

Urgent Field Safety Notice

ACHC25-01.A.OUS

Atellica CH Analyzer

Title Atellica CH Reaction Ring Cuvette Segments May Cause Imprecision on Seven (7) Assays

Date Issued Oct-2024

Issue Description Siemens Healthineers has confirmed, through the internal investigation of customer complaints that there is a potential for imprecision with seven (7) assays identified to have optical sensitivity when using a subset of lots of Atellica® CH Reaction Ring Cuvette Segments on some Atellica CH analyzers (See Appendix A Table 1). The lot numbers of potentially impacted Atellica CH Reaction Ring Cuvette Segments begin with “N15” on the packaging or “15” on the underside of the cuvette segment. Not all Atellica CH analyzers are impacted by this issue.

Quality Control (QC) failures may alert customers to the issue before patient samples are processed. See Table 2 in the Appendix A for impacted assay bias data.

This issue does not impact Atellica CH Reaction Ring Cuvette Segments which have lot numbers that begin with “11”.

Products

Product	Siemens Material Number / Unique Device Identification	Lot Numbers
Atellica CH Reaction Ring Cuvette Segment	11099326 / 00630414596143	All lots starting with “N15” or “15”

Impact to Results Erroneously elevated or depressed QC and patient results for seven (7) analytes may occur due to this issue (See Table 1 in the Appendix A). The data from internal studies are displayed in the Appendix A, Table 2. Results of these tests should be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings.

- Customer Actions**
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
 - **Review your current Atellica CH Reaction Ring Cuvette Segment stock. All Atellica CH Reaction Ring Cuvette Segments beginning with “11” are not part of this communication and can be used without restriction. Any other lot in your stock must be immediately discarded.**
 - **Locate your analyzer’s serial number within Appendix B Serial Number List. If your analyzer’s serial number is in the provided list perform the instructions to assess, inspect and/or replace Atellica CH Reaction Ring Cuvettes Segments provided in the Appendix section.**
 - Determine your laboratory’s replacement needs and provide detailed information to Siemens Healthineers for reporting to authorities. Complete and return the Field Correction Effectiveness Check Form attached to this letter within ten (10) days.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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Resolution Siemens Healthineers has confirmed Atellica CH reaction ring segments beginning with lot number “11” are not impacted, and going forward all future lots will work as expected.
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Single Registration Number (SRN) US-MF-000016560
Only for OUS USFN/CN. If SRN not available delete this row. Delete this row for US letters

Appendix A Table 1. Assays with Potential for Bias Due to Imprecision

Product Name	Siemens Material Number
Atellica CH Ammonia (Amm)	11097529
Atellica CH Acetaminophen (Acet)	11097522
Atellica CH Alanine Aminotransferase (ALT)	11097605
Atellica CH Enzymatic Hemoglobin A1c (A1c_E)	11097536
Atellica CH Creatine Kinase (CK_L)	11097640
Atellica CH Cystatin C_2 (CYSC_2)	11097647
Atellica CH Salicylate (Sal)	11097523

Table 2. Potential Bias for Impacted Assays Due to Imprecision

Assay	QC Level	Expected Result	Maximum Observed Positive Relative Bias (%)	Maximum Observed Negative Relative Bias (%)
Amm	L1	122.0 µg/dL [71.6 µmol/L]	9.8	-24.8
Acet	L1	1.4 mg/dL [92.5 µmol/L]	21.4	-14.3
	L3	13.8 mg/dL [912.2 µmol/L]	2.9	-3.6
ALT	L1	34 U/L	12.9	-16.5
	L3	195 U/L	4.3	-1.1
A1c_E	L1	4.3 % [23.5 mmol/mol]	14.0	-14.0
	L2	9.4 % [79.2 mmol/mol]	6.9	-2.8
CK_L	L1	70 U/L	80.0	>-80.0
	L3	547 U/L	18.6	-2.7
CYSC_2	L1	0.5 mg/L	34.0	-44.0
	L2	0.6 mg/L	28.3	-23.3
Sal	L1	6 mg/dL [0.4 mmol/L]	66.7	>-60.0
	L2	15 mg/dL [1.1 mmol/L]	31.3	-26.0

Assessing the Atellica CH Reaction Ring Cuvette Segments on the Atellica CH Analyzer.

