

# PHARMA TEST

## Operating Manual

PTWS 120D, PTWS 120S,  
PTWS 820D and PTWS 1420

Version 1.7



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Certificate No FS 529019/0388D

## 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	26.01.2015	PTAG	N	-
1.1	06.02.2015	PTAG	R	Updated for current firmware
1.2	17.11.2015	PTAG	R	Updated for current firmware
1.3	30.11.2015	PTAG	R	Updated for current firmware
1.4	21.01.2016	PTAG	R	Several new firmware features added.
1.5	05.04.2017	PTAG	R	Technical Data: power assumption corrected
1.6	18.09.2019	PTAG	R	Several new firmware features added.
1.7	19.05.2020	PTAG	R	PTWS 1420 added

Table 1: Document History

### Index Information - Change:

N = New Document

C = Correction

R = Revision



## 1 General Information

Thank you for choosing a Pharma Test PTWS 120D/120S/820D/1420. This document covers the PTWS 120D, PTWS 120S, PTWS 820D and PTWS 1420 models. The PTWS 120D is a compact 6 position dissolution bath with one stirrer drive for all 6 positions. The PTWS 120S contains the same functionality as the PTWS 120D, but with a single stirrer drive for every position to run different stirrer speeds for every stirrer. The PTWS 820D is based on the design and offers all features of PTWS 120D and adds a seventh and eighth stirred position and several options of automation (EPE, TM/ATM, ITM). The PTWS 1420 is also based on the design of the PTWS 120D and adds a 13<sup>th</sup> and 14<sup>th</sup> stirred position as well as a 15<sup>th</sup> and 16<sup>th</sup> non-stirred position for additional 1l vessels and several options for automation (EPE, ATM, ITM).

The PTWS 120D/120S/820D/1420 is an 6/8/14 position, compact tablet dissolution testing instrument for solid dosage forms as described in USP chapter <711/724> and EP section <2.9.3/4> as well as the DAB and Japanese Pharmacopeia section <15>. It is supplied with a staggered start feature for each of the six (eight) positions. The upper drive is electronically controlled to offer two positions: an upper cleaning and a lower working position. The electronically driven lift mechanism is located centrally above the water bath. This assures that the whole lift drive mechanism is positioned in a way so that the tool shafts are always kept parallel and at a 90° angle to the vessel walls when in the working position.

The PTWS 120D/120S/820D features the 3CS three-point individual centering system for each dissolution vessel. The vessels are held in position by three adjustable noses and are inserted into the instrument support framework. The PTWS 1420 features an automated centering system through clip in vessel holder. The access points for sampling as well as the openings for the tools are contained in an auxiliary, low evaporation, vessel cover.

The blow moulded water bath can easily be removed from the support frame for cleaning purposes. The bath cover can also be easily unscrewed for cleaning. The water bath contains a water diffuser for faster heating and to ensure that heated water is evenly distributed throughout the whole bath.

The heating system is contained in a separate stainless steel housing. The connections between the heater and the bath are made by „quick connect“ fittings for easy connection and disconnection. Water is pumped through the system using a powerful, yet quiet, circulation pump. The pump itself is spring mounted (to limit vibration transmission) and the flow-through heater is protected from overloading (overheating in case of control electronics failure) via a thermal fuse as well as a thermo switch for added security. With service and maintenance in mind, access to the compact pump and heater section is easily achieved without having to move the main body of the instrument.

The PTWS 120D/120S/820D/1420 uses the Pharma Test MonoShaft™ design. Tools consist of the main shaft plus interchangeable tool heads (adapters). The main shaft remains in place in the instrument regardless of the tool head being used. The clearance of each tool from the vessel base will always be correct once the main tool shaft has been installed and qualified with any one of the tool sets once. Each stirrer can be raised by hand into a convenient position for easy vessel removal or insertion.

A key point in today's crowded labs is the footprint of the PTWS 120D/120S/820D. The space saving design of the PTWS 120D/120S/820D offers the user the choice between a 2x3/2x4 or a 3x2/4x2 configuration with a minimal space requirement of just 46cm by 75cm (width by depth) for PTWS 820D and 46cm by 59cm (width by depth) for PTWS 120D/120S. The PTWS 1420 can be positioned in one position, but it has a small footprint (95cm by 70cm), too for offering 14 stirrer and in total 16 vessel positions.

In keeping with our cutting edge design, a touch screen allows control of the various mechanical features of the instrument such as the tool stirring speed, lift drive and heater. The instrument control is menu driven. Visual signals on the display inform the user of the status of critical instrument parameters, e.g. bath target temperature not reached. Access to the instrument can be password controlled if required. If certain operational parameters form a regular feature of the daily routine, then these can be incorporated into a test method for faster set up. These parameters can be tool speed, target bath temperature, sampling time points and so on. The test method memory capacity is almost limitless.

As soon as the test is started, a screen saver can be activated with the most important information displayed in large script so that this information remains visible even at time when the operator is not standing directly in front of the instrument. For offline automation with fraction collection the PTFC-2/8/PTFC-16 fraction collector as well as either the PT-SP8 syringe pump, a peristaltic or a piston pump can be added to the PTWS 120D/120S/820D/1420. Using the PTWS 120D/120S/820D/1420 within an automated system offers the operator full access to the vessels before and at the end of a run as the complete drive head is lifted electronically.

Sampling sequence timing, sampling volume and the optional media refilling process are programmed using the menu system of the PTWS 120D/120S/820D/1420 instrument. No external software is necessary in this system. In-situ sampling ferrules are placed into the PTWS 820D/PTWS 1420 vessels through cover holes. Each ferrule holds a 5 or 10 $\mu$  PP sinter filter. When the tablets have been dropped into the dissolution vessels the automated sampling process starts. If the refilling option is used media refilling will start automatically after a sample has been withdrawn.

It is also possible to use the DSR-M dissolution sampling robot which features the capability of sample dilution and offers excellent sampling accuracy via the fully integration piston pump module. Like the PTFC-2/8/PTFC 16, the DSR-M can be fully controlled by the PTWS 120D/120S/820D/1420.

For an online automated system it is possible to use a UV/VIS spectrophotometer with a multiple-cell-changer. The spectrophotometer and pump of such a system is controlled by the powerful WinDiss ARGUS dissolution software. WinDiss ARGUS features drivers for most commonly available UV/VIS spectrometer types, like Agilent 8453 Diode Array, or conventional UV/VIS monochromatic spectrophotometers (preferably double beam and scanning versions) such as the T70, Cecil CE and Perkin Elmer Lambda series as well as drivers for many popular types of pumps. The PTWS 120D/120S/820D/1420 can be used in stand-alone mode in these systems.

