QN1-PQ-002 SOP AND VERIFICATION OF PERFORMANCE QUALIFICATION FOR THE QNANO

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1 / SCOPE

PURPOSE

Achieving accurate size and concentration measurements with the qNano relies on correct operation of the entire system. This document:

- Records that maintenance checks have been undertaken, when and by whom.
- Defines a series of primary functionality checks that, if passed, confirm the system is operating correctly.
- Provides secondary checks in the event that the system fails any of the primary checks.
- Recommends maintenance procedures to rectify shortfalls in system performance.
- Records the state of repair of the equipment, and any maintenance steps that were undertaken to correct problems.

2 / REQUIRED MATERIALS AND DOCUMENTS

MATERIALS

The following materials are required to perform the entire PQ protocol and are not provided by Izon:

- Izon Training kit (or NP250, CPC200 and CPC400)
- Digital callipers
- 10 MΩ reference cell
- Computer with the Control Suite Software installed.
- Calibrated micropipettes - 1 µL to 1 mL
- A vortex mixer
- Filtered deionised water
- Compressed nitrogen for drying. Alternatively, clean compressed air spray is also acceptable
- Lint-free tissue
- Standing racks for tubes (optional)
- Powder-free disposable gloves
- Refrigerator
- Digital resistance meter (Min 0.1 Ω)
- 3 mm Allen key
- 320 grit sandpaper

Hardware Details

Equipment type	S/N location	Serial number
qNano Base Unit	On front of base	
Pressure Reading Module (PM2), if applicable	On underside of PM2 unit	
Fluid Cell	Engraved on metal part	
Variable Pressure Module (VPM)	On underside of base plate	
Nanopore (NP200 or 300)	On long arm of nanopore	
Izon Data Suite version	In the software "ABOUT" section	

Computer requirements

Please refer to QN1-IQ-002 section 8 for the computer minimum system and hardware requirements.

Acceptance Criteria	The computer meets the minimum requirements.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

DOCUMENTS

Confirm that the documents and drawings required to complete the PQ procedure are present and satisfactory (S) or unsatisfactory (US); and that the documents are located on the USB drive supplied with the instrument and where they will be stored as a hard copy. Prior to Performance Qualification, confirm that the Installation Qualification and Operational Qualification have been completed and have these documents available for reference:

Documents Storage Location	Title	Initial	Date
	Tester		
	Approver		

Document Code	Document Title	Doc Status S/US	Initial	Date
QN1-IQ-002	SOP and Verification of Installation Qualification for the qNano			
QN1-OQ-002	SOP and Verification of Operational Qualification for the qNano			

DOCUMENT ACCEPTABILITY VERIFICATION

Acceptance Criteria	All listed documentation must be stored in a secure known location and controlled access for authorized personnel must be available. The scope of the documentation must be sufficient to ensure that the equipment can be installed, maintained and operated in accordance with cGMP requirements and vendor recommendations.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

3 / IDENTIFICATION OF PERSONNEL PERFORMING PQ

The protocol may only be undertaken and verified by people who are qualified to do so:

Date of PQ		
Tester (Izon Certified)	Name	
	Position	
	Signature	
Approver (QA or Maintenance Representative)	Name	
	Position	
	Signature	

4 / FREQUENCY OF MAINTENANCE CHECKS

The maintenance protocol should be performed either to a schedule (annual by default, or a maximum of two years apart for infrequent users) – this is "Scheduled" maintenance OR whenever there is any doubt that the system is operating correctly – this is "Corrective" maintenance.

To ensure that the latest maintenance protocols are being used, request new documentation from Izon before undertaking formal maintenance checks. Record the date on which the maintenance procedure protocols were received from Izon and when they were performed, the dates should be less than 1 month apart.

The scheduled maintenance periods may be adjusted after corrective maintenance is undertaken (i.e. corrective maintenance can count as scheduled maintenance).

