GROWTH STRATEGY FOR A BATTERY SUPPLIER TO THE IMPLANTABLE MEDICAL DEVICE MARKET

by

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Ethics Approval

The author, whose name appears on the title page of this work, has obtained human research ethics approval from the Simon Fraser University Office of Research Ethics for the research described in this work, or has conducted the research as a co-investigator of a project, or member of a course, approved by the Ethics Office.

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ABSTRACT

This project develops strategic recommendations for the growth of the EaglePicher (EP) Medical Energy Products (MEP) group - a battery supplier to Implantable Medical Device (IMD) manufacturers. The analysis evaluates the key external competitive forces of the battery industry and finds the IMD market to be most attractive. The internal characteristics of the firm are examined using industry benchmarking and a value chain analysis. The current strategy is examined by integrating the external and internal analyses, and a rationale for future strategy is developed. A balanced scorecard approach is utilized to evaluate market alternatives using EP's decision-making criteria. This leads to the key market level recommendation of pursuing the neurostimulator market segment within the IMD industry. At the business level, the MEP group is constrained by cash flow, so it is recommended that EP seek a source of external financing to facilitate pursuit of this market segment.

DEDICATION

This work is dedicated to my family. Michèle, Adrianna and Alexa – thank you for patiently occupying yourselves while I was holed up in my study. I love you all dearly. I will always look back and remember the pain and the laughs. Mom and Dad, thanks for believing in me. Mom-in-law, thanks for your prayers.

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GLOSSARY AND LIST OF ACRONYMS

Term or Acronym	Meaning of acronym and brief definition if required
AED	Automatic External Defibrillator
cGMP	Current Good Manufacturing Practices – a set of industry guidelines for manufacturers in food, drug and medical manufacturing related to quality and traceability
CRTD	Cardiac Rhythm Therapy Device – An implanted medial device that monitors the heart for irregular rhythm and delivers a shock to induce regular heart rhythm. Differs from ICD in that it covers a wider range of irregular heart conditions and offers more software features.
EP	EaglePicher (sic) Incorporated. In the context of this document EP refers to the larger organization
GM	Gross Margin – Money earned before SG&A. Revenues minus Cost of goods
IC	Integrated circuit – custom-designed, programmable chip used to control the algorithms in an IMD
ICD	Internal Cardioverter Defibrillator – An implanted medical device that monitors the heart for irregular rhythm and delivers a shock to stop the irregular rhythm. Differs from a CRTD in that it covers a narrower range of irregular heart conditions and offers fewer programmable features.
IP	Intellectual Property – Typically refers to patents, but it can include copyright material, trademarks and trade secrets
ISO	International Standards Organization
IMD	Implantable Medical Device
Li-ion	Lithium-ion – most widely used re-chargeable chemistry. It covers a range of different cathode, anode and electrolyte combinations.
Li-MnO_2	Lithium-Manganese Dioxide – newest battery chemistry in the implantable cardioverter defibrillator market.
Li-SVO	Lithium-Silver Vanadium Oxide – incumbent battery chemistry in the implantable cardioverter defibrillator market.

Term or Acronym	Meaning of acronym and brief definition if required
MEP	Medical Energy Products – business group within the Commercial Power Division of the EP Technologies SBU
Ni-Cad	Nickel-Cadmium- Nickel based rechargeable battery chemistry category
Ni-MH	Nickel-Metal Hydride – Nickel based rechargeable battery chemistry category
OEM	Original Equipment Manufacturer
Primary Battery	Industry terminology for a non-rechargeable cell or battery.
SBU	Strategic Business Unit
Secondary Battery	Industry terminology for a rechargeable cell or battery. In general, this will mean lithium-ion
FDA	Food and Drug Administration – Regulatory body in the U.S. responsible for all medical drugs and products sold to consumers
UPS	Uninterruptible Power Supply
VC	Venture Capital – refers in general to money obtained from a venture capital firm.

1 INTRODUCTION

1.1 Purpose of the Strategic Analysis

The purpose of this applied project is to generate strategic alternatives for the EaglePicher Medical Energy Products (MEP) group and to make recommendations for strategic direction in the medical products battery market. The MEP group develops and manufactures a variety of battery technologies for use in several implantable medical devices. As a group within the Commercial Products Division of the Technologies Strategic Business Unit (see **Figure 2.1**), the MEP group has shown excellent revenue growth over the past five years. Success in winning several development contracts with major Original Equipment Manufacturers (OEMs) has proven that there is internal capability and market potential. This analysis evaluates multiple market segments in the medical device OEM space and recommends the most attractive strategic direction for the MEP group based on a match between capability and potential for attractive future profits.

1.2 Analysis Framework

This analysis begins with an overview of the EP corporation in order to get an understanding of the current strategic direction and the context in which the MEP group operates. The MEP group has recently been impacted by the fact that as of the 11th of April, 2005, EP has filed for Chapter 11 bankruptcy protection in the U.S. The need for cash has increased attention on money-making business units by an order of magnitude and it has limited cash flow to strategic business units and divisions.

The analysis surveys the global market for batteries and the market for batteries in the medical market. The attractiveness of each market is examined based on competition, potential for profit and strategic fit with EP competitive strengths. There is good reason for EP to examine the medical market in detail because the potential markets are large, the background EP has in applicable chemistry meets many of the current needs and there are few competitors with any significant depth of technology

The EP MEP group is then examined to better understand the way profit is generated based on the battery development and manufacturing lifecycle. Then, EP's activities are put into context within their industry through examination of the Implantable Medical Device (IMD) industry supply chain. By understanding how the MEP group fits into the customer supply chain, areas where it adds value and links to the customer become more obvious.

The third chapter of this analysis looks outside of the firm. The market for medical batteries is examined and segmented for the purpose of analysis and comparison. The potential OEM product applications and battery requirements for these products are also briefly described in this chapter. An application-technology matrix is used to provide a compelling basis for further market examination.

Porter's five forces model (Porter, 1979, p.6) is used to understand market attractiveness and long-term opportunity. As an extension of this analysis, the single biggest independent competitor – Greatbatch Technologies (Greatbatch) - is examined in detail. Industry dynamics such as product life cycles, growth potential and cyclicality are surveyed. The IMD industry is also examined through a PEST analysis because the medical industry can be heavily influenced by demographics, government policy and funding.

Following an external analysis, this paper looks inward at the MEP group. The MEP group and its available resources are compared to those of Greatbatch technologies to benchmark

key internal assets for success in the IMD battery market. A value-chain analysis is used to map out internal capability and highlight the MEP group strengths and weaknesses. Finally, some high level financial assessment is done to understand the financial health and constraints of the MEP group within EP.

Chapter 5 begins with a summary and assessment of current situation. It then looks at the future state of the organization and poses a question. What will the organization look like in the future if the current choices are left to run the course? It is shown that there is a compelling reason to develop new strategic alternatives. The chapter is used to focus on the critical issues facing the MEP group.

The sixth chapter examines the best market alternatives. What are the best application market segments to pursue? The most attractive segment within the IMD market is established using a GE-McKinsey Matrix. Then, a balanced scorecard is used to establish the market with the best the strategic fit to current EP strategic objectives. This chapter concludes by looking at market level alternatives that present the best opportunity for increased market share.

Finally, the project makes recommendations for future action. These recommendations recommend the next best steps to take in order to grow the business. These actions are divided into a business level category and a market segment level category.

2 PROJECT CONTEXT

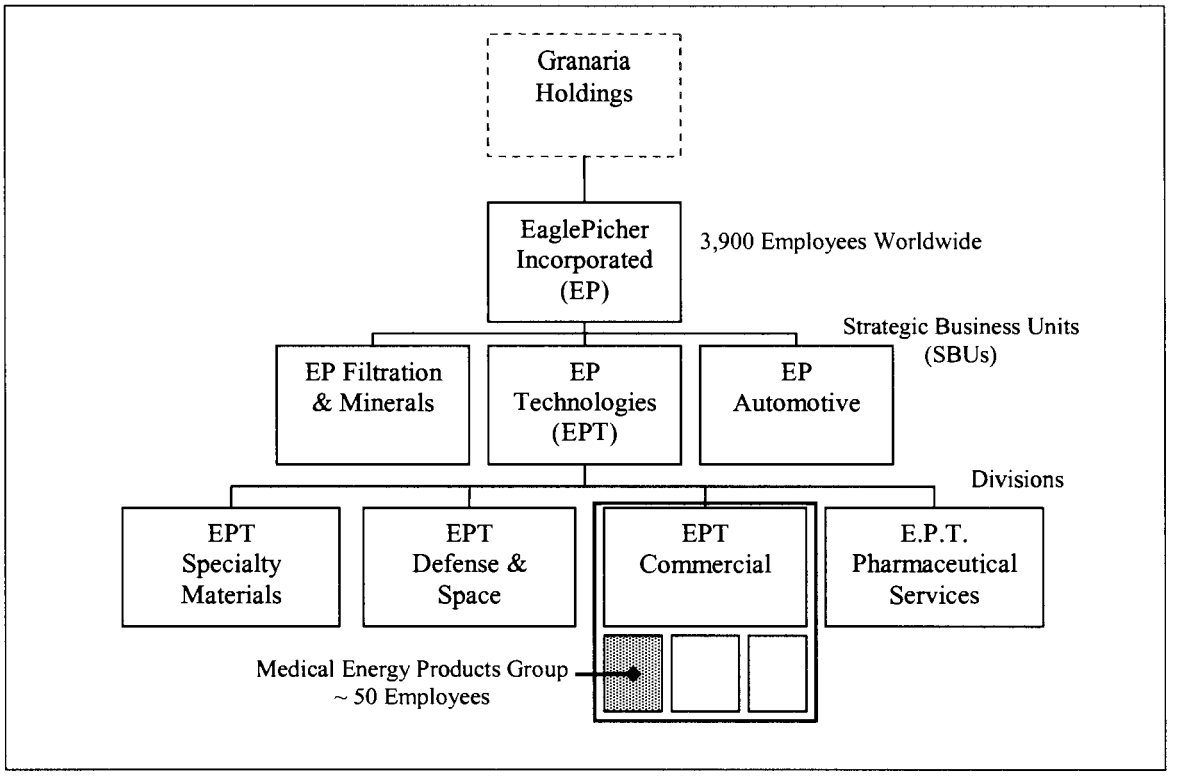
2.1 EaglePicher (EP) Organizational Overview

EaglePicher Incorporated (EP) is an international manufacturer of innovative industrial products for space, defense, automotive, pharmaceutical and commercial applications. Its long history of technical innovation and engineering has helped to propel the company into market leadership positions in several markets. It is a privately held limited corporation with headquarters in Phoenix Arizona, supported by worldwide offices and manufacturing facilities in Canada, Mexico, Germany and Asia.

EP is comprised of three major strategic business units (SBUs). These business units are EP Filtration and Minerals, EP Automotive and EP Technologies. Together these business units offer a variety of products which generated $707 million in sales in 2004 (EP form 10-K, 2004, p. 56).

Within EP Technologies, there are four divisions. Of these four divisions, two are primarily concerned with the development, manufacturing and sales of batteries and power systems. These two divisions are the Defense and Space Power division and the Commercial Power division. An abbreviated organizational structure showing the relative size and reporting responsibility is outlined **Figure 2.1**. The combined net sales of these two divisions for fiscal 2004 amounted to approximately 23% of EP Incorporated revenues. Approximately 21% of total EP revenue (about $148 million) is derived from defense and space contracts while commercial power accounts for about 2% ($14 million) of corporate revenues.

Figure 2.1 EaglePicher Organizational Chart



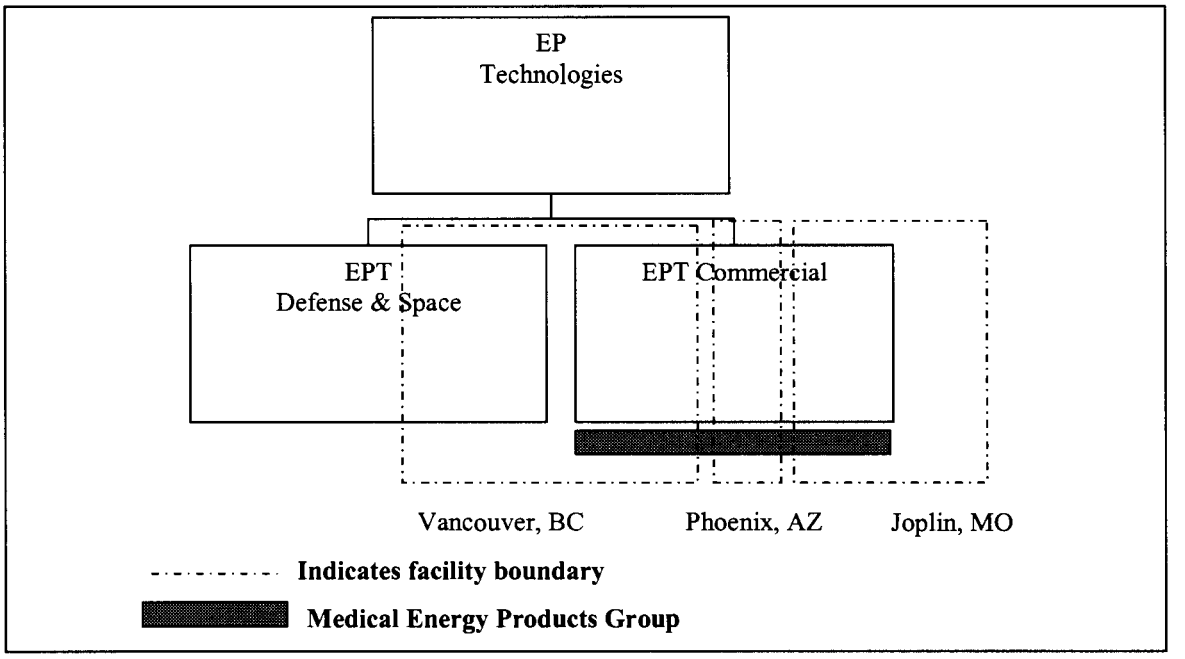
Source: EP Internal

This analysis is done in the context of the MEP group which is a part of the Commercial Power division (see **Figure 2.1**). This group currently generates only a few million dollars in revenue but the growth has been dramatic over the past three years. As a result of the rapid growth, this small group has caught the attention of the highest levels of the organization.

Geographically, both the Commercial Power division and the Defense and Space divisions are spread out across three facilities in the U.S. and Canada. The Canadian facility is a wholly owned subsidiary where the Defense and Space division shares space with the MEP group of the Commercial Power division. As indicated in **Figure 2.2**, most of the MEP group is located in Vancouver, where the facility is shared with Defense and Space. The overall MEP business responsibility lies in Phoenix. There is also a single, recently hired marketing manager located in

Phoenix. The Joplin facility holds less than 10 employees responsible for a low production volume medical cell.

Figure 2.2 Geographic Location of the MEP Group Within EP



EP Internal

The genesis of the MEP group occurred about five years ago. It was born out of a necessity to smooth out cyclical revenues in the space and defense group located in the Vancouver facility. The creation of the MEP group allowed the Vancouver facility to retain talented battery design, development and manufacturing staff at a time when military battery development was slowing. Later, a development program was transferred from the Joplin facility because of a lack of resources in that facility. Then, a business leader was assigned and the group became an official entity within the greater organization. Today, the medical market presents an opportunity for the EP Technologies Business unit to diversify the product portfolio.

Approximately four years ago, an OEM approached the development team with a proposal to begin a program for a Li-MnO_2 primary cell for and implantable Internal Cardioverter

Defibrillator (ICD). At the time, the OEM was motivated to develop a cell with a specific chemistry and to build the competence of a supplier that could act as a second source. This relationship and the experience gained in the IMD market provided a beachhead in the IMD market. Now the MEP group is a serious competitor in the IMD market with revenues increasing year over year from about $0.6 million financial year 2000 to a projected $5.0 million in financial year 2005.

