FSN Ref: 187 FSCA Ref: 187

Date: 20/08/2025

Urgent Field Safety Notice
Defibrillation electrodes F7987W

For Attention of:

- Medical devices vigilance
- Head(s) of user health department(s)
- Purchasing / Warehouse / Logistics Manager

Contact information
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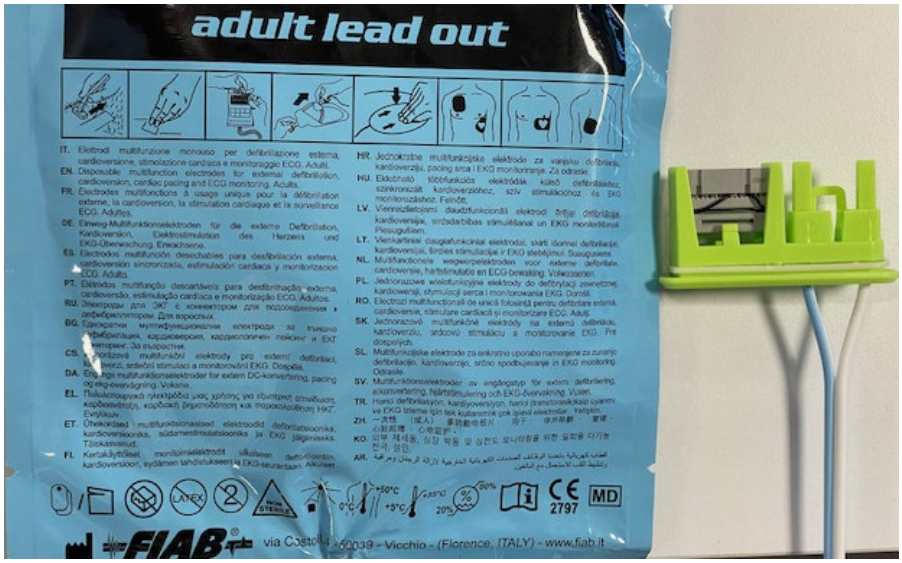
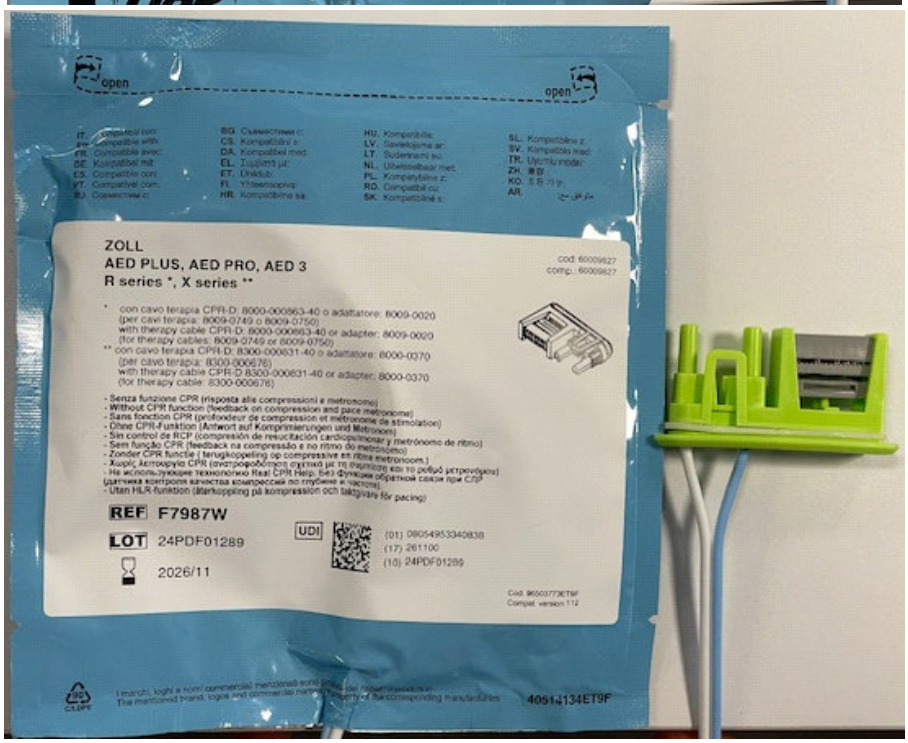
Urgent Security Alert (FSN)
F7987W Defibrillation Pads

	1. Information about affected devices
1.	1. Device Type
	Disposable electrodes for defibrillation of adult patients, FIAB model F7987W for use with the ZOLL AED PLUS, AED PRO, AED 3, R Series, X Series Automated External Defibrillator models
	
	
1	2. Commercial name
	Defibrillation electrodes model F7987W
1	3. Primary clinical purpose of devices

	Disposable adhesive electrodes for external defibrillation
1	4. Device Model
	F7987W
1	5. Affected Lot Numbers range
	Attached the complete list of affected batch numbers

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	The electrode connection system to the AED consists of a dedicated connector for ZOLL devices (see image in section 1). This connector contains an electrical circuit that, by short-circuiting (putting in electrical continuity) between two of the contacts, allows the AED to identify the electrodes as "adult," i.e., suitable for adult patients, or as "pediatric," i.e., suitable for pediatric patients, and therefore deliver the necessary energy required by the resuscitation protocols and the AED's programming for the target patient. In the affected batches, there is a remote possibility that the component through which the F7987W electrode is recognized as an adult model may, due to an unstable electrical contact, lead to the electrode being recognized as a pediatric model.
2.	2. Hazard giving rise to the FSCA
	Delay in delivering therapy due to non-immediate recognition of the electrodes or confusion in the user caused by initially incorrect recognition. Potentially ineffective therapy – reduced energy delivered by the defibrillator to the adult patient – if the adult electrodes are recognized by the AED as pediatric electrodes.
2.	3. Probability of problem arising
	The review of the risk associated with the product issue identified a potential residual risk (probability of the risk occurring) assessed as extremely rare but not zero.
2.	4. Predicted risk to patient/users
	A delay in delivering therapy can significantly decrease the chances of survival after successful defibrillation as a lifesaving therapy. Ineffective therapy due to reduced energy delivered by the defibrillator to the adult patient can significantly reduce the chances of successful defibrillation as a lifesaving therapy.
2.	5. Background on issue
	The problem was reported from the field by a user, without patient involvement. The Manufacturer's subsequent examination of the problem and assessment of the residual risk led to the conclusion that it was necessary to recall the potentially affected product batches. The corrective actions implemented by the Manufacturer were aimed at improving the reliability of the affected component within the connector and increasing the ability to identify potential assembly defects during 100% testing. The checks carried out on the production batches following the improvement actions, compared to the affected batches, confirmed the adequacy of the corrective actions, resulting in a definitive resolution of the issue. This allowed the scope of application of the FSCA to be defined for the batches produced prior to the corrective actions, as listed in the previous section 1.5 of the FSN.

	3. Type of actions to mitigate risk		
3.	**1. Actions by the User** ☑ Identify the devices from the affected batches, as listed in section 1.5 of the FSN (complete list) and in particular in the attached *Customer Response Form* (batches distributed to the individual Customer/User) ☑ Segregate devices and do not use them ☑ Contact your Local Representative, as indicated on the FSN cover page, to arrange the return of the affected devices.		
3.	2. By when should the actions be completed?	Identification and quarantine of affected devices must be completed as soon as possible, after receiving/becoming aware of the FSN	
3.	3. Is a response required from the Customer ?		YES - See attachment *Customer Response Form*
3.	**4. Actions by the Manufacturer** ☑ Removal of the Product (withdrawal from the market) for subsequent destruction		
3	5. How long should the action take to complete?	Immediately after receiving responses to FSN from Customers/Users via the *Customer Response Form*	
3.	6. Should the Field Safety Notice (FSN) be communicated to the patient/lay user?		NO

	4. General Information	
4.	1. Type of FSN	New
4.	2. Manufacturer Information (For contact details of your local representative please refer to page 1 of this FSN)	
	a. Company Name	FIAB SpA
	b. Address	Via Costoli 4, 50039 Vicchio (FI), ITALY
	c. Website	www.fiab.it
4.	3. The relevant regulatory authority has been informed of this customer communication.	
4.	4. List of attachments:	*Customer Response Form* for confirmation of receipt of FSN and responses on the actions to be taken by the Customer/User
4.	5. Name/Signature	Francesco Batistini Quality Assurance Service Manager FIAB SpA
		

	Transmission of this Field Safety Notice (FSN)
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Model F7987W – Defibrillation pads
24PDF01721
25PDF00510

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