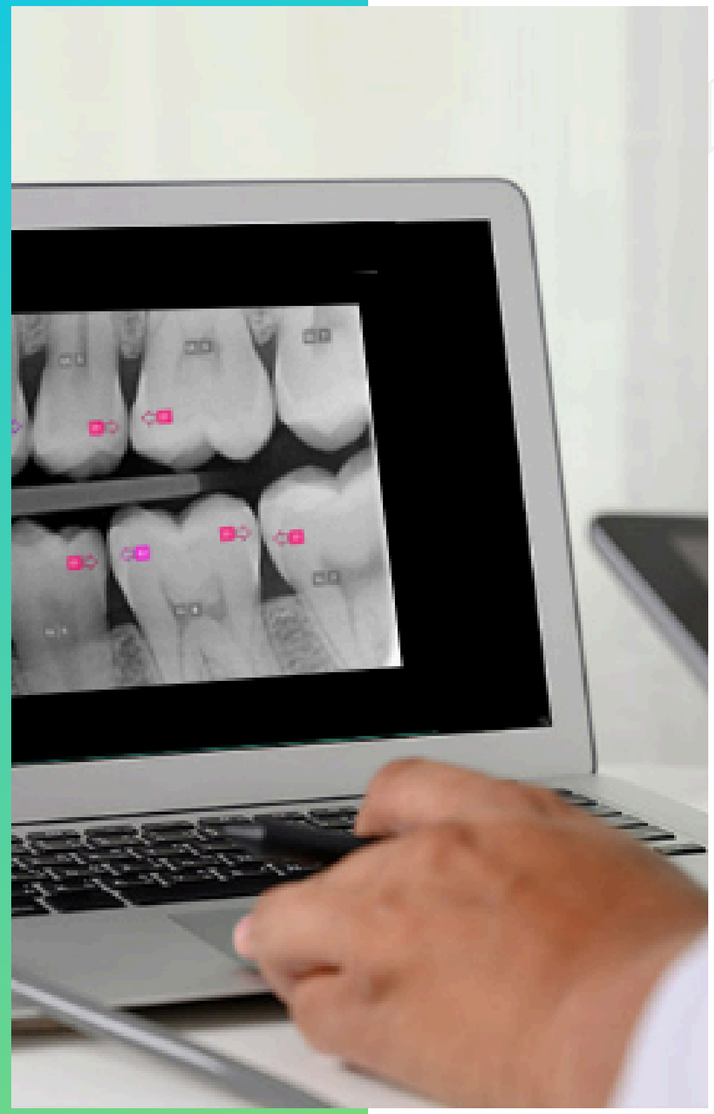

AssistDent®
User Guide

WWW.MANCHESTER-IMAGING.COM

UK CA

AssistDent v2.3 User Guide

Manchester Imaging Ltd

20241118-1230

How To Use AssistDent®

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Clinical Use

Manchester Imaging
ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE

Product Name
AssistDent
Version (UDI-DI)(UDI-PI)
Version 2.3.x
Unique Identifier Generated at build time. Displayed within the application.
Date of Manufacture
Generated at build time. Displayed within the application.
Manufacturer
Manufacturer Address:
Manchester Imaging Limited,
c/o Nexus Solicitors Limited, Carlton House, 16-18 Albert Square,
Manchester, M2 5PE, 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
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 & 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; 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.

Getting Started

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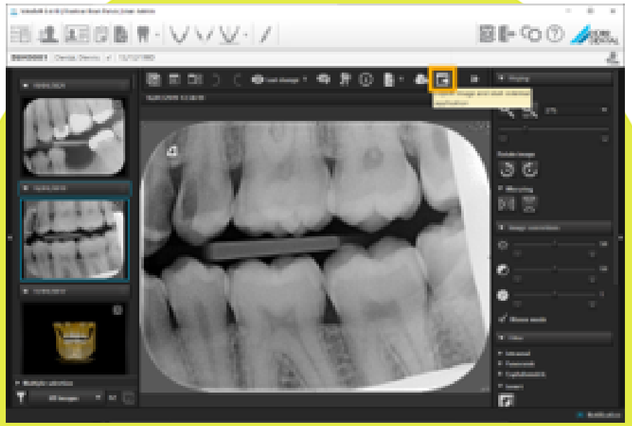
3 Ways To Open AssistDent®

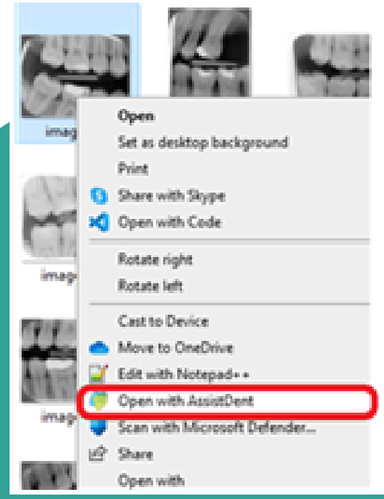
Double click on the AssistDent icon in the Start Menu or Desktop

