Communication from the ASGE Technology Committee

STATUS EVALUATION REPORT

Automated endoscope reprocessors

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration [FDA] Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized, controlled trials are lacking. In such instances large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through February 2016 for articles related to automated endoscope reprocessors (AERs), using the words "endoscope reprocessing," "endoscope cleaning," "automated endoscope reprocessors," and "high-level disinfection" (HLD).

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BACKGROUND

Approximately 20 million GI endoscopic procedures are performed annually in the United States.[1] Transmission of infectious agents by endoscopes is considered to be extremely rare, occurring with an estimated frequency of 1 in 1.8 million procedures.[2] However, this infection rate may be an underestimate because of incomplete surveillance, under-reporting, asymptomatic infections, and infections with a long incubation period.[3]

GI endoscopes are semicritical medical devices and require at least HLD after each use.[4] HLD is traditionally defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores.[5] It is operationally defined by the FDA as a 6-log reduction of mycobacteria.[6] To minimize the risk of transmission of infectious agents, standardized guidelines have been developed for the reprocessing of endoscopes.[7-11] The FDA defines reprocessing as validated processes used to render a contaminated medical device fit for a subsequent single use.[12]

Reprocessing of flexible GI endoscopes is a multistage process (Table 1) that begins immediately after completion of an endoscopic procedure. The initial step is "in-room" or bedside precleaning and aspiration of a detergent solution through the suction channel. This is followed by leak testing and then by thorough manual cleaning, with washing and brushing of accessible channels. Subsequently, HLD is performed via immersion for an appropriate duration of time in a liquid chemical germicide of appropriate concentration, followed by a water rinse, alcohol flush, and air drying of all

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TABLE 1. Endoscope reprocessing steps*

Step	Purpose	Can be performed by AER (also see Table 2)
Precleaning	• Begins in the procedure room immediately after procedure and before disconnecting the endoscope from the power source • Precleaning removes bioburden before it has an opportunity to dry	• No
Leak testing	• Detects damage to the interior or exterior of the endoscope • Leak testing is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure	• Yes
Manual cleaning	• Ensures removal of retained bioburden • Retained bioburden may inactivate or interfere with the capability of the HLD solution to effectively kill or inactivate microorganisms	• No*
Rinse after cleaning	• Removes residual debris and detergent	• Yes
Visual inspection	• Ensures the endoscope is visually clean before proceeding to HLD • Manual cleaning and rinse after cleaning should be repeated if visual inspection fails	• No
HLD	• Destroys all viable microorganisms but not necessarily all bacterial spores	• Yes
Rinse after HLD	• Prevents exposure and potential injury of skin and mucous membranes from chemical residue	• Yes
Drying	• Prevents growth of waterborne pathogens	• Yes

AER, automated endoscope reprocessor; *HLD*, high-level disinfection.
*Manual cleaning is required even when AER manufacturers claim that manual cleaning is unnecessary.[8,42]

endoscope channels.[4,9-11] Although all endoscope reprocessing steps can be performed manually, automation of some steps has been shown to be advantageous, is supported by available evidence, and is recommended by some societies.[9,13,14]

TECHNICAL CONSIDERATIONS

AERs are machines designed for the cleaning and HLD of heat-sensitive endoscopes.[10] AERs replace some of the manual steps involved in endoscope reprocessing (Table 1). Early AERs were designed to replace only the HLD step of endoscope reprocessing, but over time additional functions have been added. The FDA classifies AERs as medical devices that require 510(k) clearance.[10,15] FDA-approved AERs available for use in the United States are listed in Table 2.

Endoscopes must undergo thorough manual cleaning before placement within an AER. AERs have basins to allow endoscopes to be submerged and bathed in the HLD solution. The endoscope channels are attached to the AER using special connectors, which allow circulation of HLD solution under pressure through the channels, thus exposing interior channels and outside surfaces of the endoscope to the HLD solution. The AER circulates the HLD solution continuously during the exposure period or cycle time, which typically varies from 22 to 30 minutes. After completion of the HLD cycle, AERs automatically rinse the reprocessed endoscope with water to remove toxic HLD solution residues. Some AERs then flush the endoscope channels with forced air or with 70% to 80% ethyl or isopropyl alcohol followed by forced air to aid in drying the endoscope channels to prevent growth of waterborne pathogenic microorganisms during storage.[11] If AER reprocessing is interrupted at any point, HLD of the device cannot be ensured, and the entire process should be repeated.[8,11]

