic materials, the relative humidity must be at least 30%.
fast transient electric interference/bursts acc. to IEC 61000-4-4	±2 kV for mains leads ±1 kV for input/output leads	±2 kV for mains leads ±1 kV for input/output leads	The quality of the supply voltage should match the typical office or hospital environment.
Surge voltages acc. to IEC 61000-4-5	±1 kV Push-pull	±1 kV Push-pull	The quality of the supply voltage should match the typical office or hospital environment.
Voltage dips, short-term interruptions and fluctuations in supply voltage IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for ½ period	limited functionality	The quality of the supply voltage should match the typical office or hospital environment. NOTE: U_T is the a.c. supply voltage before application of the test levels
	40 % U_T (60 % dip in U_T) for 5 periods	Mains failure alarm Restart of unit	
	70 % U_T (30 % dip in U_T) for 25 periods	limited functionality	
	<5 % U_T (95 % dip in U_T) for 5 s	Mains failure alarm Restart of unit	
Magnetic field at a supply frequency (50 Hz) acc. to IEC 61000-4-8	3 A/m		Magnetic fields at mains frequency must comply with the typical values found in office or hospital environments.

Immunity test	IEC 60601 test level	Compatibility level	Electromagnetic environment - regulations
			Portable and mobile radio equipment should not be used closer to the Kröber O2 and the leads, than the safety distance calculated by using the equation applicable for the transmission frequency. Recommended safety distance:
radiated HF interference acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d= 1.2 √P for 80 MHz to 800 MHz d= 2.3 √P for 800 MHz to 2.5 GHz

Immunity test	IEC 60601 test level	Compatibility level	Electromagnetic environment - regulations
directed HF interference acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	d= 1.2 √P with P being the rated power of the transmitter in Watt (W) acc. to the specifications of the transmitter manufacturer and d being the recommended safety distance in metres (m). According to an in-situ examination [a] the field intensity of stationary radio transmitters is with all frequencies lower than the compatibility level [b]. In environments marked with the following symbol interferences are possible:
NOTE 1 For 80 MHz the higher value is valid. NOTE 2 These regulations may not apply in all situations. The propagation of electromagnetic waves is influenced by the absorption and reflection by building, objects and persons.			
[a] The field intensity of stationary transmitters, such as base stations of radiophones and land mobile services, amateur stations, AM- and FM-radio and television stations can theoretically not be exactly predetermined. In order to determine the electromagnetic environment and the effect of stationary HF transmitters, it is recommend to examine the corresponding location. If the detected field intensity at the location of the Kröber O2 exceeds the compatibility level specified above, the Kröber O2 must be examined at a different location, with respect to its normal operation. If unusual performance characteristics are detected, it may be necessary to apply additional measures, such as reorientation or relocation of the Kröber O2. [b] Beyond the frequency range from 150 kHz to 80 MHz the field intensity is less than 3 V/m.			

Table 2: Electromagnetic compatibility, interference emission

11.1.3 Recommended safety distances

Recommended safety distances between portable and mobile HF communication equipment and the Kröber O2			
The Kröber O2 is intended for operation in an electromagnetic environment with controlled HF interferences. The customer or user of the Kröber O2 can help to avoid electromagnetic interferences by maintaining minimum distances between the portable and mobile HF communication equipment (transmitters) and the Kröber O2, according to the maximum output power of the communication equipment, as recommended below .			
Rated power of transmitter W	Safety distance acc. to transmitting frequency m		
	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters for which the rated power is not contained in the tale above, the distance can be calculated using the equation for the corresponding column, whereby *P* represents the rated power of the transmitter in Watt (W), specified by the transmitter manufacturer. NOTE 1 For calculation of the recommended safety distance for transmitters in the frequency range from 80 MHz to 2.5 GHz an additional factor of 10/3 was used, in order to reduce the likelihood that a mobile/portable communication unit, that has unintentionally been brought near the patient, will trigger an interference. NOTE 2 These regulations may not apply in all situations. The propagation of electromagnetic waves is influenced by the absorption and reflection by building, objects and persons.			

Table 3: Recommended safety distances

11.2 Explanation of symbols on the unit

Symbol	Meaning
	Attention, observe the information in the instructions for use.
	Application part type BF
	Degree of protection II
CE 0197	Nominated authority: TÜV Rhineland
I / O	On/Off switch

12 Index

A

Accessories 40
Accident 16
Adjusting the oxygen volume flow 29
Air intake filter 18
Alarms 30
Angle connection 17
Assembly 22, 24

C

Carrier handle 17
Choosing the location 23
Cleaning intervals 35
Cleanliness 35
Coarse dust filter 17
Control panel 17
Copyright protection 11

D

Dangers 13, 16
Declaration of Manufacturer 8
Design 17
Disinfecting 35
Display 17

E

EMC 15
EMC regulations 41
Entry of air 23
Equipment fuse 39
Explanation of symbols on the unit 46

F

Fire hazard 14
Funktion 17
Fuses 18

G

General description 17

H

HF communication equipment 15
Hose fire 16
Humidifier 17

I

Instructions for use 7

L

Liability 9
Location 15

M

Mains lead 17
Maintenance 35
Maintenance plan 36
Maintenance work 38
Medical Product Law 6
Mobile phones 15

O

Operation 28
Oxygen 14
Oxygen concentrator 6
Oxygen cylinder 13
Oxygen economy system 13
Oxygen supply 6

R

Regulator 17
Replacement delivery 9

S

Safety 12
Safety during maintenance 35
Service flap 18
Side effects 6, 13
Spare parts 40
Steerable castors 17
Sterile water system 38
Storage 21
Switch 17
Symbols 10

T

Technical data 19
Transport 21
Transport carton 21
Transport damage 21
Transport inspektion 21

V

Volume flow 17

W

Warranty 9
Waste disposal 11