

## International Continence Society Guidelines on Urodynamic Equipment Performance

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These guidelines provide benchmarks for the performance of urodynamic equipment, and have been developed by the International Continence Society to assist purchasing decisions, design requirements, and performance checks. The guidelines suggest ranges of specification for uroflowmetry, volume, pressure, and EMG measurement, along with recommendations for user interfaces and performance tests. Factors affecting measurement relating to the different technologies used are also described. Summary tables of essential and desirable features are included for ease of reference. It is emphasized that these guidelines can only contribute to good urodynamics if equipment is used properly, in accordance with good practice. *NeuroUrol. Urodynam.* 33:370–379, 2014. © 2014 Wiley Periodicals, Inc.

**Key words:** urodynamics; specification; standardization

### INTRODUCTION

The International Continence Society (ICS) published a report on urodynamic equipment in 1987.<sup>1</sup> Since then, technology has changed dramatically, particularly in the application of computers to urodynamics. There is now the possibility that measurement accuracy may exceed clinical need, while new technologies being introduced to the market need benchmarks for assessment of their utility.

This article, developed under the auspices of the ICS Standardization Steering Committee, aims to:

- Summarize clinical performance requirements for urodynamic equipment.
- Relate these to specification and feature requirements.
- Develop technical specification ranges or limits from these requirements.
- Comment on different measurement technologies with respect to limitations and artefacts.
- Propose a set of tests/requirements for assessment of systems.

The readership is intended to be purchasers (to check features are actually necessary), designers (to state what is clinically required) and users (to check that equipment is actually performing). Included, therefore, are technical details, summary lists and some basic descriptions.

This document was developed according to the published methodology of the International Continence Society Standardization Steering Committee.<sup>2</sup> The group commissioned for this report developed an outline of proposed content and revised this in the light of a workshop held at the ICS Annual Scientific Meeting in Glasgow, UK in August 2011. The subsequent text was reviewed by manufacturers of urodynamic equipment before a final draft was discussed at a

workshop during the ICS meeting in Barcelona, Spain in August 2013.

The guideline contains the following sections, which include clinical requirements, measurement technologies and calibration techniques for each parameter. There are also tables for system requirements (features necessary for valid urodynamic measurements) and recommendations (features supportive of good practice).

- Uroflowmetry and voided volume.
- Infused volume.
- Pressure measurement (with special considerations of each parameter measured).
- EMG.
- User interface (recording, display and analysis).
- Standardized performance tests.

The ICS emphasizes that these guidelines can only contribute to good urodynamics if equipment is used properly. For that reason, they should not be assumed to be sufficient in isolation,

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but only alongside training and practice carried out according to the ICS Good Urodynamic Practices document.<sup>3</sup>

The basic requirement of a standard urodynamic system is that it is able to measure at least two simultaneous pressures and, in real time, calculate detrusor pressure, defined as the simultaneous difference between intravesical and abdominal pressures. Furthermore a standard urodynamic system is usually capable of measuring the flow rate of the voided volume and regulating the rate of fluid infusion. In practice there are a number of other measurements, depending on the clinical demands and the urodynamic investigation being carried out, including urethral pressure or electromyography (EMG). Simultaneous recording of pressure measurements with imaging can be required. Other measurements, such as bladder wall thickness, detrusor perfusion, and sound recording are also being researched. This document, however, is limited to equipment performance for the measurement and recording of flow, volume, pressure and EMG only.

When new urodynamic equipment appears on the market, it is recommended that its function is tested with specific equipment in specialized centers. Such tests are described in the section Recommendations for Standardized Performance Tests. All urodynamic equipment should be calibrated and its performance should be tested with procedures that can be carried out by simple means that are readily available. These tests are described in the relevant sections below. When in use, correct calibration of the equipment should be verified regularly.

## UROFLOWMETRY AND VOIDED VOLUME (see Tables I and II)

### Clinical Requirements

**Accuracy.** The accuracy of flow measurement must be sufficient to capture physiological variation. We suggest equipment should be twice as accurate as test-retest variation in individual subjects as a minimum. Studies which have measured test-retest variation have found differences of 1.4–3.3 ml/sec.<sup>6,7</sup> Accuracy should therefore be approximately  $\pm 1$  ml/sec for flow measurement over the clinically important range. In voided volume there should be a resolution of 2 ml or less in order to register leakage, while  $\pm 3\%$  error from true value is acceptable (range taken from market survey carried out by authors). This accuracy value must incorporate all variations due to hysteresis, linearity and temperature between 10 and 40°C.

**Range.** The range of flow measurement necessary is 0–50 ml/sec, with a volume range of 0–1,000 ml.<sup>1</sup> Accuracy should be maintained over this range. The expected clinical range for voiding time is between 14 and 54 sec,<sup>8</sup> while gaps between flows in the same void can occur. Equipment documentation should thus state after what time interval it automatically stops recording and should allow for flows at least 120 sec long.

TABLE I. Essential Requirements for Uroflowmetry

Parameter	Guideline value
Accuracy for flow rate	$\pm 1$ ml/sec
Accuracy for voided volume	The greater of $\pm 3\%$ of true value or $\pm 2$ ml
Range for flow rate	0–50 ml/sec
Range for voided volume	0–1,000 ml
Maximum duration of flow recordable	$\geq 120$ sec
Minimum flow recordable	$\leq 1$ ml/sec
Bandwidth of flow measurement	0 to between 1 and 5 Hz

TABLE II. Desirable Features of Uroflowmetry Equipment

Documentation should state the minimum recordable volume change or flow rate
Equipment should allow the user to set the expected density of voided fluid
Equipment with load cells should not be damaged by loads less than 5 kg
Equipment should allow the user to reset the volume recorded to zero between voids during a test
Documentation should clearly state what filtering or integration is used in signal processing
Equipment should display the delay value used when synchronizing urine flow with pressure signals, preferably allowing modification of the value
An adjustable height urine collection funnel is recommended
In order to reduce flow artefacts, good delivery of the urine stream to the meter is recommended

TABLE III. Essential Requirements for Filling Volume Measurement

Parameter	Guideline value
Accuracy	The greater of 1–5% of true value or $\pm 1$ ml/min
Range	0–1,000 ml
Range of rate of infusion	0–100 ml/min, adjustable during filling
Sample rate of volume measurement	$\geq 2$ Hz

**Registering minimum flow.** It is important that a flowmeter registers clinically relevant low flow rates, for instance in the case of severe bladder outlet obstruction or terminal dribble. Not registering low flow rates may fail to trigger the autostart or terminate the reading prematurely resulting in inaccurate volume measurement and an incomplete clinical picture (especially in the case of uroflowmetry carried out alone). Flowmeters would be expected to measure at least down to the lowest level of accuracy, that is, a flow of 1 ml/sec. It is not essential that flowmeters should measure slower urine loss than this, for example as may occur during leakage, but the minimum recordable volume change or flow rate should be documented.

**Frequency response.** Flow is the result of relatively slow detrusor muscle contractions. The risetime constant of isometric contractions of strips of bladder muscle is in the order of 2 sec<sup>9</sup> and that of isovolumetric bladder contractions in patients is comparable.<sup>10</sup> Therefore the upper limit of the bandwidth of a flow measurement system (to  $-3$  dB) need not be higher than 0.1 Hz and a sampling rate of 0.2 Hz should be adequate to record urine flow rate. However, a higher sampling rate would be desirable to allow the more common artefacts to be represented and recognized<sup>3</sup> and a measurement bandwidth from zero to between 1 and 5 Hz is recommended.

### Measurement Technologies

Flow and voided volume information are interdependent, as one is normally calculated from the other. Currently, load cell

TABLE IV. Desirable Features of Filling Volume Measurement

Equipment should allow the user to calibrate infusion rate and/or filled volume
Equipment should alert the user to infusion tube or pump blockage
Systems measuring filled volume using a load cell should allow the user to set fluid density and to set filled volume when changing containers

(gravimetric) or rotating disc technologies are commonly used. The dipstick method of measuring flow uses a capacitive technique to measure urine depth in the collecting vessel.<sup>1</sup> However, although technically validated, no reports about its use and reliability in clinical practice have been published. Drop spectrometry,<sup>11</sup> which determines flow by counting the rate of drops of urine leaving the meatus, was technically too demanding and clinically unreliable.<sup>5</sup> We therefore describe only the load cell and the spinning disc methods.

**The load cell flowmeter.** Load cell (or gravimetric) flow meter technology is used by the majority of commercial flow meters,<sup>12</sup> and measures the weight of the fluid during voiding. Knowing the density of the fluid enables volume to be calculated, while flow is rate of change of volume. The weighing scale should be in a horizontal position for reliable measurement, which is a potential problem when the equipment is fixed to a urodynamic chair or videourodynamic unit. In practice, a load cell is more vulnerable to errors in its zero point than its sensitivity, and damage normally manifests as a fixed offset in voided volume. For this reason, and because it is not always convenient to empty the flowmeter between voids, a "Set zero volume" function should be available. Equipment should use load cells that will not be damaged by loads less than 5 kg.

**The spinning disk flowmeter.** In a spinning disk or momentum-flux flowmeter, the urine stream falls on a rapidly spinning disk and the flow rate is measured by the power needed to keep the rotation speed constant. The spinning disk flowmeter thus measures mass flow; as with the load cell, the density of the fluid is required in order to calculate volume flow. Volume voided is calculated by integration of the flow rate. The design of these flowmeters must allow effective cleaning.

#### Flow Signal Conditioning and Processing

Urine flow is not continuous; by the time the stream reaches the meter, it has broken into a series of droplets. Therefore a stage of low-pass filtering typically with a cut-off frequency of 1 Hz is added (market survey carried out by authors). Equipment documentation should therefore clearly state what filtering or integration is used, and guide the user as to the effects of this filtering on the display of flow parameters.

#### Calibration of Flowmeters

**Calibration.** Empty the flowmeter. Set volume to zero and fluid density to one on the recording device. Pour a known volume of water, of the order of 300 ml, into the flowmeter at an approximately constant flow rate of 15 ml/sec. For a spinning disk flowmeter, pour it at the funnel wall, not directly on the disk. Set the recording device to register the known volume. On a load cell flowmeter the process can equally well be carried out using a known weight instead of a known volume of water.

**Verifying calibration.** The calibration of the flow measurement system should be verified regularly, for example, once every 10 urodynamic measurements. This may be done by applying the appropriate calibration procedure as described above, but rather than setting the recording device to the known volume, the volume reading is verified. If the reading is more than 20 ml different from the poured volume, recalibration of the system is recommended.

An alternative, easy method to verify calibration is to pour the urine that is collected in the flowmeter into a measuring beaker and check the volume. Another method uses an easily

constructed constant flow bottle to verify the flow rate reading.<sup>13</sup>

If frequent recalibration is necessary, the flow transducer might need to be replaced. The effort and time involved for regular verification should be balanced with the risk that all the flow rate values measured since the previous verification test are incorrect. Verifying calibration may also be necessary after calibration, since in some equipment the process of calibration can alter the zero reading. In these cases it may be necessary to repeat the calibration cycle several times in a series of successive and increasingly accurate approximations.

