October 2, 2024

Therapixel
Quentin De Snoeck
RAQA Director/CISO
455 Promenade des Anglais
Nice, 06200
FRANCE

Re: K241561
Trade/Device Name: MammoScreen BD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 4, 2024
Received: September 4, 2024

Dear Quentin De Snoeck:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part

803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241561

Device Name

MammoScreen BD

Indications for Use *(Describe)*

MammoScreen® BD is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. MammoScreen BD evaluates the breast tissue composition to provide an ACR BI-RADS 5th Edition breast density category. The device is intended to be used in the population of asymptomatic women undergoing screening mammography who are at least 40 years old.

MammoScreen BD only produces adjunctive information to aid interpreting physicians in the assessment of breast tissue composition. It is not a diagnostic software.

Patient management decisions should not be made solely based on analysis by MammoScreen BD.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K241561

This 510(k) summary of safety and effectiveness information is prepared in accordance with the requirements of 21 CFR § 807.92.

Applicant Information:

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06200 Nice
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Phone: +33 9 72 55 20 39

Submission Correspondent:

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Email: qdesnoeck@therapixel.com
Phone: +33 9 72 55 20 39

Date Summary Prepared: October 2, 2024

Device Information:

Trade Name:	MammoScreen® BD
Common Name:	Breast Density Assessment Software
Device Classification Name:	Automated radiological image processing software
Regulation Number:	21 CFR §892.2050, Medical image management and processing system
Regulation Class:	Class II
Product Code:	QIH
Submission type	Traditional 510(k)

Predicate Device:

The predicate device is WRDensity by Whiterabbit.ai, cleared under K202013 (Product code QIH).

Device Description

MammoScreen BD is a software-only device (SaMD) using artificial intelligence to assist radiologists in the interpretation of mammograms. The purpose of the MammoScreen BD software is to automatically process a mammogram to assess the density of the breasts.

For each examination, MammoScreen BD outputs the breast density in accordance with the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS) Atlas 5th Edition breast density categories "A" through "D".

MammoScreen BD takes as input a folder with images in DICOM formats and outputs a breast density assessment in a form of a JSON file. MammoScreen BD outputs can be integrated with compatible third-party software such as the MammoScreen Web-UI interface, PACS viewer (using DICOM Structured Report or DICOM Secondary Capture SOP Class UIDs), patient worklists, or within reporting software.

Note that MammoScreen BD outputs should be used as complementary information by radiologists while interpreting breast density. Patient management decisions should not be made solely based on analysis by MammoScreen BD, the medical professional interpreting the mammogram remains the sole decision-maker.

Indication for Use:

MammoScreen® BD is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. MammoScreen BD evaluates the breast tissue composition to provide an ACR BI-RADS 5th Edition breast density category. The device is intended to be used in the population of asymptomatic women undergoing screening mammography who are at least 40 years old.

MammoScreen BD only produces adjunctive information to aid interpreting physicians in the assessment of breast tissue composition. It is not a diagnostic software.

Patient management decisions should not be made solely based on analysis by MammoScreen BD.

Predicate device comparison:

The predicate device is WRDensity by Whiterabbit.ai, cleared under K202013.

	Subject Device **MammoScreen BD**	**Predicate Device** **WRDensity by Whiterabbit.ai (K202013)**
Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software
Product Code	QIH	QIH
Regulation Number	892.2050	892.2050
Medical Device Class	Class II	Class II
Indications for Use	MammoScreen® BD is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. MammoScreen BD evaluates the breast tissue composition to provide an ACR BI-RADS 5th Edition breast density category. The device is intended to be used in the population of asymptomatic women undergoing screening mammography who are at least 40 years old. MammoScreen BD only produces adjunctive information to aid interpreting physicians in the assessment of breast tissue composition. It is not a diagnostic software. Patient management decisions should not be made solely based on analysis by MammoScreen BD.	WRDensity is a software application intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. WRDensity provides an ACR BI-RADS 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. WRDensity produces adjunctive information. It is not a diagnostic aid.
Patient Population	Asymptomatic women undergoing mammography	Symptomatic and asymptomatic women undergoing mammography
End Users	Interpreting physicians	Interpreting physicians
Image Source Modalities	FFDM and DBT (using 2D synthetic (2DSM))	**FFDM** Hologic Selenia Dimensions Hologic Lorad Selenia **Synthetic 2D (2DSM)** Hologic C-View
Input: Image Data Format	DICOM Digital mammography images – For presentation: RCC, LCC, RMLO, LMLO	DICOM Digital mammography images – For presentation: RCC, LCC, RMLO, LMLO

	Subject Device MammoScreen BD	Predicate Device WRDensity by Whiterabbit.ai (K202013)
Measurement Scale	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013
Output Data	BIRADS 5th Ed. For each patient: MammoScreen BD breast density assessment	BIRADS 5th Ed. For each patient: Whiterabbit.ai WRDensity Breast Density Level, and Breast Density Level Probability
Output Device	Third-party Software dedicated to mammography	Mammography Workstation, PACS, RIS
Output Format	JSON format presented in a radiologist's compatible system (third-party software)	DICOM Structured Report and Secondary Capture Text labels presented in a radiologist's PACS and RIS patient worklist
Deployment	Virtual Machine Software	Virtual Machine Software
Assessment Scope	Results per exam	Results per exam
Assessment Type	Image feature-based with deep learning	Image feature-based with deep learning
Anatomical Location	Breast	Breast
PCCP	Predetermined Change Control Plan (PCCP) including: • Support of GE mammograms (no re-training required) • Support of Siemens mammograms (re-training required) • Pre-training of backbone using Unsupervised Machine Learning (as opposed to Supervised Machine Learning)	No PCCP

The indication for use of MammoScreen BD is similar to that of the predicate device. Both devices are intended for concurrent use by physicians interpreting breast images to help them with assessing the breast density. The devices are not intended as a replacement for the review of a physician or their clinical judgement, since they are not diagnostic software.

The assessment of the breast density is very similar to the predicate device The overall design of MammoScreen BD is the same as the design of the predicate device. Both medical devices use algorithms to provide an assessment of the breast density to the user in a similar manner and according to the ACR BIRADS 5th Edition. The technological characteristics are the same. The unsubstantial difference regarding the output format do not raise different questions about the safety and effectiveness of the device as compared to the predicate device.

Training dataset

De-identified screening mammograms used for training were retrospectively collected from 32,368 patients in 2 different US sites.

A detailed description of the training data is available in the Table below:

Total number of studies	108,775
Density distribution	A: 12.79% B: 34.58% C: 42.94% D: 9.38% Unknown (excluded): 0.31%
Patient ages	First quartile (Q1): 47.0 Mean: 56.0 Third quartile (Q3): 64.0
Patient Race / Ethnicity	White: 49.13% Asian: 7.63% Black or african american: 0.43% native hawaiian or pacific islander: 0.09% Unknown: 42.72%
Manufacturer	Hologic: 61.63% GE: 38.37%

Performance Data

MammoScreen BD is a software-only device.