AERs offer several advantages over manual reprocessing. They automate and standardize several important reprocessing steps, thereby eliminating the possibility of missed steps because of human error, and minimize exposure of endoscopy or sterile processing department personnel to HLDs or chemical sterilants.[5,16-19] A prospective study evaluating the impact of human factors and automation on endoscope reprocessing indicated that use of AERs was associated with increased consistency and compliance with endoscope reprocessing guidelines and inversely associated with skipped steps during reprocessing.[14] Furthermore, use of AERs reduced a number of health problems attributed to reprocessing among personnel involved in HLD.[14] As a result of automation of several reprocessing steps, AERs also reduce work-related repetitive movements that can potentially cause bodily injury.[5,14]

HLD solutions are germicides that eliminate all microorganisms except bacterial spores.[20] HLD solutions can act as sterilants if an increased exposure time is used.[11,20,21] However, the exposure time required to achieve sterilization with most HLD solutions is far longer

TABLE 2. AERs approved for use in the United States

Manufacturer Model	Advanced Sterilization Products EvoTech ECR*	Custom Ultrasonics System 83 Plus	Medivators DSD-201LT*	Medivators DSD Edge*	Medivators Advantage Plus*	Medivators CER Optima*	Olympus OER-PRO*,†	Steris EPS Reliance	Steris System 1E*
Endoscope Compatibility	Most models/ brands	Most models/ brands	All models/brands	All models/brands	All models/brands	All models/brands	Only Olympus endoscopes	Most models/ brands	Most models/ brands
AER Type	High level disinfector	High level disinfector	High level disinfector	High level disinfector	High level disinfector	High level disinfector	High level disinfector	High level disinfector	Liquid chemical sterilizer
Configuration	Floor Standing	Floor standing	Floor Standing	Floor Standing	Floor Standing	Tabletop	Floor Standing	Floor Standing	Tabletop
Disinfectant /Germicide Type	Cidex OPA	ortho-phthalaldehyde 25°C Glutaraldedehyde 25°C	Rapicide or RapicideOPA 28 Rapicide 35°C, Rapicide OPA28 25°C	Rapicide PA	Rapicide PA	Rapicide or Rapicide OPA28 Rapicide 35°C, Cidex OPA28 25°C	Acecide-C or Aldahol 1.8 20°C	Peracetic acid	S40 (Peracetic acid)
Temperature	50°C	Hydrogen Perioxide 20°C		30-40°C	30-40°C			48-50°C	46-50°C
Cycle Time	~30 min	~27 min (depending on disinfectant)	~27 min	~22 min	~22-28 min (depending on endoscope)	~30 min	~26 min with Acecide-C ~29 min with Aldahol 1.8	~30 min	~23 min
Endoscope Capacity	2 (1 per basin)	1-2 or 2-4 based on model	2 (1 per basin)	2 (1 per basin)	2 (1 per basin)	1 or 2 based on model	2 regular or 1 EUS endoscope	2	1
Asynchronous operation	Yes	No/Yes (model dependant)	Yes	Yes	Yes	No	No	No	N/A
Alcohol flush	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Barcode scanner	Optional	No	No	No	Yes	Yes	RFID Pad	Optional	No
Automated leak test	Yes	No	Yes	Yes	Yes	No	No	Optional	No
Scope cleaning claim‡	Yes	No	No	No	Yes	No	No	No	No
Downloadable/ electronic cycle data	Yes	Yes	Yes	Yes	Yes	No	Print (Electronic optional)	Print	Print or manually record
Networking capability	Yes	Yes	Yes	Yes	Yes	No	Yes (optional)	No	No
Remote Diagnostics	No	Yes	No	No	Yes	No	No	No	No
Water Softener required	Yes	No	No	No	No	No	No	No	No
Operating voltage	220VAC	120VAC	110VAC	110VAC	110VAC	110VAC	120VAC	220VAC	120VAC
List Price	$52,000	$39,000-$65,000	$44,655	$47,185	$67,815	$27,560	$33,500	$43,000-46,000	$31,500

