# Portable Cystometry System based on Personal Digital Assistance Device

C. G. Song , K. S. Kim, and J. H. Seo

*Abstract*—**Conventional voiding cystometry involves artificially filling the bladder with saline and reproduces their symptoms, while making precise measurements in order to identify their underlying causes. However, it is difficult to evaluate physiological functions during storage and voiding of the bladder. In this study, we constructed a portable cystometry device based on personal digital assistance (PDA) device and compared its clinical utilities while applying this device to both natural and artificial filling cystometry study. The range of errors of the pressure signals measured our constructed device was less than 1 cmH2O, and the reproducibility of two pressure channels were 2.32±2.97 and 3.67 ±5.31 %, respectively. Also, the clinical assessment of our device showed that the system has the capability to accurately monitor the types of information that contribute to the diagnosis and management of patient**

*Index terms* - ***detrusor overactivity; compliance; personal digital assistance; voiding cystometry***

## I. INTRODUCTION

Voiding cystometry, which is one of the techniques used in urodynamics studies, involves continuous measurements of the relationship between pressure and volume in the bladder, and is used to assess sensations, detrusor activity, bladder capacity and bladder compliance [1]. In conventional artificial filling cystometry (AFC), the bladder is filled with saline at a rate as high as 30 ml/min to assess the bladder function [2]. However, this method has disadvantages. Typically, it is difficult to evaluate the physiological functions of the storage and voiding of the bladder while it is artificially filled with saline [3].

On the other hand, natural filling cystometry (NFC) enables the bladder to fill naturally, resulting from metabolism. Several attempts have been made to assess bladder function in a more natural physiological manner by NFC, in which the pressure is measured while the bladder is distended gradually by the urine secretion of the patient. Webb et al. reported that detrusor instability was detected significantly more frequently in NFC than in AFC, so this finding may have important implications in the diagnosis of incontinence [4]. Rosasio et al. showed that the maximum flow rate and voiding volume in NFC were greater than in AFC, and that bladder outflow obstruction (BOO) was effectively diagnosed by NFC [5].

Radley et al. demonstrated that NFC provides objective evidence of clinically important bladder over-activity in the majority of women with symptoms suggestive of this condition, and the correlation of the symptoms with the findings of ambulatory urodynamics implies that symptomatic diagnosis of bladder over-activity is reliable [6]. Sunjay et al. applied NFC to patients in whom the diagnosis of obstruction was equivocal or no symptoms were detected using AFC, and it was found that NFC confirmed or excluded BOO in over half of these subjects [7]. Suzuki et al. reported that unexpected detrusor hyperactivity was measured using the NFC device, and that the 24-hour NFC system was useful for monitoring the natural status of the bladder in the case of spinal cord injuries [8]. Yeung assessed the feasibility of continuous real-time ambulatory bladder monitoring in infants and young children using a specially developed ambulatory urodynamics data logger with built-in on-line infrared telemetric facilities [9]. They asserted that the infrared telemetry system enabled non-invasive testing in young patients and provided a reliable and effective means of performing continuous real-time NFC. Thiruchelvam et al. determined whether foetal cystometric studies using radio telemetry have the potential to provide continuous monitoring of the fetal bladder pressure in an experimental fetal lamb with BOO [10]. They reported that radio telemetry cystometry enabled long-term monitoring of the experimental foetus, without causing death or morbidity or inhibiting growth, and that this method can discriminate between reproducible patterns of detrusor activity.

Considering the potential of natural filling cystometry and the possible advantages of enabling the patient to be completely mobile during the study, we constructed a portable voiding cystometry device, based on a personal digital assistant (PDA), which enables full ambulatory monitoring of the bladder, abdominal and subtracted detrusor pressure. As a preliminary study, we compared the data recorded using the proposed device with the data obtained using a Dantec Duet® urodynamics unit (Dantec Medical, Denmark) and provided clinical examples of its use in both AFC and NFC.

Manuscript received July 12, 2009. C. G. Song is with Department of Electronic Engineering, Chonbuk National University, Korea (corresponding author to provide phone and fax: 82-63-270-4282; e-mail: song133436@gmail.com).

K. S. Kim is with Department of Electronic Engineering, Chonbuk National University, Korea.(e-mail: keosikis@chonbuk.ac.kr).

J. H. Seo is with Department of Rehabilitation Medicine, Chonbuk University Hospital, Korea (e-mail:vivaseo@chonbuk.ac.kr).

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## II. Constructed NFC Device

The portable cystometry device, constructed by our previous work [11], comprises two disposable catheters for measuring the pressure signals, a sensor module for signal conditioning and a control module to monitor the measured data and analyze the physiological parameters. This device can measure the bladder ($P_{ves}$) and abdominal pressure ($P_{abd}$), surface electromyographic (EMG) signals and detect the leakage of urine. The bladder pressure can be recorded by a micro-tip pressure transducer catheter and the abdominal pressure can be measured by both a conventional rectal catheter and a devised algorithm using EMG and bio-impedance method. Also, the detrusor pressure ($P_{det}$) can be measured by subtracting the bladder pressure from the abdominal pressure. The system design is in accordance with the recommendations of the International Continence Society (ICS) [12].

Figure 1 shows a block diagram of the proposed system. Two catheters monitor the bladder and abdominal pressure, while the surface EMG is measured at the same time using an Ag-AgCl electrode. It is recommended that the urethral catheter be 9 Fr. Gauge or less, and highly soft and flexible, in order to avoid pressure artifacts due to bending [13]. In this study, we used a catheter with a diameter of 8 Fr. (about 2.6 mm).

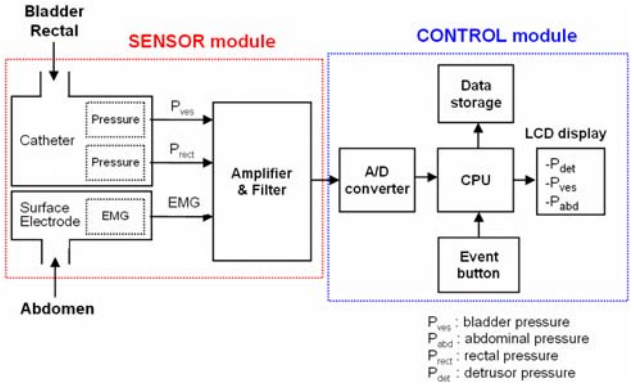


Figure 1. Block diagram of the NFC device Two catheters are connected to the sensor module

The pressure and EMG signals are pre-processed by a signal conditioning circuit in the sensor module. This circuit consists of an instrumentation amplifier and noise filtering circuit. After conditioning, the signals are digitized with an analog-to-digital converter. The data is then transferred to flash memory in the control module and the recorded data is displayed in the LCD panel. The sampling rates of the two types of pressure and EMG signals are 20 and 500 Hz, respectively, and the resolution is 14 bits. This sampling rate and resolution enable more than 24 hours of data to be stored in 256 Mb of storage memory. The total current consumption was about 300 uA. A 5V DC adapter or a portable lithium-ion battery provides the power for the device.

