visionrt

AlignRT® InBore™

Dedicated SGRT for Bore-Based Treatments

Ben Waghorn Ph.D. DABR

White Paper

For AlignRT® Advance Versions 7.0 and above

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1 INTRODUCTION

Surface guided radiation therapy (SGRT) provides safety and clinical benefits to patients receiving treatment on a wide range of treatment systems, including C-Arm linear accelerators, proton therapy treatment systems and heavy ion therapy systems. The benefits of SGRT are similar across each treatment modality and include improved initial patient setup accuracy and real time intrafraction motion management, which have been shown to increase patient safety, treatment throughput and clinical outcomes [1] [1].

While the benefits of SGRT are well documented, bore-based treatment systems introduce unique challenges for traditional SGRT solutions. As SGRT systems use optical techniques to provide real time monitoring, they rely on line-of-sight to the patient's surface. During treatment the patient is located inside the bore and therefore the ability for traditional ceiling mounted SGRT systems to reconstruct the patient's surface is limited by the occluding linac covers. Indeed, tests using an optimally located ceiling mounted AlignRT® HD camera pod outside the linac bore (Figure 1) lead to the conclusion that *"existing SGRT solutions cannot provide adequate surface coverage for intrafraction SGRT due to line of sight and size limitations*" [2]. These findings have been independently confirmed by the Vision RT research team using sophisticated in-house simulation tools.

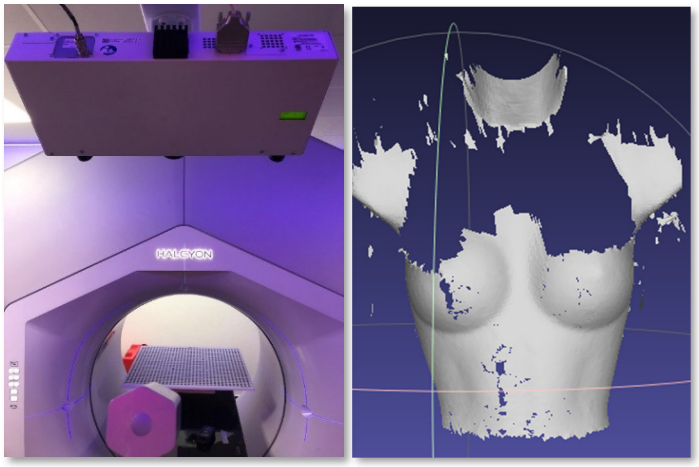

Figure 1 – Challenges of in-bore monitoring using traditional SGRT

Figure 2 – AlignRT® InBore™ Ring: bore-mounted SGRT innovation

In order to overcome these limitations and to make SGRT accessible to bore-based linacs, Vision RT have developed an innovative, miniaturized SGRT camera which can be configured to be mounted in bore-based medical systems (Figure 2, the InBore™ "ring" - patents pending). The ring, at only 12mm thickness in the lateral and lower regions, contains two miniaturized SGRT cameras units, both of which are capable of generating surfaces of the patient in real time. By mounting the ring within the treatment bore, the cameras offer a steep viewing angle thus overcoming limitations experienced by externally mounted systems. A single cable connection and locking system allows quick and easy placement and removal, which can be performed by a user following minimal training.

Any possible bore-induced occlusions between the patient and camera system are eliminated with InBore™, allowing the SGRT cameras a clear line-of-sight to the patient. The combination of two camera units provides more comprehensive surface coverage which is complemented by three built-in projectors, projecting a speckle pattern onto the patient. Of note, to account for the relatively close proximity of the ring to the patient, and to provide increased patient comfort, the projected light is invisible.

The ring does not interfere with the operation of the linear accelerator, as detailed in §3 of this white paper.

[1] See https://www.visionrt.com/education#publications for additional information

AlignRT® InBore™ is the complete SGRT solution for setup and treatment monitoring with bore-based treatment systems. InBore™ combines the benefits of the ceiling mounted AlignRT® Advance camera pods for patient setup outside the bore [3] with the bore mounted ring camera system for intra-fraction monitoring within the bore. Accounting for the workflow of setting up the patient using the 'setup' isocenter, and then applying the couch translations and delta couch shift to transition the patient to the in-bore treatment location, InBore™ delivers a seamless end-to-end SGRT solution.

