

Disruptive Technology a Heartbeat Away: Ecton, Inc.

On a pleasant day in the spring of 1998, Michael Cannon and Christopher Knell walked toward the cardiology suite of Mt. Sinai hospital in Manhattan's Upper East Side. As President and Director of Engineering at Ecton, Inc., a Philadelphia based start-up, the two were to meet the Director of the Cardiac Echo laboratory to begin patient trials of the Ecton imaging system. Mt. Sinai had agreed to serve as one of seven testing centers for the new device, which Ecton planned to release within the next year. Cannon knew that his compact echo machine, which he carried under his arm by a single handle, would have to perform competitively in a room filled with state-of-the-art echo machines made by long-standing competitors such as Hewlett Packard -- each machine weighing more than the average NFL linesman and costing nearly a quarter of a million dollars.

Over the next four years, Cannon was planning to sell 7000 of his units for \$38,000 apiece against this competition. But he worried about how he might penetrate a market that seemed to have been held so tightly for so long by capable, entrenched competitors – and about what mix of product features and services might appeal to the customers he needed to target.

Ultrasound Technology and Echocardiography

Doppler echocardiography instruments ("echo machines") are generally large (5' x 4' x 4') and heavy (400 lbs) devices on wheels, as shown in **Exhibit 1**. To view the functioning of the heart, the face of the transducer, which was usually no larger than 9 square centimeters, was placed on the patient's chest at various angles. The transducer delivered ultrasound waves into the body and these waves were reflected back to the transducer as they crossed interfaces of different acoustic impedance. More simply, the ultrasound bounced off the internal structures of the body and returned to the transducer. The transducer converted the returning sound into electronic signals that were processed by the internal computers of the instrument, to create an image of internal body tissues. These images were then displayed on the screen for the user, and videotaped for storage and off-

Dr. Edward G. Cape, MBA 1998, prepared this case under the direction of Professor Clayton M. Christensen as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

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line analysis. The Appendix describes more completely the ways in which this technology worked.

Compared to other diagnostic imaging techniques such as cardiac catheterization¹ or magnetic resonance imaging (MRI), echo machines were relatively mobile, and could easily be wheeled to multiple locations in a hospital. Most exams were performed in an "echo lab" which was located in the cardiology department. Cardiology departments typically owned a number of echo machines (depending on the patient load of the department), and they were operated by technicians known as "echo techs." Echo techs were trained to perform a standard sequence of images which were recorded on video tape for off-line "reading" by cardiologists. If necessary, the attending cardiologist could order special views for certain patients to be added to the echo tech exam, or the cardiologists could perform the imaging in the lab themselves if they needed to interrogate a specific area of the heart in great detail.

Increasingly, echo machines were also being wheeled into surgery suites to be used in combination with a special peripheral called a *transesophageal transducer*. This transducer was passed down the throat and into the esophagus of the sedated patient so that the heart could be imaged from behind. This technique was particularly useful for heart surgery in which tissue or a heart valve was repaired, since possible errors in the repair could be detected before the chest was closed. Echo machines also were often called to the intensive care unit (ICU) to image the heart functions in post-operative patients or others with cardiac difficulties. The instruments were even occasionally taken to the individual rooms of patients who had been admitted to the hospital and were too ill to be transported to the echo lab. Often, the need to move the instrument and a tech to other locations in the hospital could be disruptive to patient flow through the cardiology department's echo lab.

Other areas in the hospital in which echocardiography equipment might be used had also been suggested, such as emergency rooms, outpatient clinics and satellite clinics, but it was very difficult for these non-cardiology specialty locations to justify the capital expenditure required for a new echo machine.

The Market

The world ultrasound market in 1997 was estimated at \$2.1 billion.² Fifty-five percent of this comprised the "general imaging" market, in which physicians used ultrasound to create images of relatively static structures in the body, not including the heart. Cardiology customers comprised 35% of the market. Instruments sold to the cardiology market were used to detect structural and motion dysfunction of the heart walls and valves, to measure hemodynamics, and to detect leakage through closed valves (which should prevent reverse flow when behaving normally). Instruments were priced from about \$80,000 for lower-quality machines to high end instruments such as Acuson Corporation's

¹ In catheterization, physicians inserted a device into a large artery, typically in a patient's leg. The device was then pushed or threaded upward through the vessel into the heart, in order to obtain a clear view, or to perform a procedure such as stenting or angioplasty.

² Alex. Brown & Sons, "The Coming Revolution in Ultrasound." Research Report, March 5, 1997.

new Sequoia model provided image quality that was beginning to rival the clarity of magnetic resonance imaging (MRI) in some applications.

