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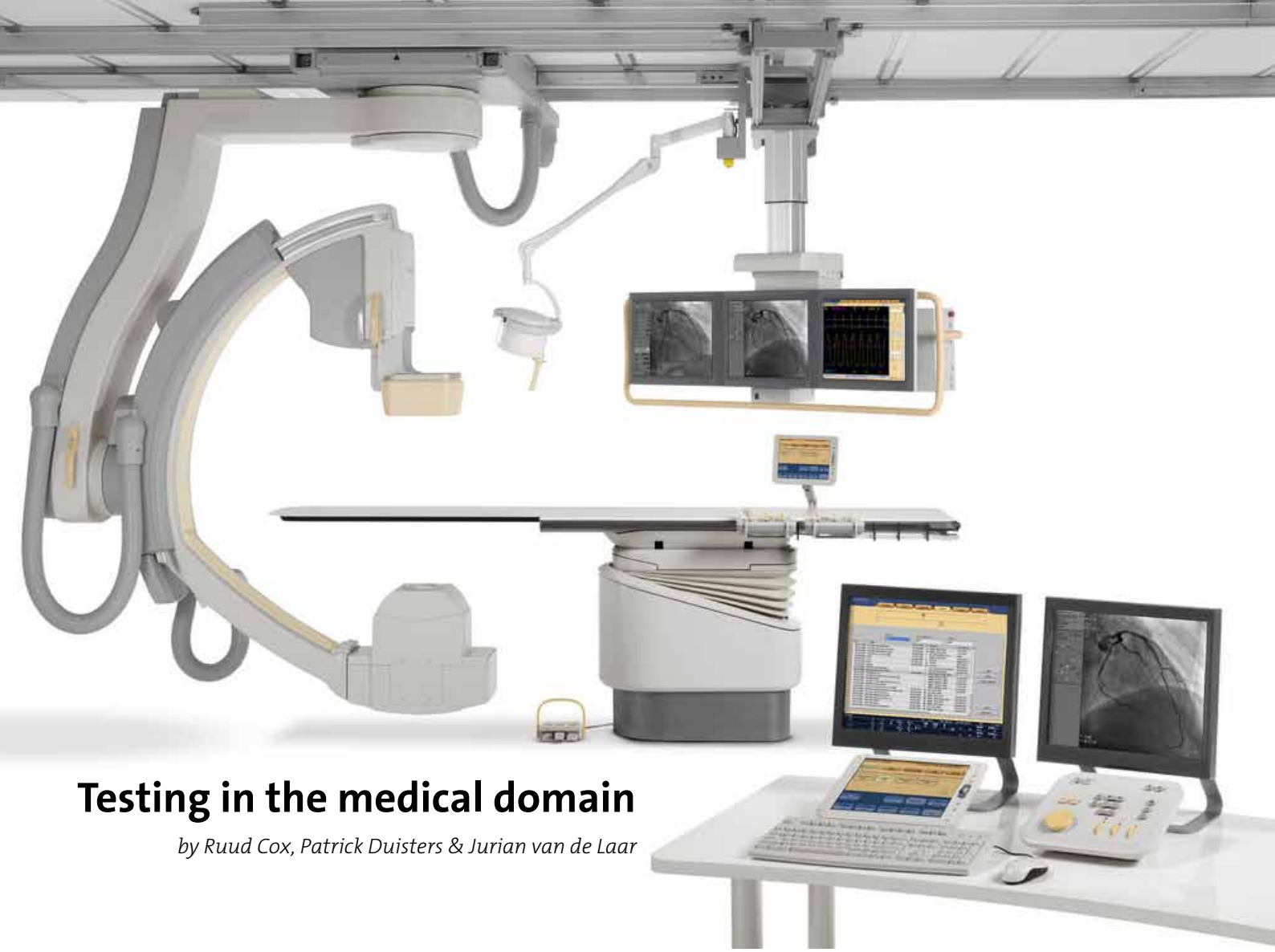

Testing in the medical domain

by Ruud Cox, Patrick Duisters & Jurian van de Laar

What is the influence of the medical domain on the way we organize our testing? Are there any typical constraints on our test approach imposed by the domain? What are the current trends and new insights regarding testing in the medical domain? Are there lessons we learned in this domain that would also be useful in other domains? These are the questions we will address in this article. The authors of the article all have experience in various testing roles in the medical domain.

For testing in the medical domain it may seem obvious to choose a formal approach because of the safety critical nature of the applications. The risks related to systems in this domain typically go far beyond financial risks, as risks can be hazardous or can cause permanent harm to people. That's one of the reasons why regulatory bodies keep track of product quality and of the development process, production and service.

We have several years of experience in the area of integration and testing of large and complex imaging systems used in hospitals all over the world to make X-ray images of the heart and vascular system of a patient for and during medical examination. In these systems complex algorithms are implemented in software (both embedded software and system software) to control the examination process, acquiring the X-ray images but also to control the movement of the X-ray tube/detector combination and the table the patient is lying on while taking into account all surrounding equipment. Everything should work together while the patient's safety as well as the safety of the doctor and other personnel may never be endangered.

The functionality of the system must be verified as well as validated. In this context 'verification' means providing objective evidence (e.g. to regulatory bodies) that specified requirements for this product actually have been fulfilled. Objective means factual, independent of someone's judgment or opinion. In other words proving - with factual test results - that the system works as specified. 'Validation' means that - apart from specifications - the system works in the hospital environment in the way that users intend to use the system. Therefore validation also implies clinical evaluation, which means that the efficacy of the system must be actually proven in a hospital environment. Besides *functionality* there are also other quality characteristics that are important when testing systems in this domain. In our experience usability, reliability, safety and security are the most important additional quality attributes for these systems.

It is typical for the medical domain that objective evidence has to be gathered by testing. This evidence has to be provided to regulatory bodies like the FDA (Food and Drug Administration of the American government). The influence of bodies like the FDA is very large, because an organization like the FDA has investigative jurisdiction and the authority to inspect and stop the export of medical devices to the United States if these devices do not comply with their regulations.

For providing this objective evidence, the tester can resort to various instruments:

1. **Risk based testing**: Like in any large and complex system, testing 'everything' is infeasible, even for safety critical systems. Actually, and *especially* for safety critical systems, it is important to apply a thorough risk analysis to ensure that the most risky parts of the system are tested the most thoroughly and with the highest priority. In our experience the PRISMA® methodology (Product RISk MAnagement) is often applied. With this approach the risk items (that can be features or requirements) are assessed in terms of likelihood (the chance that a defect might occur) and impact (the consequence of a defect if it occurs). Based on these scores the risk items are plotted in a two-dimensional 'risk matrix'. Formal records of this risk analysis are kept and the results are laid down in the (master) test plan. Based on this risk matrix a substantiated test approach is developed, differentiating in e.g. thoroughness of applied testing and review techniques.

2. **Test approach**: Based on the results of a risk analysis, the tester can apply a differentiated approach to derive tests from the test basis. Depending on the risk level he can choose from various formal or informal test design techniques. The level of formality of a test technique is determined by the extent to which the process of deriving test cases from the test basis is prescribed. For very formal test design techniques, like e.g. Decision Table Testing, all the steps from finding the test conditions in the test basis to the specification of test cases and test procedures are exactly specified. Applying such a technique is like following a recipe. In this respect, the design process becomes less dependent on the person (the tester), and the resulting test cases guarantee a certain type and level of coverage. Decision table testing, for example, guarantees that all possible combinations of the input conditions have been exercised. The process of deriving tests will be more objective. Finding the inputs (test conditions) will of course remain very strongly dependent on the skills of the tester.

3. **Traceability**: Regulatory bodies like the FDA, but also maturity models like CMMI (Capability Maturity Model Integration) require a certain level of traceability. The pitfall for many organizations - not only in the medical domain - is that they try to achieve traceability to an almost exhaustive extent, which increases the amount of work - and maintenance - exponentially. From a testing point of view the most important objective of traceability is to demonstrate (provide evidence) that requirements - typically at higher levels, e.g. system level - are exercised by related (system-) test cases.

The influence of regulatory bodies on an organization in the medical domain is quite large, especially on the testing process, for the purpose of 'providing evidence' as explained above. What are the consequences of this influence? Does this influence contribute to 'better testing' or not? We think that this influence has both positive and negative effects. The obligation to adhere to regulations can be used as enabler to improve the test process. It provides focus in the organization to deliver quality and it helps to bring the testing activities to a higher maturity level - simply because this is necessary for providing the required objective evidence. On the other hand, the risk of an FDA finding - that may lead to serious consequences for the business - is constantly lurking. Because the consequences may be so severe, it is vital for the organization to take all necessary measures to prevent this risk becoming reality. This may result in a very sensitive, risk-averse attitude. Just to be on the safe side, processes and measures may be defined or interpreted more strictly and formally than what the regulatory bodies actually require. In the following, the process may become a goal in itself, limiting the creativity and efficiency of the development organization.

