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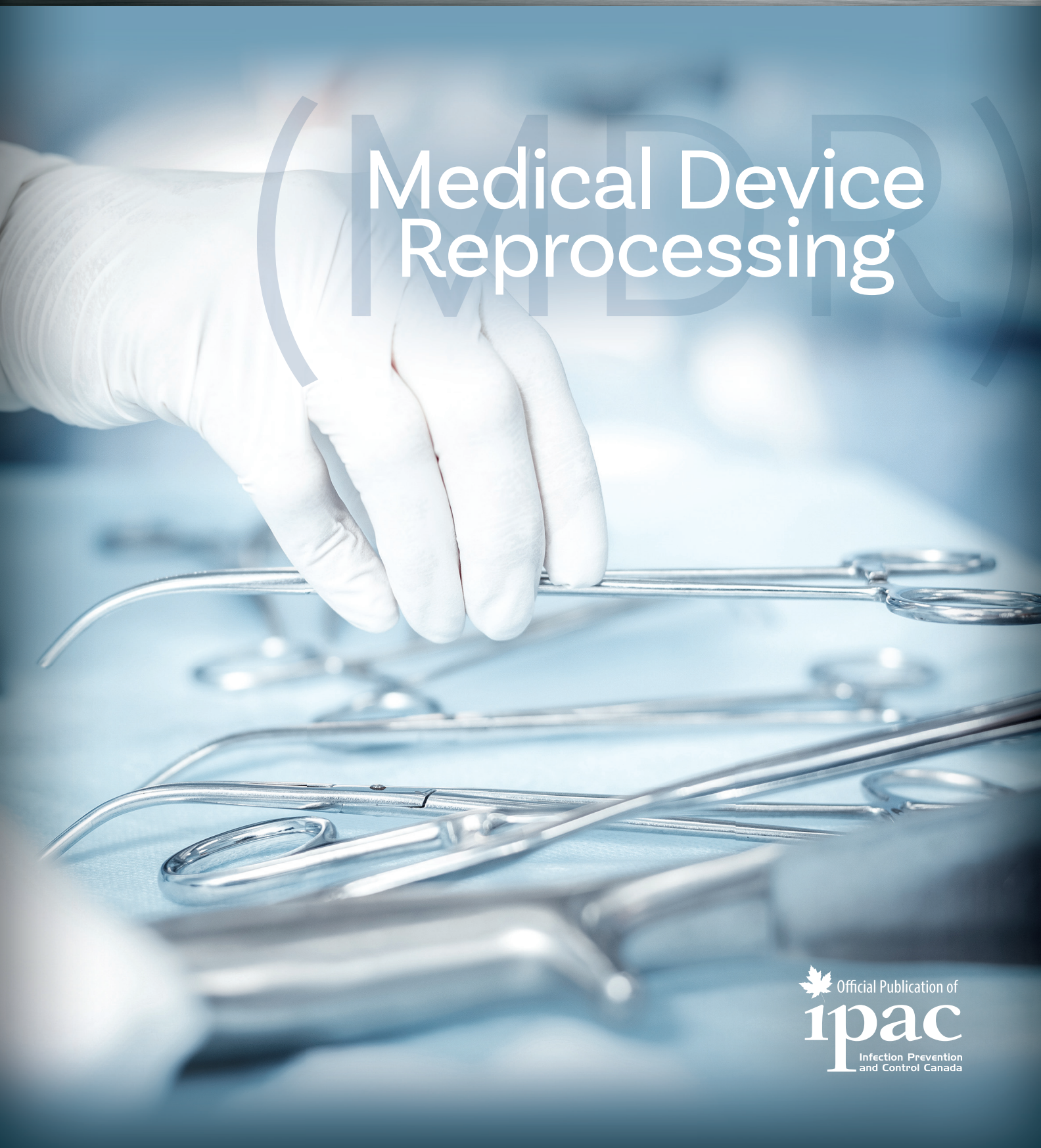
Volume 4, Number 1, Summer 2022

Medical Device Reprocessing



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1. See product label for complete list of organisms, contact times and directions for use.
2. Haq MF, *et al*. (2022). Effectiveness of a novel 1-step cleaner and disinfectant against *Candida auris*. *Infection Control & Hospital Epidemiology*, https://doi.org/10.1017/ice.2022.73
3. 1 minute indirect kill for SARS-CoV-2. Drug Identification Number (DIN) 02512211
4. A pre-clean step required for HIV-1, HBV, HCV and *C. auris*.

INDUSTRY INNOVATIONS

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Foreword

Dear Colleagues,

We are very excited to bring you the 2022 summer issue of *Industry Innovations*, showcasing new and updated reprocessing technologies which can be used in all healthcare settings. Infection Prevention and Control teams work closely with their Medical Device Reprocessing (MDR) colleagues to keep abreast of where reusable devices are used, and the standards for reprocessing. They must also keep up to date with and encourage the purchase and use of new reprocessing technologies that improve working conditions for MDR staff, while promoting safety in the workplace. Our industry partners are available to assist with education and interpretation of manufacturer instructions in any healthcare setting to ensure quality management systems for safe patient/client care.

With the summer months upon us, many of you will continue to work tirelessly with little vacation, and even with COVID-19 still lingering, it is imperative that medical device reprocessing departments and Infection Prevention and Control Practitioners continue to work together to ensure reprocessing standards are being met.

In this edition, you will read about an updated flexible endoscope automated reprocessor, which has been validated for cleaning and high-level disinfection of flexible endoscopes, new flexible endoscopes storage solutions to ensure complete drying once stored and about a new surface repair technique and application for repairing damaged healthcare equipment, such as mattresses, which will provide cost savings to an organization.

If you haven't already done so, it is important to reconnect with industry partners to find out about new and/or revised technology, and what's on the horizon! There are always new developments in reprocessing of flexible endoscopes. I encourage you to find out more and to engage in our industry partners' online education.

On another note, I wanted to provide short discussions on a few important topics regarding MDR; the definition of a healthcare setting. There continues to be healthcare providers who are unsure if the Canadian Standards Association (CSA)-Z314 MDR Standard is applicable to them. Industry partners also look to these standards as well.

"The Canadian Standards Association (CSA) CAN/CSA-Z314 definition of a healthcare setting includes ALL settings or locations where healthcare is provided, including emergency care, pre-hospital care, hospitals, long-term care, home care, ambulatory care, and facilities and locations in the community where care is provided, including but not limited to educational institutions, residential facilities, correctional facilities, dental offices, physician offices, and all private practice settings for healthcare professionals such as foot care or any home based reprocessing."

While this is not an all-inclusive list of the healthcare settings where reprocessing may occur, I recommend that you consult the standard. If you do not already have a copy, I encourage you to ensure your healthcare setting purchases a copy.

The public review for CAN/CSA-Z314 MDR Standard revision recently concluded, and CSA is in the final stages of the necessary preparation for printing of the revised Z314 Medical Device Reprocessing Standard. Look for the revised standard early 2023.

As well, CSA is currently finalizing their updated Online Community Medical Device Reprocessing courses. There are courses that include general MDR in community settings, dental, foot care and endoscopy courses for those who perform any of the reprocessing in these settings. Visit their website in mid to late fall 2022 at *www.csa.ca* for more information.

We hope that you find this edition educational and that it provides insight into some of the newer technologies used in Medical Device Reprocessing!

As always, feedback, recommendations for future issues, and submissions are always welcome.

Merlee Steele-Rodway, RN
Guest Editor, *Industry Innovations*

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Minimizing Landfill Waste with CleanPatch®: Surface Repair as a Novel Reprocessing Technique

Abstract

Patient treatment surfaces, such as mattress covers, are particularly susceptible to damage from frequent use, mechanical penetration from sharp objects, and abrasive chemical disinfectants. When this equipment is damaged, it can no longer be properly disinfected because bodily fluids and bacteria can enter the mattress and escape decontamination. Harmful pathogens can accumulate in rips and punctures and lead to healthcare-associated infections (HAIs), posing a risk to medical staff and vulnerable patients[1]. The spread of HAIs can be managed by identifying and addressing damaged soft surfaces promptly. Frequently touched patient surfaces should be regularly examined for signs of damage as compromised surfaces can have serious consequences if not properly addressed.

Because of the possible risks that damaged mattress covers pose to patients and staff, the standard protocol often dictates that the mattress must be decommissioned, disposed of, and replaced. Mattresses are typically disposed of in landfills, leading to waste accumulation and increased carbon emissions associated with the healthcare supply chain. While this practice upholds high standards of patient care, it is an expensive solution and generates large quantities of biohazardous waste. Many mattress replacement protocols are too lengthy and too expensive for healthcare facilities with limited resources to implement consistently. Alternatively, due to budgetary constraints or a lack of resources, healthcare facilities may continue to use damaged equipment, or will attempt restoration using unapproved materials such as commercial tape or wound care dressing.

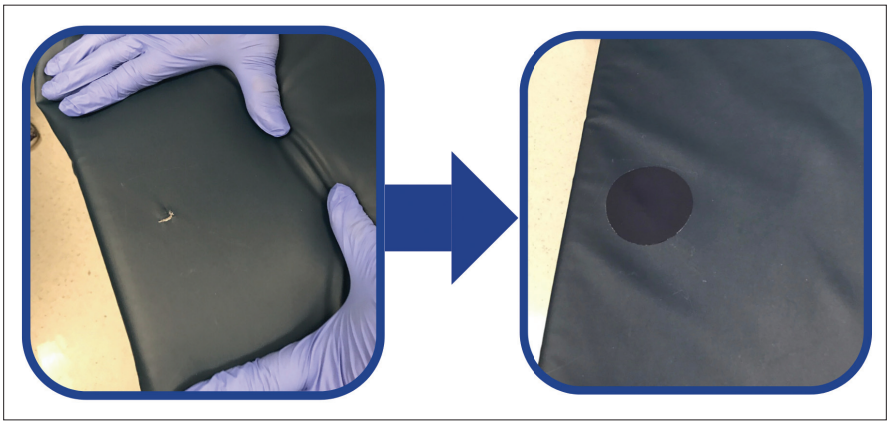

Figure 1: CleanPatch® is a safe, cost-effective solution that addresses surface damage.

