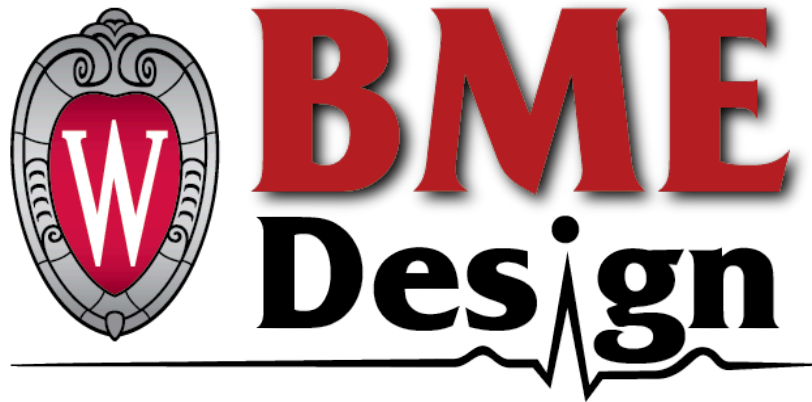




Hand-Positioning Plate for Low-Dose Radiation Therapy (SteadyHand)

Product Design Specification | September 17, 2026

BME 200/300 Design Project Lab

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Function/Problem Statement:

Severe joint pain in the hands due to osteoarthritis and other inflammatory conditions is now frequently treated using low-dose radiation therapy (LDRT). Current LDRT protocols require high setup reproducibility across 6 treatment sessions. Existing positioning systems are overly complex, use complicated indexing systems, and compress digits 2-5 together. This causes significant discomfort for patients and creates unnecessarily long setup times. This project aims to develop a hand positioning device to be used in a clinical setting that minimizes setup time and patient discomfort while ensuring exact hand placement for each treatment session.

Client requirements:

- Consistent joint placement in the field within a tolerance of 2-3 mm.
- Maximize patient comfort with finger separation and a natural hand posture.
- One therapist can set up the device in about two minutes.
- Minimize the amount of material used to not interfere with the radiation beam.
- Cleanable with hospital disinfectants.
- Simple, repeatable attachment to the treatment couch.
- Fits left and right hands and most adult hand sizes.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements

- i. The device must maintain the patient's hand position during treatment and across all 6 sessions. It must maximize patient comfort and be set up by only one technician in ≤ 2 minutes.
- ii. Average hand sizes of patients 45 and older must be accommodated. This is defined by a length of 6.8-7.6 inches, a breadth of 3.1-3.5 inches, and a circumference of 7.0-8.6 inches [1].
- iii. The device must hold up under repeated CT scans and LDRT. It will be used 7 times for each patient (initial CT scan and 6 subsequent LDRT sessions). The radiation exposure time will be approximately one minute per session.

- iv. The device must withstand repetitive loading in hand positioning locations without bending or fracturing. The average weight of one hand is 400 g [2].
- v. It must be possible to fully disinfect the device according to clinical standards.

b. Safety

- i. The device is classified as a Class II medical device and must comply with all standards and specifications listed in section 3a.
- ii. The device must not pinch patients' hands, restrict circulation, or cause excess pressure. It must not have sharp edges that could injure the patient.
- iii. It must be possible to remove the patient's hand in under 10 seconds if rapid removal is necessary.
- iv. The device must sit securely on the table or couch arm and completely immobilize the hands to ensure that radiation is accurately directed and normal tissue exposure is minimized [3].
- v. The device must not alter radiation concentration unpredictably due to attenuation [4]. Radiation and X-ray exposure must not cause an adverse reaction between device material and the patient's skin.

c. Accuracy and Reliability

- i. The device must replicate the exact initial hand position and orientation from CT scan within $\pm 2-3$ mm for each subsequent treatment round [3]. Setup time for each hand must be consistent across patients within one minute.

d. Life in Service

- i. The device must be able to undergo 6 micro radiation dose sessions of 0.5 Gray (Gy) over the course of 2-3 weeks per patient without any structural damage [5].
- ii. The devices must retain accuracy after use, ensuring replicable and comfortable hand positioning for the patients, without interference with radiation.