1



Access via external applications
E.G. VistaSoft + EXAMINEpro + DentalEye + CareStream

2



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

3

AssistDent®

Clinical Analysis (a)

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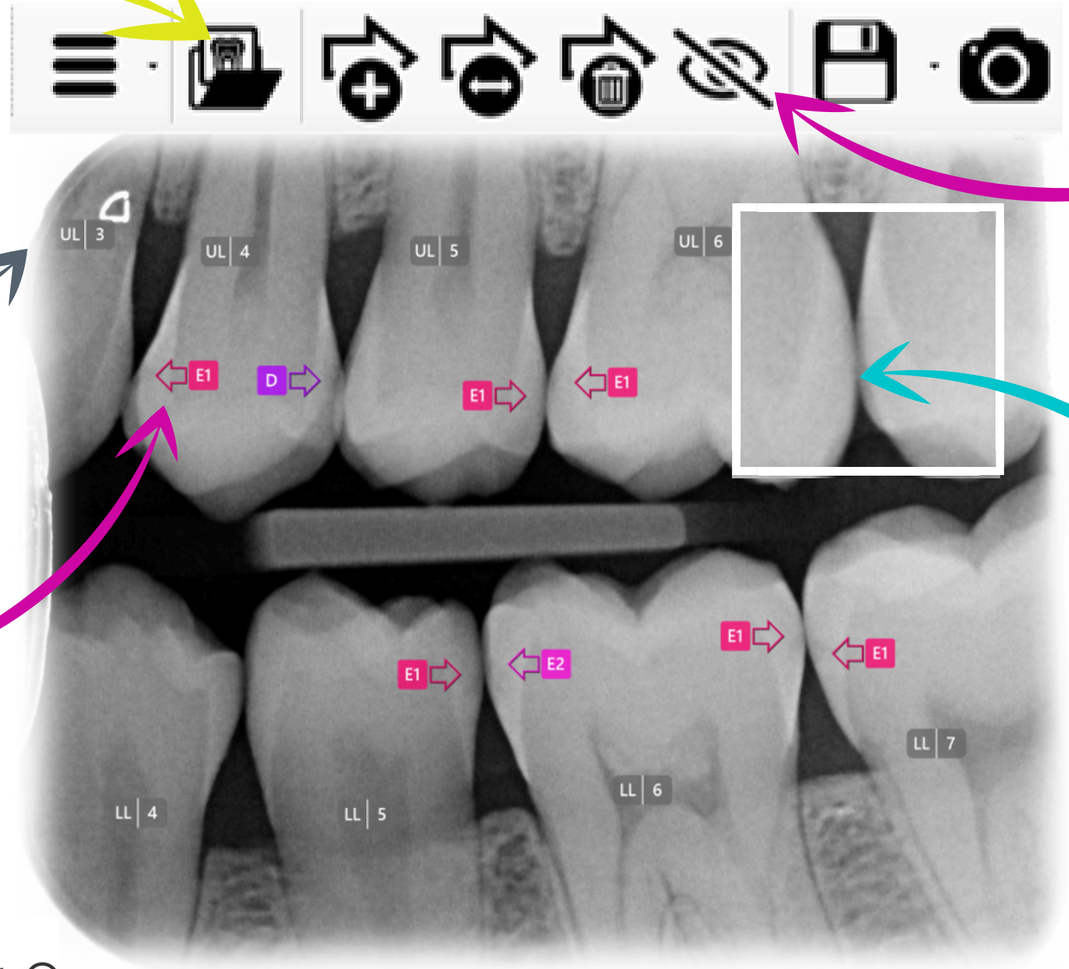
Open Image
Select a Bitewing Radiograph

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

AssistDent®

Clinical Analysis (b)

