Magnetic Localization of a Medical Tube inside the Human Body

- Application Example of Sensor Data Fusion -

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Intensive care medicine supports critically ill patients

Intensive care units in Germany [1]

- 1300 hospitals with 25.000 ICU-beds, 70-80% in use
- 10.200 high-care-beds with

  invasive ventilation systems
- ventilation duration from hours to weeks

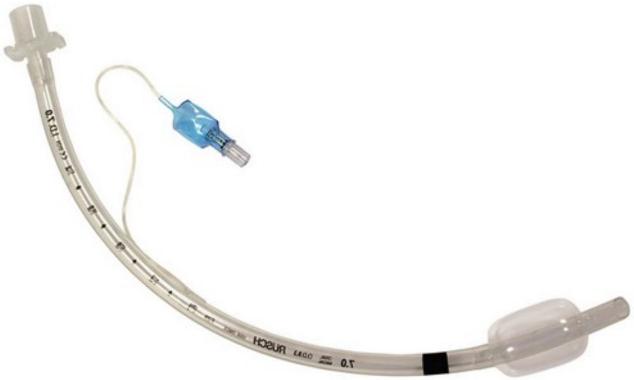
  (typ. 3-12 days)

- > 200.000 invasive ventilated patients p.a.

Ventilation as part of interacting technology in intensive medicine

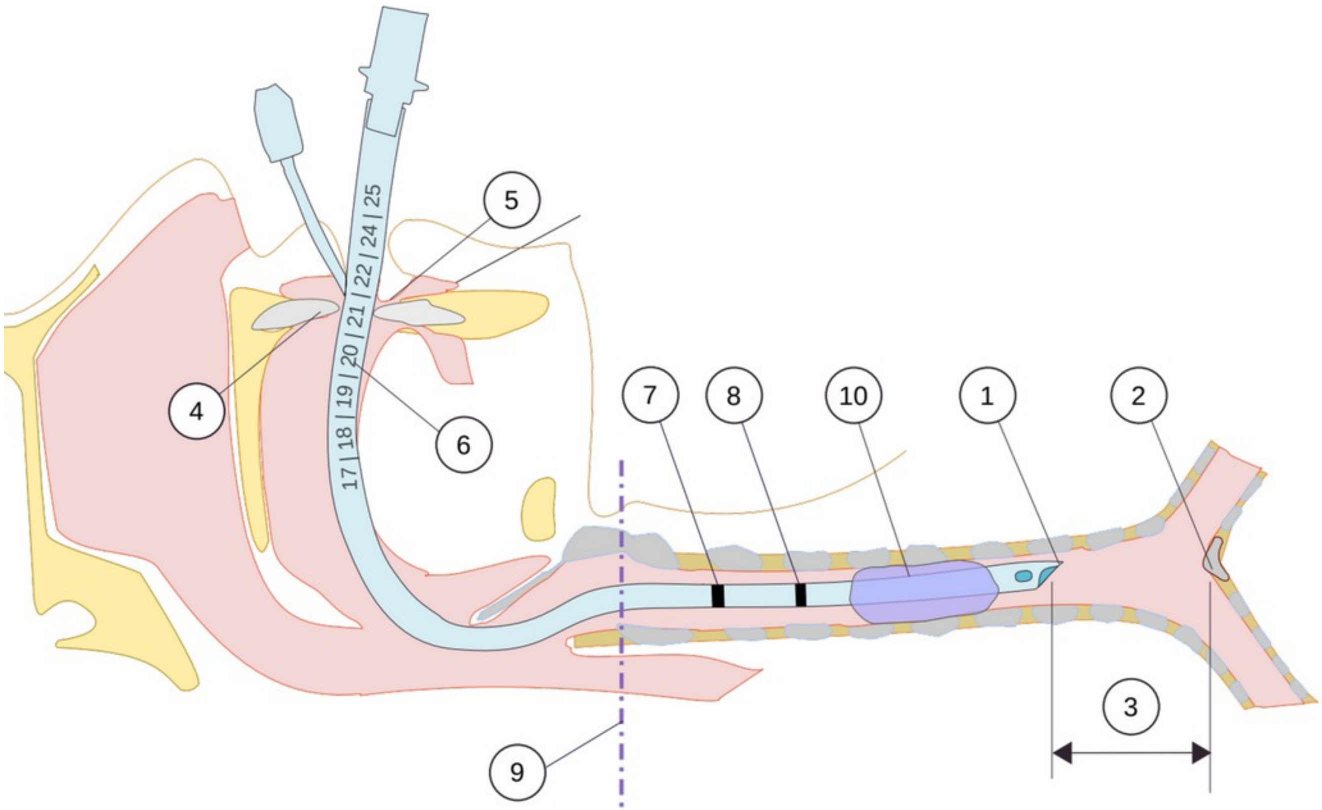
Complex intensive care systems

Ventilation system



Endotracheal tube (ETT)

Placement of the endotracheal tube (ETT) in the trachea



(1) Tube tip

(2) Carina

(3) Distance tube tip to carina (2cm)

(4) Row of teeth as reference

(5) Corner of mouth as optional reference

(6) Printed centimeter markings

(7) Ring markings for glottic passage

(8) Second ring marking (optional)

(9) Glottic level

(10) Cuff balloon

Clinical problem - unwanted displacement of the endotracheal tube

Accidental extubation incl. self removal of the ETT

- General risk factor in the intensive care setting
- Affects ~7% of ventilation cases [2][3]
- General patient endangerment and strong correlation with complications:

  ~ doubling of pneumonia cases with high mortality [2]

  ~ doubling of intensive care days [2]

SARS-COV2 pandemic (corona virus) -> increase of extubation events up to 300% [2]

- Long time ventilation with demanding sedation management
- Patient situation particularly vulnerable to ventilation errors [4]
- Every unplanned extubation was an emergency situation and an infectious hazard
- Work overload and increased virus exposure of staff

Evaluation and monitoring methods for invasive ventilation

Frequency of Observation

Unique or Rare Snapshots — Continuous or Cyclical Aquisition

Level of Automation: High — None / Low

Level of Automation	Unique or Rare Snapshots	Continuous or Cyclical Aquisition
High	Large Radiology Equipment - CT *) - MRI *) *) Additional to other Diagnostic, Qualified Evaluation required.	Patient Monitoring - Ventilation Pressure - Expiratory Tidal Volume - Inspiratory Tidal Volume - Minute Volume - Leakage Volume - Respiratory Frequency - Capnometry ...
None / Low	- Bronchoscopy *) - Sonography - Chest-Radiography *) Mostly used in Clinical Setup, also in Combination with other Diagnosis	- **Correct Position of ETT** - Auscultation - Leakage Observation - Cuff Pressure Check *) - Visual Fixation Inspection - Change in Patient Position - ... *) Automatic Solutions available

Objective

Today:

Visual and other checks of the position of ETT :

- consumes staff attention
- are discontinuous

Our Vision:

- continuously operating automated system
- no/less staff interaction
- reliable real-time alarm

Approach to address the clinical problem

Desirable system features:

Non-invasive system (outside human body) + suitable for continuous use

No staff binding → fully automated system

High specificity and sensitivity → avoids additional alarm fatigue

Deployment → consider operational effort, cost, compatibility, certification ...

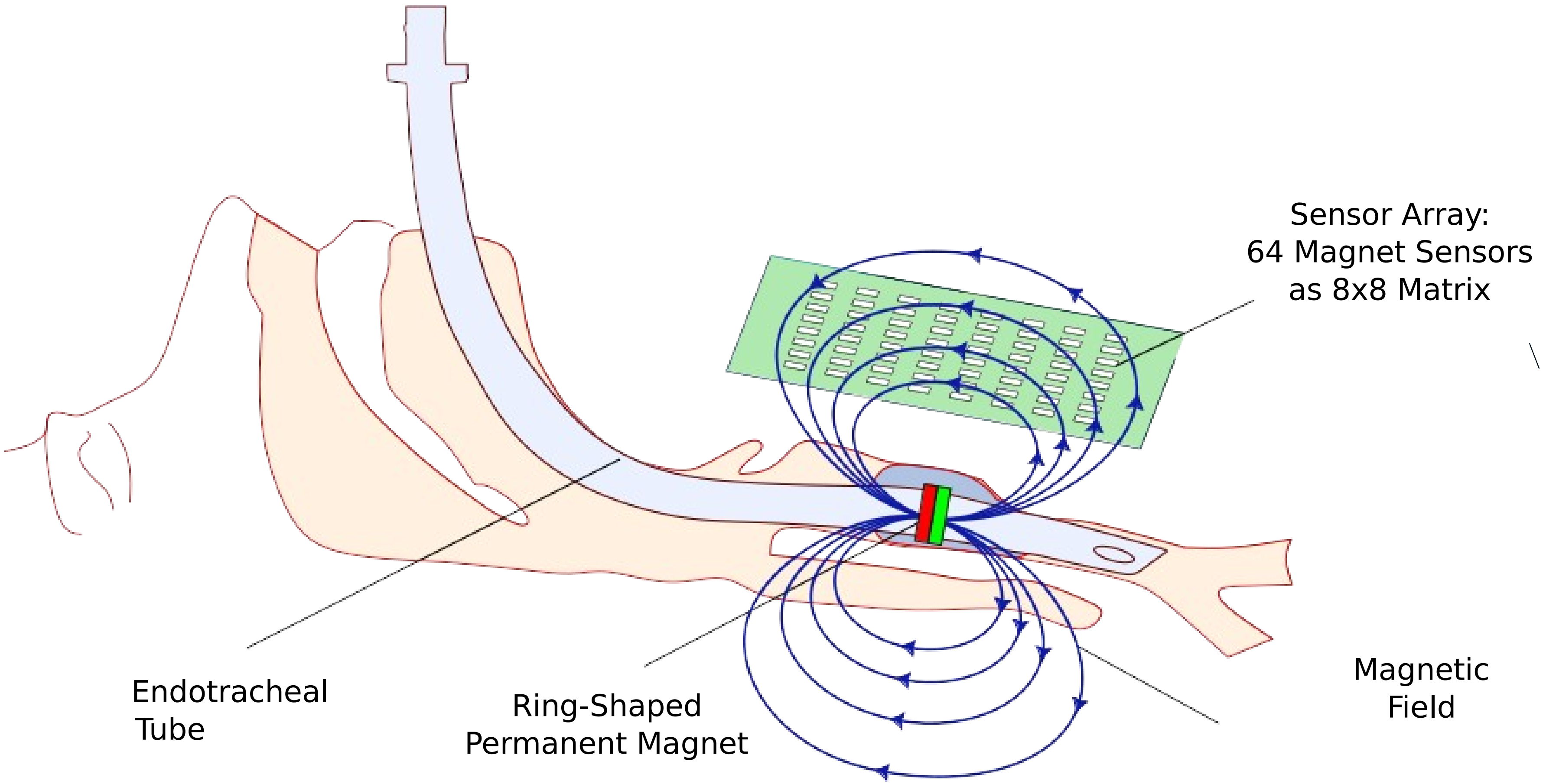
Additional wish list:

Early warning before complete extubation

Acceptance by medical staff is crucial

Seamless integration into ICU workflows

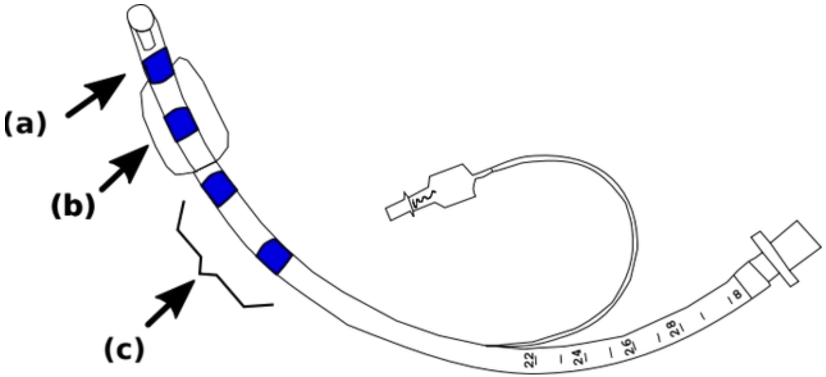
Concept of a dedicated position monitoring device for the ETT

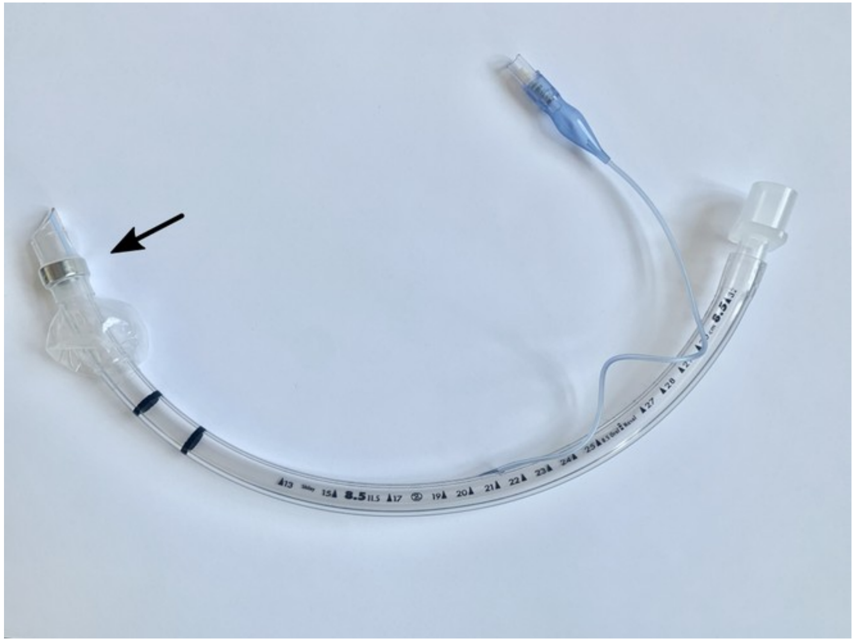


Technical Approach (I)

Magnetic field source:

- Static magnetic field (DC)
- Ring shaped permanent magnet (2 – 5 grams) - dimensions fitting to the tube
- Mounted in anatomical optimal positions at the ETT

