

# SWAN-iCare project: Towards smart wearable and autonomous negative pressure device for wound monitoring and therapy

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**Abstract**—This paper describes the SWAN-iCare system and its potential impact in the area of wound management. The SWAN-iCare project aims at developing an integrated autonomous device for the monitoring and the personalized management of chronic wounds, mainly diabetic foot ulcers and venous leg ulcers. Most foot and leg ulcers are caused by diabetes and vascular problems respectively but a remarkable number of them are also due to the co-morbidity influence of many other diseases (e.g. kidney disease, congestive heart failure, high blood pressure, inflammatory bowel disease). More than 10 million people in Europe suffer from chronic wounds, a number which is expected to grow due to the aging of the population. The core of the project is the fabrication of a conceptually new wearable negative pressure device equipped with Information and Communication Technologies. Such device will allow users to: (a) accurately monitor many wound parameters via non-invasive integrated micro-sensors, (b) early identify infections and (c) remotely provide an innovative personalized two-line therapy via non-invasive micro-actuators to supplement the negative pressure wound therapy.

**Keywords:** wound management, negative pressure, collagen, bio sensors, remote surveillance

## I. INTRODUCTION

In recent years there has been an increased focus on getting patients out of the hospital and back into their own homes as soon as possible. To reach these goals, technologies that enable and assist this transfer have been developed.

In the case of wound care, some patients with complicated hard-to-heal ulcers end up needing hospitalisation for their condition. The Negative Pressure Wound Therapy (NPWT) is increasingly applied in hospitals to treat this kind of chronic wound and performs by removing exudate and potentially infectious material. It also promotes the formation of granulation tissue by applying a negative pressure healing system, thus accelerating the wound healing. At the moment, the healthcare costs due to the application of this promising

technique are relatively high since it necessitates hospitalization and medical acts. Although, there are many reasons for hospitalisation; some patients who require negative pressure wound therapy (NPWT) are hospitalised simply because they require constant monitoring and immediate access to wound care specialists. This means that the total health care costs for the application of NPWT in this particular group of patients are relatively high despite decreasing prices of the NPWT systems themselves. Recently, portable NPWT systems have been developed and commercialised, providing several advantages for the patients such as discreteness and ease of operation. With the increasing trend to allow patients to leave the hospital the soonest, smaller, simpler and more patient-friendly devices have recently been developed. However, these devices only offer the single service of negative pressure on the wound and basic vacuum control.

To enable monitoring and treatment of patients in their home environment, the SWAN-iCare project (which started in Sep 2012 with a duration of 48 months) aims to develop a *Smart Negative Pressure Device*. This device will integrate non-invasive sensors that allow objective, continuous, real-time monitoring of critical parameters with personalised therapy tailored to supporting the patients wound condition. The device will have the potential to release active agents to assist in the wound healing process. To facilitate remote monitoring and support, the device will be equipped with information and communication technologies (ICT). Overall, the SWAN-iCare system will:

- Collect data and monitor several wound parameters via non-invasive integrated micro-sensors.
- Offer the opportunity to provide innovative personalised therapy in combination with the negative pressure wound therapy.

- Allow health care providers to be remotely aware of the patients condition and receive alerts highlighting situations that require direct actions.

The remainder of paper describes the SWAN-iCare concept, in which the physicians analysis of the collected data will be the basis for the decision and the remote control of the therapy. The closed-loop approach offered by the SWAN-iCare system provides unprecedented levels of care, improves the patients health condition and significantly lowers the costs and need of hospitalization, with obvious advantages for both the patient and health care services.

## II. POPULATION STATISTICS MOTIVATING SWAN-ICARE

The SWAN-iCare project aims at improving the monitoring and management of chronic wounds: venous leg ulcers mainly originating from vascular problems, and diabetic foot ulcers. Chronic venous insufficiency and leg ulcers affect ~0.1-0.2% of the general population, with approximately 10-20 people per 1,000 ever affected. Ulcer healing rates can be poor with up to 50% of venous ulcers open and unhealed for 9 months. Ulcer recurrence rates are worrying with up to one third of treated patients on their fourth or more episodes. In the UK leg ulcer treatment accounts for 1.3% of the total healthcare budget and up to 90% are treated in the community. In the US, venous ulcers have been estimated to cause the loss of 2 million working days and to incur treatment costs of approximately \$3 billion per year [1].

