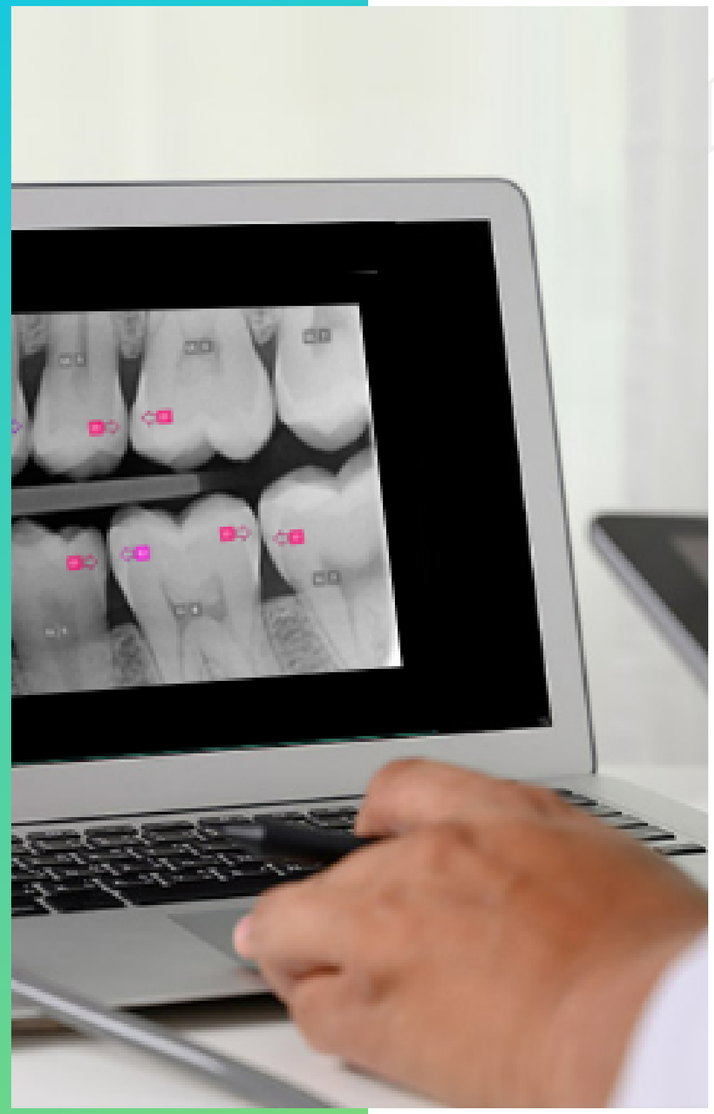

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2022

ASSISTDENT® USER GUIDE

UK CA

AssistDent v2.0 User Guide

Manchester Imaging Ltd

How To Use AssistDent®

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Clinical Use

Manchester Imaging
ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE

Product Name	**AssistDent®**
Version (UDI-DI) (UDI-PI)	This document applies to versions 2.0.x of AssistDent. The UDI containing the full version number of the software is available in the Menu Options; 'About AssistDent'.
Date of Manufacture	Generated at build time. Displayed within the application.
Manufacturer	**Manufacturer Address:** Manchester Imaging Limited, Room E43, Sackville Street Building, Sackville Street, Manchester, M1 3BU, United Kingdom
Trademark	AssistDent is a registered trademark of Manchester Imaging Limited in Australia, Canada, European Union, New Zealand, United Kingdom, United States of America.
GMDN (Global Medical Device Nomenclature) Code	65472 (Dental x-ray image interpretive software)
Medical Device Classification and Declaration of Conformity UK CA	We hereby declare that the above mentioned products meet the provisions of the United Kingdom Medical Devices Regulations 2002 as they apply in Great Britain (SI 2002 No. 618, as amended). According to MEDDEV 2.4/1 rev.9, classification of medical devices, Rule 12, this stand-alone software is a Class I medical device (without measuring function). According to MEDDEV 2.1.6 qualification and classification of stand-alone 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; carious lesions that are present in the enamel and carious lesions that have 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 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, dental therapists and dental hygienists, 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 or tooth identification, 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 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. The software may mislabel teeth and it is the dentist's duty to verify that the correct teeth are treated.

