PowerLook® Density Assessment

Version 4.0

Breast Density Assessment Software for Digital Breast Tomosynthesis and Full-Field Digital Mammography

Labeling and User Manual

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Regulatory Requirements:

PowerLook Density Assessment 4.0 Software complies with the regulatory requirements of the following:

- EN ISO 13485 Medical Devices Quality Management System.
- Quality Systems Requirements FDA 21 CFR Part 820
- Medical Device Vigilance System MEDDEV 2.12/1
- European Medical Device Directive 93/42/EEC
- Canadian Medical Devices Regulations SOR 98-282

PowerLook Density Assessment Software

CE 2797

Manufacturer:

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European Authorized Representative:

EC REP

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Explanation of Symbols used in this manual and for labeling of the PowerLook Density Assessment 4.0 Software:

Symbol	Description
	Manufacturer
	Date of Manufacture
	Refer to Manual
	***WARNING*** Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a patient or users.
	***CAUTION*** Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual.
	***NOTE*** Notes provide advice and highlight unusual points. A note is not intended as an instruction.
	CE Mark
	Authorized Representative in the European Community
SN	Serial Number
REF	Model or Catalogue Number

 ***CAUTION*****:** USA Federal law restricts the sale, distribution, and use of this device to or on the order of a physician.

Table of Contents

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1 Overview of Manual

This manual describes the PowerLook® Density Assessment 4.0 Software and provides training to physicians on the use of PowerLook Density Assessment software for breast density assessment during a mammography exam.

- **Section 2** provides background information about breast density.
- **Section 3** provides PowerLook Density Assessment device labeling.
- **Section 4** describes how the PowerLook Density Assessment Software product is intended to be used.
- **Section 5** provides a description of the output of PowerLook Density Assessment Software.
- A list of clinical references is provided at the end of this document.

2 PowerLook Density Assessment Software in Mammography

2.1 Background

For women with an average risk of breast cancer, The American Cancer Society (ACS) recommends women ages 40 to 44 should have the opportunity to begin annual breast cancer screening with mammograms if they wish to do so. For average risk women, the ACS also recommends women who are age 45 to 54 should get mammograms every year and women age 55 and older should switch to mammograms every 2 years or have the choice to continue yearly screening[1]. Mammograms may be ineffective for almost 40% percent of women who receive them due to high breast density[2].

Women with higher breast density may have an even greater need for effective breast cancer detection. The 10% of women affected with extremely dense breasts are four to six times more likely to develop breast cancer than the 10% of women with fatty breasts. Compared to women with average breast density, their risk of developing cancer is doubled[1, 3-7]. Despite this, most women are not told they have dense breasts or of the associated risks.

In addition to the inherent increased risk of developing breast cancer in women with dense breasts, [1, 3-7], research has shown that women with dense breasts have a reduced accuracy of screening mammography since dense breast tissue can mask a cancer[8-11]. Masking of a tumor can occur because cancerous tissue and mammographically dense tissue have similar x-ray attenuation, allowing tumors to go undetected by screening mammography and progress to a more advanced and aggressive stage before detection[12]. The American College of Radiology (ACR) BI-RADS Atlas® 5th edition [13] focuses on the amount of dense tissue as a relative risk to masking cancer:

a. The breasts are almost entirely fatty.
b. There are scattered areas of fibroglandular density.
c. The breasts are heterogeneously dense, which may obscure small masses.
d. The breasts are extremely dense, which lowers the sensitivity of mammography.

Note that categories c and d explicitly state the possibility of masking. Radiologists may recommend supplemental screening for patients with dense breasts, such as Digital Breast Tomosynthesis (DBT) ultrasound or Magnetic Resonance Imaging (MRI)[14]. The PowerLook Density Assessment system is designed from the perspective of measuring dense breast tissue that has the potential for masking a cancer in a mammogram. By assessing density by appearance, it directly acknowledges that one of the goals of density determination is to highlight the risk of reduced sensitivity in mammography screening as a function of breast density. Density determination also helps identify women with an inherent increased risk of developing breast cancer.

