



DENTOMO: User Manual

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1. Introduction

a. What is Dentomo and what is it for?

Dentomo is a web and desktop platform for the interpretation of CBCT images using technologies such as Artificial Intelligence and Machine Learning whose goal is to:

- **Helps clinical diagnosis:** By automating the detection of oral pathologies.
- **Management and issuance of clinical reports:** Through detailed reports where a clear and truthful report is made available to the patient about his oral health.
- **Patient Management:** Using a database for better management of records.
- **Storage of complementary patient tests:** It allows you to keep a history of the patient's various visits to the office.

b. To whom Dentomo is directed

The object of Dentomo is the identification of oral pathologies and previous treatments through the interpretation of CBCT images in DICOM format and using Disruptive Technologies such as Artificial Intelligence and Machine Learning.

However, report management modules can be operated by auxiliary staff if the professional deems it appropriate.

Dentomo is indicated as a diagnostic tool to assist dentists in the diagnosis of adult patients, not being indicated for paediatric.

c. To whom Dentomo is NOT directed

Dentomo is a tool whose main function is the Diagnostic Aid, and as such is aimed at dental professionals. Dentomo does not include any functionality for patients so its use by this group is discouraged.

d. Why use Dentomo: Benefits

Dentomo is a tool for diagnostic aid and therefore helps the dentistry professional to:

- **Identify** oral pathologies.



- **Reduce** image interpretation **time**.
- **Reduce the economic impact** that this task may have if it is outsourced.
- Provide patients with **better and more complete diagnoses**.
- Make **personalized treatments** available to the patient.

e. **Scope of responsibility**

Dentome in NO CASE replaces the criteria of the dentist, it is solely and exclusively an aid to the diagnosis, which means that the criteria of oral health professionals will always prevail over any diagnosis that the tool can make.

f. **Format images**

- **Format:** For the proper operation of Dentomo, the user must only upload files in DICOM format whose extension is “**dcm**”.
- **Presentation:** For the file upload to succeed, the user must ensure that he exports the CBCT images into a folder containing all sections of the original image. These folders usually consist of several hundred files.

2. Demo Information and Request

Users who want to access product information should go to:

www.dentomo.com (see image)

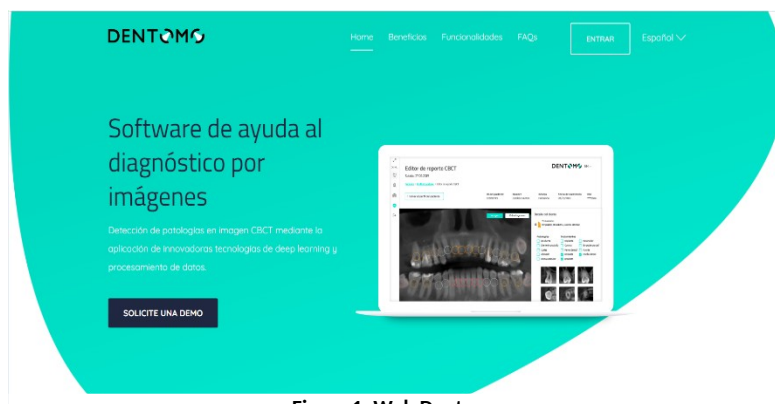


Figure 1: Web Dentomo

Here the user will be able to resolve their doubts regarding the product, as well as contact the sales team that will respond as soon as possible to any clinical and commercial doubts that may be raised by interested parties.

a. **Demo Request**

To access a demo of Dentomo users must request it through the contact form present in this section (see image).

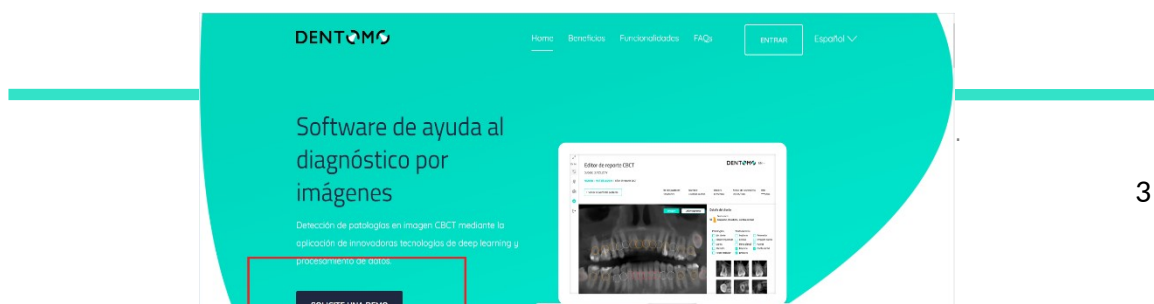




Figure 2: Demo Request

Once you have requested the demo our sales team will contact the user to provide you with:

- Web address of the platform
- Access Credentials
- Training for tool management

b. Access and registration in Dentomo

Once the login credentials are received, the Dentomo user will be able to perform basic clinical management tasks such as:

- Creating a Patient Database
- Creating professional users
- Edit my profile.
- Log out.

| Nombre y apellidos ↑ | ID de paciente | Última modificación | Fecha de carga |
|-------------------------|----------------|--------------------------------|--------------------------------|
| DEMO ASISA | 0102 | vie., 6 de mar. de 2020 13:08 | vie., 6 de mar. de 2020 13:08 |
| Demo Demo | 0039 | mar., 10 de dic. de 2019 15:05 | mar., 10 de dic. de 2019 15:05 |
| Fernando Avilés Patient | 0046 | mar., 10 de dic. de 2019 16:21 | mar., 10 de dic. de 2019 16:21 |
| Irene Adler | 0003 | vie., 29 de nov. de 2019 11:49 | vie., 29 de nov. de 2019 11:49 |
| Patient One | 0001 | jue., 28 de nov. de 2019 13:06 | jue., 28 de nov. de 2019 13:06 |

Figure 1: Sidebar Options



3. User Manual

a. Users: Creating professional users

The owner of the Dentomo license will be able to enable accounts for their contributors in this tab. To do this, you will need to click on **“New User”** and fill in the fields. **(see image)**

