

# Abridged Clinical Results

## Quantra Breast Density Software

This document includes summaries of many documented clinical studies involving Quantra™. The summaries are meant to be informative, but are not necessarily complete. When possible, please refer to the original studies for more comprehensive details.

Type	Title, Author(s), Reference, Concluding Comment	Page
Publication	<b>Ethnic Variation in Volumetric Breast Density</b> Sadaf Hashmi, Jamie C. Sergeant, Julie Morris, Sigrid Whiteside, Paula Stavrinou, D. Gareth Evans, Tony Howell, Mary Wilson, Nicky Barr, Caroline Boggis, and Susan B. Astley IWDM 2012, LNCS 7361, pp127-133, 2012 © Springer-Verlag Berlin Heidelberg 2012 <i>"This study was based on the premise that screening mammography could be made more effective by adapting the imaging modality and the interval to a woman's individual risk of breast cancer. Breast density plays an important role, not only because it is an important risk factor, but also because it can be altered by lifestyle or other interventions."</i>	2
Publication	<b>Volumetric Assessment of Breast Tissue Composition from FFDM Images</b> Hartman K, Highnam R, Warren R, Jackson V Proceedings of the International Workshop on Digital Mammography 2008, Tucson, AZ, USA, E.A. Krupinski (Ed.): IWDM 2008, LNCS 5116, pp. 33-39, 2008 <i>"We have shown that the Quantra automated breast tissue measurement algorithm is internally consistent and that it has a high degree of agreement with external validation tests."</i>	3
Scientific Poster	<b>Correlation of Age and HRT with Breast Density as Assessed by Quantra™</b> Skippage PL, Wilkinson LS, Allen SD, Roche N, Dowsett M, A'Hern R Royal College of Radiology Breast Group 2009, Belfast, UK <i>"Quantra has shown to be accurate and reproducible by its expected correlation with lifestyle and demographic data. Given its ease of acquisition and display this could be the future of breast density quantification in the digital age."</i>	3
Scientific Poster	<b>Measuring Breast Density Using Quantra™ on Full Field Digital Mammography</b> Skippage PL, Wilkinson LS, Allen SD, Roche N, Dowsett M, A'Hern R Royal College of Radiology Breast Group 2009, Belfast, UK <i>"Until now all methods available have been subjective or required manual delineation of tissue outlines. Quantra overcomes these issues and has proved to be such an effective, accurate and efficient application."</i>	3
Scientific Poster	<b>Correlation of Age and HRT with Breast Density as Assessed by Quantra™</b> Skippage PL, Wilkinson LS, Allen SD, Dowsett M, Roche N, A'Hern R RSNA 2009, Chicago, IL, USA <i>"Quantra could be used to identify women with high density breasts who would benefit from early screening."</i>	4
Scientific Presentation	<b>Validation of a New Automated Volumetric Breast Density Measurement System as a Marker of Breast Cancer Risk</b> Pinker K, Perry N, Milner S, Mokbel K, Duffy S RSNA 2009, Chicago, IL, USA <i>"Quantra automated volumetric breast density measurement is strongly associated with breast cancer risk in women aged under 50, but not in women aged 50 years or over."</i>	4
Scientific Presentation	<b>Comparison of Three Methods of Estimating Breast Density: BI-RADS Density Scores Using Full Field Digital Mammography, BI-RADS Density Scores Using Breast Tomosynthesis, and Volumetric Breast Density</b> Rafferty E, Smith A, Niklason L RSNA 2009, Chicago, IL, USA <i>"Volumetric breast density [Quantra] may provide an alternative method of determining breast density."</i>	4
Scientific Poster	<b>Qualitative and Quantitative Analysis of Fibroglandular Tissue in the Digital Environment</b> Tuncbilek N, Sezer A, Uğur U, Ulaş U, Urut U, Coşar R, Özdemir H 10th National Congress of Breast Diseases, Izmir, Turkey <i>"We believe the relationship between the breast cancer and the fibroglandular tissue density can be evaluated more accurately if the volumetric breast program which provides 3D numerical measurement is used in this assessment."</i>	5
Publication	<b>A comparative study of volumetric breast density estimation in digital mammography and magnetic resonance imaging: Results from a high-risk population</b> Kontos D, Xing Y, Bakic P, Conant E, Maidment A Proceedings of SPIE Medical Imaging 2010, San Diego, CA, USA <i>"DM [with Quantra] could provide reliable quantitative and automated volumetric breast density measures that could potentially be used as an imaging biomarker for breast cancer risk estimation during breast cancer screening for the general population."</i>	5

