

Date: 2022. DECEMBER 02.

**Urgent Field Safety Notice**  
**Device Commercial Name**

For Attention of\*:

IGZ Instruments AG  
Quality Assurance and Regulatory Responsible

**Contact details of local representative (name, e-mail, telephone, address etc.)\***

Mr. Roland Hagenbucher ;  
Mrs. Gerlinde Devaud;  
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Switzerland 8107 Buchs ZH, Furtbachstrasse 17.

**Important Note to updated Field Safety Notice:**

This Field Safety Notice (FSN) is an update of the original FSN document (document number: FSNHE20221110-11, dated: November 14, 2022). The reason for the change was a more detailed explanation of the information described in the original FSN mainly regarding a more specified risk assessment. The changes compared to the previous FSN are marked in the corresponding sections of this document.

Please notify the affected end users of this updated FSN documentation and request a confirmation of its receipt in the context of a customer reply form.

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

<b>1. Information on Affected Devices*</b>	
1	<b>1. Device Type(s)*</b>
.	Hematology control
1	<b>2. Commercial name(s)</b>
.	Diacon 3 hematology control (Normal)
1	<b>3. Unique Device Identifier(s) (UDI-DI)</b>
.	5999883586785
1	<b>4. Primary clinical purpose of device(s)*</b>
.	The control is a process control used to monitor instrument performance
1	<b>5. Device Model/Catalogue/part number(s)*</b>
.	10031724
1	<b>6. Software version</b>
.	Not relevant
1	<b>7. Affected serial or lot number range</b>
.	LOT: B1122N (Normal control)
1	<b>8. Associated devices</b>
.	This product is a hematology control used on 3-part hematology analyzers manufactured by Diatron as product families of Abacus 3, Abacus Junior 30, Abacus 380, Aquila, Abacus 3 CT, and all their equivalent variants sold under different brand names.

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	<p><u>Updated in FSN rev 2:</u>            Normal level control - LOT B1122N may have hemolysis or deterioration due to a microbial contamination.</p> <p>MCV results measured with 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.</p> <p>The low (LOT B1122L) and high (LOT B1122H) level controls show no signs of contamination and can therefore be safely used for daily quality control of the analyzers.</p>
2	<b>2. Hazard giving rise to the FSCA*</b>
.	<p>The control is a process control used to monitor instrument performance and have no impact on patient results.</p> <p><u>Addition in FSN rev 2:</u></p> <p>The instrument performs a cleaning procedure between each measurement with a cleaning solution, including the sampling probe and the internal fluidic system as well. The aim of this cleaning is to remove all residual material from the previous test, in order to</p>

	<p>prevent any carry-over of the measured parameters. Even in the theoretical case of a residual microbiological contamination of the instrument, it would need several hours or days to manifest (microbial growth) in the patient sample. Since each measurement takes only maximum 2 minutes before the next cleaning step an impact on patient results is more than unlikely.</p>
2	<p><b>3. Probability of problem arising</b></p> <p><u>Updated in FSN rev 2:</u></p> <p>The probability is difficult to estimate, potentially any vial of LOT: B1122N can be affected.</p>
2	<p><b>4. Predicted risk to patient/users</b></p> <p><u>Updated in FSN rev 2:</u></p> <p>Follow-up or review patients' previous results is not required. Justification: The control is supplied with established assay values for Diatron hematology instruments and is read via Barcode Reader. In case of measured out of range values of the provided ranges, the instrument shows a warning flag to the user. In such a case, according to the standards of Good Laboratory practice, no patient results can be reported until the cause is definitively investigated.</p>
2	<p><b>5. Further information to help characterise the problem</b></p> <p><u>Updated in FSN rev 2:</u></p> <p>Diatron recommends to inspect each control vial for deterioration before use. This can be detected as followed:</p> <p>Signs of hemolysis or deterioration of controls by professional user at the end-customer site include the observation of an unclear separation between the blood cells and the supernatant, a very dark red supernatant on visual inspection. In case of any suspicion of hemolysis or deterioration, the vial must be discarded immediately and excluded further use. This also applies in case of a warning flag of the instrument due to a measured value outside the measuring range specified in the assay sheet.</p>
2	<p><b>6. Background on Issue</b></p> <p>R&amp;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&amp;D Systems has initiated a recall of R&amp;D CBC-3D LOT B1122N which is the same product and LOT as Diatron MI product.</p>
2	<p><b>7. Other information relevant to FSCA</b></p> <p><u>Updated in FSN rev 2:</u> (this section was moved to 3.1)</p> <p>N/A</p>

