The price range for ultrasound transducers can range from thousands of dollars to tens of thousands. The overall investment and cost of ownership to a healthcare organization for their ultrasound probe inventory has a high price tag. Hospitals, imaging centers as well as dealers, manufacturers, service providers, and probe repair labs are all aware of this large investment, but all may not understand where those high costs come from. In some cases, there are alternatives or protective measures that can help members of our industry guard themselves against avoidable costs, although many of these costs are currently and simply unavoidable.

A Conquest Imaging White Paper

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# Why Do Ultrasound Probes Cost So Much?

*The expense behind transducer technology*

Bob Broschart

## PURPOSE

The purpose of this business white paper is to provide the reader an explanation of why ultrasound probes come with a high cost of ownership both in price and maintenance/repair. This paper will offer a somewhat technical explanation of how they are manufactured, as well as where the high cost of manufacturing and repair are derived from. This paper will also present those aspects of maintenance/repair that possess alternatives that can be considered by a facility to help manage costs. The purpose of this paper is strictly educational in nature and is not meant to bias the reader. Dealers, manufacturers, end-users, and those who repair probes would benefit from the contents of this paper.

## CONTENT

This paper will discuss the following:



## PROBE FUNCTION

The probe is the "heart" of any ultrasound system. It all begins with the raw data the probe receives from the patient's anatomy. The probe receives data back from the patient and the system forms the data into images that we see, doppler, etc.; if we input bad data, the diagnostic image portrayed is compromised and could deliver an inaccurate or unclear display for the physician to diagnose the patient. In essence, the system simply responds to the data it is receiving, the image the probe is gathering from the patient. The system exists to support the probe's data gathering.

Considerable engineering effort and research and development is put into the transducers that attach to each system. The original equipment manufacturer (OEM) makes this investment because of the crucial nature of each probe's contribution to the integrity of the image the system will deliver.

Since image quality is directly correlated with the diagnosis of disease, design engineers in the last decade have spent much effort on image quality improvements and enhancements which start with the probe. Because of these improvements, ultrasound has been able to expand into clinical areas that even 10 years ago was not an option. The clinical adaptations for ultrasound are ever-expanding. Back to Top



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## PROBE DESIGN

### External Probe Assembly:

The external design of an ultrasound probe does not look complex. Below is a figure of a standard imaging high frequency probe which exemplifies most probes. Each probe has a connector, housing and block that connects to the ultrasound system, some sort of locking mechanism, a cable with a strain relief on both the connector end and probe head or housing end. The probe has its housing, and probe lens which covers the array. *See Figure 1*.

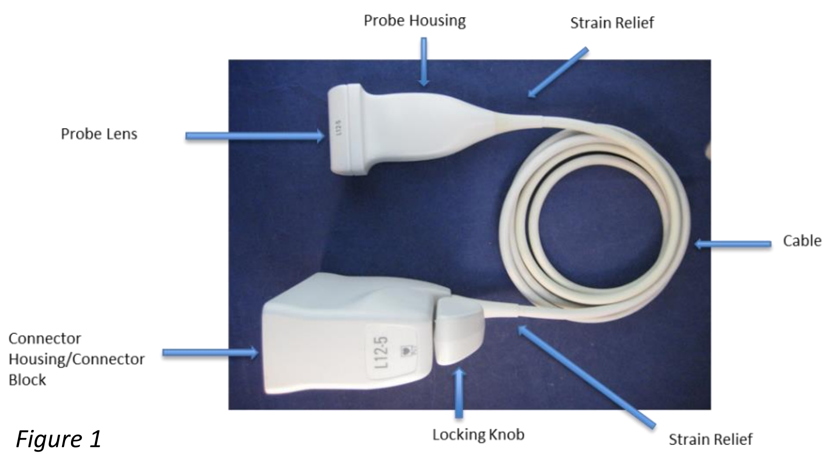


*Figure 1*

### Standard Ultrasound Parts:

The standard ultrasound probe consists of:

- Array assembly
- Cable assembly
- Electronic PCB's
- Housings
- Misc. parts. (strain reliefs, connector block, locking knobs)

Each probe has an array, which itself is an assembly, and a cable, which is also an assembly with all sorts of individual components involved. There are circuit boards and the various components within these assemblies that connect either to the array or the cable. There are plastic housings to enclose these items. Plastics and metals enclose the connectors plus all the individual pieces: strain reliefs, screws, bolts, nuts etc.

