Serstech Arx+

Installation Qualification (IQ)
Operational Qualification (OQ)

Introduction to Serstech Arx+

Serstech Arx+ Indicator Raman spectrometer (Figure 1) is a hand-held optical instrument for measuring the intensity of light relative to Raman shift from the wavelength of the exciting laser, usually expressed in wavenumbers. Serstech Arx+ enables a non-destructive identification of chemical substances and it identifies substances though bags and bottles.

Figure 1. Overview of Serstech Arx+

Introduction to Qualification as part of the validation master plan

Qualification is a part of the Validation Master Plan. Qualification refers to the carefully designed and performed steps of proving that any premises, systems and/or piece of equipment will lead to the expected results as decided by the manufacturer.

For Serstech Arx+ the Qualification Plan includes

- Installation Qualification (IQ)
- Operational Qualification (OQ)

In this document Installation Qualification (IQ) & Operational Qualification (OQ) will be described for the Serstech Arx+ Indicator.

Part A – Installation Qualification (IQ)

Installation Qualification for Serstech Arx+

The Installation Qualification (IQ) Test verifies that the Serstech Arx+ (both firmware and hardware), its accessories and peripheral systems (PC software) are present and have been installed in accordance with installation specifications. (Serstech Arx+ will hereinafter be referred to as the indicator)

The scope of the IQ testing should include the following:

- Verification that the correct version of software is used
- Verification that all components are present, and that the equipment has not undergone any damage during shipping
- Verification that the Serstech manual is included

Serial number:

1. Find the serial no in the order confirmation
2. Check serial no. on the back of the instrument
3. Start the indicator and log in using your credentials
4. Go to Settings and select-> About
5. Read serial no. from the About box
6. The serial number should match the number stated in the About box, the order confirmation as well as on the label back of the indicator. If the serial number is the same, the test is passed.
7. Fill in the information in Table 1.

Table 1. Verification of indicator serial number

Serial number in the order confirmation	**Serial number on the backside**	**Serial number in indicator firmware (About box)**	**Pass/fail**

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Accessories

In Table 2 the accessories provided by Serstech is listed. Go through all accessories you to confirm that all components are present.

Table 2: Verification of listed accessories

Item	Image	Expected number	Number delivered	Pass/Fail
Glass vials (4mL)		9		
Strap holder		1		
Point and shoot adapter		1		
Vial holder insert				
Vial holder		1		
USB C cable		1		
AC Adapter 5 VDC (incl adapters for the most common standards)		1		
ChemDash – Chemical Intelligence Client Software (USB stick)		1		

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Manuals

Check the presence of manuals and fill in table 3.

Table 3. Verification of manuals

Manual format	**Delivered Yes/No**
Electronic form	
Paper form	

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The units and items comprising this system are to be recorded in the equipment list. After confirming the product specifications for each unit, check that the delivered products satisfy the required specifications for the purpose intended and then implement the test items.

Table 4 presents the technical characteristics for the indicator.

Table 4: Technical characteristics of Serstech Arx+

Item	**Specification**
Laser excitation	785 nm
Laser output power	300 mW Max
Spectral range	400 to 2300 cm^{-1}
Spectral resolution	8 - 10 cm^{-1}
Detector type	Linear CCD Array
Display	3.5” Transflective TFT with LED backlight
Firmware	Embedded Linux
Data formats	Csv, JCAMP & txt
Connectivity	USB C & Wi-Fi
Battery	Rechargeable Li-ion, nominal voltage 3.7V, capacity 1950mAh, non-user replaceable
AC Adapter	Output 5 VDC/1 A USB C for charging
Weight	590 g (1.3 lb)
Size	149 mm x 83 mm x 28 mm (5.9 x 3.3 x 1.1”)
Operating temperature	-20°C to +50°C (-4°F to 122°F)
Storage temperature	-30°C to +50°C (-22°F to 122°F)

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Installation Qualification for client application ChemDash Pro+

Chemdash, provided by Serstech, is a standalone PC application used for data storage, management, and review. Chemdash gives the ability to review data, creating reports and building user defined libraries. Follow the below steps to get started:

1. Start the installation by clicking on the .exe file provided and complete the installation.
2. Start the application by double clicking on the ChemDash icon.
3. Connect the Indicator to the computer with the supplied USB cable. Successful connection will be indicated by a cloud with an arrow through on the top right on indicator screen. In the application, the indicator will get a green icon in the device list.

