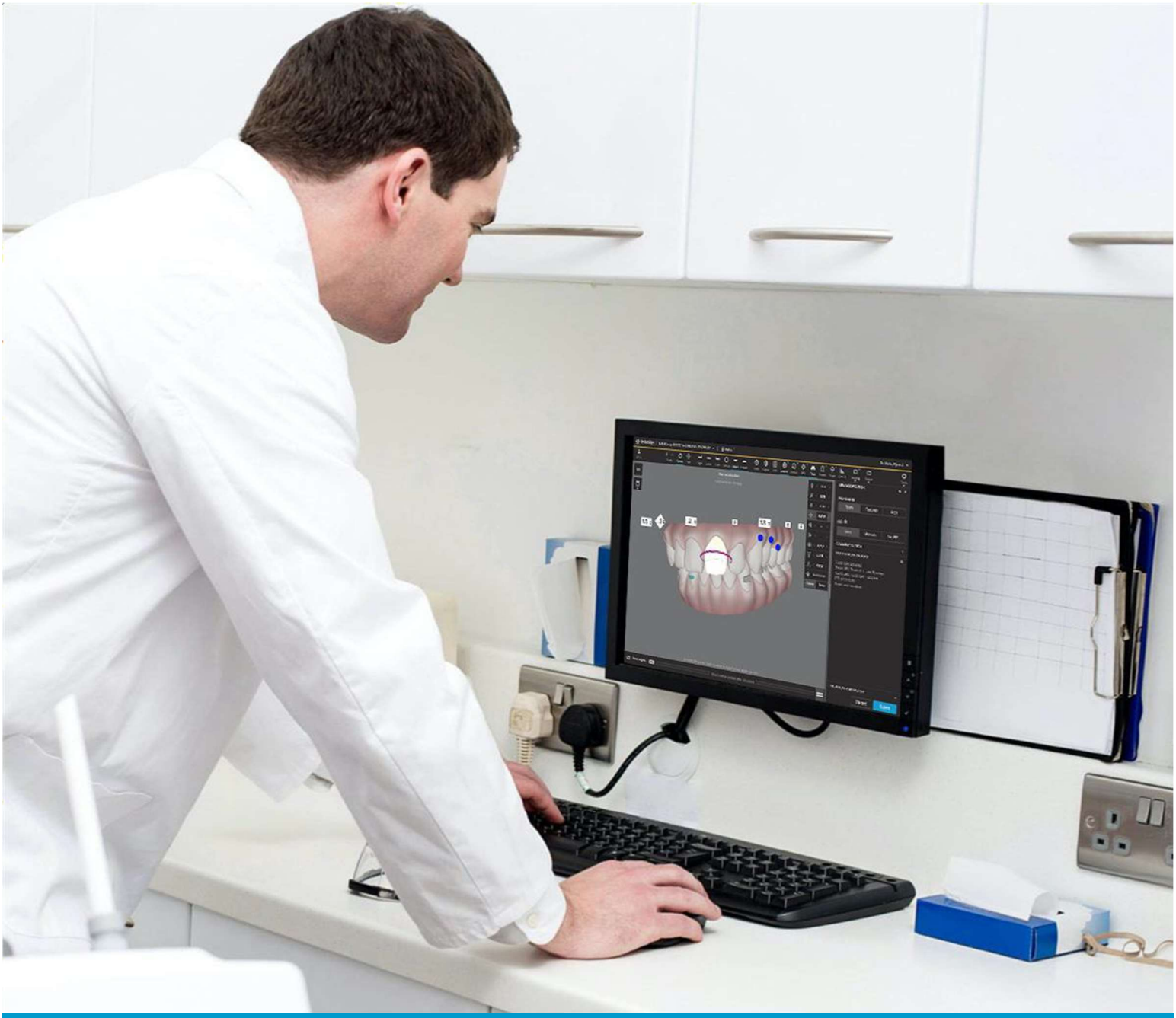

ClinCheck Pro® 6

User guide

invisalign®

English language version. ClinCheck® Pro 6, May 2022

Trademarks

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Customer support

For questions, please contact your local Customer Support. Contact details are available on your Invisalign Doctor Site under the Support tab.

Please reference Instructions for Use (IFU) for warning, precautions, and contradictions in conjunction with this user guide.

Contents

Introduction

What is ClinCheck Pro software?

ClinCheck Pro software (ClinCheck) is a proprietary 3D computer application (electronic prescription) for depicting, viewing, editing, monitoring, and approving an orthodontic treatment plan, including a virtual representation of the patient's expected tooth movement from the beginning through final stage of their Invisalign case in a virtual three-dimensional model.

ClinCheck® software is designed to be available on the treating doctor's computer and is launched by the system when the user clicks on the ClinCheck file. The software provides a computerized approximation of desired tooth movement for a specific patient and the results are simulated based on the approved ClinCheck treatment plan. The ClinCheck treatment plan includes the ClinCheck model with options such as placement of attachments or a Power Ridge feature and Interproximal Reduction (IPR) if required by the treatment plan. The doctor must review the ClinCheck treatment plans thoroughly. The doctor may make changes or modifications via the ClinCheck software prior to approving the final ClinCheck treatment plan. The doctor's approval of the customized ClinCheck treatment plan is considered a prescription and constitutes final authorization for Align to manufacture the aligners.

This software is to be used by doctor and clinical staff.

Note: All names used in this document are not intended to reflect actual persons. Any similarity to an actual person is merely coincidental.

Note: Many of the examples shown in this guide have been exaggerated for instructional purposes and may not reflect actual clinical conditions. For example, a tooth may be displayed initially hyper-rotated to show the effect of the correction tool.

Note: Keyboard Short cuts for the tool is provided within parenthesis

Indications for Use

The Invisalign® system is indicated for the orthodontic treatment of malocclusion.

Please reference Instructions for Use (IFU) for warning, precautions, and contradictions in conjunction with this user guide.

