Quantification of Nighttime Micturition with an Ambulatory Sensor-Based System

Verena Huppert, Jan Paulus, Ute Paulsen, Martin Burkart, Bernd Wullich, and Bjoern M. Eskofier, *Member, IEEE, EMBS*

***Abstract*—Among elderly males, benign prostate syndrome (BPS) is the most common urinary disorder. Nocturia is one of the major symptoms of BPS and has a considerable influence on quality of life (QoL). For assessment of BPS (including nocturia), the International Prostate Symptom Score (IPSS) is widely used, but questionnaires are prone to bias. To date, there is no objective measurement system available for nocturia. In this study, we present an unobtrusive and non-stigmatizing device for objective measurement of nighttime micturition. In a preliminary study of 6 males diagnosed with BPS and nighttime micturition ≥ 2 times, we showed that the device is accurate, with an average misdetection rate of 0.32 events and a mean absolute deviation of 3.8% when comparing the average number of nighttime micturition occurrences. In this extended study, an additional 9 males were recorded and data from an occupancy sensor were also included. The results of the preliminary study were confirmed with an average misdetection rate of 0.33 events and a mean absolute deviation of 9.1%. The system can therefore be used to objectively measure nighttime micturition, and thereby provide the basis for treatment, e.g., medication efficacy assessment.**

***Index Terms*—benign prostate hyperplasia, nocturia, pattern recognition, wearable sensors.**

I. INTRODUCTION

Nocturia (or nighttime micturition) is defined as the complaint that an individual has to wake at night at least one or more times for voiding [1]. Among elderly males, benign prostate syndrome (BPS) is the most common urinary disorder [2], and nocturia is one of the most important symptoms, with a considerable influence on quality of life (QoL) [3, 4]. Among many other instruments for the quantification of BPS symptoms and complaints, the International Prostate Symptom Score (IPSS) is used most widely [5-10]. Mild symptoms (IPSS <8) can be discriminated from moderate (IPSS 8-19) and severe symptoms (IPSS 20-35). Unfortunately, evaluation with questionnaires is confounded by several error sources. The IPSS is a questionnaire with items rated on Likert scales (from *not at all* to *almost always*). For such questionnaires, it has been shown that the perception of information on the relative frequency of an event varies among subjects [11]. In addition, patients tend to interpret moderate values as normal [12]. More generally, it has been shown that the subjective description of nocturia frequency in the IPSS only poorly agrees with an objective assessment [13]. Furthermore, among elderly men, there might be individuals with undiagnosed early stage dementia. It is a well-known fact that patients suffering from dementia try to hide their disease because they feel stigmatized [14, 15]. They might not ask for additional clarification if they have trouble understanding the questionnaire, which ultimately leads to biased information.

These observations demonstrate the need for an objective, questionnaire-independent, and non-stigmatizing method for quantification of nighttime micturition. To date, there is no objective measurement available for nighttime micturition in a routine clinical or ambulatory setting. A new possible measurement option is the use of wearable automatic, sensor-based systems. Those systems have been used for the assessment of sleep [16], daily life activities [17], Parkinson`s disease [18], and stroke [19]. In this study, we used an unobtrusive and non-stigmatizing device for the objective measurement of nighttime micturition. In a preliminary study [20] with 6 subjects, we showed that the device is accurate, with an average misdetection rate of 0.32 events and a mean absolute deviation of 3.8% when comparing the average number of nighttime micturition. In this study, we use an increased number of subjects (n = 15) and an extended methodology. By developing an automated algorithm, we established a new objective questionnaire-independent method for prospective quantification of nighttime micturition.

II. METHODS

A. Ambulatory Sensor System

An ambulatory system was chosen to be unobtrusive and non-stigmatizing for the patient. Furthermore, it was also necessary that the system require minimal interaction with the patient and that the system could record data for at least 14 consecutive nights (the same period that the IPSS questionnaire measures).

This paper was submitted on 22th of September 2014. Research supported by Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany.

V. Huppert and B. Wullich are with the Dept. of Urology of the University Hospital Erlangen, Krankenhausstrasse 12, 91054 Erlangen, Germany (e-mail: verena.huppert@uk-erlangen.de, bernd.wullich@uk-erlangen.de)

U. Paulsen and M. Burkart are with Dr. Willmar Schwabe GmbH & Co. KG, Bunsenstraße 6-10, 76275 Ettlingen, Germany (e-mail: ute.paulsen@schwabe.de, martin.burkart@schwabe.de). U. Paulsen and M. Burkart contributed to the study by providing assistance with the study design and participant recruitment.

B. M. Eskofier and J. Paulus are with the Digital Sports Group, Pattern Recognition Lab, Department of Computer Science, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany (corresponding author B. M. Eskofier; phone: +49 91318527297; fax: +49 9131303811; e-mail: bjoern.eskofier@fau.de). This project was awarded with the Eugen-Rehfisch-Award of Forum Urodynamicum e.V. 2015.

The sensor system consisted of two components for data collection: a Somnowatch Plus (SW) (Somnomedics GmbH, Randersacker, Germany) worn by the subject (Fig. 1) and a HOBO UX90-005M Room Occupancy/Light Logger (RO) (Fig. 2) (Onset Computer Corporation, Bourne (MA), USA).

Fig. 1. The Somnowatch plus that was worn by study participants. The light sensor (upper left) and the button that can be used to place a marker in the recorded data (center) are also visible.

