

DentalMonitoring Healthcare professional Instructions for use

TABLE OF CONTENTS

1. GLOSSARY	3
2. DEFINITIONS	3
3. DESCRIPTIVE INFORMATION	5
3.1. INTENDED PURPOSE	5
3.2. INDICATIONS.....	5
3.3. DESCRIPTION	6
3.4. TARGET GROUPS.....	7
3.5. TRAINING	7
3.6. CLINICAL BENEFITS	7
3.7. CLINICAL PERFORMANCES.....	8
3.8. TECHNICAL SPECIFICATIONS.....	10
3.9. SIDE EFFECTS.....	10
3.10. CONTRAINDICATIONS.....	10
3.11. LIMITATIONS.....	11
3.12. WARNINGS, PRECAUTIONS, NOTICES.....	11
3.13. LIST OF REQUIRED NON-PROVIDED PRODUCTS	11
3.14. COMPATIBILITY REQUIREMENTS.....	11
3.15. SECURITY OF INFORMATION	12
4. DIRECTIONS FOR USE.....	14
4.1. REGISTERING TO THE DASHBOARD	14
4.2. SIGNING IN TO THE DASHBOARD.....	14
4.3. DIFFERENCES BETWEEN DOCTOR AND PRACTICE EMPLOYEE ACCOUNTS	14
4.4. POTENTIAL ERROR MESSAGES.....	14
4.5. INTERFACE OVERVIEW OF THE DASHBOARD.....	15
4.5.1. NOTIFICATIONS (①).....	15
4.5.2. PATIENTS (②).....	16



4.5.3.	TO-DO LIST (③)	16
4.5.4.	CONFIGURATION (④).....	17
4.5.5.	SHOP (⑤).....	17
4.5.6.	SUPPORT (⑥)	17
4.5.7.	HELP (⑦)	17
4.5.8.	MY ACCOUNT (⑧).....	18
4.5.9.	LOGOUT (⑨)	18
4.6.	MONITORING PLANS	18
4.6.1.	PHOTO MONITORING LIGHT	18
4.6.2.	PHOTO MONITORING FULL	18
4.6.3.	3D MONITORING: LIGHT AND FULL	18
4.7.	PROTOCOLS	21
4.7.1.	WHAT IS A PROTOCOL?	22
4.7.2.	HOW TO CREATE AN ACTIVATED PROTOCOL IN THE PROTOCOL LIBRARY?.....	22
4.7.3.	PATIENT INSTRUCTIONS	24
4.7.4.	TEAM INSTRUCTIONS	26
4.7.5.	QUICKSTARTS	28
4.8.	NOTIFICATION MANAGEMENT	29
4.9.	PATIENT MANAGEMENT	30
4.9.1.	CREATE A NEW PATIENT	30
4.9.2.	START A MONITORING	30
4.9.3.	PATIENT CARD OVERVIEW	30
4.9.4.	SPECIFIC ADDITIONS TO 3D MONITORING	39
4.10.	VIDEO CONSULTATION	42
4.11.	DM APP INTERFACE	42
4.11.1.	HEALTHCARE PROFESSIONAL FUNCTIONALITIES	43
4.11.2.	PATIENT FUNCTIONALITIES	49
5.	LIFETIME	50
6.	DATE OF ISSUANCE	50
7.	INSTRUCTIONS FOR USE VERSION	50
8.	USER ASSISTANCE INFORMATION	50
9.	MANUFACTURER INFORMATION	50
	ANNEX 1 – LIMITATIONS	51
	ANNEX 2 – LIST OF OBSERVATIONS	53
	ANNEX 3 – PRODUCT DISCLAIMER.....	60



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>Smart STL</i>	Updated <i>3D model</i> feature
<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. DESCRIPTIVE INFORMATION

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*, 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*:

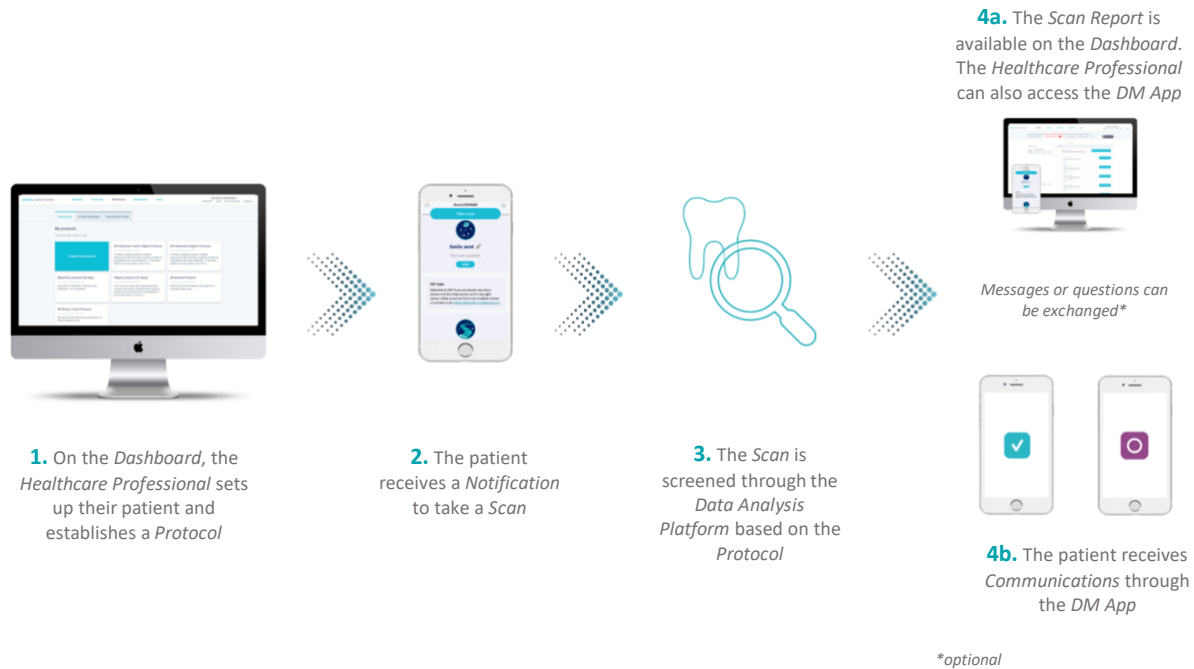
- for aligner treatments: tracking (seat/unseat), attachment loss, button loss;
- for braces: bracket debonding, tie loss, self-ligating clips, passive archwire and auxiliaries; and
- for thermoformed retainers: tracking (seat/unseat).

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



DentalMonitoring is composed of a mobile application (*DM App*), a website (*Dashboard*) accessible at www.dental-monitoring.com/doctor and a *Data Analysis Platform*.

- The *Dashboard* is where *Healthcare Professionals* can:
 - Manage and set up patient profiles (**Patient Cards**)
 - Set *Protocols* by choosing the *Clinical Parameters* they wish to monitor and the related actions to be triggered when a *Clinical Observation* occurs:
 - Send an automated message to the patient (*Patient Instructions*)
 - Display *instructions* to the *Healthcare Professionals* (*Team Instructions*)
 - Display detected *Clinical Observations* in the 'Notifications' tab
- Each time a *Scan* is due, the patient can take it directly or with the help of a third party. Once complete, it is sent through an internet connection to the *Data Analysis Platform*.
- Scans* are screened to see if any *Clinical Observations* are present within the *Clinical Parameters* being monitored according to *Protocol* and the associated *Instructions* are triggered.
- Instructions* triggered are displayed as follows:
 - For the *Healthcare Professional*:
 - On the *Dashboard*, *Clinical Observations* and the associated *Team Instructions* are displayed in the 'Notifications' tab.

- ii. In the *DM App*, *Patient Instructions* are displayed in the messages tab. Of note, *Healthcare Professionals* can also access the *DM App*.

- b. For the patient: *Patient Instructions* are displayed in the messages tab of the *DM App*.

The list of *Clinical observations* available in *DentalMonitoring* is available in [Annex 2 – List of Observations](#).

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 using the *Dashboard*, the user must have been qualified after having completed Dental Monitoring initial training program or identified as a qualified person by the practice internal procedures. Contact Dental Monitoring or Dental Monitoring-authorized representative for more information about the required training programs.

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. CLINICAL PERFORMANCES

The clinical performances of the product were demonstrated by conducting independent clinical investigations. Performances have solely been demonstrated with hardware products proprietary to DentalMonitoring: the *DM Cheek Retractor* and *DM ScanBox*.

- Occlusion parameters

The performances of the product for the occlusion parameters were validated in a prospective study involving four sites located in the US. Reference Method results were generated by measuring the occlusion parameters undergoing evaluation on 3D Models of the patients enrolled in the study. Reference Method results were generated using a CAD/CAM software.

Correlation was plotted against the Reference Method for each occlusion parameter.

	2D results
Midline Deviation	Total: 277 patients
	Slope = 0.93 [0.89, 0.97]
	Intercept = 0.0 (-0.03) [0.0, 0.0] [-0.05, 0.01]
Overbite / Open bite	Total: 301 results sourced from 285 patients
	Slope = 0.95 [0.91, 0.99]
	Intercept = 0.2 [0.1, 0.3]
Overjet	Total: 245 results sourced from 208 patients
	Slope = 0.84 [0.78, 0.89]
	Intercept = -0.3 [0.1, 0.4]

- Qualitative parameters

The performances of the product for the qualitative parameters, that were able to have the Reference Method used solely DentalMonitoring picture sets, were validated in a retrospective study. The study was performed using Scans retrospectively collected and involved a total of 15 US orthodontists.

For the qualitative parameter where the Reference Method used required 3D Models, *i.e.* passive archwire and auxiliaries, the study was conducted prospectively and involved seven sites located in the US.

Evaluation was done per tooth, interdental space or arch depending on the clinical parameter.

The clinical performances of the product are expressed as Sensitivity and Specificity. The results of the clinical studies conducted to evaluate these parameters are presented below.



- Dental parameter: soft tissue statement, dental statement, alignment:

○ Parameters with 2-level outputs (positive/negative):

Parameter		Total N =	Sensitivity	Specificity
Soft tissue statement	Black triangle	1,137 interdental spaces	81.0% [73.9 - 86.5]	98.4% [96.9 - 99.2]
Dental statement	Closure of extraction space	478 interdental spaces	100.0 % [94.2 - /]	91.8% [87.2 - 94.9]
Alignment	Closure of all anterior spaces	713 arches	98.3% [94.9 - 99.5]	83.3% [79.9 - 86.3]

- Orthodontic parameters: aligner treatments, braces, thermoformed retainers:

○ Parameters with 2-level outputs (positive/negative):

Parameter		Total N =	Sensitivity	Specificity
Aligner treatments	Attachment loss	765 teeth	98.2% [94.3 - 99.4]	100.0% [98.7 - /]
	Button loss	659 teeth	98.4% [94.0 - 99.6]	99.0% [96.9 - 99.7]
Braces	Bracket debonding	659 teeth	98.4% [93.8 - 99.6]	99.6% [98.5 - 99.9]
	Ties loss	653 teeth	93.3% [85.7 - 97.0]	96.5% [94.0 - 98.0]
	Self-ligating clips	647 teeth	91.1% [82.5 - 95.7]	88.3% [84.1 - 91.5]
	Passive archwire & auxiliaries in 2D Monitoring	730 arches	89.0% [84.9 - 92.1]	80.4% [75.1 - 84.8]
	Passive archwire & auxiliaries in 3D Monitoring	730 arches	90.4% [86.7 - 93.2]	85.5% [80.8 - 89.2]

○ Parameters with 3-level outputs:

Clinical performances for the 3-level parameters are expressed as two different Sensitivities and Specificities:

- Sensitivity and Specificity of the product in its ability to detect people with the evaluated condition from people without

Detection of patients with the evaluated condition (presence/absence)		Total N =	Sensitivity	Specificity
Aligner treatments and thermoformed retainers	Tracking (seat/unseat)	3,323 teeth	93.2% [91.3 - 94.7]	86.2% [83.4 - 88.6]



- Sensitivity and Specificity of the product in its ability to discriminate the evaluated condition at a slight level from a noticeable level

Detection of the level of the condition (slight/noticeable)		Total N =	Sensitivity	Specificity
Aligner treatments and thermoformed retainers	Tracking (seat/unseat)	1,360 teeth	91.1% [85.9 - 94.5]	90.5% [87.7 - 92.7]

- *Updated 3D Model*

The performance of the product for the Updated 3D Model were validated in a prospective study involving seven sites located in the US. Reference Method results were generated by performing a best fit between acquired 3D Models using intraoral scanners and the Updated 3D Model generated by DentalMonitoring. Reference Method results were generated using a CAD/CAM software.

252 patients were enrolled in this study and rendered a total of 536 results considering one patient could render multiple results due to the best fit being performed per arch, and one patient could be enrolled twice, rendering up to 4 results. The obtained mean average precision is 0.10 mm with [0.093; 0.103] 95% CI.

3.8. TECHNICAL SPECIFICATIONS

In complement to the [Clinical Performances](#) information of the previous section, the measurement ranges and rounding rules shown in the following table apply to the quantitative *Clinical Parameters* determined by *DentalMonitoring*.

<i>Clinical Parameter</i>	2D Monitoring & 3D Monitoring	
	Measuring range	Rounded to nearest
Midline deviation	[-4.0; 4.0] mm	0.5 mm
Overbite	[-2.0; 7.0] mm	0.5 mm
Overjet	[-3.0; 9.0] mm	0.5 mm

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

3.9. SIDE EFFECTS

No known side effects.

3.10. 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*.



3.11. LIMITATIONS

The required conditions, *i.e.* patient population (age, dentition) and the treatment setting for *DentalMonitoring* to be able to monitor each *Clinical Parameter* are provided in the table of [Annex 1 – Limitations](#). This table also provides the level of detail with which *DentalMonitoring* results are given, *i.e.* per tooth or per interdental space, as well as parts of the dentition not analyzed by the product.

3.12. 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, the patient should refer to their *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, the patient will be informed of the reason for the rejection and given advice on how to take acceptable *Scans*.

3.13. 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 device allowing web access compatible with the *Dashboard* (see [Compatibility requirements](#)).
- A smartphone with an internet access (see [Compatibility requirements](#)).
- LED Adapter (REF 1016-001)

3.14. COMPATIBILITY REQUIREMENTS

The *Dashboard* must be accessed using a computer that:

- is free of viruses or malware;
- is running the most up-to-date version of the operating system; and
- has a resolution of at least 1920x1080.

All browsers and operating systems listed below should have the latest updates installed:



- Operating Systems: Microsoft Windows (10 or newer) or Mac OS (13 or newer).
- Web browser: Google Chrome, Mozilla Firefox, Apple Safari, Microsoft Edge.

The DM App is compatible with smartphones running either:

- Android 9 and up.
- iOS 15 and up.

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 and 2D experience (ScanAssist) is available on the *DM Dashboard*. 3D Experience (ScanAssist) cannot be used with manufacturer's proprietary hardware products other than the ScanBox^{pro}. To access it:

ScanBox^{pro}

- Click on "Help" in the upper right corner or the "loop" icon in the bottom left corner. Then, select "DentalMonitoring Help Center" and navigate to [DM ScanBox, Cheek Retractor & ScanBox pro](#) > [ScanBox pro](#) > [FAQ](#).
- Alternatively, use the "Search for help" bar by typing "compatible" to find the relevant articles.

3D experience (ScanAssist)

- Follow the same steps by clicking "DentalMonitoring Help Center" and then navigating to [Patient App](#) > [ScanAssist](#) > [FAQ](#).
- Again, you can use the "Search for help" bar and type "compatible" to locate the information.

If you have any additional questions about phone compatibility, please contact customer support (support@dental-monitoring.com).

3.15. SECURITY OF INFORMATION

Dental Monitoring 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).

Dental Monitoring protects user accounts with the following measures:

- multi-factor authentication that can be activated for your account
- a login and password for the *DM Dashboard*; and
- 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.



Dental Monitoring regularly updates the *DM Dashboard* and 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 *DM App* version.
- Only the latest version of *DM Dashboard* is available. As the *DM Dashboard* is accessible over the internet, there is no user action required to update it.

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 should be noted that the *DM Dashboard* is not a Practice Management System (PMS,) and PMS back-up solution has to be ensured independently for your practice.

It is recommended that your device and your phone run 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 and phone 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 device and/or your smartphone, it is recommended that you do not use the *DM Dashboard* and/or the *DM App*, until a complete remedy.

It is recommended that you use a reliable internet connection with an up-to-date internet browser. 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 Dashboard* and/or the *DM App*, please contact the customer support at support@dental-monitoring.com.

Please note:

- For the *Dashboard* you can log out of your account at any time by clicking on the **logout** button on the top right of your screen.
- For the *DM App* you can log out of your account at any time by tapping **logout** in **Preferences**.

4. DIRECTIONS FOR USE

4.1. REGISTERING TO THE DASHBOARD

Using *DentalMonitoring* requires a verified account. Please contact *Customer Support* for more information.

4.2. SIGNING IN TO THE DASHBOARD

DentalMonitoring must be accessed by individuals only using their unique credentials:

1. Visit <https://www.dental-monitoring.com/doctor/>
2. Enter credentials: login and password
3. Click on **Sign in**.
4. Users who have chosen to enable multi-factor authentication will need to complete an additional step: They will need to enter a security code that has been sent by SMS to the phone number registered with the account.

4.3. DIFFERENCES BETWEEN DOCTOR AND PRACTICE EMPLOYEE ACCOUNTS

Please note that users with the user role **Practice Employee** will not be able to access certain features described in this guide when logged in. In particular, a **Practice Employee** will not be able to access:

- The '**Configuration**' tab and all of the associated features (with the exception of quick replies). Please note that a **Practice Employee** can still view and edit **Patient Protocols** through a patient's **Patient Card**.
- The '**Shop**' tab and all of the associated features
- The group messaging feature
- All features associated with '**My Account**' except for the ability to change their personal information (email, name, phone number, language, password, dental notation)
- The '**Shared With Me**' sub-tab (under '**Patients**'). This also includes the ability to share patients with other healthcare professionals through the New Action button '**Share Patient**' on the **Patient Card**. A user with the user role **Doctor** may not share a patient with a **Practice Employee**.

4.4. POTENTIAL ERROR MESSAGES

There are two potential types of error messages you may see when navigating the Dashboard. You can identify which type of error has occurred by looking at the error code, which is often a three-digit number beginning with either 4 or 5 (e.g. 404, 503).

User Errors

Error messages beginning with 4 indicate that there is an error on the user's side. This means either that the user has entered a URL that does not exist, or the user does not have the correct access to view the page (for example, if you are trying to view the profile of a patient that belongs to another doctor). If you



receive this error, please double check that the URL is typed in correctly and you are logged in to your *DentalMonitoring* account.

Server errors

Error messages beginning with 5 mean the error originates from the server. An example of this would be in the case where there is an update in progress. If you see this error, please contact Customer Support (details provided in [User Assistance Information](#)).

A list with common user messages is available from the dashboard, accessible by clicking “Help” in the upper right or the “loop” icon in the bottom left corner of the screen, then:

- By clicking directly on “DentalMonitoring Help Center” and accessing all “errors” articles under [DentalMonitoring Overview](#) > [FAQ](#) or using the search bar.
- Or by clicking “search for help” and using the embedded search bar, then typing “error”.

4.5. INTERFACE OVERVIEW OF THE DASHBOARD

Main Menu

① NOTIFICATIONS 90 ② PATIENTS ③ TO-DO LIST ④ CONFIGURATION ⑤ SHOP



Top Right Menu

⑥ SUPPORT ⑦ HELP ⑧ MY ACCOUNT ⑨ LOGOUT

Please note some of the above menu items may be placed inside a collapsible menu in order to adapt to your screen resolution.

The Configuration tab may not be available to some users such as **Practice Employees**.

4.5.1. NOTIFICATIONS (①)

The ‘**Notifications**’ tab contains four sub-tabs: ‘**Clinical Instructions**’, ‘**Messages**’ and ‘**Additional Scans**’ and ‘**App Not Activated**’.

The ‘**Clinical Instructions**’ tab contains notifications including:

- Actions triggered by the **Patient Protocols** as set up for each patient:
 - Detected *Clinical Observations* (see [Annex 2 – List of Observations](#))
 - Team *Instructions*
 - Patient *Instructions*
- Team *Instructions* not generated by a *Protocol*: see ‘**Send instruction to team**’ in [New Action](#)
- Specific actions taken by patients (e.g. aligner number update)

Each **Notification** will stay in the ‘**Notifications**’ tab until it is marked as reviewed. It will always be accessible in the **Patient Card**. A **Notification** is composed of:

- **Priority**: Each **Notification** has a priority: Alert, Warning, Information. The **Priority** level can be set in [Protocols](#).



- *Patient Instruction*: A communication received by the patient. Please note the '**Clinical Instructions**' tab displays the **Message Identifier** and not the actual message received by the patient. This can be set in [Patient Instructions](#).
- *Team Instruction*: This is the instruction that the *Healthcare Professional* team should follow in response to the detected *Clinical Observation*. This can be set in [Team Instructions](#).

The '**Messages**' tab contains direct messages sent by patients from their *DM App*. Each direct message will stay in the '**Messages**' tab until it is marked as reviewed.

The '**Additional Scans**' tab will contain any additional *Scans* from patients. For more information on additional *Scans* please see [New Action](#).

The '**App Not Activated**' tab will contain a list of patients who have not activated their *DM App*.

4.5.2. PATIENTS (②)

4.5.2.1. MONITORED PATIENTS

Monitored Patients contains all actively monitored patients. The **Monitored Patients** tab displays:

- The date and description of each monitored patient's latest activity
- The type of treatment
- Their **Monitoring Plan**
- The date of their latest *Scan*

Click on the patient's name to access the patient's detailed **Patient Card**.

4.5.2.2. NOT MONITORED

Contains all of the patients who are not being actively monitored: patients who have stopped being treated or no longer use *DentalMonitoring*.

4.5.2.3. SHARED WITH ME

Shared With Me contains all of the **Patient Cards** that have been shared by other *Healthcare Professional(s)*. (Sharing a **Patient Card** can be done through the: [New Action](#) button). By default, you will have two patients in this tab: one for aligners and one for braces. Please note these patients are read only and therefore you may not modify their details or communicate with them.

Patient Cards that have been sent by another *Healthcare Professional* using *DentalMonitoring* will appear here. The **Patient Card** will be accessible in read only mode once **Accept share** is clicked.

You may add a comment to a shared patient's timeline by clicking on 'add a shared comment'. This comment will be visible to the doctor who has shared the patient with you.

4.5.3. TO-DO LIST (③)



The **To-Do List** gives the option of creating a list of patients where particular actions are needed. Any patient can be added to the **To-Do List** with an optional comment. When a **To-Do** item is resolved, another comment can be added.

Examples of use:

- remember to call a patient
- reschedule an appointment
- check on a specific tooth movement

A patient can be added to the **To-Do List** through the [New Action](#) button.

4.5.4. CONFIGURATION (④)

The Configuration tab allows the user to manage:

- *Protocols*
- Quickstarts
- *Patient Instructions*
- *Team Instructions*
- Quick replies

Please note, not all users will have access to the Configuration tab.

4.5.5. SHOP (⑤)

This tab allows the user to order Dental Monitoring products.

4.5.6. SUPPORT (⑥)

This is where questions about *DentalMonitoring* can be sent to the *Customer Support* team.

support@dental-monitoring.com

<https://dental-monitoring.com/>

4.5.7. HELP (⑦)

The **Help Center** gives users access to a range of help articles and walkthroughs. This interactive tool can be accessed any time.



4.5.8. MY ACCOUNT (⑧)

My Account allows users to:

- Manage their subscriptions to certain Dental Monitoring products
- Download and pay their invoices
- Access and modify their personal information and reset their password
- View and modify their practice information and manage their practice employees
- Manage their dental notation preference
- Manage the language of the interface
- Download the history of *Clinical Observations* of all their patients

From My Account, users have the ability to activate the two-factor authentication to add an extra layer of security. To activate it, they 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.

4.5.9. LOGOUT (⑨)

The **Logout** link allows users to disconnect their *DentalMonitoring* account from the currently used computer.

4.6. MONITORING PLANS

4.6.1. PHOTO MONITORING LIGHT

Photo Monitoring Light is the most basic **Monitoring Plan**. It does not have any *Protocols*. Therefore, *Healthcare Professionals* need to review and self-assess all patient *Scans* individually.

In **Photo Monitoring Light**, patients are fixed at a 2-week **Scan Interval** which cannot be changed. However, an immediate *Scan* can be requested at any time through the **Patient Card**.

4.6.2. PHOTO MONITORING FULL

Photo Monitoring Full tracks patients through regular *Scans* of their teeth taken with the *DM App*. **Photo Monitoring Full** is only capable of tracking *Clinical Parameters* that can be visually detected. See [Clinical Parameter Settings](#).

4.6.3. 3D MONITORING: LIGHT AND FULL

There are two options for 3D Monitoring: **3D Monitoring Light** and **3D Monitoring Full**. The only difference is the minimal **Scan Frequency** available. For **3D Monitoring Light**, the shortest **Scan Frequency** is 30 days. For **3D Monitoring Full** (as well as **Photo Monitoring Full**), the shortest **Scan Frequency** is 3 days.



3D Monitoring compares the patient's ongoing *Scans* against a *3D Model* of their original dentition in order to establish an updated *3D Model*, representative of the patient's dentition throughout treatment.

3D Monitoring compares the patient's ongoing *Scans* against a *3D Model* of their original dentition in order to calculate the average movement of the maxillary and mandibular arch and the movements of each crown including:

- Mesial/distal translation
- Extrusion/intrusion
- Buccal/lingual translation
- Buccal/lingual torque
- Mesial/distal rotation
- Mesial/distal angulation

Of note, tooth movement measurements are not part of the medical device claims and are provided with a Research Use Only status. Refer to the [Annex 3 – Product Disclaimer](#).

For more details see [Specific additions to 3D Monitoring](#).

4.6.3.1. STARTING A PATIENT ON 3D MONITORING

To start a new patient on 3D Monitoring, follow the steps for creating a new patient, selecting **3D Monitoring Full** or **3D Monitoring Light** as the **Monitoring Plan**.