Part I. Reviewing treatment plans

1 Viewing treatment plans

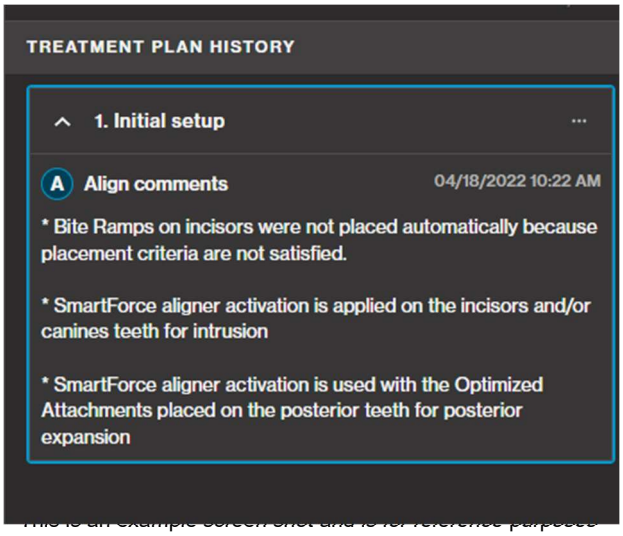
ClinCheck Pro software uses a system to allow user to view the treatment history and navigate between open treatment plans.

A Treatment plan history – Captures the history of this patient's treatment.

- To access a previous plan, click on the plan name.

B Treatment plan – Displays the active models, for example, the original Align plan and your modification.

- To view a treatment plan, click on the plan name from the Treatment plan history



only.

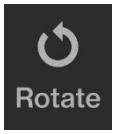
2 Setting up the model view

ClinCheck Pro software allows you to use cursor movements to rotate and pan the 3D model as needed for your analysis.

2.1 Panning the model

To pan the model, first chose the Pan mode on the toolbar. Then click and hold anywhere in the 3D Display panel, move the model to the desired screen location and release the cursor.

2.2 Rotating the model



To rotate the model, first choose Rotate mode. Then click and hold anywhere in the 3D Display panel, move the cursor to achieve the desired rotation and release the cursor. You can change the effect of the cursor movement – Free-form, Simple or Precise – using the Settings panel. (Arrow keys)

2.3 Shortcuts

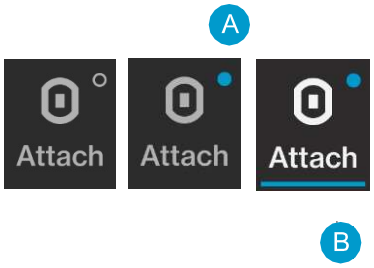
When in Rotate mode, you can momentarily switch to Pan mode by pressing the Shift key and clicking and dragging with the mouse or Shift + Right/Left arrow

3 Using tools

ClinCheck Pro software provides a rich set of tools that allow you to fine-tune the visual information shown for the 3D model.

3.1 Indicators

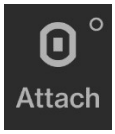
Icons may include an Indicator.



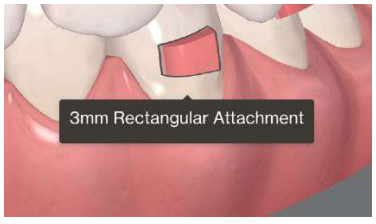
A A blue indicator next to the icon, represents that specific feature is present in the treatment plan.

B A blue line under the icon, represents the specific feature is turned on and visible in the treatment plan

3.2 Attachments tool

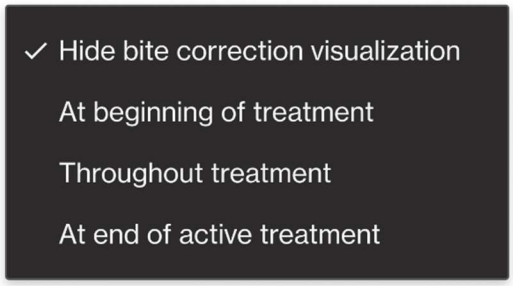


The Attachments tool displays or hides attachments and cuts. Mouse over any attachment to see the attachment type. (A)



3.3 Bite correction visualization tool

The Bite button allows you to choose one of four options from the Bite dropdown submenu.



Each option changes the Stage indicator when you play the ClinCheck® simulation. The gray dashes show the stages with bite corrections, an example is shown below.

At beginning of treatment

Throughout treatment

At end of treatment

Hide bite correction visualization

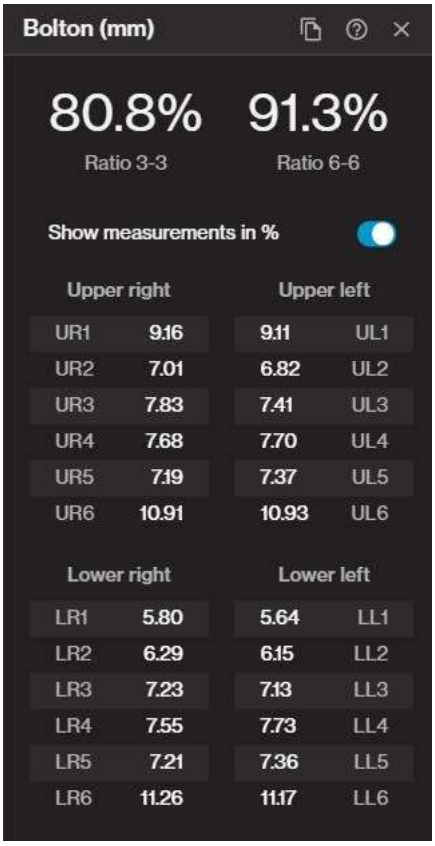
Visualization defaults

For surgical simulation, visualization is applied at the end of treatment unless you request otherwise when submitting the Rx Form.

For correction with Class II or Class III elastics, visualization is applied throughout the treatment to simulate the simultaneous bite and dental corrections. The number of stages needed to correct the bite discrepancy doesn't necessarily correlate to the number of stages needed to align and level the teeth.

