URGENT: **Medical Device Voluntarily Recall**

Terumo® Advanced Perfusion System 1
Electronic Patient Gas System (EPGS) Flowmeter

2nd May 2019

Attention: Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management
Cc: Chairman Medical Board and relevant Head of Departments

Terumo Singapore Pte Ltd is issuing this letter to inform a voluntarily recall on Terumo® Advanced Perfusion System 1 Electronic Patient Gas System (EPGS) Flowmeter.

This recall is a Correction involving replacement of a device component without physical removal of the device from its point of use.

Terumo will execute a field correction to replace the affected flowmeter within the EPGS devices. A Terumo Field Service Representative will contact users to schedule the field correction activities.

Product Impacted by Recall:

Catalog Number	Product Description
801188	Electronic Patient Gas System
Serial Number	**Dates of Distribution**
All	August 23, 2002 through March 29, 2019

Terumo is initiating a voluntary field correction of the Electronic Patient Gas System (EPGS) internal flowmeter included with Terumo System 1 devices because the gas flow rate output of the EPGS, which is reported in the Terumo System 1 Central Control Monitor (CCM), may be inaccurate.

Through internal investigation, Terumo identified that the cause of the potential inaccuracies is a defect in the EPGS internal flowmeter.

Additionally, while the user may notice that the intended gas flow setpoint (slider) and the delivered gas flow reading on the CCM display do not match, there may be no other notification of the fault condition on the CCM.

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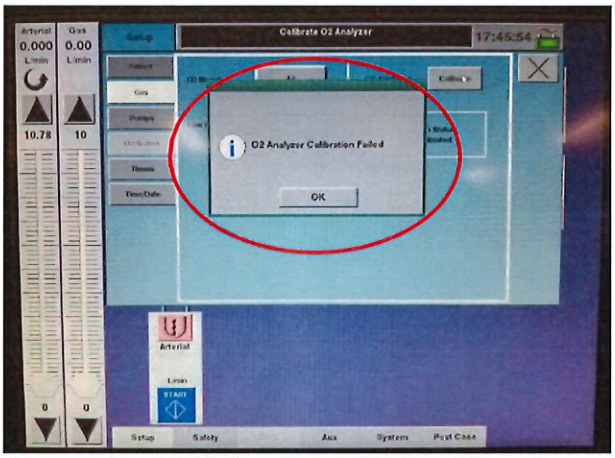
Terumo has confirmed complaints based on EPGS flowmeter failures. There have been no reported illnesses or injuries as a result of this issue. All patients requiring cardiopulmonary bypass with the assistance of a Terumo System 1 with an affected EPGS flowmeter are at risk as a result of exposure to the defect or malfunction should it occur.

The hazard potential depends on when the flowmeter failure occurs and the nature of the flowmeter defect. The following situations may occur:

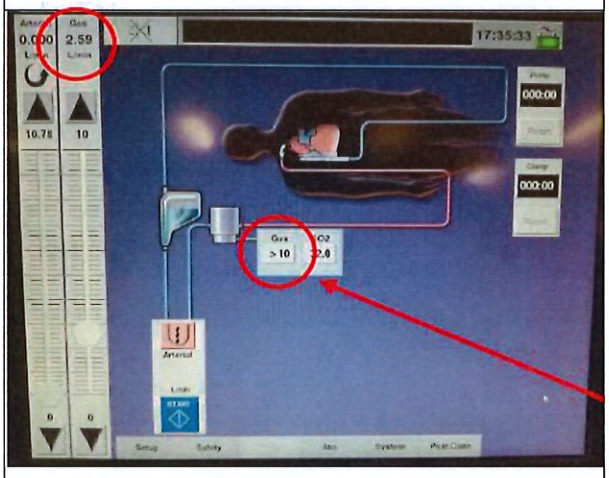
SITUATION: The EPGS fails to calibrate



Example CCM display: CCM notifies the user that the calibration has failed.

Potential Hazard
A calibration failure may result in delay in procedure.

SITUATION: The gas flow rate reported on the CCM is higher than the actual flow rate.



Example CCM display: Indicates a discrepancy between the gas flow reading displayed on the CCM (EPGS icon) and gas flow set point (slider).

