Urodynamics Without Borders Guide

..

November 20, 2025

Contents

1 Introduction **5**
1.1 Aims . . . 5

2 Theory **6**
2.1 System Control . . . 6
2.2 Pressure Measurement . . . 7
2.3 Fluid Infusion . . . 8
2.4 Uroflowmetry . . . 9

3 Supporting Information and Files **10**
3.1 PCB Design . . . 10
3.2 Suporting Structure Design . . . 10
3.3 Hardware Control Software . . . 10
3.4 User Interface Software . . . 11

4 Manufacturing Guide **12**
4.1 Components List . . . 12
4.1.1 Control System . . . 12
4.1.2 Uroflowmetry . . . 12
4.1.3 Pressure Configuration . . . 13
4.1.4 Fluid Infusion . . . 13
4.2 Ordering PCBs . . . 14
4.3 Fabricating Supporting Structures . . . 15
4.3.1 3D Printing . . . 15
4.3.2 Workshop Manufacturing . . . 15
4.3.3 Uroflowmetry Base Plates . . . 16
4.3.4 Pressure Configuration Clamp Design . . . 17
4.3.5 Infusion Pump Clamp Design . . . 18
4.3.6 Volume Infused Loadcell Clamp Design . . . 19
4.3.7 Volume Infused Fluid Mount Clamp Design . . . 20
4.4 Subsytem Assembly . . . 22
4.4.1 Control Subsystem . . . 22
4.4.2 Uroflowmetry . . . 24
4.4.3 Pressure Sensor Configuration . . . 26
4.4.4 Fluid Infusion . . . 27
4.4.5 Infusion Pump . . . 28

5 Software 29
- 5.1 Control Software . . . 29
  - 5.1.1 Control programs available . . . 29
  - 5.1.2 Requirements . . . 29
  - 5.1.3 Loading scripts onto the hardware . . . 30
- 5.2 User Interface Software . . . 31
  - 5.2.1 Requirements . . . 31
  - 5.2.2 Installation . . . 31
  - 5.2.3 Usage . . . 31

6 System Testing 33
- 6.1 Pressure Measurement Configuration . . . 33
  - 6.1.1 Purpose . . . 33
  - 6.1.2 Scope . . . 33
  - 6.1.3 Test Criteria . . . 33
  - 6.1.4 Required Equipment . . . 33
  - 6.1.5 Validation Procedures . . . 34
  - 6.1.6 Reporting of results . . . 38
- 6.2 Fluid Infusion Testing Configuration . . . 39
- 6.3 Uroflowmetry Testing Configuration . . . 40
  - 6.3.1 Purpose . . . 40
  - 6.3.2 Scope . . . 40
  - 6.3.3 Test Criteria . . . 40
  - 6.3.4 Required Equipment . . . 40
  - 6.3.5 Validation Procedures . . . 41

7 Clinicial Use 47

8 Project Change Log 48
- 8.1 System Design . . . 48
- 8.2 Support Structure CAD Files . . . 48
- 8.3 User Interface Software . . . 48
- 8.4 Hardware Control Software . . . 48
- 8.5 PCB Files . . . 48

9 Appendices 49
- 9.1 Pressure Measurement . . . 49
- 9.2 Uroflowmetry Measurement . . . 50

9.2.1 Hydrostatic Pressure Relation 50
9.2.2 Torricelli's Law 50

1 Introduction

A urodynamic (UDS) test evaluates the bladder function by assessing the pressure-volume relationship during the storage phase, and the pressure-flow relationship during the voiding phase. Bladder dysfunction can result in lower urinary tract symptoms such as frequent urination, incontinence and difficulty emptying the bladder. In severe cases, bladder dysfunction results in kidney damage and may be fatal. Determining the root cause of the bladder dysfunction allows clinicians to most effectively treatment and preserve kidney function.

During a UDS test, fluid is infused to the bladder at a set flowrate. The detrusor pressure (bladder pressure - abdominal pressure) change with infused volume is recorded. Once the patient reaches the functional bladder capacity or incontinence is elicited, permission to void is given and the pressure-flow relationship recorded. The standard urodynamic system costs approximately (US) $30,000. The acquisition and running cost of urodynamics systems are often considered prohibitive for most hospitals in the developing world.

1.1 Aims

The aim of this project was to develop and validate a urodynamic system for a total cost of $100 (excluding a computer), meeting the performance standards set out in the international continence society urodynamic equipment guidelines (click ICS Equipment Guidelines to download the ICS guidelines file).

Authors

Michael Jeffryes

2 Theory

The urodynamics system can be broken down into several sub-systems with one main board that will control the acquisition of sensor measurements and communication of those measurements to the user interface.

2.1 System Control

The mainboard is comprised of a waterproof enclosure that houses a PCB, this PCB has all required components soldered to it.

Authors

Michael Jeffryes

2.2 Pressure Measurement

There are two pressure syringes to allow measurement of the bladder and abdominal pressures. The pressure sensors used (MS5840) are factory calibrated, so calibration is not required. The measured values are sent via the mainboard to the UI Software, a zeroing value is applied to the absolute values. The detrusor pressure is calculated from the subtraction of abdominal pressure from bladder pressure.

Authors

Michael Jeffryes

2.3 Fluid Infusion

The fluid infusion sub-system uses a cantilever loadcell to measure the volume of fluid infused and to calculate the infusion rate. A DC peristaltic pump is used to infuse the fluid, a pulse wave modulation circuit is used to vary pump speed.

Authors
Michael Jeffryes

2.4 Uroflowmetry

The uroflowmetry sub-system uses a cantilever loadcell to measure the force applied by the container and the fluid voided. The loadcells raw digital value will be sent via the main board to the UI software. The UI software then applies the loadcell specific constants to obtain the applied force. The applied force is then converted into volume using the specific gravity of infusion fluid that has been used. The UI software has a calibration protocol to obtain the required constants. Using the change in time and volume the UI software calculates the flowrate of fluid voided.

Authors

Michael Jeffryes

3 Supporting Information and Files

3.1 PCB Design

The JS_UDS_PCB repository stores all files required for PCB manufacture. Navigate to the Latest directory.

3.2 Suporting Structure Design

The JS_UDS_CAD repository stores the Autocad files used to design the supporting structures as well as the STL files generated from the designs. Navigate to the Latest directory.

3.3 Hardware Control Software

The JS_UDS_Hardware repository stores the control software for the UDS equipment. There are simulation, test, and clinical investigation scripts.

