

Medical safety

To guarantee patient safety, medical ultrasound imaging equipment requires traceability of the fundamental measurements of their acoustic outputs. Through national and international bodies (such as IEC, EURAMET, FDA) there are a breadth of guidelines for manufacturers and end users to measure the output levels of their acoustic devices, and similarly acoustic limits set by regulatory

agencies that dictate what range of acoustic parameters can be applied to different tissues. To meet these guidance, and ensure safety, a calibration chain with good reliability is essential. The challenge for NMIs is to provide measurements with known uncertainties and assurances that allow medical products to be deployed safely and maximise their efficacy.

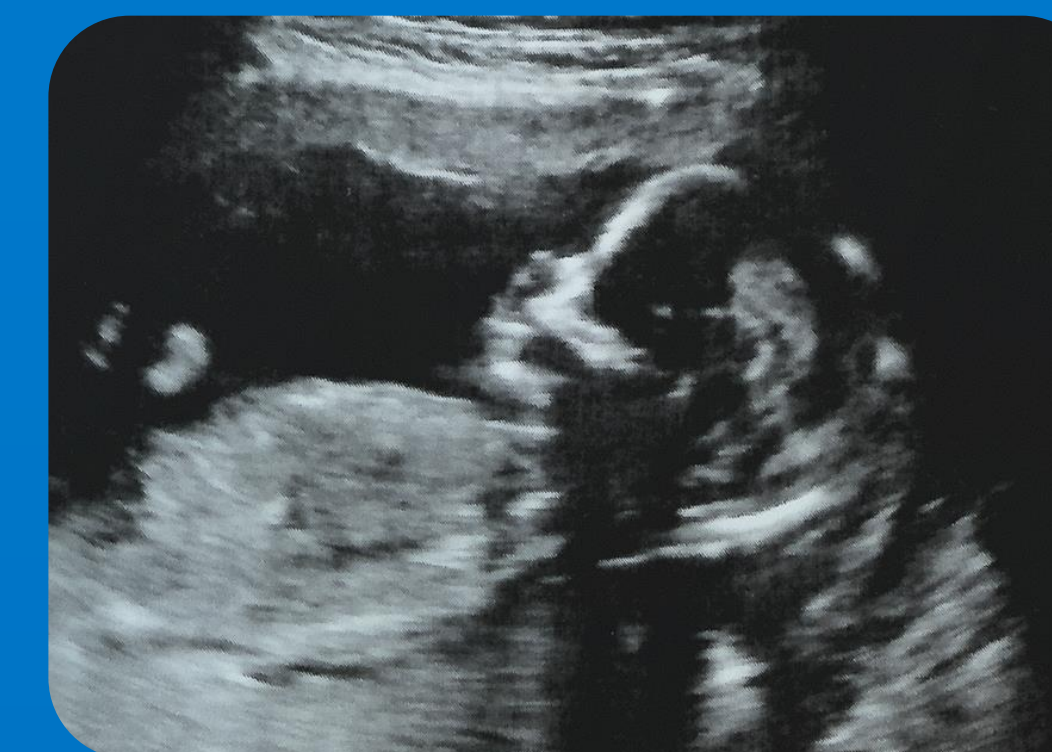


Figure 1: Ultrasound scans are the second most used diagnostic imaging modality in Europe^[1]. Providing safety assurances in the medical ultrasound industry is paramount, particularly given the technique's ubiquitous use in prenatal scanning.

Hydrophones

Hydrophones are the primary device for measuring acoustic fields, Figure 2. They are typically Polyvinylidene fluoride (PVDF) devices with a small diameter sensing element (40-500 μm) that can be immersed in a water-borne acoustic field. Hydrophones are sensitive to local pressure variations, directly generating a proportional output voltage.



Figure 2: Example hydrophone devices from different manufacturers. Hydrophones can detect the real-time acoustic pressure fields generated by medical devices. The three large devices are of *membrane* type, the mainly-silver cylinder is a *capsule* or *golden-lipstick* type, and the gold cylinder is a *needle* type.

Optical vibrometry

At NPL an optical method is used to realise hydrophone calibration. A laser vibrometer interrogates a thin-film flexible mirror placed within an ultrasound field, Figure 3. The film mirror oscillates with an amplitude proportional to the acoustic pressure incident upon it. Therefore, in measuring the mirror's displacement it is possible to provide SI traceability of hydrophone sensitivity (Volt/Pascal) to the metre.

