

To:

XXX

From:

Leonhard Lang GmbH
Archenweg 56
A-6020 Innsbruck

Innsbruck, Nov. 2, 2015

IMPORTANT SAFETY NOTICE

Reference: CAP-15-0061

Product trade name: ECG electrode

Required action: Destruction of affected products

Target group: Healthcare professionals

Ladies and Gentlemen:

This letter is to inform you of the recall of the articles listed below:

- **Art. No.**

Annex A lists the affected LOT numbers and the quantities shipped to you for each article number. Annex E explains how to identify the LOT number on the product packaging.

Please read the letter carefully and follow the steps in section 2 of this letter.

1. Description of the defect

Summary: In response to feedback from the field, it was discovered that there is a risk ECG electrodes of specific lots fail to transmit signals. The investigations initiated confirmed the defect and permitted to identify further, potentially affected products.

Conditions for the occurrence of the issue: The use of electrode listed in Annex A of this letter.

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

Safety information: With this letter, Leonhard Lang informs you of the fact that this safety notice will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to comply with the requirements of this recall action.

2. Actions and timeframe of the recall

1) Please make sure within your organization that all users of the products listed above and any other persons requiring this information receive this important safety notice.

2) **Report 1:** Please let us know how many of these electrodes you have in stock and how many you have already sold to third parties. Destroy the electrodes in your inventory. Please use the forms of Annex A (columns 3 and 4) and B to respond and return them to us not later than **November 25, 2015**.

3) **Report 2:** If products have been distributed to third parties, please forward a copy of this notification to these organizations and obtain their confirmation as to the disposition of the products (consumed/destroyed). The forms provided in Annex C and D can be used for this purpose.

Summarize your customers' replies in the 'Confirmation of destroyed / consumed products' in Annex A (columns 5 and 6) and send us this form not later than **January 29, 2016**.

Please retain the information at least until we inform you about the termination of this recall.

Timeline of communications to be sent to Leonhard Lang:



List of annexes:

Annex A: Distributor confirmation form of destroyed / consumed products - Reports 1 and 2

Annex B: Response Form for Report 1

Annex C: Template - Confirmation form of destroyed / consumed products for your customers

Annex D: Template - Response form for your customers

Annex E: LOT number identification on the product packaging

3. Replacement of the electrodes

For the termination of the recall it is necessary that you confirm in writing the destruction of all electrodes that were neither sold nor consumed. Replacement products will be provided on the basis of the data entered in columns 3 and 5 of Annex A.

As far as the **handling of the replacement** is concerned, please contact us at the following e-mail address, using "**CAP-15-0061 Replacement + your company name**" as email subject:

service@leonhardlang.at

If you have further questions, please contact one of the persons listed below:

Christine Pfanner

Quality Management

Tel: +43 512 33425 – 1989

Fax: +43 512 39 22 10

E-mail: christine.pfanner@leonhardlang.at

Bernhard Ladner

Head of Quality Management

Tel: +43 512 33425 - 39

Fax: +43 512 39 22 10

E-mail: bernhard.ladner@leonhardlang.at

We apologize for the inconveniences caused by this issue and assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact us with any questions you may have.

Yours sincerely,

Bernhard Ladner

Head of Quality Management

Tel: +43 512 33425 - 39

Fax: +43 512 39 22 10

E-Mail: bernhard.ladner@leonhardlang.at

**Annex A Distributor confirmation form of destroyed/consumed products –
Reports 1 and 2**

Article number: XXXXX

LOT numbers / quantity of affected electrodes:

		Report 1 Fill out and return to us not later than Nov. 25, 2015		Report 2 Fill out and return to us not later than Jan. 29, 2016		
1	2	3	4	5	6	7
Lot Number	Quantity received	Quantity destroyed	Quantity sold	Total customer feedback: products destroyed	Total customer feedback: products consumed	Total customer feedback: products unaccountable

With Report 1, we confirm: Unsold electrodes have been quarantined and destroyed. We declare under our sole responsibility that we will not use the affected lots on patients and that these lots have been destroyed.

With Report 2, we confirm: All electrodes reported as not consumed have been quarantined and destroyed by our customers.

Organization:

Date / Signature:

Company stamp:

Please fill out this response form and return it as an e-mail attachment (scan, then save as PDF) at the indicated dates, using "**CAP-15-0061 Response + your company name**" as email subject to:

service@leonhardlang.at

Annex B: Response Form for Report 1

Please check ALL boxes applicable to your organization.

- We have read and understood the safety notice of **Nov. 2, 2015**.
- We have notified our customers verifiably in writing of the content of this safety notice and of the necessary corrective action by forwarding this safety notice.
- Unsold electrodes as per **Annex A, Report 1** have been quarantined and destroyed.
- We enclose **Annex A** 'Confirmation of destroyed / consumed products' with the LOT numbers and quantities of affected electrodes in our company.

Please complete using capital letters:

Organization:

Address:

City:

Country:

Name:

First name:

Form of address / Title:

Fax:

Telephone:

E-mail:

Company stamp:

Date / Signature:

Please complete this response form and return it as an e-mail attachment (scan, then save as PDF) not later than **Nov. 25, 2015**, using "**CAP-15-0061 Response + your company name**" as email subject, to:

service@leonhardlang.at

Annex C: Template - Confirmation of destroyed / consumed products for your customers

Article number: XXXXX

LOT numbers / quantity of affected electrodes:

Lot Number	Quantity received	Quantity consumed	Quantity destroyed	Quantity unaccountable
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			
LOT shipped	Quantity shipped			

The electrodes not consumed have been quarantined and destroyed. We declare under our sole responsibility that we will not use the affected lots on patients and that these lots have been destroyed.

Organization:

Date / Signature:

Company stamp:

Please fill out this response form and return it as an email attachment (scan, then save as PDF) at the specified dates to:

E-mail address of your company

Annex D: Template - Response form for your customers

Please check ALL boxes applicable to your organization.

- We have read and understood the safety notice from Leonhard Lang.
- We have notified our customers verifiably in writing of the content of this safety notice and of the necessary corrective action by forwarding this safety notice.
- The unused electrodes of the 'Confirmation of destroyed / consumed products' have been quarantined and destroyed.
- We enclose the 'Confirmation of destroyed / consumed products' with the LOT numbers and quantities of affected electrodes in our company.

Please complete using capital letters:

Organization:

Address:

City:

Country:

Name:

First name:

Form of address / Title:

Fax:

Telephone:

E-mail:

Company stamp:

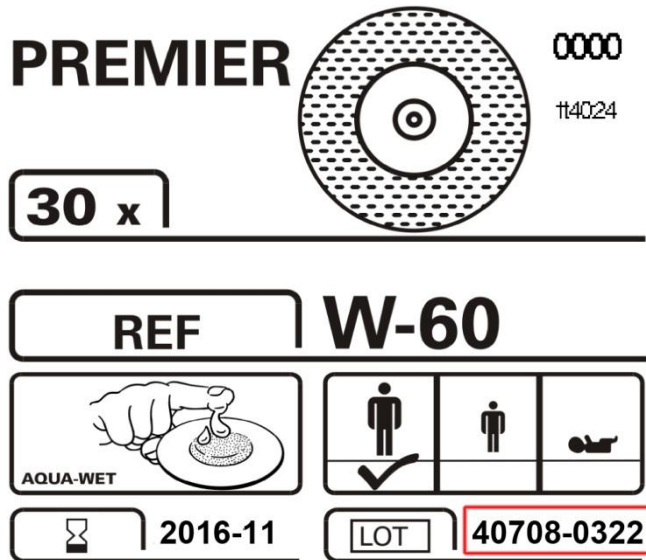
Date / Signature:

Please complete this response form and return it as an email attachment (scan, then save as PDF) not later than **XX.XX.XXXX** to:

E-mail address of your company

Annex E: LOT number identification on the product packaging

An example of an ECG electrode affected by the recall is shown below



The LOT number is shown in a red box and is always identified by the following symbol.

LOT