Date: 2021-08-11

**Urgent Field Safety Notice**

**Central Monitoring System MFM-CMS V2.66**

For Attention of\*:The detailed serial number and other tracking information, please see the attachment for < List of customer>

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| --- |
| Contact details of local representative (name, e-mail, telephone, address etc.)\* |
| EDAN Instruments GmbH, Monday to Friday 09:00-17:00 (UTC +01:00)Tel: +49 (0) 6103 202 0781 |

**Urgent Field Safety Notice (FSN)**

**Central Monitoring System MFM-CMS V2.66**

**Risk addressed by FSN**

|  |
| --- |
| 1. **Information on Affected Devices\***
 |
| 1. | 1. Device Type(s)\*
 |
| Central Monitoring System MFM-CMS V2.66  |
| 1. | 1. Commercial name(s)
 |
| Central Monitoring System |
| 1. | 1. Unique Device Identifier(s) (UDI-DI)
 |
| 06944413800229 |
| 1. | 1. Primary clinical purpose of device(s)\*
 |
| MFM-CMS provides centralized monitoring and critical care management for patients monitored by EDAN bedside monitors. From MFM-CMS, clinicians can gain access to patient information for patients on the Network. MFM-CMS displays waveforms, parameters and alarm status of EDAN bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens. |
| 1. | 1. Device Model/Catalogue/part number(s)\*
 |
| MFM-CMS |
| 1. | 1. Software version
 |
| V2.66 |

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| 1. **Reason for Field Safety Corrective Action (FSCA)\***
 |
| 2. | 1. Description of the product problem\*
 |
| Recently during internal testing, it was found that under specific circumstances, MFM-CMS Central Monitoring System V2.66 version did not effectively display SpO2 alarm information.  |
| 2. | 1. Hazard giving rise to the FSCA\*
 |
| When healthcare professionals only pay attention to the alarm on the MFM-CMS, it may cause patients with SpO2 below the alarm limit unable to get timely attention. Edan has not received any report of serious incident that caused patient injury regarding this problem. |

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|  | 1. **Type of Action to mitigate the risk\***
 |
| **3.** | 1. **Action To Be Taken by the User\***

[ ]  Identify Device [ ] Quarantine Device [ ]  Return Device [x]  Destroy Device[x] 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. | 1. By when should the action be completed?
 |  |
| 3. | 1. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients’ previous results recommended?Choose an item.Provide further details of patient-level follow-up if required or a justification why none is required |
| 3. | 1. Is customer Reply Required? \*

(If yes, form attached specifying deadline for return) | Yes  |
| **3.** | 1. **Action Being Taken by the Manufacturer**

[ ]  Product Removal [ ]  On-site device modification/inspection [x]  Software upgrade [x]  IFU or labelling change  [ ]  Other [ ]  None Provide further details of the action(s) identified. |
| 3 | 1. By when should the action be completed?
 | November 13, 2021 |
| 3. | 1. Is the FSN required to be communicated to the patient /lay user?
 | No |
| 3 | 1. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?
 |
| No Choose an item. |

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|  | 1. **General Information\***
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| 4. | 1. FSN Type\*
 | New |
| 4. | 1. For updated FSN, reference number and date of previous FSN
 | Provide reference and date of previous FSN if relevant |
| 4. | 1. For Updated FSN, key new information as follows:
 |
|  | Summarise any key difference in devices affected and/or action to be taken. |
| 4. | 1. Further advice or information already expected in follow-up FSN? \*
 | No |
| 4 | 1. If follow-up FSN expected, what is the further advice expected to relate to:
 |
| Eg patient management, device modifications etc |
| 4 | 1. Anticipated timescale for follow-up FSN
 | For provision of updated advice. |
| 4. | 1. Manufacturer information

(For contact details of local representative refer to page 1 of this FSN*)*  |
| * 1. Company Name
 | Edan Instruments, Inc. |
| * 1. Address
 | #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China. |
| * 1. Website address
 | https://www.edan.com/ |
| 4. | 1. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. \*

None |
|  |  |
|  | **Transmission of this Field Safety Notice** |
|  | 1. Edan sends field safety notice to affected customers, requesting them to stop using V2.66 MFM-CMS. 2. Edan will upgrade the MFM-CMS for affected customers. 3. Other versions of MFM-CMS work properly. They are not affected and can be used without any problem. |

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