NEPHRON+: ICT-ENABLED WEARABLE ARTIFICIAL KIDNEY AND PERSONAL RENAL CARE SYSTEM

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Abstract

Traditional haemodialysis treatment for renal patients is known to be a suboptimal approach, although the only one tested and proven in the absence of transplantation options. We present the data management and analysis aspects of a design for an ICT-enabled wearable renal support device, offering personalized care to patients outside a hospital setting. The device features real-time functional adaptation based on sensor readings. It is supported by a mobile application as well as a clinical-back-end application; all of them communicating wirelessly to exchange control signals and patient data.

1. INTRODUCTION

NEPHRON+ will provide a major leap forward in Renal Care. It aims at a next generation, integrated solution for personalized treatment and management of patients with chronic renal failure. It presents an ideal solution for continuous dialysis outside the hospital offering better blood clearance, while patients can stay mobile and active in social and economic life. It relies on an ICT-enabled wearable artificial kidney for on-body blood purification [1].

2. THE SYSTEM

NEPHRON+ is based on realizing that the clearance rate of haemodialysis could be improved drastically if the dialysis operation can be performed continuously and matched to individual conditions and context. Continuous dialysis driven by monitoring and adjustment of the treatment is necessary, so that blood parameters constantly remain within normal ranges – thus, avoiding large peaks and rapid falls. This improved treatment results in improved well-being and quality of life of the patient and reduces the relative burden and costs imposed on the medical care system. A high-level view of the system is shown in Figure 1.

The project makes use of innovative ICT technologies, new micro-sensor principles and nanofiltration materials, medical knowledge in embedded and remotely operated analysis algorithms, safe low-power wireless connections and well-accepted consumer devices such as blood pressure devices, with a purpose to build a system that offers controlled and personalized renal treatment outside a clinical setting.

The NEPHRON+ system consists of:

1. A Wearable Artificial Kidney Device (WAKD) for real-time treatment adaptation, accurate monitoring and purification of blood, enabled by a smart configuration of available and newly developed ICT components including:
   - Multiparametric monitoring via a set of bio-micro-nanosensors embedded in the device to measure potassium, sodium, urea, blood pressure and temperature;
   - An artificial nanofiltration component, providing sophisticated blood purification based on nanofiltration, which removes not only the small molecule toxins (salts, urea) as in traditional haemodialysis but also the middle molecules (such as β2-microglobulin) and the protein bound toxins;
   - Embedded software for data fusion and adaptive control;
   - Secure low-power wireless connectivity.
2. Wearable on-body sensors, including ECG/ blood pressure/ body posture & activity ones.
3. A personal renal-care application for the patient, to be used in a mobile device (such as a smartphone or a tablet PC).
4. A clinical back-end renal care application that supports clinical personnel to remotely monitor

and reconfigure treatment based on receiving patient data at constant intervals throughout each day.

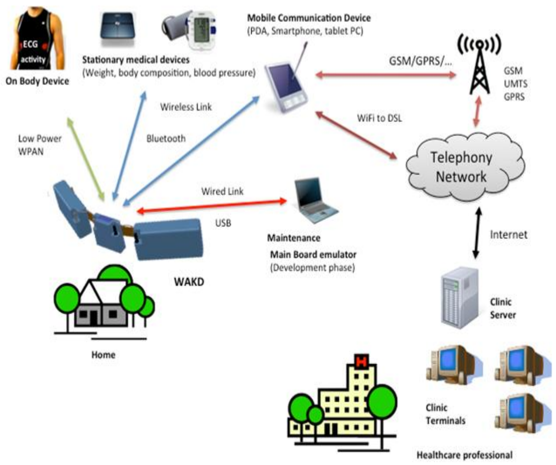

Figure 1: High level view of NEPHRON+ system

3. WAKD

The various sensors integrated within the WAKD perform measurements and produce the information on which the system's concepts and operation are based. The collected data is transferred to the WAKD control unit where the autonomous WAKD embedded software controls the dialysis process [2]. The computed values, which are extracted from the data, are used for the adaptive control of the device's function. Especially the primary function of the WAKD device, i.e. the filtration of blood, is adapted according to actual measurements. If certain predefined patterns are observed in the acquired data, notifications and alarms towards the patient and treating physician are triggered; or advice is displayed on the available screens, to initialize manual corrective measurements.

4. SMARTPHONE APPLICATION

The Smartphone/Mobile application will enable the patient, through a friendly User Interface (UI) to interact with the WAKD as well as provide information and feedback to the Clinical Back-end. More specifically, the patient will be able to receive information regarding the status of his/her disease, to safely control some functionality of the device (e.g. ultrafiltration rate etc.), to answer various questionnaires in order to provide input for his/her condition, as well as to receive alarms and reminders for remarkable variations of his/her measurements and upcoming events respectively. The UI takes care of plotting diagrams and visualizing information overall, but does not perform any data transformations. For instance, if a histogram is to be produced, value frequencies are calculated by the main application, and produced data is sent to the UI – which then draws diagrams and shows them to the user.

5. CLINICAL BACK-END

The main idea behind the clinical backend infrastructure is to be realized as a centralized horizontal platform on which relevant applications (vertical features) and functionalities will be implemented. This part of the system will allow the management of patients with renal disease, which includes: wireless retrieval of data produced by NEPHRON+ sensors and stored in the NEPHRON+ device; their analysis and monitoring as well as processing of the patient data for the decision making procedure on the various stages of the disease; the appropriate reconfiguration of the NEPHRON+ recognition of alarm situations and to adapt the treatment accordingly; to organize tasks of the various specific roles of clinicians within the workflow; or to manage medications and refills.

6. COMMUNICATIONS

NEPHRON+ is a complicated system combining components of different nature and scope. Thus in order to connect these various types of components a wide variety of protocols for guaranteeing stable, secure (e.g., HTTPS, SSL etc.) and reliable (e.g., SLIP) connections are applied. An overview of the various communication routes and the wireless technology employed is illustrated in Figure 2.

6.1. WAKD Physical Communications

The device will be wirelessly connected to several external devices, via two types of wireless technologies:

1. Standard Bluetooth technology will provide connection to Mobile Communication device/ Smart Phone, as WAKD device control and monitoring facility. Two Bluetooth Profiles will be considered for this purpose.
2. Bluetooth Low Energy technology will provide connection to On Body Sensor Device. The most significant available profile will be used for this purpose.

In order to keep the system as modular as possible on the hardware level as well as on the software level, a specific board that handles both wireless technologies will be provided, its named in the rest of the document as the Communication Board. This will abstract different communication protocols for the rest of the system. The wireless communication will be fully transparent for the WAKD on the Data/Application level.

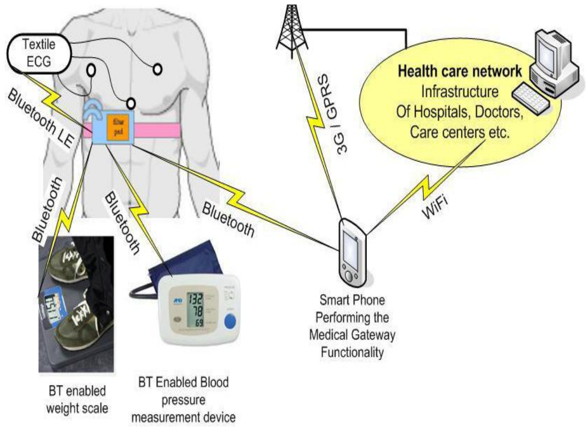

Figure 2: Supported communication routes with WAKD

6.2. Message Structure

The messages exchanged between the various parts of the system are composed of two main parts: 1) The Header that contains descriptive information on the scope of the sender of the message and 2) the payload that maintains the actual data. All the messages are transmitted in a binary format and their translation is performed internally in each application. As it was mentioned above, the communication between the WAKD and the Smartphone is done via Bluetooth and the communication between the Smartphone and the Back-end by using SOAP web services, however, the structure described is used by all sides.

The Header is a six bytes structure and it is divided in five fields:

1. recipiendId: One byte field that indicates the destination of the packet. The possible destinations of the packets are either the Smartphone or the Back-end.
2. msgSize: Two-byte field which indicates the size of the packet. The scope of this field is to recognize the where the packet ends.
3. dataId: One-byte field indicating the type of the message exchanged. The possible types of packets will be mentioned later in this section.
4. msgCount: One-byte field indicating the number of messages sent.
5. issuedBy: One-byte filed indicating the source of the message.

The Payload part differs based on the command given and its size is defined by the msgSize field of the header.

The type of messages that could be exchanged between the WAKD and the rest of the NEPHRON+ system are the following:

1. Send an alarm/notification from the WAKD to the Smartphone application or the Back-end application.
2. Request from the Smartphone for the current configuration parameters from the WAKD.
3. Trigger WAKD state change.
4. Request WAKD state.
5. WAKD sends current status to the Smartphone.
6. Configuration of WAKD parameters (e.g. patient profile, thresholds).
7. WAKD sends the measurements' values to the WAKD

Each of these types of commands is characterized from a different ID found in the dataID field of the header file in order for the receiver to recognize the command and read the data of the packet.

7. CONCLUSIONS

The NEPHRON+ is an innovating project aiming to bring new ways of treatment in Renal Care. By combining clever self-adjusting algorithms, sensing technologies, as well as the latest trends in application development presents a solution for reducing treatment costs and improving the quality of patients' life. The project, which is in its third year, has completed the first phase of integration and system development and it is now on preparations for the initial trials in animals.

8. ACKNOWLEDGMENTS

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