Enabling the ability to see radiation oncology therapy with a new perspective.

RADAR

Radiotherapy Positioning with Augmented Reality

PROGRESS REPORT #4

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DESIGN TEAM

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

Problem

Radiation therapy treats cancer by using a linear accelerator (linac) to send high doses of radiation to kill cancer cells. A typical patient treatment plan requires patients to come in to the clinic 5 days a week for 2-10 weeks. After diagnosis, a computed tomography (CT) Simulation scan is performed. Proper positioning of the patient is determined in the Simulation process, and the resulting CT scan is used for treatment planning. Accessories, such as immobilization devices, are used to help keep the patient still. Every day before radiation is administered, a radiation therapist must perform patient setup to position the patient on the treatment couch exactly like in Simulation. Detailed explanation of the current clinical workflow can be found in the Appendix.

There is a need for a more efficient way for radiation therapists to optimize the patient setup process in the radiation oncology clinic. There is currently no streamlined way to verify patient identity, accessory usage, and patient positioning during external beam radiation treatment. Setup and treatment must be completed within back-to-back 15 minute appointments. As of now, patient identification is only checked at discrete time points. If schedule changes occur, therapists can accidentally administer the wrong treatment plan to a patient, resulting in inaccurate dosing and excess radiation. Additionally, there is no way to document accessory usage. Each setup requires about 2-5 unique devices, and therapists are responsible for quickly switching these devices between treatments. They rely on their memory and notes, which leaves room for human error.

Patient positioning and motion management are the most crucial aspects of radiotherapy. Misalignment will result in radiating the incorrect target site and damaging healthy tissue. Because patients come in for treatment multiple times a week, patients need to be positioned exactly like the Simulation each time. There are two phases of positioning each day: Initial and Final Positioning. For Initial Positioning, therapists align patients to roughly the correct position by using a laser alignment system and tattoos; however, lasers are difficult to see and objects block them. For Final Positioning, X-Rays are used to fine-tune positioning; however, patients are exposed to excess radiation. Some clinics currently use surface alignment systems to fine-tune positioning; however, existing systems are cumbersome since the therapist must look back and forth between the computer monitor and the patient.

Objective

To complete this project within the span of Senior Design, we decided to narrow the scope of this project and focus primarily on patient positioning; we addressed the Initial Positioning phase of the patient setup process for this design project. The fine-precision necessary for the Final Positioning phase will be implemented in future RadAR device generations.

Our design goals are:

- Accurate placement of patient reference position
- Intuitive and convenient positioning of patient's current position with the reference position
- Easy incorporation into current treatment workflow

Design Solution

RadAR is an Augmented Reality (AR) software program created in collaboration with Varian Medical Systems that enables radiation therapists to accurately position patients during treatment. A 3D holographic model of the patient is generated from CT scans obtained during Simulation. Using a coordinate system of BB markers and Image Targets placed strategically on the treatment couch, RadAR is able to position its holograms in physical space. By looking at image targets, a therapist wearing the Microsoft HoloLens will see a 3D holographic model of the patient's correct position displayed on the treatment couch. By superimposing the patient with the holographic image, a therapist can accurately align the patient during the setup process. RadAR enables radiation therapist to safely treat cancer patients more quickly and to position them correctly each time.

Solution Assessment & Design Improvements

In order to access whether RadAR's design output meets our design specifications, we completed our Entire Device Verification procedures. These procedures test each of our metrics in our Engineering Design Specifications, and the results are shown in Table 1. The Entire Device Verification procedures and Engineering Design Specifications table can be found in the Appendix.

Table 1: Design Goals Assessment

Design Requirements	Test Conducted	Final Design Output
Device Weight < 3 lb	Measurement	1.217 lb
Device Cost < $500	Research	$3,000
Frames per Second ≥ 60 fps	Recorded fps in different HoloLens apps	51.4 fps
Reference Position Accuracy ≤ 2 cm	Utilized measurement analysis software to quantify displacement between actual objects and holographic objects	1.4 cm
500 mm < Range of Image Target Registration < 2,000 mm	Recorded physical range of when holograms are displayed	170 mm < Range of Image Target Registration < 800 mm
Warm-up time < 30 mins	Recorded average time from turning the device on and reaching the opened app	22 secs
Battery Life > 2.5 hrs	Recorded average time of using the device with the app from 100% battery to 0% battery	2 hrs 54 min[1]

[1]After 1 hour of continuous app usage, the HoloLens became too hot and needed a shut down. We anticipate that this will not be an issue as therapists only use it for part of the 15 minute appointment, before waiting for the next appointment's set up.

Overall, the most important design requirement for our objective is the Reference Position Accuracy, which is shown in Table 1 to have a passing result for our solution. The next most important requirement is the Range of Image Target Registration, and we will consider our result as a passing value. Although our resulting minimum range is much lower than our original ideal minimum range, we had gained feedback from clinical experts that have convinced us that our resulting minimum range is still acceptable. This is due to the fact that the therapists usually position the patient at close proximities, and being able to recognize the image targets at a closer range is preferred. Our design's ability to recognize image targets even closer than the ideal range allows the therapist to be extremely close to the couch and image targets to conduct positioning.

Our design also passed other requirements except for device cost and frames per second (fps). The device cost requirement of $500 was for the purpose of our senior design course, which we have fulfilled because we were able to borrow the HoloLens from our client at no charge. In reality, the device costs $3,000. This price is still extremely low from a client's (hospital's) perspective. As for our device's fps, we have determined that our result is close enough to the intended value to be satisfactory. Having a high fps only enables movement of images to be smoother, but since our hologram image just needs to be placed at a certain fixed position, our lower fps value can be accepted and will not decrease the accuracy of our device.

Value Impact

Current initial-positioning techniques have limited accuracy and are time expensive. One such technique uses a laser alignment system, which is the standard practice. This system aligns three tattoo dots on patients with three cross-hairs generated by a laser system in the treatment room. By only using three tattoo dots, the patient's body could be skewed superior or inferior to the tattoo region without the therapist's knowledge. These lasers are also difficult to see and objects can get in the way of the laser projections. Our program provides a visual reference of where the patient should be, streamlining setup and decreasing total treatment setup time.

Additionally, existing third-party positioning solutions require a therapist to look back and forth between a monitor across the room and the patient to determine what positioning adjustments need to be made. Our program offers an ergonomic solution. All the relevant information is displayed in the therapist's field of view, and the reference hologram of the patient is aligned on the couch in the proper orientation. Compared to third-party patient systems and a hospital's budget, our device has a relatively small up-front investment of $3,000. Combined with the benefits of reliable, efficient, and ergonomic initial patient positioning, this offers a quick return on investment. Our device can be used repeatedly for various patients, and with basic care, will outlast other competitors.

Future Pathway

Our long-term objective is to develop a device that will verify patient identity, accessory or equipment usage, and increase patient positioning accuracy during the Final Positioning phase of the patient setup process. The device will allow radiation oncology therapists to safely treat cancer patients more quickly and to position them within smaller margins.

As we continue to develop our knowledge of associated software, we plan to automate the 3D hologram generation process. Although creating the patient reference hologram from CT scans can be completed in only a few minutes, we would like to further simplify our device and make it even more user friendly.

With the new release of Microsoft HoloLens 2, we predict that the patient positioning accuracy will continue to improve as AR hardware technology advances. New techniques will also enable us to implement additional features such as a Green Glow positioning verification notifications.

Purchasing

Our product is a software application to be run on the Microsoft HoloLens. Validation testing is conducted with plastic phantoms. Our group borrowed two HoloLens, one from Varian Medical Systems and one from Steven Lucero in the UC Davis TEAM lab. To make our product, we used mostly open source software and utilized the educational license to get free access of other software programs. We downloaded Unity (a software development platform) for free under the restriction that our group makes less than $100,000 per year. In our project, we also utilized open source softwares like Microsoft Visual Studio, Atlassian's Bitbucket, and Box to manage software and 3D Slicer [1, 2] to create 3D holograms. Atlassian's Jira (a version control software) and a plastic phantom from Amazon are purchased and the total cost is $50. However, if the hospital or the company were to recreate our product, they will not need the verification material and version control softwares. The essential items that a client or hospital would need are the Hololens, 3D slicer, Unity, and Visual Studio Community.

Final Bill of Materials

Table 2: Final Bill of Materials

Product	Company	Clinic Cost	Unit Cost	Total Cost
HoloLens*	Microsoft	$3,000	Free to borrow from Varian	$0
Bitbucket	Atlassian	$0	Free for students	$0
Jira	Atlassian	$0	$10/month/team	$30
3D Slicer*	Kitware	$0	Free (open source)	$0
Unity*	Unity Technologies	$0	Free (we make < $100k/year)	$0
Visual Studio Community*	Microsoft	$0	Free	$0
Box	Box, Inc.	$0	$0	$0
Foam Boards	Elmer's	$0	$4	$4
Orange Cube	3D Printer	$0	Free to print	$0
Plastic Phantom	Amazon	$20	$20	$20

*Items essential for clients to purchase in order to utilize or recreate our product

Manufacturing

A coordinate system was first manufactured in order to relate the CT environment, AR virtual environment, and physical environment to each other. When a patient is first diagnosed, a CT Simulation scan is performed before the start of treatment. Proper positioning of the patient is determined during this process, and the resulting CT scan is used for treatment planning. Radiopaque BB markers are currently being used to identify specific areas of the patient on the CT scan. For our application, we place these BB markers on the Simulation couch as a reference in our RadAR coordinate system. In order to relate the AR virtual environment to the physical environment, Image Targets recognized by the HoloLens are placed on the treatment couch. These Image Targets are 13.9 x 13.9cm^2.

