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By Iec**

This first edition of IEC 62366-1, together with the first edition of IEC 62366-2 (not published yet), cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1:2014. Part 1 has been updated to include contemporary concepts of usability engineering, while also

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streamlining the  
process. Tr 62366 2

**IEC 62366-1:2015 |  
IEC Webstore**

The standard will  
replace ISO/IEC  
60601-1-6: Medical  
electrical equipment -  
Part 1-6: General  
requirements for safety  
- Collateral standard:  
Usability.

Manufacturers of  
medical electrical  
equipment who comply  
with IEC 60601-1-6

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need to also comply by  
extension to IEC 62366

as part of IEC 60601-1  
Edition 3.1.

## **IEC 62366 - Wikipedia**

Several amendments  
to the text of the  
international standard  
IEC 62366-1:

Application of usability  
engineering to medical  
devices have been  
published in June 2020.  
This standard drives  
much of the usability

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Human Factors

Research & Design

(HFR&D) team.

## **How changes to IEC 62366 affect usability**

### **engineering ...**

IEC 62366 Replaced by

IEC 62366-1 and

IEC/TR 62366-2 March

9, 2015 By Eric Shaver

Leave a Comment

[Update: 9.1.15] For a

more in-depth look at

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IEC 62366-1:2015 -

More Than A Checkbox  
at Human Factors MD .

**IEC 62366 Replaced  
by IEC 62366-1 and  
IEC/TR 62366-2 ...**

IEC 62366-1:2015. To  
assist the USER to

implement the

USABILITY

ENGINEERING

PROCESS, the technical  
report.

MANUFACTURERS in

IEC TR 62366-2 is



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available, which  
contains tutorial  
information to assist  
complying with this  
document, as well as  
more generally to  
design MEDICAL  
DEVICES that goes

**IEC 62366-1:2015/A**

**MD1:2020 -**

**Amendment 1 -**

**Medical devices ...**

This first edition of IEC  
62366-1, together with  
the first edition of IEC  
62366-2, cancels and

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replaces the first edition of IEC 62366-2 published in 2007 and its Amendment 1 (2014). Part 1 has been updated to include contemporary concepts of usability engineering, while also streamlining the process.

**ISO - IEC**

**62366-1:2015 -**

**Medical devices —**

**Part 1 ...**

The publication of the

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internationally  
harmonized usability 2

standards IEC

62366-1:20151 and IEC

TR 62366-2:20162

replaces the prior

edition of the usability

standard, IEC 62366:20

07+AMD1:20143. The

new IEC 62366-1

describes a

contemporary usability

engineering process

that is somewhat

streamlined compared

to the previously

prescribed one.

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**COMPARISON OF IEC  
62366-1:2015 AND  
IEC  
62366:2007+AMD1**

...

Re: IEC 62366 vs. IEC  
60601 - Has IEC 62366  
now replaced IEC  
60601? MMANTUNES, I  
know you've  
responded to posts in  
the past that Brazil  
requires conformance  
to the IEC standards  
(vs optional in EU). Do  
you know if Brazilian

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law includes

IEC60601-1-6 or does 2

Brazil only require  
conformance to the  
base IEC60601-1?

**IEC 62366 vs. IEC  
60601-1-6 - Has IEC  
62366 now replaced**

...

IEC 60950-1 and IEC  
60065 approvals will  
be replaced by one  
approval IEC 62368-1  
in December 2020.

This blog tells  
manufacturers

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everything they need  
to know about the  
changes.

## **Safety Standard IEC 62368-1 to Replace IEC 60950-1 and IEC**

...

What Is IEC 62368-1? It  
is the new safety  
standard for  
Information Technology  
Equipment and  
Audio/Video  
Equipment. It is  
intended to replace IEC  
60950-1 and IEC

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60065. It is a hazard-based, performance-oriented standard. Is IEC 62368-1 a Risk-based Standard? No! Unlike IEC 60601-1, 3rd Edition, risk analysis is not required.

## **FAQs: IEC 62368-1 Replacing IEC 60950-1 & IEC 60065; What ...**

IEC 62368 is an entirely new product safety concept: it isn't a merger of existing

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standards, but it does cover the older standards IEC 60065 and IEC 60950, which will be replaced in due time. IEC 62368 supports the convergence of technologies and newer state-of-the-art tech.

## **Everything You Need to Know About IEC 62368 and Where ...**

A new clause 4.3 is added, requiring a



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usability engineering process. The standard on usability and human factors engineering, IEC 62366-1, is referenced in a note at the bottom of this clause. This clause is consistent with ISO 13485:2016, which requires usability in design inputs, and refers to IEC 62366-1.

**IEC 62304:2019 or  
2020 - Next  
Generation -**

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## **Software in ...**

The standard will

replace ISO/IEC

60601-1-6: Medical

electrical equipment -

Part 1-6: General

requirements for safety

- Collateral standard:

Usability. In doing so,

ISO/IEC 62366 expands

the scope to include all

medical devices — not

just electrical ones.

## **Usability for Medical**

## **Devices: A New**

## **International ...**

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FYI: The new IEC  
62366-1 2015 Edition 2

1.0 has just been released. It replaces IEC 62366. The part 2 (IEC 62366-2) is still in process and not yet available. If you would like to read more about the new release, you are welcome to take a look at my review of the document at [StandardsForum.com](http://StandardsForum.com).

Thanks! Claudia

Claudia Bach

Document Center Inc.

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**IEC/FDIS 62366-1**  
**released in**  
**November 2014 -**  
**Software in ...**

Replace the existing references to IEC 60601-1 and IEC 62366, both modified by Amendment 1, with the following new references: IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety

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**IEC 60601-1-6:2010/2  
AMD2:2020 -  
Amendment 2 -  
Medical ...**

IEC 60446 Wiring  
colours (Withdrawn,  
replaced by IEC  
60445:2010) IEC 60447  
Basic and safety  
principles for man-  
machine interface,  
marking and  
identification -  
Actuating principles  
IEC 60450  
Measurement of the

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average viscometric

degree of  $\text{Tr}$  62366 2

polymerization of new

and aged cellulosic

electrically insulating

materials

## **List of International Electrotechnical Commission ...**

IEC 62366 is intended

to implement specific

parts of the risk

management process

defined by ISO 14971

with respect to

usability risk; however,

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IEC 62366-1:2015 was  
written based on the...2

## **Should IEC 62366 be revised?**

Beyond the above, the IEC 62366-1:2015 standard introduces other major changes. The terms “usability-validation” and “-verification” have been replaced by the term “evaluation”. The standard differentiates between “formative evaluation”, which

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takes place in parallel to design and development, and “summative evaluation” at the end of the process.

## **IEC 62366 | TÜV SÜD**

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By Lec 62366 1  
Article 7 62366 2  
reading is the simplest  
way for human to  
derive and  
constructing meaning  
in order to gain a  
particular knowledge  
from a source.

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00998ecf8427e.](https://doi.org/10.1111/1469-7610.12345)