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# Live volumetric imaging (LVI) intracardiac ultrasound catheter

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SUMMARY

The Live Volumetric Imaging (LVI) catheter is capable of real-time 3D intracardiac echo (ICE) imaging, uniquely providing full volume sectors with deep penetration depth and high volume frame rate. The key enabling technology in this catheter is an integrated piezoelectric micromachined ultrasound transducer (pMUT), a novel matrix phased array transducer fabricated using semiconductor microelectromechanical systems (MEMS) manufacturing techniques. This technology innovation may enable better image guidance to improve accuracy, reduce risk, and reduce procedure time for transcatheter intracardiac therapies which are currently done with limited direct visualization of the endocardial tissue. Envisioned applications for LVI include intraprocedural image guidance of cardiac ablation therapies as well as transcatheter mitral and aortic valve repair.



## 1. Background

Available modalities for interventional echocardiography include 3D transthoracic (TTE) and transesophageal (TEE) echo as well 2D ICE. The use of 3D echo is increasing for transcatheter aortic and mitral valve surgeries, as this provides more accurate assessment of valve annulus for prosthesis sizing as well as more intuitive views for intraprocedural guidance. The well-documented limitations of 2D compared to 3D ultrasound include: mental reconstruction required of 3D structures from multiple 2D slices; geometric assumptions for quantitative measurements leading to inaccuracy and variability, especially for asymmetric or abnormal shapes; difficulty in visualizing structural dynamics (especially cardiac) in a single plane; patient anatomy and required probe orientation precluding acquisition of optimal view. While image quality of 3D TEE is generally adequate, procedural logistics are more complicated. Additional personnel including an echocardiographer and anesthesiologist must be present for the procedure, and patient risk and discomfort are increased as TEE requires general anesthesia and esophageal intubation.

Three-dimensional ICE would provide a catheter-based interventional imaging modality providing 3D views that can be reconfigured in real time. For example, volume views can be rotated to provide a different directional perspective, and any arbitrary plane or multiple planes within the volume can be displayed in real-time without movement or repositioning of the imaging catheter. Furthermore, ICE imaging allows targets to be viewed in the near field from the right atrium with better resolution compared to TEE and TTE. An illustration of 3D ICE is shown in Fig. 1.

## 2. Technology overview

LVI catheters contain novel pMUT matrix array transducers that are manufactured using semiconductor MEMS microfabrication techniques. Matrix transducer arrays enable azimuth and elevation phasing to produce real-time 3D ultrasound images. Semiconductor processing enables miniaturization and more efficient manufacturing such that smaller element size and higher element density can be achieved more easily than with conventional machined ceramic transducers. Matrix pMUT arrays with 256 to 512 elements have been fabricated that fit within a catheter lumen of 11F or less. Conventional 2D ICE catheters contain linear transducer arrays with 64 elements that are machined from bulk piezoelectric ceramic materials. The pMUT arrays also contain a piezoelectric layer for good acoustic performance; however, rather than individually cutting and assembling transducer arrays from ceramic sheets, pMUT technology is fabricated using semiconductor photolithographic techniques. Hundreds of transducer arrays can be produced in one silicon wafer and thousands of arrays in one batch of wafers. Furthermore, taking advantage of semiconductor economies of scale can reduce component manufacturing cost of the transducer array. Photographs of a pMUT matrix array and cable assembly as well as a silicon wafer containing the arrays are shown in Fig. 2.

