



July XX, 2021
Olympus reference: QIL 154-007

URGENT FIELD SAFETY NOTICE

NOTIFICATION ABOUT SOFTWARE UPDATE FOR CV-1500 AND RESUMPTION OF USE WITH EZ1500 SERIES ENDOSCOPES

Article number	Affected Model	Affected serial numbers
N6129030 N6129050	GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 (EN) GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 (UK)	All serial numbers
N6022430 N6022450	COLONOVIDEOSCOPE CF-EZ1500DI (EN) COLONOVIDEOSCOPE CF-EZ1500DI (UK)	All serial numbers
N6022530 N6022550	COLONOVIDEOSCOPE CF-EZ1500DL (EN) COLONOVIDEOSCOPE CF-EZ1500DL (UK)	All serial numbers
N6011250	EVIS X1 VIDEO SYSTEM CENTER CV-1500	The third digit of the affected serial number is “0” or “1” as follows; 7#0####, 7#1#### and a part of 7#2#### (Software version before version 2.0)

Attention: Endoscopy Department, Risk Management Department

Dear Healthcare Professional,

Olympus Medical Systems Corporation (“Olympus”) is writing to inform you of a Corrective Action for the Olympus CV-1500, CF-EZ1500DL/I and GIF-EZ1500 (“EZ1500 series endoscopes”) devices listed above. These products are used with other supporting equipment for endoscopy and endoscopic surgery within the digestive tract.

Background Information

Olympus received complaints reporting unintentional thermal tissue damage associated with excessive light irradiation from the illumination light of the CF-EZ1500DI and GIF-EZ1500. From January 2021 onwards, Olympus requested that customers stop using the EZ1500 series endoscopes (CF-EZ1500DL, CF-EZ1500DI and GIF-EZ1500) by distributing a Field Safety Notice to all affected EZ1500 customers (Olympus reference: QIL 153-015).

Corrective Action

Olympus has now finished developing countermeasures for the CV-1500 processor to mitigate unintentional thermal tissue damage when used in conjunction with EZ1500 series endoscopes. With a new software update, the maximum light intensity will be improved and better controlled, without negative impact on the image quality.

Olympus will implement the software update to all existing CV-1500 devices in the market to ensure that users who intend to use EZ1500 series endoscopes in the future will have the latest software version with the improved light control.

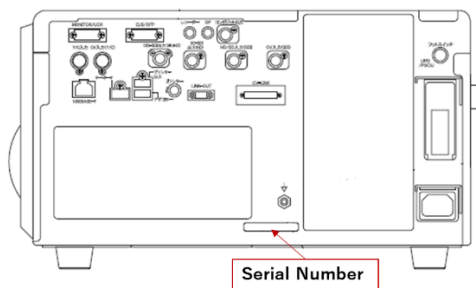
In addition, Olympus revised the OPERATION MANUAL of EZ1500 series endoscopes in order to provide a caution to users about the potential influence of intensive light on tissue. Olympus performed additional tests and recognizes there is always a certain thermal influence to the mucosa by nature of the illumination light in specific conditions, especially when the light guide lenses come into contact with tissue. The updated OPERATION MANUAL provides EZ1500 series endoscope users with further guidance on this phenomenon.

A summary of the updated OPERATION MANUAL sections can be found in **Attachment 1 “Important Information – Please Read Before Use ■Precautions for illumination light emitted from the endoscope’s distal end”**

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected CV-1500 and/or EZ1500 series endoscopes. **Olympus therefore requires you to take the following actions:**

1. Carefully read the content of this Field Safety Notice as well as the **Attachment 1 “Important Information – Please Read Before Use ■Precautions for illumination light emitted from the endoscope’s distal end”**
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the referenced attachment and append the **Attachment 1** to the existing IFU of the EZ1500 series endoscopes.
3. Inspect all CV-1500 devices in your possession and identify their serial numbers. The serial number can be found on the back of device as illustrated in the following picture.



4. Please note on the enclosed FSN Reply Form the CV-1500(s) and EZ1500 endoscope series serial number(s) available in your facility and that you have received, understood, and followed this information. Kindly also indicate the quantity of required OPERATION MANUAL hard copies for the EZ1500 series per model on the enclosed Reply Form.

Note: Please note that the updated local OPERATION MANUAL translations are available on the following Olympus webpage: www.olympus-europa.com.

When opening the webpage select 'Medical Systems', select 'Contact & Support', click on the magnifying symbol (🔍), select 'Instruction Manual' and search for the relevant model (e.g. 'GIF-EZ1500').



5. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
6. An Olympus representative will reach out to you in the coming weeks to arrange a mutually convenient time to have your CV-1500(s) updated.
Note: Only CV-1500 serial numbers mentioned on page 1 of this FSN will need a software update, all other serial numbers do already contain the software version 2.0 or 2.1 and are therefore not affected by this safety related software update.
7. Allow an Olympus employee to conduct the software update for your CV-1500 devices.
※The software update will take about 2 hours for each CV-1500
8. After an Olympus employee completes the required software update for your CV-1500 device(s), the use of the EZ1500 series endoscopes can be resumed.
9. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at [XXX] or at [XXX].

Sincerely,



REPLY FORM – QIL 154-007

URGENT FIELD SAFETY NOTICE		
NOTIFICATION ABOUT SOFTWARE UPDATE FOR CV-1500 AND RESUMPTION OF USE WITH EZ1500 SERIES ENDOSCOPES		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[Date]		
Model name	Quantity of replacement Operation manuals required	Serial numbers available in your facility
GASTROINTESTINAL VIDEOSCOPE GIF- EZ1500		
COLONOVideoscope CF-EZ1500DI		
COLONOVideoscope CF-EZ1500DL		
EVIS X1 VIDEO SYSTEM CENTER CV-1500		

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.

Further I confirm that I have transferred the content of the attached FSN and **Attachment 1** to all affected departments on which this action has an impact and attached the referenced attachment to the existing IFUs. I understand the necessity of following the updated OPERATION MANUAL carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.



Attachment 1: Revision of the Operation manual

Following warning and note have been added to GIF-EZ1500 OPERATION MANUAL (RC7075_03, P. 11) and CF-EZ1500DI/L OPERATION MANUAL (RC7080_03, P. 12)

“Important Information – Please Read Before Use

■Precautions for illumination light emitted from the endoscope’s distal end”

WARNING

Do not contact patient’s body cavity with distal end of endoscope for a long time during endoscopic observation or treatment, or irradiate certain place. Burn may result due to contact with light energy or heat caused by irradiation.

NOTE

Olympus has conducted animal testing to simulate general endoscopic operation. Results of this testing confirmed that all thermal damage was limited to the submucosa tissue. These test results were obtained under the condition where the distal end of the endoscope was in physical contact to the mucous membrane using maximum light intensity for time duration*1 indicated in the table.

Light intensity	Time duration*1
Maximum light intensity of Near focus mode	40 sec.
Maximum light intensity of Normal focus mode	15 sec.

*1 Defined by Olympus as the worst case under the general endoscopic operation