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)

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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.
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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.

HEALTH SOFTWARE –

Part 1: General requirements for product safety

1 Scope

1.1 Purpose

This Part of 82304 applies to the SAFETY and SECURITY of HEALTH SOFTWARE PRODUCTS designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for MANUFACTURERS.

1.2 Field of application

This document covers the entire lifecycle including design, development, VALIDATION, installation, maintenance, and disposal of HEALTH SOFTWARE PRODUCTS.

In each referenced standard, the term “medical device” or “medical device software” is to be substituted by the term “HEALTH SOFTWARE” or “HEALTH SOFTWARE PRODUCT”, as appropriate.

Where the term “patient” is used, either in this document or in a referenced standard, it refers to the person for whose health benefit the HEALTH SOFTWARE is used.

IEC 82304-1 does not apply to HEALTH SOFTWARE which is intended to become part of a specific hardware designed for health use. Specifically, IEC 82304-1 does not apply to:

a) medical electrical equipment or systems covered by the IEC 60601/IEC 80601 series;

b) in vitro diagnostic equipment covered by the IEC 61010 series; or

c) implantable devices covered by the ISO 14708 series.

NOTE This document also applies to HEALTH SOFTWARE PRODUCTS (e.g. medical apps, health apps) intended to be used in combination with mobile computing platforms.

1.3 Compliance

Compliance with this document is determined by inspection of all documentation required by this document.

Assessment of compliance is carried out and documented by the MANUFACTURER. Where the HEALTH SOFTWARE PRODUCT is subject to regulatory requirements, external assessment may take place.

Where this document normatively references parts or clauses of other standards focused on SAFETY or SECURITY, the MANUFACTURER may use alternative methods to demonstrate compliance with the requirements of this document. These alternative methods may be used if the process results of such alternative methods, including traceability, are demonstrably equivalent and the RESIDUAL RISK remains acceptable.

NOTE The term “conformance” is used in ISO/IEC 12207 where the term “compliance” is used in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition

cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62304:2006, *Medical device software – Software life cycle processes*
IEC 62304:2006/AMD1:2015

3 Terms and definitions

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

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

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

3.1
ACCOMPANYING DOCUMENT
document accompanying HEALTH SOFTWARE containing information for the RESPONSIBLE ORGANIZATION or USER, particularly regarding SAFETY and/or SECURITY

[SOURCE: IEC 60601-1:2005, 3.4, modified – Replace "ME EQUIPMENT, ME SYSTEM, equipment and accessory" by "HEALTH SOFTWARE" and replace "OPERATOR" by "USER" and added "and/or SECURITY".]

3.2
ANOMALY
any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences.

Note 1 to entry: ANOMALIES can be found during, but not limited to, the review, test, analysis, compilation, or use of HEALTH SOFTWARE or applicable documentation.

[SOURCE: Based on IEEE 1044:1993, 3.1]

3.3
HARM
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.4
HAZARD
potential source of HARM

Note 1 to entry: Potential sources of HARM include breach of SECURITY and reduction of effectiveness.

[SOURCE: ISO/IEC Guide 51:2014, 3.2, modified – Note 1 to entry has been added.]

3.5
HAZARDOUS SITUATION
circumstance in which people, property or the environment is/are exposed to one or more HAZARDS

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.6
*** HEALTH SOFTWARE**
software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Note 1 to entry: HEALTH SOFTWARE fully includes what is considered software as a medical device (see rationale in A.1).

Note 2 to entry: The scope of this document refers to the subset of HEALTH SOFTWARE that is intended to run on general computing platforms.

3.7
HEALTH SOFTWARE PRODUCT
combination of HEALTH SOFTWARE and ACCOMPANYING DOCUMENTS

3.8
INTENDED USE
INTENDED PURPOSE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 14971:2007, 2.5]

3.9
IT-NETWORK
INFORMATION TECHNOLOGY NETWORK
a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

Note 1 to entry: The scope of the IT-NETWORK in this document is defined by the RESPONSIBLE ORGANIZATION based on where the HEALTH SOFTWARE in the IT-NETWORK is located and the defined use of the IT-NETWORK. It can contain IT infrastructure, home health, or general computing components or systems not intended by design to be used in a healthcare setting. See also 7.2.3.2.

[SOURCE: IEC 61907:2009, 3.1.1, modified – The definition has been rephrased and Note 1 to entry has been added.]

3.10
MANUFACTURER
natural or legal person with responsibility for the design, development, packaging, or labelling of a HEALTH SOFTWARE PRODUCT, or adapting a HEALTH SOFTWARE PRODUCT before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: For a definition of labelling, see ISO 13485:2016, 3.8.

Note 2 to entry: Developer" or "developer organization" are commonly used terms instead of MANUFACTURER in the context of health information technology.

3.11
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[SOURCE: ISO 14971:2007, 2.15]

3.12
RESPONSIBLE ORGANIZATION
entity accountable for the use and proper operation of a HEALTH SOFTWARE PRODUCT

Note 1 to entry: An accountable entity is, for example, a hospital, a healthcare provider, or a telehealth organization.

[SOURCE: IEC 60601-1:2005, 3.101, modified – Replaced " maintenance of an ME EQUIPMENT or an ME SYSTEM" by " proper operation of a HEALTH SOFTWARE PRODUCT".]

3.13
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

Note 1 to entry: The probability of occurrence includes the exposure to a HAZARDOUS SITUATION and the possibility to avoid or limit the HARM

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified – Note 1 to entry updated to remove the reference to hazardous event.]

3.14
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.15
RISK ASSESSMENT
overall process comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.16
RISK CONTROL
process in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2012, 2.12]

3.17
RISK EVALUATION
process of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.14]

3.18
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and MONITORING RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.15]

3.19
SAFETY
freedom from unacceptable RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.16]

3.20
SECURITY
protection of information and data so that unauthorized persons or systems cannot read or modify them and authorized persons or systems are not denied access to them

[SOURCE: ISO 12207:2008, 4.39]

3.21
SOFTWARE MAINTENANCE
modification of HEALTH SOFTWARE PRODUCT after release for INTENDED USE, for one or more of the following reasons:

a) corrective, as fixing faults;

b) adaptive, as adapting to new hard- or software platform;

c) perfective, as implementing new requirements;

d) preventive, as making the product more maintainable

Note 1 to entry: See also ISO/IEC 14764:2006.

3.22
USER
person interacting with the HEALTH SOFTWARE PRODUCT

Note 1 to entry: In general, a USER is not considered to be a RESPONSIBLE ORGANIZATION, except for consumer type HEALTH SOFTWARE PRODUCTS, e.g., for personal health applications, or products to be used by lay persons.

3.23
VALIDATION
confirmation, through the provision of objective evidence, that the requirements for a specific INTENDED USE or application have been fulfilled

Note 1 to entry: The objective evidence needed for a VALIDATION is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for VALIDATION can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

3.24
VERIFICATION
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a VERIFICATION can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for VERIFICATION are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding state.

[SOURCE: ISO 9000:2015, 3.8.12]

4 * HEALTH SOFTWARE PRODUCT requirements

4.1 General requirements and initial RISK ASSESSMENT

The MANUFACTURER shall determine and document:

a) the INTENDED USE for the HEALTH SOFTWARE PRODUCT, including the intended USER profile and the intended operational environment;

b) the characteristics related to the SAFETY and/or SECURITY of the HEALTH SOFTWARE PRODUCT, identification of HAZARDS and estimation of the associated RISK(S). As applicable, this includes situations where the HEALTH SOFTWARE PRODUCT can be configured and/or supports interfaces to other products;

c) the need for RISK CONTROL measures for estimated RISKS that are considered unacceptable.

NOTE 1 Subclause 4.1 does not require a formal and full RISK MANAGEMENT as, for example, per ISO 14971. However, performing the initial steps of that process is considered good practice.

NOTE 2 RISK CONTROL measures can be hardware, an independent software system, health care procedures, or other means.

NOTE 3 Sources of information on SECURITY vulnerabilities include publicly available reports from authorities, as well as publications by suppliers of, for instance, operating systems and third party software.

4.2 HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall determine and document:

a) requirements that address the INTENDED USE;

b) interface requirements, including USER interface requirements where applicable;

NOTE 1 In contrast to the USER interface specification as part of the HEALTH SOFTWARE PRODUCT system requirements, USER interface requirements do not describe technical (realization) requirements. They describe the purpose of the technical requirements.

EXAMPLE "The displayed information shall be readable from a distance of 3 m in an emergency unit."

NOTE 2 IEC 62366-1:2015 provides a process to establish USER interface requirements.

c) requirements for immunity from or susceptibility to unintended influence by other software using the same hardware resources;

d) privacy and SECURITY requirements addressing areas such as authorised use, person authentication, health data integrity and authenticity, and protection against malicious intent;

NOTE 3 See 7.2.3.1 and IEC TR 80001-2-2 (list of SECURITY capabilities) for further information on SECURITY aspects.

e) requirements for ACCOMPANYING DOCUMENTS such as instructions for use (see 7.2.2);

f) requirements to support:

   1) upgrades from previous versions, including maintaining data integrity, and compatibility with prior versions,
   2) rollback to the previous version after upgrade,
   3) timely SECURITY patches and updates,
   4) software distribution mechanism that ensures integrity of installation,
   5) decommissioning, irreversible deletion, transfer and/or retention of data;

g) requirements derived from applicable regulation, including rules for protected information.

NOTE 4 In some jurisdictions, data protection regulations (e.g. European data protection directive 95/46/EC, revised in 2016) mandate citizens to maintain control over their personal data such as to delete or export data. European directive 95/46/EC will be replaced by the European General Data Protection Regulation (2016/679) on 25 May 2018.

4.3 VERIFICATION of HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall verify that the HEALTH SOFTWARE PRODUCT use requirements are:

a) defined and documented as input for system requirements;

b) such that the MANUFACTURER is able to meet the defined use requirements.

