





Enhancing Men's Health Management at Home with an Easy-to-Use, App-Connected Prostate Self-Testing Device

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Abstract: A fundamental problem in men's health is that large groups of men shy away from visiting the doctor, and specifically, often do not take part in early screening tests if they do not have complaints yet. This is particularly evident in the sensitive field of urology. Benign prostatic hyperplasia (BPH) is one of the most widespread disorders in ageing men and is associated with an increasing burden on healthcare systems. It is often underdiagnosed and undertreated and has a substantial impact on the patients' quality of life. An altered urine flow curve can be a first clue to BPH. A new developed, easy-to-use prostate self-testing device based on a Swiss high-precision flowmeter enables men to check their urine flow at home in familiar surroundings. Via a Bluetooth connection, the results can be transmitted wirelessly and stored in a digital diary so that long-term developments can be tracked. The self-testing device not only provides men with the opportunity to deal with their health with low effort and in a discreet way, but also gives them certainty about their prostate health status.

1 INTRODUCTION


Benign prostatic hyperplasia (BPH) is one of the most widespread disorders in ageing men (Madersbacher et al., 2019) and even argued to be one of the most common diseases of mankind (Vuichoud & Loughlin, 2015). It is associated with high medical and societal costs and can have an extremely negative impact on the quality of life of those affected, as they often suffer from symptoms such as nocturia that affect their daily lives and those of their partners. Due to the ageing society, the disorder may become a rising socio-economic challenge. (Speakman et al., 2015)


BPH is characterised by a change in the size of the prostate and is often associated with lower urinary tract symptoms (LUTS), such as urinary incontinence, reduced flow or feeling of incomplete emptying, which then usually lead to medical


consultation (Langan, 2019; Madersbacher et al., 2019).


A challenge is not only the treatment, but also the early detection of changes in the prostate. Despite the distressing symptoms, BPH/LUTS is often underdiagnosed and undertreated (Speakman et al., 2015) as large groups of men shy away from going to the urologist and have insufficient information about their health status (Müller, 2021). During the COVID-19 pandemic this problem has further increased as doctors are visited even less often and screening services are used less (Nossiter et al., 2022). It is therefore all the more important to provide men with an option to assess their urological health status easily at home.

One of the possible diagnostic methods for the detection of prostatic disorders is uroflowmetry, which is non-invasive and by which conditions can be

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detected based on the urine flow curve. With Kormoran11, an innovative, handy prostate self-testing device is developed for practical use in private environment. It is based on a Swiss high-precision flowmeter and is currently expanded to include a Bluetooth-based app connection, which enables the wireless transfer and storage of flow information in a digital diary. The device is developed to give men the opportunity to deal with their own health with a low hurdle at home and to give them orientation and security about this sensitive topic. Deliberately, the focus is on a simple, intuitive and comprehensible design without overwhelming the user with information.

This paper will first provide an overview of BPH and the increasing socio-economic challenges associated with it, before introducing the Kormoran11 device, its functionality and its testing.

1.1 BPH: Prevalence, Symptoms and Diagnosis

BPH affects 30-40% of men over the age of 30 and the prevalence increases almost linearly with age to 70-80% in men over 80 years (Madersbacher et al., 2019). Also the prevalence of LUTS increases with age: while around 50% of men over the age of 60 suffer from BPH-caused symptoms, the rate is already 80% for men over 80 (Miernik & Gratzke, 2020). The symptoms can be divided into different categories, e.g. storage symptoms such as increased urination frequency, urination at night or urinary incontinence, or voiding symptoms such as a slow, reduced or intermitted stream or terminal dribble (Gravas & Melekos, 2009; Miernik & Gratzke, 2020).