 

The array is key and must be designed, tested, and proven; the electronics operate the array and connect to the system, etc. Transmitting and receiving signals must be processed through the probe and electronics enable the performance of these tasks as well. Various plastics, silicone materials, and adhesives are used in the design of the probe.

Cable design is a completely different project. Cables must be custom fit to the new array, to connect to the interconnect on the array. Sometimes this is done by individually soldering every micro coax wire onto the array, sometimes with flex circuits, sometimes micro connectors are used. It varies and depends on the preferences of the engineer in order to optimize the design. The cable has to work electrically, but also acoustically it must not produce a lot of noise, signal noise problems or signal loss. The actual diameter of the micro coax varies in ultrasound probes depending upon the array and the frequency the array is operating at--much of that is due to signal loss or noise.

A lot of lenses are made from a base silicone material, but still must be designed for the optimum acoustic output/throughput to minimize signal loss. There's considerable design work that goes into the lens. Probe lenses are not easily obtained, nor are their components or the tools. Tooling is not available off the shelf—everything requires specialized tooling. To manufacture or repair probes you must have specialized tooling, which adds cost. Probes must be designed so that it is manufacturing-friendly—i.e. repeatable, consistent processes, economical costs of materials, etc. Back to Top

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## RAW MATERIALS

Various crystal type materials make up most piezoelectric arrays, ezt arrays. Many are raw earth materials used to manufacture the actual array crystal. Raw plastics which typically come in a pellet form are used and must be medical grade plastic. Silicone materials are used for lenses, any strain reliefs, and other rubber pieces. Cable (raw cable, Micro coax, which has bundles from 64 to 256 wires), PVC type of material are used to enclose the cable jacket. A wide variety of adhesives and sealants are used but must be medical grade. Some raw materials include:

- Naturally occurring crystals
- Quartz
- Berlinite ($AlPO_4$), a rare phosphate mineral that is structurally identical to quartz
- Sucrose (table sugar)
- Rochelle salt
- Topaz
- Tourmaline-group minerals
- Lead titanate ($PbTiO_3$)

 

## Material Testing, Biocompatibility:

All materials going into an ultrasound probe must be medical grade and need to be tested to biocompatibility. For ultrasound transducers the tests performed are mainly Cytotoxicity but possibly Sensitization and Irritation. The adhesives, plastics, rubber materials, etc. are all tested to insure biocompatibility and are of medical grade certification.

- As stated by the International Organization of Standards (ISO): "The primary aim of this part of ISO 10993 is the protection of humans from potential biological risks arising from the use of medical devices."

Manufacturers do not want to design a probe that runs the risk of causing harm, risk, or irritation to the patient (i.e. rash, etc.). The various materials, chemicals must be both medical grade and biocompatible. This, of course, adds to the cost of manufacturing probes.

### Lens Material Testing:

The lens touches the patient and has a complicated design. From a repair standpoint, much testing and validation is necessary before replacing a lens—must be biocompatible and high quality so it does not change the acoustical output. You can have a highly functional array, but if the lens is poor quality, the quality of the acoustic output is compromised. The shape and thickness of the lens is critical, and tests must be run to confirm the transmit signal is attenuating without signal loss, without scattering.

GE, Philips, Siemens have metals in their lenses (i.e. gold, silver, aluminum). They have added these materials in order improve the image performance. Much testing goes into the lenses from a manufacturing standpoint. Special devices are used to conduct lens testing. Much cost is added due to the lens component of the probe.

Measurement testing the lens attenuation need to be performed. This validates the acoustical performance of the lens relative to the array.

