Frequently asked questions regarding the disinfection system KR 1000

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Why do respiratory devices have to be prepared?

Turbine-operated respiratory equipment draws ambient air over a filter when creating the respiratory flow. Different studies, which have been conducted with respiratory equipment being in application (homecare and clinical devices), show an alarmingly high contamination rate. Up to **43 %** respiratory equipment being in use are contaminated in the flow-generating components. These statements have been obtained by means of the smear method.

What is the legal background for a disinfection of respiratory equipment?

- MP Directive 93/42 EWG
- Medical Devices Act (MPG)
- Medical Devices Operator Ordinance (MPBetreibV)
- Recommendation of Robert-Koch-Institute "Requirements regarding hygiene for the preparation of medical products“
- Recommendation regarding hygiene by the Spectaris Industrieverband "Hygienic preparation of resources for respiratory home therapy“
- Diverse standards

How does the disinfectant work?

Ozone or activated oxygen alters surfaces (O radical) and this effect is used for the destruction of structural and enzyme proteins of micro-organisms.

How has the micro-biological proof been furnished?

The selection of the experimental germs has been conducted on the basis of the control of surface disinfectants according to RKI, DIN EN 15883 (part 1 to 4) and selected samples from diverse studies.

In the disinfection process for respiratory equipment, the effectiveness is of special importance for germs causing pneumonia.
Following the method for validating disinfectants, several agents have been selected for each respective family of micro-organisms for the proof including at least three test runs.

Note: According to the current state of medical knowledge, the selection of the proof micro-organisms is representative for respiratory pneumonia and a selection of these chosen micro-organisms is used for the proof of surface disinfection methods.
New medical findings regarding other kinds of germs for respiratory pneumonia are published by independent associations (e.g. Deutsche Gesellschaft für Pneumologie e.V. and their neighbouring associations, Robert-Koch-Institute) and are monitored and also tested by Medizin & Service GmbH.

The micro-biological evidence is provided in cooperation with the accredited, certified test laboratory MTL $_{BE}$ (ZLG number: ZLG-P-900.98.02).

1. Sterilisation of sample carrier with an autoclave
2. Disinfection of sample carrier and of sample casing
2. Equipping of sample preparation with bioindicator
3. Inserting of sample preparation into the flow-generating component of the respiratory device
4. Connection of respiratory device to KR 1000
5. Conduction of KR1000 disinfection
6. Micro-biological analysis and evaluation by test laboratory

In terms of the MPG, the disinfection system KR 1000 is a medical product and is part of risk class IIa. The device complies with the standards according to EN 61010-2-042, EN 61010-1 :2001 and EN 61326:1997+A1 :1998+A2 :2001 and is certified by the named authority SLG (ID-number 0494). Adherence to regulations is controlled by the Regional Council Chemnitz.

Why does the respiratory equipment have to be validated?

According to the MPG, every manufacturer has to state a suitable method for preparing his medical products. Therefore, an effectiveness study is conducted for each kind of respiratory equipment, for which the KR1000 disinfection process will be used.
To proof the effectiveness of the KR1000 disinfection, the suitability is controlled and tested by a cooperation between Medizin & Service GmbH and the manufacturer of the respiratory device according to the following procedure:

- Analysis of materials in the flowed area
- Production of special adapters and adaption to respiratory device
- Constant gassing of the device (t= 20 ... 50 h) to determine material resistance
- Proof regarding micro-biological effectiveness by application of selected micro-organisms at worst case locations in the device and subsequent disinfection with KR 1000
- Determination of the lethality curve for each device by iterative approximation by means of the residence time and determination of the disinfection class following that
- Evaluation of the device by the manufacturer
- Determination of the disinfection being possible to a maximum and change intervals for components, which are damaged by disinfection according to the manufacturers' provisions
- Release for disinfection

Catchword MRSA effectiveness?

The MRSA effectiveness of the KR1000 disinfection has been proved in micro-biological tests with observance of certain parameters. The conduction of this disinfection is only allowed in special preparation rooms, after training, an audit and a final certification by Medizin & Service GmbH.

Why do higher costs accrue for the preparation of MRSA contaminated devices?

The preparator of MRSA contaminated respiratory equipment has to establish a method for logistic processing of the disinfection starting from collecting the device at the patient to delivery, disposal and preparation.
Besides that, the preparator has to furnish special locations for the disinfection, has to realise strict requirements regarding personal protection and may carry out the disinfection only according to the regulations determined by Medizin & Service GmbH. The preparation of MRSA contaminated equipment includes the disposal of the whole accessory like bags, instructions, power supplies etc., which cannot be prepared.

For the MRSA disinfection, the disinfection process needs to be carried out ***2x*** subject to the respective disinfection category.

Which kind of costs are to be expected for the operation of the device?

The disinfection device requires electrical power (230 VA, 150 W) and distilled water (250 ml per disinfection run) for the disinfection. Besides that, no additives are required.

Maintenance:
after 500 operating hours at the latest or once a year
(depending on which event occurs first)
Maintenance includes:
Cleaning / measurement control / safety control / calibration

after 1000 operating hours at the latest
Maintenance plus **exchange of the ozone generator and the sensor system**

Maintenance and repair of KR 1000 disinfection system is exclusively done by the manufacturer.

What happens to the ozone after the disinfection?

After the disinfection, the device automatically switches to the ozone degradation mode. Only after the value has fallen below the allowed limit value, the system may be disconnected (time approx. 15 min)-only molecular oxygen remains. Afterwards, the respiratory device can be applied according to its intended use and functions have to be tested (approx. 60 min).

Which devices may be disinfected?

All current devices can be found at http://www.medizinservice-sachsen.de/ under "Instruction for val. respiratory equipment". This instruction is constantly updated on our homepage and is offered to our customers in form of a download.

How long are ventilation times?

There are no ventilation times required. Drying of the respiratory device while preventing contamination is recommended.
For this purpose, the device should be operated with inserted filter within the frame of the functional test in a dry, dust-free environment for about 1 hour.
At the same time, the smell possibly occurring during the treatment with ozone is reduced by subsequent ventilation.

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