

URGENT Field Safety Notice

Patient Information Center (PIC) iX Uninterruptable Power Supply (UPS) Failures

<Date of letter deployment,> <date format: DD-MMM-YYYY, e.g. 02-JAN-2021>

<To: Name / Title / Customer Name

Street Address

City, State, Zip Code

<modify title block format as needed>

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of the possible failure of Uninterruptable Power Supply (UPS) devices supporting the Patient Information Center (PIC) iX system. This notification is intended to inform you about:

1. The problem and under what circumstances it can occur

The UPS devices are backup batteries utilized by PIC iX central monitoring stations and their associated hardware components. These devices are intended to provide power to the PIC iX system or components (monitors, networking devices, servers, etc.) in the event of power outages ensuring that the PIC iX system remains functional during power fluctuations.

It has been discovered that an internal component of the UPS devices produces less output energy than specified, resulting in the UPS' inability to power up as required, which affects the power supply to PIC iX system. These failures can occur during a power outage or when the UPS is only acting as a conduit for the sites main line power to the PIC iX system.

2. Hazard/harm associated with the issue

If UPS devices fail during clinical use, there is the potential for the associated PIC iX system to shut down due to the lack of power. This may lead to the delay in the detection of a change in a patient condition. Although unlikely, this could potentially result in patient harm.

3. Affected products and how to identify them

#	Product Name	Model
1	APC (Schneider Electric IT Corporation) 120V Uninterruptable Power Supply	SCL500RM1U (only serial number date codes prior to 2237*)
2	APC (Schneider Electric IT Corporation) 230V Uninterruptable Power Supply	SCL500RMI1U (only serial number date codes prior to 2241*)

* Affected APC UPS units were manufactured during a specific time frame. For ease in determining a unit status, individual unit serial numbers contain a number sequence to identify the year and week (YYWW) of manufacture. Using the example from Image 1 below, the unit serial number is 5S2104008943, meaning it was manufactured during week 04 of the year 2021. The serial number format is 5SYYWW123456.

Image 1:

Manufacturer Part Number is SCL500RM1U, with Serial Number 5S2104008943 on the UPS device.
Week 04 of 2021



4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

If your UPS fails:

- 1) Promptly take the UPS offline and plug any devices that had been attached to it into a different appropriate power source.

Note: It is recommended that UPS devices intended for operation in network and server rooms be kept in a temperature and humidity controlled environment, ensuring adequate airflow around the UPS to prevent UPS device failure.

This notice should be passed on to all those who need to be aware within your organization or to any organization where affected devices have been transferred.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will replace the malfunctioning UPS.

If you need any further information, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*



Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

URGENT Field Safety Notice Response Form

Reference: CR # 2024-CC-HPM-010, PIC iX Uninterruptable Power Supply (UPS) Failures

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt by email: recall.response@philips.com. Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

If your UPS fails:

- 2) Promptly take the UPS offline and plug any devices that had been attached to it into a different appropriate power source.

Note: It is recommended that UPS devices intended for operation in network and server rooms be kept in a temperature and humidity controlled environment, ensuring adequate airflow around the UPS to prevent UPS device failure.

- Review the contents of this letter with your staff.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle affected devices.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____