

FIELD SAFETY NOTICE

Replacement of Batteries for Orchestra and Pilot ranges

Date: 16. October 2024

Subject: Field Safety Notice regarding Replacement of Batteries for Orchestra and Pilot ranges

Affected Product Code:

Product	Product Code	Start of Delivery
PowerSonic Battery	Z174025	April 2023
Yuasa Battery	Z174031	March 2024

Dear Customer / Health Care Professional,

Fresenius Kabi has investigated for the product ranges Pilot and Orchestra, that the batteries with article-codes Z174025 (PowerSonic) and Z174031 (Yuasa), which replaced the original batteries during preventive maintenance since April 2023 have shorter battery-lifetimes than specified.

These batteries do not comply with the specified lifetime of 3 years. In fact, the batteries must be replaced according to the following periodicity:

Product	Product Code	Replacement
PowerSonic Battery	Z174025	Every two years
Yuasa	Z174031	Every year

Not replacing these batteries in due time could potentially result in battery autonomy inferior to 1h30, time between battery pre-alarm and out-of-battery alarm inferior to 30 minutes and switch-off after out-of-battery alarm inferior to three minutes.

To address this technical issue in the field, you will need to verify the battery used by your Orchestra or Pilot devices and replace them in due time.

Fresenius Kabi has not received any reports of patient harm related to this issue.

Kindly assure within your organization that all relevant persons are informed about this letter and the actions as described.

**PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM"
AND SEND IT BACK TO US IMMEDIATELY.**

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Fresenius Kabi is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience.

If you have any further questions concerning this FSN, please contact your Sales representative or our Quality department.

Sincerely,

FIELD SAFETY NOTICE**Replacement Batteries for Orchestra and Pilot ranges****SECTION A: Hospital / Facility Details**

Please fill out the information below and send the completed form to Fresenius Kabi.

Name of Hospital / Facility:		
Hospital / Facility Address:		
Telephone Number:		

SECTION b

I have read and understand the information provided in the letter.

Signature:	
Date:	