Approximately 4 million heart perfusion exams³ had been performed using invasive, non-ultrasound techniques in 1997, and experts anticipated that the total market for ultrasound equipment would grow modestly in 1998 and beyond. The intense pressures to control escalating health care costs proved to be a blessing in disguise for makers of high-quality ultrasound equipment, because ultrasound exams were typically less expensive than competing techniques such as MRI and cardiac catheterization. Hospitals and physicians had therefore become very interested in advanced versions of Doppler echocardiography instruments that would potentially replace more expensive methods of obtaining images of soft internal body tissues. In addition, the fact that many purchases of new machines had been deferred in the early 1990s at the onset of managed care efforts, meant that substantial pent-up demand for more modern equipment was likely to be unleashed in the future.

In addition to these economic drivers of growth in the ultrasound industry, several new applications were on the horizon which portended further potential growth of the market. As described previously, increasing use in surgical and intensive care settings suggested that these departments might increasingly purchase units that would be dedicated to their applications, if the units were more affordable. And as managed care organizations were working to push patient care out of expensive hospitals and into less expensive out-patient facilities, simpler, lower-cost ultrasound technologies that could be used in these settings seemed to be important. For example, some pediatricians were frustrated at the difficulty of assessing whether infants had congenital defects in the way their hips had formed. These needed to be detected early, so that corrective devices or surgery could be prescribed in a timely way. But x-ray diagnosis was expensive, inconvenient, and involved the use of ionizing radiation. Ultrasound could be used more safely, but it was not economical in a managed care environment to screen every infant through large, expensive hospital ultrasound labs, given the low probability that any particular infant might have the defect. Some posited that inexpensive, compact ultrasound machines that could be used in individual physicians' group offices might actually be a costeffective way to screen for a host of problems before sending patients toward the more expensive facilities, tests and procedures that ultimately would provide the necessary diagnostic precision.

One of the most exciting innovations that promised to enable substitution of echocariography for more expensive and accurate imaging techniques such as MRI and catheterization was a technique called *contrast echocardiography*. Ultrasound images are enhanced by the presence of gaseous microbubbles in the blood. In early 1998, several companies were developing and testing "contrast echo agents," which consisted of small bubbles of gas enclosed in a spherical shell approximately 4 microns in diameter, formed from biological materials such as albumin or polysaccharides. These could be injected into the blood, in order to reflect clearer images of blood flow. The appendix describes this technology in greater detail.

³ In a perfusion exam, physicians studied how blood flowed, or perfused, into the tissues of the heart in order to nourish the heart muscle. Their objective typically was to determine if blood vessels were becoming clogged in a way that would prevent blood from reaching an area of muscle—causing the muscle to degenerate or precipitating a heart attack.

The contrast agents were being developed by a number of pharmaceutical companies. In 1998, these agents were only effective if they could be injected directly into the blood in the heart through a catheter. If the agents were injected non-invasively through an IV in the arm, for example, the coating of the microbubbles tended to be destroyed as the blood passed through the lungs – before it reached the portion of the heart that needed to be imaged. One of these agents, Albunex, had recently received regulatory approval for use, but had not yet been approved for reimbursement by insurers. Their concern was that the additional image clarity created by this agent, which was partially destroyed when crossing the lungs, made little difference in the accuracy of diagnosis, or in patient outcomes. Preliminary results had shown that when Ecton's instrument was used with an agent that had been injected via catheter directly into the heart, Ecton's image clarity was very close to that provided by the established competitors' machines.

The market for ultrasound instruments was expected to grow significantly with the proliferation of contrast agents. These prospects for ultrasound-based technologies to gain market share from MRI and invasive perfusion, combined with the new applications for ultrasound described above, led the major cardiac ultrasound manufacturers (Hewlett-Packard, Acuson, Advanced Technology Laboratories, and others - see Exhibit 5) to mobilize for an intense battle for market share. It seemed clear that the leading manufacturers would wage this war by delivering sophisticated new echo modalities⁴ and drastically improved images to the customer – creating threats to Ecton's potential, as well as possibly creating opportunities.

