Abbott

URGENT MEDICAL DEVICE CORRECTION

CentriMag™ Acute Circulatory Support System Motor Model: 102956

Compatible with CentriMag™ Pump and PediMag™ Pump

September 5, 2018

Dear Clinician,

In an effort to keep you informed of important device updates that help ensure the safety of your patients, Abbott is advising you that we have received reports where damage to the cable that connects the motor to the console resulted in interruption of active support.

This communication is to remind our physician and hospital partners of the importance of following the proper method for exchanging the CentriMag System in the event your system experiences an interruption of power. Specifically, to:

- Reinforce availability of a full backup system which includes a console, motor, flow probe, and power cable
- Ensure proper care and handling of the Centrimag Motor cable
- Provide guidance on inspection of motor cable for damage

Our analysis of devices associated with the motor stop field complaints showed that the motor stop can be attributed to a break of a wire or short circuit between wires within the electrical cable where the cable exits the motor cable bend protection. This damage may be avoided by ensuring proper handling, such as avoiding tight bending of the cable, or winding the cable around the motor during storage during the life of the motor.

CentriMag System Risks and Identified Corrections

To date, Abbott is aware of two (2) instances of patient death and six (6) additional instances of serious injury related to the damaged motor cable. These events were the result of the lack of a backup system or an improper exchange when switching to a secondary back-up motor and console when a motor cable failure occurred.

The CentriMag System includes audio and visual alarms, and the Instructions for Use (IFU) require that a full backup system be in the vicinity of any patient on support. Both the backup system and the alarms help ensure that even if cable damage were to occur, resulting in interruption of support, that switching the backup system will safely resume support.

To reinforce the importance of the presence of a backup system, a warning label will be applied to already fielded consoles, as well as newly manufactured consoles. In addition, a caution statement about the prevention of motor cable damage due to improper handling and storage as well as instructions for inspecting the motor cable for damage will be added to the IFU. See Appendix 1 for the specific label and IFU updates.

Patient Management Recommendations

Below are recommendations for clinicians managing patients using the CentriMag System within a hospital or clinic:

- A full backup system must be in the immediate vicinity of every patient supported by the CentriMag System.
- Exchange the pump to the backup system as described in the CentriMag System Operating Manual and in Appendix 2. Improperly exchanging only the motor to a backup console could cause damage or harm.

- Inspection of the CentriMag Motor, including the cable, for damage should be conducted prior to use. Do not use if damaged. If the cable is damaged and not visible as part of the inspection, the console will alarm during the procedure. Further detail about the visual inspection can be found in Appendix 3.

As a reminder, if your center has a sudden influx of patients and additional backup systems are required, these can be provided for use through the existing rental program. Please contact Customer Service at 1-800-456-1477 for additional information about this program.

Future System Enhancements

Changes are being qualified that are intended to make the motor cable more resistant to damage and will be implemented after the design is fully developed and regulatory approval is received. We will promptly inform you when these designs become available.

Please complete the acknowledgement form included in this packet and return it to Abbott, as noted on the acknowledgement form.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either by phone, online, by regular mail or by fax. To submit your report:

- Complete voluntary Form FDA 3500 online
- Call 1-800-FDA-1088 to report by telephone
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages). View Form FDA 3500 Instructions

Abbott remains committed to patient safety and providing the highest quality products and services. If you have questions, please contact your local Abbott MCS Representative or the MCS HeartLine 1-800-456-1477, which is available 24 hours a day, 7 days a week.

Sincerely,

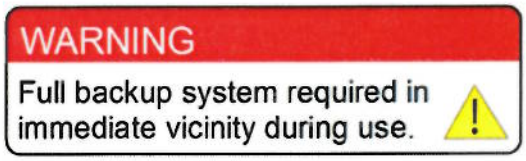
Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure

Appendix 1: Updated IFU and Console Label Information

- Caution Statement regarding cable handling in the CentriMag Motor IFU and the 2nd Generation CentriMag Circulatory Support System Operating Manual. For 1st Generation CentriMag Circulatory Support Systems, this information will be contained in a supplemental document as part of the field action communication.