Surface Medical, Inc. recognizes the importance of protecting patient safety, but it also recognizes the negative environmental impact generated by healthcare waste. To address these problems, Surface Medical created CleanPatch®, a clinically validated repair patch that restores compromised patient surfaces such as hospital mattress covers (Figure 1). CleanPatch® is a Class 1 medical device which can be applied over damage on patient surfaces to return the surface to an intact and fully cleanable state. Restoration to a cleanable state prevents the spread of HAIs, while also preventing the premature disposal of medical equipment in landfills and minimizing carbon emissions associated with the healthcare supply chain. In accordance with other medical device reprocessing (MDR) techniques, CleanPatch® provides healthcare facilities with a cost-efficient alternative to protect patient safety while also supporting environmental sustainability.

Specifications

As an alternative to patient surface disposal and replacement, Surface Medical utilized the latest in textile technology to create CleanPatch®, the first and only commercial product designed to repair minor damage safely and effectively on patient surfaces, and restore them to an intact and hygienic state. Unlike commercial tape, such as duct tape or wound care dressing, CleanPatch® is a Class 1 medical device registered with Health Canada and the Food and Drug Administration (FDA), and has been clinically validated by independent infection prevention professionals. This novel and patented repair patch technology can permanently adhere to a patient treatment surface to create an impermeable and cleanable surface if the damage is small in size, and no fluid ingress is observed. The product is compatible with common hospital-grade disinfectants, and is fully cleanable, durable, and impervious to fluids under rigorous conditions[2].

PRODUCT	CLEANPATCH®	CLEANPATCH®-V	CLEANPATCH®-P
SIZES	• Small Round 5 cm (2 in) • Medium 9x9 cm (3.5x3.5 in) • Large 9x15.2 cm (3.5x6 in)	• Small 4.5x10.1 cm (1.75x4 in) • Large 14.6x20.3 cm (5.75x8 in)	• O/S 4.5x8.9 cm (1.75x3.5 in)
COMPATIBLE SURFACES	• Hospital beds • Stretchers • Polyurethane surfaces	• Exam tables • Rehab equipment • Other vinyl upholstery	• Gel pads • Patient positioners
REPAIRABLE DAMAGE	• Repairs damage up to 12.7 cm (5 in) • Abrasions, tears, cuts, punctures • Small chemical damage	• Repairs damage up to 17.8 cm (7 in) • Abrasions, tears, cuts, punctures	• Repairs damage up to 6.4 cm (2.5 in) • Abrasions, tears, cuts, punctures

Table 1: Specifications of CleanPatch® product lines.

Metrics

Many studies have shown that cross contamination from bacteria or other microorganisms can be transferred to medical staff and patients through contact with surfaces containing pathogens, highlighting the importance of hand hygiene and disinfection of the patient environment[3,4]. This has been demonstrated by the association of *E. coli* environmental contamination and the incidence of disease, as well as a weak association with norovirus and gastroenteritis[5]. Other bacterial pathogens found on frequently touched surfaces include methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *enterococcus*, carbapenem-resistant *Enterobacteriaceae* (CRE), *Acinetobacter* species, and *Clostridioides difficile*[6-12]. Routine disinfection reduces the spread of HAIs[13], thus maintaining patient surfaces in an intact and cleanable state, which is crucial in enabling effective cleaning practices.

Fortunately, it is now well recognized that patient surface failures pose an infection risk so, to protect patient safety, the Centers for Disease Control and other regulatory bodies prohibit the use of damaged mattress covers[14]. The US FDA and the UK Medicines and Healthcare Products Regulatory Agency have issued advisories describing the risks of failing to address damaged surfaces, including patient exposure to bodily fluids and cross contamination of infectious pathogens. From 2011 through 2016, the FDA received more than 700 reports of mattress covers that failed to prevent blood or body fluids from leaking into the mattress core[15]. In 2018, a peer-reviewed study was published in the *Canadian Journal of Infection*[16], highlighting the incidence of damaged surfaces in hospital settings. The study was performed with five leading Canadian hospitals to assess more than 2,500 patient mattresses, and it was found that 32.5% of patient mattress covers were damaged. More recently, an independent study published in *Infection Control & Hospital Epidemiology* found a 72% damage rate among the 727 beds and mattresses that were inspected[17] across four hospitals.

In the 2018 study, CleanPatch® successfully addressed more than 55% of mattress damage in a clinical setting, with some healthcare facilities noting a 95.8% repair rate[16]. CleanPatch® is compatible with 95% of soft surfaces found in clinical settings, and the three product lines make it easy to address a wide variety of soft-surface damage. Microbial growth analyses were conducted in clinical settings on mattress covers restored with CleanPatch® and found no significant change in microbial growth on CleanPatch® and the mattress surface before and after terminal cleaning (Figure 2). CleanPatch® does not harbour more bacteria than expected in a clinical setting, and demonstrates the same cleanability as similar patient surfaces.

Based on these high damage rates and high repair rates, CleanPatch® can reduce a significant portion of waste generated by healthcare facilities. The healthcare sector contributes about 8% of total carbon emissions and is the second-largest contributor of landfill waste next to the food industry[18,19]. Hospital mattresses contribute to this waste, as they weigh approximately 8 kg each, and are supposed to be replaced when the surface is compromised. When applied at the early signs of damage, CleanPatch® can prevent the majority of hospital mattresses from premature disposal, thus providing a unique

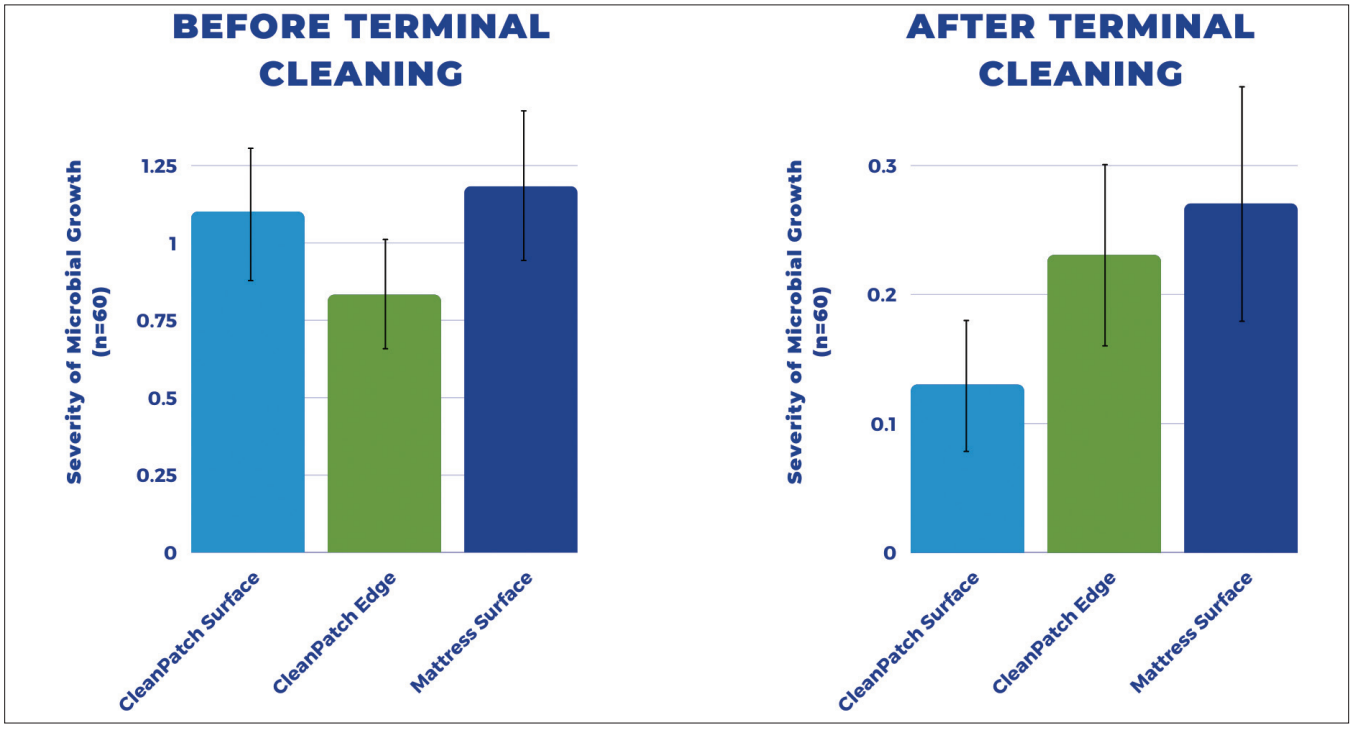

Figure 2: Clinical studies show no significant difference in microbial growth on CleanPatch® compared to the mattress surface before and after terminal cleaning[2].

opportunity to reduce waste and carbon emissions associated with the healthcare supply chain. While the disposal of damaged medical equipment is a common strategy used to maintain high standards of patient care, CleanPatch® and other MDR techniques present alternative solutions that protect patient safety while also promoting a circular economy in healthcare organizations.

Practice changes

CleanPatch® is an easy and intuitive product to use, but education is the greatest challenge to transforming everyday clinical practices. Firstly, healthcare professionals and frontline workers must have a certain level of awareness to identify surface damage and its occurrence across the medical equipment in their facility. Despite studies that show high damage rates in the hospital setting[16,17], under normal circumstances, clinical staff are not actively looking for damage and therefore may not understand the extent to which it occurs. In fact, when many healthcare professionals are introduced to CleanPatch®, they express that surface damage is not a problem at their facility, despite studies that show high damage rates across independent hospitals. This lack of awareness means that damage persists and increases while bacteria and bodily fluids enter the mattress cover.

Secondly, frontline healthcare workers must be self-motivated to report surface damage. When healthcare workers fully understand the risk that surface damage poses to patient safety, they are more likely to catch the damage early and report it. So, education plays a key role in changing clinical practices while implementing surface repair protocols, and surface damage should be incorporated into the infection prevention training of clinical staff and any healthcare personnel that come in contact with patient surfaces. Everyone on the healthcare team can be empowered to promote change in their organization and make a meaningful difference in reducing HAIs by reporting surface damage.

Moreover, a simple reporting system can be used to establish responsibility and create a culture where damage is quickly and easily addressed. CleanPatch® can be used by anyone, including frontline healthcare workers, cleaning staff, infection preventionists, and MDR and maintenance departments. Within these teams, it can be helpful to designate one person who will be responsible for managing surface damage throughout the facility. This way, there are few practice changes and less confusion about who is responsible for repair because damage can be successfully directed among staff. Once this reporting system is in place, there are little to no additional steps required to change frontline practices.