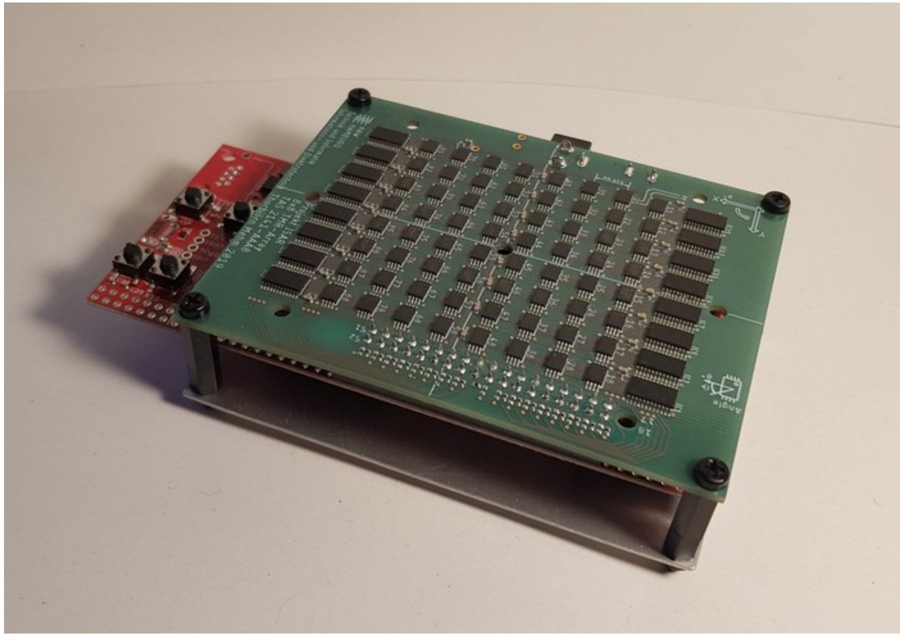




Technical Approach (II)

Large sensor array as 8x8 matrix

- Sensor chips based on Tunnel-Magnetoresitive Effect (TMR) delivers high sensitivity
- Access via analog multiplexer chips
- Control + Conversion: tiny “bare metal” microcontroller software (w.o. OS, strict real time)
- Data evaluation + visualization at PC-Environment (OS, Tools, non real time ...)



Hardware prototype:

- TMR Angle Sensor TAS2141-AAAB and TAS2143-AAAA

- Sensor array with multiplexer PCB [8][10]

- Microcontroller evaluation board

Technical approach (III)

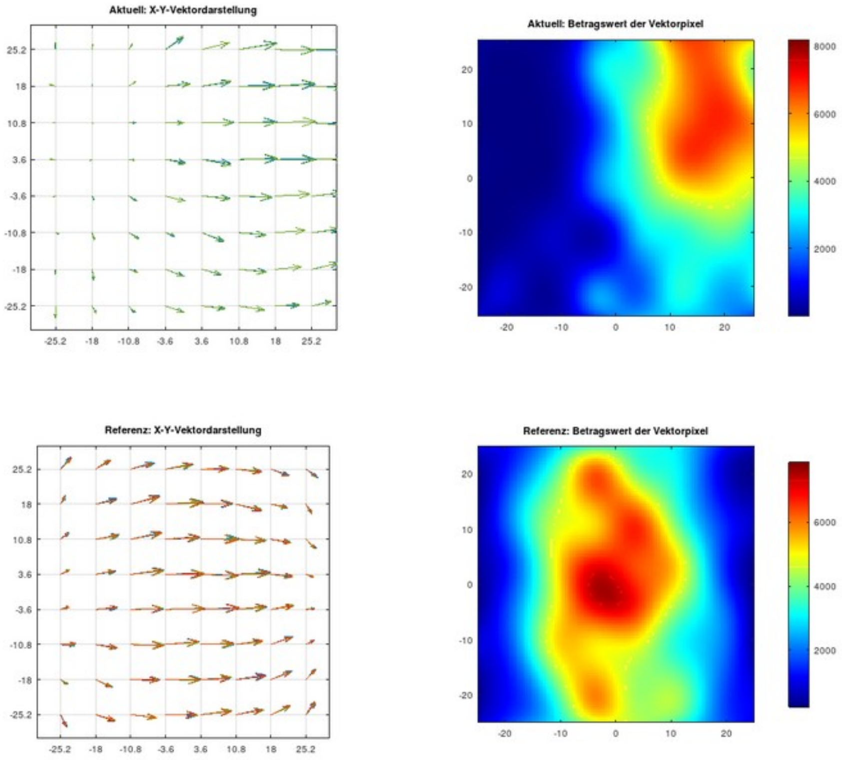
Algorithm should utilize the massive data stream from the sensor array

- 64 x 2 vector components data matrix has to be computed every few milliseconds
- Many sensor delivers best spatial resolution, but massive data to analyze with complex methods

Conceptional decision:

- deliberate avoidance of (early) data reduction
  in favor to exploiting available processing power

- use data with mainly redundant content:
  waste of computational effort, but stabilize the result

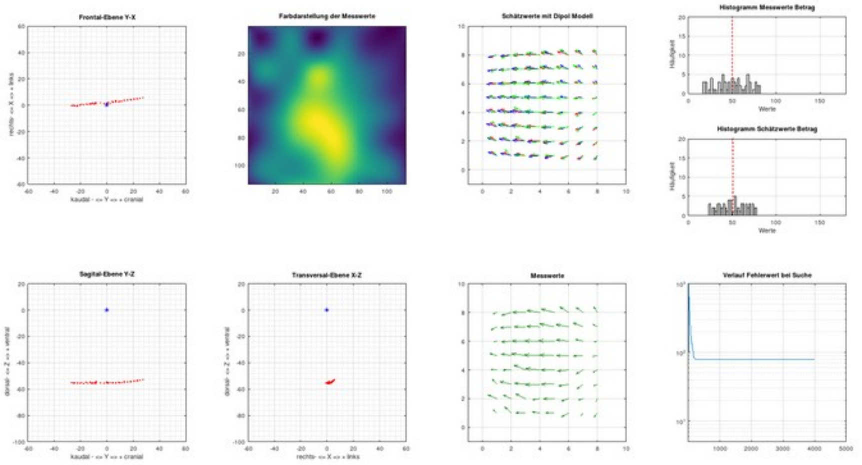


Technical approach (IV)

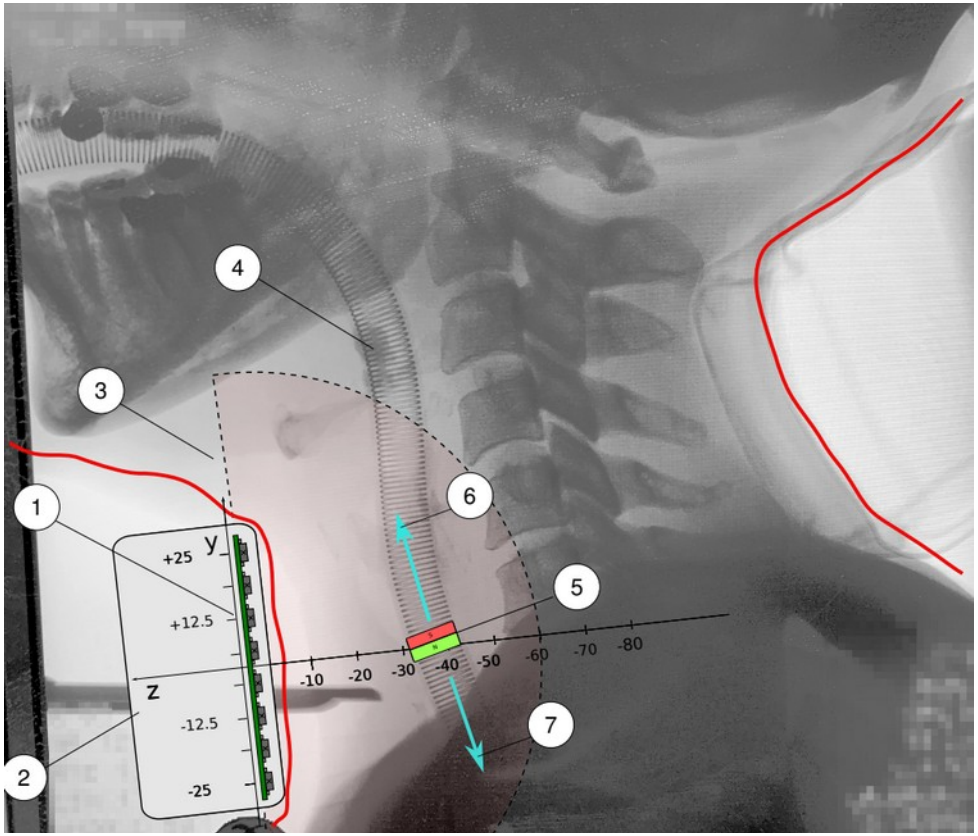
Rapid prototyping for software development

- Flexible development platform for many experimental variants with application feedback
- Open-source software, open interfaces, open community examples:

  Linux + first steps Octave => final C/C++ w. SDL2
- Tools Octave-GUI and C-lion with “moderate” AI-support
- Early, experimental visualization for data analysis + stepwise optimizing to real-time + ...



