

The Contribution of EchoNavigator Workflow Improvements on Efficiency for SHD Procedures

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The primary objective of this clinical Research is: • The objective of the study is to investigate concept and feasibility of view automation for SHD interventions. The study will explore the contribution of (semi) automatic views based procedural...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51941

Source

ToetsingOnline

Brief title

SmartVue

Condition

- Cardiac valve disorders

Synonym

heart valve disease Structural Heart Disease (SHD)

Research involving

Human

Sponsors and support

Primary sponsor: Philips

Source(s) of monetary or material Support: Philips

Intervention

- Medical device

Keyword: EchoNavigator, SHD, SmartVue, Workflow

Explanation

N.a.

Outcome measures

Primary outcome

The primary endpoint of the study is a qualitative assessment of the usefulness, accuracy and contribution to efficiency of automated views as proposed by the EchoNavigator SmartVue Investigational Device. The qualitative assessment will be based on a relative scale (e.g. ranging from **very useful** to **not useful**).

Secondary outcome

Secondary endpoints are:

- Recorded anonymized raw Echo and X-ray data that can be used to develop (AI) algorithms used for view automation, and automatic (flow) quantification
- Qualitative feedback on the user interface and the workflow that may be used to improve the investigational device
- Feedback on existing functionality and suggestions for new functionality to improve future versions of the EchoNavigator device

Study description

Background summary

The EchoNavigator SmartVue Investigational Device is developed by Philips Medical Systems. The proposed EchoNavigator SmartVue Investigational Device is based on the released EchoNavigator R3 software medical device. The intended use, clinical setting and intended operator profile of the investigational device are identical to the EchoNavigator R3 software medical device. Similar to the product, the device is an **assistive device**, procedures can be performed safely and effectively without the device: the device does not alter the clinical workflow and does not replace existing clinical (imaging) data.

EchoNavigator is a software medical device which is used during minimal

invasive Structural Heart Disease (SHD) interventions where live X-ray and Ultrasound imaging is required. EchoNavigator allows the clinical operator to merge X-ray and Ultrasound images, and place markers on the images to provide the clinical operator a better understanding of the anatomy and assist with device guidance.

Features of EchoNavigator software medical device are:

- Giving procedural-relevant context to the live X-ray and ultrasound data by:
 - o Automatically synchronizing the image orientation of both modalities (by use of the *Orientation Indicator* similar to 3DRA product), as opposed to relying solely on the echo-operator to create this context manually.
 - o Automatically aligning the Echo views (including MPR) to a clinically relevant orientation after the user selects the required anatomical preset.
 - o Automatically aligning the Echo views (including MPR) to a clinically relevant orientation based on procedural context, anatomy and device information.
- Allowing to the visualization of relevant anatomical structures in the live Echo data in multiple simultaneous user defined views
- Automatically presenting the Echo data in the same orientation as the live X-ray images from the X-ray system (so called *Follow C-arm*), as opposed to relying on the echo-operator to provide this orientation
- Allowing the X-ray user to interrogate the relevant anatomical structures in the Echo data from table side, as opposed to requesting the echo-operator to perform the interrogation
- Allowing the user to identify anatomical structures in one modality and annotate them manually with annotations. These annotations are automatically transposed to the other modality. The annotations are visualized in all selected views and are solely intended to be used as context information to help the user with the navigation of the catheter and device in the patient*s anatomy.
- Allowing the user to identify anatomical structures in the echo modality and annotate them with annotations and tissue contours as proposed by the device. These annotations are automatically transposed to the X-ray modality. The annotations are visualized in all selected views and are solely intended to be used as context information to help the user with the navigation of the catheter and device in the patient*s anatomy.
- Project the Ultrasound image or volume as overlay or only outline on top of the X-ray view
- Allowing the Echo operator to view and annotate the X-ray image from the Echo console

Compared to the EchoNavigator R3 product, the novel feature in the EchoNavigator SmartVue Investigational Device is view automation based on procedural context (e.g. procedure type, step of the procedure), anatomical information (e.g. from automatic segmentation echo data, imported CT or from AI) and device information. View automation may contribute to easier control of the imaging and a more efficient clinical workflow, as the echo operator does

not need to adjust the views manually.

