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New HTM guidance for decontamination

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Richard Bancroft, registered authorising engineer (decontamination) and science & technical director for STERIS Corporation, discusses the new HTM guidance for decontamination and examines what it means for the sector.

In 2016, the new English decontamination guidance, now known as HTM 01-01 and HTM 01-06, was published. How does this herald the new direction for re-usable surgical instrument decontamination?

The changes to the HTM 01-01 and HTM 01-06 are relatively simple, but far reaching in their implications. The changes can be summarised as follows:

- New guidance on implementation of the ACDP-TSE's subgroup's recommendations of <5 μg protein residuals.
- Clarifying the requirement for separation of instruments used on high risk tissues for patients born before and after 1 January 1997.
- New periodic in-use test for residual protein.
- New daily test on process challenge devices.

Many of us were familiar with the historical HTM 2010 and HTM 2030 (or, going back in time even further, HTM 10). The prior CFPPs were a new direction, and maybe the excitement of new guidance was tempered with the knowledge that we no longer had the prescriptive guidance of before that led the world of decontamination.

The new publication of the CFPP suite as HTMs invoked a rush of excitement, only to be brought down to earth by the realisation that the HTM guidance was almost the same as the prior CFPP, with the exception that there were new considerations from the Advisory Committee on Dangerous Pathogens (ACDP).

Personally I applaud the bold steps taken by ACDP to actually specify quantitative values for protein residuals, and at a level never specified before by a government agency.

The ACDP guidance implemented into the HTMs is interesting; interesting that bold steps have been made in the right direction for patient safety; but also interesting that some of the prior ambivalent guidance between best practice and essential quality requirements still has a significant part to play.

The Browne STF Load Check Indicator has been carefully designed for cleaning verification of instrument washer-disinfectors.

Specifying a maximum value of protein of 5 μg of protein per instrument side was an admirable step. But the statement that this must be measured using 'in-situ' protein detection was, in the eyes of many, a step too far. A statement to reduce the maximum protein contamination level must have patient safety benefits; but suggesting use of 'in-situ' technologies that are ill-proved, expensive, and invoke delays in reprocessing, have been questioned.

Detecting protein

Protein detection technologies such as ninhydrin swabs have, quite rightly, been questioned in the light of new swab technologies; ninhydrin had a place when we were looking at 9 μg protein sensitivity. But now, with technologies that can detect sub-1 μg levels of protein, must we be bound to impractical and expensive technologies? Some of these technologies require the use of protein fixative reagents that may make subsequent protein removal certainly difficult, and maybe impossible with standard cleaning techniques; additional validated methods of aldehyde-fixed protein removal may need to be considered.

In-situ protein detection has many appeals; the ability to detect, simply by looking at an instrument, presence of protein, has to be exciting. Unfortunately, reality will dictate that the areas of surgical instruments that may be hiding proteins after cleaning, are precisely those areas inaccessible by direct line of sight. Swabs have a proven track record of being able to detect protein residuals, and have a protein recovery rate in the order of 70% against bovine serum albumin (BSA) protein (Critical evaluation of ninhydrin for monitoring surgical instrument decontamination, K. Nayuni , E. Cloutman-Green, M. Hollis, J. Hartley, S. Martin, D. Perrett, Journal of hospital infection 84(2013)97 – 102); when coupled with protein reagent sensitivities in the order of 1 μg means that a real detection sensitivity of well below the 5 μg level specified in the HTMs can be achieved. If there was a technique that facilitated lumen and other inaccessible area detection, why would this not be preferential?

Monitoring matters

The new HTMs miss, in detail, something quite fundamental; of course monitoring is critical; but unless wash cycles are revalidated against new criteria, we will not achieve our intent. Indeed this is mentioned in the HTMs by use of the term 'optimise'. However, a greater emphasis on actually changing existing washer-disinfector cycles by increasing wash stage times and maybe increasing detergent concentration would have put more focus on changing these current practices rather than simply just increased monitoring of protein residuals.

In the early days of sterilisation research in the 1950s, there were what seemed insurmountable hurdles, such as defining what we mean by sterile; much profound thinking resulted in the definition of fundamental principles like half-cycle validation. If a sterilisation cycle is log-linear in inactivation, we can apply simple mathematics to show that a 6-log inactivation in a half cycle will yield a 12-log inactivation in full cycle. This is coined as a sterility assurance level, or SAL. Why can we not consider the same such basic principles with cleaning? I suspect the answer is that capacity and time are the main reasons to resist such changes. If an appropriate test soil was used to validate a half-wash cycle, which was then subsequently doubled, maybe we could use such terms as a wash assurance level, or WAL? The ISO working group responsible for washer-disinfectors is already working on how we can quantitatively define the performance of test soils, and considering lowering the definition of clean to 3 μg/cm2. The concern, of course, is that this could have an adverse impact on washer-disinfector capacity. But what is the price of clean instruments? When considering a basic main wash phase that may take as little as six minutes of the total washer-disinfector cycle, such a doubling approach could incur a time penalty of only six minutes to each wash cycle, but with significantly reduced or negligible re-wash rates and the obvious benefits to patient safety.

The Browne STF Hexalumen is a patented endoscope washer-disinfector cleaning verification test.

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The publication of the Bowie Dick Test in the Lancet in 1963 was a landmark in the safety of steam sterilisation; there are parallels to cleaning parameters here – process variables that are not possible to monitor successful achievement by simple time, temperature, pressure and chemistry. The current HTMs are admirable in requiring the use of process challenge devices (PCDs) that assess the multiple variables responsible for cleaning. These can be used as a daily verification of cleaning parameters, such as the use of the Bowie Dick test in steam sterilisers, but can also be used in each cycle to the same intent.

The English HTMs have instigated a new and pioneering approach to acceptable protein residuals; these values form the basis of a new world where improved cycles, monitoring technologies and science all have a part to play. CSJ

STERIS ARE HERE TO HELP YOU WITH THE NEW HTM GUIDELINES

6 KEY PRODUCTS TO VERIFY CLEANING IN YOUR CSSD AND ENDOSCOPY DEPARTMENTS

The new updated HTM guidance documents include a defined protein detection value and the addition of cleaning process challenge devices. As a result, you must ensure that your cleaning processes are verified and compliant to the HTM 01-01 and HTM 01-06 guidelines.

STERIS & Albert Browne Ltd commit to discuss and support your compliance needs, utilising our world class expertise and globally trusted products to ensure you get what you need, when you need it. There are 6 key product lines that will give you the reassurance required to verify that all your processes are fully compliant.

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Ready to use free rinsing instrument transport gel to keep your soiled used instruments moist during transport and storage after use.

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A choice of cleaning chemistries that cleans and protects endoscopy and surgical instruments in concentrate (2x) or ultra concentrated formulations.

Browne STF Load Check PCD

Standardised, consistent and multi-directional load check indicator for cleaning verification of instrument washer disinfectors.

Browne STF HexaLumen™ Automatic Endoscope Washer PCD

An ultra-convenient patented endoscope WD cleaning verification test.

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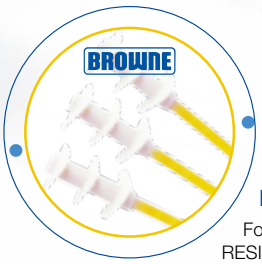
A rapid and convenient protein detection test, sensitive down to 1µg protein detection. A NEW easy to use self-contained pen format now available.



Browne RESI-TEST™ Endoscope Sampling Brush

For use with the Browne RESI-TEST™ protein detection kit.

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