# CORACARE

## **Remote Cardiac Monitoring**

Second Year Project

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## **ABSTRACT**

Wireless Body Sensor Network (WBSN) technologies are considered one of the key research areas in the medical devices industry for improving health care in the 21st century. The use of these technologies for remote monitoring has been advocated as a superior alternative to the traditional hospital-centric health care system, both from an economic and a patient comfort perspective. In this paper we present a prototype of a wireless body sensor network system for the continuous remote cardiac monitoring of at-risk patients. We also discuss the technical, legal and sociological challenges involved in designing a remote monitoring and diagnostic service. The design is mainly focused on providing continuous feedback of a patient's condition by transferring encrypted medical data from the patient to the server. Furthermore we also consider the feasibility of introducing such a device to the market.

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## Introduction

Coracare aims to reduce the number of deaths worldwide caused by heart disease by providing a remote cardiac monitoring and diagnostic service to healthcare organisations. We believe that this service would be invaluable to at risk patients by helping diagnose their problems and by allowing them to resume their normal lives, while still feeling safe in the knowledge that they are being monitored. Furthermore, we also believe that health organisations would benefit greatly from such a service, as it would reduce contact hours between patients and doctors and free up hospital beds. With western populations ageing, an increasingly high incidence of heart disease across the globe, and a rapid advancement in medical devices technology, it seems almost beyond question that the service Coracare provides will be not only very useful, but also highly profitable. The remainder of the paper is organized as follows: Section 1 describes the product and service it offers as well as explains the system's technology. Section 2, presents the market environment and related previous work. Finally, Section 3 provides a brief study of our business and financial plans.

## Section 1: Service and Device Technology

#### **Product and Service**

Coracare aims to provide remote cardiac monitoring of at risk patients through a unique service. This will allow for the early detection of cardiac disorders leading to more effective treatment. The service will consist of an end-to-end solution, meaning that Coracare will handle all stages of remote monitoring, with the healthcare provider being burdened only with the results of analysis. This bypasses the need for healthcare providers such as the NHS to revamp their IT systems or employ extra staff to monitor these services. The initial capital investment on the side of the healthcare provider is minimal, thereby making the service a more attractive venture. **Figure 1** illustrates the service on offer.



Figure 1 – Overview of Coracare's Service

The Coracare CX50 device will be the initial product used to facilitate this service. This will consist of a silicon slab to be worn on the chest. The slab will include: 5 ECG (Electrocardiogram) electrodes, a temperature sensor and accelerometer. These will provide high quality diagnostic grade ECG traces as well as providing context aware information to clinicians regarding the activity of the patient, which is invaluable when deciding whether an observed change in heart rate or rhythm is indeed an anomaly. The CX50 will communicate with approved

smartphones via Bluetooth 4. Preliminary processing is performed on the smartphone and any anomalous traces will be transmitted to Coracare servers via the cellular network or Wi-Fi for further analysis using more sophisticated algorithms. Trained Coracare technicians will be on standby to monitor transmitted traces and relay any worrying data to the patient's healthcare provider for detailed assessment. The patient's position can be inferred by using inbuilt GPS on the approved smartphone. This way, patients can be easily reached in the case of emergency.

Coracare's service aims to be interactive. We want the patient to feel that they are being cared for and not simply watched. A means of communication between patients, Coracare technicians and the physicians will thus be provided. Should a patient experience any transient or worrying symptoms they will have the option of transmitting these along with a description of their symptoms, and activity, to Coracare for analysis and discussion.

#### Technology

The Coracare CX50 is a remote ECG monitor in the form of a silicon slab that adheres to the chest. It is made to be worn by the user constantly, continuously monitoring his heart's electrical impulses as well as other data such as body temperature. **Figure 2** gives a general overview of how the different components communicate with each other.

The CX50 uses standard coin batteries for power and can last a month before the user has to replace them. The device's silicon slab holds all elements securely in place and is aimed at being comfortable to wear and easy to clean. This slab also protects the CX50 by making it waterproof and resistant to shocks.



