

U.S. Food and Drug Administration
Protecting and Promoting Your Health

FDA Recommends Health Care Facilities Transition from Custom Ultrasonics Endoscope Washer/Disinfectors to Alternate Reprocessing Methods: FDA Safety Communication

Date Issued: November 13, 2015

Updated: February 23, 2016

The FDA is revising its November 2015 Safety Communication to provide updated information about its communications with Custom Ultrasonics regarding its

November 2015 Recall Order

On November 12, 2015, in accordance with a Consent Decree entered in January 2007 with Custom Ultrasonics (Consent Decree), FDA ordered Custom Ultrasonics to recall, at its expense, all of its Automated Endoscope Reprocessors (AERs). On November 24, 2015, Custom Ultrasonics submitted a recall strategy to the FDA, which the Agency found inadequate. Custom Ultrasonics has to date made no additional proposals to FDA to recall its AERs.

On January 29, 2016, the FDA sent a **letter** to Custom Ultrasonics reinforcing the terms of the Recall Order and requiring Custom Ultrasonics to remove its AERs from the market. The FDA further notified Custom Ultrasonics that it could take additional measures under the Consent Decree should Custom Ultrasonics fail to initiate or diligently implement the recall or take other required actions.

Because Custom Ultrasonics has not demonstrated that its AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection, the Agency continues to recommend that health care facilities using Custom Ultrasonics AERs transition to alternative methods to reprocess flexible endoscopes as soon as possible, as emphasized in its November 13, 2015 Safety Communication. The full text of that safety communication appears below.

[Posted February 23, 2016]

Audiences:

- Personnel working in endoscopy reprocessing units in health care facilities
- Health care providers that perform endoscopic procedures
- Infection Control practitioners
- Risk Managers
- Purchasers and other Hospital Administration staff

Medical Specialties: Infection Control, Gastroenterology, Pulmonology, General Surgery, Anesthesiology, Internal Medicine

Product:

All Custom Ultrasonics Endoscope Washer/Disinfecter models, also known as Automated Endoscope Reprocessors (AERs).

Purpose:

In accordance with a Consent Decree entered in January 2007 with Custom Ultrasonics, the FDA ordered Custom Ultrasonics to recall all of its AERs from health care facilities due to the firm's continued violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), applicable regulations, and the Consent Decree. Within seven business days after receiving FDA's recall order, Custom Ultrasonics must provide a written recall proposal to FDA. Therefore, the FDA is recommending that health care facilities currently using Custom Ultrasonics AERs transition away from their use to alternative methods to

reprocess flexible endoscopes as soon as possible. This communication contains important information and recommended actions if you have any of these medical devices in your facility.

Summary of Problem and Scope:

AERs are free-standing units used in health care facilities to disinfect flexible endoscopes and scope accessories between uses. Custom Ultrasonics AERs are intended to wash and high-level disinfect cleaned flexible endoscopes used in gastrointestinal and pulmonary tracts.

As part of the FDA's ongoing investigation into infections associated with reprocessed medical devices and AER devices used for cleaning and disinfection, the FDA has been reviewing the validation test methods and performance data for all AER manufacturers. To date, Custom Ultrasonics has not demonstrated that its AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection.

In January 2007, Custom Ultrasonics entered into a Consent Decree because the company failed to comply with the FD&C Act and its implementing regulations. In 2012 and 2013, under the terms of the Consent Decree, FDA ordered Custom Ultrasonics to stop manufacturing and distributing all AER device models and components. The FDA ordered Custom Ultrasonics to recall AER devices after the company failed to obtain FDA clearance following a significant change to the software operating system for one of its AERs. After Custom Ultrasonics obtained clearance for the significant change to the software operating system, the cleared devices were permitted to remain on the market. Since the 2012 and 2013 orders, the FDA has not authorized Custom Ultrasonics to resume manufacturing or distributing any AERs, though the company has continued to service them.

The FDA's most recent inspection of the Custom Ultrasonics' facility in April 2015 documented continued violations. Violations include the inability to validate that the AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection. The identified violations could result in an increased risk of infection transmission. Under the terms of the Consent Decree, the Agency is ordering Custom Ultrasonics to recall all its AERs. Custom Ultrasonics must provide a written recall proposal to FDA within seven business days after receiving FDA's recall order.