In our practice we sometimes see misunderstandings and pitfalls due to this attitude. These are some examples:

- "**Testing everything after all**": Even after a risk analysis has been done, some testers still prefer to execute all available test cases instead of applying a differentiated test approach. 'Executed all available tests' is interpreted as 'Tested everything'. Especially large test suites provide a false feeling of reassurance. A large amount of tests doesn't necessarily mean high coverage and even the highest requirements coverage or code coverage do not guarantee that all defects will be detected. Testing everything is infeasible.
- "**Formal test techniques will result in higher quality**": Untrue. Formal doesn't necessarily mean that the test is better. Informal tests are often even 'smarter' because the tester uses his skills and experience to detect the most important defects.
- "**Regulatory bodies like FDA prescribe how testing must be done**": No. FDA does neither prescribe the test approach nor does it prescribe that formal test techniques should be applied. The FDA does require transparency: demonstrate (document) how the requirements have been covered and which test results you have used to determine whether the test passed or failed. It's important to show (document) what you have done and why (rationale), but the approach itself can be formal as well as informal.
- "**Thorough testing means repeating the same tests over and over again**": This is another misunderstanding. Repeating the same tests may result in 'the pesticide paradox'. When you always use the same pesticide (test suite), you won't find any new defects anymore, because the 'bugs' have become resistant for the cure.

As a next phase in the evolution of the test profession becoming more mature - probably as the result of the need for higher efficiency and more effectiveness - we see a trend to more agile and informal practices being applied in the medical domain.

Applying an approach like Exploratory Testing (ET) can be very beneficial - also in the medical domain. As mentioned above, provision of objective evidence is needed. While applying ET the common properties of ET provide support. If charters are made (and reviewed) in advance and sufficient logging is created during execution, ET can successfully be used in the medical domain.

Whereas formal techniques attempt to achieve a certain level of coverage by the way test cases are derived from the test basis (the 'recipe'), informal techniques require another kind of 'evidence'. In this case, the competence of the tester makes the difference!

Also on this issue, the regulatory bodies require evidence: resumes ('curriculum vitae'), records of test related training, and, where applicable, certifications of the testers are to be kept and can be used to convince the regulatory bodies of the skills and experience of the tester(s) involved.

What about traceability? The contents of the charters can be related to the tagged requirements. During execution the require-

ments can be referred to in the notes and system logging or video can be tagged with the requirements.

Of course, this requires some effort, but compared to formal techniques it is a rather limited effort.

Even the risk of a 'pesticide paradox' is reduced significantly by Exploratory Testing. The time saved compared to formal testing can be spent on finding new or 'other defects', defects that might not be found by formal test design techniques which are based on specified requirements.

Our conclusion is that testing in the medical domain can benefit from both formal and more informal and agile practices. We have published this article because we are convinced that other domains can benefit from these insights as well. The importance of testing in the medical domain is driven by the need for providing evidence to regulatory bodies as well as the crucial importance of developing safe products. These have been the driving force to become leading in test process maturity. The lessons learned, as described in this article, are not only useful in this domain.

Furthermore we see that the need for risk management and 'control' is also growing in other industries. In domains where software controlled safety critical systems operate this isn't a surprise. However, in our experience there are not always regulatory bodies, like the FDA, which have the authority to inspect the processes in such detail and with such consequences. In the rail industry, for example, there are regulations, but regulatory bodies don't always have authority similar to the FDA - at least not in all countries. Often regulatory organizations rely on the evidence delivered by the manufacturers. The (testing) process is not inspected on site.

We also have seen examples where independent specialized companies are asked to perform expert reviews or audits on the testing of safety critical (software) parts of the technical systems for tunnels. In these cases the governmental safety & security officers rely on the knowledge of the involved experts.

Finally, we expect that the influence of regulatory bodies will increase - also in other domains. We therefore think that the lessons learned in the medical domain may become more and more valuable to others as well. A starting point can be to just write down what you do, and do what you have written down.

> biography

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