

Please forward this information to all relevant users, biomedical staff and risk management department concerned in your facility

Subject: SoKINOX/SERViNO NO Delivery and Monitoring System

Products affected:

Product	Article No.	S/N or Batch No.
SoKINOX	66 94 550	--
SERViNO	68 81 700	--

Dear Customer,

The purpose of this letter is to inform about a potential issue found in SoKINOX and SERViNO NO (Nitric Oxide) Delivery and Monitoring System.

Our records indicate that your unit has received one or more of these devices.

Normal use and Indications

During NO therapy, when a NO cylinder runs nearly empty the system will indicate this by the "almost empty cylinder" icon. When the cylinder runs empty it will then trigger the alarm NO cylinder 1 missing (or empty) or NO cylinder 2 missing (or empty). This is indicated on the user interface by a crossed out cylinder icon. The system automatically shifts over to the other cylinder.

The following has been discovered

Due to a pressure increase after the cylinder switch-over there are 2 possible issues identified:

1. The cylinder status icon can change and erroneously indicate remaining gas in an empty NO gas cylinder.
2. The alarm "NO cylinder 1 missing (or empty)" or "NO cylinder 2 missing (or empty)" can be deactivated

Potential hazards

If the empty NO cylinder is not replaced, both NO cylinders can run empty and cause a stop in NO delivery. There have been no reports of patient injury as a result of this issue.

Precautions

During NO therapy make sure to:

- Always use two (not less than 5 l) NO cylinders and have both open during therapy.
- Check the manometers on the NO cylinders according to the Pre Use Check instructions to ensure sufficient pressure. Note that based on the settings, e.g. patient flow and gas concentration, the time to empty a NO cylinder may vary.
- Always replace NO cylinder directly after a *NO cylinder 1 missing (or empty)/ NO cylinder 2 missing (or empty)* alarm is generated.

Corrective action

A new system version 1.3 that will correct this behavior has been developed.

Getinge/Maquet will initiate an immediate update of all affected SoKINOX and SERVINO systems as soon as the system version 1.3 is released in your country. Once available you will be contacted by your Getinge/Maquet sales or service representative to plan for the update of your device.

Please maintain awareness on this notice and resulting action until your device has been updated to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause and we will do our utmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge/Maquet representative.

Sincerely,



Caroline Ybema, PhD
Product Manager Ventilation
Maquet Critical Care AB



Lars Berken
Head of Quality
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