Online Help

Visage Breast Density

Indications for Use

Visage Breast Density is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Visage Breast Density assesses breast density from a mammography study and provides an ACR BI-RADS Atlas 5th Edition breast density category to aid radiologists in the assessment of breast tissue composition. Visage Breast Density produces adjunctive information. It is not a diagnostic aid.

Visage Breast Density is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images.

Introduction

Visage Breast Density is a software application that assesses breast density from a mammography study and categorizes it into one of the four categories A, B, C, or D according to the ACR BI-RADS Atlas 5th Edition.

Visage Breast Density is intended to be used by radiologists and physicians working in breast imaging. No dedicated training is required.

The target patient population are symptomatic and asymptomatic women undergoing mammography. There are no contraindications, warnings, precautions, or adverse reactions.

System Requirements

Visage Breast Density consists of a server-side component and a client-side component.

The server-side component is installed as an additional module on a Visage 7 PACS system. It therefore supports any typical hardware supported by the Visage 7 system as render server.[1]

The client-side component runs on any Windows PC with a supported operating system, also supported by Visage 7, i.e. Windows 8.1 and Windows 10 or newer.

Cyber Security

Like any medical software, Visage Breast Density should only be used in a reasonably secure environment. End users should only log into the Visage 7 client from computers that they can trust and that have not been compromised with reasonable certainty, in order to prevent information such as passwords or patient data to be stolen or compromised. Generally recognized security standards appropriate for the environment, such as end-point protection, anti-virus software, appropriate password management, firewalls, and backups are generally required for secure operation. System administrators shall work with the Visage engineering team to review the secure configuration of the environment as part of deployment and to review ongoing security procedures, such as updates.

Input Data

Visage Breast Density can process Full Field Digital Mammograms as well as C-View images (i.e. synthetic mammograms created from tomosynthesis data sets). It processes regular CC and MLO views of the left and

[1] Specifically: Intel 64bit CPU (2014 or newer) with at least 6 cores and at least 32GB of RAM and operating system openSUSE Leap 15.1.

right breast, but not any special views, such as for example spot-mag. It only processes images from imaging equipment from validated vendors, which at present is Hologic, Inc.

Visage Breast Density performs the assessment on a per-study basis. All supported images in the study are used for the assessment. Images of prior studies are not included. No user selection of images is required. If a study does not contain supported images, a respective error message is displayed to the user.

AI Technology

Visage Breast Density applies a convolutional neural network (CNN) for the automatic classification of breast density. The network has been trained on a large database of mammography exams. In the training, the imbalance between the four categories of the BI-RADS standard has been compensated; the trained model achieves similar accuracies for all breast density categories.

When applied to a mammography image, the neural network computes four likelihoods corresponding to the four breast density categories. The category with the highest likelihood is taken as the network's classification. The classifications of all valid images are merged into a general classification of the mammography study by computing a weighted average of the likelihoods. Each image is weighted with the highest likelihood occurring in its classification, i.e. images classified with a high certainty (see below) get a high weight.

The value of the highest likelihood is also a measure for the certainty of the classification. If the value lies above 87.4%, the classification is considered to be very certain. A value between 87.4% and 73.7% indicates a reasonably certain classification, and a value below 73.7% means that the classification is uncertain.

Validation Summary

Visage Breast Density has been validated at two different large academic centers in North America. The classification computed by Visage Breast Density was compared to the breast density stated in the original radiology report for the respective data set.

In addition a “gold standard” assessment was obtained by having a group of three MQSA qualified expert readers independently and individually assess each relevant study and determining the majority opinion (“expert consensus”). It was determined that if the classification computed by Visage Breast Density and the breast density reported by the original human reader differ, the expert consensus is more often in agreement with the Visage Breast Density module than with the individual human reader.

For the validation, 500 studies, which had not been used for the training of the CNN, were selected randomly. The following confusion matrices compare the expert consensus with the results of Visage Breast Density.

Table 1: Confusion matrix relating density categories from Visage Breast Density to consensus

4 / #		**Visage Breast Density (VBD)**					
		A	B	C	D	n/a[2]	∑
Consensus	A	53	12			1	66
	B	14	221	24		2	261
	C		5	111	18	7	141
	D			2	28	2	32
	∑	67	238	137	46	12	500

[2] Twelve of the 500 studies contained only unsupported images and were not classified by Visage Breast Density.

Table 2: Confusion matrix of binary classification from Visage Breast Density versus consensus

2 / #		Visage Breast Density	
		A-B	C-D
Consensus	A-B	300	24
	C-D	5	159

In more than 80% of the cases, the classification into the four ACR BI-RADS categories computed by Visage Breast Density was identical to the expert consensus. In all other cases, it differed by at most one density category. For the binary classification dense (C-D) versus non-dense (A-B), Visage Breast Density agreed with the expert consensus in over 90% of the cases.