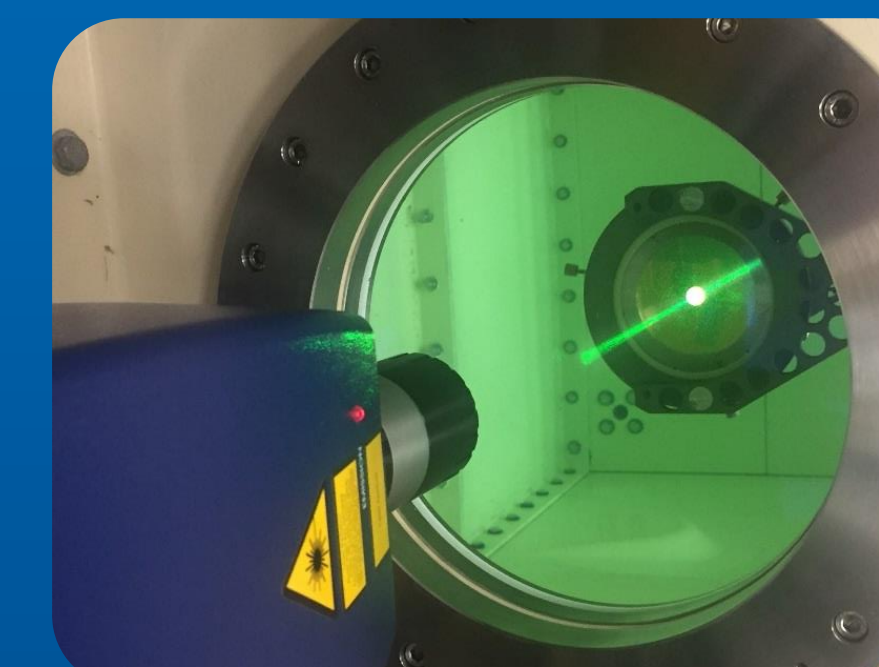


Figure 3: Image of the laser vibrometer measuring the displacement of the thin-film mirror. The reflecting layer of the mirror is thin enough (40 nm) to be partially transparent.

Challenges

Historically the application of many different acoustic fields was needed to cover the required medical frequency range (0.1 to 60 MHz). Recently a high-amplitude, short-pulsed, source has been developed that enables wideband measurement; the NPL Photoacoustic Source^[2], Figure 4. This novel device allows for simultaneous emission of frequencies covering the majority of the medical ultrasound range, in a single pulse.



Figure 4: NPL's Photoacoustic Source, a laser-generated ultrasound emitter that is capable of producing a broadband, continuous, frequency response up to 100 MHz. The device further works at close range, removing the need for time consuming alignment and minimising spatial averaging corrections.

Future development

A continual development of medical ultrasound devices is in the increase of the working frequency, and therefore improved imaging resolution. This is a further challenge to calibration methods, where higher frequencies are also difficult to generate and highly attenuated in all media. Future work will focus on generating repeatable acoustic fields up to 100 MHz, Figure 5, and the associated challenges with measuring such fields.

