

URGENT Field Safety Notice

Azurion 7 M20 FlexArm system with Maquet Magnus Table
Unavailable Motorized Table and/or FlexArm Movement Potentially Resulting in Delay or Termination
of Procedure.

08-DEC-2023

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of two potential safety issues with the Azurion 7 M20 FlexArm system (“FlexArm”) with a Maquet Magnus Table with software version 05.02.12 (“Table”). Due to communication issues between the FlexArm and the Table, motorized movements of the Table and/or the FlexArm may be lost. This Urgent Field Safety Notice is intended to inform you about:

1. What the issues are and under what circumstances they can occur

- Connection Issue: If, during a procedure, the detector is positioned at a distance of approximately four (4) cm from the patient, the connection between the FlexArm and the Table may be lost due to a software issue. When this occurs, the Table and the FlexArm-System will automatically reconnect after approximately 10 seconds, during which Table movement will be unavailable.

The connection between the FlexArm and the Table may not reestablish if the detector continues to be at approximately four (4) cm from the patient when the Table restarts. This will result in a recurring connection loss between the FlexArm and the Table, during which Table movement will be unavailable. In some cases, motorized movement of the FlexArm may also become unavailable, in which case the FlexArm will prompt user messages indicating a Table collision when the user requests motorized movement of the FlexArm.

- Date and Time Issue: When the FlexArm system is (re)started, the FlexArm and Table may not connect due to a software issue. This occurs when the date/time format includes more than three (3) leading zeros (see examples below). The connection will be established automatically once one of the leading zeros changes to a “one (1)”.

Until the connection is established, the FlexArm system will be fully functional, but Table movement will not be available. The maximum time that Table movement will not be available is 10 minutes (see Example 2 below).

	Time of Table (re)start (leading zeros underlined)	Time Table will be operational (leading zeros underlined)	Minutes Table movement not available
Example 1	<u>09</u> - <u>02</u> -2023 <u>08</u> : <u>07</u>	<u>09</u> - <u>02</u> -2023 <u>08</u> :10	3 minutes
Example 2	<u>03</u> - <u>05</u> -2023 <u>00</u> : <u>00</u>	<u>03</u> - <u>05</u> -2023 <u>00</u> :10	10 minutes

2. Hazard/harm associated with the issue

A loss of motorized Table movement due to the Date and Time Issue at start-up of the FlexArm could result in a delay of up to 10 minutes.

A loss of motorized Table movement, and potentially FlexArm movement during a procedure could result in a delay in the procedure or termination of the procedure. The potential delay in treatment and/or termination of the procedure may result in adverse outcomes, including the possibility of death for some of the most critical patients.

To date, Philips has received 28 complaints related to these issues, including one complaint alleging that due to the Connection Issue a patient was transferred to complete the procedure in another hospital and expired.

3. Affected products and how to identify them

Intended use

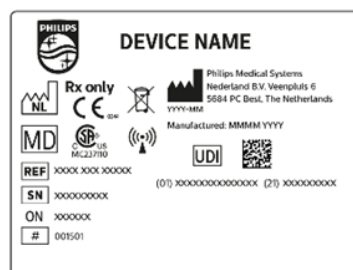
The Azurion series (within the limits of the operation room table) are intended for use to perform:

- Image guidance in diagnostic, interventional, and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular, and neuro procedures.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.
- Additionally:
 - o The Azurion series can be used in a hybrid operating room.
 - o The Azurion series contains several features to support a flexible and patient-centric procedural workflow.

Identification of affected systems.

Appendix A to this letter provides a table with the Product Codes, Device Names, Serial Numbers, and Unique Device Identifiers (UDI) of all impacted systems.

The Device Name, Product Code, Serial Number, and UDI can be found on the System Identification Label located on the FlexArm stand:

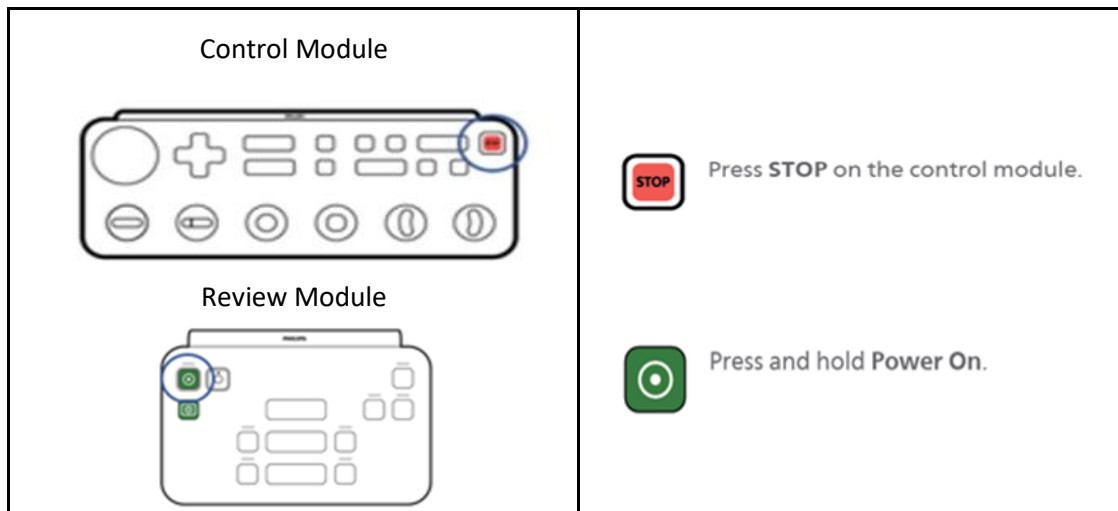


4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

Circulate this Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.

- Until Philips implements the solution in your system. during the procedure:
 - a) Avoid positioning the detector at approximately four (4) cm from the patient.
 - b) If the Connection Issue occurs, perform the following actions **in sequential order**:
 1. move the detector so that it is no longer at approximately four (4) cm from the patient.
 2. if moving the detector doesn't resolve the issue, restart the geometry of the FlexArm as follows:
 - o Press 'STOP' on the **Control Module**
 - o Press and hold the 'Power On' button on the **Review Module**

After this, both Table movement and FlexArm motorized movement will become available again.



- Keep this Urgent Field Safety Notice with the documentation of the system.
- Should you experience an issue with the communication between the FlexArm and the Table, please report the event to Philips by calling your local Philips representative.

Telephone 80 30 30 35
Email philips.service@philips.com

- Please complete and return the attached response form (page 5) to Philips promptly and no later than 3 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.

5. Actions planned by Philips IGT Systems, SRN NL-MF-000001489 to correct the problem

Philips will be installing a software update that will resolve the Date and Time Issue (reference FCO72200528). You will be contacted by your local Philips representative to schedule these activities.



Simultaneously, Philips is working on developing a solution to correct the Connection Issue (Philips reference FCO72200557).

If you need any further information or support concerning this matter, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority.

Sincerely

Peter Jangenfeldt
Head of Services & Solutions Delivery

URGENT Field Safety Notice Response Form

Reference: Azurion 7 M20 FlexArm system with Maquet Magnus Table with software version 05.02.12
Communications Issues between the Azurion 7 M20 FlexArm and the Maquet Magnus Table

Instructions: Please complete and return this form to Philips promptly and no later than 3 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

Circulate this Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.

- Until Philips implements the solution in your system. during the procedure:
 - a) Avoid positioning the detector at approximately four (4) cm from the patient.
 - b) If the Connection Issue occurs, perform the following actions **in sequential order**:
 1. move the detector so that it is no longer at approximately four (4) cm from the patient.
 2. if moving the detector doesn't resolve the issue, restart the geometry of the FlexArm as follows:
 - Press 'STOP' on the **Control Module**
 - Press and hold the 'Power On' button on the **Review Module**After this, both Table movement and FlexArm motorized movement will become available again.
- Keep this Field Safety Notice with the documentation of the system.
- Should you experience an issue with the communication between the FlexArm and the Table, please report the event to Philips by calling your local Philips representative.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected Azurion 7 M20 FlexArm system with Maquet Magnus Table with software version 05.02.12.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD/ MMM/ YYYY): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Urgent Medical Device Correction.