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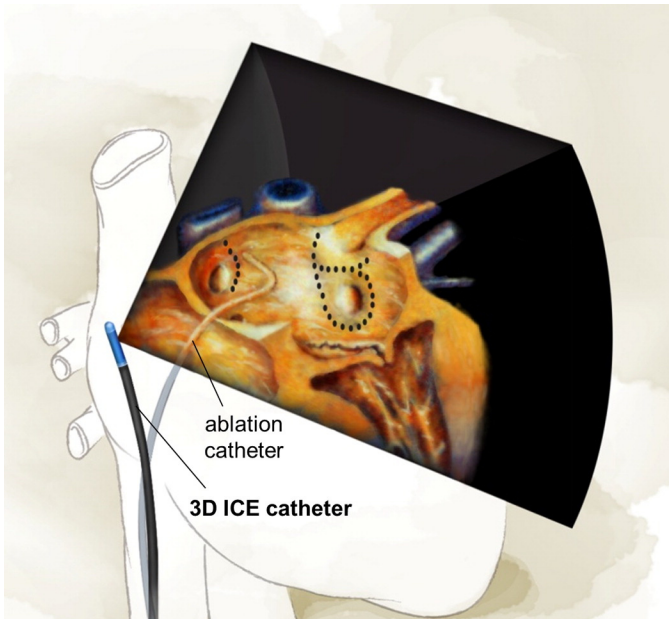


**Fig. 1.** Illustration of a 3D ICE catheter inserted into the right atrium and projecting a volume view into the left atrium to guide placement of an ablation catheter around the pulmonary veins.

The pMUT arrays are fabricated in silicon wafers and consist of piezoelectric unimorph membranes that form the active transducer elements. A lead zirconate titanate (PZT) thin film and metal electrodes are deposited on the silicon wafer and photolithographically patterned to form individual array elements. The silicon substrate is etched from the back side under each element to form a silicon membrane layer under the PZT and electrode layers. PZT is the same piezoelectric material used in conventional ceramic transducers. Because a thin film layer is used, pMUT elements possess higher element capacitance than ceramic transducers, enabling lower source impedance even for small matrix array elements to reduce parasitic losses due to cable loading.

Transducer operation for pMUT elements also differs from conventional ceramic transducers. The membrane elements in a pMUT array operate in a unique "flexure mode" enabling acoustic pressure output that is comparable to bulk ceramic transducers [1]. The piezoelectric film excites the natural resonance of the membrane structure to produce flextensional motion across the element width and buckling of the membrane, with resonance frequency inversely proportional to element width. Frequency range of 4 to 20 MHz has been produced using element widths of 50 to 130 μm. Dimensions in this range can be achieved easily using semiconductor photolithographic processes, whereas the smaller dimensions required for matrix array elements are more challenging for mechanical dicing operations used to produce bulk ceramic transducer arrays. Images of a pMUT element cross section as well as membrane deflection are shown in Fig. 3.

Another key component of the LVI technology is the integrated cable assembly which overcomes another difficulty in matrix array transducer manufacturing—the need to connect signal wires to each independent transducer element. For a matrix phased array with up to 512 elements that must fit inside a small diameter catheter,

