# Insight: cleaning medical devices

*Aaron Papadopoulos*

Cleaning has played a central role in the history of humanity for thousands of years. Over time, there have been many crucial advancements regarding the technology and process chemicals used, but the principle behind the cleaning process remains unchanged. Laundry started off being washed in rivers before progressing to the washboard and ultimately to the washing machines that can now be found in virtually every household. The chemicals used are also subject to constant development, from simple soft soap to today's innovative and resource-saving cleaning products.

This article discusses the subject of cleaning in general, explains the cleaning process and gives an insight into chemical cleaning substances. The cleaning process can be applied to any type of cleaning, in both private (e.g. washing machine, dishwasher, washing a car) and professional environments, e.g. cleaning hygienic surfaces. For the sake of simplicity, this article will focus solely on cleaning medical devices.

## Pre-cleaning medical devices

The importance of meticulous and effective reprocessing of medical devices in order to prevent infection is indisputable. Reprocessing medical devices starts with pre-cleaning in the operating theatre or examination room. Coarse soiling, residues of haemostatic agents, skin disinfectants, lubricants, etc. should be removed before the instruments are set down if possible. In the case of flexible endoscopes, the insertion part is wiped down immediately after it is removed from the patient and the channels are flushed to prevent any residues from adhering. If residues do adhere, they can be extremely difficult to remove due to the narrow lumina of the endoscopes. Dried-on soiling can also lead to material changes such as corrosion, reducing the value and service life of the instruments. Ultrasonic probes, meanwhile, can or must be wrapped in a protective cover. This cover is removed and discarded after the examination, making it easier to (pre-)clean the probes using a cloth.

This initial "pre-cleaning" is followed by the actual cleaning process. This must be carried out manually (brush cleaning) for flexible endoscopes. All other instruments can be cleaned by machine. As a general rule, machine cleaning should be favoured over manual cleaning for occupational safety reasons and because it offers better standardisation and reproducibility.

These initial cleaning steps are immensely important and are crucial to the success of subsequent reprocessing, as effective disinfection and sterilisation can only be achieved if thorough cleaning has been carried out first. In the event of inadequate cleaning, soiling – particularly proteins – could become attached to the surface. The disinfectant that is subsequently applied may be used up on the soiling, reducing its efficacy. Equally, the function of the medical device being reprocessed could be impaired.

Cleaning is defined as the "removal of contamination from an item to the extent necessary for further processing or for intended use" (DIN EN ISO 17664). Guidelines such as the "Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices" set out limit values, warning ranges and reference values for classifying and evaluating the cleaning result. The aim of the daily cleaning routine is to achieve a "visually clean" result. This result is achieved by means of the cleaning process.

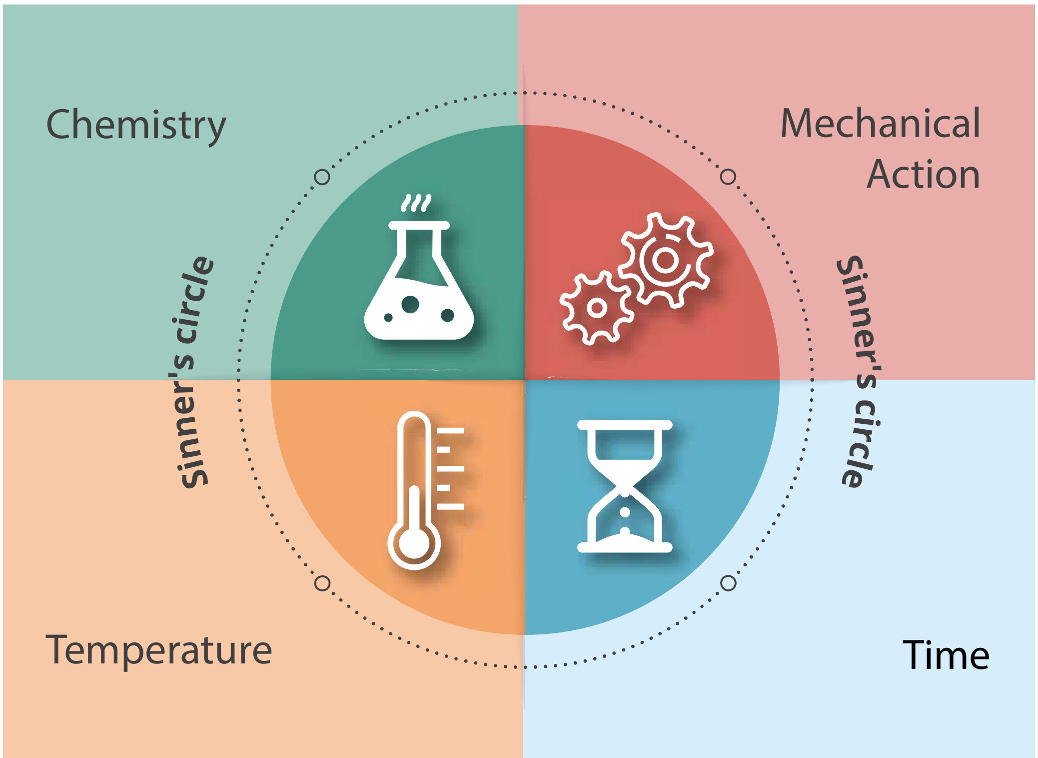
## Principles of the cleaning process

The principle behind every cleaning process is based on four interrelated factors. This process is also referred to as Sinner's circle, named after Herbert Sinner (*1900 in Chemnitz – †1988 in Hilden) who was a surfactant