3 PowerLook Density Assessment Device Labeling

3.1 PowerLook Density Assessment Overview

PowerLook Density Assessment is a software application intended for use with mammography exams containing either 2D images generated from Digital Breast Tomosynthesis (DBT) data (4.0 algorithm) or Full-Field Digital Mammography (FFDM) images (Note: See DTM135 manual for 2.1 algorithm details). PowerLook Density Assessment software assesses breast tissue composition and provides a breast density category aligned with BI-RADS® density lexicon. 2D images are used to calculate a density category. PowerLook Density Assessment 4.0 and 2.1 algorithms are designed to be used with cases with up to four 2D views. When DBT exams with FFDM images are present, with or without synthetic 2D images, PowerLook Density Assessment 2.1 algorithm is used. When exams contain only DBT and 2D images generated from DBT, the 4.0 algorithm is used. PowerLook Density Assessment software is designed to work in conjunction with iCAD's PowerLook DICOM server.

Results of the PowerLook Density Assessment software application are displayed on either a mammography workstation, high resolution monitor, or printed case report.

PowerLook Density Assessment software is available on compatible hardware and operating system.

3.2 Intended Use

PowerLook Density Assessment is a software application intended for use with digital breast tomosynthesis 2D images from tomosynthesis exams. PowerLook Density Assessment provides an ACR BI-RADS® Atlas 5th Edition breast density category to aid health care professionals in the assessment of breast tissue composition. PowerLook Density Assessment produces adjunctive information. It is not a diagnostic aid.

3.3 Installation and Service

The PowerLook Platform Service Manual (DTM164) outlines the installation process. It describes how the system is to be installed, configured and tested to ensure that it meets all product requirements.

NOTE: PowerLook Platform configurations and product features may vary (e.g. marketplaces, integrated systems, etc). PowerLook customers should contact their iCAD authorized representative/distributor for first line support.

Contact your iCAD authorized representative
Or
Contact iCAD Support:
U.S. Phone: (866) 280-2239 (Option 1)
U.S. Email: Support@icadmed.com
International Email: Support-ous@icadmed.com

3.4 Warnings

- PowerLook Density Assessment must not be used in lieu of conventional analysis by a radiologist. PowerLook Density Assessment is only intended as an aid for evaluating breast density.
- Do not use PowerLook Density Assessment without proper training. Operator training and review of user manual(s) applicable to your installation are required prior to using PowerLook Density Assessment.
- PowerLook Density Assessment results only assist in the analysis of breast density. Therefore, the results do not obviate interpretation by a radiologist.
- PowerLook Density Assessment will not always yield correct estimates of an ACR BI-RADS Atlas 5th Edition breast density category.
- PowerLook Density Assessment may consider a cancer to be part of dense tissue, and thus could potentially overestimate the dense area – and consequently, the ACR BI-RADS Atlas 5th Edition breast density category.
- The safety and effectiveness has not been established in mosaic views of a breast that is too large to fit in a single image.
- The safety and effectiveness has not been established for diagnostic views (e.g., magnification or compression views).
- The safety and effectiveness in patients with breast implants has not been established for views that do not have the implant displaced.
- PowerLook Density Assessment only supports the cranio-caudal (CC) and medio-lateral oblique (MLO) views.
- PowerLook Density Assessment does not support processing more than four 2D views per case.
- The safety and effectiveness has not been established printed or digitized film.
- There are no known direct risks to the safety or health of the user or the patient as a consequence of using this device. Indirect risks include: The device may incorrectly estimate the ACR BI-RADS Atlas 5th Edition breast density category.
- All clinical testing performed on cases with four (4) standard bilateral views including RMLO, LMLO, RCC, and LCC. The safety and effectiveness have not been established for cases where all four views are not available.

3.5 Contraindications

There are no contraindications for the use of this device.

3.6 Compatible Imaging Equipment

PowerLook Density Assessment 4.0 software and algorithm is compatible with the following DBT system's synthetic 2D images:

- Hologic Selenia Dimensions/3Dimensions (C-View)
- GE Senographe Essential with SenoClaire (V-Preview)
- GE Senographe Pristina (V-Preview)

PowerLook Density Assessment 2.1 algorithm is compatible with the following system's 2D images (Note: See DTM135 manual):

- Hologic Selenia Dimensions/3Dimensions
- GE Senographe 2000D/DS
- GE Senographe Essential
- GE Senographe Pristina
- Philips MicroDose L50/SI and L30
- FUJIFILM Computed Radiography (FCRm) Clearview CS Image Reader
- FUJIFILM Aspire HD, FUJIFILM Aspire HD Plus, FUJIFILM Aspire HD-s
- Siemens MAMMOMAT Novation[2]
- Siemens MAMMOMAT Inspiration[1]
- Siemens MAMMOMAT Revelation[1]
- Giotto Image 3D/3DL[1]
- Giotto Class[1]

[1] These devices utilize Anrad 85-micron sensors.