## 1.1 Technical Specifications

Display:	Backlit, colour LC display for no. of samples, thickness, diameter, hardness results and other information
Keyboard:	Touch screen
Stirring Speed:	20 - 250 rpm
Accuracy:	better than 2%, typically 1% of the set speed
Thermostat :	25.0° - 45.0°C
Accuracy:	better than 0.3°C, typically 0.2°C
Stirring positions:	6 at PTWS 120D/S, 8 at PTWS 820D, 14 at PTWS 1420
Water bath capacity	PTWS 120D/S: approx. 17,5l PTWS 820D: approx. 20,0l PTWS 1420: approx. 40,0l
Power Assumption:	appr. 1550W / 6,7A at 230VA appr. 950W / 8,2A at 115VAC
Space Requirements (WxDxH)	PTWS 120D/S: 59cm x 46cm x 85cm + Pump module PTWS 820D: 75cm x 46cm x 85cm + Pump module PTWS 820D: 90cm x 70cm x 90cm + Pump module
Empty weight:	PTWS120D/S: approx. 65kg PTWS 820D: approx. 74kg PTWS 1420: approx. 120kg
Calibration Procedure Thermostat:	Needs external certified digital Thermometer, menu guided calibration procedure
Calibration Procedure Stirring System:	Needs external certified digital Tachometer, menu guided calibration procedure
Performance Qualification:	Using USP RST Tablets
Standard Interfaces:	RS-232 serial port to connect a PT-RP80 protocol printer, USB port for PC connection, 5 pin diode plug to connect sampling devices, SD-card slot for firmware updates and method storage.
Optional Equipment:	PT-RP80 report printer to log speed, temperature and sampling times (if programmed) EPE-820/1420 Auto-Sampling System TM-820/1420 Manual Tablet Drop Magazine TMA-820/1420 Automated Tablet Drop Magazine ITM-820/1420 Individual Temperature Monitoring System
Automation:	Online connection of a PTFE or DSR-M fraction collector and pump Online connection of a UV/VIS Spectro-Photometer with multiple cell changer

Table 2: Technical Data

## 1.2 Standard Supply Scope

### 1.2.1 Main Unit

Part-No.	No.	Description
316-3195-8	1	Set of USP/EP compliant 1 ltr. Paddle Stirrers, mono shaft design
303-5225	6/8 or 14	USP 1 ltr. Borosilicate glass vessels and Covers
34-08500	1	EC mains cord
		Alternatively one of the following mains cords:
34-08511	1	US mains cord
34-08510	1	CH mains cord
34-08512	1	GB mains cord
34-08513	1	AR/AUS/NZ mains cord

Table 3: Supply Scope Main Unit

### 1.3 About the PTWS 120D/ 120S/ 820D/ 1420

Dissolution testing is one of the most important investigations carried out during the production of fixed forms of administration. Tests must take place under constant conditions that can be reproduced.

Tablets must be continuously dissolved in order to check the concentration in the solution. The environmental conditions during the tests also have to be very similar to those of the human organism. The most important general conditions are the temperature of the body part concerned, the pH value of the digestive tract, for example and the gradual release of the preparation in the soluble environment.

Tests shall be carried out in accordance with the regulations of the pharmaceutical body concerned. This requires a correspondingly designed Instrument that is capable of handling the volume of test cycles required. Naturally, the test results must be recorded in line with regulations and the Instrument itself must be kept in a verifiably sound condition at all times.

Several international Pharmacopoeias, like USP/EP/DAB/BP describe a tablet dissolution testing instrument. Usually six samples are placed into spherical bottom glass vessels which contain the dissolution media heated to 37.0°C. A stirring device which can be equipped with various stirrer tools rotates inside the vessels. The speed of the stirring system is steplessly adjustable within a range of 20 – 250 rpm. Samples of the media have to be removed in specified time sequences, this can be done either manually or automatically using attachable equipment such as fraction collectors or spectrophotometer systems having single or multiple cell changers.

### 1.4 Operating Principle

The PTWS dissolution test instrument series from Pharma Test Apparatebau AG is designed in such a way that it meets the requirements of the actual Pharmacopoeias as well as of the pharmaceutical industry. Suitable accessories with the necessary equipment can be found for all requirements.

Common criteria for all versions are that they work at a higher level of accuracy than is necessary according to current regulations. They must also meet all Pharmacopoeia regulations valid worldwide and may be expanded to a fully automatic system via interfaces with simple stand-alone equipment.

All components of the testing instrument are designed on the basis of the established DQ data and tolerance limits prescribed therein. The parts used, the assembly and dismantling of the instruments are correspondingly documented. This means that test results can be reproduced globally. Test conditions are monitored in such a way as to ensure that they can be relied upon to remain within the required tolerance limits and allow operation without constant supervision.

This is possible because the PTWS 120D/120S/820D/1420 is very easy to operate and can be operated practically maintenance free. The PTWS 120D/120S/820D/1420 offers high performance flexibility because of the comprehensive range of accessories to meet every operational requirement and the desired degree of automation.

The PTWS 120D/120S/820D/1420 is equipped as standard with a micro processor controlled electronics which adjusts and controls the selected temperature and the stirring speed. This is guaranteed by the high accuracy of the control system built-in. The external bath heating and pump system with a 1400W heating coil and high water throughput offers excellent temperature equilibrium inside the bath and a fast heating up to the pre-selected bath temperature. All vibrating parts inside the heating module are spring loaded to eliminate any vibration from passing over to the water bath.

Depending which kind of drug has to be tested the PTWS 120D/120S/820D/1420 can be equipped to work according to USP Method No. 1, 2, 5 and 6. The design of the instrument is in full compliance to the USP/EP and FDA requirements. To its RS-232 port a PT-RP80 report printer can be attached which logs the stirrer speed and bath temperature.

## 1.5 Available Accessories and Upgrades

Although, the standard supply scope of the PTWS is a complete package, there is 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 (Chapter 1.5.1), Magazine (Chapter 1.5.2), ITM (Chapter 1.5.3) and Tubing Cleaning device (Chapter 1.5.4) are only available for the PTWS 820D/1420 instrument, not for the PTWS 120 D/S instruments.

### 1.5.1 EPE-820or EPE-1420 Automated Sampling Manifold (PTWS 820D and PTWS 1420 only)



The EPE-820 and EPE-1420 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 820D/1420 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 8 different sampling positions can be programmed at the PTWS 820D/1420 instrument.

Part-No.	No.	Description
318-1900 or 318-2070	1	EPE-820 or EPE-1420 electronically movable auto-sampling system, includes 8 or 14 stainless steel combined sampling-, closed loop-, and media refilling tubes, stepper motor and gear drive, connecting socket to connect the EPE unit with the dissolution instrument (without tubing installation).

### 1.5.2 TM-820 Tablet Magazine and TMA-820 or TMA-1420 Automated Tablet Magazine (PTWS 820D and PTWS 1420 only)



The tablet 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 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 drive head of the PTWS 820D or PTWS 1420 instrument and therefore is automatically raised when the head is driven up. This way all vessels are easily accessible for cleaning. The magazine mounted in a flexible way to eliminate any risk of blockage while driving down the instrument head.