#### Uroflow and Voided Volume Artefacts

**Liquid density error (load cell and spinning disk).** The volume flow rate is calculated by assuming the density of urine is approximately 1 g/ml. If using a denser contrast medium or if the patient is particularly dehydrated, the indicated flow rate will be proportionally high. A prompt or display of liquid density setting, and the capacity for the user to change this, is recommended.

**Momentum artefact (load cell).** The stream of urine has momentum that is registered as a force by a load cell. This is indicated as an abrupt change in volume and a brief surge at the start of flow. The size of the effect will depend on the amount and velocity of urine hitting the load cell, the resultant movement of liquid in the jug, and the filtering in the electronics. Momentum artefact can be reduced, for example by fitting a baffle and by a funnel spout that reaches into the jug. These slow the urine flow at the impact with the load cell, but cause a time delay in the flowmeter.

**Low flow (spinning disk).** In spinning disk flowmeters, flow is measured and integrated to give volume. Integration is sensitive to small input offsets that are equivalent to a low but constant flow into the device. These small input offsets must be identified and rejected. The corollary is that the signal produced by very low urine flow rates can be missed, and this can be a clinically important effect, masking a long, dribbling flow. See the section Registering minimum flow for recommendations.

**Time delay (all designs).** There is inevitably a delay between a change in bladder pressure and the corresponding change in flow rate being detected. This is caused by mechanical delays due to urethral compliance and due to the urine flowing down into the flow sensor, particularly when the collection funnel is dry. The low-pass filter in the flow meter electronics will introduce a further delay. A total delay of 0.4–0.6 sec has been shown to be normal.<sup>14</sup> This delay is of no importance for plain uroflowmetry, but is relevant when synchronous pressure measurements are made during voiding cystometry. Systems should display the delay value to the user, and possibly allow modification.

#### FILLED (INFUSED) VOLUME (see Tables III and IV)

This section clearly does not apply to ambulatory urodynamic equipment, where natural filling occurs during the test.

#### Clinical Requirements

**Accuracy.** Measurement of infused volume should be accurate to within  $\pm 5\%$ .<sup>3</sup> Accuracy of greater than 1% is unlikely to be clinically useful. However, for very low filling rates, for instance in children or in urethral pressure profiles, accuracy to only 1 ml/min will be required. These accuracy values must

incorporate all variations due to hysteresis, linearity and temperature between 10 and 40°C.

**Range.** Typically, even for repeated cystometry, the filled volume is unlikely to be more than 1,000 ml, so the measurable volume should be between 0 and 1,000 ml. The equipment should enable the disregarding of the weight of the bag or bottle used for fluid. For filling rate, the ICS defines the maximum physiological filling rate as body weight in kilogram divided by four, expressed as ml/min. This is routinely exceeded in clinical practice, and much lower rates are used in children. Nevertheless it is rare that more than 100 ml/min be infused, and faster rates will in any case be limited by catheter diameter. The filling rate is often reduced during the test if the patient shows signs of detrusor overactivity, so the rate must be adjustable during filling. The required range is therefore 0–100 ml/min.

**Frequency response.** If 100 ml/min is the maximum required filling rate, then for 5% volume accuracy a sample should be recorded faster than every 3 sec. Considering other factors affecting accuracy, a frequency response of up to 1 Hz will therefore be acceptable.

### Measurement Technologies

Infused fluid is normally saline or contrast medium and the volume is either estimated by counting pump head revolutions or deduced from the decrease in bag weight. The section User Interface, Analysis and Post-Processing discusses how software might correct for residual volume and diuresis to estimate actual bladder volume.

**Infusion pump.** The infusion pump is normally of the peristaltic type where a series of rollers compress a flexible tube to drive the saline. This is susceptible to errors due in particular to variations in tube cross-section and downstream resistance. Equipment should therefore allow checking and calibration of infusion rate, often simply done by running the pumped fluid into a flowmeter. Many peristaltic pumps will turn even when the downstream tube is completely blocked, so equipment should register this error and alert the user. Because of this potential for error, load cell measurement of infused volume is advised.

**Load cell.** A load-cell arrangement measures actual infused volume by weighing the infusion bag. As with the flowmeter, contrast medium is denser than saline and will lead to over-indication of the filled volume if its density is not taken into account. Fluid density settings must therefore apply to both voided and filled volumes alike. In the case of voided volume, the effect of mixing contrast with saline or urine should be considered. Calibration is achieved by measuring known weights or volumes of fluid.

Where a load cell is used, there is a very obvious artefact generated when an empty fluid container is swapped for a full one. In terms of the unprocessed signal, the filled volume will increase by a few tens of ml as the container is removed, then return to approximately zero when the new bag is fitted.

Urodynamics systems should therefore have some means to correct this artefact.

It is known that filling with cooled fluid can promote detrusor contraction.<sup>17</sup> Equipment may therefore allow warming of the infused fluid to body temperature, though there is no conclusive evidence that this significantly affects the results of the cystometry. Historically, CO<sub>2</sub> gas has been used in place of saline to fill the bladder. Simultaneous pressure measurements are possible but it is not possible to measure flow rate or voided volume when using CO<sub>2</sub> gas infusion.

