

Clinical Validation

Objectives

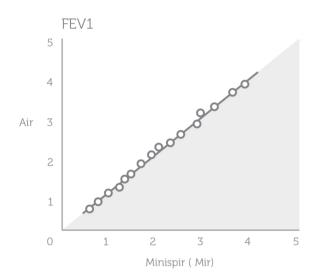
The main purpose of the validation is to establish whether Air Next Spirometer meets requirements, as specified by ATS/ ERS standards, for:

- Flow range
- Volume accuracy
- Flow accuracy
- Dynamic resistance

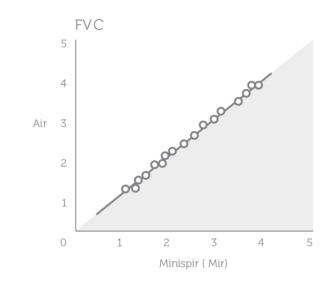
The validation performed is using a syringe calibrated pneumotachometer connected to two ATS/ ERS certified spirometers:

- Air Next Spirometer
- Jaeger® (DB, US)
- MiniSpir® (MIR, Italy)

Clinical validation Vs Minispir (MIR) 40 consecutive measurements were made and the order of the devices was changed halfway through the series (no effect of reversing the order was seen).

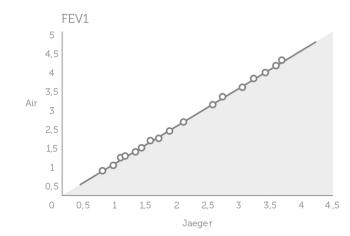


The correlation of FEV1 values between the two devices was extremely good with an r value of 0.999.

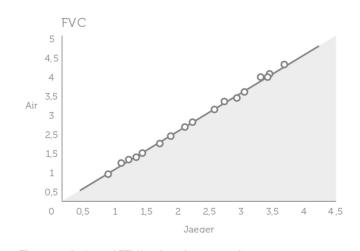


The correlation of FVC values between the two devices was very good with an r value of 0.991.

Clinical validation Vs Jaeger (BD) A factory-new pneumotach was unpacked and connected, and the MasterScreenTM was then calibrated with a traceable (ISO 17025) 3 L calibration syringe. A total of 50 exhalations, performed by 3 healthy persons, were registered.



The correlation of FVC values between the two devices was very good with an r value of 0.9972.



The correlation of FEV1 values between the two devices was extremely good with an r value of 0.9983

Measure your lung health in seconds with a professional spirometer

Breathing is everything. We breathe almost 1 billion times during our lifetime. And while most of us take breathing for granted, for 1 out of every 10 people breathing can be a struggle. Understanding your lung health is vital to living life to its fullest.

Air Next, the first bluetooth spirometer connected to a smartphone that measures your lung health in seconds, anytime, anywhere.



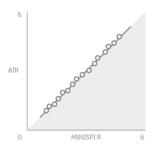
Quality

Air Next Spirometer is CE certified as a Class II Medical Device and developed according to the ISO-26782 standards.



Ultra-portable

With its compact size and cordless (bluetooth) battery operation (2x AAA)



Accuracy

Air Next is as accurate as a desktop spirometer and developed following ERS and ATS standards.



Maintanance free

With the hygienic and high precision disposable turbine there is no need for calibration.



Intuitive and clear

Powered by an user friendly app to guide and inspire the user throughout the test.



Delivered in style

The device comes with a disposable turbine, 2x AAA batteries, user manual and a cotton carrying bag all in a stylish package.



Sharing made easy

Physicians and Patients can share their spirometry results with a touch of a button.



Everything in place

With attention to detail and simplicity in use, to instill trust with the user right out of the box.

Safety Air Next has been used by thousands of patients and physicians around the world and no adverse events were reported. No additional risk can be identified compared to the numerous spirometer models that have been on the market. No training of the end user is required from a safety perspective. However, as in all measurements of clinical importance, the validity of data improves with some training so that the testing is performed correctly.

