# Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

Circular No.

29 -07-1446 H

21/2025

روية **عثمان** 2040 مسلس

**29** -01-2025

Field Safety Corrective Action of Multi Sentry 125 Uninterruptible Power Supply used with with certain Philips CT system models from Philips Healthcare (Suzhou) Co., Ltd.

SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/264		
Multi Sentry 125 Uninterruptible Power Supply used with with certain Philips CT system models.		
Philips Healthcare (Suzhou) Co., Ltd.		
Mustafa Sultan Science & Industry Co.LLC.		
Impacted Philips MR Systems Ref, Model (Serial Number(s)): 728143, Incisive CT (500619,500616,500559,500546,510004,500545) 728144, Incisive CT (500519,550024,550184,34114,34115,34113,34138,34172,552066,550341,34439, 34455,550509,550598,550327,550245,550339,550342,550340,550032,34173, 552037,550228) Please refer to the attachment for the image of Multi Sentry 125 Uninterruptible Power Supply (Riello MST 125kVA UPS).		
There is a potential for the UPS capacitor to fail which may lead to overheating and that it is necessary to replace the capacitor.		
<ol> <li>It will be scheduled by Philips a time for a Field Service Engineer (FSE) and a Riello to replace the affected products.</li> <li>Contact the local agent for remedial action.</li> </ol>		
Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:vigilance-md@moh.gov.om">vigilance-md@moh.gov.om</a>		

Dr. Mohammed Hamdan Al Rubaie Director General







Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمـان وزارة الصحـة مركز سلامة الـدواء مسقط



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

**Director General of Royal Hospital** 

**Director General of Khoula Hospital** 

**Director General of Medical Supplies (MOH)** 

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

#### After Compliments,

Please find attached our Circular No <u>21/2025</u> dated <u>29/11/2025</u> Regarding SFDA Field Safety Corrective Action of Multi Sentry 125 Uninterruptible Power Supply used with with certain Philips CT system models from (mfr: Philips Healthcare (Suzhou) Co., Ltd).

### Copy to:

- · Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information





### Riello UPS Product Recall Notification Letter

Multi Sentry 125 Uninterruptible Power Supply

3-Jan-2025

RE: Riello UPS Recall for specific Multi Sentry 125 Uninterruptible Power Supply units

Dear Customer,

Philips received the attached Riello UPS product recall letter (see Appendix A) regarding specific Riello Multi Sentry 125 Uninterruptible Power Supply (UPS) that Philips supplied to you, as a distributor, in combination with certain Philips CT system models (see Figure 1). According to the attached letter, there is a potential for the UPS capacitor to fail which may lead to overheating and that it is necessary to replace the capacitor.

Figure 1. Impacted Philips MR Systems and UPS Product image

Ref	Model	Serial Number(s)	3 <sup>rd</sup> Party Pro	duct Image
728143	Incisive CT	500619,500616,500559 500546,510004,500545	Multi Sentry	
728144	Incisive CT	500519,550024,550184 34114,34115,34113 34138,34172,552066 550341,34439,34455 550509,550598,550327 550245,550339,550342 550340,550032,34173 552037,550228	Uninterruptible Power Supply (Riello MST 125kVA UPS)	

Philips, as the distributor of the Riello product, intends to ensure that all its impacted customers receive the attached product recall letter to support deployment of the manufactures field corrective action.

We kindly ask you to sign and return the following Response Form to acknowledge receipt and understanding of the Product Recall Notification Letter in Appendix A to met.quality@philips.com.

Together with the manufacturer, Riello UPS, Philips will schedule a time for a Field Service Engineer (FSE) and a Riello representative to replace the affected products. (ref FCO72800831)

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative. met.quality@philips.com

Sincerely,

Li Xin Quality Leader Philips Precision Diagnostics (PD) China

### **PHILIPS**

## **Riello UPS Product Recall Notification Letter Response Form**

**Reference:** Riello UPS Recall for specific Multi Sentry 125 Uninterruptible Power Supply units (ref FCO72800831)

**Instructions:** Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Product Recall Notification Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:	
Street Address:	
City/State/ZIP/Country:	The state of the s
	,
	The state of the s
Customer Actions:  • Complete response form	
	anding of the accompanying Product Recall Notification Letter this Letter has been properly distributed to all users.
Name of person completing this form	:
Signature:	
Printed Name:	
Title:	
Telephone Number:	
Email Address:	
Date (DD / MMM / YYYY):	

Please complete and return the attached acknowledgment form to Philips MR via email to: met.quality@philips.com



# **Product Recall Notification Letter**

Date: November 6, 2024

#### Dear Philips Healthcare,

Riello UPS has identified an issue with a specific group of Multi Sentry 125 Uninterruptible Power Supply (Riello MST 125kVA UPS) which you may have purchased and/or sold. The issue is specifically relevant to the capacitors used in the UPS. This notification is in line with our commitment to safety, transparency, and customer satisfaction.

The affected product details are as follows:

- Product Name: Multi Sentry 125 Uninterruptible Power Supply
- · Model Number: Riello MST 125kVA UPS
- · UPS serial number and capacitor batch number are provided in separated document

Riello has been informed of an event in which a Multi Sentry 125 Uninterruptible Power Supply (Riello MST 125kVA UPS), overheated and produced smoke. Our investigation has identified that a capacitor failure is what led to the overheating.

We apologize for any inconvenience and will work with you and your customers to schedule a time to replace the capacitor at no cost. Please contact to answer any questions.

Thank you for your understanding and cooperation in this matter. We regret this situation and assure you that we are undertaking measured steps to prevent its recurrence.

Best Regards,

Stefano Sinigallia Global Key Account



RPS S.p.A. Riello Power Solutions

