

# URGENT FIELD SAFETY NOTICE

## FLOW SENSORS

|                                  |   |  |  |               |
|----------------------------------|---|--|--|---------------|
| <b>FSCA Reference:</b>           | CAPA-00395                                |  |  |               |
| <b>FSN Reference:</b>            | CAPA-00395-FSN-01                         |  |  |               |
| <b>Date:</b>                     | 20/09/2024                                |  |  |               |
| <b>Subject:</b>                  | Flow Sensor Issues                        |  |  |               |
| <b>Product:</b>                  | N5402-REV2, N5302, N5302/05, N5302/50     |  |  |               |
| <b>Scope:</b>                    | <b>Product Name</b>                       | <b>Catalogue Number</b>  | <b>Serial/Batch Number</b>   | <b>UDI-DI</b> |
|                                  | Reusable Flow Sensor - Qty 1              | N5402-REV2   | 2300990A   | 5051380001656 |
|                                  | Single Patient Use Flow Sensor            | N5302  | 2300262A<br>2300167A<br>2300093A<br>2201119A<br>2200457A<br>2200456A<br>2200443A | 5051380005517 |
|                                  | Single Patient Use Flow Sensor Pack of 5  | N5302/05   |  | 5051380004152 |
|                                  | Single Patient Use Flow Sensor Pack of 50 | N5302/50   |  | 5051380004169 |
|                                  |   |  |  |               |
| <b>Manufacturer and Contact:</b> | <b>Full Name:</b>                         | Erika Ismailova  |  |               |
|                                  | <b>Position:</b>                          | Post Market Quality Manager  |  |               |
|                                  | <b>Telephone Number:</b>                  | +44 (0)330 175 0000  |  |               |
|                                  | <b>Email Address:</b>                     | <a href="mailto:Customercomplaints@inspiration-healthcare.com">Customercomplaints@inspiration-healthcare.com</a> |  |               |
|                                  | <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

Possible interruption of ventilation.

Pressure ventilation will continue as per previous parameters until appropriate alternative ventilation is sourced. This will assist in prevention of Atelectasis, volutrauma, barotrauma and maintain continuity of ventilation.

## 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. 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-01  |
| <b>Subject:</b>        | Flow Sensor Issues |

|  |
|--|
| <b>Organisational Details</b>                      |
| <b>Healthcare Organisation Name and Address:</b>   |
| <br><br><br>                                       |
| <b>Serial Numbers / Batch Codes of My Devices:</b> |
| 1.<br>2.<br>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. |  |
| <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-01 |
| <b>Subject:</b>        | Flow Sensor Issue |

|  |
|--|
| <b>Organisational Details</b>                      |
| <b>Distributor/Importer Name and Address:</b>      |
| <br><br><br>                                       |
| <b>Serial Numbers / Batch Codes of My Devices:</b> |
| 1.<br>2.<br>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       | 2300990A                         |
| Single Patient Use Flow Sensor            | N5302            | 2300262A<br>2300167A<br>2300093A |
| Single Patient Use Flow Sensor Pack of 5  | N5302/05         | 2201119A<br>2200457A             |
| Single Patient Use Flow Sensor Pack of 50 | N5302/50         | 2200456A<br>2200443A             |