aseptium
Innovative Decontamination Solutions

Process Challenge Devices for cleaning evaluation and how to go about them

by Pawel de Sternberg Stojalowski MSc, BSc, MBA

First published in the Journal of the Institute of Decontamination Sciences
November 2018 – January 2019 // Vol.23 // No2

The idea behind PCDs

Process challenge devices (PCDs) are not a new thing, and we have been using them to monitor sterilisation processes for years. The idea is simple, a PCD is a surrogate device that mimics the challenge of the load to the process and indicates whether the process it went through was executed properly.

For sterilisation, where the aim of the process is to kill microorganisms within the load, the indicators are designed to prove that the required dose of sterilant was delivered. It can be done because there is a known correlation between sterilising dose (intensity and time of exposure) and microbial population reduction for all sterilising methods. We know, that the longer the exposure to the sterilising dose the more microorganisms will be killed, the rate is constant and depends on the intensity of the sterilant. The caveat is that all elements of the load need to be exposed to the same conditions

Because of that relation we can implement a precise safety margin like the sterility assurance level SAL. That is why it is possible to design indicators that change colour when they are exposed to specific sterilising conditions – for example 3.5 min at 134deg C saturated steam - and PCDs to challenge the process to a degree greater than the indicator alone. Equally, we can have electronic data loggers that measure temperature and pressure indicating that the correct conditions were created for sterilisation to be effective in processes such as steam sterilisation.

Cleaning processes are fundamentally different. They are different because the end goal is not to kill microorganisms but remove them and soil from the instruments. This process cannot be described by a simple mathematical equation because there are too many variables that affect it – from cleaning chemistry, through design of particular instruments, and loading patterns, to water quality, etc. In this case the process needs to be challenged in a different way. Typically we use samples inoculated with test soil that are used to simulate removal of contamination from real surgical instruments.

How do we create realistic cleaning conditions

There are three separate elements that we must take into account if we want to see the true quality of the cleaning process– the test soil and how it is applied, realistic representation of a particular cleaning challenge and an appropriate method of evaluation of the sample after the process.

The test soil is critical since it directly affects the level of the challenge. On one hand, the harder to clean it is, the more challenging it becomes for the process, on the other it is relatively easy to create test soils that are unnaturally difficult to remove, especially when synthetic materials are used. Test soil should represent the type of contamination we find on surgical instruments that are difficult to clean – representing the worst case but realistic scenario.

Development of a realistic representation of particular challenges is equally difficult as developing a good test soil. At the least, a PCD needs to simulate narrow gaps in instruments and shadowing of portions of instruments from the process – testing of horizontal and vertical cleaning effectiveness is also essential for a thorough test of cleaning. It should be also designed to be used in a normally-loaded cycle – so we get as close to the real case scenario as possible.

Cleaning of instruments with internal channels must also be evaluated – especially when such instruments are a part of a load containing different instruments. Cleaning of internal channels is an entirely different process to external cleaning. It is because it is driven by a different mechanical process and is often serviced by an independent system (pump and plumbing). Therefore, if a washer has the ability to clean instruments with internal channels it must be evaluated for internal cleaning with the same frequency as the standard instruments.

The evaluation method has the final word. Evaluation should always start from a visual check, not only because it is the fastest direct method for larger quantities of contamination but also because visually we can identify

other types of issues that analytical technologies may not pick up – for example, chemical induced discolouration indicating there may be other issues with the cleaning process. After visual inspection come solutions like fluorescence or chemical dyes that take the limit of detection far beyond the ability of naked human eye to the levels recommended by local standards.

The process and the result

PCDs themselves are just one side of the story – how you use them equally matters. The cleaning process itself is critical – and that means the entire process and not only the automated part of it! Everything that happens right from the activities that start in the OR through transportation, all pre-cleaning steps to the automated process – all affect the end result. It is critical to understand how each of these elements impact the cleaning process individually to be able to optimise it efficiently.