3.4 Bolton Analysis tool

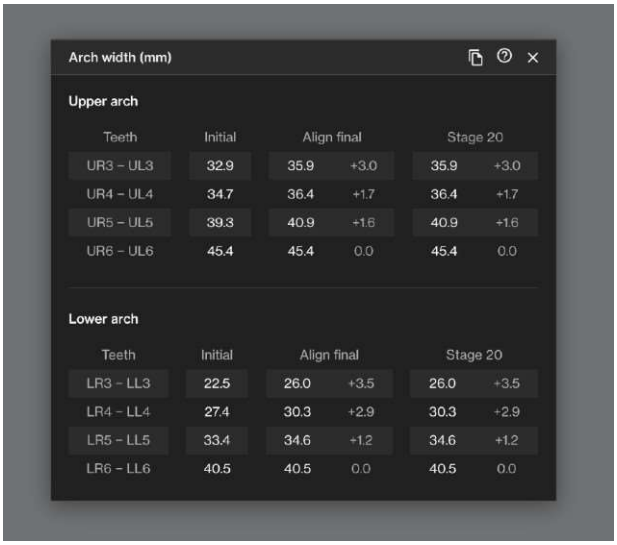
The Bolton Analysis tool provides reference information about tooth size discrepancy that is useful for planning how to address tooth inter-digitation and arch coordination. The analysis is not automatically integrated into the treatment planning setup protocol but is provided for your assessment. The Bolton Analysis window provides information on the width of permanent and primary teeth and provides the estimated width for missing permanent teeth. (Shift + B)



This is an example screen shot and is for reference purposes only.

3.5 Arch width table

The Arch width table reflects the initial and final arch width between canine, premolar (primary molar) and permanent molars. It incorporates primary and permanent teeth numbering as per teeth present in a given case. The “Doctor Final” column shows changes after Doctor’s modifications using 3D controls real time. (Shift + W)



This is an example screen shot and is for reference purposes only.

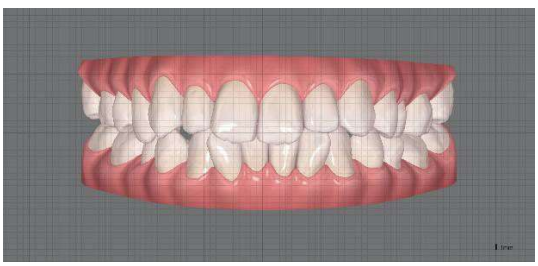
3.6 Export tool

The Export tool, located in the patient menu, allows you to export case information as STL files, screenshots, and movie

Note: STL export feature is limited to the initial and final stages of the treatment plan. This STL file is provided to help you develop more efficient dental treatment plans that may integrate with Invisalign and other dental procedures; it is not intended for manufacturing aligners or retainers to straighten or retain teeth. If the ClinCheck plan related to this STL file is not accepted or is later canceled, Align Technology, Inc. reserves the right to charge you for the creation of this STL file

3.7 Grid tool

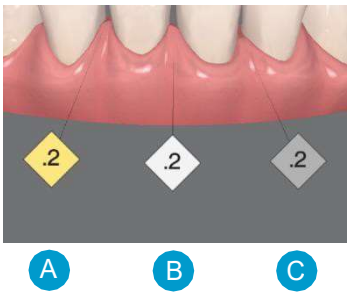
The Grid tool toggles the display of a measurement grid. When the grid is on, the view is flattened to facilitate accurate measurements. (G)



3.8 IPR tool

The IPR tool controls the display of IPR values.

When IPR values are displayed, mouse over the diamond to see more information. (I)

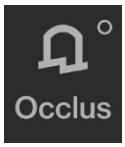


A IPR that is shaded yellow, represents IPR scheduled for current stage

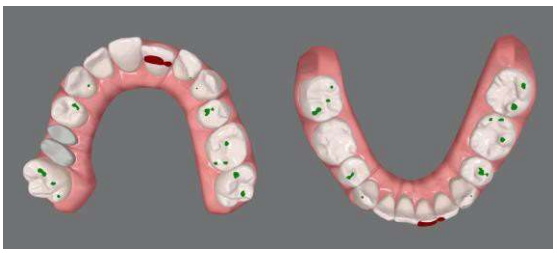
B IPR that is shaded white, represents IPR scheduled for future stages

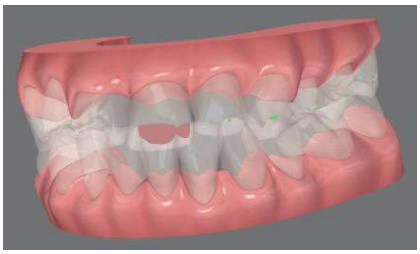
C IPR that is shaded gray, represents IPR scheduled for previous stages

3.9 Occlusal Contacts tool



When you are reviewing the Align® treatment plan, show Occlusal Contacts is available. Click on this item to toggle the display of occlusal contact in the initial and final stages. (C)





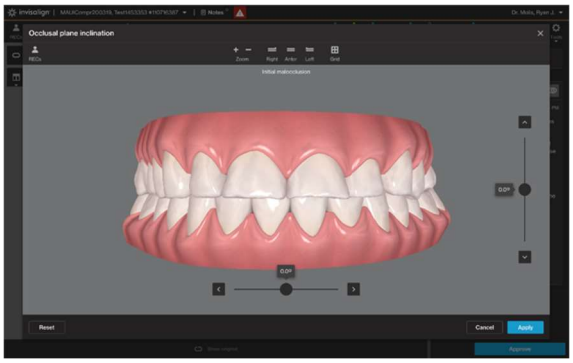
The red indicator in the Occlusal Contacts tool icon indicates the presence of heavy occlusal contacts. You can resolve them yourself or choose to let ClinCheck Pro software resolve them by clicking Auto-Resolve in 3D controls (see section 5). ClinCheck Pro software automatically makes the necessary adjustments and creates a comment in the auto-generated comments field of the Comment to tech section.

3.10 Occlusal Plane Inclination tool

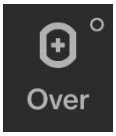
The Occlusal Plane Inclination tool allows you to match the 3D model orientation to the orientation of the patient's teeth. The occlusal plane inclination that you set is sent to Align for the current order.

To change either angle, click and hold the indicator and drag to the desired angle between -30 and +30 degrees.

