

PRoF Award abstract – Call 2016

Automated incontinence monitoring

An innovative approach to optimize, personalize and avoid incontinence care

1. Research Outline

Acronym	AIM
Project name in English	Automated incontinence monitoring - an innovative approach to optimize, personalize and avoid incontinence care
Pitch (1 sentence)	Within this project a diaper-based sensor platform was developed in order to optimize and personalize incontinence related care as well as to enable objective and accurate measurements necessary for diagnostics of urinary incontinence in any home setting
Executive summary (max. 10 lines)	
<p>This project contains the development of two diaper-based products. The Standard Smart Diaper is designed to monitor the loss of urine and feces. Caregivers are notified when to change the diaper. This system improves the quality of incontinence related care and the general comfort of the patient. It reduces the burden of caregivers and dependents and the ecological footprint. The Expert Smart Diaper is a diagnostic toolkit designed to automatically register data for a voiding diary. Today voiding diaries are obtained manually but they bring along a significant burden for patients and doctors. This toolkit allows objective, accurate and cost-efficient monitoring of miction behaviour in any setting. It can aid in a faster and accurate diagnosis and leads to adequate treatment of incontinence.</p>	

2. Cause and context of the research

Introduction

Urinary incontinence (UI) is an important medical and socio-economic problem, significantly associated with morbidity and mortality, with prevalence increases with age and vulnerability (Table). It results in a higher risk of falls and fractures, urinary tract infections and skin lesions. The subsequent higher frequency and prolonged duration of hospitalizations also lead to additional costs. It affects more women and is an important indicator of institutionalization. UI leads to negative physical, psychosocial and financial consequences for many stakeholders and has a considerable impact on family and caregivers. With the global aging population, the absolute numbers of elderly, also those who suffer from UI will increase exponentially in the future. This makes incontinence related problems more prominent and insists on a more efficient approach to handle incontinence.

	Men	Women
≥65y	21%	35%
≥80y	33%	38%
institution	58%	
45-64y	11%	34%
19-44y	5%	21%
6-18y	13%	

Problem identification

Care home and home setting

Often, when new residents arrive in care homes, they are provided with a diaper from the moment of intake, hence often being labeled as incontinent without having a diagnostic evaluation. Depending on the institution, the continence care consists of fixed diaper change and/or miction tours, taking place up to five times a day and sometimes up to three times a night. These diaper change tours are a burden to caregiver and patient as they are time as well as labor intensive for the caregiver and uncomfortable and sleep disruptive for the patient. Importantly, during these fixed changes it appears that the diapers are often not yet saturated or dry. Furthermore, residents often obtain incontinence material with the largest absorption degree. Presumably because the caregiver has no idea of the residents' miction behavior. This high absorption material is thicker and hence reduces the comfort of the patient, while causing waste due to not or poorly saturated diapers. Additionally, prolonged fecal contact has an important impact on the skin, causing incontinence associated dermatitis, which is difficult to treat and can be avoided if diapers would be appropriately changed. Currently, no systems exist that can notify presence of feces. Continence policy is currently chosen by caregivers on a generic basis with no/poor participation of the patient/family. Moreover, there is a very large impact on the continence policy by the diaper companies as they are the ones educating caregivers for the optimization of diaper usage. However without any measurement instruments, the determination of diaper management is mainly speculative. It should be noted that the majority of people, suffering from incontinence are living at home. In this case, it is often a local caregiver that is responsible for diaper change. To promote the independence of both caregiver and elderly, an alerting system

supporting continence management, can serve as an important tool that can also serve as quality label for incontinence care.

Given all abovementioned arguments, there appears to be a general need for improving continence policy and reducing needless diaper changes.

Diagnosics

The cause of urinary incontinence is often multifactorial and for this reason there is no standardized treatment for the general term 'incontinence'. As treatment is dependent on the type of incontinence, accurate diagnosis is crucial. A large number of examinations are used, based on European guidelines that burden patient and caregiver and represent a significant cost for society. Today, in Belgium, a three-day stay in the university hospital is often necessary for the frail elderly patients and this is very expensive. For the more autonomous patients multiple consultations are required, complemented by manual data registration at home during three days and urine sample collection during 24 hours. Collecting these type of data manually at home is an elaborate and inefficient method, which is susceptible to errors, however there is currently no alternative. This approach thus often leads to inaccurate results, subsequent inaccurate diagnosis and inadequate therapy.

3. Innovation results achieved

Tools: Standard/Expert Smart Diaper & Diagnostic Toolkit

To handle the incontinence related problems two types of diapers are conceived. Their measurement specifications are summarized in Table 1. Both devices make it possible to detect fecal incontinence, which is - to the author's knowledge - the first product capable of performing this measurement. Next to this, both incopads have different specifications regarding urine measurement. The Standard Smart Diaper is designed to obtain a cost efficient monitoring system, which makes it possible to obtain an optimized and personalized diaper management. The Expert Smart Diaper on the other hand is more costly but more accurate. The target market for each device goes hand in hand with its associated cost and performance. Where the Standard Smart Diaper is sufficiently accurate to measure when a diaper needs to be changed, the Expert Smart Diaper is able to estimate the urine volume very precisely. This makes the Standard Smart Diaper the preferred product for the care market, where the Expert Smart Diaper is favored for diagnosis.

