The Future of Portable Ultrasound: Business Strategies for Survival

by

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Abstract

The growth of healthcare costs in the USA, coupled with the desire for access to care in the developing world, is driving the need for low cost, high quality imaging services. The miniaturization of signal processing electronics continues to reduce the size and cost of ultrasound devices. This convergence of demand and technology has led to the rise of portable ultrasound products, disrupting the entire industry. Market share for conventional cart-based systems is being eroded by compact mobile devices. This threatens the large, multi-modality imaging companies as more focused competitors, such as SonoSite, rise to dominate the portable market. New companies continue to arrive with innovative portable products, while domestic companies in emerging markets arise with low cost devices targeting local demand.

In the face of these changes, what should companies do to adapt their business strategies and compete? In short, the established companies need to disrupt themselves and develop a portfolio of portable products. GE seems to have already acknowledged this reality and embraced the disruptive trend. Products with modular architectures will help companies reduce product cost and increase cycle times, improving their competiveness in an increasingly crowded space. SonoSite will need to find a wealth of resources to maintain its advantage, ideally leveraging the strong brand name that it has established. Looking to the future of this disruptive cycle, companies need to embrace new business models for low cost products. Verathon's line of application specific products may be a glimpse into the future.

In addition, in response to this need for, and trend towards, low cost devices, some companies, such as GE, have created a new segment of pocket portable ultrasound devices: a "visual stethoscope" that could be in the hand of every doctor. Will this type of device succeed? The reality is that they will find mixed success. Disintegrated health systems, the predominant type in the USA, present a challenging environment for value capture and will only embrace these products once they become significantly cheaper and demonstrate success as a process improvement tool. Integrated health systems, more common globally, will slowly embrace them as a screening tool. Companies in this product category need to be in it for the long haul and focus on the compelling applications in the EMT/paramedic market segment to achieve short-term success.

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Table of Contents

List of Figures

1. Introduction and Motivation

In the USA, total expenditures on healthcare have reached >17% of GDP (1). The cost of imaging services account for a large portion of this growth, driven not least by increased use of expensive CT and MRI scanners. Physicians are motivated to always use the best technology, even when it may not be necessary, to prevent litigation (2). The mounting reality of this disproportionate healthcare burden is pressuring providers to reduce reimbursement payments for imaging services (3). The recent Healthcare Reform passed by Congress, expanding access to healthcare to millions of Americans (4), and the potential debt burden associated with it, further highlights the need to reduce the cost of providing care. These developments, in addition to the developing concerns over radiation exposure from X-ray and CT scans, are pushing imaging services to the less expensive modality of ultrasound (5).

Outside of the USA, a large number of governments have integrated public healthcare systems. While many of these governments are already ahead of the USA in using ultrasound to reduce expenditures on imaging services, they nevertheless continue to expand its use further. Emerging and developing countries are also finding it attractive to adopt ultrasound as the primary method of imaging; its benefits in improving maternal health are well known and expanding its availability to rural communities has the potential to help provide better care to the masses.

The ultrasound industry is itself undergoing upheaval. New entrants, from both developed and developing countries, have introduced compact, mobile products that meet the needs of increasingly price conscious customers. These portable ultrasound devices are disrupting the industry, taking a large portion of the market share from conventional cart-based products. The big three, GE, Siemens, and Philips, are under serious threat from competition as their total market share in North American dropped 21% between 2004 and 2008 (6) (7). The growth opportunities are changing for these companies as well. Current high revenue markets in developed countries, such as the USA, are seeing lower growth than untapped developing markets, such as China, India, and Brazil. **How should companies adapt their product portfolios, configurations, and business models to react to these changes and access the growth potential in portable ultrasound?** Withholding participation, or even failing to dominate these newer markets, will be a death sentence for established players in the long-term as domestic companies grow to meet the needs of these local markets.

As these companies struggle against the forces of disruption, some have touted a new breakthrough device that could redefine the way healthcare is provided, the "visual stethoscope": a common tool, like a stethoscope, that will allow a physician to see inside the body, allowing them to make immediate diagnoses. A pocket portable device tailored to the primary care market. The GE Vscan and the Siemens ACUSON P10, are two of the products that could revolutionize the physical exam and put ultrasound at the forefront of medical care. **Is there really a compelling need and attractive business opportunity for a pocket portable device or does the primary care market want something else?**

This paper will attempt to answer these questions.

2. Ultrasound Imaging

Modern ultrasound imaging is a relatively simple concept that is made reality by sophisticated technology. High frequency sounds waves, usually 1-20 MHz (8), are transmitted into the body, encountering tissue, organs, fluid, gas, and bone. As these waves travel along, they are both absorbed and reflected by the different materials and interfaces within the human body. Some of the reflections, or echoes, return back to the transmitter. The amplitude of the returning reflections is determined by the change in impedance between mediums. Figure 1 shows some common biological interfaces ranked from weak to strong.

Reflection Amplitude Loss

Interface	dB
Muscle-Blood	-30.00
Soft Tissue-Water	-26.00
Fat-Muscle	-20.00
Bone-Soft Tissue	-3.80
Tissue-Gas	-0.01
Perfect Reflector	0.00

Figure 1 Reflection amplitude loss for common biological interfaces[1]

As you can see from Figure 1, some materials, such as bone and gas, are strong reflectors. The amplitude of the reflections is also determined by the absorption of the wave's energy by the materials it passes through. Figure 2 shows the attenuation loss coefficients for several biological materials; the larger the coefficient, the greater the absorption of energy passing through it.

Attentuation Coefficient

Material	dB/cm/MHz
Water	0.002
Fat	0.660
Soft Tissue (avg)	0.900
Muscle (avg)	2.000
Gas	12.000
Bone	20.000
Lung	40.000

Figure 2 Attenuation coefficient for common biological materials[1]

Knowing how these different materials reflect and absorb ultrasonic waves, it is possible to create real-time 2D and 3D images of the interior of a human body. Figure 3 shows how a planar image can be acquired.

[1] Table created with information from the online textbook *Ultrasound Production and Interactions* authored by Perry Sprawls, PhD (99).

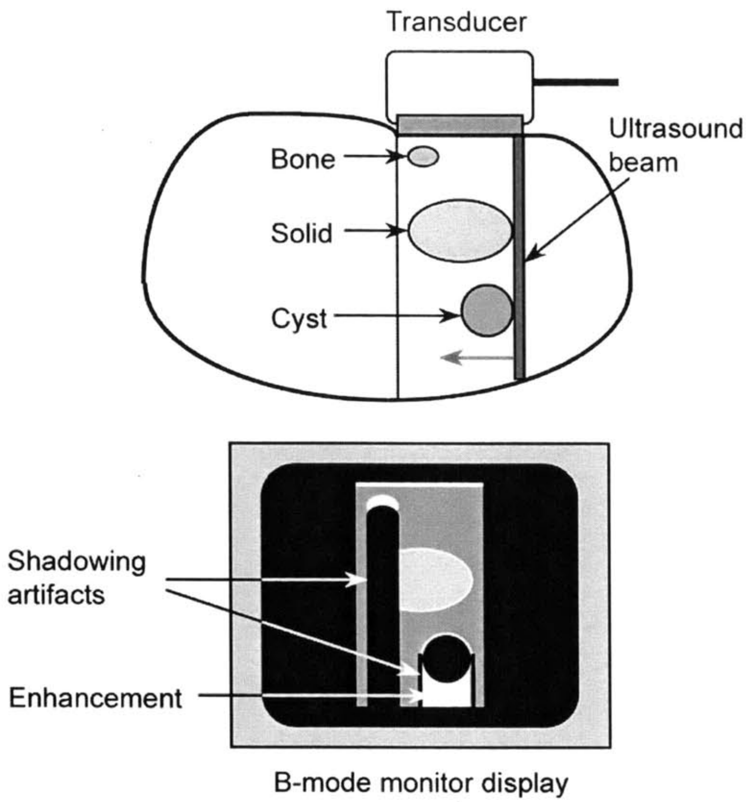

Figure 3 Illustration of the construction of a B-mode image (9)

The returning ultrasound waves can also be analyzed to identify motion within the body, calculating, for example, the velocity of blood moving through the circulatory system. All of this information can provide doctors with clues for diagnosis of disease or injury. The real-time imaging capability also allows this information to be used in operations and interventional procedures.

2.1.Safety

It is important to note that ultrasound imaging does not involve radiation and has proven to be safe to use on humans. No patient has ever suffered serious injury from a non-contrast enhancing ultrasound exam (10). This does not mean that ultrasound cannot harm tissue or cause injury. The energy from the ultrasonic pulses dissipates into the body as heat: the stronger the pulses and longer the exposure time, the greater the thermal bio-effect. In addition, the sound waves, being rapid oscillations of high and low pressure, can cause cavitations in fluid. As they pass through the body, the sudden drops in pressure can briefly turn fluid into gas. The resulting cavitations, though small, can potentially damage lung and intestinal tissue. The amount energy in the sound wave and the type of material it passes through determine the likelihood cavitations, also referred to as a non-thermal bio-effect.

In order to prevent injury, these two types of bio-effects are monitored and controlled through the thermal index (TI) and the mechanical index (MI). The TI is a relative measure used to indicate the likelihood of causing injury to tissue due to ultrasonic heating. Similar to the TI, the MI is used to measure the increased likelihood of injury due to cavitations.

Both the TI and MI are related to the amount of energy input into the transducer. Injury due to these bio-effects is prevented by using the ALARA principle. Operators are encouraged to use gain settings and exposure times that are **A**s **L**ow **A**s **R**easonably **A**chievable. The TI and MI are monitored continuously and regulations require device manufactures to display the TI and MI to the user at all times unless the product cannot produce a TI or MI >1 (10).

3. Medical Diagnostic Ultrasound

Since the initial development of medical diagnostic ultrasound in the 1940s, its use has continued to expand and find new applications (11). As a safe, non-invasive technology for imaging soft tissue, ultrasound found early diagnostic success in cardiology and obstetrics and is a standard imaging modality for the abdomen. With improvements in image quality and the advent of 3D/4D imaging, ultrasound is beginning to assist in diagnoses usually reserved for CT or MR scans, such as musculoskeletal (MSK) applications. These steady technological improvements have made soft tissue images taken by ultrasound in 2004, better than the best CT images of 1985 (2).

While ultrasound is a mature technology, it does have limitations in medical diagnostics. The inability to image through bone or gas requires an excellent knowledge of human anatomy to acquire good images. Anatomical and body type variations create additional challenges. The increased sectional thickness of obese patients can require a lower frequency probe (lower frequency = lower spatial resolution) and good technique to see far enough into the body (12) (13). Getting the best performance from an ultrasound device can also require more art than skill. It can take over 150 scans before a user can become proficient at acquiring quality images (2).

As Figure 4 shows, there are several tasks that must be performed to enable a good diagnosis from an ultrasound exam. We will discuss the roles of the individuals in the ecosystem.

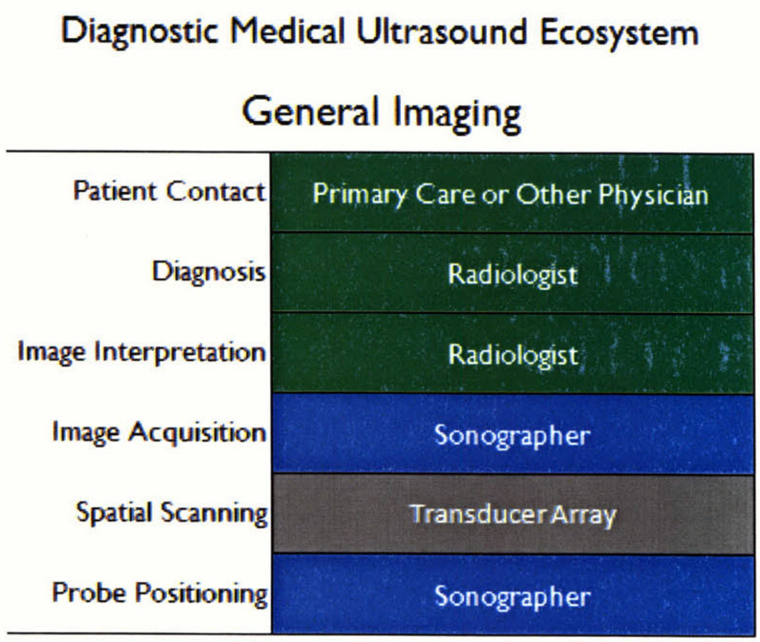

Figure 4 The ecosystem for general imaging

3.1.Sonographers (Technologists)

Sonographers, also referred to as technologists, are medically trained professionals that operate ultrasound devices and are responsible for acquiring images for many types of diagnoses. The role of Sonographers developed as radiologists offloaded the often time consuming tasks of probe positioning and image acquisition (14). This has made confidence and trust between the radiologist and Sonographer an important factor (12). Though decreasing, ~50% of all ultrasound exams worldwide are performed by a radiologist or Sonographer. This gives them significant influence over the purchasing decisions for new ultrasound devices in hospitals (11) (12).

Unlike other imaging modalities, the quality of image acquisition is very operator dependent and can require significant skill and training. Education and accreditation for Sonographers in the USA is divided into three categories: general, cardiac, and vascular. The general category allows for specialization in the abdomen, breast, fetal health, neurology, or OB/GYN (15). The American Registry for Diagnostic Medical Sonography (ARDMS) is one of the accrediting organizations for Sonographers in the USA. Sonographers are required to have a minimum of 12 months of exam experience before being certified, this is on top of basic educational requirements (12). The certification requirements to perform an ultrasound exam vary from hospital to hospital. There is also **no national regulation in the USA** mandating that ultrasound equipment is used by a trained operator. This has led other medical professionals (nurses and non-radiology physicians) to begin acquiring their own ultrasound images (16). This is particularly the case in Emergency Medicine. As ultrasound technology migrates to other specialties, both the radiologist and the Sonographer are being removed from the system. This raises a lot questions and concern regarding the quality of the image acquisition and the subsequent interpretation.

3.2. Radiology

Though ultrasound was not a technology readily embraced by radiologists, they are still a significant player and are responsible for 25% of all ultrasound purchases by unit and 40% by revenue (2). Becoming a radiology specialist in the USA requires five years of postgraduate training. They receive 2-4 months of ultrasound specific instruction during this period. The radiology board exam has 11 sections, one of which is just for ultrasound. It should be assumed that a board certified radiologists is trained in the acquisition and interpretation of ultrasound images (14). Whether or not a radiologist performs the image acquisition appears to be a matter of personal preference or availability, though it can be assumed that most images are acquired by a Sonographer.

As the demand for performing ultrasound diagnoses has spread to other specialties, radiologists are primarily left with abdominal imaging. However, they do interpret ~60% of the obstetric exams in the USA (14).

3.2.1. Global Differences

In the USA, radiologists generally provide the interpretation of ultrasound images and Sonographers provide the acquisition of the images. However, in other countries, such as Austria and Germany, internal medicine doctors provide the acquisition and interpretation of the images (2) (11).

Although most interventional radiologists in the USA prefer CT for interventional procedures, ultrasound is, however, more common in Europe for these applications (14) (16).

3.3.Cardiology

Cardiology was one of the medical specialties that helped pioneer the use of diagnostic ultrasound and therefore has its own terminology. The use of ultrasound to assess the health of the heart is referred to as echocardiography. Market projections forecast purchases by cardiology to overtake radiology in terms of revenue in the next few years (7). Cardiology is also one of the more demanding users of diagnostic ultrasound. Various Doppler modes, Color Doppler in particular, as used to measure blood flow inside the heart. While it is a demanding market, even rudimentary ultrasound can provide useful information. A-mode and M-mode imaging, some of the first uses of diagnostic ultrasound, can be used to monitor interior blood flow. Unlike radiologists, cardiologists perform their own image acquisition in addition to image interpretation (Figure 5). This makes cardiologist excellent candidates for the adoption of portable ultrasound devices.

