

## URGENT MEDICAL DEVICE RECALL

**ATTENTION:** Chief of Perfusion, Director of Operating Room Services,  
Director of Biomedical Services, Risk Management  
**CC:** Chairman Medical Board and relevant Head of Departments



### REASON FOR ADVISORY

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 User's Manual for the Terumo System 1 does not provide user instruction 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.

### WHAT TO DO IN EVENT OF A FAILURE

Please review and retain the instructions on page 3.

If you have any questions, contact Terumo CVS Customer Service:

**800-521-2818**

**Customer Service Hours:**  
**Monday-Friday,**  
**8 AM – 6 PM ET**

### **AFFECTED POPULATION**

<i>Catalog Number</i>	<i>Product Description</i>	<i>Serial Number Range</i>	<i>Dates of Distribution</i>
801763	Base for Terumo Advanced Perfusion System 1*	All units	November 26, 2002 through current

### **CUSTOMER INSTRUCTIONS**

1. Review this Medical Device Correction and **retain the instructions on page 3**.
2. Assure that all users have received notice of this issue.
3. Confirm receipt of this communication by faxing, or emailing the attached Customer Response Form to the fax number/email address indicated on the form.

#### **Questions?**

We encourage you to contact us with any questions or concerns:

**Terumo CVS Customer Service**  
**1-800-521-2818**  
**Recall Fax**  
**1-734-741-6149**

Customer Service Hours:  
Monday – Friday, 8 AM - 6 PM ET

#### ***Any adverse events experienced with the use of this product, and/or quality problems should be reported to Terumo CVS, and also the FDA's MedWatch Program by:***

- Linking to the MedWatch website at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Download form at: [www.fda.gov/Safety/MedWatch/HowtoReport](http://www.fda.gov/Safety/MedWatch/HowtoReport)  
Mail to address on form.

## WHAT TO DO IN THE EVENT OF FAILURE

In the event a user experiences a spontaneous loss of power *without the automatic initiation of the battery backup system*, Terumo CVS recommends:

- **The user first ensures that the entire system has lost power before continuing with these instructions.**
  - Check the central control monitor (CCM), the local pump displays, the LED indicators on the modules, and the battery status indicator on the front of the system.
- **Once certain the entire system has lost power, turn the main power switch on the front panel to the “OFF” position then to the “ON” position.**
  - If toggling the main power switch **is successful** in re-booting the system:
    - Power will be available to the pumps prior to the CCM.
    - Pumps can be restarted using local controls. NOTE: If using a centrifugal pump, be sure to follow emergency procedures to prevent backflow (see sidebar at right)
    - After the system has booted up, select a perfusion screen and enable all safety systems.
  - If toggling the main power switch **is NOT successful** in re-booting the system:
    - Initiate or continue manual hand cranking of the arterial pump.
    - Prepare to transition to backup equipment.
- **Contact Terumo CVS Customer Service immediately upon conclusion of the case:**

### Preventing Backflow During Power Loss with a Centrifugal Pump:

- Clamp the arterial and venous lines.
- Discontinue vacuum-assisted venous drainage, if applicable.
- Close all purge and recirculation lines to minimize the potential for air entrainment and backflow in the CPB circuit.

**800-521-2818**

**Customer Service Hours:**  
**Monday-Friday,**  
**8 AM – 6 PM ET**

## URGENT MEDICAL DEVICE RECALL

### Follow-up Activities to Previously-issued Recall

#### ATTENTION

**Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management**

**CC: Chairman Medical Board and relevant Head of Departments**

#### REASON FOR CORRECTION

Terumo Cardiovascular Systems (Terumo CVS) has continued to investigate and identify opportunities for device improvements related to Correction #AA-2012-024-C issued November 2012. Correction #AA-2012-024-C advised users of a remote possibility that the Terumo® Advanced Perfusion System 1 could experience a loss of system power.

This notice is to alert users that Terumo CVS will implement field correction activities related to Correction #AA-2012-024-C. As a reminder, Terumo CVS is including the user instructions, "WHAT TO DO IN THE EVENT OF FAILURE" that were issued in the original Correction (see page 3).

Terumo CVS received five reports of spontaneous loss of system power for the Terumo System 1 between 2003 and 2012. (As noted above, November 2012 was the date of the original recall related to loss of system power.) **Since then, no additional occurrences of Terumo System 1 loss of system power have been reported.**

#### POTENTIAL HAZARD

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.

A 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.



#### WHAT TO DO NOW

Review this Medical Device Correction.

Review the reminder user instructions included on page 3, "WHAT TO DO IN THE EVENT OF FAILURE."

Terumo CVS will contact users to schedule the field correction activities.