For BPH diagnosis and in order to assess the severity of LUTS, the American Urological Association (AUA) created the International Prostate Symptom Score (IPSS), a screening tool consisting of eight questions. This procedure has also been adopted by the World Health Organization (WHO). The questionnaire refers to BPH-related symptoms such as nocturia, weak urinary stream or incomplete emptying as well as the patient's quality of life. Each answer given by the patient is scored from 0 to 5 points. The total score correlates with the severity of the symptoms, up to 'severely symptomatic' (20 to 35 points). (Barry et al., 1992; Cockett, 1991)

1.2 Socio-Economic Challenges

Due to the high prevalence in the ageing population, BPH not only presents a medical but also a growing socio-economic challenge. The economic burden of a

disease is not only composed of direct costs for the affected patients, such as medication or interventions, but essentially also of indirect costs to be shouldered by society, as workforce or participation in public life may be decreased. According to an estimate by (Welliver et al., 2022), the cost of treating all men over 40 in the United States was at least \$1.9 billion in 2013. It is emphasised that these costs are a minimum due to few non-covered populations and do not include indirect costs. The authors also found a steady increase in expenditures by age group, which is consistent with the age-related increase in the prevalence of LUTS/BPH. A 2005 study states that the cost associated with a BPH diagnosis in the US was \$1,536 per year. The authors found that the average employee with BPH missed 7.3 hours of work per year, with about 10% of the considered group reporting some missed work related to BPH health care encounter. The sum of direct and indirect BPH-related costs was estimated to be \$3.9 billion annually. (Saigal & Joyce, 2005) Several studies assessed the LUTS/BPH-related burden for patients and society and suspect that these will potentially increase as the proportion of older men in the population increases. (Devlin et al., 2021; Speakman et al., 2015; van Exel et al., 2006)

1.3 Early Urological Screenings – Situation in Germany and Influence of the COVID-19 Pandemic

Early detection of changes in the size of the prostate volume enable early observation and treatment of symptoms. Studies show that only a few men suffer from LUTS that can be directly attributed to prostate cancer. However, a change in the prostate size is not always benign and if a nodular abnormality is present there is a chance that biopsy will result in a diagnosis of prostate cancer. (Chang et al., 2012)

For early detection of changes in the prostate, there is therefore the possibility of in-office screenings by the urologist. In Germany, an annual inspection of the external genitalia and palpation of the prostate are reimbursed by health insurance funds for all men over the age of 45. However, a 2022 health insurance research report states that this examination was only claimed by 21.7% of eligible men in 2020. (Grobe et al., 2022) Prostatahilfe Deutschland (Prostate Aid Germany) assumes various causes for this: shame about unpleasant examinations, fear of a drastic diagnosis or the understanding of many men that a doctor is only necessary when they actually have a health problem and do not seek health care

without complaints. In addition, some men are simply not used to talking about their physical or mental sensitivities. (Müller, 2021) Figures in the report in (Grobe et al., 2022) further suggest that the COVID-19 pandemic may have led to even fewer people taking advantage of early prostate screenings. Compared to 2019, the number of men undergoing the examination has decreased by 7.7%.

This connection with the COVID-19 pandemic is underlined by further recent studies. Nossiter et al. found that the number of men newly diagnosed with prostate cancer in 2020 after the first lockdown decreased by 30.8% in England compared to the same period in 2019, while those diagnosed were at a more advanced stage of disease. (Nossiter et al., 2022) A Swedish study by Fallara et al. comes to a similar conclusion. During the period of March - June 2020 36% fewer cases of prostate cancer were registered compared to the corresponding periods in 2017 - 2019. The greatest decrease of 51% was seen in men aged 75 and older. In contrast, there was no decrease in the numbers of patients receiving cancer curative treatments. (Fallara et al., 2021) There is a strong presumption that there is a link between habits changed by the COVID-19 pandemic and the use of health services, which has a particular impact on older people.

2 PROSTATE SELF-TESTING DEVICE FOR DISCREET USE AT HOME

Since large proportions of men shy away from professional urological in-office examinations, a need arises for options to discreetly deal with the health of their prostate at home. With Kormoran11, an innovative, handy flowmeter is developed for practical use in private environment. The self-testing device evaluates the urine flow curve and thus gives clues to the impairment of it by an enlarged prostate. The latest research approaches also deal with the extension to wireless evaluation and storage of the data in an app application. The device is patented under DE Patent No. 10 2014 008 760 B4 (Beck-Gscheidmeier & Simmons, 2014).

A challenge with regard to BPH diagnosis is that the patient self-assesses the severity of his LUTS when using the IPSS tool described in 1.1. An objective assessment of the severity of his symptoms is hardly possible with this procedure; moreover, the patient has to remember all micturition situations of the last month and several pages of paper have to be

filled out by hand. The Kormoran11 is supposed to offer a better alternative for this procedure that is quicker and less complicated. Especially with regard to question 5 of the IPSS (Barry et al., 1992) the device can be a suitable substitute:

Over the past month, how often have you had a weak urinary stream?

