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ASSISTDENT® USER GUIDE



UK
CA



How To Use AssistDent®



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Product Name	AssistDent®
Version (UDI-DI) (UDI-PI)	This document applies to versions 2.1.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 	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.

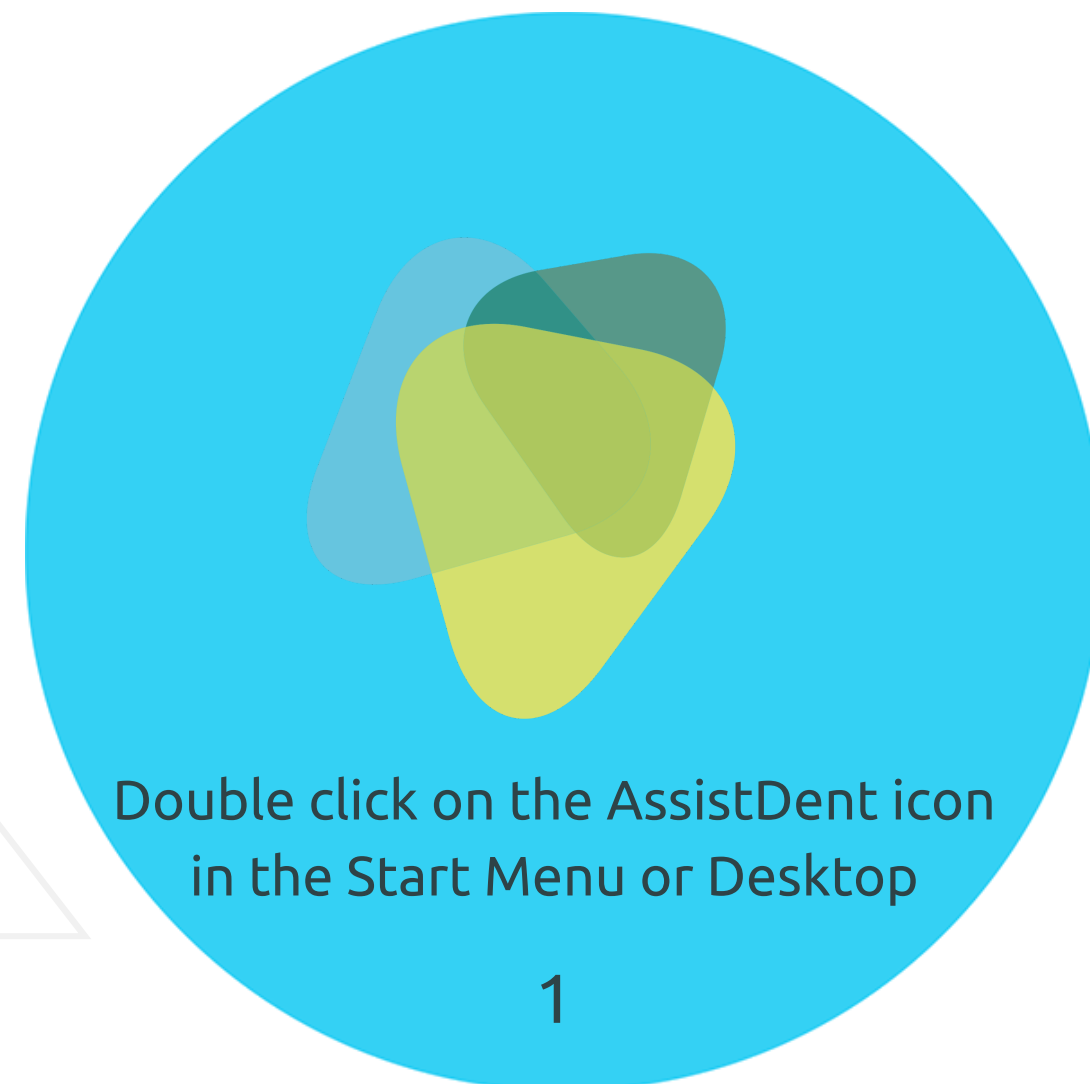


AssistDent®



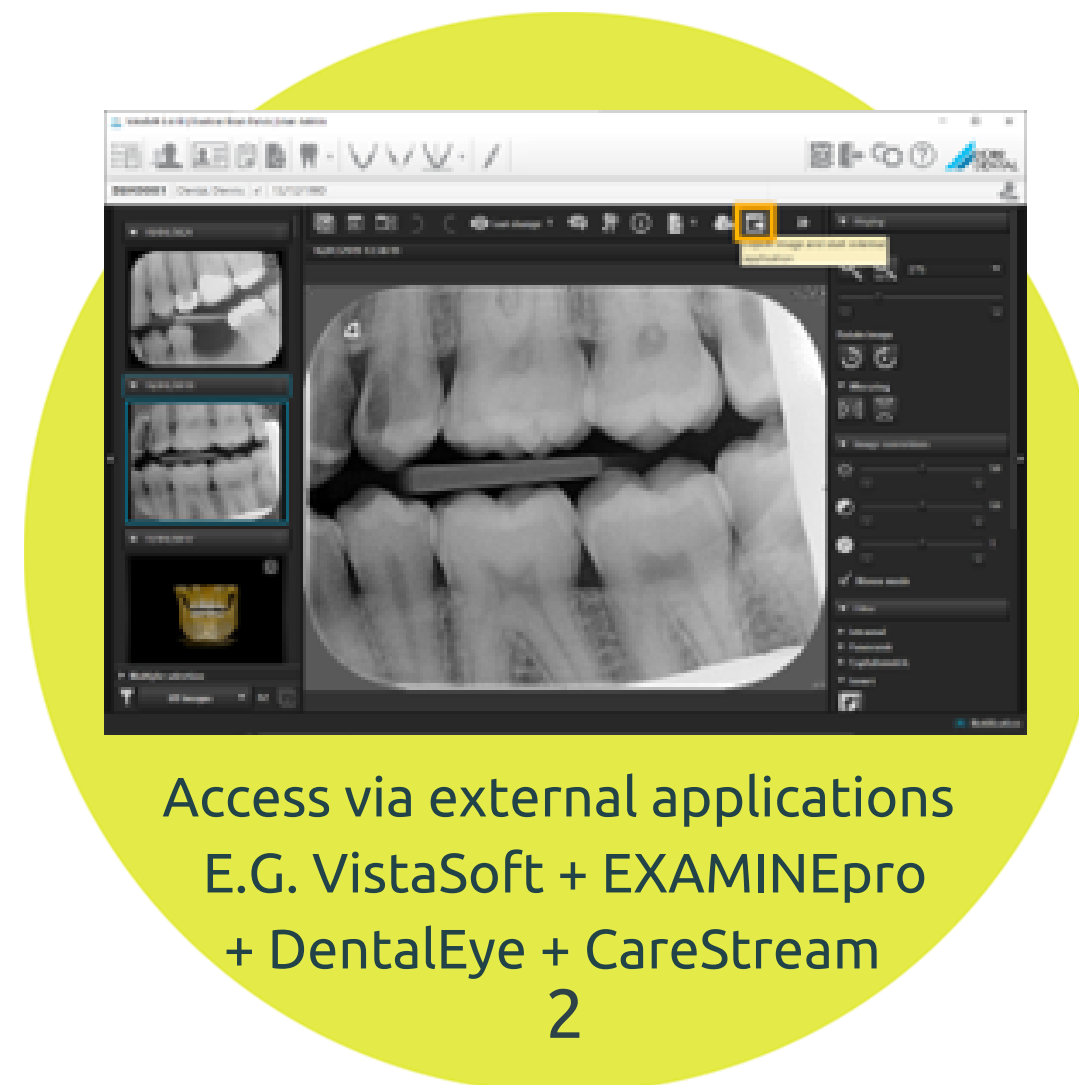
Getting Started

3 Ways To Open AssistDent®



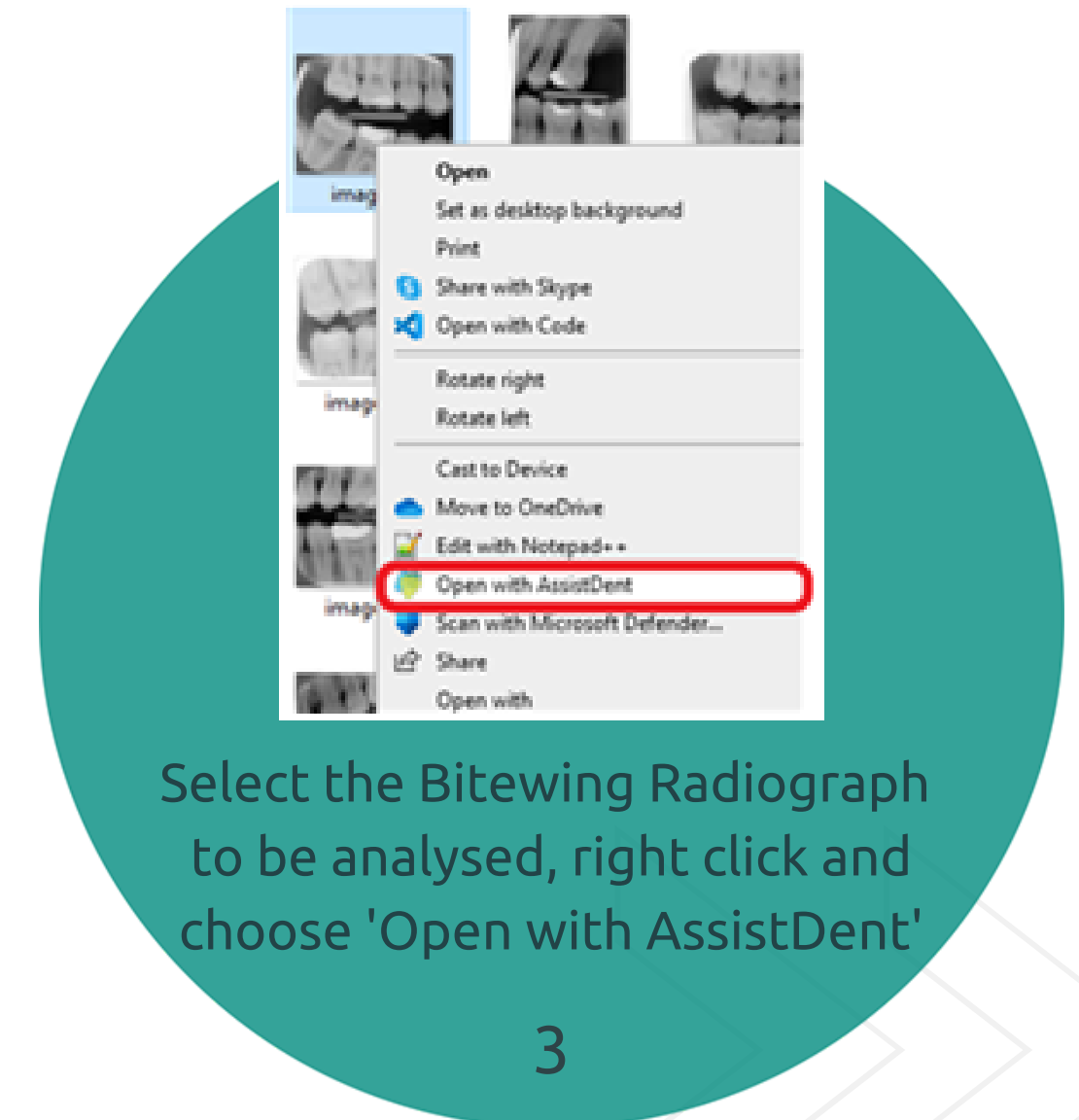
Double click on the AssistDent icon
in the Start Menu or Desktop

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'

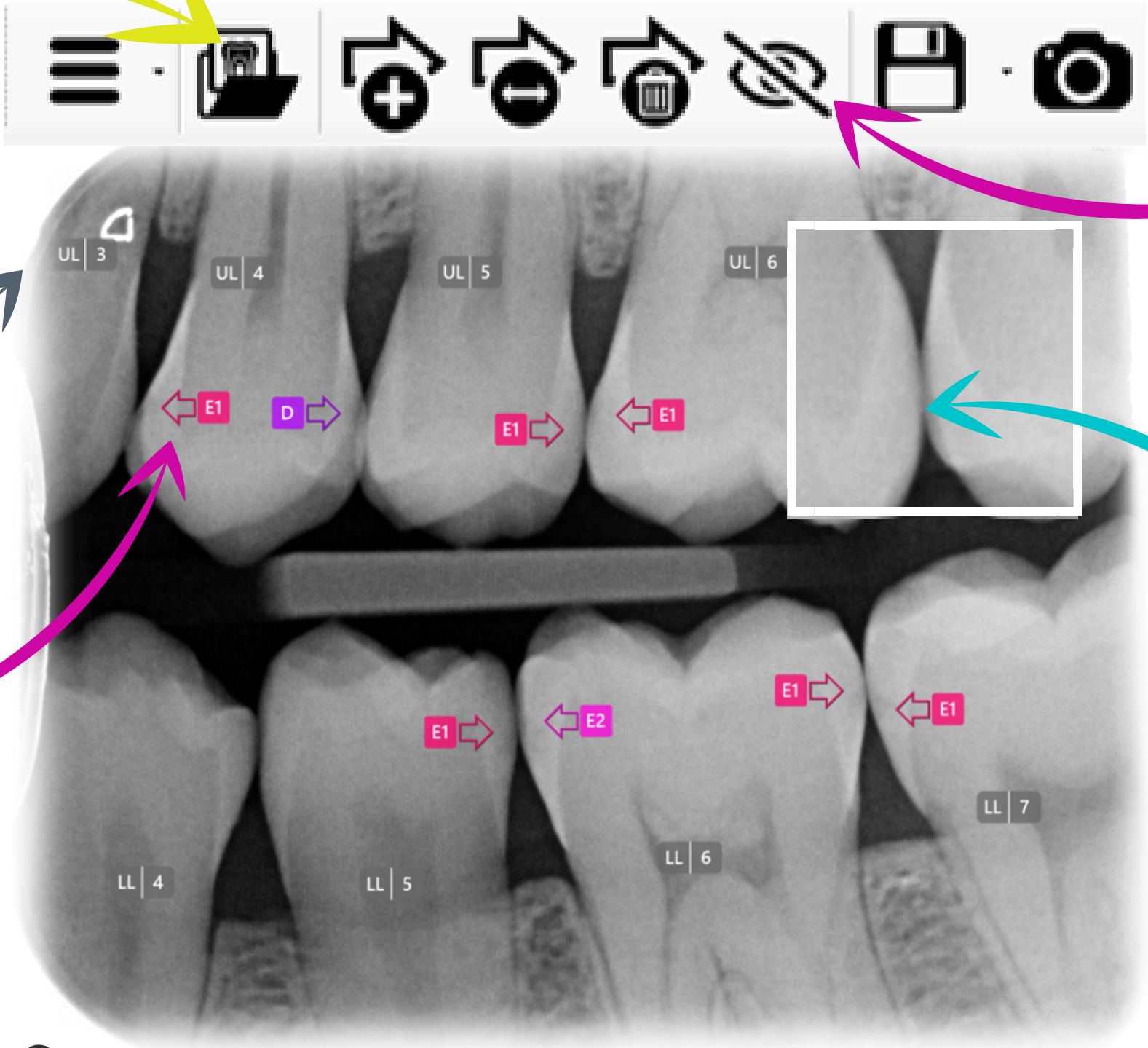
3

Clinical Analysis (a)

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

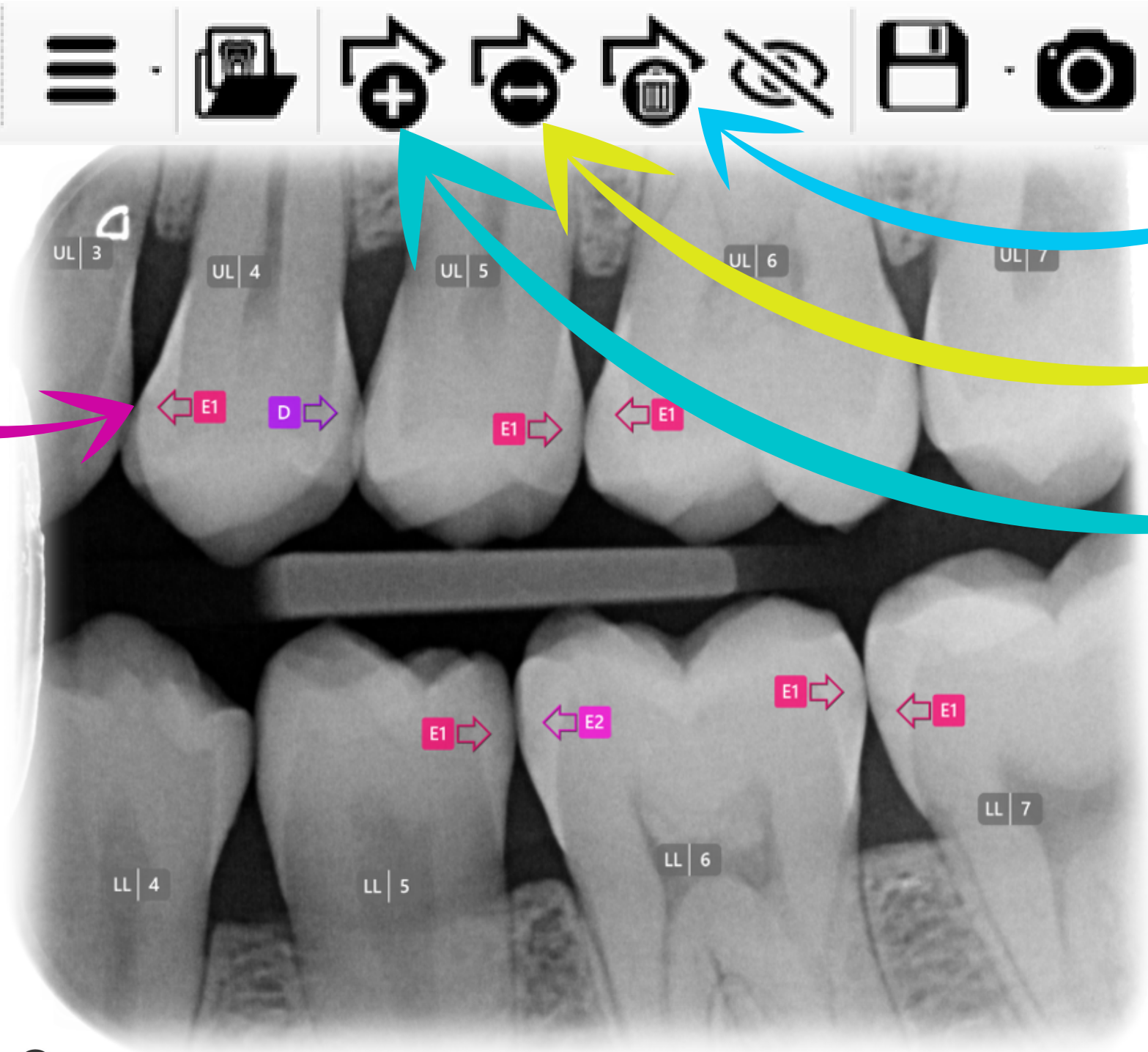
Clinical Analysis (b)

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



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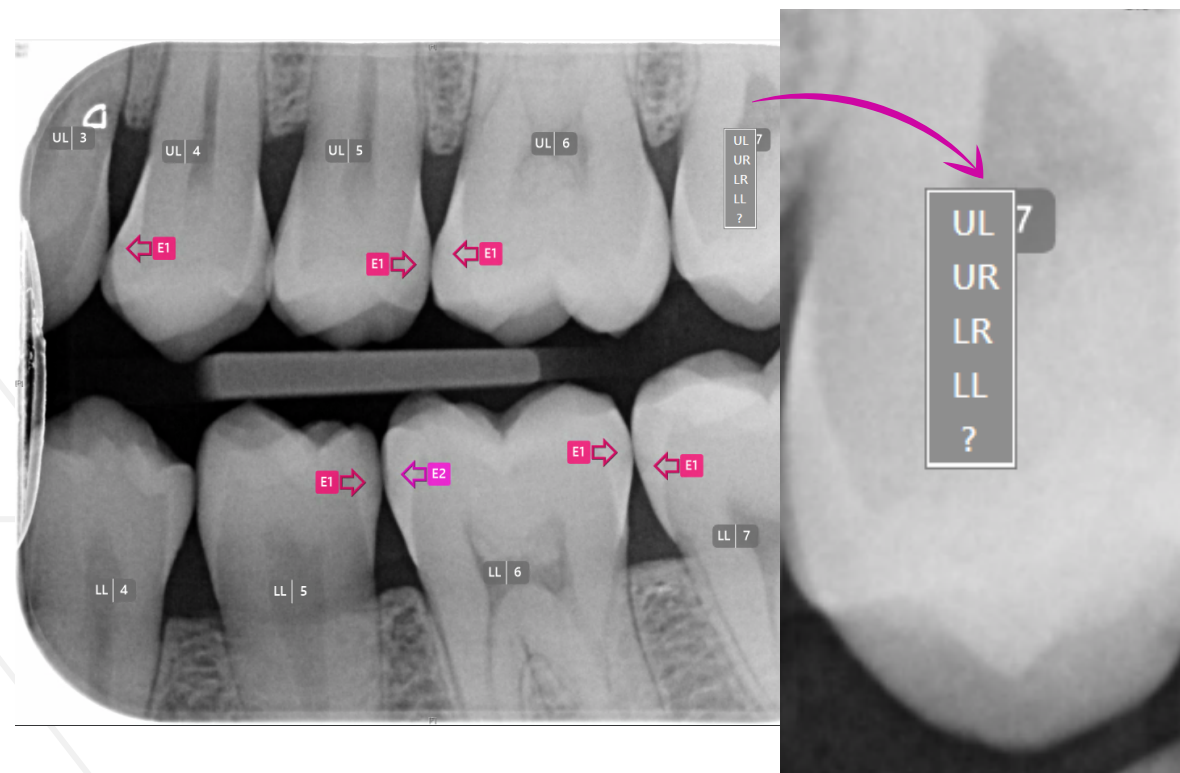
Clinical Analysis (c)