PQ Type (Scheduled / Corrective)	PQ Docs Received Date (dd/mm/yy)	PQ Date (dd/mm/yy)	Next PQ Due Date

Acceptance Criteria	The PQ documentation used was obtained from Izon less than 1 month ago.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

5 / PREPARING THE SOLUTIONS

ELECTROLYTE PREPARATION

Follow the instructions in Section 7 of QN1-IQ-002 to prepare the Measurement Electrolyte (ME). Fill out the table below to record the ME batch details used in this performance qualification.

Electrolyte Type	
Electrolyte Origin (Izon/Customer)	
Electrolyte Batch/Date of Manufacture	
Electrolyte Filtered? (Y/N)	
Filtered Electrolyte is Labelled Correctly?	

WETTING SOLUTION

Follow the instructions in Section 7 of QN1-IQ-002 to prepare the wetting solution.

Acceptance Criteria	Wetting Solution and ME are filtered into the Falcon tubes through a 0.22 µm filter and are labelled correctly.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

CALIBRATION PARTICLE PREPARATION

View Section 4 of QN1-OQ-002 for important information regarding the preparation of calibration particles. For this PQ protocol, either Training Particles (TKP 200) and Training Sample (Solution S) provided in the Training Kit or CPC200 and CPC400 can be used.

Particle Type (Circle one)	TKP200 or CPC200	Solution S or CPC400
Particle Batch Number		
Expiry Date		
Concentration (particles/mL)		
Dilution Factor		
Diluted Particles Vortexed >15 seconds? (Y/N)		
Diluted Particles Labelled Correctly? (Y/N)		

6 / FUNCTIONALITY CHECKS

Successful functionality checks will confirm that the system and components are working as intended. If any of the checks do not meet the acceptance criteria, additional checks and remedial actions are specified - (details of these checks and fixes can be found in Section 7 of this document).

CHECK RESTING BASELINE CURRENT AND RMS NOISE

Using Classic Capture, this check is undertaken without the nanopore or electrolyte present.

Fill out the following checklist to ensure that the test is being performed accurately:

- ☐ SMA Cable is connected.
- ☐ Lower fluid cell clicked into qNano base.
- ☐ Upper Fluid Cell and Fluid Cell Cap fitted.
- ☐ Signal trace turned on with zero voltage applied.

Resting Baseline Checks	Initial Check	Remedial Action Required?	Final Check
Record Current (nA)			
Record RMS Noise Typical (pA)			

If the acceptance criteria are not met, proceed to later sections in this document for trouble shooting, listed below:

- qNano check 1
- Dry upper and lower fluid cell with compressed gas.

Once the above checks have been performed, carry out the resting baseline current and RMS noise check again. If the system still does not pass the criteria, please contact Izon Support for further assistance. Do not proceed with the rest of this document is the acceptance criteria are not met.

Acceptance Criteria	• Current is 0±1 nA • RMS noise < 7 pA	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

INSTRUMENT BODY WITH REFERENCE CELL

Still using Classic Capture, install a 10 MΩ reference cell. Apply a voltage of 0 V and record data for 10 seconds. Apply a voltage of 1.0 V and record data for 10 seconds. Apply a voltage of -1.0 V and record data for 10 seconds. Process the files and record the baseline current and RMS noise in the table below.

Fill out the following checklist to ensure that the test is being performed accurately:

- ☐ SMA Cable is connected.
- ☐ Reference cell clicked into qNano base.

Applied Voltage	Current (nA)	RMS noise (pA)
0 V		
1.0 V		
-1.0 V		

Contact Izon Support and do not proceed with the rest of the testing in this document if this acceptance criteria is not met.

Acceptance Criteria	• 0 V applied gives a current of 0±1 nA • 1 V applied gives a current of 100±10 nA • -1 V applied gives a current of -100±10 nA • RMS noise < 7 pA for all three recordings	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

CHECK CURRENT SYMMETRY

Still using Classic Capture, set up the nanopore with a stable baseline current as outlined in QN1-IQ-002 Section 8.

Fill out the following checklist to ensure that the test is being performed accurately:

- ☐ Nanopore fitted and stretched to 47 mm.
- ☐ Upper Fluid Cell and Fluid Cell Cap fitted.
- ☐ ME in the upper and lower fluid cell with a stable baseline established,
  - ☐ Baseline doesn't drift by more than 0.1 nA in 30 seconds.
  - ☐ RMS noise <10 pA

Apply a voltage so as the current is ~100 nA and record the current, rms noise and voltage values in the table below. Invert the voltage (e.g. 0.24 V to -0.24 V) and allow the system to stabilise, record the current, rms noise and voltage values in the table below.

