

Read these instructions before use

Before using the Automated Notifications available with Invisalign Virtual Care AI-based Automatic Assessment Version 3.0 (Virtual Care 3.0*), patients and their parents or legal guardians should carefully read these instructions for important information, including warnings and precautions. We recommend that you save these instructions for future reference. Make sure you refer to Part III for compatible software and hardware systems needed to participate in Virtual Care 3.0. If you have questions or concerns, please contact your Doctor. You can also provide feedback to Align through the My Invisalign Application.

© 2022-2024 Align Technology, Inc. English language version. Automated Notifications available with Invisalign Virtual Care AI-based Automatic Assessment Version 3.0*, Software version 3.6, Issue Date: March 2024

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Virtual Care 3.0 is a non-medical device Clinical Decision Support (CDS) software function per US Federal Regulations. These software tools do not diagnose or treat any condition, but only provide information for health care professionals. While Virtual Care identifies and describes dental attributes, it is not intended to substitute for the advice of a dentist, orthodontist or other health care professional

*The IFU is inclusive of Version 3.0 including minor updates and patch fixes within the series.



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Customer support

If you have questions or concerns about Virtual Care 3.0, please provide your feedback through the “Contact us for help” form in the My Invisalign App.

Any serious incidents related to the device should be reported to your Doctor, who will inform Align Technology Inc. and the competent authority of the Member State in which the user and patient are established. Product availability and regulatory status may differ across countries depending on local regulations.

Contents

What is Virtual Care 3.0 Software Application?	3
Indications for use:.....	3
When Virtual Care 3.0 Software Application should not be used?	3
Warnings	3
Precautions	4
How to participate and set up Virtual Care 3.0 Software Application?	5
Part I. How to take Photos?.....	5
Part II. How to Receive feedback?	9

Part III What Software and Hardware Systems will you need?	11
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What is the Virtual Care 3.0 Software Application?

The Automated Notifications available with Invisalign Virtual Care AI-based Automatic Assessment Version 3.0 (Virtual Care 3.0) is a system that helps your Doctor monitor your treatment progress. Virtual Care 3.0 uses artificial intelligence (AI)-based calculations and your Doctor's pre-set aligner space thresholds for automatic assessments which are confirmed by trained personnel in delivering your Doctor's communications to you on the progress of your Invisalign treatment. Virtual Care 3.0 includes: Virtual Care 3.0 system includes: Virtual Care Web UI, Aligner Fit Framework for Mobile, Invisalign Support Web, Aligner Fit Machine Learning engine and Virtual Care 3.0 Aligner Fit Library . Virtual Care 3.0 also relies on your use of other software applications like My Invisalign Application to support communications with your Doctor.

Indications for use:

Virtual Care 3.0 system is intended to aid the Health Care Professional (HCP) in remotely monitoring and communicating intra-oral situations and malocclusion treatments using the Invisalign System.

Note: For the purposes of this product, the Health Care Professional is your Doctor (dentist or other qualified dental health professional). Patients must have an established relationship with a Doctor during Invisalign treatment to upload photos and receive communication.

When the Virtual Care 3.0 Software Application should not be used

Virtual Care 3.0 is contraindicated for use in the following circumstances:

Doctors who are color blind or who have any visual impairment that may impact the Doctor's ability to use this device as directed.

Warnings

1. Virtual Care 3.0 does not, nor does it seek to, provide diagnostic advice or recommendations on dental or orthodontic conditions or treatment. Any orthodontic treatment decisions supported by data generated by the Virtual Care 3.0 service is a

Doctor's responsibility. Overreliance on or substitution of this tool for the Doctor's professional judgement could lead to incorrect patient assessments and/or delays in treatment.

2. Simulations and measurements generated using AI-based systems may differ from the final clinical results.
3. A number of factors may prevent or delay the delivery of (AI)-based treatment guidance or treatment guidance from your Doctor:
 - Low bandwidth, poor connectivity, lack of compatibility or hardware failure
 - Downtime or other technical issues with Virtual Care 3.0 or the My Invisalign Application
 - Failure to receive your Doctor's notifications because My Invisalign Application notifications or alerts have been disabled in your smart phoneIn case of any concerns including serious incidents, please contact your Doctor immediately.
4. Virtual Care 3.0 is meant for Doctor use only and is solely intended to be used for monitoring and communicating the progress of Invisalign treatments. Any other use may lead to incorrect patient assessments and/or delays in treatment.