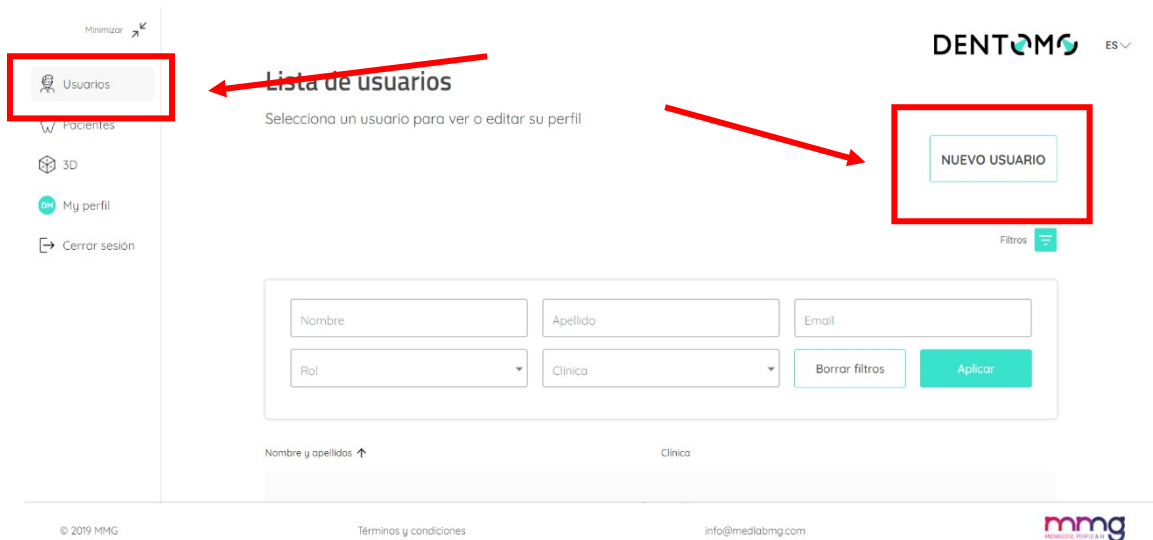


Figure 4: How to create users.

To create a new user within Dentomo you will need to fill in the following fields **(see image)**.



Registrar nuevo usuario

Rellene los datos para registrar un nuevo usuario

Usuarios > Crear nuevo usuario

< Volver usuarios

Nombre Apellido

Clinica Rol

Email Contraseña

Register

Figure 2: New User

The new user must be associated with a clinic (which will have been created previously) and assigned a role within the organization being able to choose between “Administrator” and “user” (currently the roles are the same). Once this is done, the new user must set a password.

b. Patients: Creating a Patient Database

It is in this section most of the clinical functionalities of Dentomo are concentrated, the “Patients” section allows the user to discharge as many patients as he wants. To do this within the section the user must go to “Create new patient” (see image).

Lista de pacientes

Selecciona un paciente para subir una imagen CBCT

CREAR NUEVO PACIENTE

Buscar

| Nombre y apellidos ↑ | ID de paciente | Última modificación | Fecha de carga |
|-------------------------|----------------|--------------------------------|--------------------------------|
| DEMO ASISA | 0102 | vie., 6 de mar. de 2020 13:08 | vie., 6 de mar. de 2020 13:08 |
| Demo Demo | 0039 | mar., 10 de dic. de 2019 15:05 | mar., 10 de dic. de 2019 15:05 |
| Fernando Avilés Patient | 0046 | mar., 10 de dic. de 2019 16:21 | mar., 10 de dic. de 2019 16:21 |

Figure 3: Creating Patients.



Once inside “Create new patient”, the user must fill in a simple filiation sheet where he must enter the patient's data:

Figure 4: Patient filiation data

- Name
- Surname
- Date of birth
- ID card
- Sex

Once this operation has been performed, the user will have created a new patient that will appear in the list of patients (which we will access through the already mentioned tab of “Patients”), in this section we will see our list of patients identified by a numerical “Patient id”, we will see, its creation date and the last modification made (see image).

| Nombre y apellidos ↑ | ID de paciente | Última modificación | Fecha de carga |
|-------------------------|----------------|--------------------------------|--------------------------------|
| DEMO ASISA | 0102 | vie., 6 de mar. de 2020 13:08 | vie., 6 de mar. de 2020 13:08 |
| Demo Demo | 0039 | mar., 10 de dic. de 2019 15:05 | mar., 10 de dic. de 2019 15:05 |
| Fernando Avilés Patient | 0040 | mar., 10 de dic. de 2019 16:21 | mar., 10 de dic. de 2019 16:21 |
| Irene Adler | 0003 | vie., 29 de nov. de 2019 11:49 | vie., 29 de nov. de 2019 11:49 |
| Patient One | 0001 | jue., 28 de nov. de 2019 13:06 | jue., 28 de nov. de 2019 13:06 |

Figure 5: List of patients



i. Patient Profile: Features

Within the patient profile we will see a summary of the patient's filiation (see image)

We will also be able to perform the following actions:

- Edit the patient profile.
- Find a specific CBCT image by entering the image number.
- Upload a new CBCT image.
- List of images CBCT

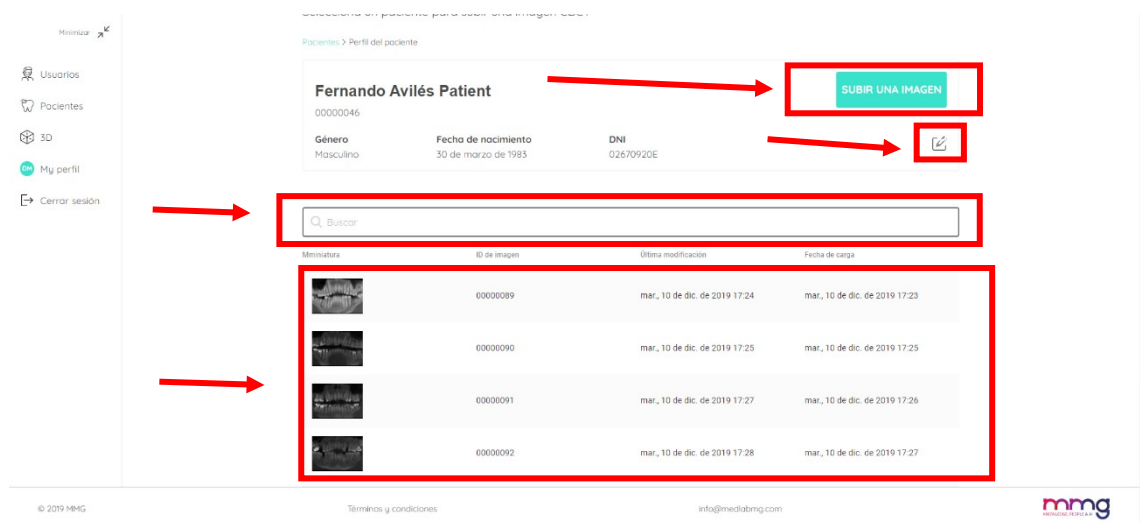


Figure 6: Patient profile and functionalities

ii. Upload a new image: Instructions for uploading DICOM files.

To upload a new CBCT image we must:

1. Click on **“upload an image”** (see **“Figure 9: Patient profile and features”**)
2. Choose one of two upload modes:
 - a. “Drag from a folder.”
 - b. **“Select folder to load” (recommended)**

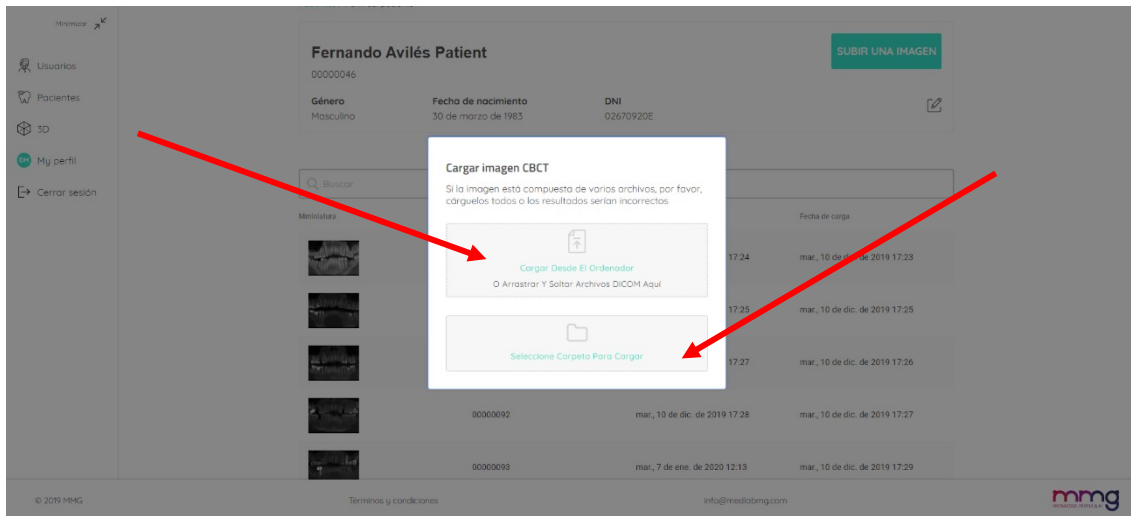


Figure 7: Image Upload Options

3. Choose the file you want to upload (See instructions for obtaining CBCT image folder)
4. Next, a pop-up window will appear which we will have to confirm by asking us to confirm the upload of the files. (see image)

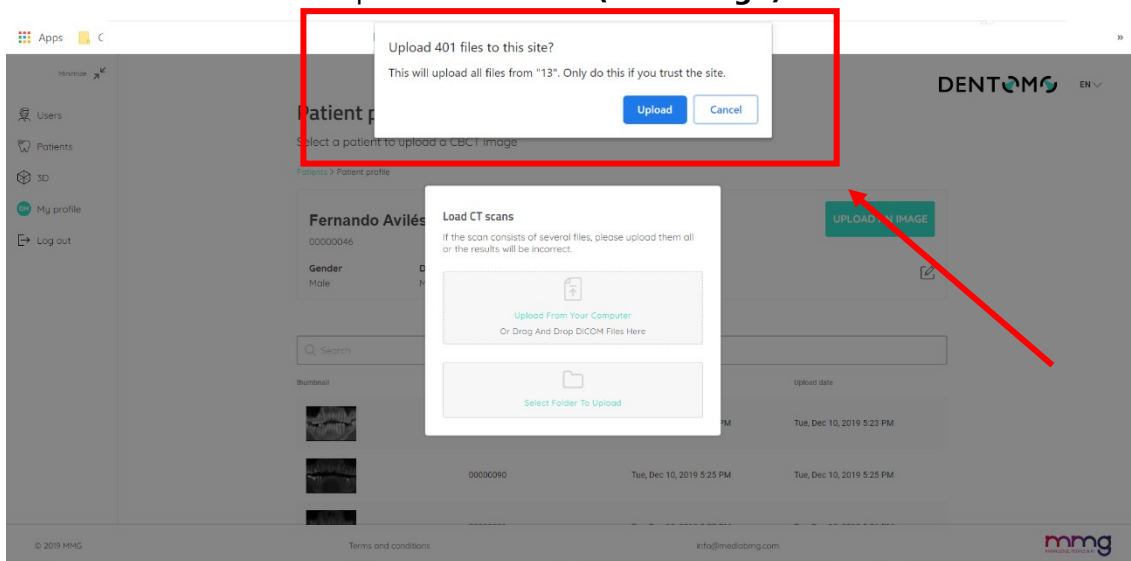


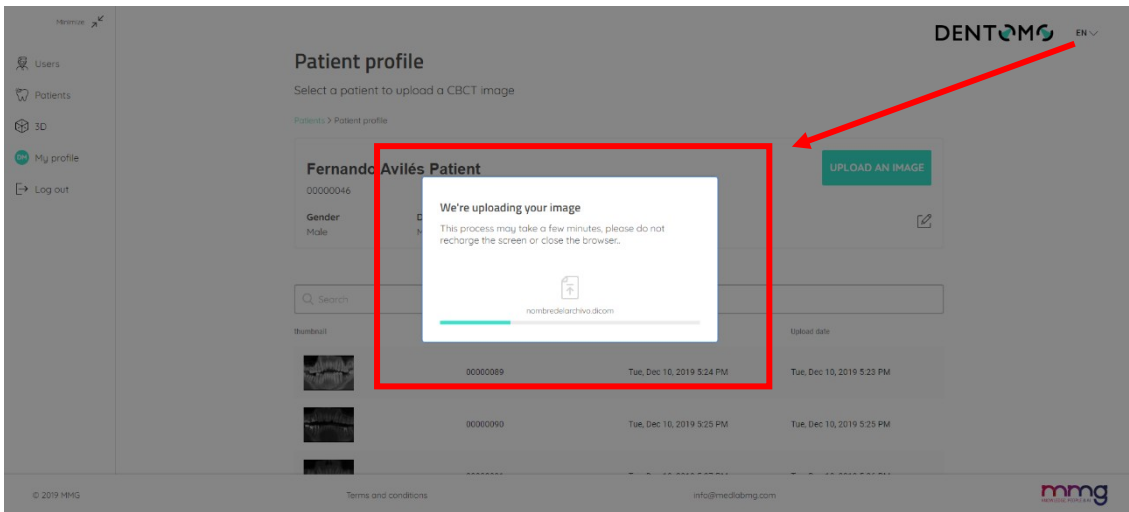
Figure 8: File Upload Confirmation

Once the load actions have been performed:

1. **Progress bar:** A dialog will appear informing us that the upload is proceeding, a progress bar (see image) will tell us how much remains to complete the upload. (During this process that will take a few minutes, depending on your internet connection, we will not have to close the



browser or reload the page, this would interrupt the upload or corrupt the final result)



2. **Report Generation:** Once the upload is complete, we will be redirected to a new window indicating that our report is being generated.
3. **Image:** After this, the image will receive a numbering and will be available along with the other previously uploaded images (**see Figure 9: Patient profile and functionalities**).

iii. CBCT Image Editor

Within the CBCT Image Editor, the user will be able to view the 2D interpretation done by Dentomo of the CBCT image.

