

**Urgent Corrective Action**  
**Operator's Guide & Quick Reference Guide for ZOLL MRI Compatible Ventilator**

May 22, 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 MRI Ventilator Operator's Guide**

- 906-0731-01-XX
- 9650-002360-XX
- 9650-002362-XX
- 9650-002363-XX
- 9650-002365-XX

**ZOLL MRI Ventilator Quick Reference Guide**

- 907-0731-XX
- 9650-000511-XX
- 9652-000499-XX
- 9652-000507-XX
- 9652-000511-XX

**REQUIRED ACTIONS**

Customers who have affected manual(s) 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](mailto:intlservice@zoll.com) and are available to assist users with any aspect of this notice.

Sincerely,

Anne E. Nadeau  
Manager of Post Market Surveillance



**Urgent Corrective Action**  
**Customer Response Form**  
 ZOLL MRI Compatible Ventilator  
 Operator's Guide & Quick Reference Guide

For reference, part numbers of ZOLL MRI compatible ventilators which have received affected documentation.

ITEM	GTIN	ITEM	GTIN	ITEM	GTIN
799-EGL2-02	00847946020910	799-EGL2-02-16	N/A	799-EMBP-05-16	N/A
799-EGL2-02-01	00847946023454	799-EMBP-05-01	00847946024185	799-EMBP-05-23	N/A
799-EGL2-02-04	00847946036867	799-EMBP-05-02	N/A	799-EMVP-05	00847946020767
799-EGL2-02-05	00847946036874	799-EMBP-05-08	N/A	799-EMVP-05-01	00847946023430
799-EGL2-02-08	N/A	799-EMBP-05-10	N/A	799-EMVP-05-05	00847946034351
799-EGL2-02-10	00847946036881	799-EMBP-05-11	N/A	799-EMVP-05-10	N/A
799-EGL2-02-11	N/A	799-EMBP-05-12	00847946036959	799-EMVP-05-15	00847946049850
799-EGL2-02-15	00847946050665	799-EMBP-05-12-68	N/A	799-EMVP-05-16	N/A

Please complete this form, in its entirety, and return to [intlservice@zoll.com](mailto:intlservice@zoll.com)

Customer Account Information		
<i>Customer Account Name</i>	<i>Account Number</i>	
<i>Address</i>		
<i>City / Town</i>	<i>Postal Code</i>	<i>Country</i>
Customer Contact Details		
<i>Individual completing this form (please print)</i>	<i>Title</i>	
<i>E-Mail Address</i>	<i>Phone Number</i>	
Acknowledgement of Notice		
<p><b>Please acknowledge this request by checking the applicable boxes below.</b></p> <p><input type="checkbox"/> We are aware that the ventilator must be placed behind the 130 Gauss field line (approximately 2 meters to the bore opening of a 3T MRI magnet) <b>AND</b> we confirm that all appropriate staff have been trained to these changes.</p> <p style="padding-left: 40px;"><input type="checkbox"/> We confirm we have downloaded the latest Operator's Guide.</p> <p style="padding-left: 80px;"><input type="checkbox"/> We confirm the disposal of obsolete manuals.</p> <p><input type="checkbox"/> We request _____ physical copies of the Quick Reference Guide(s) for our facility to be sent to our address (fill in below, if different than the above address):</p> <p><b>Ship To Address:</b></p>		
<p><b>If your facility has resold any MRI Compatible ZOLL Ventilators, please provide us with the necessary information below so we may send additional notices to impacted users.</b></p> <p><b>Check if not applicable:</b> <input type="checkbox"/></p> <p>Facility/Org: _____ Address: _____</p> <p>Contact Name: _____ Email: _____ Phone: _____</p>		
<p><b><u>I CONFIRM THIS RESPONSE FORM HAS BEEN READ AND UNDERSTOOD AND THAT ALL RECOMMENDED ACTIONS HAVE BEEN IMPLEMENTED AS REQUIRED.</u></b></p>		
<b>Print Name:</b> _____	<b>Sign:</b> _____	<b>Date:</b> _____

Please return to [intlservice@zoll.com](mailto:intlservice@zoll.com)