

schülke -+

## Clean solutions for CSSD.

Innovative products and services  
for the preparation of instruments.



the plus of pure  
performance



More than 100 years of competence in hygiene and preservation ...



**1892** | Successful fight against the cholera epidemic in Hamburg with lysol®



**1913** | Market introduction of sagrotan®, the first brand name disinfectant for domestic use



**1975** | gigasept® the first disinfectant against HBV

# Hygiene is the most important instrument.

## Secure. Clean. schülke.

Hygienic preparation and care of instruments in medical application areas require efficient and highly effective formulations which are adapted to all standards of clinical daily life.



### Sterile instruments. Safe patients.

Precision and ergonomic handling are two of the most important features of instruments, the cleaning and disinfection of these instruments must function just as precisely and simply.

The increased requirements on reprocessing make material compatibility as important as a wide spectrum of cleaning and disinfecting effectiveness.

Proven and reliable products with short contact times and low use concentration are essential in clinical daily life and guarantee smooth and fast processes.

Our comprehensive range of innovative formulations meet the highest international safety standards and, in the automated and manual decontamination of instruments, guarantees high level of safety for users and patients.

Comprehensively tested, all schülke products comply with the legal requirements. And like all other products made by schülke, they are developed to be state-of-the-art.

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**1980** | kodan® – skin-friendly antiseptic for use, for example, prior to injections



**1981** | Launch of mikroizid®, the leading fast acting disinfectant for the medical field



**1984** | Introduction of an extensive range for the mechanical processing of medical products: thermosept®

# Manual decontamination of instruments.

**Safe and effective disinfection and sterilisation can only be guaranteed with clean medical products.** According to the recommendation of the Commission for Hospital Hygiene and Infection Prevention at the RKI (Robert Koch Institute) and BfArM (German Federal Institute for Drugs and Medical Devices), the preparation of medical products<sup>1</sup> includes:

- proper preparation (if nec. pretreatment, precleaning, disassembly, opening of joint instruments, storing and transport)
- manual or mechanical pre-rinsing, cleaning, disinfection, rinsing afterwards and drying.



At the start of the cycle the instruments come to the “drop”, this is the careful placement of used instruments in the operating theatre. There are two options for the drop:

#### **a) Wet disposal:**

In order to prevent surface drying, coagulation and organic staining, used instruments are usually placed in a cleaning or disinfectant agent directly after use. A liquid-tight transport to the CSSD has to be ensured. Sometimes, corrosion can be observed after very long periods of storage.

#### **b) Dry disposal:**

In the case of a dry ‘drop’, the instruments are collected from the operating theatre without adding any cleaning or disinfectant agent and transported to the CSSD without any pretreatment.

Modern washing programmes and the use of modern and powerful, mainly alkaline cleaning agents generally ensure a flawless cleaning result, even after longer periods of drying and have thus largely superseded the wet drop. However, as a rule, blood and proteins should not be allowed to dry on for more than six hours.

Ideally, the instruments and devices to be prepared are opened and dismantled during dropping, so that they can be put into the machines in the CSSD with as few steps as possible and in compliance with the industrial safety standards.

Due to the danger from stab and cut wounds, contaminated instruments must not be re-sorted without previous disinfection.

If a manual pretreatment of the instruments is necessary to remove very obstinate staining, the use of ultrasound (not for rigid optics and other lens systems) is often suitable.

#### **Ultrasound:**

The effect of ultrasound is based on the cavitation which occurs at the water-solid interfaces. In the solution, small bubbles are formed which contain gas with low pressure. When cavities collapse, this results in very high local differences in pressure which affect the removal of dirt particles. In soft objects, e.g. rubber and silicone, this effect is not very pronounced.

**Ultrasound is particularly suitable for dissolving dried dirt at sites which are difficult to access.**

**In general instruments should be carefully rinsed after any chemical pretreatment, even prior to mechanical decontamination.**

If instruments are not carefully rinsed small amounts of the cleaning agent may still be present. These residual chemicals may cause foaming leading to a reduction in the rinsing pressure of the mechanical process. Loss of pressure would consequently effect the cleaning efficiency of the process.

