



November 12, 2012

Re: **Revised GI Endoscope Reprocessing Manual**

Dear Health Care Professional:

Olympus is pleased to announce validated improvements in endoscope reprocessing and the availability of a revised reprocessing manual for the following GI endoscopes:

- GIF-N180
- GIF-Q180
- GIF-H180
- GIF-XP180N
- GIF-H180J
- GIF-2TH180
- CF-Q180AL/I
- CF-H180AL/I
- CF-H180DL/I
- PCF-Q180AL/I
- PCF-H180AL/I
- TJV-Q180V

In an effort to improve reprocessing efficiency, Olympus has validated the use of water to perform endoscope precleaning at the patient's bedside. This eliminates the need to prepare and hold detergent in the procedure room. Other improvements in the reprocessing procedure include reductions in the quantity of fluids required to flush the auxiliary water channel during bedside precleaning. In addition, the Olympus Flushing Pump, commonly known as the OFP, has been validated for automated flushing of the auxiliary water channel as an alternative to a manual syringe flushing.

These new procedures, plus improvements in illustrations and additional informational material, are contained in the revised GI endoscope reprocessing manual now available from Olympus. The following is a brief description of the revisions that you will find in the revised reprocessing manual.

- The precleaning procedure was revised to eliminate the use of detergent in the procedure room and to provide the option for automated flushing of the auxiliary water channel using the OFP, Olympus Flushing Pump. The revised instructions specify the use of water to perform precleaning. Please note that the validation of the change to precleaning with water for the auxiliary water channel was performed with the Olympus MAJ-855 only.
- Reprocessing accessories are no longer required to be detached after detergent cleaning and after rinsing prior to high-level disinfection.
- Work flow charts were added to the manual to identify:
 - Equipment used only for patient procedures,
 - Equipment used only for reprocessing,
 - Equipment that has a role in both patient procedures and reprocessing,
 - Where to find instructions for reprocessing the equipment.
- New illustrations were added to further clarify reprocessing instructions, and additional detail was added to existing diagrams.
- Additional instructions were added regarding:
 - The reprocessing of accessories.
 - The storage of sterilized endoscopes and accessories.
- Finally, additional warnings and cautions were added to identify potential pitfalls in reprocessing practices and policies.

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One caution/warning statement in the revised manual that we would like to call to your attention addresses the issue of equipment repair provided by a non-Olympus repair facility or Independent Service Organization (ISO). Olympus does not support or authorize ISOs to repair Olympus equipment, nor does Olympus provide training or parts to ISOs to enable them to repair Olympus equipment to Olympus' standards. As a result, Olympus has no knowledge of the specifications of materials used by ISOs to repair Olympus equipment, nor the quality of such repairs. Olympus conducts a rigorous testing program to validate both compatibility of our instruments with specific reprocessing methods and agents, as well as the efficacy of such methods for reprocessing the device. Without knowledge of the materials used or the final quality of repair being provided by ISOs, Olympus is unable to validate the compatibility or reprocessing efficacy of the Olympus instructions provided in the product-specific reprocessing manual. As a result, the instructions provided in the product-specific instruction manual are invalid for Olympus equipment that has been repaired by an ISO. If your Olympus equipment was or is being repaired by a non-Olympus facility, please contact the repair facility to obtain instructions on device compatibility and reprocessing to ensure that your facility is following safe and validated reprocessing instructions.

Although the new reprocessing instructions describe bedside precleaning with water, the former precleaning procedure using detergent remains a validated process and facilities may continue this practice if they so choose.

In addition, the revised instructions are applicable to reprocessing the older model endoscopes that are listed in the table below. If you have questions regarding how to apply these new instructions to the older model Olympus endoscopes that you own, please contact Olympus.

Gastrosopes	Colonoscopes
GIF-140	CF-140S
GIF-P140	CF-140L/I
GIF-Q140	CF-Q140L/I
GIF-XQ140	CF-1T140L/I
GIF-1T140	PCF-140L/I
GIF-160	PCF-160AL/I
GIF-Q160	CF-Q160S
GIF-XP160	CF-Q160L/I
GIF-XTQ160 [†]	CF-Q160AL/I
GIF-1TQ160	
GIF-2T140	
GIF-2T160	

[†]Use channel cleaning brush specified in product-specific Reprocessing Manual.

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An electronic version of the newly revised manual is available on the Olympus Connect customer portal (www.olympusconnect.com). Hard copies may be obtained by contacting Olympus Customer Service. If you have any questions regarding the revised reprocessing manual, please contact your local Olympus sales representative or the Olympus Technical Assistance Center. To contact the Olympus Customer Service and Technical Assistance Center, please call 1-800-848-9024. Thank you.

Sincerely,

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

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