A System Dynamics Model for the Diffusion of a New Technology

by

Karin L. Knoll

Submitted to the Sloan School of Management
in May 1995 in partial fulfillment of the Requirements
for the Degree of

Master of Science in Management

at the
Massachusetts Institute of Technology

May 1995

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ABSTRACT

It is often difficult for companies producing new technologies to predict the acceptance pattern (or diffusion pattern) for the new technology in the marketplace. The expected diffusion pattern is important because it affects and is affected by the production, financial, sales and distribution strategies for the new technology, as well as decisions related to marketing and technical development. It is also useful if the projection of technology acceptance offers the firm insight into the factors that drive acceptance and the factors that contribute to rejection of the technology in the marketplace.

This thesis develops a system dynamics model for the diffusion of a new medical technology. At the model's core is a general theory of medical technology emergence proposed by Dr. Jack Homer in his 1983 Ph.D. thesis entitled "A Dynamic Model for Analyzing the Emergence of New Medical Technologies." By parameterizing Dr. Homer's general system dynamics model to suit the new technology case, it is hoped that the model will give rise to a greater understanding of the factors relevant to diffusing the technology, as well as lead to more informed managerial decision making as progress is made with the technology.

Thesis Supervisor: Professor John D. Sterman

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ACKNOWLEDGMENTS

This thesis may not have been written but for an encounter with Dr. John Sterman on the metro train in Boston, between the Kendall MIT stop and the Central Square stop. We were chatting about theses, and he asked me if I was going to do one. I said "yes, I hope so; I'd like to look at the diffusion of a new medical technology." And so it happened. Dr. Sterman referred me to Dr. Jack Homer's seminal Ph.D. thesis work, which formed the backbone of this thesis. Dr. Sterman's original idea and enthusiastic support of the project have done a great deal to motivate the work.

I am also much indebted to Dr. Jack Homer. After spending many hours reading his thesis and entering the model into VENSIM, I appreciate the quality thinking and painstaking effort that he presented. His thesis brought a richer perspective to many of the experiences I'd had while working as a Field Clinical Engineer for Medtronic, Inc., the founder of the pacing industry, prior to coming to Sloan. Near the end of this thesis work, I had the pleasure of meeting Dr. Homer and discussing the evolution of this thesis, and he contributed to part of the final stages in the model development.

Finally, I am thankful to have had the pleasure of working with the New Indications team at Medtronic, Inc. in developing the thesis. Dwight Warkentin, the business manager of the team, provided unfailing support and guidance. John Gonzales, a young MBA team member, contributed data, literature, analytical assistance, and energy to the project. The rest of the team, including Tom Bennett, Jim Carney, Jeff Ireland, and Darryl Unterecker, offered their time, ideas, and critique in meetings and phone interviews. Without their contribution, this work would have been far less meaningful.
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1. Introduction

1.1 Background
The medical technology of interest in this thesis is an Implantable Hemodynamic Monitor (IHM) that is being developed to serve patients who are afflicted with congestive heart failure (CHF). It is estimated that over 2 million people in the United States suffer from CHF, a debilitating, progressive disease characterized by the inability of the heart to pump sufficient blood to vital organs. (Pluemer, p. 1) About 400,000 new cases present in the United States each year, and mortality in the population is high. (Konstam, p. 1)

In addition to the personal suffering the disease incurs, treatment for CHF is costly to the medical system. "Total treatment costs for heart failure, including physician visits, drugs, and nursing home stays, were over $10 billion in 1990." (Konstam, 1) These costs escalate when the disease progresses. CHF patients are placed in one of four categories, New York Heart Association Classes I-IV, ranging from those who experience minor clinical symptoms to those who are severely debilitated. The sickest 20% of all CHF patients are typically hospitalized two and a half times per year. The patients who degenerate to severe stages of heart failure require substantial medical care, averaging approximately $50,000 per year in management costs associated with hospitalization, doctor visits, and other testing. (Pluemer, p. 7) The endpoint for patients with severe CHF is heart transplant, which is limited by the supply of donor hearts and is extremely expensive.

It is thought that many of the almost 1 million hospitalizations in the U.S. each year could be prevented by improved evaluation and care, reducing the $7 billion in hospitalization treatment costs for this patient population. (Konstam, 1) Close monitoring of clinical indicators of the disease state may offer clinical utility in disease management and may improve the cost-effectiveness of treating this patient population, by slowing the progression of the disease and precluding the need for transplant in some patients.

To address the need for close monitoring in the CHF patient population, a new medical technology called an "Implantable Hemodynamic Monitor" (IHM) is currently under development by Medtronic, Inc., a company leading the implantable pacemaker industry. As yet, there is no other chronic, implantable monitoring technology available that provides ongoing hemodynamic data to the physician. The technical performance of the device, currently in research clinical studies, is being validated. After the IHM's technical performance is validated, the device will undergo clinical testing to satisfy FDA requirements for market release. Once market release has been granted, the challenge for Medtronic will be to drive the diffusion of the technology into the marketplace.
1.2 Purpose and Approach
The purpose of this thesis is to examine the issues relevant to the diffusion of the IHM technology in the marketplace using a system dynamics model of the diffusion process. The model created for this thesis is based on a model created by Dr. Jack Homer for his MIT Ph.D. thesis in 1983, entitled "A Dynamic Model for Analyzing the Emergence of New Medical Technologies." The results of Dr. Homer's research were also reported in an article entitled "A Diffusion Model with Applications to Evolving Medical Technologies," in Technological Forecasting and Social Change, pp. 197-218. Dr. Homer's model provided the structure of the relationships of physician activities and manufacturer activities in a number of separate sectors. In this thesis, an additional sector was created to incorporate the effects of health care payer relationships that exist in 1995 and are expected to exist in year 2000 when the technology is planned to be ready for the general market.

The model includes both parameters that are within management's control and parameters that are outside management's control, which may also vary significantly from predicted values. By simulating several scenarios that could ensue when the technology enters the diffusion process, the management team responsible for bringing the IHM technology to market will gain insight into the factors contributing to adoption, adoption over time, rate of adoption, and drivers of innovation, etc. It is hoped that this insight will be useful in guiding marketing and distribution decisions, as well as research and development and production planning.

1.3 Overview of Presentation
The goal of the thesis is to explore the potential diffusion behavior of the IHM technology in the marketplace when it is expected to be launched in the year 2000. To do so, the presentation of the thesis begins with two chapters that provide the background for the setting for the model, Chapter 2 on heart failure management today, Chapter 3 on the technology, and Chapter 4 on the market for the technology. Chapter 5 discusses potential competition for IHM. Chapter 6 describes the manufacturer of the device, the activities of marketing and technological development, and the strategic questions of importance to the manufacturer. The payer environment is discussed in Chapter 7, with a section devoted to cost effectiveness analysis. Data from interviewing physicians and manufacturers regarding the IHM device is presented in Chapter 8. Chapter 9 outlines the most important uncertainties that will influence the diffusion of the technology, including technology performance, patient benefit, market acceptance, and payer environment.

Once the background material is well established, Chapter 10 describes the model in detail, including a model overview, model boundary, and detailed description of each of the sectors with policy diagrams. Chapter 11 discusses the base simulation case for the IHM technology, and speculates on those parameters for which simulation testing would be valuable. Chapter 12 presents the analysis of simulations after testing of critical variables, and Chapter 13 summarizes with recommendations for a technology
diffusion strategy based on the model results. Appendices include exhibits, model simulation results, full model diagrams, and equation listings.
2. Heart Failure Disease Management Today
The U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, and National Heart, Lung, and Blood Institute have published a document called “Facts About Heart Failure,” NIH Publication No. 94-923, April 1994 for patients and the general population (also available on the Internet) about congestive heart failure. Excerpts from this publication, included below, are helpful in understanding the context for and application of treatment in this patient population.

2.1. Definition of Heart Failure
Heart failure is defined as a “loss of blood-pumping ability by the heart.” (NIH Pub. No. 94-923) Usually, the loss in pumping action is a symptom of an underlying heart problem, such as coronary artery disease. Heart failure usually develops slowly, often over years, as the heart gradually loses its pumping ability and works less efficiently. The severity of the condition determines the impact it has on a person's life. At one end of the spectrum, the mild form of heart failure may have little effect on a person's life; at the other end, severe heart failure can interfere with even simple activities and prove fatal. Between those extremes, treatment often helps people lead full lives.

2.2. Types of Heart Failure
The term congestive heart failure is often used to describe all patients with heart failure. In fact, congestion (the build up of fluid) is just one feature of the condition and does not occur in all patients. There are two principal categories of heart failure, systolic and diastolic heart failure. Within each category, symptoms and effects may differ from patient to patient.

- Systolic heart failure occurs when the heart's ability to contract decreases. The heart cannot pump with enough force to push a sufficient amount of blood into the circulation. Blood coming into the heart from the lungs may thus back up and cause fluid to leak into the lungs, a condition known as pulmonary congestion.
- Diastolic heart failure occurs when the heart has difficulty relaxing, or dilating. The heart cannot properly fill with blood because the muscle has become stiff. Diastolic heart failure may lead to fluid accumulation, especially in the feet, ankles, and legs. Some patients may have lung congestion.

2.3 Incidence of Heart Failure in the United States
"Between 2 to 3 million Americans have heart failure, and 400,000 new cases are diagnosed each year. The condition is slightly more common among men than women and is twice as common among African Americans as whites. Heart failure causes 38,000 deaths a year and is a contributing factor in another 225,000 deaths. The death rate attributed to heart failure has doubled since 1968, in contrast to a greater than 50 percent decrease in coronary disease mortality during the same period. Heart failure mortality is twice as high for African Americans as whites for all age groups." (NIH Pub. No. 94-923)
"In a sense, heart failure's growing presence as a health problem reflects the Nation's changing population: More people are living longer. People aged 65 and older represent the fastest growing segment of the population, and the risk of heart failure increases with age. The condition affects 1 percent of people aged 50-59, but 10 percent of people aged 80-89." (NIH Pub. No. 94-923)

2.4. Causes of Heart Failure
The heart loses some of its blood-pumping ability as a natural consequence of aging, but a number of other factors can lead to a potentially life-threatening loss of pumping activity. Prominent risk factors include hypertension (high blood pressure), diabetes, coronary disease, cardiac arrhythmias (irregular heartbeats), heart valve problems, infections of the heart, and genetic factors contributing to risks for certain heart diseases. (NIH Pub. No. 94-923)

Uncontrolled high blood pressure increases the risk of heart failure by 200 percent, compared with those who do not have hypertension. Persons with diabetes have a three- to eight-fold greater risk of heart failure than those without diabetes, and women with diabetes have a greater risk of heart failure than men. The presence of coronary disease, especially with muscle damage and scarring caused by a heart attack, also greatly increases the risk of heart failure. (NIH Pub. No. 94-923)

A single risk factor may be sufficient to cause heart failure, but a combination of factors dramatically increases the risk. Any disorder that causes abnormal swelling or thickening of the heart sets the stage for heart failure; as such, cardiac arrhythmias also raise heart failure risk. In addition, advanced age adds to the potential impact of any heart failure risk. (NIH Pub. No. 94-923)

2.5. Symptoms of Heart Failure
A number of symptoms are associated with heart failure, but none is specific for the condition. Perhaps the best known symptom is shortness of breath ("dyspnea") resulting from excess fluid in the lungs. The breathing difficulties may occur at rest or during exercise. Fatigue or easy tiring is another common symptom. As the heart's pumping capacity decreases, muscles and other tissues receive less oxygen and nutrition, which are carried in the blood. Without proper "fuel," the body cannot perform as much work, which translates into fatigue. (NIH Pub. No. 94-923)

Fluid accumulation, or edema, may cause swelling of the feet, ankles, legs, and occasionally, the abdomen. Excess fluid retained by the body may result in weight gain, which sometimes occurs fairly quickly. Persistent coughing is another common sign, especially coughing that regularly produces mucus or pink, blood-tinged sputum. Some people develop raspy breathing or wheezing. (NIH Pub. No. 94-923)

Because heart failure usually develops slowly, the symptoms may not appear until the condition has progressed over years. The heart compensates for the underlying
problem by making adjustments that delay, but do not prevent, the eventual loss in pumping capacity. The heart compensates in three ways:

1. Enlargement ("dilation"), which allows more blood into the heart.
2. Thickening of muscle fibers ("hypertrophy") to strengthen the heart muscle, which allows the heart to contract more forcefully and pump more blood.
3. More frequent contraction, which increases circulation.

By compensating, the heart can temporarily make up for losses in pumping ability, sometimes for years. However, compensation has its limits. Eventually, the heart cannot offset the lost ability to pump blood, and the signs of heart failure appear. (NIH Pub. No. 94-923)

2.6. Diagnosis of Heart Failure
In many cases, physicians diagnose heart failure during a physical examination. Readily identifiable signs are shortness of breath, fatigue, and swollen ankles and feet. The physician also will check for the presence of risk factors, such as hypertension, obesity, and a history of heart problems. Using a stethoscope, the physician can listen to a patient breathe and identify the sounds of lung congestion. The stethoscope also picks up the abnormal heart sounds indicative of heart failure. (NIH Pub. No. 94-923)

If neither the symptoms nor the patient's history point to a clear-cut diagnosis, the physician may recommend any of a variety of laboratory tests, including, initially, an electrocardiogram, which uses recording devices placed on the chest to evaluate the electrical activity of a patient's heartbeat. Echocardiography is another means of evaluating heart function from outside the body. Sound waves bounced off the heart are recorded and translated into images. The pictures can reveal abnormal heart size, shape, and movement. Echocardiography also can be used to calculate a patient's ejection fraction, a measure of the amount of blood pumped out when the heart contracts. (NIH Pub. No. 94-923)

Another possible test is the chest x-ray, which also determines the heart's size and shape, as well as the presence of congestion in the lungs. The chest x-ray also helps rule out other possible causes of a patient's symptoms. For instance, the symptoms of heart failure can result when the heart is made to work too hard, instead of from damaged muscle. Conditions that overload the heart occur rarely and include severe anemia and thyrotoxicosis (a disease resulting from an overactive thyroid gland). (NIH Pub. No. 94-923)

After the above measures have been taken, if the physician needs more data to fully understand the patient's condition and to prescribe the correct dosage of medication, the patient may be brought to the operating room for a cardiac catheterization procedure. In this procedure, a catheter is placed in the patient's femoral artery, through the venous system to the heart. Once in the heart, pressure sensors placed in
different positions are used to measure heart pressures that indicate the status of the heart.

The catheters also contain a fluid line, which allows for blood samples to be drawn to calculate the blood flow and oxygen saturation of the blood in the heart. Acute infusions of drugs may also be done at this time, to test the heart’s response to different drug dosages. The data obtained with this procedure allows the physician to prescribe medications with more information.

2.7. Treatments Available for Heart Failure
Heart failure caused by an excessive workload are curable by treating the primary disease, such as anemia or thyrotoxicosis. Also curable are forms caused by anatomical problems, such as a heart valve defect. These defects can be surgically corrected. However, for the common forms of heart failure, those due to damaged heart muscle, no known cure exists. But treatment for these forms may be quite successful. The treatment seeks to improve patients' quality of life and length of survival through lifestyle change and drug therapy. (NIH Pub. No. 94-923)

2.7.1 Medication
Most heart failure patients must take medication. Many patients receive two or more drugs. Several types of drugs have proven useful in the treatment of heart failure:

- Diuretics help reduce the amount of fluid in the body and are useful for patients with fluid retention and hypertension.
- Digitalis increases the force of the heart’s contractions, helping to improve circulation.
- Angiotensin Converting Enzyme (ACE) Inhibitors. Several large studies have indicated that ACE inhibitors improve survival among heart failure patients and may slow, or perhaps even prevent, the loss of heart pumping activity. ACE inhibitors help heart failure patients by decreasing the pressure inside blood vessels, resulting in less work needed to pump blood through the vessels.
- Patients who cannot take ACE inhibitors may get a nitrate and/or a drug called hydralazine, each of which relaxes tension in blood vessels to improve blood flow.

For more detail, Exhibit 1 lists medications that are prescribed for congestive heart failure, and a glossary of basic terms.

2.7.2 Heart Transplant
When drug therapy and lifestyle changes fail to control its symptoms, heart failure can be life-threatening. In such cases, a heart transplant may be the only treatment option. Candidates for transplantation often have to wait months or even years before a suitable donor heart is found. Recent studies indicate that some transplant
candidates improve during this waiting period through drug treatment and other therapy, and can be removed from the transplant list.  (NIH Pub. No. 94-923)

2.7.3 Left Ventricular Assist Devices
Left Ventricular Assist Devices (LVADs) are mechanical pumps which are attached to the heart which take over part or virtually all of the heart's blood-pumping activity. Transplant candidates who do not improve sometimes need LVADs. However, current LVADs are not permanent solutions for heart failure, but are considered bridges to transplantation.

2.7.4 Cardiomyoplasty
Cardiomyoplasty is an experimental surgical procedure for severe heart failure is available at a few U.S. medical centers. The procedure involves detaching one end of a muscle in the back, wrapping it around the heart, and then suturing the muscle to the heart. An implanted electric stimulator causes the back muscle to contract, pumping blood from the heart.

2.8 Living With Heart Failure
Heart failure is one of the most serious symptoms of heart disease. About half of all patients die within 5 years of diagnosis. However, half live beyond 5 years, many well into old age. The outlook for an individual patient depends on the patient's age, severity of heart failure, overall health, and a number of other factors.

"As heart failure progresses, the effects can become quite severe, and patients often lose the ability to perform even modest physical activity. Eventually, the heart's reduced pumping capacity may interfere with routine functions, and patients may become unable to care for themselves. The loss in functional ability can occur quickly if the heart is further weakened by heart attacks or the worsening of other conditions that affect heart failure, such as diabetes and coronary heart disease. Heart failure patients also have an increased risk of sudden death, or cardiac arrest, caused by an irregular heartbeat."  (NIH Pub. No. 94-923)
3. Technology

3.1 Description of the IHM Technology
The IHM consists of 2 macro components, a pacemaker-like “can” that houses electronic circuitry that processes incoming signals, and a pacemaker-system-like “lead.” The pacemaker “can” is designed to be implanted in the pectoral region. The two sensors consist of an oxygen saturation (O₂ sat) sensor and a pressure sensor.

The sensors, when activated from outside the body using a radio-frequency communication link to the implanted device, are capable of outputting continuous O₂ sat and pressure recordings. Since activation of the sensors is non-invasive, the procedure can be done on an office visit basis. Additionally, data are stored in device memory for time frames up to three months, including heart rate data, “activity” data which indicates the patient’s motional state, O₂ data and pressure data.

3.2 The Evolution of the IHM Technology
There are two ways to think about the potential diffusion behavior of the IHM technology: 1) Where is the IHM technology in the technology innovation spectrum, i.e. the technology growth process, and 2) Where is implantable monitoring on the S-curve of adoption over time, i.e. the market growth process?

Although technical improvements have been made in the initial prototype technology, the IHM technology lies near the start of the upswing of the S-curve of technical development since there is potential for greater technology innovation to improve product performance and ease of use in the monitoring function.

In the market, the IHM device is in its infancy. IHM has been implanted on a research clinical basis in two centers worldwide to accumulate data on sensor performance relative to standard measurements, sensor performance over time, and clinical side effects of the monitoring technology.

3.3 Application of the Technology
The principal application of the IHM technology is to enable physicians to better manage patients presenting with CHF with drug regimens, and in so doing, to alleviate clinical symptoms, improve quality of life, and increase survival rates. Two parameters of interest in managing heart failure include cardiovascular system pressures and cardiovascular oxygen saturation levels; therefore, the device was designed to provide an estimate of Pulmonary Artery (PA) pressure and Right Ventricular (RV) O₂ sat data.

The data will be available both acutely and as trend data over time. To date, this type of data has not been available to physicians. Given that IHM will provide this clinical data to physicians, it is still not known whether the data will improve patient management, the effectiveness of IHM monitoring at providing clinical outcomes is yet to be proven in the clinical studies. The clinical outcomes that are desired include
reduction in patient hospitalizations, improved quality of life through better drug dosing, and improved quality of life from less frequent and/or lengthy office visits.

3.4 Alternatives to the IHM Technology

The existence of alternatives to using the IHM device is one of the most significant factors in the assessing the potential diffusion of the technology in the market. Alternatives to the IHM technology may be viewed using two approaches:

1. As a simple substitute to the measurement capability that the IHM provides
2. As an alternative clinical management approach for patients presenting with heart failure.

These two approaches have significant implications for the way the device is valued in the market.

With the current focus on containing health care costs, the cost effectiveness of alternative procedures are being critically assessed in all areas, especially in high-cost areas of medical practice like heart failure. Critical to understanding IHM’s relative value is an understanding of the costs associated with CHF management. Although detailed cost data regarding separate procedures performed for each patient is difficult to obtain, aggregate numbers are available that can be used to generate rough estimates of patient management costs.

Data reported in the National Inpatient Profile indicate that there were 767,191 hospitalizations with a primary diagnosis of CHF in 1993, and 92% of these patients were discharged alive. (HCIA National Inpatient Profile, 1994, p. 511.) 16% of these patients had an operative episode, resulting in a mean charges of $21,637, or roughly $21.6K. The 84% of patients who were not treated in an operative procedure averaged $7,883, or roughly $7.9K in charges in 1993. Using these numbers, a weighted cost average for patient hospital admissions with a principal diagnosis of CHF yields the following average cost:

\[(16\% \times 21,637 + 84\% \times 7,883) = 10.1K \text{ per admission}\]

When considering that the sickest 20% of patients average 2.5 hospitalizations per year, this means that on average, each patient in the sickest 20% category generates $25K in hospital costs alone, not to mention the costs associated with decreased quality of life. From these calculations, it appears that there is an opportunity for technology to offer a solution. If IHM could decrease hospital visits alone, while maintaining the health status of the patient, it would substantially improve the cost-effectiveness of CHF treatment.
3.4.1 Substitutes for IHM
A simple "substitute" for the IHM device would be another patient monitoring method that provides the same data for the physician. As yet, no direct substitutes exist, since there are no chronic implanted monitoring systems on the market. But there does exist an equivalent in the form of an invasive hemodynamic monitoring procedure. One example of an invasive procedure is known as a Swan Ganz catheterization procedure, which is conducted when patients are hospitalized for treatment of severe symptoms. Invasive procedures are indicated when patients present with symptoms such as pulmonary edema, severe respiratory distress, or O₂ saturation below 90% which is not due to pulmonary disease, and when the physician needs to determine the correct therapy to use. (Konstam, 6)

In the substitute monitoring procedure context, the value of IHM is clear for patients who require frequent invasive monitoring sessions. With an implantable monitor, patients would not require an invasive procedure that is both costly and unpleasant for the patient. The cost of the catheterization procedure itself contributes most to the cost. For example, for pacemaker implants, which represent a similar procedure, the average charges per procedure in 1993 were $10,332, not including medical supplies. (HCIA and Ernst & Young, The DRG Handbook, 1993 p. 71. Millar Instruments, Inc., a company which manufacturers temporary heart catheters, lists catheters with prices ranging from $395 to $4725. Disposable models are priced between $395 and $560. (Millar Instruments, Inc., price list, Feb. 01, 1995.) Therefore, each time a patient is monitored invasively it costs about $10.5K.

The cost data suggest that there may be a need for a technological solution to replace these expensive procedures for patients who require repetitive invasive monitoring. If it could be shown that implanting the IHM monitor would preclude the need for subsequent invasive monitoring, implanting the IHM monitor would be indicated whenever the expected cost of implant and subsequent monitoring by IHM, plus related costs of side effects, is less than the cost of another hospitalization and Swan Ganz procedure.

Unfortunately, however, it is not often possible to isolate which patients will require future monitoring, thus calculations of value are made more complicated. Some data indicate that "admission rates as high as 57% within 90 days have been reported in patients over the age of 70 years." (Konstam, 6) But even so, it is not known how frequently invasive cardiac catheterization procedures are performed in these patients.

3.4.2 Clinical Management Alternatives
Since it is difficult to position the IHM device as a simple substitute for acute monitoring methods because it is not always possible to predict which patients will need subsequent invasive monitoring, the value of the IHM technology will be assessed as an "alternative management strategy" for patients with CHF. In this
context, the total patient benefit in terms of addition to quality of life and the total cost of patient care will be considered to assess the value of the technology. The primary benefit that the device is targeted to offer is reduced hospitalizations; with reduced hospitalizations, quality of life would increase and cost of care will decrease.

To demonstrate the value of the IHM in this context, clinical studies will be necessary to show that managing CHF patients with the IHM device results in fewer hospital visits. At present, this position has not yet been demonstrated. Although physicians are enthusiastic about the technology, they do not know what patient benefit, in terms of clinical outcomes, will be provided by IHM. A long, detailed clinical trial with statistically significant numbers of patients and proven clinical outcomes will be necessary to demonstrate the benefits of the technology and its cost-effectiveness versus the alternatives.

But difficult though the clinical process could be, it is speculated that the long-term gains in clinical utility would be realized when the device is used in patients presenting in the earlier stages of CHF, where monitoring could potentially play a role in slowing disease progression by preventing patient “crashes” that result in hospitalization. The “crashes” are thought to be caused by inadequate management of drug regimens. If the technology proves effective in the sickest 20% of patients, the patient indications for the device could be substantially expanded from the initial critically ill population.

To compare to alternative management methods for CHF, the perceived relative advantages of each method will determine the market acceptance. Alternative management methods, described in chapter 2, have associated costs between $7225 to $410K. Exhibit 2 details the alternatives that exist for treatment of CHF at various stages of the illness, and the estimated costs, benefits, and disadvantages for each management method. The closest patient management alternatives to management with IHM are:

- Traditional patient management. This method offers conventional outpatient care at the primary care physician level. With this approach, drug therapy is prescribed, but extensive efforts to optimize drug regimen are not utilized. The benefits of this approach are that it is inexpensive up front, well-known, and the standard of care. This method exhibits varying patient effectiveness.

- Manage with intensive clinic follow up. With this approach, patients that are 75% likely to be hospitalized due to complications with CHF are enrolled in a “Congestive Heart Failure Clinic” program that manages CHF through knowledge of the patient history and current condition, in an effort to preclude “probability of inappropriate treatment and/or over utilization of (high-tech) hospital resources.” (Beyond Four Walls, p. 88) Although this method is yet to be proven, the potential benefits include possible reduced hospitalizations, improved patient compliance, and possible improved quality of life. The
disadvantage is that there is an expansion of patient population, with no firm data to show the reason to do so.

Of all of the management options, IHM is unique in that it does not provide any therapy. Instead, IHM is designed to make existing drug therapies more effective, which would then obviate the more aggressive interventions. The perceived effectiveness of using IHM's monitoring data to improve clinical outcomes will determine the perceived relative advantage of using IHM as an alternative management strategy for treatment of CHF. The benefits of IHM monitoring, therefore, will need to be assessed in long-term clinical studies to show the comparison of IHM to alternative management methods.
4. Market

In addition to the crucial role that technology performance plays in the potential diffusion of the IHM device, the complex interactions between the multi-level buyers involved in the health care system are important as well. Buyer levels include patient, general practitioner, heart failure specialist, implanting physician, hospital provider, insurance payer, and integrated service network. To assess the impact of each of the buyer levels on the diffusion of the technology, it is useful to outline each level's incentives to understand how the technology is aligned or not aligned with each buyer's goals, and to understand the mechanisms of influence at each level. Exhibit 3 shows a breakdown of the buyers and their incentives.

To fulfill each buyer's needs, IHM has to be technically effective, clinically effective, and cost effective compared to the alternatives. The general buyer categories for IHM and their incentives are patients, physicians, and payers.

4.1 Patients

The ideal patients indicated for the device are those who are ambulatory, but in later stages of heart failure. Patients who are not in critical condition do not have as great a need for close monitoring, and patients who are so sick they are already in the hospital are monitored with invasive hemodynamic lines, electrocardiogram recording devices, and other techniques. Doctors report that the ideal patient for the IHM device would be in stage III heart failure, and still lead a relatively active life. (interview with Dr. Beverly Lorell, March 16, 1995.)

The patient's interest is to remain as healthy as possible, to avoid hospitalizations from "crashing" experiences, which result when the CHF is poorly controlled, and to avoid death.

4.2 Physicians

Physicians will assess the merits of the IHM technology based on their perceptions of the patient outcomes associated with IHM-guided therapy. Their interest is to offer well-founded, competitive care to their patients, and to earn a living from their work as physicians. In the past, physicians were held responsible for choosing medical therapies without respect to cost, but as the health care environment is changing, more pressure will be exerted on physicians to make cost-effective decisions in addition to deciding what clinical course is necessary.

As the health care system has become increasingly more regulated, physicians have been required to follow reimbursement guidelines that designate which medical procedures are reimbursed by each payer. Physicians working under this system most likely choose only those procedures that are reimbursed by the patient's insurance company, unless they believe that the benefit a procedure offers a patient outweighs the cost of negotiating with the payer organization and the risk of not being reimbursed. In the "reimbursement by procedure" system, therefore, the payers take responsibility for cost-effectiveness decisions.
In the future, it may be the case that physicians are primarily reimbursed on a per-person basis for their services. Under fee-per-person "capitation" systems, the insurer (payer) pays the same monthly fee for each patient served by the physician, regardless of the work the physician does. (Quint, NYT, Feb. 09, 1995, p. A1) Capitation reimbursement is currently gaining favor among insurance payers and physicians. Capitation arrangements "now cover at least some patients of one in every four doctors, according to the American Medical Association. And one recent survey by John Alden, a Miami insurance company, showed that doctors accepting per-person contracts expect such patients to provide about two-thirds of their income in five years, compared with 16 percent now." (Quint, NYT, Feb. 09, 1995, p. A1)

Changes in reimbursement structure will affect physicians' health care technology choices. If physicians are reimbursed on a capitated basis, not only will physicians assess the benefit to risk ratio of alternative procedures, they will also assess the cost-effectiveness of alternative management strategies. Under capitated reimbursement systems, physicians' incentives are more closely aligned with containing medical costs. They will likely be financially conservative when choosing procedures for patients, since their choices affect their own compensation. Some physicians may also delay, or "balk" at, prescribing a procedure that are expensive up front, even when it is indicated, if they feel there is a possibility that the patient may do well without it.

4.3 Payers
Payers for medical care have become increasingly cost-conscious in the past ten years, and will continue to do so. The inherent interest of the payer sector is to minimize cost and maximize health outcomes. To gain payer approval, the IHM technology will have to demonstrate that it is both clinically effective and cost-effective when compared to other CHF management alternatives. The measure of cost-effectiveness will include the expected benefit the device will provide in terms of health outcomes, versus the expected total patient management costs, including the expected hospitalization costs and other medical care costs.
5. Potential Competitors
At this stage in the technology development cycle, no competitors that produce implantable monitoring technology are seen on the horizon. Likely future competitors include other pacemaker manufacturers, who also possess the prerequisite expertise in implantable technology and distribution systems, or companies that produce acute monitoring technologies.

5.1 Pacing Industry Potential Competitors
The potential competitors from the pacing industry include Pacesetter (recently acquired by a heart valve manufacturer), Intermedics, Teletronics, CPI, and smaller, more innovative companies like French ELA Medical and Biotronik. In comparison to these competitors, Medtronic has led the pacemaker market in percent market share since the beginning of the pacing industry in 1960, and Medtronic currently spends the most on R&D. With regard to positions in implantable hemodynamic monitoring, Medtronic 1) is the only one with R&D experience to date, 2) owns a portfolio of patents on the technology, and 3) possesses a superior distribution system, in size and in breadth, for marketing an array of cardiovascular technologies.

5.2 Potential Competition from Monitoring Companies
In addition to pacemaker manufacturers, other possible entrants into the chronic monitoring business are companies that produce acute (not chronically implantable) measurement technology, such as Millar Instruments, Inc. Millar has extensive experience in miniature pressure transducers, thermistors, and doppler sensors used in temporary catheters. These companies possess tremendous technical expertise and recognition in the market, and will need to be assessed closely.

