

310/4

**Economic Development for Physicists from
Developing Countries**

27 November 2006 - 1 December 2006
Trieste - ITALY

FROM UNIVERSITY TO START-UP COMPANY

**Dawood Parker
Melys Diagnostics Ltd**

From University to Start-Up Company

Dawood Parker

Managing Director

Melys Diagnostics Ltd, UK

IP First Experience: Catheter-Tip Oxygen Sensor

- Clinical background to the problem.
- What was needed.
- The invention.
- Clinical consequences.

Prior to 1950, the chance of survival for a pre-term baby of less than 1200 grams was almost nil. Today it is better than 98%.

Neocath 1000

The bipolar design obviates the need for a second electrode to provide continuity to the measuring circuit. Not only does this mean less connections to the patient, but it also ensures that the signal is not affected by electrical interference and muscle artifacts which could lead to erroneous readings.

The sampling lumen, with a smooth peripheral eye close to the tip, enables samples to be taken for calibration purposes; close to the measuring electrode. In addition, this access point permits continuous measurement of arterial blood pressure via a suitable transducer.

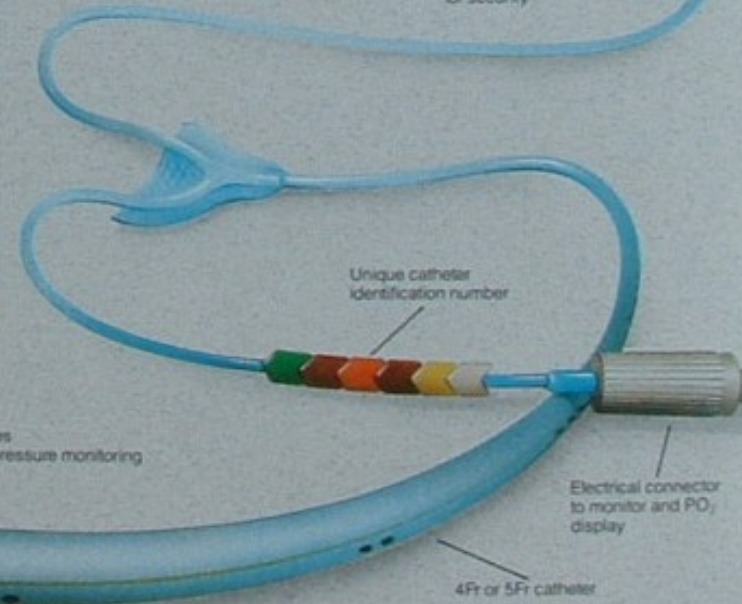
An internal rechargeable battery gives approximately 4 hours of continuous operation, or the monitor can run direct from an A/C supply ensuring universal availability.

The **NEOCATH 1000** monitor is constructed to conform with the highest international safety standards, and to provide trouble-free operation.

Confidence in the system, allows more attention for the patient.



