Challenges associated with quantifying modern medical ultrasonic fields

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Regulatory drivers … many regulations

MDD/MDR

510 (k)

MDEL

+ a myriad of others

Regulatory drivers … but common methods

Particular requirements

IEC 60601-2 Series

Normative references

IEC 60xxx, 61xxx, 62xxx, 63xxx

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IEC 62127-1

IEC 62127-1 Ultrasonics - Hydrophones

Measurement and characterization of medical ultrasonic fields

Voltage → Pressure

In frequency domain, by default

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Wide bandwidth requirements

Hydrophone calibration

$$\frac{f_{awf}}{2} < f < 8f_{awf}$$

$$f_{awf} = \textit{acoustic working frequency}$$

0.1 MHz to 5 MHz

Hydrophones needed from 50 kHz to 120 MHz

2 MHz to 15 MHz

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Voltage to pressure conversion

$$v(t) = m(t) * p(t)$$

Take Fourier transforms

$$V(f) = M_L(f) \times P(f)$$

$$P(f) = \frac{V(f)}{M_L(f)}$$

Inverse Fourier transform

$$p(t) = \mathcal{F}^{-1}\left\{\frac{\mathcal{F}\{v(t)\}}{M_L(f)}\right\}$$

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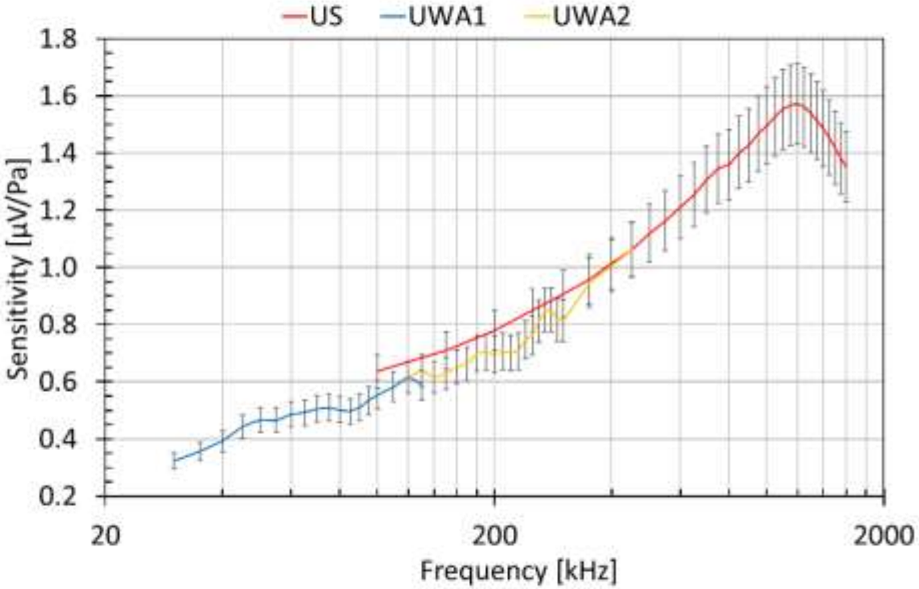
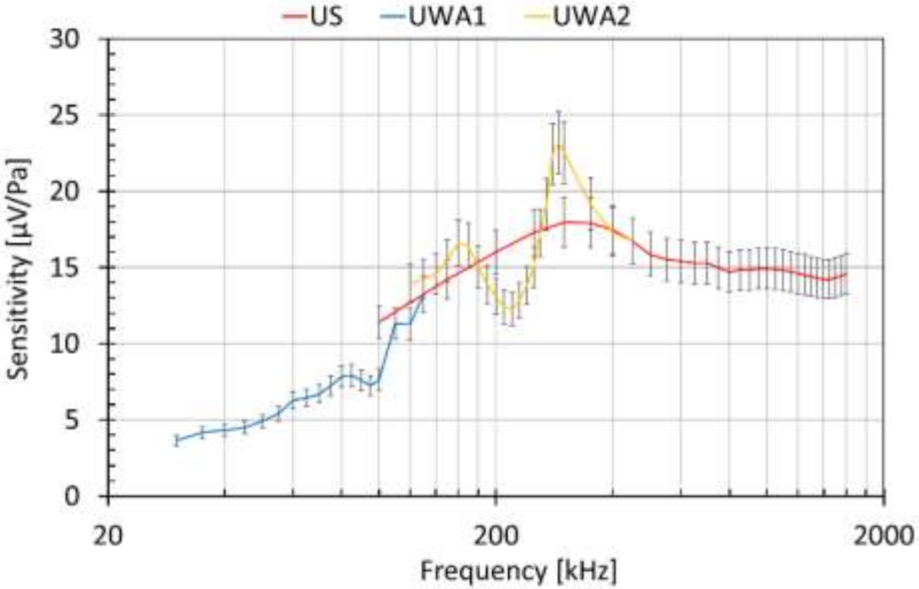
LF Bandwidth – crossover calibrations