The results of the VERIFICATION shall be recorded.

4.4 Updating HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall ensure that the HEALTH SOFTWARE PRODUCT use requirements are updated as appropriate, e.g. as a result of HEALTH SOFTWARE PRODUCT use requirements VERIFICATION (see 4.3) or as a result of VALIDATION.

4.5 System requirements

The MANUFACTURER shall specify and document the system requirements for the HEALTH SOFTWARE PRODUCT. These requirements shall include the functionality for INTENDED USE and, as applicable:

a) inter-operability;

b) localization and language support;

c) RISK CONTROL measures that have to be implemented in the HEALTH SOFTWARE PRODUCT at system level, based on the initial RISK ASSESSMENT of 4.1;

d) USER interface specification;

e) requirements on the software and hardware platforms for the HEALTH SOFTWARE PRODUCT to function as expected under expected load, and with required performance levels;

f) features that allow for SECURITY compromises to be detected, recognized, logged, timed, and acted upon during normal use;

g) features that protect essential functions, even when the software SECURITY has been compromised;

h) methods for retention and recovery of product configuration by an authenticated privileged USER.

The HEALTH SOFTWARE PRODUCT system requirements shall meet the HEALTH SOFTWARE PRODUCT use requirements (see 4.2).

NOTE 1 The website http://www.himss.org/library/interoperability-standards/what-is-interoperability provides one source of information on inter-operability.

NOTE 2 Technical requirements for the USER interface can include display colour, character size, or placement of the controls.

NOTE 3 The typical software platform includes, but is not limited to: operating system, device drivers, software libraries, and other USER application(s).

NOTE 4 There is not necessarily a difference between SOFTWARE SYSTEM requirements of IEC 62304:2006, 5.2.1 and and HEALTH SOFTWARE PRODUCT system requirements.

4.6 VERIFICATION of system requirements

The MANUFACTURER shall verify that the system requirements:

a) do not contradict each other;

b) are expressed in terms that avoid ambiguity;

c) are stated in terms that permit the establishment of test criteria and performance of tests to determine that test criteria have been met; and

d) can be uniquely identified.

The results of the VERIFICATION shall be recorded.

4.7 Updating HEALTH SOFTWARE PRODUCT system requirements

The MANUFACTURER shall ensure that the HEALTH SOFTWARE PRODUCT system requirements are updated as appropriate, e.g. as a result of modification on the HEALTH SOFTWARE PRODUCT use requirements, as a result of system requirement VERIFICATION (see 4.6), or as a result of

applying 5.2 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 (software requirements analysis).

5 * HEALTH SOFTWARE – Software life cycle processes

The system requirements for the HEALTH SOFTWARE PRODUCT established in 4.5 shall be used as primary design input for the life cycle process of the HEALTH SOFTWARE PRODUCT.

The requirements in 4.2, 4.3, Clause 5, Clause 6, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 and IEC 62304/AMD1:2015 shall apply to the HEALTH SOFTWARE in addition to the other requirements of this document.

IEC 62304:2006 and IEC 62304/AMD1:2015 normatively references ISO 14971:2007. It is recognized that the MANUFACTURER might not be able to follow all the process steps identified in ISO 14971:2007 for each constituent component of the HEALTH SOFTWARE, such as proprietary components, subsystems of non-healthcare origin, and legacy software. In this case, the MANUFACTURER shall take account of the RESIDUAL RISKS and implement RISK CONTROLS around those found to be unacceptable.

6 * HEALTH SOFTWARE PRODUCT VALIDATION

6.1 VALIDATION plan

The MANUFACTURER shall establish a VALIDATION plan addressing all HEALTH SOFTWARE PRODUCT use requirements established in 4.2.

In the VALIDATION plan, the MANUFACTURER shall:

a) identify the VALIDATION scope and the corresponding VALIDATION activities;

b) identify the constraints that potentially limit the feasibility of VALIDATION activities;

c) select appropriate VALIDATION methods, input information, and associated acceptance criteria for successful VALIDATION;

d) identify the enabling systems or services such as operating environment(s), including hardware and software platforms, needed to support VALIDATION;

e) specify the required qualification of the VALIDATION personnel; where training is required, this shall be completed before starting the VALIDATION;

f) define the appropriate level of independence of the VALIDATION team from the design team.

NOTE 1 Constraints include: technical feasibility, cost, time, availability of VALIDATION enablers or qualified personnel, contractual constraints, criticality of the mission, etc.

NOTE 2 VALIDATION methods include: inspection, analysis, analogy/similarity, demonstration, simulation, peer-review, testing or certification. Relevant information: reference to standards and other publications such as compatibility standards, regulatory authority guidance documents, and clinical literature.

6.2 Performing VALIDATION

The MANUFACTURER shall confirm readiness for VALIDATION once:

a) the VALIDATION plan has been established;

b) the VALIDATION team has been set up with the appropriately qualified personnel; and

c) as appropriate, development life cycle phases as required by Clause 5 have been completed for those parts of the HEALTH SOFTWARE PRODUCT subject to VALIDATION.