Principles of
The UroCuff® Test

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Basic urology - the flow measurement

The single most obvious and objective symptom of most men's urodynamic complaints is a hesitant flow or a poor flow rate, and so the most basic tool of the in-office prostate assessment is the flow meter, or uroflow. The UroCuff instrument has a protocol option for standalone uroflow.

Measurement of flow rate and voided volume

A flow meter provides measurements of flow rate (Q) *and* voided volume (V_{void}). V_{void} is usually measured in milliliters (ml), while Q is measured in milliliters per second (ml/s). Flow rate and voided volume are clearly related:

Flow rate is the rate of change of volume $$Q = {}^{dV}/_{dt}$$

If V_{void} can be measured, Q can be calculated.

Volume is flow rate integrated over time $$V = \int Q\, dt$$

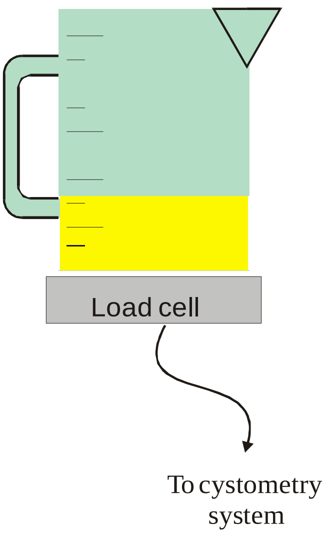
If Q can be measured, V_{void} can be calculated.

There are a few different types of flow meter, but they all measure *either* flow *or* volume, and then calculate the other parameter. The UroCuff instrument uses a load-cell flow meter to measure volume, and its topology is discussed below.

The load cell flow meter

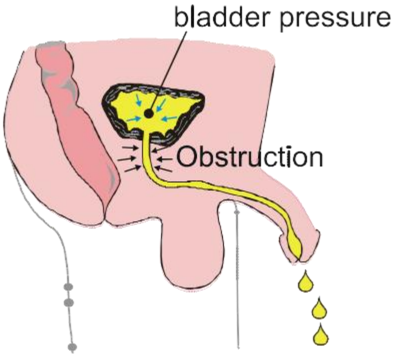
This is currently the most common type of flow meter, and is used by the majority of flow or cystometry measurement systems on the market, including the UroCuff instrument. The load cell is essentially a weighing scale - since the density of urine is (to within 3%) the same as water, the weight of the urine can be converted directly to volume, and then to flow rate.

A load cell measures weight, and not volume. Therefore the load cell makes measurements in grams (gm) and the measurement is converted into milliliters by using a density of the urine equal to that of water (1 gm = 1 ml). The load cell effectively measures volume and then calculates the flow by determining the rate of change of volume.



Limitations of a stand-alone uroflow

Why is the measurement of pressure important?



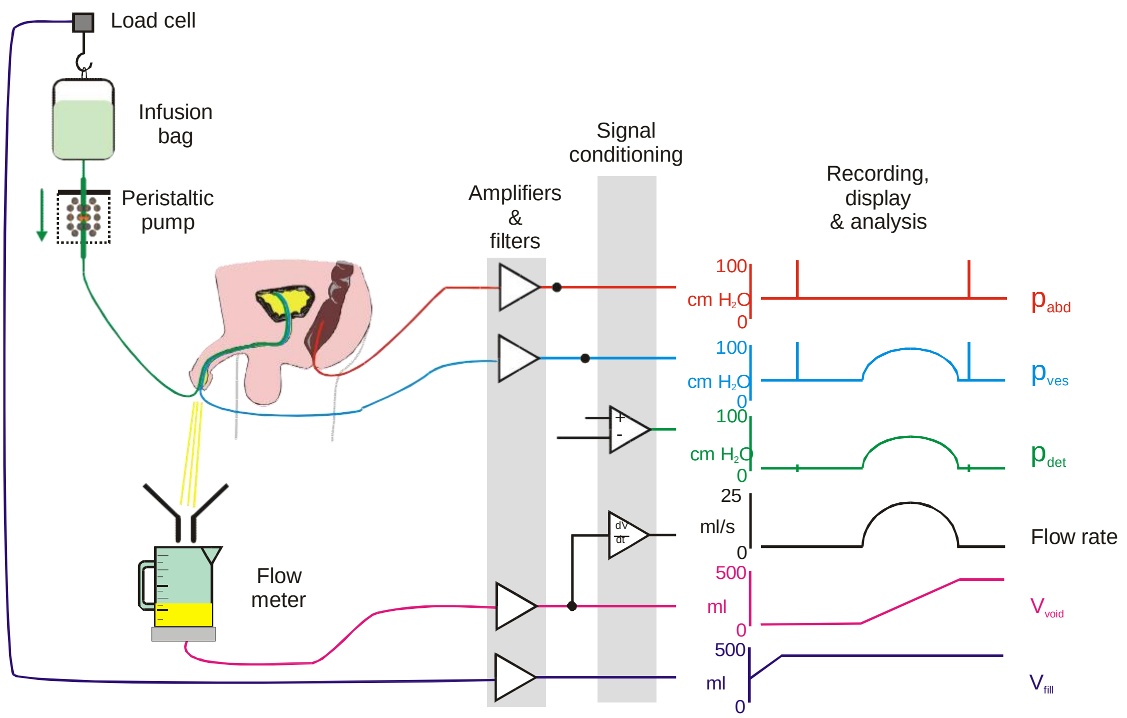
An abnormal urine flow is a key symptom of a urological complaint, but does not indicate the cause. In very general terms, the flow rate is affected two factors:

- The driving pressure from the bladder;
- The opposition to flow presented by the outlet.

Therefore, symptoms of hesitancy or a poor flow rate might be due to: a weak bladder contraction.
*Or equally, due to: a*n enlarged prostate (*right*) producing a large obstruction to flow.

The need for bladder contraction information

Clearly, a flow rate alone is not enough to distinguish these conditions. You need to measure bladder pressure as well. The picture shows the constituents of a basic urodynamics system.



The general idea is to fill the patient using a bladder line, and then ask him to void. Meanwhile, you record flow rate, and the bladder pressure required to generate the measured flow. In men, a low flow with a high bladder pressure is indicative of prostatic obstruction.

But…

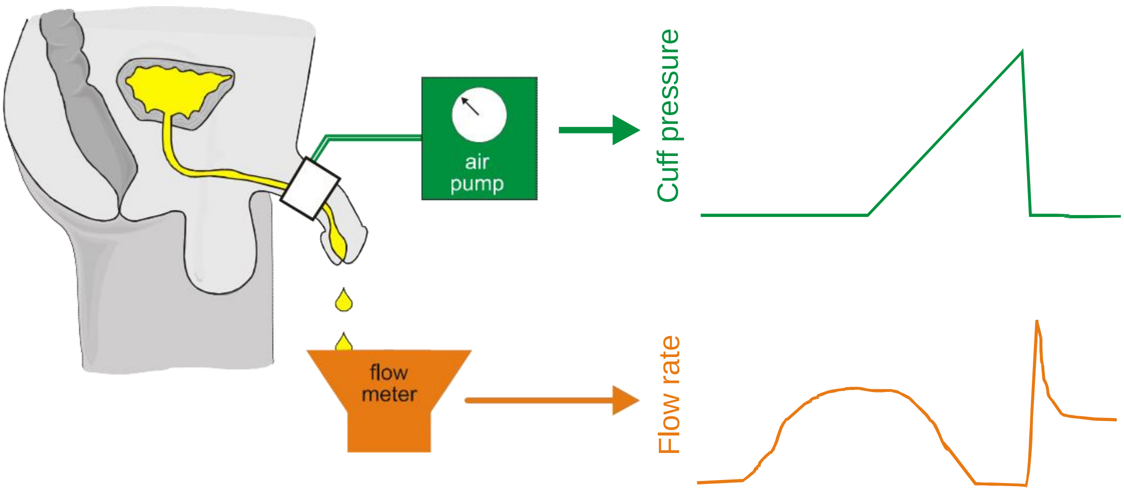
This measurement (cystometry) is time-consuming, unpleasant, and carries some risk for the patient. Some urologists believe these negative factors outweigh the usefulness of the information gained from the test, and would proceed to treatment without a definite diagnosis of obstruction (van Mastrigt & Pel, 1999).

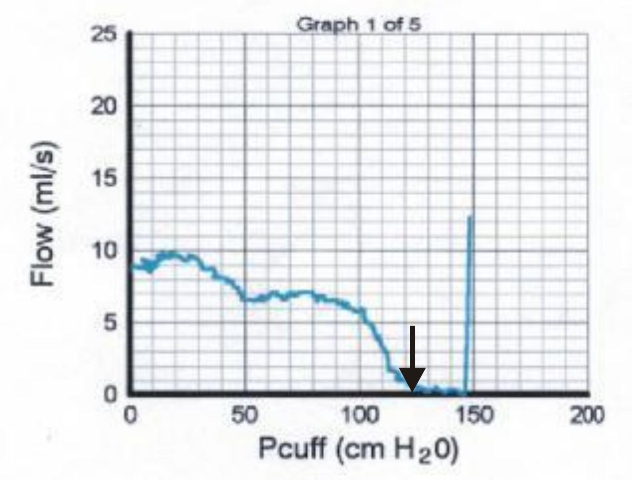
Principles of the UroCuff Test

The UroCuff Test is intended as an adjunct to a conventional flow study. While it is _not_ a replacement for cystometry (which still remains the best gold standard), the UroCuff Test gives information on bladder contraction pressure and it can therefore be used in some cases to confirm the likely diagnosis of obstruction, while avoiding the need for full cystometry.

