URGENT: Field Safety Notice

OxiMax™ N-65 Handheld Pulse Oximeter
OxiMax™ N-560 Pulse Oximeter

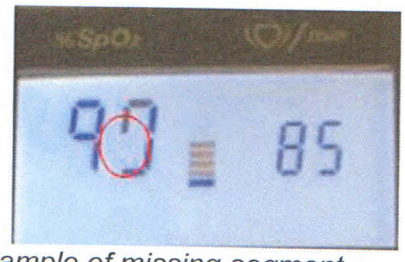
18th May 2015

FSCA Reference: Oximeter 05/15

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien, now a part of Medtronic, is issuing a Field Safety Corrective Action (FSCA) for all OxiMax™ N-65 Handheld Pulse Oximeters (Product code: N65, N65-1, N65P & N65P-1) and OxiMax™ N-560 Pulse Oximeters (Product code: N560) related to an issue identified from customer complaints. If you have any OxiMax™ N-65 Handheld Pulse Oximeters or OxiMax™ N-560 Pulse Oximeters at your facility, please read this notice carefully.

The issue is related to the oximeters not fully displaying segments of data (see example below), which may result in misinterpretation of the data being displayed.



Example of missing segment

Covidien has had no reports of serious patient injury or death associated with this issue.

Actions to be taken by the customer/user

The purpose of this communication is to remind you of the importance of conducting the automated Power-On-Self-Test (POST) prior to patient use, as described in the N65 & N560 Operator's Manual and Home-Use guide. If you observe during POST or during device use, any missing display segment or if the speaker does not sound, discontinue use and contact our Service Department as explained below.

The N-65 Operator's Manual and Home Use Guide, and the N-560 Operator's Manual may be obtained from your local Covidien representative.

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This notification is being issued with the knowledge of the MHRA. Please communicate this important information within your facility as required.

If your facility has distributed the OxiMax™ N-65 Handheld Pulse Oximeters and/or the OxiMax™ N-560 Pulse Oximeters to other persons or facilities, please promptly forward a copy of this letter to those recipients. Please maintain awareness on this notice for an appropriate time period to ensure effectiveness of this information.

Should you have any questions regarding this letter or to report any issues with the OxiMax™ N-65 Handheld Pulse Oximeters and OxiMax™ N-560 Pulse Oximeters contact your local Covidien representative, to ensure proper device reporting procedures are followed.

Sincerely,

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Amanda Woolven
Regulatory Affairs Specialist

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