**Original Paper** 

# Development of a Warning System to Detect Urinary Incontinence from Outside of a Diaper using a Reusable Sensor

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Abstract The number of elderly individuals in need of care is increasing with the growing elderly population in Japan, resulting in the increased production of disposable diapers. Several warning detectors for urinary incontinence have been developed to provide high-quality care, several of which have been marketed. Most of these detectors use disposable sensors. These sensors must be attached to a new diaper at the time of diaper changing. To reduce both the effort and the cost required to replace the sensor, we developed a warning system to detect urinary incontinence using a reusable sensor on the outside of a diaper. The newly developed system is essentially divided into a sensor unit and an alarm unit. The sensor unit consists of a pair of electrodes; a timer; a signal generator; bridge, rectifier, and smoother circuits; and a transmitter. The alarm unit consists of a receiver and LEDs. The alarm unit delivers a warning about incontinence to care staff via LED lighting. When 500 mL of tap water was absorbed into a diaper, on the outside of which the system was attached by its electrodes, the capacitance and conductance increased 2.5 times and 50 times, respectively, compared with those of a dry diaper. When 50 mL of saline was poured into a diaper that was attached to the crotch region of a torso mannequin to model incontinence, the incontinence warning functioned as intended. The impedance of the pad-type diaper, which was measured by an impedance analyzer, decreased from 270 k $\Omega$  to 86 k $\Omega$ . The electrodes remained dry after the saline was poured into the diaper. The novel warning system was evaluated in a special nursing home for the aged. Twelve elderly people participated in this trial. The system operated correctly in 49 of 65 trials.

Keywords : urinary incontinence, diaper sensor, capacitive change.

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### 1. Introduction

Over 60% of elderly residents in special nursing homes for the aged in Japan use diapers [1]. The production of disposable diapers for elderly people is increasing as the elderly population increases. The annual production of disposable diapers increased from 30 billion pieces in 2003 to 58 billion pieces in 2011 [2]. Disposable diapers for elderly people are used in various settings such as hospitals, nursing homes, and residences. Diaper is exchanged in the middle of the night irrespective of whether there is incontinence in many special nursing homes for the aged. Avoiding diaper exchange when there is no incontinence in the middle of the night would improve the quality of sleep of care receivers. In addition, diaper checks by care staff at night disturb the sleep of care receivers. Therefore, a warning sensor is needed to

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detect urinary incontinence.

Several warning sensors for urinary incontinence have been developed [3, 4], some of which are being marketed around the world[5-7]. These warning systems have also been used to study the regular urine voiding pattern of bedridden incontinent elderly [8, 9]. The sensors in these warning systems are wetted by urine and therefore have to be disposable, requiring additional cost and labor associated with sensor exchange. To overcome these problems, we developed a reusable sensor to measure impedance from the outside of a diaper using electrodes[10]. In this study, we specifically developed a sensor system that detects urinary incontinence from the outside of a diaper and evaluated the system in a clinical setting.

### 2. Outline of the System

### 2.1 Diaper Exchange and Detection Design

In nursing homes for the aged in Japan, diapers are generally used in the following manner. First a pad-type diaper is worn and then covered with a pant-type diaper. Therefore, the care receiver wears two diapers. To reduce the cost of diaper disposal, the pad-type diaper is exchanged several times a day while the pant-type diaper is exchanged once per day.

We have tried the thermister temperature sensor and sensor of the resistive coupling type to detect urinary incontinence [3], both of which are disposable. Several

commercial products to detect urinary incontinence are available. For instance, one is a rectangle-shaped sensor to be placed inside a diaper, and another is a sensor incorporated into a diaper. Almost all of these sensors are the resistive coupling type and are disposable. However, one of the sensors is reusable[11]. According to the web page of the capacitive coupling type sensor, the sensor is placed between the sheet and the mattress. A wet padtype diaper is detectable through a stack of five layers, a pant-type diaper, a pajama pant, a water proof sheet, and a sheet. We have not tested this sensor, but a capacitive coupling type is probably used. The sensor is reusable after incontinence occurs because it is not in contact with urine and remains clean. We speculate that the sensor can detect a wet pad-type diaper worn by a care receiver in supine position. However, it is probably difficult to detect a wet pad-type diaper when the care receiver is in a 30degree lateral position for preventing bed sore, because the distance between the sensor and the wet pad-type diaper is increased.