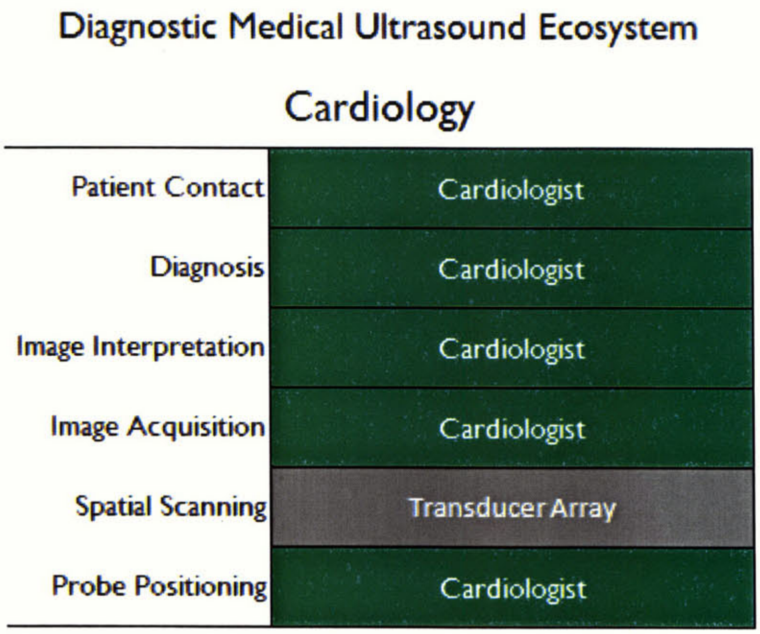

Figure 5 The ecosystem for cardiology

3.4.Obstetrics/Gynecology

Ultrasound is the primary imaging modality used to monitor fetal development and manage pregnancies (2). The fact that it is non-invasive, and does not use ionizing radiation, makes it the only cost effective imaging technology for this application. Obstetricians were also early pioneers in diagnostic ultrasound, but unlike cardiology, radiologists still interpret the majority of the obstetric images in the USA (14).

At a minimum, access to ultrasound allows a physician to identify the position of the baby before birth (breach or cephalic) (16). This can have a significant impact on maternal health and the success of the birthing process, especially in rural communities (17). It can also identify the presence, location, and number of viable fetuses (twins), although the identification of an early ectopic pregnancy can be challenging. The most demanding use of ultrasound is during examinations for high-risk pregnancies, very high resolution and Doppler capability is required.

3.5. Other Specialties

The acquisition and interpretation of ultrasound images is generally not taught in standard medical education and it is unlikely that a physician outside of the specialties list above have had any training in it during their career (16). However, this has not stopped the devices from spreading to new medical and surgical specialties. The lack of independent or government regulation controlling the use of ultrasound devices is likely to continue the migration of diagnostic ultrasound to other specialties.

3.5.1. Emergency Medicine

Outside of the traditional specialties listed above, emergency medicine (EM) is the biggest user of diagnostic ultrasound. In 2004, 20% of Emergency Rooms in the USA had an ultrasound device and physicians trained in their use (2). The need for immediate access to imaging services drove EM physicians to adopt ultrasound directly. Their use case is also probably one of the least technically demanding. Ultrasound is mostly used as a screening tool to look for internal bleeding (Figure 6), collapsed lungs, or foreign body detection. The Focused Assessment with Sonography for Trauma (FAST) exam is used on virtually all patients with blunt trauma. While EM's use of ultrasound is not technically demanding, they do need quick access to the devices. This has made EM the fastest growing market for portable ultrasound products. However, like cardiology, EM physicians acquire and interpret the majority of their own images. In some cases, nurses are even performing the image acquisition.

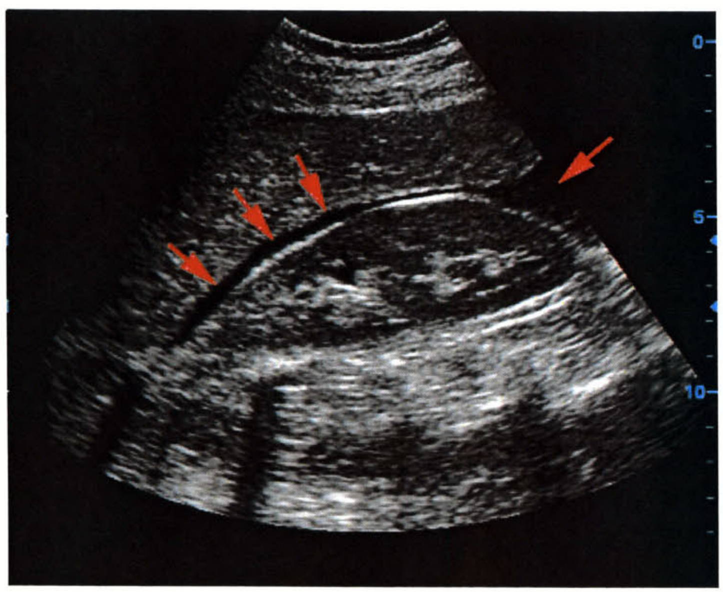

Figure 6 Identification of possible bleeding in the abdomen during a FAST exam (18)

3.5.2. Urology

The bladder and prostate, the domain of the urologist, are readily image by ultrasound. Though most imaging needs are referred to radiology, some simple tasks are migrating to the urologist. The measurement of bladder volume using ultrasound can provide an important metric in diagnosing voiding dysfunction. Many ultrasound devices have software that assists in the measurement of bladder dimensions, while some unique application specific ultrasound devices have emerged to meet this market (ex. Verathon BladderScan).

3.5.3. Ophthalmology

Ultrasound is used in ophthalmology to measure the interior dimensions of the eye. High accuracy measurement accuracy is need, leading to the use of specialty transducer probes for A-mode scanning.

3.6.Non-Diagnostic Uses

3.6.1. Interventional Radiology (IR)

A sub-specialty of radiology, IR involves the use of imaging technologies to perform minimally invasive procedures. Ultrasound is one of the imaging modalities used to perform procedures.

3.6.2. Anesthesiology

Ultrasound is being adopted in anesthesiology to assist with the administration of regional anesthesia. It can be used to guide the insertion of a needle to the appropriate anatomy. Though this use case is not technically demanding, the anesthesiologist needs to be able to move between operating rooms.

3.6.3. Rheumatology & Orthopedics

Musculoskeletal (MSK) uses for ultrasound are developing through rheumatology and orthopedic surgery. Rheumatologists are using ultrasound to guide needles for local drug delivery. Orthopedic surgeons are using ultrasound to both guide procedures and diagnose injury.

3.6.4. Surgery

Surgeons are beginning to see reasons to adopt ultrasound even when no financial incentives are provided, using it to peek inside the body and increase operational efficiency (2). Interventional radiology has also blazed the trail with its use for minimally invasive procedures. This is creating a battle between IR and surgery. Surgeons are also able to charge more for the same procedures due to the reimbursement structure in the USA (14).

3.6.5. Vascular Surgery

Another area in competition with radiology, vascular surgery uses ultrasound to map the venous system prior to surgery (16).

3.7.Primary Care

Ultrasound is not a tool currently used by primary care physicians. They often refer patients to imaging services, but do not perform the exams themselves. However, there is a push by ultrasound companies, such as GE, to provide ultrasound imaging tools to primary care physicians, giving them the ability to integrate the devices into their physical exams. In the USA, the CMS (described below) now allows first-time Medicare patients to receive a screening exam for an abdominal aortic aneurysm (AAA) (19). This is one potential opportunity for the use of ultrasound at the point-of-care (POC) by a primary care physician.

4. The Ultrasound Market

The global market for diagnostic medical ultrasound was estimated to be worth $4.4 billion in 2007 and growing at 3-5% per year of which ~$1.2 billion was from revenue in the North American market alone (7) (20). Meanwhile, the growth of other imaging modalities is projected to remain flat. There is also a significant push to reduce the radiation exposure from CT scans (5). Additionally, the drive to reduce expenditures on medical imaging services has allowed ultrasound to be a disruptive technology to other imaging modalities.

The segmentation within the ultrasound market is also seeing varying levels of growth. Figure 7 from Frost & Sullivan shows the growth potential of known market segments.

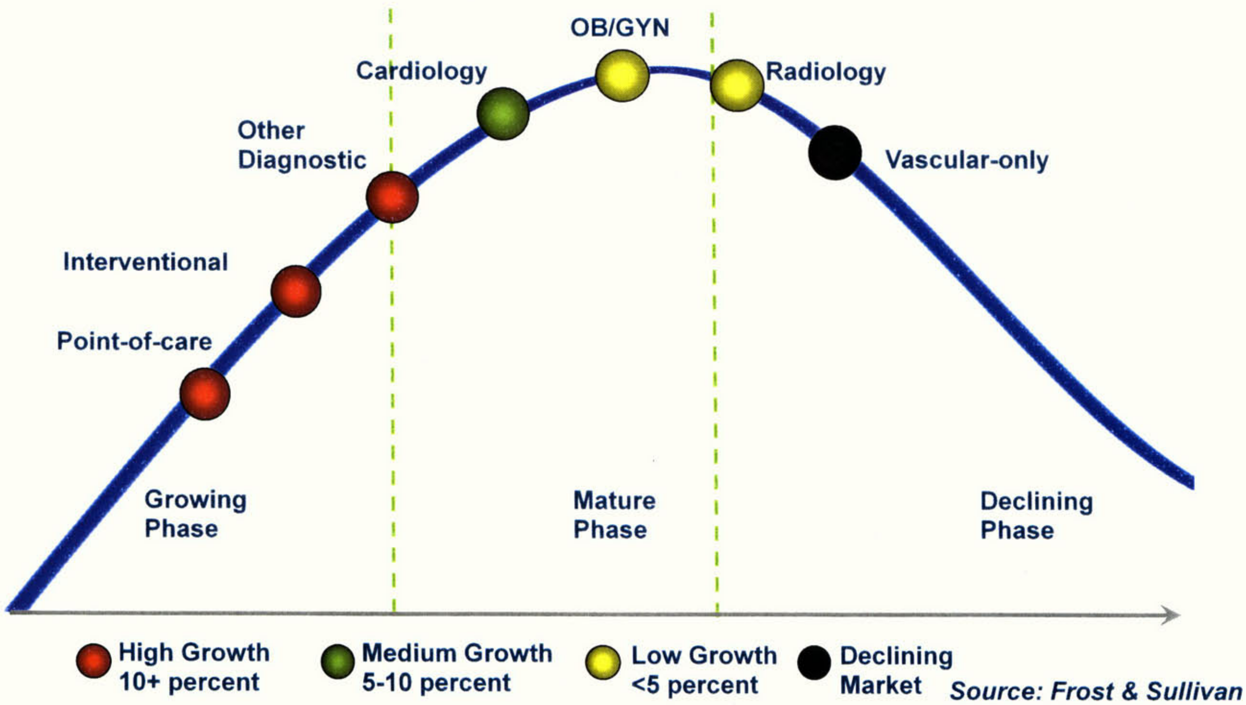

Figure 7 Growth potential for ultrasound market segments (7)

As shown in the figure, the POC markets have the highest growth potential. These market segments are perfectly suited for portable ultrasound.

While the overall global market for ultrasound is projected to grow in the coming years, higher growth rates are expected in developing markets. SonoSite currently generates 60% of its revenue from outside the USA (21). Rapid growth is expected in the large populous countries, such as China and India, along with the resource rich countries, such as Brazil and Russia (22). The global market for portable ultrasound, specifically, has grown from $4 million in 2002 to $278 million in 2008 and is growing at 20-25% per year (20) (22). Estimates for the portable ultrasound market currently project annual revenues of <$400 million for the near-term (23).

As portable ultrasound devices have entered the market, they have been a classic market disruption. Initially, they found success taking the easy diagnostic jobs (FAST exams, etc.) from cart-based systems. Gradually they have continued to perform more demanding jobs. The technology has progressed to the point where there is little difference between the high-end portable devices and the low-end cart-based systems when performing typical exams. For the most part, the portable and cart-based devices are competing for the same jobs in the same business model (reimbursed fee-for-service). The lower cost of the portable devices makes them more attractive at every turn. This is presenting existing ultrasound companies with a dilemma.

Portable ultrasound is "a great opportunity and a great threat", as Dennis Meister from GE Healthcare stated it (24). The technology used in portable devices (hand-carried units, HCUs, and pocket portables) is mostly a direct translation from the miniaturized circuits used in the high-end 3D/4D capable cart-based systems. The high growth rate of the portable market is a "great opportunity" for these companies to seize and one they should be able to do with little or no longer technological innovation. The "great threat" lies in the fact that growth in portables leads to erosion of the cart-based business. Customers, particularly those in developed markets, are buying portable products instead of cart-based systems. Why would a company want to sell less expensive products and erode revenue? In this case, they don't have an option.

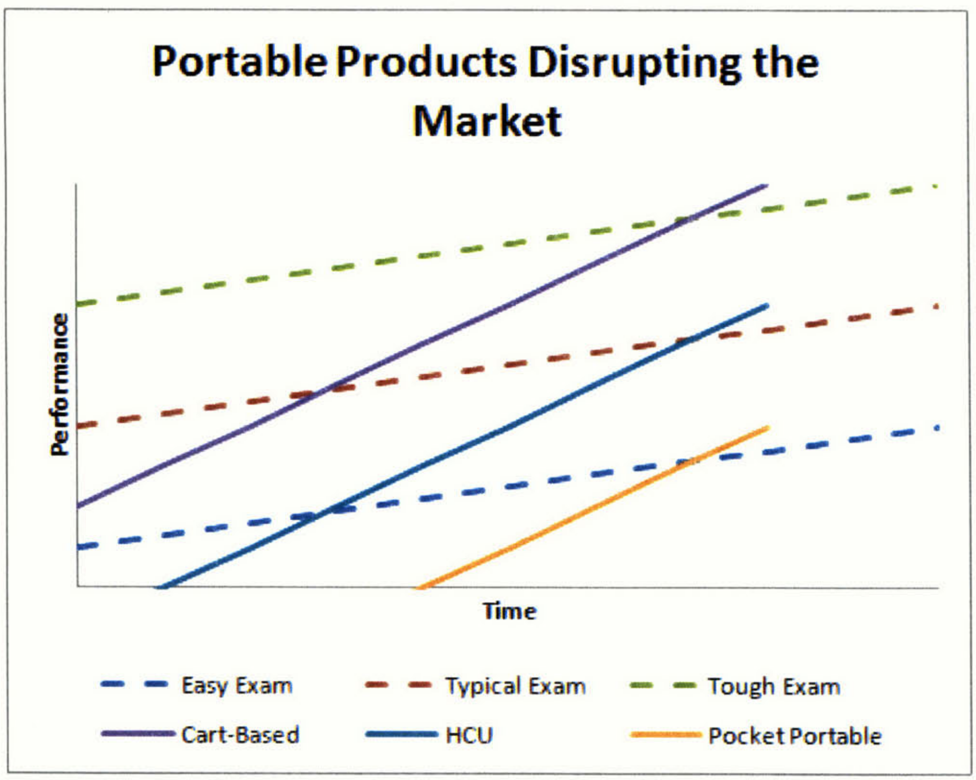

Figure 8 The disruption of ultrasound markets by portable products

The following are examples of different levels of exam difficulty:

Easy Exams

- Finding internal bleeding in the abdomen
- Finding a blood clot
- FAST exam
- Bladder exam

Typical Exams

- Finding an ectopic pregnancy
- Identifying gall stones in the gall bladder

Tough Exams

- Evaluation of a liver transplant using Doppler
- High risk fetal examination

4.1. Payment for Medical Services

In the USA, most medical services are paid for in a fee-for-service (FFS) arrangement. A sick or injured patient seeks medical care and the care provider is paid for the services provided. For patients with medical insurance, most, or all, of the service is paid for by the insurer. In most cases, the patient does not even know how much was paid. Insurers have set prices that they are willing to pay. The types of services insurers are willing to pay for and how much they pay is largely based on the fees and services paid by the Centers for Medicare and Medicaid Services (CMS). Since Medicare is the largest insurer in the USA, they have the ability to set rates and influence the medical service market, effectively an upper bound price control. If a service is not paid for by the CMS, it is likely that no insurer in the USA will reimburse for the service.

A common database has been created to track the available CMS services. The American Medical Association (AMA) maintains this database and provides a Current Procedural Terminology (CPT) code for "current" procedures. Creating a CPT code does not guarantee that the service will be paid for by CMS, but it is the first step.

