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Review

A proposed cleaning classification system for reusable medical devices to complement the Spaulding classification

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SUMMARY

A central tenet in infection prevention is application of the Spaulding classification system for the safe use of medical devices. Initially defined in the 1950s, this system defines devices and surfaces as being critical, semi-critical or non-critical depending on how they will be used on a patient. Different levels of antimicrobial treatment, defined as various levels of disinfection or sterilization, are deemed appropriate to reduce patient risk of infection. However, a focus on microbial inactivation is insufficient to address this concern, which has been particularly highlighted in routine healthcare facility practices, emphasizing the underappreciated importance of cleaning and achieving acceptable levels of cleanliness. A deeper understanding of microbiology has evolved since the 1950s, which has led to re-evaluation of the Spaulding classification along with a commensurate emphasis on achieving appropriate cleaning. Albeit underappreciated, cleaning has always been important as the presence of residual materials on surfaces can interfere with the efficacy of the antimicrobial process to inactivate micro-organisms, as well as other risks to patients including device damage, malfunction and biocompatibility concerns. Unfortunately, this continues to be relevant, as attested by reports in the literature on the occurrence of device-related infections and outbreaks due to failures in processing expectations. This reflects, in part, increasing sophistication in device features and reuse, along with commensurate manufacturer's instructions for use. Consequently, this constitutes the first description and recommendation of a new cleaning classification system to complement use of the traditional Spaulding definitions to help address these modern-day technical and patient risk challenges. This quantitative risk-based classification system highlights the challenge of efficient cleaning based on the complexity of device features present, as an isolated variable impacting cleaning. This cleaning classification can be used in combination with the Spaulding classification to improve communication of cleaning risk of a reusable medical device between manufacturers and healthcare facilities, and improve established cleaning practices. This new cleaning classification system

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will also inform future creation, design thinking and commensurate innovations for the sustainable safe reuse of important medical devices.

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Introduction

The safe use of any medical device always requires collaboration between the manufacturer and the healthcare user. For sterile, single-use medical devices, the product is provided ready for use; however, safety can only be assured when the device is handled correctly during storage and use at the healthcare facility. The requirement for this collaboration becomes even greater with medical devices intended to be processed prior to use or reuse by the healthcare facility. For reusable medical devices, greater responsibility for the mitigation of infection risk lies with the healthcare facility. This transfer of responsibility is communicated through manufacturer's instructions for use (IFU). As described in international standards, the medical device manufacturer must provide detailed processing instructions to ensure that, when followed correctly, the risk of patient infection or other complications is minimized [1–3]. The processing IFU are intended to standardize the quality of the medical device as appropriate to patient use. Product, including microbiological, quality is a qualitative concept that encompasses all activities which provide confidence that a medical device is safe for its intended use, and is more than just a consideration of the presence or absence of micro-organisms potentially remaining on a product. It includes residual chemicals or particulates which may remain on a device following use and processing that may also elicit an immune response in a patient [4].

Earle H. Spaulding defined a classification system to address the microbiological quality of medical devices processed within a healthcare facility in the 1950s [5]. This system needs to evolve in order to respond appropriately to the increasing complexity of reusable medical devices (e.g. endoscopes) since the late 1960s [5]. The Spaulding classification system for medical devices is based on the risk of transmission of infections [1]. This risk is based on the level of contact the device has with the patient. Devices are classified as critical, semi-critical or non-critical [6].

Critical devices include those that contact 'sterile' tissues (including blood and internal body spaces) during their use. Examples include surgical devices. It is recommended that these devices should be adequately cleaned, inspected and sterilized prior to patient use [1,5,7,8]. Semi-critical devices may only contact mucous membranes or non-intact skin. Examples include flexible colonoscopes, gastroscopes and respiratory equipment. It is also recommended that these devices should be adequately cleaned and sterilized prior to use. However, in many cases, they may be subjected to terminal high-level disinfection (HLD) instead of sterilization [1,5,7,8]. The purpose of HLD is to remove pathogens safely, but this may or may not include all dormant micro-organisms such as bacterial spores. Non-critical devices or instruments may contact intact skin but do not penetrate it. Examples include blood pressure cuffs, stethoscopes and skin electrodes (non-critical patient care devices). They also include a variety of equipment and environmental surfaces that may not contact the patient directly, but can become contaminated during use or over time in clinical practice (non-critical environmental surfaces). Recommended processing steps can include cleaning alone or cleaning with disinfection, where the level of disinfection can vary depending on the risk to patient or staff safety, as well as country-specific requirements [1,5,7,8].