In addition, approximately 1-4% of those with diabetes will develop a foot ulcer annually, and approximately 15% of those with diabetes will develop at least one foot ulcer during their lifetime [2]. The prevalence of diabetic foot ulcers has been estimated to be 3-8% in the diabetes population [3]. The annual incidence of foot ulcers in the US population has been estimated at 1.9% in type 1 and 2 diabetic patients. Various European studies suggest the incidence to be 2.1% and 3.6% [4], respectively. These relatively high incidences impact a growing population, since by the year 2025, it is estimated that 300 million people will have diabetes [5] and by 2030 nearly 438 million will be affected by diabetes [6], [7].

## III. SWAN-ICARE SYSTEM ARCHITECTURE

Figure 1 shows the overall architecture of the SWAN-iCare System as well as the localization of the respective sensors for wound healing/monitoring. The system comprises of a set of subsystems namely: (i) the Clinical Back-End integrated to the hospital infrastructure which includes the back-end server where the application and database run, and one or many front-ends, where the users can interact with the system, according to their assigned roles, (ii) the Mobile Client for enabling access the Patient data on the Server, (iii) the Home Device Area Network, i.e. the Hub and one or more Stationary Medical Devices, one or more Wearable Devices and one or more External Devices, which will link to the Back-End by means of the Hub, and the (iv) Smart Negative Pressure Wearable Device that applies the negative pressure wound therapy, and provides monitoring information as well as warning and alarms to both the patient and the back-end.

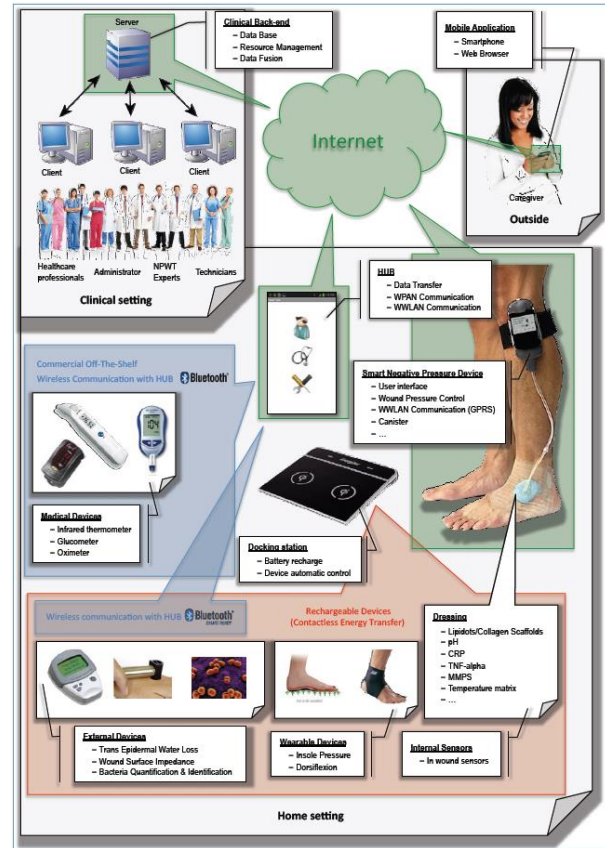


Fig 1 High level architecture of SWAN-iCare

The following paragraphs describe in more details each subsystem found in the SWAN-iCare architecture.

**Clinical Back-End:** Clinical Back-end refers to the applications running in the hospital and used by medical and administration staff. They are divided into two parts:

- **Back-end:** The Back-end is the part of the Medical Side Applications where the core functionalities are implemented. This is done by implementing an Application Server on which everything is built.
- **Front-end:** The Front-end is part of the Medical Side Applications. This part refers to what the user will see on his/her screen based on the role and access right s/he has. The Front-end communicates with the Back-end through a secure data access via the Application Server.

**Mobile Client:** The mobile client is the application running on the smartphone. Its role is supportive and its main goals are: (i) to enable the patient to provide feedback to the carers as well as (ii) to psychologically support and keep the patients motivated during the treatment. Additional self-management features (e.g. medication, upcoming events etc) are deployed targeting to patient empowerment and high user experience. The input generated through the smartphone is safely uploaded to the Clinical Back-end for further processing.

