IEC 63412-1

Edition 1.0 2024-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

IEC 63412-1:2024-07(en-fr)

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ULTRASONICS – SHEAR-WAVE ELASTOGRAPHY –

Part 1: Specifications for the user interface

FOREWORD

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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. The main document types developed by IEC are described in greater detail at 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 in the data related to the specific document. At this date, the document will be

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- withdrawn, or
- revised.

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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 https://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
c_S
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 (m s^{-1}).

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

3.3
Poisson ratio
ν
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

3.4
shear modulus derived from shear-wave speed
shear modulus
modulus of rigidity
μ
G
quotient of shear stress and shear strain

Note 1 to entry: For tissue or medium assumed to be isotropic, purely elastic (no viscosity) and linearly elastic in the range of the given shear-wave deflection, shear modulus is calculated according to

$$\mu = \rho\, c_{\mathrm{s}}^{2} \tag{1}$$

where ρ is the density of the tissue or medium.

Note 2 to entry: The shear modulus is expressed in pascals (Pa).

Note 3 to entry: The tissue or medium density ρ is expressed in units of kilogram per cubic meter (kg m^{-3}).

Note 4 to entry: In general, the complex shear modulus consists of a real and imaginary part.

3.5
Young's modulus derived from shear-wave speed
Young's modulus
elastic modulus
E
quotient of normal tensile stress and tensile strain

Note 1 to entry: For tissue or medium assumed to be incompressible (**Poisson ratio** ν = 0,5), Young's modulus is calculated according to

$$E = 2\left(1+\nu\right)\mu = 3\mu \tag{2}$$

Note 2 to entry: The Young's modulus is expressed in pascals (Pa).

Note 3 to entry: In general, the complex modulus consists of the real storage modulus and the imaginary loss modulus.

3.6
excitation frequency of source
f_{s}
excitation frequency of an external or internal source that produces the **shear wave**

Note 1 to entry: For tissue displacement due to acoustic radiation force impulses (ARFI), the push pulses are regarded as internal sources.

Note 2 to entry: For pulse excitation, the **excitation frequency of source** is not defined.

Note 3 to entry: The **excitation frequency of source** is expressed in hertz (Hz).

3.7
excitation duration of source
t_s
excitation duration of an external or internal source that produces the **shear wave**, which is 1,25 times the interval between the time when the time integral of the square of instantaneous acoustic pressure of an external or internal source reaches 10 % and 90 % of its final value

Note 1 to entry: For continuous excitations, the **excitation duration of source** is infinite.

Note 2 to entry: The **excitation duration of source** is expressed in seconds (s).

4 Symbols

c_s	**shear-wave speed** (3.2)
E	**Young's modulus derived from shear-wave speed** (elastic modulus) (3.5)
f_s	**excitation frequency of source** (3.6)
t_s	**excitation duration of source** (3.7)
μ (or G)	**shear modulus derived from shear-wave speed** (modulus of rigidity) (3.4)
v	**Poisson ratio** (3.3)
ρ	tissue density (3.4)

5 Values presented to the user

5.1 Required parameters on the user interface

The basic measurement value of all commercially available ultrasound elastography systems is the **shear-wave speed** c_s in units of metre per second (ms^{-1}). Therefore, the **shear-wave speed** value with the unit shall always be provided to the user. Both the name or abbreviation and the unit shall be visible on the user interface.

If vendors provide additional values derived from the **shear-wave speed** (e.g. **shear modulus** or **Young's modulus derived from shear-wave speed**) on their system, both name and unit shall be visible on the user interface.

5.2 Required parameters in the user manual or accompanying product documentation

5.2.1 Elastic moduli

If vendors provide additional values derived from the **shear-wave speed** (e.g. **shear modulus** or **Young's modulus**) on their system, they must clarify which value is presented, the corresponding unit, how this value was derived from **shear-wave speed** and the underlying assumptions.

EXAMPLE

Value: μ in kPa

Formula: $\mu = \rho c_s^2$

Assumptions: ρ = 1 000 kg m^{-3}, no viscosity, linear elasticity, isotropy

or:

Value: E in kPa

Formula: $E = 2(1+\nu)\rho c_s^2$

Assumptions: ρ = 1 000 kg m^{-3}, no viscosity, linear elasticity, isotropy, incompressibility (ν = 0,5)

The manufacturer shall provide the information in the accompanying product documentation.