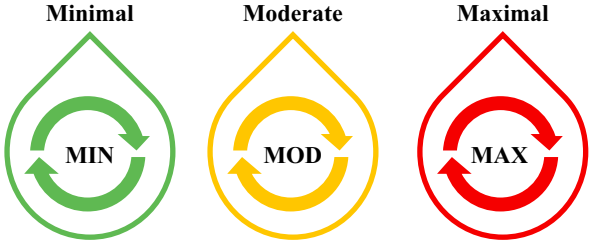

Figure 1. Examples of potential cleaning classification symbols.

The Spaulding classification focuses on the resistance of, and risks with, known micro-organisms (specifically pathogens) in parallel with the criticality of the device in clinical use. Although more information about microbial resistance profiles to inactivation is known today, this classification system, which focuses on use of disinfection and sterilization practices, is just as applicable today as it was when it was developed over 50 years ago [5]. However, criticism on the foundational resistance profiles of micro-organisms to inactivation has shown variability depending on the type of antimicrobial process being employed (especially with chemical disinfectants) [5]. It has been reported previously that exposure to implicit stresses can enable treated micro-organisms to adapt otherwise-lethal biocidal processes, particularly when embedded in complex biofilms [9]. Another topic of debate is the persistence of micro-organisms on environmental surfaces [10]. Despite being 'non-critical' surfaces, the transmission of micro-organisms from these surfaces to patients and staff has highlighted the importance of surface disinfection, particularly with bacterial spores (e.g. *Clostridioides difficile*), meticillin-resistant *Staphylococcus aureus* and, increasing problematic, Gram-negative bacteria (e.g. *Pseudomonas aeruginosa*). In these situations, it is not necessary or practical to ensure that these surfaces are treated with sporicidal disinfectants/sterilants, but does emphasize the importance of physical removal (cleaning). Overall, these examples remind us to remain vigilant in our understanding of microbiology and the potential for unwanted microbial adaptation to frontline therapeutics and disinfection practices. It is rare that reports of failure of the Spaulding classification system have led to patient infections, when applied correctly. Unfortunately, it is more common that reports of device-associated infections and other patient complications with reusable devices/surfaces have arisen due to incorrect processing practices [7]. A review of the literature highlights common examples, such as inadequate device design

or maintenance, poor water quality used at important stages of processing, use of inappropriate processing methods or antimicrobial technologies, and poor environmental controls during storage and handling of devices. Moreover, the most frequent reports appear to be related to failure of adequate cleaning, where a keyword search was completed using 'processing' and 'reusable medical device'. Of the 56 results, 18 were relevant (Table I). It should be noted that an important, yet underappreciated, consideration underpinning the earliest use of Spaulding's classification was that medical devices are clean prior to disinfection or sterilization. This assumption does not take into consideration the increasing number of different medical devices with highly complex device features that are not easy to clean, which reflects the dynamic and evolving needs of modern-day medicine.

Cleaning, defined as the removal of soil to the extent necessary for further processing or for intended use [11], is essential, and it has been demonstrated repeatedly in the literature that cleaning failures are a root cause of failing decontamination of reusable medical devices [5,12]. Many articles over the last 50 years have highlighted the need for more attention on the cleaning process related to medical devices with complex features, with increasing focus on the relationship between cleaning difficulty and hospital-acquired infections (HAIs) [13].

How clean is safe?

At the time the Spaulding classification was widely adopted, the detailed measurement techniques or endpoints for determining cleanliness had yet to be established. Visual cleanliness was the expectation, and the Spaulding classification system was established with the foundational assumption that all devices would be visibly clean prior to the microbial reduction step of disinfection or sterilization. It was assumed that vigorous cleaning would always be performed, and, in many cases, devices (and their associated features) could be inspected quickly during or following the cleaning process. If the device was visibly clean, it was assumed that the residual soil level was sufficiently low to ensure that the antimicrobial process would be effective, even in the presence of some residual soil. In regulatory approval requirements worldwide [39,40], the effectiveness of disinfection or sterilization products/methods was required to demonstrate activity in the presence of residual soil. Microbial reduction studies (i.e. disinfection and sterilization) are typically investigated under laboratory conditions with little (e.g. micro-organism titre with 5% bovine serum) or no soil remaining on the device. The resistance profile of the most resistant micro-organism to the process may change in the presence of soil, depending on soil components, as demonstrated by spore survival studies [32].