Barriers to Entry in Echocardiography Product Markets

Cardiology departments tended to choose the companies from which they buy their echo instruments through criteria with complex historical antecedents. As Doppler echocariography began to proliferate in the early 1980s, several aggressive academic cardiologists became leading experts in the specialty. Institutions such as Massachusetts General Hospital, University of California at San Diego, the University of Alabama at Birmingham, and the Mayo Clinic developed active echo research divisions, where Fellows in Cardiology were trained and innovative diagnostic techniques were developed, often combining the principles of fluid dynamics, the physics of ultrasound, and the science of cardiology into sophisticated methodologies and diagnostic algorithms. In the pediatric cardiology setting, centers of excellence emerged at The Children's Hospital in Boston, the University of California at San Francisco, and the University of Michigan.

The directors of these centers would often embrace specific machines, and as their protégés completed their training and diffused into other centers, they would carry loyalty to the instruments on which they trained (primarily Hewlett Packard). Throughout the 1980s and 1990s, "short courses" on echocardiography - usually two day seminars held in conjunction with international conferences of the American Heart Association or American College of Cardiology - would be populated by speakers who could in many cases be traced to mentors at the core institutions above. The attendees at these courses would typically be

⁴ "Modalities" refers to additional features and functions, which enable physicians to view and learn more about the body tissues they are investigating.

individuals from lower powered, non-academic hospitals who were just getting into Doppler echocardiography. These individuals would typically have heavy clinical loads back home and were already intimidated by having to learn the basic physics of ultrasound and fluid dynamics necessary to optimize the use of ultrasound. Thus, they were highly unlikely to deviate from the instrument choices made by the luminaries -- instruments which they had used to generate the visually striking slides shown at the courses.

As a result of this internal reinforcement, by 1998 the cardiac ultrasound market consisted of a small group of major players (Hewlett-Packard, Acuson, Advanced Technology Laboratories, see **Exhibit 2**) and a few minor players, all of which had held reasonably constant shares for more than a decade despite ongoing upgrades, innovations and heated competition for market share. Hewlett-Packard had benefited to an exceptional extent from this system, having been a first mover in the field and the training device for a majority of Fellows in the U.S. in the 1980s and 1990s. All of the leading manufacturers cultivated this system, and devoted extensive resources to maintaining good relationships with the clinical centers which they serviced. Indeed, one would often hear an echo lab referred to as an "HP lab" or an "Acuson lab." Hence, although entrepreneurs such as Michael Cannon and his colleagues could reasonably expect to *design* a marketable instrument, the chance of breaking into the above system was slim in the absence of a truly groundbreaking development.

Adding to this difficulty was consolidation in the hospital industry and the related consolidation of suppliers. It was becoming common, for example, for blanket supply contracts covering vast product lines to be established between hospital groups and major manufacturers. This practice enticed many major suppliers to seek competitive advantage by acquiring broader lines of equipment, services or supplies. For a start-up company, in many cases it seemed that being acquired offered the only *entré* into the hospital market.

Competitive Activities

Due to the competitive but inertial nature of the ultrasound industry, most innovations in ultrasound were enhancements of existing, highly complex machines, in response to clinical demands to provide better quantitative information or to create images that hitherto had been available only from more expensive techniques such as MRI. Hewlett Packard had led the way in producing sophisticated edge detection algorithms, which allowed the user to automatically trace the internal border of the cardiac chambers and then to process the successive frames to obtain biomechanical characteristics of the heart. Acuson had developed a reputation for providing superior image quality. Its "Sequoia" model, introduced in 1996, produced images that some felt could realistically compete with the superior but cumbersome method of MRI. ATL and Acuson had also introduced Doppler innovations such as "color Doppler power" and "color Doppler energy," which allowed users to display the power of the returning Doppler signal in addition to the blood cell velocities. Several companies were working on a new method for imaging contrast agents called "Second Harmonic Imaging." This method removed confusing signals generated by the heart tissue, so that the perfusion of the contrast agents could be more clearly followed. And a number of these companies were working to produce three-dimensional echocardiography, which would be a major step toward displacing MRI.

Ecton, Inc.

Ecton, Inc. had been founded in early 1996 with the goal of developing "technologies which allow cardiac ultrasound to become a screening and monitoring tool, instead of merely an expensive diagnostic laboratory method."⁵ The centerpiece of Ecton's development efforts was a new Doppler echocardiography instrument that was compact and easy to use. **Exhibit 3** shows a schematic of the instrument and illustrates its portability. Its strategy was to price the instrument at about \$38,000, less than half the price of the lowend full scale machines then on the market. Cannon planned to introduce its machines in markets outside the traditional cardiology settings (i.e., echo labs). Because of its low cost and compact size, Cannon hoped that the instrument could generate new market opportunities in ICUs, surgery departments, emergency rooms, physician offices, and other places that would not typically approve the capital expenditure for a conventional echo machine.

