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Infection prevention: maintaining standards

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Clare Clark, BSc (Hons) Microbiology, technical support manager at schülke UK, believes improved cleaning performance should not be achieved at the expense of material compatibility, or of increasing costs to the health service.

A study was set up at Basel University hospital to address the question of whether, under realistic clinical conditions, improvements in the efficiency of WDs is possible.¹ Two alkaline based, silicate-free cleaning agents were tested for a month in the hospital's CSSD. The two cleaners selected for testing were a new detergent - thermostept x-tra (known in the study as tX) and an older, established product – MediClean forte (mC).

This article examines the study objectives, design and results, as well as the practical implications of the findings.

Background to the study

The study researchers observed that there is constant innovation in instrument design, WD machines and the detergents used in the machines.¹

Instrument manufacturers aim to regularly update and improve their products, and this is particularly seen in the field of flexible endoscopes, in which there have been major advances in technical development.

Likewise, manufacturers of washer disinfectors are constantly seeking to improve each new WD model. Improvements can be seen in terms of more efficient rinsing mechanisms, more sensitive monitoring modules and lower energy consumption.

The chemicals used in WDs are an integral element of the effective instrument reprocessing cycle - optimum performance of WDs relies on the highest performance of the selected cleaning agent. Major advances in technology have seen significant improvements in cleaning agents - they have progressed from highly alkaline cleaners with limited material compatibility, no additional surfactants and a high level of silicates



and phosphates, to low alkaline cleaners combined with low-foam surfactants and enzymes.

It is essential that surfactants used in WD units are very low-foaming to ensure compatibility with increasingly sophisticated WDs. Silicates are no longer included in state-of-the-art detergents to inhibit corrosion, because of the negative impact on sensitive materials such as anodised aluminium and other base metals. Instead, alternative corrosion inhibitors are included in the formulation. Similarly, phosphates have been replaced by alternative cleaning intensifiers, which are essential when a detergent has to safely remove organic contamination, such as that found on flexible endoscopes.

Improving product performance, while maintaining material compatibility, are the twin goals of WD detergent product

development. The limiting factor in detergent product development is the actual chemical makeup of the detergent. For example, attempts to increase the concentration of the detergent whether in the form of highly concentrated liquids with dosages <0.1% or as concentrated solids have revealed that too high a concentration leads to a deterioration in material compatibility with instruments and some components of the WD. Over concentration can even lead to the deterioration of cleaning results.¹

In addition to the chemical constraints, in terms of improving performance of detergents, there are also regulatory and environmental restrictions. Therefore, it is becoming increasingly challenging for detergent manufacturers to improve product performance whilst remaining within all essential boundaries.¹

Study objectives

Within the background of both innovations and constraints in the field of WD detergents, a study was set up to assess whether the use of thermostept x-tra (tX) in a WD could lead to optimal cleaning outcomes, in a hospital setting. The cleaning efficacy of thermostept

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x-tra had already been established in laboratory testing.¹

In addition, given that thermostept x-tra is a new detergent, to see how it compared with an already established product MediClean forte (mC) in terms of cleaning performance and material compatibility.

A third objective was to assess the comparative influence of steam sterilisation on various materials compared to alkaline based detergents.

Study design

Two identical washer-disinfectors were used, one with product tX and the other with product mC for a one month period (total of 16 working days). To ensure the validity of the results, the two products were swapped at the half way stage of the study period.¹

The same WD programme sequence for automated cleaning was selected on both WDs - the only variance being the detergent concentration which was adjusted according to the manufacturer's instructions. A concentration of 0.5% is recommended for product tX while the manufacturer of product mC specified a concentration of 0.7%. To ensure the accuracy of the dosage, it was tested by volume and concentration.

Assessment of cleaning performance

The cleaning results were assessed both qualitatively and quantitatively on four separate days and on two treatment cycles of the WD. This meant that a set of eight cleaning test results were available for both products.

WD carts were loaded with three test trays equipped with contaminated Crile clamps and cleaning indicators (all in accordance with test guidelines). They were positioned identically for all cleaning runs and this positioning was also documented photographically.

The residual protein content of the Crile clamps used was determined by an



independent company, with the clamps being sent for testing on the respective test day.

The cleaning indicators used were assessed on-site applying a double control principle and photographic documentation.

To be able to correlate the results of the cleaning test, with the process parameters of concentration, pH, temperature profile and rinsing pressure, these values were determined on all the test days in both WDs.

Evaluation of material compatibility

Throughout the study, the influence of the two cleaners on various materials was tested for compatibility. A selection of test materials and instruments were used including stainless steel, aluminium, plastics and metal instruments.