- *Not at all (0 points)*
- *Less than 1 time in 5 (1 point)*
- *Less than half the time (2 points)*
- *About have the time (3 points)*
- *More than half the time (4 points)*
- *Almost always (5 points)*

2.1 Basics of Uroflowmetry

Uroflowmetry is a recognised procedure to confirm the suspicion of bladder emptying disorders in men. It records the volume of urine leaving the urethra per unit time during a micturition. The result is the urine flow rate measured in mL/sec, which can be displayed as urine flow curve. Uroflowmetry has the advantage of being non-invasive and does not require the use of a catheter. It can therefore be used in almost all patient groups with suspected bladder emptying disorders. The measured maximum urine flow rate Q_{max} is the parameter that plays the most important role in clinical observation and is considered reliable and easily comparable regarding prognostic and post-therapeutic assessments. It is, however, important to ensure that the micturition volume is at least 150 mL, otherwise the validity of the measurement is limited. (Hautmann & Gschwend, 2014; Schultz-Lampel et al., 2012)

The normal urinary flow curve is bell-shaped and may be slightly flatter on the right side. The urine flow increases continuously to reach a peak and then decreases. Figure 1 shows the typical course of a flow curve.

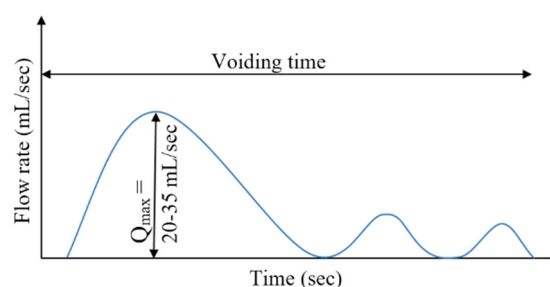


Figure 1: Schematic representation of a normal urinary flow curve. (Schultz-Lampel et al., 2012).

Some subsequent dripping, as shown in Figure 1 by the two posterior maxima, may occur and is not necessarily a pathological symptom.

A maximum flow rate of more than 20 mL/sec is often considered normal. However, this rough guideline is subject to restrictions and cannot be generalised as the flow rate depends on the voiding volume, age and sex. According to the 'Liverpool nomogram' by Haylen et al. which aims to better distinguish normal urine flow values from pathological values for different population groups, the curve of the 25th percentile of men > 50 years shows a maximum flow rate of approx. 11 mL/sec at a voiding volume of 150 mL. As the voiding volume increases, the flow rate of the considered group increases to about 15 mL/sec at 500 mL. (Haylen et al., 1989) In the guideline on therapy of benign prostatic syndrome, published by the association of German urologists, a flow rate with $Q_{\max} < 10$ mL/sec is considered 'reduced' and may indicate an obstruction of the urine flow. (Dreikorn & Höfner, 2014) In general, $Q_{\max} > 12...15$ mL/sec is considered 'normal' in the literature, even though it must be mentioned that parameters in uroflowmetry are subject to great variation and a definitive normal range cannot be defined. (Jarvis et al., 2012)

2.2 Home Uroflowmetry

The idea of home uroflowmetry was first suggested by Blaivas in 1988 to counter disadvantages of single-episode office uroflowmetry (Boci et al., 1999). Literature indicates that the latter procedure may not be sufficiently reliable to detect certain BPH-related voiding dysfunctions since many patients are unable to relax and void urine in a normal way in clinical environment. In addition, possible variations between consecutive flow measurements and circadian changes may have an impact on various voiding parameters, specifically on the peak flow rate. (Golomb et al., 1992)

Boci et al. conducted a study in 1999 to compare home uroflowmetry to conventional, free office uroflowmetry. 25 male patients at a mean age of 67 years with symptomatic BPH performed both free and home uroflowmetry. It was found that 80% of the investigated patient group considered home uroflowmetry simpler and more acceptable. 60% of the patient group felt psychologically better using home uroflowmetry. However, the crucial restriction was found that the device to be used at home must be explained to the patient in an understandable way. (Boci et al., 1999)

