Are there recommendations for ERT Respiratory devices?

For the following devices and accessories provided by ERT, we have carefully reviewed the guidelines for safe use in the respective 'Instruction for Use' (IFU) documents:

ERT Manufactured Devices

- MasterScope CT / ECG
- FlowScreen / FlowScreen CT
- SpiroSphere
- AM3 (AM3G+, AM1+, etc)
- Clean Peak Flow Meter (CPFM)
- ERT Pneumotachograph (ERT PT)

Third-Party Devices and Accessories (offered by ERT for use in clinical trials)

- MicroGard II filters (manufactured by Vyaire Medical GmbH)
- NIOX Vero (manufactured by Circassia Pharmaceuticals plc)
- NDD EasyOne PRO (manufactured by ndd Medizintechnik AG)
- Tremoflo (manufactured by Thorasys Thoracic Medical Systems Inc.)

For detailed recommendations regarding the safe use of these devices, see below:

ERT Respiratory would like to remind users of the following principles to assure the safe use of our products and to protect users as well as patients from cross-contamination of the COVID-19 virus.

Bacterial / Virus filters are expected to be used according to the respective 'Instructions for Use'. The Vyaire Medical MicroGard II filters used with some ERT devices (e.g. MasterScope / FlowScreen) have a Virus Filtration Efficiency of >99.99% according to ASTM and EN tests [1]. These filters must be used only once per patient (Single Patient Use) and have to be disposed of properly after testing is done.

According to Vyaire Medical, the MicroGard II filters are annually tested in a certified laboratory to ensure a high Viral Filtration Efficiency (VFE) [2] using test suspensions of bacteriophages that have an average size of 30nm. According to current knowledge, the COVID-19 virus has an average size of 80-160 nm; therefore, the manufacturer deems the viral filter effectiveness to be sufficient.

Where a Bacterial / Virus Filter is not required to be used, ERT devices (e.g. SpiroSphere) are equipped with disposable accessories, which are to be used in a Single Patient mode and have to be disposed after the measurement(s).

For ERT patient devices with disposable accessories (e.g. AM3): the disposable accessory has to be used in a Single Patient mode and must be replaced before the AM3 is used with another patient. Cleaning and disinfection have to be applied prior to the handover to another patient.

Devices that are intended to be a Single Patient device are never to be shared with other patients. These devices (e.g. Clean Peak Flow Meter) are required to be disposed of after use.

The cleaning and disinfection processes in the provided 'Instructions for Use' have to be followed as described, using the disinfection materials that are recommended. For these types of disinfection agents, ERT has confirmation of the effectiveness against Coronavirus contaminations – as long as they are used as described on the disinfection agent or per Instructions of Use. These cleaning and disinfection instructions include the surface of the device itself.

In addition, ERT recommends using personal protection measures to additionally improve the safe use and handling of these devices. As recommended by the World Health Organization (WHO), site personnel are expected to use disposable hand gloves for handling devices or if in contact with any potentially infected patients. Furthermore, the use of masks is recommended for health workers and people who are taking care of patients (at home or in a healthcare facility).

Local guidelines and policies for appropriate containment measures for viral management and isolation have to be considered.

For any medical device not made by ERT, we recommend consulting with the respective Instructions for Use documents and, if in doubt, to contact the vendor directly.
ERT continues reviewing the information provided by vendors and will issue updates if new information becomes available.

If you have additional questions, please contact your ERT Representative for further assistance.

References:

[1] Vyaire MicroGard® II filter specifications, revision 2019

[2] Nelson Lab Testing mechanism on VFE according to ASTM F2100, F2101 and EN 14683