Safety and performance of MammoScreen BD have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Tests have been performed in compliance with the following recognized consensus standard:

- IEC 62304:2006/A1:2016- Medical device software - Software life-cycle processes

Primary Objectives

The purpose of the validation testing is to measure the accuracy and the reproducibility of MammoScreen BD algorithm in assessing the breast density category.
The primary objective was to evaluate the accuracy of MammoScreen BD in assessing the breast density value in terms of agreement between MammoScreen BD and the ground truth (GT) established by consensus among the visual assessment of 5 breast radiologists.
The standalone performance for density assignment will be measured with:

- A confusion matrix between the density value assigned by MammoScreen BD and the ground truth.
- Accuracy, defined as the number of correctly classified examinations divided by the total number of examinations included in the dataset.

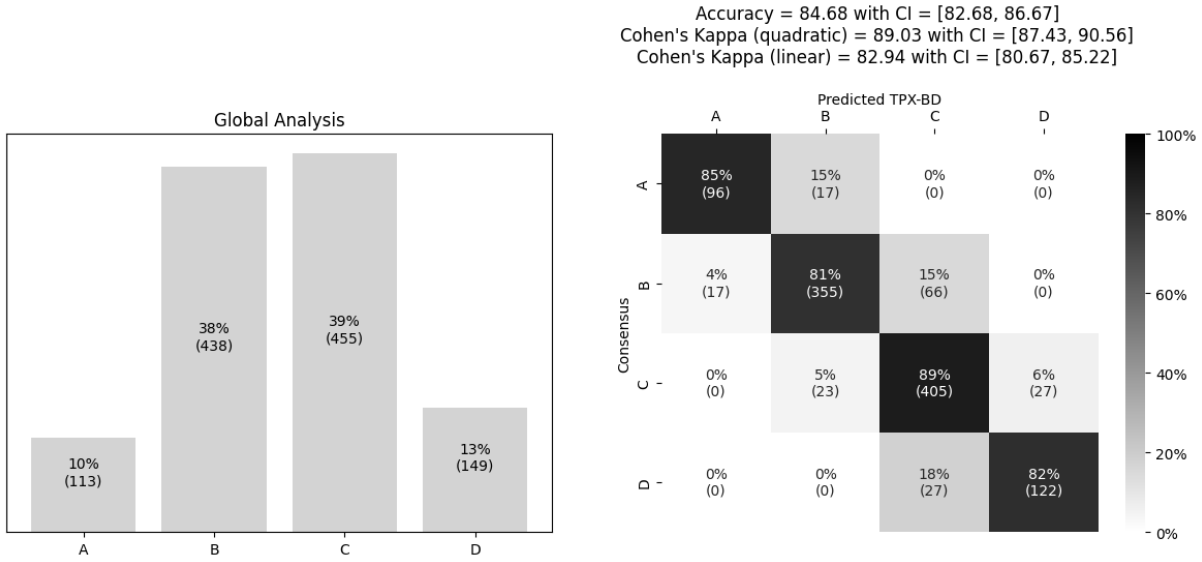
- Weighted (linear and quadratic) Cohen's kappa to give an overall estimation of the agreement.

Retrospective data of 922 women having undergone mammography at two US screening centers and one French screening center with either 2DSM (obtained from a DBT acquisition) or FFDM (total of 922 exams with 4 views each) were collected. 52.6% of the cases originate from the USA (47.4% from France). Among them, 196 patients had a 2DSM examination, 493 patients had an FFDM examination, and 233 patients had both. The provenance of the data does not intersect any of the clinical centers used for the development of the algorithm, mitigating the risk of a center-induced bias.
The whole dataset was acquired with Hologic. For the purposes of this study only FFDM and 2DSM were considered. Details of the dataset are reported in the table below:

Sources	**Origins**	**Patients**	**Studies**	**Images**	**Manufacturer (images)**	**Modalities (images)**	**Breast Densities (studies)**	**Study Dates**	**Patient Ages (y/o)**	**Patient Races**
FR_1: 437 (47.40%) US_1: 249 (27.01%) US_2: 228 (24.73%) US_3: 8 (0.87%)	USA: 485 (52.60%) FRA: 437 (47.40%)	unknown: 478 (51.84%) benign: 426 (46.20%) malignant: 14 (1.52%) undetermined: 4 (0.43%)	unknown: 478 (51.84%) benign: 426 (46.20%) malignant: 14 (1.52%) undetermined: 4 (0.43%)	benign: 2,446 (57.23%) unknown: 1,774 (41.51%) malignant: 39 (0.91%) undetermined: 15 (0.35%)	hologic: 4,274 (100.00%)	FFDM: 3,053 (71.43%) 2DSM: 1,221 (28.57%)	C: 366 (39.70%) B: 353 (38.29%) D: 106 (11.50%) A: 97 (10.52%)	min: 2015-05-22 max: 2023-02-15	min: 40 q25: 52.0 mean: 59.7 q75: 67.0 max: 90	unknown: 451 (48.92%) white: 273 (29.61%) asian: 102 (11.06%) black or african american: 88 (9.54%) american indian or alaska native: 4 (0.43%) native hawaiian or pacific islander: 4 (0.43%)
922	922	922	922	4,274	4,274	4,274	922			922

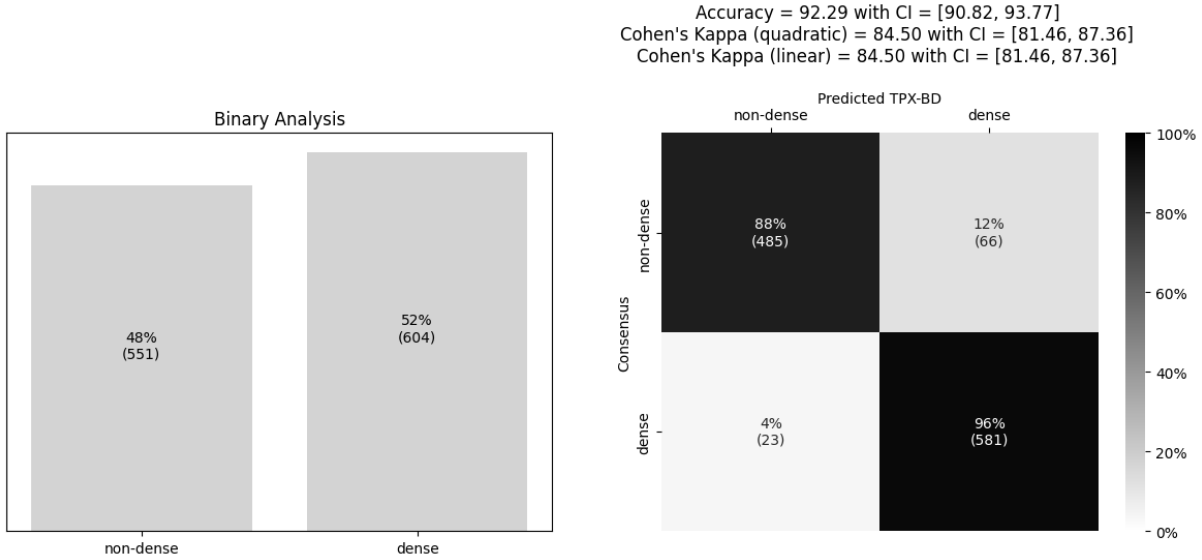
Note that the same patients may have both FFDM and 2DSM examinations.

