



UNIVERSITÀ DI PISA
DIPARTIMENTO DI INGEGNERIA DELL'INFORMAZIONE
Dottorato di Ricerca in Ingegneria dell'Informazione

Corso di Dottorato

“Design and analysis of software for interactive medical devices”

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Aula riunioni piano terra

Short Abstract: Interactive medical systems used in hospital and home care are controlled by software that governs key aspects of the user interface and performs key safety functions. If medical systems are to be used safely, it is important that user interface software is designed to make the device easy to use and mistakes made by users are corrected.

This course presents tools and techniques for design and analysis of software incorporated in interactive medical systems. The learning outcomes are: (i) understanding of the design challenges with user interface software for medical systems; (ii) understanding of model-based design and analysis techniques for user interface software; (iii) practical experience with SRI's state-of-the-art verification system PVS (<http://pvs.csl.sri.com>) and the PVSio-web tool (<http://www.pvsioweb.org>) for prototyping and analysis of medical user interface software.

While this course focuses on medical systems, the techniques presented are in fact generally applicable to other safety-critical domains, including avionics, aerospace, and automotive. The work presented in this series of lectures has been developed within the CHI+MED research project (<http://www.chi-med.ac.uk/>), and in collaboration with the Center for Devices and Radiological Health of the US Food and Drug Administration (CDRH/FDA).

Course Contents in brief:

- Introduction and motivation (3 hours)
- Usability and safety requirements for medical device software (4 hours)
- Verification and validation of medical device software (6 hours)
- Final remarks and test (3 hours)

Total 16 hours, 4 credits

Detailed schedule

Mon (13 October, 3h): 10am-1pm

Regulatory challenges for medical devices - Case study: design issues in medical device software
- Understanding the relation between use errors, human error, and software design issues

Tue (14 October, 5h): 10am-12noon / 2pm-5pm

Modelling and analysis of medical device software using formal methods technologies - Lab session: a gentle introduction to the PVS verification system - Lab session: modelling user interface software in PVS - Lab session: rapid prototyping user interface software using PVSio-web

Wed (15 October, 5h): 10am-12noon / 2pm-5pm

Hazard analysis techniques for identifying use-related hazards - From hazards identification to defining usability and safety requirements - Lab session: a gentle introduction to the PVS theorem prover - Lab session: verification of user interface software in PVS

Thu (16 October, 3h): 10am-1pm

Concluding remarks - Final test

Paolo Masci - Short biography

Paolo Masci is a postdoctoral research assistant at Queen Mary University of London. He is an expert user of verification tools such as SRI's state-of-the-art theorem proving system PVS. His research interests include: medical cyber-physical systems, user interface verification, software verification, and automated reasoning. Since 2010, he is working within chi+med (www.chi-med.ac.uk), a UK research project that aims to make medical devices safer. While based in the UK, Paolo has entered into a variety of international collaborations for the analysis of medical device software, including joint work with the Food and Drug Administration (FDA) that regulates medical devices in the USA. This year, Paolo was awarded a fellowship from SRI International for the development of novel extensions to the PVS verification system. Together with the chi+med team, he won a UK healthcare award for outstanding impact in healthcare and wellbeing.