



Operating Manual

PTWS 830, PTWS 1230 and PTWS D630 Tablet Dissolution Testing Instrument



Version 1.0

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The Documentation

This document describes the set-up, operation and general maintenance of the instrument. It should be used by the operators and the technical support staff responsible for the installation and set-up of equipment.

All attached equipment and parts have to be used in compliance with the manufacturer's manuals and papers supplied.

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We reserve all rights.

This manual should be used by the owner of the instrument only. He is allowed to copy the manual for his own use. It is forbidden to supply any copy of this document for any other purpose other than the instrument use without previous approval from Pharma Test Apparatebau AG.

How to Use the Manual

To understand the different information we use different formatting:

- **Use any key (i.e. 1 or STOP)**
- Display information
- *Information entries*
- **Select from a menu**
- Note: informs about special use or possibility



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Document History

Version	Valid from	Author	Change	Remark
1.0	10.03.2026	Pharma Test	N	First release

Table 1: Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

1 General Information

We appreciate your choice of a Pharma Test PTWS tablet dissolution testing instrument.

1.1 About Tablet Dissolution Testing

Tablet dissolution testing is an essential quality control process within the pharmaceutical industry, designed to evaluate the rate and extent at which a tablet releases its active pharmaceutical ingredient (API) into solution under standardized conditions. This procedure provides valuable predictive information regarding drug absorption and efficacy within the body. Conducting dissolution tests is crucial for determining the performance of oral dosage forms and verifying that they deliver their APIs as intended. When executed properly, dissolution testing supports the optimization of formulations for improved therapeutic outcomes.

Regulations require appropriate instruments capable of handling multiple test cycles, with results accurately documented and equipment maintained. International pharmacopoeias like USP, EP, DAB, and BP specify instruments for tablet dissolution: typically, six samples are placed in heated glass vessels (37°C) with adjustable stirring speeds (20–250 rpm). Media samples are collected at set intervals, either manually or automatically with devices such as fraction collectors or spectrophotometers.

1.2 About the PTWS Line of Tablet Dissolution Testers

This guide covers the following models: PTWS 130D, PTWS 130S, PTWS 830, PTWS 1230, and PTWS D630. The PTWS 130D is a compact unit with six positions, featuring a shared stirrer drive for all. The PTWS 130S offers the same features as the PTWS 130D but provides an individual stirrer drive for each position, allowing different speeds for each stirrer. Based on the PTWS 120D design, the PTWS 830 includes all its features plus seventh and eighth stirred positions, and various automation options—such as the EPE automated sampling manifold, TM and ATM tablet drop magazines, and ITM individual temperature monitoring system. The PTWS 1230 has 12 testing positions and also supports these automation options (EPE, TM/ATM, and ITM). As a variant, the PTWS D630 shares the PTWS 1230's capabilities but allows independent stirrer speed control for both the front and back rows.

The PTWS is a tablet dissolution tester designed for solid dosage forms, meeting standards set out in USP chapters <711/724>, EP sections <2.9.3/4>, the DAB, and Japanese Pharmacopeia section <15>. It features a staggered start for each testing position, and its electronically controlled upper drive provides 16 operating positions plus an upper home setting. The instruments are equipped with a vessel centering and holding system based on a bayonet catch mechanism. For ease of maintenance, the water baths are designed to be easily removable for cleaning. The heating system is housed separately and operates on either a 115V or 230V power supply. Connections between the heater and bath utilize self-sealing quick connect fittings, facilitating straightforward assembly and disassembly. Water circulation is managed by a robust yet quiet pump, which is self-priming and spring-mounted to minimise vibration transfer. Additionally, the flow-through heater is safeguarded against overheating by both a thermal switch and a thermal fuse.



Figure 1: USP App. 2 paddles and USP App. 1 baskets for MonoShaft™ tool system

The PTWS instruments feature the Pharma Test MonoShaft™ design, where tools are composed of a main shaft and interchangeable tool heads (adapters). The main shaft stays fixed in the instrument no matter which tool head is used. Once the main tool shaft has been installed and qualified with any tool set, each tool's clearance from the vessel base is automatically correct. Each stirrer can also be manually lifted to make removing or inserting vessels easier.

Depending which kind of drug has to be tested the PTWS instrument can be equipped to work according to USP Method No. 1, 2, 5 and 6.

Our advanced design features a high-resolution touch screen that lets users easily adjust settings like stirring speed, lift drive, and heater controls. The instrument operates through an intuitive graphical menu. On-screen visual alerts keep users informed about important parameters, such as when the bath hasn't reached its target temperature. The software provides reliable management for both users and methods, along with a detailed audit trail that records every change and event within the system.

The PTWS enables operators to fully access vessels at the start and end of runs, thanks to its electronic drive head lift. For offline automation with fraction collection, you can add the PTFC-2/8/PTFC-16 fraction collector and PT-SP syringe pumps. Sampling timing, volume, and optional media refilling are all programmed directly on the PTWS, without external software. Media refilling (optional) starts automatically after sampling if selected. The DSR-M dissolution sampling robot can also be used for sample dilution and ensures accurate sampling through its integrated piston pump module.

An online automated system may employ a UV/VIS spectrophotometer equipped with a multiple-cell changer. The spectrophotometer and pump are managed by the robust ARGUS Dissolution software, which supports drivers for most widely used UV/VIS spectrometer models. The Pharma Test ADS-L system comprises a PTWS dissolution tester, a J&M TIDAS-L diode-array spectrometer integrated with a PC operating the ARGUS dissolution software, and a peristaltic pump. Together, these components form a comprehensive and fully integrated solution.

1.3 Technical Specifications

Parameter	Specification
Compliance	Fully USP , EP , BP, DAB and JP compliant
Number of stirred vessels	PTWS 130D & PTWS 130S: 6 (3 by 2 arrangement) PTWS 830: 8 (4 by 2 arrangement) PTWS 1230 & PTWS D630: 12 (6 by 2 arrangement)
Stirring tool design	MonoShaft™ stirrer design
Stirrer speed range	25 - 250 RPM
Stirrer speed accuracy	±2% of set speed, typically < 1%
Stirrer shaft wobble	Better than 0.2 mm total run out
Heating system	Heating and circulation pump module
Heating range	25.0 – 45.0°C
Heating accuracy	± 0.2°C inside the water bath
Display & data entry	7", 1024x600 pixel resolution color LCD touch screen, backlit
Audit trail	Integrated, logging all events and changes with before and after information, multi-level filtering
User management	Unlimited number of users with password and user rights
Working positions	16 programmable stirrer immersion positions (paddle over disk, transdermal cylinder etc.)
Sampling positions	16 programmable sampling probe immersion positions including a cleaning position
Method management	Unlimited number of methods
Timer	Programmable sampling times, wake-up and sleeping mode, operation time information and timer count-down mode
Acoustic signal	Programmable acoustic signal for operator information
Calibration & PQ control	Built-in calibration programs with OQ/PQ interval warning
Printer support	External ticket printer or PT-Node network adapter
Interfaces	CAN port for remote control, RS-232 port to connect serial devices, I/O port for remote control of external instruments in automated systems, like DSR-M and PTFC
Instrument dimensions (width x depth x height)	PTWS 130D & PTWS 130S: xxx PTWS 830: approx. 75cm x 45cm x 75cm PTWS 1230 & PTWS D630: approx. 90cm x 60cm x 75cm Heater: approx. 22cm x 32cm x 22cm
Net / gross weight	PTWS 130D & PTWS 130S: xxx PTWS 830: approx. 75 / 130 kg PTWS 1230 & PTWS D630: 75 / 130 kg
Certification	All CE / EMC certification provided
Validation	All IQ & OQ documents included

Table 2: Technical Specifications

1.4 Standard Supply Scope

The PTWS instrument comes ready to use with a fully supply scope for manual operation with USP/EP App. paddles:

Part No.	Nos	Description
318-0116	1 set	USP/EP 1 liter stirrers, MonoShaft™ design
316-0210	1 set	USP/EP App. 2 paddle blades, MonoShaft™ design
315-0200	1 set	25mm depth gauge balls
302-1120	1 set	Vessel covers
303-5225	1 set	USP/EP 1 liter clear borosilicate glass vessels
319-3040	1 set	Vessel holders with bayonet catch
319-0600	1	Heater and pump box in 230V or 115V
106-0400	1	ALGEX Magenta water bath preservative
34-08400	1	Table power supply, 24V/DC, 5A, 120W
34-08500	2	EUR mains cord
or alternatively one of the following mains cords:		
34-08511	2	US mains cord
34-08510	2	CH mains cord
34-08512	2	GB mains cord
34-08513	2	AR/AUS/NZ mains cord
34-08514	2	IN/ZA mains cord
34-08550	2	BR mains cord

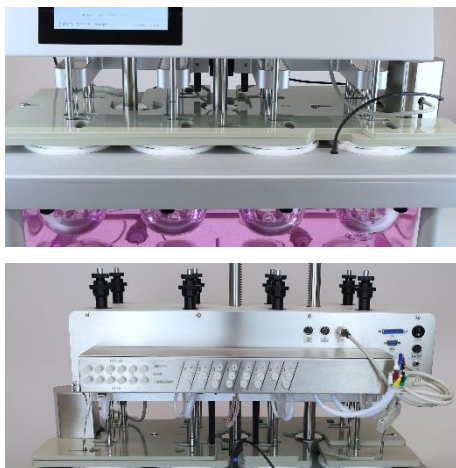
Table 3: Supply Scope Main Unit

One set refers to the number of testing stations, i.e. six for PTWS 130D and PTWS 130S, eight for PTWS 830 and 12 for PTWS 1230 and PTWS D630.

1.5 Accessories and Upgrades

The standard supply scope of the PTWS is a complete package, but there are a variety of accessories and upgrades available that enhance the usability of the system or provide means to the user to reliably qualify the instrument. The options EPE automated sampling manifold, TM and TMA tablet drop magazine, ITM individual temperature monitoring system and cleaning system are not available for the PTWS 130D and PTWS 130S instruments.

1.5.1 EPE Automated Sampling Manifold



The EPE is used to withdraw samples from the dissolution vessels. The sampling probes are automatically driven into the solution at the time interval programmed on the PTWS instrument. At the end of a sampling sequence the tube is automatically moved out of the vessel and the EPE unit remains in its upper home position waiting for the next cycle. Up to 16 different sampling positions can be programmed.

A TM or TMA tablet drop magazine is required to use the EPE.

Model	Part No.	Description
PTWS 130D	NA	NA
PTWS 130S	NA	NA
PTWS 830	319-2050	EPE-830
PTWS 1230	319-2010	EPE-1230
PTWS D630		

1.5.2 TM Manual Tablet Drop Magazine and TMA Automated Tablet Drop Magazine



The tablet drop magazine tightly covers all dissolution vessels and reduces the evaporation within 24 to < 0.5% of the filling volume at 37°C media temperature. The vessel covers are conically formed to enable the condensing water to drop back into the vessels. Using a slider, the user can drop the samples into all vessels at the same time when using the manual TM tablet magazine. When the TMA automated tablet magazine is used, the samples are automatically dropped into all vessels at the same time at the start of the test. The magazine is connected to the head of the PTWS instrument and is automatically raised when the head is driven up. This way all vessels are easily accessible for cleaning. The magazine is mounted in a flexible way to eliminate any risk of blockage while driving down the instrument head.

Model	Part No.	Description
PTWS 130D	NA	NA
PTWS 130S	NA	NA
PTWS 830	319-2060	TM-830
PTWS 830	319-2065	TMA-830
PTWS 1230	319-2020	TM-1230
PTWS D630		
PTWS 1230	319-2025	TMA-1230
PTWS D630		



If you do not use the instrument for a longer time: we recommend to park the stirring head in down position that the tablet magazine rests on the water bath to prevent the magazine from being bent by gravity.

1.5.3 ITM Individual Temperature Monitoring System



The ITM system is used to measure the actual temperature of the dissolution media individually in each of the vessels of the dissolution bath. The temperature sensors are driven into the solution together with the sampling probes of the EPE. The temperature is automatically measured and logged during each sampling interval. The last temperature measured is displayed on screen.

An EPE automated sampling manifold is required to use the ITM.

Model	Part No.	Description
PTWS 130D	NA	NA
PTWS 130S	NA	NA
PTWS 830	319-2070	ITM-830
PTWS 1230	319-2030	ITM-1230
PTWS D630		

1.5.4 Cleaning System



Cleaning system for sampling tubes of a PTWS instrument equipped with a TM or TMA tablet drop magazine, including plastic beakers for cleaning solution with magnetic holders.

A TM or TMA tablet drop magazine is required to use the cleaning system.

Model	Part No.	Description
PTWS 130D	NA	NA
PTWS 130S	NA	NA
PTWS 830	319-0700	PTWS 830 Cleaning system
PTWS 1230	319-0710	PTWS 1230/D630 Cleaning system
PTWS D630		

1.5.5 PT-Node Network Adapter



PT-Node is an adapter that connects up to two Pharma Test instruments simultaneously to a network using a wired LAN 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.

Model	Part No.	Description
Any PTWS	24-00100	PT-Node network adapter
Any PTWS	34-01203	RS-232 connecting cable, 9:9 F/M

1.5.6 Ticket Printer



The Epson ticket printer is a robust, high-performance receipt dot matrix printer that is particularly easy to use. It prints on plain paper. This printer can be used with PTWS 130D, PTWS 130S and PTWS 830 instruments, as well as an alternative to the integrated thermal printer of PTWS 1230 and PTWS D630 instruments.

Model	Part No.	Description
Any PTWS	29-02200	Ticket printer
Any PTWS	34-01227	Connecting cable

1.6 Instrument Overview

1.6.1 PTWS 130D and PTWS 130S

There are six stirred dissolution vessels in PTWS 130D and 130S arranged this way:

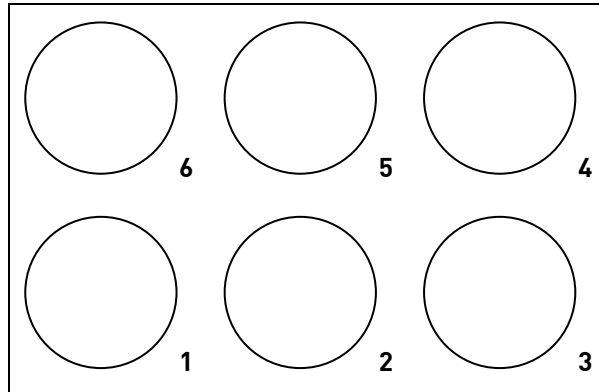


Figure 2: PTWS 130D & PTWS 130S vessel numbering

1.6.2 PTWS 830

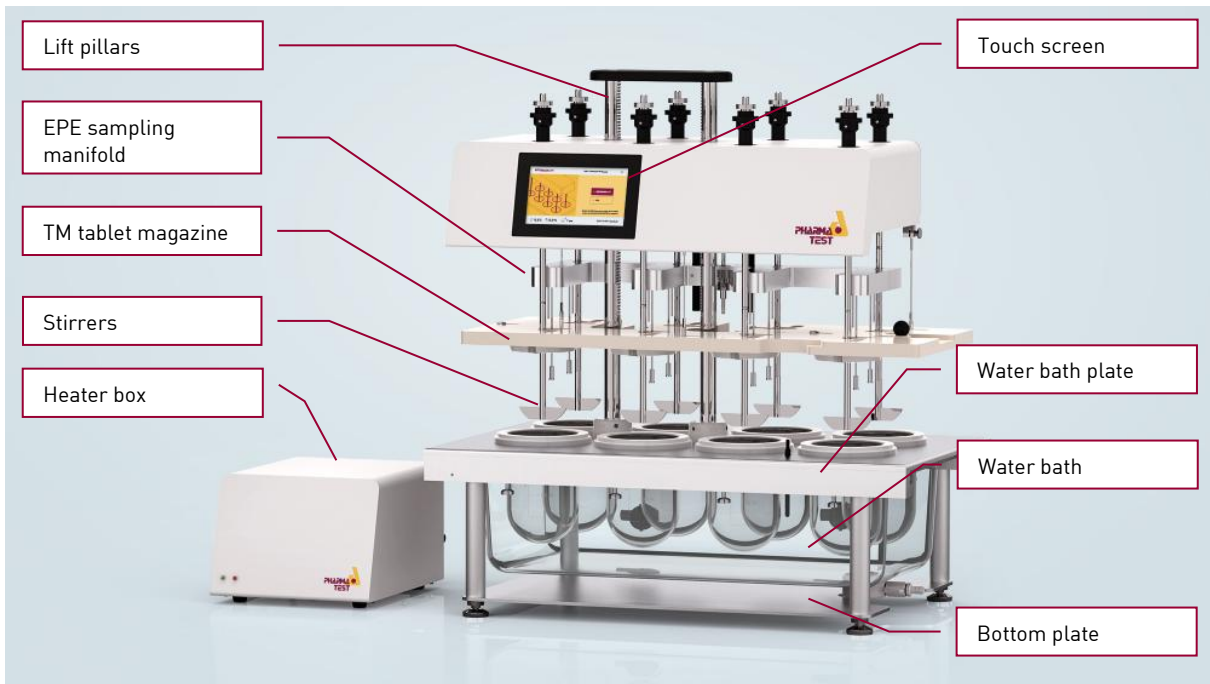


Figure 3: PTWS 830 front view

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There eight stirred dissolution vessels in PTWS 830 arranged this way:

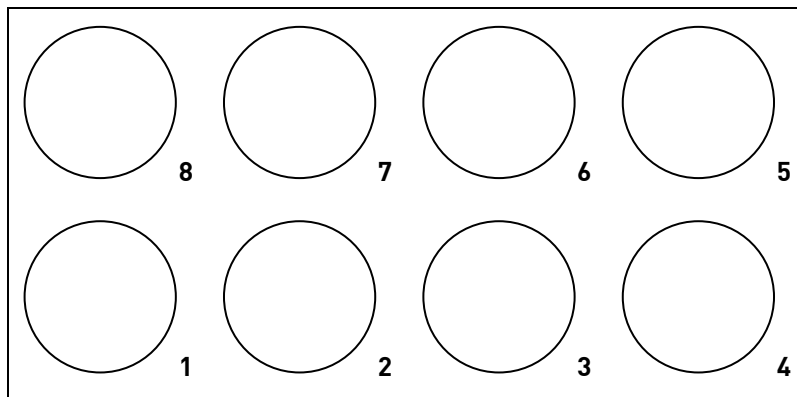


Figure 4: PTWS 830 vessel numbering

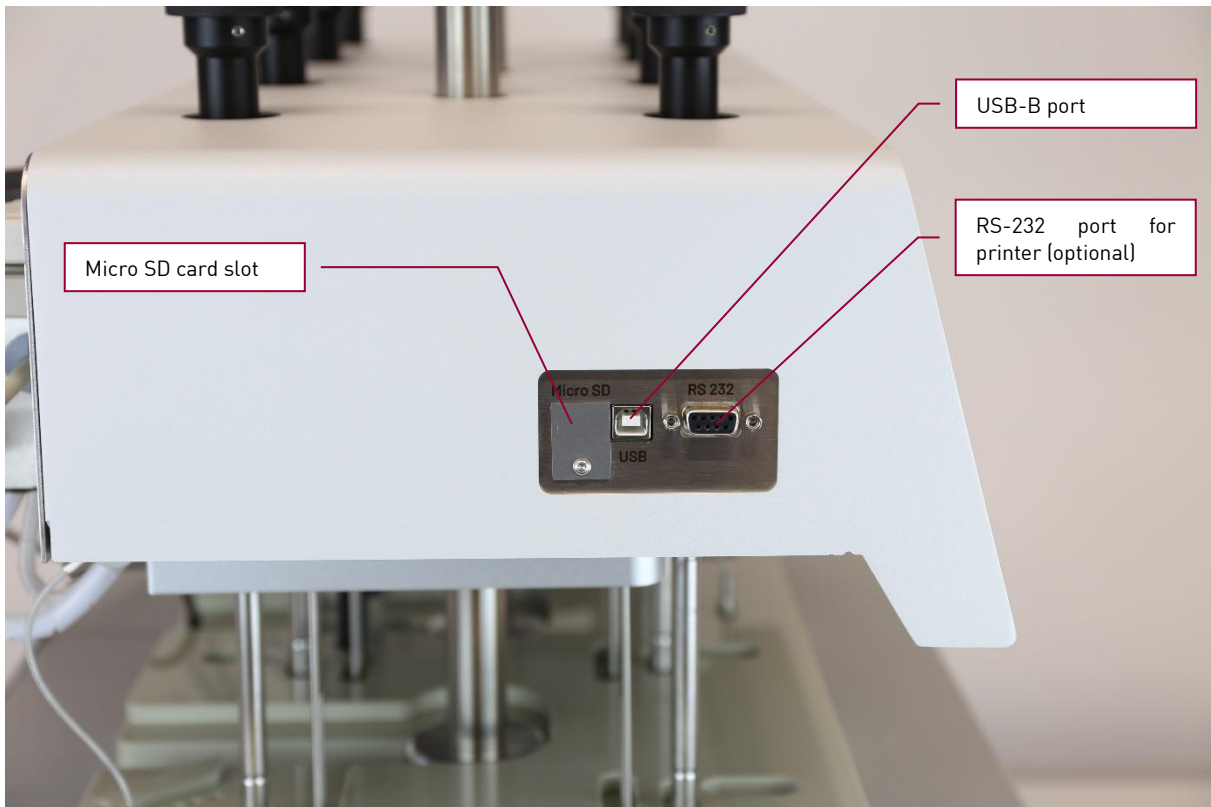


Figure 5: PTWS 830 side connections

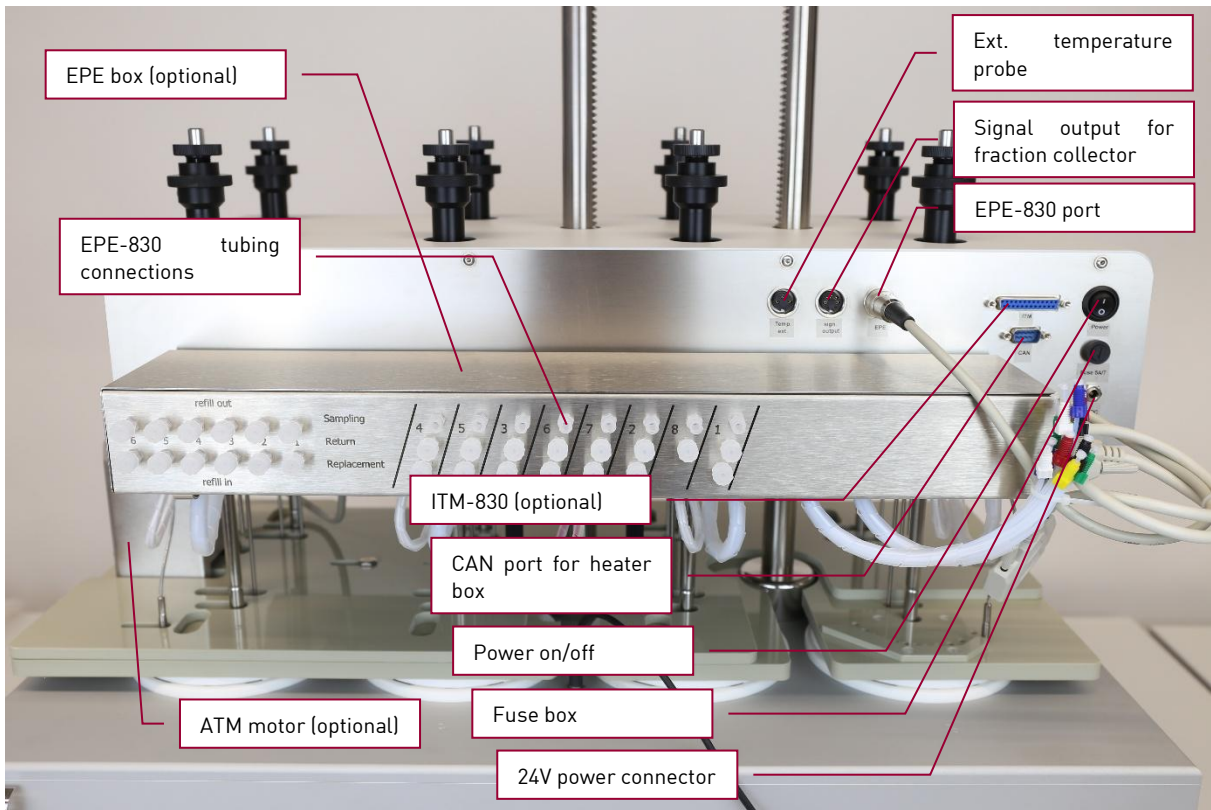


Figure 6: PTWS 830 back side connections

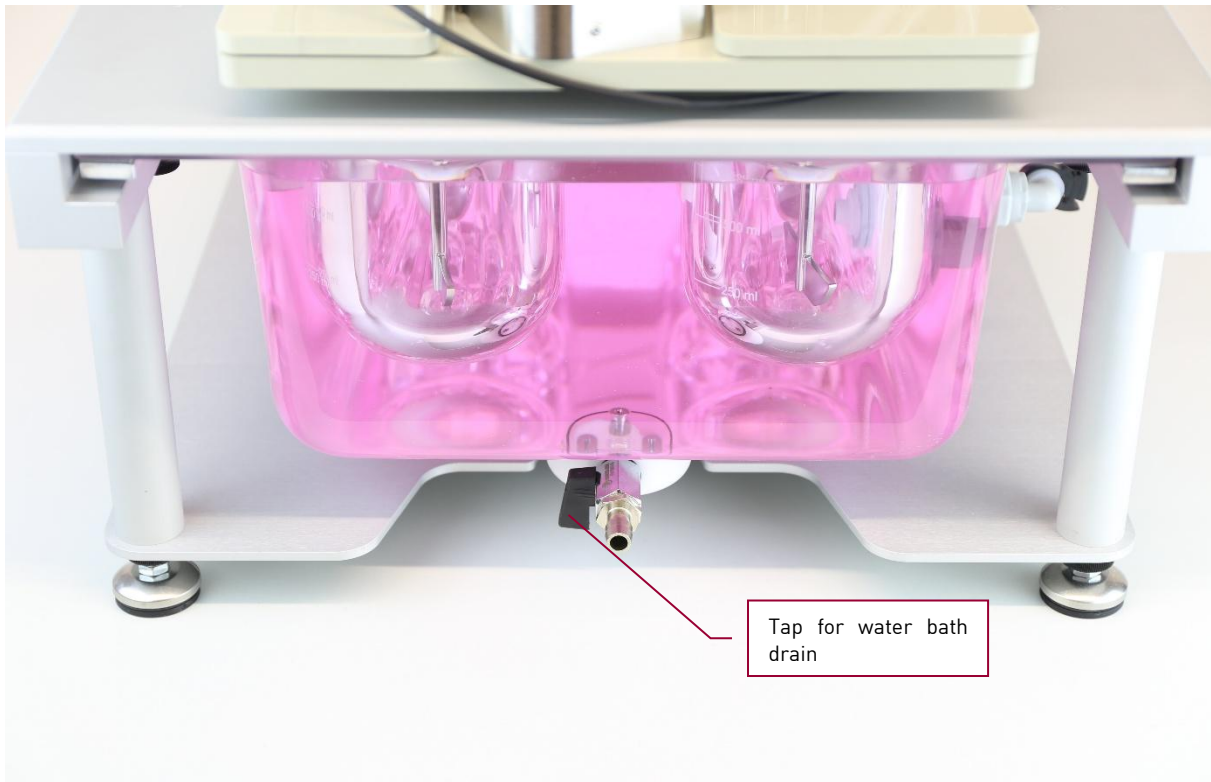


Figure 7: PTWS 830 water bath drain

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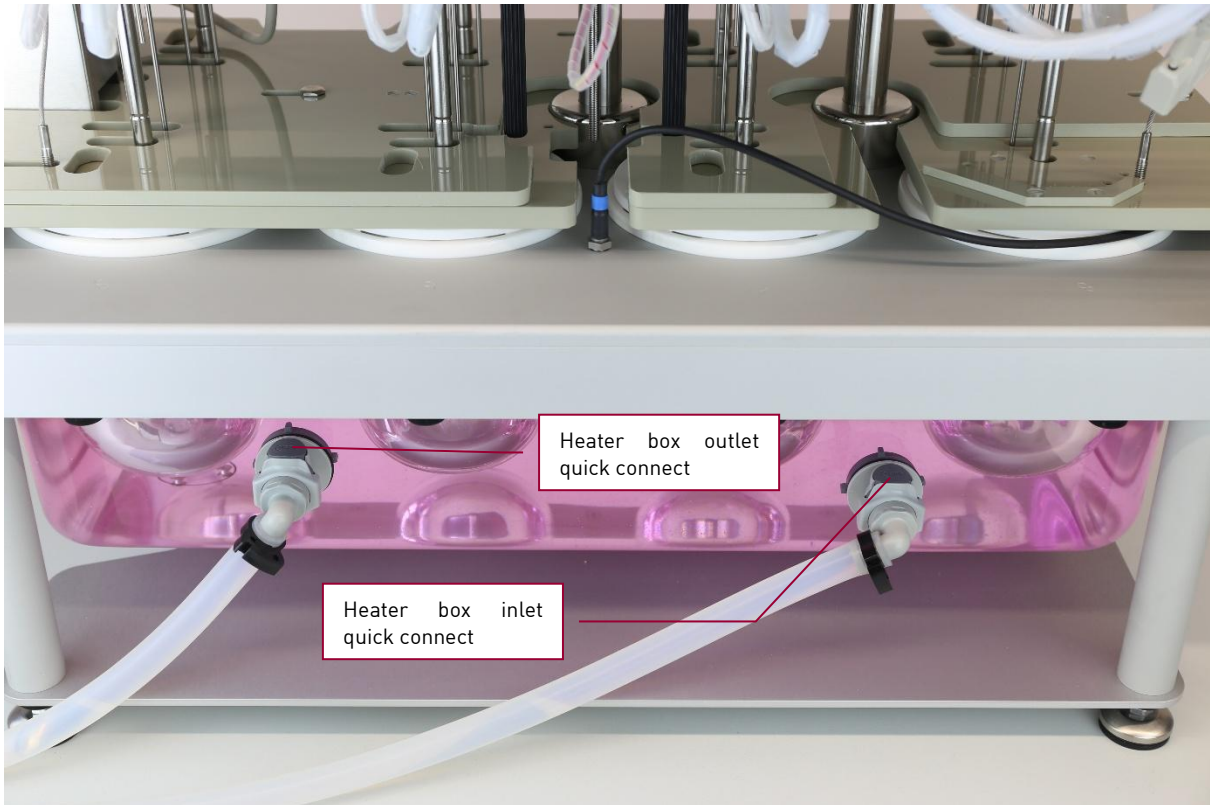


Figure 8: PTWS 830 water bath connections

1.6.3 PTWS 1230 and PTWS D630

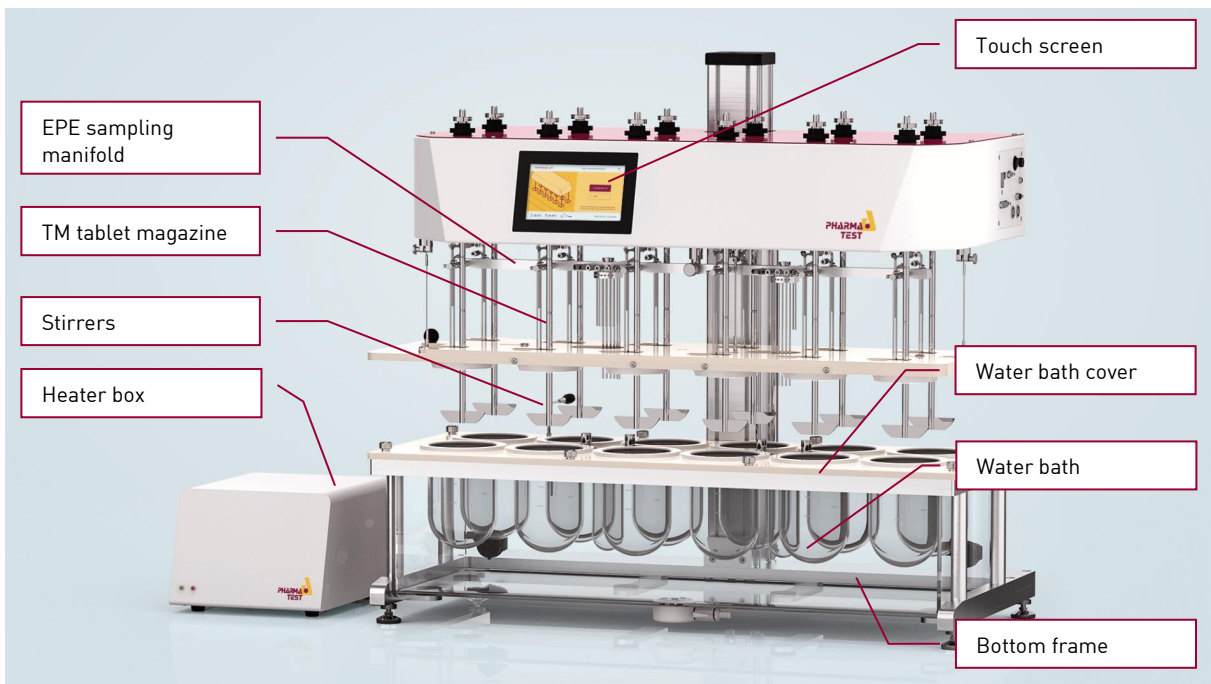


Figure 9: PTWS 1230 & PTWS D630 front view

There twelve stirred dissolution vessels in PTWS 1230 and PTWS D630 arranged this way:

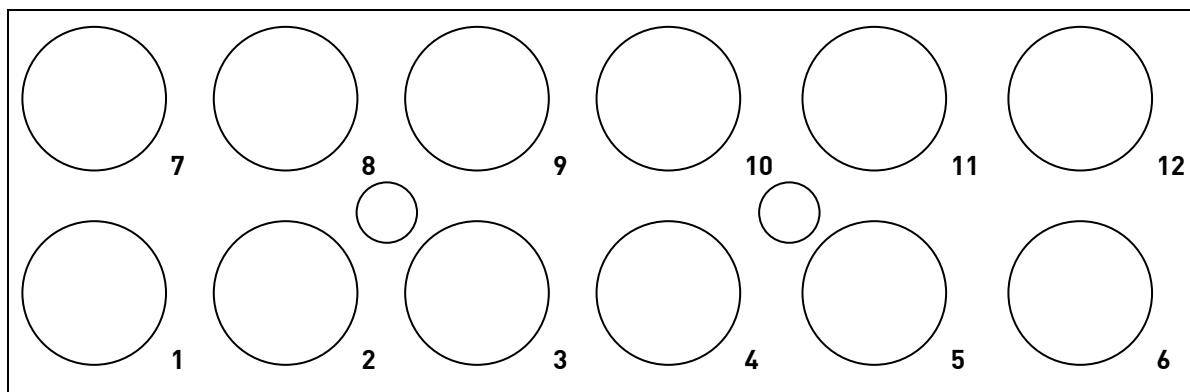


Figure 10: PTWS 1230 and PTWS D630 vessel numbering

1.6.4 PTWS Heater Box

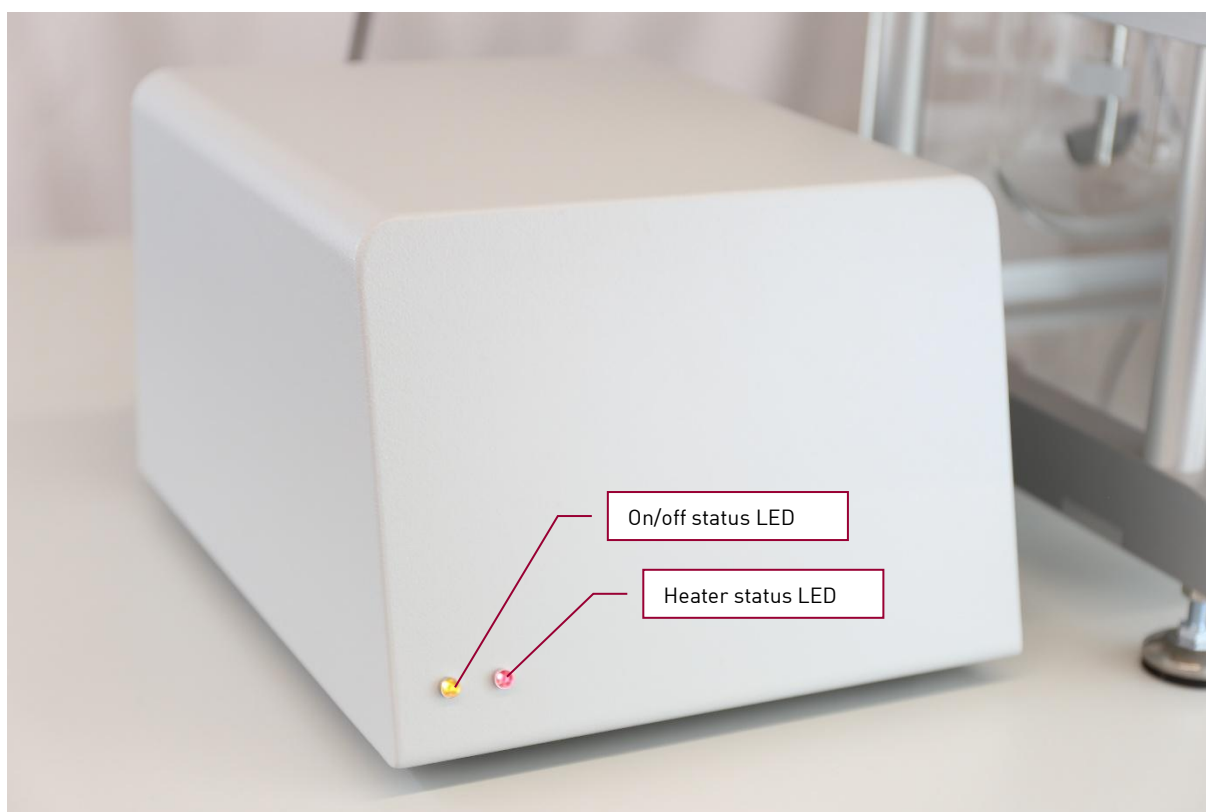


Figure 11: Heater box front

The left (yellow) LED lights up when the heater box is powered on. The right (red) LED shows the status of the heater:

LED Status	Explanation
Off	Heating is not active
Blinking	Heating is active, system is heating up
Constant on	Heating is active, target temperature is reached and is being maintained

Table 1: Heater box LED status

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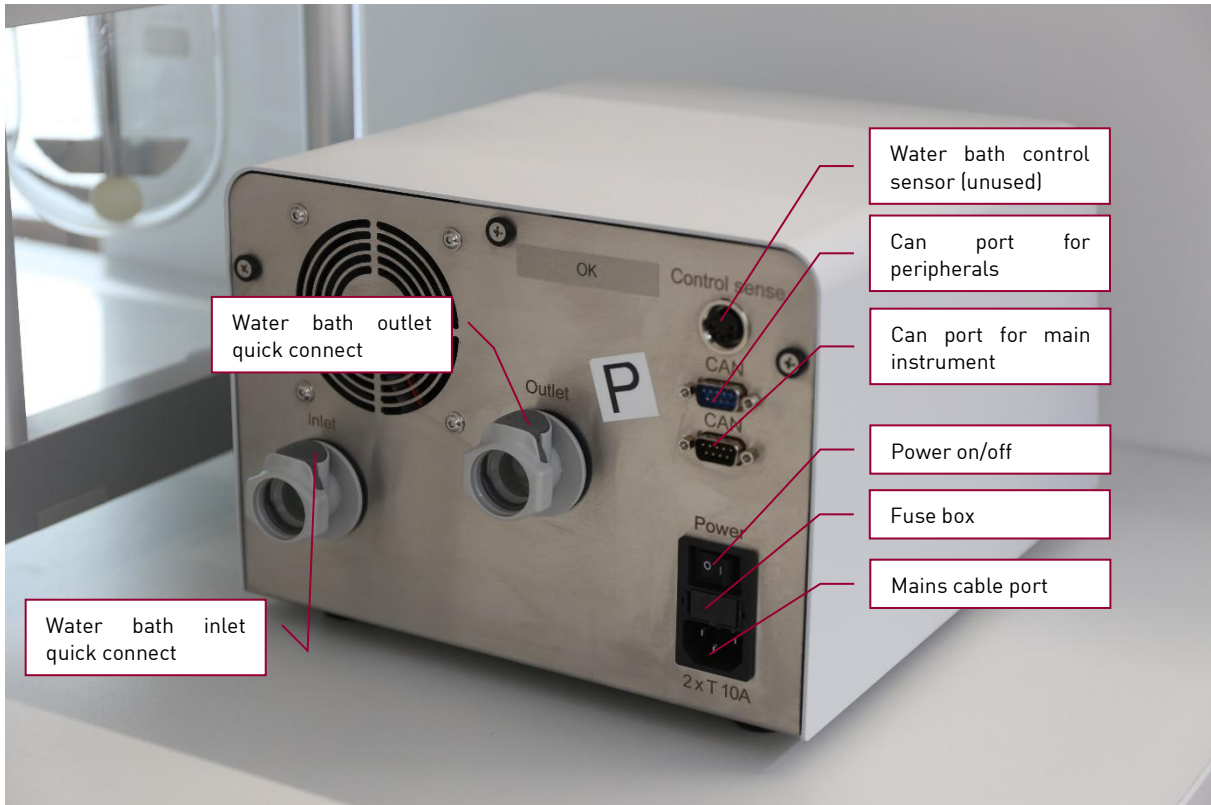


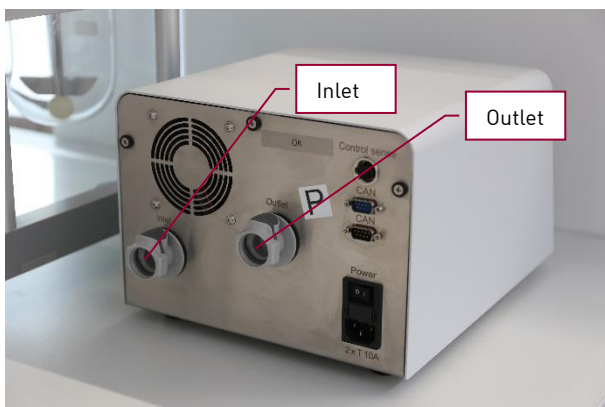
Figure 12: Heater box back side

2 Setting Up the System

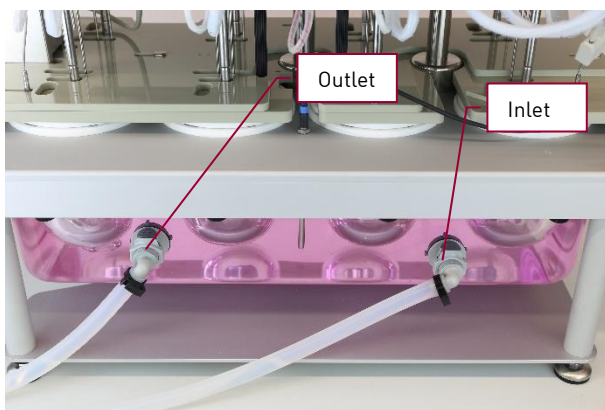
After the instrument is unpacked, check the completeness of the delivery using the supplied packing list, the delivery note and the IQ form.

Follow these steps before turning on the instrument for the first time. Make all cable connections while the main instrument and the heater box are switched off.

2.1 Connect the Heater Box Tubes to the Water Bath



Connect the inlet tube and the outlet tubes to the heater box.



Connect the inlet and the outlet tubes to the water bath.

2.2 Connect the Heater Box to the Main Instrument



Connect the CAN cable to the lower CAN port on the heater box.



Connect the other end of the CAN cable to the CAN port on the main instrument.

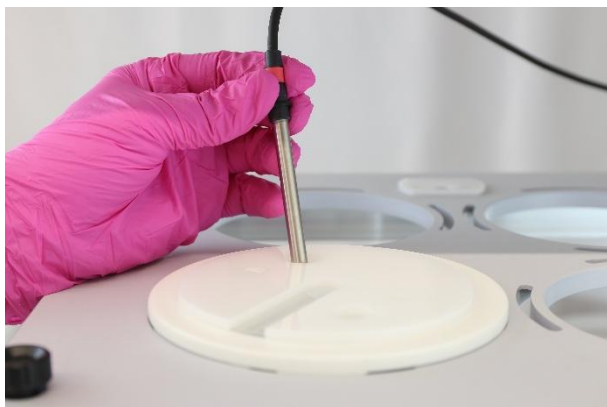
2.3 Connect the External Temperature Probe



Connect the external temperature probe to the port labeled "Temp. ext" on the main instrument.



Insert the external temperature probe into the water bath.



You can later use the external temperature probe to check the temperatures inside the vessels.

2.4 Connect the EPE (optional)

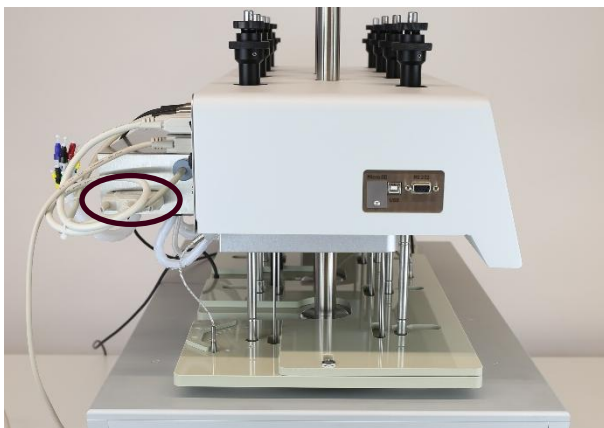


In case your instrument is equipped with an EPE automated sampling manifold, connect the cable which is fixed to the EPE box the port labeled "EPE" on the main instrument.

2.5 Connect the ITM (optional)



In case your instrument is equipped with an ITM individual temperature monitoring system, connect the 25 pin cable to the port labeled "ITM" on the main instrument.



Connect the other end of the cable to the port on the EPE box.

2.6 Connect the ATM (optional)



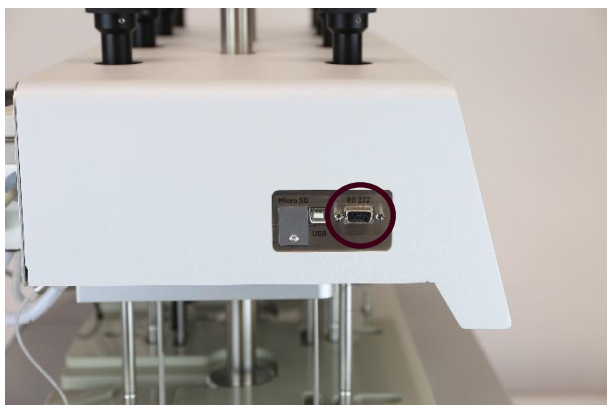
In case your instrument is equipped with an ATM automated tablet drop magazine connect the cable which is fixed to the ATM motor to the ATM port on the underside of the main instrument head.

2.7 Connect a Fraction Collector (optional)



In case your instrument should be used together with a PTFC or DSR-M fraction collector, connect the communication cable from the fraction collector to the port labeled "sign output" on the main instrument head.

2.8 Connect a Ticket Printer (optional)



In case you want to use a ticket printer with the instrument, connect the serial cable of the printer to the appropriate port on the printer and the other end of the cable to the port labeled "RS232" on the main instrument head.

2.9 Fill the Water Bath



Make sure the PTWS instrument is turned off and that the vessels are not inserted. Fill the bath through one of the vessel opening until the mark "max. water level" on the water bath is reached. When you later insert the vessels, the water level in the bath will rise and cover the vessels up to their maximum filling level.



To prevent the growth of algae we recommend using the water bath preservative ALGEX Magenta. The features a color indicator to show when the solution should be renewed. One bottle of ALGEX magenta is included with your new instrument.

2.10 Connect the Mains

Before connecting the mains, make sure the instrument is laid out for the available voltage. You can check this on the type plate on the instrument's back.



Connect the 24V table power supply to the main instrument head.

Connect the 24V table power supply mains cable to the power supply and to the power outlet.



Connect the mains cable to the power supply socket at the back side of the heater box and to the power outlet.

2.11 Turn on the Instrument

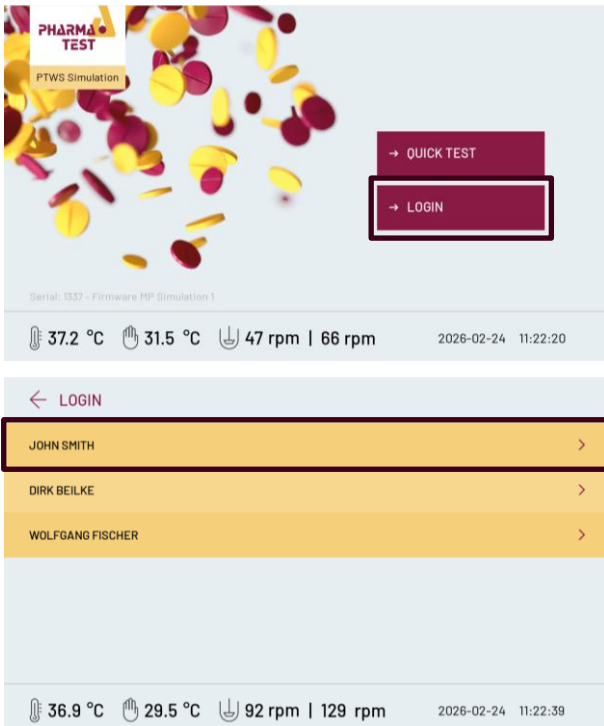


Switch on the main instrument.



Switch on the heater box.

2.12 Login for the First Time



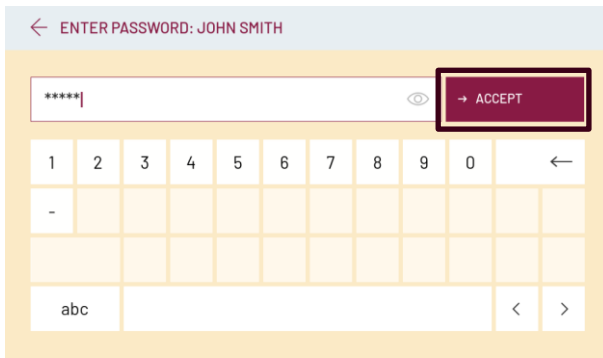
Wait until the instrument software is started and the login screen is displayed.

Press “-> LOGIN” on the touch screen.

From the list of users select “Administrator”.

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The default password for the user Administrator is:

“12admin34”

Enter this password and press “-> ACCEPT” to proceed.



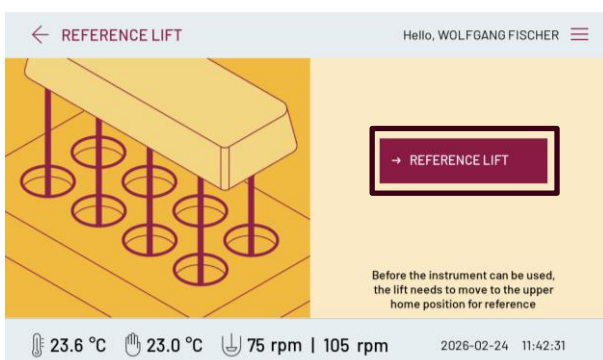
The main menu will be displayed. Press the “>” symbol or slide left to reach the control menu.



Press the cog wheel icon to enter the control menu.



Press the lift control icon to enter the lift control menu.



Before the lift can be driven freely, it must be referenced by moving to its upper home position.

Press “-> REFERENCE LIFT” and wait until the lift has reached its upper home position.

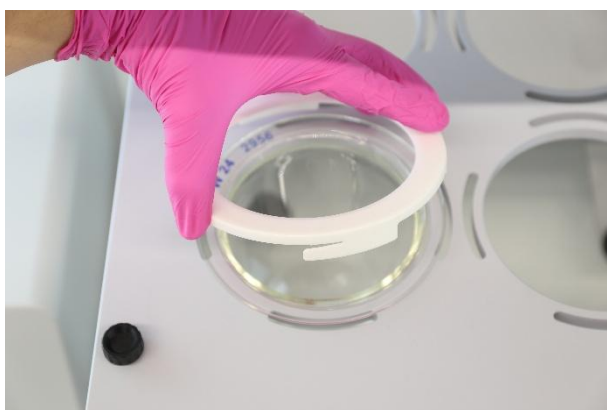
2.13 Insert the Vessels

To insert the vessels, the PTWS instrument head should be in its highest position.



Take the first vessel and insert it into the first opening of the water bath cover.

Note that the vessels are individually coded so that you track which vessel is inserted into which position of the water bath.



Take one of the supplied vessel holders, slide them over the flange of the vessel so that the bayonet catches slide into the openings on the water bath cover.



Carefully rotate the vessel holder in clockwise direction to hold the vessel in position.

Repeat these steps until all vessels are inserted.

Make sure that the vessels are completely immersed (up to the 900ml marking) in water to avoid any temperature differences inside the vessels.

2.14 Insert the Stirring Tools

The PTWS instrument is equipped with MonoShaft™ stirrers and tool adapters which are compliant to the current USP/EP Apparatus 1, 2, 5 and 6. The standard delivery scope includes USP/EP App.2 MonoShaft™ stirrers shafts and paddle adapters. Other tools are available as optional accessories.

The PTWS instrument allows for “staggered start”. This means that each stirring position can be started individually simply by pushing the stirrer clam screw downwards into its operating position.

To insert the stirring tools, the PTWS instrument head should be in its highest position.



Take a stirrer shaft and from below the slide it through the first hole in the instrument head.



Tighten the stirrer clam screws slightly, just to prevent the stirring shaft from dropping down. Insert the stirring shafts into the other positions in the same way and tighten the stirrer clams screws as well.

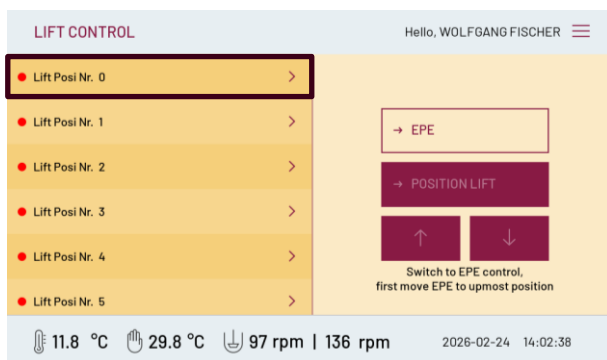


Screw the tool adapters to the stirring shafts at each testing position.



Next the correct tool immersion depth has to be adjusted for each position. The allowed tolerance is $\pm 2\text{mm}$. The standard supply scope of the PTWS instrument includes a set of 25mm diameter depth gauge balls.

Place these balls one by one into the spherical center of each dissolution vessel.



From the lift control menu, drive the head into the working position corresponding to the stirring tool you want to use.

For the supplied USP/EP App. 2 paddles, this is the first lift position from the lift on the left side. Select the item from the list of positions and press “-> POSITION LIFT” to move the head into this working position.



The depth gauge balls will automatically push up any stirrer in case it was inserted too deep in the first step. Now loosen the stirrer clamp screw of the first position. Push the complete stirring tool including its adapter gently downwards to make sure it touches the depth gauge ball.

Make sure that the depth gauge ball is still in the spherical center of the vessel.

Repeat these steps for all positions.



Now tighten the stirrer clamp screws to keep the tools in position during operation.

Using the supplied 1.5mm allen key, screw in the locking screw on the clam screw to secure the position.

3 Navigating the PTWS Menu Screens

The PTWS instrument features an interface comprising multiple screens, which users navigate via the touch screen. Each screen is clearly labeled with a title that informs the user of its specific function.

3.1 General Screen Elements of the PTWS Menus

The PTWS instrument is touch controlled by means of a capacitive touch screen. There are different types of screens with common elements. After turning on the instrument, the login screen is displayed:

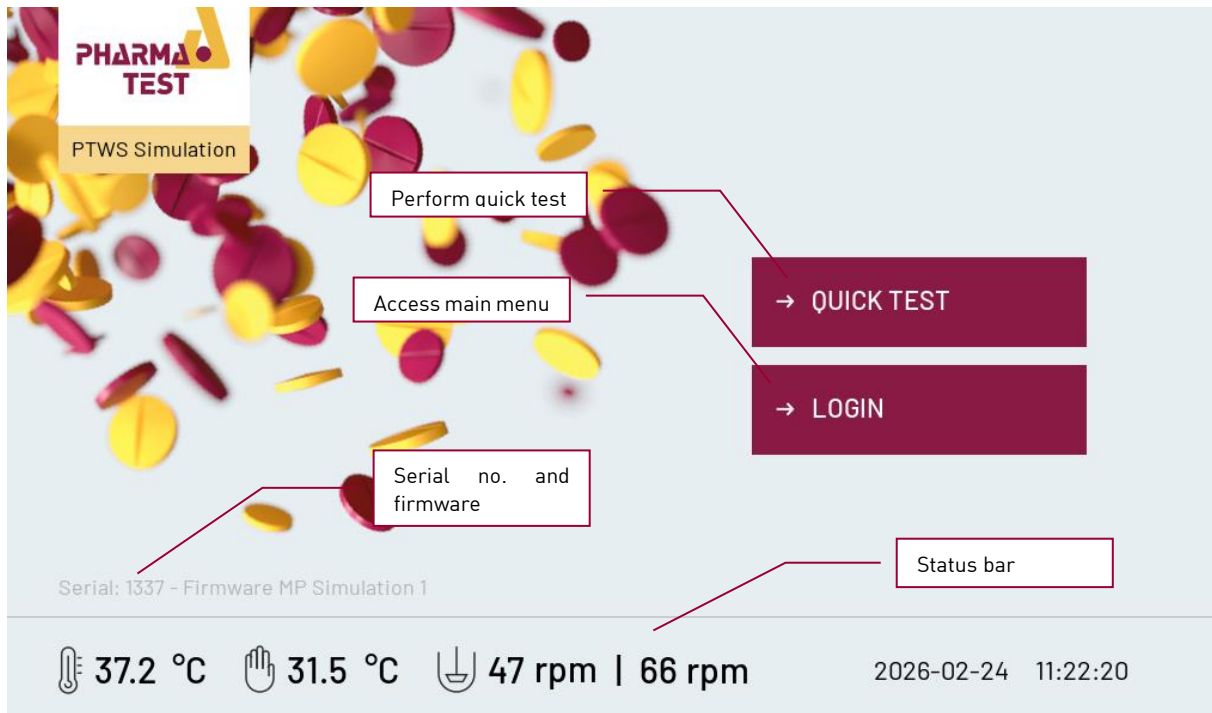


Figure 13: PTWS login screen

Here you can perform a quick test without logging in to the instrument or login to access the main menu. On the bottom of the screen the status bar is displayed. This status bar is displayed at all times and contains the following information:

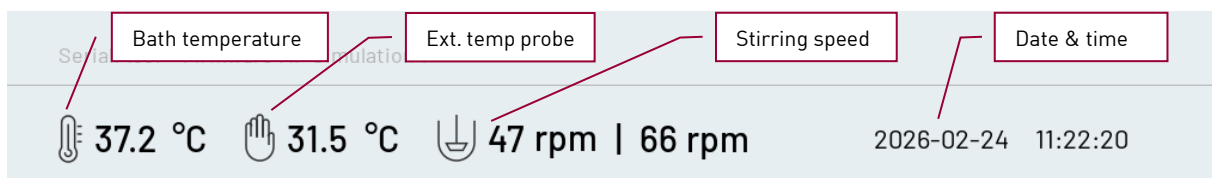


Figure 14: Status bar

The first icon represents the current temperature of the water bath. Next to it is a live temperature reading of the external temperature probe. Then the current stirring speed or speeds (depending on the actual model of PTWS instrument) is displayed. On the right side the current date and time are shown.

After logging in to the instrument the main menu is displayed:

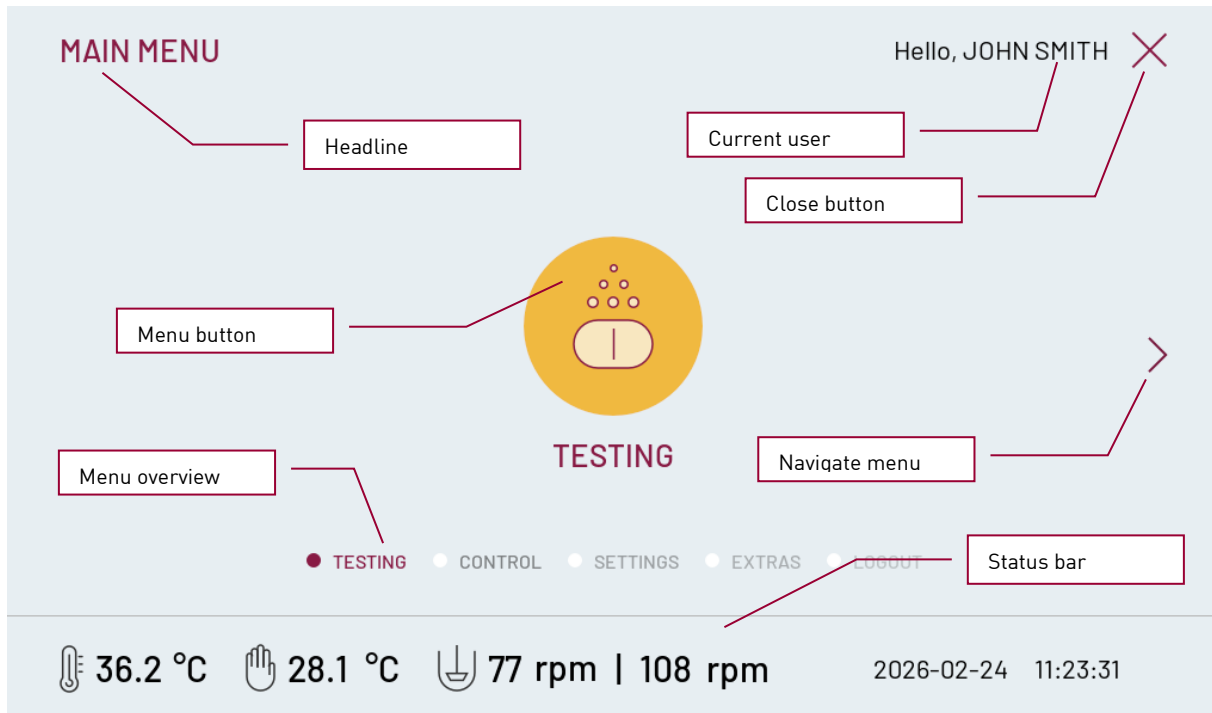


Figure 15: PTWS main menu screen

The main menu acts as an overlay over the actual screens of the PTWS instrument. Next to the headline the name of the currently logged in user is displayed. The "X" button next to the user name closes the main menu overlay.

You can navigate the main menu using the "<" and ">" button on the left and right side of the screen. Alternatively you can slide the whole screen horizontally. In the center of the screen the a menu button is displayed. Press this button to enter the corresponding menu. Below the menu button an overview of the menu items available in the current level of the menu is displayed. The currently selected menu item is highlighted in magenta color. Below this the status bar is displayed.

In various places lists are used in the PTWS menus:

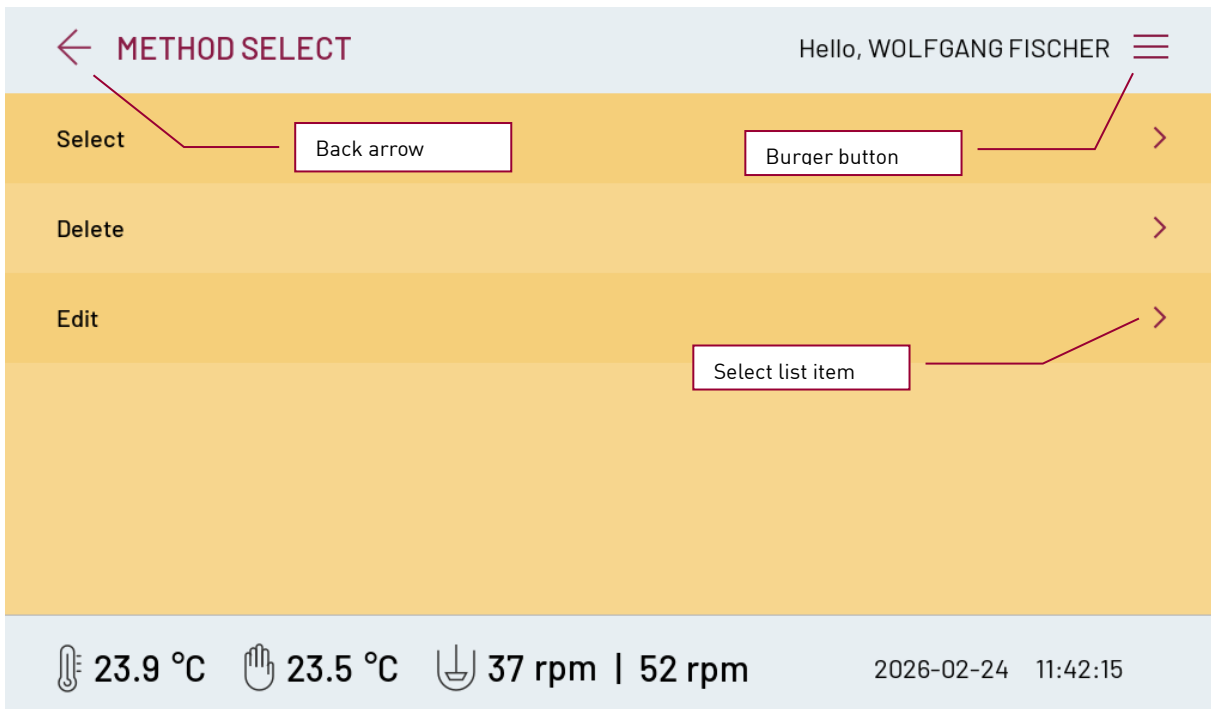


Figure 16: List screen

Use the back arrow to return to the previous screen.

Use the burger button to open the main menu.

To select an item from the list press the “>” icon.

3.2 PTWS Menu Tree

The PTWS menu is organized in two levels and contains the following menu items:

Level 1	Level 2
Testing	Methods <ul style="list-style-type: none"> ▪ Create and edit methods ▪ Run tests using a method
	Quick test Run quick tests without using a method.
Control	Lift control Directly control the operation of the lift and EPE (in case the instrument is equipped with an EPE automated sampling manifold): <ul style="list-style-type: none"> ▪ Move the lift up and down ▪ Drive the lift to programmed positions ▪ Move the EPE up and down ▪ Drive the EPE to programmed positions
	Bath control Directly control the operation of the heater and pump: <ul style="list-style-type: none"> ▪ Set a target temperature for the heater

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	<ul style="list-style-type: none"> ▪ Turn the circulation pump on or off ▪ Turn the heater on or off
	<p>Stirrer control</p> <p>Directly control the operation of the stirrers:</p> <ul style="list-style-type: none"> ▪ Set stirrer target speed(s) ▪ Turn the stirrers on or off
Settings	<p>Device settings</p> <p>Edit various settings and manage users:</p> <ul style="list-style-type: none"> ▪ Test settings ▪ Menu settings ▪ Edit user ▪ Qualification (OQ) intervals ▪ Edit lift positions ▪ Edit EPE positions
	<p>Qualification</p> <p>Perform the following operation qualification (OQ) tests:</p> <ul style="list-style-type: none"> ▪ Lift position ▪ Immersion depth ▪ Stirrer speed ▪ Pump flow ▪ Centricity ▪ Wobble
	<p>Audit trail</p> <p>View the audit trail.</p>
Extras	<p>Standby</p> <p>Program the standby function to maintain the water bath temperature when no test is currently running.</p>
	<p>Wake up</p> <p>Program wake up function to automatically pre-heat the water bath.</p>
	<p>Demo</p> <p>Activate the demo function, which deactivates the heater and pump.</p>
Logout	<p>Log out the current user and return to the login screen.</p>

Table 2: PTWS menu tree

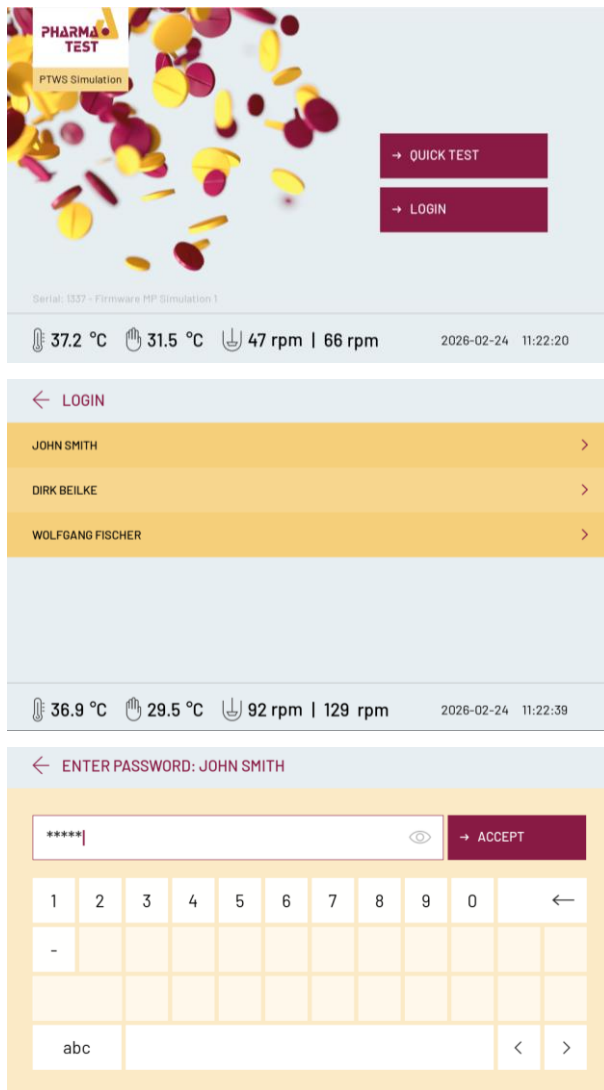
4 Logging in to the Instrument and User Management

By default a user names “**Administrator**” is available on a new instrument. The default password of the administrator user is:

“12admin34”

We strongly recommend changing this default password and note it in a secure place. The administrator has all user rights. We therefore recommend to not use the administrator for routine operation but to create additional users instead.

4.1 Login

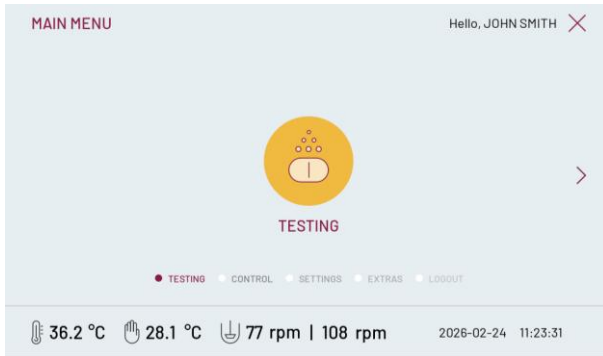


Wait until the instrument software is started and the login screen is displayed.

Press “-> LOGIN” on the touch screen.

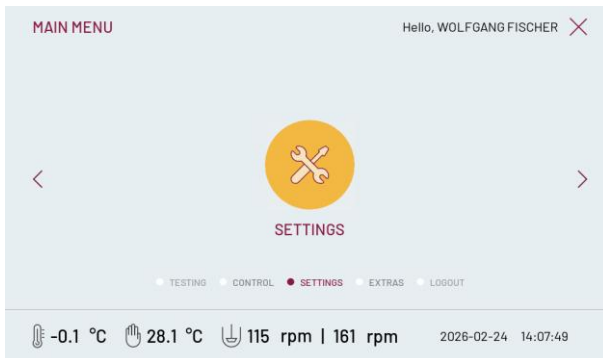
Select a user from the list.

Enter the password for this user and press “-> ACCEPT”.



Now the main menu is displayed.

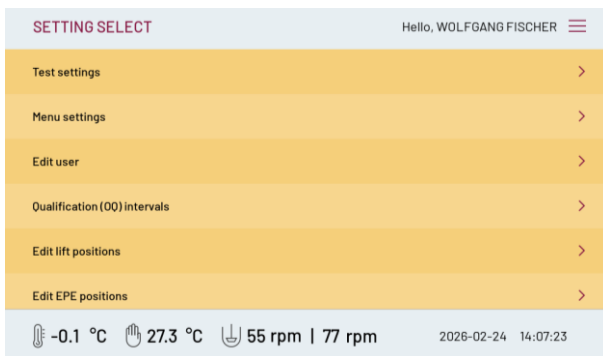
4.2 User Management



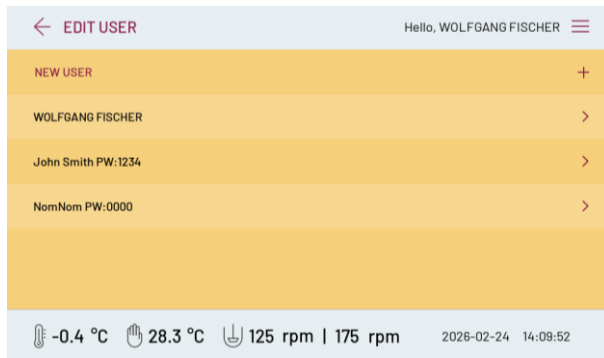
From the main menu enter the settings menu.



From there enter device settings.



From the device settings menu, select "Edit user".



From the list of user select the user you want to edit or select new user to create a new user.

There are four user rights which can be assigned to the users in any combination:

User right	Description
Right edit user	Create and edit users
Right edit methods	Create and edit methods
Right edit settings	Change settings
Right service	Access and perform service functions

Table 3: User rights

Any user can perform quick tests and test based on an already existing method.

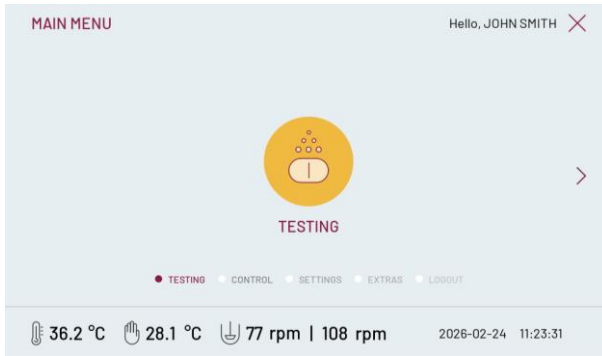
To create a user enter a user name, enter a password and confirm the password by entering it the same way again. Select any combination of user rights. Press “-> APPLY” to create the new user.

The number of user which can be created is not limited.

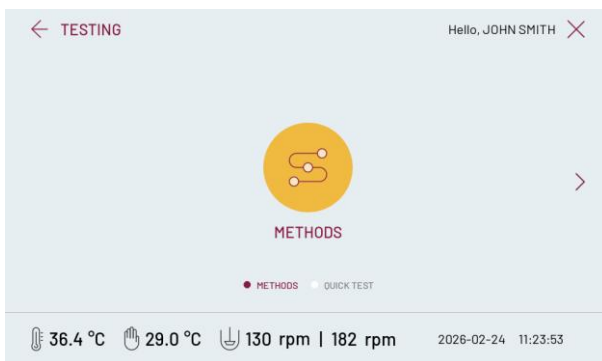
Editing an existing user is similar. Make the changes to user name, password or user rights and press “-> APPLY” to save the changes.

5 Methods

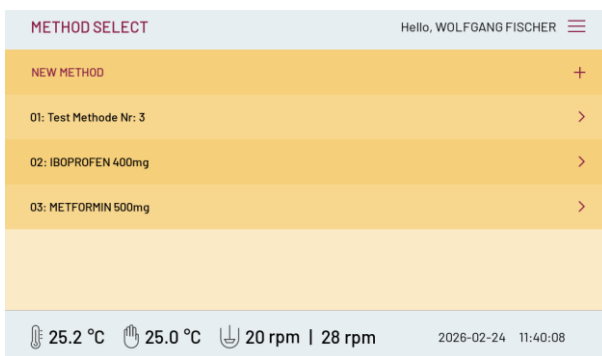
This section describes how to edit methods and explains the various method parameters.



From the main menu select testing.



Then select methods.



The list of methods is displayed. Select new method to create a new method. Select an existing method to:

Select: run a test using this method.

Delete: delete this method.

Edit: edit this method.

5.1 Method Parameters

A method contains the following parameters:

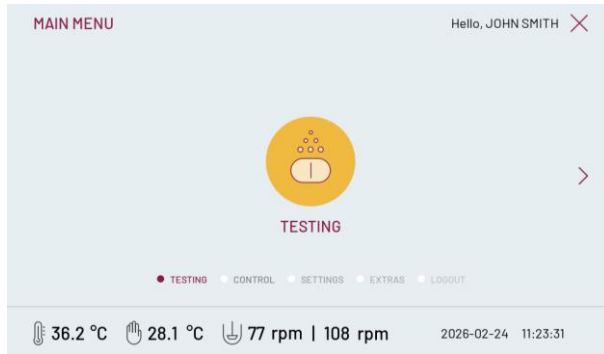
Parameter	Description
Method name	Name of the method, alpha-numeric
Product name	Name of the product, alpha-numeric
Medium	Name of the medium, alpha-numeric
Comment	A comment for this method, alpha-numeric
Target temperature	The target temperature for the water bath. The test can only be started once this target temperature has been reached.
Lift position	Select the working position to be used for this method from the list of 16 working positions.

EPE position	Select the EPE sampling position from the list of 16 EPE sampling positions. This setting is only available in case the instrument is equipped with an EPE.
Stirrer speed	The stirring speed for this method.
EPE dwell time	The amount of time the EPE should remain in the sampling position for this method. This setting is only available in case the instrument is equipped with an EPE.
Sampling intervals	Program a sequence of sampling intervals. See below for more details.
ITM before test	Check this box to perform a temperature reading inside the vessels before the test is started. This setting is only available in case the instrument is equipped with an ITM.
Infinity test active	Check this box to enable a the inifinty mode after the last sampling interval. The subsequent settings only appear in case this box is checked.
Infinity time endless manual stop required	If this box is checked the inifinity mode continues indefinitely until the test is stopped by the user.
Infinity duration	The amount of time the infinity test should run before the test is finished. This setting only appears if the box for endless infinity time is not checked.
Sample after infinity time elapsed	If this box is checked a last sampling interval will occur once the time for the infinity mode has elapsed. This setting only appears if the box for endless infinity time is not checked.
Infinity target temperature	The target temperature for the water bath for the infinity test.
Infinity stirrer speed	The stirring speed for the infinity mode.

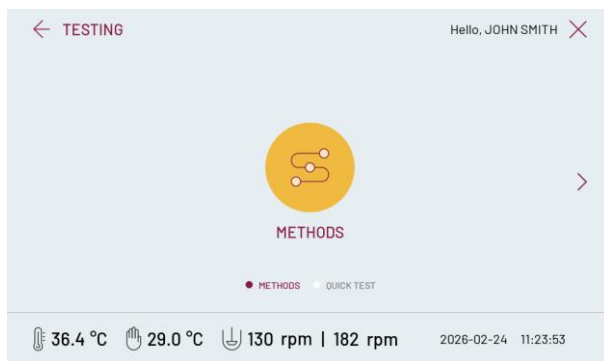
Table 4: Method parameters

6 Running a Test

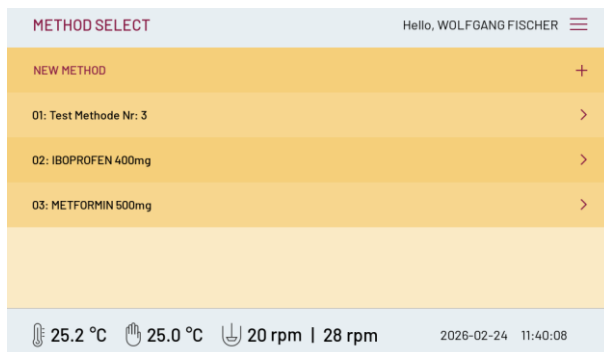
This section explains how to run a dissolution test.



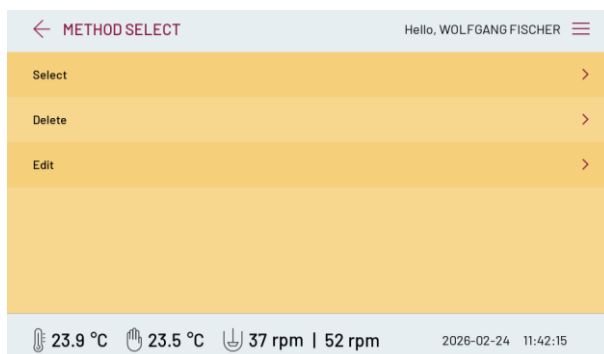
From the main menu select testing.



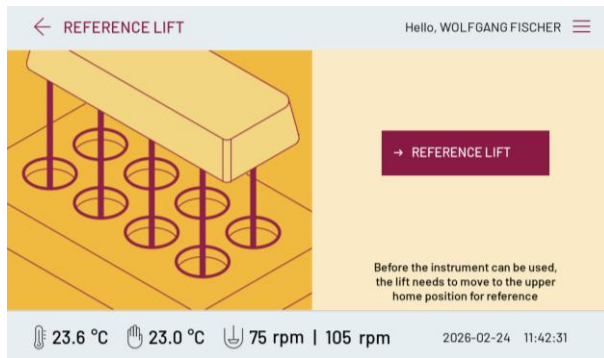
Then select methods.



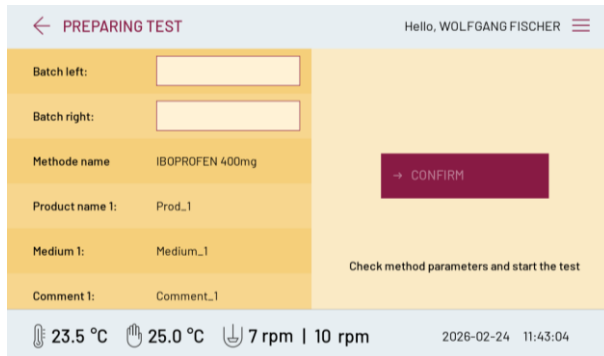
The list of methods is displayed. Select a method to use for this test from the list.



Press "Select" to start a test using this method.

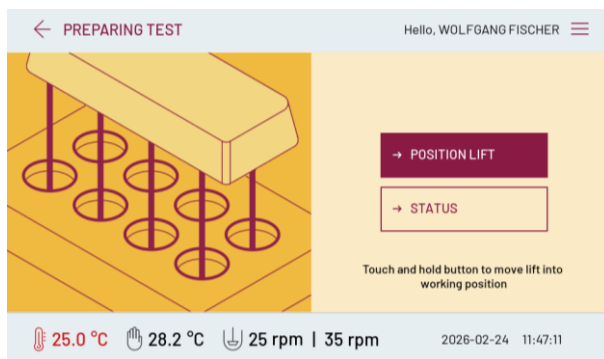


In case the lift has not already been referenced, you must do this now.

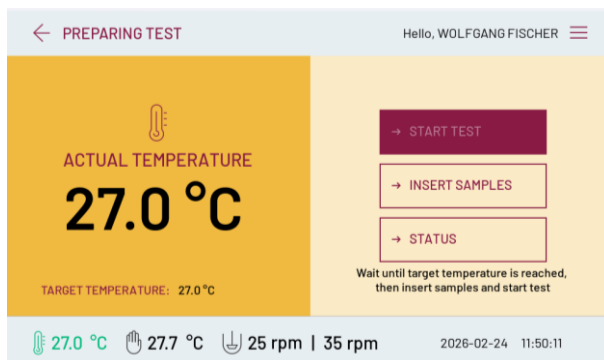


Then the preparing test screen is displayed. Here you can check the method parameters and enter a batch number.

Press “-> CONFIRM” to proceed.



Now the lift will be driven to the working position. Press and hold “-> POSITION LIFT” until the working position has been reached and the lift stops moving.



Now the pump and heater will be started. Wait until the target temperature has been reached in the water bath.

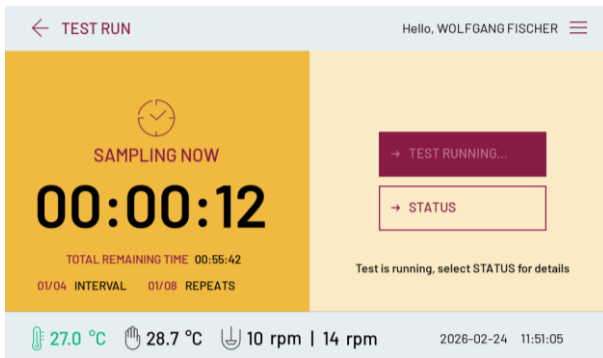
Once the target temperature has been reached the temperature displayed in the status bar turns green.

Insert the samples and press “-> INSERT SAMPLES” to confirm that the sample have been inserted.

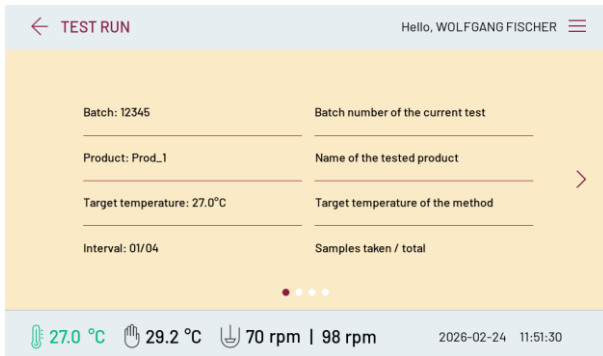
Then you can start the test by pressing “-> START TEST”.

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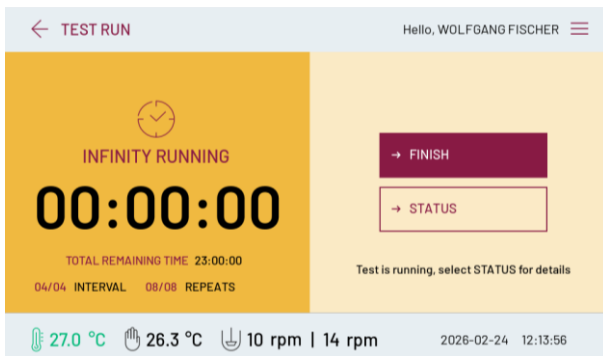
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The test is now running. The time until the next sampling interval occurs is displayed on the left side. Below this the total remaining time for the test is displayed and the number of intervals which are left.

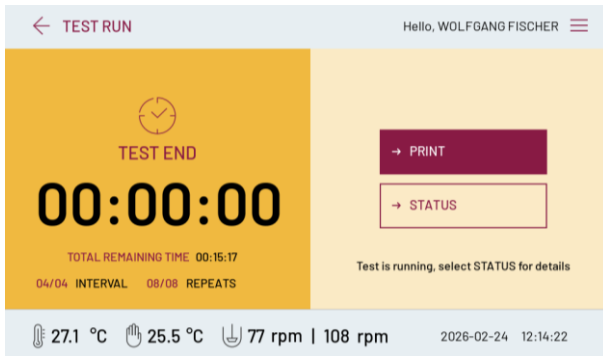


At any time during the test you can press “-> STATUS” to get more information about the current test.



In case the infinity mode is active, it will start once the regular test is completed.

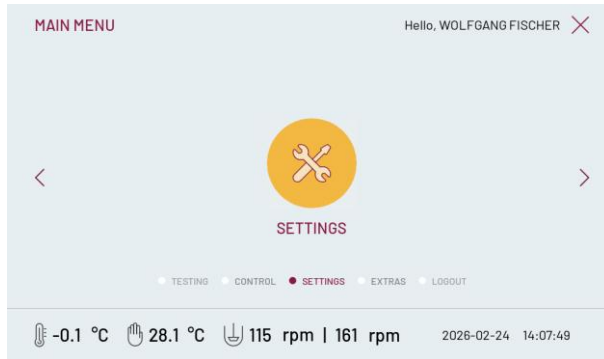
In case no infinity duration is specified in the method you must press “-> FINISH” to confirm that the test is now finished.



Once the test has ended you can press “-> PRINT” to print out the run time protocol.

7 Settings

This section describes the settings menu and explains the various items.



From the main menu enter the settings menu.



From there enter device settings.

7.1 Test Settings

Here you can set various settings related to testing:

Setting	Default	Description
Pre-time	0:30 min	In case the instrument is equipped with an EPE automated sampling manifold, the EPE will start to move into sampling position by this amount of time before the sampling starts. Usually this setting does not need to be changed by the user.
Pump pretime	0:15 min	In case the instrument is connected to a fraction collector and pump, the pump is started by this amount of time before the sampling starts.
Heater test end	Off	Select the behavior of the heater once a test is ended: On: heater and pump stay on and maintains the last target temperature ´. Off: heater and pump switch off. Standby: instrument enter standby mode.
Standby temperature	34.0°C	This temperature is maintained by the heater when the instrument enters standby mode.
Standby time	1 min	The amount of time the instrument will remain in standby mode and maintain the standby temperature. After this time has elapsed, the pump and heater will be switched off.
Lift end test	Stay	Select the behaviour of the lift once a test is ended: Stay: the lift will remain in the current working position. Move up: the lift will move to its upper home position.

Table 5: Test settings

7.2 Menu Settings

Here you can set various settings related to the user interface:

Setting	Default	Description
Time	NA	Set the current time.
Date	NA	Set the current date.
Language	English	Language of the user interface and print outs.
Display lock	0 min	Amount of inactivity time after which the instrument automatically logs out the current user.
Display brightness	50%	Brightness of the touch screen illumination.
Volume	70%	Volume of the beeper.

Table 6: Menu settings

7.3 Edit User

This settings is described above in the section 4.2 User Management.

7.4 Qualification (OQ) Intervals

Here you can set the operation qualification intervals for each of the operation qualification programs. You can set individual intervals or you can set all intervals at once. Performing one of the operation qualification programs resets the corresponding interval. Once a operation qualification interval has elapsed the instrument reminds the user that the operation qualification is due to be performed.

7.5 Edit Lift Positions

Here you can edit the names of the 16 available lift positions and change the actual positions that the lift will move to when this position is selected. The instrument is supplied with lift positions for many common dissolution tools. So in most cases, the lift positions do not need to be changed by the user.

7.6 Edit EPE Positions

This is only available in case the instrument is equipped with an EPE automated sampling manifold.

Here you can edit the names of the 16 available EPE positions and change the actual positions that the EPE will move to when this position is selected. The instrument is supplied with EPE positions for many common dissolution tools. So in most cases, the EPE positions do not need to be changed by the user.

8 Error Messages and Trouble Shooting

This section covers error messages and offer troubleshooting information for common issues.

8.1 Trouble Shooting

Fault	Possible Reasons and Solutions
The pump goes off shortly after being turned on.	<ul style="list-style-type: none"><li data-bbox="644 456 1091 488">▪ Check if there is air in the system.<li data-bbox="644 497 1391 564">▪ Remove the air by opening the fill/drain tap until all the air is gone from the system.

Table 4: Trouble Shooting

9 Cleaning and Maintenance



If you do not use the instrument for a longer time:

We recommend parking the stirring head in down position, so that the tablet magazine rests on the water bath to prevent the magazine from being bent by gravity.

All Plexiglas parts should be cleaned daily. Do not use a detergent containing alcohol, methanol or similar, this will destroy the Plexiglas. Use a soft towel and warm water only.

Clean the stainless steel parts using cleaning oil, which has been included with the shipment. This oil is in compliance with the German Pharmacopoeia monograph DAB 7.

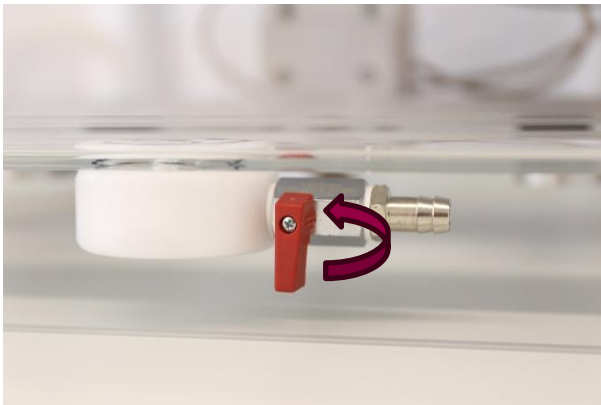
The instrument does not include any other parts which the user can maintain or repair. Repair work should be done by authorised service agents only.

In case the instrument cannot be operated without the damage to property or personnel, it has to be switched off and withdrawn from operation immediately. This is valid always when:



- The instrument mains cable or socket shows visible damages
- The instrument shows visible damages or does not work
- Any cable shows visible damages

9.1 Draining the Water Bath and Removing the Water Bath for Cleaning



Connect the tap on the bottom of the water bath to a drain. Open the tap and wait until all water is drained.

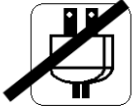


Once the water bath is empty loosen the six knurled-head screws on the underside of the water bath frame. Then you can slide out the bath to the right side of the PTWS for cleaning.

10 Safety Information



Before you open the Instrument always remove the mains cord from the mains socket. Only authorized personnel should open the instrument.



Do not use the instrument in case:

- The mains cord shows any damage
- The instrument shows visible damages
- Any supply cable is damaged