

## Automated endoscope reprocessors

*The American Society for Gastrointestinal Endoscopy (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 (Food and Drug Administration 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 cases, 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 August 2008 for articles related to automated endoscope reprocessors by using the words “endoscope reprocessing,” “endoscope cleaning,” “automated endoscope reprocessors,” and “high level disinfection.”*

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### BACKGROUND

High-level disinfection (HLD) is the accepted standard for the reprocessing of flexible GI instruments.<sup>1</sup> National standards were adopted to ensure that endoscope repro-

cessing is performed consistently by using a standardized protocol.<sup>2</sup> Automated endoscope reprocessors (AER) are designed to replace some manual reprocessing steps.<sup>3-5</sup> In addition, AERs may limit exposure of personnel to liquid chemical germicides (LCG).

### TECHNICAL CONSIDERATIONS

HLD refers to the treatment of medical devices to remove all viable microorganisms, except some spores when present in a significant load. National consensus standards for endoscope reprocessing emphasize (a) bedside cleaning and aspiration of enzymatic detergent through the suction channel, (b) manual washing and brushing of accessible channels, (c) subsequent disinfection via immersion for an appropriate duration in a LCG of appropriate concentration, followed by (d) a water rinse, alcohol flush, and air-drying of all channels. A variety of LCGs with differing contact and concentration requirements are available for the disinfection step (Table 1).<sup>6</sup>

A variety of capabilities are incorporated into the available AERs (Table 2). All models have disinfection and rinsing cycles, and some have detergent cleaning, alcohol flush, and/or extended forced-air-drying cycles. Additional features or designs may include (1) variable cycle times, (2) printed documentation of the process, (3) low-intensity US waves, (4) LCG vapor recovery systems, (5) heating to optimize LCG efficacy, (6) a variable number of endoscopes processed per cycle, (7) automated leak testing, (8) automated detection of channel obstruction, and (9) table top, floor standing, and cart-mounted models.

Not all reprocessors are compatible with all LCGs or with endoscopes from all manufacturers. Some models are designed for use with specific LCGs types and/or formulations, often on a proprietary basis. Other variations that may require attention to the design of the facility include requirements for (1) water pressure, temperature, and filtration, (2) ventilation, (3) plumbing, (4) power supply, and (5) space.

All AERs rely upon high pressure and flow rates of LCG through the endoscope channels and continuous bathing of the exterior of the instrument. Some consume and dispose of limited amounts of LCG per endoscope cycle, whereas others use a reservoir of LCG that is reused over many cycles. The latter design risks gradual dilution of LCG with repeated use and requires intermittent testing to verify maintenance of the appropriate minimum

**TABLE 1. LCGs available for HLD in the United States\***

Agent/trade name	Manufacturer	HLD conditions (min/°C)	AER specific?	Single use or multiuse	Comment†
<b>GLUTARALDEHYDE</b>					
2.4%					
ProCide 14	Cottrell Ltd, Englewood, Colo	45/20	No	14-d max reuse	Inexpensive; extensive experience; excellent material compatibility; respiratory irritant; irritating odor; fixes tissues and blood to surfaces; relatively slow mycobacterial activity
Omnicide Long Life	Cottrell Ltd	45/20	No	28-d max reuse	
CIDEX activated dialdehyde solution	Advanced Sterilization Products, Irvine, Calif (A Johnson and Johnson Co)	45/25	No	14-d max reuse	
2.5%					
Rapicide	Medivators Reprocessing Systems, Minntech Corp, Minneapolis, Minn	5/35	No	28-d max reuse	
CIDEX Formula-7	Advanced Sterilization Products	90/25	No	28-d max reuse	
Metricide 28	Metrex Research, Inc, Romulus, Mich	90/25	No	28-d max reuse	
Wavicide-01	Medical Chemical Corp, Torrance, Calif	45/22	No	30-d max reuse	
2.6%					
Metricide	Metrex Research	45/25	No	28-d max reuse	
2.65%					
TD-5‡	PCI Medical Inc, Deep River, Conn	25/25	No	28-d max reuse	
3.2%					
Cetylcide-G	Cetylite Industries, Pennsauken, NJ	40/20	No	28-d max reuse	
3.4%					
Omnicide Plus	Cottrell Ltd	45/20	No	28-d max reuse	
Metricide Plus 30	Metrex Research	90/25	No	28-d max reuse	
CIDEX Plus	Advanced Sterilization Products	20/25	No	28-d max reuse	
3.5%					
Banicide Advanced	Pascal Co, Inc, Bellevue, Wash	45/25	No	30-d max reuse	
<b>GLUTARALDEHYDE/ ISOPROPANOL</b>					
3.4%/26%					
Aldahol III HLD	Healthpoint Ltd, Fort Worth, Tex	10/20	No	14-d max reuse	

