

Reference: 2019-004K

15-Jul-2019

FIELD SAFETY NOTICE

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action for the devices listed below. The affected models and batch numbers are listed below.

Model No.	Model Description	Batch No.
MAJ-1664	Nurse Control Panel Arm (Long)	All batch numbers previous to 606852 when used with the WM-NP2 or WM-DP2 Workstations

The MAJ-1664 has been designed to allow the use of a range of compatible flat screen monitors on the Olympus-WM-NP2 or WM-DP2 Mobile Workstation (WM-NP2/DP2) and TC-C4 Compact Trolley.

OLYMPUS is initiating this action after on-going product testing has identified that the WM-NP2/DP2 when used with the MAJ-1664 could become unstable and may fall if certain conditions occur. Please note, the use of the MAJ-1664 in combination with the TC-C4 Compact Trolley is unaffected by this issue.

OLYMPUS is notifying users of the below conditions and the need of avoidance of these conditions for all future use of the MAJ-1664 with the WM-NP2/DP2:

- A monitor weighing more than 9kg (19.8lbs) is attached to the MAJ-1664.
- The Nurse Control Arm (MAJ-1664) and LCD Monitor Arm (MAJ-1641) are mounted on the WM-NP2/DP2 and are extended in the same direction, which is an unfavourable position in the same direction (e.g. towards the left or right of the workstation).



Unfavourable Position



Favourable Position

OLYMPUS SINGAPORE PTE LTD

Business Regn No. 198900566E

Business Address: 438B Alexandra Road, Alexandra Technopark Blk B, #03-07/12, Singapore 119968 Tel: (65) 6834 0010 Fax: (65) 6834 2438
www.olympus.com.sg

- Total weight of the equipment and accessories on the WM-NP2/DP2 workstation shelves of less than 30kg (66.1lbs).
- When the workstation is stationary on an incline/decline and the brakes are engaged.

Therefore monitors weighing more than 9kg (19.8lbs) are no longer compatible and should not be used with the MAJ-1664. As a result, the following monitors are no longer compatible with the MAJ-1664:

- VMC-1 monitor – 13.4kg (29.5lbs)
- Penta 17" medical PC monitor – 12.5kg (27.5lbs)
- Medisight touch panel (POC 174) – 12.0kg (26.4lbs)

OLYMPUS recommends that the MAJ-1664 is placed within its storage location (specified within the Instructions for Use, Section 9 – Transportation) and avoid the four conditions stated above when the WM-NP2/DP2 is transported.

The MAJ-1664 Instruction for Use manual has been updated to Issue 5 to inform users of the updated maximum mountable arm weight of 9kg (19.8lbs). A self-fastening strap will also be provided to all end-users who own a MAJ-1664 in order to secure the monitor arm to the WM-NP2/DP2 when the workstation is being transported. The operation of the self-fastening strap has also been included in the updated Instruction for Use, Issue 5.

If the monitor that is attached to the MAJ-1664 does not weigh more than 9kg (19.8lbs) then the above referenced conditions will not cause the WM-NP2/DP2 to become unstable.

However, in order to avoid the above conditions, the transportation and maneuvering information within the Instructions for Use should be followed for the Workstations (WM-NP2/DP2), Nurse Control Arm (MAJ-1664) and the LCD Monitor Arm (MAJ-1641). The supplied self-fastening strap for the MAJ-1664 should also be used for continued safe use.

Action(s) to be taken by end user

Our records indicate that you have purchased the affected product(s) and we request you to take the following action(s):

1. Pass this notice to all those within your facility who need to be made aware of its contents.
2. Inspect MAJ-1664 Instruction for Use (IFU) inventory and discard any existing IFUs.
3. Review the updated MAJ-1664 IFU (Issue 5) and ensure that any monitor placed on the MAJ-1664 Nurse Control Arm (Long) does not exceed the maximum loading of 9kg (19.8lbs).
4. If the monitor attached to the MAJ-1664 exceeds the updated maximum loading requirement of 9kg (19.8lbs), ensure the monitor is removed and replaced with a new monitor that does not exceed the maximum loading requirement. Please contact your local Olympus Representative for further support if required.
5. Apply the supplied self-fastening strap according to the updated MAJ-1664 IFU (Issue 5).
6. Ensure that any relevant personnel are informed of the updated MAJ-1664 IFU (Issue 5) and the updated handling instructions.
7. Complete the attached FSN Response Form, confirming you have received this FSN and implemented the corrective actions.
8. Email the completed Response Form to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus Representative.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact information

Olympus Singapore Pte. Ltd.

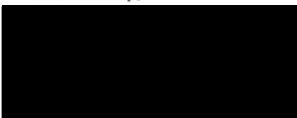
Regulatory Affairs Department

Email : mes-ra.osp@olympus-ap.com

Tel : (+65) 6833 4214

Fax : (+65) 6834 2438

Sincerely,



Loh E Thel
Division Manager
Medical Systems Business Division
Olympus Singapore Pte. Ltd.

Cc: Chairman Medical Board and relevant Head of Departments



Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:
mes-ra.osp@olympus-ap.com

To : Olympus Singapore Pte. Ltd., Regulatory Affairs Department

Fax : 6834 2438

From : _____ [Facility Name] Contact No. : _____

Date : _____

Ref : 2019-004K

FIELD SAFETY NOTICE

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

- ☐ I DO NOT have affected devices remaining. All have been condemned or discarded.
- ☐ I DO have the affected devices, which I will implement the MAJ-1664 IFU (Issue 5) and the supplied self-fastening strap, as necessary.

Model No.	Batch No.

Name : _____

Designation : _____

Signature / Facility Stamp

Date

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