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1 Preliminary statement

Your doctor has found that you require an additional oxygen supply. With the Kröber O2 4.0 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 4.0 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 4.0, you may contact your dealer at any time.

This medical care product from Kröber is labelled with the CE-sign according to MDD (Medical Device Directive).

Only use the Kröber O2 4.0 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 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 4.0 is attached to the back of the unit above the coarse dust filter.

2.3 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.

2.4 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.



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.

2.6 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.

2.7 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.

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 4.0 solely intended for use within the scope of a non-life sustaining 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 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! Danger caused by device modifications!

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!
- 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 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 humidifier with flammable 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 vicinity of the Kröber O2 4.0 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 4.0 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 4.0 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.

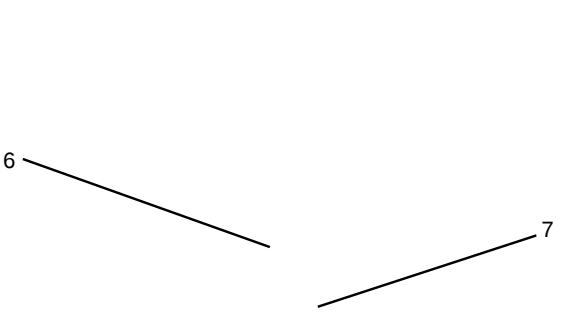
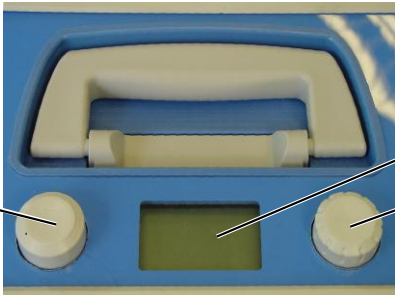
The metal connection on the oxygen outlet acts as a fire inhibitor, preventing the flames from spreading into the unit.

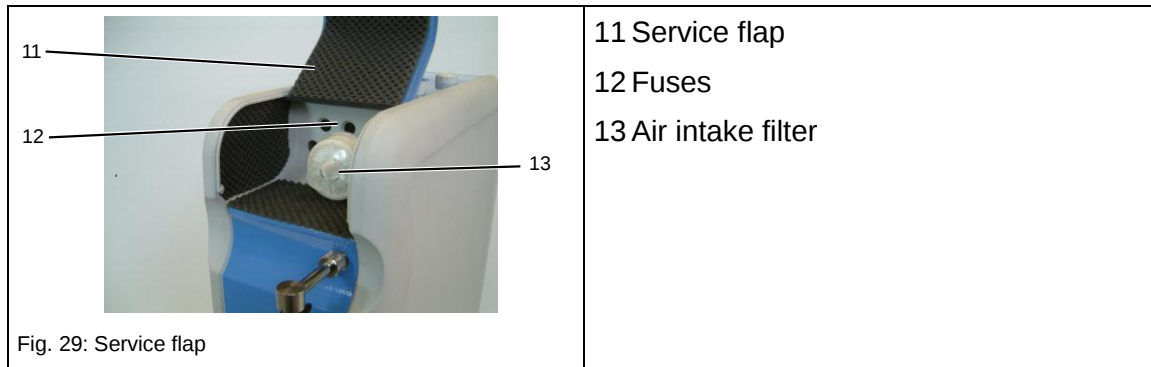
4 Design and function

4.1 General description

The Kröber O2 4.0 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. 26: Front	Design: 1 Carrier handle 2 Control panel 3 Angle connection 4 Humidifier 5 Steerable castors
 Fig. 27: Back	6 Mains lead 7 Coarse dust filter
 Fig. 28: Control panel	8 On/Off-switch 9 Volume flow regulator 10 LC display



5 Technical data

Model	Kröber O2 4.0
Classification acc. to MPG	Ila
Operating voltage	230 V, 50 Hz
Ambient operating conditions	Operation temperature: +5 to +40 °C Storage temperature: -25 to +70 °C Humidity: 15% - 93 % r.H., non-condensing Atmospheric pressure: 700 to 1060 mbar
Sound pressure level	31 dB(A)
Power input	280 W
Coarse dust filter	in back of housing
Bacteria filter	behind service flap
Fuses	mains side: 2 x T3,15 AH 250 V internal: 1 x T1,0AL 250 V
Interface	USB  WARNING! Unsafe connections! Connect only manufacturer-authorized devices to this USB port.
Weight	16 kg
Dimensions (HxWxD)	(53.5 x 20.3 x 52) cm without castors
Warranty	30.000 hours, maximum 5 years (see chapter 2.4)
O2-concentration	1 to 4 l/min. 95 % - 3 % 4 to 5 l/min. 85 % +/- 3 %
Status display O2-concentration (at operating temperature)	82% status display 60% deficiency display
max. recommended volume flow	5 l/min
Volume flow (at 0 or 7kPa)	1 - 5 l/min acc. to pre-setting
max. output pressure:	35 kPa
Overpressure relief	200 kPa (oxygen reservoir)

