

Urgent Field Safety Notice
SE-1201 Pro Electrocardiograph

For Attention of*:The detailed serial number and other tracking information, please see the attachment for < Annex - Poland_Complete_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)

Urgent Field Safety Notice (FSN)
Urgent Field Safety Notice - SE-1201 Pro Electrocardiograph
Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Electrocardiograph
1	2. Commercial name(s)
.	Electrocardiograph
1	3. Unique Device Identifier(s) (UDI-DI)
.	06944413820562
1	4. Primary clinical purpose of device(s)*
.	The electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.
1	5. Device Model/Catalogue/part number(s)*
.	SE-1201 Pro
1	6. Software version
.	Not applicable (software version is not relevant to this FSCA)
1	7. Affected serial or lot number range
.	See Annex - Poland Complete List.
1	8. Associated devices
.	Not applicable

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	On May 30, 2026, we received notification from supplier regarding a potential failure risk associated with the overvoltage protection IC (specific batch) on the mainboard of Electrocardiographs (main models: SE-1201 Pro). This overvoltage protection IC is located in the overvoltage protection circuit within the power input section of the mainboard. After the overvoltage protection IC fails, it causes the device to be unable to power on when only the adapter is connected, or to be unable to charge when both the adapter and the battery are connected simultaneously.
2	2. Hazard giving rise to the FSCA*
.	These two failure phenomena (inability to power on or inability to charge) are easily identifiable and detectable at the user end. For example, if the device cannot be turned on, the user will be unable to use the device. If charging is impossible, there will be clear indications on the power indicator light and the screen charging status. After identifying an abnormality, users are highly likely to stop using the device, and there is no further risk of harm to patients or users.
2	3. Probability of problem arising
.	Improbable.
	4. Predicted risk to patient/users

2	Based on the product risk analysis, after implementing risk control measures, the probability level of such adverse events occurring is P1 (Improbable), the severity level of the harm is S3 (Serious – Delay to Diagnosis), and the overall risk level is "Acceptable".
2	5. Further information to help characterise the problem
.	None.
2	6. Background on Issue
.	On May 30, 2026, we received notification from supplier regarding a potential failure risk associated with the overvoltage protection IC (specific batch) on the mainboard of Electrocardiographs (main models: SE-1201 Pro). This overvoltage protection IC is located in the overvoltage protection circuit within the power input section of the mainboard. After the overvoltage protection IC fails, it causes the device to be unable to power on when only the adapter is connected, or to be unable to charge when both the adapter and the battery are connected simultaneously.
2	7. Other information relevant to FSCA
.	None.

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 Edan sends Field Safety Notices to all affected customers, along with the replacement mainboards and the step-by-step replacement guidance, to instruct them on the mainboard replacement procedure.
3.	2. By when should the action be completed? April 1st, 2027
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No
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
3	6. By when should the action be completed? April 1st, 2027
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

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
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:	
4	6. Anticipated timescale for follow-up FSN	
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. * Poland	
4.	9. List of attachments/appendices:	Annex - Poland Complete List
4.	10. Name/Signature	

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.