[2] This device produces For Processing images using the same detector hardware and software as the Hologic Selenia

3.7 Clinical Studies – PowerLook Density Assessment

This section summarizes the results of experiments validating the accuracy of the PowerLook Density Assessment 4.0 algorithm BI-RADS breast density category with Hologic C-View and GE V-Preview synthetic 2D images. (Note: For results of the PowerLook Density Assessment 2.1 algorithm's outputs, see DTM135 manual). (Note: there are no known scenarios for which device performance is considered to be poor.)

3.7.1 BI-RADS Breast Density Category

PowerLook Density Assessment chooses a BI-RADS breast density category by mapping each case to one of four categories: a, b, c or d.

For the PowerLook Density Assessment 4.0 algorithm, the BI-RADS breast density category assessments of five radiologists were used, and the mode of the radiologist's BI-RADS breast density category assessment were compared to the BI-RADS 5th Edition breast density category returned by PowerLook Density Assessment. The dataset was a total of 624 cases composed of 365 Hologic C-View cases and 259 GE V-Preview cases, The GE V-Preview cases were created with both Version 3 and Version 4.1 of the V-Preview software. Only 215 of the 259 GE cases were available to be processed using V-Preview Version 4.1.

A confusion matrix between the PowerLook Density Assessment 4.0 algorithm's BI-RADS 5th Edition breast density category and the associated mode of the radiologists' BI-RADS breast density categories was produced and a summary of eight different measures is provided**.** Results for the Hologic C-View cases and both versions of GE's V-Preview cases are reported separately as well as combined in **Tables 1**, **3**, **5** and **7**.

The goal of this study was to determine the accuracy of the PowerLook Density Assessment 4.0 algorithm's BI-RADS 5th Edition breast density category output with Hologic C-View and GE V-Preview images. The acceptance criteria are based on comparison to PowerLook Density Assessment 3.4 on 2D images generated from DBT data.
Table, **4**, **6** and **8** show the benchmark system performance, the desired performance, and the observed performance numbers of PowerLook Density Assessment 4.0.

3.7.2 Performance over the Hologic C-View Dataset Bootstrapped to Represent a Screening Population

In order to represent a screening population, a bootstrap procedure was employed as follows: A screening population of 365 cases should have the following proportions: 37 a, 146 b, 146 c, 37 d. Each bootstrap sample randomly selected with replacement:

- 37 out of the 59 cases in category a
- 146 out of the 132 cases in category b
- 146 out of the 120 cases in category c
- 37 out of the 54 cases in category d

This selection was repeated for a total of 2999 bootstrap samples. For each bootstrap sample a confusion matrix was created, and performance measures were extracted. The confusion matrix and performance measures below are the median values from the 2999 samples.

Note: Each bootstrap sample had 146 category c cases. The averages for the 3 non-zero numbers are 12.2, 119.2 and 14.6 for a total of 146. The numbers shown are the median of the bootstrap samples which added to 145 instead of 146.

For 100% of the cases, the PowerLook Density Assessment BI-RADS breast density category falls within one level of the mode. The weighted Kappa score for this matrix is 0.78 indicating "substantial" agreement.

		Radiologist BI-RADS (Mode)				Totals
		a	b	c	d	
PowerLook Density Assessment 4.0 Breast Density Category	a	32	10	0	0	42
	b	5	115	12	0	132
	c	0	21	119	7	147
	d	0	0	14	30	44
Totals		37	146	145	37	365

Table 1: Confusion matrix relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for Hologic C-View synthetic 2D images.

Test	Density Assessment V3.4	Desired Performance	Observed Performance
kappa	0.78	0.61	0.78
Category a	87.2%	70%	86.5%
Category b	72.1%	70%	78.8%
Category c	73.0%	70%	81.5%
Category d	78.8%	70%	81.1%
Within One	99.5%	98%	100.0%
Fatty Correct	88.3%	90%	88.5%
Dense Correct	94.0%	90%	93.4%

Table 2: Summary of results relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for Hologic C-View synthetic 2D images.

3.7.3 Performance over the V-Preview V3 Dataset Bootstrapped to Represent a Screening Population

In order to represent a screening population, a bootstrap procedure was employed as follows: A screening population of 259 cases should have the following proportions: 26 a, 104 b, 104 c, 26 d. Each bootstrap sample randomly selected with replacement:

- 26 out of the 50 cases in category a
- 104 out of the 101 cases in category b
- 104 out of the 58 cases in category c
- 26 out of the 50 cases in category d

This selection was repeated for a total of 2999 bootstrap samples. For each bootstrap sample a confusion matrix was created and performance measures were extracted. The confusion matrix and performance measures below are the median values from the 2999 samples.

