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Choosing a high performance detergent

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Choosing a high performance detergent

Richard Bancroft, BSc (Hons), science and technical director at STERIS Corporation, discusses the importance of high performance detergents for cleaning reusable medical devices.

Water, detergent and time, together with mechanical action, are generally accepted as the key variables for successful cleaning of reusable medical devices. Herbert Sinner described the inter-relationship for cleaning between mechanical action, chemical (detergent) action, time and temperature in a water-based system, as long ago as 1959, and his work gained widespread knowledge as Sinner's Circle. The key aspect of Dr Sinner's approach is that the Circle can be described as a summation of all factors needed in order to clean optimally (see figure 1).

But perhaps one of the most useful applications of the Sinner Circle concept is that all of these variables are inter-related; a reduction in one of the variables will necessitate an increase in one or more of the other variables. The opposite is also of course true; increasing one of the variables can reduce the others. As well as consideration of external factors like energy and water consumption, the commodity that we would always like more of in our daily lives is time, hence it is possible to optimise the Sinner Circle variables to allow a reduction in process time, but necessitating an increase in the other variables (see figure 2).

Cycle variables - temperature

Increasing the temperature variable of the Sinner Circle can potentially improve the cleaning outcome; however, caution must be exercised when dealing with loads that have protein soiling; it is generally acknowledged that water that is too hot will coagulate or denature proteins. When the temperature of the process reaches these levels (typically at or above 45˚C to 50˚C), there will be a marked reduction in protein cleaning efficacy; so, while a temperature increase may help to optimise the process, increasing this temperature too much may have the opposite effect to that desired.

Cycle variables – mechanical action

In a typical washer-disinfector, the mechanical action is delivered by the force of water in the mechanical spray arms. It is of course desirable to increase the mechanical action as much as possible; this may be achieved by increasing the pump pressure, which in turn gives greater water force from each spray arm jet, giving greater impingement on the load to be cleaned. However, in practice, this can present problems as the increased water pump demands can cause cavitation within the pump. This cavitation is caused when there are extreme pressure changes within a liquid, usually caused by the pump impeller. These pressure changes cause the creation of lower-pressure vapour cavities (hence the term cavitation) in the water; as these pockets collapse, they generate significant shock waves, noise, and a significant reduction in pump pressure. The addition of a detergent to a system, and an increase in temperature of the water, resulting in a higher vapour pressure, can either create or exacerbate this cavitation phenomenon. In addition to the efficiency reduction and noise, cavitation can cause significant equipment damage too.

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Cycle variables – time

The cycle variable of time is perhaps the easiest to comprehend; greater time will result in greater cleaning efficacy, however as noted above, we are generally always looking to save time by shortening processes. There are, in addition, often unintended consequences that affect time. For example, increasing the process temperature will have an associated increase in time, as the time taken to reach a higher operating temperature will of course be longer. Reducing processing time is often a desired outcome in process optimisation, and if cleaning efficacy is not to be compromised, this will require an increase in the other process variables, as indicated by the Sinner Circle (see figure 2).

Cycle variables – chemical action

The chemical action variable is often considered to be use of a detergent, but of course must be used in combination with water. While the other cycle variables also need water – as the heat transfer agent for temperature and as the mechanical action medium, there is more of a chemical consequence of water quality or purity combined with the detergent. Water can be described as the universal solvent, and indeed, water is an excellent medium for dissolving and dispersing many substances. Water is a polar molecule, which gives it some very unique properties; we don't often think about these properties as we live with them every day, but much of what is unique about water is due to its unique properties - polarity and hydrogen bonding. As water is not always the perfect solvent, we sometimes need to modify or improve its properties; the most obvious example is the addition of detergents to water. Technically, detergents are known as surfactants (or surface active agents); they allow bonding between a polar solvent such as water, and a non-polar molecule such as a lipid, helping to allow dissolution of hydrophobic molecules into the water. They can also allow wetting of the surface by lowering the surface tension of the water; this can allow the cleaning solution to 'wet' or penetrate microscopic areas of the medical devices to be cleaned.

One of the bigger variables with cleaning in practice can be variation in water quality; pure water is a much better solvent, but can in itself be corrosive. But perhaps the biggest issue with water is the consequence of dissolved substances within it. High sodium ion content can cause excessive frothing and foaming, which in turn can impede impingement and the resulting decrease in washer-disinfector efficacy. Also, certain conditions can cause deposition of dissolved or suspended species, such as the coating of dissolved metals on instrument surfaces, which can cause staining. Chlorine can cause pitting corrosion on stainless steel surfaces, and is typically present as metal salts in the water supply, e.g. NaCl, $MgCl_2$, $CaCl_2$ etc.

