# *Cleaning of Instruments*
# An Absolute Requirement for Successful Reprocessing

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Correctly cleaned instruments are a necessity for safe reprocessing and delivery of sterile items for patient use. In this paper, we explore the application of validated techniques of reprocessing to ensure proper cleaning, as well as methods of in-house verification of the cleaning process using commercial and do-it-yourself solutions, and suggested frequencies for those procedures. We examine features of manufacturers' instructions for use (IFU) for difficult-to-clean instruments, with an emphasis on finding common features that may enable the use of a limited number of processes to clean many instrument types.

We also use this approach to provide gross and fine classifications of instrument types, and create product families. Each family should represent one type of device, and one standard procedure should be used for cleaning all instruments in that family. Typical cleaning failure modes for each product family, and general issues of external factors causing systemic difficulties, are discussed, as well as solutions for these cleaning process failures.

We incorporate the guidelines of ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*,[1] and provide guidance for evaluation of issues that apply to devices with limited reuse capabilities. We also compare the relative efficacy, strengths, and weaknesses of manual and automated cleaning.

## Verification and Validation

These terms are often used interchangeably, despite having very different meanings. Verification is the testing conducted after a process is completed, to ensure that the process was correctly carried out. Validation is a demonstration that a process works, and providing the process is carried out in accordance with procedure, does not require subsequent testing to ensure that it was successful.

In reprocessing medical devices, users can verify that a cleaning process has been correctly carried out by testing the device that has been cleaned for residual soil, hemoglobin, or protein. The instrument may need to be cleaned again following testing, as testing may leave the item unsuitable for patient use even after sterilization. If a process is validated, it may be used with confidence as long as its known limitations are not exceeded.

In a sterile processing department (SPD), there are many processes that are validated before being used. These include cleaning and sterilization processes as specified in the manufacturers' IFU of instruments. It is important to use the validated processes as they are written, but also to periodically verify that they are working correctly in your facility with your specific water supply, steam supply, machinery, and staff. This verification is the essence of quality assurance, and essential for patient safety. In summary, the

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instructions in the IFU have been validated by the manufacturer and cleared for market by the U.S. Food and Drug Administration (FDA). The way these instructions are carried out in your facility must be verified.

## Cleaning Verification

Cleaning verification can be carried out using tests with materials found in-house at most healthcare facilities, or commercially available products. Before choosing a method to verify the removal of organic soil on a device from the previous patient, the method should be evaluated to ensure that it is an appropriate test of the cleanliness of that instrument. An inappropriate approach, for example, would be to visually inspect the exterior of a lumened instrument to determine its cleanliness. This approach only provides information about the state of the exterior of the instrument, while the interior—which is where soil can be hidden—remains unexamined.

Instead, use either an elution test with sodium dodeyl sulphate (SDS)[2] solution or a swab test of the worst-case lumen (the smallest lumen) in the device. In devices where a lumen is of varying diameter, elution is preferable, as neither a brush nor a swab may contact all surfaces for cleaning and/or examination. These tests can be applied to both manual and automated cleaning procedures. The performance of automated cleaning equipment should also be verified by independent testing.

Medical devices differ in complexity and how they should be cleaned. In addition, they have different disassembly procedures (if disassembly is possible). Different class categories are described in ISO 17664:2004.[3] Each class has different requirements for effective cleaning, with different methods to ensure that the cleaning process is successful. These can be applied to both manual and automated cleaning.

## IFU

IFU provide users with validated techniques for reprocessing. Some IFU are clearly written, and some are not. For the latter, the manufacturer can be contacted to clarify the IFU, and informed that its instructions need improvement. If the manufacturer does not provide clear instructions upon request, report that to the FDA.

Assuming that the IFU can be understood, users need to follow them explicitly to ensure proper processing. As we have seen, products can be grouped into families. In addition, if items have differing cleaning times, the longest recommended time should be used to ensure that all items are cleaned properly. IFU should contain some basic information. A complete list of the required components of an IFU can be found in the FDA's *Code of Federal Regulations Title 21*, Part 801,[4] and in the AAMI standard, ST81:2010.[5]

## Failure Modes

As the complexity of a medical device increases, cleaning becomes a greater challenge, with a greater number and variation of possible failures.

## Medical Device Categories (ISO 17664:2004)[3]

***Group 1: Solid Devices***
The instruments in this group have no hidden surfaces, lumens, or blind lumens. Examples include wound retractors or nonlumened rigid endoscopes. Cleaning verification can be carried out using protein or hemoglobin detection swab tests.

***Group 2: Hinged Devices***
This group includes scissors and instruments with an insert closure, such as a box lock. Since the key challenge in cleaning is the hinge or box lock, it must be possible to elute (rinse out) the box lock to check for residual soil.

***Group 3: Sliding-Shaft Devices***
In this group, if the devices can be disassembled, they can be tested using a swab. If they cannot be disassembled, they must be tested using an elution to free any residual soil.

***Group 4: Tubular Devices***
Tubular instruments include suction devices, trocars and other lumened instruments, as well as shavers for arthroscopy.

***Group 5: Microsurgical Devices***
In this group, reprocessing methods must be tailored to these extremely delicate instruments.

***Group 6: Special Devices***
This group includes instruments that, due to their design, cannot be assigned to any of the other groups, such as orthopaedic instruments, e.g., socket boring, and pneumatic motor systems.

***Group 7: Flexible Devices***
Examples of flexible instruments include biopsy forceps, and increasingly, flexible instruments that are used in minimally invasive surgery.