For 99.6% of the cases, the PowerLook Density Assessment BI-RADS breast density category falls within one level of the mode. The weighted Kappa score for this matrix is 0.82 indicating "almost perfect" agreement.

		Radiologist BI-RADS (Mode)				Totals
		a	b	c	d	
PowerLook Density Assessment 4.0 Breast Density Category	a	22	7	0	0	29
	b	4	87	5	0	96
	c	0	9	90	5	104
	d	0	1	9	21	31
Totals		26	104	104	26	260

Table 3: Confusion matrix relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for GE V-Preview V3 synthetic 2D images.

Test	Density Assessment V3.4	Desired Performance	Observed Performance
kappa	0.78	0.61	0.82
Category a	87.2%	70%	84.6%
Category b	72.1%	70%	83.7%
Category c	73.0%	70%	86.5%
Category d	78.8%	70%	80.8%
Within One	99.5%	98%	99.6%
Fatty Correct	88.3%	90%	92.3%
Dense Correct	94.0%	90%	96.2%

Table 4: Summary of results relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for GE V-Preview V3 synthetic 2D images.

3.7.4 Performance over the V-Preview V4.1 Dataset Bootstrapped to Represent a Screening Population

In order to represent a screening population, a bootstrap procedure was employed as follows: A screening population of 215 cases should have the following proportions: 22 a, 86 b, 86 c, 22 d. Each bootstrap sample randomly selected with replacement:

- 22 out of the 41 cases in category a
- 86 out of the 82 cases in category b
- 86 out of the 47 cases in category c
- 22 out of the 45 cases in category d

This selection was repeated for a total of 2999 bootstrap samples. For each bootstrap sample a confusion matrix was created and performance measures were extracted. The confusion matrix and performance measures below are the median values from the 2999 samples.

For 99.5% of the cases, the PowerLook Density Assessment BI-RADS breast density category falls within one level of the mode. The weighted Kappa score for this matrix is 0.84 indicating "almost perfect" agreement.

		Radiologist BI-RADS (Mode)				Totals
		a	b	c	d	
PowerLook Density Assessment 4.0 Breast Density Category	a	19	5	0	0	24
	b	3	75	4	0	82
	c	0	5	71	2	78
	d	0	1	11	20	32
Totals		22	86	86	22	216

Table 5: Confusion matrix relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for GE V-Preview V4.1 synthetic 2D images.

Test	Density Assessment V3.4	Desired Performance	Observed Performance
kappa	0.78	0.61	0.84
Category a	87.2%	70%	86.4%
Category b	72.1%	70%	87.2%
Category c	73.0%	70%	82.6%
Category d	78.8%	70%	90.9%
Within One	99.5%	98%	99.5%
Fatty Correct	88.3%	90%	94.4%
Dense Correct	94.0%	90%	96.3%

Table 6: Summary of results relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for GE V-Preview V4.1 synthetic 2D images.

3.7.5 Performance over the Combined Dataset Bootstrapped to Represent a Screening Population

Results from the 365 C-View cases and 259 V-Preview cases were combined to show overall system performance. In order to represent a screening population, a bootstrap procedure was employed as follows: A screening population of 624 cases should have the following proportions: 62 a, 250 b, 250 c, 62 d. Each bootstrap sample randomly selected with replacement:

- 62 out of the 109 cases in category a
- 250 out of the 233 cases in category b
- 250 out of the 178 cases in category c
- 62 out of the 104 cases in category d

When one of the 215 V-Preview cases that were run with two different versions of the V-Preview software was selected, the version to use, V3 or V4.1, was randomly chosen to average the contribution of that case over the two different versions of software.

This selection was repeated for a total of 2999 bootstrap samples. For each bootstrap sample a confusion matrix was created and performance measures were extracted. The confusion matrix and performance measures below are the median values from the 2999 samples.

For 99.8% of the cases, the PowerLook Density Assessment BI-RADS breast density category falls within one level of the mode. The weighted Kappa score for this matrix is 0.80 indicating "substantial" agreement.

		Radiologist BI-RADS 5th Edition (Mode)				**Totals**
		a	b	c	d	
PowerLook Density Assessment 4.0 Breast Density Category	a	54	18	0	0	72
	b	8	203	19	0	230
	c	0	28	206	12	246
	d	0	1	25	50	76
Totals		62	250	250	62	624

Table 7: Confusion matrix relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for Hologic C-View and GE V-Preview synthetic 2D images.