Next, we will see each of the functionalities that we will be able to perform in this section:

- Display Selection
- Pathologies Detected
- Previous Treatments
- Healthy Pieces
- Missing parts
- Clinical Report Generation
- Professional Feedback

iv. Display Selection

Dentomo offers the user two ways to view the dental report (**see pictures**):

- **Panoramic view:** This view offers a 2D view of the patient's mouth from the interpretation of the DICOM image. Here pathologies, previous treatments, healthy or absent pieces will be surrounded with a circle of a certain color. (see pathology)

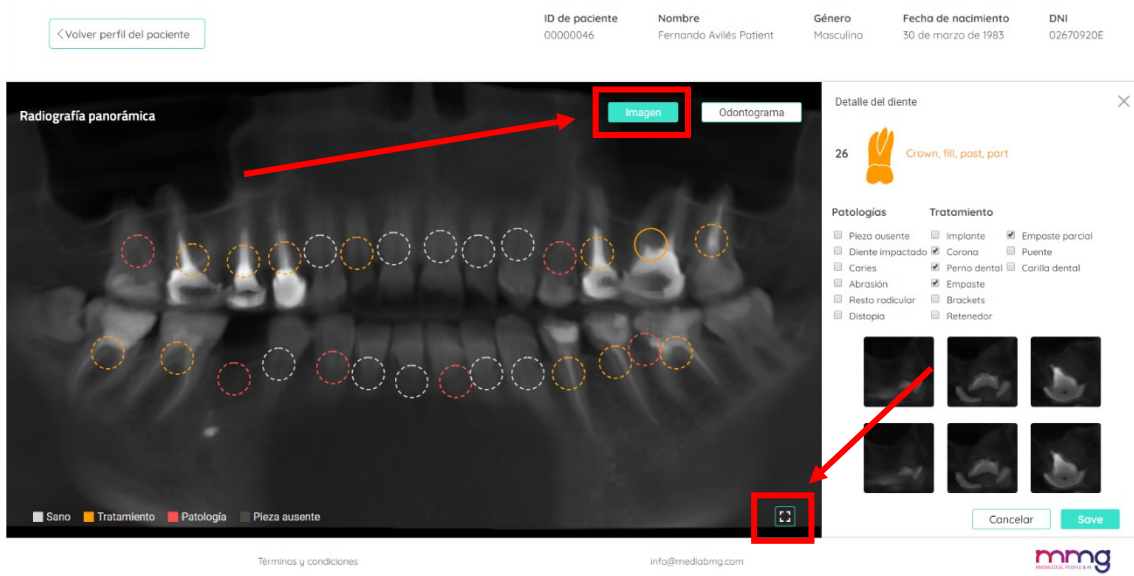


Figure 9: Panoramic view

- o **Expand Panoramic View:** To be able to see the panoramic X-ray enlarged we will click on the icon for this purpose located at the bottom right. This will allow us to access, through a pop-up window, the panoramic X-ray without Dentomo analysis for a more comfortable preview by the doctor.
- **Odontogram:** The Odontogram is a pictographic representation of each of the 32 dental pieces (**see image**).

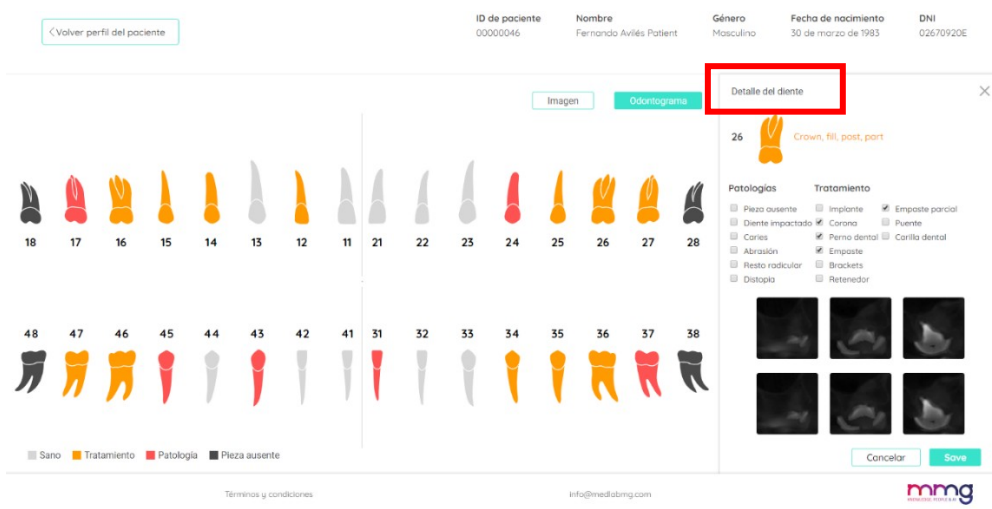


Figure 10: Odontogram view

Either option allows the user to navigate through the dental pieces and study the possible pathologies and previous treatments found.



v. Interpretation of the image

Pathologies Detected

Pathologies detected by Dentomo will be identified by a circle of red color. To date Dentomo can identify:

- Caries
- Root remains.
- Dystopia
- Abrasions
- Impacted teeth.

vi. Previous Treatments

To date, Dentomo can identify nine previous treatments, which will be identified in the panorama by an orange circle. This is the list of previous treatments:

- Implant
- Crown
- Dental Bolt
- Filling
- Brackets
- Retainers
- Partial Filling
- Bridge
- Dental Veneers

vii. Missing Parts

To see which dental parts are absent, the user must switch to the Odontogram view, there, the missing parts will be identified in black.

Note: The panoramic view does not identify the missing pieces, now the Odontogram is the only one that details them.

viii. Healthy Pieces

Healthy pieces are identified by a white circle.

ix. Detail of the tooth

Detail



If we want to access the detail of the analysis of each piece we will have to click on each circle, then a window will be displayed on the right (**see image**):

- **Pictographic image of the piece.**
- **Numbering of the dental piece.**
- **Pathology or treatment found.**
- **Details of the pathologies found:** (along with other pathologies and previous treatments).
- **Tooth sections.**
- **Save Option:** (See Diagnostic Changes section).

x. Changes in the diagnosis

If the user considers that Dentomo has not correctly identified a pathology, he may, according to his clinical criteria, change the diagnosis by clicking on any of the previous pathologies or treatments. After which you will only need to save the changes made (**see image**)

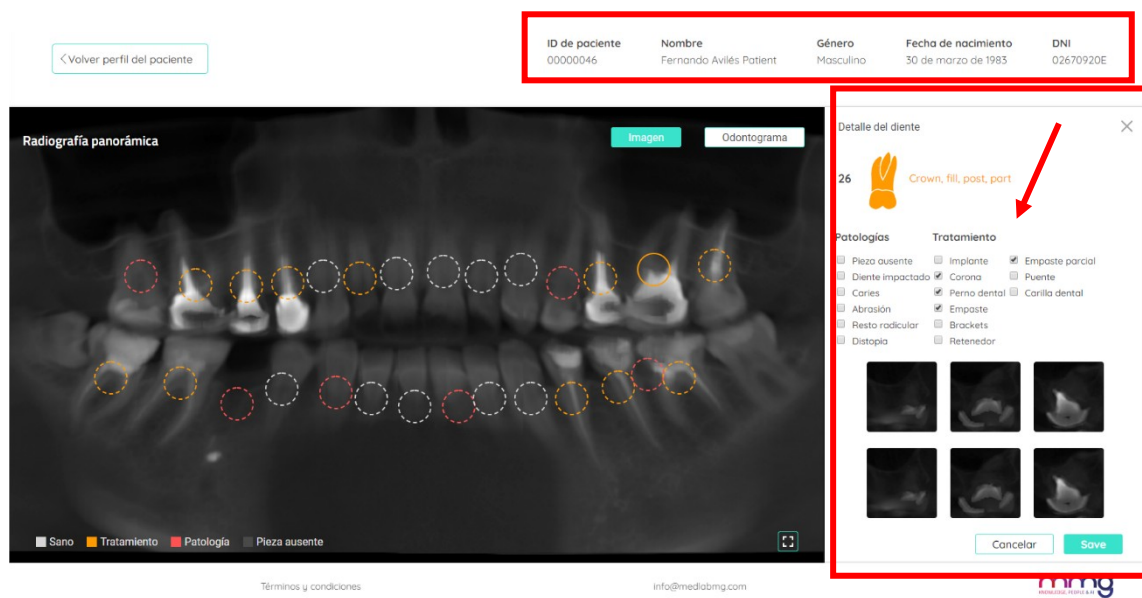


Figure 11: Diagnostic Change Options

xi. Clinical Report

The report allows us, by means of a file generated in pdf, to have a document that collects all the information related to the health of the patient at the time of undergoing the radiographic examination.

The clinical report will provide us with the following information (see pictures):

- **Patient filiation data.**



- **Odontogram** with general information.

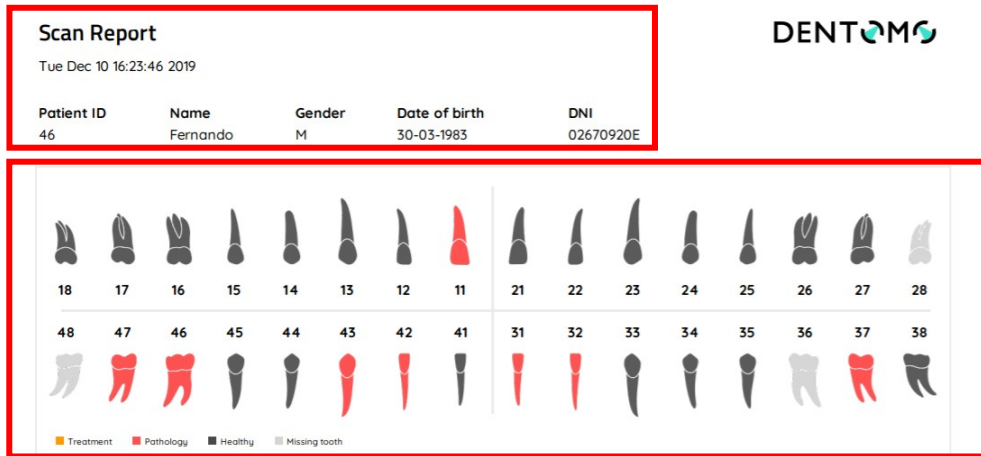


Figure 12: Report Detail (Patient Data and Odontogram)

- Detail of each dental piece with the **pathologies found**.
- **Comments** made by the professional.

Tooth detail

| | | | | | | | |
|----|-------------------------|----|---|----|---|----|----------|
| 11 | Pathologies Abrasion | 12 | Healthy | 13 | Healthy | 14 | Healthy |
| 15 | Healthy | 16 | Healthy | 17 | Healthy | 18 | Healthy |
| 21 | Healthy | 22 | Healthy | 23 | Healthy | 24 | Healthy |
| 25 | Healthy | 26 | Healthy | 27 | Healthy | 28 | No tooth |
| 31 | Pathologies Abrasion | 32 | Pathologies Abrasion | 33 | Healthy | 34 | Healthy |
| 35 | Healthy | 36 | No tooth | 37 | Pathologies radix | 38 | Healthy |
| 41 | Healthy | 42 | Pathologies Abrasion | 43 | Pathologies Abrasion | 44 | Healthy |
| 45 | Healthy | 46 | Treatment and pathologies radix, fill | 47 | Treatment and pathologies radix, fill | 48 | No tooth |

Figure 13: Detail of the dental pieces

To obtain the Clinical Report, the dentist must access the image on which the report will be made, make the appropriate annotations, and click on:

1. **Send comment:** This will cause the clinician's annotations to be recorded.
2. **Preview:** To generate the report.

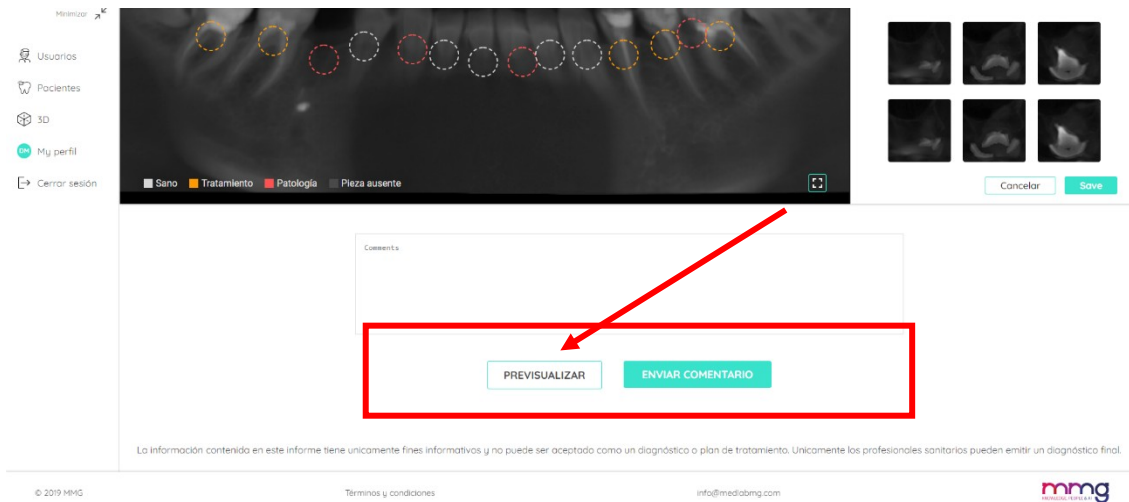


Figure 14: Generating a visit report.

