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www.event-medical.com

EUROPE
eVent Medical, Ltd
Caulfield House
Kiltroque, Claregalway
Co Galway, Ireland

Field Corrective Action

Inspiration[®] Ventilator System 12 Oct 2016 Powerboard Reset Switch Removal

eVent Medical is requiring that users of the affected devices immediately cease use of the device until the Power PCB is modified as detailed below.

Affected devices:

All Inspiration Series Ventilators shipped prior to January 1st, 2015.

Description of the problem:

eVent Medical has identified a potential problem with the power reset switch (SW3) located on the Inspiration's Powerboard (PN: F720511 or EVM300147).

If this switch malfunctions, the ventilator may shut down with no alarm.

Action to be taken by the user:

eVent Medical is requesting that all users of the Inspiration Ventilator remove the power reset switch from the Powerboard.

- **Once the switch has been removed, please notify eVent Medical of the successful modification.**



Transmission of this Field Corrective Action Notice:

Please pass this Field Corrective Action Notice to all those who need to be aware of it within your organization and maintain awareness until all units with your organization have been corrected.

The relevant national Competent Authority has been advised of this notice.

Contact reference person:

Rick Waters, Vice President RA /QA
(949) 900-1917, x232
r.waters@event-medical.com

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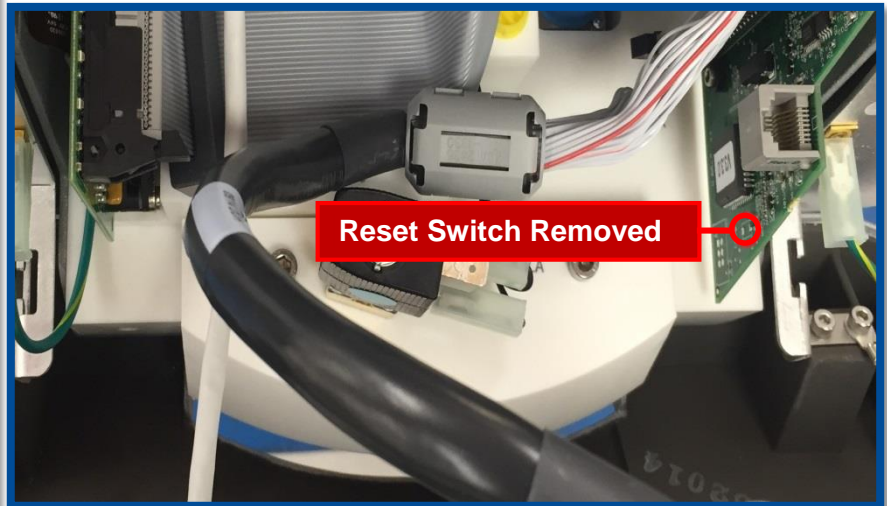


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A. To remove the reset switch from an Inspiration Ventilator follow these steps.

1. Disconnect AC power from the ventilator.
2. Disconnect the internal batteries.
3. Remove the Front Enclosure.
4. With a pair of small, needle-nosed pliers, carefully remove the power reset switch from the Powerboard.



B. Once the reset switch has been removed follow these steps.

5. Re-install the Front Enclosure.
6. Reconnect the internal batteries
7. Reconnect AC Power.
8. Turn the ventilator on. Verify that the ventilator passes the Power On Self Tests and runs normally.

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Please complete and return this page as a record to: e.fca@event-medical.com

For any questions concerning this Field Corrective Action please contact us at the address below.

Sincerely,

eVent Medical

Department of Regulatory and Quality
Email address: e.fca@event-medical.com
Fax: +1 949 900 1905

Please complete information below and on the Serial Number Listing and return to eVent Medical:

Customer / Distributor Details	
Contact Person:	Address:
Company:	City:
Title or Department:	State/Province:
Phone Number:	Postal Code:
E-Mail Address:	Country:
Total No . Affected Devices Received (see attached serial number listing):	Total No of Affected Devices Retired from Service:

Acknowledgment of Receipt /Record of Device Correction

I acknowledge receipt of the Field Corrective Action Notice

Total number of devices corrected: _____

Date: _____