Another example centres on the development of complex biofilms in or on device surfaces harbouring problematic micro-organisms, a concept that was not considered initially by Spaulding. Roberts *et al.* described traditional conditions required for biofilms to develop, including the presence of colonizing micro-organisms, surface to be colonized, sufficient nutrients and water, temperature conditions for growth, and time required for development [33]. Micro-organisms harboured in biofilms exhibit reduced metabolism or switch to a dormant state (if endospore formers), and can be protected from the otherwise-lethal action of biocides at typical labelled doses (e.g. chemicals, ultraviolet light) [29]. It is now known that dry biofilms are also a concern with reusable device processing [34]. If biofilms are allowed to develop within a device, the cleaning challenge is increased, as well as limitations to the access of antimicrobial processes for disinfection and even sterilization [33,35,36]. For example, Otter *et al.* [37] reviewed the contribution made by interfering substances in supporting microbial survival (e.g. surface-attached cells and biofilms) on hospital contact surfaces and reducing biocidal efficacy. The authors advocated that new approaches to hospital cleaning and disinfection are required, including the potential use of appropriate novel materials to reduce microbial attachment to surfaces. There is also a commensurate need to elucidate the complex nature and physiology of microbes on dry hospital surfaces, which takes into consideration the prevalence and composition of biofilms and cleaning/disinfection.

There has also been interest in defining the scientific endpoints for cleaning in the last 30 years. Part of this was due to the characterization of proteinaceous infectious particles (prions), and particular emphasis on risks of protein contamination on reusable medical devices in the wake of the bovine spongiform encephalopathy crisis in the UK and other countries [19]. However, in parallel, there continued to be reports of outbreaks and potential patient risks with surgical devices that may not have been cleaned effectively, and the risks of transmission of blood-borne pathogens. It is known from experience that many such episodes occurred but were not published, so the published literature may have underestimated the true extent of the risk to patients. To address the risk of devices not being cleaned effectively, efforts have since been completed at international level to establish cleaning performance requirements during the processing of reusable medical devices and medical device manufacturers/healthcare facilities to establish and monitor the effectiveness of the cleaning instructions. For washer-disinfectors (WDs), the International Standards Organization (ISO) 15883 series was first published in 2006 by an international group of experts [38]. The intention of this standard series was to require WD manufacturers and users to have shared responsibility for the effectiveness of cleaning (and disinfection) of the equipment. However, even at the time of publication, there was no consensus agreement on the definition of 'clean', the acceptable endpoints for a cleaning process, and validation methods to demonstrate cleanliness under laboratory or clinical conditions. The standards at this stage deferred to country-specific guidance that varied widely.

Following initial publication, a concerted effort was made by these committees to gain an internationally harmonized consensus on cleaning requirements. This culminated successfully in the recently published updated versions of ISO 15883-1 and ISO 15883-5. While ISO 15883-1 provides general requirements for all WDs, ISO 15883-5 focuses solely on the cleaning requirements. This includes a two-phase evaluation for cleaning efficacy with performance criteria commensurate to patient safety. The two phases include simulative (type testing) and clinical or typical use conditions (performance qualification). A major consideration in simulative testing is the choice and method of application of test soils to WD loads, chamber walls and load carriers [39]. The test soil is expected to be proteinaceous (unless otherwise justified for the intended use of the equipment), justified based on its relevance to

Table I
Examples of reports of healthcare-associated infections due to lapses in medical device decontamination

