PT-Node
Network Adapter for Printing and Data Transfer

Operation Qualification (OQ)

Version 1.01

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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	24.04.2023	Pharma Test	N	First Release
1.01	18.04.2024	Pharma Test	C	Corrected references to further sections in section 4.3

Table 1: Document History

Index Explanation - Change:

N = New Document
C = Correction
R = Revision

Introduction

General

Operational qualification (OQ) is the process by which all functions of the Pharma Test instrument are being validated. For all tests performed, the results are recorded and the pass/fail evaluation of all tests is determined by comparing the results with pre-determined acceptance limits. The procedure used to certify performance and any certified/accredited procedure that forms the test and certification of the equipment will be identified and/or included in the protocol.

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 five 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

Operation 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

This section includes the equipment description, part - and serial number

Section 3.0 Equipment Description

This section is used to enter the general information regarding the used calibration tools and validity

Section 4.0 Operation Qualification Procedure

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

Section 5.0 Result and Comments

This section is used to document the result of the operation qualification and for comments regarding the qualification 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: _____ (Section 1.2) Date: _____ (Section 1.1)

Section 2.0 Instrument Identification

Check if the instrument/system according to the completed IQ is present. Enter the serial number of the instrument. The serial number is printed on the type sticker on the underside of the instrument:

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

Section 3.0 Equipment Description

Section 3.1 Explanation

Not every single qualification tool in section 3.2 is necessary. Marking tools as "NA" is valid. To skip the mentioned section then by marking "NA" is valid, too.

Tools which are not marked as "optional" are obligatory!

Section 3.2 Required Qualification Equipment and Calibration Tools

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

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.0 Operation Qualification Procedure

This section provides the operational procedure to qualify the instrument. Complete each subsection as described. For more detailed information on the general usage of the instrument refer to the instruction manual.

Section 4.1 Connect Mains

Connect the supplied wall plug and the suitable cables 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 4.2 Check Display

Check that the display lights up and that all pixels are visible. Then turn off PT-Node by disconnecting the power supply from the unit.

OK	NOK	NA

Section 4.3 Determine Network Connection

PT-Node can be connected via wired ethernet (LAN) or wireless WiFi connection. It is also possible to connect PT-Node directly to a PC using an ethernet cable.

Determine which mode of network connection is to be used here and proceed with section 4.4 and then with the section mentioned below:

wired	WiFi	direct	NA
(Section 4.5 or 4.6)	(Section 4.7 or 4.8)	(Section 4.9)	

Section 4.4 Determine Network IP Address Assignment Settings

Check if the network to be used for PT-Node uses "DHCP" to automatically assign IP addresses or if static IP addresses are used:

DHCP	Static	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.5 Configure Wired Network with DHCP

Skip this section and mark it "NA" in case no DHCP wired network is being used.

If DHCP is used, connect the supplied ethernet cable or another standard ethernet cable of suitable length to PT-Node and to a network connection.

OK	NOK	NA

Switch on PT-Node. The display will light up and it will connect the wired DHCP network. Check the bottom line of the PT-Node display. Here the IP address (like for example "192.169.1.99") and a unique name (like for example "PTNODE83D63F") will be displayed. Enter both here:

IP Address	NA
Unique Name	**NA**

Section 4.6 Configure Wired Network with Static IP Addresses

Skip this section and mark it "NA" in case no wired connection with static IP addresses is being used.

In case your network uses static IP addresses check with your IT department for an IP address that is free to use for PT-Node and note the settings of your network here:

IP Address	NA
Subnet	**NA**
Gateway	**NA**
DNS Server	**NA**

Then connect the supplied ethernet cable or another standard ethernet cable of suitable length to PT-Node and to a network connection. Switch on PT-Node. The display will light up and after a short while PT-Node will create a WiFi hotspot. You must connect to this hotspot to configure the settings for your network as noted above.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Check the bottom line of the PT-Node display and note the unique name (like for example "PTNODE83D63F") displayed there. This is the name of the WiFi hotspot. Note the name here:

Unique Name	NA

Connect to this WiFi hotspot using a WiFi enabled device, for example a smartphone. The PT-Node Connection Manager will be displayed on your device.

OK	NOK	NA

In the PT-Node Connection Manager select "Ethernet" and uncheck "DHCP". Then enter the settings for IP address, Subnet, Gateway and DNS server you noted above for your network and press "Submit".

