Safety, Efficacy, and Compliance of Ultrasound in Medical Applications

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Day 1, Plenary 3, Ultrasound Physics 1
Tuesday, 10 December
Ultrasound 2024, Coventry

National Measurement System (NMS)

An infrastructure of laboratories that deliver world-class measurement science and technology and provide traceable and increasingly accurate standards of measurement.

NPL

TÜV SÜD National Engineering Laboratory

Office for Product Safety & Standards

NML UK NATIONAL MEASUREMENT LABORATORY FOR CHEMICAL AND BIO-MEASUREMENT HOSTED AT LGC

Design Unit Gear Technology

NIBSC A centre of the Health Protection Agency

University of Salford ACOUSTIC TESTING LABORATORIES

NPL

Department for Science, Innovation, & Technology

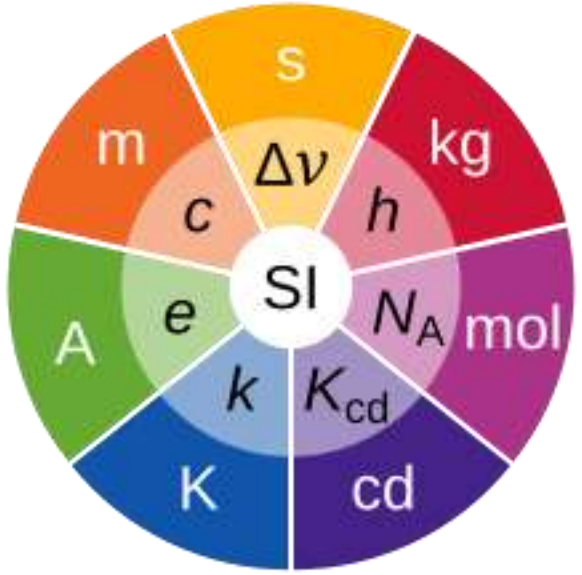
UNIVERSITY OF SURREY

University of Strathclyde Glasgow

800 scientists with a breadth and depth of metrology expertise.

Providing the UK's Measurement Capability

- Metrology is the science of measurement.
- Provides confidence in measurement results and data traceable to SI units.



SI base units (outer ring) and constants (inner ring). Except K_{cd} all others are fundamental constants of nature.

National Challenges

Department for Business, Energy & Industrial Strategy

UK Measurement Strategy

for the National Measurement System

Contents

Why Quantify Ultrasound?

Thermal and non-thermal risks exists under certain ultrasound excitation conditions

GOV.UK

Home > Brexit

Guidance

Regulating medical devices in the UK

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.

5.5.2017 EN Official Journal of the European Union L 117/1

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Guidelines for the safe use of diagnostic ultrasound equipment

Prepared by the Safety Group of the British Medical Ultrasound Society

Ultrasound 2010; 18: 52–59. DOI: 10.1258/ult.2010.100003

ALARA	Total Exposure Time	Dwell Time

Compliance to Standards

IEC standards are specific to electrical and electronic technologies

- IEC Technical Committee 62 – Medical equipment, software, and systems
  - ➢To prepare international standards, and other publications, with focus on safety and performance of medical equipment, software, and systems.
- IEC Technical Committee 87 – Ultrasonics
  - ➢Characteristics, methods of measurement, safety, and specifications of fields, equipment and systems in the domain of ultrasonics.

Safety Indices of Ultrasound

Mechanical Index (MI)

$$MI = \frac{p_{r,\alpha} \cdot f_{\mathrm{awf}}{}^{-1/2}}{C_{MI}}$$

- $p_{r,\alpha}$ derated acoustic pressure
- f_{awf} acoustic working frequency
- $C_{MI} = 1\ \mathrm{MPa\ MHz}^{-1/2}$

Thermal Index (TI)

$$TIS = \frac{P_{1\times1} \cdot f_{\mathrm{awf}}}{C_{TIS,1}}$$

- $P_{1\times1}$ bounded square-output power
- $C_{TIS,1} = 210\ \mathrm{mW\ MHz}$

Safety indices are not without their criticisms!

AIUM Technical Bulletin | Free Access

How to Interpret the Ultrasound Output Display Standard for Diagnostic Ultrasound Devices: Version 3

First published: 17 November 2019 | https://doi.org/10.1002/jum.15159 | Citations: 5

Guidelines for the safe use of diagnostic ultrasound equipment

Prepared by the Safety Group of the British Medical Ultrasound Society

Ultrasound 2010; 18: 52–59. DOI: 10.1258/ult.2010.100003

Note to Physicians and Sonographers on Potential Underestimation of Acoustic Safety Indexes for Diagnostic Array Transducers

Publisher: IEEE Cite This PDF

Keith A. Wear ; Shahram Vaezy All Authors

Abstract:

Two scientists from the U.S. Food and Drug Administration comment on limitations of acoustic safety indexes that can arise from spatial averaging effects of hydrophones that are used to measure acoustic output.

