Reference: 2021-002M

9th August 2021

URGENT - FIELD SAFETY NOTICE

To all users of Olympus Endoscope Reprocessor OER-AW

Re: Endoscope Label on Front Door of Olympus Endoscope Reprocessor OER-AW

Dear Customer,

Olympus is implementing a Field Corrective Action for the device listed below. The affected model and serial number is listed below.

Model Number	Model Description	Serial Number
OER-AW	Endoscope Reprocessor	2933077, 2933100, 2933101, 2933113, 2033164, 2033295, 2033297, 2033298, 2033299, 2033300, 2033305, 2033306, 2033307,

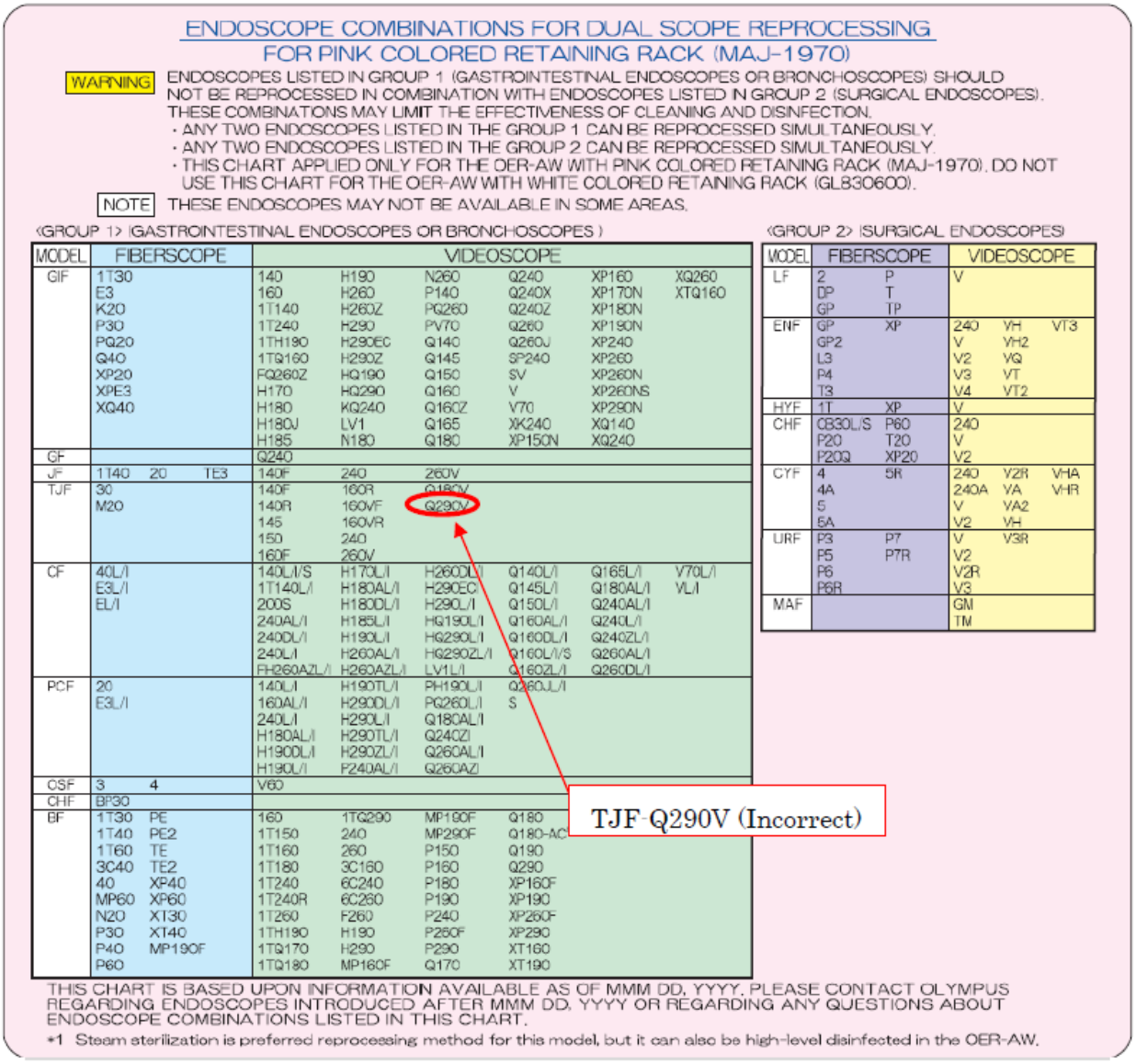
Olympus has become aware of an issue that requires your attention. This notice pertains to the consistency of the categories for Endoscope setup displayed on the "ENDOSCOPE COMBINATIONS FOR DUAL SCOPE REPROCESSING" label on the front door of OER-AW endoscope reprocessor.

On the label affixed on the front door of the affected OER-AW, the TJF-Q290V endoscope model is not correctly categorized because the TJF-Q290V must not be combined with any other endoscope and must be reprocessed individually.

The categorization of the TJF-Q290V and the fact this model must be reprocessed individually is correctly indicated on the warning label at the top lid of the OER-AW as well as the devices' Instructions for Use (IFU).

Olympus has not received any complaint associated with the incorrect categorization of the TJF-Q290V endoscope on the label affixed on the front door of the OER-AW. However, it is possible that a customer could become confused about the proper endoscope setup when reprocessing a TJF-Q290V scope with an OER-AW.

To prevent this confusion, Olympus will replace the label currently on the front door of your OER-AW with the correct label.



ENDOSCOPE COMBINATIONS FOR DUAL SCOPE REPROCESSING
FOR PINK COLORED RETAINING RACK (MAJ-1970)

WARNING ENDOSCOPES LISTED IN GROUP 1 (GASTROINTESTINAL ENDOSCOPES OR BRONCHOSCOPES) SHOULD NOT BE REPROCESSED IN COMBINATION WITH ENDOSCOPES LISTED IN GROUP 2 (SURGICAL ENDOSCOPES). THESE COMBINATIONS MAY LIMIT THE EFFECTIVENESS OF CLEANING AND DISINFECTION.
- ANY TWO ENDOSCOPES LISTED IN THE GROUP 1 CAN BE REPROCESSED SIMULTANEOUSLY.
- ANY TWO ENDOSCOPES LISTED IN THE GROUP 2 CAN BE REPROCESSED SIMULTANEOUSLY.
- THIS CHART APPLIED ONLY FOR THE OER-AW WITH PINK COLORED RETAINING RACK (MAJ-1970). DO NOT USE THIS CHART FOR THE OER-AW WITH WHITE COLORED RETAINING RACK (GL830600).

NOTE THESE ENDOSCOPES MAY NOT BE AVAILABLE IN SOME AREAS.

<GROUP 1> (GASTROINTESTINAL ENDOSCOPES OR BRONCHOSCOPES)

