

MOROCCAN WEARABLE ARTIFICIAL KIDNEY (MorWAK): REQUIREMENT AND USE CASE DIAGRAMS

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Abstract— The aim of this work is to characterize a portable ultrafiltration system allowing the treatment of hypervolemia encountered mainly in situations of End-Stage Renal Failure (ESRD) and Congestive heart failure (CHF). Indeed, changing needs and better understanding of the Pathophysiology of uremia and understanding the limitations of current ultra-filtration techniques have been challenged by the design of MorWAK overcoming the drawbacks of current techniques of liquid extraction extracorporeal way. The MorWAK device will be described according to a functional approach by the requirement and use case diagrams. Structural and behavioural approaches will be the subject of future studies.

Keywords— MorWAK - ESRD - CHF - Hemodialysis - Ultrafiltration - Functional Approach - Requirements Diagram - Use Case Diagram

I. INTRODUCTION.

Techniques of extracorporeal liquid extraction are used in the treatment of hypervolemia mainly encountered in End-Stage Renal Failure (ESRD) and Congestive heart failure (CHF). These situations require hospitalization in an intensive care unit and the use of costly and bulky machines driven by a highly skilled workforce [1] - [2]. They are more survival techniques than real alternatives to the physiological functioning of the native kidney that runs 24 hours a day [3]. In order to improve the quality of life of dialysis patients, reduce cardiovascular morbidity and mortality mainly [4], prevent and correct the metabolic complications of kidney disease, the research team Engineering and Biomedical has developed the portable device MorWAK (Moroccan Wearable

Artificial Kidney) [5]. Our team is affiliated to the Laboratory of Cellular, Molecular, Inflammatory, Degenerative and Oncological Pathophysiology (LPCMIDO) of the Faculty of Medicine and Pharmacy of Casablanca in Morocco. Our device has as objective to allow the simplification of treatment procedures for hypervolemia. The later is defined as the increase of extracellular volume. Our team made many researches in the past. They included the critical study of current extracorporeal fluid extraction techniques and the assessment in 2015 of the carbon printfoot of a dialysis activity at the Ibn Rochd University Hospital Centre in Casablanca. Then, we demonstrated that only the development of portable hemodialysis technologies seems to be the main solution to reduce the suffering of patients with ESRD and to prevent the disastrous impact of one of the most expensive and polluting health care activities on the planet.

II. TOOLS AND METHODS

To satisfy the need, you have to know it. To understand it, it must be expressed in terms of functions. To identify the functions it is necessary to have the methods and tools of analysis.

During this study, we will use a number of problem solving tools to better explain the need and characterize the MorWAK device.

A. ISHIKAWA DIAGRAM

This diagram will be used to group by category the causes that may cause a problem. In our case, it is a critical study of

dialysis as it is currently done in intensive care centres with the aim of improving the quality of life of dialysis patients [6].

B. FUNCTIONAL SPECIFICATION

The functional specification presents all the functions grouped by family. Each function is characterised by a number of assessment criteria with their levels and flexibility. The functions are ordered by importance. [7].

C. SOFTWARE Modelio SA - SysML

Maintaining the consistency and compliance with the specifications of multidisciplinary systems requires a modelling language that makes it possible to group together in a model all the trades, specifications, constraints and parameters of the entire system. Systems Modeling Language (sysML), which approaches design using the notion of blocks, is best suited to the MorWAK device [10].

D. REQUIREMENTS DIAGRAMME

This functional diagram will describe the requirements of the functional specifications. Each requirement expresses a capacity or constraint to be met by the system. A requirement may express a function to be performed by the system or a condition of technical, physical, reliability, safety, ergonomics, esthetics performance [8].

E. USE CASE DIAGRAMME

This functional diagram highlights the functional interactions between the actors and the system studied. It precisely delineates the system under study and describes what the system will do without alluding to the technological solutions adopted [9].

III. IN CENTRE HEMODIALYSIS : THE PROBLEM

Hemodialysis was introduced in the 1950s as a renal replacement technique. Willem Johan Kolff's early work resulted in the installation of hemodialysis generators. It is large devices that required prior water treatment but also saved thousands of lives. It is primarily intended for patients with chronic end-stage renal disease [11]. It is the most widely used technique for this indication in the world. Indeed, after more than sixty years of use, few changes have been made to the basic principle [12]. The main improvements have mainly concerned accessories such as the addition to almost all generators of performance monitoring tools such as ionic dialysis or modules to monitor blood volume.

Hemodialysis is a heavy and very expensive technique. It undermines the health budget in all countries regardless of their GDP. Access to this type of treatment is therefore very limited in developing countries [13]. The high technicality of hemodialysis requires a particular organization. It is very often carried out in a centre where a machine is "made profitable" by its use for several patients in the same day. Whereas the ideal solution seems to be that each patient should have a "personal" or "individual" machine. This would make the technique overpriced and therefore inaccessible for the vast majority of patients.

IV. RESULTS

The multidisciplinary Engineering and Biomedical research team is aware of the various needs in dialysis field. It includes the improvement of the quality of life, the reduction of morbidity and mortality, the prevention and correction of the metabolic complications of kidney disease. Then, we developed MorWAK (Moroccan Wearable Artificial Kidney), a portable device that simplifies hemodialysis procedures.

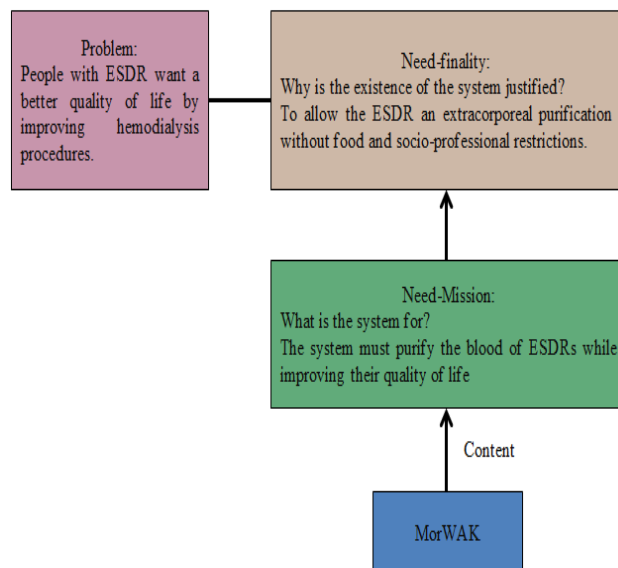


Figure 1: Initial Needs Diagram

MorWAK is therefore defined as a set of solidarity and organized elements to meet the expectations raised by ESRD patients.

The set of functions allows to identify the limits of the MorWAK, the elements which constitute it and its frontier including all the elements necessary for its functioning in all its phases of use.

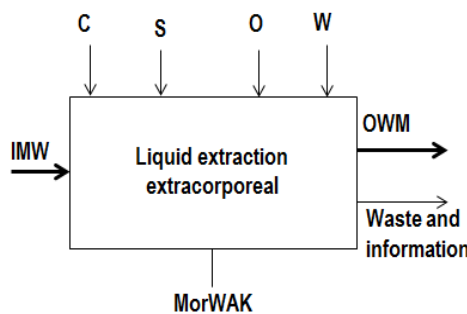


Figure 2: MorWAK SADT Model

The Incoming Work Material (IMW) contains:

- Patient in ESRD.
- Electrical energy.
- Drug.

The Outgoing Work Material (OWM) consists of:

- The dialysis patient.
- Solid and liquid waste.

- The data files.
- Real-time information on the progress of the purification operation.

The energy (W), setting (R), control (C) and operating (E) parameters allow the user to customize the purification operation.

A. NEED IDENTIFICATION

The main causes affecting patient's quality of life are grouped into five main families (5M) as follows [6]:

- **Machine (Dialyzer):** The machine is profitable by its use for several patients in the same day.
- **Material:** The dialysis of an individual greatly reduces its autonomy and socio-professional performance. The life of the patients is rhythmic (3 times 4 hours per week); which restricts their movements in addition to drastic food restrictions.
- **Manpower:** the quality of service depends on the qualification of the personnel controlling the dialysis equipment
- **Method (process):** the quality of service depends on the qualification of the personnel controlling the dialysis equipment.
- **Medium:** it is at the origin of the expansion of previously known pathologies (manual transmission in dialysis centers) and the emergence of new diseases associated with dialysis

B. FUNCTIONAL SPECIFICATIONS

The critical study of current extracorporeal purification techniques has made it possible to draw up a not exhaustive list of requirements specifying the capacities or constraints that the MorWAK must satisfy. [9]

To keep the presentation as simple as possible, we have grouped the requirements:

- Functional requirements.
- Technical requirements.
- Security requirements.
- Environmental requirements.
- Interface requirements.
- Practical requirements.
- Marketing requirements.
- Energy requirements.

These requirements constitute the technical functional specifications of MorWAK. The criteria and levels of appreciation of the functions and constraints specified by the requirements will appear in the requirements diagrams. [7]

In the following, each requirement category will be treated separately.

C. REQUIREMENT DIAGRAMS

Each of the macro requirements previously defined will be broken down into multiple unit requirements.

Functional requirements:

These requirements describe the extracorporeal purification function for which the system is designed.

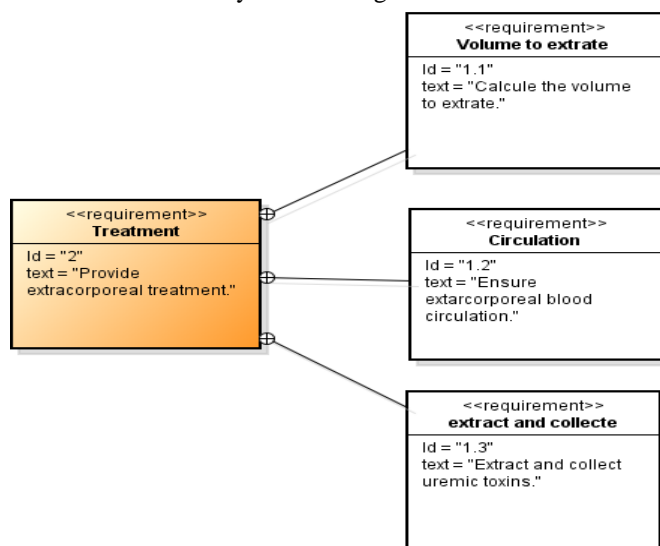


Figure 3: MorWAK Functional Requirements

Technical requirements:

This type of requirement specifies the MorWAK's performance and capabilities.

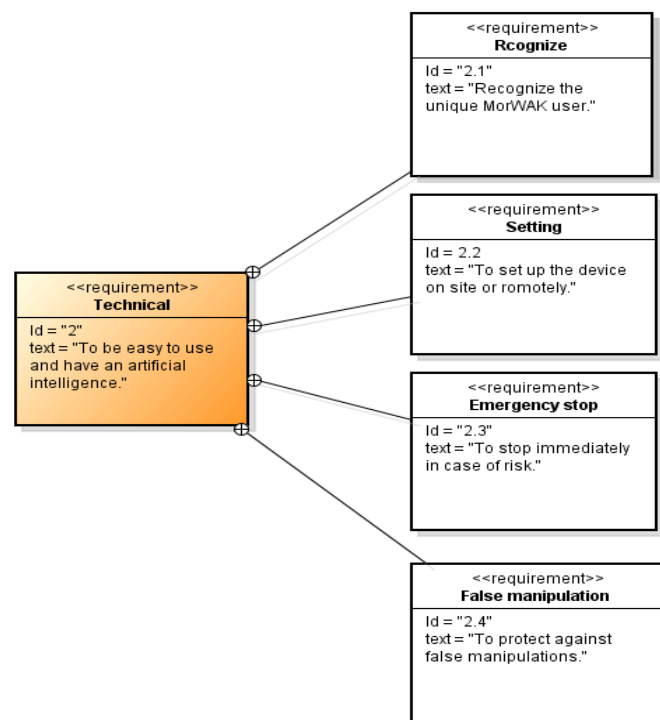


Figure 4: MorWAK Technical Requirements

Security requirements:

These requirements highlight the dangers involved in using the device for better protect the patient.

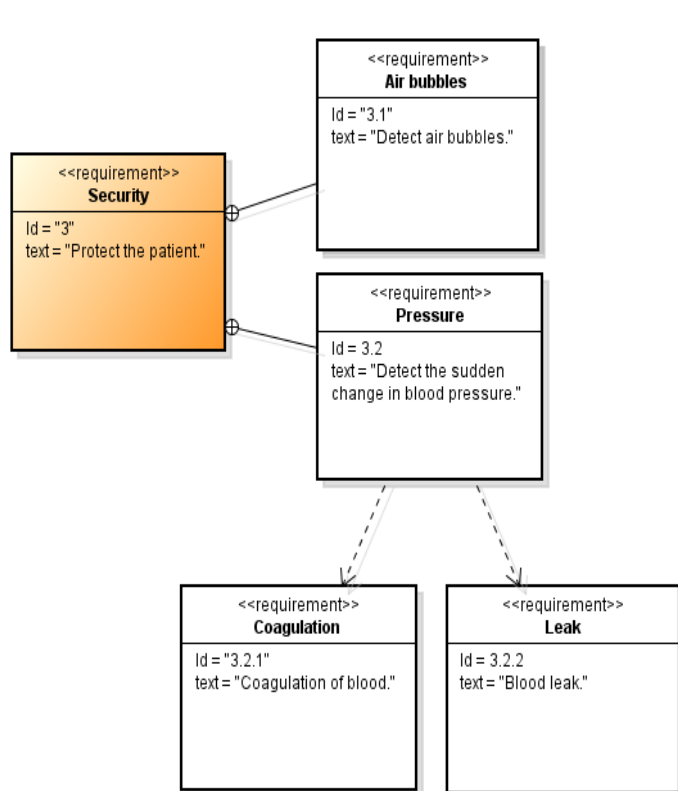


Figure 5: MorWAK Security Requirements

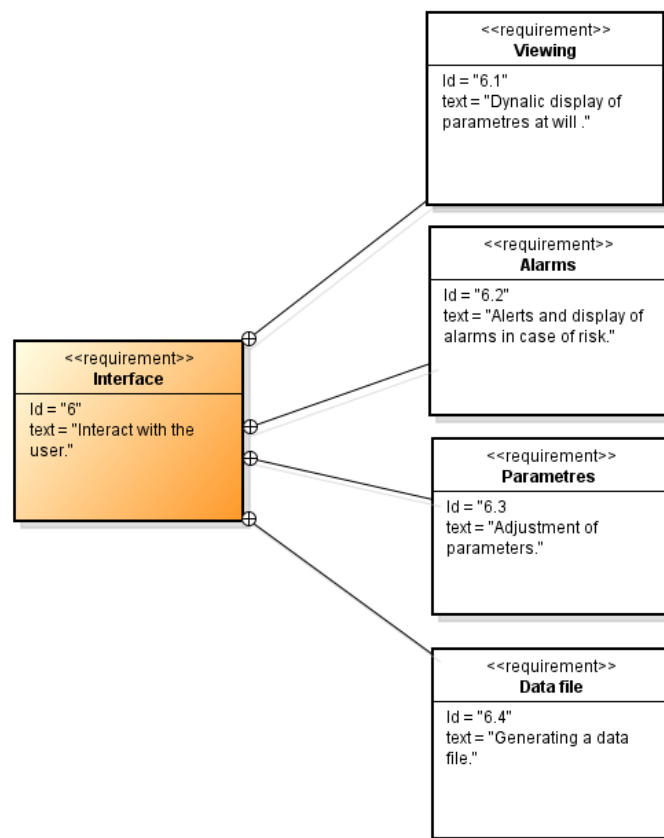


Figure 8: MorWAK Interface Requirements

Environmental requirements:

Respect for the environment is imperative; the device must produce minimum solid and liquid waste.

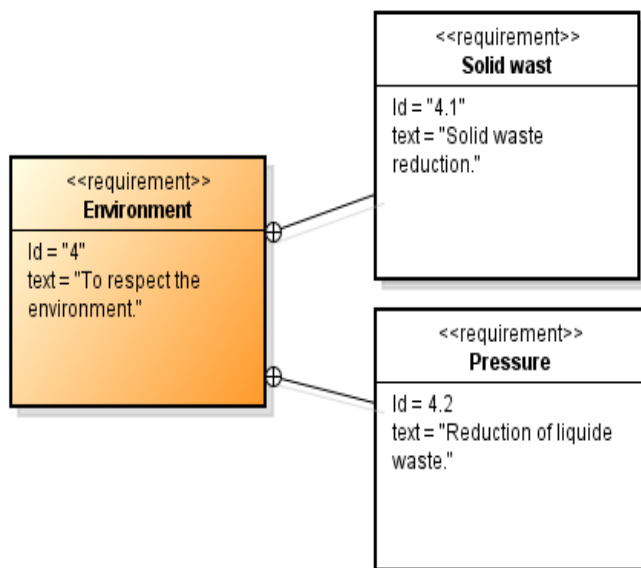


Figure 6: MorWAK Environmental Requirements

Interface requirements:

The use of a Human Machine Interface (HMI) is essential to allow a better interaction with the MorWAK.

Practical requirements:

Users are not necessarily technicians, so MorWAK must be easy to use and intelligent enough to manage risk situations independently.

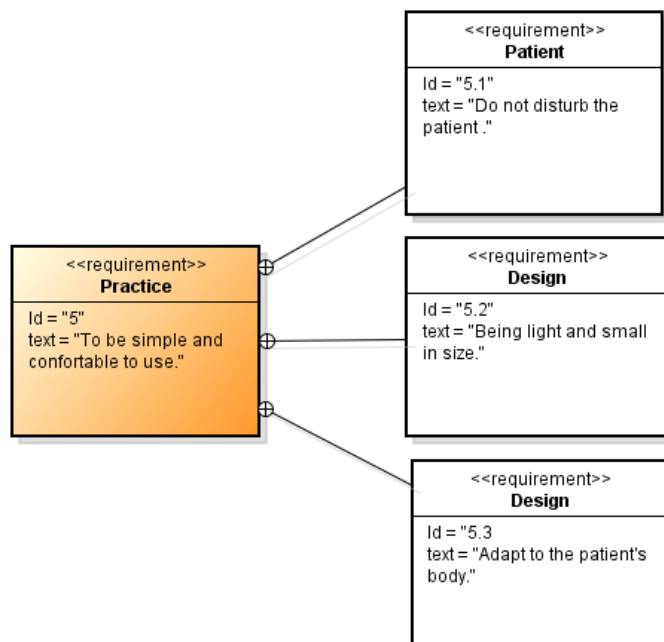


Figure 9: MorWAK Practical Requirements

Energy requirements:

The portability of the MorWAK requires better management of electrical energy. The technological solutions thus adopted must not be energy hungry.

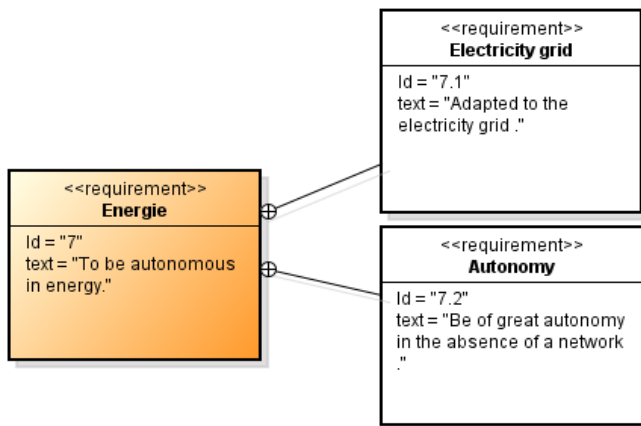


Figure 7: MorWAK Energy Requirements

Marketing requirements:

The cost of the device and its estimation functions will influence its marketing. Great attention must be focused on the choice of technological solutions.

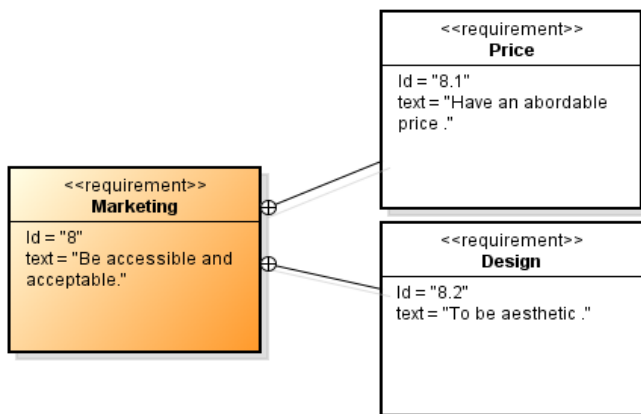


Figure 10: MorWAK Marketing Requirements

D. Use case diagram

All features visible from outside the MorWAK represent its use cases that can be summarized in four major families of features as shown in Figure 11.

V. DISCUSSIONS

Chronic renal failure is a disease, characterized by a glomerular filtration rate (GFR) below 60 ml/min per 1.73m² for three months or more [14]. The registries of developed countries show an annual evolution of the incidence of chronic renal failure between 6 and 8 % [15].

When reached, ESRD requires the use of substitution treatment is inevitable. Currently, this treatment is classified under three main modalities: hemodialysis, peritoneal dialysis and transplantation [16].

Hemodialysis, generally used throughout the world. It is a technique that purifies the blood of excess water and uremic toxins. It was used for the first time by Wilhem Kolff for the treatment of patients with acute renal injury. As well as, the rotary drum dialyzer, created by Kolff, is a device operated for large-scale clinical use in the 1960s.

The table above summarized the different stages of development of dialysis treatment of uremia [17].

TABLE I
 DIFFERENT STAGES OF DEVELOPMENT OF THE UREMIA TREATMENT

Year	Advanced dialysis
In 1913	The first attempt to produce a dialyzer designed for human use was made by John J. Abel. Its device consists of a series of 40 cm colloidal tubes.
In 1924	The first clinical trial of dialysis is executed by Dr. Georg Hass, working with patient with kidney failure was connected for 15 minutes. Despite the successful extraction of urine, it couldn't replace renal function because of the blood coagulation.
In 1944	The creation of the drum dialyzer and the use of heparin as an anticoagulant by Dr. Willem Kolff, ensures the success of a first renal replacement therapy.
In 1955	The Drs. Gordon Murray, Edmund Delorme, and Newell Thomas have developed a double-coil dialyzer. Each time, the dialysis session is performed by the latter. There is the appearance of new arterial and venous blood lines placed.
In 1950	Belding Scribner used Teflon to create a shunte, which allows regular arteriovenous access.
In 1960	A first successful treatment that ensured the survival of a uremic patient for eleven years, in order of one to two sessions per week.
In 1961	The creation of the hollow fiber dialyzer. This tubule configuration has allowed for a larger effective area in a smaller package.

After the synthesis of the hollow fiber dialyzer, the main improvements were mainly in accessories such as the addition of performance monitoring tools like ionic dialysance or modules to monitor blood volume to almost all generators. During dialysis, the patient's blood is pumped from a vascular access through plastic pipes to the dialyzer, a semi-permeable membrane that transfers small and medium molecular weight solutions into the dialysate on the other side of the membrane, and then to other pipes before leading it to the vascular approach [18]. During the dialysis session, the dialyzer must be continuously fed by the dialysate, a liquid that is brought into contact with the blood through the dialyzer. This liquid is a mixture of ultra-pure water and electrolytes added in a fixed ratio [19]. The duration of dialysis treatment is usually 3-4 hours, 3 times a week. Generally, these sessions take place with very high blood flow rates (Q_s) and dialysate flow rates in the order of 300 ml /min, for maximum exploitation of the expensive equipment (fig 12) [18].

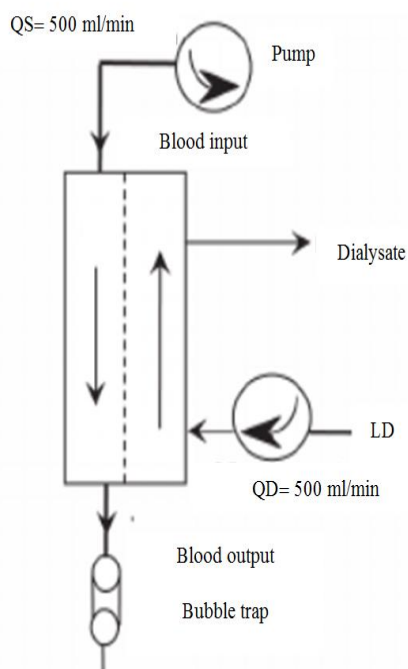


Figure 12: Schematic representation of the hemodialysis purification circuit

Currently, dialysis has become a standard treatment for chronic kidney disease. Although it ensures the survival of more than one million people with chronic kidney disease worldwide. The delicate quality of life of dialysis patients due to nutritional restrictions, intensive treatment sessions at the centre and high rates of cardiovascular morbidity and mortality make it an imperfect treatment. And, its disastrous ecological and financial impact. From an ecological point of view, Switzerland characterizes the energy and ecological impact of hemodialysis by expressing it in the form of a quantitative analysis of the

consumption of electricity, water and the production of non-recyclable waste by the Lausanne Nephrology Service. This is summarized in table 2 [20].

TABLE II
 QUANTITY OF RESOURCES AND WASTE

Parameter studied	Quantity per dialysis session
Electrical energy consumed	2200 Watts
The water consumed	500 Liter
Solid waste that cannot be reused	3,8 kg

Hemodialysis is a very sophisticated and highly accurate technique. It requires special equipment and highly qualified personnel.

In Morocco, each hemodialysis session costs 77.18 €, including other fees. Direct costs represent the major part by 778.91 dirhams (91.6%), of which the cost of the consumable dominates by 44.93%. The indirect cost represents 6.23% of the total cost. In year/patient units, the cost of hemodialysis is 12,040.31 Euros [21].

In order to improve the quality of life of dialysis patients and reduce the ecological and financial impact of dialysis at the centre, the Engineering and Biomedical research team has set itself the objective of creating the MorWAK device, which is patented under number WO2016/072826A1.

The MorWAK system is a complex mix of mechanical, electrical, electronic and hydraulic components that puts the patient's life at risk at all times. Strict technical safety standards are maintained to protect the users from any risk inherent in the use of the MorWAK. The development of portable technologies and the use of Information and communications technology (ICT) have made it possible to monitor blood and venous pressure in order to ensure the control and integrity of the extracorporeal circuit.

Particular attention is given to the monitoring of extracorporeal blood circulation in the definition of the alarm ranges planned for arterial and venous circuits. The slightest pressure difference must be detected to avoid the risk of haemolysis and haemorrhagic damage. A gyrosopic air detector is provided to avoid any gas embolism in the event of accidental disconnection. A Human Machine Interface (HMI) allows the permanent in the real-time display the parameters. The monitored and configuration can be made in the site or remote of the MorWAK in order to customize the treatment.

The first prototype is made and tested on bags of complete bovine blood and made it possible to model the extraction of the liquid according to the pressures on either side of the semi-permeable membrane and the volumes allowed by the suction bellows. The ICTs used in this way allow the real-time plotting of curves representing the parameters to be monitored, namely, blood pressure, venous pressure and the evolution of

the volume of liquid extracted. The MorWAK thus operates without dialysate [5].