Place 6 BB Markers on the Simulation Couch

1. Place the first BB marker 6.95cm away from the top edge and 6.95cm from the left edge of the couch.
2. Place the second BB marker 28.55cm below the first BB marker.
3. Place the third BB marker 28.55cm below the second BB marker.
4. Repeat steps 1-3 for the right hand side of the couch.

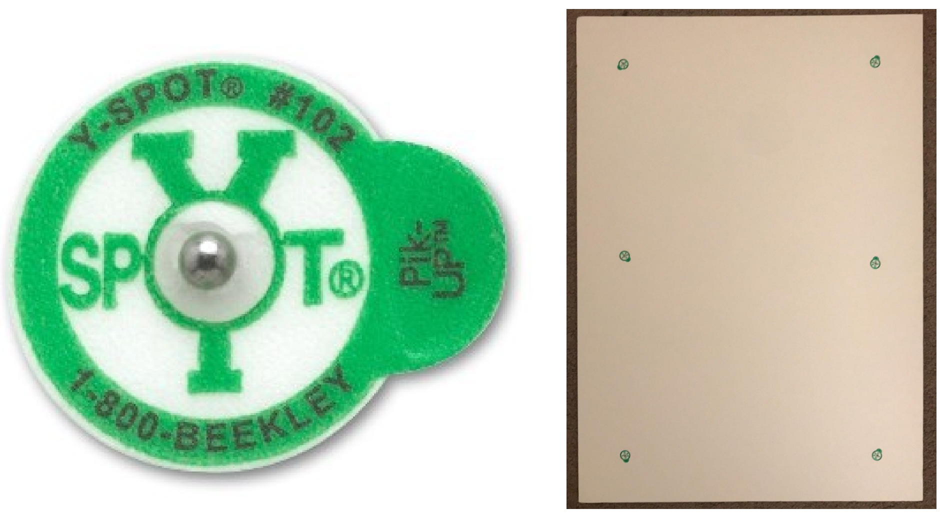


Figure 1: Radiopaque BB markers (left) are placed on our simulation couch (right).

Place 6 Image Targets on the Treatment Couch

1. Place the first target image at the very top left corner of the couch.
2. Place the second image target 28.55cm (center-to-center) below the first target image.
3. Place the third image target 28.55cm (center-to-center) below the second target image.
4. Repeat steps 1-3 for the right side of the couch.

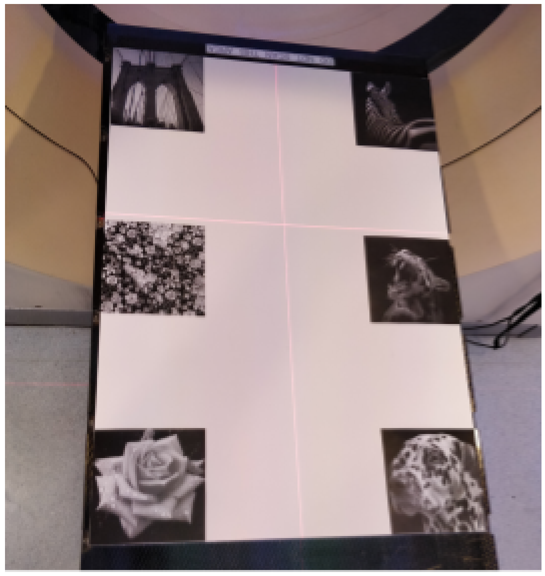


Figure 2: Image targets on treatment couch.

Assembly

Creating a Holographic Patient Model

1. Obtain CT scan from Simulation.
2. Upload CT scan DICOM files into 3D Slicer.
3. Use the Segmentation Editor's threshold, islands, and trim "effects" to specify the patient's contour as a segment.
    a. The threshold effect is used to specify what degree of radiopaque content to include in the segment and eliminate noise or artifact in the CT scan.
    b. The islands effect is used to remove any remaining noise that is not touching or connected to the patient contour (i.e. are islands).
    c. The trim effect is used to draw an outline around what content to include or remove from a segment that cannot be specified previously, since it meets the radiopaque threshold and is touching the patient contour. This is particularly useful for separating the couchtop from the patient contour.

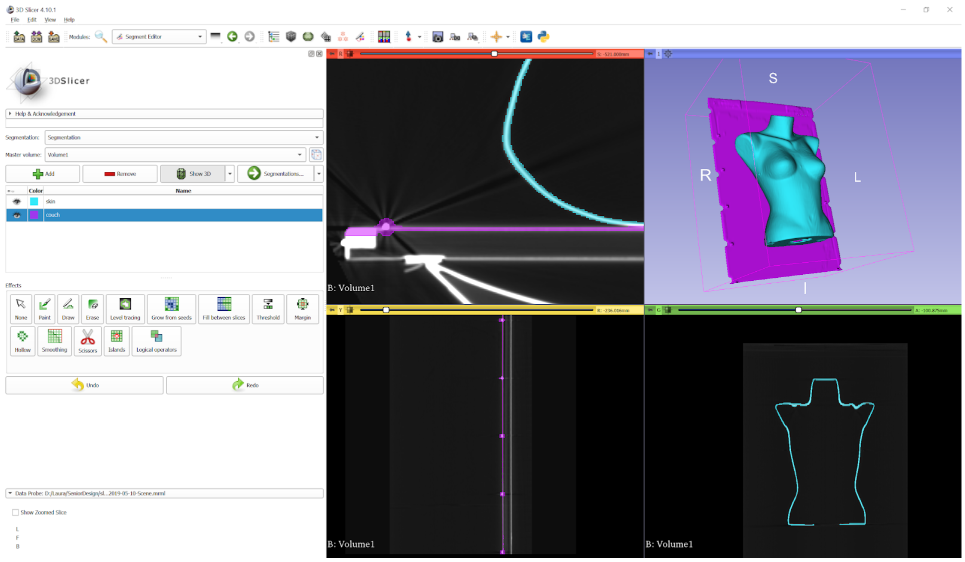


Figure 3: In 3D Slicer, the patient's contour, couch, and BB markers are defined in the uploaded CT scans from simulation. This is done in the Segment Editor module by using paint, erase, threshold, scissors, and islands effects pictured on the left side of the image. Two segments are created: the skin in blue, and the couch in purple. With the paint effect, the BB markers can be highlighted, as seen in the transverse and sagittal views, to allow for easier identification and alignment with the image targets in Unity.

4. Repeat for specifying the couch as a segment. Use the paint tool to highlight the BB markers on the couch for increased visibility and ease of positioning with the image targets once uploaded to Unity.
5. Export the segments as a combined .obj file.
6. Upload the object file into the Unity assets project folder.

Creation of Image Targets

1. On the Vuforia Developers Portal webpage, under Target Manager, upload the following 5 star rated images for the highest chance of detection and recognition.

Figure 4: Right, image targets that will be used on the couch. Bottom, Vuforia's image ranking system.

Target Name	Type	Rating	Status	Date Modified
couchBridge	Single Image	★★★★★	Active	May 21, 2019 20:43

2. On the same page, now upload a *Cuboid Target* with the dimensions (in meters) of the cube you desire. Take note that each face will have one image target, so the dimensions of the cuboid determines the size of your image targets.

3. Click on the Cuboid Target you just created and insert one image in each face of the cuboid.

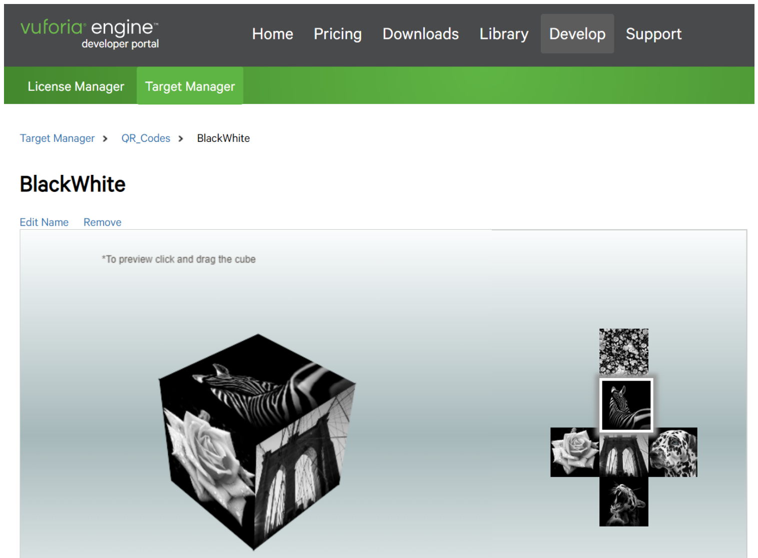


Figure 5: In Vuforia's portal, the Cuboid faces uploaded with our 6 image targets.