Total time for this procedure is ~ 90-100 minutes

- **Assess your current Atellica CH Reaction Ring Cuvette Segment stock.**
All Atellica CH Reaction Ring Cuvette Segments beginning with "11" can be used without restriction. Any other lot in your stock must be immediately discarded.

Figure 1. Location of the lot number on Atellica CH Reaction Ring Cuvette Segment



1. Enter diagnostic state (*Enter Diagnostics State in Atellica CH* per Section 18 Troubleshooting of the Atellica Solutions Operator Diagnostics Online Help).
2. Select **Subsystems > Cuvette**.
3. Select **Replacing the CH Reaction Ring Cuvette Segments > Perform > Yes**.
4. Wait for the analyzer to prepare for maintenance.

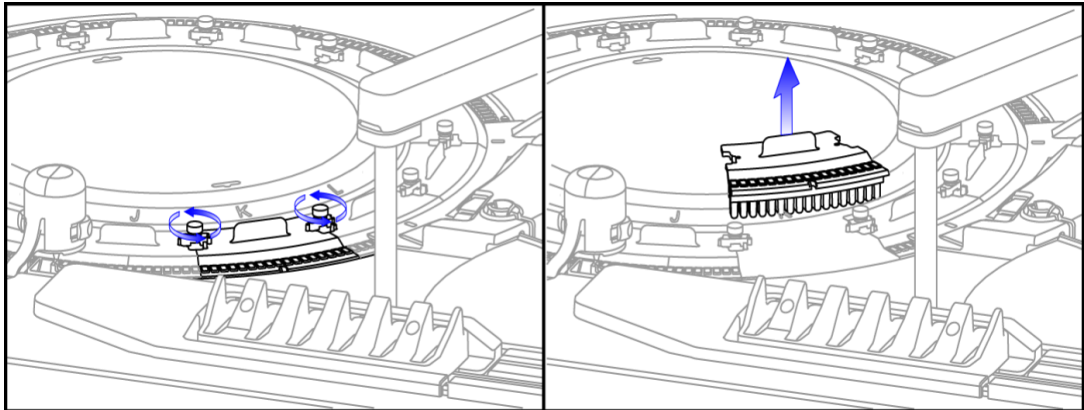
NOTE: The covers automatically unlock. If the covers are locked, select **Unlock Covers**.

5. Open the Atellica CH front cover.
6. Grasp the reaction ring and rotate it clockwise or counterclockwise to access the reaction cuvette segment.

NOTE: The analyzer identifies each cuvette segment position with a capital letter.

7. To unlock the segment, turn the thumbscrews one-quarter counterclockwise so the locking tabs are at the 12 or 6 position and the segment lifts out. (Figure 2)

Figure 2. Unlock and lift up the cuvette segment



8. To remove the segment, lift and inspect the underside barcode (see Figure 1).

- If the lot number begins with “11” it is not impacted. Re-insert the cuvette segment back into the location it was removed from.
- If the lot number begins with an “N15” or “15” locate a new segment with a barcode that starts with an “11” and place the segment on the reaction ring. If you don’t have a new segment that starts with “11” reinsert the “N15” or “15” segment and record the capital letter position and lot number. This information is needed for Siemens personnel to assess your analyzer’s performance.

