Qualification of the Implen OD600®

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1. Description of the Qualification

1.1 Objectives

This qualification is for the documented validation of the Implen OD600® , to show that all is conform with the requirements, specifications of the installation and function.

1.2 Instrument Description

The Implen OD600® measures absorbance or MFU at approximately 600nm. The absorbance range 0A to 4A and MFU 0 to 16 can be detected. The sample can be measured in standard volumes (cuvettes) and/or tubes (diameter 10mm, 12mm, 16mm and 18mm). For the detection there is a yellow LED used as light source and a photodiode as detector. The instrument is maintainance and recalibration free. This guarantees a high accuracy and linearity over the entire life-time.

The following methods are available:

- OD600 (absorbance @ 600nm)
- McFarland (MFU) - turbidity based on McFarland standards

1.3 General Data

System:	OD600	
Type:	Implen OD600®	
	New device	
	Used device	
Serial Number:	OD-01100	
Operating System:		
Location:	Company:	
	Department:	
	Person in Charge:	☎
	User:	☎
	Location:	
	Adress:	
	City:	
	State/Province & Postal:	
	Country:	

1.4 Validation Tool

The certified validation tool for the Implen OD600® is a set of two Neutral Density glass filters calibrated against a traceable NIST standard by an accredited supplier.

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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	- Quick guide Implen OD600® - USB Stick sheet (USB stick contans user manual/quick guide)	YES	
Certificates	Implen OD600® Operation Certificate Declaration of Conformity	YES	

2.3 Inspection of the Instrument

Test description:
Validation and approval of the Implen OD600® 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 Implen OD600®	Device can be operated/charged when USB power cable is plugged in (check that battery icon loading or full is shown)	YES	
	Device can be operated with integrated battery pack (check that battery icon is shown)	YES	
By switching the instrument on a self-diagnostic check is automatically performed	pass all tests - main display with OD600 and McFarland icon is shown	YES	

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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 Neutral Density glass filter - 1A @ 590nm:

As a validation tool, the Neutral Density glass filter is used as a 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 glass density filter 1A	107313	serial number correct		YES	
Valid calibration certificate:		Next calibration:	2.4.2027	YES	recalibration of the Neutral density glass filter every 24 months

Test description Neutral Density glass filter - 3A @ 590nm:

As a validation tool, the Neutral Density glass filter is used as a 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 glass filter 3A:	103080	serial number correct		YES	
Valid calibration certificate:		Next calibration:	2.4.2027	YES	recalibration of the Neutral Density glass filter every 24 months

3.2 Validation of the Absorbance Accuracy at 1A

Test description:
Method: OD600

Blank: **empty cell holder (air)**
Sample: **Neutral Density glass filter:** **S/N:** **107313**

approx. position:	590 nm
certified expected absorbance:	1,036
measured value:	1,031

Test plan			Test report	
Test parameter	**Serial number**	**Acceptance criteria**	**passed**	**remarks**
Neutral Density glass filter 1A	107313	Absorbance accuracy (see also calibration certificate) Tolerance is +/- 0,010A	YES	Filter should be clean and not damaged.

3.3 Validation of Absorbance Accuracy at 3A

Test description:
Method: OD600

Blank: **empty cell holder (air)**
Sample: **Neutral Density glass filter:** **S/N:** **103080**

approx. position:	590 nm
certified expected absorbance:	3,071
measured value:	3,067

Test plan			Test report	
Test parameter	**Serial number**	**Acceptance criteria**	**passed**	**remarks**
Neutral Density glass filter 3A	103080	Absorbance accuracy (see also calibration certificate) Tolerance is +/- 0,030A	YES	Filter should be clean and not damaged.

3.4 Validation of the Reproducibility

Test description:
Method: OD600

Blank: **empty cell holder (air)**
Sample: **Neutral Density glass filter:** **S/N:** **107313**

	expected absorbances:	tolerance	measured values:	measured values:	measured values:	measured values:	CV%
A590	1,036	+/- 0.010	1,031	1,032	1,031	1,031	0,042

Test plan			Test report	
Test parameter	**Serial number**	**Acceptance criteria**	**passed**	**remarks**
Neutral Density glass filter	107313	CV% = 0.25%	YES	

3.5 Validation of the Baseline

Test description:
Method: OD600

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

	tolerance	measured values:	measured values:	measured values:	measured values:	Abs_{max}	Δ Abs
A590	+/- 0.002	0,001	0,000	0,001	0,001	0,001	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	

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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 Implen OD600® .

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		
Approved by:	Dr. Michael Riepl		

Attachments:

1. Copy of delivery note
2. Calibration Certificates for the Implen OD600®
3. Calibration Certificate for the Neutral Density glass filter set (1A/3A @590nm)