

Cologne, 10th November 2015

Important Safety Notice**Product: ECG Electrode, REF 19.000.00.440****Lot numbers: 31209-0329, 40217-0158, 40317-0323, 40407-0329, 40516-0328,
40627-0326, 40827-0327, 40930-0325, 41103-0326, 41216-0321,
50122-0158, 50508-0323, 50713-0329, 50831-0321**

Dear Sirs,

We herewith would like to inform you about an important safety notice concerning our ECG electrodes, type 440, REF 19.000.00.440.

The affected Lot numbers with the corresponding quantities supplied to you are listed in the attached response form.

Description of the problem:

In response to feedback from the field, it was discovered that there is a risk ECG electrodes, type 440, of specific Lot numbers fail to transmit signals. The investigations initiated confirmed the defect and permitted to identify further potentially affected products. The affected Lot numbers are shown above.

There is a risk that the affected electrodes will transmit a poor signal or no signal at all before reaching the indicated expiry date. It is very unlikely that this will cause a patient risk.

We kindly ask you to undertake the following action due to this safety notice:

1. Please control your existing stock of these electrodes at your facilities, sort these affected Lot numbers out and store them separately.
2. Please fill in the attached response form and return until 25th November 2015. Kindly inform us about the still existing stock of the affected Lot numbers. In addition, please also let us know if you have already sold any of the affected lot numbers without complaints.
3. After receipt of your response form we will contact you immediately how to further proceed with the affected sorted out stock.

Communication of the herewith described information:

Please make sure within your organization that all users of this electrode and any other persons requiring this information receive this important safety notice. In case of having submitted/sold this electrode to a third party – kindly forward a copy of this safety notice.

Please keep this information until this action is finalized.

The responsible authority in your country has received a copy of this safety notice.

In case you have any questions or need further information, please contact the below mentioned

Enclosure

Response form and delivery notes

Response

Safety notice on **ECG electrodes - REF 19.000.00.440**

Please return via **FAX (02236/3913-179)** or by **e-mail**
 (m.stoeckmann@dahlhausen.de) **until 25th November 2015** latest .

ECG electrodes Type 440 REF 19.000.00.440		Total quantity:
<input type="checkbox"/> The below indicated quantity of the corresponding Lot number(s) are still available and will be blocked for sales immediately. We assure that they will not be applied at any patient anymore:		
Lot no.	delivered quantity	own stock
31209-0329		
40217-0158		
40317-0323		
40407-0329		
40516-0328		
40627-0326		
40827-0327		
40930-0325		
41103-0326		
41216-0321		
50122-0158		
50508-0323		
50713-0329		
50831-0321		
<input type="checkbox"/> The above indicated ECG electrodes are not stocked anymore and have been used without any complaint.		
Contact		
_____	Email _____	
Contact Person (in block letters)	Tel. _____	
_____	_____	
Place, Date	Signature/Stamp	