5.3 Competition from Medication
Since the IHM technology provides an incrementally improved method of managing CHF, it doesn't compete against the two closest alternative management methods, drug therapy and clinic follow up; it complements them. If new drugs should be found that are more effective in treating CHF with less need for close monitoring, IHM would be affected, but the likelihood of major drug development in the short term is small.

5.4 Competition from Other Alternative Management Strategies
Since other alternative heart failure management technologies (Left Ventricular Assist Devices, artificial hearts, heart transplant, etc.) are very different than the IHM concept, it is unlikely there will be technological innovation in separate areas that will significantly affect the relative advantage of IHM. Although these technologies serve the CHF patient population, they are therapeutic, highly invasive, and extremely expensive. Typically, these procedures are reserved for the most desperate patients. Therefore, it is expected that the market for the device will be determined based on IHM's technical and clinical performance compared to drugs and clinic follow up alone, not its comparison to other evolving technologies.
5.5 Competition from Intensive Clinic Follow Up
There is a strong threat that changes in clinical practice could substantially reduce the potential benefit that the IHM device offers. Heart failure clinics are beginning to implement intensive follow up practices, where patients are seen more frequently and cared for more closely, in order to achieve better patient outcomes and reduce health care costs. It is possible that heart failure management via intensive clinic follow up will yield the same or better clinical outcomes as with using an IHM device. If this becomes the case, it will be more difficult to demonstrate the value of the technology.
6. Manufacturer

6.1 Manufacturer Competencies
The IHM technology is aligned with Medtronic's incentives to innovate. In the organizational sense, since Medtronic's expertise is in implantable cardiac products, the IHM innovation is incremental and competence enhancing. Medtronic also possesses an extremely effective distribution network for other implantable cardiovascular products. Since IHM would add to a portfolio of cardiovascular technologies, it is also incremental in the economic sense, because would allow Medtronic to expand into a new market area.

6.2 Marketing Activity
Marketing activity includes advertising, detailing, sponsoring workshops and societies, presenting at meetings, and other selling activities. In the past, Medtronic has been successful in marketing by sponsoring physician meetings. During the evolution of the pacing industry, it is thought that "the majority of physicians probably began prescribing pacers only after a respected colleague described or demonstrated, in person, his or her own success with the technique. For this reason, the most effective early promotion of pacing was done by expert users who not only wrote articles but also took part in hospital rounds and other lectures, seminars, and symposia on the subject. This is where the pacemaker manufacturer's entered the picture, for they sponsored many such educational forums." (Homer thesis, p. 69)

Today, since insurance payers have more influence in the acceptance of new medical technologies, marketing effort is necessary to reach payer organizations as well as physicians.

6.3 Technical Development
The starting point for technical development is a definition of the ideal device that would suit the needs of the managing physician. At a minimum, the ideal monitoring device would have the following characteristics (Interview with Dr. Beverly Lorell, March 16, 1995):

- Absolute pulmonary artery diastolic (PAD) pressure measurements within +/- 1-2 mm Hg.
- Small, flexible lead design, less than 7 French size.
- Cardiac output data
- Easy to implant
- No side effects

The PAD pressure is the pressure in the pulmonary artery, the artery leading from the right ventricle into the lungs, when the heart is full of blood and is in diastole. "Diastole" means that the heart is in the part of the cardiac cycle where it is not compressing to eject the blood, versus systole, when it is compressing. French size is a measure of the outside diameter of the lead body and sensor. A French size of 7
corresponds to an outer diameter of 2.33 mm, or 0.092 inches. Cardiac output refers to the amount of blood that the heart circulates through the body; oxygen saturation is a measure of the heart's effectiveness.

Physicians are likely to compare the technical capability of the IHM device to acute measurement technologies such as the recently released right heart Millar catheter. (interview with Dr. Beverly Lorell, March 16, 1995) The Millar model MPA-372T, for example, is a 7 French size disposable sterile right heart catheter that offers a pressure sensor, polyurethane balloon, infusion lumen, and thermistor. It is advertised "for measurement of PAP (pulmonary artery pressure) by Catheter-tip Pressure Sensor, PCWP (pulmonary cardiac wedge pressure) by Catheter tip Pressure Sensor, Cardiac Output by Thermodilution, Right Atrial Pressure, and Blood Temperature." (Millar product literature) It can also be used for taking blood samples and infusing solutions. Exhibit 4 shows a diagram of the Millar catheter device.

Although the ideal characteristics for an implantable monitor are possible to elucidate, the technology takes time to develop. IHM does not offer all the features that are offered by the acute measurement catheters because it isn't possible and/or desirable to implement them chronically.

6.4 Strategic Options
The strategic options open to Medtronic for introducing the IHM technology to the market are encompassed by the following questions:

1. At what level of technology development should IHM be launched?
2. How should IHM be priced?
3. How should IHM be marketed?

The first question involves the timing of introducing the technology. Should Medtronic launch sooner, when the IHM device is still technically immature and clinical studies have not demonstrated clinical performance over longer periods of time? Or should Medtronic wait until later, for a more technically advanced IHM device and more clinical data to support it?

The second question addresses the price considerations for launching the IHM technology, and concerns the roles that technical substitution and technical change play in introducing the technology. What is the innovation worth to the customer, and how is that value demonstrated? What does it take the place of? Additionally, what added value can be ascribed to the technology? How will cost-effectiveness analysis enter into the pricing considerations?

The third question considers who should be the main targets for marketing efforts. Where is the leverage in marketing spending? Which distribution channels should be
focused on? What are the key sources of influence that will drive the acceptance of the technology in the market? How important will service be to adoption?

To answer these questions, a thorough understanding of the technology, the business opportunity, and the diffusion characteristics for the technology are required. Once understood, it is possible to quantify the relationships in the system dynamics model. Hopefully, experimentation with the model will give insight into the critical dimensions of interest in answering the strategic questions.
7. Payers for Medical Technologies and Procedures

Payers consist of private insurance agencies and government-supported medical insurance programs, such as Medicare and Medicaid. Reimbursement guidelines tend to be local in nature, related to the reimbursement policies of local insurance payers, even for government-supported insurance programs. Medicare is funded by the U.S. Health Care Financing Administration (HCFA), but it is administered by approximately 55 fiscal intermediaries that are operated locally, such as Blue Cross/Blue Shield. It is the fiscal intermediaries that make coverage decisions for procedures. (telephone interview with D. Warkentin, Apr. 10, 1995) Although a U.S. Medicare coverage manual exists, the guidelines are relatively broad, the manual is sometimes out of date, and decisions regarding new or unusual procedures are still made on the local level.

Although there is an historical differentiation between the reimbursement policies of private and government-supported programs, the gap is closing. For example, historically, private insurance tended to pay more for procedures, paying the amount that was charged, whereas Medicare, for the most part, reimbursed only the amount listed in the "Diagnosis Related Group" (DRG) guidelines. Currently, private insurance companies are formulating their own reimbursement guidelines, using technology assessment groups to make recommendations. Also, as noted above in the discussion of physician incentives, payers are opting to provide reimbursement to physicians and hospitals on a capitated basis to contain health care costs.

By the year 2000, the health care reimbursement system is likely to be primarily governed by two groups, Managed Care Organizations and Medicare. The concept of managed care is to apply business principles to the health care system. By grouping patients into large units, and organizing care providers to maximize efficiency, it is hoped that business practices such as volume pricing and cost competitiveness will induce a decrease in health care costs, while maintaining the service level that exists.

7.1 Managed Care

Managed Care includes Health Maintenance Organizations (HMOs) and Preferred Provider Organizations, for purposes of this thesis, are defined as health insurance payers who do the following (Bailit speech at MIT, October 20, 1994):

- serve a target population
- pay a fixed dollar amount for the care budget per group
- have a defined benefit for reimbursed services
- set a network of care providers for services

The proportions of the population that are covered by a managed care system is increasing as well; it has reached 25% total penetration in the market, and is expected to keep growing. (Bailit, 1994)
7.1.1 Integrated service networks:
Integrated service networks (ISNs), an advanced form of a managed care organization, coordinate the continuum of services to provide clinically and fiscally responsible service. In addition to the characteristics of managed care organizations listed above, ISNs own large components of the health care delivery system, such as doctor's offices, community hospitals, and acute care hospitals, and care is integrated between separate components. ISNs were established at around 20 hospitals across the country by July 1994, and they are continuing to expand. By 2000, it is expected that 50% of the market will be controlled under an ISN. (Bailit, 1994)

The organization of ISNs consists of:
1. One-board governance structure
2. Financial risk place on hospitals as cost centers
3. Strong physician leadership
4. Advanced information systems
5. Clinical integration

The customer interests of managed care organizations and those of ISNs are essentially the same: to control medical costs while providing quality service. To do so, there has been two strategies: 1) to control costs by carefully monitoring the procedures that are reimbursed by the organization, and 2) to reimburse physicians and hospitals with a "capitated" system, where the providers receive a set lump sum for taking care of the needs of a certain group of patients, without regard to which procedures that are chosen for individual patient management.

7.1.2 Reimbursement per Procedure
Reimbursement per procedure is the traditional methodology for paying health care costs. Physicians and hospitals bill the patient's insurance company, and the insurance company pays the provider for the service. Recently, to reduce overall health care spending, however, managed care organizations have restricted which medical procedures are reimbursed, and have required that drugs, for instance, be chosen on a formulary before they will be reimbursed.

With "reimbursement by procedure," the payer organization takes responsibility for choosing the appropriate medical procedures to implement, and the physicians are limited to reimbursement at the insurer's rate for those procedures that are mandated by the payer organization.

The mean charges for non-operative procedures for patients with CHF in 1993 were $7,883, and for operative procedures were $21,102. (HCIA 1994, p. 511) What this means for the IHM monitor is that total reimbursement, under any system, needs to fall within this range to be competitive with alternative procedures on a cost basis. In addition to the cost basis, the additional benefit the
device provides will also be taken into account when assessing the overall cost effectiveness of IHM guided therapy.

7.1.3 Capitated Reimbursement
An option to reimbursement per procedure is a system called "capitated reimbursement," in which physicians and/or hospitals are paid to manage a group of patients, and are paid based on the number of patients in the group. In capitated reimbursement, the responsibility for choosing the appropriate medical procedures for a given patient rests with the physician. In early 1995, approximately 16% of physician income came from reimbursement on a capitated basis; in 2000, the percentage is expected to reach 66%. (Quint, NYT, Feb. 9, 1995, A1)

Since the provider's pocketbook is directly affected by their care choices, the intent is to motivate providers to make the wisest decisions for both patient outcome and cost effectiveness. There is concern, however, that this system will not motivate physicians to provide the highest quality care, even when it is warranted in certain patients, or that physicians will postpone procedures that are costly up front in favor of waiting to see if less costly procedures are effective in treating the patient first.

7.2 Medicare
Medicare, the government's medical insurance program, covered approximately 80% of the patients who developed congestive heart failure in 1993, since the great majority (81.1%) of patients are over 65. (National Inpatient Profile, HCIA 1994, p. 511) Like the private insurance system, Medicare is also working to reduce total medical expenditure, in an increasingly aging US population.

In the past, Medicare has used the "Diagnosis Related Groups" or DRG's to limit expenditure, by paying a certain amount for a given disease diagnosis, or in some cases, for a particular procedure. For example, DRG 116, which covers permanent cardiac pacemaker implants in patients without AMI (acute myocardial infarction), heart failure, or shock, the total average reimbursed charges were $18,169 in 1991. (DRG handbook, 1993)

Medicare is also transitioning into managed care and capitated reimbursement systems, so the DRG's may not be the focal point in the future. Hence, the physician, again, will likely be responsible for choosing technologies and patient management methods that provide the highest benefit per cost incurred to the system.
7.3 Cost Effectiveness Analysis

With the advent of cost-controlling mechanisms in health care, as discussed above, it appears that a structurally sound analysis of the prospects for success for a new medical technology rests in the assessment of its cost effectiveness. If the technology is able to provide additional benefit to the patient that outweighs the additional costs incurred to the system, the technology will be successful in the health care marketplace.

"Cost-effectiveness analysis is designed to achieve the best tradeoffs and to rank competing health care interventions or programs to arrive at the best possible use of resources." (Kupersmith, p. 177) Usually, the data used for such analyses come from clinical trials with long time horizons. To determine cost effectiveness, either life expectancy or quality of life may be used to assess the benefit a technology provides to the patient. The cost for a therapy is also compared with an the cost of the alternative, to find the added benefit per added cost of the therapy of interest.

With the IHM monitor, the value of the device to the patient is expected to come from increases in quality of life, not quantity of life; therefore, the measurements of interest will be in the quality term. The equation used to calculate the cost-effectiveness in terms of cost-utility, when assessing changes in quality of life, is as follows:

\[
\text{Cost-Utility} = \frac{\text{Cost with New Technology} - \text{Cost without Technology}}{\text{QALY with New Technology} - \text{QALY without Technology}}
\]

where QALY = the Quality-Adjusted Life Years expected for each outcome. (Kupersmith, p. 165)

The cost-effective range of medical therapies has been explored. "It has been stated by Goldman et al in 1992 that a cost-effectiveness (utility) of $20,000 to $40,000 per quality-adjusted life year (QALY) is consistent with other funded programs..." (Kupersmith, p. 243.)

To arrive at QALY, one must assess the patient's "reduction in the value of a healthy year that is caused by pain, disability, or other poor health factors as perceived by the patient" using some numerical scale. (Kupersmith, p. 165) With heart failure patients, perhaps one way to do so is by using a standardized survey, such as the Minnesota Living with Heart Failure questionnaire, to assess how the patient's lifestyle is affected by their heart failure. If the patient has a score of 0 on the questionnaire, the patient has a Quality of Life index of 1, corresponding to 100% healthy; this means that one year of life in this patient's life equals 1 QALY. If, however, the patient scores 50, the patient is only 50% healthy; therefore, one year of the patient's life is only worth one half of one year. With this assessment method, therefore, if we expect that patients will have the same life expectancy with different treatments, the differences in benefit of different medical management methods are attributed to the differences in patient perceived outcomes.
Although assessing QALY using patient questionnaires such as the Minnesota Living with Heart Failure questionnaire makes intuitive sense, physicians indicate that surveys of this type are prone to be more related to psychological well-being than physical well-being. If patients have a positive mental attitude, they are more likely to respond positively to the questionnaire. Also, there is a strong placebo effect associated with being part of a clinical trial, where patients, perhaps subconsciously, expect that they should be reporting improvement as time goes on during the study. For these reasons, measuring quality of life directly is problematic when assessing health outcomes from medical interventions.

It may be postulated that one hospital visit is worth a fraction of a quality adjusted life year. By reducing the number of hospitalizations through improved medical management, IHM could improve a patient's quality of life by simply precluding the necessity of visiting the hospital, without even considering the possible improvements in the patient's functional status related to the improved medical management. Measuring the number of hospitalizations per year is relatively straightforward, and is a concrete measure of the health status of the patient.

A rough estimate of the benefit value of one less hospitalization, in terms of a numerical measure of QALY, can be assessed given the current costs of one hospitalization. The average cost of hospitalization, given previously, is about $10,000. Since the cost effective range has been speculated to range between $20,000 - $40,000 per QALY, if it is assumed that current hospitalization spending is cost effective, one hospitalization could be said to be worth 0.25 to 0.5 QALY. The addition to cost-effectiveness by reducing hospitalizations could alternatively be calculated by reducing the cost in the cost-utility equation, with the same result.
8. Interview Data
To gather data on the appropriate parameterization of the IHM system dynamics model, literature was reviewed, physicians were interviewed, and the Medtronic management team was consulted. Three physicians were interviewed using the interview format listed below. Data gathered in the physician interview process is presented following the survey. Due to time constraints during the interviews, not all physicians answered all questions; therefore, individual responses are noted with the physician's initials.

8.1 Introductory Statement
My name is Karin Knoll, and I am a master's student at MIT's Sloan School of Management. I am currently writing a master's thesis, using a system dynamics approach, to understand the diffusion of a new medical technology. The specific technology I am investigating is an Implantable Hemodynamic Monitor (IHM) designed to aid in the diagnosis and treatment of patients with congestive heart failure. This device is currently in the early R&D stage with Medtronic, Inc.

The thesis work is based on a large system dynamics model that was completed by Jack Homer in 1983. Dr. Homer created a general system dynamics model for the diffusion of new medical technologies that can be parameterized for different technologies. Dr. Homer tested his model against historical data for pacemakers and a drug called clindamycin. My goal with the thesis work is to parameterize his model to fit the IHM technology, by adjusting the numbers from the pacemaker case to suit the IHM case. To do this, I'd like to ask you a series of questions related to I) your background, II) the benefit, in patient outcome terms, that you would expect to achieve using the device, III) the patient eligibility for the device, and IV) the physicians that you would expect to be involved in using the device.

8.2 Physicians Surveyed

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<thead>
<tr>
<th>Name</th>
<th>Interview Date</th>
<th>Primary Position</th>
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<tbody>
<tr>
<td>Dr. Beverly Lorell (BL)</td>
<td>March 16, 1995</td>
<td>Invasive Cardiologist</td>
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<td>Beth Israel Hospital</td>
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<td>Boston, MA.</td>
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<tr>
<td>Dr. Thomas Piamonte (TP)</td>
<td>March 17, 1995</td>
<td>Invasive Cardiologist, pacemaker implanter.</td>
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<td>Private Practice</td>
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<td>Needham, MA.</td>
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<td>Dr. Terrence Norchi (TN)</td>
<td>April 02, 1995</td>
<td>Medical Resident</td>
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<td>Bay State Medical Center</td>
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<td>MIT Sloan MBA student</td>
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<td>Cambridge, MA.</td>
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8.3 Physician Interview Guide and Responses
(Note: physician responses, indicated by initials, are not direct quotes.)

1. With regards to the Minnesota Living with Heart Failure Survey, what is the average expected benefit from the device for the first patients to receive the device?

   BL: A clinical study would need to be completed to understand the benefit provided by the device. Before any benefit could be obtained, though, the accuracy of the pressure measurements would have to be clearly understood. Absolute pressure measurements are mandatory, and they have to be within 1-2 mm Hg to provide any value to the physician. I'm also a bit skeptical of taking measurements in the RV and extrapolating to determine PA pressures.

   TP: Not sure. I would expect that intensive clinic follow up might cut down hospital admissions by 1/3 or so... with IHM, how much better? Patients with IHM would have to be compared to "randomly followed" patients, I think, to see a pronounced benefit over intensive clinic follow up.

   TN: I would not expect the outcome to be substantially different than monitoring the patients with other methods; what is important is paying attention to clinical data. I think a physician can assess a patient's status pretty quickly through routine clinic assessment measures, such as weight, water retention, etc.

2. What procedures, such as jugular venous pressure measurements or Swan-Ganz procedures, could you foresee the IHM monitor taking the place of?

   BL: NA.

   TP: IHM could take the place of some of the clinical signs now used, such as sudden weight gain from water retention, chest x-ray, neck vein distension, pulmonary edema. What is important is that the patient and the physician are targeting a number closely; the process of following a patient closely, watching the clinical indicators, is the important point.

   I would really like to have the sensor positioned in the left atrium, to get a direct measure of left atrial pressure, and estimated wedge pressure. Pressures measured from the RV aren't as sensitive or predictive of heart failure.

   TN: NA.

3. Would you anticipate any kind of side effects from the device? What would you expect the frequency of occurrence of side effects to be? The duration?

   BL: I would be very concerned that the relatively large, stiff lead could perforate the thin RV wall of the dilated heart. This could happen at implant or over time.
The RV wall ranges in thickness from 2 to 7 mm; CHF patients are more at risk because their hearts are dilated, and therefore thinner. Technological development should be aimed at reducing the size of the lead; it should be possible to get the sensors and lead bodies down to the size of their temporary equivalents, such as the Millar RV Heart catheter.

TP: I think the incidence of side effects would be similar to the pacing population, but it should be considered that the sicker the patient, the more risky an implant procedure is. Patients with LV dysfunction have ejection fractions less than 25%, and have elevated resting wedge pressures; their cardiac outputs and cardiac indexes are lower, such that they are more easily compromised.

TN: NA

4. At what ratio of potential benefit to potential additional cost (in comparison to alternative management strategies) do you think you would be indifferent to using the IHM device?

BL: NA.

TP: Hmm. Difficult to say....For hypertension, patients use drugs that cost $2.00/day; a rough annual cost of $2000/year to treat them. Under capitated reimbursement systems? It would have to be cost-effective in the long run, and that's hard to know before it's been used.

TN: I would choose the same therapy for patients, regardless of cost, if I thought it was beneficial to the patients. What is important is the outcome. I would have to see if patients could be managed better using the device than with out it.

5. What is the maximum percentage of the CHF population that you think the device could ever provide benefit to?

BL: The device is best suited to Class III ambulatory patients, patients who can be at home and lead a relatively active life. Class III patients are about 30% of the patient population.

TP: 1% or less. I can think of one particular patient who would be ideal for the device. He's 75, and would be a transplant candidate, but he's too old to be on the waiting list. 6 months ago he had his mitral valve replaced. His wife is very attentive, and makes sure he takes care of himself.

TN: NA.

6. What other technologies do you see as alternatives to the IHM monitor? What technologies may exist in the future?
BL: Acute monitoring using Millar catheters.

TP: We've never had the capability before...there isn't a direct substitute for chronic O₂ sat and pressure measurements. The Swan Ganz procedure is a substitute. Another technology that is related is the Greenfield filter, that prevents clots from going into lungs.

TN: NA.

7. Do you think there may be some patients who are implanted, but do not end up using the device for follow up? If so, in what case? What fraction might you expect this to occur in?

   BL: NA.
   TP: NA.
   TN: NA.

8. Who do you think will be the physician/medical expert of choice for referring the device? For implanting the device? For following up patients with the device?

   BL: NA.
   TP: General cardiologists; invasive cardiologists and pacemaker implanters; general cardiologists.
   TN: All doctors; invasive cardiologists; all doctors.

9. How many implants a year do you think the average implanting physician could comfortably add to their patient load? Would be willing to add to their patient load?

   BL: NA.
   TP: Limitless; it's not an issue. There are too many invasive cardiologists.
   TN: NA.

10. How many follow-up patients do think the average following physician could comfortably add to their patient load? Would be willing to add to their patient load?

    BL: NA.
TP: If they are already seeing the patient anyway for other follow up care, it wouldn't be difficult to use the IHM device as part of follow up.

TN: NA.

11. Any other comments?

BL: The sensor technology development is the most critical part of this R&D project. The manufacturer will need to understand the physics of heart pressure measurements in great depth to develop chronic sensors to address this patient population. Also, the technology should be as good or better than what is used already, both in handling and performance. I would expect the IHM technology to perform as well as the new Millar right heart catheter, for example. Millar has developed expertise in miniaturizing pressure sensors that is state of the art.

TP: Perhaps the IHM monitor would be useful to get a reasonable cardiac output estimate. The clip-on O₂ saturation sensor used on the finger could be used to get the arterial (A) O₂ sat, and the venous (V) would be known from the O₂ sat sensor in the RV. One can get a "poor man's cardiac output" measure using the Fick method, by calculating the A-V difference. That could be pretty neat!

I'd be very interested in trying the device in a clinical trial. It sounds like a fascinating technology.

TN: It's going to be difficult to demonstrate the value of the technology. I think physicians can do a reasonably good job at monitoring patients without invasive technology. It's going to be tough to show additional benefit.

8.3 Manufacturer Interviews
In the course of the interaction with the Medtronic management team, the nature of the IHM business opportunity was analyzed and data was gathered to adjust the Homer model to suit the IHM technology case. Specifically, the Homer model was presented, and data was gathered from the team in regard to the expected patient population, cost of management alternatives, device performance, technology progression, market variables relevant to the IHM technology, and the expected benefit of an IHM implant to patients.
9. Uncertainties

9.1 Uncertainties in Technology Performance
In the early stages of R&D, the performance of the technology is uncertain with respect to accuracy and precision over time. The technical performance will impact the device's potential benefit to patients. If it cannot perform within the range where physicians find the information exact enough to be useful to treat patients better, or with less cost to the medical system, the value of the device will be lost.

9.2 Uncertainties in Patient Benefit (and side effects)
By far the most important uncertainty relevant to the diffusion of the IHM technology in the marketplace lies in the amount of patient benefit the technology will provide. Will knowledge of the IHM monitoring data allow physicians to titrate patient therapies to the extent that patients experience statistically fewer hospitalizations per year? Will they report better scores on the Minnesota Living with Heart Failure questionnaire? Or will the implementation of the technology in the patient's care regime help in other ways, i.e. the ability to telemeter signals over the phone allowing patients to be cared for from home instead of having to go to the follow-up clinic? The potential benefits of the technology will need to be explored in depth.

Potential side effects are unknown as well, but experienced pacing personnel believe that the IHM device will perform the same in terms of side effects as a bradycardia pacemaker implant, even though the patient population is not the same. This is reasonable given the similarity between the pacing technology and the IHM technology, and the assumption that IHM implanters will likely be experienced pacemaker implanters as well. Moreover, a relatively large fraction of the pacing population in Medtronic's database also has congestive heart failure, with no known additional complication rates reported. (telephone interview, Dwight Warkentin, April 10, 1995)

9.3 Uncertainties in Market Acceptance
The physician acceptance of the device is also uncertain. How will physicians perceive the benefit of the IHM technology? How will the level of technical development affect physician acceptance? (i.e. pressure sensor configuration, size of lead bodies, software presentation, etc.) How will their perceptions of potential side effects enter in? How will capitation affect physicians decisions? If capitation is the reimbursement method, what fraction of physicians will balk at using expensive, up-front technologies?

9.4 Uncertainties in Payer Organization Structure and Acceptance
Finally, in addition to the uncertainties in technology performance, patient benefit, and market acceptance, uncertainties at the payer level will also affect IHM diffusion. If procedures are reimbursed on a per-procedure basis, how will the IHM device's performance be perceived by payer organizations? Once device performance is assessed, how will it affect the likelihood of being reimbursed? What percentage of
physician income will be by capitation, thus affecting the decision point for technology use? What will be the key influence mechanisms that drive acceptance in each case?

These uncertainties may each be addressed with model simulation. The model will be useful in analyzing potential diffusion characteristics for each case, by displaying the behavior under each set of assumptions. Although accurate predictive value is unlikely, the general behavior of the model may provide insight into the range of possible outcomes resulting from the launch of the IHM device.
10. Description of Model

10.1 Model Overview
An overview of the model, depicted in the subsystem diagram below, shows the relationships between the individual sectors and the higher-order organization of the model. The major subsystems in the model are Physician Activities, Manufacturing Activities, and Payer Activities. Within these subsystems are major subsectors, and within the subsectors lie the individual sectors that comprise the model. As indicated by the arrows, the sectors of the model interact with one another on multiple levels.

Subsystem Diagram
### 10.2 Model Boundary

<table>
<thead>
<tr>
<th><strong>Endogenous (defined within the scope of the model)</strong></th>
<th><strong>Exogenous (input parameters that are constant over time or input variables that are dynamic over time)</strong></th>
<th><strong>Excluded (outside the scope of the model)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient Selection, Treatment, and Follow-Up</td>
<td>- Initial values for Stocks</td>
<td>- Government Regulation</td>
</tr>
<tr>
<td>- Benefit-Cost Ratios</td>
<td>- Universe of New Cases (patient incidence rate)</td>
<td>- Competition</td>
</tr>
<tr>
<td>- Relative Benefit-Cost Ratios</td>
<td>- Patient population demographics</td>
<td>- Decisions by Hospitals</td>
</tr>
<tr>
<td>- Patient Eligibility Fraction</td>
<td>- &quot;Normal&quot; values for benefit, cost, etc.</td>
<td>- Markets outside the United States</td>
</tr>
<tr>
<td>- Referring Physician Fraction</td>
<td>- Sale price of device</td>
<td>- Disaggregation of referring physician population</td>
</tr>
<tr>
<td>- Implanting Physicians over Time</td>
<td>- Fraction of Sales to Marketing and Technical Development</td>
<td>- Disaggregation of Implanting and Follow Up Physicians</td>
</tr>
<tr>
<td>- Marketing Effort</td>
<td>- Normal technical development time.</td>
<td>- Disaggregation of Payers</td>
</tr>
<tr>
<td>- Technical Development</td>
<td>- Physician acceptance and Payer approval characteristics.</td>
<td></td>
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<tr>
<td>- Payer Relationship Effects</td>
<td></td>
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<tr>
<td>- Capitation Reimbursement Effects</td>
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<td>- Implants Over Time</td>
<td></td>
<td></td>
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<tr>
<td>- Sales Revenue Over Time</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As the subsystem diagram and table above show, the model includes the basic structures relating physician activities, manufacturer activities, and payer activities. When the exogenous, or input variables, are entered, the model is capable of generating the behavior of the endogenous variables over time by relating the variables to one another as defined by the model equations. The relationships between variables are specified so that they include the stock and flow nature of variables and the information delays between device performance, follow up events, physician perceptions and manufacturer perceptions in a way that is representative of the flow of people, events, and information in the medical system.
10.3 General Diffusion Model
General diffusion theories for innovation have been postulated that describe the
conditions under which a technology or other innovation is readily accepted in the
marketplace. These models identify the characteristics of innovations that contribute
to adoption, the adoption pattern over time, the rate of adoption, and the drivers of
innovation. To understand the general form of the diffusion of the IHM technology, it
is useful to frame our analysis around these general models before delving into the
more detailed system dynamics model.

10.3.1 Characteristics of Innovations
Key to the diffusion of the IHM technology is an understanding of the factors that
contribute to the success of the innovation and factors that inhibit its adoption.
E.M. Rogers outlines five characteristics of innovations that affect the rate at
which they diffuse and are adopted: (Rogers, Diffusion of Innovations)

- **Relative advantage:** the degree to which an innovation is perceived as being
  better than the idea it supersedes.
- **Compatibility:** the degree to which an innovation is perceived as consistent
  with the existing values, past experiences, and needs of potential adopters.
- **Complexity:** the degree to which an innovation is perceived as relatively
difficult to understand and use.
- **Trialability:** the degree to which an innovation may be experimented with on
  a limited basis.
- **Observability:** the degree to which the results of an innovation are visible to
  others.

These factors are analyzed with respect to the IHM technology in Exhibit 5. The
most critical factors driving the adoption are the relative clinical and cost
advantages of the technology, and the similarities that IHM exhibits to the pacing
application of implantable devices. The factors slowing diffusion include uncertain
clinical outcomes, opposition to use of technology, opposition to permanent
implant, and unobservable initial benefits. The results of the clinical studies will be
instrumental in comparing the IHM with alternative approaches.

10.3.2 Adoption over time: a simple model
Most adoption (or diffusion) processes follow an S-shaped curve of percent
adoption over time. The basic dynamics that drive this include peer pressure,
building/acquiring complementary assets, and the presence of less uncertainty in
the market. The foundation for the understanding of these behavioral aspects of
technology diffusion over time was introduced to management science by the Bass
model in 1969. (Bass, 1969)

The Bass model assumes that there is a segment of potential adopters that are
motivated by the technology itself that will adopt first, and that there is another
group of adopters that waits to see what happens before adopting. The rationale
of the Bass Model is that once the first group of adopters is converted to the
technology, the adopters influence other potential adopters through word of mouth
interactions and social pressure to adopt the technology as well. The model is
given by the equations:

\[
dN/dT = (a + bN) (N' - N)
\]

where: \( N \) is the number of adopters
\( N' \) is the number of potential adopters
\( a \) is the coefficient of innovation, or "advertising effect."
\( b \) is the coefficient of imitation, or "word of mouth."

Coefficient "a" relates to the tendency for first-movers to adopt the technology,
from the contact with marketing messages. Coefficient "b" relates to the tendency
for followers to adopt after the initial adoption has taken place, through the word
of mouth interactions between adopters and potential adopters.

