

Qualification of the NanoPhotometer NP80

Table of Contents

1. Description of the Qualification

- 1.1 Objectives
- 1.2 Instrument Description
- 1.3 General Data
- 1.4 Validation Tools

2. Installation Qualification

- 2.1 Check of delivered items
- 2.2 Inspection and Testing of Documentation
- 2.3 Inspection and Testing of the Instrument
- 2.4 Installation of Software
- 2.5 Installation of Printer

3. Operation Qualification

- 3.1 Validation of the Calibration Standard
- 3.2 Validation of the Wavelength Accuracy - Cuvette
- 3.3 Validation of Absorbance Accuracy - Cuvette
- 3.4 Validation of the Reproducibility - Cuvette
- 3.5 Validation of the Baseline - Cuvette
- 3.6 Validation of Absorbance Accuracy - NanoVolume
- 3.7 Validation of the Reproducibility - NanoVolume
- 3.8 Validation of the Baseline - NanoVolume

4. Results and Release of Qualification

Qualification of the NanoPhotometer

1. Description of the Qualification

1.1 Objectives

This qualification is for the documented validation of the NanoPhotometer, to show that all is conform with the requirements, specifications of the installation and function.

1.2 Instrument Description

The NanoPhotometer measures spectra in the range of 200 nm to 900 nm. Due to the integrated beam deflection and the use of fiber-optic light conductors, the sample can be measured in NanoVolumes. For the detection there is a 3648 pixel CCD array used. The instrument is maintenance and recalibration free due to sealed optics, the True Path and Sample Compression Technology™. This guarantees for a high accuracy and linearity over the entire life-time.

The following methods are available:

- single and multi wavelengths
- wavescan in the range of 200 nm - 900 nm (adjustable)
- concentration calculations (pre-programmed for nucleic acids and proteins)
- frequency of incorporation/degree of labelling of various fluorescent dyes (pre-programmed for nucleic acids)
- cell density measurements
- colorimetric assays
- standard curves
- absorbance ratio calculations

1.3 General Data

System:	UV/Vis spectrophotometer		
Type:	NanoPhotometer		
	New device		YES
	Used device		YES
Serial Number:	M80945		
Operating System:	Windows10		
Location:	Company:	Implen GmbH	
	Department:	Product Management	
	Person in Charge:	Dr. Helena Funk	+49 89 726 371 80
	User:	Dr. Helena Funk	+89 726 371 80
	Location:	Production	
	Address:	Schatzbogen 52	
	City:	Munich	
	State/Province & Postal:	81829	
	Country:	Germany	

1.4 Validation Tool

The certified validation tools for the NanoPhotometer is a potassium hydrogen phthalate solution and a Holmium glass and Neutral Density glass filter calibrated against a traceable NIST standard by an accredited supplier.

Qualification of the NanoPhotometer

2. Installation Qualification

2.1 Check of delivered items

Test description:

Verification of the delivery content by checking the delivery note.

Enclose a copy of the delivery note to the qualification report.

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
Check the delivery	Complete according to delivery note	YES	

2.2 Inspection of Documentation

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
User Manuals	- Short Instructions NanoPhotometer N120/NP80/N60/N50/C40 - NanoPhotometer User Manual in digital version on USB flash drive	YES	
Certificates	NanoPhotometer Operation Certificate: NanoVolume Application Cuvette Application	YES	

2.3 Inspection of the Instrument

Test description:

Validation and approval of the NanoPhotometer installation in a technical correct manner according to the user manual of the supplier.

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
Installation of the NanoPhotometer	Power supply plugged in (operating voltage: 100-240 V, 50/60 Hz, 90W, 19 VDC) and load the battery pack at least for 3 hours prior to the first use	YES	
By switching the instrument on a self-diagnostic check is automatically performed	pass all tests - no failure message appears - main display is shown	YES	

Integrated vortexer	Activated if NanoPhotometer is switched on and deactivated if the NanoPhotometer is switched off.	YES	
---------------------	---	-----	--

2.4 Installation of Software

Test description:

Validation and approval of the software installation in a technical correct manner according to the user manual of the supplier.

