Healthcare Reprocessing

Nelson Labs™
A Sotera Health company

Reusable Device Cleaning/Disinfection Validation

Devices intended to be reprocessed in a clinical setting must have cleaning/disinfection instructions provided with the product. These instructions for use (IFUs) will detail the correct way to reprocess the device prior to use to ensure patient safety. These instructions must be validated. At Nelson Labs we offer all testing needed to meet this validation requirement, along with the technical expertise to circumvent any problems.

Nelson Labs Offering

Nelson Laboratories offers a full range of medical device cleaning/disinfection validation services to validate manufacturers' reprocessing instructions for reusable devices. These services include contamination, cleaning, and post-reprocessing effectiveness evaluations. Nelson Labs' simulated-use testing practices are employed to simulate actual clinical procedures rather than the direct inoculation methods utilized by other labs. Options are available to use validated or customized test soils to create clinically relevant conditions. The following test markers are available and should be chosen based on the products' clinical use:

TEST MARKERS:

Protein	Total Organic Carbon
Hemoglobin	Carbohydrate Residual
Cytotoxicity	Detergent Residual
Bacterial Endotoxin	Bioload Reduction

Sample Types, Required Sample Size

MEDICAL DEVICE

5 Devices are required for the validation (3 test articles, 1 positive, 1 negative or a neutralization device)

Typical Questions

What is a cleaning validation?
A cleaning validation assesses the efficacy of a process designed to affect the physical removal of contamination from all surfaces (inner and outer) of a reusable device. This is usually performed as a precursor to a prescribed terminal disinfection or sterilization process.

Do I need to perform both a manual and an automated cleaning validation?
If the device can be processed in an automated washer without incurring damage, and the healthcare facility is likely to possess automated washing capabilities, only the automated validation is required. If the device cannot be run through an automated wash cycle without incurring damage, a manual cleaning validation alone is appropriate. If the target market is unlikely to possess automated wash capabilities, it is our recommendation that both automated and manual cleaning validations be performed. Please be aware of the expectation that all procedures outlined in your instructions for use be validated.

What is a disinfection validation?
A disinfection validation demonstrates the efficacy of a process designed to reduce microbial contamination present on the exposed surfaces of a reusable device through chemical or thermal methods.

Healthcare Reprocessing

Nelson Labs™
A Sotera Health company

What level of disinfection validation is appropriate for my product?
Nelson Laboratories can help you determine what level of disinfection is appropriate for your device based on its use and where it fits in the Spaulding classification (i.e. Noncritical, Semi-critical or Critical).

Do I need to have my cleaning or disinfection validations performed according to Good Laboratory Practices (GLP)?
Given the scrutiny surrounding cleaning and disinfection validations, it is Nelson Laboratories' recommendation that reprocessing validations conducted with the intent of submittal to a regulatory body (e.g. FDA) be performed according to GLP standards. A GLP study will recruit the services of our quality assurance department (QA), subjecting all data generated to an even more extensive review and incorporating audits during active phases of the testing.

Am I required to perform cleaning and disinfection separately?
Yes. AAMI TIR12:2010 and ISO 17664 provide guidance for cleaning and disinfection validations being performed separately. They are conducted separately because the focus of a cleaning validation is the physical removal of contamination, and the focus of a disinfection validation is the killing/inactivation of microorganisms through chemical or thermal processes.

What is the minimum surface area required for testing?
In most cases a minimum of 15 cm2 of surface area is required for the performance of a cleaning or disinfection validation. Certain combinations of test markers may necessitate a slightly larger surface area. Consultation is available for more specific details regarding surface area requirements.

Do I need to validate both sterilization and disinfection?
Per ISO 17664:2017, certain markets (mainly in Europe) are increasingly recommending the validation of both disinfection and sterilization as the terminal processes for reusable medical devices. Many small healthcare facilities/clinics or emerging markets do not have access to an autoclave and would require an alternative terminal process i.e. disinfection. Both the material make up of your device and the constraints of the processor should be evaluated during the risk assessment.

When validating a surgical kit or tray, do I need to send in the whole tray?
Per AAMI TIR12:2010, a worst case, or "master product" device can be chosen as a representative for the performance of your cleaning validation. Only the identified worst case device is required for the validation of a manual cleaning procedure. If an automated cleaning is to be performed, it is recommended that the entire tray be sent so that the complete tray can be loaded into the washer for the processing of the target samples. This method will most closely simulate the conditions experienced in a clinical environment. Our Nelson Labs' Consulting Department can determine worst case or master product if needed.

What standards do you reference in your testing?
A partial list is included below for your review. The standards that pertain to your particular device and testing will be listed on your Nelson Laboratories Standard Test Protocol.

AAMI TIR12:2010
AAMI TIR30:2011
ANSI/AAMI ST81:2004
ANSI/AAMI ST79:2010
ANSI/AAMI ST35:2003
ASTM E 1837-96. (R2014)
FDA. 2000
FDA. 2002
WHTM 01-01 Part B. 2013
BS/EN/ISO 17664:2017
ASTM E 2314-03. (R2014)
FDA. 2015
ANSI/AAMI ST58:2013
ASTM E 1766-15. 2015
BS/EN/ISO 10993-5:2009
ASTM F 3208-17