Patients starting on 3D Monitoring will need to have a *3D Model* of their teeth uploaded (see: *ADDING A 3D MODEL*) as well as a *Scan* taken. It is recommended that the *3D Model* and the *Scan* are taken on the same day. If this is not the case, please note that the date of the *Scan* will be used as the reference for the basis of future movement calculations.

As the treatment progresses, the patient will continue to only take *Scans* of their teeth at regular ***Scan Frequency***. These *Scans* will be used to calculate movements.

3D Monitoring can be used for any patient and any treatment.

Please note: Using the *DM ScanBox* or *DM Scanbox^{pro}* to take the Scans is required for 3D Monitoring patients.

4.6.3.2. ADDING A 3D MODEL

A *3D Model* of the patient needs to be uploaded as two STL files (upper and lower arch, in occlusion), exported from an intraoral scanner.

To upload the file onto the patient's profile:

1. From the patient's profile, click **New Action**
2. Click on **Add a New 3D Model**
3. Select the preferred way to add the new *3D Model*

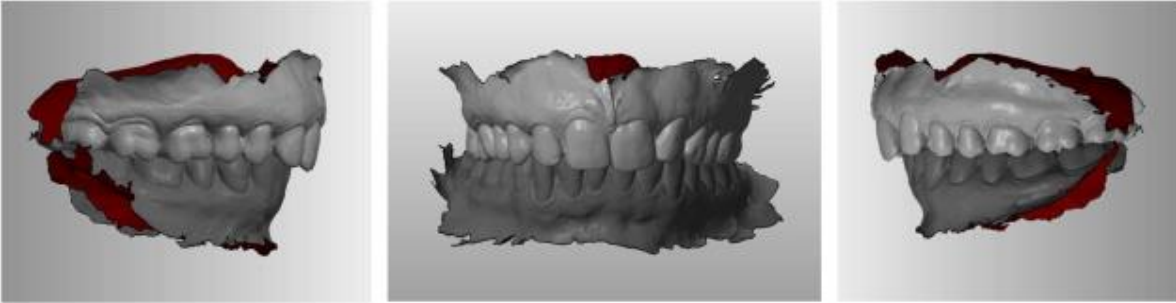
Please note: The **EXACT DATE OF THE INTRAORAL SCAN** should match the date that the impression or intraoral scan was taken to create the *3D Model*.



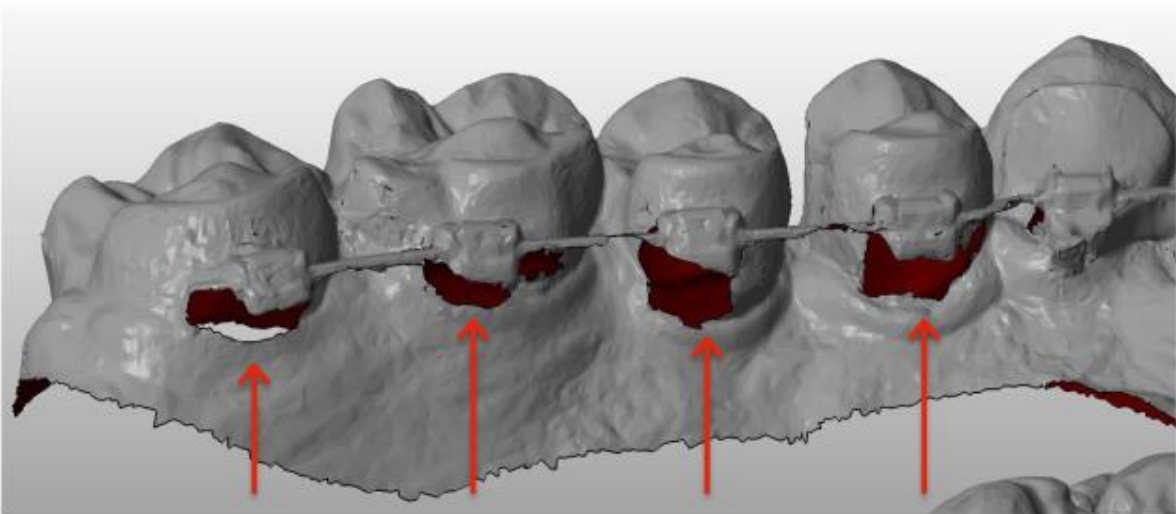
4.6.3.3. REQUIREMENTS FOR 3D MODELS

All scanners are compatible with *DentalMonitoring*, as long as:

- The files are in STL format.
- Both arches are in 2 separate files and in occlusion.

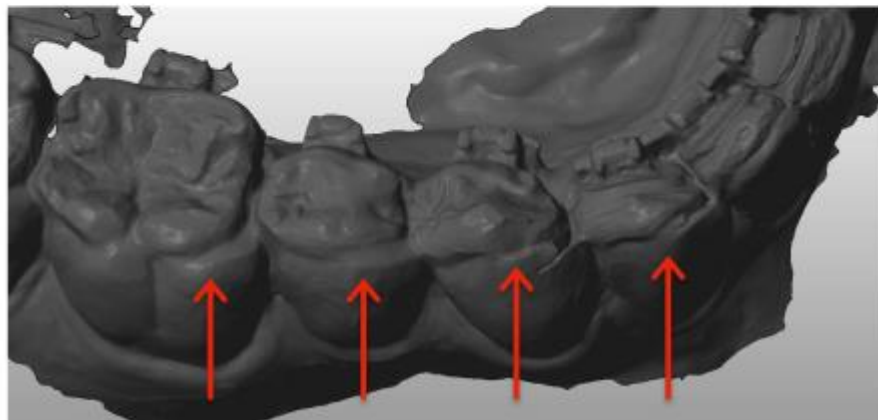
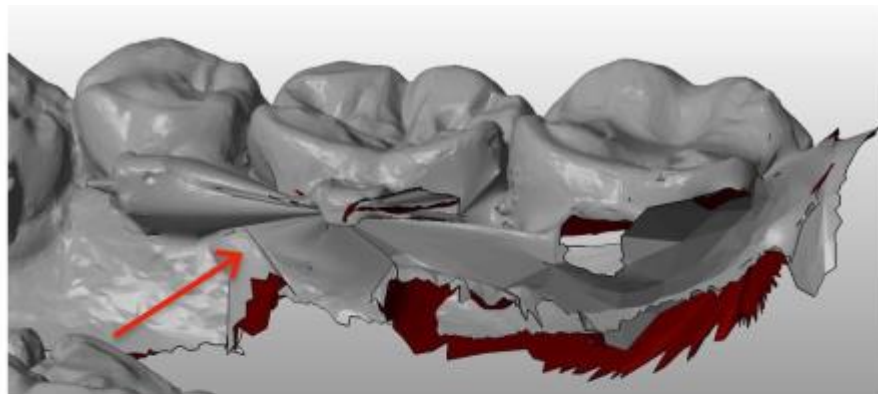
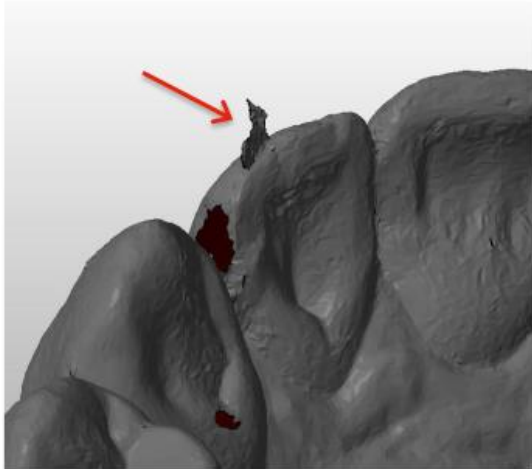


- The *3D Model* can be taken while the patient is wearing braces but the archwire must be removed. The *3D Model* must not contain holes.



- The *3D Model* must not contain holes.
- The *3D Model* must present as few artifacts, defects or distortions as possible.





If an uploaded *3D Model* does not meet the requirements, a message will be displayed in the 'Notifications' tab and an email sent to the user's registered email address. A new *3D Model* will then need to be uploaded, following the same process as described above.

Please note: the quality of the *3D Model* will influence the quality of the updated *3D Model*.

4.7. PROTOCOLS



4.7.1. WHAT IS A PROTOCOL?

A *Protocol* sets the monitored *Clinical Parameters* and the actions to be triggered once they are detected. A *Protocol* is the automated transcription of *Healthcare Professionals'* reaction/action facing a specific *Clinical Observation*. They represent an additional tool to optimize the observation of *Clinical Observations* notified by *DentalMonitoring* (see [Annex 2 – List of Observations](#)) and the associated *Healthcare Professional's* diagnostic conclusion. They fully remain under the *Healthcare Professional's* responsibility.

A user can create multiple **Activated Protocols** that can be applied to any patient and then further fine-tuned (see [Edit a Protocol applied to a specific patient \(Patient Protocol\)](#)). *Protocols* are adapted to the different treatment types within the practice population.

4.7.2. HOW TO CREATE AN ACTIVATED PROTOCOL IN THE PROTOCOL LIBRARY?

An **Activated Protocol** can only be created:

- from an existing **Activated Protocol** in the user's **Protocol Library**.
- from a **Protocol Template** provided by *DentalMonitoring*. These **Protocol Templates** cannot be directly applied to patients: they will need to be reviewed by the *Healthcare Professional* and activated. Once activated, they become **Activated Protocols**.

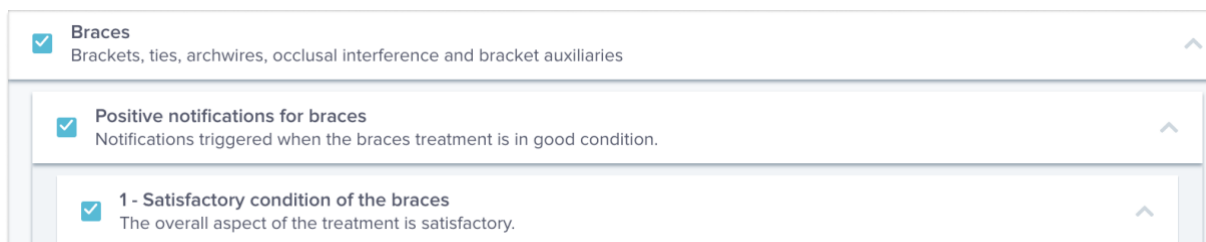
Protocols can be edited at any time. When modifying an **Activated Protocol** that has already been applied to patients, the changes made will not automatically apply to these patients. See [Apply an activated protocol to multiple patients at once](#).

A new **Activated Protocol** can be created by clicking on **Create new protocol**.

Select the *Protocol* to copy and click on **Next**.

Review the *Protocol* and modify the settings as needed:

- **Title:** Titles should help users to easily identify the intended purpose of the *Protocol*.
- **Description:** The description should reflect the *Protocol's* intended use.
- **Clinical Observations** (see [Annex 2 – List of Observations](#)) are specific findings within the *Clinical Parameters* that can trigger an *Instruction* to the *Healthcare Professional* team and/or the patient. They are organized in Categories and Sub-Categories. Each Category/Sub-category can be expanded by clicking on it. To observe a Sub-Category, it needs to be ticked, as well as the Category. There is a special category of *Clinical Observations* named [Goals](#).



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

If the Category is unticked, then no Sub-Category will be observed.

☐ Braces
 Brackets, ties, archwires, occlusal interference and bracket auxiliaries

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

4.7.2.1. CLINICAL PARAMETER SETTINGS

A *Clinical Parameter* is composed of 3 parts: *Analysis Parameters* ①, *Team Instructions* ② and *Patient Instructions* ③.

☒ **6 - Noticeable unseat still present**
 The noticeable unseats in the previous scan are still present with no improvement or deterioration.

② → **Analysis parameters**
 Priority: Silent Info Warning **Alert**

③ → **Team Instructions**

Copy notification in patient chart. Delete

Schedule an appointment. Delete

Add instruction for team

① → **Messages to patient**

NO-GO – same aligners Delete

#1 Your teeth need some time to move. Please keep wearing your current aligners. ⚠
 #2 Your tooth movement has not quite finished in the current aligners. Keep the same aligners until your next scan.
 #3 You will need to continue wearing the current aligners until your next scan.
 #4 You are not quite ready for your next aligners. You will need to continue to wear your current aligners every day until your next scan.
 #5 Do not change your aligners for now. Your teeth still need some time to move.

UNSEAT – Noticeable unseat still present Delete

#1 Your aligners still do not fit like they should.
 #2 The fit of your aligner has not improved.

CALL – call for instructions Delete

#1 Please contact the office at your earliest convenience for further instructions.
 #2 We need you to contact the office to receive instructions.

Add message for patient

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

- **Analysis Parameters ①:**

- Priority levels act as a color-coding system to easily identify the priority of each *Notification*. The 4 levels will determine whether or not it appears in the 'Notifications' tab and the color of the *Notification*:

The definition of each *Priority* is to be determined by each healthcare facility, however some suggestions are as follows:

- **ALERT:** Requires the treating *Healthcare Professional's* attention
- **WARNING:** Might require the treating *Healthcare Professional's* attention depending on the healthcare facility guidelines
- **INFORMATION:** Does not require the treating *Healthcare Professional's* attention
- **SILENT:** Will not appear in the 'Notifications' tab, however silenced *Clinical Parameters* will still be tracked.

