

To our customers of
 Dräger Polaris Multimedia: single display
 mounting system (D60 MO)

October 2022

Important Safety Notice

Potentially missing securing element

Only the following products are affected:

Dräger Polaris Multimedia: single display mounting system, ceiling bearing D60 MO, part numbers G28994 and G92759.



Dear Sir or Madam,

During the course of our global market surveillance activities, we have become aware of a case in which the swivel arm of a display dropped from a ceiling tube, whereby it was held in place by internal cabling only. There was no report of any adverse impact on the health of the patient or user.

The investigation showed that one of three elements which ensure reliable fixation over time between the ceiling tube and the swivel arm, was missing. A missing element leads to mechanical clearance in the solution. If the display mount is moved frequently and with force against the stop, the system may deteriorate internally. The remaining elements may lose their function leading to a disengagement of the swivel arm from the ceiling tube. This may lead to the swivel arm display mount falling which could result in injury.

Actions to be taken:

To verify that in your installation all three elements are mounted correctly, please:

1. Open the cap using a slotted screwdriver. The two halves of the cap can be opened from the bottom.

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 Commerzbank AG, Lübeck
 IBAN: DE95 2304 0022 0014 6795 00
 Swift-Code: COBA DE FF 230
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 IBAN: DE15 2305 0101 0001 0711 17
 Swift-Code: NOLADE21SPL

Sitz der Gesellschaft: Lübeck
 Handelsregister:
 Amtsgericht Lübeck HRB 7903 HL
 Komplementär: Drägerwerk Verwaltungs AG
 Sitz der Gesellschaft: Lübeck
 Handelsregister:
 Amtsgericht Lübeck HRB 7395 HL

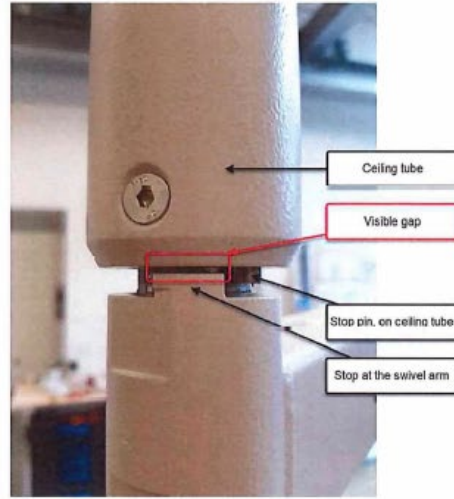
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2. Check whether there is a gap between the ceiling tube and the stop at the swivel arm:



No gap, system is not affected - **OK**



Visible gap, system is affected - **NOT OK**

3. Please contact Draeger by using the attached Reply and Order Card. If your system is affected, we will contact you and ensure the system is repaired free of charge. Depending on the condition of the stops, it may be necessary to replace parts of the installation. Therefore, we ask you to inform us within the Reply and Order Card if there is already mechanical wear in the area of the stop pin or stop of the swivel arm.

Until Dräger has repaired your installation please do not move the device with force against the stops.

If this precaution is followed, the installation can be safely used.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information to them.

Please keep this information at least until the measure has been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, one or more Dräger Polaris Multimedia single display mounting systems manufactured by Drägerwerk AG & Co. KGaA (European Single Registration Number: DE-MF-000005329) that may be affected by this issue are installed in your facility. All serial numbers are potentially affected and are listed in the attachment.

Contact:

If you have any questions, please do not hesitate to contact your local service organization.

Internal

Dräger

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We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards

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Drägerwerk AG & Co. KGaA

Attachment:

List of affected medical devices including their Serial Number

Product name	Serial Number
Ceil. Bearing D60 MO	1040710100525
Ceil. Bearing D60 MO	1040710100529
Ceil. Bearing D60 MO	1040710100527
Ceil. Bearing D60 MO	1040710100526
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Ceil. Bearing D60 MO	3217H001001061

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Ceil. Bearing D60 MO	4717H001109013
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Ceil. Bearing D60 MO	0720H002016430
Ceil. Bearing D60 MO	0720H002016429
Ceil. Bearing D60 MO	4416H001498082

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Cell. Bearing D60 MO for CSU	4719H001908539
Cell. Bearing D60 MO for CSU	4719H001908535
Cell. Bearing D60 MO for CSU	4719H001908540
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