

Urgent Corrective Action

Operator's Guide & Quick Reference Guide for ZOLL MRI Compatible Ventilator

MM DD, 2024

Dear Customer,

ZOLL Medical Corporation is voluntarily recalling a limited number of Operator's Guides and Quick Reference Guides related to 731 ZOLL Ventilators with MRI compatibility. This letter describes the issue and actions that must be taken to address the problem.

Through an internal review of product manuals, it was identified that documented Patient Safety Ventilator MRI information was inadvertently omitted from the manual. We are currently in the process of updating these manuals.

The impacted manual only state to place the ventilator behind the 2000 Gauss line. The updated language has been changed to:

You must place the ventilator behind the 130 Gauss field line (approximately 2 meters to the bore opening of a 3T MRI magnet).

This update to the instruction ensures safe distance from the MRI to ensure proper function of the ventilator and reduce the risk of delay in ventilator therapy.

ZOLL continues to offer and recommend the use of a 12 ft (3.7 m) patient circuits to accommodate the length required to place the ventilator at a safe distance from the MRI bore.

AFFECTED DEVICES

All Operator's Guides and Quick Reference Guides specific for use with MRI Compatible 731 ZOLL Ventilators.

- ZOLL Ventilator Operator's Guide
 - 906-0731-01-XX
 - 9650-002363-XX
 - 9650-002365-XX
- ZOLL Ventilator Quick Reference Guide
 - 907-0731-XX
 - 9650-000511-XX
 - 9652-000499-XX

REQUIRED ACTIONS

Customers who have affected manual should take the following steps:

- (1) Locate all old versions of affected Operator's Guides and/or Quick Reference Guides.
- (2) Complete and return the attached Customer Response Form via email, fax, or mail to request replacement guides.
- (3) Alert all users of the ZOLL Ventilator – with MRI Compatibility, to ensure they are aware of the safe distance requirements and are trained to these guide updates.
- (4) Dispose of obsolete guides.

We have notified the FDA and other regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding any problem during clinical use is our highest priority. Our 24/7 technical support number is +1 (866) 442-1011 or intlservice@zoll.com and are available to assist users with any aspect of this notice.

Sincerely,



Anne E. Nadeau
Manager of Post Market Surveillance