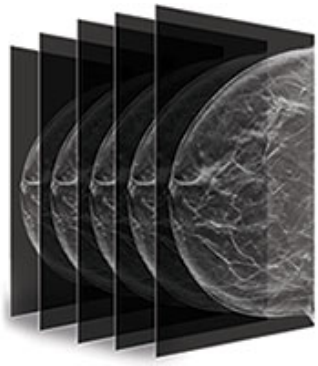
ProFound AI® Digital Breast Tomosynthesis (DBT) 3.1.(1-3) Software

Labeling and User Manual - International



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Regulatory Requirements:

ProFound AI® for Digital Breast Tomosynthesis (DBT) 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

ProFound AI® for Digital Breast Tomosynthesis Software

CE 2797

Manufacturer:

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European Authorized Representative:

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Explanation of Symbols used in this manual and for labeling of the ProFound AI for DBT 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

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1 Overview of Manual

This manual describes the ProFound AI® for Digital Breast Tomosynthesis (DBT) Software and provides training to physicians on the use of the ProFound AI for DBT Software.

- **Section 2** provides the ProFound AI for DBT Software device labeling.
- **Section 3** describes how a radiologist should use the ProFound AI for DBT Software.
- **Section 4** describes how the product is intended to be used.
- **Section 5** includes reference documentation.

2 ProFound AI for DBT Software Device Labeling

2.1 Indications for Use

iCAD ProFound AI for DBT is a computer-assisted detection and diagnosis (CAD) Artificial Intelligence (AI) software device intended to be used concurrently by physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and calcifications that may be confirmed or dismissed by the interpreting physician.

2.2 Device Description

2.2.1 Lesion Detection

The ProFound AI for DBT algorithm uses deep learning technology to identify suspicious breast lesions appearing as soft tissue densities or clusters of calcifications, taking into account each breast, view and slice. Each detected region in the tomosynthesis data is identified or represented by a mark in the form of a detection contour outlining the lesion in the tomosynthesis slice where it was detected.

2.2.2 Case and Lesion Certainty of Finding Scores

Certainty of Finding scores are relative scores assigned to each detected region and a Case Score is assigned to each case regardless of the number of detected regions. Certainty of Finding and Case Scores are computed by the ProFound AI for DBT algorithm and represent the algorithm's confidence that a specific finding or case is malignant. The scores are represented on a 0% to 100% scale. Higher scores represent a higher algorithm confidence that a finding or case is malignant. Lower scores represent a lower algorithm confidence that a finding or case is malignant. The scores are based on a population with 50% prevalence of cancer and should be interpreted as the probability of the finding or case correctly being identified as malignant in a population of 50% cancers and 50% non-cancers. These scores serve as a guide to interpreting physicians to aid in determining if a suspicious finding or case needs further work-up. **These scores are not intended to be the clinically used "probability of malignancy."** Certainty of Finding and Case Scores are not calibrated to the prevalence in the intended use population or to the prevalence in the reader study outlined in Section 2.4 of this manual, and consequently, the Certainty of Finding and Case Scores are in general higher than the actual probability of malignancy in an intended use population with less than 50% prevalence of cancer. These scores represent a relative level of concern or level of suspicion because they do not represent an absolute clinical probability of malignancy.

The end user presentation of Certainty of Finding and Case Scores (where they appear in the user interface) may vary with each mammography review application. Consult your mammography review application user manual for more information on the presentation of Certainty of Finding and Case Scores.

All detections should be considered by the interpreting physician to reduce the likelihood of missing a cancer. The product is not 100% sensitive or 100% specific. Some malignant lesions may not be detected, and some non-malignant lesions or areas that are not true lesions may be detected.

2.2.3 Operating Points

The product supports three (3) configurable operating points (low, medium, high). Each operating point represents a specific average sensitivity and specificity. The high operating point is optimized for sensitivity (highest sensitivity). The low operating point is optimized for specificity (highest specificity).

NOTE: PowerLook Platform configurations and product features may vary (e.g. marketplaces, integrated systems, etc).

2.2.4 Supported Digital Breast Tomosynthesis Systems

The following Digital Breast Tomosynthesis systems are compatible with the ProFound AI for DBT software:

- GE Senographe Pristina
- GE Senographe Essential with SenoClaire
- Hologic Selenia Dimensions/3Dimensions with standard and Clarity HD high resolution reconstruction
- Siemens MAMMOMAT Revelation
- Siemens MAMMOMAT Inspiration
- FUJIFILM Amulet Innovality with narrow and wide angle acquisition
- IMS Giotto Class

2.3 Warnings

- ProFound AI for DBT assists in breast cancer detection, not interpretation or diagnosis.
- The system is not designed to highlight interval change between mammographic exams.
- The system is not designed to highlight asymmetric breast tissue, tubular density/solitary dilated duct, skin thickening, or nipple retraction.
- The safety and effectiveness in patients with breast implants has not been established for views that do not have the implant displaced.
- The safety and effectiveness of the system has not been established in patients with biopsy proven malignant primary breast cancers that were not visible mammographically on 2D or DBT images but were detected based on ultrasound or MRI findings.
- The safety and effectiveness of the system has not been established in patients with mammographically visible malignant lymph nodes but no mammographically visible primary breast cancer.
- The safety and effectiveness of the system has not been established in images with evidence of previous surgery (e.g., surgical clips or breast reductions).

- The safety and effectiveness of the system has not been established for non-standard mammographic views (e.g., magnification/spot compression views). The system will not process or analyze non-standard views if the view is properly labeled in the DICOM header.

- Certainty of Finding and Case Scores are not intended to be the clinically used "probability of malignancy". Certainty of Finding and Case Scores are not calibrated to the prevalence in the intended use population, and consequently, the Certainty of Finding and Case Scores are in general higher than the actual probability of malignancy in an intended use population with less than 50% prevalence of cancer. These scores represent a relative level of concern or level of suspicion because they do not represent an absolute clinical probability of malignancy.

- The interpreting physician must still use diagnostic skills and any necessary additional work-up to differentiate benign from malignant lesions. Therefore, the interpreting physician work-up decision should not be altered if the system fails to detect an area that the interpreting physician has detected and has decided requires further work-up. Nor should the decision be affected if the system detects an area that the interpreting physician decides is not suspicious enough to warrant further work-up.

- Only images from a supported digital breast tomosynthesis system as defined in **Section 2.2.4** should be used with ProFound AI for DBT.

- The product is not 100% sensitive or 100% specific. Some malignant lesions will not be detected, and some non-malignant lesions or areas that are not true lesions may be detected.

- The product will detect false positives and may increase the false-positive rates as determined by the interpreting physician for both screening and diagnostic mammography. Increased false-positives may lead to unnecessary additional imaging radiation exposure, biopsy, patient anxiety, etc.

2.4 Clinical Reader Study

A clinical reader study, which was a retrospective, fully-crossed, multi-reader, multi-case (MRMC) study of iCAD's ProFound AI for DBT was conducted with 24 tomosynthesis radiologist readers and an enriched sample of 260 Hologic digital breast tomosynthesis (DBT) cases, including 65 cancer cases with 66 malignant lesions. The purpose of the study was to compare clinical performance of readers using ProFound AI for DBT detections and Certainty of Finding and Case Scores from the ProFound AI for DBT system with DBT images to that of readers using DBT without ProFound AI for DBT. The results of the study will support regulatory submissions for the ProFound AI for DBT systems.

The objectives of this reader study were the following:

A. Co-primary objectives. The co-primary objectives were to determine:

1. Whether reader performance when using ProFound AI for DBT with DBT images is non-inferior to reader performance when using DBT images without ProFound AI for DBT and
2. Whether reading time when using ProFound AI for DBT with DBT images is superior to (shorter than) reading time when using DBT images without ProFound AI for DBT.

Radiologist performance was assessed by measuring case-level area under the receiver operating characteristic (ROC) curve (AUC) for the detection of malignant lesions, where malignant lesion localization was required for a reader to correctly detect cancer in a case.

The study will be considered to have successfully demonstrated safety and effectiveness of using ProFound AI for DBT with DBT compared to using DBT without ProFound AI for DBT if the null hypothesis associated with non-inferiority of AUC is rejected and the null hypotheses associated with superiority of reading time is rejected:

- Test the null hypothesis associated with non-inferiority of case-level AUC at two-sided statistical significance level alpha = 0.05. This null hypothesis will be rejected if the lower limit of the two sided 95% confidence interval for the difference in average AUC with ProFound AI for DBT – without ProFound AI for DBT lies above the negative of the non-inferiority margin, -0.05. If and only if this null hypothesis is rejected, and
- Test the null hypothesis associated with superiority of readers reading at two-sided statistical significance level alpha = 0.05 This null hypothesis will be rejected if the upper limit of the two-sided 95% confidence interval for the difference in average reading time with ProFound AI for DBT – without ProFound AI for DBT lies below zero, i.e., if reading time decreases.