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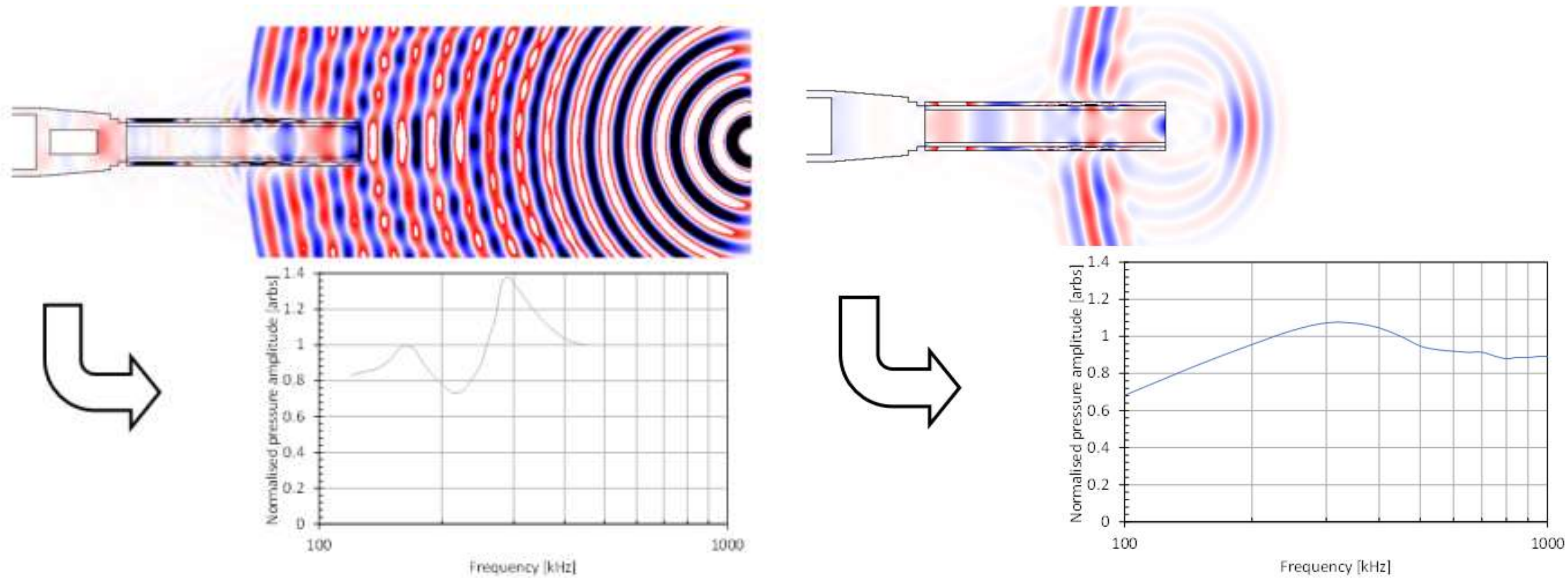
Crossover calibrations



S. Rajagopal et al. (2023), "On the Importance of Consistent Insonation Conditions During Hydrophone Calibration and Use," in IEEE Trans UFFC, vol. 70 (2), pp. 120-127,

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NPL
National Physical Laboratory