Recommendations for Health Care Facilities and Staff:

The FDA recommends that health care facilities currently using Custom Ultrasonics AERs transition away from their use to alternative reprocessing methods as soon as possible. Facilities are advised to:

- Identify and transition to alternate methods to reprocess flexible endoscopes, such as manual high-level disinfection, liquid chemical sterilization, alternative AERs, or other cleaning and sterilization methods according to the endoscope manufacturers' reprocessing instructions.
- Before transitioning to an alternative method, be sure that the endoscopes your facility uses are compatible with the alternative method by referring to the endoscope manufacturer's reprocessing instructions.
- Submit a report to Custom Ultrasonics and to the FDA via MedWatch, as described below, if you suspect your health care facility's Custom Ultrasonics AER has caused or contributed to patient infection.

The FDA continues to recommend the following endoscope reprocessing best practices:

- Perform thorough cleaning of endoscopes and their accessories before high-level disinfection, liquid chemical sterilization, or other sterilization methods.
- Ensure that staff responsible for reprocessing endoscopes have the endoscope manufacturer's instructions readily available to promote strict adherence.
- Implement a comprehensive quality control program for reprocessing endoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.
- Ensure that staff responsible for reprocessing endoscopes understand the importance of their role in reprocessing the device and maintain proficiency in performing required reprocessing tasks.
- Adhere to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals, as included in Additional Resources below.

FDA Activities:

The FDA has inspected Custom Ultrasonics to evaluate compliance with the Consent

Decree, FD&C Act, and FDA regulations, and has requested information from Custom Ultrasonics in an effort to:

- Obtain acceptable performance data to ensure that Custom Ultrasonics' AERs consistently achieve sufficient endoscope washing and high-level disinfection.
- Evaluate whether there is a link between infections and Custom Ultrasonics' AERs.
- Modify and validate Custom Ultrasonics' AER reprocessing methods and instructions to enhance their safety margin.

The FDA will provide updates as appropriate.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations](#).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements](#) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports to the agency via the [Medical Device Reporting \(MDR\)](#) process if they suspect their health care facility's Custom Ultrasonics AER has caused or contributed to patient infection. If a health care provider suspects bacterial contamination of an endoscope, we encourage the health care provider to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#).

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

Additional Resources

- [Custom Ultrasonics, Inc. - Ivmland, Pennsylvania - Letter issued 1-29-2016 \(PDF - 759KB\)](#)
- [FDA orders recall under consent decree for all Custom Ultrasonics automated endoscope reprocessors](#)
- [Recall Order to Custom Ultrasonics Under Consent Decree of Permanent Injunction \(PDF - 90KB\)](#)
- [Custom Ultrasonics, Inc. - Ivmland, Pennsylvania - 483 issued 04-24-2015 \(PDF - 310KB\)](#)
- [Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication](#)
- [Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. CDC Health Advisory. September 11, 2015](#)
- [Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication](#)
- [AAAMI Standard ST91: Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities. Published April 2015.](#)
- [American Society for Gastrointestinal Endoscopy: Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011](#)
- [Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication \[ARCHIVED\]](#)
- [The Centers for Disease Control and Prevention/Healthcare Infection Control Practices Advisory Committee \(HICPAC\). Guideline for Disinfection and Sterilization in Healthcare Facilities: 2008.](#)
- [FDA Public Health Notification: Updated Information on Custom Ultrasonics, Inc., Endoscope Washer/Disinfector \[ARCHIVED\]](#)
- [FDA Public Health Notification: Custom Ultrasonics, Inc. Endoscope Washer/Disinfectors \[ARCHIVED\]](#)
- [American College of Chest Physicians and American Association for Bronchology Consensus Statement: Prevention of Flexible Bronchoscopy-Associated Infection: 2005](#)
- [Warning Letter to Custom Ultrasonics, Inc. June 22, 2005 \[ARCHIVED\]](#)
- [Society for Healthcare Epidemiology of America \(SHEA\) position paper: Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes. July 2003](#)

[More in Safety Communications](#)

[Information About Heparin](#)

[Preventing Tubing and Luer Misconnections](#)

[Information for Manufacturers of Small-Bore Connectors and Medical Devices with](#)

[Connectors](#) [Tubing and Luer Misconnections: Recommendations for Health Care](#)

Facilities	Tubing and Luer Misconnections: Tips for Health Care	
Providers	How Luer and Other Small-Bore Connectors are Used in Clinical	
Settings	How Tubing and Luer Misconnections Occur	Examples of Tubing and
Luer Misconnections	Factors that Contribute to Tubing and Luer	
Misconnections	Report a Problem to the FDA About Tubing and Luer	
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