

Instructions for use Kröber O2 Kröber O2 Vers. 4.0







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Dok-ID: TD072508 R17 Version: EN TW 22.02.2022







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1 Preliminary statement

Your doctor has determined that you need an additional oxygen supply. With the Kröber O2/

Kröber O2 Version 4.0 you have received a German brand for oxygen supply which has been developed according to the latest findings in both medical technology and electronics. Constant quality controls guarantee a constant quality at the highest level.

The **Kröber O2/Kröber O2 Version 4.0** is a reliable oxygen concentrator, which is intended for use at home or in hospitals.

If you still have problems with the **Kröber O2/Kröber O2 Version 4.0**, you can always contact your dealer.

This medical device carries the CE mark according to MDD (Medical Device Directive).

Use the Kröber O2 only according to the medical indication and only in accordance with the medical prescription and the instructions for use.

If any side effects or severe limitations of well-being occur during therapy, please consult your doctor immediately.

In the further course of the instructions for use, only the **Kröber O2** oxygen concentrator is indicated, which is identical in operation to the **Kröber O2 Vers. 4.0**.

Any differences in the technical specifications are marked where applicable.

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 in installation, operation, maintenance and cleaning.

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

2.2 Type plate

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

2.3 Liability

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.

2.4 Warranty

We grant, in excess of the implied warranty the following extended warranty:

Warranty terms: maximum 30,000 operating hours or 5 years from the date of purchase on all functional parts (e.g. compressor, electronic circuit board, solenoid technology, etc.). The first reached condition (30.000 hours or 5 years) applies.

Condition precedent to the extended warranty is the periodic maintenance according to the Technical Service Manual.

Extent of warranty: the free-of-charge replacement of defective parts. The defective parts must be submitted to us for inspection of warranty claims. For processing the warranty claim,

the serial number as well as date of purchase and the operating hours of the affected device must be stated. If devices are sent to us for warranty repair free of charge, we will also cover the labor costs for any warranty repairs.

Locally resulting travel and service expenses are not covered by us.

Excluded from this warranty are: filters and zeolites, damage from improper handling and mechanical damage of parts (e.g.transport damage).

2.5 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.



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.

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 nondisrupted operation of the unit.

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2.6 Copyright protection

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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.

2.7 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.
- Do not dispose of the unit into the domestic household waste.
- Non-infectious used accessories (e.g. nasal cannula) can be disposed of 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.

2.8 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 7.30 a.m 4.00 p.m., Fri 7.30 a.m 2.00 p.m.
Address:	Kröber Medizintechnik GmbH Salzheck 4 D-56332 Dieblich Germany
Phone:	+49-2607-94040
Fax:	+49-2607-940422
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.

The Kröber O2 oxygen concentrator may only be used if the present operating instructions have been read and understood before commissioning the device and if instruction has been given by trained personnel (service technicians, etc.). 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 Operators 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 device is only guaranteed if it is used as intended in accordance with the information in the operating instructions.

The mains-operated, transportable Kröber O2 or Kröber O2 Vers. 4.0 oxygen concentrator is intended exclusively for use as part of a non-life-sustaining and non-life-supporting medical therapy for supplementary oxygen supply, e.g. as part of long-term oxygen therapy. The patient is intended to be the operator, and the device may only be operated by a previously instructed adult. It may be used on infants (at least 2 years of age) up to adults.

The patient is intended to be the operator, and the device may only be operated by a previously instructed adult. It may be used on infants (at least 2 years of age) up to adults. Its use in this context may be in both domestic and professional settings such as clinics, nursing homes and other healthcare facilities.

The Kröber O2 has been designed for both professional users and laypersons.



The device may only be used according to medical indications and only in accordance with the doctor's prescription and the operating instructions.

Intended use also includes following the assembly instructions as well as the instructions for cleaning and maintaining the device.

Any further and/or different use of the device is stated below and is not considered as intended use! Claims of any kind against the manufacturer and/or his authorised representatives for damage resulting from improper use of the device are excluded. The operator is solely liable for all damage resulting from improper use. This also applies to the use of non-approved application parts, such as oxygen safety hoses, nasal cannulas and masks, other parts and accessories.

