DEMONSTRATING THE EFFECTIVENESS OF A SEMI-AUTOMATED PRE-CLEANING PROCESS FOR FLEXIBLE ENDOSCOPES

Theme: endoscope reprocessing

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Contributing parties:

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Innovative Decontamination Solutions

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Contents

Background

Recent studies show that appropriate manual cleaning of endoscopes reduces the number of microorganisms and organic load by 4-6 LOGS or 99,99% (Puri 2017), highlighting the critical importance of thorough pre-cleaning. High level disinfection can only be reached with a decent pre-cleaning process, as this prevents the formation of biofilm. While the pre-cleaning process takes only a short amount of time, its importance in the reprocessing of endoscopes is critical. If the instrument is not clean, then it certainly cannot be made sterile. However, several other studies show that the present reprocessing and process control procedures are often not sufficiently adequate and safe. Recent research claims that One of the main reasons is the failing education of the staff,. (Knight 201X) It's safe to say that both current time-issues and the lack of correct knowledge leads to current problems concerning endoscopic infections. Manual cleaning is generally effective but difficult to control in practice.

Cleanliness of flexible endoscopes is critical from every patient's perspective. It is equally important to nurses and doctors, as while not being at the receiving end of the treatment, they handle multiple instruments every day and must depend on them being safe to use.

Flexible endoscopes are often considered as less critical than invasive surgical tools, however, recent data reveals the myopic aspect of such approach. For example, during colonoscopies multiple biopsies are often taken meaning various fragments of tissue, sometimes cancerous or infected with pathogenic microorganisms, are dragged though very narrow and long channels contaminating their internal walls. In this context it is not only clear mucus and small quantities of blood but tissue fragments containing proteins, entire cancerous cells and pathogenic microorganism that are not only vastly more dangerous to the patients but also a lot more difficult to clean, disinfect or sterilise.

UltraZonic has conducted a study that compares effectiveness and efficiency of current most used manual endoscope cleaning processes in a simple stainless steel sink and cleaning guns with automated cleaning processes. The study aims to answer the question to what extent automation of the cleaning process can help reduce current reprocessing issues.

This preliminary study was conducted together with Peskett Solutions and Aseptium Limited, located at the University of Highlands and Islands Campus in Inverness in the Scottish Highlands.

Aim

The aim of this study is to demonstrate the effectiveness of UltraZonic's ENDO semi-automated pre-cleaning system in its ability to remove biofilms from the internal channels of endoscopes using a combination analytical methods including Aseptium's VeriTest and the ProReveal technology.

Methods and Materials

This study utilizes both real flexible endoscopes and Aseptium's surrogate process challenge devices to demonstrate the efficacy for the UltraZonic ENDO pre-cleaning system.

Preparation of the Flexible Endoscope

To demonstrate the cleaning capabilities of the ENDO system, the flexible endoscope's internal channels were inoculated with a protein solution to emulate the presence of a biofilm contaminant.

UltraZonic's ENDO semi-automated pre-cleaning machine

The flexible endoscope, with a biofilm emulation present in the channels for 24 hours, was then subjected to the semi-automated cleaning program of UltraZonic's ENDO pre-cleaning machine. UltraZonic's ENDO machine offers a semi-automatic solution to the, typically manual, pre-cleaning process of flexible endoscopes. This ensures consistent cleaning every time with full traceability. The process involves a combination of manual brushing and automated cleaning of channels under pressure using a tri-enzymatic cleaning solution.

The ENDO process involves the following steps:

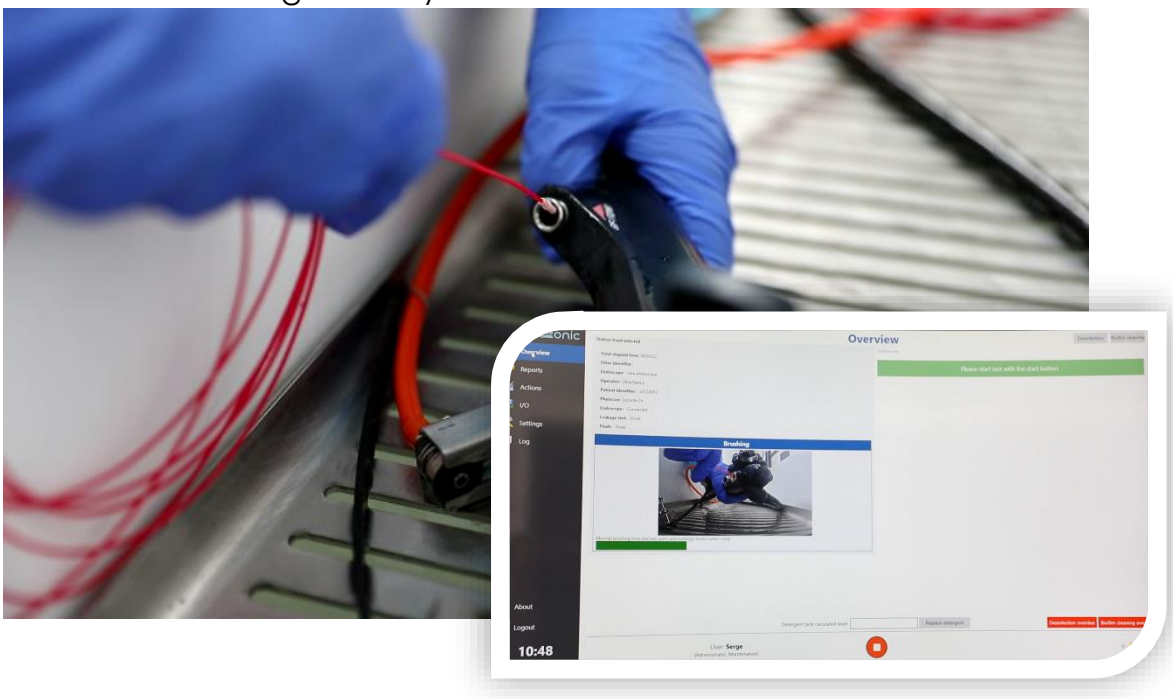
1. **Leakage test** on a dry surface during two minutes on 200 milibar

2. Leakage test continues in the water. (This will only happen if no leakage is detected. In case of a leakage the process is being cancelled and the endoscope will not submerge).

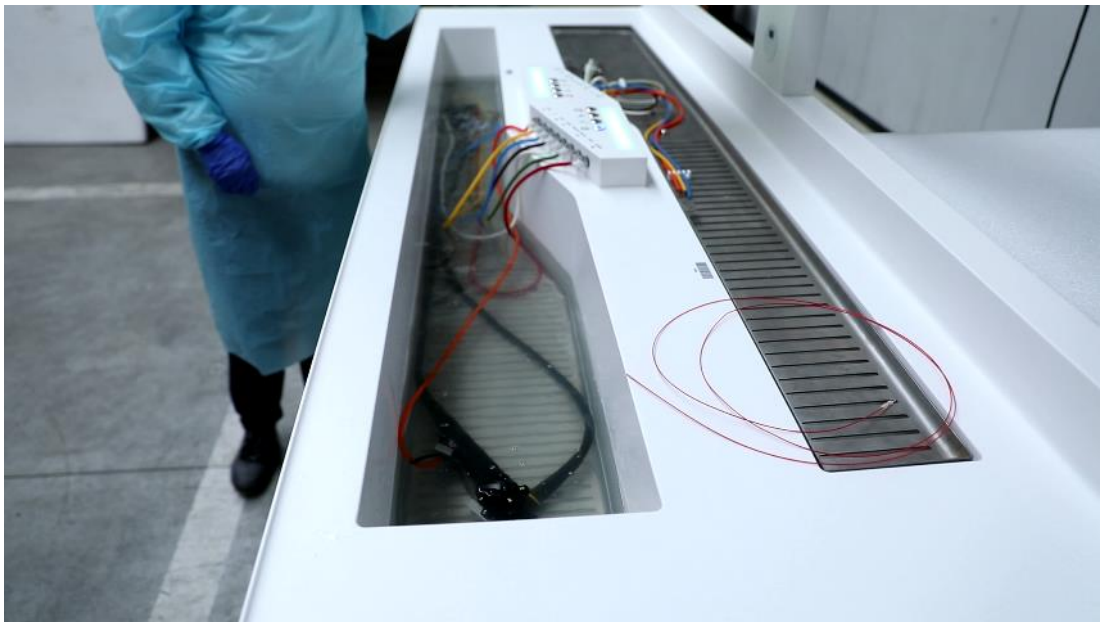
3. **Rinsing of all channels** with water and detergent (0,5% NosoZym tri-enzymatic detergent).

