Instructions for Use

aeroplus E

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CE 0197

1 Preliminary statement

Your doctor has found that you require an additional oxygen supply. With the aeroplus E 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 aeroplus E 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 aeroplus E, 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 aeroplus E 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

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

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 device 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 device.

2.2 Type plate

The type plate of the aeroplus E is attached to the back of the device above the coarse dust filter.

2.3 Liability and warranty

All details and notes for the operation, maintenance and cleaning of the device 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 device, 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 device!

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

2.4 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 device.

2.5 Copyright protection

This instruction for use is to be treated confidentially. It 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.

2.6 Return and waste disposal

- If the device 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 device may be returned to the dealer, who is then responsible for proper disposal of the device.
- Do not dispose of the device 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.

2.7 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 device.

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 device if it is incorrectly operated or used for purposes it is not intended for.

Any persons using this device 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 device 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 device.

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 device must be kept well legible at all times. Damaged or illegible decals must be replaced immediately.

3.2 Customer’s responsibility

This instruction for use must be kept near the device, 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 assured when used for the purpose it is intended for, as specified in the instructions for use.

The aeroplus E concentrates the oxygen contained in the ambient air by the so-called pressure swing adsorption process while the existing nitrogen is separated from the rest of the intake ambient air and the rest of the mixture is provided to the patient with up to 95% oxygen concentration and from 0.5 to 5 liters per minute.

The aeroplus E solely intended for use within the scope of a non-life sustaining medical therapy for the additional supply of oxygen. The device may thereby be used in hospitals, homes or at home.

The patient is intended as an operator, the operation of the device may only be done by a previously admitted adult. The application may be performed on small children (at least 2 years) up to adults.

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

In many phthalates, an impairment of male reproduction is either proven or strongly suspected. Damage to the liver, nervous system and immune system and an increase in 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.

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

NOTE!

To ensure the success of the therapy, the effectiveness of the therapy in relation to the set volume flow should be checked regularly by the attending physician.

Intended use also includes following the assembly instructions and the instructions for cleaning and maintenance of the device.

Any other use of the device 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 device are excluded. The customer is solely liable for any damage resulting from unintended use. This also applies to the use of non-approved application parts, such as oxygen safety tubes, nasal cannulas and masks, other parts and accessories.

3.4 Contraindications

No contraindications are known to Kröber Medizintechnik.

3.5 Dangers which may arise from the device

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

However, there is still a remaining risk!

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

WARNING! Small parts, choking hazard!

Contains small parts (e.g. FireSafe- check valve), keep away from children!

WARNING! Danger of side effects!

Do not modify your device. You can endanger your health.

Do not remove or open any covers (besides the coarse dust filter and service compartment cover.

WARNING! Risk of health damage!

Geriatric, pediatric or any other patients unable to communicate discomfort can require additional monitoring and or a distributed alarm system to convey the information about the discomfort and or the medical urgency to the responsible care giver to avoid harm.

WARNING! Risk of side effects!

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

Under certain conditions, an oxygen therapy may be dangerous. Before using the aeroplus E, consult a physician.

To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition the aeroplus E must

- **be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.**
- **be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.**

WARNING! Fire hazard caused by oxygen!

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

Therefore:

- **Oxygen may only be handled by trained or specially instructed persons!**
- **The misuse of oxygen, e.g. to cool down or improve the ambient air, to cool down and dust or blow off of persons, clothes, furniture etc. is dangerous and therefore prohibited!**
- **Follow all mandatory instructions for installing and use of fire-reducing equipment such as the metal connector a1nd Firesafe™ check valve.**
- **Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located.**

  If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or mask or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off before smoking.
- **There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.**
- **Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen carrying accessories.**
- **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!**
- **Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns”**

- **Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns!**
- **Oxygen considerably increases the temperature of a flame and the speed of combustion!**
- **Do not fill the humidifier with flammable fluids!**
- **Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the oxygen concentrator is turned on, but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.**

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 device!

– 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 aeroplus E.

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 device 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 aeroplus E is located on the back side of the device, the following is therefore of importance:

- **Place the aeroplus E oxygen concentrator in a well ventilated place**.

- **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 device.**
- **The aeroplus E oxygen concentrator must not be used directly beside or even stacked with other equipment.**

ATTENTION! Avoid overheating!

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

ATTENTION! Oxygen pollution!

Only install the oxygen concentrator in places without impairment by air quality or smoke.