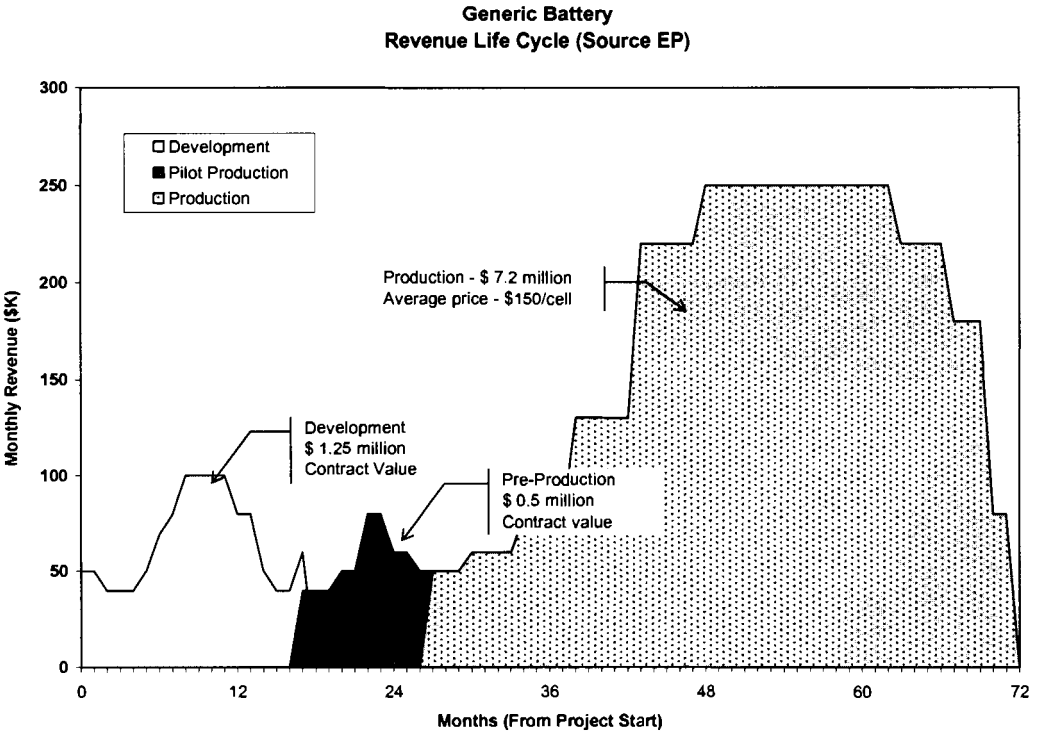
2.2 The Medical Energy Products (MEP) Group as a Business

EP MEP can be defined as an emerging business. Though the group is profitable, revenues are less than 2% of the largest competitor in the battery market supplying IMD developers and manufacturers. The group still relies on shared functions in the Vancouver facility such as materials management, human resources and accounting. In addition, there is a need for the injection of capital to cover irregular cash flow and to purchase new equipment. Further, the Chapter 11 filing by EP has forced the MEP group to operate in a cash neutral position – not unlike an emerging business with limited funds.

2.2.1 Business Model

A standard battery lifecycle is based upon the lifecycle of a product. Currently, all of the products sold by MEP are implantable grade batteries used for implantable devices. There are three distinct phases in the revenue model for these products. The expected revenue is illustrated below in **Figure 2.3**. At each phase the customer provides revenue to EP and EP has an opportunity to generate profit.

Figure 2.3 Generic Revenue Model – Product Life.



Source: EP Internal Business Model

First, there is a development stage in which EP is paid to develop the battery. Objectives for the customer vary, but in each case, the batteries have design requirements including a specific form factor, a minimum capacity requirement and a specified rate capability. Typically, at this stage, there is a negotiated contract developed with milestone payments based on key development deliverables such as completion of design, delivery of prototypes, testing and low volume production capability. The contract price is based on a proposal which takes into account the cost of labour and materials for the development effort. A margin is added to the estimated costs to determine a development contract price. Additional costs may be added during the development phase if there is an increase in scope or change in schedule necessitating an increase in contract price to retain gross margin. Each program is started with an estimated profit margin, but because the contracts are usually fixed price, the profit margin varies according to the success of the program.

Extensive testing is also carried out during the development phase to ensure battery safety and performance. This test data is used to support regulatory approval for the intended end use. The development phase is typically considered complete once the battery design has been proven through a qualification test and the customer has had a chance to integrate the battery into a product for prototype testing. By the end of this phase a very detailed procurement specification has also been finalized to ensure that all future EP batteries are delivered according to customer requirements.

The second stage is known as pilot production or pre-production. At this point both the OEM and EP are validating production processes. The primary goal is to ensure production readiness. By this stage, both the customer and EP have gained some insight into the costs of the product over a range of production volumes and a price per battery is negotiated. Costs in this stage are calculated as accurately as possible based on all of the direct inputs to the production of batteries. The direct inputs include assembly labour, machine usage costs and material costs with adjustments based on yields. The battery price is based these costs with a margin added for profit. Additional cost data is collected during this phase as improvements are made to production processes and materials supply contracts are negotiated. Typically, any savings earned in this phase are taken by EP in the form of higher gross margin. For example, if EP can reduce scrap rates at a particular stage of the production process, a cost savings can be realized, leading to higher gross margin. Alternatively, EP will attempt to renegotiate the price if costs are higher than expected in order to preserve margin.

The batteries produced may either end up as inventory for the customer or may be used for additional testing or OEM process development. At this point in the battery life cycle, higher volume manufacturing equipment is also specified and possibly purchased and incorporated into the process. The cost of capital equipment for higher volume production may be borne by EP,

shared or borne by the customer – each program is different. In a case where the costs are shared with customers, EP is often bound to prevent other programs from sharing this equipment.

The third stage is the production phase of the project. In this phase, the focus is on delivering the product to the customer. Higher volume equipment is in place to improve productivity and reliability of deliveries. Orders are placed using purchase orders based on the procurement specification done in the development and pilot production phases. It is during this phase that EP really drives internal process improvements and other cost savings measures. In some cases, a customer may drive some changes either to aid in ramping up for increased volume or to incorporate a technical change. Though the MEP group has relatively little production experience, it is believed that improved operational efficiency will improve margins, making this stage of the life cycle the largest profit generator.

The demand at the end of the production cycle drops as customers introduce their next generation products. It will be important for EP to quickly ramp down production and redeploy resources to avoid losing profits to lower productivity as the demand drops. EP will take advantage of existing equipment which can be modified to either reduce ramp up or capital requirements on future programs.

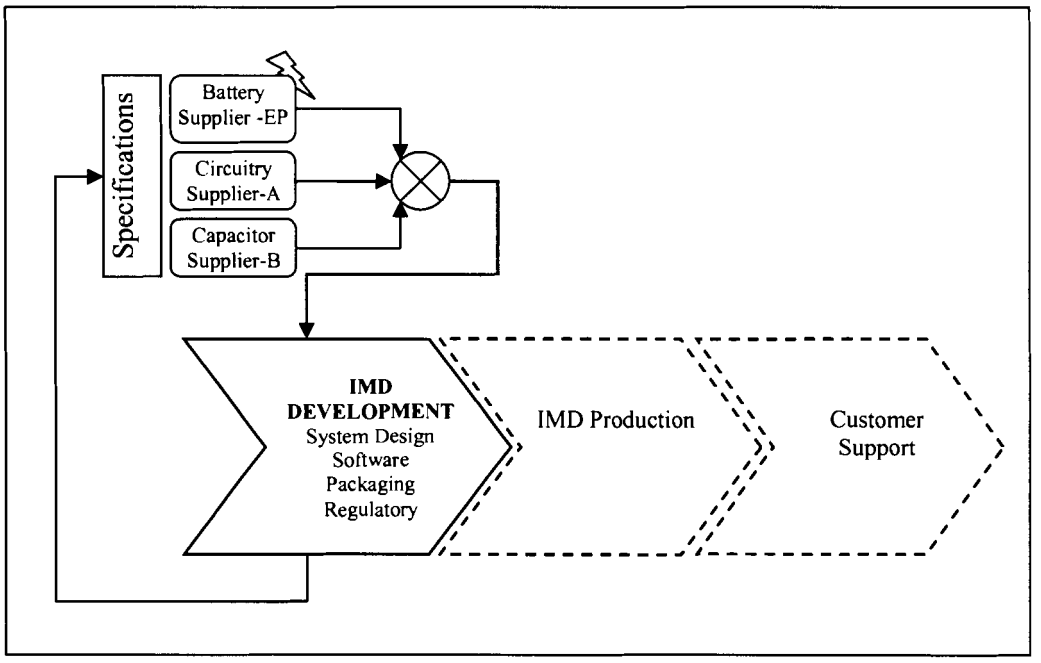
2.2.2 EP in the Implantable Medical Device (IMD) Industry Supply Chain

Rarely does an organization account for the entire supply chain between raw materials and end-user. It is more common to have a network of inter-organizational links and relationships to create a product or service. This section first presents the position of EP within the IMD industry supply chain by providing an illustrated example (**Figure 2.4**). Subsequently, the critical supporting activities that EP provides are depicted by illustrating the information and product channels between EP and the value chain of an IMD manufacturer (**Figure 2.5**). Clearly

identifying the value added by EP and the areas where EP interacts with IMD manufacturers helps to identify the critical areas necessary for successfully supporting the customer.

There are three critical functional components in each IMD. These components are a computer (typically in the form of an integrated circuit and associated electronic system), an energy storage device (typically a capacitor) and a battery. Typically, the IMD developers add value at the system integration and software level of the device. They rely on the expertise of two or more suppliers to co-operatively develop the IC, the battery and the capacitor. The IMD manufacturers manage the integration with a set of comprehensive procurement, performance and testing specifications. The portion of the industry supply represented by these critical three suppliers is shown in **Figure 2.4** below.

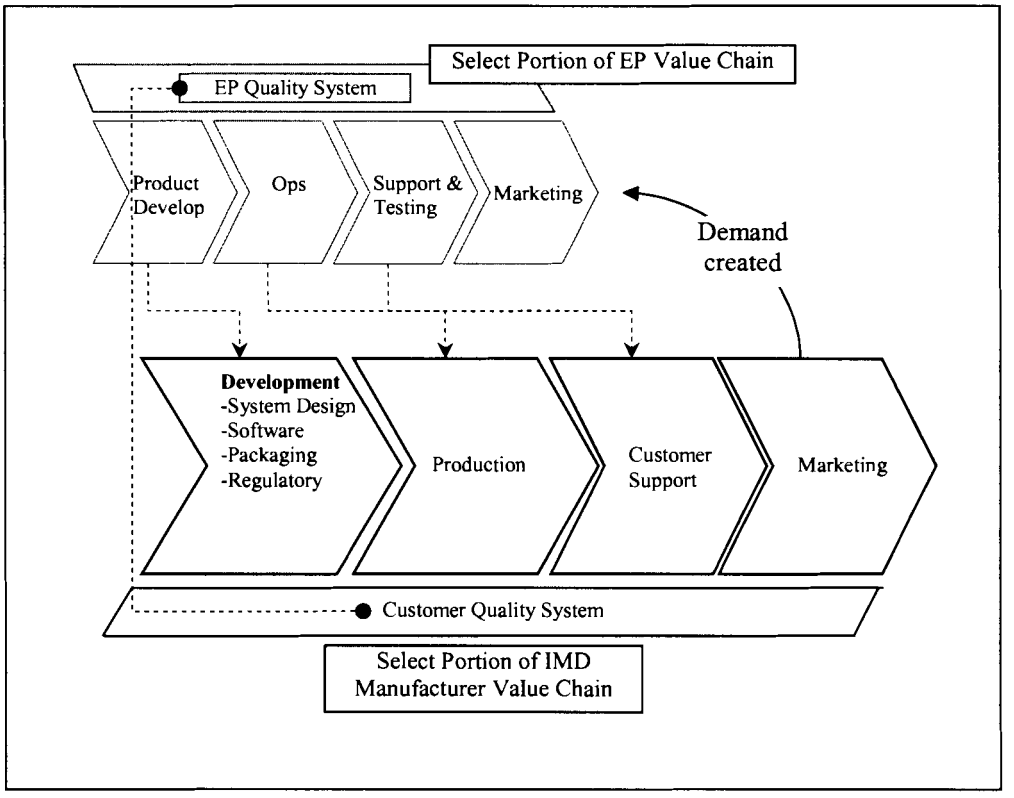
Figure 2.4 Development Portion of the IMD Industry Supply Chain



There are a few components of the IMD supply chain which directly impact EP and the way that EP does business. As indicated in **Figure 2.5**, EP interacts with the IMD manufacturer's

supply chain in a few key areas of their value chains. These areas are product development (which falls under operations), manufacturing, sales and marketing and in a secondary manner through the quality system which is part of firm infrastructure. Each of these areas is examined briefly in this section.

Figure 2.5 Interaction Between EP and IMD Manufacturer Value Chains



Product development is linked closely to the customer based on schedule and performance of the battery. IMD manufacturers rely on both timely deliveries at all phases of the product lifecycle and a battery that meets all performance specifications. The MEP group can therefore support the IMD value chain by having product development capabilities. Current customers consistently provide positive feedback about the open product development philosophy held by EP. Because the IMD manufacturers can see into the development process early, there is

more opportunity to optimize design, share technical assistance and there is less chance for negative surprises at final delivery of cells.

Manufacturing at EP is also an open process with the customer. At times, this has provided challenges in managing image because customers see EP "warts and all'. However, this is also an inherent strength because it reinforces trust and honesty with the customer[1]. Changes in demand can quickly flow to EP and challenges to meet targets are communicated quickly to customers. At this phase customers may also inject additional capital financing to improve EP's production volume capability. This additional capital would otherwise be required from the EP organization which today is a slow if not impossible process. When customers pay for equipment, the increase in productivity can be realized sooner, benefiting customers and the MEP group sooner.

Currently, marketing at EP is limited to face to face visits with IMD manufacturers regarding potential future development contracts. EP relies on IMD manufacturers to create demand for their products which generate demand for batteries that have been specified into their devices. In the IMD marketing model, patients are prescribed or recommended for IMD treatments by doctors and surgeons. The final choice of device is left to the patient, but decisions are based heavily on the specialist's recommendation. This generates demand for devices and ultimately the components that comprise these devices. However, a given device is marketed to physicians and surgeons through traditional medical channels. Surgeons and physicians and insurers are provided with technical information, performance characteristics, features and cost of various medical devices on the market. Based on their professional judgement, a particular device will be recommended.

[1] This open communication is in contrast to a major competitor in the battery market as discussed in **Section 3.4**

EP has a competitive advantage in that the MEP group is certified as ISO 13485 compliant. ISO 13485 is the international standard for the development and manufacture of medical devices. Though this level of quality competence is not a requirement for a supplier to a device manufacturer, it is a strong signal to IMD manufacturers that EP is a careful and competent supplier. The ISO 13485 quality standard compliance will smooth acceptance of products in worldwide markets. The US equivalent for medical device manufacturers is referred to as the cGMP standard (***c***urrent ***G***ood ***M***anufacturing ***P***ractices). This standard is slightly less rigorous than the ISO standard, so compliance with the ISO standard guarantees compliance with cGMP.

