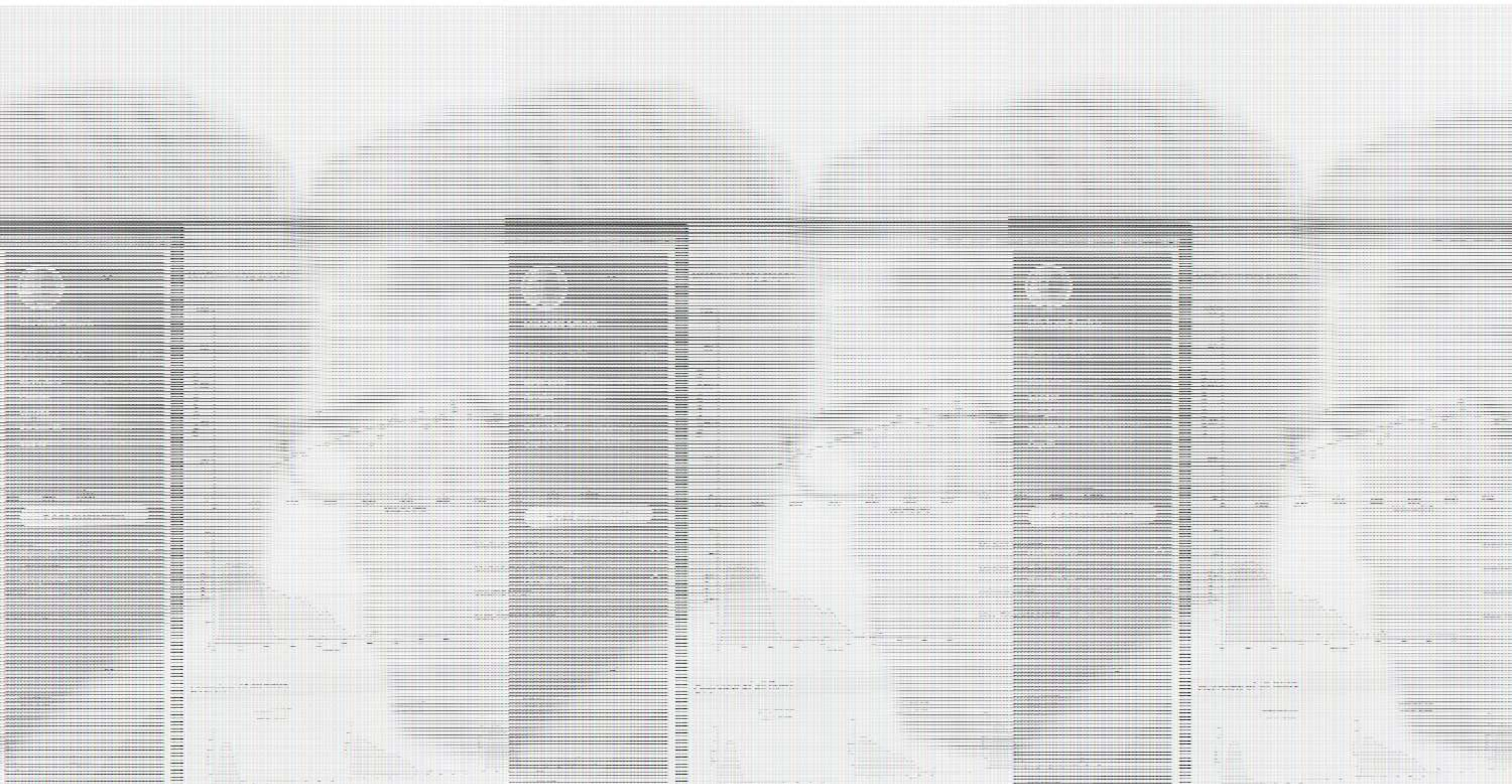
MINZE UROFLOW

SCIENTIFIC RESEARCH



MINZE UROFLOW
SCIENTIFIC RESEARCH

MINZE UROFLOW: ACCEPTANCE TESTING OF UROFLOWMETERS (2019)

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Flow meters play an important role in assessing patients with functional urology symptoms. They allow clinicians to perform flow studies and urodynamics, enabling them to offer the most appropriate treatment options. It is therefore essential that new flowmeters have been thoroughly tested before they are used to ensure they are accurate and usable.
The Bristol Urological Institute has been commissioned to test a new design of flowmeter. We developed a protocol to test the Minze uroflowmeter (Fig. 1) to assess its accuracy, usability, filtering and operation.