Finally, detergents can cause excessive foaming if they are not formulated properly or not dosed correctly. As discussed above under mechanical action, water pump cavitation can be exacerbated by detergents with a high propensity to foam.

Optimising the washing process using the Sinner Circle

The Sinner Circle can be used to optimise a washer process; this optimisation is typically focused, in practice, on two significant outcomes – cleaning efficacy, and process time. We should clearly not compromise on the level of cleaning that we need to achieve, but equally, we need to clean as time-efficiently as possible. When looking scientifically at the entire process, and utilising the Sinner Circle, the key areas we have an opportunity to manipulate are, to a small degree, temperature, and to a much greater extent, the mechanical and chemical action. When considering the chemical action i.e. the detergent, we must bear in mind that water quality can have a pronounced effect on the performance of the detergent. For a given washing performance, increases in mechanical and chemical action can significantly reduce cycle time (see figure 3).

Whilst there are significant advantages in focusing on both mechanical action and chemical action, there are also some factors that must be considered.

As briefly mentioned above, increases in mechanical action can cause problems with cavitation, and increases in detergent concentration may contribute to excessive foaming, which in turn may result in loss

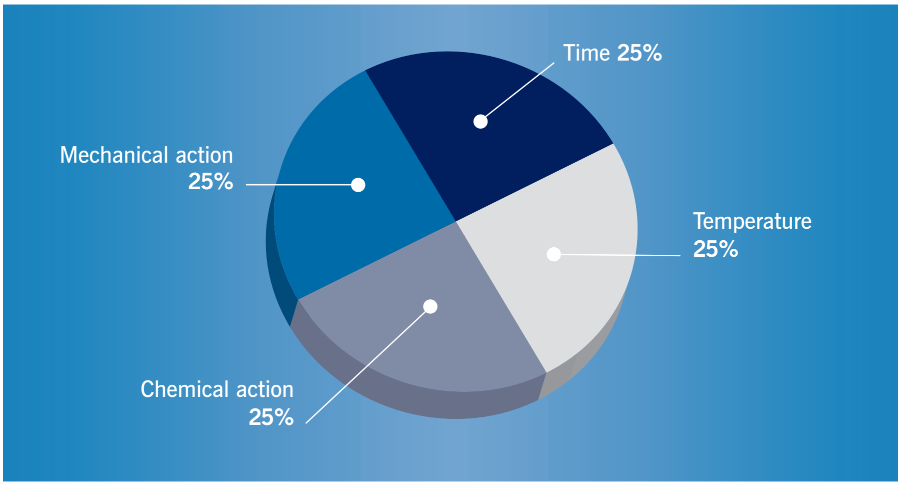

Figure 1 – An example of the Sinner Circle

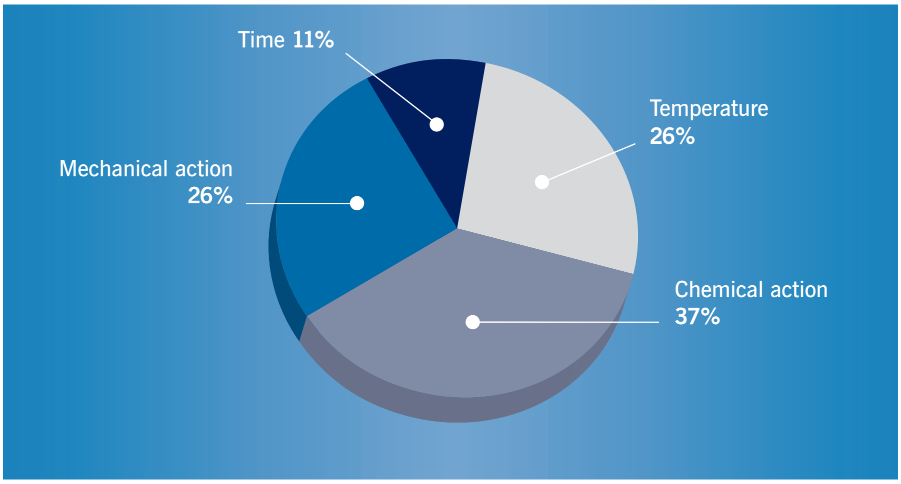

Figure 2 - An example of the Sinner Circle, showing how an optimisation of time increases the need for other variables

