

## The UroCuff Test<sup>®</sup>

*A non-invasive pressure-flow diagnostic for male LUTS patients*

## Summary of supporting evidence

# Introduction

The UroCuff Test is a technology with 40 peer-reviewed clinical publications. It is utilized by urologists in 20 countries around the world with 200,000 procedures performed, to-date. We introduced The UroCuff Test to the US in 2007, and there are currently several hundred urology practices using this diagnostic tool to improve patient outcomes.

## Summary of clinical evidence

Prospective and retrospective studies have been published in major peer-reviewed urology journals, including several publications in *The Journal of Urology*, among others:

### ***The UroCuff Test non-invasive pressure-flow has been validated as equivalent to urodynamics pressure-flow for the diagnosis of bladder outlet obstruction.***

- Multiple independent clinical trials, including a recent study at Northwestern University, directly compared UroCuff to urodynamics pressure-flow. Each of these studies have demonstrated the diagnostic equivalence of the two techniques.<sup>1,5,21</sup>

### ***The UroCuff Test is a proven predictor of BPH treatment outcomes.***

- Multiple independent trials proved The UroCuff Test's ability to reliably and consistently predict surgical outcomes prior to intervention.<sup>2,3,22</sup> For example, a recent study on 62 patients undergoing BPH surgery found The UroCuff Test to be a highly accurate predictor of surgical outcomes. Specifically, 94% of patients predicted to be obstructed had a successful outcome ( $p < 0.01$ ), and 70% of patients predicted to be not obstructed had unsuccessful outcomes after surgery ( $p < 0.01$ ).<sup>2</sup>

### ***The UroCuff's published clinical literature has been extensively reviewed.***

- International Continence Society (ICS) recently updated its comprehensive, evidence-based review of uro-diagnostic testing. The ICS conducted a complete review of The UroCuff Test's literature, and concluded that "non-invasive measurements of pressure and flow in men by the penile cuff [...] seem to be as clinically useful as the traditional invasive measurement of pressure and flow". ICS recommendations state that "[...] non-invasive measurements of pressure and flow should be considered when the patient is not required to undergo an invasive assessment of the storage function of the lower urinary tract."<sup>A</sup>
- The United Kingdom's National Health Service performed a formal evidence review of clinical literature, concluding that The UroCuff Test "[...] offers greater accuracy in diagnosis of BOO than diagnosis based on flow rate measurement alone." Furthermore, the NHS Centre for Evidence-based Purchasing concluded "[...] its prediction of outcome from surgery rivals that offered by invasive urodynamic studies."<sup>B</sup>

A complete bibliography of The UroCuff Test's peer-reviewed publications is included in this document. Reprints and summaries of each of these publications is available upon request.

The UroCuff Test is intended to replace a standalone uroflow in male patients with LUTS. Our US urology clients utilize the UroCuff data to predict surgical outcomes and identify appropriate patients for BPH treatments. This use model is discussed in the following pages.

## Procedure description

UroCuff measures urine flow rate, bladder pressure, abdominal straining and detrusor-sphincter dyssynergia non-invasively with a penile pressure cuff and surface EMG electrodes. The principle of The UroCuff Test is similar to blood pressure measurement.

When the patient is ready to void, a small pneumatic cuff is fitted to the penis and surface electrodes are placed on the perineum and abdomen. When voiding has commenced, the instrument slowly inflates the cuff until the stream is interrupted.

The cuff pressure required to interrupt flow equals bladder pressure at the time of interruption. Cuff pressure is then quickly released, allowing flow to resume. The cycle is repeated until voiding is complete.

## Clinical applications

***The UroCuff Test is a proven predictor of BPH treatment outcomes.***

Poor BPH treatment outcomes are often a result of compromised bladder health. Patients who have limited bladder health may not realize symptomatic improvements from treatments which reduce urethral resistance.

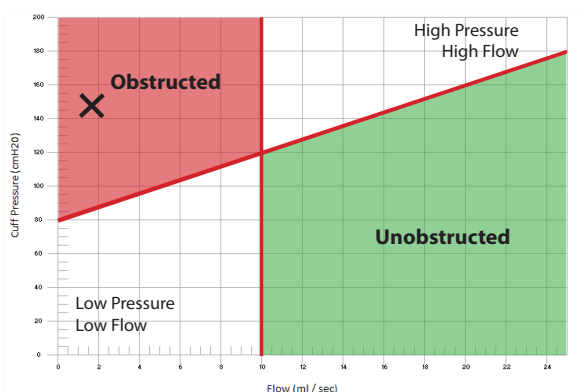
Performing a UroCuff Test instead of a uroflow provides an accurate diagnosis of bladder health and has been proven to be a strong predictor of BPH treatment outcomes. The nomograms below illustrate how The UroCuff Test can identify patients who have low bladder contractility and are at a high risk of poor BPH treatment outcome.

