PT-NODE
Network Adapter for Printing and Data Transfer

Installation Qualification (IQ)

Version 1.0

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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	20.03.2023	Pharma Test	N	First Release

Table 1: Document History

Index Information - Change:

N = New Document
C = Correction
R = Revision

Introduction

Objective

Installation Qualification (IQ) is used to verify that the Pharma Test Instrument/System (or components where applicable) has been installed according to the manufacturer's requirements. The results are documented and explained as passed (OK) or failed (NOK), compared to the requirements laid down in this form

Equipment

The Pharma Test PT-NODE instrument is composed of:

- The PT-NODE network adapter
- Wall plug with international adapters
- RJ45 patch cable
- Instrument connecting cable(s) according to customer order

PT-Node is an adapter that connects up to two Pharma Test instruments simultaneously to a network using a wired LAN or wireless Wi-Fi connection. This way you can print test results from the instrument via your web browser on any local or network printer. Furthermore, it is possible to transfer the test results from the instruments to external systems in the same network.

Instructions for Documentation Completion

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

1. Write down your signature
2. Complete all items on a form in full.
3. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
4. 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:
    a. Write down your signature
    b. Write down the date of the additions
    c. Number the addendum pages numerically
    d. Insert the addendum sheet behind the original page
    e. Make all entries in permanent ink.

Correcting Entries

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

Correcting Entries, sections and parts which are now required or available

It is possible that certain information or requirements are not available or necessary for the instrument to be qualified. This information may be a full section, a part of it or procedure. Mark this element clearly, so that it is understood that it is not necessary in this case.

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

1. Draw a diagonal line, through the wrong, invalid or incorrect information
2. Enter the correction
3. Give a brief explanation of the change.
4. Sign it using your initial
5. Enter the date of the change

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

Conditions Requiring Re-Qualification or re-calibration

The following conditions may require re-qualification or calibration:

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

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, 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, mark 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

The following conditions may require re-qualification or calibration:

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

Installation Qualification Program

This document is divided in sections.

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Section 2.0 Instrument Identification

In this section the instrument including details and serial number(s), as well as the required documentation are identified.

Section 3.0 Required Calibration Tools, Substances and Standards for the Operation Qualification (OQ)

This section includes information about the calibration tools, substances and standards required to perform the Operations Qualification (OQ) and the corresponding calibration certificates.

Section 4.0 Documentation and Installation Procedure

This section contains the installation procedure, test protocols and test results in a pass/fail format for each test.

Section 5.0 Instrument identification, supplied components, optional accessories

This section is used to control the completeness of the supply scope and optional accessories which are needed for the later use of the instrument/system.

Section 6.0 Results and Comments

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

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Section 1.1 General Date Format of this Document

Please select the date format you want to use in this document.

Date Format	Selected	NA
dd.mm.yyyy		
dd/mm/yyyy		
mm.dd.yyyy		
mm/dd/yyyy		
Other:		

Table 2 General Date Format of this document (d=day, m=month, y=year)

Section 1.2 Personnel Identification

Performer (1):

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performer (2):
(optional)

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Released by:

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 1.3 Place of Installation

Company Name: _____

Address: _____

_____

_____

Department/Bldg.: _____

Location/Bldg.: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.0 Instrument Identification

Section 2.1 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-	Operating Manual			
IQ-	Installation Qualification			
OQ-	Operation Qualification			
NA	Instrument Log Book			
QC-	QC 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.

Electrical Conditions at Installation Site

Voltage:	100/115V	☐	230/240V	☐
Frequency:	60 Hz.	☐	50 Hz.	☐

Section 2.3 Operating Environment

Temperature:	15-40°C	Rel. Humidity:	20-80%
Physical Site:	Clean, dry and levelled bench		

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.4 Clearance

A minimum of **10cm** of the rear and sides of the instrument is required.