Current Checks	Initial Check	Remedial Action Required?	Final Check
Positive Current Value "Ipos" (nA)		-	
Positive Voltage Value (V)		-	
Positive Current RMS noise (pA)		-	
Negative Current Value "Ineg" (nA)		-	
Negative Voltage Value (V)		-	
Negative Current RMS noise (pA)		-	
Calculate Ineg/Ipos			

If the acceptance criteria are not met or it is not possible to establish a stable baseline current after multiple attempts and different nanopores, proceed to later sections in this document for trouble shooting, listed below:

- System checks 1-3
- Fluid Cell contact area checks

Once the above checks have been performed, carry out the current symmetry check again. If the system still does not pass the criteria, please contact Izon Support for further assistance.

Acceptance Criteria	• Stable baseline is achievable • RMS noise <10 pA for both positive and negative voltage values • 0.9 < (Ineg/Ipos) < 1.1	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

CURRENT STABILITY AND PRESSURE SYSTEM LEAKS

Apply a pressure of 10 mBar and collect a five minute recording. Note down the applied pressure and baseline current at the start and the end of the recording.

Fill out the following checklist to ensure that the test is being performed accurately:

- ☐ Baseline current ~100 nA.
- ☐ Pressure stage adjuster pushed down so not showing red band (standard pressure range)

Pressure and Current checks	Initial Check	Remedial Action Required?	Final Check
Starting Current (nA)		-	
Starting Pressure (mBar)		-	
End Current (nA)			
End Pressure (mBar)			

Apply a pressure of -10 mBar and collect a five minute recording. Note down the applied pressure and baseline current at the start and the end of the recording.

Pressure and Current checks	Initial Check	Remedial Action Required?	Final Check
Starting Current (nA)		-	
Starting Pressure (mBar)		-	
End Current (nA)			
End Pressure (mBar)			

If the acceptance criteria are not met or it is not possible to hold a linear rate plot after multiple attempts, proceed to later sections in this document for trouble shooting, listed below:

- System check 4
- VPM check 1
- PM2 check 1

Once the above checks have been performed, carry out the functional stability check again. If the system still does not pass the criteria, please contact Izon Support for further assistance.

Acceptance Criteria	• Applied pressure does not drift more than 0.5 mBar for both positive and negative pressures. • Positive blockades not observed. • Baseline current does not drift more than 5% of initial value for both recordings. • RMS noise <10 pA. • No irregular signs in the signal trace e.g. positive spikes.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

FUNCTIONAL STABILITY

Replace the electrolyte in the upper fluid cell with the diluted CPC200 or TKP200 Calibration Particles. Apply 5 mBar pressure and optimise the applied voltage and stretch so that the blockades are around 0.2 nA.

Fill out the following checklist to ensure that the test is being performed accurately:

- ☐ 500 Pa pressure applied.
- ☐ Baseline current ~100 nA.
- ☐ Particle rate of 500-1500 particles/min (Increase applied pressure if necessary).

Capture a three minute recording. Process the files and view the blockade histogram and particle rate plot.

If the acceptance criteria are not met or it is not possible to hold a linear rate plot after multiple attempts, proceed to later sections in this document for trouble shooting, listed below:

- System check 4
- VPM check 1
- PM2 check 1

Once the above checks have been performed, carry out the functional stability check again. If the system still does not pass the criteria, please contact Izon Support for further assistance.

Acceptance Criteria	• Particles are resolved. • Particle rate plot is linear. • No irregular signs in the signal trace e.g. positive spikes.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

7 / SYSTEM MAINTENANCE CHECKS

The checks listed below need only be performed if one or more of the Functionality Checks in Section 6 do not meet the acceptance criteria. Once these checks and remedial actions are complete, repeat the failed functionality checks to confirm that the system meets the required acceptance criteria.