Published in: IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control (Volume: 68 , Issue: 3, March 2021)

ELSEVIER

Ultrasound in Medicine & Biology

Volume 25, Issue 6, July 1999, Pages 1009-1018

Original Contributions

Acoustic saturation and output regulation

Francis A Duck ª

Ultrasound Obstet Gynecol 2017; 50: 236–241
Published online 20 June 2017 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/uog.17298

Measured acoustic intensities for clinical diagnostic ultrasound transducers and correlation with thermal index

Conditionally Increased Acoustic Pressures in Nonfetal Diagnostic Ultrasound Examinations Without Contrast Agents: A Preliminary Assessment

Kathryn R. Nightingale PhD, Charles C. Church PhD, Gerald Harris PhD, Keith A. Wear PhD, Michael R. Bailey PhD, Paul L. Carson PhD, Hui Jiang PhD ... See all authors

First published: 01 July 2015 | https://doi.org/10.7863/ultra.34.7.15.13.0001 | Citations: 49

Safety Limits

FDA Document: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

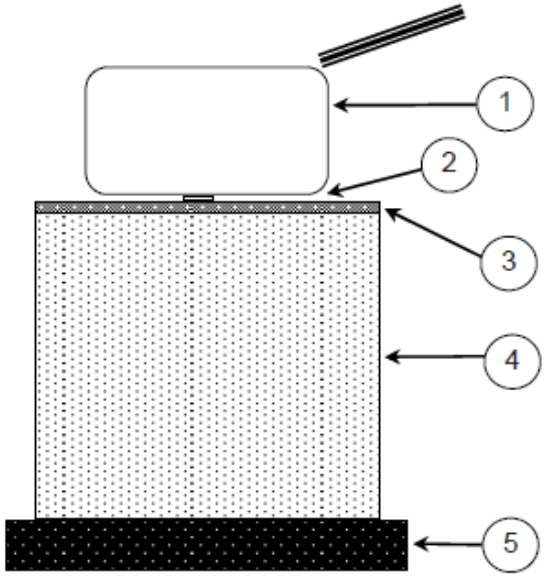
Use	$I_{SPTA.3}$ [mW / cm^2]	$I_{SPPA.3}$ [mW / cm^2]	or MI
Peripheral Vessel	720	190	1.9
Cardiac	430	190	1.9
Foetal Imaging & Other	94	190	1.9
Ophthalmic	17	28	0.23

How to Quantify Ultrasound?

What are the Different Measurands

Surface Temperature

BS EN 60601-2-37:2008+A1:2015
IEC 60601-2-37:2008+A1:2015 (E)



Components

1. ULTRASONIC TRANSDUCER under test, coupled to the test object using acoustic coupling gel
2. Thermal sensor, e.g. thin film thermocouple
3. Silicone rubber, thickness: 1,5 mm
4. Soft tissue mimicking material (TMM)
5. Acoustic absorber

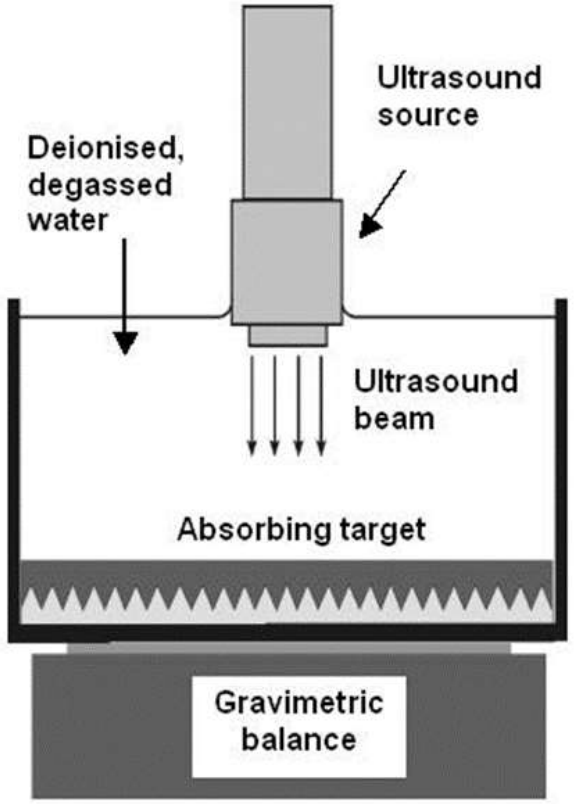
IEC 1533/07

Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers

Teirlinck et. al., DOI: 10.1016/S0041-624X(97)00150-9
Ramnarine et. al., DOI: 10.1016/s0301-5629(00)00304-5
Browne et. al., DOI: 10.1016/s0301-5629(03)00053-x

Madsen EL et. al., DOI: 10.7863/jum.1999.18.9.615
Wear et al., DOI: 10.7863/jum.2005.24.9.1235
Sun et al., DOI: 10.1016/j.ultrasmedbio.2012.02.030
Rajagopal et al., DOI: 10.1016/j.ultrasmedbio.2014.04.018

Acoustic Power



Radiation Force Balance (RFB)

- Force ∝ Power.
- Power:

$$W = m \cdot g \cdot c(\mathrm{T})$$

- where,
  - m is the mass change [kg].
  - g is the gravitational acceleration [m s^{-2}].
  - c(T) is the temperature dependant speed of sound [m s^{-1}].