Luer lock connection for security



Unique catheter identification number

Electrical connector to monitor and PO₂ display

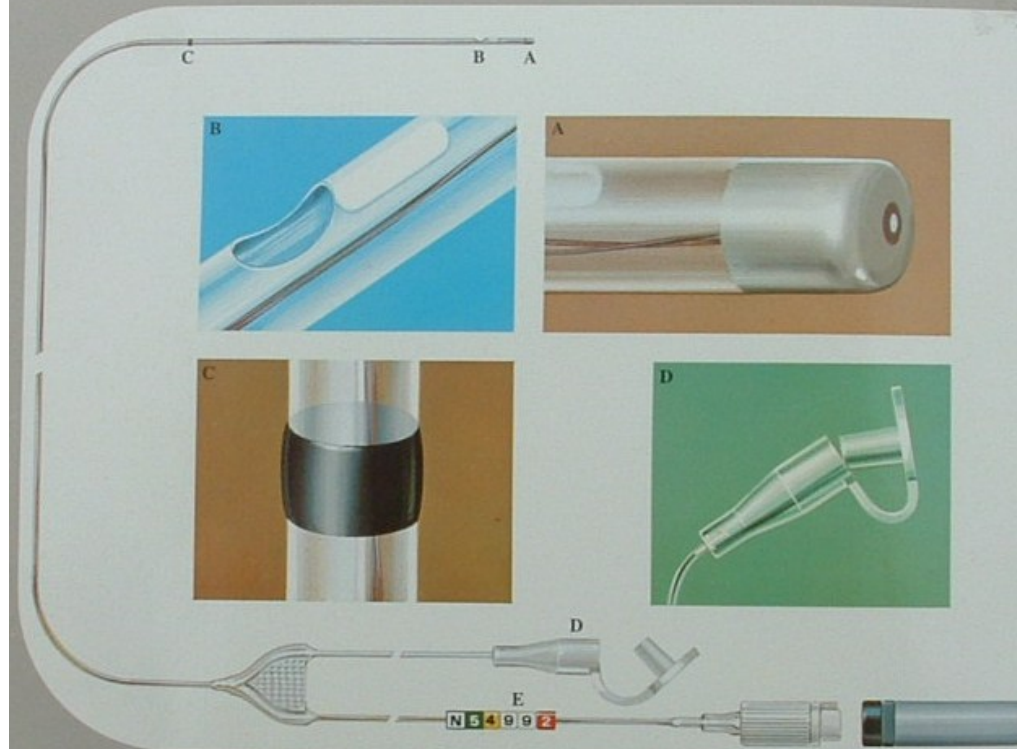
4Fr or 5Fr catheter

Bipolar oxygen electrode for accurate measurement of PaO₂