Simulation scripts:

- Pressure Simulation
- Pump Flowrate Simulation
- Volume Infused Simulation
- Volume Void Simulation
- Clinical Investigation Simulation

Test scripts:

- Pressure Testing
- Pump Flowrate Testing
- Volume Infused Testing
- Volume Void Testing

Click Full Clinical Investigationfor the clinical investigation script.

3.4 User Interface Software

Click User Interface Software for the user interface software.

4 Manufacturing Guide

This section will provide the required equipment lists, ordering requirements, fabrication, and soldering information to manufacture the full Urodynamics system.

4.1 Components List

4.1.1 Control System

Component	Quantity	Per Unit Cost(USD)	Total Cost (USD)
Main board PCB	1	0	0
Mains AC to DC Plug	1	0	0
DC connector mount	1	0	0
DC barrel jack mount	1	0	0
Buck Converter	2	0	0
Micro-USB mount	1	0	0
Arduino Nano	1	0	0
TCA9548A Multiplexer	1	0	0
1k Ohm Resistor	6	0	0
PWM Circuit	1	0	0
HX711 amplifier	2	0	0
Male 4 pin DIN connector	5	0	0
Female 4 pin DIN connector	5	0	0
Wire 4-core	1 meter	0	0

Table 1: Control Components List

4.1.2 Uroflowmetry

Component	Quantity	Per Unit Cost(USD)	Total Cost (USD)
0-5kg cantilever loadcell	1	0	0
Male 4 pin DIN connector	1	0	0
Wire (4-core)	2 meters	0	0

Table 2: Uroflowmetry Components List

4.1.3 Pressure Configuration

Component	Quantity	Per Unit Cost(USD)	Total Cost (USD)
MS5840-02BA TE Pressure Sensor	2	0	0
Pressure sensor PCB	2	0	0
Male 4 pin DIN connector	2	0	0
Wire (4-core)	3 meters	0	0
Epoxy resin solution	15 ml	0	0

Table 3: Pressure Configuration Components List

4.1.4 Fluid Infusion

Component	Quantity	Per Unit Cost(USD)	Total Cost (USD)
0-5kg cantilever loadcell	1	0	0
0-5kg cantilever loadcell	1	0	0
12v Peristaltic Pump	1	0	0
Mounted toggle switch	1	0	0
Male 4 pin DIN connector	2	0	0
Wire (4-core)	4 meters	0	0

Table 4: Pressure Configuration Components List

Authors

Michael Jeffryes

4.2 Ordering PCBs

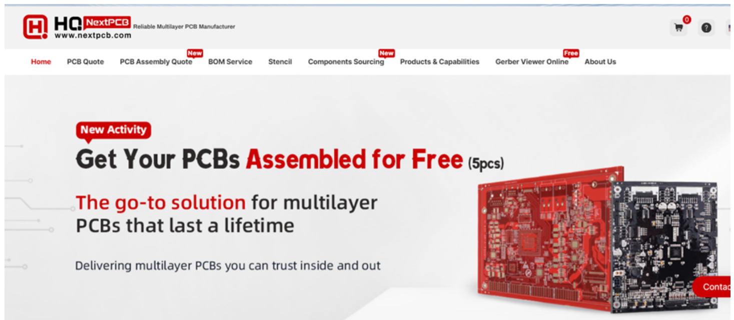


Figure 1: PCB Manufacturer

1. 3D Visit the PCBs page on the UDSWB website and download the zip files

2. Find a low-cost PCB manufacturer online and upload the zip files

Authors

Michael Jeffryes

4.3 Fabricating Supporting Structures

The sections below provide drawings with labelled dimensions and tables with the corresponding measurements. Measure the procured components and apply the dimensions to the drawings to identify suitable supporting structures for your components.

4.3.1 3D Printing

If you have access to a 3D printer, then check (XX APENDIX x) to see the measurements used to create the STL files for the components. If your component parts have the same measurements, then use the supplied files. If component measurements vary then use the drawings to design your own, at the time of writing Autodesk provide a free version of Autodesk that can be used to design the parts and export to STL files for printing. Aim to use a stiff setting filament to optimise the transmission of load for loadcell measurement.

4.3.2 Workshop Manufacturing

Use the drawings and relative measurements in each section to form the design for each part. Aim to use lightweight and stiff materials, this will ensure that the load transmission for measurement via loadcells is optimised.

4.3.3 Uroflowmetry Base Plates

The drawings below outline base plates fit for purpose, two are required. The large flat bottom provides a large stable base in contact with the floor as well as a large pad to place the fluid container on. The design centres the loadcell in the middle of the plate so that the weight of the container and fluid are over the centre of the plate. This reduces the likelihood of the container falling over if knocked.

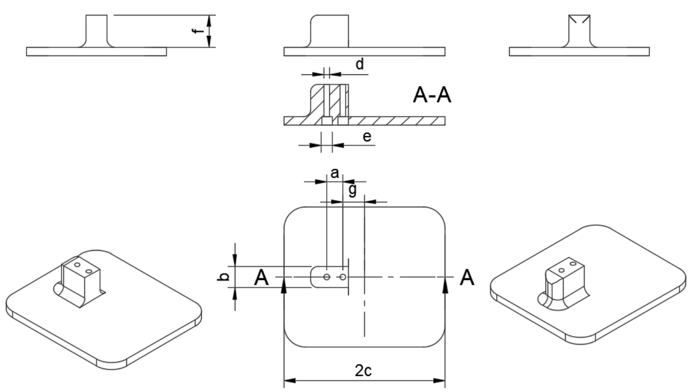


Figure 2: Uroflowmetry Base Plate Drawings

a) The distance between the centre points of the two tapped holes at each end of the loadcell

b) The width of the loadcell + > 2mm

c) Length of the loadcell

d) The bolt diameter used by the loadcell + > 1mm

e) The diameter of the head of the bolt + > 2mm

f) The height of the loadcell

g) Distance between the centre of the loadcell and the centre point of the loadcell hole nearer to the loadcell mid-point

4.3.4 Pressure Configuration Clamp Design

The drawings below outline the pressure configuration clamp, two are required. Two of these can be fixed together on a stand to provide a clamp for the pressure sensor syringes. The four bolt and nut holes allow the two parts to be clamped together around the upright support. The internal nut holes and through bolt holes allow a single bolt ant nut to act as grub screws to fix the two syringes in place and fix the clamp to the upright support. The single nut and bolt hole at the end of the part clamps the two parts together so that the syringe grub screws do not splay the parts.

