Azurion AR (Augmented Reality) study

Gepubliceerd: 15-12-2020 Laatst bijgewerkt: 18-08-2022

No formal statistical hypothesis is planned.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22889

Bron
NTR

Verkorte titel
AzurionAR

Aandoening

no disorders

Ondersteuning

Primaire sponsor: Philips Medical Systems Nederland B.V.
Overige ondersteuning: Philips Medical Systems Nederland B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

No formal statistical hypothesis is planned.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-12-2020
Aantal proefpersonen:	4
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Positief advies

Datum:	15-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
Not applicable