Priority	DM App	Notification Center	Daily Monitoring result
Alert	✓	✓	✓
Warning	✓	✓	✓
Info	✓	✓	✓
Silent	✓	✗	✗

- **Team Instructions ②:** This will determine the instructions to the team that will be displayed in the 'Notifications' tab if the corresponding *Clinical Observation* is detected.
- **Patient Instructions ③:** This will determine the communication that the patient will see in the *DM App* if the *Clinical Observation* is detected.

Changes to the **Activated Protocol** are saved after clicking on **Save** on the top of the screen. Changes are not saved automatically.

4.7.3. PATIENT INSTRUCTIONS

Patient Instructions are sets of personalized messages that are automatically sent to patients via the *DM App* when a certain *Clinical Observation* is detected. A *Patient Instruction* is composed of a *Message Identifier* and its *Message Variations*:

- The *Message Identifier* is the title that will help identify the *Patient Instruction* when setting up the *Protocols*
- *Message Variations* are predefined messages scheduled to be sent to the patient one after another. This is so that patients do not receive the same message every time. *Message Variations* will loop back after it reaches the last one in the series.



Setting up a *Message Variation* series is not obligatory but is strongly recommended for an improved patient experience.

Once created, all *Patient Instructions* can be used in any *Protocol*. When a *Patient Instruction* is updated, changes are immediately applied to all *Protocols*.

Patients Instructions are organized into the following *Categories*:

- Timeframe
- Goals
- Orthodontic parameters – Aligners
- Orthodontic parameters – Braces
- Oral health assessment
- Intraoral evaluation
- Retention
- General

When creating a *Protocol*, the *Patient Instruction* in “General” can be selected from any *Clinical Observation*, whereas the other *Patient Instructions* are only available in the matching *Clinical Observation Category*.

4.7.3.1. ADDING VARIATIONS TO A PATIENT INSTRUCTION

Variations are different ways of phrasing the same message. For example, the message “Contact the practice” can have several *Variations*, as follows:

- Variation 1: “Please contact the practice at your earliest convenience.”
- Variation 2: “The team at the practice has information for you. Please contact us as soon as possible.”

To add a *Variation*:

1. Click in the field “Add another variation”.
2. Add a text that is coherent with the initial message.
3. Click on the **Save** button on the top of the screen.

4.7.3.2. DELETING A VARIATION

Click on the **Delete** button next to the variation that needs to be deleted.

Click on the **Save** button on the top of the screen.

The **Delete** button is hidden when there is only one *Variation* left. At least one *Variation* needs to be in place for the *Patient Instruction* to be saved.

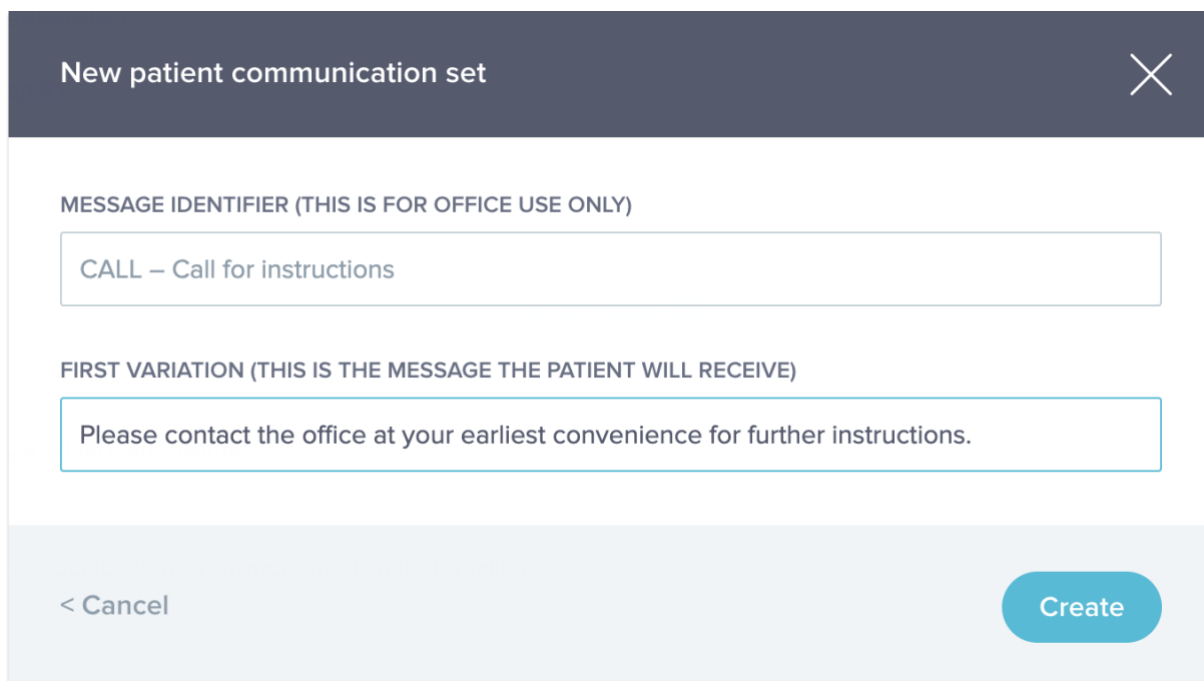


4.7.3.3. EDITING A VARIATION

Variations can be edited directly in their textbox. When the change is made, click on the **Save** button on the top of the screen.

Adding a new *Patient Instruction*

1. Click on **Add Message** at the bottom of the category that the new *Patient Instruction* will be part of.
2. Enter the *Message Identifier* and any *Variations* that will compose the *Patient Instruction*.
3. Click on the **Create** button.



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

4.7.3.4. AUTOMATED SCAN REPORT

The *Automated Scan Report* is the text that the patient will receive in the *DM App* providing feedback on their *Scan*. It is composed of a *Greeting*, the *Patient Instructions* corresponding to the *Clinical Observation(s)* detected, and a *Signature*.

The *Greeting* and *Signature* (i.e. first and last sentences) of the *Automated Scan Report* can be customized.

If there are no *Patient Instruction* sent following a *Scan*, the content of the *Scan report* – without *instructions* is sent to the patient.

Using the {patient_firstname} field in the body of the message will automatically insert the first name of the patient.

4.7.4. TEAM INSTRUCTIONS

Team Instructions will appear in the 'Notifications' tab when the corresponding *Clinical Observation* is detected.

For example, "Missing Attachment" can be set to trigger a *Team Instruction* reading "Call patient to schedule an attachment bonding appointment."

Like *Patient Instructions*, *Team Instructions* are organized by *Categories*:

- Goals
- Timeframe
- General
- Orthodontic parameters – Aligners
- Orthodontic parameters – Braces
- Oral health assessment
- Intraoral evaluation
- Retention

4.7.4.1. ADDING A TEAM INSTRUCTION

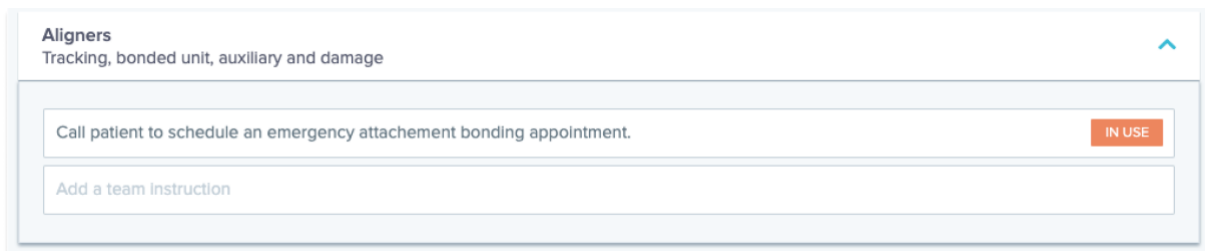
- 1- Select the category that the *Team Instruction* will be added to
- 2- Click on the text field at the bottom and add the *Team Instruction* directly
- 3- Click on **Save** at the top of the screen to save the *Team Instruction*

4.7.4.2. EDITING A TEAM INSTRUCTION

All *Team Instructions* that have been manually added (indicated by a white background) can be edited. Click the text field and change the *Team Instruction* directly and click on **Save**.

Team Instructions that are part of any **Activated Protocols** will show an "IN USE" label. Unlike **Activated Protocols**, any changes to *Team Instructions* will be automatically applied to all patients for which they are currently in use.

Please note: any *Team Instructions* in grey cannot be edited, as they are part of the *Protocol Templates*.



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

4.7.4.3. EDIT A PROTOCOL APPLIED TO A SPECIFIC PATIENT (PATIENT PROTOCOL)

After an **Activated Protocol** is applied to a patient, it becomes their **Patient Protocol** and the parameters can be fine-tuned to match their individual needs.

To edit a patient's **Patient Protocol**, go to the **Patient Protocol** tab in their **Patient Card**. Any changes or modifications made on this page will only be applied to the patient.

When the change is made, click on the **Save** button on the top of the screen.

Please note: Applying an **Activated Protocol** to a patient will erase any changes made to their **Patient Protocol**.

4.7.4.4. APPLY AN ACTIVATED PROTOCOL TO MULTIPLE PATIENTS AT ONCE

Activated Protocols can be edited at any time. When modifying an **Activated Protocol** that has already been applied to patients, the changes made will not automatically apply to these patients.

1. Open the **Activated Protocol** and click on **Select patients to update with this version** displayed below the *Protocol* title. Please note that if there are any unsaved changes to the *Activated Protocol*, this message will not be displayed.
2. Select the patients to apply this **Activated Protocol** to. Filters are available to help find patients according to various criteria.

Please note: Applying another **Activated Protocol** to a patient will erase any changes made to their **Patient Protocol**.

4.7.5. QUICKSTARTS

A Quickstart is a pre-set combination of **Monitoring Plan**, treatment, **Protocol** and **Scan Frequency**, which can be applied to a patient in one click when you start their monitoring. You do not need to set up a **Quickstart** in order to start a patient's monitoring, however this can help you save time.

To set up a **Quickstart**:

1. Go to **Configuration** → **Quickstarts** and select **New Quickstart**
2. Select the **Monitoring Plan**
3. Select the **Activated Protocol**
4. Select the **treatment phase**
5. Select the **type of treatment** and **manufacturer** if applicable. Please note that any selection for the upper arch (MX) will automatically be applied to the lower arch (MD). If you wish to select them separately you can do so by ticking "**set MD/MX options separately**"
6. Select **Scan Frequency**
7. Click **Save** to save your **Quickstart**

Your **Quickstart** will appear under the **Quickstart** menu with the title "**Quickstart for (name of the Activated Protocol selected)**". It will display the **Monitoring Plan**, **Scan Frequency**, treatment type and manufacturer selected.

Your patient will now have the associated **Monitoring Plan**, **Activated Protocol**, **Scan Frequency**, treatment type and manufacturer applied to them. You should be able to see these details in the patient profile.

4.7.5.1. GO/ NO GO notifications (Dynamic aligner change)



The GO/NO GO notifications are a functionality designed for patients treated with aligners.

When the option is enabled, each patient's *Scan* will be analyzed for the aligner fit (seat /unseat *Clinical Parameter*) and then a GO, NO GO or GO BACK notification will be sent to the patient within 12 hours to indicate whether or not they should move to the next set of aligners.

The criteria for sending a GO, a NO GO or a GO BACK is defined within the *Protocol* which is set up by the *Healthcare Professional*.

This option is activated by default for aligner treatments. If the *Protocol* selected when setting up the monitoring is not compatible with the GO/NO GO notification, a warning message will be displayed.

With the GO/NO GO notifications,

- the **Scan Frequency** must match the frequency of aligner changes intended for the patient. For aligner treatments, the Scan Frequency can differ after a GO and a NO GO notification.
- It is possible to enable the **Adaptive Scan Interval**, the scan interval can be increased or decreased automatically based on the GOs/NO GOs triggered during the monitoring.

4.8. NOTIFICATION MANAGEMENT

Unreviewed notifications can be viewed and managed from the notification center. The following actions can be done directly from the notification center:

- Mark the notification as reviewed. Once reviewed, the notification will be automatically removed from the notification center
- Assign to a doctor or practice employee. When assigning a notification, a due date and comment can be added
- Send a message to the patient. An attachment can be added to the message and a future date and time can be set for sending the message
- Execute a clinical action. Some clinical actions such as excluding teeth, changing the aligner number (for aligner treatments) and Force Go (for aligner treatments with Go/No Go notifications) can be done directly from a notification.

Multiple notifications can be selected at once using the 'Select all' 'Unselect all' action links or by manually checking multiple notifications from the list. Once a notification (or a group of notifications) is selected, it is possible to add a label or assign it to someone in the practice.

Unreviewed notifications from the same patient are grouped together. Clicking on the patient's name opens the Patient Card.

There are several types of notifications in the notification center:

- Messages: messages sent directly by the patient from the *DM App* are displayed in the message tab. They can include photos and/or attachments
- Clinical instructions: detected clinical observations set up in the Protocols with their associated Team Instructions and Patient Instructions are listed in the clinical instructions tab.
- Additional scans: additional scans taken by the patient and associated messages (optional) are listed in this tab



- App not activated: patients who have been created but have not yet activated their *DM App* are listed in this tab

From the notification center, it is also possible to send a **Group Message** to a selected list of patients. Patients will then receive the message on their *DM App*.