<sup>1</sup> Bundesgesundheitsblatt (Federal Health Gazette) 44 (2001): 1115-1126



**1989** | Introduction of octenisept®, a mucosal and wound antiseptic



**1997** | Hand disinfection product with virucidal efficacy lipophilic and hydrophilic viruses: desderman® N



**2002** | Colouring and perfume-free care series: sensiva®, also adapted to the special requirements of medical personnel

Depending on the type of application and the conditions of the instruments during and after surgery, there are many different challenges for the decontamination of instruments.



**Gynaecology instruments:**

Apart from blood, other endogenous fluids also dry quickly on specula. It has been noted that they are very difficult to remove manually. Therefore, instruments and accessories from gynaecology should principally be prepared with especially efficient mechanical cleaning procedures. Certain mucous disinfectants fix proteins and cause corrosion. These can be replaced with halide-free and non-fixing preparations.

**Orthopaedics instruments:**

Bone cement is very difficult to remove and often only completely by means of an alkaline RDG (cleaning and disinfectant devices) procedure after drying. Bone cement must be wiped off the instruments immediately after use in the operation theatre, for example, bone rasps can be freed of splinters in an ultrasound bath. These splinters can be dragged into the machine clogging up the jet spray arms and thus reduce the rinsing pressure. Particular attention should be shown to intramedullary reamers and screws. The manufacturers generally provide important advice in the operating instructions according to DIN EN ISO 17664, about how the overall quality of the decontamination can be ensured by a targeted, short manual clean.

**ENT instruments:**

In the ENT area, ointments often make reprocessing more difficult. They should be wiped off immediately and as completely as possible after the application in the operating theatre.

**MIS instruments:**

Despite receptacle containers, a manual preparation – e.g. with special brushes – is often required. Instruments which cannot be dismantled or devices without rinsing connections cannot be safely decontaminated according to today's standards and should not be used.

**Mono- and bipolar instruments:**

These instruments routinely adhere with coagulated blood and tissue which cannot be removed in a mechanical preparation. Soaking the tips in 3 % hydrogen peroxide solution, or very strong alkaline products is recommended for manual decontamination. Where necessary the tips should be wiped to remove excess product.

**Eye instruments:**

Ophthalmic surgical instruments are often very sensitive due to their filigree structure. Thus, a manual clean is not possible in most of the cases. According to the latest legal requirements (Guideline of the Robert Koch Institute and ISO 17664), the manufacturer of these products must define at least one automatic and validated procedure for their decontamination. The procedure must include, among others, details on validated processes for safe cleaning, disinfection and sterilisation. Due to the sensitivity of the eyes, it is vital to make sure, e.g. by measuring chemical parameters, that no process chemicals have remained on the tools to be prepared.

**The ideal situation for CSSD would be to work closely with the operating theatres.**

**This cooperation ensures that everyone is involved and understands which measures are used for the "drop" in order to aid the next steps of decontamination.**

**The instructions and recommendations of the instrument manufacturer should strictly be observed.**



**2006** | Surface disinfection and cleaning in one step – the recently launched terrain® product makes it possible



**2006** | antiMRSAset – the system solution for the treatment of MRSA for protection from infections

**schülke** →

**2008** | schülke, your partner in preservatives and hygiene for the 21st century

# Solutions for manual cleaning of instruments

## Cleaning



### gigazyme®

Enzymatic cleaning of flexible endoscopes and surgical instruments of all types

#### Our plus

- enhanced cleaning from the use of enzymes
- gentle to materials
- suitable for ultrasound
- cost-effective due to low application concentration
- pleasant fragrance
- no foam formation

#### Pack size

2 l bottle

5 l canister

## Cleaning disinfectant



### gigasept® instru AF

Aldehyde-free disinfection and cleaning of surgical instruments and anaesthetic equipment

#### Our plus

- innovative agent combination effective against bacteria (incl. mycobacterium terrae) and fungi
- complies with new standard methods and European norms
- tuberculocidal, limited antiviral agent\* (incl. HIV, HBV, HCV)
- excellent cleaning power
- very good material compatibility
- fresh and pleasant fragrance
- suitable for ultrasound
- use solution stable for 7 days

#### Pack size

2 l bottle

5 l canister



### gigasept® AF forte

Aldehyde-free disinfection and cleaning of surgical instruments, anaesthetic equipment and flexible endoscopes

#### Our plus

- complies with new standard methods and European norms
- tuberculocidal, mycobactericidal
- use solution stable for 7 days
- pleasant fragrance as it is aldehyde free
- suitable for ultrasound
- short contact times even under high load through optimized composition

#### Pack size

2 l bottle

5 l canister

\* acc. to RKI-recommendation of the Federal Health Gazette 01/2004

## Cleaning disinfectant

### gigasept® FF (new)



Succindialdehyde-based disinfection and cleaning of thermolabile and sensitive instruments, including flexible endoscopes and ultrasonic probes

#### Our plus

- complies with new standard methods and European norms
- virucidal, tuberculocidal, mycobactericidal, sporicidal
- formaldehyde-free
- excellent material compatibility
- lifetime of stock solution 7 days
- suitable for ultrasound
- can be mixed with the cleaning amplifier for gigasept® FF (new)

#### Pack size

2 l bottle

5 l canister

### lysetol® FF



Aldehyde disinfection and cleaning of instruments of all types, including flexible endoscopes

#### Our plus

- effective against bacteria, fungi, limited antiviral agent\* (incl. HBV, HIV), sporicidal
- use solution can be used for 10 days even in cases of heavy soiling
- excellent material compatibility
- suitable for ultrasound

#### Pack size

2 l bottle

5 l canister

## instrument trays

### instrument trays



The complete reservoir system for disinfection, cleaning and care of instruments of all types. The system is suitable for all areas in the hospital, as the trays can be selected according to the individual requirements.

#### Our Plus

- excellent material compatibility with all instrument disinfectants and cleaning products
- the instruments trays are heat-resistant up to + 55 °C

#### Order

For detailed information and order details, please request our special brochure on instrument trays!

\* acc. to RKI-recommendation of the Federal Health Gazette 01/2004

➤ Unsuitable water leads to spotting



# It all depends on the right type of water!

## Why is unsuitable water harmful?

For tap water the water quality regulations apply in general. They specify the threshold values for the substances in the water. The composition of potable water may vary within these limits, e.g. dependent on its origin and type of drinking water abstraction.

The minerals causing hardness, e.g. calcium and magnesium salts which are found in all types of tap water, produce scale when heated. If tap water dries up, the minerals causing hardness and, in addition, all other dissolved water components remain in the form of dry residue on the surface and form water spotting.

**This is why tap water is not suitable for higher temperatures (e.g. a cleaning step at 60 °C) or for a final rinse.**

For these reasons, the water quality is to be optimised by means of special procedures for the mechanical processes. In this context, a difference is made between softening and a complete demineralisation.

During **water softening**, only the minerals causing hardness, e.g. calcium and magnesium salts, are replaced by sodium salts which do not precipitate as scale at higher temperatures. This way, calcification of machines and rinsing tools is prevented.

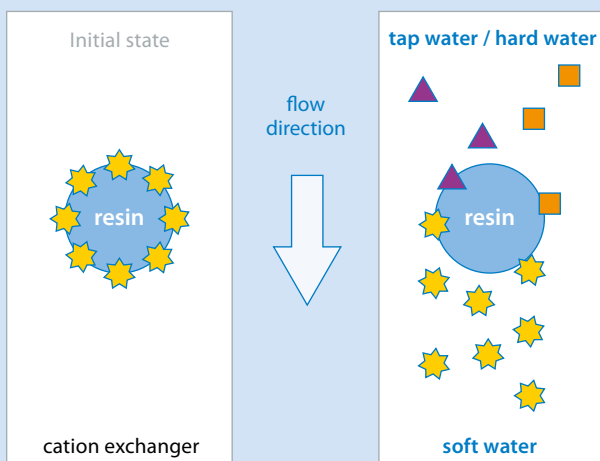
During complete **demineralisation** (demineralisation water production), all salts dissolved in the water are almost completely “removed”, so that this “demineralised” water is then particularly suitable for the final rinse.

Spotting and blooming, as well as a risk of corrosion, are reduced to a minimum or are prevented due to the removal of salts.

**For reasons of process optimisation and ease of validation, the use of demineralised water\* is recommended starting from the pre-rinsing stage.**

\* Demineralised water can be produced anywhere and independent of the original quality of the tap water with a defined and reproducible composition. On this basis, a validation of the processes is essentially facilitated.

