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SYMPOSIUM

The Role of Human Factors in the Design and Development of an Insulin Pump

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Abstract

This article discusses human factors (HF) processes and how they are applied during the development of a medical device to minimize the risk that the user interface design could lead to patient errors, adverse events, and product recalls. This process is best defined as "prevention through design." The HF design process is exemplified by three distinct phases: (1) preliminary analysis, (2) formative design evaluation and modification, and (3) design validation. Additional benefits of employing HF principles during medical device development are briefly reviewed, including reduced patient risk by eliminating design flaws, increased patient adherence through the reduction in the complexity of therapeutic regimes, and reduced likelihood for product recalls.

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Abbreviations: (FDA) Food and Drug Administration, (HF) human factors, (SUS) system usability scale

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