The report will be generated in a separate window in PDF format and can be attached to the clinical management software or delivered to the patient.

4. 3D

a. Introduction

The 3D pathology visualizer allows healthcare and auxiliary professionals to visualize different dental diseases through a sophisticated 3D software. By means of this visualizer, the clinician can quickly, visually, and explicatively inform the patient of any pathology found after the clinical examination. **(see image)**

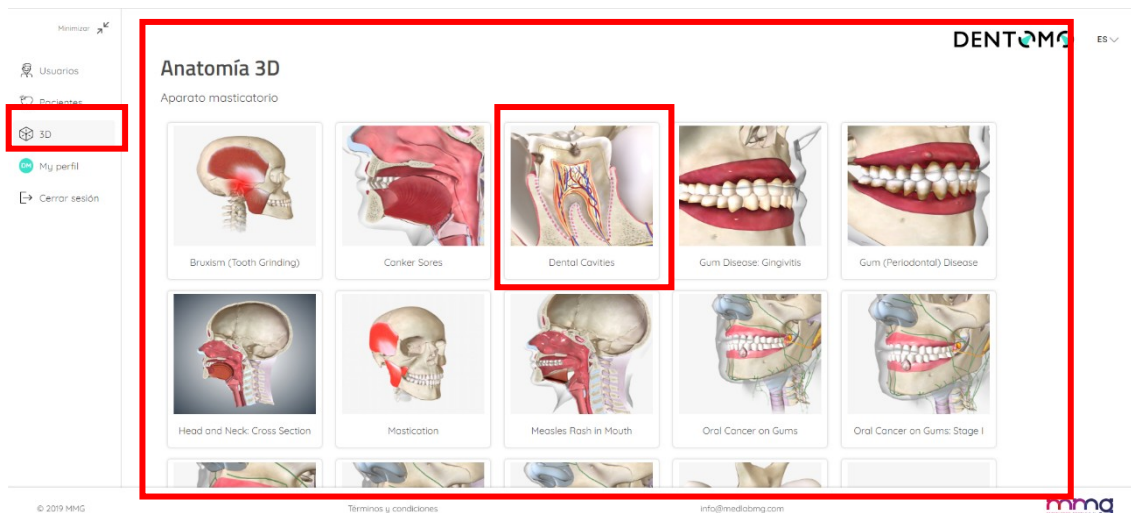


Figure 15: 3D Anatomy Tools

Next, we will look at the functionalities:

b. Access

To access we will click on the 3D tab.



c. Selection of pathology

3D functionality has several pathologies, oral, dental, soft tissue, as well as different types of oral neoplasms.

d. Explanatory text

On the left side of our screen and next to the pathology we will find an explanation that will help us explain to the patient the nature of this pathology. If we want to hide this explanation, we will only have to click on the arrow to contract it.

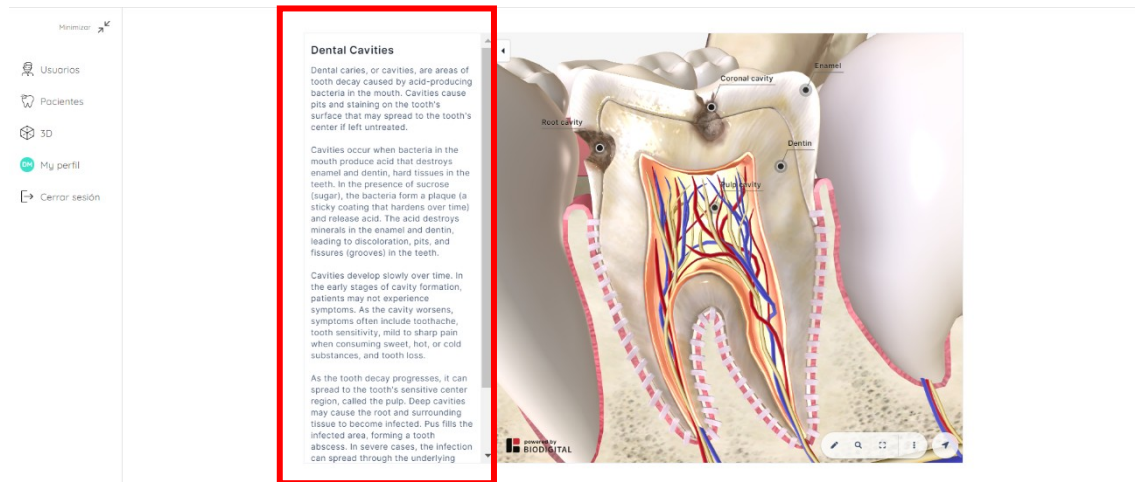


Figure 16: Explanatory text of pathologies

e. Basic functionalities

Next, we will briefly comment on the tools available for handling the 3D section (see image):

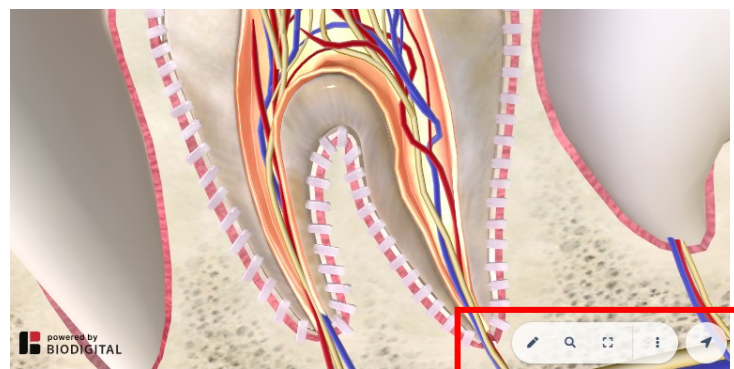


Figure 17: Basic Features Detail

- **Open Navigation Tools:** Pencil Icon
- **Perform search for terms:** Magnifying glass icon.
- **Full Screen:** Screen Icon
- **More options:** three vertical dots
 - **Request help:** Expand a help window with instructions on how to use the model from different computers and mobile phones.



- **Hide legends:** With this option we will be able to hide the legends that accompany the different anatomical models.
- **Open 3D controls:** Allows us to access the vertical toolbar to control the anatomical model according to longitudinal axes.

f. Access to tools

- Expand
- Pause
- Help

g. Explore advanced tools.

