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RASOR RESOURCE NEWSLETTER
Valuable, Proven Tools for Medical Device Industry Executives
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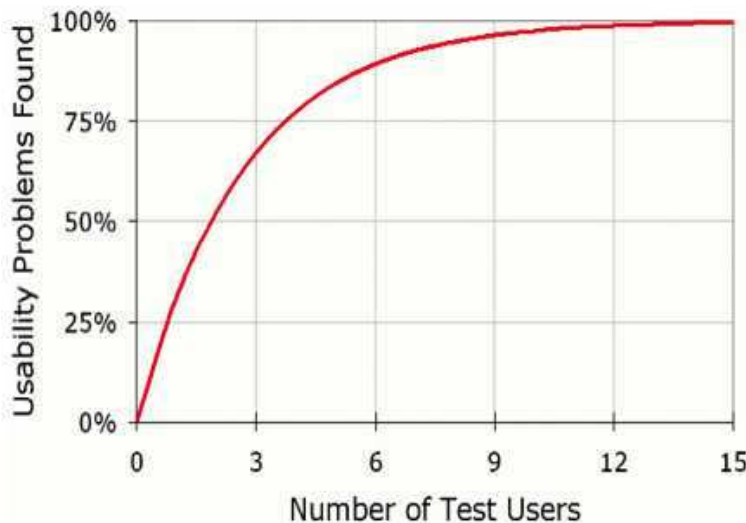
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Greetings Everyone:

Happy New Year! I am delighted to welcome you to the debut issue of Rasor Resource Newsletter from Rasor Consulting Group. Over the years colleagues have shared a plethora of useful tools that I have utilized to assist my clients, leading to results of pivotal importance. I will be sharing these tools with you via this newsletter. I hope you find these resources as useful as my clients and I have.

Julia S. Rasor
 Medical Device Strategist

Resource



Number Of Test Users	Usability Problems Found
0	0.0%
1	31.0%
2	52.4%
3	67.1%
4	77.3%
5	84.4%
6	89.2%
7	92.6%
8	94.9%
9	96.5%
10	97.6%
11	98.3%
12	98.8%
13	99.2%
14	99.4%
15	99.6%
16	99.7%
17	99.8%
18	99.9%
19	99.9%
20	99.9%

Reference: Nielsen, Jakob, and Landauer, Thomas K.: "A mathematical model of the finding of usability problems," Proceedings of ACM INTERCHI'93 Conference (Amsterdam, The Netherlands, 24-29 April 1993), pp. 206-213. [<http://www.useit.com/alertbox/20000319.html>]

Topic: Designing and Testing for Usability of a Medical Device

'Usability': A term used to denote the ease with which people can employ a particular tool or other human-made object in order to achieve a particular goal. Usability can also refer to the methods of measuring usability and the study of the principles behind an object's perceived efficiency or elegance. [<http://en.wikipedia.org/wiki/Usability>]

Problem: How many users (sample size) are needed to discover most of the usability problems with a particular medical device design? OR: FDA has required we test 20 users, what data and references exist that we could use to demonstrate to FDA that a much lower number is effective?

Solution: Jakob Nielsen states from his research shown in the graph above: "The curve clearly shows that you need to test with at least 15 users to discover all the usability problems in the design."

"So why do I recommend testing with a much smaller number of users? The main reason is that it is better to distribute your budget for user testing across many small tests instead of blowing everything on a single, elaborate study. Let us say that you do have the funding to recruit 15 representative customers and have them test your design. Great. Spend this budget on three tests with 5 users each!"

"You want to run multiple tests because the real goal of usability engineering is to improve the design and not just to document its weaknesses. After the first study with 5 users has found 85% of the usability problems, you will want to fix these problems in a redesign. After creating the new design, you need to test again. A second test will discover whether the fixes worked or whether they didn't. Also, the second test with 5 users will discover most of the remaining 15% of the original usability problems that were not found in the first test. (There will still be 2% of the original problems left - they will have to wait until the third test to be identified.)" [<http://www.useit.com/alertbox/20000319.html>]

Jakob Nielsen Recommends: To discover nearly all of the usability problems in a particular design, use an iterative approach, perform 3 tests with 5 users each, making improvements after each test.

Acknowledgement: Many thanks to my colleague who shared this Resource: Doug Worth, Director of Regulatory Affairs, Medical Robotics Company. With gratitude I thank Dr. Nielsen for his research into usability and permission to reprint his work in this issue of Razor Resource.

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 - o Board of Directors (BOD)
 - o Business Model
 - o Market Research, Product Line-up
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 - o Competitor Research
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