

Date: *May XX, 2022*

Olympus reference: QIL FY23-EMEA-03

## URGENT FIELD SAFETY NOTICE

**FIELD SAFETY CORRECTIVE ACTION ON WM-NP3/WM-DP3 MOBILE WORKSTATIONS – POTENTIAL FOR INSUFFICIENT TRANSFORMER CONNECTION THAT COULD RESULT IN WORKSTATION SHUTTING DOWN.**

**Attention: Endoscopy Department, Medical Device Safety Officer**

Product Part Number/Material Number	Product/Material Description	Serial number(s)
K10035360	WM-NP3 MOBILE WORKSTATION EU	22214467 22214468 22214597 22214675 22214676
K10035365	WM-NP3 MOBILE WORKSTATION EU GI	22214451
K10035364	WM-NP3 MOBILE WORKSTATION UK GI	22214604 22214605 22214682
K10035983	WM-DP3 MOBILE WORKSTATION UK	22214617 22214618

Dear Healthcare Professional,

Olympus has become aware of an issue that requires your attention. This Field Safety Notice pertains to the above-referenced WM-NP3 and WM-DP3 Mobile Workstations.

The WM-NP3/WM-DP3 Mobile Workstation Narrow/Double Platform 3 is intended to assist endoscopic procedures using Olympus medical devices and their accessories within medical facilities by providing a stable mains power supply and a platform for the efficient use and handling of the devices during endoscopic diagnostic and therapeutic procedures. The WM-NP3 and WM-DP3 workstation can also allow visualisation during the procedure when connected to a monitor.

## Pictorial representation of the Workstation and Serial Number location:

WM-NP3 MOBILE  
WORKSTATION



WM-DP3 MOBILE  
WORKSTATION



### Serial Number Location:

- An 8-digit serial number is located on the left-hand side of the bottom shelf. The serial number is a part of a digital barcode.
- Note: Serial number is the last 8 digits of a longer numerical barcode.

### Reason for this Action:

It has been identified during the manufacturing process that the potential existed for an incorrect transformer assembly. During the use of the WM-NP3/WM-DP3 Workstation, this issue could cause excess heat and result in the loss of power to all devices that are connected to the electrical sockets on the workstation.

To date, Olympus has not received any complaints related to this issue. The incorrect assembly has only been observed internally during the manufacturing process.

Olympus has already implemented necessary containment actions and has launched an investigation to identify the root cause and will implement the required corrective actions. In the short-term, Olympus instructs end users to follow the steps defined within this Field Safety Notice.

## **Risk to Health:**

To date, Olympus has not received any complaints or reports of serious injury associated with this matter. However, in the event of an insufficient connection in transformer assembly, continued use of the workstation could result in producing excess heat and workstation shut-down - potentially causing delays in procedures.

To prevent this potential risk, an Olympus representative will be in contact with your facility to conduct an inspection and rework activities if required.

## **Action steps to be taken by the end user:**

Our records indicate that your facility has purchased one or more of the affected WM-NP3/WM-DP3 Mobile Workstations. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this Field Safety Notice.
2. Immediately assess any product you have in stock to identify the specified models and serial numbers of WM-NP3/WM-DP3 Mobile Workstations. Cease use and quarantine the Workstation(s). There is no requirement to decommission the equipment on the Workstation.
3. If you have further distributed this product, identify your customers and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedbacks accordingly.
4. Please indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to XXXXXX latest by XXXXXXXX.
5. An Olympus representative will contact you to arrange a mutually convenient time to implement the corrective actions and conduct any rework activities if required.

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

We fully appreciate your prompt cooperation in addressing this situation and working with us to ensure your patients are treated only with safe and effective Olympus products that you have come to rely upon. If you have any questions or would like further information, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX.

Sincerely,



**REPLY FORM – QIL FY23-EMEA-03**

<b>OLYMPUS URGENT FIELD SAFETY NOTICE</b>	
<b><i>FIELD SAFETY CORRECTIVE ACTION ON WM-NP3/WM-DP3 MOBILE WORKSTATIONS – POTENTIAL FOR INSUFFICIENT TRANSFORMER CONNECTION THAT COULD RESULT IN WORKSTATION SHUTTING DOWN</i></b>	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Date]	
<b>Affected products currently located at your facility</b>	
<b>Product Name/Description</b>	<b>Serial Number</b>

I herewith acknowledge the receipt of your Field Safety Notice.  
Further, I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.  
I understand the necessity of following the steps described within the FSN.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please send your completed paper form response to **XXXXX** latest by **XXXX**.