B. Secondary objectives. The secondary objectives of the reader study included the following for radiologists when using ProFound AI for DBT with DBT compared to using DBT without ProFound AI for DBT:

1. Superiority of case-level AUC
2. Non-inferiority (with non-inferiority margin delta = 0.05) of sensitivity at the case level
3. Superiority of sensitivity at the case level
4. Non-inferiority (with non-inferiority margin delta = 0.05) of sensitivity at the lesion level
5. Superiority of sensitivity at the lesion level
6. Non-inferiority (with non-inferiority margin delta = 0.05) of specificity (case-level)
7. Non-inferiority (with non-inferiority margin delta = 0.05) of recall rate in non-cancers (case-level)

Estimates and corresponding 95% confidence intervals illustrating precision in the estimates were provided for all secondary objectives. The study employed a fully-crossed design in which all readers reviewed images from all cases in two visits separated by a memory washout period of 4 weeks or more between readings of the same case with and without ProFound AI for DBT. Each reader was assigned to review half the cases with ProFound AI for DBT and the other half without ProFound AI for DBT during the first visit and the complementary with ProFound AI for DBT and without ProFound AI for DBT cases during the second visit, in a counterbalanced fashion, such that all of the cases were read by each reader both with and without ProFound AI for DBT. The case reading order was randomized separately for each reader.

The viewing application used in the clinical reader study presented the detection outline on each of the DBT slices in the view in which it was detected. The detection outline appeared more pronounced or bold on the specific slice where it was detected. The detected outline appeared fainter (not bold) on all other slices in the view. Readers were able to click on the outline on any DBT slice and automatically advance to the DBT slice where the lesion was detected.

The study results showed that both co-primary endpoints were met. Specifically, the study showed that:

1. Reader performance using ProFound AI for DBT was non-inferior to, and statistically significantly superior to, reader performance using DBT without ProFound AI for DBT. Readers had superior

per-subject average area under the receiver operating characteristic (ROC) curve (AUC) with ProFound AI for DBT, 0.852, versus without ProFound AI for DBT, 0.795. The average difference in AUC was 0.057 (95% CI: 0.028, 0.087; non-inferiority $p < 0.01$ for non-inferiority margin delta = 0.05, and $p < 0.01$ for test of difference).

2. Reading time when using ProFound AI for DBT with DBT is superior to (shorter than) radiologist reading time when using DBT without ProFound AI for DBT. Reading time improved 52.7% with ProFound AI for DBT (95% CI: 41.8%, 61.5%; $p < 0.01$).

* *Reading times may vary based on the specific functionality of the viewing application used for interpretation.*

All pre-specified secondary endpoints also were met. In addition to superiority of case-level AUC, the reader study showed that:

- Readers had superior sensitivity at the case level with ProFound AI for DBT. Average sensitivity increased by 0.080 (95% CI: 0.026, 0.134; non-inferiority $p < 0.01$ for non-inferiority margin delta = 0.05, and $p < 0.01$ for test of difference). Average case-level sensitivity was 0.770 without ProFound AI for DBT and 0.850 with ProFound AI for DBT.
- At the lesion level, readers also had superior sensitivity with ProFound AI for DBT. Average per-lesion sensitivity across readers increased by 0.084 (95% CI: 0.029, 0.139; non-inferiority $p < 0.01$ for non-inferiority margin delta = 0.05, and $p < 0.01$ for test of difference), from 0.769 without ProFound AI for DBT to 0.853 with ProFound AI for DBT.
- Readers had non-inferior specificity with ProFound AI for DBT. Specificity was 0.627 without ProFound AI for DBT and 0.696 with ProFound AI for DBT, for an average increase of 0.069 (95% CI: 0.030, 0.108; non-inferiority $p < 0.01$ for non-inferiority margin delta = 0.05).
- Finally, readers had non-inferior recall rate in non-cancer cases with ProFound AI for DBT. In non-cancer cases, lower recall rates are better than higher recall rates. Average recall rate in non-cancer cases was 0.380 without ProFound AI for DBT and 0.309 with ProFound AI for DBT, for an average reduction of 0.072 (95% CI: 0.031, 0.112; non-inferiority $p < 0.01$ for non-inferiority margin delta = 0.05).

