Imperial College London

EE3 Group Project 2004/05

An ECG Telemetry System Part 2: Commercial Report

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Executive Summary

This marketing plan contains market research further to what was undertaken in the initial stage of the project, as well as a blueprint for marketing our products, sales targets and estimates of cost and revenue. The product will initially be marketed in the United Kingdom, and then to the rest of the world. This report specifies the strategy for starting the business in the UK.

The market research shows that there is a promising market for portable ECG equipment, for several reasons. Firstly, there are a lot of patients with heart conditions that need to be closely monitored. Conditions such as arrhythmia can be difficult to detect, and may need to be monitored over an extended period of time, such as a few days, to be correctly diagnosed.

There is a demand for more flexible healthcare - patients would often rather be at home than in a hospital ward, and if there is no immediate threat from their condition, there is no need to keep them there. Portable ECG equipment can be provided which keeps the hospital updated on the patient, while allowing the patient to continue a normal life, and free up hospital beds.

The National Health Service (NHS) is the main customer in the UK for medical equipment, and its budget is increasing substantially every year. The private healthcare sector is also an expanding industry, and so our customers have more money to spend on our product.

There are already several large companies with competing products, including Philips, General Electric Corp. and Card Guard Group. Breaking into the market may therefore be challenging.

The product will include an integrated hardware and software system. When selling products, volume sales reductions will be employed as well as marketing two versions of the product – one for large scale implementation and one for small scale – to maximise revenue. After sales services will be provided such as technical support and product repair and servicing.

We aim to provide advanced features on our products, while keeping the price in the medium band, making our product more competitive than others.

We estimate that an initial investment of £500,000 will be required for research and development of the product, with £250,000 per year following to maintain the business. Our four-year sales plan predicts revenues of £1 million at the end of the first year of sales, increasing to £5 million at the end of the fourth year of sales. The product should therefore be into profit by the end of the first year of sales.

We believe that our product has the potential to be extremely profitable, over a modest amount of time.

1. Introduction

In the health care industry, advancements in technology have opened up new areas in the medical equipment market. Different types of technology, ranging from telecommunications to software, have improved and created new medical applications such as home monitoring, radiology and patient information access. Of these applications, portable Electro Cardiogram (ECG) equipment falls into the category of telemedicine.

Portable ECG monitoring equipment is vital in the treatment of difficult-to-diagnose intermittent cardiac diseases such as arrhythmias. These conditions of the cardiac system are usually only identified at a late stage that is potentially fatal when early detection could have reduced the risks tremendouslyⁱ.

The National Health Service (NHS) is responsible for 76% of healthcare spending in the UK. The remaining 24% is accounted for by the private sectorⁱⁱ.

The telemedicine sector is a fairly stable market compared to other industries because the market is less dependent on the general trends of the economyⁱⁱⁱ. Economic downturn is usually reflected in the performance of any industry, but as healthcare is a priority for most governments, healthcare spending tends to increase irrespective of the state of the economy. The telemedicine market therefore attracts many companies and in doing so has created a very competitive market.

2. Market Summary

2.1 Target market

Our initial plan is to market our product in the United Kingdom, with International sales following. This report is therefore concerned mainly with the UK telemedicine market.

2.2 Market Size

Prevalence of targeted cardiac conditions

We are designing our product for early detection of cardiac arrhythmias of which the most common forms are atrial fibrillation and paroxysmal tachycardia. The total number of patients who consulted physicians for these episodes was 115,239 in 2002-03. However the number of patients who were admitted to hospital in a progressed state of arrhythmia that was potentially life threatening was 458,755 in 2002-03^{iv}. Furthermore, the unique design of our product permits the detection of coronary heart disease which affects 1.2 million people in the UK and leads to 300,000 deaths^v each year. These statistics reveal a huge potential market for our portable ECG monitor.

Healthcare providers

The UK healthcare market consists of 483 NHS trust hospitals, 12,000 NHS trust clinics and 120 private hospitals^{vi}. The proportion of small, medium and large hospitals is approximately equal. Tabulated below is the estimated existing number of ECG monitors per healthcare provider and our estimate for the number of portable ECG monitors required per healthcare provider based on current health statistics and NHS guidelines.