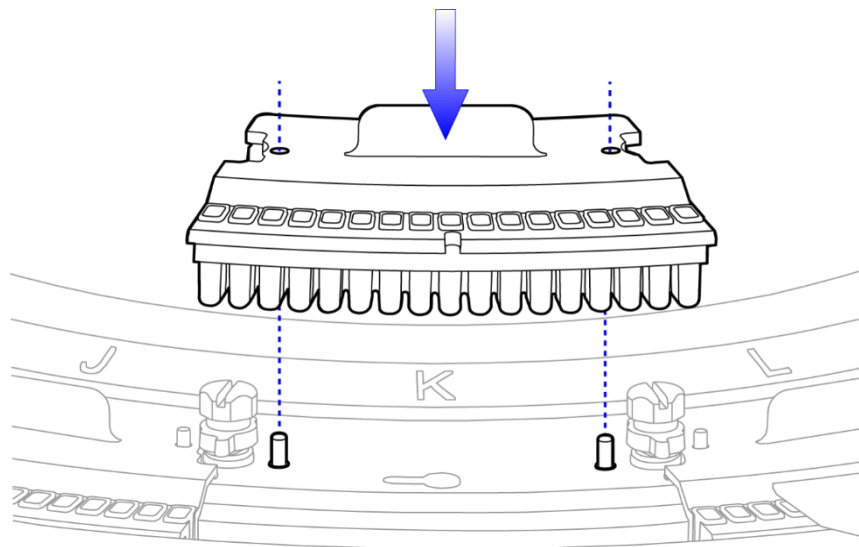


Figure 3. Install cuvette segment

9. Align the pins to the holes in the segment. (Figure 3.)

10. Tighten the thumbscrews clockwise to lock the segment in place.

11. Repeat step 6–11 by removing, inspecting, and if needed, replacing the cuvette segments

one at a time until the operator inspects all cuvette segments.

12. Close the front cover.

13. Select **Continue > Close**.

14. Select **Exit Diagnostics > Yes**.

Note: Do not mark the activity as complete in the Maintenance Log unless all cuvette segments are replaced.

15. Perform CH Weekly Maintenance (*Performing CH Weekly Maintenance on the CH Analyzer per Section 17 Maintenance of the Atellica Solutions Online Help*).

16. Wait for CH Weekly Maintenance to complete before analyzing samples.

If you are unable to complete the instructions above due to inadequate supply of product with lot number beginning with "11", contact your local technical support provider or distributor for further assistance.

Appendix B

Serial Number List

CM00136, CM00137, CM00139, CM00140, CM00144, CM00145, CM00146, CM00150, CM00155, CM00170, CM00174, CM00175, CM00177, CM00179, CM00180, CM00185, CM00186, CM00187, CM00193, CM00194, CM00195, CM00200, CM00202, CM00206, CM00214, CM00219, CM00222, CM00224, CM00227, CM00235, CM00236, CM00239, CM00245, CM00249, CM00250, CM00252, CM00253, CM00262, CM00279, CM00284, CM00287, CM00294, CM00300, CM00305, CM00307, CM00311, CM00328, CM00329, CM00334, CM00336, CM00339, CM00340, CM00348, CM00354, CM00355, CM00358, CM00362, CM00363, CM00366, CM00367, CM00368, CM00369, CM00370, CM00371, CM00378, CM00379, CM00380, CM00381, CM00382, CM00383, CM00384, CM00385, CM00387, CM00388, CM00391, CM00393, CM00401, CM00406, CM00409, CM00410, CM00412, CM00434, CM00439, CM00448, CM00450, CM00451, CM00454, CM00456, CM00461, CM00462, CM00463, CM00464, CM00466, CM00468, CM00472, CM00473, CM00474, CM00475, CM00478, CM00479, CM00487, CM00488, CM00498, CM00507, CM00511, CM00520, CM00534, CM00535, CM00536, CM00537, CM00538, CM00539, CM00540, CM00542, CM00543, CM00544, CM00547, CM00551, CM00552, CM00553, CM00555, CM00556, CM00557, CM00558, CM00560, CM00562, CM00564, CM00566, CM00568, CM00570, CM00571, CM00573, CM00578, CM00585, CM00586, CM00587, CM00591, CM00592, CM00593, CM00598, CM00608, CM00610, CM00619, CM00638, CM00642, CM00644, CM00645, CM00658, CM00660, CM00662, CM00667, CM00672, CM00673, CM00678, CM00681, CM00682, CM00683, CM00689, CM00692, CM00696, CM00697, CM00700, CM00710, CM00713, CM00717, CM00720, CM00731, CM00738, CM00750, CM00751, CM00758, CM00761, CM00771, CM00776, CM00787, CM00790, CM00791, CM00797, CM00805, CM00808, CM00817, CM00819, CM00824, CM00825, CM00827, CM00835, CM00836, CM00839, CM00840, CM00842, CM00843, CM00844, CM00845, CM00849, CM00850, CM00857, CM00860, CM00861, CM00862, CM00869, CM00873, CM00885, CM00889, CM00890, CM00891, CM00893, CM00894, CM00897, CM00898, CM00900, CM00904, CM00909, CM00910, CM00912, CM00914, CM00919, CM00935, CM00936, CM00938, CM00940, CM00944, CM00945, CM00946, CM00949, CM00950, CM00962, CM00964, CM00965, CM00966, CM00968, CM00970, CM00975, CM00980, CM00981, CM00984, CM00985, CM00986, CM00987, CM00989, CM00991, CM00994, CM01002, CM01003,

