

UPDATE: Use of Custom Ultrasonics' System 83 Plus Automated Endoscope Reprocessors (AERs) for Reprocessing of Certain Duodenoscopes: FDA Safety Communication

April 10, 2018

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' System 83 Plus Automated Endoscope Reprocessors (AERs) used in health care facilities to wash and disinfect flexible endoscopes, including duodenoscopes, and scope accessories between uses. The System 83 Plus AERs include the System 83 Plus, System 83 Plus 2, and the System 83 Plus 9 AERs.

Purpose:

The FDA is notifying health care facilities that Custom Ultrasonics has completed validation testing of the System Plus AERs with specific duodenoscopes and FDA has determined that the validation data demonstrate the System 83 Plus can effectively achieve high-level disinfection of the Olympus TJF-180V duodenoscope and the Pentax ED-3490TK duodenoscope. As a result, the System 83 Plus AERs may now be used to reprocess only the Olympus TJF-Q180V duodenoscope and the Pentax ED-3490TK duodenoscope. The System 83 Plus is not validated for the reprocessing of FUJIFILM Medical Systems, U.S.A., Inc. (Fujifilm) duodenoscopes or duodenoscopes with open elevator wire channels.

Summary of Problem and Scope:

In January 2007, Custom Ultrasonics, Inc. entered into a Consent Decree with FDA due to, among other things, repeated violations of the Quality System Regulation.

In September 2012, the FDA again ordered Custom Ultrasonics to cease manufacturing and distributing, and to recall the System 83 Plus Washer/Disinfecter.

In April 2015, FDA inspected Custom Ultrasonics to evaluate compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA's Quality System regulations, and the Consent Decree.

In the **November 12, 2015 Recall Order**

(/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/UCM472567.pdf), the FDA ordered Custom Ultrasonics to recall all of its AERs from health care facilities due to the firm's violations of the FD&C Act, applicable regulations, and the Consent Decree.

In November 2015, the FDA issued a Safety Communication recommending that health care facilities using Custom Ultrasonics' System 83 Plus AERs transition to alternate methods to reprocess flexible endoscopes, which include duodenoscopes.

In January 2016, the FDA sent a **letter**

(/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/UCM487452.pdf) to Custom Ultrasonics reinforcing the terms of the Recall Order and instructing Custom Ultrasonics to remove its AERs from the market because the Agency had determined that the Custom Ultrasonics recall strategy submitted to FDA was inadequate.

In February 2016, FDA revised the November 2015 **Safety Communication (http://wayback.archive-it.org/7993/20170722213118/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm472462.htm)** to emphasize that health care facilities using Custom Ultrasonics' AERs should transition to alternative methods to reprocess flexible endoscopes.

In May 2016, Custom Ultrasonics issued an **URGENT MEDICAL DEVICE RECALL**

(https://www.customultrasonics.com/assets/Documents/May-6-2016-Customer-Communication.pdf)

(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) for all System 83 Plus, System 83 Plus 2 and System 83 Plus 9 AERs stating that they should not be used for cleaning and/or high-level disinfection of duodenoscopes until further notice, leaving the units in place only to reprocess other endoscopes.

In August 2016, the FDA issued a **Safety Communication (http://wayback.archive-**

it.org/7993/20171115052157/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm516782.htm) reminding health care facilities to stop using Custom Ultrasonics' System 83 Plus AERs and transition to alternative methods of reprocessing of duodenoscopes.

As a follow-up, Custom Ultrasonics was inspected in April 2017. This inspection verified the corrections implemented by Custom Ultrasonics, and found the firm in compliance. Based on the inspection results on June 12, 2017, the FDA modified the September 5, 2012, order to cease manufacturing and distribution and issued a notification permitting the resumption of manufacturing, marketing, and distribution of the System 83. This FDA resumption notice allowed Custom Ultrasonics to resume manufacturing, packaging, and distributing their System 83 Plus Washer/Disinfector (including components and systems) devices provided it is marketed and labeled for use only in reprocessing flexible endoscopes that are not duodenoscopes (i.e., include a warning label specifying that the devices are not indicated for reprocessing of duodenoscopes), consistent with the May 2016 recall.

As of April 10, 2018, the FDA has determined that Custom Ultrasonics System Plus 83 AERs validation is **adequate**

(/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm483896.htm) for certain duodenoscopes. As a result, the System 83 Plus AERs may now be used to reprocess only the Olympus TJF-Q180V duodenoscope and the Pentax ED-3490TK duodenoscope. On April 10, 2018, Custom Ultrasonics issued a **MEDICAL DEVICE NOTIFICATION (http://www.customultrasonics.com/)**

(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) stating all users will receive an updated label and Operator's Manual containing information about the reprocessing of these specific scopes.

The FDA will continue to work with Custom Ultrasonics as the firm takes steps to fully comply with requirements of the FD&C Act.

Recommendations for Health Care Facilities and Staff: