Rev 2: February 2020

FSN Ref: 2025-21

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Date: 2025-11-07

Field Safety Notice

Maintenance of Li-Ion battery type P4BA-AB-UNI or PECGB-IIIa used in Unified Arrhythmia Diagnostic System PocketECG IV and Unified Arrhythmia Diagnostic System PocketECG III

For Attention of*: Distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
Medicalgorithmics S.A. Aleje Jerozolimskie 81 02-001 Warsaw, Poland, regulatory@medicalgorithmics.com

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Maintenance of Li-Ion battery type P4BA-AB-UNI or PECGB-IIIa used in Unified Arrhythmia Diagnostic System PocketECG IV and Unified Arrhythmia Diagnostic System PocketECG III

Batteries used beyond the specified service period may exhibit reduced performance and increased internal resistance, which can lead to overheating or swelling or explosion under certain conditions, which may lead to potential injury to the patient and/or user.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The PocketECG transmitter is intended to acquire, analyze, visualize, record or/and transmit the ECG and acceleration data. The results of arrhythmia are displayed, stored or/and transmitted along with the ECG signals. The acceleration signals are analyzed in order to determine the physical activity of the patient. It is assumed that the device can further transmit the ECG and acceleration signals along with analysis results using available wireless technologies. The PocketECG transmitter is powered by a Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, providing 3.7 V of nominal voltage (1700 mAh). This Field Safety Notice applies to the Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, accessory for the Unified Arrhythmia Diagnostic System PocketECG IV and the Unified Arrhythmia Diagnostic System PocketECG III.
1.	2. Commercial name(s)*
	Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, accessory for the Unified Arrhythmia Diagnostic System PocketECG IV and the Unified Arrhythmia Diagnostic System PocketECG III
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	The PocketECG transmitter is intended to acquire, analyze, visualize, record or/and transmit the ECG and acceleration data. The results of arrhythmia are displayed, stored or/and transmitted along with the ECG signals. The acceleration signals are analyzed in order to determine the physical activity of the patient. It is assumed that the device can further transmit the ECG and acceleration signals along with analysis results using available wireless technologies. The PocketECG device is intended for use under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm, and arrhythmias. Having fulfilled the working conditions specified in the manual, the device may be used when the patient is in the following places: clinic, hospital, outpatient cardiology clinic, house, business establishment, etc. The PocketECG is intended to be used by: • patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life-threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease. • patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: d) dizziness or lightheadedness; e) syncope of unknown etiology in

	which arrhythmias are suspected or need to be excluded; and f) dyspnea (shortness of breath). • patients with palpitations with or without known arrhythmias to obtain a correlation of rhythm with symptoms. • patients who require monitoring of the effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). • patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring. • patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias. • patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.
1.	5. Device Model/Catalogue/part number(s)*
	Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, accessory for the Unified Arrhythmia Diagnostic System PocketECG IV, types P4TR-CA-ADS, P4TR-CE-ADS, P4TR-AB-ADS and the Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-III
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool.
1.	8. Associated devices
	Li-Ion battery, type P4BA-AB-UNI or PECGB-IIIa (3.7 V, 1700 mAh)

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	On August 19, 2025, the manufacturer became aware that the device PocketECG IV, type P4TR-CA-ADS had caught on fire during the patient examination. During normal use of the product, it spontaneously ignited, most likely caused by the power battery (BA2623-29856A), type P4BA-AB-UNI. Patient denied any physician skin burns on his body. However confirmed sensitive pain to the areas effected but after a few days he confirmed that no longer felt the burning sensation on his skin. Based on the investigation and objective evidence, no manufacturing or design defect was identified in the device or its components. The analysis was based on objective evidence, process review, and contributing factors, ensuring traceability and compliance with applicable quality system standards. Although a single definitive root cause could not be conclusively determined, the investigation identified that the battery involved had exceeded its recommended service life of 2 years from the date of manufacture, as specified in the IFU for professional users. This condition increases the risk of battery overheating and potential swelling or explosion, as the capacity and performance of the PocketECG Li-Ion battery naturally degrade over time with normal use. The most probable root cause of the reported nonconformity is improper maintenance and handling by the customer, resulting from use of the battery beyond the recommended service life of 2 years, contrary to the Instructions for Use (IFU).Batteries used beyond the specified service period may exhibit reduced performance and increased internal resistance, which can lead to overheating or swelling under certain conditions.
2.	2. Hazard giving rise to the FSCA*

	The capacity of the Li-Ion battery decreases with normal use over time (natural aging process). Short-circuiting of the positive and negative leads of lithium-ion (Li-Ion) cells, charging with excessive current or voltage or by inappropriate methods, or use beyond the maximum number of charge–discharge cycles recommended by the manufacturer, leads to increased internal resistance and heat generation during charging or operation. Under certain conditions, this may result in overheating, swelling, or explosion.
2.	3. Probability of problem arising
	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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

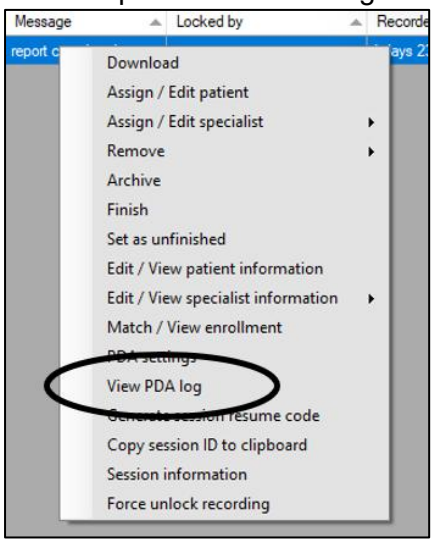
Please complete the Customer Response Form to confirm receipt of the safety notice dated [2025-11-07] regarding the above product.

