Azurion AR (Augmented Reality) study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22889

Source
NTR

Brief title
AzurionAR

Health condition

no disorders

Sponsors and support

Primary sponsor: Philips Medical Systems Nederland B.V.
Source(s) of monetary or material Support: Philips Medical Systems Nederland B.V.

Intervention

Outcome measures

Primary outcome

Meaningfulness: The operator will rate the meaningfulness on a 11 point Scale.

Secondary outcome

- Usability: The operator will rate the usability of the Azurion AR. It will be assessed by using the System Usability Score (SUS).
- Image quality: The operator will rate the image quality of the virtually presented medical

images on a 5 point Likert Scale.
- Ergonomics: The operator will indicate to what extend he/she is affected by 17 prompted symptoms using the visual fatigue questionnaire.
- Workload: The operator will fill out a task load questionnaire, the raw version of the NASA Task Load Index (TLX) to assess the workload on six subscales with 21 gradations.

Study description

Background summary

Augmented Reality (AR) has the potential to improve the clinical workflow in the future by providing greater flexibility in the way users interact with the Philips Azurion system. AR allows flexible augmented display of 2D and 3D data overlaid or mixed with the real world. It offers more natural interaction, for instance by voice control or gesture interaction. The goal of this study is to investigate the user benefits and requirements for combining AR with Philips Azurion system and to study the possibilities how an AR head-mounted display (HMD) could be used together with the Philips Azurion system in Image Guided Therapies. The study is about an application research and not about patient research.

Study objective

No formal statistical hypothesis is planned.

Study design

No follow-up is required per protocol. Patient will be followed according to regular clinical standard of care.

Intervention

N/A The study is not about patient research but application research.

Contacts

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Eligibility criteria

Inclusion criteria

- Operators who are certified IR/IOs, performing interventional vascular and oncology procedure
- Operators that are 18 years of age or older, or of legal age to give informed consent per state or national law.
- Procedures taken place in the angiography suite, with the same criteria as for the normal procedures that are not limited to standard angiographic I/O procedures and Image-Guided drainages using ultrasound or fluoroscopy.
- Patients elected for the procedures described, that are able to give informed consent per state or national law.

Exclusion criteria

- Operator or subject is Philips employee or their family members residing with this Philips employee.
- Operators that wear normal eye wear that do not fit underneath the AR HMD.
- Operators that are color blind and or have strabismus as eye deficiencies.
- All vulnerable subjects such as subjects lacking the capacity to provide consent, patients in emergency situations, pregnant or breast feeding women, or any other subject who meets an exclusion criteria, according to applicable national laws, if any.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2020
Enrollment:	4
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Positive opinion

Date:	15-12-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9127
Other	MEC-U : W20.089

Study results

Summary results
Not applicable