



Product Flash

NEWS FROM MASIMO MARKETING

Field Action: MightySat® Medical Pulse Oximeter

Description

Masimo identified MightySat Medical devices (PN: 5356) with SpO2 measurement potentially falling outside the performance specification.

Masimo has informed all consignee who received the affected MightySat Medical Pulse Oximeters which are subject to the removal. The Urgent Product Recall Notice sent provides instructions on the actions to be taken by the customers to address the issue.

This recall affects 59 devices that were only distributed in the US. Rest assured; we have corrected this problem.

There is no impact to any other Masimo products.

Masimo is committed to consistently providing high quality products and services to you, our customers. We apologize for any inconvenience this issue may have caused.

Part Number	Description
5356	MightySat Medical

Inquiries

For questions or additional information on Masimo MightySat contact [Technical Services](#). To order the replacement product, contact [Customer Service](#).

Any adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax.

