



January XX, 2021
Olympus reference: QIL 153-015

URGENT FIELD SAFETY NOTICE

QUARANTINE OF THE EZ1500 SERIES ENDOSCOPES

Attention: **Endoscopy Department, Risk Management Department**

Affected Products and serial numbers	Serial numbers
N6129030 GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 (EN) N6129050 GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 (UK) N6022430 COLONOVideoscope CF-EZ1500DI (EN) N6022450 COLONOVideoscope CF-EZ1500DI (UK) N6022530 COLONOVideoscope CF-EZ1500DL (EN) N6022550 COLONOVideoscope CF-EZ1500DL (UK)	All serial numbers

Dear Healthcare Professional,

Olympus Medical Systems Corporation ("Olympus") is writing to inform you of a quarantine action of all the above-referenced Olympus endoscope models COLONOVideoscope CF-EZ1500DL/I and GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500.

Olympus recently received one complaint of unintentional mucosal thermal injury to a patient that was reportedly associated with excessive light irradiation from the illumination light of the CF-EZ1500DI.

This phenomenon was observed by the facility while performing observations under the following two scenarios (i) using NBI (Narrow Band Imaging), and (ii) using white light illumination (WLI) and a blue stain, crystal violet.

Olympus presumes that if the light guide lens contacts the mucosa during observation, excessive irradiation from the endoscopic illumination light may cause thermal injury to that mucosa. In addition, we have received complaints that the distal ends of CF-EZ1500DL/I and GIF-EZ1500 devices were hot before starting the procedure or after removing the devices from patients.

Olympus is preparing the countermeasures to solve this phenomenon. This phenomenon occurs only with the subject EZ1500 endoscopes in combination with the VIDEO SYSTEM CENTER CV-1500. The use of other endoscopes with CV-1500 is not associated with this phenomenon.



Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more subject EZ1500 series endoscopes. Therefore, Olympus requires you to take the following actions:

1. Inspect your inventory and identify any subject EZ1500 series endoscopes listed above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Cease any further use of any subject EZ1500 series endoscopes you have. STOP USING the subject device and remove it from your inventory, and QUARANTINE it until a countermeasure is available.
* In case of emergency and the only available option for patient care is the use of the EZ1500 series endoscopes, you should give careful consideration if the benefits of conducting the procedure using the EZ 1500 scope outweigh the risks discussed in the letter. If a decision is made to proceed with the procedure using the EZ 1500 scope, to help avoid unintentional mucosal thermal injury, DO NOT USE (i) NBI or (ii) white light illumination (WLI) in conjunction with a blue stain such as crystal violet.
3. Please fill in the enclosed Reply Form confirming that you have quarantined the affected inventory and will not use the device(s) until Olympus provides you with a countermeasure. Please also include the serial numbers, as well as the total number of subject EZ1500 series endoscopes in your possession.
4. 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.
5. Olympus is currently considering the schedule and will contact you once the countermeasure can be implemented to release the quarantine.

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

Olympus is aware that the implementation of these measures may cause inconvenience to you. However, we fully appreciate your prompt cooperation in addressing this situation and working with us to ensure your patients are treated only with safe and effective Olympus products that you have come to rely upon.

In case of any questions, please do not hesitate to contact your local Olympus partner who will support you or make the necessary arrangements.

Please return the completed form to [Olympus Subsidiary/Distributor {by end of \[month\]}](#)

Yours sincerely,

[Olympus Subsidiary/Distributor](#)



REPLY FORM – QIL 153-015

OLYMPUS URGENT FIELD SAFETY NOTICE			
Quarantine of COLONOVideoscope CF-EZ1500DL/I and GASTROINTESTINAL Videoscope GIF-EZ1500 due to possible thermal injury to mucosa			
[Name & Address of Hospital/Medical Facility]			
[Dept/Attn]			
[Date]			
Model Name/Article Number	Total Quantity quarantined	Serial number(s)	

Dear Sirs,

Herewith we confirm the receipt of your Field Safety Notice. We understand the contents of this letter and have inspected our inventory of Olympus EZ1500 series endoscopes, have ceased using all affected products, and have quarantined the affected products that we located.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by **XXXX**.