# "The i-Med experience of building a fast-lane to the clinic"





November 30th, 2023

Jaap Heukelom

(CCO, co-founder)

Digital Head-mounted Microscope 3D Imaging Platform



### What do we do:

### World's First Digital Head-mounted Microscope (DHM), 3D Stereoscopic imaging

#### Wins & USP's:

- +++ Less tissue damages and complications
- +++ Vastly improved ergonomics for surgeon
- +++ Faster and more integrated workflows (patient data)
- +++ More comprehensive surgical review & education

### Specialities who crave a DHM solution

#### Surgery

- Plastic surgery
- Cardio vascular
- ENT
- Neuro surgery
- Orthopedics
- Gynaecology
- Anatomy

#### Dental

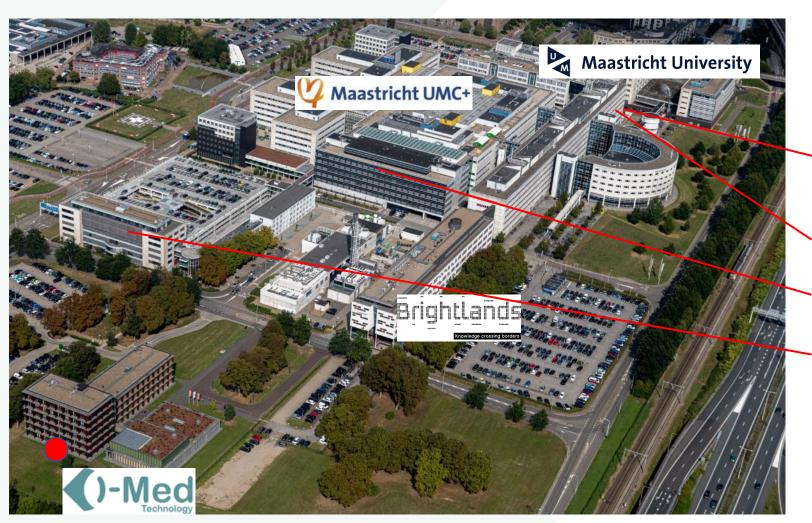
- Endodontology
- Implantology
- Periodontology
- Esthetic Dentistry
- Oral Surgery



Prof. Wouter Oosterlinck, UZ-Leuven Bypass surgery. 20-11-23



# Location @ Maastricht UMC+ Maastricht Brightlands Health Campus



#### **Brightlands Maastricht Health Campus**



120+ Healthcare Companies

Maastricht University MC+

- Surgical & Research training centre
- Anatomy & Embryology
- Operating Rooms 20x
- Training & Neuro surgery



### The i-Med journey, focus on regulatory and IP

• 2017-Oct First demonstration with 15 surgeons at MUMC+ "the idea was embraced" → Business plan made

• 2018-March Introduction European Vascular Course (1200 people)

3D Digital Head-mounted Microscope

• 2018-July Founded by Vincent Graham and Jaap Heukelom

• 2018-Q4 Start Regulatory documentation

2019-Q3 Patent request filed

METC MUMC approval for clinical OR trials

2020-Q2 Medical CE Certification MDD

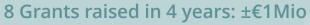
• 2023 Start MDR Process Class 2a, passed all EMC and electrical tests

2024-Q2 MDR 2a certification



Prof. Jacobs EVC Jan. 2018 First prototype















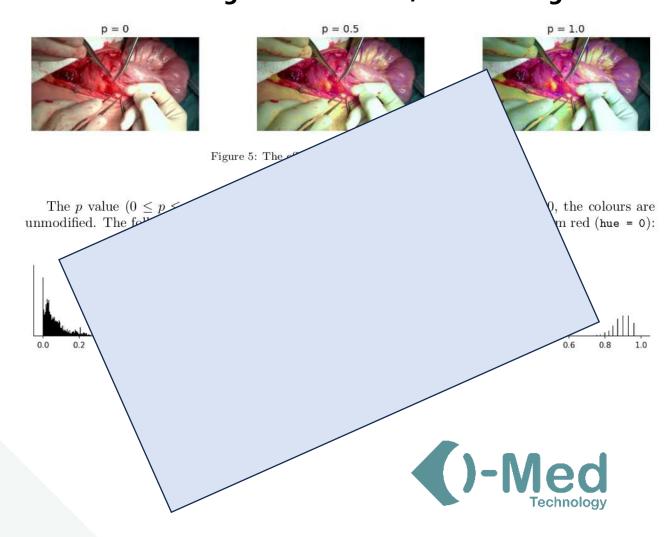


# Cooperation clinical trials for improved image quality



Maastricht University Medical Centre (UMC) Thyroid gland surgery, Prof Nicole Bouvy