Incorporating CleanPatch® and surface repair into everyday practices requires minimal training. CleanPatch® is intended to be a single-use product, and it is designed to permanently adhere to the damaged surface; however, CleanPatch® must be cleaned and disinfected at the point of terminal cleaning, like the mattress itself. The product can be safely applied by following the images on the packaging (Figure 3) or, if needed, online training is available. This online training can be completed by anyone so that every member of the healthcare

organization is better prepared to address surface damage when it is observed. CleanPatch® reduces time and costs associated with the standard practice of replacing equipment, and like other MDR techniques, it also assists healthcare facilities in their commitment to sustainable healthcare by reducing medical waste.

Implementation

Before CleanPatch® was developed, there was no clinically validated patient surface repair product, so incorporating surface repair into organizational policies and guidelines is the first step toward implementation. As stated previously, the only option available to healthcare facilities was to remove damaged equipment from service. As with many policies in healthcare, these guidelines often persist despite changes in technology, and, as a result, Environmental Services (EVS) and healthcare staff may be unaware that damaged mattress covers can be safely repaired in the clinical setting.

CleanPatch® has been well received and implemented by many healthcare communities, and guidelines are being updated to reflect this option as an alternative to equipment replacement. For example, Canada's largest integrated provincial healthcare system, Alberta Health Services, has changed its guidelines to include repair alongside replacement as an acceptable solution, when a repair is performed by trained personnel and the manufacturer's instructions for use are followed[20]. Another Canadian organization, Public Health Ontario, released an advisory in 2018 that recognized soft-surface repair as a safe practice[21]. A significant policy change in the U.S. came in 2018 when The Joint Commission amended its guidelines on environmental cleaning to condone patching damaged surfaces if the repair is performed with an approved and validated repair product[22]. The guidance specifically mentions that tape should not be used on damaged medical equipment.

Implementing CleanPatch® for the first time can require input from multiple stakeholders, but there are many resources to support facilities with the implementation process, along with many benefits for each stakeholder, and very little maintenance is required to ensure that it is operating effectively. Firstly, Infection Prevention and Control must review all relevant documents that outline the clinical safety of the product. Purchasing agents may also play a key role in evaluating the cost-effectiveness of CleanPatch® before moving forward. Secondly, biomedical engineering and facility maintenance must review the product and be trained to assess whether the damage is repairable. Finally, EVS and frontline healthcare workers must be educated about infection spread through compromised surfaces and the importance of reporting damage.

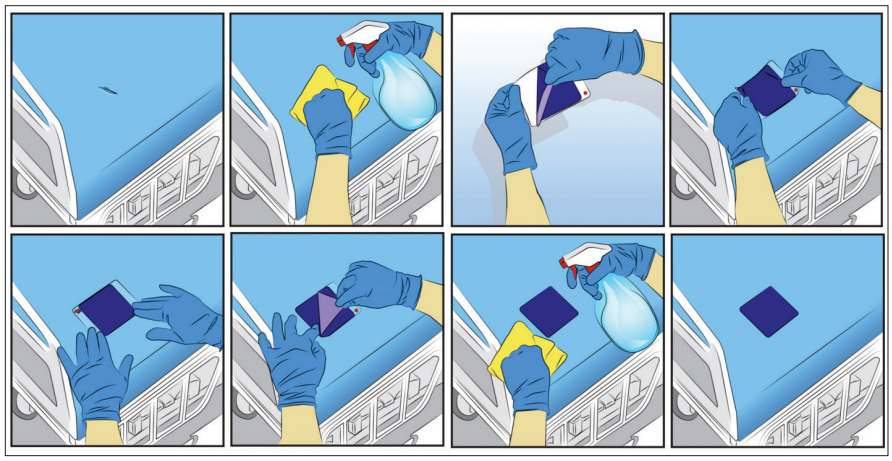

Figure 3: Instructions for use show the eight steps required to remediate damage with CleanPatch®.

The successful implementation of surface repair by the healthcare sector means that CleanPatch® can have a significant impact on our environment through medical waste reduction. It is therefore not surprising that thousands of facilities in over eight countries are taking advantage of surface repair as a novel MDR technique and one of the latest advances in sustainable healthcare.

Narrative

Imagine this scenario: you work for EVS at a hospital and notice a new tear in a mattress cover during a room turnover. The tear is only 2 cm in size and looks to have been caused by a sharp object. You make note of the damage and report it to the maintenance department. Maintenance informs you that the mattress is no longer usable and arranges for the mattress to be removed from the room. There is currently no mattress, which means that until a new one is procured, the hospital bed is not useable, and there is already a limited bed supply. Additionally, the mattress does not fit in the conventional waste disposal bins and must be housed in a storage room until arrangements can be made to remove it from the hospital and transport it to the landfill. One small tear has now created numerous problems that must be addressed.

Now, imagine the same scenario but in a different context. You are performing a room turnover and notice a tear 2 cm in size on a mattress. You document the damage and report it to the maintenance department. Maintenance informs you that someone will inspect the damage. The mattress is assessed, and a designated staff member deems that the damage is fully repairable without posing any threat to patient safety. The repair is completed in under two minutes, allowing you to proceed with routine cleaning. In this second scenario, the damaged mattress does not cause a host of complications: the mattress is not rendered unusable, the mattress does not take up storage space pending disposal, and the mattress does not end up in a landfill prematurely. When caught early, most mattress damage is repairable with CleanPatch®. The repair option saves healthcare facilities on capital expenditure, reduces

equipment downtime, and reduces their ecological footprint.

As a major contributor to carbon emissions and landfill waste, it is critical that healthcare advocates demand action and implement sustainable options into their clinical practices. As support for sustainability in healthcare gains traction, Surface Medical aims to be part of the solution. Implementing a surface repair program with CleanPatch® can promote a circular economy in hospitals by prolonging the service life of beds, stretchers, and other medical equipment (Figure 4).

Surface Medical's goal to promote sustainable practices in healthcare is shared with the goals of other MDR initiatives. For example, the Association of Medical Device Reprocessors (AMDR) is advocating for environmental sustainability programs. AMDR is a global trade association that represents regulated and commercial reprocessing and promotes reprocessing as an important healthcare strategy. Their website details the benefits of reprocessing medical equipment safely, and how collective efforts will promote a more cost-effective and environmentally friendly future in healthcare. Their agenda has demonstrated measurable success, witnessing more than $3.5 million in cost savings from reducing hospital waste disposal by reprocessing single-use medical equipment. The Canadian Association of Medical Device Reprocessing holds similar goals to reprocess medical devices while elevating quality and standards. Together, we must shift the mindset of healthcare professionals and create awareness around MDR techniques that protect both patient safety and the planet. With CleanPatch® and other innovations in the industry, healthcare organizations can make measurable and impactful changes toward a sustainable future.

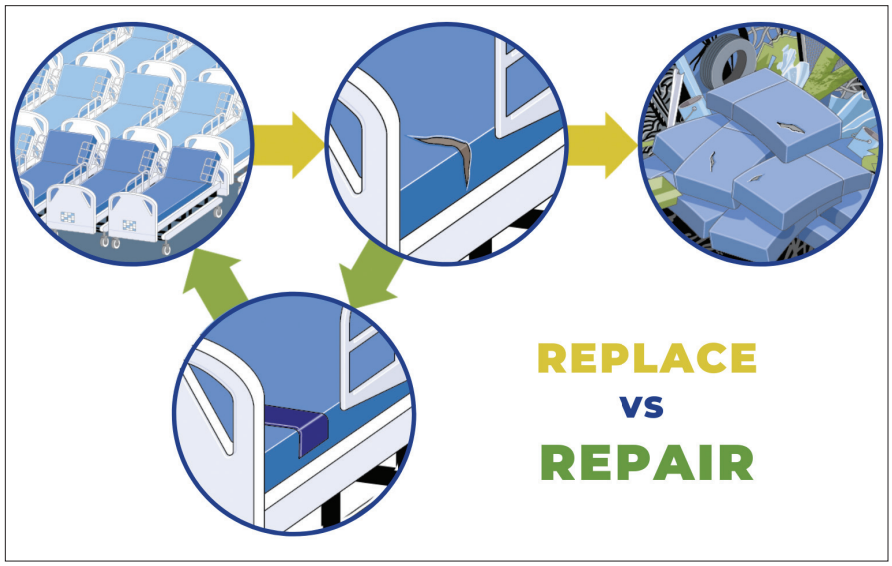

Figure 4: Implementing surface repair promotes a circular economy in healthcare organizations.

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TEEClean® Automated Cleaner Disinfector Eliminates the Unknowns from the Cleaning Process

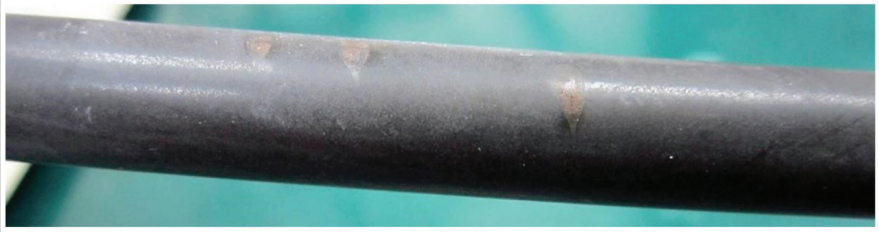
Abstract

Evidence has been presented that semi-critical devices – devices that come into 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. There is a critical need to address issues surrounding endoscope and endocavity probe reprocessing, as 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[2,3,4]. Depending upon the disinfectant and type of soil, the remaining soil on improperly cleaned devices can also bind or inactivate the disinfectant, making it ineffective in killing contaminating microogranisms[2,3,4].