Type of healthcare provider	Existing number of monitors per provider	Monitors required per provider
Small hospitals	5	10
Medium hospitals	8	15
Large hospitals	12	20
Clinics	0.5	2
Total Market	11,000	33,000

Table 1

Thus, the potential market is up to three times as large as the existing market. Furthermore the NHS plans to build 100 new hospitals by 2008^{vii}. We estimate the portable ECG monitor market to be worth £25 million by 2008 up £15 million from the existing market worth £10 million^{viii}.

2.3 Market Trends

Customers

The NHS accounts for a major part of the UK customer market. Together with a centralised buying structure, this gives the organization monopolistic advantages when dealing with its suppliers. There are other potential customers including the private healthcare sector and private individuals, however these markets are tiny by comparison.

Market Requirements

The Medical Devices Agency (MDA) is the chief medical equipment certification board in the UK^{ix}. The standards set for performance, safety and reliability of medical equipment are very high. Out product must be tested to make sure that it meets these criteria, before it can be sold.

Increasing Flexibility of Healthcare Delivery

Monitoring and diagnostic services enable patients to move from high-cost intensive-care facilities and to lower-cost areas, such as general wards and even the patients' own homes. Electro-medical equipment, such as a portable ECG, has become more flexible and user-friendly, and is easily interfaced with other systems or connected to remote monitoring stations, making it usable in standard hospital wards, doctors' offices, outpatient clinics, ambulances or patients' homes.

Increased Healthcare Expenditure

The total NHS budget is expected to rise from £65.4bn to £105.6bnⁱⁱ by 2007/2008. The private healthcare market is estimated to be £23bn by that period bringing the total healthcare budget to almost £130bn up 52% from current spending.

Research and Development

The medical equipment market is characterised by a strong R&D base. Companies currently invest up to 20% of revenues on research and development^{ix}.

Company Activities

The complexities involved in manufacturing medical equipment, requiring expertise in many

fields of science and technology, are fuelling merger and acquisition activities. Many companies are acquiring their rivals or obtaining licences to key technologies in order to obtain expertise in particular fields, or to gain strategic geographical coverage.

Technology

The electro-medical equipment market is experiencing developments in the fields of signal processing, digital design and integrated device technology. These are resulting in increasingly sophisticated but user-friendly products. Steady progress is also being made in global standardization.

2.4 SWOT analysis of UK medical market

SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) is a standard method of analysing a potential corporate strategy, such as entering the portable ECG market.

Strengths

- As discussed before, the telemedicine market is not very sensitive to economic downturn.
- A highly competitive telemedicine market has forced companies to respond quickly to changing market conditions. A small firm in such a market has the advantage of adapting quicker to changes in technology than larger firms.

Weaknesses

- The NHS controls the majority of the healthcare market in the UK and dictates conditions and prices when it comes to dealing with suppliers.
- A highly competitive market makes it difficult for small firms to compete on products and services with large firms. Smaller firms spend less on R&D which contributes to the lack of competitive strength against larger firms.

Opportunities

- 21% of the total UK population is aged over 60^x. Of deaths in people over the age of 60, between 20% and 30% can be attributed to some form of cardiac disease^{xi}. This raises the need for portable ECG equipment.
- The government is committed to increasing the number of patients being treated by the healthcare sector, which leads to increasing the amount of resources for the NHS. This also leads to higher demand for telemedicine equipment.

Threats

- If the NHS buys a large volume of a competitor's product, there may not be any further opportunity to sell a large volume of our product in the UK.
- Final debugging stages of software and hardware may take longer than anticipated, and if bugs are not caught, these may be expensive to repair.

2.5 Competitor Analysis

Marketplace

The big names in the world telemedicine market include General Electric and Philips who have diversified from a well established foothold in other electrical and electronic sectors. This however has not steered away many smaller firms like Card Guard Group who have been able to survive in this market and at the same time develop sophisticated portable ECG monitors.

The portable ECG market in the UK is dominated by Philips Medical Systems and Card Guard Group. The network software and database features are geared towards large hospitals whilst the standalone ECG monitors are targeted towards hospitals, clinics and individual buyers.

Philips recorded sales of £4.5 million in 2004 whilst Card Guard group posted sales of £2.5 million in 2004 xii. Together they were responsible for almost 70% of sales in the UK portable ECG market.