The SW contains a 12 bit analog/digital converter, a Li-ion battery, 64 MB internal data storage, a tri-axial accelerometer and an ambient light sensor. The SW recorded the summed magnitude of the three-axis accelerometer with a sampling rate of 8 Hz. Additionally it recorded ambient luminance via the light sensor with a sampling interval of 30 s. Both activity and luminance data were provided by an internal algorithm on an arbitrary linear scale between zero and 1000 in steps of one. In addition, the SW contains a button to be used by the subject to place a marker in the data. The participants were asked to use this button to indicate the beginning and end of their bedtimes.

Fig. 2. The HOBO UX90-005M Room Occupancy/Light Logger that was used during the study.

The RO contains a CR2032 Li-Mn-ion battery and a memory capacity of 364 000 measurements. The light threshold ranges over 65 lux. The maximum sensor detection range is 5 m (15.4 ft). The RO recorded room occupancy over the complete recording period with a sampling interval of 10 s. An internal sensor algorithm indicated the proportion of each 10 s interval that the room was occupied. The proportions were given in steps of ten percent. Additionally, it provided information of when the light was turned on or off during each time interval. In this study, only the occupancy data were used.

The complete ambulatory system was retrieved from study participants by the study coordinator after completion of the 14-night recording period. Afterward, the data were downloaded from both components using commercially available software. We used Domino light software (SOMNOmedics) for the watch and HOBOware Lite software (Onset Computer Corporation) for the room occupancy sensor. The extracted .csv files were stored for further processing.

B. Study Details

The ongoing study was performed in compliance with the Declaration of Helsinki and was approved by the Ethical review board of the University Hospital Erlangen, Germany (Re-No. 106_13 B). Participants were recruited by urologists (at the University Hospital Erlangen, the Martha Maria Hospital, Nuremberg, and Forchheim Hospital and by several urologists in private practice) who ensured that all inclusion criteria were met. Informed written consent was obtained from all participants. Inclusion criteria were diagnosed BPS and an average number of nighttime micturitions or two or more.

For documentation of the symptoms prior to measurement, each participant completed the International Prostate Symptom Score (IPSS) questionnaire, including the average number of nighttime toilet visits during the last 14 nights. Furthermore, the documentation included whether additional persons were using the same toilet during the nighttime as well as the duration of treatment with urological medication. Medical treatment of BPS symptoms was initiated / maintained by the treating urologists as needed. Medical treatment comprised the alpha-adrenoceptor antagonists tamsulosin and doxazosin, the 5-alpha reductase inhibitor finasteride, the muscarinic receptor antagonist fesoteridine or the herbal combination drug Prostagutt forte. Prostagutt forte 160/120 mg is a widely used prescription-free phytotherapy containing 160 mg sabal fruit extract WS® 1473 and 120 mg urtica root extract WS® 1031. Prostagutt forte has been demonstrated to significantly reduce nighttime micturition in BPS [21]. The SW and the RO sensor were presented to the participants by a staff member and were placed in an appropriate spot near the toilet. The participants were instructed to wear the SW permanently for the duration of the study. However, after preliminary data analysis, it was considered sufficient that the subject wore the SW only during bed times. The SW and the RO were initialized with the same system time as a study laptop directly before each measurement session. In addition to the ambulatory sensor system, a micturition protocol (MP) for each night was given to the participants. The protocol had to be filled in by the participant, who indicated the particular times they had to urinate during the night. We specifically asked the participants to fill in the protocol as objectively and as soon after waking as possible. The micturition protocol served as the basis for algorithm evaluation.

From the sixteen initially included subjects, data from 15 subjects were used. One individual had to be omitted from the study due to potential interference with his pacemaker implant that could not be completely clarified and because the SW was not worn for all nights. In subject 2, urethritis was diagnosed before night 10 and was treated with antibiotics. Further, subject 2 was manually labeled using only the SW and RO data without MP data because the MP entries were inaccurate.

Subject 4 underwent prostate surgery after 12 nights and therefore aborted the study earlier. The 15 subjects, together with information on their medication, are listed in Table I.

TABLE I. PATIENT CHARACTERISTICS.

		Age	Pre-study nighttime micturition from IPSS	IPSS score	Medication
Participant	**1**	67	2	6	Tamsulosin 0,4 mg
	2	60	3	14	-
	3	76	4	15	Tamsulosin 0,4 mg
	4	66	5	28	Tamsulosin 0,4 mg
	5	67	3	22	Tamsulosin 0,4 mg
	6	57	3	16	Tamsulosin 0,4 mg Prostagutt forte
	7	61	3	11	-
	8	66	5	16	Prostagutt forte
	9	80	3	9	Prostagutt forte
	10	64	3	15	Prostagutt forte
	11	61	3	21	Tamsulosin 0,4 mg
	12	76	4	13	Prostagutt forte
	13	46	4	27	Tamsulosin 0,4 mg
	14	75	3	29	Fesoterodin 4 mg
	15	65	3	19	Doxazosin 4 mg Finasterid 5 mg

TABLE II. NUMBER OF MARKERS THAT WERE MANUALLY PLACED BY THE SUBJECTS TO INDICATE BEDTIME START AND END, COMPARED TO THE NUMBER OF EVALUATED NIGHTS.

		Markers set for bedtime start	Markers set for bedtime end
Participant	**1**	13/14	13/14
	2	0/14	0/14
	3	11/14	11/14
	4	9/12	12/12
	5	14/14	13/14
	6	14/14	14/14
	7	12/14	11/14
	8	14/14	13/14
	9	10/14	9/14
	10	13/14	12/14
	11	14/14	14/14
	12	12/14	14/14
	13	14/14	14/14
	14	14/14	13/14
	15	13/14	14/14

C. Data Processing

Data processing consisted of several steps that are discussed in detail in the following sections. We used MATLAB (The MathWorks, Inc.) software for all data processing. First, the data had to be preprocessed by defining the bedtime period. Second, features were extracted from the bedtime data. Third, the data were manually labeled to train a classifier. Fourth, probabilities for events were calculated by means of classification. Fifth, post processing was applied to eliminate false candidate events. Finally, the ambulatory system and its automated data processing were evaluated for practical usage. Investigations for integration of the SW only and a combined integration of the SW and RO sensor were performed.