The company was led by President Michael Cannon, who had been an executive for 11 years with the Interspec division of ATL, a manufacturer of ultrasound instruments. Cannon had been with Interspec from the start-up stage to its ultimate status as one of the world's leading ultrasound companies, and had participated in marketing, product development and business development. A team of talented engineers, each of them previously with Interspec, comprised the product development core of the new company. Christopher Knell was director of engineering, overseeing three principal engineers Kevin Randall, Joseph Urbano, and Andrew Wood. Biographical information about the five founding members is summarized in **Exhibit 4**.

Due to the compact size and the desired price point, Ecton's instrument might necessarily be of a lower technical quality in most modalities than conventional instruments. However, having assembled an extraordinarily talented team of engineers, a key and ongoing question in product design was: how close could and should the new instrument approach the capabilities of conventional instruments with respect to each modality (i.e., echo image quality, color Doppler images, velocity accuracy, contrast echo sensitivity)? Cannon and his colleagues believed that the instrument could approach the quality of existing instruments in selected modalities in a reasonable amount of time if development efforts were targeted toward those tasks. Other modalities of the instrument might presumably perform at a level below that demanded in a traditional echo lab, but at a level high enough to satisfy the users in the alternative markets.

Ecton's engineers had been particularly successful in producing excellent image quality, and based on this success, the engineers had been able to produce prototypes that seemed to challenge higher level machines in the area of contrast imaging. The Ecton machine was not expected to be as performance-competitive in the other four or five basic modalities on the instrument. It definitely offered fewer features and less versatility than the standard machines.

⁵ Quotation taken from Ecton, Inc.'s original business plan.

Protection of Intellectual Property.

It was not clear whether the fundamental structure of Ecton's instrument hardware would be patentable. As of the spring of 1998, Ecton had expended little effort to patent its technology, although an investigation had ensured that the company did not infringe upon existing patents. The company relied on trade secrets to protect software innovations. Only recently had the company begun to speculate that the overall design of the product might indeed be patentable in a fundamental and far-reaching way.

Financing

Ecton had raised \$400,000 from private investors in its first round of funding in August of 1996. These funds were augmented by an additional \$100,000 from the Ben Franklin Technology Center of Southeastern Pennsylvania, a state-funded organization designed to promote the development of new high technology businesses and jobs in the state. This start-up capital had been used to produce the first working prototype of the imaging system.

In July of 1997, Ecton raised an additional \$1.5 million in a second round of private financing -- much of which came from the same group of investors but at a more attractive price. These financings produced the ownership structure shown in **Exhibit 5**. At the time of its second round of financing, Cannon and the investors had anticipated that fully working Ecton prototype instruments would be ready by the following summer (1998). Cannon felt that the current financing could take Ecton to that stage, and he began to consider the trade-offs between obtaining third-round funding to finance a push forward with manufacturing, marketing and sales strategies, versus a strategy of finding a larger firm that might acquire Ecton. Such a potential suitor might provide the resources and expertise for marketing and production efforts, and allow the Ecton team to liquidate some of their equity in the company.

As of the spring of 1998, Ecton had received no funding from venture capital (VC) firms. Cannon had approached several VC firms after the initial \$0.5 million seed funding, but found little interest. No respected market research reports suggested that a significant market for such small, portable machines would be emerging. At the time Ecton was looking for funds, VCs regarded medical imaging as a capital equipment industry, which was not attractive. Businesses such as therapeutic disposables (i.e., cardiovascular catheters), information technology, and medical services were far more *en vogue* amongst VC investors at the time. Cannon was nonetheless quite satisfied with his financing results in the spring of 1998, since the firm's equity was still held closely by the founders and a small group of investors who shared the company's strategic objectives and expectations.

Boards of Directors and Clinical Advisors

Cannon established actively involved board of directors and advisers. Biographical information on the board of directors is provided in **Exhibit 6**. Cannon characterized them as active, making real contributions in the areas of strategy, intellectual property protection, financing and fundraising. The members of the Board had extensive experience in medical device and technology start-ups. Directors received 1500 stock options on an annual basis,

plus expenses, in exchange for their service. All outside members of the Board had invested in the company and brought in other investors.

