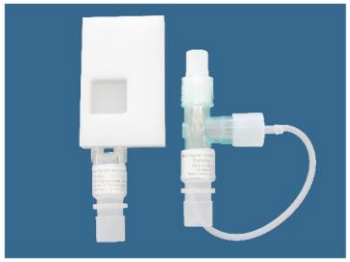
KR2000
Keredusy®

Disinfection of Ventilators with the Keredusy® KR2000

Also effective against enveloped Viruses, Rota, Noro and Adenoviruses
- Limited Virucidal+ tested -



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Keredusy®, What Does It Stand for?

Keredusy® stands in German for **Ke**im**redu**ktions**sy**stem meaning pathogen reduction system. It will be used to disinfect the inner air-conducting parts of ventilators which cannot be reached by wipe disinfection without disassembly. Before a reuse the inner air-conducting parts have to be disinfected like the casing of the ventilators.

Where and by whom will ventilators be used?

To enable ventilator-dependent patients to live at home in a familiar environment, ventilators were developed many years ago that could generate the airflow required for ventilation by drawing in ambient air. Piston or bellows systems were used in the past. Today, turbines are used exclusively for this purpose.

Thanks to modern, powerful, small and lightweight accumulators as energy supply for ventilators, patients gain a high degree of mobility and have completely new opportunities to participate in life.

However, these devices have also become established in hospitals due to their high flexibility, which allows them to be used in a variety of interesting application scenarios, e.g. for transfers and internal necessary patient transports.

As a result, ventilators are becoming increasingly widespread in hospitals and medical care centers.

Why Is a Disinfection of Ventilators Necessary?

An investigation of 700 CPAP devices done by METEC Medizintechnik GmbH revealed that **nearly the half of the devices** were contaminated in the inner part of the flow generator with **viable microorganisms**. Microbiological tests have shown that these microorganisms, especially pneumonia germs, can cause serious health problems to immunosuppressed patients. Patients who need to be provided by ventilator are often healthily handicapped and are therefore more susceptible to microbial infections.

Ensuring patient protection

Ventilators are medical devices and in the European Union they are subject to the regulations of the Medical Device Directive 93/42/EEC. Consequently, the manufacturer of a ventilator is obliged to integrate measures that allow a safe operation of his device. Therefore, the use of filters and regular filter changes are prescribed to provide patient protection against microbial contamination. This change is difficult to implement, especially in the home environment, and cannot be monitored. In hospitals, it is largely ensured by organizational measures, but there is also no automatic, technically monitored documentation of filter changes.

Ensuring the safety of the service provider

Service providers who perform technical service (maintenance, repair, etc.) on ventilators should prepare the equipment hygienically prior to service in order to comply with the rules and regulations of the Employer's Liability Insurance Association. In practice, this results in increased space and personnel requirements to protect the service provider from hazards.

Which Ventilators Are Affected?

Ventilators which generate the compressed air for patient care from the immediate ambient air, e.g. by means of a turbine, **require measures** to ensure the **treatment of the air**. To protect the device and the patient, the air inlet of the ventilator is equipped with a pollen or dust filter. There is **usually no bacterial filter** in the air inlet of the ventilator. Typically, ventilators are located in an environment where there is **a risk of microorganisms** being drawn into the device and **finding suitable survival conditions.**

The following devices are referred to as ventilators in this documentation:

Sleep apnoea breathing therapy equipment	DIN EN ISO 17510-1:2009-07
Home-care ventilatory support devices	DIN EN ISO 10651-6:2011-06
Home healthcare environment ventilators for ventilator-dependent patients	DIN EN ISO 80601-2-72:2016-04
Emergency and transport ventilators	DIN EN 794-3:2009-12
Critical care ventilators	DIN EN ISO 80601-2-12:2012-02

Stationary operated ventilators, as they are preferably used in intensive care units or for anesthesia ventilation, receive compressed air for patient care via a central air supply system. The patient application parts are disposable or sterilizable. The process presented here is not intended for these items.

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Ventilators in Home-Care and Clinical Use

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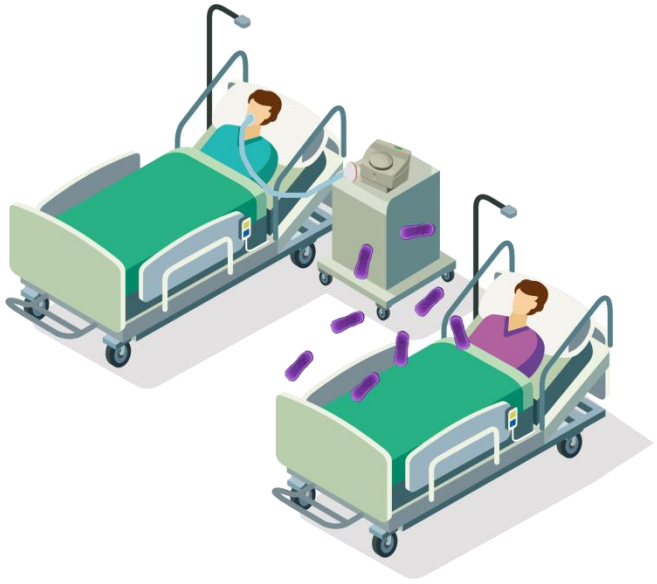

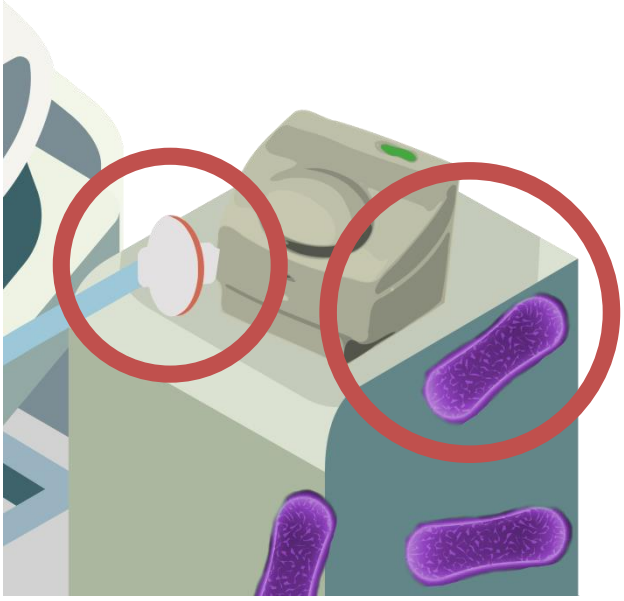

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Disinfection Options of Ventilators in Comparison

Disinfection with the Keredusy® KR2000

- simple, economical, safe, inspected and certificated

Replacement of air flowed parts

- technical service
- must be done every time when changing patient and only by trained staff
- in case of frequently patient change (e.g. in hospital) there arise high staff and material costs

Application of formaldehyde

- proven in the field of sterilization of thermolabile medical devices
- problems for ventilators: the used medium remains within the installed foam parts and therefore it causes long desorption times which make a quick re-availability not possible

Room disinfection with nebulized hydrogen peroxide solution

- simultaneous disinfection of several devices possible
- the process causes high indoor air humidity and the ventilators have to be functional
- all inbuilt materials have to be resistant to H_2O_2
- long exposure time of up to 48h
- effectiveness of disinfection inside the ventilator is not ensured

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	disinfection with the Keredusy® KR2000	replacement of air flowed parts	application of formaldehyde	disinfection with nebulized hydrogen peroxide solution
effectiveness against germ load				
disinfection of inbuilt contaminated materials without disassembly				
timely disinfection for a quick reuse				
disinfection without technical training possible				
traceability & verifiability				
ecological disinfection without high material waste and dangerous residues				

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What is the Difference between the Keredusy®-Disinfection to Current Procedures?

In the past, home ventilators were prescribed to the patient and disposed of after use. From an environmental and economic perspective, disposal is unacceptable and no longer appropriate.