Snapshot of products offered

Company	Products/Models	Product description and price
Royal Philips Electronics ^{xiii}	1. Zymed DigiTrak plus	Small, pocket sized monitor that requires only 5-electrodes placed on the body to obtain a 12-lead ECG recording. Lasts up to 48 hours on a single AA battery. Price: approx £2,000
	2. Zymed 1810 Series Software	Diagnostic Software that detects possible arrhythmias and other similar cardiac conditions. Offers editing features for ECG data as well as interconnection with a departmental ECG analysis system. Price: could not be obtained

Company	Products/Models	Product description and price
Royal Philips Electronics	3. Centralised ECG analysis system	Centralizes ECG recording, analysis and report access within a hospital department. Permits sending of patient tests via email, LAN or WAN to a central analysis location where Philips Zymed ECG analysis applications are used. Price: could not be obtained
Card Guard Group ^{xiv}	1. Self-check ECG cardiac monitor	In this product ECG measurements from electrodes placed on the body are continuously transmitted via Bluetooth technology, displayed and saved on a handheld device. Price: approx £1,800
	2. King of Hearts Express® AF	This event monitor product was designed to assist in the diagnosis and treatment of Atrial Fibrillation (AF). It has 10 minutes of ECG memory and a rechargeable battery with 2 weeks standby time. Price: approx £1,400
Table 2	3. TM- 2000 TM Receiving Software	This product is a database management tool that enables storage of patient clinical records. It allows e-mail transfer of ECG data and has user access control. Price: could not be obtained

Table 2

3. Marketing Plan

3.1 Mission

Based on the growth statistics predicted for expenditure by the NHS and the size of the medical equipment market we believe there is scope for good sales of our device. To effectively position our product at the forefront of competition, we intend to integrate our device into a complete heart monitoring system to be implemented in hospitals as described below. We will attempt to offer high value by including advanced features for a moderate price.

3.2 Product Description

Our product consists of two main components: the ECG monitoring hardware and a software product for the viewing and storage of ECG data.

ECG Monitoring Device

The device will enable doctors to customize the device dependent on the needs of a patient. The doctor will have control over the number of leads to be used for monitoring (3, 5 or 12 leads) and the mode of operation of the device. The monitor can work in either a continuous mode or event mode. In continuous (also called Holter) mode, continuous 24-hour recordings of ECG data are taken for a set time period, usually 1-2 days, whilst in event mode ECG data is only recorded when the patient pushes a button such as at the onset of cardiac discomfort. A summary of features is as follows:

- Data storage on Compact Flash card
- Capable of working in event or continuous (Holter) mode
- Support for 3, 5 or 12 lead recordings
- LCD display of heart rate
- Notification at the onset of tachycardia or bradhycardia
- 'Event' push button for use by the patient at the onset of physical discomfort
- Rechargeable lithium ion battery for up to 3 days of continuous usage and 10 days on standby

Software Solution

Our software solution allows the analysis, management and review of ECG data. Key features of the flagship product (see bundle 1 below) are as follows:

- Patients can upload ECG data using their home computer, or one provided at their local clinic.
- The incoming ECG data is automatically analysed for heart conditions, and if something is found, the doctor responsible is sent an email.
- A network database system keeps all of the important ECG data in one place, making it easy to back up.
- Members of staff can use any machine on the departmental network to view the ECG data.

3.3 Sales Strategy

To maximise revenue, we will utilise second and third degree price discrimination in marketing our product. Second degree price discrimination involves offering a different pricing scheme dependent on the quantity of goods sold. Thus we will be offering quantity discounts on higher volume purchases. Third degree price discrimination refers to segmenting customers into two or more categories based on their demand characteristics, and selling them different versions of essentially the same product, for different prices. We will bundle our product in two varieties as described below. The ECG monitoring device is the same in both packages - the variation is in the complexity of the software bundled along.

Bundle 1

This bundle is aimed at hospitals, where a large number of patients is expected. Here there is a need for not only accurate data analysis but also for a system to manage and store the data efficiently for access by multiple users. Due to the complexity of the software requirements, service agreements and software licensing will be discussed and implemented on a per hospital basis.

We will offer 10 ECG hardware products, as well as high-end software to store all patient data in a department to a database, and analyse the data to classify heart conditions. The price of £50,000 will also cover installation costs. Extra hardware units will be sold at £1,800 each, which is competitive with the Card Guard and Philips products.

