



June 5, 2009

URGENT – DEVICE CORRECTION

RE: Olympus Mobile Workstations
Models WM-DP1, WM-NP1, WM-WP1 and WM-SC
Serial Numbers 2810808 and below

Dear Health Care Practitioner:

Olympus America Inc. (“Olympus”) is initiating a corrective action to address the potential for the fuse on the transformer for the above referenced mobile workstations to overheat and arc. If the fuse overheats, it could cause open flame and smoke to briefly occur. Olympus has initiated this corrective action following investigation of customer complaints originating from outside the United States regarding fuse overheating and arcing on the above referenced mobile workstations. Olympus has not received any complaints of user injury.

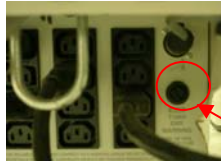
The cause of the fuse overheating is due to the fuse being loose in the fuse holder, which can cause intermittent electrical contact when the transformer is powered on. Prolonged intermittent electrical contact can cause the fuse to overheat, resulting in burning of the fuse and the fuse carrier (see picture on next page). A loose fuse may be evident to the user as the equipment installed on the mobile workstation may demonstrate signs of the intermittent electrical contact caused by the loose fuse. Specifically, endoscopic equipment installed on the mobile workstations, such as video display monitors, may show a flickering image or the equipment may fail to correctly power up when initially powered on.

This corrective action is intended to ensure that the fuse on the mobile workstations is adequately tightened to prevent arcing and smoking.

You must take the following actions. You must evaluate the fuse for looseness using a calibrated torque driver or contact Olympus to perform this evaluation. If the fuse is loose, the fuse and fuse carrier need to be inspected. A loose fuse that shows no signs of arcing or charring can be tightened using a calibrated torque driver. A loose fuse that shows signs of arcing and charring needs to be replaced. You can also contact Olympus to arrange for a field service representative to perform this inspection and tightening action.

In order to accomplish the above inspection and tightening, you must perform the following steps:

1. Identify the serial number on your mobile workstation. You can find the workstation serial number on the rear base of the workstation. Only mobile workstations with serial numbers 2810808 and below are affected by this corrective action.
2. Locate the fuse holder on the transformer on your endoscopy mobile workstation. The fuse holder is located on the rear panel of the transformer. Please reference the pictures on the following page depicting the location of the fuse holder.



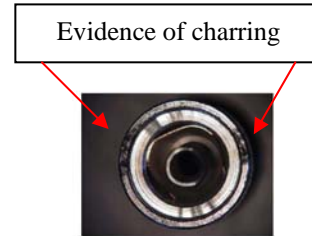
Fuse holder

Fuse carrier

3. Determine whether the fuse is appropriately secured by applying 0.5Nm force with a calibrated torque driver. If secure, there is no need to remove and inspect the fuse and fuse carrier as described in step 4.
4. If the fuse is loose, remove the fuse and inspect for any evidence of arcing or charring to either the fuse or fuse carrier. The pictures below illustrate a fuse carrier with and without charring. If no arcing or charring is present, insert the fuse back into the fuse holder and securely tighten it to 0.5 Nm. Use of a calibrated torque driver is required.



Fuse carrier without charring



Charred fuse carrier

5. If evidence of arcing or charring is present on either the fuse or fuse carrier, discontinue use of the cart, and contact Olympus at 1-800-848-9024 option 1, option 6 for assistance.

Per the above, service personnel are available to inspect and tighten the fuse on the mobile workstation. Please contact Olympus at 1-800-848-9024, option 1, option 6 to request a Field Service Engineer to visit your facility for inspection and any necessary action.

Whether or not you observe any loose fuses, Olympus requests that you please complete the attached questionnaire that indicates your acknowledgement in receiving this notice.

Olympus fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at (408) 935-5086 for any additional information on this matter.

Sincerely,

James Patrick Garvey II, RRT
Director, Regulatory Affairs & Quality Assurance

