



How to Use AssistDent®



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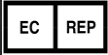
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Please contact support@assistdent.net for a paper copy of this user guide.

Clinical Use



AssistDent®

Product Name	AssistDent
Version	This document applies to versions 1.7.x of AssistDent. The UDI containing the full version number of the software is available in the 'About AssistDent' menu option.
Manufacturer	 Manchester Imaging Limited c/o Slater Heelis Limited, 86 Deansgate, Manchester, M3 2ER, United Kingdom.
EC Representative	 MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
Trademark	AssistDent is a registered trademark of Manchester Imaging Limited in Australia, Canada, European Union, New Zealand, United Kingdom, United States of America.
MHRA Regulatory Code	6364 Stand-Alone Software
Medical Device Classification and Declaration of Conformity	We hereby declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices, as amended by Directive 2007/47/EC. According to MEDDEV 2.4/1 rev.9, Classification of medical devices, MDD Rule 12, this stand-alone software is a Class I medical device (without measuring function). According to MEDDEV 2.1.6 Qualification & classification of standalone Software, this is stand-alone software (reference page 7, paragraph 2.1). According to EN62304, specifically the flowchart in section 4.3, this stand-alone software is safety class A
Intended Use	AssistDent is an aid in the diagnosis of proximal surface caries, particularly those carious lesions that are present in the enamel and have not penetrated into the dentine. It is not intended for primary diagnosis but is to be used as an adjunct to the dentist's conventional sources of diagnostic information. It is designed to assist dentists to detect early proximal carious lesions that are difficult to detect or would require significant effort to identify. The final diagnostic decision rests with the dentist.
Indications for Use	Users The use of this product to analyse patient data is restricted to qualified dentists and dental therapists, regulated by the statutory regulatory bodies to prescribe radiographs, take them, process and interpret them for dental caries. Patients Patients, on whose images the product is applied, are restricted to adults attending their dentist for a dental examination and who receive digital intra-oral radiographs as part of their examination procedure.
Contraindications	The product should not be used to analyse primary teeth. The product should not be used to analyse images other than those intended to detect dental caries.
Warnings and Precautions	AssistDent is an advisory tool. AssistDent does not provide a definitive diagnosis of caries, rather it alerts the dentist to suspicious regions. Inspecting the regions of interest highlighted by AssistDent can be used as one element of the overall clinical information gathered when making a decision to diagnose caries. The software may highlight regions that are not early proximal enamel caries, and it is the dentist's final decision whether these should be investigated further. AssistDent is not guaranteed to find all caries. It is the responsibility of the dentist to investigate areas where no regions of interest are highlighted.

Starting AssistDent



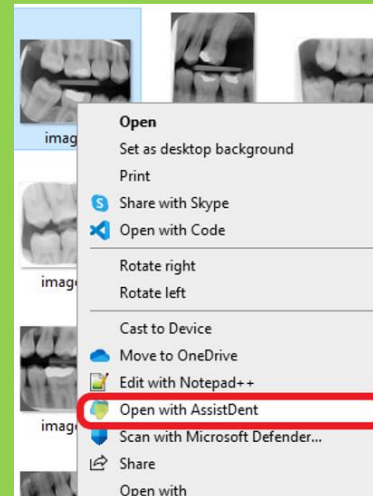
There are several ways to start AssistDent

From the Start
Menu or Desktop:

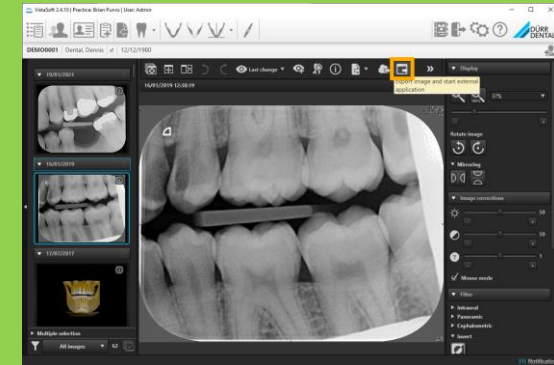


you will be prompted
to specify an image
file on your computer

By clicking on an image
and choosing
Open With AssistDent:



From VistaSoft, via the
external applications
feature:



Clinical Analysis

Open Image

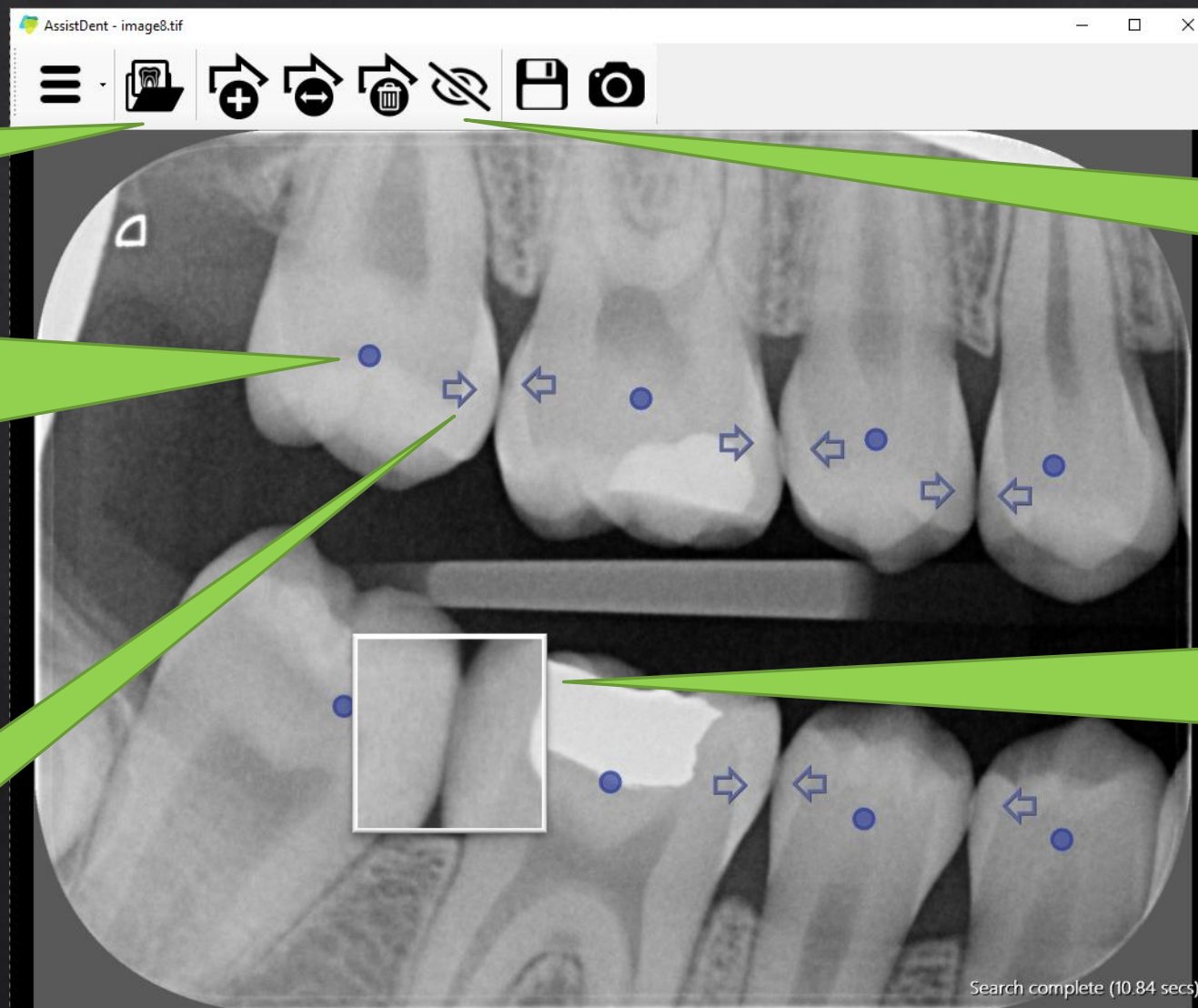
To select an image for analysis.

Tooth Indicators

Circles indicate teeth which have been analysed, (you should manually assess teeth without indicators).

Caries Indicators

Arrows indicate regions of interest where there may be caries.



Hide Overlays

Use the hide overlays button to hide all annotation on the image.

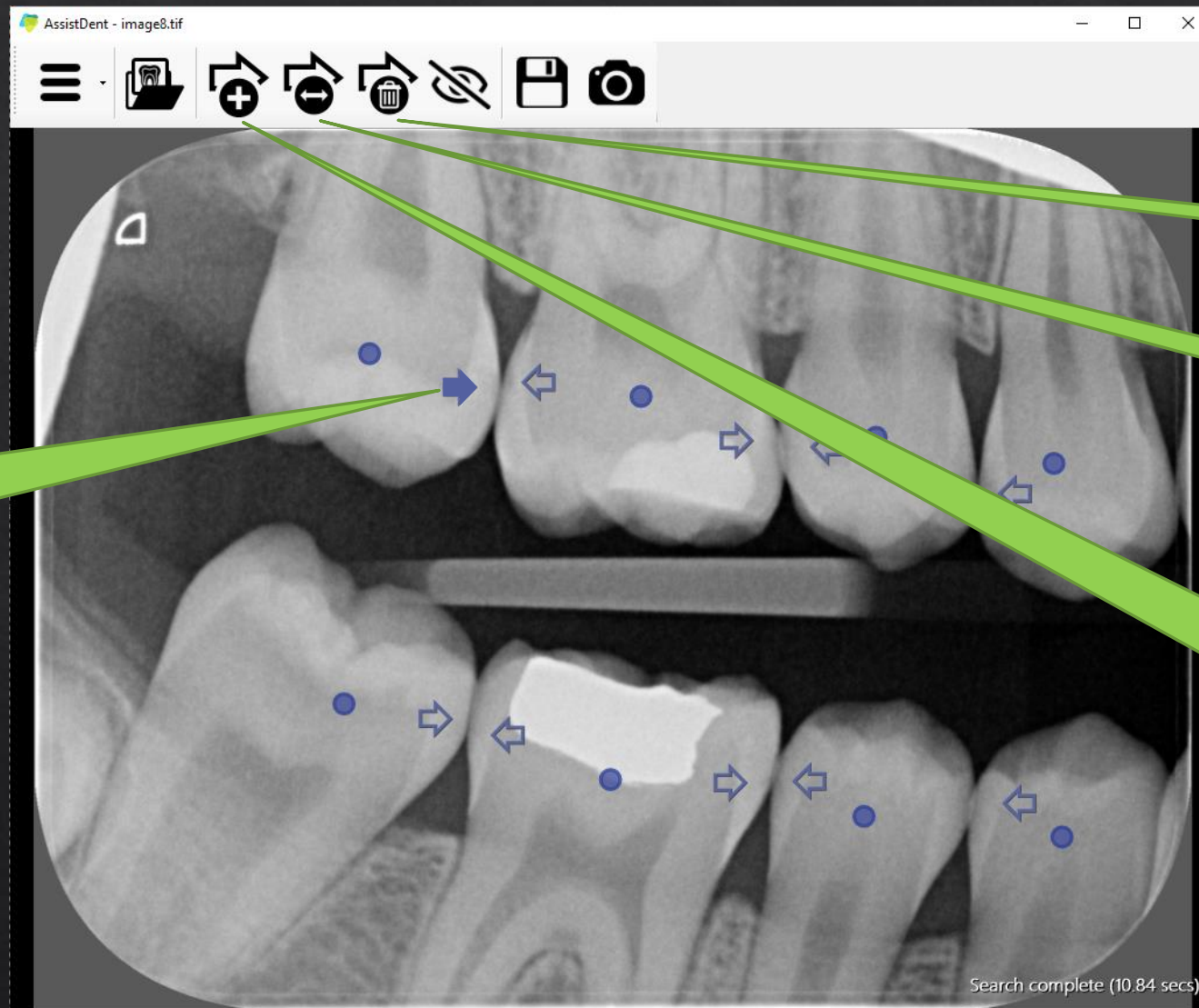
Magnification

To magnify an area of the image, click and hold the mouse button. Note the annotation is hidden when magnifying.

Edit Annotations

You can move any caries annotation by clicking and dragging an arrow.

Click on the caries annotation to select them. When selected you can ...



Delete them;

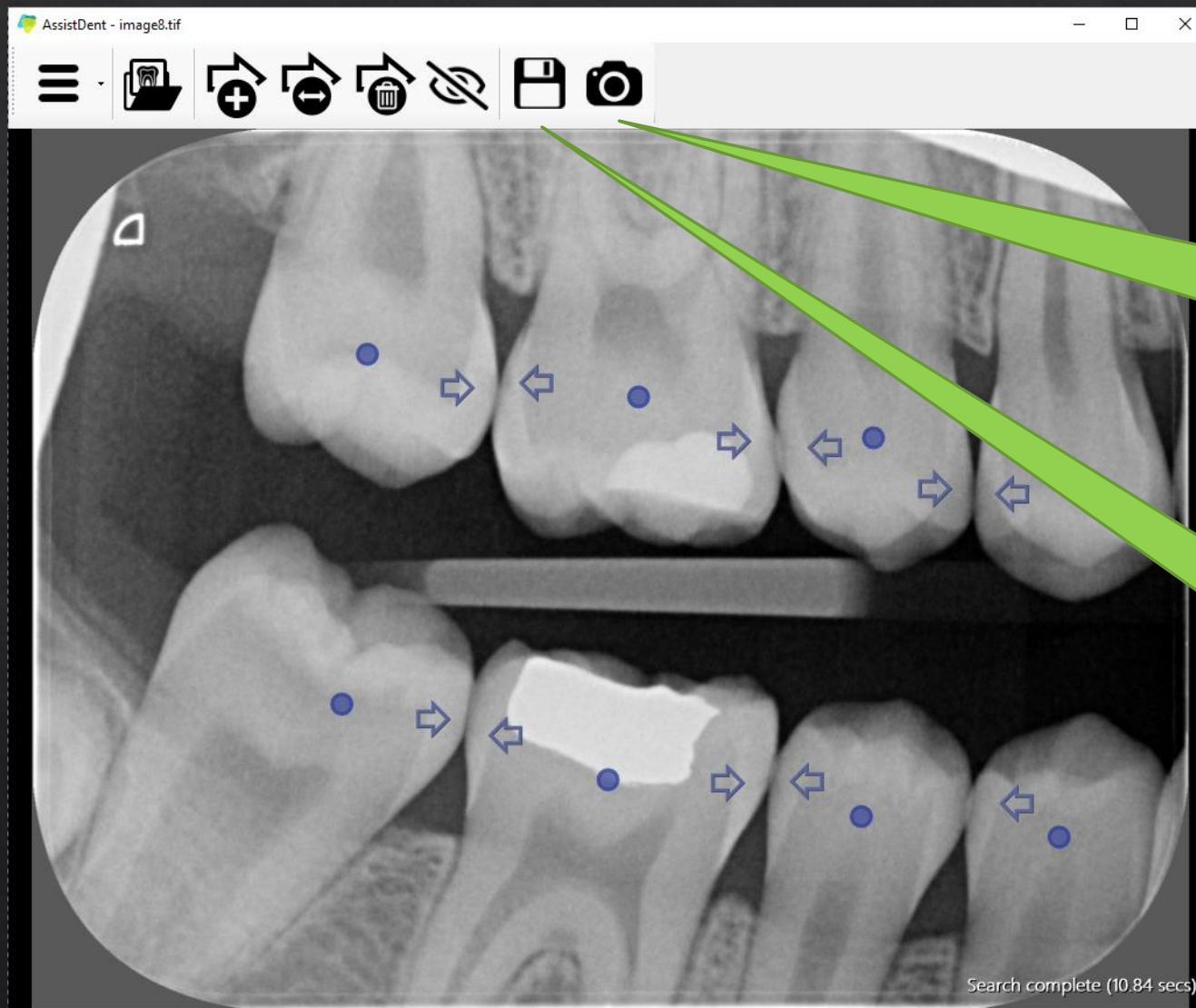
Flip their direction.

To **Add** another caries annotation, click the add button then click on a location on the image.

Export



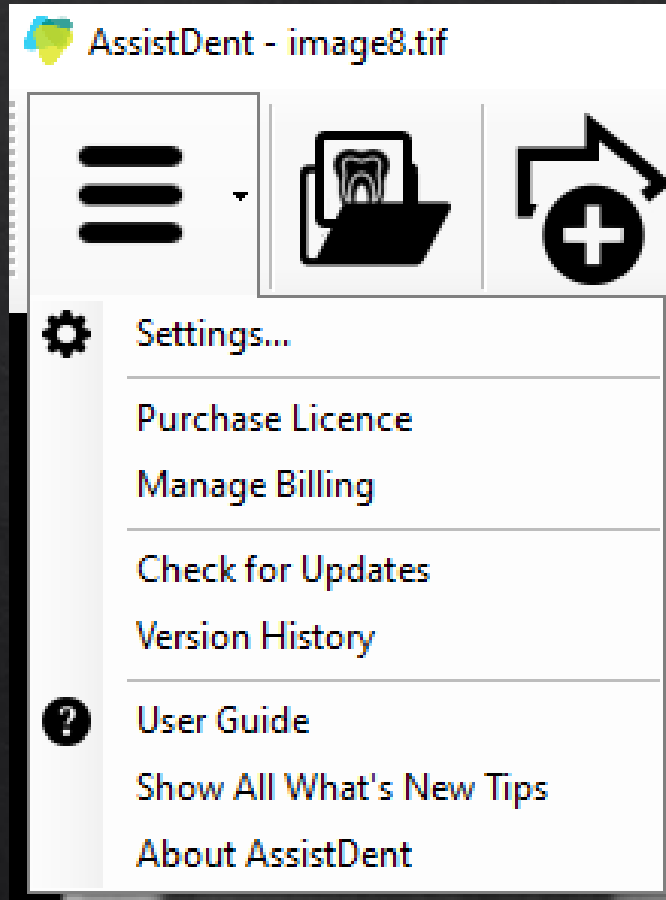
AssistDent®



Use the **Snapshot Image (copy to clipboard)** button to copy and paste the annotated image into another application.

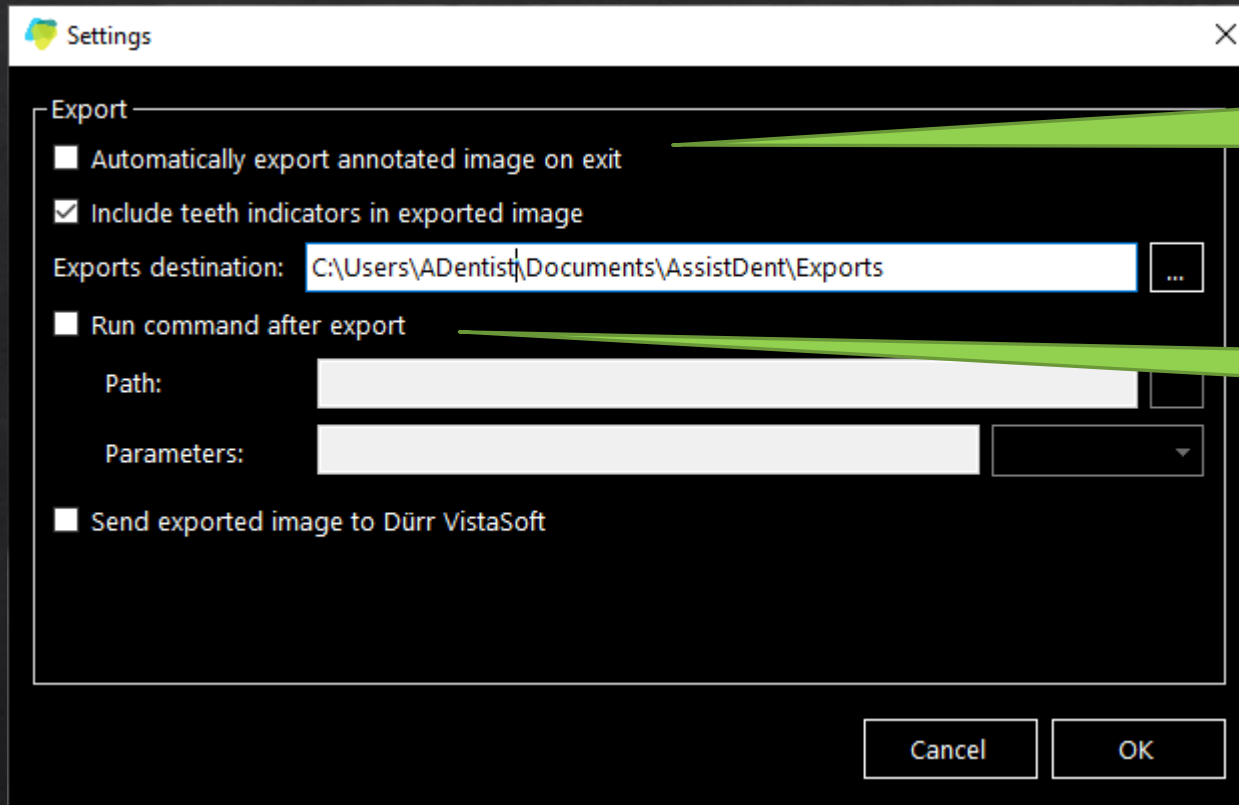
The **Export Image** button saves a copy of the annotated image in the folder specified in your settings.

Menu Options



Menu options allow you to alter the settings; purchase a subscription and manage your billing; get the latest version and learn about AssistDent's latest features.

Settings



Using Settings, you can control whether the annotated image is exported automatically, as well as the destination of the export.

AssistDent also has extended features to enable integration with dental imaging software.

Automatic Assist



To support integration with other dental imaging systems and devices, AssistDent Automatic Assist is a system-tray application which continually monitors a watch folder. When images are saved to the watch folder, AssistDent automatically analyses the images and displays the results.

AssistDent runs in the background, in the system-tray (if you cannot see the icon, click on the up arrow to show hidden icons). Right-click on the icon to open the settings.

You can change the location of the folder watched by AssistDent.

Whenever a bitewing image is copied into that folder, AssistDent will start automatically and analyse the image.