### MEASUREMENT OF PRESSURE (see Tables V and VI)

Pressure in urodynamic studies is conventionally measured in centimeters of water (cmH<sub>2</sub>O), a unit based on the pressure exerted by a column of water of measured height. A unit of cmH<sub>2</sub>O is equivalent to 98.07 Pascals (Pa), the standard unit of pressure.

Since pressure signals are sensed, transmitted, and recorded in different forms, when quoting specifications for pressure measurement, values should be quoted for the entire system, that is, transducers, catheters and processing together. The type of catheter should be specified, for example, “measured using 7Fr water-filled double lumen catheter” and ideally also the internal diameter of the pressure measurement lumen.

### Clinical Requirements

**Accuracy.** The accuracy of pressure measurement must be sufficient to capture physiological variation. We suggest equipment should be twice as accurate as test–retest variation in individual subjects. Studies which have measured this have found mean differences of 2.8 cmH<sub>2</sub>O<sup>7</sup> and 10 cmH<sub>2</sub>O<sup>6</sup>. This suggests systems should be accurate to between 1.5 and 5 cmH<sub>2</sub>O for  $p_{det}$ , and thus between 1 and 2.5 cmH<sub>2</sub>O for  $p_{ves}$  and  $p_{abd}$  (rounding to the nearest 0.5 cmH<sub>2</sub>O). These accuracy values must incorporate all variations due to hysteresis, linearity, and temperature between 10 and 40°C, even in catheter-mounted transducers that are calibrated at room temperature then used at body temperature.

**Range.** An acceptable range for pressure measurement would be 0–250 cmH<sub>2</sub>O.<sup>3</sup> In addition it is useful for water-filled catheters to allow a certain amount, say 30 cmH<sub>2</sub>O, of negative pressure to be registered while the patient is temporarily lower than the level of the transducers. Certain events, such as flushing catheters, may apply a pressure significantly higher than the working range (called an overload pressure) to the transducer. Larger diameter syringes are safer in this regard, as they are less likely to generate high overload pressures. It is suggested that the application of pressures up to 5,000 cmH<sub>2</sub>O must not damage the transducer or alter the calibration in the working range by more than 1%.

**Frequency response.** Most clinically relevant pressure signal changes in urodynamics occur below 3 Hz frequency, including the majority of the power spectrum of a cough.<sup>18</sup> Even though a

TABLE V. Essential Requirements for Pressure Measurement

Parameter	Guideline value
Accuracy	The greater of $\pm 3\%$ of true value or $\pm 1$ cmH <sub>2</sub> O
Range	–30–250 cmH <sub>2</sub> O (water-filled systems) 0–250 cmH <sub>2</sub> O (other systems)
Bandwidth of pressure measurement (whole system)	0 to $\geq 3$ Hz, equal on both channels
Required feature when water filled catheters are used and patient positions are changed during the test	Equipment must allow reference levels to be reset

TABLE VI. Desirable Features of Pressure Measurement Equipment

Equipment should allow users to compare easily current pressure values with starting (baseline) pressures
The point in time at which baseline pressures are recorded should be able to be set by the user
Equipment should allow the user to see abdominal, intravesical and detrusor pressures concurrently
Equipment should record when calibration has been carried out to enable later checks on performance and use

cough has frequency components up to 14 Hz,<sup>19</sup> registering the equal transmission of this signal by both pressure lines is clinically more important than measuring its precise maximum pressure value. To adequately register the presence of a cough signal, therefore, the bandwidth of the whole system (including catheters) should be at least 3 Hz. A higher bandwidth, however, may allow the more common artefacts to be represented and recognized.

#### Pressure Measurement Technologies

In urodynamics, the pressures to be measured are in internal cavities with limited access: the bladder, vagina, rectum or stoma, or urethra. Therefore the transducer will be associated with a catheter and tubing to gain access to the measurement site. Three different transducer arrangements are in common use, all of which require the setting of zero pressure (by convention to atmospheric pressure) and calibration. Only with external transducers and water-filled catheters, however, can the reference height be consistently known, and thus  $p_{ves}$  and  $p_{abd}$  repeatably and comparably measured.

**Water-filled catheter and external transducer.** This is recommended by the ICS.<sup>3</sup> A water-filled catheter or balloon is passed to the measurement site, with pressure transmitted along that catheter and connecting tubing to a transducer that is external to the patient. Even when set up correctly, a water-filled system is sensitive to being tapped or jostled, but responds reasonably well to fast changes in pressure.<sup>20</sup>

With a continuous column of liquid along the catheter, the pressure at the transducer is the same as that in the body *at the vertical level of the transducer*, regardless of where the catheter tip is. By convention the transducer is leveled to the pubic symphysis, an anatomical landmark for the bladder, and the zero point set to atmospheric pressure. The patient can move between supine, standing and sitting during the course of a test. Urodynamics equipment using water-filled measurement should therefore have the facility to move the transducers vertically in order to bring the transducers level with the symphysis pubis, if the patient is required to change position during the test. Alternatively, some other method of resetting the reference level is required.

**Catheter-tip transducers.** With catheter-tip transducers, the transducer is mounted in the tip of the catheter which is passed to the site of measurement. The pressure signal is converted to a voltage which is then amplified. A high measurement bandwidth (fast response) can be achieved with little or no movement artefact using catheter-tip transducers. However the transducer needs to be small, which makes it relatively difficult and expensive to manufacture.

The position of the catheter tip will affect the measurement. At the top of the bladder or rectum, the measured pressure will be typically 10 cmH<sub>2</sub>O lower than at the bottom; there is no easy way to correct for this positioning error. Systems should

therefore display clearly the pressure values at the start of the test so this artefact can be taken into account.

**Air-filled catheter and external transducer.** This arrangement is similar to the water-filled system with an external transducer, except that the catheter is filled with air, and a small balloon covers the opening at the end. The low density of air can be neglected, and the pressure is transmitted directly from the balloon at the catheter tip to the transducer. Therefore functionally, it is more similar to the catheter-tip transducer, suffering from the same uncertainty in positioning the catheter tip in the bladder or rectum. Again, therefore, it is important that the equipment allows the user to register the pressure readings at the start of the test.

There is little or no artefact due to knocking the line, but at the expense of a slowed frequency response. Air-filled catheters behave like an overdamped system, which can result in a delayed and diminished pressure response to rapidly changing pressures.<sup>20</sup>

#### Pressure Signal Conditioning and Processing

Signal conditioning would normally consist of two phases: low-pass filtering to remove high frequency artefacts, then subtraction of  $p_{abd}$  from  $p_{ves}$  to give  $p_{det}$ . The two processes are linear and can be applied in either order. However, the separate  $p_{abd}$  and  $p_{ves}$  traces are of interest, and therefore it is beneficial to filter them separately, that is, filtering before subtraction, which requires that the filters in the two channels be similar in frequency response.

Abdominal pressure signals such as a cough contain components at frequencies in excess of 10 Hz, and indeed there are some investigations, such as a cough urethral pressure profile, in which a faster frequency response is required. In this case, a higher sampling rate of approximately 100 Hz would be required if clinical precision demands this. Note that the entire system must also support the higher measurement bandwidth when required, which may exclude some arrangements.

#### Calibration of Pressure Transducers

During calibration two different pressures are set by exposing the catheter tip or sensor to two different well defined pressures. The calibration becomes more accurate when the pressure difference between the two pressures is larger (a pressure difference of at least 50 cmH<sub>2</sub>O is recommended). It may be necessary to go into some manufacturer-designed calibration routines or use one of the calibration devices available from some manufacturers. It is hoped that publication of this document will induce manufacturers to implement adequate means for calibration and include means for recording when calibration has been carried out. Calibration routines should be available for all measurement channels.

**Verifying calibration.** The calibration of pressure measurement systems should be verified regularly, for example, once every 10 urodynamic measurements for non-disposable transducers. This may be done by applying the appropriate calibration procedure as described in this section, but rather than setting zero level and the pressure reading at a defined height/depth, the pressure readings with the catheter at these levels are verified. If the pressure readings are more than 2 cmH<sub>2</sub>O different from the applied pressures, recalibration of the system is necessary. If frequent recalibration is necessary the transducer or catheter might need to be replaced. The effort and time involved for regular verification should be balanced with the risk that all the pressure values measured since the

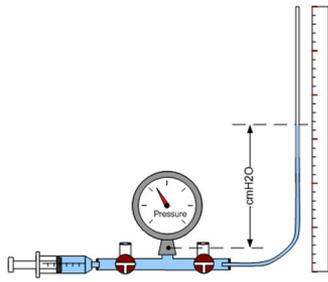


Fig. 1. Calibration of water-filled catheter by filling the line.

previous verification test are incorrect. Verifying calibration may also be necessary after calibration since in some equipment the process of calibration can alter the zero reading. In these cases it may be necessary to repeat the calibration cycle several times in a series of successive approximations.

**Calibration of water-filled catheters with external transducers.** The external transducer is connected to the recording device. Open both three-way valves to the outside air to make sure that the transducer with air-filled dome cover is exposed to atmospheric pressure, and set the zero level at the recording device. Open the valves to the syringe and the line, and completely fill the system with bubble-free water until the water level in the line is a defined level above the transducer, at least 50 cm (Fig. 1). Set that level at the recording device.

Alternatively, a water-filled pressure measuring system may be calibrated by keeping the amount of water in the line constant and moving the line up and down (Fig. 2). With the water level at the level of the transducer, set the recording device to zero. Raise the line so that the water level is at a defined level, at least 50 cm above the transducer, and set that level at the recording device.

The transducer may also be calibrated by putting the line in a water-filled container, noting that the pressure measured reflects the height difference between the water level in the container and the transducer (not the end of the catheter).

**Calibration of catheter-tip transducers.** Mount the catheter on a tripod (Fig. 3). Set zero on the recording device, while holding the catheter tip in the air. Place the catheter tip in a container, and fill to at least 50 cm above the catheter tip. Note the height of the water level above the sensor and set that level at the recording device. (Note that lowering the holder and catheter into a prefilled container will raise the water level, so measure the height with the holder and catheter submerged).

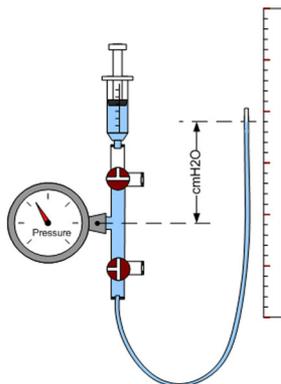


Fig. 2. Calibration of water-filled line by moving the line.

**Calibration of air-filled catheters.** Mount the catheter on a tripod (Fig. 3). Place the catheter balloon in a container and fill to at least 50 cm above the catheter balloon. Set zero on the recording device. Fill the balloon with air (repeatedly charging and discharging the balloon without properly emptying will result in a pressure rise inside the balloon and compromise the pressure measurement). Note the height of the water level above the balloon and set that level at the recording device. (Note that lowering the holder and catheter into a prefilled container will raise the water level, so measure the height with the holder and catheter submerged).

### Pressure Artefacts

Since there is redundancy in having two pressure channels, most artefacts in urodynamic pressure measurements can be recognized and dealt with through proper quality control.

**Reference level errors.** Catheter-tip transducers and air-filled transducers will have an error due to their unknown and changing height within the bladder, which is difficult to correct. The same errors can occur in abdominal pressure measurements, resulting in potentially greater error when subtracting to obtain detrusor pressure. The trace display should therefore allow easy comparison of current pressure values with starting (referred to as “baseline”) values, in order to allow the operator to compensate for initial pressure offset. It is not recommended that this offset be set to zero in software at the start of the test, as this process changes one pressure reading from its real value.

**Air bubbles.** Air bubbles introduce two issues with water-filled catheters. First, the non-uniform density of fluids in the catheter will introduce an offset to pressure measurements. The size of the offset depends on the difference in height between the two ends of the bubble, which changes as the catheter is moved and as the measured pressure changes. Second, water is incompressible and pressure changes are transmitted without flow of water. Air bubbles are compressible; a change in pressure requires flow to compress or expand the air bubble. The bubble becomes a low pass filter that dampens the frequency response of the catheter. Note that this problem does not affect air-filled catheters to the same degree, because the opposition to flow offered by air is very low. Equipment should allow the operator to compare easily the size of pressure changes on all traces, in order for instance to test for the presence of air bubbles using a cough.

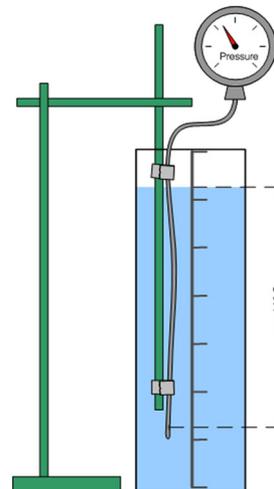


Fig. 3. Calibration of catheter-tip and air-filled transducers.

**Dislodged catheter.** A dislodged catheter that has moved from the measured body cavity can be identified by good quality control, since the measurement in the affected catheter will stop responding to coughs. If the catheter has moved significantly, the measurement may also show a dramatic offset from its baseline value. Again therefore, the trace display should allow comparison with baseline values during the test.

**Incomplete pressure transmission.** At the start of filling, it is sometimes the case that intravesical pressure is not recorded correctly, possibly due to the sensor touching the wall of an empty bladder. Equipment should therefore allow users to fill the bladder a small amount before baseline values for pressure are recorded, rather than automatically assigning baseline values at the start of filling.

**Incomplete cough cancellation.** With water-filled catheters, it is usual that the bladder line is of smaller diameter than the abdominal line. In these circumstances the characteristics of the two lines will be different, with the abdominal line usually having the faster frequency response. Therefore the complete cancellation of a cough in the detrusor trace may be difficult and any automatic processing should treat a symmetric biphasic wave on the detrusor trace as being of acceptable quality.

**Artefacts with separate lines.** With separate filling and measurement catheters, there will be a positive pressure offset in  $p_{ves}$  if the measuring catheter is not disengaged from its insertion position in the filling catheter hole ("piggy-back") before filling commences, or if filling flow faces directly onto the measurement point. This artefact disappears if the infusion pump is stopped.

**Single Lumen Artefact.** If both filling and pressure measurement are done through the same lumen of a catheter, the positive pressure from the filling pump will add an offset to the value measured, and if a roller pump is used this offset is variable and confusing. Pressure measurements should therefore be made only when the pump is not running. Alternatively, if continuous measurements are required, calibration may be done when the pump is running, or users compensate by subtracting the offset, but only when the pump is running. This artefact disappears if the infusion pump is stopped.

**Dual-lumen artefact (pump).** Dual-lumen water-filled catheters are susceptible to a filling artefact in which the pressure generated by the infusion pump affects the pressure in the parallel measuring lumen, particularly at high filling rates. The effect is due to peristalsis from the pump interacting with the compliance of the thin catheter wall, and is manifested as a rhythmic signal from the pump rollers superimposed on the  $p_{ves}$  signal. This artefact too disappears if the infusion pump is stopped.

#### Abdominal Pressure Special Considerations

Catheters in the rectum, vagina, or an abdominal stoma give an approximation to the pressure surrounding the bladder. In particular, the use of rectal transducers in urodynamics makes the assumption that they give a good measure of resting abdominal pressure.<sup>22</sup> However, the rectal transducer will often measure rectal contractions. These will be manifested as positive waves on abdominal pressure and thus negative-going waves on resting detrusor pressure that may sometimes appear to be substantially below zero. Equipment should therefore allow the user to see all pressure traces concurrently and negative  $p_{det}$  readings should be displayed and not clipped to zero.

#### Urethral Pressure—Special Considerations

In some circumstances, it may be requested to quantify the pressure along the length of a dry urethra. Some authors report

making measurements using a solid-state catheter-tip transducer coated in an aqueous lubricating gel.<sup>23</sup> In the Brown and Wickham method,<sup>24</sup> a water-filled catheter is passed *per urethram* then withdrawn using a catheter puller, typically at 2–5 mm/sec. Meanwhile, continuous pressure measurements are made. Since the distal urethra is dry, the line must be perfused with saline, typically at 2–5 ml/min. Equipment that supports urethral pressure measurement should enable perfusion and withdrawal rates within these ranges. As systems perform differently at different rates and with different catheters, centers should maintain a consistent and clearly defined protocol when making urethral pressure measurements.

#### EMG (see Table VII)

Electromyography (EMG) measurements can contribute to the interpretation of urodynamics studies in that they document the relationship between pressure and/or flow as well as the activity of the pelvic floor and striated sphincter. Consequently EMG measurements, particularly when associated with the investigation of neuropathic disorders of the lower urinary tract, can be of critical importance. In the past, needle electrodes have been used to investigate individual muscle action potentials, usually inserted in the anal sphincter providing a record of motor unit activity of the group of muscles. While not exactly reflective of pelvic floor muscle activity, needle or wire electrodes remain the current gold standard of documenting skeletal muscle activity. However needle electrodes are invasive, technically difficult to insert and are not pleasant for the patient. Therefore in centers that use it, EMG measurement is limited to surface electrodes measuring the activation of the pelvic floor muscles.

All skeletal EMG signals have a relatively high bandwidth, typically from 10 Hz up to 1 kHz. The EMG amplitude from surface electrodes is comparatively low, nominally from 10 to 100  $\mu$ V, and depends greatly on skin cleaning, electrode placement and patient morphology in terms of the amount of fat between electrode and muscle to be monitored. Given the small signal amplitude, the amplifier properties are important. In particular, it should have a high input impedance in excess of 100 MOhms, and common-mode rejection ratio (CMRR) in excess of 80 dB.<sup>1</sup> A notch filter at mains frequency is recommended.

In most cases, the high bandwidth of the EMG is addressed by using a rectify-integrate (iEMG) or a root-mean-square circuit that gives a low-bandwidth estimate of the EMG amplitude or envelope. When displayed graphically this gives a line trace where in some cases, subtle or slow changes can be missed and filtering can lose the phase relationship with the pressure or flow signals. In fact, the original EMG can be deliberately under-sampled at typically 100 Hz, which loses some information content, but nevertheless gives a distinctive EMG appearance when displayed at the timescale of urodynamic traces.

TABLE VII. Essential Requirements of EMG Measurement Equipment (Where Fitted)

Parameter	Guideline value
Minimum impedance	100 MOhms
Minimum CMRR	80 dB
Required feature	EMG processing and display variable to suit clinical need

## USER INTERFACE (see Table VIII)

## Operation

Equipment should be designed such that operation is ergonomic and safe. Surfaces likely to come into contact with clinical materials should be easy to clean, while the physical layout should be stable and allow easy access. The equipment design should be such that technicians at the user's institution can carry out electrical safety checks without causing damage to the equipment.

## Recording

Data should be recorded and stored in such a way that the study can be displayed in the same way at a later date, preferably on other equipment as well. Electronic marking of events is important for analysis of studies at a later date, as artefacts and real events can easily get confused if they are not permanently annotated on the original soft copy. The position of event markers should be adjustable after the test has finished, and the meaning of any abbreviations used for their labels should be clear. The ability to enter further diagnostic information such as post void residual volume and the results of related diagnostic tests may be useful in order to display all related information to clinicians. The ability to export in plain data format (.txt or .csv) should be available. Also required is the ability to integrate with popular electronic medical software and to export in the ICS standard format (.ics).<sup>25</sup> For data protection purposes, the system should store data securely, or allow the user's institution network to do so. Backing up of data onto remote systems or media and connection to the hospital data network should be facilitated. Data recovery in the event of power failure would be an advantage.

## Display

The ICS suggests that urodynamic tests should be displayed on a 1 mm = 5 sec scale for filling and 1 mm = 2 sec for voiding.<sup>3</sup> This allows resolution of short scale events, easy visual comparison of multiple studies and prevents misinterpretation of traces due to scaling issues. Line thicknesses on screens and on printouts should allow the clear visualization of clinically important details, and these thicknesses should not represent values greater than the accuracies recommended above. A variable on-screen scale allows both visual summary of the whole test, as well as close inspection of detailed features, but default scales and layout should conform to ICS recommendations.<sup>3</sup> The system must allow for simultaneous display of all pressure traces. For those integrating fluoroscopy, temporal synchronization or embedding of the image are necessary features. For ambulatory equipment, the option of a real time display of pressure is helpful, in order to check the setting up of transducers.

## Analysis and Post-Processing

Automated analysis is an optional extra which, if included, should not be affected by artefacts (e.g.,  $Q_{max}$  caused by knocking the flow meter,  $p_{max}$  from cough). If summary statistics and automated analysis are provided, the user should have the ability to check the values for feasibility and change the relevant ones if necessary. This implies that software should not filter or remove artefacts, but should be able to ignore them for analysis. Results of validation of any automated analyses should be available.<sup>26</sup> Established nomograms and calculated parameters may also be provided. A facility to estimate bladder volume using post-void residual, infused and voided volumes may be a useful tool, though inaccuracies in these measurements, along with any urethral infusion, diuresis, and leakage will confound calculation.<sup>27</sup>

## RECOMMENDATIONS FOR STANDARDIZED PERFORMANCE TESTS

Testing of new technologies for pressure and flow rate measurement should be done by a specialized center prior to introduction to the market to ensure that they have sufficient accuracy, linearity, minimal hysteresis and temperature dependence, and an appropriate frequency response, as well as consistent performance throughout the lifetime of the system. These tests should be performed using all components of the system as they will be utilized clinically since, for example catheter size and length can affect the frequency response of a pressure measurement system. Potential users should utilize the results of these tests to determine if a new technology would provide sufficiently accurate measurements for their needs prior to purchase.

A single study can be utilized to test linearity and hysteresis by production of a linear increase in pressure or flow rate followed by a linear decrease in pressure or flow rate. For pressure, this can be accomplished using a fluid-filled pressure chamber in which the pressure can be tightly controlled. For flow rate, this can be accomplished using a controllable flow pump.

Frequency response can be determined by changing pressure or flow rate in a controllable manner such that different frequencies are tested. Two such standard tests for measuring the frequency response of a pressure measuring system are the pop test and the frequency ramp test.<sup>20</sup> For the pop test, a piece of latex, similar to a balloon, is tightly stretched over the top of an air-filled chamber in which pressure sensing catheters are placed. The chamber is then pressurized to a standard pressure and the latex bulges out in response. The latex is then popped with a pin or needle, dropping the pressure in the chamber to zero (equal to barometric pressure in the room) nearly instantaneously. This test is therefore sometimes called a step test because of the sudden drop to zero pressure. This test enables measurement of the response of a pressure sensing

TABLE VIII. Essential Requirements of User Interfaces

Parameter	Guideline
Access and cleaning	Equipment laid out ergonomically
Display	Should allow for later review with line thicknesses representing smaller values than recommended measurement accuracy
Data export	Text/spreadsheet format, ICS format and electronic patient record interface
Data storage	Backup facility and option for network connection required
Image capture and display	Secure data storage should be made possible
Display scales	Simultaneous recording and playback with pressure traces required, if images are used
Event marking	Clearly displayed and adjustable
Automated analyses	Required
	Relevant parameters should be controlled by user, not fixed

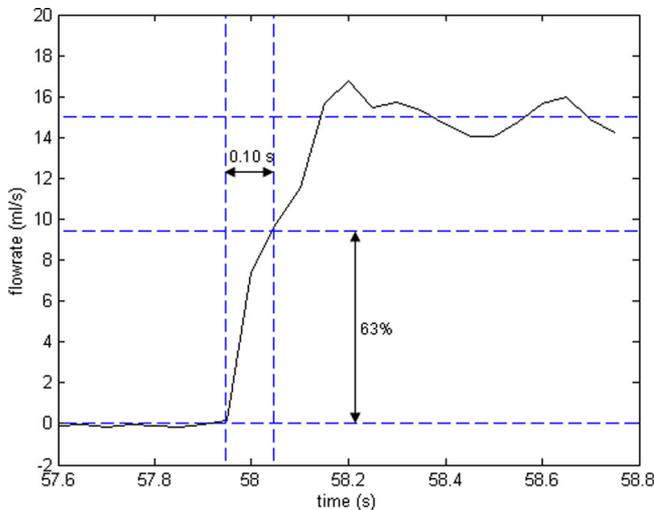


Fig. 4. Simple test for flow meter signal response. The rise time to 63% of final value should be less than 0.16 sec.

system to a sudden change in pressure. For the frequency ramp test the pressure in the pressure chamber is rapidly changed and a range of relevant sinusoidal frequencies are examined. Zero to 20 Hz is sufficient to assess urodynamic pressure measurement systems. Sophisticated software is required to characterize the pressure measurement system from the resultant data, but if done well, an accurate determination can be made and the system can be characterized by its resonant frequency and/or the  $-3$  dB frequency as illustrated with regard to a flowmeter step test (Fig. 4).<sup>28</sup> The resultant data from these tests can also be used to determine if the pressure sensing system constitutes an under- or over-damped recording system.<sup>20</sup> If the system is underdamped, the resonant frequency ought to be outside the working range of the system (greater than 20 Hz in this case). If the system is overdamped, it ought to have adequate slew rate to respond in a timely fashion to pressure changes within the working range of frequencies.

To test simply flowmeter frequency response, put the flowmeter under a running tap, and adjust the tap until the flowmeter indicates approximately 15 ml/sec. Intercept the stream for approx. 4 sec with a plastic cup. Then quickly remove the cup again, and record the flow signal for 4 sec more. Figure 4 shows a detailed recording of the time interval when the cup was removed, using a spinning disk flowmeter. Since we require a cutoff frequency of at least 1 Hz (see Table I), the time taken to rise from zero to 63% of the final value should be at most 0.16 sec.

A frequency ramp test can test new flow rate technologies by creating sinusoidal changes in flow rate whose frequencies change through the working range of flow rate frequencies, that is, 0–5 Hz as stated earlier.

Temperature dependence can be tested by performing the linearity and hysteresis test and the frequency response test at different temperatures within the working range of the system.

Disposable systems do not need to demonstrate lifetime consistency since they are marketed for single use only. Durable systems ought to be tested to ensure they have a consistent response throughout their recommended lifetime, which can be defined either according to time by utilizing an expiration date, or according to number of uses. Repetition of a simulated urodynamics test interleaved with periodic repetition of the

above benchmarking tests could determine the appropriate lifetime of a new technology, regardless of how lifetime is ultimately defined. Change of less than 1% throughout the lifetime of a system would be expected, after periodic recalibration has been undertaken.

## SUMMARY

The review contained in this article allows clinical requirements for a standard urodynamics system to lead to technical recommendations. Equipment can be over-specified (e.g., more accuracy than is required) or under-specified (unable to achieve necessary performance). It is hoped that this document will be helpful to purchasers, users and manufacturers in avoiding these errors. Purchasers can use the lists of required features to check the suitability of equipment for urodynamics. Users can perform the tests described to check ongoing performance and calibration. Manufacturers can be guided by this technical summary of clinical need when introducing new designs or techniques. The document may also encourage the establishment of standard tests for urodynamic equipment, leading to both procurer and operator assurance, and also patient benefit.

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