ClearRT™ Helical kVCT Fan-beam Imaging: Benefits Guide

Image Fidelity, Versatility, Efficiency, and Intelligent Adaptive Capabilities to See More, Know More, and Do More
Contents

**Product Summary:** What is ClearRT™ & What Does it Enable? ................................................................. 3

**Image Fidelity:** Why it is Important & How is ClearRT Different. ................................................................. 4
  - Image Uniformity ........................................................................................................................................... 5
  - Low Contrast Resolution and HU Accuracy ................................................................................................. 6

**Clinical Versatility:** How Does ClearRT Expand Clinical Capabilities? ............................................................. 7
  - Adjustable Image Quality ............................................................................................................................... 8
  - Superior / Inferior Field of View (FOV) ......................................................................................................... 9
  - Transverse Field of View (FOV) .................................................................................................................... 10

**Clinical Efficiency:** How Does ClearRT Enhance Productivity? ................................................................. 11
  - Five Simple Workflow Steps ....................................................................................................................... 12
  - Fast Scan Times ........................................................................................................................................... 13
  - Fast Patient Registration and Setup ............................................................................................................ 14

**Clinical Intelligence:** How Does ClearRT Make Adaptive Radiation Therapy (ART) Practical? ......................... 15
  - Practical Dose Monitoring ............................................................................................................................ 16
  - Practical Plan Adaptation ............................................................................................................................ 17
  - Practical Delivery Adaptation ...................................................................................................................... 18

**Benefits Summary:** How Does ClearRT Benefit Patients, Clinicians, and Practices? ........................................ 19
  - The Value of ClearRT ................................................................................................................................. 20
PRODUCT SUMMARY: What is ClearRT™ & What Does it Enable?

ClearRT™ helical kVCT is an adjustable kilovoltage (kV) helical fan-beam computed tomography (CT) imaging system on the Radixact® radiation therapy delivery platform that allows clinicians to see more, know more, and do more compared to conventional treatment systems that produce cone beam computed tomography (CBCT) images. With image fidelity approaching diagnostic quality, the industry’s longest continuous scan length, a large field of view, and extremely fast image acquisition times; ClearRT helical kVCT imaging provides clinicians with the versatility and flexibility to image and treat a broad range of cases, the speed to do so efficiently, and the image clarity to precisely and confidently setup and align all case types. ClearRT also provides images that allow automated dose monitoring with PreciseART®, images upon which clinicians can evaluate if plan adaptation would be beneficial and images upon which re-planning could be performed using PreciseRTX®.

ClearRT helical kVCT is built on the premise that the integrity of the native image acquired by the system is paramount to reliable clinical decision-making. Stable performance of image post-processing algorithms is strongly influenced by the robustness of the initial data. In image processing, junk in gets junk out.

ClearRT avoids the distortions caused by MR imaging and the artifacts associated with cone beam CT by using hardware technologies that allow the system to produce the highest quality native image. ClearRT images can be confidently used directly by clinicians and reliably fed through post processing algorithms knowing image fidelity is maintained.
Image fidelity refers to the ability of a process to render an image in a perceptually similar way to the original without distortion or information loss. ClearRT helical kVCT fan-beam images have superior quality in clarity, uniformity, anatomical accuracy, and low contrast resolution compared to CBCT images while delivering low dose to the patient. Traditional CBCT based imaging systems are inherently susceptible to scattering, beam hardening, and artifacts producing images that are grainier and less uniform. ClearRT helical kVCT images, because of the fundamental design of the system, have lower artifact presence, less noise, and therefore a greater signal to noise ratio, enabling clinicians to better differentiate low contrast objects compared to CBCT.
Images produced on CBCT imaging systems are inherently non-uniform because the wide imaging beam used results in more scatter at the imaging panel which has to be modeled. The wide imaging beam also does not pass straight through the patient causing a mismatch between image acquisition geometry and image reconstruction geometry. For these reasons, competitors provide image quality specifications at the geometric center of the image volume as the specifications are not typically met on the edges of an image slice or the beginning or end of an imaging volume. ClearRT™ images maintain quality and consistency through each slice and throughout the entire imaging volume.

ClearRT uses a fan-beam helical technology similar to diagnostic CT. The use of a narrow imaging beam means there is less scatter across the imaging panel, and the imaging beam passes through the patient in a more “slice-like” fashion. Unlike a cone beam system that makes a single slow imaging arc, ClearRT acquires images in a helical fashion, like a diagnostic CT, resulting in fewer issues with the image acquisition geometry not matching the image slice-based reconstruction. The narrow imaging beam with helical acquisition allows the small amount of scatter that does occur to be captured, measured, and effectively accounted for.
Low-contrast resolution indicates how easy it is to distinguish tissues with similar densities within a patient. ClearRT™ has better low contrast resolution compared to CBCT with a 33% better performance specification at the center of the image. (1% for a 10 mm object vs. 1% for a 15 mm object) Unlike CBCT where performance is maximum at the imaging center, ClearRT provides this low contrast resolution performance throughout the image as indicated by Hounsfield (HU) uniformity.

The Hounsfield scale is a quantitative scale for describing radiodensity and characterizing tissue types. HU uniformity indicates how much the brightness will change from the center to the edge within a single image slice. Larger numbers mean worse consistency and uniformity – with the entire image getting lighter or darker as you move away from the center. HU non-uniformity impacts the ease of visualization of the tissue away from imaging center, the densities for objects at the edges of the image volume, and the accuracy of any dose calculations performed on the images. ClearRT™ provides a specification for HU uniformity 63% better than competing CBCT systems (15 HU vs. 40 HU from center to edge).

HU accuracy indicates how accurately the brightness of a given tissue type will represent the tissue density from one image to the next. This matters most when comparing the same imaging area with images taken at different times or with different methods, or when using images for dose calculations. Again, larger numbers mean worse accuracy, and the more likely that for any given scan, the measured tissue density may not represent the actual tissue density. ClearRT images have high density value accuracy of up to +/- 15 HU.

The bottom line is that ClearRT helical kVCT allows clinicians to see and know more about patient anatomy providing a more accurate picture of the whole-patient anatomy than cone-beam kVCT on conventional systems. Utilized to set up and register every patient for every treatment delivery fraction, ClearRT can allow clinicians to do more by making this standard workflow process significantly easier and faster with the ability to see small differences in structures consistently throughout the acquired images.
CLINICAL VERSATILITY: How Does ClearRT™ Expand Clinical Capabilities?

ClearRT™ helical kVCT Imaging on the Radixact System allows clinicians to quickly customize image acquisition to clinical needs based upon the anatomy being treated and clinical objectives without disrupting or elongating clinical workflows. Industry leading capabilities in image quality, superior / inferior field of view size, and transverse field of view size combined with the ability to customize those capabilities on a per patient basis, enables clinicians to image and treat the broadest range of patients and case types.

Task matched image quality and fields of view are flexible, customizable, and right-sized to every indication and patient.

INDICATIONS
- Intracranial
- Head & Neck
- Lung
- Spine
- Breast
- Liver
- Kidney
- Pancreas
- Prostate
- Gynecological/Genitourinary
- Sarcomas
- Superficial

Body represents male and female indications and is intended for illustration purposes only.
Image quality on all kV imaging systems is affected by changing the intensity (kV) of the number of photons (mAs) in the X-ray imaging beam. CBCT based radiation therapy systems, with a fixed cone beam image size that fills the entire flat panel detector, can further alter image quality in a limited fashion, using bowtie filters to create full fan or half fan images.

ClearRT™ uses a helical fan-beam technology and uniquely allows clinicians to select the size of the fan-beam. The wider the fan-beam, the lower the image quality, but the faster the image can be acquired. The narrower the fan-beam, the higher the image quality, but the slower the acquisition time. ClearRT offers clinicians a choice of three modes: Coarse, Normal, and Fine.

The Coarse mode of ClearRT produces images of higher quality than CBCT systems yet can scan at rates of up to 1.7 cm per second which are as fast or faster than competing CBCT based systems. Clinicians can readily use coarse mode for patient alignment purposes. Clinicians can choose to use the normal mode to further improve image quality where more anatomical detail may be required for registration especially in soft tissue areas. Fine mode provides clinicians with the highest image quality diagnostic-like images. Fine mode images could even be used for creating adapted treatment plans without the need for a CT sim. This flexibility in image quality allows clinicians to match image quality with their desired clinical task.
Longest Superior / Inferior Field of View (Scan Length)

The superior / inferior field of view on CBCT based systems is fixed in size and typically ranges from 15.5 – 24.5 cm (and is typically 15.5 – 18 cm on C-arm linacs). These small fields of view, especially those of C-arm linacs, limit clinicians’ ability to see structures that are important for patient setup in many cases. Imaging for head and neck cases, prostate cases with nodal involvement, and simple breast cases is often not sufficient on CBCT systems because the full extent of the treatment area cannot be visualized. Imaging longer treatment areas such as for breast with intermammary chain, craniospinal (CSI), total marrow irradiation (TMI), or total body irradiation (TBI) indications is not possible with a single image on CBCT based systems. Some CBCT systems offer an “extended” superior/inferior field of view, but that requires acquisition of two independent CBCT datasets taken at different couch positions that are stitched together in software. This is inefficient and can result in the introduction of image artifacts at the junction of the two CBCT images.

The superior/inferior field of view on the ClearRT™ helical kVCT system, known as the scan length is flexible with the ability to go up to 135 cm in a single scan. This is accomplished by the helical design of the system which utilizes the patient couch to precisely move the patient through the system as they are imaged just like a diagnostic CT scanner. The ClearRT system allows clinicians to freely choose the scan length that matches each individual patients’ needs for their indication. Not too long, not too short, but just right. Not only can clinicians choose to capture the entire required area for alignment purposes, but they can choose to include as much surrounding anatomy as needed to enable accurate automated daily dose trending calculations using PreciseART®. This extended imaging area provides the information necessary to enable personalized adaptive patient care. Capturing the right size image with ClearRT helps to speed up workflows for typical indications and makes “3D Scout Scans” and imaging long fields for CSI, TBI, and TMI cases with a single junction free image possible.
Capturing the right size field of view in the transverse direction is also important. ClearRT™ allows clinicians to select from three field of view sizes, 27 cm, 44 cm, and 50 cm. The industry’s largest field of view (FOV) at 50 cm enables clinicians to set up large patients or large fields without cutting off anatomy. Smaller field of view sizes are appropriately matched to other patient anatomy and allow for increases in imaging speed.
CLINICAL EFFICIENCY: How Does ClearRT™ Enhance Productivity?

Standard workflows with significantly faster imaging and patient registration steps increase throughput.

It is critically important to be able to deliver high quality care in reasonable appointment times. This will become even more essential as medical reimbursement moves away from fee per service to fee per treatment models. In value-based care reimbursement models patient experience also grows in importance. With enhanced imaging provided by ClearRT™ helical kVCT clinicians can realize efficiency gains with common clinical workflows which can result in less time for the patient on the treatment couch and which may improve patient satisfaction.
Conventional radiation therapy systems have nine or more steps in their patient treatment workflow. The Radixact® System has only five simple steps as part of its treatment delivery workflow. Position the patient, image the patient, register the patient, prepare the treatment, and deliver the treatment. These same five easy steps are used for all cases from simple to complex and remain unchanged regardless of whether MVCT or kVCT imaging is used, or Synchrony® real-time adaptive delivery technology is applied. ClearRT™ helps to improve the efficiency of several of these steps which are: position the patient, image the patient, register the patient, prepare the treatment, and deliver the treatment.
C-arm linacs, in their worst quality imaging mode, half fan, which allows for the fastest imaging speed, can take a <20 cm image in between 30 and 60 seconds. With ClearRT™ the same image size, with much higher image quality, can be taken in as little as 15 seconds. Enclosed CBCT based gantries are slightly faster than C-arm linacs, imaging at similar speeds to ClearRT for very small fields. As scan length increases the speed and capabilities of ClearRT outshine the competition. At an enclosed gantry’s maximum scan length of 38.5 cm (in “extended” mode) a scan is completed in ~33 seconds whereas a ClearRT scan is completed in as little as 22 seconds. Simply put, ClearRT provides higher quality images faster than CBCT based systems so that less time is spent acquiring images. Plus, the Radixact System with ClearRT is the only radiation therapy system on the market to provide long unstitched scans with the capability of scanning a meter in less than a minute.
 Registering the patient to align them based on their daily on-table image is often one of the more time-consuming parts of the clinical workflow for all radiation therapy systems. Poor low contrast resolution, poor image uniformity, image noise, distortions, and truncated patient anatomy, common on CBCT based systems, all contribute to lengthening this step in the workflow. ClearRT™, with images approaching diagnostic quality, provides significantly better image quality and right sized image fields of view that can allow clinicians to register patients more quickly and with higher confidence compared to CBCT based systems.

Simplifying workflows and increasing the efficiency of each workflow step allows patients to spend less time on the treatment couch and allows clinicians to spend more time with their patients.
CLINICAL INTELLIGENCE: How Does ClearRT™ Make Adaptive Radiation Therapy (ART) Practical?

**Automation in dose monitoring, plan adaptation, and delivery adaptation enables treatment personalization**

Every patient is unique – and deserves highly personalized treatment. Each unique patient is also a living, breathing, often-changing individual. In fact, between treatment sessions, a patient’s anatomy may change significantly. Patients gain and lose weight. Their stomach, bladder and bowel contents change. Their organs may shift, rotate or deform. Their tumor(s) may shrink, shift or rotate. Any one of these changes can have profound implications on radiation therapy treatment objectives.

Adaptive radiotherapy (ART) using continual patient imaging to evaluate and characterize systematic and random variations – between sessions, as well as while the patient is on the table – can be used to customize the patient’s treatment plan or delivery of the treatment plan to account for patient-specific, day to day variation. For ART to be effective and widely used, it must also be practical and efficient to use in real clinical environments with existing clinical workflows.

<table>
<thead>
<tr>
<th>OFFLINE ADAPTIVE</th>
<th>ONLINE ADAPTIVE</th>
<th>REAL-TIME ADAPTIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHAT</strong></td>
<td><strong>WHEN</strong></td>
<td><strong>WHY</strong></td>
</tr>
<tr>
<td>Treatment Plan</td>
<td>In-between Fractions</td>
<td>TARGET CHANGE IN: Volume, Shape (Deformation), Rotation Position In Relation To OAR</td>
</tr>
<tr>
<td>Treatment Plan</td>
<td>Just Before Treatment Delivery</td>
<td>TARGET CHANGE IN: Volume, Shape (Deformation), Rotation Position In Relation To OAR</td>
</tr>
<tr>
<td>Treatment Delivery</td>
<td>During Treatment Delivery</td>
<td>TARGET CHANGE IN: Position</td>
</tr>
</tbody>
</table>

**WHAT**
- Treatment Plan
- In-between Fractions
- TARGET CHANGE IN: Volume, Shape (Deformation), Rotation Position In Relation To OAR

**WHEN**
- Day 1
- Day 1
- Day 1

**WHY**
- TARGET CHANGE IN: Volume, Shape (Deformation), Rotation Position In Relation To OAR

**HOW**
- Day 1 15 ...n
- Day 1 15 ...n
- Day 1-n
ClearRT™ images can be right sized so that they include as much surrounding anatomy as needed to enable accurate automated daily dose trending calculations using PreciseART®. Since ClearRT imaging is fast, clinical imaging workflows are not slowed. Since ClearRT images are high quality, uniform, and highly HU accurate, dose monitoring can be performed automatically with confidence. Patients can be enrolled in PreciseART monitoring with a single click at the time of planning. Dose monitoring can be personalized for each patient using plan quality criteria setup during planning. Patients can also be enrolled at the start of treatment, there is no change in workflow for therapists. Users are automatically notified in PreciseART when user-specified values for dose changes are exceeded, flagging the patient’s treatment for review and possible plan adaptation. Monitoring patients for ART with ClearRT is practical because it is automated, does not require the guesswork about the amount of change often required by other radiation therapy systems and can be performed with no additional clinical burden.