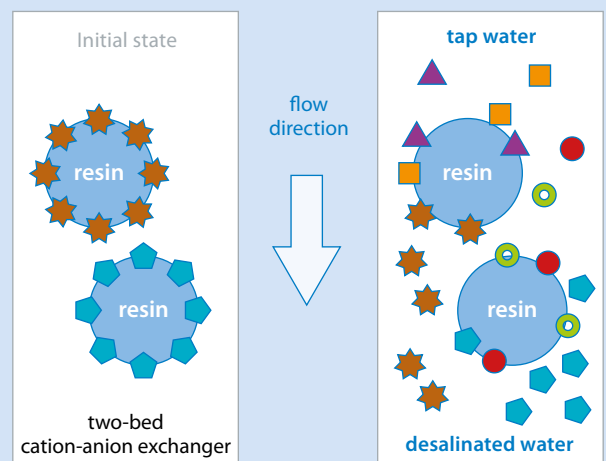
### Production of soft water



★ sodium ions  
▲ calcium ions  
■ magnesium ions

} minerals causing hardness

### Production of demineralised water



★ H<sup>+</sup>  
⬠ OH<sup>-</sup>

} H<sub>2</sub>O

▲ Ca<sup>2+</sup>  
■ Mg<sup>2+</sup>  
● Cl<sup>-</sup>  
○ SO<sub>4</sub><sup>2-</sup>

representative for all cations  
 representative for all anions

# Automated decontamination of instruments.

Depending on the type of application and the conditions of the instruments during and after surgery, there are many different challenges for the automated reprocessing of instruments.

## Surgical instruments – powerful cleaning of all materials

**Surgical instruments** exhibit high mechanical and chemical resistance. To minimise the risk of an iatrogenic transfer of prions, the RKI recommends alkaline cleaning agents with a pH value of  $> 10$ .

During reprocessing in the machine jointed instruments must be opened ensuring no areas are left unwashed. Careful handling of surgical instruments extends service life and maintains the functionality of the instruments and is therefore also essential for the patient safety.



## MIS instruments and rigid endoscopes – optimised cleaning in narrow lumen

**Instruments of minimal invasive surgery (MIS)** and rigid endoscopes consist of many different materials, such as anodised aluminium, chromium and chromium-nickel steel, plastics and sensitive optics. Due to their design, these instruments have cavities and joints which are difficult to access and difficult to clean. These peculiarities demand high standards of the cleaning performance and compatibility of materials with the cleaning agent.

The instruments are dismantled according to the manufacturer's instructions and placed in the corresponding insert basket or are attached to the rinsing connections. An accurate connection is of particular importance for optimal cleaning of the lumina.



## Ophthalmologic instruments – gentle cleaning of filigree instruments

In ophthalmology, sensitive micro instruments with very narrow channels are sometimes used. According to the RKI eye tissue is regarded as high risk, therefore safe validated cleaning procedures are called for. Specific instrument storage systems are available for the transport and the preparation.

Special load trolleys with connections and holding fixtures, e.g. for phaco hand pieces and accessories, partly with filter systems, are offered by the machine manufacturers. By using these technologies, the purging and scouring of the instruments in the cleaning and disinfection machine is considerably improved.



# I. Thermal procedures

Goals of thermal preparation of medical products include:

- ensuring sterilisation
- removal of stains as quickly and completely as possible
- reducing bacterial exposure for safe handling, e.g. during sorting

Automated procedures are preferred to purely manual procedures as they can be standardised and validated. Essential procedure parameters can be monitored and documented, which is important for traceability.

**During thermal processing the bacterial load is reduced using high temperatures over given contact times without the addition of disinfectants.**

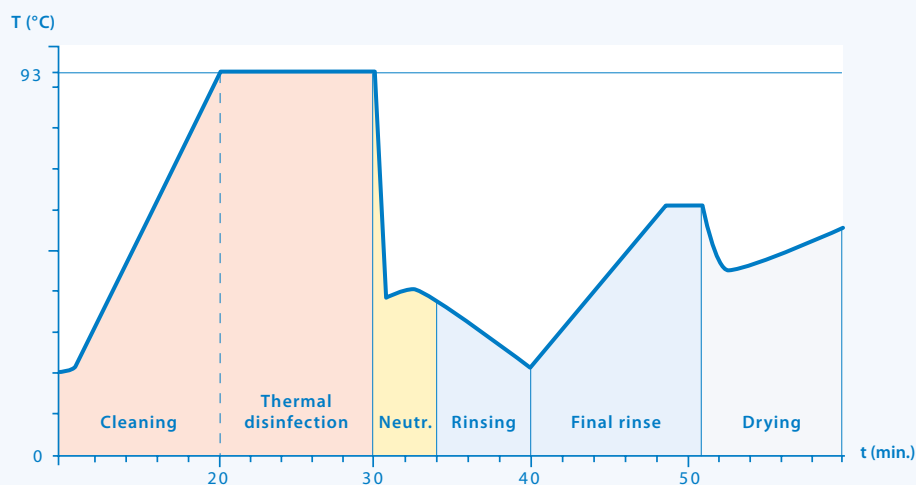
The Robert Koch Institute (RKI), for example, included for the “disinfection according to the epidemic law control”, in the past and today only in case of an epidemic, the parameters 93 °C with a contact time of 10 minutes at simultaneous record of the spheres of action A + B into the list according to § 18 IfSG (German Infection Protection Act). In order to also consider pathogens unknown so far, a high safety margin was integrated and rates of reduction in bacterial counts of 7 log steps were achieved.



## a) The RKI procedure

In this BGA (German Federal Health Department) and RKI programme, a combined cleaning and disinfection step at 93 °C was the focus of interest. The intention was to avoid pumping contaminated solutions into the waste water and therefore interrupt infection chains.

**Process flow of RKI procedure:**



# I. Thermal procedures

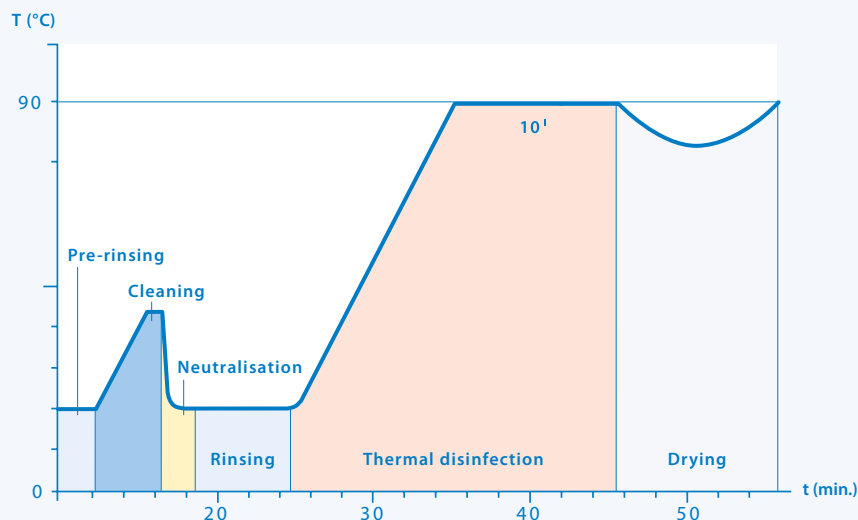
## b) The VARIO-TD procedure:

Due to the number of developments in instruments, it has become necessary to adjust also the machine programmes with regard to a preparation that is gentle and compatible with materials. The BGA programme has been optimised and almost replaced in practice by the Vario-TD-Programme developed by Miele. Today, the disinfection step takes place on the basis of new findings on the interruption of infection chains in the final rinsing step.

This makes it possible to start programmes with one or more cold water rinsing steps and thus to remove considerable amounts of water-soluble residues, e.g. blood, prior to the cleaning step.

Here, the coagulation and thus the fixation of organic material is bypassed by using temperature of up to about 55 °C.

### Process flow of Vario-TD:



Cleaning agents are selected taking the materials used to manufacture the instruments into consideration. Highly alkaline cleaning agents are used for surgical instruments made of steel. For engine systems, aluminium and titanium materials, mildly alkaline and partly neutral cleaning agents are used and combined with the corresponding temperatures. Temperatures for alkaline cleaning agents of about 55 °C with a retention time of 5 to 10 minutes have been shown to be effective. Enzymatic cleaning agents often develop their highest enzyme activity at lower temperatures around 40 °C.

In order to prevent carrying over alkalinity, an acid neutralisation step is often used after the alkaline cleaning stage.

To ensure a flawless result, neutral cleaning agents can also be combined with a low acid dosage to prevent discolouration or corrosion due to a non-optimal or varying water quality. In this case, the acid assumes the functions of an "acid cleaning agent".