~, Approximately; *AER*, automated endoscope reprocessor; *EUS*, endoscopic ultrasound; *RFID*, radiofrequency identification.
*These AER systems have completed FDA-requested validation testing of the reprocessing effectiveness of duodenoscopes with adequate performance demonstrated.[3]
†Testing for the Olympus closed elevator channel duodenoscope – the TJF-Q180 model, has been found to be adequate. Testing is still in process for the Olympus open elevator channel duodenoscope, the TJF-160VF model.[3]
‡Based on the most recent Society of Gastroenterology Nurses and Associates guidelines, manual cleaning is required even when AER manufacturers claim that manual cleaning is unnecessary.[4] The FDA recommends that the AER cleaning cycle only be used as a supplement to thorough manual cleaning according to the duodenoscope manufacturer's instructions.[3]

than is practical, and therefore these formulations are only used for HLD.[11,22] HLD solutions cleared by the FDA include those formulated with glutaraldehyde, orthophthalaldehyde, peracetic acid, chlorine, and hydrogen peroxide.[11] Some formulations contain combinations of microbicidal agents, including peracetic acid and hydrogen peroxide, glutaraldehyde and phenol/phenate, and glutaraldehyde and isopropyl alcohol.[11] The FDA periodically updates a list of approved HLD solutions along with some of their attributes such as contact time and temperature required for HLD.[23] Currently approved HLD solutions are listed in Table 3.

Most AER manufacturers specify the type of HLD solution to be used in their machines, often on a proprietary basis (Table 2). It is important to comply with AER manufacturers' instructions. Some HLD solutions are effective only at elevated temperatures. AERs that use such solutions have reservoirs with heating elements that increase the temperature of the HLD solution to the appropriate level.[10,11] Some AERs use HLD solutions that are reusable for 5 to 30 days and are maintained in a reservoir within the system. The days in use may be monitored by the AER. Test strips are used to monitor the concentration of the active ingredient in the HLD solutions.[10]

TABLE 3. High-level disinfection solutions for endoscope reprocessing

Agent/Trade Name	Manufacturer	HLD Conditions (min/°C)	AER Specific	Maximum duration for reuse (days)	Comments
Glutaraldehyde					• Inexpensive • Extensive experience • Excellent material compatibility • Respiratory irritant • Irritating odor • Fixes tissues and blood to surfaces • Relatively slow mycobacterial activity
-2.4% CIDEX® Activated	Advanced Sterilization Products, (Irvine, Calif)	45/25*	No	14	
- 2.5% Rapicide	Medivators Reprocessing Systems Minntech Corp (Minneapolis, Minn)	5/35**	No	28	
Metricide 28 Long Life Activated Dialdehyde Solution	Metrex Research, Inc (Romulus, Mich)	90/25*	No	28	
Procide D	Metrex Research, Inc	90/25*	No	28	
- 2.6% Metricide	Metrex Research, Inc	45/25*	No	14	
- 2.65% Wavicide-01	Medical Chemical Corp (Torrance, Calif)	45/22*	No	30	
- 3.2% Cetylcide-G	Cetylite Industries (Pennsauken, NJ)	40/20*	No	28	
- 3.4% Metricide Plus 30	Metrex Research, Inc	90/25*	No	28	
Procide D Plus	Metrex Research, Inc	90/25*	No	28	
Banicide Plus	Metrex Research, Inc	90/25*	No	30	
Glutaraldehyde/ Isopropanol					
- 3.4%/20.1% Aldahol 1.8	Alden Medical LLC (West Springfield, Mass) for Olympus	5/25**	No	14	
Glutaraldehyde/ Phenol/Phenate					• Lowest glutaraldehyde concentration for HLD
- 1.12%/1.93% Sporicidin	Contec (Spartanburg, SC)	20/25**	No	14	
Ortho-phthaldehyde (OPA)					• Materials compatibility • Fast action • Expensive • Stains proteins, mucous membranes, skin, clothing and surfaces gray • Contact eye toxicity • Possible endoscope material incompatibility • Slow sporicidal activity
- 0.55% CIDEX® OPA	Advanced Sterilization Products	12/20*	No	14	
		5/25**	No	14	
- 0.575% Rapicide OPA-28	Medivators Reprocessing Systems Minntech Corp	10/20*	No	28	
		5/25**	No	28	
	Advanced Sterilization Products	5/50**	Yes (EvoTech System)	Single use – diluted by system to 0.05%	
- 0.60% Metricide OPA Plus	Metrex Research	5/25**	No	14	
		12/20*	No	14	
Hydrogen Peroxide					
- 7.5% Sporox II	Sultan Healthcare (Hackensack, NJ)	30/20	No	21	• No activation required • May enhance removal of organic materials • No disposal, odor, or irritation issues • Contact eye toxicity • Possible endoscope materials incompatibility
- 2.0% Revital-Ox Resert HLD	Steris Corporation (Mentor, Ohio)	8/20	No	21	

