CBCT Integration in ClinCheck® Software- FAQ

Frequently Asked Questions

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Clinical

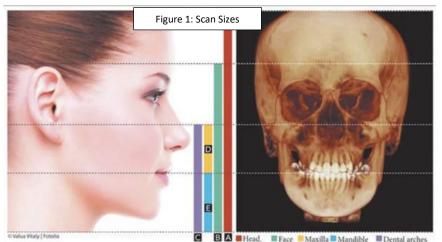
 Q: How I should interpret bone shape/fenestrations/protrusions visualization in ClinCheck software? A: Detailed instructions are located on the Invisalign Doctor Site Education page in document <u>A001623</u> <u>Rev A, CBCT Protocol Information.</u>

Planning and uploading scans

- 2. Q: What are requirements of a valid or acceptable Cone Beam CT (CBCT) scan for Invisalign® treatment planning?
 - A: Below are the requirements, recommendations, and an important note:

Requirements

- The CBCT scan shall be provided in the DICOM format
 - i. Either as a single large (usually much bigger than 100 MB) .dcm file containing all layers of the CBCT scan.
 - ii. Or as a list of small (usually about several MB) .dcm files each file contains a single layer of the CBCT scan. Typical ortho CBCT scan contains several hundred of layers.
- Align accepts "ortho" CBCT scans sizes equal to Size A (red), B (green), or C (purple) as illustrated in Figure 1. Note: Size A and B scans will be automatically truncated to Size C in the final ClinCheck treatment plan. Scans of Size D (yellow) and E (blue) are not supported.



• CBCT scan area shall <u>fully cover</u> all teeth <u>with their roots</u>, as well as unerupted/partially erupted/impacted teeth with their roots (if any).

Recommendations

- Recommended resolution for CBCT scan is no less than 0.3 mm (any dimension). Align will accept CBCT scans with lower resolution, but please be aware that the precision of resulted 3D model of roots and bone will decrease accordingly.
- Align recommends using CBCT machine manufacturer-recommended settings for taking ortho CBCT scans intended for Invisalign treatment planning

Important Note:

 CBCT case setup SLA (turnaround time from the moment of the case submission till the moment treatment plan in ClinCheck is ready for doctor's review) is the same as for Invisalign[®] Comprehensive case w/o CBCT. Please be aware that this SLA only applicable for CBCT scans taken with a scanner from officially supported CBCT scanners list (see below). If you upload a CBCT scan from the CBCT scanner which is not in the official support list, Align will attempt to process it, but we cannot guarantee any turnaround time for such case.

3. Q: What exposure parameters/radiation levels I should apply at CBCT scanner?

A: Please refer to CBCT scanner user manual for recommended settings (field of view (FOV), tube voltage (kVp), tube current (mA) exposure time, rotation arc). If the user manual does not contain required instructions, please contact your CBCT scanner vendor for recommendations.

4. Q: Should I take CBCT scans with closed bite or with slightly opened bite?

A: Slightly opened bite is preferable, though you can proceed with closed bite scans as well.

5. Q: What if my CBCT scanner failed to export to a valid (acceptable) DICOM?

A: Please refer to CBCT scanner user manual on how to export CBCT scan into DICOM format. If the user manual does not contain required instructions, please contact your CBCT scanner vendor for recommendations.

6. Q: What kind of CBCT scan (DICOM) is considered invalid for Invisalign treatment planning?

A: The following scenarios result in an invalid CBCT scan (DICOM)

- Incomplete CBCT scan that has missing layers
- CBCT scan from another patient
- CBCT scan with roots position that differs from crowns' position in the intraoral scan submitted alongside with CBCT scan for the patient (e.g. the CBCT scan taken at another stage of ortho treatment comparing to intraoral scan)
- Broken CBCT scan that has one or several DICOM files missing or damaged
- Truncated CBCT scan that does not cover all fully erupted teeth and roots, as well as unerupted/partially erupted/impacted teeth and roots (if any). See example (Figure 2)