Type	Title, Author(s), Reference, Concluding Comment	Page
Scientific Presentation	<b>A New Automated Volumetric Breast Density Measurement System Confirms Higher Breast Density Associated with Urban Women</b> Perry N, Milner S, Mokbel K, Duffy S, Pinker K European Congress of Radiology 2010, Vienna, Austria <i>"Automated volumetric analysis confirms the link between urban and higher breast density, identified by subjective radiologist classification."</i>	5
Scientific Poster	<b>Investigation of practical scoring methods for breast density</b> Ren B, Smith A, Marshall J The 10th International Workshop of Digital Mammography, IWDM 2010, Girona Catalonia, Spain, June 2010 <i>"The current algorithm has an agreement rate of 62% matching the BI-RADS score from doctors. This performance is similar to how radiologists agree among themselves with BI-RADS score."</i>	6
Scientific Presentation	<b>Quantitative Assessment of Breast Density: Comparing of Different Approaches</b> Qin N RSNA 2010, Chicago, IL, USA <i>"High correlation between breast density estimates on R2 Quantra and MRI FCM suggested the former could be used as an effective and accurate application."</i>	6
Scientific Presentation	<b>Racial Differences in Breast Density on Screening Digital Mammograms Comparing R2 Quantra™ Volumetric Computerized Software System vs. Radiologist BIRAD Density Measures</b> Richard-Davis G, Lucas L, Disber A, Montgomery-Rice V, Andrade A American Society for Reproductive Medicine 67th Annual Meeting, Orlando, FL, USA, October 2011 <i>"R2 Quantra and Subjective BIRAD readings are associated with each other. This relationship held regardless of race. R2 Quantra density did not differ between premenopausal and menopausal subjects, in contrast to other published data. This pattern also was persistent among racial groups."</i>	7
Oral Presentation	<b>Correlation of Ethnicity with Breast Density as Assessed by Quantra™</b> D. Tzias, S. George, L. Wilkinson, R. Mehta, C. Lobo, A. Hainsworth, A. Sharma Royal College of Radiologists Breast Group Annual Scientific Meeting 2011 <i>"There is a statistically significant difference between the objectively measured breast densities between these three ethnic groups. This is of relevance to the assessment of breast cancer risk."</i>	7
Publication	<b>A Comparative Study of Volumetric and Area-Based Breast Density Estimation in Digital Mammography: Results from a Screening Population</b> Despina Kontos, Predrag R. Bakic, Raymond J. Acciavatti, Emily F. Conant, and Andrew D.A. Maidment Digital Mammography © Springer-Verlag Berlin Heidelberg 2010. J. Marti' et al. (Eds.): IWDM 2010, LNCS 6136, pp 378-385, 2010. <i>"The strong correlation observed between the right and left breasts indicates that volumetric breast density measures computed with Quantra™ can provide consistent and fully-automated measures of breast density for women undergoing mammographic screening."</i>	8
Publication	<b>A First Evaluation for Breast Radiological Density Assessment by QUANTRA Software as Compared to Visual Classification</b> Ciatto S, Bernardi D, Calabrese M, et al. Breast (2012) doi:10.1016 / j.breast.2012.01.005 <i>"Computer assessed breast density is absolutely reproducible, and thus to be preferred to visual classification."</i>	8

