



DentIA

Instructions for the use of DentIA

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1. MANUFACTURER INFORMATION



Infomed Software, S.L. (hereinafter "INFOMED")
Via Augusta, 158 - 4ª Pta, 08006, Barcelona <https://www.grupoinfomed.es/>

2. DEVICE IDENTIFICATION



Medical Device Software (MDSW)
Commercial name: DentIA
Catalogue reference: 10

3. EXPECTED USE AND PRODUCT DESCRIPTION

a. Intended purpose

DentIA Software is a medical image and management processing system (MIMPS) based on neural networks, designed to assist dental professionals (users), including general dentists, in detecting dental structures and pathological findings, as well as in the processing of dental record data based on the interpretation of 2D intra oral and extra oral X-ray images.

b. Medical condition(s)

Oral health conditions.

c. Intended patient population

Only for adult population (≥ 18 years of age and without remaining primary teeth).

d. Intended users

Licensed dental professionals (dentists) or radiologists. The intended use of this product is for professionals with a high level of expertise in medical imaging.

e. Indications

DentIA software is intended for:

- Analysing dental X-rays in three forms: orthopantomographic (OPG), bitewing (BTW) and periapical (PPL).
- Processing images in PNG and JPEG formats.
- Identifying the following findings based on the form of imaging:

Type of X-ray	Natural dental structures	Possible pathologies	Previous treatments	Anatomy	Bone level measurement
Panoramic	Teeth (present and absent) Impacted teeth Bone line Periodontal line	Tooth decay Periapical radiolucency Plaque	Fillings Crowns Pontics Root canal treatment Implants	Maxillary sinuses Mandibular nerves Temporomandibular articulation	-
Bitewing	Teeth (present) Bone line Nerve Enamel Crown Root Bone Crown (top of the dentine)	Tooth decay Plaque	Fillings Crowns Pontics Root canal treatments Implants	-	Mesial and distal bone levels

Type of X-ray	Natural dental structures	Possible pathologies	Previous treatments	Anatomy	Bone level measurement
	Root (bottom of the dentine)				
Periapical	Teeth (present) Bone line Nerve Enamel Crown Root Bone Crown (top of the dentine) Root (bottom of the dentine)	Tooth decay Periapical radiolucency Plaque	Fillings Crowns Pontics Root canal treatments Implants	-	Mesial and distal bone levels

- When the pixel size of the image is known, the difference in bone levels at the mesial and distal sites can be represented according to the following thresholds. If no measurement is available for the detected bone level, it will be shown as a white line.

Colour	Bitewing X-ray	Periapical X-ray	Periodontal stage
Green	<3 mm	<15%	Stage 1
Yellow	3 mm-4 mm	15-24%	Stage 1/2
Orange	4 mm-5 mm	24-33%	Stage 2
Red	>5 mm	>33%	Stage 3/4

- Automatically generating dental graphics from image analysis, with the possibility of manual editing by the practitioner.
- Applying exclusively to the oral cavity, including the oral vestibule and associated bone structures: the jaw, maxilla, and palatine bones.
- Use only in adult patients (≥ 18 years) with no remaining primary teeth.

f. Product description and performance characteristics

DentIA is a neural network-based medical device software designed to assist dental professionals in the analysis and interpretation of dental X-ray images. The software uses advanced algorithms to detect, segment and classify clinically relevant findings in X-rays, thereby facilitating diagnosis and clinical decision-making. DentIA is designed to process and analyse three types of dental X-ray images: panoramic, periapical and bitewing .

The DentIA system is available in two configurations:

- Full settings: includes the product's back-end and front-end. The front-end is the user interface, where the user can view the results of the analysis.
- Integration settings: this provides only the back-end for integration into third-party software systems, enabling developers and technology providers to incorporate DentIA's X-ray analysis function into their own platforms, where the visualisation and management of results are handled via the third-party platform.

DentIA generates structured results, including the coordinates of the boundary rectangles and the labels. Among the conditions that DentIA can detect are tartar, pontics, implants, tooth decay, periapical radiolucencies, crowns, fillings, root canal treatments and impacted teeth. It also identifies key anatomical structures, such as the mandibular nerves, the maxillary sinuses, the temporomandibular joint, the bone line and the periodontal line. In the case of periapical and bitewing X-rays, it can provide measurements of the mesial and distal bone levels, provided the pixel size is known. The dentist can use image enhancement features (zoom and filters) on X-rays to aid clinical interpretation. DentIA can also be used to select the appropriate treatment option from a predefined list and generate a comprehensive report containing all the relevant information, thereby improving communication with the patient.

DentIA is not intended to replace professional judgement, but serves solely as a complementary tool, providing AI-generated results that enhance efficiency, consistency and accuracy in X-ray interpretation.

g. Clinical benefits

Dentia provides clinical benefits by supporting dental professionals in the analysis and interpretation of dental

radiographic images, contributing to improved efficiency, consistency, and quality of radiographic assessment within routine dental practice.

The software assists clinicians in identifying dental structures, pathological findings, and previous restorative treatments, facilitating more comprehensive radiographic evaluation. By automatically highlighting relevant findings and providing measurements such as mesial and distal bone levels, DentIA supports earlier and more reliable detection of dental and periodontal conditions, thereby contributing to more informed diagnostic and treatment-planning decisions.

Additional clinical benefits include reduction of interpretation variability, improved workflow efficiency, and enhanced communication with patients through visual representation of findings. These features may support timely clinical management and improved monitoring of oral health conditions.

Dentia functions solely as a decision-support tool and does not replace clinical judgment; final diagnostic and therapeutic decisions remain the responsibility of the dental professional.

h. Counter-recommendations

	• Using the device outside the specified patient population, clinical indication or X-ray setting. • Relying on the results of artificial intelligence as a substitute for clinical judgement or a thorough analysis of the images. DentIA should not be used as the sole source of information for making medical decisions. • Providing poor-quality or unsuitable input data, such as incompatible formats or low-quality images. • Allowing untrained or unauthorised staff to use the system without adequate supervision or controls.
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i. Residual risk

	• This product is intended for professionals with a high level of knowledge in medical imaging. • It is important to read the minimum usage requirements (section 7) before using the software. • If improvement tools are used to their limits, they can be misleading. • The professionals designated to use the application are responsible for the diagnosis. The AI result should not be used as the sole basis for providing a diagnosis.
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j. Undesirable side-effects

	There are no undesirable side effects associated with the use of this software, provided that the instructions for use and counter-recommendations are followed. Please also refer to section “06. Error and warning messages”. In the event of a medical incident related to the use of DentIA, contact gara@grupoinfomed.es. You must also notify the competent area health authority.
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k. Training requirements

There are no specific training requirements for intended users. The software has been developed to achieve an intuitive and user-friendly interface that ensures its correct handling as long as point no. “04. Recommendations and indications to ensure correct use” of these instructions is followed.

Furthermore, there are specific expertise requirements for the professionals responsible for installing the software. These requirements, together with other useful information, can be found in section “7. Minimum operating requirements”, of this manual.

4. RECOMMENDATIONS AND INDICATIONS TO ENSURE CORRECT USE

- An internet connection is needed to use DentIA.
- Make sure the hardware device from which you want to use DentIA is connected to a network with access to the DentIA server, according to the hardware device manufacturer's specifications. If in doubt, please consult the hardware device manual provided by the manufacturer. This implies having a hardware device that comes up to the minimum software requirements, and maintaining it.
- Before using DentIA, read the Instructions for Use provided with the software.
- Please check that the version of the instructions for use matches the version of DentIA you have available. This check can be made on the website: <https://www.dentiasoftware.com>.
- For correct operation, DentIA requires a stable connection between the browser from where it is used and the DentIA server, as well as the use of a web browser compatible with the software as per the minimum requirements indicated in point 7.
- Pay close attention when using DentIA, especially when interpreting the findings in the software. Any distraction may lead to a misunderstanding of the results provided by DentIA and result in an incorrect decision regarding possible diagnoses or interpretations.
- DentIA will only work with the X-rays of the patient previously selected in the Practice Management Software (PMS). DentIA will not close the browser tab automatically. Therefore, we recommend that after you finish working with DentIA X-rays, you close the browser tab.
- For the software to display the measurement between the mesial and distal levels, the image must include information on pixel size.

As it is a web-based product, it can only be accessed via a web browser on the relevant device. Infomed guarantees its correct functioning through browsers with Chromium engines ("[Google Chrome](#)" and "[Microsoft Edge](#)") version 132 or higher.

If you are using another type of browser, Infomed accepts no liability for any issues that may arise during its use. For this reason, and to ensure the best possible user experience, we recommend using Google Chrome or Microsoft Edge. Using other browsers does not prevent you from accessing DentIA; however, we cannot guarantee that they will function correctly or provide an optimal user experience.

The software operation instructions are detailed in section no. 11 of this manual, as well as the types of files that the user will be able to manage, either with DentIA or through third-party applications.

5. INFORMATION ALLOWING HEALTHCARE PROFESSIONALS TO VERIFY WHETHER THE DEVICE IS SUITABLE AND SELECT THE CORRESPONDING SOFTWARE AND ACCESSORIES

- DentIA should be used strictly for its intended purpose as described in section no. 3 of this manual.
- DentIA has been designed to work and be integrated with dental clinical patient management software (PMS) or image management software in dental practice environments.
- DentIA does not require the use of accessories.

6. ERROR AND WARNING MESSAGES

	Listed below are the error messages and warnings that could appear in the software, with a brief explanation of each one and the actions to be taken by intended users. In the software, errors appear in red and warnings in orange. The following table provides details on the specific actions performed in the software that may cause errors or warnings to appear, and indicates their location within the manual.
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a. Warnings and precautions

- Make sure always to access with the recommended browser.
- Infomed accepts no responsibility for the confirmation of the findings.
- Only for professional use with a high level of medical imaging expertise.
- Precautions related to cybersecurity:
 - Make sure you have an active and up-to-date anti-virus on your computer.
 - Use strong passwords (e.g. combinations of letters, numbers and symbols) and avoid sharing them.
 - If you are an administrator, enable two-step verification to access advanced features.
 - DentIA only works over encrypted connections (HTTPS), similar to those that protect on-line banking transactions.
 - DentIA does not store patients' personal information (such as names or addresses).
 - The medical files (X-rays, 3D models) you upload or generate are your practice's responsibility.
 - No additional network configurations are required to use the software securely.
 - DentIA is automatically updated to fix vulnerabilities and improve performance.
 - DentIA works with backup protocols (SMO Plan) to quickly recover the service in the event of incidents.
 - If you notice strange behaviour (e.g. unexpected errors or unauthorised access), contact us immediately at soporte@infomed.com. Report any concerns to our support team.

b. Error messages / Warnings

IFU section	Error / Warning	Meaning	Actions to be taken by the user
9. Start of DentIA and analysis	We were unable to analyse your image. To continue, go back to the start and choose a new image.	The image cannot be analysed because the X-ray type is not valid or it is a bad quality image.	Go back to the start and choose a new valid image (panoramic, bitewing or periapical and of good quality)
9. Start of DentIA and analysis	We have detected a problem with your Internet connection. Please, check your computer's Internet connection.	The software was unable to establish a connection to the server necessary to process the image. As a result, the image has not been analysed.	Make sure the device is connected to the internet and try again.
9. Start of DentIA and analysis	PROCESSING IMAGE. Please wait.	The system is in the process of analysing the image, which may take a few seconds.	Wait for the process to be completed. Do not close or reload the page to avoid interruptions.
9. Start of DentIA and analysis	Are you sure you want to process the image again? If you accept, you will lose all changes.	The user is about to restart image processing, which will remove any previously made changes or analysis.	Confirm only if you want to restart from scratch. Otherwise, cancel the action to keep the current changes.
13. Patterns	Are you sure you want to return to the pattern list? If you accept, you will lose all changes.	The user wants to leave the current view; if you confirm you will lose any unsaved changes.	Confirm only if you do not need to keep the changes. Save before leaving if necessary.
13. Patterns	By confirming, you are verifying that the patterns shown in the image are correct.	This message is shown when tartar is present.	Review the findings before confirming the analysis.

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7. MINIMUM OPERATING REQUIREMENTS

DentIA is a medical device that does not require installation by the intended user as it is a cloud-based product. All the requirements that the customer's device must meet in order to use the product are set out in the Product Technical Description (REG.7.3-02-04-DHF-10-TDM).

8. INSTALLATION RECOMMENDATIONS AND MAINTENANCE

DentIA is maintained by INFOMED. Additionally, as a Medical Device Software (MDSW or SaMD), there are no consumable or fungible elements that need to be used with the product

Section "7. Minimum operating requirements" provides detailed information on the conditions required for product use and maintenance, which the customer must comply with in order to use it.

9. START OF DENTIA AND ANALYSIS

From the image management software, the user will select a patient and an image and upload the relevant X-ray in image format. Once the user is in the context of the patient's record with access to the image(s), the DentIA application will be launched from the image itself.

The first time a user logs into DentIA, the product label will be displayed. The user can select the “Do not show again” option. Additionally, when launching the software after a version update, the home page will display a message indicating that the product has been updated, along with a link to the Release Notes so the user can review the changes associated with the new version.

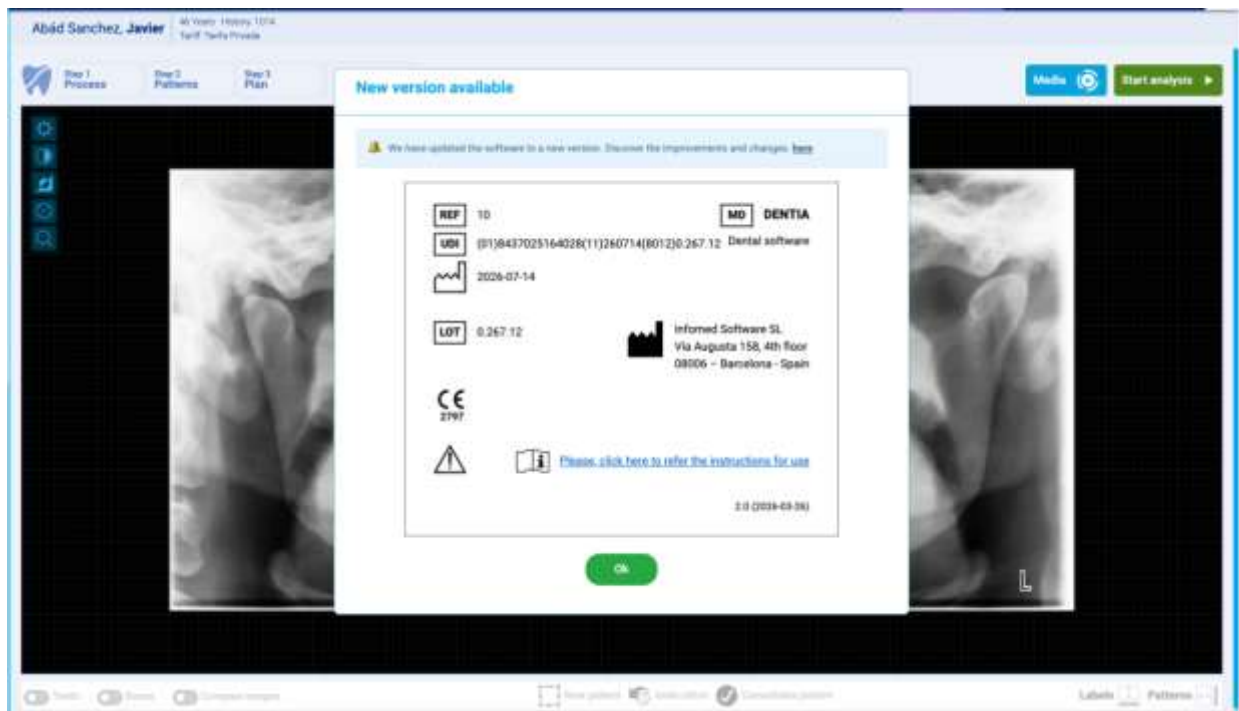


Fig. 1 The first time a user logs into a new DentIA version, the product label will be displayed.

From the DentIA icon in the upper-left corner of the screen, the product label can be displayed again on demand.



Fig. 2 Label access from top-left icon.

When the tab is closed, in the cases where it has been displayed; otherwise, automatically, the analysis will start and a “spinner” will appear, indicating that the image is being processed by the AI.

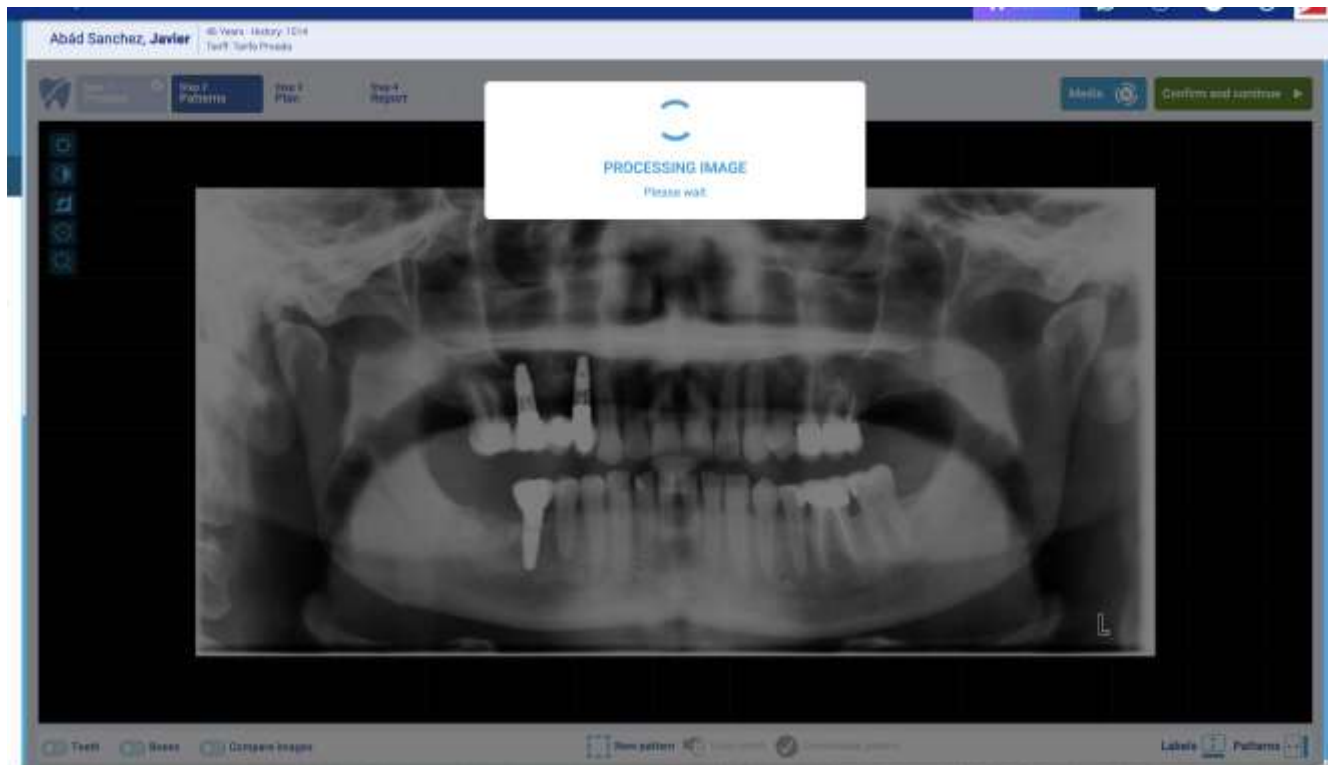


Fig. 3 When you open DentIA, the image analysis begins

Depending on the internet connection and the quality of the image, the process can take anywhere a variable time. Once the analysis is finished, the image will be displayed along with the different patterns detected.

10. DENTIA STRUCTURE

Within DentIA, you will find the following sections (see Fig. 4):

1. Image uploaded for study
2. Progress bar
3. Tools to improve image display
4. Access to multimedia information
5. Button to proceed to the next step
6. Bottom bar for viewing/editing labels and/or patterns

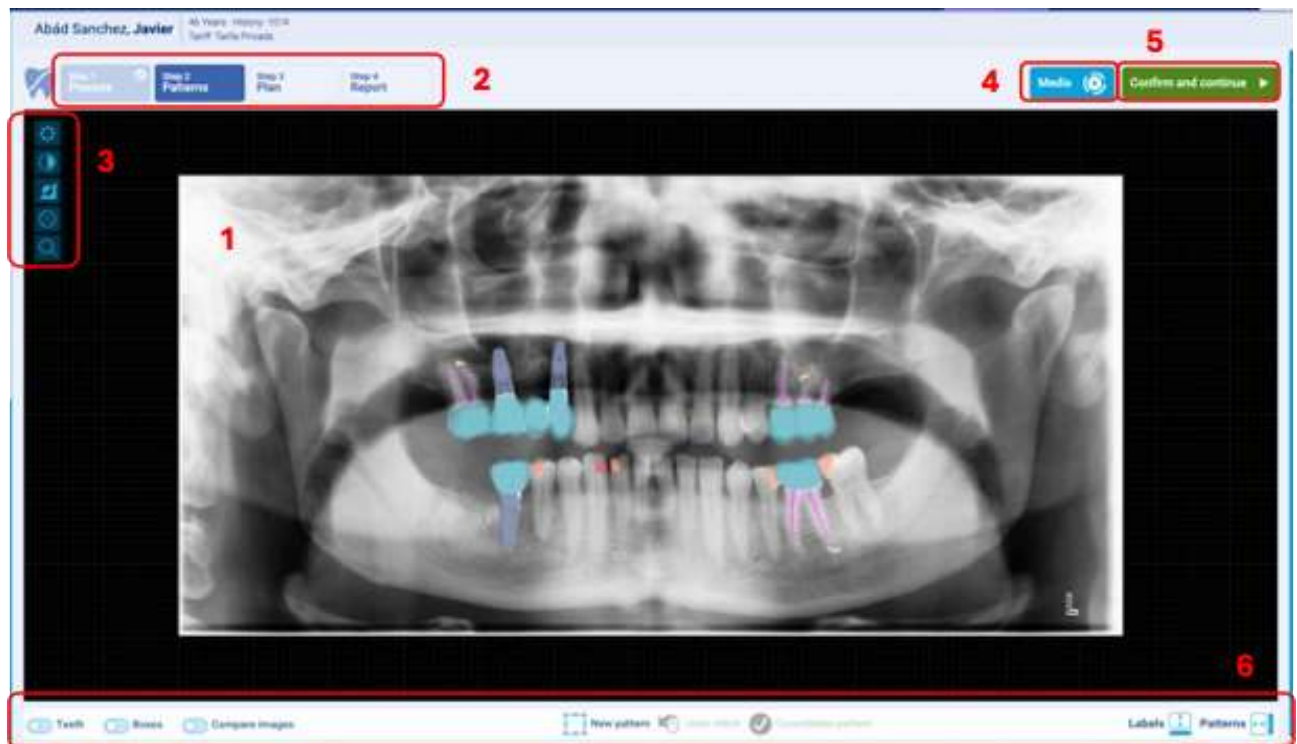


Fig. 4 DentIA structure

11. IMAGE VIEWING TOOLS

Below are the tools for improving image display:

a. Brightness

Clicking on the brightness button will enable a horizontal scrolling bar where the user can adjust the brightness level on the image, both negative and positive. You can reset the brightness to its default levels using the button on the right-hand side of the bar.