Potential Hazard
In this situation, the actual gas flow to the oxygenator may be lower than expected. If the backup external flowmeter is not incorporated in the gas system or is not observed by the clinician and an EPGS flowmeter failure occurs, the issue could be misinterpreted as an oxygenator failure that requires change out.
In some instances, actual gas flow to the oxygenator may be 0 L/min. This specific failure can be identified by the reported gas flow exceeding 10 L/min (see example) and will be accompanied by a repeated clicking noise from within the EPGS.

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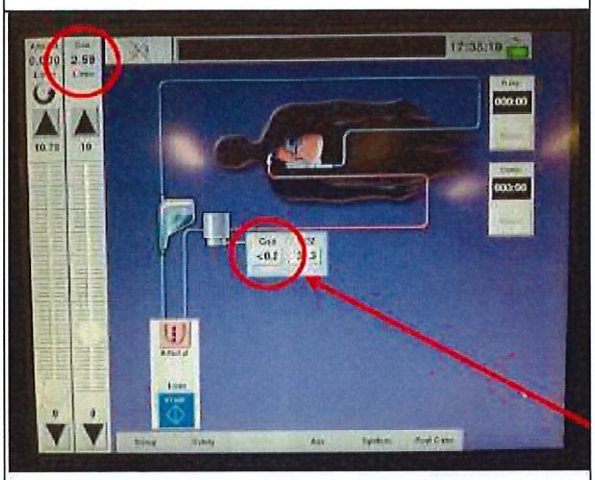
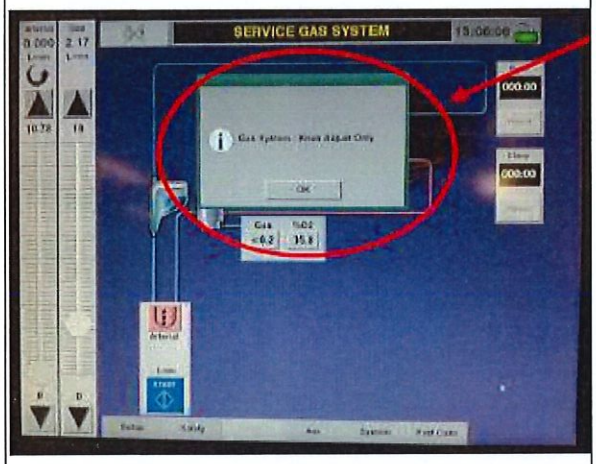
SITUATION: The gas flow rate reported on the CCM is lower than the actual flow rate





Example CCM display: Indicates a discrepancy between the gas flow reading displayed on the CCM (EPGS icon) and gas flow set point (slider).

This is followed by a notification that the EPGS can be controlled exclusively through manual controls (see Recommendations).

Potential Hazard

In this situation, the actual gas flow to the oxygenator may be higher than expected. If the backup external flowmeter is not incorporated in the gas system or is not observed by the clinician and an EPGS flowmeter failure occurs, the failure could reduce the amount of CO2 in the blood.

Under certain circumstances, actual gas flow to the oxygenator could exceed 10 L/min and potentially reach as high as 20 L/min. This specific situation can be identified by the reported gas flow approaching 0 L/min (see example). The user will be notified that the gas system has encountered an error and can be adjusted via manual controls only (see example).

If not recognized by the clinician, this situation could create a pressure imbalance in the oxygenator that could allow visible air bubbles to be forced across the semi-permeable hollow fiber membrane and into the oxygenator, potentially leading to visible air in the perfusion circuit. The greatest opportunity for the formation of visible air in the oxygenator blood/fluid path is during preparation and priming of the cardiopulmonary bypass circuit due to the lower blood phase pressures experienced during this part of the procedure. This situation can be mitigated with observance of the oxygenator manufacturer's instructions for use regarding the handling of ventilating gas and fluid flow considerations to prevent pressurization of the gas phase of the oxygenator.