A simple system dynamics model, such as the one diagrammed below,
demonstrates these effects by simulating the behavior over time given the
assumptions about the contacts between parties. The diagram shows the
relationship between Non-Practitioners (non-adopters of the technology),
Practitioners (those who have adopted the technology) and the processes that
bring about adoption. (The equations used in the model are listed after the
diagram, for closer inspection.) In this model, marketing effects are not present;
diffusion is driven only by the contacts between parties.
The following samples of equations and graphs show the assumptions used and behavior of the simple Bass model. The assumptions are described in the fifteen equations listed, and the behavior of two of the variables over time, Practitioners and adoption rate, are shown in the following graph.

Bass Model Equations

(01) adoption rate = Word of Mouth Effect
(02) CONTACT RATE = 100
(03) Contacts between Practitioners and Non Practitioners = non practitioner contacts*practitioner prevalence
(04) EFFECTIVENESS OF WOM = 0.01
(05) FINAL TIME = 100
(06) INITIAL PRACTITIONERS = 10
(07) INITIAL TIME = 0
(08) non practitioner contacts = Non Practitioners*CONTACT RATE

(09) Non Practitioners = INTEGRAL (-adoption rate, 1000)
(10) practitioner prevalence = Practitioners/total population
(11) Practitioners = INTEGRAL (adoption rate, INITIAL PRACTITIONERS)

(12) SAVE PERIOD = TIME STEP
(13) TIME STEP = 1
(14) total population = Non Practitioners+Practitioners
(15) Word of Mouth Effect = Contacts between Practitioners and Non Practitioners*EFFECTIVENESS OF WOM

Adoption Rate and Practitioners Over Time

The test results from the first run of this simple model indicates that the conversion of Non-Practitioners to Practitioners takes place over 9.5 months, with half of the
conversion completed in 6 months. The graph shows that by month 6, the adoption rate is at its peak at 250 people per month, which corresponds to Non-Practitioners = Practitioners. The Practitioners curve has an inflection point at this time as well, indicating that the change in the adoption rate is negative for the first time. At time = 9.5 months, the adoption rate = 0, and Practitioners is at the peak level. Since there is no rejection in this model, Practitioners stay at the peak for the rest of the simulation.

To test the sensitivity of the model to changes in the power of the word of mouth effect, the "Effectiveness of Word of Mouth" factor can be changed. If it is set to 0.005 instead of 0.01, the following behavior results:

![Adoption Rate and Practioners Over Time](image)

As shown in the second graph, if the effectiveness of word of mouth is half as great, 0.005 vs. 0.01, it takes approximately 11 months (versus 6) for half of the Non-Practitioners to convert, and almost 20 months (versus 9.5) for full conversion to take place. These differences in timing for the conversion rate could have important effects on a manufacturer's decisions on how to produce, distribute, and price a new product.

This example shows the value of system dynamics modeling is scanning various possibilities of dynamic behavior over time, given different assumptions. The model could be tested again with the "Effectiveness of Word of Mouth" set to 0.02, for example, to examine the behavior of a doubling in word of mouth effectiveness. The range of values for any of the variables may be tested using the system dynamics model to determine the likely system behavior over time.
The challenge for a company wishing to diffuse a new technology is to assess the range of possible diffusion patterns, and to understand how it can optimize its processes to best meet the demands in the market. It is important for the company to understand how it can contribute to the adoption process through its use of marketing spending to increase initial acceptance, and through contribution to the word of mouth effect in the practitioner population. Understanding these two phenomena may yield insight into more effective product introduction strategies.

10.3.3 Rate of Adoption
The Rate of Adoption is defined as the relative speed with which an innovation is adopted by members of a social system. It is affected by 1) the type of innovation decision, 2) the nature of the communication channels at various stages in the innovation-decision process, 3) the nature of the social system, and 4) the extent of the change agents' efforts in diffusing the innovation. (Rogers, *Communication*)

As assessed in Exhibit 6, IHM can be viewed as an incremental innovation decision, therefore increasing the rate of adoption, if it is linked to the idea of pacemaker implants and to using it to further results with drug therapy. The nature of the communication channels for doctors has historically been generally personal, with more effective messages coming from trusted peers or familiar, credible salespeople. For the larger buyers, published data on the clinical and cost effectiveness demonstrated in the clinical trials will have a greater impact, as well as the acceptance of the method by other large buying groups. The social system in the United States is generally pro-technology, but it presently requires strong cost/benefit analysis to admit new technology in the health care market. In the medical specialty fields, the social system is highly interconnected, so that the diffusion effect associated with the influence of peers is especially strong.

10.3.4 Drivers of Diffusion
The development of increasingly aggressive procedures and the new emphasis on cost containment in health care are driving innovation in CHF management. Customers are seeking alternative methods for patient management as doctors become more cost-conscious and as providers and payers have more influence on product choices in health care. Customers are also strategically aligning themselves to compete in the new managed-care marketplace, which puts additional pressure on the system to produce lower cost patient management. Technologies that will be successful in this diffusion dynamic are those which compete effectively clinically as well as in the cost management arena.

10.4 Model: Physician Activities
The first subsystem of the model, and the most complex of the three, to be presented is the Physician Activities subsystem. Physician activities broadly include the patient selection process, treatment process, and follow-up assessment process. To describe each of these processes in detail, each model sector within the broad process areas will
be presented in policy diagram form, and the important features of each sector will be discussed.

10.4.1 Patient Selection

The patient selection process involves two sectors, the referring physician sector and the patient eligibility sector. In order to be selected, a patient must a) present him/herself to a recommending physician who has adopted the technology, and b) meet the current selection criteria for receiving the device before they are referred for implant. Each of the sectors below outline the processes that lead to the referring physician fraction and to the current patient selection criteria.

10.4.1.1 Recommending Physicians

![Diagram showing the process of patient selection and physician fractions]

Recommending Physicians screen patients for possible implant of the IHM device. The acceptance level for the technology in this sector is denoted by the fraction of possible recommending physicians that have adopted the technology, the "Recommending Physician Fraction." At the launch of the technology, before acceptance has taken place, the majority of potential recommending physicians have not been educated about the technology or convinced of its merits; therefore, the Non-Recommending Physician Fraction will be high. Over time, the non-recommending physicians will accept the technology based on the effects of ("Effects of") the following:

1. The "Benefit Cost Ratio" of the device, or the amount of benefit received per the cost. This factor can also be thought of as the "relative advantage" of the IHM device.
2. "Colleague Discussion," the interaction with other physicians regarding acceptance or non-acceptance of the technology.
3. "Follow Up Reports," clinical reports and/or journal articles on the technology's effectiveness.

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4. The "Availability of Procedures," the physician's perception of the availability of devices and service to support implants.
5. "Marketing Effort," the manufacturer's marketing messages, either through sales or advertising.
6. The Payer Relationship to the technology.

Of these factors, benefit-cost, colleague discussion, and payer relationships are thought to have the most powerful effects. The equation for physician acceptance fraction (the fraction of non-recommending physicians who are converted to recommending physicians per year) is as follows:

Physician Acceptance Fraction =
Effect of Payer Relationship on Acceptance
*Physician Acceptance Fraction Normal*Effect of Availability of Implants on Acceptance
*Effect of Benefit Cost Ratio on Acceptance*(Effect of Colleague Discussion on Acceptance + Effect of Marketing Effort on Acceptance + Effect of Follow Up Reports on Acceptance)

Units: 1/year

In the equation for the acceptance fraction, since the perceived average benefit-cost ratio (or relative advantage) is critical to the assessment of the technology's underlying value, it is weighted more heavily than the other factors, and it has a multiplicative effect on the acceptance fraction.

Importantly, the perceived benefit-cost ratio also affects rejection of the technology. If the perceived average benefit-cost of the device is not great enough to justify use, physicians and payers will reject the technology. The other parameters giving rise to technology acceptance are not associated with rejection because they are not as closely related to the performance of the technology; once the initial hurdles have been overcome with the other variables, it is unlikely that they will be reversed.

The Effect of the Payer Relationship on Acceptance is given by the following equation:

Effect of Payer Relationship on Acceptance =
((1-Balk Factor)*Fraction of Capitated Reimbursement
+(1-Fraction of Capitated Reimbursement)*EPAA(Payer Approval Fraction))

Units: dmnl

The Effect of Payer Relationship on recommending physician acceptance incorporates the nature of the physician reimbursement system in place by specifying the fraction of physician reimbursement that is on a capitated basis. If physicians are paid on a capitated basis, the physician plays the deciding role in whether the technology is accepted or not. The "balk" factor may be
entered to establish what fraction of physicians would not opt to use the IHM device because it is expensive up front.

If physicians are paid on a per-procedure basis ("1-Fraction of Capitated Reimbursement" = Fraction of Per Procedure Reimbursement), the effect of the payer relationships on the Recommending Physician Fraction is to limit the fraction of recommending physicians to be less than or equal to the Payer Approval Fraction at a given point in time. The lookup table EPAA, "Effect of Payer Approval on Acceptance," establishes a one-to-one linear relationship between the Payer and Recommending Physician Fractions.

10.4.1.2 Patient Eligibility

Patient eligibility for the device changes over time as a function of the indicated eligibility fraction from follow-up reports, stemming from the reported benefit-cost ratio, and the presumed widening of scope since follow up reports were published that results from incorporation of new technical developments into practice. The eligibility criteria will expand as long as the perceived marginal benefit-cost ratio is greater than 0, and will decline once the additional benefit is outweighed by the cost.
10.4.2 Treatment

10.4.2.1 Implants

Implants may be both initial implants and repeat implants. Initial implants result from desired initial implants, which arise from the selection fraction in force at the time a patient is seen by a referring physician. Repeat implants occur in those patients who live beyond the device longevity, and elect to continue using the technology after the initial device comes to end of life. The total number of implants, then, results from the capacity of implanting physicians times the capacity utilization fraction in use; as long as desired implants do not exceed the capacity available, a device will be implanted when it is desired.
10.4.2.2 Patients

Patients are in the system from the time they are implanted (patient initiation rate) to when they die, unless they are discontinued from using the device for follow up. Should an IHM device cease to work, it is assumed that the patient will not receive a new implant in the model. If the life expectancy for patients entering the system changes as patient eligibility criteria widen, the co-flow structure for the life expectancy for patients in the system regulates the "average age" of patients in the system.

10.4.2.3 Implanting Physicians

Implanting Physicians, most likely invasive cardiologists and/or pacemaker implanters, are trained to implant the device. They are encouraged to join the implanting physician pool when more implants are desired, and thus more implanting physicians are desired as the practicing implanting physicians are increasingly utilized (implanting physician capacity utilization is high). Physicians and will drop out when existing physician capacity for IHM
implants is under-utilized and could be better spent performing other procedures.

10.4.2.4 Benefit-Cost Ratios (aggregate and marginal)

The Benefit-Cost Ratio (BCR) is the foundation upon which the whole model is based. As shown in the diagram above, the relative "Aggregate," or average, Benefit Cost Ratio is calculated from expected values of benefit and cost. The aggregate expected value of benefit accrued from the IHM technology is calculated from the Fraction of Beneficial Outcomes times the Magnitude of a Beneficial Outcome, in units of "quality-adjusted life years." Cost is calculated in a similar fashion, in units of dollars.

To find the relative benefit-cost ratio of IHM-guided therapy as compared to an alternative, the Alternative Expected Benefit and Alternative Expected Cost are subtracted from IHM's values, as in the equation below:

\[
\frac{\text{(Aggregate Expected Benefit} - \text{Alternative Aggregate Expected Benefit})}{\text{(Aggregate Expected Cost} - \text{Alternative Aggregate Expected Cost})}
\]

The alternative may be thought of as the existing standard therapy option; if IHM were being considered, physicians and payers would weigh the benefits and costs associated with IHM against the current standard of care. Various alternative options maybe simulated, simply by choosing different values for the Alternative Expected Benefit and the Alternative Expected Cost.

The Marginal Benefit Cost Ratio is calculated in a similar manner to the Aggregate Benefit Cost Ratio. The difference is in the magnitude of benefit
term. Since it is assumed that there is a decreasing benefit to using the technology as the eligibility for the device expands, the "Decrease in Relative Benefit per Doubling of Eligibility" term defines the decrease in benefit with each doubling of the eligibility. For IHM, it is speculated that the benefit is half as great when the eligibility fraction doubles. Hence, if the original patient eligibility population was 5000 patients, and the benefit from IHM for this group of patients was 4 QALY, when 10,000 patients are eligible, the benefit used in the model drops to 2 QALY.

The model equations are as follows:

Aggregate Expected Benefit =
Fraction of Beneficial Outcomes*Aggregate Magnitude of Beneficial Outcome
Units: Qual Adj Life Years/cases

Marginal Expected Benefit =
Fraction of Beneficial Outcomes*(Aggregate Magnitude of Beneficial Outcome-
(Decrease in Relative Benefit per Doubling of Eligibility*1.443)
-(Aggregate Magnitude of Beneficial Outcome*LN(2)) *
(Eligibility Fraction/Eligibility Fraction from Functional Capability)))
Units: Qual Adj Life Years/cases

Eligibility for the device will increase until the Marginal Benefit Cost Ratio is 0. As eligibility increases, Marginal Benefit Cost Ratio decreases, because of the "Decrease in Magnitude of Benefit per Doubling of Eligibility" factor. This means that the positive benefit achieved by using the device gets smaller as indications widen, reflecting that the healthier patients have less need for the device and therefore accrue less value from it. When Marginal Benefit Cost Ratio = 0, the eligibility fraction is at its maximum for the given state of the technology.

With technical improvements, an increase in product capability can lead to increases in the expected magnitudes of benefit and cost, which can then lead to respective changes in the calculations of the Benefit Cost Ratio.
10.4.2.5 Functional Capability

Functional Capability is the product of Product Capability and the Effect of Physician Experience on Functional Capability. As such, it is a measure of the given state of technology in terms of the physician's skill in using each of the features of the device. As Product Capability is increased by technical development activity, more features are available, but they are not in use until they have been incorporated into physician practice.

10.4.3 Follow-Up Assessment

10.4.3.1 Patients in Follow-Up

The patients available for follow-up are increased as patients are initiated by an implant of the device, and they are followed for the Follow Up Time. All patients who are implanted are assumed to be seen by their following physician, and hence are followed. In the case of the IHM device, since patients are expected to use the device for the rest of their life, the Follow Up
Time is synonymous with the Life Expectancy for the Patients. This pool of patients provides the data used to evaluate technology performance. During follow-up, side effects of the technology may be perceived and may affect the patient initiation rate if unexpected harm occurs.

10.4.3.2 Follow Up Reporting

Evaluation and Reporting is conducted with follow-up data as information is desired about device performance. The number of Follow-Up Reports to Date, when compared to the Desired Follow-Up Reports to Date based on the number of patients implanted and previously reported experience, determines the Adequacy of Follow-Up to date. Desired Follow-Up Reports increase when there is expansion of eligibility or there are conflicting reports of technology efficacy, generating a difference between Desired Reports and Follow Up Reports to Date.

When there is a difference between these two variables, the Adequacy of Follow Up to Date is low, and thus a larger Follow Up Evaluation Fraction is chosen to gather more clinical data on IHM performance. This increase in Follow Up Evaluation Fraction raises the Follow Up Evaluation Rate, which then increases the follow up reporting rate, leading to more Follow Up Reports to Date.
The Perceived Aggregate and Perceived Marginal Benefit-Cost Ratios used to determine patient eligibility are formulated as shown. The actual BCR's for patients in follow-up who have received a device are both observed and evaluated by physicians who care for these patients. Evaluations are reported in medical journals or clinical reports. The perceived values are then calculated using the observed and reported values, and the weights allotted to observation versus written reports.
10.5 Manufacturer Activities

10.5.1 Marketing Activity

Marketing Effort, or the amount of money the company puts into marketing expenditure, is determined by the Indicated Marketing Effort. The Indicated level is a product of the Indicated Fraction of Sales Revenue to Marketing and the Sales Revenue. The Indicated Fraction of Sales Revenue to Marketing relates the fraction that should be spent on marketing to the effectiveness expected from the expenditure, the "Effect of Recommendation Fraction on Marketing Effort," which means that marketing spending is more effective when the Recommending Physician Fraction is low than when it is high. Marketing Effort may be divided to be spent on physician and/or payer marketing activities.
10.5.2 Technical Development

Technical Development Projects are started in response to the Indicated Technical Development Project level, which is determined by the Indicated Fraction of Sales Revenue to Technical Development and the Spending per Technical Development Project. The Effect of Benefit-Cost and Effect of Perceived Return to Technical Development influence the Indicated Fraction of Sales Revenue to Technical Development; the more there is to gain by adding features, both by improving the benefit-cost ratio and increasing eligibility, the greater the fraction of sales is warranted. Spending per Technical Development Project times the number of projects equals the Technical Development Spending budget.
10.6 Payer Sector

The payer sector is similar in structure to the Recommending Physician sector. Non reimbursing payers, the "Non Reimbursing Payer Fraction," are converted into the "Reimbursing Payer Fraction" by the payer approval rate. Payers affect acceptance in the model only when the paying system is per-procedure reimbursement; if the paying system is capitated, then physicians will drive the acceptance pattern alone. The model may be run using a combination of per-procedure and capitation reimbursement by setting the Fraction of Capitated Reimbursement to a value between 0 and 1; when it is 0, payers entirely regulate the approval of the IHM technology, and when it is 1, physicians do.

The payer approval rate is affected by the normal payer approval fraction, which is the fraction of payers that would be expected to approve the technology if all of the other parameters were neutral; and the Effects of Follow Up Reports, manufacturer Marketing Effort, Benefit Cost Ratio, and the Fraction of other Payers that have approved the technology. Payer Rejection is caused by the Benefit-Cost Ratio performance. The model equation for payer approval is as follows:

\[
\text{Payer Approval Fraction} = \\
\text{Payer Approval Fraction Normal} \times \text{Effect of Benefit Cost Ratio on Payer Approval} \\
\times (\text{Effect of Payer Marketing Effort on Approval} + \text{Effect of Follow Up Reports on Payer Approval} \\
+ \text{Effect of Payer Fraction on Approval Rate})
\]

Units: /year

Although structurally very similar to the Recommending Physician sector, the weights ascribed to the various effects leading to payer approval are different. The Payer Approval Fraction Normal, for instance, is 0.05, one-third that of physicians, since it is
assumed that payers will be less likely to approve new technologies since they make
decisions that affect a much larger number of patients at a time. Also, the Effect of the
Payer Fraction, or the effect that other payers have on influencing payers to approve
the technology, is lesser, since payers do not interact as closely as physicians do. The
equations for the "Effects of" equations for the payer sector may be examined more
closely in the equation listing in the appendix.

10.7 Summary Statistics
The summary statistics section collates cumulative data from the model. The data
presented includes:

- Initial Implants to Date
- Sales Revenue to Date
- Marketing Effort to Date
- Technical Development Spending to Date
- Implanting Physicians to Date
- Beneficial Outcomes to Date
- Fraction of Beneficial Outcomes to Date
- Harmful Outcomes to Date
- Fraction of Harmful Outcomes to Date
- Benefit to Date
- Cost to Date
- Benefit-Cost Ratio to Date
11. Discussion of Model Simulation of Base Cases

11.1 Base model for pacemaker case
Dr. Jack Homer's model, parameterized for the pacemaker case, was entered in VENSIM, and simulated to verify appropriate behavior. The "basetest" simulation indicated that the model matched Dr. Homer's results and was working appropriately. Graphical output from this "basetest" file is found in Appendix B, along with copies of Dr. Homer's Base Run graphs.

11.2 Base model for IHM case
To adjust the model to suit the IHM technology, the model parameters that reflected the performance of the technology were closely reviewed. Parameters regarding the structure of Physician and Manufacturer relationships were not changed, since it was felt that the relationships between these parties were substantially the same since Dr. Homer conducted his research in 1983. Interview Data, Medtronic data, and library research data aided the reformulation of technology variables that were altered. The discussion that follows delineates the changes that were made in Dr. Homer's base model. The Payer sector, since it is newly created, was added last.

11.2.1 Variable names that were changed
Homer's model used variable names that could be generalized to suit any medical technology. To make the variable names more clear for the specific case of the IHM technology, the following variable names were altered.

<table>
<thead>
<tr>
<th>Homer model variable name</th>
<th>IHM model variable name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures</td>
<td>Implants</td>
</tr>
<tr>
<td>Administering Physicians</td>
<td>Implanting Physicians</td>
</tr>
<tr>
<td>Veterans</td>
<td>Patients</td>
</tr>
<tr>
<td>Benefit Harm Ratio</td>
<td>Benefit Cost Ratio</td>
</tr>
</tbody>
</table>

11.2.2 Parameters that were adjusted to suit the IHM case
The following equations, listed in order of the model description in chapter 10, were altered from the Homer model. One asterisk (*) in front of the equation number indicates that the equation was changed from the Homer Base model. Two asterisks (**) indicate that the equation is newly introduced in the IHM model. After each equation, the Homer model variable value will be given, with a brief explanation of why the IHM model variable differs. If just part of the equation format is different, the different part will be in italics for easy reference.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

1 A lb. Recommending Physician Fraction Equations

***(002) Fraction of Marketing Effort for Physicians = 1 - Fraction of Marketing Effort for Payers
Units: dmnl
The Fraction of Marketing Effort for Physicians is the fraction of marketing spending that is spent on physician contacts, versus payer marketing activities.

Homer: No equation for this variable. This variable was introduced to accommodate the payer sector; it divides the amount of marketing spending between the physicians and the payers.

*(024) Effect of Marketing Effort on Acceptance = EMEA(Marketing Effort * Fraction of Marketing Effort for Physicians / Marketing Effort Normal)
Units: dmnl
The Effect of Marketing Effort on Acceptance represents the overall response of physicians to the promotional marketing activities of manufacturers. It can also generate acceptance with influence increasing according to size and number, but the influence diminishes past a point. Also, the impact on acceptance of any particular promotion or report is assumed to be fairly immediate and temporary.

Homer: This variable was altered to accommodate the payer sector. It was altered as shown to adjust the marketing spending value.

**(029) Balk Factor = 0
Units: dmnl
The "Balk Factor" is the fraction of physicians who will "balk" at choosing a higher-cost procedure for short-term treatment under a capitated reimbursement system, even though cost-effectiveness analysis suggests that the procedure is warranted.

Homer: No equation for this variable. This variable was created to accommodate the payer sector.

Units: 1/year
The Physician Payer Acceptance Fraction is the fraction of non-recommending physicians who accept the technology per year. The magnitude of the acceptance fraction is based on the effects of the payer relationship, the normal acceptance fraction, availability, benefit cost ratio, colleague discussion, marketing effort, and follow up reports.

Homer: This variable was altered to accommodate the payer sector. It was done by multiplying the whole equation by the Effects of the Payer Relationship.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

*(089) Benefit Cost Ratio Normal = Benefit Normal/Cost Normal
Units: Qual Adj Life Years/dollars
The concept of a "Benefit Cost Ratio (BCR) Normal" warrants special consideration. BCR Normal is that value of BCR (for a given subset of patients) at which physicians will be indifferent between the new technology and alternatives to it, in terms of relative advantage. Cost-effectiveness literature suggests that a ratio of 1 quality adjusted life year to $20,000 is a reasonable ratio of benefit to cost, and the range may be appropriate up to $40,000 per 1 quality-adjusted life year.

Homer: This variable was altered to reflect the change in the health care environment. Instead of Benefit-Cost, the Homer model used Benefit-Harm. The Benefit-Harm Ratio Normal was defined to be 30 in the Homer model.

**(013) Initial Patient Population = 5000
Units: cases/year
The Initial Patient Population is the first set of patients who are eligible for IHM management.

Homer: No equation for this variable. This variable was introduced to define the minimum and initial eligibility fractions for the IHM device.

**(018) Cost Normal = 20000
Units: dollars
Cost Normal is the value of cost that is used to calculate the Benefit-Cost Ratio Normal value, which is used as the standard by which physicians and payers judge the cost effectiveness of alternative patient management strategies.

Homer: No equation for this variable. This variable was introduced to define the Benefit-Cost Normal variable in the IHM model.

**(028) Benefit Normal = 1
Units: Qual Adj Life Years
Benefit Normal is the value of benefit that is used to calculate the Benefit-Cost Ratio Normal value, which is used as the standard by which physicians and payers judge the cost effectiveness of alternative patient management strategies.

Homer: No equation for this variable. This variable was introduced to define the Benefit-Cost Normal variable in the IHM model.

**(037) Benefit Cost Ratio Unit = 1
Units: Qual Adj Life Years/dollars
The Benefit Cost Ratio Unit is used to correct the units in the model, when dimensionless quantities are desired.

Homer: No equation for this variable. This variable was introduced as a unit correction factor.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

*(065) Effect of Payer Relationship on Acceptance = ((1-Balk Factor)*Fraction of Capitated Reimbursement+(1-Fraction of Capitated Reimbursement)*EPAA(Reimbursing Payer Fraction))
Units: dm/ml

The Effect of Payer Relationship on Acceptance relates the type and proportion of reimbursement system to the effect these relationships have on physician acceptance. It includes the fraction of capitated reimbursement, and the "Balk Factor" for physicians who are reimbursed under capitated reimbursement systems, who "balk" at choosing expensive up-front procedures.

For reimbursement by procedure systems, the physicians are constrained to accept the technology only if the payer organization has accepted it as well; the model takes this into account through the lookup function “EPAA” (Effect of Payer Approval on Acceptance). EPAA is a linear relationship between the fraction of reimbursing payers to the fraction of physicians who could elect to accept the technology. Before they can accept, however, the payer must accept.

Homer: No equation for this variable. This variable was introduced to accommodate the payer sector.

**************************************************************************
A 2b. Eligibility Fraction Equations
**************************************************************************
No equations are different in this sector.

**************************************************************************
I B 1b. Implants
**************************************************************************

*(032) Patients Living Beyond Device Longevity =  
Fraction of Patients Living Beyond Device Longevity*Patients
Units: cases

Patients Living Beyond Device Longevity are patients that live beyond the 3 year lifetime of the device, who may also be selected to have a second device implanted so they may continue using the device for CHF management.

Homer: This variable was changed from "Patients Using Device for Long Term Treatment" to it's current name, and Fraction of Patients Living Beyond Device Longevity because IHM patients are not expected to receive a second implant. This equation is part of the loop that causes repeat implants. Allowing the Fraction to = 0 turns off the repeat implants.

*(115) Desired Repeat Implants = (Patients Living Beyond Device Longevity/Device Longevity)

*Desired Continuation Fraction for Long Term Treatment
Units: cases/year

Desired Repeat Implants result from patients living beyond the device lifetime, and the desire to continue using IHM technology to manage the patient's care.

Homer: Same as above.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

*(170) Fraction of Patients Living Beyond Device Longevity = 0
Units: dmdl
The Fraction of Patients Living Beyond Device Longevity are those that live beyond the point where the technology reaches its end of life. For IHM candidates, since most patients are not expected to live beyond 3 years, the fraction is 0.

Homer: Same as above.

*(245) Device Longevity = 3
Units: year
Device longevity is the engineering specification for device expected life.

Homer: In the pacemaker case, device longevity was a lookup table that depicted longer device lifetimes over time, reflecting the improvement in the pacemaker case. This variable is called "Procedural longevity" in the Homer model. For IHM, to be conservative, the device is only expected to last 3 years.

*(295) UNIVERSE OF NEW CASES = 400000
Units: cases/year
The Universe of New Cases is the number of new patients diagnosed with Congestive Heart Failure in the United States per year. Of these cases, a fraction will be considered candidates for the IHM technology.

Homer: In the pacemaker case, the universe of new cases was a lookup table that reflected the growth in the cardiac arrhythmia patient population over time. Again, to be conservative, the universe is kept constant in the IHM model.

********************************************************************************
I B 2b. Patients Equations
********************************************************************************

*(203) Life Expectancy for a Beneficial Outcome = 3
Units: year
The Life Expectancy for a Beneficial Outcome is the length of time patients are expected to live after they receive an implant.

Homer: Life Expectancy is a lookup table, showing increasing life expectancies as time passed, for the pacemaker case, reflecting the healthier patient population as indications expanded. Congestive Heart Failure patients are expected to live less than three years, with some only living one year. It was felt that three years was appropriate average value.

*(205) Life Expectancy for a Non Beneficial Outcome = 3
Units: year
The Life Expectancy for a Non-Beneficial Outcome, since IHM is not a therapeutic device and is not expected to decrease mortality, is the same as the life expectancy for a beneficial outcome.

Homer: As in the Life Expectancy for a Beneficial Outcome, reflecting the healthier patient population as indications expanded, life expectancies for a non-beneficial outcome is calculated using a lookup table as well, but the lifetimes are shorter.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

I B 3b. Implanting Physicians Equations

No equations are altered in this sector.

I B 4b. Benefit Cost Ratios Equations

*(010) Aggregate Expected Cost =Aggregate Magnitude of Cost Outcome+Cost per Harmful Outcome

Units: dollars/cases
The Aggregate Expected Value of Cost equals the Aggregate Magnitude of Cost Outcome multiplied by the Cost per Harmful Outcome.

Homer: This equation was modified to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. This equation replaces "Aggregate Expected Value of Harm," used to calculate the Benefit-Harm Ratio.

*(016) Aggregate Benefit Cost Ratio =
(Aggregate Expected Benefit-Alternative Aggregate Expected Benefit)/
(Aggregate Expected Cost-Alternative Aggregate Expected Cost)
Units: Qual Adj Life Years/dollars
The Aggregate Benefit Cost Ratio (BCR) is the average expected benefit-cost ratio in for the group of patients that are current candidates for the IHM technology. The benefit-cost ratio drives physician and payer decisions in a health care system that is oriented towards cost-effectiveness. It is calculated from the difference in expected benefit from IHM minus the benefit of an alternative technology, divided by the difference in costs.

Homer: This equation was modified to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. This equation replaces "Aggregate Benefit-Harm Ratio."

**(019) Cost per Harmful Outcome =
Cost per Harmful Outcome Normal*Fraction of Harmful Outcomes
Units: dollars/cases
The Cost per Harmful Outcome is found by multiplying the cost per harmful outcome normal (the average cost) by the fraction of harmful outcomes. This cost is added to the average treatment cost calculation for IHM.

Homer: This variable does not exist in the Homer model. It was added to account for additional costs associated with harmful outcomes.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

**(020) Cost per Harmful Outcome Normal = 3000
Units: dollars/cases
The Cost per Harmful Outcome Normal expresses a rough weighted average of the expected costs and probabilities of possible complications, such as perforation during implant, infection, lead dislodgment, etc.

Homer: This variable does not exist in the Homer model. It was added to account for additional costs associated with harmful outcomes.

**(025) Alternative Aggregate Expected Benefit = 0
Units: Qual Adj Life Years/cases
Alternative Aggregate Expected Benefit is the average 3 year benefit an alternative patient management is expected to provide for the patient.

Homer: This equation was added to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. This equation is used in the calculation of the Aggregate Benefit-Cost Ratio.

**(026) Alternative Aggregate Expected Cost = 0
Units: dollars/cases
The Alternative Expected Value of Cost is the expected 3-year cost of the closest alternative patient management strategy to the IHM technology.

Homer: This equation was added to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. This equation is used in the calculation of the Aggregate Benefit-Cost Ratio.

Units: Qual Adj Life Years/dollars
The Marginal Benefit-Cost Ratio is the ratio of expected benefit to expected cost difference for a patient whose condition is on the periphery of accepted applications of the technology. It is calculated from the expected outcome for "marginal" or "peripheral" patients, who receive the least value from the technology are the first to lose their eligibility if the patient selection criteria are narrowed.

Homer: This equation was altered to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. This equation is used in the same manner as the Marginal Benefit Harm Ratio the to determine the expansion in patient eligibility.

*(047) Marginal Expected Cost = (Aggregate Magnitude of Cost Outcome+Cost per Harmful Outcome+(Increase in Relative Cost per Doubling of Eligibility*1.443))
Units: dollars/cases
The Marginal Expected Value of Cost is found by computing the derivative of the total cost incurred, where total cost equals the aggregate expected value of cost difference to alternatives multiplied by the number of initial procedures.