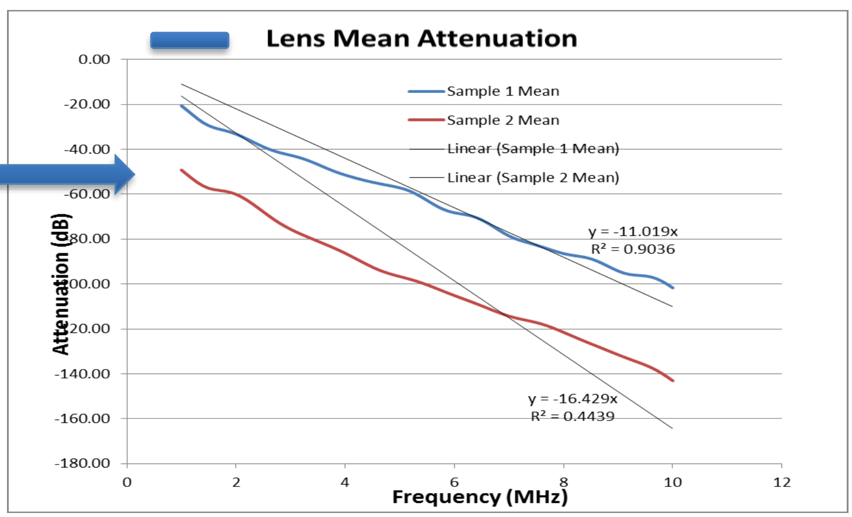


*Figure 2*

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## ARRAY MANUFACTURING

The array itself has many components (*see Figure 3*) and contains the highest cost of the components. It is critical to the performance of the probe. Design engineers continue to develop new arrays to increase clinical performance and expand applications. Array design and manufacturing is costly. Design time and material costs are high. Raw crystal, a key raw material necessary to manufacturing arrays, is very costly, currently over $1M per cubic ton.

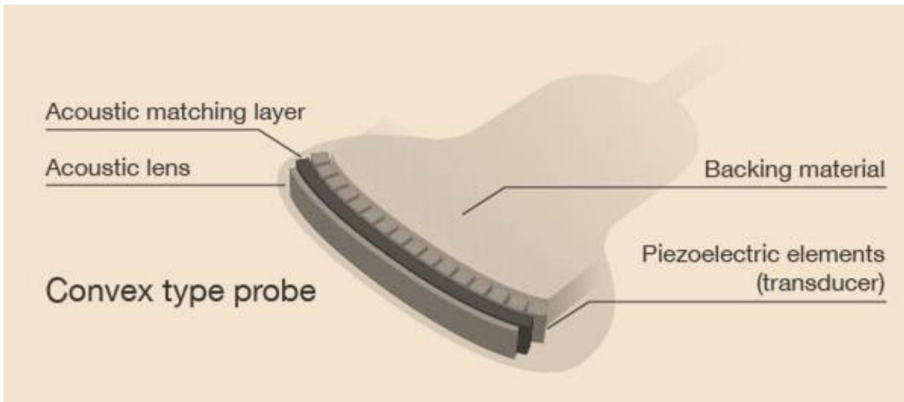


*Figure 3*

The manufacturing process is difficult with long lead-times. (*see Figure 4*). The materials must be added, mixed, molded, and heated; they must polarize the arrays and then age them. Every step needs specialized tooling.

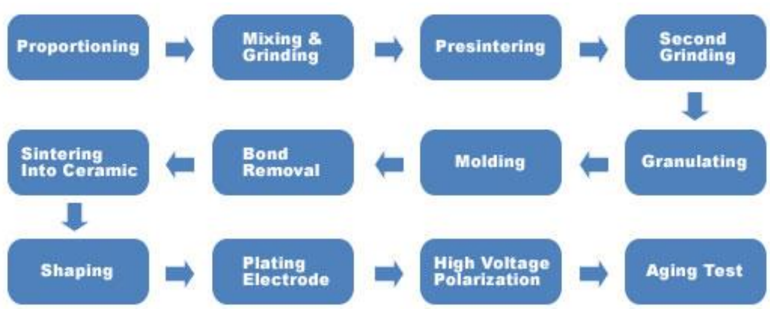


*Figure 4* – Steps in manufacturing process

There is a low yield of the arrays during their manufacture. A popular array is the single crystal array, which gives you a tremendous imaging quality, but has a low output yield. The output yield for single crystal array is just over 50%, meaning if a manufacturer is producing 100 arrays, they typically get only 50 or so for use. All the loss during production adds to the cost of the probe.

 

Raw material is processed using special ovens at high temperature. Arrays go under several thousand degrees Fahrenheit. Heat resistant tooling and machines used to produce the arrays are expensive. Advanced, specialized cutting tools (splintering), highly advanced tools and ovens are very costly.

All the special tooling, processes, manufacturing yield loss, and design time add to the cost of the final ultrasound probe. The cost of this high-priced production gets passed on to the rest of the industry.

### Array Testing:

Once an array is designed, finalized and manufactured, the OEM must get it acoustic power tested. The cost of these powered tests are several thousand dollars. The FDA requires acoustic levels are met depending upon what the array is used for (vascular, cardiac, fetal, etc.). *See Figure 5*. These levels are set by FDA and the American Institute of Ultrasound in Medicine and others and must be met by manufacturers without exceeding them.