*(continued on next page)*

TABLE 1 (continued)

Agent/trade name	Manufacturer	HLD conditions (min/°C)	AER specific?	Single use or multiuse	Comment <sup>†</sup>
<b>GLUTARALDEHYDE/PHENOL</b>					
1.12%/1.93%					Lowest glutaraldehyde concentration for HLD
Sporicidin	Sporicidin Co, Rockville, Md	20/25	No	14-d max reuse	
<b>OPA</b>					
0.55%					Fast action; materials compatibility; expensive; stains proteins, mucous membranes, skin, clothing, and surfaces gray; contact eye irritation; slow sporicidal activity
CIDEX OPA solution	Advanced Sterilization Products	12/20§	No	14-d max reuse	
		5/25	No	14-d max reuse	
5.75%					
CIDEX OPA concentrate	Advanced Sterilization Products	5/50	Yes, (EvoTech system)	Single use, diluted by system to 0.05%	
<b>HYDROGEN PEROXIDE</b>					
7.5%					No activation required; may enhance removal of organic materials; no disposal, odor, or irritation issues; contact eye toxicity; possible endoscope materials compatibility
Sporox II	Reckitt and Colman, Inc, Wayne, NJ	30/20	No	21-d max reuse	
<b>HYDROGEN PEROXIDE/PERACETIC ACID</b>					
1.0%/0.08%					No activation required; no significant odor, irritation; peracetic acid not compatible with some endoscopes
Peract 20	Minnotech Corp	25/20	No	14-d max reuse	
7.35%/0.23%					
Endospor Plus	Cottrell Ltd	15/20	No	14-d max reuse	
<b>PERACETIC ACID</b>					
3.2%					Rapid automated sterilization; rapidly sporicidal; safe byproducts; may enhance removal of organic material; expense
Reliance DG oxidizing chemistry	STERIS Corp, Mentor, Ohio	10/50	Yes	Single use only	
Rapicide PA	Medivators Reprocessing Systems	(pending FDA clearance)	Yes	Single use only	

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TABLE 1 (continued)

Agent/trade name	Manufacturer	HLD conditions (min/°C)	AER specific?	Single use or multiuse	Comment†
<b>HYPOCHLORITE AND HYPOCHLOROUS ACID</b>					
650-675 ppm active free chlorine	Sterilox Endoscopy, a division of PuriCore, PLC, Malvern, Pa	10/25	Yes (Sterilox systems)	Single use, generated on site	"Super-oxidized water" (HOCL) from electrolysis of saline solution; no exposure or disposal risks; rapid action; approved; not yet on the market in the United States

OPA, Orthophthaldehyde; max, maximum; LCG, liquid chemical germicide; HLD, high-level disinfection; AER, automated endoscope reprocessor.

\*From reference 7.

†From reference 1.

‡Primarily marketed to cardiology.

§Conditions for manual reprocessing only.

||Conditions for AER reprocessing only.

effective LCG concentration between the scheduled replacements of LCG. The AER machines and the LCGs they use also vary in the potential biochemical burden they produce as waste. Some LCGs yield environmentally harmless byproducts, whereas others require attention to disposal (Table 1).

## INDICATIONS

AERs are cleared by the U.S. Food and Drug Administration (FDA) for HLD of flexible endoscopes when used according to manufacturer's recommendations. Most are labeled for HLD after manual cleaning, as outlined by the Society for Gastrointestinal Nurses and Associates.<sup>7</sup> One device (EvoTech System; Advanced Sterilization Products, Irvine, Calif) has received labeling clearance for use after bedside precleaning only, without prior manual cleaning and channel brushing.<sup>8</sup> However, only limited proprietary bench data are available for this machine,<sup>9</sup> and, at the time of initial marketing, there were no published data from this device.

## EFFICACY

FDA clearance of LCGs and AERs requires meeting defined performance levels for reduction in residual organic loads and clearance of resistant indicator organisms (typically *Mycobacterium bovis*). All AERs marketed in the United States meet these criteria. Reprocessing by AER and by passive immersion in LCG, with manual flushing of channels with LCG, have similar efficacy for the disinfection component.<sup>10,11</sup> A small number of studies compared HLD by using differing LCGs, however, most emphasized the efficacies of the germicidal agent rather than the AER itself. There are no data that a reprocessing end point of sterilization decreases the infectious risk of reprocessed endoscopes when compared with HLD.