ATTENTION! Ensure simple separation of the device!

Install the device in such a way that an all-pole separation by pulling the mains power supply cable can easily be made at all times!

ATTENTION! No maintenance during regular operation!

Do not perform a service or maintenance routine while a patient needs the device!

ATTENTION! Accessories containing phtalats!

If children, pregnant or breastfeeding women use the aeroplus E, it is recommended to use phtalat-free accessories such as O2 hoses or nasal cannulas. Phtalats are known to increase the risk of allergies and asthma.

ATTENTION! System building!

The responsible organisation is also responsible for the compatibility of all components of the system. This has to be checked prior to the initial use of the systems.

3.6 Behaviour in case of hose fire

If, despite all precautions, a hose fire should occur, it is not sufficient to switch off the device, as oxygen will continue to flow for some time after it has been switched off.

The following steps are necessary:

- Disconnect the oxygen hose from the device to interrupt the oxygen supply.
- Suffocate the flames (e.g. with a blanket).
- After extinguishing the fire, ventilate well, as toxic gases are produced when the PVC hose burns.

The metal connection at the oxygen outlet acts as a fire brake so that the flames cannot spread into the device.

4 Design and function

4.1 General description

The **aeroplus E** oxygen concentrator for has been optimized for the oxygen supply at home.

The **aeroplus E** concentrates the oxygen of the room air by applying the pressure swing adsorption process, by removing the nitrogen portion of the room air. The remaining gas contains up to 95% pure oxygen and is supplied to the patient with up to 5 liter per minute.

4.2 Design

<table>
<tr>
<td> 
</td>
<td>Setup:
1 Carrying handle
2 O2 flowmeter
3 Control panel
4 Casters
5 Mounting bracket for humidifier</td>
</tr>
<tr>
<td> 
</td>
<td>6 Filter lid
7 Device inlet filter (behind filter lid) and air inlet
8 USB service connection (behind filter lid)
WARNING! Risk of device malfunction!
Connect only authorized devices to this port for service means
9 Mains power cable
10 Air exhaust</td>
</tr>
</table>

Display and control panel:

11 O2 connector: connects with nasal cannula or oxygen safety hoses; supply of concentrated O2

12 Mains power failure LED: activated in case of mains power loss.

13 Mains LED: permanently activated during operation of the device; flashes during the initial starting phase when the oxygen concentration has yet not reached the guaranteed specifications for oxygen purity

14 Mains power switch: switches the concentrator on and off

15 Alarm tone mute key: mutes the alarm sound for 20 seconds.

16 Symbol „consult instruction for use“

17 Technical error LED: activated in case of technical fault; always in combination with LCD error code.

18 O2 error LED: activated in case of low oxygen concentration

19 LC display: displays operating hours and error codes.

20 O2 flowmeter: sets the volume flow

5 Technical data

Model	aeroplus E
Classification acc. to MPG	IIa, rule 11
Operating voltage	230 V, 50 Hz
Storage- and Transport Conditions	Storage and transport temperature: -25 to +70 °C Relative humidity: 15% - 93 % (r.H. non-condensing) Air pressure: 700 to 1060 mbar
Ambient operating conditions	Operating temperature: +5 to +40 °C Storage and transport temperature: -25 to +70 °C Humidity: 15% - 93 % r.H., non-condensing (Operation, Storage and Transport) Pressure: 700 - 1060 mbar (Operation, Storage and Transport)
Sound power level	38,6 dB(A) [2]
Power rating	295 W
Fuses	1 x T3.15A H 250 V, 5 x 20 mm 1 x T1.0A, L 250 V, 5 x 20 mm Temperature fuse compressor compartment 84°C
Weight	17,5 kg
Dimensions (HxWxD)	60 x 29 x 40 cm
O2 purity	0,5 bis 4 l/min. 93 % +/- 3 % 4 bis 5 l/min. 90 % +/- 3 % O2 purity measurement is implemented internally under die a.m. operating conditions
min. recommended volume flow 1	0.5 l/min
max. recommended volume flow 1	5 l/min
Volume flow (@ 5l/min) 1	@ 0 kPa pressure: 5 l/min @ 7 kPa pressure: min. 4.8 l/min
max. outlet pressure:	60 kPa (normal state), 275 kPa (single fault)
IP-classification	IP 21

[1] According to ISO 80601-2-69 the sound pressure level of the aeroplus E is 40,1dB(A) @ 3l/min and 40,3dB(A) @ 5l/min. The sound power level is 56.3dB(A) @ 3l/min and 56.6dB(A) @ 5l/min.