	250 kPa (compressor)																												
O2% characteristic, at a counter pressure of 0 kPa, O2 concentration in %, dependent from height (m)	%O2 - Volume Flow <table><tr><th>Volume flow lpm</th><th>%O2 (0 m)</th><th>%O2 (2000 m)</th><th>%O2 (4000 m)</th></tr><tr><td>0</td><td>95.0</td><td>95.0</td><td>95.0</td></tr><tr><td>1</td><td>95.0</td><td>95.0</td><td>94.5</td></tr><tr><td>2</td><td>95.0</td><td>94.5</td><td>93.0</td></tr><tr><td>3</td><td>94.5</td><td>93.5</td><td>85.0</td></tr><tr><td>4</td><td>93.0</td><td>85.0</td><td>-</td></tr><tr><td>5</td><td>85.0</td><td>-</td><td>-</td></tr></table>	Volume flow lpm	%O2 (0 m)	%O2 (2000 m)	%O2 (4000 m)	0	95.0	95.0	95.0	1	95.0	95.0	94.5	2	95.0	94.5	93.0	3	94.5	93.5	85.0	4	93.0	85.0	-	5	85.0	-	-
Volume flow lpm	%O2 (0 m)	%O2 (2000 m)	%O2 (4000 m)																										
0	95.0	95.0	95.0																										
1	95.0	95.0	94.5																										
2	95.0	94.5	93.0																										
3	94.5	93.5	85.0																										
4	93.0	85.0	-																										
5	85.0	-	-																										

6 Transport, packaging and storage

The following should be noted when transporting the Kröber O2 4.0:

- 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. 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.
- 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.



NOTE!

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 **Fehler! Textmarke nicht definiert..** The address of the manufacturer should have been disclosed during initial training on the device.

The a.m. organisations should also be contacted in case of unexpected events or incidents.

 Fig. 30: Scope of delivery 1	Unit: • Unit Kröber O2 4.0 • User manual
 Abb. 31: Scope of delivery 2	Weitere Bestandteile: 1 Coarse dust filter 2 Humidifier 3 FireSafe™ check valve 4 Angular connector
 Abb. 32: Scope of delivery 3	5 Nasal cannula for oxygen 2m 6 Nasal cannula for oxygen 5m 7 Oxygen safety hose 15m 8 Wall bracket for humidifier 9 Oxygen safety hose 0.33m 10 Angular connector 11 Hose connector „christmas tree style“

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.
- The unit should be operated only in places where it is not impaired by air pollution or smoke.



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 4.0 oxygen concentrator is located in a well-vented spot.

The Kröber O2 4.0 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.



ATTENTION!

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. This device is a flow direction sensitive device. It must be placed with respect to the correct flow direction; otherwise it is ineffective and does not protect the patient in case of fire.
3. Do not install this device near an open flame or near a source of excessive heat that is likely to exceed 40°C.
4. 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!
5. 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:

 Fig. 33: Mains lead	1 Insert the mains lead into a professionally grounded socket. ! ATTENTION! The Kröber O2 4.0 is only designed for operation on a 230 Volt, 50Hz mains network.
 Fig. 34: Angle connection	2 The metal oxygen outlet is installed using a wrench (metric size 17).
 Fig. 35: Humidifier Max.-mark	3 Fill the humidifier up to the top MAX.-mark (1).