Detection area of ETT dislocation



(1) Sensor array seen from the side

(2) Monitoring device

(3) Marking of the detection area

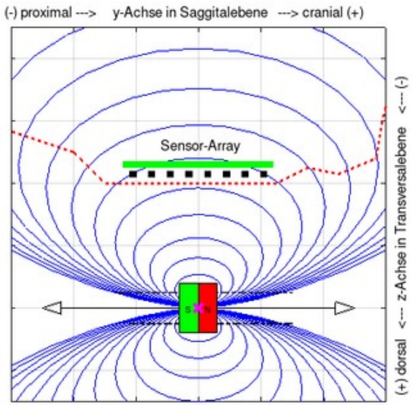
(4) Woodbrigde tube enforced with spiral

(5) Preferred ring magnet position

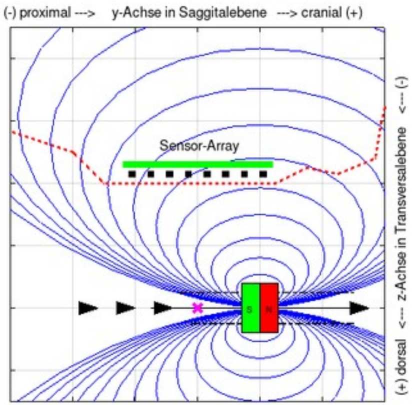
(6) Distal movement (upward)

(7) Proximal movement (downward)

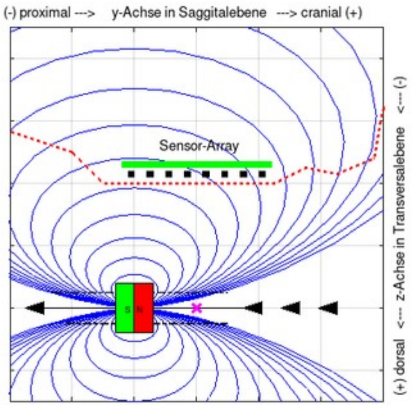
Shift of detected magnetic field = dislocation of the ETT



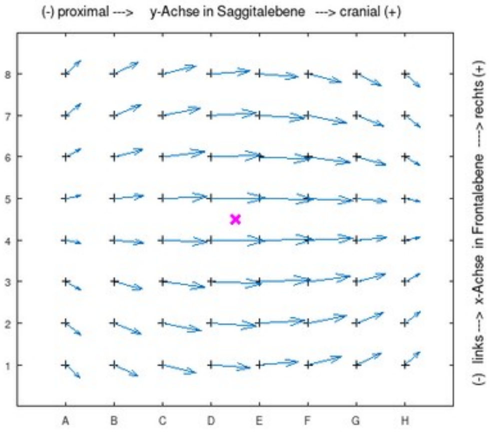
Magnet in Initialposition

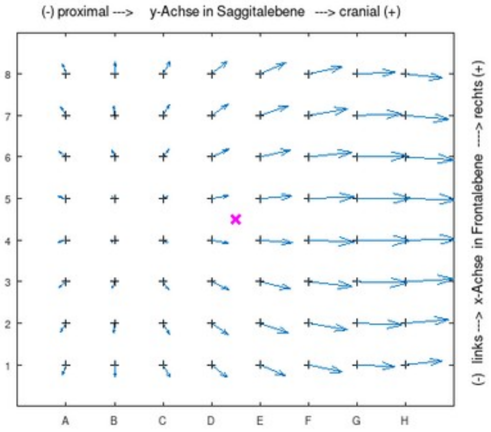


craniale Dislokation



proximale Dislokation





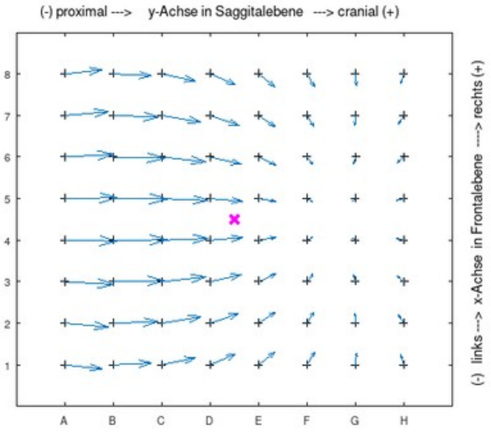


Image similarity as monitoring method

(1) Initial reference data set recorded

at correct position

(2) Cross-Correlation-Coefficient for reference

and recently measured data

(vector components and/or magnitude)

(3) Threshold values of this coefficient

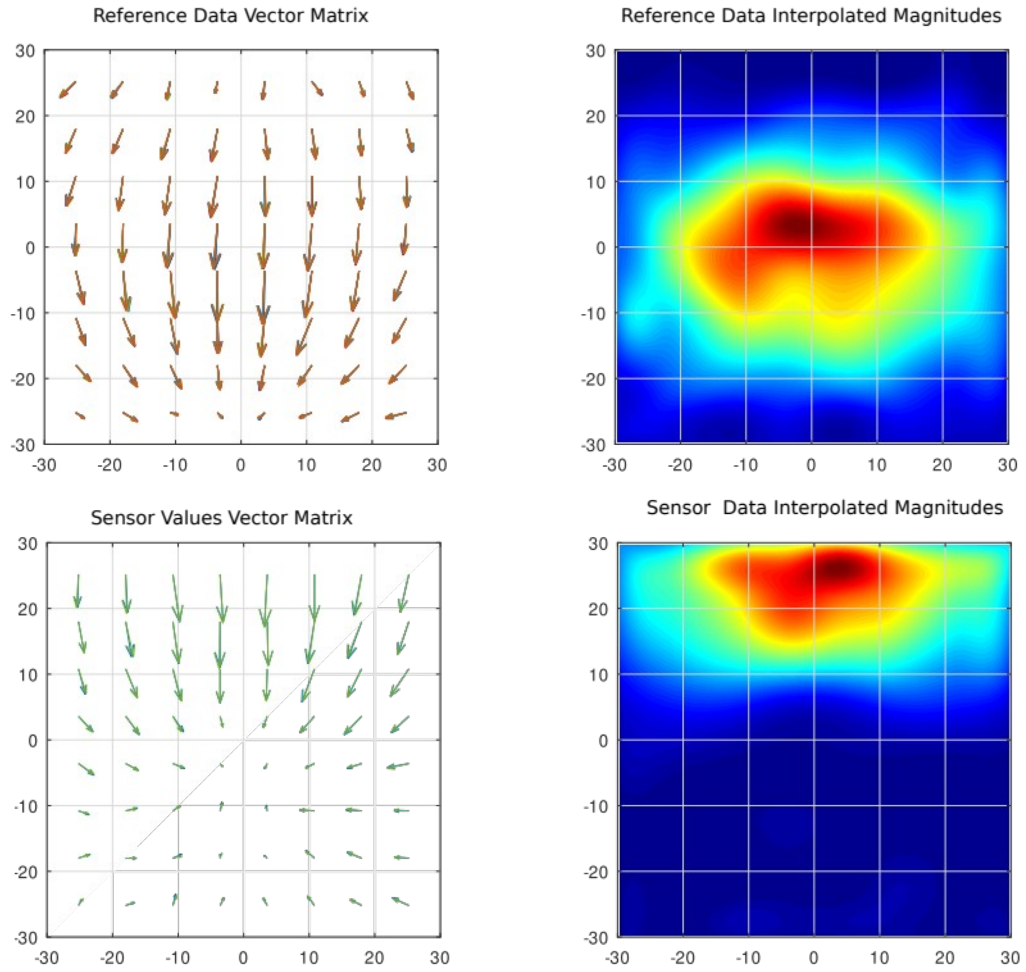
as trigger for warning and alarm

Experimental results:

Useful for limited dislocations

in range of array-dimensions ~ 50x50mm

Method is stable and easy to implement

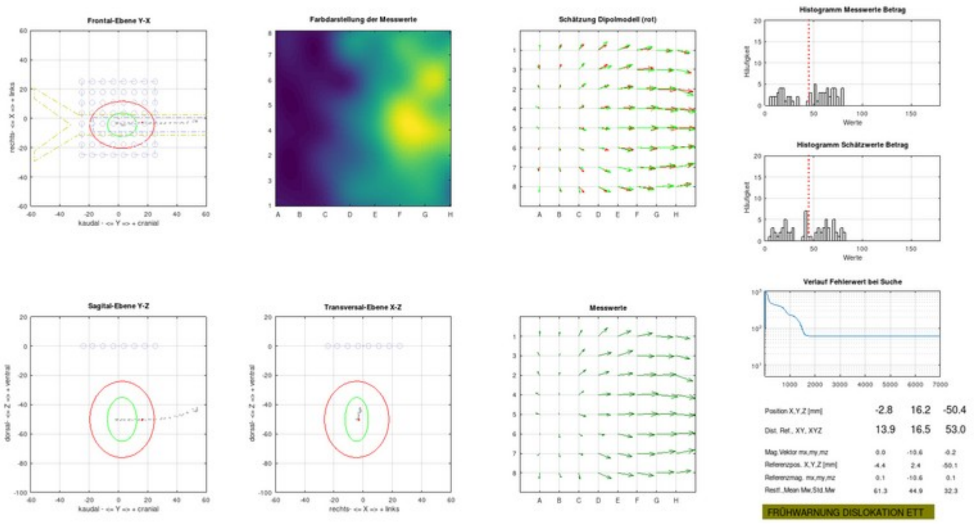


Localization of magnet position and orientation as monitoring method

- Localization Initial Reference Localization at correct position and sufficient signal quality
- Euclidean distance between current and reference localization
- Strict over-determined System, quantizied values, Six degrees of freedom ...
- Approximation search with randomly parameter variations

Experimental Results:

- Beyond array dimensions applicable: > 200 %
- Less efficient, but real time reachable
- Stability is sensible of signal quality



Powerful but more effort

- - for implementation

- finding best parameters

Localization as Inverse Problem Solution

Measurement = from physical cause to detected effects

Magnetic ring as real field source → Spatial relationship of source and sensor → Measured values of field strength by the sensor array

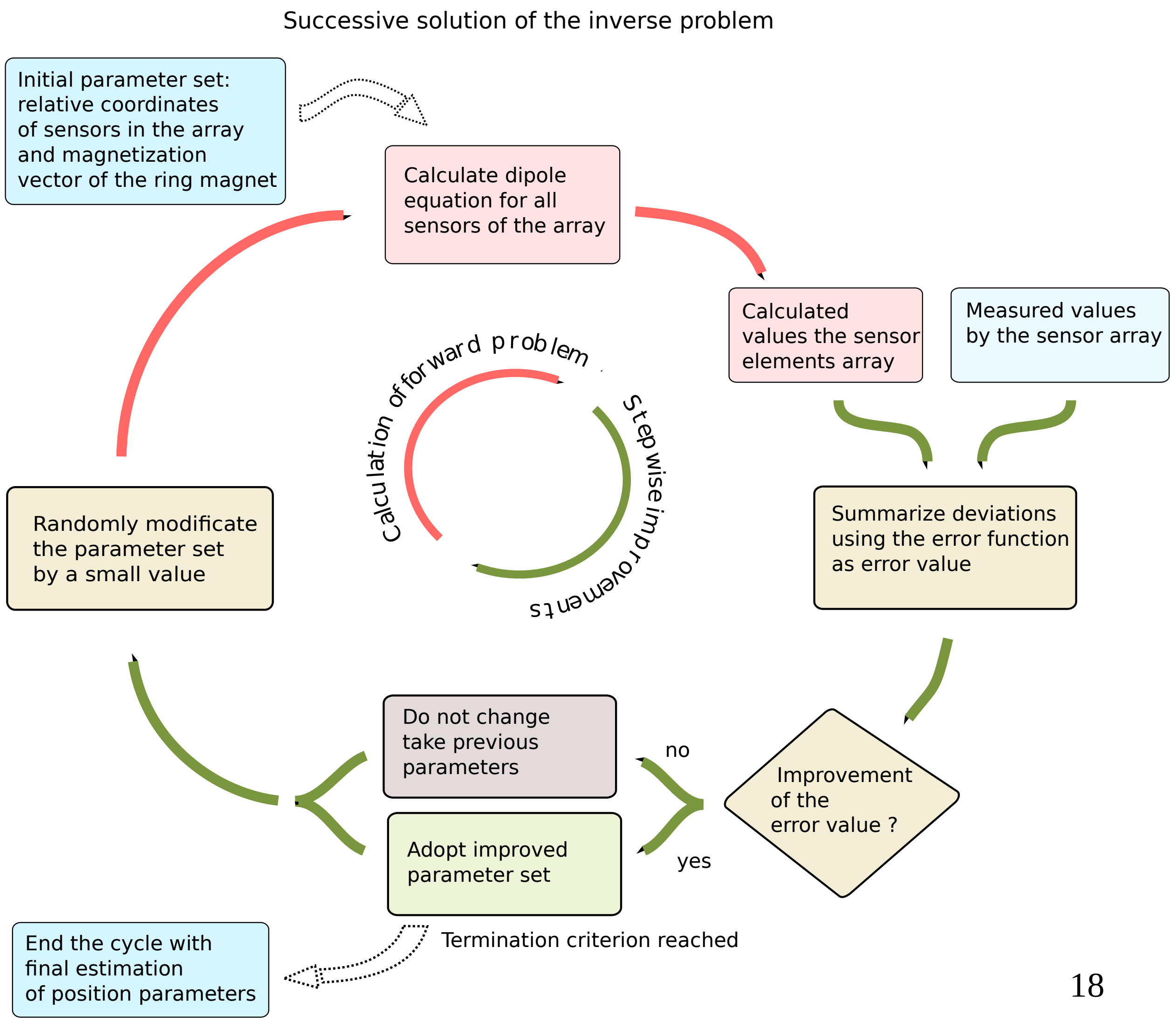
Forward problem = from cause to the effect

Dipole model with known dipole moment → Dipole equation with known spatial parameters → Calculated values of magnetic field by the sensor array

