



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

PRODUCT: Terumo® Advanced Perfusion System 1

PAGE: 1 of 2

DATE OF SERVICE: _____

ATTENTION: CHIEF OF PERFUSION

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 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.

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:

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



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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.)

NEW OPERATOR'S MANUAL

Terumo CVS is providing an updated Operator's Manual which incorporates all previous changes and addendums. (You are receiving one Operator's Manual per device at your facility.)

The April 2017 Operator's Manual (reorder number 802350), replaces the previous Operator's Manual and all previous addendums.

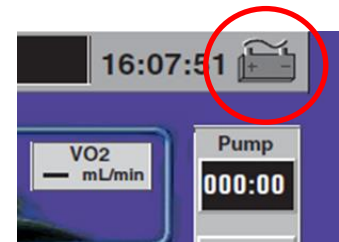
CUSTOMER INSTRUCTIONS

1. Review this Notice of Completed Field Correction Activities and ensure that all users have received notice of these device improvements.
2. Dispose of your previous Terumo Advanced Perfusion System 1 Operator's Manual and addendums, and replace them with new Operator's Manual provided. No further action is required as a result of the field correction activities to your Terumo System 1.

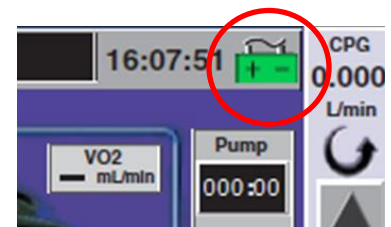
CONTACT INFORMATION

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)



Original Icon



New Icon (with Power Status Indicator LED)

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