In a laboratory study, angioscopes that were not cleaned prior to disinfection still contained infectious duck hepatitis B virus (DHBV)[5]. In contrast, researchers found that even when the disinfectant contact time was reduced, infectious DHBV could not be recovered from properly cleaned devices[5]. In the clinic, cleaning and subsequent automated disinfection reduced the microbial load on colonoscopes from 8-10 logs to 0 lgCFU/ml[6]. However, in the same study, failure to clean the colonoscopes prior to disinfection only reduced the microbial load to about 3.8 log lgCFU/ml (a 5-log reduction)[6]. Together, these studies highlight the importance of proper cleaning prior to disinfection to ensure disinfectants work effectively. 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. For reprocessing of TEE probes, the TEEClean® Automated TEE Probe Cleaner Disinfector is the first automated TEE ultrasound probe reprocessor cleared by the FDA and Health Canada, which offers automated cleaning and disinfection in the same device. TEEClean offers a solution to reduce the risk of healthcare-acquired infections from contaminated TEE probes in a reproducible and efficient manner.

For the healthcare facility and technician, TEEClean removes the unknowns that exist with manual enzymatic cleaning, and provides an added level of confidence that each TEE probe is receiving the same care during cleaning and disinfection. TEEClean allows the healthcare professional to simply place a bedside enzymatically treated (point-of-use cleaned), soiled TEE probe directly into the TEEClean, and thus removes the potential of an ineffectively cleaned TEE probe from being high-level disinfected. TEEClean provides both a scientifically verified and a repeatable method for cleaning of soiled TEE probes.

Biofilm formation due to improper cleaning technique



Improperly cleaned probes can lead to bacteria remaining on the probe. These bacteria can then form biofilms, which can protect the bacteria from disinfectants.

Specifications

TEEClean provides an automated cleaning and high-level disinfection cycle for TEE probes. A large, 7-inch colour LCD touchscreen provides the healthcare technician with vivid icons to operate the TEEClean. The LCD prompts the user, step by step, how to set up the TEEClean to properly clean and disinfect the soiled TEE probe. The user employs the barcode scanner to scan or manually enter the TEE probe identifier, user identifier, disinfectant lot number, and electrical leak test results, for each cycle. TEEClean stores user names and assigns user numbers to all trained technicians that operate the device. Selection of the user is done by scanning a barcode associated with the user number or through a manual lookup on the LCD

touch screen. Users can be easily added or deleted for administrative purposes. The user ID and number are printed on each verification report. TEEClean will manage up to 99 unique users. TEEClean also stores a list of all TEE probes that could be cleaned and disinfected with the device. The technician can simply scan a barcode for the soiled TEE probe, or select the correct probe from the list via the touch screen. TEEClean will manage up to 99 individual TEE probes. TEEClean provides prompts to the technician for completion of electrical leakage testing. Electrical leakage testing results are then recorded in TEEClean by the technician and then printed on the verification record as well as stored in system memory. These records can be retrieved later, if desired. TEEClean will provide an electronic record that is retained in the system memory and later printed out on the verification report generated at the conclusion of a successful reprocessing cycle. The electronic log contains all data entered into the device, as well as all parameters that are maintained during the cleaning and disinfection cycles of the process. The electronic record can be downloaded onto a computer and saved or printed for later reference or audit. TEEClean can manage over 15,000 disinfection logs within the system memory.

Incorporated into the cleaning cycle of TEEClean is TEEZyme. TEEZyme for TEEClean is formulated exclusively for use in the TEEClean Automated TEE Probe Cleaner Disinfector. The cleaning agents in TEEZyme, when used with TEEClean, effectively remove soil from TEE ultrasound probes. TEEZyme for TEEClean combines the power of a super-concentrate with a proven multi-enzyme formula to create the ultimate ultrasound probe cleaner. This unique combination gives TEEZyme for TEEClean superior cleaning ability to deliver fast and thorough soil contaminate removal. TEEZyme for TEEClean contains biological additives that speed the process of liquefaction and solubilization, facilitating enzymatic action and contributing to the TEEClean's overall effectiveness. TEEZyme is shipped in a box of two bottles. The expected use of TEEZyme is either 40 cycles or 180 days after first use for each bottle. TEEZyme is shipped with a barcode for easy entry into TEEClean. Additionally, a Nephros ultra-pure, 5nm water filter is integral to the TEEClean design. TEEClean rinses each TEE probe with the Nephros filtered water. The water filter is a Class II medical device that has been tested and validated to retain bacteria, viruses and endotoxins. The filter is simple to change out when required. Nephros TEEClean water filters are packaged 4 to a case. The expected useful life of each filter, after installation is 90 days. Filters are shipped with a barcode for easy entry into TEEClean system's memory and this will become part of the electronic record as well as the preventative maintenance record. TD5 is the high-level disinfectant that is integral to TEEClean's disinfection cycle. TD-5 disinfectant is a single-use, 2.65% glutaraldehyde based, high-level disinfectant that when used with the TEEClean, provides a five-minute high-level disinfection of TEE probes. Its single-use container is pierced inside the TEEClean. TD-5 is sold in packages of 32 bottles and has an expiry date of 12 months from DOM. Finally, TEEClean incorporates two chemisorptive bonded gas phase carbon filters that effectively remove and neutralize the disinfectant fumes. The main vapour management filter is housed inside the TEEClean while the secondary filter is placed on the drain to prevent drain gases from returning into the room. Both filters, the main and drain, have 12 months useful life after installation. The solid bonded carbon filters have superior residence time and capacity to ensure the safety of healthcare personnel.

Specs:

Actual size: 24" wide x 12" deep x 44" high and is 90 lbs.

Space and site requirements: 36" wide x 12" deep x 72" height from floor

Electrical requirements: 120V, 20 Amp, 60 Hz – dedicated circuit terminated in 20-amp hospital GFCI double wall receptacle

Water supply: Regulated to 30-35 PSI using a watts 263A with a pressure gauge. 1 gpm at 30 PSI minimum. Cold water.

Drain: 1-1/2" drain pipe no more than 18" above the floor. A special drain connection fitting is provided in the starter kit.

Metrics

TEEClean was developed as a solution to combat the issues surrounding the manual cleaning of TEE probes prior to high-level disinfection. 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. 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 (<6.4$\mu g/cm^2$ 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 cleaning[7]. 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 reprocessed[6]. 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 step[8]. Many of the errors made occurred during the manual cleaning stage and drying after reprocessing. Clinic cleaning times provide further support for suboptimal manual cleaning conditions in the clinic. In the study comparing manual with automated cleaning methods discussed above, scientists spent an average of 14-25 minutes manually cleaning probes, whereas the average time spent cleaning endoscopes in a clinic is about 4-7 minutes[7]. This supports the notion that manual cleaning procedures completed in clinics may not be as stringent as those in a

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.

laboratory environment. There are many reasons why manual cleaning procedures remain suboptimal in clinical settings, one of which is that clinic staff report pain and physical discomfort associated with the tedium of manual reprocessing of endocavity probes and endoscopes[8]. This physical toll of manual cleaning can lead to steps being shortened or skipped entirely, particularly if staff are required to perform multiple reprocessing procedures sequentially.

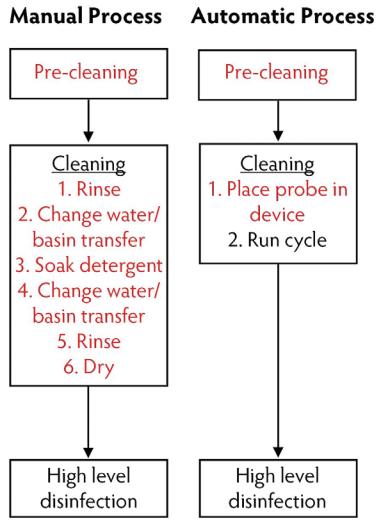
Reprocessing procedures can vary between and within healthcare facilities. 92% of infection prevention professionals report wanting to standardize processes for reprocessing ultrasound probes in their facilities[9]. The variability in cleaning between probe types also plays a factor and adds to the challenge. Some probes, with the aid of adaptors, can be completely submerged, while others, like TEE probes, cannot be completely submerged. These nuances between probes increases the stress and complexity of manual cleaning. Whether protocols differ by department, staff, probe manufacturer, or the infection status of the patient, the 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 an efficient manner to ensure an instrument is available for use. 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 reprocessed[10]. Time constraints could increase the chance that steps are skipped in the reprocessing procedure and instruments are not properly cleaned before disinfection.

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/point-of-use 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. Additionally, 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. Automated cleaning takes 7-10 minutes, 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.

TEEClean eliminates the potential of an ineffectively cleaned TEE probe being high-level disinfected. Once all the necessary information has been entered into TEEClean, the healthcare technician can walk away and allow the microprocessor-controlled device to begin the process of cleaning, disinfecting, and rinsing the inserted soiled TEE probe without any additional interaction. For traceability purposes and ease of use for end users, TEEClean uses a barcode scanner or manual entry to enter in the TEE probe identifier, user identifier, disinfectant lot number, electrical leak test results, for each cycle. This data is included on the printed verification report at the end of each cycle, and is also stored on the TEEClean. The data can be exported to PDF or Excel from the TEEClean via a provided USB.

Practice changes



Automatic cleaning reduces the number and complexity of steps that must be physically performed by staff (highlighted in red) during the cleaning procedure.

Note:
This flowchart is for illustrative purposes only and is not meant to be used as a guide for proper cleaning and reprocessing procedures.

After the installation of TEEClean, users will simply insert a TEE probe that has been bedside cleaned/point-of-use cleaned, (such as with an enzymatic sponge) into TEEClean and follow the on-screen prompts. Once the end user ID, probe ID, HLD lot number information has been logged into the

TEEClean and electrical leak testing performed, the end user can walk away and allow the microprocessor-controlled device to begin the process of cleaning, disinfecting, and rinsing the inserted soiled TEE probe without any additional interaction. At the end of the cycle TEEClean will provide a printed verification report confirming successful cleaning and high-level disinfection of the TEE probe. TEEClean simplifies the cleaning process, provides a standardized operating procedure and removes the confusion and physical burden of manual cleaning.

Implementation

Implementation of the TEEClean in a healthcare facility requires about a 2.5' x 1.5' of floor and wall space for the TEEClean itself, and then the site requirements are minimal and just require clean water supply, electricity and a drain. Usually, this equipment is installed in the Medical Device Reprocessing Department of a hospital. If the location already has a TD100, the setup is practically "plug and play". Phoenix Airmid Biomedical will assist the site with these basic pre-installation requirements and will be responsible for the installation of the TEEClean and end-user training. Regular maintenance is limited to the replacement of the enzymatic solution and water filters. Annual maintenance includes the replacement of the main vapour management filter and validation that the TEEClean is performing optimally.