Source	Micro-organism(s)/ contaminate involved	Outbreak or infection summary	Patient impact	Device issue
Srinivasan *et al.*, 2003 [14]	*P. aeruginosa*	Outbreak of *P. aeruginosa* associated with lapses in processing best practices including a contaminated, loose biopsy port cap in bronchoscopes. Bronchoscopes were cleaned by trained personnel in accordance with national guidelines and the manufacturer's recommendations (Olympus America). Bronchoscopic and reprocessing procedures were observed during random, unannounced visits. No significant breaches in technique were observed.	A total of 414 patients underwent 665 bronchoscopic procedures during the outbreak. The rate of recovery of *P. aeruginosa* from bronchoalveolar lavage specimens obtained using endoscopy suite bronchoscopes increased from a mean of 10.4% at baseline to 31.0% during the outbreak. There were 48 infections among 39 of the 414 patients (9.4%) in the 2 weeks after bronchoscopy. Based on the authors' definition, exposure to a potentially contaminated bronchoscope may have had a role in the death of three patients, all of whom were critically ill at the time of bronchoscopy.	The contamination appeared to be related to a loose biopsy port cap on the bronchoscopes, which may have sheltered organisms and thus rendered disinfection procedures ineffective.
Muscarella, 2008 [15]	*P. aeruginosa*	Literature review following laryngoscopy and suggestion for increased standardization for manufacturer's processing instructions.	Authors focused on a single case study where 15 infants were infected, with two fatalities [16]. Literature review recommended the use of sterile disposable sheaths to mitigate contamination risk.	Rigid laryngoscopes within the USA are classified as Class 1 devices and are exempt from the Food and Drug Administration oversight. Decontamination instructions, therefore, vary widely from manufacturer to manufacturer. The handle and blade of laryngoscopes have been reported with residual soil.
Cabronne *et al.*, 2010 [17]	*K. pneumoniae*	KPC-producing *K. pneumoniae* type 2 multi-hospital outbreak due to what was suspected to be an ineffectively processed duodenoscope.	Within 6 weeks, 12 patients were identified as having an HAI with the same molecular typing.	The duodenoscope was the only device used commonly among the infected patients. Although culturing of the duodenoscope did not recover the micro-organism, it was suspected that this was due to reprocessing after the contamination, and ineffective cleaning of the channels was the primary cause of the outbreak. The duodenoscope was sent back to the manufacturer for repair, so no additional analysis was completed.
Williams *et al.*, 2010 [18]	*Enterococcus spp.* *S. aureus* *Klebsiella* spp. *Acinetobacter* spp.	Evidence demonstrating HAI risk from lack of decontamination of laryngoscope handles.	Patient-ready laryngoscopes were cultured using a swabbing technique to demonstrate that 86% of the handles were contaminated with one or more species of bacteria.	The design feature of the handle was evaluated, resulting in a higher occurrence of bacteria residing on the knurled surface compared with the smooth surface. When in the closed position, the patient-contacting blade folds against the handle. This study

(*continued on next page*)

Table I (*continued*)

Source	Micro-organism(s)/ contaminate involved	Outbreak or infection summary	Patient impact	Device issue
				confirms that laryngoscope handles can be a vector for transmission of infection.
Kovaleva *et al.*, 2013 [19]	Most commonly: *Salmonella* spp. *P. aeruginosa* Mycobacteria	Literature review of the challenges with flexible endoscopy. This meta-analysis is a comprehensive review of 379 sources evaluating the infection risk from flexible endoscopes.	It is estimated that 6% of patients will experience an HAI due to improper infection control procedures.	Endoscopes have a complex design with internal lumens and multiple channels that are easy to damage and difficult to clean.
Lowman and Venter, 2013 [20]	*Enterobacter* spp. *A. baumannii*	Ineffective decontamination of laryngoscope blades is a source of microbial contamination and patient risk.	A contamination rate of 57.3% in a South African healthcare facility was reported from a total of 110 laryngoscope blades swabbed for micro-organism recovery.	Guidelines within the region specify that laryngoscope blades should be cleaned and disinfected as a semi-critical device. Blades were soaked and scrubbed prior to rinsing and high-level disinfection. The rate of contaminated samples indicates that either the decontamination procedure for the blades is ineffective, or there is contamination from the unprocessed handle or from handling during assembly.
Negri de Sousa *et al.*, 2013 [21]	Non-specific literature review	Literature review of cross-infection risk from laryngoscope blades and handles. 20 studies were evaluated.	Non-specific literature review.	As summarized in this literature review, the laryngoscope is comprised of many pieces that have features of varying complexity, including rows and furrows, that may hinder the decontamination process.
Magill *et al.*, 2014 [22]	*C. difficile*	Additional study by authors to look at multiple facilities (183 hospitals) for the detection of HAIs. Of the 11,282 patients, 4% were identified with an HAI.	Surveys conducted in 183 hospitals found that, out of 11,282 patients, 452 experienced an HAI (4.0%). Device-associated infections accounted for 25.6%.	Device-specific information was not provided in this analysis, but the authors recommend that devices should be reviewed as a vector for infection transmission.
Kola *et al.*, 2015 [23]	*K. pneumoniae*	Investigation of a German outbreak with the root cause being a contaminated duodenoscope.	7 of 13 cases of *K. pneumoniae* in two French hospitals were associated with a contaminated duodenoscope. Extraction of the scope channels was conducted by flushing 100 mL of sterile water through the channel and collecting it for microbial cultures.	Duodenoscopes must be thoroughly dried and reprocessed after a long period of storage. Special handling is required to reduce the contamination risk for duodenoscopes.
Marsh *et al.*, 2015 [24]	*K. pneumoniae*	HAI outbreak investigation with root cause being endoscopes.	Pulsed-field gel electrophoresis and multi-locus sequencing were used to evaluate 43 *K. pneumoniae* patient isolates. Two clusters were recovered from endoscopes.	Authors state that this evidence supports the growing body of literature that endoscopes are a risk for bacterial transmission.
Ofstead *et al.*, 2015 [25]	Protein Total organic carbon Adenosine triphosphate	Monitoring of 60 colonoscopes and gastroscopes in a clinical setting with demonstration of microbial contamination despite compendial processing protocols.	Individual channels were swabbed and extracted using the flush–brush–flush method with 20 mL of water and a 6-mm brush. Samples were collected after each cleaning step (i.e. bedside, manual,	Contamination was reduced with each stage of the reprocessing step. However, patient-ready devices, disinfected and stored, contained microbial contamination. Cleaning of endoscope channels is time-