Example: If a manufacturer designs an array for a vascular imaging and it exceeds 720 milliwatts per centimeters squared. They must complete a redesign, rework to get that output down below 720.

Power output for the arrays are strictly regulated and all array manufacturers must adhere to the standards. The final cost increases greatly if the OEMs performs a redesign, repeating the design process in order to adjust the acoustic level down.

**Table 2-1: Preamendments Acoustic Output Exposure Levels**

| Use | $I_{SPTA.3}$(mW/cm$^2$) | $I_{SPPA.3}$(W/cm$^2$) | or MI |
|---|---|---|---|
| Peripheral Vessel | 720 | 190 | 1.9 |
| Cardiac | 430 | 190 | 1.9 |
| Fetal Imaging & Other* | 94 | 190 | 1.9 |
| Ophthalmic | 17 | 28 | 0.23 |

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic

*Figure 5* - taken from page 19 of *Guidance for Industry and FDA Staff, Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued September 9, 2008*

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## ELECTRONICS

High performing electronics are added to maximize the performance of the probe. Increasingly, probe electronics are found in the probe heads as well as the connector, where they've been located for years. The ability to add electronics in the probe head is attributed to the introduction of the new arrays and increasing clinical performance needs. Every electronic aspect must be designed, the board flat, the component circuitry, etc. More and more probes are multiplex; they are using Complex Programmable Logic Devices (CPLD), BGA chips, etc. Some of these components are very costly even if off-the-shelf components are used. By adding multiplexing circuitry to probes, arrays can now simulate thousands of elements.



The use of multiplexing circuits, CPLD, BGA and other advanced components, provides improved clinical performance and uses for ultrasound in expanding clinical environments.

Multiplexing has allowed probes to simulate thousands of elements as opposed to 128 elements; however, the circuits must be designed based on how you want the array to send and receive, what clinical application it's used in.

Many probes are now using Matrix Array technology, these all use multiplex, all using components like CPLD. Some have firmware and software flashed on the components which adds to the software development costs.

As you can see, there are several levels of electronic design that can go into the development of a probe.

### ASIC Technology:

Many probes today use ASIC Technology. The Philips X7-2T TEE probe uses this technology. An ASIC is an application-specific integrated circuit designed specifically to do a function for a device. These are used outside of medical devices.

As opposed to off-the-shelf components, the ASIC requires custom design. ASIC use in ultrasound probes is increasing. This is allowing for expanded use of ultrasound diagnostics but is adding complexity and cost. Development costs alone for one single ASIC can run into the $400K to $500K range.

> An Application-Specific Integrated Circuit (ASIC) /ˈeɪsɪk/, is an integrated circuit (IC) customized for a particular use, rather than intended for general-purpose use. For example, a chip designed to run in a digital voice recorder or a high-efficiency Bitcoin miner is an ASIC. Application-specific standard products (ASSPs) are intermediate between ASICs and industry standard integrated circuits like the 7400 series or the 4000 series. (Wikipedia Definition)

Philips, GE, and Siemens have been successfully using this technology for years. Examples of ASIC technology in 3D TEE Probes include the Philips X7-2t, GE 6VT-D, and Siemens Z6M. Engineers have designed ASICs right in the array assemblies which makes it difficult to repair and/or diagnose. Because of the complexity of the assembly design, it is costly to have an ASIC replaced. Back to Top



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## CABLE DESIGN

Cabling is custom designed. Cable design is a long and tedious process. Micro-coax wiring, the wiring used in probes is a very specific cable and is not widely available. It is very small and there is a limited number of manufacturers. The raw cable is the key component. Micro coax must be designed to transmit and receive both high voltage for transmit pulses and receive low amplitude RF return signals--all while maintaining very low signal to noise ratios. If the wiring is not done correctly, the image can greatly be hindered due to the noise that can be created.

Many steps are taken in designing and then manufacturing the cables. From the raw cable, you must determine the different connectors, possibly circuit boards, two strain reliefs, RF shielding in addition to the outer shield of the micro-coax, determine what the outer jacket will be made of, and many other necessary small components.