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

[3] Volume flow @ room temperature and –pressure, dry air.

6 Transport, packaging and storage

The following should be noted when transporting the aeroplus E:

– The device should only be shipped and transported in its original packaging.
– For transport, e.g. by car, the device 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 stored; it may be needed if the device 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.

6.3 Acclimatisation times

Adequate acclimatization times must be observed if the device is exposed to large temperature fluctuations in order to avoid the formation of condensation water. 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	Time in hours	Temperature difference in °C	Time 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.

NOTE!

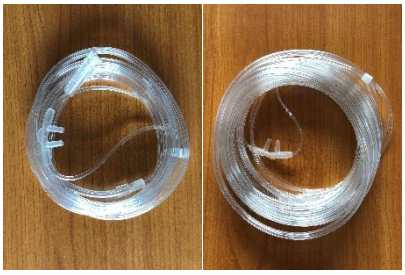
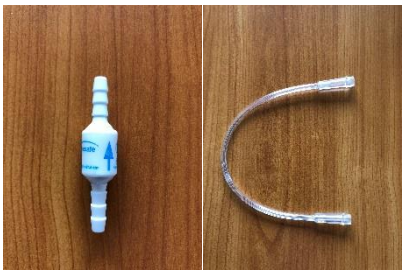
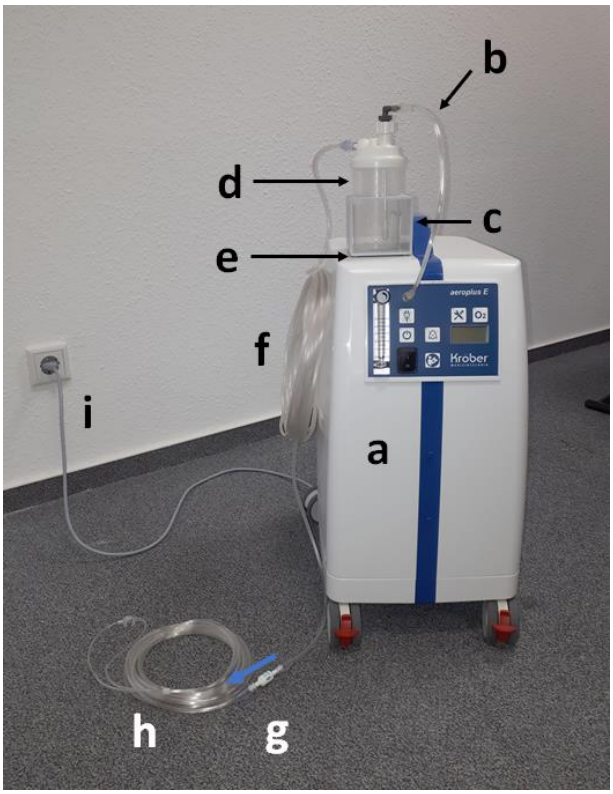
Contact the manufacturer or the local service provider if help is needed during operation or maintenance. The address of the manufacturer can be found on page 8.

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

NOTE!

After unpacking the device, the transport or storage temperature may have to be adjusted to the operating temperature. Before switching on the device, please observe the waiting times specified in section 6.3 (Acclimatization times).

	**Device:** • **aeroplus E** incl. **these instructions for use**
	• Mounting bracket for humidifier incl. screw (left) • Humidifier (right)

	• Oxygen nasal cannula 2m (left) • Oxygen nasal cannula 5m (right)
	• Firesafe check valve (left) • 2 pcs O_2 safety hose 0.33m (right)
	• O_2 safety hose 15m
	• operational setup a. Oxygen concentrator b. 0.33 m safety hose c. Humidifier holder d. Humidifier e. Mounting strips f. 15m O2 safety hose g. Firesafe valve h. 2 m oxygen nasal cannula

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 also responsible for the compatibility of all components of the system. This has to be checked prior to the initial use of the systems.

7.2 Choosing the location

Please consider the following when choosing the location:

- The device 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 device.
- The device is air cooled. It must therefore not be placed near heaters, etc. At such a location there is a risk of overheating.
- The device should be operated only in places where it is not impaired by air pollution or smoke.
- Always place the device on a horizontal surface.