We are currently developing a capacitive coupling type sensor to detect wetness in a pad-type diaper in both lateral and supine positions. We have designed a rectangle-shaped sensor that is attached to the outer surface of a diaper[10]. Ideally, wetness in the pad-type diaper should be detectable from the outside of the panttype diaper to reduce cost and labor associated with sensor exchange. In this preliminary study, we attempted to detect urinary incontinence from the outside of a padtype diaper instead of from the outside of a pant-type diaper.

# 2.2 Principle of Detection of Urinary Incontinence from Outside of Diaper

Electrostatic capacity varies with the dielectric between electrodes. Impedance between electrodes decreases due to an increase in the dielectric constant. **Figure 1** shows schematically the principle of detection of urinary incontinence from the outside of a diaper. The dielectric constant between the electrodes placed on the outside of a diaper increases due to the change in condition of the polymer from dry to wet. Therefore, the impedance between the electrodes attached to the outside of the diaper decreases when the water-absorbing polymer absorbs urine. In this study, we planned to detect the impedance change between electrodes due to urinary incontinence.

# 2.3 Electrodes

# 2.3.1 Materials

The electrodes  $(160 \times 30 \text{ mm} \text{ in size})$  are made of two comb-shaped stainless steel plates (0.1 mm in thickness)covered with plastic films (0.1 mm in thickness). **Figure 2** shows a diagram of the electrodes. The clearance between the plates is 1 mm. One side of a coaxial cable (1.5D-QEV) 500 mm in length is connected to the electrodes, and other side of the cable is connected to an SMA connecter.

#### 2.3.2 Impedance Measurement

The impedance of a pad-type diaper (Atento;  $450 \times 135$  mm; Daio Paper, Tokyo, Japan) was measured by an impedance analyzer (4294A; Agilent Technologies) from 1–100 kHz, using the comb-shaped electrodes under two conditions. First, the impedance of a dry diaper attached to the electrodes was measured. Then, a diaper that had absorbed nearly 500 mL of tap water was assessed.

**Figure 3** shows the frequency dependence of the capacitance and conductance of dry and wet diapers. The capacitance of the wet diaper was approximately 2.5 times larger than that of the dry diaper. The conductance increased as the measured frequency increased. The conductance of the wet diaper was approximately 50 times larger than that of the dry diaper. A clear difference in impedance was obtained between the dry and the wet diapers. These results suggested that urinary incontinence may be detected using electrodes attached to the outside of a diaper.

### 2.4 Design of Warning System

We designed a warning system for detecting urinary incontinence to reduce the effort and cost associated with replacing the sensor. The system essentially consists of a sensor unit and an alarm unit. **Figure 4** shows a photograph of the whole system. The electrodes are attached to the outside of a pad-type diaper using a



Fig. 1 A cross-sectional diagram of a diaper and impedance measurement.

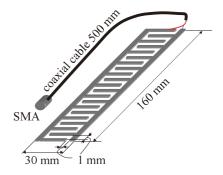


Fig. 2 Schematic diagram of electrodes.

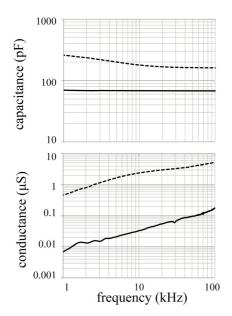


Fig. 3 Frequency dependence of capacitance and conductance of a dry diaper (solid line) and a wet diaper (dashed line).

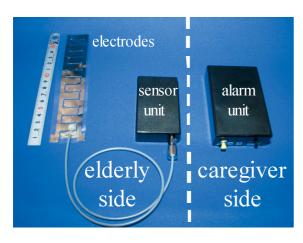


Fig. 4 A photograph of the warning system.

medical adhesive tape (Transpore, 25 mm in width; 3M). The sensor unit is placed between the pajama pants and the pant-type diaper.

If incontinence is detected, the sensor unit sends a signal to the alarm unit. When the alarm unit receives the signal, an LED illuminates as a warning. The details of the system are as follows.

### 2.4.1 Sensor Unit

**Figure 5** shows the electrical circuit of the sensor unit. The sensor unit consists of a pair of electrodes; a timer; a signal generator; AC bridge, rectifier, and smoother circuits; and a transmitter. To reduce power consumption by the battery, the entire circuit, except the timer signal generator, is operated intermittently using the timer integrated circuit (IC: LMC555CN, National Semiconductor, USA). We set the timer to work for 1 s and stand by for 29 s in the clinical trials. The signal generator generates a sinusoidal wave at 10 kHz. Since the capacitance above 10 kHz was almost flat in the wet diaper (see **Fig. 3**), we used the frequency of 10 kHz. One side of the AC bridge circuit contains the electrodes. Urinary incontinence changes the dielectric constant of the diaper, changing the impedance of the electrodes forming one side of the AC bridge circuit. The voltage difference between the terminals of the AC bridge circuit is amplified, rectified, and smoothed. Since we employed a bipolar transistor, the output voltage at the connection position B in the electrical circuit used as a threshold was 0.7 V. Eventually, the smoothed signal triggers the transmitter (FW315TX-A, Fujisoku, Tokyo, Japan).

The size of the sensor unit, excluding the electrodes, is  $80 \times 50 \times 20 \text{ mm}$  (length × width × height), and the weight is 0.059 kg, including a 3 V coin-type battery (CR2032). Standby power consumption is 0.06 mW at the lowest. Power consumption during transmission is 98 mW at the highest. The battery life is up to 72 hours.

# 2.4.2 Alarm Unit

The alarm unit consists of a receiver (FW315RX-A, Fujisoku) and two LEDs. Lighting of the green LED indicates that the alarm unit is working. The incontinence warning is conveyed to care staff by red LED lighting, which persists until a member of the care staff presses the reset button.

The size of the alarm unit is  $110 \times 65 \times 20$  mm (length × width × height), and the weight is 0.170 kg, including four batteries of the AA type. The battery life is up to 240 hours. The alarm unit also works with a 6 V AC adapter instead of batteries.

# 3. Experiments

### 3.1 Phantom Model

A pad-type diaper (Atento) was attached to the crotch region of a torso mannequin. The electrodes were placed on the outside of the diaper. Voltage signals in the electrical circuit of the sensor unit were measured by an A/D converter (PowerLab 4/26, ADInstruments) at a sampling frequency of 10 Hz. A total of 50 mL of saline was introduced into a diaper worn on a torso mannequin in three positions: standing, 30-degree lateral, and supine positions, to model incontinence. The flow speed of the saline was 15 mL/s, which is the average speed of urination in 50 to 70 year-olds [12]. Two other pad-type diapers (Salva, Hakujuji, Tokyo, Japan; Relief, Kao, Tokyo, Japan) used popularly in Japan, were evaluated using the same method as described above.

# 3.2 Clinical Evaluation

For clinical evaluation, bedridden subjects in a special nursing home for the aged, Nakagoen of the Fujimoto Medical System in Miyakonojo, Miyazaki, Japan, were monitored. The subjects used diapers (Atento) every day. The characteristics of the subjects are shown in **Table 1**. No significant differences were found between the female and the male subjects in age, height, and weight by *t*-tests.