Cannon also recruited a number of leading clinicians to serve on Ecton's Board of Clinical Advisors. They included Randolph Martin, M.D., who had played a key role in the proliferation of Doppler echocardiography since its earliest stages of development. John Ross was a Philadelphia-based echocardiographer on the faculty at Hahnemann University. Daniel Tritch, M.D., offered a viewpoint from the private practice and primary care physician angles, both critical potential alternative markets for the Ecton instrument. He was director of a large private practice in Ft. Wayne, Indiana, which provided primary and emergency care. Flordeliza Villanueva, M.D. of the University of Pittsburgh Medical Center was a specialist in the field of contrast echocardiography and provided advice on the implementation of the contrast algorithms of the instrument.

Phase III Plan - March 1998

Excitement was building at Ecton in the spring of 1998. The company had arranged for initial clinical imaging tests with seven medical centers in Philadelphia, Pittsburgh, Atlanta, New York, Charlottesville, VA, Rochester, MN, and Ft. Wayne, IN. From the company's inception, Cannon and his colleagues had struggled with a looming question: once the company achieved reasonable evidence that their product could perform acceptably, should they ramp up their marketing and production efforts, or should they seek exit strategies? Despite the thrill of being involved in delivering a new dimension of cardiac diagnosis to the market, Cannon had a responsibility to maximize the value of Ecton shares for his investors and, indeed, Ecton's founding team. Cannon did not believe that the core Ecton group added any particular value in terms of marketing, sales, and production, such that additional value would potentially be added by positioning Ecton for acquisition by a larger firm that could bring expertise and economies of scale to the marketing, sales, and distribution of Ecton instruments. From an end-user perspective, it also seemed that the integration of Ecton's promising system into one of the established companies would be the most efficient way of distributing the technology to the physicians who would put the machines in action.

In March of 1998, Cannon had prepared a "Phase III Plan" which outlined Ecton's proposed path for the coming year. It included a five point strategy:

- 1. The overall strategy is to position the company to be acquired.
- 2. Continue to build Ecton's value through concentration on technology and product development. Remain highly focused on completing the initial version of the product and starting work on new and advanced product developments.
- 3. Minimize outlays for marketing, sales, and production programs and concentrate selling efforts to a targeted list of influential "seed" accounts. Proceed with the belief that, at least through the Spring of 1999, extensive product sales will be less important to a potential acquirer than continued advances in technology.
- 4. View September 1998 through March 1999 as a transition period during which attractive acquirers would be actively pursued, at the same time that contingency preparations

were made for more extensive independent marketing and production, should this become necessary or advisable.

5. The next round of financing was anticipated to be approximately \$2.5 million. Established investors were expected to provide most or all of this new capital.

Point 3 was causing some concern. Like most start-ups, a quantitative valuation for Ecton was not easy to do. Cannon was likely to face difficult negotiations with a potential acquirer, and the fact that the company had not initiated marketing, sales, and production would limit Cannon's negotiating leverage. For the reasons outlined above, it was highly unlikely that Ecton's \$38,000 instrument could be sold to mainstream cardiology echo labs. Instead, it would likely be embraced by alternative markets that were in need of echo imaging but were unable to justify the capital expenditure for a traditional machine. In its offering memoranda, Ecton had included some estimates of the cumulative global market for its machine in the years 1999-2003 as approximately 20,000 units. These estimates did not include some potential but risky sources of revenue that could dramatically boost sales of Ecton instruments if they played out.

For example, developing nations were experiencing an increased incidence of heart disease. Cardiology clinics in these countries were buying large numbers of pre-owned echo machines that had been written off by centers in the more developed nations. By producing a basic quality instrument at a price point near that of the used machines, Ecton might find a significant market for its machines in these countries. Its portability would be an additional advantage considering the poverty and relatively poor transportation infrastructure in some of these countries that often led physicians to do their work in the field. Nonetheless, Cannon admitted, any sales projections were pure guesses. He was unsure how he could build the case that Ecton had the potential to crack open this huge market, unless in fact they had begun to crack it open before attempting to sell the company.

If Ecton did reach a stage where doing its own marketing was necessary, the characteristics of the customer were not clear in light of changes in hospital structure, despite the fact that alternative markets had been identified. For example, it was typical in many hospitals to call the echo machine from cardiology to the ICU if such an exam were required. Often, a cardiologist would go with the machine to the unit, or at least read the echo after the imaging had taken place. The billing process for such exams was currently very complex as fees would be allocated between the ICU division and the cardiology division -- for insurance reimbursement management purposes. Because cardiologists would also be required to attend in the ICU for post-operative cardiac patients, some hospitals' ICU departments were considering hiring a cardiologist, who would work solely within the ICU department. Thus, although it was quite clear that ICUs could be a significant market for Ecton machines, in 1998 it was not clear whether there was an in-place decision-making infrastructure that could decide how to buy and use an Ecton Instrument.