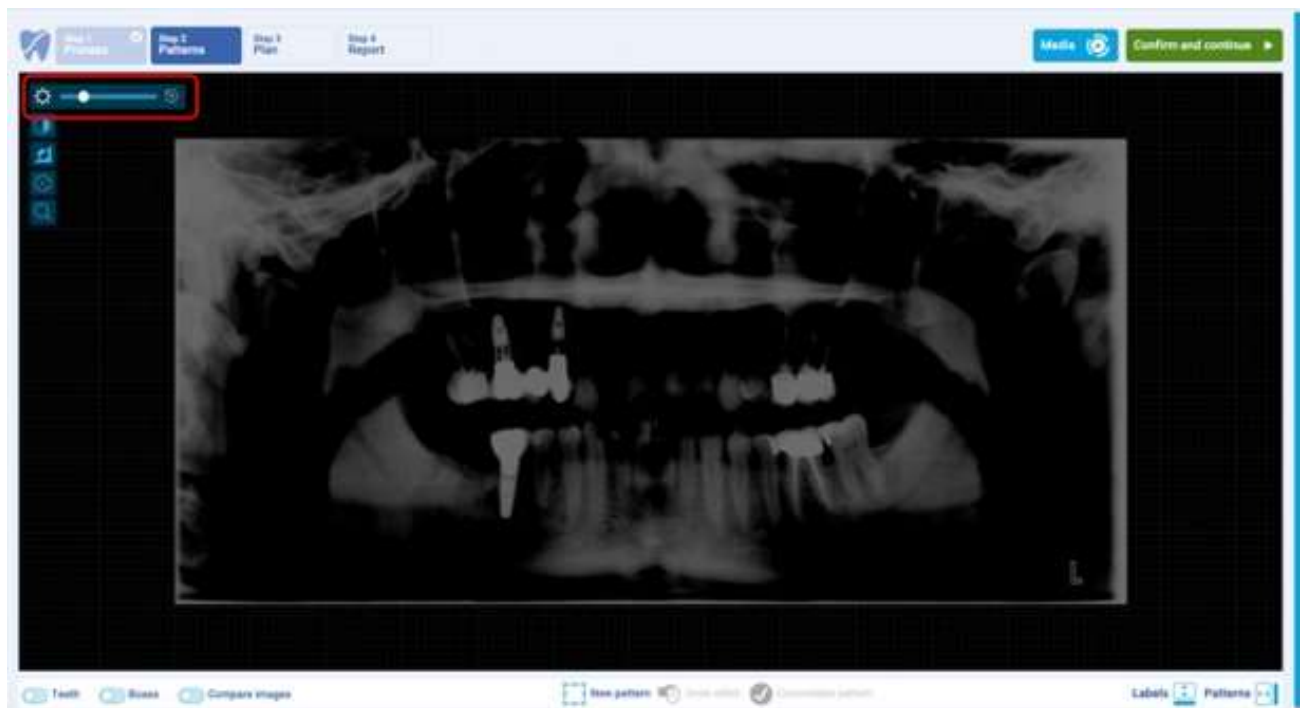


Fig. 5 Brightness adjustment

b. Contrast:

Clicking on the contrast button will enable a horizontal scrolling bar where users can adjust the contrast level on the image, both negative and positive. You can reset the contrast to its default levels using the button on the right-hand side of the bar.



Fig. 6 Contrast adjustment

c. Invert colours:

Pressing the invert colours button will invert the colours of the image. Pressing the button again will restore the original colours of the image.



Fig. 7 Colour inversion

d. Magnifying glass:

By pressing the magnifier button, the device pointer will appear with a magnifying glass. Useful for viewing some detail of the image without the need to zoom in on the whole X-ray.

A horizontal scroll bar is also enabled here that will allow more or less zoom to be applied to the magnifying glass. With the button at the end of the bar, the zoom level of the magnifying glass will be reset to the default levels.

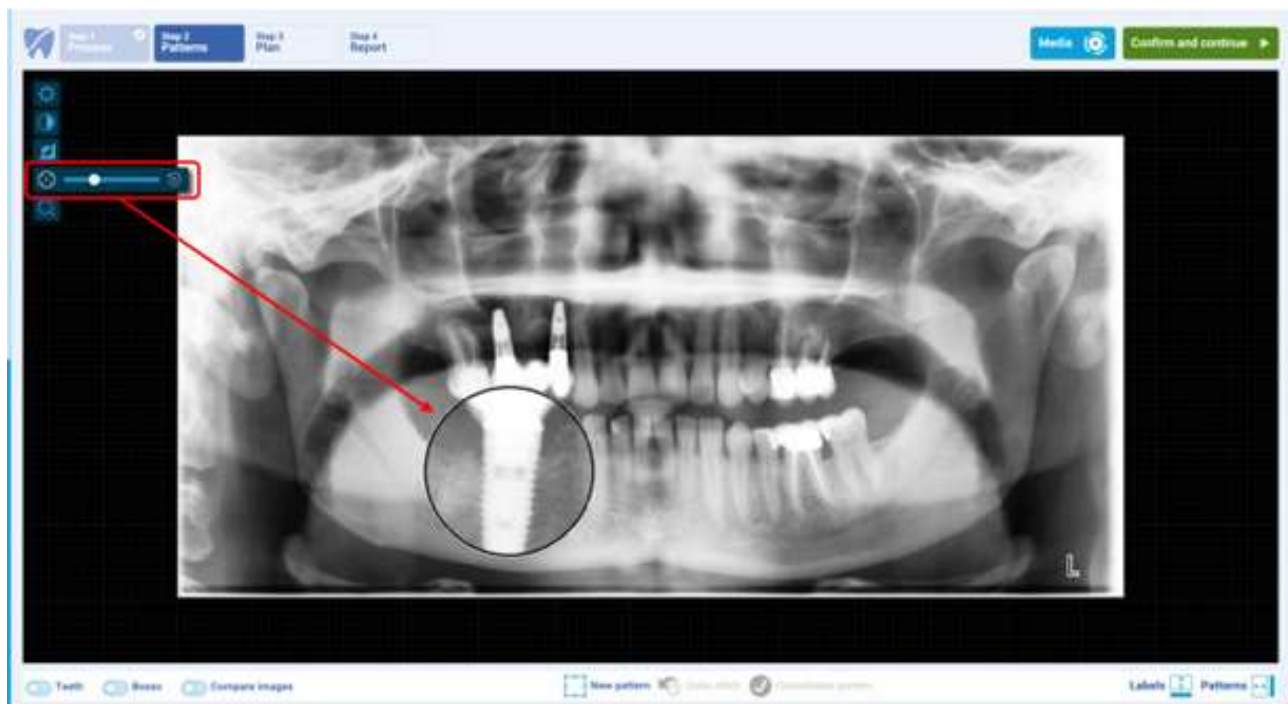


Fig. 8 Using a magnifying glass

e. Zoom:

With the zoom button, a horizontal scroll bar is enabled which allows the user to adjust the zoom level over the entire image. By holding down the device's pointer on the image whilst zooming, the user can pan the zoom across the image. With the button at the end of the scroll bar, the zoom level will be reset to the default levels.



Fig. 9 Using the zoom

All of these options only make temporary visual modifications to the image in order to allow the user to improve the display. These changes do not alter the original image in any way.

If closing or quitting the application, when reloading the DentIA software with the same image, it will appear in its original state.

12. REVIEW OF THE ANALYSIS

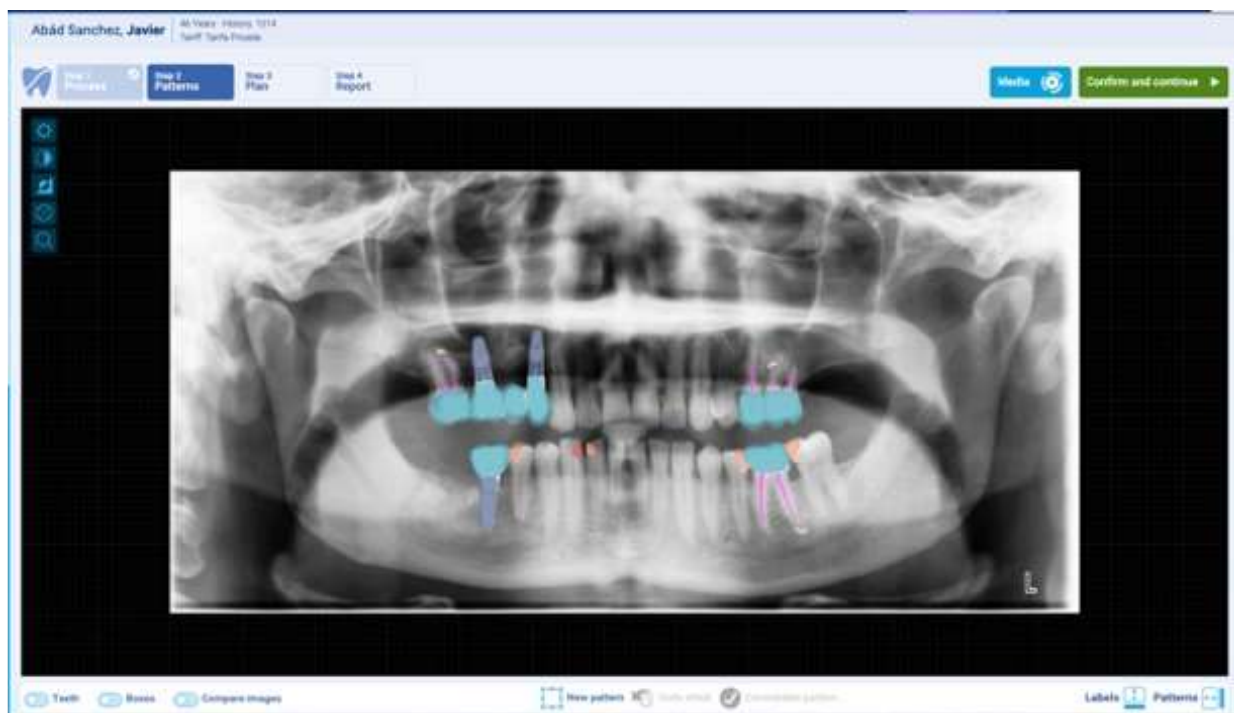


Fig. 10 X-ray with analysis made

At this point the process is at “Step 2. Patterns”. This is where users can corroborate the detected patterns, eliminate patterns that they consider erroneous or inconsistent, or even create a new pattern according to the practitioner's experience, skill or interpretation of the image.

Before proceeding to the next step, let's take a look at the different label and pattern tools at the bottom of the application.

a. Teeth:

It allows the teeth numbers to be viewed on the image based on the AI interpretation. The teeth numbers will be shown/hidden by clicking on the button.



Fig. 11 X-ray with teeth numbers

b. Squares:

When this option is selected, instead of seeing the patterns superimposed on the image, the areas where patterns have been detected are highlighted with rectangles, allowing the original image to be viewed whilst showing where a pattern is present.