For the thermal disinfection which refers to the final rinse, demineralised water must be used in order to ensure spot-free and residue-free drying.

# I. Thermal procedures



## c) The Orthovario procedure:

Certain materials, e.g. engine systems made of anodised aluminium, are not suitable for the Oxivario procedure due to their intolerance towards the high alkalinity. For this case, Miele has developed the Orthovario procedure. Here, the two cleaning steps do not have the same high alkalinity and are separately adjusted to the process requirements.

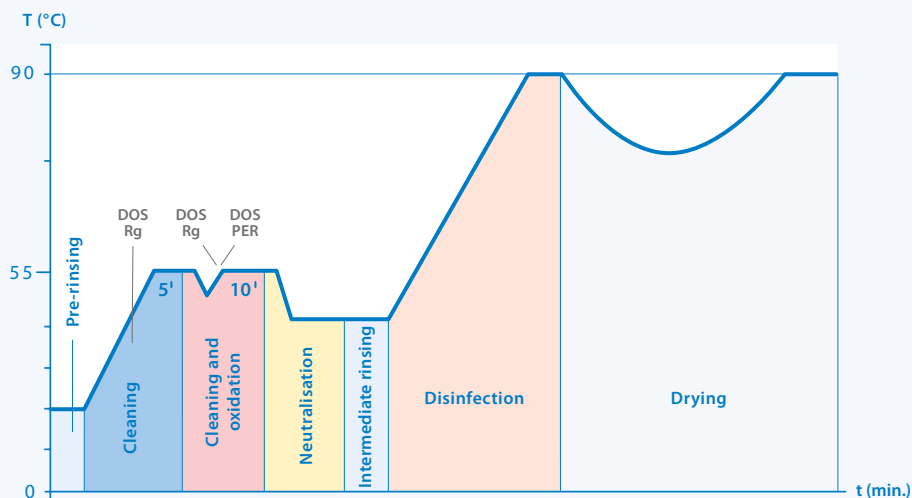
In the first cleaning step, a pH value under 10 at 55 °C is adjusted and, in the second cleaning step, a pH value of about 10.5 at 65 °C by using a higher dosage of the cleaning agent. Here, the release of the active oxygen – which stabilises the oxide layer of the aluminium – is no longer performed via the alkalinity but by means of a corresponding temperature control. As a result, the procedure becomes compatible with materials also for otherwise alkali-sensitive materials.

## d) The Oxivario procedure:

The cleaning procedure Oxivario developed by Miele releases active oxygen by a combination of a (highly) alkaline cleaning agent with hydrogen peroxide. This results in the possibility to further increase the cleaning performance of the Vario-Programme by means of an oxidative process.

Intensive care of the instruments is recommended after each preparation, as bare metal glides on each other after the optimised cleaning in the joints.

## Process flow of Oxivario:



# I. Thermal procedures

## Disinfection with the $A_0$ concept

For a more detailed description of the disinfection performance of a thermal preparation, the so-called  $A_0$  concept was introduced (EN ISO 15883-1, Appendix A).

It states that there are different temperature /time combinations – described by the  $A_0$  values – by means of which the same microbiological efficacy can be achieved. This applies to temperatures over 65 °C.

Instead of generally selecting 93 °C and a retention time of 10 minutes as the preparation parameters, a concrete  $A_0$  value can now be selected independent of the microbiological contamination and the intended purpose of the medical product.

**The  $A_0$  value 600** corresponds to the effective range A.

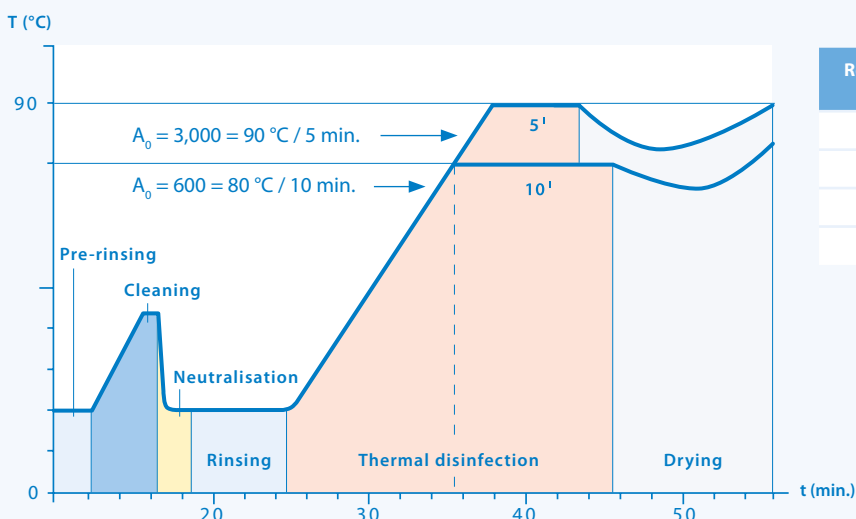
The application of an  $A_0$  value of 600 can be gained, for example, through a retention time of 10 minutes at 80 °C and is considered to be the minimum for uncritical medical product, i.e. instruments which only get into contact with unwounded skin. Alternatively, the combination of 90 °C with a tenth of the retention time, thus one minute, is also possible.