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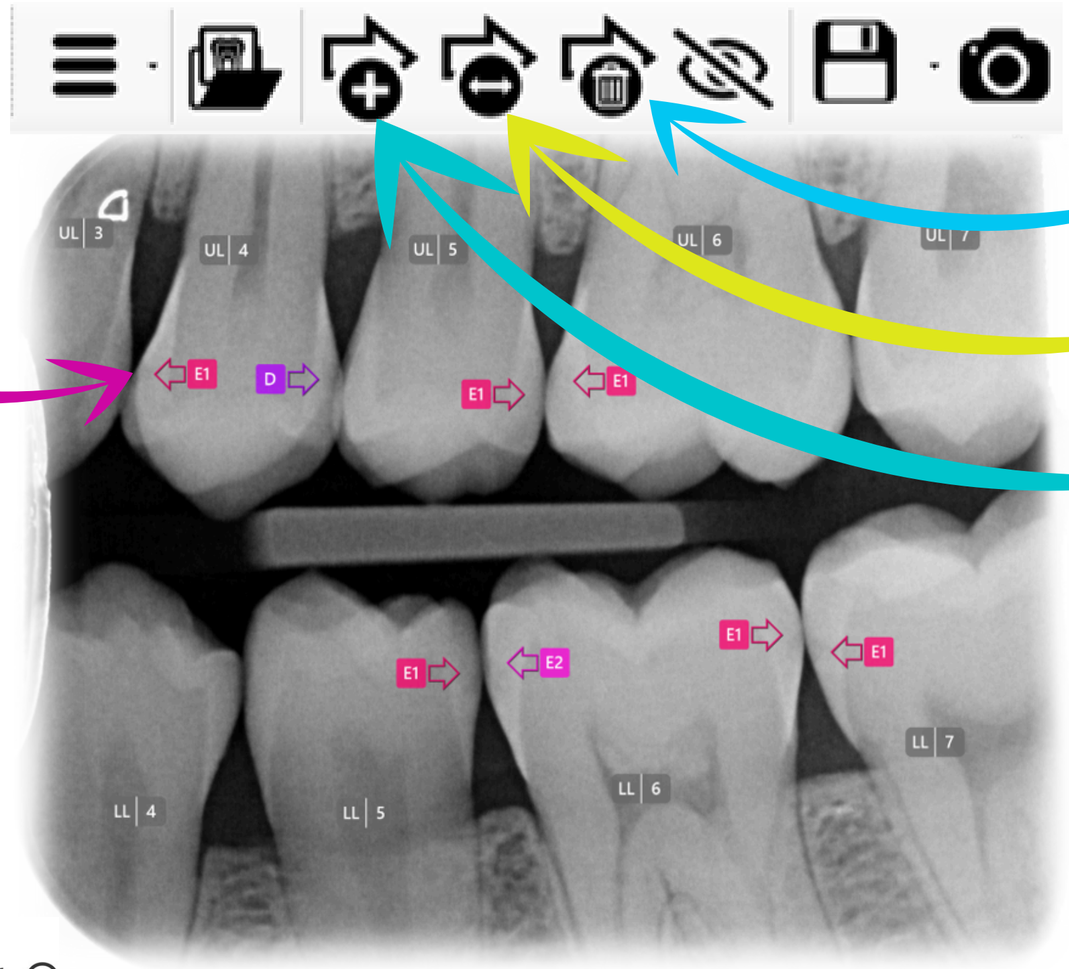
To Edit Annotations
Click on a Caries Indicator **arrow**

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

Highlight an **arrow** to enable more editing options



More Editing Options
Delete and remove

Flip directions

Add new Caries Indicator then click on a location

AssistDent®

Clinical Analysis (c)

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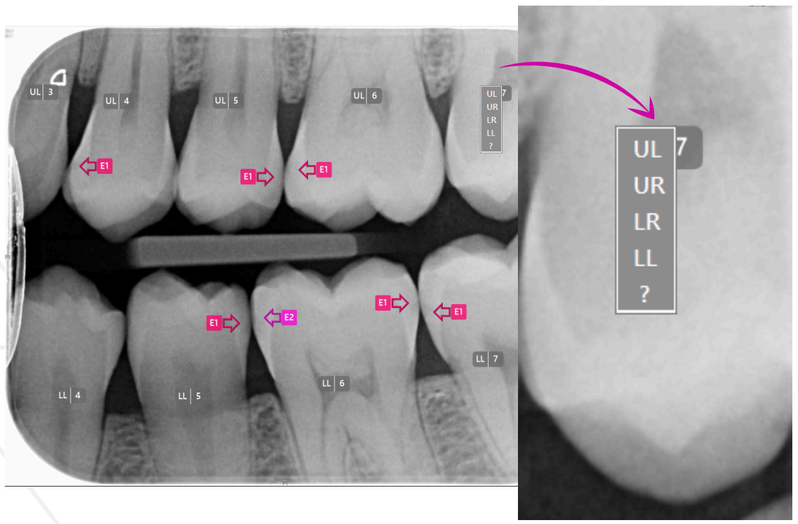
Edit Labels