In this study the following were observed:

- Average sensitivity increased by 0.120 (SE=0.040) in the subgroup of 15 cancer cases with only calcifications.
- Average sensitivity increased by 0.068 (SE=0.031) in the subgroup of 50 cancer cases with at least one soft tissue density or mixed lesion.
- Average specificity decreased by 0.027 (SE=0.038) in the subgroup of 24 benign and recalled (non-cancer) cases with only calcifications.
- Average specificity increased by 0.079 (SE=0.028) in the subgroup of 62 benign and recalled (non-cancer) cases with at least one soft tissue density or mixed lesion.
- Average specificity increased by 0.084 (SE=0.021) in the subgroup of 109 non-cancer cases with no lesions.

2.5 Standalone Performance on a Screening Population Dataset

2.5.1 Standalone Test Overview

A standalone study, which evaluated the performance of ProFound AI for DBT without an interpreting physician, was performed on the tomosynthesis slices only. Sensitivity was measured on cancer cases with at least 2 views per breast. Specificity and false positive (FP) rates were measured on bilateral 2-view non-cancer cases (2 views for the left breast and 2 views for the right breast). Standalone testing was performed at three (3) operating points (low, medium, high). Sensitivity, specificity, and FP rate per tomosynthesis view were measured at all three operating points (low, medium, high). The purpose of the standalone study was to assess the standalone performance of ProFound AI for DBT on dataset stratified to a screening population.

2.5.2 Standalone Dataset

A total of 5,718 stratified cases representing GE, Siemens (EMPIRE and Standard), Hologic (standard and high resolution), FUJIFILM and IMS Giotto tomosynthesis cases were selected from a case pool of 5,718 cases. A stratified bootstrap procedure was used to estimate performance over a screening patient population. The bootstrap procedure limits the number of cases in a particular category when computing performance measures. The test dataset was stratified to represent a screening patient population. **Tables 1 and 2** show the case distributions of stratified cases.

Table 1: Case distribution of non-cancer cases

Negative	Recalled or Benign	Total non-cancers
3,153	529	3,682

Table 2: Case distribution of cancer cases

Calcifications Only	Soft Tissue Densities	Total cancers
488	1,548	2036

2.5.3 Standalone Performance Results

The standalone test results at each operating point (low, medium, high) are represented in **Table 3**.

Table 3: Summary of ProFound AI for DBT Performance on Standalone Dataset

Operating Point	Case Sensitivity %	Case Specificity %	FP rate per 3D Volume
Low	87.48 (1781/2036) (86.04-88.91)	72.65 (2675/3682) (71.21-74.09)	0.15 (0.14-0.16)
Medium	91.60 (1865/2036) (90.40-92.81)	56.71 (2088/3682) (55.11-58.31)	0.31 (0.31-0.32)
High	94.01 (1914/2036) (92.98-95.04)	34.79 (1281/3682) (33.25-36.33)	0.59 (0.58-0.60)

2.5.4 Percent of Cancer and Non-Cancer Cases in Each Case Score Range

There is a one-to-one correspondence between CAD classifier scores and the Case Score that is displayed with each case. Higher CAD classifier scores correspond to cases with higher Case Scores.

For each decade range of Case Scores in **Figure 1,** the bars show the percent of Cancer and Non-Cancer cases in that range. The histograms in **Figure 1** are based on fractions of the cancer set and fractions of the non-cancer set such that the totals add up to 100% of each set. To gain a sense of how this relates to a screening population, **Table 4** shows the expected numbers assuming the screening population has 6 cancer cases and 994 non-cancer cases per 1000 women screened.

Clinicians may use this Case Score information to gain a sense of case complexity, which may be useful for prioritizing the reading worklist if supported by the specific worklist provider being used. For example, it is evident from **Figure 1** that less than 10% of the DBT non-cancer cases will have a Case Score at or above 70, while nearly 70% of the DBT cancer cases will be in that same range of Case Scores.