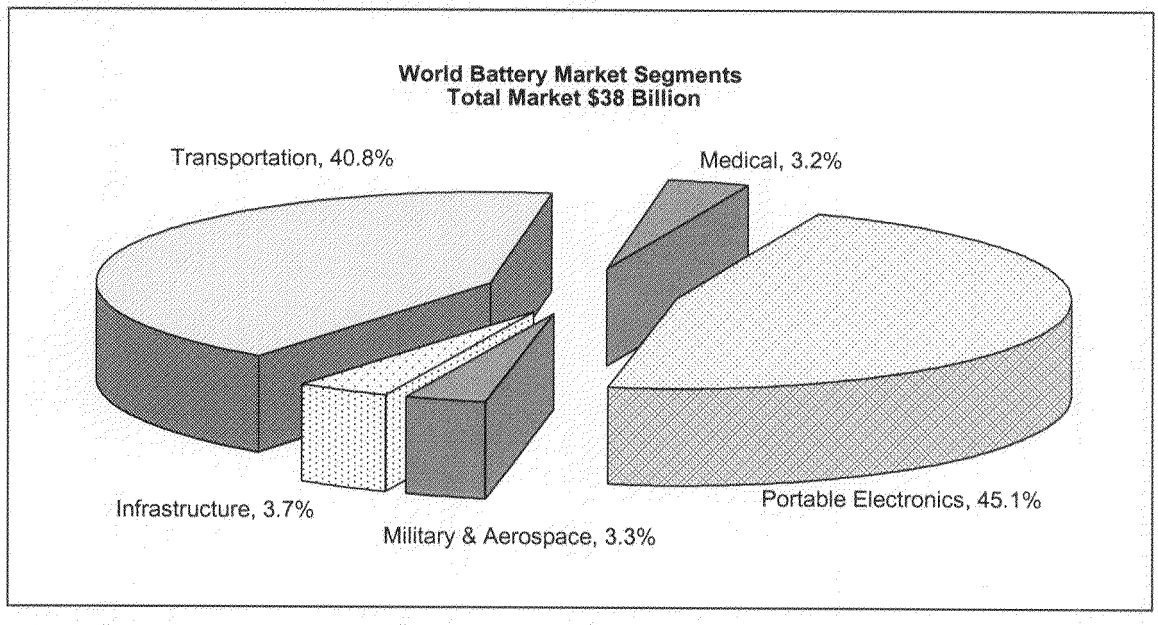
EP has a solid infrastructure for testing energy devices. Each and every part of customer required qualification testing can be done in-house. This speeds up the testing process and results in less overall cost for EP and the customer. EP has a strong calibration, maintenance and destructive testing infrastructure. EP provides reliable, world class testing and reporting capability which directly supports any IMD manufacturer's regulatory approval process.

3 EXTERNAL ANALYSIS

3.1 Global Battery Market

The worldwide battery market is currently estimated to be worth more than $38 Billion (BCG, 2004, p.10). This market can be broadly segmented into portable electronics, transportation, infrastructure, medical and defense and aerospace. As shown in **Figure 3.1**, the medical battery market is relatively small, accounting for only about 3.3% of world battery sales. However, 3.3% of the global battery market amounts to approximately $1.2 Billion worldwide.

Figure 3.1 Worldwide Battery Market by Segment



Source: Peters, Based on BCG Market Study for EP, 2004

Each of these major market segments is served by a number of different battery manufacturers and battery technology. Battery chemistry is the basis for battery technology. The chemistry determines all of the key performance characteristics and it will represent about 50% of

the cost of any given battery. The main global battery market segments are served by batteries built with a variety of chemistries as shown in **Table 3.1**. Beginning with the largest market, portable electronics, it can be seen that Alkaline, Nickel-Metal Hydride (Ni-MH) and Nickel-Cadmium (Ni-Cad) batteries account for more than 80% of the market. In the transportation segment, Lead-Acid batteries are dominant with more than 90% of the world market share. The infrastructure market, which includes primarily includes applications in utilities and buildings, is dominated by lead-acid batteries as well. Lithium primary batteries are not currently used in any applications within these market segments.

Globally, EP has a footprint in each of the major market segments, but the attractiveness of each of these markets varies. In the three largest market segments, transportation, consumer electronics and infrastructure, competition is based almost solely on price. Major market players in these segments are well established in the technologies and have invested heavily in capital equipment for automation or take advantage of less expensive foreign labour. China is also increasingly becoming a world dominating factor in many of these markets (Peters, 2004, p.20). It is becoming increasingly difficult to compete. These markets are relatively mature and there are high barriers to entry in the form of major capital equipment required for high-volume manufacturing. To sum up, the margins are low and the competition is fierce in these portions of the worldwide battery market.

In order to compete within any battery market, an organization must have the foundational knowledge in a given chemistry. The more established chemistries such as lead-acid are well-understood by existing competitors. In order for EP to compete in these markets, significant investment would have to be made in obtaining the knowledge either through R&D or acquisition. On the other hand, EP has developed an expertise in lithium batteries. Leveraging this expertise is the most attractive path to follow.

Table 3.1 Worldwide Battery Chemistry by Market Segment

Market	Approx. Market Size ($USB)	Dominant Battery Chemistries	Approx. % of Market Served by Dominant	% of Market Served by Lithium Primary
Portable Electronics	17.0	Alkaline Ni-MH Ni-Cad Li-Ion Total	58% 12% 12% 18% > 90%	**0%**
Transportation	15.4	Lead-Acid Ni-Cad Total	98% 2% 100%	**0%**
Infrastructure	2.9	Lead-Acid Ni-Cad Ni-MH Total	81% 16% 2% 99%	**0%**
Military & Aerospace	1.2	Lead-Acid Alkaline Ni-Cad Other (weapons) Total	28% 22% 8% 21% 79%	**19%**
Medical	1.2	Lead-Acid Zinc-Air Li-Ion Alkaline Total	17% 43% 6% 5% 71%	**28%**

Source: Peters, Based on BCG Market Study for EP, 2004

By looking at the global market, there are several reasons for EP to examine the medical market more closely and avoid the other markets. First, there are high barriers to entry into the portable electronics and, transportation and infrastructure markets. These barriers include high capital investment requirements and strong established competitors willing to cut prices. In addition, the MEP group does not currently have the technical competence in the incumbent battery chemistry used in these major markets.

EP already has a strong presence in the defense and aerospace market. The penetration of that market is the responsibility of another division within EP Technology SBU. This market is not considered in this work.

The medical market is attractive for several reasons. First, EP has existing expertise in a number of chemistries that cover the medical market needs. Within the global medical battery market, there are established products and customers with few choices to supply specialized batteries. There is strong potential for high margins in a market that supports health care and the demand is typically not cyclical. The market attractiveness will lure competitors, but the barriers to entry are also typically high. In this market, however, high barriers to entry help EP by keeping competitors out. With a committed, established customer base buying products that are being currently implanted, the MEP group is well positioned to leverage strengths and build a profitable business.

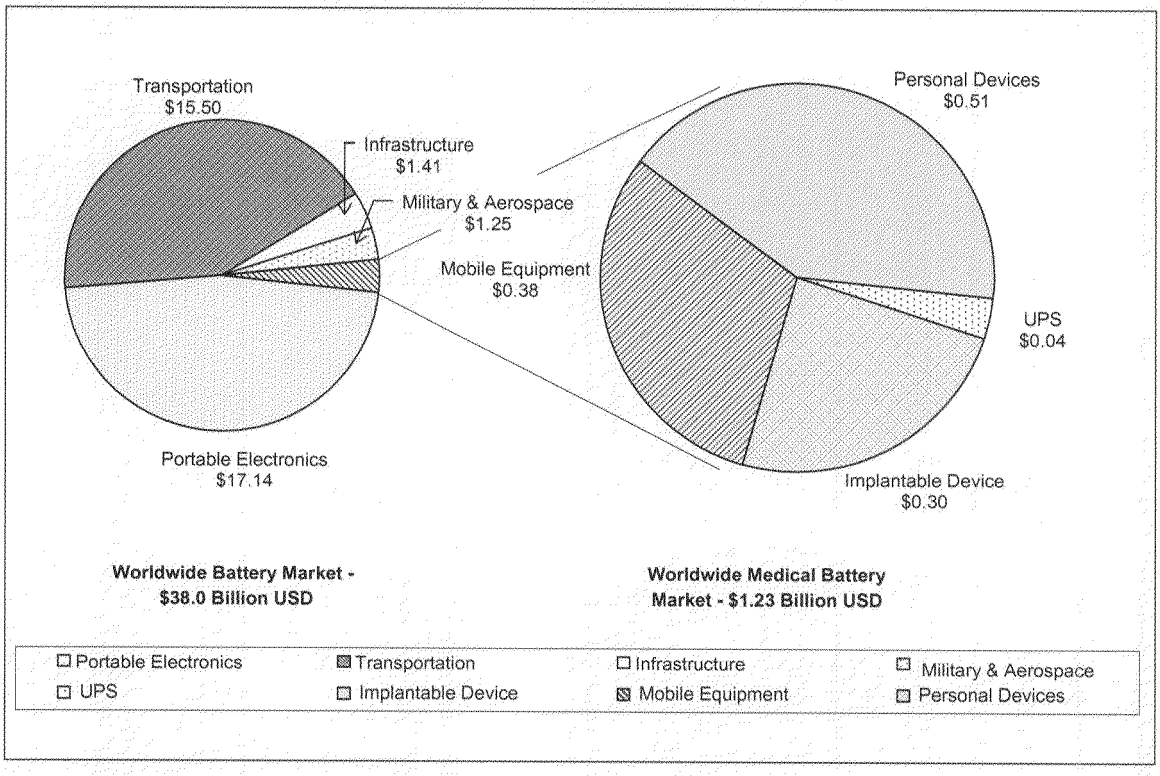
3.2 Medical Market Target Segments

This section looks at the market segments available for EP to target within the medical space, and finds the IMD market to have the greatest potential. The attractiveness of various IMD market sub-segments is examined and a more detailed analysis of the most attractive markets is done.

Market segments are divided by application because OEM requirements differ by final application. Final customers for these market segments have different needs and wants and are typically served by different OEMs. For example, companies like Hewlett Packard have a strong market presence in medical diagnostic equipment but no market presence in implantable devices. There are four primary segments that are considered to be medical market segments: the uninterruptible power supply (UPS) market for critical medical equipment, the mobile medical

equipment market, the personal medical devices market and the implantable medical market. The relative sizes of these markets are presented in **Figure 3.2.**

Figure 3.2 Worldwide Medical Battery Market by Segment ($US Billion)



Source: Peters, Based on BCG Market Study for EP, 2004

3.2.1 Medical Uninterruptible Power Supply (UPS)

This market is defined by the OEM's that supply UPS systems for critical care, measurement, monitoring and facility back up power. Certain critical equipment is built with back-up power supplies that automatically keep the power on in the case of an electrical outage. As the UPS is usually supplied to an OEM and integrated into the equipment, EP would need to sell batteries to UPS suppliers. EP is not well-known by OEM's in this market and the MEP group does not have technical expertise in this chemistry (the dominant battery chemistry for this market is Zinc-air). Alternate chemistries can not be currently manufactured to compete on a price basis against Zinc-air batteries.

3.2.2 Personal Devices

Personal devices are tools that are typically used to aid medical professionals in daily circumstances but are typically not considered critical for patient care. These devices are typically small and portable. This market represents over 50% of the medical market, but the market is well-served by low price commercial type batteries. This market is not examined in further detail here.

3.2.3 Mobile Equipment

Mobile Medical equipment is characterized as a group of equipment that can be used anywhere in a hospital or clinic. This equipment is life saving (such as an automatic external defibrillator - AED), patient mobility (portable I.V. pump) or diagnostic (blood pressure cuffs). The batteries vary by application, but the most popular batteries are lead-acid and zinc-air. Similar to the UPS market, EP is not well known and the MEP group does not have the foundational technical competence.

In the specific case of AEDs, one of the best-suited battery technologies is Lithium Manganese Dioxide (Li-MnO_2) and Lithium Sulphur Dioxide (Li-SO_2). The MEP group does have a solid technical background in these chemistries. When compared to the implantable market this market appears to have a lower potential for good margins, but it does offer the benefit of less stringent regulatory approval. The market deserves further exploration, as there may be opportunities for future sales. However, given the higher potential of the IMD segment, this market is a lower priority.

3.2.4 Implantable Medical Devices (IMDs)

Implantable medical devices can be broadly categorized as active or passive. Passive implants are typically structural devices such as vascular grafts, artificial devices and artificial valves. It is active devices that require power to replace or augment organ function or treat an

associated disease. Power to these devices can either be supplied by an external source or an internal battery that has been integrated into the device.

The single most critical factor for an implantable battery is reliability. Unlike most batteries for consumer products, these batteries cannot be replaced. Devices are hermetically sealed after the battery is hard-wired into the device. Once the battery is wired into the device, it must provide all of the power needs of the device during final testing at the factory, during shelf-storage and throughout the useful life of the device while it is implanted. From a design point of view, the battery is typically the only component with a reliably predictable life. Other components may or may not last longer. It is because the life of a battery is predictable, that it determines the serviceable life of the implant.

The battery is currently required to power the medical device for five to eight years, depending on the application. During this period, there must be minimal voltage drop and no other undesirable effects such as swelling due to internal gas generation. Most likely, by the end of five years, advances in technology would make replacement of the device attractive regardless of the state of the battery. This ultimately has implications on battery pricing because there is no opportunity for a lifelong direct replacement market.

Batteries are also expected to be as small as possible to keep implantable devices as small as possible. In general, the battery occupies approximately 50% of the space in an implantable device. Therefore, specific energy (energy per mass) and energy density (energy per volume) are key considerations for implantable batteries. Each of these measures is driven by the particular chemistry applied to the cell. The energy density is also balanced against other factors such as rate capability, discharge curve characteristics, shelf-life and cost. **Table 3.2** below highlights the both the current and future chemistries that are most appropriate for the applications. A battery developer-manufacturer's ability to provide a portfolio of chemistries will provide a means of

serving a wide variety of application needs and therefore a wide number of customers. As indicated in **Table 3.2** by shading, EP has capabilities covering a number of chemistry combinations and subsequently, EP has the potential to meet requirements across a number of OEM applications.

Table 3.2 Standard chemistry vs. Application in the IMD Market Segment

Application	ICDs CRTs		Pacemakers		Neuro-stimulators		Drug Pumps		Sensors	
	Current	Future	Current	Future	Current	Future	Current	Future	Current	Future
Chemistry										
Li-SVO/CFx	X									
Li-MnO_2	X								X	
Li-CFx/MnO_2		X		X						X
Li-SO_2										
Li-Ion					X					X
Li-CFx									X	
Li-$SOCl_2$					X				X	
Li-I_2			X							
Ultra-capacitors						X		X		
Hybrids						X		X		

Indicates EP competence

X Indicates best-fit battery chemistry for application

Data Source: EP internal analysis

3.2.4.1 Internal Cardioverter Defibrillators (ICDs)

An Internal Cardioverter Defibrillator (ICD) is similar to a pacemaker, in that it is a small, implanted, battery-powered device complete with an integrated computer. It differs from a pacemaker in that it can differentiate between faster, slower or abnormal heart rhythms. It will then deliver an appropriate shock that is appropriate to correct the abnormal rhythm. In order to

treat this kind of problem, a device will have to monitor the heart for a long period of time and then reliably provide a high energy shock (Guidant website, 2005). Therefore, this category of devices requires batteries with high rate capability and excellent storage life.

3.2.4.2 Cardiac Resynchronization Treatment Devices (CRTDs)

This device is similar to the ICD and Pacemaker in construction. However, this category is really the newest of devices and the most complex, typically providing treatment for the widest range of problems. The device computer provides for the widest range of therapy and customization for doctors. It is becoming obvious that these devices will require new battery technology to best suit the needs of the device. Early development work in the battery field shows that like the device, the most promising battery chemistry is hybrid chemistry.

3.2.4.3 Pacemakers

A pacemaker is a small battery-powered device with a tiny computer that continuously monitors the heart. If needed, the device delivers small electrical shocks directly through surgically implanted leads to the heart. The shocks are timed to simulate a natural heart rhythm. Pacemakers are the longest established implantable cardiac device available today. Battery requirements are based on a slow rate of capacity consumption and maximum energy density to ensure device longevity.

3.2.4.4 Drug Pumps

A drug pump is a similar to a neurostimulator because it is used to control chronic pain. Unlike a neurostimulator, a drug pump is an implanted device that delivers a regular measured amount of pain reducing drug to a patient. Because the drug is applied directly to pain areas, smaller doses are required. The drug pump controls the medication dose precisely. It is refilled periodically by means of a sub-cutaneous catheter (Medtronic website, 2005).

3.2.4.5 Sensing Devices

Sensing devices are used to support other major implantable devices. These devices typically require long-life, low pulse current capability. The unique feature of these batteries is the physical size and form-factor. For example, a current product in development is only 3 mm in diameter and under 10 mm long.

3.2.4.6 Neurostimulators

A neurostimulator is a device that fits into a category of treatment that uses site-specific electricity to treat a number of ailments. Typically, neurostimulators or neuromodulators are implantable, battery operated devices connected to the treatment area via electric leads. The electric stimulation can be used to interfere with pain transmission, stimulate muscle contractions or stimulate major nerves. The most common devices today that deliver pulses to the sacral or vagus nerves are also known as spinal cord stimulators. Because the treatment is continuous and requires a relatively low amount of energy at a given time, these applications are well-suited to either lithium-ion cells or low rate capability, high energy density batteries. Typically, these devices are equipped with some type of patient control feature.

It is estimated that in the U.S. alone, approximately 100 million people suffer from chronic pain. Devices already exist for treatment of a variety of pain and other semi-voluntary muscular disorders such as incontinence and gastro paresis. The list of ailments that can be potentially treated is long as can be seen in **Table 3.3** below. With such a wide range of potentially treatable and prevalent illnesses industry experts such as Chris Chavez, CEO of Advanced Neuromodulation Systems (ANS) believes that the market is just starting to open up. It is his opinion that this market is large, underserved and under-penetrated (ANS website, 2005).

Table 3.3 Ailments treatable with Neuromodulation

Ailment	Treatment	Company
Epilepsy and Depression	Electrical pulses are used to stimulate the vagus nerve in the neck to treat these disorders. Device typically chest implanted with leads to the neck	Cyberonics
Bladder Incontinence	Sacral nerve stimulation at the lower spinal cord. Electrical pulse causes bladder to tighten. Typical implant in the abdomen.	Medtronic ANS Boston Scientific (Advanced Bionics)
Chronic Back and Leg Pain	Sacral nerve stimulation as it emerges from lower spinal cord. Electrical pulses override pain impulses. Device is typically implanted in abdomen.	Medtronic ANS Boston Scientific (Advanced Bionics)
Deafness	Cochlear implants used to transmit signals which are interpreted as sounds to the brain from the inner ear. Typically requires additional apparatus on the outside of the ear.	Boston Scientific (Advanced Bionics)
Migraine Headaches	Implanted at the base of the skull. Electrical pulses are directed at the brain's occipital lobe.	Medtronic Boston Scientific (Advanced Bionics)
Post-Stroke Paralysis	Fibrous membrane that surrounds the brain is stimulated in the stroke-affected area. Device typically implanted in the chest with sub-cutaneous leads to the head.	Northstar Neuroscience
Parkinson's Disease	Deep brain stimulation (thalamus) using electrical pulses. Controls tremors. Implanted in the chest near the collar bone with sub-cutaneous leads up the neck to the head.	Medtronic

Data Source: The Body Electric, Michael Amdt, Business Week and Company Websites

The neuro-stimulation is considered to be on the cusp of an historical transition according to Jan D. Wald, a medical device analyst at A.G. Edwards & Sons. Inc. (Arndt, 2005). Doctors, engineers and scientist are leveraging existing pacemaker technology to alleviate symptoms in a very large number of illnesses. The market is expected to be about $1.4 billion in 2005 and it is expected to grow at a compound annual growth rate of about 20% over the next several years (Landy, Susquehanna Financial Group, 2005, p. 6). The main industry growth drivers are

continued technology improvements, expansion of use in new treatments and low penetration rates. The industry includes only four primary participants at this point in time. Though the market is large, the technical barriers to entry, cost, patents and intellectual property all serve to limit new competition at the device level. This means that EP must land the large customers and satisfy their requirements in a reliable manner.

3.3 Porter's Five Forces Analysis of the IMD Battery Industry

This chapter analyzes the implantable medical battery industry as suppliers to the IMD industry. The chapter helps to answer the question about attractiveness of the market based on expected profitability. Porter's model asserts that the attractiveness of an industry depends on five basic forces (Porter, 1979, p. 2). These forces are competitors, customers, suppliers, potential entrants and substitute products.

3.3.1 The Threat of Entry of New Competitors (new entrants) - low

The markets for medical batteries are attractive in a number of ways. The profit margins are high, the demand remains inelastic with price, the markets are growing as a result of technology improvements and demographics and there are few competitors. However, there are barriers to entry into the battery market.

There is significant investment required in specialized infrastructure to handle the key active chemical components of a battery. Batteries are manufactured in large rooms maintained at less than 1% relative humidity, cathode material and cells are baked at various temperatures under vacuum, testing requires specialized equipment. All of this equipment requires capital outlay of approximately $4 to $5 million. Quality systems investment must match the world-class expectations of the medical device industry.

Investment is also required in the chemistry. Though the basics of battery chemistry have been well understood for many years, the foundational level of understanding required to successfully develop and manufacture a battery requires experience. Expertise with multiple chemistries requires more investment. On average, each development program requires a team of three specialized technical personnel. In addition, there are experts from which experience with specific chemistry can be drawn.

Customer ties are strong once they are made. Medical devices are highly reliable and a great deal of trust is built when developing a battery. Extensive testing and documentation aids in the process of building trust. Once batteries are specified into a product there is a lock in to the product because of strict FDA requirements.

The largest competitor in the medical battery market has an aggressive intellectual property (IP) policy. There is the risk of new market entrants facing legal challenges. A possible entry strategy could be executed through the acquisition of an existing business. Overall, the threat of new entrants is real, but it would require significant investment. Thus, the threat of new entrants to the IMD battery industry is seen as low.

3.3.2 The Threat of Substitutes - low

There is no high energy, self contained, power source for implantable devices on the horizon. One of the most challenging issues with implantable devices is the need for implantable power. This is driven directly by OEM's who are responding to end-user needs for portability, convenience and safety. It is always difficult to replenish energy in any power source that requires fuel, such as a fuel cell.

The industry has moved toward lithium battery technology because the energy density is much higher than conventional battery technology. It is also well known for excellent shelf life.

There is some early stage research work in the area of bio-fuel cells and fuel cells that run on enzymes within the body. These technologies seem to be a good fit with medical implantable technology. However, the commercialization of these products is estimated at greater than ten years.

The industry trend today is toward re-chargeable batteries (Soykan, 2002, p.78). This is not a significant threat to a developer or manufacturer with re-chargeable (lithium-ion) battery technology available in the portfolio. Overall, the threat of substitutes for batteries in IMDs is low.

3.3.3 The Bargaining Power of Buyers – high / medium

Buyers of batteries for medical implantable devices can be placed a single category. Each and every buyer is an original equipment manufacturer (OEM). OEMs can be divided broadly into two categories. There are large, established OEM's with several existing products and there are start-up or new venture companies. There is some difference in bargaining power between larger and smaller players.

3.3.3.1 Large Established Original Equipment Manufacturers (OEMs) - high

There are three well established OEMs in the IMD market. Each of these organizations measures revenues in the billions as seen in the **Table 3.4** below. These organizations have skilled supply chain managers and a well-established supplier network. They demand quality products and timely delivery. The bargaining power of these suppliers is high.

Table 3.4 Largest IMD suppliers in the World

	No. of implantable Products	Revenue 2003 (millions)	Revenue 2004 (millions)	% Revenue from implantable
Medtronic	35+	$7,665	$9,087	>50%
St. Jude Medical	30+	$1,872	$2,294	>55%
Guidant*	35+	$3,699	$3,766	>55%

Data Source: Company web-sites

3.3.3.2 Start-ups and Other Device Manufacturers - medium

The number of start-ups and medium size ($50 - $100 million in sales) is small. When these companies develop or launch a new product, they are often bought by the large companies in the industry. These companies can be more flexible with delivery time in exchange for lower prices. However, these organizations do not promise the high volume of sales expected from large OEMs. There are also few choices for these organizations when selecting a battery supplier so the overall bargaining power is considered low.

3.3.4 The Bargaining Power of Suppliers – low to medium

The critical components of a battery can be divided into two primary categories; namely, active components and battery hardware. Each of these categories requires relationships with at least two suppliers. Other suppliers include those who provide specialized services and personnel employed in the industry. Each of the supplier categories is examined and the overall bargaining power is seen as low to medium.

3.3.4.1 Active Components – medium

The critical active components in any primary lithium based battery are metallic lithium, cathode material and electrolyte. Lithium ion cells differ in that they do not require metallic lithium but a high lithium concentration electrolyte. These materials are supplied by three different suppliers for each specific battery. In each case there are only two reliable sources for

these specialized materials. Each of these suppliers has moderate power in the bargaining process because there are limited alternatives. In additions, there are switching costs associated with changing suppliers once a product is being manufactured. Quality standards require very strict control of any changes made to processes which can ultimately affect a patient in a device. The number of suppliers of two of the key components is very low. There are only two reliable sources of raw lithium in the U.S. and there is only one supplier of porous ion-transfer membrane. These suppliers have more leverage against a company like EP. Overall, the bargaining power is seen as medium.

3.3.4.2 Hardware - low

IMD battery hardware consists of a can, cap and a feed-through. There are several suppliers in each of these categories. They are in direct competition with each other and provide similar levels of service and quality. In addition to direct competition with each other, there are a limited number of battery manufacturers that can be supplied. The largest competitor in the medical battery market (Greatbatch) has chosen to vertically integrate these capabilities by purchasing companies with expertise in these areas. This has reduced the number of potential customers and further lowered the bargaining power of these companies. The evidence of the low bargaining power can be seen in a 1 year downward price negotiation resulting in 2.4 million dollar savings for EP across the business. The MEP group also benefits from leverage that can be placed on suppliers by purchasers representing the higher volume military products.

3.3.4.3 Other Suppliers - low

Other suppliers provide standard materials for items such as packaging and consumable materials. These suppliers have a wide base of customers in a variety of industries and as such have moderate power. However, they do not affect the ability of EP to do business because there are substitute suppliers and switching costs are negligible.

3.3.4.4 Technical Workers and Labour – low

In the battery industry, technical workers and labourers include engineers, chemists, manufacturing, assembly and technologists. Batteries are unique in that they do not fit into a pure engineering or science category. Development is shared between chemical and mechanical designers. As a result, there are very few true battery designers, developers or engineers. Someone with specific experience in battery design, development or testing has relatively high bargaining power. Alternately, the battery industry can typically offer lower wages to those willing to learn the technology from other industries that may or may not be related. It is rare that a particular program will fail without the right person. The overall rating is considered low.

3.3.5 The Degree of Rivalry Between Existing Competitors - medium

This market can be loosely defined as an oligopoly with two large industry players. The two largest battery suppliers are Greatbatch and Medtronic. Medtronic is an IMD manufacturer that has vertically integrated battery supply. Greatbatch is therefore, the largest independent battery supplier in the market. Because Medtronic does not supply batteries to its competitors, there is very little choice for remaining device developers. Greatbatch has taken advantage of this situation for the past several years to earn excellent profits. Currently, EP is not seen as a threat because there is not a balance of power in the battery supplier space. As a result, Greatbatch has not made overt moves to compete with EP. Until Greatbatch sees EP as a significant threat to profitability, the degree of rivalry is seen as medium.

3.3.6 Summary of Five Forces for the IMD Battery Industry

The five forces analysis shows that overall the attractiveness of the market is high. The bargaining power of the suppliers is low to medium as is the competitive rivalry. The barriers to entry, which are based on technical expertise and capital requirements, discourage new entrants. The threat of substitutes is low, securing opportunity with existing technology. The bargaining

power of supplier can be high depending on the supplier. However, this potentially negative force, can be overcome once the customer specifies a battery into a product.

EP must be careful with Greatbatch. EP does not want to create the illusion of the balance of power and face the fierce rivalry of an arguably stronger competitor. EP has already seen one example of a proposal where Greatbatch sold the contract as a loss leader in a seemingly strategic move indicating a willingness to compete on price. Competition on price would put EP at a disadvantage in the current environment because of cash is not available to cover short term losses.

Because of the high cost of development and patient and doctor familiarity, many devices are multi-generational. A product line will remain within a market. Next generation devices will leverage existing learning to create an improved model with the same basic design. Typically, next generation devices will also rely on existing suppliers that have been specified into existing models. This may provide an advantage for EP once a battery has been specified into a first generation product

Bargaining power of suppliers – OEMs support competition in their suppliers. This is for security of supply and cost reasons. There is also a strong thread of responsibility to the end user which includes developing suppliers to provide the best quality product. OEMs are motivated to improve all parties involved in the product, including suppliers. This has benefited EP as OEMs seek partners and are willing to invest in their suppliers to ultimately develop a better product for the end user.

3.4 Three key Competitors in the IMD Battery Market

This section looks at existing competitors within the IMD battery market. A brief descriptive summary is provided for each of the three major competitors in **Table 3.5**. The

strengths, weaknesses and competitive strategy are evaluated. Where applicable, the basis of competition is examined.

Table 3.5 Major IMD Battery Suppliers

Competitor	Headquarters	Primary Market	Secondary Market	Projected Revenue Medical Batteries (2003)	Projected Revenue Medical Batteries (2004)	Estimated Market Share Excluding Medtronic
Greatbatch	Clarence, NY	Medical Batteries	Capacitors, IMD components	$135M	$155M	90%
Medtronic	Minneapolis, MN	Medical Devices	Medical Equipment	Linked to device revenue -est. value $73M	Linked to device revenue -est. value $90M	All of its own devices
Quallion	Sylmar, CA	Lithium Ion Implantable	None	Unknown (private)	Unknown (private)	<3%

Source: Company annual reports, websites

The market segments within the IMD space that each of these competitors covers is shown in **Table 3.6** below. There are no competitors that serve all markets with all future and current battery chemistries. Greatbatch, for example, has a large share of the CRT and ICD battery market, but does not currently have expertise in Li-MnO_2 chemistry, which is expected to meet the future needs of the ICD market.

Table 3.6 IMD Market Segments Covered by Competitors

Competitor	Technical Expertise Battery Chemistry	Markets Served
Greatbatch	Li-SVO Li-SVO/CF_x Li-ion Li-I_2 Li-CF_x	CRT/ICD, Neurostimulators, Drug Pumps
Medtronic	Li-I_2 Li-CF_x Li-SVO	CRT/ICD, Drug Pumps, Neurostimulators
Quallion	Li-Ion	Sensors, Neurostimulators

Source: Company annual reports, websites

Today, the IMD market is not served by a large number of competitors. This is likely due to the liability associated with developing components for implantable devices, technical expertise in chemistry best-suited for IMDs and the fact that OEMs demand incremental product development on each product. The relatively small number of batteries required for implantable devices also prevents large worldwide battery companies from entering the market. The development effort does not seem worthwhile and the price model is vastly different. For example, companies that serve large commercial markets supply on average approximately 100 thousand times the volume in batteries than the IMD market requires.

3.4.1 Greatbatch – A Large, Established Competitor

Greatbatch Technologies is considered the world leading independent developer and manufacturer of batteries, capacitors and other components used in medical implantable devices. The company has several divisions that support a number of other business segments that include commercial products, aerospace and defense. Greatbatch is examined in detail here because it is the largest direct competitor to the EP MEP group.

Originally called Wilson Greatbatch limited, after pacemaker pioneer Mr. Wilson Greatbatch, Greatbatch is a company that has existed for about 30 years. The organization grew

out of a need for superior power sources for early IMDs. Through a series of successful medical energy component products and aggressive acquisition, Greatbatch has grown to become a company serving all of the largest IMD companies with over $200 million in annual sales. Within the implantable medical device market Greatbatch has 2004 revenues of over $100 million.

Greatbatch has over 1200 employees and operates 12 facilities across the US and Mexico with a head office in Clarence, New York. This company's chemistry strength is in Li-SVO (Lithium-Silver-Vanadium-Oxide). Greatbatch has also gained technical competence in approximately 80% of all non-circuitry components for IMDs. This allows them to offer a broader customer solution rather than just a battery.

