

Proper Cleaning: How It Affects the Outcome of High Level Disinfection



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Evidence has been presented that semi-critical devices, devices that come in contact with mucous membranes or non-intact skin, such as endoscopes and endocavity probes, cause more healthcare associated infections than non-critical or critical medical devices. The number of infections from semi-critical devices is partially accounted for by the narrow margin of safety associated with reprocessing these devices by cleaning and high level disinfection (HLD)¹. Therefore, any deviation from recommended protocols can hinder HLD and leave a device contaminated with microorganisms. One critical step to achieving adequate HLD is proper cleaning of devices prior to disinfection. Cleaning is the process by which soil and contaminants are physically removed from an instrument. Cleaning can be done using manual or newer automated methods. However, automated cleaning is often the better choice because it achieves the same levels of cleanliness, but reduces human error and increases compliance with reprocessing protocols to decrease the risk of contaminated devices being used for patient procedures.

Soil Levels on Endoscopes and Endocavity Probes

After use, endoscopes and endocavity probes are heavily contaminated with microorganisms and other organic material. Microbial load, protein, hemoglobin, and ATP are the most commonly used markers for soil levels on endoscopes because they can be easily measured and represent common materials a scope may come in contact with in the body. Endoscopes can be contaminated with up to 1 billion microorganisms²⁻⁸ and over 200mg of protein²⁻⁵. However, it is important to note that microbial load and pre-cleaning soil levels vary greatly between endoscope types and individual devices. Differences in soil levels between endoscope types can probably be attributed to differences in how these endoscopes are used and the number of microorganisms in the body cavities in which they are used. For example, bronchoscopes tend to be contaminated with fewer microorganisms and less protein than colonoscopes. This is to be expected because the lower gastrointestinal tract, where colonoscopes are used, contains many more microorganisms than the throat or lungs. Further, a wide range in the number of microorganisms or soil recovered from individual endoscopes has been reported. Much of this variability likely represents differences in sampling and recovery methods, as well as other clinical or patient factors.

Despite high levels of microorganism and soil contamination on endoscopes after patient procedures, optimum cleaning alone can reduce microbial contamination by $4-6 \log_5^{2,6-8}$. In most instances, optimum cleaning is sufficient to reduce hemoglobin and protein by greater than 95% (-1.3 log reduction)³. Using observations of the pre- and post-cleaning soil levels on endoscopes, the field has defined what constitutes a "clean" endoscope using microbial load, protein, hemoglobin, and ATP levels as metrics. Currently, the most widely accepted benchmarks are: a microbial load of 100 CFU, 6.4µg/cm² protein, 2.2µg/cm hemoglobin, and 200 RLU of ATP²⁻⁴. It is important to note these benchmarks were defined using older cleaning protocols. As new and better cleaning methods have become available, these benchmarks have become easy to attain, provided cleaning is done properly. Some suggest new recommended cleaning procedures and propose lowering

the benchmarks for soil levels on clean endoscopes to a microbial load of less than 100cfu/cm², less than 2µg/cm² protein, and less than 200 RLU of ATP3. It will be up to the field to decide whether or not to accept these new proposed cleanliness benchmarks, keep the current benchmarks, or define new benchmarks entirely.

Manual vs. Automatic Cleaning

Proper cleaning of endoscopes and endocavity probes can significantly reduce soil levels prior to HLD. However, the process of cleaning these medical devices following their use can be tedious, confusing, and lacks standardization. Standardization via automation of HLD is used in many clinical settings, however, automated cleaning of endoscopes and endocavity probes has only become recently available. In a controlled laboratory environment, automated cleaning performs similarly to optimum manual cleaning. Both cleaning methods met the standard requirements for clean (<6.4µg/cm² protein, >99.9% reduction hemoglobin, and 2-4 log reduction in bioburden), suggesting that under optimum conditions there is little difference between manual and automated cleaning⁹.