Narrative

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. Thus, there is a critical need to address these issues and automated cleaning procedures seem to be the solution. 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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Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet

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Background: Automated drying may help prevent endoscopically transmitted infections. We aimed to assess the efficacy of an automated drying and storage cabinet compared to a standard storage cabinet in achieving endoscope dryness post-reprocessing and in reducing the risk of microbial growth.

Methods: Drying times of bronchoscopes, colonoscopes, and duodenoscopes using two drying platforms (an automated drying and storage cabinet vs a standard storage cabinet) were measured using cobalt chloride paper. Drying assessments occurred at: 30 minutes, 1 hour, 2 hours, 3 hours, and 24 hours. A simple linear regression analysis compared rates of microbial growth after inoculation with Pseudomonas aeruginosa following high-level disinfection at: 0, 3 hours, 12 hours, 24 hours, and 48 hours.

Results: Using the automated drying and storage cabinet, internal channels were dry at 1 hour and external surfaces at 3 hours in all endoscopes. With the standard storage cabinet, there was residual internal fluid at 24 hours, whereas external surfaces were dry at 24 hours. For bronchoscopes, colonoscopes, and duodenoscopes, the standard cabinet allowed for an average rate of colony forming unit growth of 8.1 £ 106 per hour, 8.3 £ 106 per hour, and 7.0 £107 per hour, respectively; the automated cabinet resulted in colony forming unit growth at an average rate of −28.4 per hour (P = .02), −38.5 per hour (P = .01), and −200.2 per hour (P = .02), respectively.

Conclusions: An automated cabinet is advantageous for rapid drying of endoscope surfaces and in reducing the risk of microbial growth post-reprocessing.

Approximately 54 million Americans visited healthcare providers in 2015 for management of gastrointestinal diseases [1]. Flexible endoscopy is often performed to diagnose and manage patients presenting with various gastrointestinal issues. With an increasing burden of digestive diseases in the United States, there has been a rise in the use of endoscopy with over 20 million procedures being performed annually [2].

The overall risk of patient-to-patient transmission of infection via endoscopy is exceedingly low. However, in the last decade, numerous centers around the world have reported endoscopically transmitted outbreaks of waterborne and multidrug resistant organisms [3-8]. A particular concern is that many of these outbreaks appear to have occurred despite strict adherence to endoscope reprocessing guidelines [9]. To address these concerns, in 2016, a multi-society statement provided recommendations on how to standardize endoscope reprocessing and decrease transmission of endoscope-mediated infections between patients. Recommended steps included point-of-use precleaning, pressure and leak testing, meticulous manual cleaning, visual inspection, manual and automated high-level disinfection (HLD), adequate drying, and appropriate hanging and storage [10].

Although several studies have focused on improving the performance of HLD, few have focused on assessing and enhancing the drying process [11-16]. The importance of this critical step in endoscope reprocessing should not be understated. Thaker *et al* [17] demonstrated that the instrument channels of endoscopes stored vertically overnight contained moisture 28% of the time compared to 0% of endoscopes that underwent vertical storage along with forced air drying. All endoscopes in this study had undergone extensive precleaning and automated HLD [17]. Barakat *et al* [18] reported similar findings with residual moisture noted in 43% of endoscopes after reprocessing and drying. Likewise, Ofstead *et al* [19] demonstrated residual fluid and debris in 95% of endoscope channels after HLD and drying with automated endoscopic reprocessors (AERs). Remnant fluid within endoscope channels poses a significant risk to successful endoscope reprocessing as moisture within these channels provides an ideal milieu for bacteria to organize and form biofilms. These biofilms have been identified within the channels of endoscopes despite intense decontamination [20]. However, although adequate drying is recognized as an essential step in endoscope reprocessing, there is no consensus on the most efficient method to achieve this aim [21-24].

An automated drying and storage cabinet that allows for the constant flow of compressed air (additionally filtered through a 0.01micron filter) through each individual endoscope channel may effectively automate the drying step in endoscope reprocessing. By directly connecting to each channel of the endoscope, constant airflow may remove

remnant fluid and potentially reduce the risk of subsequent bacterial growth and biofilm formation. In this study, we compared the performance of a standard reprocessing drying cabinet to a new drying and storage cabinet that provides automated drying with forced filtered air in eradicating moisture, which may reduce the risk of microbial growth.

Methods

Drying times and microbial levels of endoscopes stored in an automated drying and storage cabinet with forced filtered air (ENDODRY Drying and Storage Cabinet, Medivators, Minneapolis, MN) were compared to a standard storage cabinet (Olympus Corporation, Tokyo, Japan) without forced filtered air.

Drying and storage cabinets

Automated drying and storage cabinet

An automated drying and storage cabinet allows constant flow of compressed air to a specified purity class with respect to particles, humidity, and oil. This compressed air then passes through a 0.01micron filter for additional filtration before it progresses through each endoscope channel with direct connections to endoscope channels. In addition to the constant flow of compressed high-efficiency particulate air (HEPA), the endoscopes are placed in a cassette system, using the AER hookups that allows endoscopes to dry and store horizontally. The cabinet also has circulating air within the cabinet that intends to enhance the drying of the external surfaces of the endoscopes. The automated drying and storage cabinet will henceforth be referred to as the automated cabinet.

Standard storage cabinet

A standard storage cabinet without compressed or HEPA was used as the comparator because this is the current standard used in the United States. This cabinet provides no direct airflow through the endoscope channels or any airflow over the external surfaces. The endoscopes hang in the vertical position, which is believed to facilitate drying via gravity-aided drainage of fluid. To store the endoscope in this cabinet, all detachable components are removed. This cabinet will henceforth be referred to as standard cabinet.

Endoscopes

For this study, a total of three bronchoscopes (Olympus BF-3C20), three colonoscopes (Olympus CF-Q160AL), and three duodenoscopes (Olympus TJF-160F) were used. All endoscopes that are part of this study are the property of Cantel Medical (Minneapolis, MN). These instruments are representative of devices used in the clinical environment. All endoscopes were inspected on a regular basis and were repaired as necessary to maintain equivalence to original equipment manufacturer specifications. Rigorous inspection, including leak testing was conducted prior to each experiment to ensure consistency of results.

In between experiments, each endoscope was connected to the appropriate hookup and underwent a full cycle in the automated endoscope reprocessor (Advantage Plus, Medivators, Minneapolis, MN). The cycle in this AER begins with a leak test of the endoscope. Once the leak test has passed, water fills the basin and circulates through the spray head and hookup until the correct temperature has been reached. Next, detergent (Intercept; Medivators), is introduced into the basin and circulates for 3 minutes. Water is then rinsed through the endoscope to remove any residual detergent. The basin is filled with water again and the disinfectant solution (Rapicide PA; Medivators) is then introduced and circulates through the endoscope. The safety control unit makes sure that the contact time of 5 minutes is always met. The disinfectant is then rinsed out of the endoscope. Finally, the channels are purged with air and the cycle is complete. The parameter sets selected for this study did not include alcohol at the end of the cycle. The alcohol flush was not performed to simulate worst case scenarios for the drying study taking into consideration that the alcohol flush is not used across Europe. For the microbial part, the alcohol flush was eliminated to prevent microbial suppression of the inoculum due to alcohol residue in the endoscopes. The manual cleaning was not performed because the Advantage Plus has a cleaning claim in the United States, which provides the option to eliminate the manual cleaning of endoscopes prior to the AER cycle.

Drying study protocol

The test was performed according to BS EN 16442:2015 (controlled environment storage cabinet for processed thermolabile endoscopes) [25,26]. A total of six endoscopes: two bronchoscopes, two colonoscopes, and two duodenoscopes, were reprocessed and dried using the two different drying platforms. Each endoscope was connected to the appropriate hookup and underwent a full cycle in the AER. For the automated cabinet, the endoscopes were connected to a dry hookup and placed in a dry cassette before they underwent the determined drying cycle. For the standard cabinet, all the detachable components of the endoscopes were removed prior to being placed in the cabinet. The drying times were: 30 minutes, 1 hour, 2 hours, 3 hours, 24 hours ± 5 minutes. After the appropriate drying period, the endoscopes were removed from the cabinets, disconnected from hookups, if applicable, and were subjected to a cobalt chloride test paper (Indigo Instruments, Waterloo, Ontario, Canada) analysis. Cobalt chloride test paper

analysis is a qualitative analysis in which the cobalt paper changes colour from blue to pink in the presence of liquids. A piece of cobalt chloride test paper was used to wipe down the external surfaces of each endoscope, including all levers, controls, and other crevices. To investigate if any residual water was present in the internal channels, the endoscopes were connected to an appropriate hook up (Medivators DSD AER hookup). A piece of cobalt paper was placed in front of the distal tip at a distance of 50-100 mm, and each individual channel was subjected to an air purge at 15 psi. If water was discharged from the endoscope, the cobalt paper changed colour from blue to pink. Two observers were present during the air purge and the colour change was immediately recorded. Pictures were taken to record the results (Appendix Figure A1-3). Therefore, the endoscopes were considered dry if the colour remained blue and considered wet if any pink marks were detected on the paper.

Repetition

Each time point was tested only one time for each one of the two different drying platforms, resulting in a total of 30 drying cycles.

Controls

To assess the limit of detection for cobalt chloride paper, the endoscopes were dried for at least 48 hours in the automated cabinet, then specific volumes of water were placed inside each of the channel systems of the endoscopes using a micropipette. For each channel, the volumes used were 5, 10, 50, 100, 150, 200, and 250 µL. For the colonoscope and duodenoscope, the water was inserted in the light guide channel outlets, which mark the furthest lengths of the channel to the distal tip. For the bronchoscope, it was placed in the suction valve opening at the control head. The endoscopes were connected to appropriate Medivators DSD AER hookups, a piece of cobalt paper was placed in front of the distal tip at a distance of 50-100 mm, and each individual channel was submitted to an air purge at 15 psi. The lowest volume in which the water discharge was observed in the cobalt paper was considered to be the limit of detection for that channel. Two observers were present during the air purge and the colour change in the cobalt paper was recorded.

