

WeDiagnostiX

User Manual

Document reference: WDX_DT01_27

Document version: 01

Software version 0.1.29

24 August 2024



Warning	4
Description of the device	5
Indications	5
Contraindications	5
Users :	6
Patient characteristics	6
Performance claims	6
Qualitative and quantitative performance characteristics	6
System requirements	8
Software maintenance	9
Accessories and products to be used in combination	9
Objective and Usage Context	9
Symbols used	10
Label	11
Installation	11
Download: Windows installation	11
Download: installation on Mac intel or Mac M1, M2 and M3 (or higher).	12
Login	12
Account creation	12
Login	15
Log out	15
Forgotten password	16
Settings / Preferences	17
Application language	17
Input folder	18
User profiles	18
Adding a user	18
Deletion of a user	19
Modification	20
Mailing	21
Current profile change	21
User settings shortcut	21
Workspace	22
1: Choice of the Xray machine:	23
2: Choice of the patient management software	23
3: Choice of the type of report	24
4: Choice of the teeth numbering system	24
Saving settings	24
Upload of an X-ray	33
Viewing an X-ray	33
Zooms	33
Image enhancements	34
Moving	37
Rotation	38

Settings save	38
Analysis of an X-ray	39
Sending an X-ray for analysis	39
Sending failed	39
Examination motive	40
Patient consent	40
Results interpretation	41
Confidence thresholds	41
Display of observations	43
Invalidating an element	44
Focus on an element	45
Modifying an element	46
Teeth number	46
Diseases/observations	47
Add and delete missing teeth	48
Add observation	49
“Perio” periodontology tab	50
General	50
Dental chart	51
Managing bone level	
The bone level setting is opened by clicking on	52
Mandibular nerve display	53
Periodontal level display	53
Treatments display	53
Teeth display and numbering	53
Colour change of masks	54
Colour change of tooth contours or frames	56
Generating and exporting final report	57
Import cover page	58
Modification of the written report	60
Display option and import type	60
Saving display options	61
Export options	62
Send report by email	62
Export to Logosw	63
Contact us :	63





Warning

The WeDiagnostiX application can be used on its own as a viewer but requires a connection to the WeDiagnostiX API based on a cloud server.

The API analyses the X-ray images. The results are then returned to the WeDiagnostiX application to display the information provided.

The diagnostic tool runs on the server, and the results are displayed in the application.

All diagnostic decisions must be made by a trained dental health professional.

	<p>WeDiagnostiX (deployed on a cloud server) analyses the X-ray images. The results are then sent to the WeDiagnostiX application to retrieve and display the information provided by WeDiagnostiX.</p> <p>WeDiagnostiX can only process 2D dental panoramic radiographs. These radiographs can be acquired on a wide range of dental X-ray systems from different manufacturers. The system currently supports several common image formats: DICOM, TIFF, JPEG, PNG, BMP (maximum size 15 MB).</p>
	<p>The device is intended for use with radiographs taken on adult patients (i.e. people who have reached the age of majority in their country of residence) with permanent teeth, regardless of gender (male, female).</p>
	<p>In the event of serious injury resulting from the use of this software, it is imperative that you contact the manufacturer immediately and the competent authority in your country (for France contact ANSM).</p>
	<p>Please note that although our software uses artificial intelligence technologies to analyse 2D panoramic dental radiographs, it is possible for errors to occur in the results provided (<i>e.g. false positives, false negatives, pathology or treatment detected on the wrong tooth/error in tooth numbering</i>). Artificial intelligence is designed to help practitioners draw up radiology reports for their patients. However, it cannot replace the professional judgement and clinical expertise of specialist dental practitioners. All diagnostic decisions must be made by a qualified dental professional.</p> <p>It is imperative not to use AI results as the sole source of diagnosis. As a practitioner, you are responsible for verifying and validating the results provided by the software. Any diagnostic or therapeutic decision must be based on a complete and professional assessment of each case, taking into account the results of the software as a complementary tool and not as a definitive conclusion.</p>

Description of the device

The WeDiagnostiX application is a dental X-ray viewer for displaying panoramic dental X-rays in DICOM format or web image format (JPG/JPEG, PNG, BMP). It can be used for image processing to improve visual rendering. It enables communication with the API and pseudonymisation of the data sent.

WeDiagnostiX provides dental health professionals with assistance in writing radiology reports. WeDiagnostiX is computer-aided detection software that analyses patients' panoramic dental X-rays to detect and number their teeth, analyse pre-existing treatments and identify certain dental and extra-dental pathologies.


The viewer displays the data transmitted by the API (cloud server): the location and numbering of teeth, as well as the detection and characterisation of pathologies and other non-pathological structures. WeDiagnostiX combines clinical and epidemiological expertise in dentistry with machine learning and software engineering. WeDiagnostiX is designed to be used by dentists, radiologists and stomatologists in a professional dental environment for patients with permanent teeth.

Indications

The viewer is designed to be used on 2(D) dimensional radiographic images and allows:

- assessment of dental condition
- assessment of caries status
- search for apical lesions of endodontic origin
- look for radiolucent formations suggestive of cysts
- search for sinus pathologies
- search for joint anomalies
- periodontal bone loss status
- inferior alveolar nerve tracing

Contraindications

	<p>The viewer must not be used or cannot provide relevant results in the following cases :</p> <ul style="list-style-type: none">● Images are clinically unusable (e.g. out-of-focus or cropped due to incorrect use of radiographic equipment)● Images correspond to edentulous patients● Dental radiographs are not panoramic images (e.g. cephalometric images)● Radiographs are not dental radiographs● Radiographs show mixed dentition or lactate dentition● Algorithm fails to detect radio-opaque endo-bone lesions
---	--

Users :

WeDiagnostiX must be used by professionals trained in the interpretation of dental radiographs: dentists, stomatologists and radiologists in a professional environment.

These practitioners must have received training in dental radiography diagnosis during their studies. Diagnosing dental images is a daily task for all practising practitioners.

We recommend that you read the user manual before using the system. In the event of problems with colour perception, such as colour blindness, it is possible to adapt the colours in the settings.

Patient characteristics

The device is intended for use by practitioners treating adult patients (i.e. people who have reached the age of majority in their country of residence) with permanent teeth, regardless of gender (male, female).

Performance claims

To evaluate the performance of the WeDiagnostiX API, two dental practitioners were asked to manually annotate the test dataset to create Ground Truths (abbreviated as GT), which were then compared to the labels obtained by our neural network.

Using a test dataset consisting of 2D panoramic X-rays of patients with permanent teeth, we observed the results of the device for:

- tooth detection and numbering (456 panoramic radiographs for the test data set)
- detection of dental and extra-dental pathologies and treatments (372 panoramic radiographs for all the test data).

To this end, we measured various parameters such as: True Positive (TP), False Negative (FN), False Positive (FP), Recall and Accuracy.

The sensitivity of the model (99.44%) is high and shows that artificial intelligence (AI) can be useful for tooth identification and numbering.

The device also showed promising results in the detection of pathologies and treatments, with an overall sensitivity of 86.00% and 92.13%, achieving a performance close to that of a dental practitioner, confirming its clinical relevance. Furthermore, the pathologies and treatments detected are listed almost instantaneously by the software, saving the practitioner time when writing up the patient's radiology report.

Qualitative and quantitative performance characteristics

The viewer is compatible with various operating systems: MacOSX, Windows 10/11.

The viewer can read DICOM, .pano (Carestream Dental® proprietary file), jpeg/jpg, png, bmp, tif/tiff files encoded on 8 and 12 bits.

Transfer Syntax UID	Transfer Syntax Name	Supported
1.2.840.10008.1.2	Implicit VR Endian: Default Transfer Syntax for DICOM	✓
1.2.840.10008.1.2.1	Explicit VR Little Endian	✓

1.2.840.10008.1.2.1.99	Deflated Explicit VR Little Endian	✗
1.2.840.10008.1.2.2	Explicit VR Big Endian	✓
1.2.840.10008.1.2.4.50	JPEG Baseline (Process 1): Default Transfer Syntax for Lossy JPEG 8-bit Image Compression	✗
1.2.840.10008.1.2.4.51	JPEG Baseline (Processes 2 & 4): Default Transfer Syntax for Lossy JPEG 12-bit Image Compression (Process 4 only)	✗
1.2.840.10008.1.2.4.57	JPEG Lossless, Nonhierarchical (Processes 14)	Not documented
1.2.840.10008.1.2.4.70	JPEG Lossless, Nonhierarchical, First- Order Prediction (Processes 14 [Selection Value 1]): Default Transfer Syntax for Lossless JPEG Image Compression	✓
1.2.840.10008.1.2.4.80	JPEG-LS Lossless Image Compression	✗
1.2.840.10008.1.2.4.81	JPEG-LS Lossy (Near- Lossless) Image Compression	✗
1.2.840.10008.1.2.4.90	JPEG 2000 Image Compression (Lossless Only)	✗
1.2.840.10008.1.2.4.91	JPEG 2000 Image Compression	✗
1.2.840.10008.1.2.4.92	JPEG 2000 Part 2 Multicomponent Image Compression (Lossless Only)	Not documented
1.2.840.10008.1.2.4.93	JPEG 2000 Part 2 Multicomponent Image Compression	Not documented
1.2.840.10008.1.2.4.94	JPIP Referenced	Not documented
1.2.840.10008.1.2.4.95	JPIP Referenced Deflate	Not documented
1.2.840.10008.1.2.5	RLE Lossless	✗

1.2.840.10008.1.2.6.1	RFC 2557 MIME Encapsulation	Not documented
-----------------------	-----------------------------	----------------

It is recommended to use DICOM images by saving unprocessed images (native images / RAW).

It is recommended to use images with a minimum height of 1000 pixels or a minimum width of 2000 pixels.

It can be used in conjunction with some dental practice management software and some X-ray machine software.

It requires an Internet connection to connect to the WeDiagnostiX API. The quality of the Internet connection does not affect the quality of the diagnosis, but it does have an impact on transfer times from the user to the server and vice versa.

Once it has been sent to the server, the AI system (the WeDiagnostiX API) analyses the X-ray to search for pathologies and dental structures. The system does not take into account any image processing by the user that might have an impact on performance characteristics (for example, image rotation).

Once the analysis has been completed and retrieved in the viewer (application), the results are displayed visually in the form of a graphical overlay with the radiograph. Graphical overlays can be modified in their opacity via the application's settings window. The results are also displayed on the image and in a summary table.

Useful user functions include adding, deleting, correcting and modifying detections.

All changes made by the user are transmitted to the server and stored with the original evaluation. Once the user has completed and saved the assessment, a radiology report can be generated. The image data, initial software assessment and user modifications are stored on the WeDiagnostiX cloud server.

System requirements

The hardware and software requirements for using the WeDiagnostiX application are as follows:

Hardware and software requirements:	
Operating System	Windows 10 or higher, Mac intel (X86) with MacOS 10.15 or higher, Mac M1 with Mac OS 12.3.
RAM:	At least 8 GB
CPU:	Intel I5 or I7 sixth generation or equivalent

Required characteristics of image files (panoramic radiographs):

- The maximum file size is 15 MB
- The minimum colour depth is 8 bits.
- Laterality (left/right side) must be recognisable on the image.

- The orientation must be classic: top of the patient at the top of the image
- The file must be in one of the following formats: JPG/JPEG, TIF/TIFF, PNG, BMP, DICOM, .PANO (Carestream Dental® proprietary file)

Display:

WeDiagnostiX is designed for use on a desktop or laptop computer:

- Screen size: minimum resolution 1920*1080 px (Full HD).
- Colour depth: 24 bits.

Software maintenance

WeDiagnostiX is maintained by automatically downloaded updates. Software updates are necessary to correct errors and integrate new features. However, users are advised to check for updates on the wediagnostix.com website.










Accessories and products to be used in combination

There are no accessories required for the WeDiagnostiX viewer, but a good quality screen is recommended for better reading of X-rays.

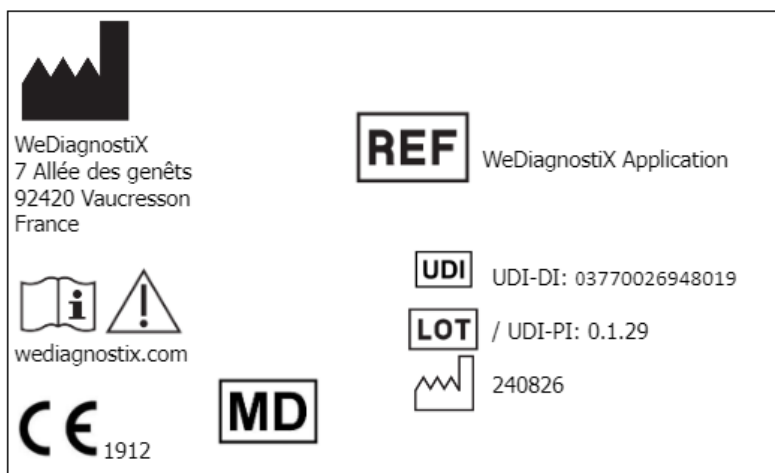
Objective and Usage Context

The system is designed for use in clinical and dental offices, including the treatment room and the practitioner's office. Typically, the environment is calm, and the dentist focuses on a single patient at a time. The user needs access to the Internet and a hardware product (PC) for the software functionality. The user should also use an appropriate display suitable for evaluating radiological images. The application is not time-critical, as in many cases, a detailed diagnostic report is generated during office hours and not during the consultation time (during patient interaction). However, WeDiagnostiX can also be used during chairside working time.

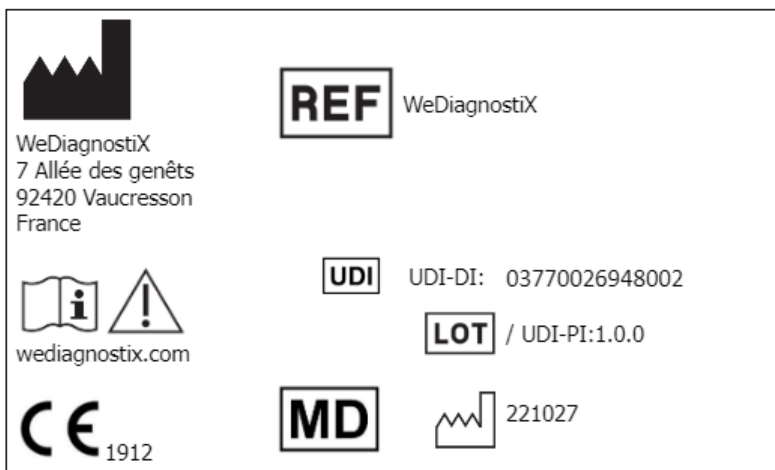
Symbols used

	Warning
	Manufacturer
	Date of manufacture
	Product reference
	Indicates that the software is a medical device
	Indicates software version
	Refers to the user manual (this document)
	CE mark (European Community)
	Unique Device Identifier

Label



WeDiagnostiX Application label (above)



WeDiagnostiX label (above)

Installation

Download: Windows installation

Download the executable file:

- Go to wediagnostix.ai and click on the "Windows" button to obtain the installation file for the Windows version.

Run the installation:

- Once the file has been downloaded (usually named `WeDiagnostiX-win.exe`), double-click on it to launch the installation.

Automatic installation:

- Installation runs automatically with no intervention required. Wait for the process to finish.

Download: installation on Mac intel or Mac M1, M2 and M3 (or higher).

Download the executable :

- Go to wediagnostix.com and click on the button corresponding to your Mac's processor type and download the "Mac Intel" or "Mac M1, M2 or M3" version to obtain the installation file corresponding to the Windows version.

Although the Intel version may work on Mac M1, 2 or 3, we recommend that you use the version optimised for your processor.

Start the installation:

- Once you have downloaded the file (usually named WeDiagnostiX-mac.dmg), double-click the file. A window will open: drag and drop the application onto the application folder.



Login

Account creation

Open the connection window by clicking on the "Connection" button



Click on "Create an account"

Connection

Email

Password

[Password forgotten](#)

[Create an account](#) [Connection](#)

Fill all fields and click on submit. When France is selected in the countries list, a new field “RPPS” appears. It is used to pre-fill some fields thanks to the publicly accessible data of the “Annuaire Santé”.

Create an account

Language

 EN-GB

Country

 France

RPPS (*facultatif*)

Import

Email *

Firstname *

Name *

Password *



Confirm password *



* Required

I accept [general conditions of use](#)

[I already have an account](#)

Next

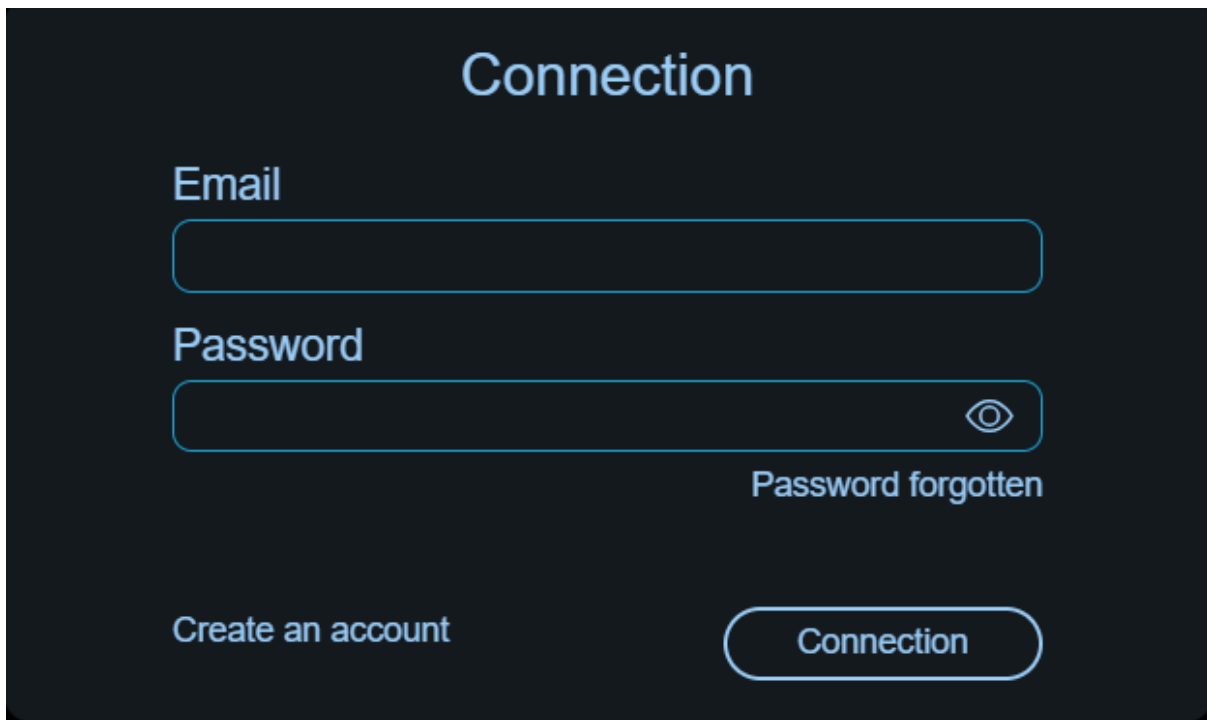
Activate the account by clicking on the link received by email to be able to log in later. Check the spam folder.

Login

Open the connection window by clicking on the "Connection" button



Enter your login and password, then click on the "Connection" button.

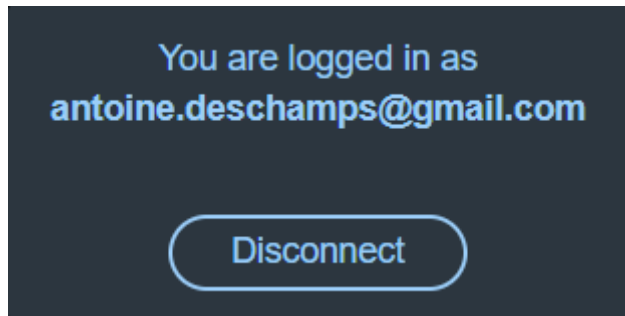
A dark-themed login form titled 'Connection'. It features two input fields: 'Email' and 'Password'. The 'Password' field has a toggle eye icon on the right. Below the 'Password' field is a link that says 'Password forgotten'. At the bottom left is a link 'Create an account', and at the bottom right is a white rounded button labeled 'Connection'.

Log out

Open the connection window by clicking on the "Connected" button



When the login window opens, click on the "Disconnect" button.



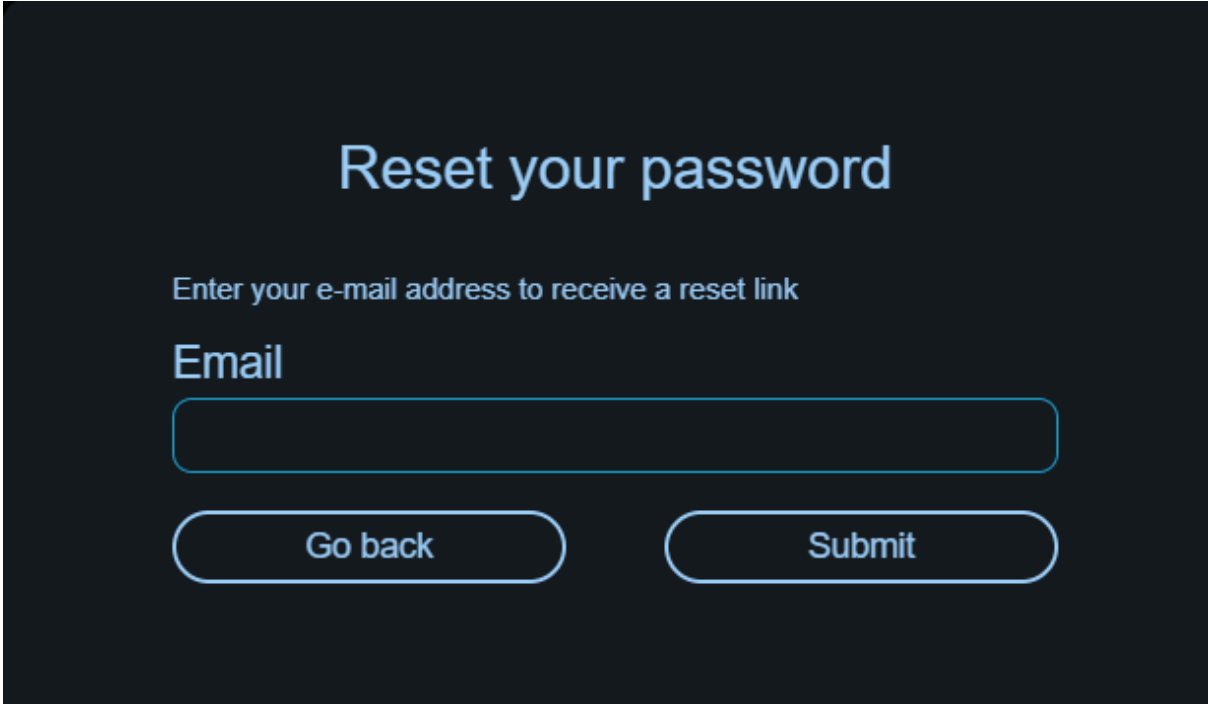
Forgotten password

Open the connection window by clicking on the "Connection" button



Click on "Forgotten password"

Fill in the email and click on "Submit".



A password reset link has been sent to the specified address. Check the spam folder.

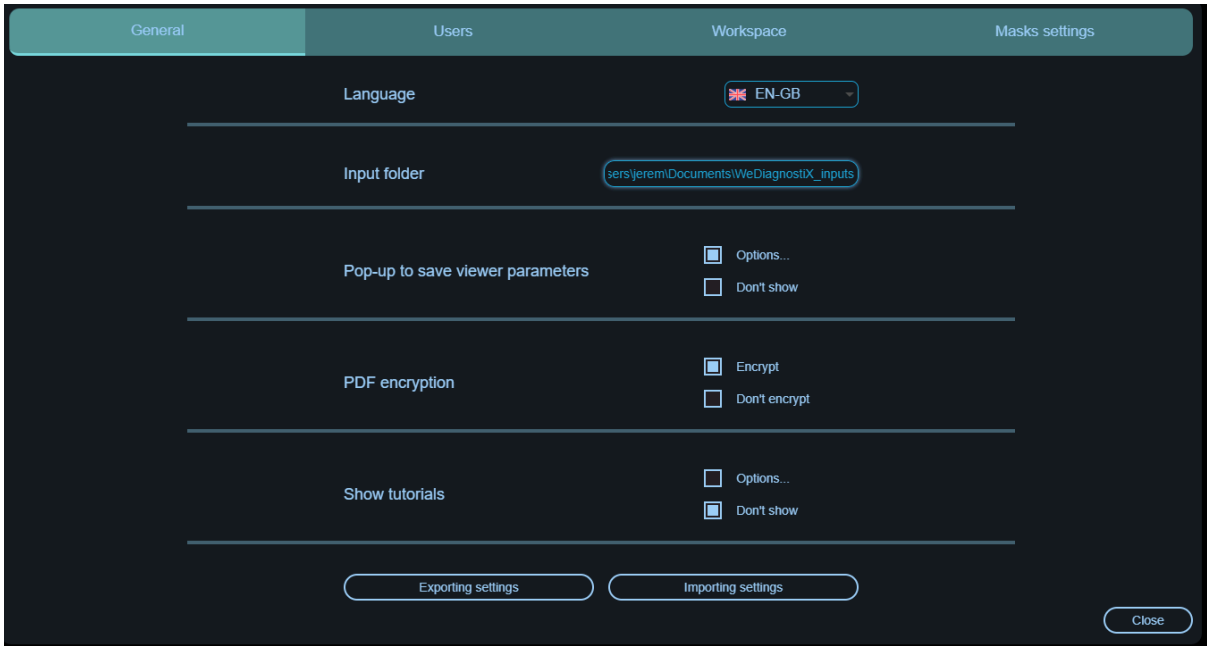
Settings / Preferences

Application language

Open settings



In the "General" tab, select the desired language from the drop-down menu.



Input folder

You can define a folder in which the images you drop are automatically read by the application. This can be interesting to automate the process of exporting Dicom files between your X-ray software and WeDiagnostiX application

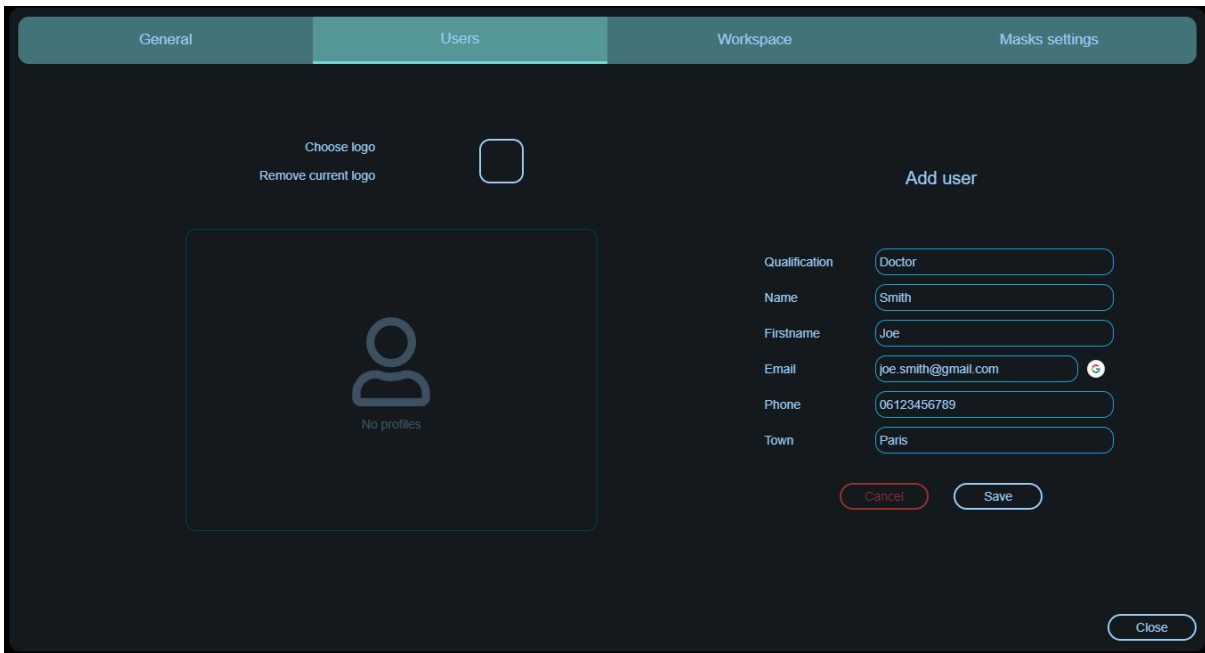
User profiles

Open settings

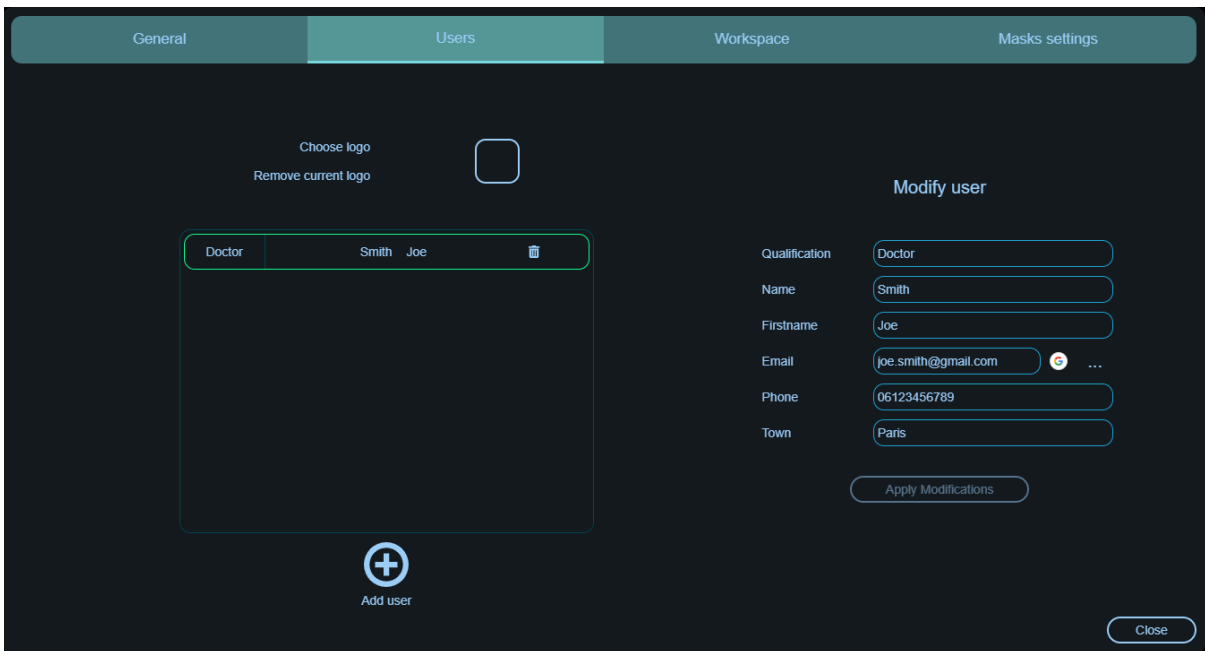


Adding a user

If no profile has been previously created, fill in the form on the right and click on save.

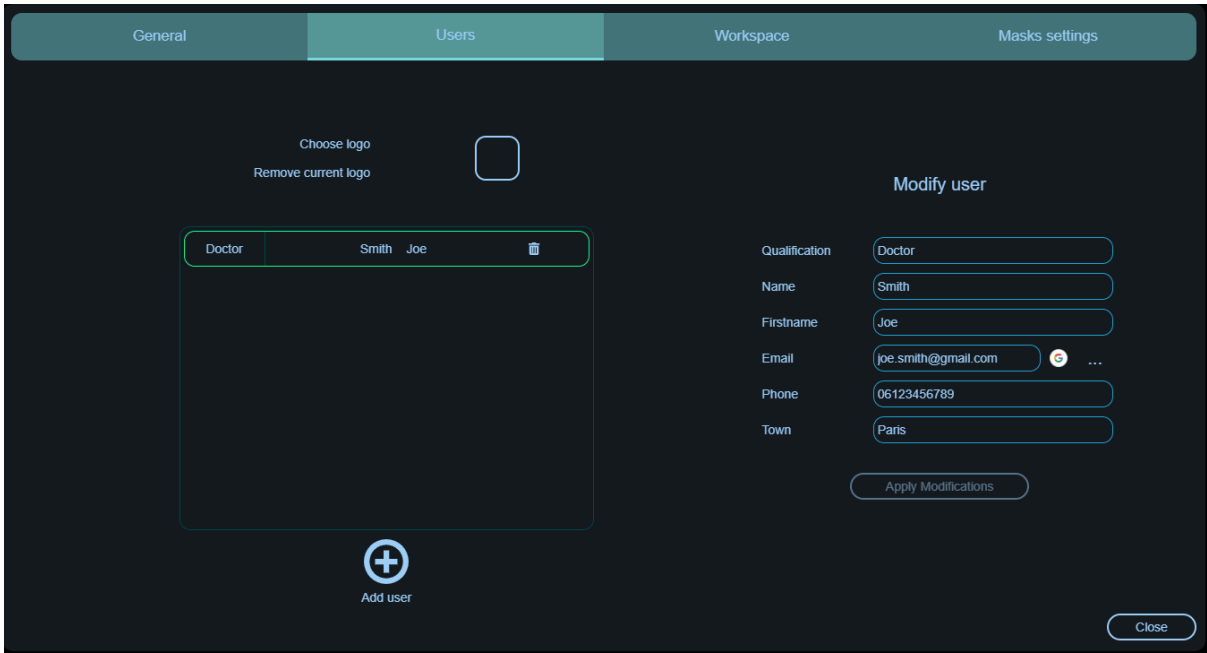


If a profile (or profiles) already exists, click on the "Add user" button and fill in the form that appears (on the right)



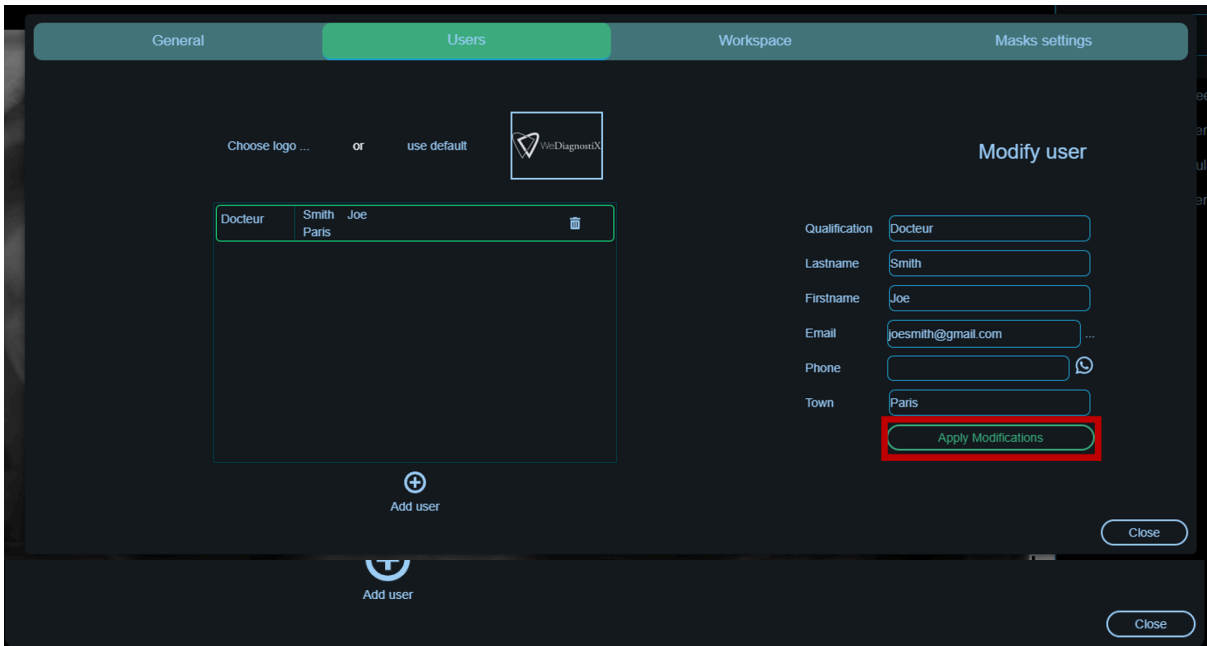
Deletion of a user

Click on the "Trash" icon next to a user's name



Modification

Select a profile from the list, fill in the form on the right and click on Apply Modifications.



Mailing

The screenshot shows the 'Users' tab with a 'Modify user' form. The form has the following fields: Qualification (Doctor), Name (Smith), Firstname (Joe), Email (joe.smith@gmail.com), Phone (06123456789), and Town (London). There is an 'Apply Modifications' button. To the right, there is a 'Mailing configuration' section with fields for Email Password, SMTP, and Port. A dropdown menu for email addresses is visible, showing 'Doctor | Smith | Joe' and 'Add user' button.

The "..." button next to the email field gives you advanced modifications of your email address, which will allow you to send a report by email (see the section **Send a report by email**):

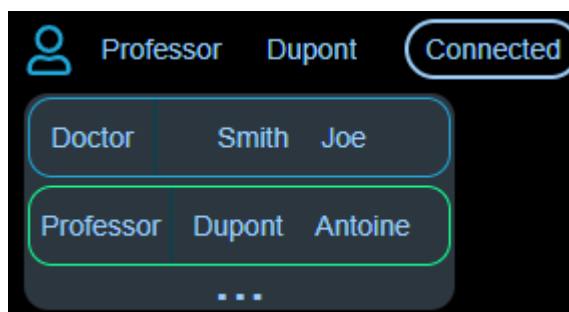
If you use a Gmail address, you cannot use your regular password. Refer to the guide to generate an application password by clicking on **Get an App Password for Gmail**.

- If your address does not have the following host (AOL, AT&T, Comcast, iCloud, Gmail, Outlook, Wanadoo, Orange, Laposte, Free), you will have to fill in the SMTP address and the Port of your mailbox manually. For the rest, they are filled automatically and unchangeable.
- If you use a Yahoo address, you cannot send emails via our application, for reasons specific to the Yahoo servers.

If your address is not Gmail, you can put your mailbox password in the Password (Email) field.

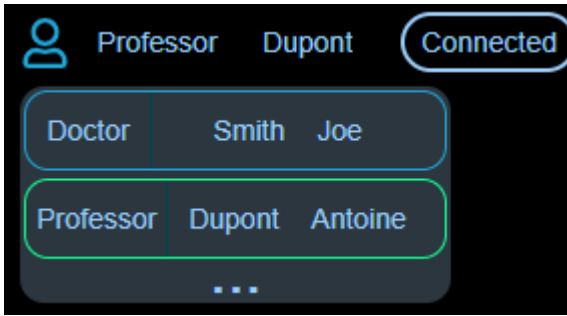
Current profile change

Click on the users icon in the application, and choose the desired profile from the drop-down menu.



