3rd UCAAT User Conference on Advanced Automated Testing

ETSI World Class Standards

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USING MBT TO CHECK SAFETY OF MEDICAL DEVICES

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QCORE medical

SELA

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- Q&A

Consultant: Natalia Meergus

- Software developer, test engineer, architect, ALM consultant
- Previous jobs: Microsoft, electric cars, birth and delivery
- Certifications: ISTQB CTFL, Ranorex Certified Professional
- ISTQB affiliate (MBT syllabus review)

Consulting company: SELA Global Group

Training

Consulting

Offshore

SDP Conference

Microsoft Partner
Gold Application Lifecycle Management
Gold Software Development
Gold Web Development
Gold Learning

ALM

22 years in IT business

Knowledge Center

The Client: QCore Medical

- Developer and producer of infusion pump devices
- Selling 10s of thousands of devices annually worldwide
- Customers including *Pfizer*
- End-users including potentially anyone

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MEDICAL DEVICES DOMAIN

“Protecting and promoting *Your* health” (USA FDA)

QCORE medical SELA

Safety above all

Epidural overdose: An anesthesiologist responds

| UNCATEGORIZED | OCTOBER 16, 2006

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Tragic event, but as usual, news reports raises more questions than answers:

The drugs used in labor epidurals are usually a dilute local anesthetic and a small amount of narcotic. Using both types of drugs in combination allows lower concentrations of each individual drug to be used, hence improving the margin of safety for each. In labor epidurals, our goal is relieve pain without causing significant weakness. That is why we use some local anesthetics over others, at low concentrations, and with narcotics (epidural narcotics relieve pain without paralyzing the patient).

This combination is typically infused via the epidural catheter at a rate of 10 to 15 cc/hr. If necessary (i.e. if the patient continues to have pain) we give additional volumes of epidural drug to try to get them comfortable.

How much? I've given up to 26 cc in an hour.

What's going on with this patient? I can think of two possibilities: Either the 'paralysis' described is from the large amount of local anesthetic she received (in which case it will resolve) or the large volume of anesthetic

Medical devices regulation

- National/regional regulation bodies and auditors
- Extensive and ever evolving regulation
  - IEC/ISO: 62304, 1025, 812, 62366
  - FDA: “General principles of software validation”, 21 CFRs
  - MEDDEV, HIPPA and more
- Development process and release times heavily affected

FDA infusion pump initiatives

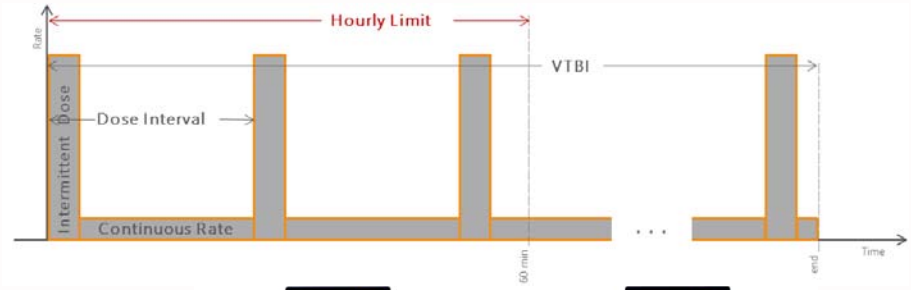
- Infusion Pump Improvement Initiative initiated
- Specific Infusion Pumps Total Product Life Cycle Guidance issued
- Generic Infusion Pump project (MBT)

MBT APPLICATION

"Experience, the child of tough mistakes" (A. Pushkin)

The case for MBT

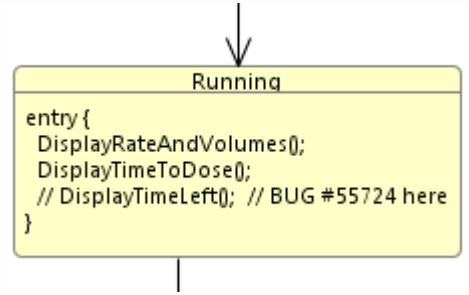
- Complicated product definition
- Limited reach of traditional testing
- Very high costs of safety-related bugs
- Numerous common functionality/code



Conventional usage of MBT – the process

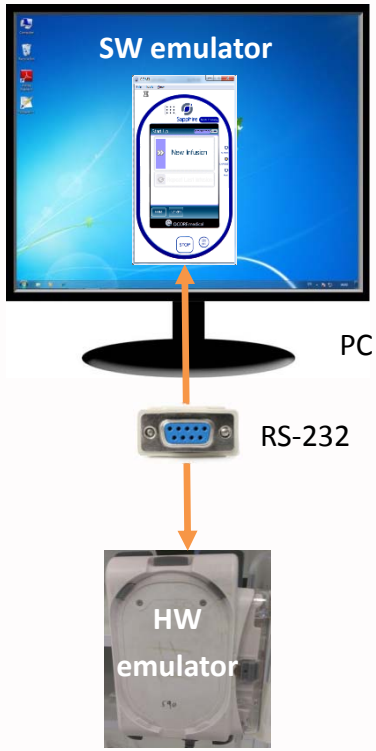
- Modeling in parallel with product development

- Pushing requirements engineering and contributing to the product design
- Updating the models to go beyond opened bugs



Conventional usage of MBT – the test system

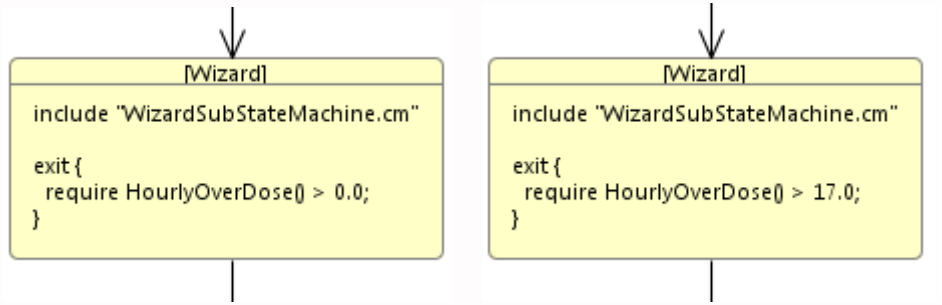
- Models creation and test generation in CONFORMIQ Designer
- Test cases export to XML followed by conversion to proprietary XML automation framework format
- Test execution on combined hw/sw emulator
- Now switching to C# framework and full software emulation of the device



Non traditional usage of MBT

The MBT tool can be used to do additional smart things for you:

- check safety constraints
- discover a defect's risk



Summary

- Extending test coverage comes at much less effort
- MBT test cases found bugs missed by manual testing
- Update of lots of test cases done by local change
- MBT tool solves additional problems on the model like checking correctness of requirements
- Allocating dedicated modeler and time to learn is a must
- Mind expected pitfalls