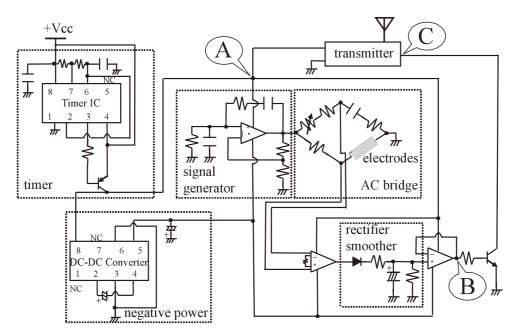


Fig. 5 Electrical circuit of the sensor unit. Capital letters indicate connection positions of the circuit (cf. Fig 6).

| no.       | sex | age            | height<br>(m) | weight<br>(kg) |
|-----------|-----|----------------|---------------|----------------|
| 1         | f   | 98             | 1.44          | 43.6           |
| 2         | f   | 90             | 1.38          | 34.8           |
| 3         | f   | 87             | 1.37          | 26.5           |
| 4         | m   | 79             | 1.67          | 47.0           |
| 5         | f   | 67             | 1.55          | 40.0           |
| 6         | f   | 95             | 1.42          | 40.3           |
| 7         | m   | 83             | 1.58          | 49.2           |
| 8         | f   | 84             | 1.35          | 33.3           |
| 9         | m   | 83             | 1.62          | 42.7           |
| 10        | m   | 79             | 1.59          | 53.2           |
| 11        | f   | 95             | 1.48          | 39.9           |
| 12        | m   | 94             | 1.42          | 36.8           |
| mean ± sd |     | $86.2 \pm 8.9$ | $1.49\pm0.11$ | $40.6\pm7.3$   |

 Table 1
 Characteristics of the subjects.

The diapers were changed 6-7 times a day, or every 3-4 hours, by care staff in the special nursing home. When the care staff changed the diapers, they recorded the status on a care record sheet, including the presence or absence of incontinence, feces, and the sensor reaction. The diaper weight was measured to estimate the amount of urine excreted when the subject had incontinence.

The experiments were performed between January 28 and February 7, 2013. Twelve subjects participated in this study. The study protocol was approved by the Fujimoto General Hospital Ethics Committee, and written informed consent was obtained from each participant or their family.

# 4. Results

### 4.1 Results of Phantom Model

When saline was absorbed into the pad-type diaper worn on a torso mannequin, the incontinence warning LED in the alarm unit was illuminated. Figure 6 shows the time course of signal voltages in the electrical circuit of the sensor unit. The power circuit supplied power for 1 s and rested for the next 29 s (A). Before the saline was introduced into the diaper, voltages at the connection positions of the electrical circuit changed as follows. At baseline, the balance of the AC bridge at connection position B was maintained, and the output voltage was zero. However, spike noise appeared because of the intermittent power supply. The transmitter works at a low trigger level. At connection position C, the trigger level remained high when power was supplied. After saline was poured into the diaper, the AC bridge was unbalanced, with an output of approximately 1.5 V at connection position B. The transmitter was activated by a low-level trigger from the spike noise because of the intermittent power supply at connection position C. Finally, the warning LED in the alarm unit illuminated.

The impedance of the pad-type diaper measured by the impedance analyzer (4294 A) decreased from 270 k $\Omega$ to 86 k $\Omega$ . The warning system worked well for two other pad-type diapers. In all of the model experiments, the electrodes stayed dry after the saline was introduced into the diaper.

# 4.2 Results of Clinical Evaluation

Table 2 shows the clinical results obtained using the newly developed urinary incontinence warning system. The minimum urine volume detected by the system was 0.170 kg (subject no. 1). The average amount of urine

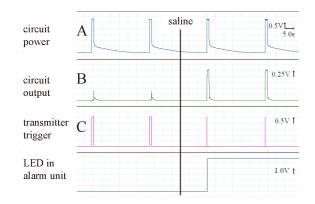


Fig. 6 Time course of signal voltages in the electrical circuit of the sensor unit. The capital letters indicate the connection positions of the electrical circuit (cf. Fig. 5).

