

# URGENT FIELD SAFETY NOTICE

## FLOW SENSORS

<b>FSCA Reference:</b>	CAPA-00395			
<b>FSN Reference:</b>	CAPA-00395-FSN-02			
<b>Date:</b>	22/10/2024			
<b>Subject:</b>	Flow Sensor Issues			
<b>Product:</b>	N5402-REV2, N5302/05, N5302/50, L6000/SU, L6000/SU/DHW, NA5000/RU/01, NA5000/RU/02, NA5000/SU/01.			
<b>Scope:</b>		<b>Catalogue Number</b>	<b>Serial/Batch Number</b>	<b>UDI-DI</b>
	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

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	<b>SRN:</b>	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](mailto: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.

<b>FSCA Reference:</b>	CAPA-00395
<b>FSN Reference:</b>	CAPA-00395-FSN-02
<b>Subject:</b>	Flow Sensor Issues

<b>Organisational Details</b>
<b>Healthcare Organisation Name and Address:</b>
<b>Serial Numbers / Batch Codes of My Devices:</b>
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.	
<b>Name:</b>	
<b>Title:</b>	
<b>Contact Information:</b>	
<b>Signature:</b>	
<b>Date:</b>	

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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.

<b>FSCA Reference:</b>	CAPA-00395
<b>FSN Reference:</b>	CAPA-00395-FSN-02
<b>Subject:</b>	Flow Sensor Issue

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

<b>Signatory</b>	
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.	
<b>Name:</b>	
<b>Title:</b>	
<b>Contact Information:</b>	
<b>Signature:</b>	
<b>Date:</b>	

## 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

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