3.4 Contraindications

Kröber Medizintechnik are not aware of any contraindications for the Kröber O2 oxygen concentrator.

3.5 Mode of operation

The Kröber O2 concentrates the oxygen contained in the ambient air by means of the socalled pressure swing adsorption process, in which the nitrogen present is separated from the rest of the ambient air drawn in and the residual mixture is made available to the patient (see chapter 5 O2 concentration).

3.6 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 savings 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! Do not modify your device. You can endanger your health.

WARNING! Choking hazard!!

Children can choke or suffocate small parts (such as the FireSafe[™] check valve). Adult supervision required.



Newborns and infants are not allowed to use the device!

ATTENTION: Danger of damage to health due to phtalate-containing accessory components!

With many phthalates an impairment of the male reproduction is either proven or there is a strong suspicion. Damage to the liver, the nervous and immune systems and increased occurrence of overweight and insulin resistance cannot be ruled out.

Phthalates can penetrate the placental barrier and damage a child in the womb. Children in particular, whose organisms are still developing, are increasingly absorbing phthalates from toys or floor coverings.

If children and pregnant or nursing women use this medical device, it is recommended to use phthalate-free accessory components such as O2 tubes or nasal cannulas. Phthalates also increase the risk of allergies and asthma in pregnant women and children.



WARNING! Danger of damage to health!

For geriatric, pediatric or any other patient who is unable to communicate, complaints may require additional monitoring and/or a distributed alarm system to pass information about the complaints and/or medical urgency to the appropriate caregiver to avoid harm!



WARNING! Danger of side effects!

If side effects or severe limitations of well-being occur during therapy, a doctor should be consulted immediately.

Under certain circumstances, long-term oxygen therapy can be dangerous. Before using the Kröber O2, seek medical advice.

To ensure a therapeutic amount of oxygen delivery according to your medical condition, Kröber O2 may only be used,

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- after one or more settings have been individually determined or specified according to your activity level,

- Only use in the specified combination with parts and accessories that comply with the manufacturer's specification and have been determined when determining your settings.



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!
- Follow all mandatory instructions for installing and use of fire-reducing equipment such as the angular connector and Firesafe[™] check valve.
- 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 during oxygen therapy is dangerous and may cause burns to the face or even death. Oxygen has a strong fire-supporting effect. Never smoke when using your oxygen concentrator or near a person undergoing oxygen therapy. Smoking while wearing nasal cannulas can cause oxygen fires, which can lead to a fire in the tube and ultimately in the oxygen device. For this reason, smoking is not permitted in the same room as the oxygen concentrator or oxygen-carrying accessories.

If you wish to smoke, you must always switch off the Kröber O2, remove the nasal cannula and leave the room where either the nasal cannula or the mask or the oxygen concentrator is located. If you are unable to leave the room, wait at least 10 minutes after turning off the oxygen concentrator before smoking.

- There is a risk of fire associated with the enrichment of oxygen during oxygen therapy. Do not use the oxygen concentrator and its accessories near sparks or open flames.
- Open flames during oxygen therapy are dangerous and may result in fire or death. Open flames within 2 m of the oxygen concentrator or accessories containing oxygen are not permitted.
- After a stay in a potentially oxygen-enriched atmosphere, the clothing must be ventilated very carefully, as the oxygen adheres very well to the clothing! A source of ignition, e.g. a burning Zi-garette, could cause a clothing fire.
- Materials that do not burn in air can burn very vividly or even spontaneously in oxygen or oxygen-enriched air. This already applies to an enrichment of a few percent!
- Before and during oxygen therapy, only use water-based lotions or ointments that are compatible with oxygen. Never use lotions or ointments based on paraffin oil or oil to avoid the risk of fire or burns!

