

# *dentally* *vision* AI<sup>+</sup>



## Dentally Vision AI User Guide

Provided by



CE

User Guide Version 0.06

*Dentally Vision AI is powered by Pearl.*

## Publication date

August 2024

## Copyright

© 2024 RealCloud Imaging, Inc. All rights reserved. No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language in any form or by any means without the prior written permission of RealCloud Imaging, Inc.

## Software license notice

Your license agreement with Henry Schein One, which is included with the product, specifies the permitted and prohibited uses of the product. Any unauthorized duplication or use of Dentally Vision and Dentally Vision AI, in whole or in part, in print or in any other storage and retrieval system is forbidden.

## Licenses and trademarks

Dentally Vision AI and the Dentally Vision AI logo are registered trademarks of Henry Schein One. Henry Schein One and its logo are trademarks of Henry Schein One. The Dexis imaging software, product names, and logo are either trademarks or registered trademarks of Dexis, LLC. The Planmeca imaging software and product names are either trademarks or registered trademarks of Planmeca USA, Inc.

[For additional Real Cloud Imaging Licence and Trademarks see page 19](#)

[For additional Second Opinion Licence and Trademarks see page 20](#)

# Table of Contents

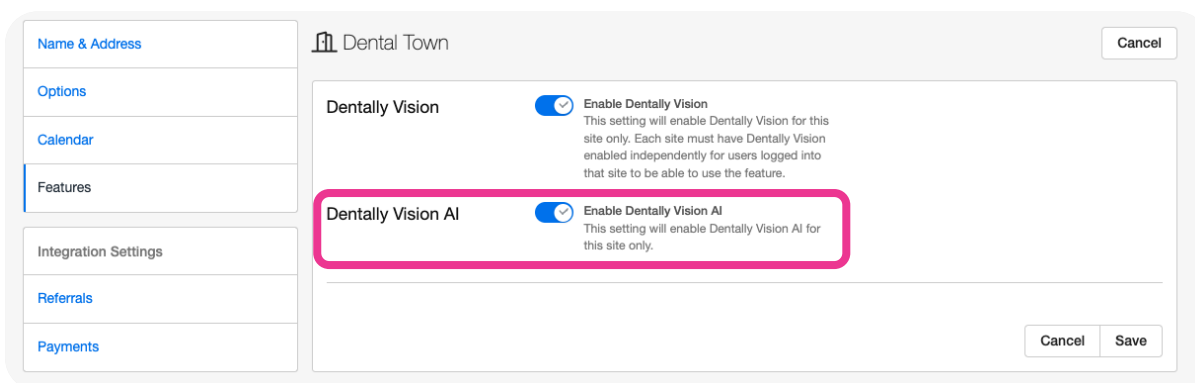
Dentally Vision AI User Guide _____	1
How to turn on Dentally Vision AI? _____	4
Acquiring Images with Dentally Vision AI _____	4
Submitting images for analysis with Dentally Vision AI _____	4
Viewing your Dentally Vision AI analysis results _____	5
Review and configure your findings _____	6
Types of results _____	9
Educating Patients with AIDE _____	12
Tooth peek _____	13
Sharing AI findings _____	14
FAQ's _____	15
Additional Regulatory Information _____	19

## How to turn on Dentally Vision AI?

After the Dentally team have installed Dentally Vision AI you can toggle this on and off from your Dentally Settings.

- Navigate to '**Settings**' > '**Site**' and click the '**Edit**' button against the site you wish to enable/disable this for.
- Click into '**Features**' from the options on the left.
- Toggle this on or off as needed, and click '**Save**'

**Important:** This can only be turned on by Level 4 at your practice.  
With AI disabled, AI results will not be available in Dentally Vision.



The screenshot shows the 'Dentally Settings' interface for a site named 'Dental Town'. On the left, there is a sidebar menu with options: 'Name & Address', 'Options', 'Calendar', 'Features', 'Integration Settings', 'Referrals', and 'Payments'. The 'Features' section is active. The main content area shows two toggle switches: 'Dentally Vision' and 'Dentally Vision AI'. Both are currently turned on. The 'Dentally Vision AI' toggle is highlighted with a red rectangular box. Below the 'Dentally Vision AI' toggle, there is a 'Cancel' button and a 'Save' button.

## Acquiring Images with Dentally Vision AI

The acquisition process for Dentally Vision AI is the same process as Dentally Vision. Images are acquired in the same way with or without Dentally Vision AI enabled.