			disinfected and stored). Of the 60 samples collected, 92% of the scopes cleaned at the bedside, 46% of scopes manually cleaned, 64% of scopes that underwent high-level disinfection and 9% of stored scopes contained micro-organisms.	consuming and can be overlooked in practice. The distal end of duodenoscopes provides a particular challenge for cleaning due to the elevator guidewire. Colonoscopes and gastroscopes have multiple channels, ports and valves that increase the risk of ineffective cleaning.
Davis, 2017 [26]	Non-specific literature review	Compilation of data reporting the rate of bioburden per patient claim records. There is an increasing trend of bioburden prevalence.	Meta-analysis of reported events related to surgical instruments. An increase in incident reporting is evident.	Authors hypothesize that the medical device design, which includes compound hinges, gaps, channels and lumens, can result in bioburden accumulation and subsequent development of biofilm.
Rauwers *et al.*, 2018 [27]	*E. cloacae* *E. coli* *K. pneumoniae*	Dutch study where duodenoscopes within the clinical setting were cultured and demonstrated high levels of bioburden post processing.	73 Dutch ERCP centres submitted duodenoscopes for microbial screening. Samples were collected by flushing the channels with sterile physiological saline. 15% of the duodenoscopes from 39% of the facilities had microbial contamination in a patient-ready state.	Results indicated that a specific design feature on the TJF-Q180V did not allow for adequate cleaning and disinfection. In addition to the design features being a risk factor, the age of the device is also a contributing factor. The brush, forceps elevator and protection cap had the highest occurrence of microbial contamination.
Rahman *et al.*, 2019 [28]	*P. aeruginosa*	Literature review of duodenoscope-associated HAIs due to difficult-to-remove biofilm.	16 publications were included in this literature review from 2000 to 2018 focusing on ERCP-associated outbreaks.	The elevator channel is a key feature that predisposes the duodenoscope to contamination.
Shenoy *et al.*, 2019 [29]	*K. pneumoniae*	HAI investigation with transmission associated with a duodenoscope.	Case study where the transmission of mcr-1-positive *K. pneumoniae* for two patients was caused by a contaminated duodenoscope as the epidemiological link. *K. pneumoniae* was recovered from the biopsy channel and distal tip.	The distal cap defect likely allowed material to penetrate a sealed area that was not accessible for cleaning. Authors advocate increased awareness of duodenoscope design with an emphasis of single-use components.
Ofstead *et al.*, 2020 [30]	Non-specific literature review	Literature review of duodenoscope-related HAIs and discussion around risk mitigation.	Literature review consisting of evidence suggesting the rate of infection is 1 in 1765 or as many as 10% of ERCP procedures.	Reprocessing failures may occur as a result of the complex design that includes elevator mechanisms in the distal end and open wires/channels that are exposed to patient soil. Suction-biopsy channels are also a source of residual contamination.
Okamoto *et al.*, 2022 [31]	*S. aureus* *S. lugdunensis* B-haemolytic streptococcus, *Enterococcus* spp.	US study investigating the contamination rate of duodenoscopes after processing.	859 new-model duodenoscopes (TJF-Q180V) and 850 older model duodenoscopes (TJF-160F/VF) were extracted for microbial contamination using the flush—brush—flush method with sterile water. The detected contamination rate for these patient-ready duodenoscopes was 5.3%.	The authors witnessed reprocessing errors in 27.7% of the procedural reviews, and recommend increased awareness of the processing instructions with ongoing staff training programmes.

