C-HOLO

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

PROGRESS REPORT #3

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BACKGROUND

Problem

Radiation therapy is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors. A typical patient treatment plan requires patients to come in to the clinic 5 days a week for a period of 2-10 weeks. When a patient is first diagnosed, a CT Simulation scan is performed. Proper positioning of the patient is determined during the Simulation process, and the resulting CT scan is used for treatment planning. Accessories and equipment such as immobilization devices are also used to help keep the patient still. Everyday before radiation is administered, a radiation therapist must perform a patient setup process in which the patient is carefully positioned on the treatment couch. The goal is to exactly replicate the positioning and setup of the patient during 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. When last minute schedule changes occur, accidentally administering the wrong treatment plan to the wrong patient would result in inaccurate dosing and hazardous excess radiation exposure to the patient. Additionally, there is currently no way to document the use of the immobilization devices. Each patient setup requires about 2-5 unique devices, and therapists are responsible for quickly switching these devices in and out between treatments. Therapists currently must rely on their memory and shorthand notes on the patient's file, leaving room for human error especially in this tight 15 minute window.

Most importantly, patient positioning and motion management is one of 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, it is essential for patients to be positioned exactly like the Simulation setup each and every time. There are two phases of positioning each day: Initial Positioning and Final Positioning. For Initial Positioning, therapists currently align patients to roughly the correct position using a laser alignment system and tattoos; however, these lasers are often difficult to see and objects can get in the way of the laser projections. For Final Positioning, X-Rays are used to fine-tune patient positioning; however, these images expose the patient to excess radiation. Some clinics currently use surface alignment systems to help fine-tune positioning; however, the existing devices are cumbersome to use since the therapist must constantly look back and forth between the computer monitor and the patient. Current devices also have resolution issues, and their cameras often have difficulties determining the distance between themselves and the patient surface in situations where the patient's skin has slight discoloration due to radiation treatments.

Objective

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.

For the purpose of completing this project within the span of Senior Design, we have decided to narrow the scope of this project and focus mainly on patient positioning. Due to feasibility concerns, we will only address the Initial Positioning phase of the patient setup process for now. The fine-precision necessary for the Final Positioning phase will be implemented in future C-HOLO device generations. Verification of patient identity and accessory/equipment usage will also only be implemented during this Senior Design project if time permits.

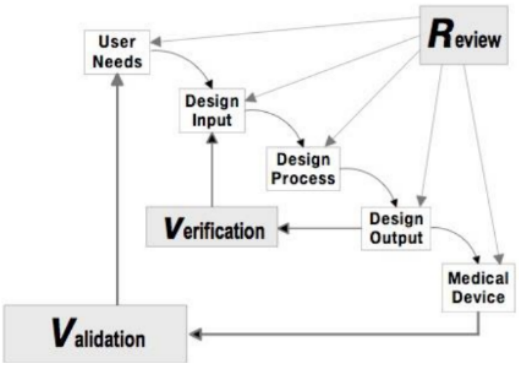

Figure 1: Waterfall Design Process [I1]

The United States Food and Drug Administration (FDA) designed the Quality System Regulation 21 CFR Part 820 in order to guide and regulate the design and production of medical devices. 21 CFR Part 820 mentions two important design controls needed in the development process: verification and validation. According to the FDA, **Verification** is the "confirmation by objective evidence that the design output meets the design input," while **Validation** means "establishing by objective evidence that specifications (specified requirements) conform with user needs and intended use(s)" [1]. These two design controls, along with others, illustrate the medical device design process in the "waterfall design process" shown in Figure 1. Verification and Validation help create a closing loop in the waterfall design process to ensure that our result matches our design input and user needs, respectively.

Before developing our verification and validation plans, we first had to investigate recognized standards for creating medical devices. The FDA has a recognized body called the American National Standards Institute (ANSI), whose mission is to improve the lives of those living in the U.S. by facilitating consensus standards [2]. There are also international bodies that create worldwide consensus standards, such as ASTM (American Society for Testing and Materials) International and the International Organization for Standardization (ISO). Once we searched through the databases of these standard-setting bodies and found some applicable standards for our project, we were able to focus our verification and validation plans. For additional guidance on our plans, we will be referring to our Engineering Design Specifications (EDS) table and User Needs chart from our Progress Report 1, as shown in the Appendix's *Original Tables* section. Since our project involves modifying software and not making a physical device, our Progress Report 1 EDS table will be modified to fit our project. The updated EDS table is shown in Table 1 below. In Table 2, we display the portion of the User Needs that we will focus on.