AssistDent®

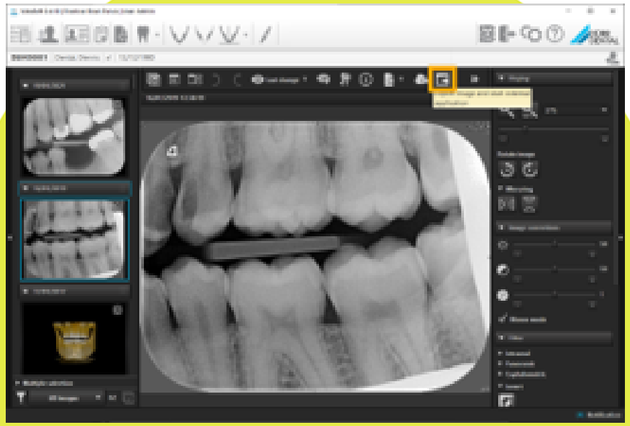
Getting Started

Manchester Imaging
ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE

3 Ways To Open AssistDent®

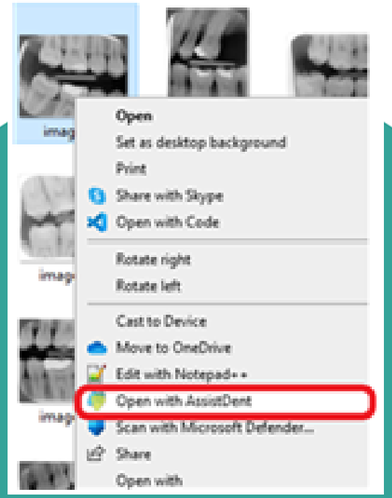
Double click on the AssistDent icon in the Start Menu or Desktop

1



Access via external applications E.G. VistaSoft + EXAMINEpro

2



Select the Bitewing Radiograph to be analysed, right click and choose 'Open with AssistDent'

3

AssistDent®

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Clinical Analysis (a)

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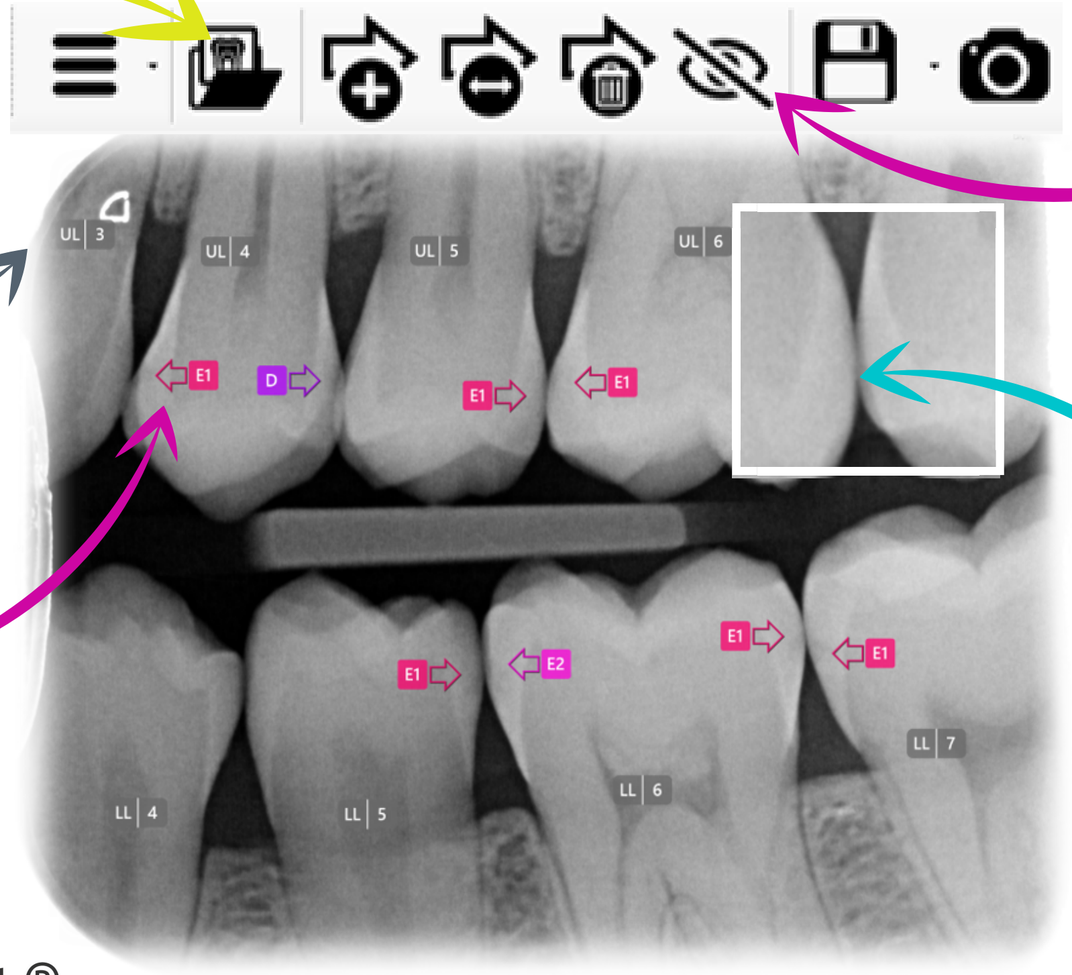
ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE

Open Image
Select a Bitewing Radiograph

Tooth Labels
Teeth analysed by AssistDent
WARNING: Teeth without indicators need to be manually assessed

Caries Indicators
Coloured Arrows:
ROI Region of Interest



Hide Overlays
Control annotation full view or hidden

Magnification
Click and hold mouse to enlarge any area.
WARNING: Annotation is temporarily obscured in this mode

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Clinical Analysis (b)

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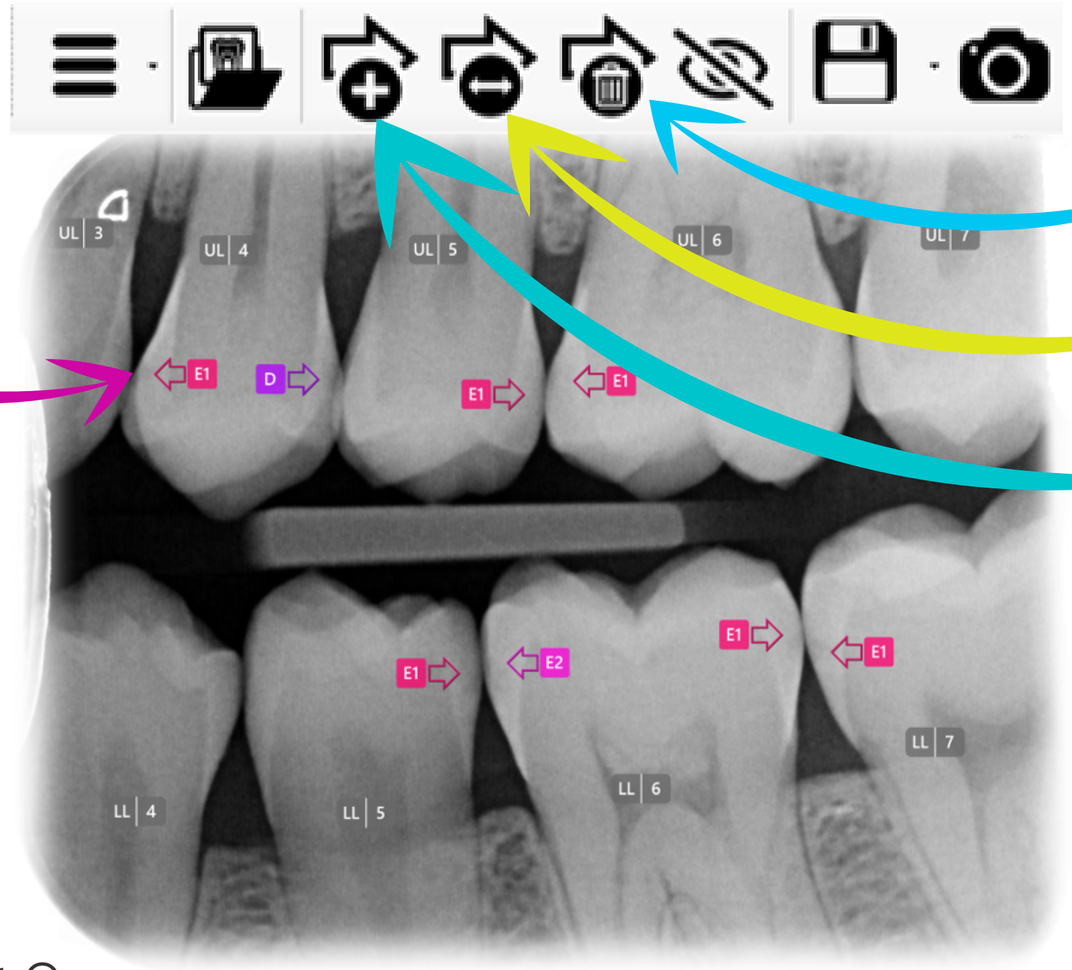
To Edit Annotations
Select and click on a Caries Indicator **arrow**