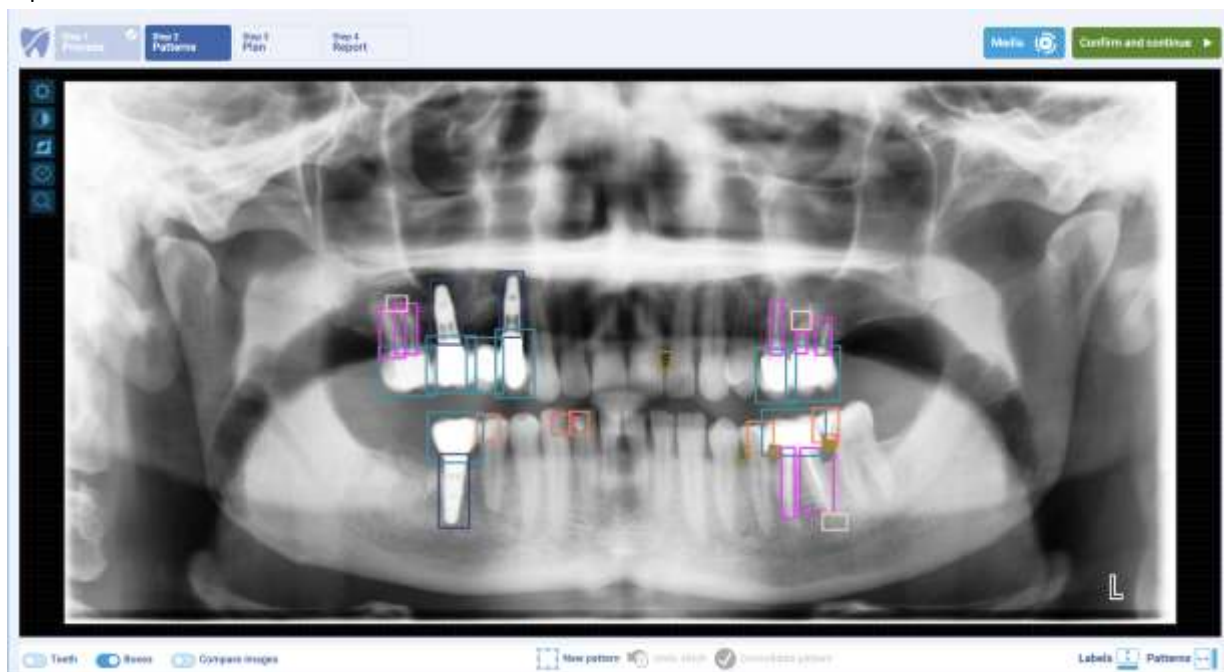


Fig. 12 X-ray with patterns marked by rectangles

c. Compare image:

When this button is activated, a vertical scroll bar will be enabled, allowing the users, as they move it to the right, to hide the pattern drawing in order to be able to see the original image. This function is useful when users want to compare whether the detected pattern actually matches the practitioner's own interpretation.



Fig. 13 Using the comparison bar

As the vertical bar is moved to the left again, the patterns proposed by DentIA will be displayed.

13. PATTERNS:

All patterns detected by DentIA will be labelled accordingly.

By clicking on the "Patterns" option in the bottom bar, a side menu of all detected patterns will be displayed, regardless of whether the corresponding labels are visible.

Patterns are ordered by default by tooth number, in rising order.

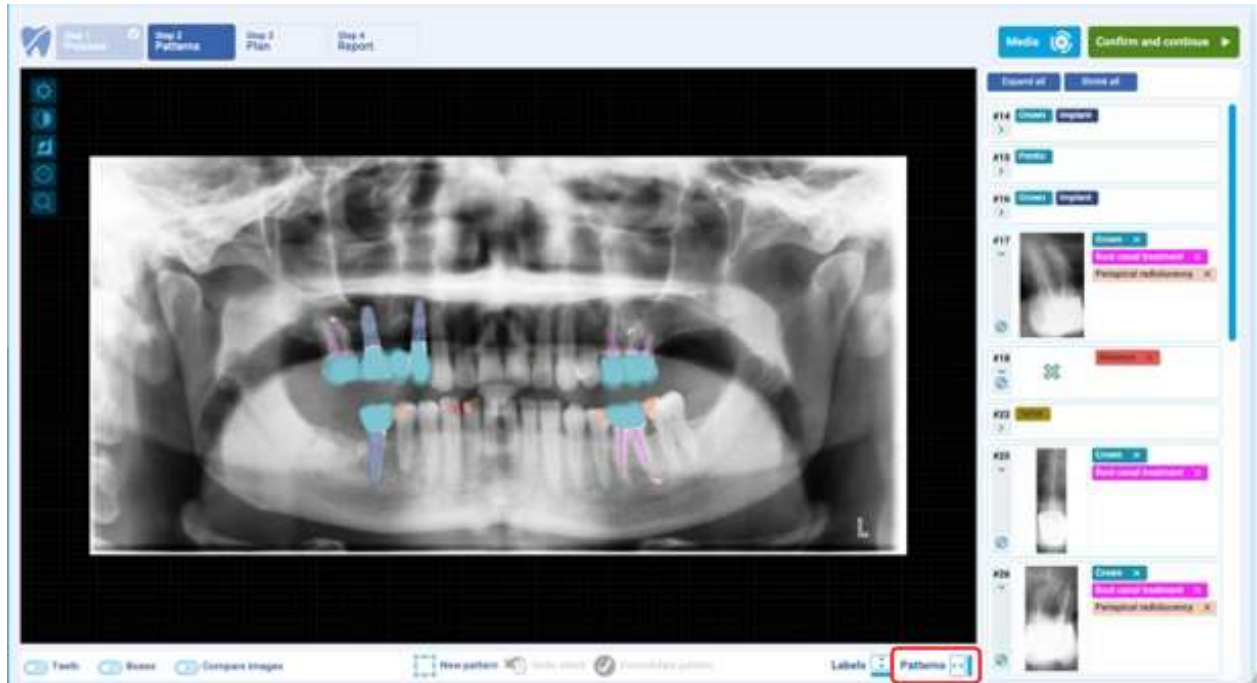


Fig. 14 X-ray and list of patterns

a. Collapse/Expand patterns:

With the top buttons of the pattern menu, users can collapse or expand the list of detected patterns.

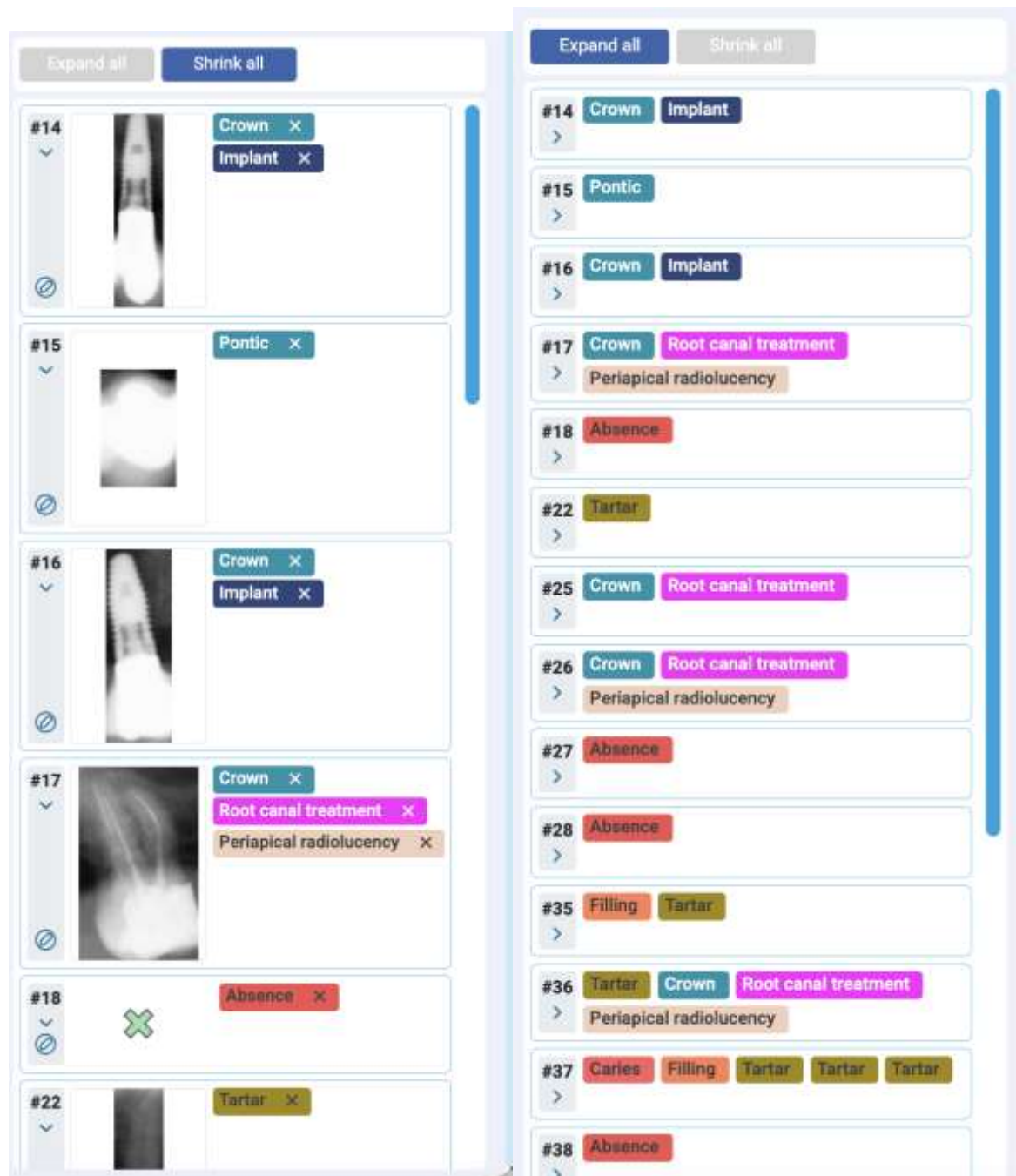


Fig. 15 List of patterns

For each pattern, the image corresponding to the affected tooth will be shown, allowing the user to locate the pattern on the X-ray on which the DentIA study has been performed.

b. Create a new pattern:

Users can create a new pattern, for instance, to document a previous treatment that the patient has already undergone but which DentIA has not detected, or if they suspect an abnormality in a specific tooth. To do this, click on the “New pattern” button in the bottom bar.