P. aeruginosa, Pseudomonas aeruginosa; K. pneumoniae, Klebsiella pneumoniae; S. aureus, Staphylococcus aureus; A. baumannii, Acinetobacter baumannii; C. difficile, Clostridioides difficile; E. cloacae, Enterobacter cloacae; E. coli, Escherichia coli; S. lugdunensis, Staphylococcus lugdunensis; HAI, hospital-acquired infection; ERCP, endoscopic retrograde cholangiopancreatography.

the intended use [40] as protein is the major contaminant detected on reusable devices following clinical use [41]. In addition, the test soil must meet new performance criteria [40,42]. The test method was developed by an interlaboratory collaboration, and based on investigations using coagulating blood as a widely used test soil and protein concentration as the analyte criteria.

The testing conditions in which the WD is challenged are intended to simulate worst-case conditions for the devices expected to be cleaned in the WD. As performance testing is carried out in both a laboratory setting and a clinical setting, the choice of challenge test soil is a critical element of the evaluation. Using the soil validation test method in Annex B of ISO 15883–5:2021 and the soil analyte concentration from the literature [41,43], a comparison of soil performance allows for standardization when assessing both phases of the cleaning efficacy test. In addition to the choice of test soil, the device is expected to be soiled as it would be in normal use. For example, the medical device should be soiled in a manner that is representative of clinical use with actuation, exposure to extreme temperatures (e.g. to simulate cauterization), simulated use of accessory chemicals (e.g. lubricants or other chemicals used during surgery), and drying prior to cleaning. The effectiveness of the method to remove the analyte from the device (i.e. extraction) [44] and the analyte detection method must also be evaluated [45]. WDs can be designed for the cleaning of single or multiple devices with various device features (e.g. lumens or internal moving parts) that can be a challenge to cleaning effectiveness; therefore, representative worst-case loads should be defined for testing purposes. This programme for standardization demonstrates confidence across the supply chain that the WD equipment will perform as expected under worst-case conditions.

In addition to the traditional requirement for visual cleanliness, the ISO 15883 series now defines acceptance criteria for specific analytes when measuring cleaning efficacy. Quantitative, analytical test methods are justified for use based on a risk assessment, with protein detection being highlighted as a recommended analyte. The acceptance criteria for analytes have been defined as both alert and action levels (Table II). Detection levels of analytes below alert levels over multiple test cycles are considered 'clean', but those falling between alert and action levels are to be further investigated as they are considered to be at high risk of failure over time. This was designed to minimize the risk of soil accumulation or periodic, insufficient cleaning during normal use of the WD. These levels have been defined, but the standard does note that country-specific requirements may also need to be considered, such as levels of total protein per device [46] or device side [47].

Table II
Analyte acceptance criteria for cleaning efficacy

Analyte	Alert level	Action level
Protein	$\geq$3 μg/cm^2	$\geq$6.4 μg/cm^2
Total organic carbon	$\geq$6 μg/cm^2	$\geq$12 μg/cm^2
Carbohydrate	$\geq$0.9 μg/cm^2	$\geq$1.8 μg/cm^2
Haemoglobin	$\geq$1 μg/cm^2	$\geq$2.2 μg/cm^2
ATP	$\geq$10 femtomoles ATP/cm^2	$\geq$22 femtomoles ATP/cm^2
Endotoxin	$\geq$2.2 EU/device	$\geq$20 EU/device

Processing residuals are also assessed to evaluate patient impact [48] or an impact on further processing.

The ISO 15883-5 acceptance criteria have also been harmonized in the requirements established recently in the USA for the validation of cleanliness requirement for reusable medical devices [49]. ANSI/AAMI ST98:2022 and the US Food and Drug Administration guidelines detail the conditions in which the processing steps for cleaning must be challenged to mitigate the risk of residuals past the point of visual cleanliness for reusable medical devices [8,49].

The established industry acceptance criteria are supported by the literature, where the primary analyte (i.e. protein) has been evaluated for patient safety [50], and the other analytes have been established as clinically relevant and measurable [51]. The two levels of acceptance criteria provide a level of safety within the test system that accounts for variability in the analyte detection method as well as test system variables that can impact detectability (e.g. sample extraction [44]). A risk assessment allows the appropriate level to be identified to ensure patient safety. For example, if during the cleaning validation medical device manufactures must be below the action level with the most challenging cleaning conditions included in the experimental design, it may be appropriate during verification testing at a healthcare facility to obtain results below the alert level for an extra margin of safety.

