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Hygienic safety of the EasyOne Pro LAB (nidd, Zurich, Switzerland)

The EasyOne Pro LAB is a device for lung function testing and has been developed for application of the Multiple Breath Washout technique (MBW). The device is equipped with two disposables that are removed after each measurement: The Spirette® protects the inside flow sensor against bacterial contamination, while the Bariette® is mounted behind the flow sensor in order to prevent bacterial contamination of the bypass unit.

Hygienic safety of the Spirette® for MBW has already been demonstrated (publication: Fuchs et al, Ped Pulmonol. 2008).

For validation of the EasyOne Pro LAB for clinical use, proof of hygienic safety of the Bariette® is required as well.

Therefore, two series of swaps were taken from different localisations behind the Bariette® between July and August 2011:

- 1) Swaps were taken from the proximal surface of the silicone valve (LV), from the sampling tube for the side stream molar mass in front of the silicone valve (AS) and from the sampling tube for the side stream molar mass behind the silicone valve (FS). Swaps were taken before the first measurement of the series and after MBW tests in six healthy adults. A total of N=21 samples were sent for microbiology to HyGES mbH Mönchengladbach, Germany. No growth of respiratory pathogens was seen in any of the specimens.
- 2) Swaps were taken from the proximal surface of the silicone valve (LV) before the first measurement and after completion of MBW measurements in each of 19 healthy children and adults and 5 patients with Cystic Fibrosis. A total of 25 samples were sent for microbiology to HyGES mbH Mönchengladbach, Germany. No growth of respiratory pathogens was seen in the specimens.

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