Precautions

1. The following factors may impact AI assessment and/or lead to inaccurate guidance to the patient: (i) Poor photo quality; (ii) Photo is not assessed by AI properly; (iii) Notifications or instructions set by your Doctor are vague or confusing. Delayed or inaccurate treatment guidance due to these issues could result in discomfort and tooth and/or periodontal tissue injury.
Virtual Care 3.0 is dependent upon:
 - Maintaining regular contact with your Doctor and following your Doctor's instructions and the steps outlined in Part I below on how to take photos properly
 - Using proper photo taking technique with a cheek retractor or other retracting device, especially when taking lateral photos (ensure premolars and 1st molars are visible) Please refer to Part 1 (How to Take Photos).
 - Following "aligners on" and "aligners off" prompts when taking "bite open" and "bite closed" photos.
2. If Virtual Care 3.0 does not perform as expected, contact your Doctor.

3. Doctor should not advise the use of Virtual Care 3.0 if patients(or their parents/guardians) do not have regular access to a smart phone, cannot access/use the My Invisalign Application, or do not have sufficient bandwidth or resources necessary to regularly take and upload pictures.

Note: Product availability and regulatory status may differ across countries depending on local regulations. Talk to your Doctor or contact Align through the feedback form in the My Invisalign App.

How to participate and set up Virtual Care 3.0

If you are reading these instructions, you have accepted your Doctor's invitation to participate in Virtual Care 3.0, as well as the terms and conditions associated with the program.

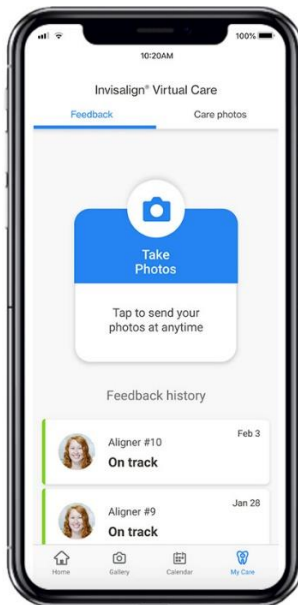
For more information about My Invisalign App, please refer to the FAQ in profile settings.

Part I. How to take photos

Make sure you refer to Part III for compatible software and hardware systems needed to participate in Virtual Care 3.0.

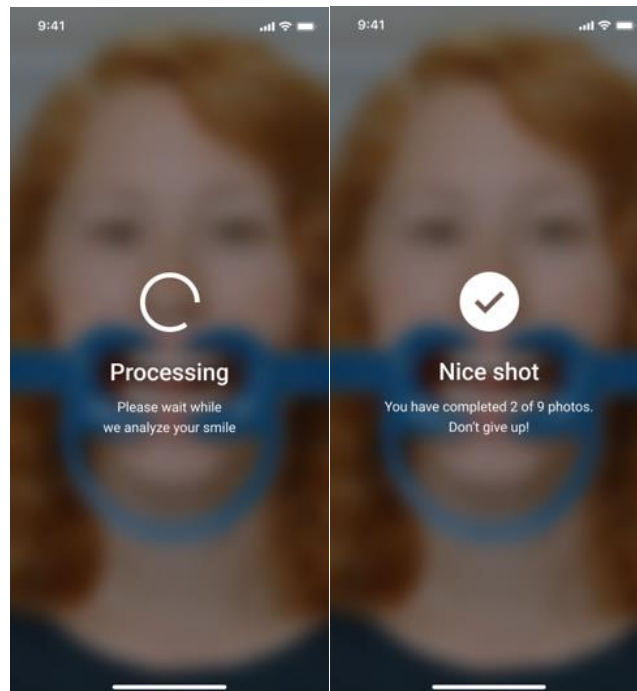
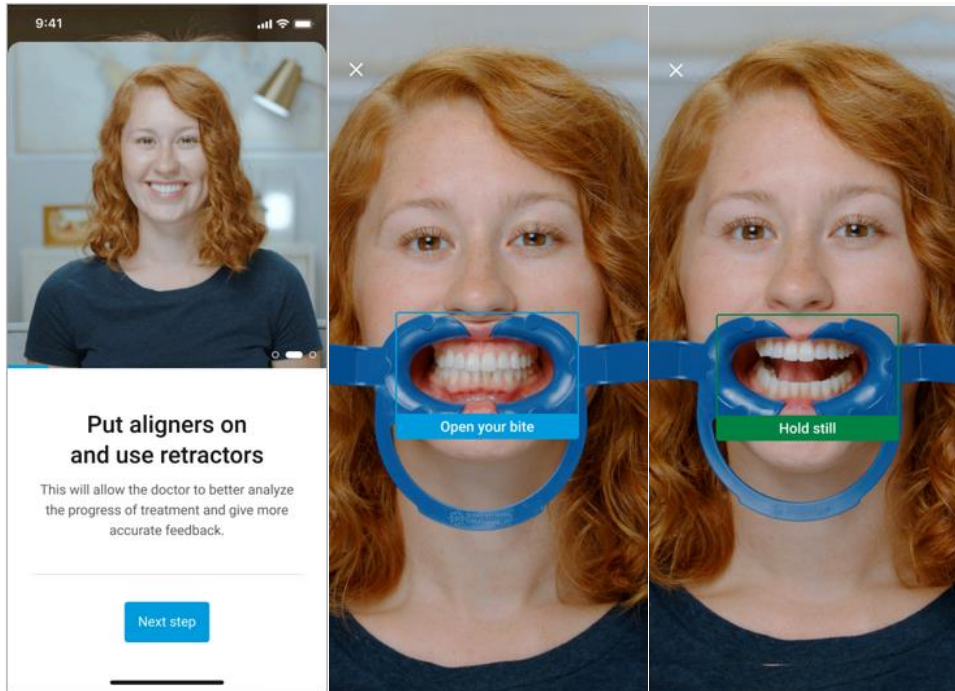
My Invisalign App notifications must be enabled to proceed.

