

INTERSTITIAL DIFFUSE OPTICAL FIBER PROBE DESIGN PROJECT DESIGN SPECIFICATIONS REPORT

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Function:

Our probe will allow for the observation and recording of optical diffusion properties within the interstitial fluid of mice and eventually in human application. In doing so, it will remain as minimally invasive as possible (keeping pace with similar medical techniques) but ensure that quality measurement is being taken hypodermically. Our end product will be reusable and remain within the patient throughout treatment, ensuring consistent and stable measurements throughout therapy.

Client Requirements:

Our Client is looking for a system that:

- Offers a sturdy and reproducible structural design
- Keeps invasiveness of the procedure to a minimum
- Offers the potential for leaving the design in-patient throughout therapy

Design Requirements:

Structure:

- The Design must hold two optical probe needles 3 mm apart
- The needles must be able to penetrate the epidermis of the skin, at least 2mm injection
 - Currently 28 gauge needle (.362mm)
- The needles must remain rotationally rigid, with the beveled edges of the needles facing in
- The clasp must hold the needles for easy skin penetration

Operation:

- Must be easy and quick to use
 - o Easy means an untrained operator must be able to use with minimal instruction
 - o Quick means setup must take no longer than 2 minutes
- Skin Penetration
 - o No data for required force application for penetration is currently recorded or a factor

Physical and Operational Characteristics:

a. Performance Requirement: This system will be single use. It is expected to breach the skin easily while maintaining structural capacity and dimension.

b. Safety: Human factors set safety demands on our product that will include acceptable methods for injection.

c. Accuracy and Reliability: Accuracy specifications are not yet determined for this study to quantify demands for our design.

d. Life In Service: The expectation is that this design will be part of the everyday life of all patients experiencing radiotherapy throughout their treatment.

e. Shelf Life: No demands for shelf life are currently anticipated

f. Operating Environment: Our device will measure optical diffusion under the epidermis, in interstitial fluid. Operating temperature is assumed close to 96-100° F.

g. Ergonomics: Our theoretical end design will include comfortable in-patient feature.

h. Size: The entire design will be as small as possible. Current restrictions are that the probes must be at least 3mm apart in any Cartesian direction.

i. Weight: Our device currently is under no expected weight demand.

j. Materials: We have yet to be introduced to the materials currently in use. These materials must be anti-coagulant, flexible in application, and rigid in structure.

k. Aesthetics/Appearance: There are no current or expected appearance requirements.

Production Characteristics:

Quantity: We will be building one overall design for mass production in mouse studies and anticipate a separate design for human application.

Target Product Costs: No real product cost or project budget has been established yet

Miscellaneous:

N/A at current time.