### Ethnic Variation in Volumetric Breast Density

Sadaf Hashmi, Jamie C. Sergeant, Julie Morris, Sigrid Whiteside, Paula Stavrinos, D. Gareth Evans, Tony Howell, Mary Wilson, Nicky Barr, Caroline Boggis, and Susan B. Astley

**Published:** IWDM 2012, LNCS 7361, pp127-133, 2012 © Springer-Verlag Berlin Heidelberg 2012

#### SUMMARY OF PUBLICATION:

The authors comment that "The work reported here uses a fully automated, volumetric breast density measure, (Quantra™ software) as opposed to visual assessment or computer assisted methods as reported previously in the literature. Whilst Quantra™ software has not yet been validated with respect to its relationship to risk to the same extent as subjective and area-based methods of density measurement, it holds several advantages over such methods including objectivity, reproducibility, suitability for population-based studies, resolution and the ability to assess absolute, rather than relative, breast density. Regardless of the degree of association with risk, the identification of women with high mammographic density is important because the detection of cancers using conventional mammography is more difficult in this case, and it may be appropriate to use alternative screening methodologies."

**The study concludes:** "This study was based on the premise that screening mammography could be made more effective by adapting the imaging modality and the interval to a woman's individual risk of breast cancer. Breast density plays an important role, not only because it is an important risk factor, but also because it can be altered by lifestyle or other interventions."

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## Volumetric Assessment of Breast Tissue Composition from FFDM Images

*Hartman K, Highnam R, Warren R, Jackson V*

**Published:** Proceedings of the International Workshop on Digital Mammography 2008, Tuscon, AZ, USA, July 20-23, 2008

### SUMMARY OF POSTER

This study investigated the stability of a new algorithm to measure volumes within the breast. The algorithm is a refinement of methods published by Highnam and Brady. Two comparisons were performed in this study. The first was a comparison between Quantra™ values measured on FFDM images and values measured through manual segmentation of parenchymal density and breast outline on MR imaging studies for the same women. The second was a comparison of Quantra values measured on left/right and CC/MLO images from the same women. The authors point out that, at the time of this study, “we have not, as yet, explored the relationship between our results and breast cancer risk”.

**The study concludes:** “Quantra™ has shown to be accurate and reproducible by its expected correlation with lifestyle and demographic data. Given its ease of acquisition and display this could be the future of breast density quantification in the digital age.”

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## Correlation of Age and HRT with Breast Density as Assessed by Quantra™

*Skippage P, Wilkinson L, Allen S, Dowsett M, Roche N, A'Hern R*

**Presented:** Royal College of Radiology Breast Group 2009, November 2-3 2009, Belfast, UK

### SUMMARY OF POSTER

This study sought to use the Hologic Quantra volumetric breast density tool to remove the impact of intra-observer variability from the consideration of density as a highly significant predictor in the risk of developing breast cancer. In addition, it sought to correct breast density assessment using other methods that do not consider the breast as a 3-dimensional organ. Analysis was performed to correlate Quantra values with variables known to be associated with risk. Under ethics approval, the study observed a population of 320/683 women (47.3%) who responded to a postal questionnaire. Statistical significance was found between Quantra assessments and age, menopausal status, family history and HRT use less than five years. The average volumetric breast density from the studied population was 19%.

**The study concludes:** “Quantra has shown to be accurate and reproducible by its expected correlation with lifestyle and demographic data. Given its ease of acquisition and display this could be the future of breast density quantification in the digital age.”