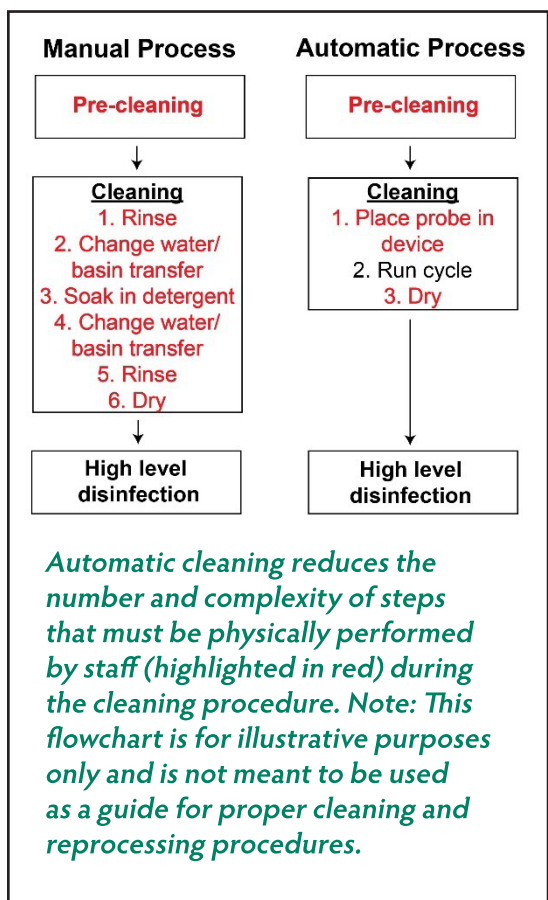
However, clinical settings often do not provide optimum conditions. Thus, though manual and automated cleaning can achieve similar levels of clean in a laboratory environment, automatic cleaning is better suited to the suboptimal clinical environments in which endoscopes and endocavity probes are cleaned and reprocessed¹⁰. Manual cleaning of endoscopes and endocavity probes is a long and tedious process. Each step must be carefully completed to ensure proper cleaning and disinfection without damaging the device. If you also consider the need to reprocess probes efficiently and in a timely manner, the reprocessing procedure quickly becomes rife with human error. One study found that only 1.4% of endoscopes reprocessed using a manual cleaning method and automated disinfection cycle were reprocessed correctly at every step¹¹. Many of the errors made occurred during the manual cleaning stage and drying after reprocessing. Further support for suboptimal manual cleaning conditions in the clinic comes from observations of clinic cleaning times. In the study comparing manual with automated cleaning methods discussed above, scientists spent an average of 14-25 min manually cleaning probes, whereas the average time spent cleaning endoscopes in a clinic is about 4-7 min⁹. This supports the notion that manual cleaning procedures completed in clinics may not be as stringent as those in a laboratory environment.



Throughout the manual cleaning process, care must be taken to ensure endoscope and endocavity probe handles and electrical components are not submerged. The elongated design of endoscopes and endocavity probes can make this task cumbersome and contributes to physical discomfort.

There are many reasons why manual cleaning procedures remain suboptimal in clinical settings. Manual cleaning of endoscopes and endocavity probes can be an arduous process. Clinic staff report pain, decreased flexibility, numbness/tingling, and physical discomfort associated with the tedium of manual reprocessing of endocavity probes and endoscopes¹¹. Given the physical toll of manual cleaning, it is easy to see how steps may be shortened or skipped entirely, particularly if staff are required to perform multiple reprocessing procedures sequentially. Reprocessing procedures can also vary between and within healthcare facilities. 92% of infection prevention professionals report wanting to standardize processes for reprocessing ultrasound probes in their facilities¹². This suggests a great amount of variability in cleaning procedures not only between facilities, but also within a given facility. The variability in cleaning between probe types also plays a factor and adds to the challenge. Some probes, with the aid of adaptors, can be completely submerged, while

others, like TEE probes, cannot be completely submerged. Making sure you do not get specific parts of the probe wet, thus ruining the probe, adds to the stress of manual cleaning. This increases the complexity of knowing all the probes and cleaning methods for each. Whether protocols differ by department, staff, probe manufacturer, or the infection status of the patient, the end result can be confusion about HLD processes. Protocol changes for devices used in infected patients also reinforces an incorrect notion that instruments used on patients without infections are less contaminated or pose less threat than instruments used on patients with known infections. Lastly, endoscope or probe reprocessing must occur in a fairly efficient manner to ensure an instrument is available to use at all times. Depending upon the number of instruments, trained staff, and procedures performed at a particular location, there may only be a short period of time available for probes to be reprocessed¹³. Time constraints could increase the chance that steps are skipped in the reprocessing procedure and instruments are not properly cleaned before disinfection.