Lateral eye to provide blood samples and continuous blood pressure monitoring

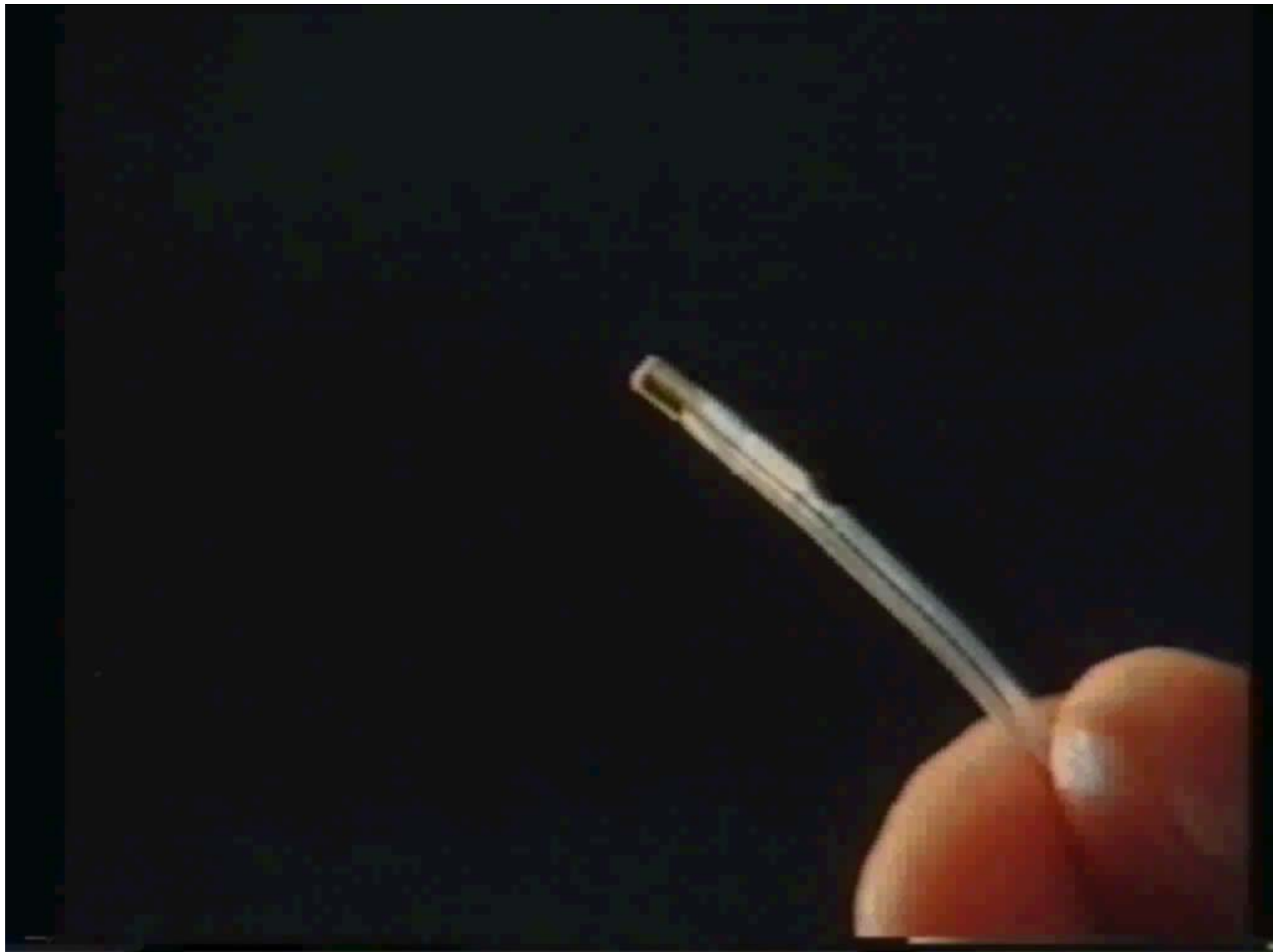
The Oxygen Probe

- A Disposable Bilumen Umbilical Artery Catheter Terminating in a Bipolar Oxygen Electrode.
- Sterilized by Gamma Radiation.
- Available in 4 and 5 Fr. Sizes.