e. Shelf Life

- i. The device must be stored in relatively dry environments due to the tendency for 3D printing materials to soak up water from the air [6].
- ii. PLA has an average shelf life of 1-3 years, and PETG has an average shelf life of 5-10 years once both are exposed to air and printed. The product's shelf life will be close to this range as well to ensure accuracy and structural integrity [6].
- iii. The device must be stored at room temperature and without any direct sunlight. PLA specifically will weaken under UV contact, while PETG will be more UV-stable [6].

f. Operating Environment

- i. The hand positioning device will be used in hospitals and clinics that perform low-dose radiation therapy (LDRT) for treatment of osteoarthritis in hand joints.
- ii. The device will be exposed to six radiation treatments of 0.5-1.0 Gy per treatment, for a total expected treatment dose of 3-6 Gy, without significant degradation or loss of structural integrity [7].
- iii. The device must maintain dimensional stability and positioning accuracy following exposure to the expected 3-6 Gy treatment dose.
- iv. The device must operate in a CT imaging environment with a temperature range of approximately 64-75°F (18-24°C) and relative humidity of 30-70% [8].
- v. The device must operate in a radiation-treatment room with a temperature range of approximately 68-75°F (20-25°C) and relative humidity of 40-60% [9]. The device must withstand repeated hospital sanitation and disinfection procedures without measurable degradation, warping, cracking, corrosion, or loss of functionality [7].
- vi. The device must remain structurally stable while being transported between the CT scanner and medical linear accelerator (LINAC) and will maintain the patient's hand position during transportation.

g. Ergonomics

- i. The device must accommodate a patient hand-size range of 17.2-19.3 cm in hand length and 7.9-8.9 cm in hand width, based on the expected clinical patient population [10]
- ii. The device must maintain the patient's prescribed hand position for the duration of the treatment session without requiring the patient to exert a continuous holding force [11].
- iii. Patient-contact surfaces must not produce a measurable pinching or excessive localized pressure.
- iv. A clinician must be able to position and secure the hand of the patient in ≤ 2 minutes.
- v. The device must maintain hand positioning within a maximum translational error of ± 1 mm [12].
- vi. The device must maintain hand positioning within a maximum rotational error of $\pm 1^\circ$ [12].
- vii. The clinician must be able to verify correct hand positioning using alignment features with a verification accuracy.
- viii. The materials of the device must not produce clinically significant interference with CT imaging or radiation delivery [12].

h. Size

- i. The device must not exceed a maximum footprint of 40cm x 40cm to remain within the available CT and radiation-treatment workspace.
- ii. The device must have the minimum practical thickness necessary to provide adequate structural stiffness and positioning accuracy.
- iii. The primary positioning plate must have a target thickness of 1-2mm.
- iv. The device must remain within the required radiation beam geometry and must not obstruct the treatment field or interfere with LINAC operation [12].
- v. The device must be capable of being transported by one clinician between the CT scanner and LINAC without assistance.
- vi. The device must minimize overall thickness and weight while maintaining the required structural stiffness and positioning accuracy.

i. Weight

- i. Low material and device weight must support ease of handling the product during low-dose radiation therapy set-up.
- ii. The product must be kept to a light weight to support storage and transportation of the device to other clinics.
- iii. Having a high-density material will affect the radiation beam, even under low doses, and will cause attenuation, which can lead to under-dosing the target area and cause unnecessary radiation exposure to healthy skin in the event of secondary electron scatter [13].

j. Materials

- i. The amount of material used for the device must be minimized to keep costs and weight to a minimum.
- ii. For the product's hand fixtures, PLA or PTEG must be used to ensure the material does not affect the radiation beam. PLA and PTEG do not degrade in their physical and mechanical properties when put under a high-dose radiation beam [14]. However, low-density foam is also a valid substitute [15].
- iii. The base plate that the hand will rest on must be made of a low-density carbon fiber or a radiation-transparent plastic material so as not to interfere with the radiation [13]. This is especially important since the radiation will come from above and below the device.
- iv. Absolutely no metals will be placed where the radiation beam hits, as this will be harmful to the patient [16].

k. Aesthetics, Appearance, and Finish

- i. Advanced indexing, such as the one on the Dexalign Hand Positioner, can be overly complicated. The product must avoid unnecessary features so that the set-up for low-dose radiation therapy does not take more time than is necessary [17].
- ii. The product must not have any sharp edges or components that could pinch the patient or the clinician setting up the device.
- iii. The density of the entire product must be similar to the density of water (1g/cm^3) so that the product doesn't cause harm to the patient through accidental beam attenuation [13].
- iv. The base plate of the SteadyHand product will be white or gray to maintain simplicity. It must also have a few black index marks to assist the physician in placing the patient's hand.