There are a variety of CPT codes available for ultrasound exams. However, the specific requirements in the code can often prevent less feature rich ultrasound products from performing the exams. As an example, most codes for ultrasound exams require that an image from the exam be documented in the patient's record. If the device cannot generate an image that can be stored (print a picture) or transmit the image elsewhere to be printed, it cannot be used for the procedure. This is true even if the device is capable in all other facets. In the development of the portable ultrasound market, SonoSite has had to fight many battles to prove the value of their products, establishing CPT codes that can be used for some POC services (2). As Clayton Christensen recommends in his book *The Innovator's Prescription*, ultrasound companies may have better luck developing business for their devices in markets that are not regulated or reimbursed in this way (25).

4.1.1. Global Differences

While the reimbursement structure in the USA has been an impediment to the development of portable ultrasound, the devices have been met with less resistance globally. The National Health Service (NHS) in the UK has, for the most part, approved their use where appropriate. The Purchasing and Supply Agency (PASA) of the NHS has written reports recommending how they should be used (26) (27). However, PASA does not make purchasing decisions for the local primary care trusts (PCTs) are responsible for making their own purchasing decisions.

4.2.Price

There is a wide disparity in global prices paid for ultrasound devices. In 2008, the average price was "$100,000 in the United States, $80,000 in Western Europe, and $60,000 in industrialized Asia" according to Clay Christensen's case study (2). The top price in the USA is as high as $350,000 for a high-end cart-based system (22). In 2009, the prices for portable ultrasound ranged from $15,000 to $100,000 (22). With such a wide disparity in average price, one wonders if they are all using ultrasound to do the same job, or if there are different levels of performance acceptability across these markets. Figure 9 helps illustrate this possibility.

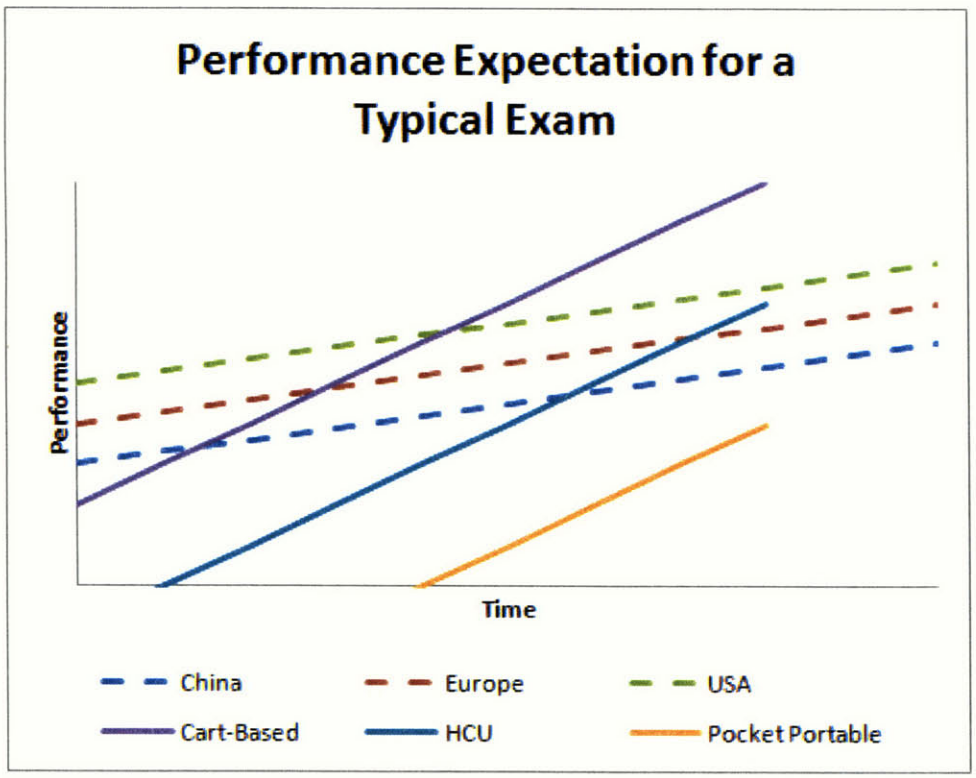

Figure 9 Global variation in performance expectations for ultrasound exams

Considering this variation further, highlights an interesting phenomenon that exists in medical markets. In a normal market, customers are equally willing to purchase products or services which deliver more "performance" for a quanta of cost increase as they are to purchase products or service which deliver less "performance" for a quanta of cost decrease. However, in the case of medical products and services, customers behave differently. They expect a greater quanta of cost change per increment of performance decrease than they expect for a performance increase. Restated, once a medical customer has been given a better product or service, they are unlikely to return to a lesser one. Figure 10 illustrates this behavior and the associated kink, known as Bernie's kink (28).

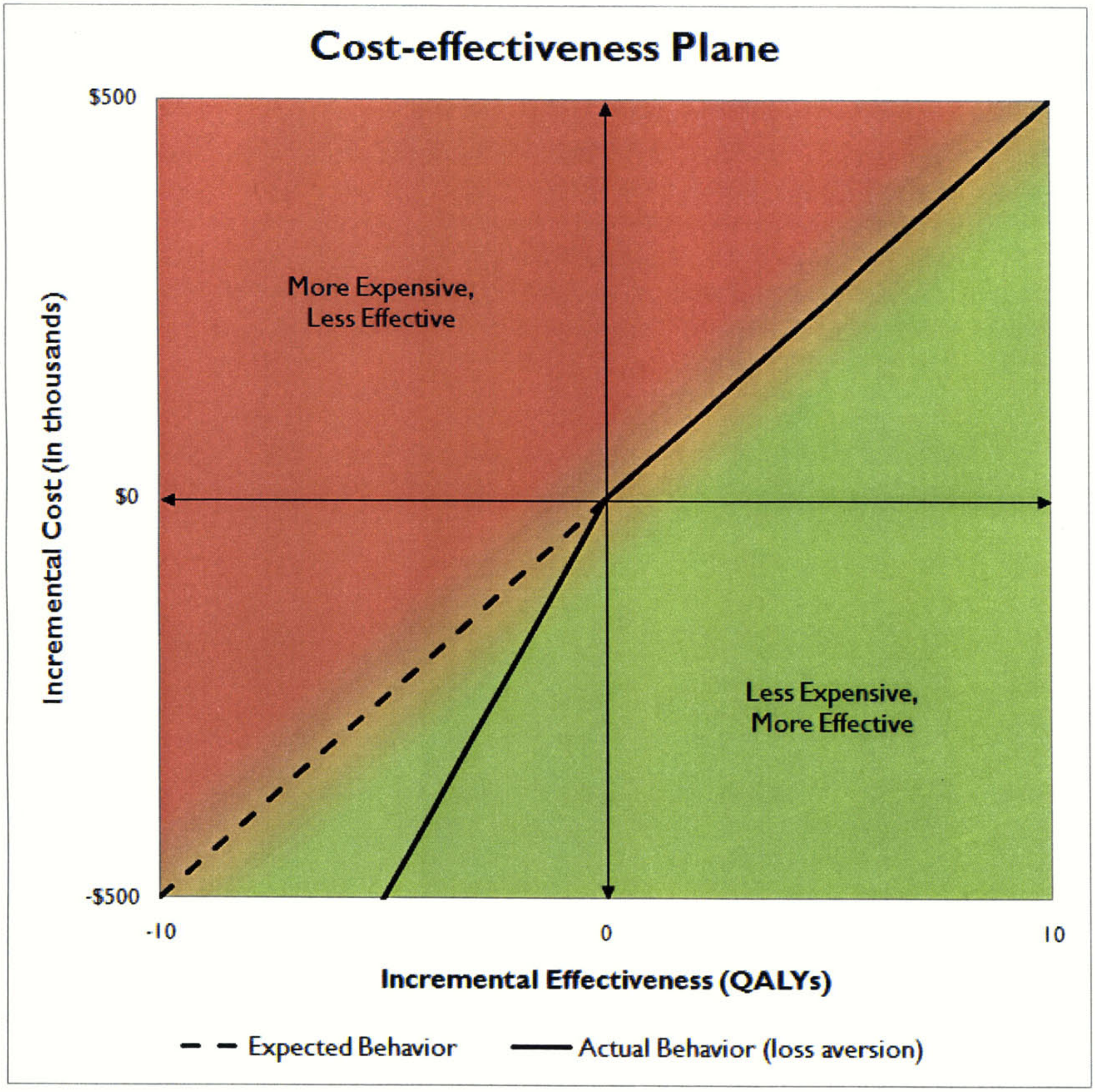

Figure 10 Cost-effectiveness Plane[2] (28) (29)

This may explain the wide disparity in average price amongst various global markets. Emerging or developing markets may be willing to accept less service for less cost than developed ones.

[2] Incremental cost is set arbitrarily to illustrate the effect.

5. Ultrasound Technology

5.1.Conventional System Architecture

To create an image using ultrasound, a Sonographer positions an array of piezoelectric elements, usually just called a transducer or transducer probe, in contact with a patient's body via a gel coupling. The Sonographer selects the appropriate imaging setting for the exam using the ultrasound machine's user interface. The beam forming controls in the device command high voltage electrical signals to be sent to the transducer elements, causing them to physically vibrate. These vibrations, occurring at ultrasonic frequencies, travel through the body reflecting off different anatomical structures. The returning echoes move the piezoelectric elements in the transducer array and create electrical signals which are sent back to the ultrasound machine and amplified for further analysis.

The transmitted and received signals are then compared to determine the change in the amplitude, time-of-flight, phase shift, and change in frequency. From these four factors, an image on the patient's interior can be constructed and displayed to the Sonographer as a 2D grayscale image. The brightness of the image corresponding to the amplitude of the returning pulses and the longitudinal position, or how deep in the body the encounter occurred, set by the time-of-flight. The phase and/or frequency shift, using the Doppler effect, can be shown in color to indicate whether the material was still or moving and if so, how much. Viewing the image, the Sonographer can then reposition the transducer probe as new images appear in real-time. Once the proper anatomy is in view, the Sonographer can record the image and store it for later use or export via a printer or other recordable media.

A conventional cart-based ultrasound system consists of one or more transducer probes attached to a cart containing the signal and image processing circuitry. Specific transducer probes are available for different applications and anatomy (abdominal, pediatric, transrectal, etc.) making them a modular component in most ultrasound systems. The signal and image processing circuitry are usually integral to the cart hardware. The different processing components (transmit/receive, TGC, beam forming, etc.) are often contained on separate circuit cards. The transmit/receive circuitry is responsible for providing the high voltage analog pulses to the transducer array and receiving the returning pulses. The time gain compensation circuit amplifies the returning signal and converts it to digital. The TX/RX beam forming circuitry provides the necessary pulse delays to the transducer elements. The image processor constructs an image from the comparison of the transmitted and received signals.

The cart also supports the user interface, display, data storage, and any other peripheral devices (printers, CD/DVD writers, etc.) and allows for the ultrasound system to be moved from one location to another. Figure 11 shows the basic structure of a simple cart-based ultrasound system.

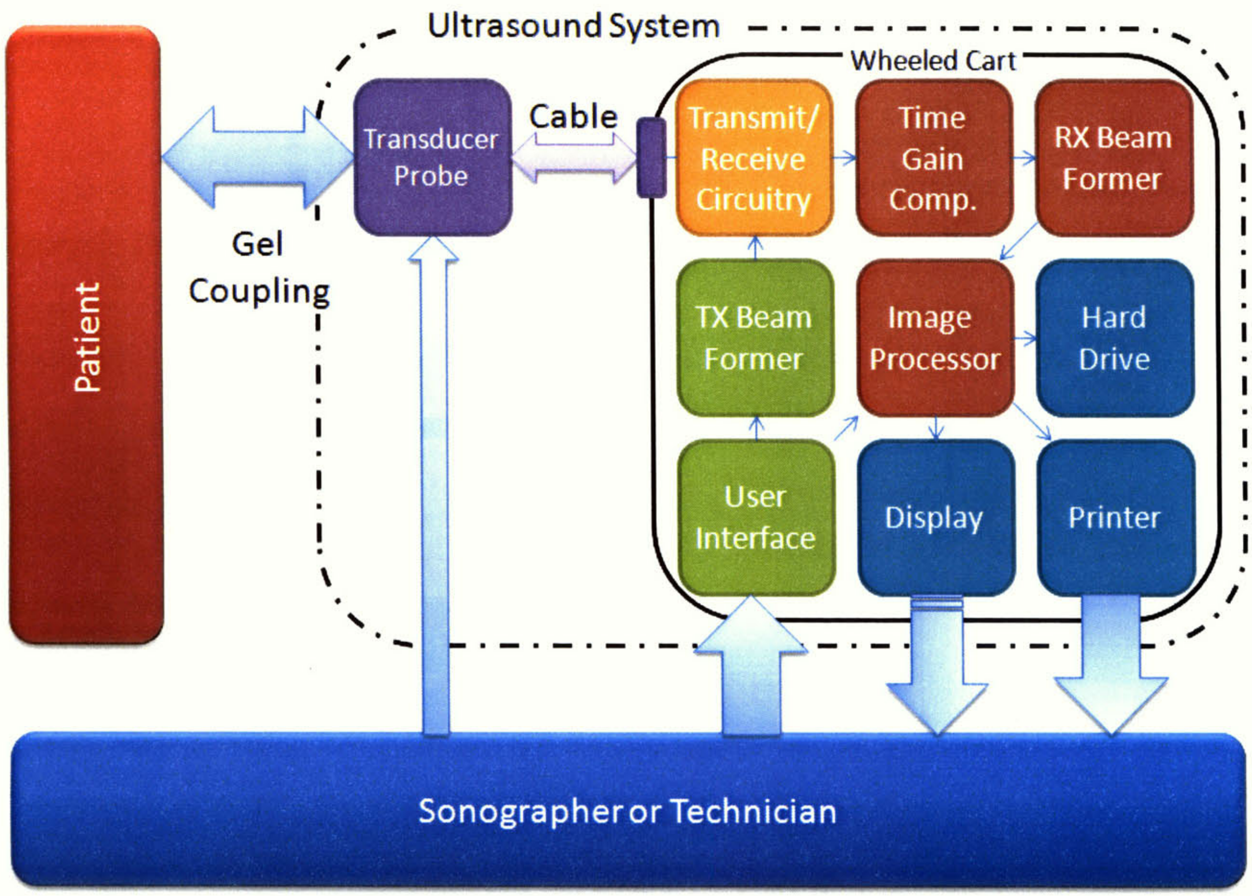

Figure 11 Simple diagram of a conventional ultrasound system

5.1.1. Transducer Probe

A transducer probe consists of an array of piezoelectric elements (1D curved/straight/phased or 2D phased) and their corresponding backing material and electrical connections (Figure 12). The probe is typically attached to an ultrasound system via a long flexible cable bundle that can be detached from the cart. Each transducer element typically has its own coaxial cable with between 48 to 256 elements in a transducer array (30). The high cost of manufacturing the tightly spaced piezoelectric elements and the need for a flexible cable, make the transducer probe the most expensive component in an ultrasound system.

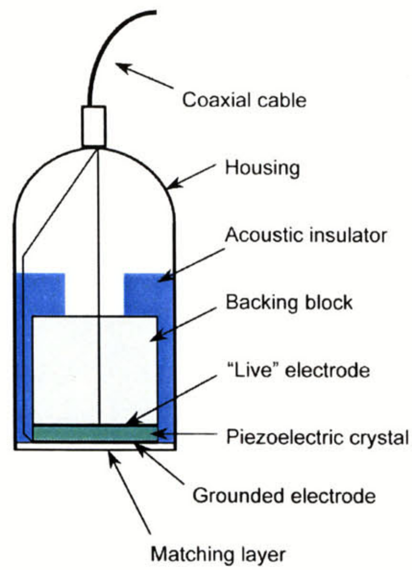

Figure 12 The interior of a single element ultrasound probe (31)

A single element transducer can provide an image of a line through the body and is known as an A-scan (Figure 13). Monitoring a line through the body over time can allow one to track the motion of particular anatomy, such as a heart valve. This is called M-mode, for motion (Figure 13). The single transducer can also be physically swept in place creating a 2D image of a section of the body. This is known as a compound B-scan (see Signostics). A-mode imaging is not very common as it tends to only be used in ophthalmology. M-mode is usually displayed in conjunction with B-mode.

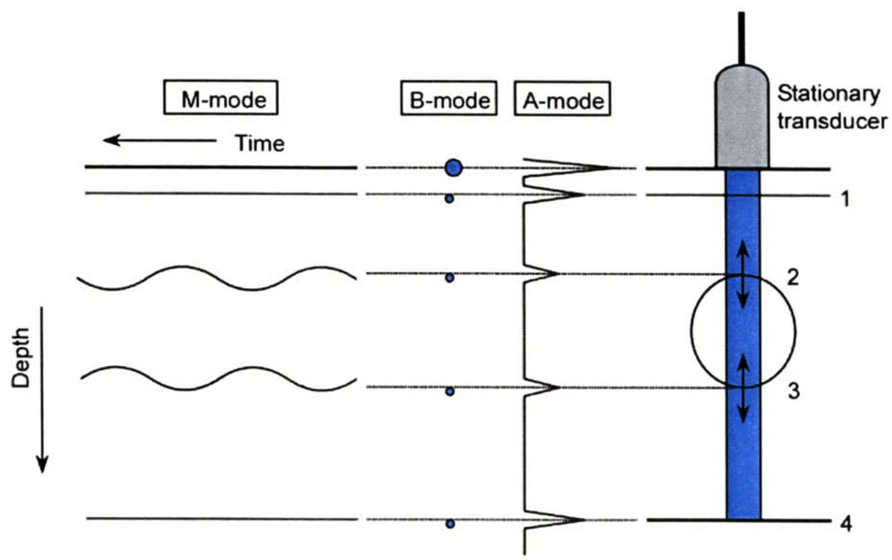

Figure 13 Illustration of M-mode, B-mode, and A-mode (32)

The more common type of transducer probe is a one dimensional, linear array of transducer elements that can scan a plane, or slice, through the body creating a 2D image known as B-mode, or brightness mode (Figure 14). The amplitude of the returning echoes is represented by the brightness of the image.

The visible area of the scanned section is determined by the shape of the transducer. A curved linear array will produce a wedge shaped image of the body section. A straight linear array (Figure 17) will produce a rectangular image of the body section. Using a curved 1D array, versus a straight 1D array, allows for a larger area to be imaged with a smaller transducer. This is at the expense of lower resolution in the deepest parts of the image (far-field), a trade-off that is acceptable in most cases.

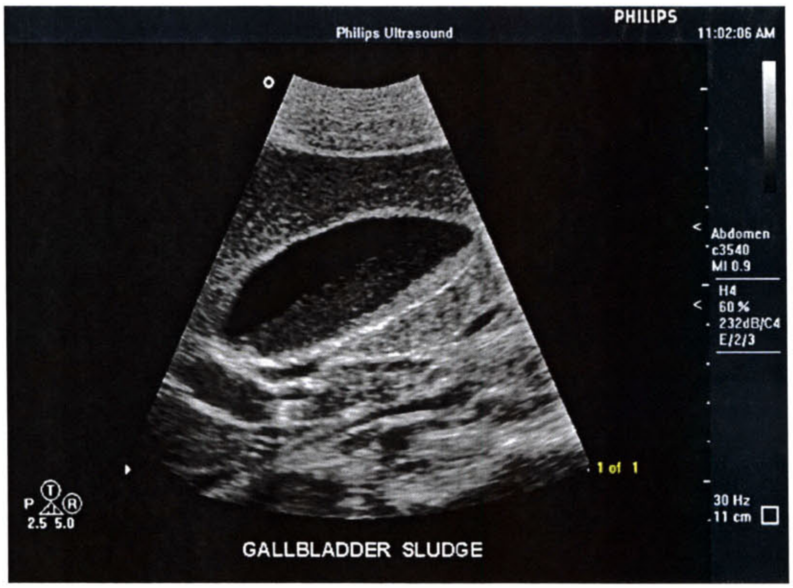

Figure 14 B-mode image of a diseased gallbladder (33)

Another type of transducer uses a phased array. Phased arrays can be either a 1D linear or 2D planar array of transducer elements. A 1D phased array can electronically steer the ultrasonic waves, allowing the image size and shape to be adjusted without changing transducer probes (Figure 15).

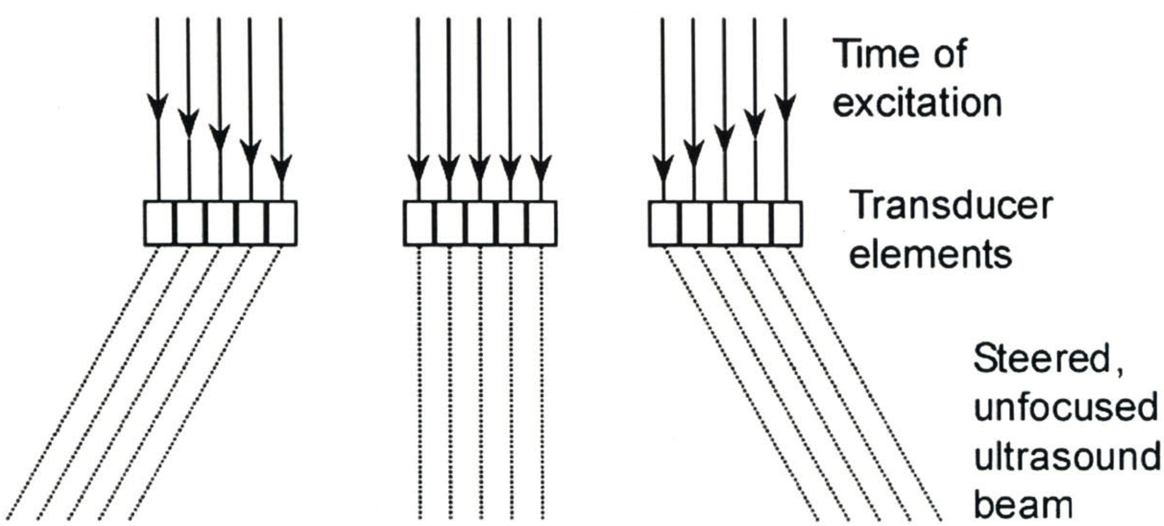

Figure 15 Illustration of electronic beam steering with a phased array (34)

A 1.5D array is a 2D array of elements with significantly more elements in one axis than the other. It creates a 2D image similar to a 1D phased array, but it allows for the beam to be focused in the non-imaging axis (Figure 16).

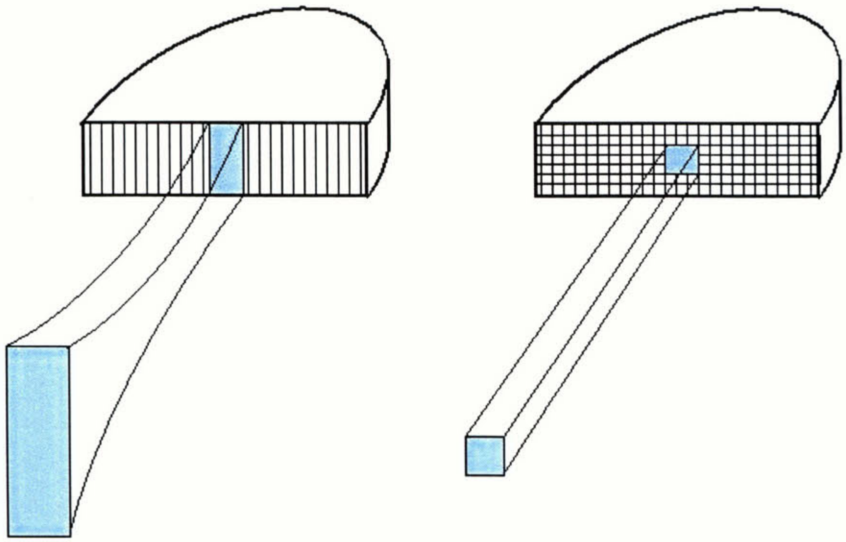

Figure 16 1D linear array (left) & 1.5D linear array (right) (35)

A full 2D array of transducers elements can scan a volume of the body creating a 3D image. However, this adds significantly to the complexity of the electronics as every transducer element requires its own coaxial cable and transmit/receive circuitry. A NxN 2D array would require N^2 circuits, or channels. The high cost of manufacturing cable bundles of more than 256 channels currently restricts the use of 2D arrays.

The exact type of transducer probe used is determined by the application and most conventional ultrasound products are capable of using multiple transducer probes. Viewing anatomy deeper in the body requires a low frequency transducer. Large, deep pieces of anatomy, such as in the abdomen, might require a curved 1D transducer, or one with beam forming capability. Anatomy near the surface, such as the carotid artery, can use higher frequency straight 1D transducers and provide better resolution. Phased arrays, with their beam steering capability, can have small apertures, allowing them to image in-between ribs. This is critical for cardiac applications.

5.1.2. Signal and Image Processing

Regardless of the type of transducer probe used, each element in an array is controlled independently. In linear arrays, the elements are grouped in clusters of 10-12 and pulsed in sequence to acquire an image (Figure 17).

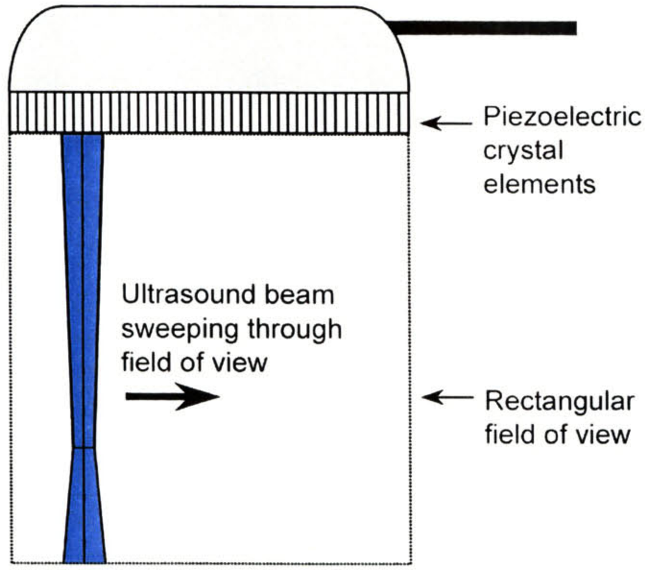

Figure 17 Illustration of pulse sequencing for a linear array (36)

The pulses sent to the element clusters can also be delayed, focusing them to a specific depth (Figure 18).

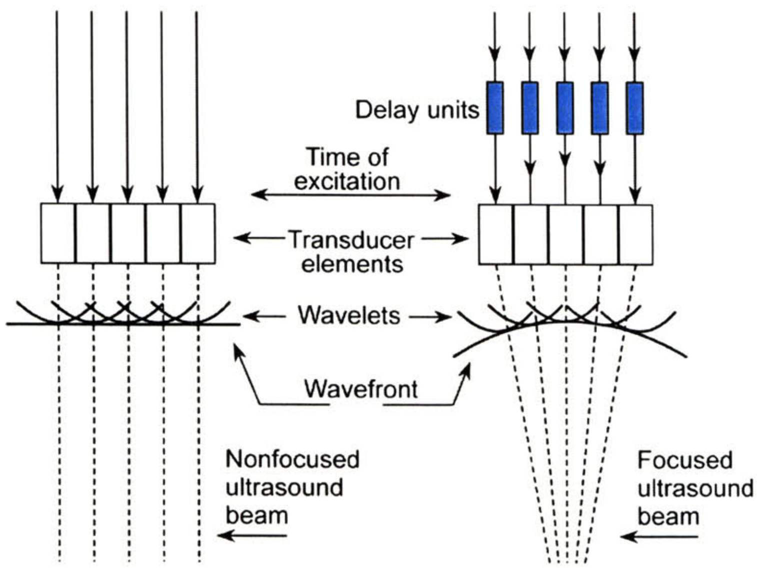

Figure 18 Illustration of electronic beam focusing (37)

In phased arrays, the timing is varied across the entire aperture, steering a beam and sweeping it across a section of anatomy (Figure 15). Again, the pulses can also be controlled to focus each beam scan to a specific depth. In either case, the transmission and subsequent receipt of the electrical pulses is sequenced by beam forming circuitry. The following is a simple diagram of the electrical circuitry for an ultrasound system.

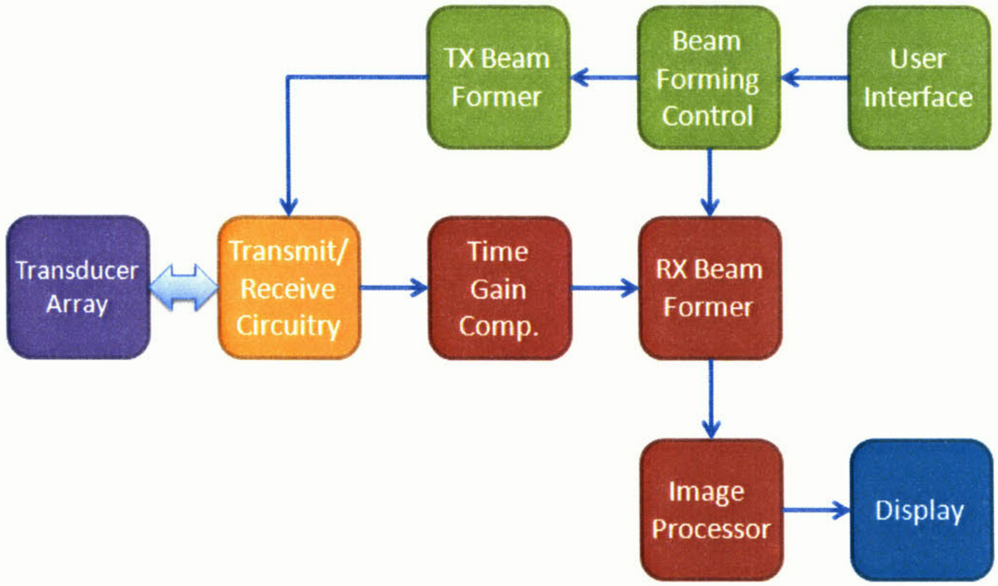

Figure 19 Simple diagram of ultrasound electrical circuitry[3]

Each element in a transducer array requires its own signal processing channel and must be processed individually. This has presented a significant technological challenge as more elements have been packed into transducer arrays. A typical 1D transducer array has between 64 and 128 elements and therefore, 64 to 128 processing channels (38). The development of 3D imaging using 2D transducer arrays has also magnified the challenge. Again, a NxN element 2D transducer array would require N^2 processing channels, meaning even a limited 64x64 array would require 4096 channels versus just 64 channels in a 1D array. As mentioned previously, limitations in cable bundle diameters frequent use of more than 256 channels.

5.2.Portable System Architecture

Most medical ultrasound devices sold today are portable in the sense that they can be moved from one location to another by a single individual with relative ease. Even the high-end devices, weighing over a hundred pounds, are mounted to wheeled frames that can be moved from one patient room to another and are therefore effectively "portable". However, in the ultrasound industry, the term portable has been reserved for devices that can be carried by a single person. The former wheeled carts are hence referred to as cart-based systems.

Further segmentation of the portable market is also developing around how or where the device is transported (hand-carried or pocket portable), contributing to a product identity crisis similar to that seen in the personal computing industry (PCs, laptops, UMPCs, netbooks, tablets, smart phones). There are even compact devices that are now being built into hospital infrastructure, units mounted at a patient's bedside. They are certainly not mobile, but they are light and compact, further adding to the identity crisis. The common feature of all products in the portable category is their "flexibility" and ease

[3] Diagram created with information from Indian Institute of Technology, Kharagpur VLSI-CAD Laboratory website (97) and an article from Analog Devices, Inc. (30). Note that Doppler circuitry is not shown.

of access, a product that is becoming a modular component in the hospital infrastructure. The following is a review of the different categories and their unique attributes.

The current terminology used by the ultrasound industry is described below.

5.2.1. Cart-Based Systems

The conventional cart-based systems are currently the largest segment of the market. Though most of these systems are mobile (mounted to a wheeled frame), they tend to be large and heavy (cannot be carried by an individual). They range from monstrous behemoths that can barely fit through a doorway to agile units that can tuck easily next to a patient's bedside. For the purpose of this paper, we will not view cart based systems as portable. However, we will consider hybrid systems where the ultrasound machine, the functioning guts of the instrument, can be separated from the cart and used independently.

5.2.2. Hand-Carried Units (HCUs)

The class referred to as HCUs was pioneered by SonoSite about 10 years ago and can be broken down into four sub-categories: luggables, laptops, tablets, and pocket portables (2). The main differences between the sub-categories are weight and form factor, but they can all be moved by a single person with relative ease. All are physically integrated designs with a display, user-controls, and at least one probe. No dominant design has yet to emerge and as we enter Fernando Suarez's fourth phase in the battle of technological dominance, the "decisive battle", we might soon see consensus (39). Will it be a laptop-like product or a tablet?

5.2.2.1. Luggables (>20 lbs)

Approximately the size of a small CRT TV set, these products where one of the earlier entries into the portable segment. Architecturally, they are not much different from a conventional system except that they are not supported by a wheeled cart. They can be moved by one person from room to room, but they are significantly heavier than newer products. This style is still common in developing markets.

Figure 20 Mindray DP-1100Plus (40)

5.2.2.2. Laptops (<20lbs, laptop-like form factor)

Based on the architecture of a PC, these devices are roughly the size of a large laptop and can be carried from room to room and operated from a flat surface. They are architecturally similar to a conventional system minus the wheeled cart and printer.

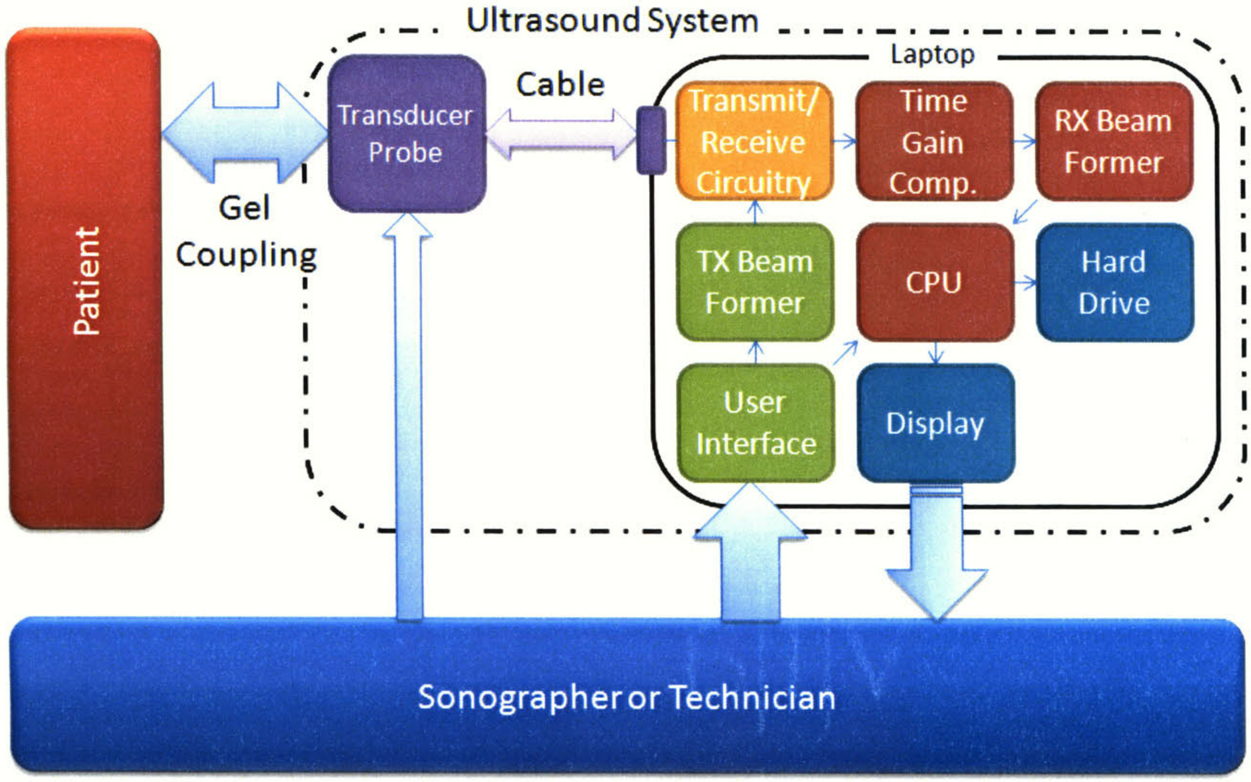

Figure 21 A simple diagram of a laptop based ultrasound system

Figure 22 Aloka ProSound C3CV (41)

While most of the products in this category are special, purpose built, "laptops" there is a unique product architecture based on a common laptop. The SeeMore ultrasound probes, sold by Interson, can be plugged into the USB port of any Microsoft Windows capable computer. The migration of some of the signal processing circuitry into the transducer probe allows for a standard USB cable to communicate with the PC. The following diagram illustrates this change.

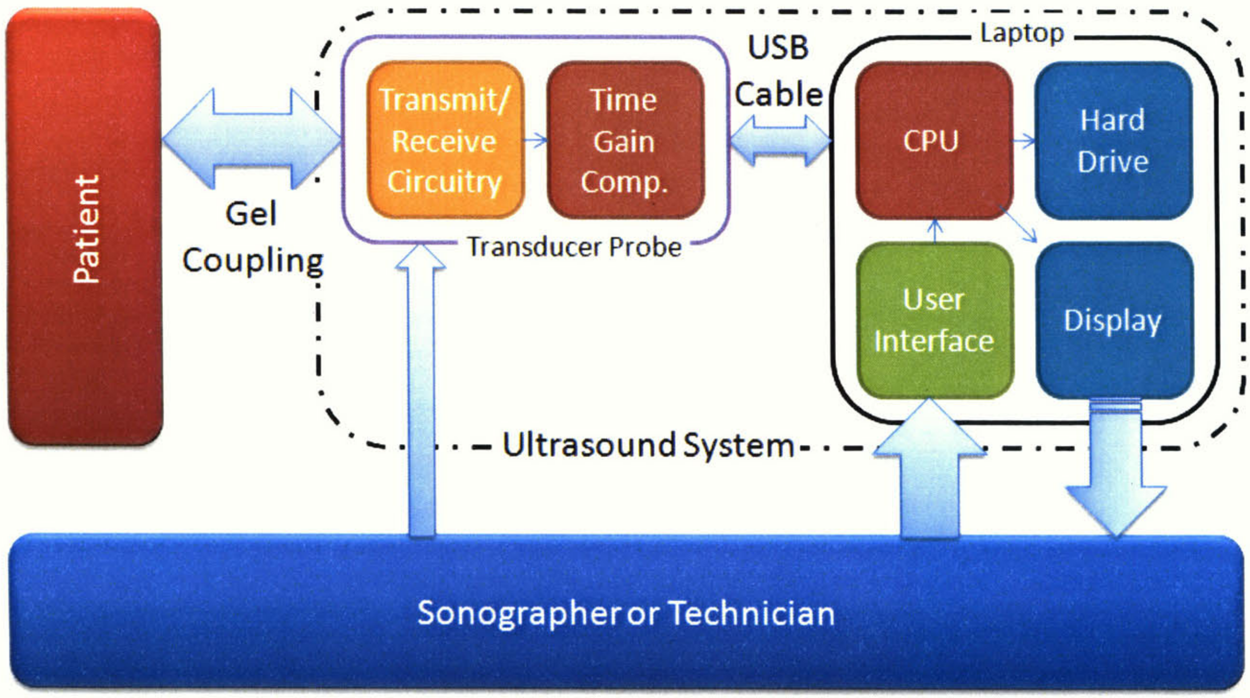

Figure 23 A simple diagram of the Interson SeeMore product architecture

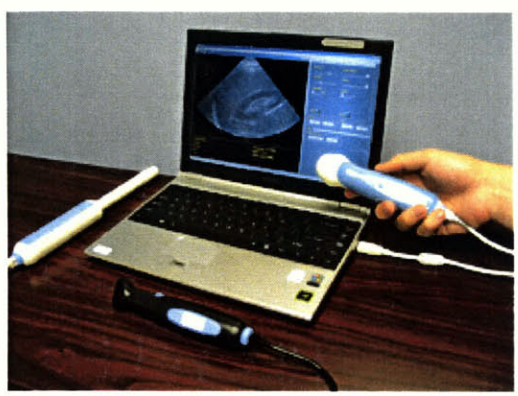

Figure 24 Interson SeeMore Ultrasound Imaging Probes (42)

5.2.2.3. Tablets (<20 lbs, tablet-like form factor)

This is a newer development in product segmentation. These devices are slightly smaller than the laptop-like ones, a simple monolithic flat slab. Some have controls on the surface others use touch screen interfaces. The integration of the display and user interface is a unique feature of this category.

They usually require mounting to a stand or fixture for use, but can also be operated from one's hand, held like a clipboard.

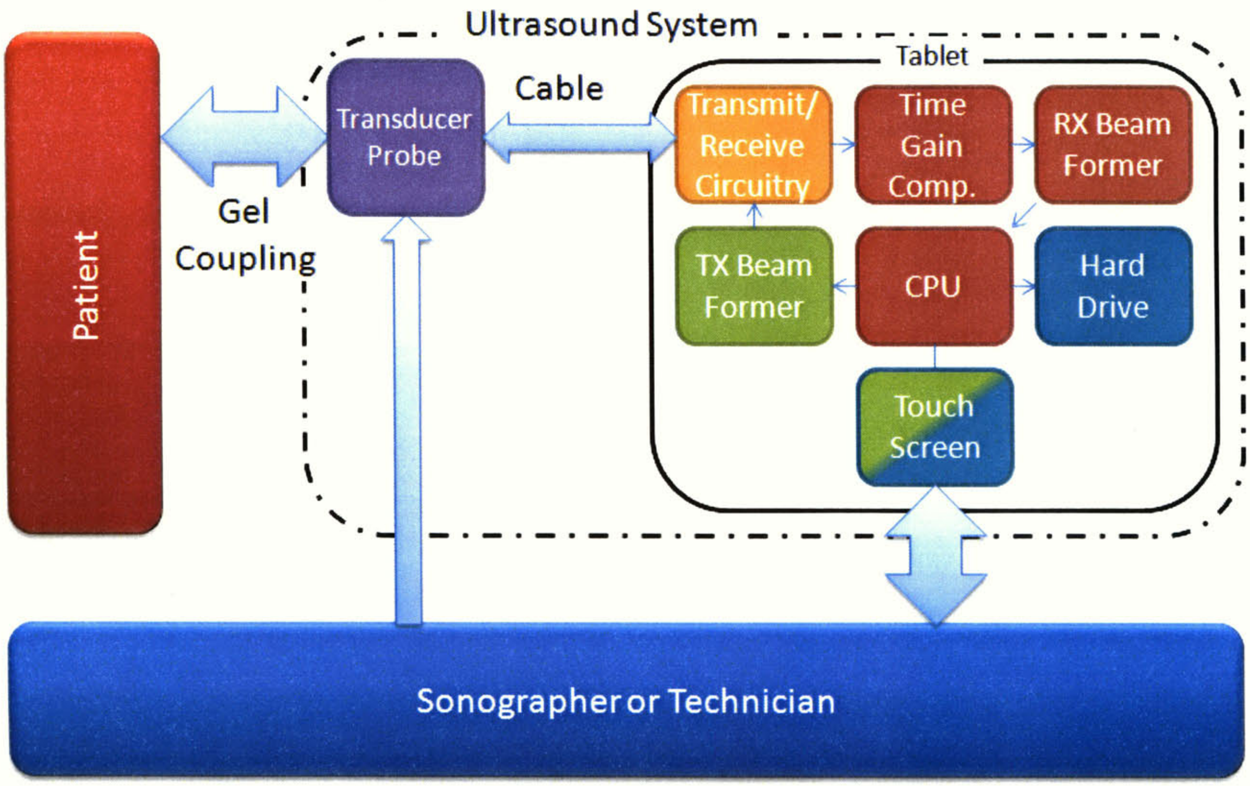

Figure 25 A simple diagram of a tablet based ultrasound system

Figure 26 SonoSite's NanoMaxx (43)

5.2.2.4. Pocket Portable Devices

A focus point of this discussion is the new class of pocket-portable devices that have recently entered the market (the Siemens ACUSON P10 was introduced in 2007) (44). These devices are also person portable, but the display unit can be held in one hand by the operator while using it. While some HCUs may also be hand-held, the chief distinction is that these pocket portable devices can fit into the pocket of a physician's lab coat. These devices are small and lightweight, but generally larger than a smart phone. They consist of a display, minimal user interface, and an integrated transducer probe.

Figure 27 GE Vscan (45)

5.2.3. Mounted Units

The now relatively low cost of these portable devices has increased their accessibility to the point where emergency rooms are starting to install these compact systems into the infrastructure at the patient's bedside, grouped with other patient monitoring devices. While they are no longer mobile, these products are "flexible". SonoSite has blazed the trail in this category by creating a product line that is meant to be installed bedside in emergency rooms and critical care facilities.

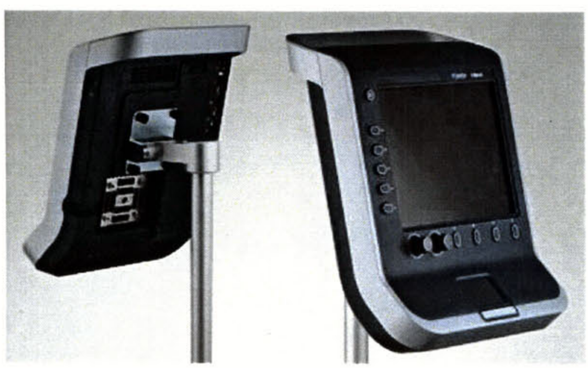

Figure 28 SonoSite S-Series (46)

5.2.4. Hybrid Systems

This is a relatively new product segment that is developing. As most portable products require a flat surface or structure to hold the display while operating it, carts are usually sold as an accessory. Some data indicates that 95% of portable products are used in this fashion. This has led some companies to take products a step further, providing increased functionality when attached the cart. This could be increased battery life or access to peripherals (displays, keyboards, printers, etc.).

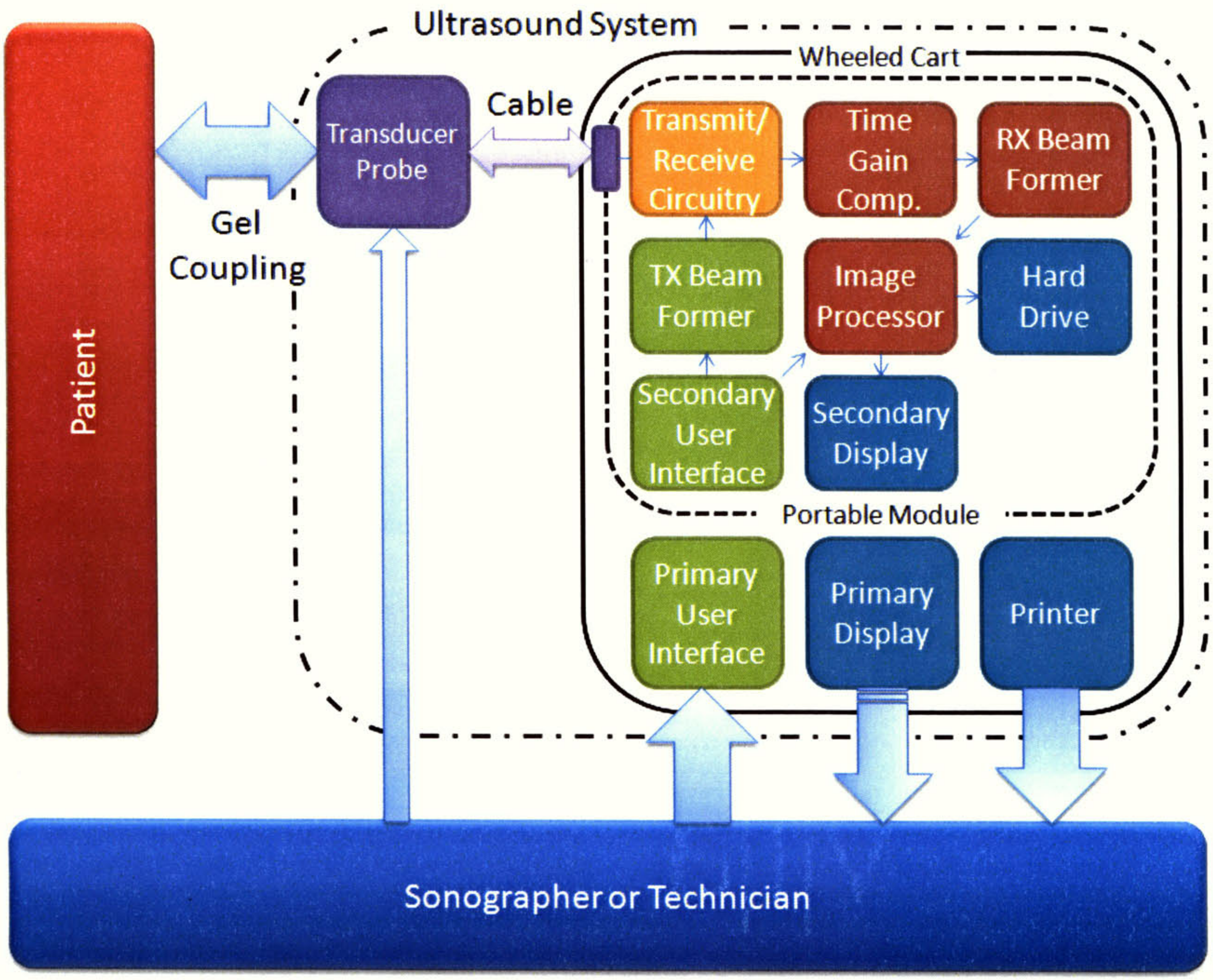

Figure 29 A simple diagram of a hybrid ultrasound system

Figure 30 Zonare z.one ultra (left) (47) & Removable Scan Engine (right) (48)

5.3.Critical Parameters

The following are important parameters that determine the performance of an ultrasound system.