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
Built-in Touchscreen	home screen is shown after starting the instrument	YES	N/A when no touch screen is connected
computer (PC/MAC)	software can be opened and the home screen of the connected NanoPhotometer is shown	YES	N/A when using the built-in touch screen, a smart phone or tablet for controlling the NanoPhotometer.
Tablet	software can be opened and the home screen of the connected NanoPhotometer is shown	YES	N/A when using only the built-in touch screen, a computer or tablet for controlling the NanoPhotometer.
Smart Phone	software can be opened and the home screen of the connected NanoPhotometer is shown	YES	N/A when using only the built-in touch screen, a computer or tablet for controlling the NanoPhotometer.
Software installataion passed		YES	

2.5 Installation of Printer

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
Printer via USB cable/network/WiFi network connected	Print icon is shown on all method screens.	YES	N/A when no printer is available
Printer is functional	Do a measurement and print the results.	YES	N/A when no printer is available
Printer installataion passed		YES	

Qualification of the NanoPhotometer

3. Operation Qualification

3.1 Validation of the Calibration Standard

For all validation tools which are used during the qualification, an actual and valid calibration certificate is necessary. Enclose a copy of the calibration certificate to the qualification report.

Test description Holmium glass filter:

As a validation tool, the Holmium glass filter is used as secondary spectrometric calibration standard. This filter is calibrated and verified against NIST approved calibration or control standards.

Test plan				Test report	
Test parameter	Serial number	Acceptance criteria		passed	remarks
Holmium glass filter	111015	serial number correct		YES	
Valid calibration certificate:		Next calibration:	14.2.2024	YES	recalibration of the Holmium glass filter every 24 months

Test description Neutral Density glass filter:

As a validation tool, the Neutral Density glass filter is used as secondary spectrometric calibration standard. This filter is calibrated and verified against NIST approved calibration or control standards.

Test plan				Test report	
Test parameter	Serial number	Acceptance criteria		passed	remarks
Neutral Density filter:	109747	serial number correct		YES	
Valid calibration certificate:		Next calibration:	14.2.2024	YES	recalibration of the Neutral Density glass filter every 24 months

Test description potassium hydrogen phthalat solution:

As validation tool a potassium hydrogen phthalat solution is used. This standard solution is calibrated and verified against NIST approved calibration or control standards.

Test plan				Test report	
Test parameter	Serial number	Acceptance criteria		passed	remarks
Solution II: Lot number	2109	lot number correct		YES	After opening a vial it can be used for one hour.
Absorbance @ 280 nm (10 mm path)	21,87	Absorbance entered		YES	The absorbance can be found on the vial.

3.2 Validation of the Wavelength Accuracy - Cuvette

Test description:

Method: More Apps - Wavescan / Stored Method (WavelengthAccuracy-Holmium.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Change to Cuvette, Pathlength 10 mm, Start Wavelength 200 nm, End Wavelength 900 nm, Baseline Correction Off, Smoothing 1

Blank: **empty cell holder (air)**

Sample: **Holmium glass filter S/N 111015**

approx. position:	241 nm	279 nm	361 nm	453 nm	536 nm	637 nm
certified expected peaks:	241,70	279,40	361,00	453,60	536,70	638,00
measured value:	242	279	361	454	536	638

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Holmium glass filter	111015	Peak positions (see also calibration certificate) Tolerance is +/- 2nm	YES	Peak position must be visible in the graph, if not listed in the table please check manual for the corresponding peak

3.3 Validation of Absorbance Accuracy - Cuvette

Test description:

Cuvette mode

Method: More Apps - Wavelength / Stored Method (AbsorbanceAccuracy-NeutralDensity.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Change to Cuvette, Pathlength 10 mm, add 5 Wavelengths: enter wavelengths 440 nm, 465 nm, 546 nm, 590 nm and 635 nm, Baseline Correction Off, Smoothing 1

Blank: **empty cell holder (air)**

Sample: **Neutral Density glass filter: S/N: 109747**

	expected absorbances:	tolerance	measured values:
A440	0,562	+/- 0.015	0,562
A465	0,524	+/- 0.015	0,522
A546	0,525	+/- 0.015	0,523
A590	0,559	+/- 0.015	0,557
A635	0,567	+/- 0.015	0,565

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Neutral Density glass filter	109747	The measured absorbances 440, 465, 546,590,635 nm) have to be in the tolerance +/- 0.015 A.	YES	

3.4 Validation of the Reproducibility - Cuvette

Test description:

Method: More Apps - Wavelength / Stored Method (Reproducibility-NeutralDensity.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Change to Cuvette, Pathlength 10 mm, enter wavelength 440 nm, 546 nm and 635 nm, Baseline Correction Off, Smoothing 1

Blank: **empty cell holder (air)**

Sample: **Neutral Density glass filter: S/N: 109747**

	expected absorbances:	tolerance	measured values:	measured values:	measured values:	measured values:	CV%
A440	0,562	+/- 0.015	0,560	0,560	0,562	0,562	0,178
A546	0,525	+/- 0.015	0,523	0,523	0,525	0,525	0,191
A635	0,567	+/- 0.015	0,565	0,565	0,567	0,567	0,177

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Neutral Density glass filter	109747	CV% = 0.75%	YES	

3.5 Validation of the Baseline - Cuvette

Test description:

Method: More Apps - Wavelength / Stored Method (Baseline-Air.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Change to Cuvette, Pathlength 10 mm, enter wavelength 280 nm, Baseline Correction 377 nm, Smoothing 1

Blank: **empty cell holder (air)**

Sample: **empty cell holder (air)**

	tolerance	measured values:	measured values:	measured values:	measured values:	Abs _{max}	Δ Abs
A280	+/- 0.002	0,000	0,001	0,002	-0,002	0,002	0,004

Test plan		Test report	
Test	Acceptance criteria	passed	remarks
Measurement against air / empty cell holder	Tolerance is +/- 0.002 A according to the technical specifications	YES	

3.6 Validation of Absorbance Accuracy - NanoVolume

Test description:

Method: More Apps - Wavelength / Stored Method (AbsorbanceAccuracy-StandardSolution.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Dilution 15, Wavelength 280 nm, Baseline Correction 377 nm, Smoothing 1

Blank: water

Volume: 1.5 µl

Sample: **Standard Solution II with lot numb 2109**

	certified expected absorbances:	measured values:
A280	21,87	21,790

Test plan			Test report	
Test parameter	Lot number	Acceptance criteria	passed	remarks
Potassium hydrogen phthalate solution (PHP)	2109	The absorbance at 280 nm has to be in the certified range	YES	

3.7 Validation of the Reproducibility - NanoVolume

Test description:

Method: Protein UV / Stored Method (Reproducibility-Water.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: OD1, Volume 1 µl- 2 µl, wavelength 280 nm, Background Correction: On, Manual Dilution: Off

Blank: water

Volume: 1.5 µl

Sample: **water/pipette once and measure four times**

	certified expected absorbances:	measured values:	measured values:	measured values:	measured values:	Abs _{max}	ΔAbs
A280	0,000	0,000	0,000	0,002	0,000	0,002	0,002

Test plan		Test report	
Test parameter	Acceptance criteria	passed	remarks
Water	Four repeated absorbance measurements tolerance is +/- 0.03 A (10 mm path) according to the technical specifications.	YES	

3.8 Validation of the Baseline - NanoVolume

Test description:

Method: More Apps - Wavelength / Stored Method (Baseline-Air.json) available on USB flash drive and for download www.implen.de/download

Parameter Settings: Dilution 15; wavelength 280 nm, Baseline Correction 377 nm, Smoothing 1

Blank: air

Sample: **air - no sample**

	tolerance	measured values:	measured values:	measured values:	measured values:	Abs _{max}	Δ Abs
A280	+/- 0.03	0,002	0,005	0,000	-0,005	0,005	0,010

Test plan		Test report	
Test	Acceptance criteria	passed	remarks
Measurement against air - no sample	Tolerance is +/- 0.03 A (10 mm path) according to the technical specifications	YES	

Qualification of the NanoPhotometer

4. Results and Release of Installation and Operation Qualification

The below listed persons confirm with their signature the successful installation and operation qualification of the NanoPhotometer .

Valuation	passed	remarks
All tests performed	YES	
All acceptance criteria fulfilled	YES	
System ready to use	YES	

	Name (block letter):	Date:	Signature:
Performed by:	Dr. Michael Riepl	16.03.2022	
Approved by:	Dr. Helena Funk	16.03.2022	

Attachments:

1. Copy of delivery note
2. Calibration Certificates for the NanoPhotometer
3. Calibration Certificate for the Holmium glass and Neutral Density glass filter set
4. Calibration Certificate for the Standard Solution