

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax: (215) 597-0875 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/09/2015 - 04/24/2015*
	FEI NUMBER 2523209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Alicia Nakonetschny, President and CEO

FIRM NAME Custom Ultrasonics, Inc.	STREET ADDRESS 144 Railroad Dr
CITY, STATE, ZIP CODE, COUNTRY Ivyland, PA 18974-1449	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

- a.) The System 83 Plus (Washer/ Disinfector) has a water inlet assembly (containing (b) (4) filters cascading from (b) (4) microns) which is used to remove bacterial contamination. The firm has not validated the retention performance of the filtration assembly over worse case conditions to ensure that variations in water quality do not have an adverse effect on the operation of the system.
- b.) The System 83 Plus has (b) (4) adapters (connector tubing) which are attached to endoscopes during reprocessing at user facilities. The pre-filters on the adapters have not been validated to determine the lifespan of the filters. The operator's manual for the System 83 Plus states that (b) (4) filters used on the (b) (4) adapters "must be replaced every six weeks or sooner if needed". The determination of when an (b) (4) filter is replaced is only based on the visual determination and the flow output of the adapters. The effectiveness of these filters prior to a user facility replacing the filters has not been evaluated by the firm.
- c.) The different germicides/disinfectants used in the System 83 Plus have not been evaluated for compatibility within the reprocessing equipment. The operator's manual for the System 83 Plus states that, "Custom Ultrasonics does not recommend a specific HLD (High Level Disinfectant) other than to require it be FDA cleared and compatible with the System 83 Plus (Washer/Disinfector) components, operation and flexible endoscopes." The firm has not validated the compatibility of the System 83 Plus with the various disinfectants being used by user facilities in reprocessing their endoscopes to effectively demonstrate adequate reprocessing capabilities.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brian S. Keefer, Investigator <i>Brian S. Keefer</i> Daniel W. Johnson, Investigator <i>Dan Johnson</i>	DATE ISSUED 04/24/2015
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d.) The firm did not perform a validation of specific duodenoscopes with a (b) (4) channel (including the (b) (4) after identifying additional challenges in reprocessing these scopes. From January 2013 to April 2015, the firm has received complaints of closed elevator endoscopes testing positive for bacterial cultures. The firm, however, did not validate these specific duodenoscopes within the System 83 Plus to address their capabilities of being reprocessed.

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Observation Annotations

Observation 1: Promised to correct.

*** DATES OF INSPECTION:**
04/09/2015(Thu), 04/10/2015(Fri), 04/13/2015(Mon), 04/14/2015(Tue), 04/16/2015(Thu), 04/17/2015(Fri), 04/22/2015(Wed),
04/23/2015(Thu), 04/24/2015(Fri)

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