Another precondition for the application of the  $A_0$  value of 600 is that only a contamination with vegetative bacteria including mycobacteria and fungi is present.

**The  $A_0$  value 3,000** corresponds to the effective range B. An  $A_0$  value of 3,000 can be achieved, for example, with a disinfection time of 5 minutes at 90 °C or equivalently, 50 minutes at 80 °C.

According to the RKI, this  $A_0$ -value is to be used for medical products which are contaminated or may be contaminated with the heat-resistant hepatitis B virus.

### The $A_0$ concept



Retention time [min.]	Temperature	$A_0$ -value
10	80	600
1	90	600
50	80	3,000
5	90	3,000

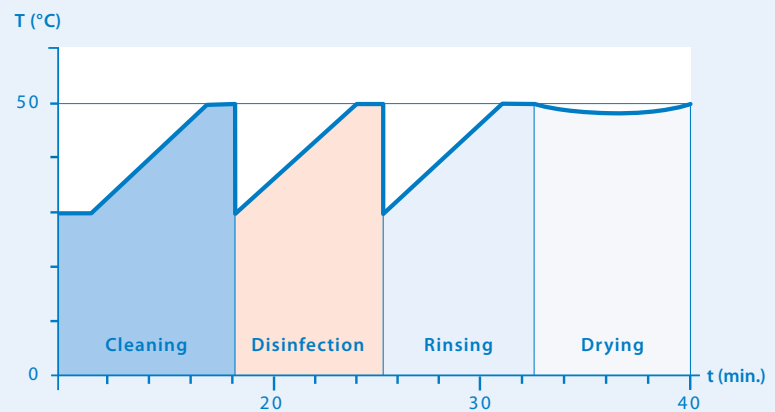
As the number and the type of microorganisms on the medical products sent for decontamination is generally unknown, the mechanical, thermal decontamination should principally be performed with an  $A_0$  of 3,000.

## II. The chemo-thermal procedure

Thermolabile material which cannot be exposed to the high temperature ranges used in thermal disinfection are decontaminated at temperatures around 60 °C whilst adding a disinfectant. The microbiological efficacy of the products must be demonstrated using expert opinions which state specific temperatures, concentrations and contact times.



Process flow of chemo-thermal procedure



# Solutions for automated decontamination of instruments

## Cleaning

### thermosept® RKN-zym

Neutral, enzymatic cleaning agent for the automated decontamination of medical instruments



#### Our Plus

- particularly suitable for sensitive materials because it is pH-balanced
- almost foam-free
- gentle to anodized aluminium

#### Pack size

5 kg canister  
10 kg canister  
30 kg canister  
200 kg barrel  
500 kg container

### thermosept® alka clean forte

Mildly alkaline liquid cleaning agent with tensides for automated decontamination of medical instruments and accessories from the fields of surgery, anaesthesia and care



#### Our Plus

- gentle to materials and suitable for aluminium because it is mildly alkaline
- powerful cleaning
- wide range of application
- to minimise the risk of an iatrogenic transfer of CJK/vCJK (acc. to RKI-recommendation)
- can also be used without neutralisation

#### Pack size

5 kg canister  
10 kg canister  
30 kg canister  
200 kg barrel

### thermosept® RKF forte

Liquid, alkaline cleaning agent for the preparation of surgical and microsurgical instruments, MIS instruments, rigid endoscopes, anaesthetic accessories, shoes for the operating theatre, baby bottles and stainless steel containers