The highlighted **arrow** can then be dragged into a new position



More Editing Options
Delete and remove

Flip directions

Add new Caries Indicator then click on a location

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Clinical Analysis (c)

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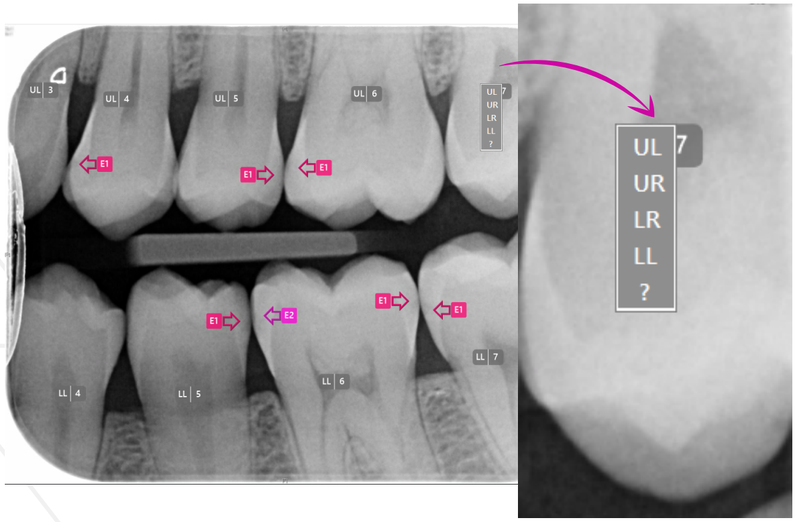
Edit Labels

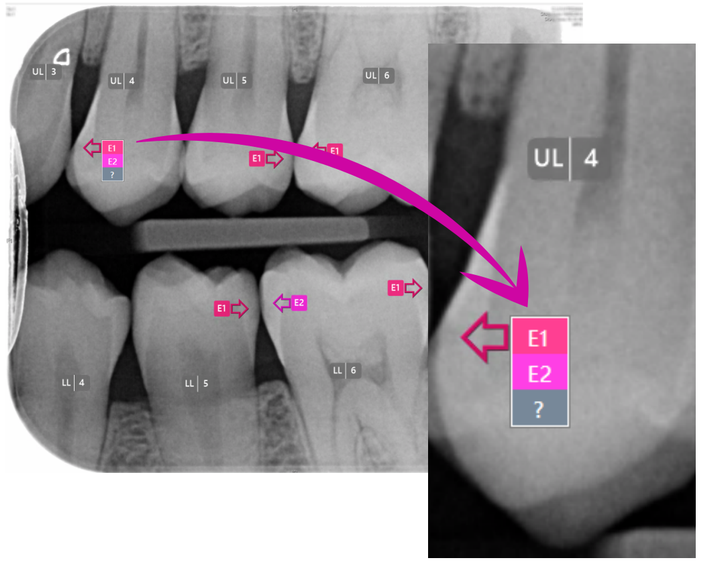
Options for clinical override of the AI analysis

