

## **Introduction to Broadsound Corporation**

March 4, 2008

### **Broadsound Diagnostic Ultrasound Transducers List**

The Broadsound Diagnostic Ultrasound Transducers List, which contains the relevant info for our currently available transducers, is attached for your reference. Also, there are many ultrasound transducers under development that will become available soon.

For stocked items, ordered transducers would be shipped out within three working days upon receiving the payment; otherwise, a maximum of six weeks may be needed to fulfill special or quantity/volume orders.

Our offering is risk-free and satisfaction guaranteed; that is, we'll refund the money paid for the transducer if you or your clients are not satisfied with its performance.

We would develop the new replacement transducers for any OEM model dependant on market demand. As you'll see, the number of models in our probe list will be constantly increasing. You are welcome to inform us of your replacement probe wish list for consideration during planning of future transducer development.

### **About Broadsound Corporation**

As you might have noticed, Broadsound Corporation is a relatively new company. Broadsound's new ultrasound replacement transducers are functionally comparable to the OEM ones in imaging of leading brands such as ATL, Aloka, Philips and Medison and Toshiba; moreover, they are of brand-new design instead of the alternative used, repaired, or cloned products.

Our preferred business model is B2B2C (Business to Business to Customer/end user); that is, Broadsound works with the local professional partners to serve regional customers/end users.

Generally, for the new replacement transducers/probes, intentionally we would serve the following two groups of customers who need reliable, cost-effective and high performance ultrasound transducers:

1. End users who have possessed the ultrasound system console for more than four/five years and are seeking for excellent transducers/probes to replace the damaged ones, and
2. Refurbished or pre-owned diagnostic ultrasound system dealers/providers.

That expensive cost for new OEM transducers as well as the safety and maintenance issues for unreliable cloned, used or repaired transducers would always make people indecisive. Now, the Broadsound's new replacement transducers, which are officially approved by European Community and U.S. FDA, may be the end user's best choice for the ultimate solution.

Considering that ultrasound transducers are high-tech products, one might ask: How could a Taiwan-based company like Broadsound Corporation supply high quality/performance ultrasound transducers/probes?

Both Dr. Jiann-Hwa Jeng and Dr. Ying-Wei Yuan, the CEO and COO of Broadsound Corporation, respectively, graduated from The Pennsylvania State University of USA with Ph.D. degrees in Engineering. The Pennsylvania State University is one of few prestigious institutes globally that are famous in developing high performance acoustic transducers.

Dr. Jeng and Dr. Yuan have over 25-years experiences on ultrasound imaging system development including transducers design. In addition, we have Dr. Lai, Ph.D. and six engineers with Master degrees as our core team, each of them with over 13-years of experience on ultrasound transducers/probes design and manufacturing.

Besides specializing in ultrasound transducer design and manufacturing, Broadsound's team also has full knowledge of electronic imaging system design, guaranteeing good matching between system console and transducer, and excellent noise/interference immunity.

Some of our customers' opinions and Broadsound's leaflet are attached for your references. Note that at the bottom-left corner of the inside page of Broadsound's leaflet, the right-sided virtually noise/interference free image was obtained by using a Broadsound AL3C34A probe which is the replacement for Aloka UST 934N-3.5. The left-sided NOISY image was gathered, in the same noisy condition, by using an original Aloka UST 934N-3.5 probe on a Aloka SSD-620 system.

Meanwhile, the super high resolution of Broadsound's AT8L125 transducer, which is the replacement for ATL L12-5/38mm, is also shown on the inside page of the leaflet. Among those probes developed for ATL HDI 3000/5000 series, the AT8L125 or L12-5/38mm probe is unique in several aspects:

1. Wideband and high frequency,
2. 192 elements,
3. Sophisticated electronics involved in both connector end and probe handle,
4. Able to immediately replace existing L7-4 and L10-5 probes, and
5. Super-high resolution.