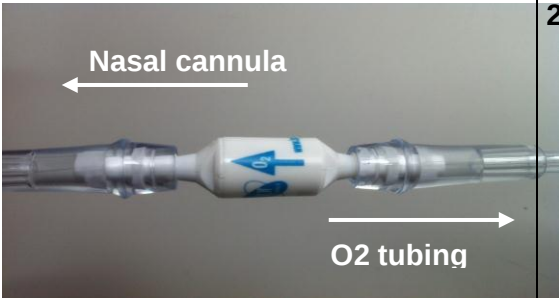
 Fig. 36: Humidifier assembly	4 Fasten the humidifier on the angular connection (1). 5 Connect the 0.33m oxygen hose to the humidifier outlet (2).
 Fig. 37: Connection to the nasal cannula	1 Plug the FireSafe Nozzle in oxygen flow direction into the nasal cannula. ! ATTENTION! Observe flow direction indicated by the arrow! ! ATTENTION! For the best protection of the patient, place the FireSafe Nozzle in the oxygen tubing routing as close to the patient as possible!
 Fig. 38: Connection with the O2 tubing	2 Connect the other terminal to the short oxygen tubing (0.33 m).



Fig. 39: Connection with the humidifier

3 Connect the oxygen tubing to the humidifier.



NOTE!

The humidifier can be used directly at the oxygen concentrator or with the kit for external humidification (near to the patient).



WARNING! Danger of tripping over!

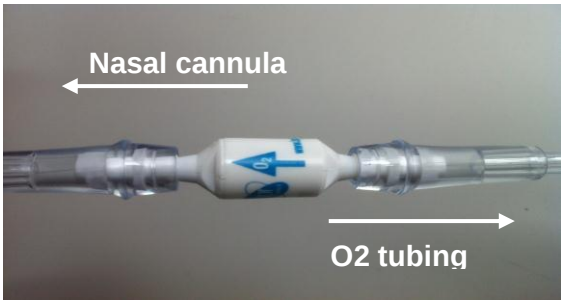
On the back of the Kröber O2 4.0 you will find a winding device for the mains lead. This should be used when the unit is out of use, to avoid any danger of tripping over.

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. 40: Mains lead	1 Insert the mains lead into a professionally grounded socket. ! ATTENTION! The Kröber O2 4.0 is only designed for operation on a 230 Volt, 50Hz mains network.
 Fig. 41: Adapter for ext. humidification	2 Screw the angle connection to the oxygen outlet of the Kröber O2 4.0 with a wrench (metric size 17).
 Fig. 42: Oxygen outlet connector	3 Connect the oxygen outlet connector.

 Fig. 43: Oxygen outlet connector	4 Connect the 15m-oxygen safety tubing to the connector.
 Fig. 44: Humidifier Max.-mark	5 Fill the humidifier up to the top MAX.-mark (1).
 Fig. 45: 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. 46: Humidifier bracket	9 Stand the humidifier into the bracket (1).  NOTE! <i>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.</i>
 Fig. 47: Connection to the nasal cannula	1 Plug the FireSafe Nozzle in oxygen flow direction into the nasal cannula.  ATTENTION! Observe flow direction indicated by the arrow!  ATTENTION! For the best protection of the patient, place the FireSafe Nozzle in the oxygen tubing routing as close to the patient as possible!
 Fig. 48: Connection with the O2 tubing	2 Connect the other terminal to the short oxygen tubing (0.33 m).



WARNING! Danger of tripping over!

On the back of the Kröber O2 4.0 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 4.0 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. 49: Control panel

- 1** Start the unit by actuating the **mains switch (1)** on top of the unit.
 - The Kröber O2 4.0 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.

After maximum 5 min, the unit will reach its complete performance according to the Technical Specifications.

During the start-up phase the unit also shows the operating hours. This information disappears after 30 seconds.

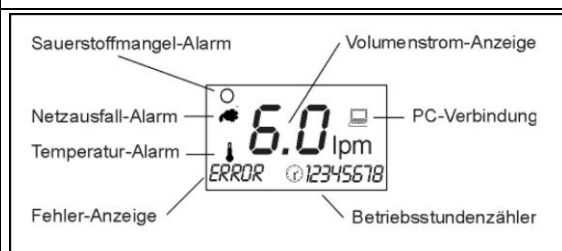


Fig. 50: LC display

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



Fig. 51: 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! Danger of strangulation!

Care for a straight oxygen hose routing to minimize the risk of strangulations!



WARNING! Skin irritations!

Care for a good fit of the nasal prongs to minimize skin irritation caused by movements and shifts of the prongs !



WARNING! Risk of health damage!

Do not smoke while operating the Kröber O2 4.0! Oxygen must NOT be used near open fire, sparks, glowing objects, etc.!

8.2 Adjusting the oxygen volume flow



Fig. 52: 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 - 5 l/min in steps 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! <i>The supplier may have restricted the available volume flow range to customized settings, such as 1 -4 lpm.</i>
--	---

 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 0.35bar. The maximum gas output temperature is maximum 6 degree higher than the ambient temperature.