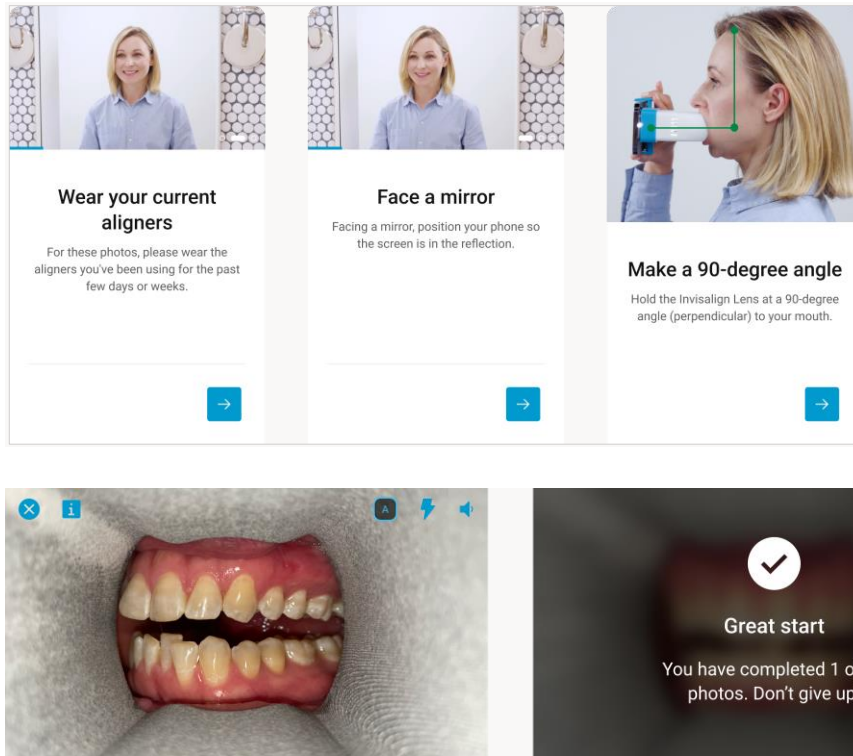
1. Press the "My Care" icon to start the process of photo taking:



2. Take 3 photos (straight on, facing right, facing left) in the following scenarios:
 - Aligners on and bite open
 - Aligners off and bite open
 - Aligners off and bite closed
 3. Take occlusal photos (upper jaw and lower jaw)**
 4. Before taking each photo, please review the short video in the My Invisalign App on how to take photos.
 - Place the Invisalign cheek retractor or Invisalign Lens* into your mouth. If you don't have a cheek retractor or similar retracting device, choose "I don't have retractors" option.
- *Note: See the Invisalign Lens IFU for assembly and instructions for use. Invisalign Lens device may not be available in your country. If you have questions or concerns, please contact your Doctor.
- **Taking occlusal photos is only available with Invisalign Lens

- For “Aligners on and bite open” photos, put your aligners in
- For “Aligners off and bite open” and “Aligners off and bite closed” photos, put your aligners out.
- To take the photos, align your mouth (as directed) with the rectangular box on your phone screen. The photo will be taken automatically.
- While taking lateral photos (in other words, photos taken with head facing right/left), make sure that your posterior (back) teeth (including premolars and 1st molars) are visible.
- While taking the occlusal photos (in other words, photos of occlusal (chewing) surfaces of the upper jaw and the lower jaw), make sure that the occlusal surface of posterior teeth is visible
- Once you’ve submitted your photos, they will be assessed by the AI based on your Doctor’s treatment settings (your Doctor will also receive the photos and can review them at any time). In Virtual Care 3.0, AI assessments are then routed to trained personnel to review and either accept or reject the assessment.