Edit Labels

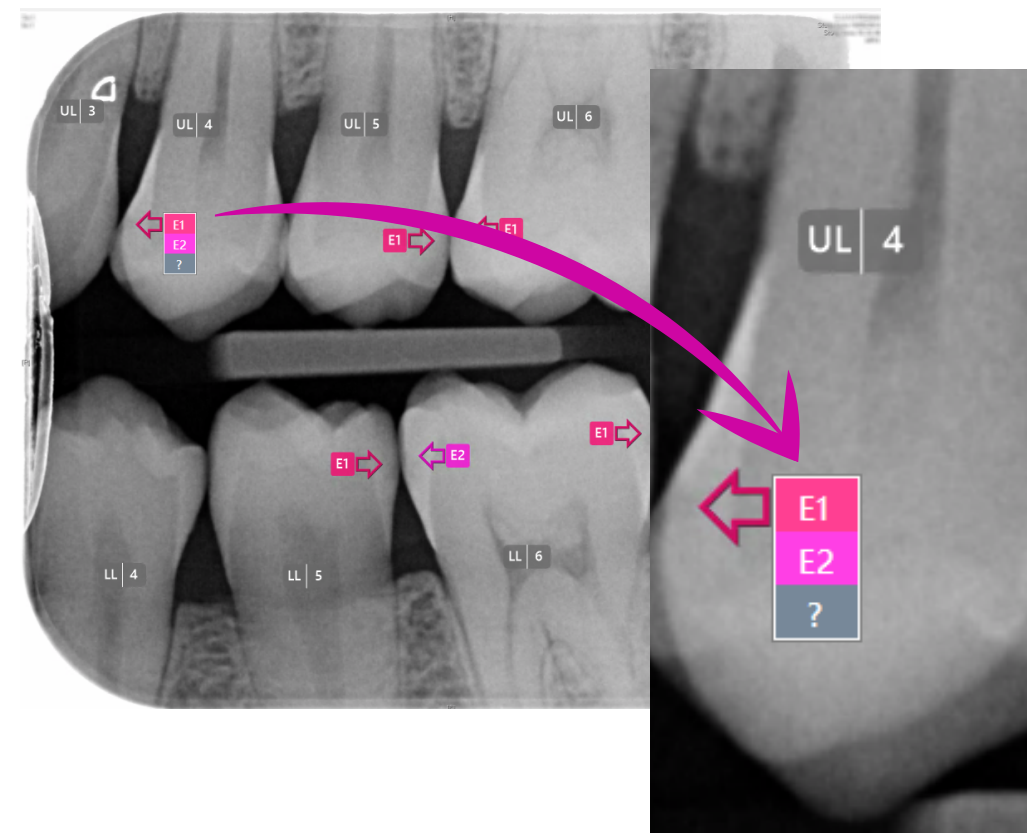
Options for clinical override of the AI analysis

Select and click the preferred label

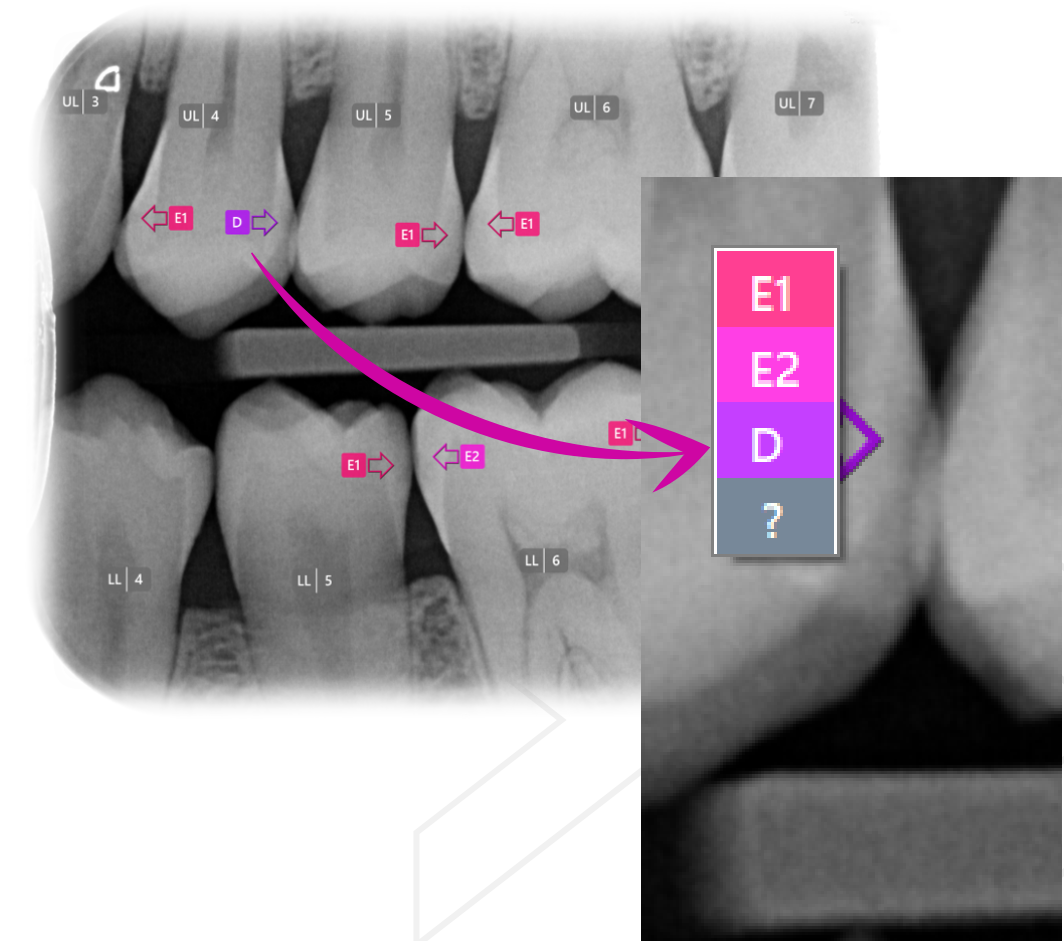
Tooth Labelling



Enamel Caries Grade



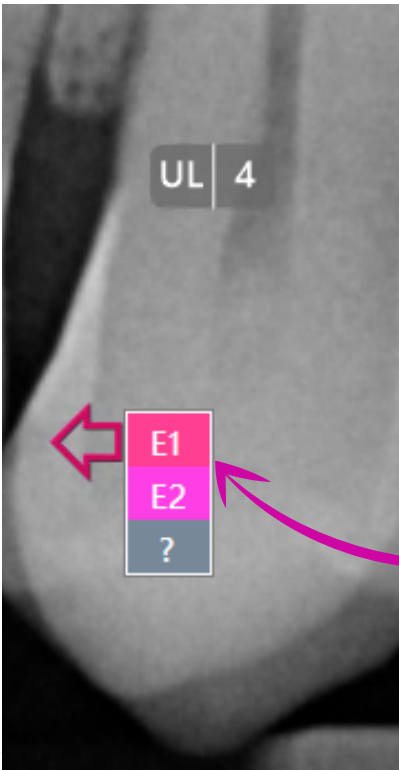
Dentine Caries Grade



Clinical Analysis (d)