NOTE!

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

ATTENTION! Ensure a sufficient air supply!

The aeroplus E oxygen concentrator is not to be used directly next to or stacked with other equipment. Ensure sufficient distance to walls etc.!

Place the aeroplus E oxygen concentrator so that the air inlet and outlet are in a well-ventilated area.

ATTENTION! Oxygen pollution!

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

ATTENTION! Humidity

Do not use or store to device in wet or moist areas!

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!

ATTENTION: Effects of pets, pests or children!

Only place the oxygen concentrator where it will not be exposed to pets, pests or children!

ATTENTION! Observe environmental conditions!

If this device is used 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!

7.3 Installing the humidifier stand

The humidifier holder provides a safe and upright storage of the humidifier during use.

	**1** Position the humidfier stand such that the holes align. **2** Tighten the screw by hand until it fits firmly to the housing

7.4 Assembly

ATTENTION!

The FireSafe ™ check-valve must always be used to prevent the flame from spreading in the event of a hose fire!

Read this entire manual before installing the check valve. This check valve may cause injury to the patient or user if used or installed without knowing how it will operate and under which conditions.

1. The FireSafe ™ check-valve is not to be used for other applications.

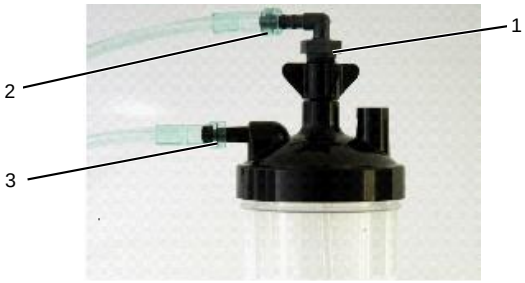
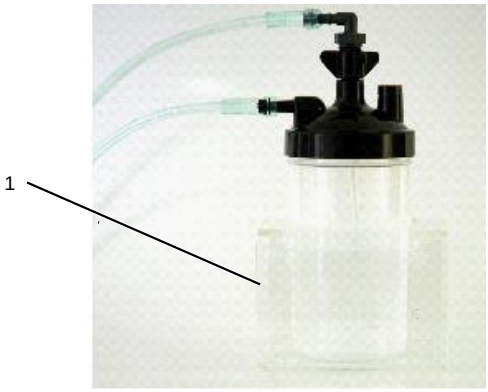
2. The FireSafe ™ check-valve is not to be stored or installed in the immediate vicinity of an open flame or a strong heat source which could exceed a temperature of 40°C. The non-return valve must not be installed or stored in the vicinity of an open flame or strong heat source which could exceed a temperature of 40°C.

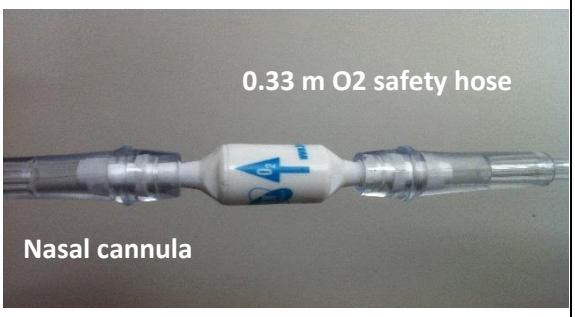
3. Do not install this FireSafe ™ check-valve near an open flame or near a source of excessive heat that is likely to exceed 40°C.

4. Oxygen itself is not flammable, whereby the speed and extent of a combustion process are considerably increased in an enriched oxygen environment. Oil and/or grease are readily combustible in the presence of oxygen. Do not use oil or grease on this connector! Do not lubricate corrugated plug connections!

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

	**1** **Insert the mains connection cable** into a mains **socket**. **ATTENTION!** **The aeroplus E is only designed for operation on a 230 Volt, 50Hz mains network.**
	2 **Connect** the 0.33m-oxygen safety hose to the oxygen concentrator outlet connector.

