

Rapid Prototyping using 3-D-Printer Technology for Development of Breath-Test-Analysers

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Introduction

For medical device technologies, there is the need for more cheap and smaller devices. The question is to bring technology into the Homecare-field which until now is expensive and therefore based in hospitals and medical practices only. Breath tests may be future technology for non-invasive and self-test devices for different disease-states also besides lung function tests [1].

Material and Methods

Based on the knowledge for clinical device design for single breath tests for expired nitric oxide, there was the question for a multi-use handheld device with possible connection to data logger like PC, Tablet or as stand-alone device. 3-D-Printing technology was decided for use for rapid and repetitive design specifications in functional models.

Results

By 3-D Printing within a short time it was possible to test variants of devices. Especially the sample tubes, airflow channels, valves, flow resistances were tested for functionality in real settings together with electrochemical sensor and electronic part.



Fig. 1) Examples of three different housing from 3-D-Printing

3-D Design enables multiple design modifications and functional tests to improve and make cheaper the development.

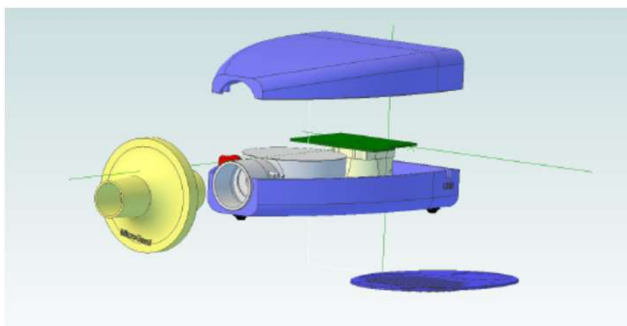


Fig. 2) 3-D Explosion-Drawing of the feasibility design study.

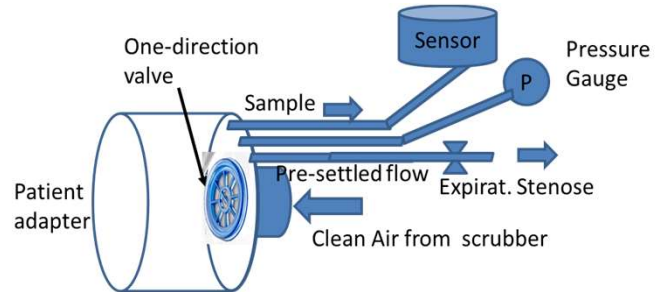
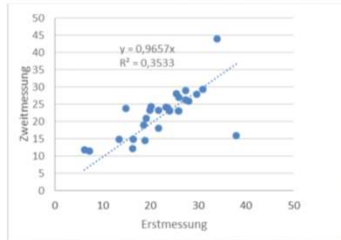


Fig. 3) Flux model for standardized sampling of breath probes

It was possible to achieve the same functionality by simplifying the design. The omit of the generally used breathing tubes allows a better infection prophylaxis by minimizing possible contaminated and re-breathing areas.

Fig. 4) One functional model for standardized sampling and Measurement of gaseous probes

Fig. 5) Reproducibility of duplicates for real expiratory NO-measurements



Conclusions

3-D Design and 3-D Printing is a rather new method for rapid functional design studies for functional evaluation for sensor applications, everywhere available.

Different available filaments for 3-D-Printers are certified as medical grade materials and may be used as short and long term solutions for housing and material testing.

The device is functional suitable for testing of exhaled NO, a marker of airway inflammation, in ppb-range. The device may be suitable for use in Homecare-applications as Self-testing device. The Standardization of sampling and measurement is mostly given by pressure and flow-resistors. Nevertheless the volunteer has to perform a specific breathing exercise. Repetitive measurements has had a correlation coefficient of >0.95.

Application of other sensors for breath tests into the same housing is very easy.

(Patent pending 2017)

Reference

[1] G. Becher: Atemkondensat-Diagnostik (Exhalat-Diagnostik); In: „Spezielle Lungenfunktionsprüfung“, Hrsg.: Prof. K.-H. Rühle, München: Dustri Verlag Dr. Karl Feistle, 2013, S. 105-124.