## Submitting images for analysis with Dentally Vision AI

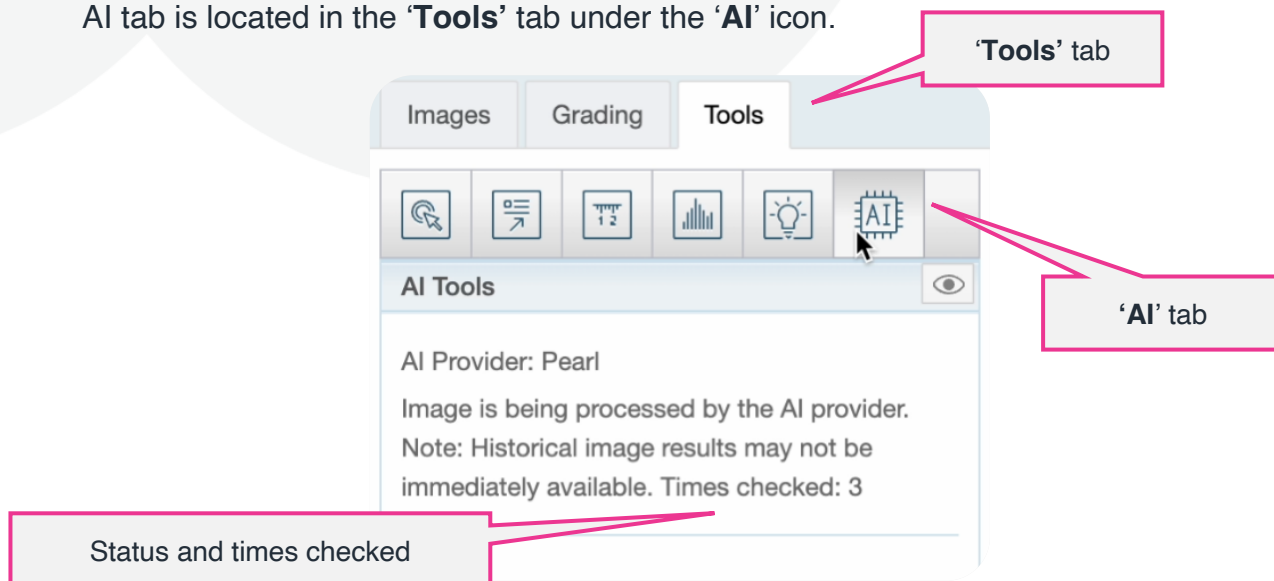
All valid images are automatically submitted to Dentally Vision AI immediately after you complete the acquisition workflow in Dentally Vision.

Make sure you are using Google Chrome at 100% zoom.

The analysis results are then expected to take 30 to 40 seconds to be processed and returned for you to view.

# Viewing your Dentally Vision AI analysis results

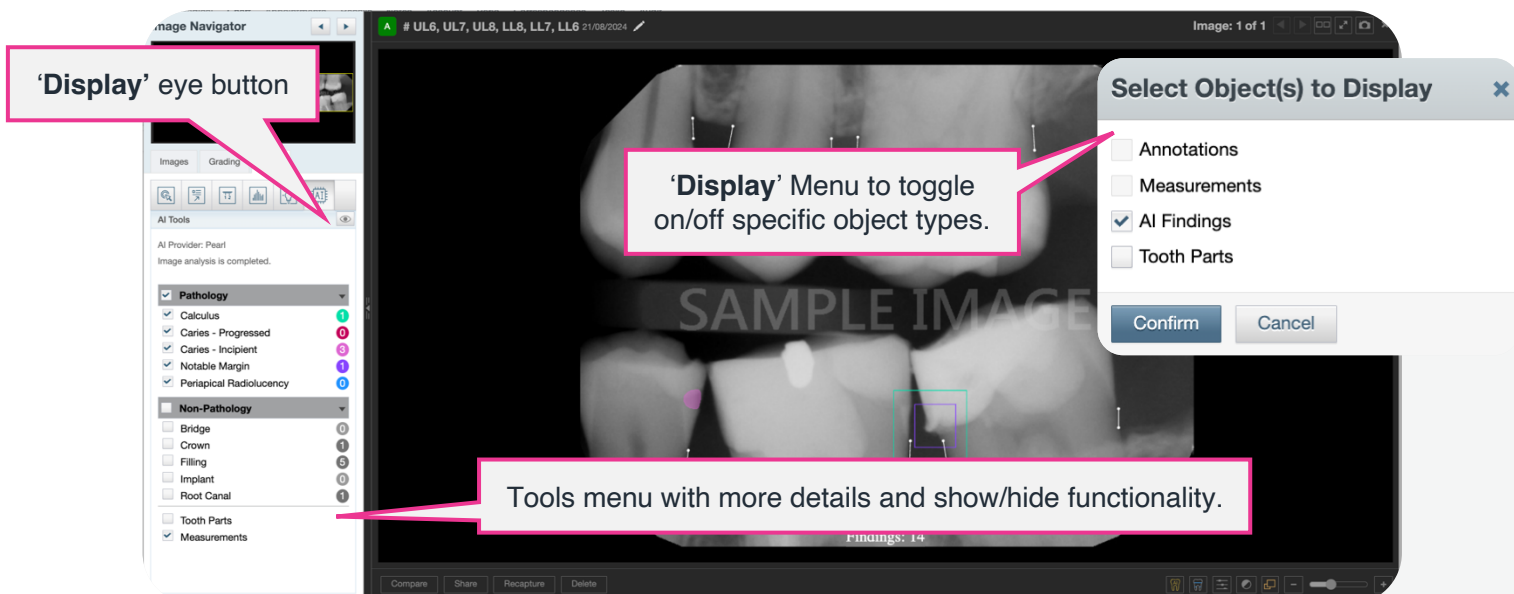
You can use the 'AI' tab in Dentally Vision to view the status and total findings. The AI tab is located in the 'Tools' tab under the 'AI' icon.



Whilst Dentally Vision AI is still in the process of analysing the image you will see, the AI Provider, the status of the review and even how many times it has currently been checked.

Once complete, the tools panel will update with all the findings.

In the 'AI' tab you can use the 'Display' eye button to toggle on and off specific objects you wish to display.



To view Annotations and Measurements you must have already added these to your images, otherwise the boxes will be greyed out under the Display options.

## Review and configure your findings

The **'Tools'** panel on the left of Dentally Vision will show you a full overview and breakdown of any Dentally Vision AI findings for the selected image.