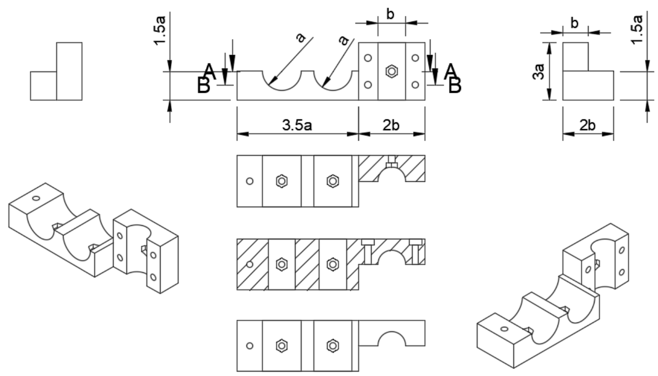


Figure 3: Pressure Syringe Clamp Drawings

a) The diameter of the pressure syringe + > 4mm

b) The diameter of the upright stand/trolley + > 4mm

Nb) Select bolts that are greater than the larger of 3a and 3b

Nb) Create holes to accommodate the chosen bolts

Nb) Create hexagonal holes to accommodate the corresponding nuts, a tight fit makes it easier to move the bolts without the nuts dropping out

4.3.5 Infusion Pump Clamp Design

The drawings below outline the infusion pump clamp, two are required. Two of these can be fixed together on a stand to provide a clamp for the infusion pump to be fixed to. The four bolt and nut holes allow the two parts to be clamped together around the upright support. The internal nut hole and through bolt hole allow a single bolt ant nut to act as grub screw to fix the clamp to the upright support. The two through holes allow bolts to pass through the part to fix the pump to the clamp.

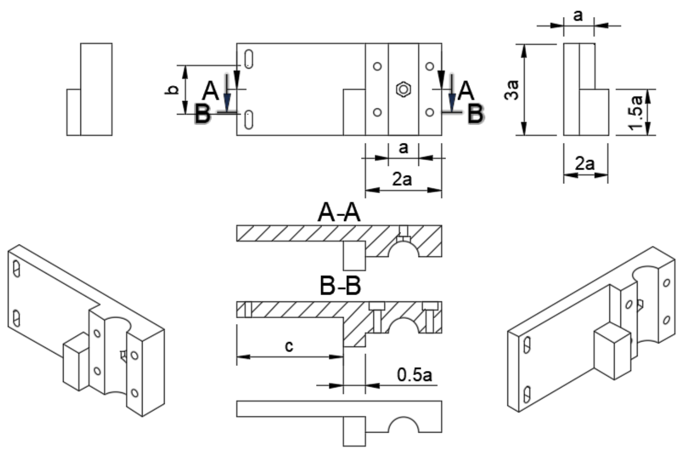


Figure 4: Infusion Pump Clamp Drawings

a) The diameter of the upright stand/trolley + > 4mm

b) The distance between the pump fixation screw holes - 5mm

c) The length of the pump + > 10mm

4.3.6 Volume Infused Loadcell Clamp Design

The drawings below outline the fluid infusion loadcell clamp, two are required. Two of these can be fixed together on a stand to provide a clamp for the fluid infusion loadcell. The four bolt and nut holes allow the two parts to be clamped together around the upright support. The internal nut hole and through bolt hole allow a single bolt ant nut to act as grub screw to fix the clamp to the upright support. The two through holes allow bolts to pass through the part to fix the loadcell to the clamp.

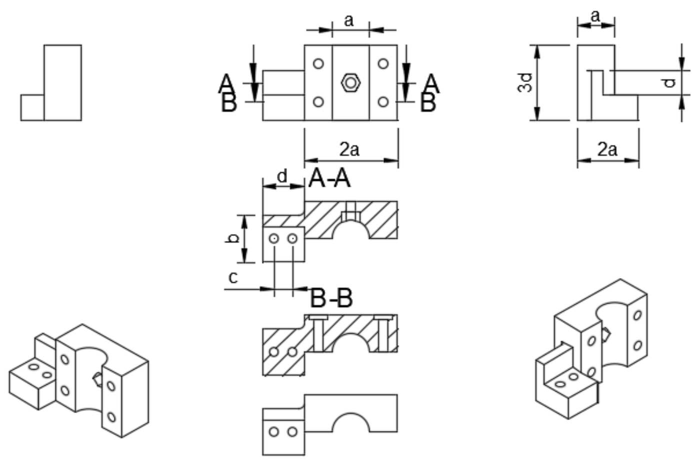


Figure 5: Volume Infused Loadcell Clamp Drawings

a) The diameter of the upright stand/trolley + > 4mm

b) Twice the width of the loadcell + 4mm

c) The distance between the centre points of the two tapped holes at each end of the loadcell

d) Height of the loadcell

Nb. Create holes to accommodate the chosen bolts

Nb. Create hexagonal holes to accommodate the corresponding nuts, a tight fit makes it easier to move the bolts without the nuts dropping out

4.3.7 Volume Infused Fluid Mount Clamp Design

The drawings below outline the fluid infusion mount, one part is required. The part is fixed to the end of the fluid infusion load cell and allows the infusion bag to be supported and weighed. The two through holes allow bolts to pass through the part to fix the loadcell to the clamp. The upright cylinder/hook acts as the point to fix the infusion fluid bag, it should be made sufficiently strong to hold a minimum of 1.25 kg.