Fig 1 Minze Uroflow (left) fits on a normal toilet and can be assembled for sitting (middle) and standing (right) position.

We describe this protocol in order to enable standardise testing by prospective users of any new flowmeter in the future (Table 1).

Area to test	Test performed	Reasons for test
Usability	Use in a flow clinic	Operational assessment
	User questionnaires (Appendix 1)	Operational assessment
Accuracy	Constant flow bottle	Test for artefacts
	Flow column with base outlet	Assess linearity
Filtering	Reproduction of common flow artefacts	Assessing recording response
	Start and stop of flow	Check of volume and max flow recorded

Table 1 A table of the test protocol used to test a uroflowmeter. Flow column with base outlet is shown on the right image

The tests showed that for the new flowmeter, the values for maximum flow rate, Qmax, and voided volume, Vvoid, were all within stated accuracy and ICS recommendations. The processing of data by the proprietary algorithm is shown in Fig 2. ICS guidelines suggest either a 2 second window filter or a 1 Hz low pass filter. Comparison of the data in Fig 2 from a 2 second window filter, the new flowmeter's algorithm filter and both filters combined shows that noise is more effectively removed by additional filtering than simply a 2 second window.

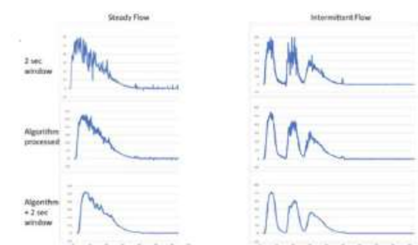

Fig 2 Comparison of steady and artefactual flow, as processed by different filtering

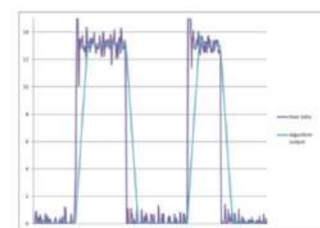

Fig 3 Response to quick changes in flow rate.

Fig 4 Flow column

The response of the flowmeter to step changes in flow (Fig. 3) showed that the signal can rise at a rate of 0.7 ml/s2, giving **an effective 3dB bandwidth of the algorithm of 0.13 Hz, well below ICS recommendations.**

The flow column (Fig. 4) test showed some deviations from a smooth decline of flow, so further checks of the linearity test are required. These variations were evident on two other manufacturer devices as well. These were possibly due to variations in column diameter, but more likely due to waves occurring in the column base, as the perturbations are cyclical.

The testing processes detailed here allow users to assess a new flowmeter in several key areas, enabling them to better critically appraise a new flow meter and understand limitations users need to be aware of. **Based on the tests performed on the Minze hospital flow meter, we concluded that algorithm processing does not reduce the accuracy of the recording nor does it omit potentially useful data.** We suggest these can be used as a set of guidelines to test any new flow meter.

HOMEFLOW: COMFORT OF UROFLOWMETRY AT HOME WITH CHILDREN (2019)

Minze
health at home

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Paper (or electronic) based frequency volume charts (FVC) are an established method for evaluation of voiding disorders in children, including enuresis nocturna, but often not reliable because of incomplete registration by the patiënt or parent. 8 patients (mean 11,1 years, 4-18 years, M:6 F:2) were included to use Homeflow at home for 2 consecutive days to keep an automated voiding diary with smartphone app. In case of an automated voiding diary, voided volume and time of void are recorded automatically by the uroflowmeter. Patient don't need to measure and manually enter it, in contrast to a paper and electronic based voiding diary (Table 1).

	PAPER BASED	ELECTRONIC	AUTOMATED
Voided volume measured	Measuring cup	Measuring cup	Minze Uroflow
Voided volume entered	**Manually** (paper)	**Manually** (electronic)	**Automatically** registered
Time of void entered	**Manually** (paper)	**Manually** (electronic)	**Automatically** registered
Urge to void entered	**Manually** (paper)	**Manually** (electronic)	**Manually, but prompted** (electronic)

Table 1 Comparison of a paper based, an electronic and an automated voiding diary.

User-experience data (completeness, reliability, feasibility) was collected through daily questionnaires by the parents/child.