User settings shortcut

By clicking on the "..." the user setting panel will open

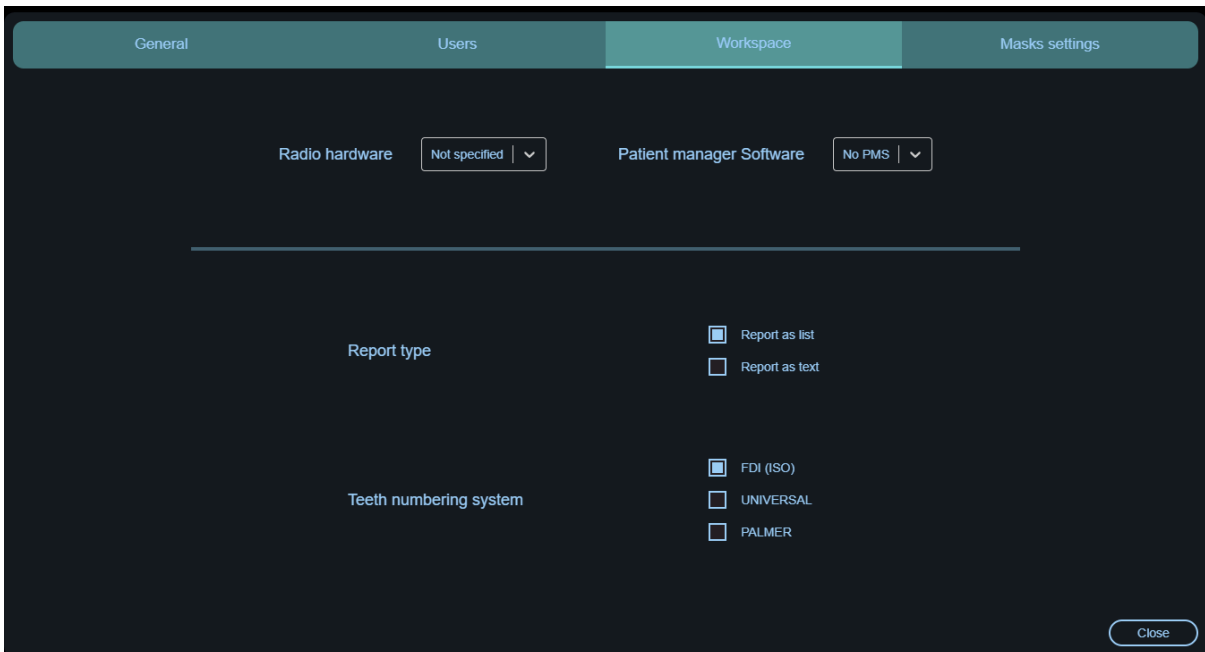


Workspace

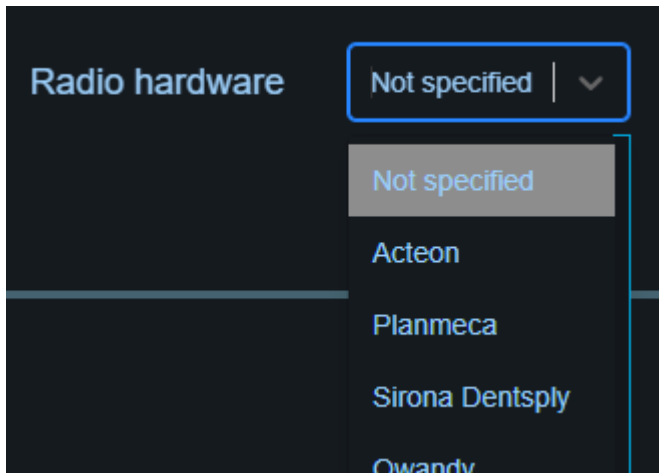
Open settings



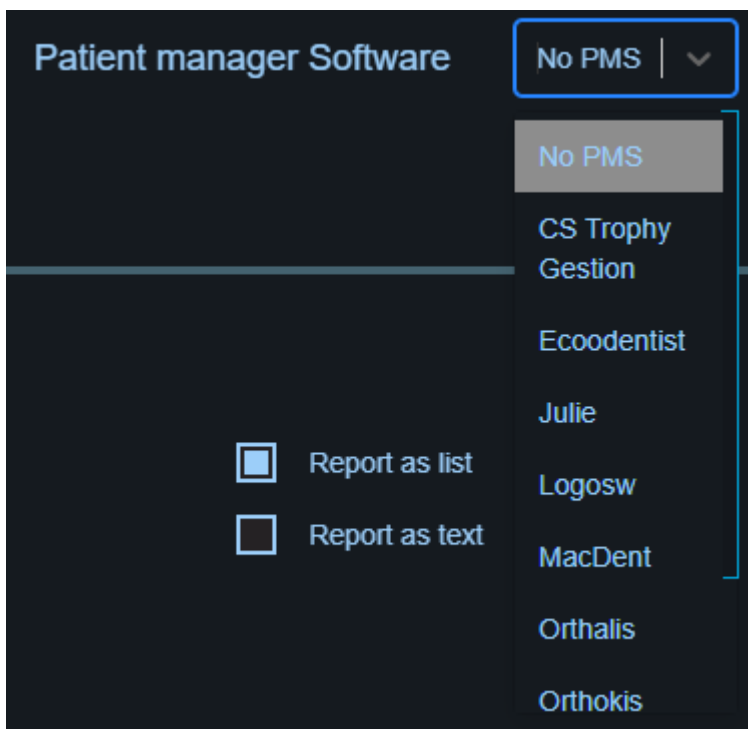
Open "Workspace" tab



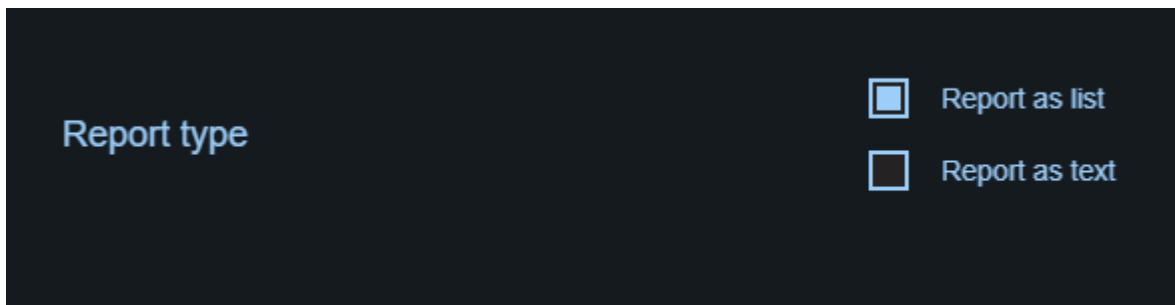
1: Choice of the Xray machine:



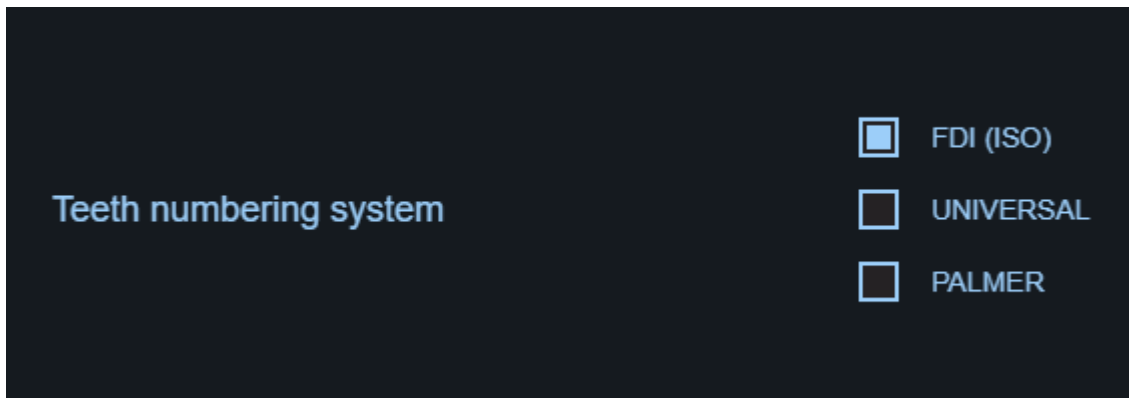
2: Choice of the patient management software



3: Choice of the type of report

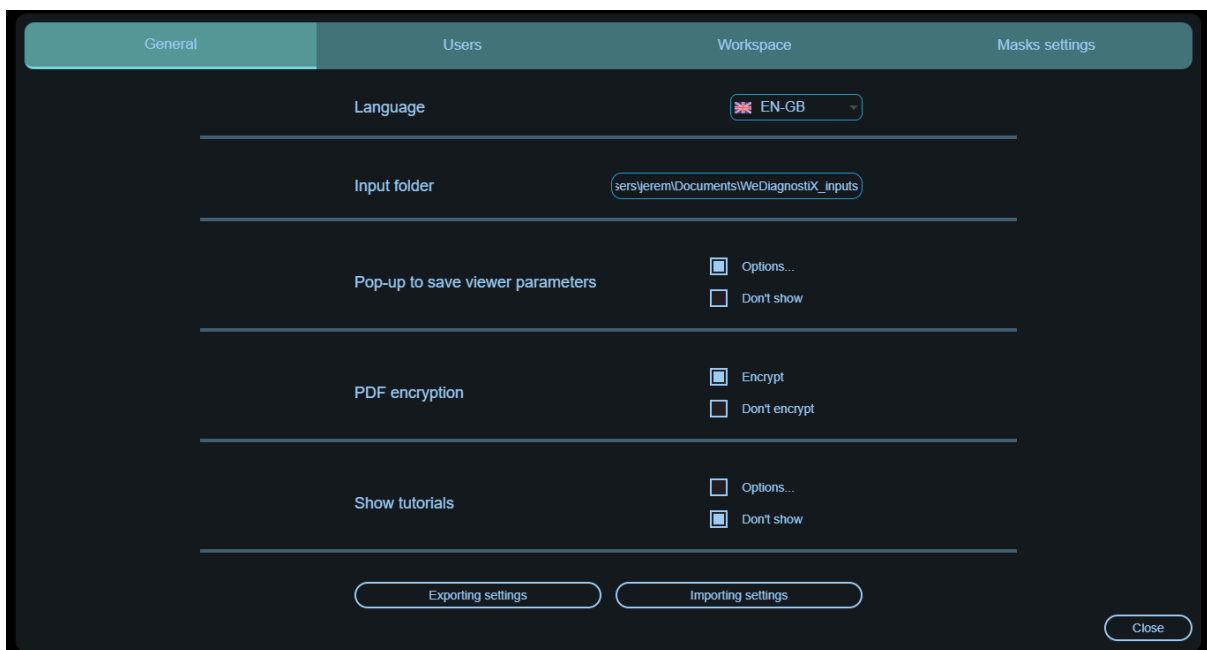


4: Choice of the teeth numbering system

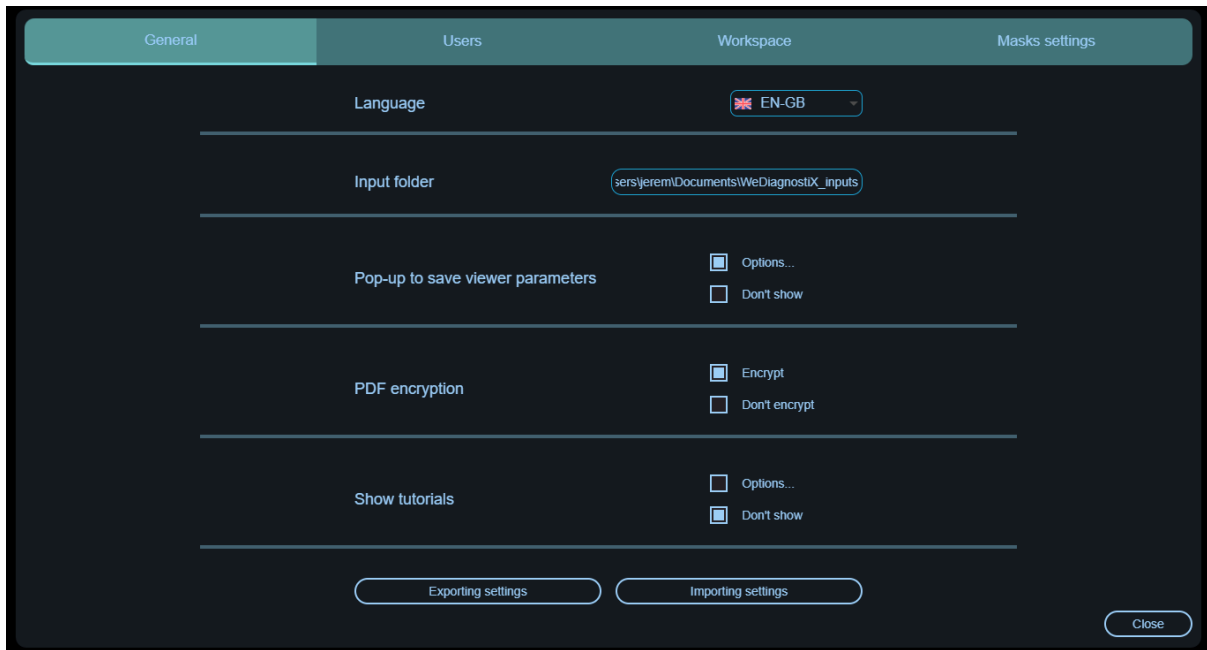


Saving settings

Settings export is accessible from the General panel of the settings.



To retrieve saved settings u can use "import settings" functionality.



Upload of an X-ray


Drag the radiograph from the file explorer to the application, or click on "Load Files" to search for the radiograph manually.

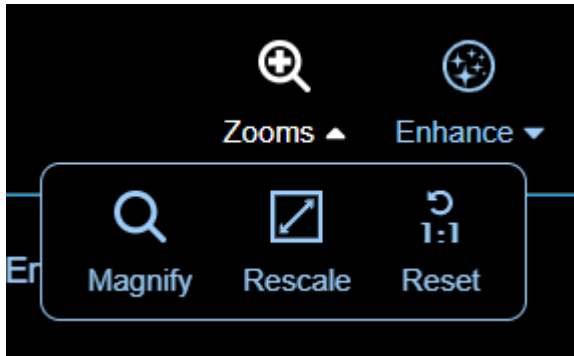


Viewing an X-ray


Zooms

1. Opening the "Zoom" menu

You can open zoom options by clicking the zoom icon  in the display options above the X-ray. Plusieurs outils s'offriront à vous :




2. Magnify tool

Accessible by clicking on the  icon in the zoom sub-menu, the magnifying glass tool will allow you, by left-clicking on the radiograph, to make a local enlargement centered around your click position:



You can move around the X-ray image while holding down the click, and the magnifying glass will follow your mouse movements. To remove the magnifying glass, release the click.

3. The Enlarge tool

Accessible by clicking on the  icon in the Zooms submenu, use your mouse wheel to zoom in / out centered on your mouse cursor position. Scroll your wheel forward or backward to zoom in / out your radiograph around the location you want.

4. Undo Zoom changes



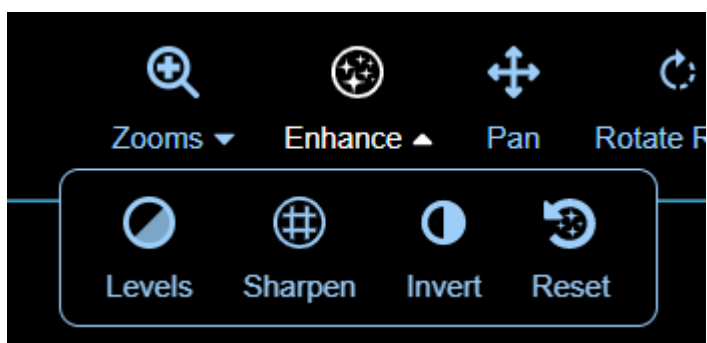
You can undo your zoom changes at any time by clicking on the  Undo button which repositions your entire radiograph to the center of the screen as it was when you first viewed it. However, this feature cancels the image zoom but does not reset any brightness/contrast/sharpness changes you may have applied to your radiograph.

Image enhancements


To improve your visibility on the X-ray, you can apply filters that will change the appearance of the image for better analysis.

1. Opening the Enhance menu

You can open the enhancement options by clicking on the  icon in the display options above the X-ray. Several tools will be available to you:



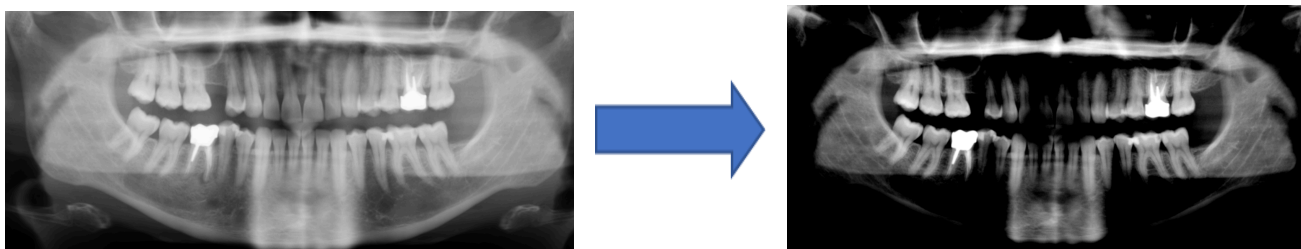
2. The Levels Tool: Brightness and Contrast

Accessed by clicking on the  icon in the Enhance submenu, this tool is dual in that you can change the brightness (the level of light) as well as the contrast (the difference between light and dark) of your image.


To vary the brightness, hold down the left click anywhere on the x-ray and drag your mouse up (increase the brightness), or down (decrease the brightness).

To vary the contrast, hold down the left click from anywhere on the radiograph and drag your mouse to the left (increase), or to the right (decrease).

For example, if I activate the tool and drag my mouse diagonally to the bottom left, I would then decrease the brightness (down) and increase the contrast (left)



3. The Sharpen / CLAHE tool


Accessed by clicking on the  icon in the Enhance submenu, the sharpening variation will be your main tool for a better reading of the radiograph. It allows you to highlight edges and reduce potentially blurred areas of the image. Hold down the left click anywhere on the radiograph and drag your mouse to the right (increase sharpness), or left (decrease sharpness). The sharpness will apply when you release the click. The further you drag your mouse, the greater the change in sharpness. Same goes for CLAHE by dragging from top to bottom.