The way in which reprocessing has been carried out so far

The surface of the devices can be disinfected without any problems by means of wipe disinfection. However, this measure does not reach the air-carrying areas of the ventilator, which are contaminated by the ambient air drawn in. For this purpose, the devices have to be disassembled by qualified personnel in a time-consuming process.

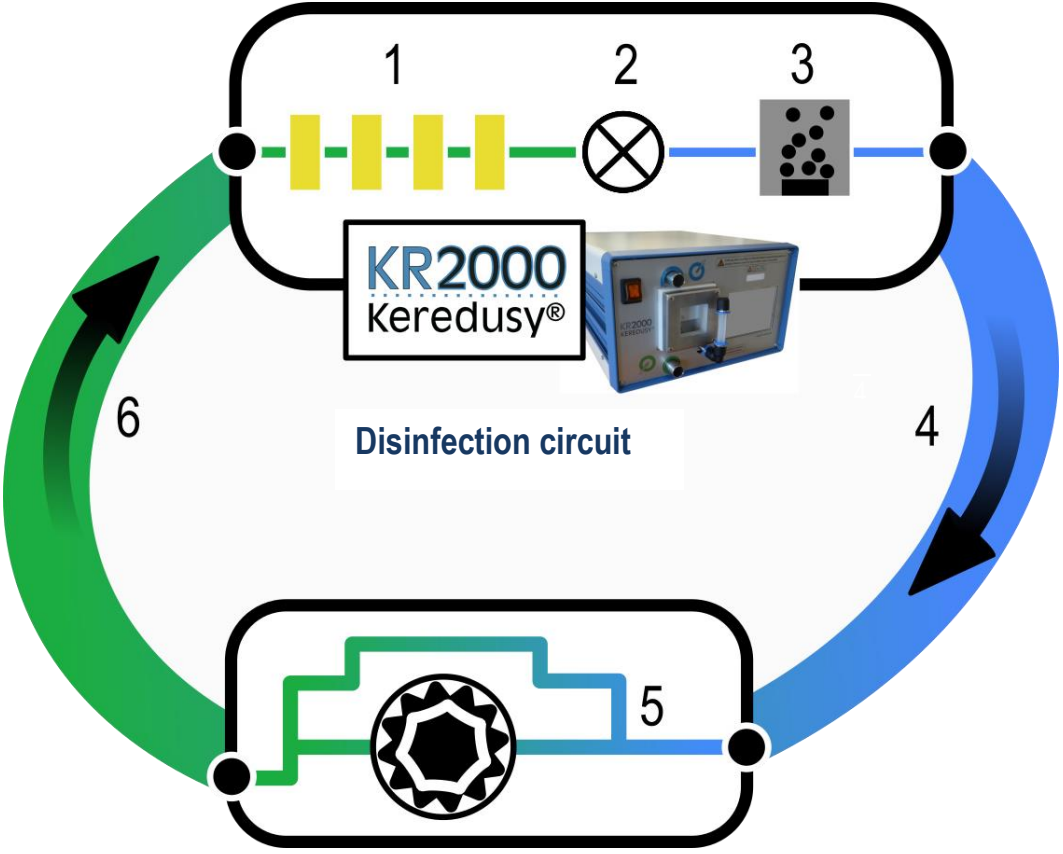
The solution

The Keredusy®, which was specially developed for the disinfection of the air-carrying areas of ventilators, ensures automatic disinfection while taking into account the specific requirements that are demanded for the reprocessing of such devices. This includes ensuring that no hazardous disinfectant residues remain in the ventilator after reprocessing. In addition, typical pneumonia pathogens must be taken into account for proof of disinfection effectiveness.

As disinfectants, the Keredusy® uses ozone (O_3) and an 8% solution of hydrogen peroxide (H_2O_2), which are distributed through the flow of the ventilator. Sensors are used to precisely control the process to ensure the best possible disinfection in the air circuit inside the ventilator.