HF Bandwidth – limits of the primary

National Physical Laboratory

Up to 60 MHz

Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin

Up to 70 MHz

Commercially,

f_{awf} up to 50 MHz

+ Harmonic imaging

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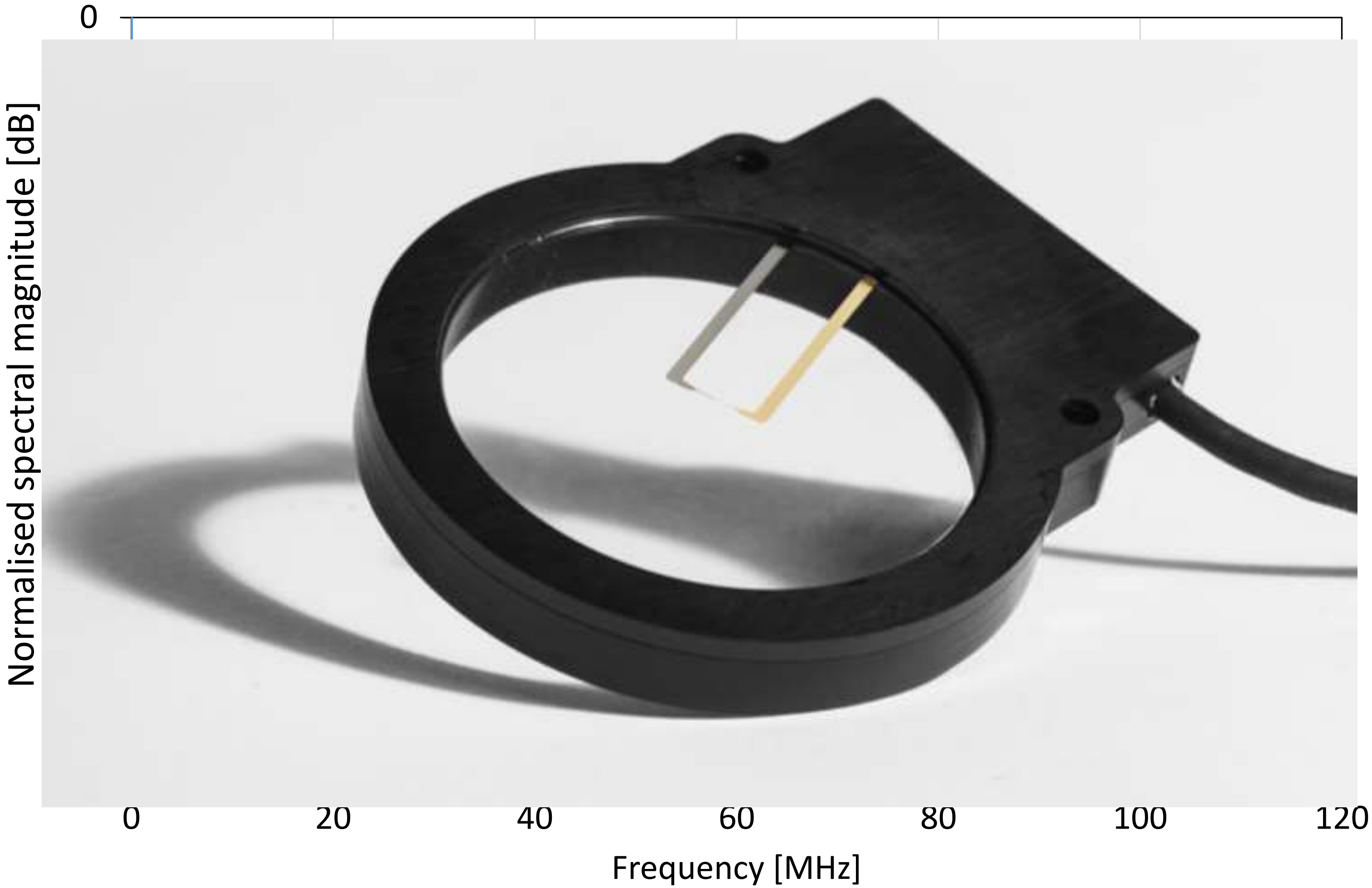
HF Limits



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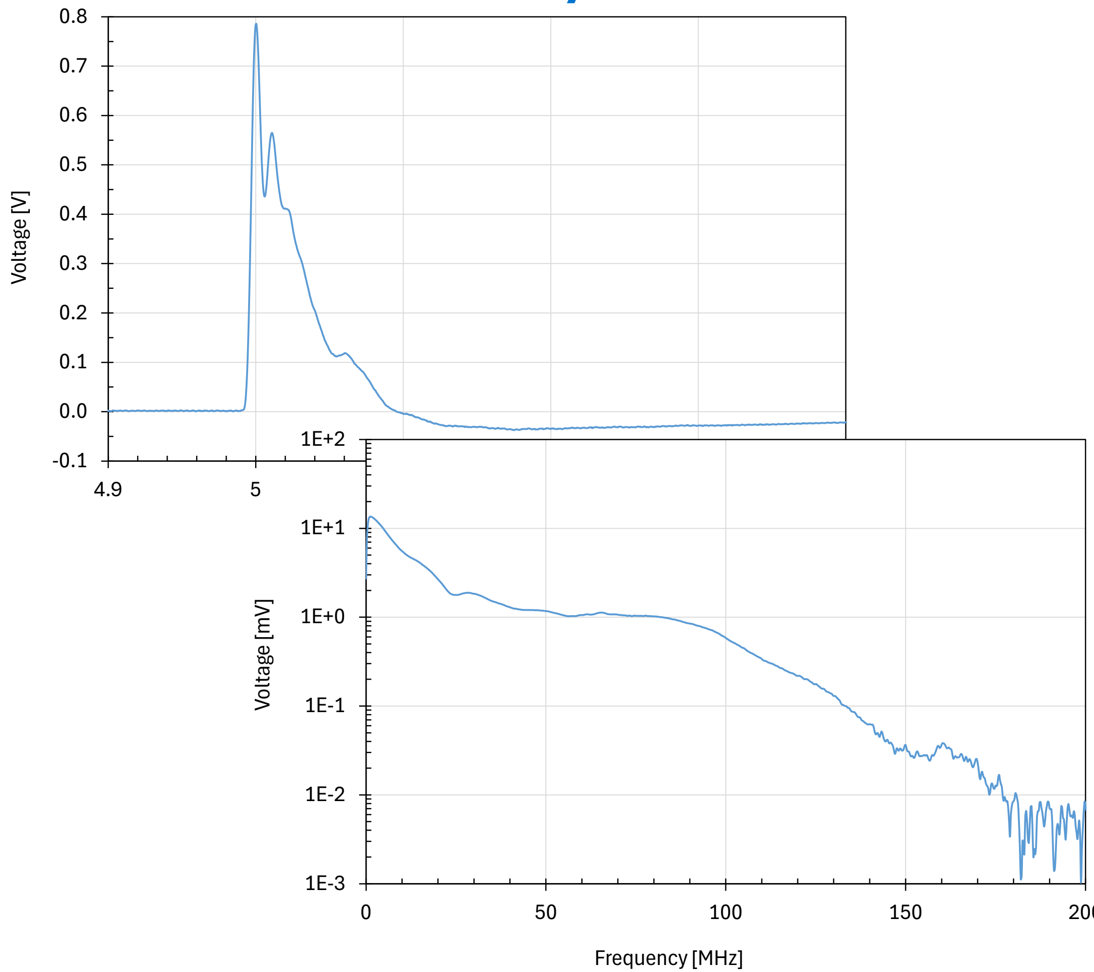
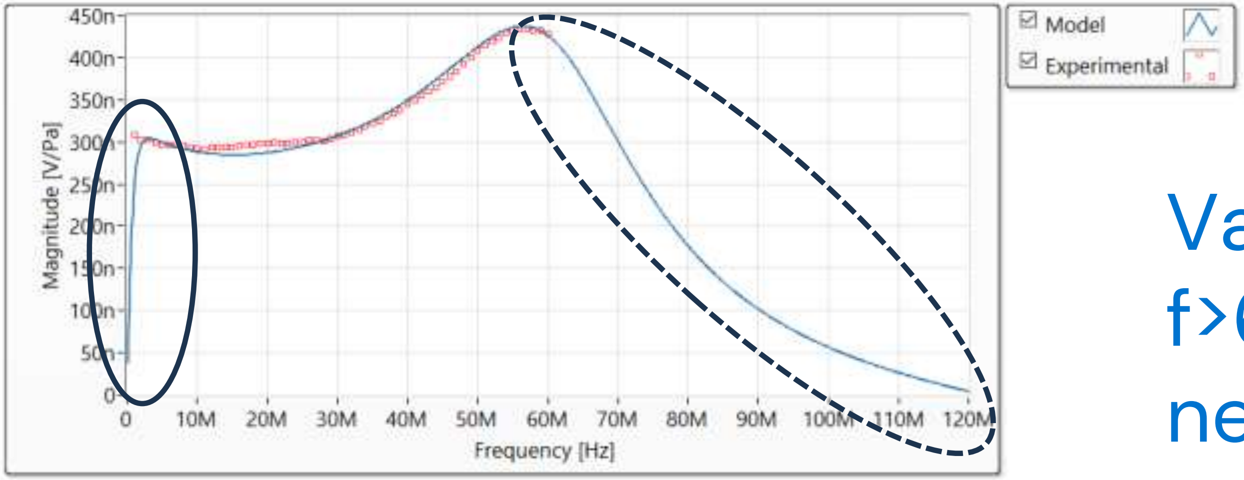
Advances to the NPL Primary standard