- Do not lubricate fittings, connections, hoses or other accessories of the Kröber O2 in order to avoid the RISIKO of fire or burns!
- Oxygen increases the temperature of a flame as well as the combustion speed considerably!
- Never fill flammable liquids into the humidifier!
- Oxygen facilitates the outbreak and spread of fire. Do not leave the nasal cannula or mask on bedspreads or chair cushions when the oxygen concentrator is switched on and not in use; the oxygen makes the material flammable. Switch off the oxygen concentrator when not in use to avoid oxygen accumulation.



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 vicinity of the Kröber O2 as close as 3.5 m.



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
- Place the Kröber O2 oxygen concentrator in a well ventilated place.
- The Kröber O2 oxygen concentrator must not be used directly beside or even stacked with other equipment.

ATTENTION! Avoid overheating!

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

ATTENTION! Air pollution!

Only install the oxygen concentrator where it is not affected by air pollution or smoke.

ATTENTION! Ensure simple device isolation! Place the KröberO2 such that a simple isolation by disconnecting the power cable from the mains electricity can be carried out!

• ATTENTION! No maintenance during operation! No maintenance or service must be carried out during operation of the KröberO2!

ATTENTION! Accessories containing phthalate!

If children and pregnant or nursing women use this medical device, it is recommended to use phthalate-free accessory components such as O2 tubes or nasal cannulas. Phthalates increase the risk of allergies and asthma in pregnant women and children.

ATTENTION! System formation!

The responsible organization is responsible for ensuring that all components of the system are compatible with each other. This must be checked before first use.

3.7 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 has been optimized for the oxygen supply at home.

The **Kröber O2** concentrates the oxygen contained in the ambient air by means of the socalled pressure swing adsorption process by separating the nitrogen present from the rest of the ambient air drawn in. The residual mixture is made available to the patient with up to 95% oxygen concentration and from 0.2 to 6 litres per minute (Kröber O2) or from 0.2 to 5 litres per minute (Kröber O2 Vers. 4.0).

12	Design: 1 Carrier handle
	2 Control panel
3-	3 Angular connector O2 outlet
4	4 Humidifier
5	5 Steerable castors
3 50	
Fig. 1: Front	
	6 Mains lead
6 7	7 Coarse dust filter
Fig. 2: Back	

4.2 Design







5 Technical data

Model	Kröber O2	KröberO2 Version 4.0
Classification acc. to MDD	Ila, Rule 11	
Operating voltage	110/120 V, 60 Hz	
Storage and transport conditions	Temperature: -25 - +70 °C Humidity: 15% - 93 % (r.H. non-condensing) Atmospheric pressure: 700 - 1060 mbar	
Operating conditions	Temperature: +5 - +40 °C Humidity: 15% - 93 % (r.H. non-condensing) Atmospheric pressure: 700 - 1060 mbar Altitude: 0 – 3000m	
Noise level ¹	35 dB(A) ²	31,1 dB(A) ²
Power input	350 VA	295 VA
Fuses (internal)	1 x T6,3A H 125V, 5 x 20 mm, 1 x T1,0A, L 250 V, 5 x 20 mm Self-resettable temperature fuse compressor compartment 75°C	
Weight	18,8 kg	17,1 kg
Dimensions (HxBxT)	53,5 x 20,3 x 52 cm	
O2-concentration (min.)	$0,2 - 5$ l/min. $93\% \pm 3\%$ 5 - 6 l/min. $90\% \pm 3\%$ internal O2 concentration measuren temperature and pressure	$0,2 - 4$ l/min. $93\% \pm 3\%$ $4 - 5$ l/min. $90\% \pm 3\%$ nent under conditions of operating
min. recommended volume flow ³	0.2 l/min	
max. recommended volume flow ³	6 I/min	5 l/min
Volume flow (@ max. I/min) ³	 @ 0 kPa counter pressure: 6 l/min @ 7 kPa counter pressure: 6 l/min 	 @ 0 kPa counter pressure: 5 l/min @ 7 kPa counter pressure: 5 l/min
max. output pressure:	55 kPa (normal), 275 kPa (failure)	
IP-Classification	IP 21	

1 For the Kröber O2 0 the sound pressure level according to ISO 80601-2-69 is 39,4 dB(A) @ 3l/min and 43,3dB(A) @ 6l/min. The sound power level is 53,7 dB(A) @ 3l/min and 55,9dB(A) @ 6l/min.