Evaluation of risk

ISO 14971 describes the evaluation of risk as being a process of comparing an estimated risk against a risk criteria to determine the acceptability of that risk [52]. The hazardous situations at the healthcare facility leading to the inadequate processing of a reusable medical device can include human factors (e.g. inadequate training) leading to the inability to execute the required cleaning process [13], the time before or during the decontamination process that can lead to increased cleaning challenge [53], available processing equipment, and effective process monitoring practices. The estimated risk for inadequate decontamination is expressed in terms of patient risk for potential infection/biofilm formation, other adverse immune responses (e.g. tissue damage or toxicity reactions from process residuals), or surgical complications/cancellations/delays or device damage. Medical device manufacturers, when developing the IFU, should assess the acceptability of the risk of inadequate cleaning, and mitigate any significant risk by either including device designs with features that are compatible for cleaning, or providing robust instructions that are validated to be reproducible.

It is reasonable to expect that processing instructions will be followed faithfully at the healthcare facility, defined by AAMI ST79 as any 'specialized facility where professionals deliver services utilizing medical devices' [54], using validated equipment that accommodates many decontamination processes. However, this has many challenges, including a wide range of staff training, in-depth knowledge of each device/set of instructions, and the fact that processing instructions can vary significantly between manufacturers. The reality is that sterile or device processing personnel are juggling many products, and handle products the best they can, in established processes that have been put in place for the efficient throughput of their facility [55]. This challenge is compounded when an increasing number of devices with unique processing

instructions are purchased, even though they have many similarities in device complexity. The pressures on equipment and sterile processing departments to meet healthcare needs cannot be underestimated. In these cases, it seems logical to increase throughput and consistency such that groups of devices can be processed together using the same steps and obtain the same endpoints despite the IFU provided [56]. There is currently no global industry guidance for how to adopt devices into such processes using a family grouping strategy. ISO 17664-1 outlines what instructions must be included in the device IFU based upon risk to provide sufficient instructions for device processing [1]. As such, it is left to the discretion of the device manufacturer to identify the level of detail provided. For example, complex devices may have pages of cleaning instructions, whereas simple devices have a single paragraph. It remains the expectation that each IFU will be followed exactly [54], but this is not practical considering the number of devices processed each day.

Standardization efforts to develop decontamination process flows based on device risk have been an initiative of various standard committees over the last 10 years, and some have been deployed based on the geographical region. For example, the US guidance for device manufacturers, AAMI TIR 12 Annex D and E, recommends processing instructions depending on the device category and based on difficulty of cleaning [57]. In Germany, the responsibility shifts to the healthcare facility, with the requirement of a process qualification to validate the cleaning process. The qualification is an assessment of cleaning performance for the processing steps, and will typically use a worst-case device or surrogate device as the process challenge device. There is often a stronger emphasis placed on complete automated processes for cleaning, and the associated requirements for qualification of cleaning processes are described in ISO 15883-1 [39]. However, it is still at the discretion of the healthcare facility to group devices and adopt them into the appropriate processing procedures.

Device manufacturers have a similar barrier in validating each device within a product portfolio that may be comprised of thousands of devices. An efficient approach to this is the identification and use of representative product families, and validation of the worst-case designs with demonstrated commonality in device materials, design features, intended use and clinical soil exposure. Processing instructions must be the same for each device in such product families [1,8,57].

Cleaning classification

When the Spaulding classification was introduced, it provided a necessary framework for manufacturers, regulators and healthcare personnel to consistently deliver an appropriate microbiological reduction for devices. However, when using the Spaulding classification alone, the entirety of the microbiological quality of the reusable medical device is not considered, as the risk to ensure cleaning is not considered in detail. The introduction of a complementary cleaning classification system would allow for effective communication between medical device manufacturers and healthcare facilities on the proper risk mitigation for associated cleaning processes.

For each device design and associated cleaning process, there is a probability of soil retention. This relationship can be quantified to assess risk. This relationship has been well described in the literature [58], and evaluated by standards organizations with the intent to inform medical device manufacturers on the cleaning steps that may need to be included in the cleaning IFU based on the device features. Michels *et al.* described an example based on current validations for reusable medical devices, regarding how they can be grouped based on feature, but did not assess the probability of the risk of soil accumulation based on the feature [59]. AAMI TIR12:2020 Annex D logically describes three device categories based on cleaning processes designated by device complexity. Category 1 devices are simple devices that can be processed using manual or automated cleaning methods. Category 2 devices have features that require human intervention, such as brushing, to remove soil which is difficult to clean. Category 3 devices require sonication to aid in the removal of soil that is not accessible or is difficult to remove using brushing and flushing [57]. The categorization of these groups was completed by evaluating the cleaning IFU for marketed devices, and applying them to the complexity of device features of the medical device. The assumption of this evaluation is that the IFU contains all necessary steps for cleaning the applicable device, but no guidance is given regarding how to assess the device for each category.