Rajagopal and Cox. (2020), "100 MHz bandwidth planar laser-generated ultrasound source for hydrophone calibration" in Ultrasonics, vol. 108, p. 106218

NPL
National Physical Laboratory

Semi analytical model vs experiment



Validation at f>60 MHz with new primary

Model still in development

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Hydrophone sensitivity function

$$M_L(f) = |M_L(f)|e^{i\varphi(f)}$$

Hydrophone sensitivity

Magnitude response

Phase response

Phase calibration only up to 40 MHz

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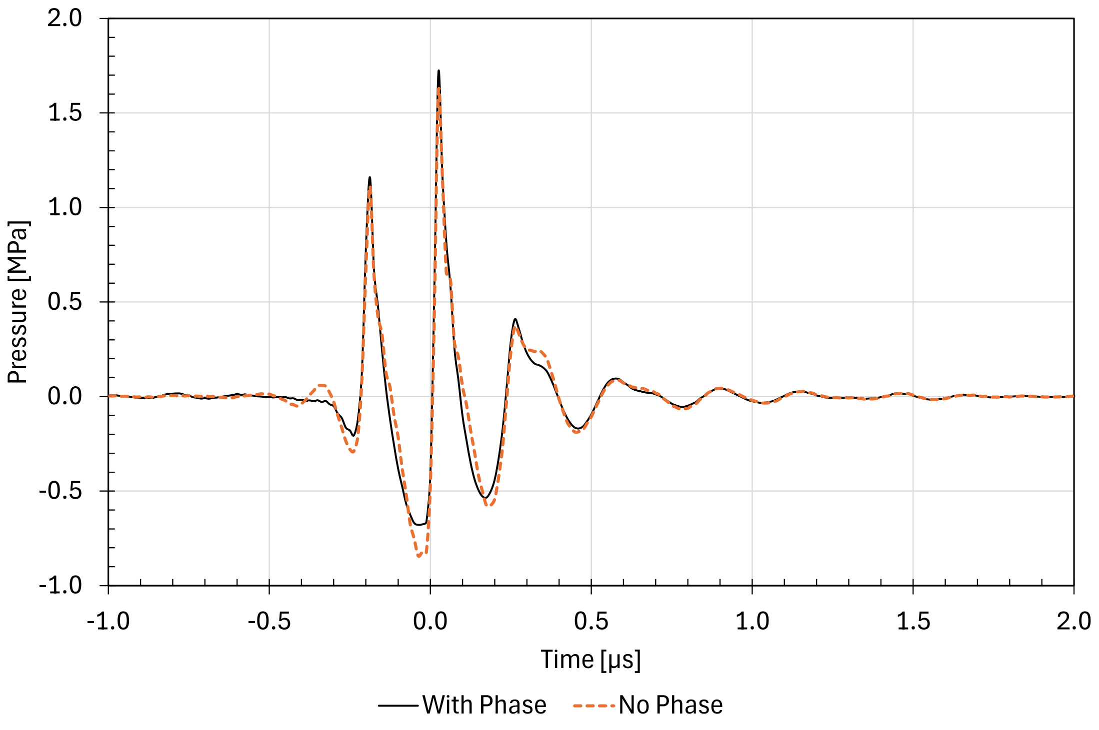
Phase response – why does it matter?