Part-No.	No.	Description
318-2020	1	TM-820 manual tablet drop magazine to simultaneously drop all samples into the vessel (TM or TMA required for EPE).
318-2021or 318-2065	1	TMA-820 or TMA-1420 automated tablet drop magazine to simultaneously drop all samples into the vessel (TM or TMA required for EPE-820).

### 1.5.3 ITM-820 and ITM-1420 Individual Temperature Monitoring Device (PTWS 820D and PTWS 1420 only)



The ITM-820 or ITM-1420 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-820 and EPE-1420. The temperature is automatically measured and logged during each sampling interval. The last temperature measured is displayed on the screen of the PTWS 820D or PTWS 1420 and can be recalled at any time.

Part-No.	No.	Description
318-2000 or 318-2060	1	ITM-820 or ITM-1420 individual media temperature monitoring system for all 8 vessels inside the PTWS 820D or all 14 vessels in the PTWS 1420 dissolution bath (ITM-820 requires installation of EPE-820 and either TM manual or TMA automated tablet drop magazine. ITM-1420 requires installation of EPE-1420 and TMA automated tablet drop magazine).

### 1.5.4 Tubing Cleaning Device (PTWS 820D and PTWS 1420 only)



Cleaning system for sampling tubes of a PTWS 820D or PTWS 1420 with a TM-820/TMA-820 or TMA-1420 tablet drop magazine, including 8 or 14 plastic tubes and magnetic holders.

Part-No.	No.	Description
318-2100	1	PTWS 820D Cleaning System for Sampling Tubes
318-0740	1	PTWS 1420 Cleaning System for Sampling Tubes

### 1.5.5 PT-RP80 Report Printer



Report printer to monitor and print programmable sequences of the actual stirrer speed, bath temperature, pH value, incl. time, date and instrument serial number.

The printer must be activated in the instruments firmware! Activation/Deactivation must be done by the Pharma Test Service!

Part-No.	No.	Description
30-50000	1	PT-RP80 dot matrix printer for report printing incl. external power supply and RS-232 cable, 58mm paper width

### 1.5.1 PTFC Fraction Collector



The PTFC fraction collector can be attached to the PTWS using either PT-SP syringe pumps, peristaltic-, or a valve-less piston pump. The dissolution media is directly sampled into covered glass vials inside the sampling dish of the PTFC.

Sampling information such as interval timing and total number of sampling sequences is programmed on the touch display of the connected PTWS or directly at the PTFC panel.

Individual pinch valves separately connected to each vessel are used to switch the liquid flow. Previous to a sampling sequence the media is circulated within a closed loop between the dissolution vessels and the PTFC. As soon as the concentration of the media is equilibrated the pinch valves open for sampling. At the end of a sampling sequence all tubes are automatically emptied. Adding an extra set of valves and a pump with more channels the PTFC can also re-fill the sampled media (not required in case of using the PT-SP syringe pump).

Part-No.	No.	Model	Description
38-03820	1	PTWS 120D/S, PTWS 820D	PTFC-2/8 Fraction Collector
38-03825	1	PTWS 120D/S, PTWS 820D	PTFC-2/8SP Fraction Collector for PT-SP Pumps
38-38155	1	PTWS 1420	PTFC-16 Fraction Collector
38-38159	1	PTWS 1420	PTFC-16SP Fraction Collector for PT-SP Pumps

A typical semi-automated dissolution testing system including a PTFC-2/8 consist of:

PTWS 820D dissolution bath, EPE-820 auto-sampling system, TM-820 or TMA-820 tablet drop magazine, PTFE tubing, PT-SP8 8-channel syringe pump, PTFC-2/8SP fraction collector. Automated media refilling is possible using a second PT-SP pump module.

A typical semi-automated dissolution testing system including a PTFC-16 consists of:

PTWS 1420 dissolution bath, EPE-1420 auto-sampling system, ITM-1420 individual temperature monitoring system, TMA-1420 tablet drop magazine, PTFE tubing, two PT-SP8 8-channel syringe pump, PTFC-16SP fraction collector. Automated media refilling is possible using a second set of PT-SP8 and PT-SP6 pump modules.



## 1.6 System Overview

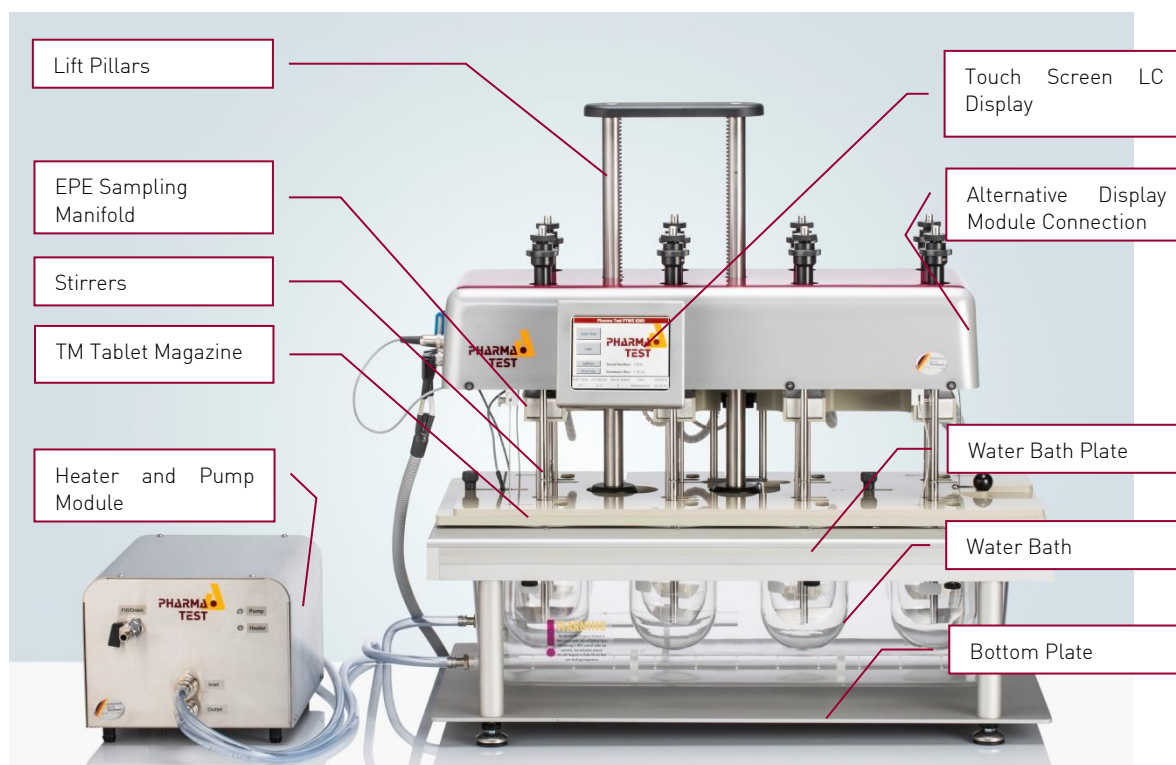


Figure 1: Instrument Front View PTWS 820D (PTWS 120D/S similar with 2 position less)

