

## Automated Reprocessing: Inter-related Process Parameters in Washer-disinfectors

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A lot has changed in recent years in the area of automated instrument reprocessing. The changes range from new instruments with new materials and designs that place special requirements on reprocessing to new procedures and flexible loading technologies in washer-disinfectors (WDs) that place special requirements on equipment technology (e.g. variable speed pump) in order to ensure constant process parameters (e.g. rinsing pressure) to new formulations and combinations for processing chemicals.

Therefore, it is definitely reasonable to pose the question of whether the current recommendations (e.g. cleaning step at 55°C with alkaline media with pH > 10 and a holding time of 10 minutes) are still valid, or whether the user/operator could adapt his or her processing steps appropriately, provided the result complies with the guidelines.

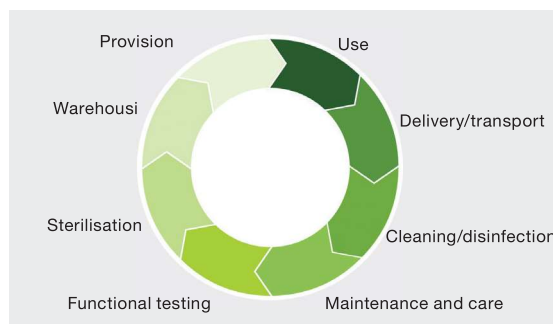
Pursuant to Section 8 of the Medical Device Operator Ordinance, the reprocessing [...] of medical devices that are used in accordance with provisions requiring that they have a low microbial count or be sterile is performed with attention to the manufacturer's specifications and with suitable validated procedures in such a way that the success of these procedures is logically ensured and that the safety and health of patients, users or third parties are not jeopardized [...].<sup>1</sup>

These "suitable validated procedures" yield a defined result (in particular: cleanliness, sterility or low microbial count, functionality), which must be reproducible and verifiable.<sup>2</sup> In addition, parameters that are necessary for adhering to the validated conditions in the particular process are established and defined.<sup>2</sup>

### Step 1: Pre-rinse

Because the conditions and reprocessing procedures differ for each reprocessing unit for medical devices (RUMED), these different parameters and individual process steps must be determined on site and in a user-specific manner. This occurs during validation, which must be repeated regularly.

Automated reprocessing should be favoured over manual reprocessing, since washer-disinfectors allow for standardised reprocessing and thus provide a high level of process safety and thus reproducibility of results. The reprocessing step in the washer-disinfectors follows specific process steps and parameters (see Figure 2). Thus, a cold pre-rinsing step, generally fed with softened water, comes first in order to remove any adhered dirt and other water-soluble and adhered contaminants.



**Figure 1:** Instrument cycle.

### Step 2: Cleaning

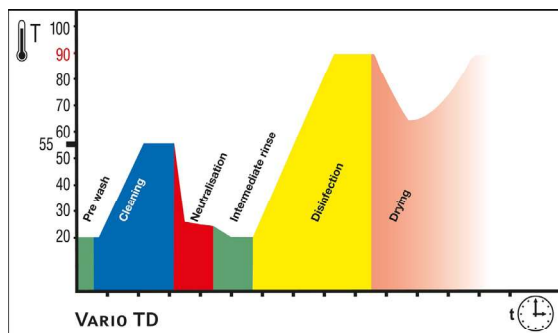
In the second step, the main cleaning should preferably be performed with softened or demineralized water. Depending on the articles being reprocessed and the processing chemicals being used, this may, for example, take place at a processing temperature of 55°C and a holding time of 10 minutes. In accordance with the AKI recommendation, the use of demineralized water is recommended in all program steps in order to optimize the process and achieve consistent quality of results in all program steps.<sup>3</sup>

Object-specific parameters (time, temperature, concentration) should be selected based on the material compatibility of the items being reprocessed and the optimal effectiveness of the detergent being used. Detergents based on enzymes, tensides, complex-forming agents, corrosion inhibitors and/or alkaline carrier agents are usually optimally effective at 50-55°C, highly alkaline detergents at 60- 70°C. Currently, the most commonly used cleaning agents in Germany and throughout Europe are (mild) alkaline detergents with different enzyme components that work at about 55°C and a pH value of between 9.5 and 10.5. Some manufacturers now include cleaning agents with pH values in the neutral-mild alkaline range in their portfolio. They are characterized by compatibility with a wide range of materials, especially with sensitive instruments, as well as by excellent cleaning performance. When selecting the cleaning agent, the pH value should

