FSN Ref: 7411

Date: 2022-01-27

Field Safety Notice: Intended Use Modification
ECG Prewired Electrodes: CLARAVUE

For Attention of: Vigilance Responsible / Healthcare team / Biomedical Engineering Department

SUMMARY:

Before using Monophasic Defibrillators, Remove the ECG Prewired Electrodes CLARAVUE.

No incidents were reported to us on the nearly 4 million of CLARAVUE sold but as preventive action, Nissha Medical Technologies has decided to inform end-user about the potential risk of using this product with **Monophasic** defibrillators.

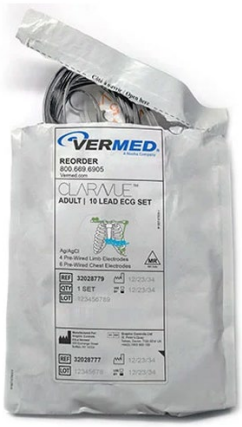
Indeed, if defibrillator is directly in contact with electrodes on each side it may hypothetically lead to sparks on the connector between wires of CLARAVUE and Trunk Cable (as shown on below picture). This potential failure may reduce the energy delivered to the patient which may lead to the inefficiency of the defibrillation. In addition, it may be a fire ignition source.

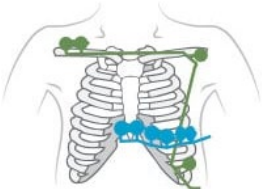
Urgent Field Safety Notice (FSN)
ECG Prewired Electrodes : CLARAVUE
Risk addressed by FSN

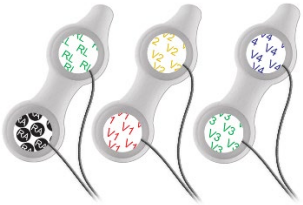
1. Information on Affected Devices

1. Device Type(s)

CLARAVUE® are prewired electrodes intended for use in electrocardiographic procedures, as passive sensors for the derivation of electrical signals from the heart, in a hospital setting by qualified medical personnel. The prewired electrodes are pre-gelled, single patient use, non-sterile, and are to be applied on clean intact skin. Intended patient groups are adults, children, and infants.







2. Commercial name(s)

The product brand is CLARAVUE

CLARAVUE®

3. Unique Device Identifier(s) (UDI-DI)

REF	UDI-DI	Description
50401	03700506300006	CLARAVUE PM NEONAT/PEDIATRIC 3 RT
50500	03700506300020	CLARAVUE PM 3
50502	03700506300044	CLARAVUE PM 12
50507	03700506300068	CLARAVUE PM 18
50600	03700506300082	CLARAVUE PM 3 RT
50601	03700506300105	CLARAVUE PM 5 RT
50602	03700506300129	CLARAVUE PM 12 RT
50603	03700506300143	CLARAVUE PM 6 RT
50604	03700506300167	CLARAVUE PM 5C RT

4. Primary clinical purpose of device(s)

ECG monitoring and diagnostic

5. Device Model/Catalogue/part number(s)

See reference is above table of section 1.3.

6. Affected serial or lot number range

No lot restriction

	2 Reason for Notification of Preventive Action
2.	1. Description of the product problem
	No incident, but potential risk of sparks if use of monophasic defibrillator
2.	2. Hazard giving rise to the FSCA
	Potential sparks while using monophasic defibrillator may lead to inefficient defibrillation due to loss of energy which may lead to failure of the resuscitation procedure.
2.	3. Probability of problem arising
	This problem is highly unlikely as no incidents were reported over the nearly 4 million products sold over the past 10 years.

	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 Check if Monophasic Defibrillator is available at your location, if yes, take necessary preventive action as training and labelling.	
3.	2. By when should the action be completed?	As soon as possible especially if Monophasic Defibrillator is available at your location
3.	3. Particular considerations for: NA Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? (**Please filled last part of the FSN and send it back to NISSHA MEDICAL TECHNOLOGIES**)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Please find enclosed the update IFU for information and diffusion.	
3	6. By when should the action be completed?	2022-02-28
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information	
4.	1. FSN Type	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	NISSHA MEDICAL TECHNLOGIES SAS
	b. Address	23-25 Boulevard de la Paix 95800 Cergy
	c. Website address	NisshaMedical.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	4. Name/Signature	Roch MIGNOT Quality & Regulatory Affairs Manager

	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 devices have been transferred. 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.

	5. AKNOWLEDGMENT OF RECEIPT **TO SEND BACK by email to : FRquality@nisshamedical.com**	
5	1. Health Institution / Distributor / Customer	
5	2. Name and Function	
5.	3. Name/Signature *I understand the FSN and I transmit the information to all users of CLARAVUE electrodes.*	