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## Measuring Breast Density Using Quantra™ on Full Field Digital Mammography

*Skippage P, Wilkinson L, Allen S, Dowsett M, Roche N, A'Hern R*

**Presented:** Royal College of Radiology Breast Group 2009, November 2-3 2009, Belfast, UK

### SUMMARY OF POSTER

This study contrasts the numerous approaches to assessing breast composition. It specifically discusses two classes of categorization system based on 1) human observations and 2) human-guided quantitative and automated quantitative measures. The study points out the inter- and intra-reader variability that results from the three most common human observations methods: Wolfe's classifications categories published in 1976, Boyd's six-category classification, and BI-RADS. In all three cases a human observer glances at the images and renders a classification based largely on “greyness” of the image, on parenchymal pattern or of the fraction of the area of the breast comprised of parenchymal density. The methods for quantitative analysis are more varied. Interactive thresholding methods such as Cumulus rely on a human operator to adjust a threshold that defines the outline of the parenchymal tissue, the basis of a fractional density measurement by area. Another method utilizes a tissue equivalent phantom within the mammographic image; because the composition of the phantom is understood, comparing pixel values within the phantom with pixel values in the breast tissue can lead to good estimates of the composition of the breast. The third quantitative method, known as SMF, extracts composition data from images, based on its understanding of the physics of the imaging chain; Quantra is a 2nd generation SMF technology.

**The study summarizes:** “Until now all methods available have been subjective or required manual delineation of tissue outlines. Quantra overcomes these issues and has proved to be such an effective, accurate and efficient application.”

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### **Correlation of Age and HRT with Breast Density as Assessed by Quantra™**

*Skippage P, Wilkinson L, Allen S, Dowsett M, Roche N, A'Hern R*

**Presented:** RSNA 2009, Monday, November 30 2009, 12:15-13:15, Chicago, IL, USA

#### **SUMMARY OF POSTER**

This study sought to use the Hologic Quantra volumetric breast density tool to remove the impact of intra-observer variability from the consideration of density as a highly significant predictor in the risk of developing breast cancer. In addition, it sought to correct breast density assessment using other methods that do not consider the breast as a 3-dimensional organ. Analysis was performed to correlate Quantra values with variables known to be associated with risk. Under ethics approval, the study observed a population of 320/683 women (47.3%) who responded to a postal questionnaire. Statistical significance was found between Quantra assessments and age, menopausal status, family history and HRT use less than five years. The average volumetric breast density from the studied population was 19%. The study did not demonstrate a significant association between Quantra and ethnicity.

**The study concludes:** "Quantra could be used to identify women with high density breasts who would benefit from early screening."

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### **Validation of a New Automated Volumetric Breast Density Measurement System as a Marker of Breast Cancer Risk**

*Pinker K, Perry N, Milner S, Mokbel K, Duffy S*

**Presented:** RSNA 2009, VB31-06, Tuesday, December 1 2009, 10:00-10:10, Chicago, IL, USA

#### **SUMMARY OF PRESENTATION**

This retrospective study sought to validate Quantra's ability to predict breast cancer risk from full-field digital mammograms. The authors used 200 biopsy-proven breast cancer cases along with 200 age-matched healthy controls. Breast density was measured on the cancer cases by applying Quantra to the contralateral breast. The study demonstrated statistically significant correlation of Quantra results to risk factors such as age. While it did not demonstrate significant association of density with risk, it did show a trend to increased risk with increased dense tissue volume. It also demonstrated significant association of density and risk in women under age 50.

**The study concludes:** "Quantra automated volumetric breast density measurement is strongly associated with breast cancer risk in women aged under 50, but not in women aged 50 years or over."

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### **Comparison of Three Methods of Estimating Breast Density: BI-RADS Density Scores Using Full Field Digital Mammography, BI-RADS Density Scores Using Breast Tomosynthesis, and Volumetric Breast Density**