## Author

Aaron Papadopoulos
Marketing Manager Instrument Reprocessing, Healthcare
ECOLAB DEUTSCHLAND GMBH
Ecolab-Allee 1
40789 Monheim am Rhein, Germany
E-mail: aaron.papadopoulos@ecolab.com
www.ecolab.com

**Fig. 1:** Four factors that make up Sinner's circle.




chemist and head of detergent application technology at Henkel. Sinner discovered that four factors are required to achieve the perfect wash result of "pure white". With a 90 °C wash programme, these factors must be weighted/set evenly. Sinner's circle can be adapted for dishwashing, manual cleaning, etc. and to take into account the evolution of cleaning chemicals and appliance technologies over the years. Today, optimum cleaning can be achieved by adjusting the individual factors so that they are weighted unevenly in Sinner's circle.

The four factors required for a successful cleaning process according to Sinner are described below:

- *Chemistry*
  Refers to the media used; for example, chemicals. These media can remove soiling from surfaces, catalyse / break down soiling, keep soiling suspended and ensure that particles do not adhere elsewhere.

- *Temperature*
  Refers to the required operating temperature in the cleaning process. The temperature should always be appropriate for the instruments being reprocessed. Some instruments (e.g. flexible endoscopes) are thermolabile and may sustain material damage at high temperatures. Excessively high operating temperatures may also result in protein fixing. The operating temperature in manual applications is much lower (25 °C on average) than in machine applications (average temperature 55 °C following initial cold pre-cleaning).

- *Mechanical action*
  Refers to the method used to remove soiling from the surface in question. In manual processes, this may involve brushing (for endoscopes) or wiping, or compressed air or a steamer may be used. Another possible method is the use of an ultrasonic bath. In automated processes, the mechanical action is provided by the wash pressure. The media (water and chemicals) are circulated and brought into contact with the surfaces with great force via the spray arms and / or internal circuit, thus removing the soiling. Modern washer-disinfectors use compressed air to blow water through lumina at certain intervals to aid the mechanical action of the water.

- *Time*
  Refers to the process time required to achieve the desired cleaning result. In manual processes, this refers to the time until the surface is visually clean. In machine processes, the time is programmed in and is usually 10 minutes. Longer wash phases offer more intensive wetting of the load items and lead to better cleaning/wash results.

All factors are dependent on each other but their weighting within a process can be adapted and changed. In the case of manual cleaning, a lower temperature is used which means that the mechanical action and powerful cleaning chemicals play a greater role in achieving the desired results. In a washer-disinfector, the temperature and mechanical action over the specified time are the key factors, while the cleaning chemicals support these factors in order to achieve optimum results.

Water is essential throughout the cleaning process as it serves as a reactant, solvent and means of transport in/with the four different factors. It is therefore extremely important that the water does not contain any substances which may impair its quality. Substances such as calcium carbonate and magnesium carbonate can leave behind limescale residues. Other substances can cause evaporation residue stains on the load items at high temperatures. Demineralised water (DI water) is therefore the best choice for machine reprocessing of medical devices as this produces the best possible results from all four factors of Sinner's circle. The water quality should be equivalent to drinking water quality as a minimum; in machine processes, the water quality often corresponds to demineralised water (DI water) in German-speaking countries.

## Cleaning components in the reprocessing process

With regard to chemicals, standard cleaning agents for reprocessing medical devices use the following key components, depending on the application:

- *Surfactants*
  Surfactants are crucial to the cleaning result and are present in virtually all cleaning agents. Due to their method of operation, they are also referred to as wash-active substances. They consist of a hydrophobic part and a hydrophilic part. Surfactants lower the surface tension of water and remove, break up, emulsify and disperse the soiling. When the surface tension of the water is lowered, the water wets a