Select and click the preferred label

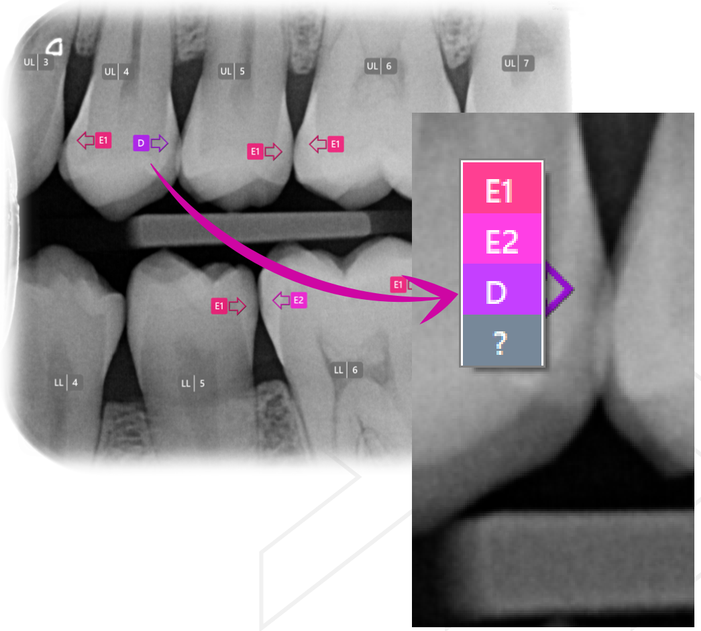
Tooth Labelling



Enamel Caries Grade



Dentine Caries Grade



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Clinical Analysis (d)

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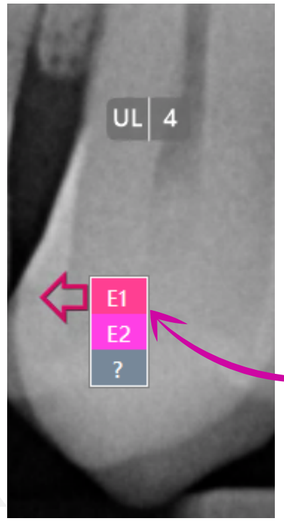
International Caries Classification Standard

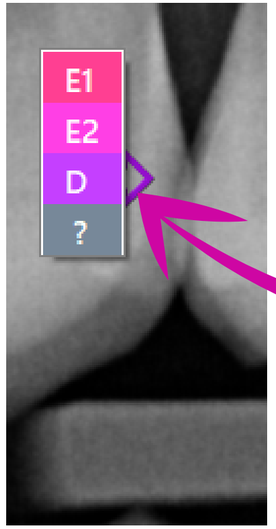
Enamel Caries Grade



The AI assigns the following labels to carious lesions that affect only enamel as listed below.

E1: Outer half of the enamel
E2: Inner half of the enamel

Dentine Caries Grade



When dentine caries detection is enabled, identification of carious lesions which have penetrated the dentine are labelled ‘D’ by the AI.

<u>WARNING:</u> In all cases, it is the prescribing clinician’s responsibility to verify or alter the AI results before determining treatment.

AssistDent®

Menu Options

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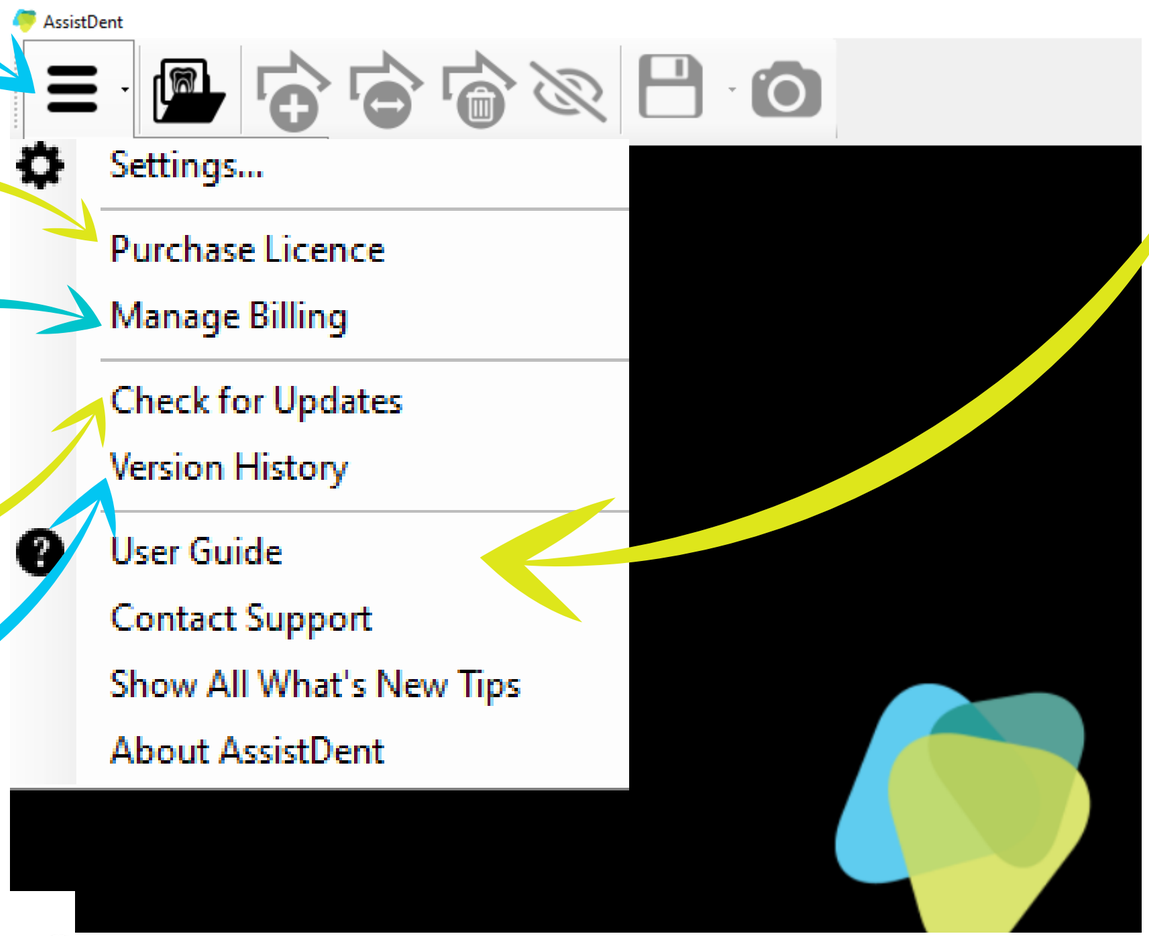
Settings
Advanced Export Criteria

