

**62366—
2013**

**IEC 62366:2007
Medical devices — Application of usability engineering to medical devices
(IDT)**



2015

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2 436 « »

3 28 2013 . 1224- -

4 62366:2007 « » (IEC 62366:2007 «Medical devices — Application of usability engineering to medical devices»).

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(www.gost.ru)

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	()	48
	F ()	51
	G ()	54
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	I ()	74
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Medical devices. Application of usability engineering to medical devices

— 2015—01—01

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 014971:2007
 (ISO 14971:2007. Medical devices — Application of risk management to medical devices)

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014971, -

3.1 / (ABNORMAL USE):

1 — 4.1.3
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3.2 (ACCOMPANYING DOCUMENT):

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[014971:2007, 2.1]
3.3 (ALARM LIMIT):

[60601-1-8:2006, 3.3]

3.4 (ALARM OFF):

[60601-1-8:2006, 3.4]

3.5 (ALARM SIGNAL):

[60601 -1-8:2006, 3.9]

3.6 (ALARM SYSTEM):

[60601 -1-8:2006, 3.11]

3.7 / (CORRECT USE):

3.8 (EFFECTIVENESS):

[9241-11:1998, 3.2]

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3.9 (EFFICIENCY):

3.10 (INFORMATION SIGNAL):

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[60601-1-8:2006, 3.23]

3.11 (MEDICAL DEVICE):

in vitro

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[0 13485:2003, 3.7) / (NORMAL USE): , -
3.12* ,

[60601-1:2005, 3.71] / -
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3.13 (PATIENT): (), -

[60601-1:2005, 3.76] (PRIMARY OPERATING FUNCTION); , -
3.14 , -

3.15 (REMINDER SIGNAL): ,

[60601-1-8:2006, 3.34] -
3.16 (RESPONSIBLE ORGANIZATION): , -
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1 — , , , -
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3.17' (USABILITY): -

3.18 (USABILITY ENGINEERING): -
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3.19 (USABILITY ENGINEERING FILE): -

3.20 (USABILITY SPECIFICATION): -
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3.21 / (USE ERROR): -

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3.22 (USE SCENARIO):

3.23* (USER): , , ,

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3.24* (USER INTERFACE): -

[ANSI/AAMI/HE 74:2001, 3.24]

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3.25 (USER PROFILE): , , -

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3.26 (VALIDATION): -

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[9000:2008, 3.8.5]

