PIE MEDICAL IMAGING

FSN Ref: FSN HDC-2545

solutions in cardiovascular analysis

Date: 27-Jun-2025

Urgent Field Safety Notice
3mensio Workstation (Vascular – Fenestrated)
Version (10.6, 10.6 SP1, 10.6 SP2, 10.6 SP3, 10.6 SP4, 10.7, 10.7 SP1)

For Attention of*:3mensio Workstation 10.6 and 10.7 - Vascular users

Contact details of local representative (name, e-mail, telephone, address etc.)*
The purpose of this letter is to advise you that Pie Medical Imaging is issuing an urgent Field Safety Notice regarding the clock position visualization in the fenestration diagram in 3mensio Workstation 10.6 (Vascular – Fenestrated layout) or 3mensio Workstation 10.7 (Vascular – Fenestrated layout). **Affected devices:** this issue exists in 3mensio Workstation 10.6 and 10.7 (including service packs) with the following UDI's: (01)08056304455505(11)240325(8012)10.6 (01)08056304455505(11)240411(8012)10.6 SP1 (01)08056304455505(11)240610(8012)10.6 SP2 (01)08056304455505(11)240926(8012)10.6 SP3 (01)08056304455505(11)250109(8012)10.6 SP4 (01)08056304455925(11)250423(8012)10.7 (01)08056304455925(11)250523(8012)10.7 SP1 The UDI can be found in the About Box, which can be found as follows: 1. Open application 2. Click on the '?' in the top left corner 3. Click on 'About'

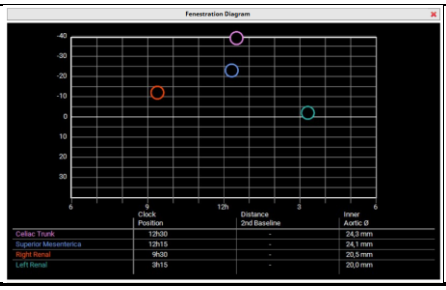
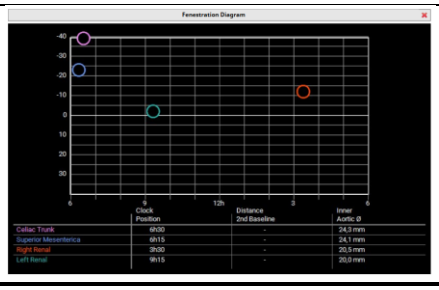
Situation: Please be aware of the following situation, which occurs resulting from the following steps:

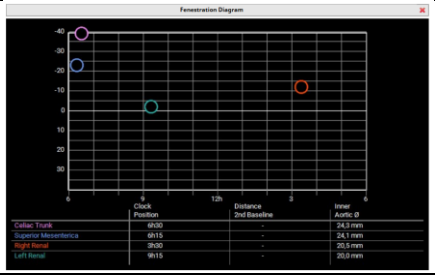
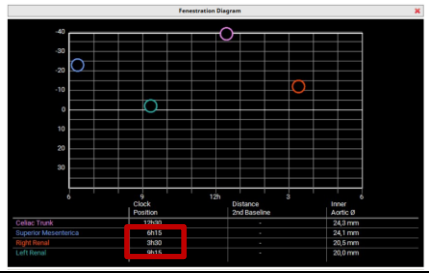
1. Open 3mensio Workstation 10.6 (Vascular – Fenestrated layout).
2. Perform a vascular planning with two or more clock measurements on the fenestration diagram.
3. Adjust the default 12h position of the clock measurements.
4. Save your analysis.
5. Reopen the session state in 3mensio Workstation 10.6 or 10.7.
6. Adjust the 12h position for one clock measurement.

Note: where the steps above mention 3mensio Workstation 10.6 or 3mensio Workstation 10.7, this includes related service packs (SP1, SP2 etc.).

Expected behaviour: In the fenestration diagram all clock measurements should be updated relative to the new 12h position.

Observed behaviour: In the fenestration diagram only the adjusted clock measurement is updated to the new 12h position. The other clock measurements are not updated relative to the new 12h position

Expected		

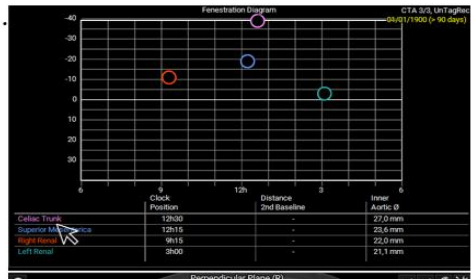
	Fenestrated analysis with clock measurements started in 3mensio Workstation 10.6 (12h in AP direction)	Changing 12h position of a single clock measurement → results in an updated fenestration diagram with all clock measurements relative to this 12h
Observed		
	Opening a fenestrated analysis with clock measurements	Changing 12h position of a single clock measurement → Only the adjusted clock measurements is updated in the fenestration diagram.

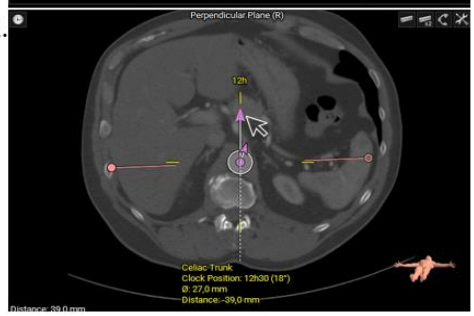
Impact: The hazard exists that the clock positions are not correct in the report causing fenestrations on a stent graft at an incorrect position. This could potentially be harmful for the patient since this could potentially lead to permanent tissue damage. If FSN advice is followed there is no residual risk.