For more in-depth information please check Chemdash user manual.

After completing all steps mentioned above, please fill in the information in table below.

Table 5: Complete installation for Chemdash-one

	Expected result	**Correct result obtained Yes/No**	**Comments**
Instrument display	Arrow in cloud		
Device management in ChamDash	Connected		

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Supplementary information

For Serstech Arx+ Indicator installation it is recommended not to attempt to repair the product by yourself.

- In case of failure or damage please contact Serstech or your Serstech reseller for service matters.
- Always follow your organization's procedure and regulations for the handling of unknown substances.
- Always use small sample amounts to limit possible hazards.
- The warranty is void if the product has been damaged by accident, misuse, or neglect.
- The warranty is void if the indicator has been opened or tampered with.
- This product is not designed to be intrinsically safe, and the user should take the necessary precautions when using the unit.
- This product is designed to be used in an everyday environment in the field and is therefore considerably more rugged than a laboratory unit. However, it is important for the user to recognize that it is a precision instrument and should be treated with care. Abuse and mistreatment may lead to a degradation of performance or premature failure.
- This equipment must be installed and used in strict accordance with the instructions given in the user documentation.
- This equipment contains no user-serviceable components. Unauthorized equipment changes or modifications will invalidate all applicable regulatory certifications and approvals.

Part B – Operational Qualification (OQ)

Introduction to Operational Qualification for Serstech Arx+

The Operational Qualification ensures that the whole equipment is operating in accordance with Good Manufacturing Practices (GMP) and meets its operational specifications. This is determined by performing a series of operational tests and documenting the results of the tests to ensure all the specifications are met.

In order to perform Operational Qualification (OQ) for the indicator is needed to perform a series of tests with a Serstechs' System Testing software. The Serstechs' System Testing software has been designed and developed by Serstech (Sweden) and follows specific procedures based on the ASTM International "Standard Practice for Testing the Performance of Scanning Raman Spectrometers" (Designation: E1683-02, re-approved 2007).

The OQ test verifies and records the instruments' ability to meet specified performance criteria after installation and repetitive use. The OQ involves comprehensive testing of the complete system using established conditions and known sample characteristics for specific applications. Note that the OQ test should be performed at room temperature (15-25°C) to be comparable to test conditions in production facility.

The Serstechs' System Testing software - OQ test series has been developed based on the identified critical control points and includes the following tests:

1. Dark background-hot pixel test
2. Resolution test
3. Throughput test
4. X-axis, accuracy, and stability test

Test 1: Dark background-hot pixel test

Equipment

Measures must be taken to prevent any ambient light from reaching the spectrometer. The collection optics must be completely enclosed in a light-tight housing using a tightly closed sampling accessory.

Procedure

The spectrometer collection lens is carefully enclosed to exclude any ambient light. Spectra should be acquired at room temperature (20-25 °C). Two separate background spectra are acquired with an integration time of 2 sec, with a noncalibrated and non-interpolated “raw pixel” x-axis. All spectral post-processing methods (e.g. baseline correction, background correction), as well as the laser itself, are required to be turned off. Additionally, an “offset” spectrum is acquired with a 20 ms integration time. The spectra are saved and transferred to suitable data analysis software (e.g. Origin). The average of the 20 ms “offset” spectrum is calculated (skip the first and last 16 pixels) and subtracted from the first raw spectrum to yield the “spectrum with fixed pattern noise”. In this spectrum, any pixels exceeding 2000 counts above the background mean are dropped, i.e. removed from the data set. The arithmetic mean of the remaining points is calculated. Additionally, the two raw spectra are subtracted from another to give the “spectrum without fixed pattern noise”. The standard deviation of the latter spectrum is calculated. The baseline should not be skewed in any of the cases.