4. Import the cuboid database package into Unity.

Cuboid to Unity

1. Place the cuboid into Unity space as a *MultiTarget* object.

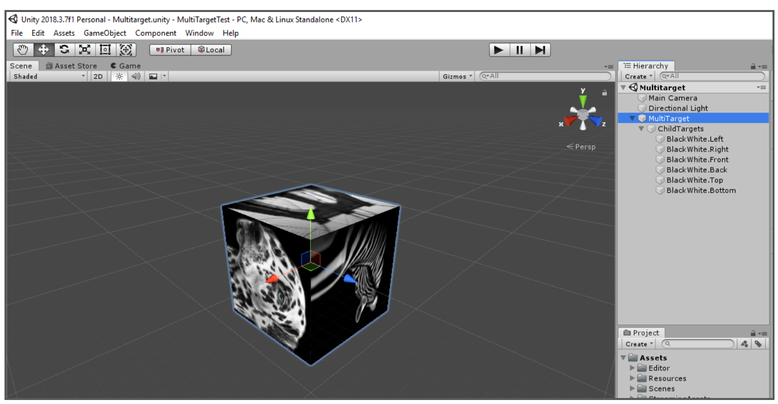
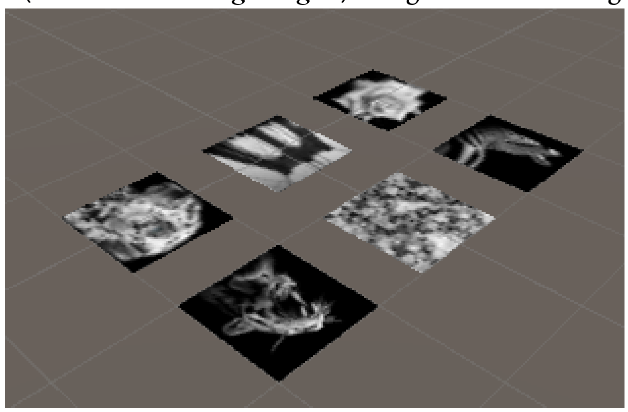


Figure 6: The Cuboid being placed into Unity as a Multi Image Target.

2. Open the cuboid's associated .xml/.xaml file and edit the translation and rotation according to where each image is positioned in reality on the couch. Once saved, each image should be positioned accordingly.

```xml
        <MultiTarget name="BlackWhite">
            <Part name="BlackWhite.Left" translation="-5.0 0 0" rotation="AD: 0 1 0 0"/>
            <Part name="BlackWhite.Right" translation="5.0 0 0" rotation="AD: 0 1 0 0"/>
            <Part name="BlackWhite.Front" translation="5 0 -5.0" rotation="AD: 1 0 0 0"/>
            <Part name="BlackWhite.Back" translation="-5 0 -5.0" rotation="AD: 0 1 0 0"/>
            <Part name="BlackWhite.Top" translation="5 0.0 5" rotation="AD: 1 0 0 0"/>
            <Part name="BlackWhite.Bottom" translation="-5 0.0 5" rotation="AD: 1 0 0 0"/>
        </MultiTarget>
```

Figure 7: Top, the .xml file of the Cuboid where the translation and rotation are modified. Bottom, the cuboid faces (referred to as *image targets*) being moved accordingly in Unity.



3. Place the 3D holographic image of the CT scan in space and position it accordingly in the middle of the image targets.

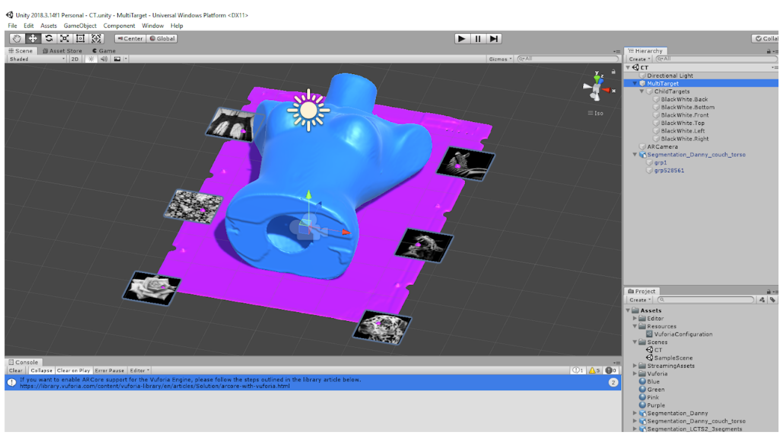


Figure 8: In Unity, the image targets and 3D CT hologram being placed with reference to each other.

4. Save your scene, build it, and deploy to the HoloLens.

Instructions for Use

1. Put on the HoloLens headset.
2. In *All Apps* select the *RadAR* application.
3. If the app asks for Camera Usage Permission, select Yes.
4. Look at the image target on the wall to display the patient's holographic information panel.
5. Look at any image targets on the couch to display the patient's holographic reference image.
6. Superimpose the patient with the hologram by moving the couch and patient.
7. The patient is correctly positioned once they are perfectly superimposed with the hologram.

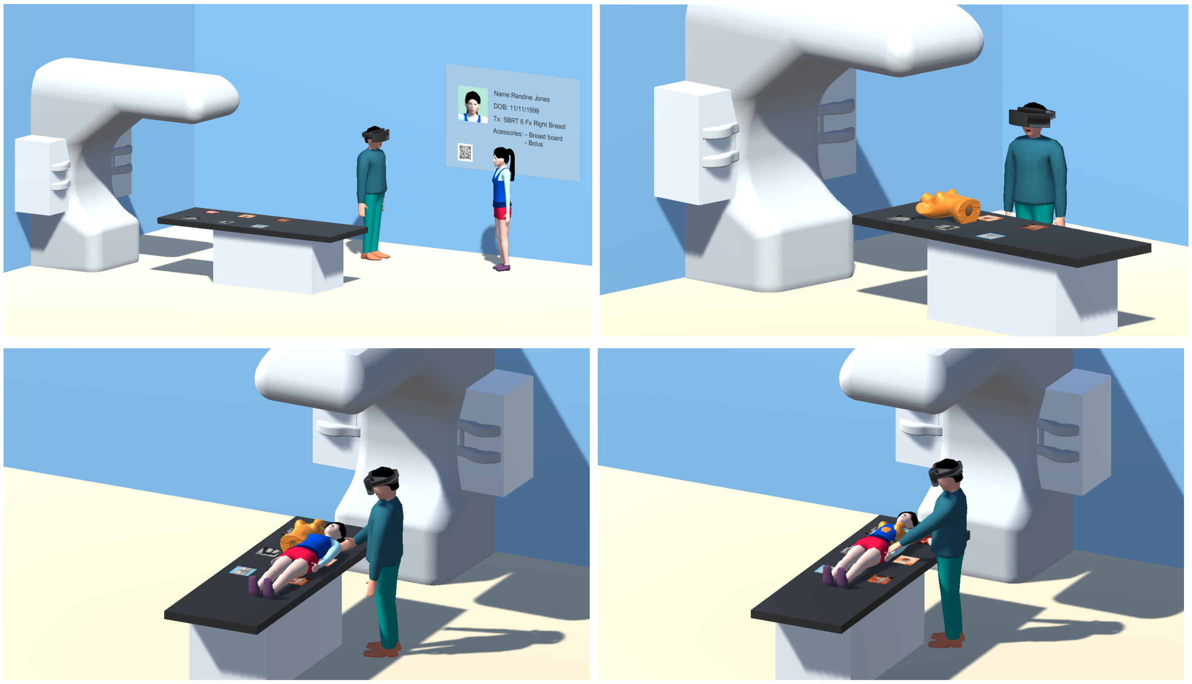


Figure 9: Top left, a visual of step 4. Top right, a visual of step 5. Bottom left, a visual of step 6. Bottom right, a visual of step 7.

Safety Precautions

Our application does not propose any direct danger to the user, but it is generally recommended that the user takes a break after 30 minutes of using the HoloLens. Using AR devices for extended amounts of time generally incites dizziness and nausea in users. However, since treatment appointments are only 15-minutes, this will not be an issue as the therapists can take off the headset after positioning is done. Positioning time is only part of the 15-minute appointments, and the therapists will have enough time for a break away from the HoloLens while performing radiation treatment until the next appointment arrives.

While our device does not have any hazards, there can be technical issues in usage. However, these issues can be easily remedied. If the HoloLens runs out of battery during positioning, the only repercussion would be that either another HoloLens must be used, or the clinic would need to wait for the device to be charged enough to be used for the remaining positioning time. Also, if the objects cover the image targets, the hologram will not appear and time will be needed to remove the objects. Going further, if these issues are not corrected for, then patient positioning will be disrupted. If the patient is incorrectly positioned, excess radiation can be delivered to healthy tissue.

Verification & Validation Procedure

Verification

Verification tests were separated into two sections: Individual Component Verification and Entire Device Verification. For Individual Component Verification, we tested the main software features that were necessary to achieve our design goals. For Entire Device Verification, we tested our overall app usage to see if it met our user needs and engineering design specifications.

Individual Component Verification

We will verify the individual components (software features) in this section. These components include registering the image targets, displaying the patient hologram, and aligning a hologram to the image targets on the couch. These tests will be detailed below and each will have a pass or no-pass result.

Registering Image Targets

Purpose: Ensure our device can recognize the image target at reasonable angles and distances.

Test Procedure:

1. Attach a cube object to an image target in Unity. Deploy test to HoloLens.
2. Hold an image target 0.3 meters away from the HoloLens at an angle 0° above the horizontal.
3. Slowly rotate the image target to face the HoloLens. With each rotation, look away from the image to get rid of the displayed hologram, then look back to see if the hologram is displayed.
    i. If the hologram is not displayed, then this test fails.
    ii. If multiple rotations display the hologram appropriately, then this test passes.
4. Repeat for 0.1 and 0.5 meters away.

