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

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OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
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TITLE:

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

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NOTE FROM TC/SC OFFICERS:

CONTENTS

CONTENTS 1
FOREWORD 3
INTRODUCTION 5
1 Scope 6
2 Normative references 6
3 Terms and Definitions 6
4 List of symbols 7
5 Values presented to the user 8
5.1 Required parameters on the user interface 8
5.2 Required parameters in the user manual 8
5.2.1 Elastic moduli 8
5.2.2 Shear-wave frequency 8
5.2.3 Shear-wave propagation 8
5.2.4 Shear-wave speed estimation method 9
5.3 Colour coding 9
Annex A Rationale (informative) 11
A.1 Colour map background 11
A.2 Description of Colour map 12

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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The text of this standard is based on the following documents:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,

- withdrawn,
- replaced by a revised edition, or
- amended.

The National Committees are requested to note that for this publication the stability date is ....

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INTRODUCTION

This International Standard specifies, with respect to shear-wave elastography systems, test procedures for the evaluation of accuracy, precision and performance of shear-wave speed measurements.

Part 1 of the standard specifies quantities and parameters which must be provided to the user.
Part 2 describes the requirements on test objects (elastic and visco-elastic phantoms), their preparation and characterization.
Part 3 defines 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 has become a state-of-the-art measurement and quantitative imaging modality. The relevant measurand is the speed of the shear waves travelling within the tissue under investigation, which is related to its elasticity. Despite the fact that ultrasound elastography is already used in clinical diagnosis, no IEC standard exists describing the relevant metrological tools, the traceable characterisation 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- 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 proposed standard 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

Scope

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

This International Standard establishes:

- In part 1, a list of quantities and parameters, which must be provided to the user, many in the image headers.

Note 1: The first edition of the standard focuses on liver applications of shear-wave elastography, but does not exclude its application to other organs (e.g. breast, thyroid, prostate, kidney, muscle).

Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-801:1994/AMD3:2021 *Amendment 3 - International Electrotechnical Vocabulary (IEV)* - Part 801: Acoustics and electroacoustics (available at: http://www.electropedia.org)

IEC 60050-802:2011 *International Electrotechnical Vocabulary (IEV)* – Part 802: Ultrasonics (available at: http://www.electropedia.org)

ISO 5577:2017 Non-destructive testing — Ultrasonic testing — Vocabulary

Terms and Definitions

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

SOURCES: ISO 5577:2017, modified and IEV 801-23-09

3.2
shear-wave speed
c_S
distance travelled per unit time by a shear wave as it propagates through a viscoelastic tissue/medium

Note 1 to entry: The shear-wave speed is expressed in meters 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/medium in directions perpendicular to the relative extension (or contraction) in the direction of loading

3.4
shear modulus derived from shear-wave speed
modulus of rigidity
μ (or G)
ratio of shear stress to shear strain

Note 1 to entry: For tissue/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

$$\mu = \rho\, c_S^2 \qquad (1)$$

where ρ is the density of the tissue/medium

Note 2 to entry: The **shear modulus** is expressed in pascal (Pa or kPa).

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

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

Note 1 to entry: For tissue/medium assumed to be incompressible (**Poisson ratio** ν = 0.5), Young's modulus is calculated according to

$$E = 2\,(1+\nu)\mu = 3\mu \qquad (2)$$

Note 2 to entry: The Young’s modulus is expressed in pascal (Pa or kPa).

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 shear-wave pulse intensity integral 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).

List of symbols

Symbol	Meaning	Clause
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
ν	Poisson ratio	3.3

ρ	tissue density	3.4

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 the unit of meters per second (ms^{-1}). Therefore, the **shear-wave speed** value with the unit must always be provided to the user. Both name (or abbreviation) and unit should 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**) on their system, both name and unit should 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.

e.g.:

Value: μ in kPa
Formula: $\mu = \rho\, c_S^2$
Assumptions: ρ = 1000 kg m^{-3}, no viscosity, linear elasticity, isotropy

or:

Value: E in kPa
Formula: $E = 2(1+\nu)\, \rho\, c_S^2$
Assumptions: ρ = 1000 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 comparison of the determined **shear-wave speed** and related elastic moduli between different devices, the **excitation frequency of source** and/or the **excitation duration of source** are relevant and must 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 [4] must 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/medium is anisotropic (e.g. muscle).

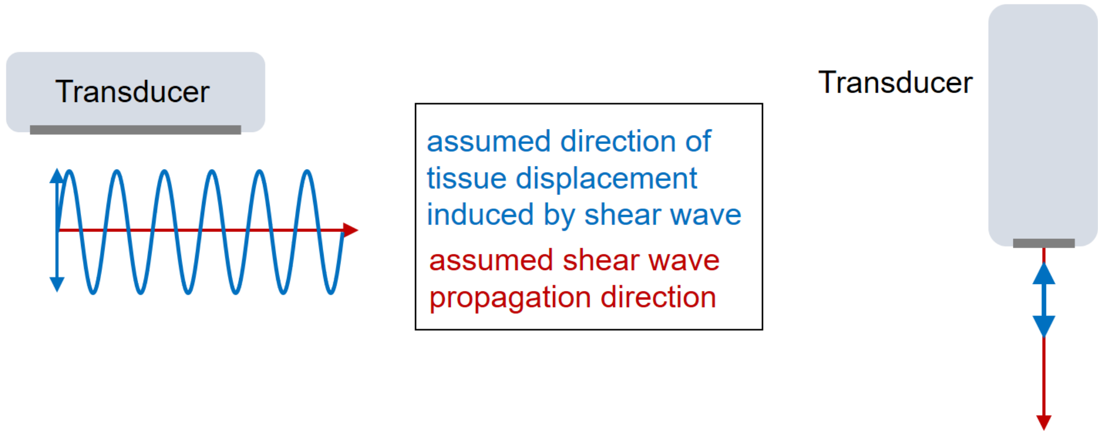

Figure 1 – Examples of directions of tissue displacement (blue) and shear wave propagation (red) – left: ARFI based methods, right: transient elastography

Information about the assumed position (or positions) of the push pulse focus (or foci) relative to the measurement spot or region (ROI) must be provided in the user manual (or accompanying product documentation), e. g. as a safety margin around the ROI.

In addition, the push pulse direction and position(s) should be indicated in the B-mode image to support the user in avoiding to expose sensitive tissue to the intense push pulses for safety reasons. This feature can be switched on an off by the user.

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 versus particle-displacement based **shear-wave** data [5]. 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 before 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 may be implemented on a given system, a more detailed description of the frequency dependence of the **shear-wave speed** estimate could include the reporting of a phase velocity at a specific frequency or presenting phase velocities over a range of frequencies. It should be noted that 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 1 Acoustic radiation force-based imaging systems tend to generate higher frequency passbands than other shear-wave elasticity imaging systems being clinically used, e.g. MRE and transient elastography (FibroScan) [1].

5.3 Colour coding

For the representation of **shear-wave speeds** acquired in two dimensions (shear-wave elastography imaging methods), the vendors must allow the user to select a standard colour map [3] (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.