For the Kröber O2 Version 4.0 the sound pressure level according to ISO 80601-2-69 is 37.7 dB(A) @ 31/min and 40.7 dB(A) @ 51/min. The sound power level is 50.9 dB(A) @ 31/min and 52.4dB(A) @ 51/min.

2 Data according to test method 14-1 03/2007 MDS-Hi, quality requirement for inclusion in the catalogue of remedies and aids

3 Volume flow data with: Room temperature and air pressure, dry air.



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 and dust-free environment. Relative humidity: max. 93 % without condensation.
- 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 -25 to +70°C.
- Avoid mechanical shocks and damages.

6.3 Acclimatisation periods

If you expose the unit to large temperature fluctuations, appropriate acclimatization periods must be observed to avoid the formation of condensation. Also note that acclimatization times may vary depending on temperature and humidity. Possible acclimatization times can be found in the table below:

Temperature difference in °C	duration in hours	Temperature difference in °C	duration in hours
10	1	40	4
20	2	50	5
30	3	60	6



7 Taking into service

7.1 Before assembling

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



Contact the manufacturer or the local service provider if help is needed during operation or maintenance. The address of the manufacturer can be found on page 9. The a.m. organisations should also be contacted in case of unexpected events or incidents.



After unpacking the device, the transport or storage temperature may have to be adjusted to the operating temperature. Before switching on, the waiting times according to Chapter 6.3 (Acclimatization times) must be observed.





	 5 Nasal cannula for oxygen 2m 6 Nasal cannula for oxygen 5m 7 Oxygen safety hose 15m 8 Stand for humidifier 9 Oxygen safety hose 0.33m 10 Angular connector 11 Hose connector "Christmas tree style"
Fig. 7: Scope of delivery 3	System, ready for operation a. Oxygen concentrator b. Humidifier c. 0.33 m safety hose d. Firesafe valve e. 2 m oxygen nasal cannula f. Mains connection

NOTE!

Only use the supplied administration accessories, such as nasal cannulas, tubes and especially humidifiers.

The use of accessories not specified for use with the oxygen concentrator may affect its performance.

The responsible organization is responsible for ensuring compatibility of the oxygen concentrator with all parts or accessories used to connect to the patient before use.

7.2 Choosing the location

Please consider the following when choosing the location:

- The unit should have 30 cm 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.
- The unit should be operated only in places where it is not impaired by air pollution or smoke.
- Always position the device on a horizontal surface.

NOTE!

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

ATTENTION! Ensure a sufficient air supply!

Ensure that the air inlet of the Kröber O2 oxygen concentrator is located in a well-vented spot. Ensure sufficient distance to walls etc.!

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.! Set up the Kröber O2 oxygen concentrator so that the air inlet and the outlet are in a well ventilated area.

ATTENTION! Ensure simple device isolation!

Place the KröberO2 such that a simple isolation by disconnecting the power cable from the mains electricity can be carried out!

ATTENTION! Air pollution!

Only install the oxygen concentrator where it is not affected by airborne contamination, such as particles and dust, or by smoke! In general, the unit should be installed in a low-pollutant area.

ATTENTION: Humidity!

Do not install the oxygen concentrator in damp rooms!

ATTENTION: Observe ambient conditions!

When using this device above an altitude of 3000 m above sea level or outside a temperature of +5 to +40°C or above a relative humidity of 93%, an adverse effect on the volume flow and the percentage of oxygen is to be expected and consequently an impairment of the quality results of the therapy!

Attention! Light and sunlight!

Only place the oxygen concentrator where it is not exposed to a direct light source/heat source, such as direct sunlight!

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.

The FireSafe Nozzle is a thermal fuse designed to stop the flow of oxygen in the event that the downstream PVC tube is ignited. In doing so, the fire in the PV tube is inclined to extinguish because PVC will not normally burn in air. The FireSafe Nozzle is fitted directly to the outlet of each oxygen delivery device, typically an oxygen flowmeter or the outlet of an oxygen concentrator!