Benefits include expediting patient treatments [3], assessing patient motion which may occur at any time including between IGRT and treatment (which is of particular interest with systems offering adaptive replanning), and to enable intra-fraction monitoring across all indications, opening up surface guided breath hold and stereotactic treatment capabilities on bore-type gantry systems.

This white paper describes some of the results obtained during extensive testing of the InBore™ system, conducted over a period of 15 months at ORLAM[2], during testing at University of California, San Diego (UCSD) [3], and through internal testing at Vision RT. The studies all conclude that AlignRT® InBore™ delivers high quality SGRT for bore-based treatment systems (comparable to C-Arm linac SGRT systems) without compromising linac workflows, delivery, or serviceability.

[2] Department of Radiation Oncology, ORLAM group, 44 rue ambroise Paré, Mâcon, France
[3] Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, CA, USA

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2 INBORE™: SGRT WITHOUT COMPROMISE

The goal of AlignRT® InBore™ is to provide a comprehensive end-to-end SGRT solution for patients undergoing treatment on bore-based linacs, without the physical design of the treatment system compromising the SGRT benefits. SGRT setup outside the bore has shown to be achievable using existing AlignRT® Advance solutions [3], and as such requires no further discussion in this white paper. Conversely, the introduction of the novel, dedicated InBore™ ring for in-bore intrafraction monitoring required extensive testing to investigate whether, despite the unique design and placement, InBore™ is able to offer SGRT benefits equivalent to standard ceiling mounted systems. This section therefore describes a series of tests and the corresponding results that were used to evaluate the SGRT performance of InBore™. The tests generally followed AAPM TG147 recommendations [4], and were independently conducted at the two clinical sites (ORLAM and UCSD), in addition to in-house Vision RT testing.

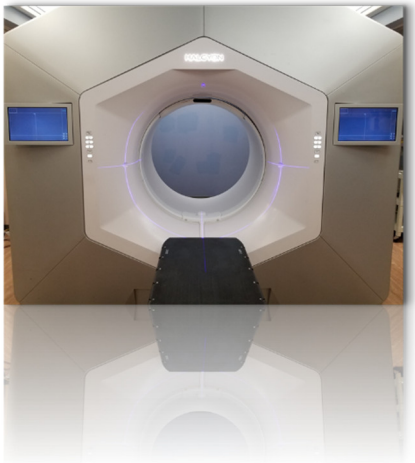

Figure 3 – InBore™ SGRT

2.1 Real Time Delta (RTD) stability

The tracking stability of InBore™ was assessed using two general test categories; 1) the inherent tracking stability of the InBore™ system when the linac was not active (i.e. not performing IGRT or beam delivery), 2) the tracking stability during normal use of the linac (including during VMAT delivery and CBCT).

In both test groups, a phantom was placed inside the bore, a reference surface was captured using the InBore™ system, and the phantom was monitored for an extended period of time (ranging from 20 minutes with a thorax phantom, to 30 minutes with the Vision RT MV calibration cube phantom, and to over 8 hours using the Vision RT acceptance test 'rigid test object'). The following data were collected for each test category;

1) For monitoring while the treatment system was not in use, InBore™ was stable during phantom tracking to within **0.2mm and 0.2°** over 8 hours (under stable room temperature conditions) (Table 1). Similar data over a shorter time duration was collected at the clinical sites.

2) Under clinical use, either during arc based IGRT (i.e. CBCT) or VMAT delivery, it is possible that vibrations of the rotating linac gantry could impact the tracking stability of InBore™, given the physical connection between the devices. Across all tests and testing sites, the maximum deviation of the RTD values over 20-30 minutes of phantom monitoring during linear accelerator use were **0.3mm and 0.2°**. Additionally, no thermal drift of the cameras was observed.

Table 1 – InBore™ Real Time Delta tracking stability over 8 hours

Real Time Delta	Lower Tolerance	Upper Tolerance	Confidence
Lateral	-0.020 mm	0.018 mm	95.9%
Longitudinal	-0.017 mm	0.018 mm	95.9%
Vertical	-0.044 mm	0.033 mm	95.9%
Pitch	-0.023 °	0.026 °	95.9%
Roll	-0.006 °	0.008 °	95.9%
Yaw	-0.012 °	0.011 °	95.9%

The stability data of InBore™ is consistent with the stability data of ceiling mounted AlignRT® Advance™.