*Rafferty E, Smith A, Niklason L*

**Presented:** RSNA 2009, SSM01-04, Wednesday, December 2 2009, 15:30-15:40, Chicago, IL, USA

#### **SUMMARY OF PRESENTATION**

This retrospective study sought to compare three methods of estimating breast density. It compared human assessment from FFDM and tomosynthesis, both using BI-RADS density scoring, and volumetric density from Quantra. 15 radiologists scored the breast density on images from 310 subjects. Images were available for all subjects both for FFDM (Hologic Selenia FFDM system) and breast tomosynthesis (Hologic tomosynthesis prototype). Quantra volumetric breast density was available for 264 subjects. Breast composition was categorized as primarily fatty (BI-RADS 1 or 2) or dense (BI-RADS 3 or 4) by each method for each case and the results compared. The average BI-RADS density scores using FFDM and tomosynthesis were nearly identical, though significant inter-reader variability was observed for both methods. When a volumetric density threshold of 13% was applied to separate dense from fatty cases, comparison showed agreement with radiologists' BI-RADS scoring in 83% of cases scored as dense and in 87% of cases scored as fatty. The study provides evidence that radiologists' estimates of breast density scored by the BI-RADS system are similar with FFDM and tomosynthesis, although significant inter-reader variability remains. Computer-based categorization of density also yielded similar density scores while offering the advantage of standardized scoring.

**The study concludes:** "Volumetric breast density [Quantra] may provide an alternative method of determining breast density."

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## Qualitative and Quantitative Analysis of Fibroglandular Tissue in the Digital Environment

*Tuncbilek N, Sezer A, Uğur U, Ulaş U, Urut U, Coşar R, Özdemir H*

**Presented:** 10th National Congress of Breast Diseases, Poster 253, 30 Sept – 4 Oct 2009, Izmir, Turkey

### SUMMARY OF PRESENTATION

In this study, 479 cases were evaluated both by Quantra™ and by a human reader. Quantra volumetric density values were divided into four 25% quartiles. The human observer scored each case using the BI-RADS breast tissue composition four-value classification system. The investigators then compared the results for Quantra and the observer. In general, Quantra placed cases into a lower category than did the human observer, indicating a systematic shift between Quantra's volumetric assessment and the area assessment of a human visual judgment from a 2-D mammogram.

**The study concludes:** "We believe the relationship between the breast cancer and the fibroglandular tissue density can be evaluated more accurately if the volumetric breast program which provides 3D numerical measurement is used in this assessment."

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## A Comparative Study of Volumetric and Area-Based Breast Density Estimation in Digital Mammography: Results from a Screening Population

*Kontos D, Bakic PR, Acciavatti R, Conant EF, Maidment ADA*

**Published:** SPIE Medical Imaging 2010, San Diego, CA, USA

### SUMMARY OF POSTER

This study compared Quantra volumetric breast density with areal breast density in 71 asymptomatic patients with bilateral digital mammography and dynamic contrast MRI studies. Density assessments were done volumetrically (authors' method) on the MRI and both volumetrically and by area (Cumulus) on the digital mammography studies. Results of the three methods were compared. The study found that volumetric density measures from Quantra and MRI were highly correlated; between Quantra and Cumulus the correlation was lower and dependent on the training background of the Cumulus operator. The authors' noted that the absolute values were quite different, with MRI reporting the lowest density values (mean ~15%), followed by Quantra (mean ~23%) and Cumulus (~29%).

**The study concludes:** "The strong association with the area-based density measures suggests that [Quantra] volumetric breast density could also potentially be used for breast cancer risk estimation."

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## A New Automated Volumetric Breast Density Measurement System Confirms Higher Breast Density Associated with Urban Women

*Perry N, Milner S, Mokbel K, Duffy S, Pinker K*

**Presented:** European Congress of Radiology 2010, Vienna, Austria

### SUMMARY OF POSTER

This study sought to confirm earlier observations that women living in London have higher breast density. The study used Quantra volumetric density assessment, applied to the full-field digital mammograms of 300 women, as the method for measuring volume of fibroglandular tissue, breast volume and the resultant volumetric breast density. The average volumetric density was significantly higher in London before and after adjustment for age. The difference was slightly higher in older women (aged 50 years or more). Neither the breast volume nor volume of fibroglandular tissue correlated to area of residence. London women were significantly more likely to have volumetric density of 25% or higher ( $p = 0.009$ ).

**The study concludes:** "Automated volumetric analysis confirms the link between urban and higher breast density, identified by subjective radiologist classification."