When using a digital resistance meter to check the resistance between components, the contact resistance (the value that the meter reads when the probes are touched together) must be subtracted from the measured resistance.

ASSEMBLY MAINTENANCE CHECKS

These checks are to confirm that the component parts are working correctly when assembled into a system.

Issues with electrical connections can generally be rectified by cleaning the contact areas – refer to the details in the components checks below.

System Check 1 – Connection of the Lower Fluid Cell to the qNano

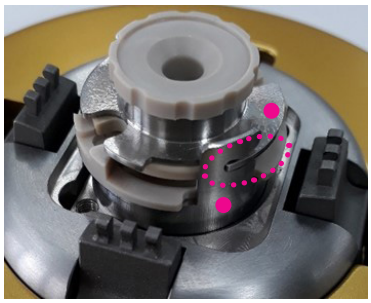
- Connect the fluid cell to the SMA Cable. The connection should be "finger tight" – no need to use a spanner.
- Check that the fluid cell snaps firmly into place.
- Check that the fluid cell does NOT rock from corner to corner.
- The resistance between the qNano body and the lower fluid cell shell can be measured at the test points shown to the right using a digital resistance meter.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
Resistance should be <1 Ω.		

If the resistance measured is NOT <1 Ω then refer to lower fluid cell check 2 and/or qNano check 2.

System Check 2 – Connection of the Upper Fluid Cell to the Lower Fluid Cell

- Connect the upper fluid cell to the lower fluid cell.
- Check that the upper fluid cell is pushed up against the top of the bayonet fitting by the spring in the lower fluid cell.
- The resistance between the upper and lower fluid cells can be measured at the test points shown to the right. Do not push down hard on the top cell test point – this could cause disconnection at the bayonet fittings (circled).

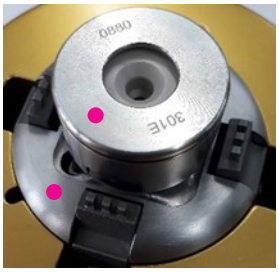


Acceptance Criteria	Results	Results Meets AC? (Y/N)
Resistance should be <1 Ω.		

If the resistance measured is NOT <1 Ω then refer to lower fluid cell check 3 and/or upper fluid cell check 1.

System Check 3 – Connection of the Fluid Cell Cap to the Fluid Cell

- Connect the fluid cell cap.
- There should be a slight resistance as the shielding cap is fitted – it should neither feel tight, nor fall into position.
- The resistance between the qNano body and shielding cap can be measured at the test points shown to the right.



Acceptance Criteria	Results	Results Meets AC? (Y/N)
Resistance should be <3 Ω.		

If the resistance measured is NOT <3 Ω then confirm that system checks 1 and 2 are both OK, failing that please contact Izon support for advice

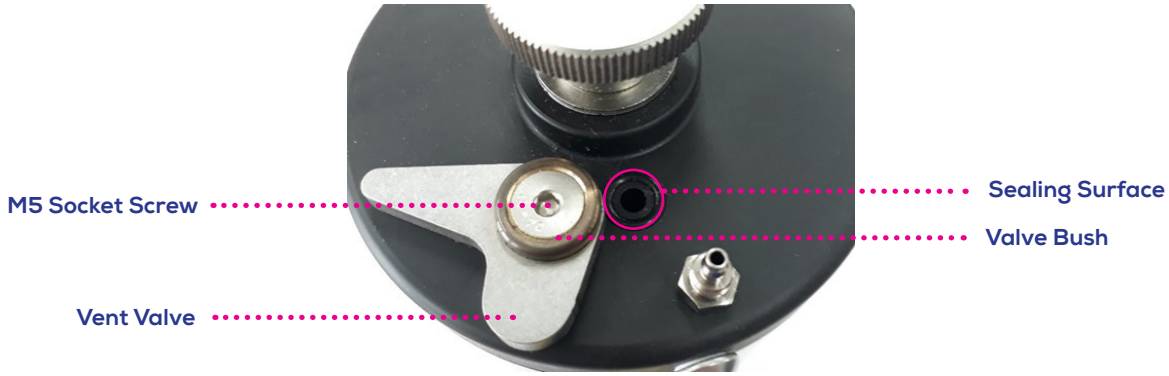
System Check 4 – Connection of the APS Nozzle to the Fluid Cell