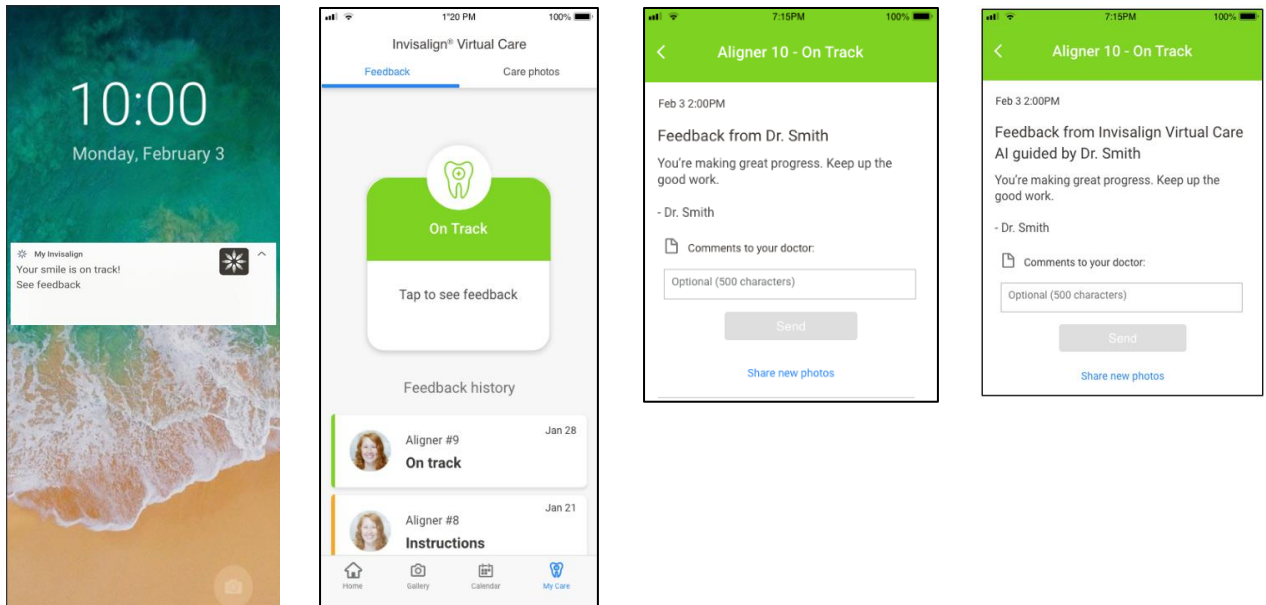




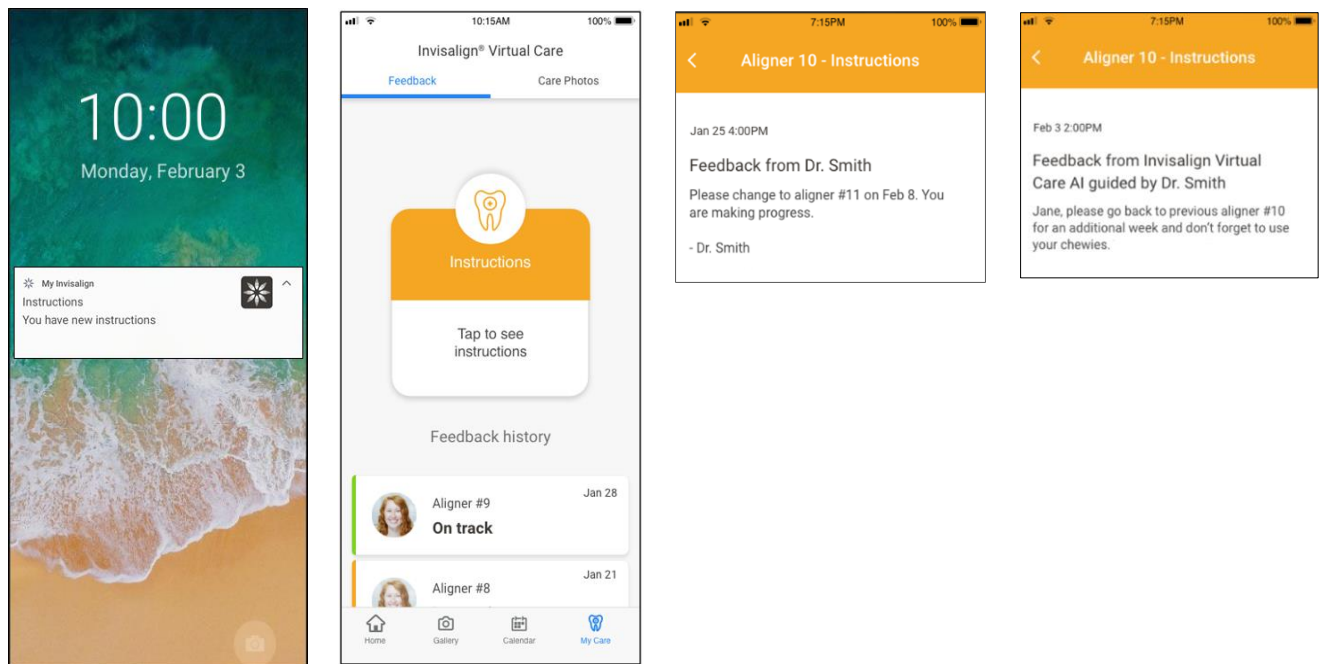
Part II. How to receive feedback?