100 % All reported their **voiding diary (voids, intake, leakages) to be complete.**

87,5 % Most considered their **voiding diary to be representative** (50%) or rather representative (37,5%) for a normal day/night.

87,5 % Most rated the **app as user friendly** (50%) or rather user friendly (37,5%).

87,5 % Most considered their **voiding posture** neutral with no refrain (87,5%).

100 % All 4 patients with pre-existing experience **preferred Homeflow** over paper based FVC.

Homeflow was preferred by parents and children over paper based FVC. Complete registration of voiding was achieved through automated measurements. Based on this user-experience data the **Homeflow is considered to be a user-friendly, comfortable method to evaluate voiding disorders at home.** More research is required to assess the increase in patients' compliance and willingness to use an automated voiding diary.

HOMEFLOW: VARIABILITY OF UROFLOWMETRIES IN CHILDREN (2019)

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Single measurement uroflows, obtained in an unnatural environment (hospital) often result in unreliable data, especially in children. In this study multiple uroflows (177) were assessed in 11 children (mean 9,8 years, 4-18 years, M:9 F:2) using Homeflow. The variability of the maximum flow rate (Qmax) and flow curve were analysed in relation to urge, time of the day and voided volume (Vvoid).

Patient	Age [years]	Amount of flows	Range Qmax [ml/s]	Mean Qmax [ml/s]	Stdev Qmax [ml/s]
P1	7	12	4 - 18	12,3	4,1
P2	9	22	6 - 19	13,7	3,4
P3	18	18	5 – 41	26,5	8,8
P4	6	9	6 - 18	12,3	3,1
P5	12	13	4 – 17	9,4	3,5
P6	4	10	7 - 14	11,0	2,4
P7	15	7	13 - 42	27,9	7,8
P8	18	13	3 – 34	19,3	9,9
P9	4	17	4 - 23	13,4	5,8
P10	8	17	6 - 9	7,8	0,9
P11	7	39	6 - 17	13,9	2,1

Table 1 Result tabel summarizing every subject's age, amount of flow, Qmax range, mean Qmax and stdev of Qmax.

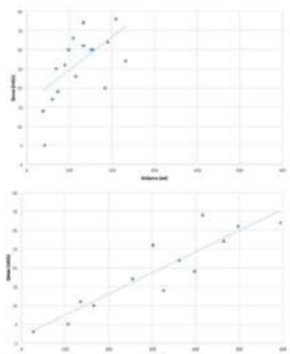

Fig 1 Qmax-Vvoid plot of subject P3 (above) and P8 (below) with the most variability in Qmax.

Huge fluctuations of intra-subject Qmax measurements were found with inter-subject Standard Deviation (SD) ranging from 0,9 to 9,9 ml/s. The result table (Table 1) summarizes every subject's age, amount of home flows, Qmax range, mean Qmax and stdev of Qmax. To demonstrate this significant variability a Qmax-Vvoid plot is illustrated of subject P3 with a Qmax stdev of 8,8 ml/s and of subject P8 with a Qmax stdev of 9,9 ml/s.

Variability in Qmax and flow curve shape could be dependent on time of day, urge and/or Vvoid. Qmax-Vvoid correlation of multiple uroflows in one individual are interesting to investigate and compare with conventional nomograms.

Fig 2 Huge variability in flow curve influenced by urge to void.

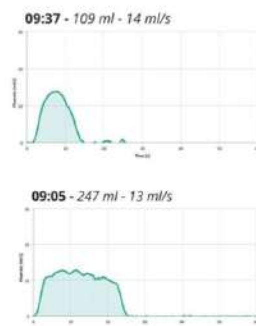

Fig 3 Huge variability in flow curve influenced by voided volume

Fig 4 Huge variability in flow curve influenced by time of day or other variables

Multiple measurements influence extreme values (either outliers or unrepresentative flows), counteracting the large potential error in a single measurement. Due to this variability, comparison between single in-clinic flows in an individual is less powerful – definitely, considering the psychological effects of the hospital environment on a child. These results underline the clinical potential of Homeflow. The cohesion of depending factors determing Qmax, Vvoid, flowcurve and urge is complex and needs more research.

CORRELATION BETWEEN QMAX AND VOIDED VOLUME OF MULTIPLE HOME UROFLOWMETRIES IN HEALTHY ADULTS (2019)

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The study where the variability of uroflowmetries in children using Homeflow was assessed, demonstrated significant variability, counteracting the large potential error of single uroflowmetry measurements. To further assess this variability, we investigated the correlation between maximum flow rate (Qmax) and voided volume (Vvoid)of multiple uroflows in one individual and compared it with conventional nomograms.