Read through this entire chapter before installing this FireSafe Nozzle. As with all medical equipment, attempting to use or install this device without a thorough understanding of its operation and limitations may result in patient or user injury

1. This device is intended to be fitted to the outlet of a medical oxygen or oxygen concentrator where breathing circuits that have low static operating pressures not exceeding those stated in the device specification. It must not be used for other applications.

2. Do not install this device near an open flame or near a source of excessive heat that is likely to exceed 40°C.

3. Oxygen is not flammable but the presence of oxygen will drastically increase the rate and severity of combustion. Oil and/or grease in the presence of oxygen become highly combustible. Do not use oil or grease on this device. In particular, do not lubricate the seals or hose barb connector!

4. Never administer oxygen or undertake oxygen therapy while smoking or when near an open flame.



7.3.1 Without external humidification

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







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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.

Oxygen safety tubes and nasal cannulas should always be laid in such a way that they do not represent any tripping or strangulation traps for third parties!



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. 18. Oxygen outlet connector	4 Connect the 15m-oxygen safety tubing to the connector. WARNING! Danger of strangulation! Ensure that the hose is laid without loops to avoid strangulation.
1 Eig 19 Humidifier Max -mark	 Fill the humidifier up to the top MAXmark (1). ATTENTION! Sterility! To ensure an adequate level of sterility, use always boiled water!
Fig. 20. Humidifier assembly	 6 Screw the angle adapter (1) to the humidifier. 7 Plug the 15 m safety hose for oxygen (extension hose) onto the angle adapter (2). 8 Push the 0.33-m safety hose for oxygen onto the outlet connector of the humidifier (3).



Fig. 21: Humidifier bracket	 9 Stand the humidifier into the bracket (1). 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.
Oxygen hose	10 Insert the FireSafe valve into the connection of the short O2 safety hose.
	ATTENTION! For the best protection of the patient, place the FireSafe Nozzle in the oxygen tubing routing as close to the patient as possible!
Nasal cannula Fig. 22: Connection to the nasal cannula	11 Attach the oxygen nasal cannula to the other side of the FireSafe valve.
Fig. 23: Connection to the nasal cannula	 12 Completely assembled system a. Oxygen concentrator b. Adapter c. 15 m O2 safety hose d. Humidifier e. 0.33 m safety hose f. Firesafe valve g. 2 m oxygen nasal cannula h. Mains connection



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.

Oxygen safety tubes and nasal cannulas should always be laid in such a way that they do not represent any tripping or strangulation traps for third parties!

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.



The adult and trained user may safely use all functions of the Kröber O2.

WARNING! Health hazard due to unsupervised operation. Pay attention to the environmental conditions for safe operation. Keep infants,

animals or pests away from Kröber O2!

8.1 Taking into service

 Start the unit by actuating the mains switch (1) on top of the unit. The Kröber O2 runs a self-test. After the self-test, the software version and then the operating hours are briefly displayed. After the self-test the oxygen production is started. Image: NOTE! The sensor and the microprocessor are automatically checked during operation. The LC-display continuously shows the current oxygen volume flow and the equipment status. Image: NOTE! After maximum 2 min, the unit will reach its complete performance according to the Technical Specifications.







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 Setting the oxygen volume flow

NOTE!

If the outlet is closed, the outlet pressure may rise to 0.7 bar. The maximum gas outlet temperature is 6 degrees above the ambient temperature.

NOTE!

The oxygen volume setting must be determined individually for each patient, taking into account the configuration of the unit and accessories.



NOTE!

The flow of the gas to the nasal cannula should be heard or felt in order to check the function of the device. Move your hand back and forth in front of the nasal cannula. If no gas flows, the connections of the nasal cannula must be checked for leaks.

ATTENTION!

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The unit has been designed for operation at altitudes of up to 3000 m above sea level. If the unit is used beyond this specification, compliance with the specified performance data can no longer be guaranteed.

8.3 Taking the device out of operation - Switching it off



8.4 Abnormal states



If an alarm cannot be eliminated by countermeasures, an alternative oxygen supply must be used immediately (e.g. an oxygen cylinder). In addition, the customer service of the manufacturer must be informed immediately.