4.9. PATIENT MANAGEMENT

4.9.1. CREATE A NEW PATIENT

To add a new patient to your account, please follow the steps below:

1. Click on **Patients** in the *Dashboard* header
2. Click on **New patient**
3. Fill in the fields and click **Create patient**. There is the option to add the practice software ID, the patient's medical file number, and a secondary email address that will receive a copy of all communications sent to the patient.

Please note:

- Newly created patients automatically have the status 'Not Monitored'. See [Start a Monitoring](#).
- Patients need to get an invite to be able to access the *DM App*. The option to send the invite is selected by default when creating the patient. The invite can be sent anytime, see [New Action](#).

The invite is sent by email and contains:

- A link to download the *DM App*.
- A link to automatically open their account on the *DM App* once downloaded.
- A link to set a password for any connection to an additional device.

4.9.2. START A MONITORING

To add a new patient to your account, please follow the steps below:

1. From the **Patient Card**, click on **Start Monitoring**
2. If you have any **Quickstart** set up, you can select the **Quickstart** that applies to this patient from the list and skip Steps 3-5. If you do not have any **Quickstarts** set up, or you wish to customize your patient's **Monitoring Plan**, proceed to Steps 3 to 5. Please note not all users will have this ability to customize their patients' **Monitoring Plan**.
3. Choose a **Monitoring Plan** for the patient. See [Monitoring Plans](#).
4. Select the details of their orthodontic treatment including treatment type and manufacturer type
5. Choose an **Activated Protocol** to apply to the patient, select the **Scan Frequency**, then click **Start**

4.9.3. PATIENT CARD OVERVIEW

4.9.3.1. HEADER



The **Patient Card** header contains the patient name and ID. It also provides the ability to manage patient labels (view, add, delete) as well as manage patient visits (add a date of a patient visit in the practice).

The **New action** button enables you to conduct a variety of tasks to manage your patients and patient monitoring information:

- **Send a clinical instruction to *DentalMonitoring*:** Any specific instructions to the *Healthcare Professional* team can be sent here. This includes tracking specific treatment objectives, especially in 3D Monitoring.
- **Add a new 3D Model** allows the user to upload a new *3D Model*.
- **Get a login link to copy:** Generates a login link that the patient can copy and paste into their browser in order to login to their *DM App*. You will need to copy this link (by clicking on '**Click here to copy to clipboard**') and send it to the patient (for example, via email or text message). This is useful if the patient changes phone or deletes and re-installs the *DM App*.
- **Send an instruction to the team:** Sends an instruction to the clinical team regarding the patient that will appear as a new notification in the 'Notifications' tab. This message can be sent immediately or scheduled to be sent at a later time.
- **Pause monitoring:** Temporarily puts a pause on the patient's current monitoring until a chosen date. Details such as **Patient Protocol**, **Monitoring Plan**, treatment type and *Scan* schedule are retained.
- **Change aligner number:** The *Healthcare Professional* can set or change the total number of aligners in the patient's set, as well as the patient's current aligner.
- **Send a message to patient:** allows the *Healthcare Professional* to communicate directly with the patient. Messages will be sent directly to the patient's *DM App*. This message can be sent immediately or scheduled to be sent at a later time.
- **Pause/Stop monitoring:** stops or restarts a patient's monitoring. When a monitoring is stopped, all data pertaining to the patient is retained and the patient will not be able to send *Scans* anymore. The patient will appear in the *Not Monitored* tab.
- **Change monitoring plan:** immediately apply a Quickstart of your choice to a currently monitored patient. This is especially useful for patients changing treatment phases, for example from active treatment to retention.
- **Add to the To-Do list:** adds the patient to the *To-Do List*. See [To-Do List](#).
- **Send activation email to patient:** sends an email to the registered email address of the patient. See [Create a new Patient](#).
- **Reset Scan Schedule to today:** This will reset the patient's *Scan* schedule so that their next *Scan* will be due today, and all subsequent *Scans* will be calculated from today's date. Your patient will immediately receive a request on their *DM App* to take a *Scan*.
- **Ask patient for an Additional Scan:** This will request an additional *Scan* from the patient, outside of their regular *Scan* schedule. This *Scan* will not be treated by the *Patient's Protocol* (i.e. will not trigger any *Patient Instructions*, *Team Instructions*, *GO/NOGOs*, etc) and will not reset the patient's



Scan schedule. As there is no automated analysis, you will need to review these *Scans* manually: once you patient takes the *Scan* using their *DM App*, the *Scan* will appear under the tab 'Additional Scans' in your Notifications tab.

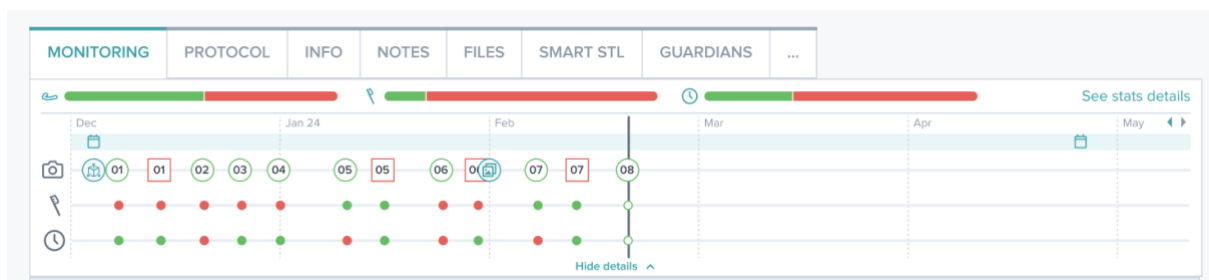
- **Share Patient:** allows **Patient Cards** to be shared in "read-only" mode between *Healthcare Professionals* using *DentalMonitoring*.
- **Start a video consultation** (Note: this option is only available to *Healthcare Professionals* who have an active subscription to the video consultation feature): Send the patient a message on their *DM App* with a link to your virtual waiting room, which will allow them to start a video consultation with you.

4.9.3.2. MONITORING SUMMARY

The **Monitoring** summary contains a quick overview of the patient monitoring information, including treatment and *Monitoring* status. In particular, it allows you to:

- View the Monitoring plan, upper/lower appliance and brand setup
- View, set and edit the patient ScanBox model
- View, set and edit the aligner number, and the total number of aligners in a set (only for aligner treatments)
- View, set and edit the patient's *Scan Frequency*
- View, set and edit the patient's *Excluded teeth*.

4.9.3.3. MONITORING TAB



The *Monitoring* tab shows the following:

- **Monitoring timeline:** it presents a treatment timeline where you can view all your monitoring start and stop date, as well as any patient visit date that was recorded manually in the Patient Card header
- **Scan timeline** section: it presents a timeline of the patient's *Scans* to date.

- If the patient is being monitored for an aligner treatment, the timeline will display aligner number as well as the following:
 - A green circle for a GO.
 - A red square for a NO GO or GO BACK.
 - The aligner number the patient was wearing during the *Scan* (displayed as a number inside the shape). If no number is associated with the *Scan*, the shape is empty.
- If the patient is being monitored for a braces or retention treatment, a timeline will display with green or red dots for each *Scan* based on the triggered *Notifications*
- A hygiene treatment line with green or red dots for each *Scan* based on the triggered *Notifications*
- A *Scan* compliance treatment line with green or red dots for each *Scan* based on the patient compliance
- A *Scan* summary section: it represents the percentage of green and red dots for each treatment line
- The *Photo Gallery*:
 - The Photo Gallery displays the photos of the selected *Scan* (the latest *Scan* is always selected by default). The *Scan* can either be selected by clicking on a *Scan* date in the timeline, using the navigation arrow or by selecting a date from the date drop down.
 - The *Photo Gallery* can be expanded to view the *Scan* photos in full screen. It enables to navigate on the photos of a *Scan* and throughout the same *Scan* photo at different *Scan* dates using the keyboard arrows
 - Two *Scans* can easily be compared using the *Compare* action. It displays two *Scan* photosets side by side, enabling an easy visual comparison of the same *Scan* photo at two separate treatment times.
 - From the *Photo Gallery*, you can annotate a scan photo by selecting 'Send Photo'. You can also record a video by selecting 'Send Video'. In both cases, you can draw on the scan photos and send it to your patients. They will be able to access it from their *DM App*.
- *Scan Report*: The *Scan Report* will display any *Clinical Observations* that were detected on the *Scan* on the given date.
- *Orthodontic indices*: they are calculated and displayed for each *Scan*. More information on orthodontic indices are available in the table below. Occlusion parameters are routinely measured for all patients regardless of the monitoring plan. For patients under 2D Monitoring, the measurement in millimeter is provided with one digit rounded to the nearest 0.5 mm. For patients under 3D Monitoring, the measurement in millimeter is provided with two digits rounded to the nearest 0.01 mm.



	Output	Monitoring plan
Canine class*	value in mm $\in [-3.0; 6.0]$ mm*	2D Monitoring
	Class I, II or II*	3D Monitoring
Molar class*	Class I, II or II*	2D Monitoring 3D Monitoring
Overbite	value in mm $\in [-2.0; 7.0]$ mm	2D Monitoring 3D Monitoring
Overjet	value in mm $\in [-3.0; 9.0]$ mm	2D Monitoring 3D Monitoring
Midline deviation	value in mm $\in [-4.0; 4.0]$ mm	2D Monitoring 3D Monitoring

Note: For patients who are on 3D Monitoring the **Monitoring** tab contains more information. See: SPECIFIC ADDITIONS TO 3D MONITORING.

4.9.3.4. PROTOCOL TAB

The *Protocol* tab displays the Protocol selected for this patient monitoring. It can be customized and saved at the patient level.

4.9.3.5. INFO TAB

The *Info* tab provides an overview of the patient's details. The patient's details can also be edited with the **Edit patient info** button.

Please note: changing the patient's primary email address will change the *DM App* login ID.

* Feature for Research Use Only. Results are provided for information purposes only. Any resulting orthodontic treatment decision is the sole responsibility of the practitioner.



4.9.3.6. NOTES TAB

Under this tab, notes can be added for each patient. Once the note is added, a message icon is added to the patient's picture to indicate the presence of the note. Hold the mouse over the message icon to see the note.

4.9.3.7. FILES TAB

The *Files* tab enables to upload patient files (such as X-Rays, STL files or pdf documents). It also list documents exchanged through the communication panel (by filtering on Source "Chat attachments").

4.9.3.8. SMART STL

The *Smart STL* is a solution for *Healthcare Professionals* to obtain an updated *3D Model* reflecting the patient's dentition at a specific time remotely, without the patient visiting the practice for an intra-oral scan. *DentalMonitoring* uses information obtained from 3D and 2D patient records and proprietary *DentalMonitoring* technology to calculate the patient's current teeth position.

To access *Smart STLs*, open the **Patient Card** on the *Dashboard*, and open the Smart STL tab.

The *Healthcare Professional* provides the initial 3D model of the patient's teeth if not already uploaded into the Dashboard. The patient provides a *DentalMonitoring Scan* via the *DM App*. The Scan should include occlusal views. *DentalMonitoring* updates the initial *3D Model* to represent the patient's dentition status at the time of the *Scan*.

Once the new *Smart STL* file has been generated, the *Healthcare Professional* is able to download it from the Smart STL tab, and later on from the My Orders tab.

In 3D Monitoring, in the event a tooth extraction is performed during the treatment and if a 3D model of the patient's teeth after the extraction is not provided by the *Healthcare Professional* to DentalMonitoring, please note that the updated *3D Model* reflecting the patient's dentition at a specific time may include gingiva not fully representative of the patient's gingiva at the location of the extraction.

In the event the HCP requires attachments to be reported on the updated 3D Model and the attachments present on the Scan differ from those present on the 3D Model provided to DentalMonitoring by the HCP, please note that the placement of attachments on the updated 3D Model may not fully represent their actual positioning on the patient's teeth.

4.9.3.9. HISTORY TAB

The *History* tab lists every *Clinical Observation* associated with a patient. The filters can be used to isolate specific actions such as Patient *Instructions* sent to patients.

4.9.3.10. SCANS TAB

Once uploaded by the patient from the *DM App*, a *Scan* is immediately accessible in the *Scans* tab. This is where the user can request an observation report, which contains the details of which observations were detected in the scan.

Please note:



- The *Scan* will be available even before being processed by the *Data Analysis Platform*.
- This tab will only show the raw, unprocessed pictures of the latest *Scan* taken by the patient.
- The pictures will appear here as soon as they are uploaded. Be aware that the pictures from the *Scan* may appear incomplete before the upload is done.

4.9.3.11. GUARDIANS TABSCHEDULED ACTIONS TAB

The Scheduled Actions tab contains information on all of the scheduled messages concerning the patient. This includes:

- Scheduled *Team Instructions*
- Scheduled direct patient messages (including annotations of pictures)

You will see a list of all of the scheduled actions that are pending for this patient. You can edit any pending scheduled actions by clicking on 'edit' next to the scheduled action.

You can also access a list of triggered and cancelled actions, and filter the list of scheduled actions by type of message.

4.9.3.12. NOTIFICATIONS PANEL

The Notifications panel shows all of the unmarked notifications that the patient has. You can mark the notification as read by clicking on the tick next to each notification.