- Low-quality CBCT scans with too low contrast, over exposed and/or image blur (due to patient movement during scanning). See example (Figure 3)
- Q: How long it would take to upload a CBCT scan?
 A. CBCT scan uploading should take about 5 min for internet connection 30 Mbit/s and no more than 2 min for internet connection 100 Mbit/s
- Can I upload CBCT scans for multiple patients simultaneously?
 A. Yes. Start patients in different browser tabs. For each patient a separate CBCT uploader tab will open as soon as you choose the CBCT option for that patient.
- 9. Q: What if CBCT uploader reports upload has failed?
 A: CBCT uploader will offer you to re-upload the scan. In case of second unsuccessful attempt please address to Technical support and provide the case's Patient ID (PID).
- 10. **Q**: Will root visibility be shown along the various staging, or is it only at the initial stage and the final stage?

A: Real roots and a reference bone (a static bone model as it segmented from CBCT scan) are visible through entire treatment plan

11. Q: How many CBCT scans can be uploaded for the patient?

A: It is possible to upload up to eight (8) CBCT scans for one patient. In every prescription (order) only one from these scans can be used.

12. Q: What if I uploaded wrong (invalid) CBCT scan?

A: If Align informs you that your submitted CBCT scan is wrong (invalid), you can refer to the below 2 options,

- Re-upload the CBCT scan for the case
- Cancel CBCT option for the case and proceed with the setup without CBCT data

Modifying order to include CBCT integration for ClinCheck software

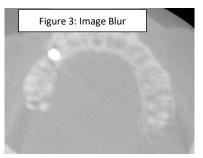
13. Q: Can I add a CBCT scan to existing Comprehensive order

A: A CBCT scan can be added to a previously created Comprehensive order if the order has not been submitted yet. If the Rx has already been submitted, then a CBCT scan cannot be added. Additional aligner orders can be submitted without a CBCT scan even if the primary order was submitted with a CBCT scan.

- 14. *Q: Can a switch from a limited stage product (such as Lite, Moderate) to a Comprehensive with CBCT?* A: Yes
- 15. **Q:** What happened if I switch from a Comprehensive with CBCT to limited stage product (such as Lite, Moderate)?

A: You can do so, but CBCT data (roots and bone) will disappear from your new Treatment Plan created for a limited-stage product

16. Q: Will the root movement values in the Tooth Movement Table be updated to reflect the real roots on cases with CBCT data?



A: No, the TMT will still display the values for the virtual roots. This improvement is planned for a future release.

Supported CBCT scanners

17. Q: Which CBCT scanners are compatible with Invisalign treatment planning?

A: The following list of scanners export CBCT file images supported by and can be uploaded to Invisalign treatment planning.

- Carestream Health
 - o CS 9600
 - o CS 9300
 - o CS 9000
- Cefla S.C.
 - NewTom 5G
 - NewTom VGi evo 0
- Danaher
 - CRANEX 3D CBCT
 - GXDP-700 series with CBCT
 - i-CAT FLX CBCT
 - Imaging Sciences International 0 (i-CAT) 17-19, 17-19DX
 - ORTHOPANTOMOGRAPH 0 OP300 CBCT
 - KaVo Pan eXam Plus 3D CBCT
 - SCANORA 3Dx
- **Dentsply Sirona**
 - Axeos
 - GALILEOS ComfortPLUS CBCT
 - **ORTHOPHOS XG 3D CBCT** 0
 - ORTHOPHOS SL
- FONA Dental, S.R.O. •
 - Stellaris 3D
- Genoray
 - Papaya 3D

- HEFEI MEYER OPTOELECTRONIC
 - TECHNOLOGY Inc.
 - o 3D pro
 - J.MORITA MFG. CORP.
 - 0 3D Accuitomo 170
 - Veraview X800 0
- LargeV
 - HiRes3D
 - Smart3D-X
 - Smart3D
- PLANMECA OY
 - Planmeca ProMax 3D CBCT
 - ProMax 3D Plus CBCT
 - o Viso G7
 - Viso G5
- PreXion
 - PreXion3D Excelsior
- Ray, Co. Ltd
 - Rayscan Alpha
- RF, Co. Ltd
 - RF Naomi CT
- Vatech
 - o Green CT
 - o PaX-i3D
 - PHT-60CFO

The above product names are trademarks of their respective owners.

