

#### **URGENT: ADVISORY NOTICE**

#### January 12, 2015

Customer Name Address City, ST ZIP

#### **Customer ID:**

Re: uSpO<sub>2</sub> and HPLP Pulse Oximetry Cable Advisory Notice

#### **Products Affected:**

This advisory notice applies to Masimo's uSpO<sub>2</sub> and HPLP Oximetry Cables.

Our records indicate you have XXX of part number(s) XXXX, which are subject to this advisory notice. Attachment 1 lists the serial and/or lot numbers of cable(s) subject to this advisory notice that our records show were shipped to you.

#### **Reason for the Advisory Notice:**

Masimo has identified a small number of Oximetry Cables with crossed-internal wires. The effect on performance when these wires are crossed is that when a low SpO<sub>2</sub> value is measured, a high SpO<sub>2</sub> value would be displayed on the monitoring device. Additionally, in the same Oximetry Cable, when a high SpO<sub>2</sub> value is measured, a low SpO<sub>2</sub> value would be displayed on the monitoring device.

Identification of an Oximetry Cable with crossed wires is straightforward using either of the methods described in the Instructions below. If an Oximetry Cable with crossed wires is used to monitor an individual with a SpO<sub>2</sub> value above 90%, the displayed value on the monitor would be <u>54% or below</u>.

#### **No Impact on Other Products:**

Please note that no other Masimo products are affected by this advisory notice.

#### **Instructions:**

Please promptly evaluate your inventory of Oximetry Cables using one of the methods described below:

1. Method 1: Perform functional test using a SpO<sub>2</sub> simulator:

Utilizing one of the  $SpO_2$  simulators listed below set the  $SpO_2$  value at 98% with the Oximetry Cable attached. If the  $SpO_2$  measurement is in the 50% range, the product is affected. If the device is unaffected, the measurement will be within  $\pm -2\%$ .

 Please complete and return Attachment 2, Tracking/Verification Form, to Masimo in order to document that the Oximetry Cables is functioning as intended.

If your assessment identified that the Oximetry Cable is affected, remove from service, segregate, and return to Masimo.

- In the United States, please call 1-800-326-4890 and select option 2 for Technical Services to return the Oximetry Cable for replacement. A Return Material Authorization Number (RMA number) will be provided.
  - If you are outside the United States, local contact information can be found at <a href="http://service.masimo.com">http://service.masimo.com</a>.

Manufacturer	Requirements	Contact Information
Pronk Technologies	OX-1 OxSim® SpO2 Simulator	(818) 768-5600
Fluke Biomedical	Index 2 XLFE SpO2 Simulator	(440) 498-2586



#### 2. Method 2: Perform functional test:

Use the Oximetry Cable to take a  $SpO_2$  measurement on a healthy individual with a confirmed  $SpO_2$  value above 90% or review  $SpO_2$  measurements taken with the Oximetry Cable and verify that measurement results were consistent with expected  $SpO_2$  values. If the  $SpO_2$  measurement(s) is consistent with the expected  $SpO_2$  value, the Oximetry Cable is not affected and can continue to be used.

 Please complete and return Attachment 2, Tracking/Verification Form, to Masimo in order to document that the Oximetry Cable(s) is functioning as intended.

If your assessment results in a SpO<sub>2</sub> measurement that is not consistent with the expected SpO<sub>2</sub> value, then the Oximetry Cable should be removed from service, segregated and returned to Masimo.

- In the United States, please call 1-800-326-4890 and select option 2 for Technical Services to return the Oximetry Cable for replacement. A Return Material Authorization Number (RMA number) will be provided.
  - If you are outside the United States, local contact information can be found at <a href="http://service.masimo.com">http://service.masimo.com</a>.
- Please complete and return Attachment 2, Tracking/Verification Form

Fax the complete Attachment 2, Tracking/Verification Form, to Masimo at 1-949-297-7700, even if you do not have or intend to use the identified Oximetry Cable(s).

If you are returning an Oximetry Cable(s), and have an RMA number, include a completed <u>Attachment 2</u> in the box with the returned cable(s) and write the RMA number on the outside of the 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, then please remove the Oximetry Cable(s) from service until you can perform the quick evaluation.

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 advisory notice.

Sincerely yours,

Mathew Jimenez

VP Quality Compliance



### ATTACHMENT 1

## LIST OF OXIMETRY CABLE(S) SUBJECT TO THE ADVISORY NOTICE

Our records indicate Oximetry Cable(s) with the following serial and/or lot number(s) were shipped to you.



**Customer ID:** 

Firm Name:

Name:

**Authorized Signature:** 

# ATTACHMENT 2 Tracking/Verification Form

Please complete this form, Attachment 2, Tracking/Verification Form, EVEN IF YOU DO NOT HAVE OR DO NOT INTEND TO USE AFFECTED PRODUCTS.

- 1. Please promptly evaluate your inventory in accordance with the instructions detailed on the advisory notice.
- 2. If any Oximetry Cable is to be returned based on your assessment as defined in the instructions, determine with Masimo Technical Services whether you will return the affected Oximetry Cables to Masimo for replacement. If you return the Oximetry Cable, obtain a Return Material Authorization Number (RMA number).
- 3. Complete this form, Attachment 2, Tracking/Verification Form, and fax it to Masimo at 1-949-297-7700, even if you do not have or intend to use the affected Oximetry Cable(s).
  - a. Draw a line through the lot and/or serial numbers of the Oximetry Cable(s) you no longer have prior to faxing the form to Masimo at 1-949-297-7700.
- 4. If you have elected to return the affected Oximetry Cables and have an RMA number, include the completed original of this form, Attachment 2, with the returned Oximetry Cables and indicate the RMA number on the outside of the return-shipping box.
  - a. If in the United States, 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

If outside the United States, local contact information can be found at <a href="http://service.masimo.com">http://service.masimo.com</a>

Pie	ase cneck ALL appropriate boxes:		
	<b>Acknowledgment.</b> I have read and understand the instructions provided in the advisory notice. <b>Verification</b> . I have verified that all areas where product could be located have been checked.		
	<b>Disposition:</b> Select all applicable statements: We no longer have any of the affected Oximetry Cable(s).		
	We are returning the Oximetry Cable(s) to Masimo for replacement. We have lined out the lot numbers and/or serial numbers for any Oximetry Cable(s) that don't apply on Attachment 1 and have included the completed Attachment 1 form, and completed Attachment 2 form, with the product. Specify quantity to be returned:		
	We have verified that Oximetry Cable(s) in our inventory function as intended and therefore do not need to be returned. We have lined out the lot numbers and/or serial numbers for Oximetry Cable(s) that don't apply.		
	We have identified and notified our customers that were shipped or may have been shipped these Oximetry Cable(s). Attached is a list of customers who received or may have received the Oximetry Cable(s).		
RMA Number: Product Return Date:			

Title:

Address:

**Telephone Number: (** 

Please fax completed form to Masimo at 1 (949) 297-7700 by <u>01/12/2015</u> and place the original form in the box with any returned products.