5.3.1. Resolution

There are three components which determine the overall resolution of an ultrasound image: spatial, contrast, and temporal.

5.3.1.1. Spatial Resolution

Spatial resolution has two components, axial and lateral. Axial resolution is perpendicular to the transducer element face and parallel to the direction of sound wave propagation. It is limited by the spatial pulse length. Higher center frequencies allow for shorter pulses providing better resolution, but do not penetrate the body as deep. Lateral resolution is parallel to the face of the transducer and perpendicular to the direction of sound wave propagation. The type of transducer array used determines the limitations on lateral resolution. A linear array is limited by the width and spacing of the transducer elements. Smaller, tightly packed elements provide higher resolution. A phased array is theoretically limited by the transducer aperture width (W), pulse center frequency (λ), and the depth of focus (D) of the beam according to the following equation (49):

$$Later\ resolution = \frac{D\lambda}{W}$$

However, since a phased array image is stitched together with series of scans, it is limited by the chosen field-of-view and the desired time to acquire the image (frame rate). Taking more time allows for more beam scans to be used in constructing the image. Also, a smaller field-of-view requires fewer beam scans.

5.3.1.2. Contrast Resolution

The contrast resolution is the ability to distinguish different levels of intensity from the returning ultrasonic echo. Since the images are displayed to the operator as shades of gray, the resolution is number of shades of grey available (usually 256, or 8 bits) and the operator's ability to distinguish the different shades. The later is usually the limiting factor, making high contrast displays important for high resolution. Ultrasound exams requiring such high resolution are preferably performed in a dark room, helping to improve the image contrast. This aids in the acquisition and interpretation of an image (similar to the special rooms for CT and MRI, but significantly cheaper).

5.3.1.3. Temporal Resolution

Temporal resolution is the ability to capture an image of a moving object without blur, or the frame rate of acquisition. A flicker-free display requires ~16 frames/second. The frame rate is determined by the amount of time taken to acquire an individual image, or frame. Therefore, it is direct trade-off with lateral resolution.

For a linear transducer array, the time required to acquire a frame is determined by the number of transducer elements, the pulse repetition period (PRP), and the number pulse echoes per scan. The PRP is the time between pulses for an individual cluster of transducer elements and usually occurs at of rate of 1-5 KHz. Imaging anatomy deeper in the body requires a longer PRP to wait for the return echoes.

For a phased array transducer, the image acquisition time is determined by the numbers scans performed as the beam is swept across the field of view. Setting a wider field of view or using more beam scans will require more time, decreasing the frame rate.

Using the Doppler effect to determine motion also requires more beam scans, increasing the time to acquire an image.

5.3.2. Color Doppler

By measuring the Doppler effect between the transmitted and received ultrasonic pulses, movement inside the body can be measured. Blood flow and its corresponding velocity is usually the motion of interest. Color Doppler is used, mostly in cardiovascular applications, to show blood flow overlaid on a 2D B-mode image. Blood flow is shown in color on top of the grayscale image (Figure 31).

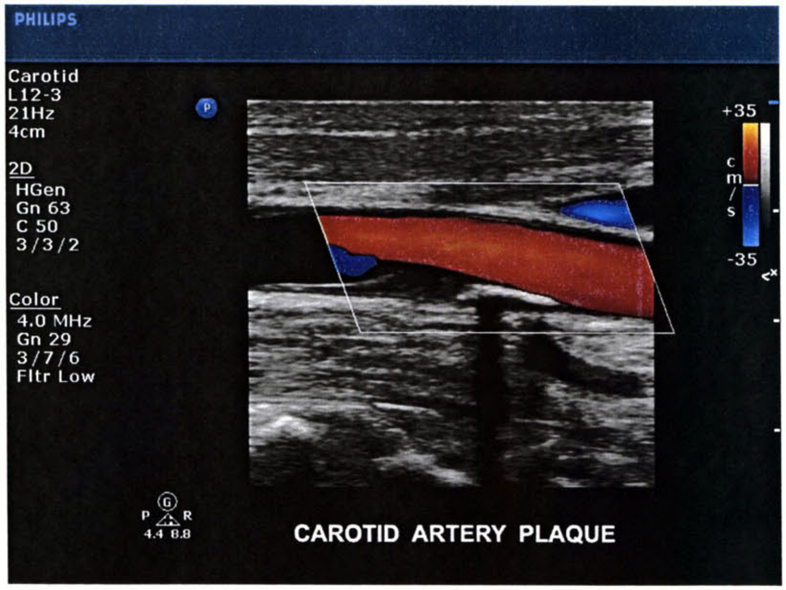

Figure 31 B-mode image with Color Doppler (50)

In systems with digital electronics, the Doppler effect is measured by autocorrelation and requires an additional 4-8 pulses per scan line. Waiting for the additional pulses reduces the frame rate of the real-time images.

5.3.3. Image Archiving & Patient Privacy

In addition to being able to display an image to the person acquiring and interpreting the ultrasound, the image must also be stored for record. Using the image to provide a diagnosis requires storing the image in the patient's file and must be maintained for several years depending on the State (usually 5+, 7 in California). In most cases, the image is stored in hardcopy after being printed on paper. This requires any ultrasound device to be able to transmit the images for printing, or provide a printer as a peripheral device.

Patient privacy is also a concern. Any images acquired must be stored in a secured fashion according to HIPPA rules. This is particularly a concern for digital images as they can still remain on electronic media even after apparently being erased.

5.4. Critical Parameters Unique to Portable Ultrasound

The technology in portable ultrasound has really developed from the miniaturization of the signal processing circuitry necessary for 3D (and 4D) imaging. As noted above, a simple 64x64 2D array squares the number of channels required when compared to a 64 element 1D array. All of these additional circuits had to fit into the same packaging, spurring efforts to make them more compact. The necessity to maintain decent frame rates and adding the ability to perform Color Doppler put even more pressure on the technology. In addition to the parameters above, portable ultrasound has the following critical parameters:

5.4.1. Product Size

The use of integrated circuitry to reduce the signal processing complexity for 3D imaging has been the driving force in reducing product size. Most portable products are the size of a laptop or smaller. While not the most important parameter, portable products need to be capable of navigating the tight environments encountered in patient care. Being able to position an ultrasound device next to a patient's beside is very important.

5.4.2. Weight

Lighter products are better when it comes to portability. The elimination of CRT displays and bulky power supplies has contributed to developing lighter products. Portable products need to be light enough to be a carried by a single person with most products weighing less than 20 lbs.

5.4.3. Battery Life

Battery life, the amount of usable time between charges, needs to at least be long enough to perform a single exam without recharging. Power management, in addition to low power displays and better batteries, has been key to increasing use times. Again, the use of integrated circuits has enabled better performance. The use time for portable products varies significantly between products with the average time of approximately 60 minutes. More time is always better in this case.

5.4.4. Boot Time

Accessibility is a key feature of portable products. Customers need them available at a moment's notice and can't afford to wait for them to boot-up. The boot time is usually dictated by the operating system software used by the device. Cart-based systems are typically based on Microsoft Windows. While this allows for software commonality between products, it creates excruciating long boot times. Portable devices seem to have greatly improved performance by using new hardware and software architecture. Boot times should be as low as possible and measured in seconds, not minutes.

6. Portable Ultrasound Device Companies

In the overall global ultrasound market, the big three, GE, Philips, and Siemens compete for leadership with Toshiba following closely behind. All four of these companies sell multiple imaging modalities and have parent companies with the resources to compete in any market. Figure 32 shows the relevance of these players in the overall North American ultrasound market.

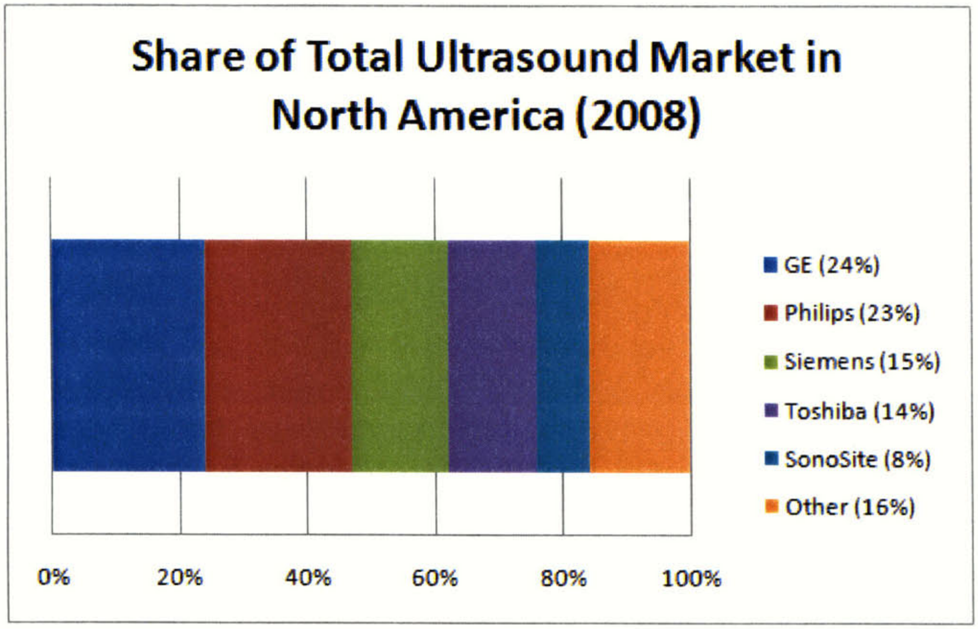

Figure 32 Overall ultrasound market share, by revenue, for North America in 2008[4]

When it comes to evaluating competition in the portable ultrasound market, the landscape looks differently. Figure 33 shows the relevant portable ultrasound device companies and the types of products they offer.

[4] Figure constructed with data from Frost & Sullivan's North American Medical Ultrasound Imaging Market report published in December 2008 (7).

Group	Company	Mountables	Cart-Based Systems	Hybrids	HCUs	Pocket Portables	Other Imaging Modalities
Major Players	SonoSite	S-Series	-	-	M-Turbo, MicroMaxx, NanoMaxx	-	-
Major Players	GE	-	Several	-	LOGIQ, Vivid, Voluson, Venue	Vscan	X-ray, CT, MRI, PET
Major Players	Siemens	-	Several	-	ACUSON P50	ACUSON P10	X-ray, CT, MRI, PET
Major Players	Philips	-	Several	-	CX50	-	X-ray, CT, MRI, PET
Interesting Competitors	Signostics	-	-	-	-	Signos	-
Interesting Competitors	Zonare	-	-	z.one mini, z.one ultra, z.one ultra sp	Scan Engine	-	-
Interesting Competitors	Ultrasonix	-	SonixTouch, SonixMDP	-	-	-	-
Interesting Competitors	Esaote	-	Several	MyLab Five, 25, 30	MyLab One, Five, 25, 30	MyLab Guide	MRI
Interesting Competitors	Interson	-	-	-	SeeMore	Mobile Phone App.	-

Figure 33 Table of relevant portable ultrasound companies and their products

6.1. Major Players

6.1.1. SonoSite

SonoSite is an ultrasound only device manufacturer that was spun-off from their parent, ATL (now Philips Healthcare), in 1998 to compete in the then nascent portable ultrasound market. They got their break in the field by taking advantage of government sponsorship in pursuing a DARPA contract to develop a portable ultrasound system for battlefield medicine (2). This gave SonoSite an excellent reputation boost and support from a key lead user as it sought mainstream markets. SonoSite's creation is a rare example of a large company attempting to disrupt its own business (2). ATL knew that it would not be able to succeed in the portable ultrasound market without changing the way it did business. By creating SonoSite as a separate entity, the new company had the freedom to create an organization that was focused on selling low cost portable ultrasound devices. However, it is arguable whether or not ATL managed the process well, by not retaining ownership of SonoSite. Since its creation, SonoSite has sold over 50,000 ultrasound devices (51).

So far SonoSite's products have mostly eroded the low margin business of the larger companies, with the exception of the development of the Emergency Medicine, Critical Care, and Anesthesia markets. It's products operate under the traditional business model that imaging exams need to be reimbursable by an insurer, although some markets are beginning to use the products as process improvement tools.

SonoSite explored the concept of an "imaging physical" by performing studies with its 180Plus product in the early part of the last decade (2). The conclusions of the testing are not known, but they appear to have backed away from its use and do not offer a true "pocket portable" product.

Current Products

SonoSite offers two laptop based products, the M-Turbo and the MicroMaxx. These products are advertised to serve the general imaging, cardiovascular, OB/GYN, and neuro POC markets with the M-Turbo used for the more demanding applications.

Figure 34 SonoSite M-Turbo (left) (52) & SonoSite MicroMaxx (right) (53)

The NanoMaxx (Figure 26) is a new high-performing tablet based product. It has a touch screen with limited surface controls. It is also advertised to meet a host of POC applications.

SonoSite's S-Series (Figure 28) is one of the only products sold specifically for mountable applications. The series consists of market specific devices based on the S platform. The products can be attached to a cart, wall, or ceiling.

6.1.2. GE Healthcare

GE's Healthcare division provides of a complete line of imaging technologies (X-ray, CT, MRI, PET). They organize their business and product offerings around the traditional three market segments in ultrasound, general imaging, cardiovascular, and OB/GYN.

GE is really working hard to establish a vision for its medical products, ultrasound in particular. Jeff Immelt, GE's CEO, discusses the company's drive to sell products to the emerging and growing markets of the world, while taking product and technology innovations from these markets to the developed world. He's coined this process "reverse innovation" (22). The concept appears to be very sound, but in discussing the reality of implementing this type of innovation with senior GE employees there will be a lot of challenges matching the company organization and structure to such a transformative idea. They are trying to leverage the vast knowledge resources from across the company by having common tools and sharing a common focus towards their customers.

Current Portable Products

GE has a wide range of portable products available, ranging from high-end Voluson Series to the pocket portable Vscan. The LOQIC Book, Vivid, and Voluson series are laptop based products and appear to meet an array of markets (general Imaging, cardiology, OB/GYN, vascular, MSK, anesthesia, and EM). In addition to this complete line of laptop based products, they have recently introduced two new products, the Venue 40 and the Vscan.

Figure 35 GE LOGIQ e (left) (54), GE Vivid e (center) (55), GE Voluson (right) (56)

The Venue 40 is a tablet-like product. The technology behind it was developed for Neonatal Intensive Care Units (NICUs) by GE's division in China back in 2007 (24). GE highlights this product as perfect example of "reverse innovation". It is advertised for use in a variety of POC markets and seems to be selling for ~$15,000 (22). It is also offered with a portable cart.

