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**Urgent Safety Information**  
***Customer Information***

***regarding***

***EC2+ low impedance cream***

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**Sender:**

SOMNOmedics GmbH  
Am Sonnenstuhl 63  
97236 Randersacker

**Adresse:**

To the users of EC2+ "low impedance cream".

**Identification of the medical devices concerned:**

EC2+ Adhesive electrode cream, water-based,

**Item number:** EC2+

Ladies and Gentlemen,

SOMNOmedics GmbH strives for the highest quality of the products and services provided. Therefore, we would like to inform you about potential incidents when using the EC2+ electrode cream. During regular quality controls and market observations, the possible occurrence of the following isolated skin reactions was identified:

- Reversible redness
- Reversible skin irritations

when used in the facial area.

**Which actions need to be taken by the addressee?**

We ask you to clean the adhesive spots in the facial area only with alcohol and to refrain from using abrasive cleaning agents on the face.

For hypersensitive patients, the use of disposable Ag/AgCl adhesive electrodes is recommended.

**Passing on the information described here:**

Please ensure in your organisation that all users of the above products and other persons to be informed are aware of this "Urgent Safety Information". If you have provided the products to third parties, please forward a copy of this information or contact the person listed below. Please keep this information at least until the action has been completed.

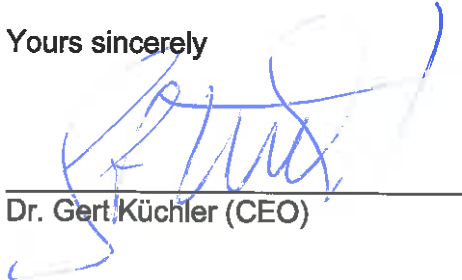
The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

We apologize for any inconvenience you may experience and hope this information will assist you in using EC2+. If you have any questions or require further information, please contact our customer service.

**Contact:**

SOMNOmedics Quality Management Department  
Phone: +49 931 / 35 90 94 – 0(Mo.-Fr. 8:00-17.00 o'clock)  
Mail: [qmra@somnomedics.de](mailto:qmra@somnomedics.de)

Yours sincerely



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Dr. Gert Küchler (CEO)

**Customer Answer:**

1. Information Regarding the customer information	
Reference Number FSN	CAPA26
FSN Date	27.11.2019
Product Number	EC2+

2. Customer Data	
Customer Number	
Name	
Address	
Contact Name:	
Phone Number:	
E-Mail:	

3. Kundenaktion im Auftrag der SOMNOmedics GmbH	
<input type="checkbox"/>	I acknowledge receipt of the FSN and that I have read and understood its contents.
<input type="checkbox"/>	I have performed all the actions requested by FSN
<input type="checkbox"/>	The necessary information and actions were brought to the attention of all relevant users and carried out.

Print Name:	
Signature::	
Date:	

4. Answer to Sender	
E-Mail:	qmra@somnomedics.de
Telefax:	+49 931 359094 - 49
Adress:	SOMNOmedics GmbH Am Sonnenstuhl 63 97236 Randersacker
Deadline for returning the customer response form	01.05.2020