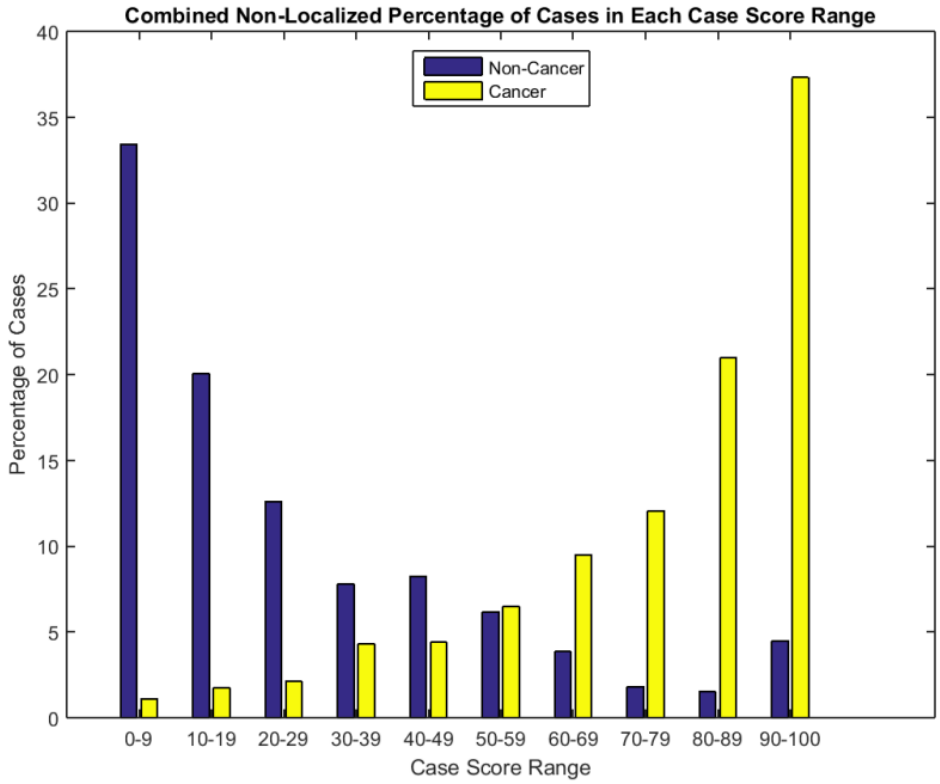


Figure 1: Combined Percent of Cancer and Non-Cancer Cases in Each Case Score Range

Table 4: Expected Numbers of Cases in a Screening Population of 1000 Women by Case

	Number of Cases from a DBT Screening Population with 1000 Women										
Case Score Range	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-100	**Total**
Non-Cancer	332	199	125	77	82	61	38	18	15	45	**994**
Cancer	0.07	0.10	0.13	0.26	0.26	0.39	0.57	0.72	1.26	2.24	**6**
Cancers/ 1,000 Screening DBTs	0.2	0.5	1.0	3.3	3.2	6.3	14.6	38.5	77.5	47.7	**6.0**

3 Detailed Product Description

The ProFound AI for DBT Software processes three-dimensional (3D) presentation X-ray image reconstructed slices, known specifically as a DICOM Digital Breast Tomosynthesis image object (DICOM BTO). Typically, CC slices and MLO slices are reconstructed for each breast to simulate a 3D view.

The ProFound AI for DBT software processes the DICOM BTO images from the tomosynthesis acquisition station and produces a DICOM Digital Mammography Structured Report (SR), DICOM Grayscale Softcopy Presentation State (GSPS), or DICOM Secondary Capture Image (SC) identifying soft tissue densities and calcifications for display with a compliant mammography review workstation. The soft tissue densities and calcifications are marked with a contour outlining the specific area of the areas of interest identified by the algorithm. These contour outlines may be projected from the DBT slices onto synthesized 2D images, dependent on the mammography and reading workstation systems. The outline marks may not represent the actual boundaries of the identified lesions. In addition to identifying suspicious areas of concern, the product will assign a Certainty of Finding Score to each detected finding and a Case Score to each case. These scores are described further in section 2.2.2 of this User Manual.

3.1 Conformance to Standards

ProFound AI conforms to the following standards:

- EN 62366-1:2015 Medical Devices – Application of Usability Engineering to Medical Devices
- IEC 62304:2015 Medical Device Software – Software life cycle processes

3.2 Installation

The PowerLook 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
International Email: Support-ous@icadmed.com

4 Use of ProFound AI for DBT Software

4.1 Overview

ProFound AI for DBT is intended to be used concurrently by interpreting physicians when reading DBT studies. When used concurrently to assist interpreting physicians in identifying regions of interest in the DBT slices, the product may improve radiologist sensitivity, specificity and reading efficiency.

4.2 Mammography Review Software

The ProFound AI for DBT results are provided in a DICOM Mammography CAD Structured Report format and are intended to be displayed using mammography review software. The display of the ProFound AI for DBT results may vary depending on the specific mammography review software features. Please consult your mammography review software user manual for specific information about how the ProFound AI for DBT results are displayed.