The primary strategy of Greatbatch is based on building competence in as many IMD components as possible, aggressively pursuing intellectual property protection and seeking to reduce overhead and labour costs by consolidating operations and relocating certain operations outside of the United States. Ironically, it seems that the aggressive pursuit to provide a total customer solution can be seen as encroachment on OEM flexibility. Anecdotal evidence from one OEM suggests that Greatbatch is limiting customer choices rather than improving service levels. In addition, Greatbatch has a tendency to take advantage of its customer's sunk costs by holding up delivery for greater profits. The consolidation of operations has recently taken place in the form closed facilities in the U.S. moving operations to another plant just inside Mexico.

From a business model view, Greatbatch is willing to sell development programs as loss leaders to OEMs with the intention of recovering development costs in the pilot and production stages of the lifecycle. Greatbatch investment in R&D about $17M per year based on the last two fiscal years (Greatbatch form 10-K, 2004, p. 36). The current active patent portfolio numbers greater than 246 in the US and over 129 patents pending (Greatbatch form 10-K, 2004, p. 7). In the past three years, Greatbatch has been awarded 113 patents. Recent acquisitions have been

used to support the "customer solution" objective of the strategy. As seen below in **Table 3.7**, acquisitions have accelerated in the last 8 years and each acquisition has added new technical capability to the organization. The acquisition of Battery Engineering in 2000 added competition to the EP Commercial Power Division.

Anecdotal evidence from EP customers suggests that Greatbatch unresponsive and closed at all phases of a battery development program. This unresponsive and closed mode of operation is a source of frustration to OEMs. In the context of the industry supply chain, this closed attitude robs the OEMs of value-added opportunities at more than one part of the development cycle.

Table 3.7 Acquisitions by Greatbatch Corporation

Acquisition Date	Acquired Co.	Description
August 1998	Hittman Materials	Founded 1962, design & manufacture of ceramic feed throughs and coatings for electrodes
August 2000	Battery Engineering Inc	Founded 1983, design & manufacture of high energy density batteries for industrial, commercial, military and aerospace
June 2001	Sierra-KD Components	Founded 1986, design & manufacture of ceramic capacitors for IMDs
July 2002	Globe Tool & Manufacture	Founded 1955, design & manufacture of precision enclosures for IMDs, commercial, electronic & aerospace sectors
March 2004	Nanogram Devices	Founded 1996, nano-material synthesis for materials used in IMDs and batteries

Source: Greatbatch website

3.4.2 Quallion

Quallion was founded in 1998 as a spin-off from the Alfred E. Mann Foundation (AEMF), a non-profit research organization. Its primary vision is developing and manufacturing

power sources for implantable devices (Quallion website, 2005). Like the EP MEP group, Quallion has expertise in the basic requirements for battery development and production and a facility in which to carry out this work. Today, the company is focused solely on Li-ion technology and it supplies only one significant customer. This customer, Advanced Bionics, was likewise spun out of the AEMF, a few years earlier. Advanced Bionics had difficulty finding a battery supplier willing to undertake a development project with the promise of such low production volume. This search led to the creation of Quallion from the AEMF. Quallion also offers product development services and a partnership arrangement with potential OEMs. The company strategy is not clear, but it appears that Quallion relies heavily upon business from industry ties to Advanced Bionics and the U.S. government in the form of research funding. To date, Quallion has no other known customers in the IMD market.

3.4.3 Medtronic – Vertical Model

Medtronic has years of experience with the development and manufacture of batteries. All of its products utilize batteries that have been internally developed with the exception of one cell. This cell is produced by EP in Joplin. In addition, Medtronic is unique among all of the largest three IMD manufacturers in that it has established experience in battery development and manufacture. The stated reason for this strategy is based on a foundational belief in its employees being the source of value. Though Medtronic has the capability, it is unlikely that it would sell batteries to any competitors in the IMD market. However, because the organization has competence in this area, it can preclude the MEP group from selling batteries to Medtronic.

Medtronic has a history of acquisition of complementary technology. This may impact the MEP group as acquired OEMs in the IMD market have future power sources developed internally by Medtronic. Conversely, the internal battery development capability may need to be supplemented as the acquisition of new devices increases demand for batteries.

3.4.4 Other IMD manufacturers – Vertical Model

Other IMD manufacturers may begin to consider a similar battery supply model to Medtronic. These IMD manufacturers may be frustrated by hold up from companies like Greatbatch or they may be frustrated by a lack of control of the quality and schedule of battery delivery. EP marketing intelligence has anecdotal evidence that at least one of the major three IMD manufacturers in the U.S. is starting an internal battery development program.

3.5 IMD Industry Dynamics

This section examines the medical device market in the context of the larger medical industry. The analysis examines the features of the IMD industry in order to best understand how demand for medical batteries is affected. Industry risks, replacement, overall structure, market growth, technology adoption and differences between European and US markets are all considered as part of the analysis. A PEST analysis is used to look at each of the major external forces that affect the medical device market and subsequently the battery market for these devices.

European markets differ slightly from US markets. The typical model for marketing and selling devices in Europe utilizes established local offices or partners. European offices typically offer front line technical support, sales and marketing functions. In the US, all functions are controlled from the organizations headquarters.

Medical device firms are typically faced with three alternatives for regulatory approval. A firm may seek approval in either the US or European market first followed by the other sequentially or it may seek parallel approval. Parallel approval requires more of the firm's internal resources, but promises quicker access to both markets. Devices may be introduced into Europe prior to the US because of a quicker regulatory approval process.

There is no replacement market for batteries used in IMDs. They are hard-wired into the devices and implanted with no expectation for component replacement. Instead, patients are scheduled for device replacement after approximately five years. After five years, the battery will need replacement. Because the replacement of a battery requires surgery, the current philosophy adhered to by most surgeons is to replace the device either after the battery power is low or after five years whichever is more conservative. The battery is typically the life-determining component of an IMD.

3.5.1 PEST Analysis for IMDs

The PEST Analysis is a framework used to scan the external macro-environment in which an organization operates. PEST is an acronym which represents the political, economic, social and technological factors, respectively, in the macro-environments. Each of these factors is examined in this section to understand the uncontrollable forces which impact the IMD market. It is evident that there are several factors which positively affect sales and growth for IMDs and therefore the sales of medical implantable batteries.

3.5.1.1 Political Factors Affecting the IMD Market

Health care and health care products and health care related policy are often featured in the major political news coverage. From stem cell research to hospital closures, the public is closely linked to health care. The FDA in the US is overwhelmed with applications for new approvals and has recently instituted a fast track policy for drugs and care products that may impact great numbers of people.

The regulatory agencies often play a role in the timing of market introduction. Introduction time for IMDs may vary by as much as a year. However, the US FDA is inclined to grant quicker approval to those companies with a proven track record who introduce similar products. This system will tend to favour established players, such as Medtronic, over new

medical device manufacturers. The approval process in the European Union is typically smoother and faster. This is a result of more resources within the agency and less stringent liability laws. This is a result of both better preparation by applicants and a comfort with known entities and individuals.

The neurostimulator market is expected to benefit from increased political awareness of pain therapy. George Bush was noted as mentioning that this decade will be known as a decade of pain control (ANS Website, 2005). The increased political awareness of the pain control market will smooth product introduction and subsequently increase opportunities.

3.5.1.2 Economic Factors Affecting the IMD Market

Record profits earned by large IMD companies have resulted in an excess of cash. This cash is primarily being invested in new technology in the form of acquisitions. Medical device companies also invest heavily in capital assets to improve reliability and productivity. Companies such as EP can also benefit from the extra cash generated by large OEMs such as Guidant. There is a willingness on the part of large device manufacturers to invest in key suppliers to improve supplier capability.

In addition to good cash flows, the medical industry tends to be insulated from economic cycles. This is a result of the relative inelastic demand for health care products. There is little drop in the demand for life-saving medical treatments no matter how high the cost. In the US, the elective nature of many procedures further amplifies this phenomenon as those who can afford more will pay more for quicker treatment.

3.5.1.3 Social Factors and the IMD market

There is an increasing percentage of the population in the age range for treatment with IMDs. This demographic shift in North America is a result of the baby boom that followed World

War II. The baby boom generation is increasingly entering into the ages where heart problems and pain are more prevalent. As more of the population enters its' senior years, the demand for medical procedures increases. Younger members of the population are not exempt from health problems. Obesity in North America is also reaching epidemic proportions. Obesity leads to heart problems and other ailments that can be treated with various IMDs. The increased demand for medical devices will translate directly into demand for more batteries.

3.5.1.4 Technological Factors and the IMD Market

The medical device industry is a unique evolution of the electronics industry and advances in biological science. Electronics can be packaged smaller and more reliably each day. As mentioned, it is assumed that technology will make each new product obsolete before the battery fails (Soykan, 2002, p. 76). Devices that were the size of a portable cassette player just ten years ago are now the size of a large cookie and packed with more features. As the devices get smaller and material science improves the devices become more comfortable and less costly for patients and the application range broadens.

The big three medical device companies spent over $1.6 billion on research and development last year alone (Annual reports, 2004). As medical device organizations grow and devices become more complex, these companies begin to examine the value chain and consider outsourcing of components. This is done to allow the organization to focus on key technology and high margin activities while reducing risk by adding alternate sources of supply.

3.6 Summary of External Analysis of Global IMD Industry

The external analysis shows that the global market for batteries is over $38 billion dollars and the medical market accounts for only about $1.23 billion of that. The IMD market is appears to offer high margins and it is best suited to chemistries supplied by the MEP group. Porter's five forces analysis showed medium to low competitive forces. The competition consists of three

suppliers, Greatbatch, Medtronic and Quallion. The PEST analysis shows that there are additional external influences that should accelerate the growth of the IMD market and therefore the market for implantable medical batteries.

4 INTERNAL CHARACTERISTICS –MEP GROUP

This chapter examines the MEP group within the greater EP organization with the intention of identifying sources of sustainable competitive advantage. The chapter begins by looking at the resources available to the medical battery group versus the resources available to the largest competitor. The MEP value chain is examined as is the current financial position of the MEP group. It is found that the MEP group has a strong technical foundation, but it suffers from a lack of capital.

4.1 Resources Available Within the Greater Organization of EP

This section looks at the available resources, capabilities and assets within the organization that are at the disposal of the MEP Group. The analysis follows the framework for strategic analysis by looking at available financial resources, physical assets, human resources, intangible assets, technological assets and long term contracts (Boardman et al,, 2004, p 16). The analysis will be done in the context of the greater organization and measured against the largest competitor in the Medical Battery market, Greatbatch. A list of the key resources required for success in the battery industry is presented in **Table 4.1**. The most important differences are discussed briefly here to help understand either areas of advantage of areas of weakness.

Table 4.1 Comparison of Key Resource EP vs Greatbatch

	GB	MEP group	Comment
Criteria: Exceptional, Strong, Satisfactory, Weak			
Financial Resources			
▪ Access to Capital $$	Exceptional	Weak	Parent (EP) has filed for chapter 11 protection
▪ Cash Flow	Exceptional	Weak	MEP group, lumpy cash flow, limited control of cash, all cash used
▪ Revenue	Exceptional	Satisfactory	MEP revenues growing, but still too small to support business growth
Physical Assets			
▪ Dry room space	Exceptional	Satisfactory	GB has a new facility. MEP has sufficient space for all programs today. MEP has little room to grow
▪ Development space	Exceptional	Satisfactory	GB has multiple facilities, MEP sufficient space for today
▪ Manufacturing space	Exceptional	Satisfactory	GB has new facility in Mexico. MEP has sufficient space, but running out of room
Logistics	Strong	Strong	
Supply chain	Strong	Weak	MEP suffers from shared supply chain resources (lack of attention)
IP	Exceptional	Weak	MEP has very few patents
HR			
▪ Marketing Team	Exceptional	Weak	MEP marketing resources limited to one individual
▪ Development Team	Exceptional	Strong	
▪ Benefits & Pay	Exceptional	Satisfactory	MEP compensation is not competitive

Data Source: Company web-sites

Referring to **Table 4.1**, it is clear that the MEP group does not meet the standard of the industry benchmark organization – Greatbatch. The most salient shortcomings are centred on the finance aspects of the business. The MEP group is suffering from access to capital. Each of the worst categories could be fixed immediately with access to capital. Greatbatch has invested heavily in facilities, infrastructure, staff and intellectual property. The deliberate corporate policy regarding the use of cash combined with the lack of funding available from a bankrupt parent is hampering the ability of the MEP group to grow faster.

4.2 Value Chain Analysis

This section evaluates EP's internal value chain. The value chain is best described as the combination of activities within and around an organization that create a product or service. It is used to assess the potential for competitive advantage and alternately, to assess the areas in which the business may be at a disadvantage. The analysis begins by breaking down the organization and its market into key activities that are divided into the major categories according to a Porter Value Chain (Grant, 1998). The analysis begins by dividing the internal organization into two categories defined as primary and secondary. The potential to add value is then assessed based on either cost advantage or differentiation. The final portion of the analysis determines a strategy that focuses on competitive advantage and a means of sustaining the competitive advantage

4.2.1 Primary Value Chain Activities

Primary activities can be defined as those activities that directly contribute to the creation or delivery of a product. These activities can be broadly categorized as inbound logistics, operations, outbound logistics, marketing and sales and finally, service. For the EP MEP group, the operations portion of the primary activities stands out as the most important part of the value chain. Each of the categories is discussed briefly in this section.

4.2.1.1 Inbound and Outbound logistics

Though inbound and outbound logistics can be a source of competitive advantage for some firms, it is not an area that provides an advantage for EP. The materials handling group is unique because the MEP group shares a facility with a portion of the defense and space group. Activities such as shipping, receiving and inventory control are shared, but there is a distinct line drawn between the medical and defense group in the materials storage and customer interaction. In general, the MEP group requires stricter control on materials because components will eventually be implanted and may have an ultimate impact on patient life. There are additional

shared activities in the materials handling for managing specialty components such as gases, metallic lithium and lab chemicals as well as waste disposal. Most shipping and receiving relies on established transportation experts such as Fedex, UPS and trucking companies. In the case of the MEP group, shipment volumes do not warrant any additional outbound logistics other than established commercial rapid transport. Though there are some unique features in the inbound and outbound logistics, there is nothing that can be leveraged for any kind of advantage.

4.2.1.2 Operations

Product Development is a critical part of medical battery supply to OEM's. Implantable Medical Devices are complex and they must be reliable. The batteries must also be reliable and integrated into the system for optimum life and performance. As previously mentioned the battery is considered one of three critical components in a medical device. The development of a custom battery is therefore, inextricably linked to the development of a device. This close link to OEM development is not all that different from supplier-OEM relationships in consumer electronics where a particular chip, for example, is specified into a particular product or product platform. The product development cycle for a battery will typically range from about 1 year to 2 years including all required design, prototypes, pilot runs, testing and qualification for device implants. It is common for any battery supplier to have some product development capability.

Though EP has quickly developed relationships with several high profile customers, the MEP group still lacks experience in one key area. There is a group of talented, dedicated, creative and loyal product development engineers and scientists, but there is a lack of experience transitioning a product from development to production. Only two products are currently in a production phase. Infrastructure is being added in the form of a disciplined transition process, but there is still little experience in this area. The problem is exacerbated by a lack of strong manufacturing expertise in the geographic area. Salary policy has also hurt the recruiting process.

There is talent and expertise available outside of Vancouver, but the EP salary range does not compete with similar industries in the U.S. or central Canada.

Manufacturing in the MEP group can be categorized as low-volume, batch processing. Typical peak volumes may only be 1000 – 2000 batteries per month. These volumes may vary from a trickle of a few hundred per month to a surge of more than 2000 per month. The battery as a product does have the unique feature of excellent shelf life. It is not uncommon to guarantee a six month shelf life prior to implant and a further five year following implant. This allows for some smoothing of the production within EP. The most unique feature of the MEP group product lines is the semi-skilled assembly team. Because the volumes remain low even at peak demand, there is rarely financial justification for significant automation of the assembly process. As such, the production of cells relies upon semi-skilled assembly technicians. Though every effort is made to document each and every process and variable, there is a lot of tacit knowledge shared among the assembly teams. The strength of the experience of the assembly teams is an asset that is not easily duplicated and it is leveraged by recycling senior members of teams into new product development.

As a result of poor corporate cash flow, the MEP group is expected to remain cash flow positive at all times. This forces the management to constantly balance the purchase of capital equipment with bringing in revenue from existing customers. This is a difficult strategy to manage because there is a risk that customers may become dissatisfied at a lack of capability due to a lack of funding.

4.2.1.3 Marketing and Sales – Informing buyers about products and services

Marketing and sales are a weakness in the MEP group. There is no marketing communications material available and there is no effort to build presence by attending trade shows or conferences. It is also difficult to find contact information for the MEP group on the

corporate web site. Instead marketing has been done by calling on selected individuals in organizations via existing customers. All of the sales and sales contracts are handled locally by one individual.

Marketing has been considered a low priority until recently. Marketing is being managed at one level higher than the majority of the organization with a single individual reporting directly to the vice president of commercial power. Marketing activities are based on developing relationships with existing and potential customers. Greatbatch, on the other hand, had a large sales and marketing staff until recently when 5 out of 9 of the staff were released (Greatbatch website, 2005). It seems that Greatbatch has relationships with all of the biggest customers and a self-proclaimed 90% of independent battery market share.

EP does not have any unique advantage in the sales and marketing area. Arguably, marketing horsepower only has a limited return because there are relatively few industry players and once a supplier is known there is little value in communicating marketing information. Perhaps there is value in creating demand by marketing to end-users - like the Intel marketing campaign - who could demand our particular product thus influencing OEM choice of battery supplier. Duracell is also using a similar strategy in a subtle manner by asking end-users of medical equipment to demand their brand.

4.2.1.4 Service

There is no formal customer service organization within MEP and there is no central database to manage customer relationships. There is also conflict and duplication of effort between Vancouver and Phoenix offices in the area of customer service and customer relationship management. The MEP group has access to a good group of technical experts who can help with after sales technical support and testing.

4.2.2 Secondary Activities for the MEP Group

Support activities include procurement, human resource management, technology development and firm infrastructure. These activities, by definition, are used to leverage and make the primary activities more effective. This section surveys the basic supporting activities within the greater EP organization the both help and hinder the MEP group. The most salient feature of the secondary activities to be noted is the shared facilities. As mentioned in **Section 2.1** (see also **Figure 2.2**) the MEP group shares facilities and supporting activities with the Defense and Space group in Vancouver as indicated in the diagram. This shared facility is both a boon and a bane to the MEP group as discovered by the analysis.

4.2.2.1 Procurement and Human Resources

Procurement and HR are shared supporting functions between the Defense and Space group located in Vancouver and the MEP group. Neither procurement nor HR offers a significant advantage to the MEP group. As mentioned earlier, one of the disadvantages that the MEP group has is an inability to attract talented staff from other geographic areas because of compensation inequality. The current human resources policies are tightly controlled locally in the shared Vancouver facility. Though the procurement function aids the group by using established forms, procedures, billing and invoicing, the supply chain group can hinder progress in the MEP group. This is simply a function of the difference in revenue generated by the MEP group versus the Defense and Space group. The revenues for 2005 are expected to be approximately 6 to 7 times greater for the Defense and Space group. This inequality in revenue immediately places all MEP procurement activities that impinge on defence activities into second place.

4.2.2.2 Product Development

There is a research function within the Vancouver facility. Chemistry capability is wider than any of the competition and it continues to grow. The senior staff members have an average

experience level of greater than ten years in battery technology and an average work experience level of greater than fifteen years. The group has developed more than ten different products in ten years and consistently delivers reliable products.

4.2.2.3 Infrastructure

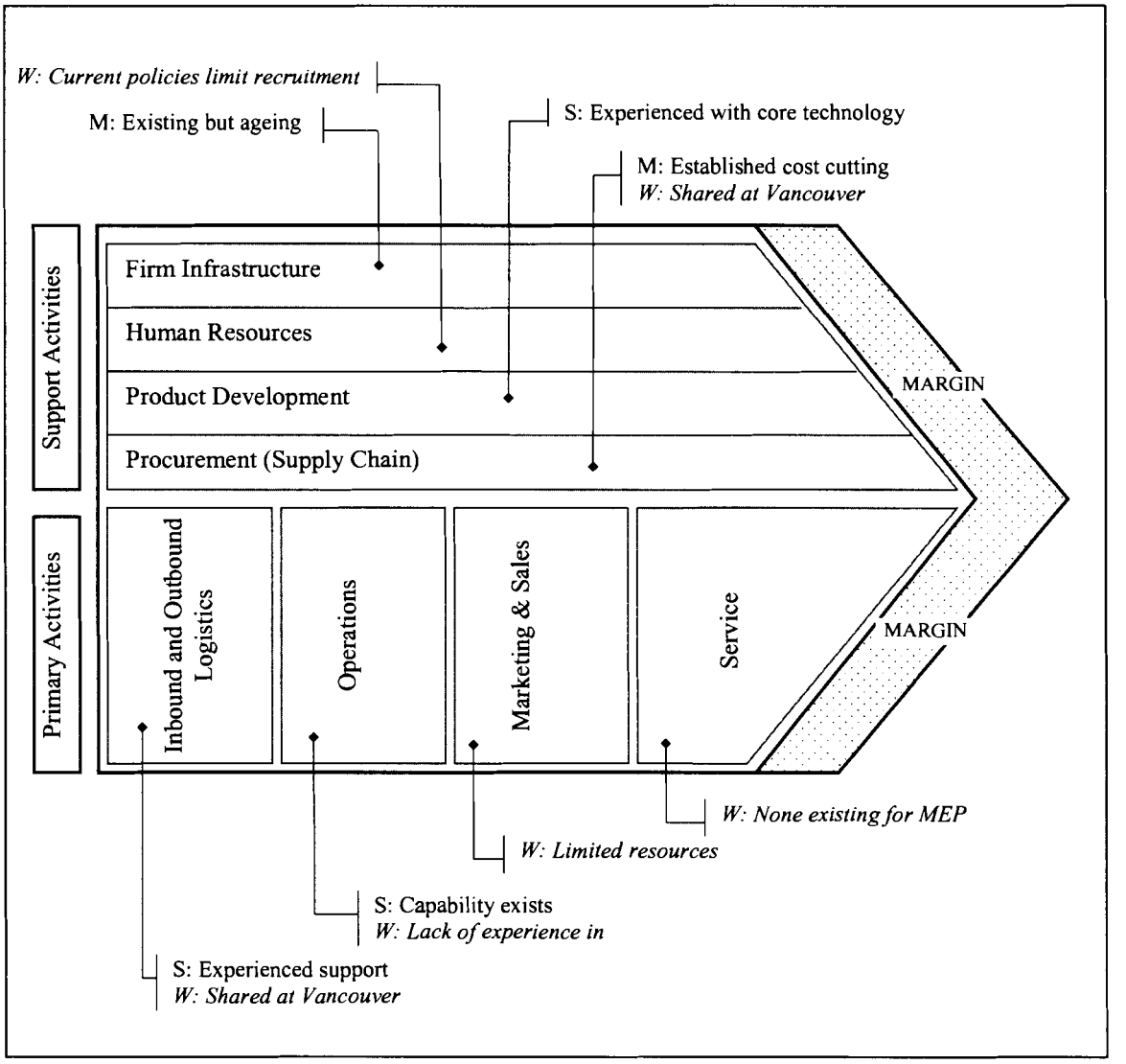
The facility in Vancouver has some advantages and disadvantages. There is existing infrastructure available for key battery development and assembly activities. These include both specialized and non-specialized test equipment, specific materials handling facilities, and dry rooms.

4.2.3 Summary of the Value Chain Analysis

The value chain analysis shows that the MEP group has both strengths and weaknesses as summarized below in **Figure 4.1**. The examination of the value chain reveals that the shared facility in Vancouver is both a means to add value and a possible source of weakness. In the shared areas of human resources, procurement, inbound and outbound logistics the MEP group benefits from having an existing structure in place and the benefit of better bargaining power. Conversely, the MEP group suffers by sharing these resources because the priorities favour the space & defence group which accounts for greater revenues.

The existing infrastructure exists but the age of the facility is showing and the space is beginning to run out as the MEP group grows. The team of talented assembly staff, battery engineers and scientists is also an advantage. This is not a pure science, and as such much of the learning comes directly from experience. One area, however, where the MEP group lacks experience is in the production of batteries that meet the strict quality criteria of the IMD industry. To date only two programs have been successfully transferred to production. There are four more products in development so the experience will come with time, but it may require some painful lessons.

Figure 4.1 EaglePicher MEP Value Chain



The MEP group has been able to build loyalty and strong relationships with an open product development model. This should also be leveraged. It is likely that this can be sustained for some period of time because Greatbatch would require a significant culture shift.

4.3 Abbreviated Financial Performance Analysis

This section examines the revenue performance of the MEP group within the Commercial Power division of EP technologies. The MEP group has established itself as an emerging supplier

in the IMD battery market. Revenues have grown year over year while improving gross margin and adding a number of customers as indicated below in **Table 4.2**. There are two things of note based on the revenue trend of the MEP group.

First, the revenues are growing at a CAGR of approximately 50%. Recall the business model described in **Section 2.2** which projects even greater revenues as new products which have been specified into OEM products are sold at production volumes. The addition of customers translates to the addition of products which translates to greater future revenues.

Table 4.2 Comparison of Revenues EP vs Greatbatch

Revenues in 000's	2002	2003	2004	2005
EaglePicher MEP	$600	$1,400	$2,947	$4,923*
No. of customers	1	2	4	5
Greatbatch – Total	$167,000	$216,000	$200,000	Unknown
Greatbatch – Batteries Only	$50,100	$66,100	$54,100	Unknown

* Forecast

Data Source: Company web-sites

Secondly, by examining the revenues of Greatbatch, it can be seen that the MEP group is gaining market share within the IMD industry. The evidence is seen in the relative total market size and the number of new customers that the MEP group is adding.

Financially, the future of the MEP points to greater revenues and greater profits. However, EP cannot fund further growth of the business. All investment in capital for improved productivity must come from profit earned by the business group. The MEP group is forced to invest as cash becomes available in a fashion similar to an emerging company using a bootstrap method of financing.

5 CURRENT STRATEGY FOR THE MEP GROUP

This section examines the current strategy of the MEP group within EP. First a summary of the strategy is presented. The summary includes a brief description of the interaction between the MEP group and EP followed by a description of the products EP offers the target market segments. The competitive position of EP is also described in this section of the analysis. The analysis of the strategy is done on two separate levels. The business level strategy is examined first followed by an evaluation of the marketing strategy. The section concludes by outlining specific strategic challenges facing the MEP group.

The current strategy for the MEP group can be summarized at a high level as using existing technology, resources and customers to generate new OEM relationships and win new contracts. The current business model dictates that a battery program must have a positive gross margin at every stage of development. Programs which are may not be profitable immediately or that may require additional technology development at the expense of the group are not considered. The current business strategy is based on leveraging existing customers and technology to grow the revenue of the business while adding as few resources as possible.

5.1 Current Strategy

The broadest purpose of EP industries is to earn profits for the owners. The strategic business units were born out of early relationships with government that led to capital injection and growth. The larger organization is comprised of different businesses with the intention of diversifying the portfolio of products across industries in order to maximize profits and reduce risk. The goal of the EP Commercial Power Division, as a part of the EP Technologies strategic business unit is to leverage existing technology used in large government contracts to penetrate

new markets. The products are new (but related to existing products) and the markets are new. In the Innovation literature, this would be considered to be incremental innovation.

The strategy examined in this section is specific the MEP group. The analysis looks at the current MEP strategy broadly and stands the strategy beside the organization to look at fit. The competitive position and the success to date also fall out of the analysis. The chapter concludes with a balanced score card evaluation of the company strategy.

5.1.1 MEP and the Technologies Group

The MEP group is just a small part of the EP Technologies group. It shares many of the characteristics of a start up company. Though there is an organization behind the group, it is isolated from the greater organization geographically and organizationally. In addition, as mentioned in **Section 4.4**, the MEP group is forced to operate in a cash neutral position funding all of its own capital requirements.

The current strategy for the MEP group is similar to that of any young company with a small number of customers and a relatively small top line. The key elements of the strategy include driving a profit centred mindset into a group that thought of itself as a research group, landing new customers to grow the top line, creating a differentiator with the existing market lion in the form of a world class quality system and unique open style of development, and developing new technology to compete in more market segments.

The portfolio of technology in the form of different chemistry offered by EP is a strong foundation for diversification into different market segments. This is the cornerstone of future business development in any battery market. The MEP group wants to offer the widest range of product choices to customers in the IMD battery market. In addition, the MEP group wants to

partner with IMD manufacturers to develop new products that are custom designed to fit their products.

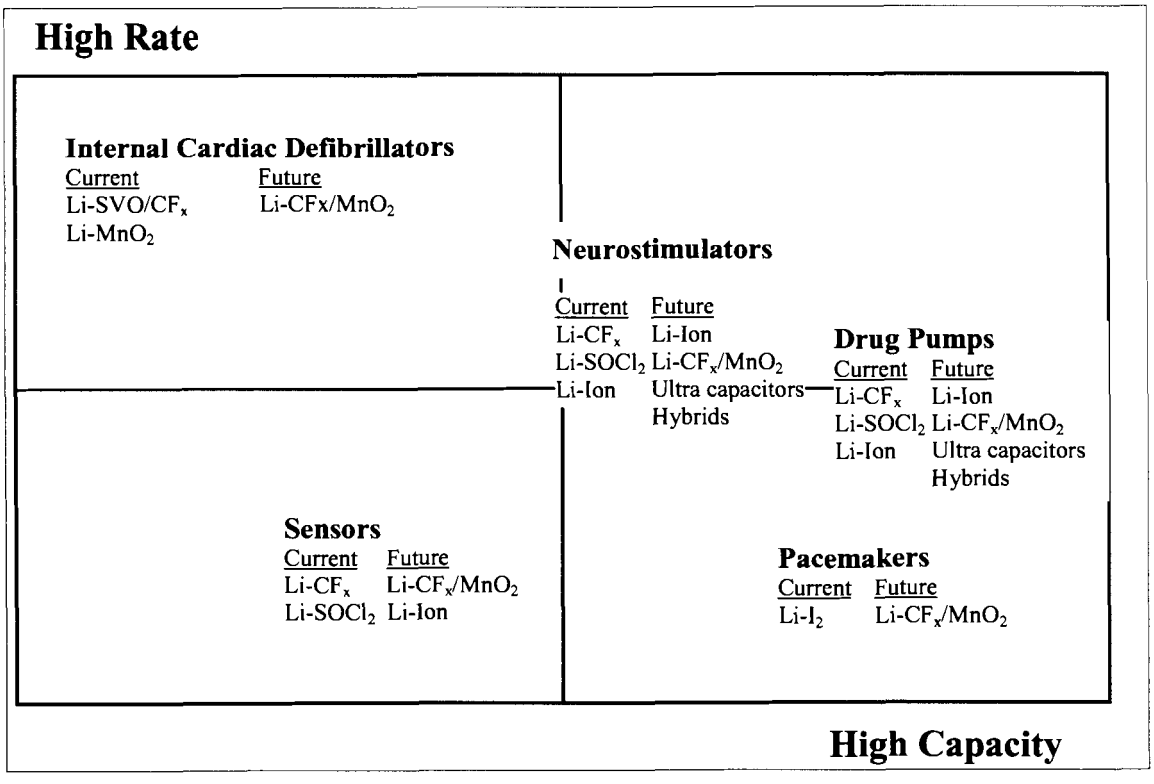
Because of cash flow issues from the EP, the MEP group is being forced to remain both cash flow positive and profitable at all times during growth. Previously, during quarters where the cash flow was lumpy, the larger organization was relied upon to provide injections of cash to smooth out the cash flow. In the current environment the larger organization also retains all profits.

5.1.2 Product vs. Application Market Segment for IMDs

The products currently offered to IMD manufacturers by the MEP group represent every major segment of the current IMD market with the exception of pacemakers. That is, the MEP group has a development program or a product that serves a device in each of the IMD market sub-segments. As can be seen in the grid below (**Figure 5.1**), the MEP group is well positioned with technology to serve the key IMD markets.

The current strategy based on product development and diversification suits the nature of the company and the market. Each new IMD product, even if based on the same product platform, arguably requires a new battery. This need from OEMs therefore necessitates a product development strategy on the part of the MEP group. On the other hand, it can be argued that this is a market penetration strategy because the fundamental technology (battery chemistry) does not change from generation to generation. EP is simply increasing market share by delivering more products to the same market segment. The truth is probably somewhere in between, but the fundamental customer relationship and the means for product development along with competence in a certain chemistry are the critical factors that determine future sales.

Figure 5.1 Most Applicable Battery Chemistry for IMD Markets



Source: Peters, Based on BCG Market Study for EP, 2004

5.1.3 MEP Competitive Position Strategy

The first products that the MEP group developed were largely based on price competition and a bit of luck. There was one OEM that turned away from the competition because of frustration and another product was inherited from existing business in another location. Currently, the MEP group is focused on timely delivery, quality and an open development approach with OEMs. Though these are not strong differentiators, customers have responded favourably because the open development approach and commitment to quality ultimately provide value by decreasing development costs and reducing risk.

In addition to these intangible factors, the MEP group can offer a wider variety of chemistry than the competition. The MEP group can serve more customers (IMD manufacturers) with this basic competence in technology. The key elements required to deliver a product if the

foundational chemistry is understood are design engineering, manufacturing engineering and quality. In conversations with existing and potential customers, the technology competence and quality function are always stressed as key differentiators. The group also relies on positive industry referral. Though the IMD manufacturers compete, there are many existing personal relationships in the industry based on early product development work.

There is poor understanding of the cost model for the implantable medical batteries. The MEP group pricing strategy has been somewhat arbitrary. A major price push was made last year with each existing customer with the simple philosophy of push until we lose a customer. Clarity on actual costs is difficult to obtain for two different reasons. First, the shared facility and resources in Vancouver make it difficult to understand true overhead costs. Currently, costs are split on a square foot and person basis. However, it's not clear whether this hurts or helps the bottom line for the MEP group. Secondly, the MEP group has limited experience with production. Only two product lines are being run as true lines and they have only been running as such for less than a year.

5.1.4 MEP Fit with Current Strategy

As discussed earlier, the corporate strategy of business diversification was based on historical evidence of cyclical cash flows and profitability, as well as opportunity to build on early expertise. At a business division level, the mandate for Commercial Power is to complement this strategy by leveraging technology expertise in government related contracts, such as military and space, to build commercial products. The MEP group was a natural extension of the chemistry experience gained in military markets. The high level look at the medical industry in general was enough to convince senior managers of market potential.

The current group has a good foundation to begin implementation of a strategy that leverages existing technology, but there are issues facing the business. Much of the technology

exists and there are some assets available to successfully develop new products. There are customers representing a number of application segments and the product development group has successfully launched two products into medical devices in use today. However, there are constraints.

The MEP group is severely constrained on capital assets. Customers are demanding more and more product and the group is struggling to keep up. In order to increase production either a capital investment must be made to increase productivity or variable resources must be added. Unfortunately, just adding resources does not always address quality issues that arise from assembly variability. Machines can more reliably reduce product variation. This is a direct result of the cash flow limitations of the parent corporation.

The MEP group also lacks both production experience and transition to production experience. This experience can be gained by either hiring seasoned staff or fumbling through the process with existing personnel several times. The latter choice risks more mistakes and is considered costlier in the long run. However, current hiring policy is limiting EPs ability to attract experienced personnel. The compensation packages are not competitive in the industry and again the cash constraints of the greater organization limit choices.

5.2 MEP Business Level Strategic Challenges

The MEP group business level strategy does not address all of the issues currently facing the group. These challenges are identified here to help with the analysis of future strategy. The main challenges are related to cash flow and internal capability. The leadership of the group has changed three times in the last three years and none of the business leaders developed or communicated strategy clearly to the MEP team.

The finance-related issues are related to the history and the effects of the larger organization on the MEP group. First, the overhead being charged to the group is high compared to revenue. The MEP group can compared to a start-up company being charged big company rent. The burden of organizational overhead is impacting the bottom line of the group. Secondly, there is a lack of capital to finance growth opportunities. This is a result of the cash flow challenges of the parent organization. Conservative financial policies are hindering the relatively higher risk growth opportunities. One policy, for example, requires a one year return on investment (ROI) on any assets purchased regardless of useful life or future cash flows. Lastly, the price model is not well-understood. Prices are being determined on a cost-basis, but true costs are not well-understood. This is especially challenging, at the product development stage of the life cycle. Neither is there a basis to extrapolate costs from previous production of medical batteries because the group is so young. In addition to finance issues, there are issues related to the structure of the organization.

There are inefficiencies resulting from the management and technical team separation. As shown in **Figure 2.2**, which describes the geographic location of the MEP group, a team of about forty is spread across three cities in two countries. The senior management team is disconnected from the core of the programs and there is little technology sharing across facilities. These different locations foster communication gaps, slow decision making, create technology barriers and result in some redundancy.

Thirdly, pure technology development is not being done or funded. Again, this is likely a result of cash restraint issues. The group is fully committed to delivering on current development, pilot and production contracts. This adds risk to development programs because there is no toolbox of technology from which to draw and it is short-sited. It can be seen that future chemistries are the best path to future OEM markets. The lack of funding for pure technology

development will hinder future opportunities. The biggest competitor, Greatbatch, spends approximately $18.5 million on R&D yearly (Greatbatch form 10-K, 2004, p. 36)

The competition is strong. Greatbatch accounts for approximately $70M in revenues in the medical battery market and has customers in each of the IMD market segments. Greatbatch has demonstrated a willingness to sell development programs below cost to win the potential for future production work. The IP position of the competition can be characterized as strong with over 246 active patents on medical implantable device batteries and components. The current strategy to match up against the biggest competitor relies upon dissatisfied customers and smaller OEMs that have had trouble getting serious attention from Greatbatch.

The final two which may hinder successful implementation of strategy are also related to the financial situation of the greater organization. Current key technical resources are too limited as are shared development and lab equipment. Cost control measures are being exercised at the lowest levels of the organization. In addition, the MEP group has had difficulty in attracting quality recruits to certain key positions because of a below average compensation strategy. For one position, three separate individuals were either disqualified or rejected offers strictly as a result of inadequate compensation.

5.3 Marketing Level Strategy

The marketing level strategy at this stage is simple. It consists of face-to-face relationship building with contacts in as many IMD companies as possible. The need to build revenues today is the primary impetus behind most of the marketing activity. However, this strategy is somewhat short sighted and it does not take advantage of all that the MEP group has to offer.

There are some issues facing any individual acting in a marketing role for the MEP group. Firstly, there is a lack of good pricing information for future products. This is a result of

limited experience with the production of medical batteries as well as limited support from supply chain staff.

The MEP group is not deep enough to provide total customer solutions in all cases. This makes it difficult to sell some programs because they either require partners or reduced selling prices. In addition, the product portfolio is limited. The MEP group does not offer any off-the-shelf batteries for either more price sensitive OEMs or for faster development programs.

6 BEST MARKET ALTERNATIVES

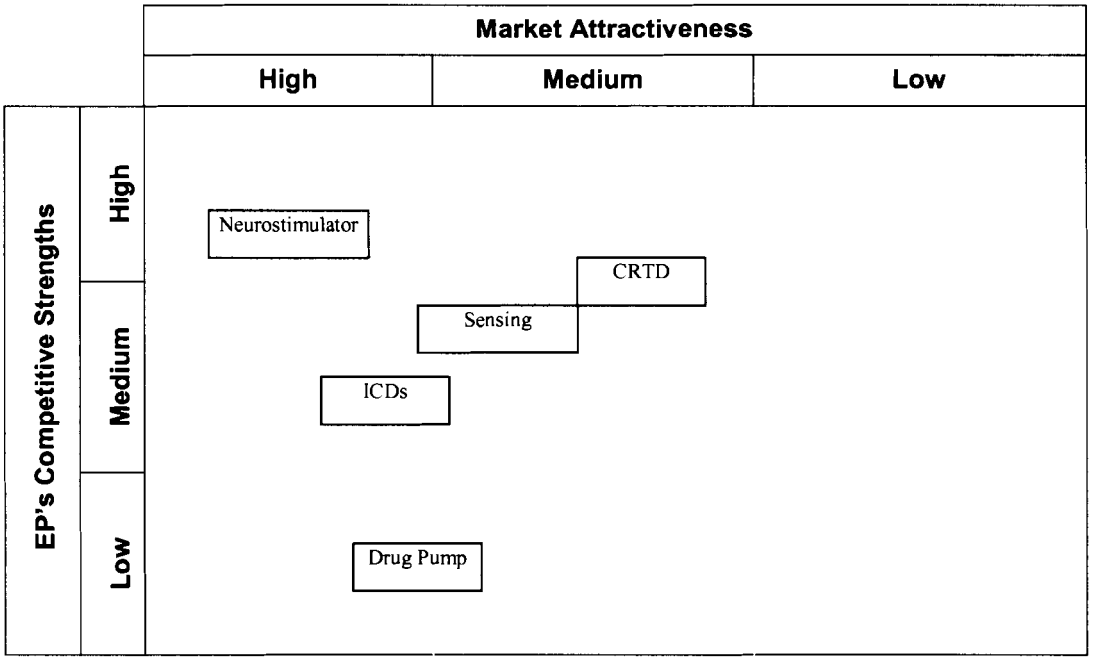
This section is used to logically analyze the alternatives that the MEP group has at the market level and the business level. A balanced scorecard is used to compare the market segments in the IMD market against the strategic objectives and measures most suitable to the MEP group at this time. Higher level business alternatives for the MEP group are also examined in this section. Finally, potential ideas for increased market share are presented.

6.1 Most Attractive IMD Market

This section examines the market potential for the MEP group in the IMD and each of the sub-segments of the IMD market. It begins with a brief overview of market attractiveness for each of these sub-segments of the IMD market building on the work done in **Section 3.2.4**. Items that make the overall IMD market, well-suited to EP are surveyed. Then a detailed comparison is made between the various IMD market segments. The most attractive sub-segment of the market is examined in more detail.

According to classic strategy theory, the best business portfolio is the one that exploits the most attractive opportunities while taking advantage of an organization's strengths. The McKinsey-General Electric matrix is used to help place the various segments of the IMD space in relation to the EP MEP Group. Market attractiveness is plotted against EP's competitive strengths in **Table 6.1** below.

Table 6.1 McKinsey-GE Matrix for EP's Position the IMD market



A range of factors are considered when placing the various applications in the appropriate locations. A few key factors are worth noting in the analysis. Drug pumps rank relatively low on competitive strength because EP has no technical competence with the current leading battery technology, no existing market share and no customer loyalty draw from which to gain market share. The Cardiac Resynchronization Therapy Device (CRTD) market is large, growing and potentially profitable, but it is heavily dominated by EP's largest competitor in the medical space. This customer has built strong ties with OEM's, and is well known in the industry. In addition, the current preferred technology for battery chemistry is lithium-SVO, which accounts for greater than 90% of the market. This is an area where the MEP group does not have significant technical expertise.

The most attractive market today is the neurostimulator market. The market is on the cusp of large growth due to the wide range of potential treatments and advances in the technology. The price margins are excellent for a supplier like EP and the prices and demand is generally inelastic because these devices are used in health care.

The MEP group also has some competitive strength in this market. EP has proven success with one customer in this segment (ANS), which is considered a market leader in this area. The MEP group has strong knowledge and application experience in the preferred technology - lithium-ion. In this market, EP has a relative advantage over the competition and operates from a position of strength.

6.2 Goals & Evaluation Criteria – Balanced Scorecard (BSC)

The balanced scorecard (BSC) is a business methodology performance measurement tool that balances measures in the areas of financial, customer, growth and learning, and internal business processes (Kaplan & Norton, 1996, p.18). The BSC is used as a tool for market selection because it considers a range of criteria beyond financial measures. Norton and Kaplan argue that organizations that innovate require skills to manage intellectual assets. To remain competitive an organization must invest in employees, the business processes and must understand the customer. The financial model, alone, cannot be used to measure the potential success or failure of an organization investing in new capabilities. The balanced scorecard is used here to compare strategic objectives and measures against potential markets.

The vision of the MEP group at the most basic level is clear. The group exists to earn profit by selling product development services, testing services and manufacturing services to customers in need of high energy density batteries. The translation of this vision into a strategy is currently constrained by access to capital as a result of a Chapter 11 filing in the U.S operations of EP. Because of cash constraints, the MEP business is expected to be profitable at all times. The impact of this constraint is seen in the balanced scorecard evaluation presented here. Each of the five IMD market segments is rated against the strategic measures on a scale of 1 to 5, with 1 generally being a low benefit and 5 generally being a high benefit. The balanced scorecard measures are examined here in detail because the criterion for each strategic objective is

evaluated differently to take into account the success factors specific to the objective. First, the most heavily weighted financial measures are explained. Then, each of the other measures is described to clarify the ratings used to develop the final weighted score. The section concludes with a summary of the results in a table and a discussion of the scorecard analysis as a whole.

6.2.1 BSC Measures – Financial 45%

The first of the financial measures, product profitability is based on EP's reasonably expected ability to win and execute a program within a given market while meeting a gross margin (GM) of 20%. A score of 1 against this measure translates to an unprofitable or non-existent development and pilot production phase. That is, the MEP group would be required to develop a battery and develop final manufacturing processes before earning any profit. A score of 5 translates to an estimated gross margin of more than 20% at each of the stages of a battery program. The remaining scoring criteria are summarized below in **Table 6.2**

Table 6.2 BSC Financial Scoring Criteria – Measure 1

Score	Criteria
1	No product development profit, no pilot profit. Production only profit only. Customer wants off-the-shelf product.
2	None of the three stages gross margin (GM) > 10%
3	1 or more stages GM >10%
4	1 or more of the stages GM > 20% and 1 or more stages GM >10%
5	All stages have an estimated GM > 20%

The second of the financial measures is the potential for current and future sales volume in the IMD market sub-segment. It is based on the potential to secure sales quickly and to secure as much revenue as possible related to the sales. The future sales potential is a qualitative estimate based on the number and strength of competitors and EP's expertise in the dominant chemistry. For example, in the case of greater competition, the sales potential is negatively

impacted. In markets where EP must secure customers with smaller development budgets, sales potential is also negatively impacted. As seen in **Table 6.3**, a rating of 1 corresponds to a sales potential of less than $1 million and an expected sales cycle of more than 2 years. A rating of 5 will be given to markets that have potential for sales contract wins within a year and revenue of greater than $1 million.

Table 6.3 BSC Financial Scoring Criteria – Measure 2

Score	Criteria
1	Potential for sales >2 years away, risk weighted sales potential < $ 1 million
2	Potential for sales >2 years away, risk weighted sales potential > $ 1million
3	Potential for sales >1 year away, risk weighted sales potential > $ 1million
4	Potential for sales <1 year away, risk weighted sales potential < $ 1million
5	Potential for sales <1 year away, risk weighted sales potential > $ 1million

The third measure is a result of the lack of capital available to the MEP group for investment in equipment or machinery that would increase productivity. A market consisting of customers that have the ability and willingness to fund the purchase of equipment used for production of a battery specific to the application is viewed favourably. **Table 6.4** summarizes the scoring measures used against this financial objective. A rating of 1 is given to markets with fewer, profitable customers that have no history of investing in supplier capability. A rating of 5 will be given to an industry consisting of well-established, highly profitable IMD developers with a history of investing in their suppliers.