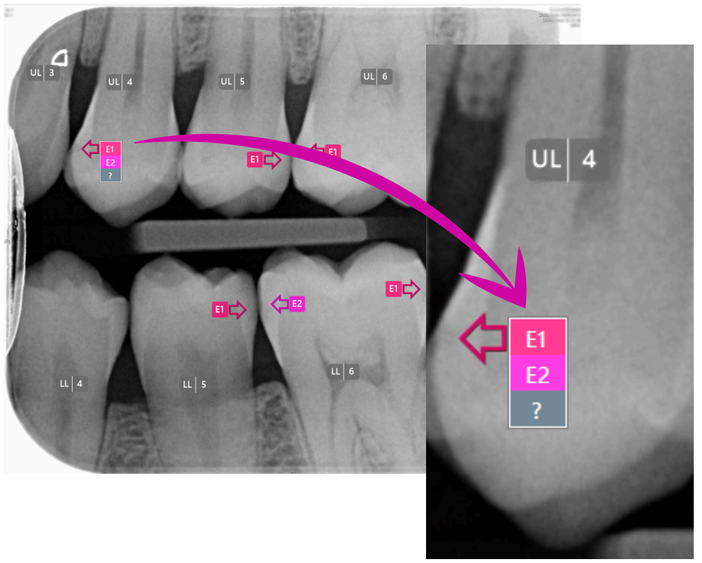
Options for clinical override of the AI analysis

Select and click the preferred label

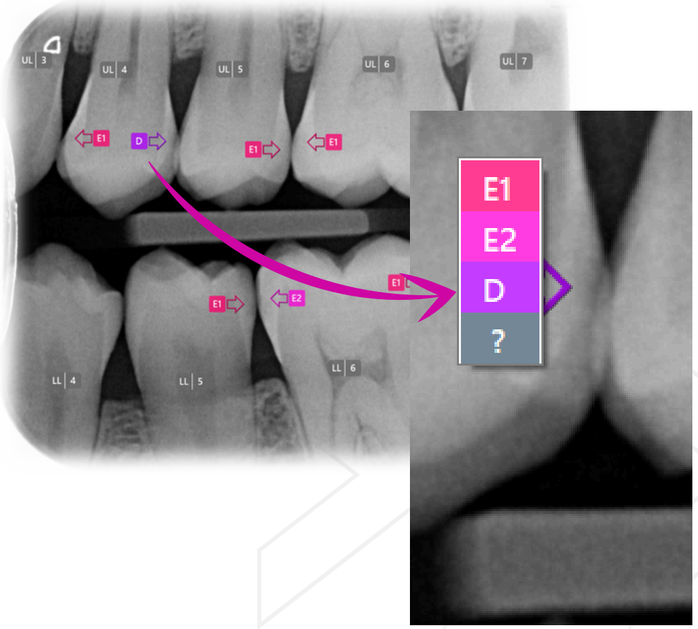
Tooth Labelling



Enamel Caries Grade



Dentine Caries Grade



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Clinical Analysis (d)

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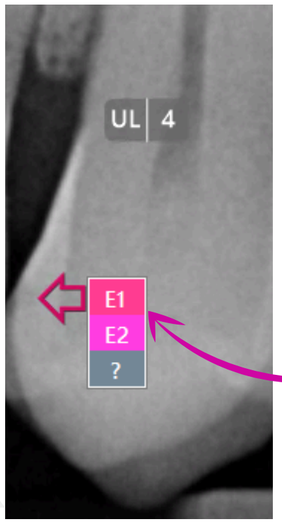
International Caries Classification Standard

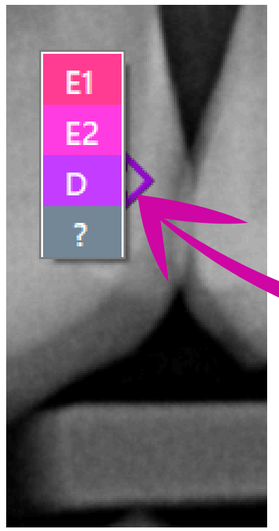
Enamel Caries Grade



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.

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Clinical Analysis (e)

