BS EN IEC 63412-1:2024

BSI Standards Publication

# Ultrasonics — Shear-wave elastography

Part 1: Specifications for the user interface

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The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

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# European foreword

The text of document 87/851/FDIS, future edition 1 of IEC 63412-1, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63412-1:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2025-05-20
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

# ULTRASONICS – SHEAR-WAVE ELASTOGRAPHY –

## Part 1: Specifications for the user interface

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| Draft | Report on voting |
|---|---|
| 87/851/FDIS | 87/871/RVD |

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

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A list of all parts in the IEC 63412 series, published under the general title *Ultrasonics – Shear-wave elastography*, can be found on the IEC website.

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# INTRODUCTION

The IEC 63412 series specifies, with respect to shear-wave elastography systems, test procedures for the evaluation of accuracy, precision and performance of shear-wave speed measurements.

This document specifies quantities and parameters which are essential for users of shear-wave elastography systems. A future Part 2 will specify the requirements on test objects (elastic and viscoelastic phantoms), their preparation and characterization. A future Part 3 will define test parameters and procedures to determine performance and constancy of shear-wave elastography systems.

Elastography imaging (EI) in general and shear-wave elastography (imaging) in particular have become a state-of-the-art measurement and quantitative imaging methodology. The relevant measurand is the speed of the shear waves travelling within the tissue under investigation, which is related to its elasticity. Even though ultrasound elastography is already used in clinical diagnosis, no IEC standard exists describing the relevant metrological tools, the traceable characterization of elastography phantoms and methods for EI system testing and quality assurance.

The determined shear-wave speeds (and so the derived elastic moduli) depend on many technical, operator-related and patient-related factors, such as the device used and method, the measurement depth, the size and shape of the region of interest (ROI), the number of averaged samples, the patient's position, breathing phase, body-mass index (BMI), diet, blood pressure and also the operator's experience. To underpin and further establish shear-wave elastography as a well understood, accurate and reproducible quantitative-imaging modality requires the metrological assessment of the method and devices. Thus, the IEC 63412 series allows comparison of elastography images and determined quantitative parameters as a function of time, across different types of equipment and patients. This procedure likely will lead to advances in the sensitivity and specificity of clinical diagnosis, improving patient care and ensuring efficient use of resources.

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