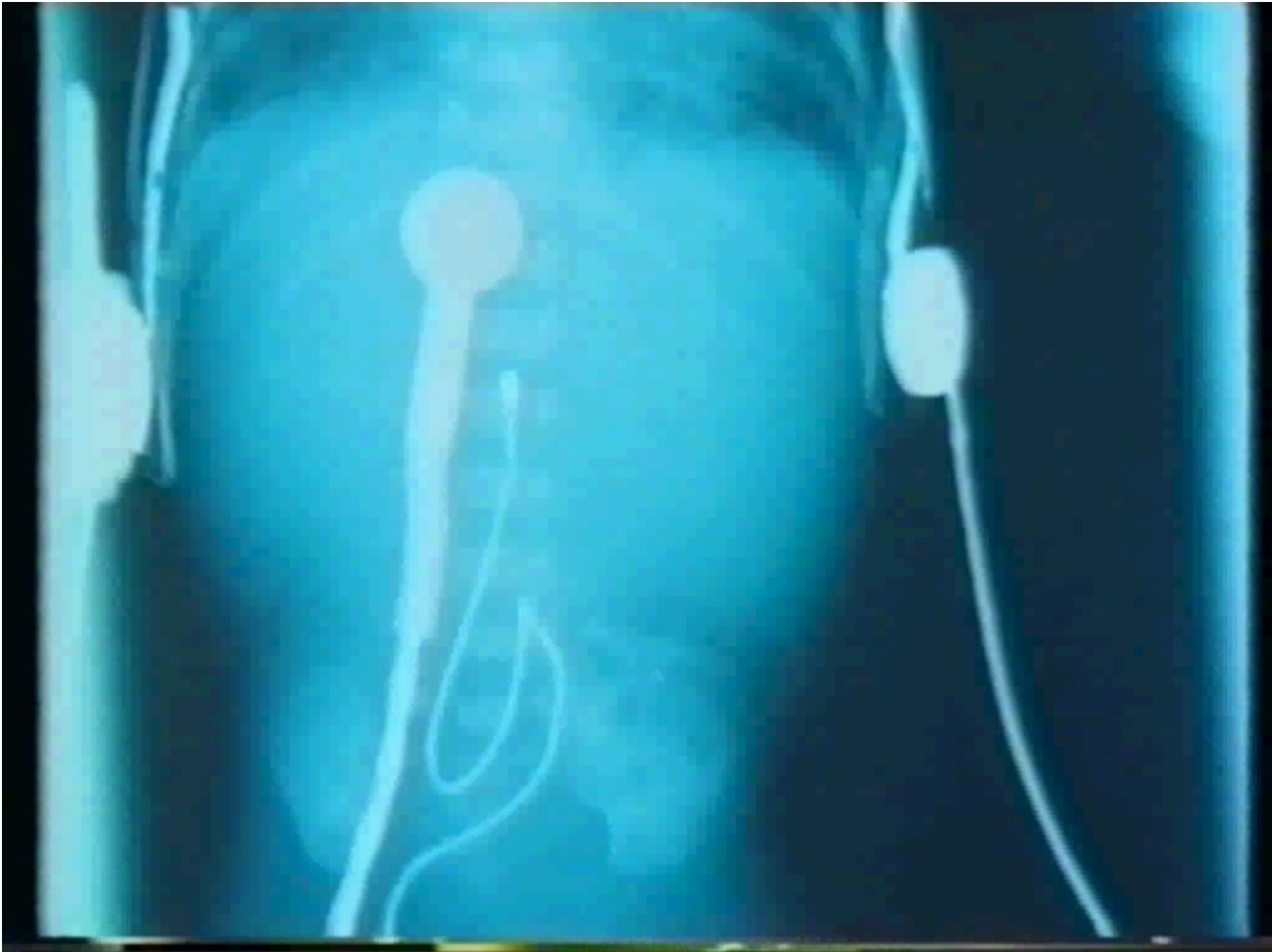


- A. Membrane-covered Ag, Ag/AgCl Electrode Provides Continuous Measurement of Oxygen Tension in Flowing Blood.
- B. Radiopacity Is Provided by the Catheter Tip and the Electrode Wires Contained in One Lumen of the Catheter. The Second Lumen and Sampling Eye Can Be Used for Blood Sampling, Infusion, and Pressure Measurements.
- C. 10 cm Depth Mark Assists Accurate Insertion into the Descending Aorta.
- D. Luer Connector Accepts Standard Syringes and Blood Pressure/Sampling/Infusion Devices.
- E. Control Number Identification.









What were the options at this point?

1. Apply for a patent.
2. Assign the invention to a company in exchange for research funding.
3. Assign the invention to a patent organisation – share royalties.
4. Start your own company on the basis of the invention.

Option Taken

Assigned the invention to a patent organisation and shared the royalties (50%/50%).

Also received research funding.

Case One: Monitoring Devices for Newborn Intensive Care.

- What were the products required in newborn intensive care?
- Started company on the basis of the above - Physiological Instrumentation Ltd (retained university position.)
- Protected intellectual property.

Non-Invasive sensor for measuring Oxygen and Carbon Dioxide

Transcutaneous Oxygen and Carbon Dioxide Monitoring System

For continuous monitoring of transcutaneous O_2 and CO_2 partial pressures.

Single transcutaneous Sensor
Measurement of both oxygen and carbon dioxide is performed using a single sensor head.

Simple sensor preparation
Easy "snap-on" membrane assembly allows user to prepare sensor in seconds prior to calibration.

Calibration using precision gas mixtures
A two point calibration for both oxygen and carbon dioxide allows fine tuning of the system for maximum accuracy.

Direct digital pO_2 and pCO_2 readout
Readouts of transcutaneous pO_2 and pCO_2 are displayed simultaneously on monitor.

Automatic warning of $tcpO_2$ and $tcpCO_2$ fluctuations
Both audible and visual alarms are triggered by values outside of preset limits.

Two completely separate temperature monitoring circuits in combined sensor
Inappropriate power supply to the sensor will automatically cause all power to be shut down to the sensor, eliminating problems associated with overheating.

Battery operated
The monitor utilizes rechargeable batteries which are automatically recharged when monitor is plugged into mains supply.