(*continued on the next page*)

TABLE 3. Continued

Agent/Trade Name	Manufacturer	HLD Conditions (min/°C)	AER Specific	Maximum duration for reuse (days)	Comments
Hydrogen Peroxide/ Peracetic Acid					• No activation required • No significant odor, irritation • PA not compatible with some endoscopes
- 22%/5% Rapacide PA	MediVators Reprocessing Systems Minntech Corp	5/30**	Yes (MediVators Advantage Plus or DSD Edge)	Single use	
Peracetic Acid					• Rapid automated sterilization • Rapidly sporicidal • Safe by-products • May enhance removal of organic material • Expense • Room temperature
- 3.2% Reliance™ DG Dry Germicide	Steris Corp	10/50**	Yes (Reliance EPS)	Single use only	
- 35% S40	Steris Corp	23/46-55**	Yes (System 1-E)		
- 3100-3400ppm Acecide-C	Best Sanitizers, Inc (Penn Valley, Calif) for Olympus	7/20**	Olympus OER Pro	5	

AER, automated endoscope reprocessor; *HLD*, high-level disinfection.
*Conditions for manual reprocessing only.
**Conditions for AER reprocessing only.

One AER (Steris System 1E; Steris Corp, Mentor, Ohio) has received clearance by the FDA for liquid chemical sterilization, as opposed to HLD, for heat-sensitive devices that cannot be sterilized by traditional means.[24] This system uses filtered, ultraviolet-treated water that enters the AER and mixes with a peracetic acid–based formulation that is subsequently heated to 46° to 55°C for liquid chemical sterilization.[25]

Not all AERs are compatible with endoscopes from all manufacturers (Table 2). Compatibility of AERs with the types of endoscopes in a facility's inventory should therefore be examined before purchase.

Reprocessing of duodenoscopes

Duodenoscopes, used to perform ERCP, have been linked to transmission of serious infections, both in and outside of the United States.[10,26-32] Although nearly all endoscope-associated infections had in the past been linked to inadequate reprocessing, investigation of recent ERCP-associated outbreaks did not reveal any reprocessing deficiencies.[27,29,33,34] Instead, these outbreaks have been attributed to the complex design of duodenoscopes with hidden and often difficult to reach crevices and channels that can retain organic debris despite brushing and cleaning before HLD.[35] The elevator mechanism of the duodenoscopes, particularly those with a closed elevator channel design, have proven problematic to clean adequately and have been suggested to be a source for infection transmission.[28,35] At least 1 duodenoscope manufacturer (Olympus; Center Valley, Pa, USA) has since modified the design of the closed elevator channel to create a tighter seal[36] and has also updated the operation manual and reprocessing instructions for their duodenoscopes.[37] In October 2015 the FDA asked the 3 manufacturers of duodenoscopes to revise and validate their reprocessing instructions.[38] This led to the modification of manufacturers' reprocessing protocols with a larger emphasis on precleaning and manual cleaning before HLD.[39-41]

The FDA also requested that AER manufacturers conduct additional validation testing to evaluate AER reprocessing effectiveness with regard to the recess around the duodenoscope's elevator area.[42] An FDA communiqué released in February 2016 indicated that validation testing on 3 AER models, Advantage Plus (Medivators; Minneapolis, Minn, USA), DSD Edge (Medivators), and System IE (Steris Corp), was complete and adequate.[42] Given the complex design of duodenoscopes, the FDA communiqué also recommended that the cleaning cycle of AERs only be used as a supplement to thorough manual cleaning according to the duodenoscope manufacturer's instructions.[42]

SAFETY

It is important that users follow manufacturers' recommendations when reprocessing endoscopes using AERs. This will decrease the risks associated with the use of AERs. There have been reports of chemical-induced colitis related to inadequate manual rinsing of endoscopes after disinfection in older AERs.[43] In most new AERs, however, rinsing and drying of the endoscopes after reprocessing is performed automatically. There have been reports of contamination of AERs with bacteria,[44,45] which may result in patient exposure to pathogens. Some AERs have self-disinfection cycles using either an HLD solution

or thermal methods.[11] Contamination can also occur because of a defective or malfunctioning AER.[46] Compliance with manufacturer-recommended preventive maintenance is important to avoid AER contamination because of malfunction.