From the Notification panel you can also access the following actions:

- Force GO
- Send an instruction to the team
- Add patient to the TODO list

4.9.3.13. COMMUNICATION PANEL

On the right side of the **Patient Card**, you can access the Communication panel. This section displays the communications exchanged with the patient and allows you to send a direct message to the patient.

From this section, you can review your communication history with the patient. Please note this section may contain:

- *Automated Scan Reports*
- Any direct messages sent to and from the patient, including group messages
- Any annotated pictures and associated messages
- Any messages that are attached to a particular action, such as *Scan* schedule resets, additional *Scan* requests, or a paused monitoring.

You can type your message directly into the communication panel or using a *quick reply* previously set up from your Configuration. To do so, select '**Use a quick reply**', and select a quick reply from your library. You can then edit your message if needed.

It is also possible to use AI suggestions to generate a patient message, either with or without a prompt. The AI suggestions take into account some of the patient information (age, treatment type) and the latest



conversations. AI suggestions always need to be reviewed by the practice staff before being sent to the patient (they are never sent automatically).

Finally, you can add an attachment to your message by selecting 'Add attachment'. You can upload or drag and drop any document provided that:

- The file size is 150MB max
- The uploaded file uses one of the following formats: DCM, DXF, GIF, JPEG, JPG, MP3, MP4, OBJ, PDF, PNG, STL.

Please note, if your screen resolution is less than 1920 wide, the communication section will automatically

be hidden. You can make it appear by clicking on the  icon.

4.9.3.14. GOALS PANEL

A **Goal** is a special type of *Clinical Observation* that represents a treatment objective or milestone that can trigger *Team Instructions* and/or *Patient Instructions*. They differ from other *Clinical Observations* in that you can choose to delay the sending of any *Instruction* if the **Goal** is reached before the **Notification Delay Period**, as well as be alerted if the **Goal** is not reached after the deadline.

a) Configuring Goals in the Protocols

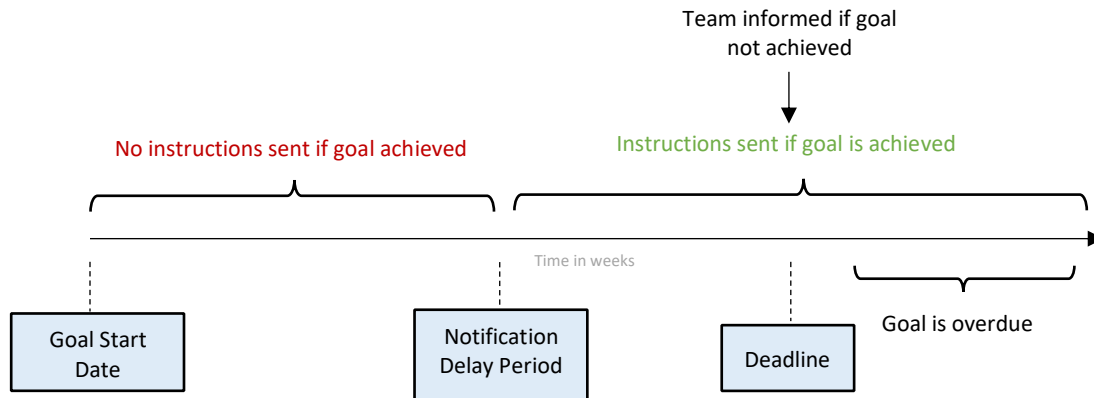
Goals are configured in the protocols.

Once a goal is selected in the protocol, the following parameters can be configured:

- Ability to auto-start the goal. If this option is activated, the goal will automatically start when the patient monitoring is started.
- Edit the Notification Delay Period. This is the earliest time, in weeks, at which Patient Instructions and Team Instructions will be triggered if the goal has been achieved. This period is calculated from the date the goal has been started.
- Edit the Goal deadline. If a goal has not been achieved after a deadline, you will receive a notification informing you of such.
- Set or edit the Patient *Instructions* to be triggered when a specific **Goal** is reached after the **Notification Delay Period** (please refer to the [Patient Instructions](#) section under *Protocols*)
- Set or edit the Team *Instructions* to be triggered when a specific **Goal** is reached after the **Notification Delay Period** (please refer to the [Team Instructions](#) section under *Protocols*)

The messaging behavior of a tracked **Goal** can be summarized below:





Please note you cannot configure the Team *Instructions* sent when a **Goal** has passed its deadline (*i.e.* becomes overdue). When this happens, you will simply see the message 'this goal is overdue' in your Notification Center. Overdue **Goals** do not trigger *Patient Instructions*.

If a **Goal** is achieved before the **Notification Delay Period**, it will still appear with the status "achieved" in the **Patient Card** and *Scan* timeline, but the *Instructions* will not be triggered until the **Notification Delay Period** has passed.

Please note this will not start the Goal - Goals can only be started from the Patient Card. Unticking a **Goal** that is being actively tracked will automatically stop it

b) Starting and tracking Goals

Once goals are activated in the protocols, they are accessible on the left side of the **Patient Card**, below the patient information.

You can start **Goals** you wish to track for each patient from their **Patient Card**. To start a **Goal**, you will need to find the **Goal** you wish to track and click on the  button. This will start the goal directly, using the default configuration set in the protocols.

Alternatively, you can edit the goal deadline before you start a goal. To edit the goal deadline, just click on the goal name and the goal details panel will open. Once the goal deadline is edited, click on the 'Start' button to start the goal.

c) Goal statuses

Once a **Goal** has been started, the **Patient Card** will display the goal progress (number of weeks ongoing / number weeks set in the goal deadline).

Opening the goal panel details shows how much time is remaining before the deadline is reached, or if the deadline has already passed, by how long the **Goal** is overdue. It also provides access to the History module, where the actions of Start/Stop the goal and associated owner and timelines are listed.



At any time, you have the ability to stop a *Goal*, to modify the chosen deadline, or to reset it after it has been achieved.

d) Parameter definition within Goals

	Goal definition	Associated value
Canine class*	Patient attains a canine class I	[-1.0mm; 1.0mm]
Molar class*	Patient attains a molar class I	[-1.0mm; 1.0mm]
Overbite	Patient attains a normal overbite	[1.0mm; 3.0mm]
Overjet	Patient attains a normal overjet	[1.0mm; 3.0mm]
Midline deviation	Patient midline deviation is corrected	[-0.5mm; 0.5mm]

4.9.4. SPECIFIC ADDITIONS TO 3D MONITORING

For patients on 3D Monitoring, additional Research Only features are available.

The features described in this section are intended for research use only. Their results are provided for information purposes only. Any resulting orthodontic treatment decision is the sole responsibility of the practitioner.

4.9.4.1. ACTIVITY GRAPH

The **Activity Graph** shows the average movement of all the patient's teeth, compared to their position on the *3D Model*.

The average movements for the upper arch (MX) and the lower arch (MD) are represented as two different lines. The Y axis shows the distance of movement in millimeters.

* Feature for Research Use Only. Results are provided for information purposes only. Any resulting orthodontic treatment decision is the sole responsibility of the practitioner.





4.9.4.2. TOOTH MOVEMENT INDICATOR

The tooth movement indicator is composed of two graphs: The **Crown Translation Graph** and the **Crown Rotation Graph**. Selecting a tooth in the top bar will automatically display results in both graphs. Results are expressed per tooth. Each point on the graphs corresponds to a *Scan* taken by the patient, with the date displayed when clicked.

The **Crown Translation Graph** shows tooth movement in millimeters compared to the position on the first *Scan*.

Results are expressed according to the following parameters:

- Mesial/distal translation
- Extrusion/intrusion
- Buccal/lingual translation

The **Crown Rotation Graph** shows tooth movement in degrees compared to the position on the first *Scan*. Results are expressed according to the following parameters:

- Buccal/lingual torque
- Mesial/distal rotation
- Mesial/distal angulation

Please note: due to poor quality *Scans*, movements cannot always be calculated. These *Scans* are represented by a square rather than a circle on the graph.



4.10. VIDEO CONSULTATION

You can invite your patients for a teleconferencing session through the *DentalMonitoring Dashboard* thanks to integration with doxy.me – a third-party HIPAA-GDPR-compliant telemedicine solution. This feature needs to be activated in your *DentalMonitoring Dashboard* before you can access it. For more information regarding the features of doxy.me, please consult the [doxy.me help center](#).

How to activate video consultation:

Under '**My Account**' you will find the option to subscribe to teleconferencing. Click on '**Subscribe**' and confirm your subscription.

It will take roughly 24 hours for this feature to be activated. You will receive an email when this is ready. Once your account is activated, your new credentials will appear on the same page where you subscribed.

To go to the teleconferencing website you will need to click '**Click here to enter your Virtual Waiting Room**' and enter the credentials (login/password) as they appear on your *DentalMonitoring* account.

How to invite a patient to teleconferencing:

From your *DentalMonitoring Dashboard*, go to your patient's profile and click '**New action → request a video consultation**'. You may modify the message before sending it to your patient (for example, adding a time and a date for the video consultation) but please do not change the URL link as this is what the patient will need to click on to start the teleconference with you. Once you click '**Send the request**' your patient will receive this message in an email and also on their *DM App*.

4.11. DM APP INTERFACE

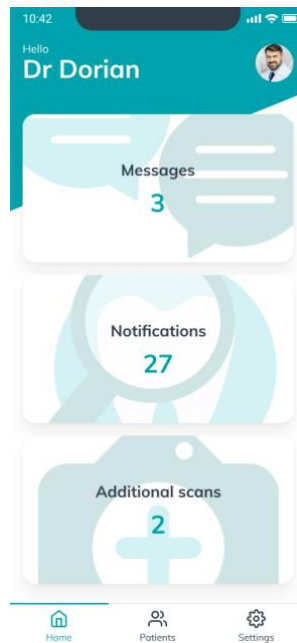
Healthcare Professionals can have access to the *DM App* by logging in using their *Dashboard* credentials. If the multi-factor authentication is activated on their account, before accessing the app, *Healthcare Professionals* will have to enter a code sent by SMS to the phone number saved on their *Dental Monitoring* account.



4.11.1. HEALTHCARE PROFESSIONAL FUNCTIONALITIES

Please note that every action done on the DM App (such as marking a notification as reviewed or sending a message to patient) will be reflected on the *Dashboard* and inversely.

Home page



The home page allows access to:

- The list of unreviewed Messages
- The list of unreviewed *Notifications*
- The list of unreviewed *Additional Scans*
- The patients list
- The App settings

4.11.1.1. MESSAGES

From the '**Messages**' card on the Home page, you can access the message inbox.

The '**Inbox**' contains direct messages sent by patients from their *DM App*. Messages are grouped by patients. Each patient will stay in the '**Inbox**' tab until all their messages have been marked as reviewed.

Clicking on a patient sends to the communication thread with a patient. This page displays the communications exchanged with the patient and allows you to send a direct message to the patient.

From this page, you can review your communication history with the patient. Please note this section may contain:

- *Automated Scan Reports*

- Any direct messages sent to and from the patient, including group messages
- Any annotated pictures and associated messages
- Any messages that are attached to a particular action, such as *Scan* schedule resets, *Additional Scan* requests, or a paused monitoring.

You can mark the notification as read by clicking on the tick next to each message.

Click on the patient's name to access the patient's detailed **Patient Card**.

From this page, you can also send a message to the patient. To send a message, click on the text field and write your message

You can also write your message using a *quick reply* previously set up from your *Dashboard*. To do so, click the '+' icon, press '**Send a quick reply**', and select a quick reply from your library. You can then edit your message if needed.

Another option is to send a video message to a patient. To record a message, click the '+' icon and press '**Record a video**'. Before recording a video for the first time, you will need to grant access to your camera and microphone following the app prompts. Once the video is recorded, you can review it and add a message.

Once the message is ready click on the '**Send Message**' icon.

4.11.1.2. NOTIFICATIONS

From the '*Notifications*' card on the Home page, you can access the list of unreviewed notifications.

This page contains notifications grouped by patient, including:

- Actions triggered by the **Patient Protocol** as set up for each patient:
 - Detected *Clinical Observations*
 - Team *Instructions*
 - Patient *Instructions*
- Team *Instructions* not generated by a *Protocol*
- Specific actions taken by patients (e.g. aligner number update)

You can mark the notification as read by clicking on the tick next to each notification.

Each *Notification* will stay in the '**Notifications**' page until it is marked as reviewed. It will also be accessible in the **Patient Card**.

Each item of the list can be collapsed or expanded.

Click on the patient's name to access the patient's detailed **Patient Card**.



4.11.1.3. ADDITIONAL SCANS

From the '**Additional scans**' card on the Home page, you can access the list of unreviewed notifications related to **Additional Scans** and grouped by patient.

This list will contain 2 types of notifications:

- **Additional Scans** sent by patients
- **Additional Scans** that had been requested by the practice and have been canceled by patient

Each event will stay in the **Additional Scans** list until it is marked as reviewed.

You can mark the notification as read by clicking on the tick next to each additional *Scan*.

By clicking on the notification, you can see more detailed information, such as the pictures sent by the patient.

Each item of the list can be collapsed or expanded.

Click on the patient's name to access the patient's detailed **Patient Card**.