On the four-class task, MammoScreen BD achieved a quadratically-weighted Cohen's kappa of 89.03, 95% confidence interval [87.43 – 90.56]. A confusion matrix demonstrating the level of agreement between the breast density level and the radiologist consensus for each BI-RADS breast density category can be found in the right part of the figure below:



(Left) Distribution of breast density based on the consensus established among 5 radiologists. (Right) Confusion matrix comparing the performance of MammoScreen-BD against the radiologist consensus assessment of breast density for the four-class BI-RADS breast density task. The number of exams within each bin is shown in parentheses.

On the binary classification task, MammoScreen BD achieved a quadratically-weighted Cohen's kappa of 84.50, 95% confidence interval [81.46, 87.36]. The confusion matrix is presented in the figure below:

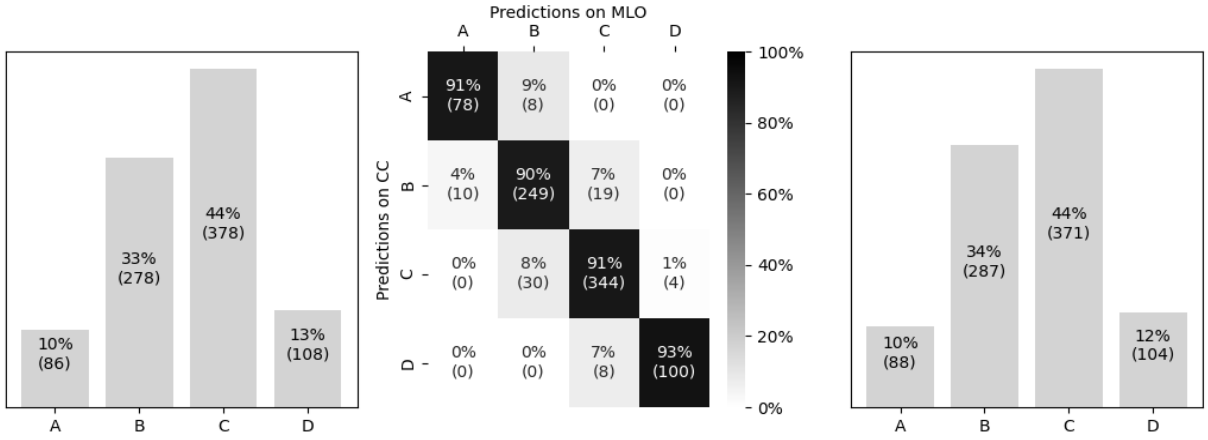


(Left) Distribution of breast density ground truth labels grouping dense (BI-RADS C+D) and non-dense (BI-RADS A+B). (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density for the binary breast density task. The number of exams within each bin is shown in parentheses.

Secondary Objectives

- **Same woman CC and MLO views**

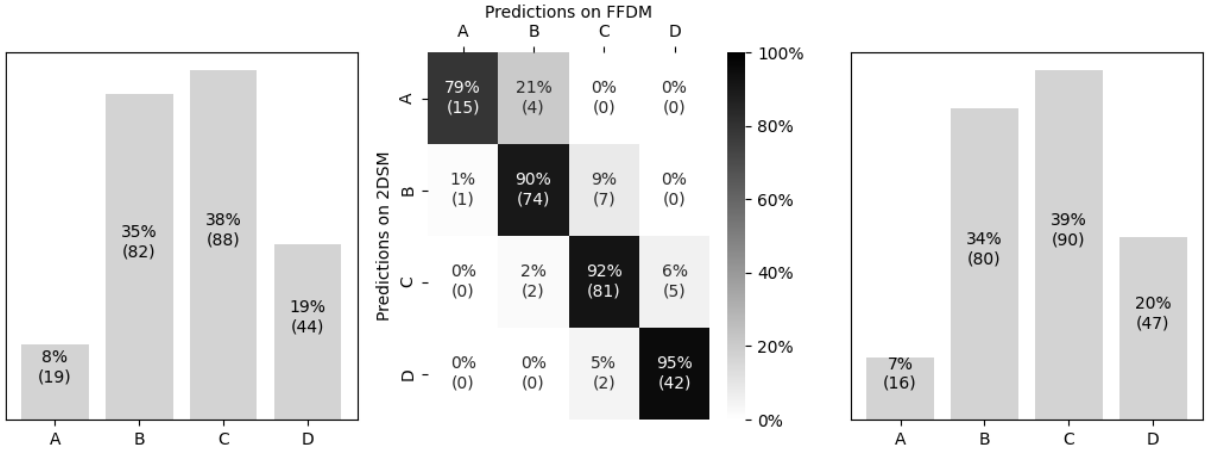
In addition to what was evaluated with the primary objectives, for a deeper understanding of MammoScreen BD, consistency was evaluated separately on CC and MLO views of the same patients (see the figure below). Consistency was assessed by evaluating the agreement, in terms of percentage of cases, between the density value for the mediolateral-oblique (MLO) and cranio-caudal (CC) views of the same breast. We observe a good agreement between breast density assessment on CC and MLO views, with a minimum of 90% on breast density B and a maximum of 93% on breast density D. This indicates that MammoScreen BD behaves equally well independently on CC and MLO views.



Contingency matrix comparing the breast density assessment (four-class BI-RADS breast density) of MammoScreen BD on CC and MLO views of the same patient. Individual assessments for CC (left) and MLO (right) are given. The number of exams within each bin is shown in parentheses.

- **Same woman 2DSM and FFDM**

Reproducibility was further evaluated on 2DSM and FFDM mammograms of the same patients (see the figure below). 233 patients had both types of examinations and were used during this analysis. We observe a fair agreement between breast density assessment on 2DSM and FFDM. The highest breast density of type D (95%) and the smallest agreement is obtained on breast density of type A (79%).