Cannon was also concerned about the impact that an acquisition might have on Ecton's product development process. The entire founding team had worked together at Interspec, a medium-sized (\$65 million annual sales) manufacturer of ultrasound equipment that had in 1994 been acquired by ATL, Inc., a large manufacturer (\$450 million annual sales). Coming from that environment, where development projects were constantly being interrupted to solve problems with products in the field or to rescue other projects that were in trouble, the founders had been exhilarated at how straightforward the development of

Ecton's first product had been. With such a clear focus and few distractions, the Ecton development team had met most of their project milestones on schedule, at significantly lower cost than they had planned, based upon their past experience. The Ecton founders worried that if their company were absorbed into a larger organization after acquisition, their development efforts for next-generation products would get mired in the same sort of complexity that they had experienced at ATL and Interspec. Perhaps, they reasoned, their efforts would be more successful in the long run if they remained independent until they had refined a development process (at this point Ecton had only developed a product once) that might survive acquisition and integration.

Michael Cannon wondered how the coming year would unfold. Would the established cardiology and emerging alternative markets absorb Ecton's innovation? Would a larger acquiring firm facilitate that penetration, or destroy the innovative culture that had brought Ecton to its current stage? The company had operated on a long term strategy that assumed being acquired and the financial structure reflected this. Minimal capital had been raised and a minimal corporate infrastructure had been built. If Ecton proceeded with marketing, sales, and production steps, what type of customers should it target?

Appendix: Additional Detail on Ultrasound Technology

Ultrasound refers to sound waves with a frequency above the audible range (in general, 20,000 Hz is cited as the maximum audible frequency for humans). It is used in numerous contemporary medical technologies, usually with the goal of noninvasively imaging solid structures or measuring the velocity of materials such as blood cells. *Echocardiography*, for example, is an ultrasound technique used by cardiologists to obtain cross-sectional images of the heart in what appears to be real time. Exhibit 7 (upper panel) shows frames from an echocardiogram. This "long-axis" view of the left side of the heart clearly delineates the left ventricle, the left atrium and the opened mitral valve which separates the two chambers. Such snapshots of the heart can be updated approximately thirty times per second and displayed in video format on conventional instruments. Since the adult resting heart rate is about 70 beats per minute (or, slightly faster than one beat per second), frames viewed at a frequency of 30/second are for most practical purposes in real time. Echocardiography has revolutionized the field of diagnostic cardiology over the past two decades. Prior to the advent of echocardiography, invasive techniques such as cardiac catheterization were used to assess most common heart lesions before undertaking surgical correction. (Cardiac catheterization, unfortunately, is a time consuming process, often semiquantitative at best, involves the use of ionization radiation in some cases, and can be a traumatic experience for the patient.)

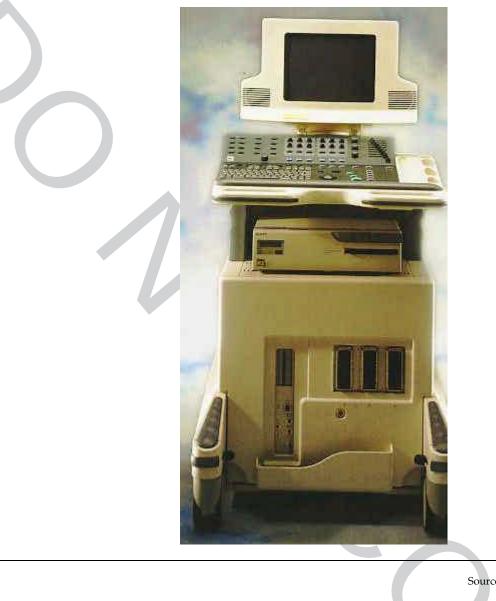
Doppler Echocardiography allows blood cell velocities to be obtained in addition to the images of solid structures. As shown in Exhibit 7 (lower panel), a cursor can be placed on the echocardiographic image to select a location of velocity measurement, and the velocities are then displayed on a strip chart-type section of the video screen (this is commonly referred to as "spectral Doppler"). Alternatively, using the technique of color Doppler echocardiography, velocities can be displayed throughout the cardiac chamber in a color coded fashion. Color Doppler was introduced to the cardiology market in the early 1980s and was available on most ultrasound instruments sold in 1998. "Doppler Echocardiography" usually refers to instruments that can provide echocardiographic imaging and Doppler measurements through the spectral and color flow techniques. Doppler echocardiography replaced a number of invasive exams by allowing the physician to assess hemodynamics (blood flow information) in a noninvasive fashion. For example, obstructed heart valves were traditionally characterized by a measurement of pressure drop across the valve. The pressures on both sides of the valve were measured directly by a catheter interfaced to a pressure transducer, after it had been passed through the patient's arteries and into the heart chambers. Using Doppler echocardiography, the cardiologist was able to measure the abnormally high velocity blood flows ejecting from the narrowed valve, and convert these velocities into the desired pressure gradient using engineering principles (in this case, the Bernoulli equation). This velocity information could be obtained noninvasively and quickly by simply placing the Doppler transducer on the patient's chest. The exam could be performed in virtually any setting to which the "echo machine" could be pushed on its wheels. (Although catheterization was playing a reduced role as a diagnostic tool, it was gaining activity in the treatment of disease, by replacing more invasive/traumatic methods such as open heart surgery in some cases. For example, obstructed heart valves that previously required surgical replacement with a prosthetic valve, could often be expanded by a balloon mounted on the end of a catheter in 1998.)