The room disinfection devices used by some operators to disinfect ventilators are, according to their intended purpose, only intended to disinfect rooms and surfaces, and this surface disinfection of ventilators can be easily and safely achieved by wipe disinfection. There are no studies on the effectiveness of room disinfection in reducing the bacterial count of the air-conducting parts of the ventilator or on possible damage to ventilator components, nor are there any statements by the manufacturers of room disinfection devices. Therefore, such misuse is to be discouraged.

How Does the KR2000 Disinfection System Work?



1. sensors for process control
2. ozone generator
3. humidifier
4. conduit of the disinfection agent to the ventilator
5. airway to be disinfected in the ventilator
6. recirculation

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Connecting

The ventilator is connected to the Keredusy® with 2 hoses and device specific adapters. On the one hand with the air inlet and on the other hand with the air outlet (patient side). This creates a closed circuit between the ventilator and the Keredusy®. The Keredusy® uses the air flow of the ventilator to be disinfected.

Process and documentation

The control of the disinfection device and the documentation of the disinfection is done on a PC with specially developed software. The disinfection sequence is carried out automatically after the start. With the help of sensors, the process is constantly monitored and, if necessary, readjusted to ensure the process. The disinfection report is automatically generated and can be printed or digitally archived as a PDF file.

Traceability of the disinfection is ensured by:

- ventilator details (manufacturer, type, serial number)
- date, time, operator
- data to the used program parameters used
- Serial number of the KR2000 used.

In addition, during the disinfection process, you have all the important parameters at a glance on the PC and on the built-in display.

Validation of the Effectiveness According to the Keredusy® KR2000

The effectiveness proof of the disinfecting effect of the Keredusy® KR2000 disinfection process is based on the relevant norms for proofing microbicidal effectiveness of disinfectants.

DIN EN 14561:2006-08	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2); German version
DIN EN 14562:2006-08	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2); German version
DIN EN 14563:2009-02	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2); German version

Execution and analysis of microbiological examinations in the context of the Keredusy® KR2000

Disinfection evaluation:

Labor L+S AG, Mangelsfeld 4, 5, 6 97708 Bad Bocklet-Großenbrach Germany http://www.labor-ls.de/

Consultation for planning and execution of the microbiological tests including the assessment of the results:
Institut Schwarzkopf GbR PD Dr. Andreas Schwarzkopf
medical specialist for microbiology and infection epidemiology, publicly appointed and sworn expert for hospital hygiene, Mangelsfeld 16 97708 Bad Bocklet Germany

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Validation Keredusy® KR2000 and Tested Germs

Germ	ATCC*	Norm relation	10^x
Staphylococcus aureus	ATCC 6538	bactericidal effectiveness according to DIN EN 14561:2006-08	10^5
Enterococcus hirae	ATCC 10541	bactericidal effectiveness according to DIN EN 14561:2006-08	10^5
Pseudomonas aeruginosa	ATCC 15442	bactericidal effectiveness according to DIN EN 14561:2006-08	10^5
Escherichia coli	ATCC 10536	bactericidal effectiveness facultative referring to DIN EN 14561:2006-08	10^5
Acinetobacter baumannii	ATCC 19606	bactericidal effectiveness facultative referring to DIN EN 14561:2006-08	10^5
Streptococcus pneumoniae	ATCC 33400	bactericidal effectiveness facultative referring to DIN EN 14561:2006-08	10^5
Candida albicans	ATCC 10231	fungicidal effectiveness according to DIN EN 14562:2006-08	10^4
Aspergillus brasiliensis	ATCC 16404	fungicidal effectiveness facultative referring to DIN EN 14562:2006-08	10^4
Bacillus subtilis Sporen	ATCC 6633	sporicidal effectiveness facultative referring to DIN EN 14562:2006-08 / DIN EN 13704:2002-05	10^4
Mycobacterium avium	ATCC 15769	mycobactericidal effectiveness facultative in dependence on DIN EN 14563:2009-02	10^4
Mycobacterium terrae	ATCC 15755	tuberculocidal effectiveness facultative in dependence on DIN EN 14563:2009-02	10^4

10^x is the inverse function of the common logarithm of the reduction of germs which is required according to the norm.
Accordingly at 10^5, 99.999% of the respective germs or pathogens are reduced.
*American Type Culture Collection

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What Does "Limited Virucidal PLUS" Tested Mean?