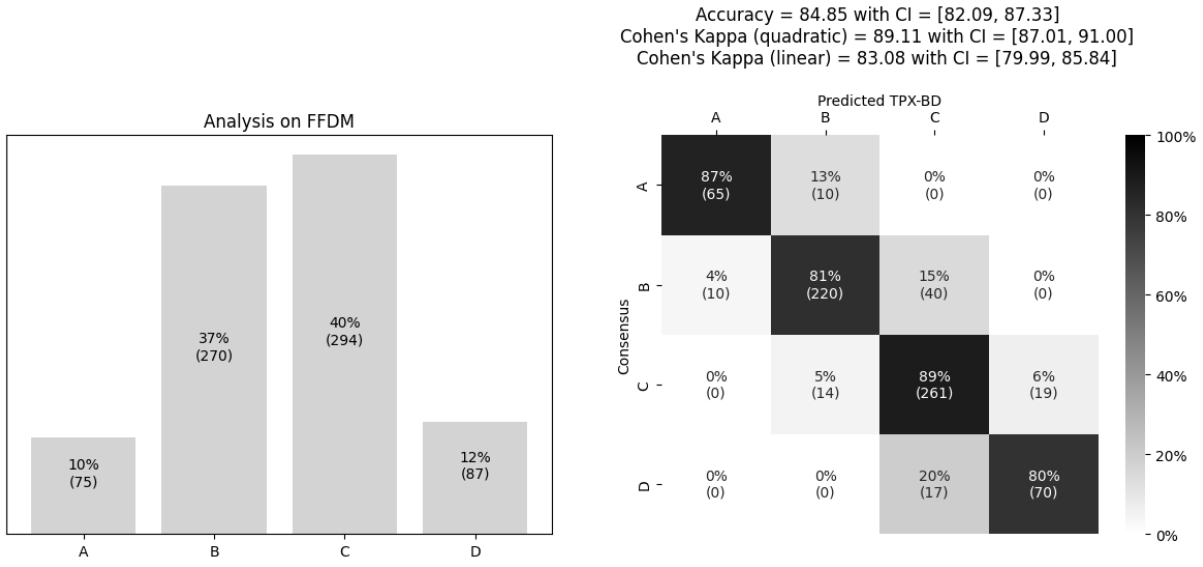


Contingency matrix comparing the breast density assessment (four-class BI-RADS breast density) of MammoScreen BD on 2DSM and FFDM of the same patients. Individual distribution of assessments for 2DSM (left) and FFDM (right) are given. The number of exams within each bin is shown in parentheses.

- **Subgroup analysis**

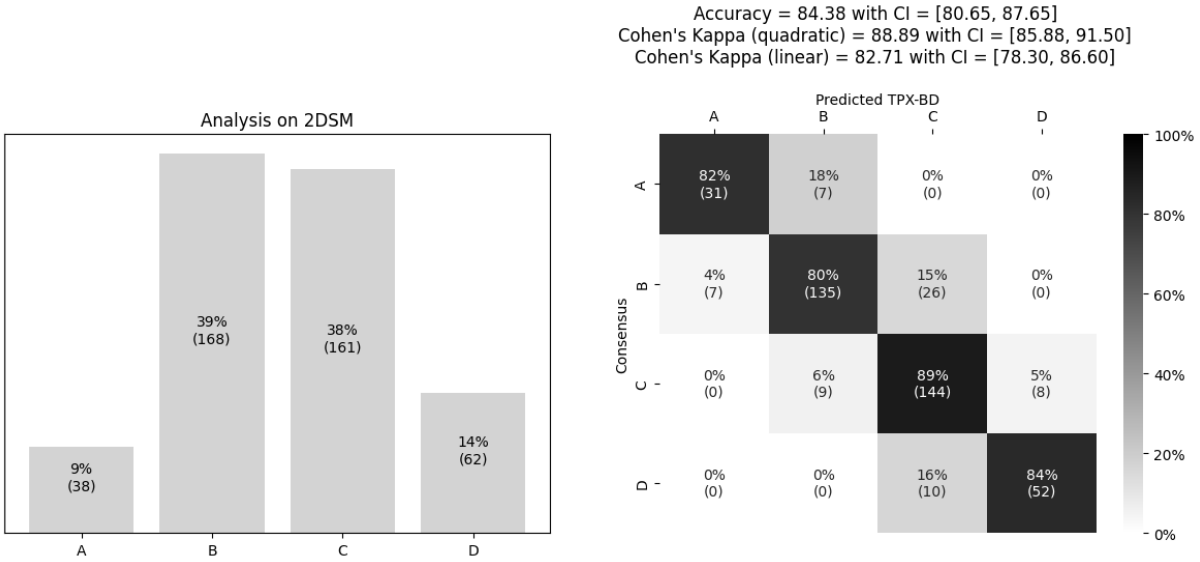
  - **Image modality**

When considering FFDM mammogram only, MammoScreen BD achieved a quadratically-weighted Cohen's kappa of 89.11, 95% CI [87.01 – 91.00] (see the figure below).



(Left) Density label distribution on FFDM mammograms only. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on FFDM mammograms.

The same metric achieves a value of 88.89, 95% CI [85.88 – 91.50] when evaluated on 2DSM mammograms (see the figure below). Overall, performances on FFDM and 2DSM are comparable with those observed in the primary objectives.



(Left) Density label distribution on 2DSM mammograms only. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on 2DSM mammograms.

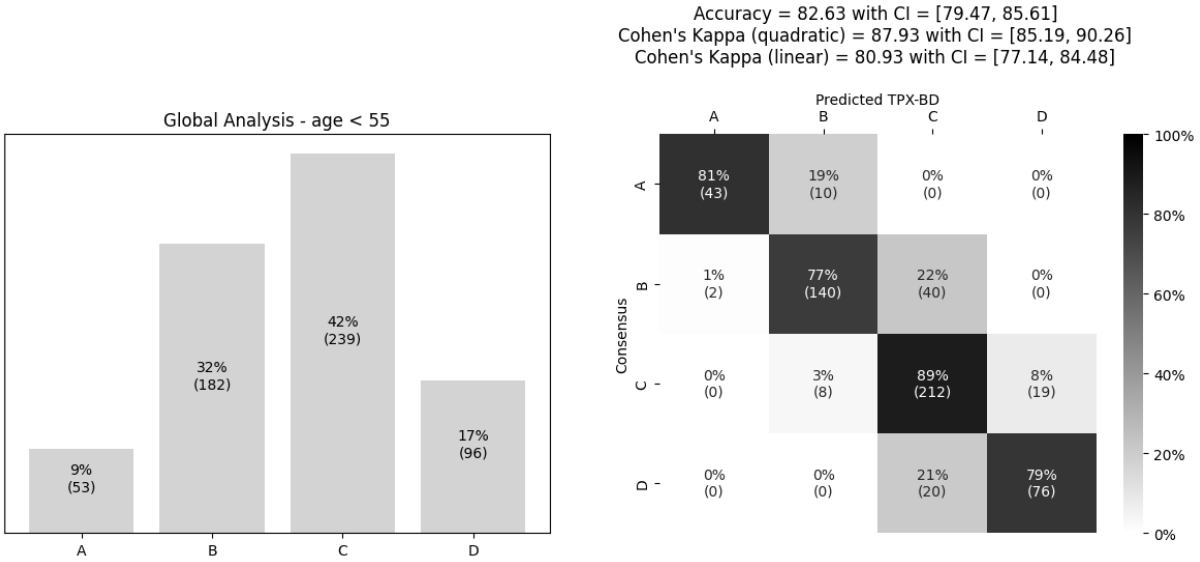
- **Age**

Performances of MammoScreen BD in terms of quadratically-weighted Cohen's kappa on different age groups were evaluated as follows:

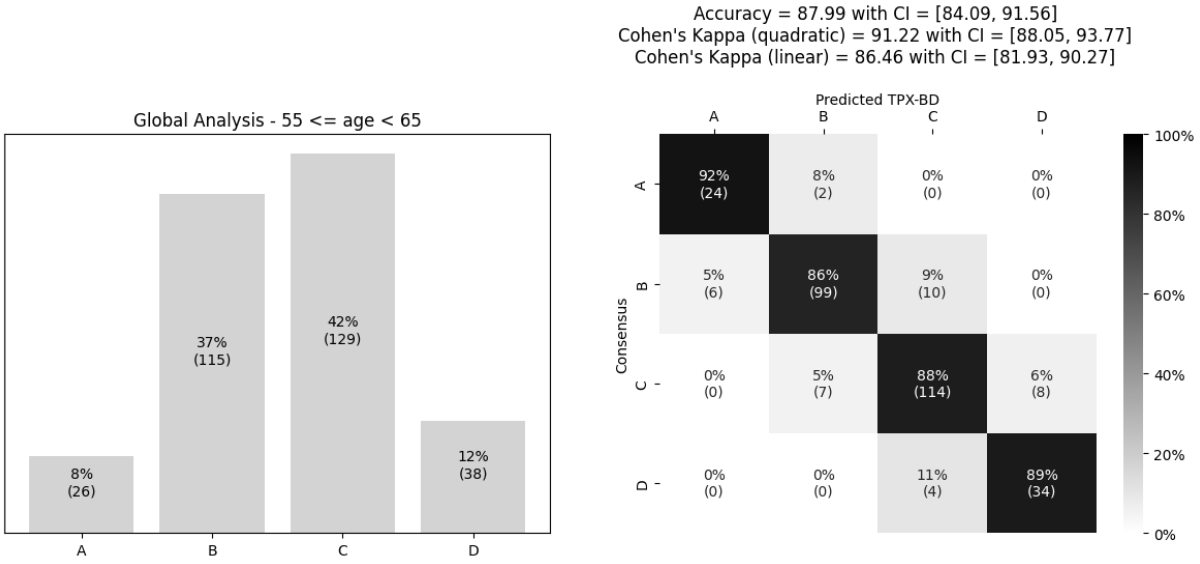
- Age < 55: 87.93 (95% CI: 85.19 – 90.26)
- 55 ≤ Age < 65: 91.22 (95% CI: 88.05 – 93.77)
- Age ≥ 65: 87.15 (95% CI: 82.70 – 90.96)

MammoScreen BD performances on subgroups based on age are comparable with performances observed in the primary objectives. A slightly lower agreement of MammoScreen BD compared to radiologists is observed on the oldest age group (age ≥ 65) with a quadratically-weighted Cohen's kappa of 87.15.

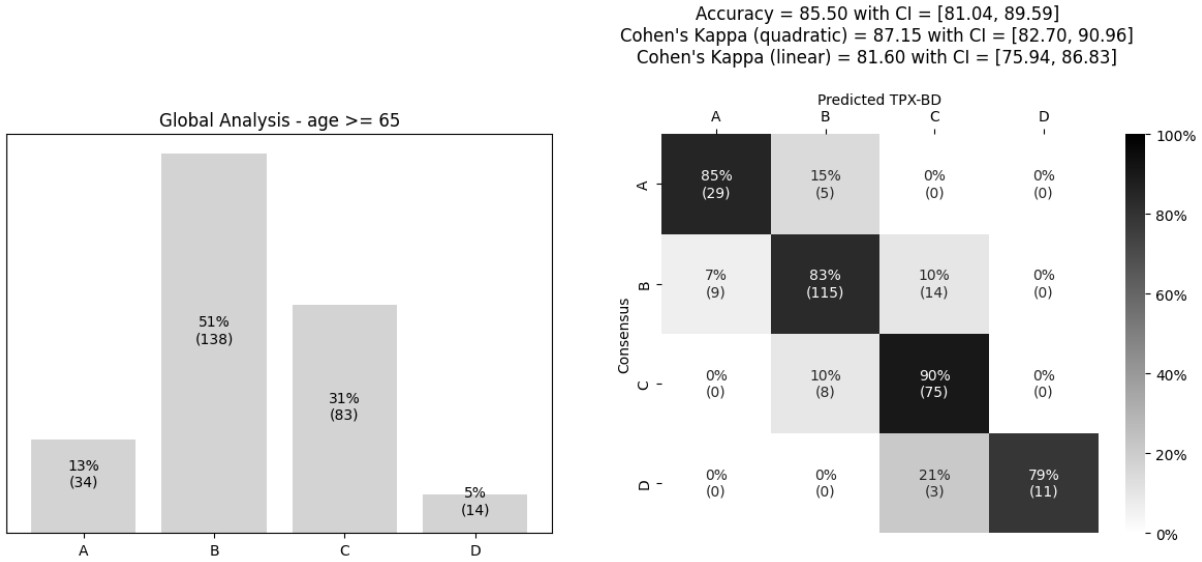
Please see the related figures below.



(Left) Density label distribution on patients younger than 55 years old. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such patients.



(Left) Density label distribution on patients between 55 and 65 years old. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such patients.



(Left) Density label distribution on patients older than 65 years old. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such patients.

