# C-HOLO

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

## PROGRESS REPORT #1

*March 7, 2019*


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# PROBLEM FORMULATION

## Background

Cancer refers to cells that have mutations in their DNA, lose their specialized functions, and divide uncontrollably. Concentrated in one area, the cells can form a tumor. Cancer cells can also spread, or metastasize, to other parts of the body, getting in the way of normal functioning cells [1]. In the United States, there is an approximate one in three chance of developing cancer at some point during one's lifetime [2]. Cancer was the second leading cause of death in the United States with over an estimated 1.7 million cases in 2018 [3, 4]. When a patient is diagnosed with cancer, their doctor will discuss various treatment options with them. Surgery, chemotherapy, targeted therapy (specialized chemotherapy), immunotherapy, and radiotherapy are common treatment options [5]. Treatments can use a single or a combination of treatment options. Radiotherapy is used in the majority of treatments [6]. Radiotherapy involves applying radiation to cancer cells, damaging their DNA, and eventually killing them [6]. There are multiple methods of treating cancer using radiotherapy, with the most popular being external beam radiation therapy [7]. Other methods include internal radiotherapy, where radioactive elements are put inside the body, such as via an implant [8].

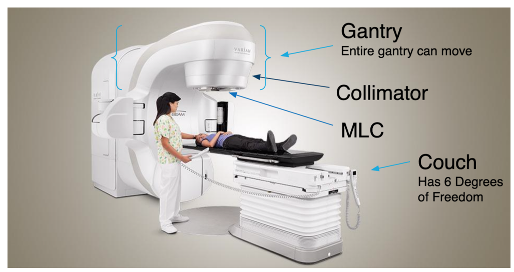



**Figure 1:** Varian Medical System's TrueBeam linear accelerator [IR1]

In external beam radiotherapy, a patient may come in for treatment five days a week for a period of two to ten weeks [9]. Electrons, photons, or protons are directed at the patient by a linear accelerator, or "linac" for short [10, 11]. A linear accelerator is shown in Figure 1. The patient is carefully positioned on the "couch," or the treatment bed, which can be adjusted in space so that the patient is properly aligned with where the radiation beam will be. The radiation beam is directed through the *collimator* (the part of the machine that focuses the beam), and exits through the *multileaf collimator (MLC)*, which shapes the radiation beam to match the shape of the tumor. Figure 2 shows a light projection of the beam exiting the machine. The linac's *gantry,* which is the main body of the linac, can rotate around the patient to deliver radiation from various angles. Given the adjustability of the couch, gantry, and MLC, the radiation beam can be targeted at the cancerous area and away from healthy tissue.

**Figure 2a:** CIAO. Complete Irradiation Area Outline (Gold) [IR2].

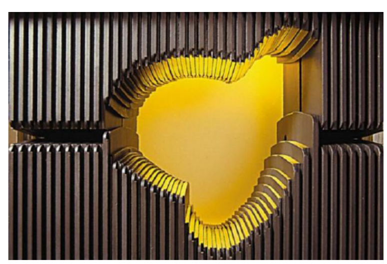


**Figure 2b:** Multi-leaf Collimator (MLC) [IR3].

However, before external beam radiation treatment can begin, many steps must take place in preparation. Personalized *immobilization devices* are constructed to help keep the patient still and ensure reproducibility of positioning during all imaging and treatment sessions  (Figure 3). Additionally, tattoos are placed on the patient's skin or immobilization device to be used as reference markers for a laser alignment system that is present in imaging and treatment rooms (Figure 4). Then, the patient will  get a preparatory CT (computed tomography) scan.

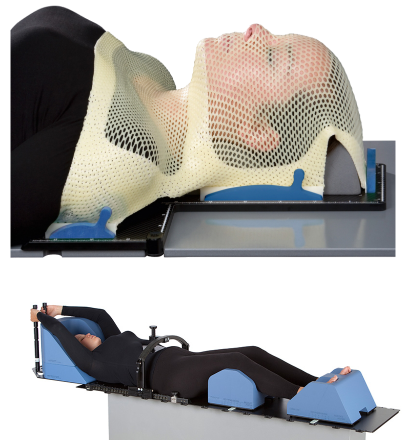


**Figure 3:** Immobilization Devices [IR4, IR5].

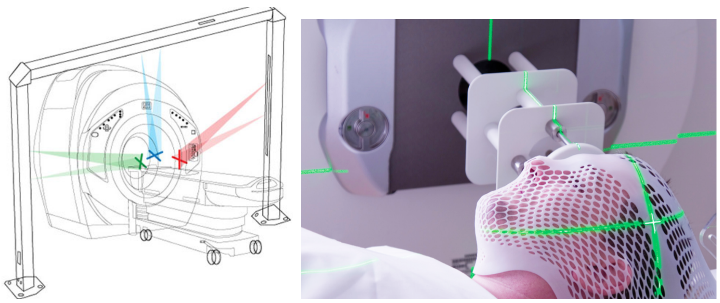


**Figure 4:** Patient positioning with lasers [IR6, IR7].

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, and Figure 6 in Appendix). They must also be wary not to create a plan in which a collision between the gantry and the patient or couch can occur [12].

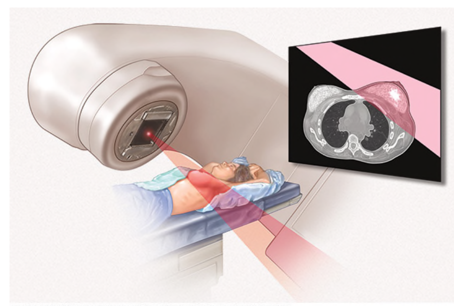



**Figure 5:** The gantry rotating during treatment [IR8].

Once treatment plans are created, the patient can begin treatment. Each day patients go into the clinic for treatment, they will begin by verifying their identity and what body part they are receiving treatment for [13]. Next, the patients will undergo two phases of positioning: Initial and Final Positioning. For Initial Positioning, therapists currently put the immobilization devices on the couch and patients before aligning patients to roughly the correct position using a laser alignment system. However, these lasers are often difficult to see and objects can get in the way of the laser projections. For Final Positioning, alignment is fine tuned by aligning X-Ray images of the patient's current location with the reference location; however, these images expose the patient to excess radiation. Once the two phases of positioning are done, the patient then begins treatment when the therapist commands the linac to execute the treatment plan. See Appendix for a more detailed description of planning and treatment workflow.

Therapists receive a continuous flow of patients throughout the treatment day. They only have 15-minutes to setup and execute the treatment plan for each patient. Verification of patient identity is a crucial part of treatment setup. Treating a patient with the wrong plan would result in disastrous consequences and hazardous excess radiation exposure. Amidst schedule changes in an already hectic environment, patient confirmation by checking a patient's ID card or asking verification questions can sometimes be overlooked. Patients typically have two to five immobilization devices and accessories associated with their treatment, and therapists must quickly change these out in between patients. Therapists often setup these devices and accessories by following shorthand notes on the patient's file, and many clinics do not have a way to record and document when an immobilization device or accessory is properly placed. This leaves room for human error. In addition to setting up the right devices and accessories, it is important for each patient to be placed within the devices in the correct way for his/her particular treatment plan. Many patients require the same type of immobilization devices, so the particular way each patient is placed in them may sometimes be difficult to determine. When this occurs, a therapist would have to spend extra time extracting pictures of the patient's initial planning setup from deep within his/her patient file. Apart from using lasers for coarse alignment, once the patient is properly positioned using the immobilization devices, some clinics currently utilize surface alignment systems to help fine tune patient positioning. However, the current surface alignment systems can be cumbersome to use and require therapists to constantly direct their gaze back and forth between the patient and a monitor across the room. 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.