2.3 Device Architecture and Functionality

The aim was to develop a device with which the urine flow can be checked at home in familiar surroundings to give men certainty about their health status. From the literature and clinical feedback, the self-testing device should be easy to use and understand by non-professionals. The Kormoran11 is intended to serve for self-monitoring in case of a suspected new decrease in urine flow, to observe the consequences of medication treatment or after surgical intervention on the urethra or prostate. As pictured in Figure 2, the device consists of a funnel and a measuring unit in which the flow rate is evaluated. A high precision turbine-based flow measurement method (Digimesa AG, Ipsach, Switzerland) is used for this purpose. The sensor system consists of a reed switch, which is integrated in the circuit board, and permanent magnets, with which 2 of the 4 turbine blades are equipped. To set the turbine in rotation, the outer area of the rotor blades is exposed to the flow, as indicated in Figure 2. When the user urinates into the funnel, the flow is directed through the measuring unit and leaves it at the outlet. To assess the urine flow, the measured peak value of the flow curve is compared with the maximum flow rate of $Q_{\max}=11$ mL/sec. If the critical value is exceeded, a green led lights up on the device when the measurement is completed; otherwise, there is a red led signal. The housing of the pictured measuring unit is injection moulded.

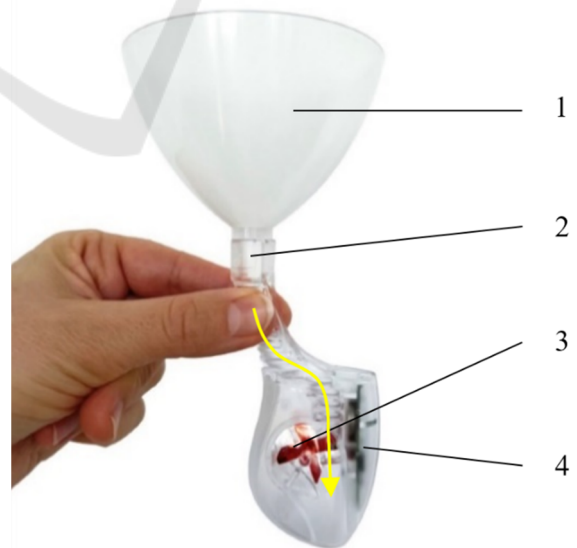


Figure 2: Prostate Self-Testing-Device Kormoran11, consisting of a funnel (1) into which urine is passed, a flow channel (2), the flow measuring unit (3) and a circuit board with microcontroller, reed switch, battery and LED lights (4). The yellow arrow indicates the course of the flow channel.

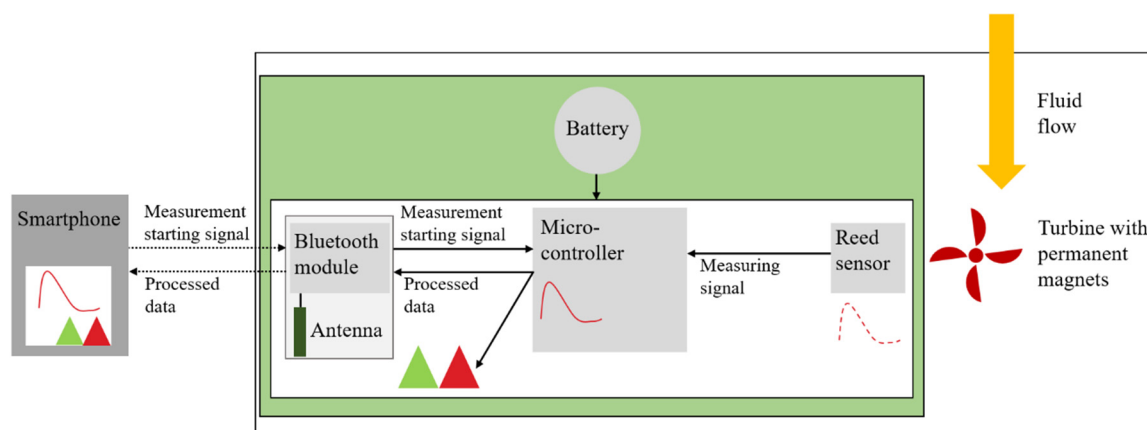


Figure 3: Schematic diagram of the device architecture and the integrated circuit board. The outer white box represents the Kormoran11 device, the circuit board is shown in green. It is equipped with the nRF52832 Bluetooth Low Energy Module by Adafruit. The processing of the measurement data takes place on the circuit board so that information can be provided also directly on the device via the red and green led lights (indicated by the red and green triangles).