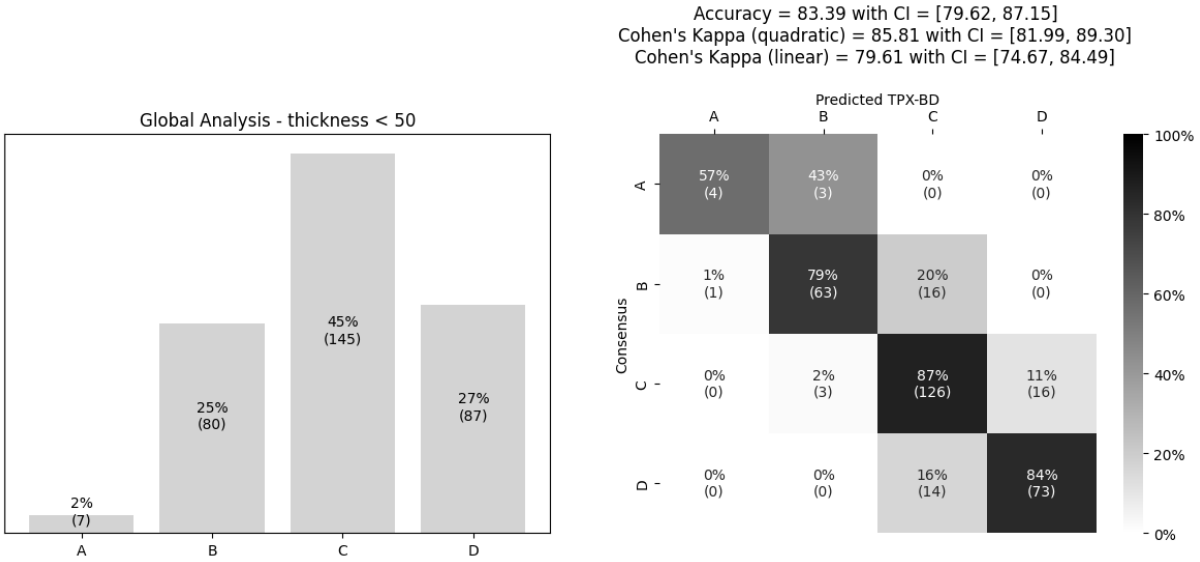
- **Breast thickness**

Performances of MammoScreen BD in terms of quadratically-weighted Cohen's kappa on different breast thickness groups were evaluated as follows:

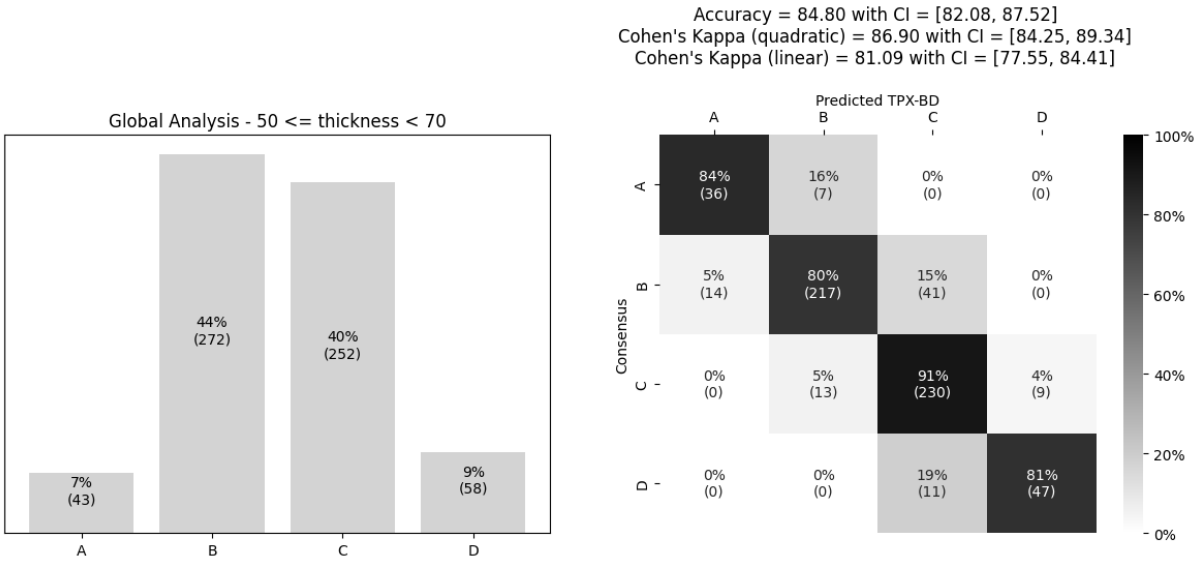
- Thickness < 50 mm: 85.81 (95% CI: 81.99 – 89.30)
- 50 mm ≤ Thickness < 70 mm: 86.90 (95% CI: 84.25 – 89.34)
- Thickness ≥ 70 mm: 89.29 (95% CI: 85.19 – 92.89)

A lower agreement on low-dense breasts (density A) on thickness less than 50 mm is observed, but few data were available (7 cases). Similarly, a lower agreement on high-dense breasts (density D) on thickness greater than 70 mm is observed. Likewise, few samples were available (4 cases). Overall, MammoScreen BD performances on subgroups based on breast thickness are comparable with performances observed in the primary objectives.

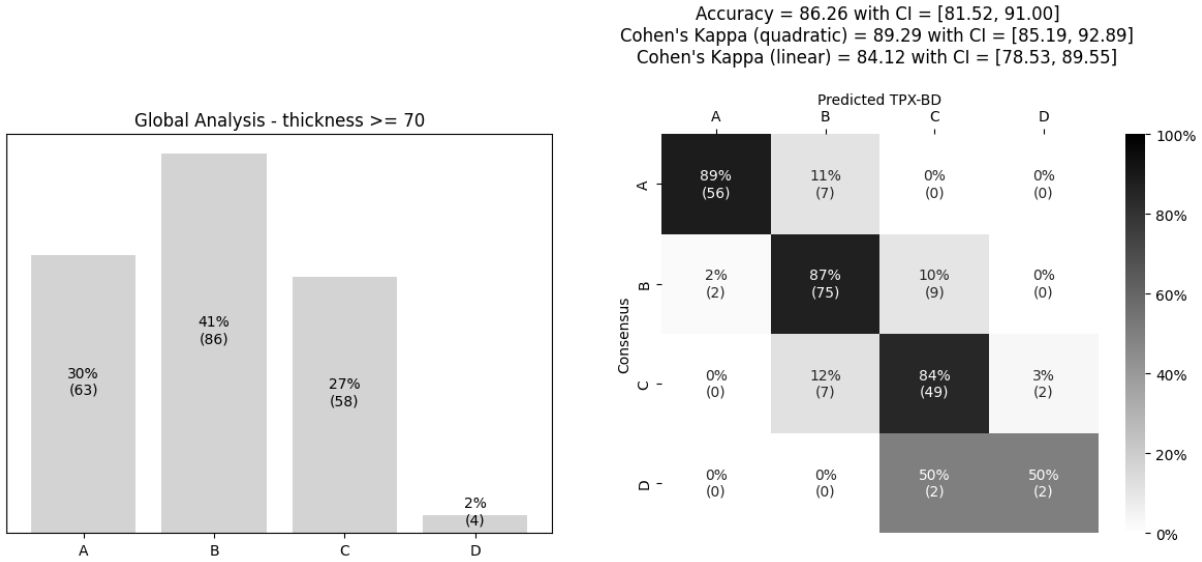
Please see the related figures below.



