

## Field safety notice

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| <b>FSN-Ref: CA-25-EX-04_Meta Sensoren</b> | <b>FSCA-REF: not yet assigned</b> | <b>Date: 2025/09/23</b> |
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To ESCHWEILER customers,

ESCHWEILER has determined that metabolite sensors with high slope values in ESCHWEILER devices have lower technical measurement limits than stated. This can lead to a falsely low measured value being assumed as true, resulting in a health-threatening treatment decision. This limitation of the measuring range must be communicated to the user immediately. Furthermore, the output of potentially erroneous measured values must be prevented.

This letter is addressed to dealers and users who commission and use ESCHWEILER devices with metabolite sensors. Dealers are required to inform all users of the devices in question of this letter.

The necessary data for implementing this measure are described below.

|                                                  |                                                                                      |
|--------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>1. Information about the affected product</b> |                                                                                      |
| <b>1.1</b>                                       | <b>product types</b>                                                                 |
|                                                  | ESCHWEILER combiline / ESCHWEILER modularPro with Glucose and/or Lactat Sensors      |
| <b>1.2</b>                                       | <b>trade names</b>                                                                   |
|                                                  |                                                                                      |
| <b>1.3</b>                                       | <b>Unique device identification</b>                                                  |
|                                                  | --                                                                                   |
| <b>1.4</b>                                       | <b>Intended purpose</b>                                                              |
|                                                  | The metabolite sensors are used to determine metabolic balance in human whole blood. |
| <b>1.5</b>                                       | <b>Model/Catalog/Part Number</b>                                                     |
|                                                  | BGA+M, BGA+E+M                                                                       |
| <b>1.6</b>                                       | <b>Affected serial/lot number range</b>                                              |
|                                                  | all devices with Glucose and/or Lactat Sensors                                       |
| <b>1.7</b>                                       | <b>Related Products</b>                                                              |
|                                                  | Not applicable                                                                       |

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| <b>2. Reason for the field corrective action (FSCA)</b>                                                                                                                                                                                                                 |                                                                   |
| <b>2.1</b>                                                                                                                                                                                                                                                              | <b>Description of the product problem*</b>                        |
| Metabolite sensors with high slope values in Eschweiler devices have lower technical measurement limits than stated. This means that high metabolite concentrations in the blood cannot be measured at high sensor slopes. This has not yet been communicated to users. |                                                                   |
| <b>2.2</b>                                                                                                                                                                                                                                                              | <b>Threat that triggers FSCA</b>                                  |
| A falsely low reading may be assumed to be true, which could lead to a health-threatening treatment decision.                                                                                                                                                           |                                                                   |
| <b>2.3</b>                                                                                                                                                                                                                                                              | <b>probability of the problem occurring</b>                       |
| rare                                                                                                                                                                                                                                                                    |                                                                   |
| <b>2.4</b>                                                                                                                                                                                                                                                              | <b>Anticipated risk to patients/users</b>                         |
| The consequences can range from minor to potentially life-threatening.                                                                                                                                                                                                  |                                                                   |
| <b>2.5</b>                                                                                                                                                                                                                                                              | <b>Further information on the characterization of the problem</b> |
| Not applicable                                                                                                                                                                                                                                                          |                                                                   |
| <b>2.6</b>                                                                                                                                                                                                                                                              | <b>Background information on the topic</b>                        |
| Not applicable                                                                                                                                                                                                                                                          |                                                                   |
| <b>2.7</b>                                                                                                                                                                                                                                                              | <b>Other information relevant to the FSCA</b>                     |
| Not applicable                                                                                                                                                                                                                                                          |                                                                   |