Preprocessing: To process bedtime data exclusively, the bedtime beginning and end had to be manually detected. First, the start of bedtime was identified. As described previously, the subjects were asked to use the SW button to place a marker in the data to indicate the start and end of their bedtimes. If a marker was placed manually by the subject, the exact time of this marker was used (see Table II). If no marker was placed, we defined the beginning of bedtime as the start of the first period of at least twenty minutes of activity and luminance values below the empirically defined threshold value of ten. The end of bedtime was identified accordingly. If a marker was placed by the subject, the exact time of the marker was used. If there was no marker placed, we defined the end of bedtime by the start of the first period of at least 60 minutes of activity and luminance values above the threshold value of ten.

Because the SW luminance and activity data were sampled at different sampling rates, the light sensor was linearly interpolated to correspond with the sampling rate of the activity data.

Feature Extraction: Features were calculated on the SW data only. A sliding window of 180 seconds with an overlap of 90 seconds was used on data from each bedtime. Six features were calculated separately on the activity and luminance data in each window: mean value, standard deviation, variance, maximum, energy, and median. Afterward, the features of both data sources were appended to a 12-dimensional feature vector in each window.

Data Labeling: To train the classifier for nighttime micturition, the feature vectors were labeled using the MP, the RO, and the SW data. To improve the accuracy, all three data sources were combined. The documented time points in the MP were not precise in the range of minutes or seconds and had deviations of several minutes from the time of the actual micturition event. The data from the room occupancy sensor could be biased by other persons entering the bathroom. The SW data could display unrelated activities for several reasons (e.g., fitful sleep or leaving the bed for reasons other than to urinate). First, the data of the room occupancy sensor were analyzed. Candidate nighttime micturition events were identified if the room occupancy sensor detected occupancy values above 10% in a sliding window of 60 second length. Second, the time code of these candidate events was compared with the activity and luminance data of the SW. If activity and luminance values higher than the selected threshold of ten were detected within the same time frame and the subject noted a micturition event in the MP within 30 minutes around the candidate event, the candidate event was defined as a nighttime micturition. Third, for a more detailed analysis, the start and end of a defined toilet visit were identified. The first instant of activity values above ten after a period of 10 s of consecutive activity values below ten was defined as the start of the toilet visit. Analogously, the last instant of activity values above ten before a period of 10 s of consecutive activity values below ten was defined as the end of the toilet visit (Fig. 3). The feature vectors were labeled accordingly.

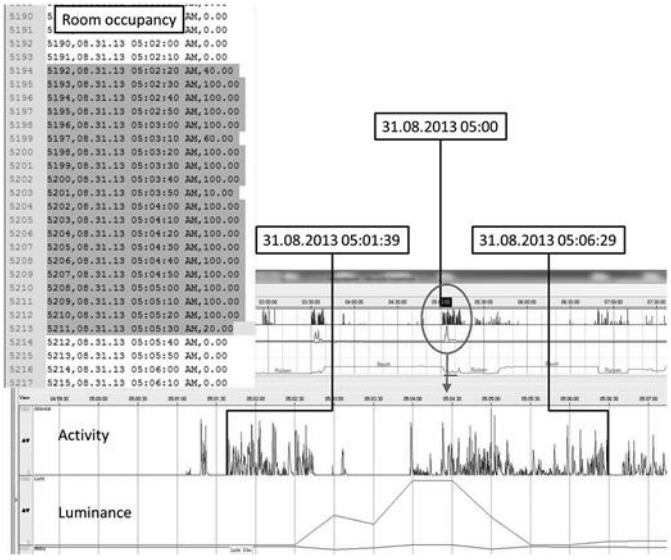

Fig. 3. Example of a nighttime micturition. The participant noted a micturition at 05:05:00. The room occupancy data (upper left part) identifies a time slot between 05:02:20 and 05:05:30. Connected activity clusters in the watch data (lower central part) around this time slot with a luminance change within this time slot yield to a labeling between 05:01:39 and 05:06:29.

Classification: All feature vectors from one night were used for classification. As there were only few feature vectors that actually represented a micturition event, a statistical classifier, Linear Discriminant Analysis (LDA), was selected that allowed the adjustment of prior probabilities.

Post-Processing: As mentioned above, the SW data could contain other activities apart from a micturition event for several reasons. In effect, it could be classified only if a subject performed activities that were more intense than calmly lying in bed. Therefore, post-processing was applied, with the assumptions that there should not be two micturition events within 40 minutes and that there should not be a micturition event within 20 minutes after bedtime start. First, the probabilities of an event occurring within 20 minutes after bedtime start are set to zero. Second, a sliding window of 60 minutes with an overlap of 30 minutes was applied to the classified probabilities for each night. All probabilities within the window that were different from the local maximum probability of the window were set to zero. Third, the global maximum probability in the post-processed night data were identified. All probabilities that were 40 minutes before and after this maximum were set to zero. This was repeated for the next highest probabilities in the processed night data until the remaining candidate events had a temporal offset of at least 40 minutes. Fourth, candidate events were counted as a nighttime micturition if their probabilities were above the empirical threshold of 0.8. The procedure was intended to prevent consecutive activities after micturition (e.g., fitful sleep) to be counted as an additional event.