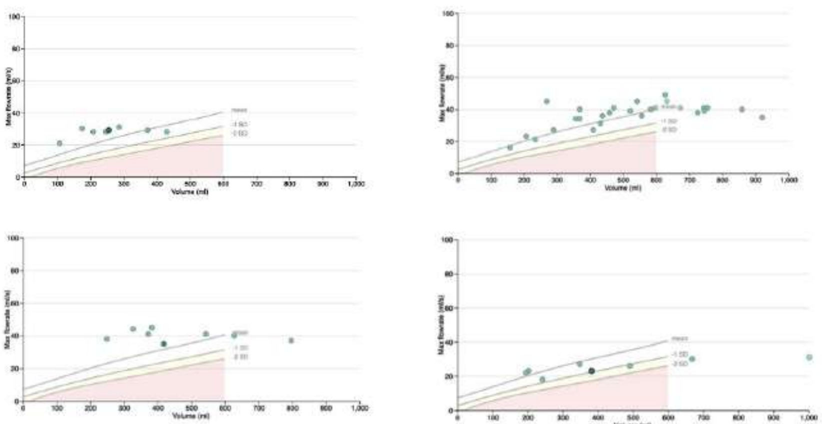

Fig 1 Qmax-Vvoid plot of multiple uroflowmetry measurements of four male individuals compared with the male Liverpool nomogram

8 normal, asymptomatic adults (mean 32,3 years, 26-37 years, M:4 F:4) used Homeflow to collect multiple uroflows. We used the male (<50 years) and female Liverpool nomograms to compare the uroflow results from the test subjects using Homeflow. The Liverpool nomograms provide normal reference ranges for the maximum flow rate over a wide range of voided volumes. According to these nomograms a positive correlation between Qmax and Vvoid exists, which is close to linear.

The multiple uroflow results from the 8 participating normal adults are plotted in a Qmax-Vvoid plot and compared to the male (Fig. 1) and female (Fig. 2) Liverpool nomograms. **Different correlations between Qmax and Vvoid were observed, different from each other (all normal asymptomatic adults) and different from the nomograms. Comparing the uroflow results to the nomograms, suggests different conclusions at different voided volumes (above or below average/normal).**

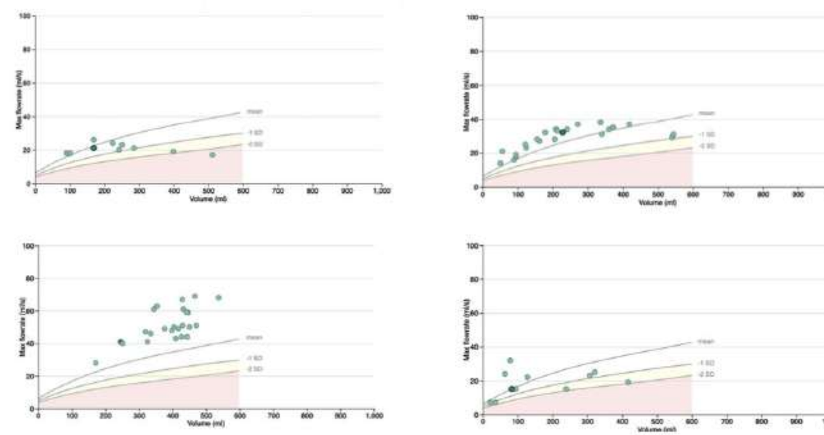

Fig 2 Qmax-Vvoid plot of multiple uroflowmetry measurements of four female individuals compared with the female Liverpool nomogram

These results raise the question on how effectively normality is assessed today with a single measurement approach using nomograms. More research is needed to assess the value of the correlation between Qmax and Vvoid of multiple measurements of one individual in the evaluation of the lower urinary tract function.

A FEASIBILITY STUDY OF A UROFLOWMETER POTTY FOR TODDLERS (2019)

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Uroflowmetry is a simple and noninvasive test to evaluate lower urinary tract function. Since it requires voiding on command, the available data on pediatric uroflows –and especially toddlers- are scarce and varied. In addition, such tests can be affected by the unnatural hospital/study environment and by the lack of a proper posture on the big, currently available uroflowmeter seats (Fig. 1). In this study, the feasibility of a novel uroflowmeter potty is assessed to obtain uroflows from toddlers.