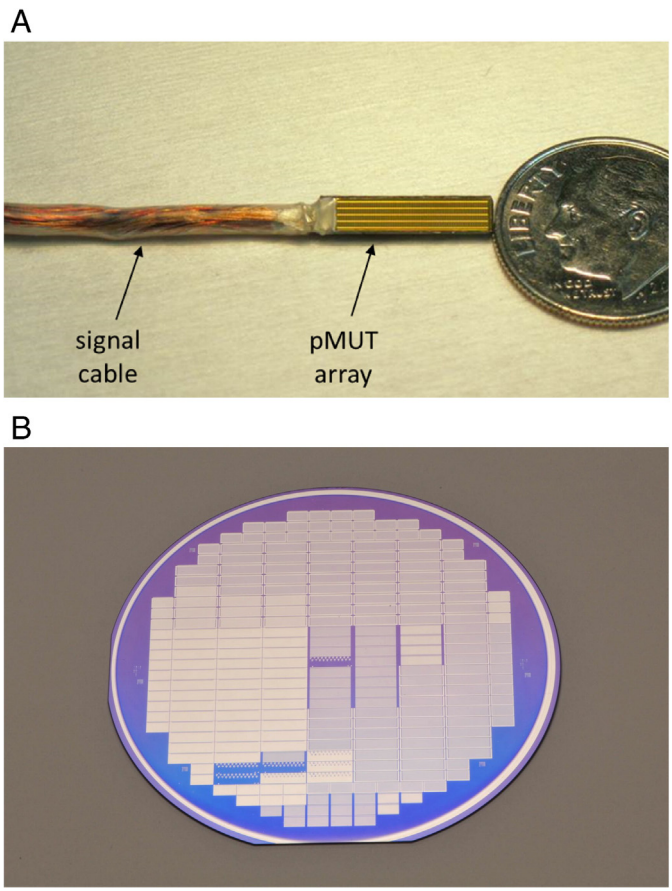


**Fig. 2.** (A) Matrix pMUT array containing 256 elements interconnected to a cable assembly. (B) Silicon wafer (100 mm diameter) containing over 200 pMUT arrays.

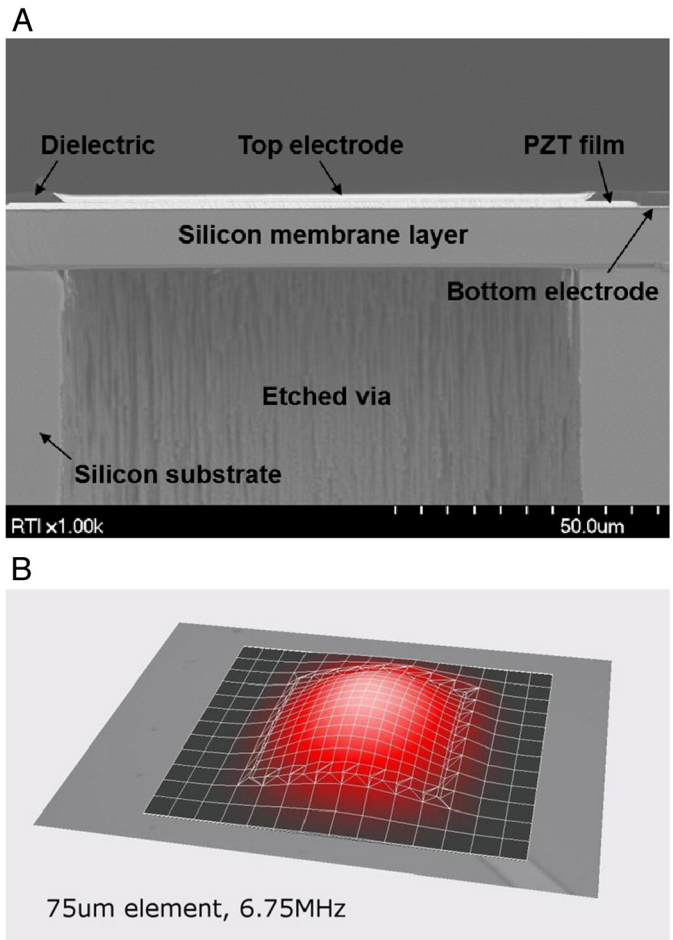


**Fig. 3.** (A) Cross sectional image of a pMUT membrane obtained using a scanning electron microscope. (B) Measurement of maximum mechanical deflection of a pMUT membrane operating at 6.75 MHz obtained using a high-speed optical interferometer.

