Rev 1: September 2018

FSN Ref: FSNHE20221110-09 ver2 FSCA Ref: FSCAHE20221110

Date: 2022. December 02.

# Urgent Field Safety Notice
# Device Commercial Name

For Attention of*:

Guder Medizintechnik GmbH & Co. KG
Quality Assurance and Regulatory Responsible

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
|---|
| Mr. Heyko Dettke<br>dettke@guder-medizin.de;<br>info@guder-medizin.de;<br>+49 5731 8697080<br>Zum Bache 2, 32549 Bad Oeynhausen |

## Important Note to updated Field Safety Notice:

This Field Safety Notice (FSN) is an update of the original FSN document (document number: FSNHE20221110-09, 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

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Hematology control |
| 1. | 2. Commercial name(s) |
| | Diacon 3 hematology control (Low) 6x<br>Diacon 3 hematology control (Normal)<br>Diacon 3 hematology control (High) 6 |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 5999883586778<br>5999883586785<br>5999883586792 |
| 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)* |
| | 10031722<br>10031724<br>10031784 |
| 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 Abacus 3, 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* |
| | *Updated in FSN rev 2:*<br>Normal level control - LOT B1122N may have hemolysis or deterioration due to a microbial contamination.<br><br>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.<br><br>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. |

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| 2. | 2. Hazard giving rise to the FSCA* |
| | The control is a process control used to monitor instrument performance and have no impact on patient results.<br><br>*Addition in FSN rev 2:*<br><br>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 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. |
| 2. | 3. Probability of problem arising |
| | *Updated in FSN rev 2*:<br><br>The probability is difficult to estimate, potentially any vial of LOT: B1122N can be affected. |
| 2. | 4. Predicted risk to patient/users |
| | *Updated in FSN rev 2*:<br><br>Follow-up or review patients' previous results is not required.<br>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. |
| 2. | 5. Further information to help characterise the problem |
| | *Updated in FSN rev 2*:<br><br>Diatron recommends to inspect each control vial for deterioration before use. This can be detected as followed:<br><br>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. |
| 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 |
| | Updated in FSN rev 2: (this section was moved to 3.1)<br><br>N/A |

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| | **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

Addition in FSN rev 2:

1) Identify normal control LOT: B1122N in your stock and discard the vials
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.
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.
4) LOW, NORMAL and HIGH controls can be inspected for signs of hemolysis or deterioration:
    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.
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.

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| 3. | 2. By when should the action be completed? | modified to 2022.12.16 |

3. 3. Particular considerations for:

Is follow-up of patients or review of patients' previous results recommended?
No

Control measurements does not affect the patient reportable results.

Addition in FSN rev 2:
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

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| | **must not be reported** until the problem is resolved and the controls indicate proper performance. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ 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 | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | Update |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Number: FSNHE20221110-09<br>Date: 14th 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: FSNHE20221110-09, 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:<br>- Section 2.1: Description of the product problem (update)<br>- Section 2.2: Hazard giving rise to the FSCA (addition)<br>- Section 2.4: Predicted risk to patient/users (update)<br>- Section 2.5: Further information to help characterise the problem (update)<br>- Section 2.7: Other information relevant to FSCA (update)<br>- Section 3.1: Action To Be Taken by the User (addition)<br>- Section 3.3: Particular considerations (addition) | |
| 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 | |

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| 4 | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | 7. Manufacturer information<br>(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 ver2;<br>Field Safety Notice Customer Reply Form ver2 |
| 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.
Date: 2022. December 02.

Date: 2022. December 02.

# Urgent Field Safety Notice
# Device Commercial Name

For Attention of*:

LumiraDx B.V.
Quality Assurance and Regulatory Responsible

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
|---|
| Uwe Klimpe<br>Uwe.Klimpe@LumiraDx.com;<br>1728123263<br>Bijsterhuizen 30-41 6604 LV Wijchen |

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# 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) |
| | LUMIRATEK H3 CONTROL KIT 3x2x3.0 mL |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | |
| 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)* |
| | 10031738 |
| 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 Abacus 3, Abacus Junior 30, Abacus 380, Aquila, Abacus 3 CT, and all their equivalent variants sold under different brand names. |

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| 2. | 2. Hazard giving rise to the FSCA* |
| | The control is a process control used to monitor instrument performance and have no impact on patient results.<br><br>*Addition in FSN rev 2:* |

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| | 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 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. |
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| | Updated in FSN rev 2: (this section was moved to 3.1)<br><br>N/A |
| | |

| | |
|---|---|
| | **3. Type of Action to mitigate the risk*** |

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|---|---|---|
| 3. | **1. Action To Be Taken by the User*** | |
| | ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☒ Destroy Device<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☒ Other ☐ None<br><br>Addition in FSN rev 2:<br>1) Identify normal control LOT: B1122N in your stock and discard the vials<br>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.<br>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.<br>4) LOW, NORMAL and HIGH controls can be inspected for signs of hemolysis or deterioration:<br>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.<br>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. | |
| 3. | 2. By when should the action be completed? | modified to 2022.12.16 |
| 3. | 3. Particular considerations for:<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>Control measurements does not affect the patient reportable results.<br><br>Addition in FSN rev 2:<br>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 **must not be reported** until the problem is resolved and the controls indicate proper performance. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |

| | | |
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| 3. | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ 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 | |

| | | |
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| | **4. General Information*** | |
| 4. | 1. FSN Type* | Update |
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| 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<br>(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 |

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|---|---|---|
| 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 ver2; Field Safety Notice Customer Reply Form ver2 |
| 4. | 10. Name/Signature | Insert Name and Title here and signature below |

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

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Date: 2022. December 02.