	**3 Fill the humidifier** with water up to the top MAX.-mark **(1)**. *NOTE!* *Only use the supplied or equivalent humidifier with type designation AEE:* **ATTENTION!** **To ensure a sufficient level of sterility, only use boiled water.**
	**4 Screw the angle adapter (1)** to the humidifier. **5 Plug the already installed 0.33 m safety hose for oxygen** (extension hose) **onto** the **angle adapter (2)**. **6 Push the other 0.33-m safety hose** for oxygen onto the outlet connector of the humidifier (3).
	**7 Put the humidifier** into the **holder (1)** of the device



8 **Plug the FireSafe check-valve** in oxygen flow direction into the **nasal cannula.**

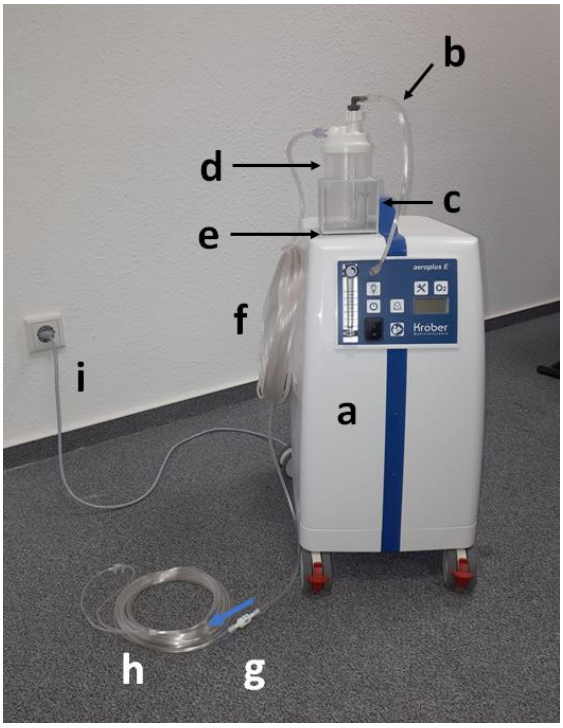
ATTENTION!

Observe flow direction indicated by the arrow!

ATTENTION!

For the best protection of the patient, place the FireSafe check-valve in the oxygen tubing routing as close to the patient as possible!

9 **Connect the other terminal** to the **short oxygen tubing** (0.33 m).



10 **Completely assembled system with:**

a. Oxygen concentrator
b. 0.33 m O2 safety hose
c. Holder for humidifier
d. Mounting strips
e. Humidifier
f. 15 m O2 safety hose
g. Firesafe check valve
h. 2 m O2 nasal cannula
i. Mains connection cable

WARNING! Danger of tripping over!

On the back of the aeroplus E you will find a winding device for the mains connection cable. This should be used when the device is out of use, to avoid any danger of tripping over and strangulation.

Oxygen safety hoses and nasal cannulas shall be always routed such that no tripping or strangulation are created!

8 Operation

WARNING! Health risk!

Inappropriate use of the aeroplus E can lead to severe personal and/or material damage.
Therefore, only operate the device in accordance with the instructions for use and the safety instructions.

NOTICE!

Only the trained and adult patient may safely use all functions of the aeroplus E.

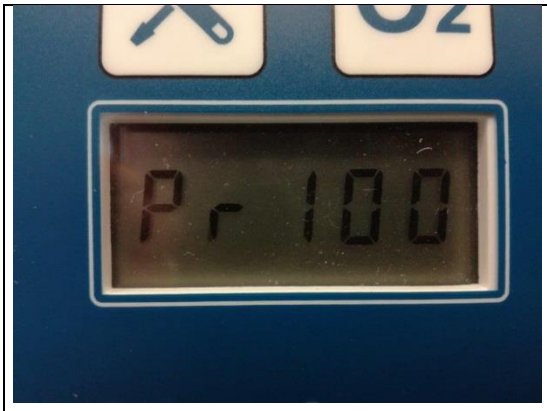
WARNING! Health risk by unsupervised operation.

Pay attention to the environmental conditions for a safe operation. Keep animals, vermin as well as children away from the aeroplus E!

8.1 Taking into service – switching on

1 Start the device by actuating the **mains switch** in the front panel.

– The aeroplus E performs a self-test: all LEDs (except the power failure LED) are switched on, the LCD segments light up and the buzzer is activated.
– The sensor and the microprocessor itself are automatically checked during operation.
– After the self-test, the software version is briefly displayed.
– and then the operating hours are displayed.
– After displaying the operating hours, the display is switched dark and only activated in the event of an error.

