Rev 2: February 2020
FSN Ref: EU-REC-2026-01-27-001-FSN-EN-V1 FSCA Ref: EU-REC-2026-01-27-001
Date: 2026-1-27

# Urgent Field Safety Notice
# EDAN Patient Monitoring and Fetal Monitoring Devices

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.)* |
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| EDAN Instruments GmbH, europe@edan.com, Tel: +49 (0) 6103 202 0781, Robert-Bosch-Str. 11A, 63225 Langen (Hessen), Germany, Monday to Friday 09:00-17:00 (UTC +01:00) |

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# Urgent Field Safety Notice (FSN)
# EDAN Patient Monitoring and Fetal Monitoring Devices
# Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Please refer to the annex |
| 1. | 2. Commercial name(s) |
| | Please refer to the annex |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | Complete when this becomes available. |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Please refer to the annex |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | Please refer to the annex |
| 1. | 6. Software version |
| | Only where relevant. |
| 1. | 7. Affected serial or lot number range |
| | Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool. |
| 1. | 8. Associated devices |
| | Within context of the FSCA eg for IVD reagents and platforms. |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
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| 2. | 1. Description of the product problem* |
| | 1. Labeling issue: An inappropriate publicly routable IP address was used as an example in the user manual for demonstrating user-configurable IP address settings. 2. Default setting issue: An inappropriate publicly routable IP address was used as the factory default configuration. However, this IP address is not hard-coded in the system and can be modified by users through the User Maintenance interface.To date, we have not received any customer complaints or incidents related to these issues. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Customers may be misled by the user manual or factory default IP settings, in extreme scenario, resulting in the following risk:An attacker may exploit unintended communication with an external public IP to send falsified data to the monitor, resulting in abnormal operation of the monitor and delayed treatment of patients. |
| 2. | 3. Probability of problem arising |
| | Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise. |
| 2. | 4. Predicted risk to patient/users |
| | From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect). |
| 2. | 5. Further information to help characterise the problem |
| | Include any further relevant statistics to help convey the seriousness of the issue. |
| 2. | 6. Background on Issue |
| | Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc. |
| | 7. Other information relevant to FSCA |

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| 2. | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. |

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| | **3. Type of Action to mitigate the risk*** |
| **3.** | **1. Action To Be Taken by the User*** <br><br> ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device <br><br> ☐ On-site device modification/inspection <br><br> ☐ Follow patient management recommendations <br><br> ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) <br><br> ☒ Other ☐ None <br><br> Verify that the prohibited IP address range 202.114.4.* is not configured in the device's User Maintenance settings. If it is, instruct users to update the network settings to an appropriate IP address in accordance with the Instructions for IP Settings Configuration. |
| 3. | 2. By when should the action be completed? — Specify where critical to patient/end user safety |
| 3. | 3. Particular considerations for: Choose an item. <br><br> Is follow-up of patients or review of patients' previous results recommended? Choose an item. <br><br> Provide further details of patient-level follow-up if required or a justification why none is required |
| 3. | 4. Is customer Reply Required? * (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 <br><br> Provide further details of the action(s) identified. |
| 3 | 6. By when should the action be completed? — Specify where critical to patient/end user safety |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? — Choose an item. |
| 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? <br> Choose an item. Choose an item. |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Provide reference and date of previous FSN if relevant |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Summarise any key difference in devices affected and/or action to be taken. | |
| 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: | |
| | Eg patient management, device modifications etc | |
| 4 | 6. Anticipated timescale for follow-up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Edan Instruments, Inc. |
| | b. Address | #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China. |
| | c. Website address | https://www.edan.com/ |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * None | |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| 4. | 10. Name/Signature | Insert Name and Title here and signature below |

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| | **Transmission of this Field Safety Notice** |
| | Edan notifies the affected customers by email of the Field Safety Notice and requests them to notify their downstream customers and provide feedback. |

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