

**URGENT FIELD SAFETY NOTICE**  
**SCP Control panel (Subset)**  
**Replacement of pump rotary speed control**

**FSCA Identifier:** CP-MUN-2019-001

**Affected Devices:** Pump rotary speed control in a subset of SCP Control panels

**Date:** August 23<sup>rd</sup>, 2019

**Attention:** SCP system users (Cardiac Surgery Operating Room Responsible, Cardiac surgeons, Perfusionists, biomedical engineers/technicians ...)

Dear Valued Customer:

**Reason for this Letter and affected products**

The purpose of this letter is to inform you that LivaNova<sup>1</sup> is initiating the replacement of the angle encoder in a limited subset of SCP control panels (references 60-02-15 & 60-02-50) due to an observed trend in reported complaints. The angle encoder is a subpart of the control panel mechanism<sup>2</sup> used to control the rotary speed of the pump in the SCP<sup>3</sup> system.

You are receiving this communication because, according to our records, there is in your facility at least one SCP system control panel equipped with an affected angle encoder.

The list of the affected SCP system control panel(s) in your facility can be found in **Attachment 1**. Any SCP control panel not listed in Attachment 1 is not impacted by the corrective action described in this communication.

**Description of the addressed issue**

The affected angle encoders may present with premature wear of the encoder shaft, leading to difficult or impossible rotation.

When this issue occurs on the SCP system control panel, the speed control knob appears blocked or stiff and/or does not appear to be controlling the drive unit.

**Risk to health associated to the issue**

The loss of function of the angle encoder during bypass may result in an inability to set the intended flow rate leading more or less blood flow than intended.

It should be noted no patient harm has been reported to date as a result of this issue.

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<sup>1</sup> LivaNova PLC is a U.K. holding company with a number of wholly owned subsidiaries, including LivaNova Deutschland GmbH. In this document, we refer to all entities using the brand name LivaNova.

<sup>2</sup> The rotary knob in front of the SCP control panel is mounted on the shaft of the angle encoder 97-103-603. The angle encoder converts the rotation of the shaft into a series of electrical pulses used to set the pump rotary speed.

<sup>3</sup> The SCP System is intended for use as a centrifugal pump during cardiopulmonary bypass. The SCP System consists of the pump control panel, the drive unit, the flow probe and the Revolution ®.

## Corrective measures

LivaNova is initiating the proactive replacement of potentially affected angle encoder lots in the field in order to reduce the likelihood of the occurrence of the above described issue.

## Actions to be taken by the Customer/User

Pending the replacement of affected angle encoder(s) would be completed, LivaNova is kindly requesting SCP system users to take the following actions, without any delay:

1. Affected SCP control panel(s) listed in **Attachment 1** should be quarantined. Your LivaNova representative may support you in this activity (refer to contact reference person at the end of this letter).
2. In case of urgent medical need, affected devices could be used, provided the SCP system operating instructions would be strictly followed, especially safety instructions related to the pump operation. Users should:
  - a. ensure to have a SCP emergency drive unit ready for use,
  - b. be familiar with the mounting as well as the functioning of the emergency drive unit.

As reported in the operating instructions, hand cranking remains an option in case it would become necessary to operate the SCP manually.

3. Please complete and return the Customer Response Form (**Attachment 2**) by e-mail to Rachel.Cheong@livanova.com.

Your LivaNova representative will contact you to organize the replacement of the angle encoder in affected SCP system(s) in your facility.

## Transmission of this Field Safety Notice

Please ensure this Field Safety Notice is passed on to all personnel within your organization who need to be aware of it.

In case you have transferred products to a third party, please pass this information on to them and inform the below mentioned contact person.

## Contact reference person

For questions regarding this Field Safety Notice, please contact your LivaNova representative [Rachel.Cheong@livanova.com], or LivaNova Customer Quality organization at [LivaNova.FSCA@livanova.com](mailto:LivaNova.FSCA@livanova.com).

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

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,  
Enrico Milani, Customer Quality Director, Europe & International



## Enclosed:

Attachment 1: List of the affected SCP system control panel(s)



Health innovation that matters

Attachment 2: Customer Response Form

## Affected devices list

### URGENT FIELD SAFETY NOTICE

#### SCP Control panel (Subset) - Replacement of pump rotary speed control CP-MUN-2019-001, August 2019

According to our records, you have one or more affected SCP system control panel(s) at your facility.

Pending the replacement of the angle encoder would be completed, LivaNova is kindly requesting SCP system users to quarantine affected SCP control panel(s) listed in following table, without any delay.

Your LivaNova representative may support you in this activity (refer to contact reference person at the end of the letter).

SCP Control Panel Part Number (REF)	SCP Control Panel Serial Number (SN)

The SCP Control Panel Serial Number can be found on the label at the rear of the device:



**Customer Response Form****URGENT FIELD SAFETY NOTICE****SCP Control panel (Subset) - Replacement of pump rotary speed control  
CP-MUN-2019-001, August 2019**

According to our records, you have one or more affected SCP control panel(s) at your facility (**Attachment 1**). Thank you for your cooperation for the execution of this action.

Please complete this Customer Response Form and return it to LivaNova - [local contact information to be inserted] at your earliest convenience, and if possible, within two weeks after reception, to ensure timely execution of the corrective action and to avoid repeated notification of this information.

Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova via your LivaNova representative [local contact information to be inserted] or directly to [customerquality@livanova.com](mailto:customerquality@livanova.com).

We have reviewed and understood the attached Field Safety Notice. The information and required actions have been brought to the attention of all relevant users:

☐ Yes ☐ No

Affected SCP control panels have been quarantined:

☐ Yes ☐ No

In case No was answered, please explain:

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Next lines may be used for any question/request/comment to be submitted to LivaNova:

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Facility Name: 

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Customer Name & Title: 

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City & Country: 

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Contact information: 

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Signature

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Date

## FIELD SAFETY CORRECTIVE ACTION Pump rotary speed control in a subset of SCP Control panels

### Information for LivaNova Distributors

**FSCA Identifier:** CP-MUN-2019-001

**Affected Devices:** Limited subset of SCP control panels (references 60-02-15 & 60-02-50)

**Date:** August, 23<sup>rd</sup>, 2019

Dear Distributor,

The purpose of this letter is to inform you that LivaNova<sup>1</sup> is initiating a corrective action in the field for limited subset of SCP control panels (references 60-02-15 & 60-02-50).

Here follows the description of the strategy that LivaNova has planned for the FSCA implementation. You are expected to support FSCA deployment as per below described points: More details can be found in the QA instructions documentation.

#### **Description of the actions associated to FSCA / Description of the actions to be taken by LivaNova Distributors:**

1. Distributors are expected to confirm receipt and understanding of this FSCA using the Distributor Response Form (Attachment 1) no later than 2 weeks after reception of this letter.
2. The FSN have was translated into the following local languages. The translation will have to be verified, corrected by a native speaker as appropriate, and updated with local contact data and product information:
  - Arabic (AR)
  - Chinese (ZH-CN)
  - German (DE)
  - Italian (IT)
  - French (FR)
  - Polish (PL)
  - Portuguese (PT)
  - Russian (RU)
  - Spanish (ES)
  - Turkish (TR)
  - Serbian (SR)

In case, the local language for countries/areas you're responsible for is not listed above, use the English version of the FSN. If local regulation or practice requires the FSN to be translated in local language, please manage it locally and inform Customer Quality of the situation.

FSN translations are available at: <https://livanova.box.com/s/t7p7n2ahgzlf5sw9icfdct6a9sojcbra>

**NB: the FSNs shall be used as they are. In case any modification is contemplated (rewording, addition of a cover letter), please contact Customer Quality for approval before proceeding.**

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3. According to local regulation, inform the Competent Health Authority in your countries/areas of responsibility.  
In case you would need any support to manage communication and/or questions from the Health Authorities, please contact Customer Quality.
4. Using A3-CP-MUN-2019-001-Affected devices:
  - a) Update the traceability to end users and prepare the consignee list (customers in receipt of the affected products) using the format of A2-CP-MUN-2019-001-Customer Notification Log: one file per country, one line per affected SCP control panels in the country.
  - b) Update the Attachment 1 in the FSN with the list of affected devices at each end user facility.
5. Deliver the FSN as soon as possible to all affected customers. The FSN Customer Response Form (CRF) in Attachment 2 of the FSN) should be obtained.
6. Provide to your usual LivaNova partner all the evidences the corrective action has been implemented:
  - a) A2-CP-MUN-2019-001-Customer Notification Log file tracking:
    - Date FSN was delivered
    - Date the FSN CRF was obtained or a comment documenting why it cannot be obtained
  - b) All FSN CRF
  - c) Proof of submission to Health Authority when applicable. In case it's not applicable, it should be explained in the Distributor Response Form (Attachment 1)

We thank you for your cooperation in this matter.

**We remain available for any questions/comments: please contact your usual LivaNova partner or Customer Quality at [LivaNova.FSCA@LivaNova.com](mailto:LivaNova.FSCA@LivaNova.com).**

Sincerely,

LivaNova  
Customer Quality, Europe & International  
[LivaNova.FSCA@livanova.com](mailto:LivaNova.FSCA@livanova.com)

Attachment 1: Distributor Response Form

## DISTRIBUTOR RESPONSE FORM

**FIELD SAFETY**

**CORRECTIVE ACTION**

FSCA-CP-MUN-2019-001

Pump rotary speed control in a subset of SCP  
Control panels

Please return and complete the attached form by e-mail to Customer Quality and/or your LivaNova partner

In case of any question and/or concern, please contact your LivaNova partner and/or Customer Quality: [LivaNova.FSCA@livanova.com](mailto:LivaNova.FSCA@livanova.com)

Section 1: FSCA Execution		YES	NO
1	We HAVE reviewed and understand the attached FSCA material	<input type="checkbox"/>	<input type="checkbox"/>
2	We WILL implement and complete all required actions	<input type="checkbox"/>	<input type="checkbox"/>
3	If NO was answered for 1 and/or 2, explain why:		
Section 2: Local Health authority Information			
1	Date the local Health Authority was informed:		
2	Language in which documents were translated (if applicable):		
3	In case the local Health Authority was not informed, explain Why:		
Section 3: Distributor Information			
Country:			
Distributor Name:			
Contact Name:			
Email:			
Fax / Phone number			
Section 4: Distributor Acknowledgement			
Submitted by:		Date:	
Signature			