On November 13, 2015, the FDA issued a recall under consent decree for all Custom Ultrasonics (Ivyland, Pa, USA) AERs because of the company's inability to validate that their AERs were able to adequately wash and disinfect endoscopes to mitigate the risk of patient infection.[47] The safety communiqué issued by the FDA recommended that healthcare facilities using Custom Ultrasonics AERs transition to alternative methods to reprocess flexible endoscopes. The FDA's action was also based on reports that endoscopes reprocessed by Custom Ultrasonics AERs had been in use in some healthcare facilities that reported the transmission of serious bacterial infections associated with endoscopy.[47] In a subsequent safety communication, released on August 17, 2016, the FDA revised its prior recall. The new communication recommends that healthcare facilities not use Custom Ultrasonics System 83 Plus AERs for reprocessing duodenoscopes and transition to alternative methods for duodenoscope reprocessing. However, Custom Ultrasonics System 83 Plus AERs remain available for reprocessing flexible endoscopes that are not duodenoscopes, because the FDA's ongoing investigations have not demonstrated an association between Custom Ultrasonics AERs and bacterial infections in nonduodenoscope flexible endoscopes.[48]

FINANCIAL CONSIDERATIONS

The costs associated with AERs include the unit price, installation, maintenance, chemicals, and consumable items such as filters and test strips and costs associated with chemical disposal. List prices for AERs available in the United States are provided in Table 2. Additional costs may include the need for water softener equipment or the installation of a special power supply and personnel training and competency verification. These costs may be offset by reduced procedural delays, increased productivity, and decreased need for endoscope repairs.[49] A recent study suggested that the use of AERs may be associated with a positive financial impact in some endoscopy centers.[49]

FUTURE DIRECTIONS

Future changes are needed in both AER and endoscope design that facilitate HLD to further reduce the risk of transmission of infections related to endoscopy. The design of flexible GI endoscopes has traditionally focused on enhanced function and performance and not on ease of cleaning and HLD. In some endoscopes, such as the duodenoscope, the complex design presents a particular challenge to cleaning and HLD.[35] AER manufacturers have been asked by the FDA to validate their reprocessing instructions, particularly for AERs that reprocess duodenoscopes. Improved collaboration among manufacturers, healthcare providers, accrediting organizations, professional societies, and government agencies may help resolve problems associated with endoscope and AER design, risk of infection transmission, and other issues related to endoscope reprocessing on a continuous basis. Such collaboration will benefit all stakeholders.

The role of bacteriologic surveillance for both AERs and endoscopes needs to be evaluated further in large studies. Studies should also determine the optimal HLD solutions for use in AERs. The quality of endoscope reprocessing within a centralized institutional sterile processing department with dedicated technicians should be compared with HLD performed within the endoscopy unit by endoscopy unit personnel. Similarly, further study is needed of the impact of submitting duodenoscopes for ethylene oxide gas sterilization on the quality of endoscope reprocessing. Compliance with reprocessing instructions by AER and endoscope manufacturers has been an area of concern. This may be in part because of the complexity and lack of clarity of the instructions. User education and clear and feasible instructions and guidelines may improve adherence.

SUMMARY

AERs can enhance the efficiency, consistency, and reliability of endoscope reprocessing by automating and standardizing several important reprocessing steps, thereby reducing the possibility of human error. Use of AERs reduces exposure of reprocessing personnel to harmful chemical germicides and may lessen health problems attributed to reprocessing of endoscopes. The use of AERs for endoscope reprocessing is therefore strongly recommended by the ASGE.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: AER, automated endoscope reprocessor; ASGE, American Society for Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration; HLD, high-level disinfection.

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