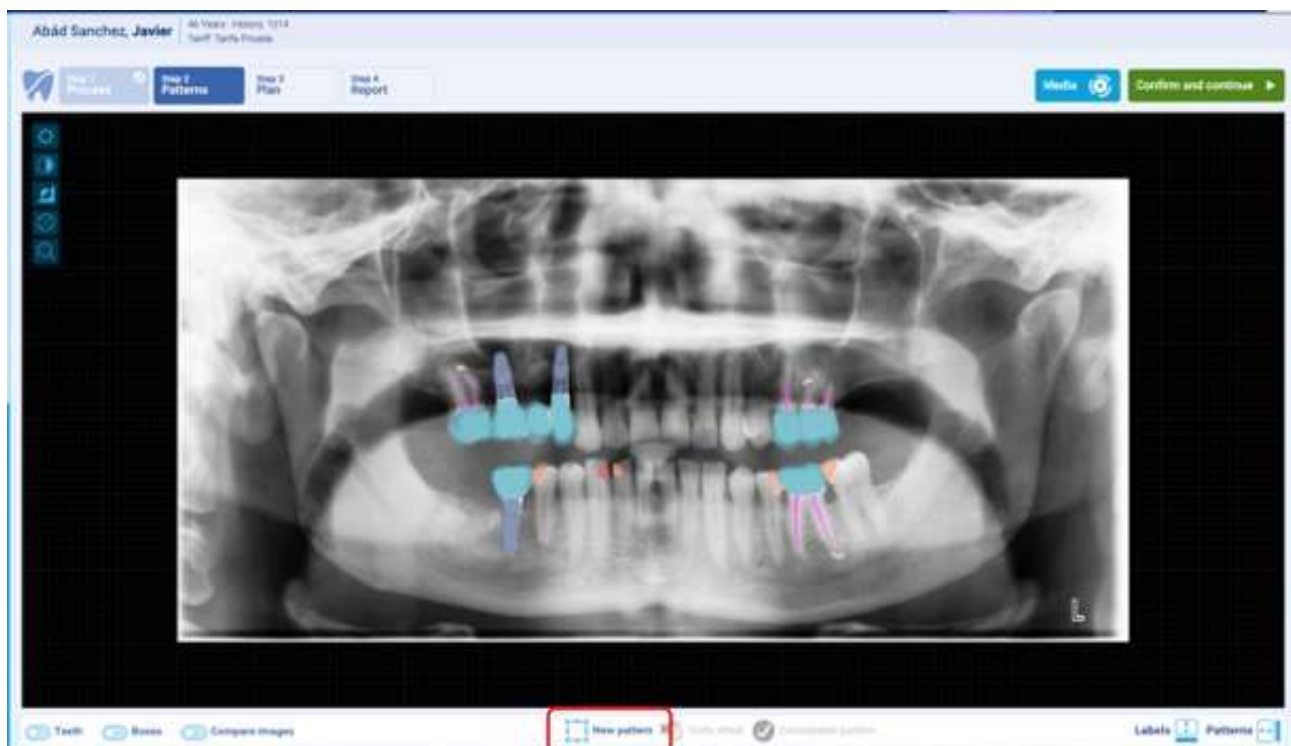


Fig. 16 Creating a new pattern

In the pop-up window, mark the tooth where the pattern is to be created and indicate the type of pattern. Then click on “Draw pattern”.

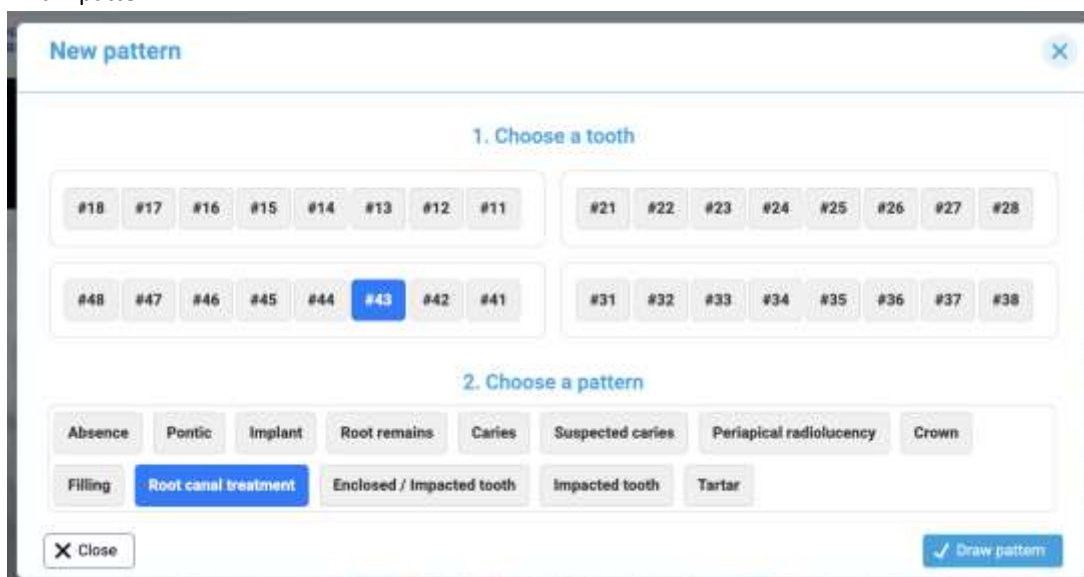


Fig. 17 Choosing the tooth number and the pattern to be created

From here, the pointer will draw the pattern by clicking. The bottom bar contains the “Undo point” button, allowing users to correct a mistake at any point.

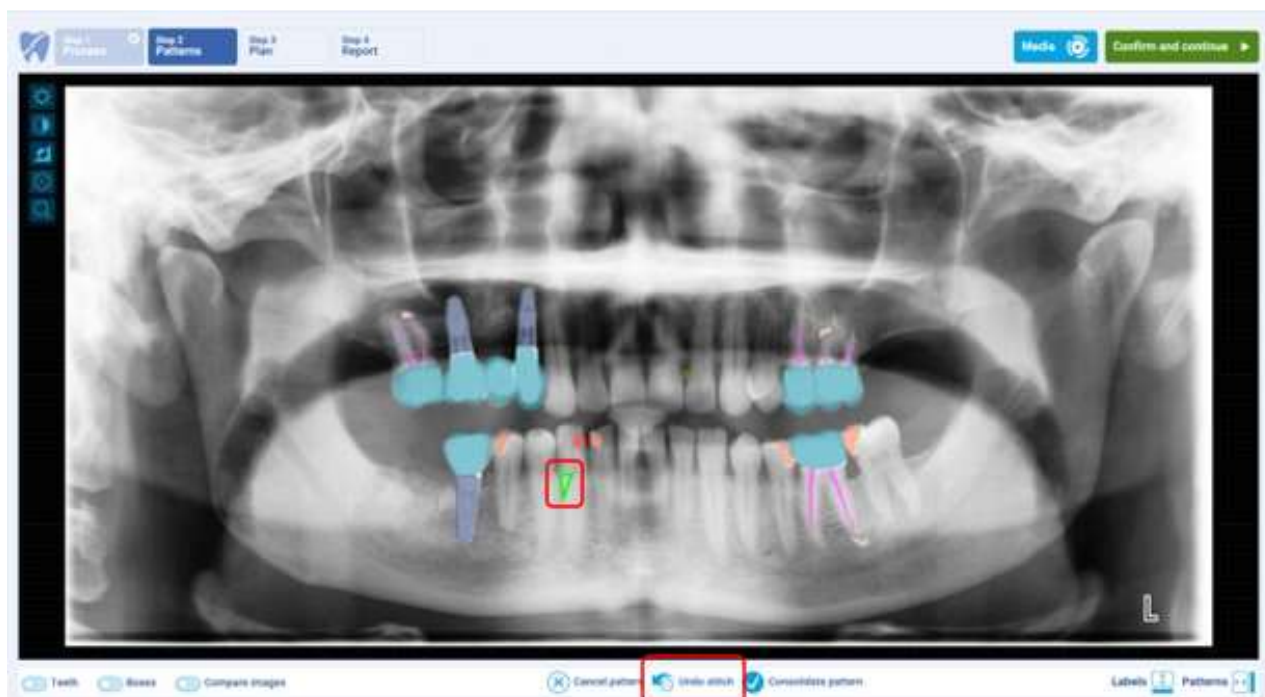


Fig. 18 Undo point

When the pattern is drawn correctly, click on the “Consolidate pattern” button. If the user ultimately decides not to make this pattern, they should click on “Cancel pattern”.

If the pattern has been consolidated, the drawing made will appear in the colour of the chosen label, and this new pattern will appear in the pattern side menu.

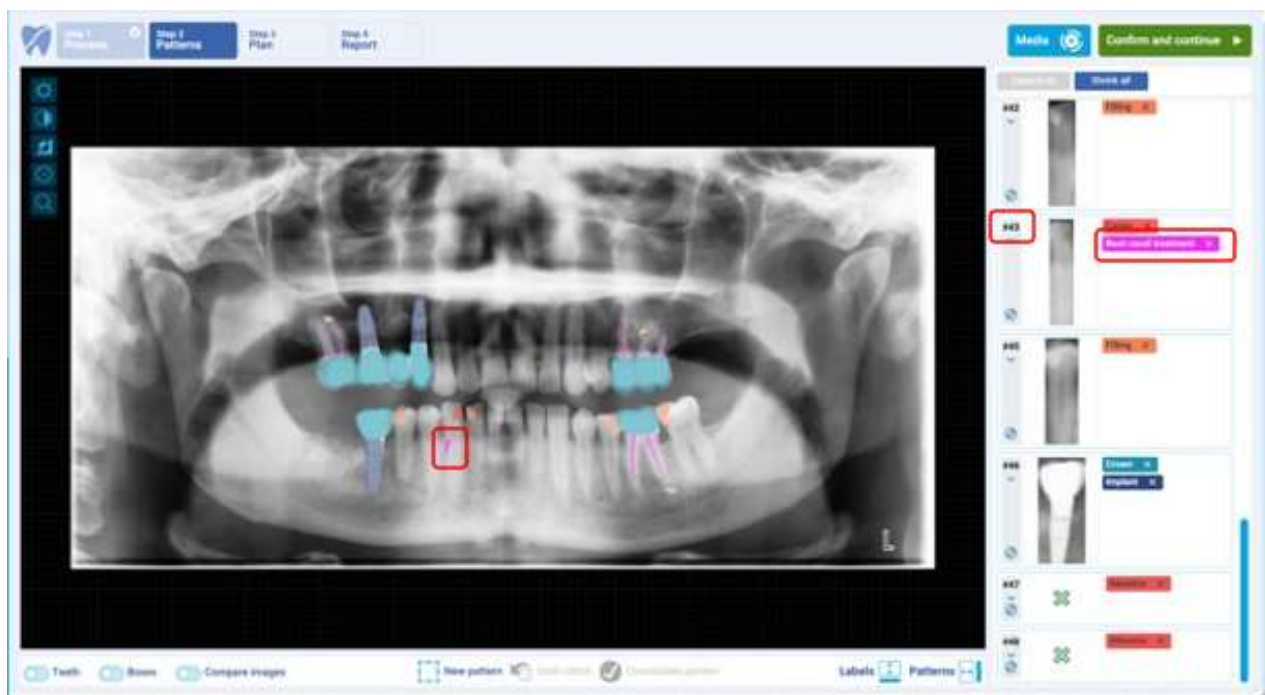


Fig. 19 Consolidated pattern

c. Edit tooth number:

The edit button will be used to change the relevant tooth, if necessary. By clicking on the edit icon in the side menu pattern, the affected tooth can be reassigned.



Fig. 20 Tooth number change

Under no circumstances may the pattern design, whether those detected by DentIA or those generated manually, be altered. If you need to modify the design, it is advisable to delete the pattern and create a new one.

d. Delete pattern:

To delete a pattern, locate the pattern you wish to remove in the side menu, then tap the delete icon on the label.