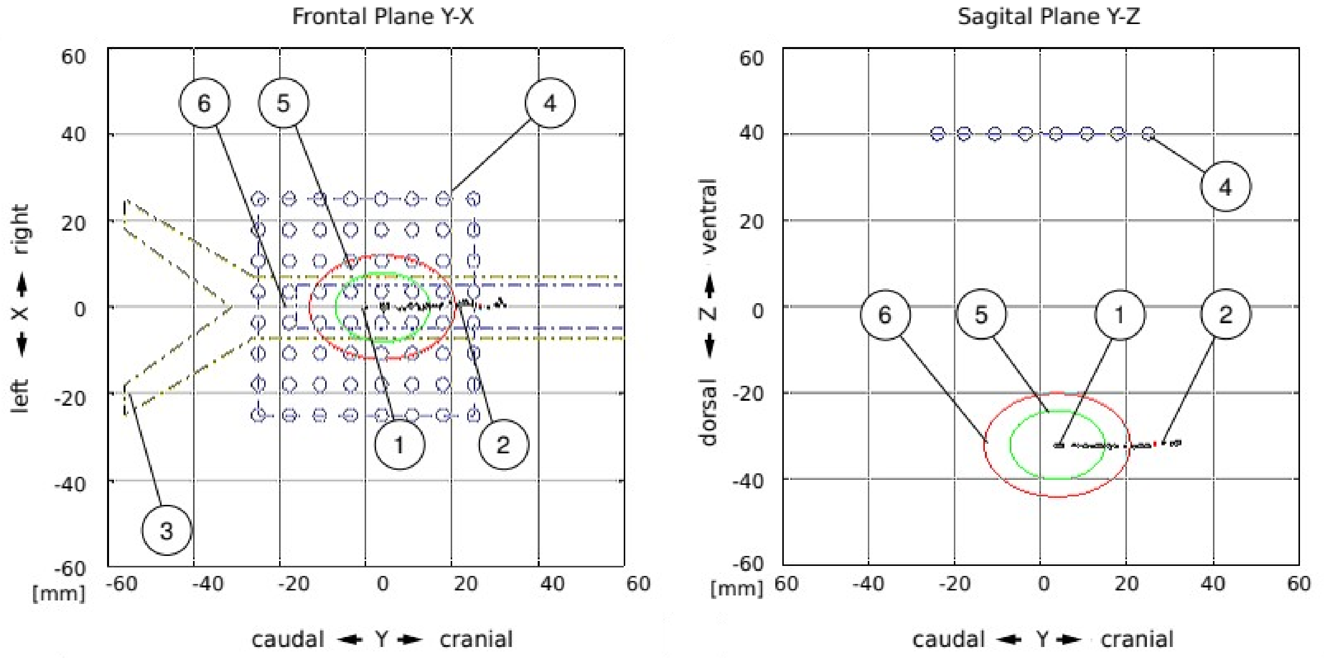
Inverse problem = from effect to the cause

Dipole model with known dipole moment ← Dipole equation with spatial parameters to be estimated ← Measured values of field strength by the sensor array

Stepwise search for the localization



Tracking of ETT movements with localisation series



(1) Initial reference position

(2) Track of magnet movement

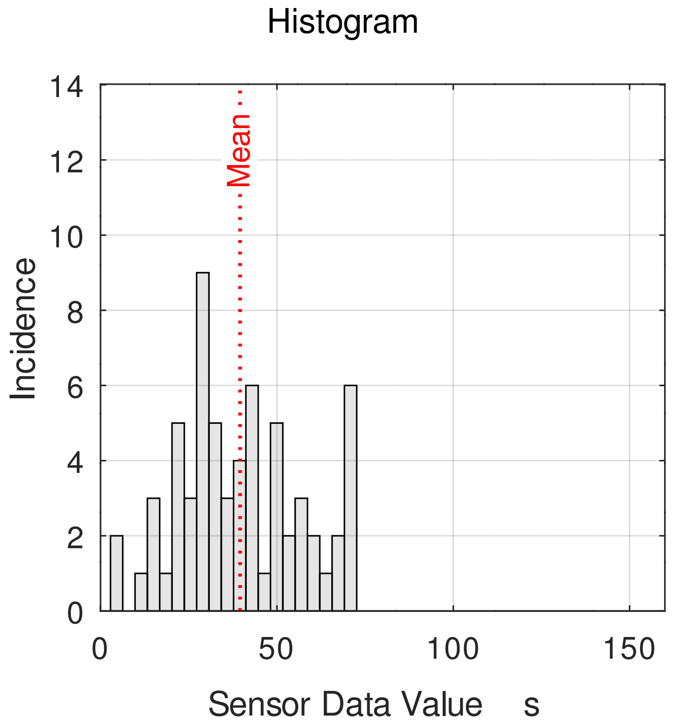
(3) Simplified trachea

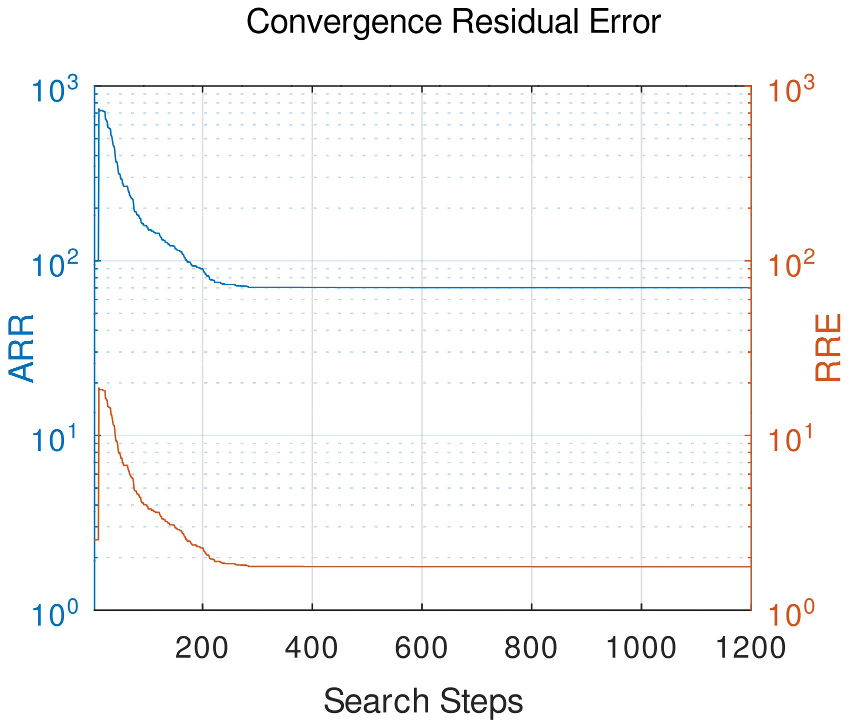
(4) Sensor array

(5) Warning threshold limits

(6) Alarm threshold limits

Additional Features: Signal quality histogram and convergence behaviour





ARR = Absolute Residual Error = raw value
RRE = Relative Residual Error = normalised to mean signal value

Examples of tube movement

Top:

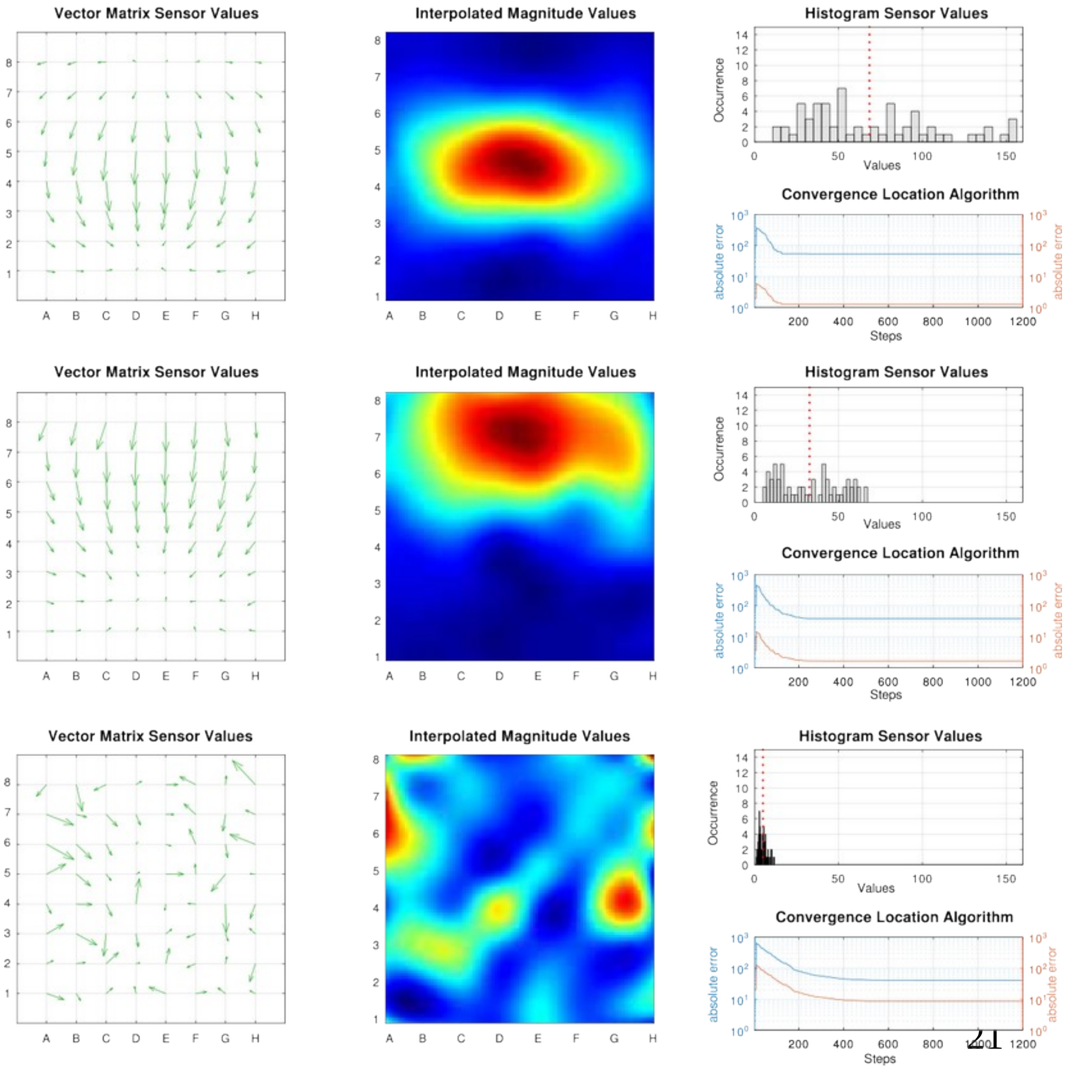
- Best inital position
- well distributed signal strength
- efficient convergence

Center:

- Moderate dislocation
- Adequate distributed signal strength
- Sufficient convergence

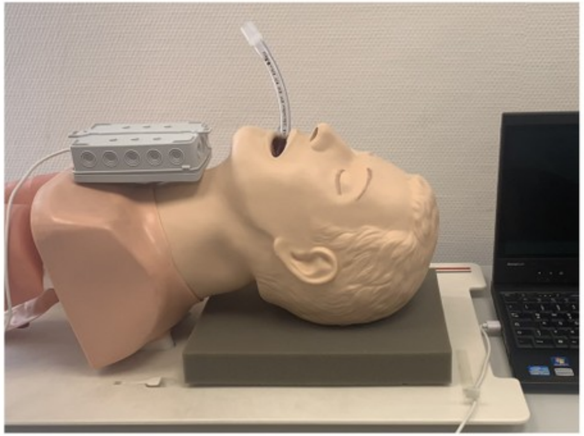
Bottom:

- Complete dislocation
- Weak signal strength, narrow distribution
- Convergence w. large relative residual error

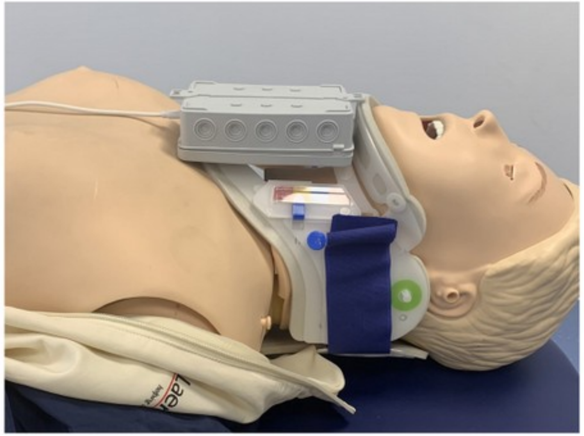


Demonstration at phantom dummy model

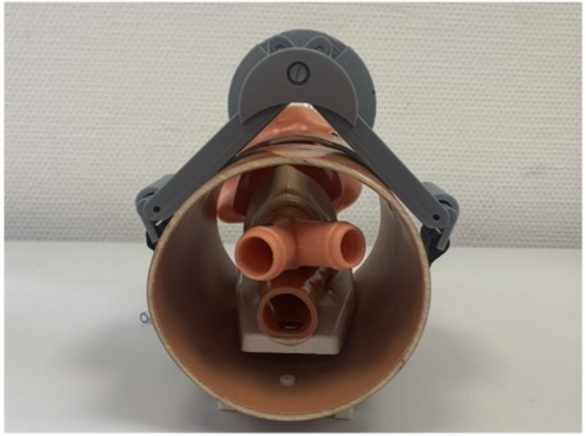
(a)



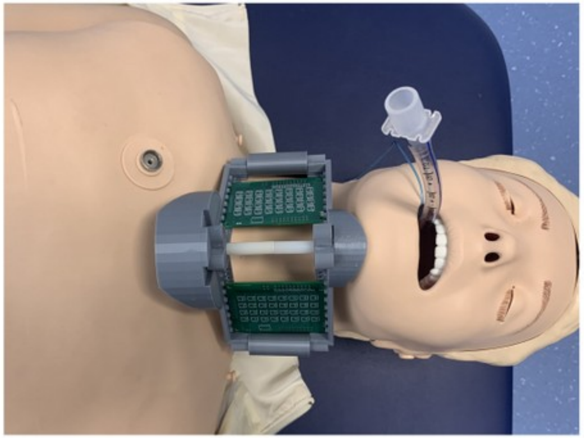
(b)



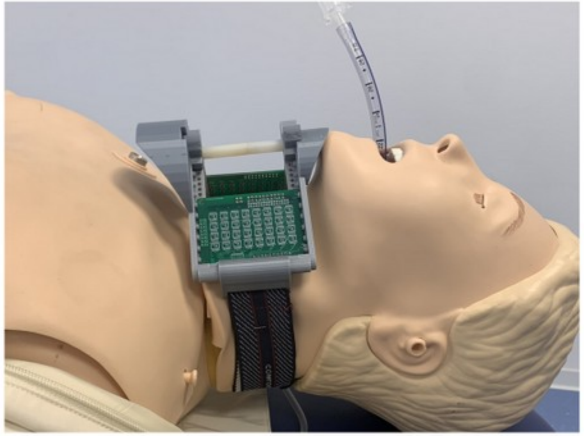
(c)



(d)