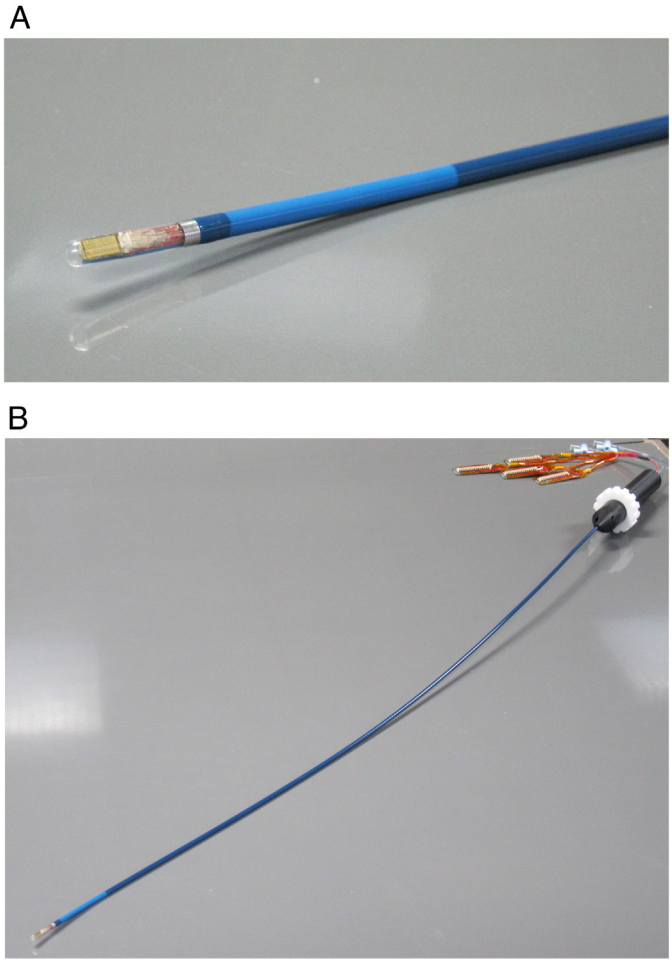


**Fig. 4.** (A) Photographs of the distal end of a 14F intracardiac catheter containing a pMUT matrix array with 512 elements. (B) Full prototype assembly including catheter shaft with 90 cm working length, steering handle and termination circuit boards.

conventional wiring approaches cannot be used due to limited interconnect density. Cable assemblies have been developed with signal wires attached to each transducer element that fit within a cross-sectional diameter as small as 2.5 mm. These assemblies are interconnected directly to the pMUT arrays using semiconductor advanced packaging and interconnect technologies.

## 3. Catheter prototypes

Prototype LVI ICE catheters were fabricated containing pMUT matrix arrays operating at 5 MHz. Fig. 4 shows a catheter assembly with pMUT array contained in a braided Pebax shaft, with marker band, stainless steel pull wire (not shown) and steering handle to deflect the catheter tip. The transducer cable was terminated directly to circuit boards proximal to the steering handle for connection to the ultrasound system cable.

Animal experiments were completed demonstrating *in vivo* intracardiac imaging in an adult swine using a prototype volume ultrasound scanner. The ultrasound scanner was capable of 16:1 receive parallel processing, enabling B-scans to be generated at up to 72 frames per second and volumes at up to 60 volumes per second. The catheters were inserted through a 14F introducer sheath in the femoral vein and advanced through the inferior vena cava and into the right atrium to produce real-time 3D echo imaging of various cardiac structures. Full volume sectors from 60° × 60° to 80° × 80° were obtained with penetration depth of 8 to 10 cm at frame rates from 20 to 30 volumes per second [2]. This is a substantial improvement over other intracardiac 3D echo modalities. For example, an ICE catheter containing a mechanically scanned linear array was reported with volume sector of 60° × 90° but at shallower 6 cm depth and frame rate of only 6 volumes per second [3]. The AcuNav-V ICE catheter is limited to a narrow 22° × 90° volume sector [4]. Three-dimensional TEE probes can produce a 60° × 60° volume at 7 to 10 volumes per second, but higher frame rates require reduction of volume size [5].

The LVI catheter containing novel pMUT matrix array technology can uniquely provide full volume intracardiac views at high volume frame rate. Furthermore as an ICE imaging modality, it is anticipated that better resolution can ultimately be achieved with targets closer to the imaging catheter and viewed in the near field. This combination of features can enable real-time three-dimensional imaging of cardiac volumes, with adequate frame rate to capture cardiac dynamics, and resolution sufficient to clearly visualize cardiac structures and defects and enable real-time tracking of therapeutic tools.

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