The condition of each test specimen was assessed and documented, so that accurate evaluations could be made. All test specimens were subjected to visual assessment before the study began, at the study midpoint and at the end of the study. Materials were evaluated

after cleaning with the test detergents and also following steam sterilisation, and the plastic test specimens were also evaluated in terms of density changes.

Evaluation of cleaning performance

At the end of the cleaning cycles, a visual inspection was performed to assess the degree of removal of the individual experimental contaminants. No differences in terms of cleaning performance could be detected between the test detergents.

In terms of residual protein, both cleaners showed far lower residual protein than the guideline benchmark of $< 80\mu$.

The cleaning indicator gke-L4 red cleaning indicator was cleaned off more efficiently with tX compared to mC, even though tX was used at a 25% lower dosage than mC.

The overall cleaning performance of both products was assessed to be 'very good', however it was shown that product tX could be used at a 25% lower concentration without any loss of cleaning performance. This has potential cost and environmental advantages.

Evaluation of material compatibility

Compared to the test specimens only subjected to cleaning with the two detergents, those which had also undergone steam sterilisation showed demonstrably greater damage. The damaging effects of steam sterilisation after only a few treatment cycles were measurable and clearly visible.

All metal test specimens showed clearly visible damage after autoclaving and were particularly sensitive to the treatment step of steam sterilisation. The test specimens only subjected to cleaning with either of the two alkaline detergents showed no visual material changes.

Test specimens made of material such as stainless steel, which is used in many medical devices, clearly showed visible material changes after steam sterilisation. At the end of 48 treatment cycles with exclusive cleaning with test detergents, no ►



visible changes were identified, and material abrasion of less than 0.01% was measured. In contrast, all test specimens subject to steam sterilisation showed visual changes in the form of clearly visible discoloration and staining.

Looking specifically at the material compatibility results for the anodised aluminium specimens, there were significant differences between the detergents. The amount of material abrasion from test product tX was significantly less than that from product mC, indicating differing material compatibilities between the detergents.

The study also found that unlike stainless steel, the treatment of anodised aluminium in an autoclave actually strengthens the stability of the aluminium oxide layer and appears to have a positive influence on the durability of the material.

The plastic test specimens were only evaluated in terms of cleaning with the detergents and were not subject to steam sterilisation due to their thermal instability. Good compatibility with the products was demonstrated in terms of visual appearance, density measurement and Shore hardness changes. A striking observation was a significant change in the Shore hardness scale amounting to > 12% after treatment with product mC, compared to 2% for the product tX.

Summary

Testing the detergents under realistic clinical conditions, it was demonstrated that at a 25% lower dosage of test product tX, a comparably good cleaning result was achieved in terms of both protein removal and various other cleaning indicators. The cleaning indicator gke-L4 (red) revealed that tX has an improved cleaning performance compared to mC. Also, product tX demonstrated overall improved material compatibility for various test materials.

The study identified both economic and environmental savings which could potentially be made with at least equal cleaning performance by using product tX.

Another interesting result was the negative impact of steam sterilisation on material compatibility. The study showed that material damage is often attributable to the sterilisation process. In comparison, the material damage attributed to the two detergents is almost insignificant in comparison. Although it was noted that the material compatibility of the anodised aluminium specimens behaved differently to that of the other test specimens, suggesting that the sterilisation step has a positive influence in terms of material durability.

However, steam sterilisation is an integral part of the reprocessing cycle and some of the observed negative impacts on materials is of less importance than safe reprocessing.

It means that staff should be aware that process related material wear is part of the effective cleaning/sterilisation process, and reprocessed instruments should be checked at regular intervals for signs of wear.

This study is likely to stimulate further investigations into potential developments to the reprocessing system including the use of improved detergents.

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Reference

- 1 Comparative Study of Mechanised Cleaners in Practical Use at the University Hospital Basel – Background
- 2 Professor Widmer, Medical Director and Head of the Hospital Epidemiology department, Mr Schnurbusch, Head of CSSD, University Hospital, Basel

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Clare Clark is the Technical Support Manager at Schülke UK. She has a BSc (Hons) in Microbiology and is a Member of the Royal Society of Biology (MRSB).



Clare has also successfully completed the Advanced Course in Sterilisation Technology (ACIST).

'I have been working as the Technical Support Manager' in the UK since 2002. During this time Technical support has evolved from a small 1 person department to a full service operation employing 5 technicians. Technical support offers product and regulatory advice to UK customers and incorporate a microbiology laboratory carry out preservative efficacy testing for our global cosmetic customers.'

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