 Table 2
 Results of clinical evaluation.

| sex   | incon-<br>tinence | trials | LED | err. | urine weight<br>(kg) |
|-------|-------------------|--------|-----|------|----------------------|
| f     | +                 | 34     | 28  | 6    | $0.267 \pm 0.115$    |
|       | _                 | 0      | 0   | 0    | _                    |
| m     | +                 | 30     | 20  | 10   | $0.372 \pm 0.156^*$  |
|       | _                 | 1      | 0   | 0    |                      |
| total |                   | 65     | 48  | 16   | mean ± sd            |
|       |                   |        |     |      | * : p < 0.005        |

voided by the male subjects was significantly larger than that by the female subjects. In total, 48 of 64 episodes of urinary incontinence were detected correctly, including 8 episodes of urinary incontinence with feces. One episode of no urination was also detected correctly.

Sixteen of 64 episodes of urinary incontinence were detected incorrectly. The errors in the system were mainly caused by

- 1. *Incorrect sensor positions*. In subject no. 4, seven of fourteen episodes were not detected. In this patient, most of the urine was absorbed in the central portion of the pad because the pad-type diaper was wrapped around his penis. In subject no. 10, one of six episodes was not detected for the same reason as above. Moreover, urine leaked out from the side of the pad-type diapers in subject nos. 3 and 12 in one episode each.
- 2. *Battery shutoff.* We asked the care staff to change the battery in the alarm unit every 2 days. However, the battery was changed on the third day and the sixth day for subject no. 3. Therefore, three episodes of urinary incontinence were not detected in this subject.

Unfortunately, we received no detailed report from the care staff for the remaining three episodes where the warning system failed to detect urinary incontinence.

# 5. Discussion

The warning system that we developed correctly

detected 75.4% of urinary incontinence episodes in the clinical evaluation. We focused on whether the diaper was dry or wet in this paper. As we described in the section '4.1 Results of Phantom Model', the transmitter was triggered by at least 50 mL of saline. In the clinical evaluation, the minimum volume of voided urine correctly detected by the system was 0.170 kg. We experienced no episode that the sensor system gave false positive warning due to humidity or temperature from the body in the clinical evaluation.

The sensor unit used a coin-type battery, and battery change was needed every two days. When the care staff becomes familiar with the warning system, the battery problem might be reduced. The detection rate is nearly 80% if the battery problem is excluded. Incorrect sensor position is an issue of the warning system. To improve the detection rate, the position of the electrodes has to be investigated.

In this study, the sensor was evaluated in bedridden subjects. If this sensor is used in active care receivers instead of bedridden subjects, the influence of the sensor output by body movement has to be reduced. The electrodes were attached to the outside of the pad-type diaper using medical adhesive tape in this study. In the future, the attachment technique should be improved to maintain the ideal shape of the electrodes during clinical use.

The frequency of urinary incontinence in elderly patients has been evaluated using sensor systems [8, 9]. In these studies, a new sensor has to be attached to a diaper during every change. However, in care facilities where diaper changing is needed in the care of elderly people, the care staff dislikes the task of installing a sensor in the diaper. The warning system that we developed detects urinary incontinence from the outside of a diaper, and the electrodes stay dry and clean even after urinary incontinence. The pant-type diaper is exchanged once a day. Care staff can obtain information on the status of urinary incontinence by attaching the sensor to the outside of a pant-type diaper once a day. In our next study, we shall develop a warning system that detects urinary incontinence from the outside of a pant-type diaper, by modifying the shape of the electrodes and improving the sensing of capacitance changes.

### 6. Conclusion

A warning system for detecting urinary incontinence from the outside of a diaper was developed to provide high-quality care. The impedance of the pad-type diaper decreased from 270 k $\Omega$  to 86 k $\Omega$  after saline was introduced into the diaper. The detection rate of the status of urinary incontinence in a clinical evaluation was 75.4% .

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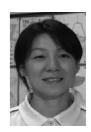
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