MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

<u>**URGENT: PRODUCT RECALL**</u>

Date

CUSTOMER
ADD1
ADD2
CITY
ST   ZIP   COUNTRY
Customer ID: CID

Re: rainbow® Reusable Sensors (for rainbow SET® Devices with SpCO®, SpO2, and SpMet®)

<u>Products Affected</u>:
This notice applies to Masimo rainbow sensors with the specific reference numbers and LOT numbers shown in the table below**.** Our records indicate that you have one or more such rainbow sensors.

Date Shipped	Box Ref#	Box LOT#	Sensor Ref#-LOT#	Description	Qty Shipped
SHIPPED_DATE	PART_ID	LOT_ID	5 Digit - Lot	SO_DESC	QTY

<u>Reason for the Recall:</u>
Masimo has identified specific LOTs of sensors that were manufactured with incompatible configurations. This could result in sensors that will either not provide readings for the SpCO and SpMet parameters or inaccurate readings. The specific behavior will depend on the firmware version of the technology board in the device.

SpCO measurements, when displayed, could be incorrectly elevated throughout the measurement range.

SpMet measurements above 6% could be affected by a negative bias of 1.5%, on average.

<u>No Impact on Other Products</u>:
Please note that this recall only applies to the rainbow sensors in the table above. No other Masimo products are subject to this recall.

<u>Instructions</u>:
1. Please promptly remove and segregate all rainbow sensors with the part numbers listed above from use and from inventory.
2. Please assess your inventory of rainbow sensors to determine if they are subject to this recall.
3. Please call 1-800-326-4890 and select option 2 for Technical Services. Determine with Technical Services whether you will be returning affected sensors for replacement. If you are returning affected sensors, obtain a return authorization number (RMA). For locations outside the US, local contact information may be found at http://Service.Masimo.com.
4. Complete the tracking/verification form in Attachment 1 and email to Masimo as instructed.
5. If you are returning affected sensor and have an RMA number, please indicate the RMA number on the outside of the return shipping box.

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Visual Reference

Refer to the image at right for the location of the **Reference Number** and **LOT Number** for the sensor. Both are located on the **DO NOT DISCARD** label.

Refer to the image below for the location of the **REF Number** and **LOT Number** for the packaged product. Both are located on the product label.


If Unable to Promptly Comply with the Instructions:

Masimo urges you to promptly follow the instructions above. If you are not able to comply with the instructions and assess your inventory of sensors, please remove all rainbow sensors with the part numbers listed above from use until you can confirm whether they are subject to this recall.

We apologize for any inconvenience this issue may cause. 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 product recall. Local contact information may be found at http://Service.Masimo.com.

Sincerely,
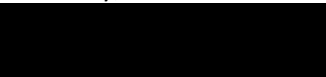
Mathew Jimenez
Sr. VP Quality
mjimenez@masimo.com

ATTACHMENT 1

Please enter date:

CUSTOMER
ADD1
ADD2
CITY
ST   ZIP   COUNTRY
Customer ID: CID

Re: rainbow® Reusable Sensors (for rainbow SET® Devices with SpCO®, SpO2, and SpMet®)

Please follow the instructions below EVEN IF YOU DO NOT HAVE OR INTEND TO USE AFFECTED PRODUCTS.

Step 1: Please acknowledge receipt of Masimo's rainbow® Reusable Sensors Product Recall Notice by November 13, 2015 by following the instructions provided below.

Step 2: Promptly remove all affected product from use and your inventory and segregate these sensors.

Step 3: Please complete the table below. Indicate the quantity of sensors located by LOT Number Record in the far right column. If no sensor(s) are located for any or all LOT numbers, enter a 0 (zero) for that LOT Number in the "QTY Located" box.

Date Shipped	Box Ref#	Box LOT#	Sensor Ref#-LOT#	Description	Qty Shipped	Qty Located
SHIPPED_ DATE	PART _ID	LOT_I D	5 Digit - Lot	SO_DESC	QTY	

Step 4: Send the completed Attachment 1 (this page) by electronic mail (email) to recall@Masimo.com. If unable to send by email, contact your local Masimo Technical Service location. Local contact information may be found at http://Service.Masimo.com.

Masimo will promptly respond with directions for sensor replacement to the contact information you provide below.

Authorized Signature & Date:		
Name:		
Email Address:		
Company:		
Ship-to Address:		
City:	State:	Postal Code:
Country:		