Table 1: Engineering Design Specifications (Updated)

Metric #	Metric	Needs	Units	Value Range	Ideal Value
1	Weight	A1, A2, C1, D1, D2	lb	1.2 - 35 lb	< 3 lb
2	Cost	A4, B4, B5, C4, C5, D4	USD ($)	$300 - 1000	< $500
3	Frames per Second	A3, A4, D4	Frames/Second	10 - 120 frames/sec	60 frames/ sec
4	Reference Position Accuracy	A3, A4, A5, B2, B3	mm	0.5 - 3 mm	< 5 mm
5	Range of QR Code Registration	A3, A4, C1, D2	mm	100 - 5000 mm	<500mm & >2000mm
6	Warm-up time	A1, A2, C3	mins	1 - 45 mins	< 30 mins
7	Battery Life	A2, B5, C1, C5, D2	hr	2 - 8 hrs	> 2.5 hrs
8	QC (Quality Check) Time	A1, B4, D2, D5	mins	5 - 60 mins	< 15 mins

Table 2: User Needs Flowchart (Partial)

Essential				
Accuracy of Patient Positioning [A4]	Integrates with Current Hardware & Software [D4]	Reproducibility of Patient Positioning [A3]	Verification of Correct Couch/Gantry Position [B2]	Verification of Patient Identity [B1]

Important				
Cleanable [C2]	Verification of Accessory Usage [B3]	Affordable [C4]	Easy to Operate [D2]	Portable [C1]

Consensus Standards

To find consensus standards to follow, we looked into the databases of ANSI, ASTM International, and the International Organization for Standardization. Since our project is software-based, we focused on looking for standards that applied to parts of our software, such as imaging and optical tracking. In addition, since our project is considered a medical device, it was important to identify medical device standards.

Software-based Standards

We counted software-based standards as any standard that was related to the programs and information used by our computers. By following these standards, we will ensure that our programs follow the recognized formatting and procedures used by other medical device software of the same focus. Such standards are listed below.

ANSI/AAMI/IEC 62304: Medical Device Software - Software Life Cycle Processes [3]

This standard details the requirements for the life cycle of medical device software. This will ensure that we properly develop our software. Phases of this development life cycle include analysis, design, implementation, testing, release, and maintenance.

ASTM E2807 - 11(2019): Standard Specification for 3D Imaging Data Exchange, Version 1.0 [4]

This standard details the data file exchange format for 3D imaging data. This will ensure proper data interoperability and that our project can properly read in and store 3D imaging data as other similar devices do.

ASTM 2919 - 14: Standard Test Method for Evaluating the Performance of Systems that Measure Static, Six Degrees of Freedom (6DOF), Pose [5]

This standard details the test methods, metrics, and procedures needed to collect and analyze data in order to determine the performance of a rigid body pose measurement system. This will ensure that our HoloLens software, which will be used to measure and analyze data on the performance of a rigid body, performs correctly and is properly tested for.

ASTM E3064 - 16: Standard Test Method for Evaluating the Performance of Optical Tracking Systems that Measure Six Degrees of Freedom (6DOF) Pose [6]

This standard details a set of metrics and testing procedures to use when analyzing optical tracking system performance. This will ensure that we can properly test the performance of our HoloLens, which will be used to optically track patient positioning.

Medical Device Standards

Since our project is a medical device, we looked into general medical device standards. This would help us ensure that our product follows medical device testing regulations and is monitored appropriately. Such standards are listed below.

ANSI/AAMI/ISO 14971 : 2000: Medical devices - Application of risk management to medical devices [7]

This standard details a process to identify medical device hazards in order to identify, evaluate, and control these risks. This will ensure that we can correctly identify ways that our software can cause harm, so we can properly find an appropriate mitigation or prevention method.

ANSI/AAMI/ISO 13485: Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes [8]

This standard details the requirements of a quality management system for an organization's medical device. It ensures that our team can develop a device that consistently meets user and regulatory requirements.

Verification

The verification process will consist of individual component verification and entire device verification. For individual component verification, we will be testing the sub-functionalities of our software program. The sub-functionalities, or software features, are the building blocks to the overall software program. Unit tests will be created for each of these features so that they can be tested individually. This aids in identifying bugs along our program's workflow, and the passing of the tests is critical for overall program functionality.

In entire device verification, we will be testing the device's overall functionality by ensuring that our device meets our design metrics listed in the EDS table (Table 1). However, some of our metrics are hard to test for due to the risk of damaging our HoloLens device, or they are outside the scope of our project. Therefore, in order to complete entire device verification on such metrics, we will utilize and analyze the specifications listed by Microsoft on their HoloLens device.

Individual Component Verification

We will verify the individual components (software features) in this section. These components include registering the QR codes, displaying the patient hologram, aligning a hologram to the QR codes on the couch, and having the hologram glow green when perfectly aligned with a real-life object. These tests will be detailed below and each will have a pass or no-pass result.

Some tests require the use of an anthropomorphic phantom. This phantom is a plastic mannequin that closely resembles the human form. Our team has already CT scanned this phantom at the UC Davis Medical Center to generate its corresponding holographic image. The phantom in the following testing procedures is referred to as "Danny Phantom." Radio-opaque markers, or BBs, may also be required. These are stickers with a small metal center that show up on CT scans.

<u>Registering QR Codes</u>

Purpose: Ensure our device can "see" the QR codes at reasonable angles and distances.
Test Procedure:

1. Attach a cube object to a QR code target in Unity. Deploy test to HoloLens.
2. Hold an QR code target 0.3 meters away from the HoloLens at an angle 0° above the horizontal.
3. Slowly rotate the QR code target to face the HoloLens. Record the angle at which the cube hologram becomes visible.
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. Measure the distance between BB (radio-opaque) markers on Danny Phantom (our plastic mannequin).
2. Convert Danny Phantom's CT scan into a hologram.
3. Deploy hologram to HoloLens.
4. While keeping the HoloLens stationary, mark the locations of the hologram BBs on a real piece of paper.
5. Measure the distance between the BBs on the paper.
6. Compare with the measured distance between BBs on Danny Phantom. Check for equality.