International Caries Classification Standard

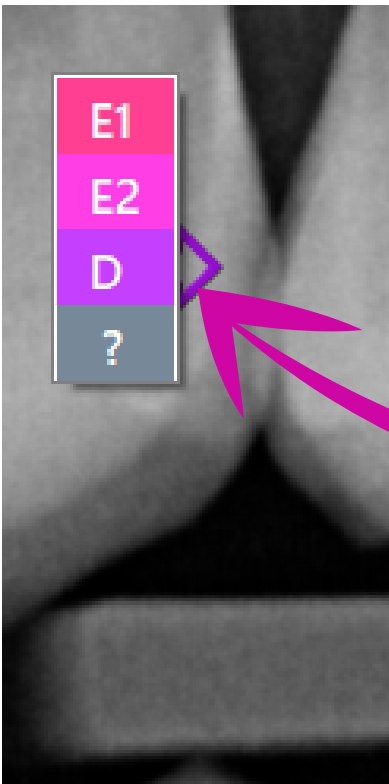
Enamel Caries Grade



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.

WARNING: In all cases, it is the prescribing clinician's responsibility to verify or alter the AI results before determining treatment.

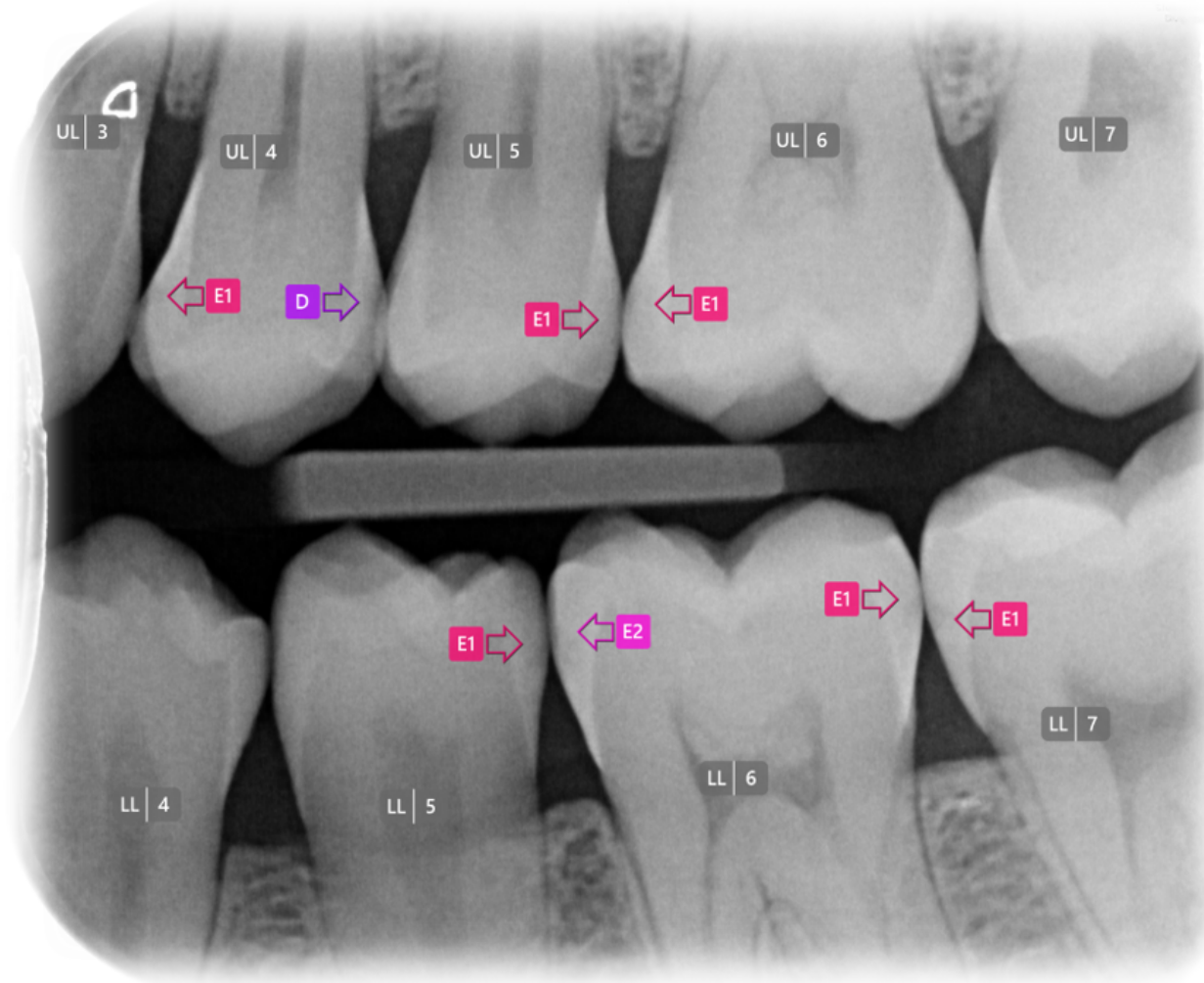


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Clinical Analysis (e)

Snapshot Short Reporting



Manchester Imaging

ARTIFICIAL INTELLIGENCE DENTAL SOFTWARE



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

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%)

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

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%)



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Clinical Analysis (f)

Comprehensive Full Reporting

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%)