4.3 Principles of Operations

ProFound AI for DBT uses a deep learning algorithm to identify suspicious lesions in digital breast tomosynthesis. The digital breast tomosynthesis system creates digital 3D mammographic images that are input to ProFound AI for DBT, and these algorithms use advanced image processing, feature computations, and pattern recognition technology to analyze the images for potential areas of concern. These potential areas of concern are displayed for the interpreting physician by overlying detections at the appropriate locations of the tomosynthesis images within the mammography review software. The detected areas of concern are used by the interpreting physician as an additional tool in breast cancer detection.

4.4 Interpreting Physician Review with ProFound AI for DBT Findings

The ProFound AI for DBT detections should be turned on when reviewing the tomosynthesis views. Depending on the specific mammography review software being used, the detections may either be on automatically when the tomosynthesis views are displayed or the interpreting physician may need to turn them on. Consult your mammography review software user manual for more information about turning detections on and off and for specific information about how to navigate to the detected findings in the tomosynthesis slices.

The Certainty of Finding score should be used by the interpreting physician to help assess the likelihood that the finding is malignant. The Certainty of Finding score is represented as a percent between 0% and 100%. For example, a detection with a Certainty of Finding score of 90% means that of all the detections in the iCAD database that are similar to the detected lesion, 90% are malignant and 10% are non-malignant.

In addition to the Certainty of Finding scores assigned to each detection, the tomosynthesis study will also have a Case Score. The Case Score is represented as a percent between 0% and 100%. For example, a Case Score of 80% means that of all the cases in the iCAD database that are similar to the case being read, 80% are malignant and 20% are not malignant.

The Certainty of Finding and Case Scores are supporting information to assist the interpreting physician in making a clinical decision about whether to further work-up an area of concern or a case.

Work-up decisions should not be based solely on what is detected by ProFound AI for DBT or the Certainty of Finding and Case Scores. The interpreting physician should use all appropriate clinical information available to render a final clinical opinion. It is very important to remember that it is the interpreting physician who makes the final decision about a suspicious finding or case.

Areas of concern detected by ProFound AI for DBT include suspicious clusters of microcalcifications, spiculated and non-spiculated masses, architectural distortions, and focal asymmetric densities.

Below is the recommended case review process with ProFound AI for DBT:

1. Case Scores and Certainty of Finding scores, if available, can be used to prioritize the reading worklist if supported by the specific worklist provider being used.
2. Review patient history, including clinical information and prior imaging studies if available.
3. Evaluate any 2D images (FFDM or synthetic), if available, prior to viewing the tomosynthesis views.
4. View the tomosynthesis images. Consult your mammography review software user manual for more information about how to navigate to the regions detected by ProFound AI for DBT.
5. Use the Certainty of Finding and Case Scores, if available, to assist in determining if further work-up of the lesion or case is required. The Certainty of Finding and Case Scores should not be the only information used in rendering a clinical decision.
6. The case should be read in accordance with the tomosynthesis manufacturer's recommendations, with concurrent analysis of the ProFound AI for DBT findings.
7. Render clinical decision.

Use of Certainty of Finding and Case Scores

Certainty of Finding and Case Scores represent how difficult it is for the algorithm to determine if a detection is malignant. For example, a detection with a Certainty of Finding score of 10% means that of all the detections in the iCAD database that are similar to the detected lesion, 10% are malignant and 90% are non-malignant. Similarly, a Case Score of 80% means that of all the cases in the in the iCAD database that are similar, 80% are malignant and 20% are non-malignant. Please refer to example images in the next section.

The iCAD database does not contain an equal number of malignant and non-malignant detections or cases. Therefore, the number of detections or cases is weighted such that the proportions of malignant and non-malignant detections or cases are 50% each (50% prevalence of cancer).