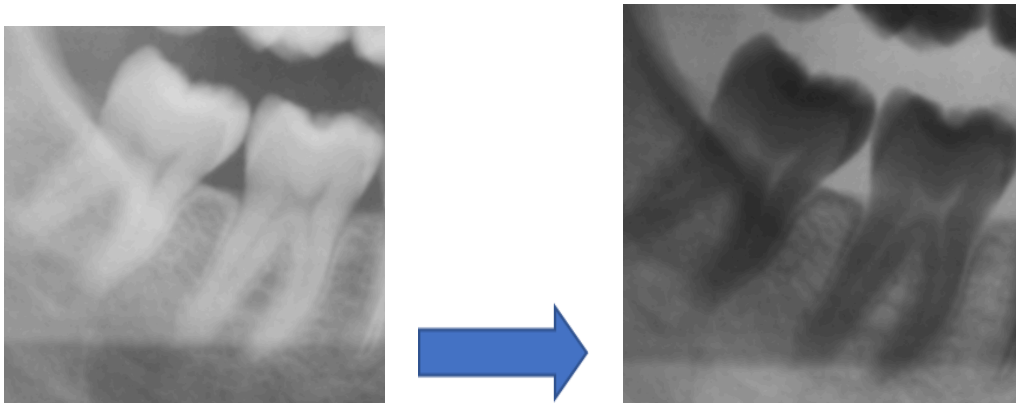


Note that the operation is cumbersome and may take one or two seconds to apply. You cannot change anything until the change is applied.



4. The invert tool

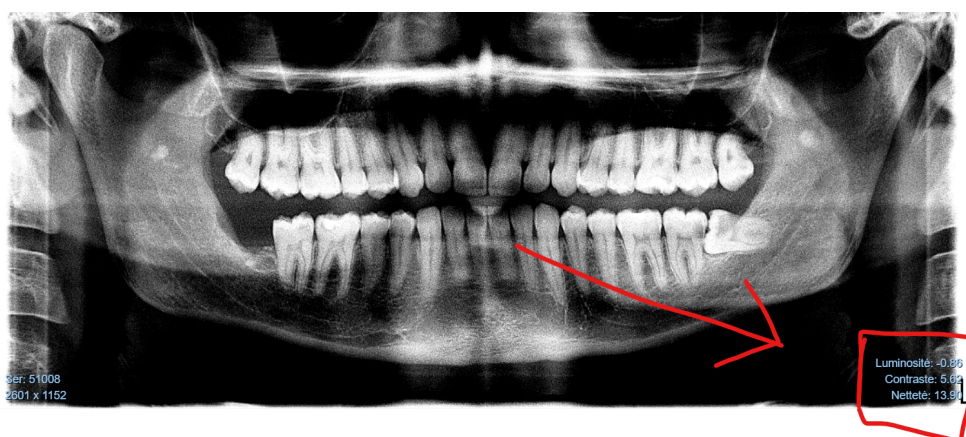
By clicking on the  icon in the Enhance submenu, the image will be inverted, i.e. dark will become light and light will become dark. Click the button again to return to the usual lighting.




5. Notes

Enhancements applied to the radiograph are cumulative, so you can change the brightness, contrast, sharpness and inversion on the same image. Activating a tool will not undo changes made by another enhancement tool previously used.

The brightness/contrast/sharpness values are visible in real time at the bottom right of the X-ray:





6. Undo changes

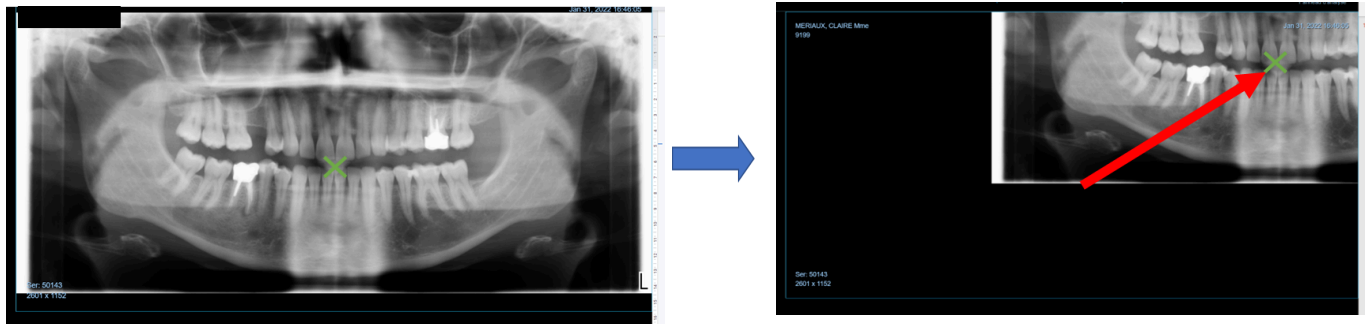
You can undo the enhancements made to an image at any time by clicking the  button in the Enhance submenu, which will restore the radiograph to the way it was when it was opened in the Viewer.

This feature undoes the image enhancements but does not reset any potential zoom changes you may have applied to your radiograph.


Moving

Clicking on the  icon in the toolbar above the radiograph will activate the Move tool. Hold down the left mouse button anywhere on the image and drag the mouse wherever you want to move the radiograph (for example, if you drag the mouse to the right while holding down the mouse button, the image moves to the right).

You can undo a move made by re-centring the image by clicking on the  button in the Zooms submenu of the toolbar.



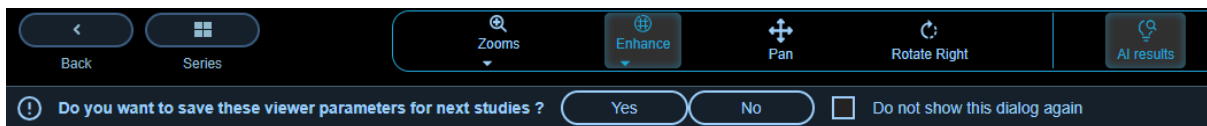
Rotation

By clicking on the  icon in the toolbar above the X-ray, you activate the Rotate Right tool. The image will then be rotated by 90°. You can click as many times as you like to continue the rotation (4 clicks in a row will apply a complete rotation of the image and return it to its original orientation)

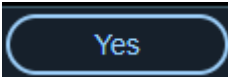
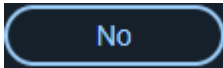
You can cancel a rotation by clicking on the  button in the Enhance submenu of the toolbar.

Settings save


When you change the brightness / contrast or sharpness of the image, a popup will appear at the top of the image asking you the following:



The settings you change can therefore be saved in the application, so that they are automatically applied when you open a next X-ray.

If you click on the  current values for brightness, contrast and sharpness will be saved and at the next X-ray openings. If you click on  the pop-up will close until the next change and the settings will not be saved.

You can check the box **Do not show this dialog again** that disables the pop-up from appearing when the Viewer settings are changed.

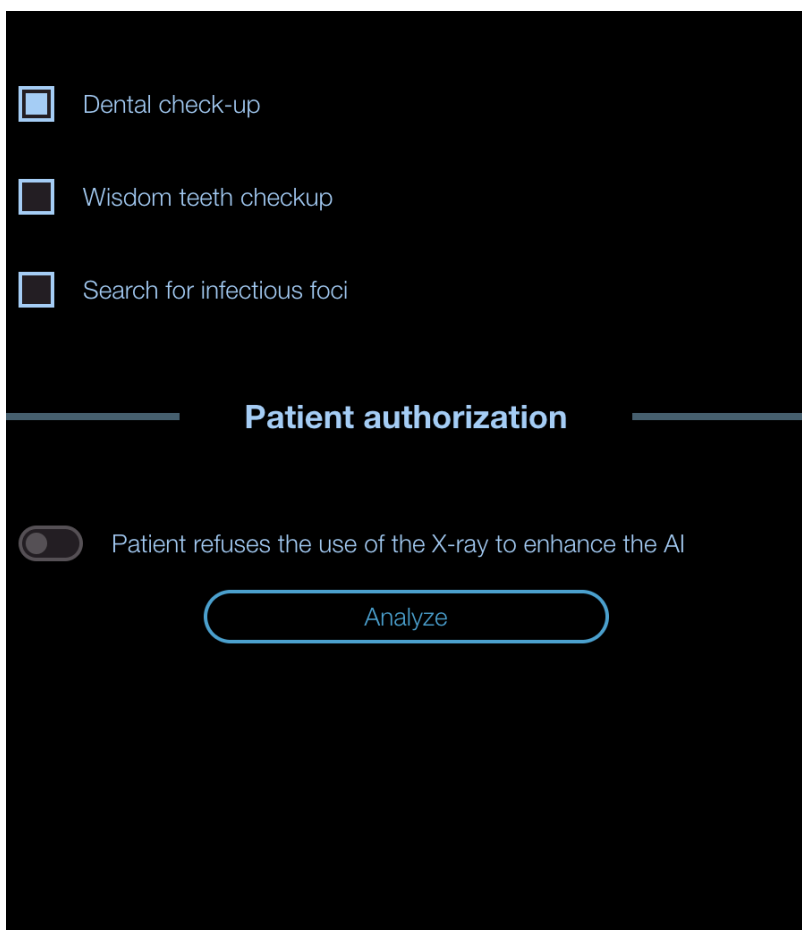
However, you can make it reappear at any time by going to the  settings at the top right of the application and then to General:



Analysis of an X-ray

Sending an X-ray for analysis

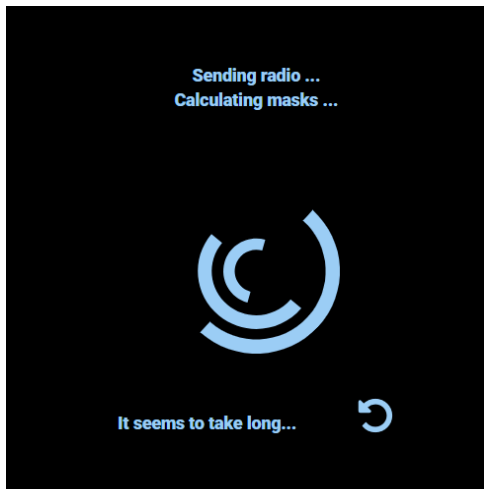
In order to send an X-ray click on the “Analyze” button.



Once you’ve clicked it, the state of the analysis will be displayed in the panel.

Sending failed

Sending of the X-ray can fail due to multiple causes. In this case a retry message will be displayed.



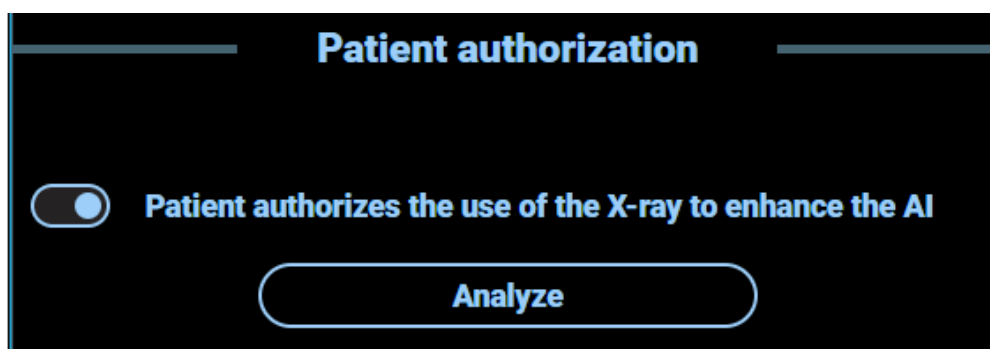
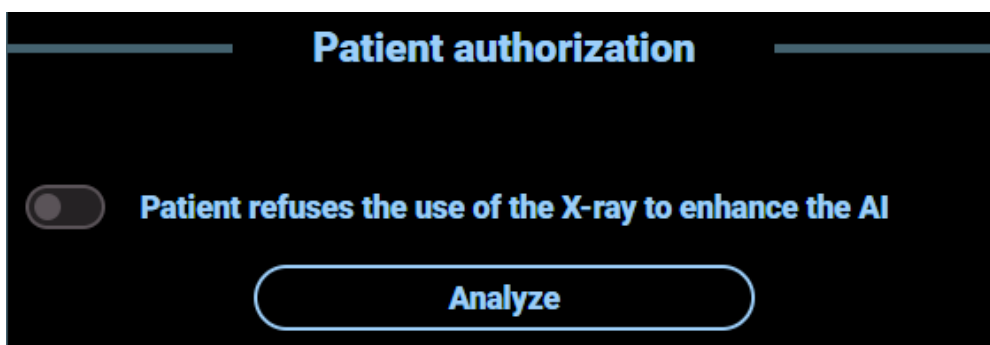
Just click on the refresh arrow to send the x-ray again.

Examination motive

This feature is currently under development and will allow the information in the report to be prioritised according to the main reason for the examination chosen.

Patient consent

You should inform the patient that the use of WeDiagnostiX involves the transfer of data to a remote server hosted by Dassault Systèmes (hosted in France). This data will not be reused unless expressly authorised. In which case, it will only be used for research purposes to improve the detection capabilities of the algorithms. It will not be resold, transferred or published and is kept for a period of 12 years in accordance with the legal obligations in force.

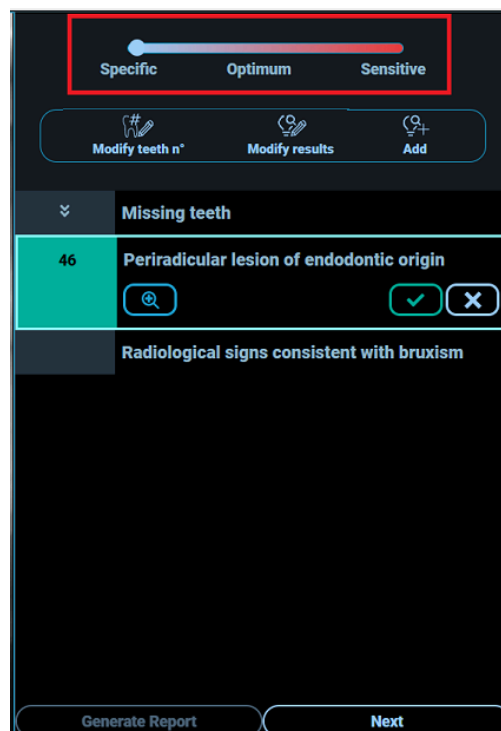


Results interpretation

Confidence thresholds

The results obtained by artificial intelligence are classified into 3 categories: Specific, Optimal and Sensitive. A specific result is most probably certain, but if we only look at specific results, it's likely that not all the elements present on the X-ray will be detected. On the other hand, a sensitive result does not necessarily correspond to a clinical reality; it may be a false detection. Optimal results are compromises between the other two types.

You can change the type of result displayed by dragging the slider.



Why do we have three confidence levels?

In our automated X-ray reading application, we use neural networks to identify dental lesions. To ensure that the results are useful in medical practice, we have determined three confidence thresholds for each pathology:

1. **Threshold Sensitive:** This mode is designed to be very vigilant in detecting as many lesions as possible. This means that it will detect a large number of lesions, even if some of the proposals made by the algorithm are not real lesions (false positives). This is particularly useful for ensuring that no potential lesions are missed, in order to attract the practitioner's attention.
2. **Optimal threshold:** This mode represents a compromise between the Sensitive and Specific thresholds. It is designed to minimise both false positives and false negatives, offering a compromise between sensitivity and specificity. This is the recommended setting for most clinical applications, as it offers overall reliability.

3. **Specific threshold:** This mode is very strict and only detects lesions with a very high level of confidence. This means there are few false positives, but some lesions may be missed (false negatives). This setting is used when precision is critical, and you want to avoid detection errors and false positives as much as possible.

In all cases, it's important to remember that panoramic radiographs are only a means of providing a general overview, not the reference standard for diagnosing pathology.

Why can a confidence index be misleading?

The confidence index is a score assigned by the neural network to each detected lesion, indicating the probability that the lesion is real.

It's important to understand that :

- X-rays can vary in quality and complexity, which can affect AI performance. Poor image quality can make the confidence index less reliable.
- **A high confidence index does not always guarantee that a lesion is real or that it is correctly identified** (for example, a tonsillar calcification may actually be a carotid calcification). Conversely, a lower confidence index may still correspond to a real lesion in simpler cases.
- Error balance: In sensitive mode, we accept more false positives to minimise false negatives. In specific mode, we minimise false positives but accept more false negatives.

Understanding Reliable Detection

In our lesion detection system, we have several types of lesions identified by neural networks.

Here are a few key points to help you understand how we manage these detections:

1. **Common lesions:** For common lesions, our system has a large number of training samples. This enables neural networks to achieve a high recognition rate for these types of lesions.
2. **Rare anomalies:** Our system can also detect rarer anomalies, which are infrequent in our dataset and in the general population. For these detections, reliability is lower due to the lack of training samples. It is important to consider these detections as aids to report preparation rather than definitive diagnoses.
3. **Role of the practitioner:** To guarantee the accuracy of the final results, we give users the option of validating detections. Detected lesions, whether common or rare, appear in the report only if they are validated by the operator with a single click. This approach ensures that only clinically relevant lesions are included in the final report.
4. **Flexibility of use:** We have chosen to allow almost all detected lesions to be displayed, even those for which we have little certainty. This gives users greater flexibility, enabling them to spot potential anomalies that might otherwise go unnoticed.

Conclusion :

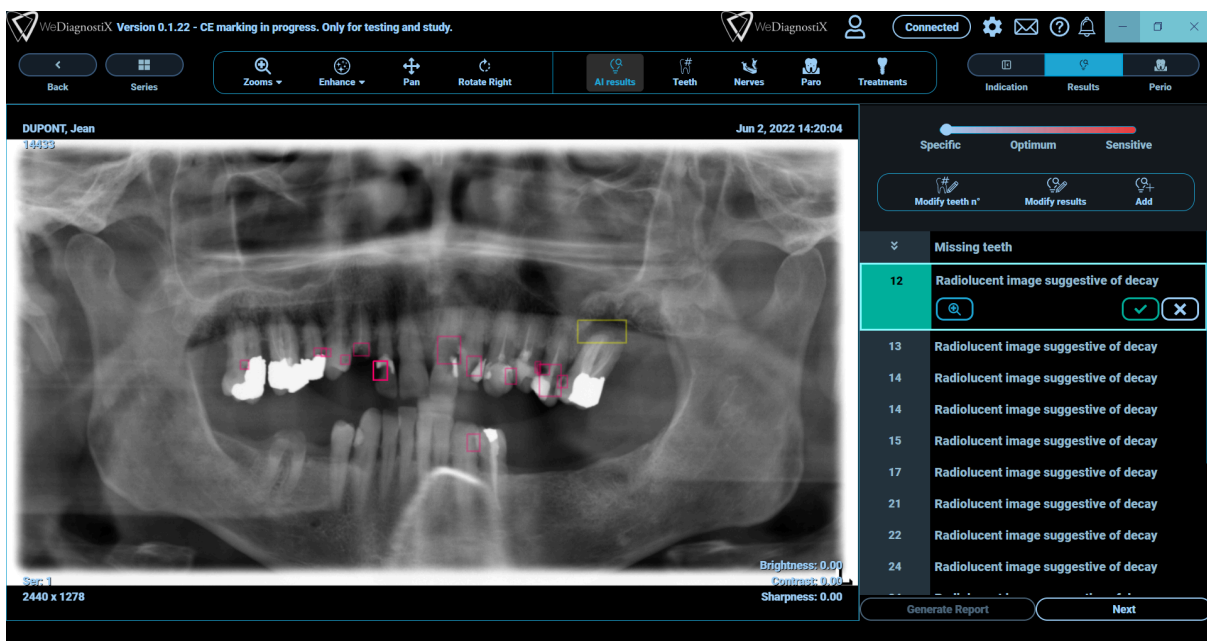
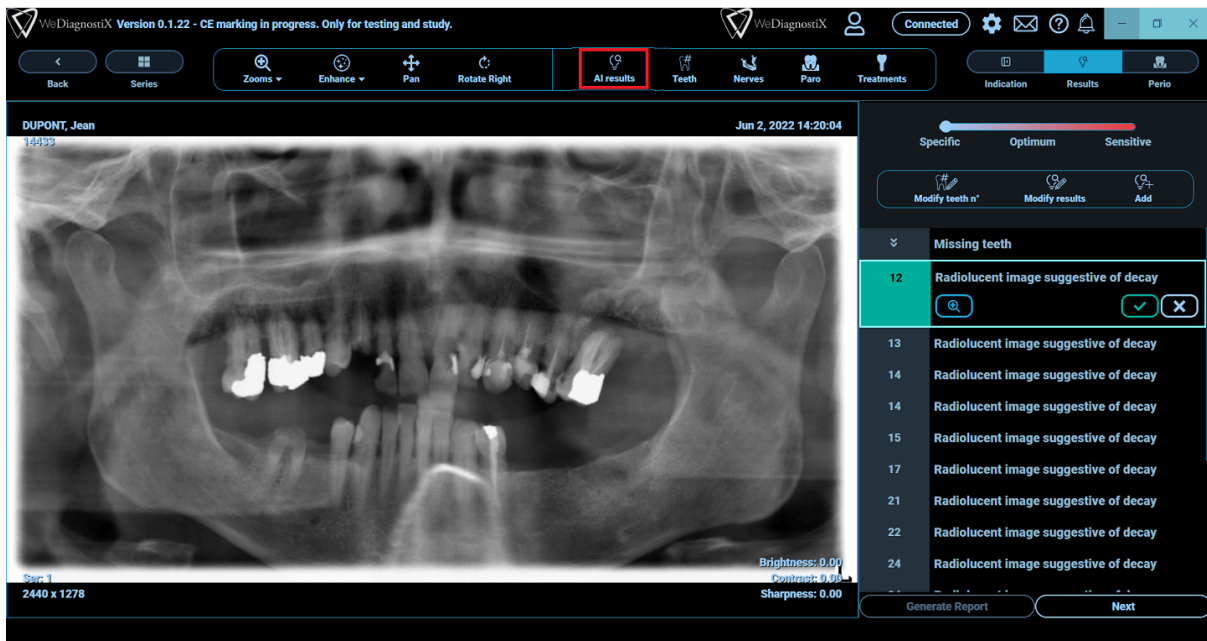
Our three confidence threshold system allows lesion detection to be tailored to specific clinical needs. Our system is designed to maximise lesion detection with particular attention to reliability. **Operator validation ensures that only relevant and confirmed detections appear in the final**

results. This balanced approach enables users to benefit from the advanced detection capabilities of our AI while maintaining a high level of accuracy and clinical relevance.

