Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 238 **dated** 28/12/2022 **Regarding NCMDR Field Safety Corrective Action of Polaris Multimedia from (mfr: Draeger Medical Systems Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED
ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
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Circular No. 238 / 2022

04 -06-1444 H

28 -12-2022

Field Safety Corrective Action of Polaris Multimedia from Draeger Medical Systems Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=17357
Product	Polaris Multimedia
Description	Surgical equipment/ Anaesthesia - surgical equipment
Manufacturer	Draeger Medical Systems Inc
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Bearing D60 MO, part numbers G28994 and G92759.
Reason	The swivel arm of a display dropped from a ceiling tube, where by it was held in place by internal cabling only
Action	1. Please contact Draeger by using the forms in the attached FSN if there is already mechanical wear in the area of the stop pin or stop of the swivel arm. 2. For the affected systems, Draeger will contact the user to ensure the system is repaired. Depending on the condition of the stops, it may be necessary to replace parts of the installation. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

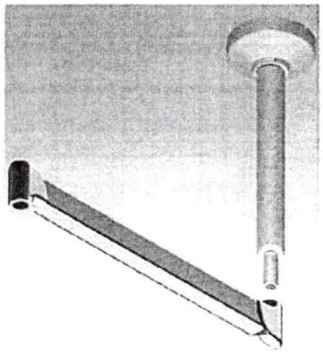
Dräger

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.

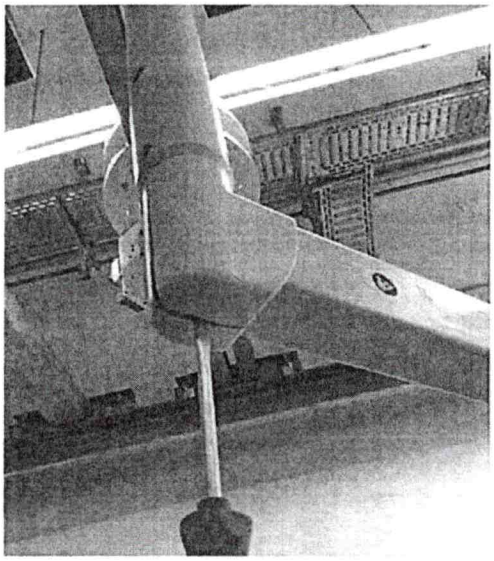
Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Deutschland
Postanschrift:
23542 Lübeck, Deutschland
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE135082211

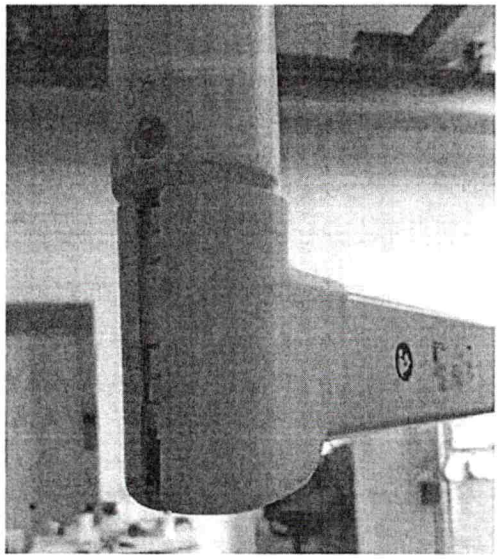
Bankverbindungen:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

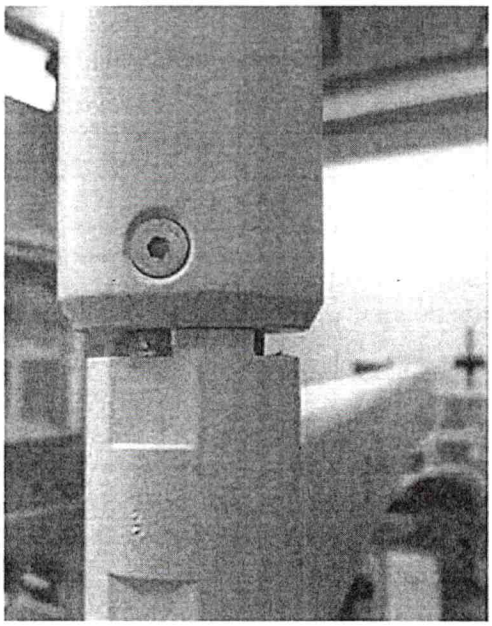
Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG:
Stefan Lauer
Vorstand:
Stefan Dräger (Vorsitzender)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Dräger

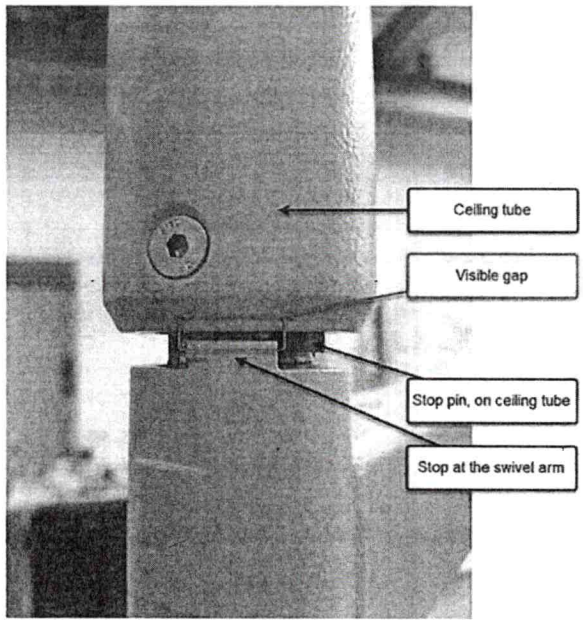




2. Check whether there is a gap between the ceiling tube and the stop at the swivel arm:



No gap, system is not affected - OK



Visible gap, system is affected - NOT OK

Dräger

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.

Dräger

We apologize for any inconvenience caused by this measure.

We thank you for your support.

Director Quality, Regulatory Affairs and Purchasing
Business Unit Workplace Infrastructure
Medical Division
Drägerwerk AG & Co. KGaA

Dräger

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
Ceil. Bearing D60 MO	1040710100528
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Ceil. Bearing D60 MO for CSU	1947133
Ceil. Bearing D60 MO for CSU	1947136
Ceil. Bearing D60 MO for CSU	2838693
Ceil. Bearing D60 MO for CSU	1947135
Ceil. Bearing D60 MO for CSU	1947134
Ceil. Bearing D60 MO for CSU	2164612
Ceil. Bearing D60 MO for CSU	2164611
Ceil. Bearing D60 MO for CSU	2164615
Ceil. Bearing D60 MO for CSU	2164616
Ceil. Bearing D60 MO for CSU	2164617
Ceil. Bearing D60 MO for CSU	2838696
Ceil. Bearing D60 MO for CSU	2838697