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC25-01.A.OUS dated Oct-2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. Have you read and understood the instructions provided in this letter? Yes No
- 2. Do you have the affected product(s) on hand? Please check inventories before answering. Yes No
- 3. Were affected Site Personnel notified? Yes No
- 4. Was a copy of the letter retained and posted with the current product labeling? Yes No

If the answer to the question #2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required		
Atellica CH Reaction Ring Cuvette Segments / 11099326 / Lots "N15" or "15"			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	Zip Code:
Phone:		Country:	

Please send a scanned copy of the completed form via email to fscreportingunit.my@siemens-healthineers.com

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Urgent Field Safety Notice

ACHC25-01.B.OUS

Atellica CH Analyzer

Title Atellica CH Reaction Ring Cuvette Segments May Cause Imprecision on Seven (7) Assays

Date Issued Oct-2024

Issue Description Siemens Healthineers has confirmed, through the internal investigation of customer complaints that there is a potential for imprecision with seven (7) assays identified to have optical sensitivity when using a subset of lots of Atellica® CH Reaction Ring Cuvette Segments on some Atellica CH analyzers (See Appendix Table 1). The lot numbers of potentially impacted Atellica CH Reaction Ring Cuvette Segments begin with “N15” on the packaging or “15” on the underside of the cuvette segment. Not all Atellica CH analyzers are impacted by this issue.

Quality Control (QC) failures may alert customers to the issue before patient samples are processed. See Table 2 in the Appendix for impacted assay bias data.

This issue does not impact Atellica CH Reaction Ring Cuvette Segments which have lot numbers that begin with “11”.

Products

Product	Siemens Material Number / Unique Device Identification	Lot Numbers
Atellica CH Reaction Ring Cuvette Segment	11099326 / 00630414596143	All lots starting with “N15” or “15”

Impact to Results Erroneously elevated or depressed QC and patient results for seven (7) analytes may occur due to this issue (See Table 1 in the Appendix). The data from internal studies are displayed in the Appendix, Table 2. Results of these tests should be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings.

- Customer Actions**
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
 - **Review your current Atellica CH Reaction Ring Cuvette Segment stock. All Atellica CH Reaction Ring Cuvette Segments beginning with “11” are not part of this communication and can be used without restriction. Any other lot in your stock must be immediately discarded.**
 - Instruments connected to Smart Remote Services (SRS) were assessed remotely on **07-Oct-2024**. Your analyzer(s) was determined to be **NOT** impacted. **However, if you have replaced your cuvettes since 07-Oct-2024 then inspect and/or replace Atellica CH Reaction Ring Cuvettes Segments provided in the Appendix below.**
 - Determine your laboratory’s replacement needs and provide detailed information to Siemens Healthineers for reporting to authorities. Complete and return the Field Correction Effectiveness Check Form attached to this letter within ten (10) days.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
-

