PTWS Series
Dissolution Test Instrument

Installation Qualification (IQ)

Version 1.5

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DIIN EN ISO 9001-Certificate No FS 529019/0388D

Section 1.0 Scope Introduction

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Introduction

Objective

Installation Qualification (IQ) is used to verify that the Pharma Test PTWS x20 instrument (or components where applicable) has been installed to the manufacturer's requirements and performs its functions as per specification.

Equipment

The Pharma Test PTWS x20 Dissolution Instrument is composed of:

- PTWS x20 dissolution testing instrument
- All required accessories
- Options supplied as specified by customer

The PTWS x20 Dissolution Tester contains six to sixteen sample vessels and six to fourteen stirrer positions. It is used for the dissolution testing of a variety of pharmaceutical compounds including; tablets, capsules, transdermal patches and membranes. The PTWS x20 can be used in several configurations that satisfy USP criteria e.g. rotating baskets or paddles (USP Apparatus 1 and 2), paddles over disk (USP Apparatus 5) and rotating cylinder for transdermal applications (USP Apparatus 6). The PTWS x20 is supplied with a thermostatically controlled water heater/circulator system. The heater temperature can be controlled by the PTWS x20 as are all other operating parameters such as paddle speed.

Tablet (capsule) can be dropped into the vessel sequentially. The Pharma Test dissolution tester PTWS x20 is designed of two major instruments, the drive and heating system which is connected to the water bath and separated from the drive to prevent vibration transfer into the vessels.

A run time protocol can be printed, when the PT-RP80 report printer or any Pharma Test dissolution software is used with the instrument. The temperature sensing probe measures and records the actual temperature of the water bath. Temperature readings can be taken before, after, and periodically during a run to ensure complete compliance throughout the run by using an external certified thermometer. Bath temperature readings are displayed on the screen of the PTWS x20 dissolution instrument.

Optional installation accessories for the PTWS x20 are:

- TM-x20 manual tablet drop magazine
- TMA-x20 automated tablet drop magazine
- EPE-x20 movable, automated sampling system (requires TM-x20 or TMA-x20)
- ITM-x20 individual media temperature monitoring device

Document History

Revision	Valid from	Author	Change	Remark
1.0	02.12.2015	PTAG	N	New Document
1.1	11.03.2016	PTAG	R	First revision
1.2	12.07.2016	PTAG	R	Second revision
1.3	02.02.2018	PTAG	R	Sequence unpackaging / Equipment description changed
1.4	19.05.2020	PTAG	R	New instrument added (PTWS 1420)
1.5	06.03.2023	PTAG	C	Introduction and headline 2.1.5 corrected

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 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 PTWS x20 according to the delivery note/packing list has been received. 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.
30-41000	Dissolution Testing Instrument	PTWS 120D				
30-41100	Dissolution Testing Instrument	PTWS 120S				
30-48000	Dissolution Testing Instrument	PTWS 820D				
30-46000	Dissolution Testing Instrument	PTWS 620				
30-41200	Dissolution Testing Instrument	PTWS 1220				
30-46600	Dissolution Testing Instrument	PTWS D620				
30-41400	Dissolution Test Instrument	PTWS 1420				

PTWS x20 Details

Voltage	☐ 230V 50 cycl.
	☐ 115V 60 cycl.
Asset No. or Lab ID No.	

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.1 Instrument Identification – Testing Positions

Whenever stirrer or vessel positions are referenced in this document the following numbering applies. Only at PTWS 120D/S and 820D: there are two ways of orientation when setting up a PTWS 120/820 instrument. Mark below in which mode of orientation the instrument is installed:

Section 2.1.1 PTWS 120D/S:

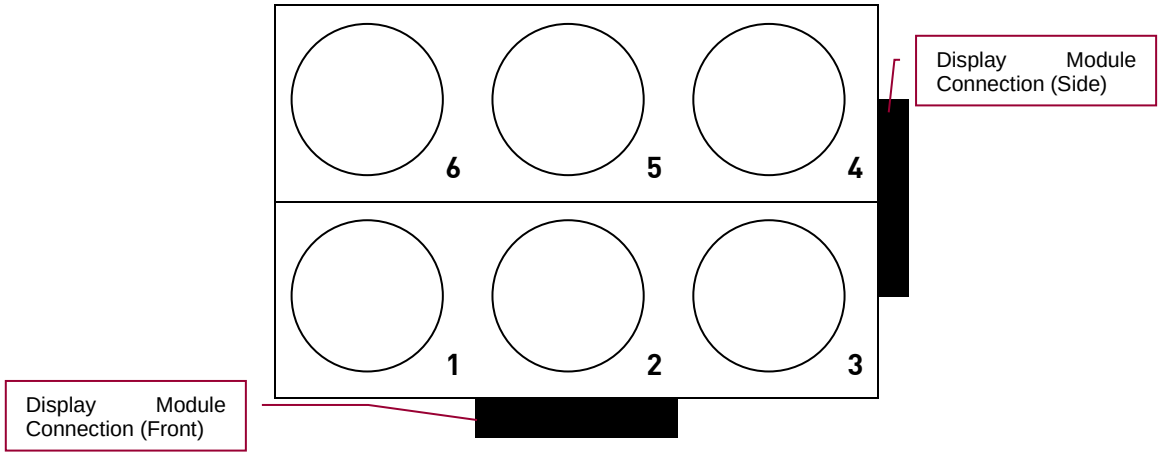

Figure 1: Vessel Numbering of the PTWS 120D/S Orientation A

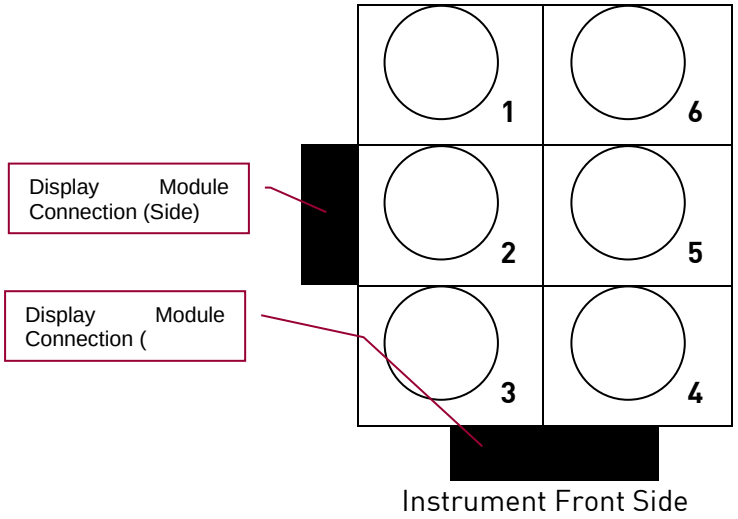

Figure 2: Vessel Numbering of the PTWS 120D/S – Orientation B

Mode of Orientation	OK	NA
Mode A - 3 x 2		
Mode B - 2 x 3		

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.1.2 PTWS 820D:

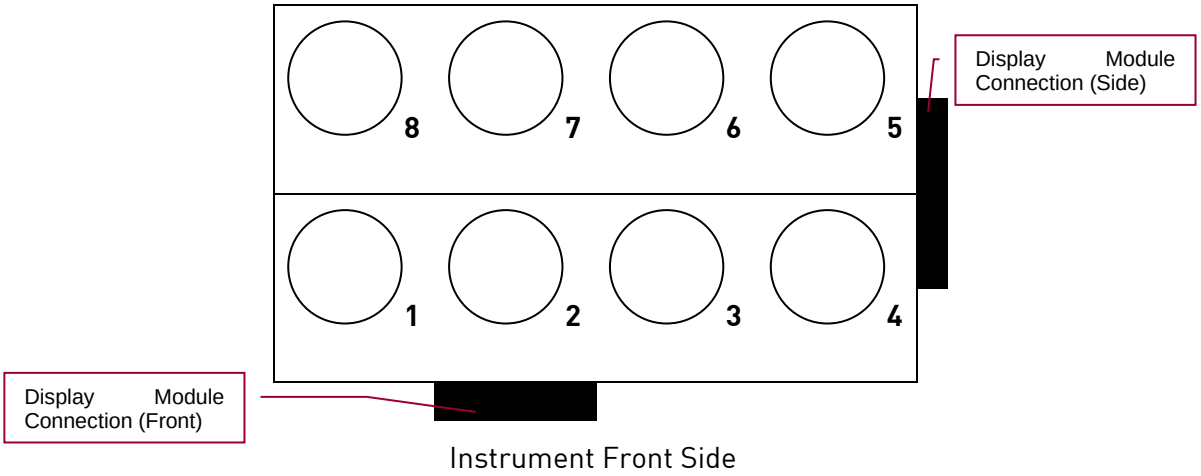

Figure 3: Vessel Numbering of the PTWS 820D – Orientation A

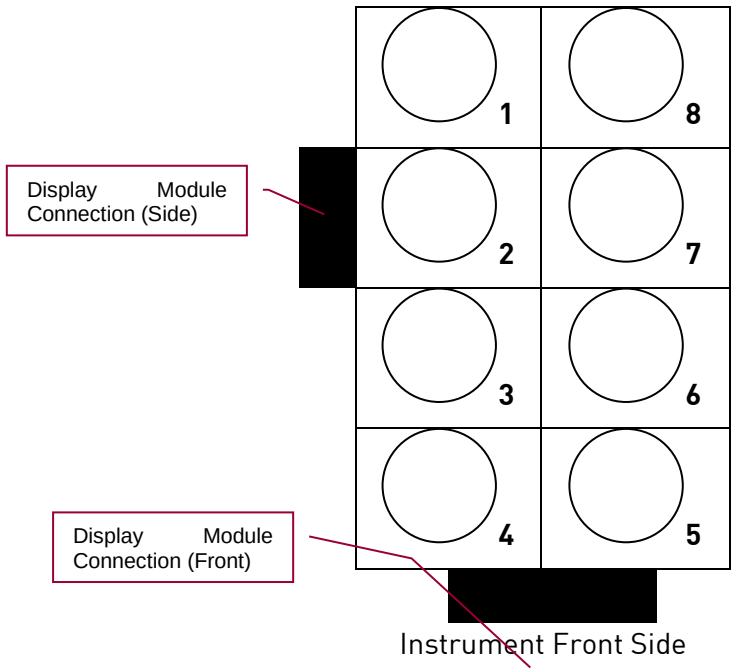

Figure 4: Vessel Numbering of the PTWS 820D – Orientation B

Mode of Orientation	OK	NA
Mode A - 4 x 2		
Mode B - 2 x 4		

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.1.3 PTWS 620:

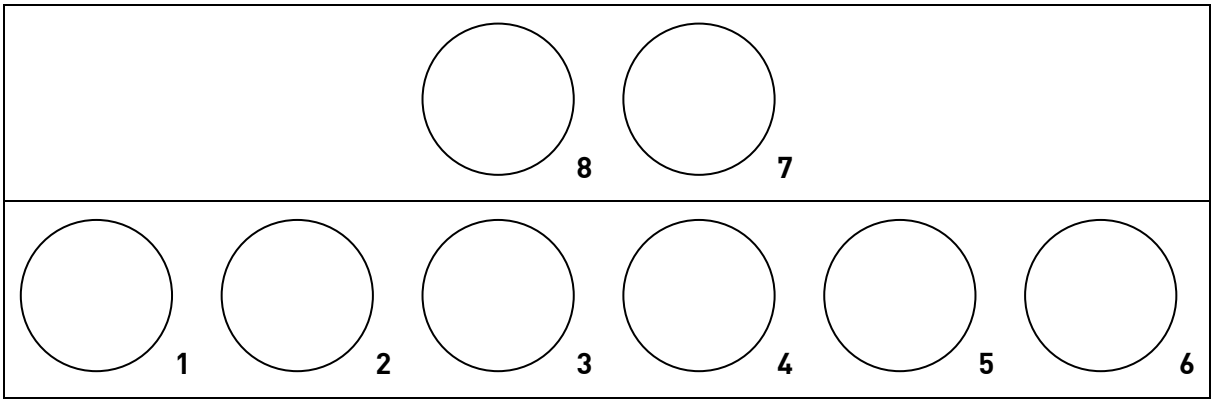

Figure 5: Vessel Numbering of the PTWS 620

Section 2.1.4 PTWS 1220/D620:

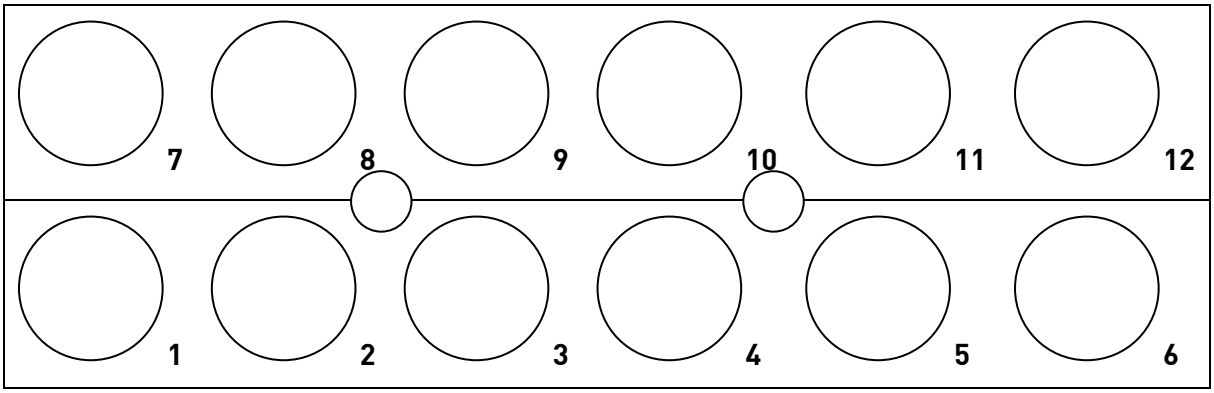

Figure 6: Vessel Numbering of the PTWS 1220 and PTWS D620

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.1.5 PTWS 1420:

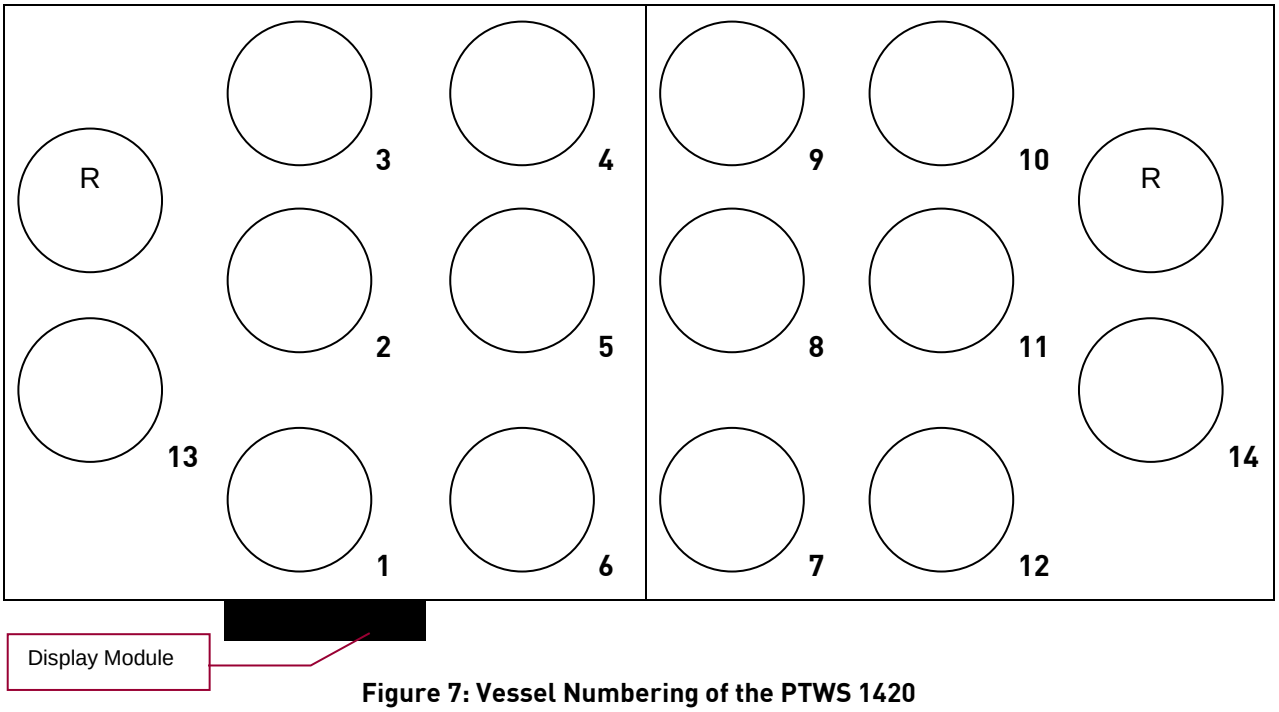

Figure 7: Vessel Numbering of the PTWS 1420

Section 2.2 Instrument Identification – Supply Scope

Check if all items according to the delivery note/packing list have been received:

pass	fail	NA

If not all items have been received list the missing items below:

Part-No.	No.	Description	miss.

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.3 Required Documentation

Ordering Information

Customer Order Number	
Supplier Invoice Number	
Supplier Delivery Note	

Equipment Documentation

Part-No.	Description	rec.	NA	miss.
B-30-4xxxx	PTWS x20 Operating Manual			
IQ-30-4xxxx	PTWS x20 Installation Qualification			
OQ-30-4xxxx	PTWS x20 Operation Qualification			
NA	Instrument Log Book			
QC-30-4xxxx	QC/DQ Test Report			
NA	Delivery Note			

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 2.4 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: 115V ☐ 230V ☐ Frequency: 60Hz ☐ 50Hz ☐

Section 2.5 Operating Environment

Note: This dissolution instrument MUST be installed on a level surface. The supporting bench MUST be able to take at least 150kg of weight continuously. The parallel operation of the tester head with the water bath and the resulting perpendicular placement of the dissolution tools are all part of the USP / EP requirements for qualified instrument operation. Failure to comply with this will ultimately lead to failed Performance Qualifications (PQ) and non-compliance of the instrument for GMP use. Pharma Test Apparatebau AG is not responsible for inadequate site planning and installation. We are however, happy to advise if help is required.

Section 2.6 Operating Environment

This instrument requires solid laboratory bench and needs to be installed in a laboratory environment.

Temperature: 10-40°C	Rel. Humidity: 20-80% (non condensing)
Physical Site: Clean, dry and level bench	Weight Support: Approx. 150 kg
Dimensions (Depending on instrument Type and orientation (Width x Depth x Height):	1000 x 750 x 1000mm for PTWS 120 & 820 1400 x 600 x 1000mm for PTWS 620, 1220 & D620

Section 2.7 Clearance

A minimum of 10cm of the rear and sides of the instrument is required. Approximately 90 cm of total bench space is required for the PTWS x20 (does not include space for options such as pump and fraction collector or spectrophotometer).

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.0 Unpack the PTWS x20 from the Wooden Crate

Unscrew the crate cover. Remove cardboard boxes where accessible. Unscrew and remove the crate front wall. Unscrew and remove the crate side wall. Unscrew and remove the remaining crate walls. Always lift the instrument with two people using the proper lifting points. Never lift the instrument from any other points (i.e. the head) as this may damage the instrument! Carefully place the instrument on the installation location. Remove the wrapping material and unpack all accessories. Assure that there has been no physical damage caused to the instrument or accessories during shipment.

pass	fail	N/A

Section 3.1 Equipment Description – Vessels

Check if the vessels as per the order confirmation have been received and note the serial numbers below. Refer to the numbers in the table below when installing the vessels in their positions later:

Vessel Pos.	Vessel SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.2 Equipment Description – Stirrer Shafts

Check if the stirrer shafts as per the order confirmation have been received and note the serial numbers below. Refer to the numbers in the table below when installing the shafts in their positions later:

Shaft Pos.	Shaft SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

Section 3.3 Equipment Description – Paddles (USP/EP App. 2)

Check if the paddles as per the order confirmation have been received and note the serial numbers below. Refer to the numbers in the table below when installing the paddles in their positions later:

Paddle Pos.	Paddle SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				

Performed by: _____ Date: _____

Signature MM/DD/YYYY

10				
11				
12				
13				
14				

Section 3.4 Equipment Description – Baskets (USP/EP App. 1, optional)

Check if the baskets, basket adapters and support rings as per the order confirmation have been received and note the serial numbers below. Refer to the numbers in the table below when installing the baskets in their positions later:

Basket Pos.	Basket SN.	Adapter SN.	Support Ring SN.	Rec.	NA	miss.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.5 Equipment Description – Additional Vessels (optional)

In case additional vessels were ordered, check if these have been received and note the serial numbers below. Refer to the numbers in the table below when installing the vessels in their positions later. Vessel type: _____

Vessel Pos.	Vessel SN.	Rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.6 Equipment Description – Additional Tools (optional)

In case additional tools were ordered, check if these have been received and note the serial numbers below (mark NA in case field does not apply). Refer to the numbers in the table below when installing the tools in their positions later. Tool type: _____

Tool Pos.	Tool SN.	Adapter SN.	Rec.	NA	miss.
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

Copy this page in case more vessels or tools are supplied. Attach and number the copies.

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.0 Personnel Identification

Installation (1):	Engineer	Name (print)	Initials
		Signature	Date (MM/DD/YYYY)
Installation (2): (optional)	Engineer	Name (print)	Initials
		Signature	Date (MM/DD/YYYY)
Installation (3): (optional)	Engineer	Name (print)	Initials
		Signature	Date (MM/DD/YYYY)
Approved by:		Name (print)	Initials
		Signature	Date (MM/DD/YYYY)

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.1 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	Calibr. since	OK	N/A	miss.
30-31005	Digital laser tachometer					
30-31006	Digital tachometer					
30-31007	Digital thermometer					
10-61000	Stop watch					
30-31080	Digital goniometer					
307-1205	Precision dial gauge for SWT					
30-31206	Axial Position testing Gauge SCT					
46-01810	Digital caliper					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					
315-0200	Depth adjustment ball, 25mm					

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.2 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 Connect the Tubing Set (Optional)

In case the instrument is supplied as part of an automated system, connect the tubing set by following the labels on the tubing and the color coding of the "Luer"-connectors.

pass	fail	N/A

Section 5.2 Connect the Mains

Set the mains switch to the "off"-position. Connect the mains cable to the local power outlet and to the PTWS x20.

pass	fail	N/A

Section 5.3 Connect the Display (PTWS 120D/S/ PTWS 820D and PTWS 1420 only)

Plug the Display on the preferred Sub-D-female connector at the head and fix it with the black knurled head screw in the head bottom.

pass	fail	N/A

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 6.0 Required Qualification Materials

Section 6.1 Verify Vessels and Stirring Tools

Check that all supplied vessels and stirring tools are qualified by the manufacturer and all certificates are enclosed.

pass	fail	N/A

Section 6.2 Verify the Digital Laser Tachometer

Check if the digital laser tachometer is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.3 Verify the Digital Tachometer

Check if the digital tachometer is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.4 Verify the Digital Thermometer

Check if the digital thermometer is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.5 Verify the Stop Watch

Check if the stop watch is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 6.6 Verify the Digital Goniometer

Check if the digital goniometer is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.7 Verify the Precision Dial Gauge

Check if the precision dial gauge is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.8 Verify the Digital Caliper

Check if the digital caliper is qualified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Section 6.9 Verify the Depth Adjustment Ball

Check if the depth adjustment ball is certified by the manufacturer, or if ordered with a calibration certificate, by a qualified external testing authority. Check that all certificates are enclosed.

pass	fail	N/A

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 6.10 Verify Other Materials (optional)

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 PTWS x20 instrument.

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Released by: _____ Date: _____

Signature MM/DD/YYYY