There are different PCDs available on the market for evaluation of the automated washers – some contain synthetic and some natural test soils. Instructions for use often disregard the part of the process that precedes automated cleaning and focus on what happens in the washer only – in that case they only monitor this part of the process. What makes matters worse, is that some of them provide only a qualitative, binary answer – clean or not clean. The critical information that should be obtained is to know at what point and under what load configurations the PCD fails the test. Ideally, we would like to know how changes in the process affect the end result. For that, we need to use evaluation methods that allow quantification of the result.

In any case, knowing at what point of the cleaning process PCD crosses the threshold between *not clean* and *clean* is critical. As described earlier, there are many variables affecting the cleaning process and therefore it is best to empirically test or simulate these problems at each site individually. Simply, this must be done to better understand the consequences of problems with the process. What is also important, is to find out how the PCDs correlate with real surgical instruments – and to what extent the PCDs represent the real load. This gets really tricky when instruments undergo many pre-cleaning steps and PCDs test only the automated cleaning because technically they go through different processes. It is best to evaluate each process individually and then as a whole.

When a PCD always results in a “pass” and it is not known when exactly it goes from *fail* to *pass*. It is possible that a particular PCDs very easily “passes” the process. Such an approach is, unfortunately, an expense that brings very little value – if any.

With quantitative/semi-quantitative methods like fluorescence or some colorimetric dyes it is possible to evaluate the cleaning performance level. This approach is so far the most reliable periodic monitoring method available. It allows testing and optimisation of the entire cleaning process. Process failures, like missing pre-cleaning steps or issues with automated wash, affect the performance level and quantitative evaluation of PCDs will pick them up.

Quantitative evaluation can also identify which changes improve the process most and at what cost. When PCDs are based on realistic, difficult to clean, test soils it is valuable to put them through the same process as the instruments including pre-cleaning. This way, we can evaluate the overall value of practices like keeping the instruments moist after use, pre-soaking in detergents, etc. In the same way we can scrutinise the automated washers - evaluate the value of duration of each stage as well as the amount and type of of chemistry used against the costs.

Different instruments, different challenges

Surgical instruments differ considerably between each other in terms of size, design, purpose and the difficulty in cleaning. Certain common features of instruments become really problematic from that point of view – narrow gaps, joints and internal channels being good examples. Loading patterns add another layer of complication because of shadowing. Shadowing happens when an instrument or an entire tray block or shadow other instruments from the mechanical force of water making cleaning “capability” of the washer uneven in

different areas. For these reasons, PCDs should test cleaning processes against such challenges. In order to do that, PCDs should directly represent those different challenges or use accessories to achieve same effect.

The value of identifying what went wrong

PCDs are not only used for process monitoring but can be used as a troubleshooting tool. Before they are used routinely, they should be used to map cleaning performance within the washing chamber. This exercise challenges the uniformity of performance in different positions within the washing chamber. With use of quantitative evaluation methods it is possible to determine differences in cleaning actions between different locations in the chamber (also on multilevel carriers in high volume washer disinfectors). Once the areas of lower performance are identified, they should be used as “worst-case-scenario” locations for periodic monitoring.

Bringing everything together

There are many different reasons why cycles fail the PCD test – from issues with loading and pre-cleaning through spray arm blockages and issues with chemicals to mechanical defects of washers and process design failures. Some of those will indicate immediate issues while others may show gradual decline in performance. PCDs can provide valuable information and help managing and improving cleaning processes. PCDs can also support troubleshooting processes, equipment maintenance as well as, what is most valuable, provide a quick feedback when simple errors like blocked spray arms cause serious cleaning issues.

There are many elements to efficient and effective cleaning process monitoring. Process Challenge Devices can make it a lot simpler and add value to the quality control and management. They all come at a cost – the trick is to use those that provide value at the same time.

For more information about the author and Aseptium Ltd please visit aseptium.com

Aseptium Limited
info@aseptium.com
aseptium.com

VAT no. 938938657
Registered in England and Wales no. 6390678
Registered address: The Old Court House, 26A Church St, Bishop's Stortford, Hertfordshire, CM23 2LY