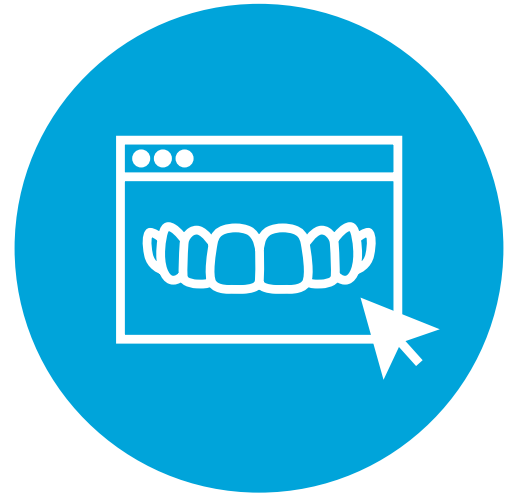


CBCT Protocol Information

ClinCheck® software with CBCT integration.

Align now offers doctors the option to integrate cone-beam computed tomography (CBCT) scan data into the visual renderings displayed during the ClinCheck treatment planning process.

While we are excited to build additional information and data into your treatment planning workflow, we want to make sure you understand implications to our visual rendering and treatment planning process.



How to understand and use new imaging and renderings

CBCT scan root and bone data, imaging and renderings which may be integrated into the ClinCheck treatment plan are provided **for doctors' informational purposes only**.

Please note that pending development of an evidence-based clinical protocol, Align is not making any changes to the anatomy or position of the bone during or at the end of treatment, and is only making some minor adjustments to the final position of the teeth solely for improvement of root parallelism.

Align is not addressing virtual fenestrations or other issues, and is making no changes to the staging of teeth, feature placement thresholds, or clinical protocols in reliance on CBCT scan data.

Rendering of fenestrations in ClinCheck simulation after initial stage

When reviewing ClinCheck treatment plans showing integrated roots and bone from CBCT scans, doctors should note that the depiction of fenestrations and the positioning of bone relative to roots and teeth can be considered realistic **in the initial stage of treatment** (when the visual rendering of alveolar bone is based on contemporaneous scan data).

However, the degree of realism in virtual images of root fenestrations depicted in ClinCheck software thereafter (while the teeth move in staging or when they are in their final position) will vary. Additionally, in cases where the anterior teeth are retracted significantly (e.g., bicuspid extraction cases or Class II correction with upper distalization), doctors are likely to observe virtual palatal/lingual virtual fenestrations as well as a “step” between the alveolar bone and the teeth on the buccal since the rendering of alveolar bone in ClinCheck software is currently static and will not reflect changes in bone structure related to larger palatal tooth movements.

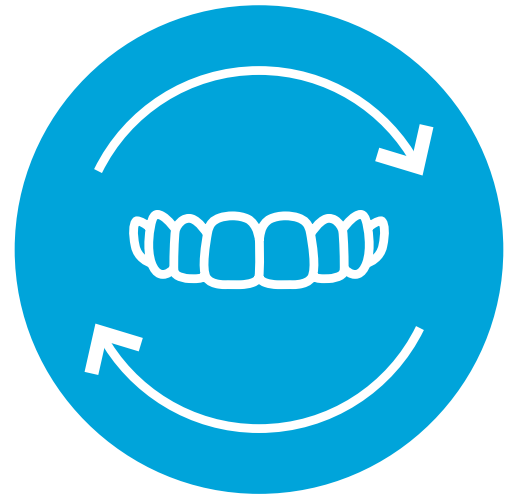
CBCT Protocol Information

ClinCheck® software with CBCT integration. (cont.)

Factors which may affect ClinCheck simulations

Several factors (including the nature of the prescribed treatment plan, the resolution of the scans provided by the doctor, or the presence of actual fenestration) may impact the depiction of virtual fenestrations in the ClinCheck treatment tool.

In addition, as noted above, the visual rendering of alveolar bone in ClinCheck software is currently static throughout treatment (unlike that of the teeth, gingiva and roots).



Doctors' responsibility with regard to virtual fenestrations

Treating doctors are responsible for deciding how to approach the assessment and handling of virtual fenestrations based on their treatment philosophy, experience, and knowledge. Among other things, doctors should take into consideration potential differences or gaps between the desired treatment outcome expectation as compared to the ClinCheck treatment plan simulation throughout the course of treatment.

Doctors' approaches to handling virtual fenestrations in ClinCheck treatment planning might include (as an example): 1) adjusting tooth positions with 3D Controls; 2) changing treatment goals to minimize posterior expansion or anterior proclination; and 3) assessing the impact of any overtreatment/ overcorrection in the ClinCheck treatment plan on the depiction of fenestration throughout the treatment simulation. Doctors should keep in mind that all treatment planning decisions may impact how realistic the rendering of virtual fenestrations is.

Treatment planning – specific guidance on tooth movement

In all cases, throughout treatment planning, doctors must provide **specific guidance regarding clinical tooth positions, regardless of the presence or absence of virtual fenestrations.**

When directing CAD designers to modify a treatment plan, doctors should always include specific instructions for changes to tooth positions.

An ambiguous instruction to “remove fenestrations,” which does not tell the CAD designer how the doctor would like to move the teeth, is insufficient and may impact the final position of the teeth in the ClinCheck treatment plan.