



March 26, 2015

RE: 100% Ethylene Oxide Gas for Sterilization of Olympus Flexible Endoscopes in North America

Dear Health Care Practitioner:

The purpose of this letter is to inform customers that Olympus has successfully validated the efficacy and compatibility of 100% Ethylene Oxide (EtO) gas for sterilization of Olympus endoscopy products. Material compatibility and sterilization validation testing were performed using the EtO sterilization parameters listed below. These parameters are representative of the 3M™ Steri-Vac™ 5XL and Steris Amsco® Eagle® 3017 EtO Sterilizers. If using a different model EtO sterilizer, please confirm with the manufacturer that the sterilizer operates according to the validated parameters listed below.

EtO Phase	Parameter	Value
Conditioning (In Chamber)	Temperature	55 °C
	Vacuum	≤ 0.016 MPa (≤2.3 psia)
	Relative Humidity	50 – 70%
	Humidity pulses	4 pulses
	Time	40-80 minutes
Sterilization	Temperature	55°C
	Vacuum	0.05-0.07 MPa (7.25-10.15 psia)
	Relative Humidity	50 – 80%
	EtO Gas Concentration	0.735-0.740 mg/cm ³ (735-740 mg/liter)
	Exposure time	60 minutes
Post Exposure Evacuation	Vacuum	≤ 0.016 MPa (≤2.3 psia)
	Air Purge Process	Programmed
Aeration	Time	12 hours at 50-57°C or 7 days at room temperature

Caution

Repeated use and reprocessing of endoscopes leads to gradual wear and tear. But reprocessing methods that employ higher temperatures and more caustic/corrosive materials may lead to faster deterioration. In general, sterilization processes are harsher on equipment than disinfection processes. Before each patient procedure, inspect the endoscope for damage, according to the instructions described in each “REPROCESSING MANUAL” and its companion “OPERATION MANUAL”.

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The following Olympus flexible endoscopes and probe models are compatible with and validated for sterilization using 100% EtO gas.

GI ENDOSCOPES		
TYPE	Series	Model(s)
CF	10/20/30/40 100/130/140/160/180/190	ALL
CHF	10/20/30	ALL
		P60
GIF	10/20/30/40 100/130/140/160/180/190	ALL
JF	20/30/40 130/140	ALL
OSF		3 V60
PCF	130/140/160/180/190	ALL
PJF	160	7.5
SIF	100/140/180	ALL
TJF	20/30 130/140/160/180	ALL

SURGICAL ENDOSCOPES		
TYPE	Series	Model(s)
AF		14/22A/28C
BF	20/30/40/60 200/240 160/180/190	ALL
CYF		2/3/4/4A/5/5A/5R 200/240/240A V/V2/V2R/VH/VHR/VHA/VVA/VA2
ENF		P2/P3/P4 L3/T3 GP/XP V/V2/VT/VT2/ V3/VH/VQ
HYF		1T P/XP V
LF		2 P/DP/GP T/TP V



SURGICAL ENDOSCOPES (continued)		
LTF		V/V2/V3 VH/VP/VP-S S190-5/ S190-10 190-10-3D 160/240
MAF		TM/GM
PEF		V
URF		V/V2/V2R P2/P3/P5/P6/P6R

ULTRASOUND ENDOSCOPES		
TYPE	Series	Model(s)
BF	Electronic Ultrasound	UC160F-OL8 / UC180F
CF	Mechanical Ultrasound	UM20
GF	Mechanical Ultrasound	UM30P UM130/UMQ130 UM160
GF	Electronic Ultrasound	UC30P UC140P-DO5 UC140P-AL5 UC160P-OL5 UC160P-AT8 UCT140-DO5 UCT140-AL5 UCT160-OL5 UCT160-AT8 UE160-AL5 UCT180
TGF	Electronic Ultrasound	UC180J
Probe	Ultrasonic Probe for Esophagus	MH-908
Probe	Ultrasonic Probe	RU-75M-R1 / RU-12M-R1 UM-2R-3 UM-3R-3 UM-BS20-26R UM-DG20-31R UM-DP12-25R UM-DP20-25R UM-G20-29R UM-S20-17S / UM-S20-20R UM-S30-20R / UM-S30-25R



If you have any additional questions, please contact your local Olympus sales representative, the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 (Canada).

This letter will be updated when additional information becomes available. Thank you.

Sincerely,

A handwritten signature in black ink, reading "Mary Ann Drosnock". The signature is written in a cursive style.

Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM)
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