

# White Paper

Observations made on a new spirometer based on pressure sensor technology

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## Purpose

This paper is written to give the reader an insight on the findings discovered in a mini-test using the Spiromagic® spirometer, which is based on a new pressure sensor Technology.

## Background

In 2016 founders of a medical company, today known as Spiromagic® contacted me. They claimed having found a new method of measuring lung function with a spirometer, using a highly accurate pressure sensor using the pitot tube principle instead of more commonly used principles like e.g. a turbine or pneumotach.

## Findings

In 2017 I received a number of spirometers from Spiromagic® with this new pressure sensor technology. I performed a mini-test limited to 20 medical students, 10 relatives incl. one with Asthma and myself. I also compared the new spirometers with high accurate benchtop spirometers that we use at the hospital. The outcome of the mini-test was positive. Although the new spirometer from Spiromagic® was not designed to perform inhalation measurements, the accuracy of the exhalation measurements performed, turned out to be in line with our benchtop spirometers, with an accuracy of < 3% for FEV1.

Except for larger deviations at PEF's < 1,0 l/s and FEV1 & FEV 6 < 0,6 Liters, measurements performed on a calibrated lung machine (ISO13485 test lung) with > 10 devices at various flows, was consistent with my first findings. The devices that we used seem to both measure accurately within the flow and volumes measured, showing both stability and good reproducibility over time. Spiromagic claims that they have had devices back from the field after several years of use, showing no signs of drift. I have no evidence to support the correctness of this statement.

The spirometer connects to a smartphone where data can be viewed. Spirometer values like PEF, FEV 1, FEV 6 and FEV 1/FEV 6 ratio etc. is shown in the Graphical User Interface as well as the weather condition at the present location. The tests that I initiated with the persons stated above, performed well and the test persons where in general content operating the device, finding the app intuitive and easy to use with no or little introduction required. Additionally, the test persons found the spirometer to be small and handy. I found the mouthpiece to be optimal from a cross contamination point of view, with very low risk of passing on diseases from one patient to another, provided the mouthpiece is changed for every new patient. On some spirometers one only exchanges the mouthpiece / part where the patient's lips are in contact, whereas the remaining parts e.g. rotating parts potentially can result in contamination of the next patient. Other spirometer designs require a bacterial filter to be mounted, to avoid contamination.

## Conclusion

Despite the limited scale of testing I believe that the spirometer from Spiromagic®, that recently achieved the CE Medical Device certification Class IIa, could be well suited for general screening purposes of patients with pulmonary diseases, and for self-monitoring. Profound investigations of patients however, has to be conducted using a table top spirometer with extensive features, including capability of exhalation and inhalation measured at any flow required.