### Red contrast image enhancement, filter testing

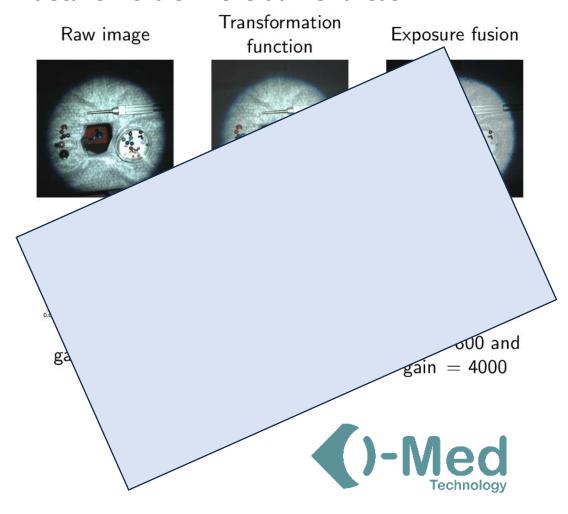


# Cooperation clinical trials for image quality



Zuyderland Hospital, Sittard Depuytren hand operation, 28-11-22, Dr Rutger Schols

# To prevent over exposure and get more details visible in the darker areas

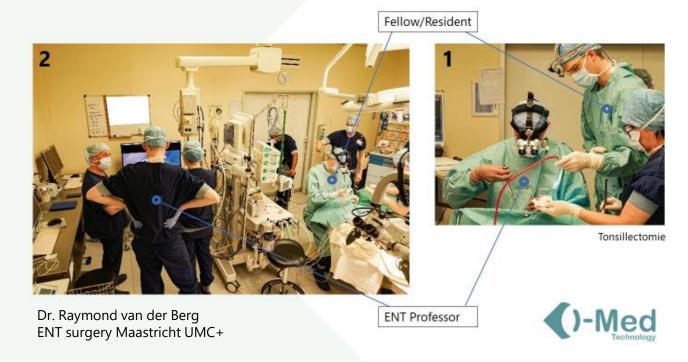


## **Cooperation education: Anatomie spine and ENT**



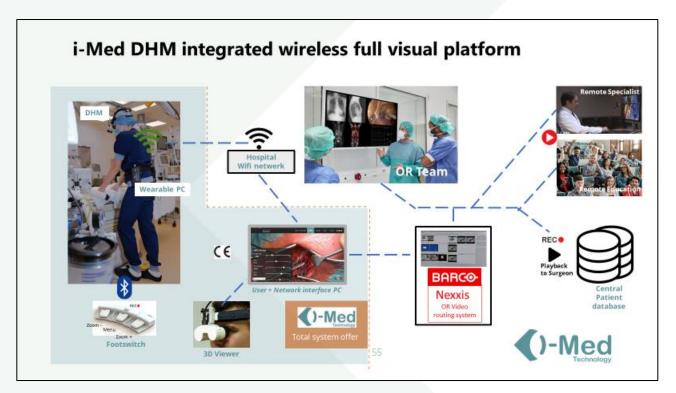
Prof. Henk van Santbrink Dr Andreas Herrler Anatomy Maastricht UMC+

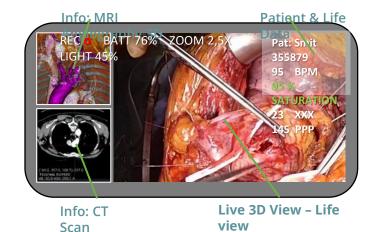
### Assist and assess surgeons/fellows/trainees during surgeries