Display of observations

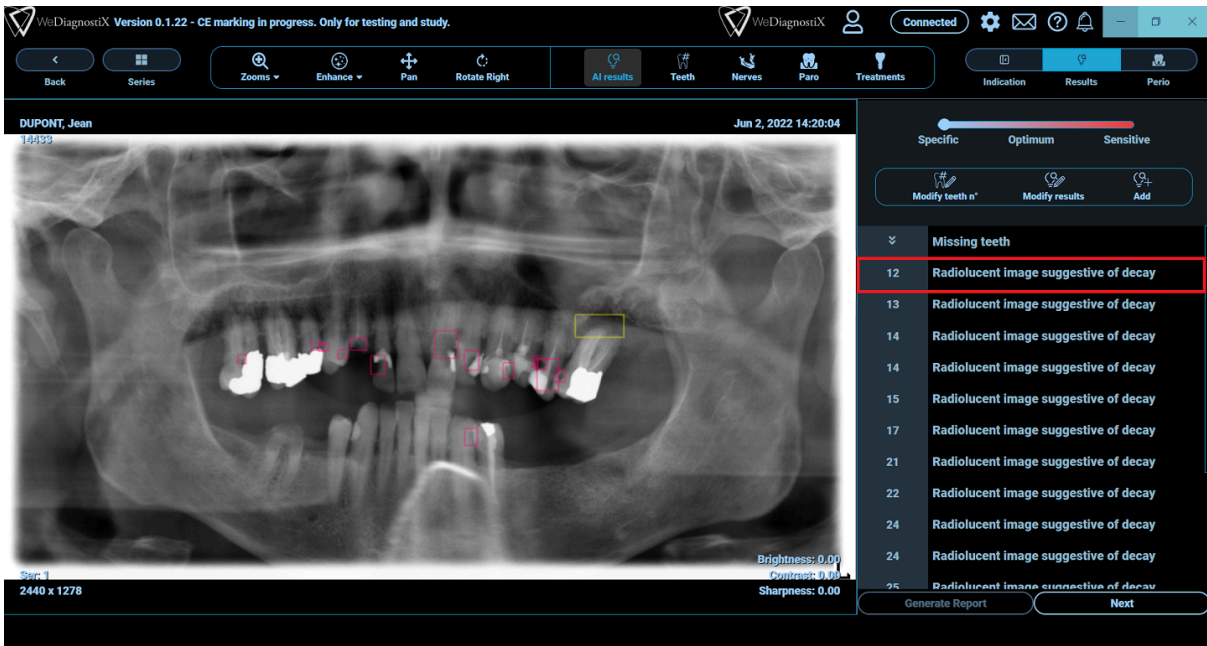
To display the AI results on the X-ray, click on the “AI Results” button. Alternatively, if the results are not displayed, clicking on an item in the right-hand panel will display the items automatically.

Cavities are indicated with red squares, apico-dental lesions with yellow squares and other observations with blue squares (colours are customizable in the settings).

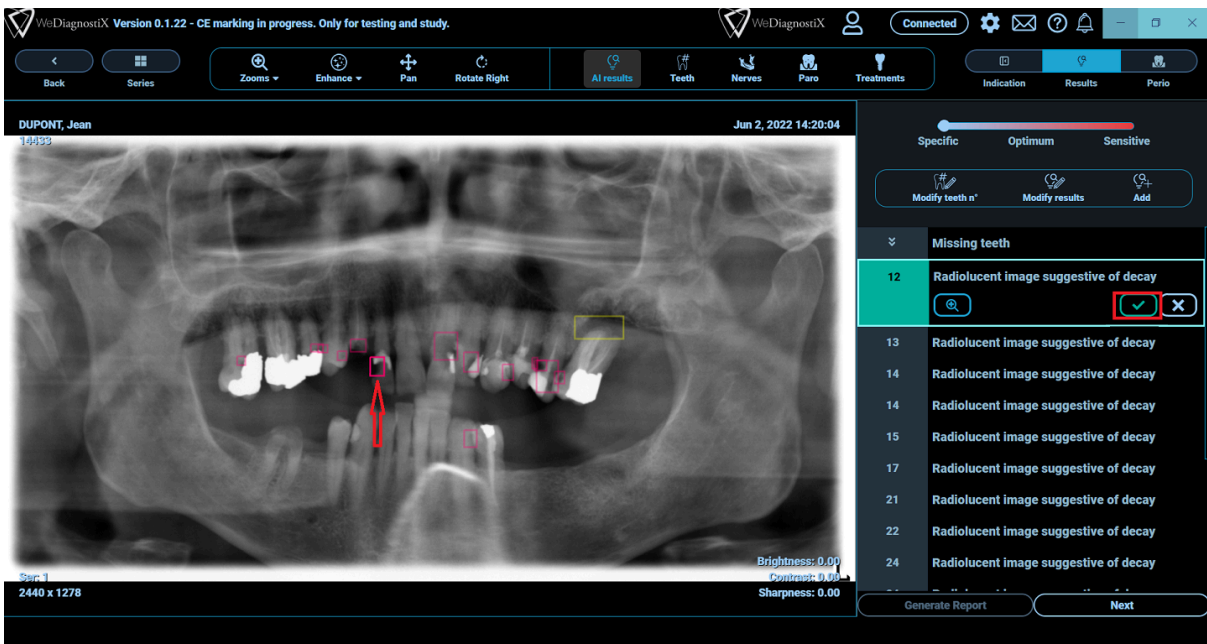


Validation of an element

Click on an item in the results panel.

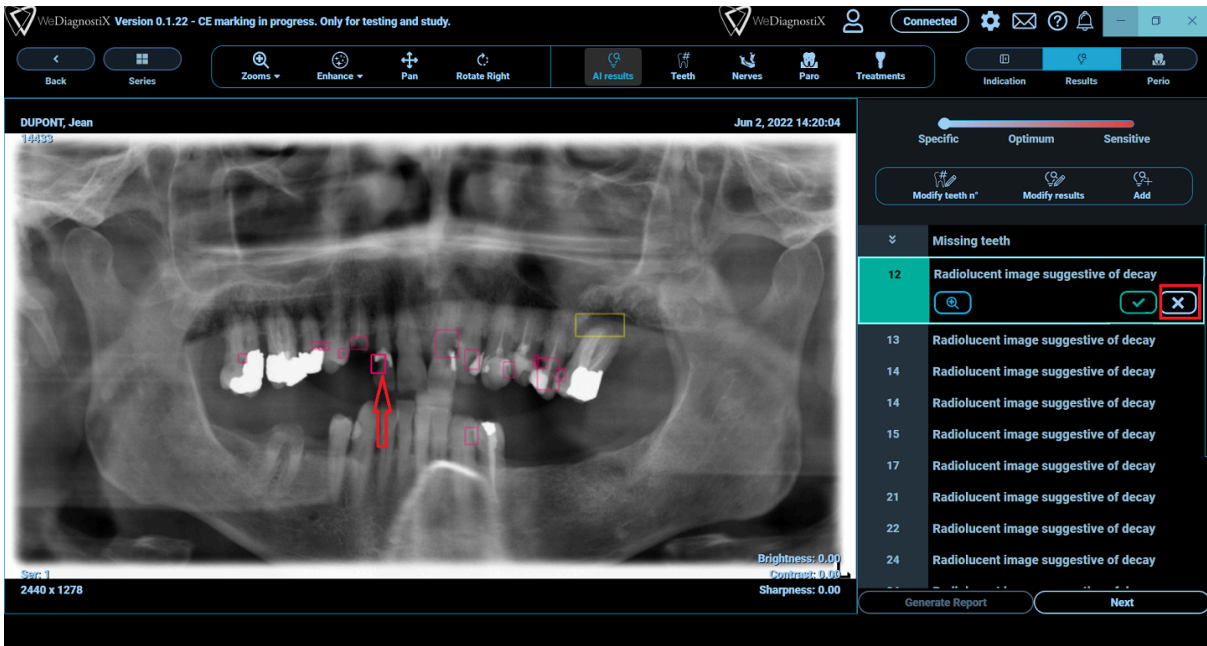


The element is highlighted on the X-ray. You can validate it by clicking on the validation button that appears.




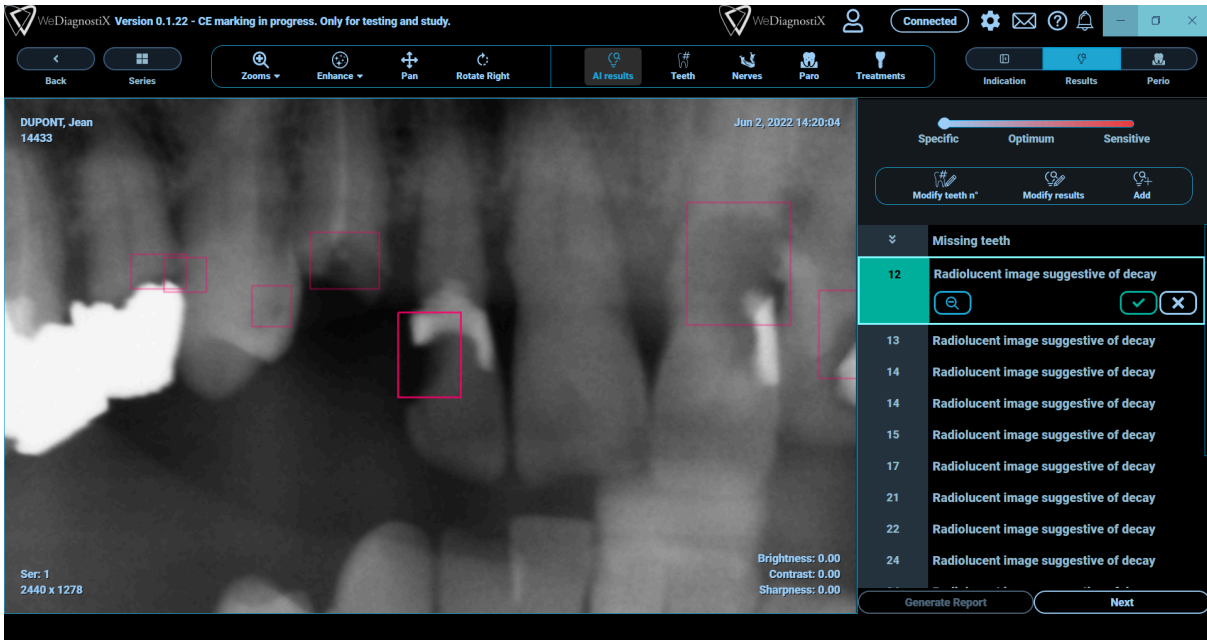
Invalidating an element


You can invalidate an item by clicking on the invalidate button.



Focus on an element

You can use the Zooms tool in the viewer settings to scroll to the indicated pathology, but you can also click on the  button in the results list to have the viewer automatically focus on the selected pathology. This tool remains active between selections.

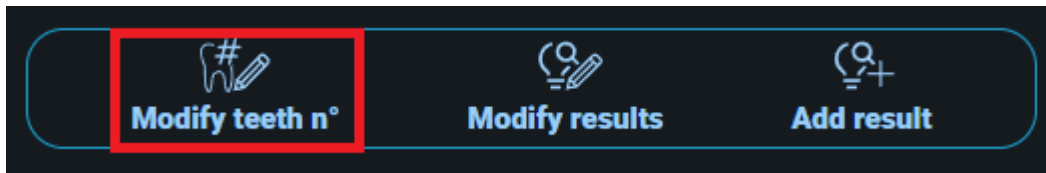


When this tool is active, you can click on the  button at any time to cancel the focus between pathologies.

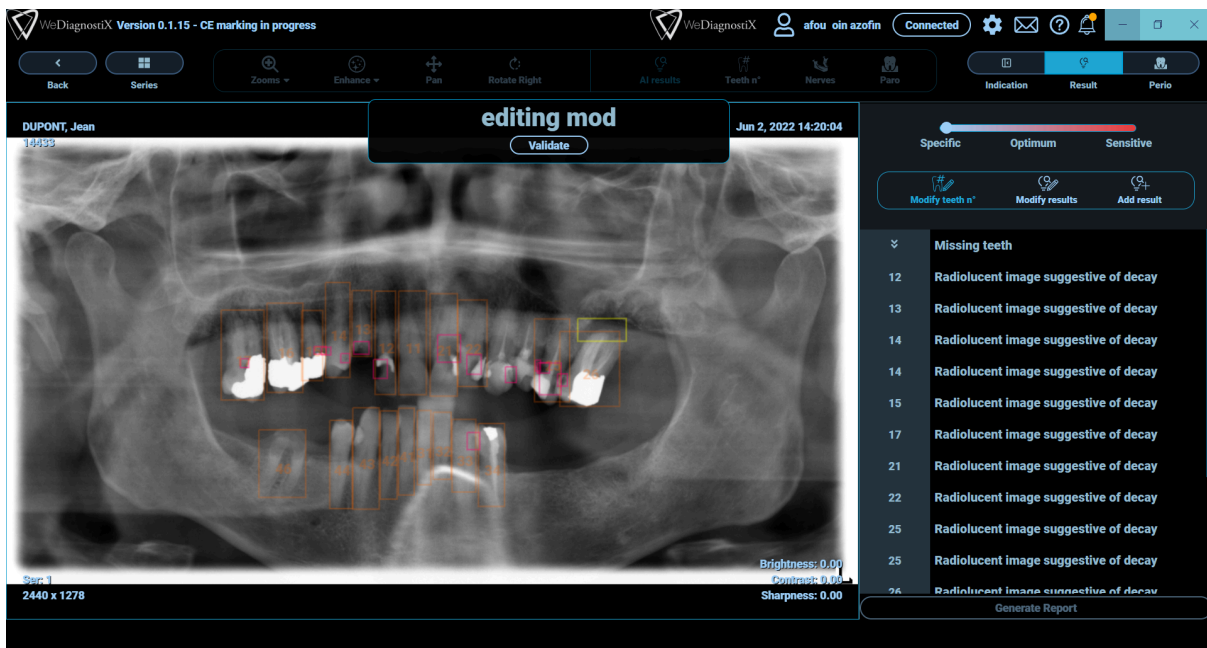
Modifying an element

Teeth number

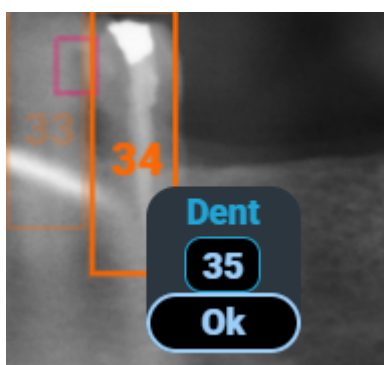
To modify the tooth numbering, first click on the “Modify teeth n” button.



You are now in edit mode



Once in this mode, simply click in the frame of the tooth whose number you wish to change and enter the new number.

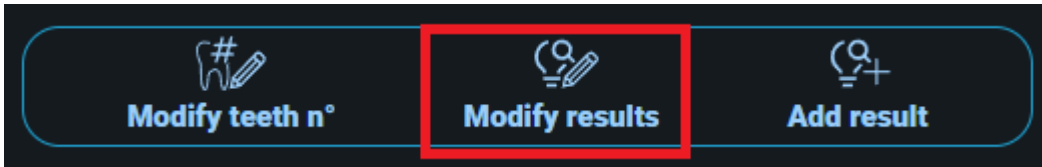


When all changes have been made, simply click on the “Modify tooth no.” button or the validate button to exit edit mode.