Note: the ENDO will make sure that the correct water temperature is used. So, there is no risk that the water temperature may not be according to the IFU. A continuous measurement of the water temperature takes place, keeping the temperature stable. Detergent contact time is also automatically monitored to ensure repeatability of the process.

4. **Visually recorded manual brushing procedure** using Pull Thru brush for increased cleaning efficacy.



5. **Second and final flushing** procedure with water and detergent to remove any debris. (1.5 min of flushing) – once again detergent contact time and water temperature monitored during the entire procedure.



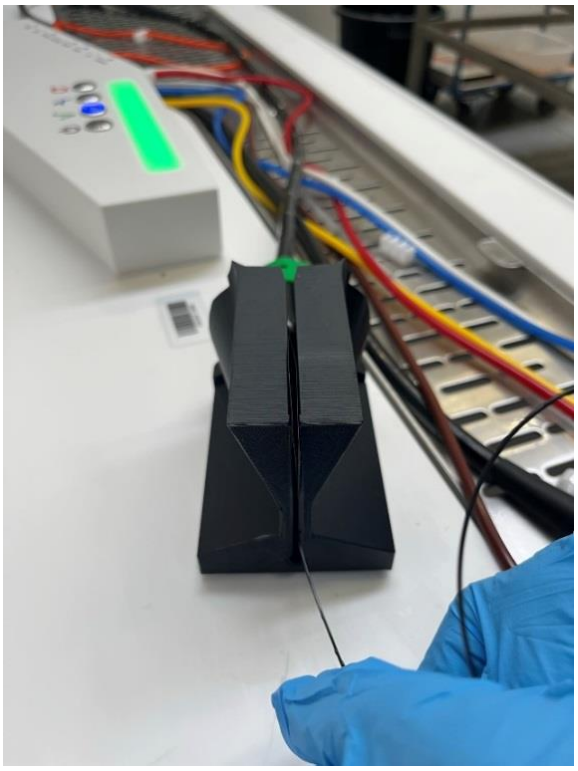
After this process was completed, two verification methods used were: ProReveal ChannelSafe protein qualification and Aseptium's Flex-E Process Challenge Device.

ProReveal Channel Safe

Once the automated cleaning process was complete, the endoscope was then tested using ProReveal's Channel Safe technology. ProReveal machines allow for the accurate quantification of protein residue via a reagent which binds to proteins and causes the resulting molecules to fluoresce under the presence of UV light. ProReveal machines analyse this fluorescence to determine the protein quantity present in µg. Typically, ProReveal technology is used to measure protein residue on the surface of stainless-steel surgical instruments or surrogate process challenge devices (PCDs). To tackle the issue of internal channel verification, the Channel Safe accessory was developed to allow for the inoculation of internal channels with the ProReveal Reagent and the subsequent collection of this fluid using a Channel Safe wipe device.

The distal end of the endoscope is fastened to the "Cone Holder" accessory which contains a black paper cone. The internal channel is then flushed with ~1mL of Reagent.

The Channel Safe wipe is then fed through the internal channel until it exits the distal end. This is then pulled through the length of the channel, with the "wiper" end collecting the Reagent present in the channels.



As the wipe exits the endoscope, the reagent is collected onto the surface of the cone. The wiper head is then separated from the rest of the device using clean scissors, and contained within the cone.

