

## Urgent FIELD SAFETY NOTICE

Device: Terumo® Advanced Perfusion System 1 - Heart-Lung Machine:  
Loss of System Power  
Reference: FSN1213 – Follow- up actions - 2014-10  
Action: Inspection & Upgrade

Attention: Chief of Perfusion, Department of Cardiovascular Surgery, Director of Operating Room Services

**This Field Safety Notice is a follow-up action to FSN1213 issued in February 2013 (see attached document).**

### DESCRIPTION

As communicated in the advisory action FSN1213, Terumo CVS originally received five reports of loss of system power for the Terumo System 1 between 2003 and 2012. Since then, no additional occurrences have been reported.

Terumo CVS has continued to investigate and identify opportunities for device improvements related to this issue. Terumo CVS has developed a field correction plan to address the identified causes of the Terumo System 1 experiencing loss of system power.

### DETAILS ON AFFECTED DEVICES

Reference	Description	Serial Number Range
801764	Terumo® Advanced Perfusion System 1 Base 220-240V	0006 to 1422

### CORRECTIVE ACTION:

All System 1 customers have previously received a safety advisory. Subsequent to this action, the following corrections will be implemented in **consecutive phases**:

- Torque adjustment of power supply fasteners to specified values.
- Replacing the On/Off power switch with a new design to prevent switch failure.
- Adding a switch protector to the On/Off power switch to prevent inadvertent shut off.
- Implementing design changes and upgrades to improve the reliability of power switching and battery backup.

### CUSTOMER INSTRUCTIONS

- 1) Review this Field Safety Notice, and assure that all users are aware of this notice.
- 2) Based on the confirmed base serial number as provided in your response to previous actions, your local Terumo CVS representative will contact you to schedule a service appointment and collect evidence of action completion accordingly. The first action that will be initiated is the torque adjustment of power supply fasteners, initiation of other listed actions will be spread over the coming two years.



We confirm that this *Field Safety Notice* has also been notified to your national Competent Authorities.

We encourage you to contact us or your local Terumo representative with any questions or concerns:

Organisation (to be completed by the sales or dealer)

Contact name (function)

Contact phone, mobile, email

  
MD Vigilance Expert  
Terumo Europe NV  
Leuven, Belgium

**ATTACHED DOCUMENT**

**Urgent FIELD SAFETY NOTICE**

Device: **Terumo® Advanced Perfusion System 1: *Loss of System Power***  
Reference: **FSN1213 2013-02**  
Action: **Advisory**

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Attention: Chief of Perfusion, Department of Cardiovascular Surgery, Director of Operating Room Services

**DESCRIPTION OF THE PROBLEM**

Terumo Cardiovascular Systems (CVS) has become aware of a remote possibility that Terumo® Advanced Perfusion System 1 could experience a spontaneous loss of system power. It is issuing this advisory because the Operators Manual for the Terumo System 1 does not provide user instructions for responding to such an event.

Terumo CVS has received five reports of spontaneous power loss for the Terumo System 1 between 2003 and 2012:

- In all reports, the systems lost full power and did not switch to battery backup. This occurred without warning.
- In one report, the system re-booted automatically after approximately 30 seconds. In the remaining reports, the system regained power after the user toggled the main power switch.
- In all reports, the user was able to establish full function for the remainder of the case and the system did not exhibit the malfunction again.

At this time, no root cause has been determined and Terumo CVS will continue its investigation. Should its investigation conclude that a corrective action is necessary, Terumo CVS will notify all users in the affected population.

**POTENTIAL HAZARD**

The complete loss of system power would result in loss of all patient support functions, including arterial blood flow, myocardial protection, venting and suction capabilities, safety systems, system alarms and system information. Depending on the response of the clinical team and the availability of backup equipment, a prolonged lack of such support could result in death or serious injury.

The potential patient injuries range from no injury to varying degrees of neurologic dysfunction, cardiac dysfunction due to inadequate myocardial protection, end organ dysfunction, or death in the case of an extended period of no flow.

There are no known reports of patient injury as a result of this issue. In all instances, the systems resumed full function and the event did not recur.

**DETAILS ON AFFECTED DEVICES**

Reference	Description	Serial Number Range
801764	Base for Terumo® Advanced Perfusion System 1	0006-1422



#### CORRECTIVE ACTION:

Terumo CVS is issuing this Field Safety Notice to alert all Terumo System 1 users about the issue and to provide specific instructions on what to do in the event of failure.

#### CUSTOMER INSTRUCTIONS:

1. Review this Field Safety Notice, and assure that all users are aware of this notice.
2. Retain the instructions on page 3 in the front of the Operators Manual.
3. Fill out and return the enclosed Customer Reply Form as quickly as possible.

We confirm that this Field Safety Notice has also been notified to your national Competent Authorities.

We encourage you to contact us or your local Terumo representative with any questions or concerns:

Organisation (to be completed by the sales or dealer)  
Contact name (function)  
Contact phone, mobile, email

  
MD Vigilance Expert  
Terumo Europe NV  
Leuven, Belgium

  
MD Vigilance Officer  
Terumo Europe NV  
Leuven, Belgium