OLYMPUS

URGENT: MEDICAL DEVICE CORRECTION

Olympus EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE

Product Name:

Catalog number	Serial Number	UDI-DI
GIF-1TH190	All	04953170343360 04953170437014

Date: 31-Oct-2024

Attention: Endoscopy Department, Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you that high-level disinfection ("HLD") with Acecide-C disinfectant in the Olympus OER-Pro Automated Endoscope Reprocessor ("AER") has been removed as a compatible reprocessing method from our Instructions for Use when reprocessing the GIF-1TH190 EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE ("GIF-1TH190"). The GIF-1TH190 endoscope is intended for use in the upper digestive tract, including the esophagus, stomach and duodenum. This action is directed to GIF-1TH190 customers who use the OER-Pro plus Acecide-C disinfectant for high level reprocessing.

Reason for Action:

This corrective action is being taken after Olympus conducted a retrospective review of past changes to the GIF-1TH190 and submitted a new 510(k) application to the Food and Drug Administration. Olympus conducted additional reprocessing validation for the GIF-1TH190 and determined the following change is required:

- High-Level Disinfection with Acecide-C disinfectant in the Olympus OER-Pro Automated Endoscope Reprocessor is removed as a compatible reprocessing method. The GIF-1TH190 can continue to be reprocessed with Aldahol® 1.8 disinfectant in the OER-Pro. High-level disinfection with Acecide-C is still compatible for the GIF-1TH190 in the OER-Elite Automated Endoscope Reprocessor.

Risk to Health:

Additional and more rigorous reprocessing validation that more accurately simulates clinical use of the device was conducted with the Acecide-C disinfectant in the OER-Pro did not meet the required high-level disinfection endpoint, as per updated FDA guidelines. The official FDA guidance requires that all inoculation sites must achieve a minimum of 6-$\log_{10}$ microorganism reduction when submitted to a high level disinfection cycle. At the conclusion of two studies, all inoculation sites (four sites per device) tested within the scopes achieved greater than a 6- $\log_{10}$ microorganism reduction except for three inoculation sites. Three of the eighteen representative inoculation sites achieved a 5.2, 5.48 and 5.6-$\log_{10}$ reduction in the air-water channel test location instead of the 6-$\log_{10}$ reduction needed to satisfy the acceptance criteria for high-level disinfection. All other validation testing passed for the GIF-1TH190, including the OER-Pro with Aldahol, the OER-Elite with Aldahol and Acecide-C, Ethylene

Oxide sterilization and manual endoscope reprocessing. Please note that while manual high-level disinfection is a validated and appropriate method, many professional societies advise against it due to the increased risk of human error. [1]

As a result, Olympus conducted a Health Hazard Assessment of the GIF-1TH190, including a retrospective review of positive microbial cultures and infections associated with the GIF-1TH190. This analysis conservatively included five adverse events for which the root cause of these complaints could not be identified and the relationship between the GIF-1TH190 and the reported events could not be confirmed. While the probability of patient exposure to microorganisms (device contamination) is low at 0.00013% (calculated by the number of adverse events divided by the number of clinical procedures), contamination under certain circumstances can potentially lead to patient infections, although the actual incidence depends on a number of factors. The overall risk to health has been assessed and is deemed not likely to cause infection for all patient populations. Out of an abundance of caution and to minimize the risk of infection to the fullest extent possible, Olympus is removing compatibility of the OER-Pro with Acecide-C of the GIF-1TH190 for reprocessing from the Instructions for Use.

Olympus continues to investigate this matter and we are performing additional testing focused on identifying the root cause of the obtained test results. We will communicate further on alternative programs for users regarding Acecide-C removed from OER-Pro labeling for the GIF-1TH190 reprocessing.

Corrective Action Required: Customers Who Use the OER-Pro with Acecide-C to Reprocess the GIF-1TH190

Olympus is revising the labeling such that the GIF-1TH190 is no longer a compatible endoscope for reprocessing with Acecide-C in the OER-Pro. The GIF-1TH190 is compatible with Acecide-C in the OER-Elite. You can continue to use the OER-Pro with Acecide-C for reprocessing other Olympus endoscope models.

Because Olympus recognizes the importance of patient care continuity, Olympus is offering programs to help address and resolve this situation.

Your sales representative will contact you within the next month to discuss potential OER-Elite and GIF-1TH190 transition programs. To ensure optimal patient safety, we encourage transitioning to the OER-Elite as soon as possible. Alternatively, you may choose to transition to another compatible automated endoscope reprocessor. For non-Olympus AER models, please contact the AER manufacturer to confirm compatibility with the GIF-1TH190 endoscope. If your facility does not have alternatives, you may consider assembling a multi-disciplinary team to conduct a risk assessment on the use of the OER-Pro with Acecide-C in accordance with your healthcare facility protocols after weighing the potential benefits of continued OER-Pro with Acecide-C use versus the potential risk to health as described above.

[1] Society of Gastroenterology Nurses and Associates (SGNA). Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes. 2023; Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST91:2021, Flexible and Semi-Rigid Endoscope Reprocessing in Health care Facilities. 2021

Olympus requires you to take the following actions:

1. Carefully read the content of this Medical Device Correction notification.
2. Please ensure reprocessing staff and other users of the OER-Pro AER are aware of this corrective action.
3. Olympus requests that you acknowledge receipt of this letter through our Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0462"
    c. Complete the form as instructed.
4. If you have further distributed the GIF-1TH190, identify the recipients and forward this notification to them.

Olympus requests that you report any complaints, including infections or persistent microbial colonization associated with any Olympus endoscope to the Technical Assistance Center (TAC) at 1- 800-848-9024 (option 1), and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

If you require additional information about the GIF-1TH190 reprocessing, you can obtain additional information from our Technical Assistance Center (TAC) at 1-800-848-9024 (option 1).

Olympus fully appreciates your prompt cooperation. If you require additional information, please do not hesitate to contact me by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas