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
FIAB SpA Via Costoli 4 50039 Vicchio (FI) ITALY Tel.- +39 0558497970 Email.- orders@fiab.it – debora.racanati@fiab.it

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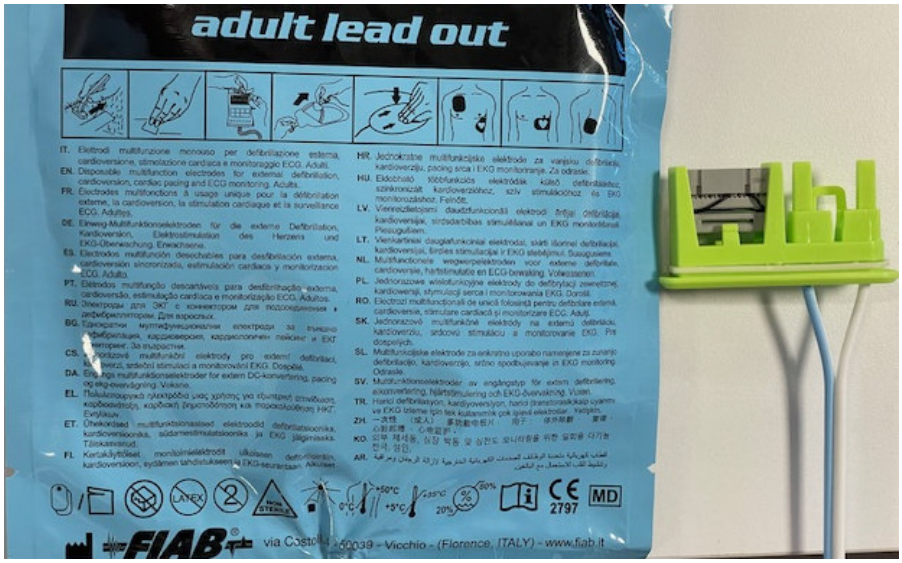
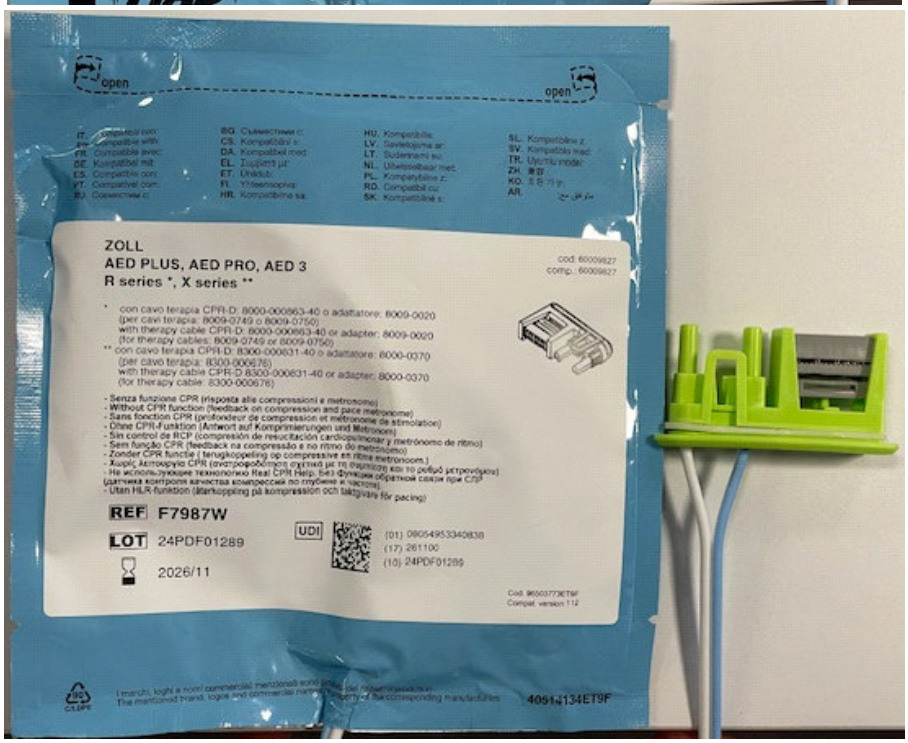
Urgent Security Alert (FSN)
F7987W Defibrillation Pads

	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			
24PDF00728	24PDF01528	24PDF02414	24PDF03351
24PDF00748	24PDF01572	24PDF02460	24PDF03371
24PDF00749	24PDF01636	24PDF02470	24PDF03387
24PDF00794	24PDF01642	24PDF02472	24PDF03421
24PDF00823	24PDF01663	24PDF02488	24PDF03430
24PDF00863	24PDF01664	24PDF02536	24PDF03443
24PDF00917	24PDF01680	24PDF02537	24PDF03498
24PDF00919	24PDF01700	24PDF02559	24PDF03500
24PDF00957	24PDF01721	24PDF02611	25PDF00028
24PDF00960	24PDF01773	24PDF02641	25PDF00031
24PDF01009	24PDF01776	24PDF02697	25PDF00032
24PDF01017	24PDF01777	24PDF02722	25PDF00096
24PDF01044	24PDF01821	24PDF02726	25PDF00100
24PDF01097	24PDF01860	24PDF02748	25PDF00115
24PDF01108	24PDF01932	24PDF02772	25PDF00154
24PDF01112	24PDF02017	24PDF02785	25PDF00180
24PDF01149	24PDF02019	24PDF02789	25PDF00182
24PDF01160	24PDF02050	24PDF02790	25PDF00183
24PDF01209	24PDF02069	24PDF02815	25PDF00204
24PDF01231	24PDF02071	24PDF02868	25PDF00223
24PDF01235	24PDF02130	24PDF02882	25PDF00226
24PDF01254	24PDF02142	24PDF02899	25PDF00245
24PDF01258	24PDF02166	24PDF02957	25PDF00246
24PDF01283	24PDF02167	24PDF02984	25PDF00353
24PDF01284	24PDF02212	24PDF02985	25PDF00436
24PDF01289	24PDF02219	24PDF02998	25PDF00466
24PDF01315	24PDF02279	24PDF03015	25PDF00473
24PDF01330	24PDF02303	24PDF03139	25PDF00494
24PDF01331	24PDF02343	24PDF03140	25PDF00495
24PDF01367	24PDF02344	24PDF03171	25PDF00510
24PDF01399	24PDF02362	24PDF03206	25PDF00515
24PDF01405	24PDF02371	24PDF03238	25PDF00516
24PDF01407	24PDF02374	24PDF03257	25PDF00583
24PDF01466	24PDF02378	24PDF03313	25PDF00619
24PDF01467	24PDF02401	24PDF03347	25PDF00633

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
Unità operative: Via Passerini, 2-3-4-6 – Via della Resistenza, 18
Tel. +39 0558497999 - Fax +39 0558497979 - www.fiab.it
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