31-October-2025

URGENT Medical Device Safety Alert

OLYMPUS AUTOMATED ENDOSCOPE REPROCESSORS

Product Name	Model/Catalog Number	Serial/Lot Number(s)	UDI PI
AUTOMATED ENDOSCOPE REPROCESSOR (AERs)	OER-Elite	All	04953170404047
	OER-PRO		04953170258589
	OER-Mini		04953170331619

ATTENTION: Reprocessing Department, Biomedical Department, Risk Management

Dear Health Care Professional:

Olympus is writing to inform you of a Medical Device Safety Alert on all Olympus Automated Endoscope Reprocessors (AER). Olympus Endoscope Reprocessors are intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes and their accessories.

Reason for Action:

Olympus received notification of a fire-related incident involving the OER-PRO. There were no patient or staff injuries that occurred during this incident. After an extensive investigation of this incident, including by external fire subject matter expert, the root cause of this incident could not be conclusively determined. Out of an abundance of caution, Olympus is providing Warnings/Cautions reminders associated with all Olympus Endoscope Reprocessors on the list above. Additionally, we are proactively evaluating whether further enhancements to Olympus AER devices could be implemented and will inform you of future design updates as appropriate.

Olympus reminds users to follow the Warnings/Cautions and inspections outlined in all Olympus Endoscope Reprocessor Operation Manuals which are important to reduce the potential risk of fire to the device. If any irregularity is observed during the inspections, do not use the equipment and contact Olympus. Using the equipment when an irregularity has been detected may impair operation of the equipment and could cause leakage, electric shock, burns and/or fire.

Pertinent Warnings/Cautions from the Olympus Endoscope Reprocessor Operation Manual are outlined below.

- Do not block the ventilation openings on the gas filter cases with the replacement date indication sticker or any other foreign material. Blocking the ventilation not only hinders deodorization but may also cause the device to malfunction.
- When using disinfectant solution and alcohol, Olympus recommends using gas filters and running this equipment in well-ventilated areas. Refer to the guidelines related to ventilation stated in the Olympus Endoscope Reprocessor Operation Manual.
- Always remove the tank from the detergent/alcohol drawer before putting detergent or alcohol in the tank. If detergent or alcohol is spilled on the detergent/alcohol drawer, it could get inside the equipment and contact an electrical part inside, causing an electric shock or fire hazard.
- Do not install this equipment in any place where any of the following is present:
    - High oxygen concentration
    - Oxidizing substances, such as Nitrous Oxide (N2O)
    - Flammable anesthetic gas

Please refer to the Olympus Endoscope Reprocessor Operation Manual for additional Warnings/Cautions. Please follow the recommended maintenance schedule and ensure that only properly trained personnel conduct repairs and maintenance.

Risk to Health:

Harms associated with a fire or thermal event involving an Olympus Endoscope Reprocessor may include user burns or respiratory difficulties. Thermal injuries sustained in facility reprocessing room fires could pose critical or life-threatening risks, particularly in environments where flammable gases, oxygen sources, or combustible materials may be present. Additionally, exposure to smoke or fumes emitted during such events may result in respiratory difficulties with prolonged exposure. Further, this issue can cause operational disruptions, including delays or cancellations of procedures due to the need to acquire replacement devices or implement alternative reprocessing methods. Olympus has received 32 complaints that were found to exhibit possibly related failure modes resulting in burning smells, smoking, and overheating. Olympus has not received any reported injuries.

Actions Required:

Our records indicate your facility purchased one or more affected Automated Endoscope Reprocessors. **Olympus requests you take the following action:**

1. Carefully read the content of this notification.
2. Inspect your inventory for the referenced devices and identify any device with the model names specified in the top section of this letter.
3. Ensure all personnel are completely knowledgeable and thoroughly aware of the contents of this letter.
4. Olympus requests that you acknowledge receipt of this letter through our recall web portal:

   a. Go to https://olympusamerica.com/recall

   b. Enter the recall number: "0480"

   c. Complete the form as instructed.
5. If you have further distributed the affected product, please identify these customers, and forward this notification to them.

Olympus requests that you report any complaints, including but not limited to fire, smoke or burning smell, to 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.

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

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager, Field Corrective Action, Americas