

Qualification of the NanoPhotometer

Table of Contents

1. Description of the Qualification

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

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

3. Operation Qualification

- 3.1 Validation of the Validation Tool
- 3.2 Validation of the Wavelength Accuracy - Cuvette
- 3.3 Validation of the Absorbance Accuracy - Cuvette
- 3.4 Validation of the Reproducibility - Cuvette
- 3.5 Validation of the Baseline - Cuvette
- 3.6 Validation of the 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 standard volumes (cuvettes) and/or 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 and protein)
- 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		NO
Serial Number:	M80798		
Operating System:	Windows 7		
Location:	Company:	Implen GmbH	
	Department:	Product Management	
	Person in Charge:	Dr. Helena Funk	☎ +49 89 726 371 80
	User:	Dr. Helena Funk	☎ +49 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 Didymiumglassfilter calibrated against a traceable NIST standard by an accredited supplier and a potassium hydrogen phthalate solution calibrated against a certified UV/Vis spectrophotometer. Calibration certificates can be furnished upon request.

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 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: 90-250 V, 50/60 Hz, 80W, 18/19 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	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	

Qualification of the NanoPhotometer

3. Operation Qualification

3.1 Validation of the Calibration Standard

Test description Didymiumglassfilter:

As a validation tool, the Didymiumglassfilter is the secondary spectrometric calibration standard used. This filter is calibrated and checked against calibration- or control standards, which are NIST proven. 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 plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Didymiumglassfilter:	E849	serial number correct	YES	
Valid calibration certificate:		Next calibration: 28.3.2018	YES	recalibration of the Didymiumglassfilter every 24 months

Test description potassium hydrogen phthalat solution:

As validation tool a potassium hydrogen phthalat solution used. This solution is calibrated and checked against a certified UV/Vis spectrophotometer.

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Lot number	1606	lot number correct	YES	After opening a vial it can be used for one hour.
Absorbance @ 280 nm (10 mm path)	21,40	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

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

Blank: air

Sample: Didymiumglassfilter S/N E849

approx. position:	329 nm	472 nm	512 nm	681 nm
certified expected peaks:	329,91	472,50	513,16	681,40
measured value:	330	472	513	681

Tolerance is +/- 2nm

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Didymiumglassfilter	E849	Peak positions (see also calibration certificate)	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

Parameter Settings: Change to Cuvette, Pathlength 10 mm, add 4 Wavelengths: enter wavelengths 270 nm, 280 nm, 320 nm and 340 nm, Baseline Correction Off, Smoothing 1

Blank: air

Sample: **Didymiumglassfilter S/N E849**

	certified expected absorbances:	tolerance	measured values:
A270	1,068	+/- 0.050	1,080
A280	0,939	+/- 0.046	0,951
A320	0,547	+/- 0.046	0,549
A340	0,515	+/- 0.034	0,517

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Didymiumglassfilter	E849	The measured absorbances (270, 280, 320 and 340 nm) have to be in the tolerance range defined in the calibration certificate	YES	

3.4 Validation of the Reproducibility - Cuvette

Test description:

Method: More Apps - Wavelength

Parameter Settings: Change to Cuvette, Pathlength 10 mm, add 4 Wavelengths: enter wavelengths 270 nm, 280 nm, 320 nm and 340 nm, Baseline Correction Off, Smoothing 1

Blank: air

Sample: **Didymiumglassfilter S/N E849**

	certified expected absorbances:	tolerance	measured values:	measured values:	measured values:	measured values:	ΔAbs
A270	1,068	+/- 0.050	1,079	1,081	1,081	1,082	0,003
A280	0,939	+/- 0.046	0,952	0,953	0,952	0,952	0,001
A320	0,547	+/- 0.046	0,548	0,551	0,550	0,549	0,003
A340	0,515	+/- 0.034	0,517	0,518	0,518	0,516	0,002

Test plan			Test report	
Test parameter	Serial number	Acceptance criteria	passed	remarks
Didymiumglasfilter	E849	Four repeated absorbance measurements tolerance is +/- 0.002 A according to the technical specifications.	YES	

3.5 Validation of the Baseline - Cuvette

Test description:

Method: More Apps - Wavelength

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

Blank: air

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

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

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

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

Blank: water

Volume: 1.5 µl

Sample: vial with lot number 1606

	certified expected absorbances:	measured values:
A280	21,40	21,660

Test plan			Test report	
Test parameter	Lot number	Acceptance criteria	passed	remarks
Potassium hydrogen phthalate solution (PHP)	1606	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

Parameter Settings: BSA; Volume 1µl - 2µl; wavelength 280nm; 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	-0,010	-0,005	-0,003	0,000	0,010

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

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 _{max}
A280	+/- 0.03	-0,001	-0,007	-0,004	-0,001	0,001	0,006

Test plan		Test report	
Test	Acceptance criteria	passed	remarks
Measurement against air / empty cell holder	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 fullfiled	YES	
System ready to use	YES	

	Name (block letter):	Date:	Signature:
Performed by:	Dr. Helena Funk	11.10.2016	
Approved by:	Dr. Michael Riepl	11.10.2016	

Attachments:

1. Copy of delivery note
2. Calibration Certificates for the NanoPhotomter
3. Calibration Certificate for the Didymiumglassfilter