 NOTE!

After adjusting the oxygen flow setting, the alarms and status messages for oxygen concentration and volume flow deviations are deactivated for approximately one minute until the unit has reached a steady state. During this period alarms are muted.

 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 Status messages and alarms

8.3.1 Status messages



NOTE!

Status messages are **NOT** accompanied with acoustical warning signals!

8.3.2 Status message

Status message / LC display	Description
Oxygen status alarm 	The oxygen concentrator oxy 6000 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! According to the specifications of the oxy 6000, the oxygen status alarm is an allowed situation and not an error state for volume flow setting of greater than 5.0 lpm.

8.3.3 Alarm priorities

We differentiate between two alarm priorities:

Alarm priority	Description
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.

8.3.4 Alarm categories

Alarm category / LC display	Description
Temperature alarm 	Medium 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! <i>The oxygen supply is immediately stopped to protect the patient. However, the compressor keeps on running.</i>
System alarm 	Medium priority Micro-processor fault. Countermeasures – Switch off the unit immediately and inform the customer service.  NOTE! <i>Output and generation of oxygen is stopped for safety reasons.</i>

Alarm category / LC display	Description
Mains failure alarm 	Medium priority The power supply for the unit is interrupted. This causes immediate function failure of the oxy 6000! 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! <i>Further information concerning checking the equipment fuse of the oxy 6000 can be found in section "Maintenance".</i> 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! <i>If the alarm is triggered again after switching on, you should inform the service department.</i>
Lack of oxygen alarm 	Low priority The oxygen concentrator oxy 6000 is equipped with an innovative multi-function sensor to monitor the oxygen concentration of the oxygen output. If it is detected that the actual concentration does not match the technical specifications, the alarm is activated. . Countermeasures – Check humidifier and hoses for leaks – Inform the customer service.

Alarm category / LC display	Description
Sensor alarm 	Low 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. – Search for kinks of the oxygen supply tubing.
Volume flow alarm 	Low 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. – Switch from longer tubing lengths to shorter tubing lengths.  NOTE! <i>If the volume flow output is too high, the output and generation of oxygen is temporarily interrupted for safety reasons.</i>



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!

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 Kröber O2 4.0 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! <i>With extremely dirty ambient air the filter must be changed earlier.</i>
with changing patients	The oxy6000 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 4.0 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 Kröber O2 4.0 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

As average life times, we expect:

Article	Life time
Kröber O2-4.0	5 years min.
Humidifer	1 year
Oxygen hoses, nasal cannula	1 month
Coarse dust filter	1 month
Device inlet filter	1 month

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 4.0 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 4.0. 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 4.0. 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
KRO240.01	Instructions for use for Kröber O2 4.0, english
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, 2 m
KRO2.08	Nasal cannula, 5 m
KRO2.09	Coarse dust filter for Kröber O2 4.0
KRO2.10	Air intake filter
KRO2.11	Bacteria filter
KRO2.94	FireSafe cannula

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 4.0 is intended for use in an environment as described below. The operator of the Kröber O2 4.0 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 4.0 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 4.0 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 2: Electromagnetic compatibility, interference emission

11.1.2 Electromagnetic compatibility, interference emission

Regulations and declaration of manufacturer - Electromagnetic compatibility, interference emission			
The Kröber O2 4.0 is intended for use in an environment as described below. The operator of the Kröber O2 4.0 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 4.0 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	$d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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}	$d = 1.2 \sqrt{P}$ 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 4.0 exceeds the compatibility level specified above, the Kröber O2 4.0 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 4.0. ^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 4.0			
The Kröber O2 4.0 is intended for operation in an electromagnetic environment with controlled HF interferences. The customer or user of the Kröber O2 4.0 can help to avoid electromagnetic interferences by maintaining minimum distances between the portable and mobile HF communication equipment (transmitters) and the Kröber O2 4.0, 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 $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
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 table 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	Explanation
	Attention, observe instructions for use!
	Attention, observe instructions for use!
IP 21	Degree of protection for the ingress of liquids and small parts
	Applied part type BF
	Class II
CE 0197	Notified Body: TÜV Rheinland LGA Products GmbH
I / O	On / Off
	Do not smoke !
	No open fire !
	No oil or grease !
	Do not remove any covers!



Do not dispose of in household waste !

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