

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Ultrasonics – Shear-wave elastography –  
Part 1: Specifications for the user interface**

**Ultrasons – Élastographie par ondes de cisaillement –  
Partie 1: Spécifications pour l'interface utilisateur**



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**ULTRASONICS –  
SHEAR-WAVE ELASTOGRAPHY –**

**Part 1: Specifications for the user interface**

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IEC 63412-1 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

The text of this International Standard is based on the following documents:

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.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://www.iec.ch/publications).

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.

Terms defined in Clause 3 are written in **bold** throughout this document.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

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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.

# ULTRASONICS – SHEAR-WAVE ELASTOGRAPHY –

## Part 1: Specifications for the user interface

### 1 Scope

This part of IEC 63412 specifies quantities and parameters which it is essential to provide to the user of shear-wave elastography systems, many in the image headers.

This document is applicable to medical, diagnostic, ultrasonic shear-wave elastography systems, exciting (internally or externally) **shear waves** and tracking their propagation within biological tissue.

NOTE This document focuses on liver applications of shear-wave elastography but does not exclude its application to other organs (e.g. breast, thyroid, prostate, kidney, muscle).

### 2 Normative references

There are no normative references in this document.

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

#### 3.1

##### **shear wave**

##### **transverse wave**

wave in which the direction of displacement of particles is perpendicular to the direction of the propagation of the wave.

[SOURCE: ISO 5577:2017, 3.3.2, modified – Note 1 to entry has been deleted.]

#### 3.2

##### **shear-wave speed**

distance travelled per unit time by a **shear wave** as it propagates through a tissue or medium

Note 1 to entry: The **shear-wave speed** is expressed in units of metre per second ( $\text{m s}^{-1}$ ).

Note 2 to entry: SWS is a common abbreviation for **shear-wave speed**.

#### 3.3

##### **Poisson ratio**

$\nu$

ratio of the relative contraction or extension of a tissue or medium in directions perpendicular to the relative extension or contraction in the direction of loading