A cleaning risk-based approach is proposed that considers the probability of risk for residual soil to remain on or in the various design features of a device following cleaning. For effective cleaning to occur, the cleaning chemistry (cleaning agent and water) must have access to the soil with enough exposure (e.g. spray, soak) or force (e.g. brush, flush, sonication) to solubilize and remove the residual soil for surface removal. The device feature is, therefore, the key variable of a reusable medical device that can influence this relationship. Three categories have been established to describe this risk, and are described in Table III.

The cleaning classification uses device features as the key elements for risk analysis for the device cleaning process. As described previously, the device feature approach provides a more conservative estimate of residual analytes on a reusable medical device, and allows for identification of the most probable location for soil accumulation, and thereby risk to the cleaning process. This approach allows the medical device manufacturer to assess the risk during the development and

Table III
Cleaning classification

Risk category	Description
Maximal	Complex device features with a high probability of soil accumulation with a medical device
Moderate	Accessible device features that require specific intervention (e.g. brushing or flow through lumens, mated surfaces requiring disassembly or opening/closing to ensure access)
Minimal	Low-risk reusable medical devices where all features are exposed without specific intervention for cleaning

validation of the device processing IFU, and to bring the attention of the healthcare personnel to these high-risk areas (e.g. focus on inspection protocol) [60]. Consider a device where the geometry seems simple but, when evaluating the features for the cleaning challenge, the device contains a lumen [the most difficult-to-clean feature [61] with a junction point (i.e. bend)]. If evaluating the entire device during the cleaning validation, the surface area of the whole device may dilute the residual protein concentration from the lumen, and under-report patient risk [59].

For example, if a medical device is used to flush a solution into a patient, the lumened portion of the device is the highest risk feature, as the fluid pathway of the lumen will deposit fluid into the patient whereas the rest of the device is only communicating externally. Although other features within the device may be difficult to clean, if the surface of the lumen has direct contact with the fluid being flushed through it, remaining soil in the lumen is of the highest risk to the patient. Once fluid flows through the lumen, any residual soil solubilized in the fluid pathway and inserted into the patient becomes a major concern. When using the typical recommended method to determine cleaning efficacy, it is typical for the entire surface area of the device (or, in some cases, each side of a device) to be used to calculate the residual concentration compared with the surface area [49]. This method may under-report the concentration of residual soil in the most difficult-to-clean portion of the device, diluting the analyte to below the limit of detection for the test method. However, when using the device feature approach, the most difficult-to-clean area of the medical device is scrutinized for cleanability, and reported against the established acceptance criteria. The device feature approach is therefore the most appropriate and conservative method for a risk assessment.

This cleaning classification is a quantitative risk-based categorization approach utilizing the probability of soil accumulation for the challenging device feature. It can provide guidance to manufacturers to improve the design for cleanability, and how to label the medical device within the IFU to communicate the cleaning risk effectively to healthcare personnel. Examples of associated symbols with a description of the device feature that resulted in the categorization are suggested for inclusion within the IFU (Figure 1). Communication of this information to the healthcare facility can inform the device risk for cleaning, and alert when special considerations for equipment or training are required to ensure effective and consistent processing. Using the medical device example from above, the cleaning classification might be set as 'maximal', leading the manufacturer to require enhanced visual inspection steps (e.g. use of borescope) to assess it for cleanliness and mitigate risk.

Decontamination risk mitigation

Ineffective device processing is a major risk for HAIs and other patient complications. Complex features of devices can make visual inspection and monitoring for cleanliness difficult, thereby increasing the risk of soil accumulation and biofilm development. Medical device manufacturers can use this cleaning classification in conjunction with the Spaulding definitions to assess the risk for the entire decontamination process for reusable medical devices. This can improve cleaning and disinfection/sterilization validation methods, improve device design, and ensure that risks are clearly communicated and mitigated at healthcare facilities. The Spaulding classification provides an easy mechanism to connect manufacturers and healthcare facilities regarding how devices must be validated and processed. By complementing this with a classification to assess the cleaning risk in more detail, the appropriate processing methods can be defined and optimized, thereby further decreasing the risk to patient safety. This combined approach can help safeguard against and tackle the emergence of increasingly recalcitrant microbial pathogens, including drug-resistant fungi [62,63].

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