ndd Medizintechnik AG

new diagnostic design

Zurich, 19 March 2020

ndd Hygiene Solution – Effective Protection for Patient and Technician

This letter is a response to the recent inquiries if ndd products are suitable for the use in patients, that are potentially infected with the SARS-CoV-2 virus (Coronavirus). The following paragraphs describe the effectiveness of our hygiene solution as well as general considerations. Based on the current information available about infection and transmission of this virus, ndd concludes that the information provided in this letter is also applicable and valid for the SARS-CoV-2 virus and the devices can be used safely, if the instructions in the respective Operator's Manuals are followed.

The unique ndd hygiene solution, which uses the inserts spirette, FlowTube and barriette, requires no cleaning of internal tubing or sensor components. Only surface cleaning is required.

In tests carried out at various laboratory centers (Toxicon, Zollinger), the ability of the inserts to stop aerosolized material from penetrating, was shown to be comparable to that of commercially available pulmonary function testing filters, i.e. >99.9%. This includes the "filtration" efficiency of the mesh material at inspiration and expiration, as well as its efficiency during the process of removing used, potentially contaminated inserts and replacing them with unused ones. Even under improbable double error conditions, the filtration efficiency is excellent (>99.9%). It has also been shown that ndd's hygiene solution works independently of the size of the microbes, being effective for bacteria as well as small size viruses.

Additionally, two validation studies conducted under normal clinical use have shown that the ndd hygiene concept is effective to prevent cross-contamination [1] (see also attachment: Wesel).

At the same time, the ndd hygiene solution ensures excellence in measurement quality.

The open flow path of the ndd spirometry system is a key factor in achieving the superior accuracy and excellent trial-to-trial and test-to-test reproducibility for which it is known. Resistance in the flow path reduces measured peak flow and FEV1, because it makes it harder for the patient to exhale air at high flow rates. It is analogous to blowing through a drinking straw, where air flow is reduced due to the straw's resistance. Because of its effect on accuracy, the ATS/ERS has specified the maximum acceptable resistance in the measurement path to be 1.5 cm H_2O at 12L/S. This is an upper limit – it should not be exceeded. A lower limit would be better [2], and zero resistance would be ideal.

Managing Workplace Hygiene

In order to avoid cross infection in a pulmonary function lab, it is essential to analyze potential sources of contamination and to implement appropriate measures of effective infection control.

Potential sources of infection include, for example, coughing before, after or during the PFT test, and patient contact with the PFT equipment, the surroundings and the hospital staff.

In addition to the safety precautions mentioned in our Operator's Manuals, these potential sources of infection can be effectively managed by applying the "ATS Recommendations for PFT Lab Hygiene" [3] and the "Standard Precautions" [4].

Physical barriers for technician:

One recommendation is that the test technicians wear a surgical mask to protect themselves against airborne infections due to the patient's sneezing or coughing (common in spirometry testing); and they should wear protective gloves to avoid the transfer of infections from handling used disposables that have been in the patient's mouth or parts close to the test apparatus that may have been otherwise contaminated. These procedures are recommended regardless of the type of test apparatus used.

Laboratory infrastructure:

Another important measure is to ensure adequate ventilation and air sterilization in the lab and hospital itself to clear out carriers of airborne diseases.

Sputum exiting the spirette or FlowTube is only one of various sources of potential infection in a PFT lab. Therefore, using an inline filter does not reduce the number of measures necessary to ensure workplace hygiene. On the other hand, using a spirette or FlowTube does not require taking any additional hygiene measures.

One general recommendation is establishing a distinct testing area and positioning the patient so that any droplets released by the patient's coughing end up in a controlled space and not on the technician, the surrounding equipment, or the furniture.

The laboratory infrastructure is crucial to avoid cross infection. The exposed surface areas, the general clutter, the quality of the upholstery, air conditioning (if present), temperature and humidity, and the frequency of use are known to have an effect on cross infection in the PFT laboratory [5].

With their smooth surfaces ndd products are easy to clean and the devices do not require any internal cleaning or disassembly to ensure hygiene, as everything that comes into contact with the patient's breath is replaced with every test. This is one of the reasons why it has been established that the risk of transmission of infection is minimal with an ultrasonic sensor-based spirometer [5].

Separation of patients:

To appropriately separate potentially infectious patients, health care workers who are their first point of contact in facilities should be trained to ask questions that will facilitate identification of

patients with signs and symptoms suggestive of TB, immunocompromised status and significant exposure to communicable diseases such as chicken pox and measles [5].

The ATS/ERS recommends testing high-risk patient groups (e.g., tuberculosis) in their rooms [3]. This is possible thanks to ndd's highly mobile point of care equipment.

Issues with in-line filters

Some manufacturers use or recommend using disposable in-line filters to address hygiene issues. While the idea can be appealing, a closer examination reveals shortcomings: The main purpose of such filters is to protect the test apparatus from contamination, not to protect the staff or general area. An in-line filter only functions during the spirometry exhalation itself but not before or after, when the patient could be coughing or sneezing in the test area. In-line filters are not 100% effective in blocking airborne microbial transfer and adequate cleaning is still required [6]. It is also important to note that, when performing forced maneuvers, in-line filters can lose part of their effectiveness [6].

In addition to this, the added resistance of filters can push the total system resistance to or above the maximum limit recommended by the ATS. Even when the ATS/ERS recommendations are not exceeded, measurements are still influenced by the filter's resistance. A study by David P. Johns et al., for example, showed that the addition of the filter introduced errors in PEF and FEV1, reducing these values by 5.3% for PEF and 1.7% for FEV1 [2].

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