

AssistDent[®] User Guide

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AssistDent v2.2 User Guide
Manchester Imaging Ltd

2024-06-05-0730

How To Use AssistDent®



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Clinical Use

Product Name

AssistDent

Version (UDI-DI)(UDI-PI)

Version 2.2.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

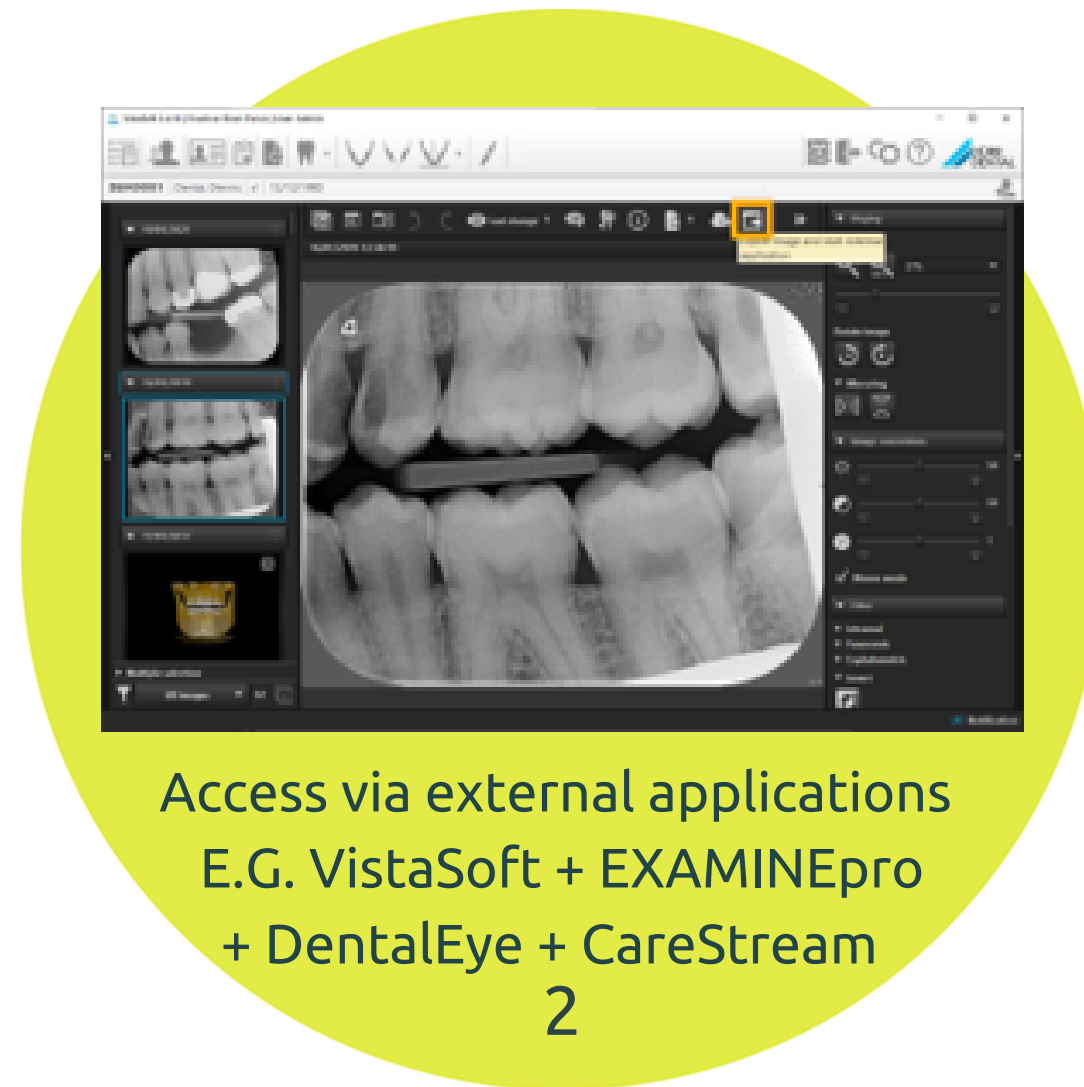


3 Ways To Open AssistDent®



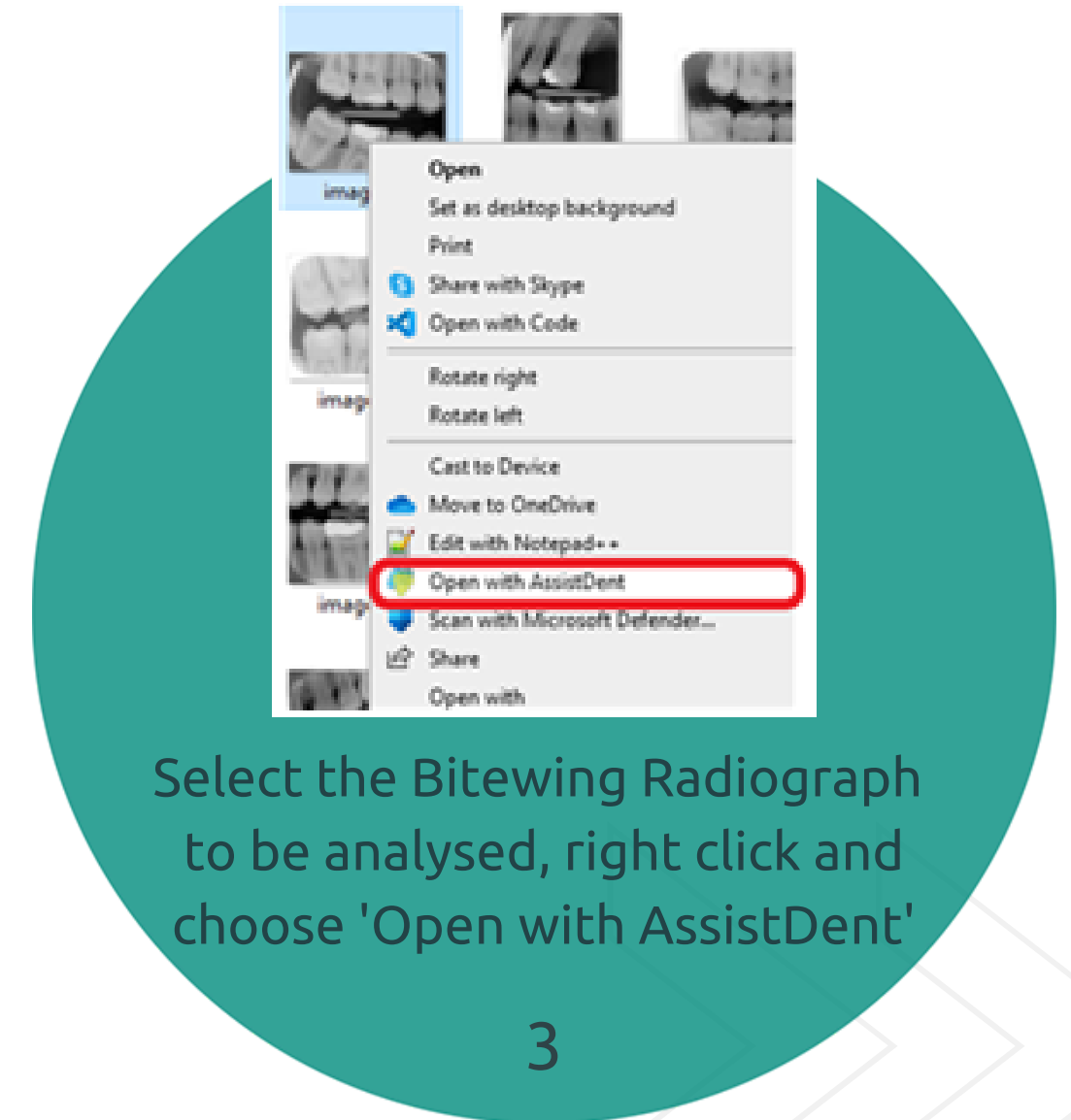
Double click on the AssistDent icon in the Start Menu or Desktop

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®



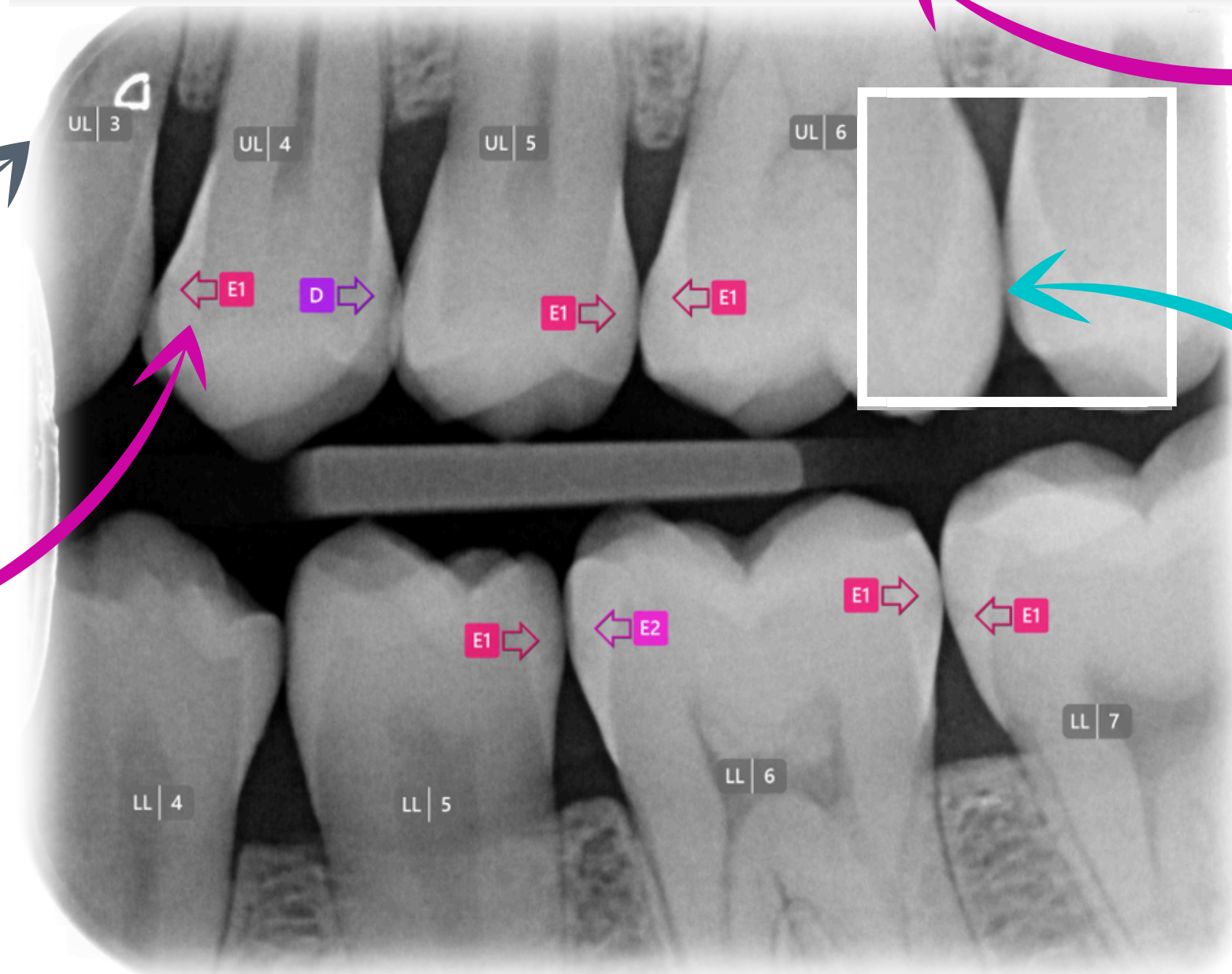
Clinical Analysis (a)



Open Image
Select a Bitewing Radiograph



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



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

Caries Indicators
Coloured Arrows:
ROI Region of Interest



Clinical Analysis (b)



