

Fine Needle Aspiration (FNA) Device

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December 12, 2006

Function: Fine needle aspiration is a biopsy method of collecting tissue samples. The procedure is currently manual and requires repetitive low yield sampling to collect enough viable cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We propose to develop a device that automates the current biopsy procedure, and tests the sample yield by varying the frequency and needle stroke. The test results will determine the optimal operating frequency at various stroke lengths to provide a maximum cell yield. The automation of the device will reduce operating time, cost and discomfort for the patient.

Client requirements: The device must:

- be reusable
- be durable
- be user-friendly
- be sanitary to clients standards
- comply with given hospital safety standards
- be dependable and precise
- test variations in frequency and needle stroke

Design requirements:

- 1) Physical and Operational Characteristics
 - a) Performance Requirements:
 - i) Reusable
 - ii) Withstand constant oscillation
 - iii) Withstand multiple procedures
 - iv) Withstand sterilization methods
 - v) Needle force requirements
 - vi) Vacuum mechanism to draw cells into needle easily operated by second person
 - b) Safety:
 - i) No risk of electric shock
 - ii) Non-toxic and non-allergenic
 - iii) Preserve needle integrity
 - c) Accuracy and Reliability:
 - i) Variable needle insertion depth (10mm to 20mm)
 - ii) Frequency must be variable and measurable
 - iii) Biopsy sample must be retained within needle shaft
 - d) Life in Service: Device must be operable over 30 minute interval
 - e) Operating Environment:

- i) Sterile hospital environment
 - ii) 23°C standard room temperature
 - f) Ergonomics:
 - i) Functional at varying angles of operation without losing maneuverability
 - ii) Controls must be easily accessible
 - g) Size:
 - i) Small and slender
 - ii) Must not restrict maneuverability and accessibility
 - h) Weight:
 - i) Must not strain arm and hand
 - ii) Light weight
 - i) Materials:
 - i) Light weight materials
 - ii) Easily sanitized, especially materials potentially in contact with patient
 - j) Aesthetics, Appearance, and Finish:
 - i) Marketable (aesthetically pleasing to patient and doctor)
 - ii) Maintains professional medical device appearance
- 2) Production Characteristics
- a) Quantity: 1 prototype
 - b) Target Product Cost: minimal, constrained by budget
- 3) Miscellaneous
- a) Standards and Specifications: FDA approval (human testing standards)
 - b) Customer:
 - i) Minimal training
 - ii) Low production costs
 - iii) User-friendly
 - c) Patient-related concerns:
 - i) Sterilized between uses
 - ii) Minimal time, cost and pain
 - iii) Professional aesthetics
 - d) Competition
 - i) Manual fine needle aspiration technique
 - ii) Cameco Syringe Gun
 - iii) Vacuum needle
 - iv) Fine Needle Gun (Patent 7008383)