Quality Assurance (QA) for Health Products

QA Notice

IN Nº 2024-01 Version 1 – 02 May 2024	Communication related to the recall initiated by Masimo Corporation (USA) on certain Masimo Rad-G® Pulse Oximeter devices.

Addressees

- Through Health Product Management (HPM) specialists, all Principal Recipients (PR) reporting procurement of the impacted product financed by the Global Fund.
- Any procurer, buyer reporting procurement of the impacted product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Notice to share information on a recall related to certain Masimo Rad-G® Pulse Oximeter devices distributed worldwide by the manufacturer Masimo Corporation (USA).

Identification of the product(s) and manufacturer

Name of Manufacturer(s)	Masimo Corporation 52 Discovery Irvine CA 92618-3105 United States of America
Commercial / Brand Name(s)	Masimo Rad-G® Pulse Oximeter
Formulation	Not applicable
Reference Number (REF) and Unique Device Identifier (UDI)	- Masimo Rad-G® Pulse Oximeter with temperature (W/Sensor), REF: 9210, UDI: (01)00843997008013 - Masimo Rad-G® Pulse Oximeter (W/Patient Cable), REF: 9895, UDI: (01)00843997013789 - Masimo Rad-G® Pulse Oximeter (W/Patient Cable), REF: 9849, UDI: (01)00843997000666 - Masimo Rad-G® Pulse Oximeter (W/Sensor), REF: 9847, UDI: (01)00843997013284
Serial number(s)	Multiple
Manufacturing / Release Date	Between June 2022 and December 2022

Background

On 15 April 2024 the Global Fund Quality Assurance and Compliance Team received information on an urgent recall initiated by Masimo Corporation related to certain Rad-G® Pulse Oximeter devices.

Nature of defect(s)

Details of defect or problem	Masimo Corporation (USA) identified certain of its Rad-G® Pulse Oximeter devices powering off and on without pressing the power button. Masimo Corporation's investigation identified an issue that can result in an unintentional change in the power state. If the device powers off unexpectedly, it could result in a loss of patient monitoring and consequentially delayed patient care.
Is there any evidence or suspicion of a risk to user/ patient?	Yes, if the device powers off unexpectedly, it could result in a loss of monitoring, which could potentially result in a delay in patient care.
Extent of the problem (e.g. No. of batches).	Please refer to Masimo Corporation notice (https://professional.masimo.ca/globalassets/assets/pdf/_resources/plf-1484a-product-flash-product-recall-for-select-rad-g-and-rad-g-temperature-devices-global_final_for-web.pdf), and the U.S. FDA Medical Device Recalls Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=94170) for a list of the serial numbers of the Masimo Rad-G® Pulse Oximeter devices subject to this Quality Notice.
Extent of distribution of the product / batch (es).	Worldwide
Number of patients potentially impacted	Not identified

Action/Investigations to be taken

Addressees are advised to identify and promptly remove impacted Masimo Rad-G® Pulse Oximeter devices from use and contact the Technical Services of Masimo Corporation (https://professional.masimo.com/company/global-services/technical-services/).

Users and/or Patients

Patients and/or users who have experienced any adverse reaction or quality problems with the use of the impacted product may report this to the relevant National Regulatory Authorities, manufacturer and the Global Fund Health Product Management Specialist.

Transmission of QA Notice

This QA Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially affected products have been transferred.

Please maintain awareness of this QA Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contacts

This QA Notice does not require a specific written response from PRs and procurers to the Global Fund.

PRs and procurers should copy the Global Fund's Health Products Management Specialist on correspondences regarding the matter for follow-up.

Please direct the respective answers and any questions about this matter to the technical contact listed below.

Organization	**Name / Function**	**E-mail address**
Global Fund	Your respective HPM specialist for the portfolio	
Global Fund	Xiao Xiao, Specialist, MDs & PPEs Quality Assurance Specialist	xiaoxiao.ding@theglobalfund.org