(Left) Density label distribution on screen with breast thickness lower than 50mm. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.



(Left) Density label distribution on screen with breast thickness between 50mm and 70mm. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.



(Left) Density label distribution on screen with breast thickness greater than 70mm. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.

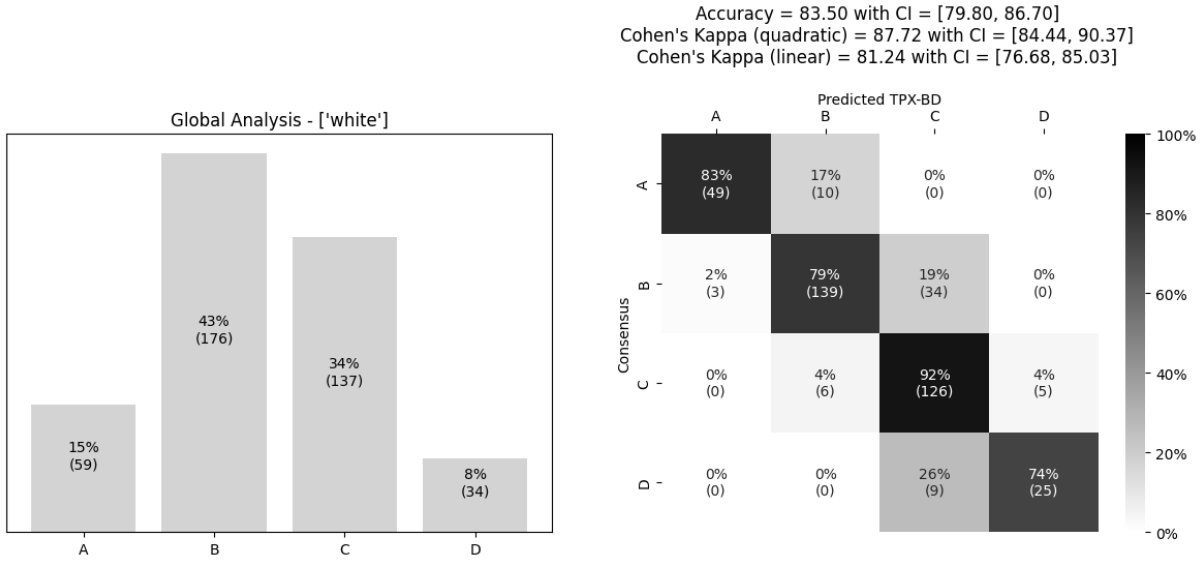
- **Race**

Performances of MammoScreen BD in terms of quadratically-weighted Cohen's kappa on different race groups were evaluated as follows:

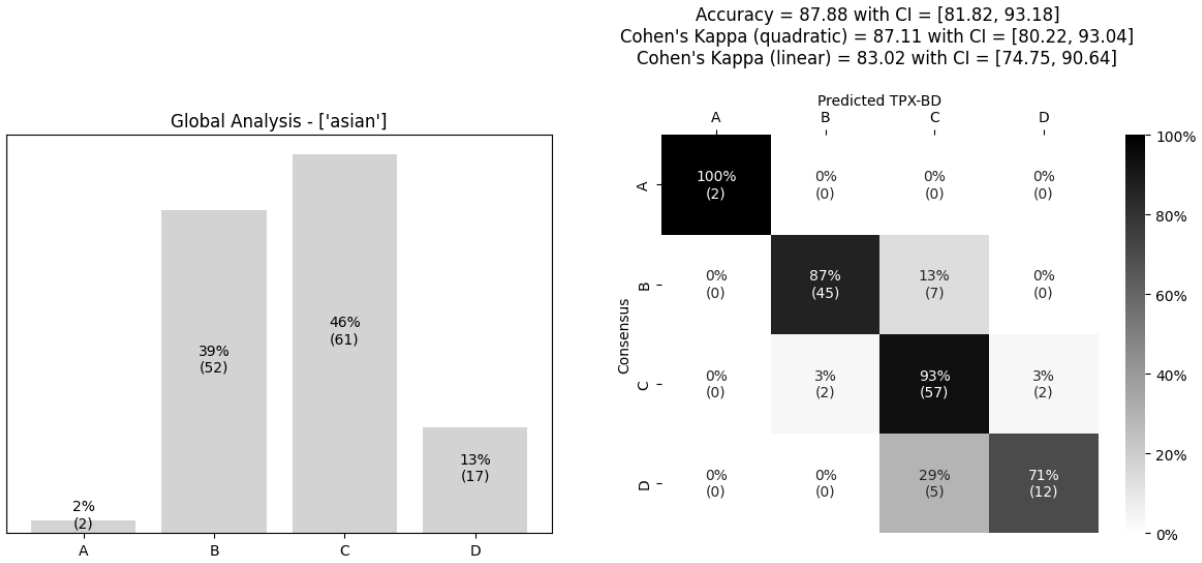
- White: 87.88 (95% CI: 81.82 – 93.18)
- Asian: 87.11 (95% CI: 80.22 – 93.04)
- Black or African American: 90.82 (95% CI: 85.58 – 94.97)
- American Indian or Alaska native or native Hawaiian or Pacific islander: 53.85 (95% CI: 0.00 – 83.33)

A lower agreement of MammoScreen BD compared to radiologists is observed on the last group including American Indians, Alaska natives, native Hawaiians and Pacific islanders with a quadratically-weighted Cohen's kappa of 53.85. However, this result is mainly due to the limited size of this group (8 patients in total). Overall, MammoScreen BD performances on subgroups based on race are comparable with performances observed in the primary objectives and does not appear to be biased with respect to race.