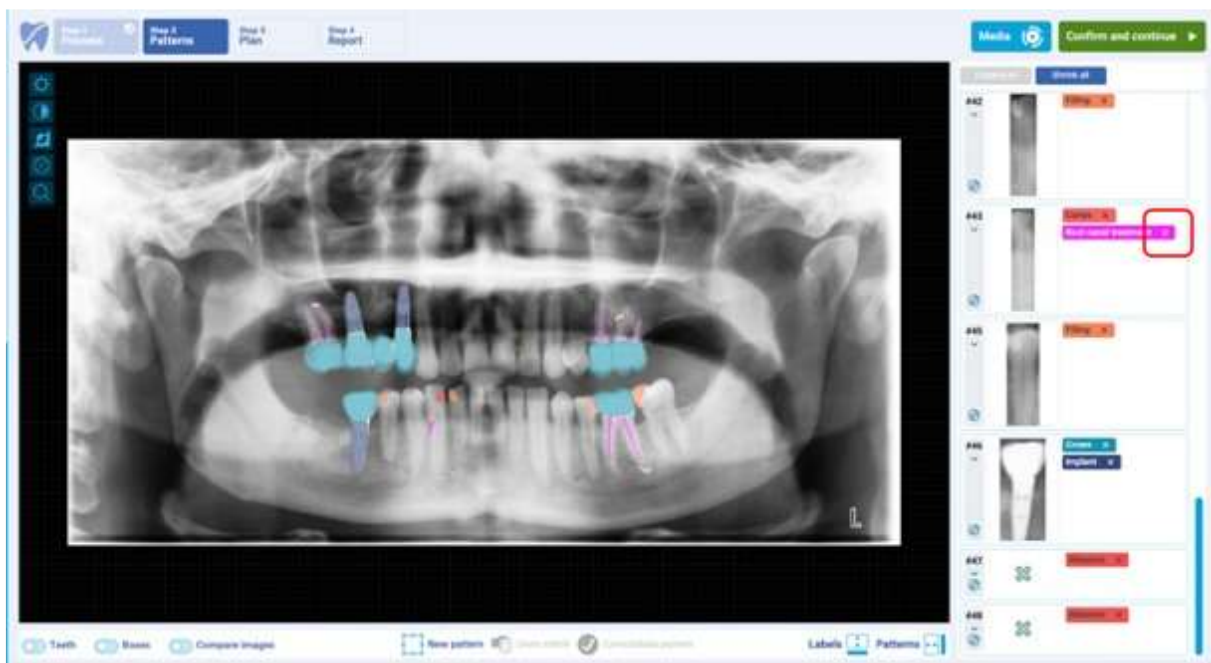


Fig. 21 Pattern deletion

Automatically, the pattern will disappear from the side menu and the corresponding X- box.

14. LABELS:

All patterns, whether generated by DentIA or manually by the practitioner, have a label. From the "Labels" section at the bottom, the user can show or hide the different existing labels.

By clicking on the option, the bottom menu will be enabled where the user will have access to the different existing labels.



Fig. 22 Show labels

The labels are grouped as follows:



Fig. 23 Labels

- General:** it will be possible to display the “healthy” teeth or to mark/unmark all labels. In the case of bitewing or periapical flaps, a drop-down menu showing the parts of the tooth will also be displayed.
- Bone-periodontal profile:** this allows you to show or hide the bone line, the periodontal line (on panoramic images only) and the difference between the two on the X-ray. In intra oral X-rays, if the image includes the pixel size, this difference is expressed in millimetres or as a percentage relative to the apex of the tooth root. The line will be plotted according to the following thresholds:

Colour	Bitewing X-ray	Periapical X-ray	Periodontal stage
Green	<3 mm	<15%	Stage 1
Yellow	3 mm-4 mm	15-24%	Stage 1/2
Orange	4 mm-5 mm	24-33%	Stage 2
Red	>5 mm	>33%	Stage 3/4

If no measurement is available for the detected bone level, it will be shown as a white line.

- Anatomical structure:** for panoramic X-rays, the anatomical structures in the image can be shown or hidden, revealing the maxillary sinuses, the mandibular nerves and the temporomandibular joint.
- Pathological findings:** cavities, periapical radiolucencies and tartar will be visible.
- Bone structure:** impacted teeth or missing teeth.
- Previous treatments:** any previous treatments detected by DentIA, such as fillings, root canal treatment, implants, crowns, etc., will be marked on the X-ray.

By marking the different existing labels, users will be able to display the corresponding patterns directly on the image.

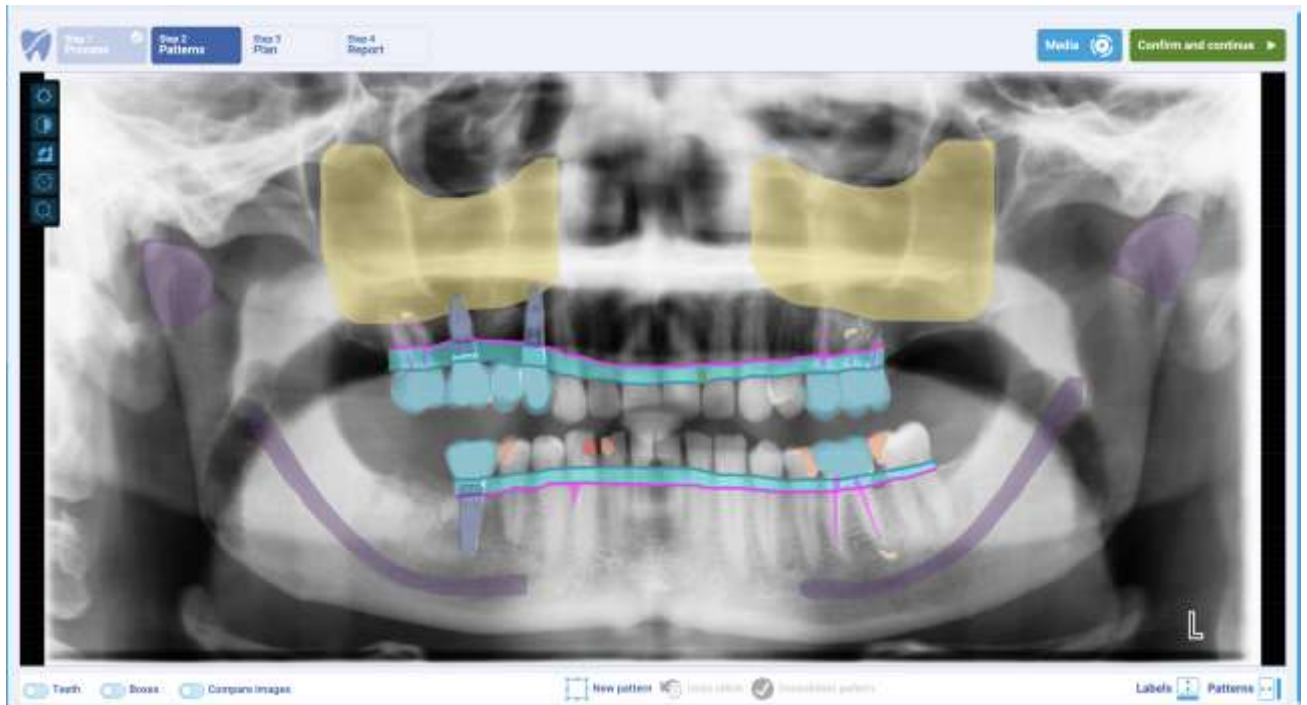


Fig. 24 Patterns visible on the X-ray

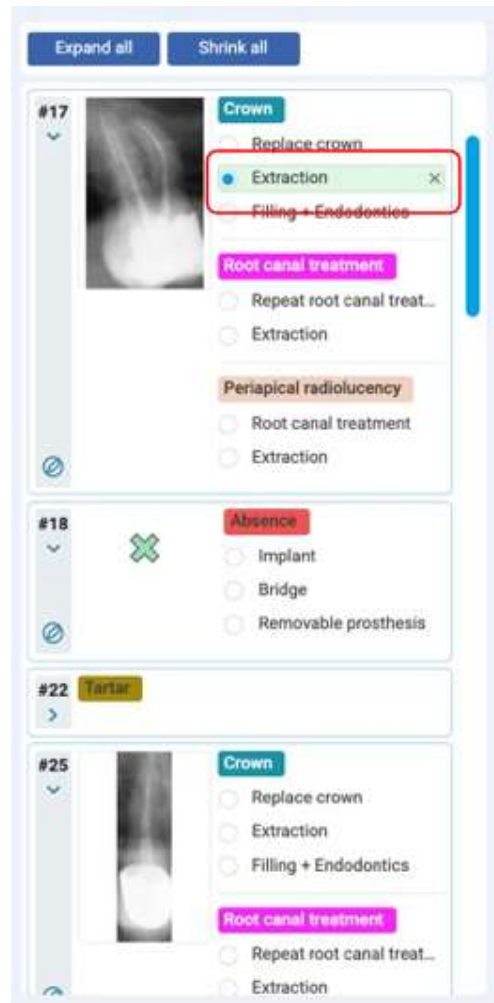


Fig. 27 Selection of treatment by pattern

In the event of error, the treatment can be deleted by selecting it and clicking on the delete icon (X).

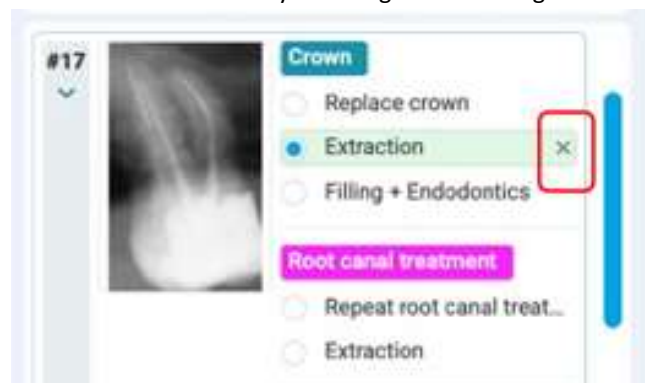


Fig. 28 Delete treatment

It is not necessary to select one treatment per pattern. The practitioner will decide on the treatments that best suit the patient's circumstances according to the indicated patterns.

The relationship between the patterns and the treatments proposed by DentIA is as follows:

- **Absence:**
 - Implant.

- Bridge
- Removable prosthesis
- **Implant:**
 - Hygiene
 - Surgery
 - Crown
 - Bridge
- **Tooth decay:**
 - Filling
 - Filling and root canal
 - Extraction
- **Suspected tooth decay:**
 - Remineralisation
- **Periapical radiolucency:**
 - Root canal treatment
 - Extraction
- **Crown:**
 - Crown replacement
 - Extraction
 - Filling and root canal
- **Filling:**
 - Filling replacement
 - Filling and root canal
 - Extraction
- **Root canal treatment:**
 - Repeat root canal treatment
 - Extraction
- **Tooth included/impacted:**
 - Extraction
 - Orthodontics
- **Plaque:**
 - Hygiene
 - Scraping
 - Periodontal surgery

b. Via a PMS that is integrated with the quotes

In this case, when the practitioner clicks on the “Confirm and continue” button in the previous step, a pop-up window will appear allowing them to choose which action to take: complete the analysis and quit, generate a quote and report, or just generate a report:

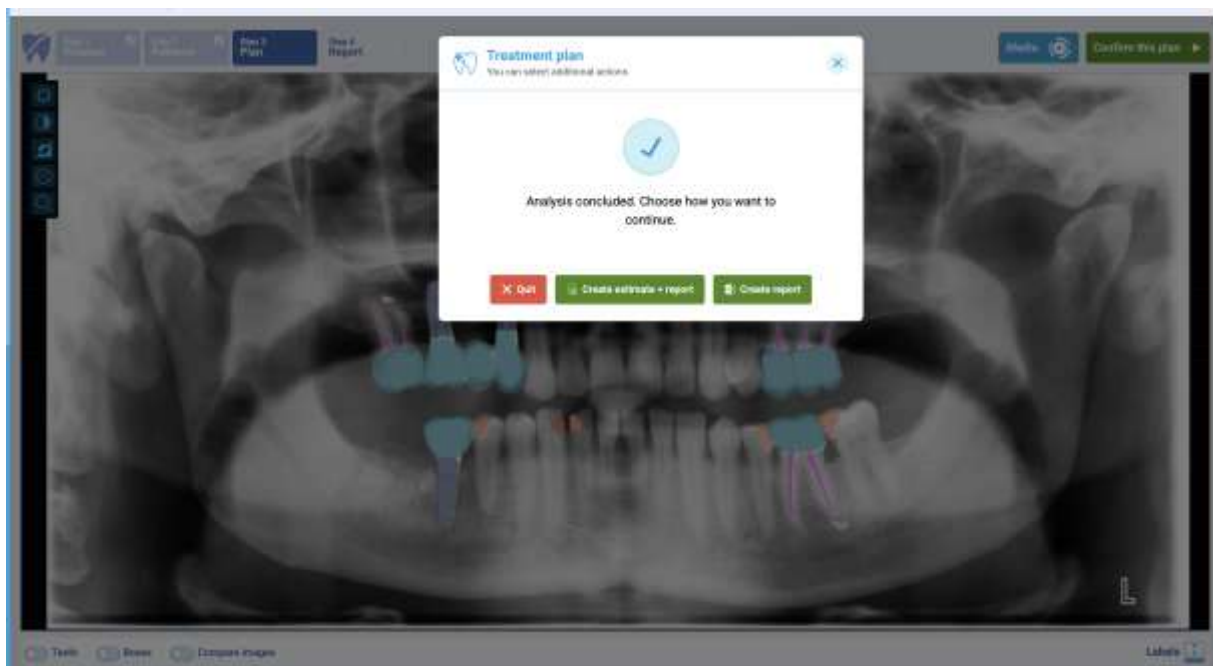


Fig. 29 Pop-up window for selecting an action

If they choose to view only the report, they will be taken directly to the final section of DentIA, where the report showing the patterns confirmed by the dentist is displayed.

If they choose to prepare the quote and the report, these would be included in the treatment selection section alongside the quotes provided by the PMS. For example, in the case of the GesdenOne PMS, it would look like this:



Fig. 30 Selection of treatments in the GesdenOne PMS

Users can add treatments by clicking on the DentIA templates and selecting the specific treatment offered by the PMS:

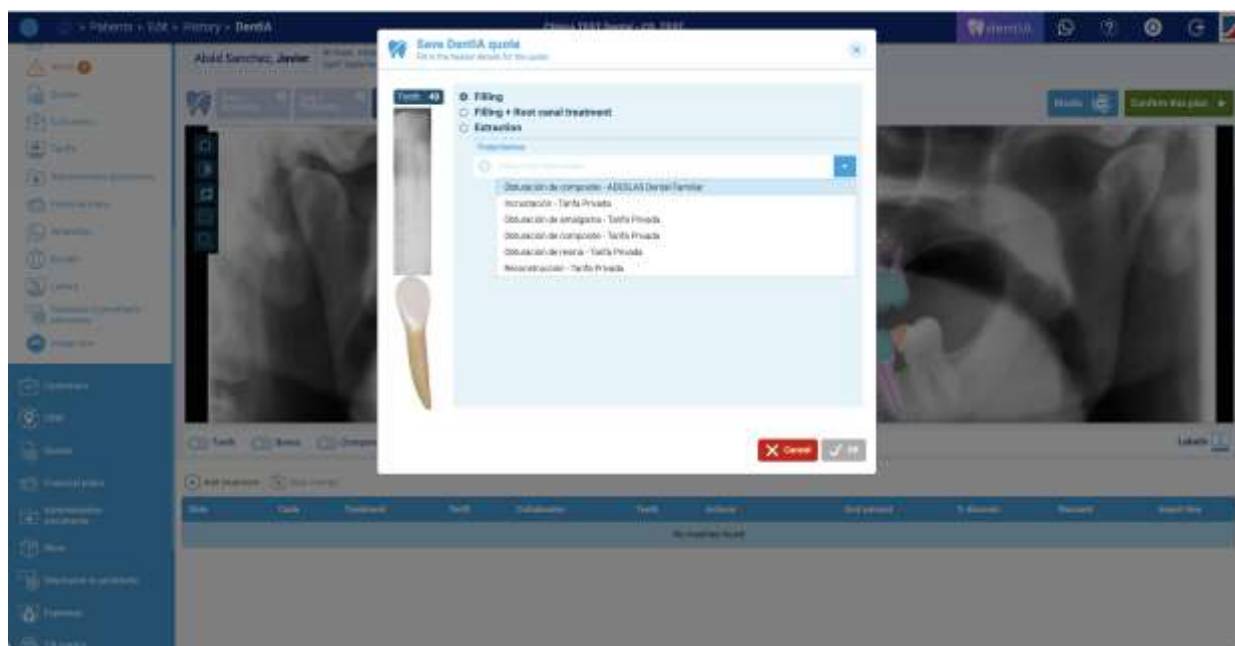


Fig. 31 Selection of treatments in the GesdenOne PMS

f. Complete the treatment plan

Once the treatment plan has been completed, regardless of the PMS, click on “Confirm this plan” to continue.



Fig. 32 Confirm this plan to continue

16. MULTIMEDIA:

Throughout every stage of the DentIA process, the dentist has access to a 'Multimedia' section, which is useful for explaining to the patient at any time what the findings mean and/or what the various treatments involve.

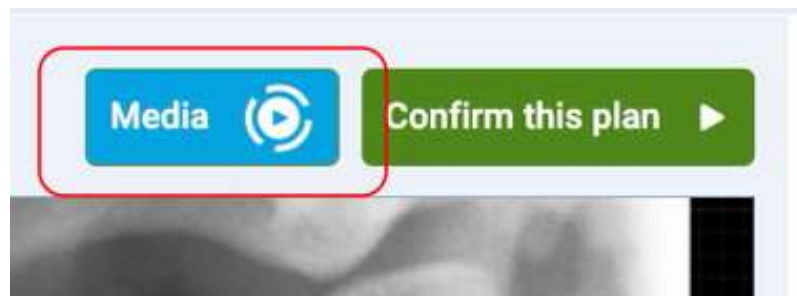


Fig. 33 "Multimedia" button

By clicking on the "Multimedia" button, a new window will open where a large number of didactic videos on dental pathologies and treatments are available.

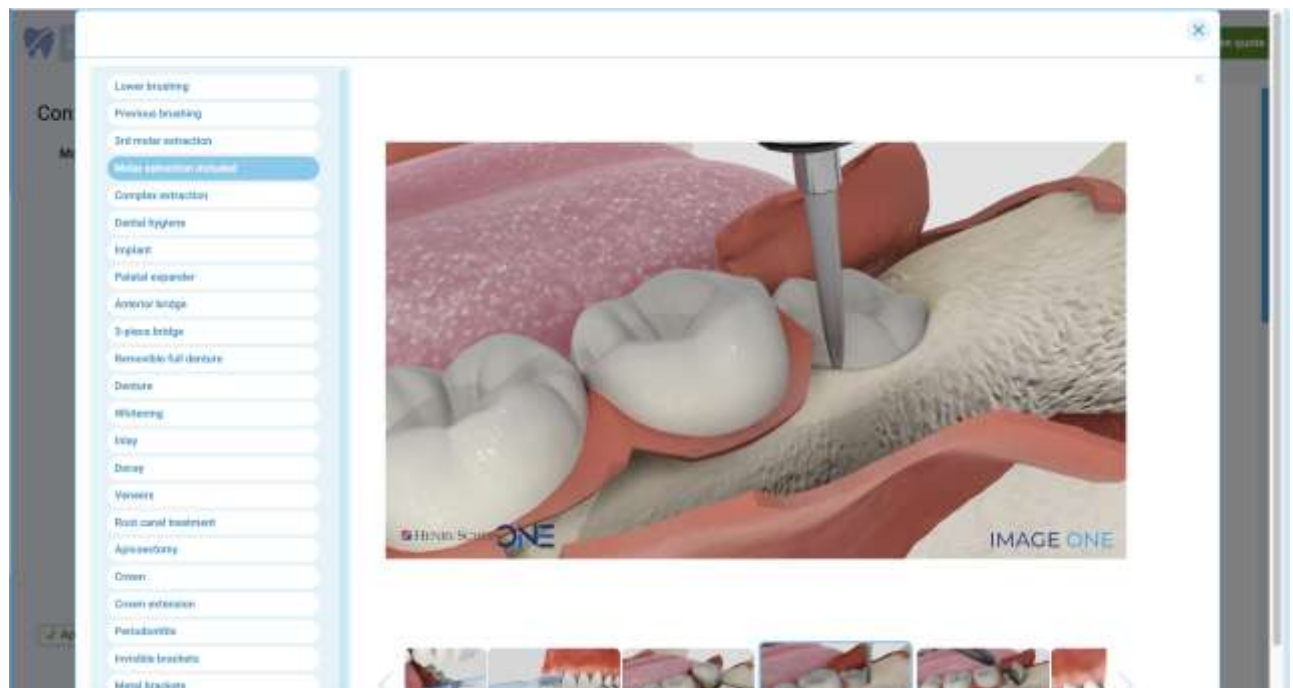


Fig. 34 Example of available multimedia content

17. REPORT:

In the final step of DentIA, a report will be displayed which the dentist can download and send to the patient. This report will include an image of the X-ray on which the examination was based, showing the findings in their corresponding colours, as well as a list of the treatments recommended by the practitioner.

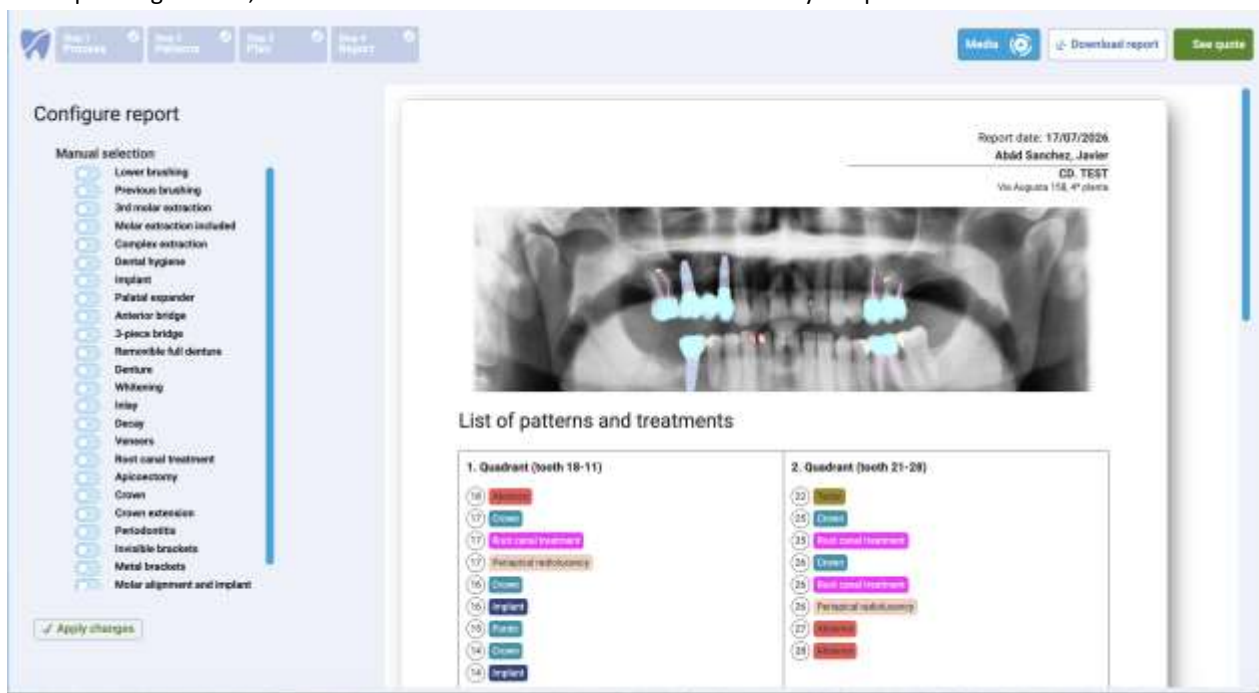


Fig. 35 Report

At the bottom of the report, below the X-ray, the teeth with the patterns and, if a treatment has been selected, the type of treatment recommended by the practitioner, will be detailed by quadrants.