- Connect the APS nozzle into the upper fluid cell.
- Check that there is a slight resistance as the nozzle is inserted – it should neither feel tight, nor fall into position.
- If the APS nozzle is slightly tight, it may be possible to accidentally disconnect the top cell when removing the nozzle. To avoid accidental fluid cell disconnection, it is good practice to avoid rotating the nozzle when removing or inserting it from the upper fluid cell.
- If the nozzle is too loose, contact Izon Support for assistance.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
Slight resistance to nozzle insertion, not too tight and not too loose.		

PRESSURE SYSTEM HARDWARE MAINTENANCE CHECKS

VPM Check 1 – Vent Valve and Seal



Check the condition of the vent valve assembly.

Acceptance Criteria	Results Meets AC? (Y/N)	Solution
Check that the sealing surface has no damage (e.g. pits, flat spots or cuts).		Request replacement from Izon Support (Size 010).
Check that the vent valve closes smoothly over the sealing surface without any sticking or squeaking.		Request advice on Food Grade O-ring grease from Izon Support.
Rotate the vent valve and check that the valve bush and M5 socket screw remain static.		Tighten screw with a 3 mm Allen key. DO NOT over tighten the screw.

PM2 Check 1 – Nozzle O-Ring Seal

The nozzle O-ring seal which connects the PM2 to the upper fluid cell can suffer mechanical or, with incompatible fluids, chemical damage.

- Check that the O-ring is still flexible and that the sealing surface has no significant damage.
- The nozzle O-ring should normally be dry and NOT have any grease applied.
- If in doubt, request a replacement O-ring from Izon (size MR003x1 – material N70):
  - Remove the old O-ring by sliding a tool down the side and levering it up.
  - Press the replacement O-ring into place.

Take care to avoid scratching the plastic nozzle component when replacing the O-ring.

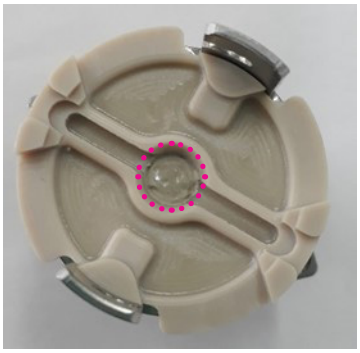
Acceptance Criteria	Results	Results Meets AC? (Y/N)
O-ring in good condition.		

FLUID CELL MAINTENANCE CHECKS

Fluid cell maintenance checks focus mainly on the electrical contact areas. These can become dirty or oxidised over time, which degrades the signal quality. Lift the fluid cell out of the qNano, unscrew the SMA connector and separate it into its three sections (lower fluid cell, upper fluid cell and shielding cap).

Lower Fluid Cell Check 1 – The Lower Electrode

The lower electrode consists of a ring of silver wire recessed in the plastic component, which is coated with an Ag/AgCl electrode paste. The colour of the paste can vary from being very similar to the plastic to quite a lot darker, depending on usage.

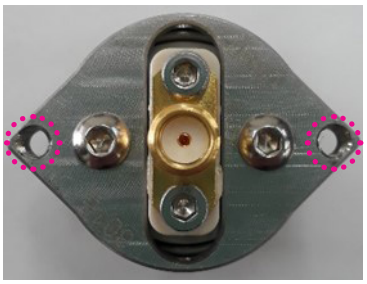


Check that the electrode paste is still present and has not been damaged by incompatible cleaning agents or physical abrasion (the example electrode here is in good working order). If in doubt, send a photo of the electrode to Izon. Isopropyl Alcohol/Isopropanol/IPA is NOT compatible with the electrode paste and should not be used to clean the upper or lower fluid cells.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
Electrode paste in good condition.		

Lower Fluid Cell Check 2 –Lower Fluid Cell qNano Contact Area

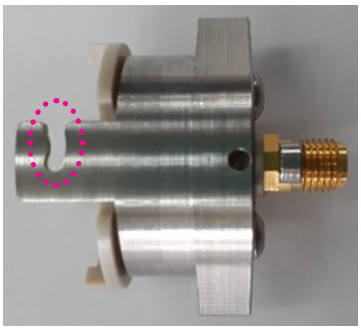
When the fluid cell is "clicked" into the qNano base, it sits on the two contact areas shown.



- Check that the contact areas are clean, if not then use a piece of 320 grit sandpaper to gently clean these areas. Take care to blow away any debris.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The contact areas are clean and free of debris.		

Lower Fluid Cell Check 3 – The Lower Fluid Cell Bayonet Contact Area

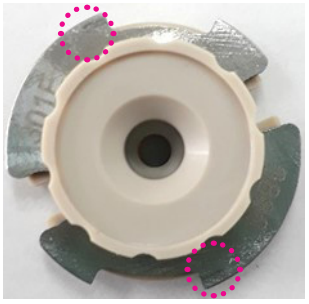


The electrical earthing connection between the lower and upper fluid cells is made via the two contact areas on the bayonet arms.

- Check that the contact areas are clean, if not then use a piece of 320 grit sandpaper to gently clean these areas. Take care to blow away any debris.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The contact areas are clean and free of debris.		

Upper Fluid Cell Check 1 – The Bayonet Contact Area

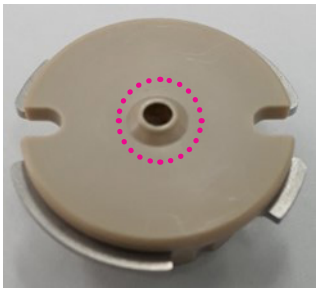


The electrical earthing connection between the lower and upper cells is made via the two contact areas on the bayonet arms.

- Check that the contact areas are clean, if not then use a piece of 320 grit sandpaper to gently clean these areas. Take care to blow away any debris.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The contact areas are clean and free of debris.		

Upper Fluid Cell Maintenance Check 2 – The Upper Fluid Cell to Nanopore Sealing Area



A sliding seal is maintained between the upper fluid cell and the nanopore, which allows the nanopore to be stretched and relaxed without any leakage of fluid.

Check that the sealing area of the upper fluid cell is free of any deep grooves or scratches.

A damaged seal will result in leakage of fluid from the upper cell, especially when pressure is applied, or when working at low stretches (around 43 mm). Contact Izon Support if a replacement part is required.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The sealing area is in good condition		

QNANO MAINTENANCE CHECKS

qNano Check 1 – The SMA Cable

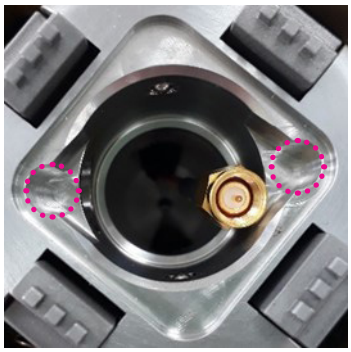
Removal of the fluid cell requires lifting and lowering of the SMA cable that feeds down the middle of the qNano. Occasionally the plastic sheath on the cable can be damaged, which can result in high RMS noise or in extreme cases shorting of the signal to the earth which causes current "railing" (very high positive or negative current values).

- Lift the SMA connector up from level with the top of the qNano to 50 mm above (this is the recommended maximum height).
- Check that the cable lifts smoothly without any obvious "catches".
- Look down the centre of the qNano when the cable is up and check for any damage (typically visible as an angled cut) to the cable sheath at the bottom end.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The cable lifts smoothly.		
No damage to the cable sheath.		

qNano Check 2 – The Lower Fluid Cell to qNano Contact Area

When the fluid cell is "clicked" into the qNano base, it sits on the two contact areas shown.



- Check that the contact areas are clean.
- If a stable baseline current cannot be obtained and there is a high electrical resistance between the qNano and the lower fluid cell shell, use a piece of 320 grit sandpaper to clean these areas.
- Take care to remove any debris and avoid dropping it down the centre of the qNano.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The contact areas are clean and free of debris.		

qNano Check 3 – The USB Cable

The connection between the qNano and the PC is made through a standard USB to Mini USB cable. These cables can degrade with usage and occasionally cause faults. If in doubt, try a new USB cable.