To Edit Annotations

Click on a Caries Indicator **arrow**

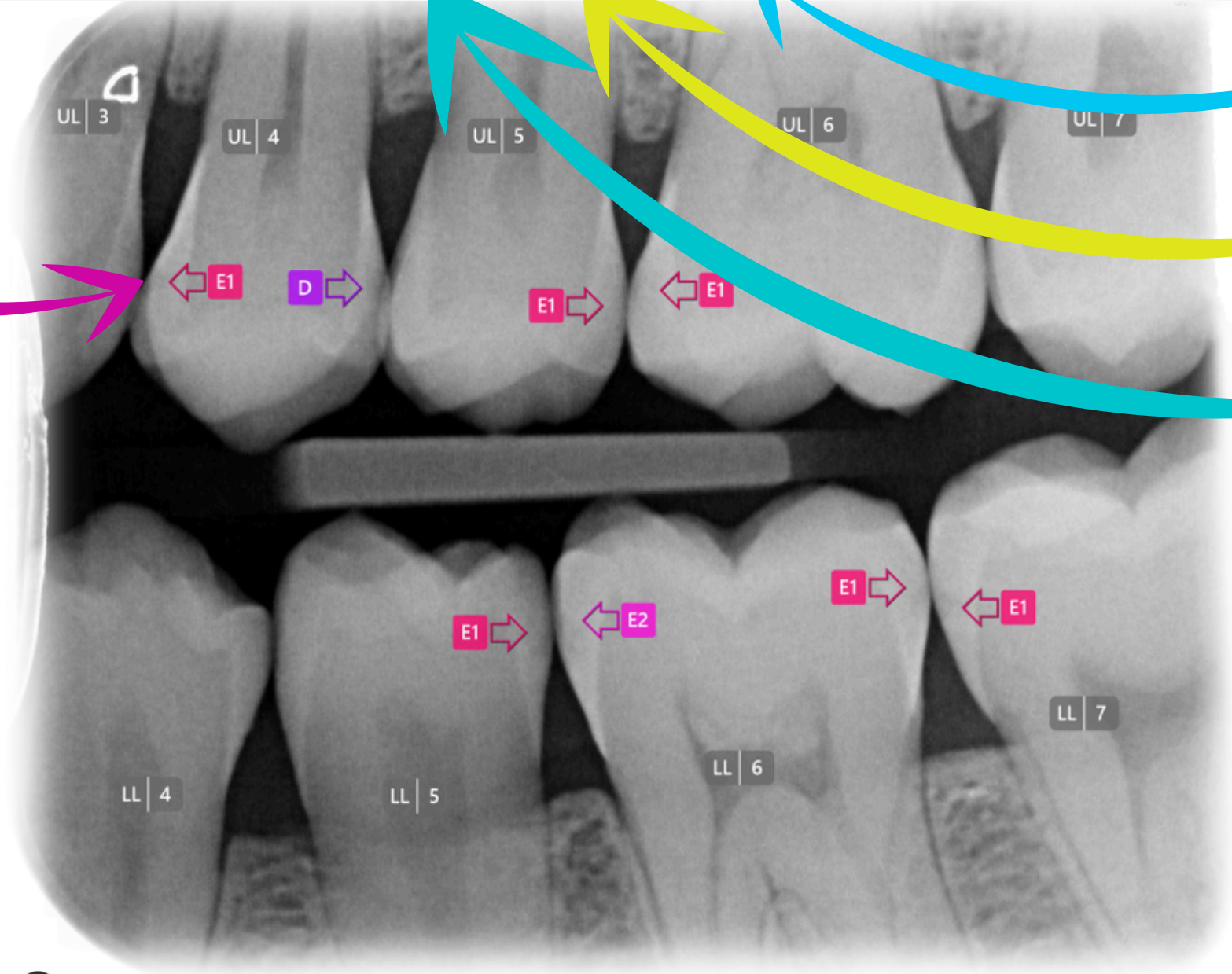
The **arrow** can then be dragged into a new position

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

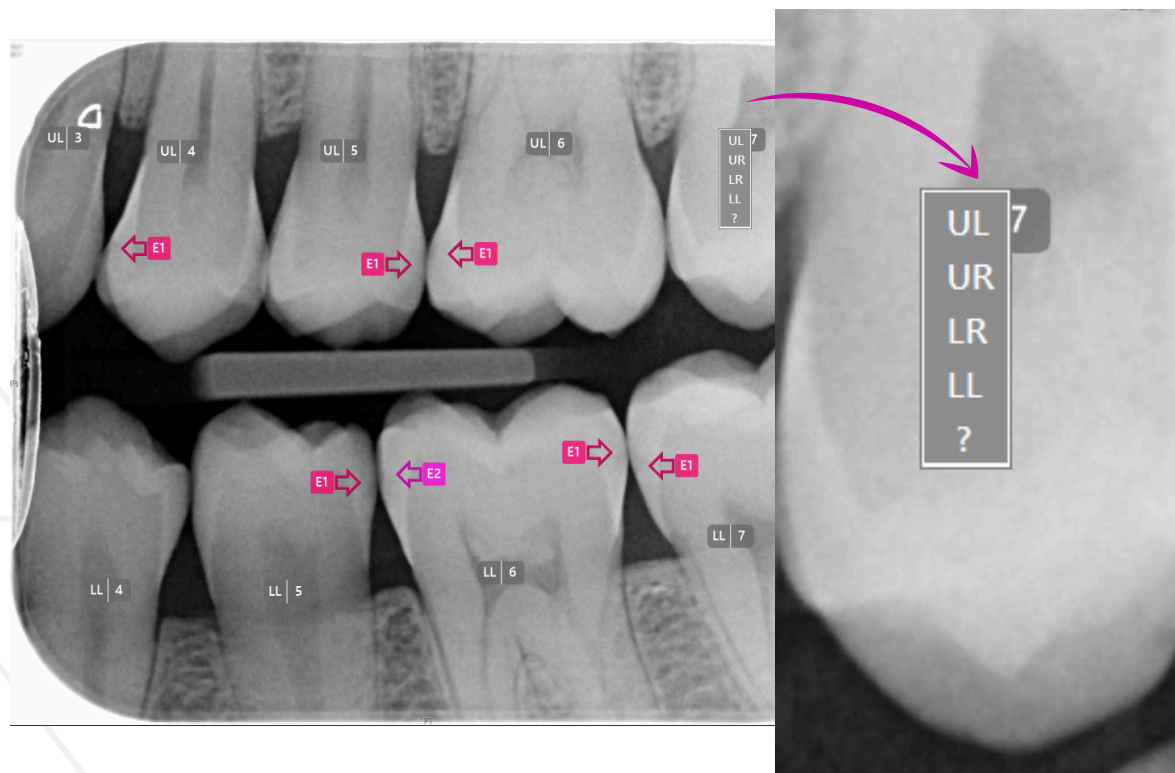


Clinical Analysis (c)