Section 2.5 Other Services Required

The instrument has to be installed on a level surface. The supporting bench must be able to support the weight of the instrument, as well as 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.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.6 Main Instrument

Check if the instrument/system according to the order confirmation has been received and enter the serial number. The serial number is printed on the type sticker on the bottom of the instrument:

Part-No.	Instrument Description	Serial No.	OK	NA
24-00100	PT-NODE network adapter			

Section 2.7 Instrument Connection Cables

Check if the correct instrument connection cables as per customer order have been received:

Part-No.	Instrument Description	Rec.	Miss.	NA
34-00311	Connecting cable for PTB 111E, PTB 311E, PTB 511E, PTBA 211E, PTB 420 and PTB 420 Auto instruments			
34-01203	Connecting cable for PTZ AUTO, PTZ AUTO EZ, PTWS 120D, PTWS 120S, PTWS 820, PTWS 620, PTWS 12220, PTWS D620, PTWS 1420, PTB 420 and PTB 420 AUTO instruments			
34-01205	Connecting cable for PT-TD300, PTF 100, PTF 200, PTF 300, PTF 600, PTZ 100 und PTZ 300 instruments			

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 3.0 Required Calibration Tools, Substances and Standards for the Operation Qualification (OQ)

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
10-61000	Stopwatch				

Section 3.1 Calibration Certificates for the Tools, Substances and Standards

Part-No.	Description	Calibration Date	Rec.	Miss.	NA
101-3200	Calibration certificate for Stopwatch				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.0 Documentation and Installation Procedure

This Section describes the performance and documentation of the Installation Qualification of the instrument/system. Complete each section as described.

Full information about the use and operation of the instrument/system is available from the supplied Operating Manual.

Section 4.1 Check Packaging Material

Check the packaging material the instrument/system has been delivered in for any defects or signs mishandling during transport. In case any defects or signs are found document them by picture and check whether this has already been reported to the forwarder by the good's recipient.

OK	NOK	NA

Section 4.2 Unpacking

Unpack the network adapter and accessories. Make sure that there are no more parts inside the packing material or box. Make sure that the instrument has not been damaged during transportation

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 5.0 Instrument Identification, Supplied Components, Optional Components

All parts required for the standard operation of the instrument are listed at the supplied delivery note (invoice). Each part is labeled with its part-no. Please check the completeness of the delivery scope using the delivery-note (or invoice) attached.

Description	OK	NOK
All items as per attached delivery note have been fully supplied		

In case any item is missing, please be so kind and inform Pharma Test immediately. Please mention your Purchase Order No., the instrument serial number, the part number which is missing, as well as the number of the delivery note. If the missed part is essential for the operation of the instrument, you can only proceed with the Installation Qualification after the part has been received.

Section 5.1 Connect Mains

Connect the supplied wall plug and the suitable adapter to the PT-NODE network adapter. Connect and verify connection of the wall plug into the ground fault protection AC outlet. Check that the mains cord and socket do not show any visible damage.

OK	NOK	NA

Section 5.2 Turn on the Instrument

The instrument turns on automatically once the wall plug is connected. The display will light up. Make sure that the display lights up correctly and that all parts visible and show no defects.

OK	NOK	NA

Section 5.3 Turn off the Instrument

Turn off the instrument by disconnecting the wall plug from the power outlet.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 5.4 Qualify the Stop Watch

Each instrument, which is used for the functional qualification (OQ) of this instrument has been tested and qualified at factory. A certificate issued from an authorized laboratory is only supplied when it has been ordered

The stopwatch is used to qualify the internal timer

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

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Section 6.0 Result and Comments

Type		Serial Number	
Mains Voltage		Firmware Version	

Addendum Sheet/s attached to this document Yes ☐ No ☐

If yes, how many:

The instrument has passed the operation 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 applicable sections of the installation qualification have to be repeated once the reason for failure has been eliminated.

Comments

This completes the installation qualification of the tested instrument.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Released by: _____ Date: _____

Section 1.2 Section 1.1