2.2 SGRT tracking accuracy

The localization accuracy of InBore™ provides a valuable measurement of the ability of InBore™ to accurately detect motion within the bore. Tests to measure the localization accuracy were performed using various approaches between the different test sites. In-house Vision RT testing utilized a calibrated Faro Arm (Faro Technologies, Inc, Lake Mary, Florida) to deliver very accurate known shifts of the Vision RT cube phantom, against which the InBore™ measured surface shifts could be compared. Testing at the clinical sites employed couch shifts to perform the known shift tests on the phantom, with IGRT providing confirmation of the shift.

Using the Faro Arm to make the known shifts the intra-fraction localization accuracy of the InBore™ system during tracking was measured to be **≤0.3mm and ≤0.1°**, for both mid (9cm) and deep (14cm) isocenters.

Similarly, using the treatment couch to apply the known shifts, the InBore™ system was measured to be accurate to **<0.1mm** for applied shifts ranging from 1mm to 1cm in all translational directions for the Vision RT MV cube phantom, and **≤0.3mm** when separately tracking head and thorax phantoms with up to 2cm shifts. Note that rotational accuracy is not reported here as the treatment system used for testing does not allow for rotational shifts.

The tracking accuracy data of InBore™ is consistent with the accuracy data of ceiling mounted AlignRT® Advance™.

2.3 InBore™ working volume

The field of view of the InBore™ system needs to provide adequate surface coverage to track a region of interest on the patient/phantom while inside the bore. In order to quantify this, reference captures of a flat plate were taken with the surface positioned at different locations within the bore. From the surfaces created from these captures, the extreme point coordinates were read out for each reference capture from which the minimum extents in longitudinal, lateral, and vertical displacement at the isocenter height were measured. These measurements defined the field of view, or working volume, of InBore™. The measured values were shown to be >510 mm longitudinally, >690 mm laterally and >360mm vertically.

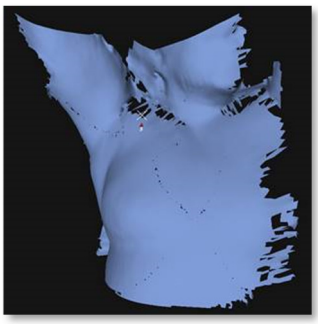

Figure 4 – InBore™ Surface Coverage

To provide some practical, clinical context to these measurements, extensive onsite testing with InBore™ has demonstrated that the system can provide acceptable surface information to perform SGRT on a wide range of patient treatment sites and body habitus (Figure 4).

2.4 Isocenter co-calibration

The process of patient setup on bore-based treatment systems can be more dynamic than many other treatment systems, with the patient initially being setup to an external isocenter before transitioning to the in-bore treatment isocenter. The two AlignRT® camera systems, namely the ceiling mounted camera pods and the InBore™ ring, are calibrated to the out-bore and in-bore isocenters respectively. As with common treatment workflows, where the transition from out-bore setup isocenter to in-bore treatment isocenter is accurately co-calibrated using daily phantom tests, the two AlignRT® systems need to maintain co-calibration with each other, in addition to being co-calibrated with the treatment system isocenters.

While description of the co-calibration process is beyond the scope of this white paper, the process involves using standard AlignRT® calibration phantoms and workflows and uses the calibrated couch motions to provide an accurate link between the two calibration locations.

Following isocenter co-calibration, an initial test was performed to assess the absolute setup accuracy of the InBore™ ring system in isolation. To do this, an end-to-end test was performed, whereby the Vision RT cube phantom underwent a CT scan, treatment planning and initial positioning using AlignRT® on the InBore™ system. The phantom was subsequently imaged using CBCT, and the auto-match tool displayed the IGRT shift required to accurately position the phantom at treatment isocenter. Following initial AlignRT® setup, with near-zero residual RTDs, the CBCT shifts were defined as the absolute setup accuracy of the in-bore component of AlignRT® InBore™. The absolute setup accuracy of the InBore™ ring was measured to be **≤0.5mm**, consistent with traditional ceiling mounted AlignRT® systems.

In an extension to this test, the co-calibration between the AlignRT® ceiling mounted and in-bore systems was measured by first positioning the phantom at the setup isocenter using the ceiling mounted system, and subsequently transitioning the couch (and phantom) to the in-bore treatment isocenter. Any residual RTDs at the treatment isocenter provide a measure of the co-calibration uncertainty. Possible contributions from couch motion uncertainty were minimized by performing CBCT to confirm shift accuracy. At both clinical centers the co-calibration accuracy between the two AlignRT® systems was measured to be within **0.3mm and 0.1°**.