Please complete and return this form via email to FCO.Nordic@philips.com

APPENDIX A
List of affected products

Product Code	Device Name	Serial Number	UDI Number
722224	Azurion 7 M20	3	(01)00884838099258(21)3
722224	Azurion 7 M20	20	(01)00884838099258(21)20
722224	Azurion 7 M20	36	(01)00884838099258(21)36
722224	Azurion 7 M20	60	(01)00884838099258(21)60
722224	Azurion 7 M20	62	(01)00884838099258(21)62
722224	Azurion 7 M20	134	(01)00884838099258(21)134
722224	Azurion 7 M20	144	(01)00884838099258(21)144
722224	Azurion 7 M20	150	(01)00884838099258(21)150
722224	Azurion 7 M20	157	(01)00884838099258(21)157
722224	Azurion 7 M20	197	(01)00884838099258(21)197
722224	Azurion 7 M20	211	(01)00884838099258(21)211
722224	Azurion 7 M20	212	(01)00884838099258(21)212
722224	Azurion 7 M20	252	(01)00884838099258(21)252
722224	Azurion 7 M20	257	(01)00884838099258(21)257
722224	Azurion 7 M20	272	(01)00884838099258(21)272
722224	Azurion 7 M20	278	(01)00884838099258(21)278
722224	Azurion 7 M20	280	(01)00884838099258(21)280
722224	Azurion 7 M20	347	(01)00884838099258(21)347
722224	Azurion 7 M20	352	(01)00884838099258(21)352
722224	Azurion 7 M20	355	(01)00884838099258(21)355
722224	Azurion 7 M20	370	(01)00884838099258(21)370
722224	Azurion 7 M20	379	(01)00884838099258(21)379
722224	Azurion 7 M20	387	(01)00884838099258(21)387
722224	Azurion 7 M20	388	(01)00884838099258(21)388
722224	Azurion 7 M20	395	(01)00884838099258(21)395
722224	Azurion 7 M20	424	(01)00884838099258(21)424
722224	Azurion 7 M20	455	(01)00884838099258(21)455
722224	Azurion 7 M20	468	(01)00884838099258(21)468
722224	Azurion 7 M20	474	(01)00884838099258(21)474
722224	Azurion 7 M20	477	(01)00884838099258(21)477
722224	Azurion 7 M20	495	(01)00884838059191(10)1.6.6.1
722224	Azurion 7 M20	537	(01)00884838099258(21)537
722224	Azurion 7 M20	539	(01)00884838099258(21)539
722224	Azurion 7 M20	549	(01)00884838099258(21)549
722224	Azurion 7 M20	555	(01)00884838099258(21)555
722224	Azurion 7 M20	572	(01)00884838099258(21)572
722224	Azurion 7 M20	575	(01)00884838099258(21)575
722224	Azurion 7 M20	606	(01)00884838099258(21)606
722079	Azurion 7 M20	630	(01)00884838085268(21)630
722224	Azurion 7 M20	633	(01)00884838099258(21)633
722079	Azurion 7 M20	638	(01)00884838085268(21)638
722224	Azurion 7 M20	639	(01)00884838099258(21)639

722224	Azurion 7 M20	645	(01)00884838099258(21)645
722224	Azurion 7 M20	647	(01)00884838099258(21)647
722224	Azurion 7 M20	648	(01)00884838099258(21)648
722224	Azurion 7 M20	690	(01)00884838099258(21)690
722224	Azurion 7 M20	712	(01)00884838099258(21)712
722224	Azurion 7 M20	730	(01)00884838099258(21)730
722079	Azurion 7 M20	743	(01)00884838059191(10)1.6.6.1
722079	Azurion 7 M20	748	(01)00884838085268(21)748
722079	Azurion 7 M20	756	(01)00884838085268(21)756
722224	Azurion 7 M20	764	(01)00884838099258(21)764
722079	Azurion 7 M20	768	(01)00884838085268(21)768
722224	Azurion 7 M20	771	(01)00884838099258(21)771
722224	Azurion 7 M20	772	(01)00884838099258(21)772
722224	Azurion 7 M20	778	(01)00884838099258(21)778
722224	Azurion 7 M20	781	(01)00884838099258(21)781
722224	Azurion 7 M20	799	(01)00884838099258(21)799
722079	Azurion 7 M20	812	(01)00884838085268(21)812
722079	Azurion 7 M20	824	(01)00884838085268(21)824
722224	Azurion 7 M20	861	(01)00884838099258(21)861
722224	Azurion 7 M20	863	(01)00884838099258(21)863
722079	Azurion 7 M20	866	(01)00884838085268(21)866
722224	Azurion 7 M20	879	(01)00884838099258(21)879
722224	Azurion 7 M20	887	(01)00884838099258(21)887
722079	Azurion 7 M20	893	(01)00884838085268(21)893
722224	Azurion 7 M20	895	(01)00884838099258(21)895
722224	Azurion 7 M20	896	(01)00884838099258(21)896
722224	Azurion 7 M20	917	(01)00884838099258(21)917
722079	Azurion 7 M20	929	(01)00884838085268(21)929
722079	Azurion 7 M20	934	(01)00884838085268(21)934
722224	Azurion 7 M20	937	(01)00884838099258(21)937
722079	Azurion 7 M20	952	(01)00884838085268(21)952
722224	Azurion 7 M20	969	(01)00884838099258(21)969
722079	Azurion 7 M20	1005	(01)00884838085268(21)1005
722079	Azurion 7 M20	1079	(01)00884838085268(21)1079
722079	Azurion 7 M20	1086	(01)00884838085268(21)1086
722079	Azurion 7 M20	1122	(01)00884838085268(21)1122
722079	Azurion 7 M20	1135	(01)00884838085268(21)1135
722079	Azurion 7 M20	1169	(01)00884838085268(21)1169
722079	Azurion 7 M20	1172	(01)00884838085268(21)1172
722224	Azurion 7 M20	1177	(01)00884838099258(21)1177
722079	Azurion 7 M20	1202	(01)00884838085268(21)1202
722224	Azurion 7 M20	1216	(01)00884838099258(21)1216
722079	Azurion 7 M20	1241	(01)00884838085268(21)1241
722079	Azurion 7 M20	1248	(01)00884838085268(21)1248
722224	Azurion 7 M20	1249	(01)00884838099258(21)1249
722224	Azurion 7 M20	1250	(01)00884838099258(21)1250

