

Date: Friday 21 June 2019

URGENT: FIELD SAFETY NOTICE

Action Identification Number: **FSCA-2019-001**

Type of Action: Field Safety Corrective Action

Affected Products:

MAJ-1664 Nurse Control Panel Arm (Long) - K10021798

Affected Lot Numbers:

All Lot Numbers previous to 606852 when used with the WM-NP2 or WM-DP2 Workstations

Dear Customer / Health Care Practitioner,

Olympus is writing to inform you of a matter that requires your attention. This Field Safety Notice affects the above-referenced MAJ-1664 Nurse Control Panel Arm (MAJ-1664).

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. At the time of issuing this Field Safety Notice no adverse events have been reported.

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 Medical is an operating division of KeyMed (Medical & Industrial Equipment) Ltd. Company Registered in England No. 966736.

Registered office and address for services as above

Olympus KeyMed has been certified by BSI to ISO 9001, ISO 14001, ISO 50001, OHSAS 18001 and ISO 13485 under certificate numbers FM 20993, EMS 65964, ENMS 583869, OHS 592754, and MD 83891.



CIPS
SUSTAINABILITY
INDEX
Rated Supplier
10 0835 - Valid to: Mar/2019



- Total weight of the equipment and accessories on the WM-NP/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 manoeuvring 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.

Olympus requires you to take the following immediate action:

1. Pass this notice to all those within your facility who need to be made aware of its contents
2. Inspect your MAJ-1664 Instruction for Use (IFU) inventory and discard any existing IFU's
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 Field Safety Notice Reply form confirming you have received this Field Safety Notice and implemented the Corrective Actions.
8. Return your Field Safety Notice Reply form; [regardless of whether you have any affected inventory in your facility] on page 3 by **XXXXXXXXXX**.

Olympus KeyMed
KeyMed House
Stock Road
Southend-On-Sea, Essex
SS2 5QH
United Kingdom

9. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attachments, and appropriately document your notification process
10. This action should be initiated immediately.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused by this action and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support to perform this corrective action, please do not hesitate to contact your local Olympus Representative or contact Olympus by email at regulatoryaffairs@olympus.co.uk

XXX

Olympus KeyMed
KeyMed House, Stock Road, Southend-on-Sea, Essex, SS2 5QH, UK

Ene. Field Safety Notice Reply Form

Date: Friday 21 June 2019

URGENT: FIELD SAFETY NOTICE REPLY FORM
Action Identification Number: **FSCA-2019-001**

Affected Products:

MAJ-1664 Nurse Control Panel Arm (Long) - K10021798

Affected Lot Numbers:

All Lot Numbers previous to 606852 when used with the WM-NP2 or WM-DP2 Workstations

Please send the completed and signed reply form by post, fax or a digitally scanned e-mail to:

Email: regulatory.affairs@olympus.co.uk

Fax: 01702 465677

Dear Olympus,

I acknowledge receipt of your Field Safety Notice. Further, I confirm that I will discard any existing inventory of Instruction for Use of the MAJ-1664. I will ensure the content of the attached FSN is circulated to all affected departments on which this action has an impact. I understand that the updated maximum loading guidelines and handling instructions must be followed when operating the MAJ-1664 and that the self-fastening strap should be used in accordance to the Instruction for Use.

I have indicated below the number of affected MAJ-1664 Nurse Control Panel Arm (Long) - K10021798 that are held by our facility.

Product Details	Quantity
MAJ-1664 Nurse Control Panel Arm (Long)	

Please print details below

Name & Job Title: _____

Facility Name & Address: _____

City & **County**: -----

Postal Code: _____ Telephone number: -----

Email Address: -----

Signature and **Date** -----