Snapshot Short Reporting

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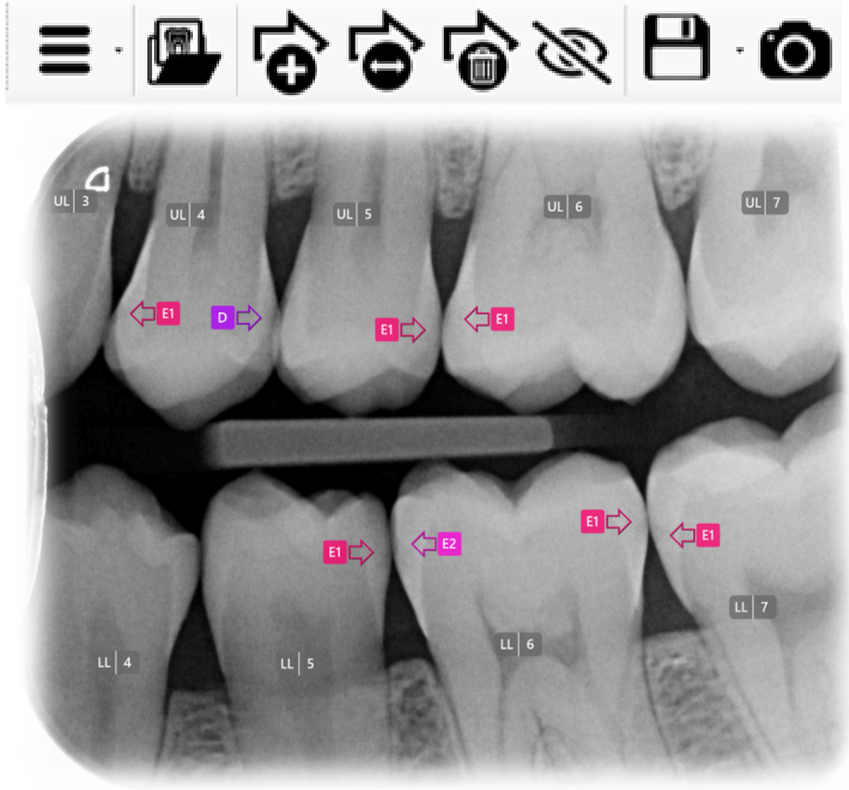

Clinical Report

Bitewing Orientation: Left
Teeth Present: 9 (UL3-7, LL4-7)
D Caries: UL4(dis)
E2 Caries: LL6(mes)
E1 Caries: UL4(mes), UL5(dis), UL6(mes), LL5(dis), LL6(dis), LL7(mes)

Radiograph Quality

Status	Metric	Comments
Pass	Resolution	Medium(1816...
Pass	GrayScale	True
Pass	Contrast	Medium(48%)
Pass	Blur	Low(36%)

Clinical Short Report
Copy to clipboard and paste into the patient's record

Clinical Snapshot Overview
Auto-generated text report of the analysed and annotated radiograph

Radiograph Quality Metrics - Pass Status
Assesses the radiograph status according to quality standards

Example Failed Status

Status	Metric	Comments
Fail	Resolution	Very Low(50...
Pass	GrayScale	True
Pass	Contrast	Medium(53%)
Pass	Blur	High(59%)

Failed status indicates the image is sub-optimal for AssistDent analysis.

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Clinical Analysis (f)

Comprehensive Full Reporting

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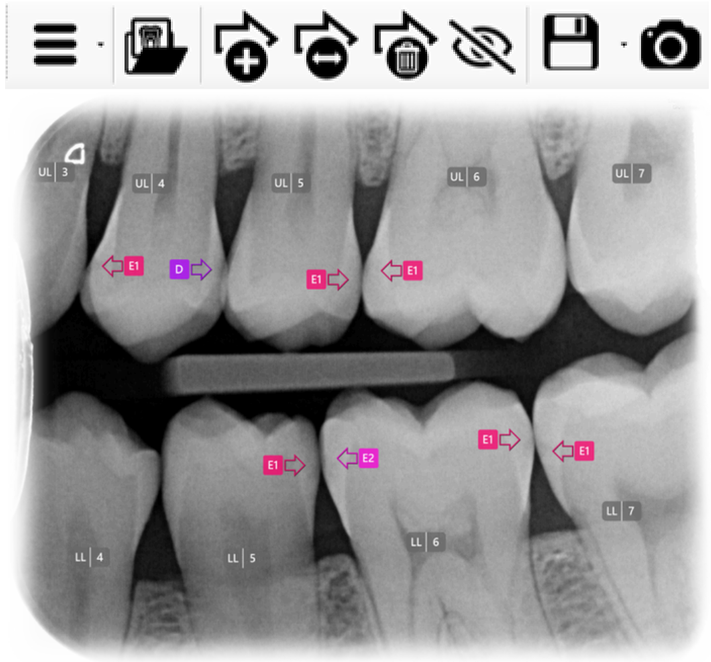