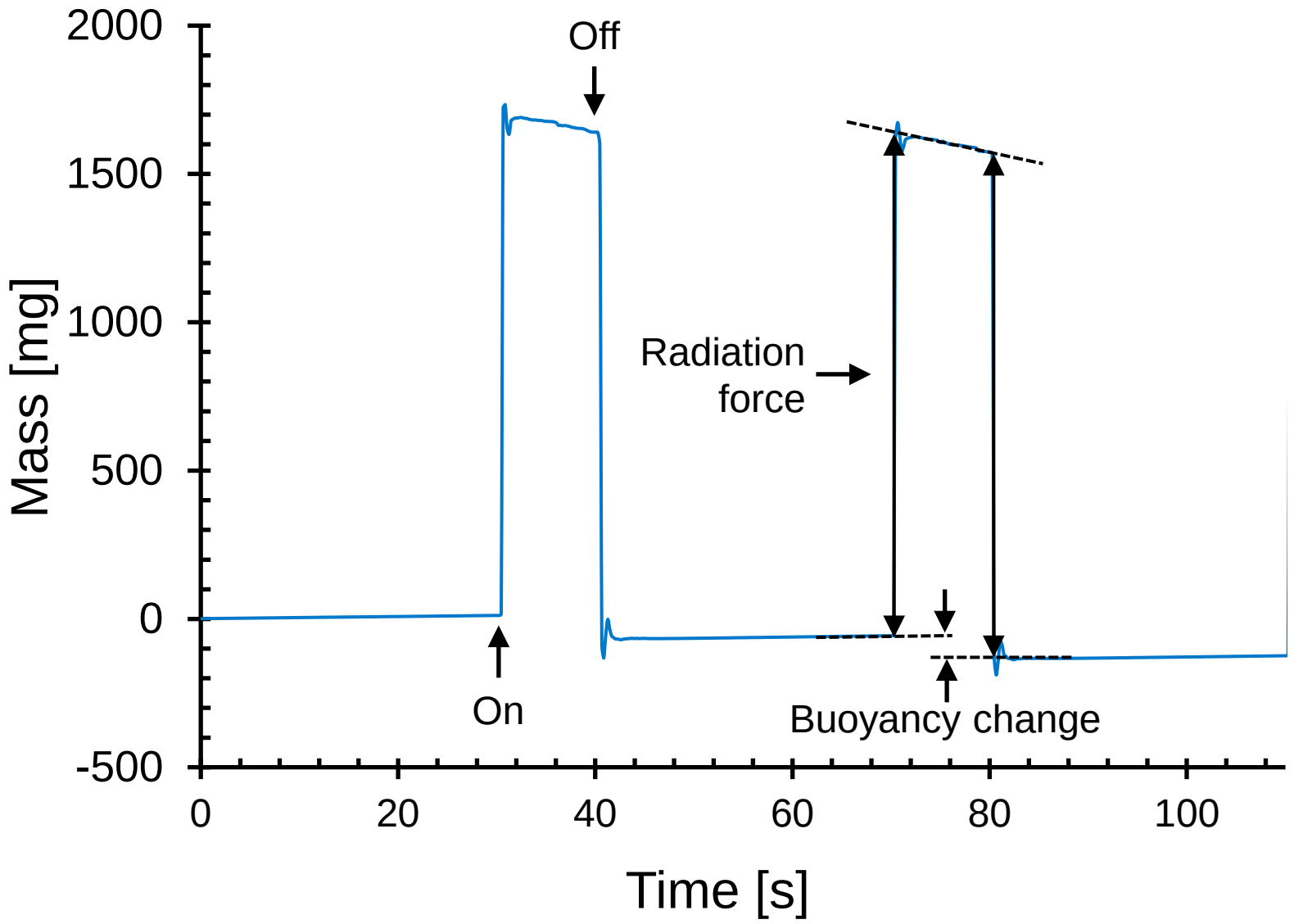
RFB Implementations

Precision Acoustics Ltd

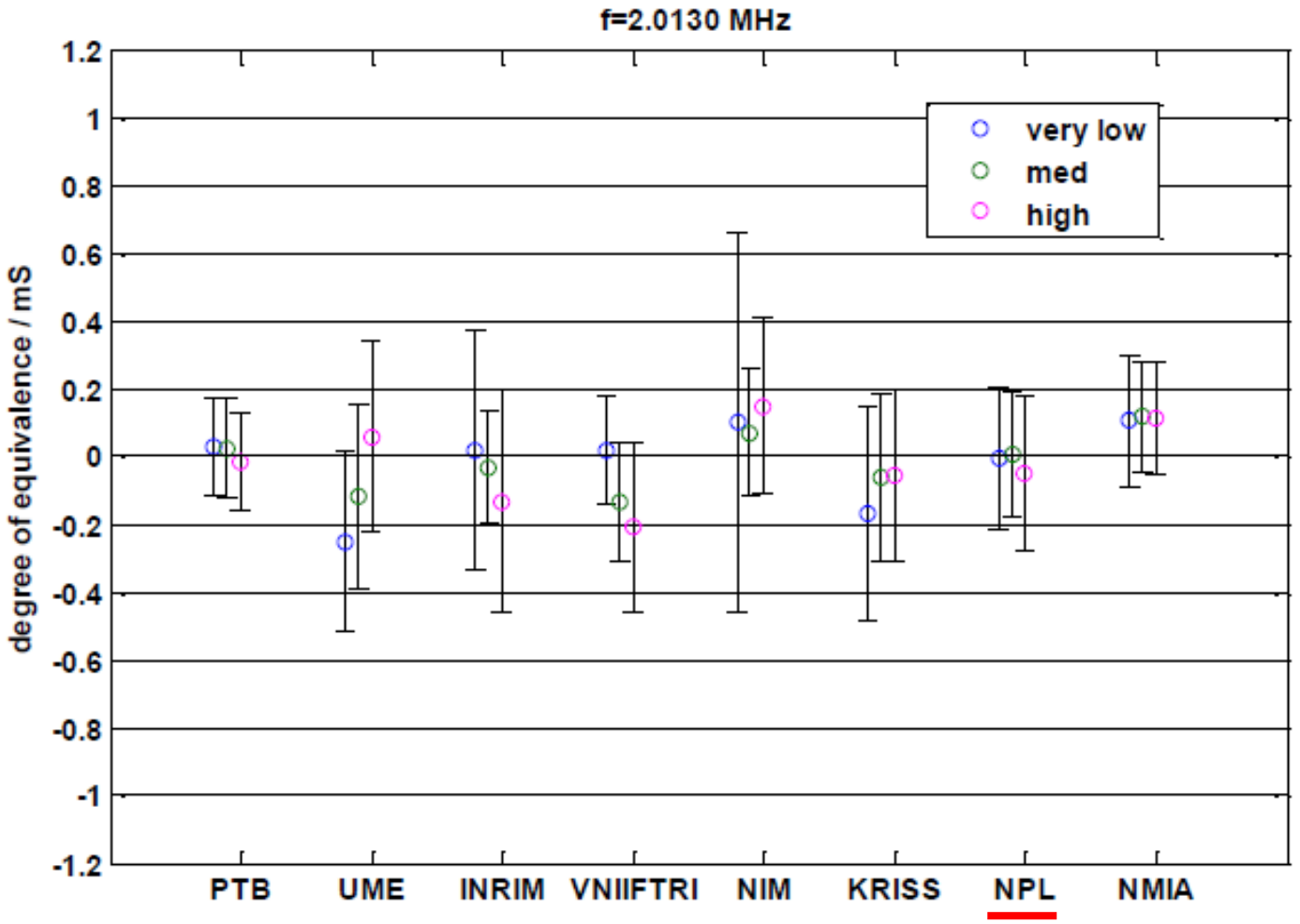
Onda Corporation

NPL - Buoyancy change target

RFB Typical Measurement



Acoustic Power – International Equivalence



Acoustic Pressure

Membrane type hydrophones

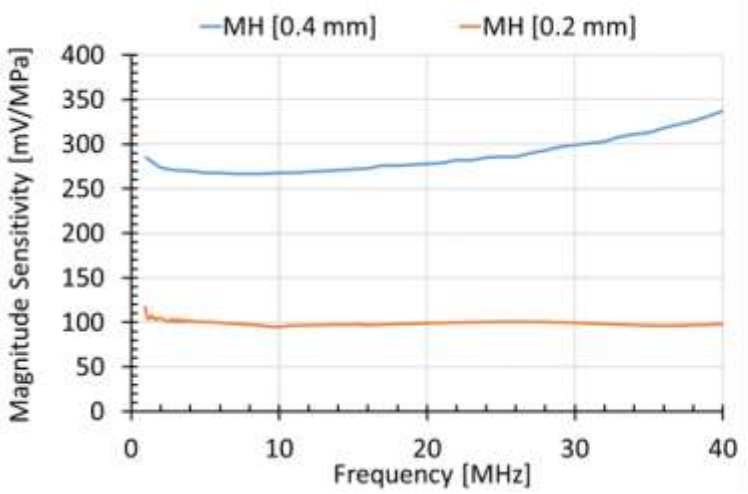
Needle hydrophones

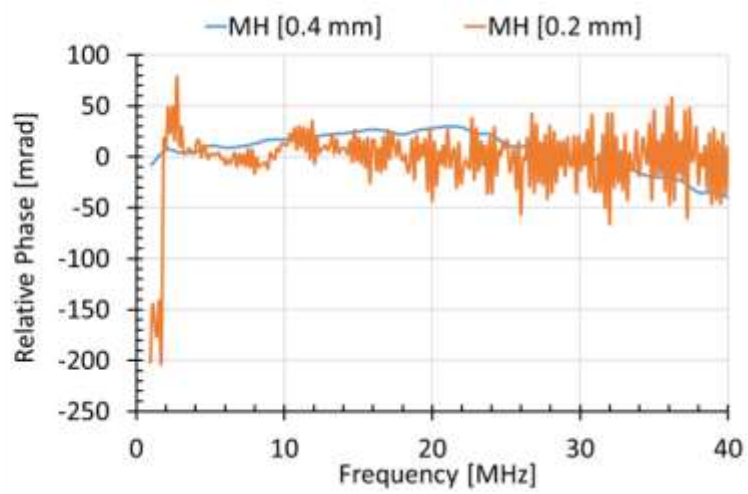
Fibre optic hydrophone

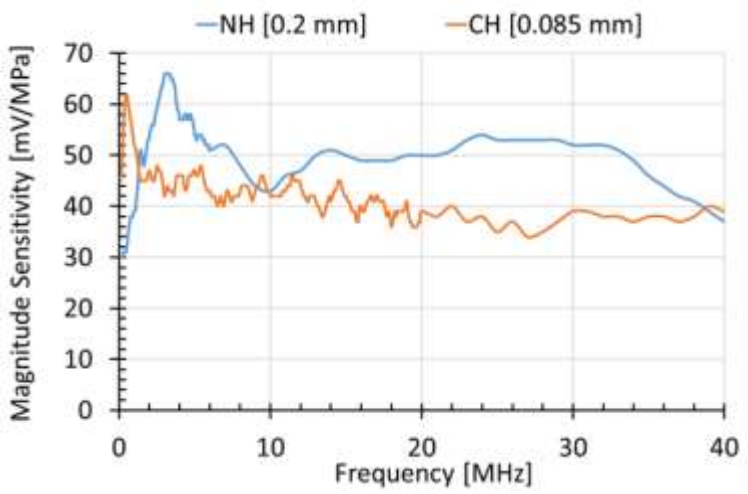
- **Sensitivity:** A known relationship, M, between the incident acoustic pressure and measured output voltage.
- Units in $\mathrm{V} \cdot \mathrm{Pa}^{-1}$.
- Associated uncertainty, $\pm u$.
- Example:

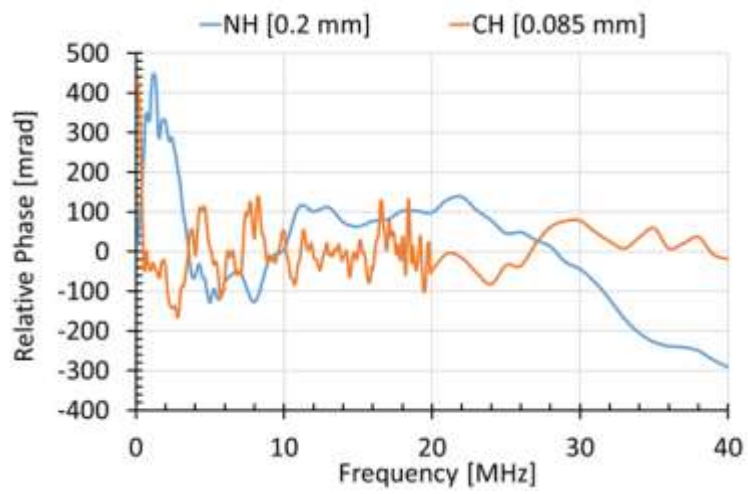
$M\ (f = 1\ \mathrm{MHz}) = 27\ \mathrm{mV} \cdot \mathrm{MPa}^{-1} \pm 6\%$.

Hydrophone Typical Responses

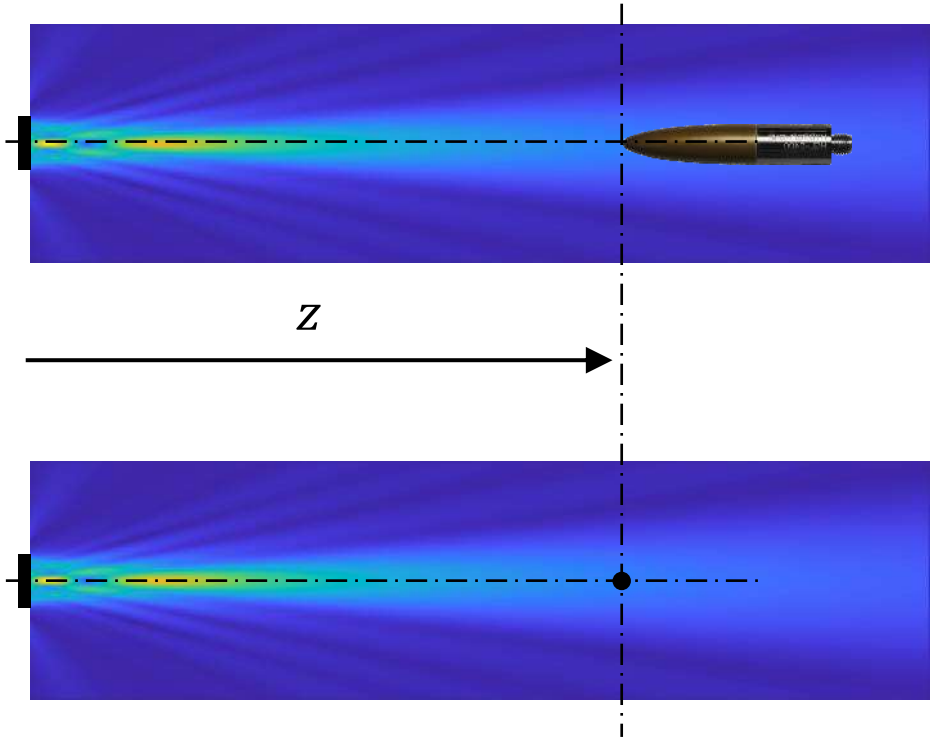








Hydrophone Sensitivity Calibration



Hydrophone voltage, $u_L(t)$ in response to incident acoustic pressure

Acoustic pressure, $p(t)$ in the absence of hydrophone

$$\underline{M}_{\mathrm{L}}(f) = \frac{\mathcal{F}(u_L(t))}{\mathcal{F}(p(t))}$$

