



VOLUNTARY MEDICAL DEVICE RECALL URGENT

2nd Generation CentriMag Primary Console
(Model Numbers: 201-90421, L201-90421)

May 2024

Dear Healthcare Professional,

Abbott is notifying users of a potential issue identified through our internal process with the **CentriMag Console (2nd Generation CentriMag Primary Console)** which is a part of the CentriMag™ Circulatory Support System. Internal testing showed that due to a component change, the CentriMag Console may not conform to the IEC 61000-4-5 standard. If subjected to a power surge above 1.8kV and up to 2.0 kV, the CentriMag Console may shut down completely without alarm. A power surge may be caused by, including, but not limited to the following: lightning strike, unregulated power switching, or faulty equipment. Pumping would cease and the patient would have to be switched to a backup.

There have been no reported complaints for distributed products and no reports of patient harm or adverse events due to this issue. Only surge voltage above 1.8 kV may shut down the CentriMag console without alarm. The ability of the user to transfer to a backup console to restore system function is not impacted. The affected product is not being removed from the field and does not need to be returned.

This letter contains important information and recommendations on how to use CentriMag Console if the system shuts down without an alarm.

Abbott discovered that certain CentriMag Console manufactured since March 21, 2016 are impacted by this issue. Please review Appendix A for the specific model and serial numbers within the scope of this notification.

Impact and Associated Risks

When affected CentriMag Console is exposed to surge voltage above 1.8 kV and up to 2.0 kV, if the Console shuts down without alarming, resulting impact can be delay in hemodynamic support while support is transferred to the backup system, or potentially thromboembolism if patient support is not transferred in a timely manner.

Recommendation

If the CentriMag Console shuts down without alarms or alerts present, follow Abbott Instruction for Use (IFU) for *Console and Motor malfunction* as described in the Section “Emergency / Troubleshooting”, and switch to a backup CentriMag Console which must be prepared as required backup components in the immediate vicinity.

Note: When the backup CentriMag console is put into use, the previously used console can be restarted and set up as a backup console.

Per the IFU and current practice, a full CentriMag Console backup system is always required to be available in the immediate vicinity of each patient whenever the CentriMag system is used.



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Abbott performed additional testing and confirmed that the ability to pump and alarm is not affected in backup systems. As stated in the IFU these backup systems should have a battery charge sufficient for at least one hour of operation, be connected to wall power, and be powered off.

Abbott is in the process of implementing an additional in-process test by Q3 of 2024, which will ensure that all systems which will be distributed are confirmed to withstand a surge up to 2.0 kV.

Please complete the acknowledgement form included with this letter and return to Abbott. Please distribute this notice to those who need to be aware within your institution and to any organization where potentially affected devices may have been transferred in the event that devices were transferred elsewhere.

Abbott has notified applicable regulatory agencies about this issue. Adverse reactions or quality problems experienced with the use of this product may be reported to your local Abbott representative.

Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process. Should you have any questions about this communication, please contact Abbott Customer Service at 1 (800) 456-1477 or your local Abbott representative.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Dan Lack', is positioned above the printed name.

Dan Lack
Senior Manager Quality
Quality Management Representative
Abbott Heart Failure

Appendix A: Specific Model and Serial Numbers Distributed in Canada

Model Number	Serial Number
201-90421	19474336
201-90421	19606869
201-90421	19606873
201-90421	L04780-0005
201-90421	L04966-0002
201-90421	L04966-0003
201-90421	L04966-0004
201-90421	L05654-0003
201-90421	L05776-0001
201-90421	L05776-0002
201-90421	L05776-0003
201-90421	L06470-0010
201-90421	L06482-0001
201-90421	L06482-0003
201-90421	L06491-0004
201-90421	L06525-0008
201-90421	L06530-0010
201-90421	L06557-0008
201-90421	L06557-0009
201-90421	L06557-0010
201-90421	L06580-0008
201-90421	L06580-0009
201-90421	L06580-0010
201-90421	L06581-0009
201-90421	L06581-0010
201-90421	L06590-0001
201-90421	L06590-0002
201-90421	L06590-0003
201-90421	L06593-0001
201-90421	L06593-0002
201-90421	L06593-0004
201-90421	L06593-0005
201-90421	L06755-0001
201-90421	L06755-0002
201-90421	L06755-0003
201-90421	L06755-0004
201-90421	L06755-0005
201-90421	L06755-0006
201-90421	L06755-0007
201-90421	L06755-0008
201-90421	L06755-0009
201-90421	L06755-0010
201-90421	L06802-0001
201-90421	L06802-0002
201-90421	L06802-0003
201-90421	L06802-0004

Model Number	Serial Number
201-90421	L06802-0005
201-90421	L06802-0006
201-90421	L06802-0008
201-90421	L06877-0001
201-90421	L06877-0002
201-90421	L06877-0003
201-90421	L06877-0004
201-90421	L06877-0005
201-90421	L06907-0005
201-90421	L06907-0006
201-90421	L06907-0007
201-90421	L06907-0008
201-90421	L06907-0009
201-90421	L06927-0009
201-90421	L06927-0010
201-90421	L07161-0001
201-90421	L07162-0001
201-90421	L07189-0001
201-90421	L07244-0001
201-90421	L07462-0001
201-90421	L07463-0001
201-90421	L07569-0001
201-90421	L07572-0001
201-90421	L07573-0001
201-90421	L07577-0001
201-90421	L07578-0001
201-90421	L07579-0001
201-90421	L07580-0001
201-90421	L07581-0001
201-90421	L07582-0001
201-90421	L07584-0001
201-90421	L07585-0001
201-90421	L07586-0001
201-90421	L07588-0001
201-90421	L07589-0001
201-90421	L07591-0001
201-90421	L07592-0001
201-90421	L07595-0001
201-90421	L07598-0001
201-90421	L07599-0001
201-90421	L07600-0001
201-90421	L07601-0001
L201-90421	L01716-0010
L201-90421	L04780-0001
L201-90421	L06482-0005