Evaluation: The results of the automatic data processing described above were compared with the curated reference data obtained by manual data labeling. The evaluation strategy was a Leave-one-subject-out cross-validation. In each iteration, one subject was selected as a test subject. The classifier was trained with the feature vectors of all other subjects. Prior probabilities for the LDA classifier for each test subject were obtained by computing the relative frequencies of feature vectors for "micturition" of the training subjects compared to their feature vectors that did not represent a micturition. Feature vectors that were 20 minutes before and after a toilet visit were not used for training as they represented high activity but were not captured by the RO sensor. However, for testing, all feature vectors were included. Two evaluation strategies were performed to quantify the accuracy of the automatic data processing:

1. The first strategy exclusively considered the data collected by the SW and the resulting classifications and post-processing results. It was assumed that in a practical application, the subject would only wear the SW and that the RO sensor would not be used to reduce hardware requirements. Consequently, the data from the RO sensor were used only for manual data labeling for the curated reference data as described above. Therefore, the automatic data processing processed only feature vectors based on the SW data including classification and post-processing.

2. The second strategy considered both the data returned by the SW and the RO data. It was assumed that in a practical application, the subject would wear the SW and that the RO sensor would be used as an additional data source. Consequently, the automatic data processing included the comparison of classified "micturition" events with the RO data. Therefore, activities outside the range of the RO sensor could be eliminated.

III. Results

Table III shows the number of sensor-detected micturitions (SW data only, evaluation strategy 1) for each night and each participant compared with entries in the micturition protocols.

Table IV shows the number of false detections (SW data only, evaluation strategy 1) that were not labeled as micturition events in the ground truth data. Note that a correct detection of a micturition event (e.g., the way to the toilet) will also be listed as a false detection here if the detection is not exactly located during the labeled toilet visit. The average number of false detections per night, according to the above definition, was 6.06 without post-processing and 0.80 with post-processing.

Table V shows the number of sensor-detected micturition (SW data and RO data, evaluation strategy 2) for each night and each participant compared with entries in the micturition protocols.

Table VI shows the number of false detections (SW data and RO data, evaluation strategy 2) that were not labeled as micturition events in the ground truth data. Again, correct detections will be listed as false detections if the time of the detections does not match the labeled events exactly. The average number of false detections per night, according to the above-given definition, was 0.99 without post-processing and 0.25 with post-processing.

TABLE III. NUMBER OF NIGHTTIME MICTURITIONS AS ENTERED IN THE PROTOCOL (LEFT NUMBER) AND SIGNED DEVIATION AS DETECTED BY THE AMBULATORY SENSOR SYSTEM (RIGHT NUMBER) USING EVALUATION STRATEGY 1.

		Participant number														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Night number	**1**	2±0	1±0	5±0	5±0	3+1	4±0	1+1	5-1	2+1	2±0	2-1	4-1	3-1	3±0	3±0
	2	1±0	1+1	3±0	5±0	3±0	2+1	2±0	3±0	1±0	2±0	2±0	4±0	3±0	3±0	2±0
	3	1±0	1±0	4±0	5-1	2+1	3-1	2±0	4+1	2±0	2±0	3+2	5±0	4-1	3±0	3±0
	4	2+1	2+1	5±0	6+2	3±0	2+1	2+2	3±0	2±0	2+1	2+2	4+1	4-1	3±0	2±0
	5	1±0	1+1	4±0	6±0	2±0	3+1	1+1	3±0	1±0	2±0	1±0	5+1	3-2	2+1	3-1
	6	2±0	3±0	4±0	5+1	2±0	4+1	2±0	3±0	1±0	2+1	2+2	5+1	3±0	2±0	3±0
	7	0±0	1+3	7±0	3+1	2+1	3-1	0±0	4+1	2±0	2±0	2+1	4+1	3-1	3±0	3+1
	8	2±0	2+2	6±0	3+1	2+1	2±0	2+1	4+1	1±0	2+1	1±0	4+1	3-1	3±0	3±0
	9	1+2	3±0	4±0	5+1	2+1	3±0	2±0	3+1	1±0	2±0	2+1	5+1	3+1	4-1	3±0
	10	1±0	0+2	5±0	3+1	2±0	3+1	3+1	3±0	1±0	2±0	1+2	4+1	4±0	3±0	2-1
	11	0±0	2+2	7-1	6±0	2±0	1±0	2+1	3±0	1+2	2+1	2±0	5±0	2-1	2+1	3+1
	12	2±0	1±0	4±0	4-1	2±0	3±0	3+1	2±0	0+1	2±0	1+1	3+1	4-1	2±0	2±0
	13	2+1	1±0	6-1	-	3+1	2±0	3±0	5-1	1±0	2±0	2-1	5±0	4±0	3±0	3±0
	14	0±0	1+4	3±0	-	2±0	3±0	2±0	4±0	1±0	2±0	1-1	4+1	3-2	2±0	3±0

TABLE IV. NUMBER OF FEATURE VECTORS THAT HAVE BEEN ASSIGNED BY THE CLASSIFIER TO A MICTURITION EVENT BUT WERE NOT LABELED AS A MICTURITION EVENT WITH AND WITHOUT POST-PROCESSING (PP) USING EVALUATION STRATEGY 1.

		Participant number														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
False positives	**Without PP**	18	147	95	196	68	37	161	75	48	69	67	162	16	75	38
	With PP	4	17	1	32	19	3	21	20	5	5	14	15	2	8	3

TABLE V. NUMBER OF NIGHTTIME MICTURITIONS AS ENTERED IN THE PROTOCOL (LEFT NUMBER) AND SIGNED DEVIATION AS DETECTED BY THE AMBULATORY SENSOR SYSTEM (RIGHT NUMBER) USING EVALUATION STRATEGY 2.

		Participant number														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Night number	**1**	2±0	1±0	5±0	5±0	3±0	4±0	1+1	5-1	2±0	2±0	2-1	4-1	3-1	3±0	3±0
	2	1±0	1±0	3±0	5±0	3±0	2+1	2±0	3±0	1±0	2±0	2±0	4-1	3±0	3±0	2±0
	3	1±0	1±0	4±0	5-1	2+1	3-1	2±0	4±0	2±0	2±0	3±0	5-1	4-1	3±0	3±0
	4	2+1	2±0	5±0	6-1	3-1	2+1	2+2	3±0	2±0	2±0	2+1	4±0	4-2	3±0	2±0
	5	1±0	1±0	4±0	6±0	2±0	3+1	1+1	3±0	1±0	2±0	1±0	5±0	3-2	2±0	3-1
	6	2±0	3±0	4±0	5±0	2±0	4±0	2±0	3±0	1±0	2+1	2±0	5±0	3±0	2±0	3±0
	7	0±0	1+1	7±0	3+1	2+1	3-1	0±0	4+1	2±0	2±0	2±0	4±0	3-1	3-1	3+1
	8	2±0	2±0	6±0	3±0	2+1	2±0	2+1	4+1	1±0	2±0	1±0	4±0	3-1	3±0	3±0
	9	1+2	3±0	4±0	5±0	2+1	3±0	2±0	3±0	1±0	2±0	2±0	5±0	3±0	4-1	3±0
	10	1±0	0±0	5±0	3±0	2±0	3+1	3+1	3±0	1±0	2±0	1±0	4-1	4±0	3±0	2-1
	11	0±0	2±0	7-1	6±0	2±0	1±0	2+1	3±0	1+1	2±0	2±0	5+1	2-1	2±0	3+1
	12	2±0	1±0	4±0	4-1	2±0	3±0	3±0	2±0	0+1	2±0	1+1	3+1	4-1	2±0	2±0
	13	2+1	1±0	6-1	-	3+1	2±0	3±0	5-1	1±0	2±0	2-1	5-1	4±0	3±0	3±0
	14	0±0	1±0	3±0	-	2±0	3±0	2±0	4±0	1±0	2±0	1-1	4±0	3-2	2±0	3±0

TABLE VI. NUMBER OF FEATURE VECTORS THAT HAVE BEEN ASSIGNED BY THE CLASSIFIER TO A MICTURITION EVENT BUT WERE NOT LABELED AS A MICTURITION EVENT WITH AND WITHOUT POST-PROCESSING (PP) USING EVALUATION STRATEGY 2.

		Participant number														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
False-positives	**Without PP**	16	6	4	26	18	13	67	7	2	3	5	20	0	6	14
	With PP	4	2	0	5	6	5	16	3	2	1	2	3	0	1	2

Table VII shows the mean absolute deviation (MAD) of the number of sensor-detected micturition for each participant compared with entries in the micturition protocols. MAD 1 shows the deviation for the SW data (evaluation strategy 1). Additionally, MAD 2 includes the RO sensor data (evaluation strategy 2). The mean absolute deviation over all participants and all nights was 0.53 in MAD 1 and 0.33 in MAD 2.

TABLE VII. MEAN ABSOLUTE DEVIATION (MAD 1) OF THE NUMBER OF NIGHTTIME MICTURITIONS AS DETECTED BY THE AMBULATORY SENSOR SYSTEM IN ABSOLUTE NUMBERS AND PERCENTAGE OF CORRECT MICTURITIONS. MAD 1 REPRESENTS EVALUATION STRATEGY 1, MAD 2 REPRESENTS EVALUATION STRATEGY 2.

		MAD 1	MAD 2
Participants	**1**	0.29 (23.53%)	0.29 (23.53%)
	2	1.14 (80.00%)	0.07 (5.00%)
	3	0.14 (3.13%)	0.33 (3.13%)
	4	0.75 (13.78%)	0.28 (6.12%)
	5	0.43 (18.75%)	0.43 (18.75%)
	6	0.50 (18.42%)	0.43 (18.79%)
	7	0.57 (29.63%)	0.50 (25.93%)
	8	0.43 (12.25%)	0.29 (8.16%)
	9	0.29 (23.53%)	0.14 (11.76%)
	10	0.29 (14.29%)	0.07 (3.57%)
	11	1.00 (58.33%)	0.36 (20.83%)
	12	0.71 (16.39%)	0.43 (9.84%)
	13	0.86 (26.09%)	0.86 (26.09%)
	14	0.21 (7.89%)	0.14 (5.26%)
	15	0.29 (10.53%)	0.29 (10.53%)

Table VIII shows the average number of nighttime micturitions as entered in the protocol (ANP) and as detected by the sensor system (ANS), and the deviation between the values (DEV). ANS 1 and DEV 1 represent the SW data (Evaluation strategy 1). ANS 2 and DEV 2 represent the SW data including the RO data (Evaluation strategy 2). The mean absolute value of all deviations was 19.0% for DEV 1 and 9.1% for DEV 2.

TABLE VIII. AVERAGE NUMBER OF NIGHTTIME MICTURITIONS AS ENTERED IN THE PROTOCOL (ANP), AVERAGE NUMBER OF NIGHTTIME MICTURITIONS AS DETECTED BY THE AMBULATORY SENSOR SYSTEM USING EVALUATION STRATEGY 1 (ANS 1), AND DEVIATION (DEV 1) BETWEEN THE TWO VALUES. ANS 2 AND DEV 2 REPRESENT THE DATA USING EVALUATION STRATEGY 2.