Bundle 2

This bundle is geared towards clinics where we expect single license usage of our software. We will include a less powerful version of our software without the networking capabilities described above. This will enable a single machine to collect data from the device and review this data. Data can be only saved to the hard-disk of this one machine. A single hardware product and single workstation license will be sold for £1,800.

3.4 Services

Installation

As mentioned above this service will be part of bundle 1. Services offered under the umbrella of this service are analysis of hospital requirements and implementation of the ECG analysis system on a departmental network.

Product Support

We will offer a 1-year warranty on all products sold. After-sales service will include ECG hardware maintenance and repair as well as software troubleshooting and upgrades. Customer service is an important aspect of our business and we will always strive to provide the best support possible for our product.

3.5 Advertising and Promotion

We plan to promote our product to the NHS and the private sector through the trade press, relevant conferences and exhibition as well as through our company website. Exhibitions are seen as the most direct way of creating awareness of our product to health representatives. Among numerous events organised, the most prominent for our needs is the NHS confederation annual conference and exhibition attended by hundreds of delegates from the UK health sector.

Advertisements of our product will be placed in some of the leading medical journals and magazines in the country for example the British Medical Journal (BMJ). We will also seek to have our product reviewed independently and have these results published.

4. Business Case

4.1 Cost Estimate

Fixed Costs

Our fixed costs are costs that do not change with production. We have broken this down further into research and development costs and overhead costs. Our plan assumes a steady decline in advertising costs as we gain a foothold in the market.

Fixed costs (£)**	2005	2006	2007	2008	2009
Research and development					
Hardware development					
Design (5000 hours*)	75,000				
Prototyping material costs	5,000	-	-	-	-
Software Development					
Design and development (5000 hours)	75,000				
Debugging (2000 hours)	30,000				
Interest on loan for R&D costs	30,000	30,000			
Overhead costs					
Rent and utilities		25,000	25,000	25,000	25,000
Salaries (Permanent staff of 10)		200,000	200,000	200,000	200,000
Advertising and promotion		30,000	25,000	25,000	25,000
Other		10,000	10,000	10,000	10,000
Total	215,000	295,000	260,000	260,000	260,000

Table 3

The permanent staff is 8 technicians for technical support and installation and 2 administration staff.

The costs associated with the final stages of development could be very high – having the device accepted by the Medical Devices Agency, as well as removing software and hardware bugs and user testing could take a long time and a lot of money.

^{*}labour is assumed to be £15 per hour

[^]interest rate is assumed to be 15% which is the base lending rate as of February 2005. Loan settled after 2 years.

^{**} Since these figures are rough estimates, the effects of interest have not been considered

Manufacturing Costs

We plan to out-source all manufacturing. This will save money for two reasons: the costs of running a manufacturing plant is taken on by another company, and effectively shared by all of its customers, and manufacturing companies are competing against each other to provide the best deal. Below is a table defining the approximate incremental cost for each device. This excludes fixed costs such as tooling charges.

Manufacturing costs	Price (£)
Hardware components	
Analogue (amplifiers, A/D converter etc)	100
Digital (FPGA, processor etc)	20
Peripherals (screens, buttons)	20
Compact flash card (2GB)	100
Manufacturing (assembling, soldering etc)	20
Total	260

Table 4

4.2 Sales target and break-even analysis

We have set up a 4-year sales plan targeting the UK market. The plan calls for sales of 300 units (comprising 15 sets of bundle 1 and 150 sets of bundle 2) worth £1 million in the first year moving up to 2000(comprising 50 sets of bundle 1 and 1500 sets of bundle 2) units worth £5 million by the end of the fourth year. A graph of our expected sales is as shown below.

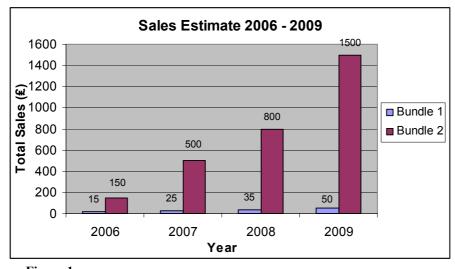


Figure 1

Break-even volume represents the minimum number of units we have to sell to break even financially. The price used is the weighted average of the unit cost for the two bundles we offer.

