

Improved Incontinence Management using RFMicron's "Smart Diapers™"

Overview

RFMicron's technology and products have generated strong interest within the rapidly growing adult diaper/briefs market and from long term elderly care providers struggling with the problem of managing incontinence. RFMicron's sensor technology is enabling a "smart diaper" solution that allows a caregiver to remotely detect if an incontinence event has occurred, which is part of RFMicron's Internet of Things strategy to connect the unconnected, sense the surroundings, and make the data available on the greater internet. RFMicron has established a development partnership for a "stand-alone" solution that can attach to any adult diaper by assisted living or skilled nursing staff. RFMicron is in the process of integrating these passive sensors into the diaper during manufacturing.

Benefits:

- Ability to remotely, wirelessly and accurately detect if an incontinence event has occurred
- Improved quality and dignity of care by not having to disturb or disrupt the patient or resident
- Enable timely changes when needed while reducing unneeded brief checks/changes
- Provide better incontinence management by automatically data logging events, tracking activity patterns, and performing analytics for intelligent trend analysis and patient decision making
- Lower total cost of care by reducing time dedicated to toileting, lowers risk, and can be a market differentiator for Long Term Care providers

The Problem: A Silent Epidemic

Incontinence refers to the involuntary loss of bladder or bowel control. Bladder and bowel incontinence are conditions affecting older persons that can have serious implications for quality of life, caregiving, and service delivery. According to the Illinois Department of Public Health, approximately 13 million Americans are incontinent. Incontinence is most common among the elderly.^{1,2} Between thirty and fifty percent or more of elderly persons living at home or in long-term care facilities



are incontinent. Sufferers may experience emotional as well as physical discomfort. Many seniors affected by loss of bladder or bowel control isolate themselves for fear of ridicule and loss of self-esteem.

Nursing home (NH) staff report that urinary incontinence care is difficult and time-consuming.³ Practice guidelines specify that a resident's soiled garments should be changed and skin cleansed in a timely fashion.^{4,5,6,7,8} Prior NH research has demonstrated that perineal skin disorders correlate with frequency of incontinence.⁹ In addition, skin exposure to urine due to infrequent adult brief changes can produce a

significant increase in skin wetness, with increased rubbing and abrasion predisposing the skin to breakdown.¹⁰ Urinary and fecal incontinence also predispose the perineal area to skin irritation and impairs the healing process of pressure ulcers, and fecal incontinence may present even more risk to skin integrity.^{11,12,13} Studies have shown that infrequent adult brief changes are believed to increase the vulnerability of skin damage due to urine and fecal exposure.¹⁴

Incontinence presents a significant financial burden to the individual and to society. In the United States, the cost of urinary incontinence among adults in 2007 was \$65.9 billion and is projected to grow to \$82.6 billion in 2020.¹⁵ A majority (50%–75%) of the costs are attributed to resources used for incontinence management or "routine care" such as absorbent pads, protection, and laundry.¹⁶

Impact on Nursing Homes and Assisted Living Facilities

The Centers for Medicare and Medicaid Services (CMS) determines whether a nursing home is able to abide by government standards through a series of nursing care surveys conducted by contracting agencies in each state.¹⁷ Each survey is intended to measure different levels and dimensions of quality and to certify that the home is continually meeting federal requirements. As part of the Nursing Home Quality Initiative (NHQI), CMS has made urinary incontinence (UI) a quality indicator. In addition, CMS issued revised guidance on UI and catheters (known as tag F315) for nursing homes regarding compliance in the evaluation and

management of UI and catheters and an investigative protocol for state nursing home surveyors to use during regulatory inspections.

Since UI is a quality indicator of the NHQI, the metric is meant to serve as an indicator for consumers about the quality of care delivered by nursing homes.¹⁸ Deficient institutions and even caregivers can face a variety of severe sanctions, such as civil monetary penalties, termination of participation in federal and state funding programs, or closure of the facility, depending on the violation. As such, nursing Homes and assisted living facilities are in need of an incontinence management solution that provides a safe and easy way to monitor incontinence problems of patients.

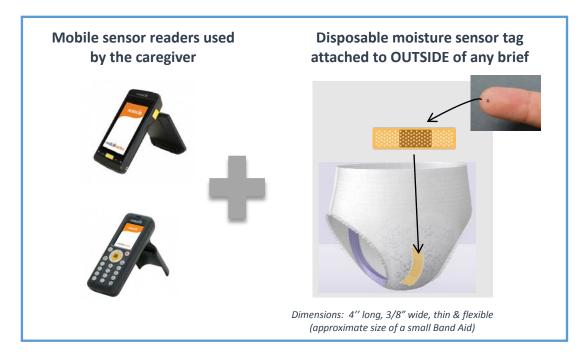
RFMicron's "Smart-DiaperTM" Solution

RFMicron has developed a new, low cost, wireless, battery-free sensor that turns any standard adult diaper or brief into a Smart-DiaperTM, which allows a caregiver to remotely and non-invasively detect patient incontinence events. As shown in the figure below, the solution includes a simple peel-and-stickTM, disposable sensor that attaches to any off-the-shelf diaper and a handheld wireless sensor reader. The sensor, which determines wetness / dryness, is approximately the size of a small Band Aid, and the handheld reader is similar in size to a cell phone.

Incontinence afflicts 13 million seniors and is projected to cost >\$80 billion annually by 2020







RFMicron's technology has been incorporated into the Magnus[®] S family of products, which are the Industry's first passive, wireless, single-chip sensors. Through commercial partnerships, RFMicron and its healthcare system integrators enable new markets that have not been cost effective or are prone to costly mistakes. RFMicron currently offers a "stand alone" solution that can attach to any adult diaper or brief by assisted living or skilled nursing staff. RFMicron and its partners are also developing the option to integrate sensors directly into adult diapers during manufacturing.