2.5 Calibration stability

The final SGRT test addressed the impact that the linac operation may have on general InBore™ calibration stability. For these tests, AlignRT® Calibration was performed, followed by running DailyQA to demonstrate near-zero RMS values indicating successful and stable calibration. A phantom was then positioned in the treatment position and a reference surface was captured with the InBore™ ring. Various activities were then performed on the treatment system to measure the possible impact on tracking stability (measured using RTDs), and the calibration stability (measured with DailyQA RMS values). The normal activities included opening and closing the rear service access doors, delivering VMAT treatments, performing various IGRT procedures, and gently contacting the inner bore and ring.

Following all of these normal operating procedures, the maximum residual RMS values calculated during DailyQA were **0.3mm**, consistent with the typical values from a ceiling mounted AlignRT® system. The RTD tracking stability was similarly small, with maximum observed RTD values of **0.2mm**.

It should be noted that larger impacts beyond those expected during normal clinical use, such as colliding with the InBore™ ring with enough force to trigger the linac collision alarm, or forcefully closing the rear service access doors, did increase the observed RTD values. To recognize these disturbances, the clinical AlignRT® InBore™ system contains motion detection mechanisms that will alert the user of any unexpected ring motion, indicating the possible need for recalibration.

3 THE IMPACT OF INBORE™ ON BORE-BASED LINACS

InBore™ has been designed to deliver the benefits of SGRT without compromising any aspect of the treatment system workflows, delivery, or serviceability. Care was taken in designing the ring to ensure that the introduction of a physical device into the gantry bore (Figure 5) does not impact the clinical capabilities of the system such as beam delivery and imaging systems, does not introduce a risk to the patient or clinical team, does not impact the serviceability or mechanical state of the linac and has no negative impact on the clinical workflow. No modifications to the linac are required.

Figure 5 - Non-impact design and placement

Table 2 summarizes the tests and respective conclusions following tests performed on the combination of AlignRT® InBore™ and the bore-based linac.

Table 2 - Summary of impact testing

Test	Impact of InBore™
Delivered dose	Not statistically significant
Imaging	None
Collision avoidance	None
Collision notification	None
In-room CCTV function	None
Serviceability / usability	None
Calibration	None

The following sub-sections detail the testing performed by clinical medical physicists at the aforementioned sites, and by Vison RT staff to assess the impact of AlignRT® InBore™ on bore-based treatment systems, and on clinical workflows.

3.1 Quantifying the impact on delivered dose

As the InBore™ ring is mounted in close proximity to the treatment beam, albeit outside the direct line of the beam, it is prudent to confirm that the ring does not impact the beam (either by attenuation or scatter) or ultimately the dose delivery. To confirm this, tests were independently conducted at the two clinical sites comparing delivered dose distributions with and without the ring co-located. A range of treatment plans of different field sizes and degree of modulation (both static IMRT and VMAT) were delivered, in addition to the largest possible open treatment field. Data was collected with and without the ring inserted using a range of phantoms, and separately using EPID portal dosimetry, ArcCHECK® and SRS MapCHECK™ (Sun Nuclear, Melbourne, USA).

With the widest possible treatment field size delivered both with and without AlignRT® InBore™, the global gamma analysis (γ_{global}) using a criterion of 1% / 1 mm was 100% (γ_{local} = 100%). Even at a criterion of 0.5% / 0.5 mm, γ_{global} was 98.1% (γ_{local} = 96.9%), therefore showing no statistically significant dosimetric impact with the ring in place.

Similarly, when analyzing the dose distribution of over 15 treatment plan deliveries at ORLAM (including IMRT breast, VMAT breast, VMAT head and neck, VMAT pelvis and VMAT SRS) there was no statistically significant difference ($p > 0.25$) in the planned versus delivered distribution, with versus without the ring co-located. Similar tests conducted at UCSD using portal dosimetry for treatment plans from three different disease sites (static whole brain, VMAT head and neck and VMAT prostate) found deviations with versus without the ring of 0.18±0.06 %. Both centers concluded that the presence of the ring in the bore did not impact dose delivery.

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3.2 The impact of InBore™ on imaging protocols

With similar rationale as described in §3.1, the possible impact of the ring on the treatment machine imaging system was studied. At both clinical centers the Catphan® 540 phantom (The Phantom Laboratory Inc., Salem NY, USA) was used to measure contrast, resolution, and noise for a range of radiographic imaging protocols, both with and without the ring co-located. Additionally, the EPID QC phantom (PTW, Freiburg, Germany) was used to assess MV-MV image quality at ORLAM.

