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White Paper
Bernard Garbe, Vitalograph

Spirometry Hygiene

There are three main potential sources of cross contamination whilst performing spirometry testing, skin contact, aerosolised particles and saliva/body fluids.

To protect against the cross infection risk from aerosolised particles a delay of at least five minutes between spirometry test subjects is required. This delay allows aerosolised organisms to be removed by gravitational sedimentation between tests, more sophisticated spirometry devices may be equipped with fans and filters to speed this process.

The main cross infection risk is from contact with body fluids - namely saliva from subjects previously tested on the device. Such cross infection is almost always caused by the failure to use or replace the disposable mouthpiece or filter.

The risk of cross infection may be greatly reduced by the use of a SafeTway® mouthpiece or the BVF™ (bacterial/viral filter). The BVF has the advantage of protecting sensors and the internal surfaces of the spirometer from damage and reduce the corroding effects of cleaning agents and disinfectants. Both types of types of mouthpiece must be used only by one test subject and must be disposed of between test subjects.

The Difference between Cleaning and Disinfection

The term "cleaning" particularly relates to the removal of proteinaceous accumulations during the removal of visible particulate contamination. Cleaning may be as simple as wiping over surfaces but may involve washing and mechanical removal of surface particulates.

The measuring elements of flow sensing type spirometers need more frequent cleaning than volume displacement spirometers due to the long breathing tube, which increases the distance from the test subject to the sensor. The deposition of saliva and other bodily fluids is directly proportional to the distance from the mouth, most deposition occurs within a few centimetres of the mouth with corresponding decrease of deposition further away from the mouth. A high proportion of deposition occurs within the mouthpiece in addition to the major risk from the saliva on the outside of the mouthpiece.

Once cleaning has been completed, some or all parts of medical devices may require disinfection. "Disinfection" is a process aimed at reducing the survival rate of micro-organisms, for example by immersing the item in a disinfecting solution.

For spirometers, all surfaces need to be cleaned. Parts of the device that might carry contamination, such as flowheads, may also be disinfected, according to your facility's procedures for hygiene.

In the event of a contamination that cannot be eliminated with the procedures and facilities available the contaminated components should be removed and replaced. This should be a consideration in the facility's risk assessment and is a special consideration for mass screening.

In no circumstances should contaminated devices be posted to a service facility. If the user is uncertain what to do the device should be isolated, bagged and labelled while advice is sought. Healthcare facilities should ensure that a risk assessment is carried out to assess the risks presented to both operator and subject and an action plan devised to minimise the chance of cross infection occurring, particularly where known infectious or immuno-deficient subjects are being tested. An assessment should be made of methods of decontamination available to the operator and their effectiveness against potential risks - a table of materials used in the spirometer device is essential to enable this. In cases of high risk where no effective disinfection method is available the contaminated parts should be removed and disposed of safely.

Timetable of Hygiene Procedures

AFTER EVERY TEST: A new mouthpiece should be used for each subject. A delay of at least 5minutes should be allowed between subjects to allow settling of previously aerosolised particles in the measuring device.

DAILY: Perform a visual inspection at the end of testing. If there is visible contamination to the flowhead, or elsewhere on the device, undertake cleaning and disinfection.

WEEKLY: Clean all parts of the equipment which have come into contact with patients.

MONTHLY: The flowhead screens or breathing tubes should be replaced regularly. The frequency of this is dependent on the facilities' risk assessment, usage, and test environment, but should be at least monthly or every 100 subjects (500 blows). They should also be replaced in the event of damage, or if visibly contaminated.

ANNUALLY: Annual inspection, maintenance and calibration certification should be obtained from the manufacturer or a qualified service supplier. All components of the breathing circuit should be replaced.