MASIMO CORPORATION
Forty Parker
Irvine, CA 92618

URGENT: MEDICAL DEVICE CORRECTION AND REMOVAL

March 8, 2013

Customer Name
Address

City, ST ZIP
Customer ID

Re: Rad-8 Pulse Oximeter Medical Device Correction and Removal

Products Affected:
This medical device correction and removal notice applies to Masimo Rad-8 pulse oximeters manufactured from March 27, 2009 to January 24, 2013.

Our records show that you have XXX Rad-8 device(s) subject to this correction and removal. Attachment 1 lists the serial numbers of the Rad-8 device(s) that our records show were shipped to you and that are subject to this correction and removal.

Reason for Correction and Removal:
Masimo has identified a very small number of Rad-8 devices that, when moved, can power off without the operator pressing the power button. If a change in power status goes unnoticed by the caretaker, a delay of care could result.

No Impact on Other Products:
Please note that no other Masimo products are affected by this correction and removal.

Instructions:

1. Please promptly remove all Rad-8 device(s) from use and your inventory and segregate these devices.
2. Please call 1-800-326-4890 and select option 2 for Technical Services. Determine with Technical Services whether you will return the affected device(s) to Masimo for repair or if eligible, receive a repair kit. If you will return the device(s) for repair, obtain a Return Material Authorization Number (RMA number).
3. Complete the Tracking/Verification Form in Attachment 2 and fax it to Masimo at 1-949-297-7700, even if you do not have or intend to use the affected device(s).
4. If you are eligible and intend to repair units onsite fax the completed original form in Attachment 2 to Masimo at 1-949-297-7700.
5. If you have elected to return the affected device(s), and have an RMA number include the completed original Form in Attachment 2 with the returned device(s) and indicate the RMA number on the outside of the return-shipping box.

If Unable to Promptly Comply with the Instructions:

Masimo urges you to promptly follow the instructions above. If you are unable to promptly comply with the instructions and must continue to use the affected device(s), then please check to verify that there is no unintended change in power status whenever an affected device is moved.

We apologize for the inconvenience. Please be assured that Masimo is committed to consistently providing high quality products and services to you, our customers. We thank you for your patience and cooperation while we actively work to resolve this issue.

Please contact Masimo Technical Services with any questions or assistance you may need regarding this notice.

Sincerely yours,

Mathew Jimenez
VP Quality Compliance

ATTACHMENT 1

LIST OF RAD-8 DEVICE(S) SUBJECT TO MEDICAL DEVICE CORRECTION AND REMOVAL

Our records indicate the following Rad-8 device(s) were shipped to you.

ATTACHMENT 2
Tracking/Verification Form

Please follow the instructions below EVEN IF YOU DO NOT HAVE OR INTEND TO USE AFFECTED PRODUCTS, AND EVEN IF YOU ELECT TO PERFORM THE REPAIR, WHERE PERMITTED:

1. Please promptly remove all Rad-8 device(s) from use and your inventory and segregate these devices.

2. Please call 1-800-326-4890 and select option 2 for Technical Services. Determine with Technical Services whether you will return the affected device(s) to Masimo for repair or if eligible, receive a repair kit. If you will return the device(s) for repair, obtain a Return Material Authorization Number (RMA number).

3. Complete the Tracking/Verification Form below and fax it to Masimo at 1-949-297-7700, even if you do not have or intend to use the affected device(s).

    a. Draw a line through the barcode(s) for the serial numbers of the devices you no longer have prior to faxing the form to Masimo at 1-949-297-7700.

4. If you are eligible and intend to repair units onsite, fax a copy of the completed form below to Masimo at 1-949-297-7700.

    a. Draw a line through the barcode(s) for the serial numbers of the devices you no longer have prior to faxing the form to Masimo at 1-949-297-7700.

5. If you have elected to return the affected device(s) and have an RMA number, include the completed original of this form with the returned device(s) and indicate the RMA number on the outside of the return-shipping box.

    a. Draw a line through the barcode(s) for the serial numbers of the devices you no longer have on the original form and place it into the box with the returned devices.

    b. If you are returning the product to Masimo, package any Rad-8 device(s) that are being returned in an appropriate shipping box. Place the signed original copy of this form in the box, appropriately seal the box, and send it **as soon as possible** to:

        Masimo Corporation
        40 Parker
        Irvine, CA 92618
        RMA: _____

Customer Name:		
Address:		
City:	**State:**	**Zip Code:**
Country:		

1. Acknowledgment. I acknowledge receipt of Masimo's Rad-8 Medical Device Correction and Removal notice dated March 8, 2013, and will follow the instructions provided below.

2. Verification. I have verified that all areas where product could be located have been checked.

3. Select all applicable statements:

_____ We no longer have any of the affected Rad-8 device(s).

_____ We are returning the Rad-8 device(s) to Masimo for repair and have lined out the barcodes for the serial numbers for any devices that don't apply.

_____ We have been identified as eligible to perform the Rad-8 device(s) repair onsite and have lined out the barcodes for the serial numbers for any devices that don't apply.

Complete page 2 of 2 of Attachment 2 with returned device information or information on the units to be repaired onsite.

ATTACHMENT 2
Tracking/Verification Form

Serial Numbers of Rad-8 Pulse Oximeter(s) that are being returned or will be repaired onsite.

RMA Number:	**Product Return Date:**
Authorized Signature:	
Name:	**Title:**
Date:	**Telephone Number: ( ) Ext**

Please fax completed form to Masimo at 1 (949) 297-7700 by **April 15, 2013** and place the original form in the box with any returned products.