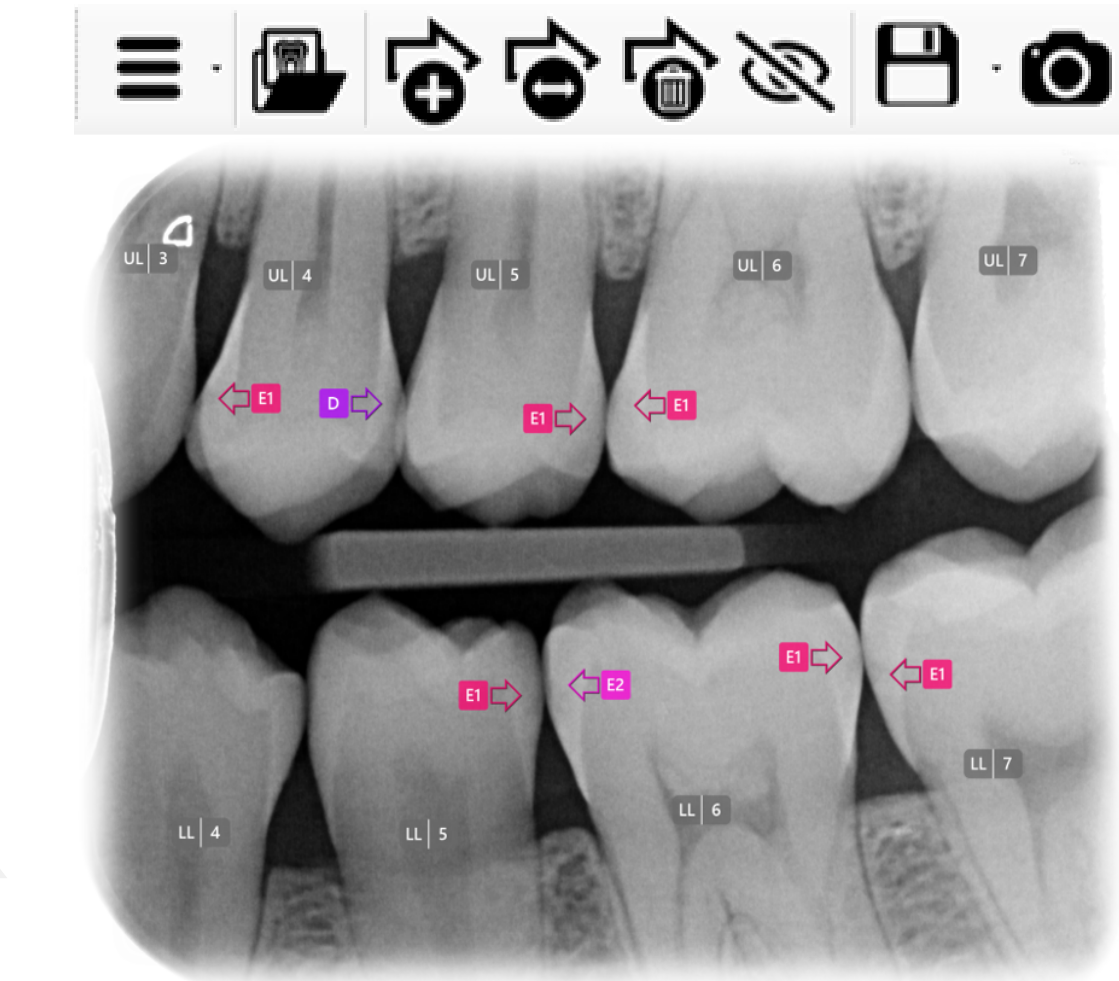
BlurStatus: True

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

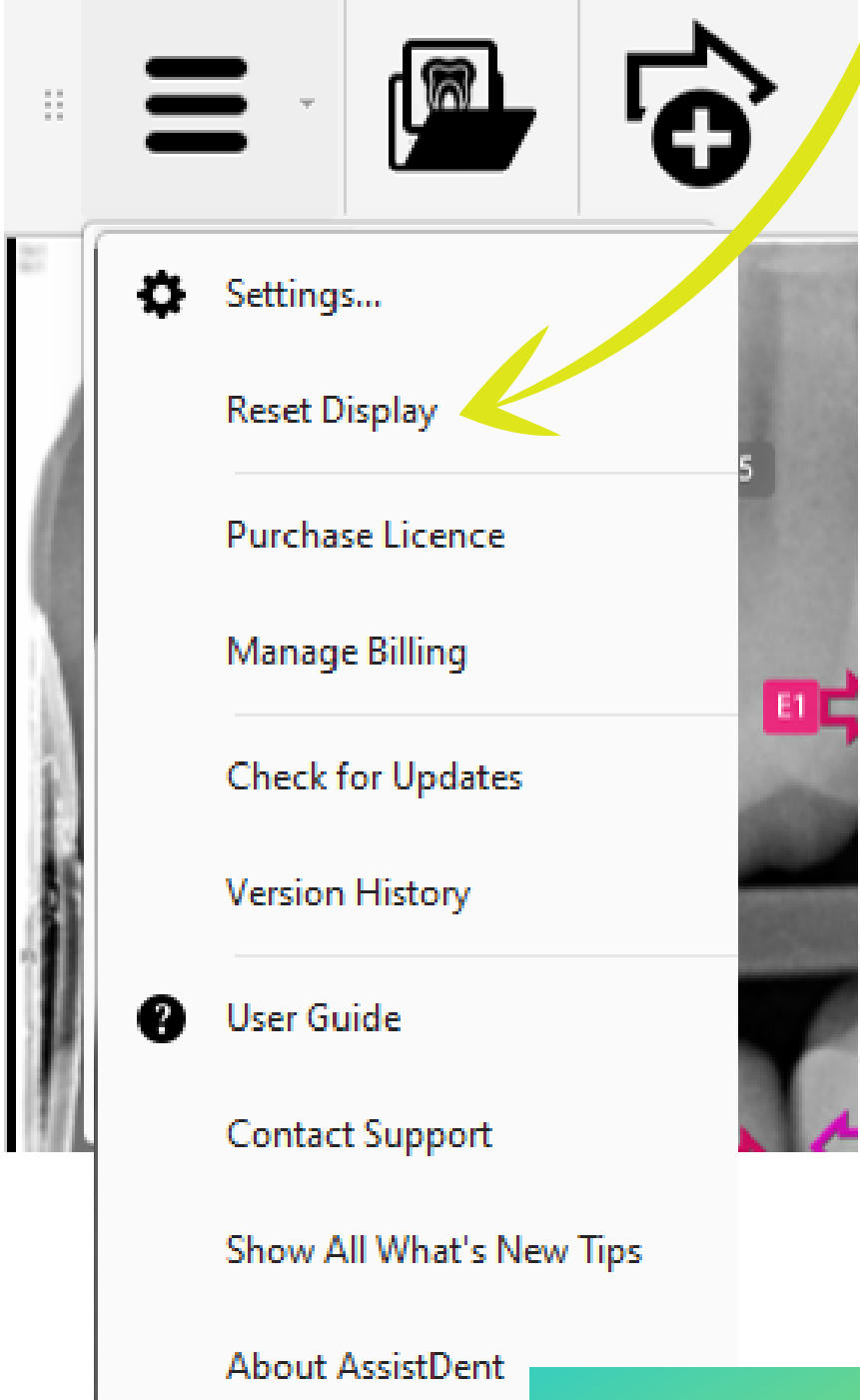
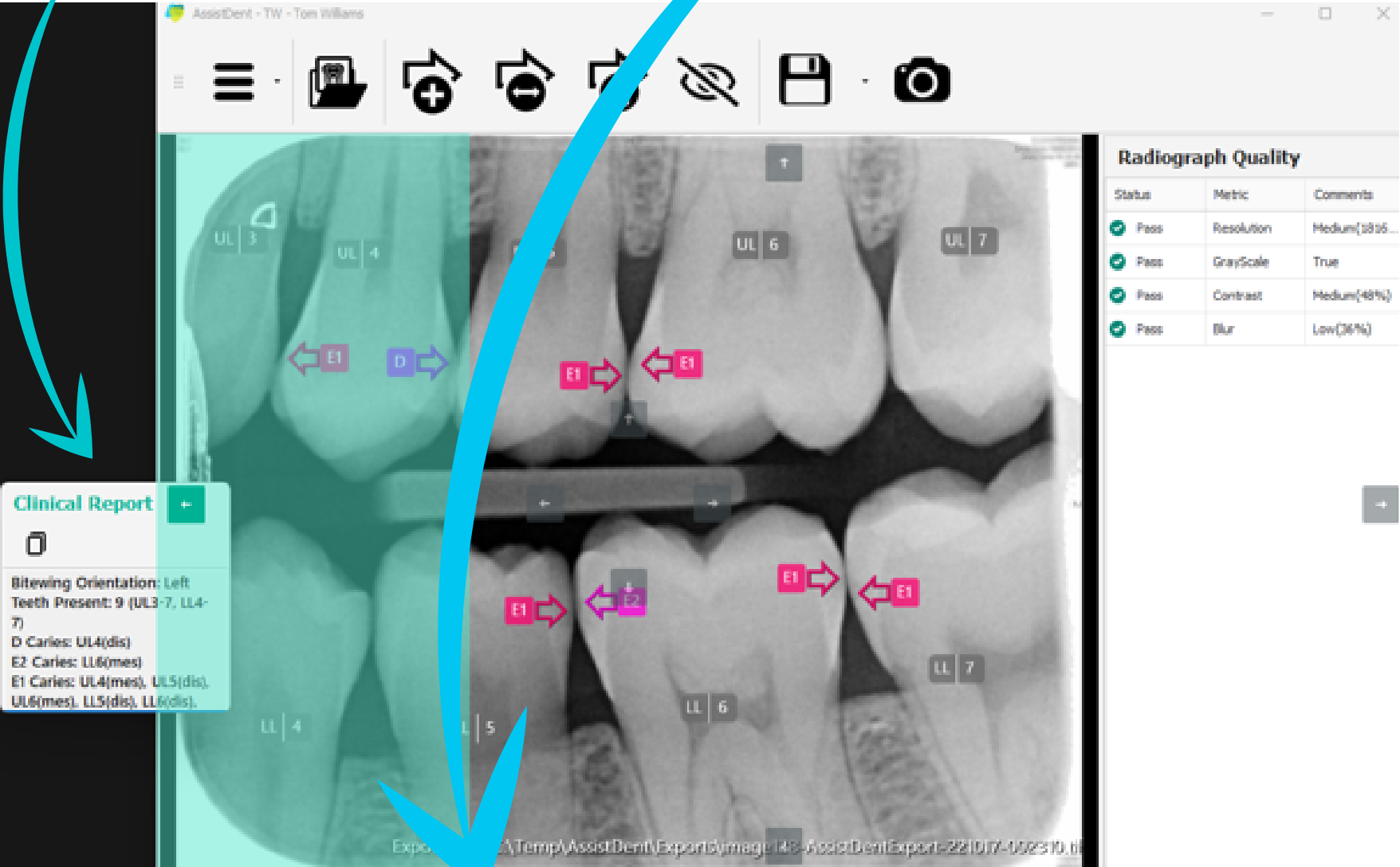