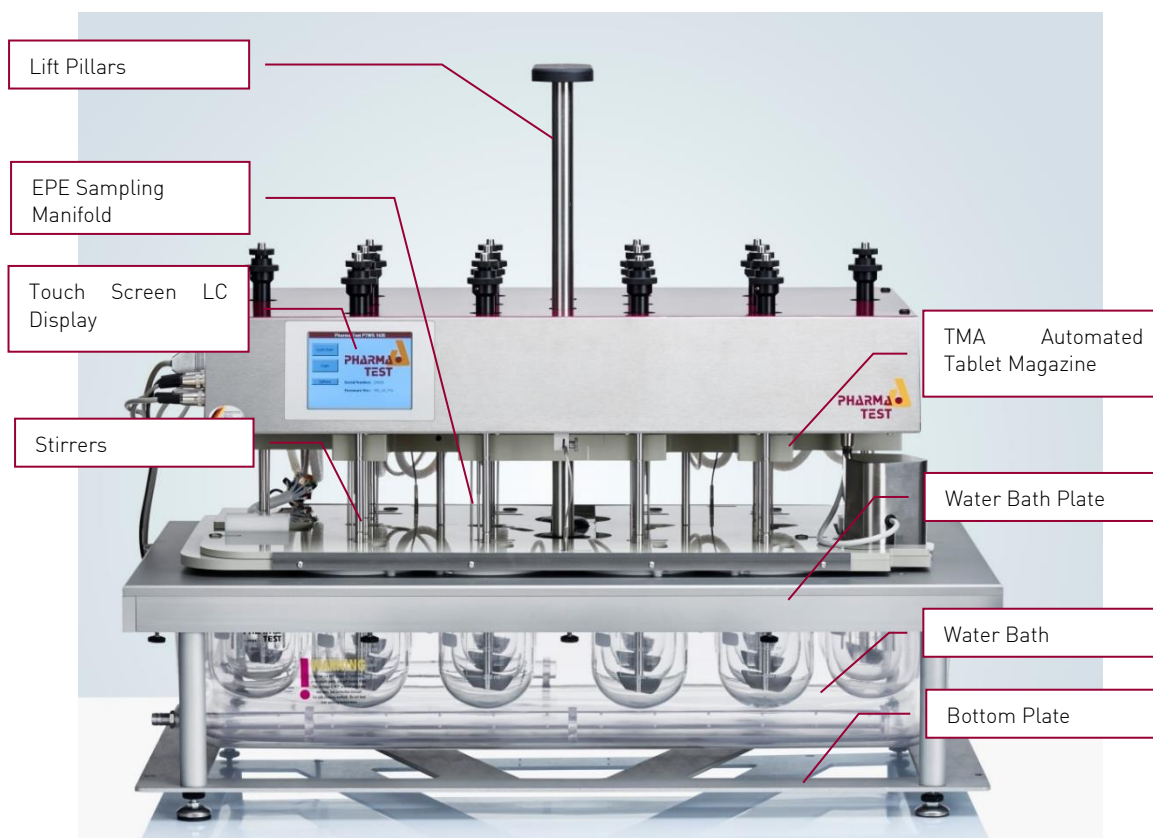


Figure 2: Instrument Front View PTWS 1420 (heater and pump module not in the picture)

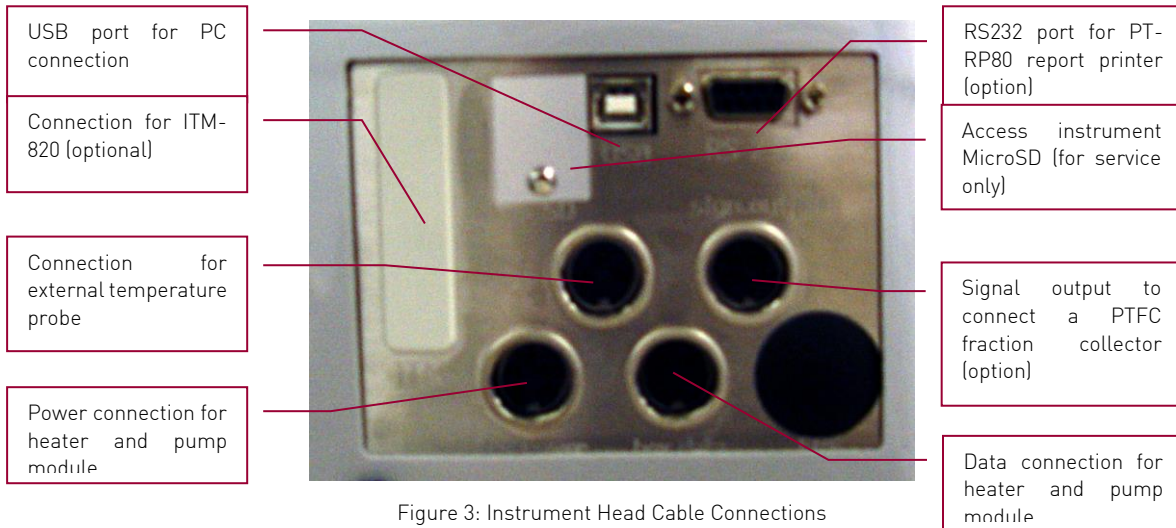


Figure 3: Instrument Head Cable Connections



Figure 4: Water Bath Connections

There are six stirred dissolution vessels in PTWS 120D/ 120S:

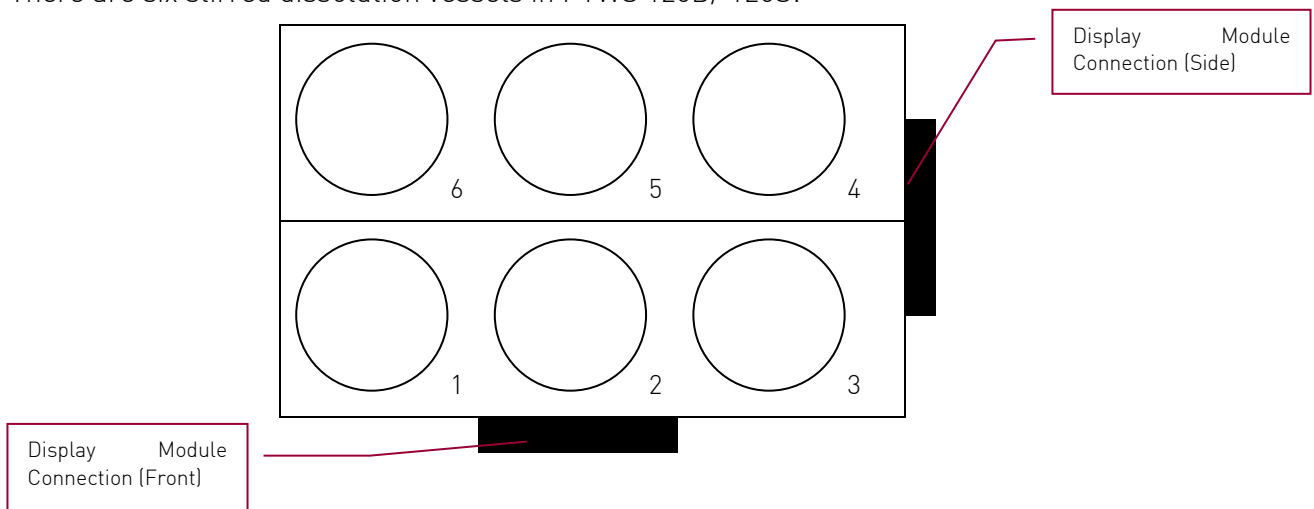


Figure 5: Vessel Numbering of the PTWS 120D/120S

There are eight stirred dissolution vessels in PTWS 820D:

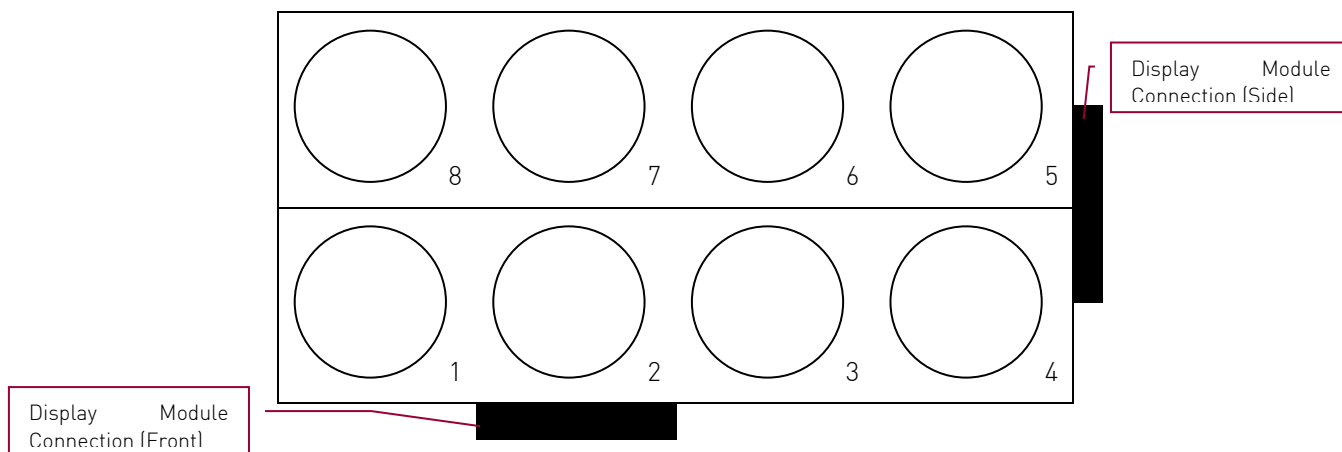


Figure 6: Vessel Numbering of the PTWS 820D

There are 14 stirred dissolution vessels in PTWS 1420:

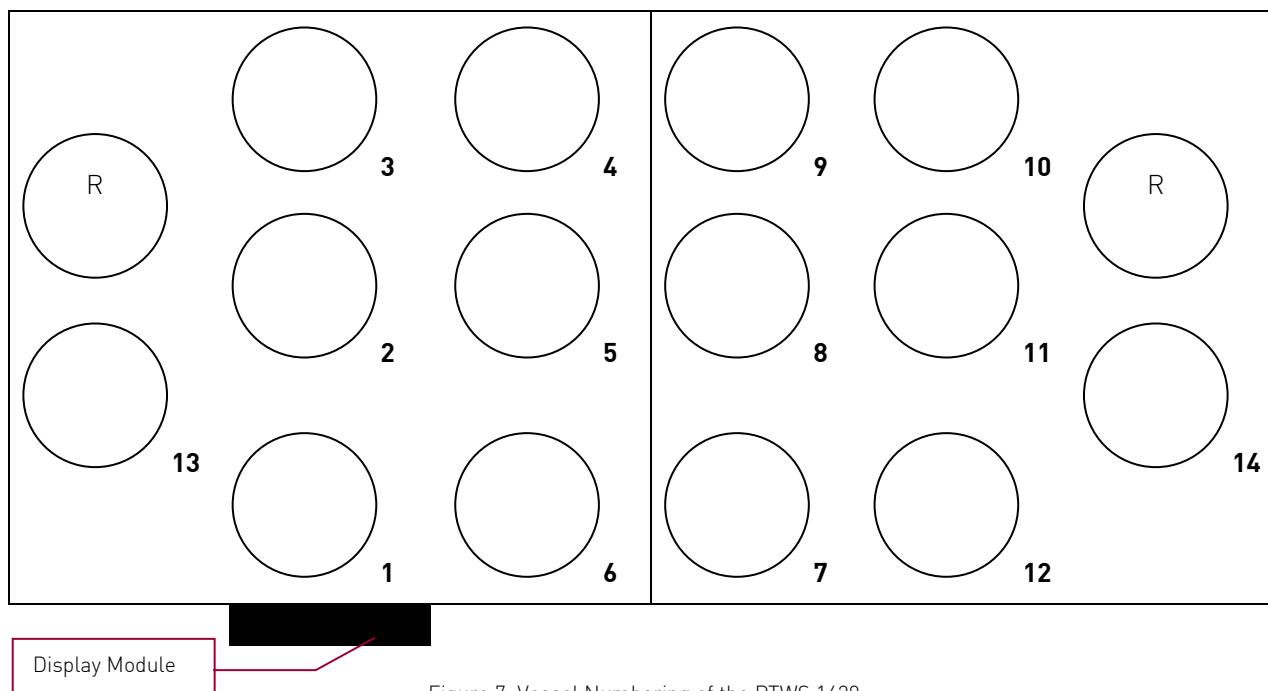


Figure 7: Vessel Numbering of the PTWS 1420

## 2 Setting Up the System

Make sure you follow these steps before turning on the instrument for the first time.

After the instrument is unpacked, please check the completeness using the supplied packing list, the delivery note, the IQ form and your order copy.

