# Hardware/Software Architecture for Improving the Safety of Implantable and Wearable Medical Devices

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## Technology description

Implantable and wearable medical devices (IWMDs) have become increasingly sophisticated over the years and are now commonly equipped with advanced features. However, unsafe operations of IWMDs such as software bugs, malicious attacks, or even user errors are of utmost concern to patients since they can be life-threatening.

Inventors at Princeton University in the Department of Electrical Engineering and at Purdue University have developed a novel approach for enhancing the IWMD's safety, identifying unsafe IWMD operations, and preempting them before they can have an adverse effect on the patient.

There are many considerations in the design of a safe IWMD architecture. For example, high-level context awareness is essential for accurate decision making regarding safety. Additionally, unsafe operations should be identified and blocked in a proactive manner before they are performed, because operations of IWMDs may be irreversible. It is preferred that the safety checking be performed in a computing environment that is isolated from the normal functions of the medical device to prevent propagation of failure. Further, due to the stringent power constraints imposed on IWMDs, the power overheads imposed by the checking mechanism should be kept be as low as possible.

This invention describes a hardware/software architecture for improving the safety of IWMDs. The safety coprocessor is integrated into the IWMD such that it has full visibility of the I/O transactions performed by the host microcontroller. Utilizing the transaction information, the coprocessor applies a multi-layered decision process to evaluate the safety of IWMD operations. In order to ensure that unsafe operations are pre-empted, all actuator commands issued by the host microcontroller need to be validated by the safety coprocessor before they can reach the appropriate peripherals. In effect, the safety coprocessor acts as a last line of defense to prevent unsafe operations from affecting the patient. To provide for flexible and robust safety checking, the safety coprocessor was implemented using a low-power microcontroller that is physically isolated from the host microcontroller within the IWMD.

Key Words

Implantable and wearable medical devices, safety, coprocessor, host microcontroller, multi-layered decision, unsafe operations, preemption.

## Application area

• Safety monitoring and attack preemption for IWMDs
• Cybersecurity

## Advantages

• High visibility of the operational state of IWMDs
• Control of the IWMD immediately following the detection of unsafe operations
• Isolation of safety assurance mechanism from medical functionality of IWMDs
• Can be integrated into existing IWMDs
• Low power requirement

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