Innovations in Spirometry
EnPRO 357

background
product
technology
customers
competition
business plan

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Innovations in Spirometry

Spring 2002
30 million Americans currently suffer from lung disease

Lung disease is #3 cause of death in the US
A spirometer is a medical device used to assess lung function

- Measures velocity of air flow
- Relates velocity to clinically relevant lung parameters
Currently available diagnostic spirometers:

- Expensive capital investment ($1500 – 3000+)
- Require computer for operation
- Require daily calibration with bulky equipment
- Require separate purchase of mouthpieces ($2+ per patient per test)
The IIT spirometer exceeds the capabilities of traditional spirometers:

- Lightweight and user-friendly
- Meets or exceeds all ATS standards for spirometry
The IIT spirometer exceeds the capabilities of traditional spirometers:

- Measures and stores diagnostically relevant information
- Measures $\text{FEV}_{1.0}$ and Peak Flow
The IIT spirometer exceeds the capabilities of traditional spirometers:

- Inexpensive
- Easy cleaning and sterilization
- No moving parts design provides durability
fluidic oscillator

Inlet

Oscillatory Chamber

Outlet

Nozzle

Obstacle

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The IIT spirometer proven for operation under steady-state flow conditions

To proceed to final development:

– Must be proven for operation under unsteady flow conditions
Experimental approach to prove unsteady flow case

- Design and build a lung function simulator
experimental approach
**Dynamic Flow Experimental Data**

**Pressure vs. Time**

<table>
<thead>
<tr>
<th>Testing up to 8L</th>
<th>ATS Standards (Diagnostic)</th>
<th>IIT Spirometer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEV\textsubscript{t}</strong></td>
<td>±3% of reading</td>
<td>±0.6%</td>
</tr>
<tr>
<td><strong>FVC</strong></td>
<td>±3% of reading</td>
<td>±0.6%</td>
</tr>
<tr>
<td><strong>Precision</strong></td>
<td>±3% of reading</td>
<td>±0.95%</td>
</tr>
<tr>
<td><strong>Resolution*</strong></td>
<td>0.05L</td>
<td>0.045L</td>
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</tbody>
</table>

\*Monitoring standards
Primary marketing target:

Physicians who use spirometers

~15,000 pulmonologists

~7,000 allergists
Secondary marketing targets: physicians who do not currently use spirometry regularly

- will benefit fiscally and clinically

- 8-9,000 spirometry tests performed per year at The University of Chicago Hospitals alone
Surveys and Interviews:
- Physician
  - To gain better understanding of the market
  - To seek advice on enhancing the spirometer functions.
- Patient-Consumer
  - To identify potential customer types
  - To define market supportable price range
  - To discover ways to improve on current products.
Spirometry market is crowded

Many companies selling similar products:

- Based on pneumotachigraph technology
- Periodic calibration required
Many companies selling similar products:

- Disposable pieces required
- PC dependent for operation

We can compete on the basis of:

- No disposable pieces
We can compete on the basis of:

- No need for calibration
- PC independent
- Increased accuracy
- Price
Establish independent company to bring spirometer to market

Initial business model will follow SBIR plan
Investments in a series of 6-9 month phases

- Phase I: Evaluation ($100,000)
  - Solve technical issues
  - Complete spirometer development
  - Define manufacturing protocol
- Goal: Increase value of business 2-3 times
- Phase II: Testing and Market
  - Clinical trials
  - Initial product sales
  - Build client list
- Goal: Establish $1-2 million business
Formal consulting relationships being formed with prominent physicians at:

- National Jewish Research and Medical Center
- The University of Chicago Hospitals
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Humanitarian Benefits

Capitalist Benefits
Existing Market
Ease of Use
Retail Price
Low Risk

Return on Investment!
The Team

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