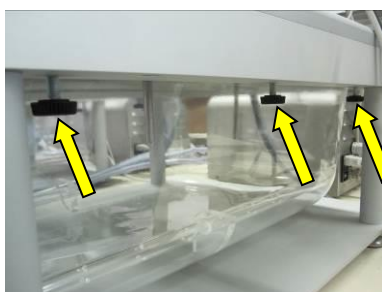
Cable connections are only allowed to be done when all instruments are switched off.

### 2.1 Inserting the Water Bath



Insert the empty water bath without the vessels from the right side of the PTWS 120D/120S/820D/1420 and slide it all the way in.

Note: When you remove the water bath for cleaning make sure you first empty the bath and remove all sensors and the vessels.



Screw in the six knurled-head screws (three on the left side and three on the right side) on the underside of the water bath frame to fix the water bath position in the frame.

### 2.2 Connecting the Display Module (only for PTWS 120D/120S/820D)

The PTWS 120D/120S/820D features two display module connects to enable the user to set up the instrument in a way that accommodates available shelf space as efficiently as possible. So, first choose whether you want to set up the PTWS 120D/120S/820D with three (four) vessels in front or with two vessels in front:

#### 2.2.1 Connecting the Display Module for Three (four) Vessels in Front Orientation (3x2 resp. 4x2)



Use the display module connection port in front of the instrument for a three (four) vessel in front orientation.



The display module is secured by the knurled-head screw included in the supply scope.



Plug the display module into the connector in front of the instrument.



Screw in the knurled-head screw to secure the display module.

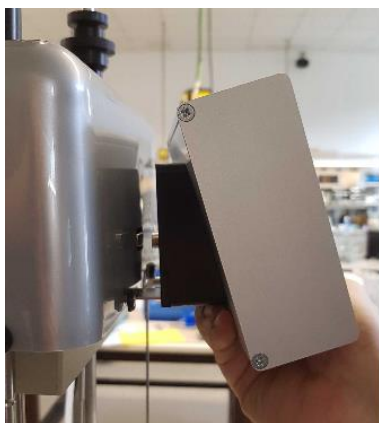
## 2.2.2 Connecting the Display Module for Two Vessels in Front Orientation (2x3 resp. 2x4)



Use the display module connection port on the right side of the instrument for a three vessel in front orientation.



The display module is secured by the knurled-head screw included in the supply scope.

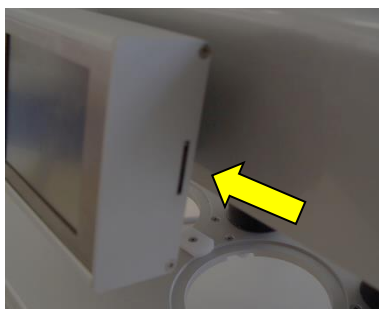


Plug the display module into the connector on the right side of the instrument.



Screw in the knurled-head screw to secure the display module.

### 2.3 Inserting the User SD Card



PTWS 120D/120S/820D stores data like methods and test reports on a standard SD card. This card is called the "user SD card". A second card inside the instrument stores configuration data of the instrument and only needs to be accessed for service purposes. This is a micro SD card and it is called "machine SD card".

Insert the user SD card provided with the instrument into the slot on the right side of the display module. For the PTWS 1420 please use the SD card slot right to the display.



The card clicks into place. To remove the card again, gently push it towards the display module, the holding mechanism will unlock the card and it can be pulled out.

The contents from the SD card can be copied to a PC for backup purposes. The method files can also be copied from one instrument to another this way. For the PTWS 1420 you have a small shield above the slot to prevent unauthorized access.

## 2.4 Connecting a PT-RP80 Report Printer (optional)



Connect the printer cable to the RS 232 port on the left side of the instrument's head.

Plug the other end into the appropriate port on the data logger.

The printer must be activated in the instruments firmware! Activation/Deactivation must be done by the Pharma Test Service!

### 2.4.1 PT-RP80 Communication Settings

Use the following communication settings for the PT-RP80:

Parameter:	Setting:
Baud rate	9600
Parity	None
Data bits	8
Stop bit	1

Table 4: PT-RP80 Communication Settings

For more information on how to setup your PT-RP80 report printer refer to the operation manual.

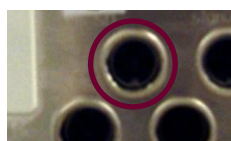
## 2.5 Connecting the PTWS 120D/120S/820D/1420 to a PC (optional)



Connect a USB cable (not included in standard supply) to the USB port labeled "USB/S" on the left side of the instrument's head.

Plug the other end into a USB port on the PC.

## 2.6 Connecting the External Temperature Probe

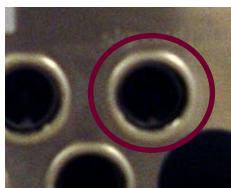


Connect external temperature probe (labeled "ext.temp") to the port labeled "ext.temp" on the left side of the PTWS 120D/120S/820D/1420 head.



Put the sensor end into the water bath through the hole without threading in the water bath plate.

## 2.7 Connecting a PTFC Fraction Collector (optional)



Connect the PTFC signal cable to the signal output port labeled "sign.output1" on the left side of the PTWS 120D/120S/820D/1420 head.

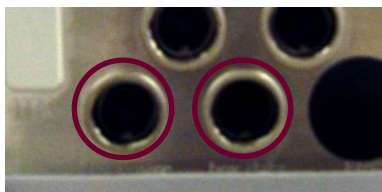
Connect the other end to the PTFC fraction collector. Refer to the PTFC manual for further instructions.

## 2.8 Connecting the Heater and Pump Module



There are two connections between the heater and pump module and the PTWS 120D/120S/820D/1420 head. One connection is used to transfer the data and control commands between the two units and the other one to supply the power to the PTWS 120D/120S/820D/1420.

Connect the data supply cable to the port labeled "box data" on the PTWS 120D/120S/820D/1420 head.

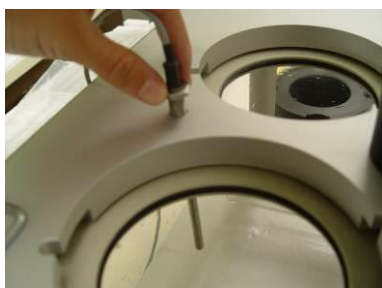


Connect the power supply cable to the port labeled "box power" on the PTWS 120D/120S/820D/1420 head.

## 2.9 Connecting the Bath Control Sensor



Plug in the sensor connector to the port labeled "control sense" on the heater and pump module.

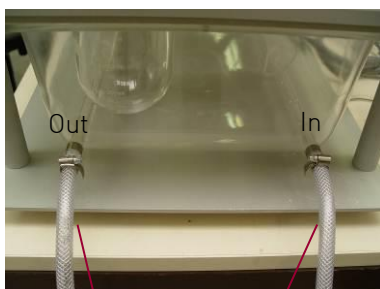


Screw the sensor end into the water bath through the threaded hole water bath plate.