This section will be accessed from the basic tools panel identified by the icon of a pencil see **(image)**:

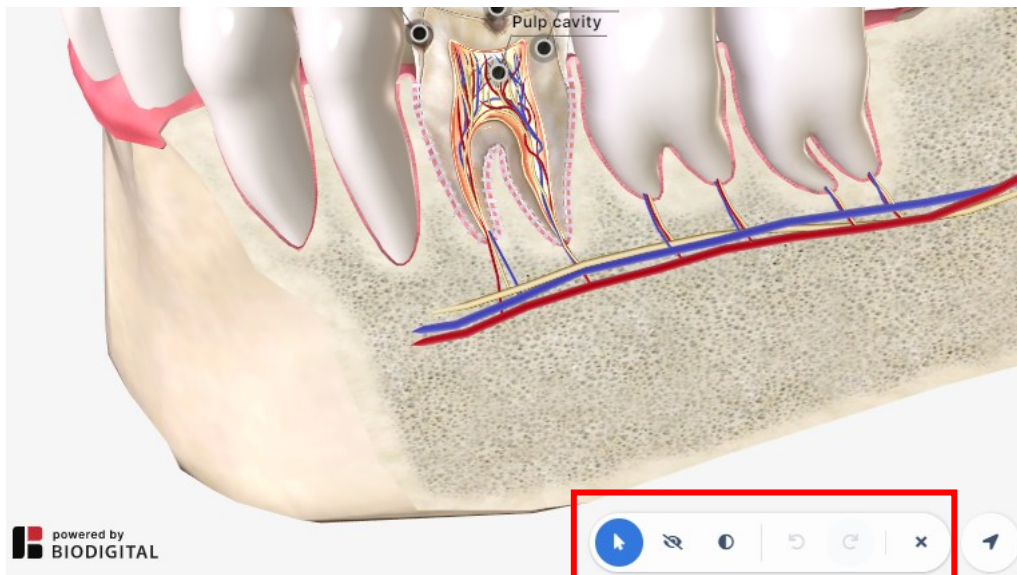


Figure 18: Advanced Tools.

- **Hide:** This functionality will allow us to hide parts or sections of the anatomy of the mouth, thus facilitating any didactic approach you want to carry out.
- **Translucent:** Unlike the option of “Hide” this functionality allows us to apply transparency to bone and soft tissues without removing them.
- **Undo Editing:** It allows you to correct actions and undo any changes you made previously.
- **Close advanced tools:** Click the blade icon to close the horizontal toolbar.

h. Accessing 3D Controls

The direction arrow, located at the end of the basic toolbar, will allow us to display the 3D control bar (see image):

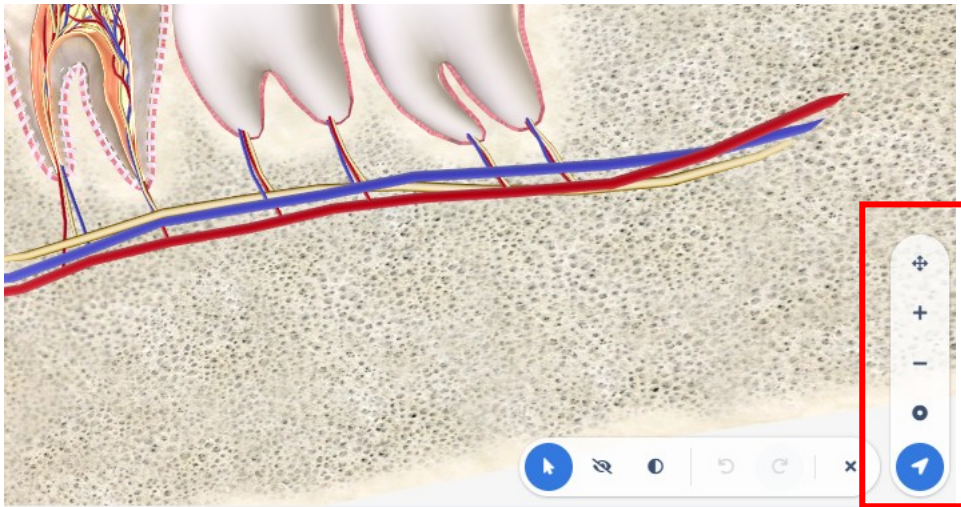


Figure 19: 3D Controls of the Anatomical Model

- **Rotate or fix (pan mode/rotation):** With this option we can switch between the options **to rotate**, where we will rotate the model according to **x and y** axes. And the option to move, where we will move the model as if it were a flat element.
- **Zoom in:** Zoom in on the objects to see them in detail.
- **Zoom out:** Zoom out objects to view them in general.
- **Center Model:** This functionality returns the anatomical model to the center of the screen.

5. Feedback

In this section, the owner of the Dentomo license can contact the Technical Team to report any issue experienced during the operation of the application. To help us improve Dentomo please follow these simple steps:

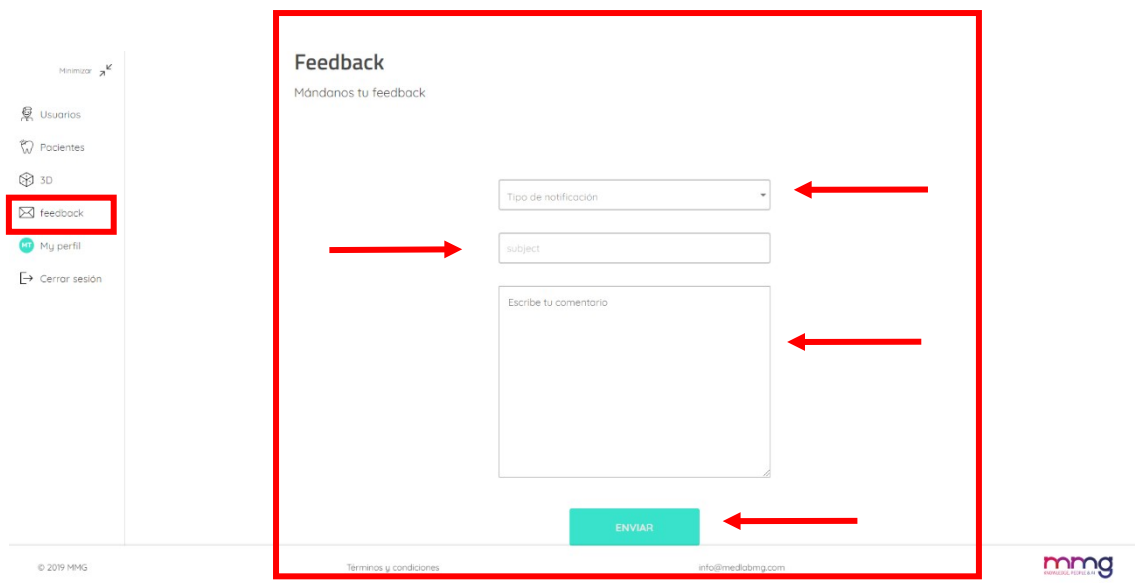


Figure 20: Sending User Feedback

a. Notification Type

In this section the user must specify the nature of his communication, being able to choose between:

- **Complaint:** If expectations do not correspond to the reality of the product.
- **Tip:** If you think any process should be changed or included
- **Error:** If you experience any failures while using the
- **Detection problem:** If Dentomo is not correctly identifying a pathology or previous treatment.

b. Subject

Specify the nature of the incident.

c. Message text

For a better understanding of the incidence, we recommend that you:

- Try to be **concise**.
- Specify **in which section you have found the issue**.
- **What action was taking** or expected to take,
- **What happened** next.