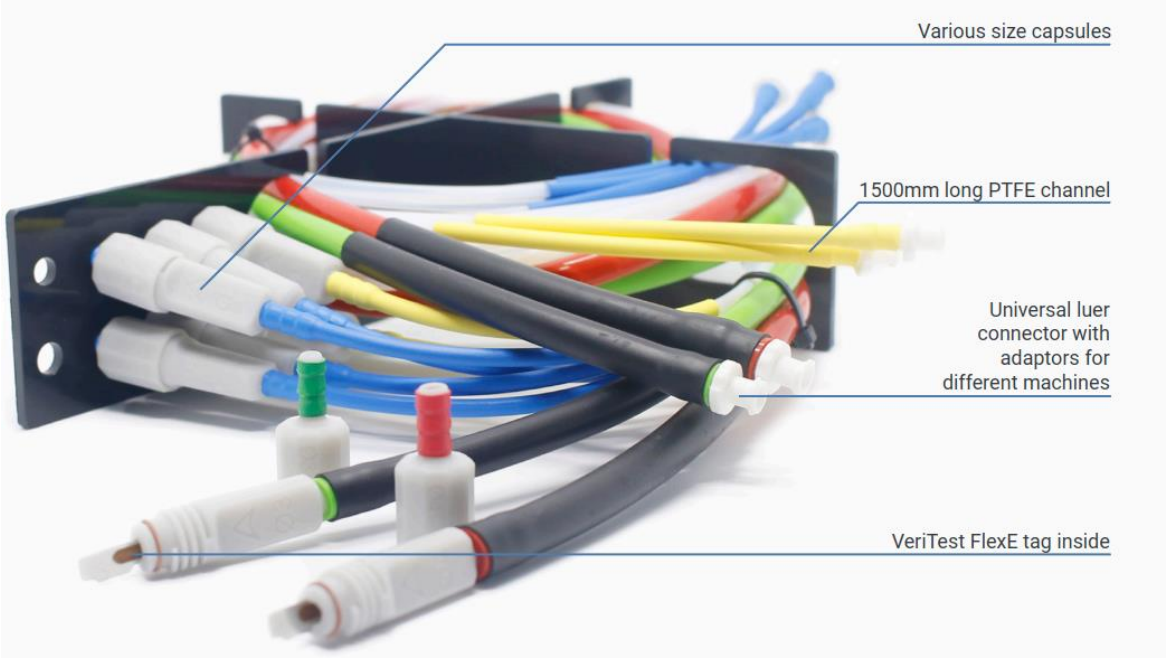
The cone, containing the reagent and the wiper head, is then transferred onto the holder which is then placed into the ProReveal machine for analysis.

A test is then performed to measure the protein content left on the ChannelSafe "head" and within the reagent that has been collected on the cone's surface. This is expressed in "µg" of residual protein.

Aseptium's VeriTest FlexE

Testing of real endoscopic channels is an effective way to demonstrate the cleaning capabilities of the ENDO machine, but routine testing and analysis of real instruments and equipment often necessitates their reprocessing after testing.

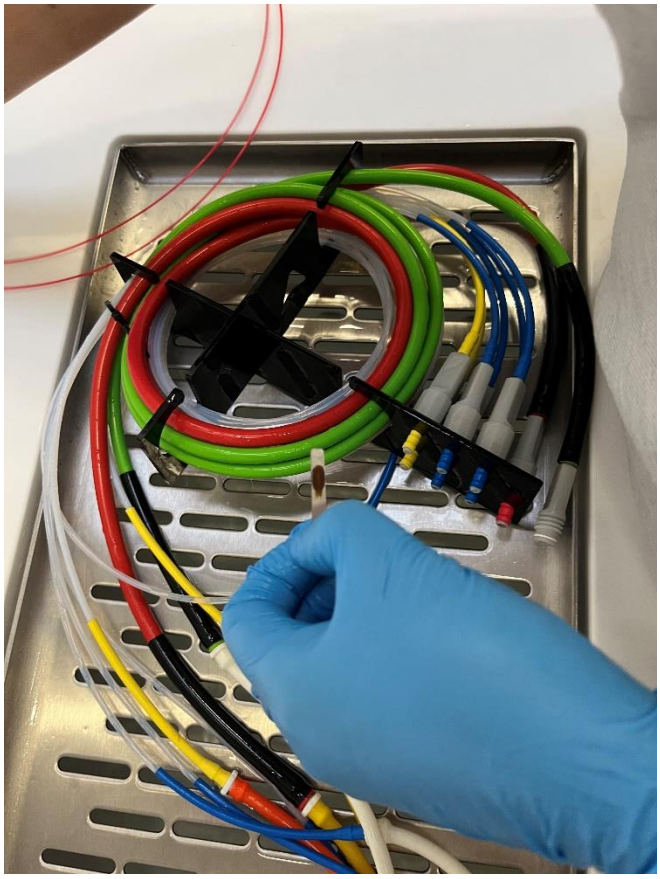
Aseptium's VeriTest FlexE device offers a complete solution in the form of a Process Challenge Device. These devices are designed to emulate the internal channels of flexible endoscopes and the difficult to remove contamination found within.



