



URGENT: ADVISORY NOTICE

January 12, 2015

Customer Name
 Address
 City, ST ZIP

Customer ID:

Re: uSpO₂ and HPLP Pulse Oximetry Cable Advisory Notice

Products Affected:

This advisory notice applies to Masimo’s uSpO₂ 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 SpO₂ value is measured, a high SpO₂ value would be displayed on the monitoring device. Additionally, in the same Oximetry Cable, when a high SpO₂ value is measured, a low SpO₂ 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 SpO₂ value above 90%, the displayed value on the monitor would be **54% or below**.

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:

- Method 1: Perform functional test using a SpO₂ simulator:

Utilizing one of the SpO₂ simulators listed below set the SpO₂ value at 98% with the Oximetry Cable attached. If the SpO₂ measurement is in the 50% range, the product is affected. If the device is unaffected, the measurement will be within +/- 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 <http://service.masimo.com>.

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

- Please complete and return Attachment 2, Tracking/Verification Form

2. Method 2: Perform functional test:

Use the Oximetry Cable to take a SpO₂ measurement on a healthy individual with a confirmed SpO₂ value above 90% or review SpO₂ measurements taken with the Oximetry Cable and verify that measurement results were consistent with expected SpO₂ values. If the SpO₂ measurement(s) is consistent with the expected SpO₂ 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 SpO₂ measurement that is not consistent with the expected SpO₂ 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 <http://service.masimo.com>.
- 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 Attachment 2 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



MASIMO CORPORATION
Forty Parker
Irvine, CA 92618

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.