Homer: This equation was altered to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

*(081) Aggregate Magnitude of Beneficial Outcome Normal = 3
Units: Qual Adj Life Years/cases
Aggregate Magnitude of Beneficial Outcome Normal. The Aggregate Magnitude of Beneficial Outcome equation is formulated so that when the capability effect is neutral and the eligibility fraction equal to its minimum value, the Aggregate Magnitude of Beneficial Outcome will equal its "normal" value.

Homer: In the Homer model of the pacemaker case, the magnitude of a beneficial outcome normal is 10 QALY.

*(082) Aggregate Magnitude of Cost Outcome = (Aggregate Magnitude of Cost Outcome Normal*Effect of Product Capability on Magnitude of Cost)+(Increase in Relative Cost per Doubling of Eligibility*1.443)*\(\ln(\text{Eligibility Fraction}/\text{Minimum Eligibility Fraction})\)
Units: dollars/cases
The Aggregate Magnitude of Cost Outcome expresses the average additional cost to a patient who receives the IHM technology, and also incorporates a factor related increases in product capability to the cost.

Homer: This equation was altered to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. In the Homer Model, this equation is the "Aggregate Magnitude of A Harmful Outcome."

*(083) Aggregate Magnitude of Cost Outcome Normal = 18,250
Units: dollars/cases
The Aggregate Magnitude of Cost Outcome Normal corresponds to a situation in which Eligibility Fraction = Minimum Eligibility Fraction and the functional capability effect is neutral. It reflects the purchase, implant, and followup costs associated with the first "market-released" version of the IHM technology.

Homer: This equation was altered to reflect the changes in the health care environment, towards cost-effectiveness versus benefit harm. In the Homer Model, this equation is the "Aggregate Magnitude of A Harmful Outcome Normal," with a value of 1.

*(110) Decrease in Relative Benefit per Doubling of Eligibility =0.5
Units: Qual Adj Life Years/cases
The Decrease in Relative Benefit per Doubling of Eligibility is the decline in benefit as the eligibility level for the device doubles.

Homer: In the Homer Model, the value of the Decrease in Relative Benefit per Doubling of Eligibility is 0.4. The difference is due to the difference in potential application of the pacemaker device versus the IHM device to their respective broad patient populations. Since IHM is not therapeutic, the potential benefit it offers declines more quickly than that of the pacemaker.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

*(144) Effect of Product Capability on Magnitude of Cost = EPCMC(Product Capability/Maximum Functional Capability)
Units: 1
The Effect of Product Capability on Magnitude of Cost relates the product capability to the magnitude of cost.

Homer: In the Homer model, this equation relates the product capability to the magnitude of harm, instead of the magnitude of cost.

*(172) Fraction of Harmful Outcomes = FHO(Functional Capability/Maximum Functional Capability)
Units: 1
The Fraction of Harmful Outcomes, defined by lookup table "FHO," has been assumed to be a function of functional capability, which combines technology capability and physician experience. Since the IHM device is so similar to a pacemaker, and since pacing is so widespread and the physicians who implant IHM are most likely going to be experienced pacemaker implanters or other invasive cardiologists, the Fraction of Harmful Outcomes was set to the minimum level, 0.01, for all levels of functional capability with IHM.

Homer: In the Homer model, "FHO" is different. See explanation above.

*(187) Increase in Relative Cost per Doubling of Eligibility = 0
Units: dollars/cases
The Increase in Relative Cost per Doubling of Eligibility expresses the possibility that as eligibility widens, the cost relationship as well as the benefit relationship of the technology to the patient changes. For IHM, we do not consider that the costs will change.

Homer: In the Homer model, the equation is "Increase in Magnitude of Harm per Doubling of Eligibility = 0.8." Since cost does not change, in the IHM model this variable is set to 0.

Units: Qual Adj Life Years/dollars

Homer: In the Homer model, this equation is the Marginal Benefit Harm Ratio, and the equation does not include any alternative technologies.

*(212) Maximum Eligibility Fraction From Capability = 1
Units: 1
Maximum Eligibility Fraction from Capability represents the highest fraction of the universe of cases that the technology may be applied to.

Homer: The universe of new cases for the pacemaker case included all cardiac arrhythmias; of those, only 40% were possible candidates for a pacemaker. For IHM, since potentially 100% of the CHF population could be considered candidates for the technology, the value is 1.

**************
IB 5b. Functional Capability Equations
**************

No equations were altered in this sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

I C 1b. Patients in Follow Up Equations

No equations were altered in this sector.

I C 2b. Evaluation and Reporting Equations

**(230) Perceived Adequacy of Follow Up to Date = SMOOTHI(Adequacy of Follow Up to Date, Perception Time, 0)
Units: 1
Perceived Adequacy of Follow Up to Date. This variable was constructed to eliminate the simultaneous equations problem when computing Follow Ups to Date.

Homer: This variable was added to eliminate a "simultaneous equation" simulation issue. It is smoothed over just one time step, so it should not affect the dynamics of the model.

**(239) Perception Time = 0.0625
Units: year
Perception Time is set to the time step of the model to allow calculation of "Perceived Adequacy of Follow-Up to Date."

Homer: Same as above. This variable was added to eliminate a "simultaneous equation" simulation issue. It is smoothed over just one time step, so it should not affect the dynamics of the model.

Information from Follow Up-Aggregate Benefit Cost Ratio Equations

**(091) Benefit Cost Ratio Reference = Benefit Normal/Cost Normal
Units: Qual Adj Life Years/dollars
Benefit-Cost Ratio Reference. This ratio is used as a reference value for comparing benefit cost ratios. It takes the same numerical value as the BCR Normal.

Homer: In the Homer model, this equation is called "Benefit Harm Reference," and it has a value of 30 in the pacemaker case. (The same numerical value as the Benefit Harm Ratio Normal.) Hence, it the IHM model, it has the same form and value as the Benefit Cost Ratio Normal.

I C 4b. Information from Follow Up-Marginal Benefit Cost Ratio Equations

No equations altered in this sector.

I C 5b. Information from Follow Up-Eligibility Equations

No equations altered in this sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

II A lb. Marketing Equations

*(196) Initial Marketing Effort = 0
Units: dollars/year
The Initial Marketing Effort represents the initial "kickoff" of marketing effort by the manufacturer.

Homer: A three-parameter logical switching function was used in the Homer model set for the initial marketing effort. It was allowed to switch between the indicated marketing effort and the exogenous initial marketing effort. In the IHM case, the initial marketing spending is simply set to an exogenous input parameter.

*(278) Sales Revenue per Implant = 7000
Units: dollars/cases
Sales Revenue per Implant is the selling price of the IHM technology.

Homer: For the historical pacemaker case, the sales revenue per procedure increased over time. To create this increase, a lookup table was used.

II B lb. Technical Development Equations

*(200) Initial Technical Development Projects = 0
Units: Projects

Homer: A three-parameter logical switching function was used in the Homer model set for the initial technical development. It was allowed to switch between the indicated technical development and the exogenous initial technical development projects. In the IHM case, the initial technical development is simply set to an exogenous input parameter.

*(276) Return to Technical Development Normal = 0.1
Units: 1/Projects
Return to Technical Development Normal is the "normalized" value for the expected increase in product capability from technical development.

Homer: The Return to Technical Development Normal = 0.25 in the pacemaker case. It was felt that this value should be reduced for IHM, since technical development projects are not expected to have as dramatic an impact on improvements in product capability.

III A lb. Payer Equations

**(001) Fraction of Marketing Effort for Payers = 0
Units: dmnl

Homer: No equation for this variable. This variable was created to accommodate the payer sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

** (003)  Payer Rejection Fraction =
Payer Rejection Fraction Normal*Effect of Benefit Cost Ratio on Payer Rejection
Units: 1/year

** (004)  Payer Rejection Fraction Normal = 0.01
Units: 1/year
The Rejection Fraction Normal times the Effect of Benefit Harm Ratio on Rejection yields the
current Rejection Fraction used in the rejection rate for Recommending Physicians.

Homer: No equation for this variable. This variable was created to accommodate the payer
sector. This value is the same as the analogous value in the Recommending Physician sector.

** (011)  Effect of Benefit Cost Ratio on Payer Approval =
EBCRPA(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmnl
The Effect of the Benefit-Cost Ratio on Payer Approval of the technology can suppress the rate of
acceptance when the perceived relative advantage is low and boost it when this ratio is high, with
the same relationship to payers as what is described for physician acceptance.

Homer: No equation for this variable. This variable was created to accommodate the payer
sector. This value is the same as the analogous value in the Recommending Physician sector.

** (012)  Effect of Benefit Cost Ratio on Payer Rejection =
EBCRPR(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmnl
The Effect of Benefit Cost Ratio on Payer Rejection is described by a lookup table "EBCRPR"
that relates the Perceived Aggregate BCR from Follow Up to the Benefit-Cost Ratio Normal.
When the Perceived Aggregate BCR from FU (PABCRF) is greater than or equal to the "normal"
value of BCR (BCRN), the rejection fraction will be very small, but if PABCRF/BCRN (which
represents the perceived overall relative advantage of the technology) drops below 1, payers may
abandon the product and switch to a competing technology.

Homer: No equation for this variable. This variable was created to accommodate the payer
sector. This value is the same as the analogous value in the Recommending Physician sector.

** (021)  Effect of Follow Up Reports on Payer Approval =
EFURPA(follow up reporting rate/Follow Up Reporting Rate Normal)
Units: dmnl
The Effect of Follow Up Reports on Payer Approval represents the response of payers to journal
reports evaluating clinical outcomes using the technology. Like product promotions, reports are
more influential when there are more of them and the impact on acceptance is fairly immediate and
temporary, but a limit to the impact of the professional media undoubtedly exists.

Homer: No equation for this variable. This variable was created to accommodate the payer
sector. This value is the same as the analogous value in the Recommending Physician sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

** (033) Payer Approval Fraction =

\[
Payer\ Approval\ Fraction\ Normal \times \text{Effect of Benefit Cost Ratio on Payer Approval} \\
\times (\text{Effect of Payer Marketing Effort on Approval} + \text{Effect of Follow Up Reports on Payer Approval} + \text{Effect of Payer Fraction on Approval Rate})
\]

Units: 1/year

The Payer Approval Fraction is determined by effects of benefit-cost, other payer interactions, marketing effort, and follow-up reports.

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

** (034) Payer Approval Fraction Normal = 0.05

Units: 1/year

The Acceptance Fraction Normal represents the fractional rate of payer approval when a) the product is fully available, b) the technology has a neutral perceived relative advantage, and c) the combined impact of the various communication channels is equivalent to the maximum impact that contacts with other payers can exert alone. The normal payer approval fraction is 2/3 lower than the normal physician acceptance fraction because payers are less likely to approve technologies because of the scale their decisions encompass.

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

** (035) Initial Reimbursing Payer Fraction = 0.01

Units: 1

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

** (042) Non Reimbursing Payer Fraction = 1 - Reimbursing Payer Fraction

Units: 1

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

** (045) Effect of Payer Fraction on Approval Rate = EPFAR(Reimbursing Payer Fraction)

Units: d$m$1

The Effect of Payer Fraction on Approval Rate is the effect that previous payers have on influencing future potential payers to include the IHM device on their reimbursing list.

Homer: No equation for this variable. This variable was created to accommodate the payer sector. The value, entered in the lookup table function, is one-fifth as great as the analogous value in the Recommending Physician sector, since it is expected that payers will not be as influenced by other payers as physicians are influenced by other physicians.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

**(049)  payer rejection rate = Reimbursing Payer Fraction*Payer Rejection Fraction  
Units: 1/year

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

**(050)  payer approval rate = Non Reimbursing Payer Fraction*Payer Approval Fraction  
Units: 1/year

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

**(057)  Reimbursing Payer Fraction = 
INTEG(payer approval rate-payer rejection rate, Initial Reimbursing Payer Fraction)  
Units: 1

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector.

**(058)  Fraction of Capitated Reimbursement = 1  
Units: dmnl

The Fraction of Capitated Reimbursement is the fraction of physician reimbursement that is made on a capitated basis, or on the basis of number of patients served versus on a per-procedure basis. This is speculated to affect the way physicians make therapy choices, since their choices will affect their own compensation.

Homer: No equation for this variable. This variable was created to accommodate the payer sector.

**(063)  Effect of Payer Marketing Effort on Approval = 
EMEPA(Marketing Effort*Fraction of Marketing Effort for Payers/Marketing Effort Normal)  
Units: dmnl

The Effect of Marketing Effort on Acceptance represents the overall response of payers to the promotional marketing activities of manufacturers. It can also generate approval with influence increasing according to size and number, but the influence diminishes past a certain point. Also, the impact on approval of a particular promotion or report is assumed to be fairly immediate and temporary.

Homer: No equation for this variable. This variable was created to accommodate the payer sector. This value is the same as the analogous value in the Recommending Physician sector. The additional "Fraction of Marketing Effort for Payers" variable splits the marketing spending between payers and physicians.

******************************************
IV A 1b. Summary Statistics Equations  
******************************************

Other than variations in the labeling of variables, no equations were altered in this sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

IHM payer model equations

*(166) FINAL TIME = 2020
Units: year
The final time for the simulation

Homer: The pacemaker model ended at 2000.

*(202) INITIAL TIME = 2000
Units: year
The initial time for the simulation.

Homer: The pacemaker model started at 1960.

IHM payer model lookup tables

**(005) EBCRPA ([0,0.01],(0.5,0.25),(1.0,1.75),(2.25),(2.5,3.25),(3.4),(3.5,4.5),(4.4,7.5),(4.5,5.5),(5.0,5.0)
Units: 1
Table: The Effect of Benefit-Cost Ratio on Payer Approval.

Homer: No equation for this lookup table. This lookup table was created to accommodate the payer sector. The values are the same as in the analogous lookup table in the Recommending Physician sector.

**(006) EBCRPR ([0,0.01],(10.0,100)],(0.25,50),(0.5,25),(0.75,10)
,(1.1),(1.25,0.8),(1.5,0.7)
Units: dmml
Table: Effect of Benefit Cost Ratio on Payer Rejection.

Homer: No equation for this lookup table. This lookup table was created to accommodate the payer sector. The values are the same as in the analogous lookup table in the Recommending Physician sector.

**(020) EMEPA ([0,0.01],(2.1,5)],(0.25,0.3),(0.5,0.6),(0.75,0.8)
,(1.1),(1.25,1.2),(1.5,1.3),(1.75,1.4),(2.1,4)
Units: dmml
Table: Effect of Marketing Effort on Payer Approval.

Homer: No equation for this lookup table. This lookup table was created to accommodate the payer sector. The values are the same as in the analogous lookup table in the Recommending Physician sector.
(11.2.2 Parameters that were adjusted to suit the IHM case continued)

***(041) EPAA ((0,0),(10,10),(0,0),(1,1))**

Units: dmnl

Table: Effect of Payer Approval on (physician) Acceptance. The table is constructed so that the fraction of payers relates linearly with the fraction of approving payers.

Homer: No equation for this lookup table. This lookup table was created to accommodate the payer sector.

***(044) EPFAR ((0,0),(1,1),(0,0),(0,0),(0,0,0.0025),(0.1,0.25)
,(0.25,0.5),(0.5,0.5),(0.6,1),(0.9,1),(1,1))**

Units: dmnl

Table: Effect of Payer Fraction on (payer) Approval Rate. The table function has a shape that suggests that only 1% of payers have approved the device, it has 0 effect on other payers. If 10% of the Payers have approved the use of IHM, there is a 25% weighting that it will influence future payers. If 50% have approved the use of IHM, there is a 50% weighting, and if 60% or greater have approve use of the device, there is a 100% chance that it will influence future Payers to approve the use of the device.

Homer: This lookup table is analogous to the "Effect of Colleague Discussion" lookup table in the Recommending Physician sector, but this lookup table was altered (see description) to suit the payer sector.

***(053) EFURPA ((0,0),(1.5,1.5),(0,0),(0.25,0.3),(0.5,0.6),(0.75,0.8)
,(1,1),(1.25,1.2),(1.5,1.3),(1.75,1.4),(2,1.4))**

Units: dmnl

Table: Effect of Follow-Up Reports on Payer Approval.

Homer: No equation for this lookup table. This lookup table was created to accommodate the payer sector. The values are the same as in the analogous lookup table in the Recommending Physician sector.

**(055) FHO ((0,0),(20,10),(0,0.01),(0.6,0.01),(0.7,0.01),(1,0.01),(10,0.01))**

Units: dmnl

Table: Fraction of Harmful Outcomes

Homer: This lookup table was also part of the Homer model. FHO relates the ratio of Functional Capability (arising from product capability and physician expertise) to Maximum Functional Capability to the Fraction of Harmful Outcomes. The table was altered to reflect that physicians who will be implanting the IHM are likely to already have experience in implanting pacemakers, and manufacturers have technical experience in implantable devices. Therefore, it is not expected that there will be any greater fraction of harmful outcomes at lower values of functional capability for IHM. The Homer pacemaker case lookup table has values as follows, with the altered values in bold: FHO ((0,0),(20,10),(0,0.1),(0.05,0.1),(0.6,0.1),(0.7,0.01),(1,0.01),(10,0.01))
11.2.3 IHM Base Case

In the IHM base case, the model is programmed to the expected values related to technology acceptance, alternative management strategies are not considered, and the payer sector is not activated. This case represents the potential physician acceptance of the IHM technology versus drugs alone, the standard of therapy in CHF patients, without the effects of payers or competition from intensive clinic follow up or more invasive procedures. Physicians will assess the merits of the IHM technology versus a cost-effectiveness standard, the benefit-cost ratio normal. The critical variables of interest include the expectations of the benefit that IHM will provide, the additional cost of IHM, and the benefit and cost of alternatives.

To calculate the expected benefit and cost of IHM, we need to make some assumptions. The Aggregate Magnitude of a Beneficial Outcome Normal value is the additional benefit over the current standard of care, drug therapy alone, that is expected to be provided to the minimum patient population. To observe the dynamics of the model through a range of eligibility fractions, it is best to start with the smallest patient eligibility fraction. Since the most desperate CHF patients, which may likely be transplant patients on the waiting list, number about 5000, this is considered the minimal patient population for the IHM technology.

Using assumptions based on the literature, the Aggregate Magnitude of Beneficial Outcome Normal is estimated at 6 QALY for the most desperate patient population. From the estimates of the Aggregate Magnitude of Cost Outcome Normal for IHM, which is estimated at $18,250 of additional cost over drug therapy, the variables in the base case IHM model is determined. The payer sector is "turned off" in the base case as well. The base case, therefore, is formed by setting the following variables:

Aggregate Magnitude of Beneficial Outcome Normal = 6 QALY
Aggregate Magnitude of Cost Outcome Normal = $18,250
Alternative Aggregate Benefit = 0 QALY
Alternative Aggregate Cost = $0
Benefit-Cost Ratio Normal = 1 QALY/$20,000
Fraction of Capitated Reimbursement = 1
Fraction of Marketing Effort for Payers = 0
Balk Factor = 0
11.2.4 IHM base case model results

The tables below show the parameters that were programmed in the base case, (in the simulation table) and the resulting data from the model.

<table>
<thead>
<tr>
<th>Simulation</th>
<th>Benefit Cost Ratio Normal (QALY per $)</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alt. Est. 3-year Benefit in QALY</th>
<th>Alt. Est. 3-year Costs in $</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHMBASE</td>
<td>1/20,000</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Results from simulation are as follows:

<table>
<thead>
<tr>
<th>DATA Simulation</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHMBASE</td>
<td>213,288</td>
<td>2.158 M</td>
<td>0.5363</td>
<td>0.00012</td>
<td>.9941</td>
</tr>
</tbody>
</table>

The following graphs depict the behavior of the model over time under the base case conditions. Implants in the base case conditions look very similar to the Initial Procedures in the Homer pacemaker model, but the time span over which the behavior occurs in the IHM model is shorter. The similarities in curve shape are due to the similarities in model structure.

The shorter time span probably indicates that the relative values of Benefit-Harm used in the Homer Model and Benefit-Cost used in the IHM model are different from one another. A quick calculation of the relative BHR and BCR ratios examined in the model shows that the IHM base case starts with a higher relative ratio:

**Homer Pacemaker Case:**

BHR Normal = 30  
*AMBON = 10  
**AMHON = 1  
BHR Ratio = \( \frac{10/1}{30} = 0.33 \)

**IHM Base Case:**

BCR Normal = 1/20,000  
AMBON = 6  
***AMCON = 18,250  
BCR Ratio = \( \frac{6/18,250}{1/20,000} = 6.57 \)

AMBON = Aggregate Magnitude of Beneficial Outcome Normal  
AMHON = Aggregate Magnitude of Harm Outcome Normal  
AMCON = Aggregate Magnitude of Cost Outcome Normal
Model behavior shown in the Patient Selection graph is similar as well, but the IHM model is again faster than the Homer model. In both simulations, the majority of Recommending Physicians accept the technology within ten years, and the eligibility and selection fractions reach towards but do not meet the maximum values. (for the Homer model, the maximum eligibility fraction was 0.4, and the simulation shows a final value of approximately 0.75; in the IHMbase case, the maximum eligibility fraction is 1.0, and the simulation reaches just over 0.5.)
With regard to acceptance factors, again, most of the model variables appear to exhibit similar but accelerated behavior compared to the Homer Model. The "Effect of Benefit Cost Ratio on Acceptance," however, starts at its maximum value in the IHM model, and declines over time to a greater extent. This is due to the model formulation of cost versus harm. Whereas harm declines with technology progression in the Homer model, such that the BHR increases, cost stays the same in the IHM model, so as benefit decreases cost stays the same. This causes the overall BCR to decline over time in the IHM model.

Factors Affecting Acceptance

Benefit Cost Ratios for IHM

Perceived Aggregate Benefit Cost Ratio from Follow Up - IHMBA\textsuperscript{Qual Adj Life Years/dollars}
Aggregate Benefit Cost Ratio - IHMBA\textsuperscript{Qual Adj Life Years/dollars}
Marginal Benefit Cost Ratio - IHMBA\textsuperscript{Qual Adj Life Years/dollars}
Perceived Marginal Benefit Cost Ratio from Follow Up - IHMBA\textsuperscript{Qual Adj Life Years/dollars}
The functional capability performance shows that the IHM model performs in an accelerated fashion when compared to the Homer model, but the dynamic evolution of the model behaves very similarly.

11.3 Addition of the Payer Sector
Since the health care market has changed drastically since 1983, and more change is expected in the future, payer environment considerations play a critical role in assessing the potential diffusion of the IHM technology. As discussed in Chapter 10, the model has been formulated to address these issues with the payer sector.

The payer sector is activated when the Fraction of Capitated Reimbursement is less than one; this means that the decision to utilize IHM technology is not only in the jurisdiction of the physicians. The fraction of implants that are in the jurisdiction of the payers is (1-Fraction of Capitated Reimbursement). For an IHM to be implanted when governed by the payers, the Payers must approve the use of the technology, in a similar fashion to the acceptance by Recommending Physicians. This approval process will thus constrain the diffusion of the IHM for the fraction for which it controls, if it is the limiting factor (e.g. other than eligibility fraction or recommending physicians.)

The other variables that are programmed to influence the behavior of the payer environment are the Physician "Balk" Factor and the Fraction of Marketing to Payer Organizations. The "Balk" factor, to review from Chapter 10, is the fraction of physicians who will elect not to use an expensive-up-front technology in a capitated reimbursement environment. This fraction will effectively limit the fraction of Recommending Physicians. The Fraction of Marketing Effort for Payers is the fraction of the total marketing spending that is directed to payers versus physicians; the total marketing spending, however, is determined in the same fashion as in the Homer model.
The payer base case (PAYBASE) will have the variables programmed as outlined in the following table. Since it is uncertain as to how capitated reimbursement programs will evolve, for the base case the fraction of capitation is set to 0.5. Since half of the implants, therefore, in the model are "governed" by the payers, the fraction of marketing spending is similarly 0.5. Also, given human nature, it was felt that some fraction of physicians would balk at choosing IHM, so the base case Physician Balk Factor was estimated at 0.25.

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alt. Est. 3-year Benefit in QALY</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capitation Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mkting to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHM BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PAY BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
</tbody>
</table>

The tabular data comparing the simulations is as follows:

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
<th>Reimbursement Payer Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHM BASE</td>
<td>213,288</td>
<td>2.158 M</td>
<td>.5363</td>
<td>0.00012</td>
<td>.9941</td>
<td>.8969 (inactive)</td>
</tr>
<tr>
<td>PAY BASE</td>
<td>212,402</td>
<td>2.004 M</td>
<td>.5364</td>
<td>0.00012</td>
<td>.9899</td>
<td>.9821</td>
</tr>
</tbody>
</table>
The table results observed with the graphs below indicate that the model generates quite similar data for the IHMBASE the PAYBASE cases. The cumulative implants after 20 years is only 154,000 less with the PAYBASE simulation, and is due to the longer delay in payer approval than is represented in physician acceptance. The delay in payer approval comes from the approval fraction parameters discussed in detail in Chapter 10. Also, the Payer Reimbursing Fraction is .09 greater in the PAYBASE simulation due to marketing spending; in the IHM base case, no marketing spending is directed to payers; all of the payer “approval” (even though the sector is inactivated) is due to the other parameters that influence payer approval. The rest of the variables reported in the table are not remarkably different for both cases.

Graph for Implants

The graph for Recommending Physician Fraction and Reimbursing Payer Fraction below shows the difference between acceptance and approval patterns between the two cases. The difference between the Recommending Physician Fraction acceptance patterns is due to the Balk Factor (25% less are candidates for the approval fraction each year) and to the decrease in marketing spending. The difference between Reimbursing Payer Fraction behavior is due to the marketing spending difference. Marketing spending dramatically increases the speed of Payer Approval.
The graph for eligibility fraction shows that there is no appreciable difference in patient eligibility in the two cases.
12. Presentation and Analysis of Scenario Simulations
To fully grasp the range of possible outcomes for the diffusion of the IHM technology, simulation of

12.1 Benefit -Cost Ratio Normal
The following tables summarize the variables that are tested in the base case simulation environment with varying values used for the Benefit-Cost Ratio Normal. The tables report a portion of the data resulting from simulation. Because the Benefit-Cost Ratio Normal (BCR Normal) is so critical to the dynamics of the model, since it is the standard to which all cost-effectiveness measures are compared, several simulations are run using three different values of Benefit Cost Ratio Normal. The range of accepted values for the benefit cost ratio in cost-effectiveness analysis is thought to be 1 QALY/$20,000 up to 1 QALY/$40,000. (Kupersmith, p. 243) The model will be tested using the endpoints of this range. For the base case, the BCR Normal = 1/$20,000, since this is the conservative endpoint of the published range. To test an even more conservative scenario, a third simulation will be run using a Benefit Cost Ratio Normal of 1 QALY/$10,000.

<table>
<thead>
<tr>
<th>Simulation</th>
<th>Benefit Cost Ratio Normal (QALY per $)</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alt. Est. 3-year Benefit in QALY</th>
<th>Alt. Est. 3-year Costs in $</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHM BASE</td>
<td>1/20,000</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BCR2</td>
<td>1/40,000</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BCR3</td>
<td>1/10,000</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHM BASE</td>
<td>213,288</td>
<td>2.158 M</td>
<td>0.5363</td>
<td>0.00012</td>
<td>.9941</td>
</tr>
<tr>
<td>BCR2</td>
<td>309,091</td>
<td>2.764 M</td>
<td>0.7757</td>
<td>0.00009</td>
<td>.9961</td>
</tr>
<tr>
<td>BCR3</td>
<td>94,917</td>
<td>865,169</td>
<td>0.2392</td>
<td>0.00018</td>
<td>.9916</td>
</tr>
</tbody>
</table>

The tabular data above shows that in the base case, when BCR Normal = 1 QALY/$20,000, the model predicts that after 20 years, a total of 2.158 million IHM devices would be implanted, and the annual implant rate in 2020 would be 213,288 implants/year. The implant rate is primarily constrained by the patient eligibility for the device; the patient eligibility fraction in year 2020 for the base case is just over half of the CHF patient population (Universe of New Cases). Physician acceptance is almost 100%, as indicated by the Recommending Physician Fraction of 0.9941.
Should the acceptable cost-effectiveness range extend to $40,000 per quality adjusted life year, more implants are achieved, and the patient eligibility is extends to over 75% of the CHF patient population. If the cost effectiveness range is more conservative, at $10,000 per QALY, even though physician acceptance is still 99%, less than half of the base case implants occur, and patient eligibility for the device is limited to less than 25% of the CHF patient population.

The following graphical output reveals the timing in which events unfold in each of the three cases. In the graph for implants below, we see that in the base case, in year 2010 the implant rate reaches 100,000 implants/year. For the more aggressive BCR = 1/40,000, the implant rate reaches 100,000 approximately three and a half years earlier, at 2006.5. In contrast, in the conservative case, the implant rate doesn't reach 100,000 per year by the end of the simulation at 2020.
The graph for Eligibility Fraction below is also telling. The dynamics of the patient eligibility fraction are the same as for the implant rate, indicating that it eligibility that is \textit{driving} the implant rate rather than physician acceptance. As the BCR Normal is varied, the patient eligibility fraction varies as well, showing that if the acceptable range of BCR Normal is as high as 1 QALY/$40,000, eligibility could come close to 80\% of the patient population by 2020, versus in the more conservative case, patient eligibility would only reach approximately 25\% of the patient population.
The graph for Recommending Physician Fraction demonstrates that varying the BCR Normal has a slight effect on the timing of physician acceptance, delaying the acceptance pattern by approximately two and a half years in the conservative case versus the base case, but it does not have an appreciable effect on end-stage physician acceptance. In all cases, the Recommending Physician Fraction reached 99% by 2010.

12.2 Benefit and Cost
In addition to exploring the response of the IHM base model to different values of BCR Normal, it is instructive to examine the range of behavior using different assumptions for the patient benefit that IHM will provide and the additional cost IHM therapy will incur, without yet considering the effects of competing patient management alternatives or payer issues. In the scenarios below, the model was programmed to the base case, with BCR Normal = 1 QALY/$20,000, and the payer sector "turned off."

As indicated in the table below, the base case benefit value is 6 QALY for the first 5000 patients, at an additional cost of $18,250. To test for a 50% decrease in the expected benefit that IHM will provide, in simulation 1 the "Aggregate Magnitude of a Beneficial Outcome Normal" variable is programmed to 3. In simulation 2, to test the model's response to a doubling of benefit, the "Aggregate Magnitude of a Beneficial Outcome Normal" is set to 12 QALY. To test the sensitivity of the model to an aggressive cost reduction, in simulation 3 the cost variable is set to half of the expected additional 3 year cost for IHM management.
<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alt. Est. 3-year Benefit in QALY</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita -tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mkting to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>9,125</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Tabular results from the simulations are as follows:

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
<th>Reimbursement Payer Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASE</td>
<td>213,288</td>
<td>2.158 M</td>
<td>.5363</td>
<td>0.00012</td>
<td>.9941</td>
<td>.8969</td>
</tr>
<tr>
<td>1</td>
<td>26,590</td>
<td>340,198</td>
<td>.0670</td>
<td>0.00009</td>
<td>.9916</td>
<td>.4347</td>
</tr>
<tr>
<td>2</td>
<td>422,606</td>
<td>3.424 M</td>
<td>1.0</td>
<td>0.00023</td>
<td>.9961</td>
<td>.9396</td>
</tr>
<tr>
<td>3</td>
<td>308,875</td>
<td>2.762 M</td>
<td>.7752</td>
<td>0.00019</td>
<td>.9961</td>
<td>.9392</td>
</tr>
</tbody>
</table>

As in the previous experiment with BCR Normal, varying the patient benefit and cost variables markedly affects the implant rate per year and the cumulative number of implants by 2020. The most dramatic shift occurs when the benefit value is changed. If the 3-year Benefit from IHM for the first 5000 patients is 3 QALY, versus the expected 6 QALY, the cumulative implants drops from 2.158 million to 340,198 over 20 years. Similarly, if the expected benefit is doubled to 12 QALY for the first 5000 patients, cumulative implants skyrocket to 3.424 million and implants per year in 2020 are 433,606. The differences in implant rates are primarily due to the difference in eligibility fractions for each case, which are determined by the marginal benefit cost ratios. When the initial benefit is very high, the eligibility fraction grows until the marginal benefit cost ratio is 0.