Displaying the Patient Hologram

Purpose: Ensure the CT scan is properly converted into a hologram and that it is displayed to scale.

Test Procedure:

1. Attach the CT hologram to an image target in Unity. Deploy test to HoloLens.
    i. If the CT hologram is not displayed, then this test fails.
2. If the CT hologram is displayed, superposition the CT hologram with the actual object of the CT scan.
    i. If the CT hologram is not the same size as the actual object, then this test fails.
    ii. If the actual object is the same size as the actual object, then this test passes.

The most difficult and crucial individual component test was "Aligning a Hologram to the Image Targets." We created a special procedure called the "Orange Cube Phantom Superposition Test" to test how accurate the reference hologram was positioned in its expected location. For this test, we used a 3D printed orange cube phantom. The desired location of the cube was set directly to the right of an image target. A model of the orange cube phantom was uploaded into Unity, and its position was set to the same distance from the image target in Unity as it was in real life. This uses the same positioning technique as our actual app. The Orange Cube app was deployed to HoloLens. Participants were asked to look at the real-life image target to position the real-life orange cube. The surface area of the footprint of the cube that was displaced from where it should be was used to quantify accuracy.

Aligning a Hologram to an Image Target (Orange Cube Phantom Superposition Test)

Purpose: Ensure that the reference holograph is at the correct location

Test Procedure:

1. Place a sheet of paper adjacent to the image target, and outline the desired location of the orange cube phantom on this piece of paper.
2. Ask the subject to look at the image target and place the orange cube phantom where they see the orange cube hologram.

3. Outline the orange cube phantom footprint of where the subject placed the orange cube phantom.
4. Quantify displacement area in ImageJ
    a. Scan the paper with the orange cube phantom desired and subject-placed traces, and upload into ImageJ.
    b. Set the scale of the image knowing that the trace of the cube is 12.7cm wide.
    c. Outline the displaced area with the polygon tool. Add this area to the ROI manager and click measure to determine the area.
    d. Repeat c for the displaced area on the opposite side of the trace and average the results. This accounts for errors in the fitting of the polygon to the displaced area.

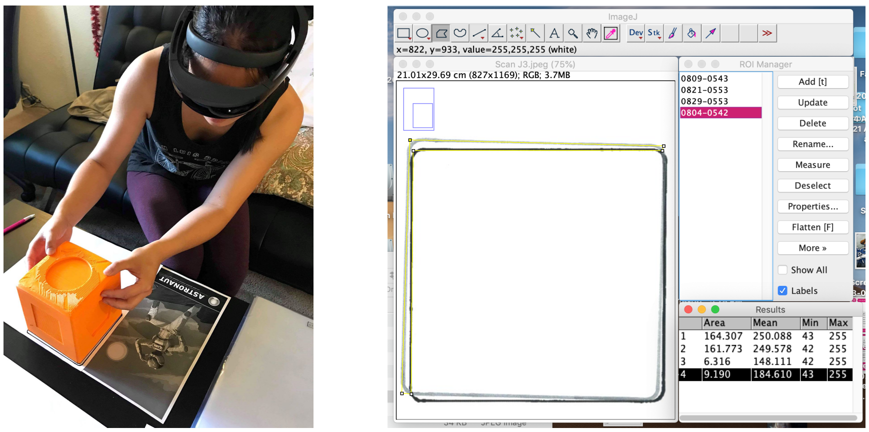


Figure 10: Left, verification test using the orange cube phantom. Right, area displacement calculation using ImageJ.

Entire Device Verification

We will verify the entire device in this section. These tests include testing for weight, frames per second, reference position accuracy, range of image target registration, warm-up time, and battery life. For certain device metrics (cost, camera resolution), we referred to the specifications of the Microsoft HoloLens, and this information will be recorded in Table 3. These table values can then be compared with the ideal values in the EDS table for verification purposes. The remaining software-related tests were detailed to ensure that individual components of our software meets the standards of the software in the field.

Table 3: Specifications Obtained from Microsoft

Metric #	**Metric**	**Units**	**Value**
2	Cost	USD ($)	3,000[11] USD
4	Camera Resolution	Pixel (px)	720 (1268x720)[12] px

<u>Weight</u>

Purpose: Ensure that our HoloLens device is not too heavy for the user to use.

Test Procedure:

1. Zero a scale.
2. Place the HoloLens device on a scale and record the weight.

3. Repeat with at least two more trials and average the results.

Frames per Second

Purpose: Ensure that our HoloLens device is able to produce smooth holographic images.

Test Procedure:

1. Open one of our Unity projects that displays a hologram.
2. On the HoloLens, open the Holographic Remoting Player app and say "enable diagnostics."
3. Record the FPS number listed.
4. Switch to a second Unity project that displays a hologram. Repeat steps 2-3. Repeat this step with a third Unity project if available.
5. Switch to a second computer and repeat steps 1-3. Repeat this step with a third computer.
6. On one computer, repeat steps 1-3 on a second WiFi network. Repeat this step with a third WiFi network.

   Note: This test was generated with the knowledge that the FPS can change depending on [3]:

   - *The complexity of the Unity project*
   - *The PC computer's graphics card*
   - *The speed of the WiFi connection*

Reference Position Accuracy

Purpose: Ensure that our software leads to accurate positioning.

Test Procedure:

1. Outline an object onto a paper "couch."
2. Remove the object.
3. Use the HoloLens to display a holographic image of the object onto the "couch."
4. Outline the placement of the holographic object.
5. Use ImageJ (an image processing program) to quantify the displacement of the actual and holographic object outlines in units of surface area.

Range of Image Target Registration

Purpose: Ensure that our device is able to register the image targets at a reasonable range away from the treatment couch.

Test Procedure:

1. Stand on the side of the couch length.
2. Using HoloLens and making sure the patient hologram is displayed, walk further from the couch until the hologram is not displayed anymore.
3. Record the distance from the user to the couch.
4. Repeat steps 2-3 but on the side of the couch width.
5. Using these two values, calculate the range of image target registration. This will be the maximum range of image target registration.
6. Repeat steps 1-5, but instead of walking away from the couch, the user will walk as close as possible to the image targets until the codes can not be read anymore, and the hologram is not displayed anymore. This will be the minimum range of image target registration.

Warm Up Time

Purpose: Ensure the device warm up time is within the expected range.
Test Procedure:

1. Turn on the Hololens and start timing immediately after the power button is pressed.
2. After the home menu shows up, open up the program and select the patient profile.
3. Stop timing after the patient profile is finished loading.
4. Repeat this procedure two more times.

<u>Battery Life</u>
Purpose: Ensure that our HoloLens device will last long enough for usage in the clinical setting.
Test Procedure:

1. Charge the HoloLens to full battery.
2. Open our software app on the HoloLens.
3. Let it stay open and check on the device to ensure it did not go into sleep mode.
4. When it turns off, note the time it took to get to that point.
5. Attempt to turn on the device to check if the shut-down had occured due to zero battery. If it was, then keep the recorded value. If it was not, then redo this whole procedure.
6. Repeat steps 1-5 a second time. If time permits, repeat it a third time.

Validation

Validation tests were conducted after the software prototype had been created to ensure that our software continuously fulfils our user requirements. We gave the HoloLens and RadAR application to radiation therapists to test with an anthropomorphic phantom. This phantom is a plastic mannequin that closely resembles the human form. Our team had previously CT scanned this phantom at the UC Davis Medical Center to generate its corresponding holographic image. The phantom in the following testing procedure is referred to as "Danny Phantom."

Quantitative Validation

Quantitative validation tests were performed to provide numerical quantities of patient position accuracy during use in the radiation oncology clinic. Radiation therapists (RT) practiced positioning Danny Phantom in this validation procedure. To quantify the accuracy of positioning, the following procedure was created to confirm that the HoloLens and our RadAR software are able to align patients to the acceptable tolerances of less than 2cm.

<u>Accuracy of Danny Phantom Positioning</u>
Purpose: Ensure the accuracy of RT superimposing the phantom and the patient.
Test Procedure:

1. Superimpose the hologram and the Danny Phantom.
2. Check if the BBs on Danny Phantom matches with the laser crosslines.
3. Record distances between the BBs and the laser crosslines using a ruler with a 0.5mm minimum measurement.
4. Repeat the same procedure two more times.

Figure 11: Left, an image of UCDMC staff utilizing our device and software to conduct Danny Phantom Positioning test. Right, measurement of our device's positioning accuracy with a ruler.

Qualitative Validation

After the radiation therapists practiced positioning Danny Phantom using RadAR, they were asked to evaluate their experiences in a survey. The therapists answered the survey questions by circling whether they agreed with each corresponding question statement. The response options were: Strongly Disagree, Disagree, Neutral, Agree, and Strongly Agree. The survey also included questions regarding the RadAR Treatment Workflow.

<u>RadAR Treatment Workflow</u>

1. CT scan the patient during Simulation.
2. Generate holographic body contour of the patient using the CT scan (automated).
3. Therapist wears HoloLens .
    a. Scans patient ID barcode (verifies patient identity).
    b. Holographic wall panel displays: patient info, accessories, and treatment plan.
4. Therapist superimposes the physical patient with the hologram.
5. Fine tune positioning with CBCT.
6. Perform radiation treatment.