A digital version of the device contains a Bluetooth module, which allows the wireless transmission of the results to a smartphone. There the measured data can be stored in a flow rate diary in order to track long-term developments, which can give the user and urologist indications of possible pathological changes.

the supporting circuit and a Bluetooth antenna already integrated and measures only 10 x 16 mm. The processing of the measurement data takes place on the board so that it can provide information also directly on the device via the red and green led lights. For app connected use, the device is placed next to a Bluetooth-enabled smartphone and the recording can be started in the app. The flow data is then transmitted continuously during the measurement, followed by the red or green indicator. In the app the result of the measurement is provided with the date and time, so that the flowmetry results can be observed over a longer period. Figure 4 shows the prototyped user interface.

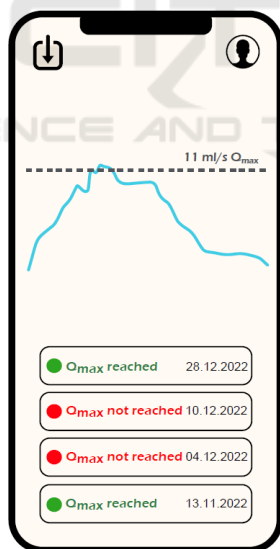


Figure 4: Prototyped user interface of the flow rate diary. Green and red dots indicate whether the target value $Q_{max}=11$ mL/sec has been reached or not.

Figure 3 shows a schematic diagram of the device architecture. For the Bluetooth connection, the integrated circuit board is equipped with the nRF52832 Bluetooth Low Energy Module by Adafruit (New York, United States). It has a BLE radio (Nordic Semiconductor, Trondheim, Norway),

2.4 Testing of the Device

Functionality and accuracy of the Kormoran11 were determined in laboratory in various flowmetry tests on a test bench. Water was used as the test liquid. A measuring programme with 13 measurement points was carried out for each test. On the test bench, which is pictured in Figure 5, the flow rate is varied with the aid of a controllable flow regulator. To determine the average flow rate, a valve is opened for a measurement period of 7 seconds and the amount of liquid passed is measured using digital scales. As water passes through the measuring unit of the device, it causes the turbine to rotate. The rotation of the turbine blades is detected magnetically and converted into electric pulses. The sensor pulse frequency is directly related to the turbine speed and thus to the flow velocity.

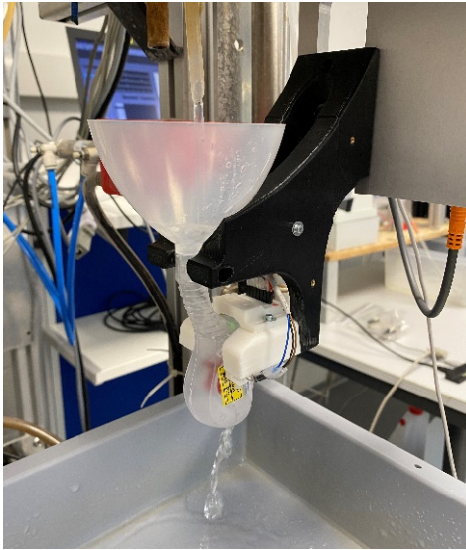


Figure 5: Laboratory testing of the Kormoran11 device on a test bench. The flow rate can be varied using a controllable flow regulator; the amount of liquid passed is measured using digital scales.

Figure 6 shows the relationship between the frequency of detected sensor pulses and the flow rate around the critical range of the switching point over a measurement series consisting of eight single measurements. This gives information about the performance of the sensor over the flow rate. The resulting curve is used to calibrate the device and requires repeatability and linearity. It can be seen that from about 580 mL/min the curves lie well together on almost a straight line, which shows good repetition over the test series.