		ANP	ANS 1	ANS 2	DEV 1	DEV 2
Participants	**1**	1.21	1.50	1.50	0.29 (23.53%)	0.29 (23.53%)
	2	1.43	2.57	1.50	1.14 (80.00%)	0.07 (5.00%)
	3	4.57	4.43	4.43	-0.14 (-3.13%)	-0.14 (-3.13%)
	4	4.67	5.08	4.50	0.42 (8.93%)	-0.17 (-3.57%)
	5	2.29	2.71	2.57	0.43 (18.75%)	0.29 (12.50%)
	6	2.71	2.93	2.86	0.21 (7.89%)	0.14 (5.26%)
	7	1.93	2.50	2.42	0.57 (29.63%)	0.50 (25.93%)
	8	3.50	3.64	3.50	0.14 (4.08%)	0.00 (0.00%)
	9	1.21	1.50	1.36	0.29 (23.53%)	0.14 (11.76%)
	10	2.00	2.29	2.07	0.29 (14.29%)	0.07 (3.57%)
	11	1.71	2.29	1.64	0.57 (33.33%)	-0.07 (-4.17%)
	12	4.36	4.93	4.07	0.57 (13.11%)	-0.29 (-6.56%)
	13	3.29	2.57	2.43	-0.71 (-21.74%)	-0.86 (-26.09%)
	14	2.71	2.79	2.57	0.07 (2.63%)	-0.14 (-5.26%)
	15	2.71	2.71	2.71	0.00 (0.00%)	0.00 (0.00%)

Table IX shows the number of pre-study nighttime micturitions as entered in the IPSS questionnaire compared to the average number of nighttime micturitions as detected by the ambulatory sensor system (ANS 2) with the deviation between the two groups (DEV 1). Additionally, it shows the number of pre-study nighttime micturitions as entered in the IPSS questionnaire compared to the number of nighttime micturitions as entered in the protocol (ANP) and the deviation between the two groups (DEV 2).

TABLE IX. NUMBER OF PRE-STUDY NIGHTTIME MICTURITIONS AS ENTERED IN THE IPSS QUESTIONNAIRE COMPARED TO THE AVERAGE NUMBER OF NIGHTTIME MICTURITIONS AS DETECTED BY THE AMBULATORY SENSOR SYSTEM (ANS 2) USING EVALUATION STRATEGY 2 WITH THE DEVIATION BETWEEN THE TWO GROUPS (DEV 1). NUMBER OF PRE-STUDY NIGHTTIME MICTURITIONS AS ENTERED IN THE IPSS QUESTIONNAIRE COMPARED TO THE NUMBER OF NIGHTTIME MICTURITIONS AS ENTERED IN THE PROTOCOL (ANP) AND THE DEVIATION BETWEEN THE TWO GROUPS (DEV 2).

		Pre-study nighttime micturitions from IPSS	ANS 2	DEV 1	ANP	DEV 2
Participants	**1**	2	1.50	0.50	1.21	0.79
	2	3	1.50	1.50	1.43	1.57
	3	4	4.43	-0.43	4.57	-0.57
	4	5	4.50	0.50	4.67	0.33
	5	3	2.57	0.43	2.29	0.71
	6	3	2.86	0.14	2.71	0.29
	7	3	2.42	0.58	1.93	1.07
	8	5	3.50	1.50	3.50	1.50
	9	3	1.36	1.64	1.21	1.79
	10	3	2.07	0.93	2.00	1.00
	11	3	1.64	1.36	1.71	1.29
	12	4	4.07	0.07	4.36	-0.36
	13	4	2.43	1.57	3.29	0.71
	14	3	2.57	0.43	2.71	0.29
	15	3	2.71	0.29	2.71	0.29

IV. DISCUSSION

In this report, we propose a sensor-based system for ambulatory quantification of nighttime micturition frequency. Two different evaluation strategies were pursued. The first strategy exclusively considered the data returned by the SW and the resulting classifications and post-processing, whereas the second strategy considered the data returned both by the SW and the RO. The results showed that the second strategy obtains more accurate results, with an average misdetection rate of 0.33 events (vs. 0.53 in strategy 1) and a mean absolute deviation of 9.1% (vs. 19.0% in strategy 1) when comparing the average number of nighttime micturition. Hence, we suggest that the second strategy is currently the more

elaborated strategy although an additional hardware component (RO sensor) has to be used.

Regarding the first strategy without an additional RO sensor, the automated algorithm showed reliable quantification of the average number of nighttime toilet visits for most of the participants. However, the detection of nighttime toilet visits for each individual night showed higher errors. One possible reason behind this is the insufficient information returned from the SW as activity data. Because only the magnitude of acceleration is returned from the device, spatial information is lost. Therefore, specific classification of a certain activity was not possible. Only the "strength" of an activity was classified, which led to misclassifications in several cases. This can be observed, for example, in the case of participants getting up during the night without visiting the toilet or in the case of participants writhing in bed restlessly. The writhing of participants occurred mainly during sleep onset and recovery. Further, many subjects labeled the first toilet visit after the end of bedtime as a nighttime toilet visit. Therefore, toilet visits or getting up without visiting the toilet could not be discriminated accurately enough. To overcome the difficulties during sleep onset, the first 20 minutes were assumed to not contain nighttime toilet visits in general, which means the probabilities for a toilet visit were set to zero for all participants and all nights. If a subject was a restless sleeper, toilet visits could hardly be discriminated from other activity. The incorporation of the RO sensor data could improve the performance of the algorithm by setting probabilities for a nighttime toilet visit to zero if the RO sensor did not show any occupancy (Table VII, VIII). However, even under these conditions, misclassifications were possible. For example, if a life partner`s toilet visit occurred simultaneously to a restlessly moving participant in bed. Additionally, pets could potentially activate the RO sensor while participants were writhing in bed. Therefore, the incorporation of RO sensor data could not avoid the detection of every false-positive event. Additionally, technical limitations of the RO sensor made it impossible to identify a nighttime toilet visit accurately if the life partner visited the toilet almost simultaneously. The additional incorporation of the RO sensor's luminance data, which could, for example, help discriminate pets from humans, exhibits a possible improvement opportunity.