Figure 36 GE Venue 40 (57)

The Vscan (Figure 27) is a pocket portable device developed in the USA. It is touted by some as a visual replacement for the stethoscope, putting ultrasound in the physician's pocket. It is focused on the POC markets, primary care in particular, but the product was developed by the cardiovascular imaging group based in Wisconsin. The division leveraged the power management and miniaturized circuitry advancements from their high-end 3D/4D capable products. The Vscan was developed as a side project. Improvements in lower power displays and higher energy storage in batteries also facilitated its introduction. The Vscan is not intended to be a traditional ultrasound machine, rather it is a "portable visualization device" (23). It has three operating modes (cardiac, abdominal, obstetrics) which tailor the product's performance to the specific use case. In addition to the POC markets in developed countries, they are also exploring sales globally (China, India, and, to a lesser extent, Latin American and CIS countries). Their sales and distribution strategy is to sell the product in bulk to large integrated organizations with a single buyer.

6.1.3. Siemens Healthcare

Siemens Healthcare division is also a complete provider of imaging technologies, which added to its ultrasound product line with the purchase of Acuson Corporation in 2000. The Acuson Cypress[5] was the first portable product to be added to its portfolio (2). Weighing ~20 lbs the product was a luggable device focused on the cardiology market segment. The Cypress is no longer available and it may have met the fate of other portable cardiology products that existed at the time (OptiGo, SonoHeart) (2) (23).

At some point over the last decade, it appears that Siemens devalued the importance of ultrasound technology in its imaging portfolio. They bet on the growth of the superior quality imaging modalities, such as CT and MRI, which seemed to be less operator dependent. However, as these technologies have become more ubiquitous, they are proving to be more operator dependent than expected. Siemens may be trying to reverse this position, but their underinvestment in a portable ultrasound portfolio has diminished its role and market share (24).

Current Portable Products

The ACUSON P10 (Figure 37) is the only indigenously developed portable product in their portfolio. Released in 2007, it is labeled as the "first" pocket ultrasound device (58). Like the GE Vscan, it is small enough to fit into the pocket of a physician's lab coat. They are currently working on the evolution of this device, mostly focused on improving product functionality (59).

[5] The Cypress was a product acquired by Acuson Corporation prior to their purchase buy Siemens.

Figure 37 Siemens ACUSON P10 (60)

In addition to the P10, they also sell another device called the ACUSON P50. This is a laptop based system that Siemens distributes for a company called Terason (the Terason t3000). However, it is rumored that Siemens will not be continuing its relationship with Terason. This may be due to a report published by PASA (the purchasing report agency for the UK's NHS) in the fall of 2009 that showed nearly equal performance between the P10 and P50, despite the P50's significantly large price tag (~$30,000 vs. ~$10,000).

Figure 38 Siemens ACUSON P50 (61)

6.1.4. Philips Healthcare

A complete provider of imaging technologies, Philips acquired ATL, the former parent of SonoSite, in 1998 to add ultrasound to its portfolio (2). Philips also acquired Agilent Technologies' Health Care Solutions Group in 2001, adding a portable ultrasound product, the OptiGo (2). However, the OptiGo product was eventually cancelled. Some attribute the failure to the fact that the product was focused solely on the cardiology market (22) (23). Similar to SonoSite's SonoHeart, the OptiGo did not have the full feature-set to qualify for reimbursement. In this case, it was the lack of a QWERTY keyboard, necessary for inputting patient information that prevented its use for reimbursable services and ultimately sealed its fate.

Current Portable Products

They currently have a laptop sized portable device called the CX50. It is also offered with a portable cart. They are also working on a new product to serve the POC market.

Figure 39 Philips CX50 (62)

6.2. Interesting Competitors

6.2.1. Signostics

Signostics is an Australian company that has developed a unique pocket portable ultrasound device called the Signos. The simple device has a 1D transducer probe that the operator can use to create compound B-scan images or view a linear section in M-Mode. It appears to be selling for ~$4,000 (63).

Figure 40 Signostics Signos (64)

6.2.2. Zonare

Zonare is a relatively new competitor that started selling its z.one hybrid (Figure 30) ultrasound systems back in 2005. It sells three different cart configurations all based on the same Scan Engine laptop based module. The Scan Engine can be used independently like most hand-carried portable products. The carts provide varying levels of additional options for users. It has sold over 3,000 units to date (65). Zonare also uses a new scanning technique for its transducers (Zone Sonography), allowing their products to scan a 52 element transducer ten times faster than normal (66). The faster scan times allows the Zonare products to trade between better resolution, higher frame rates, or more features.

6.2.3. Ultrasonix Medical Corporation

Ultrasonix is also a relatively new ultrasound company, founded in 2000 (67). They do not sell any hand-carried, mountable, or hybrid devices. However, they do sell unique battery powered cart systems. Their SonixTouch and SonixMDP platforms appear to span the ultrasound markets. They also tout a modular software architecture that allows for easy upgrades (68).

Figure 41 Ultrasonix SonixMDP (69)

6.2.4. Biosound and The Esaote Group

Biosound and its parent company, The Esaote Group, offer an interesting variety of portable products. The MyLab Guide (Figure 42) is a small, nearly pocket portable product designed to assist with vascular access and biopsy procedures. The MyLab One is a tablet-like, "arm-held" high-performance ultrasound device that can be worn by the user. The MyLab Five, 25 and 30 product lines are all hybrid systems that have a laptop-like portable module that can be removed from a peripheral cart.

Figure 42 MyLab Guide (70)

6.2.5. Interson

Interson is a manufacturer of ultrasound transducer probes and has been an OEM supplier to the industry since 1989 (71). Recently, Interson has developed a line of probes that include some of the ultrasound signal processing circuitry. As mentioned previously, these probes connect to any Microsoft Windows capable PC via USB, effectively creating an ultrasound system with a unique modular architecture. Using their free, proprietary Windows-based software, one can use the SeeMore probes (Figure 24) to create B-mode images. Their products are focused on the POC markets and sell for ~$6,000 (72).

In addition to the low cost of the product, the low voltage USB connection to the probe makes them very safe. The USB connection also allows them to overcome the limitations of cable length that most ultrasound devices have. There is also an open source software program that is available for Windows Mobile devices (Figure 43) (73). One limitation of the SeeMore product line is that it does not provide Color Flow Doppler, limiting its usefulness in cardiovascular applications.

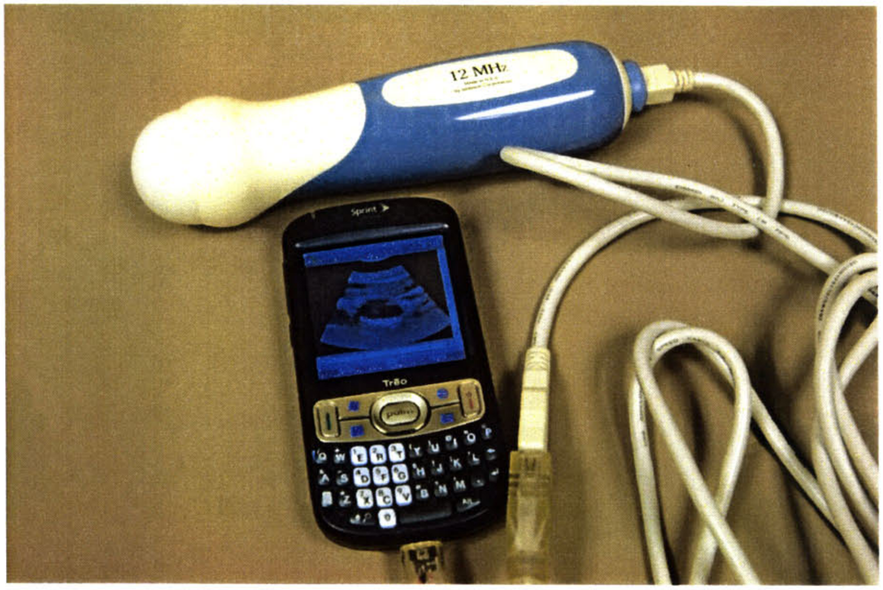

Figure 43 Interson probe with a Windows Mobile Palm Treo 800w running Cell Phone SDK (74)

Currently, Interson sells its products online and through distributors. They are exploring new ways of selling/distributing the product and are likely to have challenges similar to those of other low cost providers (ex. Medison's MySono).

6.3.Secondary Players

6.3.1. Aloka

Based out of Japan, Aloka has two products that qualify as HCUs. One, the SSD-900, is a luggable product.

Figure 44 Aloka SSD-900 (75)

The laptop based product, ProSound C3CV (Figure 22), is actually the Terason t3000 which is also the same as the Siemens ACUSON P50.

6.3.2. Terason

Terason is a company owned by Teratech, a spin-off from MIT's Lincoln Laboratory back in 1994. Similar to SonoSite (ATL at the time), Teratech received a grant from DARPA to develop a hand-carried ultrasound device for the battlefield (2). Terason has two versions of a laptop based ultrasound system. Their two products are the 2000+ and t3000. The unique feature of Terason's products is their architecture. Terason uses a "fully-custom ultrasound chipset" as opposed to an ASIC (76). However, a comparison by PASA from the NHS in the UK showed the t3000 product (sold as the ACUSON P50 by Siemens) to have lower performance than the ACUSON P10 for most imaging needs (26). They appear to have distribution agreements with both Aloka and Siemens. Aloka sells the product as the ProSound C3CV and Siemens sells theirs as the ACUSON P50, although it is rumored that Siemens will not be continuing this relationship.

Figure 45 Terason t3000 (77)

6.3.3. Medison

Medison is a Korean ultrasound company. They offer a variety of ultrasound devices and have two portable products. The Sonoace Pico is a luggable product. The Mysono U5 is a laptop based product. In a situation similar to ATL, Medison spun-off a smaller company, Mysono, in 2000 to develop a low cost laptop based ultrasound product called MySono201. The MySono201 was to be sold primarily online (78). The website is still active, but has not been updated since 2000.

6.4.Emerging Market Competitors

6.4.1. Mindray

Mindray is a Chinese medical device company that sells a complete line of ultrasound devices. Their M5 is a laptop based product that targets the more demanding ultrasound markets. Additionally, they sell several luggable products from their DP line. The DP-1100Plus and similar products go after the low-end. As GE seems to be well aware, Mindray, with its low cost products, is a direct threat to all ultrasound companies globally (22). Their products occupy a large portion of the ultrasound market in China and they are beginning to see market share grow internationally.

Figure 46 Mindray M5 (left) (79) & Mindray DP-1100Plus (right) (40)

6.4.2. Shantou Institute of Ultrasonic Instruments (SIUI)

SIUI is another Chinese ultrasound company and like Mindray, they offer a complete product line. The Apogee 1100 and CTS-8800 are very capable luggable products. Also like Mindray, SIUI is starting to secure market share outside of China.

Figure 47 SIUI Apogee 1100 (left) (80) & SIUI CTS-8800 (right) (81)

6.5. Inactive Players

6.5.1. Toshiba

Toshiba has a large line of imaging technologies (X-ray, CT, MRI) and was the leading provider of ultrasound in Japan and industrialized Asia (2). Toshiba does not currently offer any hand-carried, mountable, or hybrid products. However, as noted above, Toshiba has a large share of the conventional ultrasound market. If they decide to direct their efforts towards portable ultrasound, they could become a serious competitor. In the past, Toshiba has made technology agreements with companies to integrate competitor's technology into Toshiba branded products.

6.5.2. Hitachi

Hitachi also has a line of imaging technologies (CT and MRI), including cart-based ultrasound. Hitachi does not currently offer any hand-carried, mountable, or hybrid products.

6.6. Interesting Products

6.6.1. Verathon

Verathon is a medical device company that has two unique ultrasound platforms, the BladderScan and AortaScan. These platforms are application specific and portable. The BladderScan is used to make bladder measurements used in the diagnosis of bladder dysfunction (82). The AortaScan is used to measure the size of the abdominal aorta to screen for an abdominal aortic aneurysm (AAA) (83). Both assist a physician in diagnosis and can be operated without a Sonographer. The two device platforms use similar technology and they even sell a combination device that performs both functions.

Figure 48 Verathon BladderScan BVI 9600 w/AortaScan Mode (84)

6.6.2. Insituvue

Insituvue is a start-up company in the process of commercializing an ultrasound device that can display a B-Mode image in relation to a patient's anatomy while an exam is being performed. Their product, called the Sonic Flashlight (Figure 49), is being designed to assist medical professionals during vascular access (85).

Figure 49 A prototype of the Sonic Flashlight imaging a hand (86)

7. Dominance in Portable Ultrasound

The development of the portable ultrasound product segment over the last ten years has redefined the entire ultrasound industry. Large, expensive cart-based systems are being displaced by compact, low cost portable systems, upsetting the market share of established companies. This disruption will continue as portable products improve and take on more demanding tasks in the existing markets, further displacing entrenched products. New products, such as the pocket portables, are developing to compete in the low-end markets, threatening the market share the current portable products have just secured. **With these changes in mind, what should companies do to compete in this new environment? And, is the "visual stethoscope" a serious product segment that can win the primary care market?**

The cycle of disruption will continue. Accepting this process as the status quo, companies must decide where to compete. Hold onto the high-end market, continuously pushing performance ahead of others? Be a disruptor and steal the low-end business from your competitors? Abandon the fight and search for new markets and business models? Or, slug it out and fight for the middle? With most customers having moderate needs for performance, this is where most companies will find themselves.

In meeting the needs of less technically demanding customers, companies need to worry less about performance and more about the architecture of their products. As Clayton Christensen discusses in his article, *Skate to Where the Money Will Be*, modular architectures can allow companies to reduce product cost and increase cycle time (87). This is a trend we are already seeing with hybrid cart systems (Zonare) and software based interfaces (GE Venue 40, SonoSite S-Series, Ultrasonix, etc.).

7.1. The Battle for the Middle

SonoSite has a sizeable lead in market share over all competitors with GE following in a distant second (20). Though the major players have been slow to adapt to the changing markets, they are starting to compete. New competitors are also entering the game. Looking at Fernando Suarez's timeline in the battle for technological dominance, SonoSite has already blazed the trail through the first three milestones (R&D build up, technical feasibility, and market creation) for portable ultrasound devices. This leaves us in the fourth phase, the decisive battle (39). Using Suarez's framework to evaluate the situation, one can see that the environmental factors are not very strong (39). The fact that ultrasound devices are almost completely interchangeable amongst competitors shows the lack of strong networking effects. Knowing this, and the stage of the battle, companies need to focus on the two decisive elements they can control to unseat SonoSite from its position: credibility and complementary assets. New entrants with unique product configurations, such as Zonare with its hybrid cart systems, will need to develop credibility quickly. At this stage, the markets will start to coalesce around a dominant design. Unless SonoSite's market share is challenged soon, they will dictate the preferred product architecture. This could alienate unique designs from consideration. Larger medical device manufacturers can use their existing credibility and complementary assets to gain markets share. In defense, SonoSite can also try to leverage its installed base, though network effects are weak. Touting its strong product brand will give them some edge in fending off competition.

For the companies that have stayed on the sidelines for the beginning of this battle, they can take solace from the knowledge that being first isn't always best. While intentionally entering a market late is usually not sound business strategy, companies finding themselves in this situation are not without hope. As Fernando Suarez discusses in his article, *The Half-Truth of First-Mover Advantage*, the conditions for benefiting from first-mover status do not exist in all situations (88). Looking at new markets in ultrasound one can see two things: the markets are changing quickly and so is the technology. It seems that new applications for flexible ultrasound devices are found in every corner of medicine. In addition, ultrasound circuitry continues to benefit from the rapid advancements in silicon integration and power scaling (89). Knowing that both the markets and technology are evolving quickly puts first-movers in a tough situation, or as Suarez refers to it, "rough waters". This is the worst situation for a first-mover meaning SonoSite's initial advantage is likely to be short-lived. Holding onto it will require substantial resources in marketing, distribution, and R&D (88).

7.2. In Search of New Markets

Just as SonoSite disrupted the conventional cart-based products, there are likely to be opportunities to do the same to portables. With growth opportunities appearing to be strongest in developing countries, companies should focus on low cost solutions, not necessarily more effective ones (Figure 10). These new markets are likely to have little existing exposure to ultrasound technology and, therefore, not suffer from loss aversion. A product, such as Signostics Signos, that provides less capability at less cost might be acceptable to customers that have never used an ultrasound device. Application specific products that eliminate skilled professionals from the workflow, such as Verathon's BladderScan, are also good directions to consider.

