URGENT FIELD SAFETY NOTICE

FLOW SENSORS

FSCA Reference:	CAPA-00395			
FSN Reference:	CAPA-00395-FSN-01			
Date:	07/10/2024			
Subject:	Flow Sensor Issues			
Product:	N5402-REV2, N5302, N5302/05, N5302/50			
Scope:	**Product Name**	**Catalogue Number**	**Serial/Batch Number**	**UDI-DI**
	Reusable Flow Sensor - Qty 1	N5402-REV2	2300990A	5051380001656
	Single Patient Use Flow Sensor	N5302	2300262A 2300167A 2300093A 2201119A 2200457A 2200456A 2200443A	5051380005517
	Single Patient Use Flow Sensor Pack of 5	N5302/05		5051380004152
	Single Patient Use Flow Sensor Pack of 50	N5302/50		5051380004169
Manufacturer and Contact:	**Full Name:**	Erika Ismailova		
	Position:	Post Market Quality Manager		
	Telephone Number:	+44 (0)330 175 0000		
	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

Dear Valued Customer,

This letter is to advise you that SLE Ltd is conducting a Field Safety Corrective Action (FSCA) for the Reusable Flow Sensor and Single Use Flow Sensor. Flow sensor batch numbers that could lead to calibration errors are listed in Appendix 1: *Table 1: List of the affected batch numbers.*

Description of the Issue

We have received an increase in customer complaints referring to Flow Sensor Calibration alarms.

Upon investigation, we determined that there are variations in the flow sensors manufacturing process causing some sensors to be outside of the calibration specification. Consequently, causing calibration failures on ventilators.

Our records indicate that you have received the affected batch numbers.

2. CLINICAL IMPACT

When the flow sensor data is unavailable, it will result in the following:

- Interruption of volume-targeted ventilation, causing a change to pressure-controlled ventilation with the parameters active when the flow sensor becomes unavailable.
- Loss of flow and volume waveforms, along with the corresponding loop display.
- Loss of measured and calculated values, including leak, compliance, resistance, expired tidal volume (Vte), minute volume (Vmin) and compliance index (C/20C).

When the flow sensor becomes unavailable, ventilation will continue with the previous parameters. It is important to check the delivered Peak Inspiratory Pressure (PIP) to ensure it is appropriate for the patient's current clinical needs. Pressure-controlled ventilation will continue, and the pressure wave will be displayed on the ventilator screen. This ongoing ventilation will support gas exchange and help prevent atelectasis due to potential ventilation loss.

Continuing ventilation in pressure mode allows for either replacement of flow sensor or a controlled and planned transition to another device, minimising the potential risks (barotrauma and volutrauma) associated with emergency manual ventilation. This allows for the management of the specific clinical situation.

3. REQUIRED USER ACTION

1. Please contact SLE Ltd at customercomplaints@inspiration-healthcare.com to inform us of your stock status of the Flow Sensors, within 2 working days of receipt of this letter.
2. SLE will then arrange the replacement parts.
3. You may continue to use the identified Flow Sensor batches until replacements have been received.
4. Once the replacements received, the affected parts can be discarded at the premises or returned to SLE Ltd.

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.

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4. ACTION BEING TAKEN BY SLE

1. SLE Ltd will provide free of charge replacement Flow Sensors within the scope of this FSCA.
2. We will take the necessary actions to prevent further reoccurrence of this issue.

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

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FLOW SENSORS

USER/CUSTOMER 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-00395
FSN Reference:	CAPA-00395-FSN-01
Subject:	Flow Sensor Issues

Organisational Details
Healthcare Organisation Name and Adress:
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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FLOW SENSORS

USER/CUSTOMER 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-00395
FSN Reference:	CAPA-00395-FSN-01
Subject:	Flow Sensor Issue

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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Appendix 1

Product Name	Catalogue Number	Serial/Batch Number
Reusable Flow Sensor - Qty 1	N5402-REV2	2300990A
Single Patient Use Flow Sensor	N5302	2300262A 2300167A 2300093A 2201119A 2200457A 2200456A 2200443A
Single Patient Use Flow Sensor Pack of 5	N5302/05	
Single Patient Use Flow Sensor Pack of 50	N5302/50	

Table 1: List of the affected batch numbers

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