



Miele & Cie. KG, P.O. Box 100107, 33501 Bielefeld, Germany

Bielefeld plant

07.10.2024

URGENT SAFETY INFORMATION

Important safety information for the washer-disinfectors for endoscopes Olympus ETD

Product name	Model/catalog number	Serial numbers
ETD Premium PAA	WD00304A	Insert serial number(s) of the affected products
ETD Premium GA	WD00305A	Insert serial number(s) of the affected products

Dear medical professionals,

We hereby inform you of a possible safety issue with the Olympus ETD washer-disinfector for endoscopes, which is manufactured by Miele & Cie. KG and distributed and serviced by Olympus.

According to our records, washer-disinfectors for endoscopes of this type are installed in your facility.

We were made aware of a case, where a customer's loading basket was not reliably connected to the device during some reprocessing procedures and at the same time the RFID scan for recognizing the endoscope was not working reliably. In this case, there is an increased risk that the inner channels of endoscopes are not properly cleaned and disinfected. The cause of this coupling error was an external force acting on the basket. In the event of greater mechanical stress due to improper handling, there is a possibility that the adjusting ring will slide.

However, the hazardous situation can only occur if the endoscopes are not detected during the RFID scan, the user ignores the information ("no endoscope detected") shown on the display and in the process documentation as part of their reprocessing obligations and the loading basket does not connect.

Olympus service personnel will shortly rework the loading baskets at your premises. The adjusting ring will be modified in a way, that it can withstand even greater mechanical loads. The positioning of the endoscopes will also be changed so that the RFID scan functions reliably.

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Commerzbank AG Gütersloh
BIC: COBADE33HAN; IBAN: DE65 4784 0065 0151 2128 00
: Olaf Bartsch, Dr. Stefan Breit, Dr. Axel Kniehl, UniCredit Bank
BIC: HYVEDE33HAN; IBAN: DE41 1002 0890 0002 6688 58

The user must always ensure the following points:

1. All reprocessed endoscopes are correctly recognized by the RFID scan of the washer-disinfector for endoscopes.
2. The messages in the display and the process documentation must be checked for each batch. If the message "No endoscope detected" is displayed for a batch and an endoscope was reprocessed, this endoscope and adapter must be quarantined, and Olympus Service must be informed immediately.
3. If the basket has been impacted to greater force, e.g. falling from the worktop, or due to a massive impact, or if visual changes are visible, Olympus Service must be informed immediately before the next use. The basket may only be used again after approval by Olympus Service. Independent repair of the basket is prohibited.

If you are not the correct contact person, please forward this letter to the relevant office. The competent national authorities have been informed of this measure.

We are always available for further questions.

We are and will remain there for you. Thank you for your cooperation.

Yours sincerely

Miele & Cie. KG

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