To set the angle, click the Apply button. The Anterior, Left Buccal and Right Buccal views will now be displayed at this angle. The value of the occlusal plane inclination is also stored with the current treatment plan for use by Align technicians. (Shift + O)



3.11 Overcorrection tool



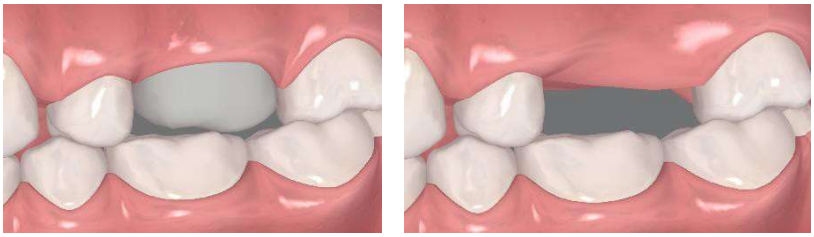
The Overcorrection tool toggles the visualization of three additional stages as specified by the doctor. Movements prescribed in these stages are optional, for example, virtual c-chain to tighten contacts at the end of treatment. (O)

A Treatment stages

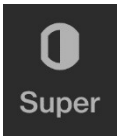
B Overcorrection stages

3.12 Pontic tool

The Pontic tool toggles between showing and hiding the pontics in the 3D model. In the examples below, pontics are shown on the left and hidden on the right. (P)



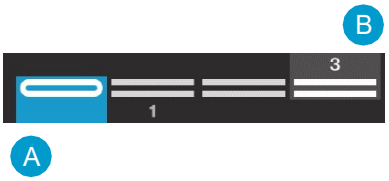
3.13 Superimposition tool



The Superimposition tool allows you to visualize the relative movements of teeth from one stage to another along the viewing axis, that is, forward or backward from the viewer's perspective. When the Superimposition tool is selected, two controls appear on the stage selection slider as shown directly below. (S)

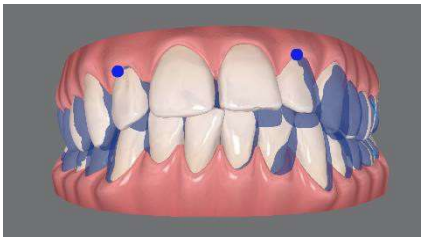
A Stage displayed in blue

B Stage displayed in opaque ivory

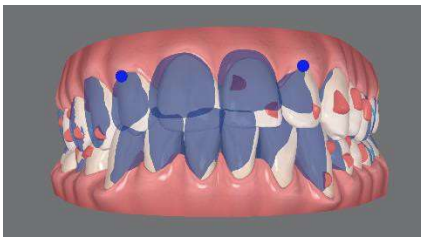


Superimposition can be visualized in two ways, depending on which slider you use for the evaluation (later) stage as shown below.

White areas are moving towards viewer. Only the edges of the translucent colored teeth are visible.

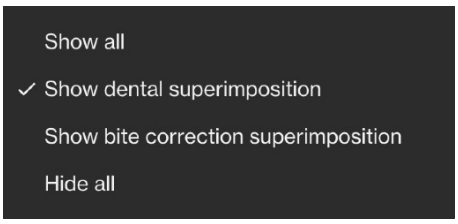


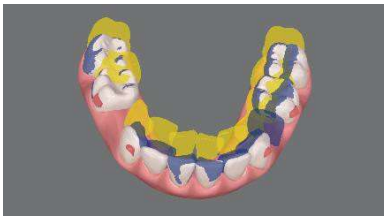
White areas are moving away from viewer.



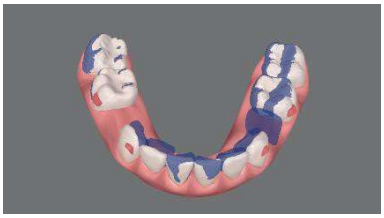
Superimposition with Bite Correction

In cases where Bite Correction visualization is present, the Superimposition tool allows you to visualize both the relative dental correction (in blue) as well as the bite correction movements (in yellow).





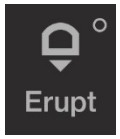
Show all



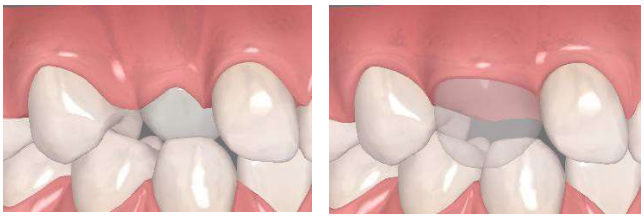
Show dental

Show bite correction

3.14 Erupt tool



The Erupt tool controls the visibility of eruption features for pre-teen and teenage patients. The examples below show the same patient with the Erupt tool off and on. (E)



Erupt tool off Erupt tool on

3.15 Tooth Movements Table tool

The Tooth Movement Table displays the values of all the movement programmed for each tooth. By selecting the Tooth Basis buttons, these values display the linear movement at either the center of the crown or the virtual root apex; the angular values don't change since they are not affected by the tooth basis selection. (Shift + T)

When making changes with 3D Controls, the Tooth Movement Table displays:

- The total movement programmed in the original plan
- The total movement programmed by the doctor with 3D controls
- The values of how much movement was added or removed by the doctor, instead of the total movement that has been programmed.

When in Comparison mode, you can view the values of Align® final, Doctor final or the difference between the two "Comparison".

Leading movements are underlined

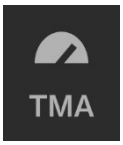
Tooth movements table — Align final | **Doctor final** | Comparison

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Extrusion/Intrusion, mm	-	0.2 I	0	0.4 E	0.4 E	0.7 E	0	0.1 I	0.6 I	0.3 E	0.9 E	0.4 E	0.4 E	0.2 E	0.1 E	-
Relative Ext/Int, mm	-	0.1 E	0.1 I	0.2 E	0.2 E	0.7 E	0.8 I	1.2 I	1.0 I	0.1 E	0.8 E	0.2 I	0	0.1 E	0	-
Translation, B/L, mm	-	0.3 L	0.5 B	1.2 B	0.7 B	0.2 L	2.0 B	2.0 B	0.7 B	0.4 B	0.1 B	1.5 B	1.5 B	0.7 B	0	-
Translation, M/D, mm	-	0	0	0	0.2 D	0.1 D	0	0.6 D	0.2 M	0.2 D	0.3 D	0	0.1 M	0	0.1 M	-
Rotation, °	-	2.1 D	9.2 D	3.1 D	3.2 M	0.6 D	7.3 D	11.2 M	21.7 M	15.9 M	5.0 M	2.0 M	1.9 D	5.1 D	3.2 D	-
Angulation, °	-	0.8 D	2.7 D	1.2 M	6.9 M	3.1 M	0.2 M	1.4 D	2.1 M	0.9 D	1.5 M	3.3 M	2.0 M	0.9 D	0.1 D	-
Inclination, °	-	3.1 L	0.2 L	2.2 B	2.8 B	0.1 B	7.4 B	12.7 B	6.1 B	0.9 L	0.3 B	10.6 B	6.3 B	1.4 B	0.7 B	-

◉ Upper ○ Lower Tooth basis ◉ Crown ○ Root

This is an example screen shot and is for reference purposes only.

