

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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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

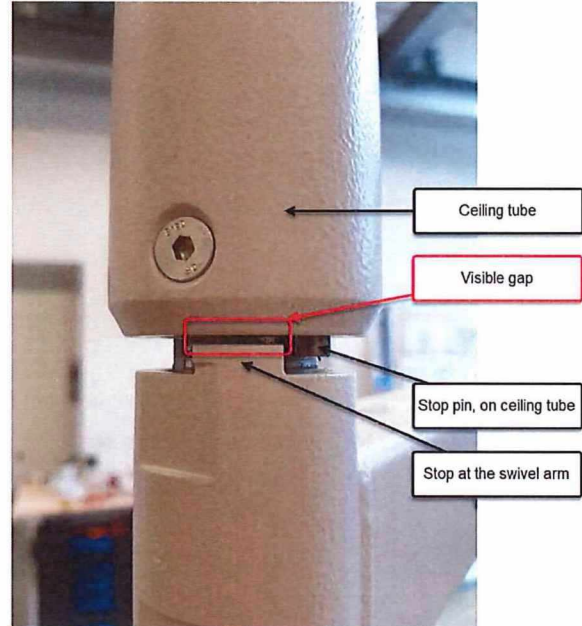
Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG:
Stefan Lauer
Vorstand:
Stefan Dräger (Vorsitzender)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner



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.

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We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards



Marcus Vorwerk

Director Quality, Regulatory Affairs and Purchasing
Business Unit Workplace Infrastructure
Medical Division
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	3716H000691576
Ceil. Bearing D60 MO	3716H000691580
Ceil. Bearing D60 MO	3716H000691579
Ceil. Bearing D60 MO	3716H000691581
Ceil. Bearing D60 MO	3716H000691582
Ceil. Bearing D60 MO	3716H000691583
Ceil. Bearing D60 MO	4216H000718310
Ceil. Bearing D60 MO	3716H000691578
Ceil. Bearing D60 MO	4216H000718308
Ceil. Bearing D60 MO	4216H000718311
Ceil. Bearing D60 MO	4216H000718312
Ceil. Bearing D60 MO	4216H000718309
Ceil. Bearing D60 MO	4216H000718295
Ceil. Bearing D60 MO	4216H000718307
Ceil. Bearing D60 MO	4216H000718305
Ceil. Bearing D60 MO	4216H000718294
Ceil. Bearing D60 MO	4216H000718299
Ceil. Bearing D60 MO	4216H000718293
Ceil. Bearing D60 MO	4216H000718298
Ceil. Bearing D60 MO	4216H000718297
Ceil. Bearing D60 MO	4216H000718296
Ceil. Bearing D60 MO	0717H000845265
Ceil. Bearing D60 MO	3316H000673676
Ceil. Bearing D60 MO	3316H000673687
Ceil. Bearing D60 MO	0917H000854213
Ceil. Bearing D60 MO	3316H000673685
Ceil. Bearing D60 MO	0717H000845263
Ceil. Bearing D60 MO	3316H000673683
Ceil. Bearing D60 MO	0717H000845266
Ceil. Bearing D60 MO	3316H000673680
Ceil. Bearing D60 MO	0717H000845256
Ceil. Bearing D60 MO	3316H000673684
Ceil. Bearing D60 MO	3316H000673679
Ceil. Bearing D60 MO	0717H000845257
Ceil. Bearing D60 MO	0717H000845258

Ceil. Bearing D60 MO	0717H000845261
Ceil. Bearing D60 MO	0717H000845259
Ceil. Bearing D60 MO	0717H000845253
Ceil. Bearing D60 MO	0717H000845254
Ceil. Bearing D60 MO	0717H000845252
Ceil. Bearing D60 MO	3416H000674546
Ceil. Bearing D60 MO	3416H000674559
Ceil. Bearing D60 MO	3416H000674560
Ceil. Bearing D60 MO	2217H000929378
Ceil. Bearing D60 MO	2217H000929368
Ceil. Bearing D60 MO	2217H000929377
Ceil. Bearing D60 MO	0717H000845255
Ceil. Bearing D60 MO	0717H000845260
Ceil. Bearing D60 MO	2217H000929379
Ceil. Bearing D60 MO	2217H000929370
Ceil. Bearing D60 MO	2217H000929374
Ceil. Bearing D60 MO	2217H000929375
Ceil. Bearing D60 MO	2217H000929373
Ceil. Bearing D60 MO	2217H000929371
Ceil. Bearing D60 MO	2217H000929376
Ceil. Bearing D60 MO	3217H001001047
Ceil. Bearing D60 MO	10412939951
Ceil. Bearing D60 MO	10412939954
Ceil. Bearing D60 MO	3217H001001048
Ceil. Bearing D60 MO	3217H001001046
Ceil. Bearing D60 MO	3217H001001049
Ceil. Bearing D60 MO	3217H001001056
Ceil. Bearing D60 MO	3217H001001057
Ceil. Bearing D60 MO	3217H001001059
Ceil. Bearing D60 MO	3217H001001051
Ceil. Bearing D60 MO	3217H001001055
Ceil. Bearing D60 MO	3217H001001050
Ceil. Bearing D60 MO	3217H001001058
Ceil. Bearing D60 MO	3217H001001060
Ceil. Bearing D60 MO	3217H001001062
Ceil. Bearing D60 MO	3217H001001061

Ceil. Bearing D60 MO	4717H001109012
Ceil. Bearing D60 MO	4717H001109011
Ceil. Bearing D60 MO	3217H001001065
Ceil. Bearing D60 MO	4717H001109013
Ceil. Bearing D60 MO	4717H001109009
Ceil. Bearing D60 MO	3217H001001053
Ceil. Bearing D60 MO	1118H001217363
Ceil. Bearing D60 MO	3217H001001052
Ceil. Bearing D60 MO	2716H000637660
Ceil. Bearing D60 MO	4717H001109014
Ceil. Bearing D60 MO	1118H001217360
Ceil. Bearing D60 MO	4717H001109006
Ceil. Bearing D60 MO	4717H001109005
Ceil. Bearing D60 MO	3217H001001054
Ceil. Bearing D60 MO	3217H001001063
Ceil. Bearing D60 MO	4717H001109007
Ceil. Bearing D60 MO	2716H000637655
Ceil. Bearing D60 MO	1118H001217358
Ceil. Bearing D60 MO	2716H000637661
Ceil. Bearing D60 MO	4717H001109008
Ceil. Bearing D60 MO	2716H000637658
Ceil. Bearing D60 MO	4717H001109010
Ceil. Bearing D60 MO	3217H001001064
Ceil. Bearing D60 MO	1118H001217352
Ceil. Bearing D60 MO	1118H001217353
Ceil. Bearing D60 MO	1118H001217355
Ceil. Bearing D60 MO	1118H001217369
Ceil. Bearing D60 MO	1118H001217372
Ceil. Bearing D60 MO	1118H001217370
Ceil. Bearing D60 MO	1118H001217371
Ceil. Bearing D60 MO	1118H001217375
Ceil. Bearing D60 MO	1118H001217373
Ceil. Bearing D60 MO	1118H001217374
Ceil. Bearing D60 MO	1118H001217351
Ceil. Bearing D60 MO	1118H001217359
Ceil. Bearing D60 MO	1118H001217365

Ceil. Bearing D60 MO	5019H001935498
Ceil. Bearing D60 MO	5019H001935497
Ceil. Bearing D60 MO	5019H001935500
Ceil. Bearing D60 MO	5019H001935499
Ceil. Bearing D60 MO	5019H001935507
Ceil. Bearing D60 MO	5019H001935490
Ceil. Bearing D60 MO	4719H001908593
Ceil. Bearing D60 MO	4719H001908589
Ceil. Bearing D60 MO	4719H001908590
Ceil. Bearing D60 MO	4719H001908591
Ceil. Bearing D60 MO	4419H001884621
Ceil. Bearing D60 MO	4419H001884622
Ceil. Bearing D60 MO	4719H001908580
Ceil. Bearing D60 MO	4719H001908581
Ceil. Bearing D60 MO	4719H001908577
Ceil. Bearing D60 MO	4419H001880711
Ceil. Bearing D60 MO	4719H001908592
Ceil. Bearing D60 MO	4719H001908583
Ceil. Bearing D60 MO	4719H001908585
Ceil. Bearing D60 MO	4719H001908588
Ceil. Bearing D60 MO	4719H001908587
Ceil. Bearing D60 MO	4719H001908586
Ceil. Bearing D60 MO	4719H001908584
Ceil. Bearing D60 MO	4719H001908579
Ceil. Bearing D60 MO	4719H001908578
Ceil. Bearing D60 MO	4719H001908582
Ceil. Bearing D60 MO	0720H002015762
Ceil. Bearing D60 MO	0720H002016431
Ceil. Bearing D60 MO	0720H002015761
Ceil. Bearing D60 MO	0720H002016426
Ceil. Bearing D60 MO	2217H000929369
Ceil. Bearing D60 MO	2217H000929372
Ceil. Bearing D60 MO	0720H002016428
Ceil. Bearing D60 MO	0720H002016430
Ceil. Bearing D60 MO	0720H002016429
Ceil. Bearing D60 MO	4418H001498062

