

## A Hazard Analysis for a Generic Insulin Infusion Pump

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### Abstract

#### **Background:**

Researchers at the Food and Drug Administration (FDA)/Center for Device and Radiological Health/Office of Science and Engineering Laboratories have been exploring the concept of model-based engineering as a means for improving the quality of medical device software. Insulin pumps were chosen as a research subject because their design provides the desired degree of research complexity and these types of devices present an ongoing regulatory challenge.

#### **Methods:**

Insulin pump hazards and their contributing factors are considered in the context of a highly abstract generic insulin infusion pump (GIIP) model. Hazards were identified by consulting with manufacturers, pump users, and clinicians; by reviewing national and international standards and adverse event reports collected by the FDA; and from workshops sponsored by Diabetes Technology Society. This information has been consolidated in tabular form to facilitate further community analysis and discussion.

#### **Results:**

A generic insulin infusion pump model architecture has been established. A fairly comprehensive hazard analysis document, corresponding to the GIIP model, is presented in this article.

#### **Conclusions:**

We believe that this work represents the genesis of an insulin pump safety reference standard upon which future insulin pump designs can be based to help ensure a basic level of safety. More interaction with the diabetes community is needed to assure the quality of this safety modeling process.

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**Abbreviations:** (BG) blood glucose, (FDA) Food and Drug Administration, (GIIP) generic insulin infusion pump, (ISO) International Organization for Standardization, (MBE) model-based engineering, (PHA) preliminary hazard analysis

**Keywords:** hazard analysis, insulin pump, safety

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