If you have questions, contact Terumo CVS Customer Service:

**1-800-521-2818**

**Customer Service Hours:  
Monday – Friday  
8 a.m. – 6 p.m. ET**

**Terumo Cardiovascular Systems Corporation**

6200 Jackson Road, Ann Arbor, MI 48103 U.S.A

**TOLL FREE: 800-262-3304**

**PHONE: 734-663-4145**

**WEB: [www.terumo-cvs.com](http://www.terumo-cvs.com)**

## **CORRECTION**

Terumo CVS is implementing field correction activities to address the identified causes of the Terumo System 1 experiencing loss of system power. These activities will be implemented in a phased approach beginning late 2015:

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

A Terumo Field Service Representative will contact users to schedule the field correction activities once the activities are ready to be implemented.

## **AFFECTED POPULATION**

<b>Catalog Number</b>	<b>Product Description</b>	<b>Serial Number Range</b>	<b>Dates of Distribution</b>
801763	Base for Terumo Advanced Perfusion System 1, 100/120V	All units	August 23, 2002 through current
801764	Base for Terumo Advanced Perfusion System 1, 220/240V	All units	August 23, 2002 through current

## **CUSTOMER INSTRUCTIONS**

- Review this Medical Device Correction and assure that all users have received notice of this issue.
- Complete and return the enclosed Customer Response Form.
- Terumo CVS will contact users to schedule the field correction activities.

### **Questions?**

We encourage you to contact us with any questions or concerns:

**Terumo CVS Customer Service**  
**1-800-521-2818**

**Fax**  
**1-734-741-6149**

Customer Service Hours:  
Monday – Friday, 8 a.m. – 6 p.m. ET

***Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:***

- Linking to the MedWatch website at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Download form at:  
[www.fda.gov/Safety/MedWatch/HowtoReport](http://www.fda.gov/Safety/MedWatch/HowtoReport)  
Mail to address on form.

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## WHAT TO DO IN THE EVENT OF FAILURE

In the event a user experiences a spontaneous loss of power *without the automatic initiation of the battery backup system*, Terumo CVS recommends:

- **The user first ensures that the entire system has lost power before continuing with these instructions.**
  - Check the central control monitor (CCM), the local pump displays, the LED indicators on the modules, and the battery status indicator on the front of the system.
- **Once certain the entire system has lost power, turn the main power switch on the front panel to the “OFF” position then to the “ON” position.**
  - If toggling the main power switch **is successful** in re-booting the system:
    - Power will be available to the pumps prior to the CCM.
    - Pumps can be restarted using local controls.  
NOTE: If using a centrifugal pump, be sure to follow emergency procedures to prevent backflow (see sidebar at right).
    - After the system has booted up, select a perfusion screen and enable all safety systems.
  - If toggling the main power switch **is NOT successful** in re-booting the system:
    - Initiate or continue manual hand cranking of the arterial pump.
    - Prepare to transition to backup equipment.
- **Contact Terumo CVS Customer Service immediately upon conclusion of the case:**

### Preventing Backflow during Power Loss with a Centrifugal Pump:

- Clamp the arterial and venous lines.
- Discontinue vacuum-assisted venous drainage, if applicable.
- Close all purge and recirculation lines to minimize the potential for air entrainment and backflow in the CPB circuit.

**Terumo CVS Customer Service**  
**1-800-521-2818**

Customer Service Hours:  
Monday – Friday, 8 a.m. – 6 p.m. ET





## NOTICE OF COMPLETED POWER SWITCH UPGRADE

PRODUCT: Terumo® Advanced Perfusion System 1

DATE: February 12, 2016

PAGE: 1 of 1

### ATTENTION: CHIEF OF PERFUSION

CC: Chairman Medical Board and relevant Head of Departments

Terumo Cardiovascular Systems (Terumo CVS) has continued to work on device improvements and is now implementing an important field correction activity that addresses one of the identified causes of the Terumo® Advanced Perfusion System 1 experiencing loss of system power. This is one of several follow-up activities related to recall AA-2014-002-C.



A Terumo CVS Service Technician completed the following service on your Terumo System 1:

- Added a switch protector to the On/Off power switch to prevent inadvertent shut off.
- Replaced the On/Off power switch with a new design to prevent switch failure.

Users will notice the following differences in the On/Off power switch:



**Before:** Switch face is open.



**After:** Switch location remains the same. New switch protector acts as a guard and covers lower portion of the new switch to protect access and help prevent inadvertent shut off.

### CUSTOMER INSTRUCTIONS

Review this Notice of Completed Power Switch Upgrade and ensure that all users have received notice of this device improvement.