The principle of the test is similar to blood pressure measurement. When the patient is ready to void, a small pneumatic cuff is fitted round the penis. When voiding has commenced, the cuff is inflated under automatic control until the stream is interrupted. The cuff pressure required to interrupt flow should equal bladder pressure at the time of interruption (Griffiths *et al*, 2002; Drinnan *et al*, 2003a).

Then cuff pressure is quickly released, allowing flow to resume. The cycle is repeated until voiding is complete.





The UroCuff instrument plots a graph of flow rate versus cuff pressure, to enable the cuff pressure to be determined at the moment when flow stopped *(left).* This forms our estimate of bladder pressure - 125 cm H_2O in the example.

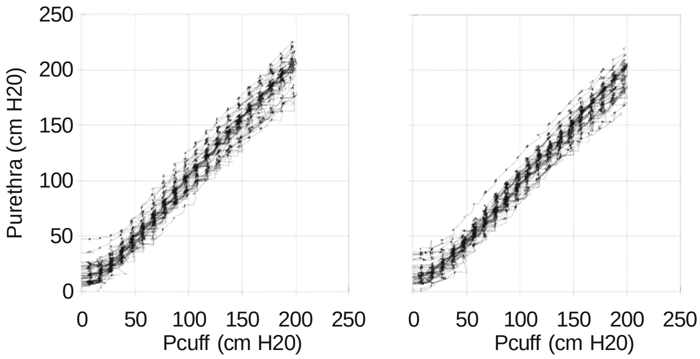
Because the measurement is made when flow is zero, the test measures *isovolumetric* bladder pressure.

Principles underlying the UroCuff Test

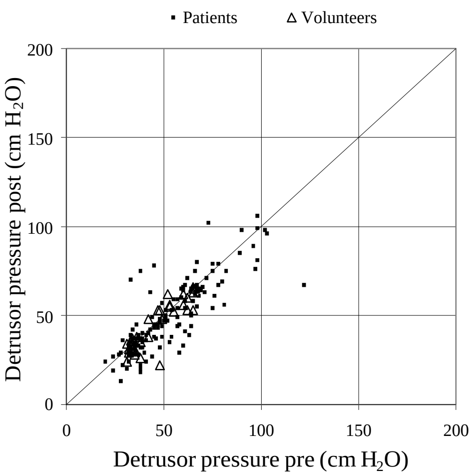
To work properly, the Urocuff Test depends on three key principles:

Inflation pressure in the penile cuff is transmitted to the penile urethra

First, pressure in the cuff must be transmitted to the penile urethra so that when cuff pressure exceeds the fluid pressure, flow stops. To this end, we have made simultaneous measurements of cuff and urethral pressure for a range of cuff materials and sizes (Drinnan *et al*, 2001a). The figure shows this relationship for the two cuff widths finally used - 38mm (*left*) and 48mm (*right*).



The bladder maintains its contraction throughout the test

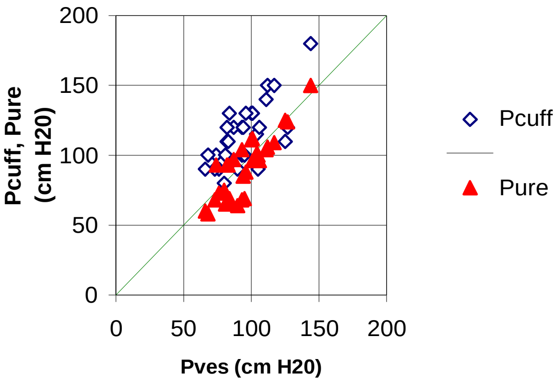


When the flow stops, it is important that the bladder contraction be maintained during the interruption. To test this hypothesis, we used conventional cystometry lines to measure the detrusor pressure immediately before and after the cuff test (*left*) in 135 cuff measurements from 31 subjects (McIntosh *et al*, 2003a).

There was a detectable but clinically insignificant mean decrease of 4 cm H_2O, which was probably due to the expected decline in bladder pressure through the void.

The urethra acts as a fluid-filled catheter

Finally, when the flow stops, there must be a continuous column of fluid between the bladder and the urethra next to the cuff so that the urethra serves as a fluid filled catheter for the purpose of the test.

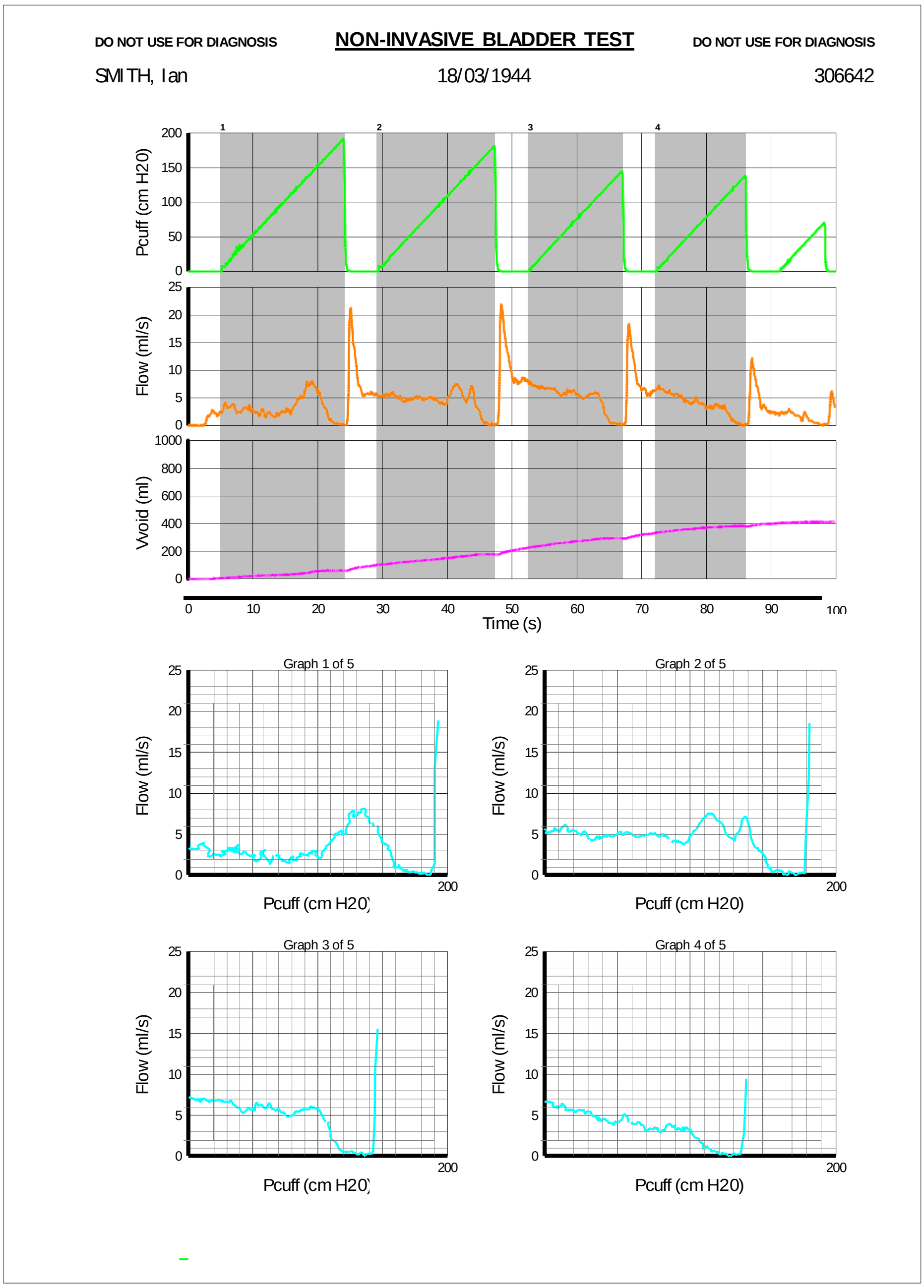


In 11 patients we used a triple-lumen catheter to measure cuff and urethral pressures at the time of flow interruption (Drinnan *et al*, 2001b). This figure shows that the three pressure measurements were closely related, giving evidence that the pressure in the bladder is transmitted along an open urethral lumen.

In addition, we have conducted simultaneous video cystometry in a limited number of subjects. We have yet to observe a subject where the urethra closed during the test.

The UroCuff instrument printout

The UroCuff instrument produces a printout like the one shown below. In the top half of the page are the original cuff pressure (*green*), flow rate (*orange*) and voided volume (*magenta*) signals. The shaded grey areas correspond to periods when the cuff was actively inflating, as can be judged from the rising cuff pressure. Beneath are the four graphs of flow versus cuff pressure, corresponding to the four shaded areas of cuff inflation. From these graphs can be estimated the bladder pressure at the point of flow interruption.