Radiograph Text Report: DO NOT ACT ON THIS REPORT WITHOUT REVIEWING THE ANALYSED RADIOGRAPH
Original Radiograph File Path: C:\User\Dentist\image128.tif
Analysed Radiograph File Path: C:\User\Dentist\image128-AssistDentExport-221017-092310.txt
Bitewing Orientation: Left
Teeth Present: 9
UL3: no caries
UL4: D caries(distal), E1 caries(mesial)
UL5: E1 caries(distal)
UL6: E1 caries(mesial)
UL7: no caries
LL4: no caries
LL5: E1 caries(distal)
LL6: E1 caries(distal), E2 caries(mesial)
LL7: E1 caries(mesial)
Caries Present: 8
D Caries: UL4(distal)
E2 Caries: LL6(mesial)
E1 Caries: UL4(mesial), UL5(distal), UL6(mesial), LL5(distal), LL6(distal), LL7(mesial)
ResolutionStatus: True
ResolutionComments: Medium(1816 x 1479)
GrayScaleStatus: True
GrayScaleComments: True
ContrastStatus: True
ContrastComments: Medium(48%)
BlurStatus: True
BlurComments: Low(36%)

Detailed Clinical Report

Saved as text with the same filename as the associated analysed image

Contains a detailed Clinical Report which can be copied and imported into the patient's clinical records

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Clinical Analysis (g)

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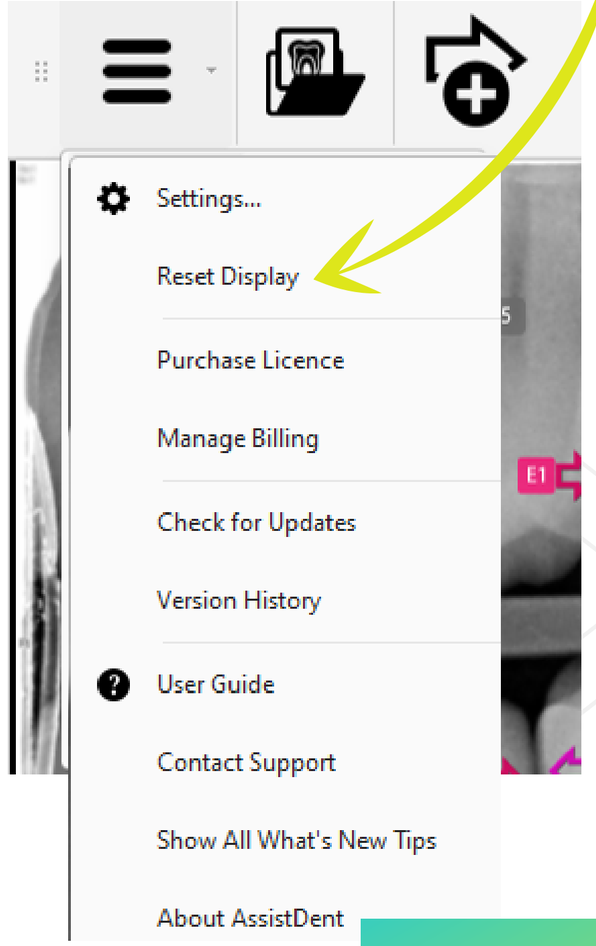
Dockable Panels
Drag a section to personalise a layout

