

DentalMonitoring patient

Instructions for use

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1. GLOSSARY



CE Marking



Manufacturer



Date of manufacture



Caution: consult the instructions for use for important cautionary information



Consult instructions for use



Batch code (software version number)



Catalog number



Medical device



Unique Device Identification



Caution: In the USA, Federal law restricts this device to sale by or on the order of a dental professional.

2. DEFINITIONS

<i>3D Model</i>	3D intraoral dental model
<i>Clinical Observation</i>	Finding amongst the possible outputs for any monitored <i>Clinical Parameter</i>
<i>Clinical Parameter</i>	Parameter within the indications for use statement <i>DentalMonitoring</i> monitors
<i>Dashboard</i>	Web-based interface for the <i>Healthcare Professional</i>
<i>Data Analysis Platform</i>	Platform analyzing <i>Scans</i> for <i>Clinical Parameters</i> as set-up by the <i>Healthcare Professional</i> in <i>Protocol</i>

<i>DentalMonitoring</i>	Software using image processing algorithms to analyze pictures of the oral cavity. It comprises a mobile application (<i>DM App</i>), a web-based interface (<i>Dashboard</i>), and a <i>Data Analysis Platform</i> .
<i>DM App</i>	<i>DentalMonitoring</i> mobile application
<i>DM Cheek Retractor</i>	Cheek retractor sold by Dental Monitoring to be used with DM ScanBox
<i>DM ScanBox</i>	Phone support sold by Dental Monitoring to be used with DM Cheek Retractor
<i>Healthcare Professional</i>	Licensed or non-licensed healthcare professional exercising in a healthcare facility with proficient skills
<i>Instruction</i>	Sent to <i>Healthcare Professional</i> through the <i>Dashboard</i> and/or to patient through the <i>DM App</i>
<i>Scan</i>	Set of intraoral pictures taken with the <i>DM App</i> .
<i>ScanBox^{pro}</i>	Cheek retractor tube and phone support sold by Dental Monitoring
<i>Adapter</i>	Device that attaches to the phone support, allowing the cheek retractor tube to be farther apart from the phone.
<i>LED Adapter</i>	Device that attaches to the phone support, making phones incompatible with the <i>ScanBox^{pro}</i> able to take scans. It carries LEDs that replace the flash of the phone.



3. INSTRUCTIONS FOR USE

3.1. INTENDED PURPOSE

DentalMonitoring is a medical device software using image processing algorithms to analyze pictures of the oral cavity (hereinafter *Scans*). *Scans* are taken using the *DM App* and a smartphone, and the manufacturer's proprietary hardware products.

Scans are taken by the patient, a non-healthcare professional, or a *Healthcare Professional*. The *Scan* is taken in healthcare facilities, such as a dental practice, or in a non-healthcare environment, such as the patient's own home. For some *Clinical Parameters*, *DentalMonitoring* requires a *3D Model*.

The product is designed to assist *Healthcare Professionals* in remotely monitoring dental treatments, orthodontic treatments, oral health, and treatment progress. The results of *DentalMonitoring* are intended to be used as an aid in diagnosis and not on a stand-alone basis for clinical decision-making.

DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.

3.2. INDICATIONS

DentalMonitoring can monitor the following *Clinical Parameters*:

- soft tissue statement: black triangle;
- dental statement: closure of extraction space;
- alignment: closure of all anterior spaces; and
- dental occlusion (2D results): midline deviation, overbite/open bite, overjet.

Additionally, the following *Clinical Parameters* specific to orthodontic treatment types or phases can be monitored using *DentalMonitoring*:

- for aligner treatments: tracking (seat/unseat), attachment loss, button loss;
- for braces: bracket debonding, tie loss, self-ligating clips, passive archwire and auxiliaries; and
- for thermoformed retainers: tracking (seat/unseat).

Based on an initial 3D Model provided by a healthcare professional, *DentalMonitoring* can also provide *Healthcare Professionals* with *3D Models* representative of the patient's dentition and treatment progress.

This device is a prescription device and is not intended for over-the-counter use.

3.3. DESCRIPTION OF THE DEVICE

DentalMonitoring is composed of a mobile application (*DM App*), a website (*Dashboard*) and a *Data Analysis Platform*.

3.3.1. DM APP

The *DM App* is the interface primarily used by patients. The *DM App* can also be used by *Healthcare Professionals* and non-*Healthcare Professionals* assisting the patient.

The *DM App* captures pictures of the oral cavity via the smartphone built-in camera.

The *DM App* also enables communication between the patient and their *Healthcare Professional*.

3.3.2. DASHBOARD

The *Dashboard* is a web-based interface dedicated to *Healthcare Professionals*.

The *Dashboard* is used to:

- set-up monitoring *Protocols*
- review *Scans*
- review *Clinical Observations* occurring within the monitored *Clinical Parameters*
- communicate with patients

3.3.3. DATA ANALYSIS PLATFORM

The *Data Analysis Platform* processes *Scans* taken with the *DM App* and triggers *Instructions* based on the detected *Clinical Observations* and the associated criteria defined in the *Protocol*.

Results are then sent to *Healthcare Professionals* through the *Dashboard*.

Patients receive an *Instruction* in their *DM App* when needed as defined in the *Protocol*.

3.4. TARGET GROUPS

- Target population: *DentalMonitoring* is indicated for use for patients over the age of 6.
- Intended users: *DentalMonitoring* product can be used as follows:
 - the *DM App* is intended to be used by healthcare professionals or lay persons, patients themselves or third parties, in:
 - Professional healthcare facilities, such as a dental practice, or.
 - A non-healthcare environment, such as the patient's own home.
 - the *Dashboard* is intended to be used solely by healthcare professionals in a healthcare environment

3.5. TRAINING

Before starting home-based use of the mobile application (*DM App*), patients and caregivers shall be trained by the healthcare professional and provided with the patient instructions for use. Training within the practice should include taking the first Scan with the *DM App*.

3.6. CLINICAL BENEFITS

- *DentalMonitoring* provides additional information compared to traditional orthodontic treatments follow-up.
- Patient compliance to orthodontic treatment requirements.
- Enhanced communication between patients, healthcare providers and caregivers

3.7. TECHNICAL SPECIFICATIONS

DentalMonitoring compatibility requirements are described in section [Compatibility requirements](#).

3.8. SIDE EFFECTS

No known side effects.

3.9. CONTRAINDICATIONS

DentalMonitoring should not be used on patients under the age of 6.

DentalMonitoring should not be used by patients presenting systemic conditions affecting connective tissues not allowing them to open/close their buccal cavity sufficiently to acquire acceptable *Scans*.

3.10. LIMITATIONS

DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.

3.11. WARNINGS, PRECAUTIONS, NOTICES

The following population should be assisted by a third party to perform *Scans*:

- children up to 12;
- adults or children visually impaired;
- adults or children hearing impaired;
- or any condition that might prevent the patient from adopting the right position to take a *Scan*.

DentalMonitoring is not intended to replace standard practices for diagnosis or treatment. Final clinical decisions remain the sole responsibility of the *Healthcare Professional*. In order to establish a diagnosis, further examinations are required according to the current standard of care, such as dental radiographs and/or tactile examinations with instrumentation.

In the event of pain, discomfort, or any other symptom during treatment, you should refer to your *Healthcare Professional* since the latter has the ultimate responsibility for making medical decisions.

DentalMonitoring results are limited only to elements visible in the input *Scans*. *DentalMonitoring* does not provide results on non-visible elements. *DentalMonitoring* does not provide results on lingual surfaces.

Some *Scans* may be rejected if they cannot be processed by *DentalMonitoring*. In such cases, you will be informed of the reason for the rejection and given advice on how to take acceptable *Scans*. Please see [Why was my Scan rejected?](#) for a list of reasons your *Scan* may be rejected.

3.12. LIST OF REQUIRED NON-PROVIDED PRODUCTS

- *DM Cheek Retractor* (REF 1002-001, REF 1003-001, REF 1004-001) in association with *DM ScanBox* (REF 1001-001) – mandatory accessories
- *ScanBox^{pro}* – mandatory accessory: 1x *ScanBox^{pro}* - Phone support (REF 1005-001) + 1x *ScanBox^{pro}* - Cheek retractor tube in size S (REF 1006-001), M (REF 1007-001) or L (REF 1008-001) + 1x *ScanBox^{pro}* – Adapter (REF 1013-001)
- A smartphone with an internet access (see [Compatibility requirements](#)).
- LED Adapter (REF 1016-001)

3.13. IMPORTANCE OF THE NEED TO FOLLOW THE INSTRUCTIONS SENT THROUGH THE DM APP

Please be aware that the *DM App* is also a tool to facilitate the communication between you and your *Healthcare Professional*. For best results, you will need to ensure you follow all given instructions and advice related to the use of the *DM App*. This includes:

- taking your *Scan* as soon as possible when you receive the push notification on your smartphone;
- reading *Instructions* and direct messages sent on the *DM App* and replying if asked to; and
- contacting your *Healthcare Professional* or customer support (see: [User assistance information](#)) if you encounter use difficulties with the *DM App*.

A list with common user messages is available under the [DM App](#) section of the “DentalMonitoring Help Center”, using the embedded search bar, and typing “error”.

3.14. SECURITY OF INFORMATION

DentalMonitoring has implemented strong information security control measures in order to guarantee the confidentiality, integrity, availability and traceability of data, including personal health data (also known as ePHI).

DentalMonitoring protects user accounts with the following measures:

- multi-factor authentication that can be activated for your account,
- a login and password OR magic link for the *DM App*.

A strong password rule is implemented for user accounts (minimum 8 characters with at least one letter, one number and one special character). Create a new password to use our services and do not re-use an old password you have already used on any other service. It is strongly recommended to use a password manager to generate and store your password.

DentalMonitoring regularly updates the *DM App*, including cybersecurity updates.

It is recommended you enable automatic updates from the App Store (iOS) or the Google Play Store (Android) to ensure you always have the latest app version.

Dental Monitoring performs regular backups to ensure the integrity and availability of data, including ePHI. In case of an incident, Dental Monitoring implements policies and procedures to restore backups and recover the services.

It is recommended that your device runs the latest available version of the operating system. To update your operating system, please follow the advice from your device and/or your phone's manufacturer. Please also refer to the [Compatibility requirements](#) section of this document.

It is strongly advised that your device and your phone have an active lock mechanism in place, such as a passcode or fingerprint. Please see your device manufacturer's guides on how this can be set up. You should never leave your device unattended and unlocked at the same time.

It is recommended that you use a device with up-to-date protection against virus and malware. If you suspect a security issue on your smartphone, it is recommended that you do not use the Dashboard and/or the *DM App*, until a complete remedy.

It is recommended that you use a reliable internet connection while using the app. On your device, standard internet network ports (443 and 8443) should be open to receive/send data.

If you identify or suspect a breach of information security within the DM App, please contact the customer support at support@dental-monitoring.com.

Please note, you can log out of your account at any time by tapping logout in Preferences.

From this section onwards, the content of this document exclusively covers the use of the *DM App* by non-Healthcare Professionals since other parts of *DentalMonitoring* are only intended to be used by *Healthcare Professionals*.

4. DIRECTIONS FOR USE

4.1. SETUP INSTRUCTIONS

The *DM App* requires an initial setup.

At the end of the setup process, you will be able to log in into your account and take your first *Demo Scan*. Follow the step-by-step instructions carefully.

In case of any question or problem, please see [User assistance information](#).

4.1.1. COMPATIBILITY REQUIREMENTS

In order to set up and use the *DM App* on your smartphone you need:

- An internet connection (Wi-Fi or Cellular).
- A smartphone running on either:
 - Android 9 and up. Please see [Install and setup on Android phones](#)
 - iOS 15 and up. Please see [Install and setup on iPhones](#)

Smartphones are required to encompass a flashlight, autofocus, and an aspect ratio of 4/3.

Smartphones running on Android require the closest resolution to 2,752*2,064 pixels (with a maximum height of 3,500 pixels) while smartphones running on iOS require a 4,032 x 3,024 pixels resolution.

A list of phone models that are not compatible with the ScanBox^{pro} can be found in the **FAQ** section at the following [link](#), and for the 3D Experience (ScanAssist) at this [link](#). 3D Experience (ScanAssist) cannot be used with manufacturer's proprietary hardware products other than the ScanBox^{pro}. If you have any further questions about phone compatibility, please contact customer support (support@dental-monitoring.com).

4.1.2. INSTALL AND SETUP

Install and setup on Android phones	Install and setup on iPhones
1. In your email inbox, you will be sent an invitation to download the <i>DM App</i>. This invitation is sent by your <i>Healthcare Professional</i>. 2. Open the invitation email on your smartphone and follow the instructions. Click on Android. You will be redirected to	1. In your email inbox, you will be sent an invitation to download the <i>DM App</i>. This invitation is sent by your <i>Healthcare Professional</i>. 2. Open the invitation email on your smartphone and follow the instructions.



the Google Play Store to download the <i>DM App</i>. - In the Play Store, tap on 'install' to install the <i>DM App</i>. Wait until the installation is complete. - If multi-factor authentication is not activated in your account, in the invitation email, click on → click on the activation link. This link will open your <i>DM App</i> and log you in. - If multi factor authentication is activated in your account, log in using your email address and password. Before accessing the app, you will have to enter a confirmation code sent by SMS on the phone number shared with your doctor when creating your <i>DentalMonitoring</i> account. - When the <i>DM App</i> opens for the first time, you will be asked to allow the <i>DM App</i> to send you notifications. Follow the on-screen instructions carefully. Please note: access to notifications is mandatory to be informed when a <i>Scan</i> is due and when you receive an <i>Instruction</i> or direct message.	Click on iPhone. You will be redirected to the AppStore to download the <i>DM App</i>. - In the AppStore, tap on GET to install the <i>DM App</i>. Wait until the installation is complete. - If multi-factor authentication is not activated in your account, in the invitation email, click on → click on the activation link. This link will open your <i>DM App</i> and log you in. - If multi factor authentication is activated in your account, log in using your email address and password. Before accessing the app, you will have to enter a confirmation code sent by SMS on the phone number shared with your doctor when creating your <i>DentalMonitoring</i> account. - When the <i>DM App</i> opens for the first time, you will be asked to allow the <i>DM App</i> to send you notifications. Follow the on-screen instructions carefully. Please note: access to notifications is mandatory to be informed when a <i>Scan</i> is due and when you receive an <i>Instruction</i> or direct message.
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4.2. INTERFACE OVERVIEW

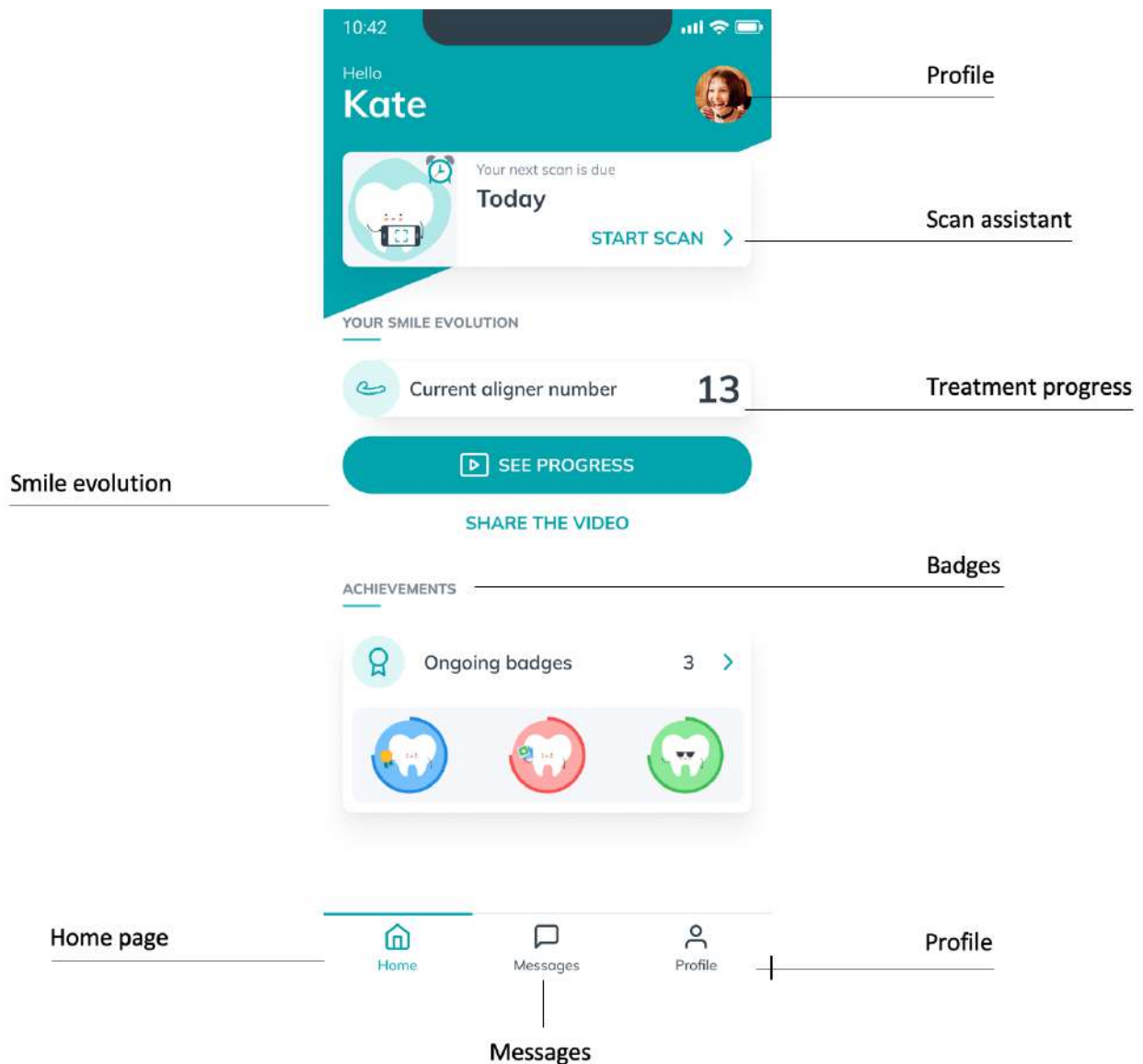
The main page of the *DM App* is the **Home tab**. It allows you to:

- open the **Scan Assistant**;
- access the **Messages tab**;
- access the **Profile Settings**;
- get information on your treatment progress;



- view your smile evolution; and
- view progress on badges related to your treatment





Screenshot provided for illustrative purposes; The language shown may differ from that of your software interface.

4.2.1. HOME TAB

The **Home tab** is where the *DM App* displays:

- when your *Scan* is due
- information on your treatment progress
- your smile evolution
- progress on badges related to your treatment

You can also access your **Profile Settings** in the top right corner.

4.2.2. BADGES

Along your treatment journey, you will earn badges to encourage you and help you measure your progress.

You can access the '**Badges**' page from the '**Achievements**' section available from the app home page. You will have access to all badges not yet unlocked.

Badges are classified by categories (all categories may not be available to you, depending on your treatment type):

- **Treatment milestones:** The badges in this section can be unlocked throughout your treatment and highlight specific milestones you have reached.
- **Number of scans taken:** This section keeps track of the number of scans you have taken since the beginning of your monitoring, including additional scans.
- **Number of scans taken on time:** This section is dedicated to compliance. A scan is considered taken on time if it is uploaded less than 48 hours after it was due. You can adjust the time of your reminders from your profile to make sure to take your scans on time.
- **Number of GOs in a row** (aligners patients only): Each time you receive the instruction to move on to the next aligner after taking a scan, a GO is recorded. This section groups badges computing consecutive GOs. Keep wearing your aligners 22 hours a day to increase the chance to receive GO instructions.

From the '**Badges**' page you can also access the '**Badges earned**' page, where you will find all badges already unlocked, classified by category.

4.2.3. MESSAGES TAB

The **Messages tab** is where you can:

- See messages exchanged between you and your *Healthcare Professional*
- Be able to send a direct message to your *Healthcare Professional*
- Receive your *Scan Report*
- Access your previous *Scans*

4.2.4. SCAN ASSISTANT

The **Scan Assistant** will be guiding you through the different steps to take a *Scan*, including:

- *Scan* setup
- video tutorials
- *Scan* capture
- *Scan* review

You will enter the **Scan Assistant** by tapping the '**Start Scan**' button from the **Home tab**.

4.2.5. PROFILE

The **Profile tab** is where you will be able to:

- Switch account or log in to a new account
- Log out
- Add/edit a profile picture
- Setup *Scan* preferences
- Set your *Scan* reminder notification time and access notification settings
- Set up your preferences for badges
- Access your previous *Scans*
- Run a Training *Scan*. See [How can I do a Training Scan?](#)
- Watch video tutorials at any time
- Access the help center
- Contact DentalMonitoring support
- Send feedback about the *DM App*
- Access regulatory information
- Request an Additional *Scan*
- Update audio resources

4.3. OPERATING INSTRUCTIONS

Make sure that you always use the *DM App* in a well-lit environment to avoid eye strain.

4.3.1. BEFORE TAKING YOUR SCAN

We recommend that you wash your hands and your scanning equipment (such as the *DM Cheek Retractor* or the *Cheek Retractor Tube* provided with the *ScanBox^{pro}*) before each *Scan*, as well as clean your smartphone regularly.

We recommend that you take your *Scan* in front of a mirror in a well-lit room with a clean surface to put your equipment on (e.g. a bathroom). In case you are being assisted by a third party in taking your *Scan*, you do not require a mirror.

Please note: the front camera cannot be used to take *Scans* due to the absence of a flashlight.

The *DM App* will send you a push notification each time you are required to take a *Scan*. See [Reminder time](#).

Before taking a *Scan*, you need to gather:

1. your smartphone with the *DM App*
2. your scanning equipment: either your *DM Cheek Retractor*, *DM ScanBox* or your *ScanBox^{pro}*
3. *if applicable:* your adapter.
4. *if applicable:* your LED adapter with some charge left.
5. *if applicable:* your removable appliances (e.g. aligners)

6. *if applicable: your DM ScanBox. Please note:* if you do not have a *DM ScanBox*, see [Patients not using DM ScanBox](#)



4.3.2. TAKING YOUR SCAN

Please be aware that initiating the *Scan* process will automatically activate both your phone's sound and flashlight. Do not look directly into your phone's flashlight.

Before taking a *Scan* for the first time, your phone will request access to the smartphone's camera. You must allow access to be able to take *Scans*.

For instructions on how to put on your retractor refer to the instructions for use of the product you are using.

4.3.2.1. Patients using a DM Cheek Retractor along with a DM ScanBox

When placing your phone in the *DM ScanBox* do so over a soft surface to avoid damage to the phone in the event it falls out. For instructions on how to pair up your smartphone with the *DM ScanBox* refer to the *DM ScanBox* instructions for use.

Follow Steps 1-6 described hereinafter to take a *Scan*. Double tap on the screen to proceed to the next step.



1. In the **Home tab**, tap on '**Start Scan**' to enter the **Scan Assistant**
2. Fill in the pre-scan checklist according to the instructions given by your *Healthcare Professional*:
 - a. Select the *DM ScanBox* and *DM Cheek Retractor* icon
 - b. Choose whether you will be using a mirror or be assisted by a third party when asked 'How are you taking this Scan?'
 - c. Adjust the volume for the audio instructions until you can clearly understand what is being said.
3. Set up your *DM ScanBox* following the video tutorial in the **Scan Assistant**.
4. You may be asked to perform additional steps depending on your treatment type. If you do not have any of the following treatments, you can skip this part and go directly to step 7.
 - a. **Patients with aligners:**
 - you may be prompted to confirm the aligner number you will be taking your *Scan* with.
Please note: Unless your *Healthcare Professional* has instructed otherwise, these aligners are the ones you have been wearing for the last few days.
 - You may be asked to choose if you want to scan first wearing your aligners or not. Listen carefully to the audio instructions to know when to insert or remove your aligners during your *Scan*.
 - b. **Retainers or other removable appliances:**
 - you will be asked to remove your removable appliances before taking your *Scan*



- for thermoformed retainers, you will be instructed to put the thermoformed retainers back on. Make sure you wait until you hear this instruction.
5. Click on '**Start Scan**' to start your *Scan*.
 6. Follow the video and audio instructions carefully. Looking at your phone's screen in a mirror while you take your *Scan* will enable you to see what your camera sees and will therefore facilitate taking a *Scan*. To start a step, double tap on your phone's screen.
 - a. As you hear the sound of your camera, you shall start moving your *DM ScanBox* following the speed of the gauge on your smartphone's screen



- b. Your movement should be wide from ear-to-ear to ensure all your teeth are scanned



- c. If necessary; you can restart your scan by pressing the '**retry**' button



- d. Now you can take your *DM ScanBox* off. To do so, hold the *DM Cheek Retractor* in place with your thumbs and pull the *DM ScanBox* forward. You can now take the *DM Cheek Retractor* out





- e. Review your *Scan*: you will be prompted to review the pictures taken during your *Scan* for each step: biting down on your back teeth, slightly open mouth (with and without aligners where applicable), mouth wide open.
If the pictures do not match the description provided in the *DM App* for a specific step, you can select '**Retake this step**'.
- f. After reviewing your *Scan*, a summary page will be displayed indicating if each step has successfully been conducted based on your review. If all steps were conducted successfully, press on '**Send Scan**', if not, press on '**Retake pictures**'. If you need to retake part of your *Scan*, refer back to Step 6.

4.3.2.2. Patients using a ScanBox^{pro}

When placing your phone in the ScanBox^{pro} do so over a soft surface to avoid damage to the phone in the event it falls out. For instructions on how to pair up your smartphone with the ScanBox^{pro} refer to the ScanBox^{pro} instructions for use.

Follow Steps 1-9 described hereinafter to take a *Scan*.

1. In the **Home tab**, tap on '**Start Scan**' to enter the **Scan Assistant**
2. Fill in the pre-scan checklist according to the instructions given by your *Healthcare Professional*:
 - a. Select the ScanBox^{pro}
The adapter or LED Adapter may be required depending on your phone model; the application automatically detects whether the adapter is required and informs you accordingly. If so, make sure to follow the instructions about the use of the adapter or LED Adapter.
 - b. Choose whether you will be using a mirror or be assisted by a third party when asked 'How are you taking this Scan?'
 - c. Adjust the volume for the audio instructions until you can clearly understand what is being said.
3. You may be asked to perform additional steps depending on your treatment type. If you do not have any of the following treatments, you can skip this part and go directly to Step 4.
 - a. **Patients with aligners:**
 - you may be prompted to confirm the aligner number you will be taking your *Scan* with.

Please note: Unless your Healthcare Professional has instructed otherwise, these aligners are the ones you have been wearing for the last few days.



- You may be asked to choose if you want to scan with aligners in our out first. Listen carefully to the audio instructions to know when to insert or remove your aligners during your *Scan*.
- b. **Retainers or other removable appliances:**
 - you will be asked to remove your removable appliances before taking your *Scan*
 - for thermoformed retainers, you will be instructed to put the thermoformed retainers back on. Make sure you wait until you hear this instruction.
- 4. Click on '**Start Scan**' to start your *Scan*.
- 5. Set up your *ScanBox^{pro}* following the video tutorial in the **Scan Assistant**.
- 6. Step 6 depends on your scan mode:

a. Patients scanning with the 3D Experience (ScanAssist)

The model you see on the screen follows your movements and mouth opening in real time.

During the scan, we want to capture all the areas of your mouth. Each area is represented with a colored dot. Move the Cheek Retractor Tube inside your mouth to scan all the dots.

Follow the video and audio instructions carefully. Looking at your phone's screen in a mirror while you take your *Scan* will enable you to see what you are doing and will therefore facilitate taking a *Scan*.

Depending on your physiology and the size of the *Cheek Retractor Tube*, it might be difficult to reach for side dots. Try to move as close to the dot as possible and an Assistance mode will be automatically activated to help you catch the dot. on side targets.

During the scan, you can remove you Cheek Retractor Tube at any time. This will pause the scan and give you access to the *Scan* menu. From the menu you can:

- Adjust the volume of audio instructions
- Turn on/off the visual aid. The visual aid allows you to see what your camera sees in addition to the 3D model. This can help you complete the *Scan*.
- Skip a step if you're not able to complete it until the end
- Stop the *Scan*
- Access help content

Please Note: If you're experiencing lag between your movements and the 3D model movements, or if you're not able to properly adjust the *ScanBox^{pro}* to *scan*, your device might not be compatible with the 3D experience. You can change mode and scan without the 3D experience. To do so, go to the *Scan settings* available from the *Profile* page.

b. Patients scanning without the 3D experience

During the *Scan*, double tap on the screen to proceed to the next step.

Follow the video and audio instructions carefully. Looking at your phone's screen in a mirror while you take your *Scan* will enable you to see what your camera sees and will therefore facilitate taking a *Scan*. To start a step, double tap on your phone's screen.

- As you hear the sound of your camera, you shall start moving your *ScanBox^{pro}* following the speed of the gauge on your smartphone's screen
- Your movement should be wide from ear-to-ear to ensure all your teeth are scanned
- If necessary; you can restart your scan by pressing the '**retry**' button





7. Remove the *Cheek Retractor Tube* from your mouth.
8. Review your *Scan*: you will be prompted to review the pictures taken during your *Scan* for each step: biting down on your back teeth, slightly open mouth (with and without aligners where applicable), mouth wide open.
If the pictures do not match the description provided in the *DM App* for a specific step, you can select 'Retake this step'.
9. After reviewing your *Scan*, a summary page will be displayed indicating if each step has successfully been conducted based on your review. If all steps were conducted successfully, press on 'Send Scan', if not, press on '**Retake pictures**'. If you need to retake part of your *Scan*, refer back to Step 6.

4.3.2.3. Taking your scan with the assistance of a third-party

When taking your *Scan* with the assistance of a third party, in the pre-scan checklist, make sure to choose the 'assisted by a third party' option when asked 'How are you taking this Scan?'. This will make the text displayed during the *Scan* readable by the third party to better assist you while taking the *Scan*.

During the *Scan*, the third party should be the one manipulating the *DM ScanBox* or *ScanBox^{pro}* and interacting with the *DM App*. You should keep your head straight and follow the third-party instructions.

For instructions on how to take the *Scan*, you can refer to the sections above.

4.4. REMINDER TIME

By default, reminders to scan are set to 7AM; however, you can easily change this on the *DM App*:

1. Go to your **Profile**. If you do not yet have notifications enabled, enable them (see: [What should I do if I am not receiving notifications?](#)).
2. Under the **Your Notifications** section, short tap on the time indicated to set **Notification time**. You can then choose an alternative time for the alerts (the clock will show both 12H and 24-hour time).



4.5. DESCRIPTION OF MAINTENANCE AND WHO SHOULD DO IT

4.5.1. MANDATORY UPDATES

The *DM App* will alert you when a mandatory update is ready to be downloaded and installed. The app will redirect you to download the new update. It will install automatically.

4.5.2. REGULAR UPDATES

Regular updates are not mandatory to keep using the *DM App*, but it is strongly recommended that you keep your *DM App* updated with the latest available version.

5. DISPOSAL

You can dispose of the *DM App* by uninstalling it from your smartphone. Please follow your phone manufacturer's guide on uninstalling apps.

6. FREQUENTLY ASKED QUESTIONS

6.1. HOW CAN I DO A TRAINING SCAN?

You can perform a *Training Scan* at any time on your *DM App*. From your **Profile**, tap on **Training Scan** which is located under the *Scan* section. This will open up the *Scan Assistant*. You will be guided through the same steps as you would for a real *Scan* -the only difference is that the acquired *Scan* is not sent or saved.

6.2. WHY DOES THE *DM APP* ASK FOR ACCESS TO MY CAMERA?

The *DM App* needs access to your camera in order to take *Scans* of your teeth.

6.3. HOW TO CHECK MY VERSION OF THE APP?

You can find the current version of your *DM App* in **Profile**: It is displayed at the bottom of the screen.

6.4. HOW CAN I SEND A DIRECT MESSAGE TO MY HEALTHCARE PROFESSIONAL?

You can send a direct message to your *Healthcare Professional* via the messaging icon on your **Messages** tab.

6.5. HOW DO I REINSTALL THE *DM APP* IF I HAVE LOST THE EMAIL?

If you delete the *DM App* and wish to re-install it, you can do so at any time from the Play Store (Android) or the App Store (iOS). Search for 'Dental Monitoring'. Once reinstalled, you will need to connect using your current credentials or reset them with a password recovery procedure.

6.6. HOW CAN I MANAGE THE TWO-FACTOR AUTHENTICATION?

From the Profile tab, you have the ability to activate the two-factor authentication to add an extra layer of security.

To activate it, you will need to provide a mobile phone number and validate a code sent by SMS. Once activated, two levels of authentication (password + SMS code) will be required to log in.

To deactivate the two-factor authentication, the support team need to be contacted at support@dental-monitoring.com.

6.7. WHY WAS MY SCAN REJECTED?

When you complete a *Scan* via your *DM App*, your photos will be sent to our platform for analysis. These photos need to meet a minimum standard of quality, otherwise our system will not be able to analyze them correctly (or create the before/after photos that you see in your *DM App*). If this happens, you may get a message saying that your *Scan* has been rejected. Don't panic! All this means is that you will need to take the *Scan* again, following the suggestions given to you in the *DM App*.

First the photos below show you examples of good quality scans allowing a good analysis:



Examples of a good-quality *Scan* taken with a ScanBox^{pro}

Let's have a look at some of the common reasons you *Scan* may get rejected.



Please note that the use of a *DM ScanBox* along with a *DM Cheek Retractor*, or use of a *ScanBox^{pro}* will greatly reduce the likelihood of you coming across these problems. This is because the *DM ScanBox* or the *ScanBox^{pro}* controls the distance, lighting, color balance as well as synchronizing the movement of the camera and the *DM Cheek Retractor* to ensure a perfect *Scan* is captured each time. If you do not have a *DM ScanBox* and *DM Cheek Retractor*, or a *ScanBox^{pro}*, please contact your clinic.

- **Reason #1:** your photos are blurry



Example of blurry photo

If you move your camera too fast while taking your *Scan*, you may end up with blurry photos. Follow the on-screen guide while moving your *ScanBox^{pro}*: this will maximize the chance of taking sharp pictures.

- **Reason #2:** your photos are too dark



Example of photos that are too dark

Your *DM App* should trigger the camera's flash automatically, but in some cases your photos may still appear too dark, make sure to take your *Scans* in a well-lit room, ensuring the photos are bright enough to clearly see your teeth, and ensure that your phone's flash is not obscured by the *ScanBox^{pro}* phone support and is visible through the pairing window.

- **Bonus tip:** If you are using a *DM ScanBox*, make sure that your phone is set up correctly: the camera lens should line up with the arrow as indicated in the picture below and the *DM ScanBox* should not obscure the flash.



- **Bonus tip:** color balance

Although it is not a reason for your *Scans* to be rejected, you should try your best to take your *Scans* in similar lighting conditions every time. This will ensure that the color balance of your photos are consistent.

- **Reason #3** your camera is not in the middle of the tube (for patients using a *ScanBox^{pro}*)



Example of photos that are not centered on the mouth

Make sure your camera's lens is positioned correctly when taking your *Scans*. If your phone has more than one lens, the best way to ensure you are using the correct one is to open your app, take a demo *Scan* and adjust the position of your phone in the phone support until you can see it positioned inside the *Cheek retractor tube*.



- **Reason #4:** your back teeth are not visible



Photo where we can see all of the back teeth.



Photo where we cannot see the back teeth enough.

When scanning from side to side, you need to make sure you pull the *DM Cheek Retractor* or *Cheek retractor tube* as far back as possible (without causing you any discomfort of course!) so that your molars (the teeth at the back) are visible. In the photos above, the molars are completely hidden by the *Cheek retractor tube*.

- **Reason #5:** your occlusal (up/down) views are not clear enough



An example of a good occlusal photo



An example of an occlusal photo where we cannot see enough of the teeth

If you are asked for an occlusal photo, make sure you tilt your head back/forward so that we can see the biting surface of your teeth.

- **Reason #6:** lips or tongue hiding teeth



Tongue is hiding the biting surface of the teeth



Lips are hiding the teeth

When taking your *Scans*, make sure that your lips or tongue do not cover the surfaces of your teeth or your gums. This can be avoided by making sure the *DM Cheek Retractor* or *Cheek Retractor tube* is inserted correctly, and that you keep your tongue in a retracted position when taking occlusal photos.

- **Reason # 7:** Fogged up lens



Example of fogged photos

If you breathe out through your mouth while taking your *Scans*, you may cause condensation to appear on your lens making your scans appear 'foggy'.

To avoid this, breathe through your nose while scanning.

- **Reason # 8:** *DM Cheek Retractor or Cheek retractor tube* too small



Examples of photos when the Cheek Retractor is too small

The *DM Cheek Retractor* and *Cheek retractor tube* come in different sizes to adapt to different mouth sizes. If you use a size that is too small, we won't be able to see your teeth and gums well enough. You should be using the biggest size that is possible to wear without causing discomfort. You may need to contact your clinic or supplier to get a larger *DM Cheek Retractor* or *Cheek retractor tube*.

6.8. WHAT HAPPENS IF I HAVE NO INTERNET CONNECTION?

The *DM App* will automatically display a warning at the top of the screen if there is a problem with the internet connection. If this happens, you can tap on the '**retry**' link to try to re-establish a connection.

If no internet connection is present, the *DM App* will not be able to upload any *Scans* taken or refresh to show the most recent messages from the *Healthcare Professional*.

6.9. WHAT DO I DO IF I CANNOT HEAR THE AUDIO INSTRUCTIONS?

When you take your *Scan*, you should be able to hear an audio prompt that will guide you through each step of your *Scan*.

If you cannot hear this audio prompt, please check that your phone is not on silent mode and that the volume is turned up. Please refer to your phone manufacturer's instructions for further information.

6.10. WHAT SHOULD I DO IF I AM LATE ON A SCAN?

It is very important to take your *Scans* on time. If you are late on a *Scan*, take the *Scan* as soon as possible.



6.11. WHAT SHOULD I DO IF I AM NOT RECEIVING NOTIFICATIONS?

You need to enable push notifications on your phone in order to receive reminders from your *DM App* to take your *Scans*. Please check the instructions from your phone's manufacturer to ensure that you have enabled push notifications from the *DM App*.

6.12. WHAT SHOULD I DO IF I AM HAVING TROUBLE OPENING MY *DM APP*?

If you are encountering problems opening your *DM App*, please check that your version of the phone's operating system is up to date. Otherwise, please contact customer support (see: [User assistance information](#)) to report the issue.

6.13. HOW CAN I STOP THE TUTORIAL VIDEOS FROM SHOWING?

You will be able to watch tutorial videos showing you how to scan each time you open the **Scan Assistant**. If you want to stop these tutorials from appearing, you need to go to your **Profile tab** and tap on the video you no longer wish to see to deactivate this.

7. ADDITIONAL INFORMATION

7.1. TRAVEL OR INTERNATIONAL USE

When travelling to another time zone:

1. Upon arrival, get a stable internet connection
2. Open the *DM App* to synchronize the time of the reminder to your new time zone. Example: if your reminder is set to 7PM, it will be set to 7PM in the new time zone.

8. LIFETIME

Any version of the *DM App* from the last force update to the current one is supported by Dental Monitoring.

If the user does not upgrade the version of the *DM App* through the force update provided by Dental Monitoring, they will not be allowed to use the previous version as support on this version ends.

9. DATE

The present Instructions for use were issued in February 2026.

10. INSTRUCTIONS FOR USE VERSION

IFU_MON_P_MD_05_En

11. USER ASSISTANCE INFORMATION

Please report any serious incident that occurred in relation to the device to support@dental-monitoring.com and to the local competent authority for medical devices. To find your local user assistance phone number: <https://dental-monitoring.com>, Contact Us.

These instructions for use are provided in electronic instead of paper form. In case a paper copy is required, please address your request to support@dental-monitoring.com, it will be provided at no charge.

12. MANUFACTURER INFORMATION



Dental Monitoring
75 rue de Tocqueville
75017 Paris
France

The device bears the CE marking in accordance with Regulation (EU) 2017/745 on medical devices since 19 November 2024.