### Step 3: Interim rinse

In order to rule out chemical residues in the rest of the process, a rinsing step (interim rinse) is performed. The result should comply with the biocompatibility values for final rinse water indicated by the manufacturer of the processing chemicals to prove absence of processing chemical residues. When reprocessing instruments from highly specialised fields (e.g. ophthalmology), an additional interim rinse step may be necessary. The guide value in  $\mu\text{S}/\text{cm}$  is often used as a parameter for allowable processing chemical residues (cleaning and neutralising agents)<sup>2</sup>. The manufacturers of the process chemicals make available the relevant overviews of biocompatibility values and allowable residual amounts.

**The reprocessing procedures must deliver the valid process and the corresponding parameters in a batch-specific, reproducible manner.**



**Figure 2:** Conventional course of the process in a washer-disinfector.

### Step 4: Thermal disinfection

Finally, thermal disinfection takes place, for example at temperatures between 90 and 95°C and for 5 minutes (A0 value of 3000). Depending on how the risk of the articles to be reprocessed is classified, a lower A0 value can also be used. If permissible in terms of biocompatibility and materials compatibility, a final rinsing agent can be used in this processing step in order to shorten the drying time. The rinsing agent reduces the water's surface tension, so the instrument surfaces dry faster because the layer of water droplets is not as thick. Depending on the equipment, drying can occur as a next step of mechanical reprocessing in the washer-disinfector.

play a secondary role, since the proven cleaning performance is most decisive.<sup>2</sup>For alkaline media, neutralisation is performed after cleaning in order to neutralise the alkalinity that remains on the articles being reprocessed and in the washer-disinfector chamber and systems that carry or come into contact with water. For (mild) alkaline products, this is not usually necessary, since the alkalinity is diluted in the next process step (interim rinse). In the authors' opinion, conventional neutralisation using acid is to be recommended, because it strengthens the passive layer of the instrument's surface (improves the chrome-to-iron ratio) and therefore helps preserve the value of the instrument.

The reprocessing procedures must deliver the valid process and the corresponding parameters in a batch-specific, reproducible manner. Approval depends on compliance with the parameters and is based on visual inspection. Process indicators can be used in addition and regularly. These process indicators are added to the reprocessing procedures and evaluated. Different models are available on the market, ranging from

visual evaluation through objective reading of these indicators with subsequent manual/digital storage and documentation.

## Conclusion

Automated reprocessing procedures are validated in an object-specific fashion, and the results meet reprocessing requirements such as the acceptance criteria in the guidelines of the German Society of Hospital Hygiene (DGKH), the German Society for Sterile Supply (DGSV) and the Instrument Reprocessing Working Group for the validation and routine monitoring of mechanical cleaning and thermal disinfection



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processes (2017).<sup>4</sup> The final parameters for valid reprocessing depend:

- on the articles being reprocessed: design, materials used, classification of risk.
- the initial contamination: different challenges in the case of contamination and residues in fields like orthopaedics, gynaecology, etc.
- the washer-disinfector: in accordance with relevant standards, assurance of and adherence to the permissible parameters with respect to dose monitoring, temperature range, rinse pressure on the basis of the loading configuration and program phases.
- the process chemicals: contents, concentration, cleaning performance, optimal temperature, dosing temperature.
- the available water quality and temperature.

Modern cleaning agents may have a pH value <10, thereby making possible cleaning performance as described in the guidelines. These enzyme-tenside combinations can now be found in many sterile processing departments, as they can be dosed at low concentrations and also offer broad materials compatibility. What is decisive for the use of

mechanical cleaner is not the pH value but rather, as a rule, the proven cleaning performance. Instrument manufacturers have also continually introduced new materials, and supplemented conventional stainless steel instruments (which can be reprocessed without being compromised at pH values > 10) with new materials like anodised aluminium and titanium. These materials react sensitively to alkaline reprocessing, so surface changes may occur more frequently. Automated reprocessing involves inter-relationships among instrument, washer-disinfector and the process chemicals being used.

In 2014, the Robert Koch Institute<sup>5</sup> took up the question of prion-effective processing again, specifically the question of “What pH value is necessary for prion-effective processing?”, considering the matter independently of the discussion about “Prion cleaning and prion-inactivating characteristic”. For the evaluation of cleaning processes, the particular proven cleaning performance, regardless of pH value or cleaning time and temperature, has been found to be decisive.

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