



Technology Transfer in Computing Systems

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TETRACOM TTP 48: Personalized Nutrition Control Aid for Insulin Patch Pump

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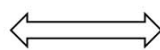
Diabetes is a chronic condition marked by high levels of glucose in the blood. In type 1 diabetes, the body completely stops producing any insulin, a hormone that enables the body to use glucose found in foods for energy. People with type 1 diabetes must daily receive insulin to survive. Insulin pump therapy offers efficient metabolic disorder control and represents a cost effective alternative to multiple daily insulin injections. Compared with 'classical' pumps, insulin patch pumps offer patients more freedom. They are the 'next generation' devices: discreet, smaller (the size of the patch) and a lot more convenient to wear. They allow patients to engage in everyday activities such as sport and even swimming.

The Insulin Patch Pump developed by IPD Med is designed for continuous insulin delivery according to personalized, pre-programmed plan. The device provides both basal and bolus modes of insulin delivery. It consists of a reusable shell that attaches to a disposable unit. The device is attached to a body with an adhesive patch. The shell contains a battery powered microprocessor with corresponding controls, alerting devices and RF circuitry. The disposable unit includes a pumping mechanism, proprietary insulin reservoir and COTS/OEM infusion set. An RF remote control unit is provided to manage and program the device.

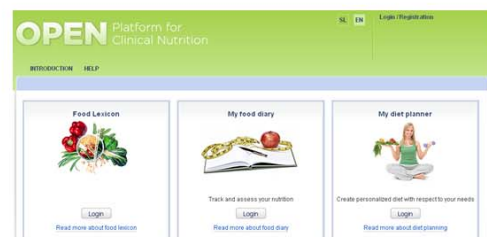
The disposable unit represents only 0.5% of the total price, which is a considerable advantage in comparison with existing devices on the market. However, even more significant step forward is expected by providing the users with the possibility to access OPEN Platform For Clinical Nutrition developed by Jozef Stefan Institute (JSI). OPEN is a web-based application (<http://opkp.si/>) that supports food and physical activity recording and diet planning. OPEN enables online interaction between a dietitian and his (her) patient. To support its use in different countries, OPEN allows translation of the user interface into other languages as well as the use of any food composition dataset that complies with Food data structure and format standard (BS EN 16104:2012). OPEN refers to international, evidence-based dietary recommendations, which can be modified by the dietitian to suit the needs of individuals.



Insulin Patch Pump developed by **IPD med**



Personalized user interface



OPEN Platform For Clinical Nutrition developed at the Jozef Stefan Institute supports food and physical activity recording and diet planning (<http://opkp.si>)

In connection with OPEN platform, the Personalized Nutrition Control Aid for Insulin Patch Pump will provide the user simple means to obtain detailed data on his/her nutrition intake needed for the prediction of insulin dosing profile. Personalized user interface will help the user to determine carbon hydrate intake with higher accuracy than currently established methods. Consequently, the insulin therapy is improved by reducing the risk of hypoglycemia caused by improper data input. The aid will also allow the user to keep the food diary and provide access to extensive food lexicon. Personalized user interface is currently under construction. Its concept closely resembles a similar one designed as a mobile app in the frame of PD_Manager, which aims of collecting data about nutrition in patients with Parkinson's disease (<http://www.parkinson-manager.eu/#>).

Since the designed Insulin Patch Pump is classified as class IIb medical device according to MDD 93/42/EEC, in-depth risk management including usability testing must be performed. In this regard, extensive risk analysis has been performed by IPD Med, while JSI, who has proven expertise in human-computer interaction has prepared the assessment usability test plan in accordance with Standard IEC 62366 (Medical devices – Application of usability engineering to medical devices). Usability testing with a target group of volunteers is planned for September. While work on the project is still running and in accordance with the contract between JSI and IPD Med will continue until the end of October 2016, the current results of the TTP supported by TETRACOM represent an important step toward TRL 7.