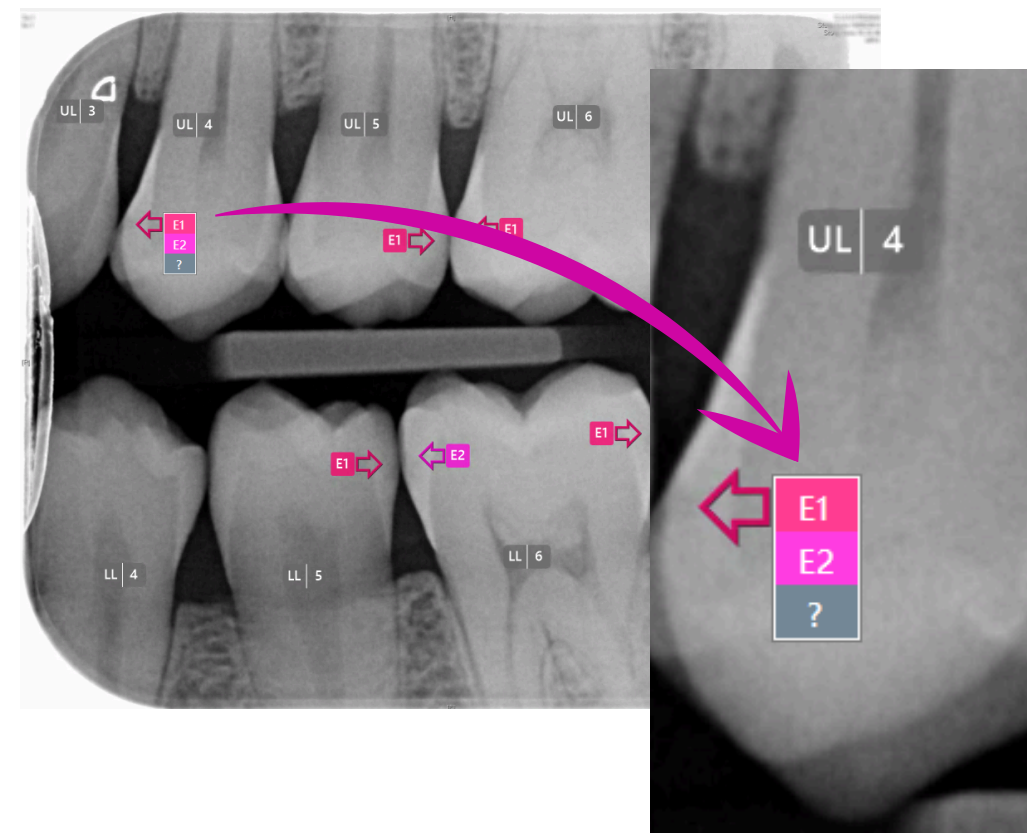
Edit Labels

Options for clinical override of the AI analysis
Select and click the preferred label

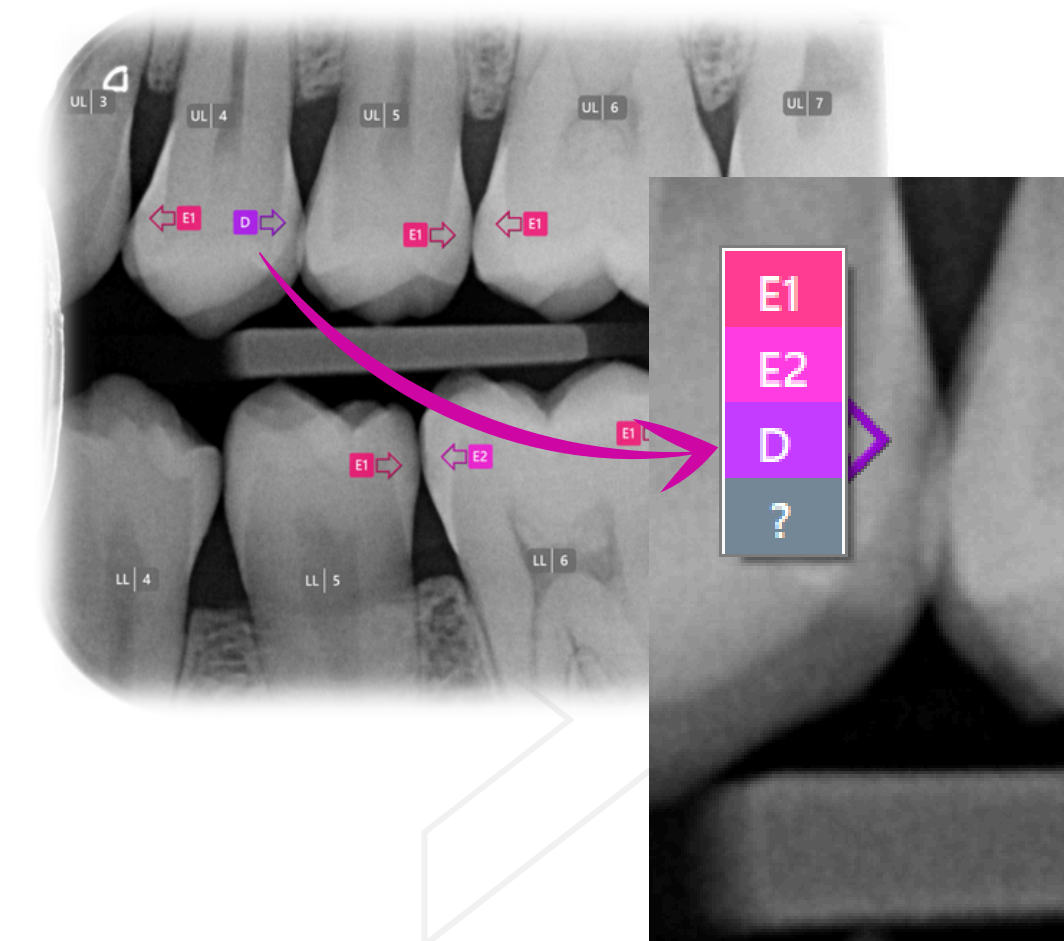
Tooth Labelling



Enamel Caries Grade



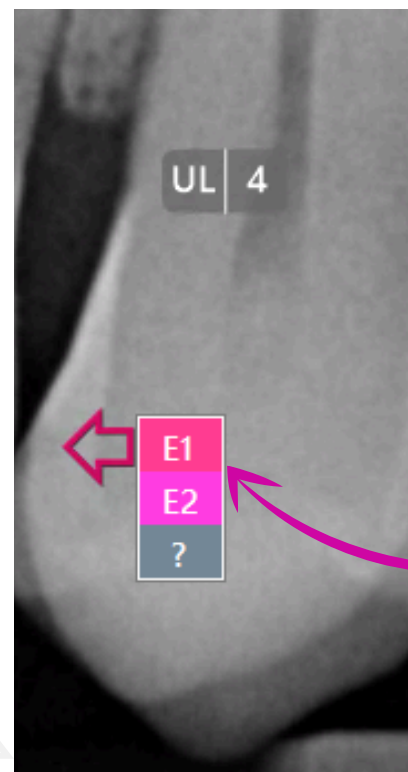
Dentine Caries Grade



Clinical Analysis (d)

