Digital Technologies: Using AR/VR/XR

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February 13, 2023

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Agenda

- Intro
- What is AR/VR/MR-XR?
- How is it used, e.g., Physician Training
- Technological & Regulatory Considerations
- Q&A

Did you know the first virtual reality headset was created over 50 years ago?

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What is VR, AR, MR/XR

Virtual Reality (VR)

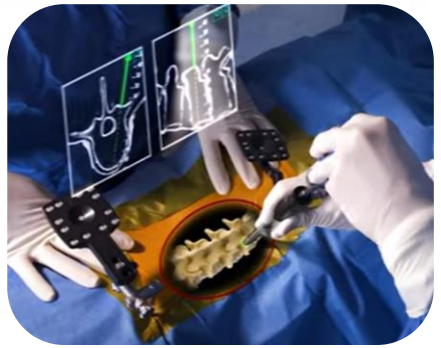
Completely digital environment. Fully enclosed, synthetic experience with no sense of the real world.

Augmented Reality (AR)

Real world with digital information overlay. Real world remains central to the experience, enhanced by virtual details.

Mixed Reality (MR)

Real and virtual components interact with each other. The virtual content is altered based on changes in the physical environment.



Relevant To Multiple Display Technologies

Virtual Reality (VR)

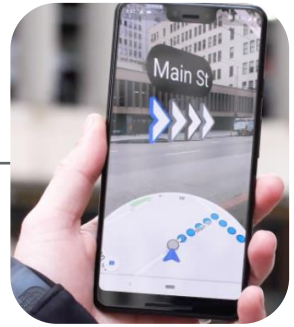
Augmented Reality (AR)

Mixed Reality (MR)

Headset

Fixed Viewer

Screen: Monitor / Tablet / Phone



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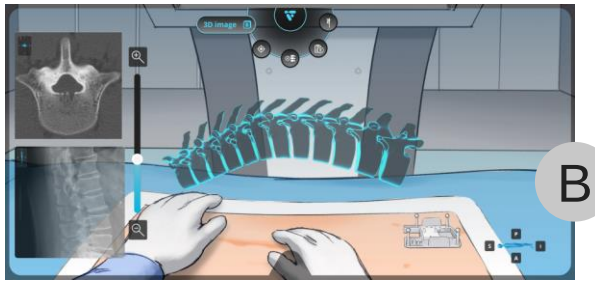
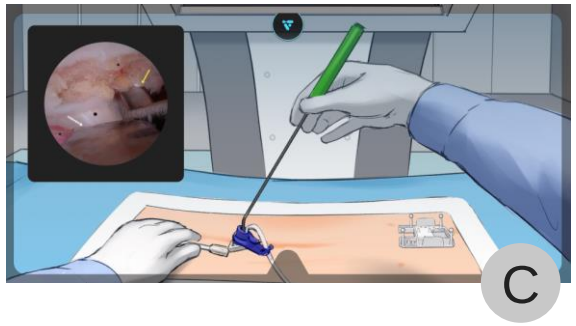
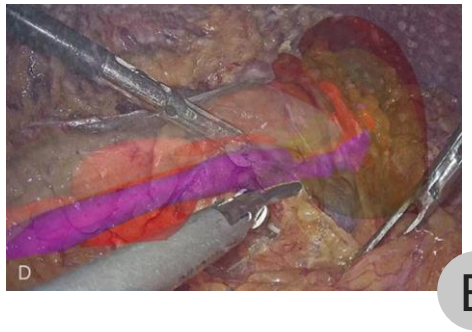
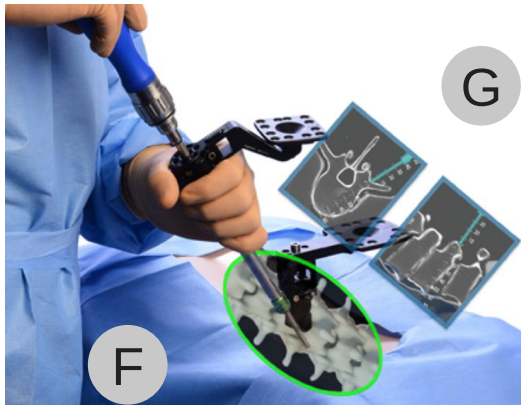
VR/AR/MR Use Cases