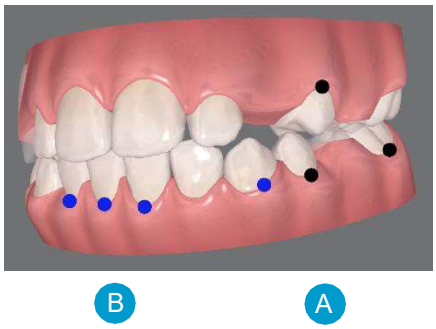
3.16 Tooth Movement Assessment tool



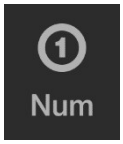
The Tooth Movement Assessment (TMA) tool shows larger tooth movements that could be more difficult to achieve in the treatment. These assessments are also shown in the patient drop down menu under treatment overview.

A Black dots – Advanced movement

B Blue dots – Moderate movement



3.17 Tooth numbering tool



The NUM button toggles the display of tooth numbers on the 3D model. When pontics are displayed, they are marked with a P. (N)

To change the default numbering system – Universal, Palmer or Federation Dentaire Internationale – go to the clinical preferences section of the Invisalign Doctor Site.

Part II. Making modifications

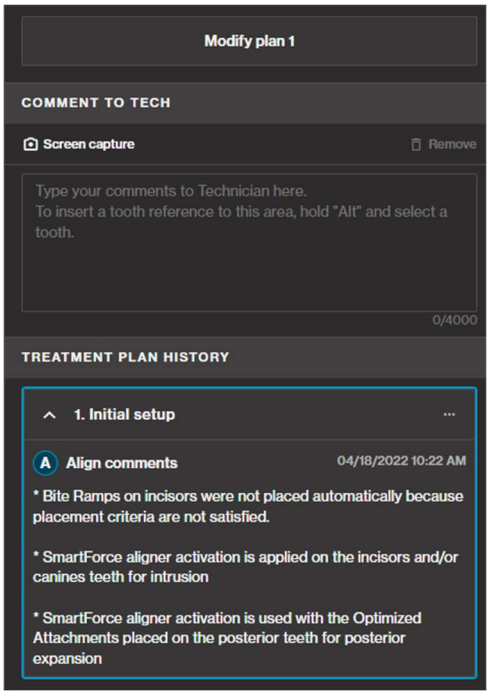
You have two options for modifying the treatment plan:

- Provide written instructions to the Align® technician each of these options is described below.
- Create a modified plan using 3D controls

4 Modifying plans with written instructions

4.1 Reviewing comments history

The Comments History section contains comments from Align CAD designers about the current treatment plan. Because it captures a record of treatment history, it may not be edited. When you first open a new ClinCheck® plan, please review the comments from Align at the top of the Comments History.

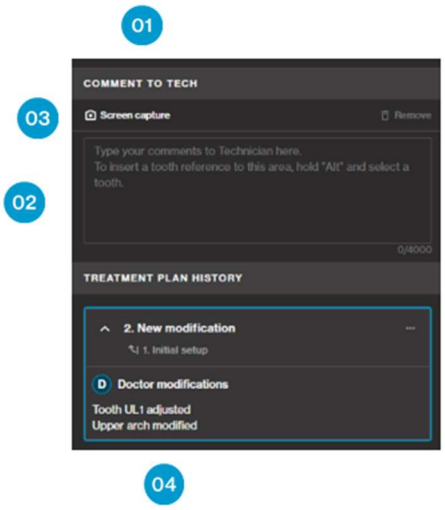


This is an example screen shot and is for reference purposes only.

4.2 Adding comments to modify

To add comments communicating your desired changes, type into the Comment to Tech section.

When you use 3D controls to modify a treatment plan, each modification is automatically recorded in the Doctor Modifications section. For example, when you adjust a tooth, ClinCheck® Pro software generates the comment “Tooth X adjusted.”



1. Text Comments for technician. Use this area to request desired changes and provide information to the Align technician.

   Note: ClinCheck® does not allow comments over 4000 characters. Long comments should be given audibly by calling Customer Support.

2. Tooth Number. To display the number of a modified tooth, Alt-click on the tooth in the 3D model. The tooth ID is copied to the doctor’s comments box. You can then add additional notes as needed.

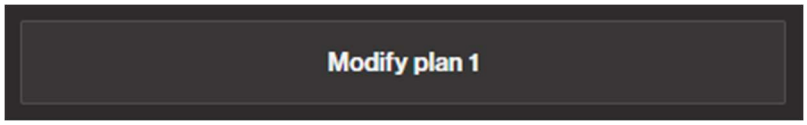
3. Add Screen Capture. To capture the current 3D model view for the Align technician, click the Screen Capture button. A camera icon linked to the screen capture image appears in the Comment to Tech box (Ctrl/Command + shift + V)

4. Doctor Modifications. This area contains comments that are automatically generated by the ClinCheck® Pro software when using 3D controls.

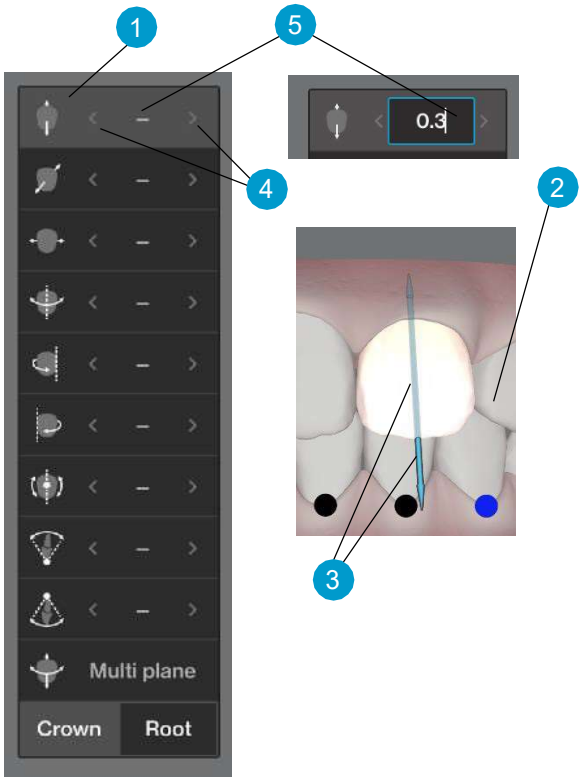
5 Creating a modified plan using 3D controls

