

URGENT

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential Legionella Bacteria exposure for Unity Service Users

Product: Elekta Unity

Scope: All installed Unity systems

Notification Released: May, 2020

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Description of Problem:

There is a potential risk where Legionella bacteria may be present in the Unity machine room, specifically the heat exchanger condensation collection tray.

This risk is only significant to service users working directly on the condensation collection tray and immediate area. Clinical users and patients have no exposure to this potential hazard.

Details:

Elekta has identified an area within the Elekta Unity system that has the potential environmental conditions for Legionella bacteria to form. The area with this potential is the condensation collection system for the heat exchanger located within the Unity Machine room. The Unity machine room has restricted access and shall only be accessed by trained personnel.

In normal operation there is no risk of any users or patients being exposed to legionella bacteria should it be present. There has been no reported presence of legionella bacteria in Elekta Unity systems, this has been identified as a potential hazard only.

What are legionella bacteria and the potential human harm?

When small droplets of legionella bacteria are inhaled by humans Legionellosis disease can be contracted. Legionellosis is a collective term for diseases caused by legionella bacteria including the most serious Legionnaires' disease. Legionnaires' disease is a potentially fatal form of pneumonia.

Clinical Impact:

The presence of legionella bacteria in the Unity Machine room does not impact the safe operation of the system nor does it pose any change to delivery of a treatment. There is no change in risk to the patient or clinical user. Only service users working directly on the area of potential legionella bacterial growth are at risk. This risk does not apply to machines under installation.

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Recommended User Action:

No change in treatment delivery or clinical workflows are necessary. The identification of this risk will not impact the normal operation of the Unity system.

However, there is potential for serious harm to the service users directly exposed to legionella bacteria and therefore service engineers will be informed to only perform service activities on this region of the machine with the correct personal protective equipment (PPE) and means to safely eliminate or reduce any bacteria.

As part of corrective measures to eliminate or reduce the growth of legionella, a Preventative Maintenance (PM) activity will be introduced whereby the Elekta Engineer would be required to treat the condensate with chlorine.

For the introduction of this PM activity, it is essential to ensure the safe and effective disposal of chlorinated water. The site must ensure that the condensate outlet is connected to a suitable drain for the safe and effective disposal of chlorinated water based on local regulations. Elekta recommends connecting it to a sewage drain. This may already be in place at your site but if it is not, the customer is expected to make necessary modification.

If the customer cannot change the connection to a sewage drain, the CUSTOMER shall appoint a competent person to conduct risk assessments and ensure compliance to local regulations concerning the safe disposal of chlorinated water.

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel, working with this product, on the content of this letter.

Elekta Corrective Actions:

Elekta takes the welfare of our patients, customers and service personnel seriously. As such Elekta will release new measures to reduce the likelihood of legionella bacteria growth. These will include treatment of the collected condensate making the water uninhabitable for bacteria. The condensate treatment will be part of the scheduled Preventative Maintenance (PM). Additionally, service users will be instructed to use appropriate personal protective equipment (PPE) for completing service activities on this area of the system.

This notice has been submitted to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

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Acknowledgement Form

In order to meet regulatory requirements, you are required to either acknowledge receipt of this notification via the Elekta Care Community or complete this form and return it to Elekta immediately upon receipt, but no later than within 30 days.

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| Classification: Important Field Safety Notification | FCO Reference Number: 200-01-801-009 |
| Description Potential Legionella Bacteria exposure for Unity Service Users | |

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| Hospital: | |
| Device Serial No(s): (if applicable) | Location or Site: |

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| I acknowledge that I have read and understood this Notice and accept the implementation of any given recommendation. | |
| Name: | Title: |
| Customer Signature: | Date: |

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| New installation confirmation to be signed by the installing Elekta engineer or a Representative employee, when the installed product has a physical IFU/manual: | |
| I acknowledge that the customer has been informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual: | |
| Name: | Title: |
| Signature: | Date: |