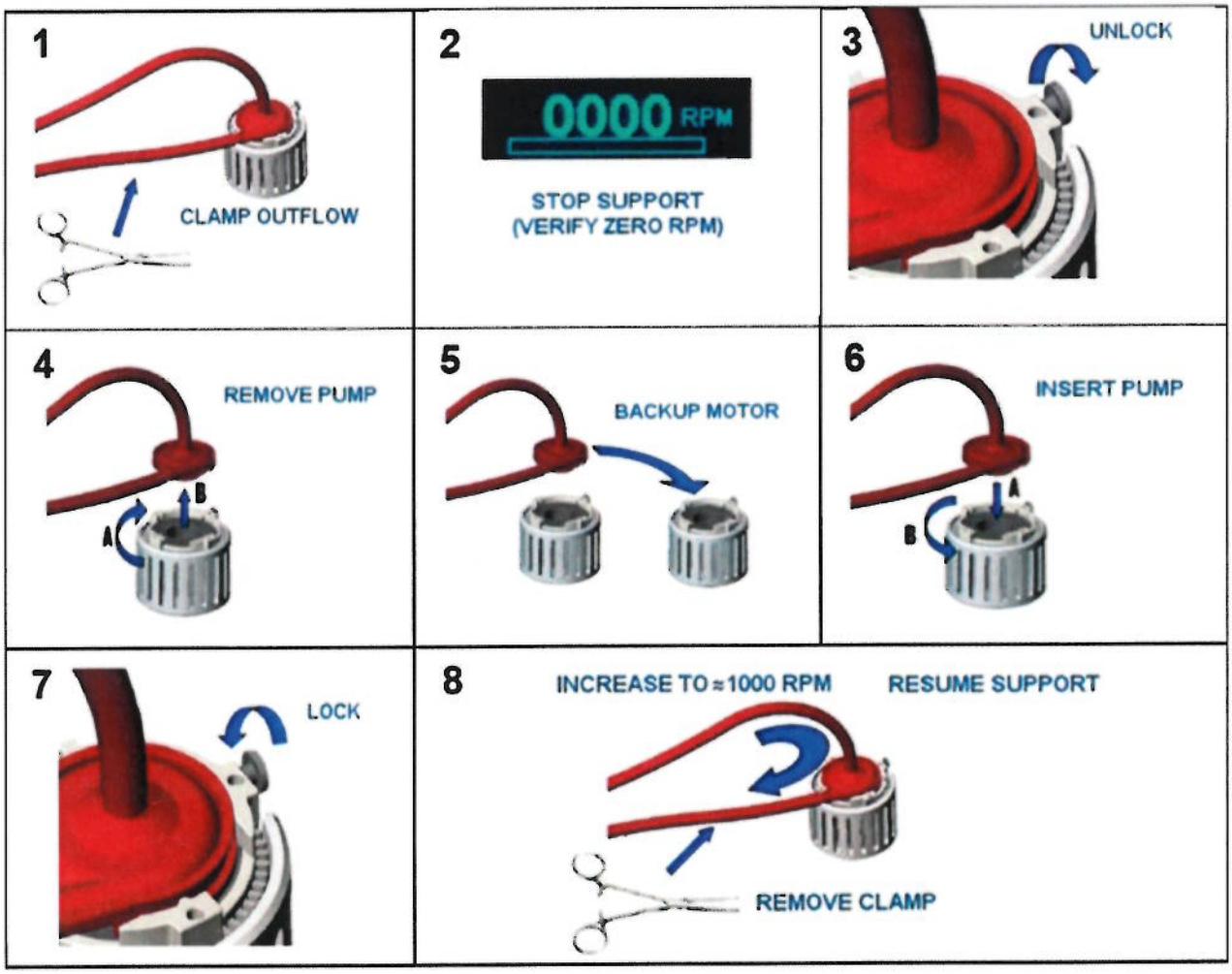
CAUTION
Before each use, verify that the cable connecting the Motor to the Console is not kinked, which can occur with improper handling such as wrapping the cable tightly around the Motor. If the cable is kinked, replace the Motor.

- Caution statement label to be placed on the console requiring the presence of a backup system. This label will be placed on the back panel of CentriMag Circulatory Support Systems.