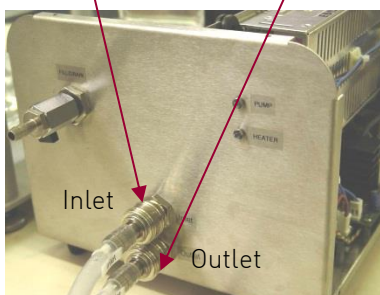
Please avoid drilling the cable too much!



## 2.10 Connecting the Water Bath Tubing



Connect the left tap labeled "Out" on the water bath with the fast coupling labeled "Inlet" on the heater and pump module.



Connect the right tap labeled "In" on the water bath with the fast coupling labeled "Outlet" on the heater and pump module.



Screw all hose clamps in tightly.

## 2.11 Filling the Water Bath

Make sure the PTWS 120D/120S/820D/1420 is turned off and the vessels are outside of the water bath. Open the fill/drain labelled valve. Connect the valve to the water tap. Do not turn on the PTWS 120D/120S/820D/1420 while the bath is being filled. Fill up the water bath slowly until the water "max." level is reached.

When later inserting the vessels the water level will rise.

## 2.12 Draining the Water Bath

Connect the fill/drain labelled valve to a drain. Open the valve and start the pump of the PTWS 120D/120S/820D/1420. You can start the pump from the Main Menu – "Bath Control" – "Heater On" (turning on the heater always turns on the pump automatically as well). Wait until the pump turns itself off. The water bath will be about 80% empty by then. Then remove the return and inflow labelled tubes and empty the remaining water into the drain. 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 120D/120S/820D/1420 for cleaning.

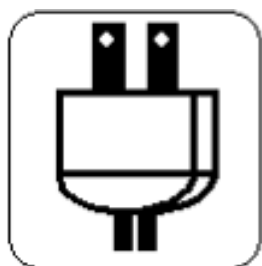
## 2.13 Connecting the Mains



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 mains cable to the power supply socket at the right side of the instrument's back.



Plug the other end into the power outlet.

## 2.14 Inserting the Vessels



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

Note that the vessels are individually coded and should always be inserted in the same position.



Release the vessel holder so that it can go inside the hole smoothly.



Turn the fixing screw slightly clockwise to lock it into position.

Repeat these steps at each one of the 3 positioning fingers and for all vessels.

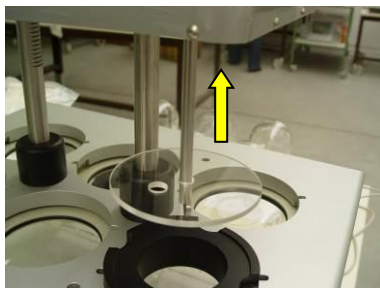
Make sure that the vessels are always completely immersed (up to the 900ml marking) in water when heated to avoid different temperature areas inside the vessels.

## 2.15 Inserting the Stirrers

The PTWS 120D/120S/820D/1420 is equipped with MonoShaft™ stirrers and tool adapters which are in compliance to the current USP/EP Apparatus 1, 2, 5 and 6. The standard delivery scope includes MonoShafts™ and paddle adapters (USP/EP App.2).

The PTWS 120D/120S/820D/1420 allows operation with “staggered start”. This means that each individual stirring position can be started individually by simply pushing the stirrer clam screw downwards into its operating position.

To introduce the stirrers the PTWS 120D/120S/820D/1420 head should be in its highest position. See the chapters below for instructions on how to move the PTWS 120D/120S/820D/1420 head.



Attach the tip adapter of the SWT2 tool to the MonoShaft™. Push the whole assembly from below through the corresponding hole in the PTWS 120D/120S/820D/1420 drive head.

Repeat this action for all stirring positions, while you just insert the stirring shafts.



Tighten the stirrer clam screws slightly at each position, just to prevent that the stirring shaft drops down.

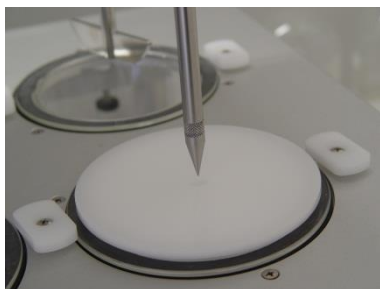


Forerunning information:

After setting the stirrer immersion depth (chapter 2.17) screw in the locking screw on the clam screw with an Allen key to secure the position (tighten to avoid that the shaft can fall down).

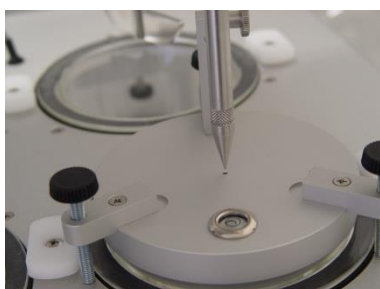
Repeat these steps for all stirrers.

## 2.16 Adjust the Vessel Position



For vessel centering the stirring shafts need to be installed. The stirring shafts should be tightened. Use the centering cover and fix the TIP Adapter onto the stirring shaft. Move the complete shaft assembly into the center hole of the cover or SWT2. Push the cover downwards to center the vessel in its conical part. Hold the centering cover in this position and now tighten the 3 positioning fingers using the attached screws to ensure the vessel in this position.

This picture shows the centering cover which has a 10mm hole into which the tip of centering adapter has to fit.



Both tools can be used to center the vessels with the stirring shafts. This picture shows the use of the SWT2 which has a 1mm positioning hole which has to be touched by the tip of the centering adapter

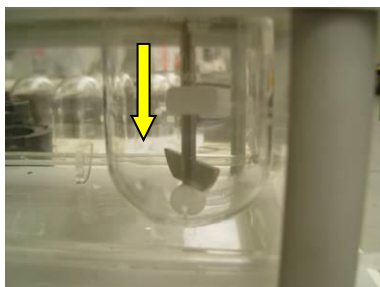


Keep the centering cover or SWT2 in its centered position. Now use a screw driver and fix the positioning "fingers" by tightening the screws.

## 2.17 Adjusting the Stirrer Positions

Each stirrer has to be adjusted for correct tool immersion depth. The allowed tolerance is  $\pm 2$  mm. The standard supply scope of the PTWS 120D/120S/820D/1420 includes six 25 mm diameter depth gauge balls. The PTWS 120D/120S/820D/1420 furthermore has the capability to store up to eight lift positions for the various stirrer tools. For more information on how to edit these positions, refer to the chapter on instrument settings below.

Place these balls one by one into the spherical centre of each dissolution vessel. Drive the head into the position corresponding to the stirrer tool you want to use.



Release the stirrer clamp screw and push the complete stirring tool with its attached tool adapter (USP App. 1, 2 or 6) downwards to touch the ball.

