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TECHNOLOGY STATUS EVALUATION REPORT

## AUTOMATIC ENDOSCOPE REPROCESSORS

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### INTRODUCTION

In order to promote the appropriate use of new or emerging endoscopic techniques, the ASGE Technology Committee has developed a series of status evaluation papers. By this process relevant information about these technologies may be presented to practicing physicians for the education and care of their patients. In many cases, data from randomized control trials is lacking and only preliminary clinical trials are available. Practitioners should continue to monitor the medical literature for subsequent data about efficacy, safety and socioeconomic aspects of the technologies.

### BACKGROUND

High level disinfection is the accepted standard for the reprocessing of flexible gastrointestinal instruments.<sup>1</sup> Appropriate manual (mechanical) cleaning of the endoscope is required prior to the use of an automatic endoscope reprocessor (AER). AERs are designed to ensure that reprocessing is performed consistently using a standardized protocol and to replace some manual disinfection steps.<sup>2,3,4</sup> In addition, AERs may limit exposure of personnel to liquid chemical germicides (LCG).<sup>2</sup>

### TECHNICAL CONSIDERATIONS

AERs have a liquid chemical germicide (LCG) cycle followed by a water-rinse (Table 1). Some models have detergent and/or extended forced-air cycles. Additional features may include:

1. variable cycle time
2. printed documentation of the process
3. low intensity ultrasound waves
4. glutaraldehyde vapor recovery system
5. heater to optimize disinfectant efficacy
6. variable number of endoscopes processed per cycle
7. table top, floor standing, cart-mounted models

Not all reprocessors are compatible endoscopes from different manufacturers or all LCGs. Facility design considerations include 1) water pressure, temperature and filtration, 2) ventilation, 3) plumbing, 4) power supply, and 5) space. Test strips are used to verify the appropriate minimum effective concentration of an LCG.

### INDICATION/EFFICACY

AERs are FDA-approved for high level disinfection of flexible endoscopes when used according to manufacturer's recommendations. There are no data that sterilization decreases the infectious risk of reprocessed endoscopes when compared to high level disinfection. One study suggested that the use of peracetic acid liquid sterilization increased repair costs for reprocessed flexible cystoscopes.<sup>5</sup>

### SAFETY

#### Patient

Inadequate rinsing of the endoscope following disinfection has been associated with chemical-induced colitis<sup>6</sup>, although some manufacturers provide documentation that all LCG residues are removed from the endoscope after AER reprocessing. Furthermore, AERs may become contaminated, resulting in potential patient exposure to pathogens. Gram-negative bacilli have been isolated from contaminated AERs.<sup>7</sup>

#### Personnel

Exposure of Endoscopy staff to 2% glutaraldehyde has caused asthma, sinusitis, serious skin sensitivity, and conjunctivitis.<sup>2</sup> AERs reduce direct contact with LCGs. Staff should continue to follow established guidelines for the use of appropriate personal protective equipment.<sup>8</sup> Vapor recovery sys-

**Table 1 Liquid chemical germicides**

	Trade Name	Manufacturer's Recommended		Estimated cost per cycle*
		Soaking Time	Concentration	
Glutaraldehyde**	Cidex Metricide Omnicide Procide	45-90 Minutes†	2%- 3.4%	\$1.32
Peracetic Acid (PA)	Steris-20	12 minute	0.2%	\$4.95
Hydrogen Peroxide (H <sub>2</sub> O <sub>2</sub> )	Sporox	30 minutes	7.5%	\$1.98
Peracetic Acid and Hydrogen Peroxide	Cidex-PA Peract	25 minutes	.08% PA 1% H <sub>2</sub> O <sub>2</sub>	\$2.50

\*Based on 5 gallon list price and estimated reuse life (variable). Prices determined as of 9/98.

\*\* Glutaraldehyde LCGs that contain surfactant (generally those with reuse life exceeding 14 days) are not compatible with AERs

† ASGE recommends soaking time of 20 minutes.

**Table 2. Automatic endoscope reprocessors**

Unit	LCG Compatibility	Endoscopes per cycle	Extended drying phase	ListPrice*
Advanced Sterilization Products (formerly Unitrol)	glutaraldehyde, peracetic acid/ hydrogen peroxide**	1 or 2	Yes	\$17,900
Steris	peracetic acid	1	No	\$16,200
Olympus	glutaraldehyde, hydrogen peroxide	1 or 2	Yes	\$21,600
Chris Lutz	glutaraldehyde, hydrogen peroxide	1 or 2	Yes	\$14,030
Custom Ultrasonics	glutaraldehyde; hydrogen peroxide can be used if upgraded with all-steel tubing	1, 2, or 3	Yes	\$19,400-\$56,000

\* Prices determined 9/98

\*\* LCG must not contain surfactants to be compatible with this reprocessor

tems and adequate ventilation may reduce exposure to LCG vapor.

### FINANCIAL CONSIDERATIONS

Automatic endoscope reprocessors range in price from \$14,000 to \$56,000. Variable costs include site preparation and installation, AER maintenance, LCG cost per cycle (see table 1), and potential impact on endoscope repair costs.<sup>4</sup> These costs may be offset by increased productivity of the endoscopy unit.

### COMPARATIVE TECHNOLOGIES

Mechanical reprocessing and AERs have similar efficacy.<sup>9,10</sup>

### SUMMARY

Automatic endoscope reprocessors can replace some manual reprocessing steps. However, thorough mechanical cleaning is still required prior to their use. Use of an AER may reduce exposure of personnel to chemical germicides. There is insufficient data to recommend a particular method or device to achieve high level disinfection.

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