Rev 1: September 2018
FSN Ref: FSN- REC-2021-08-02-001-EN-NEW FSCA Ref: REC-2021-08-02-001

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>

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.	2. Commercial name(s)
	Central Monitoring System
1.	3. Unique Device Identifier(s) (UDI-DI)
	06944413800229
1.	4. 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.	5. Device Model/Catalogue/part number(s)*
	MFM-CMS
1.	6. Software version
	V2.66

2 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.	2. 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.

	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
	Provide further details of the action(s) identified.

3.	2. By when should the action be completed?	
3.	3. 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.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	November 13, 2021
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?	
	No Choose an item.	

	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 (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	

	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.