Figure 2 - Block Diagram of the Coracare CX50. The main processing component is the TI CC2540F128. The Coracare capacitative electrodes will each have an analog to digital converter.

#### **ECG Use**

ECG monitors detect small electrical changes near the heart, which are caused by depolarization of the cardiac muscle during heartbeats. A typical heartbeat is initiated by a small pulse of electric current. This pulse quickly travels around the heart causing the muscles to contract. This activity produces an electric field on the skin's surface, which can then be detected using appropriate monitors <sup>(1)</sup>.

Collected ECG data can detect conditions such as arrhythmia, myocardial ischemia and infarction, chamber hypertrophy (enlargement of cells or organs due to increase in size of cells) and drug toxicity (drugs which may have an effect on the functionality of the heart)<sup>(2)</sup>.

#### **ECG Technology**

The CX50 will use a 5-electrode ECG system, which detects electrical heart impulse from 6 different directions (refer to **Figure 2**). This system can be more cumbersome to use than single lead ECG set up but is superior in quality as it allows for diagnosis as well as monitoring, something a single lead system cannot achieve  $^{(3)}$ .



Typical ECG monitors require skin contact in conjunction with the use of sticky pads, paste or gel. This can cause skin irritation of the patient. Additionally, if the user moves during the use of such a device the ECG nodes can easily disconnect.

Coracare will instead use a new type of ECG sensor, which is capacitive. This sensor allows for unterhered high quality monitoring of heart activity. Currently, the only company to offer such a sensor is QUASAR which has developed a small capacitive ECG node suited for our application.

The QUASAR ECG does not compromise accuracy and has typical common-mode rejection ratio of 50 to 70dB <sup>(4)</sup>, meaning that noise is a minimal problem. It also has a 16-bit resolution, which is more than necessary for diagnostic purposes. We will therefore downscale to 10-bit for data efficiency purposes - this still allows the collected data to be used for diagnostics.

#### **Context-aware sensors**

The CX50's main processing device will be the Texas Instruments CC240F128 which is a low energy System-on-Chip which comes with integrated Bluetooth components. It comes in a standard 6 mm x 6mm size, typically uses 235  $\mu$ A when simply processing data (though it will be using extra current interfacing with the external memory) and uses 19 to 24 mA when transmitting data wirelessly. The CC240F128 has 21 general-purpose I/O pins, which is enough to interface with all the used components. The version with 128KB program was chosen over the 256KB version because it is cheaper, uses slightly less power and the program that manages incoming data will not be too complex.

The CX50 will use the recently approved Bluetooth 4 low energy heart rate profile protocol specifications for smartphone communication. This protocol is a low power standard made especially for heart rate monitoring, typically using 15mA when run on coin cell batteries <sup>(5)</sup>. Bluetooth 4 will reduce costs as we will not have to incur royalties in using other wireless standards such as ANT.

#### **Smartphone**

The CX50 will first send the collected data to the user's smartphone. Coracare decided on this solution as 1 person out of 7 worldwide is expected to own a smartphone by  $2016^{(6)}$ .

Due to health regulations, every smartphone used in healthcare applications must be individually approved. Thus, Coracare will focus on getting at least the most widely used (Android and iPhone platform) smartphones approved as well as lower cost handsets for users who do not yet own one. Currently, the iPhone 4 and the Samsung Galaxy S II are the two most popular smartphones on the market and both support the required Bluetooth standards.

#### Smartphone-side Data Processing

The 5 leads of the CX50 will sample data at a rate of 500Hz with a resolution of 10 bits. The maximum useful frequency for ECG measurement is 250Hz. However, due to aliasing effects measurements must be taken above the Nyquist frequency, which in this case is 500Hz. This means that the bitrate is 500x10 bit = 0.625kB ytes/s, a speed that the TI CC2540F128 can easily manage.

	Data/second	<b>Data/minute</b>	<b>Data/hour</b>	Data/half	Data/day	Data/day –	
	(bits)	(bits)	(bits)	day (bits)	(bits)	compressed (bits)	
5 leads	$1.25 \times 10^{4}$	7.5×10 <sup>5</sup>	4.5×10 <sup>7</sup>	5.4×10 <sup>8</sup>	1.08×10 <sup>9</sup>	2.7×10 <sup>8</sup>	

 Table 1 – Description of the amount of data transmitted at different intervals during the day.

 The royalty-free and lossless DEFALTE algorithm is used to compress the data.

Data is sent to the phone every minute, thus ensuring that any problem is detected within a one-minute delay period, while also preserving battery life. Cyclical Redundancy Check (CRC) algorithm is used to ensure the integrity of transmitted data.

On the smartphone, detected abnormalities are sent to the server. Abnormalities are defined as being outside certain thresholds, specific to each patient and previously determined by the patient's normal heart pattern. A full day's worth of data is estimated to be only around 30MB. Data will be passed through frequency filters to get rid of motion noise, which is typically less than  $1\text{Hz}^{(7)}$ .

At the end of the day, if no data has been uploaded, all remaining data is sent to the Coracare servers once a Wi-Fi connection has been made. For a full month's usage, the data's size will be around 1GB. An option to have the data transmitted over mobile networks will also be available. This option will still allow robust transmission and will require just under 2 minutes 30 seconds using the very common EDGE network.  $\left(\frac{33[MB]}{236[kB/s]}\right) = 2 \text{ mins } 22 \text{ s}$ .

Once processed on the server, if data is found to indicate a potential critical condition, a warning is issued to the patient's doctor who is then presented with the patient's past medical history and the last hour of data from their ECG scan.

#### Server-side Processing

Coracare will host the data processing servers, which will be stored and maintained in the Coracare offices. This will allow for faster upgrades of IT systems and algorithm software than if each hospital had its own server. Servers will be backed up every day and will be able to hold the 12GB/year that each patient uses. The HP Integrity NS16000 is the perfect choice with a reputation for exceedingly high reliability, which is vital when storing patient's medical data. Multiple Back-up servers will be deployed to ensure continuity of service in the event of server failure.

The server will use multiple algorithms to detect any anomalies in a patient's heartbeat. Open-source ECG data analysis software will be used such as OpenECG<sup>(8)</sup> as well as software that Coracare will license such as BioQT by Oxford BioSignals<sup>(9)</sup>. This software will continuously run, monitoring any incoming data.

Coracare's server will ensure that all patients' data is private and will remain encrypted at all times using the military grade AES-256 encryption algorithm. Patient data will only be shared with their doctors, except in the case of an emergency, when all relevant medical data will be provided to the doctor on standby.

Patients will also be able to log into the Coracare website to view all their recorded data and obtain a personalized statistics report with the results of the algorithms used for problem detection. Doctors will also have a login available for them to view all of their patient's history with irregularities flagged for further analysis. Furthermore, the set of algorithms deployed can be customised to meet the needs of each individual patient.

#### **Power supply**

Power consumption is a central aspect of the CX50. This will run off 4 CR2477 Sony lithium batteries at a 3.3V rating.

Low power Bluetooth is used and has a speed of 1Mb/s meaning that a full minute's worth of data gets transmitted in just under a second  $\left(\frac{750\ 000\ [bits]}{1\ [Mb]/[s]} = 0.75\ [s]\right)$ . As extra data is transmitted, CRC checks are done to ensure data integrity. Setup time is 3ms and it will be assumed that the Bluetooth hardware is on for 2 seconds every minute. Therefore Bluetooth communications will only use on average 0.63mA.

Data is stored on a Micron 512MB NAND (flash storage) which uses  $0.027 \mu$ J/byte for read operations, and  $0.034\mu$ J/byte for write operations (15). On a system with a 3.3V rating the current usage is 0.013mA and 0.016mA for read and writes operations respectively.

The TI CC2540F128 will be mainly in low power mode so as to maintain storage of collected data. Full power will only be utilised in the few seconds before and during transmission to the smartphone.

Therefore, with 4000mAh available, the CX50 can be expected to last around a month (31 [days] 5 [hours] =  $\frac{4000 \text{ [mAh]}}{5.34 \text{ [mA]}}$  which makes it hassle free for the user.

	Usage (mA)	CC2540F128 Connection (mA)	Total (mA)
ADXL212 – Accelerometer	0.7	0.01	0.71
MLX90614 – Thermometer	1.5	0.01	1.51
TI CC2540F128 Transfer + data preparation (6.7mA for 4/60 of the time)	0.446	( <b>n</b> / <b>a</b> )	0.44
CC2540F128 Data management	0.235	(n/a)	0.235
Micron NAND Storage	0.128	0.01	0.138
Micron NAND Read	0.102	( <b>n</b> / <b>a</b> )	0.102
Blue tooth Low Power 15mA (runs 2/60 of a minute)	0.633	(n/a)	0.633
5 ECG nodes (0.303 mA each) (16)	1.515	0.05	1.565
Total (mA)			5.34

Table 2 - Average milli-amp usage of the CX50 over a period of 60 seconds.

## Section 2: Market Analysis

#### **Market Environment**

Amongst today's biggest problems are ageing populations in developed countries and increasingly high rates of cardiovascular disease (CVD) worldwide. CVD is the largest cause of death globally <sup>(10)</sup>. 23.6% of all deaths worldwide <sup>(10)</sup> and 32% of deaths in the United Kingdom can be attributed to CVD <sup>(11)</sup>, the majority of which result from myocardial infarction (heart attack). Worryingly, 30% of victims die before even reaching hospital <sup>(12)</sup> and more than half of the survivors die within the first 28 days <sup>(12)</sup>. This illustrates two of the fundamental issues faced by healthcare providers today; firstly getting to patients fast enough after or during the heart attack episode, and secondly long term monitoring of at-risk patients to avoid a repeat episode. The Coracare service is the perfect solution to these problems, offering early warning, patient location and diagnostic grade monitoring.

For Coracare to be successful, its customers must have the need for, and the financial capacity to afford its services. The target market is healthcare providers, which are undoubtedly the most efficient distribution channel for us to reach our target user. The health service industry is vast, for example in 2009 the UK government spent £141bn on the NHS alone <sup>(13)</sup>. Also, countries which are members of the Organisation for Economic Co-operation and Development (OECD), which includes the US, UK and Japan, spent an estimated \$3.5 trillion in 2005 on healthcare and are expected to spend \$10 trillion in  $2020^{(14)}$ . Therefore, there is no concern of our target market being unable to support or afford Coracare's services.

It is estimated that CVD costs the British economy  $\pm 30.6$ bn a year<sup>(16)</sup>, of which  $\pm 14.4$ bn results from the direct cost of healthcare for patients. The remaining  $\pm 16.6$ bn manifests itself in productivity losses, for example due to the death/illness of those in employment. Furthermore, an ageing population and an increasing incidence of lifestyle diseases (i.e. obesity) in the UK will contribute towards a higher rate of CVD<sup>(17)</sup> increasing the cost of care to the NHS. In 30 years, the number of people over the age of 65 is expected to rise by 25%, and it is thought that by 2030 48% of men and 43% of women will be obese<sup>(15)</sup>. Therefore the demand for Coracare services will only increase as the NHS struggles under the weight of a growing patient population.

#### Previous works and competing technologies

In the UK there is no widely adopted method of remote cardiac monitoring. An insight into existing technologies can highlight the new functionalities that our project will bring to the table, which is not provided by existing models.

A company that has adopted a similar solution to that proposed is the Swiss Life Watch AG. They have produced the proprietary owned Life Watch Ambulatory Cardiac Telemetry (ACT) system. Their main product consists of a three lead ECG set up. Unlike the CX50, the user's skin has to be prepared (washed and shaved) before applying the electrodes, and context aware sensors (temperature and skin conductance sensors etc) are not present. Communication is achieved via wired link to a PDA with inbuilt GSM connection for transmission of ECG data in the event of abnormalities.

The system has been very successful, particularly in the USA, where in 2010 the CMS (Centre for Medicare and Medicaid services) has decided to acknowledge Life Watch's ACT "for its Value and Proven Contribution to the US heal" <sup>(18)</sup>. According to the company's statistics, in 2011 over 300,000 U.S. patients were subscribed<sup>(19)</sup>.

Unlike ACT platinum, Coracare's implementation will revolve around capacitive non-contact electrodes, wirelessly linked via Bluetooth to compatible smartphones, thus minimising clutter and increasing patient comfort. This also reduces the cost incurred in providing a proprietary PDA. In addition, a more comprehensive ECG trace and context aware data should provide us with a strong competitive advantage.

Another competitor, Toumaz Limited, a company specialising in wireless communications, has introduced a revolutionary system on chip, the Sensium digital plaster. This monitors multiple patient parameters (ECG, heart rate, temperature, respiration and physical activity). However, the single lead ECG electrode setup provides a poor quality ECG trace compared to Coracare's high quality 5 Electrode ECG trace. The system on chip communicates with wireless base stations (which are connected to the internet) via Radio Frequency. The data is then passed to IT servers where they can be processed and analysed by software applications. This approach mainly aims to monitor patients at home or in hospital environments.

This system has also had much success, having passed trials at St Mary's Hospital London and been approved by the FDA (Food and Drug Administration, U.S.) in 2011. Its initial launch will be at selected hospitals in the U.S. Furthermore, California Capital Equity, a capital venture company has agreed to invest up to \$25 million in commercialising the digital plaster <sup>(20)</sup>. It is worth noting that Toumaz ltd does not provide a service, they only provide the medical devices. It is down to the Healthcare provider to set up the infrastructure and perform any necessary maintenance required for remote monitoring. This will obviously result in a significant initial capital investment on the part of the customer.

In contrast, the CX50 will provide a more accurate representation of the patient's vital signs, as well as allowing for ubiquitous monitoring by virtue of the cellular network. Furthermore, no investment in IT service to run the system will be needed on the part of the healthcare provider.

### **Section 3: Business and Financial Plans**

#### Industry

Despite the 2007 world economic recession, the market for medical devices had a Compound Annual Growth Rate (CAGR) of 5.2% for 2006-2009, with a forecast CAGR of 9.8% between 2009 and  $2015^{(21)}$ . In the UK alone, the medical devices market was valued at £8.2bn in 2009 and is expected to reach £14.4bn by  $2016^{(13)}$ . The largest demand for medical devices in the world is in Europe and North America, which between them account for 80% of the world's medical devices market<sup>(22)</sup>. However the market's growth is not restricted to the West alone: Asia's market for medical devices has at present a CAGR of 9.6%. To put some of these figures in perspective the global pharmaceutical industry had a CAGR of only 5.6%. To summarise, the outlook for the global medical devices industry is very positive: it is currently strong and is expected to grow dramatically in the near future with a lot of untapped potential not only in the West, but also in Asia as well.

The principle industry drivers in Europe and America are: large disposable incomes, increasing incidence of lifestyle diseases, ageing populations and a rapid recent advancement in technology. In the US alone, there are 40 million people over the age of 65, and in the UK 34.1% of those aged 65-74 and 44% of those aged 75 or over suffer from some sort of cardiovascular problem <sup>(11)</sup>.

In terms of cardiac related medical devices in the UK, the cardiac device market, valued at £0.83bn in 2009, is forecast to grow by 4.7% annually for the next seven years to reach £1.2bn in 2016, by which time the US cardiac device market will be worth around £3.8bn alone  $^{(13,22)}$ . As a result, due to the medical devices industry being so new, fast growing and lacking any dominant players, now is the perfect time to launch the Coracare product so as to position ourselves as a market leader and therefore capitalize on this inevitably profitable industry.

#### **Business Model**

Coracare will generate revenue by selling a service package to healthcare providers that allows for the monitoring of a specific number of patients over a year. Once they have subscribed, all they have to do is distribute the CX50 device to their patients and make sure the Coracare application is installed on the patient's phone.