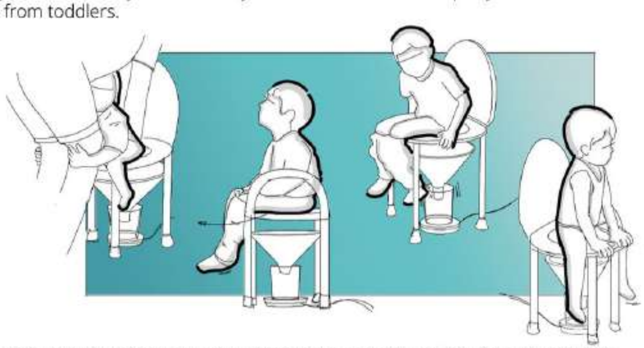

Fig 1 Currently available uroflowmeter seats don't support a proper voiding posture for toddlers.

Uroflowmetry studies with the novel Minze uroflowmeter potty were performed on 10 healthy toddlers (mean age 3 years, range 2-4 years, male:7 female:3) following their normal potty training routine. Voided volume, maximum flowrate (Qmax) and uroflowcurve shape were analysed. Additionally, different potty designs were evaluated on their ergonomics (Fig 2).

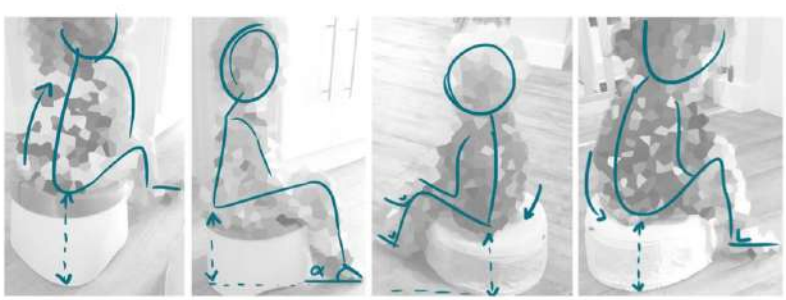

Fig 2 Different potty design prototypes used to analyse and optimize the design to enable proper voiding posture

20 uroflows were successfully recorded with a mean voided volume of 50.4 ml (SD 28.8 ml; range 10-147 ml) and a mean Qmax of 7.8 ml/s (SD 3.0 ml/s; range 4-14 ml/s). **Analysis of the curve shape showed 50% bell-shaped, 30% interrupted and 20% plateau curves** (Fig. 3).

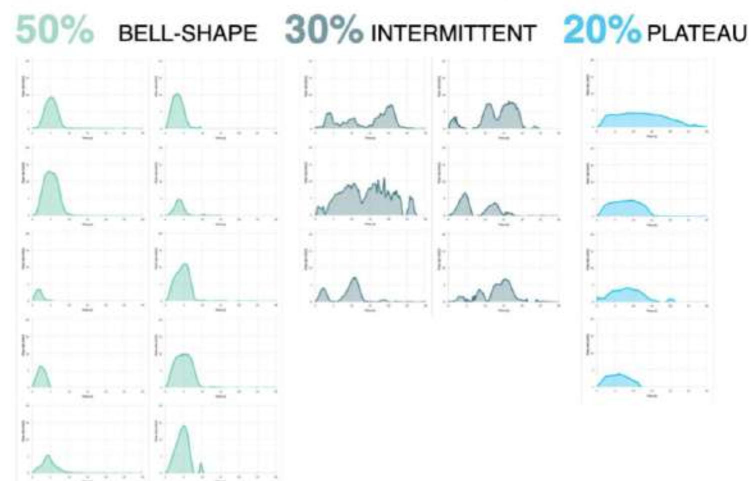

Fig 3 Overview of the 20 uroflow curves recorded of which 50% bell-shaped, 30% interrupted and 20% plateau curves

Fig 4 Final potty design including the Minze uroflowmeter

The design of the potty was optimized to enable a proper voiding posture – flat feet on the floor and horizontal pelvis position. An oval-shaped potty design (30×25 cm) with a 18 cm height was found most ergonomic and comfortable (Fig. 4).

The novel uroflowmeter potty is considered a comfortable and valuable tool to obtain uroflows in toddlers, enabling more research in pediatric uroflowmetry.