

Use of out-of-service ventilator systems

In view of the situation with the Coronavirus disease COVID-19, we hereby want to provide the following statement regarding the use of our older out-of-service ventilator systems:

- In March 2004, production of the Servo Ventilator models 300 and 900 was discontinued. 10 years later, on December 31 2014, production of preventive maintenance kits and all spare parts was finally discontinued.
- Using ventilators that can no longer be maintained according to service instructions may pose patients risks including lower safety and performance than expected. This situation has not been part of our product risk analysis and clinical evaluation.
- We recognize that during a crisis such as we now face with COVID-19, the medical profession is expected to take extraordinary steps to treat and save as many lives as possible. The decision to use these ventilator systems on patients, and deviations to meet current medical device standards and regulations, is purely up to the discretion of the responsible healthcare provider with regard to medical risks vs benefits.
- However, when an emergency decision has been taken we believe it is very important that the healthcare provider uses all available knowledge to assure that use of these ventilators can be done as safe as possible, including careful functional testing prior to use according to the User's manual and additional patient monitoring.

Refer to User's manuals for SV 300 and SV 900 on our COVID-19 Resource Centre:
<https://www.getinge.com/uk/insights-results/covid-19-resource-center/>

Yours sincerely,

Dr. Miray Kärnekull
Medical Director
Maquet Critical Care AB

Jennie Haag
Director of Product Management
Maquet Critical Care AB