

Recommendations by the Quality Task Group (97)

Disinfection of surfaces and medical devices – Part 2

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→ **PREFERENCE** should be given to automated cleaning and thermal disinfection.

→ **FOR MEDICAL DEVICE REPROCESSING** preference should be given to thermal disinfection in a washer/disinfector (WD) based on the A_0 concept.

→ **CHEMO-THERMAL DISINFECTION** is possible e.g. for thermolabile devices.

→ **MANUAL CHEMICAL DISINFECTION** is carried out at room temperature as immersion or wipe disinfection.

I 5. Disinfection of medical devices

The hygiene requirements governing medical device (MD) reprocessing are set out in the corresponding KRINKO/BfArM Recommendation [2] and, based on risk assessment, the MDs are assigned to one of the following groups:

- Non-critical
- Semi-critical
- Critical

The KRINKO/BfArM Recommendation advocates that → **PREFERENCE** be given to automated cleaning and thermal disinfection.

5.1 Thermal disinfection

For → **MEDICAL DEVICE REPROCESSING** the KRINKO/BfArM Recommendation advocates that preference be given to thermal disinfection in a washer/disinfector (WD) based on the A_0 concept [10]. This is expressed as the A_0 value:

- A_0 600, i.e. at least 1 min at 90 °C (assures bactericidal, fungicidal, incl. levurocidal, mycobactericidal, incl. tuberculocidal, efficacy)
- A_0 3000, i.e. at least 5 min at 90 °C (assures bactericidal, fungicidal, incl. levurocidal, mycobactericidal, incl. tuberculocidal, efficacy) in addition to virucidal action.

In Germany, surgical instruments are generally disinfected with A_0 3000. A_0 600 is used following risk assessment e.g. for disinfection of bedpans.

5. Chemothermal disinfection

If thermal disinfection is not possible, e.g. for reasons of material incompatibility, → **CHEMO-THERMAL DISINFECTION** is conducted in a WD. This means that a disinfectant is used at high temperature in the WD (e.g. 55 – 60 °C).

If thermal disinfection is used as the final disinfection step for semi-critical medical devices (e.g. flexible endoscopes), the latter must be disinfected as per the KRINKO/BfArM Recommendation using a disinfectant endowed with bactericidal, fungicidal, mycobactericidal and virucidal action; the virucidal efficacy must be tested in accordance with the DVV/RKI method [3] (see also Section 6.3).

5.3 Chemical disinfection

Chemical, or also → **MANUAL**, disinfection is normally carried out at room temperature. Immersion disinfection, using a disinfectant intended for medical instruments, should be used to disinfect instruments, if possible. If immersion disinfection is not possible, wipe disinfection is carried out using a surface disinfectant endowed with the requisite spectrum of action.

Disinfection of medical devices

Based on the KRINKO/BfArM Recommendation, there are no specific requirements governing the spectrum of action for non-critical medical devices. For critical medical devices where disinfection is followed by sterilization the Quality Task Group recommends at least bactericidal, levurocidal and limited virucidal efficacy.

Final disinfection of semi-critical medical devices

The KRINKO/BfArM Recommendation stipulates the spectrum of action required for the → **FINAL DISINFECTION** of semi-critical medical devices. According to the latter, this must be bactericidal, fungicidal, mycobactericidal and virucidal, with the virucidal efficacy tested in accordance with the DVV/RKI method [3] (see also Section 6.3).

→ **FOR THE FINAL DISINFECTION** für of semi-critical medical devices the spectrum of action is stipulated in the KRINKO/BfArM Recommendation.

I 6 Test methods and disinfectant lists

Both European (EN or DIN/EN) and national standardized test methods (e.g. VAH) are available for demonstration of the → **EFFICACY** of disinfectants. The principle underlying disinfectant test methods is based on investigation of the respective disinfectant efficacy against several representative microorganisms. If the disinfectant product is effective against these microorganisms a general statement can be made about the overall group of similar microorganisms (*example*: testing and demonstration of the efficacy of the respective disinfectant against three representative species of bacteria validates the general statement: bactericidal). → **SUITABLE MICROORGANISMS** are selected by experts and defined in the respective test methods (EN or VAH).

→ **THE EFFICACY** of disinfectants can be proven with European or national standardized test methods.

In the case of viruses it is often not possible to grow and test the relevant viruses in the laboratory, hence → **SURROGATE VIRUSES** are used for test purposes. Since the surrogate viruses have properties similar to the viruses they are meant to represent, the test results can accordingly be applied to the relevant viruses.

→ **SUITABLE MICROORGANISMS** are used for the tests.

→ **SURROGATE VIRUSES** that have properties similar to the relevant viruses are used for test purposes.

6.1. European test methods (EN Tests)

→ **EN TESTS** comprise several phases with a separate test required for each microbial group and category of antimicrobial efficacy (e.g. bactericidal efficacy):

→ **EN TESTS** comprise several phases.

Phase 1: Basic test

Oriental testing not tailored to any specific type of application (of relevance only to manufacturer).

Phase 2/Level 1: Quantitative suspension test

Takes account of application conditions (temperature, contamination/bioburden, time)

Phase 2/Level 2: Practice-oriented germ carrier tests

These reflect the everyday setting, e.g. simulation tests of various surfaces.

Phase 3: Everyday practice/field tests

Not available to date, hence of no relevance for everyday practice.

European test methods provide for testing and evaluation of disinfectants used for both manual and automated disinfection. Which standard is to be invoked for which antimicrobial efficacy claims is set out in EN 14885 [4]

6.2 Association of Applied Hygiene (VAH) List

In Germany the Association of Applied Hygiene (VAH) has published methods for testing disinfectants. These → **TEST METHODS** which also serve as the basis for inclusion on the VAH List [5] generally concord with the EN methods.

→ **THE TEST METHODS** published by the VAH generally concord with the EN methods.

A disinfectant that appears on the VAH List will have at least bactericidal and levurocidal efficacy. Additional statements can be included as an option on efficacy against the causative agent of tuberculosis or against moulds and viruses. Products used for chemothermal disinfection do not at present appear in the VAH List.

6.3 Efficacy against viruses

In Germany, there are in addition to the EN methods the DVV/RKI methods for testing efficacy against viruses. But the latter differ from the European test methods.

The DVV/RKI or the European test methods can be used to test limited (or complete) virucidal efficacy.

However, based on the KRINKO/BfArM Recommendation, only disinfectants tested for efficacy according to the → **DVV/RKI METHODS** are permitted for the terminal disinfection of semi-critical medical devices.

→ **ONLY DISINFECTANTS TESTED ACCORDING TO THE DVV/RKI METHODS** are permitted for the terminal disinfection of semi-critical medical devices.

To date, products with efficacy against viruses have only rarely been featured on the VAH List. For further information please consult the IHO Virucidal Efficacy List [6].

6.4 RKI List for officially decreed decontamination measures

For officially decreed decontamination measures disinfectants and disinfectant processes set out in Section 18 of the Protection against Infection Act must be used, i.e. products and processes that appear on the → **RKI LIST** [7]. These are tests, evaluated and listed in accordance with the RKI's own methods. It is important to observe the dosage and exposure time specified in the list.

→ **THE RKI LIST** lists products and processes to be used for officially decreed decontamination measures.

→ **THE INSTRUCTIONS SUPPLIED BY THE MANUFACTURER** of medical devices and disinfectants have to be observed.

Practical tips

In general, the → **INSTRUCTIONS** supplied by the medical device and disinfectant manufacturers should be observed, e.g.

- Observance of concentration, temperature and exposure time
- Recommendations on material incompatibility
- Elimination of process chemical residues

If you have any queries please contact the respective manufacturer. ■

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