Test	Density Assessment V3.4	Desired Performance	Observed Performance
Kappa	0.78	.61	0.80
Category a	87.2%	70%	87.1%
Category b	72.1%	70%	81.2%
Category c	73.0%	70%	82.4%
Category d	78.8%	70%	80.6%
Within One	99.5%	98%	99.8%
Fatty Correct	88.3%	90%	90.7%
Dense Correct	94%	90%	93.9%

Table8: Summary of results relating BI-RADS 5th Edition breast density categories from PowerLook Density Assessment 4.0 to radiologists' BI-RADS 5th Edition category mode for Hologic C-View and GE V-Preview synthetic 2D images.

4 Use of PowerLook Density Assessment Software

4.1 Overview

End users of PowerLook Density Assessment software must be trained prior to system use in a clinical environment. Training is provided by iCAD-authorized personnel and includes: intended use, performance specifications, network configuration, data workflow, functional operation, safety precautions, and service and support requirements.

4.2 Radiologist Training Requirements

Prior to using PowerLook Density Assessment software radiologists must have a full understanding of the functions and capabilities as appropriate, to:

- Identify the PowerLook Density Assessment intended use (**Section 3.2**)
- Identify the PowerLook Density Assessment warnings. (**Section 3.4**)
- Identify the PowerLook Density Assessment performance characteristics (**Section 3.7**)

5 PowerLook Density Assessment

5.1 Description

PowerLook Density Assessment software analyzes FFDM (2.1 algorithm) or 2D synthetic images created from DBT images (4.0 algorithm) and measures the total breast area and the breast area covered by dense tissue to compute Percent Breast Density (PBD). A texture or dispersion feature that determines whether all the dense tissue is together in one large clump or whether it is dispersed into many smaller clumps is also computed. Using these measurements, for each case, PowerLook Density Assessment 4.0 software reports a BI-RADS 5th Edition breast density category.

5.1.1 BI-RADS Breast Density Category

For each case, PowerLook Density Assessment 4.0 software reports a BI-RADS 5th Edition breast density category. The BI-RADS 5th Edition breast density category is determined by mapping the PBD and the distribution of dense tissue to a letter from "a" to "d". This mapping was calibrated to the consensus of 5 radiologists for tomosynthesis (synthetic 2D views) images.

Figures 1-4 present typical examples for each BI-RADS 5th Edition breast density category.

Figure 1 ACR 5th Edition BI-RADS Breast Density Category 'a' (Almost Entirely Fatty)