OK	NOK	NA

PT-Node will now restart and then it will connect to the wired network you have just configured. Check the bottom line of the PT-Node display. Here the IP address you entered above and a unique name (like for example "PTNODE83D63F") will be displayed. Enter both here:

IP Address	NA
Unique Name	**NA**

Section 4.7 Configure WiFi Network with DHCP

Skip this section and mark it "NA" in case no wireless WiFi network with DHCP is being used.

Check with your IT department for the name or "SSID" and password of the WiFi network to use for PT-Node and note the SSID here:

SSID	NA

Confirm that you have the password required for this WiFi network:

OK	NOK	NA

Then switch on PT-Node. The display will light up and after a short while PT-Node will create a WiFi hotspot. You must connect to this hotspot to configure the settings for your network as noted above.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Check the bottom line of the PT-Node display and note the unique name (like for example "PTNODE83D63F") displayed there. This is the name of the WiFi hotspot. Note the name here:

Unique Name	NA

Connect to this WiFi hotspot using a WiFi enabled device, for example a smartphone. The PT-Node Connection Manager will be displayed on your device.

OK	NOK	NA

In the PT-Node Connection Manager select "WiFi" and enter the SSID and password you noted above for your WiFi network. Make sure "DHCP" is unchecked and press "Submit".

OK	NOK	NA

PT-Node will now restart and then it will connect to the WiFi network you have just configured. Check the bottom line of the PT-Node display. Here the IP address (like for example "192.169.1.99") and a unique name (like for example "PTNODE83D63F") will be displayed. Enter both here:

IP Address	NA
Unique Name	**NA**

Section 4.8 Configure WiFi Network with Static IP Addresses

Skip this section and mark it "NA" in case no wireless WiFi network with static IP addresses is being used.

In case your WiFi network uses static IP addresses check with your IT department for an IP address that is free to use for PT-Node and note the name or "SSID" and the settings of your network here:

SSID	NA
IP Address	**NA**
Subnet	**NA**

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Gateway	NA

DNS Server	NA

Confirm that you have the password required for this WiFi network:

OK	NOK	NA

The switch on PT-Node. The display will light up and after a short while PT-Node will create a WiFi hotspot. You must connect to this hotspot to configure the settings for your network as noted above.

Check the bottom line of the PT-Node display and note the unique name (like for example "PTNODE83D63F") displayed there. This is the name of the WiFi hotspot. Note the name here:

Unique Name	NA

Connect to this WiFi hotspot using a WiFi enabled device, for example a smartphone. The PT-Node Connection Manager will be displayed on your device.

OK	NOK	NA

In the PT-Node Connection Manager select "WiFi" and enter the SSID and password here. Uncheck "DHCP". Then enter the settings for IP address, Subnet, Gateway and DNS server you noted above for your network and press "Submit".

OK	NOK	NA

PT-Node will now restart and then it will connect to the WiFi network you have just configured. Check the bottom line of the PT-Node display. Here the IP address you entered above and a unique name (like for example "PTNODE83D63F") will be displayed. Enter both here:

IP Address	NA

Unique Name	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.9 Configure Direct PC Connection

Skip this section and mark it "NA" in case no wired direct connection to a PC is being used.

In case you do not want to use an existing network but want to connect PT-Node directly to a PC follow these steps below. On your PC access the network settings and manually set an IP address, for example "192.168.15.1". Set the subnet mask to "255.255.255.0". Other settings can remain blank. Note the settings you made in the network settings of your PC here:

IP Address	NA
Subnet	**NA**

Then connect the supplied ethernet cable or another standard ethernet cable of suitable length to PT-Node and to your PC. Switch on PT-Node. The display will light up and after a short while PT-Node will create a WiFi hotspot. You must connect to this hotspot to configure the settings for your network as noted above.

Check the bottom line of the PT-Node display and note the unique name (like for example "PTNODE83D63F") displayed there. This is the name of the WiFi hotspot. Note the name here:

Unique Name	NA

Connect to this WiFi hotspot using a WiFi enabled device, for example a smartphone. The PT-Node Connection Manager will be displayed on your device.