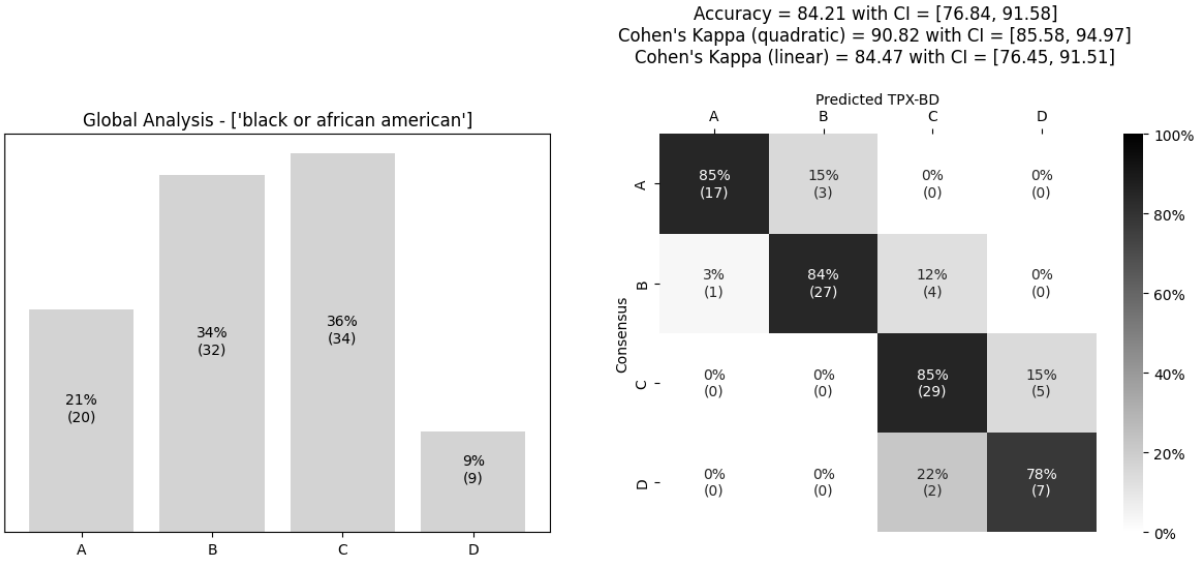
Please see the related figures below.



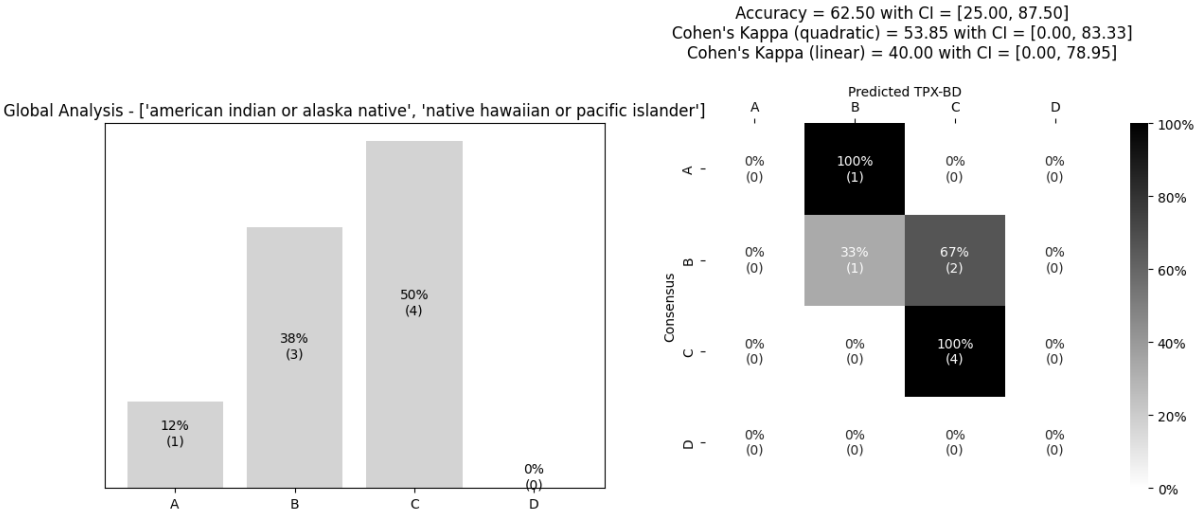
(Left) Density label distribution on White patients. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.



(Left) Density label distribution on Asian patients. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.



(Left) Density label distribution on Black patients. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.



(Left) Density label distribution on American Indians, Alaska native, native Hawaiian or pacific islander patients. (Right) Confusion matrix comparing the performance of MammoScreen BD against the radiologist consensus assessment of breast density on such screens.

The performance testing results indicate that MammoScreen BD does not pose any new concerns regarding safety or effectiveness. Additionally, it was established that MammoScreen BD is non-inferior to the targeted performance.

Predetermined Change Control Plan (PCCP)

MammoScreen BD is powered by machine-learning neural architectures. Therapixel will make future algorithm improvements under a PCCP. The plan describes the future modifications, assesses their impact, and a modification protocol details how data management, re-training, performance evaluation and update procedures will be handled.

The table below explains, for each Predetermined change, the data used for development/modification and testing, and the monitoring methodology.

	Modification 1: **Support of GE mammograms (no re-training required)**	**Modification 2:** **Support of Siemens Mammograms (re-training required)**	**Modification 3:** **Pre-training of backbone using Unsupervised Machine Learning (as opposed to Supervised Machine Learning)**
Data used for development and modifications, representing the target population	No new data collection is foreseen for this change.	Siemens, FFDM Siemens, 2DSM	No new data collection is foreseen for this change.
Comprehensive testing for planned changes	Agreement testing against the visual assessment of 5 radiologists on GE mammograms.	Agreement testing against the visual assessment of 5 radiologists on Hologic mammograms. Agreement testing against the visual assessment of 5 radiologists on Siemens mammograms.	Agreement testing against the visual assessment of 5 radiologists on Hologic and new manufacturer(s) mammograms.
Acceptance criteria of the updated device	Quadratic kappa on GE mammograms superior to 0.85. Linear kappa, accuracy, and density bins (A, B, C and D) on GE	Quadratic kappa on Siemens and Hologic mammograms superior to 0.85 Linear kappa, accuracy, and density	Quadratic kappa on Hologic mammograms superior to 0.85. Linear kappa, accuracy, and density bins (A, B, C and D)

	mammograms non-inferior to the comparator device (K241561) on Hologic mammograms.	bins (A, B, C and D) on Siemens and Hologic mammograms non-inferior to the comparator device (K241561) on Hologic mammograms.	on Hologic mammograms non-inferior to the comparator device (K241561) on Hologic mammograms.
Characterization of the device before and after implementation of changes	The device will be accessible to more centers, and thus to more woman. Prevents obsolescence of MammoScreen BD. Better representation of breast tissue diversity leading to higher overall performances and a better generalization on unseen data.		
Monitoring, detection, and response to deviations in device performance.	Therapixel monitors customer sites. The distribution of breast density assessment obtained is determined on a representative screening distribution, which serves as a Reference Distribution. Device monitoring compares breast density assessment in real conditions to the reference distribution and alerts of any deviations. The investigation can result in a field-safety notice, a Medical Device Report.		

Conclusions

Performance testing results demonstrated that the device is safe and effective.

Therapixel has applied a risk management process following FDA-recognized standards to identify, evaluate, and mitigate all known hazards related to MammoScreen BD. All identified risks are effectively mitigated, and it can be concluded that the residual risk is outweighed by the benefits. Considering all data in this submission, the data provided in this 510(k) supports the safe and effective use of MammoScreen BD for its indications for use and substantial equivalence to the predicate device.