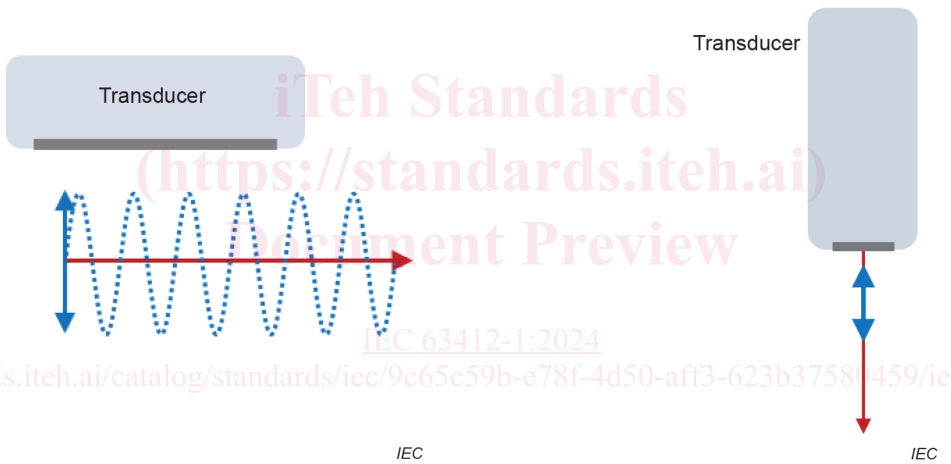
5.2.2 Shear-wave excitation

For the harmonization of the methods to determine **shear-wave speed** and related elastic moduli, the **excitation frequency of source** or **excitation duration of source** or both are relevant and shall be provided in the accompanying product documentation.

When conditions are different for each probe, all cases shall be specified.

5.2.3 Shear-wave propagation

The assumed direction of **shear-wave** propagation and tissue displacement in relation to the transducer orientation [1][1] shall be provided in the user manual or accompanying product documentation by means of an image such as the one presented in Figure 1. This information is relevant in cases where the tissue or medium is anisotropic, e.g. muscle.



a) ARFI based methods **b) Transient elastography**

Figure 1 – Examples of directions of tissue displacement induced by shear wave (blue) and shear wave propagation (red)

The push pulse direction and position or positions should be indicated in the B-mode image to support the user in avoiding exposure of sensitive tissue to the intense push pulses for safety reasons. This feature can be switched on and off by the user.

In addition, the area outside the ROI in the lateral direction which is affected by high intensity focused push pulses shall be declared in the user manual (or accompanying product documentation).

1 Numbers in square brackets refer to the Bibliography.

5.2.4 Shear-wave speed dispersion effects

Shear-wave speed estimates in viscoelastic tissue can be significantly different as a function of **shear-wave** frequency content due to the dispersion introduced by the tissue viscosity. Group **shear-wave speeds** that contain all frequency content of the **shear-wave** field, in contrast to phase velocities that are reported at specific frequencies, can be biased if based on the use of particle-velocity based **shear-wave** data rather than particle-displacement based **shear-wave** data [2]. More specifically, particle velocity data have a positive bias in frequency compared to displacement data in dispersive media. Therefore, it should be stated in the accompanying product documentation, whether the method used for the estimation of the **shear-wave speed** is particle-displacement based or particle-velocity based or both, depending on the application. Additionally, any filtering applied to the **shear-wave** data prior to speed estimation which is applied to the **shear-wave** data and could impact the bandwidth of the **shear-wave** data should also be disclosed.

Given the variety of **shear-wave speed** estimation signal processing steps that can be implemented on a given system, a more detailed description of the frequency dependence of the **shear-wave speed** estimate could include reporting a phase velocity at a specific frequency or presenting phase velocities over a range of frequencies. The spectral content of **shear-wave** is dependent on the stiffness of the medium being imaged, which means that this frequency range will change as a function of the tissue target and disease state.

NOTE Acoustic radiation force-based imaging systems tend to generate higher frequency passbands than other **shear-wave** elasticity imaging systems being clinically used, e.g. magnetic resonance elastography (MRE) and transient elastography (TE) [3].

5.3 Colour coding

For the representation of **shear-wave speeds** acquired in two dimensions, including **shear-wave** elastography imaging methods, the vendors shall allow the user to select a standard colour map [4]. For details see Annex A. For display of images of derived moduli, the standard colour-map intensity shall vary linearly with **shear-wave speed** so that the image of derived moduli appears identical to the image of **shear-wave speed**.

The required standard colour map is optimized with respect to the perceptual contrast. The availability and application of the standard colour map are fundamental for comparison of image representations of 2D **shear-wave speed** maps acquired with different devices.