International Caries Classification Standard

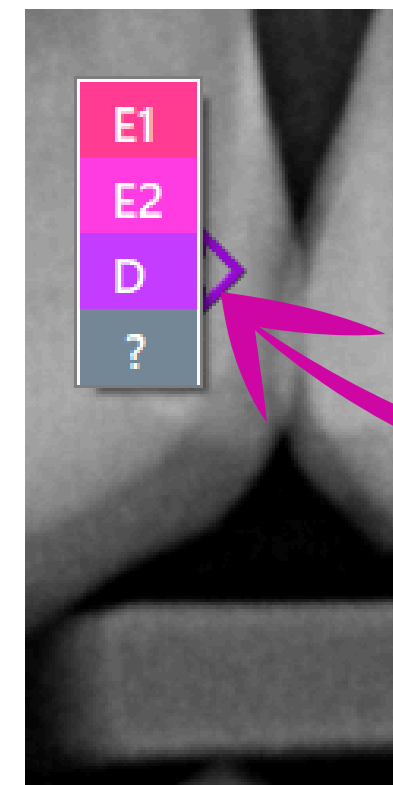
Enamel Caries Grade



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



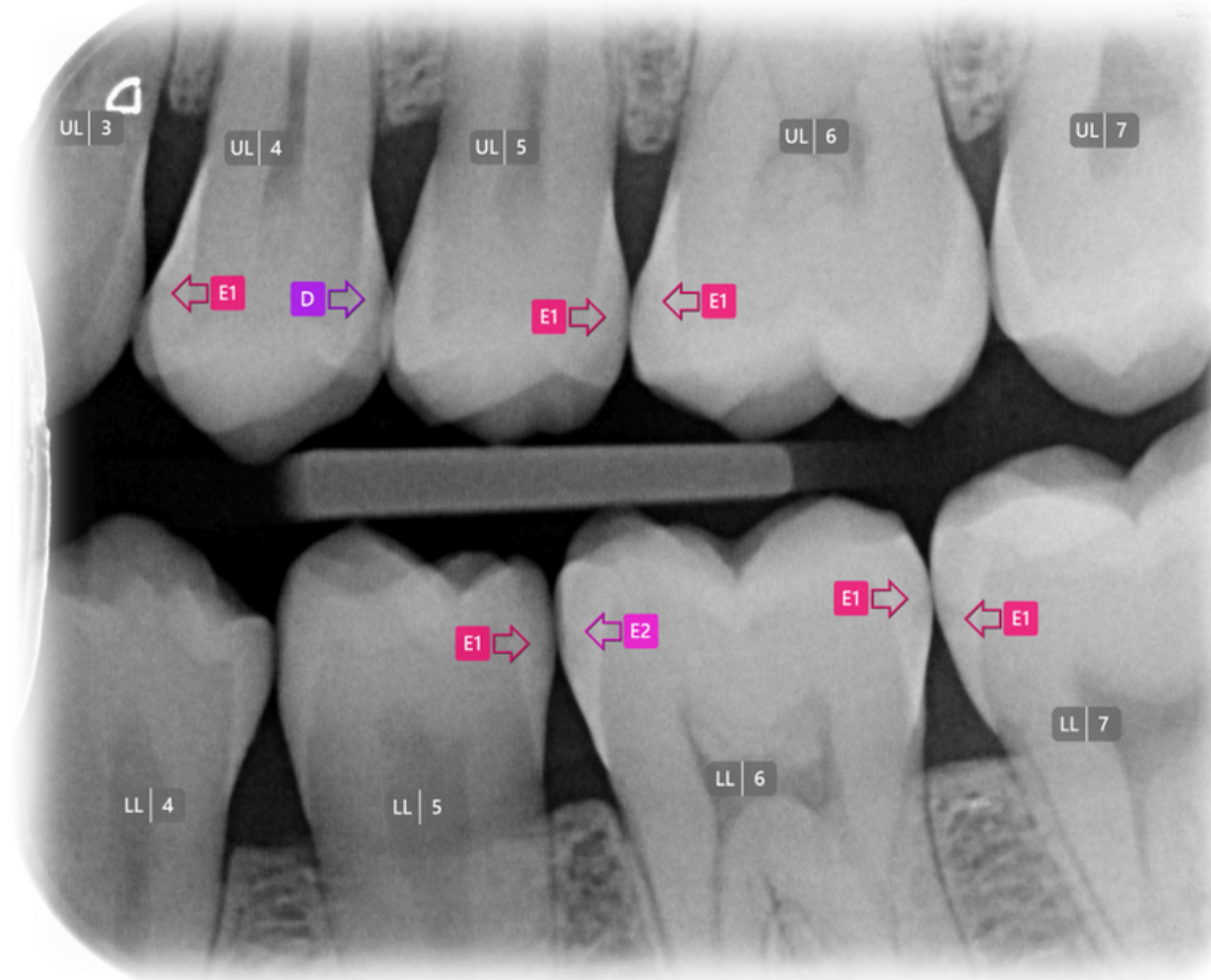
When dentine caries detection is enabled, identification of carious lesions which have penetrated the dentine are labelled 'D' by the AI.

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



Clinical Analysis (e)

Snapshot Short Reporting



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.



AssistDent®



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%)