Purchase Licence
Subscription Purchase
Licence Details

Manage Billing
Update Payment Methods

Check for Updates
New alert notifications

Version History
Tour of Latest Features



User Guide
About AssistDent

Contact Support
Email help request

Show All What's New Tips
AssistDent 'in action' with
quick videos of key functions

About AssistDent®
Summary of User licence
Product details

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Methods of Export

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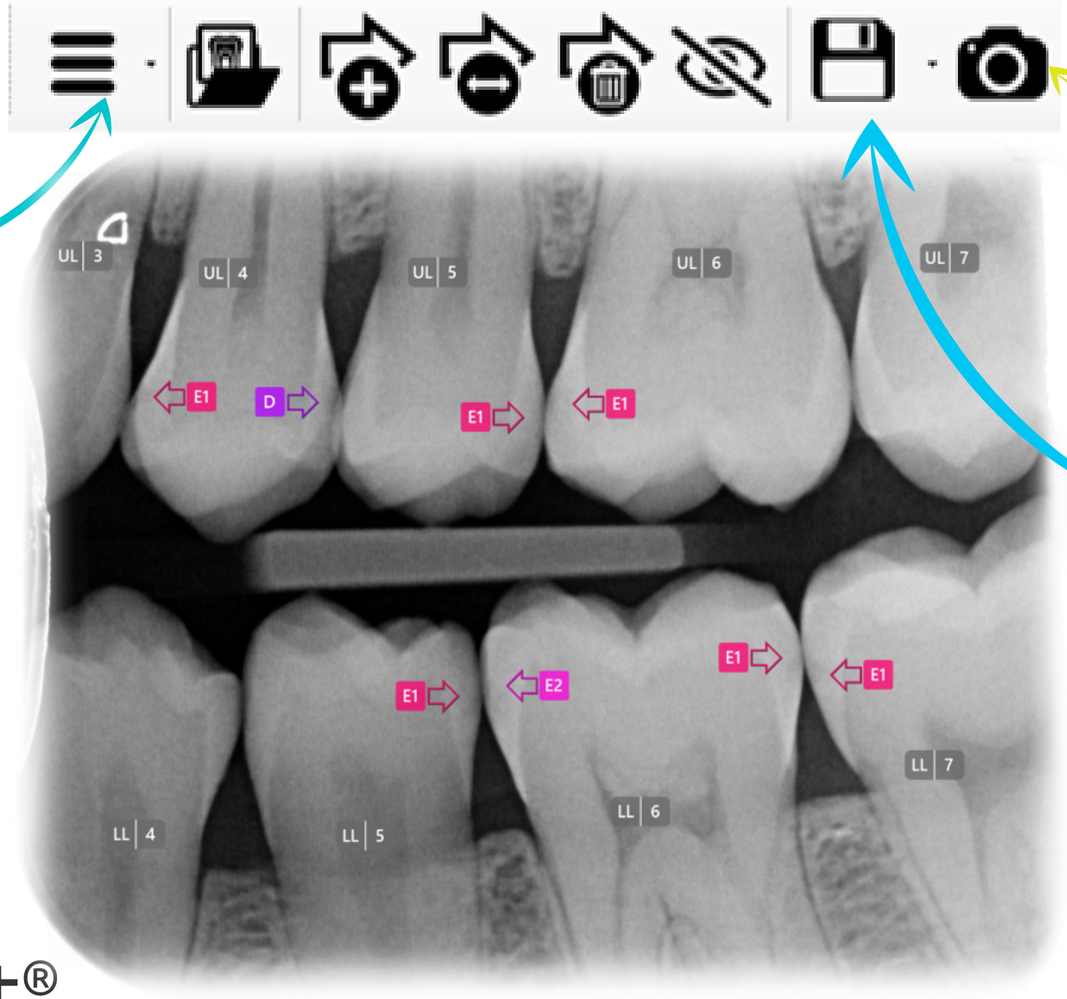