Reducing cost by a factor of two, on the other hand, does not exhibit as powerful an effect as halving or doubling the benefit. Implants are increased, and eligibility fraction displays a proportional increase, but the results indicate that although the effects are significant, focusing on the same relative change in benefit will bring about a greater response in the model. Cost does not play a significant role in physician acceptance.
12.3 Payer Sector Scenarios
To test the effects of differences in payer environment, the model simulated the following combinations of the payer variables:

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alt. Est. 3-year Benefit in QALY</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capitation Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mkting to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>.5</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>.25</td>
<td>0</td>
</tr>
</tbody>
</table>

Results from the simulations were as follows:

<table>
<thead>
<tr>
<th>DATA</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
<th>Reimbursing Payer Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>212,402</td>
<td>2.004 M</td>
<td>.5364</td>
<td>0.00012</td>
<td>.9899</td>
<td>.9821</td>
</tr>
<tr>
<td>4</td>
<td>201,847</td>
<td>920,590</td>
<td>.5275</td>
<td>0.00012</td>
<td>.9565</td>
<td>.9581</td>
</tr>
<tr>
<td>5</td>
<td>212,779</td>
<td>2.067 M</td>
<td>.5364</td>
<td>0.00012</td>
<td>.9916</td>
<td>.9825</td>
</tr>
<tr>
<td>6</td>
<td>212,897</td>
<td>2.140 M</td>
<td>.5364</td>
<td>0.00012</td>
<td>.9921</td>
<td>.8882</td>
</tr>
</tbody>
</table>

The greatest difference in results occurs in cumulative implants, in simulation number 4. In simulation number 4, the payer environment is 100% payer reimbursement; the Frac. of Capitation is 0. The delay in payer approval, coupled with the fact that none of the physicians could accept the technology without payer approval, reduced cumulative implants by 50% from the PAYBASE case. Other than the significant delay in payer approval, and hence physician acceptance, the end state parameters in each of the runs is quite similar. The physician "balk" factor plays a comparatively minimal role in long-term acceptance of the technology.
12.4 Alternative Management Approach: Intensive Clinic Follow Up

In this section, IHM will be compared to the alternative management strategy of intensive clinic follow up in the "payer base" model environment. To compare IHM to intensive clinic follow up, average additional benefit and cost values for intensive clinic follow up will be entered in the "Alternative Aggregate Expected Benefit" and "Alternative Aggregate Expected Cost" variables. Since IHM will be compared to intensive clinic follow up in this simulation, intensive clinic follow up will be considered the "standard" therapy. For the model to work appropriately, only a single, average value can be used; therefore, the values entered for the alternative management strategy will represent the average values for 20% of the CHF patient population.

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alternative Estimated 3-year Benefit in QALY, at 20% eligibility level</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita -tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mkting to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>7 (exp)</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>18,250</td>
<td>1.5</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>9</td>
<td>6</td>
<td>18,250</td>
<td>3.0</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>10</td>
<td>6</td>
<td>18,250</td>
<td>4.5</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
<th>Reimbursement Payer Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>212,402</td>
<td>2.004 M</td>
<td>.5364</td>
<td>.000012</td>
<td>.9899</td>
<td>.9821</td>
</tr>
<tr>
<td>7 (exp)</td>
<td>135,064</td>
<td>1.400 M</td>
<td>.3412</td>
<td>.000012</td>
<td>.9985</td>
<td>.9809</td>
</tr>
<tr>
<td>8</td>
<td>79,264</td>
<td>829,808</td>
<td>.2005</td>
<td>.000011</td>
<td>.9882</td>
<td>.9763</td>
</tr>
<tr>
<td>9</td>
<td>19,806</td>
<td>140,034</td>
<td>.0539</td>
<td>.000010</td>
<td>.9177</td>
<td>.8550</td>
</tr>
<tr>
<td>10</td>
<td>661</td>
<td>4,906</td>
<td>.0126</td>
<td>.00008</td>
<td>.1303</td>
<td>.0368</td>
</tr>
</tbody>
</table>
The model output once again displays the powerful effect that benefit has in driving the diffusion of the IHM technology. In this scenario, it is the relative advantage of the IHM that is driving the model; if the difference in benefit between IHM and intensive clinic follow up is great, the relative advantage of IHM is high, and diffusion is quick and significant. If the relative advantage is low, the diffusion of the technology is not as significant.

The expected case, based on the analysis of benefit and cost for the intensive clinic monitoring management alternative, is simulation number 7. With this case, as is shown in the results table, cumulative implants are reduced from the Payer base case by approximately 600,000 implants, and annual implants in 2020 are reduced by approximately 75,000 implants/year. These reductions are primarily the function of a narrower eligibility criteria for the device, but reimbursing payer fraction and recommending physician fraction also play a role in slowing acceptance.

Should the relative advantage of IHM narrow with respect to intensive clinic follow up, the diffusion of the technology will continue to be affected, as shown in the following graphs. In the end, if IHM demonstrates no significant relative advantage than management with intensive clinic follow up, because it is the costlier choice of the two, no adoption would occur.

Graph for Implants

<table>
<thead>
<tr>
<th>Year</th>
<th>Implanted Cases/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>PAYBASE</td>
</tr>
<tr>
<td>2001</td>
<td>IHM7</td>
</tr>
<tr>
<td>2002</td>
<td>IHM8</td>
</tr>
<tr>
<td>2003</td>
<td>IHM9</td>
</tr>
<tr>
<td>2004</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td></td>
</tr>
</tbody>
</table>
12.5 Alternative Management Approach: LVAD

Left Ventricular Assist Devices (LVAD’s) are also a potential alternative management strategy for CHF management. Although LVAD’s are considered an alternative, to compare IHM to LVAD using the model IHM would need to be considered the "standard" of care, because LVAD is also an evolving therapeutic approach to CHF treatment.

Since the underlying technology is so different, with different risk characteristics, technology development, patient application, etc., all of the benefit-cost, technology development, physician expertise, functional capability, physician acceptance, and payer acceptance variables in the model would need to be adjusted to suit the LVAD technology case to run the model using LVAD as the technology in question. Although potentially very important to the success of the IHM in the marketplace, this effort is outside the scope of this thesis.
12.6 Best and Worst Cases
To estimate the widest possible range of potential diffusion behavior that could be expected at this stage of technology development and market uncertainty, without considering the effects of additional marketing or technological development spending, the following scenarios consider the best expected possible and worst expected possible cases. The expected values, versus the best or worst imaginable values, are used to try to stay within the context of the real world situation as much as possible. The model parameters for each are as follows:

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alternative Estimated 3-year Benefit in QALY, at 20% eligibility level</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita - tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mkting to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>6</td>
<td>18,250</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>BEST</td>
<td>6</td>
<td>18,250</td>
<td>0.75</td>
<td>1425</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>WORST</td>
<td>3</td>
<td>18,250</td>
<td>1.5</td>
<td>1425</td>
<td>0</td>
<td>0</td>
<td>0.75</td>
</tr>
</tbody>
</table>

In the best possible case, the IHM and Intensive Clinic Follow Up benefit and the costs are as expected. The payer environment is such that physicians are completely in control of deciding which clinical options to choose, and none of them balk at expensive-up-front alternatives. The Benefit-Cost Ratio Normal is 1 QALY/$40,000. Also, 100% of the marketing budget is spent to educate and train physicians.

In the worst possible case, the IHM has a small relative advantage to Intensive Clinic Follow Up. The payers are entirely in charge of approving the technologies that physicians use, and to be realistic, 75% of the marketing budget is spent on the payers. The Benefit-Cost Ratio Normal is 1 QALY/$20,000.

The results of simulation are as follows:

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Patient Eligibility Fraction at 2020</th>
<th>Aggregate Benefit Cost Ratio at 2020</th>
<th>Physician Recomm. Fraction at 2020</th>
<th>Reimbursement Payer Fraction at 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAY BASE</td>
<td>212,402</td>
<td>2.004 M</td>
<td>.5364</td>
<td>.000012</td>
<td>.9899</td>
<td>.9821</td>
</tr>
<tr>
<td>BEST</td>
<td>175,774</td>
<td>2.145 M</td>
<td>.4412</td>
<td>.000096</td>
<td>.9958</td>
<td>.9335</td>
</tr>
<tr>
<td>WORST</td>
<td>43</td>
<td>940</td>
<td>.0125 (the min.)</td>
<td>.000078</td>
<td>.0087</td>
<td>.0179</td>
</tr>
</tbody>
</table>
As the simulation data bears out, there is quite a separation between the best possible and worst possible cases, even when predicting parameters that are felt to be within the expected range. The IHM R&D project could result in as good an outcome as a business rivaling the pacemaker business in volume, or it could fail so badly that less than a thousand implants occur in twenty years.
12.7 Maximum Selection Fraction

It is important to note that the model simulations have been run with the assumption that the IHM monitor is potentially applicable to 100% of the CHF patient population. While this is theoretically true, in reality, it seems unlikely that the monitor would be used in the healthier fraction of the patient population. For this reason, it is useful to run the model with "Maximum Eligibility Fraction From Capability = 0.5," instead of 1 as in the IHM BASE and PAYBASE simulation runs. Also, it is most instructive to compare the results of simulation using the parameters of the expected case, simulation number 7 from section 12.4.

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alternative Estimated 3-year Benefit in QALY, at 20% eligibility level</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita -tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mktin g to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>MAX SELEC = 0.50</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
</tbody>
</table>

As shown in the tables and graphs below, the simulation output demonstrates that if the maximum eligibility for the device is thought to be half of the patient population, the number of implants is substantially reduced. This is because the Eligibility that results from Functional Capability is half as great, since the "Maximum Eligibility from Functional Capability = 0.5" instead of 1.0. The Eligibility resulting from the Perceived Benefit-Cost Ratios is not substantially affected.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (exp.)</td>
<td>135,064</td>
<td>1.4 M</td>
<td>0.3412</td>
<td>0.00012</td>
<td>.9895</td>
<td>.9809</td>
</tr>
<tr>
<td>MAX SELEC = 0.50</td>
<td>80,904</td>
<td>900,529</td>
<td>0.2042</td>
<td>0.00013</td>
<td>.9904</td>
<td>.9814</td>
</tr>
</tbody>
</table>


Graph showing the trends of Recommending Physician Fraction and Reimbursing Payer Fraction over time.

- **Recommendung Physician Fraction - IHM7**: 1
- **Reimbursing Payer Fraction - IHM7**: 1
- **Reimbursing Payer Fraction - MAXSEL50**: 1
- **Recommendung Physician Fraction - MAXSEL50**: 1

12.8 Manufacturer Controlled Variables

The manufacturer is in control of two sectors in the model, marketing and technological development. In the expected case, marketing spending and technological development spending are set to a fraction of sales per year, with initial values set to 0. With small numbers of implants in the initial phase, there is not a "kickoff" to start the adoption process; instead, the adoption occurs more gradually as the word of mouth effect dominates the diffusion of the technology.

To assess the expected effects of additional marketing spending and technological development spending, the model may be run with various levels of Initial Marketing Spending and Initial Technical Development. To test the effects of marketing spending, the model will be run with Initial Marketing Spending set to $1 million, and the $2 million. The remaining variables in the model will be set to the same values as in simulation number 7, the expected case without additional marketing spending or technological development.

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alternative Estimated 3-year Benefit in QALY, at 20% eligibility level</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita -tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mktin g to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (exp)</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>MKT1M</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>MKT2M</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
</tbody>
</table>

As shown in the tables and graphs below, the simulation output demonstrates that spending to develop the market initially does affect the initial ramp-up of acceptance technology acceptance, but it does not appreciably affect the steady-state behavior of the model (as expected, since the additional spending is initial marketing spending, and it only occurs in the first year.) Spending $1 million in initial marketing results in 44,000 more implants over 20 years, due primarily to higher implant rates in the first ten years. Spending $2 million in additional marketing results in 68,000 more implants. The implant graphs show the first 10 years and the first 5 years of implants over time.

If more marketing spending is done over time, by increasing the Fraction of Sales Revenue to Marketing Effort from 25% to 50%, the impact is spread out, but the effect is not appreciably different in terms of the total number of implants achieved. This is the case even though the cumulative marketing spending is almost double. Therefore, we can conclude that the model is more responsive to changes in patient benefit from the technology and hence the perceived benefit-cost ratio of the technology, over the effects of marketing spending.
<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Marketing Spending per year at 2020</th>
<th>Cumulative Marketing Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (exp) MKT0M</td>
<td>135,064</td>
<td>1.4 M</td>
<td>$236.17 M</td>
<td>$2.215 B</td>
</tr>
<tr>
<td>MKT1M</td>
<td>135,066</td>
<td>1.444 M</td>
<td>$236.20 M</td>
<td>$2.292 B</td>
</tr>
<tr>
<td>MKT2M</td>
<td>135,066</td>
<td>1.468 M</td>
<td>$236.21 M</td>
<td>$2.336 B</td>
</tr>
<tr>
<td>MKTFR50</td>
<td>135,067</td>
<td>1.468 M</td>
<td>$472.40 M</td>
<td>$4.666 B</td>
</tr>
</tbody>
</table>

![Graph for Marketing Effort](image)
To explore the effects of greater technical development spending, the Fraction of Sales Revenue to Technical Development may be varied. The fraction is varied, instead of the initial value, because customer feedback is expected to have an effect on the type of technological changes that are developed. In the expected case, the fraction is set to 0.12. Subsequent simulations are run with Fraction of Sales Revenue to Technical Development set to 0.20 and 0.30.

<table>
<thead>
<tr>
<th>Simul. #</th>
<th>IHM Est. 3-year Benefit in QALY for first 5000 patients</th>
<th>IHM Est. 3-year Costs in $</th>
<th>Alternative Estimated 3-year Benefit in QALY, at 20% eligibility level</th>
<th>Alt. Est. 3-year Costs in $</th>
<th>Frac. Capita -tion Reimb.</th>
<th>Phys. &quot;Balk&quot; Factor</th>
<th>Frac. Mktin g to Payer Org's</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (exp) techdv12</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>techdv20</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>techdv30</td>
<td>6</td>
<td>18,250</td>
<td>.75</td>
<td>1425</td>
<td>0.5</td>
<td>0.25</td>
<td>0.5</td>
</tr>
</tbody>
</table>

As shown in the tables and graphs below, the simulation output demonstrates that spending 20% of sales revenue on technical development, versus 12% as in the expected case, results in approximately 10,000 more implants in 20 years at an additional expense of approximately $350 million. These results calculate to roughly $35,000 per additional implant achieved! This expense seems exorbitant for the return achieved in terms of cumulative implants.

The behavior of the model is explained by looking at the graph of Product Capability over time. The returns to technical development spending occur in the early years, when technical development spending increases the product capability. Spending a greater fraction earlier in the diffusion process causes the product capability to increase more quickly, effectively moving the curve by 6 months with each step increase in the fraction of sales devoted to technical development. After 2010 or 2011, however, no returns are achieved, since the product capability has already reached it's maximum level, but the model still calculates the Fraction of Sales Revenue to Technical Development and accrues the cumulative expenses associated with it.

If simulation is done using an "IF THEN" statement in the Fraction of Sales Revenue to Technical Development to cause it to be 20% up to year 2010, and 0% thereafter, the results demonstrate that it has NO effect on the implant rate or cumulative implants. This suggests that technical development by itself is not the constraining factor in the acceptance of the technology. Money would be better of spent on marketing expenditures, or on development efforts that would substantially change the expected benefit the device provides to the patient. (Note that the relationship
between technical development spending and the expected widening of scope and effect on magnitude of benefit were not altered from the Homer model fitted to the pacemaker case.)

<table>
<thead>
<tr>
<th>DATA Simul. #</th>
<th>Implants per year at 2020 years</th>
<th>Cumulative Implants after 20 years</th>
<th>Technical Development Spending per year at 2020</th>
<th>Cumulative Technical Development Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (exp) techdv12</td>
<td>135,064</td>
<td>1.4 M</td>
<td>$46.26 M</td>
<td>$607.38 M</td>
</tr>
<tr>
<td>techdv20</td>
<td>135,062</td>
<td>1.410 M</td>
<td>$76.76 M</td>
<td>$955.65 M</td>
</tr>
<tr>
<td>techdv30</td>
<td>135,061</td>
<td>1.417 M</td>
<td>$114.92 M</td>
<td>$1.376 B</td>
</tr>
<tr>
<td>td-ifthen</td>
<td>135,064</td>
<td>1.4 M</td>
<td>$46.26 M</td>
<td>$607.38 M</td>
</tr>
</tbody>
</table>

![Implants Graph](image)

**Implants**

- Implants - IHM7 cases/year
- Implants - TECHDV20 cases/year
- Implants - TECHDV30 cases/year
- Implants - TD-IFTHEN cases/year
13. Conclusion and Recommendations
The system dynamics model developed for this thesis provides a tool to predict the possible diffusion of the IHM technology in the marketplace. The results from simulation display a range of potential behavior, depending on the assumptions used in each case. Although it must be acknowledged that there exists uncertainty in variables that are in the model as well as outside the model, the results from simulation may offer insight into the most critical elements relating to technology diffusion.

Analysis of the simulations presented in Chapters 11 and 12 give rise to the following conclusions:

- The IHM technology, based on the assumptions described in the thesis, is expected to reach relative maturity in the market within 10 to 15 years. This is evidenced by the peaking and leveling-off behavior in the Recommending Physicians, Eligibility Fraction, Functional Capability, and Benefit-Cost Ratio variables in a wide range of simulations.

- Addition of the payer sector to the model, if the model assumptions are correct, indicates that payers may substantially delay (up to eight years), but not limit, acceptance of the IHM technology over time if they control the market. If physicians are reimbursed by capitation, as long as the benefit-cost parameters attest to the value of the technology, the dynamics of acceptance will be only marginally delayed.

- The most sensitive model variable relative to the technology diffusion is the magnitude of benefit that the technology provides to patients.

- The relative advantage offered by IHM over Alternative Management Strategies is the second most critical element to technology diffusion. It is related to the magnitudes of benefit and cost of the IHM technology versus those offered by alternatives.

- The cost-effectiveness criteria used by the medical community in assessing the value of medical management approaches is also very important to the IHM case. Variations in the standard accepted benefit-cost ratio will impact the diffusion of the technology.

- Analysis of best and worst cases, constructed with feasible parameter values, suggests that there is great variation in possible outcomes in the market. This suggests that there is considerable risk to launching the device in the market.

- Simulation of manufacturer-controlled variables suggests that the manufacturer may influence the diffusion of the technology more by means of marketing spending than technological development spending.
The expected case, described in section 12.4, predicts that the IHM device will reach 135,064 implants/year by 2020, with a cumulative total of 1.4 million implants in the initial 20-year period in the market.

The conclusions drawn from simulation lead to a number of recommendations for an effective launch of the technology in the marketplace. The recommendations that are based on model simulation are, of course, limited by the assumptions used in the model. Recalling the strategic questions outlined in section 6.4, strategic consideration of the conclusions lead to the following recommendations:

1. Maximize the benefit the technology provides to the patient. The management team should focus on how the IHM technology brings value to the health care marketplace, and develop the technology accordingly.

2. Launch the technology as soon as it reaches a stage where it delivers benefit. Since it appears that technological development is not a constraining force in the diffusion of the technology, it is important to begin diffusion and hence revenue collection as early as possible. It is not critical that the technology be perfect before it is used in the market.

3. Price such that IHM device management falls within the cost-effectiveness range.

4. Market the IHM technology to maximize the impact on the most powerful customer. The most powerful customer could be the physician in a capitated reimbursement system, the payer organizations in a reimbursement by procedure system, or a combination thereof.

5. Minimize risk by utilizing an existing sales network as much as possible in the early phase of technology diffusion. This strategy will be useful in maximizing the relationship impact of the marketing program as well, and could play a role in facilitating word of mouth contacts between physicians and/or payers.

6. Align production and distribution strategies to accommodate demand for the technology as it grows over time.

It is hoped that this exploration of the technology diffusion process using the system dynamics modeling approach will contribute to the IHM program.
APPENDICES

Appendix A: Exhibits

Exhibit 1: National Institute of Health Medication Listing and Glossary
Source: National Institutes of Health Publication No. 94-923, April 1994

ACE Inhibitors.
These prevent the production of a chemical that causes blood vessels to narrow. As a result, blood pressure drops and the heart does not have to work as hard to pump blood.

Side effects may include coughing, skin rashes, fluid retention, excess potassium in the bloodstream, kidney problems, and an altered or lost sense of taste.

Digitalis.
Increases the force of the heart's contractions. It also slows certain fast heart rhythms. As a result, the heart beats less frequently but more effectively, and more blood is pumped into the arteries.

Side effects may include nausea, vomiting, loss of appetite, diarrhea, confusion, and new heartbeat irregularities.

Diuretics.
These decrease the body's retention of salt and so of water. Diuretics are commonly prescribed to reduce high blood pressure. Diuretics come in many types, with different periods of effectiveness.

Side effects may include loss of too much potassium, weakness, muscle cramps, joint pains, and impotence.

Hydralazine.
This drug widens blood vessels, easing blood flow.

Side effects may include headaches, rapid heartbeat, and joint pain.

Nitrates.
This drug is used mostly for chest pain, but may also help diminish heart failure symptoms. It is a smooth-muscle relaxer and widens blood vessels. It acts to lower primarily systolic blood pressure.

Side effects may include headaches.
Exhibit 1 continued: Glossary of Heart Failure Terminology
Source: National Institutes of Health Publication No. 94-923, April 1994

Angiotensin converting enzyme (ACE) inhibitor--A drug used to decrease pressure inside blood vessels.

Arrhythmia--An irregular heartbeat.

Cardiomyoplasty--A surgical procedure that involves detaching one end of a back muscle and attaching it to the heart. An electric stimulator causes the muscle to contract to pump blood from the heart.

Congestive heart failure--A heart disease symptom that involves loss of pumping ability by the heart, generally accompanied by fluid accumulation in body tissues, especially the lungs.

Diastolic heart failure--Inability of the heart to relax properly and fill with blood as a result of stiffening of the heart muscle.

Dyspnea--Shortness of breath.

Echocardiography--Recording sound waves bounced off the heart to produce images of the heart.

Edema--Abnormal fluid accumulation in body tissues.

Electrocardiogram (EKG or ECG)--Measurement of electrical activity associated with heartbeats.

Heart failure--Loss of blood-pumping ability by the heart.

Left ventricular assist device--A mechanical device used to increase the heart's pumping ability.

Pulmonary congestion (or edema)--Fluid accumulation in the lungs.

Sudden cardiac death--Cardiac arrest caused by an irregular heartbeat.

Systolic heart failure--Inability of the heart to contract with enough force to pump adequate amounts of blood through the body.

Valves--Flap-like structures that control the direction of blood flow through the heart.
<table>
<thead>
<tr>
<th>Management Method</th>
<th>Number of potential patients per year</th>
<th>Estimated average 5 year costs</th>
<th>Estimated Benefits</th>
<th>Estimated Disadvantages</th>
</tr>
</thead>
</table>
| **Conventional**  | total population = 4 million patients | $7225 (total average drug revenue per pt.) | • Well-accepted  
• Readily available  
• Improved survival  
• Not optimized | • Doesn't prevent disease progression  
• Ineffective in some patients  
• Significant side effects |
| Traditional Method: Drugs (all receive) | 2000/year (out of 15,000 candidates) | $255-$410K | • Well-accepted  
• Solid long-term survival data  
• 70% survival at 5 years, 80-90 at 2 yrs | • Limited supply of donor hearts (30% of status 1 patients die waiting)  
• Extremely invasive  
• High cost |
| Emerging (not yet proven) | | GOALS:  
• improve survival and quality of life  
• reduce number of days in hospital  
• 10% reduction in hosp > -$2B cost | • not yet proven |
| IHM-guided therapy | 20% of CHF patient population = 80,000 | Approx. $7000 for device, + followup | • Improved management than without ongoing monitoring  
• Possible improved survival | • many of same disadvantages as with drug therapy |
| Cardiomyoplasty | 100,000-150,000 | $78-95 ($25K for tech.) | • Alternative to transplant | • Must be done prior to end-stage cardiac failure |
| Left Ventricular Assist Devices (LVAD) | 15,000 | 170-240K ($50K each for device) | • Partially implantable device that off-loads some or all of the work of LV. Alternative to transplant.  
• No rejection risk or supply constraints | • Device reliability and longevity  
• External power source  
• Extremely invasive surgery  
• Relatively noisy |
| Total Artificial Hearts | Remainder of heart transplant patients, = 13,000/yr | Unknown. | • Bi-ventricular support  
• Appropriate for very sick  
• No supply or rejection risks | • Not yet available  
• External power source; noisy  
• Device failure is catastrophic |

## Exhibit 3: Buyer Levels for the IHM Technology

<table>
<thead>
<tr>
<th>Buyer Level</th>
<th>Incentives</th>
<th>Influence Mechanisms</th>
</tr>
</thead>
</table>
| Patients                             | • Desire to feel healthy  
• Simple, non-invasive followup                                             | • Doctor                                                  |
| Physician: Primary Care              | • Patient care revenue  
• Competitive with other doc's.  
• Quality care                                                              | • Insurance network reimb.  
• Industry marketing/sales  
• Physician Word of Mouth (WOM)  
• Publications                                                               |
| Physician: Implanter                 | • Implantation revenue  
• Competitive with other doc's.  
• Quality care                                                              | • Practice guidelines/Publications  
• Publications  
• WOM                                                                        |
| Physician: CHF followup              | • Follow-up revenue  
• Competitive with other doctors.                                            | • Practice guidelines  
• Publications  
• Word of Mouth                                                              |
| Medical Director (hospital level, provider level) | • Make decisions to put on/off formulary based return total cost of therapy and/or improved clinical outcomes and cost effectiveness.  
• Want clear patient selection criteria                                      | • Clinical study data  
• Physician approval                                                           |
| Hospital Provider                    | • Hospital revenue  
• Reimbursable service  
• Competitive with other hosp's.                                             | • Practice guidelines/insurance payment guidelines  
• Doctors                                                                     |
| Insurance Payer                      | • Lower patient management costs  
• Quality care                                           | • Cost-benefit analysis  
• Doctors                                                                     |

- Medicare  
- HMO  
- Integrated Service Network
Exhibit 4: Diagram of the Millar Right Heart Catheter

MILLAR®

FLOW DIRECTED MIKRO-TIP®
PRESSURE TRANSUDER/INFUSION CATHETER
WITH POLYURETHANE BALLOON

(THERMODILUTION AVAILABLE IN SPECIFIC MODELS)

MODELS MPA-372, MPA-372T, MPA-383, MPA-383T

FOR SINGLE USE ONLY
STERILE AND NONPYROGENIC ONLY IF
PACKAGE IS NOT OPEN OR DAMAGED
STERILIZED BY ETHYLENE OXIDE

READ ALL INSTRUCTIONS, WARNINGS AND
PRECAUTIONS CAREFULLY PRIOR TO USE

(MODEL MPA 383T SHOWN)
### Exhibit 5: Characteristics of the IHM Innovation and Adoption

<table>
<thead>
<tr>
<th>Relative Advantage (+)</th>
<th>Compatibility (+)</th>
<th>Complexity (-)</th>
<th>Observability (+)</th>
<th>Trialability (+)</th>
</tr>
</thead>
</table>
| • Eliminates need for a fraction of hospitalizations, leading to cost reduction in health care system  
• Allows potential improved/optimized pharmacologic therapy, leading to improved clinical outcomes  
• Is not therapeutic in itself  
• Costs less than repeated current in-hospital monitoring methods  
• Costs less than more aggressive therapy  
• Monitoring is less invasive post-implant  
• No supply or infection issues  
• Wholly implantable | • Compatible with aggressive western medical practice  
• Similar to idea to pacemaker implant  
• Physicians have felt need for monitoring device of this nature before  
• Some may be opposed to a permanent implant | • Initial explaining to doctors and patients relatively complex  
• Basic idea simple  
• User interface critical to creating simplicity  
• Device should be ACCURATE: it should provide not only relatively relevant values, but accurate parameters of O2 sat and Pulmonary Artery wedge pressure to minimize confusion about relationship between device measurement values and physiologic parameters. | • Benefit is not directly observable. Chronic studies are needed to assess efficacy of IHM-guided therapy. | • Device is trialable on a patient-by-patient basis. If necessary, devices may be removed, but with some operating risk. |
### Exhibit 6: IHM and Rate of Adoption

| Type of innovation decision | • Incremental benefit to managing patients without an implanted monitoring device.  
| | • Incremental to idea of implanted pacemaker as well.  
| Nature of communication channel at various stages | • Presentation to clinical study doctors, the "innovators". Generally accepting audience.  
| | • Publication of clinical results for doctors and payors. Skeptical audience.  
| | • Presentation of clinical results and cost/benefit analysis to payors in Health Care system. Skeptical audience.  
| | • Word of Mouth between physicians. Trusting audience.  
| | • Sales efforts to stimulate word of mouth.  
| | • Sales support of further adoption. Generally trusting audience when coming from credible salespeople.  
| Nature of the social system | • The present social system of health care is such that cost/benefit is extremely important.  
| | • Although the system has historically concentrated on technology, future evaluations will steer away from technology if there is not a proven cost/benefit improvement over existing therapies.  
| Extent of change agents' efforts | • The more that the company sponsors awareness through publication, advertising, and sales word-of-mouth information transfers, the greater the likelihood of increased adoption.  
| | • The direct effectiveness of the marketing dollar is not yet known, however.  

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Appendix B: Homer Model BASE Outputs - Verification Testing

The graphs in this appendix were created with the Homer model after it was entered in VENSIM software. Below each graph is a copy of the base run output published in Jack Homer's thesis, which were created using DYNAMO software.
Homer Base Case: Patient Selection

Homer Thesis Model output, p. 434:

Figure 7-4: Pacemaker Base Run--Patient Selection
Homer Thesis Model output, p. 435:

**Figure 7-5:** Pacemaker Base Run—Factors Affecting Acceptance
Homer Base Case: Actual and Perc'd Marginal BHR's

![Graph showing Homer Base Case: Actual and Perc'd Marginal BHR's]

Perc'd Marg BHR from FU - HOMERBAS
Marg Benefit Harm Ratio - HOMERBAS

"Perc'd Marg BHR from FU" = Perceived Marginal Benefit-Harm Ratio from Follow Up
"Marg Benefit Harm Ratio" = Marginal Benefit Harm Ratio

Homer Thesis Model output, p. 437:
Homer Base Case: Functional Capability

<table>
<thead>
<tr>
<th>Year</th>
<th>Capability Index</th>
<th>Capability Index/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1966</td>
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<td>1990</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1996</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Func Cap - HOMERBAS
Prod Cap - HOMERBAS
prod cap incr rate - HOMERBAS

Homer Thesis Model output, p. 439:

Figure 7-9: Pacemaker Base Run--Functional Capability
Appendix C: Complete IHM Model Base Case Diagrams and Equations

Note: One asterisk (*) in front of the equation number indicates that the equation was changed from the Homer Base model. Two asterisks (**) indicate that the equation is new to the IHM model.

I. Physician Activities

A. Patient Selection

I A 1a. Recommending Physician Fraction

I A 1b. Recommending Physician Fraction Equations

**(002) Fraction of Marketing Effort for Physicians = 1-Fraction of Marketing Effort for Payers
Units: dmnl
The Fraction of Marketing Effort for Physicians is the fraction of marketing spending that is spent on physician contacts, versus payer marketing activities.

*(024) Effect of Marketing Effort on Acceptance =
EMEA(Marketing Effort*Fraction of Marketing Effort for Physicians/Marketing Effort Normal)
Units: dmnl
The Effect of Marketing Effort on Acceptance represents the overall response of physicians to the promotional marketing activities of manufacturers. It can also generate acceptance with influence increasing according to size and number, but the influence diminishes past a certain point. Also, the impact on acceptance of any particular promotion or report is assumed to be fairly immediate and temporary.
**Balk Factor = 0**
Units: dmnl
The "Balk Factor" is the fraction of physicians who will "balk" at choosing a higher-cost procedure for short-term treatment under a capitated reimbursement system, even though cost-effectiveness analysis suggests that the procedure is warranted.

*(064) Physician Acceptance Fraction =
Effect of Payer Relationship on Acceptance*Physician Acceptance Fraction Normal
*Effect of Availability of Implants on Acceptance*Effect of Benefit Cost Ratio on Acceptance
*(Effect of Colleague Discussion on Acceptance
+ Effect of Marketing Effort on Acceptance + Effect of Follow Up Reports on Acceptance)
Units: 1/year
The Physician Payer Acceptance Fraction is the fraction of non-recommending physicians who accept the technology per year. The magnitude of the acceptance fraction is based the the effects of the payer relationship, the normal acceptance fraction, availability, benefit cost ratio, colleague discussion, marketing effort, and follow up reports.

(067) Physician Acceptance Fraction Normal = 0.15
Units: 1/year
The Physician Acceptance Fraction Normal represents the fractional rate of acceptance when a) the product is fully available, b) the technology has a neutral perceived relative advantage, and c) the combined impact of the various communication channels is equivalent to the maximum impact that colleague discussions can exert alone. It corresponds to the exogenous (outside the model) attributes of the technology as they appeal to potential referring physicians for the technology, such as compatibility with physician's needs and values.

(068) physician acceptance rate =
Non Recommending Physician Fraction*Physician Acceptance Fraction
Units: 1/year
The acceptance rate for the technology is determined by the number of outstanding Non-Recommending Physicians and the current Acceptance Fraction, which is determined by several factors such as product availability, relative advantage, personal, professional, and commercial channels of communication on the adoption decision.

(084) Implant Availability Perception Time = 0.5
Units: year
The Implant Availability Perception Time is the time required to perceive that implants are available, i.e. that devices and implanting physicians are ready.

*(089) Benefit Cost Ratio Normal = Benefit Normal/Cost Normal
Units: Qual Adj Life Years/dollars
The concept of a "Benefit Cost Ratio (BCR) Normal" warrants special consideration. BCR Normal is that value of BCR (for a given subset of patients) at which physicians will be indifferent between the new technology and alternatives to it, in terms of relative advantage. Cost-effectiveness literature suggests that a ratio of 1 quality adjusted life year to $20,000 is a reasonable ratio of benefit to cost, and the range may be appropriate up to $40,000 per 1 quality-adjusted life year.

(129) Effect of Availability of Implants on Acceptance = EAVIA(Perceived Availability of Implants)
Units: dmnl
The Effect of the Availability of Implants on Acceptance can suppress the rate of acceptance when there is an inadequate perceived supply of implants, shown schematically in lookup table "EAVIA."
(132) Effect of Benefit Cost Ratio on Acceptance = 
EBCRA(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmnl
The Effect of the Benefit-Cost Ratio on Acceptance of the technology can suppress the rate of acceptance when the perceived relative advantage is low and boost it when this ratio is high; the curve describing the relationship is shown in lookup table "EBCRA." The features of this curve, namely its steepness around the normal point, its curvature, and its maximum value, will depend on how critical the benefit-cost ratio is to acceptance of the technology. In the case of a technology as radical and likely to be resisted as pacemakers were, some physicians will need to be convinced that the technology is not only as good as its competition but actually much better before they are willing to accept it. This situation can be represented by a table for EBCRA which continues to rise considerably beyond its normal point before further increases in Perc'd Aggregate Benefit Cost Ratio from FU finally have little impact on acceptance. In contrast, in the clindamycin case, in which the competing technologies already do such a good job that BCRN is quite high, acceptance will drop off quickly if the new technology is perceived to be not up to existing high standards. IHM is probably somewhere in between these two cases, since it does not offer a cure for CHF but is one of the first technologies to address the chronic monitoring needs of disease management.

(133) Effect of Benefit Cost Ratio on Rejection = 
EBCRR(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmnl
The Effect of Benefit Cost Ratio on Rejection for referring physicians is described by a lookup table "EBCRR" that relates the Perceived Aggregate BCR from Follow Up to the Benefit-Cost Ratio Normal. When the Perceived Aggregate BCR from FU (PABCRF) is greater than or equal to the "normal" value of BCR (BCRN), the rejection fraction will be very small, but if PABCRF/BCRN (which represents the perceived overall relative advantage of the technology) drops below 1, adopters may quickly abandon the product and switch to a competing technology.

(135) Effect of Colleague Discussion on Acceptance = ECDA(Recommending Physician Fraction)
Units: dmnl
The Effect of Colleague Discussion on Acceptance represents the ability of referring physicians to persuade their colleagues to adopt the technology; other things being equal, as the number of referring physicians increases, so will the overall persuasive power of colleague discussions. It is the "word-of-mouth" effect. The magnitude of this effect is linear; it is proportional to the number of Referring Physicians, as is assumed in all Bass-Type diffusion models. The use of the table function "ECDA" allows for testing different assumptions concerning this relationship.

(141) Effect of Follow Up Reports on Acceptance =
EFURA(follow up reporting rate/Follow Up Reporting Rate Normal)
Units: dmnl
The Effect of Follow Up Reports on Acceptance represents the response of physicians to journal reports evaluating clinical outcomes using the technology. Like product promotions, reports are more influential when there are more of them and the impact on acceptance is fairly immediate and temporary, but a limit to the impact of the professional media undoubtedly exists. It is played out through journal article reports of the technology efficacy. The effectiveness is proportional to the size and number, but at a certain point, the impact diminishes.

(178) Follow Up Reporting Rate Normal = 6000
Units: cases/year
The Follow-Up Reporting Rate Normal is defined to be the rate of follow up reporting at which the persuasive impact is equal to the maximum impact of colleague discussions.
(199) Initial Recommending Physician Fraction = 0.01
Units: 1
The Initial Recommending Physician Fraction is the fraction of physicians at the beginning of the simulation that recommend the technology.

(221) Marketing Effort Normal = 1.6e+007
Units: dollars/year
Marketing Effort Normal is the standard marketing spending level for a marketing program.

(224) Non Recommending Physician Fraction = 1 - Recommending Physician Fraction
Units: 1
The Non-Recommending Physician Fraction is simply one minus the Recommending Physician Fraction, from the pool of potential referring physicians for the technology.

(232) Perceived Availability of Implants = SMOOTH(Implants/Desired Implants, Implant Availability Perception Time)
Units: 1
The Perceived Availability of Implants corresponds to the recent ratio of supply and demand for implant procedures; a sudden change in availability may require some time to be perceived by physicians deciding whether or not to adopt the technology.

(261) Recommending Physician Fraction = INTSEG(physician acceptance rate - physician rejection rate, Initial Recommending Physician Fraction)
Units: 1
The Recommending Physician Fraction represents the fraction of screening physicians who recommend the technology to some subset of their patients, and is determined by the degree to which the technology has been accepted by the relevant physician population. In the above formulation, it is given by the integration of the acceptance rate minus the rejection rate over time, with the initial value of "Initial Recommending Physician Fraction."

(263) Rejection Fraction = Physician Rejection Fraction Normal*Effect of Benefit Cost Ratio on Rejection
Units: 1/year
The Rejection Fraction for Recommending Physicians depends on the physician's perceptions of the Aggregate Benefit-Cost Ratio. When the Aggregate Benefit-Cost Ratio is perceived to be greater than or equal to its "normal" value, the rejection fraction will be very small, but if the ratio of the two, which represents the perceived overall relative advantage of the technology, drops much below 1, adopters may quickly abandon the product and switch to a competing technology.

(264) Physician Rejection Fraction Normal = 0.01
Units: 1/year
The Physician Rejection Fraction Normal times the Effect of Benefit Harm Ratio on Rejection yields the current Rejection Fraction used in the rejection rate for Recommending Physicians.

(265) physician rejection rate = Recommending Physician Fraction*Rejection Fraction
Units: 1/year
The rejection rate of Recommending Physicians occurs at some fractional rate, which is assumed to depend solely on physicians' perceptions (based on followups) of the aggregate benefit-harm ratio.

**(013) Initial Patient Population = 5000
Units: cases/year
The Initial Patient Population is the first set of patients who are eligible for IHM management.
**(018) Cost Normal = 20000
Units: dollars
Cost Normal is the value of cost that is used to calculate the Benefit-Cost Ratio Normal value, which is used as the standard by which physicians and payers judge the cost effectiveness of alternative patient management strategies.

**(028) Benefit Normal = 1
Units: Qual Adj Life Years
Benefit Normal is the value of benefit that is used to calculate the Benefit-Cost Ratio Normal value, which is used as the standard by which physicians and payers judge the cost effectiveness of alternative patient management strategies.

**(037) Benefit Cost Ratio Unit = 1
Units: Qual Adj Life Years/dollars
The Benefit Cost Ratio Unit is used to correct the units in the model, when dimensionless quantities are desired.

**(065) Effect of Payer Relationship on Acceptance = ((1-Balk Factor)*Fraction of Capitated Reimbursement+(1-Fraction of Capitated Reimbursement)*EPAA(Reimbursing Payer Fraction))
Units: dmnl
The Effect of Payer Relationship on Acceptance relates the type and proportion of reimbursement system to the effect these relationships have on physician acceptance. It includes the fraction of capitation reimbursement, and the “Balk Factor” for physicians who are reimbursed under capitated reimbursement systems, who “balk” at choosing expensive up-front procedures.

For reimbursement by procedure systems, the physicians are constrained to accept the technology only if the payer organization has accepted it as well; the model takes this into account through the lookup function “EPAA” (Effect of Payer Approval on Acceptance). EPAA is a linear relationship between the fraction of reimbursing payers to the fraction of physicians who could elect to accept the technology. Before they can accept, however, the payer must accept.
A 2b. Eligibility Fraction Equations

(066) Initial Eligibility Fraction = (Initial Patient Population/UNIVERSE OF NEW CASES)
Units: 1
Initial Eligibility Fraction is the first fraction of the patient population that is indicated for the technology.

(098) change in eligibility fraction = (Indicated Eligibility Fraction-Eligibility Fraction)/Time to Adjust Eligibility Fraction
Units: 1/year
Change in eligibility fraction: Recommending physicians will change their eligibility criteria in response to information indicating that the current criteria are too wide or too narrow, making this adjustment over a time period represented by the time to adjust eligibility fraction.

(130) Effect of Benefit Cost Ratio on Eligibility = EBCRL(1.443*LN(Perceived Marginal Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal))
Units: dmm
The Effect of the Benefit Cost Ratio on Eligibility is given by the lookup table relationship EBCRL, which relates the ratio of perceived marginal benefit cost ratio to the BCR Normal to determine whether more or less eligibility is warranted.
Eligibility Fraction = \text{INTEG}(\text{change in eligibility fraction, Initial Eligibility Fraction})

Units: 1

The Eligibility Fraction is the fraction of new cases that the average recommending physician considers eligible for the new technology; it is thus an operational definition of the average criteria for patient selection. Recommending physicians will change their eligibility criteria in response to information indicating that the current criteria are too wide or too narrow.

\text{(191) Indicated Eligibility Fraction =}
\text{Indicated Eligibility Fraction from Follow Up + Presumed widening of scope since Follow Up}

Units: 1

The Indicated Eligibility Fraction is based primarily on followup assessments of treatment but may also take into account to some extent product improvements not reflected in recent followups. The indicated eligibility fraction is related to the marginal benefit harm ratio for the most recent patient population treated; if the marginal BCR > 1, physicians will tend to expand the indications; if < 1, the indicated eligibility fraction will be less than that corresponding to the patients whose outcomes were assessed.

\text{(192) Indicated Eligibility Fraction from Follow Up = MAX(Minimum Eligibility Fraction, Perceived Eligibility Fraction from Follow Up \times Effect of Benefit Cost Ratio on Eligibility)}

Units: 1

The Indicated Eligibility Fraction from Follow Up represents the way in which eligibility decisions are based on past experience with the technology. If the benefit-harm ratio for "marginal" patients appears to have been higher than normal, physicians will tend to expand the selection criteria beyond the level reflected in the patient followups, and vice versa. The nature of this relationship is described by lookup table "EBHRL."

\text{(217) Minimum Eligibility Fraction = Initial Patient Population/UNIVERSE OF NEW CASES}

Units: 1

The Minimum Eligibility Fraction for the IHM technology is defined by the Initial Patient Population divided by the universe of new cases. This is the first group that is considered eligible for the technology, and the resulting benefit-cost ratios that are found in this group will determine the extent to which the technology may spread further.

\text{(240) Presumed scope widening rate = Presumed widening of scope per Technical Development \times Incoroporation of Technical Developments into Physician Practice}

Units: 1/year

The Presumed scope widening rate is the expected expansion of eligibility coming from product capability enhancements from technical development projects that are incorporated into physician practice.

\text{(241) Presumed scope widening rate since Follow Up =}
\text{SMOOTH(Presumed scope widening rate, Perceived Time Since Implants in Follow Up)/2}

Units: 1/year

The Presumed scope widening rate since FU is simply a smoothed value of the presumed scope-widening rate, where the smoothing time is assumed to be half of the elapsed time since followed-up procedures were performed.

\text{(242) Presumed widening of scope per Technical Development = Presumed widening of scope per Technical Development Normal \times(Product Capability Increase per Technical Development Normal)}

/ \text{Product Capability Increase per Technical Development Normal}

Units: 1/Projects

The Presumed widening of scope per Technical Development is assumed to be proportional to the actual improvement in product capability per technical development.
(243) Presumed widening of scope per Technical Development Normal = 0.005
Units: 1/Projects
Presumed widening of scope per Technical Development Normal.

(244) Presumed widening of scope since Follow Up = Presumed scope widening rate since Follow
Up*Perceived Time Since Implants in Follow Up
Units: 1
The Presumed widening of scope since Follow Up can give a boost to eligibility during periods when the
product is improving and outcome assessments are therefore somewhat obsolete due to the
"moving target effect." The amount of "self-evident" improvement that has taken place between
the time at which the assessed procedures were performed and the present time is equal to the
average rate of such improvement during this time interval multiplied by the length of the
interval.

(293) Time to Adjust Eligibility Fraction = 0.5
Units: year
The Time to Adjust Eligibility Fraction is the time necessary to change the eligibility criteria in use
for selecting patients.

(030) Follow Up Evaluation Fraction = Maximum Follow Up Evaluation Fraction*EXP(Coefficient for
Follow Up Evaluation Fraction*LN(1-Perceived Adequacy of Follow Up to Date+1e-007))
Units: 1/year
The Follow Up Evaluation Fraction will be responsive to the adequacy of existing follow-up data: the
fraction will be greatest when no data are available and smallest when the need for reports is
eliminated. Thus, as the adequacy of follow-up reports increases, the evaluation response
will decrease.
B. Treatment

I B 1a. Implants

UNIVERSE OF NEW CASES:

\[ \text{Pat} \text{ient Select} \text{ion Fraction} \]

\[ \text{Des} \text{ired Initial Implants} \]

\[ \text{Des} \text{ired Repeat Implants} \]

\[ \text{Device Longevity} \]

\[ \text{Patients Living Beyond Device Longevity} \]

\[ \text{Fraction of Patients Living Beyond Device Longevity} \]

\[ \text{Des} \text{ired Continuation Fraction for Long Term Treatment} \]

I B 1b. Implants

*(032) Patients Living Beyond Device Longevity = Fraction of Patients Living Beyond Device Longevity * Patients

Units: cases

Patients Living Beyond Device Longevity are patients that live beyond the 3 year lifetime of the device, who may also be selected to have a second device implanted so they may continue using the device for CHF management.

(092) Capacity for Implants = Capacity per Implanting Physician * Implanting Physicians

Units: cases/year

Capacity for Implants is defined by the capacity per implanting physician times the number of implanting physicians in the system.

(093) Capacity per Implanting Physician = 100

Units: cases/Physicians/year

The Capacity per Implanting Physician is the maximum number of implants a physician would be able to complete per year.

(094) Implanting Physician Capacity Utilization Fraction = CAPU \text{f}( \text{Des} \text{ired Implants/Capacity for Implants})

Units: \text{dmil}

The Implanting Physician Capacity Utilization Fraction is the fraction of total physician capacity that is utilized in a given time period.
Implanting Physician Capacity Utilization Fraction Normal = 0.65
Units: 1
Implanting Physician Capacity Utilization Fraction Normal is the average utilization expected by the system.

Desired Continuation Fraction for Long Term Treatment = DCFLT(Patient Selection Fraction/selection fraction for repeat patients)
Units: dmnl
The Desired Continuation Fraction for Long-Term Treatment is defined by a table function that relates the ratio of total Selection Fraction to Selection Fraction for Previously Implanted Patients to the Desired Continuation Fraction. The table function is almost linear, but slightly convex between 0 and 1, to indicate that if the current selection fraction is lower than it was at the time of implantation for the average implanted patient, the fraction of implanted patients due for a new implant who actually receive the technology again will be less than one.

Desired Initial Implants = UNIVERSE OF NEW CASES*Patient Selection Fraction
Units: cases/year
Desired Initial Implants are requested for patients selected from the Universe of New Cases, according to the current selection fraction used.

Desired Implants = Desired Initial Implants+Desired Repeat Implants
Units: cases/year
Desired Implants corresponds to requests or recommendations for treatment made by those physicians responsible for patient selection, and is the sum of Desired Initial Implants and Desired Repeat Implants. Requests are generally made by the cardiologists who diagnose the patient’s condition. A general practitioner or internist may consult with a specialist before prescribing the drug, which effectively makes the consulted physician the source of recommendation.

Desired Repeat Implants = (Patients Living Beyond Device Longevity/Device Longevity)
Desired Continuation Fraction for Long Term Treatment
Units: cases/year
Desired Repeat Implants result from patients living beyond the device lifetime, and the desire to continue using IHM technology to manage the patient’s care.

Fraction of Patients Living Beyond Device Longevity =0
Units: dmnl
The Fraction of Patients Living Beyond Device Longevity are those that live beyond the point where the technology reaches its end of life. For IHM candidates, since most patients are not expected to live beyond 3 years, the fraction is 0.

Initial Implants = Implants-Repeat Implants
Units: cases/year
Initial Implants are requested for some fraction (the selection fraction) of those patients who constitute the “universe of new cases”, and the Initial Implants that actually occur is simply the difference between the total number of implants and the number of Repeat Implants. In the case of a shortage of supply of implanting capacity, it is assumed that priority will be given to repeat implants.

Device Longevity = 3
Units: year
Device longevity is the engineering specification for device expected life.
(246) Implants = Capacity for Implants * Implantaing Physician Capacity Utilization Fraction
Units: cases/year
The number of Implants is found by multiplying the combined capacity of Implanting Physicians by the fraction of capacity which is utilized. Implants may be of two types, initial and repeat.

(272) Repeat Implants = Min(Desired Repeat Implants, Implants)
Units: cases/year
Repeat Implants will be desired for those past recipients whose condition is chronic, whose initial procedure has, in some sense, expired, and whose physicians still consider them appropriate recipients.

(280) Patient Selection Fraction = Recommending Physician Fraction * Eligibility Fraction
Units: dmnl
The Selection Fraction is the product of the degree to which the technology has been accepted by the relevant physician population (the recommending Physician Fraction) and the criteria for patient selection used by these adopters (the Eligibility Fraction.) In other words, the technology will be requested for a patient only if the patient’s physician EVER requests it, and then only if the patient is considered eligible.

*(295) UNIVERSE OF NEW CASES = 400000
Units: cases/year
The Universe of New Cases is the number of new patients diagnosed with Congestive Heart Failure in the United States per year. Of these cases, a fraction will be considered candidates for the IHM technology.
I B 2a. Patients Diagram

I B 2b. Patients Equations

(103) \[
\text{Co Flow of Life Expectancy for Patients} = \\
\text{INTEG}(\text{patient initiation rate} \times \text{life expectancy for new patients} - \text{patient death rate} \times \text{life expectancy for current patients}) \\
= \text{life expectancy for new patients} \times \text{Patients} \\
\text{Units: year} \times \text{cases} \\
\text{The Co Flow of Life Expectancy for Patients expresses the change over time of the expected Life} \\
\text{Expectancy of recipients of the technology, based on the mix of new patients and the extent to} \\
\text{which they are benefitted by the technology.}
\]

(105) \[
\text{Co Flow of Selection Fraction for Patients} = \\
\text{INTEG}(\text{Patient Selection Fraction} \times \text{patient initiation rate} - \text{selection fraction for repeat patients} \times \text{patient death rate, Patient Selection Fraction} \times \text{Patients}) \\
\text{Units: cases} \\
\text{The Co Flow of Selection Fraction for Patients calculates the changes in the selection fraction utilized by} \\
\text{the implants that are in the patient stock.}
\]

(165) \[
\text{Fatal Fraction of Harmful Outcomes} = 1 \\
\text{Units: 1} \\
\text{The Fatal Fraction of Harmful Outcomes is the fraction of harmful outcomes that result in a quicker death.}
\]

(167) \[
\text{Frac of Non Fatal Outcomes} = \\
1 - (\text{Fatal Fraction of Harmful Outcomes} \times \text{Fraction of Harmful Outcomes}) \\
\text{Units: 1} \\
\text{The Fraction of Non-Fatal Outcomes is the fraction of patients who survive the implant procedure, and is} \\
\text{found by taking the inverse of Fatal Fraction of Costly Outcomes times the total Fraction of} \\
\text{Costly Outcomes.}
\]
*(203) Life Expectancy for a Beneficial Outcome = 3
Units: year
The Life Expectancy for a Beneficial Outcome is the length of time patients are expected to live after they receive an implant.

*(204) life expectancy for new patients = 
Life Expectancy for a Beneficial Outcome*(Fraction of Beneficial Outcomes/Frac of Non Fatal Outcomes) + (Life Expectancy for a Non Beneficial Outcome*(1-(Fraction of Beneficial Outcomes/Frac of Non Fatal Outcomes)))
Units: year
The average Life Expectancy for new Patients depends on whether the outcome is beneficial or not, and is calculated from the probabilities for differing outcomes.

*(205) Life Expectancy for a Non Beneficial Outcome =3
Units: year
The Life Expectancy for a Non-Beneficial Outcome may be directly related to the criteria used for determining patient eligibility, and is computed in the model by the natural history of the condition being treated and the availability of alternatives to the technology, both of which may be directly related to the criteria used for determining patient eligibility. It is formulated using a table look-up function (LXNBO) relating life expectancy to the ratio of Eligibility Fraction to the Minimum Eligibility Fraction.

*(206) life expectancy for current patients = Co Flow of Life Expectancy for Patients/Patients
Units: year
The life expectancy for current patients is calculated using a co-flow structure.

*(281) selection fraction for repeat patients = Co Flow of Selection Fraction for Patients/Patients
Units: 1
The selection fraction for repeat patients is the selection fraction used for patients who may live beyond the longevity of their first IHM device, and who wish to continue treatment using IHM.

*(296) patient death rate = Patients/life expectancy for current patients
Units: cases/year
The patient death rate is determined by the life expectancy following the initial procedure.

*(297) patient initiation rate = Initial Implants*(Frac of Non Fatal Outcomes)
Units: cases/year
The patient initiation rate is synonymous with non-fatal initial procedures.

*(298) Patients = INTEG(-patient death rate+patient initiation rate,0.001)
Units: cases
Patients are defined to be all of the recipients of the technology who are still living. Their ranks are increased by the "initiation rate" (synonymous with non-fatal initial implants) and decreased by the "death rate" in an integrated manner.
**I B 3a. Implanting Physicians Diagram**

- Implanting Physician Start Up Fraction Normal
- Implanting Physician Drop Out Fraction Normal
- Implanting Physician Adjustment Time
- Desired Implanting Physicians
- Effect of Capacity Utilization on Physician Drop Out
- Recent Implanting Physician Capacity Utilization Fraction Normal
- Capacity Utilization Smoothing Time
- Implanting Physician Capacity Utilization Fraction

**I B 3b. Implanting Physicians Equations**

(070) Implanting Physician Adjustment Time \( = 0.5 \)
Units: year
The Implanting Physician Adjustment Time is the time it takes to alter the number of implanting physicians to meet capacity demands.

(071) Implanting Physician Drop Out Fraction Normal \( = 0.04 \)
Units: 1/year
Implanting Physician Drop Out Fraction Normal is the normal fraction expected to leave the system, without being caused by technology experience or performance.

(072) implanting physician drop out rate = Implanting Physicians\(^*\)
Implanting Physician Drop Out Fraction Normal\(^*\)Effect of Capacity Utilization on Physician Drop Out
Units: Physicians/year
The Implanting Physician Drop-Out Rate represents the decision to discontinue regular administration of the technology. Under conditions of normal utilization, physicians will drop out at a fractional rate which may be closely (and inversely) related to the length of a career in the relevant medical specialty. However, unusually low or high utilization may affect a physician's decision to continue spending the time and money necessary to keep abreast of the technology and support its continued use. (e.g. outlays for specialized staff.) If utilization has been low and business is clearly slackening, the drop-out fraction may this be higher than normal; conversely, if utilization has been high, administering physicians may be encouraged to continue using the technology in their practice somewhat longer than normal.

(073) Implanting Physician Start Up Fraction Normal = Implanting Physician Drop Out Fraction Normal
Units: 1/year
The Implanting Physician Start Up Fraction Normal is the same as the drop out fraction normal.

(074) implanting physician start up rate =
\[ \text{MAX}(0, \text{Implanting Physicians} \times \text{Implanting Physician Start Up Fraction Normal}) 
+ (\text{Desired Implanting Physicians - Implanting Physicians})/\text{Implanting Physician Adjustment Time} \]
Units: Physicians/year
The implanting physician start up rate is determined by the start up fraction plus a factor to adjust to meet demand and capacity contraints.

(076)  Implanting Physicians =
INTEG(implanting physician start up rate-implanting physician drop out rate,
Desired Implanting Physicians)
Units: Physicians
The stock of Implanting physicians is found by integrating the implanting physician start up rate minus the drop out rate, with an initial level given by the desired implanting physician level.

(096)  Capacity Utilization Smoothing Time = 1
Units: year
Capacity Utilization Smoothing Time is the time necessary to fully adjust the capacity utilization.

(117)  Desired Implanting Physicians = Desired Implants/
(Implanting Physician Capacity Utilization Fraction Normal*Capacity per Implanting Physician)
Units: Physicians
The number of Desired Implanting Physicians is determined by the desired implants versus the physician capacity available.

(147)  Effect of Capacity Utilization on Physician Drop Out =
EUPHD(Recent Implanting Physician Capacity Utilization Fraction
/Implanting Physician Capacity Utilization Fraction Normal)
Units: daml
The Effect of Capacity Utilization on Physician Drop Out refers to the tendency for physicians to drop out if the added capacity they offer is not needed. If demand for the technology wanes, extra physicians will reallocate their time to more productive procedures.

(260)  Recent Implanting Physician Capacity Utilization Fraction =
SMOOTH(Implanting Physician Capacity Utilization Fraction,Capacity Utilization Smoothing Time)
Units: 1
The Recent Implanting Physician Capacity Utilization Fraction is the time-smoothed perceived value of physician utilization for implanting physicians.
I B 4a. Benefit Cost Ratios Diagram

I B 4b. Benefit Cost Ratios Equations

*(010) Aggregate Expected Cost = Aggregate Magnitude of Cost Outcome + Cost per Harmful Outcome
Units: dollars/cases
The Aggregate Expected Value of Cost equals the Aggregate Magnitude of Cost Outcome multiplied by the Cost per Harmful Outcome.

*(016) Aggregate Benefit Cost Ratio =
(Aggregate Expected Benefit - Alternative Aggregate Expected Benefit) /
(Aggregate Expected Cost - Alternative Aggregate Expected Cost)
Units: Qual Adj Life Years/dollars
The Aggregate Benefit Cost Ratio (BCR) is the average expected benefit-cost ratio in for the group of patients that are current candidates for the IHM technology. The benefit-cost ratio drives physician and payer decisions in a health care system that is oriented towards cost-effectiveness. It is calculated from the difference in expected benefit from IHM minus the benefit of an alternative technology, divided by the difference in costs.

**(019) Cost per Harmful Outcome =
Cost per Harmful Outcome Normal * Fraction of Harmful Outcomes
Units: dollars/cases
The Cost per Harmful Outcome is found by multiplying the cost per harmful outcome normal (the average cost) by the fraction of harmful outcomes. This cost is added to the average treatment cost calculation for IHM.

**(020) Cost per Harmful Outcome Normal = 3000
Units: dollars/cases
The Cost per Harmful Outcome Normal expresses a rough weighted average of the expected costs and probabilities of possible complications, such as perforation during implant, infection, lead dislodgement, etc.

**(025)** Alternative Aggregate Expected Benefit = 0
Units: Qual Adj Life Years/cases
Alternative Aggregate Expected Benefit is the average 3 year benefit an alternative patient management is expected to provide for the patient.

**(026)** Alternative Aggregate Expected Cost = 0
Units: dollars/cases
The Alternative Expected Value of Cost is the expected 3-year cost of the closest alternative patient management strategy to the IHM technology.

**(043)** Marginal Benefit Cost Ratio = (Marginal Expected Benefit)/(Marginal Expected Cost)
Units: Qual Adj Life Years/dollars
The Marginal Benefit-Cost Ratio is the ratio of expected benefit to expected cost difference for a patient whose condition is on the periphery of accepted applications of the technology. It is calculated from the expected outcome for "marginal" or "peripheral" patients, who receive the least value from the technology are are the first to lose their eligibility if the patient selection criteria are narrowed.

**(047)** Marginal Expected Cost = (Aggregate Magnitude of Cost Outcome + Cost per Harmful Outcome + (Increase in Relative Cost per Doubling of Eligibility * 1.443))
Units: dollars/cases
The Marginal Expected Value of Cost is found by computing the derivative of the total cost incurred, where total cost equals the aggregate expected value of cost difference to alternatives multiplied by the number of initial procedures.

**(079)** Aggregate Expected Benefit = Fraction of Beneficial Outcomes * Aggregate Magnitude of Beneficial Outcome
Units: Qual Adj Life Years/cases
The Aggregate Expected Value of Benefit equals the probability of benefit, or the Fraction of Beneficial Outcomes, multiplied by the Aggregate (average) Magnitude of Beneficial Outcome.

**(080)** Aggregate Magnitude of Beneficial Outcome Normal = (Aggregate Magnitude of Beneficial Outcome Normal * Effect of Product Capability on Magnitude of Benefit) - (Decrease in Relative Benefit per Doubling of Eligibility * 1.443) * LN(Eligibility Fraction/Minimum Eligibility Fraction)
Units: Qual Adj Life Years/cases
The Aggregate Magnitude of a Beneficial Outcome is formulated to take into account the magnitude of benefit for the first patient eligibility level (the "normal" benefit) and the decrease in the magnitude of benefit as the eligibility fraction increases. The aggregate benefit will decline until the marginal benefit is 0, and the eligibility criteria has reached it maximum.

**(081)** Aggregate Magnitude of Beneficial Outcome Normal = 6
Units: Qual Adj Life Years/cases
Aggregate Magnitude of Beneficial Outcome Normal. The Aggregate Magnitude of a Beneficial Outcome equation is formulated so that when the capability effect is neutral and the eligibility fraction equal to it's minimum value, the Aggregate Magnitude of Beneficial Outcome will equal its "normal" value.

**(082)** Aggregate Magnitude of Cost Outcome = (Aggregate Magnitude of Cost Outcome Normal * Effect of Product Capability on Magnitude of Cost) + (Increase in Relative Cost per Doubling of Eligibility * 1.443)
*(LN(Eligibility Fraction/Minimum Eligibility Fraction))
Units: dollars/cases
The Aggregate Magnitude of Cost Outcome expresses the average additional cost to a patient who receives the IHM technology, and also incorporates a factor related increases in product capability to the cost.