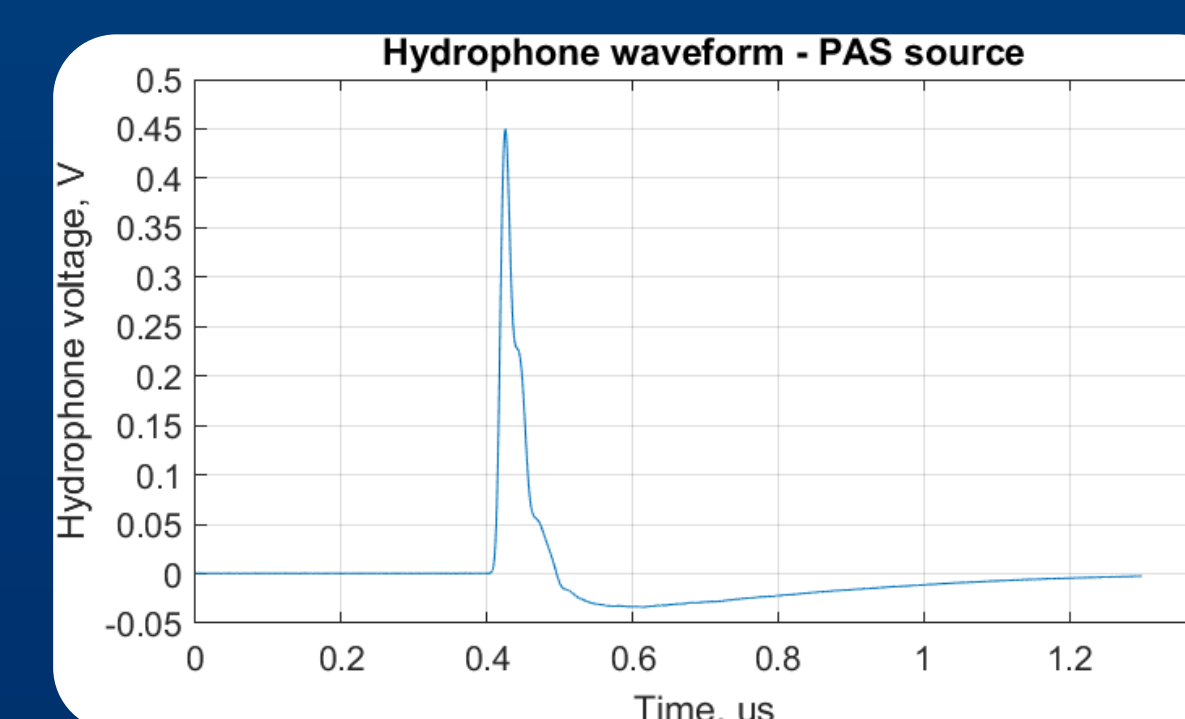
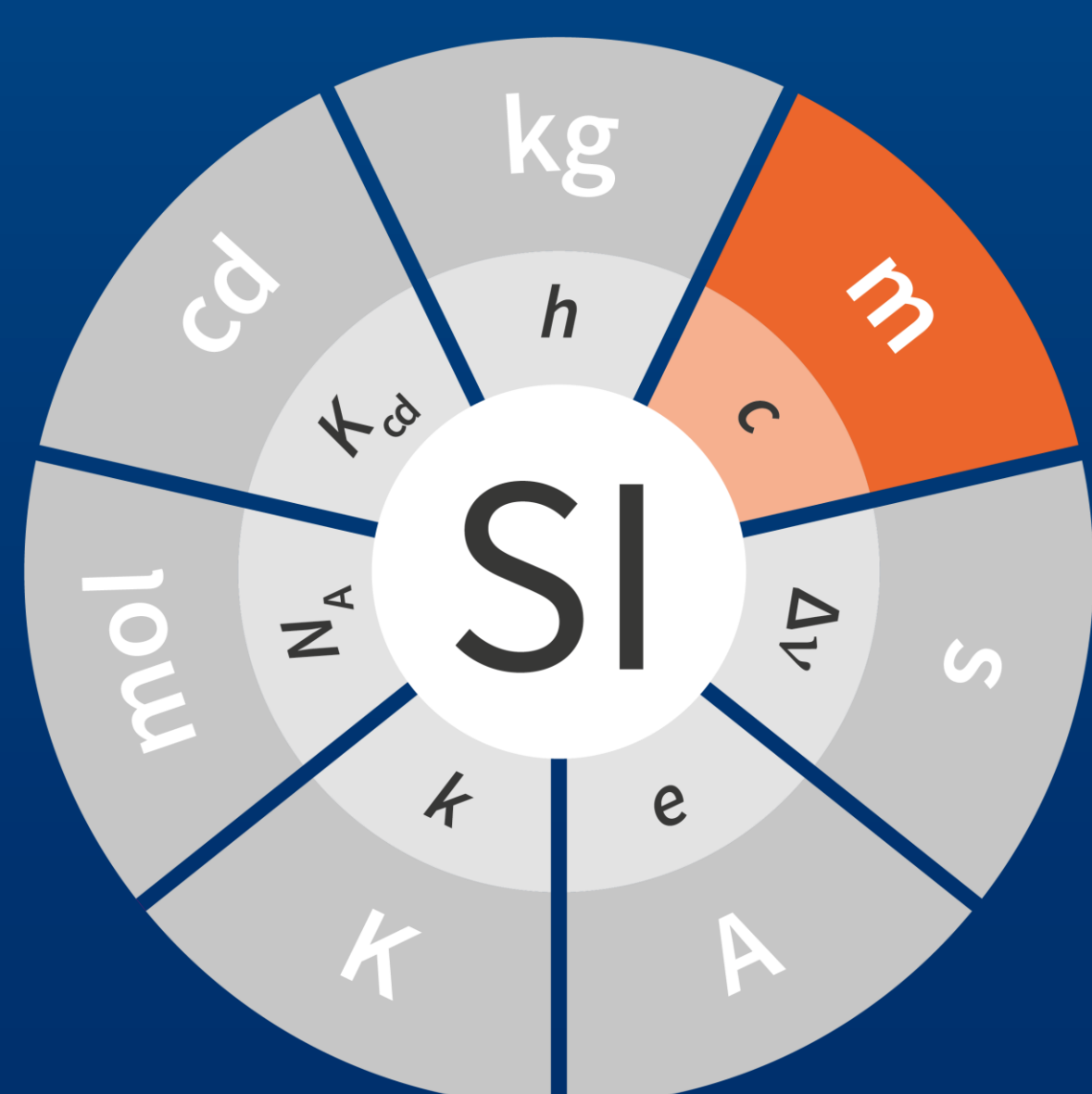


Figure 5: An example hydrophone waveform of an acoustic field generated by the Photoacoustic Source. This waveform was found to contain continuous frequency information up to and above 80 MHz.



References

- [1] Bolondi, Ultrasound in Medicine and Biology, Volume 26, S162 - S164
- [2] Rajagopal et al., J. Acoust. Soc. Am. 153, 2649 (2023)