

Field Safety Notice

Please forward this information to all relevant users and biomedical staff your facility.

Possible Flow Sensor Board failure

Products affected:

Product	Article No.	S/N or Batch
SERVINO delivery and monitoring system	68 81 700	20000-tbd (until corrective action is implemented)
SoKINOX NO delivery and monitoring system	66 94 550	1-tbd (until corrective action is implemented)

Dear Customer/user of SERVINO and SoKINOX

We have received a limited number of user reports with the "Flow sensor line blocked" alarm, where there has been no resolution available to the user, other than replacing the device. We are sending this letter to share with you the findings of our investigation as well as proposed next steps.

Description of the issue

The description of the issue is the following:

1. In rare occasions, the flow sensor board of the SERVINO/SoKINOX sends out an erroneous flow signal - either negative, positive, or zero.
2. This erroneous signal from the individual flow sensor board can be intermittent.
3. When the sensor board erroneously signals a negative flow, this triggers the following alarm condition and message; "Flow sensor line is blocked". The alarm text can be misleading because the underlying issue could be caused by other conditions than that the sensor line being physically obstructed e.g. a faulty flow sensor board. When this alarm is triggered, NO delivery is stopped when in Auto sense mode.
4. The most serious clinical implication is when NO delivery stops during HFOV (High Frequency Oscillatory Ventilation) as the backup system cannot be used in combination with HFOV. This leaves the user to make a medical decision to either support the patient with NO through the backup system or continue HFOV.

Intermediate remedial action

To provide improved and detailed instructions prior to the availability of a software update, we recommend the following immediate actions when faced with the "Flow sensor line blocked" alarm:

1. If the "Flow sensor line blocked" alarm occurs, the user should check that the line is not bent or blocked. If it is, please fix it or change the flow sensor.
2. If the flow sensor line is satisfactory, go to the Status / General tab and check the value of the ventilator flow. If the flow is negative, zero or if the flows being read by the flow sensor are obviously incorrect, continue at 3 or 4 below.
3. If you are using conventional ventilation, switch SERVINO/SoKINOX to the backup mode and hand ventilate the patient, or
4. If you are using HFO ventilation, we recommend to switch SERVINO/SoKINOX to the Constant rate mode, calculate and enter the ventilator total flow for the current ventilator mode (total flow = minute ventilation value + ventilator bias flow). In the Constant Rate mode, the system delivers NO in order to achieve a constant NO concentration at the flow rate entered by the user. The flow rate is independent of the flow sensed by the external flow sensor. Hence, this dosing mode requires close user monitoring of the device-monitored NO value in order to titrate the NO delivery by adapting the calculated flow, to achieve the appropriate NO delivery. It is therefore important to set appropriate NO alarm limits as well as to stop treatment and go on standby if the ventilator is disconnected.
5. Lastly, contact your service technician to investigate the event. Replacement of the device or flow sensor board may be required.

Preventive action

To mitigate this issue, a software change to improve the handling of this rare occurrence will be released, v1.4.1.

Getinge is planning to have the software updated during 2021.

We will work with you and your technical support team to schedule this upgrade at a convenient time and once available.

Should you have questions or require additional information related to this matter, please contact your local Getinge representative.

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