URGENT FIELD SAFETY NOTICE

FLOW SENSORS

FSCA Reference:	CAPA-00395			
FSN Reference:	CAPA-00395-FSN-02			
Date:	22/10/2024			
Subject:	Flow Sensor Issues			
Product:	N5402-REV2, N5302/05, N5302/50, L6000/SU, L6000/SU/DHW, NA5000/RU/01, NA5000/RU/02, NA5000/SU/01.			
Scope:		**Catalogue Number**	**Serial/Batch Number**	**UDI-DI**
	Reusable Flow Sensor - Qty 1	N5402-REV2	See Appendix 1	5051380001656
	Single Patient Use Flow Sensor Pack of 5	N5302/05		5051380004152
	Single Patient Use Flow Sensor Pack of 50	N5302/50		5051380004169
	SLE6000 Starter Kit. S/U Flow Sensor	L6000/SU		5051380005357
	SLE6000 Starter Kit. S/U Flow Sensor. DHW Circuit	L6000/SU/DHW		5051380005333
	SLE5/4000 Starter Kit. S/U Flow Sensor. R/U Circuit	NA5000/RU/01		5051380000789
	SLE5/4000 Starter Kit PLUS. S/U Flow Sensor. R/U Circuit	NA5000/RU/02		5051380000796
	SLE5/4000 Starter Kit. S/U Flow Sensor. S/U Circuit	NA5000/SU/01		5051380000079

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

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

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.

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-02
Subject:	Flow Sensor Issues

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

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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-02
Subject:	Flow Sensor Issue

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

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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

Table 1: List of the affected batch numbers.

Product Name	Catalogue Number	Serial/Batch Number
Reusable Flow Sensor - Qty 1	N5402-REV2	1026696
SLE5/4000 Starter Kit. S/U Flow Sensor. R/U Circuit	NA5000/RU/01	1015404
SLE5/4000 Starter Kit PLUS. S/U Flow Sensor. R/U Circuit	NA5000/RU/02	1012698 1033176
SLE5/4000 Starter Kit. S/U Flow Sensor. S/U Circuit	NA5000/SU/01	1024793
SLE6000 Starter Kit. S/U Flow Sensor	L6000/SU	1013318 1014004 1015660 1017859 1018074 1018295 1019450 1023697 1024796 1025310 1027124 1033195 1035708
SLE6000 Starter Kit. S/U Flow Sensor. DHW Circuit	L6000/SU/DHW	1012640 1012681 1015649 1020035 1020459 1020465 1032088 1035355 1035436 1035640
Single Patient Use Flow Sensor Pack of 5	N5302/05	2200443A 2200456A 2200457A 2201119A 225614094 2300093A 2300167A 2300262A

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Single Patient Use Flow Sensor Pack of 50	N5302/50	1012442 1012688 1012996 1013214 1013238 1013514 1013881 1013991 1013993 1013994 1013995 1013996 1013997 1013998 1013999 1014000 1014001 1014021 1014053 1014585 1015061 1016916 1017086 1017118 1017122 1018097 1018283 1018461 1018616 1018629 1019430 1019441 1020013 1020027 1020058 1020469 1020935 1021178 1021179 1022794 1023349	1023355 1024161 1025100 1025438 1025741 1026698 1027230 1028112 1029122 1029349 1029746 1029885 1030049 1030329 1031006 1031330 1031942 1032391 1032398 1032584 1032875 1033023 1033175 1033771 1033922 1034059 1034653 1034740 1035005 1035142 1035370 1035399 1035435 1035639 1035645 1035752 1035753 1035754 1035776 1035796

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