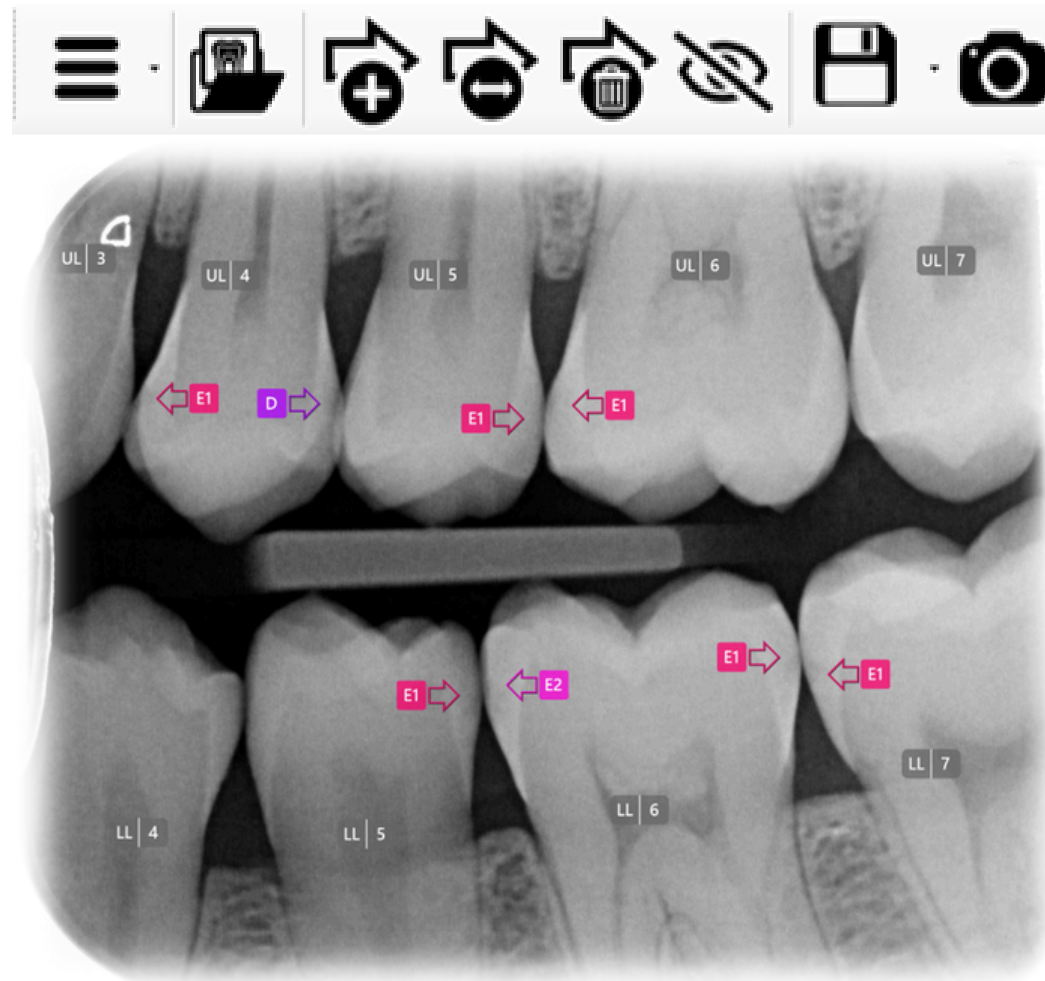
BlurStatus: True

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

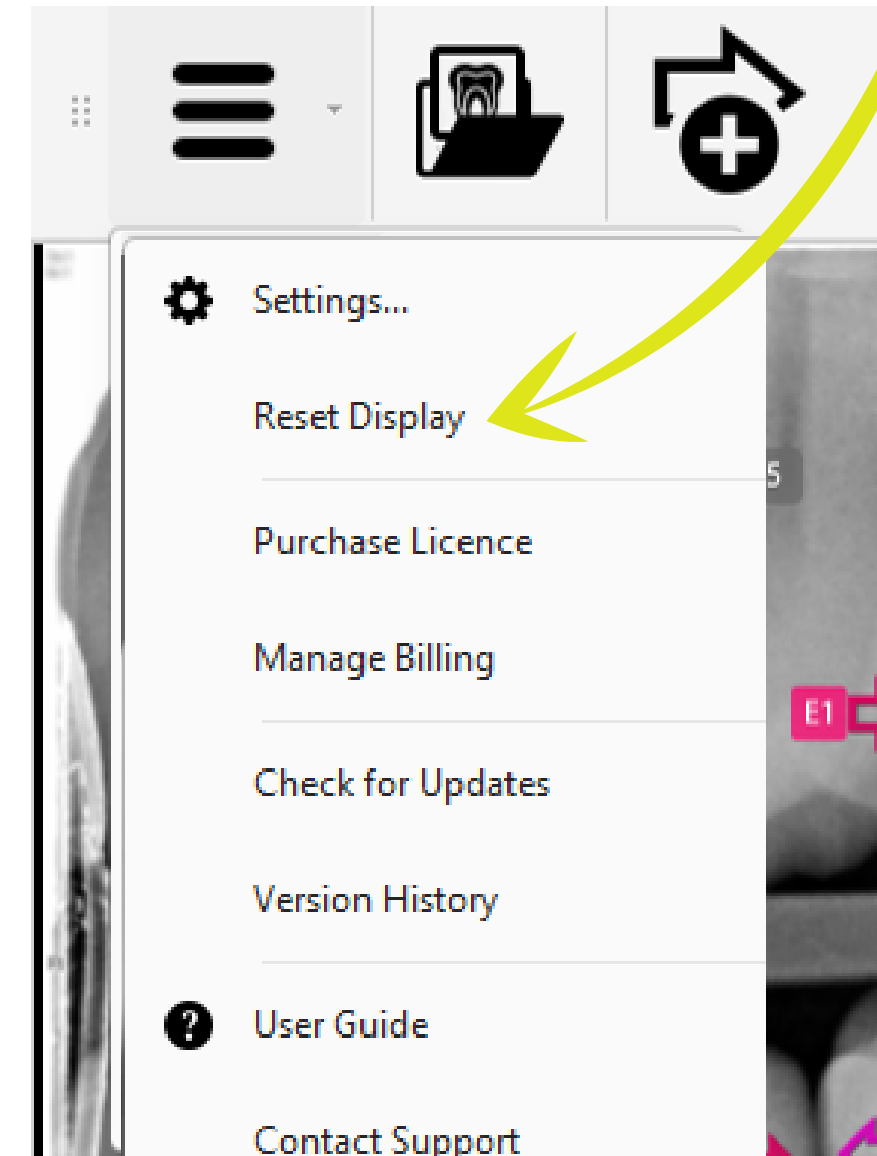
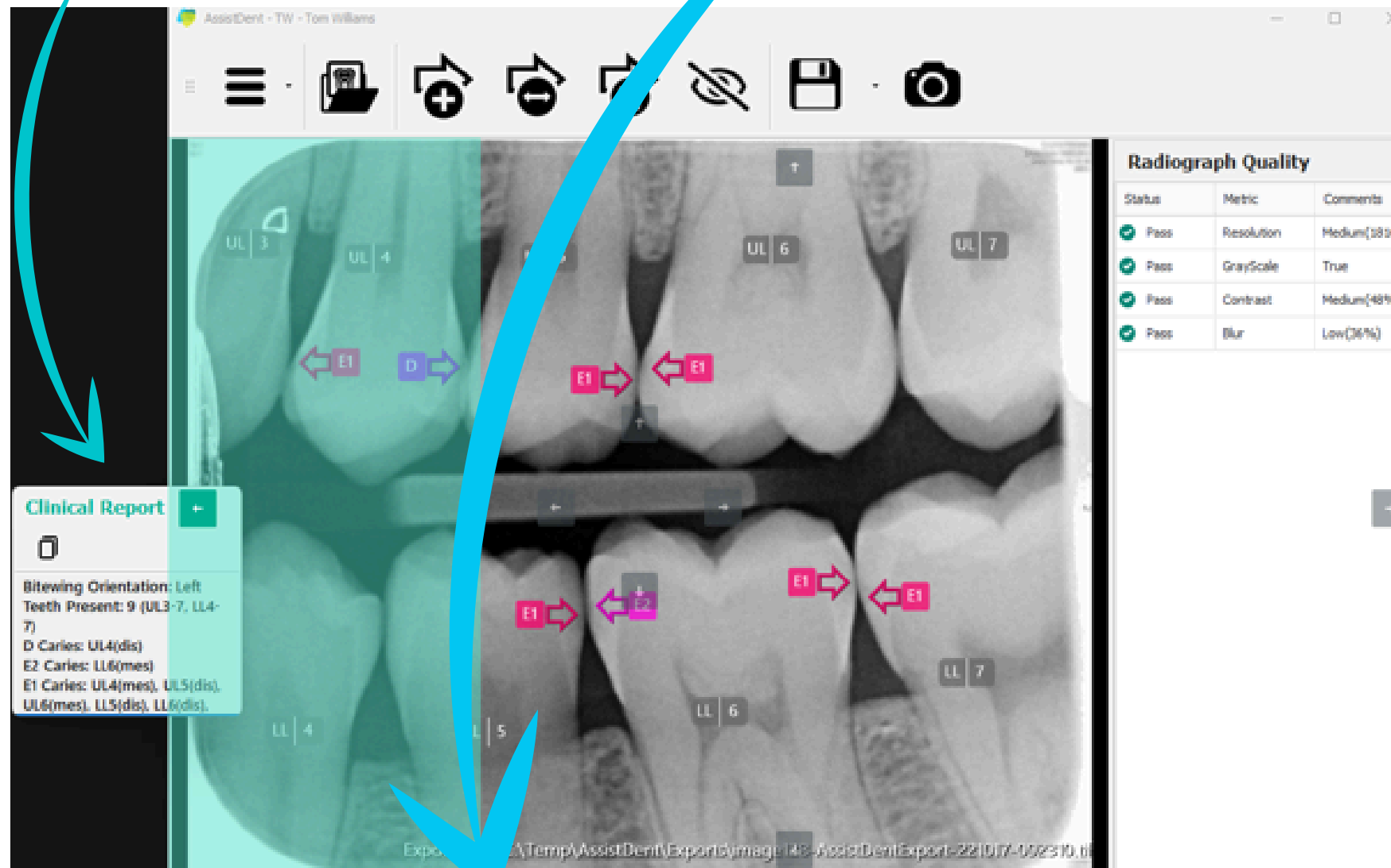
Drag a section to personalise a layout