### Needs Statement

There is a need for a more efficient way for radiation therapists to optimize the patient setup process. There is currently no streamlined way to verify patient identity, accessory/equipment usage, and patient positioning during external beam radiation treatment in the radiation oncology clinic.

### Objective Statement

Our objective is to develop a device that will verify patient identity, accessory/equipment usage, and patient positioning accuracy. The device will allow radiation oncology therapists to safely treat cancer patients more quickly and to position them within smaller margins.

## CLIENT NEEDS ASSESSMENT

### Survey Results

To assess the clinical need for a streamlined patient setup and verification device, we created a survey that was distributed to experts in radiation oncology. Sevelin Stanchev, our main point of contact for our client, Varian Medical Systems, had distributed our survey within the company so we would have results from an industry perspective. Our main points of contact at the UC Davis Medical Center (UCDMC), Dr. Robin Stern (Professor and Chief Clinical Physicists) and Dr. Sonja Dieterich (Professor/Physics Residency Co-Director), had distributed our survey to their clinical colleagues at different hospitals. Physicians, medical physicists, dosimetrists, and radiation therapists from the Department of Radiation Oncology at the UC Davis Medical Center, Sutter

Medical Center, UC Davis Veterinary Medicine Center, and Varian Medical Systems responded to our questionnaire.

The questions in the survey were created to understand what device functionalities would be clinically important. We categorized the questions into four categories: Patient Setup, Clinical Operations, Physical Requirements, and User Experience in order to identify the user needs and preferences in all aspects of the clinical workflow. To quantify the importance of each feature within the four categories, we had responders rank the functionalities on a scale of 1 (least important), 2 (less important), 3 (moderately important), 4 (somewhat important), and 5 (most important). The survey results generated from 9 survey respondents are represented below in Table 1. Because our clients are Varian Medical Systems and we have corresponded most with the UC Davis Medical Center, we prioritized their opinions when calculating the weighted averages. The full survey questions and informational interviews are listed in the Appendix.

**Table 1: Survey Results**

| Needs | Descriptions | Varian Medical Systems | UC Davis Medical Center | Veterinary Medical Center | Weighted Averages |
|---|---|---|---|---|---|
| *Group A* | *Patient Setup* | | | | |
| A1 | Fast Patient Setup | 1.75 | 1 | 1 | 1.43 |
| A2 | Ease of Patient Setup | 1.75 | 2 | 2 | 1.86 |
| A3 | Reproducibility of Patient Positioning | 4.25 | 4.5 | 4 | 4.29 |
| A4 | Accuracy of Patient Positioning | 4.75 | 4.5 | 5 | 4.71 |
| A5 | Effective Immobilization | 2.5 | 3 | 3 | 2.71 |
| *Group B* | *Clinical Operations* | | | | |
| B1 | Verification of Patient Identity | 4.5 | 3.5 | 1 | 4.17 |
| B2 | Verification of Correct Couch/Gantry Position | 4.25 | 4 | 5 | 4.29 |
| B3 | Verification of Accessory Usage | 3.25 | 3 | 4 | 3.29 |
| B4 | Compatible with Most Machine Brands | 1.75 | 3.5 | 3 | 2.43 |
| B5 | Wireless Transfer of Verification Data | 1.25 | 1 | 2 | 1.29 |
| *Group C* | *Physical Requirements* | | | | |

| | | | | | |
|---|---|---|---|---|---|
| C1 | Portable | 3.75 | 2.5 | 2 | 3.14 |
| C2 | Cleanable | 4 | 3.5 | 3 | 3.71 |
| C3 | Reusable | 2.5 | 3 | 4 | 2.86 |
| C4 | Affordable | 1.75 | 5 | 5 | 3.14 |
| C5 | Long Battery Life | 3 | 1 | 1 | 2.14 |
| *Group D* | *User Experience* | | | | |
| D1 | Ergonomic | 2.25 | 3 | 1 | 2.9 |
| D2 | Easy to Operate | 3.5 | 3 | 2 | 3.14 |
| D3 | Requires Minimal Training | 2 | 2.5 | 3 | 2.29 |
| D4 | Integrates with Current Hardware & Software | 5 | 4 | 5 | 4.71 |
| D5 | Easy to Maintain & Update | 2.25 | 2.5 | 4 | 2.57 |

In addition to our ranking questions, we asked the clinical experts some follow-up multiple choice and free response questions within each category. From the additional questions asked in the Patient Setup category, we learned that patient setup typically takes approximately 5 minutes, patient setup needs to be adjusted about 13% of the time after imaging, acceptable margins when positioning the patient is less than 2mm, and field lights/lasers are sometimes difficult for radiation therapists to see when the accessories/equipment extend out and block wall/ceiling lasers. From the additional questions asked in the Clinical Operations category, we learned that it would be advantageous to visualize beam production, 2D/3D original and current body contour displacement, and 2D/3D original and current internal organ displacements models overlaid on the patient when they are on the couch during positioning. From the additional questions asked in the Physical Requirements category, we learned that patient setup devices are actively used for more than 8 hours during a typical day. Lastly, from the additional questions asked in the User Experience category, we learned that a portable (wearable device) device would be most convenient to use compared to portable (handheld) and stationary (monitor) modalities.

## Needs Flowchart

**Table 2: Needs Flowchart**

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

| | | | | |
|---|---|---|---|---|
| | [D4] | | [B2] | |

| 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] |

Based on the results of the survey, the user needs were separated into 4 categories: Essential, Important, Nice to Have, and Not Necessary. The functions with the five highest scores were deemed "Essential." These needs are crucial for our patient setup device to have and therefore will be implemented with the highest priority. *Accuracy* and *reproducibility of patient positioning* along with *verification* of the setup process (including *patient identity* and *couch/gantry position*) was a common theme within this category. The needs that were categorized as "Important" are strongly encouraged and fulfilling these functions will be helpful for the clinical staff. These functions, such as *portability* and *easy to operate*, are significant to the clinical workflow because they allow clinicians to use the new device without complicating their current procedures. The needs that fell within the "Nice to Have" category may increase the convenience of use; however, they do not significantly affect the functionality of the device. This category includes *ergonomic* and *reusable* because those needs would only provide comfort to the user, and won't necessarily affect the safety or accuracy of patient setup. Lastly, the "Not Necessary" needs are those that are given least priority. They are not critical for the patient setup workflow and will only be implemented if there is time. *Wireless transfer of verification data* and *long battery life* are examples of needs included within this category. Therefore, it will not be necessary to implement those functionalities in the final design.

## Development of Metrics

The following 16 metrics displayed in Table 3 were determined to quantifiably represent the user needs found in the survey. The metrics address all four categories of needs, which include Patient Setup, Clinical Operations, Physical Requirements, and User Experience.