8.4.1 Alarm priorities

Alarm priority	Description	Acoustic
Low	Increased attention of the user is required.	Beep-beep – 20 sec pause – beep-beep …

8.4.2 Alarms

Alarm type	Description
Display	

Temperature	Possible cause:
	The operating temperature inside the concentrator is too high (> 50°C).
	Countermeasures:
	 The unit must be switched off immediately.
↓ 	 Check whether an unobstructed air inlet and outlet is possible. Furthermore, it must be ensured that there is sufficient distance to objects (wall, cabinet, etc.) and to heaters, etc.
	 It may be necessary to replace the input filter in the rear panel of the unit. Further information can be found in the "Maintenance" section.
	NOTE!
	For protection, the supply of oxygen is stopped after reaching 50°C. However, the compressor continues to run.
	Checking the alarm function:
	 Close the exhaust air heat opening.
	NOTE!
	If the internal temperature exceeds 75°C, the internal temperature switch responds. The compressor is switched off, but the device continues to alarm. Switch off the device to prevent the compressor from switching on automatically after cooling down!

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Alarm type	Description
Display	
Power outage	Possible cause:
Power failure LED on No LC display	The power supply to the unit is interrupted. This leads to an immediate malfunction of the Kröber O2!
	Countermeasures
	 Is the power cord securely plugged into the wall outlet?
	 Has a home fuse been tripped? Check the fuse.
	NOTE!
	If a functional test of the power failure alarm is to be carried out, this can be done as follows:
	 Disconnect the mains plug from the socket.
	 Switch on the unit.
	Check the alarm function:
	 Disconnecting the mains plug during operation
	NOTE!
	For safety reasons, an attempt is made to interrupt oxygen release and oxygen production.
Mains undervoltage	Possible cause:
	The power supply to the unit is insufficient.
	Countermeasures
	 Use of a voltage stabilizer in areas with known voltage dips in the public supply
🛛 🚽 🖉 📕 🖊 🖊 🖊 🖊 🗌	Check the alarm function:
!	 Can only be carried out by technicians with an adjustable power supply.

Alarm type Display	Description
O2 Concentration < 82%	Possible cause:
	The Kröber O2 oxygen concentrator is equipped with a sensor that monitors the oxygen concentration of the oxygen released.
	If the average value of the oxygen concentration is less than 82% for approx. 15 seconds, this alarm is triggered - provided that the oxygen concentrator has been in operation for more than 2 minutes.
	Countermeasures
	 The Service must be notified.
	Check the alarm function:
	 Only possible by a technician.
Sensor	Possible cause:
	The sensor system does not provide reliable data repeatedly or for at least 5 s.
	Countermeasures
	 The Service must be notified.
	Check the alarm function:
	 Not possible because of self-diagnosis
	NOTE!
	After the malfunction has ended, the Kröber O2 resumes normal operation.



Alarm type Display	Description
System	Possible cause:
	There is a microprocessor error.
	The displayed number is an error code for the technician.
	Countermeasures
	 The device must be switched off and the service must be notified.
🛆 ! 🛛 🕜 Error	NOTE!
	For safety reasons, an attempt is made to interrupt oxygen delivery and oxygen production.
	NOTE!
	The displayed error code (e.g. here 80) helps the technician to diagnose the problem.
	Check the alarm function:
	 Not possible because of self-diagnosis.
Volume flow	Possible cause:
	The concentrator cannot deliver the required volume flow or the volume flow fluctuates too much.
~i i ., .	Countermeasures
	 Check whether oxygen hoses are kinked.
\land	 Check whether an oxygen hose is blocked (e.g. by a chair leg or a wheelchair wheel).
	 Check whether the humidifier has calcified.
	- Otherwise: Contact the service department.
	Check the alarm function:
_ I/min	- Reep the outlet connection closed
\bigtriangleup !	