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## Investigation of practical scoring methods for breast density

*Ren B, Smith A, Marshall J*

**Presented:** The 10th International Workshop of Digital Mammography, IWDM 2010, Girona, Catalonia, Spain, June 2010

### SUMMARY OF PRESENTATION:

This study was conducted to determine if reporting breast density with scoring methods correlated to patient distribution might offer more easily interpretable clinical value. The study consists of 942 patients, acquired from several clinical sites, and with the BI-RADS score available for each patient. The breast density of each mammogram was calculated with Quantra breast density assessment software. In this paper, we describe two new scoring methods for breast density, and evaluate them with a database of 942 patients. Our first method aims to generate a BI-RADS type score to assist doctors to correlate to breast density to BI-RADS category number. The BI-RADS distributions of our database were compared with the population distributions in the ACRIN DMIST [3] study and good agreement was established between the two, suggesting that our database represented a good screening population. With both the breast density and the BI-RADS score results available, we developed two practical scoring methods to generate new quality scores based on breast density results.

**The study concludes:** Our first method aims to generate a BI-RADS type score to assist doctors to correlate to breast density to BI-RADS category number. The current algorithm has an agreement rate of 62% matching the BI-RADS score from doctors. This performance is similar to how radiologists agree among themselves with BI-RADS scores. Our second method aims to provide statistical information on how a patient's breast density result is compared with a reference population, thus adding insight into the breast density result. Both methods need to be further evaluated to justify them as new methods for breast density.

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## Quantitative Assessment of Breast Density: Comparing of Different Approaches

*Qin N*

**Presented:** RSNA 2010, Friday, December 3, 2010, 11:00-11:10, Chicago, IL, USA

### SUMMARY OF PRESENTATION:

The purpose of this study was to compare the numerous approaches to assessing breast density, and to evaluate Quantra's ability to estimate breast density. Digital mammography studies were performed in the craniocaudal and mediolateral views on 58 patients. Breast density was evaluated by Quantra and human observation methods. Two radiologists estimated breast density using Wolfe classification and BIRADS density scoring. Two radiologists also assessed the breast density in 3D MRI datasets independently. Each assessment method was repeated after two months. Spearman and Pearson correlations of inter-and intra-reader and intermodality density estimates were computed.

**The study concludes:** High correlation between breast density estimates on R2 Quantra and MRI FCM suggested the former could be used as an effective and accurate application. Quantra automated volumetric breast density measurement may provide an alternative method of determining breast density which has shown to be more accurate and reproducible than other methods.

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## Racial Differences in Breast Density on Screening Digital Mammograms Comparing R2 Quantra™ Volumetric Computerized Software System vs. Radiologist BIRADS® Density Measures

*Richard-Davis G, Lucas L, Disher A, Montgomery-Rice V, Andrade A*

**Presented:** American Society for Reproductive Medicine 67th Annual Meeting; Orlando, FL, USA, October 2011

### SUMMARY OF POSTER:

Breast cancer is the second leading cause of death in women. African-American women experience a higher death rate, are more likely premenopausal and triple negative. High mammographic breast density is one of the strongest known risk factors for Breast Cancer with a 4-5X increase. High Breast Density is also associated with 10% to 29% lower sensitivity in radiologist interpretation.

The objective of the study was to 1) compare breast density quantity on digital mammography using radiologist interpretation vs. Quantra computerized software and 2) correlate with race and menopausal status.

Density on digital mammography was not significantly different using BIRADS; 2.25 in Caucasian vs. 2.15 in African American ( $p=0.5$ ). BD measured by R2 Quantra volumetric computerized software correlated with interpretation by radiologist. BMI was comparable in Caucasian 31.76 vs. 31.62 in AA ( $p=0.49$ ).

**The study concludes:** R2 Quantra and subjective BIRAD readings are associated with each other. This relationship held regardless of race. R2 Quantra density did not differ between premenopausal and menopausal subjects, in contrast to other published data. This pattern also was persistent among racial groups.