The presence of the ring did not introduce any artifacts in any of the imaging protocols, namely MV, kV-CBCT and MVCT. Similarly, no statistically significant differences in contrast-to-noise ratio, resolution or noise were measured following introduction of the ring for either the Catphan® or EPID QC phantoms. These conclusions were consistent across all CBCT imaging acquisition protocols (namely Head, Chest, Breast and Pelvis), and MVCT protocols (High quality and Low quality).

Additional measurement looking at HU constancy and uniformity equally resulted in passing monthly IGRT QA tests [5] both with and without the ring.

The independent studies both concluded that AlignRT® InBore™ introduced no adverse effects on either beam delivery (§3.1) or image quality (§3.2).

3.3 Assessing the risk of collision

Bore-based treatment systems employ several safety measures to mitigate the risk of collision between the patient or treatment accessories and the bore. Examples include treatment planning buffers designed to maintain a margin between any contoured structure of the patient / accessories and the ring, and collision sensor systems detecting an impact on the inside of the bore. To maintain a margin between the patient and the bore, the InBore™ ring was designed to be as small as possible while maintaining structural stability and rigidity. As a result, in the region of closest proximity to a possible collision, the ring extends only 12mm into the bore cavity. This is within typical default treatment planning margins for bore-based linacs, and thus maintains a physical gap between the patient and bore.

To assess any increase in collision risk the InBore™ ring may introduce, a series of tests were performed including; 1) testing the sensitivity of the two anti-collision sensors with and without the ring in place to ensure continued functionality, 2) end-to-end testing of clinical workflows with the bore in place, and 3) reviewing workflows within the treatment planning software to increase collision buffers, if needed. The results from these three series of tests are as follows;

1) Using a force gauge for measurement, the presence of the ring did not affect the sensitivity of the anti-collision sensors. Additionally, applying pressure directly to the InBore™ ring, thus simulating a collision with the ring, also triggered the linac anti-collision system. Therefore, the ring was concluded to not interfere with this safety feature.

2) Following ongoing end-to-end testing of clinical workflows with the ring in place, the evaluating physicist concluded that under normal clinical conditions there was minimal risk of collision between the couch / accessories and the ring.

3) By adding an air equivalent structure of given thickness (e.g. 12mm, the thickness of the ring in proximity to the patient) to any outer contour within the treatment plan it was shown that the default planning ‘collision’ margin could be maintained, even in the presence of the ring. This margin can be added to the couch (Figure 6), patient and / or accessories. The resultant small reduction in the maximum couch displacement with this added buffer was deemed not to be of clinical significance. The necessity to add this buffer

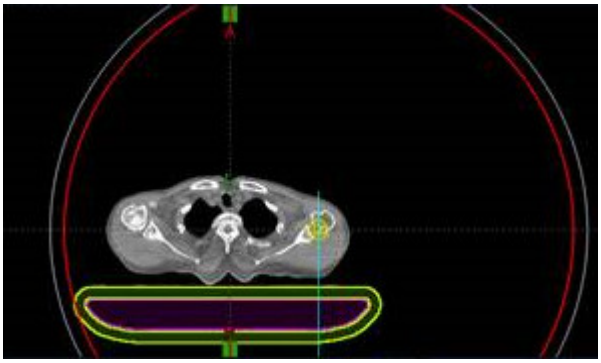

Figure 6 – Example treatment planning with an additional 'collision' buffer added to the couch

given the already compact size of the ring was questioned by the site physicist and may be evaluated on a case-by-case basis.

The combined conclusion from all collision tests conducted at both sites was that the introduction of the ring did not negatively impact the risk of patient or equipment collisions, and if there were clinical instances with increased risk, mitigating workflows can be employed.

3.4 The impact on camera visualization systems

Based on feedback from both ORLAM and UCSD, the ring systems with the three inbuilt projection systems did not impact the clinical use of either the inbuilt linac camera systems or the room CCTV cameras.

3.5 The impact on general linac serviceability and usability

The InBore™ system has been designed with the intention of providing clinical benefit to all patients, and as such can remain in place for all clinical cases. However, there are instances when the ring may need to be removed, and as such this process has been factored into the ring design. The ring has been designed such that a trained user can remove and replace the system in approximately 2 minutes, with a safe and secure storage system being provided for whenever the system is not in the bore. There is a single cable connection used to connect the InBore™ ring to the AlignRT® system (with no linac interfacing), and a simple locking mechanism for securing and removing the ring without the need of any tools.