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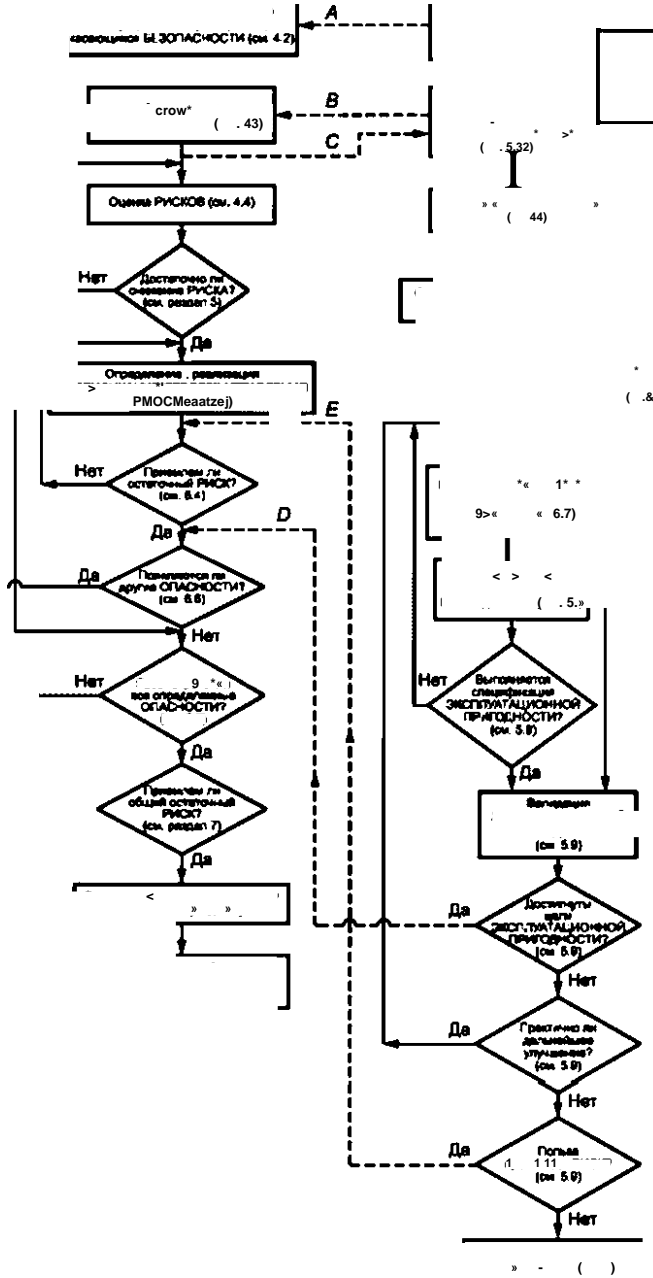
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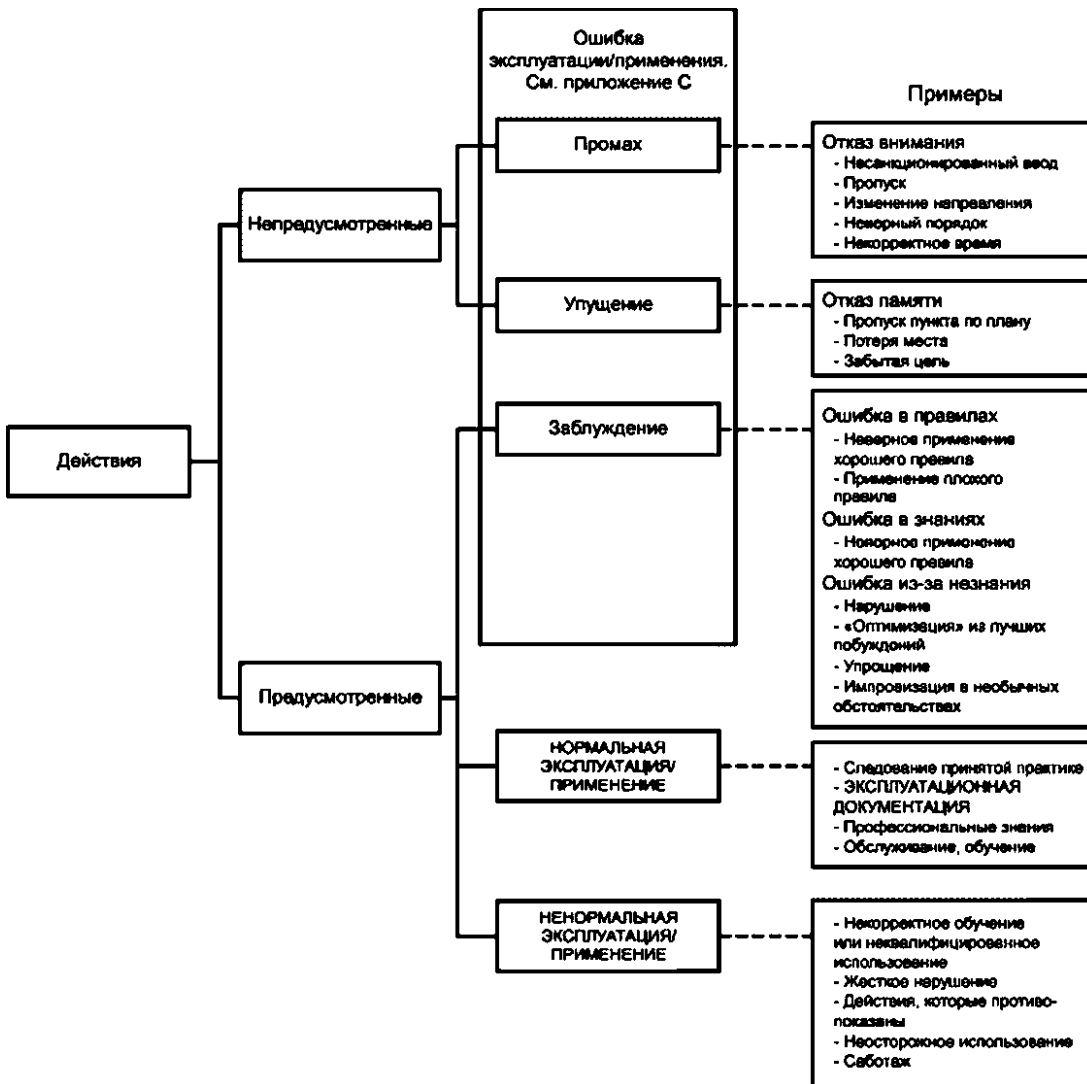
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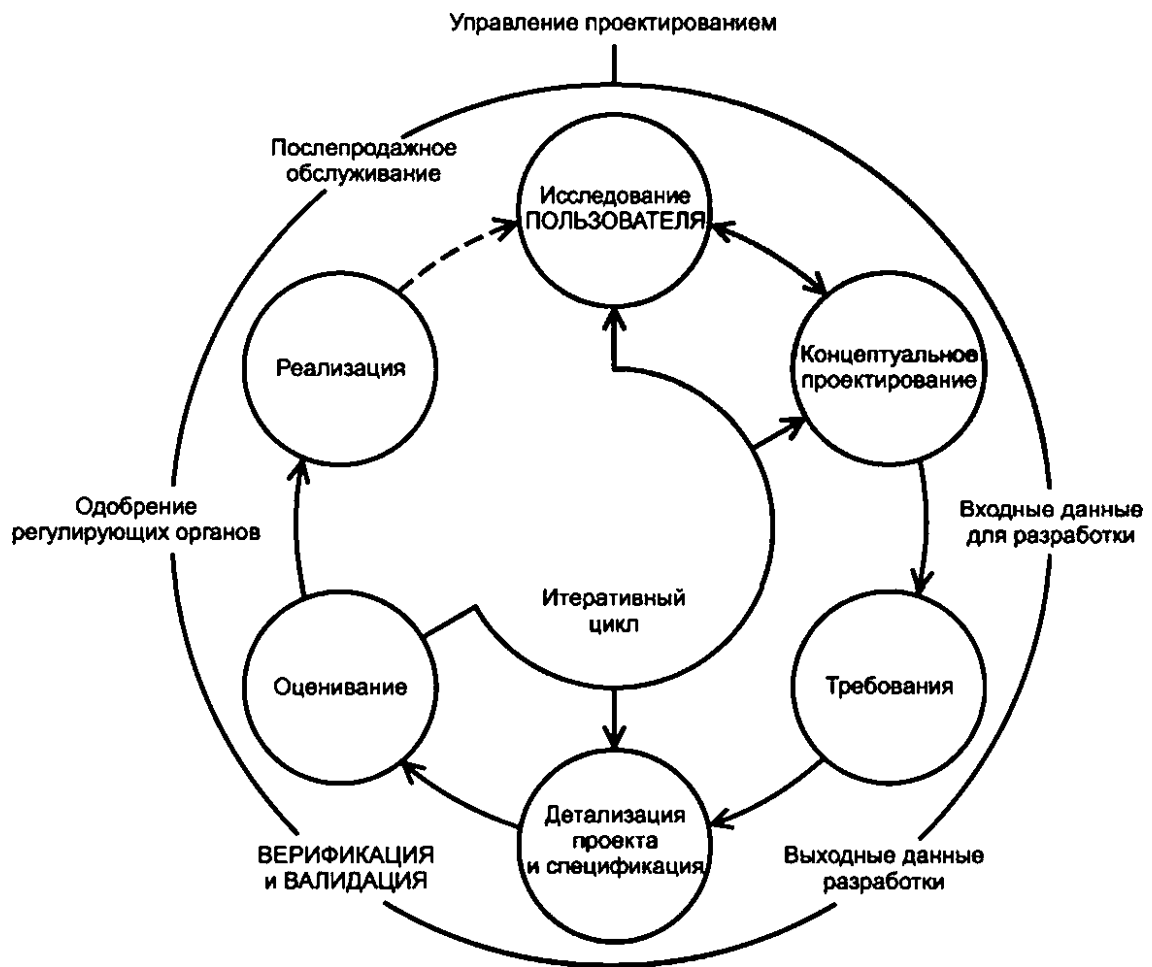