5.1 Creating a new modification

To begin the process, click the New Modification button. By modifying this model using the 3D controls, you can communicate your desired treatment plan to Align. (Ctrl/Command + Shift + M)



5.2 Modifying tooth positions



1 Choose the desired modification from the Tooth menu. (Ctrl + Down arrow)

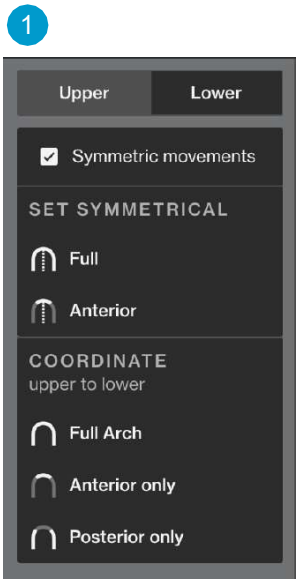
2 Click on the tooth to be modified. The tooth turns white. Hold the Control key to select multiple teeth, all of which will be modified at once.

3 Click and hold on the handle. Drag the handle to make the desired changes.

4 You can also click the arrows on the modification icon to make more precision changes. (Ctrl + right/left arrows)

5 A third way to modify the tooth, is by manually entering the exact value you like in 3D controls

5.3 Modifying arches

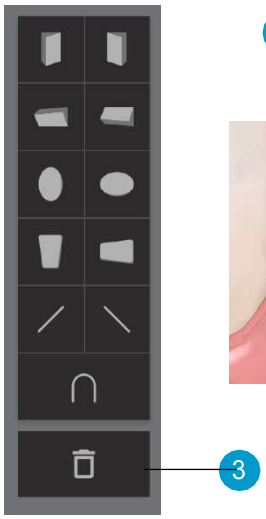


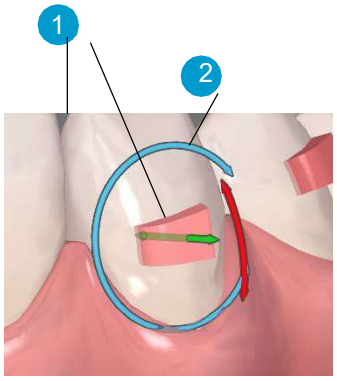
1 Choose the desired arch adjustment parameters:

- Arch to adjust: Upper or lower
- Symmetric movements: Applies to the selected arch only
- Full or Anterior symmetry: Applies to the selected arch only
- Coordinate lower to upper: Allows you to coordinate the opposite arch to the adjusted arch. Full, Posterior only or Anterior only

2 Click and drag any of the nine handles to modify the arch shape as desired.

5.4 Managing attachments and cuts





1 In Modifications, click on the Features icon, then click desired attachment or cut and drag it to the tooth, then release.

- If precision wings cover more than 15% of the tooth, attachments and cuts cannot be added

2 Use the handles to change the orientation as desired.

3 To delete an attachment or precision cut, click and drag it to the trash can icon, then release. (Backspace)

4 If visible red zones appear, then attachments cannot be added

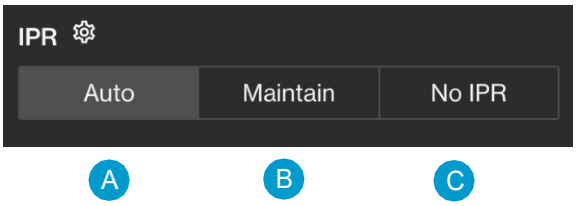
5.5 Adjusting IPR

The IPR tool within 3D controls provides three options for managing interproximal reduction:

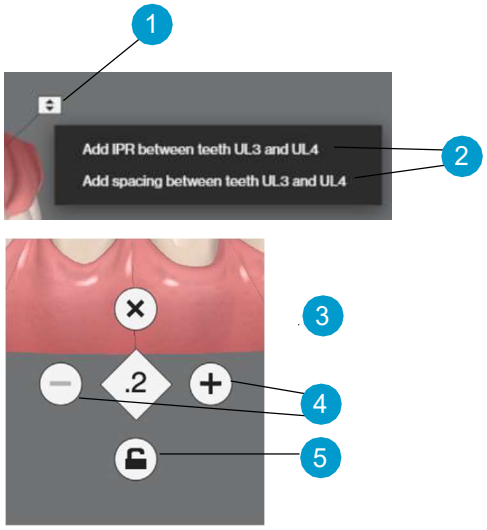
A Auto: ClinCheck® automatically adds, removes, increases and decreases IPR when teeth are adjusted.

B Maintain: The IPR prescriptions are maintained when teeth are adjusted.

C No IPR: All existing IPR is removed and IPR will not be added when teeth are adjusted.



5.6 Managing IPR and spacing



1 To add IPR or spacing click on the flags

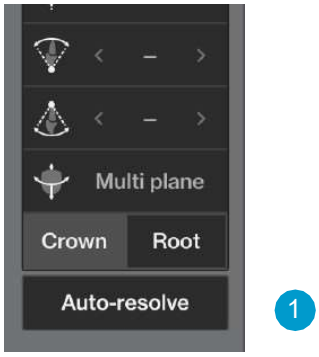
2 Select either IPR or spacing.

3 To remove IPR or spacing, click the X and select the option to remove the IPR or Spacing.

4 Adjust values by clicking on the + or - sign besides the diamond (IPR) or rectangle (spacing).

5 To prevent auto-adjusting of the IPR or spacing value, make sure the padlock is closed (click to toggle the state of the padlock).