One of the most exciting innovations that promised to enable substitution of echocardiography for more expensive and accurate imaging techniques such as MRI and catheterization was a technique called *contrast echocardiography*. Ultrasound images are enhanced by the presence of gaseous microbubbles in the blood. In early 1998, several companies were developing and testing "contrast echo agents," which consisted of small bubbles of gas enclosed in a spherical shell approximately 4 microns in diameter, formed from biological materials such as albumin or polysaccharides. The bubbles reflected the ultrasound waves back to the transducer with much greater clarity than could be achieved simply by attempting to image normal blood. In using contrast echo techniques, a contrast agent was injected through a needle in the patient's arm, after which it passed through the veins into the right side of the heart, then to the lungs, and finally into the left side of the heart which is the primary pumping chamber and the location of most heart disease in adults. Contrast enhanced blood pumped from the left ventricle passes through the aorta to nourish the body's tissues, but a small portion of it is diverted into the coronary arteries to feed the heart tissue. Therefore, an echo image of the heart of a patient who has received an injection of contrast agent would show enhanced image intensity in the regions of heart tissue where the agent has perfused. If the coronary arteries become blocked, the heart tissue begins to die in the regions of non-perfusion and no enhancement will occur in these regions. By viewing an echocardiogram of a contrast-injected patient, the cardiologist could map with greater accuracy regions of the heart tissue which were enhanced by the presence of contrast agents, and those that were not -- thus identifying in a noninvasive manner regions of the heart tissue that were beginning to receive reduced blood flow at very early stages before a heart attack was likely to occur.

Contrast echocardiography had been shown to work well in experimental studies in which the agents were injected directly into the left ventricle using a catheter. Developers of contrast agents, however, were having some difficulty in designing agents which could survive passage across the lungs after injection in a less invasive site. Selected agents had shown promise in clinical trials and were awaiting FDA approval. In early 1998, it was overwhelmingly felt by cardiologists, scientists, and Wall Street analysts following the industry, that high quality agents would reach useful clinical applications within 1-2 years.

In the future, it was suggested by some that the agents might be of use as drug delivery agents, since it was well known that the agents can rupture in the presence of interrogation by ultrasound: i.e., by encapsulating a drug within the shell, then targeting the desired delivery point with ultrasound, as the agents pass they would rupture and release their contents to the target.

Exhibit 1 - A Typical Echocardiography Machine.



Source: Ecton, Inc.

Exhibit 2 - Major Cardiac Ultrasound Manufacturers, 1996

| <u>Company</u> | Market Share (%) | |
|-----------------|---|--|
| Hewlett Packard | 64% | |
| Acuson | 11% | |
| ATL | 9% | |
| Toshiba | 6% | |
| Biosound | 5% | |
| Vingmed | 4% | |
| Others | 1% | |
| Sour | rce: Casewriter estimates, synthesized from various sources | |





Exhibit 4 – Founders of Ecton, Inc.

Michael G. Cannon had been in the healthcare industry for over 16 years. For 11 years he was a marketing and general management executive with (ATL) Interspec, Inc. Cannon joined Interspec at its inception and was a central figure in building the company from a start-up to a part of the world's largest diagnostic ultrasound company. He directed the marketing, product development and business development for products in the cardiology, radiology, vascular and surgical markets and had extensive responsibilities in worldwide sales management. He holds a B.A. from Haverford College, with Honors, and a graduate diploma from the Wharton Management Program at the University of Pennsylvania.