Microbial study protocol

Growth of *Pseudomonas aeruginosa* culture and inoculum preparation

The bacterial culture was obtained from ATCC, (*P aeruginosa* ATCC 15442; ATCC, Rockville, MD). A working culture was prepared by subculturing directly from defrosted cryovials, 0.1 mL of *P aeruginosa* was inoculated into 150 mL tryptic soy broth (Becton, Dickinson and Company, Franklin Lakes, NJ) and incubated at 37 ± 2°C for two days. Optical density at 550 nm was used to estimate the population of the test organism. The inoculum concentration for duodenoscopes and colonoscopes was approximately 4 £104 colony forming units (CFU)/15 mL and the inoculum concentration for bronchoscopes, due its smaller channel, was approximately 7 £103 CFU/2 mL to reproduce the scenario in which an endoscope would be re-contaminated by microorganisms present in the water used in the final rinsing stage. The *P aeruginosa* culture was diluted per EN 16442 diluent to prepare the inoculums [25]. The inoculums were serially diluted and enumerated through membrane filtration method to confirm the inoculum population. The filters were plated on tryptic soy agar (Becton, Dickinson and Company) and incubated for two days at 37 ± 2°C.

Inoculation of the endoscopes

Before the first inoculation and between trials, the endoscopes underwent HLD cycle in the AER with the appropriate hookup attached. Wearing sterile personal protective equipment, each endoscope was aseptically placed in a covered sterile plastic tub and transferred to a laminar flow hood. Sterile deionized water was flushed through the channels before the inoculation to establish baseline conditions. The total inoculum for duodenoscopes and colonoscopes was 15 µL, distributed into the endoscope channels via the hookup, based on overall volume of the channels: 10 µL for suction/biopsy channel, 4 mL for the air/water, and 1 µL for elevator or auxiliary channel. The bronchoscopes were inoculated with 2 µL of inoculum in the suction/biopsy. Each channel was inoculated separately, in which the distal end of the endoscope was immersed in the tube with the inoculum, and the bacterial suspension was drawn up each channel through the distal end by pulling up through the appropriate hookup port using a sterile catheter syringe. After BS EN 16442:2015 [26], the inoculum remained in the endoscope channels for 30 ± 5 minutes at the ambient temperature before it was manually purged with air using a sterile catheter syringe to remove the excess inoculum. The endoscopes sat at ambient temperatures in the laminar flow hood for 1-1.25 hours before being placed in the cabinets to simulate the time between reprocessing and storage that might occur in a clinical scenario.

For the standard cabinet, the hookups were removed before the endoscopes were placed in this cabinet. For the automated cabinet, the endoscopes were connected to other appropriate hookups and cassettes that had been previously HLD before it was dried and stored in this cabinet. The cabinets were cleaned between each trial with disinfectant wipes to maintain baseline conditions.

Microbial recovery from the endoscopes

At the appropriate storage times of 0 hours, 3 hours, 12 hours, 24 hours, and 48 hours ± 15 minutes, the endoscopes were taken out of the cabinets using sterile personal protective equipment and transferred to a laminar flow hood to be sampled. The endoscopes were connected to the appropriate reusable HLD hookups and valves; the distal end of the endoscope was placed in a sterile wide-mouth bottle. Using a sterile syringe, the air and water channel was flushed with 18-22 mL of sampling solution (EN 16442), followed by 20 mL of air, then 8-12 mL sampling solution with another 20 mL of air. The suction/biopsy channel was flushed with 95-105 mL of sampling solution and 100 mL of air. The biopsy channel was brushed from the control head to the distal tip 6 times using a sterile channel brush. As the brush emerges from the distal tip, the

brush tip was submerged in the sampling solution to remove any additional adherent organisms.

The suction channel was thereafter flushed with 45-55 mL of sampling solution and 100 mL of air. The bottle contents were serially diluted and filtered through 0.22 μm membrane filters and rinsed with two 25-30 mL portions of 0.85% saline solution. The filters were plated on tryptic soy agar (Becton, Dickinson and Company) and incubated for two days at 37 ± 2°C. The time point zero was used to enumerate the microbial population in the scope after the pre-storage procedure. In addition, to evaluate long-term storage conditions for the automated cabinet, a 31-day storage time point was completed following the same procedure only for this cabinet. To assess microbial levels, recovered bacteria at different time points were quantified as CFUs. The total CFU recovered from the endoscopes at different time points after drying (0 hours, 3 hours, 12 hours, 24 hours, 48 hours, and 31 days) was compared using a logarithmic scale.

Repetition

Each time point was tested in duplicates for each 1 of the endoscopes tested. The time points 3 hours, 12 hours, and 24 hours ± 15 minutes were tested in the two different drying platforms, whereas the time point 31 days was tested only in the automated cabinet. The time point 0 hour was tested before the insertion of the scopes in the drying platforms. For all time points mentioned earlier, there was a positive control kept in the counter for each type of endoscope. Therefore, there were a total of 90 tests performed. Three endoscopes of each type were used per time point, two for the duplicates and one as the positive control.

Controls

The suitability of the sampling solution, rinsing solution, and diluent with test organism was tested by performing toxicity tests. The growth medium was tested for sterility through negative controls. Saline and sampling solution also had negative control plates that were filtered and incubated with the sample plates. The microbial air quality of the cabinet was monitored with tryptic soy agar settle plates inside the cabinet for 3 hours with doors closed and incubated for five days at 37 ± 2°C. For each time point, one endoscope of each type was kept on the counter at room temperature for the same time period to demonstrate that the bacteria do not die over time inside of the endoscope.

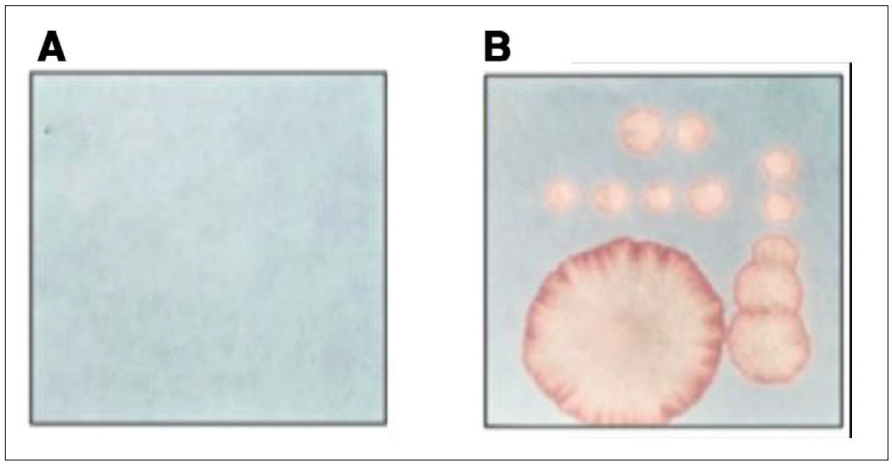

Figure 1: Cobalt chloride paper (A) negative result (B) positive result—small and large water droplets.

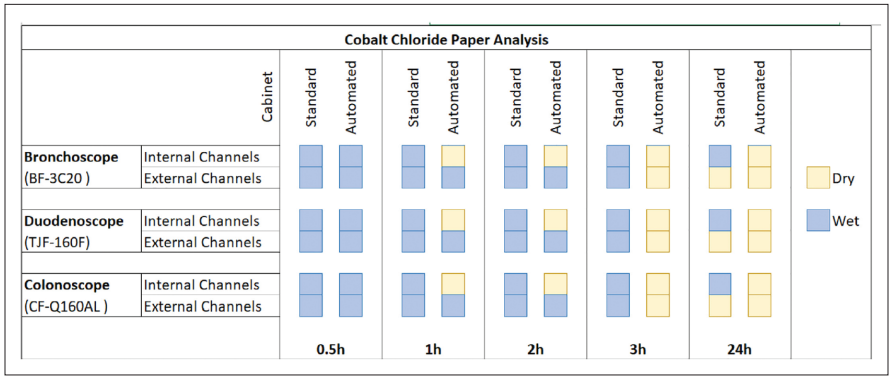

Figure 2: Graphic representation of cobalt chloride paper analysis to assess internal and external channel dryness for bronchoscopes, duodenoscopes, and colonoscopes

Data analysis

To assess microbial levels, recovered bacteria at different time points were quantified as CFUs. The total CFU recovered from the endoscopes at different time points after drying (0 hours, 3 hours, 12 hours, 24 hours, 48 hours) was compared using a logarithmic scale. A simple linear regression analysis compared rates of microbial growth over time. A P value of $<.05$ was considered to be significant.

Results

Drying effectiveness

Drying effectiveness was tested by measuring the drying time necessary to remove all residual water from the external and internal surfaces of the endoscopes. Qualitative assessments of internal and external scope dryness were made using cobalt chloride paper (Figure 1).

For all three types of endoscopes, residual water was not observed on the cobalt chloride paper used to wipe the external surfaces of the endoscopes at 24 hours of drying in the standard cabinet, and at 3 hours of drying in the automated cabinet. Residual water continued to be observed on the cobalt chloride paper used to assess any discharge of water of the internal channels at 24 hours of drying in the standard cabinet and was not observed on the

cobalt chloride paper at 1 hour of drying in the automated cabinet (Figure 2).

The controls showed that the limit of the detection of the cobalt paper for the bronchoscope is 5 μL of water. For the duodenoscope, the limit of detection is 250, 100, and 50 μL of water for the air water channel, suction biopsy channel, and elevator channel, respectively. For the colonoscope, it is 100, 150, and 10 μL of water for the air water channel, suction biopsy channel, and elevator channel, respectively. Therefore, all endoscopes considered dry could have retained values equal to or less than levels of water established as limits of detection for each channel.

Microbial assessment

The differences between microbial levels after drying in the standard cabinet compared to the automated cabinet are demonstrated in Figure 3. After 48 hours of drying, compared to the standard cabinet, the automated cabinet resulted in 8 log, 7 log, and 9 log fewer recovered organisms for bronchoscopes, colonoscopes, and duodenoscopes, respectively.

For bronchoscopes, colonoscopes, and duodenoscopes, the standard cabinet allowed for an average rate of CFU growth of 8.1£10^6 per hour, 8.3£10^6 per hour, and 7.0£10^7 per hour, respectively; the automated cabinet resulted in CFU growth at an average rate of −28.4 per hour (P = .02),−38.5perhour (P = .01), −200.2perhour (P = .02),respectively.

