URGENT FIELD SAFETY NOTICE

SLE1500 & INTERFLOW GAS BLENDER

FSCA Reference:	CAPA-00422			
FSN Reference:	CAPA-00422-FSN-02			
Date:	December 2025			
Subject:	Unexpected Resetting			
Product:	SLE1500 & Interflow Gas Blender			
Scope:	**Product Name**	**Catalogue Number**	**Serial/Batch Number**	**UDI**
	SLE1500 Gas Blender (NIST)	LBL151N000	Serial numbers up to and including 9260001002	5051380009959
	SLE1500 Gas Blender (DISS)	LBL151D000	Serial numbers up to and including 9250001408	5051380009966
	InterFlow Gas Blender (NIST)	LBL7210000	Serial numbers up to and including 8250001403	5051380006071
	InterFlow Gas Blender (DISS)	LBL721D000	Serial numbers up to and including 8260001050	5051380006088
	Spare Part - SLE1500 Blender front housing assembly	LBL1520000S	All	N/A
	Spare Part - Blender Control PCB	ABL2396000	All	N/A
Manufacturer and Contact:	**Full Name:**	Joseph Carter		
	Position:	Regulatory Affairs Manager		
	Email Address:	CustomerComplaints@inspiration-healthcare.com		
	SRN:	GB-MF-000004155		

SLE Ltd, Commerce Park, Commerce Way, Croydon, United Kingdom, CR0 4YL T: +44 (0)330 175 0000
customercomplaints@inspiration-healthcare.com www.inspirationhealthcaregroup.com Registered Office as above. Registration No.: 01649988

1. REASON FOR THIS NOTIFICATION

This Field Safety Notice (FSN) contains an update to previously reported Field Safety Corrective Action (FSCA) with the reference "CAPA-00422". This FSN provides:

1. Information about the root cause of the issue.
2. Information about the solution being implemented by SLE.
3. Actions to be taken by SLE.
4. Actions to be taken by the customer/user.

Root Cause:

The cause of the potential repeating cycle of resets is caused by a timing error present in the internal microcontroller (PIC32).

The problem causes interrupts and exception errors, which halt the processor and can cause the device to enter a repeating cycle of resets.

2. CLINICAL IMPACT

Neonatal Patients

Should the fault occur, patients may lose respiratory support potentially leading to physiological compromise due to respiratory insufficiency.

In the event of flow levels increasing, this may additionally lead to pneumothorax due to the excess level of flow outside of normal settings for this patient group.

Paediatric & Adult Patients

Should the fault occur, patients may lose respiratory support potentially leading to physiological compromise due to respiratory insufficiency.

3. REQUIRED USER ACTION

Affected User/Customers should work with SLE in order to select an option below best suited to their needs:

1. Option 1 – Self-correction of affected devices at customer site
   SLE will provide replacement parts and instructions to enable on-site correction of affect devices without the need to return them to SLE.

2. Option 2 – Return the device to SLE for correction
   A free-of-charge collection of affected device(s) will be arranged in order to implement the correction at SLE's facilities.

Please post this Field Safety Notice in a place accessible to all users and all those who need to be made aware within your organisation.

Please distribute this Field Safety Notice to any organisation where the potentially affected devices have been transferred (as appropriate).

Please report all device-related incidents to SLE, the distributor or local representative, and the National Competent Authority if appropriate, as this provides important feedback.

4. ACTION BEING TAKEN BY SLE

SLE will provide a replacement front panel assembly free of charge for each affected device which will resolve the issue. Users/Customers have two options for correction of affected devices, as listed in section 3 ("Required User Action") in this FSN.

The relevant National Competent Authorities have been advised of the FSCA where applicable.

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USER REPLY FORM

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the Corrective Actions. You are requested to respond within 2 days of receipt.

FSCA Reference:	CAPA-00422
FSN Reference:	CAPA-00422-FSN-02
Subject:	Unexpected Resetting

Organisational Details
Healthcare Organisation Name and Address:
Serial Numbers / Batch Codes of My Devices:
1. 2. 3.

Signatory	
I acknowledge that I have read and understood the contents of this Field Safety Notice and accept the implementation of any actions given. I confirm the contents of this Field Safety Notice has or will be brought to the attention of everyone in my organisation who needs to be made aware.	
Name:	
Title:	
Contact Information:	
Signature:	
Date:	

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DISTIRBUTOR/IMPORTER REPLY FORM

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the Corrective Actions. You are requested to respond within 2 days of receipt.

FSCA Reference:	CAPA-00422
FSN Reference:	CAPA-00422-FSN-02
Subject:	Unexpected Resetting

Organisational Details
Distributor/Importer Name and Address:
Serial Numbers / Batch Codes of My Devices:
1. 2. 3.

Signatory	
I acknowledge that I have read and understood the contents of this Field Safety Notice and accept the implementation of any actions given. I confirm the contents of this Field Safety Notice has or will be brought to the attention of everyone in my organisation who needs to be made aware. I commit to informing all organisations to whom affected devices have been transferred.	
Name:	
Title:	
Contact Information:	
Signature:	
Date:	

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