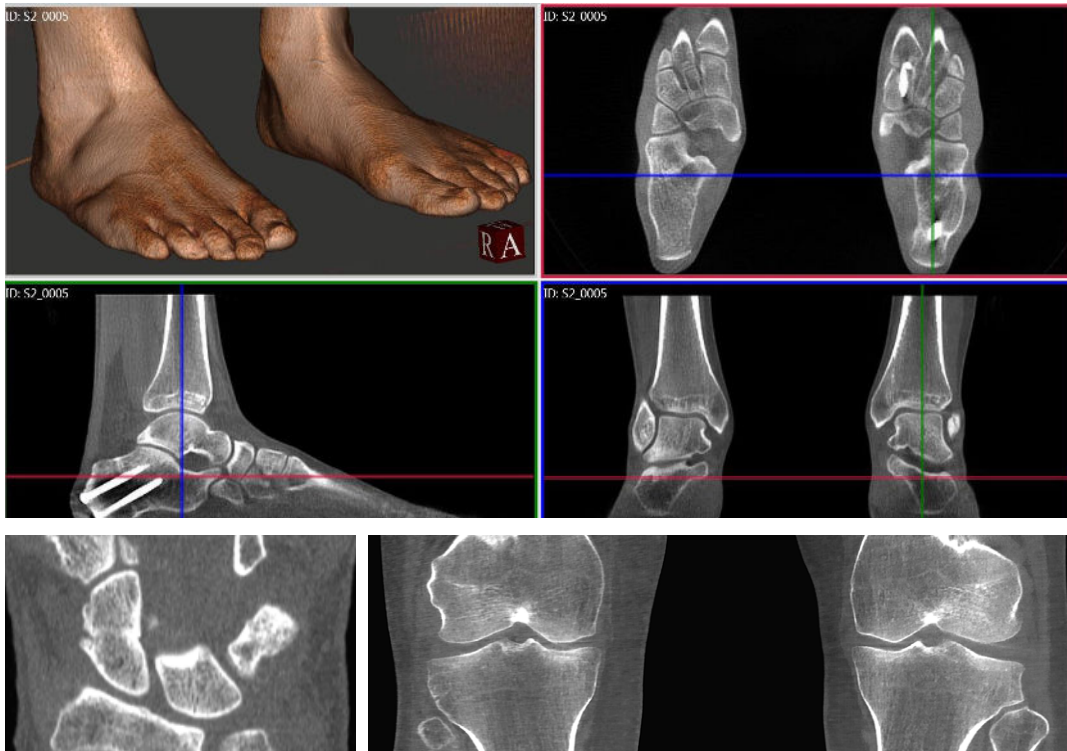


Orthopedic Cone Beam CT: A Primer for Radiologists

CurveBeam AI Cone Beam CT (CBCT) systems are designed to capture three-dimensional weight bearing and non-weight bearing volumetric images of the body extremities.



Weight Bearing Advantage

Weight bearing CT (WBCT) imaging systems scan the patient while he or she is standing naturally. The resulting study gives orthopedic surgeons a 3D view of bone morphology, alignment, and joint spaces in the lower extremities.

Lower extremity specialists may elect to order WBCT scans for the same indications they would have otherwise requested weight bearing radiographs. The indications for weight bearing CT are broader than the indications for conventional medical CT.

Common uses for weight bearing CT include:

- Weight bearing structural assessment
- Complex deformity evaluation
- Fracture characterization and occult injury detection
- Chronic osseous conditions and joint pathology
- Preoperative planning
- Postoperative assessment, hardware

3D Visualization Dedicated to MSK

Visualize bone architecture in detail, which can be obscured on X-Ray especially in the presence of splints and casts, to aid in the assessment of fracture healing.



Talar Process Fracture - Sagittal View



Talar Process Fracture - Axial View

A patient suffered an accident while snowboarding, and presented with a swollen ankle. The radiograph results were normal, except for swelling. A WBCT scan revealed a lateral talar process fracture.

(M. O'Malley, MD, single-patient clinical case, 2014)

CPT Codes*

73200 - CT Upper Extremity w/o contrast
 73700 - CT Lower Extremity w/o contrast
 73201 - CT Upper Extremity w/ contrast

73701 - CT Lower Extremity w/ contrast
 76376 - 3D Render with Interpretation Post-Processing

Low Dose Distal Extremity Imaging

CurveBeam AI systems are specifically designed to expose the patient to radiation dose that is As Low as Reasonably Achievable (ALARA) while acquiring the images. The following chart depicts the effective dose to the patient in milliSieverts, depending on the protocol selected. Please note mA ranges from 5 - 20, and kVp ranges from 100 - 120.

InReach hand/wrist scan:	0.001 mSv
HiRise standard foot/ankle scan:	0.022 mSv ³
HiRise standard knee scan:	0.018 mSv ³

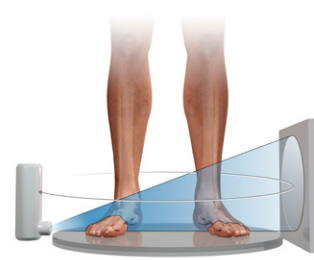
*These guidelines are intended to outline the basis for coverage and reimbursement for certain imaging services to the extent the services may be covered by a particular payor. They do not in any way guarantee actual payment and are not intended as legal advice. Healthcare providers should exercise clinical judgement when selecting codes and submitting claims to accurately reflect the services rendered. Further, proper coding may require analysis of statutes, regulations or payor contracts and policies, and as a result, the proper code result may vary from one payor to another. It is the provider's responsibility to determine and submit appropriate codes, modifiers and charges for the services that are rendered. For appropriate code selection, you should contact your local payor prior to submitting claims.