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Alarm type Display	Description
Communication	Possible cause:
	Communication between electronic components is interrupted.
	Countermeasures
	 Restart the device.
	 If the error persists: Service must be notified.
! trror	Check the alarm function:
	 Not possible, since self-diagnosis.
Hardware	Possible cause:
	Internal hardware problems
	Countermeasures
	 Restart the device.
	 If the error persists: Notify the service department.
	Check the alarm function:
	 Not possible, since self-diagnosis.
	NOTE!
	The displayed error code (e.g. here 20) helps the technician to diagnose.

WARNING! Risk of health damage!

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



8.4.3 Alarm tone muting

Alarm type Display	Description
∃. □ × I/min	After pressing the setting knob, the audible alarm tone is suppressed for 120 seconds. The display shows the alarm suppression. This state can be reversed immediately by pressing the setting knob again. The alarm suppression is hidden in the display.



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.



The mains cable should be checked regularly for damage. A necessary replacement, which is described in the Technical Service Manual, may only be carried out by authorised service personnel.

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!

Do not use lubricants other than those recommended by the manufacturer.

External contamination of the gas path is possible due to the design from the outer gas outlet to the internal check valve including silicone tubing.

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.
- For cleaning and disinfecting the surfaces of the unit or of the equipment cart, we recommend a wipe disinfection. Adhere to the proper use instructions of the manufacturer of the disinfectant.

9.3 Maintenance plan

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

All below mentioned maintenance work may be carried out by the user. Eventually, a new spare part has to be purchased beforehand. Please contact your service provider or the manufacturer.



WARNING! Danger due to lack of authorization!

All maintenance work and in particular repairs not described in these operating instructions may only be carried out by persons who have been authorised by the manufacturer to do so in accordance with the instructions in the service manual.



WARNING! Patient as operator!

Service and maintenance must not be carried out while the device is in use.



WARNING! Risk of infection!

When oxygen delivery accessories such as nasal cannulas are used together, infection cannot be ruled out if the product is used by different users together.

Every user of the Kröber O2 should therefore use his own application set!

9.3.1 Clinical / Non-clinical Use (for the same patient)

Component	Clinical Use	Non-clinical Use
KröberO2	Weekly cleaning and disinfection	Weekly cleaning
Humidifier	Weekly cleaning and disinfe replace annually	ection
Mounting bracket for humidifier	Weekly cleaning and disinfection	Weekly cleaning
Nasal cannula	Weekly cleaning and disinfection replace monthly	Weekly cleaning replace monthly
Oxygen safety tubing	Replace every 6 months	
FireSafe check valve	Replace every 6 months	



Component	Clinical Use	Non-clinical Use
Oxygen mask	Weekly cleaning and disinfection replace monthly	Weekly cleaning replace monthly
Coarse dust filter	replace monthly	
Device inlet filter	replace annually / after 5000) operating hours

9.3.2 When changing patients

Component	
KröberO2	Cleaning and disinfection
Humidifier	Replace & dispose of
Mounting bracket for humidifier	Cleaning and disinfection
Nasal cannula	Replace & dispose of
Oxygen safety tubing	Replace & dispose of
FireSafe check valve	Replace & dispose of
Oxygen mask	Replace & dispose of
Coarse dust filter Device inlet filter Bacterial filter	Replace & dispose of

9.3.3 After technical service

Component	
KröberO2	Cleaning and disinfection
Humidifier	Replace & dispose of



Component	
Mounting bracket for humidifier	Cleaning and disinfection
Nasal cannula	Replace & dispose of
Oxygen safety tubing	Replace & dispose of
FireSafe check valve	Replace & dispose of
Oxygen mask	Replace & dispose of
Coarse dust filter Device inlet filter Bacterial filter	Replace & dispose of

Interval	Inspection
Annually	Safety inspection by an authorized service provider

9.3.4 Life times

As average life times, we expect:

Article	Life time	Shelf life/storage capacity	
Kröber O2	5 years min.	3 months, then 24 hours continuous operation	
Humidifier	1 year	5 years min.	
Oxygen tubing	6 months	5 years min.	
Nasal cannula	1 month	5 years min.	
Coarse dust filter	1 month	5 years min.	
Device inlet filter	1 year	5 years min.	