**Table 3: Metrics and Units**

| Metric Number | Metric | Needs | Units |
|---|---|---|---|
| 1 | Weight | A1, A2, C1, D1, D2 | Pound (lb) |
| 2 | Cost | A4, B4, B5, C4, C5, D4 | USD ($) |
| 3 | Frames per Second | A3, A4, D4 | Frames/Second (fps) |
| 4 | Camera Resolution | A3, A4, D4 | Pixel (Px) |
| 5 | Reference Position Accuracy | A3, A4, A5, B2, B3 | mm |
| 6 | Patient Surface Coverage | A3, A4 | mm |
| 7 | Patient Verification | B1, B5, D4 | Yes/No |
| 8 | Accessory Verification | B3, B5, D4 | Yes/No |
| 9 | Training | A2, D2, D3, D4 | Days |
| 10 | QC (Quality Check) Time | A1, B4, D2, D5 | Minutes (mins) |
| 11 | Warm-up time | A1, A2, C3 | Minutes (mins) |
| 12 | External Cameras | A3, A4, B5, C4, D5 | # |
| 13 | Display | A1, A2, B4, B5, C1, D2 | Type |
| 14 | Battery Life | A2, B5, C1, C5, D2 | Hours (hrs) |
| 15 | Required Sterility | A1, A2, C2, D2, D5 | Cleaning Level |
| 16 | Warranty | C3, C4, D5 | Years (yrs) |

The definition of each metric is listed below:

1. **Weight** – The weight of the device
2. **Cost** – Price of the device in dollars
3. **Frames per Second** – How many images can be scanned/displayed per second
4. **Camera Resolution** – How clear the camera images are
5. **Reference Position Accuracy** – How accurate the reference position needs to be to the true reference position
6. **Patient Surface Coverage** – How large a surface can be read and analyzed by the software
7. **Patient Verification** – Confirming the patient's identity
8. **Accessory Verification** – Confirmation of the accessories being used and/or their positions
9. **Training** – How much training time is needed before use

10. **QC (Quality Check) Time** – Time it takes to verify that the device is calibrated
11. **Warm - Up Time** – The time it takes for the device or software to start up
12. **External Cameras** – Number of cameras used to acquire patient images
13. **Display** – Type of device used to view the image
14. **Battery Life** – How long can the device run after fully charged
15. **Required Sterility** – The level of being free from bacteria or living organisms, based on the officially recognized sterility level
16. **Warranty** – How many years the company provides free service on device issues

## Needs-Metrics Correlation Matrix

In Table 4, the metrics and their corresponding units are related to each of the clinical needs. The matrix is a visual representation of how each of the user needs are related to each metric.

**Table 4: Needs-Metrics Correlation Matrix**

| Needs | | | Metrics | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pound (lb) | USD ($) | Frames/Second (fps) | Pixel (Px) | mm | mm | Yes/No | Yes/No | Days | Minutes (mins) | Minutes (mins) | # | Type | Hours (hrs) | Cleaning Level | Years (yrs) |
| | | | Weight | Cost | Frames per Second | Camera Resolution | Reference Position Accuracy | Patient Surface Coverage | Patient Verification | Accessory Verification | Training | QC (Quality Check) Time | Warm-up time | External Cameras | Display | Battery Life | Required Sterility | Warranty |
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| Needs | **Group A** | **Patient Setup** | | | | | | | | | | | | | | | | |
| | A1 | Fast Patient Setup | X | | | | | | | | | X | X | | X | | X | |
| | A2 | Ease of Patient Setup | X | | X | | | | | | X | | X | | X | X | X | |
| | A3 | Reproducibility of Patient Positioning | | | X | X | X | X | | | | | | X | | | | |
| | A4 | Accuracy of Patient Positioning | | X | | X | X | X | | | | | | X | | | | |
| | A5 | Effective Immobilization | | | X | | X | | | | | | | | | | | |
| | **Group B** | **Clinical Operations** | | | | | | | | | | | | | | | | |
| | B1 | Verification of Patient Identity | | | | | | | X | | | | | | | | | |
| | B2 | Verification of Correct Couch/Gantry Position | | | | | X | | | | | | | | | | | |
| | B3 | Verification of Accessory Usage | | | | | X | | | X | | | | | | | | |
| | B4 | Compatible with Most Machine Brands | | X | | | | | | | | X | | | X | | | |
| | B5 | Wireless Transfer of Verification Data | | X | | | | | X | X | | | | X | X | X | | |
| | **Group C** | **Physical Requirements** | | | | | | | | | | | | | | | | |
| | C1 | Portable | X | | | | | | | | | | | | X | X | | |
| | C2 | Cleanable | | | | | | | | | | | | | | | X | |
| | C3 | Reusable | | | | | | | | | | | X | | | | | X |
| | C4 | Affordable | | X | | | | | | | | | | X | | | | X |
| | C5 | Long Battery Life | | X | | | | | | | | | | | | X | | |
| | **Group D** | **User Experience** | | | | | | | | | | | | | | | | |
| | D1 | Ergonomic | X | | X | | | | | | | | | | | | | |
| | D2 | Easy to Operate | X | | | | | | | | X | X | | | X | X | X | |
| | D3 | Requires Minimal Training | | | | | | | | | X | | | | | | | |
| | D4 | Integrates with Current Hardware & Software | | X | | X | | | X | X | X | | | | | | | |
| | D5 | Easy to Maintain & Update | | | | | | | | | | X | | X | | | X | X |

## STATE-OF-THE-ART

### PATENT, MARKET, AND ACADEMIC LITERATURE SEARCH

Patent, market, academic literature, and Food and Drug Administration (FDA) searches were conducted in order to identify different aspects of the needs statement which include verification of patient identity, accessory/equipment usage, and patient positioning. Once we researched different products that performed similar functions, we identified the engineering metrics associated with each project. These metrics were then incorporated during our benchmarking process for our own device.

## *PATENT SEARCH*

A patent search was first conducted to analyze ways that the market conducts patient positioning. In addition, we wanted to find different methods that could help with verification in the clinical setting. We have included three such patents in this section.

### i. System and Method for Positioning with Nuclear Imaging [14]

*Patent Number:* US20140235921 A1
*Inventor(s):* Thomas Wendler, Christian Hieronimi, Jörg Traub

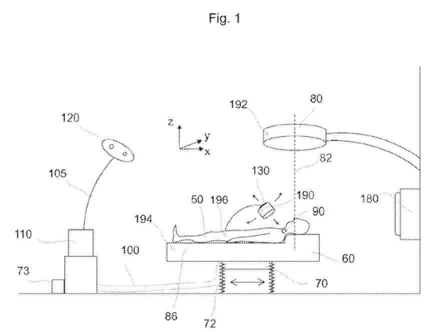



Figure 8: A system for positioning [IR11].

This invention is intended to be utilized on a system that uses at least one detector to image the radiation distribution emitted from a radiation source. The imaging is performed before calculating the difference between the position of the target tissue region and the comparison position. The device then sends the correctional values to a radiation therapy device or patient positioning device. While this provides a way to monitor patient position without using X-Rays (thereby sending a dose to the patient on each scan), the radiation in the room can affect the detector's image acquisition.

### ii. Patient Positioning System and Methods for Diagnostic Radiology and Radiotherapy [15]

*Patent Number:* US8002465 B2
*Inventor(s):* Peter Hyung-Kyun Ahn

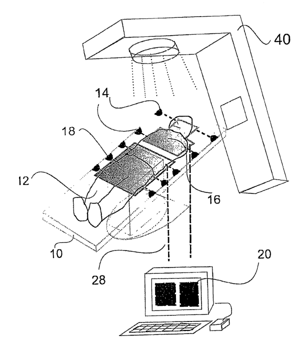


Figure 9: A patient lying on a pressure-sensitive couch [IR12].