The efficacy of disinfection procedures against viruses is divided into three ranges of efficacy:

1. limited virucidal efficacy:
   this efficacy is characterized by the fact that the disinfection process ensures efficacy against all enveloped viruses.
2. limited virucidal PLUS efficacy:
   this efficacy is characterized by the fact that the disinfection process ensures efficacy against all enveloped viruses and additionally against Noro, Rota and Adenoviruses.
3. virucidal effective:
   this efficacy is characterized by the fact that the disinfection process ensures efficacy against all enveloped and non-enveloped viruses.

Testing of the virucidal efficacy of KR2000 Keredusy® disinfection in combination with hydrogen peroxide solution (8%) was carried out in accordance with:

DIN EN 17272:2020 " Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities".

In accordance with the standard, the virucidal efficacy of the KR2000 Keredusy® disinfection process in combination with hydrogen peroxide solution (8%) was demonstrated on the following viruses:

- - Adenovirus, type 5 (Adenoid 75)
- - Murine Norovirus (S99)

The investigations were conducted under the direction of Dr. Christian Jursch in the laboratory:

Eurovir Hygiene-Labor GmbH

Im Biotechnologiepark TGZ I

D-14943 Luckenwalde (Germany)

successfully performed.

With the successful demonstration of limited virucidal PLUS efficacy, our previous recommendation to quarantine ventilators according to relevant scientific publications on surface viral survivability until possible viral contamination is no longer viable should no longer be considered.

Effectiveness Against Multiple Drug Resistant Pathogens (MDR)?

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A frequently asked question about the Keredusy® is the effectiveness against antibiotic resistant pathogens. The KR2000 disinfection process is effective against the following types of antibiotic resistant germs using 8% hydrogen peroxide solution (H_2O_2):

- Methicillin-resistant Staphylococcus aureus (MRSA) and Oxacillin-resistant Staphylococcus (ORSA)
- Vancomycin-resistant Enterococci like Enterococcus faecium and faecalis (VRE) or also glycopeptide –resistant Enterococci (GRE)
- Clostridium difficile
- Multi resistant gram-negative pathogens (rod-shaped)
  (MRGN, 3MRGN, 4MRGN)
    - Extended-spectrum β-lactamase (ESBL) forming pathogens
        - Escherichia coli
        - Klebsiella (K. oxytoca, K. pneumoniae)
        - Enterobacter spp.
        - Pseudomonas aeruginosa
        - Acinetobacter baumanii
    - New-Delhi-metallo-β-lactamase (NDM), Verona-integron-encoded metallo-β-lactamase (VIM), German-imipenemase (GIM-1) forming pathogens
    - Carbapenemase (KPC) forming pathogens

Which Arrangements Have to Be Taken?

When disinfecting against various germs, the user of the Keredusy® system has to make the following suitable arrangements to protect the staff:

- provision of effective disinfectants for hands and surfaces
- measures for personal safety
- arrangements for access authorization to reprocessing area
- arrangements to avoid cross-contamination with other devices (separated rooms, process organization)

To avoid germ carry over, accessories that may be contaminated and cannot be disposed of safely. It must not be reused under any circumstances.

Requirements and recommendations for disinfection rooms including the special demands for the use of the Keredusy® KR2000 (excerpt)

- the processing area should only be used for reprocessing medical devices
- the area can be disinfected, that means i.e. floors, desktops, walls (up to a working height of approx.1.60 m) have to be resistant to disinfectants
- organizational or better physical separation of the areas

For reasons of space, this is an excerpt. There are additional requirements that you can request in detail. In order to optimize this process - the space required for the treatment - we offer a special disinfection cabinet, which is described in Accessories.

