FSN reference: CAPA21-006

Subject: Urgent Field Safety Notice Evone

Date: 31-May-2021

For attention of hospital staff responsible for medical devices.

| Contact details of local representative* |
|---|
| <For Benelux>: Please contact Ventinova directly via manufacturer information<br><For other countries> Please contact <include distributor details> |

# Urgent Field Safety Notice (FSN)
# EVONE
# Failure to start ventilation

| 1 | **Information on Affected Devices** |
|---|---|
| **1.1** | **Device Type(s)*** |
| | Evone is a mechanical ventilator for use in operating rooms and ICU environments in hospitals. |
| **2** | **Commercial name(s)** |
| | Evone |
| **3** | **Unique Device Identifier(s) (UDI-DI)** |
| | 08718969590150 |
| **4** | **Primary clinical purpose of device(s)*** |
| | Evone is intended to be used for ventilation of patients requiring FCV or jet ventilation modes. |
| **5** | **Device Model/Catalogue/part number(s)*** |
| | REF: 6000 |
| **6** | **Software version** |
| | Not relevant |
| **7.** | **Affected serial or lot number range** |
| | All serial numbers starting with '20' and used in facilities with supply pressures above 5 bar. |
| **8** | **Associated devices** |
| | Not relevant |

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| 2 | Reason for Field Safety Corrective Action (FSCA)* |
|---|---|
| 2.1 | **Description of the product problem*** |
| | The device may fail to start ventilation when used with supply pressures (oxygen or air) above 5 bar. In situations where the supply pressure varies, the device may pass the start-up test and then fail to start ventilation. |
| 2.2 | **Hazard giving rise to the FSCA*** |
| | The device provides an alarm. A failure to start ventilation may lead to a delay of the procedure as the procedure must be re-planned or completed using an alternative means of ventilation. |
| 2.3 | **Probability of problem arising** |
| | The chance of an event where the start-up test passes but the device cannot start ventilation is estimated as two or three times a month on the complete installed base. |
| 2.4 | **Predicted risk to patient/users** |
| | A delayed procedure or the application of an alternative means of ventilation may lead to some form of patient injury although in the majority of these cases, no injury is expected. Estimated is some form of serious injury in 1 out of 100 procedures. |
| 2.5 | **Further information to help characterise the problem** |
| | The device may fail the start-up check or may provide an alarm when starting ventilation. |
| 2.6 | **Background on Issue** |
| | Ventinova received two complaints indicating the described event. Further investigation showed the events were reproducible when using supply pressures (far) above 5 bar. Further testing of a range of devices showed the event was limited to specific serial numbers. |

| 3 | Type of Action to mitigate the risk* | |
|---|---|---|
| 3.1 | **Action To Be Taken by the User*** | |
| | ☐ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device | |
| | ☐ On-site device modification/inspection | |
| | ☐ Follow patient management recommendations | |
| | ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) | |
| | ☐ Other ☐ None | |
| | **Please do not start new procedures and quarantine the device if medical gas supply pressures in your facility are potentially above 5 bar.** | |
| 3.2 | **By when should the action be completed?** | Within one week after receiving this FSN |

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| | | |
|---|---|---|
| **3.3** | **Is customer Reply Required? ***<br>(If yes, form attached specifying deadline for return) | Yes |
| **3.4** | **Action Being Taken by the Manufacturer**<br>Ventinova will update the affected device once a technical solution is designed, verified and validated. | |
| **3.5** | **By when should the action be completed?** | No date is yet defined for the deployment of the technical solution. |
| **3.6** | **Is the FSN required to be communicated to the patient /lay user?** | No |

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|---|---|---|---|
| **4** | **General Information** | | |
| **4.1** | **FSN Type** | | New |
| **4.4** | **Further advice or information already expected in follow-up FSN?** | | No |
| **4.7** | **Manufacturer information** | | |
| | See footer. For all correspondence, use support@ventinova.nl | | |
| **4.8** | **The Competent (Regulatory) Authority of your country has been informed about this communication to customers.** | | |
| **4.9** | **List of attachments/appendices:** | | FSN reply form |
| **4.10** | **Name/Signature** | ……, RA Manager | |
| | | <to be signed after review> | |

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|---|---|
| | **Transmission of this Field Safety Notice** |
| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |