



Cambridge Heart, Inc.:
Trajectories in Progress

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1 Abstract

Cambridge Heart, Inc. is a biomedical start-up specializing in cardiac imaging. We detail a history of this company and draw on readings by Donald MacKenzie and Tracy Kidder to define success and analyze Cambridge Heart's struggle to achieve it. We develop a model of the internal trajectory of a company, its internal path of development that is influenced by outside forces. Applying this model to Cambridge Heart, we find that the company in fact developed and employed multiple internal trajectories. We identify Cambridge Heart's ability to smoothly transition from one internal trajectory to another as the key to its success. Finally, we speculate on the future development of Cambridge Heart's trajectory, both internally and within the larger biomedical industry.

2 Introduction

It all began with a phone call. MIT had spent \$200,000 to secure a number of patents for Whitaker Professor Richard Cohen and now John Preston from the Technology Licensing Office had issued an ultimatum. If Cohen did not license his ideas to a company willing to develop them, MIT would not fund any more patents for him.¹ The result was the birth of a new company in 1992 to bring Cohen's ideas to fruition, Cambridge Heart.

Wishing to remain in academia, Cohen had to find someone else to be the CEO of the new medical imaging company he had created. "I don't do startups," was MIT alumnus Jeffrey Arnold's initial reaction to the headhunter attempting to recruit him in 1993. But, as he heard more, something about Cambridge Heart intrigued Arnold. He became excited by an impressive list of directors, a brilliant founder, and a host of promising patents to develop.

With visions of a \$20 billion cardiology imaging market dancing in his head,² Arnold began meeting in the basement of his home in the summer of 1993 with two of Cohen's former students who were also recruited for Cambridge Heart: former masters student Kevin Librett, and former post-doc Paul Albrecht. Since its inception, Cambridge Heart has developed two of the four patents it has licensed from MIT, and has successfully turned one into a product that was recently released to the market. Funding has come in no small supply as investors were attracted to the opportunity Cambridge Heart presented.

But the path toward success has not been an easy one. Technological and regulatory setbacks have shaken up Arnold's unbridled optimism and delayed the release of their products. The trajectory the company has taken is nothing that could have been expected. Faced with

¹ Pressman, Interview.

² Arnold, Technology Breakfast presentation.

roadblocks that sometimes left employees wondering if they should update their resumes, Arnold was able to shift technological and marketing strategy smoothly enough to keep Cambridge Heart afloat while avoiding the roadblocks.

This paper will serve as a guide to this roundabout path, uncovering the keys to how Cambridge Heart has been successful in the pursuit of its goals. We will first need to define some terms to talk about Cambridge Heart's progress.

2.1 Trajectories and Success

In *Inventing Accuracy*, Donald MacKenzie identifies and explains the concept of a technical trajectory while chronicling the history of nuclear missile guidance. He defines such a trajectory as “a direction of technical development that is simply natural, not created by social interests but corresponding to the inherent possibilities of the technology.”³ In the context of nuclear missile guidance, he examines this idea, and shows that it cannot really exist; there is no such thing as a natural trajectory.

The idea of a “natural” trajectory indicates that once it is set in motion, external forces will have little influence on its progress. We know this is not the case in most science and engineering endeavors. Social, governmental, political, and economic pressures all affect technological development. MacKenzie illustrates this point by exploring why accuracy has been such a desirable quality in a nuclear missile, a weapon of massive destruction. He discovers that it may not have been a natural progression within this industry at all, but rather a path that was heavily influenced by the military, politics, economic forces, and individuals such as Charles Stark Draper of Draper Laboratories.⁴

³ MacKenzie, 167.

⁴ Ibid.

Here we will be dealing not with the trajectory of a technology, but rather the managerial, commercial, and technical trajectory within a company. We will refer to this type of trajectory as an *internal* trajectory, a development path chosen by company leaders and measured by their own standards. Similar to technological trajectories, internal trajectories are in no sense “natural.” The path they follow is a result of both internal and external influences. These include company leadership, technical ability, funding, future willingness of consumers to buy the product, and government auspices. A company may, in fact, have multiple internal trajectories. It may pursue multiple technologies at once, multiple markets at once, or multiple management structures at different levels of the company. In effect, there may be, and usually is, more than one possible vision for the company’s future.

In light of this, it is interesting to explore the notion of success itself. With a framework consisting of multiple internal trajectories, can success only be achieved when all such paths have resulted in something tangible for the company? Or should each trajectory be treated with its own metric? Simply stating that success arises when goals have been attained no longer becomes meaningful when we speak of different trajectories. In academia, results must be reproducible therefore one could argue that the means to the end actually constitutes success or failure. For industry it has been stated that “The goal of the firm is to make money.”⁵ In our analysis of Cambridge Heart we will explore successes and failures as they apply to each component of this company’s internal trajectory.

To form a basis of comparison, we will first examine the trajectories of projects undertaken by Draper Laboratories’ Charles Draper, and by Data General’s Tom West. Then, by applying the idea of a technological trajectory and its social shapings to the development of medical imaging, we will identify key external forces and their effects in this industry. We will then fit Dr. Cohen’s

founding of Cambridge Heart into this trajectory, determining the company's role in the industry. Once we have the industry background in place, we will examine the history of Jeff Arnold's development of Cambridge Heart and show that the key to successfully employing multiple internal trajectories in industry is the ability to transition smoothly from one to another. Finally, we will speculate on Cohen and Arnold's future vision and if it is enough to support Cambridge Heart in the long run.

2.2 A Question Raised

Looking at Draper Lab's development up until second-order accuracy of missile guidance technology was achieved, (gyroscope drift rate of a hundredth of a degree per hour), we could have guessed that Draper would eventually meet his goal of third-order accuracy (drift rates three to four orders of magnitude smaller).⁶ He had the drive, the technical ability, and the outside support to achieve that goal. In fact, "the method was in essence simple, and was a continuation into the 1960s and beyond of how Draper had created his original second generation sensors."⁷ Draper continually leveraged his host of political contacts and his reputation for technical success to secure funding and convince the military of a need for the technology. Draper intentionally chose to pursue this seemingly rigid internal trajectory. There were a number of gyro technologies being developed around the world at the time, but Draper did not concern himself with most of them. He was very good at "pruning the decision tree," as Jeff Arnold would say.⁸ Draper came up with many possibilities for gyro design, but narrowed down quickly and decisively. He had a clear

⁵ Goldratt, 40.

⁶ MacKenzie, 187.

⁷ MacKenzie, 188.

⁸ Arnold, interview.

vision for the future of the lab and concentrated development solely on the single-degree-of-freedom floated gyro because that was the type he believed could achieve third order accuracy.⁹

Mackenzie calls Draper a heterogeneous engineer because he is an engineer who must work on several fronts at once: economic, social, political, and cultural. When Draper encountered a roadblock, be it technical, political, or economic, he powered through it in heterogeneous style. When faced with technical difficulties, Draper hired the best and the brightest specialists to solve them. When it seemed the military would discontinue funding, Draper used contacts and his reputation to bring everyone into his camp. By operating on several different fronts, Draper was able to pursue his intended course with little variation.

Tom West had a similar definitive goal for the Eagle project: a 32-bit VAX-killer. The pacing of the Eagle project at Data General, however, was vastly different than the steady progress of the nuclear missile guidance project at Draper Labs. The Hardy Boys and Microkids, two factions that developed within the Eagle team, were forced to concentrate more on meeting deadlines and hunting down obscure bugs than out-designing DEC's powerful machine. West was so absorbed in the technical and financial aspects of the project that he neglected to provide for the team. Resources were scarce and moral support from West was non-existent. Every day, West only built up more pressure for his team, ending in burnouts and frustration. Kidder's account of the Eagle project in *The Soul of a New Machine* builds into a maddening crescendo as the project nears completion.

West, like Draper, was very rigid in his management. Roadblocks were powered through by demanding his team to solve them. West had his own share of heterogeneous engineering skill and used it to keep Data General from shutting down the Eagle project despite upper management's initial disapproval. He could even benefit from his own reputation. His secretary, Rosemarie

⁹ MacKenzie, 188.

Seale, pointed out that “there has to be a strong person in Tom’s position. He’d be laughed out of the department if he wasn’t, and no one ever laughs at Tom.”¹⁰

Draper and West worked in two very different worlds of research and industry. Yet both had a fair amount of heterogeneous skill and employed the same focused managerial style, powering through opposition to a clear goal. Why is it that Draper succeeds at following only one of many possible internal trajectories while West fails? How could multiple internal trajectories be better employed to succeed in industry? We turn now to Cambridge Heart for possible answers to these questions. To lead us there, we will start by discussing Cambridge Heart’s place in the history of medical imaging.

3 Background

3.1 The Trajectory as it Applies to Medical Instrumentation

When medical imaging technology first arrived on the scene with Roentgen’s discovery of X-rays in 1895¹¹, one can say that the trajectory it followed was quite natural. The idea of looking inside the body caught nearly everyone’s attention with awe and wonder. Since the very first x-ray images were so crude, the next steps were obviously to refine and clarify the visual data. But as time went on, other factors started to influence the development of X-ray imaging. Perhaps the most obvious external factor was the government. Society saw a need to regulate and monitor progress in the health care arena in the interest of the common good, so governmental regulations were born.¹² Our analysis of Cambridge Heart shows that in today’s environment, a “natural” trajectory in medical technology does not exist. Scientists and engineers still strive to display the

¹⁰ Kidder, 228.

¹¹ Kevles, 1-2.

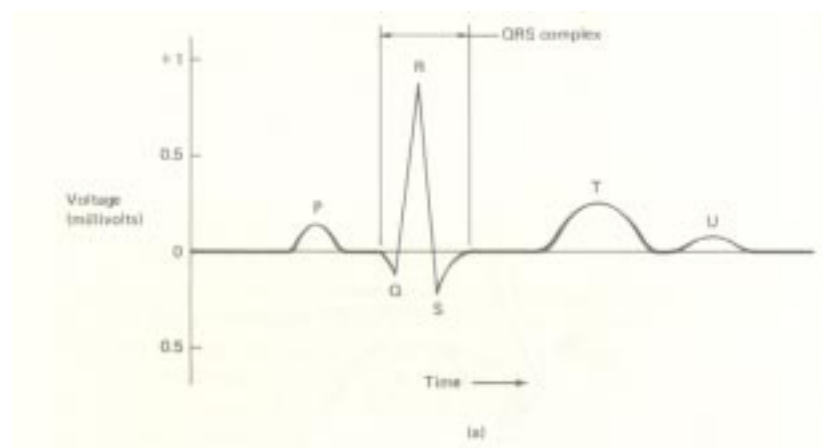
¹² Kevles, 79-82.

clearest signal possible, but there are many outside forces that currently guide development. The way these forces have influenced the development of electrocardiographic equipment will now be explored.

3.2 A History of Heart Signal Analysis

The time at which Roentgen’s discovery made headlines could not have been more favorable. The turn of the century marked a period of new, different ideas and an abandonment of past social restrictions in many disciplines. These trends in art, music, and psychology, to name a few, were further enhanced by the discovery of x-rays. Instantly anyone could delve beneath another’s skin, eroding barriers that the Victorian era strove so hard to protect. A surge of technological innovations in medicine followed, allowing doctors and scientists to learn more about the inner workings of man than they ever dreamed possible.

In 1903, Willem Einthoven, the “father of electrophysiology,” published a paper in German detailing his invention of the electrocardiograph.¹³ Within 10 years, perhaps bolstered by the x-ray



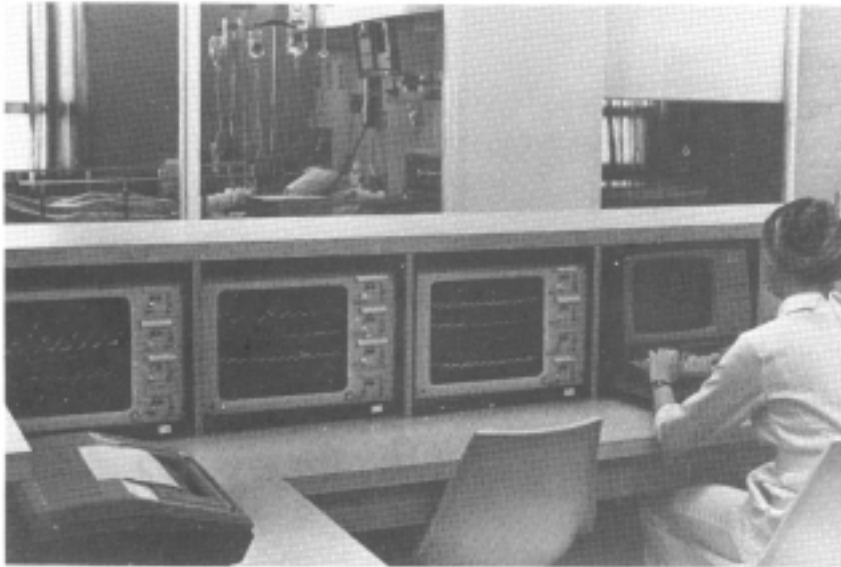
¹³ Snellen, H. A. Willem Einthoven (1860-1927), Father of Electrocardiography: Life and Work, Ancestors and Contemporaries.

phenomenon, electrocardiogram (ECG) recorders were appearing in hospitals everywhere. Not only did Einthoven publish his results to share the information he had gained, but he also specified where electrodes should be placed on the body for more accurate readings and he identified different parts of the ECG waveform.¹⁴ A picture of the ECG signal with segments labeled is shown on the previous page. His extensive work inspired his colleagues and provided a strong base for future development. After World War II, surplus electronic equipment was available and soon modified by technicians and engineers for medical applications.¹⁵ By the 1960s, machines were being designed and developed first-hand. The new technology helped shape medical care, as coronary care units became established in hospitals. Likewise, in response to the new needs of these units, the technology adapted. Continuous electrocardiographic monitoring systems became the norm in any coronary care unit (CCU), as illustrated below.

¹⁴ Cromwell, 127.

¹⁵ Bronzino, 13.

Central station computer system to aid medical staff in continuous electrocardiographic monitoring of up to eight patients. This system consists of four principal components: digital computer, video display terminal, hard-copy device, and strip chart writers. Typically these components are integrated into the central station of a coronary care unit. (Courtesy of Electronics for Medicine, Inc., White Plains, New York)



As the American healthcare system evolved from care by independent physicians to hospital-based care throughout the 1960's and 1970's, emphasis was placed on interventive and preventative procedures. Hospitals became high-tech medical centers, displaying the latest and greatest machines, but they were also aware of rising medical costs.¹⁶ They sought out patients who were at risk of developing diseases prior to the onset of illness, in the hopes of avoiding the expensive treatments that would usually follow if the symptoms were left untreated. The ECG machines offered hospitals a relatively low-cost diagnostic tool that did prove to be quite accurate in portraying heart arrhythmias. These tools were non-invasive, which reduced the time to setup and also prevented the risks of infection and pain associated with invasive techniques. As Cromwell writes: "Much of the emphasis in new instrumentation design and development is on non-invasive methods of measurement that will hopefully further reduce the number of invasive methods still in clinical use."¹⁷ Though these new diagnostic tools were quickly embraced by the health care industry, they did meet with some opposition among the medical community. Some doctors were uncomfortable with letting machines influence their own diagnoses. Today, this balance is still of concern with medical diagnostic manufacturers.¹⁸

Another factor in the development of ECG machines was the growing computer industry. As semiconductor labs developed smaller, faster, and cheaper chips, computers became more powerful and more affordable. The use of computers became commonplace in a medical surrounding, as smaller, safer, and more reliable equipment became available.¹⁹ Advanced graphics allowed machines to display multiple waveforms simultaneously, and also enabled the

¹⁶ Cromwell , 4.

¹⁷ Cromwell, 15.

¹⁸ Cromwell, 212.

¹⁹ Bronzino, 20.

exploration of two-dimensional imaging of the heart as well. Indeed, the industry and the technology shaped each other dynamically.

Despite all these new enhancements, the basic technology behind an ECG machine has not changed noticeably over the years.²⁰ As far as a trajectory goes, from one angle it may appear that nothing has moved at all. But perhaps we can attribute this lack of motion to the relative plane of observation. There are many other factors that have shaped the evolution of cardiac diagnostic tools. Some factors are evident in our research of Cambridge Heart.

First and foremost is the environment. Just as the successful development of nuclear guidance technology at Draper Labs was dependent on America's perceived "need" for it, so too would society provide the appropriate breeding ground for medical innovations. If society had remained in the dark about physiological phenomena beneath the skin, there would have been no need to develop a machine to display cardiac signals. Case in point here is the fact that electrical activity of the body had actually been detected in the eighteenth century by an Italian anatomy professor, Luigi Galvani.²¹ In 1887 another scientist, Waller, had recorded an electrocardiogram, but his apparatus was too insensitive to be practical.²² When Einthoven came on the scene, however, the world was ready.

As more technical innovations flooded the medical health care market, the market itself began to shift. The move to a more hospital-based system provided a haven for large machines, which hospitals could label as capital expenses. These technologies may not have been developed if the medicine was still operating on a very local, community-based platform. With the recent surge of managed health care, however, hospitals have begun seeking less costly methods of

²⁰ Cromwell, 126.

²¹ Cromwell, 83.

²² Cromwell, 127.

diagnosis, such as noninvasive testing. This technique could be particularly helpful for identifying patients with cardiac abnormalities.

4 Cambridge Heart

4.1 The Inception of Cambridge Heart

The history of Cambridge Heart begins with the work of biomedical engineering Prof. Richard Cohen of MIT's Health Sciences and Technology department. Prof. Cohen worked in cardiovascular technology for many years and joined the faculty of MIT in 1979. During the course of his research, a half dozen or so patents were filed both domestically and internationally. Cohen personally believed that research should be used to help patients. While publication was one step toward that goal, it was at most a small one, and commercial avenues had to be pursued to fully achieve it. Cohen initially considered working with large corporations, but realized that an idea has the tendency to be lost as it filters through the corporate hierarchy. Instead, he chose to found his own company.²³

In June 1992, Cambridge Heart was incorporated but only existed as a legal structure without operations. They obtained funding for legal fees from KBL Healthcare, an investment bank with several contacts in the medical industry. During this time, deals were negotiated with MIT to license the technology to the company. A board of directors and a scientific advisory board were formed. The scientific board included members such as a former president of the American Heart Association (AHA) and a president of the North American Society of Pacing and Electrophysiology (NASPE). While Cohen was interested in developing the technology, he was not particularly interested in running the company. Thus, the search for a CEO began.

²³ Cohen, interview.

A headhunter who happened to get word of the position at Cambridge Heart knew just the person for the position. He called MIT alumnus, Jeff Arnold, with the proposition. Upon being presented with it, Arnold's first reaction was one of skepticism. "I don't do medical stuff anymore and I don't do start-ups."²⁴ Arnold soon reconsidered, however. One reason for this was the potential for Cambridge Heart's two core technologies, T-wave alternans detection (TWA) and cardiac electrical imaging (CEI), which will be discussed in the following sections. Arnold especially found the clinical data for T-wave alternans to be compelling. Furthermore, he found Richard Cohen and the members of the scientific advisory board and board of directors to be impressive.

More importantly, however, Arnold liked the odds. He knew that only "one out of five [companies were] successful. One out of five goes belly-up."²⁵ But Cohen had more than one promising patent, presenting an opportunity akin to being in more than one startup at once, increasing the chances of success. Having multiple technologies available within Cambridge Heart allowed for development of a diverse portfolio, therefore minimizing risk.

To raise money for the new company, Cohen had decided against working with venture capitalists who had a reputation of pushing out the founders once the company became successful. He chose instead to work with an investment bank to raise money by private placement. In private placement, investment opportunity is offered to high-net-worth individuals. Cohen stipulated that at least three million dollars be raised before he would be interested. Cohen and Arnold managed to secure four million from private investors. INVESCO, a mutual fund house in Denver, Colorado, produced another two-and-a-half million dollars. Cohen's wish to avoid venture capital funding was maintained.

²⁴ Arnold, interview.

²⁵ Arnold, interview.

At first, the company focused on research and development. Commercially, the company was not planning to hit the market for quite some time. Arnold needed to rely on investors until some technology was developed and FDA approval was obtained. With the \$6.5 million he and Cohen had raised during Arnold's first summer as CEO, this did not present much of a problem. The management at Cambridge Heart was new to their jobs, but not new to the industry. In fact, management stayed mostly stable throughout Cambridge Heart's history, both in terms of people and policy. Technologically, Cambridge Heart was starting out with just a touch above nothing. The research was there and licenses for four patents had been obtained, but no commercially viable product had even been suggested.

4.2 Parallel Development and Design Choices

The two technologies that held the most promise were cardiac electrical imaging (CEI) and T-wave alternans (TWA) detection. CEI gives a two-dimensional detailed picture of the heart beyond what a standard ECG provides and is important for many applications. One is to detect ischemia, which is a condition where blood supply is reduced or absent from an organ, in this case, the heart.²⁶

The benefits provided by CEI are evident upon examining some statistics about these conditions. Ischemia can be detected during exercise and so about 8 to 9 million stress tests are performed annually.²⁷ A stress test, a recording of the electrical activity during exercise, is often inaccurate and only has a sensitivity of about 67 percent. Sensitivity indicates the percentage of correctly identified positive events. Thus, only about two out of every three patients with the

²⁶ www.skyscape.com/ocm/allergy/5217.html

²⁷ CH Annual Report, 5.

condition are correctly identified. Thallium tests costing about a thousand dollars more must therefore be performed in many cases.

CEI, on the other hand, is much more sensitive to regions of ischemia, which was shown by a study conducted by Cambridge Heart. In this study, ischemia created by occlusion of the artery by an angioplasty balloon could be detected by CEI, but could not be detected using conventional ECG electrodes using the same processing technique.²⁸

Over time, ischemia can result in the second condition which CEI can detect, known as myocardial infarction (MI). Acute MI is a condition in which a portion of the heart tissue dies and becomes electrically inert.²⁹ Better detection of acute MI afforded by CEI is beneficial because about four to eight percent of cases of patients with symptoms of a heart attack are misdiagnosed and sent home annually and about one-quarter die. Those who remain in the hospital, but are kept unnecessarily, account for about 1.6 million admissions to the coronary care unit, which produces eight billion dollars of unnecessary medical expense.

The original business plan that started Cambridge Heart heavily emphasized the pursuit of CEI. The initial rationale set forth by the investment bank was that providing a high-resolution image of the beating heart would be a vast improvement over the conventional ECG, and thus it would be instantly popular. That view proved to be overly simplistic. In the medical community, diagnostic tests are used to detect diseases for which there are treatments. To justify the need for CEI would mean that the technology would need to be tied to detecting a particular disease, such as ischemia or acute MI.

During this initial phase of deciding how to apply CEI, the founders of the company also considered, the detection of T-wave alternans as an alternative and parallel plan. This was an area

²⁸ Arnold, interview.

²⁹ www.skyscape.com/ocm/allergy/5217.html.

that Cohen had been studying extensively. The earliest known observation of this phenomenon dates from 1910.³⁰ The T-wave is the portion of the ECG where the heart repolarizes, or recovers from the contraction, and a T-wave alternans appears as a fifteen-microvolt or smaller fluctuation of the T-wave amplitude occurring on every other heart beat.³¹ Alternans are important because they are associated with vulnerability to ventricular arrhythmia, which can be a factor in sudden cardiac death. Their small amplitude and presence in noise that may be an order of magnitude greater have been reasons for the difficulty in their detection. Signal processing techniques and modern electronics, however, have enabled better analysis and detection. Cohen indicated that much of the work he had done involved computer simulations of the ECG, which helped him develop these new signal processing techniques to detect T-wave alternans. Cohen had even patented a signal processing technique for detecting alternans at the microvolt level. The difficulty remained, however, on finding a way to elevate the heart rate to about one hundred beats per minute, the point where T-wave alternans are observed.

Three options for raising the heart rate included esophageal pacing, drug treatment, and exercise. If exercise proved to be the best option, then there could be a synergy between the two technologies. CEI would provide better detection of ischemia, T-wave alternans would provide better diagnosis of cardiac sudden death, and both could be implemented in one marketable system.

³⁰ Rosenbaum, 241.

³¹ Rosenbaum, 235.

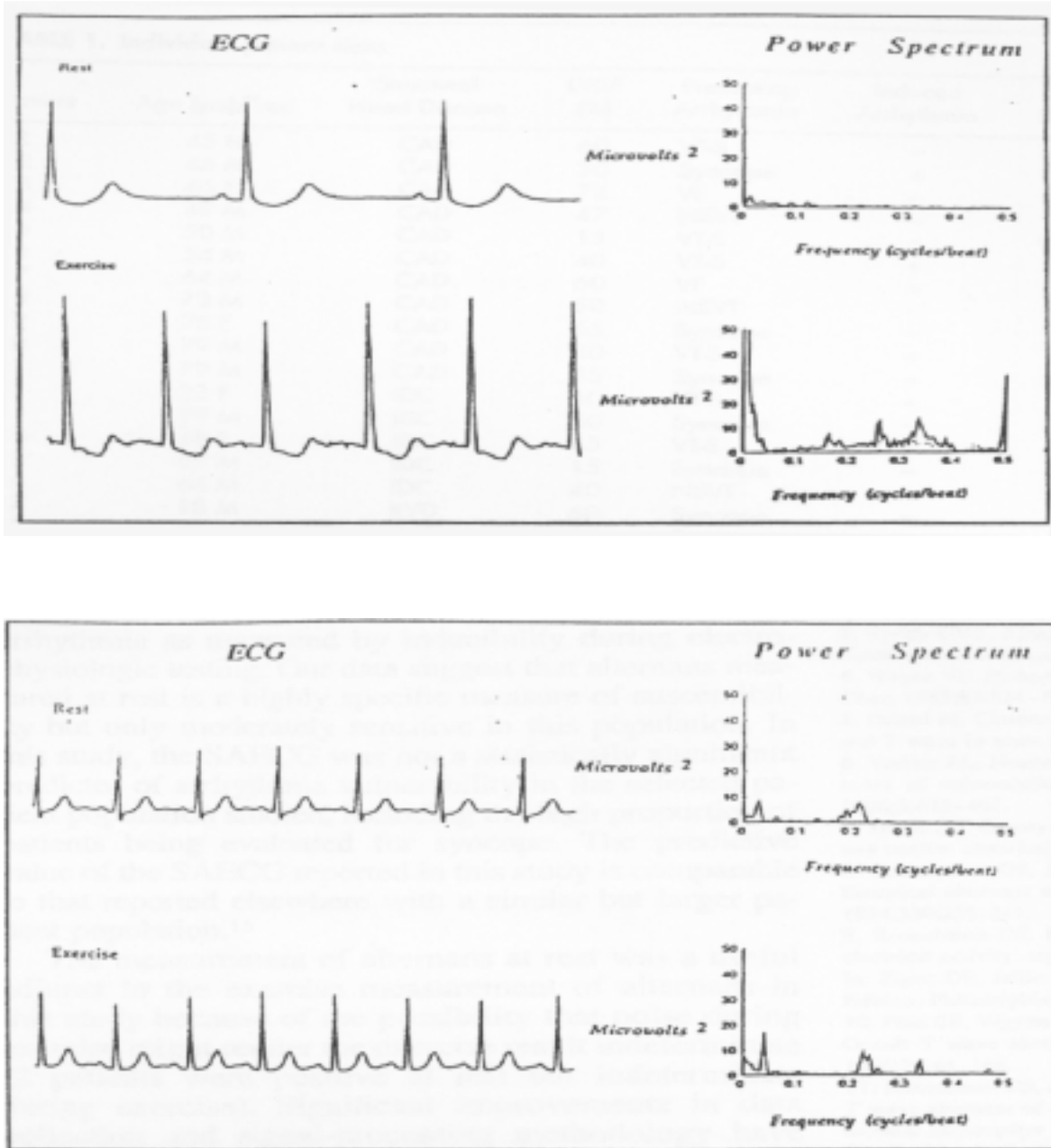


Figure 4.2.1: The alternans positive ECG reading (top) shows a spike at 0.5 cycles/beat, which corresponds to the alternans frequency. Note that it is only observed during exercise and is absent from the normal ECG plot (bottom).

Cambridge Heart thus had a decision tree with one branch as CEI and the other as T-wave alternans. If they pursued CEI, they would need to develop electrodes that were sensitive enough

to produce the high-resolution images of CEI. If they chose to pursue T-wave alternans instead, they would need to investigate the three possibilities for raising heart rate.

One factor in Cambridge Heart’s decision making was the economics of the biotech industry. Companies who make capital equipment as opposed to disposable components had a difficult time making a profit. “The selling costs are too high, doctors are hard to please, and the FDA is difficult to get through.”³² The lifecycle of a stress test machine, for example, was about eight or nine years. With sales so infrequent and a “market simply not large enough to do well in,”³³ Cambridge Heart was faced with a challenge.

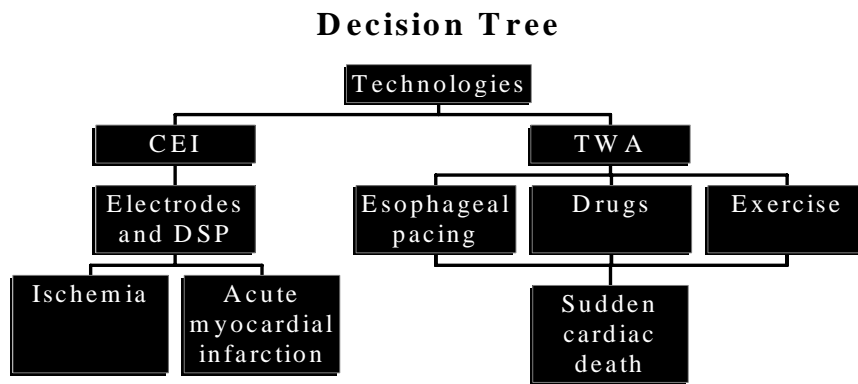


Figure 4.2.2

The solution was to develop a disposable element in the test so that a hospital could charge the patient once per test. The disposable for CEI was a special electrode pack that could only be used once per patient and produced high-resolution images that were not possible with standard ECG electrodes. Thus, Cambridge Heart’s initial concern was to develop a reliable electrode system to work with CEI.

³² Arnold, interview.

5 The Technology

5.1 Cardiac Electrical Imaging

At the time, a CEI electrode pack consisted of a large inflatable cuff covered with center dot and ring electrodes. When the difference in voltage between the dot and the ring is measured, the second spatial derivative of body surface potential is obtained. The advantage of this configuration over the standard ECG electrode is that it provides for rapid decay of the detection area. Normal point electrodes have a sensitivity that falls off as the inverse square of the distance from the electrode. The ring and dot electrode has a sensitivity that falls off as a fourth order relation, meaning that it has a more localized detection area. Localized sensitivity means that the electrode only detects signals immediately beneath it. If an array of center dot and ring electrodes is placed over the chest, then a detailed picture of time-course behavior of the heart may be obtained. Figure 5.1.1 shows the structure of a ring and dot electrode.

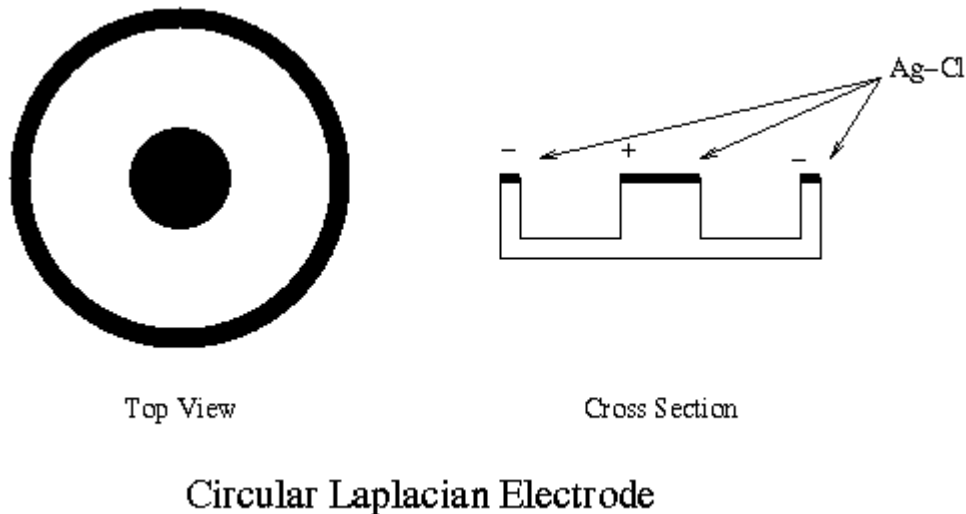
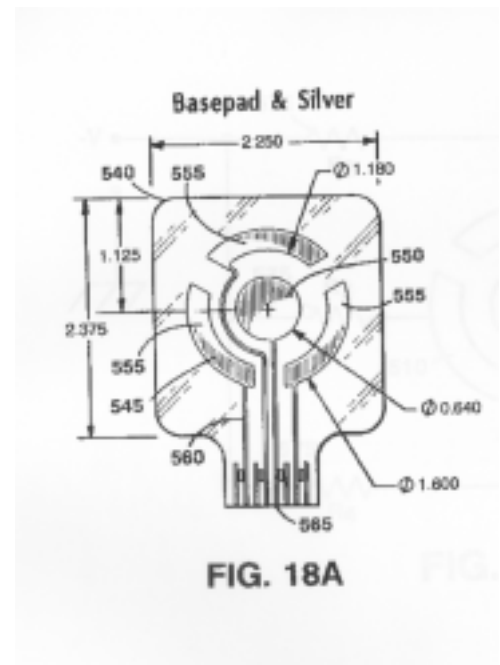


Figure 5.1.1

³³ Arnold, interview.

This last statement illustrates one difficulty of CEI: many electrodes are needed all around the heart. Thus, design issues such as the size the electrodes had to be to provide optimum sensitivity, had to be dealt with. Also, since the electrodes are particularly sensitive to the area immediately below them, then another question was raised: should electrodes be larger on the backside of the patient than on the front side, given that the heart was closer to the front of the chest than the back? Yet another problem that arose was the sensitivity of the electrodes to skin impedance. Arnold and his colleagues found in their initial trials that they could not repeat their measurements on subsequent trials; measurements varied erratically even with the slightest movement of the electrodes on the skin surface. The root of the problem, they found, was due to shaving, a common preparation for electrode placement.

During shaving, the scraping of the skin produces areas with varying impedance. The effect is caused by the removal of portions of the stratum corium, or the top layer of the skin by abrasion during shaving.³⁴ When impedance varied around the ring electrode, the signal was no longer being averaged around the whole ring. Therefore, the electrode acted more like a dipole in a conventional point electrode than a ring a dot electrode. The result was that the first spatial derivative rather than the second spatial derivative was measured, and the signal



strengths detected were an order of magnitude greater than expected.³⁵ Furthermore, the dipole electrode that was in effect produced was sensitive to changes in the impedance as it was moved around on the skin surface, thus explaining the inconsistent results. Subjects during Cohen's initial

³⁴ Webster, 251.

³⁵ Arnold, interview.

studies were young and relatively hairless, so sensitivity to impedance variations was never observed. Patients observed in Cambridge Heart's clinical trials, however, were older men with chest hair that had to be shaved, making this problem evident.

Cambridge Heart's solution to the problem was to devise special electrodes that contained multiple segments, as shown here in the patent diagram. Each segment would then be connected to a high impedance input, either a buffer amplifier or a high-value resistor. For each electrode, each segment's amplifier output would be tied to a summing junction before processing. In this configuration, the effect of changes in the skin impedance would be reduced since it would be small in comparison to the input impedance of the amplifier or resistor. Typical biopotential amplifiers have input impedances of at least ten megaohms.³⁶ Arnold and his colleagues found that a high-value resistor proved to be an unworkable solution since the thermal noise drowned out the small signals they were measuring, so they chose to use amplifiers, as shown in Figure 5.1.2.

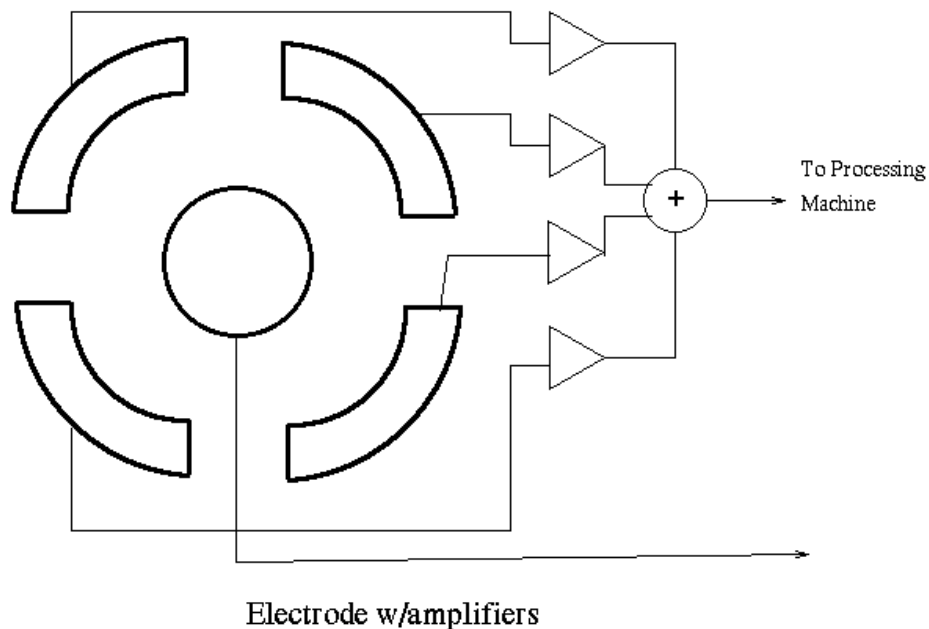


Figure 5.1.2

The next design question was what the number of segments in the electrode should be. A larger number of segments would make for better performance but would require more amplifiers and connections. Ultimately, they found that an electrode with four segments would provide adequate performance. Therefore, five amplifiers (four segments plus the center dot) would be necessary for each measurement. They estimated that one hundred such measurements would be needed for CEI, meaning five hundred amplifiers would be required. Another problem arose when they considered that five hundred amplifiers meant that five hundred connections needed to be made to the disposable. Standard connectors could not be used because they did not provide enough connector density to pack five hundred contacts in a small space.

Because Cambridge Heart only had five employees at the time (the four initial founders and a new engineer), Arnold and his colleagues realized that they had to look outside for a solution to the connector problem. They came upon Product Genesis, a consulting company founded by individuals from MIT. Working with Product Genesis, they discovered that a material with the property of being Z-axis conductive could be obtained. A Z-axis conductive material consists of gold wires embedded in a silicone or rubber substrate in such a way that it conducts electricity only from one surface of the material to the other, but not across its surface. Such materials were used in the semiconductor fabrication industry to connect integrated circuits to printed circuit boards and boards to each other.

Arnold and his colleagues thus made a printed circuit board with gold connectors arranged in a grid pattern. Z-axis conductive material attached to one side of the printed circuit board would connect to the processing station. The mylar film, which contained an array of silver/silver chloride electrodes with printed traces, attached to the other side of the circuit board. The whole assembly would be clamped together. Since the Z-axis conductive material could have a very high

³⁶ Webster, 288.

conductor density and the printed traces on the mylar film could be made very close together, they had successfully devised a connector that had sufficient conductor density to make five hundred connections in a small space. Furthermore, the connector assembly took advantage of a two-dimensional topology rather than the linear topology of traditional connectors. Arnold and his colleagues realized that they could further refine the design of their electrode array so that common segments were shared between electrodes, reducing the number of required connections by approximately one half. This is diagrammed in Figure 5.1.3.

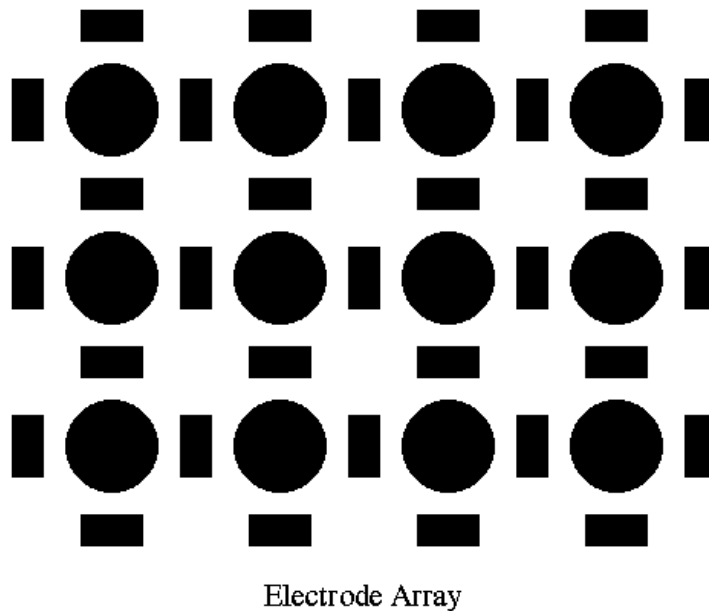


Figure 5.1.3

With the new electrode array in hand, they commenced on a study of patients undergoing angioplasty. The study produced favorable results, except that they found that mylar did not stretch, so it could not go around the compound curves of patient's torsos. Moreover, they were testing the electrode on individuals lying on an operating table, not running on a treadmill, as in a stress test. They seemed very far away from their goal.

Three possible solutions to the problem of inflexibility were proposed. One was to make “fingers,” breaking the electrode into strips connected to one common base. The disadvantage, however, was that segments between adjacent electrodes could no longer be shared and thus more connections were needed. Another option was to use z-fold in the mylar design, allowing it to stretch like an accordion. Finally, they could also print the electrical traces on a more stretchable material such as urethane. This change, however, required special inks and the material itself would have to stretch continuously and regularly in each direction or they would again have the problem that the electrode would not be detecting the second spatial derivative.

By this time, Cambridge Heart had spent a year on CEI development and was nearing the end of 1994. The founders were involved in a project with no solution in sight. Each was thinking it was time to update his resume.

5.2 A New Direction

We have called Arnold’s approach to company development “flexible,” but this does not fully describe his policy. Any company needs to be flexible to survive. Its internal trajectory must bend to fit the external trajectories of the industry. Draper was lucky enough to be successful at what he originally envisioned doing and thus did not have to rethink his company’s goals to keep it afloat. Tom West, on the other hand, had to abandon some of his engineering goals, such as the mode bit, to keep the Eagle project alive within Data General.³⁷

Cambridge Heart has been more than merely flexible in its internal trajectory. It had been developing two internal trajectories in parallel, CEI and T-wave alternans detection. As with many startup companies, Cambridge Heart’s first concern was to get a product to market.

³⁷ Kidder, 41.

Arnold believed that the secret of every research project was risk reduction. What were the risks? How can I identify and eliminate the risks as soon as possible? Industrial research was very different from academic research. In academic research, it does not matter if the project turns out to be commercial nonviable, just as long as a thesis can be written. In industry, one cannot afford to waste time and resources on a solution that will not work.

Arnold drew the analogy of developing a product to pruning a tree. The tree's branches corresponded to different solutions to the problem. The object was to develop a wide tree at first, providing plenty of possibilities to reduce risk. That was the reason they had chosen two target applications for CEI, ischemia and myocardial infarction, and three options for T-wave alternans detection, esophageal pacing, drugs, and exercise, as was shown in Figure 4.2.2. Then the tree is trimmed as quickly as possible to avoid wasting time. A cost-benefit analysis is performed at each "node" so paths can be compared and the best chosen.

The founders wisely chose to minimize risk by pursuing parallel development. Faced with technical roadblocks in CEI, Cambridge Heart now had the ability to direct their efforts towards T-wave alternans detection.

5.3 Switching Internal Trajectories: TWA Detection

During development of T-wave alternans detection, Cambridge Heart researchers had found that their initial methods of elevating the heart rate to required levels (greater than 100 bpm) were infeasible. Arnold and Paul Albrecht, chief scientist, tried esophageal pacing personally and found it to be a very unpleasant method. Esophageal pacing involves either swallowing a pill electrode or having a catheter inserted down the esophagus to the level of the heart. After trying it himself,

Arnold commented, “There was no way in which this was going to be a widespread technique.”³⁸

Atropine, a pharmacological agent used to increase heart rate, did not produce visible T-wave alternans in patients who had previously tested positive.³⁹ Exercise was the only option.

The problem now became the detection of microvolt signals in the presence of significant electrical noise. One solution was to have the patient pedal on an exercise bike at one-third or two-thirds the heart rate. That would move rhythmic noise away from alternans frequency of one-half the heart rate. This helped to some extent. Another technique to help reduce noise lay in signal processing. From their experience with CEI, Arnold and colleagues decided that it would be best to place many electrodes on the chest. The beating heart was abstracted as a moving dipole that projected upon the twenty or so electrodes around the chest. Arnold described that the projection of the heart dipole on the electrodes had to be coherent with the geometry of how the measurements were to be processed. The part that was not coherent could be regarded as noise. By finding a relationship between the electrode signals while the patient was sitting still, they could create a model. Then while the patient was exercising, this model could be used to weigh the inputs from each electrode to obtain the best three-dimensional picture of the heart dipole. As Arnold explains, there are many ways to construct a three-dimensional output from a twenty-dimensional input by taking different combinations of inputs. The problem would be to develop an algorithm that found in real time the optimum configuration of twenty electrodes to produce the lowest noise result. That problem was tractable and could be done.⁴⁰

Cambridge Heart then proceeded to Tufts to perform a clinical study. The first test produced very poor results, and the second test looked no better. Counting on a successful test run,

³⁸ Arnold, interview.

³⁹ Arnold indicated at the Technology Breakfast (12/2/98) that alternans were observed with drug-induced heart rate elevation and they are currently exploring this option.

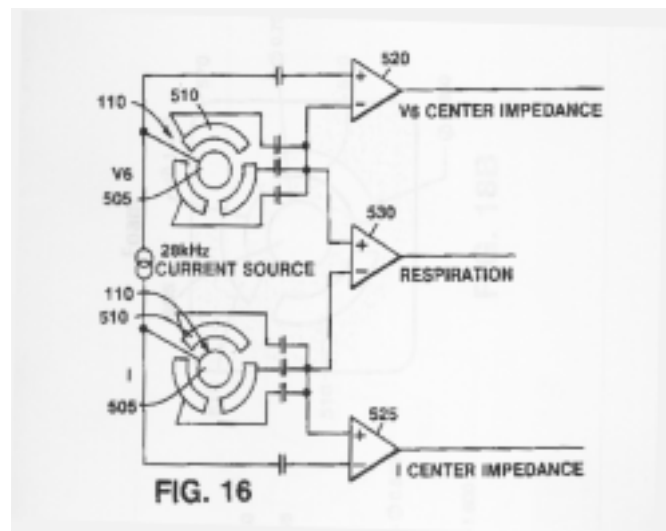
⁴⁰ Arnold, interview.

Cambridge Heart had ambitiously signed up for a booth at the North American Society of Pacing and Electrophysiology (NASPE) conference. With such poor results, Arnold and his colleagues debated whether they should attend. They finally decided that they had nothing to lose by attending, and fortunately, the clinical tests improved just before the trade show.

Acceptance by industry groups such as NASPE were critical to a young start-up such as Cambridge Heart. Donald MacKenzie mentions the importance of cultural endorsement. The gyro culture set into motion by Draper greatly facilitated the acceptance of his theories. A positive showing at the conference would likewise be important for future networking and sales for Cambridge Heart.

5.4 Merging Technologies

Through initial tests, Cambridge Heart discovered that T-wave alternans detection needed many electrodes and they had to be very sensitive. At this point, Arnold and his colleagues realized that they had already solved the problem for CEI. T-wave alternans detection required only twelve electrodes as opposed to the one hundred needed for CEI. Thus, the problems that they had encountered with the inflexibility of mylar were not an issue, since only the sensitivity afforded by the segmented electrode was needed. Why not combine the two technologies, which would give them a disposable component for T-wave alternans



detection as well? This satisfied two members of the Board of Directors from KBL Healthcare,

who had pointed out that T-wave alternans tests had no disposable and thus would not be profitable. One path of development contributed successfully to another as Cambridge Heart continued to make progress along its trajectory.

During this time, Arnold and his colleagues found that they could further reduce the noise in the ECG. A problem known as baseline wander is caused by deformation in the gel column in the electrode, which appears as high frequency impedance. They devised a three terminal measurement technique by injecting high-frequency current into the center dot of the electrode, as shown here in the patent diagram. The outer ring could then be used to measure how the underlying substrate responded to the high-frequency current and thus they could calculate the contact impedance of the electrode. Furthermore, they found that they could correlate changes in impedance with baseline wander and remove the drift by doing adaptive cancellation.

Thus, three techniques allowed Cambridge Heart to successfully detect T-wave alternans: having the patient pedal at a different frequency than the alternans frequency, using more electrodes to produce a higher dimensional model, which could then be used to find the optimum three dimensional picture, and using adaptive cancellation to eliminate baseline wander.

6 Commercialization

6.1 A New Player: The FDA

One big factor that has played a role in the trajectory of medical devices in general, but does not necessarily enter into other fields as readily, is that of risk and regulation. When x-rays swept the world off its feet, people were disbelieving, perhaps even unaware, of the Pandora's box that lay within the technology. Over time it became evident that in some situations x-rays could harm

more seriously than they could help. The federal government realized this potential could exist in other biomedical applications, and therefore enacted regulatory laws to control development.

The first act to mention medical devices was the Federal Food, Drug and Cosmetic Act of 1938. In this, the FDA could prevent false labeling of medical devices. But since this act only gave the FDA authority after the products had been marketed, it was not very effective. The Medical Devices Amendments were then enacted in 1976 to give the FDA pre-market authority over medical devices.⁴¹ Clinical studies and pre-market approval became required before a company could commercialize and distribute a product.

One important submission that will come into play in our story of Cambridge Heart is the pre-market notification, more commonly known as the 510(k). It is made to the FDA to “demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to pre-market approval (PMA).”⁴² Pre-market approval is a very lengthy and involved process, and represents the tightest control available for Class III (highest risk) medical devices. The 510(k), on the other hand, can be used for Class I or Class II products, or products which have a legal equivalent which is currently being marketed. Basically the 510(k) compares the new device to existing “predicate” devices, thus ensuring their safety and effectiveness. Today, the success or failure of many small medical device firms hinges on their regulatory compliance. Thus the external force of government plays an extremely large role in the trajectories of medical engineering.

⁴¹ Bronzino, 198.

⁴² www.fda.gov/cdrh/devadvice/314.html#link_1

6.2 Bringing the Technology to Market

By the end of 1994, Cambridge Heart had filed a 510(k) to the FDA for the CH2000, their new stress test machine that also measured T-wave alternans. A 510(k) required ninety to one hundred twenty days for approval or rejection. If Cambridge Heart could not get the CH2000 approved under a 510(k), as Arnold believed, then they could be forced to file a pre-market approval (PMA), which could take up to two years. With only two and half million dollars in cash left, which would last another year, they decided not to risk waiting for the FDA to process the 510(k) since it would be more difficult to raise money if they were rejected.

Commercially, Cambridge Heart had yet to leave the starting gate. Arnold was forced to remain dependent on investors until the government would consent to letting loose their tight reins on Cambridge Heart's trajectory. Given the studies they had already done at this point linking T-wave alternans to predicting sudden cardiac death, Cambridge Heart seemed to be in good shape. When the approval was granted, the commercial aspect of the internal trajectory would rise as the transition into industry would be made. But the approval did not come as expected. The trajectory was affected by the government.

The FDA had requested that they send more data on several occasions. In the end, Cambridge Heart had to negotiate for the 510(k) approval under the condition that no claim of the clinical efficacy of T-wave alternans could be made. In other words, they could claim that their stress machine could measure T-wave alternans, but they could not claim that it could be used to predict risk of sudden cardiac death. With this caveat, approval was secured in February 1996. Approval for the multi-segmented electrode followed in September 1996 after a delay from complications in the testing of the gel. Instead of letting Cambridge Heart's progress stall at the FDA step, Arnold had kept the company moving forward. While they had not received the labeling

they had desired, they had gotten approval to sell, which was important for them to attract investors. The goal then was to design a large study with the FDA to get full approval. At this point, Cambridge Heart was no longer a pure research and development company. The commercial aspect of its trajectory jumped and landed them in business. The outside force of the government loosened the reins just enough.

By February 1996, Cambridge Heart had decided to go public. They had already received partial FDA approval and needed to follow it up with clinical data. At the April 1996 board meeting, they formally voted to go public and raised twenty million dollars by August 1996. Cambridge Heart stock was initially offered at nine dollars per share and promptly fell to seven dollars.⁴³ In fall 1996, Cambridge Heart negotiated the details of a large study with the FDA to get full labeling. In spring 1997, they discovered, while doing a more detailed analysis of their existing data, that they needed to redesign and restart the study. The stock fell from fourteen dollars where it was at to seven dollars.⁴⁴ Arnold recalls that a portfolio manager at Fidelity Investments called him asking, “Are you incompetent or a crook?”⁴⁵ Cambridge Heart changed the study and completed it in the summer of 1998 with exceptional results. In August 1998, they submitted the results of the study to the FDA. The company expects full approval of complete labeling in the spring of 1999. Once that approval arrives, Cambridge Heart’s trajectory will veer closer to its original course. Until that time, they must print the following disclaimer in their Physician’s Guide:

NOTICE: This guide is for investigational use only and should be used only for background information in the design of clinical studies. Correlation of the alternans results with a specific clinical diagnosis or prognosis when alternans is not visually apparent on the ECG has not been clinically established. Cambridge Heart makes no claims with regard to the clinical utility of TWA and makes no

⁴³ www.corporate-ir.net/ireye/ir_site.html

⁴⁴

⁴⁵ Arnold, interview.

recommendations with respect to the use or interpretation of TWA data in clinical practice.⁴⁶

6.3 Marketing

With Cambridge Heart finally in industry, Arnold and his colleagues have done some market research to better understand the customers they are selling to, primarily clinical cardiologists. An invasive procedure that is performed to assess a patient's risk for sudden cardiac death is known as the electrophysiology or EP test. In EP, a catheter is inserted into the patient, then used to induce arrhythmia or fibrillation by stimulating the heart with electrical impulses. If the patient's heart loses rhythm, it can be reverted immediately with a defibrillator. The rationale is that it is much better to forcibly induce such a disorder in the hospital laboratory than to have it happen while the patient is, for example, running to catch a bus. The ability to induce such arrhythmia or fibrillation under certain conditions is indicative of risk of sudden death.

One problem is that in many cases, candidates for EP studies do not get referred to the appropriate specialist. The reason is that physicians who perform EP studies tend to be cardiologists themselves. Thus, clinical cardiologists do not like to refer patients to other cardiologists for fear of losing the patient. The promise of T-wave alternans detection is that they have been shown to be as effective as EP in measuring this risk. The results of a study published in *Heart* indicated that for those who tested positive on the EP test, a large percentage died of sudden death within twenty months. The noninvasive T-wave alternans tests identified these individuals just as well as the invasive EP test, as shown in Figure 6.3.1.⁴⁷

Since many patients are on the borderline in terms of whether they really need the EP study performed or not, Cambridge Heart believes that clinical cardiologists can use the T-wave alternans

⁴⁶ CH2000 Physician's Guide.

⁴⁷ Armoundas, et al, 254.

detection machine to decide who to refer for an EP test. Moreover, they can perform the T-wave alternans test in their office. Since Cambridge Heart's studies have shown a high correlation between EP studies and T-wave alternans as predictors of sudden cardiac death, cardiologists can be assured that the T-wave alternans test will be equivalent to the EP test.

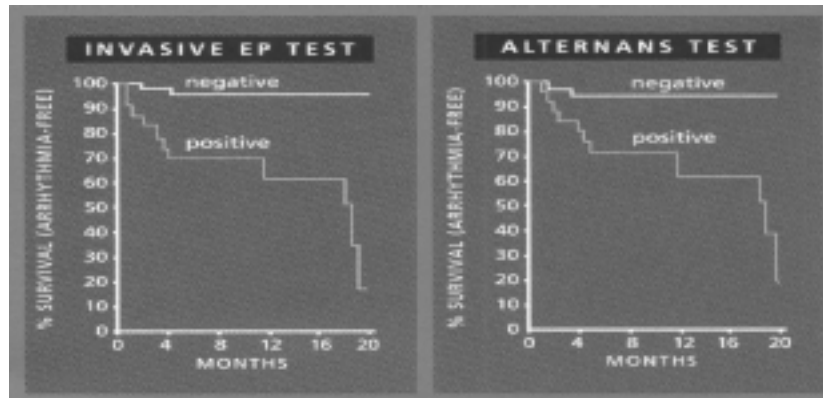


Figure 6.3.1

A second problem uncovered in the market research was that of reimbursement. Arnold claims that one argument for the T-wave alternans test is that many expensive and unnecessary EP tests can be avoided. T-wave alternans tests are non-reimbursable by HMO's at the present and Cambridge Heart does not expect a billing code to be available until the year 2001.⁴⁸ Cambridge Heart's strategy to achieve reimbursement in the meantime has proceeded in two directions. In one direction, they have chosen to sell their T-wave alternans technology embedded within a stress test machine, the CH2000, shown in the picture here.



⁴⁸ Arnold, Technology Breakfast presentation.

Cambridge Heart's sales strategy has thus been to market the CH2000 to cardiologists who are looking to replace their old ECG machines, but have an eye toward the ability to detect T-wave alternans.⁴⁹ As evidence for this strategy, the CH2000 is sold for \$18,000 without software that can perform T-wave alternans detection, while \$26,000 buys a unit with the technology included. T-wave alternans tests are not popular at present⁵⁰, but as the results of recent studies are published linking T-wave alternans to risk of sudden cardiac death, Cambridge Heart hopes that more and more cardiologists will choose to use the T-wave alternans test in their practice.

As another strategy to achieve reimbursement, Cambridge Heart has exploited a common associated tests which is reimbursable. This test is known as the signal averaged ECG test, which is known not to work. It is convenient for Cambridge Heart that the measurements for this test can be collected from the same electrode positions as the T-wave alternans test, and that it is performed by having the patient sit at rest for five minutes. Thus, the CH2000 is designed to perform the signal averaged ECG test in addition to the T-wave alternans test, so that cardiologists can piggyback the alternans test with signal averaging. The reimbursement for a stress test is one hundred dollars, but this is less than the cost of the cardiologist's time and the fifty dollars for Cambridge Heart's electrodes. The signal averaged ECG test can be billed at \$173, which turns out to be sufficient. While this strategy does not get access to the major portion of the population that is at risk for sudden death, it is a way for Cambridge Heart to get into the market. Cambridge Heart is currently performing a study to show that patients who have no prior symptoms of arrhythmia can be at risk for sudden death and that alternans can be a method of identifying those patients.

7 The Future

⁴⁹ Baskett, interview.

⁵⁰ Bloomfield, interview.

7.1 Technical Trajectory

Cambridge Heart has positioned itself carefully in the medical market by having two products: one very narrowly based, and one for more general usage. Professor Cohen believes that the detection of T-Wave alternans is the more promising product of the two. Jeff Arnold places his bets on the Computer Imaging technology. Having the two technologies to draw from allows them to deal with the impossibility of predicting the future.

Cambridge Heart has still not focused down to a single core technology. They will continue following both technologies until one is proven unprofitable since both evolved in symbiosis. The detection of T-Wave alternans created a need to improve ECG technology to state of the art. Computer ECG imaging and related implementation developments made reliable analysis of T-wave alternans feasible.

Cambridge Heart's goal with these products is to place a unit in every cardiologist's office. They plan to do this by making a modular extension to a stress test that performs CEI and T-wave alternans testing. Most of all, it allows the cardiologist to make a diagnosis of sudden death syndrome (SDS) or ischemia without invasive surgery. This will be appreciated by cost-based medical plans like HMOs.

Being able to detect a life-threatening situation is a valuable mechanism, but it brings up a controversial subject: how much is life worth?

The TWA module does not add significant cost compared to the standard equipment that cardiologists use. This low cost translates to lower fees for patients. This means that there is less of an advertising push that is necessary to sell the product.

The T-Wave alternans technology defines a sudden death syndrome risk group. At that point, the health care provider has a number of options:

1. Warn the patient, and recommend a change in lifestyle
2. Put the patient under constant supervision and monitoring
3. Install an internal defibrillator

Each of these has costs and risks. Giving nothing but advice is obviously the cheapest and least debilitating (physically) but has the highest risk of death. Putting the patient under monitoring has a greater chance of catching the event, but also has the highest debilitation factor, since the individual needs to stay in an institution or subscribe to a home-based monitoring system. Along with the debilitation, the cost of this approach is higher, since the equipment must be contracted or purchased for the duration of the monitoring.