The need for a micturition protocol is the unavoidable limitation of the study. However, it has to be noted that the micturition protocol was not used to detect micturition but only served as a reference value for data labeling. The three data sources (MP, SW and RO senor) were used to label our data for building a ground truth. The resulting labels were solely used for training the classifier. No MP data were used to classify unknown data. The classifier did not use any labels or other information other than the sensor data for testing. Therefore, in practical use, no MP is required after the classifier is trained. However, even the ground truth data may be biased by well-established limitations of questionnaires such as lacking compliance, embarrassment and subjective bias. Specifically, some of the misdetections shown in Table III and V could potentially be errors in the self-report. However, application of a micturition protocol was the only available instrument for providing ground truth information. Alternatively, to be independent of the participants' memory, we considered using a mobile app or a stop watch instead of a micturition protocol. However, in Germany, most elderly people do not have smartphones or they have difficulty handling smartphones. Furthermore, both a mobile app and a stop watch would be additional devices and would represent an additional task for the participants. We chose the micturition protocol directly after getting up because filling in a protocol after bedtime is clearly a separate process from pressing the start/stop button on the SW in the evening and morning. From our point of view, an additional device during the nighttime would lead to bias by e.g., mistakenly pressing the SW button during the night instead of indicating a toilet visit.

In this context, comparing the nighttime micturition frequency from the IPSS with the average number of nighttime micturitions entered in the micturition protocol (Table IX, DEV 2) shows interesting results. By excluding the 5 participants taking Prostagutt forte to avoid bias (see the penultimate paragraph), there is an average deviation of 0.76 events between the IPSS data and the MP data. Nine of 10 participants showed higher values in the IPSS questionnaire, which could exhibit a slight overestimation in the IPSS. We assume that the choice of a daily micturition protocol provides more precise results because the MP is completed very soon after waking, which means that the retrospection is less biased than the IPSS. We therefore believe that the MP is the more reliable source of ground truth information.

According to Table VIII, the SW system provides accurate quantities of nighttime micturition compared to the MP. Eventually, it may appear questionable whether there is a substantial need for such a system if the written MP gives equivalent results without the use of technology. It has to be mentioned that the MP is a questionnaire which is generally not used in a routine setting. Because compliance with completing daily questionnaires is generally lower, particularly over a longer period of time, and the IPSS includes more information than only nocturia data, the standardized IPSS is preferred by physicians. However, as we mentioned in the previous paragraph, the IPSS may be more biased as a result of retrospection. The SW appears to be the appropriate solution for both retrospection bias and lack of compliance. Once the algorithm for the SW is established, it is independent from any questionnaire, i.e., the data are now collected prospectively. Furthermore, with the SW, the interaction with the patient is minimized, unobtrusive, and non-stigmatizing. We therefore believe that the SW system will make participants willing to take part in future studies on, e.g., medication assessment as well as in a routine clinical assessment for longer periods of time.

Finally, we also included a pilot study to show that the Somnowatch system is actually applicable for the assessment of medication success (see Table X, Appendix). Five of the 15 participants were treated with Prostagutt forte, which has been demonstrated to significantly reduce nighttime micturition in BPS [21]. We could show that the trend in nighttime micturition frequency is toward less frequent toilet visits in 4 of 5 (80%) participants after starting Prostagutt forte intake.

In summary, the proposed system is unobtrusive, non-stigmatizing, and works with minimal interaction from the

patient. We showed that the system provides accurate quantities of nighttime micturition and that the application in an ambulatory assessment of nocturia is feasible. The system has the potential to deliver accurate and objective values for defining treatment and measuring therapeutic and medication success in nocturia in an appropriate study design.

ACKNOWLEDGMENT

We thank all of the participants in our study. We also thank the urologists who provided access to the patients: Drs. E. Eder, D. Elsässer, T. Henschel, R. Kühn, and T. Rith.

REFERENCES

[1] P. van Kerrebroeck, P. Abrams, D. Chaikin, J. Donovan, D. Fonda, S. Jackson, *et al.*, "The standardisation of terminology in nocturia: report from the Standardisation Sub-committee of the International Continence Society," *Neurourol Urodyn*, vol. 21, pp. 179-83, 2002.

[2] V. L. Kumar and S. Dewan, "Alpha adrenergic blockers in the treatment of benign hyperplasia of the prostate," *Int Urol Nephrol*, vol. 32, pp. 67-71, 2000.

[3] E. D. Miranda, C. M. Gomes, F. C. Torricelli, J. J. de Bessa, J. E. de Castro, B. R. Ferreira, *et al.*, "Nocturia is the Lower Urinary Tract Symptom With Greatest Impact on Quality of Life of Men From a Community Setting," *Int Neurourol J*, vol. 18, pp. 86-90, Jun 2014.

[4] C. J. Girman, R. S. Epstein, S. J. Jacobsen, H. A. Guess, L. A. Panser, J. E. Oesterling, *et al.*, "Natural history of prostatism: impact of urinary symptoms on quality of life in 2115 randomly selected community men," *Urology*, vol. 44, pp. 825-31, Dec 1994.