What is the Difference to the Keredusy® KR1000?

The Keredusy® disinfection process is based on the disinfecting effect of ozone (O_3). It is known from the water conditioning that the ozone disinfection is in aqueous environments very effective. Therefore nebulized water was added to the disinfection process with ozone in the Keredusy® KR1000, which was launched in 2005.

Instead of water the KR2000 uses hydrogen peroxide solution 8% (H_2O_2) which has been nebulized to increase the disinfecting effect. Thus, taking into account the low organic load, a full:

- mycobactericidal,
- tuberculocidal,
- sporicidal,
- levurocidal,
- fungicidal and
- bactericidal

efficacy is achieved. By using hydrogen peroxide the necessary disinfection time is halved!

All ventilators which were tested since 2010 regarding their suitability for the Keredusy® procedures have been tested for both the effectiveness of ozone in combination with water and effectiveness of ozone in combination with hydrogen peroxide.

In order to be able to ensure the disinfecting effect, the specific requirements for processing of the ventilation technique and the following disinfection parameters must be observed during the entire disinfection process:

- ozone concentration (at least 80 ppm)
- relative humidity (at least 80 %, max. 99 %)
- air flow (approx. 60 l/min)

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Why do Ventilators Have to Be Validated?

Every manufacturer of reusable medical devices has to specify a suitable process for hygienically reprocessing his product after use on the patient and preparing it for safe reuse on the next patient. With our Keredusy® system, we support ventilator manufacturers by providing a new process for disinfecting the internal, air-conducting parts of the ventilator. Due to the different designs, materials used in the air path, different air ducts inside the device, measurement and control technology, turbines and valves, each type of ventilator must be tested before KR2000 disinfection:

- Are the materials and components installed in the device sufficiently resistant to ozone and hydrogen peroxide?
- How often can a device be disinfected with the KR2000?
- How can the device be adapted to the KR2000?
- Which settings have to be selected on the ventilator for disinfection?
- Which KR2000 process settings are required to achieve the normally required reduction in germ number?

After our investigation, the manufacturer of the ventilator receives a report on the suitability of his device for the KR2000 disinfection. If a manufacturer releases his device for the disinfection process, the device will be published on our list:
„List of validated ventilation technology“
http://www.medizinservice-sachsen.de/en/files/kr1000_liste_validate_en.pdf

We publish also the specific process instructions for this device and provide the necessary adapters for the operators of a Keredusy® disinfection device.

Until now we have already tested more than 90 types of ventilators from over 20 manufacturers which are suitable for the Keredusy® disinfection system and are published on this list.

What Happens After Disinfection?

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What happens to the ozone?

After the disinfection the devices automatically enters an ozone depletion mode. The ventilator may only be disconnected from the Keredusy® after the permissible limit has been dropped below (time approx. 15min). The ozone decomposes again into harmless oxygen during this time.

What happens to the hydrogen peroxide?

As part of the subsequent drying, hydrogen peroxide decomposes into oxygen and water

How long are the ventilation times?

Ventilation times are not observed. After the disinfection, the ventilator has to be dried. For this purpose, the ventilator is operated with filter inserted in a dust free environment for about 30 minutes. Differing drying times are given in the processing instructions for the respective ventilator.

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Disinfection Workflow with the Keredusy® KR2000

Delivery of the contaminated device

Disposal of single-use materials

Reprocess reusable accessories according to manufacturer's instructions

Wipe disinfection of the surface

Disinfection of the air-conducting parts of the device with Keredusy® KR2000

Fully disinfected device

Drying, function check, repair

Documentation, supplement of disposal material

Packaging and distribution

What Costs Arise During Operation of the Device?

The disinfection device requires electrical energy and hydrogen peroxide solution 8 % (H_2O_2). No other things are necessary.

Once a year a maintenance with the following contents is scheduled

- cleaning
- metrological examination
- safety related check
- replacement of wearing parts
- software update
- sensor calibration

In addition, it is necessary to replace the ozone generator after a maximum of 1,000 operating hours. The maintenance and repair of the KR2000 disinfection system is carried out exclusively by the manufacturer.

