



REVOLUTIONARY INSULIN PUMP SYSTEM

PharmaSens AG has been active in Diabetes Management for several years with a clear business strategy aimed at revolutionizing the insulin pump market with new products. Their first product “niia essential” consists of a very compact insulin patch pump, assorted consumables for insulin handling, and tablet software for the pump configuration. Ease of use and user experience are a central focus for all products.

Single fault safety tablet software

The development team for the insulin pump system involved several partners and was led by PharmaSens. konplan was responsible for developing the tablet software for the insulin pump configuration. Together with an intuitive user interface, the central focus of this sub-task was on the architecture and implementation of a single fault safety software. This guarantees that user input is written to the insulin pump without errors and the pump is configured correctly.

The tablet software and the BLE communication to the pump were fully verified and documented in accordance with the FDA “Enhanced Documentation Level” (formerly “Major Level of Concern”) including cyber security aspects.

Successful FDA submission

The FDA approval application for the insulin pump system was timely submitted by PharmaSens. konplan provided support for the successful submission with their medical technology know-how and the quality of the documentation and software development.

Result

- Agile project setup
- DHF-compliant documentation
- 100% test coverage of critical components
- Successful FDA submission

Methodology & Technologies

- Single fault safety
- IEC 62304, IEC/TR 80002-1
- Bluetooth LE (BLE secure)
- Android, kotlin / Java

Scope of Services

- Requirements management
- Software architecture
- Risk analysis
- Complete implementation & verification of the software



12 months



5 employees – konplan



Requirements, architecture, implementation, configuration, verification, support

Customer

