IEC 82304-1

Edition 1.0 2016-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Health software –
Part 1: General requirements for product safety

Logiciels de santé –
Partie 1: Exigences générales pour la sécurité des produits

IEC 82304-1:2016-10(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
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 corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
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 It also gives information on projects, replaced and withdrawn publications.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
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing 20 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
65 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - 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: csc@iec.ch.

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.

Catalogue IEC - webstore.iec.ch/catalogue
Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub
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
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org
Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 15 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
65 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.

IEC 82304-1

Edition 1.0 2016-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Health software –
Part 1: General requirements for product safety

Logiciels de santé –
Partie 1: Exigences générales pour la sécurité des produits

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 35.240.80

ISBN 978-2-8322-3733-5

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

HEALTH SOFTWARE –

Part 1: General requirements for product safety

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

International Standard IEC 82304-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO technical committee 215: Health informatics.

It is published as a double logo standard.

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

FDIS	Report on voting
62A/1140/FDIS	62A/1151/RVD

Full information on the voting for the approval of this part of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 21 P members out of 22 having cast a vote.

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

Terms defined in Clause 3 of this standard are printed in SMALL CAPITALS.

For the purposes of this standard:

– “shall” means that compliance with a requirement is mandatory for compliance with this standard;

– “should” means that compliance with a requirement is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement; and

– “establish” means to define, document, and implement.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication 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.

NOTE The attention of National Committees is drawn to the fact that manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

HEALTH SOFTWARE PRODUCTS, within the context of this document, are software-only products. These products are intended to be used with computing equipment not explicitly developed for running the software. HEALTH SOFTWARE PRODUCTS may require specified platforms.

HEALTH SOFTWARE PRODUCTS are intended by their MANUFACTURER for managing, maintaining or improving health of individual persons, or the delivery of care. Some HEALTH SOFTWARE can contribute to a HAZARDOUS SITUATION. Accordingly, Clause 5 requires a RISK MANAGEMENT process for all HEALTH SOFTWARE. For HEALTH SOFTWARE that can contribute to a HAZARDOUS SITUATION, RISK CONTROL is needed to prevent HARM or reduce the likelihood of HARM occurring. Testing of the finished product is not, by itself, adequate to address the SAFETY of HEALTH SOFTWARE. Therefore, requirements for the processes by which the HEALTH SOFTWARE is developed are necessary. This document relies heavily on IEC 62304:2006 and IEC 62304:2006/AMD1:2015 for the software development process which can be applied to HEALTH SOFTWARE PRODUCTS.

Whether a HEALTH SOFTWARE PRODUCT has to meet regulatory requirements is a matter of national legislation. This document makes no attempt to determine whether a HEALTH SOFTWARE PRODUCT is or should be regulated.

This document aims to provide requirements for the SAFETY and SECURITY of HEALTH SOFTWARE PRODUCTS; it can only provide such requirements for software-only products. Situations where HEALTH SOFTWARE is a part of—or embedded in— a physical device are outside the scope of this document as these combined products are considered separately in, for example, IEC 60601-1 and associated collateral and particular standards.

This document understands health in a meaning similar to the WHO definition: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 1946). This definition appears not highly suitable for practical purposes: ”a state of complete well-being” or the inclusion of social well-being could be interpreted more widely than seems reasonable. For example dating software, games, or flight simulator software could be considered within the scope of the standard. That is clearly not the intent. However, a precise definition – or even delineation – of “health” for practical use in “HEALTH SOFTWARE” is not available.

HEALTH SOFTWARE refers to software that contributes to the health of individual people as observed and/or demonstrated using measurable health parameters or clinical expertise. This is a subset of “health” as defined by the WHO. The requirements of the standard apply to the software that impacts such health parameters, and/or to software where SECURITY violations would undermine privacy or confidentiality of health and wellbeing information.

The reader is kindly referred to the Table A.1 for examples of what is in the scope and what is outside the scope of this document.