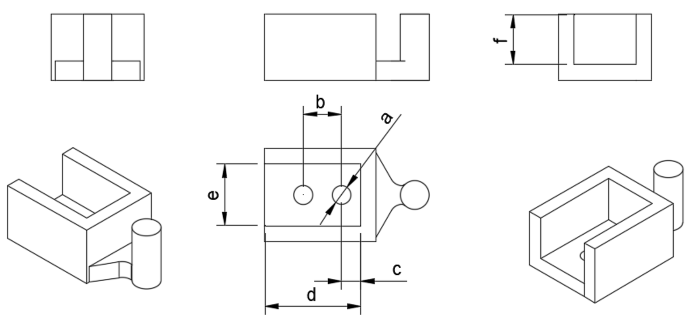


Figure 6: Volume Infused Fluid Mount Clamp Drawings

a) The diameter of the upright stand/trolley + > 4mm

a) The bolt diameter used by the loadcell + > 1mm

b) The distance between the centre points of the two tapped holes at each end of the loadcell

c) The distance between the centre points loadcells outermost hole and the end of the loadcell + 1mm

d) Distance from the end of the loadcell to the innermost holes edge + > 5mm

e) The width of the loadcell + 4mm

f) Height of the loadcell

Authors

Michael Jeffryes

4.4 Subsytem Assembly

4.4.1 Control Subsystem

1. Solder the resistors in place. (Tight to the board and not intruding other components)

2. Solder the PWM circuit components. (The transistor pins can be bent to 90 degrees to avoid it sticking up)

3. Solder the support pins to the 2 buck converters

4. Solder the 3.3v connection on one buck converter and the 5v on the other

5. Solder the buck converters to the designated spot (3.3v to the 3.3v spot. . .)

6. Solder the DC barrel jack mount to the PCB

7. Solder the support pins to the TCA9548A Multiplexer, the Arduino Nano and the 2 HX711 amplifiers

8. Solder the TCA9548A Multiplexer, the Arduino Nano and the 2 HX711 amplifiers to the PCB

9. Cut 6x10cm and 5x5cm lengths of 4 core wire

10. Fix female 4 pin DIN connectors to the ends of 5cm lengths of wire

11. Fix male pin connectors to the other ends of the 5cm lengths

12. Solder the 10cm lengths of wire to the PCB (2 of the wires will only require 2 cores to be soldered)

13. Fix female pin connectors to the other ends of the 10 cm lengths

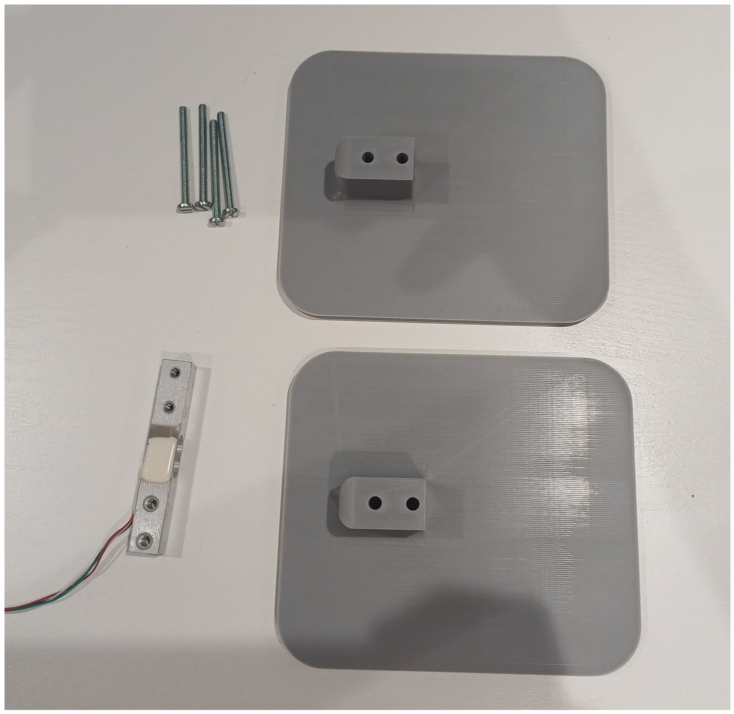
14. Cut holes in the waterproof casing just large enough to fit the female DIN connectors, the micro-USB connector, the DC plug and the switch

15. Fix the female DIN connectors, the micro-USB connector, the DC plug and the switch in place

16. Place the PCB inside and connect each of the male and female pin connectors
17. Test the continuity of each female 4 pin DIN connector to the PCB to ensure that the pins are connected in the correct order
18. Screw the waterproof casing lid on to finish

4.4.2 Uroflowmetry

1. 3D print or manufacture the supporting parts using the STL files



2. Connect the 2m 4 core wire to the 4 wires attached to the loadcell (Note the order of the wires attached)

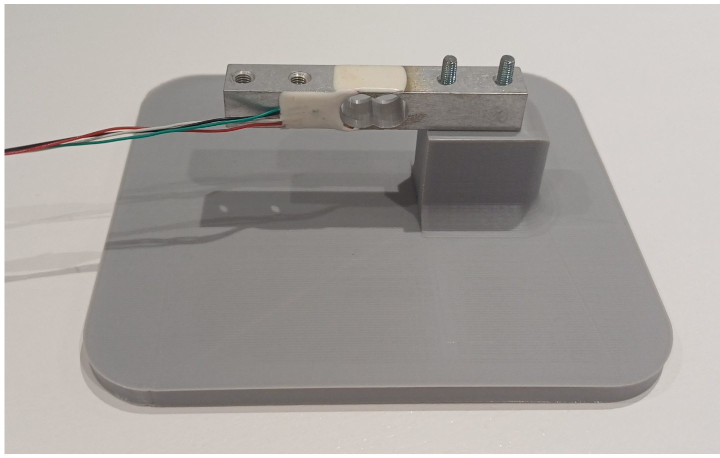
3. Solder the male 4 pin DIN connector to the other end of the

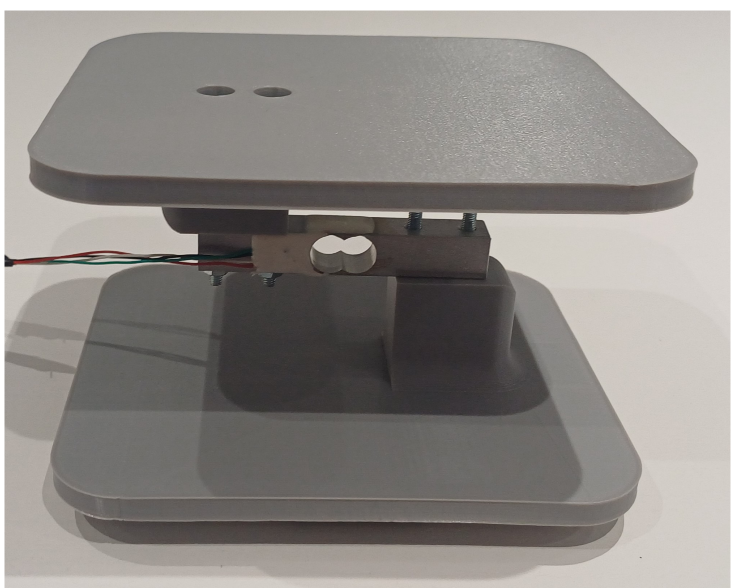
Pin	Wire
1	E+
2	E-
3	A-
4	A+

Table 5: Uroflowmetry Loadcell Pin Out

4. Screw the loadcell into the first baseplate

5. Screw the second base plate onto the loadcell





4.4.3 Pressure Sensor Configuration

1. Solder the pressure sensors to the PCBs
2. Fix the male 4 pin DIN connector to the 4-core wire
3. Cut a hole axially through the syringe plunger to allow the 4-core wire to pass through
4. Solder the 4-core wire to the PCB (pressure sensor facing up)

Pin	Wire
1	GND
2	VCC
3	SCK
4	SDA

Table 6: MS5840-02BA Pressure Sensor Pin Out

5. Mix the epoxy resin and use it to cover the PCB ensuring not to go over the aperture of the pressure sensor. The resin should form a seal at the top of the plunger to stop fluid passing through the hole cut to allow the wires to pass through.