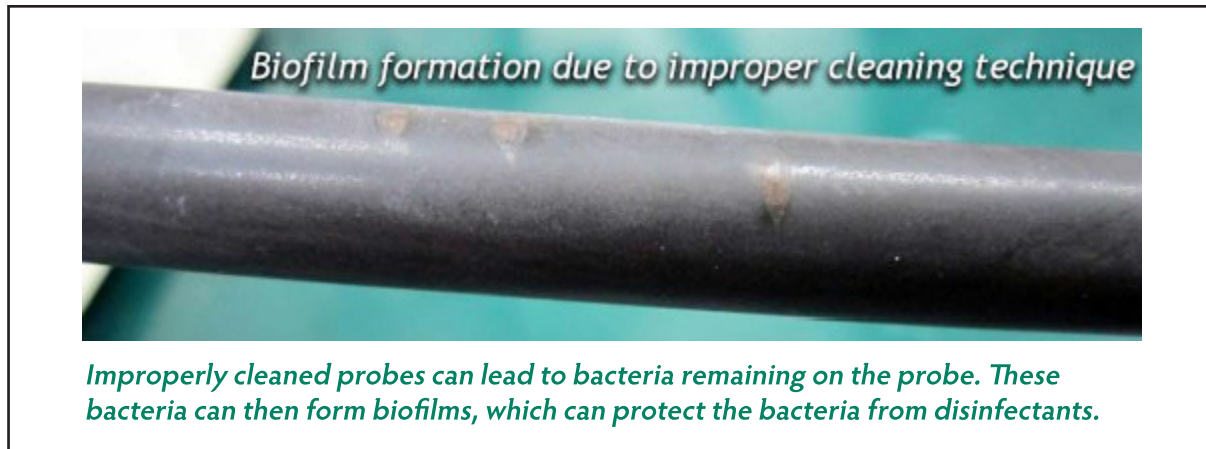
Multiple solutions have been proposed to combat the issues associated with manual cleaning. Enzymatic cleaning wipes or sponges for endocavity ultrasound probes are commercially available solutions to simplify the cleaning process. Prepackaged wipes or sponges can reduce the number of steps involved in cleaning and potentially reduce cleaning times by eliminating the need to soak probes in detergent. However, they require that the user evenly wipe the surface of the device, leaving the potential risk that small areas of the device could be missed. Therefore, complete automated cleaning of endoscopes and endocavity probes is likely the best solution to reduce failures associated with reprocessing. Automated cleaners and disinfectors, such as the TEEClean® Automated TEE Probe Cleaner Disinfector, require users to pre-clean devices before finishing the process by placing them in the automated cleaning device. This minimizes the amount of physical washing and basin transfers that must be completed by the user; thus reducing the number of steps subject to human error, while reducing the physical demands on staff. Indeed, compliance with automated cleaning and disinfection procedures was observed to be much higher (75.4%) than that of manual cleaning (1.4%)¹¹. Further, automated cleaning procedures are designed to remain consistent between runs, eliminating possible changes in the cleaning protocol resulting from error or differences in staff and training. Each probe is cleaned and disinfected under the assumption it

is contaminated with potentially harmful microbes to adhere to standard precautions in healthcare¹⁴. Automated cleaning takes 7-10 min and requires little hands-on time by a technician. Less hands-on time helps alleviate issues with short staffing or heavy workload in healthcare settings where few personnel are trained on reprocessing procedures. Therefore, automated cleaning devices can meet the time constraints and reprocessing efficiency required in a clinical setting without compromising patient safety.