Healthcare providers will have to pay per annum to renew the service. The cost of service for one year will be £250 per patient package based on the cost of producing the CX50, paying trained technicians to monitor the data, and any projected required maintenance. We expect a profit margin of 55% in our eighth year.

Coracare's sales strategy will involve selling directly to large healthcare providers, starting in the UK and expanding over time to Europe and then the US. The main providers that Coracare will target in the UK are the NHS, BUPA, BMI, Aviva, Four Seasons and Southern Cross. The largest budget and patient population falls under the NHS. Selling to the NHS is difficult and failure to do so could result in a significant setback. Coracare will aim to improve its chances dramatically by demonstrating its product and service to the National Institute of Health and Clinical Excellence (NICE), whose role is to give national appraisals on healthcare and medical products. With a technology appraisal from NICE selling to the NHS should become far easier. Coracare will also apply to the Small Business Research Initiative (SBRI), a program that offers support and funding for companies that are developing technologies that the UK could benefit from. SBRI is at present already calling for a product that could free up hospital space, and help patients with long term illness, both of which could be solved by the proposed service. Gaining access to the SBRI program would be invaluable as it offers an excellent bridge between Research and Development products and procurement.

#### **Personnel Requirements**

Coracare will need to employ people over a range of disciplines to ensure that the service provided will run smoothly. Trained technicians will be employed to monitor traces that are flagged up as problematic and then act accordingly. A team of highly skilled, motivated, software and hardware engineers will be hired with the aim of regularly introducing new and improved medical devices to the market. Naturally, professionals with backgrounds in marketing and sales, human resources, logistics will be employed along with an experienced managerial team. We approximate the total cost of salaries to be between £550,000-£650,000.

#### Legal

All wireless medical sensors should have the following characteristics:

- Low power requirements
- Reliability and device mobility
- Security and patient-doctor confidentiality
- A design that conforms to regulations
- Provision of sufficient accuracy (for devices with a measuring function)

Once the manufacturer is satisfied that his product meets all of the above, he must register with the Competent Authority (CA). The latter charges  $\pounds$ 70 for registration, notification, update or change of the device's registered information<sup>(23)</sup>.

Since the CX50 is non-intrusive, it is considered a low risk device. Thus, we can avoid extremely costly clinical trials by simply demonstrating the safety, intended use and performance of the device with a combination of nonclinical data (i.e., bench and animal testing), and previously published clinical data on the device or an equivalent one  $^{(24)}$ .

To be able to affix the CE mark on the device and place it on the market, the manufacturer must then get in touch with a Notified Body (NB). The latter is an independent commercial organization that implements regulatory control over medical devices. NBs certify, assess and verify the quality of the systems, and most importantly can issue the CE mark. A company is free to choose any NB designated by the authorities to assess the device under review.

Once the product has market approval, post-market studies should be performed. The purpose is to produce data that can support the manufacturer's claims of device performance, benefits to patients as well as clinical and cost effectiveness. This evidence will form the basis for further marketing and sales to healthcare providers<sup>(25)</sup>.

Coracare's risk to losing market share to existing UK and EU competition is low as there is currently a market vacuum. However, to reduce risk, our service will focus on comfort, device simplicity and patenting the concept (e.g. the contactless ECG nodes) to make it more difficult for competitors to copy. Comfort is a major decisive point in this sector and something users have complained about consistently with regards to current devices.

In the long term, Coracare aims to develop a relationship with its users to obtain their feedback on services and products. This will allow Coracare to produce even more comfortable devices using users' insight thereby increasing positive differentiation with our market competitors.

Due to the cost of changing ECG monitoring services by health organisations, new entrants face high barriers to entry as they need to convince health organizations to change provider. We can keep this threat high by ensuring that health professionals remain very satisfied with our device. To avoid new competitors, we will also aim to reduce the cost of our service over time as supply costs goes down (thus maintaining profit margins). This will increase the cost of entry for any new competitor.