Clinical Analysis (g)

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



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Menu Options

Overview

Settings

Advanced Export Criteria

Reset Display

Organise layout

Purchase Licence

Subscription Purchase
Licence Details

Manage Billing

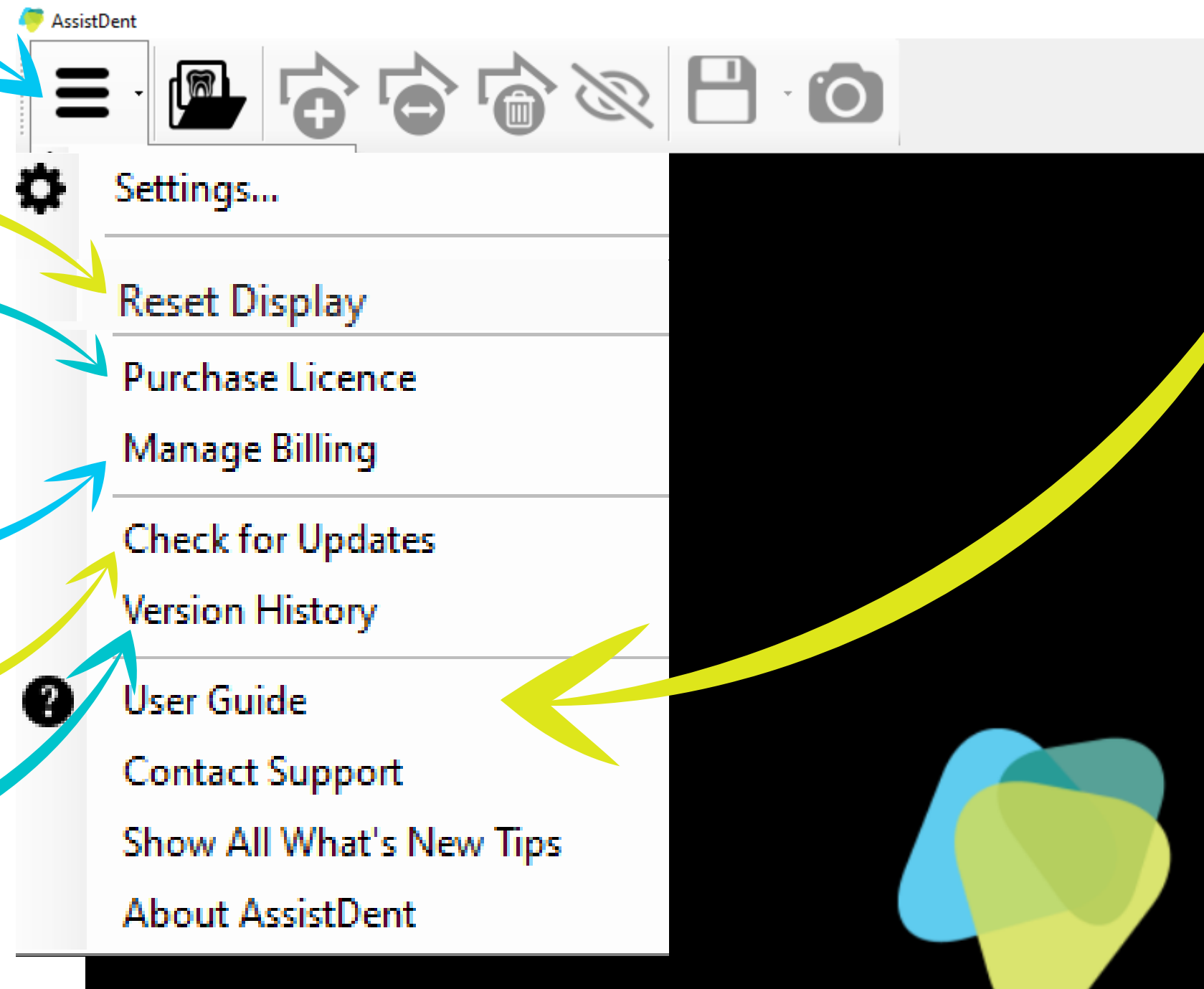
Update Payment Methods

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

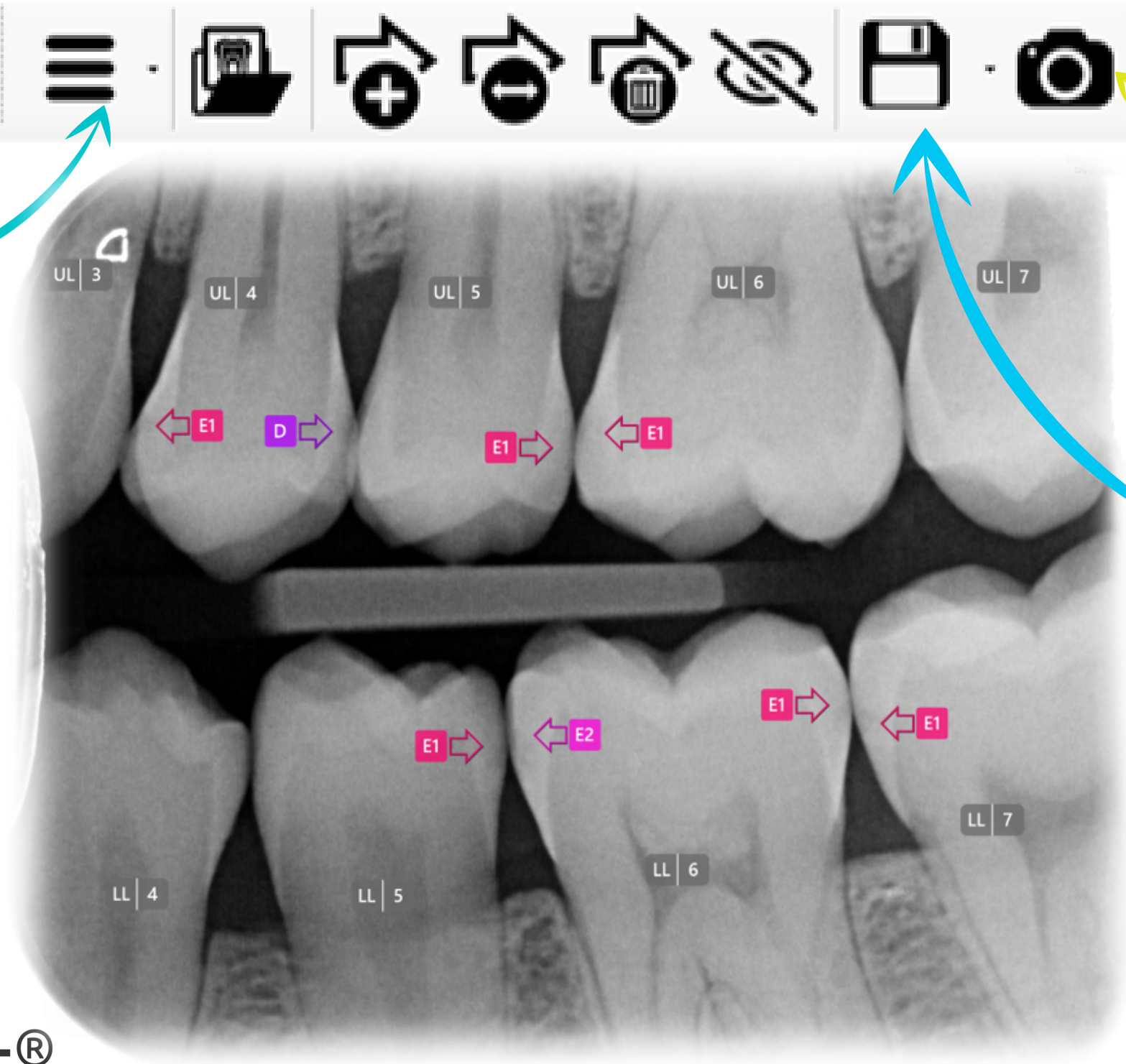
About AssistDent®

Summary of User licence
Product details

Methods of Export

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



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Advanced Export Settings

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