This system checks patient positioning during set up and patient movement during its treatment process. It uses pressure-sensors attached to immobilization devices or the couch to record measurements of the patient's weight and pressure distribution. These measurements include patient weight and pressure distribution. This provides a new way to monitor patient position without needing to incorporate large new devices into the treatment room. By having sensors incorporated into current devices, this means there is less material that could interfere with the radiation beam during treatment. However, these pressure sensors may not be as accurate as other methods, as they would not be able to tell where specifically in space a body part is, which is needed for accurate alignment.

### iii. Holographic User Interfaces for Medical Procedures [16]

*Patent Number:* US20140282008 A1
*Inventor(s):* Laurent Verard, Raymond Chan, Daniel Simon Anna Ruijters, Sander Hans Denissen, Sander Slegt

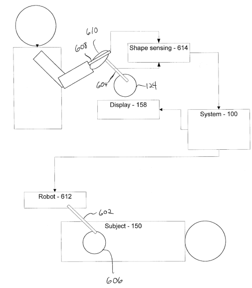



FIG. 6

**Figure 10:** A system for using a holographic image [IR13].

This interactive holographic display system displays a holographic anatomical image. The system is programmed to define a space on or around the image to be monitored. The holographic image can then be triggered to change and react to the surrounding environment when the user interacts with the image or the area surrounding the image. By using holographic technology with other current technologies, it could simplify any workflow it is being added to. It could also simplify instrument selection due to its flexibility in functions. However, due to limitations in displaying such holograms, the viewing window or screen could be small. Using such holographic devices would also require some training time to use, and any usage longer than thirty consecutive minutes could lead to disorientation. Therefore, breaks will be required with long term use.

## *MARKET SEARCH*

A market search was conducted to see which market products exist that are relevant to our project goal. We identified three companies whose products aligned with patient positioning, patient verification, and accessory usage and listed them below. We then examined the product characteristics to analyze their performance. Any FDA search results that appeared for these products were also noted.

### i. IDENTIFY [17]

*Company:* HumediQ

HumediQ's IDENTIFY system (shown in Figure 1) guides patient set up for radiation therapy treatment. The system includes IDENTIFY PALM, which is a patient identification and verification system that uses a palm reader to verify that the patient going in for treatment matches the patient's palm vein profile in the system. IDENTIFY also recognizes patient accessories and their position on the treatment couch. Lastly, IDENTIFY gives surface renderings of the patient's position using cameras. These surface images compare the target and actual patient positions on a computer monitor display. This product includes an easy way of patient and accessory verification on top of patient positioning. However, the device requires the therapist to continuously look back and forth between the patient on the couch to the computer monitor across the room to check the positioning. Also, the color mapping used to show patient positioning can sometimes be unclear, and using it is not very intuitive. It will take training time for users to get used to using it.

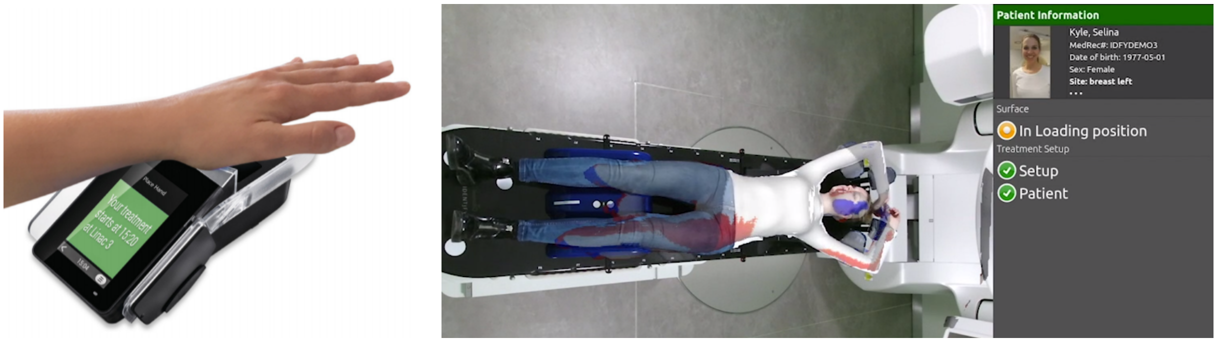



**Figure 11:** Left, IDENTIFY PALM [IR14]. Right, surface rendering visualization [IR15].

## ii. AlignRT [18]

*Company:* VisionRT


**Figure 12:** AlignRT interface [IR16].

VisionRT's AlignRT system (shown in Figure 2) tracks patient positioning before and during radiation therapy. It uses cameras to track the skin surface for comparison to the reference position, and the system can pause radiation treatment if the patient moves out of position. AlignRT is also capable of performing breath holds in which the patient respiratory chest motion is monitored. When the patient breathes in, the chest expands outwards and AlignRT will allow the linac to administer radiation. When the patient exhales, the chest lowers and AlignRT will prevent the linac from administering radiation. This product is nice because it is easy to visualize how much tolerance in positioning the therapist has, and it automates breathing instructions to the patient so the therapist does not need to do it themselves. However, just like HumediQ's IDENTIFY, this product is shown on a computer monitor across the room, so the therapist will need to continuously look back and forth between the patient and the screen.

### FDA Search [19]:

*Device Class: 2*

*Regulation Number: 892.5050* [20]

VisionRT sent a notice to all customers on 21-Oct-2014, stating that AlignRT had the chance of failing to assert an interlock. Only 7 products were in commerce at the time, 6 of which were in the US. Customers were informed that their devices did not need to be returned, but they should notify all employees about the software issue. Customers were told to notify VisionRT if they believe any harm occurred because of this issue. As of 10-May- 2016, the recall status was terminated.

### iii. Catalyst [21]

*Company:* C-Rad

Figure 13: C-Rad's Catalyst system [IR17].

C-Rad's Catalyst system (shown in Figure 3) is a device attached to the ceiling that monitors patient position and breathing. Using light projected onto the patient, Catalyst displays a color map that indicates when the patient is in the incorrect position. In addition to this surface projection, position shift signals are also displayed on monitors in the room. Catalyst also includes automatic couch movement and automatic beam hold. Beam hold occurs when Catalyst prevents the linac from administering radiation. During treatment, the patient wears glasses that display their breathing pattern. Through Coached Breathing (shown in Figure 4), the system will guide the patient to inhale and exhale using the visual glasses and audio system. Just like VisionRT's AlignRT, this product automates instructional breathing to the patient, but this product has the instructions be both visual and audio. This provides more accuracy and makes it more clear to the patient when to hold their breath. The disadvantage of this product is that just like IDENTIFY and AlignRT, C-Rad also displays positioning onto a computer screen across the room and is inefficient to use for the therapist.

**Figure 14:** Catalyst's visual coached breathing [IR17]. The treatment occurs once the patient breathes in enough.

## *ACADEMIC LITERATURE SEARCH*

Augmented Reality (AR) is documented to be used in surgery and preoperative planning to improve efficiency. AR systems are very useful in organs that allow little movement and deformation, for example, skull, brain, and pancreas [22]. Surgeons use AR to view holographic 3D images (holograms) generated by concatenating diagnostic radiological image slices. The holograms allow the surgeons to "see through" the patient and help them navigate and dissect accurately during operations. Surgeons use AR to make a more personalized plan for patients because variations in patient anatomy can be seen on the holograms, which also allows surgeons to make adjustment faster if needed [23]. This is similar to aligning the hologram with the patient to position them for radiotherapy. In this section, we include such a system developed by a university for academic research purposes.