Consequences of Improper Cleaning on HLD and Patient Safety

Improper cleaning of reusable medical devices leads to inadequate disinfection. When devices are not cleaned correctly, remaining soil on the device can decrease the effectiveness of the subsequent disinfection cycle by physically preventing the disinfectant from making contact with the surface of the device^{8,15,16}. Depending upon the disinfectant and type of soil, the remaining soil on improperly cleaned devices can also bind or inactivate the disinfectant, making it

less effective in killing contaminating microorganisms^{8,15,16}. In a laboratory study, angioscopes that were not cleaned prior to disinfection still contained infectious duck hepatitis B virus (DHBV)¹⁷. In contrast, researchers found that even when the disinfectant contact time was reduced, infectious DHBV could not be recovered from properly cleaned devices¹⁷. In the clinic, cleaning and subsequent disinfection reduces the microbial load on colonoscopes from about 10 logs to 0¹⁰. However, in the same study, failure to clean the colonoscopes prior to disinfection only reduced the microbial load to 3.8 log cfu/mL (a 5 log reduction)¹⁰. Together, these studies highlight the importance of proper cleaning prior to disinfection to ensure disinfectants work effectively.



Effective disinfection is critical to maintaining patient safety and avoiding infection from endoscopes and endocavity probes. In 2016, Joint Commission estimated that 74% of immediate threat to life declarations were related to improperly sterilized or high-level disinfected equipment¹⁸. Outbreaks resulting from improperly disinfected endoscopes and endocavity probes have been reported worldwide¹⁹⁻²³. In the US, an outbreak of *Escherichia coli* in 2006 was caused by contaminated TEE probes¹⁹. Subsequent investigation determined the probes were not disinfected or stored properly. Additionally, one probe was found to have a physical defect allowing for bacteria to accumulate and avoid disinfection. Use of contaminated TEE probes in two hospitals in Japan, led to outbreaks of multidrug-resistant *Pseudomonas aeruginosa* and *Enterobacter cloacae*, which resulted in one patient death^{20, 22}. The *P. aeruginosa* outbreak was traced back to a physical defect in the probe²². However, it is suspected the outbreak of *E. cloacae* was likely caused by deviations in the cleaning and disinfection protocols because enforcement of disinfection procedures and implementation of single-use sheath covers reduced the number of *E. cloacae* infections in the hospital to baseline levels²⁰.

The *E. coli* outbreak in the US and the outbreak of multidrug-resistant *P. aeruginosa* in Japan highlight the importance of manual inspection of the probe, as well as conducting electrical leakage tests between each use. Leakage tests not only alert the user to issues with the electrical workings of the device, but can also help identify breaches in the outer insulation barrier of the probe. Cracks or deformities in the outer barrier of the probe or scope can become contaminated with bacteria. Once bacteria are trapped within these areas, they tend to thrive for two reasons. First, detergents and disinfectants may not reach deep within cracks/deformities, allowing trapped bacteria to avoid killing. Second, moisture tends to be trapped within cracks or deformities, which further facilitates microbial growth. The end result is that even cleaned and disinfected probes remain contaminated with bacteria and put patients at risk for infection.

Fortunately, the *E. coli* and *P. aeruginosa* occurrences were localized to single facilities for limited times. In the case of widespread contamination of healthcare facilities and/or infection of patients, cleaning failure could have provided the path for uncontrolled pathogen transmission. This type of situation, where there is a prevalent pathogen plus a disinfection failure, was the underlying mechanism for the spread of HIV to hemophiliacs from 1980 to 1990. In that case, the pathogen was the HIV virus and the disinfection failure was a process shortcoming in hemostatic replacement factor

manufacturing (e.g., see White, 2010 24). A current challenge regards whether or not widespread COVID-19 infection of critically ill patients undergoing TEE and various endoscopic procedures present a similar potential for widespread disease transmission.

Conclusion

Without proper cleaning and disinfection, a contaminated endoscope or endocavity probe serves as a vehicle for infection transmission between patients. However, meeting the logistical and physical demands of the manual cleaning process in clinics has proven difficult and has led to multiple outbreaks. Thus, there is a critical need to address issues surrounding endoscope and endocavity probe reprocessing. Automated cleaning procedures seem to be the solution. For reprocessing of TEE probes, the TEEClean® Automated TEE Probe Cleaner Disinfector is the first automated TEE ultrasound probe reprocessor cleared by the FDA that offers automated cleaning and disinfection in the same device. TEEClean® eliminates the physical demands of manual cleaning and maintains consistency in reprocessing procedures to ensure devices are reprocessed correctly each time. The limited hands-on time means a reproducibly clean probe can be achieved efficiently to meet the needs of a busy hospital. Thus, TEEClean offers a solution to reduce the risk of healthcare acquired infections from contaminated TEE probes in a reproducible and efficient manner.

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