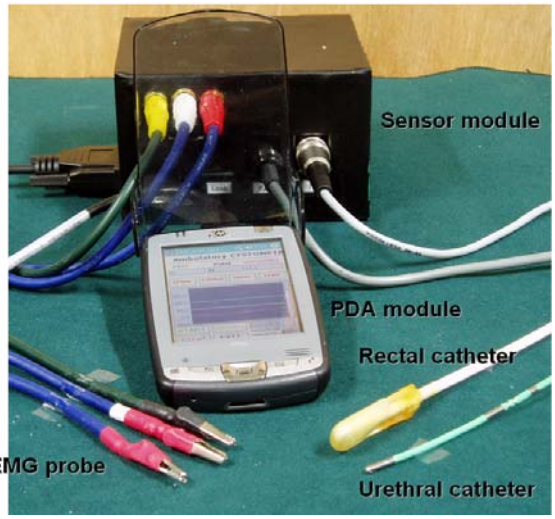


Figure 2. Photograph of the constructed device

This system was capable of monitoring data over a period of about 12 hours, so it is suitable for an NFC study. The size and weight of the system were 10 × 7 × 4 cm and 320 g, respectively, which is sufficient for an NFC study (Figure 2).

At the conclusion of the study, the data is retrieved from the recorder with a standard USB interface and stored on the hard-disk of the host computer (desk-top or lap-top computer) which enables the monitoring of the clinical parameters. All traces are drawn to the same scale, but the bladder and detrusor traces are drawn with offsets equivalent to 50 and 100 $cmH_2O$, respectively, to avoid overlap. The traces are plotted in different colors to facilitate their interpretation.

## III. Quality Test

In order to evaluate the performance of our system, we compared the actual pressure values measured by the pressure calibration kit (DPT9022K0122, Medtronics, U.S.) with the data recorded by our device, as follows;

(1) The tip of the kit water tube was positioned at a height of 0 cm from the ground during 10 seconds.

(2) The differences between the mean values of the pressure signals recorded by Duet® and those recorded by our NFC device were calculated.

(3) After raising the tip to a height of 10 cm, Step (2) was repeated. If the tip is positioned at a height of 10 cm from the ground, this means that a pressure of 10 $cmH_2O$ is exerted on the pressure transducer.

(4) The differences at each pressure level were repeatedly measured until the tip was situated at a height of 100 cm.

Table 1 The mean and Standard Deviation (S.D.) Values of the Pressure Signals Measured using the Constructed Device

| **Real pressure** | | **0** | **10** | **20** | **30** | **40** | **50** |
|---|---|---|---|---|---|---|---|
| **Mean (S.D.)** | **CH 1** | 0.21 (0.54) | 9.38 (1.50) | 19.32 (0.85) | 29.07 (1.58) | 39.39 (0.90) | 50.20 (0.67) |
| | **CH 2** | 1.18 (1.89) | 11.85 (1.20) | 21.13 (0.83) | 31.56 (1.44) | 40.55 (0.67) | 50.58 (0.53) |
| **Real pressure** | | **60** | **70** | **80** | **90** | **100** | **Error** |
| **Mean (S.D.)** | **CH 1** | 59.49 (0.64) | 69.63 (0.58) | 79.48 (0.48) | 89.73 (0.56) | 99.05 (0.34) | 0.83 (0.40) |
| | **CH 2** | 59.59 (0.55) | 69.52 (0.57) | 79.49 (0.59) | 89.73 (0.58) | 98.24 (0.45) | 0.87 (0.46) |

To test reproducibility and reliability, Steps (1) to (4) were repeated 20x. Table 1 shows the mean and standard deviation of the pressure signals obtained from the pressure calibration test. The range of errors of the pressure signals measured using our device was less than 1 $cmH_2O$, and the reproducibility of two pressure channels were 2.32 ± 2.97 and 3.67 ± 5.31 %, respectively. Also, our device could record the pressure and EMG signals and monitor the physiological changes of the detrusor muscle over a period of about 12 hours, thus confirming its suitability in an NFC study according to the recommendation of the ICS.

## IV. Clinical Assessment in Spinal cord Injuried

The study group consisted of 9 patients (5 males and 4 females) diagnosed with spinal cord injury. Their mean age was 51.8±9.5 years. All patients had a neurogenic bladder caused by spinal cord injury. Subjects were excluded from the study if they could not contract their abdominal muscles voluntarily or their bladder capacity was less than 100 ml.