Christopher B. Knell had 17 years of engineering and management experience in designing complex data acquisition and real-time signal processing systems. He has managed technologically complex projects involving signal and image processing, hardware design, software design and system integration. Knell managed product development for Interspec, Inc. for over 8 years. He is expert in the areas of ultrasound system architectures, digital scan conversion techniques, video graphics applications and digital image acquisition. He holds a B.S. in Electrical Engineering from Virginia Polytechnic Institute and State University and an M.S. in Systems Engineering from Drexel University.

Kevin S. Randall is an analog and RF design engineer with a series of technical and product accomplishments in the area of high resolution diagnostic ultrasound. He has been the lead designer of linear, convex, annular phased and linear phased array beamformers in his 10 years at (ATL) Interspec. His work has resulted in numerous innovations in the areas of low noise switching, high dynamic range and high data rate data acquisition circuitry and filter design. Randall holds a B.S. in Electrical Engineering from Lehigh University and an M.S. in Electrical Engineering from Drexel University.

Joseph A. Urbano spent nine years at (ATL) Interspec managing system level design and development through manufacturing with a concentration in blood flow detection with color flow mapping and spectral Doppler processing, as well as digital scan conversion. Urbano has extensive digital signal processing expertise and has worked extensively with fast memory interfaces, state machines, video circuits, digital filters, algorithm development and microprocessors. He has a B.S. in Electrical Engineering from Drexel University and an M.S. in Electrical Engineering from the University of Pennsylvania.

Andrew J. Wood developed ultrasound beamformers and color flow and Doppler processors at (ATL) Interspec for 8 years. He is an expert in developing medical imaging systems to meet worldwide regulatory standards, including European EMC regulations and ISO9000. He is a certified ISO9000 internal auditor. At GE Aerospace and RCA Advanced Technology Laboratories, Wood has a B.S. in Electrical Engineering from Rensselaer Polytechnic Institute and an M.S. in Electrical Engineering from Drexel University.

Source: Private Placement Memorandum

Exhibit 5 - Ownership Structure

| <u>Owner</u> | Percent After Second Financing Round (1997) | <u>Percent Expected After Third</u> <u>Financing (1998)</u> |
|---|--|--|
| Founders | 60 | 40 |
| Largest Individual Shareholder | 5 | 15 |
| Members of an "Angel" Investor Group | 10 | 10 |
| All Others | 25 | 35 |
| Total | 100 | 100 |
| | | Source – Ecton, Inc. |

Exhibit 6 - Board of Directors

Biographical sketches of Michael G. Cannon and Christopher B. Knell, internal directors, were included in Exhibit 6. Ecton's outside directors were:

Michael B. Keehan was of counsel with the law firm of Potter, Anderson & Corroon, Wilmington, Delaware. He was the former Vice President and General Counsel of Hercules, Inc. of Wilmington, Delaware. In addition to chemical engineering, Mr. Keehan's career involved a leadership role in patent and intellectual property as well as general corporate law. He was a member of the Executive Committee, Intellectual Property Section, and Corporate Practice Section of the Delaware Bar.

Lennart Hagegard was an active private investor and merchant banker in the Philadelphia area where he was President of Select Ventures and a leader in several private investment organizations. He held a number of senior management positions in operations and finance with ASEA Brown Boveri in Switzerland and his native Sweden.

George J. Magovern, MD was a leading cardiothoracic surgeon. In 1998 Dr. Magovern served as Executive Vice President for Health Services Delivery and Professor of Surgery at Allegheny University of the Health Sciences/Allegheny General Hospital. For nearly 30 years Dr. Magovern was director of the Department of Surgery at Allegheny General. He was a co-founder and director of Respironics, Inc., a Pittsburgh-based manufacturer of cardio-pulmonary healthcare products. Dr. Magovern had published widely and was an international pioneer in the development of new techniques in cardiothoracic surgery.

Bernard Steinberg, Ph.D., was an authority on advanced arrays and imaging technology, having led in development of high resolution microwave radar imaging and adaptive signal processing for defense applications. Most recently, Dr. Steinberg had conducted pioneering research in ultra-high resolution ultrasound imaging for the detection of breast disease. Steinberg was a Professor of Electrical Engineering at the Moore School of Engineering, University of Pennsylvania, and was Director of the University's Valley Forge Research Center. Steinberg was co-founder, Chairman, and Chief Scientist of Interspec, Inc.

Source - Private Placement Memorandum - July 1997

699-018

Exhibit 7: Images of a Heart's Function, Taken from an Echo Cardiography Machine

