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### The Complicating Effects of Patient Limb Position on the Development of a Localised Impedimetric-Based Hydrational Index for the Remote Monitoring of Home-Based Dialysis Patients

A. Montalibet <sup>a</sup>, W. Arkouche <sup>b</sup>, P. Bogonez Franco <sup>a</sup>, S. Bonnet <sup>c</sup>, A. Clarion <sup>d</sup>, G. Delhomme <sup>a</sup>, C. Gehin <sup>a</sup>, S. Gharbi <sup>c</sup>, R. Guillemaud <sup>c</sup>, P. Jallon <sup>c</sup>, B. Massot <sup>a</sup>, P. Pham <sup>c</sup>, E. Ribbe-Cornet <sup>d</sup>, E. McAdams <sup>a,\*</sup>

<sup>a</sup> Institut des Nanotechnologies de Lyon, INL-UMR5270, INSA Lyon, 21 av. Jean Capelle, 69100 Villeurbanne, France
<sup>b</sup> Association pour l'Utilisation du Rein Artificiel dans la région Lyonnaise (AURAL), 124, rue Villon, 69008 Lyon, France
<sup>c</sup> CEA-LETI, Université Grenoble-Alpes, Minatec Campus, 38054 Grenoble, France
<sup>d</sup> BioparHom, 89 rue Pierre et Marie Curie, 73290 La Motte Servolex, France

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#### Abstract

Bioimpedance measurements have been used to assess the effects of haemodialysis on patients and to help determine when the desired "dry weight" has been achieved and hence the optimum moment to stop the procedure.

In the present research project we seek to develop a localised (on the calf), integrated measurement system capable of transmitting hydrationrelated impedimetric data, periodically between dialysis sessions, from patients undergoing home-based treatment to a remote monitoring clinic.

We have found that the effects of the subject simply lying or sitting down gives rise to fluid changes in the calf which appear as significant and as long lasting as those due to the haemodialysis procedure itself.

If correct, these preliminary findings will necessitate careful consideration of these two, possibly competing, effects on the determination of, for example, the moment the desired "dry weight" has been achieved during clinical haemodialysis treatments.

Measures are being taken to address this problem in our own remote monitoring of the wellbeing of home-based dialysis patients.

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#### 1. Introduction

## 1.1. The need for home-based treatment and monitoring of dialysis patients

Chronic Renal Failure (CRF) is one of the leading causes of death in the world. Approximately 1 in 10 citizens suffer from some form of renal disease (the number is increasing) and,

\* Corresponding author. *E-mail address:* eric.mcadams@insa-lyon.fr (E. McAdams). given the high cost of treatment, in the form of dialysis or renal transplant, CRF is a top priority in modern health care.

In France, the overall cost of the treatment of the complete or nearly complete irreversible loss of renal function, or end-stage renal disease (ESRD), is estimated to amount to 2% of the total health care budget while only benefiting around 0.01% of the population.

Home-based dialysis has been found to be an attractive, lower cost option which also avoids the high cost of transportation to and from the Dialysis Unit several times per week [1]. Extra benefits for the patient include enhanced autonomy and

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quality of life, more time to send with family or in work and the possibility of travel and holidays.

In order to encourage the desired development of homebased dialysis or self-care haemodialysis (HD) units, the technical and other hindrances to these promising modalities must be overcome. New methods of dialysis are already being developed which enable a better tolerance of the dialysis sessions and a better patient quality of life. These systems involve daily "low flow" HD using machines specifically designed for home use.

There remains however the challenge of adequately monitoring and supervising dialysis patients remotely in their homes to detect and/or avoid life-threatening complications linked to a poor estimation of or a pathological variation in a patient's "dry weight", with a process allowing a transfer of the data by telemedicine to a remote monitoring clinic.

Dialysis patients are characterised by marked variability in their hydration status. An inaccurate assessment of a patient's "dry weight" (the weight at which the patient's body fluids are considered similar to those in healthy subjects) can mask a state of over hydration or dehydration, both of which can lead to serious complications. In dialysis patients, mortality resulting from cardiovascular problems is very high, approximately 50% [2].