18. Can I submit CBCT scans from scanners not listed as compatible with Invisalign treatment planning and will that impact my order?

A: Orders with scans from CBCT scanners not listed as compatible will be attempted. If any issues arise the customer will be notified and the CBCT scan removed from the order. Standard delivery time may be impacted.

General functionality & user interface

19. What is the case submission process for orders with the CBCT integration option?

A: Details of the case submission process is outlined in the training module located at the Align Education site - <u>CBCT Integration landing page {insert appropriate link if needed</u>}.

20. Will there be a difference in the turnaround time for a ClinCheck treatment plan with the CBCT option compared to one without?

A: Various factors affect the standard delivery time, but the turnaround time is expected to be similar.

- 21. Do additional uploaded CBCT scans lead to better accuracy in root renderings?
 - A: Uploading multiple scans does not increase the accuracy of the model.
- 22. Can PVS impressions and CBCT scans be submitted together for a case with CBCT?

A: No. CBCT integration can only be supported for cases submitted with the iTero scanners or other <u>supported</u> third-party intraoral scanners. <u>{insert appropriate link if needed}</u>

23. If I am using Invisalign Personalized Plan, which prescription form should I select for CBCT cases?A: Traditional RX

24. Can I export a CBCT integrated treatment plan?

A: Yes, the movie and screen export option will export the currently active view in ClinCheck software (i.e. roots only).

25. What are the guidelines for submitting CBCT scans with artificial restorative implants?

A: There are no special guidelines.

26. Is a new CBCT scan required for Additional Aligner orders?

A: If you choose to upload a CBCT scan for the Additional Aligner order, it must be a new scan, however, Additional Aligner orders can be submitted without a CBCT scan even if the primary order was submitted with a CBCT scan.

Modifying treatment plan

- 27. How will the gingival margin behave in setups with CBCT integration where the doctor can also see the crestal bone margin?
 - A: The gingival margin will continue to behave as it currently does. It will follow the tooth.

28. Will grid support root measurement?

A: Yes. Please note the new ruler feature will not be supported for roots.

29. Where can I get additional information about modifying treatment plans with CBCT integration?

A: Details on the case modification process is outlined in the training module located at the Align Education site - <u>CBCT Integration landing page {insert appropriate link if needed}</u>.

Product applicability & limitations

30. What products, features or ClinCheck versions are supported with the initial release of CBCT Integration for ClinCheck software?

A: See chart below

Description	Supported in launch
 Supported Products: ¹ Comprehensive package (Adult and Teen) Phase 2 Comprehensive package (Teen) Invisalign Adult (China only) 	Yes
Additional Aligner Orders	Yes
ClinCheck Pro 6.0 Software	Yes
ClinCheck Pro 5.0 Software	No
ClinCheck Live Update for 3D controls	No
Invisalign Personalized Plan, GLR or MLS cases	No
Mandibular Advancement	No
In-Face Visualization	No
1- All other Invisalign products other than those noted above are not supported at launch.	1

31. Will Invisalign Personalized Plan and ClinCheck Live Update for 3D controls be compatible with CBCT integration?

A: Not in the initial release. It is currently in development.

32. What are the supported browser versions and devices?

A: The CBCT integration feature is part of ClinCheck Pro 6.0 software and utilized the same browsers and devices. Refer to the most recent ClinCheck Software User Guide for located on the Invisalign Education page (search "user guide").