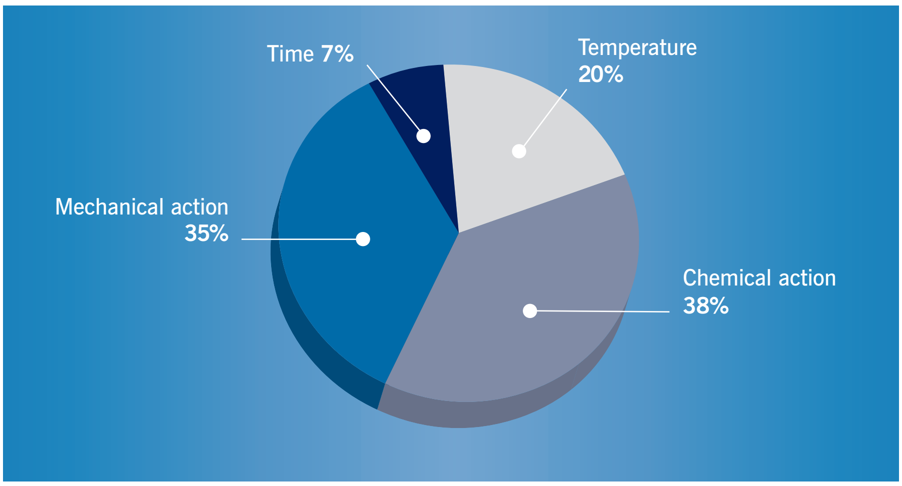

Figure 3 – The Sinner Circle, showing an optimisation of cleaning performance

of pump pressure. The detergent may not be the only contributor to foaming, of course; dissolved sodium ions in the water supply may also cause excessive foaming, as can the presence of proteins, which may be present on the load (much soiling occurring on reusable medical devices consists of blood and other high-protein soils).

> In order to allow a greater spectrum of detergent efficacy in a range of water quality supplies, certain chemicals can be added to addresses these negative effects of hard water and metal ions. These chemicals are typically known as sequestrants.

Detergent formulations

The detergents used in medical device decontamination contain one or more surfactants to provide the detergency necessary for suspending various soils; detergents are typically complex formulations of a wide range of chemicals in order to achieve the desired cleaning properties and detergent shelf life.

Additionally, detergents contain other chemicals that significantly enhance their performance. These other chemicals typically give the detergent formulation their classification name - enzymatic, alkaline and neutral.

These detergents should aid in the removal of adherent infectious agents and the organic matter that protects them, thus ensuring a better contact between the disinfectant/sterilant and any remaining infectious agents in subsequent stages of the decontamination process. Formulating a detergent that is inherently low-foaming is of course desirable, but also making sure that if foaming does occur due to high sodium ions or high protein soiling of the load, the detergent is able to dramatically defoam the washing solution.

Types of high performance detergents

Enzymatic detergents are detergents that contain enzymes as well as surfactants. Enzymes are bio-organic molecules; the vast majority of these enzymes are actually proteins. The enzymes are designed to break down larger molecules into smaller, more water-soluble ones, a process known as hydrolysis, and are extremely efficient biocatalysts. The active site is in the shape of a 3D cleft or pocket, containing the catalytic/binding site; this site promotes the formation and degradation of specific bonds. These enzymes are very selective and only target specific soil components and will have negligible effects on other molecules. The detergent formulation is typically neutral to mild alkaline pH in order to prevent damage to these enzyme proteins. These enzymatic detergents generally work better in immersion systems used for manual cleaning, but are also widely used in automated washer-disinfectors.

Enzymes are typically named after the substances they help to break down; for example, proteases help to break down protein, amylases help to break down starch, lipases help to break down fats/lipids and cellulases help to break down cellulose; typically, however, only proteases are useful in medical device cleaning formulations due to protein being of particular interest as a model soil. Different proteases can be combined to broaden pH or temperature effectiveness, but using a higher concentration of the same enzyme will not necessarily increase efficacy; enzymes are only one part of the process of breaking down soils, and other elements are still required to wash and remove all types of soil.

An important note is that enzymatic detergents that contain multiple enzymes, i.e. protease, amylase and lipase may be unstable in the presence of one another; studies have shown relatively rapid destruction of one enzyme by another enzyme in as little as a few months' storage at room temperature; this degradation may be much faster at elevated temperatures.

