



Urgent Field Safety Notice
2nd Generation CentriMag Primary Console
(Model Number: 201-90401, 201-90701)

Heart Failure Division
Thoratec Switzerland GmbH
Technoparkstrasse 1
CH-8005 Zürich Switzerland

May 2024

Dear Valued Customer,

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 your Abbott contact. 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 your local Abbott representative.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Dan Lack'.

Dan Lack
Senior Manager Quality
Quality Management Representative
Abbott Heart Failure

Appendix A: Specific Model and Serial Numbers Distributed in India

Model Number	Serial Number
201-90401	19450863
201-90401	19450864
201-90401	19535367
201-90401	19981957
201-90401	L04306-0003
201-90401	L04306-0007
201-90401	L046730007
201-90401	L046730008
201-90401	L047340007
201-90401	L047420002
201-90401	L04948-0004
201-90401	L05229-0001
201-90401	L05229-0009
201-90401	L05229-0010
201-90401	L05254-0009
201-90401	L05254-0010
201-90401	L06338-0008
201-90401	L06404-0002
201-90401	L06405-0003
201-90401	L06405-0005
201-90401	L06405-0009
201-90401	L06407-0001
201-90401	L06407-0002
201-90401	L06407-0005
201-90401	L06407-0008
201-90401	L06487-0002
201-90401	L06487-0009
201-90401	L06488-0006
201-90401	L06489-0002
201-90401	L06489-0008
201-90401	L06491-0009
201-90401	L06495-0006
201-90401	L06495-0010
201-90401	L06521-0001
201-90401	L06521-0010
201-90401	L06522-0001
201-90401	L06522-0002
201-90401	L06522-0004
201-90401	L06522-0005
201-90401	L06522-0006
201-90401	L06525-0007
201-90401	L06527-0004
201-90401	L06528-0010
201-90401	L06530-0003
201-90401	L06530-0005
201-90401	L06582-0002

Model Number	Serial Number
201-90401	L06583-0005
201-90401	L06583-0006
201-90401	L06583-0008
201-90401	L06586-0001
201-90401	L06586-0003
201-90401	L06586-0006
201-90401	L06586-0007
201-90401	L06617-0004
201-90401	L06619-0007
201-90401	L06622-0002
201-90401	L06622-0010
201-90401	L06625-0009
201-90401	L06627-0009
201-90401	L06628-0002
201-90401	L06628-0009
201-90401	L06628-0010
201-90401	L06753-0010
201-90401	L06754-0003
201-90401	L06754-0009
201-90401	L06774-0007
201-90401	L06775-0001
201-90401	L06878-0008
201-90401	L06924-0004
201-90401	L06929-0007
201-90401	L06935-0002
201-90401	L06936-0008
201-90401	L06938-0007
201-90401	L06938-0009
201-90401	L06940-0004
201-90401	L06943-0010
201-90401	L06945-0004
201-90401	L06945-0010
201-90401	L06947-0005
201-90401	L07005-0001
201-90401	L07012-0001
201-90401	L07036-0001
201-90401	L07037-0001
201-90401	L07043-0001
201-90401	L07044-0001
201-90401	L07052-0001
201-90401	L07057-0001
201-90401	L07058-0001
201-90401	L07060-0001
201-90401	L07061-0001
201-90401	L07069-0001
201-90401	L07070-0001

Model Number	Serial Number
201-90401	L07214-0001
201-90401	L07215-0001
201-90401	L07216-0001
201-90401	L07217-0001
201-90401	L07218-0001
201-90401	L07219-0001
201-90401	L07220-0001
201-90401	L07221-0001
201-90401	L07222-0001
201-90401	L07258-0001
201-90401	L07261-0001
201-90401	L07265-0001
201-90401	L07266-0001
201-90401	L07267-0001
201-90401	L07271-0001
201-90401	L07273-0001
201-90401	L07274-0001
201-90401	L07277-0001
201-90401	L07278-0001
201-90401	L07391-0001
201-90401	L07396-0001
201-90401	L07408-0001
201-90401	L07409-0001
201-90401	L07410-0001
201-90401	L07411-0001
201-90401	L07415-0001
201-90401	L07416-0001
201-90401	L07417-0001
201-90401	L07418-0001
201-90401	L07422-0001
201-90401	L07423-0001
201-90401	L07424-0001
201-90401	L07431-0001
201-90401	L07432-0001
201-90401	L07434-0001
201-90401	L07436-0001
201-90401	L07482-0001
201-90401	L07483-0001
201-90401	L07486-0001
201-90401	L07488-0001
201-90401	L07490-0001
201-90401	L07491-0001
201-90401	L07493-0001
201-90401	L07496-0001
201-90401	L07497-0001
201-90401	L07498-0001

Appendix A: Specific Model and Serial Numbers Distributed in India

Model Number	Serial Number
201-90401	L07499-0001
201-90401	L07535-0001
201-90401	L07543-0001
201-90401	L07544-0001
201-90401	L07546-0001
201-90401	L07554-0001
201-90401	L07555-0001
201-90401	L07556-0001
201-90401	L07557-0001
201-90401	L07558-0001
201-90401	L07560-0001
201-90401	L07563-0001
201-90401	L07564-0001
201-90401	L07566-0001
201-90401	L07570-0001
201-90401	L07607-0001
201-90401	L07609-0001
201-90401	L07614-0001
201-90401	L07621-0001
201-90401	L07625-0001
201-90401	L07628-0001
201-90401	L07629-0001
201-90401	L07634-0001
201-90401	L07635-0001
201-90401	L07636-0001
201-90401	L07638-0001
201-90401	L07668-0001
201-90401	L07813-0001
201-90401	L07838-0001
201-90401	L07839-0001
201-90401	L07844-0001
201-90401	L07845-0001
201-90401	L07857-0001
201-90401	L07858-0001
201-90401	L07860-0001
201-90401	L07862-0001
201-90401	L07868-0001
201-90401	L07883-0001
201-90401	L07886-0001
201-90401	L07892-0001
201-90401	L07918-0001
201-90401	L07921-0001
201-90401	L07922-0001
201-90401	L07925-0001
201-90401	L07928-0001
201-90401	LO44940007

Model Number	Serial Number
201-90401	LO44940008