Resolution Siemens Healthineers has confirmed Atellica CH reaction ring segments beginning with lot number "11" are not impacted, and going forward all future lots will work as expected.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Single Registration Number (SRN)

US-MF-000016560

Appendix Table 1. Assays with Potential Bias Due to Imprecision

Product Name	Siemens Material Number
Atellica CH Ammonia (Amm)	11097529
Atellica CH Acetaminophen (Acet)	11097522
Atellica CH Alanine Aminotransferase (ALT)	11097605
Atellica CH Enzymatic Hemoglobin A1c (A1c_E)	11097536
Atellica CH Creatine Kinase (CK_L)	11097640
Atellica CH Cystatin C_2 (CYSC_2)	11097647
Atellica CH Salicylate (Sal)	11097523

Table 2. Potential Bias for Impacted Assays Due to Imprecision

Assay	QC Level	Expected Result	Maximum Observed Positive Relative Bias (%)	Maximum Observed Negative Relative Bias (%)
Amm	L1	122.0 µg/dL [71.6 µmol/L]	9.8	-24.8
Acet	L1	1.4 mg/dL [92.5 µmol/L]	21.4	-14.3
	L3	13.8 mg/dL [912.2 µmol/L]	2.9	-3.6
ALT	L1	34 U/L	12.9	-16.5
	L3	195 U/L	4.3	-1.1
A1c_E	L1	4.3 % [23.5 mmol/mol]	14.0	-14.0
	L2	9.4 % [79.2 mmol/mol]	6.9	-2.8
CK_L	L1	70 U/L	80.0	>-80.0
	L3	547 U/L	18.6	-2.7
CYSC_2	L1	0.5 mg/L	34.0	-44.0
	L2	0.6 mg/L	28.3	-23.3
Sal	L1	6 mg/dL [0.4 mmol/L]	66.7	>-60.0
	L2	15 mg/dL [1.1 mmol/L]	31.3	-26.0

Assessing the Atellica CH Reaction Ring Cuvette Segments on the Atellica CH Analyzer.

Total time for this procedure is ~ 90-100 minutes

- **Assess your current Atellica CH Reaction Ring Cuvette Segment stock.**
All Atellica CH Reaction Ring Cuvette Segments beginning with "11" can be used without restriction. Any other lot in your stock must be immediately discarded.

Figure 1. Location of the lot number on Atellica CH Reaction Ring Cuvette Segment



1. Enter diagnostic state (*Enter Diagnostics State in Atellica CH* per Section 18 Troubleshooting of the Atellica Solutions Operator Diagnostics Online Help).
2. Select **Subsystems > Cuvette**.
3. Select **Replacing the CH Reaction Ring Cuvette Segments > Perform > Yes**.
4. Wait for the analyzer to prepare for maintenance.

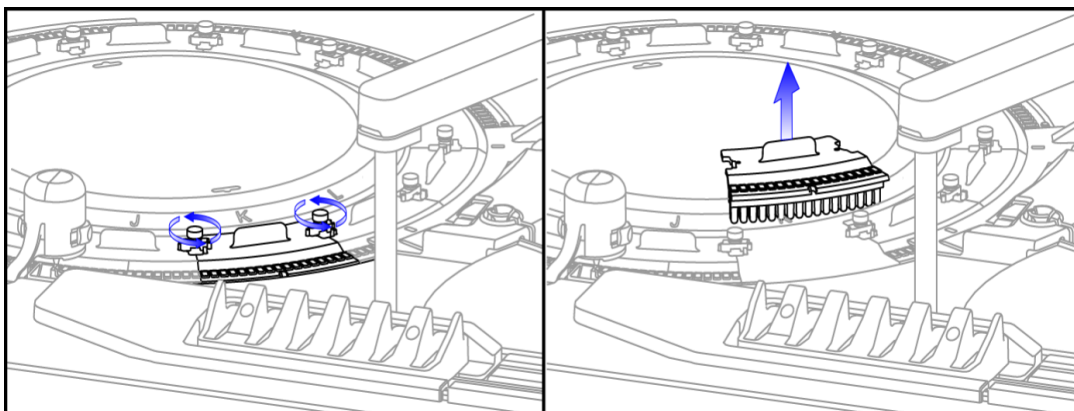
NOTE: The covers automatically unlock. If the covers are locked, select **Unlock Covers**.