Alkaline detergents are detergents that contain alkalis as well as surfactants. These alkaline detergents are so-called as they form a solution in water that is high in pH, typically greater than pH 10; they usually contain metal hydroxides such as sodium hydroxide (NaOH) or potassium hydroxide (KOH), producing the hydroxide ion (OH-) in aqueous solution. These detergents demonstrate high efficacy at removing fats, oils and proteins, as the alkali results in hydrolysis of large proteins and lipids, breaking them into smaller water soluble pieces. They are more effective at higher temperatures (greater than 60˚C), but high pH and high temperature may have material compatibility issues (i.e. alkaline corrosion), however this is very much dependent upon the concentration used. Another interesting aspect of alkaline detergents is that they have shown to be capable of the inactivation of prion proteins.

Neutral detergents are detergents that form a solution in water that is near neutral pH, typically between 6.5 to 8 (with pH 7 of course being neutral). These detergents are normally used as a two-part cleaning regime – firstly an enzymatic detergent is used, followed by a neutral detergent. These are typically used as an alternative to alkaline detergents where material compatibility could be an issue; as well as being less aggressive than alkaline detergents, there is usually an increased cycle time and a need for a higher temperature for equivalent cleaning efficacy.

Sequestrants and chelating agents

In order to allow a greater spectrum of detergent efficacy in a range of water quality supplies, certain chemicals can be added to addresses these negative effects of hard water and metal ions. These chemicals are typically known as sequestrants. These sequestrants have a specific chemical structure that allows them to bond or react with metal ions in the hard water. A specific form of sequestrant is known as a chelating agent; these chelating agents have a structure like a claw which can bind the free metal ions, and hence make water act as though the metal ions (that impart water hardness) were not present, thus enhancing the effects of the detergent system used. The ions for which chelates are particularly useful are multivalent ions such as Ca, Mg, Fe, Cu, Zn, Ni etc. Chelates typically prevent deposition onto instruments and allow the detergent to perform the cleaning as expected. They can also inhibit scale formation and remove scale deposits, as well as destabilise secondary protein structures and hence contribute towards cleaning. It is important to note that the best chelant or sequestrant for the system is not always the one that can handle the most water hardness; a combination of at least one chelant and at least one sequestrant can typically outperform each individual component. Chelants perform stoichiometrically, meaning that they have a specific molar ratio to the metal ions, whereas sequestrants do not.

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Soils typically encountered on reusable medical devices

The soils found on devices to be cleaned may be organic, inorganic or both in nature. Organic soils may be comprised of muscle, skin, connective tissue, fat, grease, proteins (blood), carbohydrates, micro-organisms and other bodily fluids. Organic soils tend to be predominantly proteinaceous in nature. Inorganic soils may consist of rust, scale (hard water deposits), residues from cleaners and residues from medical solutions (iodine, saline, skin preparations). Combination (organic and inorganic) soils may originate from substances such as bone.

Medical device protection

Rust (Fe_2O_3) is a corrosion product sometimes found on medical devices containing iron (which of course includes stainless steel). Depending upon its oxidation state, this corrosion can be reddish-brown through to black. Some rust can be easily wiped off (sometimes called flash rust), whereas pitting corrosion is referred to as persistent rust, and is very difficult to remove. Detergents can be formulated with corrosion inhibitors to prevent this corrosion.

Other components can be formulated together collectively impart not only cleaning, but also allow:

- Wetting of the surface
- Sequestration
- Chelation
- Soil elevation and help to prevent redeposition

Choosing a high performance detergent

There is much more to a detergent than just a surfactant in aqueous solution, and the correct formulation can make a significant difference to enhance its cleaning efficacy. Additional components may be added that will enhance the suitability of the product for its intended purpose. Selecting the best detergent clearly requires an appreciation of all of these attributes.

Through a process of scientific studies and washer validation, a number of high level conclusions can be drawn:

- Alkaline-based detergents are generally better at rendering surfaces non-infectious than enzymatic detergents
- Alkaline and enzymatic detergents have been demonstrated to be effective at inactivating transmissible spongiform encephalopathies (TSEs) such as prion proteins
- The precise formulation may have more of a bearing on cleaning performance than whether the detergent is classified as alkaline or enzymatic
- The suitability of a given detergent formulation will depend upon the washer-disinfector cycle parameters, the particular washer-disinfector used, and the water quality at the point of use
- Detergents should be formulated to be low foaming and have the ability to defoam
- Have high performance against difficult soils such as proteins
- Protect surgical instruments from corrosion and staining
- Reduce maintenance costs by minimising pump cavitation
- All detergent formulation components should be biodegradable, non-toxic to aquatic life and free from environment-damaging chemicals
- Provided in minimal packaging by concentrating the formulation. CSJ

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