SHORT OVERVIEW OF KEY CHANGES TO EMEA REGION TJF-Q180V OPERATING AND REPROCESSING MANUALS - March 2016

This document is provided as a short overview of the key changes made to the operating (RC 2609_02 (EN Version)/ 5.0 (other EU languages)) and reprocessing (RC 2603_02 (EN Version)/ 6.0 (other EU languages)) manual.

This overview is intended only for use by customers located in Europe, Middle East and Africa to enhance the understanding of the recently started FSCA for the TJF-Q180V and does not replace the paper versions of the operating and reprocessing manuals provided by Olympus. Please refer to the operating and reprocessing manuals before using or reprocessing Olympus equipment.

Overview of key changes to the TJF-Q180V operating manual RC 2609_02 (EN Version)/ 5.0 (other EU languages):

- Inclusion of inspection procedures of the elevator mechanism after each patient procedure (Chapter 6.1)
- Inclusion of inspection procedures of the distal end of the endoscope before each patient procedure (Chapter 6.2)
- Inclusion of a necessity for annual inspection by Olympus service personnel (Chapter 6.3)
- Inclusion of the ETD Automated Endoscope Reprocessor into the appendix (Appendix)

Overview of key changes to the reprocessing manual RC 2603_02 (EN Version)/ 6.0 (other EU languages):

- Inclusion of a warning about the requirement to move the forceps elevator during leakage testing (Chapter 1 precautions, Chapter 5 Section 5.3)
- Inclusion of a warning that the endoscope should be fully reprocessed following any kind of microbial test or other test using extraction fluids from the endoscope (Chapter 1, precautions)
- Inclusion of the requirement to perform precleaning and manual cleaning when AER systems are used (Chapter 1 precautions, chapter 4.2 workflow; Chapter 7)
- Inclusion of additional instruction for leakage testing (Chapter 5 Section 5.3)
- Inclusion of a warning that debris must be sufficiently removed from the distal end of the endoscope (Chapter 5, brushing and flushing the elevator recess)