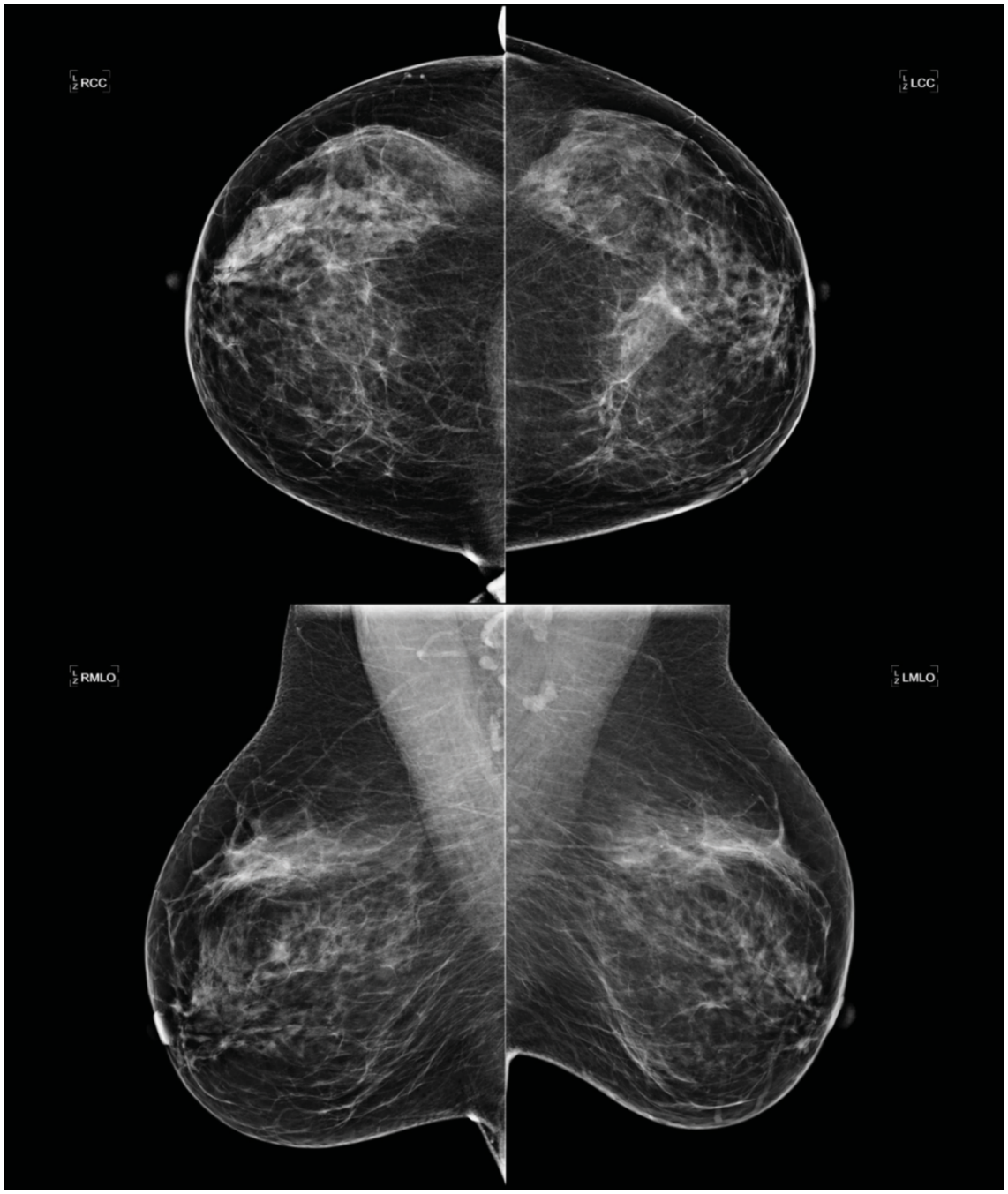

Figure 2 ACR 5th Edition BI-RADS Breast Density Category 'b' (Scattered Fibroglandular)