# Cooperation technical OR trials integration & applications







- Picture in Picture scans & data
- 2-way streaming
- Conference setting
- Remote support, proctoring
- Hospital network integration



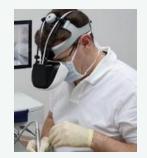


# Cooperation clinical trials for ergonomics, weight reduction



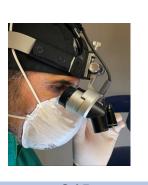


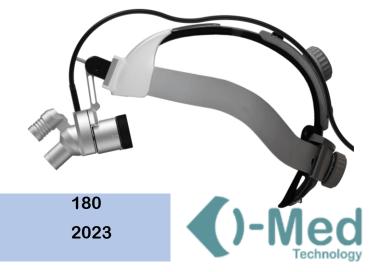
Eye Clinic Maastricht University Medical Centre Plastic eye surgery, Dr Asli Ayvaz











Gram 600 Year 2017 550 2018 340 2020

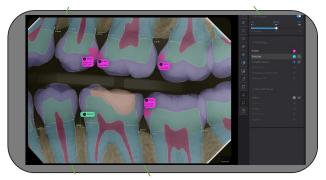
245 2022

### **Future challenges and focus**

- Forensic research
  - Patalogy
  - Materials investigation
  - Crime scene 3D
  - Court 3D Video evidence
  - ......



- Al: Artificial Intelligence
  - realtime big data access
  - analyses



Xray image real time analyzed by Pearl "second opinion

• Image enhancement.... "Making the invisible visible"



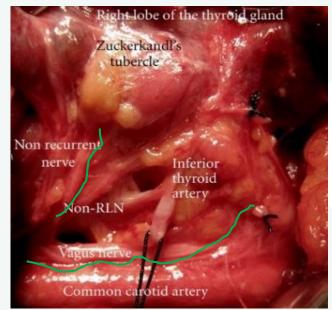
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## **Cooperation clinical trails innovative projects:**

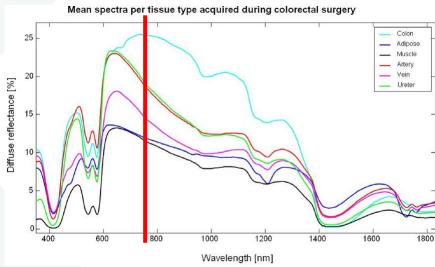
H3D-VISIOnAiR – Head-worn 3D-Visualization of the Invisible for Surgical Intra-Operative Augmented Reality

#### **Principle:**

Identifying critical anatomic structures example: NIR identification tissues, AR overlay



Normal sight (< 780 nm): difficult



Normal + NIR sight: easy



















### Making the fast lane to the clinic possible





Prof. dr. Dr Nicole Bouvy,
Professor of Innovative
Surgical Techniques
Surgeon at the Maastricht
UMC +
Head of innovative surgery.



Prof. dr. Henk van Santbrink Spinal Neurosurgery Maastricht UMC+ Faculty FHML Maastricht University



Dr. Andreas Herrler Ass. Prof., MSc Anatomie & Embryology FMHL Maastricht University



Prof. dr. Dr. Michael Jacobs, cardiovascular surgeon Maastricht and Aachen. Head of the Heart / Vascular Center at Maastricht UMC+ Head of Vascular Surgery at Uniklinik RWTH Aachen



Dr. Peter Bouckaert MD, PhD Ret. Gynaecologist surgeon i-Med Medical advisory



Dr. Raymond van de Berg, ENT-surgeon Head of the Vestibular Lab. and the Department of Audiology at Maastricht UMC+.



Fokko P. Wieringa (PhD) is Principal Scientist imec. Associate prof. of medical technology at Utrecht University



Prof. Dr. Rutger Schols
Plastic surgeon
Maastricht UMC+
UZ Brussel, heading Schisis team



Prof. dr. ir. Gabrielle Tuijthof Biomedical Device Design & Production at University Twente



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Compliant with following standards:

- 93/42/EEC Medical Device Directive MDD as amended with the 2007/47/EEC.
- IEC60601-1 Safety of Medical Electrical Equipment.
- IEC60601-1-2 Electromagnetic Compatibility.

