Rev 1: September 2018

FSN Ref: Manufacturer's ref number FSCA Ref: FSCAHE20221110

Date: DD:MMM:YYYY.

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Hematology control
1.	2. Commercial name(s)
	Add as Appendix if necessary.
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	The control is a process control used to monitor instrument performance
1.	5. Device Model/Catalogue/part number(s)*
	Add as Appendix if necessary.
1.	6. Software version
	Not relevant
1.	7. Affected serial or lot number range
	LOT: B1122N (Normal control)
1.	8. Associated devices
	This product is a hematology control used on 3-part hematology analyzers manufactured by Diatron as product families of Abacus3, Abacus Junior 30, Abacus 380, Aquila, Abacus 3 CT, and all their equivalent variants sold under different brand names.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	LOT B1122N, Normal Level may exhibit hemolysis or deterioration due to a microbial contamination. MCV results measured with Normal level of Diacon 3 control LOT B1122N are discrepant from the values specified in the assay sheet. The values measured with the normal level control are about 20% higher than specified. This alteration affects the calculated Hematocrit and MCHC parameters derived from the MCV values, too. Low level and High level controls do not show signs of contamination and can be safely used for the daily QC of the analyzers.
2.	2. Hazard giving rise to the FSCA*
	Microbiological contamination might cause contamination of the analyser and might cause cross contamination of any LOW or HIGH level control that was also tested in the same time. The control is a process control used to monitor instrument performance and does not have any clinical impact.
2.	3. Probability of problem arising
	The problem is expected to be seen for each vial of normal control, LOT: B1122N
	4. Predicted risk to patient/users

2.	As the control is a process control used to monitor instrument performance and does not have any risk to patient/users.
2.	5. Further information to help characterise the problem
	When control measurement is done using normal and low or high control, the analyser shows out of range result for MCV, HTC and MCHC while shows in range values for the same parameters in case of low and high controls.
2.	6. Background on Issue
	R&D Systems, Bio-Techne Co. (OEM manufacturer of the control) informed Diatron MI in an Important Product Notification document that LOT B1122N, Normal Level may exhibit hemolysis or deterioration due to a microbial contamination. R&D Systems has initiated a recall of R&D CBC-3D LOT B1122N which is the same product and LOT as Diatron MI product.
2.	7. Other information relevant to FSCA
	Distributor shall instruct customer about the following: 1) Identify normal control LOT: B1122N in your stock and discard the vials 2) If vials from LOT: B1122N normal control was used in any device, the device fluidics system shall be decontaminated as per the User Manual. If any LOW or HIGH level control was also tested in the same time, discard those control tubes due to risk of microbiological cross contamination. 3) LOW level and HIGH level controls do not show signs of contamination and can be safely used for the daily QC of the analyzers.

	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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	2022-11-16
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Control measurements does not affect the patient reportable results.	
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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	2022.11.25
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	
	N/A	

	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? *	Not planned yet
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	Diatron MI Plc
	b. Address	Táblás u. 39, 1097 Budapest, Hungary
	c. Website address	www.diatron.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Field Safety Notice Distributor Reply Form; Field Safety Notice Customer Reply Form
4.	10. Name/Signature	Insert Name and Title here and signature below

	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.