



Reference: 2021-004M

05-Jul-2021

FIELD SAFETY NOTICE

Notification about software update for CV-1500 and resumption of use with EZ1500 series endoscopes

Dear Sir/Madam,

Olympus is implementing a Field Safety Corrective Action for the devices listed below. The affected models and serial numbers are listed below.

Model Number	Model Description	Serial Number
GIF-EZ1500	Gastrointestinal Videoscope	All serial numbers
CF-EZ1500DI	Colonovideoscope	
CF-EZ1500DL	Colonovideoscope	
CV-1500	Evis X1 Video System Center	Third digit of the serial number is "0" or "1" as follows; 7#0#####, 7#1#####, and a part of 7#2#### (Software version before version 2.0)

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 onward, 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.

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"**

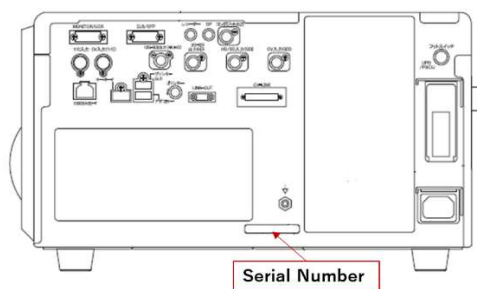
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Action(s) to be taken by end user

Our records indicate that you have purchased the affected product(s) and we requests you to take the following action(s):

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. Send the completed FSN Response Form back to your Olympus representative.
5. 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.
6. 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
7. 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.
8. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.



Contact information

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Sincerely,

**Loh E
Thel**

Digitally signed
by Loh E Thel
Date: 2021.07.05
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Loh E Thel
Division Manager
Medical Systems Business Division
Olympus Singapore Pte. Ltd.

Cc: Chairman Medical Board and relevant Head of Departments

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Attachment 1: Revision of the Operation manual

Following warning and note have been added to GIF-EZ1500 OPERATION MANUAL and CF-EZ1500DI/L OPERATION MANUAL

“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