*The nomogram to the left* is an example of an obstructed patient with good bladder health and a low urine flow rate. This patient is likely to have symptomatic relief from a BPH treatment when the resistance in his prostatic urethra is reduced.

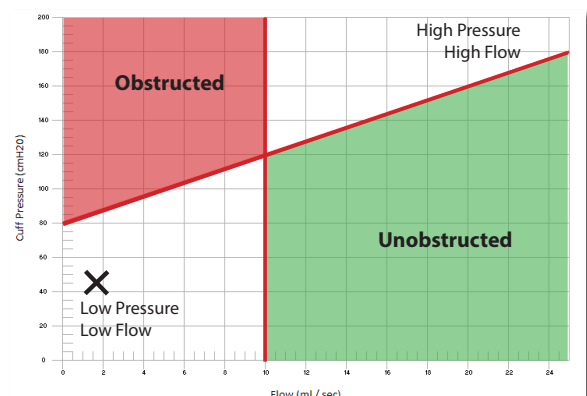
*The nomogram to the right* is an example of a patient with poor bladder health and a low urine flow rate. This patient is at risk to have limited symptomatic relief when the resistance in his prostatic urethra is reduced, as his bladder may not be capable of emptying.

If these patients performed a uroflow instead of a UroCuff, they may have had identical uroflow results to one and other, as one patient has low flow rate due to bladder outlet obstruction and the other patient has a low flow rate due to low bladder contractility.

### High Pressure-Low Flow Example



### Low Pressure-Low Flow Example

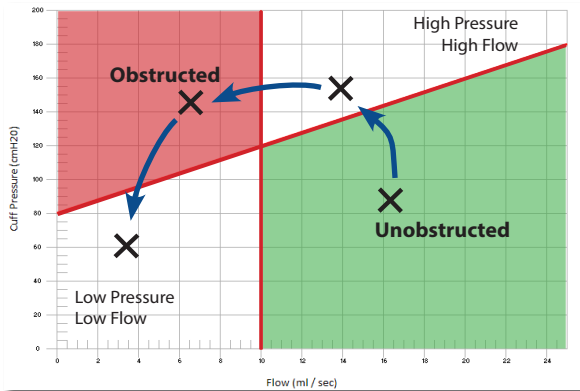


## Clinical applications (cont.)

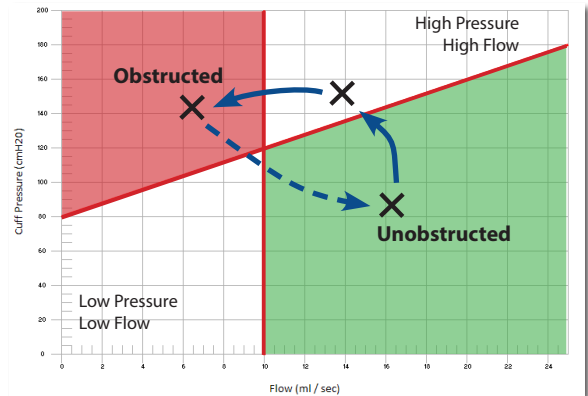
**The UroCuff Test identifies patients who are good candidates for successful BPH treatments.**

Patients who are being medically managed, or who are in watchful waiting, can be periodically evaluated to monitor bladder health. Rather than relying only on the patient's self-reported symptoms, the urologist can use bladder health as a clinical trigger to identify patients whose bladder health is at risk and could benefit from a BPH treatment. This results in performing more successful BPH treatments with improved certainty and patient satisfaction.

### Unmanaged Patient Example



### Managed Patient Example



## Reimbursement

Please refer to the SRS Medical UroCuff Quick Code Guide for specific coding information. Coding for The UroCuff Test has been independently reviewed and approved by Physician Reimbursement Systems Network (PRS Network).<sup>C</sup>