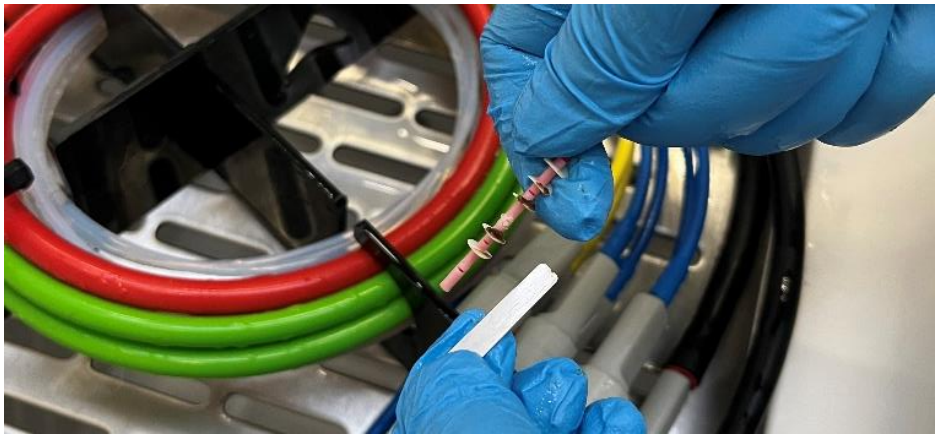
The FlexE device consists of an array of different channels, each with differing diameters to suit your needs and ensure that every size of instrument is capable of cleaning. The capsule end holds a "VeriTest AW" tag, made of surgical grade stainless steel and inoculated with a test soil consisting of real blood and tissue to stay true to what is found under real world circumstances. The purpose of this device is to test the cleaning capabilities of irrigation systems such as those present in the ENDO machine.

The VeriTest FlexE capsules are each firstly loaded with a single VeriTest AW tag. The design of the capsules ensures tags are loaded in the same orientation every time.

The VeriTest FlexE channels are then connected to the irrigation ports and the pre-cleaning cycle is run as normal, including the enzymatic cleaning chemicals.



Once the cycle is complete, the tags are removed and inspected for any residual soil. These tags can then go on for further analysis such as ProReveal testing or using VeriTest Blue



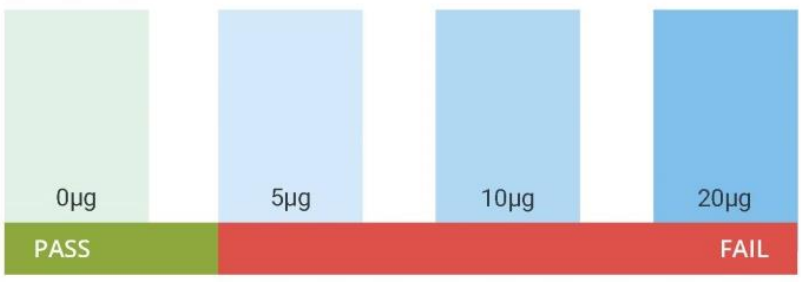
Results

Typical Cleaning

To demonstrate the effectiveness of the ENDO system, it is important to highlight the ways in which typical cleaning processes fail to achieve adequate cleaning. The results below, provided by Aseptium, showcase how typical (manual) cleaning methods involving manual brushing with single or double headed brushes can leave unacceptable levels of contamination behind.