*(083) Aggregate Magnitude of Cost Outcome Normal = 18250
Units: dollars/cases
The Aggregate Magnitude of Cost Outcome Normal corresponds to a situation in which Eligibility Fraction = Minimum Eligibility Fraction and the functional capability effect is neutral. It reflects the purchase and implant costs associated with the first "market-released" version of the IHM technology.

(087) Beneficial Fraction of Non Harmful Outcomes =
EXP(-LN(2)*(Eligibility Fraction/Eligibility Fraction from Functional Capability))
Units: 1
The Beneficial Fraction of Non Harmful Outcomes is related exponentially to the ratio of eligibility to the highest eligibility fraction available at a given state of technology development and physician experience, the eligibility fraction from functional capability.

*(110) Decrease in Relative Benefit per Doubling of Eligibility =0.5
Units: Qual Adj Life Years/cases
The Decrease in Relative Benefit per Doubling of Eligibility is the

(143) Effect of Product Capability on Magnitude of Benefit =
EPCMB(Product Capability/Maximum Functional Capability)
Units: dmnl
The Effect of Product Capability on Magnitude of Benefit reflects the effect of increased product capability on the amount of benefit the technology offers.

*(144) Effect of Product Capability on Magnitude of Cost =
EPCMC(Product Capability/Maximum Functional Capability)
Units: 1
The Effect of Product Capability on Magnitude of Cost relates the product capability to the magnitude of cost.

(151) Eligibility Fraction from Functional Capability =
Maximum Eligibility Fraction From Capability*(Functional Capability/Maximum Functional Capability)
Units: dmnl
The Eligibility Fraction from Functional Capability is defined to be that value of eligibility fraction at which the Beneficial Fraction of Non-Costly Outcomes equals one-half and is proportional to the technology's functional capability. As the functionality of the technology increases, the eligibility fraction which will result in any given value of BFNCO increases proportionally; conversely, for any given level of eligibility, there is a one-to-one correspondence between functionality and BFNCO.

(171) Fraction of Beneficial Outcomes =
Beneficial Fraction of Non Harmful Outcomes*Fraction of Non Harmful Outcomes
Units: 1
The Fraction of Beneficial Outcomes is determined by the beneficial fraction of those outcomes that were not harmful times the fraction of total outcomes that were not harmful to the patients.

*(172) Fraction of Harmful Outcomes = FHO(Functional Capability/Maximum Functional Capability)
Units: 1
The Fraction of Harmful Outcomes, defined by lookup table "FHO," has been assumed to be a function of functional capability, which combines technology capability and physician experience. Since the IHM device is so similar to a pacemaker, and since pacing is so widespread and the physicians who implant IHM are most likely going to be experienced pacemaker implanters or other invasive cardiologists, the Fraction of Harmful Outcomes was set to the minimum level, 0.01, for all levels of functional capability with IHM.

\[(173) \quad \text{Fraction of Non Harmful Outcomes} = 1 - \text{Fraction of Harmful Outcomes} \]
Units: 1
The Fraction of Non Harmful Outcomes is simply 1 - the Fraction of Harmful Outcomes.

*(187) \quad \text{Increase in Relative Cost per Doubling of Eligibility} = 0
Units: dollars/cases
The Increase in Relative Cost per Doubling of Eligibility expresses the possibility that as eligibility widens, the cost relationship as well as the benefit relationship of the technology to the patient changes. For IHM, we do not consider that the costs will change.

Units: Qual Adj Life Years/dollars

\[(210) \quad \text{Marginal Expected Benefit} = (\text{Fraction of Beneficial Outcomes})*\]
\[(\text{Aggregate Magnitude of Beneficial Outcome}-(\text{Decrease in Relative Benefit per Doubling of Eligibility})*1.443)-(\text{Aggregate Magnitude of Beneficial Outcome}*\text{LN}(2))\]*\[(\text{Eligibility Fraction/Eligibility Fraction from Functional Capability}))\]
Units: Qual Adj Life Years/cases
The Marginal Expected Benefit is found by computing the derivative of the total benefit received by patient initiates with respect to initial implants, assuming that incremental changes in initial implants, assuming that incremental changes in initial implants occur as a result of changes in eligibility fraction. The total benefit received, in turn, equals the aggregate expected value of benefit multiplied by the number of initial procedures.

*(212) \quad \text{Maximum Eligibility Fraction From Capability} = 0.5
Units: 1
Maximum Eligibility Fraction from Capability represents the highest fraction of the universe of cases that the technology may be applied to.
I B 5a. Functional Capability Diagram

I B 5b. Functional Capability Equations

(009) Co Flow of Experience for Implanting Physicians =
INTEG(co flow of experience increase rate-co flow of experience decrease rate).
Experience per Skilled Implanting Physician*Implanting Physicians)
Units: cases
The Co Flow of Experience for Implanting Physicians calculates the level of experience in the implanting physician population.

*(015) Incorporation of Technical Developments into Physician Practice =
INTEG(technical development project completion rate/Technical Development Incorporation Time -
Incorporation of Technical Developments into Physician Practice/Technical Development Incorporation Time, Initial Incorporation of Technical Developments)
Units: Projects/year
Incorporation of Technical Developments refers to the physician's use of new technical features in clinical practice. It takes time for new developments to be utilized in the patient management.

(101) co flow of experience decrease rate =
(Co Flow of Experience for Implanting Physicians*Physician Experience Depreciation Fraction) + (implanting physician drop out rate*Experience per Implanting Physician)
Units: cases/year
The Co Flow of Experience for Implanting Physicians calculates the level of experience in the implanting physician population.
(102) co flow of experience increase rate = Implants
Units: cases/year
The Co Flow of Experience for Implanting Physicians calculates the level of experience in the implanting physician population.

(138) Effect of Experience on Functional Capability =
EXFC(Experience per Implanting Physician/Experience per Skilled Implanting Physician)
Units: 1
The Effect of Experience on Functional Capability represents the relative skill of the average implanting physician, expressed in the lookup table EXFC. When practitioners are relatively inexperienced, the technology's effectiveness and risk may be affected, as discussed in regard to pacemaker implantation, but beyond a certain level of experience, further increases in skill are negligible.

(162) Physician Experience Depreciation Fraction = 0.5
Units: 1/year
Physician Experience Depreciation Fraction is the time necessary for physicians to "lose their touch," if they haven't performed an implant in the near past.

(163) Experience per Implanting Physician =
Co Flow of Experience for Implanting Physicians/Implanting Physicians
Units: cases/Physicians

*(164) Experience per Skilled Implanting Physician =25
Units: cases/Physicians

The Experience per Skilled Implanting Physician is the number of implants required for a physician to be a highly skilled implanter, such that he/she incorporates a large percentage of technical developments into physician practice, resulting in high functional capability.

(183) Functional Capability =Product Capability*Effect of Experience on Functional Capability
Units: capability index
Functional Capability is an index-scaled measure of the true scope of effective application of the technology as it is used by the average implanting physician. The technology's functionality may be affected by both the characteristics of the product and the relative skill of the practitioners, which implies that both of these factors may affect health outcomes.

(195) Initial Incorporation of Technical Developments = 0.001
Units: Projects/year
Initial Incorporation of Technical Development refers to the initial physician use of the technology in clinical practice.

(214) Maximum Functional Capability = 1
Units: capability index
Maximum Functional Capability refers to the highest level of functionality possible from the technology, resulting from product capability and physician incorporation into practice.
Product Capability Increase per Technical Development =
Product Capability Increase per Technical Development Normal
*PCITD(Product Capability/Maximum Functional Capability)
Units: capability index/Projects

Product Capability Increase per Technical Development, defined by the lookup table function PCITD,
reflects the degree to which technical developments increase the product's capability. It
decreases as product capability approaches its maximum value; as such, the modification
success rate declines as the functional limit of the technology is approached, and eventually
falls to zero. The steepness of the curve reflects the degree to which the technology can be
improved before decreasing returns to technical development begin to become significant.

Product Capability Increase per Technical Development Normal = 0.4
Units: capability index/Projects

Product Capability Increase per Technical Development Normal: When Product Capability is low, the
improvement per per technical development is equal to it's "normal" value (0.4 capability index/project, in this case), but as Product Capability/Max Functional Capability approaches one, this marginal improvement rate falls to 0.

Product capability increase rate =Incorporation of Technical Developments into Physician Practice*Product Capability Increase per Technical Development
Units: capability index/year

The product capability increase rate is based on physicians incorporating into their practices recent
technical developments which make the product more effective or safer. The simplifying
assumption is that all technical developments do eventually get incorporated into general
practice.

Product Capability = INTEG(product capability increase rate,0.6)
Units: capability index

Product Capability is the intrinsic capability of the product, represented by the effective scope of the
technology as currently used by fully-skilled practioners. It may be increased when
physicians incorporate into their practices recent technical developments which make the
product more effective or safer, a process which requires time.

Technical Development Incorporation Time = 1.75
Units: year

The Technical Development Incorporation Time is the time necessary to incorporate new technical
developments into physician practice.
C. Follow Up

1 C 1a. Patients in Follow Up Diagram

1 C 1b. Patients in Follow Up Equations

(027) Average Patient Tenure = Time-Average Time of Initial Implant for Patients
Units: year

(052) Evaluated Range of Patient Tenure = MIN(Coefficient for Evaluated Range of Patient Tenure*Average Patient Tenure, Time-INITIAL TIME)
Units: year

(059) Observed Range of Patient Tenure = MIN(Coefficient for Observed Range of Patient Tenure*Average Patient Tenure, Time-INITIAL TIME)
Units: year
The Observed Range of Patient Tenure can be no larger than the total time that has elapsed since the technology was introduced and may be much smaller. It can be thought of as a random variable whose observed range is a multiple of its mean value.

(085) Average Time of Initial Implant for Patients = Co Flow of Time of Initial Implant for Patients/Patients
Units: year
The Average Time of Initial Implant for Patients is the average time of the simulation that patients were implanted. It is used to calculate the flows in and out of the patient population pool.

(106) Co Flow of Time of Initial Implant for Patients =
INTEG(-Average Time of Initial Implant for Patients*patient death rate+Time*patient initiation rate, Initial Co Flow of Time of Initial Implant for Patients)
Units: cases*year

160
(108) Coefficient for Evaluated Range of Patient Tenure = 2.2
Units: dmml
The Coefficient for Evaluated Range of Patient Tenure was chosen by Jack Homer to match historical data on follow up reporting.

(109) Coefficient for Observed Range of Patient Tenure = 1.8
Units: dmml
The Coefficient for Observed Range of Patient Tenure was chosen by Jack Homer to match historical data on follow up reporting.

(118) Duration of Side Effects = 1
Units: year
Duration of Side Effects. Side Effects are results of therapy occurring in conjunction with but unrelated to the desired therapeutic effect. The impact of side effects is usually to reduce the BCR below what it would be if there were no side effects.

(174) follow up completion rate = Patients in Follow Up/Follow Up Time
Units: cases/year

(181) Follow Up Time =
(Fraction of Patients Living Beyond Device Longevity*life expectancy for current patients)
+(1-Fraction of Patients Living Beyond Device Longevity)*Follow Up Time for Short Term Treatments
Units: year
The Follow Up Time is the average period of time that recipients of the technology are followed prior to being discharged from Follow-Up. For long-term treatments, the follow-up time is synonymous with their life expectancy.

(182) Follow Up Time for Short Term Treatments =
MAX(Perceived Duration of Side Effects,Minimum Follow Up Time for Short Term Treatments)
Units: year
The Follow Up Time for Short Term Treatments will equal the follow-up time based on prior experience with similar technologies or, if it is longer, the duration of significant side effects actually seen with the new technology.

(193) Initial Co Flow of Time of Initial Implant for Patients = Time*Patients
Units: cases/year
The Initial Co Flow of Time of Initial Implant for Patients is the initial value of a co-flow structure designed to calculate the Time of Initial Implants.

(201) Initial Patient Level =0.001
Units: cases
Initial Patient Level is the initial value for the stock of Patients.

(218) Minimum Follow Up Time for Short Term Treatments = 0.25
Units: year
Minimum Follow Up time for Short-Term Treatments is the least amount of time that patients would be seen following an initial implant.

(227) Observed Duration of Side Effects = MIN(Observed Range of Patient Tenure,
Duration of Side Effects)
Units: year
The Observed Duration of Side Effects is the duration typically observed by physicians. Side effects are results of therapy occurring in conjunction with but unrelated to the desired therapeutic process.
effect. They are usually undesirable, but not necessarily so. The impact of side effects is therefore usually to reduce the BHR below what it would be if there were no side effects.

(233) Perceived Duration of Side Effects = \text{MAX}(\text{Observed Duration of Side Effects, Reported Duration of Side Effects})
Units: year
The Perceived Duration of Side Effects is simply the greater of the duration typically observed by physicians and the duration reported in the medical literature. Both the observed and reported duration of side effects will be less that the actual duration of side effects if the number of recipients with long tenure as veterans is small. As long as the perceived duration of side effects is less than the actual duration, some fraction of total side effects will remain unperceived.

(268) Reported Duration of Side Effects = \text{DELAY3}(\text{Evaluated Duration of Side Effects}\times\text{Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time})/\text{DELAY3}(\text{Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time})
Units: year
The Reported Duration of Side Effects is the duration reported in the medical literature, and is essentially a delayed version of the evaluated duration of side effects. The co-flow formulation, however, reflects the idea that larger studies will receive more attention than smaller studies printed in the same journals.

(299) Patients in Follow Up = \text{INTEG}(-\text{Follow up completion rate}+\text{patient initiation rate, Initial Patient Level})
Units: cases
Patients in Follow Up are those patients who remain under observation by their physicians, either because they are still undergoing treatment or because their physicians feel further effects of the procedure may yet be seen. Patients in FU is increased by the patient initiation rate and decreased by the follow-up completion rate. Patients are discharged from follow-up after a period of time whose average is the "follow-up time."
I C 2a. Evaluation and Reporting Diagram

I C 2b. Evaluation and Reporting Equations

(056) Coefficient for Follow Up Evaluation Fraction = 2
Units: dmnl
The Coefficient for Follow Up Evaluation Fraction.

(069) Adequacy of Follow Up to Date = Follow Up Reports to Date/Desired Follow Up Reports to Date
Units: 1
The Adequacy of Follow Up to Date is the ratio of follow up (FU) reports to date to Desired FU reports to date, and impacts the current Follow Up Evaluation Fraction for patients using the technology.

(112) Desired Follow Up Reports to Date = MAX(Desired Reports to Date from Eligibility, Follow Up Reports to Date*Effect of Changing Evaluations on Desired Reports)
Units: cases
The Desired Follow Up Reports to Date, or the desired quantity of follow-up data, will be determined by one of two factors: 1) the demand for data may be expected to increase as the eligibilty fraction increases, due to increased statistical patient pool needs and 2) more follow-up data may be desired as a result of discrepancies between new and old findings. (critical in drug study) In general, new evaluations that seriously contradict previous reports will cause both evaluating physicians and medical journals to devote more time and space to investigating the technology.

(116) Desired Reports to Date from Eligibility = Minimum Desired Reports to Date + (Increase in Desired Reports per Doubling of Eligibility*1.443*LN(Eligibility Fraction/Minimum Eligibility Fraction))
Units: cases
Time of Initial Implant for Patients in Follow Up is the average time that is used to calculate the time that patients have been implanted who are being followed, calculated using a flow structure.
(134) Effect of Changing Evaluations on Desired Reports =
ECEDR(1.443*LN(Relative Encouragement of Current vs Past Evaluations))
Units: dmnl

(175) Follow Up Evaluation Rate = Patients in Follow Up*Follow Up Evaluation Fraction
Units: cases/year
The Follow Up evaluation rate corresponds to the annual number of cases selected for analysis which do
eventually make it into the journals. Some fraction of the patients in followup will be
selected for evaluation.

(176) Follow Up Evaluation Reporting Time = 1.25
Units: year
The Follow Up Evaluation Reporting Time represents the total time required to write, submit, and publish
an article on clinical outcomes.

(177) follow up reporting rate = DELAY3(Follow Up Evaluation Rate, Follow Up Evaluation Reporting
Time)
Units: cases/year
The Follow Up reporting rate is assumed to affect current acceptance of the technology. It is a delayed
version of the evaluation rate, the delay representing the total time required to write,
submit, and publish an article on clinical outcomes; the publication stage alone often takes a
year or more.

(179) Follow Up Reports to Date = INTEG(follow up reporting rate, Initial Follow Up Reports to Date)
Units: cases
The number of Follow Up Reports to date represents the cumulative number of recipients whose implants
appear in the (broadly recognized) published clinical literature on the technology.

(186) Increase in Desired Reports per Doubling of Eligibility = 700
Units: cases
Increase in Desired Reports per Doubling of Eligibility refers to the need for more follow up reporting
as the patient population expands.

(194) Initial Follow Up Reports to Date = 1e-007
Units: cases
Initial Follow Up Reports to Date is the starting level of reports in publication when the technology is
launched.

(213) Maximum Follow Up Evaluation Fraction = 0.3
Units: 1/year
The Maximum Follow Up Evaluation Fraction occurs when the adequacy of Follow Up Reports to Date is
0, and is related to such factors as the novelty of the technology, the degree to which its users are
academically oriented, and the number of influential journals which are appropriate forums for
reporting on the technology. Gov't initiatives may also have an effect on the medical
community's basic responsiveness to the need for more evaluative data.

(216) Minimum Desired Reports to Date = 100
Units: cases
The Minimum Desired Reports to Date is the minimum desired follow up reports by the medical
community.
**(230)  Perceived Adequacy of Follow Up to Date = SMOOTHI(Adequacy of Follow Up to Date,Perception Time,0)
Units: 1
Perceived Adequacy of Follow Up to Date. This variable was constructed to eliminate the simultaneous equations problem when computing Follow Ups to Date.

**(239)  Perception Time = 0.0625
Units: year
Perception Time is set to the time step of the model to allow calculation of "Perceived Adequacy of Follow-Up to Date."

(266)  Relative Encouragement of Current vs Past Evaluations =
EBCRA(Evaluated Aggregate Benefit Cost Ratio/Benefit Cost Ratio Normal)/
EBCRA(Recently Reported Aggregate Benefit Cost Ratio/Benefit Cost Ratio Normal)
Units: dmnl
The Relative Encouragement of Current versus Past Evaluations compares the acceptability of the technology implied by new, unpublished evaluations with the acceptability implied by recent publications (which represent current public knowledge.) If this discrepancy is large, evaluating physicians and journal editors will call for a much closer look at the technology's benefits and risks.
**I C 3a. Information from Follow Up-Aggregate Benefit Cost Ratio Diagram**

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**Information from Follow Up-Aggregate Benefit Cost Ratio Equations**

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(077) **Aggregate Benefit Cost Ratio for Patients in Follow Up =**

\[
\text{Co Flow of Aggregate Benefit Cost Ratio for Patients in Follow Up/Patients in Follow Up}
\]

Units: Qual Adj Life Years/dollars

The Aggregate Benefit-Cost Ratio (BCR) for Patients in Follow Up is the weighted average of aggregate BCR over all patients in follow-up, and is calculated using a co-flow.

(078) **Aggregate Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects =**

\[
\text{Aggregate Benefit Cost Ratio for Patients in Follow Up/Effect of Side Effects on Benefit Cost}
\]

Units: Qual Adj Life Years/dollars

Aggregate Benefit-Cost Ratio (BCR) for Patients in Follow Up (FU), Excluding Side Effects: If none of the side effects has been observed, the observed aggregate BCR will equal the Aggregate BCR for Patients in FU Excluding Side Effects.

(088) **Benefit Cost Ratio Evaluation Bias = 1**

Units: dmnl

The Benefit-Cost Ratio Evaluation Bias reflects the idea that even published studies are often poorly designed and subject to investigator bias. A value of 1 indicates that the effect of the bias is neutral.

*(091) **Benefit Cost Ratio Reference = Benefit Normal/Cost Normal**

Units: Qual Adj Life Years/dollars

Benefit-Cost Ratio Reference. This ratio is used as a reference value for comparing benefit cost ratios. It takes the same numerical value as the BCR Normal.
Co Flow of Aggregate Benefit Cost Ratio for Patients in Follow Up =
\[ \text{INTEGR}(-\text{Aggregate Benefit Cost Ratio for Patients in Follow Up} \times \text{follow up completion rate} + \text{Aggregate Benefit Cost Ratio} \times \text{patient initiation rate, Aggregate Benefit Cost Ratio} \times \text{Patients in Follow Up}) \]
Units: Qual Adj Life Years/dollars/cases

The Co Flow of Aggregate Benefit Cost Ratio for Patients in Follow Up is a flow structure designed to calculate the moving average of the aggregate BCR for all patients who are in follow up at a given time.

Effect of Duration on Evaluation of Side Effects =
\[ \text{EDESE} = \frac{\text{Evaluated Duration of Side Effects}}{\text{Duration of Side Effects}} \]
Units: dml

The Effect of Duration of the Evaluation of Side Effects increases towards 1 as the evaluated duration of side effects approaches the actual duration; the shape of this relationship may be the same as that seen in table "EDOSE."

Effect of Side Effects on Benefit Cost = \[ \text{ESEBC} = \frac{\text{Aggregate Benefit Cost Ratio for Patients in Follow Up/Benefit Cost Ratio Reference}}{\text{Aggregate Benefit Cost Ratio}} \]
Units: dml

The Effect of Side Effects on Benefit-Cost depends on the technology's actual value. In the lookup table "ESEBC," the shape of the curve reflects the assumption that the impact of side effects will be substantial unless the technology's relative value is large.

Evaluated Aggregate Benefit Cost Ratio = Benefit Cost Ratio Evaluation Bias
*\[ \text{Aggregate Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects} \]
*\[ \text{EXP(Effect of Duration on Evaluation of Side Effects} \]
*\[ \text{Effect of Frequency on Evaluation of Side Effects} \times \text{LN(Aggregate Benefit Cost Ratio for Patients in Follow Up/Aggregate Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects))} \]
Units: Qual Adj Life Years/dollars

The Evaluated Aggregate Benefit-Cost Ratio is formulated in a way analogous to that for Observed Aggregate BCR.

Evaluated Duration of Side Effects =
\[ \text{MIN(Evaluated Range of Patient Tenure, Duration of Side Effects)} \]
Units: year

The Evaluated Duration of Side Effects is formulated along the same lines as the Observed Duration of Side Effects, taking into account the range of patient tenure as well as the duration of side effects.

Follow Up Smoothing Time = 0.5
Units: year

The Follow Up Smoothing Time represents the time over which physicians adjust their attitudes about the technology; it will be longer for a more tradition-bound group of physicians, whose response to new information may be long delayed.

Observed Aggregate Benefit Cost Ratio = Benefit Cost Ratio Observation Bias
*\[ \text{Aggregate Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects} \]
*\[ \text{EXP(Effect of Duration on Observation of Side Effects} \times \text{Effect of Frequency on Observation of Side Effects} \times \text{LN(Aggregate Benefit Cost Ratio for Patients in Follow Up/Aggregate Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects))} \]
Units: Qual Adj Life Years/dollars

The Observed Aggregate Benefit-Cost Ratio may change as the actual BCR of patients in follow-up changes and also may change as side effects are discovered. Aside from these changes, observations may be consistently biased if lack of control groups typical of information assessment leads
to and under- or over-assessment of benefits.

(231) Perceived Aggregate Benefit Cost Ratio from Follow Up = \( \exp(\text{Weight of Observations in Perceiving Information from Follow Up} \times \ln(\text{Recently Observed Aggregate Benefit Cost Ratio/Benefit Cost Ratio Unit}) + \text{Weight of Reports in Perceiving Information from Follow Up} \times \ln(\text{Reporting Benefit Cost Ratio Communication Bias*Recently Reported Aggregate Benefit Cost Ratio/Benefit Cost Ratio Unit})) \)
Units: Qual Adj Life Years/dollars
The Perceived Aggregate Benefit-Cost Ratio from Follow Up represents a referring physician's assessment of the technology's value to the average eligible patient. In general, this assessment will be based upon both unpublished, local observations and published studies communicated through channels both professional and commercial. The relative weights given to observations and reports reflect the amount of time devoted to colleague discussions versus the media and depend largely on the physician's perception that the full distribution of outcomes can be judged in a reliable way on the basis of local evidence. It combines recently observed and reported values of the Benefit-Cost ratio, where the reported BCR is a delayed version of the version of the evaluated BCR. The particular analytic formulation used combines observed and reported values of aggregate BCR in a non-linear fashion which is meant to reflect the idea that bad news about a medical technology, regardless of its source, will tend to overshadow good news, given physicians' basic risk-aversion. As formulated, the Perceived Aggr BCR will be closer to the lower input value than a purely linear combination of the two would indicate.

(252) Recently Observed Aggregate Benefit Cost Ratio = SMOOTH(Observed Aggregate Benefit Cost Ratio,Follow Up Smoothing Time)
Units: Qual Adj Life Years/dollars
The Recently Observed Aggregate Benefit Cost Ratio is a smoothed version of the instantaneously observed aggregate BCR and is used as the input from observation to Perceived Aggregate BCR from FU.

(257) Recently Reported Aggregate Benefit Cost Ratio = SMOOTH(Reported Aggregate Benefit Cost Ratio,Follow Up Smoothing Time)
Units: Qual Adj Life Years/dollars

(273) Reported Aggregate Benefit Cost Ratio = DELAY3(Evaluated Aggregate Benefit Cost Ratio*Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time)/ DELAY3(Follow Up Evaluation Rate,Follow Up Evaluation Reporting Time)
Units: Qual Adj Life Years/dollars
The Reported Aggregate Benefit Cost Ratio is a delayed version of the evaluated BCR.

(275) Required Patients for Observation of Side Effects = 2000
Units: cases
The Require Patients for Observation of Side Effects is the number required to satisfactorily (statistically) note the occurrence of side effects.

(090) Benefit Cost Ratio Observation Bias = 1
Units: dmnl
The Benefit Cost Ratio Observation Bias is a factor that indicates the tendency for an observer to subjectively "skew" observed data. When it is one, the effect is neutral.

(137) Effect of Duration on Observation of Side Effects = EDOSE(Observed Duration of Side Effects/Duration of Side Effects)
Units: dmml
The Effect of Duration on Observation of Side Effects represents the idea that as long as the observed duration of the most delayed side effects is less than the actual duration, some fraction of total side effects will remain unobserved; this relationship is shown graphically in table "EDOSE."

(140) Effect of Frequency on Observation of Side Effects = EFOSE(Patients/Required Patients for Observation of Side Effects)
Units: dmml
The Effect of Frequency on Observation of Side Effects represents the idea that physicians may not see certain side effects in their own practices for years, simply because these side effects are rare.

(267) Reporting Benefit Cost Ratio Communication Bias = 1
Units: 1
The Reported Benefit-Cost Communication Bias represents the exaggerations, distortions, and omissions that often occur in the process of communicating a study's results to physicians.

(300) Weight of Observations in Perceiving Information from Follow Up = 1-Weight of Reports in Perceiving Information from Follow Up
Units: 1
The Weight of Observation in Perceiving Information from Follow Up corresponds to the relative time physicians use for colleague communications versus interactions with the reporting media. It is used in the calculation of Perceived Aggregate Benefit Harm Ratio.

*(301) Weight of Reports in Perceiving Information from Follow Up = 0.4
Units: 1
The Weight of Reports in Perceiving Information from Follow Up corresponds to the relative importance, because of the amount of time spent with reports, that physicians ascribe to reported data versus time spent with colleague discussions. In this example, reports are weighted 10% of the total.
I C 4a. Information from Follow Up-Marginal Benefit Cost Ratio Diagram

I C 4b. Information from Follow Up-Marginal Benefit Cost Ratio Equations

(017) increase in co flow of marginal benefit cost ratio =
Marginal Benefit Cost Ratio\times\text{patient initiation rate}
Units: (Qual Adj Life Years\times\text{cases})/(dollars\times\text{year})

The increase in co flow of marginal benefit cost ratio is the rate which adds to the marginal BCR calculation.

(023) decrease in co flow or marginal benefit cost ratio =
Marginal Benefit Cost Ratio for Patients in Follow Up\times\text{follow up completion rate}
Units: (Qual Adj Life Years\times\text{cases})/(dollars\times\text{year})

The decrease in co flow of marginal benefit cost ratio is the rate which subtracts from the marginal BCR calculation.

(046) Perceived Marginal Benefit Cost Ratio from Follow Up =
\exp(\text{Weight of Observations in Perceiving Information from Follow Up} 
\times\ln(\text{Recently Observed Marginal Benefit Cost Ratio/Benefit Cost Ratio Unit})
+\text{Weight of Reports in Perceiving Information from Follow Up} 
\times\ln(\text{Reporting Benefit Cost Ratio Communication Bias} 
\times\text{Recently Reported Marginal Benefit Cost Ratio/Benefit Cost Ratio Unit}))
Units: Qual Adj Life Years/dollars

The Perceived Marginal Benefit-Cost Ratio from Follow Up is used by referring physicians to adjust their
criteria for patient selection.

(104) Co Flow of Marginal Benefit Cost Ratio for Patients in Follow Up =
INTEG(-decrease in co flow or marginal benefit cost ratio+increase in co flow of marginal benefit cost ratio, Marginal Benefit Cost Ratio*Patients in Follow Up)
Units: Qual Adj Life Years/dollars*cases
The Co Flow of Marginal Benefit Cost Ratio for Patients in Follow Up is a co-flow structure designed to calculate the moving average value of the marginal benefit cost ratio.

(139) Effect of Frequency on Evaluation of Side Effects =
EFSESE(Patients/Required Patients for Evaluation of Side Effects)
Units: dmm
The Effect of Frequency on the Evaluation of Side Effects is described in the lookup table "EFSESE," which correlates the number of patients with the effects of frequency. For IHM, since the side effects are likely to be revealed in a gradual way, the curve has a monotonically increasing shape.

(160) Evaluated Marginal Benefit Cost Ratio = Benefit Cost Ratio Evaluation Bias
*Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects
*EXP(Effect of Duration on Evaluation of Side Effects
*Effect of Frequency on Evaluation of Side Effects
*LN(Marginal Benefit Cost Ratio for Patients in Follow Up
/Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects))
Units: Qual Adj Life Years/dollars

The Evaluated Marginal Benefit Cost Ratio is that which has been scrutinized and reported in medical journals and the like.

(208) Marginal Benefit Cost Ratio for Patients in Follow Up =
Co Flow of Marginal Benefit Cost Ratio for Patients in Follow Up/Patients in Follow Up
Units: Qual Adj Life Years/dollars

The Marginal Benefit Cost Ratio for Patients in Follow Up is the value of BCR at a given point in time for patients who are being followed at that given point in time.

(209) Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects =
Marginal Benefit Cost Ratio for Patients in Follow Up/Effect of Side Effects on Benefit Cost
Units: Qual Adj Life Years/dollars

The Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects is the value of BCR at a given point in time for patients who are being followed at that given point in time, not including the fraction of patients who are subject to side effects.

(228) Observed Marginal Benefit Cost Ratio = Benefit Cost Ratio Observation Bias
*Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects
*EXP(Effect of Duration on Observation of Side Effects
*Effect of Frequency on Observation of Side Effects
*LN(Marginal Benefit Cost Ratio for Patients in Follow Up
/Marginal Benefit Cost Ratio for Patients in Follow Up Excluding Side Effects))
Units: Qual Adj Life Years/dollars

Observed Marginal Benefit Cost Ratio is the benefit-cost ratio that is observed by physicians as they follow patients who are using the technology.
(254) Recently Observed Marginal Benefit Cost Ratio =
SMOOTH(Observed Marginal Benefit Cost Ratio, Follow Up Smoothing Time)
Units: Qual Adj Life Years/dollars
Recently Observed Marginal Benefit-Cost Ratio is formulated in the same manner as the aggregate BCR measures.

(259) Recently Reported Marginal Benefit Cost Ratio =
SMOOTH(Reported Marginal Benefit Cost Ratio, Follow Up Smoothing Time)
Units: Qual Adj Life Years/dollars
The Recently Reported Marginal Benefit Cost Ratio is a smooth of the reported marginal BCR.