Specifications	Standard Smart Diaper	Expert Smart Diaper
Comfortable, reusable, cleanable measurement modules	Yes	Yes
Detection of faeces	Yes	Yes
Accuracy volume measurement	100ml	5ml
Time between measurements	From 1h down to 5 minutes (adjustable)	From 1h down to 1 second (adjustable)
System generates incontinence alert based upon thresholds (urine & faeces)	Yes	yes
Possible to read out measurement data	No	yes
Target market	Optimization of incontinence care in terms of optimized diaper usage and changes	Diagnostic tool for doctors and specialists

Table 1: Smart diaper specifications

The **diagnostic toolkit** for 48h monitoring comprises five components of which the Expert Smart Diaper forms the basis:

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 1. The **Expert Smart Diaper** makes it possible to measure urine losses due to incontinence in terms of volume and frequency
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 2. A **toileting tool (disposable uroflow)** uses the same technology as the Expert Smart Diaper, is also able to measure volume and frequency of urine losses but now the person urinates on the sensor, which hangs into a conventional toilet
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 3. **Biosensors** present in the smart diaper based tools (1 & 2) are able to give an indication about urine concentrations
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 4. A **bladder scanner (optional)** will complete the diagnostic toolkit. With this scanner the bladder volume can be estimated
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 5. An **app** will be used for patients' input of urological complaints and drinking behaviour

The diagnostic toolkit will have its most and significant added value for patient and society when combining the Expert Smart Diaper with the disposable flow meter, which uses the same technology. This allows to automatically and accurately construct all miction and urine loss patterns. Together with the digital registry of voiding behaviour and complaints, this forms a bladder diary, which is the

most basic and essential part in the diagnostics of UI. The biosensors and bladder scanner is an option for certain patients were this additional measurement data is required.

The combination of these components makes it possible for caregivers and patients to automatically perform accurate measurements in the setting where incontinence normally occurs. This is in contrast with the current stressful and costly situation when a patient is hospitalized or in the ambulatory setting with manual elaborate and inaccurate registration of the different components.

A market research was performed in order to find all the necessary ingredients for this toolkit. Nevertheless, cost-efficient off-the-shelf solutions for accurate voiding measurements are not available, not in diaper (1) nor in flow meter solutions (2). The other components of

the kit can be ordered at third parties; the biosensors (3) and the bladder scanner (4), or can be engineered in a straightforward way, as is the case for the app (5).

Both diapers are currently developed within an ongoing IOF Advanced project as part of a collaboration between the department of urology (UZ Gent; Ugent) and CMST (Ugent-imec), a specialist in sensor technology (October 2015 - September 2016). This project allows clinical validation of the smart diaper, the necessary steps towards the diagnostic tools and business model development for the diagnostic toolkit. Regarding the technological smart diaper solution two patents are pending, a collaboration with a major diaper producer has been started and a spin-off company will be launched during 2016 which will create the service and hardware for this smart diaper.

4. Link to the PRoF values

We would like to illustrate the need and added value of the automated incontinence measurement devices and their link to the PRoF values by presenting three use cases:

A. *Optimization incontinence care*

Case 1: Standard smart diaper for elderly person with excessive urinary incontinence in a care home setting for optimized diaper usage.

Marie is 72 years old, lives in a care home, suffers from dementia and has a serious incontinence problem that cannot be treated. She sits in a wheel chair. She continuously wears a diaper. She is placed on a toilet at 4 fixed moments a day using a nurse assisting lift, after which her diaper is changed. This takes a lot of time and is very labour-intensive. Every night, she is woken twice routinely for a diaper change.

Case 2: Standard smart diaper for elderly person with excessive urinary incontinence in a care home setting for optimized bladder training and diaper usage.

Stefaan is 69 years old and lives in a care home. He has complaints of urinary incontinence for which he wears a diaper. Nurses change his diaper at 4 fixed moments every day and once at night. He is not capable of changing himself. Stefaan does not like this, it affects his privacy and disturbs his rest.

For cases 1 and 2 the **Standard Smart Diaper** system can be used, which allows to monitor urine losses and to alert the nursing personnel whenever a diaper change is necessary. Also miction training for a subgroup of more autonomous patients (case 2) can be initiated to improve continence status.

- **Minimal comfort:** Unnecessary diaper changes during the day and at night will be overcome and limited to only the necessary changes, increasing the patients' quality of life. This personalized approach can also prevent falling events, skin irritation and wounds. Follow-up of the quality of a persons' continence care is possible.