Break even volume = Total fixed cost / (price – variable cost)

Thus the break even volume for each of the 4 years is 152, 103, 106 and 117 units respectively. Revenue, total cost and profit data are summarised in the graph below.

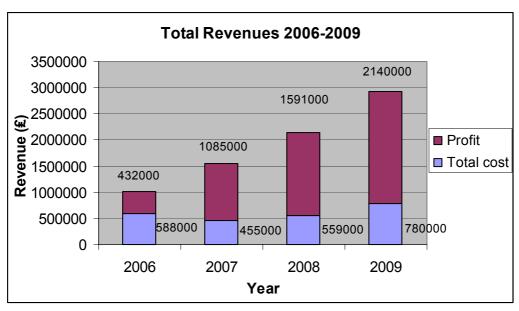


Figure 2

The graph above shows an increase in profits as sales go up and total costs remain approximately constant. Our market share should be 20% by 2008. We estimate that 70% of our sales will be from the NHS and 30% from private hospitals.

Conclusion

There is a clear market for our product, and if the marketing plan and sales targets are carried out, sales should cover the development costs within 2 years of the beginning of the project. The product has the potential to be very profitable.

5. Management Plan

This shows the work to be done in the implementation phase, and who will be doing it. A more complex system such as a Gantt chart is not suited to this plan, because there is not a fixed budget for labour in the prototype stage.

Task	Work necessary to complete manufacture of prototype
Hardware	
Analogue Mark, Shyam, Ashwin	Design & manufacture of Printed Circuit Board (PCB)
	Assembly & testing of 8 instrumentation amplifiers.
	Assembly & testing of Nyquist filter.
Digital	Design of PCB.
Mark	Assembly of components onto circuit board.
Power Supply	Assembly of components onto circuit board.
Mark, Ashwin	Testing
Mechanical	Selection of enclosure.
Mark, Ashwin, Shyam	Final manufacturing of enclosure (drilling holes for fittings etc.)
Software / PLD Firmware	Writing & simulation of microprocessor code.
Mark, Shyam	Writing, simulation and synthesis of PLD code.
	Testing & debugging.
Software	
Patient Upload Software	Low-level object-oriented design of application structure.
Ramanan	Writing, testing and debugging of Java code.

Task	Work necessary to complete manufacture of prototype
ECG Review Application for Physician (Front-End)	Low-level object-oriented design of application structure.
Martin	Implementation of Graphical User Interface in Java code.
	Implementation of communication interface with Back-End software.
	Writing, testing and debugging of Java code.
Back-End software and Database Implementation	Low-level object-oriented design of application structure.
Martin, Ramanan	Synthesis of High Level data structure using Microsoft Access Database.
	Implementation of database queries with SQL.
	Implementation of communication interface with Front-End software.
	Integration of Back-End software with parameter detection and classification code.
	Writing, testing and debugging of Java code.
Signal Processing for ECG parameter detection and	Writing of signal processing code for parameter detection.
classification of heart conditions.	Writing of code for condition classification.
Amrit, Ramanan	Performance optimisation of code.
200710071007	Testing & debugging.

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http://www.medical.philips.com/main/products/cardiography/products/holter/index.html

xiv Card Guard Group – *Products page*

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ⁱ The American Heart Association – *Sudden Cardiac Death* - http://www.americanheart.org/presenter.jhtml?identifier=4741

ii Key Note Market Report 2003 - Medical Equipment

iii Key Note Market Report 2003 – Market definition

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^v National Institute for Clinical Excellence – Notes on technologies for specialist cardiac services http://www.nice.org.uk/page.aspx?o=10242

vi The total listing of Acute trusts and Primary care trusts in NHS website – http://www.nhs.uk/England/AuthoritiesTrusts/Default.cmsx

vii The NHS plan - Executive Summary

viii Estimates formed from information by marketing representatives of Card Guard Group

ix Key Note Market Report 2003 – Industry Background

^x National Statistics website – Ageing population

x1 British Heart Foundation - G30 Coronary Heart Disease Statistics Book 2004, Executive Summary

xii Information from marketing representatives of Card Guard Group and Philips

xiii Royal Philips Electronics website – Zymed holter monitoring