OK	NOK	NA

In the PT-Node Connection Manager select "Ethernet" and uncheck "DHCP". Then enter an IP address in the same range as the one you entered above for your PC, for example "192.168.15.4". The first three number must be identical to the IP address of your PC. The last number must be a different number between 0 and 255. Note the IP address you entered on PT-Node here:

IP Address	NA

For Subnet enter the same setting you entered above for Subnet Mask on your PC.

OK	NOK	NA

For Gateway and DNS Server, set both to "0.0.0.0" and then press submit.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

PT-Node will now restart and then it will connect directly to your PC. Check the bottom line of the PT-Node display. Here the IP address you entered above and a unique name (like for example "PTNODE83D63F") will be displayed. Enter both here:

IP Address	NA
Subnet	**NA**

Section 4.10 Access the Web Interface and Login

Open up your web browser on your PC. Enter the unique name of your PT-Node followed by ".local" into the address line of your browser, like this "ptnode83d63f.local". Note that the exact name will be different for your PT-Node. You noted the exact name above and it is displayed in the bottom line of the PT-Node screen.

The web interface of PT-Node is displayed in your browser.

OK	NOK	NA

Note the serial number displayed on the left side and check that it matches the documentation your received with your PT-Node.

SN	OK	NOK	NA

Note the software version displayed next to the serial number.

Version	NA

Click on "Login". Enter "admin" for Username and enter "admin" again for Password. Click on the red "Login" button. You are now logged in as administrator.

OK	NOK	NA

You should now change the passwords for administrator, and FTP connection and note them in a secure place.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.11 Check the Timer

The actual date and time are displayed in the web interface of PT-Node. In "Settings" – "Date & Time" check if the correct time zone for your region is set. If not change it to the correct region.

OK	NOK	NA

Check if your network offers a time server or if a public time server in the internet can be accessed. If neither are available, uncheck "NTP Server" and enter the current date and time manually.

OK	NOK	NA

Use the stop watch to check the PT-Node internal clock for one minute.

TARG	MEAS	OK	NOK	NA
58-62 sec				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.12 Setup a Device to Use With PT-Node

Now setup a Pharma Test device to use with PT-Node.

Which device is going to be used?

Instrument	NA
Serial Number	**NA**
Firmware Ver.	**NA**

Check that the correct connection cable for this model is available and connect it to one of the ports of PT-Node and to the proper port of the instrument. A list of connection cables is included in the PT-Node manual. Also refer to the instructions on how to setup this instrument there and to which port of the instrument the connection cable needs to be connected to.

OK	NOK	NA

Again check the user manual of PT-Node on how to setup this instrument and if there are any settings to be changed on the instrument to enable interfacing with PT-Node. Perform these settings.

OK	NOK	NA

Now, in the web interface of PT-Node enter the device manager. Select the proper device family for your instrument for the port you connected your instrument to. Check the user manual of PT-Node for any additional settings you must make here and perform these. Enter a name for the data folder.

OK	NOK	NA

Repeat these steps for any additional instrument you want to use with this PT-Node. You can copy this page for this and attach the copy hereto.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.13 Test Communication With the Device

Perform a test with the instrument you configured in the section above and transmit the data via its interface. The exact way to do this differs from instrument to instrument. Refer to the user manual of PT-Node and the instrument's user manual for more information.

When data is transmitted note the following: on the display of PT-Node, the port number the instrument is connected to starts to blink.

OK	NOK	NA

This means that communication has successfully been established.

A new file is created. The name of the file is displayed below the port number and selected device family.

OK	NOK	NA

This means that the results have been received by PT-Node and that a new file has been created.

Now check the file index on the web interface of PT-Node. Check that a folder with the name you set as data folder in the section above has been created.

OK	NOK	NA

Open this folder. A new file with the name as displayed on the screen of PT-Node has been created.

OK	NOK	NA

Open this file. The file contains the correct results as obtained from the instruments.

OK	NOK	NA

Perform a second test with the same instrument and transmit this data again. Check that a new filename is displayed on the PT-Node screen and that a new file appears in the file index on the PT-Node web interface. Reload the page to see any new files.

OK	NOK	NA

Repeat these steps for any additional instrument you want to use with this PT-Node. You can copy this page for this and attach the copy hereto.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

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Section 5.0 Result and Comments

Instrument Type	PT-Node	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 operation qualification have to be repeated once the reason for failure has been eliminated

Comments

This completes the operation qualification of the tested instrument.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Released by: _____ Date: _____

Section 1.2 Section 1.1