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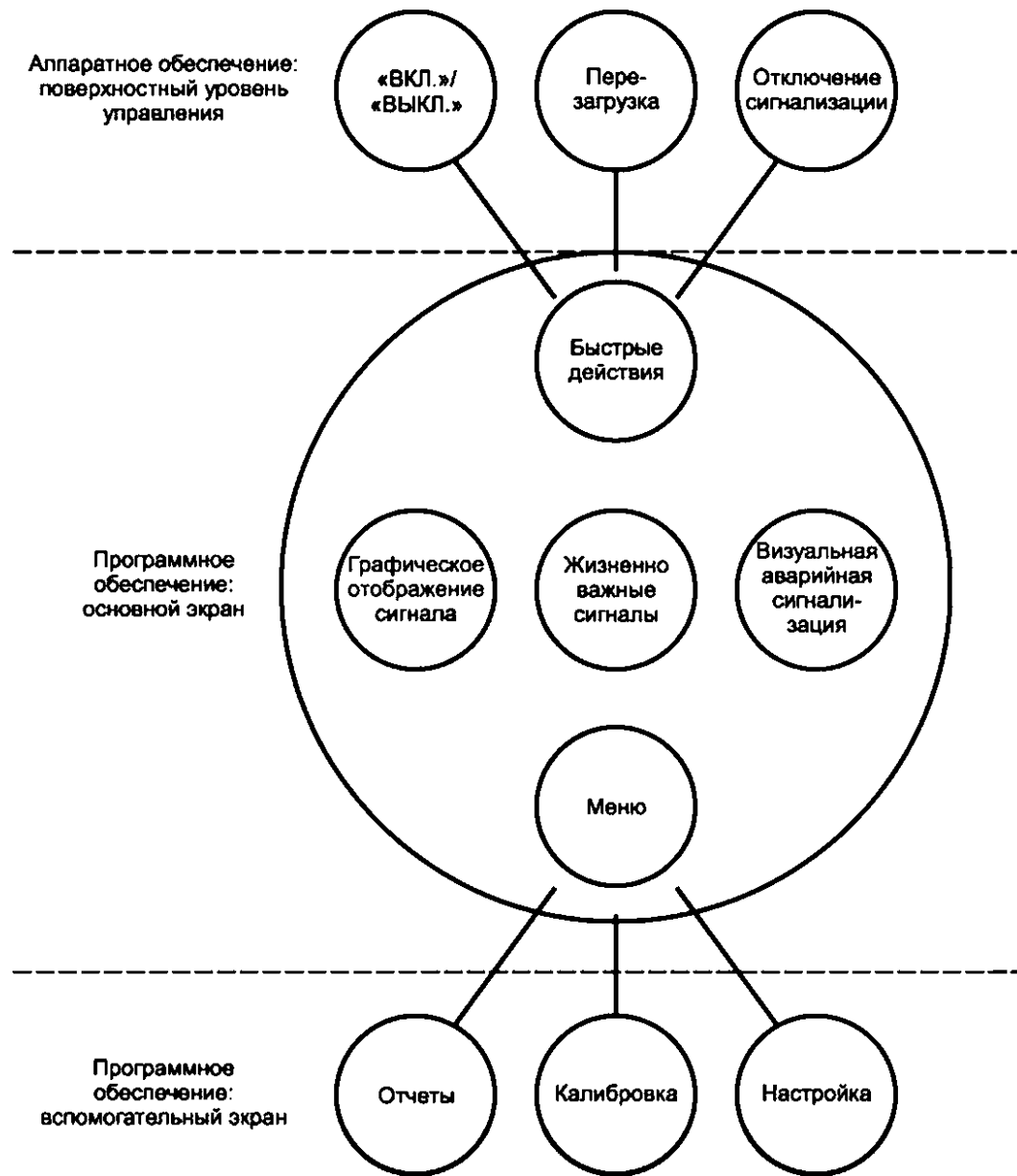
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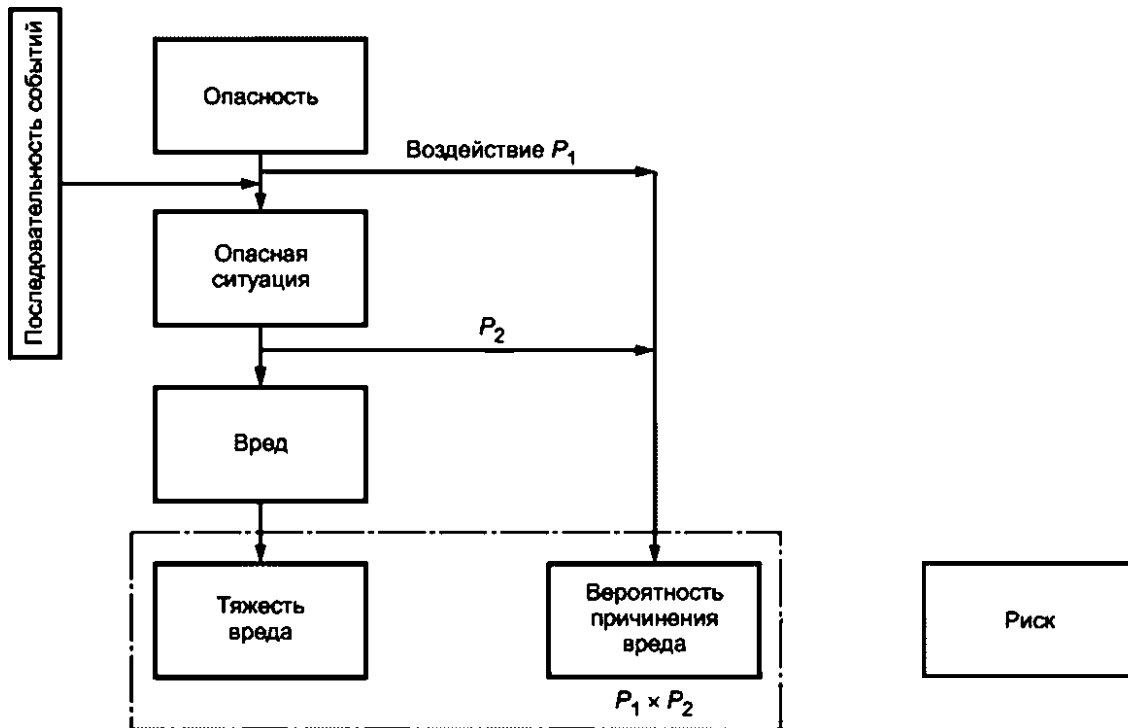
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G.4.4

- (. G.11); (-) (. G.12).
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G.5

G.1—G.12

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<p>,</p> <p>-</p>	<p>85 %</p> <p>-</p> <p>,</p> <p>20</p>	<p>-</p> <p>,</p> <p>,</p>	<p>,</p> <p>,</p> <p>.</p> <p>,</p> <p>,</p> <p>,</p> <p>,</p> <p>,</p>
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Association for Computing Machinery, Special Interest Group on Computer-Human Interaction — <http://www.acm.org/sigchi>

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