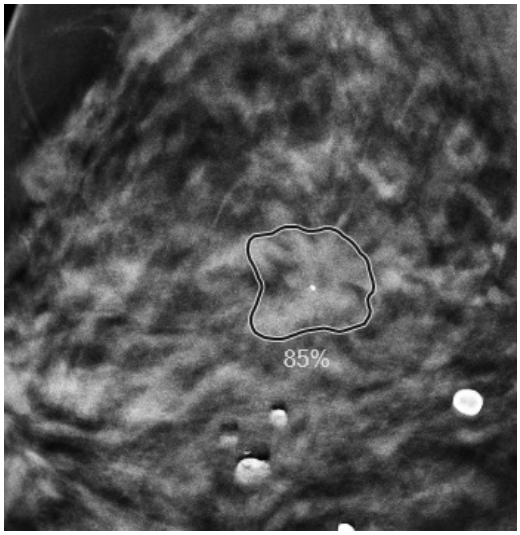
NOTE: The Certainty of Finding and Case Scores are not intended to be the clinically used "probability of malignancy". Certainty of Finding and Case Scores are not calibrated to the prevalence in the intended use population, and consequently, the Certainty of Finding and Case Scores are in general higher than the actual probability of malignancy in an intended use population with less than 50% prevalence. These scores represent a relative level of concern or level of suspicion because they do not represent an absolute clinical probability of malignancy.

All cases and detections should be reviewed by the interpreting physician and the final clinical decision is the responsibility of the interpreting physician. The Certainty of Finding and Case Scores serve to assist the interpreting physician in making a final clinical decision.

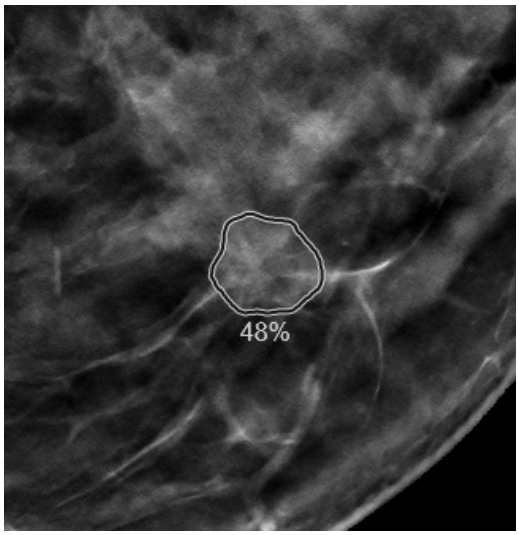
4.5 Example Images

The example images show how the ProFound AI for DBT findings should appear in the tomosynthesis images. Each mammography review software may vary in how the detected findings are presented to the radiologist. All mammography review applications should, at a minimum, render a visible contour line around the detected lesion. The examples below are for both soft tissue densities and calcifications.