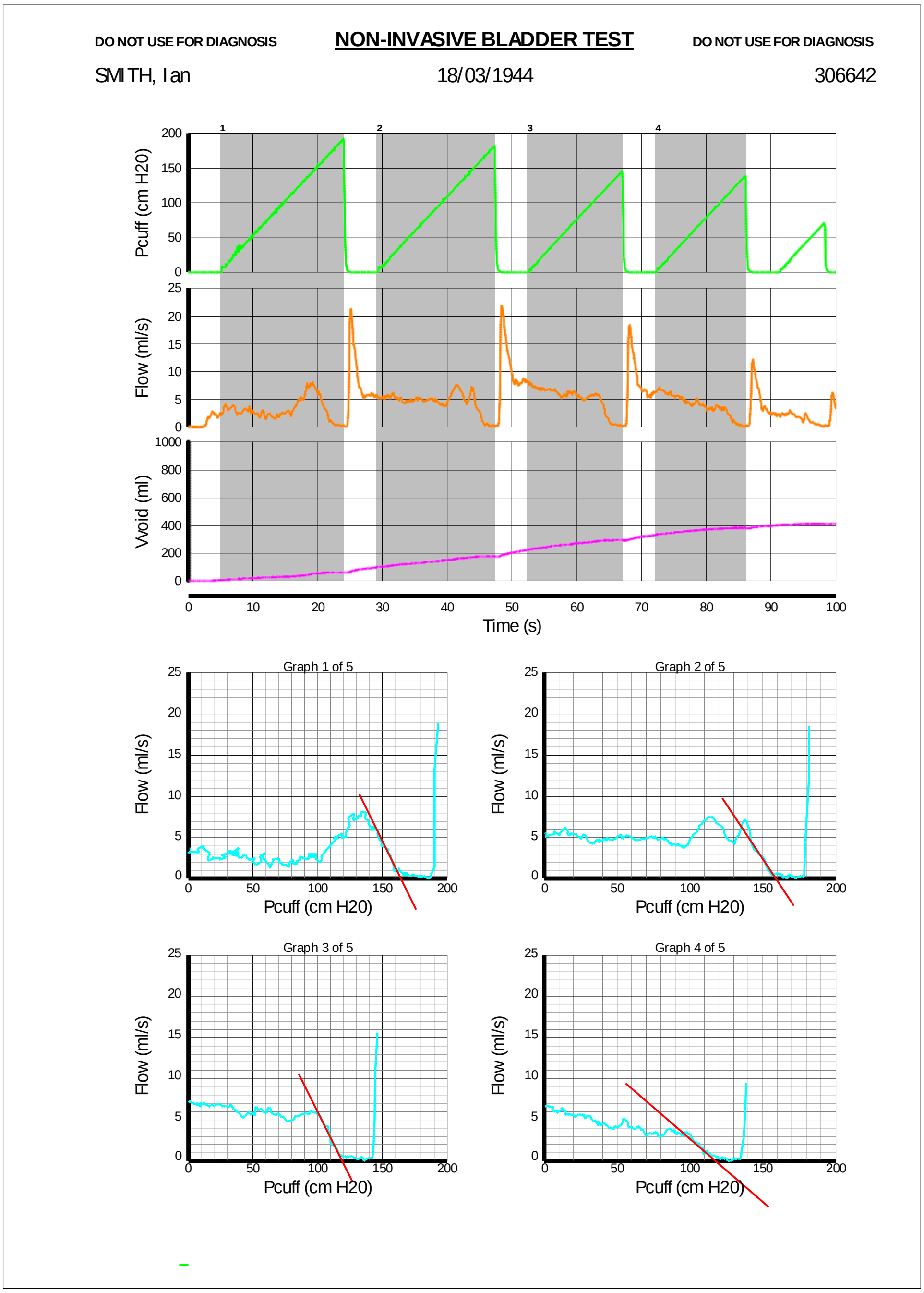


NOTE: There is a fifth inflation shown at the top of this page, but not shaded in grey. The corresponding graph of flow versus cuff pressure will be shown on the next page printed by the cuff machine.

Estimation of cuff interruption pressure

For interpretation of the measurements, the UroCuff instrument extrapolates the downward slope of the *flow* versus *Cuff pressure* graph, and estimate where it would reach zero flow.

This example shows four cuff measurements where it is relatively easy to estimate the interruption pressure. In each case, the red line shows our 'best fit' to the downward slope.



We would automatically accept these four inflations and make estimates of 160, 160, 120 and 115 cm H_2O respectively for interruption pressure in the four graphs. There are certain inflations in which the system does not automatically accept the inflation or does not automatically make interrupt estimates.

Exclusion rules

In the example, all the cuff inflation cycles are easy to interpret. In other cases, we do not automatically accept the inflation and estimate interruption pressure.

An inflation cycle should be excluded immediately if:

(1) There was no recovery of flow after cuff deflation

When the cuff is released after an inflation cycle, one normally expects a brief surge of urine stored in the proximal urethra, followed by the resumption of flow. This is seen clearly in the printout on the previous page. If there is no flow recovery, this indicates that the void finished sometime during the current inflation cycle, and that the cuff may not be responsible for stopping the flow.

(2) There was an erratic flow trace, leading to ambiguity about the cuff pressure at flow interruption

In some cases the flow trace is erratic, making it difficult to estimate accurately the exact moment of flow interruption. As with uroflowmetry, we have some evidence that this may be due to straining, and we also suspect contractions in the pelvic floor or membranous urethra.

Manually accepting or rejecting an inflation

Immediately after the cuff test, the clinician can review each inflation and manually accept or reject an inflation and/or manually adjust any of the interrupt pressures or flow rate.

Review of the entire void

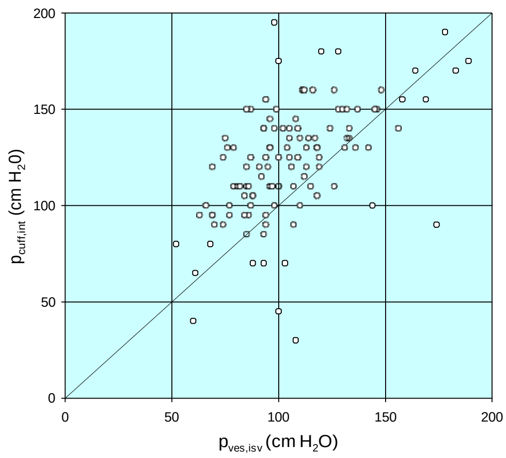
As with many clinical tests, there are times when an apparently genuine measurement is inconsistent with other measurements in the same subject, and it is appropriate to treat the erratic measurement with suspicion. In the cuff test this might be due to the cuff slipping (leading to an artificially high value of pressure) or a mid-void contraction of the pelvic floor muscles (leading to an artificially low value of pressure).

According to current urodynamic theory, one would expect a relatively constant value of bladder pressure, which may however diminish towards the end of the void, and indeed this is our experience. The repeat measurements through the void give the observer an opportunity to assess the repeatability of the test, and to discard measurements that are clearly out of keeping with the rest of the void.

Validation studies

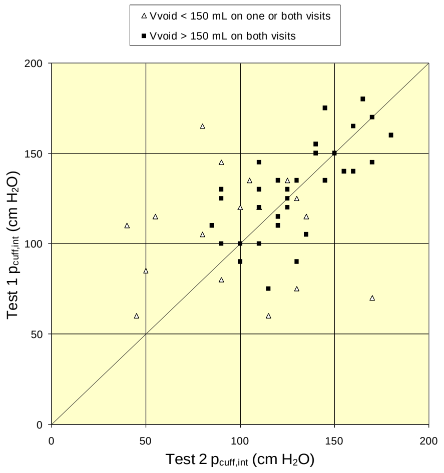
Agreement of cuff interruption pressure with true bladder pressure

As we have said, the cuff interruption pressure should give an estimate of the simultaneous value of isovolumetric bladder pressure. In 153 patients we performed the cuff measurement with simultaneous invasive cystometry (McIntosh *et al*, 2003). For each cuff inflation cycle we estimated the cuff pressure $p_{cuff,int}$ at which flow was reduced to zero, and from the cystometry data measured the simultaneous bladder pressure $p_{ves,isv}$.



The results are shown in the figure; on average, $p_{cuff,int}$ over-estimated $p_{ves,isv}$ by 16.4 ± 27.5 cm H_2O, and possible reasons for the discrepancy are discussed later.

Test-retest repeatability



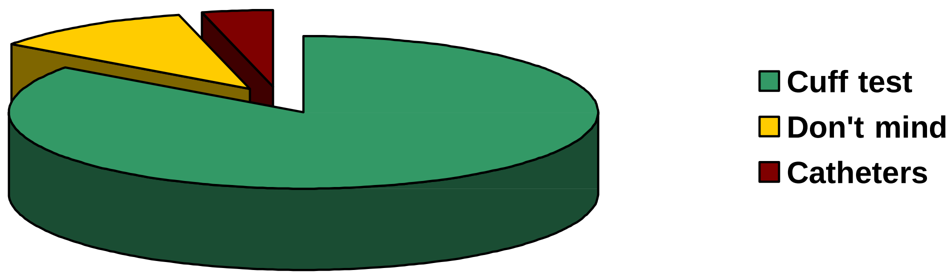
In the same study (McIntosh *et al*, 2003), a proportion of patients agreed to return for repeat cuff tests without invasive cystometry lines. The graph shows the relationship of the two measurements in the same individual.

In common with flow rate measurements, note that within-patient reproducibility is better for voided volumes of 150 ml or more.

We therefore recommend that where the voided volume is < 150 ml, the test be repeated.

Acceptability of the test

In the clinical study 85% of patients expressed a preference for the non-invasive cuff test (Robson *et al*, 2002), as shown in the figure below. Younger men and men with very powerful bladder contraction may experience brief discomfort at the time of interruption.

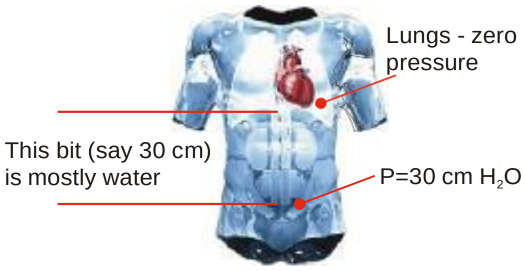


Abdominal pressure and straining

One of the key features of cystometry is the provision of a rectal line, for measurement of abdominal pressure. Since the UroCuff Test is non-invasive, it does not provide any measurement of abdominal pressure, and we have considered the potential implications.

The origin of abdominal pressure

The resting pressure in the abdomen is caused by the weight of body tissues sitting within the abdomen. Since the lungs and diaphragm must be at (approximately) atmospheric (zero) pressure, and the body is largely water, you might estimate a resting pressure (in an upright patient) as the distance from the diaphragm to the pubic symphysis (*below*).



Detrusor versus vesical pressure

In conventional cystometry, subtracted or detrusor pressure is the most commonly quoted measure of bladder contraction. Detrusor pressure is determined by subtracting the abdominal pressure from the vesical pressure; the vesical pressure p_{ves} is that actually measured in the bladder. As it turns out, abdominal pressure (from a rectal line) is reasonably consistent between individuals; the mean (±SD) abdominal pressure during voiding for 76 patients was 35 (±9) cm water, and this agrees with other similar studies. There is a detectable effect due to the patient's weight, but this is too small to be of clinical importance (McIntosh *et al*, 2003b).

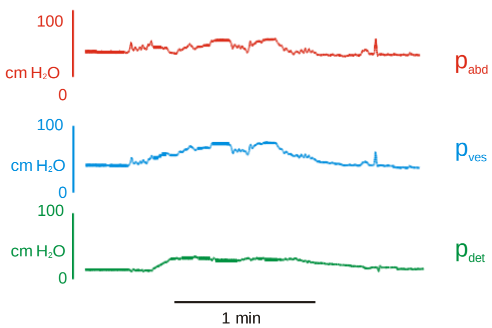
In the UroCuff Test, there is a further small offset because the cuff is positioned typically 8 cm below the pubic symphysis, the datum for invasive measurements. Beneath the cuff, the fluid pressure measured will be correspondingly 8 cm H_2O higher due to the hydrostatic gradient.

In principle, it would be possible for the UroCuff instrument to apply an automatic correction for these factors. In practice, we prefer to present the data *as recorded*.

The cuff pressures will therefore be higher than the detrusor pressures in the same individual, which means the measurements must be interpreted differently.

Abdominal straining

Straining is a way for the patient to generate an artificially high bladder pressure by contracting the abdominal muscles.



In conventional cystometry, the strain has little or no effect on the subtracted detrusor pressure.

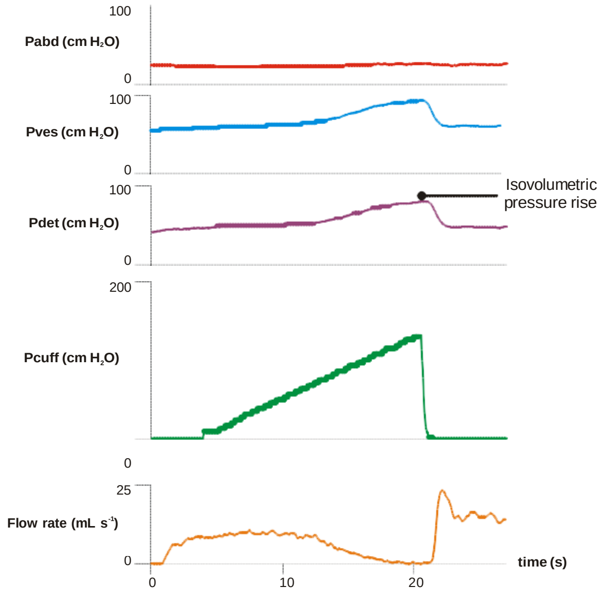
In addition, the abdominal pressure line gives a clue about straining. In the example (*left*) recorded during a voiding phase, there is a clear rise in p_{abd} due to the strain.

For the UroCuff Test, straining *will* affect the measured pressure, and can be detected utilizing The UroCuff's abdominal EMG measurement system.

During trials with invasive lines, patients were asked not to strain. When the request was made in terms they understood, 83% were able to comply, as judged from their abdominal pressure measurements.

Bladder contractility and isovolumetric pressure

As we have already said, the UroCuff Test estimates *isovolumetric pressure*. The *isovolumetric pressure* is the pressure in the bladder when flow is *completely stopped*, and is therefore an indicator of bladder contractility under known conditions



The figure shows invasive data recorded during a UroCuff Test. As the cuff is inflated (*green trace*), the flow is reduced and finally stops (orange *trace*). At this point, the isovolumetric detrusor pressure can be read from p_{det} (*purple trace*).

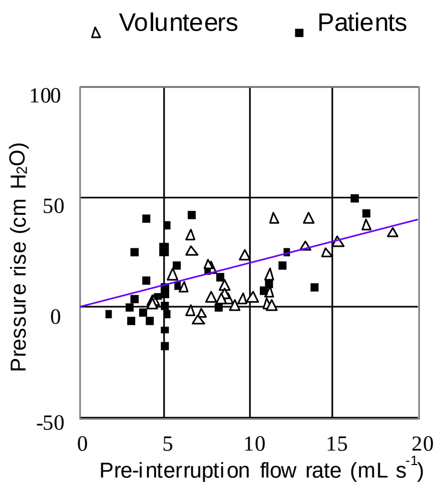
As the flow was stopped, the detrusor pressure p_{det} (~90 cm H_2O) has clearly risen from its original value (~50 cm H_2O).

This can be thought of as the bladder's response to the increasing obstruction, but in fact can be explained by the Hill equation and the bladder physiology.

There is an extremely sound theoretical basis for measuring isovolumetric pressure, and some authorities (Griffiths & van Mastrigt, 1985; Comiter *et al*, 1996) would claim it is a more appropriate measurement of bladder contractility than the more common $p_{det,Qmax}$, which is measured at maximum flow.

However once again, this isovolumetric pressure rise means that pressures measured using the UroCuff Test will be higher than those from a conventional cystometry.

Magnitude of the isovolumetric pressure rise



To assess the effect of the isovolumetric pressure rise on the cuff measurement, we have assessed the relationship between isovolumetric pressure and pressure at maximum flow in three separate studies.

One set of results is shown in the figure (*left*), with the best fit shown in blue; the effect amounts to a pressure rise of 2cm H_2O for each 1ml/s reduction in flow, and this value was extraordinarily consistent (within 5%) between the three studies.

Using this statistic, an allowance can be made in the construction of a specific nomogram for the non-invasive data (Griffiths *et al*, 2003). This is considered next.

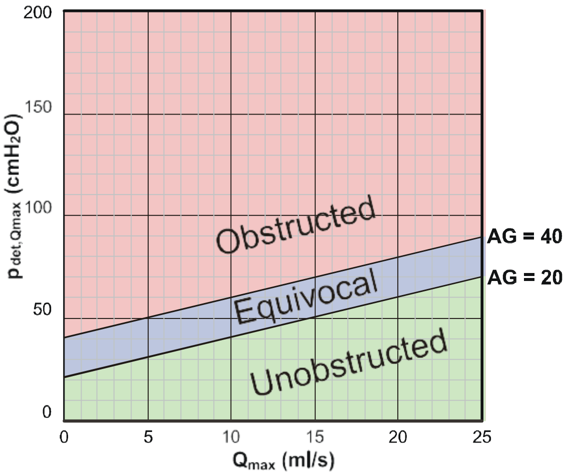
Using the data – the case for a modified ICS nomogram

The ICS nomogram

The ICS nomogram (*right*) is similar to earlier nomograms produced by Paul Abrams & Derek Griffiths, and by Werner Schäfer. The stages in using the ICS nomogram are as follows:

- Determine Q_{max} from cystometry;
- Determine $p_{detQmax}$ from cystometry;
- Plot a point on the nomogram using those values.

The point will lie in one of the regions *unobstructed*, *equivocal* or *obstructed*.



A comparable UroCuff Test nomogram

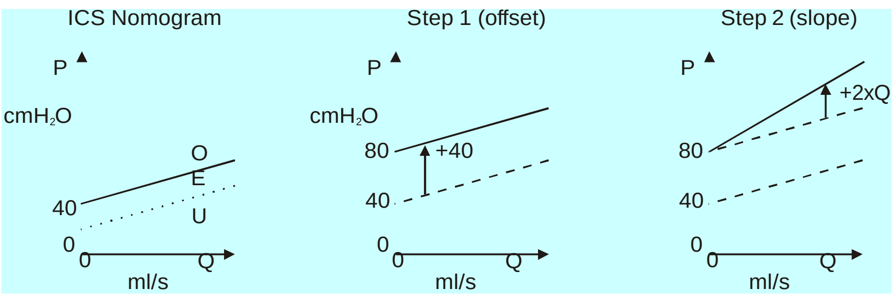
Using the ICS nomogram as a starting point, a comparable nomogram can be constructed for the UroCuff Test. Since the ICS, Schäfer, Abrams and Griffiths all agree on the position of the uppermost (*obstructed* versus *equivocal*) line, we use this as the starting point. {A similar argument could be applied to the lower line, when the authorities finally agree on its rightful position.}

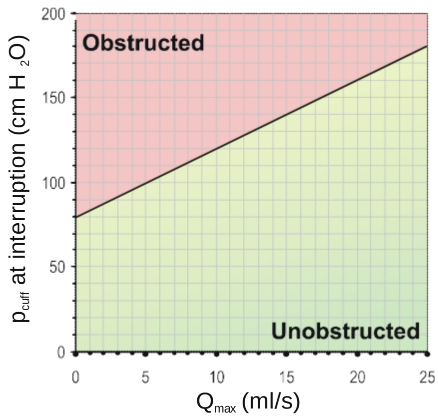
To recall, the pressures recorded by the UroCuff Test will be higher than those from cystometry. To allow for these differences, the ICS nomogram can be modified in 2 steps:

STEP 1 In the cuff measurement, the abdominal pressure component has not been subtracted. This means that 'cuff' pressures will be higher than 'cystometry' pressures by about 40 cm H_2O

***STEP* 2** In the cuff measurement, pressures are measured at zero flow, and due to the isovolumetric pressure rise will be higher than those in cystometry at full flow. We estimate this effect is about 2 cm H_2O for every 1 ml/s flow, and this affects the slope of the line.

The effect of these two steps is shown pictorially in the diagram…→

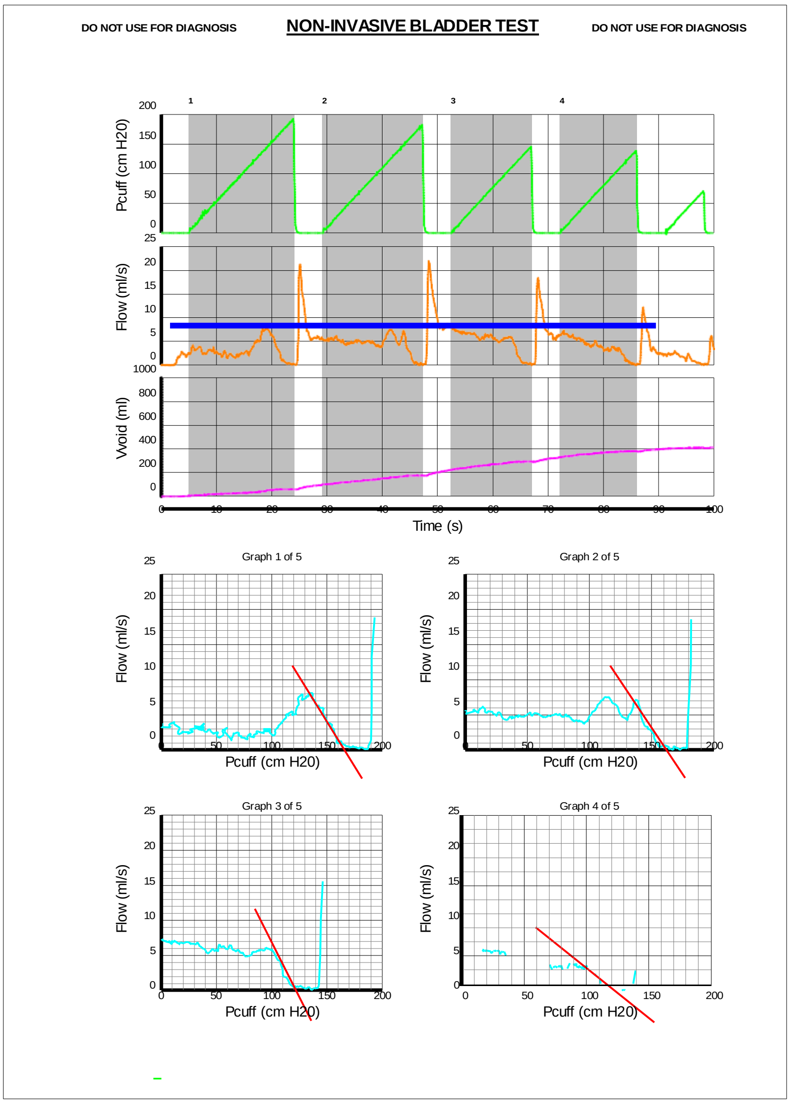




←…and the result is a new nomogram that looks like this.

This is the modified ICS nomogram.

Using the modified nomogram



In the earlier example (reproduced *left*), we made estimates of 165, 160, 120 and 120 cm H_2O interruption pressure in the four graphs.

We take the largest as the peak interruption pressure, representing the patient's best bladder contraction:

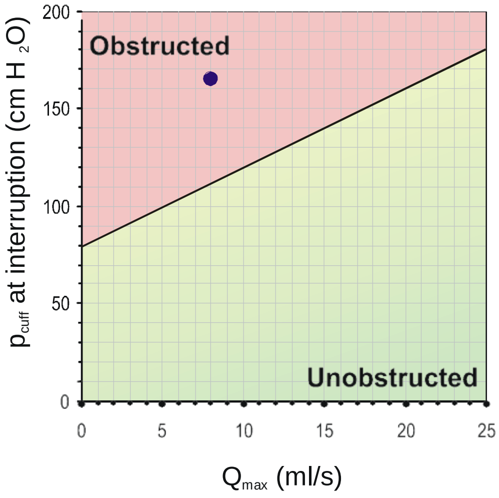
$$p_{cuff,int} = 165 \text{ cm } H_2O$$

We have also added our estimate of peak flow to the flow trace:

$$Q_{max} = 8 \text{ ml/s}$$

Note that we ignore the surge of urine occurring every time the cuff is released.

It now remains to plot the point, exactly as for the ICS nomogram…→

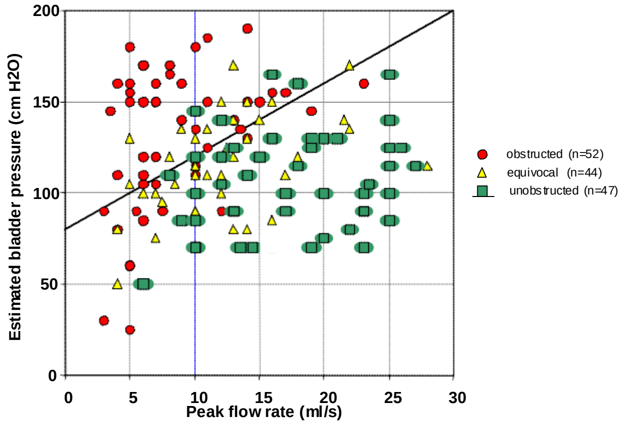


…so we think this patient is obstructed. And

that's it.

The Newcastle – Bristol validation study

To validate this new nomogram, we present data from 143 subjects who had free cuff tests (ie. *without* simultaneous cystometry) in either Newcastle or Bristol. Each was also classified according to the ICS standard using invasive cystometry, giving rise to the red, yellow and green colors of the points plotted.



Since it was derived from the equivalent line on the ICS nomogram, the line on the modified nomogram ought to separate *obstructed* subjects (above the line) from *equivocal* and *unobstructed* patients (below the line).

For a long time, standard flow rate criteria (Q_{max}<10 ml/s, indicated by the blue line on the graph) have been used to diagnose obstruction. The table below summarizes the classification for the UroCuff Test, and for the flow criterion.

	Sensitivity	Specificity	PPV	NPV
Modified ICS Nomogram	69%	82%	68%	81%
Qmax < 10 ml/s	63%	84%	69%	80%
For the 68% of patients where flow classification and cuff classification agree:				
Combined cuff & flow	76%	94%	85%	90%

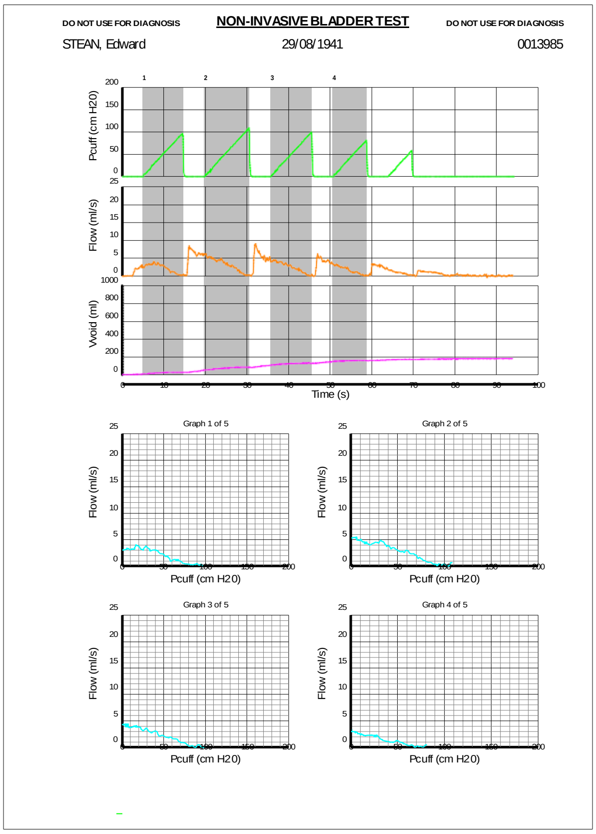
At present, we believe this indicates the most useful algorithm for using the UroCuff Test:

- *If flow and cuff measurements agree the patient **is obstructed**, there is an 85% probability they **are obstructed**.*
- *If flow and cuff measurements agree the patient **is not obstructed**, there is a 90% probability they **are not obstructed**.*
- *In the 32% of patients where flow and cuff measurements disagree, the patient may be referred for cystometry.*

On this basis we repeat our earlier statement: *The UroCuff Test is an adjunct to a conventional flow study. It is not a replacement for cystometry (the best gold standard), the UroCuff Test gives some information on bladder contraction pressure. It can be used in some cases to confirm the likely diagnosis of obstruction, while avoiding the need for full cystometry.*

Example recordings and interpretation

Some typical good recordings



This is typical for a good UroCuff Test. The key points are:

- Flow stops on every inflation;
- Flow recovers after the cuff is deflated, as seen in the top panel.
- There is no ambiguity about the cuff interruption pressure.

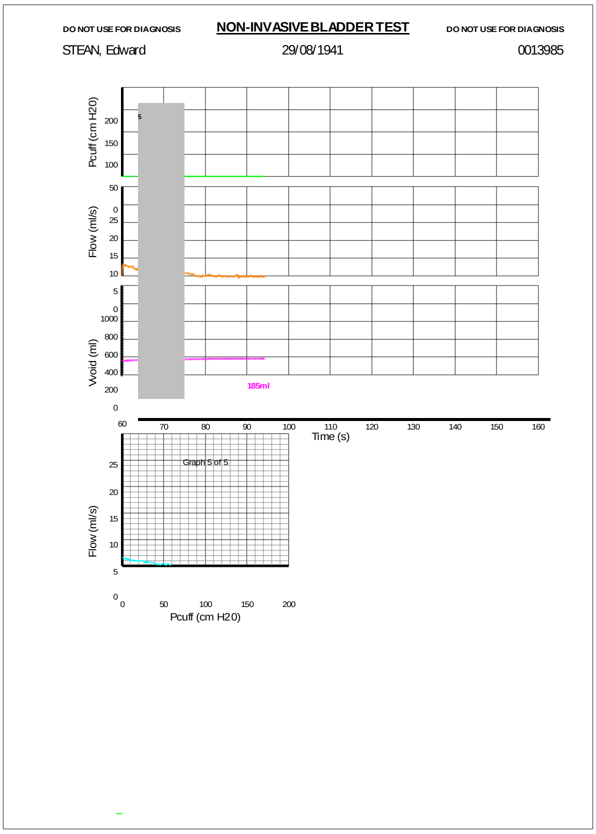
The UroCuff instrument makes calculations of 70, 85, 80 and 60 cm H_2O for the cuff interruption pressures.

These are broadly consistent with each other, and so we would accept this as a good UroCuff Test.

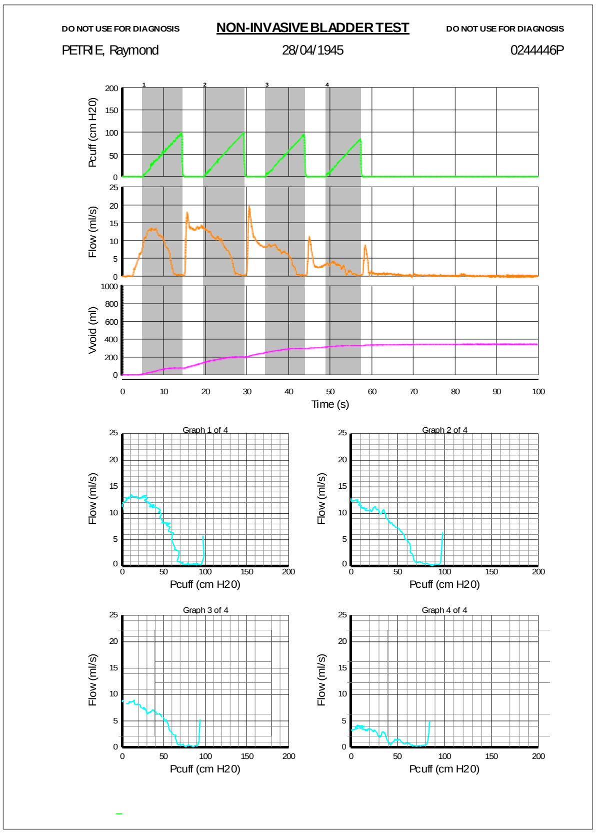
In conjunction with a peak flow of around 6 ml/s, we would classify this patient *unobstructed*, but only just. In fact, this patient was unobstructed on cystometry, but had DI.

For completeness, here is the final inflation from the same patient:

In this case, there is little or no flow recovery after the inflation. The void is complete, and the UroCuff instrument excluded this inflation according to the rules.



More good recordings



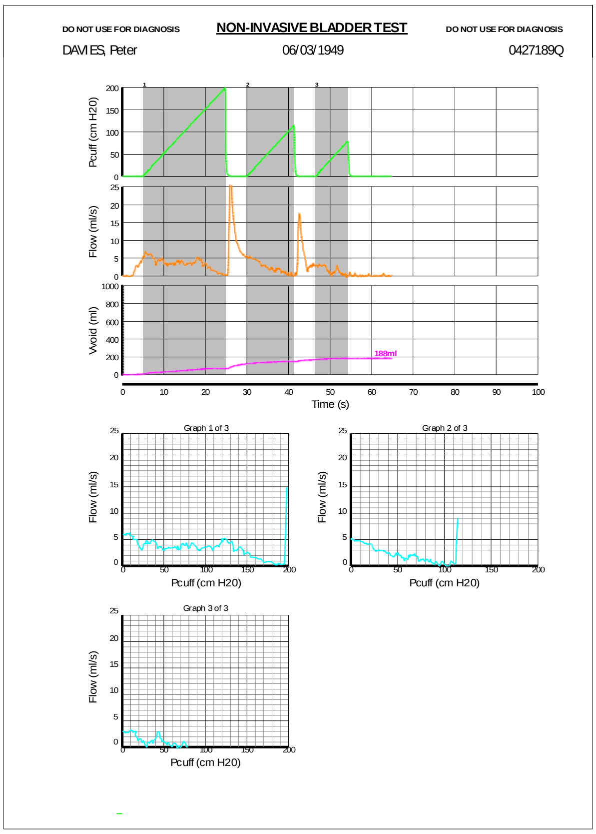
This is another one in the same vein:

- The UroCuff instrument calculates the peak flow Q_{max} to be around 13 ml/s.
- The UroCuff instrument calculates measurements of 70, 70 and 65 cm H_2O for the first three cuff interruption pressures.
- Flow does not recover after the fourth inflation, and so the system excludes it according to rule 1.
- According to the nomogram, this patient is more clearly unobstructed. On cystometry, his AG number was 8.

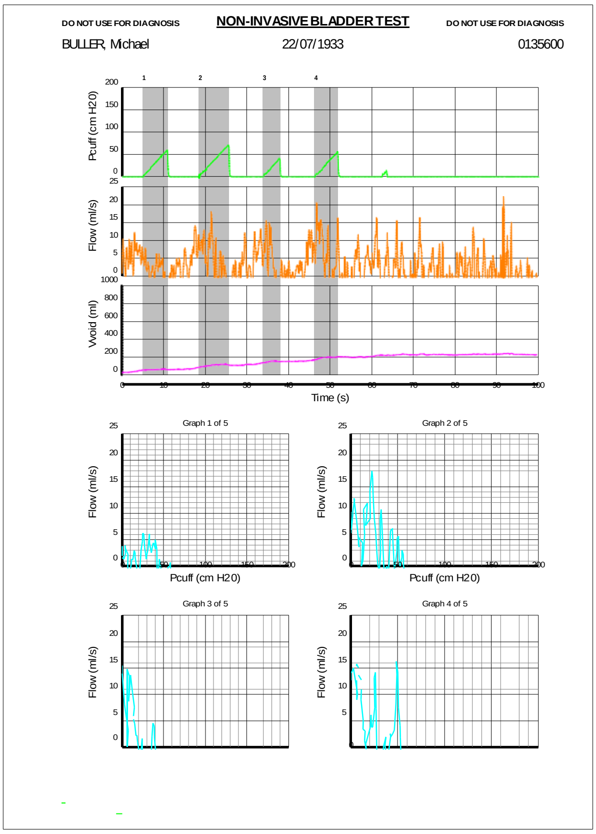
And another. For this one, the instrument calculates measurement of 175 cm H_2O from the first inflation, with a peak flow of 6 ml/s. This makes the patient *obstructed*, as was demonstrated on cystometry by an AG number of 85.

The second inflation would be acceptable, but the pressure is by this time diminishing towards the end of the void.

The system excludes the third inflation because there was no recovery of flow afterwards.



Applying the exclusion criteria - rule 2 (ambiguous interruption pressure)



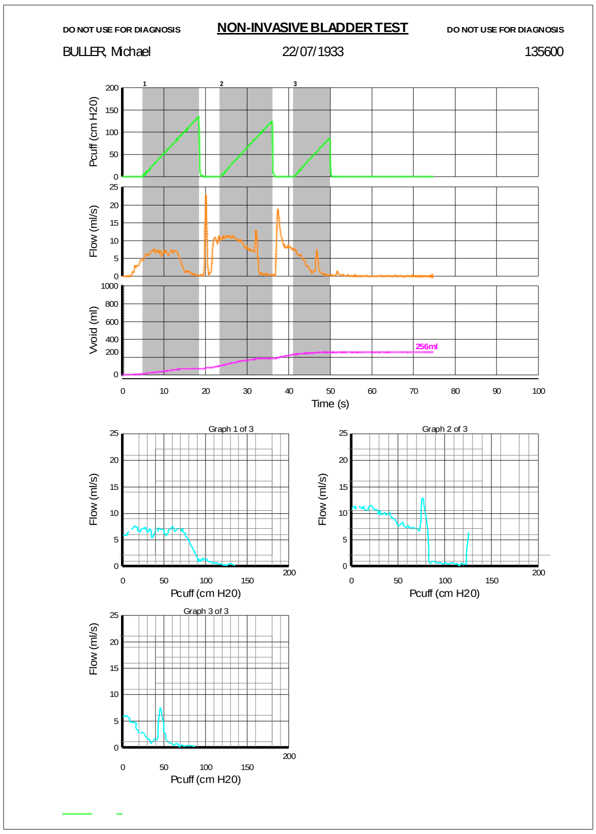
In this one, the interruption pressures are anybody's guess.

On cystometry his AG number was 33 (equivocal), so this might be straining secondary to outlet obstruction.

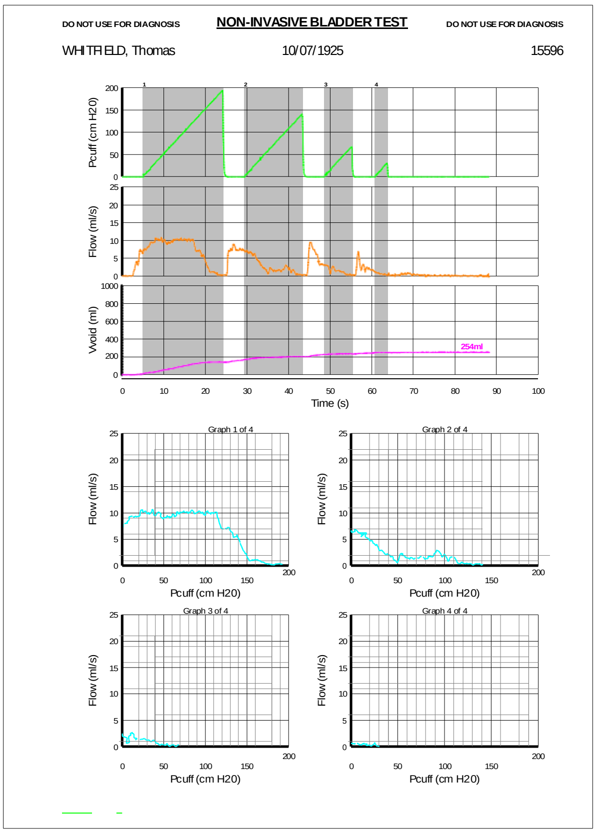
Or maybe he was leaning on the flow meter.

In any case, you would ask the patient to try again without straining and without touching the flow stand:

- This is the result - usable values of 90 and 85 cm H_2O from inflations 1 and 2.
- Inflation 3 is excluded because there was no recovery of flow.
- With a peak flow of 11ml/s, he would be classified *unobstructed* by the nomogram, but lies in the area close to the dividing line.



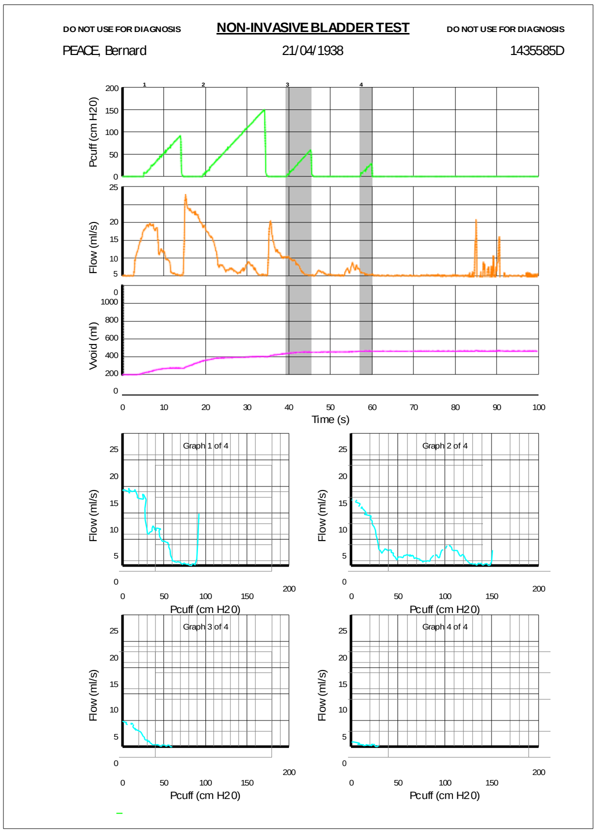
Applying the exclusion criteria - rule 2 (ambiguous interruption pressure)



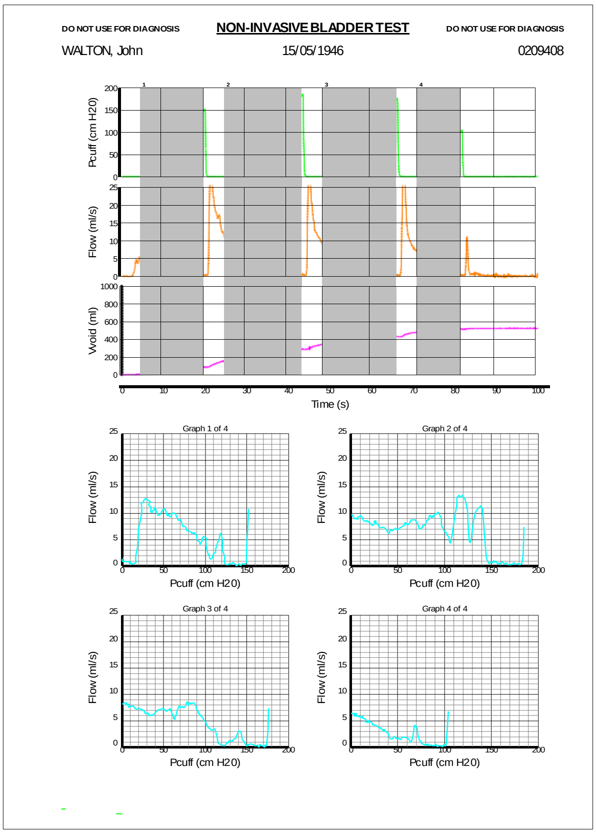
- Here, inflation 2 gives a good example for the application of rule 2.
- In this case, measurements of 50 and 115 cm H_2O are both possible candidates.
- The system would therefore exclude inflation 2 in favor of a measurement of 155 cm H_2O from inflation 1.
- With this high bladder pressure giving a a peak flow of 10 ml/s, this patient was classified *obstructed*. On cystometry, his AG number was almost 60.

Here's another example of the same thing.

- The system would exclude inflation 2 in favor of a measurement from inflation 1.
- Inflations 3 and 4 are both excluded for lack of flow recovery.
- A peak flow of (about) 15 ml/s for a pressure of (about) 65 cm H_2O makes this patient *unobstructed*. This agrees with cystometry.



Some more difficult recordings (1)



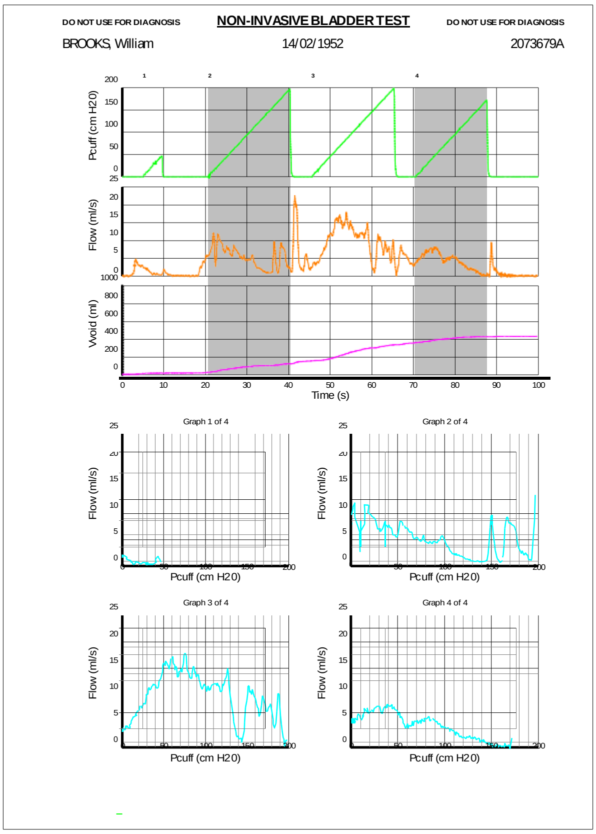
We suspect this patient was straining from the erratic flow trace.

- For inflation 1, it would initially seem the cuff interruption pressure should be around 110 cm H_2O, but the final kick causes some ambiguity.
- For inflation 2, there is again an erratic flow, though a pressure of 145 cm H_2O seems reasonable.
- Inflation 3 follows the expected pattern; the final kick is half-hearted, and we'd probably ignore it.
- Flow does not recover after inflation 4, and so it is excluded.

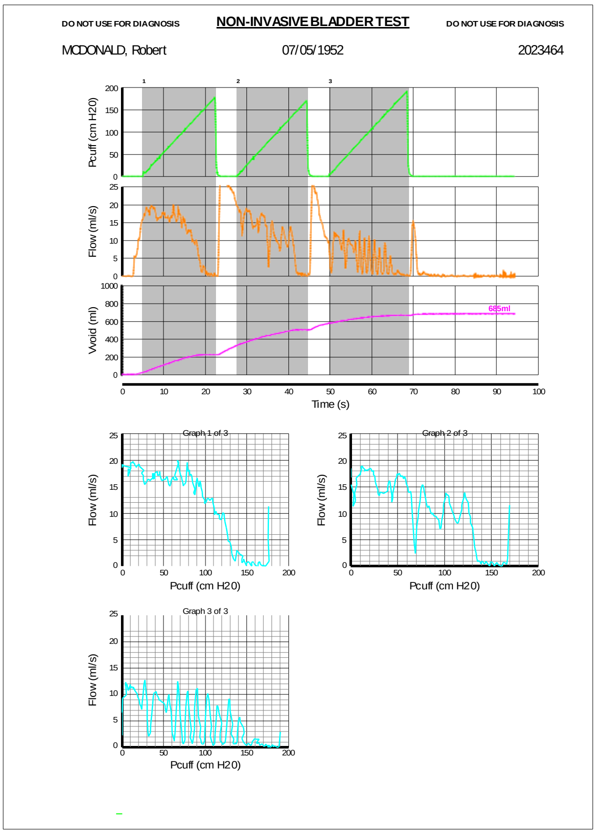
On review, inflations 1, 2 and 3 seem consistent with each other, and so we would be happy to use these results. A pressure of 145 for a peak flow of 10

Here's another difficult example:

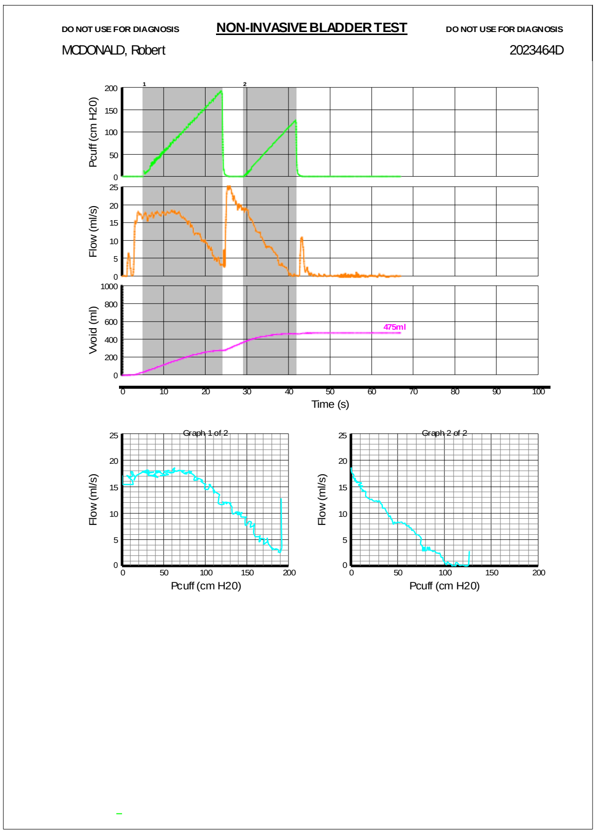
- We could reject inflations 2 and 3 on the grounds that they are ambiguous.
- We should also reject inflations 1 and 4 because there is no flow recovery.
- However - for inflations 3 and 4 we can say the interruption pressure is *not less than 140 cm H_2O.*
- For a peak flow of 14 ml/s, this would put the patient just into the *obstructed* category. On cystometry, he was *equivocal*.



Some more difficult recordings (2)

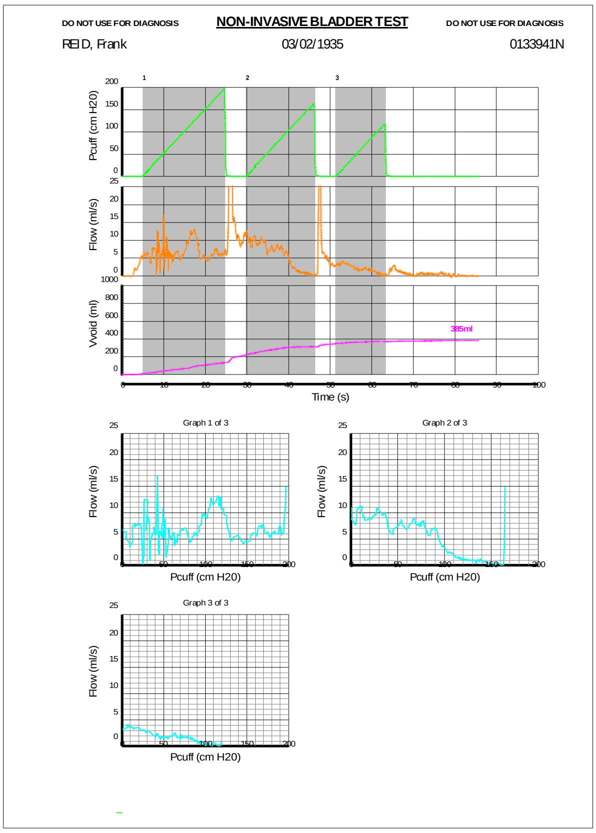


- This is one where we think the patient was straining (inflation 3). Even if they weren't flow didn't recover so we would exclude the inflation.
- We would also look on inflation 2 with some suspicion.
- We would, however, be happy to make a measurement of 135 cm H_2O from inflation 1.
- In conjunction with a peak flow of perhaps 15 ml/s, this patient would be close to the dividing line on the nomogram.



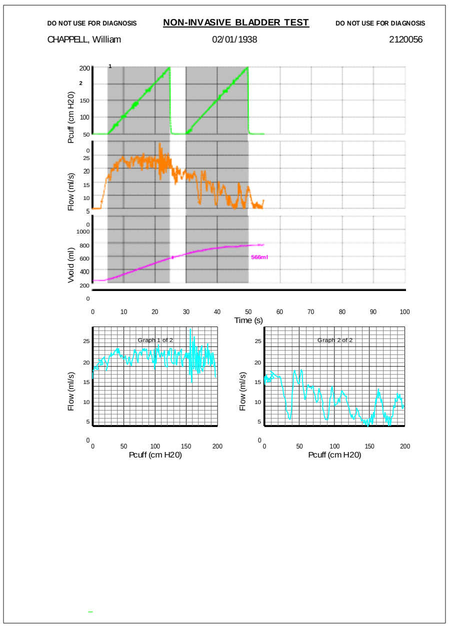
- On this one (from the same patient on a later date), you might be tempted to exclude the first inflation on the grounds that flow doesn't stop.
- But you would also exclude the second inflation because flow doesn't recover.
- In practice, it is clear that inflation 1 was following the normal pattern.
- You could even make an estimate of the interruption pressure, at least 200 cm H_2O. We would be happy to use this pressure.

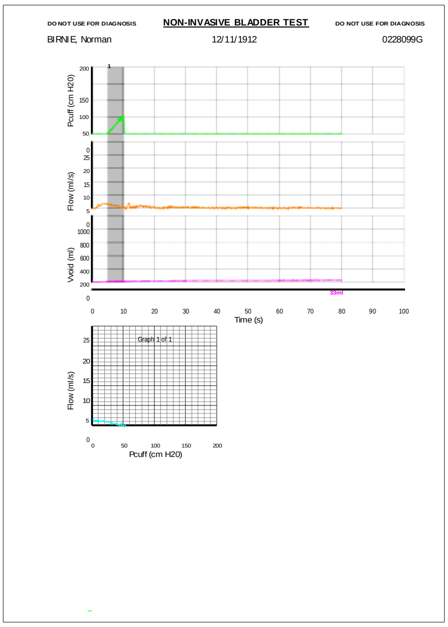
Some more difficult recordings (3)



- In this example, the peak flow is difficult but around 9-10 ml/s seems reasonable.
- We would not attempt to analyse inflation 1. It would be excluded on the grounds of high variability (rule 2).
- Inflation 2 is usable, and we would estimate $p_{cuff,int}$ = 120 cm H_2O.
- Inflation 3 would probably be excluded because flow does not recover afterwards (rule 1).
- For a maximum flow rate of 10 ml/s, this patient would lie right on the line. On cystometry, he had an AG number of 75, which means *extremely obstructed*.

Who knows what to do with these two? We would probably cut our losses and try to repeat the tests.





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