Communication from the ASGE Technology Committee

STATUS EVALUATION REPORT

Automated endoscope reprocessors

Prepared by: ASGE TECHNOLOGY COMMITTEE

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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