4. Virtual Care 3.0 uses your Doctor's notification settings to provide one of two types of feedback after the AI assesses your photo submission (your doctor may also provide you with feedback directly): "On track" or "Instructions".

- "On track" indicates that your new smile is progressing according to your custom treatment plan. Continue wearing your aligners as directed.



- “Instructions” indicates that your Doctor or Virtual Care 3.0 (based on your Doctor’s settings) has provided you additional guidance, for example, an instruction to wear your current aligners for additional time, or to use ‘chewies’ to help seat your aligners properly.



- If you have any questions about feedback notifications, please contact your Doctor's office
- If you have questions or concerns about Virtual Care 3.0, please provide your feedback through the "Contact us for help" form in the My Invisalign App.

Always follow treatment instructions to keep your new smile on track.

Part III What Software and Hardware Systems will you need?

This section presents system requirements and explains important information about data security.

5. How is your data security maintained?

Align takes great care in protecting the integrity and confidentiality of data from the moment it is collected. The patient data that is backed up to our servers is transmitted over transport layer security (TLS 1.2 and above) encryption using trusted certificates. This helps to prevent an attacker from capturing patient and customer information while in transit. In addition, PII information is encrypted at rest.

While it is the your responsibility to protect access to their mobile device as well as install appropriate malware protections, Align has the following recommendations for protecting devices/data:

- Protect your mobile device with a passcode
- Set a pin code or biometric authentication (if your device supports it)
- Lock the screen of the device during periods of inactivity.
- Use only on private, firewalled networks.
- Avoid the use of My Invisalign App on rooted or jailbroken devices (Note: Rooting/jailbreaking describe the acquisition of complete administrator rights on the device, allowing third-party programs to perform operations that were not originally possible).
- Keep operating system patches up-to-date to address vulnerabilities
- Do not run proxies on the mobile device
- Swipe away the application from your App Switcher to fully close it after use

6. System requirements

To take photos and get notifications from your Doctor or from Virtual Care 3.0 (based on your Doctor's treatment settings), you must have Internet access and your mobile device should meet the minimum specifications below. If software loses functionality (e.g. specific Aligner features are not displayed), please contact Customer Support.

6.1. Minimum & recommended OS requirements:

Platform	OS
iOS	13.0 and above
Android	6.0 (Marshmallow) and above










6.1.1. Recommended devices

Platform	Model
iOS	iPhone 6 and above including SE
Android	<ul style="list-style-type: none"> • Samsung S8 and above • Galaxy Note 4 and above, • Galaxy Z series • Galaxy A series • Huawei P series – P30 and above • Google Pixel 3 and above

6.2. Software update

Align recommends installing all recent My Invisalign App updates to keep it up to date. If you experience issues accessing Invisalign Virtual Care, please contact your Doctor.

6.3. Symbols glossary

Symbol	Title	Explanatory text	Standard reference
	Manufacturer	Indicates the medical device manufacturer,	ISO 15223-1 Reference # 5.1.1
	Medical device*	An indication that the device is a medical device.	ISO 15223-1 Reference # 5.7.7
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Reference #5.4.3
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1 Reference #5.7.10
	Country of manufacture	To identify the country of manufacture of products	ISO 15223-1 Reference #5.1.11
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community.	ISO 15223-1 Reference #5.1.2
	Swiss authorized representative	Indicates the authorized representative in Switzerland	N/A
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1 Reference # 5.1.8
	CE Mark European Conformity Conformité Européene	Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations	NA

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