User Interface

Visage Breast Density is designed as an add-on module to the Visage 7 PACS system.

The results of Visage Breast Density are displayed by the Visage 7 client. Clicking the dedicated tool button opens a dialog that shows the density classification and a measure for the certainty of the classification. If the currently loaded mammography study contains no supported images, a respective error message is displayed in the dialog.

The user can confirm the predicted breast density or adjust the classification. By clicking the “Accept” button, the breast density classification is stored in the database on the Visage 7 server.

The four figures below show examples of typical mammography images with different breast density categories and the corresponding results of Visage Breast Density.

Figure 1: Example images and classification result with breast density category A

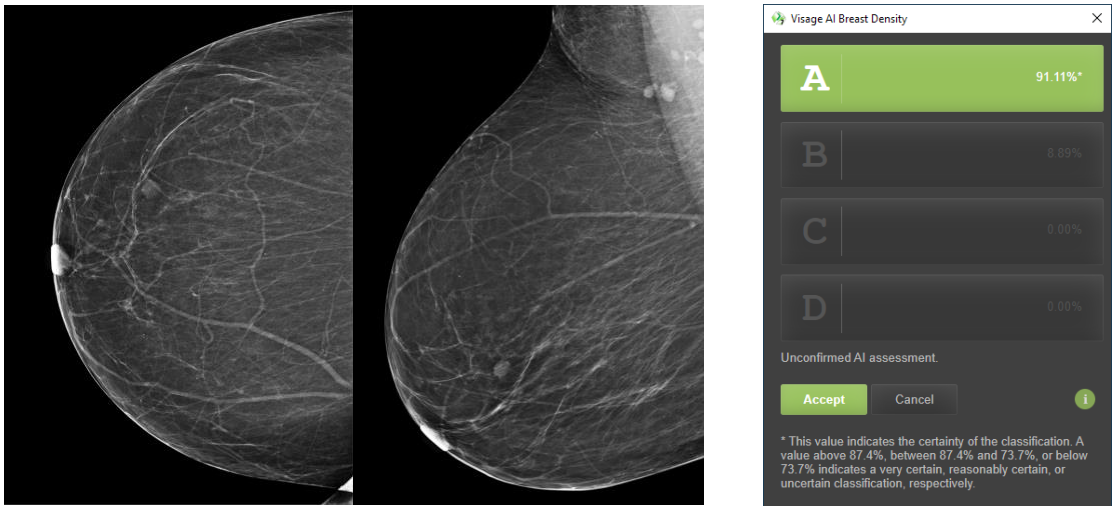


Figure 2: Example images and classification result with breast density category B

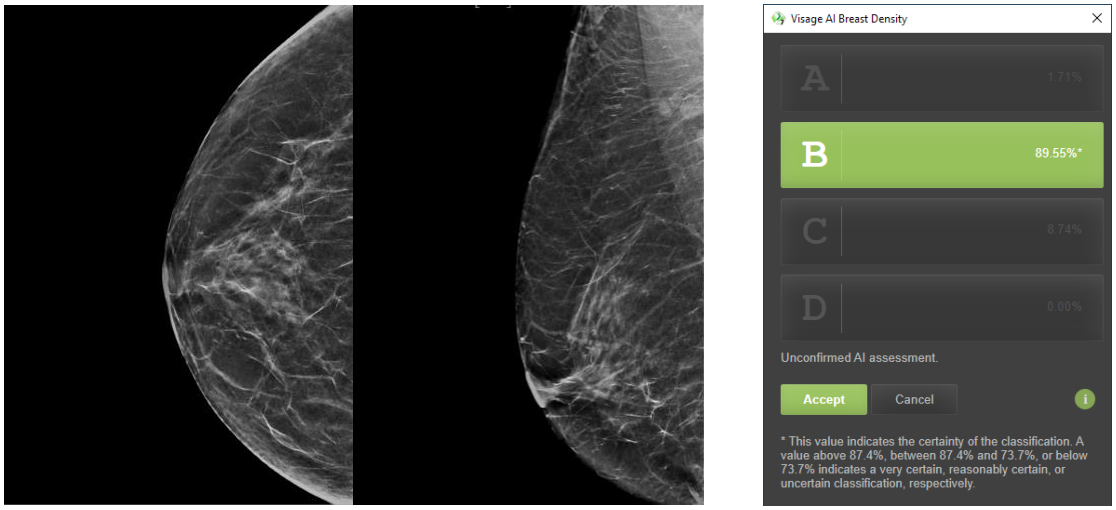


Figure 3: Example images and classification result with breast density category C

