FAILURE ANALYSIS OF AN ARTIFICIAL PANCREAS – DOUBLE SUBCUTANEOUS VS. DOUBLE INTRAPERITONEAL APPROACH

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MOTIVATION

Aim: Artificial pancreas (AP)
- Continuous glucose monitoring
- Fully automated insulin infusion
- No user input

Safety requirements
Increased degree of automation
- Increased safety and reliability needs
- Need for automatic fault detection

FMEA

Failure Modes and Effects Analysis (FMEA) [3]
- Conducted by the authors with competence in cybernetics, control engineering, sensor technology, endocrinology, and medical care for patients with diabetes mellitus type 1

SYSTEM

General assumptions
- No hardware failures due to manufacturing process
- No software failures

Insulin infusion
Off-the-shelf insulin pump
Off-the-shelf consumables

Controller
- Capable of keeping nominal blood glucose level under normal circumstances
- No safety features implemented

Glucose sensing
- Enzyme-based
- Amperometric sensors

REFERENCES