### **Online Information for CE<sub>0197</sub>**

The CE<sub>0197</sub> mark on Broadsound's transducers/probes is granted by the Notified Body: TÜV Rheinland Product Safety GmbH of Germany and the number 0197 is the Notified Body number for TÜV Rheinland Product Safety GmbH.

The pertinent information is listed as following:

- 1 Approval EC Directive 93/42/EEC Annex II, Article 3  
Full Quality Assurance System, Medical Devices

- 2 Certificate of Quality Management System for Medical Devices  
According to EN ISO 13485:2003
- 3 Certificate for a Quality Management System, Standard Conformity  
According to EN ISO 9001:2000
- 4 Certificate of Conformity

The above information is available at the website of TUVdotCOM ([www.tuvdotcom.com](http://www.tuvdotcom.com)), where Item 4 can be found under “Search for certified products” by manufacturer: “Broadsound Corporation”, and the above-mentioned Items 1, 2, and 3 can be found under “Search for certified products” by TUVdotCOM ID number: “0000007881” which is exclusively assigned to Broadsound Corporation.

### **U.S. FDA’s New Policy toward Ultrasound Replacement Transducers**

It is worth noticing that both U.S. FDA and European Community have revealed clear policies toward non-OEM ultrasound replacement transducers that include new replacement as well as repaired and remanufactured transducers. Basically it seems that they are determined to regulate those repaired and remanufactured transducers, which have been in the “GRAY AREA ZONE” for past forty years.

For your information, the U.S. FDA’s new policy is quoted below:

“ *Appendix A*

#### *Non-OEM Replacement Transducers*

*These transducers are generally those that are manufactured by a party **other than the original equipment manufacturer (OEM)** and are intended to replace a transducer originally provided by the system manufacturer. They can be either **new transducers** or original equipment transducers that have been **modified or remanufactured**. **A new 510(k) premarket notification should be submitted for all non-OEM transducers.** .....*

—— Draft version of Appendix A in “*Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*”, Issued by **FDA, U.S.A.**

I am glad to share with you that, on October 15, 2007 U.S. FDA formally informed us that for our first batch of new ultrasound replacement transducers, the submission of 510(k) Premarket Notification has been cleared.

Aside from earning the CE<sub>0197</sub> mark of European Community, this is another and perhaps the most important milestone for Broadsound Corporation. Now Broadsound Corporation is the sole company in the world that has both CE<sub>xxxx</sub> mark and FDA 510(k) Marketing Clearance on new ultrasound replacement transducers.

### **Online Information for Premarket Notification (510(k))**

The information of 510(k) Premarket Notification for Broadsound's products can be found at the U.S. FDA's website as follows:

1. Enter web page "http://www.fda.gov/cdrh/databases.html"
2. Select "Premarket Notifications (510(k)s)"
3. Search by keying in 510K Number: K070195.

The K070195 covers the 510(k) Premarket Notification for our first batch of ultrasound transducers totaling nine models.

### **Marketing Consideration**

Contrast to the cloned, repaired and used transducers market, the market of new replacement transducers is a new business sector, and some end users may have some concerns.

Firstly, their major concern may regard the issues of safety and compatibility; or more specifically, will the Broadsound's new replacement transducers harm the patient and/or damage the system console? The answer is an absolute "No", which can be justified by the fact that Broadsound's new replacement transducers comply with all relevant safety regulations and are officially approved by European Community and U.S. FDA.

Secondly, how are the performance and image quality for Broadsound's new replacement transducers? Recently Echoserve of USA has evaluated Broadsound AT3C52B and AT8L125 that are the replacement transducers for ATL C5-2 and ATL L12-5/38 mm, respectively. The evaluation report of Echoserve is attached for your information. Those images shown in the report were taken with a HDI 5000 SonoCT. Meanwhile, we've received much field feedback from our customers. Overall we've had many satisfied compliments and hardly hear complaints.

With our risk-free offering, and guarantees in performance, image quality, and safety, Broadsound's new replacement transducers are the best choice to meet your transducer needs.

Sincerely,  
Ying-Wei Yuan, Ph.D.  
Chief Operating Officer