Ceil. Bearing D60 MO for CSU	2019H001696391
Ceil. Bearing D60 MO for CSU	1119H001629936
Ceil. Bearing D60 MO for CSU	2019H001696394
Ceil. Bearing D60 MO for CSU	2019H001696385
Ceil. Bearing D60 MO for CSU	1119H001629932
Ceil. Bearing D60 MO for CSU	1119H001629934
Ceil. Bearing D60 MO for CSU	1119H001629935
Ceil. Bearing D60 MO for CSU	2019H001696395
Ceil. Bearing D60 MO for CSU	1119H001629931
Ceil. Bearing D60 MO for CSU	2019H001696390
Ceil. Bearing D60 MO for CSU	2019H001696383
Ceil. Bearing D60 MO for CSU	2019H001696389
Ceil. Bearing D60 MO for CSU	2019H001696388
Ceil. Bearing D60 MO for CSU	2019H001696387
Ceil. Bearing D60 MO for CSU	3119H001772922
Ceil. Bearing D60 MO for CSU	3119H001772914
Ceil. Bearing D60 MO for CSU	3119H001772921
Ceil. Bearing D60 MO for CSU	3119H001772917
Ceil. Bearing D60 MO for CSU	3119H001772920
Ceil. Bearing D60 MO for CSU	3119H001772919
Ceil. Bearing D60 MO for CSU	3119H001772916
Ceil. Bearing D60 MO for CSU	3119H001772918
Ceil. Bearing D60 MO for CSU	3119H001772915
Ceil. Bearing D60 MO for CSU	2019H001696378
Ceil. Bearing D60 MO for CSU	2019H001696384
Ceil. Bearing D60 MO for CSU	2019H001696382
Ceil. Bearing D60 MO for CSU	2019H001696386
Ceil. Bearing D60 MO for CSU	3119H001772925
Ceil. Bearing D60 MO for CSU	2019H001696380
Ceil. Bearing D60 MO for CSU	3119H001772923
Ceil. Bearing D60 MO for CSU	3119H001772924
Ceil. Bearing D60 MO for CSU	2019H001696379
Ceil. Bearing D60 MO for CSU	2019H001696381
Ceil. Bearing D60 MO for CSU	4719H001908541
Ceil. Bearing D60 MO for CSU	4719H001908536
Ceil. Bearing D60 MO for CSU	4719H001908537

Ceil. Bearing D60 MO for CSU	4719H001908539
Ceil. Bearing D60 MO for CSU	4719H001908535
Ceil. Bearing D60 MO for CSU	4719H001908540
Ceil. Bearing D60 MO for CSU	4719H001908543
Ceil. Bearing D60 MO for CSU	4719H001908534
Ceil. Bearing D60 MO for CSU	4719H001908545
Ceil. Bearing D60 MO for CSU	4719H001908542
Ceil. Bearing D60 MO for CSU	4719H001908538
Ceil. Bearing D60 MO for CSU	4719H001908544
Ceil. Bearing D60 MO for CSU	5119H001947132
Ceil. Bearing D60 MO for CSU	5019H001942411
Ceil. Bearing D60 MO for CSU	5119H001947131
Ceil. Bearing D60 MO for CSU	5019H001942412

Ceil. Bearing D60 MO for CSU	5019H001942409
Ceil. Bearing D60 MO for CSU	5019H001942410
Ceil. Bearing D60 MO for CSU	5019H001942407
Ceil. Bearing D60 MO for CSU	5019H001942408
Ceil. Bearing D60 MO for CSU	5119H001954602
Ceil. Bearing D60 MO for CSU	5119H001954605
Ceil. Bearing D60 MO for CSU	5119H001954604
Ceil. Bearing D60 MO for CSU	5119H001954603
Ceil. Bearing D60 MO for CSU	5119H001954606
Ceil. Bearing D60 MO for CSU	5119H001954607
Ceil. Bearing D60 MO for CSU	2164620
Ceil. Bearing D60 MO for CSU	2164618
Ceil. Bearing D60 MO for CSU	2164619

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