Long-term storage and microbial assessment

The automated cabinet resulted in low microbial levels after long-term storage of 31 days in all three endoscopes types. There were no microorganisms recovered from the colonoscope and from the bronchoscope after 31 days of storage; these scopes had been inoculated with approximately 4.77£ 10^4 and 7.88 £10^3 CFU of *P aeruginosa*, respectively. The duodenoscope was inoculated with approximately 4.11 £104 CFU, and only one CFU was recovered after 31 days of storage in the automated cabinet.

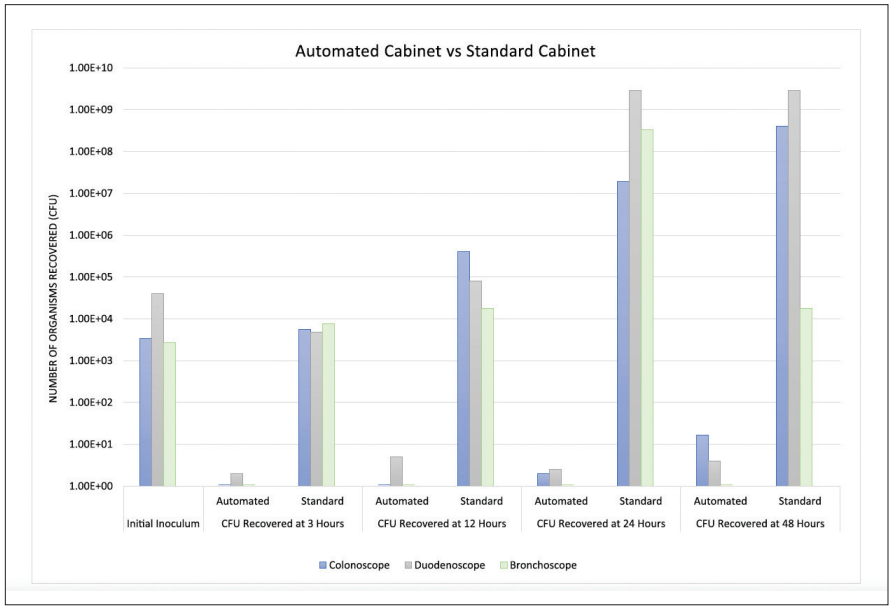

Figure 3: Bar graph demonstrating the number of organisms recovered from bronchoscopes, colonoscopes, and duodenoscopes that were inoculated with *Pseudomonas aeruginosa* prior to drying and storage using the automated and the standard cabinets. *CFU*, colony forming unit.

Discussion

In this study, an automated cabinet was found to be superior to a standard cabinet in its ability to dry the internal channels and external surfaces of three types of commonly used endoscopes. Based on cobalt chloride test paper analysis, the automated cabinet facilitated drying of internal channels at 1 hour and external surfaces at 3 hours; endoscopes stored in the standard cabinet still had internal fluid at 24 hours of drying. Furthermore, this cabinet was only able to dry the external surfaces of the endoscopes at 24 hours. This difference in the drying time of internal channels is important in clinical practice. Although external surfaces can be dried expediently with manual wiping, internal channels pose a challenge. In addition, comparing the automated cabinet to the standard cabinet in microbial burden of contaminated endoscopes, the automated cabinet demonstrated lower microbial levels at all time points. Finally, our study demonstrates that the automated cabinet resulted in low microbial levels after long-term storage at 31 days.

With the emergence of endoscope-related waterborne and multidrug-resistant infections despite reported adherence to manufacturer guidelines, there has been intense scrutiny of the many steps involved in endoscope reprocessing [3-8]. With this attention in addition to prior research on this topic [11-16], it has become clear that residual moisture after HLD of endoscopes may result in bacterial proliferation and biofilm formation [13,20]. Lack of adequate drying during endoscope reprocessing and endoscope storage have been identified as key issues with the existing standard for endoscope reprocessing [21]. Our study confirms the role of moisture in facilitating bacterial growth and demonstrates that an automated cabinet may aid in remedying these issues.

Endoscope drying can be performed manually, within AERs [16], or in automated cabinets. Manual drying is limited by human error.

Although AERs may have an optional short drying cycle, they are typically inadequate for attaining complete drying. Ofstead *et al* [19] demonstrated residual fluid and debris in 95% of endoscopes and microbial growth in 60% of endoscopes within inner channels after HLD and drying with AERs during a seven-month longitudinal study. In contrast, automated cabinets, now recommended by some guidelines [27,28], force HEPA for a prolonged period of time through endoscope inner channels and store endoscopes in an enclosed environment. Residual fluid is present in nearly half of endoscope

working channels after 24-48 hours of standard nonventilated storage [17], which is a sufficient timeframe for biofilm formation. Nevertheless, a survey of 249 centres revealed that not even half performed drying with forced filtered air, despite its established importance in optimal reprocessing [17].

For decades, failures in endoscope reprocessing were attributed to human error resulting in breaches of existing reprocessing protocols. It is becoming increasingly apparent that although human error can play a role, existing protocols for endoscope reprocessing may also be insufficient [29]. Scrutiny in the wake of highly publicized endoscope-related infections has revealed the potential for reprocessed endoscopes to remain contaminated, to some extent, on a detailed evaluation [3-8]. If moisture remains after endoscope reprocessing, recolonization with bacteria during endoscope storage can occur [21]. Without the drying step in endoscope reprocessing, fluid may reside within endoscopes for days [17]. As there is a paucity of data regarding the optimal method and duration of drying post-HLD in endoscope reprocessing, validating new drying techniques is essential.

In this study, we highlight the efficiency and efficacy of automated drying with forced filtered air to achieve endoscope dryness and reduce risk of microbial growth. Our study demonstrates that filtering of air used for drying, along with direct hookups to endoscope inner channels, may be critical in reducing endoscope recolonization with pathogens. Duodenoscopes have the most complex design due to elevator channels and large channel diameter, and there are known challenges associated with duodenoscope reprocessing that have contributed to endoscope-mediated multidrug-resistant infections. In this study, the automated cabinet maintained markedly lower bioburden compared to the standard cabinet even in duodenoscopes. Bronchoscopes dried and stored in the automated cabinet, despite narrow channels that may be challenging to clean and dry, showed no presence of test organism at all time points. Colonoscopes, which present a different challenge with the longest channel length, also showed comparatively low microbial presence at all time points when stored in the automated cabinet.

Our study has multiple strengths. First, our study directly examined bioburden by sampling microbial cultures, rather than using a surrogate marker such as adenosine triphosphate bioluminescence [16]. Positive and negative controls validate the efficiency of our culturing methods and ensure absence of external contamination. Furthermore, three types of commonly used endoscopes were studied in our investigation, including duodenoscopes, which have been implicated in the transmission of multidrug-resistant infections between patients. The three endoscopes were selected for worst case scenarios: owing to their small caliber (bronchoscope), long channel configuration (colonoscope), or large channel diameter with elevator mechanism (duodenoscope). These characteristics make these devices the most challenging endoscopes to reprocess in terms of drying. In addition, the choice of *P aeruginosa*, a waterborne organism, as this agent is among the most common organisms to contaminate stored endoscopes [6-8]. Finally, the demonstration of low bioburden using the automated cabinet at 31 days after inoculation suggests that unused endoscopes may be stored with reduced risk of microbial growth for extended periods of time. Because it is currently routine practice at many institutions to repeat reprocessing of unused endoscopes even after one week of storage, the automated cabinet may transform clinical practice by reducing unnecessary reprocessing cycles and associated costs.

There are several important limitations to this study. First, the small sample size of endoscopes studied limits our capacity to stratify the efficacy of our drying method by degree of endoscope wear-and-tear, which may impact the quality of drying and microbial condition. Secondly, the dryness evaluation and culture acquisition were not blinded. However, we posit that cobalt chloride testing is an objective method to ascertain endoscope dryness. Moreover, although our test organism, *P aeruginosa*, is a commonly encountered nosocomial waterborne bacteria, its growth characteristics may not be entirely generalizable to the numerous bacterial agents that could potentially contaminate endoscopes. In addition, the efficacy of the drying process may not overcome endoscopes that have pre-existing biofilm formation. Furthermore, to allow for precise inoculation of bacteria, our experiments were not conducted on endoscopes that are actively being used in humans and therefore do not simulate a clinical scenario. Finally, direct visualization of moisture within endoscope working channels via a borescope was not performed.

Additional investigation is warranted to examine the impact of automated cabinets on reducing microbial burden in the setting of existing biofilms [25]. Future studies should examine a wider range of endoscope types and microbial pathogens. Nonetheless, we believe that our data represents a significant step forward in delineating the efficacy and adequacy of automated cabinets in accomplishing endoscope drying that may reduce the risk of microbial growth.

Conclusions

To our knowledge, our study is the first in the United States to demonstrate that an automated cabinet with forced filtered air efficiently and efficaciously eliminates residual endoscope moisture that can lead to microbial growth. This process advances us beyond the current standard of care in endoscope reprocessing, which involves either manual drying or limited drying with AERs followed by vertical hanging [10]. Moreover, vertical hanging, which is a current multi-society recommended reprocessing step [10], may become obsolete because of the compact horizontal storage provided by automated cabinets that also can more adequately reduce the risk of recolonization with waterborne pathogens, as demonstrated in this study. Finally, automated cabinets may allow for extended storage that may reduce unnecessary reprocessing cycles and associated costs.

Supplementary Materials

Supplementary material associated with this article can be found in the online version at *https://doi.org/10.1016/j.ajic.2019.02.016*.

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- Inform corrective and preventive actions
- Drive continuous quality improvement
- Standardized audit methodology assures effective auditing with appropriate outcomes

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POSITION STATEMENT

Cleaning and Disinfection of Non-critical Multi-use Equipment and Devices in Community Settings

The full text of this document can be found at *https://ipac-canada.org/position-statements-practice-recommendations*.

This document was developed by IPAC Canada based on best available evidence at the time of publication to provide advice to Infection Prevention and Control Professionals. The application and use of this document are the responsibility of the user. IPAC Canada assumes no liability resulting from any such application or use.

Background

Multi-use equipment and medical devices in health care have been linked to an increased infection risk [1,2]. Cleaning and disinfecting of non-critical equipment in the community between clients, or even on a regular basis, has not been well practiced [3,4]. Outbreaks related to lapses in infection control procedures have been associated with physician offices and clinics [5].