<u>Survey Questions</u>

1. The RadAR Treatment Workflow integrates well with the current workflow.
2. RadAR has the potential to decrease patient setup time.
3. RadAR has the potential to increase patient positioning accuracy and reproducibility.
4. RadAR is more convenient, ergonomic, and easy to use than the current state of the art.
5. I can see myself using RadAR for patient positioning in the future.
6. I can see myself using AR technology within the clinic for additional purposes such as collision detection, treatment planning, and reducing patient anxiety.

Verification & Validation Results

The following graphs represent the data obtained from performing the Verification and Validation Procedures.

Individual Component Verification Results

<u>Registering Image Targets</u>

Purpose: Ensure our device can recognize the image target at reasonable angles and distances.

Test Procedure Results:
We conducted nineteen trials with nineteen participants at the UCDMC. For each trial, the image targets were rotated slowly, and participants did multiple checks to see if the hologram would still be displayed while viewing image targets at multiple rotations. The hologram continued to be displayed in the correct orientation at the necessary angles and distances, so this test passes.

<u>Displaying the Patient Hologram</u>
Purpose: Ensure the CT scan is properly converted into a hologram and that it is displayed to scale.
Test Procedure Results:
With the same nineteen participants at the UCDMC, we conducted another nineteen trials to test the display of the patient hologram. For all trials, the CT scan was properly converted into a hologram is displayed. Initially, the hologram was at the correct scale. However, after the first hour of our four hour testing period, the scaling of the hologram magnified due to technical glitches. Therefore, the first several participants had passing results, while the rest failed. If the glitches did not occur, then we hypothesize that our trials all would have been passing results. Our team is currently working on improving this implementation and researching additional techniques to mitigate this issue.

<u>Aligning a Hologram to an Image Target (Orange Cube Superposition Test)</u>
Purpose: Ensure that the reference holograph is at the correct location

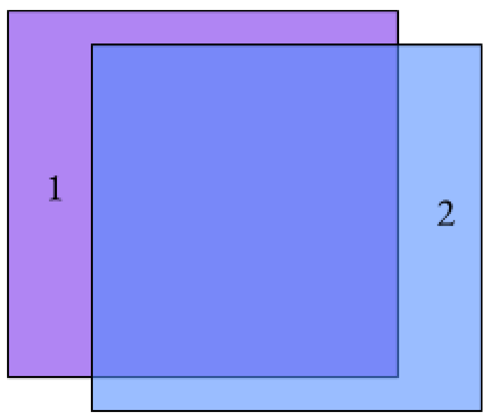
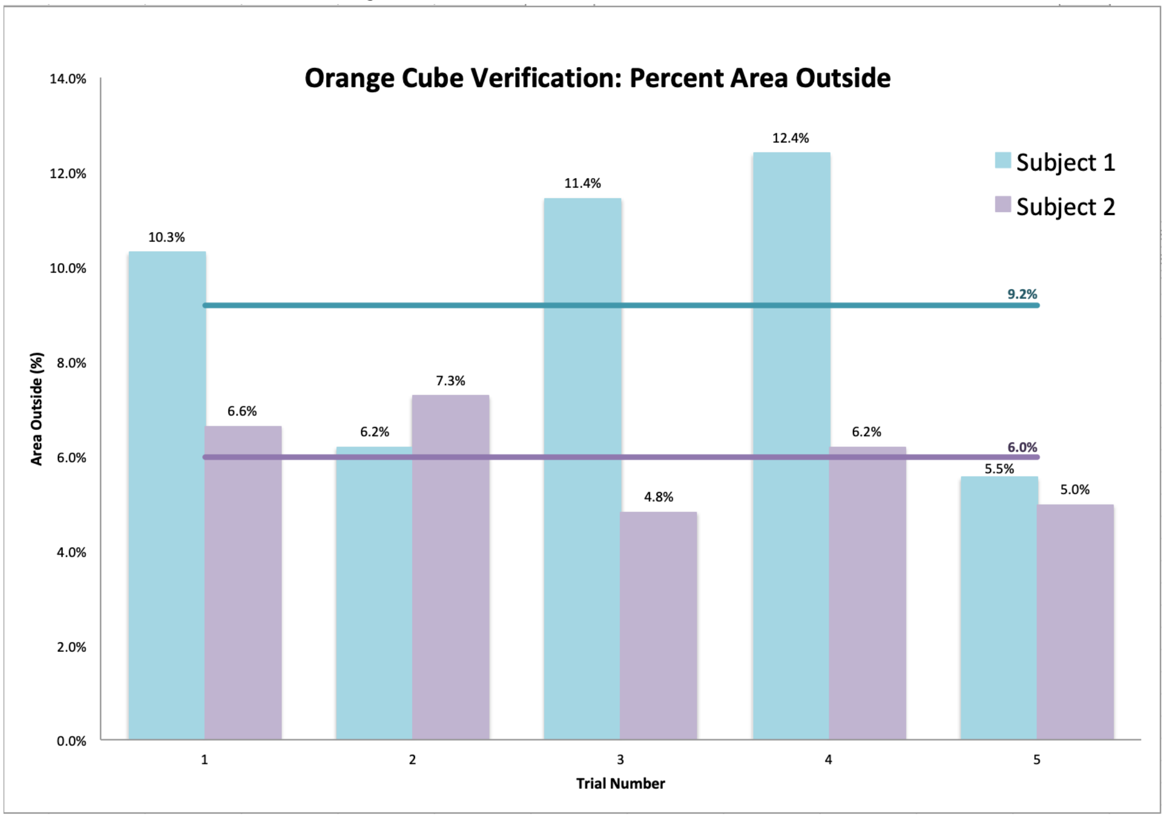


Figure 12: Percent area outside is calculated by dividing the area of one square outside of the overlap by the area of the square. $\frac{\text{<1>}}{\textit{<Area of Square>}}$ and $\frac{\text{<2>}}{\textit{<Area of Square>}}$ are then averaged and reported in Graph 1 below.

Test Procedure Results:

Graph 1: Orange Cube Phantom Verification: Percent Area Outside



A total of 10 trials were performed in total. The following represent the statistical analysis of the results.

- Subject 1:
  - Average percent area outside = 9.3%
  - Standard deviation = 0.031
- Subject 2:
  - Average percent area outside = 6.0%
  - Standard deviation = 0.011
- Total percent area outside = 7.6%
- Total standard deviation = 0.023

Verification results for the Orange Cube Phantom were analyzed for intra- and intraoperative error. Percent area displaced was calculated as the area displaced over the total area of the orange cube phantom footprint.

Presented in the graph above, of the two subjects tested, Subject 1 averaged 9.3 % area outside (s.d. ±0.031) and Subject 2 averaged 6.0 % area outside (s.d. ± 0.011). Overall, the average was 7.6 % area outside (± 0.023). Subject 1 had a relatively large intraoperator error (seen by the great variability in percent area outside among the five trials) as compared to Subject 2: Subject 1's standard deviation was three times as great as Subject 2. Some users become accustomed to using RadAR for alignment better than others. This in part can be attributed to the fact that the reference hologram shifts position slightly depending on consistency of eye dominance. With more practice, it is expected that intraoperator error will decrease as therapists begin to use RadAR more consistently. With that, it is also expected that various operator's average percent area displaced outside will decrease and converge, thus also decreasing inter-operator error. As experiencing augmented reality is new to many people, we expect initial training to progress slowly, but there be a quick learning curve after a brief time to get acquainted to the environment.

Entire Device Verification Results

Table 1: Design Goals Assessment

Design Requirements	Test Conducted	Final Design Output
Device Weight < 3 lb	Measurement	1.217 lb
Device Cost < $500	Research	$3,000
Frames per Second ≥ 60 fps	Recorded fps in different HoloLens apps	51.4 fps
Reference Position Accuracy ≤ 2cm	Utilized measurement analysis software to quantify displacement between actual objects and holographic objects	1.4 cm
500 mm < Range of Image Target Registration < 2,000 mm	Recorded physical range of when holograms are displayed	170 mm < Range of Image Target Registration < 800 mm
Warm-up time < 30 mins	Recorded average time from turning the device on and reaching the opened app	22 secs
Battery Life > 2.5 hrs	Recorded average time of using the device with the app from 100% battery to 0% battery	2 hrs 54 min[1]

[1]After 1 hour of continuous app usage, the HoloLens became too hot and needed a shut down. We anticipate that this will not be an issue as therapists only use it for part of the 15 minute appointment, before waiting for the next appointment set up.

Overall, the most important design requirement for our objective is the Reference Position Accuracy, which is shown in Table 1 to have a passing result for our solution. The next most important requirement is the Range of Image Target Registration, and we will consider our result as a passing value. Although our resulting minimum range is much lower than our original ideal minimum range, we had gained feedback from clinical experts that have convinced us that our resulting minimum range is still acceptable. This is due to the fact that the therapists usually position the patient at close proximities, and being able to recognize the image targets at a closer range is preferred. Our design's ability to recognize image targets even closer than the ideal range allows the therapist to be extremely close to the couch and image targets to conduct positioning.

Our design also passed other requirements except for device cost and frames per second (fps). The device cost requirement of $500 was for the purpose of our senior design course, which we have fulfilled because we were able to borrow the HoloLens from our client at no charge. In reality, the device costs $3,000. This price is still extremely low from a client's (hospital's) perspective. As for our device's fps, we have determined that our result is close enough to the intended value to be satisfactory. Having a high fps only enables movement of images to be smoother, but since our hologram image just needs to be placed at a certain fixed position, our lower fps value can be accepted and will not decrease the accuracy of our device.