During the onsite testing (which in the case of ORLAM has been ongoing for over 15 months), the process of placing and removing the ring was frequently tested (including across various prototype hardware iterations). All users were able to perform this straightforward task with minimal training. Additionally, even after many months of testing and use, no marks were apparent on the inner case of the bore, primarily due to cushioning rubber contact points between the ring and the bore.

During general service of the linac, the ring is located such that rear service doors can be accessed without any considerations of the ring co-location status. Equally, opening and closing these doors was shown not to impact the SGRT stability (see §2.5). If more invasive service is required and the internal covers and ring need to be moved, the ring can remain co-located within the treatment machine covers as they are removed. Alternatively, a trained user can easily remove the ring from the inner bore if desired. In either case, the conclusion from the evaluating physicists are that there is minimal impact on the serviceability of the treatment system with the InBore™ ring placed within the bore.

3.6 The impact on linac calibrations

To further test the design of InBore™ with regards mitigating the impact on treatment system workflows, calibration procedures were repeated on the linear accelerator both with and without the ring in place. Inbuilt QA and calibration tools provided the platform for assessing the impact across a relatively comprehensive set of system tests. There were no discernable changes in the MPC measurements between the pre- and post-placement of the InBore™ ring.

4 SUMMARY AND CONCLUSIONS

The studies described within this white paper demonstrate that AlignRT® InBore™ delivers an overall SGRT performance comparable to the ceiling mounted AlignRT® Advance solution, thus enabling an SGRT solution for bore-based linacs (Table 3). These benefits are delivered with no adverse effects on beam delivery or image quality.

AlignRT® InBore™ delivers sub-half-mm patient tracking accuracy across the entire solution (including the ceiling mounted cameras for setup, and InBore™ ring for intra-fraction monitoring) (§2). Additionally, the InBore™ system offers frame rates of 20-30fps, at least as high as the ceiling mounted system running the same AlignRT® software. With the inclusion of a co-calibration technique, linking the respective isocenter locations of the treatment system, AlignRT® InBore™, setup and treatment isocenters, AlignRT® InBore™ delivers a comprehensive SGRT solution for bore-based treatments, without compromise.

As is described with the extensive testing presented in §3 and summarized in Table 2, with careful design of InBore™ it has been shown that the introduction of the ring has no negative impact on any aspect of the linac operation, including clinical delivery, patient safety or serviceability.

Table 3 – InBore™ SGRT results [4]

Test	AlignRT® Advance Ceiling mounted SGRT	AlignRT® InBore™ Ring SGRT
Absolute Positioning Accuracy (relative to MV or kV isocenter position)	≤0.5mm translations ≤0.5° rotations	≤0.5mm translations [5] (§2.4)
Motion Monitoring Accuracy (with ACO) [6]	≤0.3mm translations ≤0.1° rotations	≤0.3mm translations ≤0.1° rotations (§2.2)
Tracking Stability (During 8 Hours of Continuous Monitoring)	≤0.2mm translations ≤0.2° rotations	≤0.2mm translations ≤0.2° rotations (§2.1)

[4] This data is not intended to be used as the formal system specification or claims for InBore™
[5] 6DoF shifts were not reported with the CBCT auto-match, so only translational values are reported in this table
[6] The ceiling mounted system includes data for both coplanar and non-coplanar treatment, while InBore™ only reports coplanar tracking values as bore-based linacs typically only offer coplanar treatment deliveries

Acknowledgments

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References

[1] Hoisak JDP, et al. Surface Guided Radiation Therapy. Boca Raton: CRC Press, 2020.

[2] Nguyen D. AlignRT with Halcyon: From Patient Setup to Monitoring. *European SGRT meeting, London* 2019.

[3] Flores-Martinez E, et al. Assessment of the use of different imaging and delivery techniques for cranial treatments on the Halcyon linac. *Journal of Applied Clinical Medical Physics* 2020;21 (1):53-61.

[4] Willoughby T, et al. Quality assurance for nonradiographic radiotherapy localization and positioning systems: report of Task Group 147. *Med Phys* 2012;39 (4):1728-1747.

[5] Klein EE, et al. Task Group 142 report: quality assurance of medical accelerators. *Med Phys* 2009;36 (9):4197-4212.