Cohen's choice, an implantable cardioverter defibrillator (ICD) is the newest of the three and least debilitating after the unit is installed. It also has the best chance of keeping a patient alive when his heart unexpectedly goes into fibrillation. Unfortunately, even with a perfect rate of detection, studies showed that T-Wave alternans have a 19% false positive rate.⁵¹ Installing a unit into a patient who is not at risk increases the possibility of injury or death through complications since it requires a major surgical procedure. In addition, a major economic problem lies in how incredibly expensive it is to install and maintain. The total price for 20 years of service is 2.5 million dollars, averaging to \$125,000 per year.⁵²

To a medical plan, this is a lot of money, however other factors make it more attractive. Currently HMO's are not installing automatic defibrillators in practically any of their patients. The reason is that no major study has yet shown that an ICD will prevent sudden cardiac death. In fact, one major study found ICDs do more harm than good.⁵³ Dr. Cohen, however, believes that studies to be released in the near future will show that an ICD will reduce the chances of sudden cardiac

⁵¹ Adam, Harkness and Hill, p. 5.

⁵² Cohen, interview.

death. This is because it restores cardiac function before the onset of death, a condition known to occur within four minutes of a fatal arrhythmia. At that point, HMOs will begin to be pressured by doctors and the government to implant ICDs in anyone at risk of sudden cardiac death.

Increasing numbers of doctors are directly employed by HMOs. These doctors are paid a fixed amount per patient cared for per year. This means that they will be reluctant to spend money on any treatment not needed since it will essentially come out of their own pockets. For these doctors to want to use the TWA technology, there will have to be a treatment available for patients that test positive. Therefore, these doctors will not simply be able to bill for the stress test and signal-averaged ECG to be reimbursed. They are never reimbursed. The link between installing an ICD and preventing sudden cardiac death is critical to widespread use by doctors of TWA technology, regardless of what HMOs decide.

7.2 Commercial Trajectory

In addition to using research methods in order to increase possible future sales, Cambridge Heart is also getting assistance from some powerful groups. On June 10, 1997 they came to an agreement with Hewlett-Packard of distribution of their units.⁵⁴ Medtronic, the world's largest supplier of implantable cardiac defibrillators, and the NIH(National Institutes of Health) have begun a study of the prevention of sudden death syndrome through the use of ICD's, eagerly awaited by Cohen.⁵⁵ The study would allow them to forge an alliance with Medtronic, the largest seller of ICD's in the world.

⁵³ Ibid.

⁵⁴ Goldman Sachs Market Research Study, p. 8.

⁵⁵ Adam, Harkness and Hill, p. 6.

In terms of corporate economics, Cambridge Heart has steadied. Its economic status has followed that of most startups: explosive growth and inflated stock prices, followed by a period of slow decline until the next product is released. The Adams, Harkness & Hill report believes that things will stay that way and probably lose money in the year 2000. However, a doubling of Revenue at approximately \$4 million is expected to occur for 1999. The belief is that things will pickup soon afterwards with the revised labeling scheme's scheduled release, in Spring 1999. This new label would allow Cambridge Heart's T-Wave alternans to be advertised as being effective in the diagnosis of sudden death syndrome, one of the major concerns mentioned in their SEC 10-Q risk analysis.

7.3 Managerial Trajectory

Draper was always thinking ahead. He always had the next 20 years mapped out, not only in his mind, but also in his communications to others: single precision, double precision, then triple precision guidance accuracy. And the gyro development was able to proceed with this in mind. He eventually disregarded lasers while working on double precision, not because they wouldn't be good for double precision, but because they wouldn't work for the eventual triple precision he sought.

West, on the other hand, as much as he talked about hating kludges, provided a hotbed for kludge activity. The Eagle was riddled with a patchwork of hacks and temporary fixes that got the product out the door. This was West's greatest failing, especially in his own eyes. His goal for the Eagle project was not simply to get a machine out the door, but rather to play "pinball," to catapult the team from one project to the next. The way he treated his team prevented his dream from becoming reality. He used people up and burnt them out without so much as a "by your leave," or

even sufficient resources. As much as he thought about the long run, he sure didn't plan for it in the present.

Cambridge Heart must be careful to prepare for the long run as well. In every conversation we have had with Jeff Arnold and in the lectures he gives, he refers to the fireworks that will go off for Cambridge Heart in the summer of 1999. What happens then? Cambridge heart is a company that is developing two specific products with explicit uses. Of course, every successful company can only develop so much at once and the health care industry actually mandates that the application for the product be thoroughly defined. But there must also exist some vision to be a leader in the general sense of the cardiac imaging industry.

What are Jeff Arnold's plans? He was brought in by a headhunter to head up the company. Does he have any lasting interest in Cambridge Heart? His previous employment was a temporary CEO-ship during a turn-around period at another company. Does his interest lie in the exciting periods of company leadership, e.g. the startup and turnaround phases?

Cohen had very different motivations for being involved with Cambridge Heart. He wanted to bring his ideas to fruition in industry where they could actually contribute to improving health care. Does he have any lasting interest in Cambridge Heart besides the application of his patents? His current position is only as a technical consultant one day a week. It took the technology licensing office to get him out of the lab and into industry.

Regardless of Cohen and Arnold's interest in Cambridge Heart's distant future, the real success story is a medical one: saving lives and reducing medical costs.

8 Conclusions

Cambridge Heart is still in the middle of its startup stage, but they have a viable product, the CH2000, that is receiving good reviews from its users. However, the market penetration has not occurred yet, as cardiologists are not lining up left and right to get one of them. This will not happen unless the studies come back proving that TWA and CEI are valuable tools, but Cohen is betting that it will and soon.

We now have evidence that smoothly transitioning between multiple trajectories has allowed them to reach this point. If they had not been developing TWA at the same time as CEI, they would not have been able to make the jump from one to the other when a roadblock arose. More than likely, they would still be stuck trying to figure out how to make CEI work and have run out of money. Luckily, the ability to switch allowed them to produce a product and create a constant source of income to fund research, including research to continue CEI. Since they have survived a year after going public, and according to Arnold (Technology Breakfast), finally solved the electrode problem in CEI, it seems that they will eventually be very successful.

We have discovered that West's failing was his inability to utilize the multiple trajectories present in the Eagle project. Unlike Draper Labs, Data General was a company in industry and could not afford to waste time on any one product. Also, West was working with less resources than Draper and could not afford to power through his obstacles in the same way. If West had had Cambridge Heart's example from which to learn, he might have seen that Arnold's approach would have had a positive impact on the Eagle project.

Why didn't Draper utilize the multiple trajectories available to him? First of all, he didn't need to. Draper had the resources and know-how to power through obstacles by hiring the experts

in the field and funding whatever needed to be funded. Being a research institution, Draper Labs didn't have any pressure to put out a product and could work without anything near as stringent a time frame as a company in industry. The purpose of research is to solve hard problems, not pray you will avoid them. Switching trajectories when a roadblock is encountered is contrary to the purpose of research. If the current path will eventually lead you toward your long-term goal, there is no reason to run from a hard problem.

As far as the pressure Draper was under, that pressure came from the military to produce highly accurate guidance systems. Draper may have helped convince the military initially of its need for highly accurate guidance but, once he did so, he had to produce. Had he at any point reconsidered his initial feeling that floated gyros would have the best chance of achieving third order accuracy, Draper would have switched his technological trajectory to the more promising technology. However, Draper never changed his mind on the matter and turned out to be correct in his initial assessment. This, as much as anything, allowed Draper to be successful without utilizing his many possible trajectories.

Unlike, West had limited resources with which to work. He could not afford to explore many ideas in parallel, or perhaps even any. Coupled with limited resources was limited time. West was in business, not research, and had to have a product out the door before very long. He must not have felt he had the option to spend time in multiple places and risk not getting anything done.

In contrast, Cambridge Heart has saved time by pursuing multiple ideas in parallel. Roadblocks are not as stifling to progress when there are other options, as long as changing focus does not cost more than plowing through the setback. Cambridge Heart, like the Eagle project, is

under commercial pressure that Draper never saw. However, Cambridge Heart has had generous funding which allowed for more development time and freedom.

The biomedical industry is a lucrative but challenging environment. The forces of the market and the FDA approvals make the resources required almost prohibitive. Yet somehow Cambridge Heart has survived and even flourished. The question is how. Cambridge Heart did not have Draper's institutional resources, or Tom West's tenacity. Instead, it has followed a varied trajectory that allows it to be reactive to its environment. If this company continues with this strategy and follows it further, Cambridge Heart will continue to be a success story.

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