In terms of how the Smart-Diaper[™] sensor works, RFMicron's Magnus[®] S single chip family of ICs supports a new class of fully-functional wireless passive sensors consisting of nothing more than the Magnus[®] chip and an antenna, which constitutes a smart sensor. RFMicron's technology enables the unique ability

RFMicron's Smart-Diaper[™] technology was independently tested at a long term elderly care facility.

to passively (i.e. no battery) and wirelessly, sense the presence of urine or any bowel movement. While attached to the outside of the Smart-Diaper[™], the sensor can detect the presence of less than 50ml of urine.

During the first quarter of 2015, RFMicron's smart diaper technology was independently tested at a long term elderly care facility. This initial proof of concept test was shown to reliably detect incontinence events.

RFMicron's energy-harvesting sensor tags are powered and communicate over the industry-standard ISO 18000-6C UHF protocol, which is used today by billions of RFID tags within retail and apparel stores. The technology is completely safe and RFMicron's Smart DiaperTM tag is classified as a Class 1 medical device with the US Food and Drug Administration, just like an elastic bandage or tongue depressor. Since all elements of the system are external to the body, it is deemed in the "lowest risk" category of medical device.

RFMicron's non-intrusive Smart DiaperTM solution benefits everyone affected by long term care, as highlighted below.



The Resident / Patient

- Better quality of life and reduction in incontinence-related injuries
- Awkward, embarrassing incontinence discussions are eliminated

<u>The Family</u>



- Peace of mind that the best care is being given to your loved one
- Knowing that a proactive, proven incontinence management solution is being utilized

The Caregiver

- Provides improved, more dignified care for the resident/patient
- Can dedicate more attention to the needs of the resident/patient by reducing time consumed by toileting assistance and cleanup



The Long Term Care Provider

- Eliminates the guesswork of incontinence management and decreases preventable admissions for Urinary Tract Infections
- Reduces governmental monetary penalties and lowers total cost of care
- Enhances the resident experience, which is a market differentiator

To learn more, contact RFMicron at:

Smart Passive Sensing

5000 Plaza on the Lake - Suite 120 Austin, TX 78746 Tel: (512) 535-4647 www.rfmicron.com ⁶ American Medical Directors Association. Urinary incontinence: clinical practice guideline. Columbia, MD: AMDA; published 1996 and revised 2005.

⁷ Schnelle JF, Cretin S, Saliba D, et al. Chapter in Report to Congress: Appropriateness of minimum nurse staffing ratios in nursing homes. II. Health Care Financing Administration; 2000. Minimum nurse aide staffing required to implement best practice care in nursing homes; pp. 14-1– 14-68. Chapter 14.

⁸ Schnelle JF, Alessi C, Simmons SF, Al- Samarrai RN, Beck J, Ouslander JG. Translating Clinical Research into Practice: A randomized Controlled Trail of Exercise and Incontinence Care I Nursing Home Residents. J Am Geriatr Soc. 2002;50:1476–1483.

⁹ Schnelle JF, Adamson G, Cruise P, Al-Samarrai RN, Sarbaugh F, Uman G, Ouslander JG. Skin Disorders and Moisture in Incontinent Nursing Home Residents: Intervention Implications. JAGS.1997;45:1182–1188.

¹⁰ Fader M, Clarke-O'Neill S, Cook D, et al. Management of night-time urinary incontinence in residential settings for older people: an investigation into the effects of different pad changing regimes on skin health. Journal of Clinical Nursing. 2003;12:374–386.

¹¹ Ouslander JG, Schnelle JF. Incontinence in Nursing Home. Internal Medicine. 1995;122(6).

¹² United States Agency for Health Care Policy and Research. Pressure Ulcers in Adults: Prediction and Prevention. Rockville, Maryland: U.S. Department of Health and Human Services, Public Health Services, Agency for Health Care Policy and Research; 1992.

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¹⁴ Allman RM. Pressure sores among hospitalized patients. Annals of Internal Medicine. 1986;105:337–342.

¹⁵ Coyne KS1, Wein A, Nicholson S, Kvasz M, Chen CI, Milsom I. Economic burden of urgency urinary incontinence in the United States: a systematic review. J Manag Care Pharm. 2014 Feb;20(2):130-40.

¹⁶ Subak LL, Brubaker L, Chai TC, Creasman JM, Diokno AC, Goode PS, et al. High costs of urinary incontinence among women electing surgery to treat stress incontinence. Obstet Gynecol 111(4):899–907. 2008.

¹⁷ Kohl T. Watching out for grandma. Fordham Urban L J. 2003;30:2083-2106.

¹⁸ U.S. Department of Health and Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS). (2006). Quality measures.

¹ Illinois Department of Public Health, Women's Health, Facts about Incontinence. www.idph.state.il.us/about/womenshealth/factsheets/inc.htm

² Ouslander JG, Schnelle JF, Uman G, Fingold S, Gilater J, Nigam G, Tuico E, Bates-Jensen B. Predictors of successful prompted voiding among incontinent nursing home residents. JAMA. 1995;273:1366–1370.

³ Schnelle JF, Ouslander JG, Simmons SF. Predicting Nursing-home resident responsiveness to a urinary incontinence treatment protocol. International Urogynecology Journal. 1993;4:89–94.

⁴ HCFA (Health Care Financing Administration) Long-term care facility resident assessment instrument (RAI) user's manual: for use with version 2.0 of the HCFA minimum data set, resident assessment protocols, and utilization guidelines. Eliot Press; Natick, MA 01760: 1999.

⁵ AHCPR. Clinical practice guideline: pressure ulcers in adults. Rockville, MD: AHCPR; 1994.



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