Geratherm®
Respiratory

Geratherm Respiratory GmbH · Kasernenstraße 4 · 97688 Bad Kissingen · GERMANY

TO WHOM IT MAY CONCERN

May 6, 2020

+ + + Technical Note on Covid-19 + + +

In view of the current situation of the corona pandemic, we have compiled the following recommendations for action regarding our Spirostik devices

According to the ERS statement "Lung function testing during COVID-19 pandemic and beyond" (https://ers.box.com/s/zs1uu88wy51monr0ewd990itoz4tsn2h), lung function tests should be kept to a minimum during the Pandemic phase. The ERS also recommends to use in-line bacterial and viral filters in this phase.

Although the two screens inside the Spiraflow keep back saliva and sputum, it does not have sufficient filter efficiency to act as bacterial and viral filter. The Spiraflow is also not intended to be used in combination with a bacterial and viral filter.

For the post-peak phase, the ERS states that all testing procedures can be reintroduced with extra precautions. In addition to the organizational and infection control recommendations published by the ERS, we recommend following procedures to minimize the risk of cross-contamination during spirometry with Spiraflow:

- Use an approved hand sanitizer between each patient.
- Wear personal protective equipment (Gloves, Face mask).
- Perform the measurement in a separated room which is reserved for spirometry testing.
- Ensure that the testing room is well ventilated to keep the contamination of the ambient air with viruses to a minimum.
- When measuring, make sure that you are not in the exhaled air stream of the patient. It is best to position yourself at a 90 degree angle to the patient and have a distance of at least 1.5m to the patient.
- The patient should perform the maneuver in the direction of a surface that is easy to clean and disinfect, e.g. an upright plexiglass panel. This surface should be disinfected after each patient.
- Dispose of single-use parts after usage.
- Perform a wipe disinfection of the handle (including the rubber sealing inside the handle) and all surfaces touched by the patient.

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Where there are local or regional recommendations, these must also be given due consideration.

Please note that a disinfection of the tubes of the handle is not necessary, as the flow tubes are just used to transmit a pressure signal to the device. Hence there is no risk of air displacement into the direction of the patient which could lead to a cross-contamination between patients.

Of course, we will continuously check these recommendations for validity. As soon as new findings become known, we will incorporate them into our recommendations and publish them again.

Please note that this recommendation is based on the best of our knowledge and we assume no liability based on this information.

We wish all of you to stay healthy through these challenging times and are at your disposal for questions and suggestions

Yours sincerely

Manuel Heinz
Vice President of Product Management

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