Appendix 2: Blood Pump Exchange Instructions

- Graphic regarding cable handling in the relevant CentriMag Circulatory Support System Operating Manual demonstrating the proper steps from transitioning a pump between the primary and backup systems.



Appendix 3: Visual Inspection for Cable Damage

- Visual inspection regarding inspection for motor cable damage from the CentriMag Circulatory Support System Operating Manual and supplemental pages (for 1st Generation Consoles)

1. Visually inspect the CentriMag Motor connector for bent or broken pins. Check for burn marks or melted plastic.

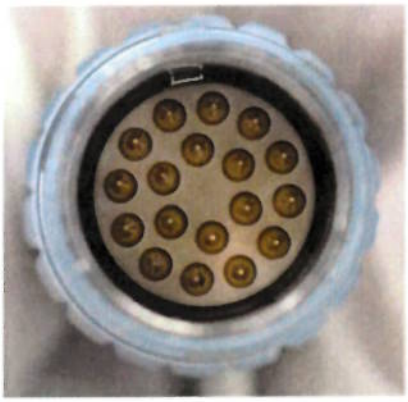


Figure 2: Motor Connector Pin View

Note: If there are any issues while connecting the CentriMag Motor to the CentriMag Console, inspect the Motor port on the rear of the Console for damage, particularly for any broken pins that may be lodged inside.

2. Visually inspect the entire length of the CentriMag Motor cable, including both bend reliefs (see Figures 3 and 4), for any damage such as separations of the bend reliefs, deformations, kinks, or cuts. These types of damage indicate wear and tear or previous rough handling of the cable, which has the potential to result in internal wire damage. Cable thickness and shape should be uniform throughout the length of the cable.

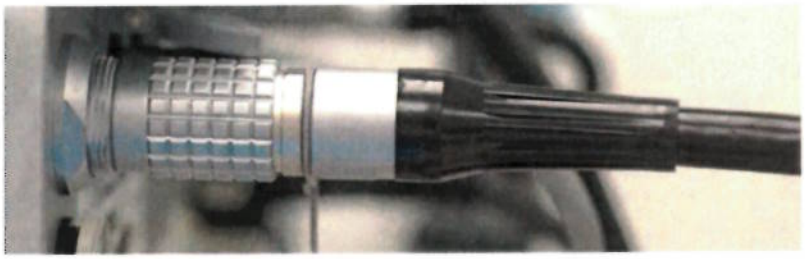


Figure 3: Cable Bend Relief at the Console Connector

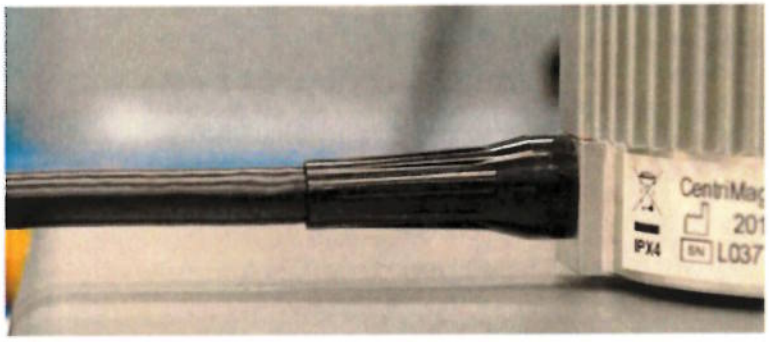


Figure 4: Cable Bend Relief at the Motor

Appendix 3: Visual Inspection for Cable Damage (cont'd)

Figure 5: Cable Damage at the Motor Bend Relief

Figure 6: Undamaged and Intact Motor Cable

Figure 7: Damaged Motor Cable

Figure 8: Damaged Motor Cable

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Acknowledgement Form

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

CentriMag™ Acute Circulatory Support System
Motor Model: 102956

By signing below, I acknowledge that I understand the information that Abbott has provided in the Urgent Medical Device Correction notice related to damaged motor cables and requirement for a backup Centrimag System to be present.

Name (print): _____

Title (print): _____

Signature: _____

Facility Name: _____

Date: _____

Phone Number: _____

E-mail: _____

PLEASE RETURN THIS ACKNOWLEDGEMENT FORM TO ABBOTT
Email: CentriMagNotices@Abbott.com