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| <b>3. Type of risk mitigation measures</b>                                                                                                                                         |                                                                                                                                                                                |                                   |                         |
| <b>3.1</b>                                                                                                                                                                         | <b>Actions to be taken by the user*</b>                                                                                                                                        |                                   |                         |
| Enclose a warning notice regarding the limitation of the measuring range with the device.                                                                                          |                                                                                                                                                                                |                                   |                         |
| <b>When should the measure be completed?</b>                                                                                                                                       |                                                                                                                                                                                |                                   |                         |
| Immediately after receiving this FSN                                                                                                                                               |                                                                                                                                                                                |                                   |                         |
| <b>3.2 Action to be taken by the distributor</b>                                                                                                                                   |                                                                                                                                                                                |                                   |                         |
| As soon as ESCHWEILER provides a software update, install it on all devices.                                                                                                       |                                                                                                                                                                                |                                   |                         |
| <b>When should the measure be completed?</b>                                                                                                                                       |                                                                                                                                                                                |                                   |                         |
| By the end of 2025.                                                                                                                                                                |                                                                                                                                                                                |                                   |                         |
| <b>3.3</b>                                                                                                                                                                         | <b>Special Considerations</b>                                                                                                                                                  |                                   |                         |
| Not applicable                                                                                                                                                                     |                                                                                                                                                                                |                                   |                         |
| <b>3.4</b>                                                                                                                                                                         | <b>Is a response from the customer required? *</b><br><b>(If yes, attach form stating the return deadline)</b>                                                                 |                                   |                         |
| No.                                                                                                                                                                                |                                                                                                                                                                                |                                   |                         |
| <b>3.5</b>                                                                                                                                                                         | <b>Measure taken by the manufacturer</b>                                                                                                                                       |                                   |                         |
| All retailers will be informed and will receive this FSCA implementation action plan along with a form for confirmation of implementation. The action plan includes the following: |                                                                                                                                                                                |                                   |                         |
| 1. Inform all customers immediately. Ensure that the warning notice is included with all devices.                                                                                  |                                                                                                                                                                                |                                   |                         |
| 2. As soon as ESCHWEILER releases a software update, install it on all devices.                                                                                                    |                                                                                                                                                                                |                                   |                         |
| <b>By when should the measure be completed?</b>                                                                                                                                    |                                                                                                                                                                                |                                   |                         |
| Point 1: immediately after receiving this instruction                                                                                                                              |                                                                                                                                                                                |                                   |                         |
| Point 2: 12/2025                                                                                                                                                                   |                                                                                                                                                                                |                                   |                         |
| <b>3.6</b>                                                                                                                                                                         | <b>Does the FSN need to be communicated to the patient/non-professional user?</b>                                                                                              |                                   |                         |
| Not applicable                                                                                                                                                                     |                                                                                                                                                                                |                                   |                         |
| <b>3.7</b>                                                                                                                                                                         | <b>If so, has the manufacturer provided additional information for the patient/non-professional user in an information letter/sheet for the patient/non-professional user?</b> |                                   |                         |
| Not applicable                                                                                                                                                                     |                                                                                                                                                                                |                                   |                         |

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| <b>4. General information</b>                                               |                                                                                                                               |
| <b>4.1</b>                                                                  | <b>FSN type*</b>                                                                                                              |
| new                                                                         |                                                                                                                               |
| <b>4.2</b>                                                                  | <b>For updated FSN,<br/>Reference number and date of the previous FSN</b>                                                     |
| Not applicable                                                              |                                                                                                                               |
| <b>4.3</b>                                                                  | <b>For updated FSN, new key information as follows</b>                                                                        |
| not applicable                                                              |                                                                                                                               |
| <b>4.4</b>                                                                  | <b>Further information that is already expected in the following FSN*</b>                                                     |
| Not applicable                                                              |                                                                                                                               |
| <b>If another FSN is expected, what should the further notice refer to?</b> |                                                                                                                               |
| Not applicable                                                              |                                                                                                                               |
| <b>4.5</b>                                                                  | --                                                                                                                            |
| <b>4.6</b>                                                                  | <b>Expected timeframe for subsequent FSN</b>                                                                                  |
| see point 3                                                                 |                                                                                                                               |
| <b>4.7</b>                                                                  | <b>manufacturer's specifications<br/>(The contact details of the local representative can be found on page 1 of this FSN)</b> |
| <b>Name:</b>                                                                |                                                                                                                               |
| ESCHWEILER GmbH & Co. KG                                                    |                                                                                                                               |
| <b>Address:</b>                                                             |                                                                                                                               |
| Holzkoppelweg 35, 24118 Kiel                                                |                                                                                                                               |
| <b>Website:</b>                                                             |                                                                                                                               |
| <a href="https://www.eschweiler-kiel.de">https://www.eschweiler-kiel.de</a> |                                                                                                                               |
| <b>4.8</b>                                                                  | <b>The competent (regulatory) authority has been informed of this communication to customers*</b>                             |
| <b>4.9</b>                                                                  | <b>list of attachments</b>                                                                                                    |
| Appendix 1 – Warning information for users – 1 page                         |                                                                                                                               |
| Appendix 2 – Dealer Response Form – 1 page                                  |                                                                                                                               |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Transmission of this safety instruction in the field</b></p> <p>This instruction must be passed on to all persons who need to be aware within your organization or to any organization to which the potentially affected equipment has been transferred, as appropriate.<br/>         Please forward these instructions to other organisations affected by this measure (as appropriate)<br/>         Please observe these instructions and the resulting actions for a reasonable period of time to ensure the effectiveness of the remedial action.<br/>         Please report any incidents related to the device to the manufacturer, distributor or local representative and, where appropriate, to the competent national authority, as this will provide important feedback.<br/>         IN PARTICULAR, this letter is addressed to dealers and users who commission and use ESCHWEILER devices with metabolite sensors.</p> <p><b>The distributors are obliged to inform all users of the devices in question with this letter.</b></p> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