**i. smARtsKin [24, 25]**

*Researchers:* Juergen Meyer, James Eagle, Steve Marsh, Mochamad Prananda, Teyu Chyou, Raphael Grasset, Adrian Clark, James Talbot, Andreas Mueller

The smARtsKin system checks for potential collisions between the patient and the linear accelerator, and monitors the patient's position and breathing during the treatment process. The system superimposes the holographic patient body contours with the physical patient captured by real-time camera (see Figure 6). If the patient or immobilization devices are not in the right position, the holographic patient contours will not be aligned with the patient.

Figure 15: A virtual patient contour [IR18].

The system uses an AR tracking library called "ARToolKit" which reads special tracking markers on the patient and places the hologram in a position with the markers as references. Markers are also put on a registration cube (see Figure 7) that is placed at the isocenter (the center of radiation beam focus) to register the coordinates. The AR tracking software tracks the cube to locate the 3D model. Some limitations to the smARtsKin system include:

1) Error in registering the cube
2) Tracking accuracy of the markers due to room lighting, camera angle, camera focus, camera resolution, the size of the tracking markers, and the distance of the camera from the markers
3) Camera calibration accuracy
4) Room laser accuracy.

Figure 16: A registration cube [IR19].

The smARtsKin has functions like collision detection and patient movement monitoring which makes it special cause a lot of systems can only do one of the two tasks. However, this system depends on different components like cameras, registration cube, and AR tracking software, these components may create errors and they need to be calibrated. The accuracy of the hologram placement relies on the different parts and there are many things to look at for getting the correct accuracy. It requires time and is hard to calibrate all of the components at the same time. Moreover, if this system is used to position patients, the holographic image is displayed on a screen and therapists need to look back and forth between the hologram and the screen. It is not convenient for the therapists and patient set up time is long..

## *FDA LITERATURE SEARCH*

Various FDA databases (device listing, MAUDE, MDR databases) were searched and there were no results for related devices. Under the 510(k) premarket notification database, OpenSight by

Novarad Corporation and True 3D Viewer Software and Echo True 3D Viewer by EchoPixel Inc. are found as medical devices that are allowed to be marketed. A 510(k) clearance is required prior to marketing a device in order to ensure the device is safe and effective. Of the products that we list below, an FDA search was conducted, and no recalls of these devices were found.

### i. OpenSight Augmented Reality system [26]

*Company:* Novarad

Novarad's OpenSight Augmented Reality system has been cleared by the FDA and has received 510(k) clearance for medical use in pre-operative surgical planning. It is classified as a class II medical device [27] and uses the Microsoft Hololens headset to allow clinicians to see the patient's 2D, 3D, and 4D images placed on top of the actual patient (see Figure 8 Right). The images are acquired from compiling scans taken from computed radiography (CR), computed tomography (CT), and magnetic resonance imaging (MRI). The OpenSight system also allows clinicians to highlight patient anatomy and use them as a planning tool before surgeries. The system has a camera that detects the patient surface, and virtual tags (see Figure 8 Left) are placed on the patients to track patient movement and improve accuracy. Another feature that OpenSight has is patient and anatomy image verification. Surgeons can start surgical planning if the image data and the patient matches.

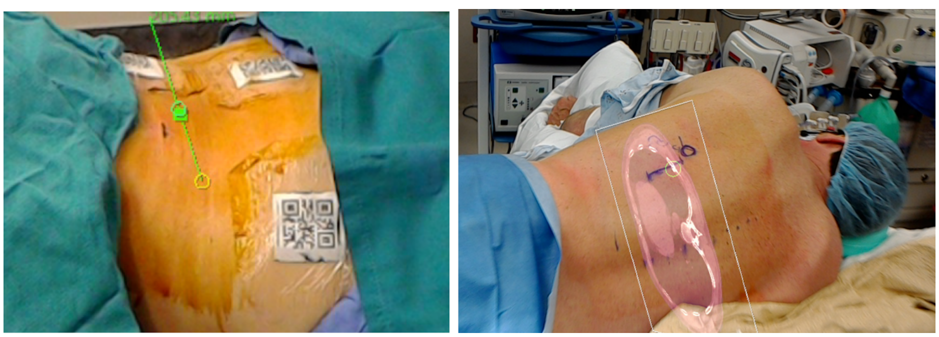


**Figure 17:** Left, tracking tags on patient. Right, a holographic plane [IR20].

QR codes are needed to calibrate the location of the surgery site and the calibration can takes a long time. Although this is not a technology for positioning patients in radiotherapy, the idea to use QR code as reference location to put the hologram is similar to our project.

### ii. True 3D system [28]

*Company:* EchoPixel

EchoPixel's Echo True 3D Viewer and True 3D Viewer Software have been approved for FDA's 510(k) clearance and is classified as a class II device [29, 30]. The hologram comes out of the screen (See Figure 9 Left). Users wear specialized glasses to turn 2D images obtained by CT scans and MRI scans into 3D objects. The images can be manipulated using specialized tools to grasp, dissect, and resize anatomy features (see Figure 9 Right). The system can also measure surface area and volume of the selected anatomy.

**Figure 18:** Left. EchoPixel's True 3D system [IR21]. Right, users can zoom in on holographic areas for a detailed view [IR22].

The Echo 3D system requires the paired usage of its AR glasses, AR screen, and tool which is inconvenience for user if one of the 3 components is broken and the system can't be used. Also, this system is designed for stationary usage and it is not a system designed for the purpose of patient positioning in radiology oncology.

## BENCHMARKING

An in depth analysis of market products is necessary to identify the quantitative metrics for our project. Table 5 identifies the strengths and weaknesses of products currently in the market, so we can take the characteristics into account as we design our product. Most of these products seem to value being noninvasive, optical, accurate in positioning, cleanable, and reusable. An overwhelming number of products also seem to have monitor-based display, with glasses-based and projector-based display being rarely used options. Metrics that seem to fluctuate on priority include cost, accessory and patient verification, QC time, and number of external cameras. Finally, it is clear that not many products prioritize portability.

**Table 5: Benchmarking table of existing products out in the market**

| Metric # | Metric | Needs | Units | Identify | AlignRT | Catalyst | smARtsKin | OpenSight | EchoPixel |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Weight | A1, A2, C1, D1, D2 | lb | N/A | N/A | 35 | N/A | 1.2 | 20.2 |
| 2 | Cost | A4, B4, B5, C4, C5, D4 | USD ($) | 291,200 + 49,9 86.72/yr | 197,992.35 to 296,988.53 + 26,398.98/yr[1] | N/A | N/A | N/A | 25000/yr[2] |
| 3 | Frames per Second | A3, A4, D4 | Frames/ Second | 10 | 15 | 80 | N/A | 60 | 120 |
| 4 | Camera Resolution | A3, A4, D4 | Pixel | N/A | 1024 x 768 | N/A | 2300000 | N/A | 1920 x 1080 |
| 5 | Reference Position | A3, A4, A5, B2, B3 | mm | < 0.5 mm | < 1 mm | < 1 mm | 3 mm | N/A | N/A |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Accuracy | | | | | | | | |
| 6 | Patient Surface Coverage | A3, A4 | mm | N/A | N/A | up to 1300 | N/A | N/A | N/A |
| 7 | Patient Verification | B1, B5, D4 | Yes/No | Yes | No | Yes | No | Yes | N/A |
| 8 | Accessory Verification | B3, B5, D4 | Yes/No | Yes | No | No | No | No | No |
| 9 | Training | A2, D2, D3, D4 | Days | N/A | 2.5 | N/A | N/A | N/A | N/A |
| 10 | QC Time | A1, B4, D2, D5 | mins | N/A | N/A | < 5 | ~15 | N/A | N/A |
| 11 | Warm-up Time | A1, A2, C3 | mins | N/A | N/A | 30 | N/A | N/A | N/A |
| 12 | External Cameras | A3, A4, B5, C4, D5 | # | 2 | 3 | 1 | 1 or 2 | N/A | N/A |
| 13 | Display | A1, A2, B4, B5, C1, D2 | Type | Monitor | Projector, Monitor | Monitor, Projector, Glasses[3] | Monitor | Glasses | Monitor |
| 14 | Battery Life | A2, B5, C1, C5, D2 | hr | N/A | N/A | N/A | N/A | 2.5 -5.5 hrs | N/A |
| 15 | Required Sterility | A1, A2, C2, D2, D5 | Cleaning Level | LLD* | < LLD | < LLD | < LLD | < LLD | < LLD |
| 16 | Warranty | C3, C4, D5 | Years | 5 | 1 | 1 | N/A | N/A | N/A |