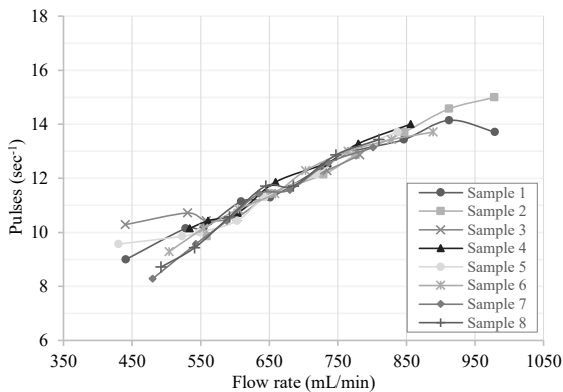


Figure 6: Detected sensor pulses as a function of the flow rate around the critical range of the desired switching point of 0.66 L/min.

In order to show the accuracy and reliability of the sensor unit, the LED switching points from RED to GREEN were also examined in various tests. Figure 7

shows the results of an exemplary series with eight single measurements. A value of -1 corresponds to RED and $+1$ corresponds to GREEN. This allows the display of the flow rate at which the transition from RED to GREEN was indicated for each test in the series.

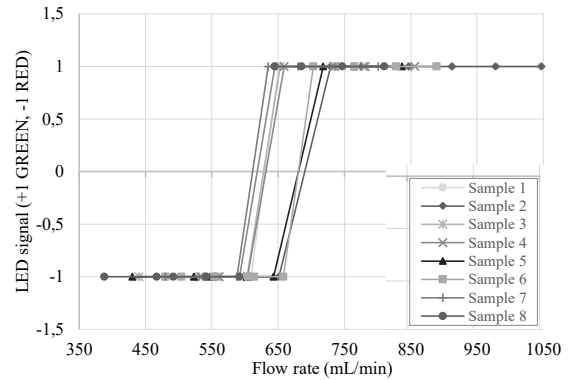


Figure 7: Switching point from RED to GREEN for a measurement series of eight tests. A value of -1 corresponds to RED and $+1$ corresponds to GREEN.

From Figure 7 it can be observed that below 588 mL/min the sensors in all tests indicate RED, the first sensor indicating GREEN does so at 635 mL/min. The last sensor to indicate RED is at 658 mL/min. At 729 mL/min, all sensors indicate GREEN. The aim was to reliably determine the value of 660 mL/min (equals $Q_{max}=11$ mL/sec) with a band of $\pm 10\%$, i.e. from 594 to 726 mL/min. This can be confirmed by this series of measurements.

3 CONCLUSIONS

In this paper, the newly developed, easy-to-use prostate self-testing device Kormoran11 is presented, which enables men to assess their urine flow simply and discreetly in the familiar surroundings of their own home. The application of the device represents not only a low hurdle when men do not want to go to the urologist or first approach the sensitive subject themselves. It also enables repeated and regular measurement to obtain as much certainty as possible despite fluctuating parameters that have an influence on urine flow, such as circadian changes. The Kormoran11 signals whether normal urine flow is ensured and indicates possible changes in the prostate, bladder or urethra. The device has been shown to operate accurately and to have high repeatability in detecting the set Q_{max} value of 11 mL/sec. The operation is simple and the indication with a red and green led light is easy to understand.

In a version without app connection, the Kormoran11 is already approved as a medical device and available on the market.

The digital functions and the app connection were introduced specifically at the suggestion of the urologists accompanying the project. It is expected that the possibility of observing the long-term development of measurements will enable a better medical assessment and that the device will also be accepted and used by younger users. However, with regard to the older target group, it should be noted that a digital connection is not necessary to fulfil the function of Kormoran11.

It must be emphasised that the self-test result can only be a first indication and that the final diagnosis by a urologist is essential. The device is intentionally not a measuring instrument, but serves to introduce men to the sensitive subject in a simple way and to familiarise themselves with their prostate health status. The user is educated that a red light means that the current flow is too weak. He is instructed to repeat the measurement on other days at other times in that case. If the signal is predominantly red, a visit to the doctor is advised.

In conclusion, the authors are convinced that this work can make a great contribution to men's health. However, future studies need to test the willingness of men to purchase and use the Kormoran11 device and further development work is needed to make the app-connected version ready for series production. In addition to home use, it is also conceivable that the device could be used in day care, nursing homes and general practitioners' offices.

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