	*NOTICE!* *When an abnormal condition is displayed, follow the recommended action sequence acc. To chapter 8.4.*
	Oxygen delivery is started. *NOTICE!* *During the initial warm-up phase, the green mains LED flashes indicating that the oxygen concentrator has yet not reached the guaranteed performance level.* *Once this can be assured, the mains LED stops flashing and stays in active mode.*

2 **Set the prescribed volume flow rate**. (s. chapter 8.2)

3 **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.

NOTICE!

The correct setup and positioning of the nasal cannula is important for the effectiveness of the therapy.

NOTICE!

After switching on, it takes 2 minutes maximum before the oxygen concentrator reaches the specified oxygen concentration.

WARNING! Danger of strangulation!

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

WARNING! Skin irritations!

Make sure that the nasal cannula does not rub against the upper lip to avoid skin irritation.

WARNING! Risk of fire!

Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located!

8.2 Setting the oxygen volume flow

NOTICE!

The maximum limited outlet pressure at the oxygen connector will not exceed 0,7 bar. The maximum gas output temperature is at most 6 degrees higher than the ambient temperature.

NOTICE!

The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories.

	**1 By turning the dial of the flowmeter, the volume flow rate can be adjusted.** by turning the dial clockwise, the flow of oxygen is decreased; by turning the dial counter-clockwise, the flow of oxygen is increased. *NOTE!* *The exact flow rate is given at the center of the ball.*

NOTICE!

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

NOTICE!

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

ATTENTION!

The device is designed for operation up to an altitude of 3000 m above sea level. If the device is operated outside this specification, compliance with the specified performance data cannot be guaranteed.

8.3 Taking out of service – switching off

	**1 To switch the device off, use the mains switch in the front cover.** – The aeroplus E stops the oxygen concentration process including the compressor. *NOTE!* *Although the device is switched off, some oxygen may still continue to flow.*
	**2 Take off the nasal cannula**. When not needed for a prolonged period, empty the humidifier also.

8.4 Abnormal conditions

WARNING! Risk of health impairment!

If the cause for an alarm condition cannot be resolved, immediately switch to alternative or backup means to receive supplemental. In addition consult your oxygen solutions provider.

8.4.1 Alarm priorities

Alarm priority	Meaning	Signals
low	Increased attention is neccesary.	Beep-beep – 20 sec. paused – beep-beep …

8.4.2 Alarme

Alarm type Display	Description
Temperature Technical message LED + LCD Error code E001	**Possible cause:** The operating temperature inside the device is too high (> 65°C). **Counter measures:** – The device should be switched off immediately. – Check whether the air flow into the device is restricted. Also make sure that the device has a sufficient clearance to other objects (wall, cupboard, etc.). – It may be necessary to replace the device inlet filter in the back wall of the device. Further information concerning this matter can be found in the section “Maintenance”. *NOTE!* *For protection, the oxygen supply is set after a further waiting period and the error code "nOP" is displayed. However, the compressor continues to run.* **Checking the alarm function:** – Temporary blockage of the exhaust opening. *NOTE!* *If the internal temperature exceeds 84°C, the temperature fuse is activated and shuts off the device. In this case, contact your service provider.*

Mains failure Mains failure LED No LC display	**Possible cause:** The mains power connection to the device is interrupted. This leads to an immediate loss of operation of the aeroplus E. **Counter measures:** The following should be checked: – Is the mains connection cable properly plugged into the socket? – Has a fuse tripped? Check the fuse, replace if necessary. **Comment** If a functional test of the power failure alarm is to be performed, this can be done as follows: - Disconnect the mains plug from the socket. - Switch on the device. **Checking the alarm function:** – Disconnect the device from the mains power supply. NOTE! *For safety reasons, attempts are made to interrupt oxygen release and oxygen production.*
O2 purity < 82% **LED O2 (Escalation level 1)** **nOP (Escalation level 2)**	**Possible cause**: This oxygen concentrator is equipped with an innovative multi-function sensor to monitor the oxygen concentration of the oxygen output. If the average value for oxygen purity is less than 82% for more than 15 seconds, this alarm is activated (only after a minimum of 2 minutes of operation). **Counter measures:** – Contact your service provider. **Checking the alarm function:** – Set the volume flow to "maximum", beyond 5 l/min.
Sensor Technical message LED **+** LCD Error code **E-010**	**Possible cause:** No sensor data is available for 5 seconds. **Counter measures:** – Contact your service provider. **Checking the alarm function:** – Not possible – self diagnostics

