November XX, 2020
Olympus reference: QIL 153-012

URGENT FIELD SAFETY NOTICE

RE: UPDATED INSTRUCTIONS FOR USE FOR SEVERAL OLYMPUS ULTRASOUND ENDOSCOPES

Attention: Operating Room Manager, Risk Management Department and Reprocessing Units

	Model Name	Serial number
OLYMPUS Endoscopic Ultrasound Endoscopes	**GF-UC140P-AL5,** **GF-UCT140-AL5,** **GF-UE160-AL5,** **GF-UE260-AL5,** **GF-UCT260,** **GF-UCT180,** **GF-UE190,** **GF-UE290,** **GF-UC240P-AL5,** **GF-UCT240-AL5,** **GF-UM20,** **GF-UM130,** **GF-UMQ130,** **GF-UMP230,** **CF-UMQ230,** **GF-UM240,** **GF-UMQ240,** **GF-UM160,** **GF-UC160P-OL5,** **GF-UCT160-OL5,** **GF-UM2000,** **GF-UC2000P-OL5,** **GF-UCT2000-OL5**	All

Dear Healthcare Practitioner:

Olympus is writing to inform you of a Field Safety Corrective Action for the Olympus Endoscopic Ultrasound Endoscopes ('EUS') listed above. The above referenced EUS endoscopes are used with other supporting equipment for endoscopic real-time ultrasound imaging and endoscopic surgery within the gastrointestinal tract.

Olympus issues validated, revised instructions for use for the referenced EUS endoscopes after an investigation indicated a potential risk of infection due to residual blood and foreign matter in the air/water channel of the GF-UCT260, GF- UCT240-AL5, GF- UCT140-AL5, and GF-UC240P-AL5 Ultrasound endoscopes. The referenced EUS endoscope models affected by this FSCA have a similar structure to the four Ultrasound endoscopes. To further mitigate this risk, Olympus has updated the instructions for use for the affected EUS endoscope models by adding an inspection step before reprocessing to help determine if there is complete blockage of the air/water channel. If air/water channel blockage is identified, **do no longer use the endoscope** and contact Olympus to make arrangements to repair the endoscope.

Please find the detailed descriptions about the required actions to determine if there is a full blockage of the air/water channel in the attached '*Addendum to Operation Manuals for OLYMPUS ULTRASOUND ENDOSCOPES*'. **This new inspection steps should be implemented immediately.**

Olympus continues analyzing this finding. Should the manufacturer Olympus Medical Systems Corporation identify any additional recommendations that could further mitigate the potential risk of infection, you will be contacted accordingly including potential recommendations and instructions.

Action steps to be taken by the end user:

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

1. Inspect your inventory for the referenced devices and identify any device with the model number specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model number can be found on the device as illustrated in the following picture.

2. Carefully read the content of this Field Safety Notice as well as the attached '*Addendum to Operation Manuals for OLYMPUS ULTRASOUND ENDOSCOPES*'. This Addendum contains the instructions on how to determine if there is a full blockage of the air/water channel. Attach the enclosed Addendum to the existing Instruction for Use documents.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the new inspection steps. The new inspection steps shall be performed immediately after the clinical procedure and prior to endoscope reprocessing.
4. Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice including the attached Addendum and the importance of following the operation instructions carefully by returning the completed Reply Form back to your Olympus representative (xxx) latest by XXXX. Kindly also indicate the quantity of required instructions for use hard copies per Model on the Reply Form. Please note that Olympus is currently still adopting all the affected instructions for use and will update the local translations afterwards. Once the instructions for use have been updated the most current language version will be 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. 'GF-UE190').

5. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attached Addendum, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

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

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,

REPLY FORM – QIL 153-012

OLYMPUS URGENT FIELD SAFETY NOTICE **UPDATED OPERATION MANUALS FOR SEVERAL OLYMPUS ULTRASOUND ENDOSCOPES**			
[Name & Address of Hospital/Medical Facility]			
[Dept/Attn]			
[**Date]**			
Additional Operation Manual request Should you require hard copies of these updated instructions for use, please indicate in the table below behind each model the total quantity required. Your local Olympus organization will then arrange to send you the hard copies once the translation updates are completed.			
Model name	**Quantity of replacement manuals required**	**Model name**	**Quantity of replacement manuals required**
GF-UC140P-AL5		**GF-UMQ130**	
GF-UCT140-AL5		**GF-UMP230**	
GF-UE160-AL5		**CF-UMQ230**	
GF-UE260-AL5		**GF-UM240**	
GF-UCT260		**GF-UMQ240**	
GF-UCT180		**GF-UM160**	
GF-UE190		**GF-UC160P-OL5**	
GF-UE290		**GF-UCT160-OL5**	
GF-UC240P-AL5		**GF-UM2000**	
GF-UCT240-AL5		**GF-UC2000P-OL5**	
GF-UM20		**GF-UCT2000-OL5**	
GF-UM130			

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN and Addendum to all affected departments on which this action has an impact and attached the referenced Addendum to the existing instructions for use. I understand the necessity of following the EUS operation instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

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