

Field Safety Notice
OCS™ Heart Console
REF #: 1200

June 1, 2017

TransMedics' reference: FSN 2017-001

Dear OCS Heart Customer,

TransMedics is issuing a Field Safety Notice for the OCS Heart System. As part of our product quality monitoring process, we identified a potential issue with the OCS Heart device that could affect proper operation. In particular, the blood warmer may heat beyond the set limit if the Heart Perfusion Module (HPM) is not installed in the OCS Console prior to taking the system out of Standby.

Our records show that there is an OCS Heart Console installed at your facility. Please refer to the attached Product Information Bulletin (PIB-17001) to ensure proper operation of your OCS Heart System.

Please share this notification with others in your organization as appropriate. If your OCS console has been moved to another facility (or another area of your facility), please forward this Field Safety Notice to this 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 (978) 552-0999 or email (service@transmedics.com) with any questions.

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 issue may cause. Please be assured that patient safety and product quality remain our primary concern.

Sincerely,

MKO'Hara

Michael O'Hara
Sr. Director of Quality Assurance
TransMedics, Inc.
(978) 552-0909

Internal reference: FSN 2017-001