Journal of Diabetes Science and Technology
Volume 5, Issue 6, November 2011

ORIGINAL ARTICLE

Generic Safety Requirements for Developing Safe Insulin Pump Software

Yi Zhang, Ph.D.,[1] Raoul Jetley, Ph.D.,[1] Paul L. Jones, MS/CE,[1] and Arnab Ray, Ph.D.[2]

Abstract

Background:

The authors previously introduced a highly abstract generic insulin infusion pump (GIIP) model that identified common features and hazards shared by most insulin pumps on the market.

The aim of this article is to extend our previous work on the GIIP model by articulating safety requirements that address the identified GIIP hazards. These safety requirements can be validated by manufacturers, and may ultimately serve as a safety reference for insulin pump software. Together, these two publications can serve as a basis for discussing insulin pump safety in the diabetes community.

Methods:

In our previous work, we established a generic insulin pump architecture that abstracts functions common to many insulin pumps currently on the market and near-future pump designs. We then carried out a preliminary hazard analysis based on this architecture that included consultations with many domain experts. Further consultation with domain experts resulted in the safety requirements used in the modeling work presented in this article.

Results:

Generic safety requirements for the GIIP model are presented, as appropriate, in parameterized format to accommodate clinical practices or specific insulin pump criteria important to safe device performance.

Conclusions:

We believe that there is considerable value in having the diabetes, academic, and manufacturing communities consider and discuss these generic safety requirements. We hope that the communities will extend and revise them, make them more representative and comprehensive, experiment with them, and use them as a means for assessing the safety of insulin pump software designs. One potential use of these requirements is to integrate them into model-based engineering (MBE) software development methods. We believe, based on our experiences, that implementing safety requirements using MBE methods holds promise in reducing design/implementation flaws in insulin pump development and evolutionary processes, therefore improving overall safety of insulin pump software.

J Diabetes Sci Technol 2011;5(6):1403-1419

Author Affiliations: [1]Office of Science and Engineering Laboratories, Center for Device and Radiological Health, U.S. Food and Drug Administration, Silver Spring, Maryland; and [2]Fraunhofer Center for Experimental Software Engineering, College Park, Maryland

Abbreviations: (BG) blood glucose, (GIIP) generic insulin infusion pump, (MBE) model-based engineering, (V&V) verification and validation

Keywords: insulin pump, model-based engineering, safety requirement, software

Corresponding Author: Yi Zhang, Ph.D., Office of Science and Engineering Laboratories, Center for Device and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993; email address Yi.Zhang2@fda.hhs.gov