(270) Reported Marginal Benefit Cost Ratio =
DELAY3(Evaluated Marginal Benefit Cost Ratio*Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time)/DELAY3(Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time)
Units: Qual Adj Life Years/dollars
Reported Marginal Benefit Cost Ratio is the marginal benefit-cost ratio published in clinical reports and medical journals, and is delayed from the time of evaluation.

(274) Required Patients for Evaluation of Side Effects = 1000
Units: cases

The Required Patients for the Evaluation of Side Effects is the number necessary to statistically analyze the numbers in order to draw conclusions regarding side effect occurrence in medical journal reports.
I C 5a. Information from Follow Up-Eligibility Diagram

I C 5b. Information from Follow Up-Eligibility Equations

(062) Recently Reported Time of Initial Implant = SMOOTH(Reported Time of Initial Implant, Follow Up Smoothing Time)

Units: year

The Recently Reported Time of Initial Implants is a smooth of the reported time of initial implants.

(100) Co Flow of Eligibility Fraction for Patients in Follow Up = INTEG(-follow up completion rate*Eligibility Fraction for Patients in Follow Up + patient initiation rate*Eligibility Fraction, Eligibility Fraction*Patients in Follow Up)

Units: cases

The Co Flow of Eligibility Fraction for Patients in Follow Up is the co flow structure used to calculate the eligibility value used for the patients who are currently undergoing follow up evaluation.

(107) Co Flow of Time of Initial Implants for Patients in Follow Up = INTEG(-follow up completion rate*Time of Initial Implant for Patients in Follow Up + patient initiation rate*Time, Time*Patients in Follow Up)

Units: cases*year

The Co Flow of Time of Initial Implant for Patients in Follow Up is the co flow structure used to calculate the initial implant time used for the patients who are currently undergoing follow up evaluation.

(150) Eligibility Fraction for Patients in Follow Up = Co Flow of Eligibility Fraction for Patients in Follow Up/Patients in Follow Up

Units: 1

Eligibility Fraction for Patients in Follow Up is the eligibility value used for the patients who are currently undergoing follow up evaluation.
(234) Perceived Eligibility Fraction from Follow Up =
(Weight of Observations in Perceiving Information from Follow Up
*Recently Observed Eligibility Fraction) +
(Weight of Reports in Perceiving Information from Follow Up
*Recently Reported Eligibility Fraction)
Units: 1
The Perceived Eligibility Fraction from Follow Up represents the eligibility fraction corresponding to those cases whose outcomes are reflected in the Perc'd Marg BCR from FU, and together with Perc'd Marg BCR from FU determines the indicated eligibility fraction from follow up. It is a weighted average of the recently observed eligibility fraction and the recently reported eligibility fraction, where the weights correspond to the relative time physicians use for colleague communications vs. interactions with the reporting media.

(237) Perceived Time of Initial Implant From Follow Up =
(Weight of Observations in Perceiving Information from Follow Up
*Recently Observed Time of Initial Implant) +
(Weight of Reports in Perceiving Information from Follow Up
*Recently Reported Time of Initial Implant)
Units: year
The Perceived Time of Initial Implants from Follow Up is a weighted average of the recently observed time of initial procedures and the recently reported time of initial procedures.

(238) Perceived Time Since Implants in Follow Up =
MAX(Follow Up Smoothing Time, Time-Perceived Time of Initial Implant From Follow Up)
Units: year
The Perceived Time Since Implants in Follow Up is used to compute the presumed widening of scope since FU, and is the present time minus the perceived average time of initial procedure, and represents the average age of Follow-Up information.

(253) Recently Observed Eligibility Fraction =
SMOOTH(Eligibility Fraction for Patients in Follow Up, Follow Up Smoothing Time)
Units: 1
The Recently Observed Eligibility Fraction is a smooth of the Eligibility Fraction for patients in Follow-up.

(255) Recently Observed Time of Initial Implant = SMOOTH(Time of Initial Implant for Patients in Follow Up, Follow Up Smoothing Time)
Units: year
The Recently Observed Time of Initial Implants is simply the smooth of the times that implants occurred for patients who are in follow up.

(258) Recently Reported Eligibility Fraction =
SMOOTH(Reported Eligibility Fraction, Follow Up Smoothing Time)
Units: 1
The Recently Reported Eligibility Fraction is a smoothed version of the Reported Eligibility Fraction.

(269) Reported Eligibility Fraction =
DELAY3(Eligibility Fraction for Patients in Follow Up*Follow Up Evaluation Rate,
Follow Up Evaluation Reporting Time)/
DELAY3(Follow Up Evaluation Rate, Follow Up Evaluation Reporting Time)
Units: 1
The Reported Eligibility Fraction is a delayed version of the Eligibility Fraction for Patients in Follow Up, with the delay caused by the processes of evaluation and reporting.
(271) Reported Time of Initial Implant =
DELAY3(Time of Initial Implant for Patients in Follow Up*Follow Up Evaluation Rate,
Follow Up Evaluation Reporting Time)/
DELAY3(Follow Up Evaluation Rate,Follow Up Evaluation Reporting Time)
Units: year
Reported Time of Initial Procedures is the published follow-up data time period; it is a delayed report.

(291) Time of Initial Implant for Patients in Follow Up =
Co Flow of Time of Initial Implants for Patients in Follow Up/Patients in Follow Up
Units: year
Time of Initial Implant for Patients in Follow Up is the average time that is used to calculate the time that patients have been implanted who are being followed, calculated using a co flow structure.
II. Manufacturer Activities

A. Marketing Effort

II A 1a. Marketing Diagram

II A 1b. Marketing Equations

(145) Effect of Recommending Physician Fraction on Marketing Effectiveness = ERFME(Recent Recommending Physician Fraction)
Units: dml

The Effect of Recommending Physician Fraction on Marketing effectiveness is a lookup table function that relates the physician acceptance to the effectiveness of further marketing spending.

(168) Fraction of Sales Revenue to Marketing Normal = 0.25
Units: 1

The Fraction of Sales Revenue to Marketing Normal is the fraction of sales revenue spent on marketing activities that would prevail if all other factors were neutral.

(188) Indicated Fraction of Sales Revenue to Marketing = Fraction of Sales Revenue to Marketing Normal\*Effect of Recommending Physician Fraction on Marketing Effectiveness
Units: dml

The Indicated Fraction of Sales Revenue to Marketing will normally be set to some traditional value but may decrease if manufacturers perceive that their promotional efforts are less effective than usual due to saturation of the market, represented in the model by a large recommending physician fraction.

(189) Indicated Marketing Effort = Indicated Fraction of Sales Revenue to Marketing\*Sales Revenue
Units: dollars/year

The Indicated Marketing Effort is assumed to be some fraction of sales revenue from the product, which is
to say that the money put into promotion of the product is generated by previous sales of the product; this was clearly the case for pacemakers.

*(196) Initial Marketing Effort = 0
Units: dollars/year
The Initial Marketing Effort represents the "kickoff" of marketing effort by the manufacturer.

(211) Marketing Effort =
INTEG(marketing effort startup rate-marketing effort termination rate, Initial Marketing Effort)
Units: dollars/year
The Marketing Effort represents real expenditures on all promotional activities, which may include detailing or promotion by sales representatives, journal advertising, direct mailing, medical conference sponsorship and attendance, and running demonstrations or training clinics in medical schools and hospitals.

(219) Marketing Effort Adjustment Time = 1
Units: year
The Marketing Effort Adjustment Time represents the typical time between marketing budget reviews.

(220) Marketing Effort Termination Time = 1
Units: year
The Marketing Effort Termination Time is an average time period related to marketing programs; it is determined by such factors as the typical duration of employment in the sales force and advertising campaign lifetimes.

(222) marketing effort startup rate =
MAX(0,marketing effort termination rate+(Indicated Marketing Effort-Marketing Effort)/Marketing Effort Adjustment Time)
Units: dollars/(year*year)
The marketing effort startup rate initiates new efforts in an attempt to adjust the total level of efforts toward a desired or indicated level. If manufacturers are satisfied with the current level of marketing, new marketing efforts will be initiated simply to replace terminations; or if indicated Marketing Effort differs from current Marketing Effort, the gap will be closed over an adjustment time, the Marketing Effort Adjustment time.

(223) marketing effort termination rate = Marketing Effort/Marketing Effort Termination Time
Units: dollars/year/year
The marketing effort termination rate is responsible for the phasing-out of various promotional activities over an average time period represented by the Marketing Effort Termination Time.

(256) Recent Recommending Physician Fraction =
SMOOTH(Recommending Physician Fraction,Recommending Physician Fraction Smoothing Time)
Units: 1
Recent Recommending Physician Fraction is a smooth of the Recommending Physician Fraction.

(262) Recommending Physician Fraction Smoothing Time = 2
Units: year
The time it takes to adjust the recommending physician fraction.

(277) Sales Revenue = Implants*Sales Revenue per Implant
Units: dollars/year
Sales Revenue is simply implants multiplied by sales revenue per implant.
*(278)  Sales Revenue per Implant = 7000
Units: dollars/cases
Sales Revenue per Implant is the selling price of the IHM technology.
B. Technical Development

II B 1b. Technical Development Diagram

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II B 1b. Technical Development Equations

(022) Indicated Fraction of Sales Revenue to Technical Development = 
Fraction of Sales Revenue to Technical Development Normal 
*Effect of Benefit Cost on Technical Development*Effect of Perceived Return on Technical Development

Units: 1

Indicated Fraction of Sales Revenue to Technical Development relates the effect of benefit harm on technical development and the effect of perceived return to technical development to the amount that should be spent to develop the technology further.

(131) Effect of Benefit Cost on Technical Development = 
EBCTD(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)

Units: dmnl

The Effect of Benefit Cost on Technical Development is the effect that the perceived average benefit cost ratio compared to the benefit cost ratio normal has on the decision to pursue further technical development efforts.

(142) Effect of Perceived Return on Technical Development = EPRTD(Perceived Return to Technical Development/Return to Technical Development Normal)

Units: dmnl
The Effect of Perceived Return on Technical Development is the effect that the expected return, in terms of increased patient benefit or widening of scope, versus the normal return, plays in decisions to continue technical development.

(169) Fraction of Sales Revenue to Technical Development Normal = 0.12
Units: 1
The Fraction of Sales Revenue to Technical Development is currently set to 12% in the model, but may change in response to perceptions (usually on the part of physicians, at first) that a) significant improvements are needed to make the product more acceptable, or b) further modifications are unlikely to be as successful as they once were.

(185) Incorporation into Physician Practice Smoothing Time = 1.5
Units: year
Incorporation Smoothing Time is the time necessary for new technical developments to be integrated into physician practice.

(190) Indicated Technical Development Projects =
(Indicated Fraction of Sales Revenue to Technical Development
*Sales Revenue)/Spending per Technical Development Project
Units: Projects

Indicated Technical Development Projects are those that are recommended, based on the "Indicated Fraction of Sales Revenue" and the sales revenue.

*(200) Initial Technical Development Projects = 0
Units: Projects

Initial Technical Development projects is simply the initial value.

(235) Perceived Fractional Change in Eligibility =
SMOOTH(change in eligibility fraction/Eligibility Fraction, Time to Perceive Change in Eligibility)
Units: 1/year
Perceived Fractional Change in Eligibility is a smooth of the change in eligibility fraction.

(236) Perceived Return to Technical Development = Perceived Fractional Change in Eligibility/Recent Incorporation of Technical Developments into Physician Practice
Units: 1/Projects
The Perceived Return to Technical Development is the relative impact of recent developments in the size of the market, as reflected in the percentage changes in the eligibility fraction.

(251) Recent Incorporation of Technical Developments into Physician Practice =
SMOOTH(Recent Incorporation of Technical Developments into Physician Practice
,Incorporation into Physician Practice Smoothing Time)
Units: Projects/year
Recent Incorporation of Technical Developments is a smooth of the Incorporation of Technical Developments into clinical practice over the incorporation smoothing time.

*(276) Return to Technical Development Normal = 0.1
Units: 1/Projects
Return to Technical Development Normal is the "normalized" value for the expected increase in product capability from technical development.

(282) Spending per Technical Development Project = 1e+006
Units: dollars/year/Projects
Spending per Technical Development Project is the average cost of a technical development project.
Technical Development Project Adjustment Time = 1
Units: year
The Technical Development Project Adjustment Time is the time required to develop a new technical development project.

technical development project completion rate = Technical Development Projects/Technical Development Project Completion Time
Units: Projects/year
The technical development project completion rate represents the successful completion of a project and coincides with the introduction of the modification to the market.

Technical Development Project Completion Time = 3
Units: year
Technical Development Project Completion Time represents the time required to complete a technical development project, once it is initiated.

technical development project start up rate =
MAX(0,technical development project completion rate
+(Indicated Technical Development Projects-Technical Development Projects)
/Technical Development Project Adjustment Time)
Units: Projects/year
The technical development project start up rate represents the initiation of new projects which may simply begin as fuzzy ideas but eventually result in product modifications. This start up rate has both a replacement component and a component which adjusts the number of projects toward a level indicated by the available budget for technical development. Thus the fraction of sales revenue allocated to technical development may change as it is noted that significant improvements are needed to make the product more acceptable.

Technical Development Projects =
INTEG(-technical development project completion rate+technical development project start up rate
,Initial Technical Development Projects)
Units: Projects
Technical Development Projects are the activities of manufacturers which result in product modifications intended to improve the technology.

Technical Development Spending =
Technical Development Projects*Spending per Technical Development Project
Units: dollars/year
Technical Development Spending is the product of the number of Technical Development Projects and the Spending per each Project.

Time to Perceive Change in Eligibility = 1
Units: year
The Time to Perceive Change in Eligibility is the time necessary to perceive that the eligibility criteria for the technology has changed from its previous value.
III. Payer Sector

A. Payer Activities

III A 1a. Payer Diagram

--- Diagram of Payer Activities and Equations ---

III A 1b. Payer Equations

**(001)  Fraction of Marketing Effort for Payers = 0
Units: dmnl

The fraction of Marketing Effort for Payers is the fraction of the indicated marketing effort, from the marketing sector, that will be allocated for activities related to payer contacts and advertising.

**(003)  Payer Rejection Fraction =
Payer Rejection Fraction Normal*Effect of Benefit Cost Ratio on Payer Rejection
Units: 1/year

The Payer Rejection Fraction is that fraction of Reimbursing payers that subsequently reject the IHM technology, based on the effect of the benefit cost ratio on their decision to reject.

**(004)  Payer Rejection Fraction Normal = 0.01
Units: 1/year

The Rejection Fraction Normal times the Effect of Benefit Harm Ratio on Rejection yields the current Rejection Fraction used in the rejection rate for Recommending Physicians.
**011** Effect of Benefit Cost Ratio on Payer Approval =
EBCRPA(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmml
The Effect of the Benefit-Cost Ratio on Payer Approval of the technology can suppress the rate of acceptance when the perceived relative advantage is low and boost it when this ratio is high, with the same relationship to payers as what is described for physician acceptance.

**012** Effect of Benefit Cost Ratio on Payer Rejection =
EBCRPR(Perceived Aggregate Benefit Cost Ratio from Follow Up/Benefit Cost Ratio Normal)
Units: dmml
The Effect of Benefit Cost Ratio on Payer Rejection is described by a lookup table "EBCRPR" that relates the Perceived Aggregate BCR from Follow Up to the Benefit-Cost Ratio Normal. When the Perceived Aggregate BCR from FU (PABCRF) is greater than or equal to the "normal" value of BCR (BCRN), the rejection fraction will be very small, but if PABCRF/BCRN (which represents the perceived overall relative advantage of the technology) drops below 1, payers may abandon the product and switch to a competing technology.

**021** Effect of Follow Up Reports on Payer Approval =
EFURPA(follow up reporting rate/Follow Up Reporting Rate Normal)
Units: dmml
The Effect of Follow Up Reports on Payer Approval represents the response of payers to journal reports evaluating clinical outcomes using the technology. Like product promotions, reports are more influential when there are more of them and the impact on acceptance is fairly immediate and temporary, but a limit to the impact of the professional media undoubtedly exists.

**031** Payer Approval Fraction =
Payer Approval Fraction Normal*Effect of Benefit Cost Ratio on Payer Approval
*( Effect of Payer Marketing Effort on Approval + Effect of Follow Up Reports on Payer Approval +
Effect of Payer Fraction on Approval Rate)
Units: 1/year
The Payer Approval Fraction is determined by effects of benefit-cost, other payer interactions, marketing effort, and follow-up reports.

**034** Payer Approval Fraction Normal = 0.05
Units: 1/year
The Acceptance Fraction Normal represents the fractional rate of payer approval when a) the product is fully available, b) the technology has a neutral perceived relative advantage, and c) the combined impact of the various communication channels is equivalent to the maximum impact that contacts with other payers can exert alone. The normal payer approval fraction is 2/3 lower that the normal physician acceptance fraction because payers are less likely to approve technologies because of the scale their decisions encompass.

**035** Initial Reimbsuring Payer Fraction = 0.01
Units: 1
The Initial Reimbsuring Payer Fraction is simply the starting point for simulation.

**042** Non Reimbursing Payer Fraction = 1-Reimbursing Payer Fraction
Units: 1
The Non Reimbursing Payer Fraction are those payers who do not approve the IHM technology, and who therefore do not reimburse for procedures associated with IHM.
**(045)** Effect of Payer Fraction on Approval Rate = EPFAR(Reimbursing Payer Fraction)
Units: dmnl
The Effect of Payer Fraction on Approval Rate is the effect that previous payers have on influencing future potential payers to include the IHM device on their reimbursing list.

**(049)** payer rejection rate = Reimbursing Payer Fraction*Payer Rejection Fraction
Units: 1/year
The payer rejection rate is the rate at which Reimbursing Payers reject reimbursing for the technology.

**(050)** payer approval rate = Non Reimbursing Payer Fraction*Payer Approval Fraction
Units: 1/year
values.
The payer approval rate is the rate at which Non Reimbursing Payers approve reimbursing for the technology.

**(057)** Reimbursing Payer Fraction =
INTEG(payer approval rate-payer rejection rate,Initial Reimbursing Payer Fraction)
Units: 1

The Reimbursing Payer Fraction is that fraction of payers who approve of, and therefore reimburse medical charges related to, the IHM technology.

**(058)** Fraction of Capitated Reimbursement = 1
Units: dmnl
The Fraction of Capitated Reimbursement is the fraction of physician reimbursement that is made on a capitated basis, or on the basis of number of patients served versus on a per-procedure basis. This is speculated to affect the way physicians make therapy choices, since their choices will affect their own comI8nsation.

**(063)** Effect of Payer Marketing Effort on Approval =
EMEPA(Marketing Effort*Fraction of Marketing Effort for Payers/Marketing Effort Normal)
Units: dmnl
The Effect of Marketing Effort on Acceptance represents the overall response of payers to the promotional marketing activities of manufacturers. It can also generate approval with influence increasing according to size and number, but the influence diminishes past a certain point. Also, the impact on approval of a particular promotion or report is assumed to be fairly immediate and temporary.
IV. General Model

A. Summary Statistics

IV A 1a. Summary Statistics Diagram

IV A 1b. Summary Statistics Equations

(007) Harmful Outcomes to Date = INTEG(Initial Implants*Fraction of Harmful Outcomes, Initial Implants to Date*Fraction of Harmful Outcomes)
Units: cases

Harmful Outcomes to Date is the cumulative total of implants that resulted in a harmful outcome.

(014) Marketing Effort to Date = INTEG(Marketing Effort,0)
Units: dollars
Marketing Effort to Date is the integration of the marketing effort over time.

(031) Fraction of Beneficial Outcomes to Date = Beneficial Outcomes to Date/Initial Implants to Date
Units: 1
Fraction of Beneficial Outcomes to Date is simply the ratio of the beneficial outcomes to the initial procedures to date.
(036) Benefit Cost Ratio to Date = Benefit to Date/Cost to Date
Units: Qual Adj Life Years/dollars
Benefit-Cost Ratio to Date is the ratio of the total benefit to date for all of the patients who have
used the technology divided by the total cost to date.

(039) Benefit to Date = INTEG(Initial Implants*Aggregate Expected Benefit,
Initial Implants to Date*Aggregate Expected Benefit)
Units: Qual Adj Life Years
The Benefit to Date is the cumulative total, or integration, of all of the benefit accrued in the system

(051) Cost to Date = INTEG(Initial Implants*Aggregate Expected Cost,
Initial Implants to Date*Aggregate Expected Cost)
Units: dollars
Cost to Date is the integration of average amount of cost incurred over time.

(054) Sales Revenue to Date = INTEG(Sales Revenue,0)
Units: dollars
Sales Revenue to Date is the integration of sales revenue over time.

(060) Fraction of Harmful Outcomes to Date = Harmful Outcomes to Date/Initial Implants to Date
Units: 1
The Universe of New Cases is the number of new patients diagnosed with Congestive Heart Failure per
year. Of these cases, a fraction will be considered candidates for the IHM technology.

(061) Technical Development Spending to Date = INTEG(Technical Development Spending,0)
Units: dollars
Technical Development Spending to Date is the integration of the technical development spending over
time.

(075) Implanting Physicians to Date = INTEG(implanting physician start up rate,Implanting
Physicians)
Units: Physicians
Implanting Physicians to Date is the integration of the implanting physician start-up rate.

(086) Beneficial Outcomes to Date = INTEG(Initial Implants*Fraction of Beneficial Outcomes,
Initial Implants to Date*Fraction of Beneficial Outcomes)
Units: cases
Beneficial Outcomes to Date is the integration of the initial implants times the fraction of beneficial
outcomes, with an initial value given by the initial implants to date times the fraction of
beneficial outcomes.

(197) Initial Implants to Date = INTEG(Initial Implants,1e-007)
Units: cases
Initial Implants to Date is the cumulative total of Initial Implants in the simulation.

(225) Implants to Date = INTEG(Implants,0)
Units: cases
Implants to Date is the cumulative total of total Implants in the simulation.
B. Model Equations

*****************************************************************************
IHM payer model equations
*****************************************************************************

(166) FINAL TIME = 2020
Units: year
The final time for the simulation.

(202) INITIAL TIME = 2000
Units: year
The initial time for the simulation.

(279) SAVEPER = TIME STEP
Units: year
Save Period: The frequency with which output is stored.

(292) TIME STEP = 0.0625
Units: year
The time step for the simulation.

*****************************************************************************
IHM payer model lookup tables
*****************************************************************************

** (005) EBCRPA ([0.0,0.01],[0.5,0.25],[1.1],[1.5,1.75],
(2.2,5),(2.5,3.25),(3.4),(3.5,4.5),(4.4,75),(4.5,5),(5,5),(10,5))
Units: 1
Table: The Effect of Benefit-Cost Ratio on Payer Approval.

** (006) EBCRPR ([0.0,10.0,100],[0.80],[0.25,5],[0.5,25],[0.75,10],
(1.1),(1.25,0.8),(1.5,0.7))
Units: dmm
Table: Effect of Benefit Cost Ratio on Payer Rejection.

** (020) EMEPA ([0.0,2.1,5],[0.0],[0.25,0.3],[0.5,0.6],[0.75,0.8],
(1,1),(1,1),(1,1),(1.25,1.2),(1.5,1.3),(1.75,1.4),(2,1.4))
Units: dmm
Table: Effect of Marketing Effort on Payer Approval.

** (041) EPAA ([0.0,10.10],[0.0],[1,1])
Units: dmm
Table: Effect of Payer Approval on Acceptance. The table is constructed so that the fraction of payers
relates linearly with the fraction of recommending physicians.

** (044) EPFA ([0.0,1,1],[0.0],[0.01,0],[0.05,0.0025],[0.1,0.25],
(0.25,0.5),(0.5,0.5),(0.6,1),(0.9,1),(1,1))
Units: dmm
Table: Effect of Payer Fraction on (payer) Approval Rate. The table function has a shape that suggests
that only 1% of payers have approved the device, it has 0 effect on other payers. If 10% of the Payers
have approved the use of IHM, there is a 25% weighting that it will influence future payers. If 50% have
approved the use of IHM, there is a 50% weighting, and if 60% or greater have approve use of the device,
there is a 100% chance that it will influence future Payers to approve the use of the device.
** (053) EFURPA ([(0,0)-(1.5,1.5)],(0,0),(0.25,0.3),(0.5,0.6),(0.75,0.8)
,(1,1),(1.25,1.2),(1.5,1.3),(1.75,1.4),(2,1.4))
Units: dm
Table: Effect of Follow-Up Reports on Payer Approval.

* (055) FHO ([(0,0)-(20,10)],(0,0.01),(0.6,0.01),(0.7,0.01),(1.0,0.01),(10,0.01))
Units: dm
Table: Fraction of Harmful Outcomes

(097) CAPUF ([(0,0)-(2,1)],(0,0),(0.2,0.2),(0.4,0.4),(0.6,0.6),(0.8,0.8)
,(1,0.9),(1.2,0.95),(1.4,0.98),(1.6,1),(1.8,1))
Units: dm
Table: Capacity Utilization Fraction for Implanting Physicians.

(119) EAVIA ([(0,0)-(1,2)],(0,0.2),(0.2,0.4),(0.4,0.6),(0.6,0.75),(0.8,0.9),(1,1))
Units: dm
Table: Effect of Availability of Implants on Acceptance.

(120) EBCRA ([(0,0)-(10,6)],(0,0.01),(0.5,0.25),(1,1)
,(1.5,1.75),(2.2,2.5),(2.5,3.25),(3,3.4),(3.5,4.5),(4.4,75),(4.5,5),(5,5),(10,5))
Units: 1
Table: The Effect of Benefit-Cost Ratio on Acceptance for Referring Physicians.

(121) EBCRL ([(0,0)-(200,2)],(-4,-0.2),(-3,0.3),(-2,0.5),(-1,0.7)
,(0,1),(1.1,4),(2.1,7),(3,1.85),(4,1.9))
Units: dm
Table: Effect of Benefit-Cost Ratio on Eligibility.

(122) EBCRR ([(0,0)-(200,100)],(0,80),(0.25,50),(0.5,25),(0.75,10)
,(1,1),(1),(1.25,0.8),(1.5,0.7))
Units: 1
Table: Effect of Benefit-Cost Ratio on Rejection (recommending physician rejection.)

(123) EBCTD ([(0,0)-(200,10)],(0,6),(0.5,4),(1.2,5),(1,5,1,6),(2,1,2),(2.5,1),(3,1))
Units: dm
Table: Effect of Benefit-Cost on Technical Development.

(124) ECDA ([(0,0)-(1,1)],(0,0),(0.25,0.25),(0.5,5),(0.75,0.75),(1,1),(1,1))
Units: dm
Table: Effect of Colleague Discussion on Acceptance.

(125) ECEDR ([(0,0)-(4,6)],(-4.6),(-3.4),(-2.2,75),(-1.1,5),(0,1),(1,1,5),(1,1,5),(2,2,75),(3,4),(4,6))
Units: dm
Table: Effect of Changing Evaluations on Desired Reports.

(126) EDESE ([(0,0)-(1,1)],(0,0),(0,1),(0.2,0.05),(0.3,0.1),(0.4,0.2)
,(0.5,0.3),(0.6,0.5),(0.7,0.7),(0.8,0.85),(0.9,0.95),(1,1))
Units: dm
Table: Effect of Duration on the Evaluation of Side Effects.

190
(127) EDOSE $\left(\{(0,0)-(1,1)\},\{(0,0),(0,1,0),(0,2,0.05),(0,3,0.1),(0,4,0.2),
(0,5,0.3),(0,6,0.5),(0,7,0.7),(0,8,0.85),(0,9,0.95)\}\right)$
Units: dml
Table: Effect of Duration on the Observation of Side Effects.

(128) EFESE $\left(\{(0,0)-(1,20)\},\{(0,0),(0,1,0),(0,2,0.05),(0,3,0.1),(0,4,0.2),
(0,5,0.3),(0,6,0.5),(0,7,0.7),(0,8,0.85),(0,9,0.95)\}\right)$
Units: dml
Table: Effect of Frequency on Evaluation of Side Effects

(148) EFOSE $\left(\{(0,0)-(1,4)\},\{(0,0),(0,1,0),(0,2,0.05),(0,3,0.1),(0,4,0.2),
(0,5,0.3),(0,6,0.5),(0,7,0.7),(0,8,0.85),(0,9,0.95)\}\right)$
Units: dml
Table: Effect of Frequency on the Observation of Side Effects.

(152) EPCMB $\left(\{(0,0)-(20,20)\},\{(0,1),(0,5,1),(0,6,1),(0,7,1),(0,8,1),(0,9,1),(1,1),(10,1)\}\right)$
Units: dml
Table: Effect of Product Capability on Magnitude of Benefit.

(153) EPCMC $\left(\{(0,0)-(20,20)\},\{(0,1),(1,1),(10,1)\}\right)$
Units: dml
Table: Effect of Product Capability on the Magnitude of Cost.

(154) EPRTD $\left(\{(0,0)-(2000,1)\},\{(0,0,4),(0,2,0.8),(0,4,0.95),(0,6,1),(0,8,1),(1,1),(10,1)\}\right)$
Units: dml
Table: Effect of Perceived Return on Technical Development

(155) ERFME $\left(\{(0,0)-(1,1)\},\{(0,1),(0,2,1),(0,4,1),(0,5,1),(0,6,1),
(0,7,1),(0,8,1),(0,9,1),(1,1),(1,1)\}\right)$
Units: dml
Table: Effect of Recommending Physician Fraction on Marketing Effort

(156) ESEBC $\left(\{(0,0)-(200,1)\},\{(0,1),(0,5,1),(1,1),(1,5,1),(2,1),
(2,5,1),(3,1),(3,5,1),(4,1),(4,5,1),(5,1)\}\right)$
Units: dml
Table: Effect of Side Effects on Benefit-Cost

(157) EUPHD $\left(\{(0,0)-(2,3)\},\{(0,3),(0,25,2,6),(0,5,2),(0,75,1,4),(1,1),(1,25,0,8),(1,5,0,7)\}\right)$
Units: dml
Table: Effect of Utilization on Physician Drop Out

(161) EXFC $\left(\{(0,0)-(1,1)\},\{(0,0,25),(0,2,0.5),(0,4,0.7),(0,6,0.85),(0,8,0.95),(1,1),(1,1)\}\right)$
Units: 1
Table: Effect of Experience on Functional Capability.

(184) EFURA $\left(\{(0,0)-(1.5,1.5)\},\{(0,0),(0,25,0.3),(0,5,0.6),(0,75,0.8),
(1,1),(1,25,1.2),(1,5,1.3),(1,75,1.4),(2,1.4)\}\right)$
Units: dml
Table: Effect of Follow-Up Reports on Acceptance.

(207) LXNBO $\left(\{(0,0)-(10,10)\},\{(0,2),(1,3,6),(2,5,1),(3,6,4),(4,7,5),(5,8,3)\}\right)$
Units: year
Table: Life Expectancy for Non Beneficial Outcome.
Table: Effect of Marketing Effort on Acceptance.

(215) EMEA ((0,0)-(2.2.2), (0,0), (0.25,0.3), (0.5,0.6), (0.75,0.8),
(1,1), (1,1), (1,1), (1.25,1.2), (1.5,1.3), (1.75,1.4), (2,1.4))
Units: dmnl

Table: Product Capability Increase per Technical Development

(229) PCITD ((0,0)-(1,1), (0.00515464,0.5), (0.0773196,0.483553),
(0.154639,0.447368), (0.224227,0.375), (0.306701,0.296053), (0.399485,0.223684),
(0.5,0.154605), (0.590206,0.108553), (0.721649,0.0559211), (0.850515,0.0230263),
(1,0), (1,0), (1,0))
Units: 1

Table: Desired Continuation Fraction for using the Device for Long-Term follow-up

(283) DCFLT ((0,0)-(200,1), (0,0), (0.2,0.25), (0.4,0.5), (0.6,0.7),
(0.8,0.9), (1,1), (1,1), (1.2,1))
Units: dmnl
Appendix D: REFERENCES


