

Statistical investigations about the repeatability and reproducibility of a 4-phase-rhinomanometer and PNIF

Klaus - Dieter Wernecke/ Germany
Rudolf Viksne/Latvia,
Klaus Vogt /Germany and Latvia

1



ERS & ISIAN, Thessalonike, September 2021

The Authors declare no conflict of interest

Why do we need a systematic analysis and review of nasal function tests ?

2

- The introduction of physically based nasal function tests into the clinical practice started about 50 years ago by COTTLE (head-out-plethysmograph) and MASING (rhinomanometry). After the introduction of computer aided rhinomanometry (Vogt&Wernecke, J.Pallanch, E.B.Kern) it was necessary to create international standards. The International Standardization Committee for the Objective Assessment of the Upper Airways (ISCOANA) was established in 1983 by the International Rhinologic Society as a consortium of medical doctors
- **After the standard of 1984 no progress according to new techniques was considered or published by ISCOANA!**
- A standard in function tests has to be created by physicists, technicians, statisticians AND physicians! The criterion of a medical standard is
 - **EVIDENCE BASED MEDICINE !**

Riga 2016 – a new begin

3

- By invitation of the University of Latvia a group of experts in aerodynamics, mathematicians, physicists and engineers and clinical rhinologists resumed the state of art in functional rhinology and created new standard, which was published in 2018

K. Vogt - G. Bachmann-Harildstad - A. Lintermann - A. Nechyporenko - F. Peters - K.D. Wernecke

The new agreement of the international RIGA consensus conference on nasal airway function tests

Rhinology 56-2: 133-143, 2018

- The participants of the conference started together with the German SMEs MedContact and Sutter the **Rhinodiagnost-program** supported by the Austrian and German Government



The aim: Evidence Based Medicine (EBM)

4

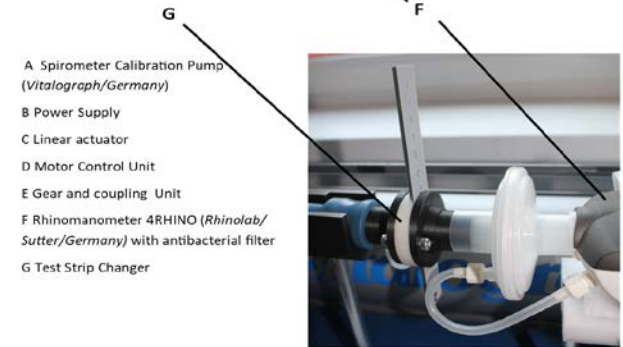
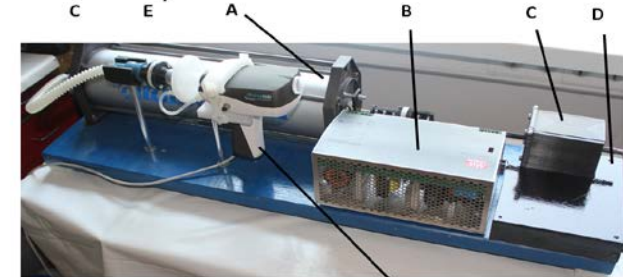
Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

The practice of EBM means the integration of individual clinical expertise with best possible external evidence from systematic research and correct technical equipment.

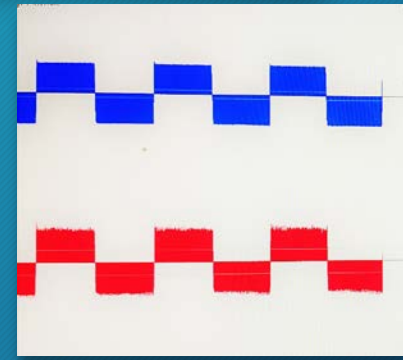
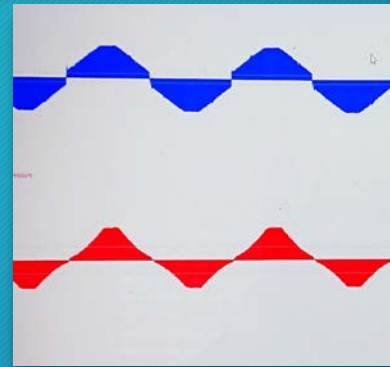
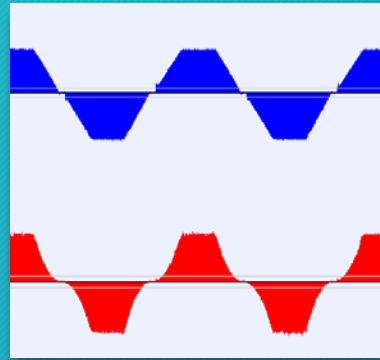
Sackett, D.L., Rosenberg, W.M., Haynes, R.B., Richardson, W.S. (1996): Evidence based medicine: what it is and what it isn't. BMJ, 1996, Jan 13; 312(7023); 71-2

Technical reliability

Simulation of the nasal airstream as tool for reproducibility and quality management



- A Spirometer Calibration Pump (Vitalograph/Germany)
- B Power Supply
- C Linear actuator
- D Motor Control Unit
- E Gear and coupling Unit
- F Rhinomanometer 4RHINO (Rhinolab/Sutter/Germany) with antibacterial filter
- G Test Strip Changer



Variability of 4 serial 4-phase-rhinomanometers

	Lreffln	Lreffex	Lreff	LVrin	LVrex
Mean	0,951	0,902	0,926	0,963	0,932
SD	0,018	0,015	0,017	0,035	0,025
N	46	46	46	34	34
SD % of mean	1,91	1,67	1,79	3,63	2,66

Measurement Capability

7

This includes in particular:

- Precision and accuracy of measurements as given by technical equipment,
- Software details (evaluating gauge repeatability and reproducibility),
- Variability of the given process,
- Statistical analyses by using two-way analyses of variance,
- Agreement with other methods of measuring,
- Comparability under different clinical conditions.

Measurement Capability: Results

8

- 4-Phase-Rhinomanometry is reliable and delivers correct parameters.
- The analysis of the total process variability by using two-way analysis of variance (ANOVA) resulted in significant repeatability and reproducibility of 4-Phase-Rhinomanometry
- PNIF is very good reproducible but delivers physical and physiological nonsens because of restricting any information about the physiology of the nasal valve.
- Statistically representative results of 4-phase-rhinomanometry in 36.500 cases show a remarkable influence of elastic deformation in 34%.
- **A method as PNIF completely neglecting the influence of elastic components is not acceptable as diagnostic method in clinical rhinology!**

Difficulties in Transferring Information

9

- Shortage of rational, transparent justifications about medical decisions in daily routine (about 60%- 80%)
- Rarely transparent, defective, slowly transfer process of research to practice (> 10 years)
- Precipitous implementation of procedures into practice without rational validation
- Increasing speedily aging of medical knowledge (half-value time up to 4 years)

Please, help us to avoid nonsens!