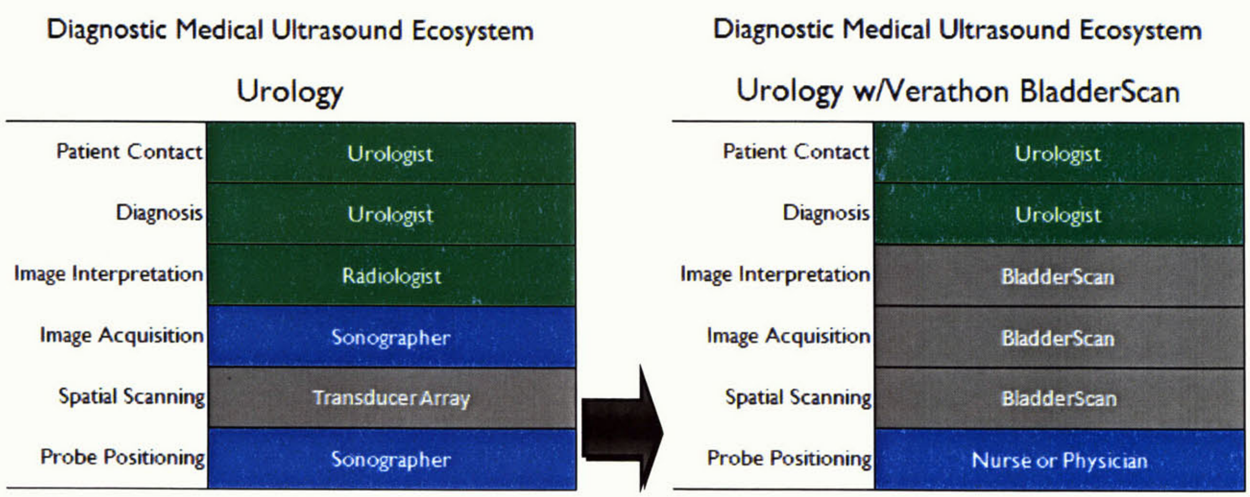

Figure 50 Change in urology imaging ecosystem due to Verathon's BladderScan

In developing products for new business models, companies need to consider product architecture. The same modular products that are competing in the mainstream portable market are not likely to succeed in a heavily cost driven one. The technology advances required to drive down cost usually necessitate tight integration of components. For example, as Verathon shows us with their BladderScan product, an integral architecture is necessary to meet performance and lower cost.

While a product like the BladderScan fits into the existing FFS reimbursement business model, companies should be wary of cramming their new innovative products into these existing and well established business models. As Clay Christensen warns in his book *The Innovator's Prescription*, "When disruptive innovators assume that relying on the existing value network is a cheaper, faster way to succeed, they invariably find that ensconcing their "piece" of the system into the old value network kills their innovation—or it co-opts and reshapes their disruptive business model so that it conforms to that system. Vice versa never happens." (25)

8. The Future of the "Visual Stethoscope"

The concept of using an ultrasonic device to perform routine physical examinations is not a new one. As mentioned by Clayton Christensen is his case study on SonoSite (2), Dr. Jacques Souquet a scientist at ATL ultrasound, envisioned an "ultrasonic stethoscope" back in 1978. As mentioned earlier, SonoSite explored the concept of an "imaging physical" back in the beginning of the last decade (2). Siemens also envisioned a visual stethoscope back in 2002 (90). Today, circuit miniaturization and other improvements in technology have made a stethoscope-like ultrasound device possible. The Siemens ACUSON P10, GE Vscan, and Signostics Signos can all be labeled such devices. Despite portable ultrasound devices being around for almost 10 years, they are not in every physician's office yet. Will these new pocket portable devices finally lead to the mass adoption of ultrasound in primary care?

8.1. Ultrasound in Primary Care

While ultrasound is quickly spreading to the POC markets and into the offices of many specialists, such as cardiologists, the primary care market has been left largely untapped. This is not due, however, to a lack of effort; SonoSite, for example, has attempted to access this market ever since it developed the SonoSite 180 back in 1999 (91). What is the challenge is penetrating the primary care market?

The success of ultrasound in primary care is likely to vary depending on the type of health system it is being used in. As Clayton Christensen describes in his book *The Innovator's Prescription*, health systems can be broken into two types: disintegrated; and integrated. A disintegrated health system, such as the one most American's are in, operates primarily on a fee-for-service basis and has little interest in keeping a patient healthy. Revenue is generated when patients are sick. An integrated health system, such as a Health Management Organization (HMO) like Kaiser Permanente, earns revenue by charging membership fees and loses money when they have to provide service. Integrated health systems have a financial incentive to keep you healthy and provide proactive and preventative services (25).

Most studies on the use of ultrasound in primary care center on its use as a tool to screen patients before referring to an imaging specialist (cardiology, OB/GYN, or radiology). The intent is to reduce the number of full imaging exams and reduce total expenditures on imaging services. However, it is not obvious that incentives are well aligned to encourage this behavior in all types of health systems.

8.1.1. Integrated Health Systems

Integrated health systems, such as the Veteran's Administration in the USA or the UK's NHS, do have a financial incentive to reduce the number of full ultrasound exams while providing adequate patient care. According to an evaluation report by the NHS on the Siemens ACUSON P10, there are situations where a pocket portable device can reduce cost by eliminating full imaging exams (26). By performing more frequent low cost exams at the primary care level, the frequency of more expensive exams by specialists can be reduced. The use of ultrasound by primary care physicians in integrated health systems seems to make more sense in these circumstances.

8.1.2. Disintegrated Health Systems

A disintegrated health system has no financial links between service providers. There is no incentive for a primary care physician to perform a screening exam unless it is reimbursed by the CMS or other health insurance providers. For specialists, there is no incentive to use a low cost method of diagnosis when a more expensive, and potentially profitable, method is currently reimbursable by the CMS (25). There is also significant inertia built into the system encouraging physicians to refer patients to specialists for treatment. Adding a service that does not generate income or provide additional value will not make any sense for the primary care physician. The question then becomes, can ultrasound provide additional value in another way, as a process improvement tool?

8.1.3. Process Improvement Tool

In the fee-for-service business model, the more services provided the more money made. Providing a physician with a tool that allows them to increase patient throughput is an easy sell. If a low cost ultrasound device can allow a physician to process more patients in the same amount of time with equal or better quality, the device becomes financially attractive. This is one of the reasons for the growth of portable ultrasound in emergency rooms (ERs), where diagnosing patients sooner allows the ER to transfer them, increasing throughput and minimizing costs as most ERs are a financial burden to hospitals (25).

It is not as obvious as to whether or not portable ultrasound can improve the speed of diagnosis for primary care physicians or other specialties. A simple calculation provides an estimate as to how much a device would have to speed the process in order to make sense economically.

Physician Salary - $200,000 per year[6]

Cost of Device - $10,000 with a 2 year warranty

If the physician works 40 hours per week and sees 20 patients per day (15 minutes per patient). The device would need to save them ~1 minute per patient.

This math makes sense for a physician performing exams looking for very specific information (checking abdominal pain or taking a quick look at the heart). However, the use of ultrasound in a generic physical exam may actually take more time than it saves. The success of ultrasound as a process improvement tool is inconclusive.

8.2. Adoption

The rate at which the "visual stethoscope" concept is adopted will rely less of the advancement of technology and more on the resistance of physicians to use them. Though the benefits may be apparent, the use of the device as an exam tool will still require a significant change in behavior by the physician. Looking at John Gourville's framework for new product adoption, the high degree of behavior change required to use a "visual stethoscope" most likely qualifies it as a "long haul" (92). This means exactly as it sounds. Companies pushing these devices need to be in it for the long haul and plan for slow growth. Strategic vision, big pockets, and continuous R&D will all be required.

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[6] Rough annual salary for an average Internal Medicine Physician in Cambridge, MA provided by Salary.com.

8.3. Form Factor

The pocket portable device category is defined by the size of the products, "pocket sized", and their cost, <$10,000. These are the key parameters currently differentiating them from HCUs. The feature set for the devices (lack of Color Flow Doppler, limited visual depth, and low resolution) only limit the diagnoses they can be used for, they do not define the category.

In discussing the GE Vscan with Dr. Yang, a Hospitalist at BIDMC in Boston, he pondered "Why does it need to be pocket sized?" (93) The convenience of a pocket portable device is nice, but is size the most important parameter? Several other common physician tools (ophthalmoscopes, otoscopes, and sphygmomanometers) are rarely carried at all times, even though they are pocket sized. Instead, these tools are available in almost every exam room or nurse station, **easily accessible**, but not carried personally by physicians or nurses. This is partially due to their cost (a few hundred dollars each) and their limited utility (only good for specific anatomy). Conversely, the common stethoscope is a tool that nearly all physicians and nurses carry constantly. Why? The very personal nature of the device (it sticks in your ears!) and its relatively low cost (~$100) make sharing less desirable (I don't want your earwax in my ear!) and less necessary (even medical students can afford them). The current pocket portable ultrasound devices do not share the need for personalization nor are they inexpensive (~$10,000).

This raises the question about the necessity of a pocket portable device category. Does a physician really need an ultrasound device in their pocket at all times, or just one that is easily accessible? Sure it would be nice to have, but will they pay a premium for the convenience? The pocket sized form factor will only be a necessity for a few cases, such as certain medical specialists who repeatedly perform very specific exams or operate in resource limited settings, requiring information immediately. From this criterion, emergency medical technicians (EMTs) and paramedics may be the best, and potentially only, market for a pocket portable device in the near-term. Until the price of the products is reduced significantly, they may only be looked at as a novelty.

8.4. Managing the Hype Cycle

With a number of adoption barriers against it (economics, behavior change), a good way to establish the market for a new product, such as the "visual stethoscope", is hype. Generating excitement in a core base of users is critical to eventually getting the product to mainstream consumers. The Gartner Hype Cycle and Moore's Chasm illustrate the challenges of this process and the need to move from generating expectations to delivering results as one shifts from innovators and early adopters to the mass mainstream market (see figure below) (94) (95). We will explore some opportunities for the pocket portable companies to navigate this process.

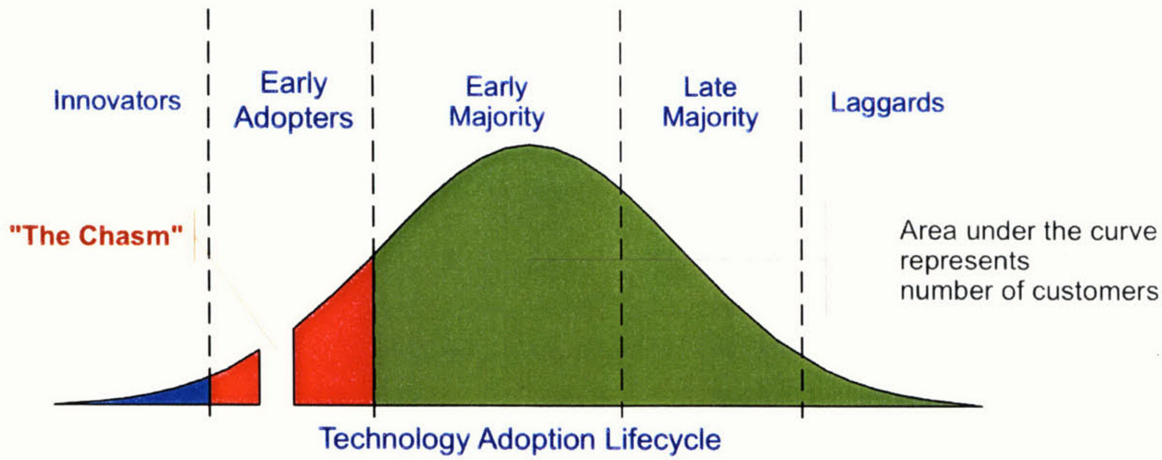

Figure 51 Technology adoption lifecycle with Moore's Chasm shown (96)

GE

How will GE get the Vscan through the hype cycle? They have played the cycle well so far, proselytizing the product at every opportunity and laying out a vision for its future. But as they approach the "Peak of Inflated Expectations", will they find a simple success story to hang onto through the "Trough of Disillusionment"? Maybe EMTs and paramedics? The introduction of the Venue 40 also has the potential to confuse GE's vision, but it may be a good bet for them to shift to if they need to "jump ship" as described by the paper from Velocity Partners (94). If the primary care market does not materialize, they may need to narrow the market segment for the product, focusing on ambulatory medicine. The Venue 40 will allow them to shift the attention and hype from the Vscan, saving face.

Siemens

To date, the ACUSON P10 has been a bust. Selling only a few hundred units per year, Siemens missed the critical opportunity to start the hype cycle (59). As GE now blazes the path with its Vscan product, Siemens has the opportunity to ride along and capture some of the attention GE is creating. As the "Peak of Inflated Expectations" is reached, Siemens can remind the world that it was the pioneer of the pocket portable market and steal a little bit of the spotlight. This does require Siemens to ensure there are success stories for the product. It has been available for three years (501k approval Jan. 4th 2007) (44). There must be a niche out there that can't live without it, right? Paramedics, EMTs, battlefield medicine? Siemens needs to find the story and tout it.

The NHS's Purchase and Supply Agency (PASA) published a relatively flattering review of the product in September of 2009 (26). PASA did not object to its use and provided purchasing guidelines for profitable business use cases, but it did raise concerns about untrained use and the potential impact on patient care. The jury still seems to be out as to whether or not the device is a net benefit for healthcare.

Signostics

The Signos product is clearly in the southwest quadrant of the cost-effectiveness plane (Figure 10) when compared to the Vscan and the P10 (less effective, less expensive). The real question is whether or not they are ahead of Bernie's Kink (28). Loss aversion makes the product a challenge to sell in developed markets. It may find use in resource limited settings where the time to perform the scan is available and is therefore better targeted to developing markets. Signostics will need to "hype" their product by themselves.

9. Conclusion

The desire for healthcare in developing countries, and the need to reduce costs in developed ones, provides an opportunity for portable ultrasound. The steady reduction in the size and cost of ultrasound circuitry, driven by advancements in 3D/4D imaging, is creating products that meet the need for affordable and accessible care. This convergence and the growth of the portable ultrasound market is disrupting the entire ultrasound industry. The established companies are threatened and new challengers are emerging. SonoSite has led the way, becoming a leader in portable products. Other companies follow, along with the rise of domestic competitors in global markets. Confronted with the changing environment, what should companies do to adapt?

Established Companies (GE, Siemens, Philips, etc.)

- Established companies (Siemens and Philips in particular) must embrace the changing market and develop a portfolio of portable ultrasound products, allowing them to disrupt themselves, or risk becoming displaced from the industry entirely. GE seems to be well along this path.
- Focus on creating products with modular architecture. This should help reduce product cost and increase cycle times.

SonoSite

- SonoSite needs to find deep pockets to develop the marketing, distribution, and R&D resources required to maintain its market advantage. It can also try to leverage its strong brand and large installed base to help fend off competition. GE will be a particularly tough challenger.

New Entrants

- New entrants with unique architectures must act quickly to gain a foothold in the market. Failure to act soon will leave them out of the debate as the markets settles on a dominant design.

All Companies

- Continue the cycle of disruption and look for opportunities to provide low cost products in new business models. Consider Verathon's BladderScan and AortaScan as models for future disruptions to the ultrasound industry.

In attempting to leap ahead and further disrupt the portable ultrasound market, some companies, such as GE, are pitching their vision for a "visual stethoscope": a pocket portable device that every physician will want to own. What will happen to these products?

- These products will find a market in integrated health systems (HMOs, VA, UK's NHS, etc.), but it will take a long time to be adopted as physicians adapt their behavior to its use. The pocket portable nature of the current products is likely to prove irrelevant as cost becomes the most important factor driving adoption.

- They will be resisted by the wider disintegrated health system in the USA. It may, however, find niche use as a process improvement tool.
- Companies selling these devices will need to continue hyping the products through the slow adoption process. Highlighting their successful use in a specific market, such as with EMTs and paramedics, will be critical to keeping interest alive.
- Signostics should focus on selling its product in developing markets.

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