*Note: Fields marked with \* are required for all FSNs. Others are optional.*

**Kiel, 23.09.2025**

\_\_\_\_\_  
 Place, Date

\_\_\_\_\_  
 Signature of Management

**ESCHWEILER GmbH & Co. KG**  
**Holzkoppelweg 35**  
**24118 Kiel**

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### APPENDIX 1 – Warning information for users – Page 1/1

Please enclose this information with the ESCHWEILER modularpro or ESCHWEILER combiline with metabolite sensors. The affected device is:

|                                             |  |
|---------------------------------------------|--|
| <b>device type</b>                          |  |
| <b>serial number of the affected device</b> |  |

Description of the measuring range of glucose and lactate sensors depending on the sensor slope:

| <b>ESCHWEILER modularpro</b> |                                  |                       |                                  |
|------------------------------|----------------------------------|-----------------------|----------------------------------|
| <b>Slope GLU in %</b>        | <b>Measuring range in mmol/l</b> | <b>Slope LAC in %</b> | <b>Measuring range in mmol/l</b> |
| 30 – 108                     | 0 – 30                           | 30 - 128              | 0 – 20                           |
| 109 – 130                    | 0 – 28                           | 129 – 150             | 0 - 17                           |
| 131 – 150                    | 0 – 25                           | 151 – 170             | 0 - 15                           |
| 151 – 170                    | 0 – 22                           | 171 – 190             | 0 - 13                           |
| 171 – 190                    | 0 – 18                           | 191 – 210             | 0 - 12                           |
| 191 – 210                    | 0 – 15                           | 211 – 230             | 0 - 11                           |
| 211 – 230                    | 0 – 14                           | 231 – 250             | 0 - 10                           |
| 231 – 250                    | 0 – 13                           | 251 – 270             | 0 – 9,5                          |
| 251 – 270                    | 0 – 12                           | 271 – 290             | 0 – 8,7                          |
| 271 – 300                    | 0 – 11                           | 291 – 300             | 0 - 8                            |
|                              | GLU <sub>max</sub> =3276,8/slope |                       | LAC <sub>max</sub> =2560/slope   |

| <b>ESCHWEILER combiline</b> |                                  |                       |                                  |
|-----------------------------|----------------------------------|-----------------------|----------------------------------|
| <b>Slope GLU in %</b>       | <b>Measuring range in mmol/l</b> | <b>Slope LAC in %</b> | <b>Measuring range in mmol/l</b> |
| 30 – 172                    | 0 – 30                           | 30 – 203              | 0 – 20                           |
| 173 - 200                   | 0 - 26                           | 203 – 230             | 0 – 17,7                         |
| 201 – 230                   | 0 – 22,5                         | 231 - 250             | 0 – 16,2                         |
| 231 – 250                   | 0 – 21                           | 251 - 270             | 0 – 15                           |
| 251 – 270                   | 0 – 19                           | 271 - 290             | 0 – 14                           |
| 271 – 300                   | 0 – 17                           | 291 – 300             | 0 – 13,5                         |
|                             | GLU <sub>max</sub> =5200/slope   |                       | LAC <sub>max</sub> =4062,5/slope |

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### APPENDIX 2 – DISTRIBUTOR RESPONSE FORM

This confirms that the measures (according to point 3.2) of this FSN have been taken.  
ESCHWEILER greatly appreciates your cooperation in this matter.  
If you need further information, please contact [info@eschweiler-kiel.de](mailto:info@eschweiler-kiel.de).

|                                               |  |
|-----------------------------------------------|--|
| <b>Name distributor</b>                       |  |
| <b>address</b>                                |  |
| <b>name of the contact person</b>             |  |
| <b>serial numbers of the affected devices</b> |  |

Immediately after carrying out the measure, please send the enclosed response form, completed and signed, as a scanned copy by email to [info@eschweiler-kiel.de](mailto:info@eschweiler-kiel.de) !

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature