# Qualification of the NanoPhotometer NP80

## Table of Contents

# 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 sprectra 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 maintainance 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 Managment | | |
| | Person in Charge: | Dr. Helena Funk | ☎ | +49 89 726 371 80 |
| | User: | Dr. Helena Funk | ☎ | +89 726 371 80 |
| | Location: | Production | | |
| | Adress: | 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<br>- NanoPhotometer User Manual in digital version on USB flash drive | YES | |
| Certificates | NanoPhotometer Operation Certificate:<br>NanoVolume Application<br>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 | | 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: | $Abs_{max}$ | $\Delta$ 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 succsessful 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. Michael Riepl | 16.03.2022 | |
| Approved by: | Dr. Helena Funk | 16.03.2022 | |

**Attachments:**

1. Copy of delivery note

2. Calibration Certificates for the NanoPhotomter

3. Calibration Certificate for the Holmium glass and Neutral Density glass filter set

4. Calibration Certificate for the Standard Solution