4.11.1.4. PATIENTS LIST

The patient list gives access to the list of all your patients. A filter is available to easily identify currently monitored patients. The "Monitored" status is selected by default. The results of the search field consider the status of the filter.

A search feature is available to easily find a patient. You can search by:

- patient name
- patient profile ID
- patient email

Clicking on a patient name will open the **Patient Card** of this patient.

Patient creation is available from the patient list.

4.11.1.5. PATIENT CARD

a) Patient Card summary

The **Patient Card** summary contains a quick overview of the patient's details, including full name, profile ID, birth date, phone number. It allows the user to:

- Access the communication thread with this patient and send a message to the patient
- Call the patient
- View and edit the **Scan Frequency**
- View and edit the aligner number, including the total number of aligners in a set (only for aligner treatment)
- View the next scheduled *Scan* date

From the "More actions" button, more actions are available for the patient. This list of available actions may vary depending on the patient's status. It allows to:

- View and share the Before/After of a patient
- Start, pause, resume and stop a monitoring



- Send activation code to patient
- Ask the patient for an additional *Scan* or cancel the request
- Send an instruction to the team (without delay option)
- Take a training *Scan* for the patient

View and share the Before/After of a patient

The morphing video can be shared on social media apps.

Start, pause, resume and stop a monitoring

Monitoring can be started from an existing **QuickStart** created on the *Dashboard*.

Once the monitoring is paused, there is an option to resume it from the “More actions” button, as the start option is if a monitoring was stopped.

Take a training *Scan*

A training *Scan* is a *Scan* designed to teach patients how to properly take a *Scan*. The sequence of the training *Scan* is customized according to the patient’s monitoring and is the same as a regular *Scan*, except that the training *Scan* will not be uploaded. No processing will be done on a training scan.

To start a training *Scan*, press ‘**Take a training scan**’ and follow the app prompts.

b) General notifications

The Notifications panel shows all the unmarked notifications that have been triggered outside *Scan* schedule.

You can mark the notification as read by clicking on the tick next to each notification. Notifications will automatically disappear after a refresh of the page.

This section can be collapsed or expanded.

c) Timeline of *Scans*

This section presents a timeline of the patient's *Scans* to date. For each *Scan*:

- In case of aligner treatments, the timeline will display aligner number as well as the following:
 - A green circle for a GO.
 - A red circle for a NO GO or GO BACK.
- The aligner number the patient was wearing during the *Scan* (displayed as a number inside the shape).
- A preview of the first picture of the *Scan* is displayed
- Any *Clinical Observations* that were observed on the *Scan* on the given date are listed below the picture. You can mark the observations as reviewed by clicking on the tick next to them. *Clinical Observations* stay displayed even after they have been reviewed.
- An option to force the go for the next *Scan*. This option is only available for aligner treatments.

You can click on the preview of the picture to open the gallery. The gallery will display all pictures from the given *Scan* with the *Clinical Observations* that were observed on the *Scan*. You can mark the *Clinical Observations* as reviewed by clicking on the tick next to them. *Clinical Observations* stay displayed even after they have been reviewed.



You can zoom inside pictures and navigate between them.

Each *Scan* can be collapsed or expanded.

d) Send annotated photos to the patient

You can annotate any photo from a patient's gallery and send it to the patient with an accompanying message.

1. From the gallery, select the photo you wish to annotate. Click on the **Send with a note** icon
2. A new window will open displaying the photo you have selected, along with a textbox. If you wish to edit the picture, click on the desired options from the menu bar. You can draw freehand, create shapes or write text.
3. When you are done annotating the photo, you can add a message to accompany the annotated photo if you so wish.
4. Click on the **Send message** icon to send the annotated photo to your patient along with your message. This will appear on the patient's *DM App*.

e) Scan comparison

From the **Gallery**, you can compare any two different *Scans* taken by the patient on different dates.

To start the comparison, from the **Gallery**, select the photo you wish to compare. Click on the Compare icon.

By default, the *Scan* taken just before the initial *Scan* is displayed under the initial *Scan*.

You can change any of the two *Scans*. To do so, click on the 'Calendar' icon on the *Scan* you want to change.

A new window will open displaying a list of *Scans* taken by the patient. Clicking on a *Scan* date will display the *Scan* pictures for that date in the **Gallery**.

When navigating through pictures of one of the *Scans*, the equivalent picture will automatically be displayed on the other *Scan*.

When you are done comparing the *Scans*, click '**Stop Comparison**'.

4.11.1.6. SETTINGS

From the '**Settings**' page:

- Add or update the profile picture by clicking on the generic avatar or the existing profile picture (this will only apply to the *DM App*)
- The 'Switch account' button gives the ability to switch to an already connected account or connect a new account
- The **Logout** button allows users to disconnect their *DentalMonitoring* account from the currently used device.

a) App notifications

From the '**Settings**', you can activate push notifications. Push notifications are automated messages sent by *DentalMonitoring* on your mobile device to inform you when an event occurs.





The list of available push notifications is:

- **'Message from patients'** - sends a push notification when a patient sends a direct message through the DM App
- **'Message from DM Support'** - sends a push notification when the *DentalMonitoring* Support Team sends a message about a patient
- **'Scan notifications'** - sends a push notification when a new *Scan* is published for a patient.
- **'Goal overdue'** - sends a push notification when a **Goal** has passed its deadline for a patient.
- **'Timeframe reached'** - sends a push notification when a timeframe is reached for a patient.
- **'Additional scan to review'** - sends a push notification when a patient sends an additional *Scan*.
- **'Additional scan canceled by patient'** - sends a push notification when a *Scan* that was requested by the practice is canceled by a patient.

All push notifications are turned off by default and can be activated individually. Push notifications are sent to your mobile device only and do not impact your *Dashboard* experience.

Please note that you need to give permissions to the *DM App* in order to receive push notifications.

b) Legal and regulatory information

The Legal and Regulatory Information section gathers the last version of legal and regulatory documents that have been signed on your *DentalMonitoring Dashboard*. You can open a document by clicking on it.

c) Advanced settings

- **Update audio resources**

This section allows you to check if the audio resources of your app are up to date. If you notice that audio instructions in the *Scan* experience are not fully translated into your language, press 'Update resources'. The app will check for available updates and download them.

4.11.2. PATIENT FUNCTIONALITIES

For detailed instructions on the *DM App*, please refer to the *DentalMonitoring* Patient Instructions for Use provided to you in a separate document.

5. LIFETIME

The lifetime of *DentalMonitoring* software is 3 years in case of no major update or no force update.

6. DATE OF ISSUANCE

The present Instructions for use are issued in February 2026.

7. INSTRUCTIONS FOR USE VERSION

IFU_MON_H_MD_06_en

8. 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.

9. 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.



ANNEX 1 – LIMITATIONS

Clinical parameter	Patient population			Dentition		
	Age & dentition	No orthodontic treatment	Orthodontic treatment	Detail level per result	Included	Excluded
Black triangle	Permanent dentition	✓	✓	Per interdental space	All interdental spaces excluding those between second and third molars Buccal and occlusal surfaces	Interdental spaces between: - Second and third molars - Primary teeth
Closure of extraction space	Permanent dentition	✓	✓	Per interdental space	All interdental spaces excluding those between second and third molars Buccal and occlusal surfaces	Interdental spaces between: - Second and third molars - Primary teeth
Closure of all anterior spaces	Permanent dentition	✓	✓	Per interdental space	All interdental spaces from canine to canine Buccal and occlusal surfaces	Interdental spaces: - Other than from canine to canine - Between primary teeth - Lingual surfaces
Overjet	Permanent central incisors	✓	✓	/	Central incisors (permanent)	Central incisors (primary)
Overbite/open bite	Permanent central incisors	✓	✓	/	Central incisors (permanent)	Central incisors (primary)
Midline deviation	Permanent central incisors	✓	✓	/	Central incisors (permanent)	- Central incisors (primary) - Presence of supernumerary teeth
Tracking (seat / unseat)	Permanent dentition	/	✓ Aligners Retainers	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth
Attachment loss	Permanent dentition	/	✓ Aligners	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth
Button loss	Permanent dentition	/	✓ Aligners	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth
Bracket debonding	Permanent dentition	/	✓ Braces (traditional, ceramic, self-ligating)	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth - Lingual surfaces
Tie loss	Permanent dentition	/	✓ Braces (traditional, ceramic)	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth
Self-ligating clip	Permanent dentition	/	✓ Braces (self-ligating)	Per tooth	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth



Clinical parameter	Patient population			Dentition		
	Age & dentition	No orthodontic treatment	Orthodontic treatment	Detail level per result	Included	Excluded
Passive archwire and auxiliaries	Permanent dentition	/	✓ Braces (traditional, ceramic, self-ligating)	Per arch	All permanent teeth excluding third molars Buccal and occlusal surfaces	- Third molars - All primary teeth - Lingual surfaces
Updated 3D Model	Permanent dentition*	✓	✓ Aligners Retainers	3D Model	All permanent teeth	- Orthodontic treatments other than aligners - All primary teeth

* Provided the teeth present on the *Scan* acquired with *DentalMonitoring* were also present on the *3D Model* provided to *DentalMonitoring* by the *HCP* with at least two thirds of the crown present on the *3D Model*. In 3D Monitoring, in the event a tooth extraction is performed during the treatment and if a 3D model of the patient's teeth after the extraction is not provided by the Healthcare Professional to *DentalMonitoring*, please note that the updated 3D Model reflecting the patient's dentition at a specific time may include gingiva not fully representative of the patient's gingiva at the location of the extraction. In the event the HCP requires attachments to be reported on the updated 3D Model and the attachments present on the *Scan* differ from those present on the 3D Model provided to *DentalMonitoring* by the HCP, please note that the placement of attachments on the updated 3D Model may not fully represent their actual positioning on the patient's teeth.



ANNEX 2 – LIST OF OBSERVATIONS

CATEGORY	Timeframe	
	Messages triggered following a certain timeframe in the patient's monitoring journey	
	SUB-CATEGORY	
OBS.		Days after monitoring start date
		This event will be triggered a certain number of days after the patient's monitoring start date
OBS.		# day(s)
		Event calculated from the monitoring start date

CATEGORY	SUB-CATEGORY	Goals:	
		Track precise milestones in your patient's treatment including: Anteroposterior, transverse and vertical corrections	
		Anteroposterior	
		Canine and molar class corrections, closure of anterior and extraction spaces	
		OBSERVATIONS	Class I canine - RIGHT [-1.0; 1.0] mm*
			This goal is achieved when the patient attains a canine class I between -1.0 and 1.0 mm on the right side
			Class I canine - LEFT [-1.0; 1.0] mm*
			This goal is achieved when the patient attains a canine class I between -1.0 and 1.0 mm on the left side
			Class I molar - RIGHT [-1.0; 1.0] mm*
			This goal is achieved when the patient attains a molar class I between -1.0 and 1.0 mm on the right side
			Class I molar - LEFT [-1.0; 1.0] mm*
			This goal is achieved when the patient attains a molar class I between -1.0 and 1.0 mm on the left side
		OBS.	Closure of all anterior space(s)
			This goal is achieved when all the patient's anterior spaces are closed
		OBS.	Closure of extraction space(s)
			This goal is achieved when all spaces created by the extraction of a tooth are closed
		OBS.	Normal overjet [1.0; 3.0] mm
			This goal is achieved when the patient attains an overjet between 1.0 and 3.0 mm
		Transverse	
		Midline deviation and crossbite corrections	
		OBSERVATIONS	Correction of midline deviation [-0.5; 0.5] mm
			This goal is achieved when the patient's midline deviation is corrected between -0.5 and 0.5 mm
			Correction of crossbite – RIGHT*
		OBS.	This goal is achieved when the patient's right crossbite is corrected
			Correction of crossbite – LEFT**
		OBS.	This goal is achieved when the patient's left crossbite is corrected
		Vertical	
		Overbite correction	
		OBS.	Normal overbite [1.0; 3.0] mm
			This goal is achieved when the patient attains an overbite between 1.0 and 3.0 mm
		General	
		Passive archwire and appliances, loss of all deciduous teeth	
		OBSERVATIONS	Passive archwire and auxiliaries - UPPER
			This goal is achieved when no clinically significant tooth movement is detected on the upper arch for two successive scans
			Passive archwire and auxiliaries - LOWER
			This goal is achieved when no clinically significant tooth movement is detected on the lower arch for two successive scans
		OBS.	Loss of all deciduous teeth*
			This goal is achieved when all of the patient's deciduous teeth are lost

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CATEGORY	Orthodontic parameters - Aligners	
	Tracking, attachment loss, auxiliary appliance, aligner damage, aligners remaining, aligner number reached	
	SUB-CATEGORY	Tracking
		<i>Satisfactory aligner tracking, slight or noticeable unseat</i>
		OBSERVATIONS
		First scan - welcome message <i>Welcome message congratulating the patient on their first scan</i>
		Satisfactory aligner tracking <i>No noticeable unseat, nor slight unseat has been detected on any teeth</i>
		Slight unseat <i>The aligner fit is not in intimate contact with the tooth, minor gap between the incisal/occlusal edge of the tooth and the aligner</i>
		Slight unseat still present <i>Previously notified slight unseats are still present with no improvement or deterioration</i>
		Noticeable unseat <i>Poor fit of the aligner with major/noticeable halo effect around the tooth</i>
		Noticeable unseat still present <i>The noticeable unseats in the previous scan are still present with no improvement or deterioration</i>
		Attachment loss
		<i>Missing attachments</i>
		OBS.
		Loss of attachment <i>Loss of attachment on the tooth surface in comparison to previous scan</i>
		Attachment still absent <i>An attachment that was detected as lost on the previous scan is still absent</i>
		Auxiliary appliance
		<i>Debonding or damage of aligner auxiliary appliance</i>
	OBSERVATIONS	Aligner auxiliary debonding* <i>Aligner auxiliary debonding (includes Carriere Motion appliance, power arms, etc)</i>
		Aligner auxiliary damage* <i>Aligner auxiliary damage includes break of Carriere Motion appliance, segmental archwires</i>
		Loss of button <i>A button is missing compared to the previous scan</i>
		Button still absent <i>A button that was detected as lost on the previous scan is still absent</i>
		Aligner damage
	OBS.	<i>Distortion, fracture, crack and other damage to the shape or structural integrity of the aligner</i>
		Aligner damage* <i>The aligner is visibly damaged (distortion, fracture, crack and other damage to the shape or structural integrity of the aligner)</i>
	OBS.	Aligners remaining
		<i>Triggered based on the number of aligners remaining in the patient's current aligner set</i>
	OBS.	# aligner(s) remaining <i>When the patient has # aligners left to wear in their current aligner set</i>
		Aligner number reached
	OBS.	<i>Triggered when the patient starts wearing a specific aligner number</i>
		Aligner # <i>Triggered when the patient is told to switch to aligner #</i>

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CATEGORY	SUB-CATEGORY	Orthodontic parameters - Braces <i>Brackets, bracket ligature, archwire, auxiliaries</i>	
		Positive notifications for braces <i>Notifications triggered when braces treatment is going well</i>	
		OBS.	Satisfactory condition of the braces* <i>The overall aspect of the treatment is satisfactory</i>
		Bracket <i>Includes braces, tubes, bands and self-ligating clips</i>	
		OBS.	Bracket debonding <i>A bracket is missing in comparison to the previous scan, or still present but debonded and displaced along the archwire</i>
			Bracket still debonded <i>A bracket is still missing or present but debonded and displaced along the archwire since the previous scan</i>
			Bracket damage* <i>Includes fracture or distortion of eyelet, hook, self-ligating clip or desoldering of band attachment</i>
			Bracket still damaged* <i>A bracket is still damaged since the previous scan</i>
			Open self-ligating clip <i>A self-ligating clip is partially or fully open</i>
			Self-ligating clip still open <i>A self-ligating clip notified as open on the previous scan is still open</i>
		Bracket ligature <i>Ties, springs and chains</i>	
		OBSERVATIONS	Loss of tie <i>Missing tie on a bracket. If a tie is present but not fully engaged on all wings of the bracket, it will not be detected as lost</i>
			Tie still absent <i>A tie detected as lost on the previous scan is still absent</i>
			Powerchain damaged or disengaged* <i>A powerchain is disengaged or damaged</i>
			Powerchain still damaged or disengaged* <i>A powerchain is still damaged or disengaged since the previous scan</i>
			Spring damage* <i>A spring is broken or disengaged</i>
			Spring still damaged* <i>A spring that showed damage in the previous scan is still damaged</i>
		Archwire <i>Disengagement, distortion, fracture or passivity of archwire, loss of hook</i>	
		OBSERVATIONS	Archwire disengagement* <i>An archwire is fully or partially disengaged. Please note that an archwire will be notified as disengaged if it was engaged in the previous scan.</i>
			Archwire disengagement still present* <i>An archwire that was fully or partially disengaged on the previous scan is still disengaged</i>
			Noticeable archwire distortion* <i>An archwire is considered as distorted when abnormal deformation is visible</i>
			Noticeable archwire distortion still present* <i>An archwire distortion detected in the previous scan is still present</i>
			Archwire fracture* <i>An archwire is fractured</i>
			Archwire fracture still present* <i>An archwire fracture detected in the previous scan is still present</i>
			Archwire hook missing* <i>An archwire hook visible in the previous scan is now missing</i>
			Archwire hook still missing* <i>An archwire hook lost in the previous scan is still missing</i>

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OBSERVATIONS	Archwire is passive <i>3D monitoring only - triggered when no clinically significant tooth movement is detected for two successive scans</i>
	Archwire is still passive <i>3D monitoring only - an archwire that was notified as passive in the previous scan is still passive</i>
	Auxiliaries <i>Occlusal interferences, missing or damaged auxiliaries</i>
	Appliance damage* <i>A fixed or removable appliance is broken, distorted or debonded. Appliances include: quadhelix, expander, transpalatal bar, forsus, Herbst rod or any removable vacuum or acrylic appliance</i>
	Appliance damage still present* <i>The appliance is still damaged since the previous scan</i>
	Occlusal interference* <i>Visible occlusal interference with an archwire or bracket</i>
	Occlusal interference still present* <i>The visible occlusal interference in the previous scan is still present</i>
	Bite opening composite missing* <i>Bite opening composite is no longer present</i>
	Bite opening composite still absent* <i>A bite opening composite that was previously detected as missing is still absent</i>
	Button debonding* <i>A button is missing compared to the previous scan</i>
	Button still absent* <i>A button that was detected as lost on the previous scan is still absent</i>
	TAD missing* <i>A TAD that was previously visible on scans is now absent</i>
	TAD still absent* <i>A TAD that was missing in the previous scan is still absent</i>

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Oral health assessment			
Oral hygiene, gingivitis, soft tissue statement, spots, suspected cavities, dental statement			
CATEGORY	SUB-CATEGORY	Oral hygiene	
		Oral hygiene and calculus	
		OBSERVATIONS	Satisfactory oral hygiene*
			No visible dental plaque, calculus or food residue
			Oral hygiene still satisfactory*
			Oral hygiene continues to be satisfactory
			Dental plaque / food residue*
			Presence of dental plaque, food residue on one tooth at least or on appliance
			Dental plaque / food residue still present*
			Presence of dental plaque, food residue on one tooth at least or on appliance since previous scan
	Buccal dental calculus*		
	Perceptible buildup of dental calculus		
	Persistent buccal dental calculus*		
	Persistent perceptible buildup of dental calculus since previous scan		
	Gingivitis		
	Gingivitis		
	OBSERVATIONS	Slight gingivitis*	
		Slight gingival edema and redness without glazing	
		Slight gingivitis still present*	
		Persistent slight gingival edema and redness without glazing since previous scan	
		Noticeable gingivitis*	
	Moderate or marked gingival redness, edema and glazing		
	Noticeable gingivitis still present*		
	Persistent moderate or marked gingival redness, edema and glazing since previous scan		
	Soft tissue statement		
	Mucosa alteration, signs of aphthous stomatitis, gingival recession, black triangle		
	OBSERVATIONS	Mucosa irregularity*	
Mucosa irregularity indicating: suspected inflammation, abscess, ulcer, white plaque, embedding of appliance or archwire poking			
Persistent mucosa irregularity*			
Suspected mucosa irregularity is still present since the previous scan			
Noticeable black triangle			
Dark triangle visibility between contact point and papilla			
Noticeable black triangle still present			
A noticeable black triangle is still visible since the previous scan			
Gingival recession*			
A gingival recession was detected in comparison to a specific anterior scan			
Persistent gingival recession*			
Persistent gingival recession since the previous scan			
Spots and suspected cavities			
Suspicion of cavities, spots			
OBSERVATIONS	Spots on teeth*		
	Perceptible white, yellow, brown or black spots which could include cavities from Level 1 to 2 in ICDAS Code		
	Spots on teeth still present*		
	Perceptible white, yellow, brown or black spots which could include cavities from Level 1 to 2 in ICDAS Code still visible since the previous scan		
	Suspected cavity*		
	Localized enamel breakdown or/and distinct cavities with visible dentine; ICDAS Code Level 3 to 6		
	Suspected cavity still present*		
	Localized enamel breakdown or/and distinct cavities with visible dentine; ICDAS Code Level 3 to 6 still visible since the previous scan		
Dental statement			
Tooth wear, debonding of dental restoration, tooth fracture, tooth color change			

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		OBSERVATIONS	Tooth wear*	
			Loss of tooth characteristics including sharpening of incisal edges and loss of cusps of teeth in comparison to a specific anterior scan	
			Tooth wear still present*	
			Occlusal tooth wear still present since the previous scan	
			Debonding of dental restoration*	
			Dental restoration is missing	
			Debonding of dental restoration still present*	
			Dental restoration is still missing since the previous scan	
			Noticeable tooth fracture*	
			Tooth fracture that may require clinical attention	
Noticeable tooth fracture still present*				
Tooth fracture is still present since the previous scan				
Noticeable tooth color change*				
A notable change in tooth color due to intrinsic factors has been detected				
CATEGORY	SUB-CATEGORY	Intraoral evaluation		
		Tooth position, occlusion		
		OBSERVATIONS	Tooth position	
			Crossbite or rotation during tooth eruption, ectopic eruption, all deciduous teeth lost	
			Tooth eruption in crossbite*	
			Tooth erupting in crossbite. The notification will specify: edge-to-edge, lingual or buccal	
			Unchanged tooth eruption in crossbite*	
			Previously notified tooth eruption in crossbite has not changed since the previous scan	
			Tooth erupting severely rotated*	
			Tooth erupting in severe rotation that may require clinical attention	
			Noticeable submerged tooth*	
			A tooth is below the plane of occlusion	
			Noticeable submerged tooth still present*	
			A submerged tooth is still submerged since previous scan	
			Ectopic eruption*	
			A tooth has erupted out of position	
		Ectopic eruption still present*		
		Ectopic eruption still present since the previous scan		
		All deciduous teeth lost*		
		Every deciduous tooth has been lost since the previous scan		
Occlusion				
Crossbite or midline deviation development				
OBSERVATIONS	Edge-to-edge crossbite*			
	New edge-to-edge crossbite is discovered			
	Persistent edge-to-edge crossbite*			
	Edge-to-edge crossbite is still present since the previous scan			
	Crossbite development*			
	Crossbite has developed since the previous scan			
	Crossbite still present*			
Crossbite is still present since the previous scan				
Midline deviation developing				
This notification will occur when the midline deviation is greater than 3.0 mm				
Midline deviation still present				
Midline deviation is still present since the previous scan				

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CATEGORY	Retention	
	<i>Movement, diastema and retainer</i>	
	SUB-CATEGORY	Removable retainer tracking
		<i>Satisfactory removable retainer tracking, slight or noticeable unseat</i>
		OBSERVATIONS
		Satisfactory retainer fit <i>No noticeable or slight unseat has been detected on any teeth</i>
		Slight unseat <i>The retainer fit is not in intimate contact with the tooth, minor gap between the incisal/occlusal edge of the tooth and the retainer</i>
		Noticeable unseat <i>Poor fit of the retainer with major/noticeable halo effect around the tooth</i>
		Retainer damage
		<i>Distortion, fracture and other damage to the shape or structural integrity of the retainer</i>
		OBSERVATIONS
		Fixed retainer damage* <i>The notification will specify if the fixed retainer is debonded, fractured or missing. Notification of a debonded or fractured retainer requires visual signs</i>
		Removable retainer damage* <i>Notification will specify fracture or distortion</i>
		Relapse
		<i>Modification of parameters since the beginning of monitored retention</i>
		OBSERVATIONS
		Satisfactory stability (3D)* <i>(3D) No clinically significant change in tooth alignment compared to the previous scan</i>
		Slight movement (3D)* <i>(3D) Mild change in tooth alignment since the previous scan</i>
		Occlusion relapse* <i>Evolution of more than 1.0 mm from the beginning of retention for any of: overbite/open bite, overjet, canine class, molar class and midline. Clinically significant change for crossbite developing.</i>
		Alignment relapse* <i>Clinically significant tooth movement during retention phase indicating: spacing, crowding, misalignment of occlusal edges</i>

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ANNEX 3 – PRODUCT DISCLAIMER

The following indications can be used for the remote monitoring of dental treatments, orthodontic treatments, oral health, and treatment progress:

- closure of all anterior spaces,
- closure of extraction space,
- black triangle,
- overjet value in millimeters (2D results),
- midline deviation value in millimeters (2D results),
- overbite/open bite value in millimeters (2D results),
- for aligner treatments:
 - tracking (seat/unseat),
 - attachment loss,
 - button loss,
- for braces:
 - bracket debonding,
 - tie loss,
 - self-ligating clips,
 - passive archwire and auxiliaries (2D Monitoring and 3D Monitoring),
- for thermoformed retainers:
 - tracking (seat/unseat).

The above are approved as a medical device. Only for use on all permanent teeth excluding third molars and lingual surfaces. Mandatory use of DentalMonitoring's proprietary hardware products.

Smart STL feature: The provided STL files are representative of the patient's dentition and treatment progress. These files are approved as a medical device. Only for use on permanent teeth. Mandatory use of DentalMonitoring's proprietary hardware products.

Results of all other product features are considered for Research Use Only and are provided for information purposes only. Any resulting orthodontic treatment decision is the sole responsibility of the practitioner. Only for use on permanent teeth. Mandatory use of DentalMonitoring's proprietary hardware products.