#22- Characterization of Pleural Fluid

September 10, 2010

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Client: Dr. Steven Yale

Advisor: Professor Chris Brace

Function:

Dr. Steven Yale has requested a non-invasive, clinical method to characterize the fluid properties of the pleural effusion to determine whether the pleural effusion is exudative or transudative.

Client Requirements:

Cost effective

Portable

User friendly

Accurate

Design Requirements:

- 1) Physical and Operational Characteristics
 - a) Performance requirements
 - i. To determine the fluid properties of the pleural effusion (pH, glucose, catalase, protein content, blood content, specific gravity)
 - b) Safety
 - i. No negative biological effects
 - ii. Corrosive hydrogen peroxide needs to be well contained
 - iii. Minimal exposure of body fluid
 - c) Accuracy and Reliability
 - i. Test strips accurately detect concentrations of components of fluid
 - ii. Accurately differentiate between exudative and transudative effusion
 - d) Life in Service
 - i. Single use

ii. With additional strips the glucose meter can be reused
e) Shelf Life
i. 3 months
ii. Strips deteriorate 90 days after breaking seal
f) Operating Environment
i. Patient hospital rooms
ii. Military zones
iii. Veterinary hospitals
iv. Third world countries
v. Clinics without lab support/ equipment
g) Ergonomics
i. Easily maintained
ii. Symmetric design
iii. Consistent layout
iv. Easy to read
h) Size
i. 10.2cm wide, 12.7cm long, and 1.9cm high
i) Weight
i. 231 grams
j) Materials
i. No latex
ii. High density polyethylene
iii. Clear plastic test tube – 8.573cm tall, 1.27cm in diameter
k) Aesthetics
i. Easy to read results
ii. Symmetrical design
2) Production Characteristics
a) <i>Quantity</i>

- i. One model
- b) Target Product Cost
 - i. \$38.37– with glucose meter
 - ii. \$8.38 without glucose meter
- 3) Miscellaneous
 - a) Standards and Specifications
 - i. FDA approval is required if placed in the market
 - b) Customer
 - i. Medical schools
 - ii. Hospitals
 - iii. Military
 - iv. Veterinary clinics
 - v. Veterinary schools
 - c) Patient-related concerns
 - i. If test is inconclusive, further lab work is needed
 - d) Competition
 - i. Magnetic resonance spectroscopy
 - ii. Ultrasound
 - iii. Protein analysis