Soft Tissue Density Examples

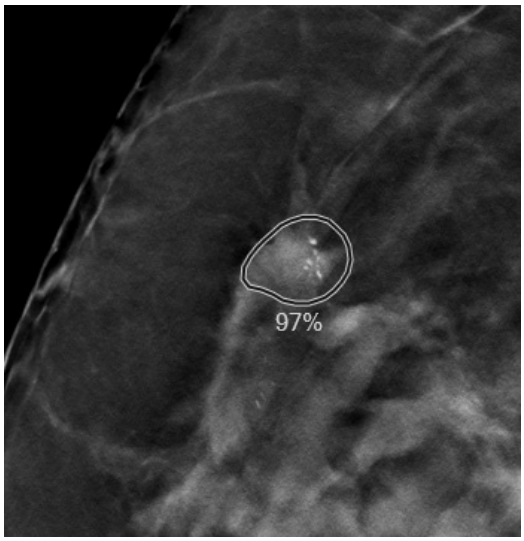


85% Certainty of Finding

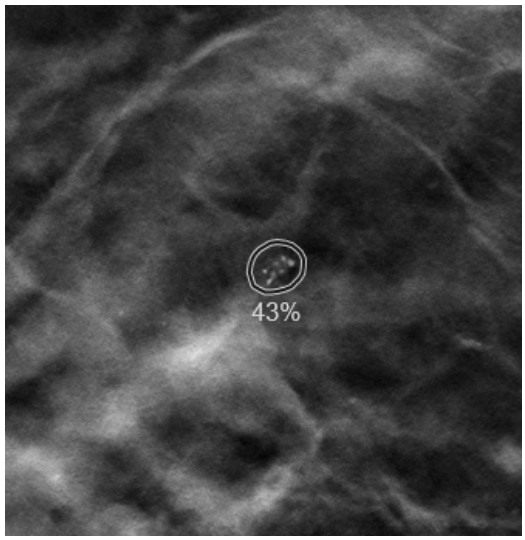


48% Certainty of Finding

Calcification Examples

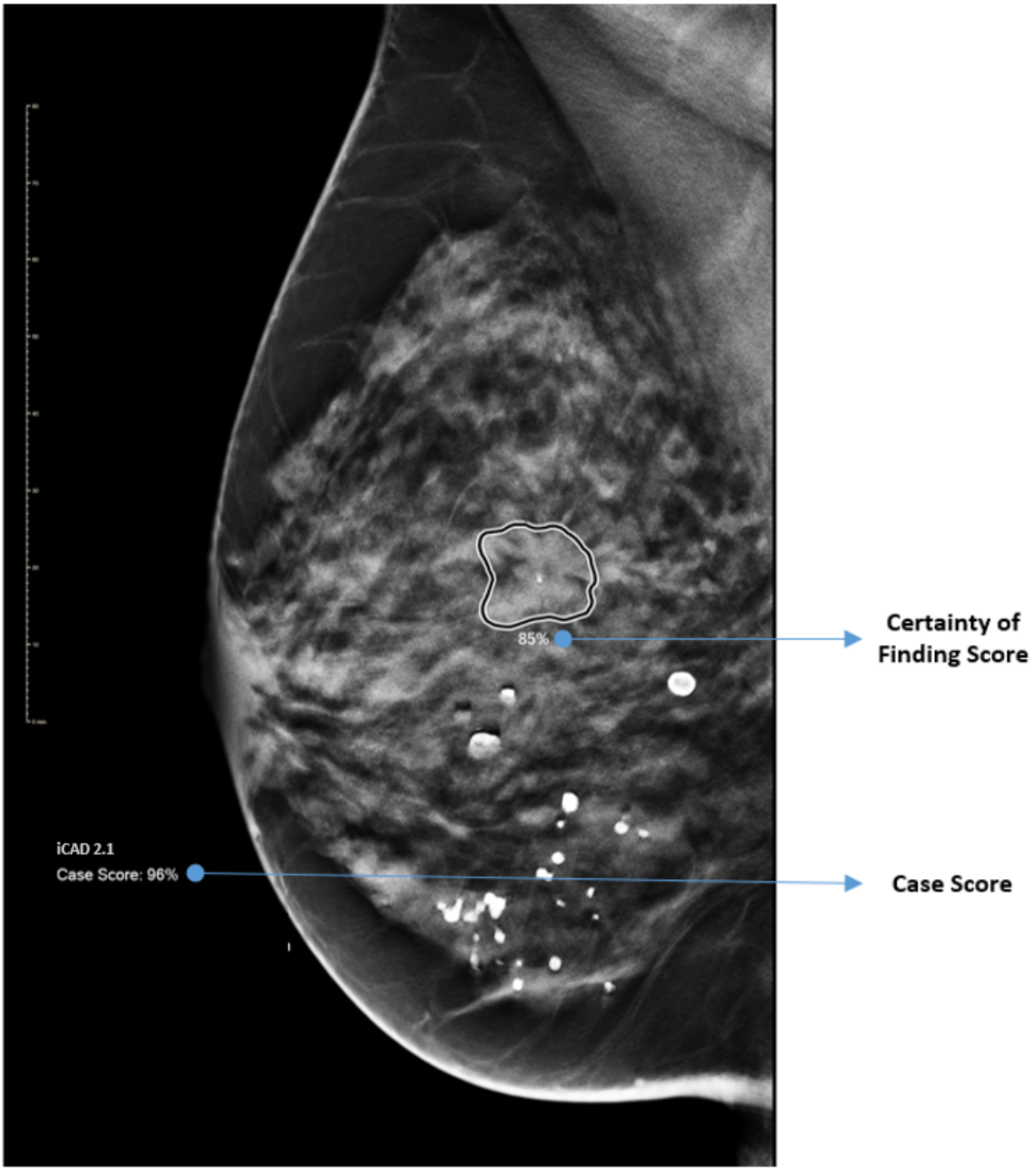


97% Certainty of Finding



43% Certainty of Finding

Example of Certainty of Finding and Case Score Presentation



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Description

DTM187 ProFound AI DBT 3.1.(1-3) Software Labeling and User Manual - US Rev. N/A to 0. Change: Initial release. (duplicated original from DTM163 revision 3.) DTM188 ProFound AI DBT 3.1.(1-3) Software Labeling and User Manual - International Rev. N/A to 0. Change: Initial release (duplicated original from DTM183 revision 0).

Justification

This document is created to comply SOP-22. Risk Assessment: There are no new hazards from this ECO Attachments: None Associated Project: 0077-2042 ProFound AI 3.1.1.1, 3.1.2.1, 3.1.3 Project Plan

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