6. My Profile

In this section the user will be able to make changes related to **(see image)**:

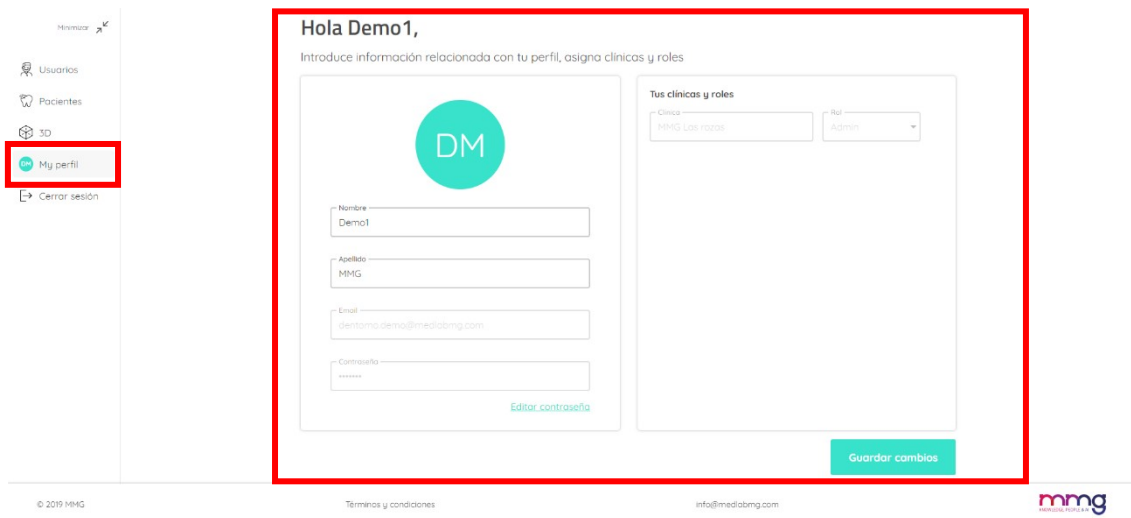


Figure 21: User Profile

- **Name and surname**
- **Password**

Once the changes have been made, you need to record the changes to be saved.

Note: Any changes to the workplace must be communicated to the account administrator for further action.

7. Log out

Using this option, we will be able to log out of Dentomo, which will take us back to the login screen (**see image**).

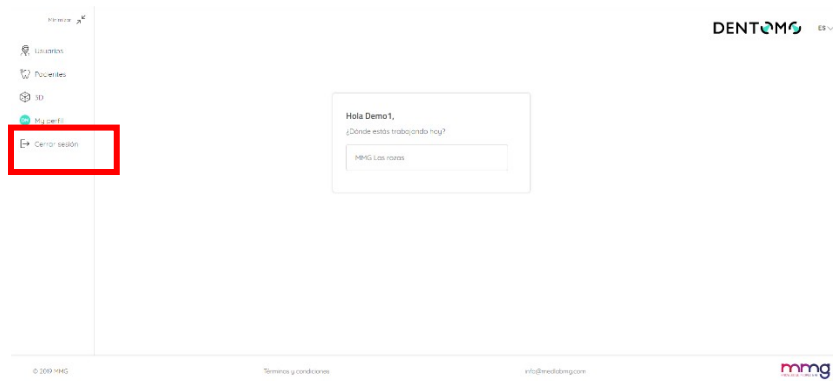


Figure 22: Log Out

8. Technical Specifications: (Minimum requirements, connection, security)

Dentomo is a diagnostic aid tool that can be accessed through your computer's browser. However, in order to enjoy an optimal experience, it is recommended that the Dentomo user:



i. Minimum web browser versions

- Chrome 49 (release: 2016/3/2)
- Firefox 50 (release: 2016/11/15)
- Safari 10 (release: 2016/9/20)
- IE 10 (release: 2012/10/26)
- Edge 14 (release: 2016/2/18)

ii. Connection quality



- Upload speed: minimum 100Mbps/SC
- Download speed: 300Mbps/SC or higher.

9. User responsibility for negligence



Dentomo does not directly or indirectly affect the patient's health. It is a tool whose function is to aid the diagnosis for dentistry professionals and therefore the last decision falls to the doctor. The responsibility for the erroneous diagnosis of a pathology that may affect the health of the patient lies entirely with the doctor.

10. Identifying Label Elements

The Dentomo identification card collects the official logos certifying, among others, the license numbers and the CE marking in response to the standards required for medical software.

| | |
|---|---|
|  | <p>Medical software license number.</p> <p>YY: Year of manufacture ZZZ: Reference XXXX: Serial number</p> |
|  | <p>CE Marking logo (compliance with MDR Regulation 745/2017)</p> |



| | |
|---|---|
|  | Manufacturer of the software Dentomo, physical address of the company. |
|  | Logo indicating the mandatory reading of the user's instruction manual. |

11. Warnings

Dentomo is a software that helps dental diagnosis and despite its high degree of accuracy, an incorrect diagnosis is feasible. The user needs to perform a final validation that corroborates the result of Dentomo before giving it good. The Dentomo software is not designed for use in primary dentition so it is not recommended for use in teeth with these characteristics. The response parts of this type can generate incorrect results.

12. Date of publication and last revision

Date of creation: March 17

Author: Fernando Avilés

Last review by Ignacio Arranz

Date of last review: 6th of July of 2022

This instruction manual was completed on 17 March 2020. To date, the following revisions have been made:

| Autor and date | Sections |
|----------------------------|---------------|
| Fernando Avilés (17/03/20) | First Edition |



| | |
|---------------------------------|------------------------------------|
| Ignacio Arranz (17/07/2020) | Cambios(section 11.) |
| Daniel Gimeno (06/07/2022) | Patient profile added (seccion 1b) |

Manufacturer details



Made by: MMG.

Address:

Web site:

The medical software does not have any possible adverse effects. However, in case of any undesirable clinical effect, you can contact the manufacturer and the Spanish Medicines Agency (902 101 322).