

May 6, 2020

Extended Use of Pall Corporation's Breathing Circuit Filter Model BB50T by the FDA during COVID-19

Dear End User

This letter is being sent to you to explain a change recently authorized by the FDA under Enforcement Policy to extend the service life of the Pall BB50T Breathing System Filter previously cleared in 510(k) K791307. This FDA authorization allows the BB50T filter to be used for 168 Hours (7 days) challenged with humid air in a unidirectional flow mode in concordance with the existing product instructions for use in conjunction with the Pall Corporation recommendations summarized below.

The FDA has issued this authorization:

- The BB50T filter product code (CAH) has been included as a respiratory device accessory in their guidance document "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" to help expand the availability of ventilators as well as other respiratory devices and their accessories during the Coronavirus Disease 2019 (COVID-19) pandemic. The inclusion of the BB50T filter can be found on the chart in sub-section C "Use of Ventilator and Anesthesia Gas Machine Breathing Circuit Devices Beyond Their Indicated Shelf Life and Duration of Use under section IV entitled "Policy for Modifications to FDA-Cleared Devices". This FDA guidance document is available at www.fda.gov/media/136318/download.
- This was based on supporting laboratory test documentation held by Pall Scientific Laboratory Services that replicated the BB50T filters performance in a representative use environment to include mechanical ventilation with a patient model to simulate the characteristics of inspiratory and expiratory gases.

The indications for use and environment of use of the BB50T filter remain the same, consistent with its FDA clearance.

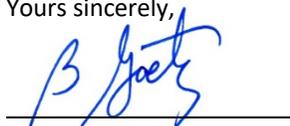
The potential risks associated with extending the use life include reduced integrity of the filter and/or blockage, but these risks are mitigated by ventilator alarms, compliance with hospital monitoring procedures and the following recommendations to further ensure the safety and efficacy while extending the service life of the Pall BB50T filter for 168 hours:

- Use of an additional heat and moisture exchanging (HME) filter in the patient side of the breathing circuit.
- Positioning the BB50T filter when active humidification is used such that water build up can drain away from the patient side of the filter.
- When drug nebulization is applied, it should be between a Pall Ultipor 100 Heat and Moisture Exchanging Filter positioned at the Y-connection and the patient's endotracheal tube. **Note: If drug nebulization is used outside the above Ultipor 100 application, e.g. positioning the nebulizer in the inspiratory limb of the breathing circuit or at the patient's endotracheal tube the service life of the BB50T cannot be extended.**

These recommendations and other reference documents can be found at <https://medical.pall.com/en/mechanical-ventilation/coronavirus.html>

You may report any adverse events associated with use of this device by email at gamedical@pall.com or 800-645-6478. Please feel free to reach out to us should you have any questions or concerns.

Yours sincerely,



Brian Goetz, Senior Manager Regulatory Affairs – Official Correspondent