- **Privacy:** The diaper system links diapers to individual users, where data are protected in a similar way as the patient file in a care home. Next to the protection of the measurement data, also the privacy of the person itself is less disturbed due to the fact that the amount of diaper changes (and together with that the amount of contact at genitals by caregivers) is reduced significantly.
- **Security:** The smart diaper system consists of a disposable diaper with the same features of a conventional diaper without any comfort or safety/security loss.
- **Anti-loneliness:** The consequences of a personalized and optimized diaper change and continence management can affect self-esteem and social behavior. As diaper changes will occur in more controlled way, patients can be relieved of insecurity of being left for hours in a wet or soiled diaper.
- **Non-stigmatising solutions:** people that need to wear diapers are sometimes embarrassed about their incontinence. Just for this reason they will not call a nurse because they assume the nurse does not like to change the diaper (when the diaper is full before the normal incontinence check still occurs). Due to this behavior these patients cannot lead a normal social life and will become isolated. With our system adequate diaper changes are provided when needed without attracting any attention. In this way, the social life of the patient can be guaranteed.
- **Inter-generational:** This product is not only useful for elderly care homes. It can also be used in a home setting with family care givers. Due to the automated alerting system, the psychological burden for family care givers can be reduced significantly. In this way, the relation between care givers and the elderly, is significantly improved.
- **Respect:** Respect from the society towards the incontinent elderly is showed due to the optimized and personalized nature of the system they are providing towards them by implementing this system. In this way, the elderly can lead a normal life, because they are worth it.
- **Flexibility:** Objective measurements and characterization of urine/faeces losses will allow automatic selection of correct diaper thicknesses and adequately timed diaper changes (day/night). The diaper change limit can be set intelligently for each individual based on personal data and thus allows personalized diaper management. In this product, a training module applicable to case 2, can be integrated. Furthermore, optimizing diaper management for each patient brings also reduced costs along.

B. Optimization diagnosis

Case 3: Diagnostic kit for home monitoring of urinary incontinence in a home setting or hospital environment

Jeanne is 74 years old and lives at home. She has complaints concerning urinary loss during several years now and she avoids talking about it. She feels very insecure about this urine loss because of which she is afraid to leave the house. She is ashamed about wearing a

diaper and afraid that her friends will notice or even smell it. She becomes more and more isolated because of this.

In case 3 the diagnostic kit will be used, which allows objective and accurate measurement of volume and frequency over time of all urine losses, in any setting. The toolkit additionally measures bladder residue along with patients' input of urological complaints and drinking behaviour.

- **Minimal comfort:** The Expert Smart Diaper allows accurate diagnosis and quantification of severity of the UI, which allows more adequate treatment. This can be implemented in the current diagnostic protocol and releases the patient/caregiver from intensive urine loss registration. The use of the entire diagnostic toolkit could substitute for a hospital stay or manual home registration, allowing comfortable testing in any setting and obtaining accurate and objective data which can be automatically transferred to the doctor.
- **Privacy:** Idem section A.
- **Security:** Idem section A.
- **Anti-loneliness:** People who suffer from incontinence are often ashamed and embarrassed and become socially isolated, out of fear that other people will see or smell whenever they have a leak. Consequently, incontinence is often associated with depression and anxiety. This product lowers the threshold to act on one's incontinence problem and allows an improved continence status through more accurate and objective measurements for diagnosis with minimal efforts from a home setting. The adequately treated patient will become more autonomous again and can enjoy a social life.
- **Non-stigmatising solutions:** Often patients are reluctant to consult a doctor for this problem because they are too embarrassed to discuss such a matter. The diagnostic kit offers the basis of UI diagnostics from a more private home setting, avoiding larger hospital investigations or elaborate measurement efforts by the patient him/herself. This means that an accurate diagnosis can be achieved in a more correct treatment can be achieved in an earlier phase.
- **Inter-generational:** The diagnostic kit has been developed from the point of view of the elderly. This affects not only the condition of the elderly person him/herself but there is a high burden for family (partner, children,...) and caregivers which can be released by improving continence status.
- **Respect:** People suffering from UI often have psychosocial difficulties. The idea of developing a diagnostic toolkit has partially emerged from observing physical and psychosocial burden for such patients. Therefore, the system is developed in a way that takes into account physical and psychosocial functions of each user, aiming to diagnose UI in a discrete way and increasing a person's self-esteem by improving his/her continence condition.
- **Flexibility:** The diagnostic toolkit becomes personalized for every individual user, as an intake questionnaire will determine which components from the kit should be used

by each patient. The kit can be used in any setting (home, care home, hospital,...) releasing both patients and caregivers from labour-intensive diagnostic tests. With adequate therapy, the UI condition is likely to improve. Incontinent people are more likely to end up early in care homes as they need more care, therefore improving the incontinence condition can keep patients longer at home longer.

5. Applicable IPR rules

At this point the IP is owned by UZ Ghent, UGent and imec. It is the purpose to valorize these obtained results and products by means of a spin-off trajectory.

6. Information on the partners

The gap in *diagnostic* assessment of incontinence has been identified by Prof. Everaert, Urology, UGent. In looking for solutions, collaboration has been started with CMST, an expert in sensor technology & smart textiles. Discussing needs and solutions resulted in a novel inventive approach with the conceivment of two smart diaper types, discussed above.

Addendum: Contact information

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