### Cable Manufacturing:

Cable manufacturing is complex. Every ultrasound probe cable assembly is handmade. Each wire must be cut and prepped using a laser. Testing includes high-pot testing and conductivity tests. Hand soldering and bar soldering is needed for the wires. Manufacturing also requires molding of strains and other rubber/plastic parts. Back to Top

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## PLASTICS, CONNECTORS, SILICONE MATERIALS

Probes use a variety of plastic parts. These include:

- Housings
- Nose pieces
- Domes
- Handles, etc.

All plastic parts should be medical grade material. For this grade of plastics, the cost goes up dramatically. Everything in the plastic house must have CAD design work done during development: housings, handles, domes, etc. Special features to add ergonomics, comfort and aesthetic appearance add cost to the design and manufacturing tooling of these parts. Even colorants add cost.

 

### Plastics Manufacturing:

Raw materials are fed into an injection mold machine. The material is heated and flows into the specially designed mold tool to make the part. As with arrays, there is a loss of material during manufacturing.

### Connectors:

Every probe must connect to the ultrasound system. Some require specially designed connectors. Others can use standard off-the shelf connectors. Regardless, the connector is designed to fit both the cable assembly and the system connector PCB. A locking mechanism must be designed. To keep costs down, more OEM's are using available connectors made by large connector manufacturers.

Obviously, the connector chosen has to fit into the housing design. This requires coordination between the teams/engineers assigned to each component part.

### Rubber Components (Silicone/Polymers):

All probes require rubber/silicone components.

- Strain reliefs
- Lenses (most)
- Misc. parts. (bladders for 3D/4D; tubes for TEE, etc.)

Rubber tooling runs from the simple to the complex. Insertion tubes for TEE probes are more complex and require significant engineering and tooling to manufacture.
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## FINAL PROBE ASSEMBLY

Once a probe has all the material pieces designed, the next step is sub-assembly and final assembly. Each component of the probe must be assembled and tested through the manufacturing process, this includes:

- Array
- Cable
- Electronics
- Connectors
- Mechanical parts in 3D/4D and TEE if applicable.

Even with today's automated manufacturing systems, ultrasound probes and sub-assemblies continue to be manufactured primarily by hand. This includes every cable, PCB, array and even the final assembly of the finished probe product. The labor cost is high in probe manufacturing. Any re-work needed due to material or workmanship problems will add to the manufacturing cost. Back to Top

 

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## IN CONCLUSION-WHERE THE COSTS ARE

As we have seen, the probe assembly is a complex product. Much of the “cost” is in Intellectual Property (IP). Manufacturers have a right to cost for that. Material costs such as the array are also high, plus power testing. Labor to assemble all the various components is very costly.

Finally, all the development costs, manufacturing costs, yield losses, etc. add up quickly. TEE and 3D/4D probes add a whole other level of cost and complexity. Mechanical parts, liquid mediums, motors, etc. All this adds to the end user price. The more complex the probe, the more cost. New technologies tend to be more expensive. Back to Top

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## PROTECTING YOUR INVESTMENT

With the high cost of probes, their initial cost at point of purchase, potential repair costs, and eventual replacement costs, you must look at ways to protect your probe inventory. This is best conducted one probe at a time over the lifetime of the probe.

Catching problems at a minor stage will protect you in the long run. The damage to an array is always a high-cost problem. By conducting periodic inspections, you can reduce the number of array replacements and potentially probe replacements in your department or facility.

You want to check your probes at every Preventative Maintenance check and every service event to make sure they are working properly. Verifying the process used for disinfection with the OEM is consistent with the process used at your facility is essential. Performing electrical leakage tests as well as inspecting the cables and lens are also very important.

> For a more detailed description of a probe inspection, see our white paper, *“Protecting Your Investment—Ultrasound Probe Care.”*

Although you cannot predict when a probe is going to fail, you can protect and predict which probes are going to fail due to misuse. With proper care, use and maintenance, you can reduce the cost of ownership and lengthen the lifetime of your probes. Back to Top

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Author: Bob Broschart

Bob Broschart, transducer expert, has over 30 years of experience in medical equipment manufacturing, engineering, service and sales management. Bob helped to launch Axess Ultrasound, where he built their probe repair lab, R&D and operations. Bob currently serves as the VP of Depot Repair at Conquest Imaging's Fishers, Indiana repair lab facility where he oversees the entire operation.

Conquest Imaging, a Merry X-Ray Company
Conquest Imaging Headquarters
1815 Industrial Drive, Suite 100
Stockton, CA 95206
U.S.A.

Inquiries:
Phone: 1-209-942-2654
www.conquestimaging.com

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