Pictured is the combined transcutaneous sensor which measures oxygen and carbon dioxide simultaneously.



What were the options at this point?

1. Develop intellectual property to production stage.

Risks... significant investment required

competition

full-time commitment to company
(incompatible with university position).

Benefits... increased value of company

2. Sell company (with all intellectual property).

Option Taken

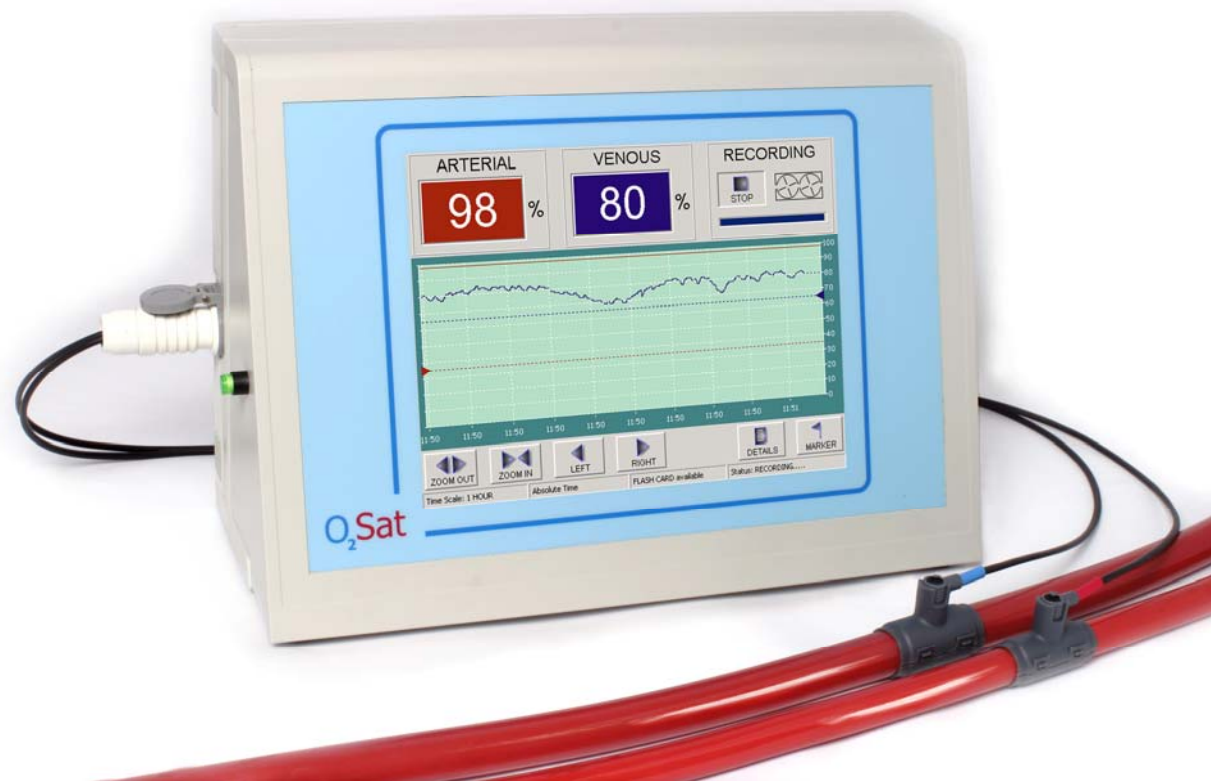
Company sold in response to acquisition bid
by US Patient Monitoring company.

Case Two:

Whitland Research Ltd.

- Formed non-invasive monitoring company, Whitland Research Limited.
- Accepted investment from UK entrepreneur.
- Protected intellectual property.
- Developed products to engineering prototype stage.

O₂Sat



What were the options at this point?

1. Take invention to production stage.

Risks... significant investment required
competition

Benefits... increased value of company

2. Sell company (with all intellectual property).

Option Taken

Company sold to US Multinational company.

The technology, not the product, was the driving force behind this acquisition.