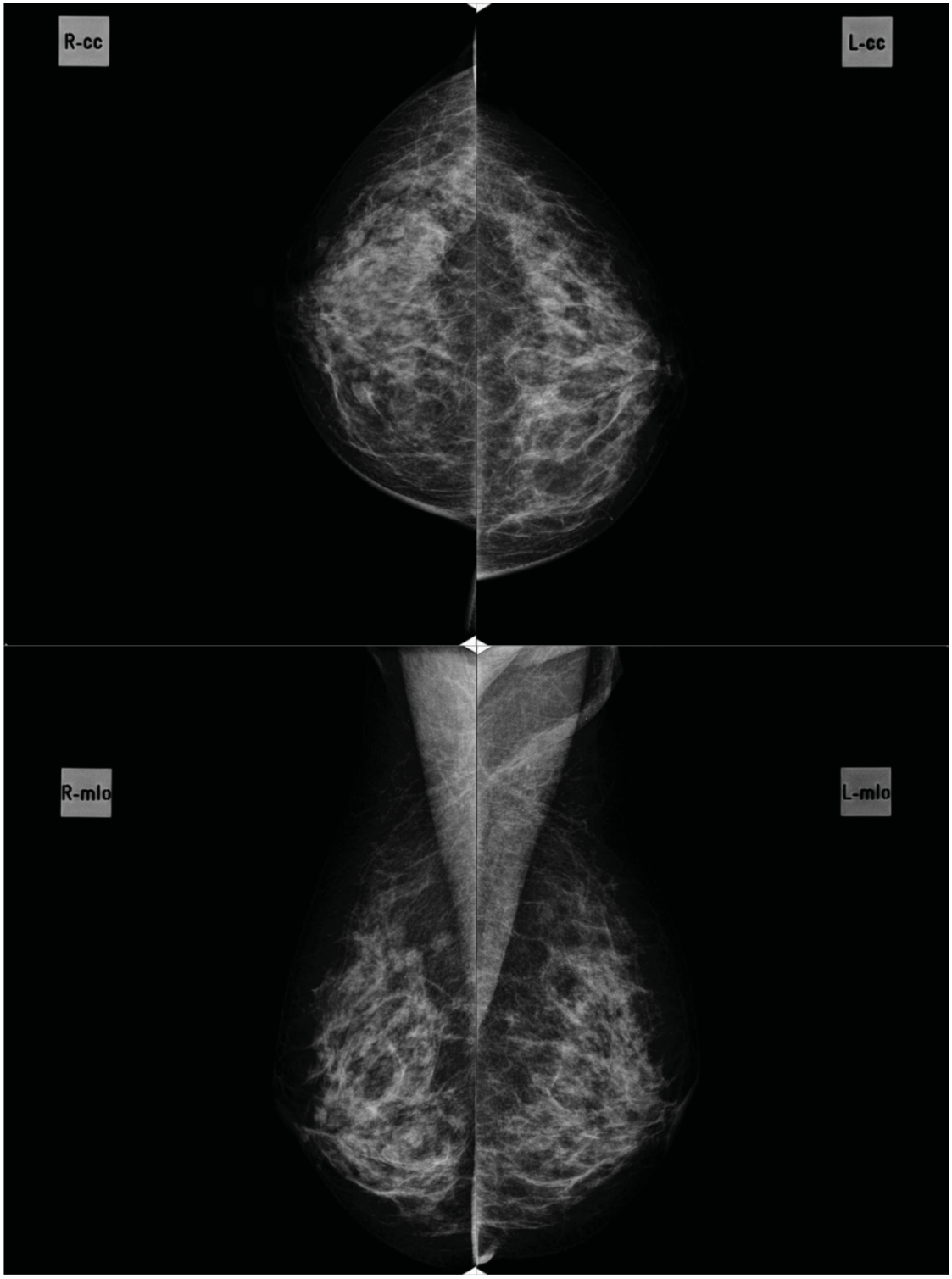

Figure 3 ACR 5th Edition BI-RADS Breast Density Category 'c' (Heterogeneously Dense)