System **Technical message LED + LCD Error code E-020** **Technical message LED + LCD Error code E-080** **Technical message LED + LCD Error code E-100** **Technical message LED + LCD Error code E-400** **Technical message LED + LCD Error code E-800**	**Possible cause:** Various kinds of microprocessor errors. **Counter measures:** – Switch off the device immediately – Contact your service provider. NOTE! *For safety reasons, oxygen concentrating process is stopped. However the compressor keeps on running.* **Checking the alarm function:** – Not possible – self diagnostics
Gas temperature **Technical message LED + LCD Error code E-008**	**Possible cause:** The gas temperature exceed 60°C. The oxygen concentration cannot be determined. **Counter measures:** – see “counter measures for temperature alarm” – Contact your service provider. **Checking the alarm function:** – Block the exhaust air stream. NOTE! *If the internal temperature exceeds 84°C, the temperature fuse is activated and shuts off the device. In this case, contact your service provider.*
Low pressure alarm **Technical message LED + LCD Error code E-002**	**Possible cause:** The pressure in the reservoir is less than 550 hPa. This system pressure is too low to ensure a stabile oxygen production process. **Counter measures:** – Check if the volume flow exceeds 5 l/min! – Check if the device inlet filter (hinter der Service lid in the back) is blocked. – Otherwise: Contact your service provider. **Checking the alarm function:** – Set the volume flow to „maximum“, exceeding 5 l/min

Obstruction alarm Technical message LED **+ LCD Error code E-004**	**Possible cause:** The oxygen concentrator is not able to supply the set volume flow. **Counter measures:** – Check whether the oxygen hose is buckled or squeezed. – Check whether the accessories are correctly connected. – Check if the humidifier is calcified. – Otherwise: Contact your service provider. **Checking the alarm function:** – Block the oxygen outlet

WARNING! Risk of health impairment!

Before taking the device back into operation, make sure the alarm and the cause have been resolved properly.

9 Maintenance

9.1 Safety

WARNING! Danger of electric current!

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

WARNING! Danger of electric current!

The mains power cable shall be checked regularly for integrity. A necessary replacement that is described in the Technical Service Manual may only be conducted by authorized technical staff.

9.2 General notes

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

The following cleaning instructions comply with the recommendations of the German respiratory industry advisory group SPECTARIS$^{med.}$

An external contamination of the gas pathway is possible from the oxygen outlet nipple connector to the internal check valve.

9.2.1 Cleaning

– The device 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 Disinfection

– 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.
– Use wipe disinfection cloths that are soaked with disinfectant. Use a cross strategy by applying horizontal wiping followed by vertical wiping. After the disinfectant-specific exposure time, the device may be used.

9.3 Maintenance schedule

Maintenance and cleaning instruction shall be followed according to the table below.

All maintenance activities can be carried out by the operator. Eventually, a new spare part has to be used in case of a replacement. 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 instructions for use may only be carried out by persons authorized 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 performed while the device is in use.

WARNING! Risk of infections

If oxygen accessories such as nasal cannulas are shared by different users, an infection cannot be precluded.

Every user of the aeroplus E must have his own set of oxygen accessories!

9.3.1 Hospital / out-of-hospital use

Component	Hospital use action	Out-of-hospital use action
aeroplus E	Weakly cleaning and disinfection	Weakly cleaning
Humidifier	Weakly cleaning and disinfection Replace monthly	
Holder for humidifier	Weakly cleaning and disinfection	Weakly cleaning
Nasal cannula	Weakly cleaning and disinfection Replace monthly	Weakly cleaning Replace monthly
Oxygen safety hoses	Replace every 6 months	

Component	Hospital use action	Out-of-hospital use action
FireSafe check valve	Replace every 6 months	
Oxygen mask	Weakly cleaning and disinfection Replace monthly	Weakly cleaning Replace monthly
Device inlet filter	Replace yearly / after 5000 operating hours	

9.3.2 With changing patients

Component	Required action
aeroplus E	Cleaning and disinfection
Humidifier	Dispose of
Holder for humidifier	Cleaning and disinfection
Nasal cannula	Dispose of
Oxygen safety hoses	Dispose of
FireSafe check valve	Dispose of
Oxygen mask	Dispose of
Device inlet filter	Dispose of

9.3.3 Following a Technical Service

Component	Required action
aeroplus E	Cleaning and disinfection
Humidifier	Dispose of
Holder for humidifier	Cleaning and disinfection
Nasal cannula	Dispose of