Result

The arithmetic mean of the cleaned “spectrum with fixed pattern noise” is called background mean, and the number of faulty pixels equals the number of data points dropped during the procedure. The calculated standard deviation of the “spectrum without fixed pattern noise” is the background noise.

Please fill in the Table 10 the information you obtained from the dark background-hot pixels test.

Table 6: Dark background-hot pixels test results

	Target values	**Acceptance range**	**Obtained value**	**Pass/Fail**
Background Mean	2500 Cts	≤ 3000 Cts		
Background Noise	50 Cts	≤ 100 Cts		
Hot pixels	0	≤ 2		
Hot pixels (700 2800)	0	0		

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Test 2: Resolution test

The optical resolution for the indicator is determined.

Equipment

The Mercury Argon Calibration Source
Optical fiber, 50 µm diameter
Optical fiber adapter

Procedure

Connect the optical fiber to the Mercury Argon Calibration Source and attach the other end of the fiber to optical fiber adapter. Place the optical fiber adapter on the probe of the indicator, snap into position.
Allow lamp to warm up then collect spectrum from lamp.

Result

The optical resolution is determined as the maximum of all determined gas lamp peak FWHM values and is given in cm^{-1}.

Fill in the results you obtained in the Table 7 below.

Table 7: Optical resolution results

Expected (cm^{-1})	Measured (cm^{-1})	Within range, Yes/No	Pass/Fail
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Test 3: Throughput test

The signal throughput, noise and signal to noise is assessed.

Equipment

- Cyclohexane (Sigma Aldrich)
- Glass vial
- Vial holder

Procedure

The cyclohexane is placed in a 4 ml vial that is subsequently placed in a vial holder. The vial holder is snapped in position on the probe tip. Run the test.

Result

The absolute intensity of the peak at 801.3 cm^{-1} (peak height) divided by the exposure time is reported as count rate and is a measure of spectrometer throughput. The standard deviation of the peak locations for baseline (500 cm^{-1} – 750 cm^{-1}) is reported as baseline noise. The quotient of the absolute peak height and the baseline noise is the signal-to-noise ratio (SNR). Additionally, the measured exposure time is recorded. After performing the test, fill in the information in the Table 8.

Table 8: Throughput test results

	Target values	**Acceptance range**	**Obtained value**	**Pass/Fail**
Count rate 801.3 cm^{-1}	110 Cts/ms	>50 Cts/ms		
Baseline noise	30 Cts	≤ 60 Cts		
SNR	1800	≤ 1500		
Exposure time	500 ms	≤ 750 ms		

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Test 4: X-axis accuracy & stability test

For the substance cyclohexane, four measured peak positions are compared to the standard reference values for several measurements done over a longer period with an interval pause of five min.

As “accuracy” is defined the mean value for each peak of the peak positions and as “stability” is defined the standard deviation of all the measurements for each peak.

Equipment

- Cyclohexane (Sigma Aldrich)
- Glass vial
- Vial holder

Procedure

For the substance cyclohexane, four measured peak positions are compared to the standard reference values for several measurements done over a longer period with an interval pause of five min.

As “accuracy” is defined the mean value for each peak of the peak positions and as “stability” is defined the standard deviation of all the measurements for each peak.

Result

After performing the x-axis accuracy and stability test, fill in the results in Table 9 obtained for the ASTM peak positions for cyclohexane.

Table 9: x-axis accuracy and stability test for cyclohexane peak positions

ASTM Peak positions (cm-1) (2)	Measured Peak Positions (cm-1)	Difference within +/- 4 (cm-1)	Pass/Fail
801.3			
1028.3			
1266.4			
1444.4			

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This manual is issued by:

Serstech AB

Contact information:

Åldermansgatan 13

SE-227 64 Lund, Sweden

Email: info@serstech.com

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