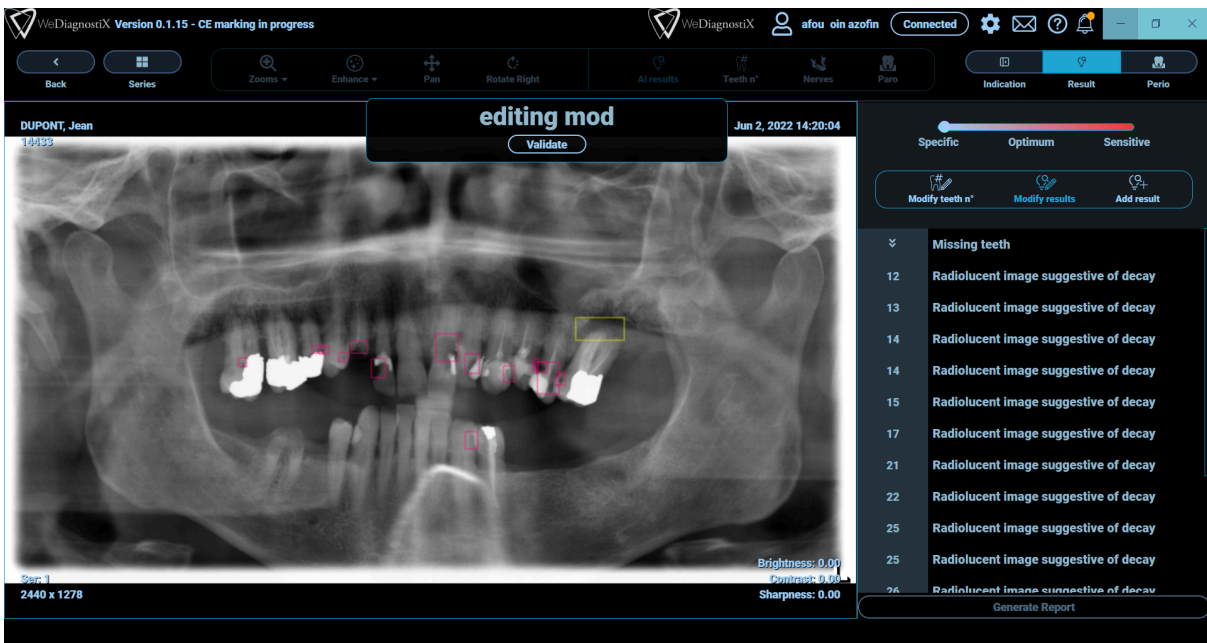


Diseases/observations

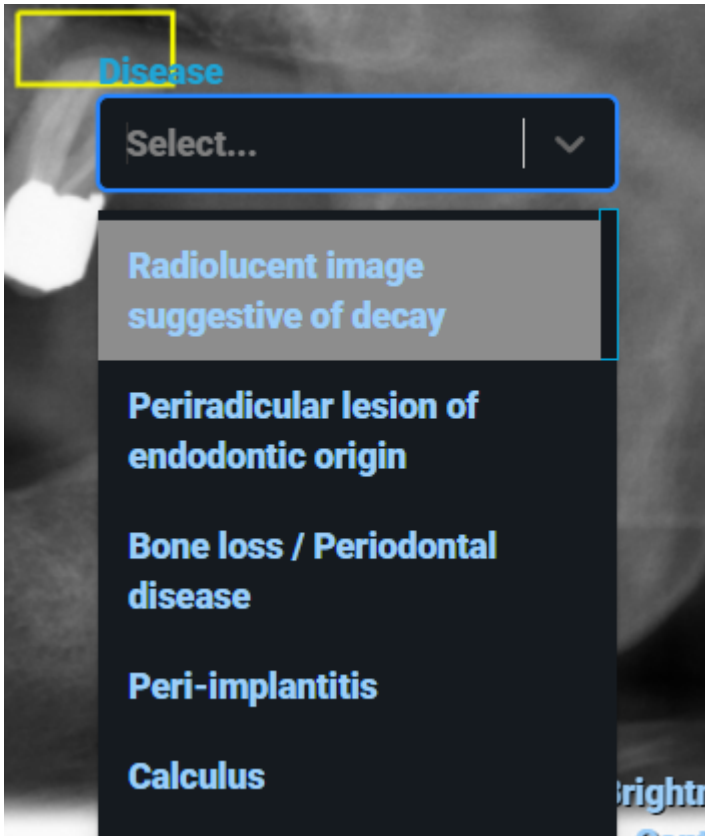
To modify a result, first click on “Modify results”.



You are now in Edit mode



Once in this mode, click on the rectangle corresponding to the disease you wish to modify. You can then choose a new disease from the list

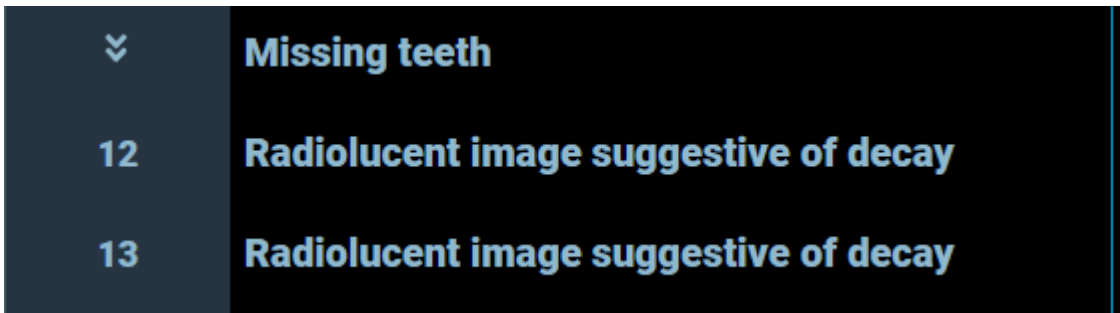


When all changes have been made, simply click on the “Modify tooth no.” button or the validate button to exit edit mode.



Add and delete missing teeth

Missing teeth are displayed in the results list.

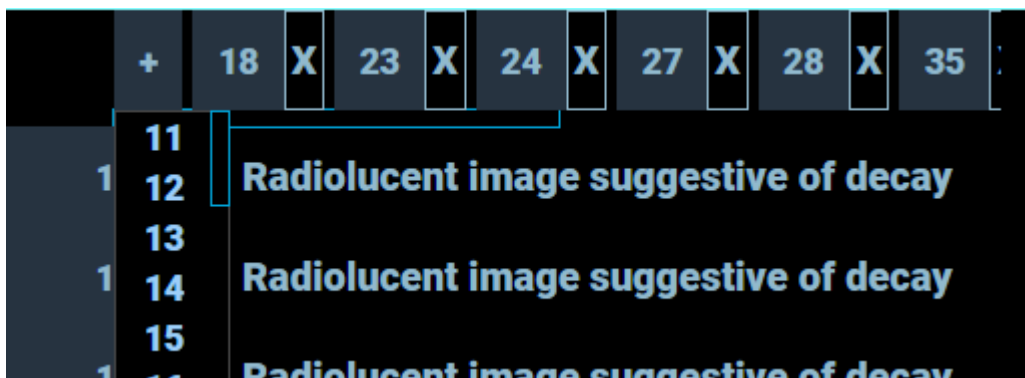


Click on “Missing teeth” to view details.



Once the details are displayed, you can delete a missing tooth by clicking on the cross of the corresponding tooth.

Click on the “+” to add one or more teeth.



Add observation

To add an observation, click on the “add” button:



You are now in add mode:

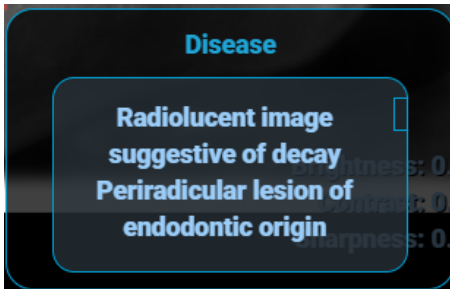
Use the mouse to frame the observation to be added. A selector appears, allowing you to choose whether to add a disease or a tooth.



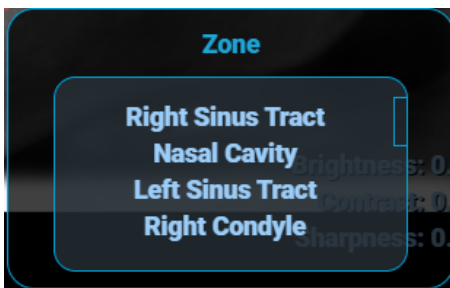
selecting a tooth will open an input panel to define the number of the added tooth



By selecting “Disease”, a list will prompt you to choose the disease identified.



If the disease is close to/on a tooth, it will be associated with it, otherwise a new list will prompt you to choose a zone.



Once all observations have been added, click on  or on the “Add” button again.

“Perio” periodontology tab

General

The perio tab can be accessed, after analysis, by clicking on the “Perio” button.

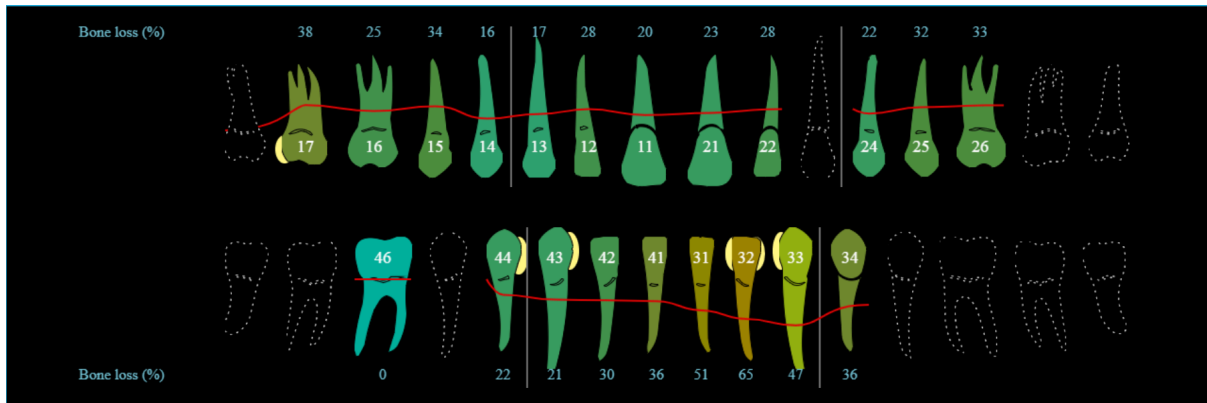


On this page you will find different results from the main results panel:

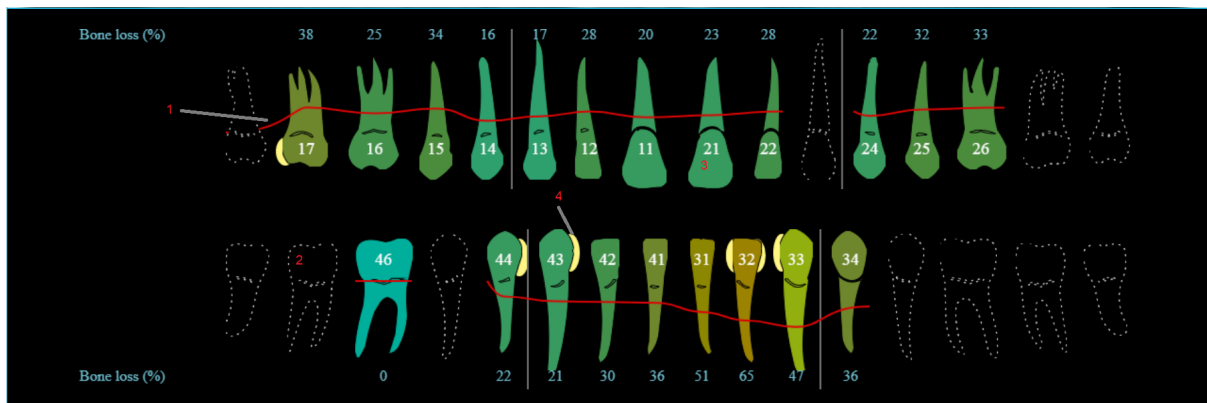
- tartar
- periodontal pockets

- bone loss, represented by the space between the cementum-amelara line and the bone line.

You'll also find a dental diagram illustrating bone loss and showing which teeth are present or missing.



Dental chart



1: The red line indicates the level of bone loss

2: An empty location (here 47) indicates that the corresponding tooth is missing

3: A tooth. It's colour correspond to the level of bone loss

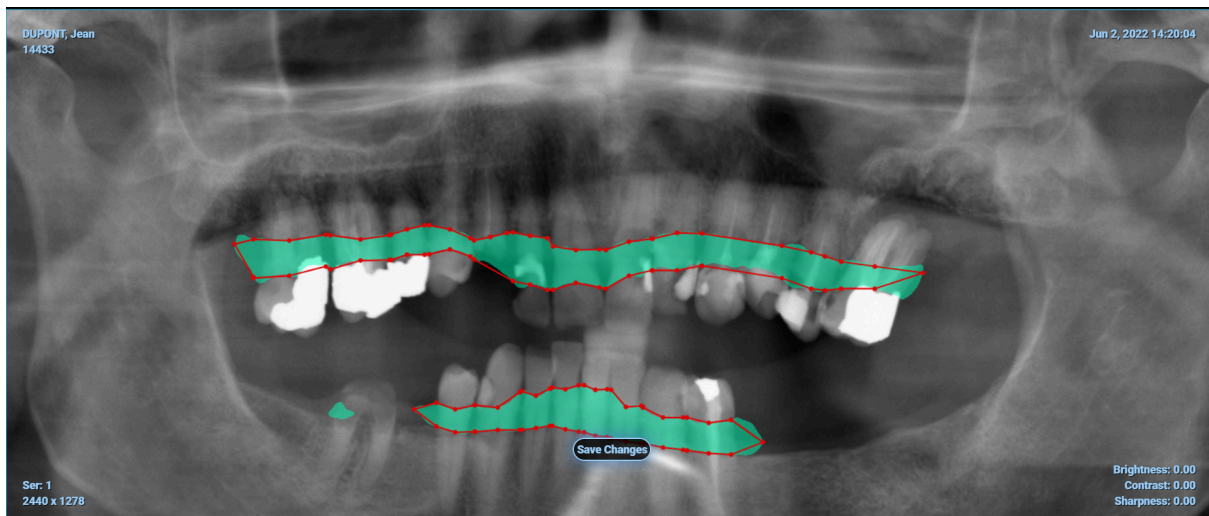
4: Calculus

Interaction: Clicking on a tooth changes it from present to absent. Clicking on tartar highlights it on the radio.

Managing bone level

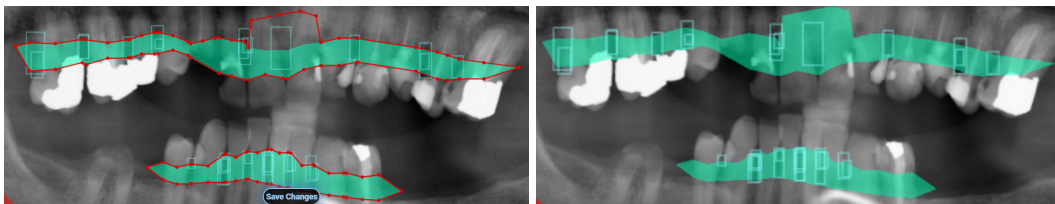
The bone level setting is opened by clicking on

Manage bone level



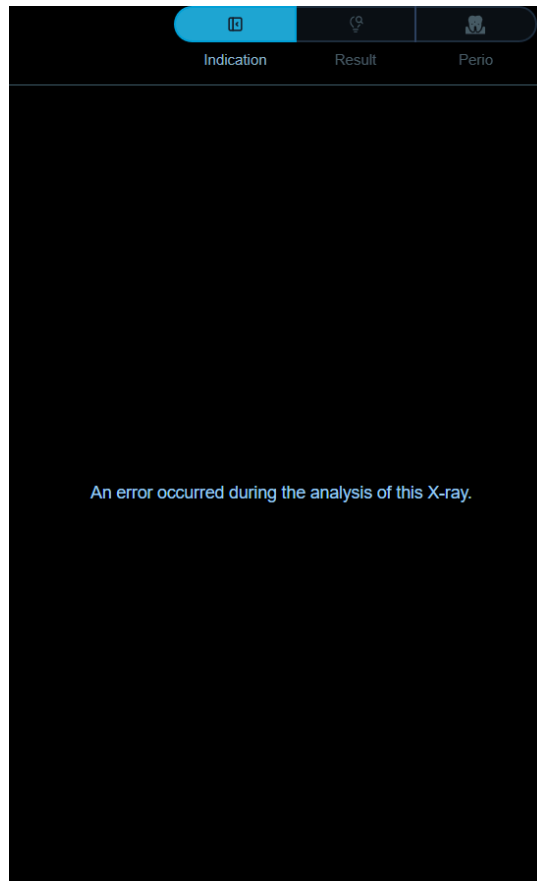
To adjust the level, simply click and drag a point. Once you've made your changes, press

Save Changes



Error during analysis

If an error occurs during analysis, a message will be displayed in the panel to the right of the image.



Although this is extremely rare, it means that this X-ray cannot be analyzed for the time being. This problem can be reported to us so that we can correct it as quickly as possible.

