

**Evaluation of TaiHao Breast Ultrasound Diagnosis Software RN-CES  
Descartes**

**NCT number: n/a**

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## **I. Objective**

The Evaluation of TaiHao Breast Ultrasound Diagnosis Software RN-CES Descartes is an AI-based software that received PMDA approval in November 2020 (Approval number: 30200BZX00379000). While the software device currently requires input images captured using the 'Acuson S2000' imaging device (certification number: 220AIBZX00055000), we recognize the potential benefit of expanding compatibility with additional imaging devices from Canon, GE, and Fujifilm. As such, we have conducted an evaluation of the TaiHao Breast Ultrasound Diagnosis Software performance using input images obtained from ultrasound diagnostic equipment from the aforementioned manufacturers, with the aim of enhancing its contribution to the field of medical care.

## **II. Purpose**

The Standard of Truth (SOT) is based on the image diagnostic results of case data reviewed by expert radiologists. This study will compare and verify the detection results of the detection function (CADe function) of this software device with SOT, in order to estimate the detection performance of the CAdE function.

## **III. Device Description**

BR-FHUS Navigation is a standalone software device installed on a Windows-based computer for recording and storing electronic image. The device is an accessory to standard ultrasound systems and allows the digital recording images from those standard ultrasound devices, along with the spatial position coordinates of the recorded images. During breast ultrasound scanning, a series of images are continuously recorded, and the computer-assisted lesion detection function can be used to highlight the suspicious lesion for the current image. After finishing the scanning, the series of images are saved for further review.

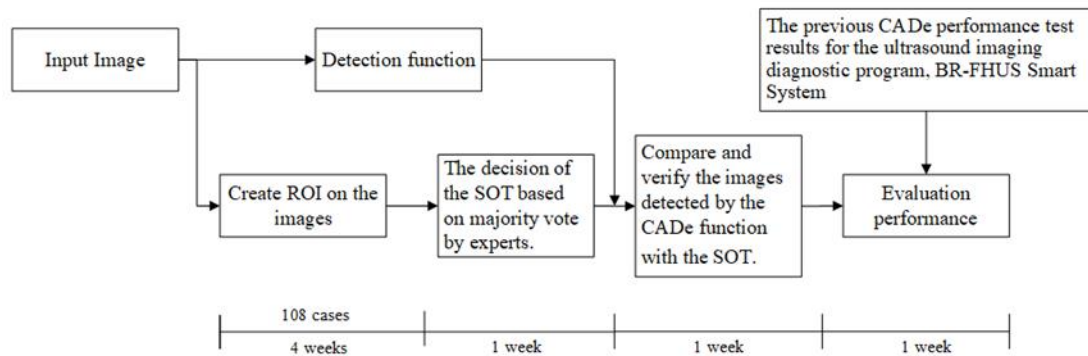
BR-FHUS Viewer is intended as a standalone software device installed on a Windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. BR-FHUS Viewer provides the capability to visualize two-dimensional ultrasound images along with the scanning paths and position information of probe that stored in the DICOM file in advance. During breast ultrasound reviewing, the computer-assisted lesion detection function can be used to highlight the suspicious lesions for the loaded image, assisting the

physicians to select images with lesions.

#### IV. Case criteria

- i) Inclusion Criteria: Female patients aged 20 to 69, including those with and without breast lesions.
- ii) Exclusion Criteria: a pacemaker or prosthetic valve or a post-surgery follow-up patient.

#### V. Study Design



- i) Three experts independently review the image and create ROIs (regions of interest) suspected of breast lesions.
- ii) The SOT is adopted by selecting the region where the ROIs of two experts overlap.
- iii) Using the CADe function, we detect regions suspected of breast lesions in 108 cases of images.
- iv) We compare and verify the images detected by the CADe function with the SOT.
- v) The detection results of the CADe function are estimated in conjunction with the results of the CADe performance test for the BR-FHUS Smart System ultrasound imaging diagnostic.

#### VI. Study endpoint

- i) Primary Outcome Measure:  
The average performance of the 4 machines, in terms of sensitivity for detecting suspicious breast cancer, is not inferior to Siemens performance.

The average of 4 types of machines (Canon Aplio i800, GE Logiq E10, GE Invenia ABUS, Fuji ARIETTA 60) performance compared to Siemens performance which was submitted to PMDA last time.

ii) Secondary Outcome Measures:

The performance of each of the 4 machines, in terms of sensitivity for detecting suspicious breast cancer, is not inferior to Siemens' performance.

Each machine (Canon Aplio i800, GE Logiq E10, GE Invenia ABUS, Fuji ARIETTA 60) performance compared to Siemens performance which was submitted to PMDA last time.