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Solna, Sweden

Use of one ventilator for multiple patients simultaneously [UPDATED]

In view of the situation with the Coronavirus disease COVID-19, we hereby want to provide the following statement regarding the use of one ventilator for multiple patients simultaneously.

Getinge designs and manufactures Servo ventilators that are intended for use on a single patient at a given time. We have not tested or validated the performance or effectiveness of these devices when one unit is used concurrently on multiple patients. Therefore, our indications for use are specific to the use of one unit with one patient at a time, but not using it concurrently on multiple patients.

Getinge is working closely with global regulatory authorities and we are monitoring what scientific, clinical and technical organizations recommend. We hope that our device users have access to the most accurate and relevant information, to enable safe and effective use of our equipment while addressing the critical needs of the patient. Furthermore, we are aggressively engaged in increasing the supply and availability of our products and accessories, including seeking approval of Emergency Use Authorizations to ensure product availability or to temporarily expand indications or Instructions For Use.

During a crisis such as COVID-19, we acknowledge the need for the medical profession to take extraordinary steps to treat and save lives. This includes evaluating the risks and benefits of using a Servo ventilator on multiple patients due to the scarcity of ventilators.

We are receiving frequent requests for information and guidance relative to the use of Getinge Servo ventilators with more than one patient simultaneously. Furthermore, there are numerous articles and publications that reference the use of ventilators on multiple patients concurrently. We at Getinge acknowledge there is no consensus in the medical community about the balance of risks and benefits of using one ventilator on multiple patients. Here are some references with different viewpoints:

- Consensus Statement from US clinical associations including SCCM, AARC, ASA, ASPF, AACN and CHEST; advising against Multiple Patients Per Ventilator (March 26, 2020)
  https://www.sccm.org/Disaster/Joint-Statement-on-Multiple-Patients-Per-Ventilato
  https://www.aarc.org/joint-statement-guidance-document-on-multiple-patients-per-ventilator/
- FDA guidance relative to “Ventilator Supply Mitigation Strategies: Letter to Health Care Providers” (March 22, 2020)
  https://www.fda.gov/medical-devices/letters-health-care-providers/ventilator-supply-mitigation-strategies-letter-health-care-providers.

Maquet Critical Care AB
Röntgenvägen 2
17154 Solna
Sweden

Phone: +46-10-335 73 00
www.getinge.com

- ECRI guidance on “Strategies to Mitigate Ventilator Shortages” (April 1, 2020) https://www.ecri.org/landing-covid-19-ventilator-shortages.
- New York - Presbyterian Hospital “Working Protocol for Supporting Two Patients with a Single Ventilator” (March 24, 2020) https://www.gnyha.org/news/working-protocol-for-supporting-two-patients-with-a-single-ventilator/

The decision to use one ventilator on multiple patients is up to the user’s medical judgement regarding risks vs benefits. While simultaneously ventilating more than one patient with one ventilator is not recommended or validated by Getinge, we have provided Appendix 1 which contains a list of identified risks and strategies to reduce those risks. Getinge believes this appendix will assist in making this critical decision based on medical judgement. We again want to stress that the decision to use a ventilator on more than one patient is up to the user, but is not something that Getinge recommends.

We strongly recommend that caregivers fully review all relevant information (even beyond this letter and the attached Appendix) on the use of one ventilator for multiple patients simultaneously, including guidance from professional and medical associations, medical advisors, legal counsel and ethics teams.

Getinge continues to work with technical and regulatory bodies to identify possible solutions to address the critical shortage of ventilators. As we receive more information, we will endeavor to provide whatever further information we believe is necessary to be given to our customers and user.

Yours sincerely,

Dr. Miray Kärnekull
Medical Director
Maquet Critical Care AB

Jennie Haag
Director Product Management
Maquet Critical Care AB

Appendix 1 – Risks and risk reducing strategies

The table below contains a list of identified risks and strategies to reduce those risks on Servo ventilators This is not an exhaustive list of risks and these strategies will not fully mitigate the risks. The procedure of simultaneously ventilating more than one patient with one ventilator is not recommended or validated by Getinge.

Risk		Risk reduction
1	The accuracy of the settings and the response to ventilator support cannot be assessed properly if more than one patient is connected to the ventilator.	In order achieve as correct pressure and volume setting of the individual patient as possible; the settings should be identified for the individual patient based on when the patient is connected individually to a ventilator. This baseline should then be used when ventilating multiple patients on one ventilator.
2	During multiple patient ventilation, it is not possible to control the flows and volumes going to each individual patient. This may cause one patient to significantly influence the flow to the other patient(s).	Do not use Volume Control (VC) mode or volume derived ventilation modes (i.e. modes where a volume is set). This includes VC (incl Automode VC-VS and SIMV (VC) + PS), Pressure Regulated Volume Control (PRVC) (incl Automode PRVC-VS and SIMV (PRVC) + PS), Volume Support (VS).
3	Spontaneous efforts from one patient triggering the ventilator could negatively affect the other patient(s).	The clinician must assure that the multiple patients do not have spontaneous breathing efforts (i.e. all patients shall be sedated and paralyzed with neuromuscular blockers). This necessitates ventilation in controlled mode. With the risk reductions of Risk 2 above, this limits the mode chosen to Pressure Control.
4	Suboptimal ventilation - the ventilatory needs of patients connected to the same ventilator varies significantly.	Patients should be well matched in their clinical needs, most importantly in the following parameters: • Driving pressure • PEEP • FiO_2 • Breath rate Only patients, when connected individually to a ventilator, with similar settings for these parameters should be considered for sharing a ventilator.
5	Delayed weaning, as weaning of a patient cannot be done from the level of sedation required for multiple patient ventilation.	Weaning of patients requires patient specific ventilator.

Risk		Risk reduction
6	Cross contamination between patients. Specifically if kinks on tubes or patient coughs should occur, causing gas flows in opposite directions from normal flows.	Viral/Bacterial filters on both inspiratory and expiratory limbs of the breathing circuit for each patient should be used.
7	Tidal (Minute) volume monitoring will not be accurate for the individual patient. The monitoring and its' accuracy will be for the combined patient ventilation. Alarms for minute volumes will not be reliable.	Do not use the "autoset alarm limits" function. To achieve a higher degree of certainty, the Minute volume alarm limits should be set as per the patient with the tightest alarm settings window. This will cause an increased risk of nuisance alarms. Separate external monitoring (e.g. SpO2, CO2 and/or tidal volume) will enable early detection of insufficient ventilation.
8	An occlusion of the inspiratory or expiratory limb for an individual patient will go unnoticed. This may happen (e.g. due to clogged filters or kinked tubes) and may cause hypoxia or hypoventilation for the occluded patient and possibly hyperventilation for the other patients.	Separate external monitoring (e.g. SpO2, CO2 and/or tidal volume) will enable early detection of insufficient ventilation. Pressure Controlled modes will not cause hyperventilation of the other patient(s) connected to this ventilator. Additionally, each patient should be clinically assessed frequently, at a minimum of 15-30 minute intervals, including vital signs, oxygen saturation level, end tidal Co2, examinations of the chest for bilateral air movement, and, if indicated, assessments of arterial blood gas findings to assure clinical stability on the shared system.
9	CO2 monitoring can only be performed on one patient with the ventilator.	Separate external monitoring (e.g. SpO2, CO2 and/or tidal volume) will enable early detection of insufficient ventilation.
10	One patient causes accidental extubation on one or several other patients.	The clinician must assure that the patients are muscularly relaxed (i.e. the patients shall be sedated and paralyzed). The low PEEP alarm could identify extubation.
11	Alarms cannot be referenced to an individual patient.	If the shared ventilator alarms for any reason, clinical assessments of each patient are indicated immediately in order to determine which patient is triggering the alarm. The ventilator cannot indicate which patient is triggering the alarm. Providers need to assess all patients, consider suctioning and proper tube placement, and disconnect any unstable patient, considering mechanical bagging if necessary.

Risk	Risk reduction
12 Off-label procedures may cause user induced errors and hazards.	Develop a protocol for work procedures for use of one ventilator for multiple patients simultaneously.