**Planned Dose vs Scaled Daily Delivered Dose**

<table>
<thead>
<tr>
<th>Contour</th>
<th>Constraint Name</th>
<th>Planned Dose Rx: 70 Gy</th>
<th>Fulfilled</th>
<th>Scaled Daily Delivered Dose</th>
<th>Fulfilled</th>
<th>% Change</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandible</td>
<td>Max &lt;70 Gy</td>
<td>70.41 Gy</td>
<td>✔</td>
<td>68.46 Gy</td>
<td>✔</td>
<td>-2.77</td>
<td>-1.95</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Mean &lt;34 Gy</td>
<td>33.38 Gy</td>
<td>✔</td>
<td>31.42 Gy</td>
<td>✔</td>
<td>-5.87</td>
<td>-1.96</td>
</tr>
<tr>
<td>PTV 70</td>
<td>D95</td>
<td>69.82 Gy</td>
<td>✔</td>
<td>67.02 Gy</td>
<td>✔</td>
<td>-4.01</td>
<td>-2.08</td>
</tr>
<tr>
<td>PTV 63</td>
<td>D95</td>
<td>63.50 Gy</td>
<td>✔</td>
<td>58.63 Gy</td>
<td>✔</td>
<td>-7.67</td>
<td>-4.87</td>
</tr>
<tr>
<td>PTV 58</td>
<td>D95</td>
<td>58.47 Gy</td>
<td>✔</td>
<td>57.49 Gy</td>
<td>✔</td>
<td>-1.68</td>
<td>-0.98</td>
</tr>
<tr>
<td>PTV 54</td>
<td>D95</td>
<td>54.46 Gy</td>
<td>✔</td>
<td>51.49 Gy</td>
<td>✔</td>
<td>-5.45</td>
<td>-2.97</td>
</tr>
<tr>
<td>R-Parotid</td>
<td>Mean &lt;26 Gy</td>
<td>22.69 Gy</td>
<td>✔</td>
<td>21.95 Gy</td>
<td>✔</td>
<td>-3.26</td>
<td>-0.74</td>
</tr>
<tr>
<td>L-Parotid</td>
<td>Mean &lt;26 Gy</td>
<td>23.55 Gy</td>
<td>✔</td>
<td>27.11 Gy</td>
<td>✔</td>
<td>15.12</td>
<td>3.56</td>
</tr>
<tr>
<td>Cord</td>
<td>Mean &lt;45 Gy</td>
<td>29.32 Gy</td>
<td>✔</td>
<td>31.40 Gy</td>
<td>✔</td>
<td>7.09</td>
<td>2.08</td>
</tr>
</tbody>
</table>
Traditional CBCT based systems are inherently susceptible to scattering, beam hardening, and artifacts producing images that are grainier, less uniform and lack the HU accuracy that is required to use them for treatment planning purposes. ClearRT™ images provide excellent soft tissue contrast for confidence in automated deformation and integration with an adaptive system. Proper HU’s throughout the image improve accuracy of dose accumulation for adaptive cases. Since ClearRT images are high quality, uniform, and capable of accurately measuring tissue density (see HU accuracy), clinicians can choose to use these images directly for adaptive purposes. ClearRT images can be fed directly into PreciseART® which enables clinicians to monitor every patient and efficiently adapt plans, helping clinics of all sizes to deliver more precise treatment to more patients.