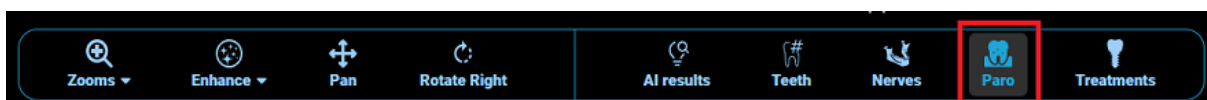
Mandibular nerve display

Click on the Nerves button



Periodontal level display

Click on the Paro button



Treatments display

click on the treatments button



Teeth display and numbering

Click on the tooth number button

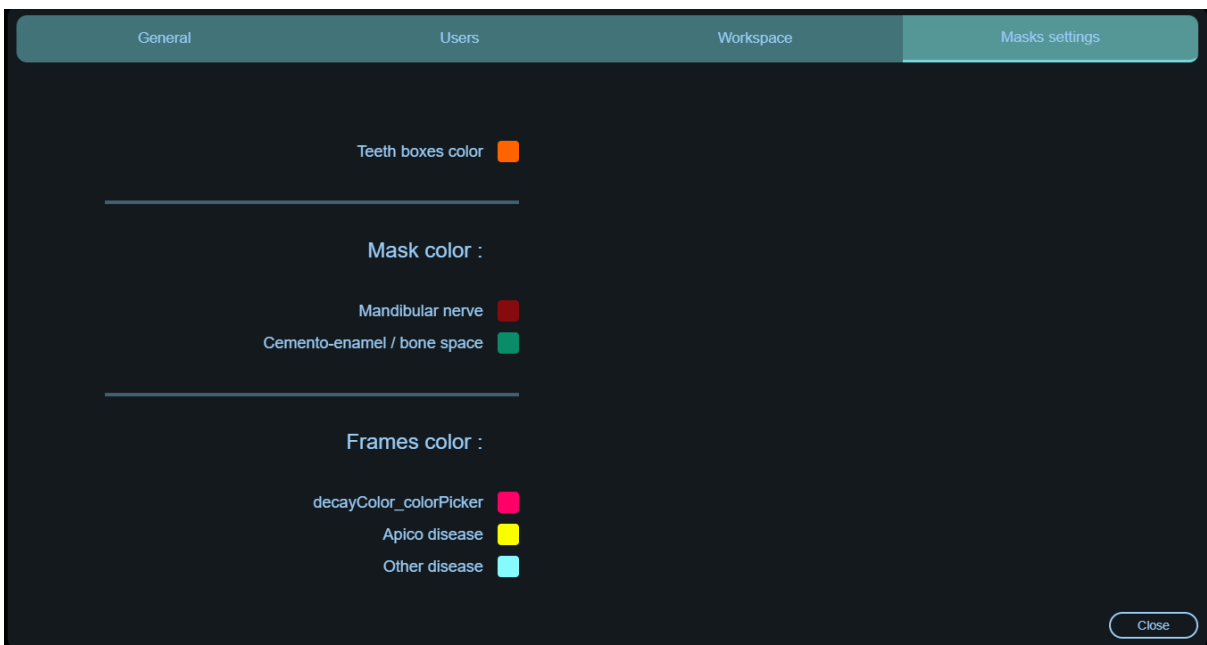


Colour change of masks

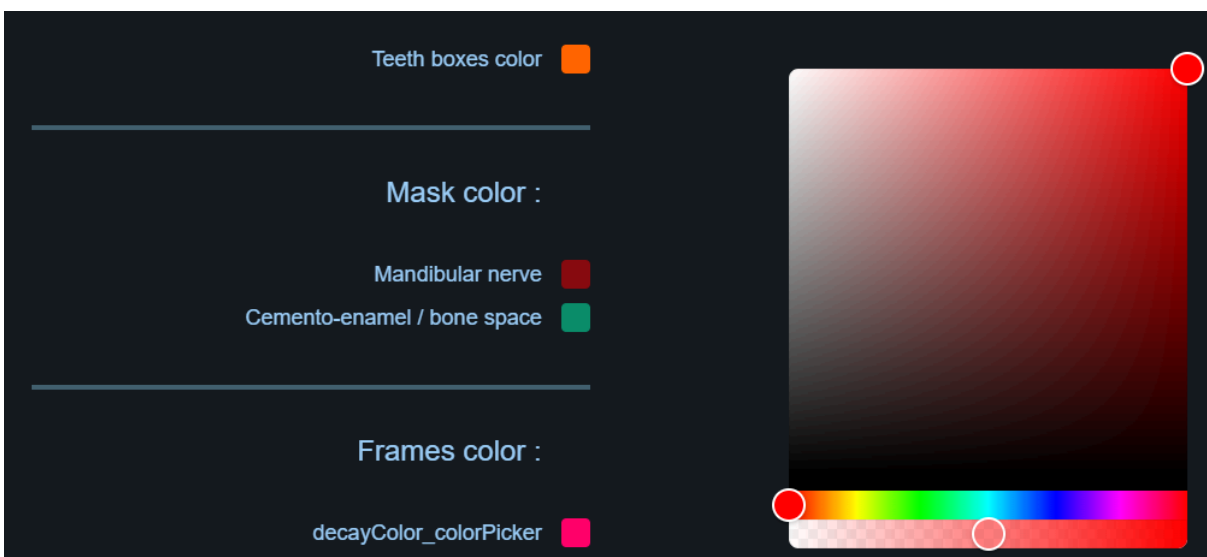
Open settings



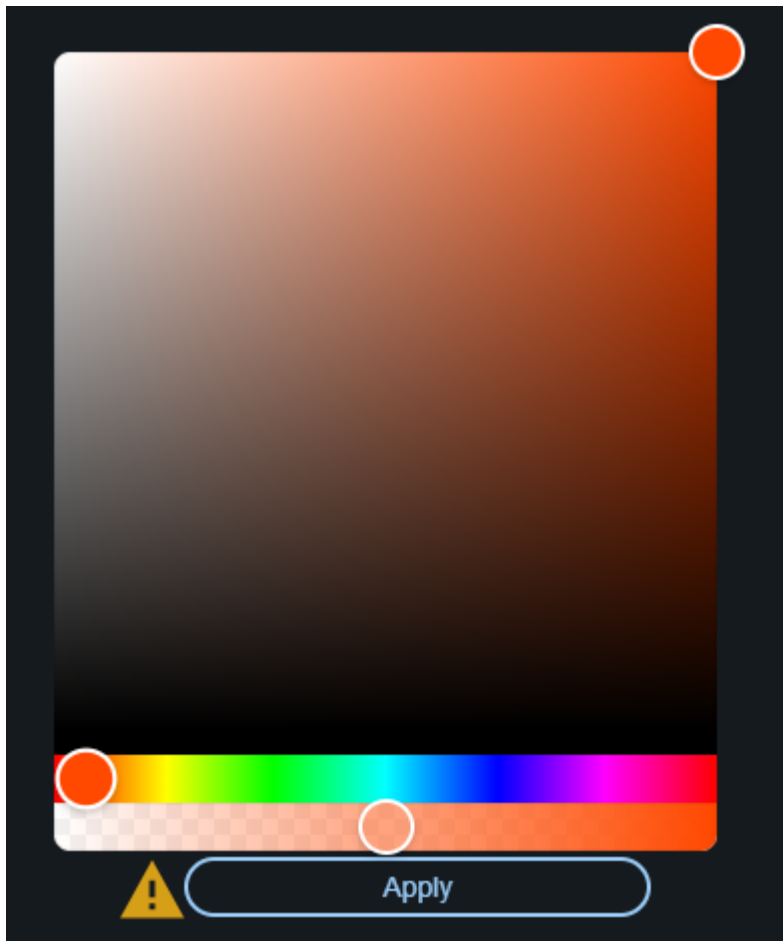
Select the colour to change



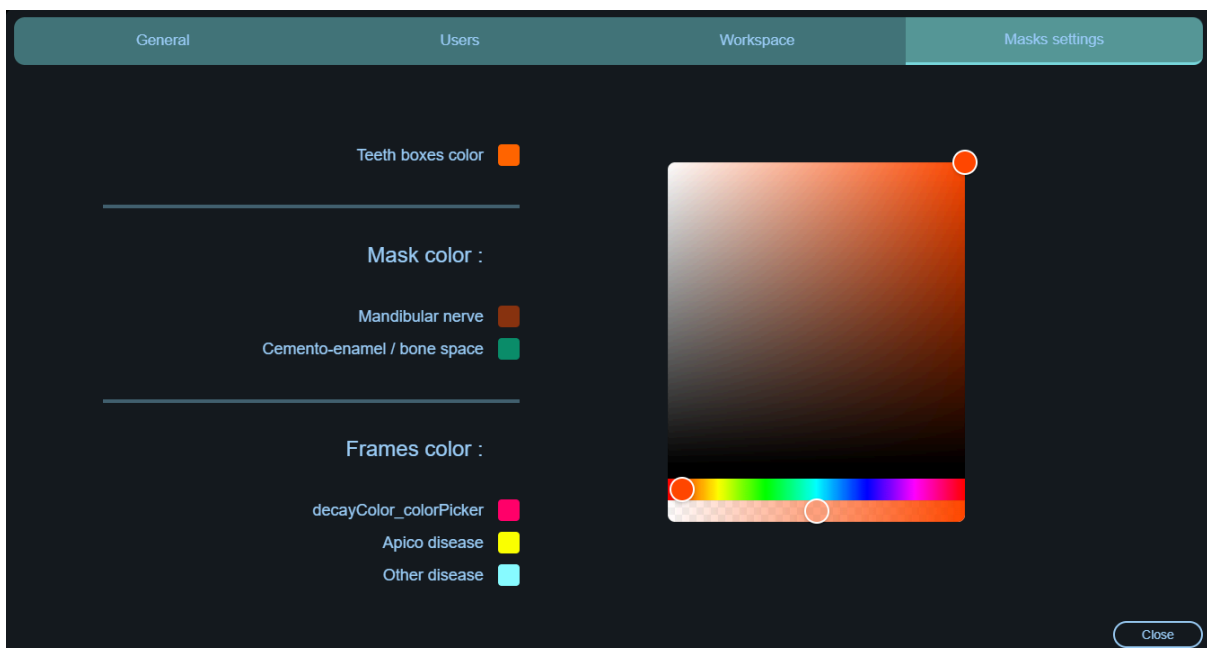
Choose your colour using the colour palette



If the mask is loaded during the change (after analysis), apply the change before closing the panel:



Otherwise close the panel.



Colour change of tooth contours or frames

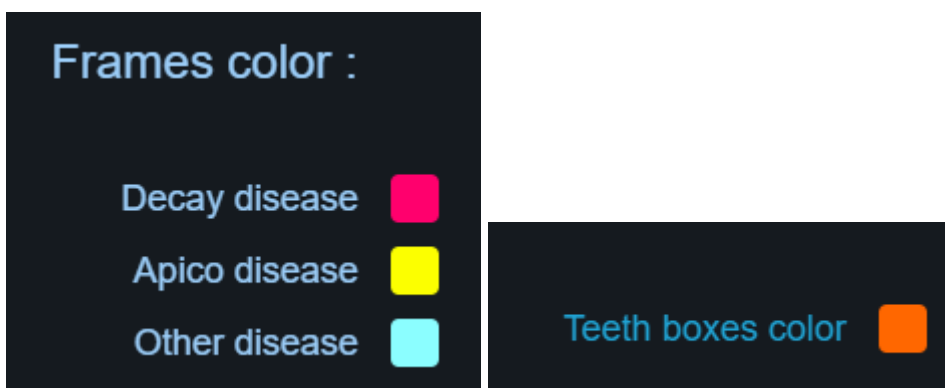
Open settings



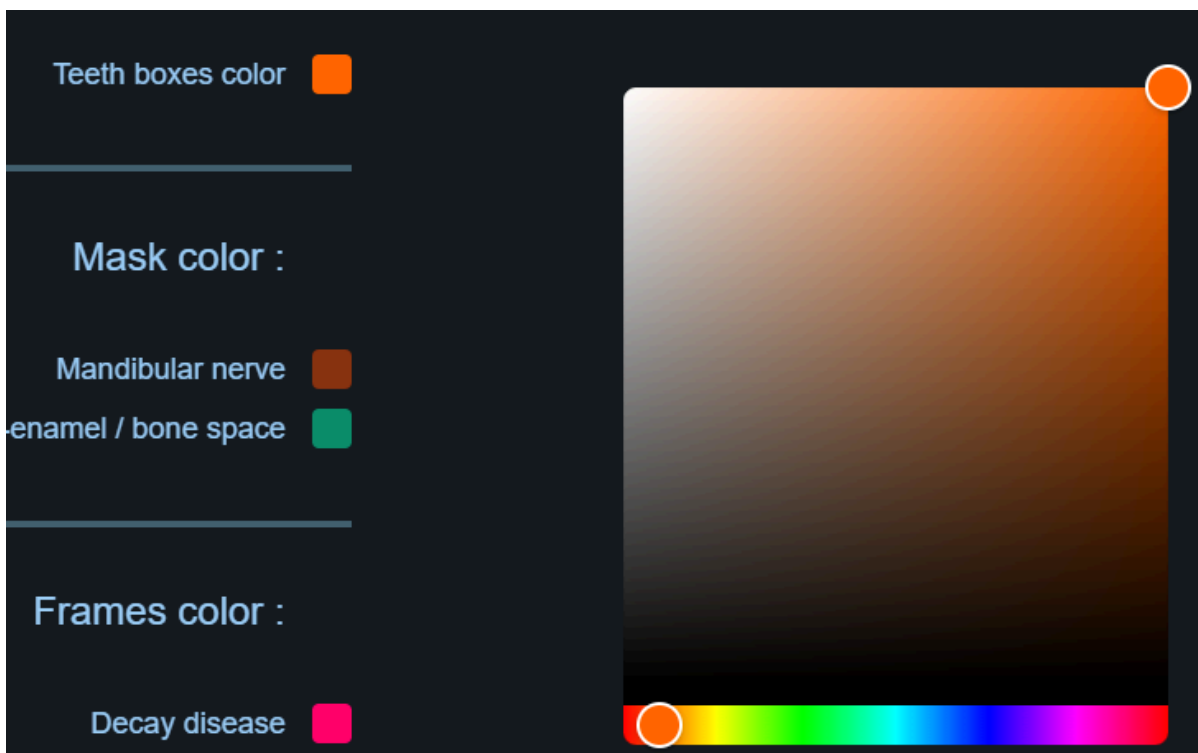
Go to masks settings



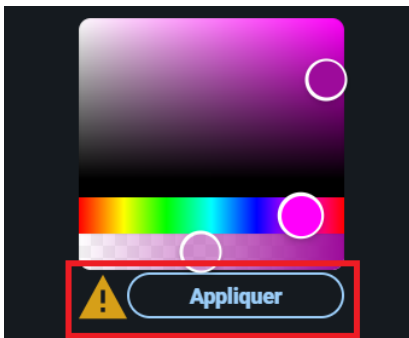
Select the colour to change



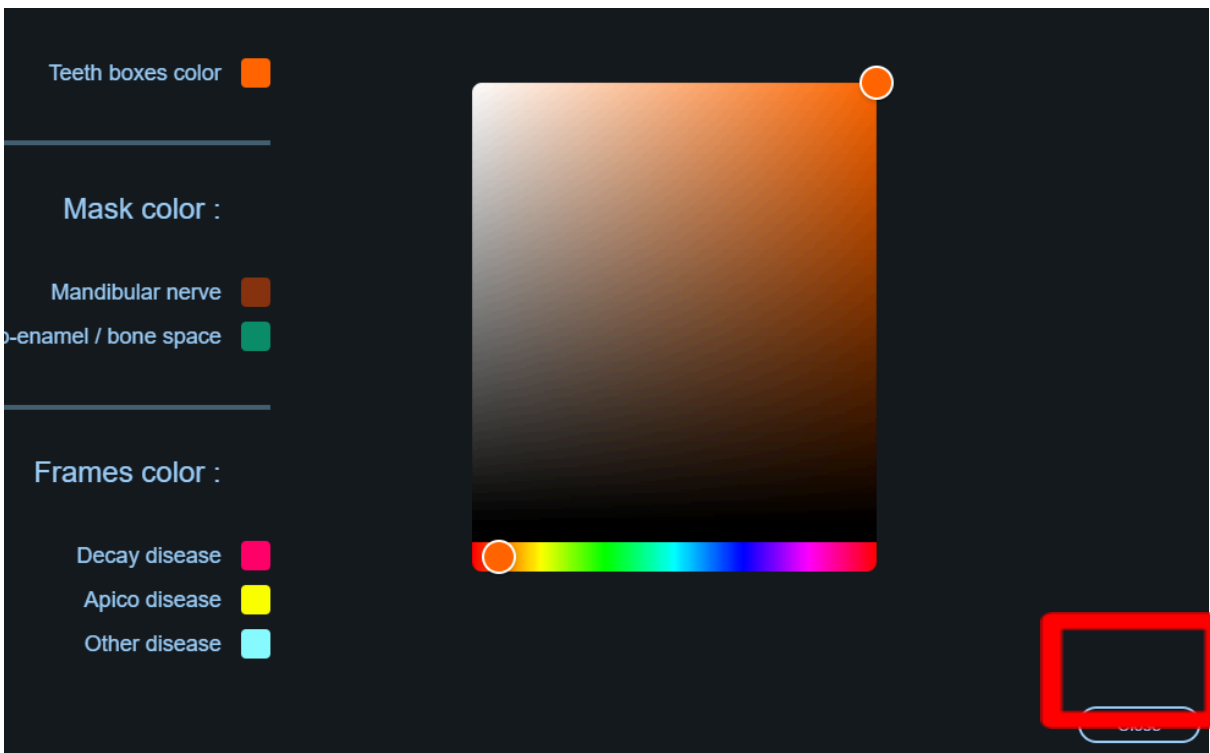
Choose your colour using the palette.



If the mask is loaded during the change (after analysis), apply the change before closing the panel:



Otherwise close the panel.

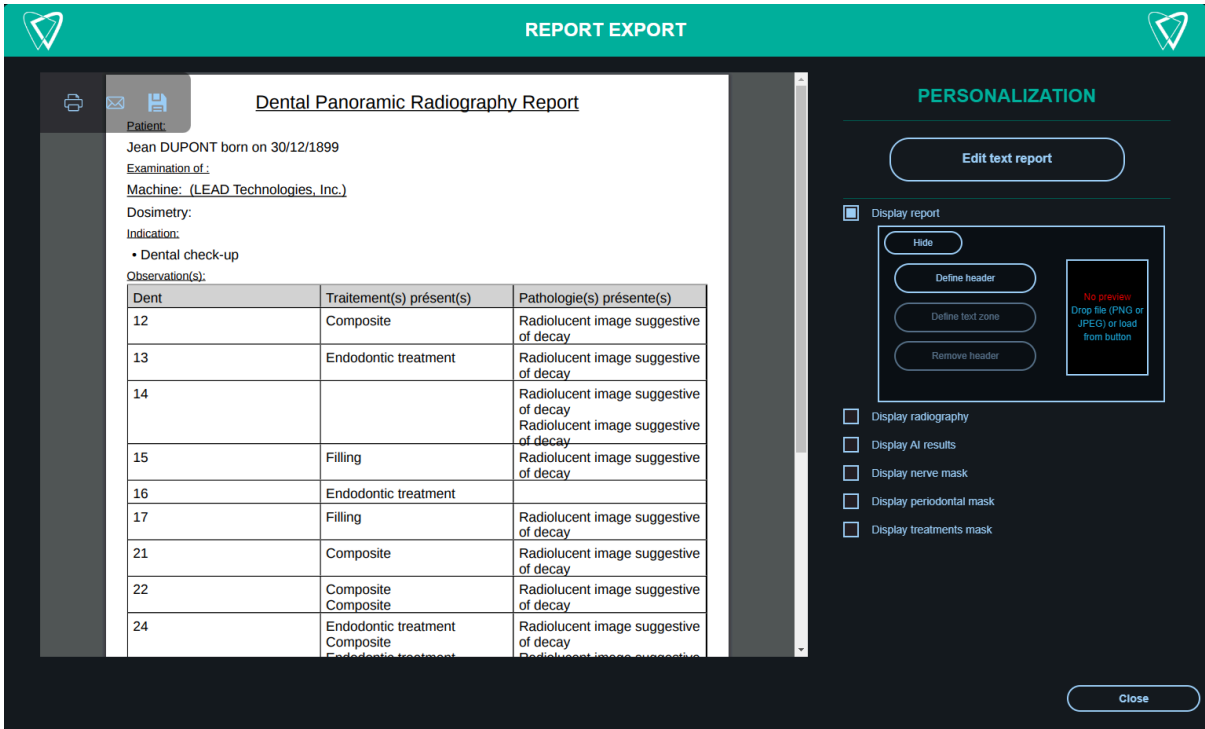


Generating and exporting final report

Once the AI results have been validated or invalidated, the “Report” button opens and you can click on it :



The following window appears:



The first thing you'll need to do once you've run the report export for the first time is **to import your cover page into the application** for display in your report.

Import cover page



The cover page must be a .PNG or .JPEG image to be imported into the application. If your cover page is in PDF format, there are a number of sites that can convert a PDF into an image (e.g. <https://pdf2png.com/>).

You can drop your header directly into the “No preview” frame by dragging it from your file explorer or by clicking on the “Define cover page” button, which will open an explorer.