The initial assessment of the constructed system was performed in patients with differing underlying pathological conditions, in order to determine its clinical efficacy. At first, the patients underwent an AFC investigation according to the standard laboratory procedure in accordance with the ICS recommendations. All patients were informed of the aims and progression of the experiment. Voiding cystometry was performed with the patient in the supine position, using saline at body temperature with a filling rate of 30 ml/min. A double-lumen fluid-filled catheter with a diameter of 6 Fr. was introduced transurethrally or suprapubically through the urethra, to fill the bladder, and the bladder pressure was recorded. A balloon catheter was positioned in the rectum, to measure the abdominal pressure. EMG was performed by means of two contact electrodes placed over the left rectus abdominis muscle (2 cm lateral and caudal to the umbilicus) in order to monitor patient's movement. All pressure readings, EMG signals and times were recorded by both a Duet® Urodynamic system (Dantec, Denmark) and our device. EMG signals were immediately converted to RMS and downsized at 20 Hz. During filling, we asked the patient to cough once or twice for every 100 ml, to monitor the correct position of the catheter during the test. The infusion was stopped when there was leakage of urine, or when 500 ml of saline had been infused. All volunteers asked to mention spontaneously the sensory

Table 2 The Characteristics of Patients

| **No.** | **Sex** | **Age** | **ASIA*** | **Lesion#** |
|---|---|---|---|---|
| 1 | M | 50 | D | Incomplete L2 |
| 2 | M | 44 | C | Incomplete C3 |
| 3 | M | 48 | D | Incomplete T10 |
| 4 | M | 65 | D | Incomplete C5 |
| 5 | M | 39 | D | Incomplete T12 |
| 6 | F | 64 | D | Incomplete T3 |
| 7 | F | 56 | D | Incomplete L2 |
| 8 | F | 42 | A | Complete C6 |
| 9 | F | 58 | D | Incomplete T12 |

* ASIA : American spinal injury association
# C : cervical, T : thoracic, L : lumbosacral

pattern consisting of a first sensation (F.S.) of bladder filling, first desired to void (F.D.) and strong desired to void (S.D.) [14]. The F.S. of bladder filling is the feeling the patient has when he/she first becomes aware of the bladder filling. The F.D. is defined as the feeling that would lead the patient to pass urine at the next convenient movement, but voiding can be delayed if necessary. The S.D. is defined as a persistent desired to void without the fear of leakage. The mean study period was 15 minutes 37 seconds and the standard deviation (S.D.) was 3 minutes 2 seconds (The range was 10 minutes to 18 minutes 5 seconds).

Next, NFC studies was performed with the same patient while they stayed at own bed of a ward. The patients were asked to perform a free void before catheterization. After free voiding, the patient took a 0.5 T diuretic in order to reduce the period of the NFC study. Instead of fluid-filled catheter, a micro-tip pressure transducer catheter with a diameter of 8 Fr. was used to record the bladder pressure and detect the leakage of urine, and a rectal catheter was positioned within the rectum in order to record the abdominal pressure. Also, the surface EMG electrodes were attached at the same position with an AFC. The volume of the urine loss during the test was measured using a disposal diaper. The test was stopped when the patient cannot bear to void any more or the fatal symptoms, such as a spasm, sudden stack or a back flow to the kidney, were appeared. The mean study period was 30 minutes 37 seconds (S.D.: ± 12 minutes 25 seconds, range: 49 minutes to 11 minutes). Table 3 shows the comparison of the clinical parameters obtained from AFC study with those from NFC. There was no significant among all clinical parameters ($p$<0.05), but the leakage of urine and detrusor overactivity was detected more frequently in NFC rather than in AFC.