Positioning Panels
Sections can be moved to the sides or below

Reset Display
Reorganise sections back to their original layout



AssistDent®

Menu Options

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Overview

Settings
Advanced Export Criteria

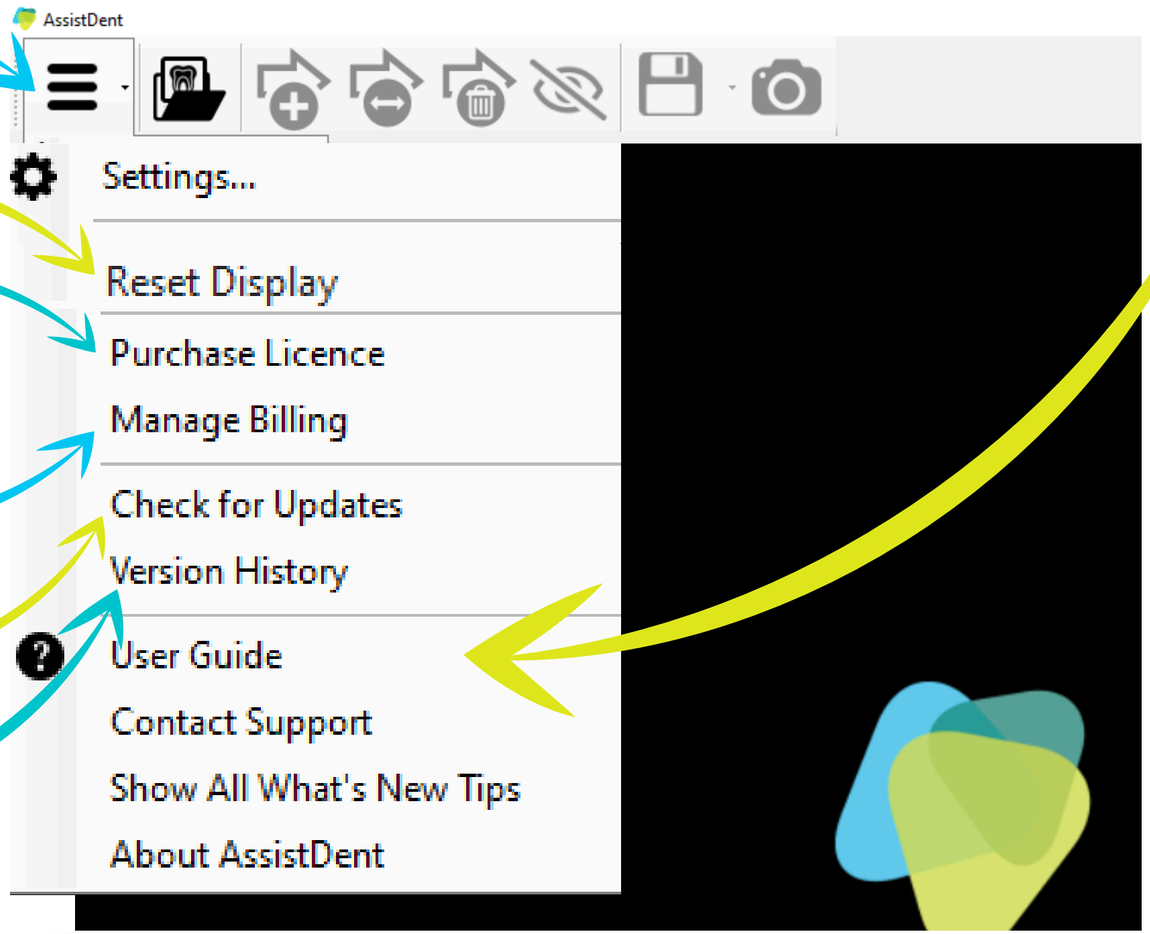
Reset Display
Organise layout

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

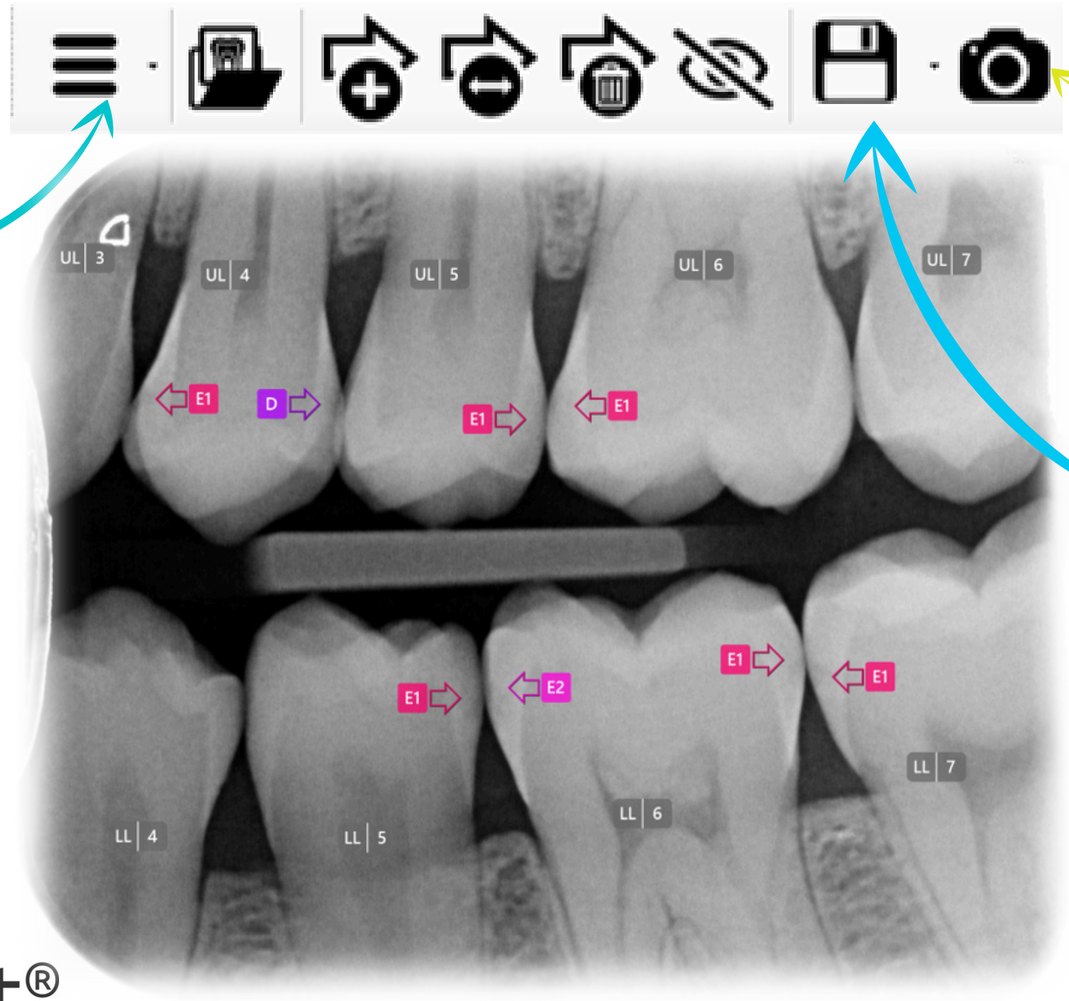
Show All What's New Tips
AssistDent 'in action' with quick videos of key functions