MODEL	FIBERSCOPE	VIDEOSCOPE
GIF	1T30, E3, K20, P30, PQ20, Q40, XP20, XPE3, XQ40	140, 160, 1T140, 1T240, 1TH190, 1TQ160, FQ260Z, H170, H180, H180J, H185, H190, H260, H260Z, H290, H290EC, H290Z, HQ190, HQ290, KQ240, LV1, N180, N260, P140, PQ260, PV70, Q140, Q145, Q150, Q160, Q160Z, Q165, Q180, Q240, Q240X, Q240Z, Q260, Q260J, SP240, SV, V, XK240, XP150N, XP160, XP170N, XP180N, XP190N, XP240, XP260N, XP260NS, XP290N, XQ140, XQ240, XQ260, XTQ160
GF		Q240
JF	1T40, 20, TE3	140F, 240, 260V
TJF	30, M20	140F, 140R, 145, 150, 160F, 160R, 160VF, 160VR, 240, 260V, Q180V, Q290V
CF	40L/I, E3L/I, EL/I	140L/I/S, 1T140L/I, 200S, 240AL/I, 240DL/I, 240L/I, FH260AZL/I, H170LI, H180AL/I, H180DL/I, H185L/I, H190L/I, H260AL/I, H260AZL/I, H260DL/I, H290EC, H290L/I, HQ190L/I, HQ290L/I, HQ290ZL/I, LV1L/I, PH190L/I, PQ260L/I, Q140L/I, Q145L/I, Q160AL/I, Q160DL/I, Q160L/I/S, Q160ZL/I, Q165L/I, Q180AL/I, Q180L/I, Q240AL/I, Q240L/I, Q240ZL/I, Q260AL/I, Q260DL/I, V70L/I, VL/I
PCF	20, E3L/I	140L/I, 160AL/I, 240L/I, H180AL/I, H190DL/I, H190L/I, H190TL/I, H290DL/I, H290L/I, H290TL/I, H290ZL/I, F240AL/I, PQ260L/I, Q180AL/I, Q240ZI, Q260AL/I, Q260AZI, Q260JL/I, S
CSF	3, 4	V60
CHF	BP30	
BF	1T30, 1T40, 1T60, 3C40, 40, MP60, N20, P30, P40, P60, PE, PE2, TE, TE2, XP40, XP60, XT30, XT40, MP190F	160, 1T150, 1T160, 1T180, 1T240, 1T240R, 1T260, 1TH190, 1TQ170, 1TQ180, 1TQ290, 240, 260, 3C160, 6C240, 6C260, F260, H190, H290, MP160F, MP290F, P150, P160, P180, P190, P240, P260F, P290, Q170, Q180, Q180-AC, Q190, Q290, XP160F, XP190, XP260F, XP290, XT160, XT190

<GROUP 2> (SURGICAL ENDOSCOPES)

MODEL	FIBERSCOPE	VIDEOSCOPE
LF	2, DP, GP, P, T, TP	V
ENF	GP, GP2, L3, P4, T3, XP	240, V, V2, V3, V4, VH, VH2, VQ, VT, VT2, VT3
HYF	1T, XP	V
CHF	CB30L/S, P20, P20Q, P60, T20, XP20	240, V, V2
CYF	4, 4A, 5, 5A, 5R	240, 240A, V, V2, V2R, VA, VA2, VH, V2R, VHA, VHR
URF	P3, P5, P6, P6R, P7, P7R	V, V2, V2R, V3, V3R
MAF		GM, TM

TJF-Q290V (Incorrect)

THIS CHART IS BASED UPON INFORMATION AVAILABLE AS OF MMM DD, YYYY. PLEASE CONTACT OLYMPUS REGARDING ENDOSCOPES INTRODUCED AFTER MMM DD, YYYY OR REGARDING ANY QUESTIONS ABOUT ENDOSCOPE COMBINATIONS LISTED IN THIS CHART.

*1 Steam sterilization is preferred reprocessing method for this model, but it can also be high-level disinfected in the OER-AW.

Figure 1. Incorrect "ENDOSCOPE COMBINATIONS FOR DUAL SCOPE REPROCESSING" label

Action(s) to be taken by end user:

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

1. Please read through carefully the enclosed information and share this notice to any healthcare professional from your organization as appropriate.
2. Please inspect your inventory of OER-AW device to identify any of the specified serial number listed in above table.
3. Complete and return the 'Response Form' to Olympus.
4. Upon receiving your 'Response Form', an Olympus representative will contact you to replace the label at the front door of your OER-AW device.

Olympus regrets any inconvenience caused 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 for enquiries
Regulatory Affairs Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7886 9188
Fax : (603) 7887 2833

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

坂口 有史
.....
Yuji Sakaguchi
Managing Director
Olympus (Malaysia) Sdn. Bhd.

Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7887 2833 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2021-002M

URGENT - FIELD SAFETY NOTICE

Re: Endoscope Label on Front Door of Olympus Endoscope Reprocessor Model OER-AW

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been used or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

Serial Number	

Name: _____

Designation: _____

....
Signature & Company Stamp Date