



March 25, 2009

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 ± 2°C
	Vacuum	≤ 0.01 MPa (≤1.5 psia)
	Relative Humidity	50 – 70%
	Time	60-80 minutes
Sterilization	Temperature	55°C
	Vacuum	0.056-0.058 MPa (8.12-8.41 psia)
	Relative Humidity	50 – 70%
	EtO Gas Concentration	0.735 mg/cm ³ (735 mg/liter)
	Exposure time	60 minutes
Post Exposure Evacuation	Vacuum	≤ 0.01 MPa (≤1.5 psia)
Aeration	Time	12 hours @ 50-57°C or 7 days @ room temperature

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

GI ENDOSCOPES		
Type	Series	Model(s)
CF	10/20/30/40 100/200 140/240 160/180	ALL
CHF	20/30	ALL
		P60



GI ENDOSCOPES (continued)		
Type	Series	Model(s)
GIF	10/20/30/40 100/200/130/230 140/240 160/180	ALL
JF	20/30 130/140	ALL
OSF		3 V60
PCF	130/140/160/180	ALL
		20/40 S
PJF		7.5
SIF	100/140/180	ALL
TJF	20/30 130/140/160	ALL

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



SURGICAL ENDOSCOPES (continued)		
Type	Series	Model(s)
LTF		160/240 V/V2/V3 VH/VP
URF		P2/P3/P5 V

ULTRASOUND ENDOSCOPES		
Type	Series	Model
BF	Electronic Ultrasound	UC160F-OL8 BF-UC180F
CF	Mechanical Ultrasound	UM20
GF	Mechanical Ultrasound	UM30P UM130/UMQ130 UM160
GF	Electronic Ultrasound	UC30P UC140P-DO5 UC140P-AL5 UC160P-OL5 UCT140-DO5 UCT140-AL5 UCT160-OL5 UE160-AL5
Probe	Ultrasonic Probe for Esophagus	MH-908

ENDOSCOPIC ACCESSORIES		
Type	Series	Model
CD	Heat Probe	11Z 21Z

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 ext 703211 (Canada).

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

Sincerely,

Olympus