2. Production Characteristics

a. Quantity

- i. The design will consist of one base plate that will have all of the necessary components and indexing to hold the patient's hands comfortably and with recurring accuracy.
- ii. Only one device is necessary. However, documented instructions of the fabrication process must be provided to ensure accurate reproducibility by other clinics.

b. Target Product Cost

- i. The budget for the product will not exceed \$200. The budget will include costs for materials to produce the product as well as prototypes. There will be an additional \$50 budget available for 3D printing in the Wendt Design Innovation Lab.
- ii. The product will be cost-effective and reproducible for other clinics. The cost of the device will aim to be lower than the cost of current competitors.

3. Miscellaneous

a. Standards and Specifications

- i. SteadyHand will be classified as a Class II Medical Device Accessory under FDA 21 CFR 892.5050 [18]. Accessories that sit directly in a radiation beam path and come into direct contact with human skin are considered moderate-risk devices that require certain standards to guarantee safe performance [19].
- ii. AAPM Task Group 176 provides guidelines for assessing the radiological safety of patient immobilization devices. Their findings validate that a 1 to 2mm carbon fiber base and printed PLA components maintain high radiolucency, preventing beam attenuation and unwanted skin dose disruptions during radiation therapy [13].

- iii. Since SteadyHand will come into direct contact with human skin, it must comply with ISO 10993-1, which deals with biocompatibility and skin contact, specifically cytotoxicity, irritation, and sensitization [20]. The nature of contact is with intact skin for a limited duration (< 24 hours). Devices that contact intact skin only and use low-risk materials no longer require biocompatibility test reports if a safe history of use is documented [21].
- iv. Since SteadyHand will be used in clinics, it must adhere to CDC / AAMI ST79 [22]. This standard mandates that all surfaces can withstand hospital-grade chemical disinfection without the material degrading. If PLA or other 3D-printed materials are used, layer lines must be sealed or post-processed to prevent pathogen entrapment.

b. Customer

- i. Clinicians and radiation therapists will be using the device to immobilize patients' hands during LDRT. The device must allow therapists to set up patients quickly and in the same position for every treatment. One therapist should be able to set up the device in about two minutes.
- ii. Patients are typically in their mid-forties or older. They all have painful hand joints from osteoarthritis or something similar, and awkward hand positions are hard to hold. SteadyHand must minimize patient discomfort by allowing a relaxed hand position. Digits 2-5 should not be compressed together, and the device should allow for space between the palm and base plate.

c. Patient-related concerns

- i. The product will be manufactured to ensure patient comfort and prevent irritation. The device will consider finger placement, adjustability, and natural hand positions to maximize patient experience.
- ii. The product will withstand typical hospital disinfectants to ensure sterility and minimize potential contaminants.
- iii. The device will not contain any metal parts or other materials that interrupt radiation flow or alter the consistency of the treatment.

d. Competition

- i. Dexalign Hand Positioner is the prominent solution used for patients undergoing low-dose radiation therapy. The device allows for consistent placement for each session for over 95% of hand sizes and types [8]. The hand positioning product aligns with

radiation therapy requirements and advertises a rapid setup time for a seamless experience. Dexalign immobilizes both hands without enclosing the whole extremity.

- ii. Orfit Extremities System is another device used for patients undergoing low-dose radiation therapy. The device will allow patients to lie down or sit upright while immobilizing their hand using a thermoplastic mask. The device streamlines setup and ensures comfort with soft cushions [10].
- iii. Extremity Lock by CDR Systems provides a device to lock limbs in a fixed position for a prolonged period of time. The device uses imaging-compatible material to accurately reproduce ideal positions for low-dose radiation therapy [23]. In addition to LDRT, the product is used for CT scans, MRI's, and on-board imaging.

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