4.4.4 Fluid Infusion

1. 3D print or manufacture the supporting parts using the STL files
2. Connect the 4-core wire to the load cell
3. Connect the 4-core wire to the peristaltic pump
4. Fix the male 4 pin DIN connector to the other end of the 4-core wire (x2)

4.4.5 Infusion Pump

1. get pump

Authors

Michael Jeffryes

5 Software

5.1 Control Software

The Control Software repository stores all scripts required to simulate signals, test sub-systems and perform clinical urodynamics.

5.1.1 Control programs available

- Simulation
  - Pressure Simulation - Simulates pressure sensor input
  - Pump Flowrate Simulation - Simulates infusion pump
  - Volume Infused Simulation - Simulates volume infused
  - Volume Void Simulation - Simulates volume void
  - Clinical Investigation Simulation - Simulates clinical investigation
- Testing
  - Pressure Testing - Pressure configuration testing
  - Pump Flowrate Testing - Pump testing
  - Volume Infused Testing - Volume infused testing
  - Volume Void Testing - Volume void testing
  -
- Full Clinical Investigation - Performing clincial investigations

5.1.2 Requirements

1. Install VS Code
2. Install the PlatformIO extension for VS Code
3. Download the code repository from Control Software
4. Manufacture the urodynamics system

5.1.3 Loading scripts onto the hardware

1. Connect the hardware to via USB
2. Open the subdirectory of the control program you would like to upload
3. Using the PlatformIO extension
   (a) Build the script
   (b) Upload the script

5.2 User Interface Software

The User Interface Software repository stores user interface software for system testing and performing clinical urodynamics.

5.2.1 Requirements

1. Download the latest Windows installer file (User Interface Software).

5.2.2 Installation

1. Use the installer file to install the user interface software

5.2.3 Usage

1. Open the user interface software

2. Follow in app instructions

Authors

Michael Jeffryes

6 System Testing

6.1 Pressure Measurement Configuration

6.1.1 Purpose

This protocol defines the validation tests used to verify the accuracy, range, and performance of the pressure measurement system used in the Urodynamics Without Borders system. It ensures that the bladder (P_{ves}) and abdominal (P_{abd}) pressure channels provide reliable and reproducible measurements.

6.1.2 Scope

Applies to all pressure-measuring channels ($P_{\text{ves}}$and P_{abd}) and the associated system controller software. Testing should be completed after the urodynamics system has been assembled and before it is used clinically.

6.1.3 Test Criteria

Parameter	**Acceptance Criteria**
Accuracy	$\pm 3\%$ of the true value or ± 1 cmH_2O
Range	-30 to 250 cmH_2O
Bandwidth	The sampling rate of both channels should be ≥ 3 Hz.
Reference level reset	Equipment must allow reference levels to be reset.

Table 7: Pressure Measurement Test Criteria

6.1.4 Required Equipment

Confirm the pressure system has been manufactured correctly (according to section 4.4.3). Additional test equipment required:

- Stand ($\geq 1m$) and clamp for catheter outlet positioning
- Ruler or scale (mm precision)
- Syringe and tubing to create a water column
- Water (preferably distilled)

Each validation step must be repeated for both $P_{\text{ves}}$and P_{abd}channels.

Maintain an error log during testing for observations or anomalies (e.g. drift, air bubbles, instability, or unexpected readings).

6.1.5 Validation Procedures

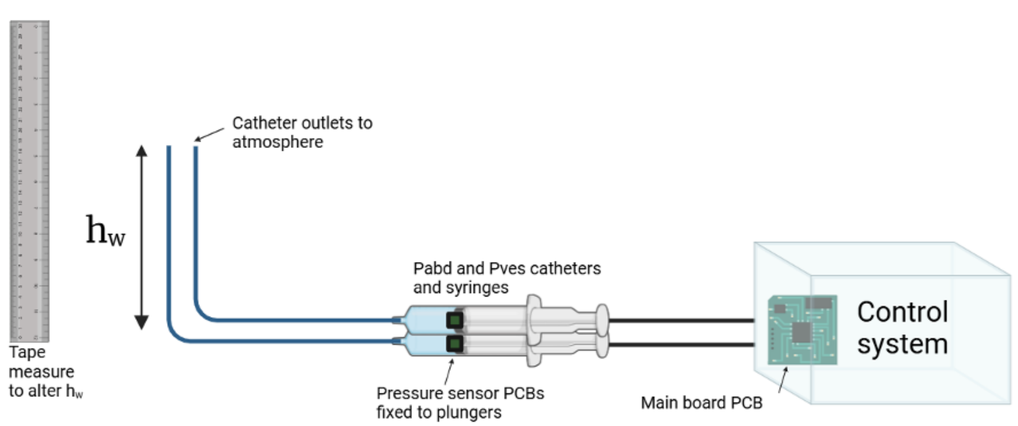


Figure 7: Pressure Measurement Test Setup

Pre-test Setup

This section is to confirm that the system has been set-up and manufactured correctly. It will confirm if the reference level reset is functioning correctly, and that baseline drift is minimal.

1. Verify all connections by visual inspection (DIN connectors, Tubing, sensors etc.)
2. Fill and prime the system with water (priming the system), ensuring no visible air bubbles remain.
3. Align the transducer diaphragm with the catheter outlet (same vertical level). *Note: Clinically, this will be the height of the superior border. For testing it just needs to be in line with the catheter outlet of the catheter.*
4. Use 'Zero channels' operation to reset baselines.