It will list the AI provider and the Image analysis status at the top of the tools AI menu. You will be presented with a list of checkboxes to show/hide of all finding types:

The screenshot shows the 'Tools' panel with the following findings:

Category	Finding Type	Count
Pathology	Calculus	1
	Caries - Progressed	0
	Caries - Incipient	3
	Notable Margin	1
	Periapical Radiolucency	0
Non-Pathology	Bridge	0
	Crown	1
	Filling	5
	Implant	0
	Root Canal	0
	Tooth Parts	1
	Measurements	1

Callouts from the image:

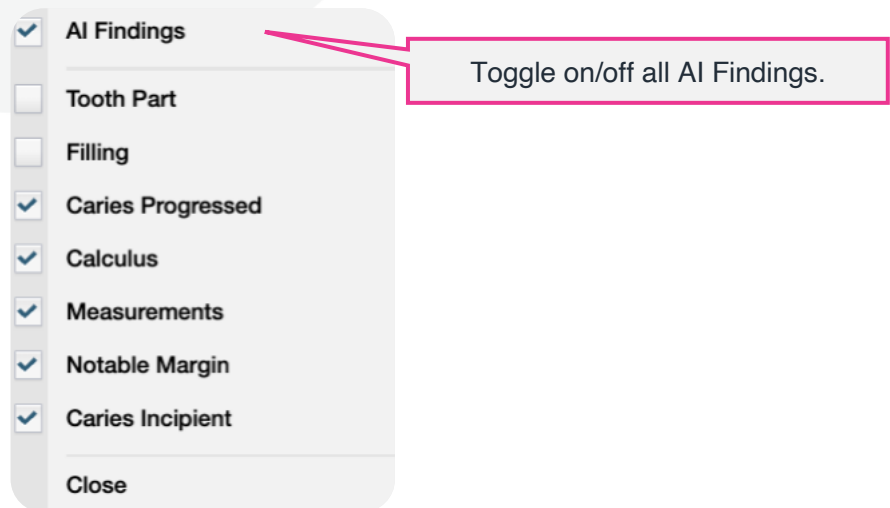
- AI Provider and Image Status details.
- Show/Hide all for the specified category.
- Use checkboxes against individual finding types to toggle these on/off.
- Numbers in circle will reflect the amount of that finding.
- Coloured circle to match finding colour on image.
- Toggle on/off 'Tooth Parts' and 'Measurements' too.

Both **'Pathology'** and **'Non-Pathology'** categories can be toggled on/off as a group, or you can extend each section to see the individual finding types, which can then be toggled on/off individually as well.

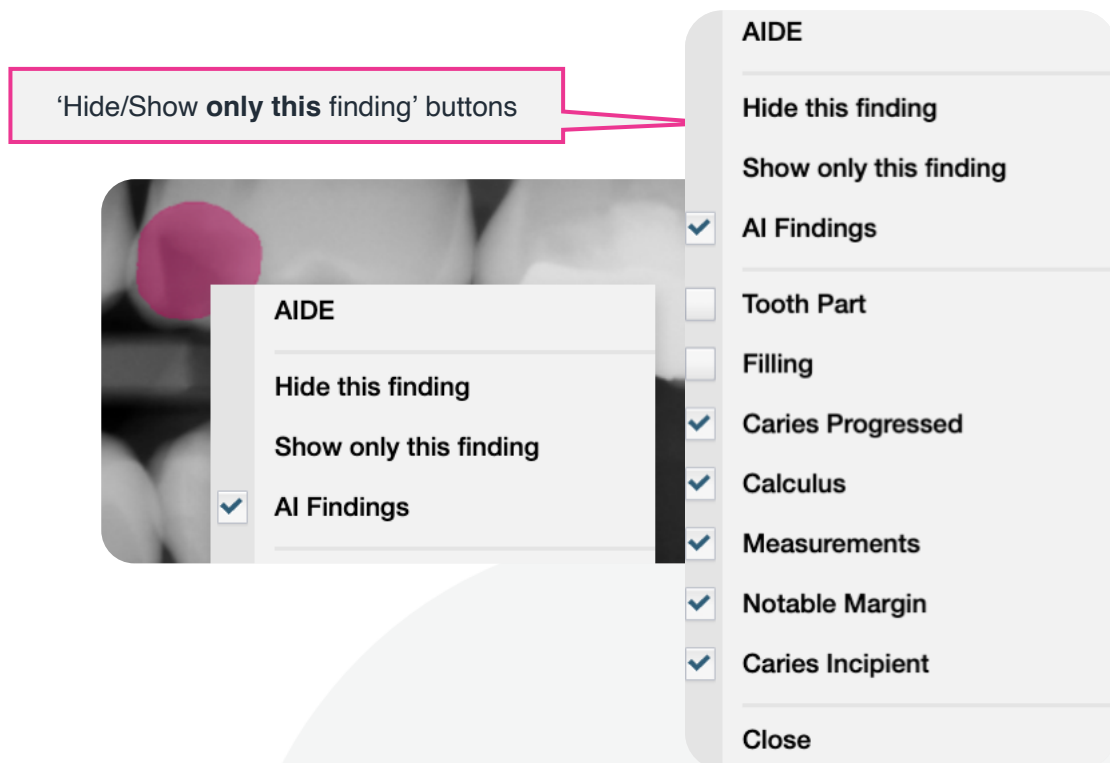
The coloured circle next to each finding type, matches the finding colour and the number in the circle lists the count of that finding on the image. **'Tooth Parts'** and **'Measurements'** can also be toggles on/off from here as well.

Left clicking anywhere on the image will open the AI menu where you can configure which AI findings are visible at any one time.

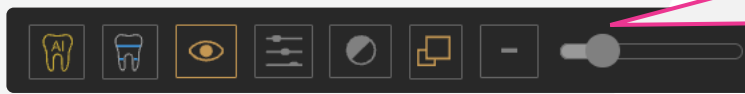
The options in this list will vary depending on the results of the AI analysis. Simply tick or untick the desired findings.



Left clicking on an **individual finding** will show you additional options to show or hide that specific finding. (*Image above on the right.*)

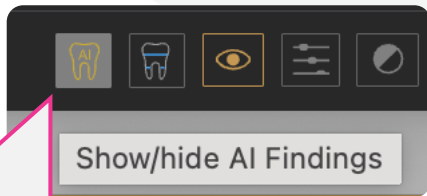


You can use the footer buttons to manage your AI findings 🦷 (yellow tooth) and AI Tooth parts 🦷 (blue tooth).

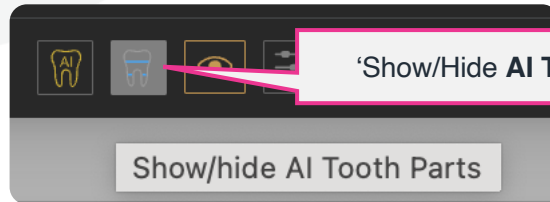


Footer across the bottom of your image when being viewed in Dentally Vision

Clicking these icons will toggle on/off their respective finding type on/off in bulk.



'Show/Hide **AI Findings**' button



'Show/Hide **AI Tooth Parts**' button



# Types of results

These are a few examples and not an exhaustive list of the types of results.

Tooth parts



Anatomy

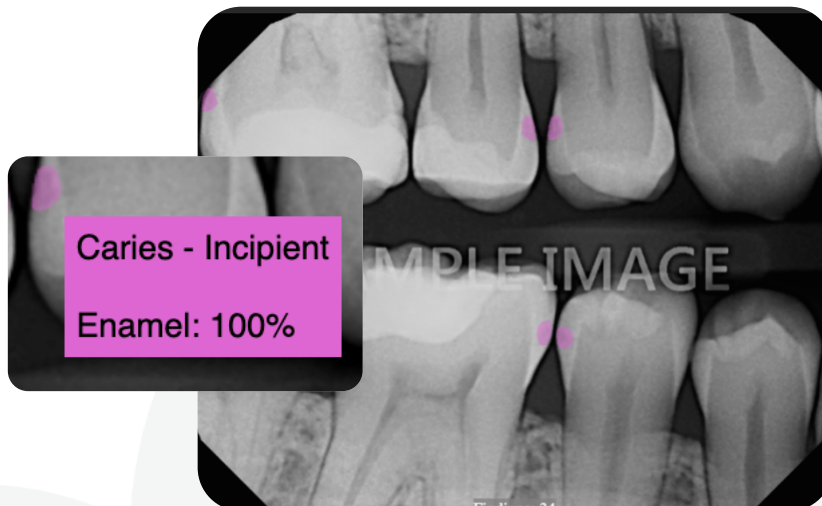


Caries - Progressed



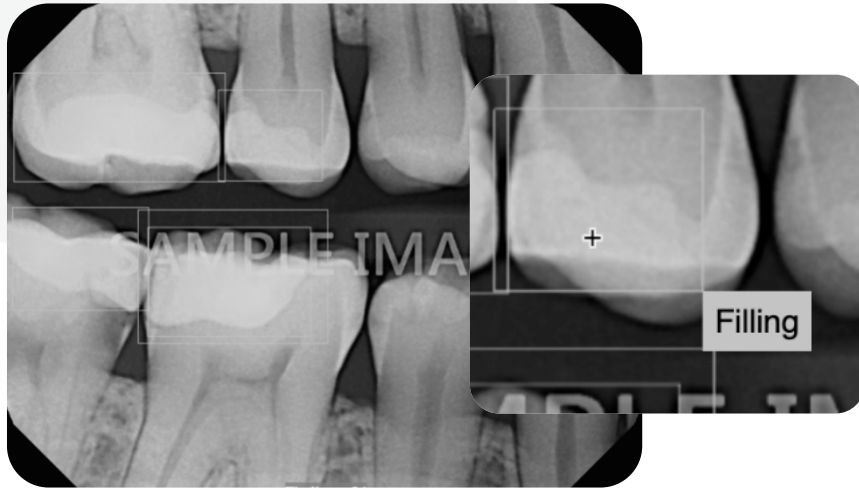
**Caries - Progressed**  
Cementum: 3%  
Dentin: 82%  
Enamel: 15%

Caries - Incipient



**Caries - Incipient**  
Enamel: 100%

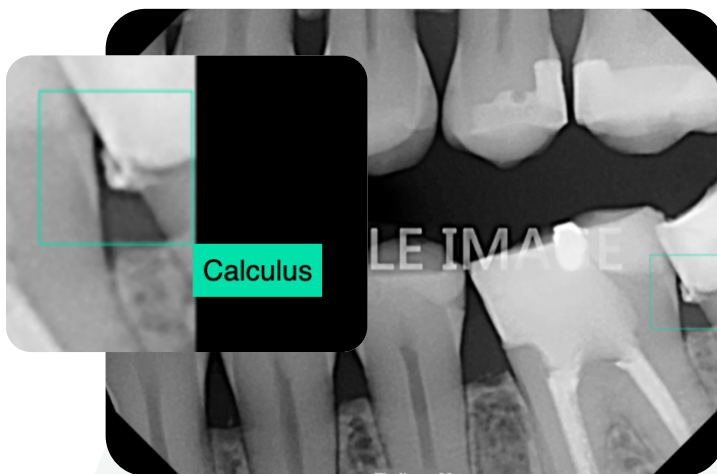
Filling



Root Canal



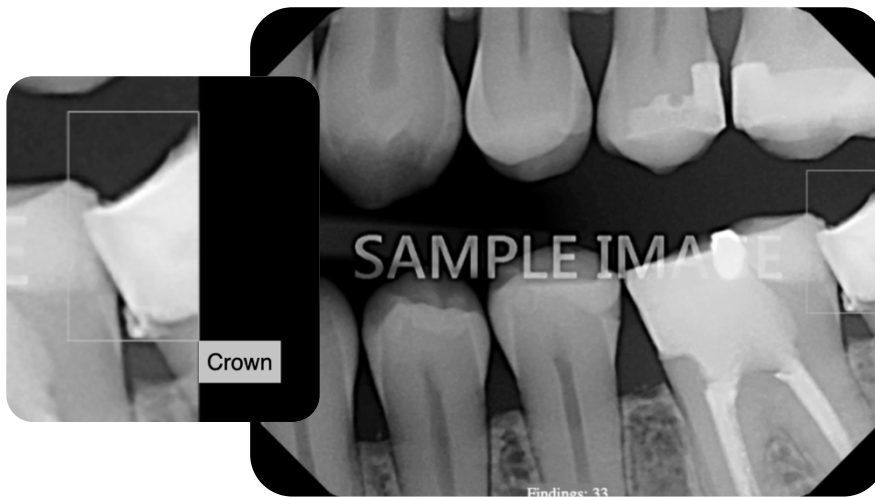
Calculus



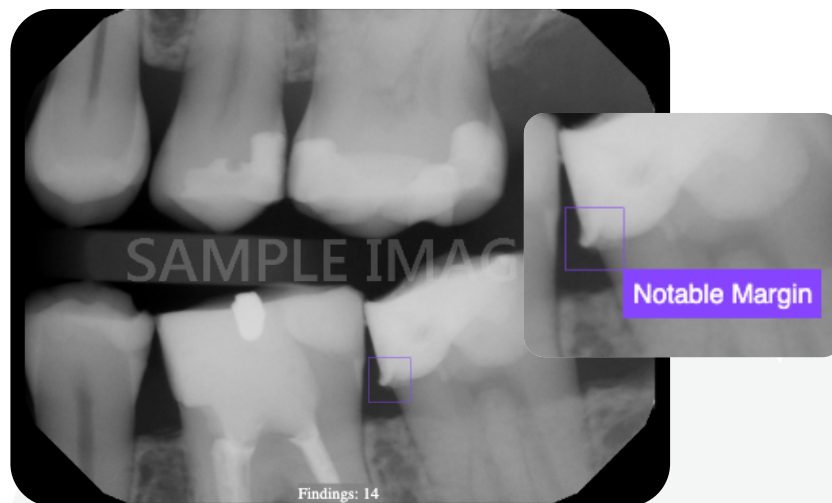
### Measurements



### Crown



### Notable Margin

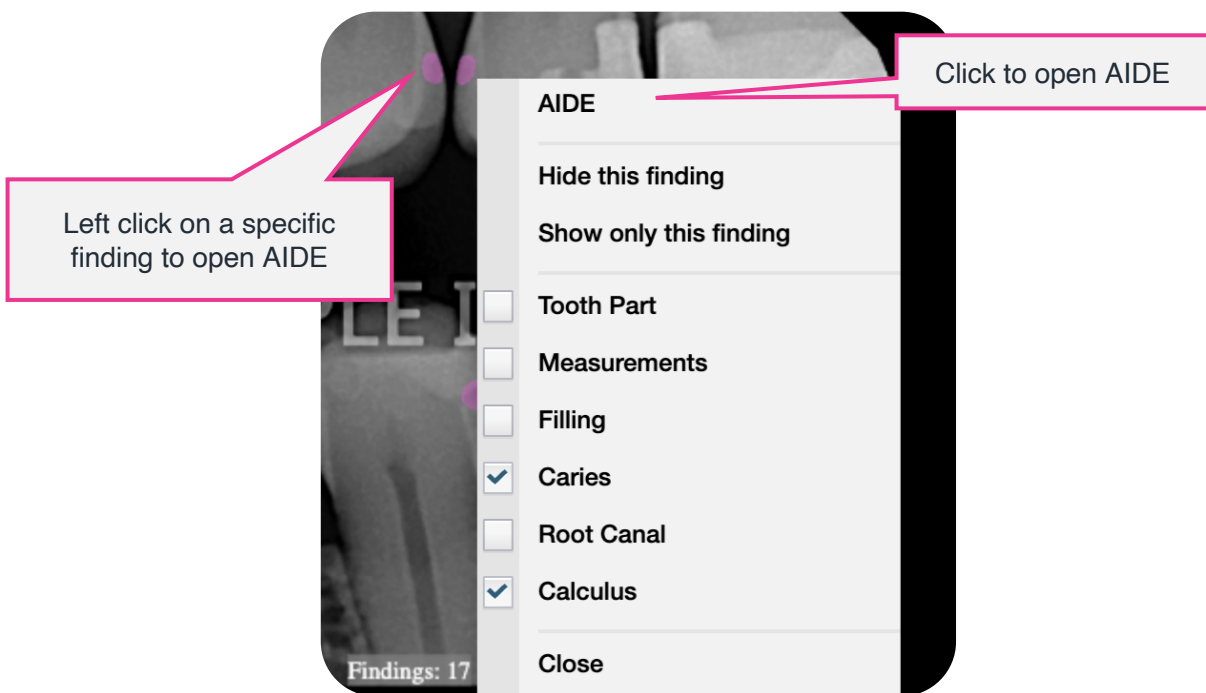


# Educating Patients with AIDE

**What is AIDE?** Artificial Intelligence Detection Enhancement

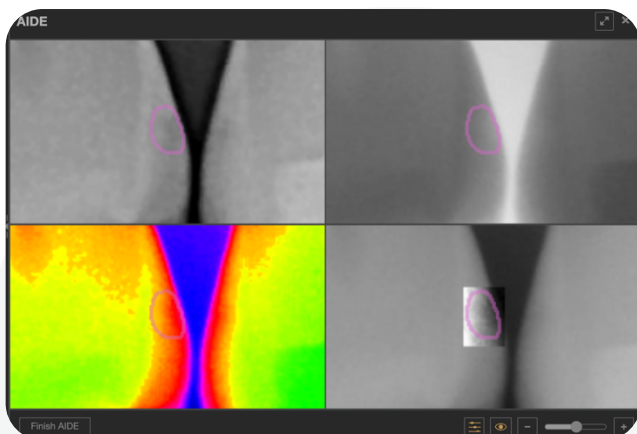
AIDE is a great tool for patient education, AIDE automatically zooms and applies common spotlights and enhancements to your images.

Left click on a finding and click '**AIDE**'. Make sure you left click exactly on the finding you wish to view with AIDE, otherwise you will open the standard AI menu, and you will not see the AIDE option.



After clicking on '**AIDE**' a zoomed-in view of the specific finding will open. You will be presented with 4 windows showing different views on the finding for you to explore further to reach a diagnosis or to educate patients on their oral health.

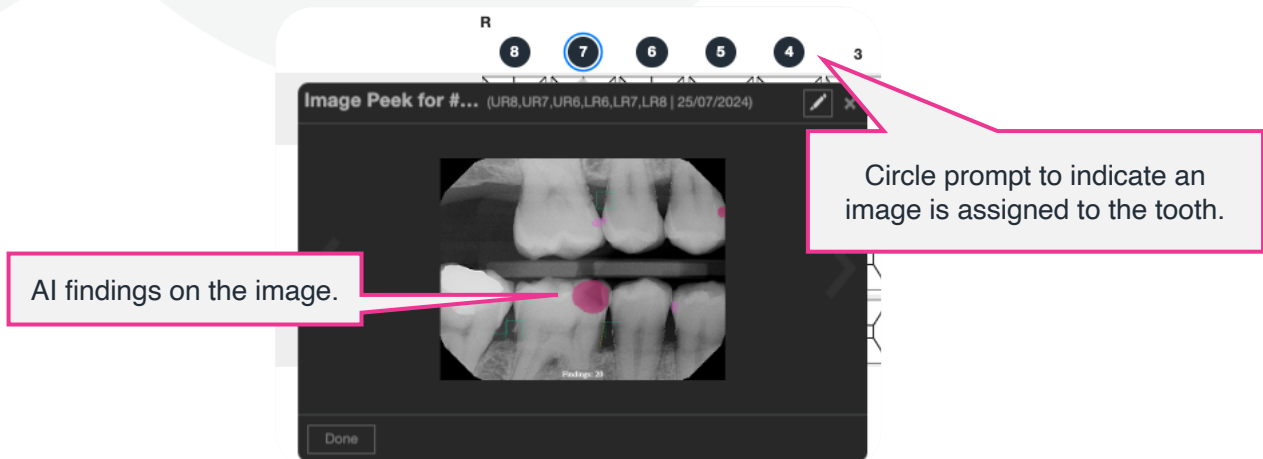
Once you are ready simply click '**Finish AIDE**' to return to the main Dentally Vision window.



## Tooth peek

Your AI findings will also be visible on the tooth peek pop up on the patient's chart.

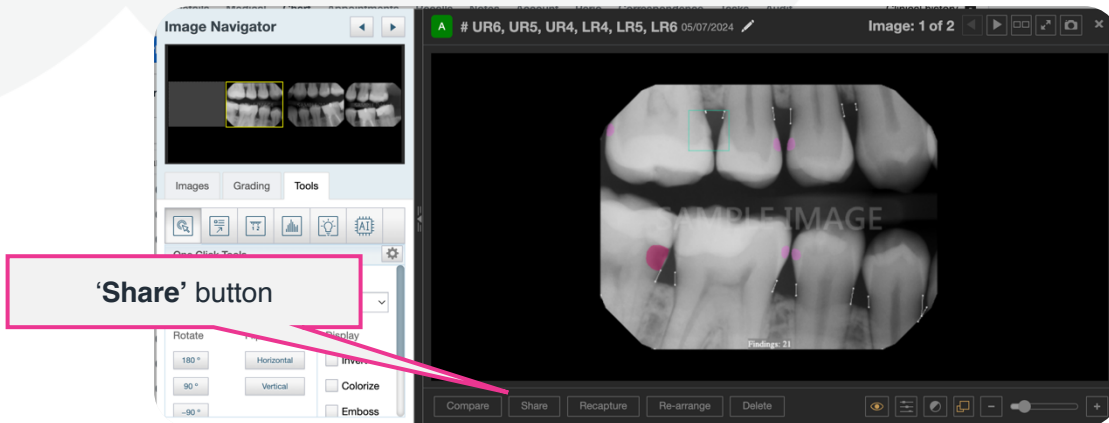
When an image is assigned to the tooth upon acquisition, a black (or grey if the image is older) circle will appear over the tooth number.



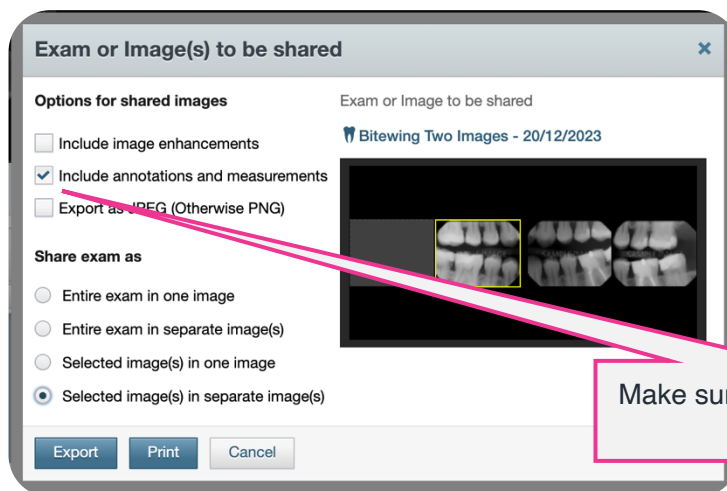
Click on the circle over the tooth number to open the sneak peek of the images assigned to that tooth. If there are any AI findings they will also be present.

# Sharing AI findings

After assessing and diagnosing an image with Dentally Vision AI, you can share AI findings using the **'Share'** button located underneath the image in Dentally Vision.



All visible AI findings will be included in the printed or exported image provided the **'Include annotations and measurements'** checkbox is ticked on the sharing window.



## FAQ's

### **What is Dentally Vision AI?**

Dentally Vision AI is a cutting-edge, fully integrated cloud-based system powered by Pearl. It is designed to enhance patient outcomes and streamline your clinical workflows.

It features advanced AI clinical detection capabilities that allow for more accurate diagnoses and effective treatment plans. Dentally Vision AI combines leading disease detection and case presentation utilities into one seamless package, elevating both patient care and practice efficiency.

### **Why is Dentally Vision AI useful?**

Dentally Vision AI is incredibly useful because it aids in enhancing patient outcomes through advanced AI clinical detection capabilities.

It helps foster patient trust and can even assist in increasing treatment acceptance by providing clear, easy-to-understand results that can be reviewed chair side with your patient. This way, patients are more informed and comfortable with their treatment options.

Additionally, Dentally Vision AI elevates your clinical workflow with a seamless experience, integrating all these features into one smooth application that saves time and improves efficiency.

### **How can I get Dentally Vision AI?**

Dentally Vision AI is available only for sites who have Dentally Vision. Get in touch with support via Live Chat to discuss your options and register your interest today.

### **What is the install process for Dentally Vision AI?**

Dentally Vision AI is turned on by the Dentally team in the background and will be instantly available for you to use. There is no need for any downtime and with this guide to hand you can be ready to go as soon as we have switched this on.

The process will differ if you do not yet currently use Dentally Vision. [Get in touch with our team here to find out more.](#)

## What does Dentally Vision AI detect?

Dentally Vision AI detects and displays the following:

### Pathologies and other conditions

- Bone Levels
- Calculus
- Caries
- Impaction
- Margin Discrepancy
- Periapical Radiolucency

### Existing restorations

- Bridge
- Crown (Metal, including zirconia)
- Crown (Non-metal)
- Filling (Metal)
- Filling (Non-metal)
- Implant
- Root Canal

## Does Dentally Vision AI make a diagnosis?

No. Think of Dentally Vision AI as your radiology assistant, It simply aids you in making your decisions.

It is NOT intended for use as a diagnostic device and all decisions are still left in the hands of appropriately trained and licensed dental healthcare professionals.

## Is Dentally Vision AI always right?

No. Dentally Vision AI has been taught from the diagnostic data provided by human dentists and radiologists, and as you know, dentists often disagree with one another regarding diagnosis. Therefore Dentally Vision AI will sometimes make detections that you don't agree with.

Dentally Vision AI can still provide great value by highlighting areas of interest that you may have missed, and you should disregard any detections that you do not feel are accurate.

The software is intended to support you, but all final diagnostic decisions are yours and yours alone.



## **How does Dentally Vision AI work?**

Dentally Vision AI will automatically assess your images straight after acquisition and will take around 40 seconds to load its assessment and diagnosis of the image. Read more about how Dentally Vision AI works and how to use it in our full user guide [here](#).

## **Can my older images be reviewed by Dentally Vision AI?**

Yes, We do have the ability to run a back fill on your historic images (over the last 12 months only) for a one off cost. Once run, Dentally Vision AI will be able to provide you with the same diagnosis across existing images as it does with all future images.

This will require you to have your historic images in Dentally Vision. Previous images can be imported into Dentally Vision as part of the initial Dentally Vision implementation costs.

## **Can Dentally Vision AI assess both dentitions?**

Dentally Vision AI is designed to be used on permanent dentitions only. It is not recommended for use on deciduous teeth.

## **What happens if I change my mind and no longer want to use Dentally Vision AI?**

Dentally Vision AI can be turned off and you can continue to use Dentally Vision as per normal. However once you start seeing the benefits of increased case acceptance and condition detection we are confident that you will not go back!

## **If I choose to leave Dentally does the AI information come with my digital images?**

No, the Dentally Vision AI overlay is provided as a feature which is only viewable while you are still using Dentally Vision AI in Dentally Vision

## **Can I integrate a different AI product into Dentally Vision?**

No, we do not currently support any other AI products in Dentally Vision.

## **Will Dentally Vision AI diagnose imported images?**

Yes, if you have the need to import images through the acquisition workflow for example from a referral patient, Dentally Vision AI will still assess the image.

Bear in mind, the image must be imported through the Dentally Vision acquisition workflow, and if it is a valid image then Dentally Vision AI will make its assessment and diagnosis as normal.

# Additional Regulatory Information

## Real Cloud Imaging

### Version

You can find the UDI (Unique Device Identifier) followed by the current version number of Dentally Vision by doing the following: You can go to the Developer Tools panel (in Chrome) or on the Web Inspector panel (in Safari), select the Console tab, and then open Dentally Vision. A line of text similar to “Imaging: (01)00864058000302(10)1.1.8595.29819 7/14/2023 4:33 PM “appears.



Real Cloud Imaging Inc.  
2625 North Loop Drive, Suite 2130  
Ames, IA 50010, United States



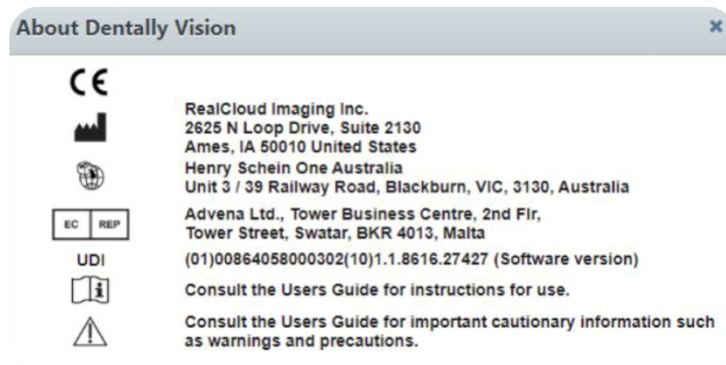
Henry Schein One Australia  
Unit 3/39 Railway Road, Blackburn, VI, 3130, Australia



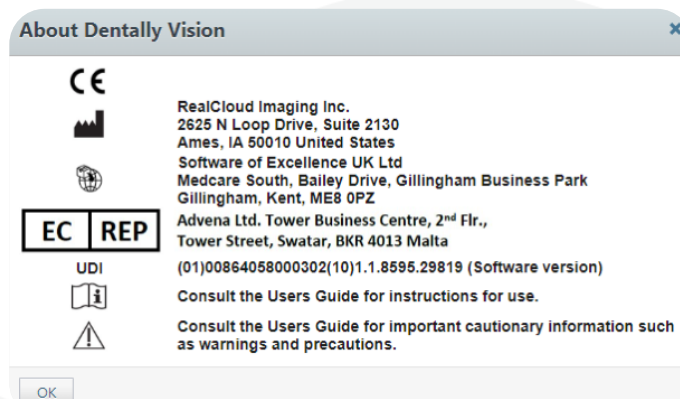
Advena Ltd., Tower Business Centre, 2nd Floor,  
Tower Street, Swatar, BKR 4013, Malta

Alternatively, you can view the UDI by going to the “About Dentally Imaging” button in the bottom right-hand corner of the Cloud Gallery

### Australia and Canadian Label



### UK Label



## Second Opinion



### Regulatory Compliance

*Second Opinion®* complies with the regulatory requirements of the following:

- ENISO13485:2016 entitled Medical Devices.
- Quality Management Systems Requirements for regulatory purposes, FDA 21 CFR Part 820 entitled Quality System Regulation (QSR).
- EU Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Device (MDR)
- Medical Device Single Audit Program (MDSAP)
- Canadian Medical Devices Regulations SOR 98-282
- The Health Insurance Portability and Accountability Act (HIPAA)
- The Australian Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.

### Indications for Use

Second Opinion® is a computer aided detection ("CADe") software to identify and mark regions, in bitewing and periapical radiographs, in relation to suspected dental findings which include: Bone level measurement, segmentation of Caries, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, impacted teeth, Crown (metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge and Implants. In addition, Second Opinion® is CADe software to identify and mark regions, in panoramic radiographs, in relation to suspected dental findings which include: Segmentation of Caries, Periapical radiolucency, and Impacted teeth. It is designed to aid dental health professionals to review bitewing, periapical and panoramic radiographs of permanent teeth in patients 12 years of age or older as a second reader.



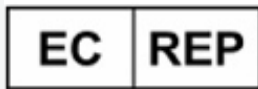
**Manufacturer- Pearl Inc.**

2515 Benedict Canyon Dr.  
Beverly Hills, CA 90210 USA



Basic UDI-DI: ++D087SECONDOPINION2H8  
Labeler Identification Code (LIC): D087  
Model Identifier: SECONDOPINION2  
Check Character: H8

## Additional EU Details

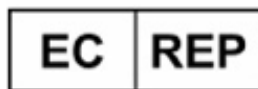


ALPA Medical Srls  
Via Chimienti 8, 72100, Brindisi, ITALY  
amministratore@alpamedical.com 000007276 IT-AR



MedEnvoy Global BV  
Prinses Margrietplantsoen 33 | Suite 123  
2595 AM The Hague | The Netherlands  
www.MedEnvoyGlobal.com

## Additional UK Details



### UK Responsible Person (or UKRP)

Alpa Medical  
29 Rowner Crescent,  
Sherfield-On-Loddon Hampshire,  
RG27 0SW  
United Kingdom



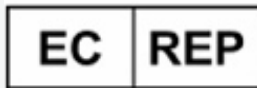
### Importer

MedEnvoy UK Limited 85,  
Great Portland Street,  
First Floor  
London  
W1W7LT  
United Kingdom

## Additional CA Details

MDEL  
17820

## Additional AU Details



AJ W Technology Consulting GmbH  
Königsallee 106  
40215 Düsseldorf  
+49 (0) 211 3013 2232  
[www.ajwtech.com](http://www.ajwtech.com)