**Home Device Area Network:** Home device area network refers to the equipment found in patients home for both measuring patients health parameters and transmitting the information to the clinical back-end infrastructure. The home

device area network consists of the following subsystems:

- Stationary Medical Devices are devices available on the market which fulfill the SWAN-iCare medical needs.
- Wearable Devices refer to sensors that patients carry with them, fixed either around a leg or vices will be developed within the Extracted parameters will be recorded to the Hub and from there to the Healthcare and the NPWT expert.
- External Devices are used only change. The data resulting from the available for the Healthcare Professional Expert.
- The Hub copes with two main recharging of Wearable and External docking station and (ii) data transfer of the SNPD. The device will be able to all the devices at the same time. For reasons no electrical contact will be implement a Wireless Personal Area interface to download data from the less Wide Area Network (WWAN) for with the Clinical Back-End (Server), send the recorded data on a daily basis

**Smart Negative Pressure Wearable Device:** The Smart Negative Pressure Wearable Device (SNPD) is composed with the Smart Negative Pressure Device (SNPD), which is non-disposable and with a disposable part (Canister, Tubing, Dressing and Integrated Multi-Sensors). SNPD controls the pressure of a pump used to extract the excess of exudates generated by the wound and collects it in a canister or a waste bag. The device also integrates an activity sensor, and electronic interface for reading real-time values from the integrated multi-sensor, i.e. MMPs, CRP and TNF-alpha, pH and wound temperature sensors. The monitored data from the SNPD's integrated multi-sensors will be utilized for real-time evaluation of the wound inflammation and infection levels.

#### IV. SWAN-iCARE SENSORS

The SWAN-iCare sensors and actuators are designed to provide clinically useful information concerning different medical parameters relevant in wound healing: the status of the wound and the perilesional skin, the presence of inflammation and infection, global information on the patients health. For this purpose, different sets of sensors are used (Figure 2). Technological developments are focused on targeting easy-to-implement-and-produce sensors, while achieving the sensitivity and technical specifications required for wound monitoring and healing application.

**Global information on patients health:** A body temperature sensor and a pedometer provide an overview of the patients general condition. The pedometer, based on a 3D-accelorometer included in the Smart Negative Pressure Device, is important to estimate patients' activity, as well as compliance to medical advice. The body temperature sensor is a commercial device which communicates data with the system. Its use is particularly important in case of infection indication. A glucometer (commercial device) is added in the case of diabetic patients since high glucose blood levels are detrimental for a fast healing. A dorsiflexion sensor, based on a flexible polymer material, can be added on the patient's ankle to monitor the range of ankle movements, since extended VLU usually impede normal flexion of this articulation.

**Status of the wound and perilesional skin:** Different external sensors are used to evaluate the status of the wound

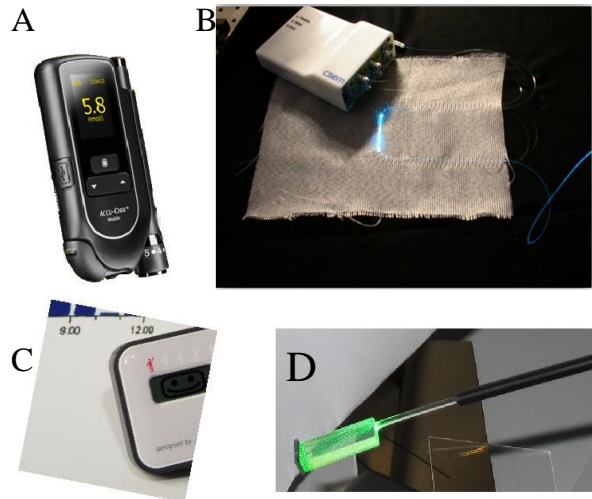


Fig. 2. Photographs of commercial devices or prototypes of sensors that are included in the SWAN-iCare system. A) Commercial glucometer - Entra Health Systems; B) Actimeter; C) and D) Optical sensors for MMP and bacteria detection

or perilesional skin on a weekly basis. Important parameters are the qualitative evolution of tissues in the wound, the hydration and blood flow of the skin surrounding the wound. The evaluation of the permeability of the skin to water can help the assessment of the conditions of the perilesional skin. Trans-epidermal water loss (TEWL) is commonly accepted to assess structural damages of the epidermis and this specific sensor can thus add relevant information for the physician about the evolution and recovery of chronic wounds or the efficacy of treatments. An oxymeter is used to estimate blood flow, as circulatory issues directly impact on the healing process. In addition, the relevance of bioimpedance measurements to estimate the healing stage is being investigated. It is expected that the appearance of granulation tissue, an important hallmark of wound healing, can be detected using this technique. Another important point is to limit wound extension. In particular in the case of diabetic foot ulcers located on the foot sole, it is important to avoid any pressure on the wound. Specifically patient-tailored shoes are designed by orthopedics to off-load pressure on the wound location when the patient stands or walks. Pressure sensors are designed to be located in sensitive area, like the heel, the toes, and the skin around the wound, and easily included in the shoe.

**Monitoring inflammation:** Inflammation is the first stage of the wound-healing process and is characterised by redness, pain, increased temperature and fever. Its function is to neutralise and destroy any toxic agents at the site of injury and to restore the tissue homeostasis. Since inflammation is associated with increased temperature values, a wound temperature sensor is being designed to be included in the wound dressing to allow a real-time remote monitoring of this parameter. Technical challenges include the integration in the soft dressing of the electrochemical sensor, based on polymer material, and biocompatibility concerns since the sensor should be in direct contact with the wound. Inflammation

status is also assessed by the quantification of biomarkers, such as metalloproteases (especially MMP2 and MMP9), C-Reactive Protein (CRP) and TNF-alpha (Tumor Necrosis Factor). Sensors for biomarker quantification are based on optical sensors, which sensing parts are included in the top of the dressing.

**Monitoring infection:** A certain level of bacterial burden is normal in every wound, but when it becomes excessive an infection develops that requires antibiotic treatment. The proliferation of bacteria in the wound leads to increased pH values. For example, in chronic venous leg ulcers and in pressure ulcers, an alkaline or neutral pH value, compared with the normal surrounding skin, is considered a sign of infection. Electrochemical pH sensors are therefore designed to be included in the dressing material to provide continuous monitoring of pH wound. In addition to body temperature measurements that can be recorded by the SWAN-iCare system, this data can help in the early detection of an infection. In addition, an external device for the detection of the most encountered antibiotic-resistant bacteria strains (MRSA: Methicillin Resistant Staphylococcus Aureus; ESBL: Extended Spectrum Beta-Lactamase resistant bacteria) requiring tailored medical treatments, is being developed. The antibiotic-resistant bacteria sensor will be based on the optical detection of volatile organic compounds emitted by the bacteria. The early identification of bacterial infections based on sensor monitoring could help removing some of the errors and misinterpretations which are common in the clinical practice, currently based on the visual observation of the wound colour and the viscosity or volume of the exudate.

## V. EXPECTED BENEFITS

The development of wearable medical devices with sensors and ICT that allow remote monitoring of wound conditions is expected to lead to benefits for patients and medical support teams at numerous different points along the treatment pathway [8]. The expected benefits are summarized below:

### Improved clinical outcomes:

- Earlier identification of wound infections and wound deterioration, encouraging hope of a lower amputation rate.
- Better control and monitoring of exudate and compression.
- Access to detailed real-time quantitative data will contribute to evaluation of treatment effectiveness and wound healing progress and allow for fine-tuned treatment regimes.

### More efficient use of resources:

- Reduced healthcare costs as a consequence of fewer complications and faster healing.
- Reduced healthcare costs as a consequence of a reduced need for hospitalisation and fewer visits to specialist wound centres through remote monitoring.
- Reduced time spent on dressing changes on nursing visits, allowing more time to be focused on other medical needs.
- Less potential waste of dressing materials as a result of a reduction in unnecessary dressing changes.
- Reduced cost to the social system and minimised loss of productivity associated with the patient returning to work earlier due to an improved wound management process.

### Increased patient satisfaction and quality of life:

- Reduced disturbance to the patients life and possible reduced need for hospitalisation due to early identification of wound deterioration and faster healing.
- Personalised treatment adjusted on a daily basis to meet each patient's individual needs.
- Patients can stay out of hospital while receiving treatment and thus feel more comfortable while being reassured that their condition is being remotely monitored.
- Less dependency on clinical visits that will reduce time and resources spent on transportation to specialist care units.

### Better monitoring and documentation:

- Detailed and continuous data collection on central parameters important for wound healing will increase the level of knowledge and competence among the different service providers involved in wound care.
- Deeper understanding of wound healing through correlation and analysis of multiple wound parameters.

## VI. CONCLUSION: HOW FAR ARE WE FROM REALISING THE SWAN-ICARE GOALS

By February 2015 a prototype SNPD will have been developed. However, the technological development is itself only one part of the challenge of getting these types of systems integrated into routine care provision.

Large-scale deployment and real-market uptake requires additional work to understand how implementation of these ICT systems will affect current workflows and any potential changes to the roles and responsibilities of staff involved in service provision throughout the treatment pathway. If this is not understood and accounted for, implementation could be hindered simply because organisations and staff are not ready to transform the way routine care is being provided.

Another aspect is the business model. Clarification of where the reimbursement of such a system is to come from in different health care settings is a challenge that has hampered the uptake of similar products. For patients that end up receiving treatment and care from multiple sectors, the impact on budget for all the different levels of service providers will not be easy to establish. It may not always be obvious that the ones bearing the costs are the ones benefiting from the savings generated.

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