Cone Beam CT

Cone Beam CT images are initially acquired as two-dimensional projections, using a rotating gantry with a fixed-anode X-Ray tube ring, a pulsed X-Ray beam, and a flat panel detector. The gantry rotates 360 degrees and acquires image projections, which are then reconstructed to create a series of axial slices. The term “raw data” refers to projection data, not reconstructed axial slices, which may differ with terminology utilized in conventional CT.

The osseous (high contrast) details in CBCT datasets should be at par with (or very close to) MDCT. This is the primary diagnostic objective for CBCT scans.

The default reconstructed voxel size on CurveBeam AI's weight bearing systems ranges between 0.25mm - 0.5mm, depending on the protocol selected. The default voxel size for the InReach is 0.2mm. Scans can be reformatted to larger slice thicknesses to reduce file size.

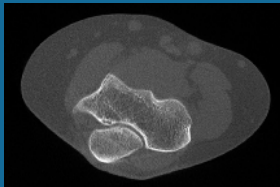


Cone Beam CT vs Conventional Medical CT

Some Differences may be noted when compared to typical MDCT images.

1

Soft tissue detectability is expected to be inferior, although the denser soft tissue structures, as well as the skin surface, can be visualized with good detail.



2

CurveBeam AI systems utilize very low tube current, as low as 5 mA, which results in reduced radiation dose to the patient. The images will appear noisier, but the trabecular detail and desired diagnostic information is not compromised. The HiRise includes protocol settings up to 20 mA, allowing for better image quality in patients with a larger body habitus.

3

The weight bearing aspect of the scans depicting true bio-mechanical alignment of bones under natural load bearing conditions is the most crucial and unique advantage of the pedCAT, LineUP and HiRise scans.

5

Since the X-Ray beam in a CBCT system is cone-shaped instead of fan-shaped, a much wider anatomical region is exposed and captured in a single projection, resulting in a larger scatter component. Hence the HU (CT number) accuracy and tolerance is somewhat inferior to MDCT.

6

Filters and Kernels applied during reconstruction are not changeable, and are set to accentuate hard tissue and bone edges, hence soft tissue windowing is limited.

7

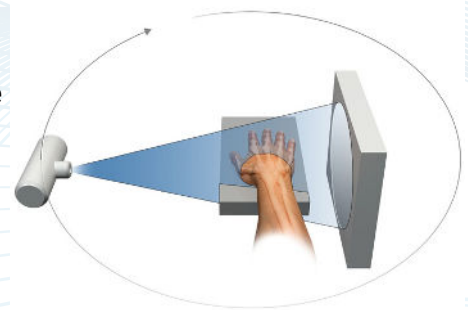
The Field Of View for a MDCT can be adjusted by adding slices during the scanning process. The field-of-view on CurveBeam AI systems is limited to one or two diameter settings and a fixed height/length setting, which is dictated by the dimensions and off-centering of the detector. Limited collimation capabilities means some air slices will be created during reconstruction and reformat creation. Post-processing software tools provide operators the ability to crop a smaller region-of-interest and remove the air slices.

Orientation

By default, CurveBeam AI WBCT axial images will be oriented based on the DICOM anatomical model, looking up from the plantar surface of the feet, so the bottom of the foot is standing on the platform at the base of the machine.

As patients are standing on a platform parallel to the rotation axis of the flat panel detector, the axial slices will align with the base of the foot.

With the InReach, the same DICOM anatomical model is used for setting the image orientation, hence upper extremity scans will always have the fingers pointing up in any third-party viewing software. Prone, supine, and decubitus left/right orientation is selected by the operator on the device prior to a scan, which is based on how the operator positions the patient on the positioning platform (similar to the table in a MDCT).



InReach



With the HiRise and InReach, the hand, wrist, or elbow is typically inserted straight into the bore, so the long bones are parallel to the axis of rotation and axial images are created on the transverse plane. The systems' bores diameter is limited in size compared to a MDCT, so when scanning a bent wrist or elbow, there may be some restrictions on the extent of flexion depending on the size of the patient. Most wrist positions utilized with a MDCT scan can be replicated with these systems.

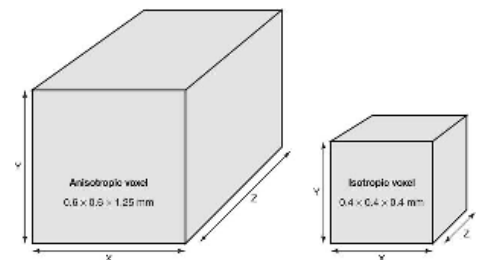


HiRise

All CurveBeam AI device voxels are isotropic, so any orthogonal/oblique reformats or volume renderings created from the original axial slices are undistorted and have the same resolution as the original axial slices. One or more series of thicker slices (i.e. 2-3mm) can be created from any viewing angle at a workstation equipped with CubeVue post-processing software, and then sent to a PACS system or other DICOM nodes. High-Resolution Reformats aligned with a particular bone axis can be created by a technologist at any CubeVue equipped workstation. Guidance for the correct alignment and reformat creation should come from a facility's established protocols, or the interpreting Radiologist.

One or more series of volume rendered images with an animated rotation orbit can also be created and sent from a CubeVue equipped workstation.

For additional technical information about CurveBeam AI images, image acquisition and image properties, please contact CurveBeam AI at info@curvebeamai.com.



Enhanced HiRise is CE Marked, FDA 510(k) cleared, is entered in the ARTG, (462546), and licensed by Health Canada under the Canadian Medical Devices Regulations. InReach is CE Marking, FDA 510(k) cleared, and is entered in the ARTG, (472005).