5.7 Adjusting occlusal contacts



1 In order to resolve heavy occlusal contacts, click the Auto resolve tool at the bottom of 3D controls

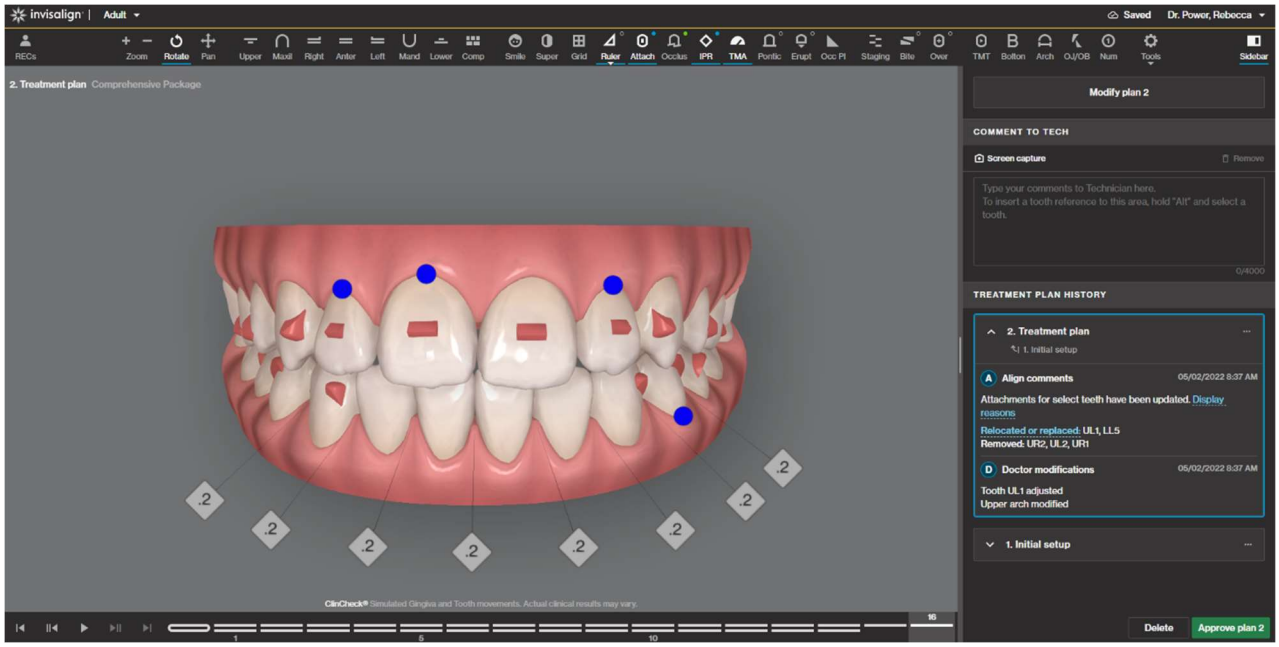
6. Live Update

6.1 3D controls with Live Update

Once modifications are complete using 3D controls, use the Live Update button to update the treatment plan in real time in under 2 minutes. By using the Live Update feature, the treatment plan will update with features, attachments, staging and more.

Update Modifications in Real time

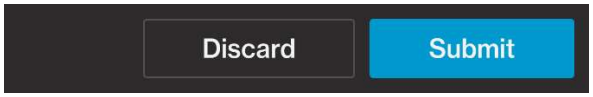
1. To begin the process, after you've completed all desired changes you'd like to make using the 3D controls, click the Live Update button.
2. The plan will take up to 2 minutes to update and will create a new treatment plan card once completed
3. If the updated plan meets expectations, then click on the Approve button on the bottom left of the page (updated image with green approve button)



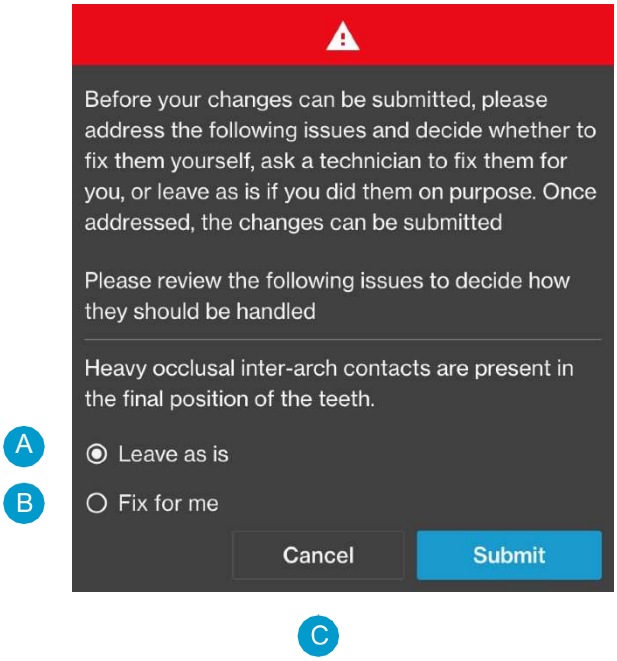
7

Submitting changes

When you are satisfied with the new plan, submit the changes using the Submit changes button at the bottom right of the ClinCheck®.



This action initiates an automatic inspection of your new plan. ClinCheck® Pro software generates an inspection report as shown below. You have three choices for how to proceed.



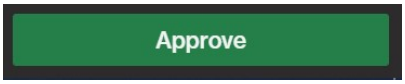
A Leave as is. Align technician will not change your modifications.

B Fix for me. Align technician will find the best resolution consistent with your intended changes.

C Cancel and go back to plan. You need to make more changes before you are ready to submit the plan to Align

8 Finishing evaluation and approving the treatment plan

Clinical and patient data (e.g., patient name, patient ID, and specific Invisalign features) must be manually reviewed before the treatment plan is ready to be approved. Once the doctor has evaluated the plan against their clinical objectives, they can approve the plan using the “Approve” button as shown below on the bottom right of your ClinCheck®.



An approval confirmation message will be shown in order to prevent accidental approval of the treatment plans prior to completion. In case of an accidental approval, please contact Customer Support.

If ClinCheck software is not functioning correctly or the doctor is having difficulties locating the proper Clinical and Patient Data, please contact Customer Support.

Part III. Software operation

This section presents system requirements, explains important information about data security and describes the use of the mouse and keyboard.