Positioning Panels

Sections can be moved to the sides or below

Reset Display

Reorganise sections back to their original layout



AssistDent®



Menu Options



Overview

Settings

Advanced Export Criteria

Reset Display

Organise layout

Purchase Licence

Subscription Purchase
Licence Details

Manage Billing

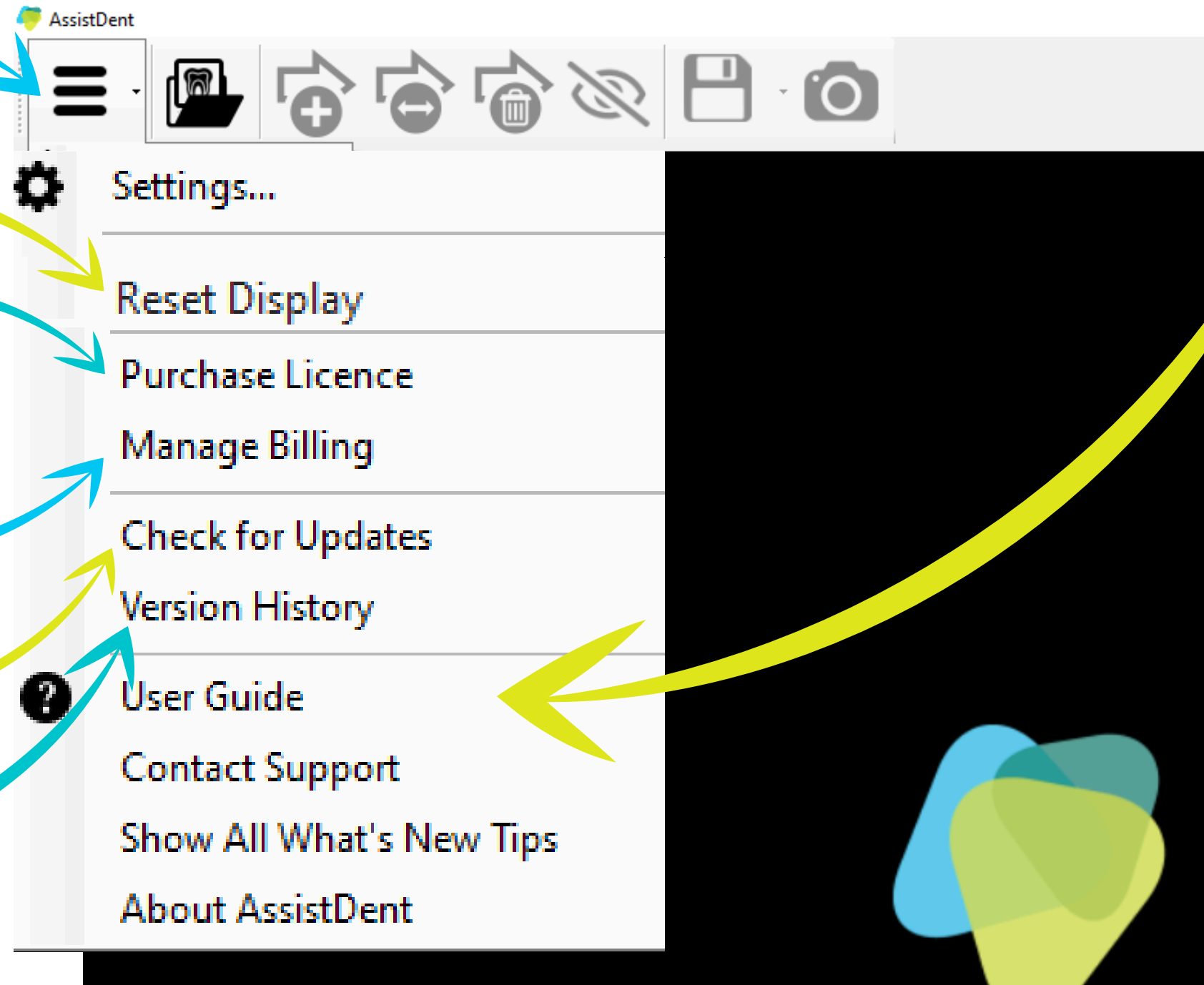
Update Payment Methods

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

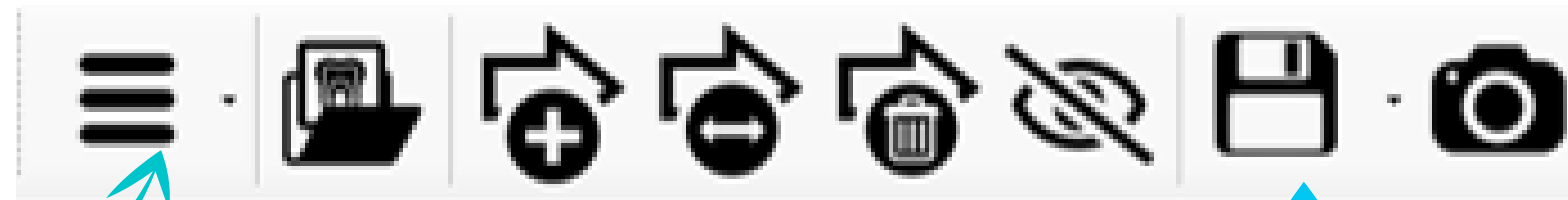
AssistDent 'in action' with
quick videos of key functions

