

Customer Notification Letter

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

COVID-19: Enabling ventilation of Adults with the Servo-n neonatal/pediatric ventilator

Products affected:

Product	Article No.	S/N or Batch No.
Servo-n	6688600	All

Dear Customer,

In view of the situation with the Coronavirus disease COVID-19, we hereby want to provide the following statement regarding the potential use of the Servo-n neonatal/pediatric ventilator for ventilation of Adult patients.

The Servo-n is intended for treatment of neonatal and pediatric patients. However, as the COVID-19 is largely affecting adult patients and the need for ventilators that can treat these patients is exceeding supply we have implemented an action for emergency use during the pandemic. Through a special procedure, Getinge representatives can enable the Adult patient category in the Servo-n ventilators for a period of time (more details below), giving the Servo-n performance for adult patients similar to the Servo-u universal ventilator.

Procedure to enable Adult patient category in Servo-n for emergency use

To activate the Adult patient category in your Servo-n ventilators, a combination of two tools is used:

- an existing tool making it possible to try out software options not yet installed in a Servo-n ventilator (Tryout option) for one or more periods of 28 days.
- a specially developed software tool to enable the Adult patient category in Servo-n ventilators.

These tools are distributed to Getinge representatives worldwide. Contact your local Getinge representative to enable this in your Servo-n ventilators.

When the Adult patient category is activated in your Servo-n, you will see the background color of the User Interface during ventilation changing from blue to dark grey. The activation does not change anything else in the ventilator; it will keep the same options and system version.

The number of 28 days tryout periods that can be enabled on a specific Servo-n ventilator depends on the System version of the ventilator. If the Tryout option tool has been used previously several times on that specific Servo-n all periods may already be spent.

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NOTE: The Adult patient category will not be deactivated during ventilation. The option will only be disabled after 28 days has passed AND the ventilator is restarted with the on/off switch two times:

1. On the first restart after the end of the 28 day period, an information text stating "The tryout options will expire soon" will be presented
2. On the second restart, an information text stating "The tryout options have expired" will be presented and the option is disabled.

When preparing the ventilator for a new COVID-19 patient, make sure that the Adult patient category is still active.

When the adult patient category has been enabled in a Servo-n, your Getinge representative should provide a digital version of the Servo-u User's manual for the correct System version and language. It is also recommended that the Servo-n ventilator is clearly marked with the date of deactivation of the Adult patient category according to the suggestion below:

Adult option deactivation date: _____

NOTE: deactivation will not occur during ventilation,
only when restarting the ventilator with the on/off switch

Activation date: _____ Remaining periods: _____

Sincerely,

Jennie Haag
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Maquet Critical Care AB

Pernilla Sandberg
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