FUTUREMADEPRESENT

Urgent Field Safety Notice

Commercial name of the affected product: AMICA-GEN

FSCA identifier: R2400360

Type of action: Recommendation for operators in case of generator malfunction

Date: January 15th, 2023

Details on affected devices:

DEVICE NAME: AMICA-GEN

DEVICE CODES: AGN-H-1.x, AGN-3.x, AGN-R-1.x

Serial Numbers: All

UDI-DI	
AGN-3.0	08033055149273
AGN-3.1	08058983742068
AGN-3.2	08058983742471
AGN-3.3	08058983744864
AGN-H-1.0	08033055149280
AGN-H-1.1	08058983742457
AGN-H-1.2	08058983742488
AGN-H-1.3	08058983744772
AGN-R-1.0	08033055149297
AGN-R-1.1	08058983742464

Description of the problem:

The user reported that, during a radiofrequency ablation of a thyroid nodule, the generator displayed an impedance higher than 200 Ohm and a power of 6W while 40W were set up. The user decided to stop the ablation and removed the electrode which, during the removal, burned the subcutaneous tissues and muscles. This is the first case that we are aware of such behavior by the generator.

The anomaly was caused by the failure of the RF module, due to the breakage of an internal component. However, if the generator had been turned off during the electrode removal, there wouldn't have been any energy emission, preventing the harm to the patient.

Advice on action to be taken by the users:

When the operator decides to stop the treatment for any reason, particularly in case of any anomaly, the generator must be turned off before removing the applicator from the patient by pushing the "Power" button.

This will prevent risks or undesired burnings in case of malfunctioning.

Transmission of this Field Safety Notice

This notice must be passed to all operators working with generators AMICA-GEN.

Please, pass this notice to other organizations on which it has an impact.

Please, within 30 days after reading this notice, send us an e-mail confirming that the information here contained have been reported to final users.

Contact Reference person:

Laura Lenzi

Responsabile Assicurazione Qualità e Ufficio Regulatory Affairs

HS Hospital Service SpA

The undersigned confirms that this notice has been reported to foreign National Competent Authorities.

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Reply form

Commercial name of the affected product: AMICA-GEN

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In order to be compliant with regulatory measures, please complete and return this form by email to the address:

s.anelli@hshospitalservice.com

H.S. Hospital Service S.p.A.

I confirm the receipt of the field safety notice related to AMICA-GEN device and that I have forwarded it to end users.

Name _____ _____

Position _____

Date _____

Signature _____ _____