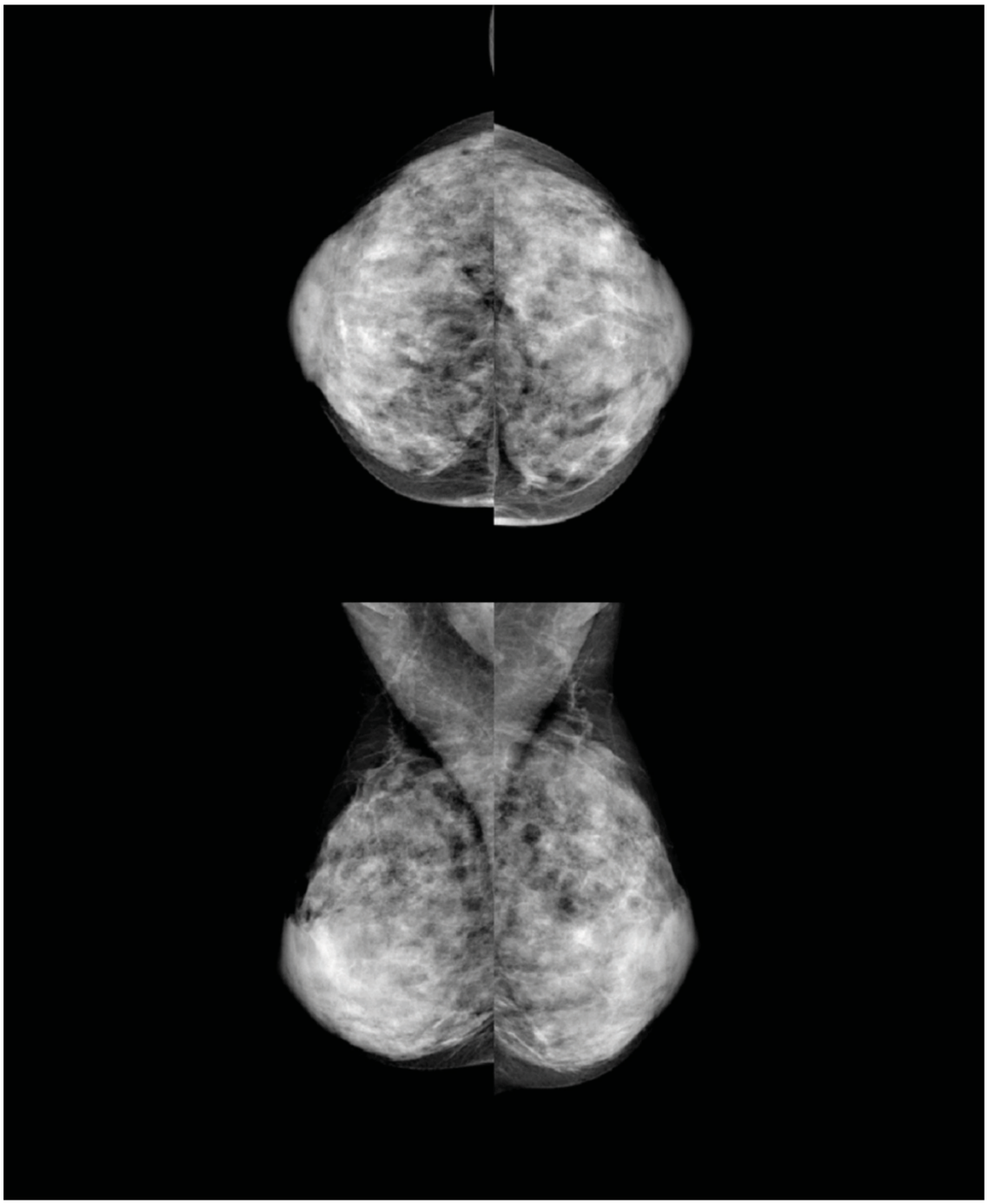

Figure 4 ACR 5th Edition BI-RADS Breast Density Category 'd' (Extremely Dense)

5.1.2 PowerLook Density Assessment Software Output

For each case, PowerLook Density Assessment software reports:

- Overall BI-RADS 5th Edition breast density category
- Value of the BI-RADS 5th Edition breast density score and where it falls on the BI-RADS breast density scale
- A '+' or '-' next to the overall BI-RADS 5th Edition breast density category to designate whether the BI-RADS breast density score is within the upper 75% or the lower 25% of the BI-RADS breast density category.

Figure 5 shows the output as a DICOM Secondary Capture image. For sites wanting Structured Report outputs, the PowerLook Density Assessment software values will be populated in the report, and the review station can display the results to the user.

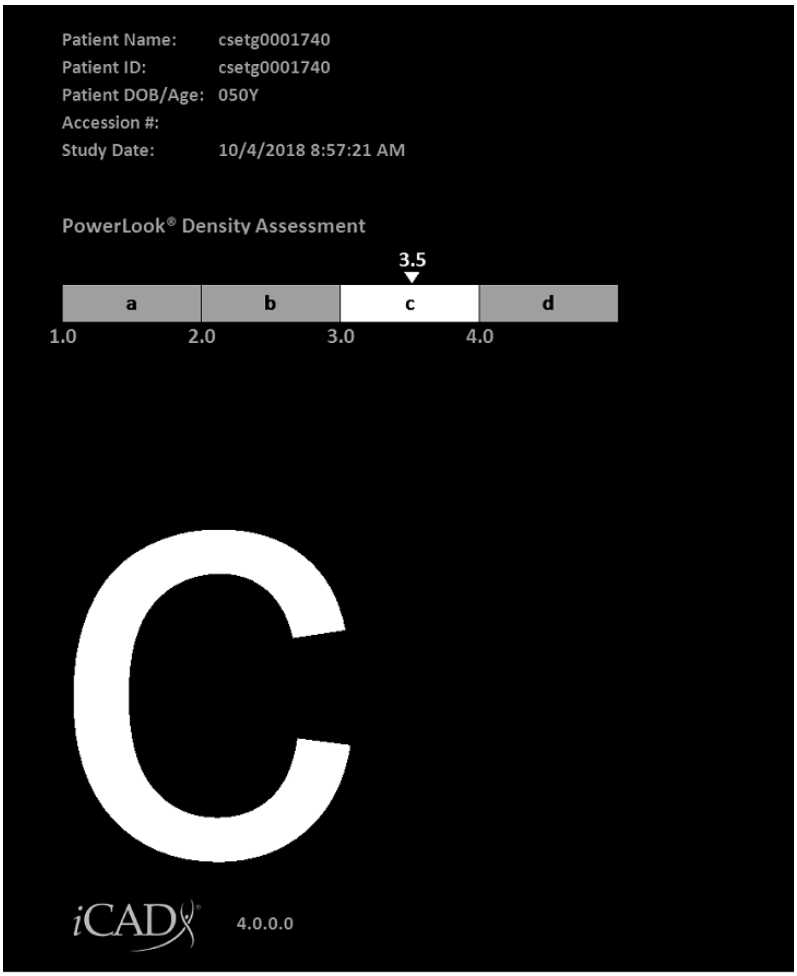

Figure 5 PowerLook Density Assessment Software Output

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