How to prevent this issue:
In case you open a session state with saved clock measurements created in **3mensio Workstation 10.6** and there is a need to adjust the **12h position** for the clock positions, make sure to update **all** individual clock measurements in the perpendicular plane by the following steps:

1. Click on the clock position.
2. Update the 12h pointer of the clock in the perpendicular viewport.
3. Perform step 1 & 2 for all clock measurements in the analysis.

After updating all 12h pointers, the information shown in the fenestration diagram is correct and functionality is restored.

1. 

2. 

Scope of issue
This issue can only occur with session states created with 3mensio Workstation (Vascular – fenestrated layout) v10.6 (or related service pack). For session states created with other versions, this issue does not occur.

Actions PMI is taking:

- Users will be actively informed about this safety issue
- This issue is not applicable in new analysis in 3mensio Workstation 10.7 so PMI will support users to upgrade to this version
- PMI will update the readme of 3mensio Workstation 10.6 and 10.7

Actions you should take:

- When (re)opening a fenestrated analysis created in 3mensio Workstation 10.6 (or related service pack) and adjusting the 12h for an individual clock measurement ALWAYS manually check the other clock measurements on the perpendicular plane.
- Pass and post this notice for all who need to be aware within your organization or to any organization where the potentially affected product is in use.
- Please complete and return the enclosed Customer Acknowledgement Form to PMI.

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	3mensio Workstation 10.6 (Vascular Fenestrated workflow) 3mensio Workstation 10.7 (Vascular Fenestrated workflow)
1.	2. Commercial name(s)
	3mensio Workstation
1.	3. Unique Device Identifier(s) (UDI-DI)*
	(01)08056304455505(11)240325(8012)10.6 (01)08056304455505(11)240411(8012)10.6 SP1 (01)08056304455505(11)240610(8012)10.6 SP2 (01)08056304455505(11)240926(8012)10.6 SP3 (01)08056304455505(11)250109(8012)10.6 SP4 (01)08056304455925(11)250423(8012)10.7 (01)08056304455925(11)250523(8012)10.7 SP1
1.	4. Primary clinical purpose of device(s)*
	3mensio Workstation 10.6 is standalone diagnostic bioimaging software and intended to measure and visualize cardiovascular structures. The Vascular Fenestrated workflow is used for preplanning of stent placement in the aorta.
1.	5. Device Model/Catalogue/part number(s)*
	See section 1.3.
1.	6. Software version
	See section 1.3
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	This field safety notice relates to the situation that results from opening a Vascular session state created in 3mensio Workstation version 10.6 and/or subsequent service pack versions (SP1/SP2/SP3/SP4) with fenestrated clock measurements in the analysis. If the user adjusts the 12h position of one of the clock measurements in the session, the other clock measurements are not updated accordingly. This is visible in the fenestration diagram and when clicking on the clock measurement. The user will see that the 12h indication is not pointing in the same direction as the updated clock.
2.	2. Hazard giving rise to the FSCA*
	The hazard exists that the clock positions are not correct in the report causing fenestrations on a stent graft at an incorrect position. This could potentially be harmful for the patient since this could potentially lead to permanent tissue damage. If the instructions of this FSN are followed there is no residual risk.
2.	3. Probability of problem arising
	The probability of the problem arising is deemed very unlikely since a sequence of events must happen for the problem to occur. This only concerns fenestrated analyses with clock

	measurements created in 3mensio Workstation version 10.6 and only occurs when these analyses are reopened and clock measurements are being adjusted. In such an analysis, adjustment of the 12h position of one of the clock measurements does not trigger the rest of the clock measurements to be updated accordingly. The user can recognize this, since this is visible on screen that the fenestration diagram is not updated and when clicking on the other clock measurements the 12h position is still pointing in the direction as initially placed.
2.	4. Predicted risk to patient/users
	FMEA (Failure Mode and Effects Analysis) is a commonly used risk analysis tool. FMEA scoring result: Low
2.	5. Further information to help characterise the problem
	Since commercial release of 3mensio Workstation version 10.6 in March 2024, this is the first time this issue has been reported. There is already a new version (10.7, April 2025) commercially released where storing sessions cannot cause this issue to arise. Only when opening session states that include fenestrated analyses with clock measurements created in 3mensio Workstation 10.6 are opened, this issue can still arise, unless instructions of this FSN are followed.
2.	6. Background on Issue
	This issue was recognized by a user who reached out to us directly. Due to an update in the software this issue was already addressed and fixed in the newer version of the software (10.7). This issue only occurs in 3mensio Workstation version 10.6, session states that are created in 3mensio Workstation version 10.6 without adjustment in the clock measurement(s) and are being opened in 3mensio Workstation version 10.7 will not have this issue.
2.	7. Other information relevant to FSCA
	None.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None When a user performed a vascular analysis in 3mensio Workstation software version 10.6 and did a fenestrated case analysis with clock measurements, the user must be aware of the following: after reopening the session, adjusting the 12h of one of the clock measurements does NOT update in all clock measurements and the user must manually check and update all clock measurements. After updating all 12h positions of the different clock measurements everything works as expected again.	
3.	2. By when should the action be completed?	When user re-opens a case with fenestrated analysis.

3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? Yes It is recommended to verify if results of ordered devices are correct.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Workaround provided for 3mensio Workstation 10.6 users Additional check for these specific session states will be added in 3mensio Workstation 10.7 SP2	
3	6. By when should the action be completed?	August 31, 2025
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Pie Medical Imaging BV
	b. Address	Demertdwarsstraat 8A01, 6227 AK, Maastricht, The Netherlands (until recently this was Philipsweg 1, 6227 AJ Maastricht, The Netherlands)
	c. Website address	piemedicalimaging.com
4.	8. The Regulatory Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	René Guillaume, CEO Pie Medical Imaging BV

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.