Advanced Export Options
Go to 'Menu Options' and select 'Settings' to create a preset destination folder

Camera Icon
To get a snapshot image and enables a copy and paste function into another application from the clipboard

Export Icon
Saves a copy to the preset destination folder on the User's System, or choose 'Save As' to save in a different location and file name

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Advanced Export Settings

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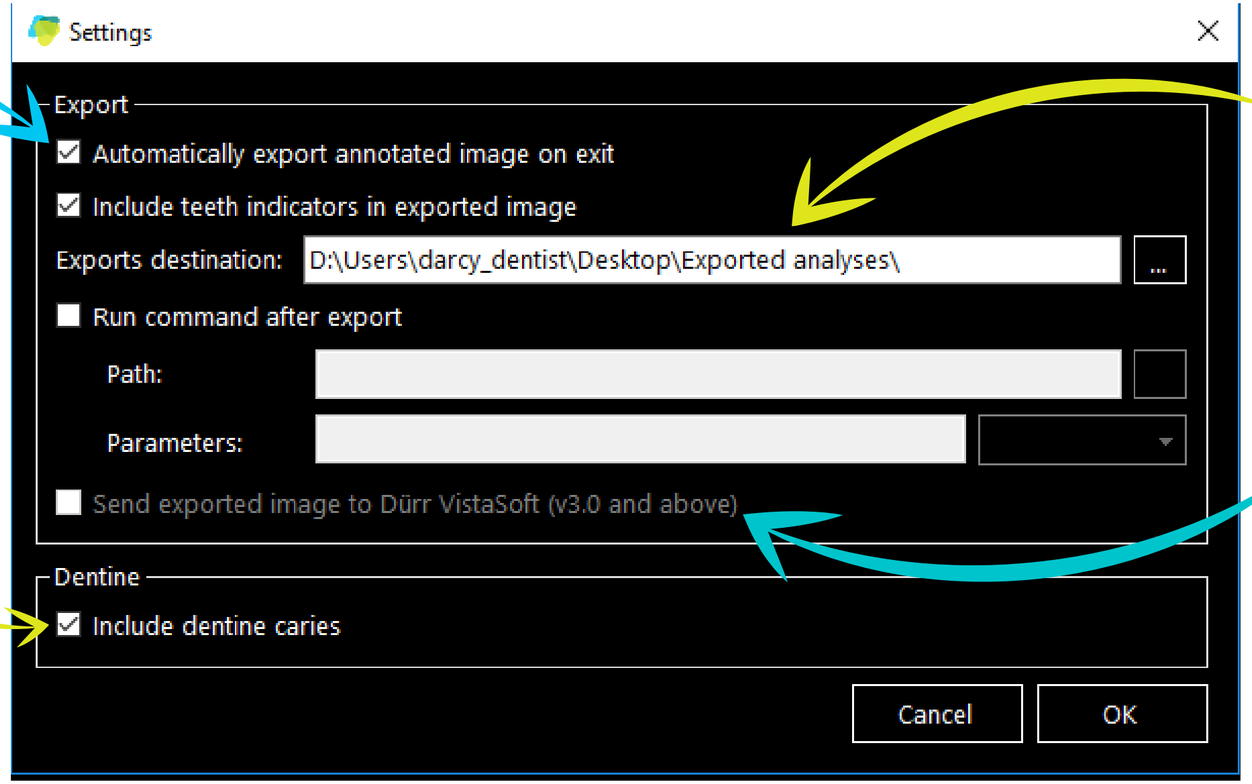
Automatic Export Option
Set the system to autosave annotated radiographs to a specified destination upon exit from AssistDent