9.4 Maintenance work

All below mentioned maintenance work may be carried out by the user. Eventually, a new spare part has to be purchased beforehand. Please contact your service provider or the manufacturer.

Maintenance work	Description		
Cleaning Kröber O2	WARNING! Danger from electric current!		
	Before cleaning, switch off the appliance and disconnect		
	1 Wipe the surface of the appliance with a clean cloth.		
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	1 Disconnect the hose of the nasal cannula from the Kröber O2.		
cannula / oxygen hoses / masks	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.		
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 2	Open the service flap. Pull the old air intake filter with a slight twist off the filter off the filter holder.
	3 4	Plug the new filter element on. Close the service flap
	•	

Checking the equipment fuse	WARNING! Danger of electric current!		
	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 with the same model and rating.6 Reinstall the fuse.		

1

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.

p/n Kröber	p/n Product	Description
KRO2.01.EN KR4.01.EN		Instructions for use for Kröber O2 Instructions for use for Kröber O2 Vers. 4.0
KRO2.05	KRO2.05	Bracket for humidifier
KRO2.02	KRO2.02	Angular connector, metal
K683	K683	Angular connector, plastic
KRO2.4-1	HSA02-6	Tube connector, white
KRO2.06	HAB01-916	Humidifier, refillable, up 6 l/min, safety valve 410 mbar
KRO2.07	HSB11-S	Nasal cannula, 2 m, up to 6 l/min, up to 1 bar,
KRO2.08	HSB11-S5	Nasal cannula, 5 m, up to 6 l/min, up to 1 bar,
KRO2.10	HGF01-0-INTAKE	Intake filter
K686	HSS11-15	O2 tubing 15 m, up to 6 l/min, up to 1 bar,
K685	HSS11-2	O2 tubing 2 m, up to 6 l/min, up to 1 bar, UPHT DEHP
KRO2.07-1	HSS11-0.33	O2 tubing 0.33 m, up to 6 l/min, up to 1 bar, UPHT DEHP
KRO2.94	HSV03-FS	FireSafe, up to 6 l/min, up to 1 bar
KRO2.09	HGF02-K	Coarse dust filter, 5 pcs

The following article numbers should be used when ordering:



11 Appendix

11.1 Explanation of symbols on the unit

Symbol	Explanation
	WARNING! General warning sign
	WARNING! Electricity
!	ATTENTION
R ²	NOTE!
\triangle	ATTENTION
	Attention, observe instructions for use!
IP 21	Degree of protection for the ingress of liquids and small parts
Ŕ	Applied part type BF
	Class II



Symbol	Explanation		
C € 0197	Notified Body: TÜV Rheinland LGA Products GmbH		
Ι/Ο	On / Off		
	Do not smoke!		
	No open fire!		
	No oil or grease!		
\bigotimes	Do not remove any covers!		
	Do not dispose of in household waste!		
	Manufacturer		
	Manufacturing date		
SN	Serial number		



Symbol	Explanation
	Temperature alarm (LCD symbol)
	Mains voltage alarm (LCD symbol)
O ₂	Low oxygen concentration alarm (LCD symbol)
	Operating hours (LCD symbol)
×	Alarm tone muting/Audio paused (LCD symbol)
÷	USB connection for Service (LCD symbol)
PHT DEHP	PVC parts with Phthalates (DEHP)

12 Recommended Safety Distances

Recommended safety distances between portable and

mobile HF communication devices and the Kröber O2

The Kröber O2 is designed for operation in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Kröber O2 can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile RF communication devices (transmitters) and the Kröber O2 as recommended below according to the maximum output power of the communication device.

Transmitter rated power	Protective distance according to transmission frequency			
W	m			
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz	
	d=1.2√P	d=1.2√P	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 whose rated power is not given in the table above, the distance can be determined using the equation associated with the column, where P is the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 To calculate the recommended protective distance of transmitters in the 80 MHz to 2.5 GHz frequency range, an additional factor of 10/3 was used to reduce the likelihood that a mobile/portable communication device unintentionally introduced into the patient area would cause interference.

NOTE 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and people.