VeriTest Blue Results	
Double-Head Brush	**Single-Head Brush**
	
Clean Control	**Dirty Control**
	

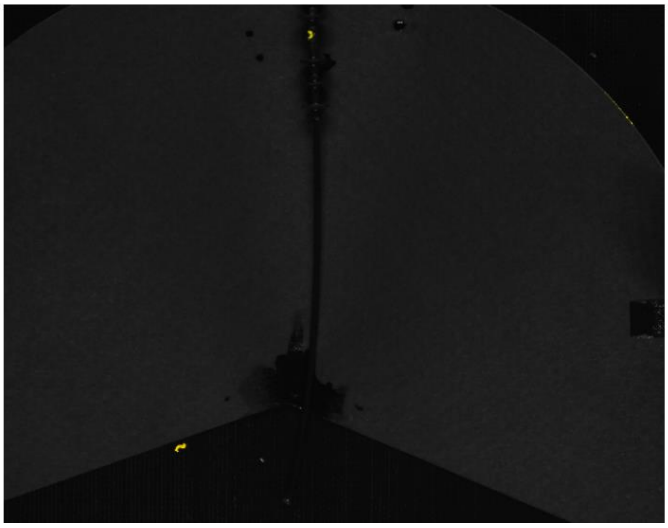
VeriTest Blue changes colour depending on the concentration of proteins in the solution. The darker the blue colour, the more protein present.



ProReveal Channel Safe

The image below is sample result showing the ProReveal Channel Safe cone and wiper head under the UV light of the ProReveal Machine. Glowing yellow/orange pixels indicate protein presence. The results from this particular test with the ENDO device showed a protein residue level of just 0.243µg.

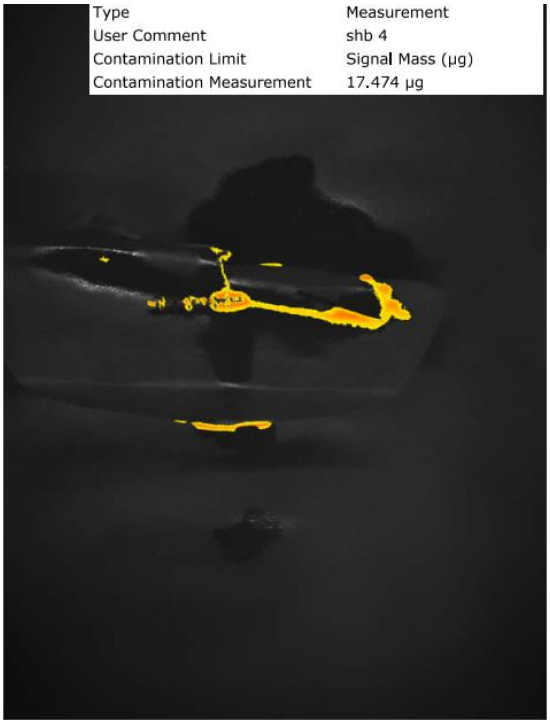
01037 220915105747



Equipment ID	PRVL/1037
Measurement ID	220915105747
Date & Time	15/09/2022 10:57:47
Type	Measurement
Sample Description	Channel Safe Device
Process ID	ENDOSCOOP01
Reagent ID	(01)05060532110009(17)230225(10)00024
Wash Unit	UltraZonic ENDO Pre-Wash
Contamination Limit	Signal Mass (µg)
Contamination Measurement	0.243 µg

To compare, the image to the right shows high level of protein(17.474µg)found after manual-cleaning was performed using a single-headed brush.