[1] Values were originally given in Euros and were converted to USD. The listed range is the listed market price, in addition to a yearly service charge.
[2] Price is the annual subscription fee for the EchoPixel software.
[3] C-Rad's Catalyst displays patient surface comparison images on a display monitor, as well as projecting them onto the patient. In addition, glasses are used as visual coached breathing for respiratory gating.

# DEVELOPMENT OF ENGINEERING METRICS

## Engineering Design Specifications

To make our Engineering Design Specifications Table (shown below in Table 6), we used the information we obtained from our research, surveys, and interviews in order to determine the average value ranges and ideal ranges of each metric. From our research, we found that the reference position accuracy could range anywhere from 3mm or below. We were able to narrow this range to an ideal value of below 2mm from our survey. The survey asked clinical experts to rank features in order of importance, and some features that were heavily prioritized include verification of patient identity, a projection of body contour displacement, portability, cost, and ease of integration with the current hardware and software. From this, we were able to decide that we want a device that includes patient verification and a way to project parameters onto the patient setup environment, in addition to being portable, affordable, and integratable with the current treatment workflow. These survey results, along with our background research done in Table 5, contribute to conclusions on our ideal values for each metric in Table 6.

**Table 6: Engineering Design Specifications**

| 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 |

## House of Quality

The House of Quality, Table 7, shows how strong user needs and our design metrics are related to each other. It is an extension of Table 4 and demonstrates the relationships between the needs and the metrics. These relationships are classified into three categories: strong, moderate, and weak. The table also states whether each of our design metrics are correlated and whether the correlations are positive or negative, allowing us to determine the direction of improvement for each of our metrics. Furthermore, the House of Quality indicates relative weight of user needs based on the information gathered from the survey. The importance ranking of each metric is calculated by finding the sum of the number of strong relationships multiplied by 9, number of moderate relationships multiplied by 3, and number of weak relationships multiplied by 1. Using this table provides a visual representation of what the customer desires and enable us to understand which needs and metrics are important for our project.

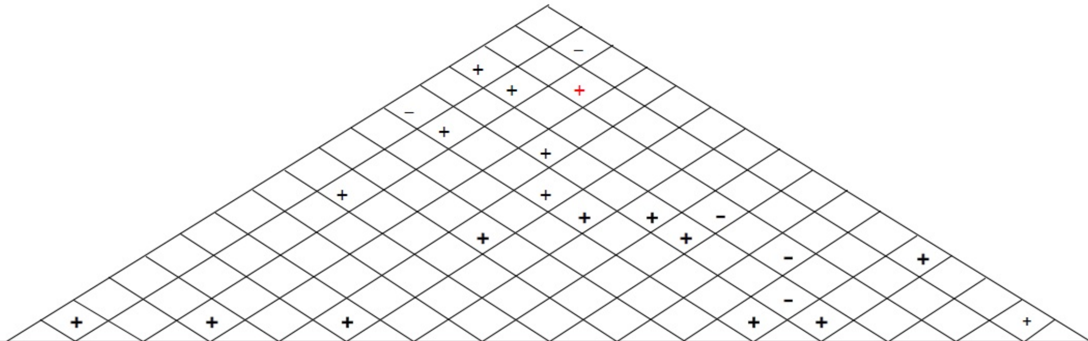
By analyzing our House of Quality, we concluded that the most important considerations are reference position accuracy, the ability to wirelessly transfer data, cost, and the display modality. A primary need is accurate patient positioning, which has a strong relationship with reference position accuracy: one cannot accurately align something if the thing it is being aligned to is not lined up in the first place. There were strong relationships between device verification functionalities and wireless transfer of data: A device that can wirelessly transfer patient ID verification and accessory verification would allow for a more smooth incorporation into the clinical workflow and minimize the number of extra steps therapists would need to take to allow for verification functionalities. Having a projector display strongly addresses many of our needs. A projector modality is different from most other existing devices, which often utilize a monitor. Tying in cost, we found a positive correlation between a variety of metrics and cost, including the number of external cameras. There is also a positive correlation between the number of external cameras and reference position accuracy. Tools that offer a greater resolution often come at a greater cost, so how well we address our need for accurate patient positioning will likely have heavy influence from our budget. Our cost target is below $500. Many devices cost a couple of thousands. Our goal is for an affordable device an order of magnitude less to help optimize adaptability of our efficient device improving treatments.

QFD: House of Quality
Project: C-Holo
Revision: 2
Date: 02/02/19

| Correlations | |
|---|---|
| Positive | + |
| Negative | − |
| No Correlation | |

| Relationships | |
|---|---|
| Strong | ● |
| Moderate | ○ |
| Weak | ▽ |

| Direction of Improvement | |
|---|---|
| Maximize | ▲ |
| Target | ◇ |
| Minimize | ▼ |



