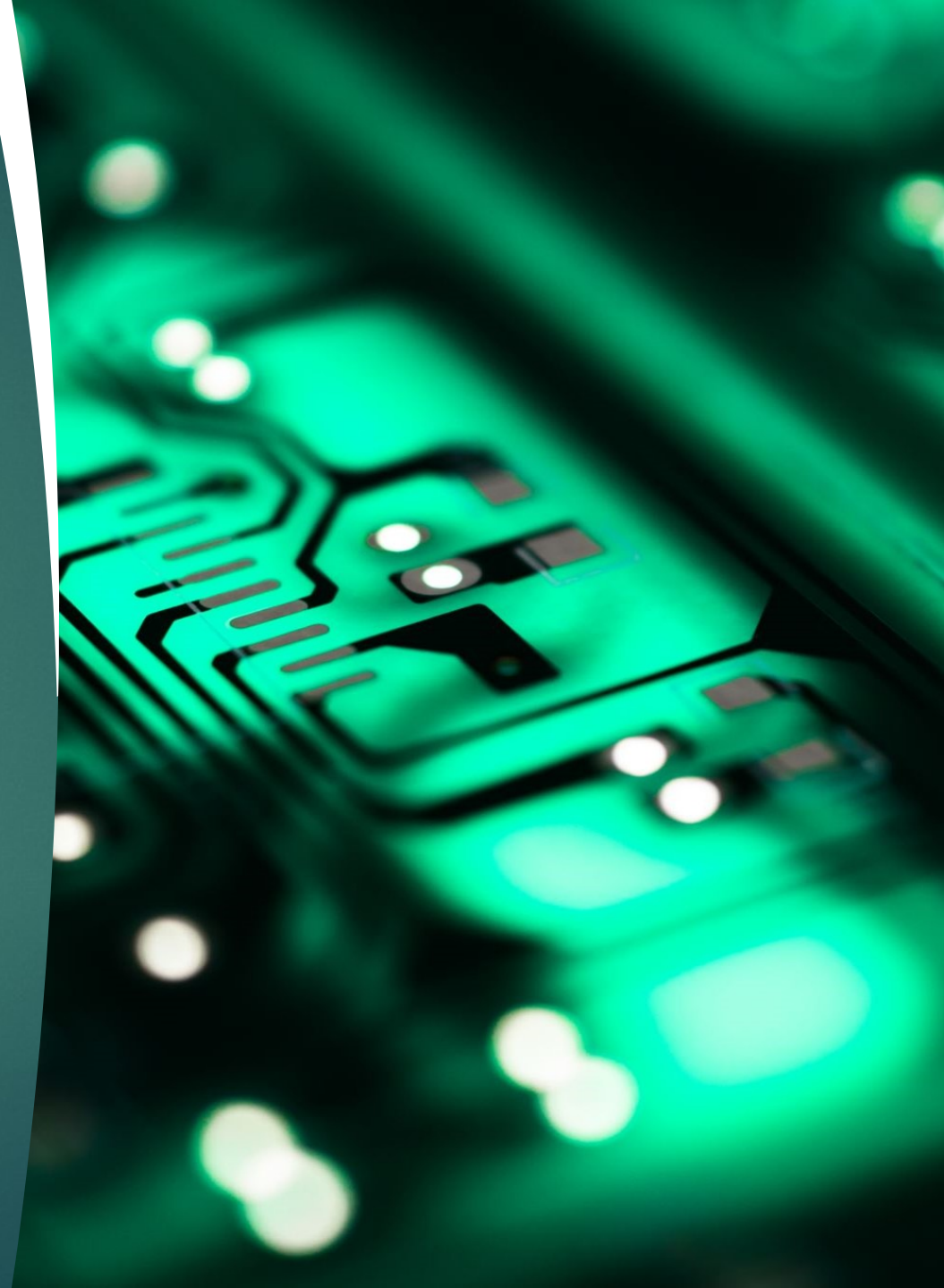
Development and first tests of a new 4-phase-rhinomanometer

CHRISTOPHER KOHN , MICHAEL STIER — MEDCONTACT GMBH, BURLADINGEN-SALMENDINGEN
MATTHIAS PRILL — GREVESMÜHLEN
DAVID LANG — EMBEX GMBH, FREIBURG /BSG.
KLAUS VOGT — SUTTER GMBH,FREIBURG BSG., UNIV. OF LATVIA

Aims

- To develop a technique for producing medical devices in low numbers in an economical way under the conditions of MDR
- Easy variability of the shape of entire devices or parts during the development and test processes
- A wireless rhinomanometer as an example for additive manufacturing



Hardware requirements for a contemporary rhinomanometer

- Easy to handle by unexperienced personnel
- Reliable cleaning and sterilization
- Wireless
- To combine with future diagnostical techniques (elastography)
- Low instrumental airway resistance
- High sensitivity and precision
- Electrical safety

Injection moulding or 3D-printing ?

- For 7 parts of the housing and connector more then 120 corrections and test prints have been printed
- Easy modification possible for additional connections for elastography
- 8 different materials tested for optimal results

4PR2

1.The sterilizable mass flow sensor, connector, silicone mask and pressure tube can be easily separated from the handpiece with electronic and battery

2. The bluetooth connection allows investigations in different body positions and in remote conditions as in environmental medicine and allergology

Software requirements

- Self explaining surface
- Implementation in documentation systems of hospitals, practice software or statistical evaluation systems
- Realisation of the principles of 4-phase-rhinomanometry including the classification of nasal obstruction and including a Visual Analogue Scale (VAS)
- Additional scientific mode for performing medical or experimental studies

4PR2

28 new updates of software for 4-phase-rhinomanometry

- Active anterior and posterior rhinomanometry
- Decongestion tests, multiple measurements, single unilateral and bilateral measurements
- Specific evaluation software for medical studies
- Included in the rhinomodul of the ENT-statistics program (INNOFORCE)
- Can be incorporated in different hospital and practice software

4PR2 Software

- Automatic zero calibration and uptake stop after 3 valid breathes, invalid measurements declined
- Automatic classification of resistances depending on age
- VAS included