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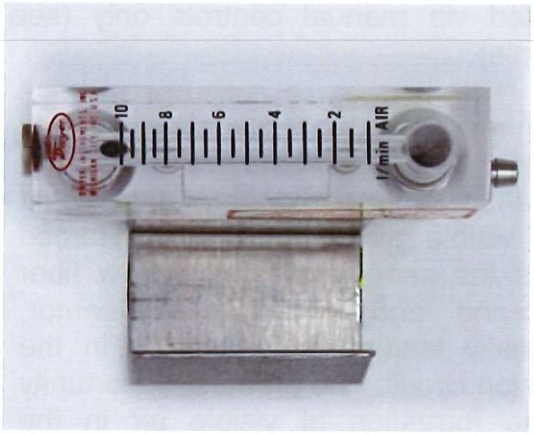
Please be assured that we take the safety and quality of our products very seriously. Our customers are our top priority and we want to ensure that you have a high-quality product, which meets your daily needs. We greatly appreciate your understanding and prompt assistance, and apologize for any inconvenience this may have caused.

Advisory for User:

Use of backup external flowmeter:

Use of the backup external mechanical flowmeter (supplied in the Terumo System 1 Accessory Kit, part number 147361) is strongly recommended per the Terumo System 1 Instructions for Use and is required until this correction is completed to facilitate system diagnosis and troubleshooting.

Position the backup flowmeter just before the oxygenator to detect any possible gas leak between the gas outlet and the oxygenator, and as a backup to monitor gas flow and the gas flow status of the EPGS in the event CCM capability is lost. If you cannot locate your external flowmeter, or require an additional external flowmeter, contact Terumo CVS Customer Service.



Backup external flowmeter, part number 147361. Use an external flowmeter to confirm true flow rate

If initial calibration fails:

If the EPGS fails to calibrate upon initial start-up, users should follow the Terumo System 1 Instructions for Use and take the following actions:
- Check for flow restrictions in the inlet and outlet lines of all components connected between the gas outlet and the oxygenator.
- Use the backup flowmeter to verify that no gas leaks are present.
- Retry calibration.

If calibration is unsuccessful again during setup:
- Use the local knob controls for FiO2 and gas flow adjustment.
- Use the external backup flowmeter to measure flow.
- If available, use an external O2 analyser to measure oxygen content.

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Maintenance of gas and fluid phase pressures during priming:

Users should not supply gas during priming without adequate arterial pump flow during recirculation in order to prevent the pressure in the gas phase from becoming higher than the fluid phase. In addition, the blood phase pressure must always be higher than the gas phase pressure in order to avoid air embolism.

During priming, to ensure that the system is completely de-aired and that no leaks in the system exist, recirculate the priming solution at a rate of 4 L/min or higher and establish a system pressure that mimics clinical conditions. Performing these manoeuvres will assure the gas/blood phase pressure relationship will prevent the passage of visible air into the blood phase if the high gas flow condition should occur. This can be accomplished by partially occluding the arterial line distal to the oxygenator and pressure monitoring transducer location.

Alternative gas supply options:

There are two primary alternatives to using the EPGS for controlling gas flow to the oxygenator. As an interim solution, users may connect a stand-alone O2 tank directly to the oxygenator and meter gas flow to the oxygenator directly from the tank per AmSECT Standards and Guidelines for Perfusion Practice, May 2017. Alternatively, a pole-mounted gas blender (Terumo part number 164235 or 3500CP-G21) may be used; users may need assistance from hospital personnel (i.e., hospital biomed) to setup and initiate use of the blender.

Instructions for User:

1. Review this Medical Device Recall notice.
2. **Ensure that all users have received notice of this issue, and prominently display this notice where all users may access it.**
3. Continue use of the device in conjunction with the backup external mechanical flowmeter found in the Terumo System 1 Accessory Kit.
4. Confirm receipt of this communication by completing and returning the attached Customer Response Form.
5. Terumo will contact users to schedule the field correction activities.

Note: Terumo recommends that users continue using their Terumo System 1 with EPGS, with the required backup external mechanical flowmeter, while waiting for this correction.

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Reporting of Adverse Event

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Terumo Singapore Pte Ltd. Alternatively, healthcare professionals may report the adverse events to the Medical Device Branch, health Products Regulation Group, HSA at Tel: 6866 1048,or report online at www.hsa.gov.sg/ae_online. Events that are reported to Terumo Singapore Pte Ltd. will be investigated and subsequently reported to HSA.

If you have any further questions or comments, please do not hesitate to contact us at 6291 3606 (Office Tel. No.)

Yours Sincerely,

[redacted]

Joyce Soh
Regulatory Affairs Department

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