9 Data security

Align takes great care in protecting the integrity and confidentiality of data from the moment it is collected. The treatment plan file is exchanged with the doctor in an Align-proprietary format (ADF) using ClinCheck software and the transmission of these files is encrypted. While it is the customer's responsibility to protect access to their computing device as well as install appropriate malware protections, Align has the following recommendations for protecting devices/data:

- Lock the screen of the device during periods of inactivity.
- Sign out of your Invisalign Doctor Site account when finished.
- Run up-to-date anti-virus software.
- Use ClinCheck software only on private, firewalled networks.
- Avoid the use of ClinCheck software 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.

10 System requirements

To view ClinCheck® treatment plans and return feedback to Align, you must have Internet access and your computer should meet the minimum specifications below. If software loses functionality (e.g. specific Aligner features are not displayed), please contact Customer Support.

10.1 Minimum & recommended OS requirements – Windows PC

	Windows OS minimum requirements	Windows OS recommended requirements
Operating system	Windows 8.1, latest update, 32-bit	Windows 10, latest update, 64-bit
Video card / reference model	WebGL2.0 supported AMD Radeon HD 7470 **https://webglreport.com/?v=2**	AMD™ Radeon™ R5 340x or Intel® UHD Graphics 620 with latest drivers
Memory	8 GB RAM	16 GB RAM
Internet	2 Mb/s internet connection wireless and wired network connection. No satellite network connection support.	100 Mb/s internet connection wireless and wired network connection. No satellite network connection support.
Resolution	1024 x 768 minimum display resolution	1920 x 1080 display resolution
Input	Hardware keyboard and mouse or touch pad required. Other input devices are not supported.	

10.2 Minimum & recommended MacOS – Apple devices

	MacOS system requirements	
Reference model	**Optimal experience:** MacBook Pro 16'' (Retina, 8th generation, mid 2019) using latest MacOS **Compatible MacOS system(s):** Mac models released in 2017 and newer, with latest MacOS are fully compatible Mac models released in 2013 and newer, with the latest MacOS may be compatible* Mac devices that cannot be upgraded to the latest MacOS may not be compatible*	
Input	Hardware keyboard and mouse or touch pad required. Other touch input devices not supported.	
Memory	**Minimum requirement:** 2 GB available hard drive space	**Recommended requirement:** 10 GB available hard drive space
Internet	**Minimum requirement:** 2 Mb/s internet connection wireless and wired network connection. No satellite network connection support.	**Recommended requirement:** 100 Mb/s internet connection wireless and wired network connection. No satellite network connection support.
Resolution	**Minimum requirement:** 1024 x 768 minimum display resolution	**Recommended requirement:** 1920 080 display resolution

10.3 Minimum & recommended iPad OS requirements – Apple devices

	iPadOS system requirements	
Reference model	iPad devices released in 2017 and newer with latest iPadOS are fully compatible iPad devices that cannot be upgraded to the latest iPadOS may not be compatible	
Input	Touch input shall be supported. Hardware keyboard, mouse and other input devices are not supported.	
Internet	**Minimum requirement:** 2 Mb/s internet connection wireless. No satellite network connection support.	**Recommended requirement:** 100 Mb/s internet connection wireless. No satellite network connection support.

10.4 Supported Operating Systems (OS) and internet browsers

ClinCheck Pro software supports the following combinations of browsers and operating systems.

Device	OS/browser	Chrome 76 and newer	Safari 11.3 and newer	360 Secure browser 10 and newer	Microsoft Edge 17 and newer
PC desktop / laptop	**Windows® 8.1** **Windows 10**	Yes Yes	N/A N/A	Yes Yes	N/A Yes
Mac	**MacOS 10.12 and higher**	Yes	Yes	N/A	N/A
iPad	**iOS 11.3 and higher**	N/A	Yes	N/A	N/A

10.5 Software requirements

10.5.1 Activated SSL 3

10.5.2 Protection hardware/software must be configured accordingly to allow the Invisalign® Doctor Site to send/receive data (allow port 80 for http and port 443 to https for inbound and outbound)

10.5.3 No toolbars – or need to be configured accordingly

10.5.4 Cookies enabled for all supported browsers

10.5.5 Ensure you install the latest graphics drivers

10.6 Adobe Acrobat Reader version 9 requirements

If your system does not have the latest version of Adobe Acrobat Reader, follow this procedure:

1. Open a browser window.
2. Go to www.adobe.com/reader
3. Download Acrobat Reader latest version

10.7 Pop-up blocker requirements

The ClinCheck Pro software relies on several pop-up windows to function. If you have pop-up blocking software installed it may prevent ClinCheck Pro software and other VIP tools from operating correctly. Many pop-up blockers are available commercially. These pop-up blockers can be configured to allow pop-ups from specific websites. Consult the pop-up blocking software help files for more information on how to configure this feature. Usually you will need to indicate a root URL in your configuration to allow pop-ups from specific web sites. Use the following values to configure the ClinCheck Pro software:

10.7.1 http://*.aligntech.com

10.7.2 http://*.invisalign.com

As an alternative to configuring your pop-up blocking software, you may choose to turn off any pop-up blocker when using ClinCheck Pro software to avoid a conflict.

10.8 Anti-virus software requirements

You must configure your anti-virus software if it is installed in your computer to allow the ClinCheck® software to communicate with the servers running the Invisalign® service. For information about configuring your anti-virus software, ask your computer support technician or contact Align Customer Care. You can find information about Align Customer Care on the Support page on the Invisalign Doctor Site.

10.9 Graphics driver requirements

The ClinCheck software displays 3D models that require up-to-date graphics drivers. To obtain help installing the graphics driver software, ask your computer support technician or contact Align® Customer Care. You can find information about Align Customer Care on the Support page on the Invisalign Doctor Site.

10.10 Automatic software update

ClinCheck Pro software will automatically update when new versions become available. If you experience issues accessing ClinCheck, please contact Customer Support.

11 Symbols glossary

Symbol	Title	Explanatory text	Standard reference
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC.	EN ISO 15223 Medical devices-Symbols to be used with medical device labeling and information to be supplied- Part 1: General requirements, Reference 5.1.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	EN ISO 15223 Medical devices-Symbols to be used with medical device labeling and information to be supplied- Part 1: General requirements, Reference 5.1.2
Rx only	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	US Code of Federal Regulations, Title 21, Part 801.109(b)(1)
CE 0344	CE marking Conformité Européene Notified Body Reference no. 0344	Signifies European technical conformity.	MDD 93/42/EEC Articles 4,11,12,17, Annex II