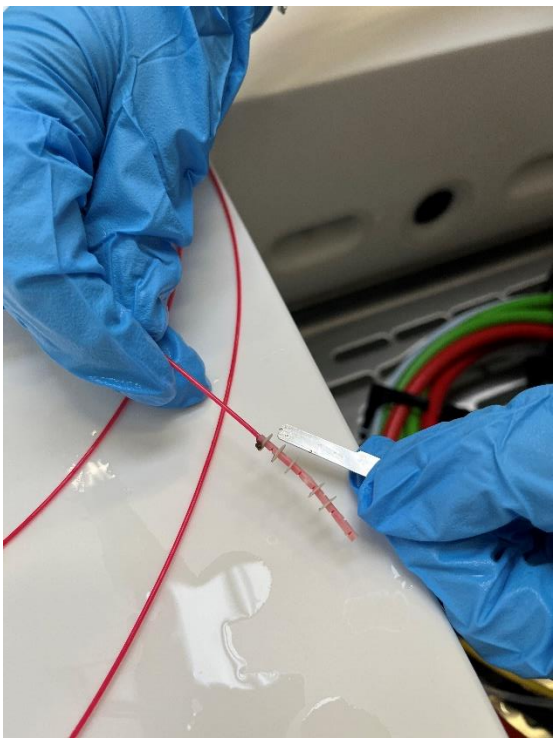
Full data from the ProReveal analysis is available upon request as an independent study.



VeriTest FlexE

VeriTest Flex-E were inspected visually after the ENDO pre-cleaning program was complete. Visual inspection showed no visible protein residue on the surface of the tags.

Further analysis of tags will be presented in the full study, showing VeriTest Blue results alongside ProReveal Protein Quantification.



This preliminary study demonstrates the cleaning performance of the ENDO machine. Current data indicates a significant advantage of the semi automated process developed by UltraZonic over any manual processes routinely used in hospitals.

Conclusions

Adequate pre-cleaning is of utmost importance to achieve a safe, process-ready endoscope. Testing of new technologies that aim to improve on patient safety are crucial, as demonstrating efficacy of repeatable and traceable processes is essential for the adoption of such methods. This preliminary study has demonstrated superiour cleaning performace of UltraZonic's ENDO pre-cleaning washer.

The study used both real flexible endoscope and process challenge devices designed by Aseptium to specifically simulate internal channels of contaminated endoscopes. Contamination was desorbed by a uniquely engineered Channel-Safe device from Peskett Solutions proven to remove over 94% of contamination from the channels paired with advanced UV protein detection system the ProReveal as well as proprietary protein detecting dye from Aseptium – VeriTest Blue. The study is based on protein contamination analysis that is clinically relevant to the type of contamination found in flexible endoscopes including biofilms. The chosen analytical tools allow for visualisation and quantification of contamination, evidencing the effectiveness of the UltraZonic ENDO pre-cleaning system.

Results from the pilot study show a significant performance difference between the ENDO device in the most important aspect of contamination removal in comparison with standard manual processes using bristle brushes. That difference was visible on all protein detection methods used in the study with the ProReveal system not only visualising the outcome but quantifying the results as well.

This study highlights the efficacy of UltraZonic's ENDO device and offers a unique insight into the innovative methods for reprocessing of flexible endoscopes and offers direction for further studies, as well as product development with a view of making sure that reprocessing is effective, efficient and user friendly.

Once the study has reached completion, a full analysis of results will be conducted to compare the cleaning efficacy of ENDO versus the typically manual processes used in many hospitals today. The research continues to find the most effective and efficient bioburden removal pre-cleaning techniques, but first results already clearly indicate that automatic pre-cleaning devices ensure a highly increased cleaning efficiency compared to manual cleaning (sinks). Automated cleaning solutions also guarantee that no cleaning steps are missed and that each endoscopes undergoes the exact same cleaning routine. Procedure after procedure, and therefore

continuously obtaining the same outcome. Bespoken results demonstrate the effectiveness of their ENDO semi-automated pre cleaning device, that greatly improves cleaning and cleaning surveillance directly improving patient's safety as well as the ease and convenience of reprocessing of these super-complex instruments.

References / Acknowledgements

Puri P (2017) Hospital Infection Control Endoscopy, www.infectiousdiseaseadvisor.com/home/decision-support-in-medicine/hospitalinfectioncontrol/endoscopy/?fbclid=IwAR08j9zWfBOPTbrORKWePHj72M6tx1cXiS4w0dKOF zNh8wn6TyBtna9OwEA#:~:text=Endoscopy related infections occur endogenously, from endoscopy personnel to patients

Knight A (2019) Outpatient Surgery, https://www.aorn.org/outpatient-surgery/articles/enews-briefs/may-6 2021?utm_content=165756196&utm_medium=social&utm_source=linkedin&hss_channel=lcp-464485#story