When the header is loaded, you'll need to move the written report area so that it is positioned as you wish in relation to the cover page:

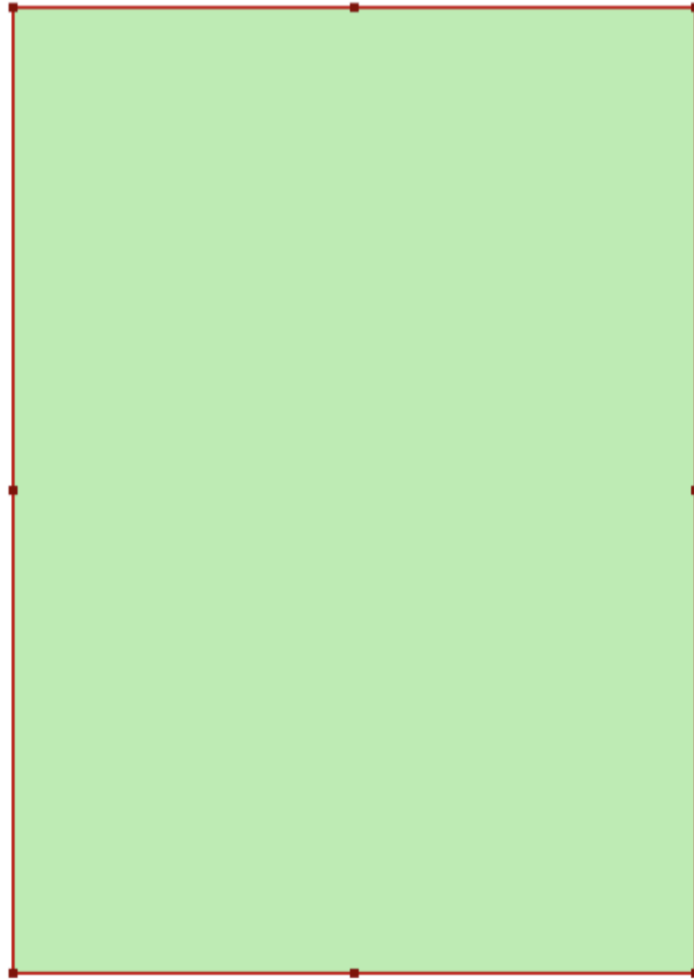
DOCTEUR JOHN DOR
RADIOLOGIST
ORAL AND MAXILLO-FACIAL RADIOLOGY
ANCIEN INTERNE DES HÔPITAUX DE PARIS
ANCIEN CHEF DE CLINIQUE À LA FACULTÉ
ASSISTANT DES HÔPITAUX DE PARIS

2, AVENUE DE CHAMPS ELYSÉE
75008 PARIS

RENDEZ-VOUS : 01-56-56-56-56
URGENCE : 06-06-06-06-06

CONSULTATION TOUS LES JOURS

N° 75 : 62 60783
RPPS : 1000195712



MEMBRE D'UNE A. C. A. - LE RÈGLEMENT DES HONORAIRES PAR CHÈQUE EST ACCEPTÉ

Drag and resize the square on your header to choose where you want to put the text report

Zone is valid

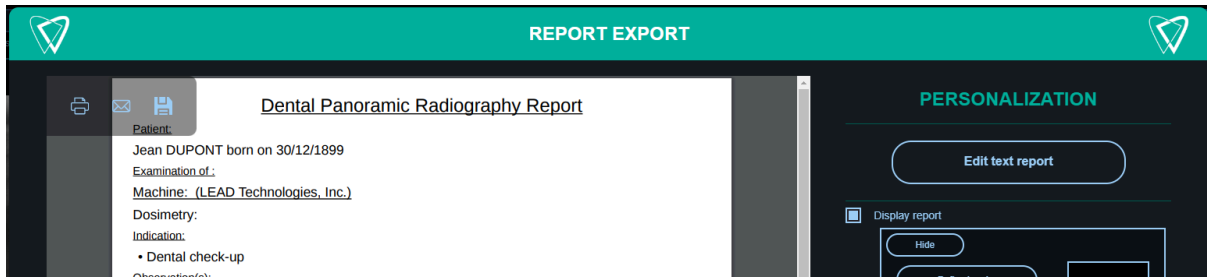
Submit

Cancel

The green rectangle symbolises the minutes text area on your cover page. Move and resize this square to adapt it to your letterhead. Be careful, however, not to make the area too small: if you do, the text area will change from Green to Red.

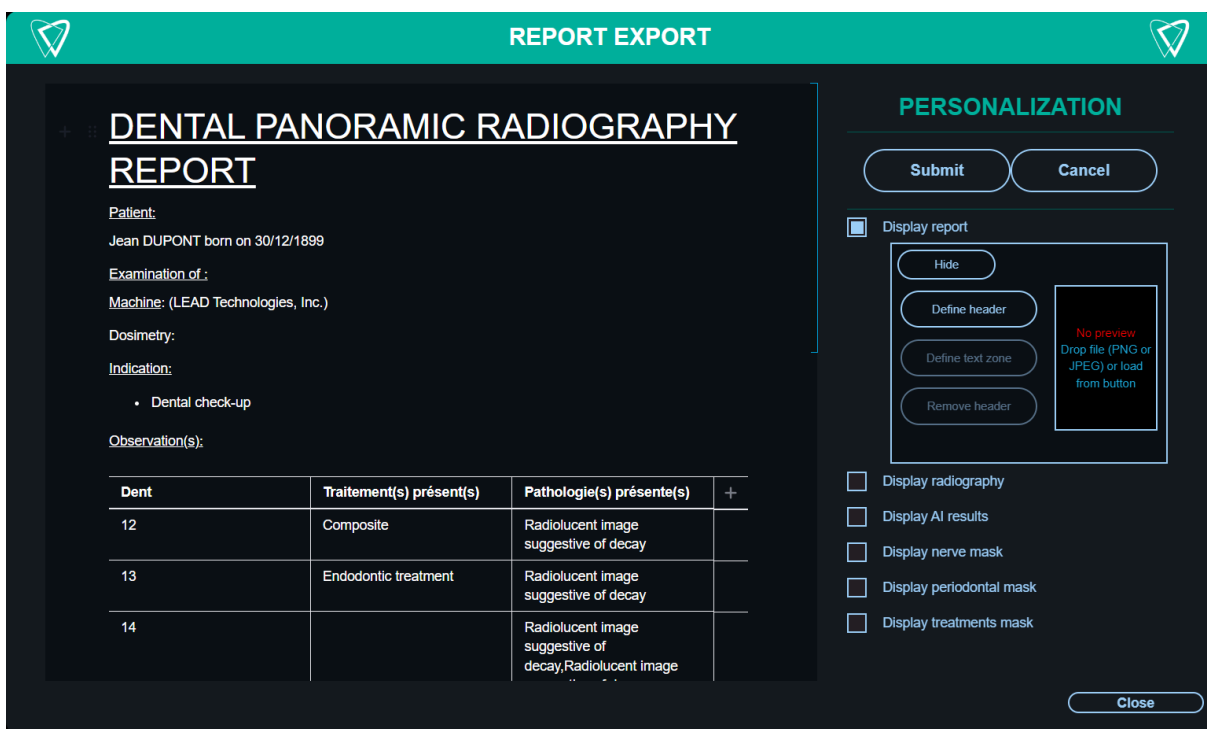
The **report** is an automatically generated text. It contains the information required to produce a complete radiology report, such as patient details, dosimetry and the results of the artificial intelligence you have previously validated.

This automatically generated text can be modified by clicking on the “Edit text report” button.



Modification of the written report

Use this editing mode as you would any text editor. Once you're done, click on Validate and your changes will be applied directly in the PDF preview. Click on Cancel to return to the written report before modifications.



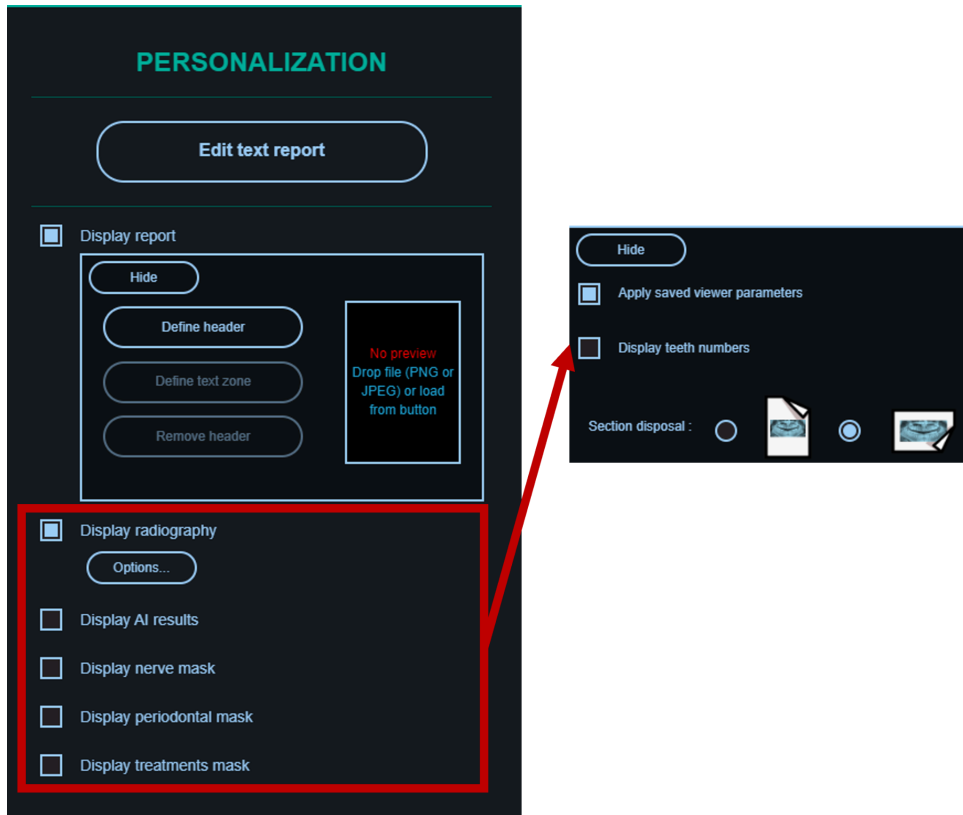
Display option and import type

You can choose to display on your PDF :

- The native radiograph as imported into WeDiagnostiX
- X-ray and analysis results (with legend to help understand indications)
- X-ray and nerve mask
- X-ray and periodontal mask (with dental diagram)

- **X-rays and treatment masks**

Decide whether or not to display these images on your document by checking the boxes to the right of the window:



For each image display, you will have the following options (by clicking on the Options button below the corresponding box)

- **Apply viewer settings (brightness, contrast and sharpness changes saved on viewer display)**
- **Apply viewer settings (brightness, contrast and sharpness changes saved on viewer display)**
- **Set the image in portrait or landscape format on the PDF (landscape format takes up an entire page for one image)**



The radio displayed in the PDF preview does not faithfully reproduce the quality of the final PDF. When the PDF is finally exported, the original image quality will be restored.

Saving display options

The options checked in customize and the header are automatically saved internally in the application. For example, you won't have to import the header for each new export, or check all the display boxes if you want to see all the results on the PDF.

Export options

Once your PDF is complete, it's time to take it out of the application. You have four options:

- **Print**
- **Send by E-Mail**
- **Save (locally on computer)**
- **Export to Logosw**

Send report by email

Hover your mouse over the “Send by...” button and click on “Mail” :

REPORT SENDING

From : antoine.dupont@gmail.com

To : Patient email

Subject : Professor Dupont - Dental radiography report of DUPONT Jean

Body : Hello Madam/Sir,
Please find enclosed the report of your dental examination
Kind regards,
Professor Dupont

PDF Key : UOoTMYJI

Attachment : dupont_report.pdf

Buttons: Rename, Download, Send, Cancel

When sent by e-mail, the attachment is encrypted for security reasons.

You'll find the password to open the pdf above it.

PDF Key : ahYqJEmP

Attachment : dupont_report.pdf

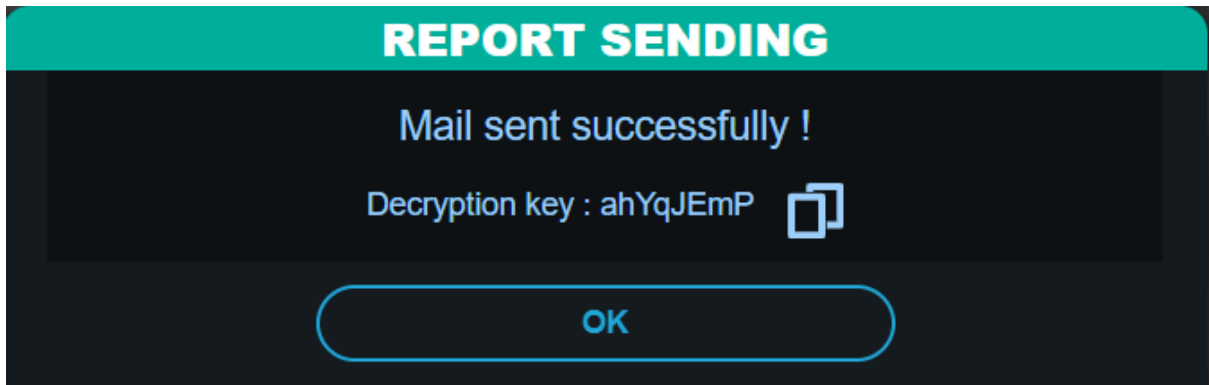
Buttons: Rename, Download

If you are unable to send an e-mail :

- Check that the recipient's address is valid
- Check that your address is valid and that you have entered your mailbox password in the settings, then refer to the Mailing section when creating a Profile.

If the mail has been sent :

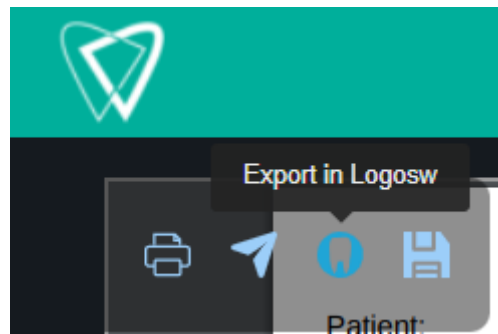
- You should see a popup indicating that the e-mail has been sent successfully, with a reminder of the attached document's encryption password.



Export to Logosw

This option is only available if “Logosw” is selected in Settings, “Workspace” tab -> “Patient management software”.

When the PDF report is open, the option appears at the top left of the window

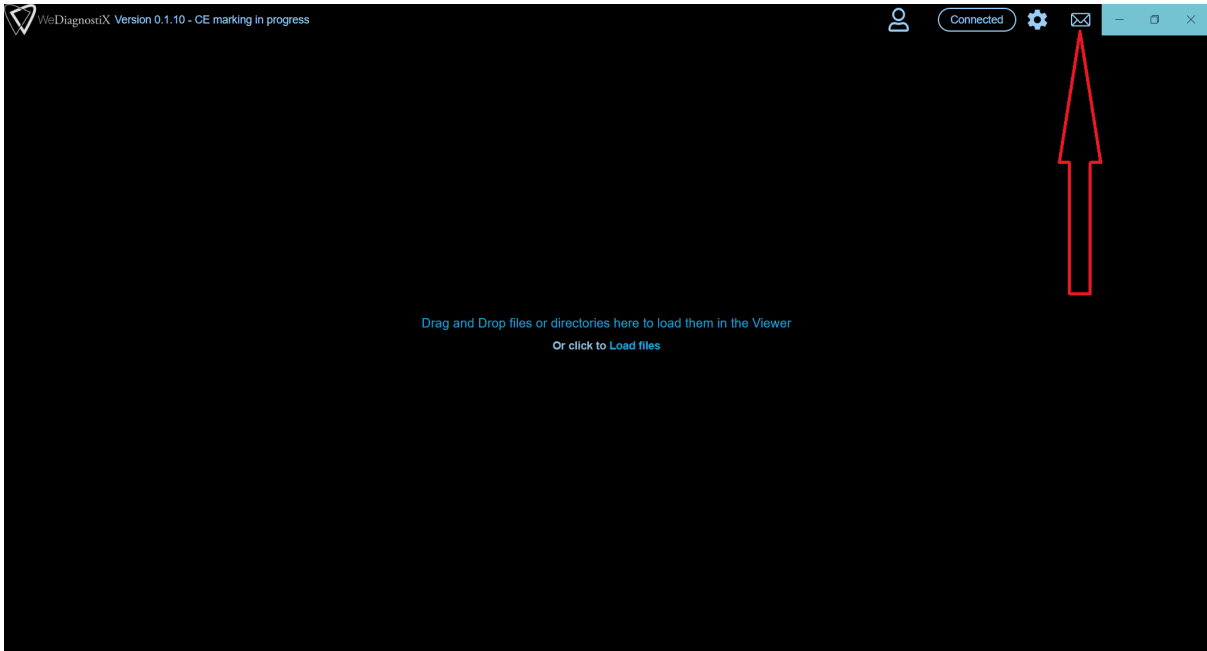


This option allows you to update Logosw's dental diagram and attach the PDF report to the patient file.

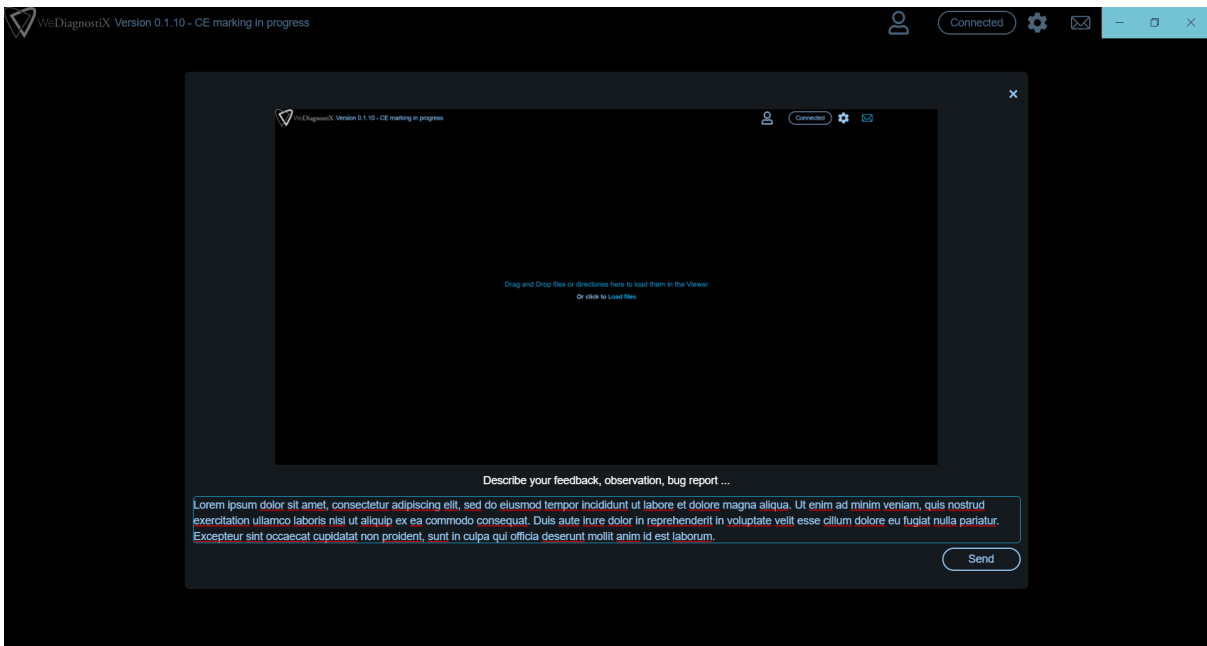
Contact us :

You can use the following e-mail address support@wediagnostix.com or :

Open the contact form by clicking on the envelope icon.



A screenshot of the application is automatically generated. Fill in the form and click on send to send us an email with your feedback.



Uninstalling the software

On Windows, go to the Control Panel, “Add and Remove Programs” tab, then look for WeDiagnostiX in the list, click on the “...” and choose Remove.

Open the Control Panel :

- Click on the Start button (bottom left of your screen).

- Type Control Panel in the search bar, then select it from the results.

Accessing installed programs :

- In the Control Panel, select Programs.
- Then click on Programs & Features. This will take you to a list of all the programs installed on your computer.

Find the program to remove :

- Scroll down the list of programs to find WeDiagnostiX (or type it into the search bar).
- Once you've found a program, click on it to select it.

Uninstall the program :

- After selecting the program, several options will appear. Click on the Uninstall button at the top of the list.
- A confirmation window may appear, asking you to confirm the uninstallation. Click Yes or Confirm to continue.

Finalise deletion :

- Follow the on-screen instructions to complete the uninstall procedure. The process may take a few minutes, depending on the size of the program.

Electronic user manual

This manual is supplied in digital format and can be downloaded, or the latest version can be downloaded from www.wediagnostix.com/en/user-manuel/

A printed version of the manual is available free of charge on request, please contact the manufacturer.

CE Declaration

WeDiagnostiX is a Class IIa medical device in accordance with EU Regulation 2017/745.

The CE declaration for this device is available on request.

The medical CE was first affixed to this device on (date).

Manufacturer

WeDiagnostiX
7 allée des Genêts
92420 Vaucresson
FRANCE
www.wediagnostix.com

Revision history

Version	Date	Modification
01	24/08/2024	Issuing of the document