| Row # | Weight Chart | Relative Weight | Customer Importance | Maximum Relationship | Column # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Direction of Improvement | ▼ | ▼ | ▲ | ▲ | ▲ | ▲ | ◇ | ◇ | ▼ | ▼ | ▼ | ▼ | ◇ | ▲ | ◇ | ◇ |
| | | | | | Metrics / Needs | Weight | Cost | Frames per Second | Camera Resolution | Reference Position Accuracy | Patient Surface Coverage | Patient Verification | Accessory Verification | Training | QC Time | Warm-up Time | External Cameras | Display | Battery Life | Required Sterility | Warranty |
| 1 | | 2% | 1.43 | 9 | A1 - Fast Patient Setup | ○ | | | | | | | | | ▽ | ▽ | | ● | | ▽ | |
| 2 | | 3% | 1.86 | 9 | A2 - Ease of Patient Setup | ○ | | | | | | | | ○ | | ▽ | | ● | ▽ | ▽ | |
| 3 | | 7% | 4.29 | 9 | A3 - Reproducibility of Patient Positioning | | | ○ | ▽ | ● | ● | | | | | | ○ | | | | |
| 4 | | 8% | 4.71 | 9 | A4 - Accuracy of Patient Positioning | | ▽ | ○ | ▽ | ● | ● | | | | | | ● | | | | |
| 5 | | 4% | 2.71 | 1 | A5 - Effective Immobilization | | | | | ▽ | | | | | | | | | | | |
| 6 | | 7% | 4.17 | 9 | B1 - Verification of Patient Identity | | | | | | | ● | | | | | | | | | |
| 7 | | 7% | 4.29 | 1 | B2 - Verification of Correct Couch/Gantry Position | | | | | ▽ | | | | | | | | | | | |
| 8 | | 5% | 3.29 | 9 | B3 - Verification of Accessory Usage | | | | | ▽ | | | ● | | | | | | | | |
| 9 | | 4% | 2.43 | 9 | B4 - Compatible with Most Machine Brands | | ▽ | | | | | | | | ▽ | | | ● | | | |
| 10 | | 2% | 1.29 | 9 | B5 - Wireless Transfer of Verification Data | | ▽ | | | | | ● | ● | | | | ▽ | ● | ▽ | | |
| 11 | | 5% | 3.14 | 9 | C1 - Portable | ● | | | | | | | | | | | | ● | ● | | |
| 12 | | 6% | 3.71 | 9 | C2 - Cleanable | | | | | | | | | | | | | | | ● | |
| 13 | | 5% | 2.86 | 9 | C3 - Reusable | | | | | | | | | | | ▽ | | | | | ● |
| 14 | | 5% | 3.14 | 9 | C4 - Affordable | | ● | | | | | | | | | | ● | | | | ● |
| 15 | | 4% | 2.14 | 9 | C5 - Long Battery Life | | ▽ | | | | | | | | | | | | ● | | |
| 16 | | 5% | 2.9 | 3 | D1 - Ergonomic | ○ | | | | | | | | | | | | | | | |
| 17 | | 5% | 3.14 | 9 | D2 - Easy to Operate | ○ | | | | | | | | ● | ▽ | | | ● | ● | ▽ | |
| 18 | | 4% | 2.29 | 9 | D3 - Requires Minimal Training | | | | | | | | | ● | | | | | | | |
| 19 | | 8% | 4.71 | 3 | D4 - Integrates with Current Hardware & Software | | ▽ | ▽ | ▽ | | | ▽ | ▽ | ○ | | | | | | | |
| 20 | | 4% | 2.57 | 9 | D5 - Easy to Maintain & Update | | | | | | | | | | ● | | ● | | | ● | ● |

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Target | <3 lb | < $500 | 60 frames / sec | 1920 x 1080 | < 2mm | < 1,300mm | Yes | Yes | < 2.5 days | < 15 minutes | < 30 minutes | < 3 cameras | Projector | > 2.5 hours | <LLD | 1 year |
| Max Relationship | 9 | 9 | 3 | 1 | 9 | 9 | 9 | 9 | 3 | 1 | 1 | 9 | 9 | 9 | 9 | 9 |
| Importance Rating | 21 | 14 | 24 | 3 | 21 | 18 | 19 | 19 | 24 | 12 | 3 | 31 | 54 | 29 | 21 | 36 |
| Relative Importance | 6% | 4% | 7% | 1% | 6% | 5% | 5% | 5% | 7% | 3% | 1% | 9% | 15% | 8% | 6% | 10% |
| Weight Chart | | | | | | | | | | | | | | | | |
| **Other Products** | | | | | | | | | | | | | | | | |
| humediQ Identify | N/A | 291200 | 10 | N/A | < 0.5 mm | N/A | Yes | Yes | N/A | N/A | N/A | 2 | Monitor | N/A | LLD | 5 |
| VisionRT AlignRT | N/A | 197,992.35 | 15 | 1024*768 | < 1 mm | N/A | No | No | 2.5 | N/A | N/A | 3 | Monitor | N/A | <LLD | 1 |
| C-Rad Catalyst | 35 | N/A | 80 | N/A | < 1 mm | up to 1300 | Yes | No | N/A | < 5 | 30 | 1 | Monitor | N/A | <LLD | 1 |
| smARtsKin | N/A | N/A | N/A | 2300000 | 3 mm | N/A | No | No | N/A | -15 | N/A | 1 or 2 | Monitor | N/A | <LLD | N/A |
| OpenSight | 1.2 | N/A | 60 | N/A | N/A | N/A | Yes | No | N/A | N/A | N/A | N/A | Glasses | 2.5-5.5 hrs | <LLD | N/A |
| EchoPixel | 20.2 | 25,000 | 120 | 1920*1080 | N/A | N/A | N/A | No | N/A | N/A | N/A | N/A | Monitor | N/A | <LLD | N/A |
| Column # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| Difficulty (0 is easy to accomplish and 10 is hard to accomplish) | 1 | 8 | 1 | 5 | 3 | 5 | 3 | 3 | 3 | 5 | 3 | 6 | 3 | 6 | 2 | 1 |

**Figure 19:** House of Quality.

# APPENDIX

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## Terminologies

- **Chemotherapy** - The treatment of disease by using chemical substances such as drugs.
- **Immunotherapy** - The treatment of disease with substances that cause a reaction from the immune response
- **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.

- **Collimator** - A part of the linear accelerator that narrows a beam of particles or waves. It is located above the multileaf collimator in the linac, and both are placed right before the particles exit the entire machine.

- **Multileaf Collimator** - The part of the linear accelerator that is made up of individual "leaves" (small metal plates) of a high atomic numbered material (usually Tungsten). The MLC can move independently in and out of the beam path during treatment. It is used to conform the beam shape further (after the particles pass the Collimator) into the more accurate shape of the tumor.

- **Computed Tomography (CT)** - Radiography where a 3D image of a body structure is generated from many cross-sectional images of a patient.

- **Complete Irradiation Area Outline (CIAO)** - The projection of what the beam output would look like onto a body surface after the beam exits the linear accelerator.

- **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."

- **Dosimetris**t - A member of the radiation oncology department who analyzes patient CT scans and maps out the intensity and locations of the radiation beam necessary to meet the oncologists' prescription.

- **Isodose lines** - Gradient lines that indicate what intensity of radiation different parts of the body are exposed to.

- **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.

- **Computed Radiography (CR)** - An image acquisition and processing system for radiography that uses computers and laser technology. The images are recorded on or transmitted to a laser-printed film and digitally stored.
- **Magnetic Resonance Imaging (MRI)** - A type of image created by a strong magnetic field and radiowaves.

## Detailed Figure Descriptions and Not-In-Text Figures

**Figure 1:** Varian Medical Systems' TrueBeam linear accelerator.
Patients lie on the "couch," which is adjustable to 6 degrees of freedom. The "gantry" can rotate around the patient, to administer radiation from different angles. The radiation beam exits through the collimator and is shaped by the MLC (multileaf collimator).

**Figure 2a:** CIAO aka Complete Irradiation Area Outline (Gold). Beam output shape is created by MLC shape.

**Figure 2b:** Multi-leaf Collimator (MLC) leaves retract or extend to adjust the shape of the beam to match the tumor shape.

**Figure 3:** 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. Depending on the location of treatment, patients may be asked to hold their hands comfortably across their abdomen, or to grasp grip rods during treatment.

**Figure 4:** Patients are positioned on the couch using tattoos/markers on their skin/immobilization devices and reference lasers in the treatment room.

**Figure 5:** The gantry can rotate around the patient to deliver radiation at an optimum angle. The patient is being treated for breast cancer. A visual of the radiation beam is overlaid on the patients CT scan. Dosimetrists analyze patient CT scans and map out the intensity and locations of the radiation beam necessary to meet the oncologist's prescription.

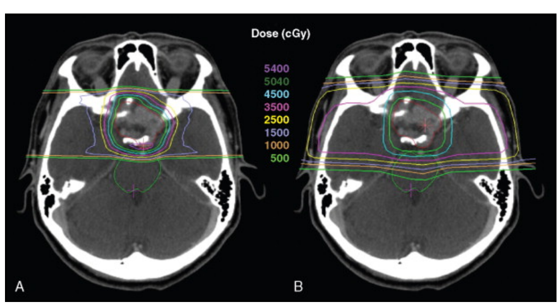


**Figure 6:** Isodose lines are gradient lines that indicate what intensity of radiation different parts of the body are exposed to [IR9].

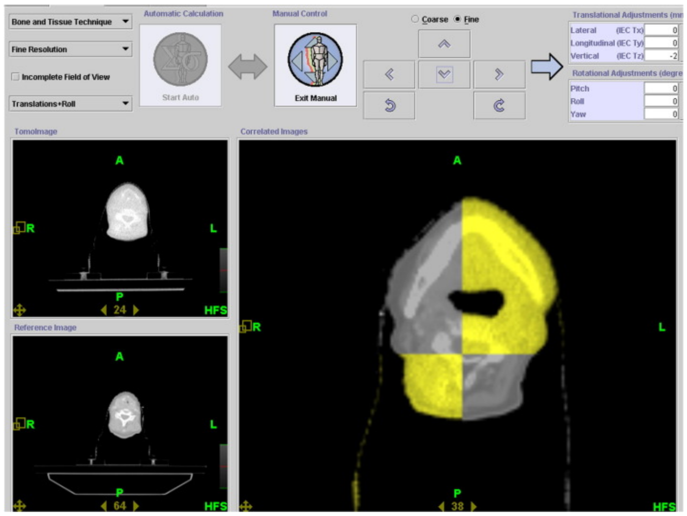


**Figure 7:** The original planning CT scan is "co-registered" with the current CT scan, to achieve alignment of internal structures. The direction and shape of the radiation beam is based off of the planning CT, so aligning with the planning CT ensures the beam will be directed at the appropriate target tissues. The two yellow quadrants represent the current day's CT scan overlayed with the planning CT in the gray quadrants [IR10].

**Figure 8:** A system for positioning using nuclear imaging.

**Figure 9:** A patient lying on a treatment couch that has a grid of pressure sensors.

**Figure 10:** A system for using a holographic image.

**Figure 11:** Left picture shows the IDENTIFY PALM system, where the device reads the palm vein profile to verify the patient's identity. Right picture shows a surface rendering visualization according to humediQ's IDENTITY system.

**Figure 12:** The AlignRT interface. The user can see the couch orientation numbers, along with which axis needs to be adjusted according to the software's surface rendering. The surface rendering is computed by comparing the measurements of the current surface scan with the measurements of the reference surface scan.

**Figure 13:** C-Rad's Catalyst system, which is composed of this one device.

**Figure 14:** Catalyst's visual coached breathing, which is used along with the glasses. The glasses, which come with audio aid through earphones, uses both visuals and audio to signal the patient to breathe in and out. Once the patient breathes in, the orange bar rises, and when the bar reaches the green box, it is within treatment parameters, so the system signals for the treatment machine to turn on the radiation.

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## Survey

**Patient Setup Device Survey**

We (Priscilla Chan, Hailey Huang, Janice Leung, Laura Oelsner) are senior Biomedical Engineering undergraduate students from UC Davis. For our Senior Capstone Project, our team (C-HOLO) is working to develop a device that can improve the patient setup process in external beam radiation therapy. In particular, we are very interested in developing a device that can aid in verifying patient identity, accessory/equipment usage, and patient positioning. As we work towards creating a device to help serve the clinical staff, we would greatly appreciate your input and knowledge of radiation oncology.

This survey is anonymous. Please reach out to C.HOLO.ucd@gmail.com if you have any questions.

Where do you work?

- UC Davis Medical Center
- Vet Med Center
- Varian Medical Systems
- Other: ___

What is your job title?

- Radiation Therapist
- Medical Physicist
- Dosimetrist
- Physician
- Other: ___

***Group A: Patient Setup***

Please rank the following in order of importance (1 - Least important, 2 - Less important, 3 - Moderately Important, 4 - Somewhat Important, 5 - Most important):

- Fast Patient Setup
- Ease of Patient Setup
- Reproducibility of Patient Positioning
- Accuracy of Patient positioning
- Effective Immobilization

1. How long does initial patient setup and positioning take for a head/neck treatment? (Not including image guidance)
    - Less than 5 minutes
    - 5 - 7 minutes
    - 7 - 10 minutes
    - More than 10 minutes
2. How often does patient setup need to be adjusted after imaging (excluding couch shift)?
    - Less than 5%
    - 5 - 15%
    - 16 - 25%
    - More than 25%
3. What is the typical acceptable margin (between tattoos and lasers) when initially positioning the patient?
    - Less than 2mm
    - 2 - 4mm
    - 5 - 7mm
    - 8 - 10mm
4. What is the typical acceptable margin when positioning the patient with 3rd party devices (such as AlignRT)?
    - Less than 2mm

    - 2 - 4mm
    - 5 - 7mm
    - 8 - 10mm
5. How often do the gantry, imaging arms, or accessories make it more difficult for therapists to maneuver and see field lights/lasers during patient setup?
    - Rarely
    - Sometimes
    - Often
    - Always
6. Please elaborate on your answer to question 5 and explain in what situations the field lights/lasers would be difficult to see. Type N/A if not applicable. [*long answer textbox*]

***Group B: Clinical Operations***
Please rank the following in order of importance (1 - Least important, 2 - Less important, 3 - Moderately Important, 4 - Somewhat Important, 5 - Most important):

- Verification of Patient Identity
- Verification of Correct Couch/Gantry Position
- Verification of Accessory Usage
- Compatible with Most Linacs
- Wireless Transfer of Verification Data

7. Please rank how advantageous it would be to visualize each of the following models overlaid on the patient when they are on the couch during positioning:
    - Beam Projection
    - Colormap/Isodose Curves
    - 3D Body Contour
    - 3D Internal Organs
    - (2D/3D) Original and current body contour displacement
    - (2D/3D) Original and current internal organ displacements

***Group C: Physical Requirements***
Please rank the following in order of importance (1 - Least important, 2 - Less important, 3 - Moderately Important, 4 - Somewhat Important, 5 - Most important):

- Portable
- Cleanable (easy to sanitize)
- Reusable (use for every patient while still being patient specific)
- Affordable
- Long Battery Life

8. How many hours would a patient setup device be actively in use during a typical day?
    - 2 - 4 hours
    - 5 - 6 hours
    - 7 - 8 hours
    - More than 8 hours

***Group D: User Experience***

If you were asked to use a portable patient positioning device to setup a patient, please rank the following characteristics based on their importance (1 - Least important, 2 - Less important, 3 - Moderately Important, 4 - Somewhat Important, 5 - Most important).

- Ergonomic
- Easy to Operate
- Requires Minimal Training
- Integrates with the Current Hardware & Software
- Easy to Maintain & Update

9. Which device modality would be most convenient to use?
    - Stationary (monitor)
    - Portable (wearable device)
    - Portable (handheld)
10. Are there any particular areas within radiation oncology or the clinical workflow that have potential to be improved on? How? [*long answer textbox*]

## 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.