Field Safety Notice

2018-09-07 | EVU-185397 |

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.
SERViNO	68 81 700	See device list
SoKINOX	66 94 550	See device list

Dear Customer,

The purpose of this letter is to inform about a potential issue found in SoKINOX/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.

Since it was found that these pressure creeps were not fully addressed with SW version 1.3, version 1.3.1 was developed which contains additional improvements to further reduce the risk of the scenario described above.

Potential hazards

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

Corrective action

A new system version 1.3.1 that will correct this behavior has been developed.
Getinge will initiate an immediate update of all affected SoKINOX/SERViNO systems as soon as the system version 1.3.1 is released and licensed in accordance with local regulations. Once available you will be contacted by your Getinge/Maquet/Maquet-Dynamed sales or service representative to plan for the update of your device in your country.

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 outmost to carry through this action as swiftly as possible.

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

Sincerely,

Caroline Ybema, PhD
Product Manager Ventilation
Maquet Critical Care AB

Lars Berken
Head of Quality
Maquet Critical Care AB