



URGENT FIELD CORRECTION

December 23, 2015

REVISED OPERATION MANUAL: Cleaning, Disinfection and Storage, CODE 202B1259902D

Dear Valued Customer:

This letter is to advise you of the revised FUJIFILM Operation Manual (Cleaning Disinfection and Storage) for the duodenoscope models ED-250XL5, ED-250XT5, ED-450XL5 and ED-450XT5. The ED-250XT5, ED-250XL5, ED-450XT5 and ED-450XL5 are medical endoscopes for the duodenum and upper G.I. tract. They are intended for observation, diagnosis, and endoscopic treatment of the esophagus, stomach and duodenum.

FUJIFILM Medical Systems, U.S.A., Inc., Endoscopy Division is providing all users of the FUJIFILM ED-250XT5, ED-250XL5, ED-450XT5 and ED-450XL5 duodenoscopes with a revised Operation Manual, labeled "ED-530XT Operation Manual (Cleaning, Disinfection and Storage)" and a box of new disposable distal end cleaning brushes at no charge. This Operation Manual (identified above) has been revised to reflect newly validated manual cleaning and high-level disinfection procedures. Please note that while the revised reprocessing instructions have only been validated for the ED-530XT thus far, the revised Operation Manuals should also be used to reprocess the ED-250XT5, ED-450XT5, ED-250XL5 and ED-450XL5 endoscopes, while they undergo further validation testing.

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on endoscopes used for Endoscopic Retrograde Cholangiopancreatogram (ERCP) procedures. Given these reports and in an abundance of caution, FUJIFILM Medical Systems, U.S.A., Inc. has been working with the U.S. Food and Drug Administration ("FDA") to validate the reprocessing procedures that are provided in the revised Operation Manuals.

Per the company's discussions with FDA, comprehensive revisions as described below have been made to the instructions in the ED-530XT Operation Manual (Cleaning, Disinfection and Storage). These revisions modify the cleaning and disinfection processes and require the use of a new disposable distal end cleaning brush [Model WB1318DE] to be used for the cleaning of the duodenoscope's distal tip, forceps elevator and elevator recess, in addition to use of the existing Fujifilm valve cylinder cleaning brush [Model WB11002FW2]. A box containing twenty WB1318DE disposable distal end brushes is being provided per scope model along with this Field Correction letter and a copy of the revised ED-530XT Operation Manual (Cleaning Disinfection and Storage) containing FUJIFILM reprocessing recommendations. These new distal end brushes [Model WB1318DE] will be provided at no charge to accommodate up to six months of scope usage after the release date of this notification letter.



Below are the main differences in the revised manual reprocessing (cleaning and high-level disinfection) procedures:

Pre-Cleaning

- ❖ *During immersion of the scope tip in detergent solution, move the forceps elevator back and forth and aspirate detergent solution while the forceps elevator is raised and while lowered.*

Manual Cleaning

- ❖ *Additional brushing of the distal tip, forceps elevator and elevator recess first using the existing Fujifilm valve cylinder cleaning brush [Model WB11002FW2] and then using the new disposable [Model WB1318DE] cleaning brush.*
- ❖ *Additional flushing of detergent and rinse water onto the forceps elevator/recess while the elevator is both raised and lowered.*
- ❖ *Additional flushing steps and increased channel flushing volumes of detergent and rinse water.*

Manual High-Level Disinfection

- ❖ *Additional flushing of disinfectant and rinse water onto the forceps elevator/recess while the elevator is both raised and lowered. Additional raising and lowering of the elevator while immersed in disinfectant solution and rinse water.*
- ❖ *Additional flushing steps and increased flushing volumes of disinfectant and rinse water through the scope's internal channels.*

The revised reprocessing techniques were developed and validated in accordance with FDA's recommendations set forth in its March 17, 2015, guidance document entitled, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*.

One copy of the revised Operation Manual and one box of the disposable distal end cleaning brushes [Model WB1318DE], with 20 brushes per box are included with this notice. Additional copies of manual and boxes of brushes can be requested through your local sales representative.

PLEASE NOTE: NO OTHER FUJIFILM MEDICAL SYSTEMS, U.S.A., INC., ENDOSCOPY DIVISION PRODUCTS ARE INVOLVED IN THIS FIELD ACTION.

All prior versions of the ED-250XT5, ED-450XT5, ED-250XL5 and ED-450XL5 Operation Manuals (Cleaning, Disinfection and Storage) are superseded by the revised Operation Manual coded **202B1259902D** and should be destroyed. Please check with your facility's applicable supply departments to determine if you have any copies of the superseded Operation Manuals.



Please complete the enclosed tracking/verification form and return it to FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division via e-mail to fnonmedicalqa@fujifilm.com or via fax to (973) 633-8818.

Please note that you must return the completed form even if you do not have any Operation Manuals to destroy. Your local sales representative can assist you in completing this form. This information is essential in order to maintain recall effectiveness information required by FDA.

FUJIFILM Medical Systems, U.S.A., Inc., Endoscopy Division has a dedicated team of Clinical Specialists (CS) who visit customer facilities and perform reprocessing in-servicing and training. If you would like to set up a site visit with our CS team to have an in-service regarding these updated FUJIFILM duodenoscope reprocessing instructions, please contact Stephen Budda, Senior Manager, Clinical Education and Product Coordination at (316)-281-5625 or via email at fmsuesdin-service@fujifilm.com.

Thank you for your support. Please contact your FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division sales representative if you have any questions regarding this field correction, any of our products, or would like assistance.

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

Faye Dunn
Director Regulatory Affairs

Enclosures

http://www.fujifilmusa.com/products/medical/endoscopy/pdf/ED250XL5_ED450XL5_ED250XT5_ED450XT5_CDS.pdf

TRC-002.04.00



STEPS FOR URGENT FIELD CORRECTION

The Tracking/Verification Form attached to this letter must be completed and returned even if you do not have any superseded operation manuals to destroy.

- 1. Segregate the Product.** Please immediately remove **all** superseded operation manuals from your inventory (regardless of their location) and destroy this product.
- 2. Complete the Tracking/Verification Form.** Complete and return the enclosed tracking/verification form (even if you do not currently have any of the superseded operation manuals to destroy). Your FUJIFILM Medical Systems, U.S.A., Inc., Endoscopy Division sales representative can assist you in completing the form.
- 3. Return the Complete Tracking/Verification Form** via e-mail to fnonmedicalqa@fujifilm.com or via fax to (973) 633-8818.



VOLUNTARY FIELD CORRECTION

Tracking/Verification Form for Effectiveness Check

PLEASE FILL OUT AND RETURN

(via e-mail to fnonmedicalqa@fujifilm.com or fax to 973-633-8818)

**We have received the current version of the OPERATION MANUAL:
Cleaning, Disinfection and Storage, CODE 202B1259902D**

(Please check one of the following options)

- 1. We do not have superseded versions of the aforementioned Operation Manuals (Cleaning Disinfection and Storage) in stock or on hand.
- 2. We have destroyed all superseded versions of the aforementioned Operation Manuals (Cleaning Disinfection and Storage) we had in stock or on hand.

(Please also let us know if you no longer own any of the following endoscope models by checking below)

- 1. We no longer own the *ED-250XT5, ED-450XT5, ED-250XL5 or ED-450XL5* endoscope(s).

ACCOUNT NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

PRINTED NAME: _____

TITLE: _____

SIGNATURE/ DATE: _____

CURRENT E-MAIL / TEL. NO.: _____



ATTACHMENT 1

REVISED OPERATION MANUAL:

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