Table 6.4 BSC Financial Scoring Criteria – Measure 3

Score	Criteria
1	Current customers in segment are not profitable, < 2 years old
2	Potential customers in segment are profitable, EP has no products in category
3	Current customers are profitable > $10million, < 5 years old
4	Current customers are profitable > $10million, established >10 years old, no history of investment in suppliers
5	Current customers are profitable > $50million, established >10 years old, history of investment in suppliers

6.2.2 BSC Measures – Customer 15%

The customer measures are the second highest weighted at 15%. The EP objectives of improved customer satisfaction are directly derived from the goals of increasing revenue rapidly. It is assumed that the cost to satisfy an existing customer is far less than the cost to acquire a new one. The measures are based on remaining competitive against EP rivals, delivering superior service to customers and maintaining world class quality. In order to apply a rating to these measures several questions are asked. First, does the MEP group have at least one established customer in the market sub-segment? Second, does the MEP group have a history of delivering service and quality at a level that meets customer needs? Is the pricing competitive? How is this measured? A qualitative measure of customer satisfaction is based upon customer retention, customer feedback and referrals received from existing customers. A score of 1 against this measure would indicate that the MEP group has lost a customer due to an inability to deliver on any of price, service, quality timing or technical expertise. A score of 5 indicates that EP has successfully retained a customer in a given market sub-segment The best proof of a satisfied customer is repeat business in the form of increased demand for batteries in production and additional product development contracts for future products. A further breakdown of scoring criteria is presented in **Table 6.5**.

Table 6.5 BSC Customer Scoring Criteria

Score	Criteria
1	Customer has been lost in market (dissatisfied)
2	No customers in market, MEP lacks technical expertise at present to satisfy customer
3	No customers in market, pricing not competitive, quality system meets customer standards, customers willing to refer MEP group to new customers
4	Customer in market - *single* product Pricing competitive, quality system meets customer standards, customers willing to refer MEP group to new customers
5	Customer(s) has(ve) *multiple* products with MEP group (repeat business), pricing competitive, quality system meets customer standards, customers willing to refer MEP group to new customers

6.2.3 BSC Measures – Internal 5%

The internal measures are the lowest weighted measures along with learning at 5%. These measures are based on EP's ability to improve operational efficiency in order to reduce costs and improve gross margin. These measures are related to the MEP group's ability to successfully transition from product development to production and to improve manufacturing processes. The measures examine the experience of the team in a given market segment and the relative time frame that is required to make a transition. Has the MEP group proven that it can successfully develop and deliver a product in a timely, cost efficient manner? The table below (**Table 6.6**) matches the score of the criteria with the answers to these questions. A score of 1 indicates that the MEP group has no experience in the market. A score of 5 indicates that the MEP group has successfully moved a produce through the development process, is producing batteries with an experienced team and has established process improvement metrics.

Table 6.6 BSC Internal Scoring Criteria

Score	Criteria
1	No products in market
2	No transition experience in market
3	Single products in transition, cost overruns, > 6 months time, experienced team not in place
4	Single product has been transferred, > 6 months, experienced team in place
5	Multiple products have been transferred, on budget, < 6 months, experienced team in place, process metrics in place

6.2.4 BSC Measures – Learning 5%

The learning measure is viewed as an opportunity for the MEP group to build technical competence in new areas. Either the opportunity will add complementary technology such as competence in charging circuitry or it will add foundational knowledge in a new area of battery chemistry. A score of 5 indicates an opportunity to expand fundamental chemistry knowledge and gain access to another sub-segment such as next generation pacemakers. Alternately a score of 1 indicates that the MEP group gains little new technical knowledge by developing and selling a product. Learning scoring criteria are summarized here in **Table 6.7.**

Table 6.7 BSC Learning Scoring Criteria

Score	Criteria
1	No significant technical learning for MEP group
2	Learning is incremental, based on existing knowledge of dominant chemistry
3	Learning opportunity for improved service of existing customers
4	Learning is incremental in existing chemistry *and* opportunity for improved service of existing customers
5	Learning opportunity will offer MEP group new competitive strength in new chemistry

6.2.5 Summary of BSC Evaluation

The results of the balanced scorecard analysis are summarized here in **Table 6.8**. To derive the final weighted scores each of the scores for a given market segment are multiplied with

the weight assigned to the strategic measure. These weighted scores are then summed to obtain a total weighted score indicated in bold at the bottom of the table. The market with the highest weighted score is considered to be the best alternative based on the analysis. As highlighted in **Table 6.8** below, the best market alternative is the Neurostimulator market.

The critical financial objectives for the MEP group are related to growing revenues and maintaining profitability at all times. The financial metrics total 75% of the weighting in the analysis because of the financial constraints imposed on the MEP group by EP. Practically, this means that the outcome of the analysis will be heavily weighted toward the financial objectives of the MEP group. Based on the financial portion of the analysis alone, ICD/CRTD market ranks highest with a combined weighted score of 3.75. The Neurostimulator market ranks a close second with a weighted financial score of 3.65. The key differentiator between the Neurostimulator and the ICD/CRTD markets is the proven investment in the MEP group. One of the most important customers to the MEP group has invested capital directly into the program at the EP facility. In addition to cash this customer has sent technical experts to solve technical problems and improve processes. Other markets rank lower either because of greater uncertainty in EP's ability to secure sales (such as in the pacemaker market) or the lower profit potential (such as in the sensor market).

Table 6.8 BSC Evaluation of IMD Markets

			WEIGHT (%)	ICD and CRT	Drug Pumps	Sensors	Pacemakers	Neurostimulators
	Strategic Objectives	**Strategic Measures**						
75%	**Financial** ▪ Immediate Profitability ▪ Top Line Growth ▪ High Margin Product ▪ Stabilizes Revenue	▪ Profitability *Target: Gross Margin >20%*	45%	5	3	3	3	5
		▪ High potential for sales volume *Target: Sales < 1year and potential > $1M*	20%	5	2	4	2	5
		▪ Can customers support capital requirements if necessary? *Target: Established company, profitable, history of investing in suppliers*	10%	5	4	3	2	4
15%	**Customer** ▪ Improve customer satisfaction with products and quality ▪ Maintain solid communication with customer	▪ Customer satisfaction interviews, repeat business, retention *Target: Repeat customers, MEP competitive with price, service, quality*	15%	4	3	4	2	5
5%	**Internal** ▪ Transfer to production ▪ Production management	▪ Improved transfer from development to production, and process capability (lower production costs) *Target: Multiple product experience, experience team, metrics in place for cost improvements*	5%	4	1	3	1	4
5%	**Learning** ▪ Develop Key Competency	▪ Add new technical capability *Target: Learning opportunity to leverage MEP competitive position*	5%	3	5	3	4	4
Total Weighted Scores				**4.70**	**2.90**	**3.35**	**2.50**	**4.80**

The primary objectives in the customer segment are related to building positive relationships with the IMD manufacturers. The Neurostimulator market receives the best weighted score in this measure (0.75) because the MEP group has secured repeat business with customers in this segment. The sensor and ICD/CRTD market segments rank next with equal scores on the BSC. The MEP group has customers in each of these segments and the customers have provided positive feedback regarding quality, service and adaptability. At least one customer in this segment has also provided a referral to the MEP group for additional work.

The internal processes are focused on improving operational efficiency. The MEP group is relatively inexperienced at transferring product from development to production. Any market that offers experience in transfer to production will score attractively. The two markets that will most quickly aid in gaining this experience are the Neurostimulator and ICD segments because each of these segments has products that have either just entered production or are entering production.

Each of the market segments offers opportunity to add some kind of capability. However, because the MEP group has no experience with customers in the Drug Pump market, this market provides the greatest opportunity for learning. Pacemakers for example, require investment in a chemistry in which the MEP group has little experience so the BSC score is higher. The foundational knowledge in chemistry required to compete in the pacemaker market provide the MEP group with potential future competence.

In summary, the BSC analysis provides a method to evaluate the strategic objectives of the MEP group in a deliberate manner considering four perspectives. The analysis here shows that the best alternative is the neurostimulator market. This market provides good opportunity for immediate profitability and the MEP group has proven customer relationships in this segment. It

provides good opportunity for learning and the MEP group has some experience in transferring the technology to production.

6.3 Business Level Strategic Alternatives for the MEP group

6.3.1 Seek Acquisition

The MEP group may be able to secure some form of bank financing based on assets. This scenario is unlikely because though the MEP group generates profit, the MEP group does not own significant capital assets. Financing would either be at a high cost and the amount would likely be too small to offer significant help.

Alternately, the MEP group may seek financing or an acquisition from a customer. This alternative has the benefit of an existing relationship and a familiarity with the technology. There are two possible acquirers. Each of these companies has profits that far exceed the requirement for injected capital the MEP group needs. An IMD manufacturer would also gain a security of supply and more control of business and quality processes to better support its corporate goals. The one significant challenge to this option is the risk of alienating or losing other existing customers. An acquiring organization may even mandate the dissolution of existing customer relationships. An IMD manufacturer may not wish to fund or support any activities that may support competitors. The current IMD customers that the MEP group has do not compete across all market segments. Because of the potential difficulty in negotiation with existing, competing customer, the timeline for an acquisition may stretch beyond the timeframe needed to grow the business today.

6.3.2 Seek a Merger

Another alternative may be the search for a partner. A merger could be sought to gain access to capital, lower overhead (at least keep it the same) with a shared facility, and add

complementary technology. The best choice for a merger would be one in which the MEP group adds capability such as electronic capability or additional battery chemistry experience – such as zinc-air or commercial lithium-ion cells. The timeline for a search like this may be excessive for the MEP group. A long search may jeopardize meeting existing commitments in a timely manner.

6.3.3 Seek Venture Capital (VC) financing

The third potential source for capital injection is venture capital money. The estimated amount of money required to secure the MEP group growth is well within the range of a VC firm. The MEP group makes money and has firm purchase orders from existing, reliable customers. The business and markets are growing and therefore attractive. A venture capital firm can offer support and help to place a good growth business leader for a currently leaderless group. Venture capital money also has the advantage of a timeline that is possible within one year. On the negative side, a VC will gain ownership and have heavy influence of the longer term strategy of the company which may not be compatible with the customers – such as exit strategy.

6.4 Strategic Alternatives for Increased Market Share

There are several possibilities for increasing market share within the IMD space. Each of these is compared with key MEP group objectives to help determine the best course of action. The three alternatives are to maintain the status quo, target a specific market within the IMD space or acquire market share. The options are compared below in **Table 6.9**, with the preferred alternate emerging as "Target Single Segment".

Table 6.9 Alternatives for Increased IMD Market Share

Category total		Weight (%)	Status Quo	Target Single Segment	Acquire
75%	Requires significant capital	10%	3	3	1
	Provides short term profitability	12%	4	5	2
	Improves top line revenue fast	45%	4	5	5
15%	Retains existing customers	15%	4	4	3
5%	Able to execute with existing talent	5%	5	5	3
5%	Adds new technology competence	5%	3	3	4
	Total Weighted Scores		**3.58**	**4.75**	**3.39**

6.4.1 Maintain Status Quo

This option uses existing staff and resources and continues to develop new customer relationships at the same rate. It relies upon the fact that the IMD market is so big that there is room for the MEP group along side of Greatbatch and Quallion. The group can continue with this strategy and can expect the same order of magnitude of returns.

6.4.2 Seek Single Market Segment Dominance (Target Single Segment)

This strategy follows a similar philosophy to Geoff Moore in Crossing the Chasm who uses a D-Day analogy for securing a market beachhead followed by market dominance (Moore, 2002, pages 63-87). The MEP group establishes a beachhead market in a segment of the IMD space such as the neurostimulator market. The group then aggressively captures the entire market by providing complete customer solutions and superior products. This strategy requires building a network of customers who will refer the MEP group to other potential customers. Based on the analysis above, this strategy appears to be the most attractive.

6.4.3 Acquire Market Share via Merger or Acquisition

Another alternative may be the search for a partner or acquisition. The MEP group could target a company with existing market share in the IMD space. The synergy of a merger could make the MEP group more competitive with Greatbatch and it could offer customers a more complete solution. The biggest challenges of this option are the time required to secure a deal and the potential costs for a business unit that is already cash strapped.

7 RECOMMENDATIONS

From the preceding analysis, several recommendations are made for the EP MEP group. These recommendations are divided into business level and market level recommendations. The business level recommendations assume that EP will remain in Chapter 11 for at least one year.

7.1 Business Level Recommendations

There are many positive factors that make the IMD business attractive for future profit potential, including existing customers, products and a strong technical team upon which to build. However, there are also several challenges facing the MEP group. The predominant challenge is that the group is currently suffering from cash related issues. The recommendations required at the business level are presented here.

First, the group must actively develop a plan to inject capital into business. There are limitations to the productivity and therefore the profitability of the group because of a lack of capital equipment. The situation is precarious because customers continue to demand product but there is a risk that the group may not be able to deliver. It is recommended that the group seek alternative sources of equity rather than wait for the EP to emerge from bankruptcy protection. There are three possible sources of external financing. The sources discussed in this work include, acquisition, merger or VC financing.

To gain more operational efficiency and improve strategic communication, all MEP group activities should be integrated into one facility. The group would benefit from easier access to more technology and easier access to leadership. The customers would benefit from simplified lines of communication and technical synergies between battery programs.

The MEP group must land more customers or sell more products to existing customers to accelerate top line growth. The overhead structure is a huge burden to the profitability of the group. The lack of scale within the MEP group is very challenging. Shared functions with fixed costs such as quality, marketing will be spread across a larger number of programs. Shared facility and asset costs are also shared across multiple programs improving the bottom line.

Finally, the MEP group must build competency at developing accurate price models to better understand areas for improved margins. By understanding the cost of products, the group can offer competitive pricing with confidence of retaining profit margins. In addition, a better cost model will provide more accurate development contract pricing. With more accurate pricing earlier in the program, less time, effort and money will be wasted re-negotiating for price increases with customers.

7.2 Improving Neurostimulator Market Share

The MEP group can take several steps to improve market share. These recommendations include leveraging brand to increase OEM awareness, leveraging technology to develop new products with existing customers, offering additional services that target the IMD manufacturing value chain and improving customer management.

First, the MEP group must actively market capabilities at trade shows and conferences and leverage positive aspects of brand association. The brand strategy should establish key differentiators between EP and the biggest market competitor, Greatbatch. As a minimum, EP must be perceived to be equally competent to Greatbatch. Key differentiators for EP currently, are the ISO 13485 quality capability and the open product development philosophy. EP can also market its supporting role in preparation for FDA (regulatory) approval. To accelerate acceptance of a the EP brand in a business to business relationship, the MEP group must engage in industry related trade events and conferences (Bendixon et al, 2003, p. 379). This strategy builds the

critical awareness portion of the buying decision. It also serves as a basis for relationship building and networking

A second recommendation is for the MEP group to seek new product opportunities with existing customers. The MEP group can use existing relationships to undertake projects with slightly higher technical risk in areas related to battery development and production. For example, the MEP group could invest in a capacitor project for an existing customer. This allows the MEP group to develop complementary capability while minimizing the risk of technical failure. An existing customer already has sunk costs associated with a battery development program and is less likely than a new customer to seek another supplier. Once the MEP group has developed some basic capability in the new area, future products can be designed and sold to other customers. This presents a more complete customer solution in the future.

A potential source of additional revenue for the MEP group is additional service work for existing customers. The MEP group can offer services to customers that do not add value in their respective value chains. For example, the MEP group has access to some specialized test equipment and space that is not easily duplicated. Test services can be offered to IMD manufacturers. The MEP group benefits by leveraging relationships with existing customers. By adding business with existing customers, the MEP group reduces business development costs. Customers will benefit by being able to sub-contract non value-added work and to take advantage of existing knowledge sharing.

If the MEP group had a standard cell for a particular market segment, there is an opportunity to sell a product quickly and at a lower cost. The group should develop an off-the shelf cell in each of the existing markets beginning with Li-ion (rechargeable). Currently there is no standard cell that can be offered to a medical customer in any of the existing chemistries. Customers benefit from a shorter lead time and a lower cost resulting from amortized

development costs. Customer feedback suggests that cell with a common capacity and standard shape could be valuable to speed development and eliminate development costs. The only drawback to an off-the-shelf component is the loss of flexibility and optimization.

Lastly, the MEP group needs to assign product management responsibilities to one or more team members. Either assign an individual familiar with the technology and the current customers or develop the product management skills of the existing program management team. The key benefits will be consistent messages to customers, clear communication between product lines, and better direction to future technology development and product responsibility during the transition and production phases of the lifecycle.

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