There is therefore a need for the regular and accurate monitoring of the hydrational status (and other key parameters) of home-based dialysis patients if this attractive modality is to reach its full potential.

### 1.2. BioImpedance analysis as an indicator of patient hydrational status

A range of techniques are available in the clinical setting which can aid the detection and interpretation of variations in body composition associated with metabolic changes. These approaches are generally not suitable for the home-based patient due to the complexity, cost, invasiveness and/or accessibility of the equipment/technique.

Over the past few decades, Bioelectrical Impedance Analysis (BIA) has shown promise as an objective, non-invasive method of detecting and evaluating changes in the hydrational and nutritional status of patients with renal disease. It has been used to estimate the 'dry weight' of dialysis patients [3]. Although this technique is presently used in a hospital environment, it holds promise, with further development, of lending itself to the regular remote assessment of the wellbeing of dialysis patients in out-of-hospital settings including the home.

BIA is based on the fact that different tissues in the body have different resistivities. Lean muscle tissue contains large amounts of water and electrolytes and is thus highly conductive, whereas bones and fat on the contrary are poor conductors. When current flows through a human body, it will therefore tend to concentrate in the water-containing, lean "fat free mass" (FFM). Measured impedance is therefore proportional to Total Body Water volume (TBW) [4].

More recent BIA systems use multifrequency measurements (MF-BIA, sometimes termed BioImpedance Spectroscopy (BIS)) and involve more fully characterising the tissues over a wide range of frequencies and thus better distinguish between intra- and extra-cellular contributions. In standard "whole body" MF-BIA, a 4-electrode measurement technique is generally used and a small constant current, typically around 100  $\mu$ A, is generally applied ("injected") using a first pair of standard disposable pre-gelled ECG electrodes attached to the extremities of the body, on the right hand and on the right foot. A second pair of voltage measuring electrodes is generally placed slightly proximally to the current injecting electrodes, on the associated wrist and ankle. The advantage of the 4-electrode technique is that, in theory, the four electrode–gel–skin interfaces do not influence the measurement of the 'core' tissue impedance – unlike the standard two-electrode technique.

Although there have been quite a few publications focused on the clinical validation of the monofrequency and multifrequency BIA for the diagnosis of hypervolemia in dialysis patients, there are presently only two devices on the market specifically targeted at and approved for haemodialysis monitoring – that of Fresenius [5,6] (BCM – Body Composition Monitor) and the Z-Hydra marketed by BioparHom [7], one of the partners in the present project.

The "whole-body" impedance traditionally measured involves the contributions of the subject's right arm, the thorax, the abdomen and the right leg impedances. Recently, Segmental BIA (SBIA) approaches have been developed that seek to separate and study these individual contributions. They model the body in terms of five separate conductive cylinders each with relatively uniform properties, shapes and cross-sections. BIA segmental measurement is carried out by placing additional voltage sensing electrodes on the superior and inferior limbs and on the trunk, measuring the bioimpedance of the individual segments separately and then estimating total body fluid volumes as a sum of the segmental values. The technique is not yet standardised and electrode positions, etc. vary from researcher to researcher.

As a result of their smaller cross-sections, the distal extremities contribute disproportionately to the whole body measurement. Fairly typical percentage contributions of body segments to whole-body impedance have been found to be as follows: trunk 10%, leg 43% and arm 47% [8]. One can therefore deduce that any changes in fluid volume within the abdominal cavity will have relatively minor influence on the whole body measurement.

Although it has been found that there are difficulties in assessing total body water using segmental BIA, some reports indicate that segmental measurements on the leg, for example, can be used to better reflect dialysis patients' fluid shifts [9-11].

A few groups have endeavoured to further reduce the area of measurement and these "intra-segmental" or "localised" measurements appear to hold promise [12,13], with the possibility of being more accurate than whole body measurements [14]. They have suggested and/or shown that the (lower) leg is especially promising for the monitoring of fluid shifts in HD patients [15–17].

A very relevant project was the European HAEMOSCAN project (EU-FPIV COOP-CT-2003-508154, 2004–2007) involving the "Development of a Technology to Measure Body

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