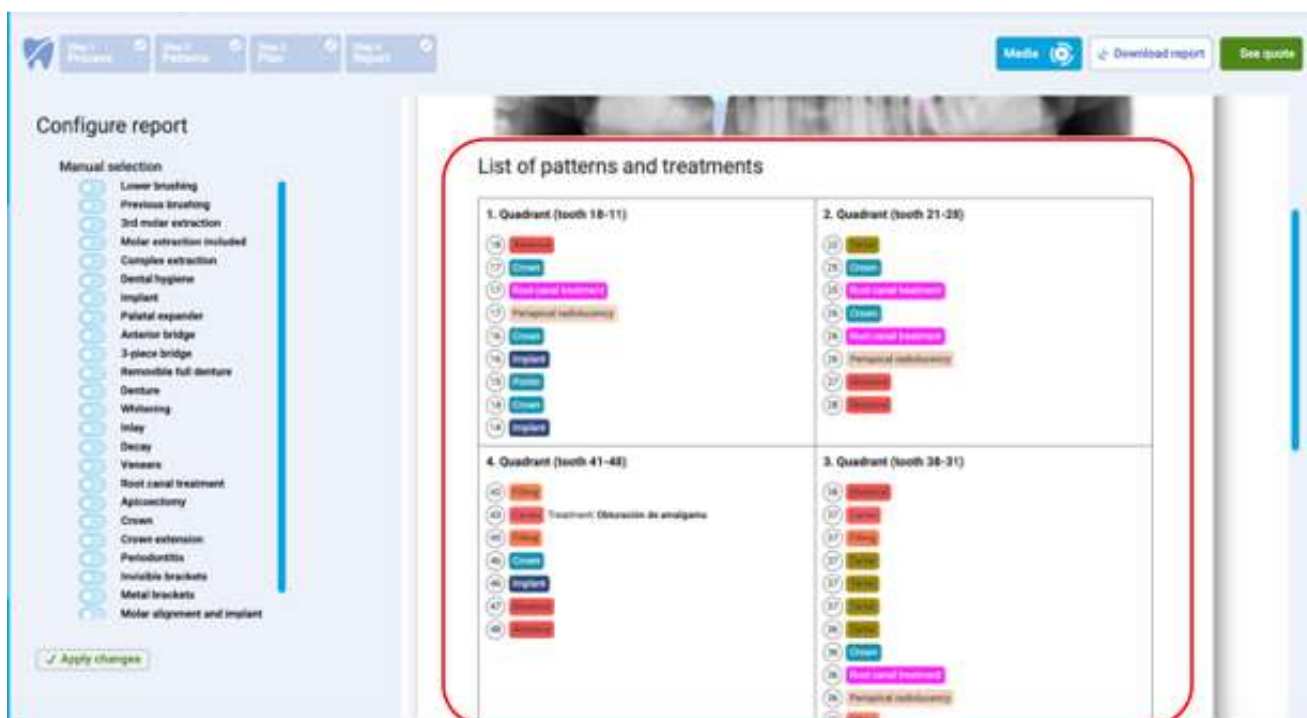


Fig. 36 Report

On the left-hand side, there are infographics related to the videos in the “Multimedia” section, which the user can add to the report if they wish. By clicking on “Apply changes”, the selected infographics will be added to the end of the report.

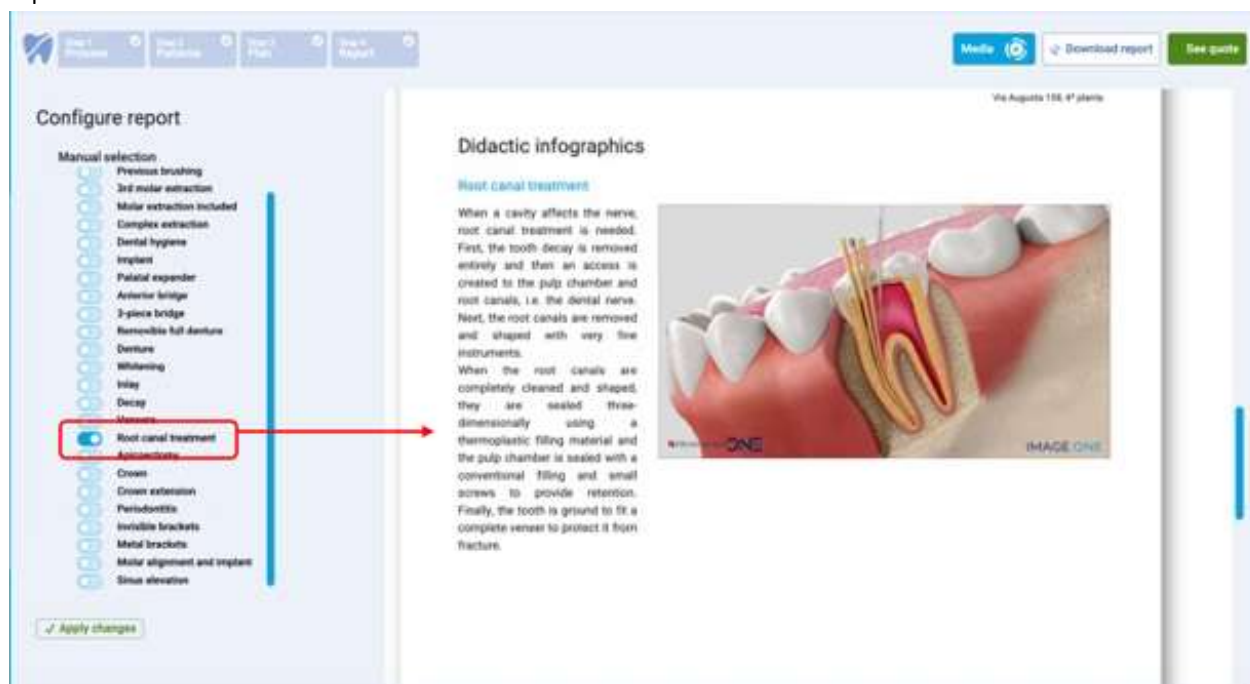


Fig. 37 Configure report

Clicking the “Download report” button will download the generated report in PDF format. The document will be saved to the device's downloads folder, depending on the browser settings.

18. PMS INTEGRATIONS:

DentIA can be integrated with different management programs or PMS.

For further information on software compatible with DentIA, contact the Infomed Commercial Department.

19. REQUIREMENTS TO VIEW THE INSTRUCTIONS FOR USE

The instructions for use can be found on the web: <https://dentiasoftware.com>

They can also be accessed via the tag by clicking on the icon labelled “ Click here to view the instructions for use”

To download the instructions for use, take into account the following:

- If your operating system is Windows, you must have the latest version of the Adobe PDF Reader software installed.
- To install the program, visit <https://get.adobe.com/es/reader/>, ensuring that your system meets the requirements listed on the website.
- It is recommended to download and keep a copy of the last version of the manual on your system, in order to deal with occasional cuts in the contracted internet connection. Take into account that the most recent and updated version of the instructions of use is that found on the web.

Physical instructions for use:

A paper copy of the DentIA instructions for use can be requested from our organisation, by indicating the version and licence number.

Within 7 days you will receive a copy of the Instructions for Use free of charge. You can contact us on 902104466, from Monday to Friday from 08:30 to 21:00 hours. If the Instructions for Use are not received or in the event of any incident related to the request, contact the same telephone number.

20. TECHNICAL ASSISTANCE SERVICE & SERIOUS INCIDENT REPORTING

	If technical assistance is required, please contact: soporte@grupoinfomed.es In the event of a medical incident related to the use of DentIA, contact gara@grupoinfomed.es. You should also notify the competent area health authority.
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21. PROCEDURE FOR DECOMMISSIONING AND DISPOSAL OF HEALTH SOFTWARE

If necessary, DentIA will be removed and disposed of by INFOMED.

22. DEVICE(S) INTENDED TO BE USED WITH THE SOFTWARE MEDICAL DEVICE

No specific device is required to use the full range of DentIA products.

23. LABEL:

Content:

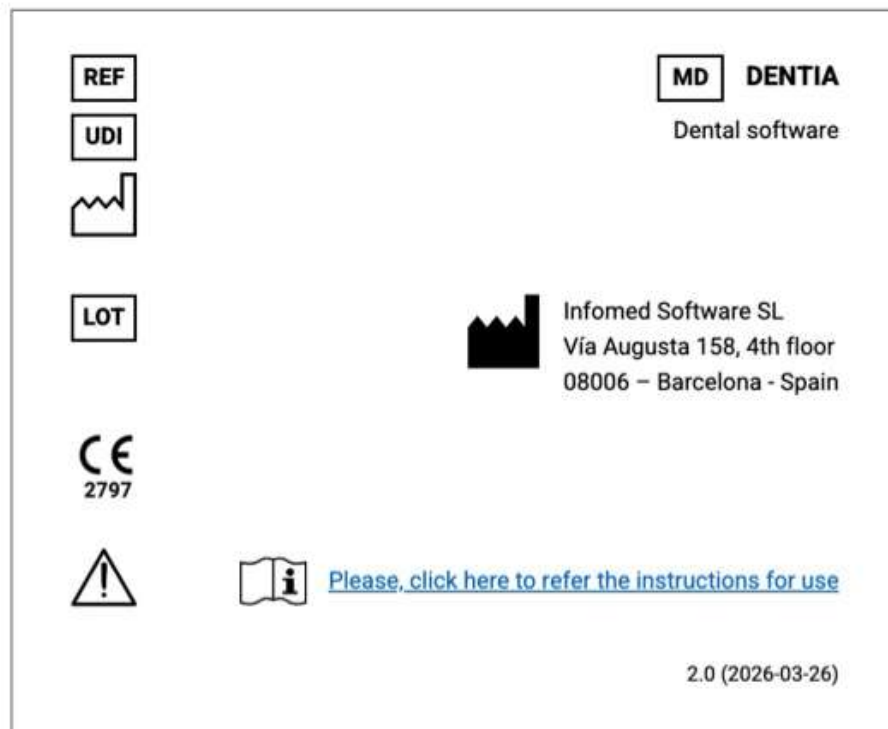


Fig. 38 Product label

Pictogram	Description
	Medical device.
	Reference of the medical device.
	Unique product identifier. (01) Product code (11) date of manufacture (8012) software version.
	Date of manufacture.
	Software version.
	Address of the company manufacturing the product.
	Caution
	See the electronic instructions for use (eIFU)
	Compliance with European safety and performance standards for health products. 2797 – Belongs to the Notified Body (Netherlands BSI) responsible for the conformity assessment of the medical device.