## SAFETY

### Patient

Inadequate rinsing of the endoscope after disinfection has been associated with chemical-induced colitis.<sup>12</sup> Some manufacturers provide documentation that all LCG residues are removed from the endoscope after AER reprocessing. Contamination and colonization of AERs may result in patient exposure to pathogens. Gram-negative bacilli have been isolated from contaminated AERs.<sup>13</sup> Failure to correctly attach and flush all endoscope channels has led to reprocessing failure and associated infectious outbreaks among patients.<sup>14</sup>

### Environmental exposure

Exposure of the endoscopy staff to some LCGs can cause a variety of reactions (Table 1). Glutaraldehyde has caused asthma, sinusitis, serious skin sensitivity, and conjunctivitis.<sup>3</sup> AERs reduce direct contact with LCGs. The staff should continue to follow established guidelines for the use of appropriate personal protective equipment.<sup>15</sup> Vapor recovery systems and adequate ventilation may reduce exposure to LCG vapors. Available AERs and associated LCGs may produce variable amounts of organic and inorganic waste, and facilities may need to consider local environmental regulations.

## FINANCIAL CONSIDERATIONS

AERs have a wide range of prices (Table 2). Additional variable costs include site preparation and installation, AER maintenance, LCG cost per cycle, and potential impact of the LCG type on endoscope repair costs.<sup>16</sup> In 1 study, it was suggested that the use of peracetic acid liquid sterilization increased repair costs for reprocessed flexible cystoscopes.<sup>17</sup> These costs may be offset by increased

TABLE 2. AERs approved for use in the United States

Manufacturer	Device	LCG compatibility	Basins and endoscopes per cycle	Model*	Cycle time	Features	List price, \$ (Aug 2008)
<b>Advanced Sterilization Products, a Johnson and Johnson Co (Irvine, Calif)</b>	ASP AER	Glutaraldehyde or OPA solutions	1 Basin, 1 or 2 endoscopes per basin	Floor standing on casters	Variable, user selected	D+R, FAD, VCT, PD, H	20,895
	EvoTech ECR System	CIDEX OPA concentrate	2 Basins, 1 endoscope per basin	Floor standing on casters	33 min	D+R, DC, FAD, AF, VCT, VR, H, LT, OD	57,000
<b>Custom Ultrasonics (Ivlyland, Pa)</b>	System 83 Plus 2	Multiple agents	1 Basin, 1 or 2 endoscopes per basin	Floor standing	8 min plus HLD contact time	D+R, DC, FAD, AF, VCT, PD, USW, H, VR, SD, OD	24,256
	System 83 Plus 9	Multiple agents	2 Basins, 1 or 2 endoscopes per basin	Floor standing	8 min plus HLD contact time	D+R, DC, FAD, AF, VCT, PD, USW, H, VR, SD, OD	41,574
<b>Medivators Reprocessing Systems; Minntech Corp (Minneapolis, Minn)</b>	Medivators ADVANTAGE	Glutaraldehyde or OPA	2 Basins, 1 or 2 endoscopes per basin	Floor standing on casters	Variable, user selected	D+R, DC, FAD, AF, VCT, PD, VR, H, SD, IWF, OD, LT	54,775
	Medivators ADVANTAGE Plus (pending FDA clearance)	Rapicide PA—peracetic acid (pending FDA clearance)	2 Basins, 1 or 2 endoscopes per basin	Floor standing on casters	Variable, user selected	D+R, DC, FAD, AF, VCT, PD, VR, SD, IWF, OD, LT	56,850
	Medivators: DSD-201 and DSD-201LT	Glutaraldehyde or OPA	2 Basins, 1 endoscope per basin	Floor standing (casters optional)	Variable, user selected	D+R, DC, FAD, AF, VCT, PD, VR, H, SD, IWF, LT (optional)	33,650 36,320 w/LT
	Medivators: SSD-102 and SSD-102LT	Glutaraldehyde or OPA	1 Basin, 1 endoscope per basin	Floor standing (casters optional)	Variable, user selected	D+R, DC, FAD, AF, VCT, PD, VR, H, SD, IWF, LT (optional)	23,090 24,850 w/LT
	Medivators: CER-1 and CER-2 (MV-1, MV-2)	Glutaraldehyde or OPA	1 Basin; 1 or 2 endoscopes per basin, depending on model	Counter-top or mobile cart	Variable, user selected	D+R, DC, FAD, AF, VCT, VR, H, IWF	11,780 CER-1 19,220 CER-2
<b>PuriCore (Malvern, Pa)</b>	Maxigen E200, Midigen E100; Sterilox endoscopy HLD system	Hypochlorite and hypochlorous acid	NA	Floor standing	NA	Not available in the United States at this time	FDA approval received in April 2007
<b>Steris (Mentor, Ohio)</b>	SYSTEM 1 sterile processing system	Peracetic acid	1 Basin, 1 endoscope per basin	Counter top	30 min	PD, IWF, SC	22,250
	Reliance endoscope processing system	Peracetic acid	1 Basin, 2 endoscopes per basin	Under the counter or floor standing, with or without a pedestal	42 min with wash phase, 30 min with no wash phase	D+R, PD, DC, FAD, LT, SC, SD, IWF	46,607 with leak test option; 43,427 with no leak test option