This Field Safety Notice applies to the Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, accessory for the Unified Arrhythmia Diagnostic System PocketECG IV, types P4TR-CA-ADS, P4TR-CE-ADS, P4TR-AB-ADS and the Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-III.

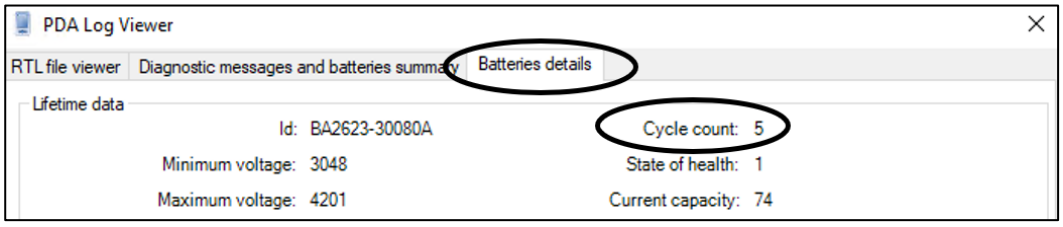
The capacity of the PocketECG Li-Ion battery decreases with normal use over time (natural aging process). Therefore, the manufacturer recommends replacing the battery with a new one after 300 charging cycles or after 2 years of using.

All users of all PocketECG types with a battery type P4BA-AB-UNI or PECGB-IIIa are required to:

- Follow the revised Instructions for Use (IFU) for Professional Use for the Unified Arrhythmia Diagnostic System PocketECG IV or the Unified Arrhythmia Diagnostic System PocketECG III, you shall:
  - verify whether two years have passed since the battery's date of manufacture (as indicated on the battery label in the format (YYYY-MM-DD)
  - check the number of charge cycles of the Li-Ion batteries in the diagnostic software PocketECG PC Client as follows:
    1. Select the session for which you want to view battery information.
    2. Right-click to open the context menu in the session.
    3. Select the option 'View PDA log'



    4. In the 'PDA Log Viewer' window, select the 'Batteries details' tab.



    5. On the right-hand side, locate 'Cycle count.' This field shows the number of charging cycles for each battery used in the selected test, as shown in the example above.

  in accordance with the Instructions for Use (IFU) for Professional Use detailed in:

  - Section 8.3.3 for PocketECG IV, type P4TR-CA-ADS and P4TR-CE-ADS;
  - Section 7.2.3 for PocketECG IV, type P4TR-AB-ADS;
  - Section 7.2.3 for PocketECG III.

	– Discontinue use of any batteries that exceed either: o 300 charge cycles, o or 2 years from the date of manufacture in accordance with the replacement recommendations specified in the Instructions for Use (IFU) for Professional use detailed in: • Section 13 for PocketECG IV, type P4TR-CA-ADS and P4TR-CE-ADS; • Section 12 for PocketECG IV, type P4TR-AB-ADS and PocketECG III. – Fill out the Customer Response Form to acknowledge receipt of the Field Safety Notice dated relating to the above product. In addition: – The batteries check shall be conducted periodically. – Ensure proper handling, storage and transport of the devices. Users are strongly recommended to comply with all guidelines described in the Instructions for Use for the Unified Arrhythmia Diagnostic System PocketECG IV and PocketECG III. – If any malfunction is detected, the end user must immediately contact Medicalgorithmics at technical@medicalgorithmics.com, report the issue via the ticketing system, and send the device for repair. No product return or modification is required.
3.	2. By when should the action be completed? — Specify where critical to patient/end user safety.
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 **Clarifications in Instructions for Use for the Unified Arrhythmia Diagnostic System PocketECG IV and Unified Arrhythmia Diagnostic System PocketECG III to remind users how to check the number of charge cycles of the Li-Ion batteries in the diagnostic software PocketECG PC Client, as proper inspection helps ensure the device functions as intended and safeguards patient safety.**
3.	6. By when should the action be completed? — Specify where critical to patient/end user safety.

3.	7. Is the FSN required to be communicated to the patient /lay user?	Choose an item.
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?	
	Choose an item. 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	Medicalgorithmics S.A.
	b. Address	Aleje Jerozolimskie 81 02-001 Warsaw, Poland
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Karolina Rudzka *Regulatory Affairs and Quality Assurance Manager Medicalgorithmics S.A.*
		Karolina Rudzka

	Transmission of this Field Safety Notice
	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.*

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

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025-21
FSN Date*	2025-11-07
Product/ Device name*	Lithium-ion battery, type P4BA-AB-UNI or PECGB-IIIa, accessory for: • the Unified Arrhythmia Diagnostic System PocketECG IV, types: – P4TR-CA-ADS or – P4TR-CE-ADS or – P4TR-AB-ADS and/or the Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-III
Product Code(s)	P4BA-AB-UNI or PECGB-IIIa
Batch/Serial Number (s)	N/A

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	

☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	regulatory@medicalgorithmics.com
Customer Helpline	+48 22 825 12 49
Postal Address	Medicalgorithmics S.A. Aleje Jerozolimskie 81 02-001 Warsaw, Poland
Web Portal	https://www.medicalgorithmics.com/
Fax	N/A
Deadline for returning the customer reply form*	Please complete, sign, and return this form to the above email address within 30 days of being sent by Medicalgorithmics S.A.

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.