Comparison and cost listing

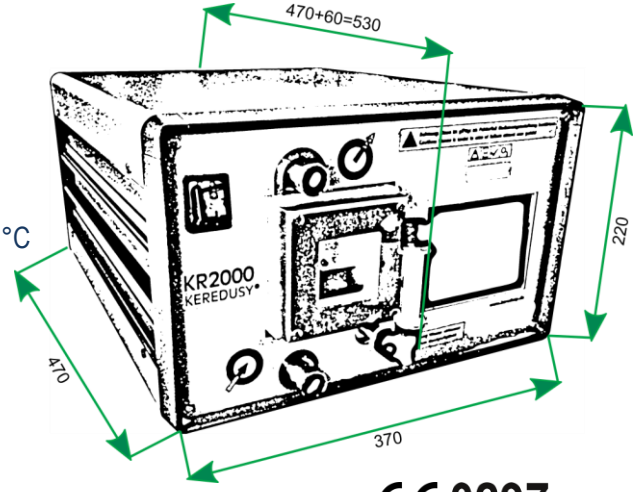
In contrast to replacing all inner air flowed parts of the ventilator, which will tie your technicians up to several hours of work, as well as the material costs, the Keredusy® offers you an optimized disinfection procedure and only one-time training costs. Your **staff will be semiskilled** and can process the **disinfection faster** and you can save on personnel costs. After only a few disinfection processes **the costs per disinfection are amortizing**. As a result, you will have **lower costs in medium- and long-term** due to an optimized disinfection process and you can work towards, if it is used regularly, to a **double- digit Euro amount per disinfection**.

Keredusy® KR2000 Technical Specifications

The Keredusy® KR2000 can be used to disinfect ventilators, respiratory devices and similar devices in accordance with statutory regulations.

Technical specifications

Display	5.7“ (~14.5 cm) color display
Body material	aluminum alloy / steel powder coated
Connection flange	2× for 22 mm inner-ø hoses
Weight	15.5 kg
Power supply	110 - 240 V AC / 50 - 60 Hz
Maximum power consumption	100 W
Operating temperature	+20 - +40 °C
Humidity range	0 - 80% @ 31 °C / 0 - 50% @ 40 °C
Interface	RS 232
IP code	IP 20
Class according to 93/42/EEC	IIa
Software requirements	Windows® 7, 8, 8.1, 10, 11
Output of the documentation	PDF file or print by PC
Available languages	English, French, German, Spanish, Italian, Turkish



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Accessories for the Keredusy® KR2000

Keredusy®-Cabinet

- spatially separate disinfections
- optimal handling
- enormous saving of space
- improved staff safety
- ideal integration

Decontamination-Kit

- according to the required minimum protection by the German professional association
- non-woven protective gown, nonsterile, water repellent surface
- chemically resistant protective gloves
  (Latex protective gloves, powder-free; latex-free is also possible)
- face mask 8002 filter class FFP2 (Filter effectivity 99 % of 0.1 micron germs)

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Service At and Around Keredusy® KR2000

Service for manufacturers of ventilators

You produce ventilators and want to have these devices tested for suitability to our Keredusy® disinfection system?

Gladly we examine your ventilator regarding its suitability for our disinfection system.

Service for operators of ventilators

Do you operate ventilators and want these devices to get hygienic processed?
If the operating of an own Keredusy® is not economical for you, we can name competent service providers in your area that offer you the disinfection as a service with our Keredusy® disinfection system.

Service for Keredusy® operators

- professional training in handling the Keredusy®
- hygiene training for processing of ventilation technology
- maintenance, inspection, repair
- spare parts service
- loaner service
- consumables

You are interested in our KR2000 Keredusy® disinfection system?
Our competent Medizin & Service customer service team will help you gladly.
Call us at +49 371 / 560 36 0 or send an email to kd@medizinservice-sachsen.de

03/2023