Zero reference reset check

1. Set $H_w$to zero and re-zero the system.
2. Confirm both pressure channels read 0 ± 1 cmH_2O, wait 10 seconds and check that the readings remain stable ($\leq \pm 1$ cmH_2O drift at rest).
3. Move the catheter outlets $10cm$ above the syringe inlet (generating a pressure equal to $+10$ cmH_2O). *Confirm the system reads* $+10$ *$cmH_2O \pm 1$ cmH_2O.*
4. **Re-zero** the system
5. The reading should now display 0 cmH_2O.
6. Now re-apply another pressure change, by increasing the head by another $+10cm$ ($H_w = 20cm$ from original position). *The reading should display* $+10$ *cmH_2O(i.e. the new offset is correctly measured relative to the new zero point).*

Static accuracy test

Purpose: To test whether the system accurately measures a change in static pressure by varying the head of water (H_w).

1. Vary H_w from $10 - 100$ cmH_2O in 10 cmH_2O increments
2. Record and document the corresponding measured pressures for each height (for both P_{ves} and P_{abd} channels)
3. Compute mean difference and standard deviation between true and measured pressures.
4. Repeat the test three times
5. Plot a Bland-Altman graph to assess accuracy (see figure 8)

Acceptance: Mean difference $\leq \pm 1$ cmH_2O; SD $\leq \pm 0.5$ cmH_2O.

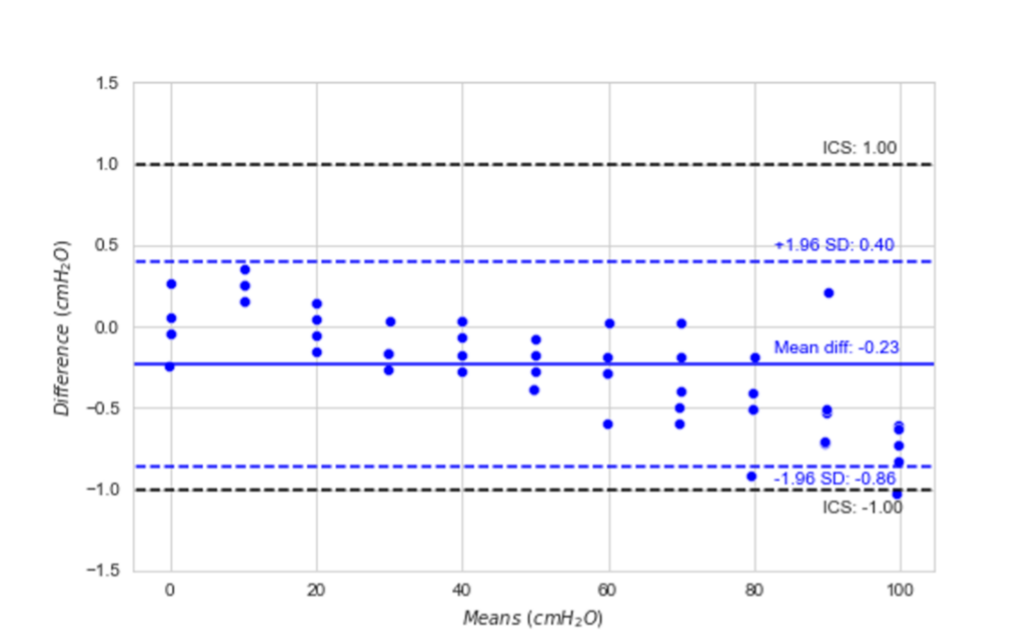


Figure 8: Example Bland-Altman plot for static accuracy test. The solid line represents the mean difference, while the blue dashed lines indicate the limits of agreement ($mean \pm 1.96 * SD$). The black dashed line represents the ICS guideline.

Range Verification

1. Repeat the static accuracy test at values -30 and 250 cmH_2O
2. Verify that the sensor and the control system function correctly across their full range without:
   - Saturation (so the signal reaching a max/min limit)
   - Clipping (peaks abruptly flattened)
   - Non-linearity near the extremes.

If using a weight for the upper limit: Use the following equations to calculate the mass that needs to be applied to give 250 cmH_2O (it will vary depending on diameter of cylinder):

$$F = mg \tag{1}$$

$$A = \frac{\pi d^2}{4} \tag{2}$$

$$P = FA \tag{3}$$

Bandwidth/Sampling rate validation

1. Sampling frequency
   (a) Operating both channels under their normal recording mode.
   (b) Export a segment of the pressure data (30 to 40 seconds including timestamps)
   (c) Calculate the average time interval between the samples (Δt)

   $$\Delta t = t_n - t_{n-1} \tag{4}$$

   (d) Calculate the sampling frequency (f)

   $$f = \frac{1}{\Delta t} \tag{5}$$

   (e) Repeat this 5 times to confirm consistency
   (f) Verify average sampling frequency $\geq 3Hz$
2. Dynamic response
   (a) Operating both channels under their normal recording mode.
   (b) Simulate a rapid pressure change (e.g. tap the catheter outlet or quickly move it vertically by a small amount).
   (c) Check whether the output pressure waveform is preserved (no excessive smoothing) and amplitudes and gradients are reasonable.

Verification of Pdet calculation

Purpose: Confirm that the detrusor pressure calculation is implemented correctly in the software.

$$P_{\text{det}} = P_{\text{ves}} - P_{\text{abd}} \tag{6}$$

1. Hold one channel constant (e.g. P_{abd}= 0 cmH_2O)

2. Vary the other channel (e.g. P_{ves}) and record the output
3. Record both channel readings and the displayed P_{det}.
4. Confirm whether the systems output of value of P_{det} matches that of the $P_{\text{ves}}-$ P_{abd} values
5. Repeat three times, altering H_w

Note: this should only be done once the values of P_{ves} *and* P_{abd} *have been validated.*

6.1.6 Reporting of results

Document the results of all tests, including:

- Date of testing
- Personnel involved
- Equipment used (including calibration status)
- Environmental conditions (e.g. temperature, humidity)
- Status (pass/fail)

Authors

Michael Jeffryes and Emma Mitchell

6.2 Fluid Infusion Testing Configuration

Authors

Michael Jeffryes

6.3 Uroflowmetry Testing Configuration

6.3.1 Purpose

This protocol defines the validation tests used to verify the accuracy, range, and performance of the uroflowmetry sub-system used in the Urodynamics Without Borders system. It ensures that the subsystem accurately measures the voided volume and flow rate of fluid during testing, and that these values are correctly displayed by the user interface (UI) software.

6.3.2 Scope

Applies to all uroflowmetry hardware and software components, including:

- The uroflowmetry device setup (cantilever load cell and mechanical assembly)
- The signal conditioning and UI

Testing must be completed following system assembly and prior to clinical use.

6.3.3 Test Criteria

Parameter	Acceptance Criteria
Flow rate (Q) measurement	Accuracy: ±1 mL/s Range: 0–50 mL/s Minimum flow recordable: $\leq$ 1 mL/s
Volume void measurement	Accuracy: greater of ±3% of true value or ±2 mL Range: 0–1000 mL
Maximum recording duration	$\geq$ 120 seconds

Table 8: Uroflowmetry Test Criteria

6.3.4 Required Equipment

Confirm the uroflowmetry system has been manufactured correctly (see Section 4.4.2 for details).

Additional test equipment required:

- Calibrated digital scales (precision ±1 g or better)

- Gravity-fed infusion tank (wider tanks preferred to maintain constant head pressure) with:
  - Flexible pipe width (P_w) $\approx$ 6–7 mm
  - Adjustable flow clamp/valve (to vary flow rate)
- Infusion fluid (density $\approx$ 1.00 g/mL; water at room temperature is sufficient)
- Graduated cylinder or volumetric flask (1000 mL minimum)
- Stopwatch or timing software
- Stand and clamp for securing container

Maintain an error log throughout testing for any observations or anomalies (e.g. unexpected readings).

6.3.5 Validation Procedures

Set up the system as shown in Figure 9

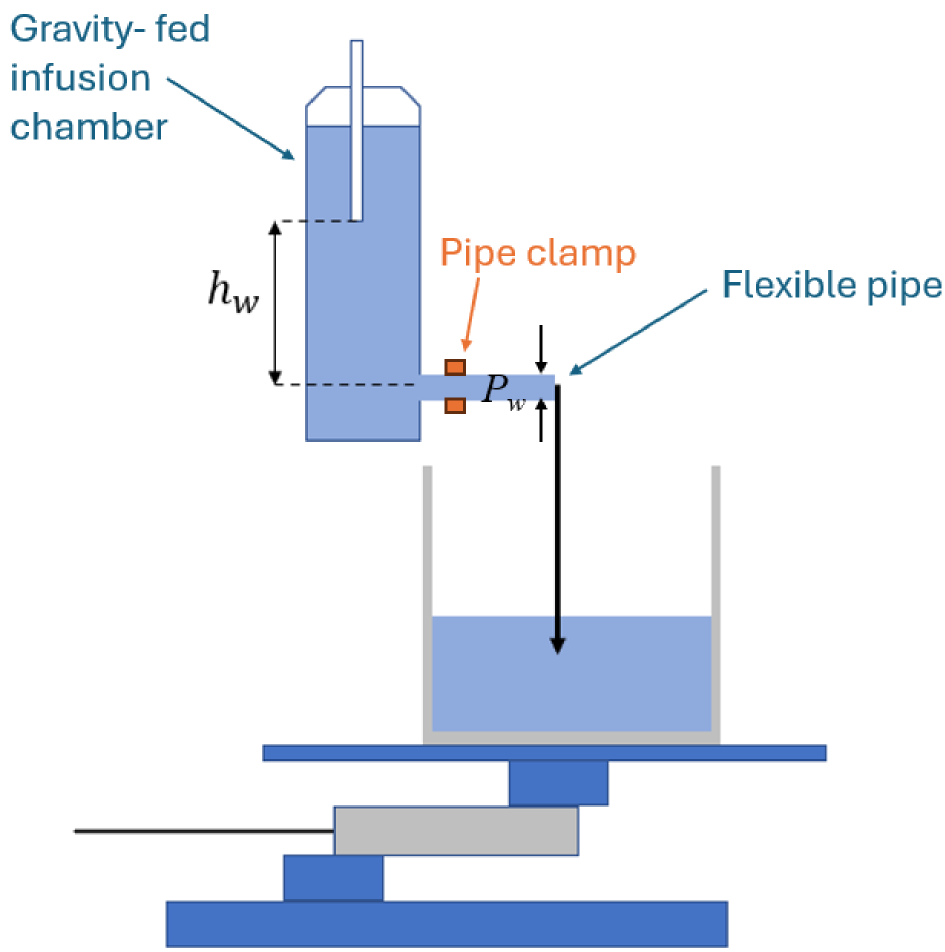


Figure 9: Example set-up for uroflowmetry testing.

(a) Pre-test Set-up

This section confirms that the system has been set up and manufactured correctly.

- Verify all hardware connections and ensure the load cell and container are mounted securely.

- Confirm that the UI software is communicating with the main board and displaying real-time force data (press down on the uroflowmetry device to check for a response).
- Ensure the container is placed on the uroflowmetry system with no fluid present.
- Re-zero the system (to set the baseline).
- Confirm the system reads 0 mL/s flow rate.

(b) Volume Measurement Accuracy Test

Purpose: Confirm that the measured voided volume corresponds to the true volume.

Procedure:

1. Place the empty collection container onto the uroflowmetry device.
2. Re-zero (tare) the system so the displayed volume is 0 mL.
3. Add known quantities of fluid (e.g., 100, 200, 400, 600, 800, 1000 mL) slowly into the container.
4. Independently verify the true added volume using a calibrated digital scale (1 g $\approx$ 1 mL for water-based fluid).
5. Record the system's measured volume from the UI for each quantity.
6. Calculate the percentage error for each measurement:

$$\text{Percentage error} = \frac{V_{\text{Measured}} - V_{\text{True}}}{V_{\text{True}}} \times 100\%.$$

7. Repeat the full set of measurements three times.
8. Compute (and plot) the mean and standard deviation across repeats.

Acceptance Criteria: Mean difference $\leq \pm 3\%$ or ± 2 mL.

(c) Flowrate Measurement Accuracy Test

Purpose: Verify that the flow rate calculations are accurate across the clinical range (0–50 mL/s).

Procedure:

1. Set up the gravity-fed infusion system (see figure 9) with a flexible outlet pipe discharging into the uroflowmetry container and re-zero the system.

2. Use an adjustable flow clamp to produce target flowrates of 5, 10, 20, 30, 40, 50 mL/s.
   Note: As a guide, estimate the head of water (h_w) and pipe width (P_w) needed to produce the desired floe rate using Torricelli's Law (Appendix 9.2.2).