5. Open the Atellica CH front cover.
6. Grasp the reaction ring and rotate it clockwise or counterclockwise to access the reaction cuvette segment.

NOTE: The analyzer identifies each cuvette segment position with a capital letter.

7. To unlock the segment, turn the thumbscrews one-quarter counterclockwise so the locking tabs are at the 12 or 6 position and the segment lifts out. (Figure 2)

Figure 2. Unlock and lift up the cuvette segment



8. To remove the segment, lift and inspect the underside barcode (see Figure 1).

- If the lot number begins with “11” it is not impacted. Re-insert the cuvette segment back into the location it was removed from.
- If the lot number begins with an “N15” or “15” locate a new segment with a barcode that starts with an “11” and place the segment on the reaction ring. If you don’t have a new segment that starts with “11” reinsert the “N15” or “15” segment and record the capital letter position and lot number. This information is needed for Siemens personnel to assess your analyzer’s performance.

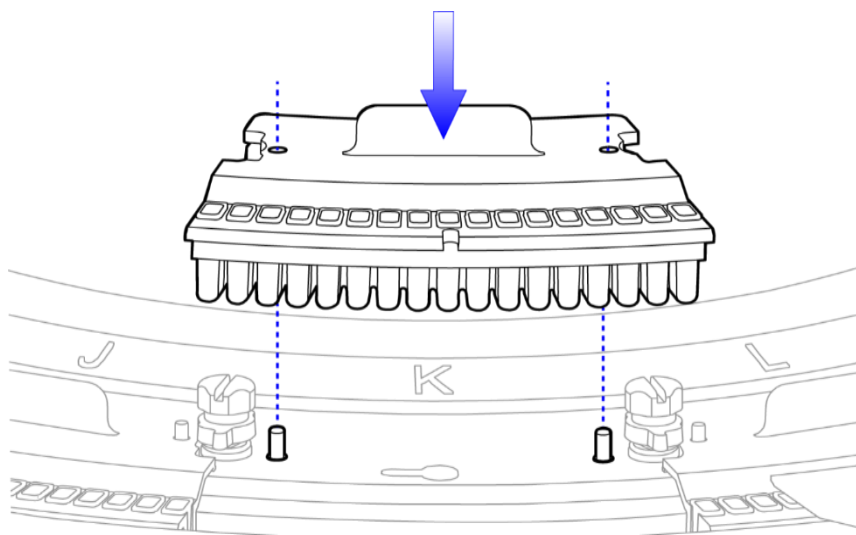


Figure 3. Install cuvette segment

9. Align the pins to the holes in the segment. (Figure 3.)

10. Tighten the thumbscrews clockwise to lock the segment in place.

11. Repeat step 6–11 by removing, inspecting, and if needed, replacing the cuvette segments one at a time until the operator inspects all cuvette segments.

12. Close the front cover.

13. Select **Continue > Close**.

14. Select **Exit Diagnostics > Yes**.

Note: Do not mark the activity as complete in the Maintenance Log unless all cuvette segments are replaced.

15. Perform CH Weekly Maintenance (*Performing CH Weekly Maintenance on the CH Analyzer* per Section 17 Maintenance of the Atellica Solutions Online Help).

16. Wait for CH Weekly Maintenance to complete before analyzing samples.

If you are unable to complete the instructions above due to inadequate supply of product with lot number beginning with "11", contact your local technical support provider or distributor for further assistance.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC25-01.B.OUS dated Oct-2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. Have you read and understood the instructions provided in this letter? Yes No
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