Current Company: Melys Diagnostics Ltd

Step One:

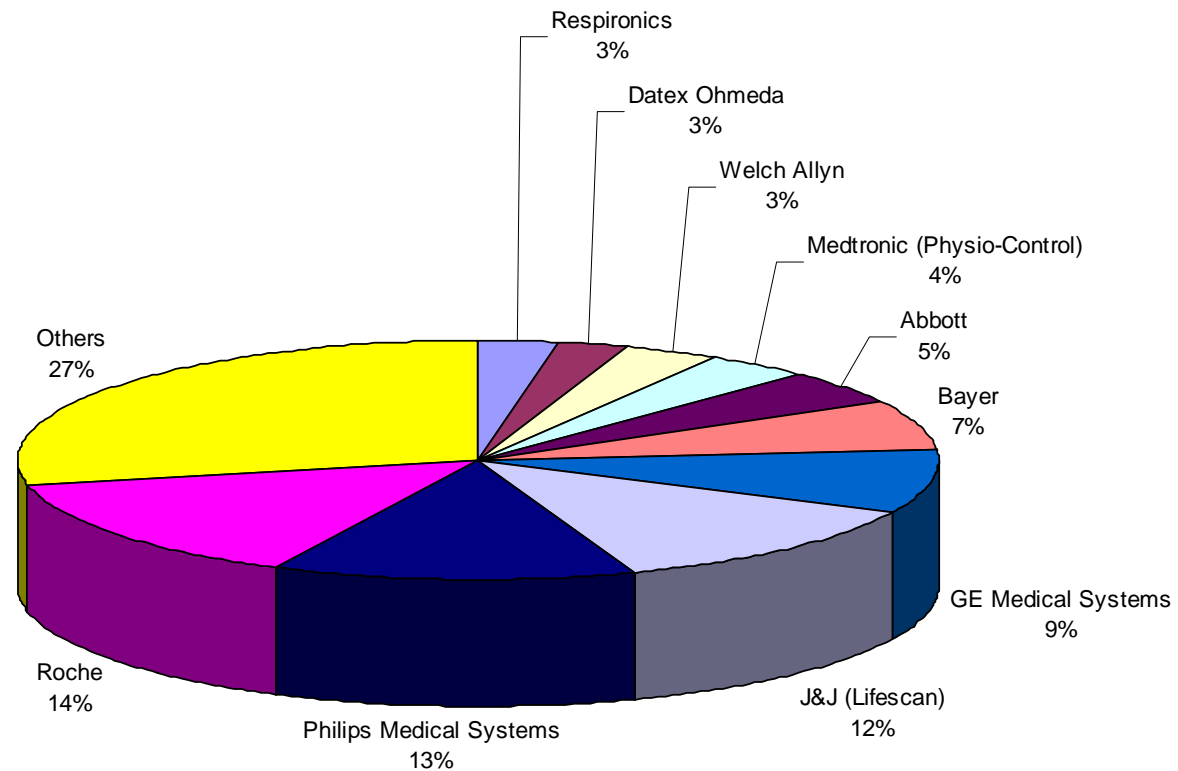
Identify business opportunities in
patient monitoring.

Market Opportunities

- Fetal and neonatal monitoring
- Cardiovascular monitoring
- Diabetes glucose self-monitoring
- Blood pressure monitoring
- Anaesthesia monitoring
- External defibrillators
- Telemetry
- EEG diagnostic and monitoring



Global Patient Monitoring Market Shares



Business Opportunity

Step Two:

Select business opportunity:

Non-Invasive Glucose Monitoring.

US Glucose Monitoring Market

Large patient population: ~17 million diabetics in the U.S; almost 6 million still remain undiagnosed.

