

Hygienic Safety of an Ultrasonic Flow Sensor for Multiple Breath Washout

To the Editor,

Prognosis and survival of patients with Cystic fibrosis (CF) are adversely affected by infection and colonization with CF related pathogens. As patient–patient transmission has been increasingly demonstrated and epidemiology of pathogens in CF has become more and more complex, hygienic precautions are mandatory even if pathogens have not yet been detected. Screening of newborns for CF and more intensive treatment has created a relatively healthy young CF population that mixes with older CF patients constituting a major microbial reservoir from which non-infected patients can be infected in outpatient clinics.¹

This appears particularly relevant when performing lung function measurements where BTPS conditions increase the risk for contamination. Measurement of lung function in CF therefore requires strict adherence to highest hygienic standards.¹

The multiple breath washout (MBW) technique has been shown to be sensitive in detecting early lung disease in CF and is therefore discussed as a potential new surrogate marker for multicenter trials.^{2,3}

We have recently published data where we have used a novel prototype equipment (EasyOne Pro, MBW Module, ndd Medical Technologies, Zurich, Switzerland) using the Spiroson[®] ultrasonic flow sensor (USFS, ndd Medical Technologies) for MBW that allows assessment of indices of ventilation inhomogeneity, such as the Lung Clearance Index (LCI).^{3,4}

The USFS is a handheld device that samples flow and molar mass of the inspired and expired gas. For MBW, the sensor is connected to a bypass system providing tracer gas supply during the wash-in phase. In the bypass system, some parts are disposables and some parts can be reused after disinfection. The outside flow sensor is disinfected with antiseptic solutions after use. The inside should be kept dry because of the uncovered ultrasonic transmitters mounted in the inner side chambers. This part of the device, where the patient breathes through, is protected against bacterial contamination by a disposable insert (Spirette[®]) during the measurements.

Originally, the Spirette has been designed for the short spirometric measurements.

In contrast MBW takes 20–60 min/patient while the membranes of the Spirette[®] are exposed to BTPS conditions and increased salivation.

Therefore the aim of this prospective study was to evaluate, whether the Spirette[®] is hygienically safe even with the extended test duration of MBW.

MBW was performed in 46 patients with CF. Age ranged between 6.2 and 53.1 years. Sixteen out of forty-six were colonized with *Pseudomonas aeruginosa*. Swaps from inside the device were taken following removal of the Spirette[®] after each test and sent for microbiology. Hundred percent of the samples were sterile.

From these data we conclude that the disposable insert fully protects against bacterial contamination of the USFS, even when used for the long MBW measurement.

Provided common hygienic standards such as hand hygiene and disinfection of reusable parts are applied and all disposable parts of the ultrasonic equipment are changed for each patient, MBW using the USFS can be performed without any hygienic risk and can therefore be recommended for multicenter application. We would like to emphasize the need to thoroughly assess hygienic safety when new equipment is being introduced particularly in children with CF where transmission and cross-infection may have life-long negative consequences.

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REFERENCES

1. Saiman L, Siegel J. Infection control in cystic fibrosis. *Clin Microbiol Rev* 2004;17:57–71.
2. Gustafsson PM, Aurora P, Lindblad A. Evaluation of ventilation maldistribution as an early indicator of lung disease in children with cystic fibrosis. *Eur Respir J* 2003;22:972–979.
3. Fuchs SI, Sturz J, Junge S, Ballmann M, Gappa M. A novel sidestream ultrasonic flow-sensor for multiple breath washout in children. *Pediatr Pulmonol* 2008;43:731–738.
4. Fuchs SI, Buess C, Lum S, Kozłowska W, Stocks J, Gappa M. Multiple breath washout with a sidestream ultrasonic flow sensor and mass spectrometry: a comparative study. *Pediatr Pulmonol* 2006;41:1218–1225.