Study objective

The primary objective of this clinical Research is:

- The objective of the study is to investigate concept and feasibility of view automation for SHD interventions. The study will explore the contribution of (semi) automatic views based procedural context, anatomy and device information on the ease of use and efficiency of the procedure

The objectives are descriptive in nature and are intended to provide additional information. There will be no pass or fail criteria.

The secondary objective is/are:

- Collect image data for further (AI) algorithm development and automatic (flow) quantification
- Collect usability feedback to improve the user interface
- Collect clinical user feedback for potential future improvements of the device
- Report all adverse events
- Report all adverse device effects
- Report all device deficiencies that could have led to a serious adverse event

The objectives are descriptive in nature and are intended to provide additional information. There will be no pass or fail criteria.

Study design

This is a prospective, non-randomized, unblinded, observational, single-center study.

Agreement(s) will be set-up between sponsor and investigational site(s), including roles and responsibilities and financial or in-kind compensations and ensure that any reportable events are notified by the investigator(s) to the sponsor in a timely manner.

During this study 1 (one) investigational device will be used: EchoNavigator SmartVue Investigational Device R1.1

There are no comparators. There are no additional devices or medications required for the study.

Intervention

EchoNavigator SmartVue Investigational Device

Study burden and risks

The risk assessment process that Philips follows is in accordance with ISO 14971. This will ensure that the level of risk is acceptable prior to start of the study.

The anticipated clinical benefits of the EchoNavigator functionality in general are:

- Improved understanding of ultrasound
- Improved understanding of the relationship between X-ray and ultrasound
- Improved communication between Echocardiographer/sonographer and Interventional cardiologist/operator
- Support for device guidance and navigation
- Increased control from table side

The additional anticipated clinical benefits of the SmartVue Investigational Device functionality are:

- Easier control of the imaging and a more efficient clinical workflow

There is a possibility that the patient may not benefit from participating in the study, however patients participating in the study receive the normal standard of care that they would also receive when they would not participate in the study.

There are no possible interactions with concomitant medical treatments.

The outcome of the Safety Risk Assessment for this device is that the residual risks for the investigational device are outweighed by the medical benefits and safety and performance of the device. Therefore, on the basis of both clinical evaluation and risk profile, study of the investigational device under the conditions described in clinical study plan is justified.

Contacts

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Trial sites

Trial sites in the Netherlands

St. Antonius Ziekenhuis

Target size: 50

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Subject is a patient that requires SHD intervention for which routine fluoroscopy and TEE guidance is used, such as: transcatheter mitral and tricuspid therapies (TTMT), left atrial appendage closure (LAAC), transcatheter aortic valve replacement (TAVR). Subject is able to give informed consent and is 18 years of age or older, or of legal age to give informed consent per state or national law.

Exclusion criteria

Subjects who are unsuitable to accept TEE imaging during a structural heart disease intervention

- Subject is an adult who lacks the capacity provide consent
- Subject is in an emergency condition
- Subject participates in a potentially confounding drug or device trial during the course of the study
- All vulnerable subjects, or any other subject who meets an exclusion criteria, according to applicable national laws, if any.
- * Subject is pregnant or breast feeding woman

* Subject is Philips employee their family members residing with this Philips employee.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	28-03-2023
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	EchoNavigator SmartVue Investigational Device
Registration:	No

IPD sharing statement

Plan to share IPD: No

Plan description

N.a.

Ethics review

Approved WMO
Date: 07-01-2022
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 07-10-2022
Application type: Amendment
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 09-04-2025
Application type: Amendment
Review commission: MEC-U

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	NL9468
CCMO	NL78381.100.21
Research portal	NL-006147