722079	Azurion 7 M20	1303	(01)00884838085268(21)1303
722079	Azurion 7 M20	1313	(01)00884838085268(21)1313
722224	Azurion 7 M20	1332	(01)00884838099258(21)1332
722224	Azurion 7 M20	1337	(01)00884838099258(21)1337
722224	Azurion 7 M20	1349	(01)00884838099258(21)1349
722079	Azurion 7 M20	1357	(01)00884838085268(21)1357
722079	Azurion 7 M20	1361	(01)00884838085268(21)1361
722224	Azurion 7 M20	1388	(01)00884838099258(21)1388
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722224	Azurion 7 M20	1431	(01)00884838099258(21)1431
722224	Azurion 7 M20	1463	(01)00884838099258(21)1463
722224	Azurion 7 M20	1534	(01)00884838099258(21)1534
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722224	Azurion 7 M20	1778	(01)00884838099258(21)1778
722224	Azurion 7 M20	1925	(01)00884838099258(21)1925
722224	Azurion 7 M20	2025	(01)00884838099258(21)2025
722224	Azurion 7 M20	2035	(01)00884838099258(21)2035
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722224	Azurion 7 M20	2042	(01)00884838099258(21)2042
722224	Azurion 7 M20	2057	(01)00884838099258(21)2057
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722224	Azurion 7 M20	2208	(01)00884838099258(21)2208
722224	Azurion 7 M20	2231	(01)00884838099258(21)2231
722224	Azurion 7 M20	2283	(01)00884838099258(21)2283
722224	Azurion 7 M20	2307	(01)00884838099258(21)2307
722224	Azurion 7 M20	2309	(01)00884838099258(21)2309
722224	Azurion 7 M20	2576	(01)00884838099258(21)2576
722224	Azurion 7 M20	2611	(01)00884838099258(21)2611
722224	Azurion 7 M20	2716	(01)00884838099258(21)2716
722079	Azurion 7 M20	703346	(01)00884838085268(21)703346
722079	Azurion 7 M20	703351	(01)00884838085268(21)703351
722079	Azurion 7 M20	703385	(01)00884838085268(21)703385
722079	Azurion 7 M20	703456	(01)00884838085268(21)703456
722079	Azurion 7 M20	703461	(01)00884838085268(21)703461
722079	Azurion 7 M20	703615	(01)00884838059191(10)1.6.6
722079	Azurion 7 M20	703638	(01)00884838085268(21)703638
722079	Azurion 7 M20	703705	(01)00884838085268(21)703705
722079	Azurion 7 M20	703706	(01)00884838085268(21)703706
722079	Azurion 7 M20	703810	(01)00884838085268(21)703810

722079	Azurion 7 M20	703845	(01)00884838085268(21)703845
722079	Azurion 7 M20	703959	(01)00884838085268(21)703959