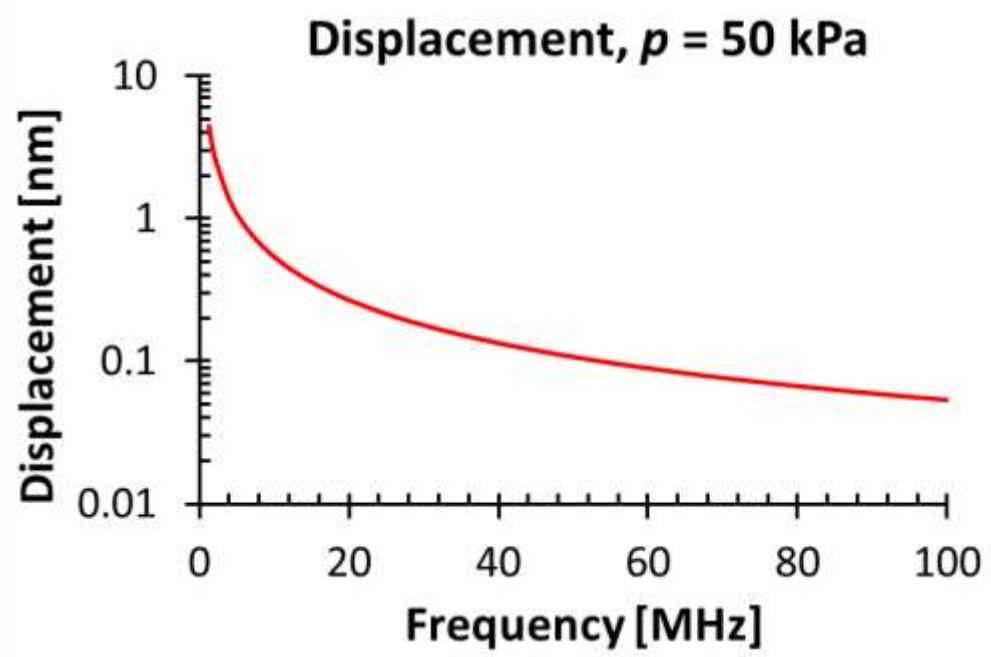
How to Quantify Pressure?

Consider the acoustic plane wave relationship:

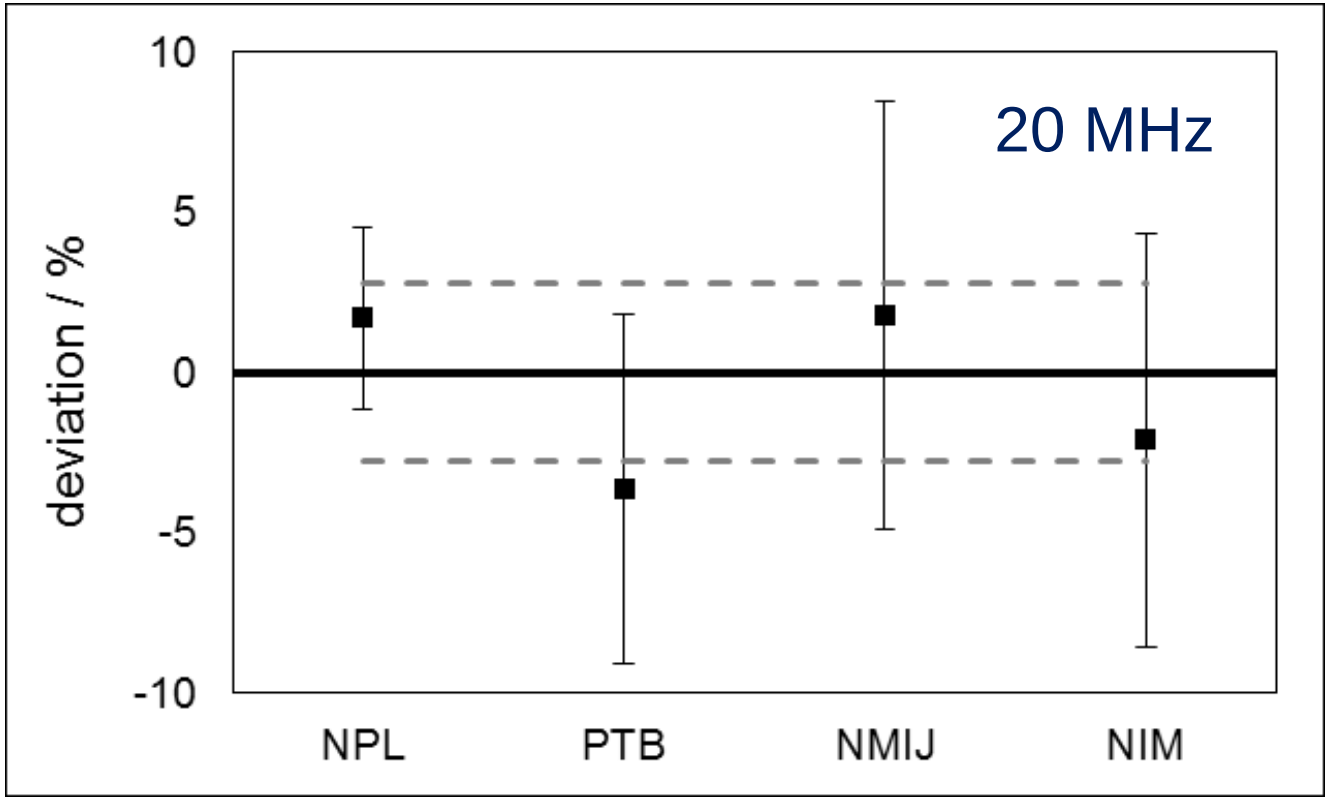
$$p = \rho_0(T)c_0(T)\omega\xi$$

where:

- p, acoustic pressure $[\mathrm{kg} \cdot \mathrm{m}^{-1} \cdot \mathrm{s}^{-2}]$.
- T, temperature of water [K].
- ρ_0, ambient density of water $[\mathrm{kg} \cdot \mathrm{m}^{-3}]$.
- c_0, ambient sound-speed of water $[\mathrm{m} \cdot \mathrm{s}^{-1}]$.
- $\omega = 2\pi f$ $[\mathrm{rad} \cdot \mathrm{s}^{-1}]$.
- ξ, acoustic displacement [m].



Acoustic Pressure – International Equivalence



High-frequency Inter-comparison (*informal*)