Aligning a Hologram to the QR Codes
Purpose: Ensure that holograms are placed in reference to the QR codes as intended.
Test Procedure:

1. Create a cube in unity, and displace 0.15 meters from a QR code target.
2. Deploy test to HoloLens.
3. Mark the holographic cube's displacement from the QR code target.
4. Measure and verify the displacement equals 0.15 meters.

Green Glow Indicator
Purpose: Ensure the model hologram glows green only when the real-life object is sufficiently aligned with the hologram.
Test Procedure:

1. In Unity, attach Danny Phantom's hologram to a QR code target. Enable the green glow indicator.
2. Deploy test to HoloLens.
3. Gaze at the QR code target. Danny Phantom's hologram will appear.
4. Partially align Danny Phantom to her hologram. Verify no green glow occurs.
5. Repeat #4 with different orientations of partial alignment.
6. Align Danny Phantom within a few millimeter margin with her hologram. Verify the green glow occurs.

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 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.

Table 3: Specifications Obtained from Microsoft

Metric #	Metric	Units	Value
2	Cost	USD ($)	3000[11] USD
4	Camera Resolution	Pixel (px)	720 (1268x720)[12] 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 [13]:
   - *The complexity of the Unity project*
   - *Your 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 QR Code Registration

Purpose: Ensure that our device is able to register the QR codes 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 QR code registration. This will be the maximum range of QR code registration.
6. Repeat steps 1-5, but instead of walking away from the couch, the user will walk as close as possible to the QR codes until the codes can not be read anymore, and the hologram is not displayed anymore. This will be the minimum range of QR code 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.

Battery Life

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.

QC (Quality Check) Time

Purpose: Ensure that users can confirm the software is working properly in an efficient time frame.
Test Procedure:

1. Have a team member run through each test listed above, but only doing one trial of each.
2. Record the total time it took to do all the tests.
3. Have another team member repeat steps 1-2. Repeat until all team members have done this.

Validation

Once our software is working, we will conduct our validation tests to ensure that our software continuously fulfills our user requirements. We will give the HoloLens to a radiation therapist to test with Danny Phantom, and the therapists will receive an evaluation form at the end of their usage test. This evaluation form will indicate how well our product fulfills the User Needs in Table 2.

Qualitative Validation

A radiation therapist (RT) will practice positioning Danny Phantom, our anthropomorphic phantom, in this validation procedure. Using the HoloLens and our software application, the RT will perform the patient setup workflow from start to finish and evaluate their experiences in a survey.

Patient Setup Workflow

Purpose: Ensure that daily positioning using our device is able to be realistically implemented in the radiation oncology clinic.
Test Procedure:

1. The RT puts on the HoloLens and starts up the hologram application.
2. RT scans Danny Phantom's ID barcode.
3. RT gazes at the treatment couch and Danny Phantom's hologram appears.
4. RT aligns Danny Phantom with the hologram by sliding and rotating Danny Phantom on the treatment couch.
5. The alignment process stops when the hologram glows green.
6. Ensure the laser crosshairs hit the center of the BB markers on Danny Phantom.

Survey
Purpose: Ensure that the essential user needs identified in Table 2 are met using our Patient Setup Workflow.
Test Procedure:

1. After the whole patient setup workflow process is completed, the RT will fill out an evaluation form from our team. The form will include topics such as:
    a. The accuracy of the positioning
    b. The reproducibility of patient positioning
    c. The ease of use and integration with their current workflow
    d. Ergonomics of using the HoloLens

Training
Purpose: Ensure that our software is easy enough for someone without experience with HoloLens to use and place an object.
Test Procedure:

1. Select a volunteer. Note if they have had interaction with the HoloLens before.
2. Tell them to place an object on the couch.
3. Teach them to turn on the HoloLens and display the holographic image of the object onto the couch.
4. Teach them to superimpose the physical object with the holographic image.
5. Teach them to turn off the application and HoloLens.
6. Ask the volunteer to do this procedure by memory the next day and provide help and more training if they are stuck. Repeat until they remember the procedure fully without help. Note the number of days it took for them to fully remember the procedure.
7. Repeat steps 1-6 for at least two more volunteers.

Quantitative Validation
Quantitative validation tests will be performed to provide numerical quantities of patient position accuracy during use in the radiation oncology clinic. To quantify the accuracy of positioning, two methods were created to confirm that the HoloLens and our software are able to align patients to the acceptable tolerances of less than 5mm.

Accuracy of Danny Phantom Positioning
Purpose: Ensure the accuracy of RT superimposing the phantom and the patient.
Test Procedure:
Method 1:

1. Superimpose the hologram and the Danny Phantom.
2. Check if the BBs on the Danny Phantom matches with the laser crosslines.