<b>3. Type of Action to mitigate the risk*</b>
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<p>3.</p>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input checked="" type="checkbox"/> Identify Device    <input checked="" type="checkbox"/> Quarantine Device    <input type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other                      <input type="checkbox"/> None </p> <p><u>Addition in FSN rev 2:</u></p> <ol style="list-style-type: none"> <li>1) Identify normal control LOT: B1122N in your stock and discard the vials</li> <li>2) LOW level and HIGH level controls do not show signs of contamination and can be safely used for the daily QC of the analyzers.</li> <li>3) 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, these control vials must also be discarded as a purely precautionary measure.</li> <li>4) LOW, NORMAL and HIGH controls can be inspected for signs of hemolysis or deterioration: <ol style="list-style-type: none"> <li>a. Signs of hemolysis or deterioration include observing an unclear separation between the blood cells and the supernatant, a very dark red supernatant or obtaining unacceptable results when the control is run on the hematology analyzer.</li> </ol> </li> <li>5) If signs of hemolysis or deterioration are noted, discard the tube per the Instructions for Use. Do not use the product if hemolysis or deterioration is suspected.</li> </ol>	
<p>3.</p>	<p>2. By when should the action be completed?</p>	<p>modified to 2022.12.16</p>
<p>3.</p>	<p>3. Particular considerations for:</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>Control measurements does not affect the patient reportable results.</p> <p><u>Addition in FSN rev 2:</u> When the results measured with the control material that is used in a test run is out of the acceptable range, the run is considered to be "out of control". In this case the testing process should be stopped and the technologist must immediately identify and correct problems. Once possible sources of error have been identified and corrections have been made, the control material should be rechecked. If they read correctly, then patient samples, along with another control measurement, should be repeated. Patient results <b>must not be reported</b> until the problem is resolved and the controls indicate proper performance.</p>	
<p>3.</p>	<p><b>4. Is customer Reply Required? *</b> <b>(If yes, form attached specifying deadline for return)</b></p>	<p>Yes</p>

<b>3.</b>	<b>5. Action Being Taken by the Manufacturer</b>	
	<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input type="checkbox"/> Other	<input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None
3	6. By when should the action be completed?	modified to 2022.12.16
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	

	<b>4. General Information*</b>	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	Number: FSNHE20221110-11 Date: 14 <sup>th</sup> November, 2022
4.	3. For Updated FSN, key new information as follows:	
	This Field Safety Notice (FSN) is an update of the original FSN document (document number: FSNHE20221110-11, dated: November 14, 2022). The reason for the change was a more detailed explanation of the information described in the original FSN mainly regarding a more specified risk assessment. Changes to previous FSN is marked in the relevant and below listed sections: <ul style="list-style-type: none"> <li>- Section 2.1: Description of the product problem (update)</li> <li>- Section 2.2: Hazard giving rise to the FSCA (addition)</li> <li>- Section 2.4: Predicted risk to patient/users (update)</li> <li>- Section 2.5: Further information to help characterise the problem (update)</li> <li>- Section 2.7: Other information relevant to FSCA (update)</li> <li>- Section 3.1: Action To Be Taken by the User (addition)</li> <li>- Section 3.3: Particular considerations (addition)</li> </ul>	
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	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: Yes	
4.	9. List of attachments/appendices:	Field Safety Notice Distributor Reply Form ver 2; Field Safety Notice Customer Reply Form ver 2
4.	10. Name/Signature	András Vámos, Head of Quality, Diatron MI Plc

<b>Transmission of this Field Safety Notice</b>	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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

Date: 2022. DECEMBER 02.

## Field Safety Notice Customer Reply Form

### Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSNHE20221110-11 ver2
FSN Date*	2022 December 02
Product/ Device name*	Diacon 3 hematology control (Normal)
Product Code(s)	10031724
Batch/Serial Number (s)	LOT B1122N

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
<input checked="" type="checkbox"/>	I confirm receipt of the Field Safety Notice FSNHE20221110-11 ver2 and that I read and understood its content.	Customer to complete or enter N/A		
<input checked="" type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input checked="" type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<input checked="" type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input checked="" type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):	Not applicable		

<input type="checkbox"/>	I do not have any affected devices.	Not applicable
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Not applicable
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

<b>4. Return acknowledgement to sender</b>	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



## Field Safety Notice Distributor/Importer Reply Form

### Distributor/Importer Reply Form

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number*	FSNHE20221110-11 ver2
FSN Date*	2022.12.02.
Product/ Device name*	Diacon 3 hematology control (Normal)
Product Code(s)	10031724
Batch/Serial Number (s)	LOT: B1122N

<b>2. Distributor/Importer Details</b>	
Company Name*	IGZ Instruments AG
Account Number	100259
Address*	Switzerland 8107 Buchs ZH, Furtbachstrasse 17.
Shipping address if different to above	
Contact Name*	Mr. Roland Hagenbucher ; Mrs. Gerlinde Devaud; Mr. Daniel Blaser; Arind Ramadani;
Title or Function	
Telephone number*	+41 4 456 33 66
Email*	r.hagenbucher@igz.ch; g.devaud@igz.ch; d.blaser@igz.ch; a.ramadani@igz.ch; igz@igz.ch;

<b>3. Return acknowledgement to Sender</b>	
Email	support@diatron.com
Distributor/Importer Helpline	support@diatron.com
Postal Address	Táblás u. 39, Budapest, H-1097, Hungary
Web Portal	www.diatron.com
Deadline for returning the Distributor/Importer reply form*	2022.12.15

<b>4. Distributors/Importers (Tick all that apply)</b>		
<input checked="" type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice FSNHE20221110-11 ver2	Distributor/Importer to complete or enter N/A
<input checked="" type="checkbox"/>	I have checked my stock and quarantined inventory	PLEASE ENTER QUANTITY AND DATE:
<input checked="" type="checkbox"/>	I have identified customers that received or may have received this device	PLEASE CONFIRM OR or enter N/A
<input type="checkbox"/>	I have attached customer list	N/A
<input checked="" type="checkbox"/>	I have informed the identified customers of this FSN	PLEASE CONFIRM OR or enter N/A
<input checked="" type="checkbox"/>	I have received confirmation of reply from all identified customers	PLEASE CONFIRM OR or enter N/A

<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	N/A
<input checked="" type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	PLEASE ENTER QUANTITY AND DATE:
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	N/A
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.