



NIR Imaging System PT-IM100

Installation Qualification (IQ)

Version 1.0

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Section 1.0 Scope Introduction

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Introduction

Objective

Installation Qualification (IQ) is used to verify that the Pharma Test PT-IM100 (NIR imaging system) has been installed according to the manufacturer's requirements.

Equipment

The Pharma Test PT-IM100 is composed of:

- The main instrument
- Vials for samples
- White and Black References
- Software Package (SL predictor)

Document History

Revision	Valid from	Author	Change	Remark
5.0	16.04.2014	PTAG	N	

Index Information - Change:

N = New Document

C = Correction

R = Revision

Instructions for Documentation Completion

All performers and reviewers must complete qualification forms using the following guidelines:

Complete all items on a form in full.

Document any deviation from defined protocols and accepted results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.

Write additional comments on an addendum sheet when there is not enough space on a form to accommodate all comments. Follow these three steps when adding an addendum sheet:

1. Write down your initials
2. Write down the date of the additions
3. Number the addendum pages alphanumerically
4. Insert the addendum sheet behind the original page
5. Make all entries in permanent ink.

Correcting Entries

If you need to make corrections on a form, use the procedures described below:

Correcting Short Entries

To correct a short entry (such as a single word or test result) on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write down the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Write down your initial
5. Write down the date of the change

Correcting Long Entries

To correct a long entry or information block on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write the correction on a separate addendum sheet
3. Give a brief explanation of the change.
4. Write down your initial
5. Write down the date of the change
6. Number the addendum pages alphanumerically
7. Insert the addendum sheet behind the original page

Marking Elements That Are Not Applicable

Some elements may not apply to your system's configuration. The elements that are not required may be a procedure or part of a procedure and/or a form or part of a form. Mark each element carefully according to the instructions below, so that it will be clear that the element is unnecessary and that you have not skipped or forgotten the element.

1. Draw a diagonal line, bottom left to upper right corner, through the element that is not required
2. Write down the letters "NA" (for "Not Applicable"), your initials, and the current date above the line
3. Include comments above the line or on the form to document the reason the element is not required
4. Where NA is indicated as an option, check this field
5. Mark the section "rec." (for "received") if the part has been identified
6. Mark the section "miss." (for "missing") if the part has not been identified and needs to be sent immediately to finish the installation; in that case make sure that the missing part has been ordered by you and has been confirmed by us for shipment

The performer and reviewer must sign and date all forms as usual, even when part or all of the form is marked "NA".

NOTE: All original entries must remain legible after any corrections have been made.

Conditions Requiring Re-Qualification

CAUTION: The following conditions require re-qualification:

- When a system modification has been completed which affects the installation qualification
- When this system is being removed from where it was originally installed

Re- calibration/ Re-certification Requirements

The following conditions require Operation Qualification (OQ) re-calibration/re-certification:

- When the software or firmware has been upgraded or changed
- A pre-determined period of time or use has passed
- After any minor service has been done
- After any parts have been replaced
- When this system is being removed from where it was originally installed

Installation Qualification Program

This document is divided in sections.

Section 1.0 Scope Introduction

This section explains the purpose and use of this document and the general installation qualification procedure.

Section 2.0 Instrument Identification

In this section the instrument including details and serial number(s), the required documentation and site installation requirements are identified.

Section 3.0 Equipment Description

This section has the purpose of identifying the equipment at hand, including all parts and accessories.

Section 4.0 Personnel Identification

In this section the user of the equipment, the equipment required for qualification is identified and the end user information is written down to complete the qualification.

Section 5.0 Installation Procedure

This section contains the installation procedure, test protocols and test results in a pass/fail format for each test. Where accreditation is held for the calibration of the equipment being qualified, this procedure will be referenced. Where applicable, copies of these procedures are available from Pharma Test upon request.

Section 6.0 Required Qualification Materials

In this section the qualification and adjustment equipment and tools to perform the installation and operation qualification of the instrument are described.

Section 7.0 Result and Comments

This section is used to document the result of the installation and for comments regarding the installation procedure.

Section 2.0 Instrument Identification

Check if the PT-IM100 according to the order confirmation has been received and enter the serial number of the instrument. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Type	rec.	NA	miss.	Serial No.

PT-IM100 Details

Voltage

115 V ☐ or 230/240 V ☐ 50/60 cycl.

Asset No. or Lab ID No.

Section 2.1 Required Documentation

Ordering Information

Customer Order Number

Supplier Invoice Number

Equipment Documentation

Part-No.	Description	rec.	NA	miss.
B-42-10000	Operating Manual			
	Installation Qualification			
	Operation Qualification			
NA	Instrument Log Book			
	QC/DQ Test Report			
NA	Delivery Note			

Section 2.2 Instrument Installation Site Requirements

NOTE: This instrument requires electrical installation with a quality, noise free ground (earth). In this case, as in all electrical installations where liquid handling is an integral part of the instrument function, all mains (line) supplies should be protected with an RCD (Residual Current Detector) which typically trips out when current leakage to ground (earth) of approx. 30mA is detected.

Performed by:

Date:

Signature

DD/MM/YYYY

Electrical Conditions at Installation Site

Voltage: 115V ☐ 230/240V ☐ Frequency: 60Hz ☐ 50Hz ☐

Section 2.3 Other Services Required

The PT-IM100 has to be installed on a level surface. The supporting bench must be able to support the weight of the instrument, the tablet hardness tester and other equipment installed on the same bench continuously.

NOTE: Pharma Test is not responsible for adequate site planning and installation. We are however, happy to advise if our help is requested.

Section 2.4 Operating Environment

Temperature: 15-40°C	Rel. Humidity: 20-80%
Physical Site: Clean, dry and level bench	Weight Support: Approx. 12 kg
Dimensions (Width x Depth x Height):	Approx. 61 x 56 x 61cm

Section 2.5 Clearance

A minimum of 10cm of the rear and sides of the instrument is required. Approximately 60 cm of total bench space is required for the PT-IM100 (does not include space for tablet hardness tester).

Performed by: _____	Date: _____
Signature	MM/DD/YYYY

Section 3.0 Equipment Description

Section 3.1 Main Unit NIR Imaging System – PT-IM100

These parts are included in the standard supply scope of the PT-IM100:

Part-No.	No.	Description	rec.	NA	miss.
35-20000	1	NIR Analysis System			
413-0021	1	Black Standard			
413-0020	1	White Standard			
413-0010	10	Glass Test Vials			
413-0011	10	Covers for the Glass Test Vials			
002-0462	1	USB Cable (2 m)			
95-42200	1	SL Predictor Software			
10-60010	1	DAB stainless steel cleaning oil, 1 bottle = 100ml.			
34-08500	1	IEC/EUR mains cord			
34-08511	1	US mains cord			
34-08512	1	GB mains cord			
34-08513	1	ARG/AUS/NZ mains cord			

Section 3.2 Optional Software Packages

These parts are optional software packages.

Part-No.	No.	Part Description	rec.	NA	miss.
95-42215	1	SL Utilities			
95-42205	1	SL Calibration Wizard (CWiz) with Dongle			
95-42210	1	SL Workshop			

Section 3.3 Optional Equipment

These parts are optional. Check if the received supply scope is according to the order confirmation, enter the received number of items and mark not ordered items as "NA":

Part-No.	No.	Part Description	rec.	NA	miss.
413-0041-7	1	Traceable Reflectance Standard			
413-0100	1	Stamp for liquids and gel substances			
		other: _____			

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.0 Personnel Identification

Installation Engineer (1):

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Installation Engineer (2):
(optional)

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Approved by:

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Released by:

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Performed by:

Signature

Date:

MM/DD/YYYY

Section 4.1 Required Qualification Equipment Identification

Part-No.	Description	Serial No.	rec.	N/A	miss.
413-0041-7	Traceable Reflectance Standard				

Section 4.2 Certificates for Required Qualification Equipment

Part-No.	Description	Calibration Date	rec.	N/A	miss.
	Certificate for the item 4.1 above				

Section 4.3 End User Information

Company Name: _____

Address: _____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature

MM/DD/YYYY

Section 5.0 Installation Procedure

For more detailed information on the general usage of the instrument refer to the instruction manual.

Section 5.1 Remove the instrument from the Packaging Material

Remove all wrapping and insure that no physical damage was caused to the PT-IM100 during shipment.

pass	fail	N/A

Section 5.2 Connect Mains

Keep main power switch of the instrument at off position. Connect and verify connection of the power cable into the ground fault protection AC outlet. Check that the mains cord and socket do not show any visible damage.

pass	fail	N/A

Section 5.3 Turn on the Instrument

Turn on the instrument using the power switch on the rear left side of the instrument. All displays will light up.

pass	fail	N/A

Section 5.4 Verify installation of SL-Predictor Software

The SL Predictor software has to be installed on a PC; a connection has to be established with the PT-IM100 after starting the SL Predictor. Please follow the instructions for installing the SL Predictor.

Verify availability and compatibility of PC:

pass	fail	N/A

Installing of SL Predictor:

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 5.5 Verify installing of other software packages (Optional)

Install other software package(s) if ordered by the customer. Follow the instructions for installing of each package. Consult the user manual for the system requirement. These packages can be installed on different PCs.

Installation of Software Package	pass	Fail	N/A
SL Utilities			
SL Wizard			
SL Workshop			

Section 5.6 Turn off the Instrument

Turn off the instrument using the power switch on the rear left side of the instrument.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 6.0 Required Qualification Materials

Section 6.1 Verify the Reflectance Standard

Each supplied Reflectance Standard is qualified by the manufacturer, or if ordered with a calibration certificate by a certified external testing authority.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 7.0 Result and Comments

The instrument has passed the installation qualification procedure.

Yes ☐

No ☐

Check yes if all tests have passed. In case one or more tests failed check no and document the reason for the failure on this report. In this case the installation qualification has to be repeated once the reason for failure has been eliminated.

Comments

This completes the installation qualification of the PT-IM100 electro-magnetic test tablet.

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Approved by: _____ Date: _____
Signature MM/DD/YYYY

Released by: _____ Date: _____
Signature MM/DD/YYYY