Microbiologist Identifies Noncritical Device Disinfection Challenge

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In the reusable medical device industry, there is a small but growing niche that needs to be considered when discussing sterilization, and in turn, patient safety of reprocessed devices. This niche consists of noncritical devices that cannot be immersed during reprocessing. Currently, a limited—and sometimes flawed—set of means is available to clean and disinfect these devices.

Due to design features including materials, exposed electronic components, size, and stationary location, devices such as bedpans, reusable anesthesia masks, blood pressure cuffs, infusion pumps, ventilators, and skin electrodes are not traditionally immersed for cleaning and/or terminal disinfection. In these cases, chemically saturated wipes are used to not only clean but to disinfect these medical devices prior to reuse.

Generally, each wipe brand includes a label claim for cleaning purposes plus a label claim for disinfection purposes. The label claims typically relate to contact times. These times were established using a number of test methods, such as the Modified AOAC Germicidal Spray Method, the Quantitative Tuberculocidal Suspension Test, and U.S. Environmental Protection Agency guidelines. Such tests are generally performed on representative hard surfaces or in solution, based on AOAC INTERNATIONAL's *Official Methods of Analysis*, and do not take into account the complexity of medical devices.

At Nelson Laboratories, noncritical device cleaning and disinfection procedures using chemically saturated wipes are validated regularly. In our experience, the complexities of a medical device can sometimes prove too difficult for the label claims for reasons such as crevices being too small to get a gloved finger into, or multiple materials causing the chemical to dry at different rates.

This creates a challenge for the testing laboratory and the device manufacturer. If the desired organic residual levels, as detailed in AAMI TIR30:2011, and disinfection log reduction are not met, what are the next steps?

The first step would be to ask some pointed questions: Would it be better to start again with a new chemical or increase the contact time? Is another brand as easily accessible as the brand tested originally? How likely is the end user to read the manufacturer's instructions for use rather than the wipe brand label claims? Should a device redesign be considered to eliminate the problem areas? How difficult can the instructions be before the healthcare facility is unable to execute the process?

These questions are critical for the manufacturer's decision-making process and should foster collaboration between the device design experts and the testing laboratory experts.

The next step relies on incorporating regulatory agencies into discussions regarding the reprocessing of noncritical devices. Currently, the potential to distinguish between patient-contacting noncritical devices and indirect patient-contacting devices, such as computer equipment inside an operating room, exists within validation requirements. But questions remain: Since these devices have different levels of contamination, should these two categories be grouped together? Are the current requirements too rigorous and conservative for non-patient-contacting devices and the reprocessing methods available? Are people able to follow one wipe manufacturer's label claims better than others for a specific device type?

Though not an imminent risk to patient safety, noncritical device cleaning and disinfection validations warrant industry discussion to improve and streamline the validation process.

For any questions about testing, please contact Nick Workman at **nworkman@nelsonlabs.com**. ■