$$I = \frac{p^2}{\rho c}$$

Phase insensitive

$$MI = \frac{p_{r,0.3}}{\sqrt{f_{awf}}}$$

Phase sensitive



With: −0.68 MPa, Without: −0.84 MPa

MI Overestimate: 25%

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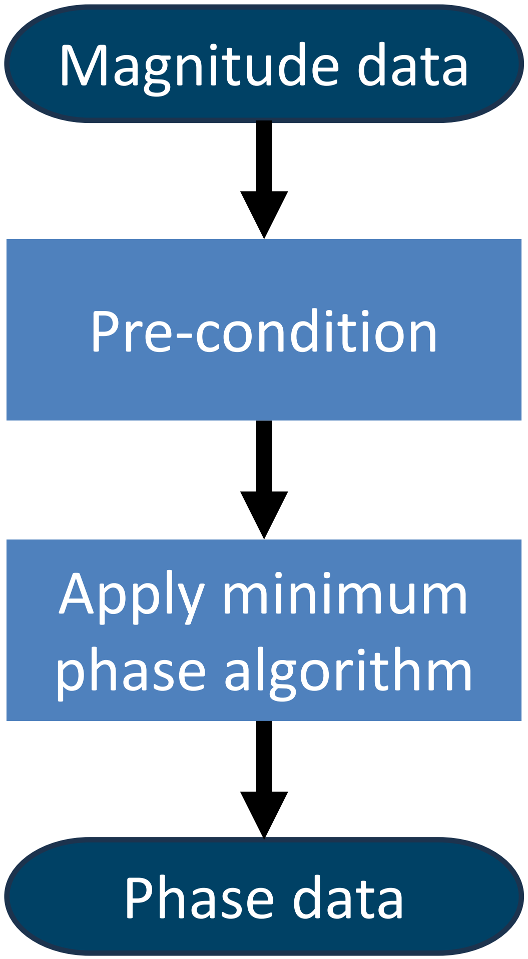
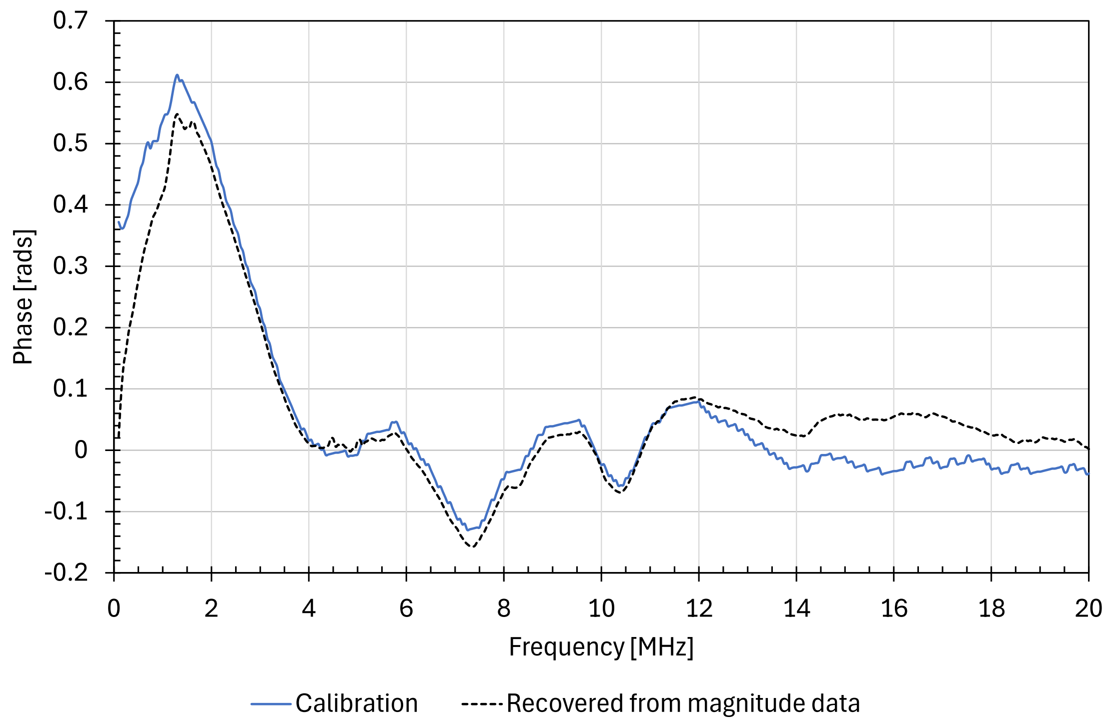
Phase retrieval





Koruk et al (2024) (In preparation), "Evaluation of the Use of Minimum Phase Approach for the Prediction of Phase Response and Uncertainty"

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To summarise

Ultrasound metrology still has substantial "unknowns"

Subtle variations can make a big difference

The devil is in the detail!

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