About AssistDent®

Summary of User licence
Product details

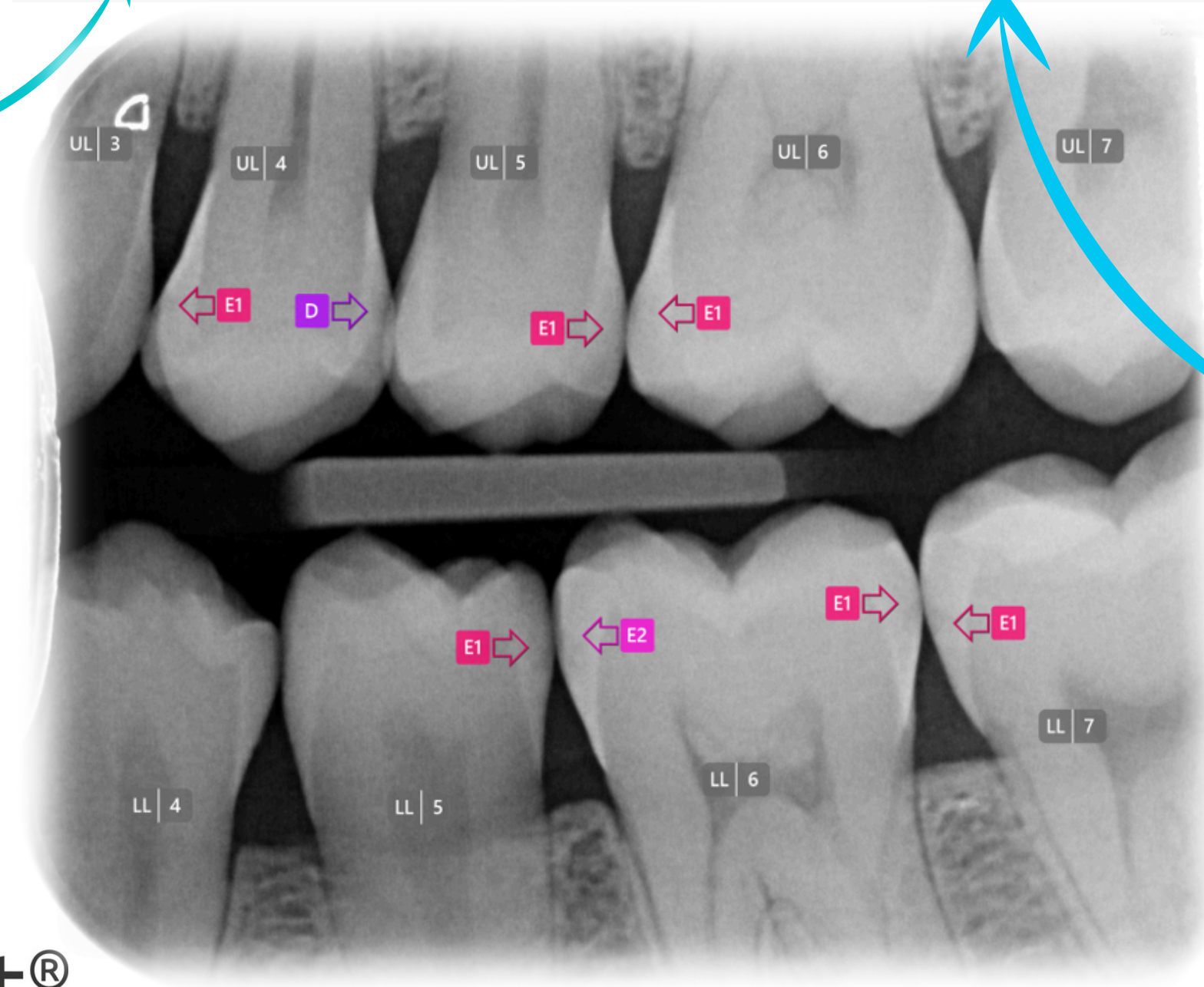


Methods of Export



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



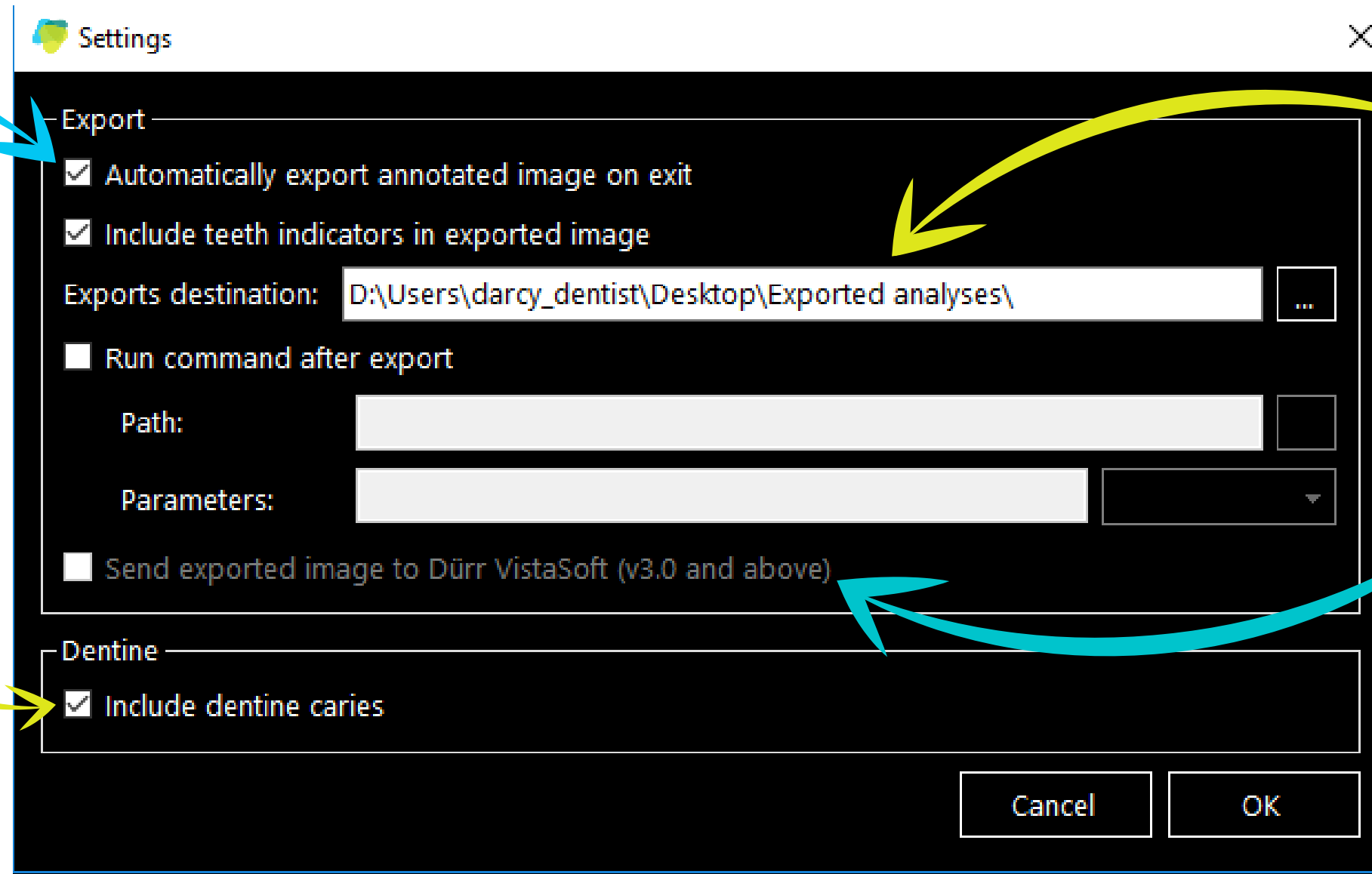
Advanced Export Settings

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: D:\Users\darcy_dentist\Desktop\Exported analyses\
- 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 Dürr Dental Imaging Software

AssistDent has additional capability to enable external integration





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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