Figure 3 shows examples of the data recorded by both the (a) AFC and (b) NFC of a patient (No. 8 in Table 3) with a normotonic and hypoactive bladder, due to neurogenic bladder and bowel caused by a spinal cord injury. In the artificial filling cystometry, the volume of the first sense (F.S.), first desired to void (F.D.), strong desired to void (S.D.) of urine and total bladder volume was 166 ml (at time 5 minutes 51 seconds), 180 ml (at time 6 minutes 20 seconds), 192 ml (at time 6 minutes 45 seconds) and 200 ml, respectively. Also, the

Table 3 Comparison of the Clinical Parameters obtained from AFC study with those from NFC

| No | F.S. (ml) | | F.D. (ml) | | S.D. (ml) | | Compliance (ml/cm$H_2O$) | | Max. $P_{det}$ (cm$H_2O$) | | Leakage | | D.O. | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *AFC* | *NFC* | *AFC* | *NFC* | *AFC* | *NFC* | *AFC* | *NFC* | *AFC* | *NFC* | *AFC* | *NFC* | *AFC* | *NFC* |
| 1 | 413 | 540 | 500 | 730 | - | 775 | 41.6 | 14.3 | 40 | 25 | + | | | |
| 2 | 244 | 165 | 336 | 170 | 475 | 380 | 23.0 | 25.0 | 83 | 59 | | + | | |
| 3 | 205 | - | - | 220 | - | 465 | 93.0 | 100 | 29 | 28 | | + | | |
| 4 | 379 | 285 | - | - | - | - | 93.0 | 36.7 | 83 | 81 | | + | | |
| 5 | 391 | 300 | 457 | 330 | - | 340 | 22.1 | 4.8 | 33 | 68 | | | | |
| 6 | 214 | 100 | 271 | - | 410 | 140 | 21.4 | 95.0 | 75 | 3 | | | + | |
| 7 | 172 | 45 | 250 | 68 | 386 | - | 84.3 | 14.0 | 23 | 13 | | | | |
| 8 | 166 | 120 | 180 | - | 192 | 175 | 31.8 | 6.1 | 29 | 103 | | + | | + |
| 9 | 355 | 230 | 372 | 450 | 473 | 500 | 88.3 | 62.0 | 49 | 31 | | | | + |
| Mean | 282 | 223 | 338 | 328 | 387 | 396 | 55.4 | 39.8 | 49 | 46 | | | | |
| S.D. | 101 | 156 | 115 | 237 | 116 | 215 | 33.2 | 37.2 | 24 | 34 | | | | |
| *p* | 0.05 | | 0.70 | | 0.27 | | 0.29 | | 0.79 | | | | | |

F.S.: first sensation, F.D.: first desire to void, S.D.: strong desired to void, Max. $P_{det}$: maximum detrusor pressure, D.O.: detrusor overactivity, AFC: artificial-filling cystometry, NFC: natural-filling cystometry

compliance of the bladder was 31.8 ml/cm$H_2O$, and the peak of the detrusor pressure during filling and that during voiding were 12 and 29 cm$H_2O$, respectively, as shown in Table 2. On the other hand, in the natural filling cystometry, the F.S., S.D. and compliance were 120 ml (at time 42 minutes 33 seconds), 175 ml (at time 58 minutes 48 seconds) and 6.1 ml/cm$H_2O$, respectively. Also, leakage of urine was recorded at time 13 minutes 10 seconds (the volume of the leakage was 50 ml) and the bladder volume was 200 ml. The maximum detrusor pressure during filling and that during voiding were 103 and 27 cm$H_2O$, respectively.