This position statement does not apply to equipment and devices deemed to be semi-critical (requiring high-level disinfection) or critical (requiring sterilization) according to Spaulding's classification [6-8]. Non-critical equipment/devices are defined by Spaulding's classification as equipment/devices that touch only intact skin and not mucous membranes, or do not directly touch the client [6-8].

Position Statement

Each community health care organization has the responsibility to identify non-critical equipment used in the delivery of care and to ascertain the appropriate cleaning and disinfection method and frequency. Written policies and procedures should be in place and reviewed annually. Multi-use equipment and devices should not be purchased until it is confirmed that they can be cleaned and/or disinfected using established modes and products. As well, audits of cleaning and disinfection practices and the implementation of a quality improvement process related to the audit results are important. It is essential to clean and disinfect non-critical multi-use equipment and devices appropriately, safely, and consistently using an approved low-level disinfectant which must have a Health Canada Drug Information Number (DIN), following manufacturer's safety label guidelines, and considering Occupational Health and Safety [6-15].

Glossary

Low-level disinfectant: Disinfectants that kill most vegetative bacteria (e.g., MRSA) and some fungi as well as enveloped (lipid) viruses (e.g., hepatitis B, C, hantavirus, and HIV). Low level disinfectants do not kill mycobacteria (e.g., TB) or bacterial spores (e.g., *C. difficile*) and they must have a Health Canada Drug Information Number (DIN).

Participants in Development of Position Statement

This position statement was developed by the Community Health Interest Group and reviewed and updated in collaboration with Standards and Guidelines Committee.

Chair/Contact: Madeleine Ashcroft / Catherine Richards

Principal Authors: Risa Cashmore, Shelley Sing, Wendy Runge

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POSITION STATEMENT

Reprocessing of Critical and Semi Critical Devices in Community Healthcare Settings

The full text of this document can be found at *https://ipac-canada.org/position-statements-practice-recommendations*.

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Background

Reprocessing of critical and semi-critical medical equipment/devices [1] in community healthcare settings, when not performed according to current standards [2], has been linked with healthcare-associated infections and outbreaks [3-15]. The purpose of this document is to provide infection prevention and control (IPAC) recommendations for the management and reprocessing of critical and semi-critical medical equipment/devices used in community healthcare settings so that consistent reprocessing standards are applied in all healthcare settings. This includes cleaning, disinfection, sterilization, and storage. This position statement does not address the cleaning and disinfection of endoscopes.

Position Statement

Clients expect and require safe care regardless of where the procedure is performed and standards of reprocessing shall be met in any setting where it is carried out.

All employers and healthcare providers are responsible to:

Adhere to best practices and standards for reprocessing when using any semi-critical and critical equipment/devices during provision of care [2,16].

Comply with standards for transportation and storage of reprocessed medical equipment/devices and Transportation of Dangerous Goods Act requirements on transportation of soiled equipment/devices [2,17-19,20].

Have written procedures based on current standards [2,19].

Ensure individuals who clean, disinfect or sterilize reusable medical equipment/devices are educated, trained, and have competency assessments to meet the national and provincial guidelines. This training shall be documented and reviewed yearly and when there are updates [2,16,18].

As a minimum, have sufficient medical equipment/devices/kits available to accommodate daily client needs.

Have a documented process for recall of medical equipment/devices in the event of reprocessing failure [2].

Follow IPAC and Occupational Health and Safety guidelines, such as Routine Practices and Additional Precautions, personal protective equipment, safe sharps management, hand hygiene, disposal of high-level disinfectants (HLD), and procedures for staff exposures that occur during reprocessing [2].

Reprocessing critical and semi-critical medical equipment/devices (including loaned, leased or borrowed medical equipment/ devices) shall be in accordance with Spaulding's classification1, meet manufacturers' instructions for use (MIFU) and current national guidelines (i.e., Canadian Standards Association (CSA) [2], the Public Health Agency of Canada [PHAC/ Health Canada]), and provincial standards [17,21], including specialized staffing, auditing [22], and dedicated space). If there is a disagreement between the MIFU and published guidelines, the more stringent level shall be used [2].

Prior to purchasing medical equipment/devices:

The employer and health care provider shall determine that the recommended reprocessing methods, as validated by the manufacturer, meet current recommended standards and the reprocessing methods can be met by those responsible for reprocessing.

The employer and healthcare provider shall determine if it can be cleaned/ reprocessed according to MIFU. Items that cannot be cleaned/reprocessed according to the MIFU shall not be purchased. If already purchased, the item shall be replaced or be designated single-use.

Medical equipment/devices that are labelled as single-use by the manufacturer have not been validated to be reprocessed therefore these devices shall be disposed of after use. All needles and all syringes are single use only and shall be discarded after one use [2,16,17].

Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor. There are reprocessors in the USA licensed by the United States Food and Drug Administration [2] but none currently based in Canada. Third party reprocessors must also be licensed in Canada [23].

"Noncritical and semi-critical medical equipment/devices that are owned by the client; reused by that client and used only by that client in their home;

and not used for another purpose, do not require disinfection between uses, provided that they are adequately cleaned and stored dry between uses." [16] Examples include respiratory equipment and lancet holding devices.

All semi-critical equipment/devices that can be sterilized, will be sterilized according to the MIFU. If a semi-critical device cannot be sterilized, then it shall, at a minimum, be high-level disinfected according to the MIFU between patient uses [2] (e.g., trans-vaginal probe).

Note: In some jurisdictions (e.g., Ontario), high level disinfection is not permitted in dentistry. Semi-critical reusable dental instruments that contact the mucous membranes or non-intact skin (e.g., mouth mirrors, amalgam condensers, reusable impression trays, handpieces,) shall be cleaned followed by sterilization [24].

The use of liquid chemicals for sterilization of instruments is not recommended for critical medical equipment/devices that are used for sterile procedures due to the limitations in maintaining sterility to point of use. "Devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant to maintain sterility following processing and during storage." [19]

Immediate-Use Steam Sterilization (IUSS, formerly referred to as flash sterilization) is not recommended except where there is an urgent, unplanned need, with no other options available.

Glass bead sterilizer, microwave oven, boiling, chemiclave, and ultraviolet irradiation are unacceptable as means of sterilization [16].

Option 1: Use single-use disposable equipment/devices and discard after use [2,19] .

Option 2: Reusable critical and semi-critical medical equipment/devices reprocessed using the contracted services of a Medical Device Reprocessing Department (MDRD) such as a hospital or private service-provider. The employer and health care provider are responsible to verify the MDRD meets current CSA standards (e.g., sterilization verification documents provided upon request, and documentation to demonstrate reprocessor technician training) [2]. Accreditation Canada states: "Preferably, medical device reprocessing (MDR) is done through a centralized system that provides reprocessing services to multiple areas within the organization. From a safety and cost-effectiveness perspective, centralizing reprocessing services is preferred to replicating them in several areas of the organization. If reprocessing services are decentralized, they are held to the same standards as the MDR department." [18]

Option 3: The health care provider and/or organization chooses to reprocess reusable equipment/devices themselves. The current pertinent CSA standards shall be followed for reprocessing practices. If there is sufficient capacity to reprocess the critical and semi critical medical equipment/devices to meet current CSA standards, then the reprocessing may occur on the site.

In addition to #1-10 above, the employer and health care provider must follow quality assurance recommendations:

Monitor and document physical, chemical and biological indicators, for all sterilizers following MIFU [2].

Monitor and document high level disinfectants (e.g., minimum effective concentration, date of dilution/replacement, contact time) following the MIFU.

Incorporate a preventative maintenance schedule according to medical equipment/device MIFUs.

Participants in Development of Position Statement

This position statement was developed by the Reprocessing Interest Group and has been reviewed by the Community Healthcare Interest Group
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Principal Authors: Clare Barry, Cara Wilkie, Anne Augustin, Brenda Dewar, Donna Perron, Fiona Mattrasingh, Nicki Gill, Merlee Steele Rodway, Andrea Neil

Cross References:

Cleaning and Disinfection of Non-critical Multi-use Equipment and Devices in Community Settings. IPAC Canada. 2018. Available from https://ipac-canada.org/photos/custom/Members/pdf/17Jan_Cleaning%20NonCrit%20Equip%20Comm%20Position%20Statement_revised_Jan2018_final.pdf

Reprocessing of Critical Foot Care Devices. IPAC Canada. 2019. Available from https://ipac-canada.org/photos/custom/Members/pdf/Position%20Statement%20%20_ReprocessingCriticalFootCare_RevisedJuly2019.pdf

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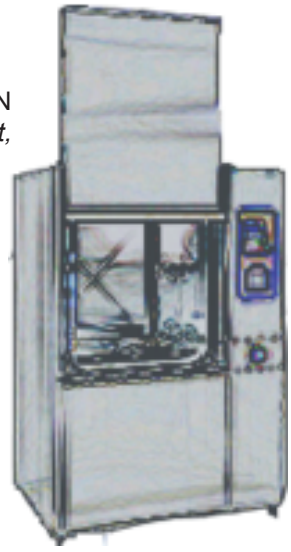

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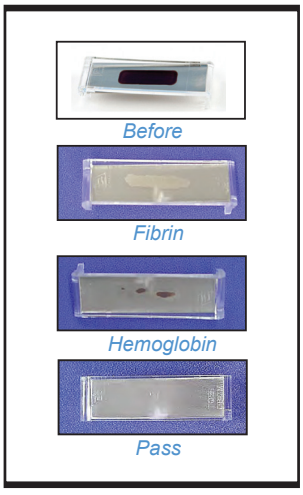

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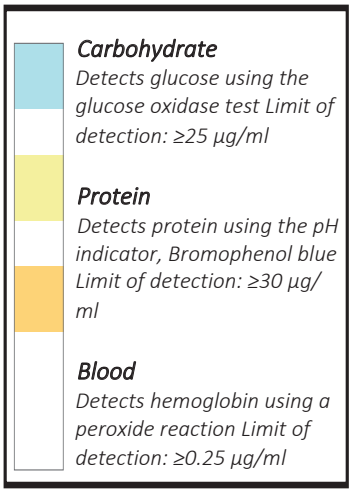

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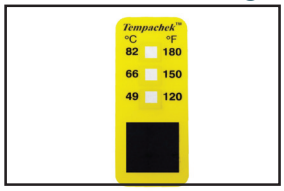

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