

FIELD SAFETY NOTICE

Product: Ultrasonic Endoscope

- EG-530UT2
- EG-530UR2

Type of Action: Notification of the instruction manual revision

Dear Customers,

Fujifilm is issuing this Field Safety Notice for Ultrasonic Endoscope EG-530UT2/EG-530UR2.

This Field Safety Notice is intended to inform you about the following:

- what the problem is
- the actions that should be taken by the customer/user

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Description of the problem

It was pointed out that evaluation of the cleaning and disinfection are insufficient in October 2013 by authority of Germany. Therefore, Fujifilm conducted the evaluation of manual cleaning, disinfection, combination evaluation of washer disinfector and reflected the cleaning, disinfection condition at the time of the evaluation in the instruction manuals.

Fujifilm will provide the revised instruction manuals "Cleaning, Disinfection and Storage".

According to the procedure of the revised instruction manuals, please conduct cleaning and disinfecting after this.

Below are the main differences in the instruction manual revision:

- Quantification of brushing times
- Quantification of the amount of injecting liquid

Actions to be taken by customer/user

- (1) According to the procedure of the revised instruction manuals, please conduct cleaning and disinfecting for target product.
- (2) Please discard all instruction manuals of the previous version.

FUJIFILM is committed to providing products and services of the highest quality. Your satisfaction with FUJIFILM products and with our response to this issue is very important to us. If you have any questions about this matter, please contact your local FUJIFILM office.

Yours sincerely,

FUJIFILM

Aquilant Endoscopy

Aquilant House, Unit B1-B2, Bond Close, Kingsland Business Park, Basingstoke, Hampshire,
RG24 8PZ, England - Tel.: 01256 365 456

FIELD SAFETY NOTICE

Customer Feedback Form

Please complete this feedback form and fax or email it back.
Thank you for your cooperation.

Customer/Facility Name:

Address:

Instrument Serial Number:

I confirm that I have received and understand the attached notice.

This notice does not apply to my facility.

The device has been transferred to another organization.

Customer Name:

Position:

Signature:

Date:

Phone number:

If we have the wrong contact information about you, please correct below:

Customer/Facility Name:

Address:

Please FAX or email this completed form to:

Aquilant Endoscopy

Aquilant House, Unit B1-B2, Bond Close, Kingsland Business Park, Basingstoke,
Hampshire, RG24 8PZ, England:

FAX: 01256 365 486

Email: qualitycontrol@aquilantservices.com