## Complete list of peer-reviewed clinical publications

1. The UroCuff test: a non-invasive alternative to pressure flow studies in adult males with lower urinary tract symptoms secondary to bladder outlet obstruction. Matulewicz, R. S., & Hairston, J. C. *The Canadian Journal of Urology* (2015), 22(4), 7896-7901
2. Correlation between penile cuff test and pressure-flow study in patients candidates for trans-urethral resection of prostate. Bianchi D, Di Santo A, Gaziev G, Miano R, Musco S, Vespasiani G and Agrò EF, *BMC Urology* (2014), 1471-2490/14/103
3. Non-invasive urodynamics predicts outcome prior to surgery for prostatic obstruction. Losco G, Keedle L, King Q. *BJU International* (2013) 2: 61–64
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5. The Role of Non-Invasive Pressure Flow Study in Highly Symptomatic/Bothered Men with Bladder Outlet Obstruction. N Batezini, ME Girotti, F Almeida, JP Zambon, E Pinto, M Skaff, *Journal of Urology* (2010), Volume 183, Issue 4, Supplement , Pages e623-e624
6. Review of invasive urodynamics and progress towards non-invasive measurements in the assessment of bladder outlet obstruction. CJ Griffiths, RS Pickard. *Indian Journal of Urology* (2009), Volume 25, Issue 1. p83-91
7. Positioning Invasive versus Non-Invasive Urodynamics in the Assessment of Bladder Outlet Obstruction. Arnolds M. *Current Opinion in Urology* (2009): Volume 19 - Issue 1 - p 55-62
8. The penile cuff test: A clinically useful non-invasive urodynamic investigation to diagnose men with lower urinary tract symptoms. C. Harding, W. Robson, M. Drinnan, S. McIntosh, M. Sajeel, C.J. Griffiths, R.S. Pickard. *Indian Journal of Urology*, (2009), Volume 25, Issue 1 p116-121
9. Interobserver agreement for noninvasive bladder pressure flow recording with penile cuff. McArdle F, Clarkson B, Griffiths C, Drinnan M, Pickard R. *Journal of Urology* (2009), Vol. 182, 2397–2403
10. The Urodynamic Evaluation of Lower Urinary Tract Symptoms in Men. Griffiths D, Abrams P, D’Ancona CA., van Kerrebroeck P, Nishizawa O, Nitti VW, Foo KT, Tubaro A., Wein A. and Belal M. *Current Bladder Dysfunction Reports* (2009) Volume 3, Number 1, 49-57, DOI: 10.1007/s11884-008-0008-5
11. Multisite evaluation of noninvasive bladder pressure flow recording using the penile cuff device: assessment of test-retest agreement. Clarkson B, Robson W, Griffiths C, McArdle F, Drinnan M, Pickard R. *Journal of Urology* (2008), Vol. 180, 2515-2521
12. Categorization of obstruction using noninvasive pressure flow measurements: sensitivity to change following prostatectomy. Sajeel M, Harding C, Robson W, Drinnan M, Griffiths C, Pickard R. *Journal of Urology* (2007), Sep;178 (3 Pt 1):996-1000; discussion 1000-1. Epub 2007 Jul 16



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14. Functional Studies to Assess Bladder Contractility. Sullivan M., Yalla S.V. *Journal für Urologie und Urogynäkologie* (2007), 14 (1): 7–10
15. The Role of Non-Invasive bladder pressure measurement by the penile cuff device for assessment of men with lower urinary tract symptoms. R.S. Pickard, C. Harding, W. A. Robinson, S. L. McIntosh, M. Sajeel, P. Ramsden, M. J. Drinnan, C. J. Griffiths. *Urologica* (2006), 16: 298-309.
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18. Variation in invasive and non-invasive measurements of isovolumetric bladder pressure and categorization of obstruction according to bladder volume. Harding CK, Robson W, Drinnan MJ, Ramsden PD, Griffiths C, Pickard RS. *Journal of Urology* (2006), Volume 176, Issue 1, Pages 172-176.
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20. A nomogram to classify men with lower urinary tract symptoms using urine flow and noninvasive measurement of bladder pressure. Griffiths CJ, Harding C, Blake C, McIntosh S, Drinnan MJ, Robson WA, Abrams P, Ramsden PD, Pickard RS. *Journal of Urology* (2005), Oct;174 (4 Pt 1):1323-6; discussion 1326; author reply 1326.
21. Comparison of invasive and non-invasive bladder pressure measurements by calculation of the bladder outlet obstruction index (BOOI). Griffiths C, Drinnan M, Harding C, Robson W, Ramsden P, Pickard R. *Neurourol Urodynamics* (2005), vol 24, number 5/6, pages 529 – 531
22. Change in Bladder contraction strength following TURP. Harding C, Robson W, Genner S, Drinnan M, Ramsden P, Griffiths C, Pickard R *Neurourol Urodynamics* (2005), vol 24, number 5/6, pages 529 – 531
23. Non-invasive assessment of bladder contractility in men. McIntosh SL, Drinnan MJ, Griffiths CJ, Robson WR, Ramsden PD, Pickard RS. *Journal of Urology* (2004), 172: 1394-1398
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25. Non-invasive techniques for the measurement of isovolumetric bladder pressure. Blake C, Abrams P. *Journal of Urology* (2004), 171: 12-19

## Peer-reviewed clinical publications (cont.)

26. Non-invasive measurement of bladder pressure: does mechanical interruption of the urine stream inhibit detrusor contraction? McIntosh SL, Griffiths CJ, Drinnan MJ, Robson WA, Ramsden PD, Pickard RS. *Journal of Urology* (2003), 169; 1003-06.
27. Non-Invasive Bladder Pressure: The Case for Using a Modified ICS Nomogram. Griffiths C1, Blake C2, Harding C3, McIntosh S3, Drinnan M, Robson W, Pickard R, Abrams P, Ramsden P, *Neurourology and Urodynamics* (2003), Volume 22, Issue 4, pages 367-368.
28. The relationship of abdominal pressure and body mass index in men with LUTS. McIntosh SL, Griffiths CJ, Drinnan MJ, Robson WA, Ramsden PD, Pickard RS. *Neurourol Urodynamics* (2003), 22: 602-605.
29. Inter-observer agreement in the estimation of bladder pressure using a penile cuff. Drinnan MJ, McIntosh SL, Robson WA, Pickard RS, Ramsden PD, Griffiths CJ. *Neurourol Urodynamics* (2003), 22: 296-300.
30. Assessment of prostatic obstruction - a cuff may be enough. Drinnan MJ, Pickard RS, Ramsden PD, Griffiths CJ. *Neurourol Urodynamics* (2003), 22: 40-43.
31. Non-invasive measurement of bladder pressure using controlled inflation of a penile cuff: comparison with simultaneous invasive measurements in patients and volunteers. Griffiths CJ, Rix D, MacDonald A, Reddy M, Drinnan MJ, Pickard RS, Ramsden PD. *Journal of Urology* (2002), 167: 1344-47.
32. Non-Invasive Measurement of Bladder Pressure in the Assessment of Men with LUTS. McIntosh S, Pickard R, Drinnan M, Griffiths C. *Urology News* (2002), Volume 5, Number 5
33. Reproducibility of non-invasive urodynamics, using the cuff-urowflow, for the diagnosis of bladder outlet obstruction in males. Vírveda MC, Salinas JC, Arredondo FM, Teba FP, Vázquez DA., *Scand J Urol Nephrol.* (2002), 36(6):431-4
34. Measurement of Bladder Pressure by Controlled Inflation of a Penile Cuff. Griffiths CJ, Rix D, MacDonald AM, Drinnan MJ, Pickard RS, Ramsden PD, *Journal of Urology* (2002), Volume 167, Issue 3, Pages 1344-1347.
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36. Penile Urethral Compression-Release Maneuver as a Non-invasive Screening Test for Diagnosing Prostatic Obstruction. Maryrose P. Sullivan and Subbarao V. Yalla, *Neurourology and Urodynamics* (2000), 19:657-669.
37. A new method for noninvasive measurement of voiding pressures? Assessment of penile cuff occlusion. Griffiths C, Pickard R, Tuckey J, Thomas D, Davies J, Ramsden P. *Neurol Urodyn* (1999) 18: 256-7
38. Noninvasive Urodynamics: A Study of Male Voiding Dysfunction. D. Gleason, M. Bottaccini, L. McRae. *Neurourology and Urodynamics*, (1997), Volume 25, p 93-100

## Peer-reviewed clinical publications (cont.)

39. Noninvasive Quantitative Method for Measuring Isovolumetric Bladder Pressure and Urethral Resistance in the Male: I. Experimental Validation of the Theory, L. McRae, M. Bottaccini, D. Gleason  
Neurourology and Urodynamics, (1995), Volume 14, p 101–114

## Technology assessments

- A. Mediplus CT3000 cuff machine for diagnosis of bladder outlet obstruction: Evidence review. E. Skryabina, C. Davey, Bath Institute of Medical Engineering; Centre for Evidence-based Purchasing (CEP), Policy and Innovation Directorate, NHS Purchasing and Supply Agency, UK, 2007.
- B. International Continence Society: Dynamic Testing, in Incontinence: 4th International Consultation on Incontinence (2015), Hosker G, Rosier P, Gajewski J, Sand P, Szabo L, Capewell, A, Pages 413-522.

## Reimbursement assessments

- C. *CT3000 UroCuff Test Position Paper*  
PRS Network 2017  
On file with SRS Medical



**The UroCuff Test**

More information online at:  
[www.srsmedical.com](http://www.srsmedical.com)



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