Additional Advanced Analysis Option
Toggle to include dentine caries diagnostics



Export Command
Upon exit the image is saved into a specific folder on the User's System

Export To Durr Dental Imaging Software
AssistDent has additional capability to enable external integration

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Automatic Assist

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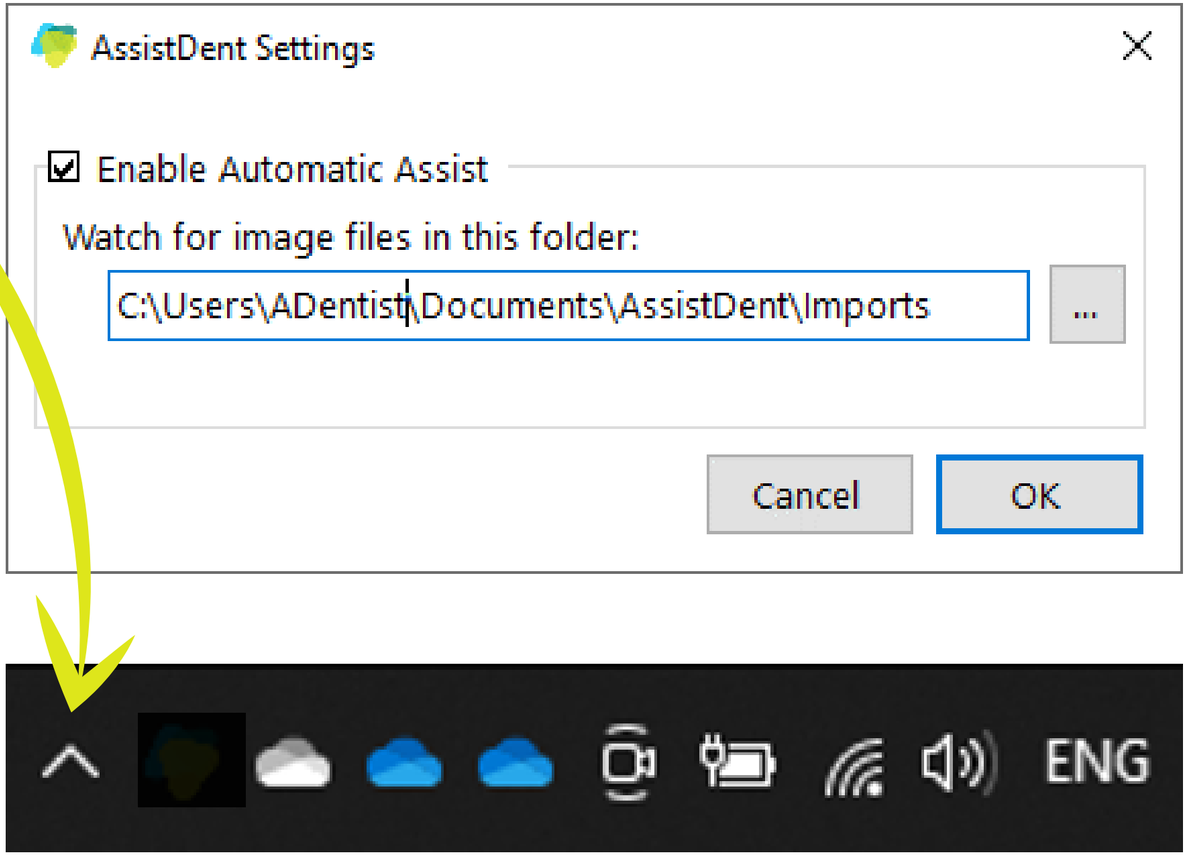
To activate AssistDent Automatic Assist
Click the ^ arrow in the system tray located on the right-hand side of the Windows Taskbar

To open AssistDent Automatic Assist
Double click or right click on the AssistDent icon



AssistDent Automatic Assist
A 'system tray' application which runs in the background

It continuously monitors a dedicated 'watched' folder

All Bitewing Radiograph images saved to the 'watched' folder automatically open AssistDent generating results

The 'watched' folder can be changed at any time

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CONTACT US

Our friendly customer support is here to help...

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07916 312 546

For a Paper Copy of this User Guide contact:-
support@manchester-imaging.com

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