*Visible Failures*

The presence of residual protein on the surface of an instrument can be indicated by droplets or water spotting that nucleates on the protein. However, hard water can also result in water droplets and/or spots. Since all devices under consideration in this article are semicritical or critical, the remedy for hard water residue is to always carry out a final rinse with deionized or reverse osmosis water.

AAMI TIR34:2007[6] discusses appropriate water quality in detail. The source of the droplets, protein, or hard water, may be identified with a commercially available swab test, or by using 3% hydrogen peroxide solution, which will bubble if it comes into contact with protein. As hydrogen peroxide is somewhat nonspecific, a swab test is preferred.

Stains on the instruments can come from a great number of sources. These include contaminants in the water, insufficient rinsing resulting in autoclaved residual detergent, contaminants in the steam, contaminants in the packaging or cart liners, and improper cleaning, to name a few sources. Attribution of the staining to improper cleaning can be done with a hemoglobin or protein test swab, and the procedures can be examined to determine where in the process the error occurred.

**Lumens and internal mechanisms hide residual contamination effectively.**

*Invisible Failures*

A visibly clean device is not necessarily clean. For example, fibrin—a blood protein—is invisible. In addition, lumens and internal mechanisms hide residual contamination effectively, and are not readily visible. Cleanliness of lumens is easier to evaluate than cleanliness of internal mechanisms, as users can generally run a swab or pipe cleaner through lumens and do a visual, hemoglobin, or protein test. This should be carried out periodically to ensure that the lumens are, in fact, being cleaned.

If automated cleaning equipment is used, there are a number of surrogate devices that can be used to test the ability of the device to provide a baseline level of cleaning performance. This falls into the category of verifying the cleaning equipment's performance. As we have seen, this is not the same as validating it (this is not a controlled study with soiled instruments), but the test does provide the end user some assurance of a reasonable level of performance.

For internal mechanisms, this is more difficult, as one really cannot see inside a device, and these mechanisms are difficult to access without destroying the instrument. Generally, soil contained within the instrument will only make its presence known if some is removed during reprocessing, use, or (if and when) the instrument needs repair. Because users cannot test cleaning efficacy in this case, it is essential to follow the manufacturer's IFU exactly.

## ANSI/AAMI ST79

ST79 has become the de facto reprocessing Bible. With respect to cleaning and cleaning verification, Section 7 of the standard presents a thorough and well-reasoned approach to cleaning, including the need to ascertain to what contaminants the instrument has been exposed—for example, brain tissue, and therefore potentially prion diseases—and ensuring that the procedures to be used are compatible with the device's construction and construction materials.

Where appropriate to the instrument at hand, ST79 recommends the following sequence of cleaning steps:

1. *Presoaking, or maintaining a moist environment after use,* to ensure that the soil does not become hardened and more difficult to remove.
2. *Disassembly* to ensure that all parts that should be exposed to the cleaning process are, in fact, cleaned.
3. *Cleaning*
   - For items that have been exposed to blood, tools such as soaking, scrubbing, use of high-pH or enzyme detergents, and high pressure water spraying should be used, as appropriate to the challenges presented by the device.
   - Cleaning methods: manual, ultrasound, mechanical, or rinsing.
   - Verification—Annex D of ST79 details available means to verify cleaning. Commercial products are available for these purposes, but, as there are no standards, a comparison under actual working conditions is in order before selecting a verification product.

### Components of a Well-Written IFU

- Range of applicability of the technique—if it is limited to parts of the item (for example, to an orthopaedic hand piece, and not to its batteries), this should be made clear in the IFU.
- Specific limitations of solutions to be used on the device
- Specific instruction on how to prepare the device (for example, where to set a switch, or how to disassemble the device)
- Description of brushes and brushing techniques to be used
- Specific information on cleaning lumens if any
- Specific instructions relative to immersion of the device, particularly if the device has electrical connections
- Instructions to activate manually activated parts, if any, during cleaning
- Cleaning temperature ranges for all steps of the cleaning process
- Inspection techniques to determine the success or failure of the cleaning process
- Loading instructions for washers/washer-disinfectors, including connection instruction for washers that have lumen connections
- Validated automated washer/washer-disinfector cycle parameters including:
  - Phase times (including dry time)
  - Water temperature
  - Detergent type
  - Maximum pressure to be delivered to any plumbed connection to the device

### Manual Versus Automated Cleaning

Both manual and automated cleaning techniques are effective. One costs human capital; the other costs fiscal capital. The key advantage of manual cleaning over automated cleaning is that SPD personnel can respond to particularly resistant spots as they appear (a machine cannot "know" that these are present).

**Scrupulous care must be taken to ensure that the cleaning approach for each device is appropriate.**

The key advantage of automated cleaning over manual cleaning is that the cleaning will be completed in the same way each time. Humans are not as consistent. Since there is no way to verify and record the results of each cleaning session, automated cleaning is preferred, and in some countries, is the law, as an automated cleaning process can be validated.

### Summary

Cleaning of medical devices, and the validation and verification of this cleaning, has advanced greatly, even in the last five years. It is recognized as an essential part of the reprocessing of reusable medical devices, and is becoming more and more consistent as device manufacturers and the FDA give cleaning more consideration when a device is brought to market.

Scrupulous care must be taken to ensure that the cleaning approach for each device is appropriate (but similar items can be reprocessed in a similar manner). There is no replacement for excellent training and maintenance of equipment, but available tests can help ensure that failures are caught earlier rather than later. ■

### References


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