Nephron+: First WAKD Prototype Finalized and Results from First Animal Trials

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The European project Nephron+ aims at developing an integrated solution for personalized treatment and management of patients with Chronic Kidney Disease on a daily basis outside the hospital setting. When compared with standard haemodialysis treatment at the hospital, the Nephron+ solution will offer better blood clearance as a key medical progress. At the same time the Neprhon+ concept will improve the patient's quality of life by improving the patient mobility, enabling an increased social interaction and working activities.

Nephron+ is a complex ICT-enabled system, centered on the WAKD, which is in charge of carrying out the medical treatment and sustaining the continuous renal replacement therapy. The system is complemented by the Back-End at the hospital, composed by a Server that hosts the Nephron+ application and a Database to manage patient data. The application allows doctors to monitor the patient evolution with the support of the linking infrastructure based on a GSM/GPRS/UMTS network. Figure 1 shows a block diagram of the complete system architecture.

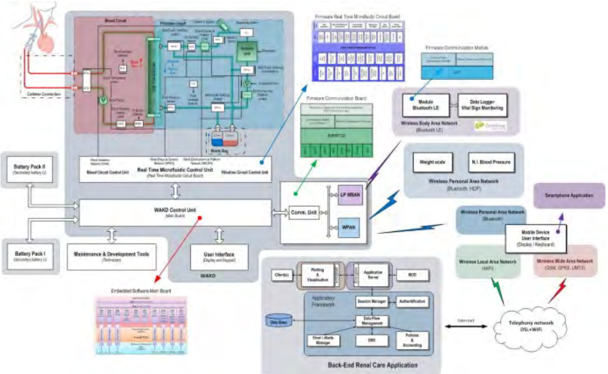

Figure 1: Nephron+ complete system architecture.

The innovation that the WAKD brings is the closed-loop working principle, where a Sorbent Unit replaces the dialysis infrastructure at the hospital, by demanding a relatively small amount of dialysate throughout the whole process, avoiding in this way the need of being connected to a source of dialysate while the patient is dialyzing.

A medical outcome of this source independence of the dialysate, besides the freedom of motion, is that the treatment can run more slowly and the dialysis session can be executed more often, which highly benefits the patient because the vital and physiological parameter changes are smoother.

However, the method is not easy to achieve and challenging. The Sorbent Unit bases the toxin removal on a combination of nanosorbents delivery, electro-oxidation, electro-deionization and regeneration processes. These processes require the WAKD microfluidic circuit to be reconfigured in order to run a four-step operating cycle, together with the continuous measurement of physical, physiological and electrochemical variables. Moreover, the method also requires the injection (and measurement) of vitamin C to neutralize the chloramines the electro-oxidation produces and the use of a degassing module to allow freeing the circuit from the pressure resulting from the gases it introduces. The system complexity is translated into the design, the manufacturing, the programming and the system integration and will have a considerable impact on the test procedures. Several requirements had to be considered, starting by safety and reliability, but also the usability, the power consumption and the data protection, among many others. At the end of the third year of the European project, the first prototype of the Wearable Artificial Kidney Device (WAKD) has been implemented and a preliminary animal trial has been carried out at UMCU [1], conducted by them together with the project partner NANO [2]. The tests lasted two hours non-stop without any major technical issue. Figure 2 shows the prototype that was used for the first time on goats.

Figure 2: One of the goats being dialyzing with the first prototype of the Nephron+ WAKD unit.

Three prototypes are now being prepared for the next step, which consists of several months of periodic testing following strictly the protocol designed by Nephron+ medical partners. This is only a first step of a long process of testing, adjustments and improvements before approaching to a 'close to commercial device', but the perspective that opens with this working WAKD prototype is highly promising in terms of proof of concept and business opportunities.

The Nephron+ project partners are EXUS A.E. (GR), TNO (NL), Nierstichting Nederland (NL), IMST GmbH (DE), NANO [2] (NL), CEA (FR), Universitaet für Weiterbildung Krems (AT), UMCU [1] (NL), OFFIS EV (DE). The role of CSEM in this project is the design of the complete system, the design of components not yet available on the market and the manufacturing of the prototypes.

This work is partly funded by the European Commission. CSEM thanks them for their support.

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