There is also the risk of technological obsolescence as the CX50 relies on approved smartphones, which are part of a fast moving market. Coracare's response to this will be to develop an add-on in the form of a watch that will be a substitute to the smartphone application giving the user more choice. Furthermore, the QUASAR capacitive electrodes to be used in the setup are yet to be medically approved, this will need to occur before Coracare can hit the market.

Strengths - End to end solution - Comfortable device - Competitive price - Ubiquitous monitoring - New technology in the UK - Initial investment on behalf of the customer is low	Weaknesses - Capacitive ECG electrodes have not yet been approved - Each smartphone needs to get aproved individualay - Large initial startup costs - Need to find and train technicians				
Opportunities - Large market: High number of CVD sufferers. - Young market: Lack of established companies in this domain in the UK. - Large government and private expenses on healthcare - Increased percentage of obesity and other lifestyle diseases	<ul> <li>YSIS</li> <li>Established overseas companies may bring service to the UK</li> <li>Risk of obsolence as system on chip designs emerge</li> <li>Delays in obtaining CE mark.</li> </ul>				

Figure 4 – SWOT analysis

#### **Financial Projections**

An 8-year financial projection predicts that Coracare will begin turning a yearly profit in year five (i.e. after 2 years of full operation) and break even after 8 years (i.e. after 5 years of operation). Coracare will need 3 years before it starts selling to pass the necessary tests to gain medical licensing from the MHRA, and also to properly prototype, research and refine the CX50 device and heart care service. Figure 5 (below) describes in detail our 8 year plan.

There are approximately 2.6 million people presently suffering from heart disease in the UK, so a pessimistic outlook would say that our market size is 10% of this, i.e. 260,000 people who could benefit from the services that the CX50 provides. After 2 years of selling, Coracare should have gained approximately 1% of the market share, i.e. 2600 device sales, and after 10 years Coracare should be making sales of around 50-60,000 devices. This will represent 20% of the market share, which will cement Coracare's position as a market leader.

#### [CORACARE: REMOTE CARDIAC MONITORING.]

		Stage 1: Build and Test					Stage 2: Product licensing and marketing						
		Year 1			Year 2 Year 3		Year 4	Year 5	Year 6	Year 7	Year 8		
_		Q1	Q2	Q3	Q4	H1	H2						
	Obtain Investor Funding												
	Obtain Office Space												
	Hire Employees							1					0 
ø	Build prototype			1	1								
gag	Bench testing/revising prototype				v	8				5:	6		
ŝ	Apply for patients												
	Testing on patients												
	System inspection and re-evaluation												
	CE mark												
	Advertising												
N	Manufacturing												
e	Distribution												
ta	Product endorsed in the UK												
S	Product endorsed in Europe												
	Break even												
	Start generating annual profit												
	Management												

Figure 5 – Gantt Chart

	FY 2013	FY 2014	FY 2015	Financial Year 2016	Financial Year 2017	Financial Year 2018	Financial Year 2019	Financial Year 2020
Units sold	0	0	0	1100	1980	3564	6415	11547
	£	£	£	£	£	£	£	£
Unit Price	-	-	-	250.00	250.00	250.00	250.00	250.00
Total	£	£	£	£	£	£	£	£
Revenue	-	-	-	275,000.00	495,000.00	891,000.00	1,603,800.00	2,886,840.00

Table 3: 8-year projected sales and revenue

This sales growth is based on a model of 100% growth each year with 10% loss of customers each year, typical of most successful companies.



Figure 6: Graph showing 8-year projected PBT





#### Conclusion

Coracare's service has the potential to reduce the number of deaths accruing from CVD, as well as reduce the economic burden on the UK economy. Reliable existing technologies, based on medical protocols (i.e. Bluetooth 4 HCP) will be used to create an affordable system. Analysis of the statistics included shows a steady rise both in the incidence of CVD, and the medical device industry accordingly. The lack of dominant players in the UK market can allow Coracare to cement a significant market share early on and position itself as a market leader in remote monitoring solutions.

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