Docusign Envelope ID: B1D95D32-C990-8D4D-83DD-EC90BB73F2A1

Rev.01

URGENT FIELD SAFETY NOTICE

Commercial name of the affected product:	P/N: EP59-49750 Slimline Lithium Battery (Rev. A)
Part number(s):	

Part Number	Product Description
1204-P-3065	Vantage+ Bulb/Slimline Kit A
1204-P-3067	Vantage+ Bulb/Slimline & Charger
1204-P-3068	Vantage+ BLB Student Kit-Wireless2
1205-P-1014	Vantage+ LED Wireless2 In Carton
1205-P-1016	Vantage+ LED/Slimline Kit A
1205-P-1020	Vantage+ LED/Slimline & Charger
1205-P-1022	Vantage+ LED Student Kit Wireless2
1205-P-2000	API2 LED Wireless Slimline + Charger
1205-P-2003	API2 Wireless Slimline No Charger
1205-P-2007	LED Slimline Student Kit
1205-P-2030	LIO 532 Kit
1205-P-2040	LIO 577 Kit
1205-P-5010	Vantage+ Digital Kit

MHRA FSCA Identifier:	2026/008/017/601/056
Quality Management System (QMS) CAPA	CAPA-000021
Manufacturer Incident Reference:	RI00075 28.07.2026
Type of action:	Field Safety Notice / Advisory Notice
Date:	25 Sep 2026
Attention:	Distributors and Users
Transmission of this Field Safety Notice:	This notice must be communicated / passed on to all those who need to be aware within your organisation; this must include Quality/ Regulatory/ Maintenance/ Purchasing Departments/ Theatre/ Clinical Users

Description

Dear Valued Customer,

Keeler Ltd, is issuing this communication as a Field Safety Notice / Advisory Notice relating to Slimline battery configurations that may utilise specified Slimline Lithium battery assemblies - P/N: EP59-49750 Slimline Lithium Battery (Rev. A). Patient and customer safety is our highest priority, and this notice provides important inspection and battery replacement guidance.

Keeler Ltd, has become aware of an incident involving a Vantage+ LED / Slimline & Charger system fitted with a Slimline Lithium-Ion Battery. The affected device was reportedly placed on charge in its docking station when it caught fire. Emergency services attended and extinguished the fire. Preliminary information indicates that the battery may have been the source of the incident. No patient injury has been reported. This is a single reported incident across over 12,500 units sold during that time period.

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When reviewing inventory records and installed-base information, please identify all products listed in the table below that were purchased between 2007 and 2013 and/or include part number EP59-49750.

The affected battery had reportedly remained in service for approximately 15 years. The root cause investigation remains ongoing. Keeler is reviewing battery maintenance guidance, replacement recommendations, servicing policies and product documentation.

Please review the part numbers listed below to determine whether any affected products are currently in use within your organisation.

Details of Affected Devices

All Devices listed in the table below that were purchased between 2007 and 2013 and/or include part number EP59-49750 (Slimline Lithium Battery (Rev. A)):

Part Number	Product Description
1204-P-3065	Vantage+ Bulb/Slimline Kit A
1204-P-3067	Vantage+ Bulb/Slimline & Charger
1204-P-3068	Vantage+ BLB Student Kit-Wireless2
1205-P-1014	Vantage+ LED Wireless2 In Carton
1205-P-1016	Vantage+ LED/Slimline Kit A
1205-P-1020	Vantage+ LED/Slimline & Charger
1205-P-1022	Vantage+ LED Student Kit Wireless2
1205-P-2000	API2 LED Wireless Slimline + Charger
1205-P-2003	API2 Wireless Slimline No Charger
1205-P-2007	LED Slimline Student Kit
1205-P-2030	LIO 532 Kit
1205-P-2040	LIO 577 Kit
1205-P-5010	Vantage+ Digital Kit

Particular attention should be given to batteries that:

- Have been in service for more than 4 years.
- Are of unknown age.
- Show signs of physical damage, overheating, swelling, leakage, or abnormal charging behaviour.

Cause

The root cause investigation remains ongoing.
Current evidence indicates that:

- The incident most likely involved the battery whilst charging.
- The affected battery had reportedly remained in service for approximately 15 years.
- Further examination of the returned device is required to confirm the precise cause.
- Keeler is reviewing battery maintenance guidance, replacement recommendations, servicing policies and product documentation.

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Advice on Action to be Taken by User

Immediate Actions: PLEASE FOLLOW THE GUIDANCE AND COMPLETE AND RETURN THE FORM WHICH IS LOCATED AT THIS END OF THE FIELD SAFETY NOTICE USING THE CONTACT DETAILS PROVIDED.

1. Identify all Vantage Plus, All Pupil II, LED, Bulb, Student, Digital and LIO kit configurations listed in the affected product table currently in service within your organisation.
2. Inspect all Slimline Lithium-Ion Batteries for:
   - Swelling
   - Cracking
   - Leakage
   - Corrosion
   - Signs of overheating or discoloration
   - Charging abnormalities
3. Remove from service immediately any battery exhibiting the above conditions.
4. Review available maintenance records to determine battery age.
5. Remove from use any battery that:
   - Has been in service for more than 4 years.
   - Has an unknown service history;
   - Cannot be verified as suitable for continued use.
6. Ensure batteries are only charged using approved Keeler charging equipment and in accordance with the Instructions for Use.
7. If a battery becomes hot, emits smoke, shows evidence of damage, or is suspected of malfunctioning:
   - Disconnect power if it is safe to do so.
   - Isolate the device.
   - Follow local fire safety procedures.
   - Contact Keeler Technical Services immediately.

Keeler Lithium-ION Slimline Battery 1919-P-5338 Lithium Swell Check

Over time Lithium cell batteries are known to swell, through aging and charge cycles, with general guidelines that lithium cell batteries should be replaced on a periodic basis.

As an indication of the battery condition, you can check the swell level on a Slimline battery by laying a flat edge diagonally over the label side of the pack.



No Swell – the edge lays flat with a minimal / small gap against the battery



Swelling Visible – the edge is raised with a gap of 2-3mm at the corner of the measured surface.



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Remedy

Field Safety Corrective Action (FSCA): Keeler Ltd recommends that distributors and users assess all Slimline battery configurations that may utilise specified Slimline Lithium battery assembly - P/N: EP59-49750 Slimline Lithium Battery (Rev. A) currently in service within their organisation. For devices that are more than four (4) years old, replacement batteries should be obtained through your local authorised distributor.

Identify and Notify Distributors (Action with Keeler Ltd) - 25th Sep 2026;
Identify End Users & Communicate the FSN (Action with Distributors) - 06 Nov 2026;
Obtained Acknowledgement Forms from End Users - 3 - 6 months (from 6th Nov 2026)

For further information, please contact the following:

Keeler Contact for this Notice

Gavin Colley
Keeler Ltd
Clewer Hill Road
Windsor
Berkshire
SL4 4AA
United Kingdom

Email: Gavin.Colley@keeler.co.uk
Telephone: +44 (0)1753 827116

Signature

The undersigned confirms that the appropriate Competent Authorities have been informed of this action.

DocuSigned by:
03365BA1DB9E428...

Arminder Purewal
Global Head of RA & EMEA QA - Keeler Ltd
25 Sep 2026

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Medicines & Healthcare products Regulatory Agency

What are FSNs and FSCAs?

A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative.

FSNs tell you what you need to do to reduce the specified risks of using the medical device. They give you either new information or highlight/remind you about existing advice. The actions are referred to as 'field safety corrective actions' (FSCAs).

If you receive a field safety notice from a manufacturer, **always act on it**.

Do not wait for a communication from the MHRA.

It is important that your organisation takes the actions detailed in the FSN and that you tell the manufacturer that you have received the FSN.

Your organisation's reply is the evidence that the manufacturer, and the MHRA, needs to monitor the progress of the corrective actions to ensure patient safety.

Without your reply the manufacturer can't know if their important message has been received and the MHRA may need to issue a safety communication.

May 2025

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CUSTOMER ACKNOWLEDGEMENT FORM

URGENT FIELD SAFETY NOTICE			
HOSPITAL/ ORGANISATION			
ADDRESS			
CONTACT (NAME)			
DEPARTMENT			
TELEPHONE NO.			
EMAIL ADDRESS:			
I/we acknowledge receipt of the Keeler Field Safety Notice Issue 01 dated 25 Sep 2026, in relation to the P/N: EP59-49750 Slimline Lithium Battery (Rev. A) and confirm that the information has been communicated to all relevant personnel.			
DEVICE SERIAL NO.:			
SIGNATURE:		DATE:	
NAME:		POSITION:	

ONCE COMPLETED, PLEASE RETURN THIS FORM TO KEELER USING THE CONTACT DETAILS BELOW:

BY POST:
Gavin Colley
Keeler Ltd
Clewer Hill Road
Windsor
Berkshire
SL4 4AA
United Kingdom

BY EMAIL:
Gavin.Colley@keeler.co.uk