Flow rate (mL/s)	P_w **(mm)**	h_w **(mm)**
5	3	52
10	4	66
20	5	107
30	5	243
40	6	208
50	6 or 7	325 or 175 (respectively)

Table 9: Example flow rate estimates using Torricelli's law

3. Measure true flowrate over 20 seconds using:

   - Volume or chnage of mass collected over time (graduated cylinder or scales),
   - A stopwatch.

   True flowrate:
$$Q_{\text{true}} = \frac{\text{Volume}}{\text{Time}}.$$

4. Simultaneously record the system's measured flowrate from the UI.

5. Repeat each test three times to confirm repeatability.

6. Compare measured vs. true flowrate at each target flowrate.
7. Compute (and plot) the mean and standard deviation across repeats (see figure 10 for an example).

Acceptance Criteria Mean difference $\leq \pm 1$ mL/s.

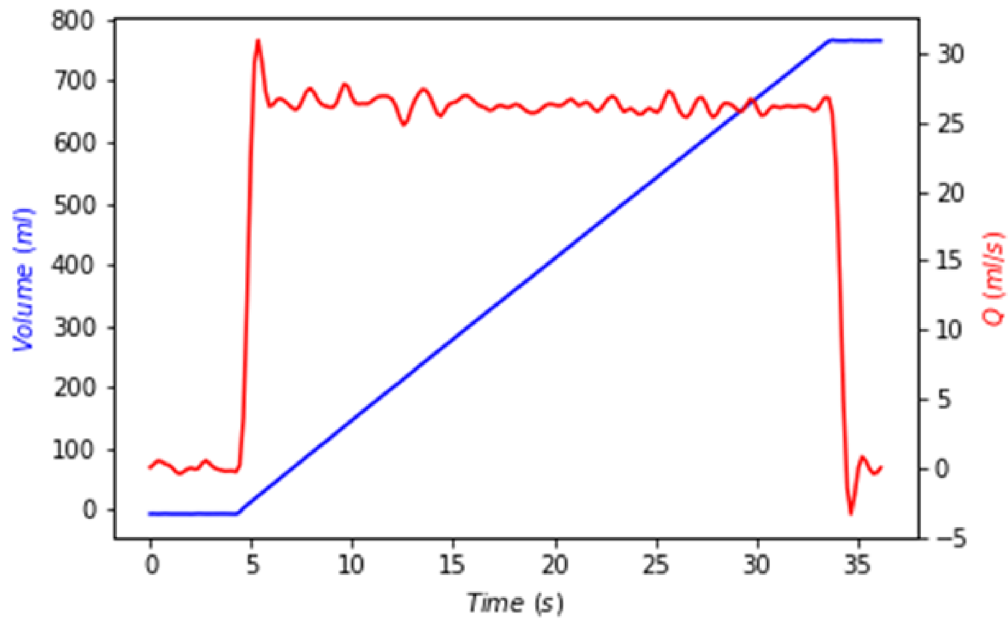


Figure 10: Example plot for flow rate testing

(d) Minimum Flowrate Accuracy Test

Purpose: Validate that the system can accurately record a flow rate of 1 mL/s.

Procedure:

1. Repeat the flowrate measurement procedure with a target of 1 mL/s.
   Note: This can be achieved using the gravity-fed infusion system with restricted outlet clamp.
   Reference values: $P_w = 1$ *mm,* $h_w = 169$ *mm* $\Rightarrow$ *approx. 1 mL/s.*

(e) Maximum Recording Duration Test

Purpose: Verify that the system can continuously record volume/time data for at least 120 seconds.

Procedure:

1. Start a continuous, slow fluid flow (e.g. ≤ 8 mL/s – *to ensure the max volume isn't over 1000 mL*).
2. Allow the system to record for at least 10 minutes.
3. Observe the live display on the UI, look for any drift, discontinuities or data loss.
4. Confirm that the full volume and time are recorded accurately.

Acceptance Criteria:

- Maximum recording duration ≥ 120 seconds (document maximum time tested).
- No signal saturation, clipping, or discontinuity.

Results Documentation

Include:

- Date
- Operator
- Pass/fail outcome for each of the above tests
- Signature

Authors

Michael Jeffryes and Emma Mitchell

7 Clinicial Use

Authors

Michael Jeffryes

8 Project Change Log

8.1 System Design

8.2 Support Structure CAD Files

8.3 User Interface Software

8.4 Hardware Control Software

8.5 PCB Files

9 Appendices

9.1 Pressure Measurement

Assumptions for pressure measurement calculations in Urodynamics Without Borders system.

Gravity has been assumed to be:

$$g = 9.81 \text{ m/s}^2 \tag{7}$$

Water density has been assumed to be:

$$\rho = 1000 \text{ kg/m}^3 \tag{8}$$

The pressure exerted by a static fluid column is given by the equation, the gravity and water density constants are used to express pressure in cmH_2O

$$P = \rho g h_w \tag{9}$$

The pressures used in all calculations are the gauge pressures (relative to atmospheric pressure) not the absolute pressures.

Authors

Michael Jeffryes and Emma Mitchell

9.2 Uroflowmetry Measurement

9.2.1 Hydrostatic Pressure Relation

For these tests, assume that 1 cm ≈ 1 cmH_2O using:

$$P = \rho g h_w$$

where

P	hydrostatic pressure (cmH_2O)
ρ	fluid density (≈ 1000 kg/m^3)
g	9.81 m/s^2
h_w	height difference (m)

9.2.2 Torricelli's Law

Torricelli's law describes jet speed based on fluid height:

$$v = C_d\sqrt{2gh_w}$$

where v = outlet velocity, C_d = discharge coefficient (0.6–0.8).

Flow rate:

$$Q = Av = C_d A\sqrt{2gh_w}.$$

Solving for h_w:

$$h_w = \frac{1}{2g}\left(\frac{Q_t}{C_d A}\right)^2.$$

Example (50 mL/s, 5 mm tube, $C_d = 0.7$):

$$A = \pi\left(\frac{0.005}{2}\right)^2 = 1.96 \times 10^{-5}\ \text{m}^2,$$

$$h_w = 0.68\ \text{m}.$$

Flow rate (mL/s)	P_w **(mm)**	h_w **(mm)**
10	4	66
20	4	264
30	5	243
40	5	432
50	6	325

Table 10: Example values from Torricelli's law