

FIELD SAFETY NOTICE

Possibility of Delayed Electronic Remote-Controlled (ERC) Tubing Clamp Closure

Affected Devices:	CP5 control panels and HLM bubble sensors and EP packs manufactured prior to February 10, 2017
Date:	24 oktober 2017
Reference:	CS-MUN-2017-005
Attention:	Perfusionists, risk managers
Reason:	Notification of a required upgrade for CP5 Control Panels and heart-lung machine (HLM) bubble sensors and EP packs manufactured prior to February 10, 2017 due to possibility of delayed Electronic Remote-Controlled (ERC) tubing clamp closure

Dear Customer:

Description of the issue:

During internal testing, LivaNova identified that there is a possibility that the automatic line closure by the ERC clamp after detection of an air bubble could take longer than is intended by design in the CP5 system. This could lead to the remote possibility of an air bubble reaching a patient before the clamp closes if the blood flow rate is high and the distance between the bubble sensor and the patient is set at the minimum required by the IFU (1 meter).

LivaNova has not received any reports that an air bubble has passed the ERC clamp, nor have there been any reports of patient injury associated with this issue.

Actions taken by LivaNova to address these issues:

1. This issue has been corrected in all CP5 control panels and HLM bubble sensors and EP packs manufactured on February 10, 2017 and later; and
2. LivaNova has developed a firmware upgrade for CP5 control panels, and HLM bubble sensors and EP packs manufactured prior to February 10, 2017.

Action to be taken by the user:

1. As recommended in the Instructions for Use (IFU), placing an arterial filter on the arterial line will reduce the probability of air ingress to the patient's bloodstream; and
2. No other actions by the user are required at this time, other than to continue to follow the IFU and the above-mentioned recommendation. A LivaNova representative or local agent will contact you to plan the upgrade of your affected products.

Transmission of this Field Safety Notice:

Please ensure that this notice is passed on to all personnel within your organization who need to be aware of this Field Safety Notice. In case you have transferred products to a third party, please pass this information on to them and also inform the below mentioned contact person.

Contact reference person:

For questions regarding this Field Safety Notice, please contact Christian Peis, Director Quality Engineering, LivaNova Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com.

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agency in your country who is aware of these actions.

Thank you for your cooperation in this matter. LivaNova is committed to providing quality products and we apologize for any inconvenience this may have caused.

Sincerely,

.....