OPA, Orthophthaldehyde; D+R, HLD and rinse; FAD, forced air drying; VCT, variable cycle times; PD, printed documentation; H, LCG heating; IC, independent cycles; DC, detergent cleaning; AF, alcohol flush; VR, vapor recovery system; LT, automated leak testing; OD, automated obstruction detection; USW, low-intensity US waves; SD, internal self disinfection; IWF, internal water filtration; NA, not available; SC, sterilization claim; AER, automated endoscope reprocessor; LCG, liquid chemical germicide.

\*Table-top, floor-standing, or cart-mounted models.

productivity of the endoscopy unit as a result of enhanced capabilities of the AER or reduced cycle times related to LCG type and characteristics.<sup>18</sup>

## SUMMARY

National consensus standards provide guidance on the requisite steps to achieve HLD of flexible endoscopes. AERs can enhance efficiency and reliability of HLD by replacing some manual reprocessing steps. Precleaning is required before use of any AER, and manual cleaning remains the standard of care before disinfection. Use of an AER may also reduce exposure of personnel to chemical germicides. There are insufficient data to recommend a single method, device, or agent to achieve HLD.

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

## REFERENCES

- Banerjee S, Shen B, Nelson DB, et al. Infection control during gastrointestinal endoscopy. *Gastrointest Endosc* 2008;67:781-90.
- American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc* 2003;58:1-8.
- ECRI. Flexible endoscope reprocessors, automatic. Health Care Product Comparison System November 1996:1-17.
- ECRI. Liquid disinfecting and sterilizing reprocessors used for flexible endoscopes. *Health Devices* 1994;23:211-53.
- ECRI. Flexible endoscope reprocessors, automatic. Health Care Products Comparison System June 1998:1-19.
- FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices: September 28, 2006. Available at: <http://www.fda.gov/cdrh/ode/germlab.html>. Accessed August 15, 2008.
- Society of Gastroenterology Nurses and Associates, Inc. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 2000;23:172-87.
- Food and Drug Administration. EvoTech System 510(k) submission. Available at: <http://www.fda.gov/cdrh/pdf6/K061899.pdf>. Accessed April 30, 2007.
- Advanced Sterilization Products. Available at: [http://www.sterrad.com/Products\\_&\\_Services/Evotech\\_ECR\\_System/Literature/EvoTech%20White%20Paper%20\(Rv.%20B\)%20FINAL.pdf](http://www.sterrad.com/Products_&_Services/Evotech_ECR_System/Literature/EvoTech%20White%20Paper%20(Rv.%20B)%20FINAL.pdf). Accessed August 15, 2008.
- Deva AK, Vickery K, Zou J, et al. Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes. *J Hosp Infect* 1998;39:149-57.
- Fraser V, Zuckerman G, Clouse R, et al. Prospective randomized trial comparing manual and automated endoscope disinfection methods. *Infect Control Hosp Epidemiol* 1993;14:383-9.
- Jonas G, Mahoney A, Murray J, et al. Chemical colitis due to endoscope cleaning solutions: a mimic of pseudomembranous colitis. *Gastroenterology* 1988;95:1403-8.
- Babb JR, Bradley CR. Endoscope decontamination: where do we go from here? *J Hosp Infect* 1995;30S:543-51.
- Subhas Banerjee S, Nelson DB, Dominitz J. Reprocessing failure. *Gastrointest Endosc* 2007;66:869-71.
- Carr-Locke DL, Conn MI, Faigel DO, et al. Personal protective equipment. *Gastrointest Endosc* 1999;49:854-7.
- Burdick JS, Hambrick D. Endoscope reprocessing and repair costs. *Gastrointest Endosc Clin N Am* 2004;14:717-24.
- Fuselier HA Jr, Carrington M. Liquid sterilization versus high level disinfection in the urologic office. *Urology* 1997;50:337-40.
- Hession SM. Endoscope disinfection by ortho-phthalaldehyde in a clinical setting. *Gastroenterol Nurs* 2003;26:110-4.

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