About AssistDent®
Summary of User licence
Product details

AssistDent®

Methods of Export

Manchester Imaging
ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE



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 of the annotated image and a detailed Clinical Report to the preset destination folder on the User's System, or can choose 'Save As' to save in a different location and file name

AssistDent®

Advanced Export Settings

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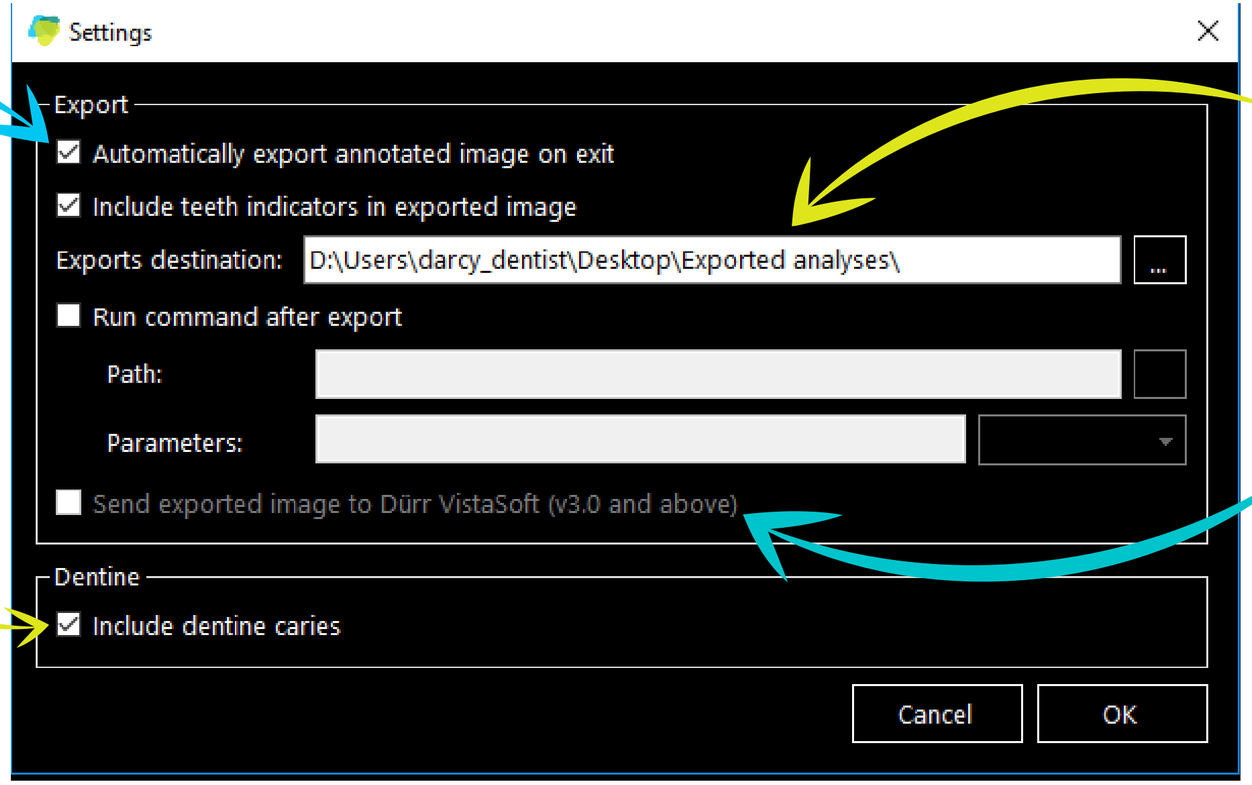
Automatic Export Option
Set the system to autosave annotated radiographs to a specified destination upon exit from AssistDent

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

AssistDent®

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CONTACT US

Our friendly customer support is here to help...

support@manchester-imaging.com

07776 481 645

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

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