Component	Required action
Oxygen safety hoses	Dispose of
FireSafe check valve	Dispose of
Oxygen mask	Dispose of
Device inlet filter	Dispose of

Interval	Inspection
annually	**Safety inspection** *Notice!* *The safety inspection may only be carried out by trained and authorized staff.*

9.3.4 Life time

As average life times, we expect:

Component	Life time
aeroplus E	5 years min.
Humidifier	1 year
Nasal cannula	1 month
Oxygen hose	6 months
Coarse dust filter	1 month
Device inlet filter	1 year

9.4 Maintenance

All maintenance activities can be carried out by the operator. Eventually, a new spare part has to be used in case of a replacement. Please contact your service provider or the manufacturer.

Maintenance activity	Description
Cleaning the aeroplus E	**WARNING! Danger of electric current!**

Maintenance activity	Description
	Before starting cleaning the device must be switched off and disconnected from the mains supply. **1** Use a damp cloth to wipe down the exterior case
Cleaning the humidifier	1 Unscrew the humidifier from the angle connection. 2 Unscrew the lid from the humidifier and pour out any remaining water. 3 Clean the humidifier with clear, warm water. 4 Fill fresh water into the humidifier 5 Screw cover onto humidifier 6 Screw angle connection to humidifier **Sterile Water Prefilled Humidifiers** When using sterile water prefilled humidifier systems: – Prefilled Humidifiers may 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 nasal cannulas, oxygen hoses and masks	**1** Disconnect the hose of the nasal cannula from aeroplus E. **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 inlet filter	**1** Open the blue service lid in the back of the device. **2** Remove the old inlet filter by pulling it smoothly back. **3** Attach the new inlet filter. **4** Close the blue service lid.

10 Spare parts and accessories

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 device, can severely affect the performance of the device.

The following part numbers should be used when ordering:

Part number Kröber	Part number Product	Part description
AEE.01		Instructions for Use
AEE.02 R2		Holder for humidifier
KRO2.06	HAB01-916	Humidifier, refillable, up to 6 l/min, safety valve 410 mbar pressure
KRO2.07	HSB11-S2	Nasal cannula, 2 m, up to 6 l/min, up to pressure 1 bar, PHT DEHP
KRO2.08	HSB11-S5	Nasal cannula, 5 m, up to 6 l/min, up to pressure 1 bar, PHT DEHP
KRO2.10	HGF01-0-INTAKE	Inlet filter for aeroplus E
K686	HSS11-15	O2 hose 15 m, up to 6 l/min, up to pressure 1 bar, PHT DEHP
KRO2.07-1	HSS11-0.33	O2 hose 0.33 cm, up to 6 l/min, up to pressure 1 bar, PHT DEHP
KRO2.94	827-0001	FireSafe, up to 6 l/min, up to pressure 1 bar, PHT DEHP

11 Symbols

Symbols	Explanation
	WARNING! General warning sign
	WARNING! Electricity
	ATTENTION!
	NOTE!
	CAUTION; ATTENTION
	Attention, observe instructions for use!
	Applied part type BF
	Protection class II
IP 21	Degree of protection for the ingress of liquids and small parts:
CE 0197	Notified Body: TÜV Rheinland LGA Product GmbH
I / O	On-/Off switch
	Do not smoke!
	No open fire!
	No oil or grease!
	Do not remove any covers!

Symbols

Symbols	Explanation
	Do not dispose of in household waste!
	Manufacturer
	Manufacturing year
SN	Serial number
	Technical message
	Oxygen concentration outside of manufacturer's specifications
	Stand-by / on
	Mains failure
	Alarm mute

11.1.1 Recommended safety distances

Recommended safety distances between portable and mobile HF communication equipment and the aeroplus E			
The aeroplus E is intended for operation in an electromagnetic environment with controlled HF interferences. The customer or user of the aeroplus E can help to avoid electromagnetic interferences by maintaining minimum distances between the portable and mobile HF communication equipment (transmitters) and the aeroplus E, 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 tale above, the distance can be calculated using the equation for the corresponding column, whereby *P* represents the rated power of the transmitter in Watt (W), specified by the transmitter manufacturer. NOTE 1 For calculation of the recommended safety distance for transmitters in the frequency range from 80 MHz to 2.5 GHz an additional factor of 10/3 was used, in order to reduce the likelihood that a mobile/portable communication device, 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.			