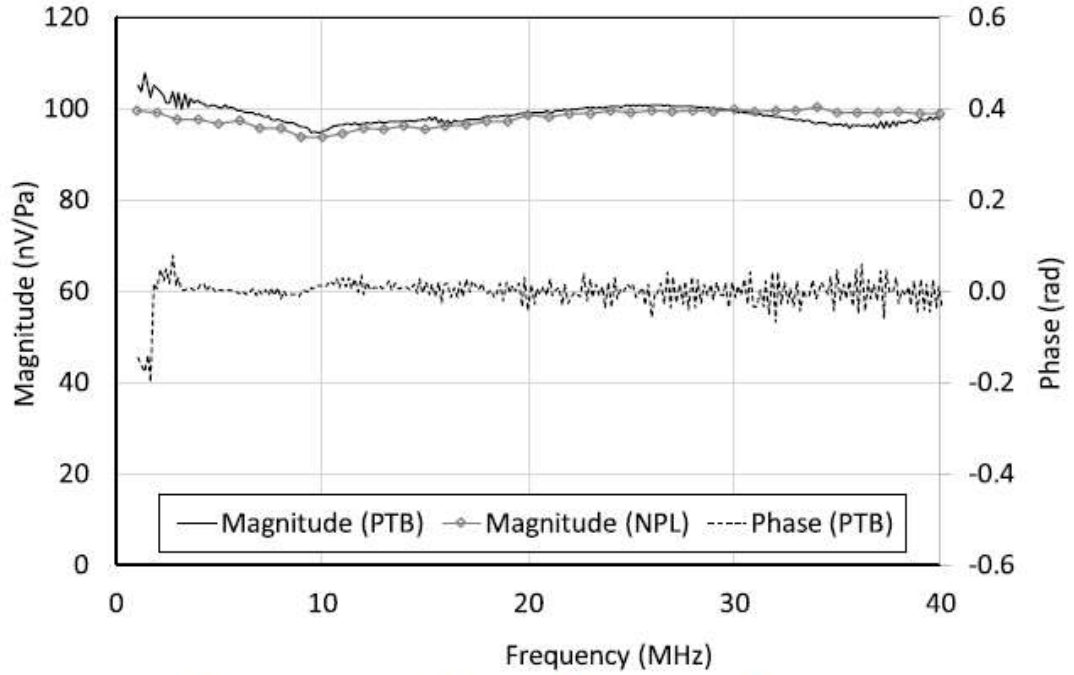


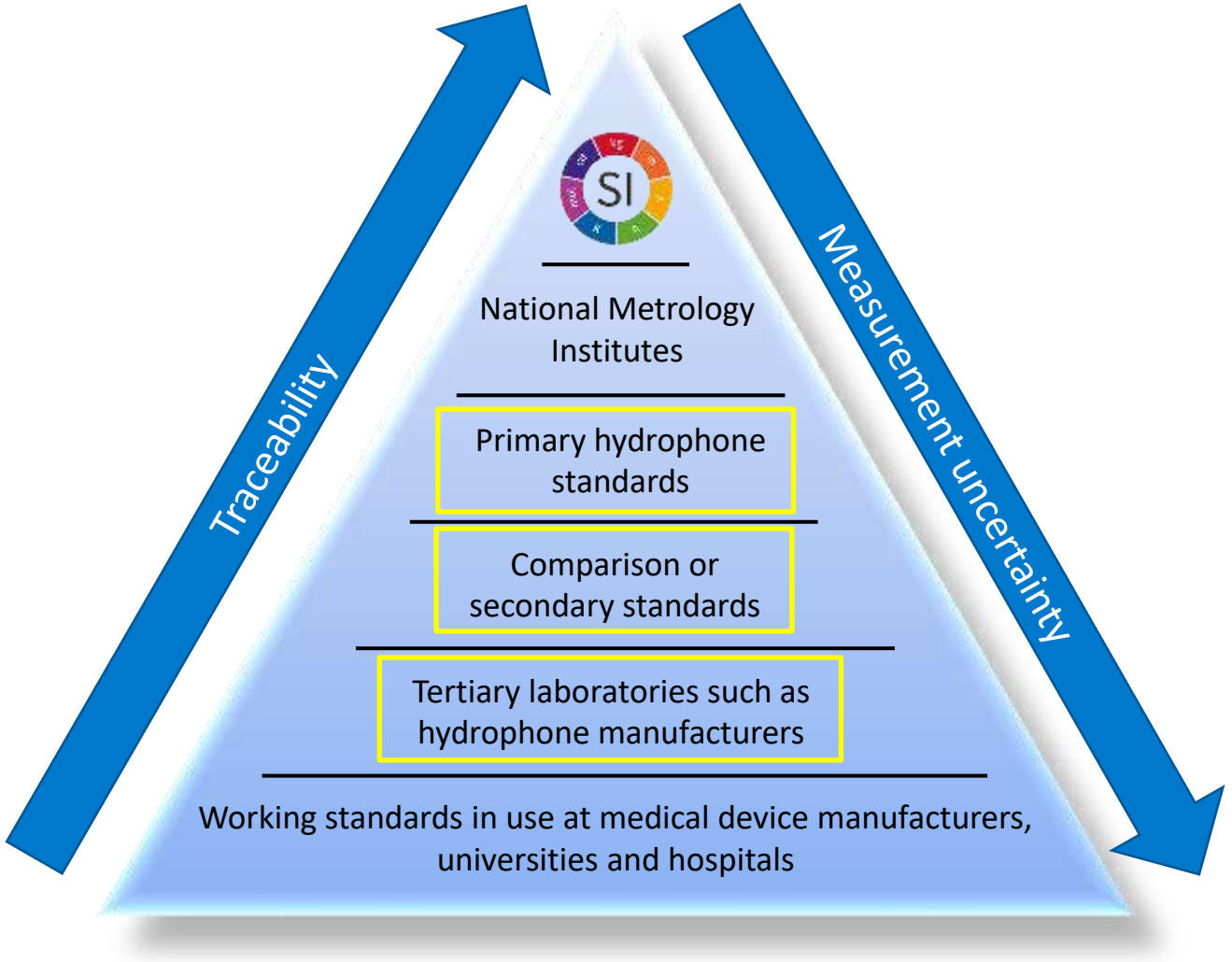
Fig. 2. Magnitude and phase calibration of the 0.2 mm-diameter, 11 μm-thick PVDF membrane hydrophone used as a phase reference source GAMPT GmBH (Merseberg, Germany). Calibration provided by PTB (Braunschweig) and NPL (London).

IEEE TRANSACTIONS ON ULTRASONICS, FERROELECTRICS, AND FREQUENCY CONTROL, VOL. 64, NO. 1, JANUARY 2017

The Practicalities of Obtaining and Using Hydrophone Calibration Data to Derive Pressure Waveforms

Andrew M. Hurrell and Srinath Rajagopal

Traceability Pyramid



Dissemination to the User Community

Calibration Services

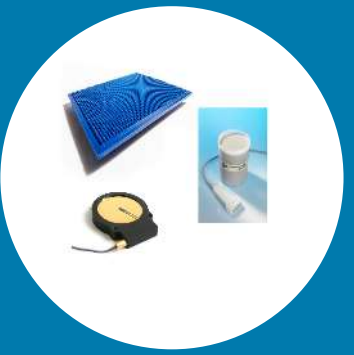
- Calibration services are provided to nearly all the scanner manufacturers
- Integral when seeking regulatory approval from MHRA for safety
- Periodic international comparison of measurement standards

Standards Development

- Led/contributed to calibration and equipment performance standards over three decades
- At least 10 international standards for diagnostic and therapy devices
- Current focus is on **elastography** standards

Consultancy Services

- A comprehensive range of consultancy services available for developing and testing of devices
- Supported >10 SMEs via UK-RI funded Analysis for Innovators (A4I) scheme
- Commissioned equipment to other NMIs



Sale of Artefacts and Licences

- Surface temperature test phantom is used to test compliance with the limits of transducer surface temperature specified in IEC 60601-2-37
- NPL innovations are exclusively licensed to UK based SME, Precision Acoustics Ltd

Ultrasound Metrology

Collaborations with NHS

Joint appointment with Guy's and St Thomas' Hospital

Development of instrumented phantom for performance assessment of MR guided High-Intensity Therapy Ultrasound (MRgHIFU) system

NHS Scientist Training Programme

Supported an ultrasound workshop funded by the South East Imaging Training Academy for medical physics trainees of the NHS STP

Quality Assurance of Ultrasound Imaging Systems

A project comparing commercial ultrasound phantoms enabled to study many aspects of ultrasound QA testing at University Hospitals Sussex NHS Trust

NHS
Brighton and Sussex University Hospitals
NHS Trust

Questions?