The MorWAK device will be transportable, simply handling and guarantees total patient safety. The following table provides a comparative study between MorWAK and the current system.

TABLE III
 COMPARATIVE TABLE BETWEEN THE MORWAK AND THE CURRENT SYSTEM

Parameters	MorWAK	Dialysis machine currently available
Size	Small size	Large size
Modality	Ultrafiltration	Hemodialysis
Device arrangement	The MorWAK is always available to the patient, which ensures continuity of treatment.	The current Dialysis Machine can only be used at the dialysis centre, which results in discontinuity of treatment.
Solid Waste Production.	The personalization of the MorWAK device minimizes the amount of consumables required.	The current multi-use of machines requires a large quantity of consumables.
Energy autonomy	The MorWAK is equipped with a rechargeable battery, which provides a 12-hours battery life.	The current Dialysis Machine needs a direct and continuous connection to the electrical grid.
Electricity consumption	The electrical energy consumption is 10W.	The electrical energy consumption is 2200 W.
Water consumption	MorWAK operates without dialysate.	The current dialysis machine requires 500 L of water per week for dialysate preparation.

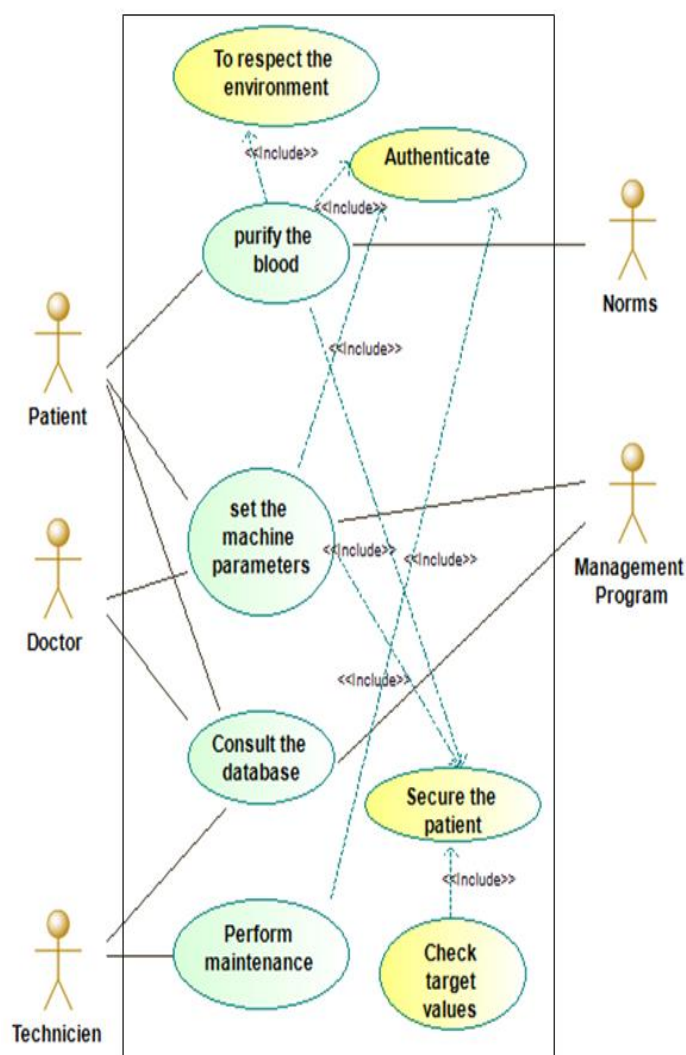


Figure 11: MorWAK Use case diagram

VI. CONCLUSIONS

The systems engineering approach adopted in this study made it possible to describe the system according to a functional approach in the form of graphs (SysML diagrams). The decomposition of requirements into macro requirements has simplified the representation of the system. The structural approach will define the overall hardware and software architecture of the MorWAK. This architecture is summarized under a tree representation of the blocks as well as the material, energy or information flows between the internal blocks. The behavioural approach will describe the states and transitions governing state changes and the sequence of messages between actors and MorWAK for each use case. Both approaches will be the subject of future studies.

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