



AI IN MAMMOGRAPHIC BREAST DENSITY

MEDICAL FIELD, OR MEDICAL METHOD

Mammography / Breast Cancer Screening / Medical Imaging

TYPE

Decision support Autonomous decision making

CATEGORY

Prevention Detection Diagnosis Treatment
 Other

DESCRIPTION

AI-powered radiological software using the structured learning capacity of modern AI to produce pattern recognition based radiological breast density scores.

AIM / PURPOSE

Reproducibility for health care providers eliminating visual scoring by radiologists. Efficiency gain for radiologists by automation of visual scoring of radiographic breast density.

OUTPUT / RESULTS

New 5th Edition of BI-RADS Atlas recognizing the importance of texture analysis in determining fibroglandular breast tissue from mammography views.

Technologies based solely on algorithmic determination of breast density have difficulties matching the visual reference of breast density determined by radiologists, who are evaluating the dense tissue pattern. Hologic Quantra 2.2 was developed using AI to analyse pattern and texture in the process of

objectively assessing breast density.

Performance of this automatic breast density scoring have been validated in a reader study (n>4.500 mammographic views; 5 readers, 230 cases each with 4 views).

The inter-observer agreement between radiologists in the study based on the BI-RADS four breast density categories averaged to 76% (range 63-86 %).

The agreement between the automatic scoring with the radiologist cohort was 77% (overall results).

Reducing the categories to dense and non-dense, personalizing of screening, the agreement was 96% for 2D mammography and 93% for Tomosynthesis breast examinations.

AI METHODOLOGY

A Multi-Class Support Vector Machine based classification technique to segregate breast types into four categories based on breast parenchymal tissue was trained using over 6.000 cases previously annotated by radiologists as ground truth (during screening).

INPUT / SIZE OF THE DATA

Mammography images (DICOM images of adult patients)

REFERENCE DOCUMENTS / LINKS / PUBLICATIONS

FDA submission summary available at:
https://www.accessdata.fda.gov/cdrh_docs/pdf16/k163623.pdf

SOURCE

Hologic Inc.