### CONTACT INFORMATION

If you have questions about this notice, please contact your Terumo representative or contact Terumo CVS Technical Service:

**800-441-3220 extension 6932**

Technical Service Hours: Monday – Friday, 8 a.m. – 6 p.m. ET (24/7 Emergency Hours)

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**Terumo Cardiovascular Systems Corporation**

6200 Jackson Road, Ann Arbor, MI 48103 U.S.A

**TOLL FREE:** 800-262-3304

**PHONE:** 734-663-4145

**WEB:** [www.terumo-cvs.com](http://www.terumo-cvs.com)



## NOTICE OF COMPLETED FIELD CORRECTION ACTIVITIES FOR AA-2014-002-C

PRODUCT: Terumo® Advanced Perfusion System 1 (Power Manager Components)

PAGE: 1 of 3

DATE OF SERVICE: \_\_\_\_\_

### **ATTENTION: CHIEF OF PERFUSION** **CC: Chairman Medical Board and relevant Head of Departments**

Terumo Cardiovascular Systems (Terumo CVS) has continued to work on device improvements and is now implementing the final correction activities to address identified causes of the Terumo® Advanced Perfusion System 1 experiencing loss of system power. This is the final phase of the correction activities related to recall AA-2014-002-C.

A Terumo CVS Service Technician implemented both hardware and software upgrades on your Terumo System 1 which result in the following improvements:



**A new service message on the Central Control Monitor (CCM) Main Screen** notifies Terumo System 1 users of the need for backup battery replacement every two years.



**A new maintenance reminder message on the CCM Main Screen** notifies Terumo System 1 users to perform battery charge level testing every two months.

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## NOTICE OF COMPLETED FIELD CORRECTION ACTIVITIES FOR AA-2014-002-C

PRODUCT: Terumo® Advanced Perfusion System 1 (Power Manager Components)  
PAGE: 2 of 3

**An update to the Power Status Display (battery icon)** makes the icon more noticeable to Terumo System 1 users and provides information related to the power status of the battery backup system.

The Power Status LED provides information about battery life as follows:

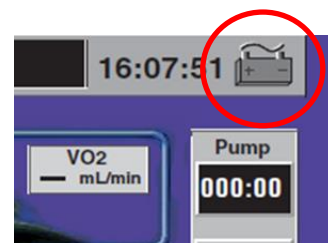
When operating from AC (Mains) power:

- **Steady green** indicates a battery system with greater than one hour run time with a fully loaded system.
- **Steady red** indicates a battery system with less than one hour run time with a fully loaded system.

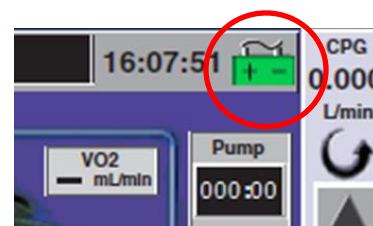
When operating from the battery system:

- **Flashing green** indicates 30 minutes or more battery life at present discharge rate.
- **Flashing yellow** indicates 15 minutes or more, but less than 30 minutes battery life at present discharge rate.
- **Flashing red** indicates less than 15 minutes battery life at present discharge rate.

(See Section 3, System Base, in the Operator's Manual.)



Original Icon



New Icon (with Power Status Indicator LED)

### NEW OPERATOR'S MANUAL

An updated Operator's Manual is available which incorporates all previous changes and addendums. The November 2017 Operator's Manual (Version 883325) replaces the previous Operator's Manual and all previous addendums. This updated manual is being provided to users in electronic (PDF) format.

The following table is provided for users who may have Terumo System 1 devices in different stages of upgrade:

If your Terumo System 1 received this upgrade:	Download this PDF version:	With this version date:
Power Manager Components (final activities for AA-2014-002-C)	834186	April 2017
Power Manager Components (final activities for AA-2014-002-C) + EPGS and CCM Components	883325	November 2017



## NOTICE OF COMPLETED FIELD CORRECTION ACTIVITIES FOR AA-2014-002-C

PRODUCT: **Terumo® Advanced Perfusion System 1 (Power Manager Components)**  
PAGE: **3 of 3**

Access to download the PDF version of the updated Operator's Manual is being provided through Terumo CVS' online Learning Management System, the *Terumo Learning Center*. An email is being sent to a primary contact at your facility which allows access to the secure site.

It is important that your facility's primary contact accesses and downloads the new Operator's Manual, and makes it available for all users at your facility, prior to users operating the upgraded device.

If you have questions about your facility's primary contact or the *Terumo Learning Center*, contact the TLC Helpdesk at 734-663-4145 ext. 5750 or email [TLC.help@terumomedical.com](mailto:TLC.help@terumomedical.com). If you prefer a printed copy of the Terumo System 1 Operator's Manual, contact Terumo CVS Customer Service at 734.663.4145 or 800.521.2818 and request reorder number 802350.

### CUSTOMER INSTRUCTIONS

1. Review this Notice of Completed Field Correction Activities and ensure all users have received notice of these device improvements.
2. Dispose of your previous Terumo Advanced Perfusion System 1 Operator's Manual.
3. Ensure your facility's primary contact downloads the new Operator's Manual and makes it available to all device users.

### CONTACT INFORMATION

If you have questions about this notice, please contact your Terumo representative or contact Terumo CVS Technical Service:

**800-441-3220 extension 6932**  
Technical Service Hours:  
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(24/7 Emergency Hours)