



Breathing care into all we do.

FIELD CORRECTION NOTICE

Newport e360 Software Upgrade to Version 3.8

June 15, 2009

Customer Name

Address

Address

Address

Address

Dear Valued Customer:

Newport Medical is expanding the e360 field correction software upgrade to require all e360 ventilators (not just those with software version 3.0 or higher) to be upgraded to software version 3.8.

In December 2008, Newport initiated a field correction to upgrade e360 ventilators with software versions 3.0 or higher to software version 3.3. As a result of this upgrade, some customers experienced unexpected device alert alarms. Newport's investigation into these complaints confirmed that the 3.3 software responds too quickly to certain situations, giving a false device alert. Newport conducted extensive software testing which not only confirmed the false Device Alert alarms but also identified an additional remote possibility for a valid Device Alert audible alarm to stop sounding prematurely (the LED alarm and screen message remain intact but the audible alarm clears in approximately 5 seconds). This can only happen as a result of the Control microprocessor failing which has never happened in an e360 ventilator. Newport has revised the e360 software to correct both the false Device Alert alarm and the audible alarm for the hypothesized microprocessor failure. The revised software is the 3.8 version.

As previously stated, this software upgrade is required for all e360 ventilators regardless of current software version to ensure that all Device Alert alarms function as intended. Please see the enclosed Product Bulletin for a complete description of the updated features and improvements that you will get by upgrading your ventilator to 3.8 software.

Please complete the attached form to verify that you have completed your upgrades. This will allow us to ensure that all e360 ventilators have been upgraded. Should you have any questions, please contact our Technical Support Department at 800.451.3111/+1.714.427.5811, ext.500.

Newport Medical apologizes for the inconvenience of this correction but greatly appreciates your assistance with this matter.

Thank you very much,


Vice President Regulatory Affairs/Quality



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Acknowledgement Form

I acknowledge that the e360 ventilators on the attached list have been upgraded to software version 3.8.

Attach a listing of all serial numbers upgraded.

Name (Print):

Signature:

Business Name:

Date:

PLEASE FAX THIS COMPLETED FORM TO:
Newport Medical Instruments
ATTN: Regulatory Affairs
(714)427.0489

Note: If Fax is not available, completed form can be mailed to the address below to the attention of Regulatory Affairs Department. Completed form may also be scanned and emailed to Regulatory@NewportMedical.com



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**Listing of All e360 Ventilators Sold to Your
Company**