US 2002 total market size: \$2.6 billion

Meters market: 13%, Strips market : 87%

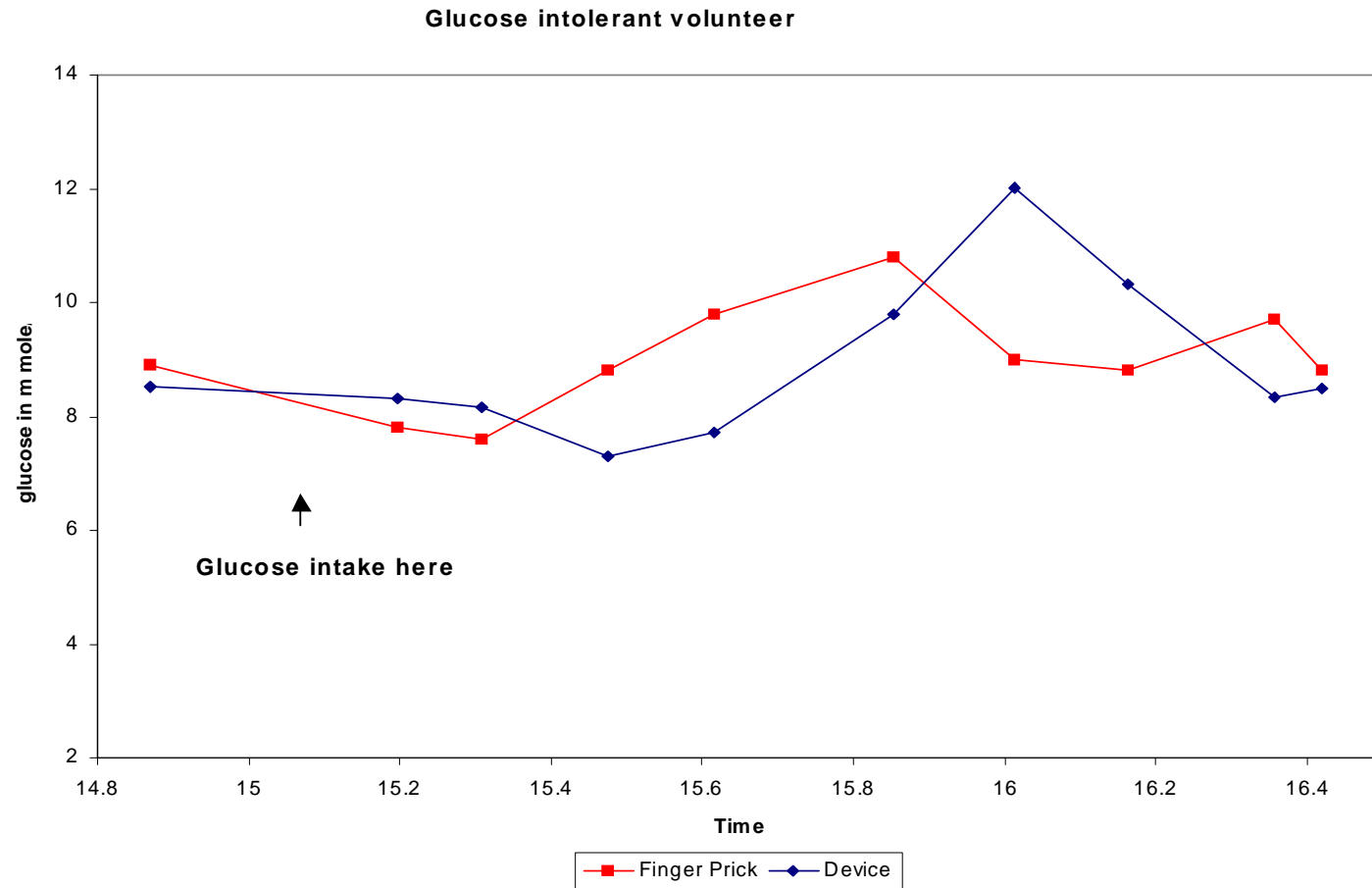
Growth Areas:

Product innovations that are reducing the perception of pain from finger-stick testing. The pain associated with testing was a key reason for low compliance.

New technologies: continuous monitoring systems, non- and minimally invasive technologies

The Dilemma

What is the value of this IP?



Current Model

Nursery unit generating intellectual property for subsequent sale to major international companies.

Advantages: Low investment requirement

Low risk

Disadvantage: Low to medium level of reward