A. Pre-operative display of surgical plan / simulation in 2D/3D

B. Intra-operative display of surgical plan in 2D/3D

C. Intra-op display and management of real time 2D/3D video and data suspended over patient

D. Broadcasting of surgeon FOV for remote collaboration

E. Immersive, magnified view of virtual data (e.g., 3D model) overlaid onto live MIS surgical video and viewed in VR/XR

F. Intra-op overlay of virtual data (e.g., 3D model) anchored to patient anatomy

G. Intra-op navigation of instruments vs plan

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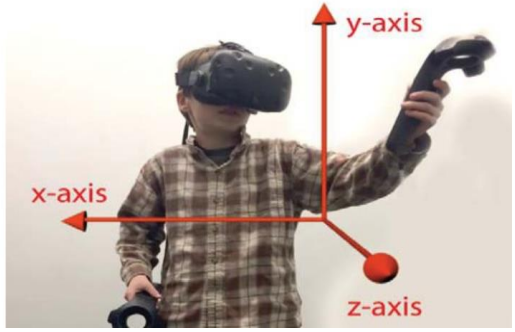
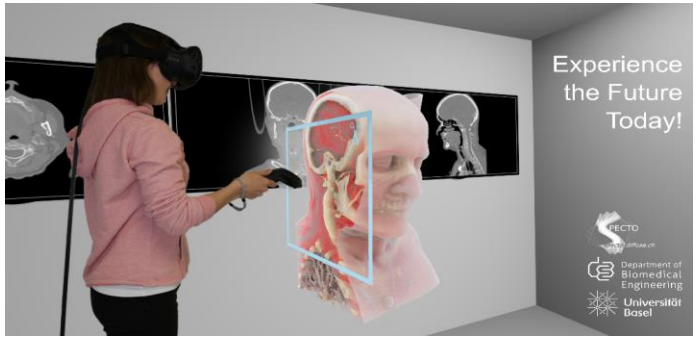
Importance of Application / Intended Use

Training

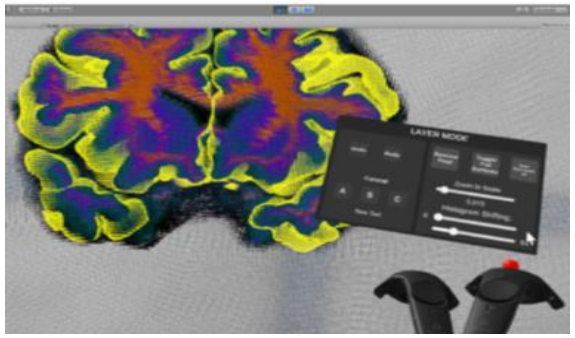
Pain Management



Visualization



Diagnostics



Challenging for Regulatory Science?

Variety of Indications for Use

- Diagnostics
- Surgery
- Mental Health
- Rehab, Pain

Technology is in early stages and continually developing

- VR
- AR
- Innovative optics and photonics
- Mobile and computing integration
- Growing use in multiple industries

Sponsors often use off-the-shelf consumer-grade headsets and sensors

- Different limitations for different devices and indications
- Sponsors may not have access to all specifications

Lack of characterization and evaluation methods and consensus

- Gaps in relevant standards and guidance
- Small digital companies without characterization expertise

Significant technological difference from predicates

- Image quality
- Human factors
- Training

Additional Considerations

- Technical Characterization
  - Luminance, contrast, temporal and spatial resolution, field of view, dynamic range, refresh rate, latency, transmission, and optical aberrations like distortion
- Accuracy of Info
- Control Mechanism
- Quantitative System Validation (Cadaver)
- Human Factors / Usability
- Step-by-step screen shots
- Clinical Data / Endpoints

Thank You