

Urgent Field Safety Notice / Field Safety Corrective Action

OCS™ Heart Console (REF # 1000) / OCS™ Lung Console (REF # 2000) / OCS™ Liver Console (REF # 3000)

July 30, 2018

TransMedics' reference: FSCA 2018-002

Dear OCS Customer,

TransMedics is initiating a voluntary Field Safety Corrective Action affecting OCS Heart, OCS Lung and OCS Liver Consoles. As part of our product quality monitoring process, we identified a potential issue with the OCS device that could affect proper operation. In particular, the OCS Console may lose communication with the Perfusion Module if the OCS contact buttons are not cleaned and maintained properly per the provided instructions for use.

Our records show that an OCS Heart, OCS Lung or OCS Liver Console is installed at your facility. Please refer to the attached Product Information Bulletin (PIB 16-001) regarding proper preventive maintenance of your OCS Console, including application and use of the enclosed Diamond Paste Metal Cleaner (REF 1460), if needed.

Please share this notification with others in your organization as appropriate. If your OCS console has been moved to another facility, please forward this Field Safety Notice to the facility immediately and notify TransMedics so that we can ensure proper notification is delivered.

Please contact myself at the number below, your local support representative, or TransMedics' Customer Service by phone at +1 (978) 552-0999 or email (service@transmedics.com) with any questions.

Please complete the attached form and return it using one of the methods specified.

TransMedics has notified the appropriate Regulatory Agency in your country of this action.

On behalf of the company, I thank you for being a TransMedics customer. We appreciate your cooperation and apologize for any inconvenience that this notice may cause. Please be assured that patient safety and product quality is our primary goal.

Sincerely,

MCO'Hara

Michael O'Hara
Sr. Director of Quality Assurance
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