## V. Discussions

Urodynamics studies are performed in order to investigate the physiological functions of the detrusor muscle during the voiding and storage of urine; the pressure changes of the bladder and the activity of the detrusor muscle is monitored. However, the conventional method required a surgical operation; thus, the patient suffers a degree of discomfort and pain. Specially, for patients with spinal cord injuries, continuous follow-up monitoring of the bladder function is very important and it must be performed regularly. Various urodynamics devices have been developed, especially for NFC studies, in order to overcome the disadvantages of the AFC and

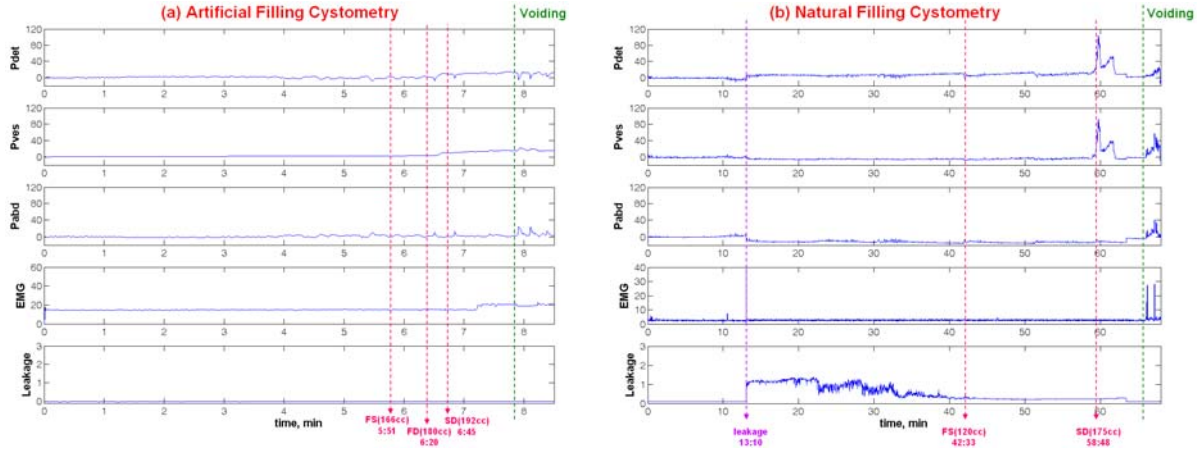


Figure 3 Clinical examples of (a) conventional artificial and (b) natural filling cystometry study of a patient with normotonic and hypoactive bladder ($P_{det}$: detrusor pressure, $P_{ves}$: bladder pressure, $P_{abd}$: abdominal pressure, I.S.: initial sense, F.S.: full sense, U.V.: urge to void)

analyze the physiological functions of the lower urinary tract with much greater accuracy [4-9]. So, in this study, we developed a full NFC system which improves on the conventional AFC device.

The NFC system developed herein has the following advantages over the conventional device; (1) Its size and weight are much smaller than those of the conventional device, and it enables physiological changes of the detrusor muscle and the activity of the abdomen muscle to be monitored over a period of about 12 hours. Therefore, it can be used for ambulatory monitoring. Moreover, voiding cystometry studies can easily be performed in a ward or at home, thus, immobile patients do not need to go to the laboratory and they experience pain reduction. (2) The bladder is allowed to fill naturally and the patient can move freely during the test. Thus, the NFC study is a more natural physiological study than AFC.

The system developed herein provided good quality monitoring and should prove useful in future evaluations of natural filling urodynamics studies. It has the potential to provide reliable monitoring of bladder, rectal and subtracted detrusor pressures during cystometry. The capability of the system to provide good subtraction was assessed by visual inspection. Clinical studies showed that the system is capable of accurately monitoring the types of information that contribute to the diagnosis and management of patients. The sample rate of 20 Hz is sufficient for most clinical investigations, because the rate of change of the bladder pressure is low.

## VI. Conclusion

In this study, we developed a fully portable cystometry device. The results of system quality insurance showed that the proposed system provides good quality monitoring and will prove useful in future evaluations of natural filling urodynamics studies. It provides the potential to achieve reliable monitoring of the bladder, abdominal and subtracted detrusor pressures during cystometry. Clinical studies showed that the system has the capability to accurately monitor the types of information that contribute to the diagnosis and management of patients. In a further study, we will apply the proposed system to patients with various lower urinary tract symptoms, in order to verify its clinical efficacy.

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