3. Record distances between the BBs and the laser crosslines.
4. Repeat the same procedure two more times.

Method 2:

1. Place BBs on the QR codes on the treatment couch.
2. CT scan Danny Phantom (and BBs on the couch)
3. Overlay the original CT scan and current CT scan.
4. Using ImageJ, calculate the difference in surface area misaligned.

Large Scale Validation

For this project, our focus was towards human patient positioning. Therefore, we would eventually need to conduct human testing through clinical trials, which is important for validation testing. However, animal testing in at least two different species must be conducted, an Investigational Device Exemption (IDE) must be received, and an approval from the Institutional Review Board (IRB) must be acquired before clinical trials can begin [15, 16]. Once these approvals are achieved, we would conduct our large scale validation.

Statistical Analysis

After a pilot study with 5 people is performed, the G*power suite [14] software tool will be utilized to determine the power and sample size required to fully validate our product. Our pilot study will provide data on standard deviation and error, which are necessary metrics for the sample size calculation. With the determination of sample size, we will recruit the necessary number of volunteers from the UC Davis Medical Center, as well as STEM peers (as they have a relatively similar educational background to radiation therapists), to use our application in the Quantitative Validation procedure.

Data will additionally be collected on current positioning methods to statistically evaluate our patient positioning accuracy compared to existing state of the art methods. Study volunteers will position Danny Phantom using VisionRT's AlignRT. Then a CT scan will be taken and the surface area of misalignment compared to Danny's original CT scan will be calculated using ImageJ. After both sets of data are collected from positioning with our application and with an existing third party application, a t-test will be performed to determine if our positioning system is significantly more effective.

PRELIMINARY HAZARDS ANALYSIS

A Failure Mode and Effect Analysis (FMEA) is a procedure to evaluate potential failure modes to determine their effect on the system. Our FMEA table is represented in Table 4 below. We identified failure modes systematically, by critically analyzing each step of the user workflow and considering the software components involved at each step. A failure happens when an object does not fulfill its requirement and a failure mode describes the event of failure being observed. The level of concern of each failure mode can be classified based on the risk priority number which is the product of severity, occurrence, and detection factors (these three factors are ranked in a scale from 1 to 10). *Severity* (1 = no clinical effect, 10 = catastrophic) is one of the consequences of a failure mode and it takes into account the degree of harm in a failure. A severity level of 1 means that the patient or physician expectation is not met, and a severity level of 10 means that failure will lead to patient death or permanent disability.

The *frequency of occurrence* (1 = improbable, 10 = frequent) is the probability of the device failing, and *detection* (1 = control is certain to detect the problem, 10 = control is certain not to detect the problem) is how likely the failure is to be detected. The *risk priority number* can be divided into three categories where:

a. Values of 1 - 20 (color coded purple) indicate that the overall risk is broadly acceptable, and no action is required.
b. Values of 21 - 40 (color coded yellow) means that the risk is as low as reasonably possible, and some actions are required to improve the device.
c. Values of 40 and up (color coded red) means that the risk is intolerable, and immediate actions are needed to control the risk.

Table 4: FMEA Table

Process	Failure Mode	Effects of Failure	Severity (1-10)	Potential Causes	Current Prevention Controls	Occurrence (1-10)	Current Detection Controls	Detection (1-10)	Risk Priority Number	Recommended Actions
Software	Inacurate Patient Barcode Registration	The scanned barcode brings up the wrong patient information / holograms.	6	Patient barcode and information aren't correctly matched in the database. Wrong patient information is put under patient's name.	Patient holograms is entered into the database at the same time as each patient's specific barcode. The therapist cannot accidentally click the wrong patient.	2	Therapists perform a visual sanity check that the patient looks similar to the associated hologram.	1	12	Tag holograms with patient identifiable information to provide a more obvious method to visually confirm patients match their data.
	Inacurate Verifcation Notification	The thereapist is notified with a green glow of sufficiently accurate patient alignment prior to this actually being true.	6	Low accuracy of HoloLens spatial mapping.	Time delay of green glow from onset of accurate alignment allows HoloLens to confirm positioning over multiple timepoints and bars an outlier alignment notification.	2	Therapists will verify positing with a CT scan at the final patient positioning phase.	2	24	Only use hololens for inital patient setup, and use CT imaging to fine-tune setup prior to beam-on.
Hardware	Battery Runs Out	When battery runs out in the middle of patient positioning, patient might be positioned inaccurately and the positioning needs to be paused until the Hololens is charged.	1	The battery is not powerful enough to support a long period of use.	Between each patient is treated, therapists will charge the Hololens.	4	Before the therapists treat the patient, they can check the battery percentage of the Hololens.	2	8	The hololens can be charged overnight and during the period in between treating patients.
	Immobolization or Sheets Covering The QR Code	Immobolization devices or sheets might cover the QR code. Hololens can not recognize the QR and place the holograms.	1	The immobolization devices and sheets are not transparent and they block the QR code.	Use transparent plastic sheets or don't use sheets.	7	By estimating the distance between the QR codes and the immolization devices, the therapist look at the QR codes to avoid covering them.	1	7	Use transparent sheets or place more QR codes so QR codes can be recognize easily.
Device Setup	Therapist Can't Produce The Right Gesture to Use the HoloLens	Therapist will take more time to use the device and make appointment time longer.	1	Therapists have trouble gesturing and it will make each treatment appointment longer.	Therapists go through training so that they can master gesturing for Hololens.	1	Therapists are asked to use gestures to open the software on Hololens as a way to detect if they can gesture for Hololens properly.	1	1	Have therapists go through trainings to learn and practice on using the Hololens through gesturing.
User Operation	Dizziness Caused by Wearing Hololens	Hololens is recommended to be wore for 30 minutes period. Staring at AR devices for a long time can cause discomfort.	2	Defect of the AR technology.	Therapists take periodic break when using the Hololens.	2	Therapists wear the Hololens for a period of time to see if discomfort symptoms that come up.	1	4	Therapists take break in between treating each patient and set the Hololens aside when charging it.
	Skipped Steps in The Workflow	When therapists skip part of the workflow (e.g. patient identity verification), our program might not recgonize that on its own and program might crash.	1	Program is designed to have step by step workflow.	Therapist needs to check boxes to confirm their steps.	2	Therapist performs a visual sanity check on materials displayed on the Hololens.	2	4	Have checkbox for therapists to check off tasks that they have done.

Based on our risk priority number, most of our failure modes fall in the purple range, meaning that the overall risk is broadly acceptable. The failure mode with the highest risk priority number is the *inaccurate verification notification*, it is in the yellow color range meaning that risk is as low as reasonably possible, so we will work on improving the accuracy of verification notification. The precautions can primarily be implemented on the software side, and the limits of use can primarily be implemented in terms of the therapists' workflow. In our program, we will require therapists to intentionally confirm each step of the workflow; they will not be able to jump to future steps without confirming the steps beforehand. Given more time, we would implement facial recognition into patient ID verification to provide an extra layer of protection.

For the patient positioning aspect, we are implementing a system that relies on many QR codes in order to allow detection and hologram placement even if some QR codes are covered by the patient, immobilization devices, or the hospital sheet. Additionally, a plan to prevent mis-notification is to implement a green glow that notifies the

user of successful overlay of the patient and the hologram. As for the workflow, the therapists should only use the HoloLens for initial patient setup and still use CT scans for fine-tuning positioning. It is recommended that therapists also make a habit of charging the HoloLens when not in use to ensure the battery power is sufficient.

SOCIETAL IMPACT

Value Proposition

Current initial-positioning techniques have limited accuracy and are time expensive. One such technique is the utilization of a laser alignment system, which is standard practice for initial positioning. 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 region with tattoos, and the therapist would not know. Our program provides a visual reference of the patient body during the initial setup process, which allows for more accuracy in initial positioning. Reducing the number of modifications needed to be made during the fine-tuning phase would ultimately decrease total treatment setup time. Existing third-party patient positioning solutions that perform positioning on a large portion of the body, require a therapist to look back and forth across the room at a monitor and at the patient to determine what position adjustments need to be made. Therapists must also transform the information on the monitor to map it to the patient's orientation on the couch. If the patient on the monitor were oriented ninety degrees from the patient on the couch, then each adjustment indicated on the monitor would have to be transformed ninety degrees in the therapist's head to apply it to the real patient. Our program offers an ergonomic solution. With our utilization of Microsoft HoloLens, this back-and-forth does not need to exist. 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.

The HoloLens and our software program provides a high return on investment. In terms of cost, existing positioning solutions are expensive and have a limited lifetime. Referencing our benchmarking table in Progress Report 1, AlignRT, a surface-guided system using external cameras, and similar products are on the order of $200,000 up-front and an additional $25,000 per year[17]. Compared to third-party patient positioning systems and a hospital's budget, our device has a relatively small up-front investment: the HoloLens costs $3,000. Apart from the man-hours associated with uploading patient data to our program and periodic quality assurance, there are no recurring costs associated with our device. 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. A key reason for why our device has such an impressive lifetime is because it does not remain in the treatment room during treatment. It is only used for initial positioning before the linear accelerator is turned on, which lends itself protection from radiation that many existing positioning techniques are subject to.

Ethical Considerations

Our device would likely be classified as a Class II medical device. Class II devices have a greater risk to patients and require more regulatory control than Class I devices, which causes minimal harm to the user and has the least amount of regulatory control. Our device serves as a helpful function in positioning patients for radiation therapy, but as it is only used for initial positioning, it does not pose the risk of improper irradiation of the patient if it were to fail. The only foreseeable medical side effects of use would be on the therapist wearing the HoloLens. The therapist could cut off some blood circulation if they wear the head strap on the HoloLens too tight, which can cause a headache. Additionally, the augmented reality experience itself can cause headaches if the user experiences them for an extended, continuous period. Because the HoloLens is expected to be used for approximately 5 minutes at a time during patient setup, we do not expect headaches to be an issue and recommend that therapists take occasional breaks. Verification and validation testing can be done without actual patient interaction by using

plastic objects and mannequins, thus there is no potential harm to patients. Potentially the largest ethical concern associated with our device is regarding privacy. Our device relies on accessing patient data and functions to display that data. At a minimum, we need access to patient CT scans, as this is what we decided to use as the basis for generating the patient model holograms. The typical DICOM file format used to store CT scans contains identifiable patient information. Future iterations of our device would display patient information to the therapist and include facial recognition to verify the identity of the patient. Turning each patient's data into a usable format and uploading it to the HoloLens application means that there will be a lot of movement of sensitive data which will be stored on the HoloLens. Regulations associated with the Health Insurance Portability and Accountability Act will need to be considered and patient data be securely locked. The question remains, however, if patients will be okay with the implementation of facial recognition software. All other data required for our application is already obtained as part of the treatment workflow. Storing data on a patient's facial features would be new data, so this would require additional patient consent.

Green Engineering

A product's life cycle follows: design → manufacture → use → retire. Since the HoloLens is developed by Microsoft, our design phase primarily used software programs as resources, which have no direct material waste or carbon footprint on the environment. In making our product available in the radiation therapy market, we would make our product available for installation. Depending on the chosen mode of delivery, the installation can be downloaded over the internet, meaning there would be no waste involved with the packaging of our product. The only waste directly associated with using our device includes the electricity used to charge the battery and perhaps microfiber towelettes used to wipe down the HoloLens' lenses for sterilization. Many different applications can be run on the HoloLens, so the HoloLens itself is reusable, which minimizes hospital costs and manufacturing wastes. Additionally, our device can be reused for many patients without the use of more materials. New generations of our software can also be uploaded directly onto the HoloLens clinics had been using before. When the original HoloLens retires, it can be repurposed to serving other areas of the hospital, and used as an educational tool for patients, for example, to ease anxieties and provide them expectations for the treatment.

Regulatory Path

There exists multiple uses of augmented reality as medical teaching tools and surgical planning tools. We would most likely obtain 510(k) approval to bring our product to market, with a predicate device: Novarad's OpenSight. OpenSight received Class II medical device classification and 510(k) pre-market notification approval, numbered K172418 [9]. OpenSight software overlays holograms of imaging data, such as CT scans, onto the actual patient using Microsoft's HoloLens. Our product would most likely be similarly classified as a Class II medical device, as it also uses Microsoft's HoloLens with the goal of getting the patient superimposed with their hologram. Additionally, our product remains outside the body and it is a tool for initial patient setup. It is not intended for use in fine-tuned patient positioning (final patient setup). We also would need to prove that our device is substantially equivalent in order to get a 510(k) premarket notification. However, if we were not able to obtain 510(k) approval, we would have to apply for premarket approval (PMA). With PMA, an Investigational Device Exemption (IDE) would be needed to perform clinical trials and collect data [16]. Before we could use the device in the human clinic, we would need perform animal testing and gain approval from the Institutional review board (IRB) [17]. We would be able to conduct the animal trials at the UC Davis Veterinary Center because the radiation treatment workflow for animals would be similar to the clinical workflows at the UC Davis Medical Center. In order to continue past animal trials, there would need to be substantial evidence of safety and effectiveness [10].

CONSULTATION WITH INNOVATION ACCESS

Our team is working in collaboration with Varian Medical Systems and we had already connected Varian Medical Systems with UC Davis legal representatives during Fall quarter 2018. We have signed an Intellectual Property (IP) agreement and it is titled *Memorandum of Understanding for sponsorship of Capstone Design Classes at UC Davis' College of Engineering.* The document is signed by John Van Heteren (Director of Applied Research), Anthony Passerini (Faculty Supervisor), Alyssa Panitch (Department Chair), and all the members of Team 11 (Priscilla Chan, Yuqing (Hailey) Huang, Janice Leung, and Laura Oelsner). We met with Dr. William Tucker, an innovation access representative, on April 17, 2019 to discuss the process for filing a patent, what details of our project we are allowed to present to faculty and other students, and what aspects we must keep confidential (meeting notes can be found in the Appendix).

Since we signed an IP agreement and Varian Medical Systems owns the IP of this project, we are awaiting feedback from our client about the materials we are authorized to present to the public. We had also asked our client whether or not they were interested in filing a patent on our technology. Our team plans to send an outline of future poster and presentations we create to Varian before presenting them to the College of Engineering Showcase. Moreover, we have been permitted to discuss this project on our resumes and to future recruiters; however, we will need to use general terms and generic statements in our descriptions. For future project development after the quarter ends, we plan on discussing our ideas with Varian Medical Systems to see if there might be opportunities to continue working with them on this technology.

APPENDIX

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Image References

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Terminologies

- **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.
- **Quick Response (QR) Code** - A barcode with a matrix of dots that can be converted into numbers or a string of characters. This barcode can be scanned with a QR scanner or a smartphone with a built-in camera to retrieve the data stored on it.

Original Tables

Engineering Design Specifications (EDS) Table from Progress Report 1

Metric #	Metric	Needs	Units	Value Range	Ideal Value
1	Weight	A1, A2, C1, D1, D2	lb	1.2 - 35 lb	< 3 lb
2	Cost	A4, B4, B5, C4, C5, D4	USD ($)	$300 - 1000	< $500
3	Frames per Second	A3, A4, D4	Frames/Second	10 - 120 frames/sec	60 frames/ sec
4	Camera Resolution	A3, A4, D4	Pixel	1024 x 768 - 1920 x 1080 pixel	1920 x 1080 pixel
5	Reference Position Accuracy	A3, A4, A5, B2, B3	mm	0.5 - 3 mm	< 2 mm
6	Patient Surface Coverage	A3, A4	mm	1000 - 2000 mm	< 1300 mm
7	Patient Verification	B1, B5, D4	Yes/No	Yes or No	Yes
8	Accessory Verification	B3, B5, D4	Yes/No	Yes or No	Yes
9	Training	A2, D2, D3, D4	days	1 - 7 days	< 2.5 days
10	QC (Quality Check) Time	A1, B4, D2, D5	mins	5 - 60 mins	< 15 mins
11	Warm-up time	A1, A2, C3	mins	1 - 45 mins	< 30 mins
12	External Cameras	A3, A4, B5, C4, D5	#	2 - 4 cameras	< 3 cameras
13	Display	A1, A2, B4, B5, C1, D2	Type	Monitor, Glasses, Projector	Projector
14	Battery Life	A2, B5, C1, C5, D2	hr	2 - 8 hrs	> 2.5 hrs
15	Required Sterility	A1, A2, C2, D2, D5	Cleaning Level	Low-level Disinfection - Sterilization	< LLD
16	Warranty	C3, C4, D5	Years	1 - 5 years	1 year

Needs Flowchart from Progress Report 1

Essential				
Accuracy of Patient Positioning [A4]	Integrates with Current Hardware & Software [D4]	Reproducibility of Patient Positioning [A3]	Verification of Correct Couch/Gantry Position [B2]	Verification of Patient Identity [B1]

Important				
Cleanable [C2]	Verification of Accessory Usage [B3]	Affordable [C4]	Easy to Operate [D2]	Portable [C1]

Nice to Have				
Ergonomic [D1]	Reusable [C3]	Effective Immobilization [A5]	Easy to Maintain & Update [D5]	Compatible with Most Machine Brands [B4]

Not Necessary				
Requires Minimal Training [D3]	Long Battery Life [C5]	Ease of Patient Setup [A2]	Fast Patient Setup [A1]	Wireless Transfer of Verification Data [B5]

Clinical Workflow

Treatment Planning

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 (Figure 3).
    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 (Figure 4). 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 (Figure 5). 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 [11].

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 [13].
    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 (see Figure 4).
        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* (Figure 7). 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.

Additional Procedures

Testing Multiple QR codes

Purpose: To ensure that multiple QR codes can be read in by the HoloLens, and can output *one* holographic image of the reference CT scan in the same position at all times.

Test Procedure:

1. Place 4 QR codes on the couch.
2. Place an object at the origin position (where the clinic room's laser crosshairs meet) on the couch.
3. Use HoloLens to display a holographic image of the object on the couch with reference to the QR codes. See if the holographic image is shown properly.
4. Increase the number of QR codes to 8 and repeat steps 2-3.
5. Increase the number of QR codes to 16 and repeat steps 2-3.

Meeting Notes with Innovation Access

BIM 110: Biomedical Engineering Senior Design
Consultation with UC Davis Innovation Access

Please answer the following questions prior to your meeting:

1. Briefly describe the problem you are trying to solve and your proposed design solution.

Our team is collaborating with Varian Medical Systems, who specialize in treating cancer with radiation therapy. For treatment, patients need to go into the clinic every day for 15 minute appointments, and in those 15 minutes, radiation therapists need to efficiently and accurately position the patient on the treatment bed before starting radiation treatment. If the patient isn't accurately positioned, it can lead to radiation hitting healthy tissue instead of cancer cells.

Currently, therapists use a laser alignment system, immobilization devices, and x-rays all to just set up and position the patient on the treatment couch. However, these can take up a lot of time. Therefore, our team's goal is to make use of the Microsoft HoloLens and Augmented Reality to superimpose the patient with a holographic image of where the patient should be positioned in order to help streamline the patient set up process.

2. Briefly describe the technology space from your research on this project. What existing products, patents, benchmarks have you identified?

Note that the products, patents, and benchmarks here are only a few examples of what we have found. This is only a brief description of some of what we have found. More examples are listed on our Progress Report #1.

Existing Products:

AlignRT by VisionRT
Surface guided optical system that visually informs therapists on a monitor what parts of the patient need to be spatially adjusted.

OpenSight by Novarad
FDA "510(k) clearance for use in pre-operative surgical planning" to overlay CT and on medical images onto the patient.

Existing Patents:

Holographic User Interfaces for Medical Procedures
Patent Number US20140282008 A1
The creation of an interactive holographic display system that shows a holographic anatomical image.

Based on our research (a few listed above here, with more listed in Progress Report #1), we came up with some benchmarks to consider as we make our product. These include: weight, cost, camera resolution, reference position accuracy, patient surface coverage, and battery life.

3. How does your proposed solution differ from these other technologies?

Our solution differs from other technologies because it utilizes Augmented Reality (AR) to show positioning data directly overlaid onto the patient. Many current market products require the therapist to remove their gaze from the patient and look at a computer monitor across the room. Additionally, we are addressing cancer patient positioning during radiation treatment, which other AR devices, to our knowledge, do not address. Novarad has FDA approval for *pre*-operative surgical *planning*, but our device is to *position* patients in preparation for their *actual* treatment. Many AR devices help medical staff determine how their *tools* should be oriented in the patient, while our device helps staff orient the *patient*.

4. Who might be interested in your solution? (What populations might it serve? What companies provide similar products?)

Radiooncology clinics will be interested in our solution. Our product serves therapists, medical physicists, and dosimetrists. The OpenSight Augmented Reality System from a company named Novarad provides a similar product. The system is used for preoperative surgical planning. The OpenSight AR system also uses the Microsoft Hololens headset and it allows clinicians to see patient images on top of the actual patient.

5. Have you discussed issues of IP with your client?

Yes, we have. Back in fall quarter, we had already connected Varian Medical Systems with UC Davis, and we already signed an IP agreement. It is titled *Memorandum of Understanding for sponsorship of Capstone Design Classes at UC Davis' College of Engineering.* The document is signed by John Van Heteren (Director of Applied Research), Anthony Passerini (Faculty Supervisor), Alyssa Panitch (Department Chair), and all the members of Team 11 (Priscilla Chan, Yuqing Huang, Janice Leung, and Laura Oelsner).

6. From the *Principals of IP Ownership in Capstone Design Courses* document provided to the class, which category best describes your project/ team?

Category 3 - company originated or funded projects

Document the results of your meeting here:
Timestamp = 10:08 AM - 11:20 AM
Attendees: William (Bill) Tucker, Laura Oelsner, Janice Leung, Priscilla Chan, and Yuqing Huang

Outline of what we talked about:

- We started the meeting with a summary of our project and how our project is different from other state-of-the-art technologies. The way of how we acquire the model is also different from other technologies.

- What claims do we make if we were to file a patent?
    - Our way of using augmented images is different than what's currently there. For the current methods, users move augmented images and our project allows user to move the physical patient instead.
    - Some questions that we can think about are: What is the inventive step? What is unique (the overall system)?
    - It is also important to document the design process and the design process can be guided by the following questions: How did we find preferred solution (x over y)? What did we decide was too complicated/unnecessary to do? What did we improve on?
- We reuse existing tools in our own way. For example, we do research on tools and we combine the tools to create a project to achieve the desired functions.
    - Unique combinations of different tools are protectable by patent laws.

    - How we use a 3D model could be novel if it's not obvious since we use it as a registration guide for treatment. There are no previous input or obvious way to combine existing pieces.
- Comparing the accuracy of our alignment method with existing methods, our method uses whole body positioning as opposed to a couple reference points on part of the body. Our method uses 3D holograms and the current methods uses 2D images.
- Think about how we would use a phantom to do calibrations. In the industry, calibrations are done using phantoms already, there is a potential that our project can help the company with their machines and improve their technology.
- If we want to get patent, we will be talking about a system (with appropriate steps)
    - If our AR is as accurate as the CT scans, we can prob incorporate this into part of the machine since most machines come with the function to take CT scans of patients. We can make the machine less expensive.
- On claim, file as broad as possible and some questions to think about are below:
    - "Perhaps can incorporate this idea into the TrueBeam machine" (Ideas for how our idea can be used). Where else can the project go? How can it be extended? What's next after this project?
    - At the end, we should get feedback from the company on like what did they think about the project and was there anything we should've taken into consideration.
- Patents are usually written broadly so there is room to wiggle and confine ideas. If patent office looks at the application and accepts fast, then we wrote it too narrow. Write all in 1 claim broadly then specify ways to do it.
    - It is good to start broad so that there are still materials left after some contents are selected out. For example, patent lawyer might pick out the top layer or one of the specific ones but we still have more materials left.
    - One thing we could do is to write the patent for placing 3D objects, not just positioning patients on a linac.
- To file patents, the patent can be totally conceptual and the claims and examples don't need to be completed. After submitting the document to the patent office, the office may ask for more data. The first person to file the patent has full possession of the idea so it is always good to file patent early. The worst thing we can do is wait until the project is completed because someone can file ahead of us.

Questions for Dr. Tucker and his answers:

1. **Can we do project relevant work after Senior Design is over?**

    We need to talk with Varian and ask them for feedback on our project to see if there are any future opportunities to work with them or continue with the project.

2. **To what extent we can tell people about our project (on resume, to recruiters, to our designer, on showcases/poster)? To what extent can we ask peers/advisors for software help?**

    We can submit a report or an outline of what we want to talk about to Varian and they will give us feedback on the information that we are going to present. The senior design showcase is a public disclosure and if we disclose before we file, that's a bar to patenting. We want to make sure no one will do what we did with what we disclose. We can put our senior design on our resume but the descriptions will need to be in general terms and generic statements. Instead of talking about the details of what our project is about and how we accomplish tasks, we can talk about the story of teamwork, the technical skills and information about confidential identity that we learned.