Wearable Artificial Kidney Device

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In the frame of the Nephron+ European project CSEM develops further its competencies in the domain of artificial organs. The Nephron+ project aims at an integrated solution for personalized treatment and management of patients with chronic kidney disease (CKD). It introduces the ideal solution for continuous dialysis outside the hospital, offering a better blood clearance, while patients stay mobile and active in social life. The solution relies on an ICT-enabled wearable artificial kidney for on-body blood purification. This blood treatment can be adjusted to individual parameters and can be remotely controlled by health care specialists. The system enables real-time, continuous, and multiparametric monitoring of both the patient and the device via innovative sensors.

The dialysis treatment within the Nephron+ project with its fundamental two processes, haemodialysis and ultrafiltration, will sustain the continuous renal replacement therapy using the wearable artificial kidney device (WAKD). Moreover, a zero net filtration exists during the dialysis-operating mode, creating two opposite exchanges, filtration and backfiltration. In addition, the filtration circuit can have several configurations to remove the toxins in the Sorbent Unit, the element that replaces the dialysis infrastructure at the hospital. Figure 1 gives a detailed overview of the complete microfluidic circuit.

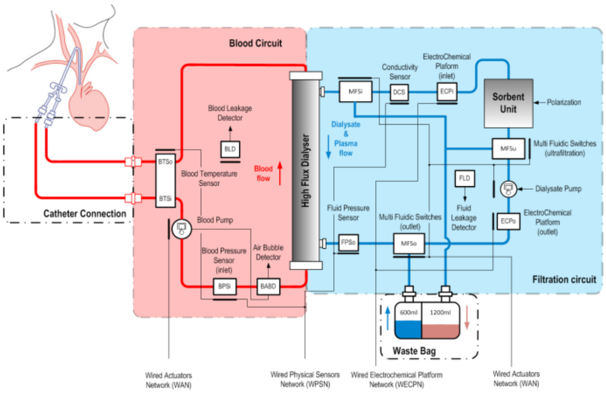

Figure 1: WAKD microfluidic circuit

According to the different combination of the multifluidic switches (MFS) states, which are 3-way valves, the filtration circuit is reconfigurable. Three modes are possible:

- Dialysis mode - haemodialysis method with zero net filtration (no water extraction from the body)
- Regeneration mode - new physiological fluid is forced to circulate from one waste bag through the absorbent unit towards a second waste bag compartment. The physiological fluid extracts in this way, the toxins from the Sorbent unit
- Ultrafiltration mode - it modifies the hydrostatic pressure of the dialysate compartment and causes the free water and some dissolved solutes to move across the membrane along the created pressure gradient.

In the following, the key building blocks of the WAKD device such as actuators, physical and electrochemical sensors, sorbent and control unit will be described.

Actuators - both the blood and the filtration circuits need pumps to ensure the circulation of the media. The constraints for these pumps are different. The blood pump has to be hemo-compatible and accurate hemolytic design has to enable a continuous operation, even during regeneration mode to prevent clot in the extracorporeal bloodline. The dialysate pump requirements concern mainly the biocompatibility. Because of the three operating modes, the filtration circuit has to be configurable and the use of 3-way valves is required.

Physical sensors - the technology used for the physical sensors is based on the optimization of the features to fit as best as possible to the application requirements. Accuracy, size, no contact with blood and filtration fluid, and low power consumption are the main constraints. The implemented physical sensors are the following:

- Pressure sensor in blood and filtration circuit. These sensors are used for safety and predictive maintenance
- Blood temperature in the blood inlet and outlet line. These sensors know if the temperature increases due to the power dissipated in the WAKD
- Conductivity sensor in the filtration circuit. Redundant sensor for the sodium concentration measurement.

Electrochemical sensors - these sensors monitor in real time the sodium potassium, urea concentrations and pH before and after the sorbent unit in the filtration circuit. The fluid is composed of small ions and small proteins coming from the blood-plasma. The sensors are used for patient safety and sorption process.

Sorbent unit - Nanodialysis, a partner of the project develops the sorbent unit. The mechanism for the removal of toxins is based on a combination of the following three technologies: (i) nano sorbent, (ii) electro oxidation and (iii) electro-deionization.

Control unit - in addition to the complete design of the WAKD, CSEM is responsible for the two-level control system. The first level concerns the real time control of the two fluidic circuits. It is responsible for making the right decision to insure patient safety. The second level is in charge of running the multi-variable algorithms, which control the flow rate of the blood and dialysate versus the potassium concentration and the polarization level in the sorbent unit versus urea concentration.

The resulting device will be portable and attached to a belt around the waist. Its total weight is around 2.5 kg (the module and with its batteries) and the autonomy before sorbent unit regeneration will be of around 6 hours. The cartridge with the disposable elements will last one week.

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