

Innsbruck, 23 February 2015



## LEONHARD LANG

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### IMPORTANT SAFETY NOTICE

**Product trade name:** ECG electrode

<b>Cardionetics W60</b>	<b>59629</b>
<b>Dalhausen W60</b>	<b>58688</b>
<b>Skintact F40</b>	<b>58009</b>
<b>Skintact FS50</b>	<b>58028</b>
<b>Skintact T60</b>	<b>58046</b>
<b>Skintact FSRB4</b>	<b>50543</b>
<b>Stable Base T60</b>	<b>50547</b>

**Required action:** Quarantine the product  
**Target audience:** Healthcare professionals

**Details of the affected product:** See "Description of the problem"

#### Description of the problem

In response to feedback from the field, it was discovered that ECG electrodes of a specific lot fail to transmit signals. This malfunction could be demonstrated with reserve samples retained for backtesting. An examination of the raw material batches involved was initiated immediately and the investigation showed that several lot numbers are or could be affected by the problem. Leonhard Lang therefore urgently recommends healthcare professionals to stop using ECG electrodes with the lot numbers listed below and to quarantine them.

### Measures to be taken by the user

1. Identify all affected ECG electrodes in your facility and quarantine them.
2. Complete the enclosed acknowledgment form and send it to Leonhard Lang by **e-mail or fax** as instructed. This step is intended as proof that the issue has been communicated to all customers.
3. Be sure to return the enclosed acknowledgment form (**even if you do not have the product affected by the recall in stock**).
4. Upon receipt of your acknowledgment, Leonhard Lang will inform you of how to dispose of the quarantined products and will provide you with replacement goods.
5. If the affected product has been forwarded to other healthcare facilities, please provide them with a copy of this safety notice and send them a list with the serial numbers of the products concerned by fax or e-mail.

If you have questions or concerns about this safety notice, please contact one of the persons listed below:

Sophia Hurmann  
Sales Department  
tel: +43 512 33425 - 45  
fax: +43 512 39 22 10  
e-mail: [sophia.hurmann@leonhardlang.at](mailto:sophia.hurmann@leonhardlang.at)

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Stefan Rudig  
Quality Department  
tel: +43 512 33425 - 15  
fax: +43 512 39 22 10  
e-mail: [stefan.rudig@leonhardlang.at](mailto:stefan.rudig@leonhardlang.at)

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Bernhard Ladner  
Qualitäts Manager  
tel: +43 512 33425 - 39  
fax: +43 512 39 22 10  
e-mail: [bernhard.ladner@leonhardlang.at](mailto:bernhard.ladner@leonhardlang.at)

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Leonhard Lang herewith informs you that this safety notice has also been communicated to the appropriate National Competent Authorities. Please observe the obligations imposed by the Medical Device Directive concerning vigilance reporting.

We apologize for any inconvenience caused by this issue and assure you that safety and quality are our first and foremost priorities. If you have any question, please contact us immediately.

**Affected lot numbers:**

<b>59629 Cardionetics</b>	<b>W60 Lot: 40115-0159</b>
<b>58688 Dahlhausen</b>	<b>W60 Lot: 40116-0151</b>
<b>58046 Skintact</b>	<b>T60 Lot: 40115-0158</b>
<b>58028 Skintact</b>	<b>FS50 Lot: 40120-0093</b>
<b>58028 Skintact</b>	<b>FS50 Lot: 40117-0092</b>
<b>58028 Skintact</b>	<b>FS50 Lot: 40117-0091</b>
<b>58028 Skintact</b>	<b>FS50 Lot: 40116-0099</b>
<b>58009 Skintact</b>	<b>F40 Lot: 40115-0098</b>
<b>58009 Skintact</b>	<b>F40 Lot: 40115-0097</b>
<b>50547 Stable Base</b>	<b>T60 Lot:40116-0323</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40120-0326</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40120-0154</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40117-0325</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40117-0153</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40116-0152</b>
<b>50547 Stable Base</b>	<b>T60 Lot: 40115-0322</b>
<b>50543 Skintact</b>	<b>FSRB4 Lot: 40116-0319</b>
<b>50543 Skintact</b>	<b>FSRB4 Lot: 40115-0318</b>

**COMPLETE THIS FORM AND SEND IT TO:**

Sophia Hurmann  
Sales Departement  
tel: +43 512 33425 - 45  
fax: +43 512 39 22 10  
e-mail: [sophia.hurmann@leonhardlang.at](mailto:sophia.hurmann@leonhardlang.at)

**Ref. CAP-15-0053**

An / To	
CC	
Von / From	
FAX No. or email	
Datum / Date	
Unterschrift/ Signature	

<b>ANORDNUNG / ORDER</b>	Die folgenden Produkte / Lots <b>MÜSSEN SOFORT UNTER QUARANTÄNE</b> gestellt und im Lager zurückgehalten werden.
	The following products / lots <b>MUST BE QUARANTINED IMMEDIATELY</b> and held in storage until further notice.

	1	2	3	4
Produktbezeichnung und Nr. Product number and name				
Lot #				
Anzahl erhalten Quantity received				

<b>BESTÄTIGUNG / CONFIRMATION</b>	Dieses Formular muss sofort an den Sender zurückgeschickt werden als Nachweis über die Durchführung der Anordnung!
	This form must be returned to sender immediately as confirmation that order has been completed!

Bestätigung über gesperrte Ware / Confirmation of quarantined goods				
	1	2	3	4
Produktbezeichnung und Nr. Product number and name				
Lot #				
Menge gesperrt Quantity quarantined				

Gesperrt durch / Quarantined by	
Datum / Zeit Date / Time	
Unterschrift / Signature	