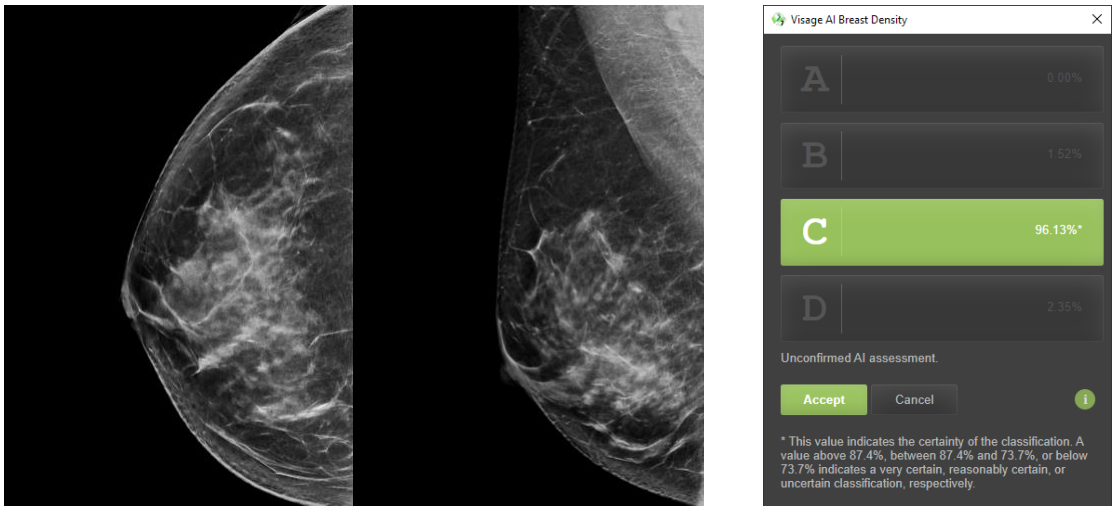
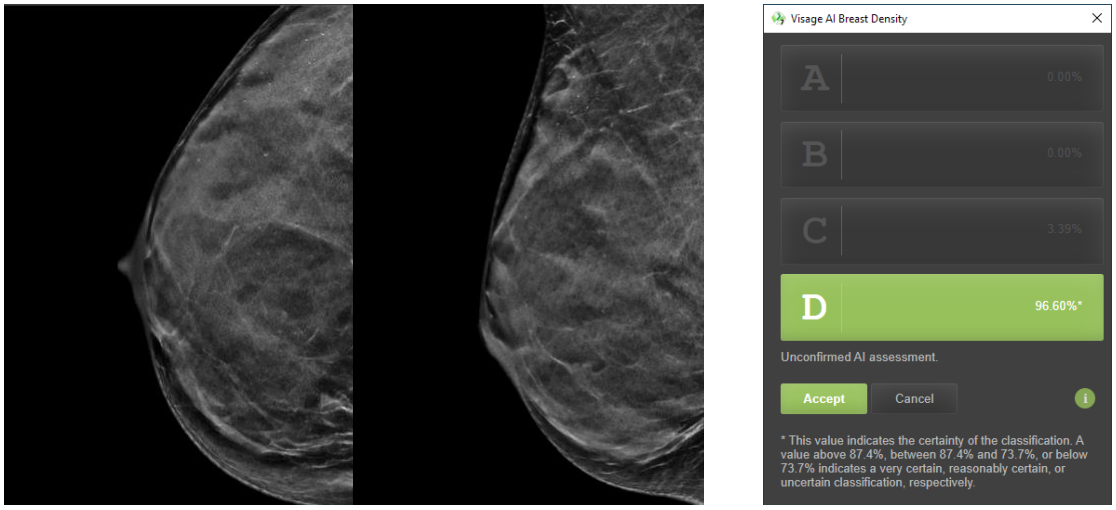


Figure 4: Example images and classification result with breast density category D



This software is CE-compliant and is defined as a class IIa medical device in accordance with Annex VIII of Regulation (EU) 2017/745 on medical devices.

The product lifetime of Visage Breast Density is regulated to two years after the product is discontinued, i.e., two years after the release date of the successor version of the product. Support is guaranteed only within the product lifetime.

Some of the specifications described herein may not be currently available in all countries. Please contact your local sales representative for the most current information.

Information in this manual may be subject to changes without prior announcement.

Caution

US federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Any serious incident that has occurred in relation to the medical device must be reported to the manufacturer and the responsible competent authority.

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