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## Correlation of Ethnicity with Breast Density as Assessed by Quantra™

*D. Tzias, S. George, L. Wilkinson, R. Mehta, C. Lobo, A. Hainsworth, A. Sharma*

**Presented:** Royal College of Radiologists Breast Group Annual Scientific Meeting 2011

### SUMMARY OF PRESENTATION:

It is widely accepted that there is an association between mammographic density and breast cancer risk. Various studies have examined relationships between ethnicity and breast density patterns using the Wolfe classification system with a view to investigating potential breast cancer risk. Quantra™ is a volumetric assessment tool, which allows reproducible objective measurement of mammographic breast density, eliminating inter-observer variability. This study was designed to investigate the correlation between ethnicity and breast density using Quantra™ measurements.

Quantra values were recorded from mammograms of symptomatic breast patients over a 6 month period. Three different ethnic groups were compared; Black (African and Afro-Caribbean), Asian (Indian subcontinent) and White (Caucasian). Mean Quantra™ values were calculated for each group and the Kruskal Wallis test was applied.

**The author concludes:** “There is a statistically significant difference between the objectively measured breast densities of these three ethnic groups. This is of relevance to the assessment of breast cancer risk.”

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## A Comparative Study of Volumetric and Area-Based Breast Density Estimation in Digital Mammography: Results from a Screening Population

*Despina Kontos, Predrag R. Bakic, Raymond J. Acciavatti, Emily F. Conant, and Andrew D.A. Maidment*

**Published:** Digital Mammography © Springer-Verlag Berlin Heidelberg 2010. J. Marti' et al. (Eds.): IWDM 2010, LNCS 6136, pp 378-385, 2010.

### SUMMARY OF PUBLICATION:

This study is a comparison of volumetric versus an area-based breast density estimation method in digital mammography. Volumetric density was measured with Quantra™ ( Hologic, Inc.) and area density was estimated using Cumulus (Ver 4.0, Univ. Toronto). Correlation and regression analysis was performed to determine the association between 1) density from left vs. right breasts, and 2) volumetric vs. area based measures.

Bilateral digital mammography images from 71 asymptomatic women were collected and analyzed using Quantra™ volumetric breast density software. The volumetric breast density measures obtained with Quantra™ are strongly correlated, but statistically significantly different that the corresponding area based breast percent density measures obtained with Cumulus. As expected, volumetric density estimates are lower than the corresponding area-based estimates. Both methods were found to be highly consistent.

**The author concludes:** “The strong correlation observed between right and left breasts indicates that volumetric breast density measures computed by Quantra™ can provide consistent fully-automated measures of breast density for women undergoing mammographic screening.”

## A First Evaluation for Breast Radiological Density Assessment by QUANTRA Software as Compared to Visual Classification

*Ciatto S, Bernardi D, Calabrese M, et al.*

**Published:** Breast (2012) doi:10.1016 / j.breast.2012.01.005

### SUMMARY OF PUBLICATION:

Radiologic breast density has been associated with breast cancer risk, and to mammography sensitivity. The method most commonly used for classification is commonly determined on a visual basis. In this study a set of digital mammography exams were classified according to BIRADS quantitative density classification by a panel of experienced radiologists, and by Quantra Breast Density Assessment software. The aim was to compare the two methods.

A set of 418 two view digital mammograms , randomly selected, were used for this study. Visual assessment of breast density was performed independently by 11 radiologists using the BIRADS density categories. The majority report (mode) was used to compare visual to Quantra classification. Intraobserver reproducibility was rather high, with substantial or almost perfect agreement being recorded for 5 or 6 readers.

Although visual classification looks reproducible on a statistical basis, it might have a suboptimal performance when used for a practical purpose. For example, if breast density were to be used as a determinant for a personalized screening protocol, subjects classified as dense by visual classification would range between 25 and 50% according to the study findings.

**The author concludes:** “Computer assessed breast density is absolutely reproducible, and thus to be preferred to visual classification.”