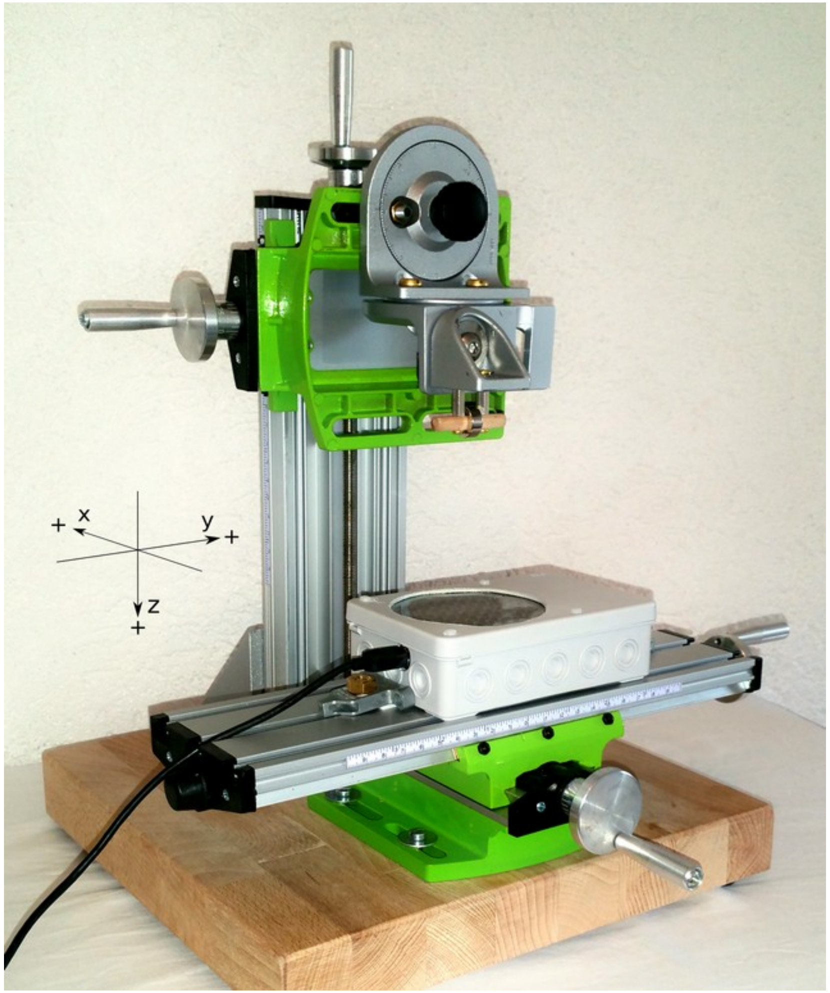


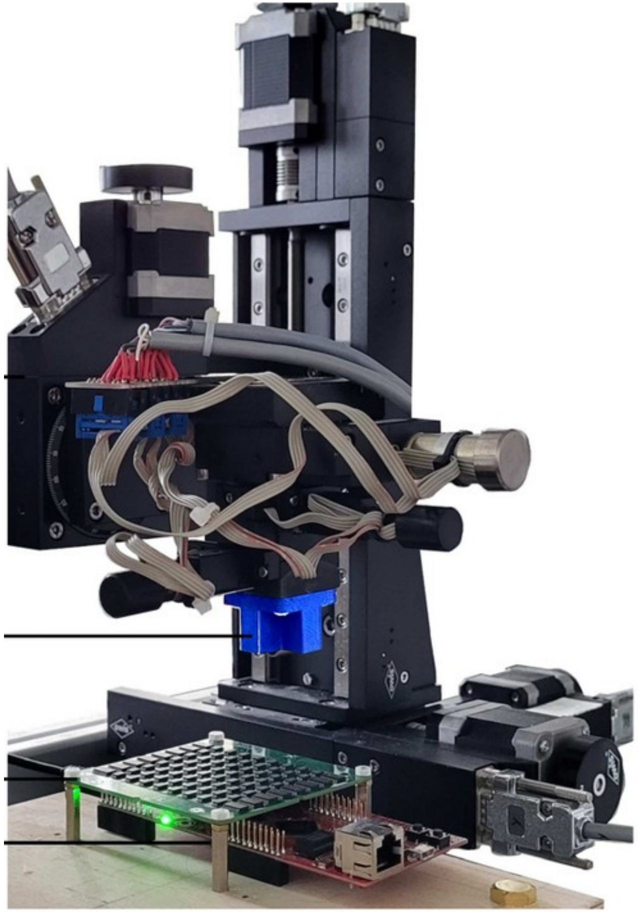
(e)



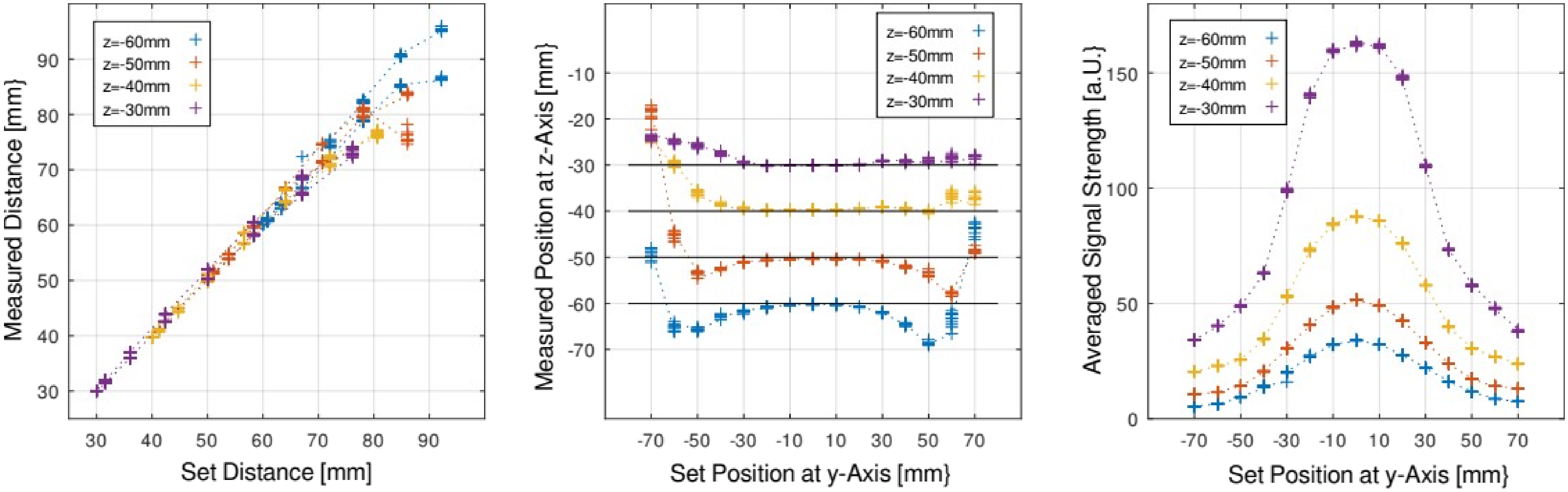
(f)

Mechanical and automated test setup





Measurement results



Next steps ...

Technical tasks

- Evaluation, combination image similarity + localization + other features with classification methods
- Testing further magnetic sensor types (analog amplification, 3D, digital Interface …)
- Improved system sensitivity = smaller ring magnet for smaller ETTs
- Earth-field and noise suppression by signal processing

Medical tasks

- Evaluation in the clinical practice, define requirements for the end users
- Statistical observation of the rate of dislocation events
- Combination with other ventilation and vital parameters
- Fixation for different anatomic circumstances
- Other applications, e.g. during surgical interventions or catheters

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