Dose review on ClearRT image and dose difference display on planning CT
Synchrony® enables personalized real-time adaptive delivery of radiation treatment to targets while they are in motion by synchronizing the delivery beam position to the target location precisely and accurately during continuous delivery of a treatment fraction. The same kVCT beamline that is used to produce ClearRT™ 3D images is used to produce 2D image snapshots during treatment deliveries that use Synchrony. These snapshots continuously provide information about the 3D position of the treatment target enabling treatment delivery to be adapted to the detected or the predicted motion. Synchrony is artificial intelligence (AI) driven as it autonomously perceives changes in the target position, adapts treatment delivery in real-time to those observed changes, and reacts to the real-life changing circumstances of the patient during the delivery of a treatment fraction. This makes the use of Synchrony practical as it does not disrupt clinical workflows, require human intervention, or prolong treatment delivery like gating, breath-holding, or use of restraints with conventional systems. Real-time treatment delivery adaptation is only available from Accuray with the purchase of the Synchrony option.
BENEFITS SUMMARY: How Does ClearRT™ Benefit Patients, Clinicians, and Practices?

Unique capabilities allow clinicians to see more, know more, and do more

- Unique fan-beam imaging produces diagnostic-like image quality
- Inherently fewer artifacts produce better image uniformity and fidelity through entire image set
- Soft-tissue clarity speeds patient registration, broadens applicable indications for treatment, and allows for possible margin reduction
- Task matched image quality and fields of view are flexible, customizable, and right-sized to every indication and patient
- System versatility provides flexibility to image and treat all case types from simple to complex
- Standard workflows with significantly faster imaging and patient registration steps increase throughput
- Automation in dose monitoring, plan adaptation, and real-time delivery adaptation enable treatment personalization
- Workflow friendly adaptive radiation therapy is practical and efficient for every patient
ClearRT™ helical fan-beam kVCT delivers valuable benefits to clinicians and patients not available on conventional CBCT based treatment delivery systems. With image fidelity approaching diagnostic quality, the industry’s longest continuous scan length, a large field of view, and extremely fast image acquisition times; ClearRT helical kV imaging provides clinicians with the versatility and flexibility to image and treat the broadest range of cases, the speed to do so efficiently, and the image clarity to precisely and confidently setup and align all case types. These benefits are provided without disrupting current clinical workflows and provide clinicians with a practical path to monitor dose, adapt treatment delivery, and adapt treatment plans based on individual patient needs.

The Radixact® System with ClearRT and Synchrony® allows clinicians to effectively provide personalized medicine to each and every patient without breaking their current clinical ecosystem and its associated workflows. Right sized images, high quality images, precise patient alignment, adaptive delivery and plan adaption can help clinicians ensure radiation dose is delivered to the target, radiation dose to healthy tissue and organs at risk are minimized, and conditions are optimized for the best possible clinical outcomes.

No clinician wants to spend time thinking about whether the radiation therapy system they are using can deliver their desired clinical and financial outcomes. Today, Accuray is proud to offer versatile, worry-free and future-proof solutions: ready to perform today, tomorrow, and in the future of value-based care.
**Important Safety Information**

Most side effects of radiotherapy, including radiotherapy delivered with Accuray systems, are mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, however, leading to pain, alterations in normal body functions (for example, urinary or salivary function), deterioration of quality of life, permanent injury and even death. Side effects can occur during or shortly after radiation treatment or in the months and years following radiation. The nature and severity of side effects depend on many factors, including the size and location of the treated tumor, the treatment technique (for example, the radiation dose), the patient’s general medical condition, to name a few. For more details about the side effects of your radiation therapy, and if treatment with an Accuray product is right for you, ask your doctor.

© 2021 Accuray Incorporated. All Rights Reserved. The stylized Accuray logo, TomoTherapy, H Series, Tomo, TomoH, TomoHD, TomoEDGE, TomoHelical, TomoDirect, Hi-Art, PlaniTouch, PrecisoART, PreciseRTX, Radiact, Accuray Precision, iDMS, ClearRT, Synchrony Fiducial Tracking, Synchrony Lung Tracking and Synchrony Respiratory Modeling are trademarks or registered trademarks of Accuray Incorporated in the United States and other countries and may not be used or distributed without written authorization from Accuray Incorporated. Use of Accuray Incorporated’s trademarks requires written authorization from Accuray Incorporated. Other trademarks used and identified herein are the property of their respective owners. MKT003436