#### Our Plus

- foam-free, suitable for Oxi Vario
- improved cleaning performance due to increased alkalinity\*
- good emulsifying and dispersing power
- effective corrosion protection

\* not suitable for aluminium

#### Pack size

5 kg canister  
10 kg canister  
30 kg canister  
200 kg barrel

## Neutralisation



### thermosept® NKZ

Neutralising agent based on citric acid for automated decontamination

#### Our Plus

- phosphate-free
- gentle to materials
- optimises the cleaning result after alkaline and neutral cleaning

#### Pack size

5 kg canister  
10 kg canister  
30 kg canister  
200 kg barrel  
500 kg container

## Rinse aid



### thermosept® BSK

pH-balanced rinsing aid

#### Our Plus

- pH-balanced
- almost foam-free
- spot-free drying of laundry
- well suited to be combined with thermosept® NDR to reduce the drying period

#### Pack size

30 kg canister  
200 kg barrel  
500 kg container

## Disinfection



### thermosept® DK

Aldehyde-based disinfectant for chemo-thermal processing

#### Our Plus

- pH-balanced
- gentle to materials
- wide spectrum of efficacy
- for combination with thermosept® RKF or RKN-zym

#### Pack size

5 kg canister  
10 kg canister  
30 kg canister  
200 kg barrel

## Pumping Station



Should you require further information please request our schülke pumping station folder.

Folder schülke pumping station  
Mat-No. 2123



# Information material

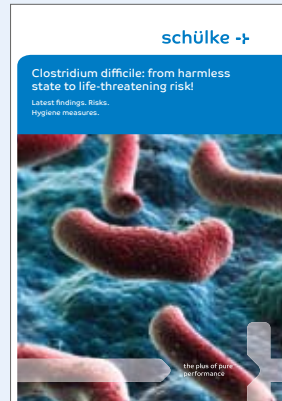
► For further information please visit our website [www.schuelke.com](http://www.schuelke.com) and request our other brochures.



Folder Hygiene technology  
Mat-No. 2122



Folder Norovirus  
Mat-No. 2056



Folder Clostridium difficile  
Mat-No. 2102



Folder Tuberculosis  
Mat-No. 2106



# Our services for your CSSD.

Extra services	Benefits
<p><b>Preparation result and process quality:</b> Analyses, assessments and recommendations with regard to procedure and total concepts</p>	Shorter preparation times, less usage, lower costs, higher result quality, faster routes, value retention
<p><b>Process control:</b> Measurement and documentation of program parameters</p>	Nominal-actual-comparison, verification of values, A <sub>0</sub> concept
<p><b>Surface analytics:</b> Examination of surface changes, et al. with X-ray fluorescence</p>	Implementation of counter measures and guarantee of functionality
<p><b>Water and working solution composition:</b> Analysis of selected parameters, e.g.:</p> <ul style="list-style-type: none"> <li>• pH values</li> <li>• Conductivity</li> <li>• Silicate</li> <li>• Chloride</li> <li>• Hardness, carbonate and residual hardness</li> <li>• Determinations of concentration</li> </ul>	<p>Observance of limit values, guarantee of nominal values, value retention, prevention of surface changes</p> <p>Compliance with general recommendations, e.g. RKI</p> <p>Testing for possible residual quantities and transmission</p> <p>Avoidance of persistent discolouration</p> <p>Protection from pitting</p> <p>Guarantee of sufficient water quality</p> <p>Testing and optimisation of cleaning capacity</p>
<p><b>Validations:</b> Planning, preparation</p>	<p><b>One-stop service:</b> A responsible and competent contact for all CSSD concerns</p>
<p><b>Recirculation and feed systems:</b> Design, planning and installation in existing equipment, for rebuilds and new developments, testing and maintenance</p>	Simplification of dosing, fulfilment of highest requirements for exact dosing, e.g. for individual machines, discontinuous belt systems and container cleaning units
<p><b>Dosing systems:</b> Commissioning, inspection, maintenance and repair</p>	Sustained correct and safe dosing
<p><b>Product advice:</b> Advice on selection of process chemicals and creation of individual program processes</p>	Consideration of specific requirements on site, coordinated products
<p><b>Legal requirements:</b> Suggestions for adaptation of processes</p>	Legal certainty through compliance with legal requirements, e.g. Medical device law , RKI, DIN EN



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