MEDICALgorithmics
INNOVATIVE SOLUTIONS IN MEDICINE

Urgent Field Safety Notice

Name of the affected product:

Unified Arrhytmia Diagnostic System PocketECG III, type PECGT-III and/or Unified Rehabilitation System PocketECG CRS, type PECGT-IIIV

FSCA-identifier (e.g. date): *2022-02*

Type of FSCA: Notice to Distributors (Customers/Partners) regarding the use of the medical device

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Date: *2022-08-25*

Attention: *Distributors (Customers/Partners) and end users*

Details on affected devices:

Outdated Instructions for Use for Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-III and/or Unified Rehabilitation System PocketECG CRS, type PECGT-IIIV dedicated to patients that were shipped with the devices to customers/partners between 2020-04-30 and 2022 03-31

Description of the problem:

Manufacturer Medicalgorithmics S.A. has identified outdated Instructions for Use for PocketECG III, type PECGT-III and PocketECG CRS, type PECGT-IIIV dedicated to patients, which were shipped with the devices to customers/partners between 2020-04-30 and 2022-03-31.

Information dedicated to the patient that was out of date:

1. *Tabulated values in Chapter 12.1 Electromagnetic compatibility/Electromagnetic compatibility (EMC), which was updated to comply with IEC 60601 1 2:2014 (ed.4)*
2. *No Chapter 12.2 Effective radiated power/Effective radiated power (ERP), which was added to comply with IEC 60601 1 2:2014 (ed.4).*
3. *Frequency band of 2100 Hz in Chapter 13 Technical parameters/Technical parameters, which was removed.*

The use of outdated versions of the Instructions for Use did not carry the risk associated with the continued use of the device and the associated risk to the patient, user or others. The risks associated with providing the user with outdated instructions for use were assessed and determined to be marginal and considered acceptable.

The above mentioned changes to the Instructions for use did not/or potentially could not lead to a serious incident.

Advise on action to be taken by the user:

All patient Instructions for use included with Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-III and/or Unified Rehabilitation System PocketECG CRS, type PECGT-IIIV devices manufactured during the indicated period need to be replaced or missing chapters completed. The distributor (Customer/Partner) may print the current user manual sent by the Manufacturer or the user manual/errata may be provided by the Manufacturer. All subsequent shipments of the purchased PocketECG III and/or PocketECG CRS device shall include the current patient Instructions for use.

The distributor is obliged to include an updated version of the Instructions for use with the device.
The user is obliged to follow the Instructions for use according to the intended use of the device.

Transmission of this Field Safety Notice: (If appropriate)

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. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (If appropriate)

Contact reference person:

Name/organization, address, contact details:

Medicalgorithmics S.A.
Aleje Jerozolimskie 81
02-001 Warsaw, Poland

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Signature A. Romowicz .....