



**URGENT: FIELD NOTIFICATION**

**December 22<sup>nd</sup>, 2010**

*BY FEDERAL EXPRESS*

Name.  
Address

**Attn: Biomedical/Clinical Engineering Departments**

**Re: Inability to retain user default settings on Rad 8 device after power cycle.**

**Reason for Advisory Notice:**

Rad-8 device has been noted to revert back to factory default settings after power cycle. Device functions as intended once user settings are configured or verified after power cycle, there is no impact to performance.

**Affected Product:**

Rad-8 devices that are used with custom configured settings.

**Impact Assessment:**

The directions for use for the Rad-8 device indicate that user settings shall be verified at each use. If the end user fails to verify user settings after a power cycle, it is possible that an end user may unintentionally monitor a patient with a Rad-8 device that has reverted back to factory default settings, which may or may not be appropriate for the patient's clinical condition.

**Action to be Taken:**

If your unit is used with custom configured settings please take one of the following two actions:

- 1) Verify functionality of your device using the instructions provided in the URL below. If your device has successfully passed all instructions your device is not affected by this notification and you may resume use.

**URL: <http://www.masimo.com/training/rad8>**

OR

Masimo Technical Services will guide you through a comprehensive screen via phone to determine whether or not your device is affected by this notice.

- 2) If your device did not pass the screening, please discontinue use of the device in use case scenarios where custom settings are required. Contact Technical Services to obtain a free software upgrade which will restore user default retention functionality of your device. This upgrade will require sending the Rad-8 device back to Masimo.



**Contact Information:**

Contact Masimo to obtain a Returned Authorization number or answer any questions or concerns you may have regarding the information above. Region specific contact information is listed below.

<b>Region</b>	<b>Address &amp; Phone Number</b>
Americas	<b>Masimo Corporation (HeadQuarters)</b> Tel: +1 (800) 326-4890 Option 2
Asia Pacific	<b>Masimo Asia Pacific</b> Tel: +65-6392-4085
Australia	<b>Masimo Australia Pty Ltd</b> Tel: 1-300-MASIMO
Austria	<b>Masimo Österreich GmbH</b> Tel: +43-1-533-73-61
Canada	<b>Masimo Canada ULC</b> Tel: 1-888-336-0043
China	<b>Masimo China</b> Tel: +86-10-5823-6155
France	<b>Masimo Europe Limited</b> Tel: +33 (0)4 72 17 93 73
Germany	<b>Masimo Europe Ltd. Niederlassung Deutschland</b> Tel: +49 89 800 65 899-0
International Headquarters	<b>Masimo International Sàrl</b> Tel: +41 32 720 11 55 (Tech Services) techserviceeu@masimo.com
Italy	<b>Masimo Italy</b> Tel: +39 02 450 76 308
Japan	<b>Masimo Japan</b> Tel: +(81) 3-3868-5201
Latin America	<b>Masimo Latin America</b> Email: <a href="mailto:info-latam@masimo.com">info-latam@masimo.com</a>
Middle East	<b>Masimo Middle East</b> Tel.: +962 6 4886641
Netherlands	<b>Masimo Nederland</b> Tel: +31 135 832 479
Rest of Europe	<b>Masimo International Sàrl</b> Tel: +41 32 720 11 55 (Tech Services) techserviceeu@masimo.com
Spain	<b>Masimo Europe - España</b> Tel: +34 91 8049734
Switzerland	<b>Masimo International Sàrl</b> Tel: +41 32 720 11 66
UK	<b>Masimo UK</b> Tel: +44 (0)1256 479988



Please be assured that Masimo Corporation is committed to consistently providing high quality products and services to our customers. We apologize for any inconvenience this issue may cause you and would like to thank you in advance for your patience and cooperation while we actively work to remedy the issue presented above.

Sincerely,

A handwritten signature in blue ink that reads "Tony Roberts".

Tony Roberts  
Vice President of Quality Assurance  
40 Parker  
Irvine, CA 92618 USA