Model-based Dependability Analysis of Medical Infusion Pumps

Sriram Sankaranarayanan and Clayton Lewis
University of Colorado, Boulder.

Abstract:

Infusion pumps are commonly used in home/hospital care to inject drugs into a patient at programmable rates over time. However, in practice, a combination of faults including software errors, mechanical failures and human error can lead to catastrophic situations, causing death or serious harm to the patient. Dependability analysis techniques such as failure mode effect analysis (FMEA) can be used to predict the worst case outcomes of such faults and facilitate the development of remedies against them. Recently, there has been much interest in the use of formal tools to facilitate model-based dependability analysis.

We present the use of model-checking to automate the dependability analysis of programmable, real-time medical devices. Our approach uses timed and hybrid automata to model the real-time operation of the medical device and its interactions with the care giver and the patient. Common failure modes arising from device failures and human error are modeled in our framework. Specifically, we use ``mistake models'' derived from human factor studies to model the effects of mistakes committed by the operator. We present a case-study involving an infusion pump used to manage pain through the infusion of analgesic drugs. The dynamics of analgesic drugs are modeled by empirically validated pharmacokinetic models. Using model checking, our technique can systematically explore numerous combinations of failures and characterize the worse case effects of these failures.