- Check the connection into the qNano by gently moving the cable side to side when the signal trace is turned on. A small movement of the plug should not cause the system to freeze.
- Always set the qNano system up so that the USB connection is not under stress, and the cable is not near other cables that may cause interference (e.g. keep it away the vortex power supply cable).

Acceptance Criteria	Results	Results Meets AC? (Y/N)
Movement of the USB cable doesn't cause the system to freeze.		

qNano Check 4 – Stretching Mechanism

The stretching mechanism should turn smoothly without any tight spots, squeaking or rattling. If the mechanism feels rough or excessive force is required to turn the handle, contact Izon for advice.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The stretch mechanism turns smoothly.		

qNano Check 5 – The Power Supply

Check your power supply type, it will be either two-pin or three-pin (earthed). Historically the qNano system has been supplied with a two-pin power supply, however with advancing technology it is now supplied with a three-pin earthed power supply which provides better protection against electrical noise from external sources such as the computer, lab equipment, or lighting. Please contact Izon Support if you have a two-pin power supply and wish to upgrade it.

Acceptance Criteria	Results	Results Meets AC? (Y/N)
The power supply is three-pin.		

8 / FUNCTIONALITY AND MAINTENANCE SIGN-OFF

Once sections 6 and 7 have been completed, fill in the appropriate boxes following the results of the previous sections.

Maintenance Sign-Off (complete one row below)	Date	Initial
Functionality checks passed without remedial maintenance actions. **System Approved for Ongoing Use.**		Tester: Approver:
Functionality checks passed with remedial maintenance actions. **System approved for ongoing use.**		Tester: Approver:
Functional checks not all passed. Consult with Izon Support to rectify remaining issues before continuing use.		Tester: Approver:

9 / PARTICLE SIZE AND CONCENTRATION ANALYSIS

Follow sections 5 and 6 in QN1-OQ-002 to obtain size and concentration data for Solution S (or CPC400s). Review the particle size distribution histogram for this sample and ensure that it shows a normal distribution, the mean diameter is within 10% of the certified value (shown on the original vial), and that the particle concentration is within 25% of the certified value.

Once this section has been completed, clean the nanopore in accordance with Section 7 of QN1-OQ-002.

Acceptance Criteria	Results	Results Meets AC? (Y/N)	
Mean Diameter (nm)	(MMD)	(CMD)	CMD x 0.1 = Acceptable Variance (AV) MMD must fall within the range of CMD±AV
Concentration (particles/mL)	(MC)	(CC)	CC x 0.25 = Acceptable Variance (AV) MC must fall within the range of CC±AV

Acceptance Criteria	• Sample particle size distribution histogram shows an approximate normal distribution. • The measured mean diameter of sample particles is within ±10% of the certified value. • The measured sample particle concentration is within ±25% of the certified value.	
Result satisfies AC? (Y/N)		Tester Initial/Date:
		Approver Initial/Date:
Notes		

10 / CONCLUSION / COMPLETION OF PQ

List any discrepancies between anticipated/accepted and actual results of the previously described sections. Describe any corrective actions that are required to certify execution of the PQ.

Protocol Section	Further Action Required	Are There GMP Implications?	Corrective Action Number

Circle the appropriate answer from the bolded words below:

According to the information collected and reviewed as a result of this PQ process, it is our opinion that the required work **has been / has not been** completed and satisfactory results **have been / have not been** obtained, with the exception of those related to the following items on which corrective action is required:

- Number of items requiring Corrective Action: _____

This PQ cannot be approved if any of the outstanding Corrective Actions (CA) could compromise the company's cGMP procedures or standards.

- The number of outstanding CAs is: _____
- Do these CAs have cGMP implications: YES / NO

IF YES THEN THIS DOCUMENT CANNOT BE SIGNED OFF AS COMPLETED.

Signing this block below confirms that all variations and failures listed within this PQ have been accounted for in the PQ Report. This PQ has therefore been completed.

PERFORMANCE QUALIFICATION COMPLETION

Name	Title	Signature	Date

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