

<b>STN</b>	<b>Ultrazvuk</b> <b>Shear-wave elastografia (SWE)</b> <b>Časť 1: Špecifikácie používateľského rozhrania</b>	<b>STN</b> <b>EN IEC 63412-1</b>  34 1000
------------	---	--

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

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/24

Obsahuje: EN IEC 63412-1:2024, IEC 63412-1:2024

139435



EUROPEAN STANDARD

**EN IEC 63412-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2024

ICS 17.140.50

English Version

**Ultrasonics - Shear-wave elastography - Part 1: Specifications  
for the user interface  
(IEC 63412-1:2024)**

Ultrasons - Élastographie par ondes de cisaillement - Partie  
1: Spécifications pour l'interface utilisateur  
(IEC 63412-1:2024)

Ultraschall - Scherwellen-Elastographie - Teil 1:  
Spezifikationen für die Benutzerschnittstelle  
(IEC 63412-1:2024)

This European Standard was approved by CENELEC on 2024-08-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.



European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**EN IEC 63412-1:2024 (E)****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 (dop) 2025-05-20 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-08-20 document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

**Endorsement notice**

The text of the International Standard IEC 63412-1:2024 was approved by CENELEC as a European Standard without any modification.



IEC 63412-1

Edition 1.0 2024-07

# 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**



**THIS PUBLICATION IS COPYRIGHT PROTECTED****Copyright © 2024 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

**About the IEC**

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

**About IEC publications**

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

**IEC publications search - [webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)**

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

**IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)**

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

**IEC Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)**

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [sales@iec.ch](mailto:sales@iec.ch).

**IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)**

Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

**Electropedia - [www.electropedia.org](http://www.electropedia.org)**

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

**A propos de l'IEC**

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

**A propos des publications IEC**

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

**Recherche de publications IEC -****[webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)**

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

**IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)**

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

**Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)**

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [sales@iec.ch](mailto:sales@iec.ch).

**IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)**

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications, symboles graphiques et le glossaire. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

**Electropedia - [www.electropedia.org](http://www.electropedia.org)**

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.





IEC 63412-1

Edition 1.0 2024-07

# 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**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 17.140.50

ISBN 978-2-8322-9224-2

**Warning! Make sure that you obtained this publication from an authorized distributor.  
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

## CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references .....	6
3 Terms and definitions .....	6
4 Symbols .....	8
5 Values presented to the user .....	8
5.1 Required parameters on the user interface .....	8
5.2 Required parameters in the user manual or accompanying product documentation .....	8
5.2.1 Elastic moduli .....	8
5.2.2 Shear-wave excitation .....	9
5.2.3 Shear-wave propagation .....	9
5.2.4 Shear-wave speed dispersion effects.....	10
5.3 Colour coding .....	10
Annex A (informative) Rationale for the definition of a standard colour map.....	11
A.1 Colour map background .....	11
A.2 Description of colour map .....	12
Bibliography.....	20
Figure 1 – Examples of directions of tissue displacement induced by shear wave (blue) and shear wave propagation (red).....	9
Figure A.1 – Example for a typical colour map used in commercially available ultrasonic elastography systems .....	11
Figure A.2 – Composition of the colour-map test image (example with grey colour map).....	11
Figure A.3 – Test image mapped using a typical colour map currently used in commercial elastography applications.....	12
Figure A.4 – Test image mapped using the proposed colour map.....	12
Figure A.5 – Proposed perceptually uniform, colour map visualized as colour bar .....	13
Figure A.6 – Plot of the RGB components of the proposed colour map with respect to intensity ranged from 0 to 1 .....	13
Table A.1 – RGB values of recommended perceptual uniform colour map.....	13

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS –  
SHEAR-WAVE ELASTOGRAPHY –****Part 1: Specifications for the user interface**

## FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

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

- reconfirmed,
- withdrawn, or
- revised.

**IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

## 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.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**