Settings

Export

☒ Automatically export annotated image on exit

☒ Include teeth indicators in exported image

Exports destination: ...

☐ Run command after export

Path:

Parameters:

☐ Send exported image to Dürr VistaSoft (v3.0 and above)

Dentine

☒ Include dentine caries

Cancel

OK

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

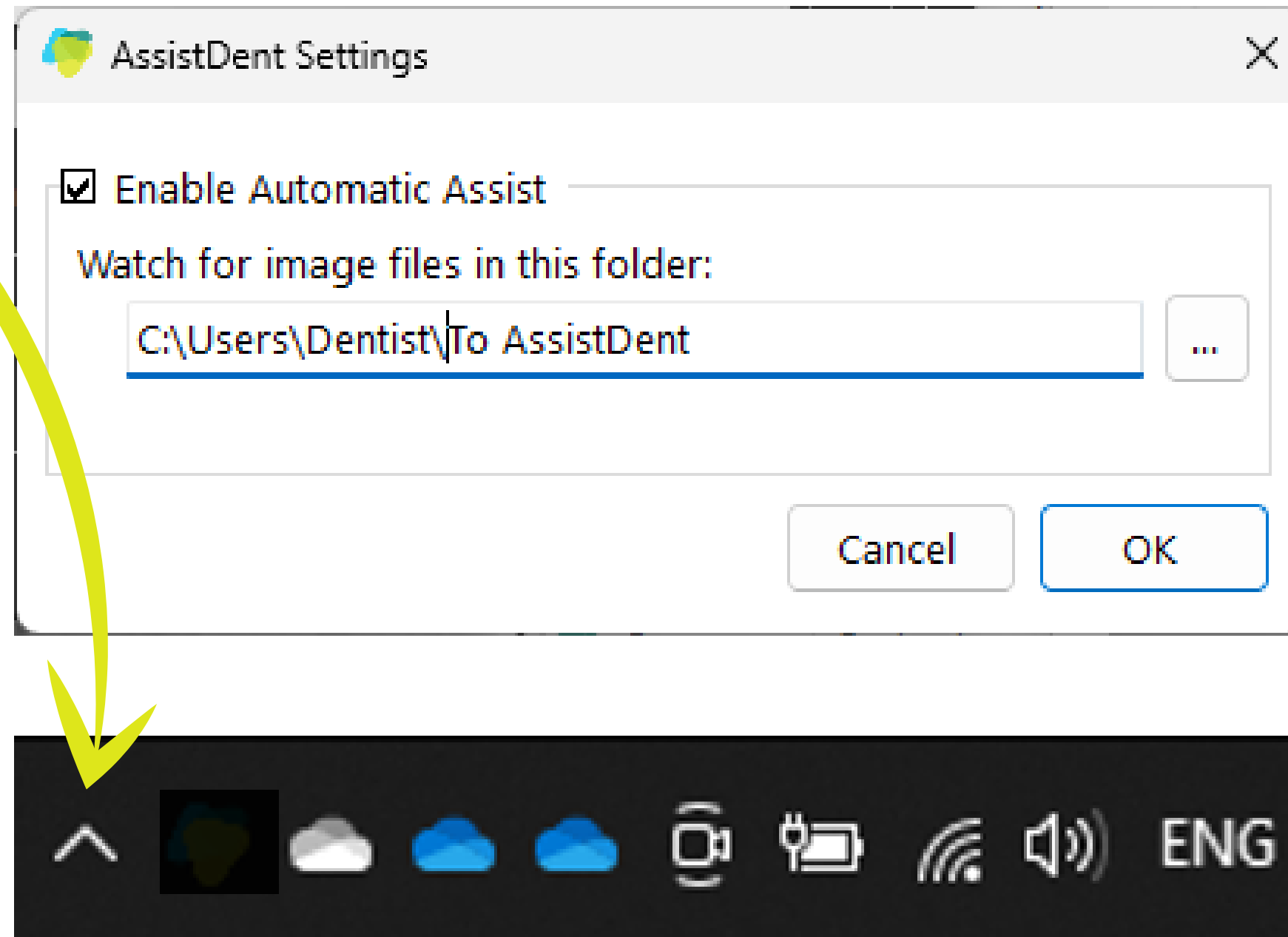
Automatic Assist

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



CONTACT US

Our friendly customer support is here to help...



support@manchester-imaging.com



07916 312 546

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



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