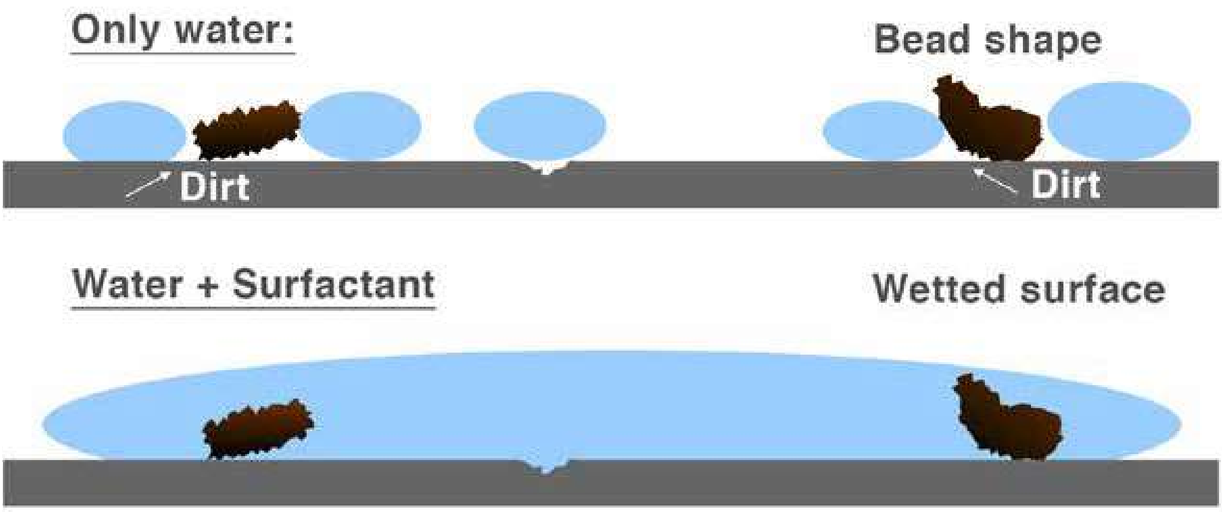



**Fig. 2:** Surfactants lower the surface tension of water.

When selecting the cleaning chemicals, it is important to ensure that they are compatible/coordinated with the cleaning process in question.

larger area and penetrates into lumina and narrow spaces in order to cover the particles of soiling. For example, water droplets sitting on a surface will only wet a small area due to surface tension. If a surfactant is added, the surface tension is reduced and the water wets a larger area, as shown in Fig. 2.

Another way in which surfactants improve cleaning is via their emulsifying properties. Emulsification is the process of mixing two incompatible liquids to form a single liquid. These incompatible liquids will separate out again over time, but the surfactant slows down this process (example: oil and water).

Finally, surfactants improve the cleaning power of water by suspending particles of soiling. This suspension prevents the particles of soiling from settling back on instruments and surfaces after they have been removed. Surfactants keep the particles of soiling separated and suspended in the solution, preventing them from collecting and settling back on the instruments when they are removed from the cleaning tank.

There are four different types of surfactants which are used in the chemicals depending on the application in question:

- Anionic surfactants: excellent cleaning performance, high foam formation
- Cationic surfactants: disinfection component
- Amphoteric surfactants: no cleaning performance, used to regulate foam
- Non-ionic surfactants: good cleaning performance, low foam formation

- *Enzymes*
  Enzymes are molecules that act as catalysts in a cleaning agent in order to improve the processing of particles of soiling. Enzymes can catalytically break down soiling such as proteins, carbohydrates or fats in order to remove them from the surfaces. There are many different enzymes for all kinds of soiling and application areas. The enzymes most commonly used in instrument cleaning agents (for both manual and machine processes) are proteases, lipases and amylases. The type of cleaning agent used should be tailored to the type of soiling being removed. With regard to the enzyme reaction, it is important to note that time, concentration and temperature affect the enzymes' ability to remove soiling. Enzymes need time to break down soiling. If the instruments do not have at least 3–5 minutes of activation time, the use of enzymes will not improve the overall cleaning process. Enzymes must be used at the right temperature and concentration in order to deliver optimum results. Concentrations and water temperatures above or below the manufacturer's recommendation may reduce the efficacy of the cleaning agents.

When selecting the cleaning chemicals, it is important to ensure that they are compatible/coordinated with the cleaning process in question. For example, when carrying out machine reprocessing of medical devices, cleaning products that also contain foam-sensing and lime-complexing components are used. If foam develops during machine cleaning, this can cause a technical fault in the washer-disinfector and form a barrier layer between the load items and the cleaning factors of temperature, mechanical action and cleaning chemicals, resulting in inadequate cleaning results. In manual processes, there is an increased risk of injury for the staff member as the instruments are no longer visible in the cleaning tank. When using chemicals, the manufacturer's instructions regarding dispensing and application area must always be followed.

## Summary

Every cleaning process follows the same principle in accordance with the specified parameters: chemistry, mechanical action, time and temperature. All factors are dependent on each other but their weighting within a process can be adapted and changed.

If one parameter in Sinner's circle is reduced, it must be compensated by another factor. In everyday life, process times should be as short as possible, which means that the cleaning factors of time, mechanical action and temperature are all reduced. This just leaves the factor of cleaning chemicals, which need to be appropriately compatible and powerful in order to avoid any gaps in Sinner's circle. Thanks to new and improved chemicals with minimal application concentrations in accordance with washer-disinfector developments, overall processes can be shortened and, result in optimised cleaning results in less time and with reduced use of resources.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