[5] P. Abrams, J. G. Blaivas, S. L. Stanton, and J. T. Andersen, "The standardisation of terminology of lower urinary tract function. The International Continence Society Committee on Standardisation of Terminology," *Scand J Urol Nephrol Suppl*, vol. 114, pp. 5-19, 1988.

[6] P. Abrams, "New words for old: lower urinary tract symptoms for "prostatism"," *BMJ*, vol. 308, pp. 929-30, Apr 9 1994.

[7] P. Van Kerrebroeck, P. Abrams, D. Chaikin, J. Donovan, D. Fonda, S. Jackson, *et al.*, "The standardization of terminology in nocturia: report from the standardization subcommittee of the International Continence Society," *BJU Int*, vol. 90 Suppl 3, pp. 11-5, Dec 2002.

[8] J. L. Bosch, W. C. Hop, W. J. Kirkels, and F. H. Schroder, "The International Prostate Symptom Score in a community-based sample of men between 55 and 74 years of age: prevalence and correlation of symptoms with age, prostate volume, flow rate and residual urine volume," *Br J Urol*, vol. 75, pp. 622-30, May 1995.

[9] S. Madersbacher, G. Alivizatos, J. Nordling, C. R. Sanz, M. Emberton, and J. J. de la Rosette, "EAU 2004 guidelines on assessment, therapy and follow-up of men with lower urinary tract symptoms suggestive of benign prostatic obstruction (BPH guidelines)," *Eur Urol*, vol. 46, pp. 547-54, Nov 2004.

[10] C. G. Roehrborn, J. D. McConnell, B. Saltzman, D. Bergner, T. Gray, P. Narayan, *et al.*, "Storage (irritative) and voiding (obstructive) symptoms as predictors of benign prostatic hyperplasia progression and related outcomes," *Eur Urol*, vol. 42, pp. 1-6, Jul 2002.

[11] B. Rohrmann, "Empirische Studien zur Entwicklung von Antwortskalen für die sozialwissenschaftliche Forschung.," *Zeitschrift für Sozialpsychologie*, vol. 9, pp. 222-245, 1978.

[12] N. Schwarz, B. Scheuring, "Selbstberichtete Verhaltens- und Symptomhäufigkeiten: Was Befragte aus Antwortvorgaben des Fragebogens lernen.," *Zeitschrift für klinische Psychologie*, vol. 21, pp. 197-208, 1992.

[13] J. H. Ku, S. K. Hong, H. H. Kim, J. S. Paick, S. E. Lee, and S. J. Oh, "Is questionnaire enough to assess number of nocturic episodes? Prospective comparative study between data from questionnaire and frequency-volume charts," *Urology*, vol. 64, pp. 966-9, Nov 2004.

[14] S. C. Burgener, K. Buckwalter, Y. Perkhounkova, M. F. Liu, R. Riley, C. J. Einhorn, *et al.*, "Perceived stigma in persons with early-stage dementia: Longitudinal findings: Part 1," *Dementia (London)*, Dec 2 2013.

[15] S. C. Burgener, K. Buckwalter, Y. Perkhounkova, and M. F. Liu, "The effects of perceived stigma on quality of life outcomes in persons with early-stage dementia: Longitudinal findings: Part 2," *Dementia (London)*, Dec 2 2013.

[16] S. Gradl, H. Leutheuser, P. Kugler, T. Biermann, S. Kreil, J. Kornhuber, *et al.*, "Somnography using unobtrusive motion sensors and Android-based mobile phones," *Conf Proc IEEE Eng Med Biol Soc*, vol. 2013, pp. 1182-5, 2013.

[17] H. Leutheuser, D. Schuldhaus, and B. M. Eskofier, "Hierarchical, multi-sensor based classification of daily life activities: comparison with state-of-the-art algorithms using a benchmark dataset," *PLoS One*, vol. 8, p. e75196, 2013.

[18] P. Kugler, C. Jaremenko, J. Schlachetzki, J. Winkler, J. Klucken, and B. Eskofier, "Automatic recognition of Parkinson's disease using surface electromyography during standardized gait tests," *Conf Proc IEEE Eng Med Biol Soc*, vol. 2013, pp. 5781-4, 2013.

[19] S. Patel, R. Hughes, T. Hester, J. Stein, M. Akay, J. Dy, *et al.*, "Tracking motor recovery in stroke survivors undergoing rehabilitation using wearable technology," *Conf Proc IEEE Eng Med Biol Soc*, vol. 2010, pp. 6858-61, 2010.

[20] B. M. Eskofier, J. Paulus, U. Paulsen, M. Burkart, B. Wullich, and V. Huppert, "An Ambulatory Sensor-Based System for Quantification of Nighttime Micturition for Accurate Nocturia Assessment.," presented at the Ann. Int. Conf. of the IEEE Engineering in Medicine and Biology Society, Chicago, 2014, accepted for publication.

[21] M. Oelke, R. Berges, S. Schlafke, and M. Burkart, "Fixed-dose combination PRO 160/120 of sabal and urtica extracts improves nocturia in men with LUTS suggestive of BPH: re-evaluation of four controlled clinical studies," *World J Urol*, Jun 18 2014.

APPENDIX

TABLE X. AVERAGE NUMBER OF NIGHTTIME MICTURITIONS BEFORE (PROSTAGUTT-) AND AFTER (PROSTAGUTT+) MEDICATION WITH PROSTAGUTT FORTE.

		Prostagutt-	Prostagutt +	Starting day of Prostagutt forte intake
Participants	**6**	2.8	2.5	6
	8	4.0	3.4	3
	9	3.0	1.2	1
	10	3.0	2.0	2
	12	4.0	4.4	1