HOLOGIC®

Customer Technical Bulletin

CTB-01102

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Product: 3Dimensions™   **Subsystem:**   Genius AI™ Detection,
                Dimensions®   ImageChecker® CAD

Subject: Frequently Asked Questions Regarding Genius AI™ Detection and
               ImageChecker® CAD Functionality

Purpose

The purpose of this Customer Technical Bulletin (CTB) is to answer common questions related to the availability of Computer Aided Detecton (CAD) results when both Genius AI Detection and ImageChecker CAD are licensed on a 3Dimensions or Dimensions systems (referred to as "Dimensions" below). These Freqently Asked Questions (FAQs) are applicable only to Dimensions systems in the United States and Canada.

References

MAN-05228 - *Understanding ImageChecker CAD 10.0 User Guide*

MAN-07021 - *Genius AI Detection Physician User Guide*

MISC-07215 - *Genius AI Detection Workstation Feature Checklist*

WP-00178 - *Genius AI Detection for Breast Tomosynthesis White Paper*

Background

Customers who have recently adopted Genius AI Detection (GAID) on their Dimensions systems have had questions regarding missing CAD results on images. The series of questions and answers in this Customer Technical Bulletin are meant to assist in understanding some of the situations that may arise, and the options available for meeting expectations.

Before using this document, please consult Agile for the latest revision.

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Frequently Asked Questions

What is the difference between Genius AI Detection and ImageChecker CAD?

Please consult WP-00178 for understanding the signficant technology and performance differences between GAID's Deep Learning algorithm and ImageChecker CAD's traditional CAD machine learning algorithm. For the purpose of explaining displayed results in this FAQ document the differences are simplifed to:

- **GAID** is generated from <u>3D mammography</u> image data and can be displayed on both 3D and 2D image types using information contained in the DICOM headers of the image data and the Mammography CAD Structured Report(s).

- **ImageChecker CAD** is generated from <u>conventional 2D or synthesized 2D mammography</u> image data and can be displayed on conventional 2D or synthesized 2D images.

Why am I not seeing GAID results for certain mammography view types?

GAID Deep Learning has been approved by the FDA for use with CC and MLO mammography screening views only. ImageChecker CAD customers may be familiar with receiving CAD results for additional view types such as ML, XCCL, XCCM, LM, ISO, and more. The regulatory process for AI deep learning algorithms has changed since ImageChecker CAD 10.0 was cleared, requiring extensive data collection that is not yet available for additional views. Hologic is investigating options for extending GAID to additional mammography view types.

Why am I not seeing GAID results for all CC and MLO mammography view types?

ImageChecker CAD users may be familiar with receiving CAD results for Implant Displaced, Rolled, Axillary Tissue, Nipple in Profile, Tangential, and other modified CC and MLO view types. In the years since ImageChecker CAD 10.0 was cleared, the FDA approval criteria have changed regarding the amount of data necessary for submission. At this time, GAID results are NOT approved by the FDA to process modified CC and MLO views. Hologic is investigating options for extending GAID to modified CC and MLO views.

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Why am I not seeing GAID results display on both 3D and 2D images?

GAID results can be displayed on 3D 1mm slices, 3DQuorom SmartSlices, Intelligent 2D™ or C-View™ synthesized 2D images, and conventional 2D images. The information contained within the DICOM output provides all the necessary detail for properly projecting results onto each image type. Hologic SecurView® workstations 11.0 and later have this functionality.

For non-Hologic workstation users, Hologic has a program working with many PACS vendors to ensure they are: aware of GAID and the information available in the DICOM header, have sample data for testing, and have access to technical resources. The document, "MISC-07215 Genius AI Detection Workstation Feature Checklist" may be used to evaluate your workstation's GAID results display capabilities.

For those workstations that are not able to project GAID results for the slices onto the corresponding synthesized 2D or conventional 2D images, the Dimensions AWS can be configured to send Mammography CAD Structured Reports that directly reference the synthesized 2D and conventional 2D images.

For those workstations not yet able to render GAID results from Mammography CAD Structured Reports, the Dimensions AWS can be configured to send GAID results as a DICOM Secondary Capture Image, where the CAD results are presented on a scaled down version of the CC and MLO views in a 2x2 layout. Any imaging workstation should be able to display this very basic image format.

Hologic Technical Solutions Specialists and Field Connectivity Specialists are available to work with customers regarding which configuration options are possible for their specific reading environment.

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My Dimensions has both GAID and ImageChecker CAD licenses. I see GAID results on CC and MLO views, but do not see ImageChecker CAD results for the patient, especially on the views and modified views that do not have GAID results at this time. What is happening?

GAID Deep Learning technology finds cancers with better accuracy than ImageChecker CAD, Hologic's previous generation CAD[1-2]. A White Paper is available to help understand the differences between Genius AI Detection and ImageChecker CAD algorithms (see References section). Because both GAID and ImageChecker CAD algorithms are available on Dimensions, Hologic designers carefully thought through the impact of running GAID on 3D mammography data, and ImageChecker CAD on 2D image data for the same patient study. As a result, it was decided that ONLY GAID should be run on a study if a patient has any GAID eligible views (CC and MLO views), and ImageChecker CAD processing will NOT be applied to the patient's procedure to avoid any confusion of markings and ensure the superior software is utilized.

While Hologic believes this design decision is in the best interest of our customers and their patients, for those with concerns over this behavior, workarounds are available. These workaround options are NOT recommended by Hologic, but are possible.

- Customers may split up procedures to isolate the views eligible for ImageChecker CAD processing from the GAID eligible CC and MLO views, thereby receiving algorithm results for all views at the workstation. Display and presentation of the results will be subject to the workstation's hanging protocols and functionality.

- Customers may also consider using an external Cenova™ server to apply ImageChecker CAD to a procedure with views not supported by GAID, producing ImageChecker CAD results from Cenova in addition to the GAID results coming from Dimensions. This will result in multiple Mammography CAD Structured Reports being sent to the workstation, potentially with different CAD marks provided for the views supported by both algorithms. Display and presentation of the results will be subject to the workstation's capabilities.

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[1] Reference FDA Clearance: K201019
[2] Reference DHM-10095_002 MAN-036822. Understanding R2 ImageChecker CAD 10.0. Image Checker PMA Approval P970058

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<u>Technical Support</u>

To contact technical support regarding the content of this Customer Technical Bulletin, please see below.

<u>Customers in the United States</u>

Please use the following contact information to reach technical support:
Phone:1 (877) 371-4372
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<u>Hologic Field Service Engineers</u>

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