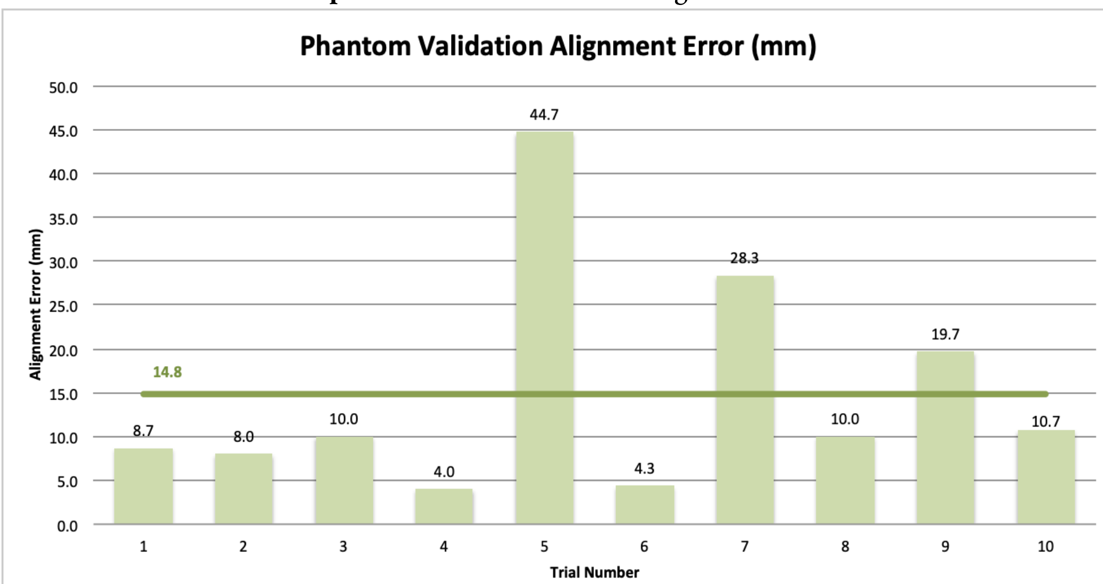
Quantitative Validation Results

Accuracy of Danny Phantom Positioning

Purpose: Ensure the accuracy of RT superimposing the phantom and the patient.

Test Procedure Results:

Graph 2: Phantom Validation Alignment Error



10 trials were performed in total and our results are as follows:

- Average alignment error = 14.83mm
- Standard deviation = 12.91mm
- There was an outlier = 44.7mm
    - 44.7mm is larger than 44.65mm, which was calculated using the definition of an outlier (the average plus two times the standard deviation)

- Removal of the outlier results in:
    - Average alignment error = 11.5mm
    - Standard deviation = 8.38mm

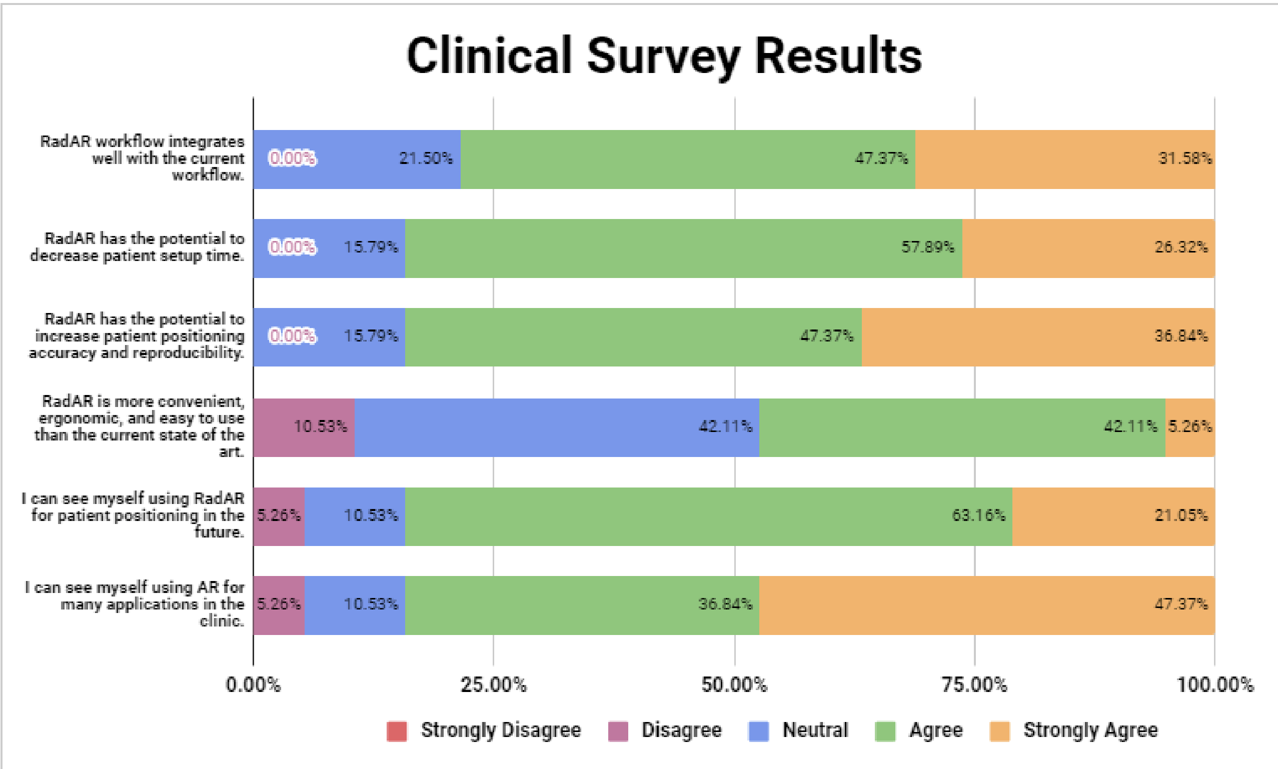
The outlier of 44.7mm resulted from user error. Initially, we had hypothesized that the jittery hologram was caused by a software glitch. Jittering holograms have occured in different RadAR prototype iterations in which different image targets and different image target sizes were used. However, upon further analysis, this particular error was determined to be due to the user not looking at all of the image targets before positioning the phantom. By not fully looking at all the image targets, the HoloLens was not able to spatially recognize its location.

If the outlier was removed, the average alignment error of 11.51mm with a standard deviation of 8.83mm falls even more within the 2cm target metric. Overall, the results from the Danny Phantom

Positioning Verification Test have shown that the concepts and techniques utilized in RadAR has demonstrated potential efficacy for Initial Positioning in radiotherapy patient positioning. Having hit our initial target, future iterations and user training will strive to achieve an alignment error even closer to the current 2mm gold standard for overall positioning.

Qualitative Validation Results

Graph 3: Clinical Survey Results



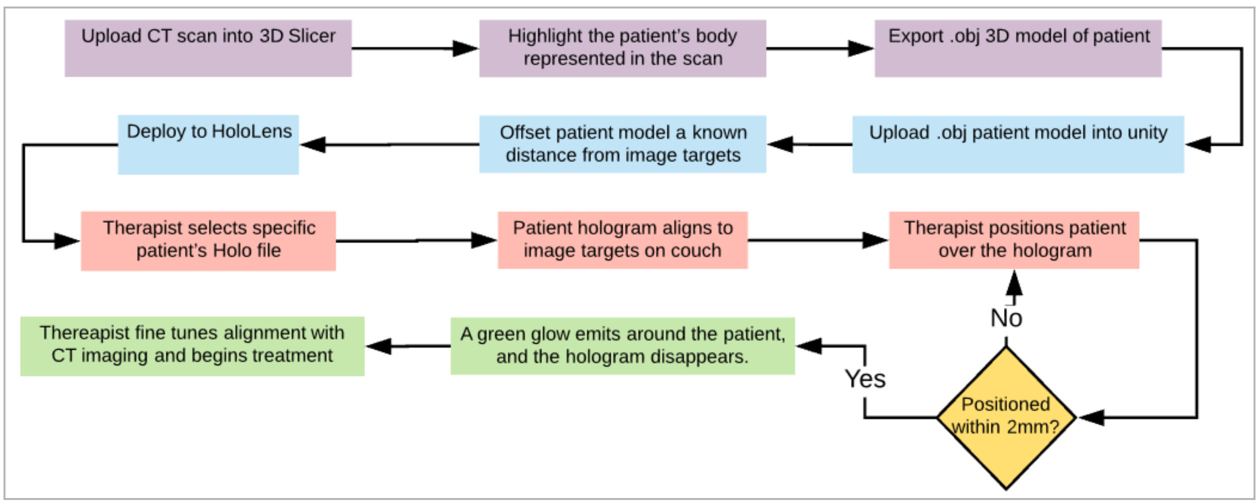
A total of 19 radiation therapists and clinical experts had taken the Clinical Validation Survey. Based off of the survey results, 78.95% of clinicians either Agreed or Strongly Agreed that the RadAR workflow integrates well with the current workflow. 84.21% either Agreed or Strongly Agreed that RadAR has the potential to decrease patient setup time. 84.21% either Agreed or Strongly Agreed that RadAR has the potential to increase patient positioning accuracy and reproducibility. Discussions with the therapists indicated that radiotherapy is moving towards markerless positioning, making our product very relevant. Additional feedback included that patient and accessory identification would be useful additions to RadAR in the future, and that those steps would also integrate well with the current workflow.

47.37% either Agreed or Strongly Agreed, and 42.11% were Neutral about RadAR being more convenient, ergonomic, and easy to use than the current state of the art. Upon further analysis and follow-up discussions, the relatively high Neutral response is due to the longer training time required to get used to the HoloLens. Augmented Reality often requires users to conduct hand gestures to navigate through an app and through the HoloLens home environment. In addition, some therapists suggested we lowered the brightness of the holograms because the high intensity colors and display were too harsh on the eyes.

When asked if the therapists could see themselves using RadAR for patient positioning in the future, 84.21% either Agreed or Strongly Agreed. 84.21% also Agreed or Strongly Agreed that they could see themselves using AR for many applications in the clinic, including collision detection, treatment planning, and reducing patient anxiety. Many physicians taking the survey had expressed interest in using RadAR during patient consultations. They explained that a lot of information is given to the patient in their 30 min consultation appointment, and many of the patients become overwhelmed or forget important information during this stressful time. The physicians emphasized that seeing the treatment room and simulating the treatment from the perspective of a patient lying on the treatment couch would help reduce patient anxiety.

Engineering Flowcharts & Diagrams

Overall Technical Flowchart



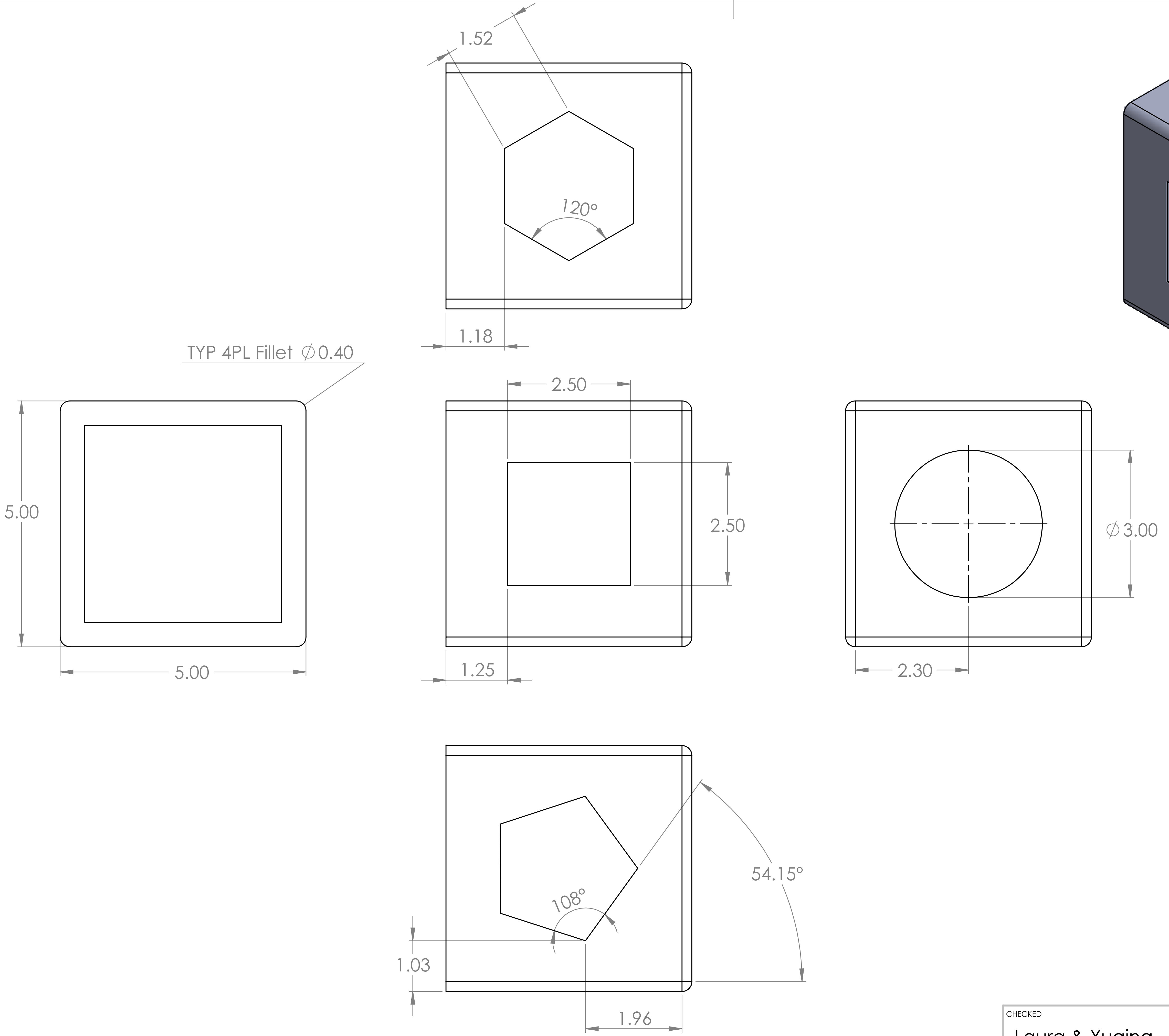
Needs Finding Flow Chart

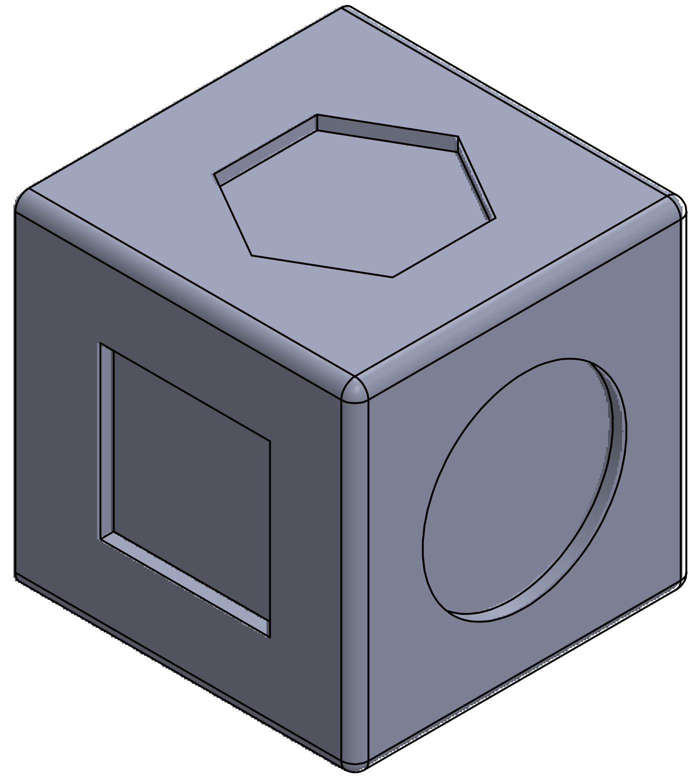
Essential				
Accuracy of Patient Positioning	Integrates with Current Hardware & Software	Reproducibility of Patient Positioning	Verification of Correct Couch/Gantry Position	Verification of Patient Identity

Important				
Cleanable	Verification of Accessory Usage	Affordable	Easy to Operate	Portable

Nice to Have				
Ergonomic	Reusable	Effective Immobilization	Easy to Maintain & Update	Compatible with Most Machine Brands

Not Necessary				
Requires Minimal Training	Long Battery Life	Ease of Patient Setup	Fast Patient Setup	Wireless Transfer of Verification Data





DATE 5/21/2019	REVISION 3
MATERIAL: Polylactic Acid (PLA)	
TITLE: Orange Cube Phantom	
CHECKED Laura & Yuqing	DESIGNERS Janice & Priscilla
All units are in inches unless specified	SCALE:1:2 SHEET 1 OF 1

REFERENCE LIST

[1] A. Fedorov, R. Beichel, J. Kalpathy-Cramer, J. Finet, J.-C. Fillion-Robin, S. Pujol, C. Bauer, D. Jennings, F. Fennessy, M. Sonka, J. Buatti, S. Aylward, J. V. Miller, S. Pieper, and R. Kikinis, "3D Slicer as an image computing platform for the Quantitative Imaging Network," *Magnetic Resonance Imaging*, vol. 30, no. 9, pp. 1323–1341, 2012.
[2] "3D Slicer," *3D Slicer*. [Online]. Available: https://www.slicer.org/. [Accessed: 31-May-2019].
[3] JonMLyons. "Holographic Remoting Player - Mixed Reality." Mixed Reality, Microsoft, 20 Mar. 2018, docs.microsoft.com/en-us/windows/mixed-reality/holographic-remoting-player.

APPENDIX

Terminology

- **Linear Accelerator (linac)** - A system that accelerates high energy x-rays or electrons to conform to a tumor's shape and destroy cancer cells.
- **Couch** - The treatment bed of a linear accelerator machine.
- **Gantry** - The main part of a linear accelerator machine that rotates around the patient. It holds radiation detectors and/or a radiation source that is used to treat patients.
- **Computed Tomography (CT)** - Radiography where a 3D image of a body structure is generated from many cross-sectional images of a patient.
- **Immobilization Devices** - Immobilization Devices are used to keep patients accurately aligned beneath the beam of radiation. For cancers in the head and neck area, a mask would be molded around the head and shoulders. Foam or plastic blocks can also support the patient's body in certain orientations.
- **Accessories** - Includes electron applicators that are added onto a linear accelerator when switching usage to electron therapy. Can also include boluses (a small rounded mass of substance that is used to imitate skin during radiation therapy) and other additional parts that can be used in radiation oncology that are not included under "immobilization devices."
- **BBs** - BBs Skin Markers; used in radiation oncology to identify important points on the image scan of the body.
- **Radiation Therapist** - A member of the radiation oncology department who brings patients to the treatment room and positions patient to match the reference position.
- **Augmented Reality (AR)** - Technology that overlays a computer-generated image (called a *hologram*) on top of the user's view of the real environment around them.
- **Hologram** - A three-dimensional image that is either computer-generated or formed by the interference of light beams.
- **Unity** - A 3D game development environment we use for creating augmented reality applications for HoloLens.

- **Vuforia** - A toolkit add-on to Unity with computer vision capabilities, which allows the app to recognize patterns / image targets
- **Image Target** - An user-specified image defined in Vuforia with a recognizable pattern that holographic content can be attached to
- **3D Slicer** - A DICOM viewing environment capable of contouring and exporting 3D body segments from CT scans
- **Noise (CT scans)** - Artifacts in the CT scan that are inappropriately marking things radiopaque

Treatment Workflow

1. Patient receives a *planning CT*.
    a. According to the oncologist's directions, the patient lies on the couch in a certain orientation. Therapists construct *immobilization devices* to help keep the patient in position.
    b. In each of the imaging and treatment rooms, there is a universal laser system that produces cross-hairs on the patient's skin or immobilization device. The patient's exact position is recorded by putting tattoos the size of a freckle on these cross-hairs. Come treatment time, aligning the tattoos with the lasers will ensure the patient is in the same position as during the planning CT. It is important that the patient's exact position on the couch is reproducible because the location where the linac irradiates during treatment will be determined by the patient's spatial alignment from this initial scan.
    c. Scan the patient to get CT images of the tumor and surrounding internal body structures.
2. Oncologists and dosimetrists plan where to irradiate.
    a. From the CT scans, a dosimetrist will identify cancerous tissue and plan the treatment by defining the shape and angle of the radiation beam. With the aid of computer software, dosimetrists plan for the correct dose of radiation to target cancerous tissue and leave healthy tissue maximally untouched. The *isodose lines* in Figure 6 show the amount of dose various tissues receive. Dosimetrists must also be wary not to create a plan in which a collision between the gantry and the patient or couch can occur.
3. Patients begin their multi-week treatment regime. Each day patients go into the clinic for treatment:
    a. They verify their identity and what body part they are receiving treatment for. This ensures that the correct patient is given the correct treatment.
    b. Patients are aligned on the couch. It is of utmost importance that the patient is accurately positioned on the couch, so when the treatment plan is performed, radiation is administered to the correct location in the patient. Without accurate patient alignment on the couch, radiation would be directed at and damage healthy, non-cancerous tissues. Additionally, the radiotherapy would be ineffective, since the beam won't be focused on the target tissue. The current process for aligning patients can be broken down into three steps.
        i. First, the personalized immobilization devices are placed on the couch/patient, along with any machine accessories prescribed in the treatment plan to help focus the radiation.
        ii. The couch's 6-degrees of freedom (x, y, z, pitch, roll, and yaw) are adjusted, so that markers placed on the patient's body prior to treatment align with reference lasers in the treatment room.
        iii. Images of the patient's current location and reference location are aligned. This image alignment process can be surface guided using cameras in the treatment

room, and/or guided by a new CT scan taken by imaging panels extending off of the linac. The new CT scan is superimposed with the planning CT, and the displacements between the internal body features can be calculated. This is called *co-registering*. The couch is adjusted according to the calculated displacements that were determined during co-registering, and finally, the patient is accurately positioned.

c. The therapist commands the linac to execute the treatment plan.

Clinic Validation Survey

Treatment Workflow

1. CT scan the patient during Simulation
2. Generate holographic body contour of the patient using the CT scan (automated)
3. Therapist wears HoloLens
    a. Scans patient ID barcode (verifies patient identity)
    b. Holographic wall panel displays: patient info, accessories, and treatment plan
4. Therapist superimposes the physical patient with the hologram
5. Fine tune positioning with CBCT
6. Perform radiation treatment

Accuracy of Danny Phantom Positioning

Purpose: Ensure the accuracy of RT superimposing the phantom and the patient.

Test Procedure:

1. Superimpose the hologram and the Danny Phantom.
2. Check if the BBs on the Danny Phantom matches with the laser crosshairs.
3. Record distances between the BBs and the laser crosshairs.
4. Repeat the same procedure two more times.

Please answer the following questions.

Question 1: The RadAR Treatment Workflow integrates well with the current workflow.

Strongly Disagree   Disagree   Neutral   Agree   Strongly Agree

Question 2: RadAR has the potential to decrease patient setup time.

Strongly Disagree   Disagree   Neutral   Agree   Strongly Agree

Question 3: RadAR has the potential to increase patient positioning accuracy and reproducibility.

Strongly Disagree   Disagree   Neutral   Agree   Strongly Agree

Question 4: RadAR is more convenient, ergonomic, and easy to use than the current state of the art.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Question 5: I can see myself using RadAR for patient positioning in the future.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Question 6: I can see myself using AR technology within the clinic for additional purposes such as collision detection, treatment planning, and reducing patient anxiety.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Entire Device Verification Procedures

We will verify the entire device in this section. These tests include testing for weight, frames per second, reference position accuracy, range of QR code registration, warm-up time, battery life, and QC (Quality Check) time. For certain device metrics (cost, camera resolution), we will be referring to the specifications of the Microsoft HoloLens, and this information will be recorded in Table 3. These table values can then be compared with the ideal values in the EDS table for verification purposes. The remaining software-related tests will be detailed to ensure that individual components of our software meets the standards of the software in the field.

Specifications Obtained from Microsoft

Metric	Units	Value
Cost	USD ($)	3,000 USD
Camera Resolution	Pixel (px)	720 (1268x720) px

Weight

Purpose: Ensure that our HoloLens device is not too heavy for the user to use.

Test Procedure:

1. Zero a scale.
2. Place the HoloLens device on a scale and record the weight.
3. Repeat with at least two more trials and average the results.

Frames per Second

Purpose: Ensure that our HoloLens device is able to produce smooth holographic images.

Test Procedure:

1. Open one of our Unity projects that displays a hologram.
2. On the HoloLens, open the Holographic Remoting Player app and say “enable diagnostics.”
3. Record the FPS number listed.
4. Switch to a second Unity project that displays a hologram. Repeat steps 2-3. Repeat this step with a third Unity project if available.
5. Switch to a second computer and repeat steps 1-3. Repeat this step with a third computer.

6. On one computer, repeat steps 1-3 on a second WiFi network. Repeat this step with a third WiFi network.

Note: This test was generated with the knowledge that the FPS can change depending on [3]:

- *The complexity of the Unity project*
- *Your PC computer's graphics card*
- *The speed of the WiFi connection*

<u>Reference Position Accuracy</u>

Purpose: Ensure that our software leads to accurate positioning.

Test Procedure:

1. Outline an object onto a paper "couch."
2. Remove the object.
3. Use the HoloLens to display a holographic image of the object onto the "couch."
4. Outline the placement of the holographic object.
5. Use ImageJ (an image processing program) to quantify the displacement of the actual and holographic object outlines in units of surface area.

<u>Range of Image Target Registration</u>

Purpose: Ensure that our device is able to register the image targets at a reasonable range away from the treatment couch.

Test Procedure:

1. Stand on the side of the couch length.
2. Using HoloLens and making sure the patient hologram is displayed, walk further from the couch until the hologram is not displayed anymore.
3. Record the distance from the user to the couch.
4. Repeat steps 2-3 but on the side of the couch width.
5. Using these two values, calculate the range of image target registration. This will be the maximum range of image target registration.
6. Repeat steps 1-5, but instead of walking away from the couch, the user will walk as close as possible to the image targets until the codes can not be read anymore, and the hologram is not displayed anymore. This will be the minimum range of image target registration.

<u>Warm Up Time</u>

Purpose: Ensure the device warm up time is within the expected range.

Test Procedure:

1. Turn on the Hololens and start timing immediately after the power button is pressed.
2. After the home menu shows up, open up an application.
3. Stop timing after the application is fully opened.
4. Repeat this procedure two more times.

<u>Battery Life</u>

Purpose: Ensure that our HoloLens device will last long enough for usage in the clinical setting.

Test Procedure:

1. Charge the HoloLens to full battery.
2. Open our software app on the HoloLens.
3. Let it stay open and check on the device to ensure it did not go into sleep mode.
4. When it turns off, note the time it took to get to that point.

5. Attempt to turn on the device to check if the shut-down had occured due to zero battery. If it was, then keep the recorded value. If it was not, then redo this whole procedure.
6. Repeat steps 1-5 a second time. If time permits, repeat it a third time.

Engineering Design Specifications (Updated)

Metric #	Metric	Units	Value Range	Ideal Value
1	Weight	lb	1.2 - 35 lb	< 3 lb
2	Cost	USD ($)	$300 - 1,000	< $500
3	Frames per Second	Frames/Second	10 - 120 frames/sec	60 fps
4	Reference Position Accuracy	mm	0.5 - 3 mm	< 5 mm
5	Range of Image Target Registration	mm	100 - 5,000 mm	<500 mm & >2,000 mm
6	Warm-up time	mins	1 - 45 mins	< 30 mins
7	Battery Life	hr	2 - 8 hrs	> 2.5 hrs