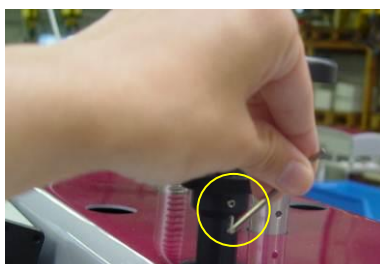
The depth setting ball must be in the centre of the vessel.

The balls will automatically push up any stirrer further into the bearing, if it has been too far out.



Now tighten the stirrer clamp screw to keep the tool in position during operation.

Move the head up and down again to verify the setting; all stirrers need to touch the 25mm  $\emptyset$  balls.



Screw in the locking screw on the clam screw with an Allen key to secure the position (tighten to avoid that the shaft can fall down).

Repeat these steps for all stirrers.

An 1,5mm allen key is part of the standard supply scope.

### 3 Navigating the PTWS 120D/120S/820D/1420 Menu Screens

The interface of the PTWS 120D/120S/820D/1420 consists of screens that are navigated by the user by means of the touch screen. Every screen has a title which gives information to the user about the purpose of the screen.

#### 3.1 Operating Elements of the PTWS 120D/120S/820D/1420

The PTWS 120D/120S/820D/1420 is touch controlled by means of a resistive touch screen. The screen reacts on pressure and therefore is best used by means of a stylus pen. Do not use regular pens as the sharp edges may damage the touch screen.

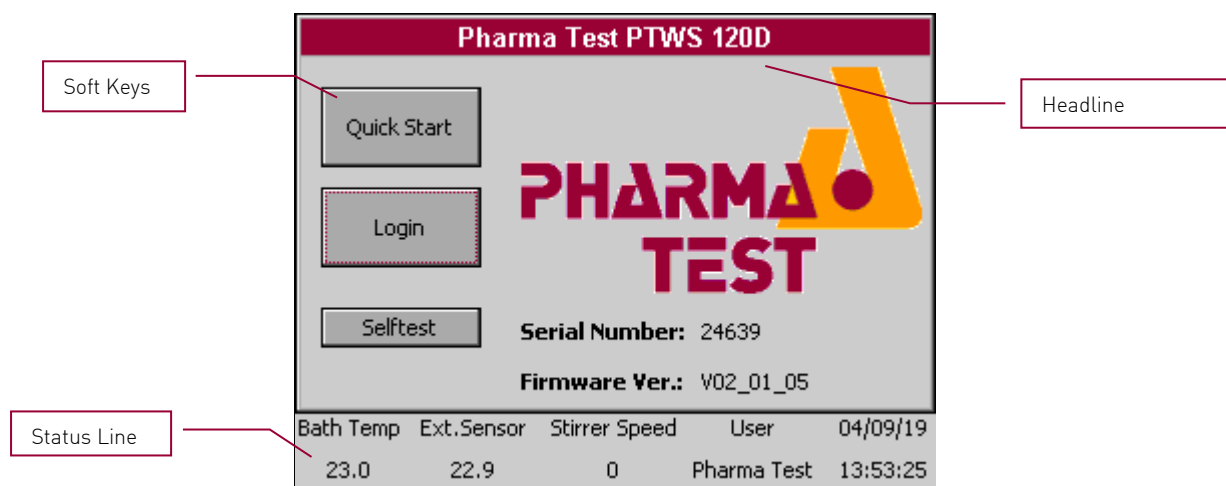


Figure 8: PTWS 120D/120S/820D/1420 Display Elements


No.	Element Name	Function Description
1	Headline	Every screen has a headline identifying the main purpose of that screen
2	Soft Keys	The menu system of PTWS 120D/120S/820D/1420 is navigated by using the onscreen soft keys. Each soft key is labelled according to its function.
3	Status Line	A status line shows important instrument parameters at all times: <ul style="list-style-type: none"> <li>▪ The current bath temperature</li> <li>▪ The temperature measured by the external sensor probe</li> <li>▪ The current stirrer speed</li> <li>▪ The name of the user currently logged in</li> <li>▪ The actual date and time</li> </ul>
	 Close Button (not shown on start screen)	Press the close button to close the current screen and to return to the previous screen.

Table 5: PTWS 120D/120S/820D Display Elements

### 3.1.1 Using the Onscreen Keyboard

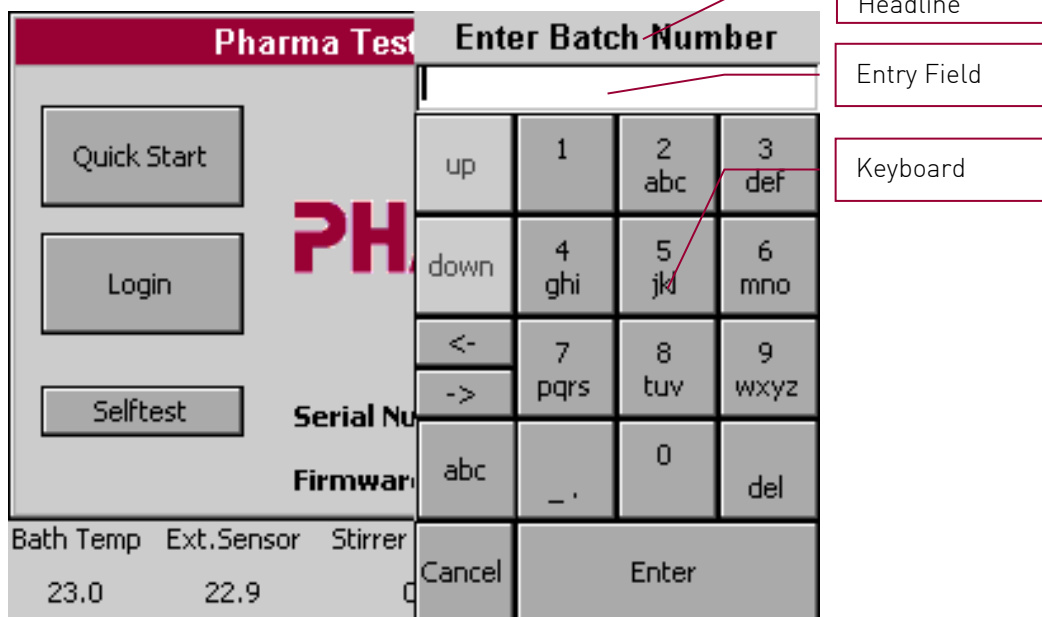


Figure 9: PTWS 120D/120S/820D/1420 Onscreen Keyboard

Whenever text or numeric entries are required, an onscreen keyboard will be displayed. The headline identifies which kind of data is supposed to be entered, i.e. the batch number in the example above. Below the headline, the current entry is displayed.











Picture	Key Name	Function Description
	Up/down keys	Use to either increment (up) or decrement the entry, when making numeric entries.
	Combined numeric and alpha-numeric keys	Press to enter the corresponding character. Press multiple times to cycle to the possible characters of a key (for example 2, a, b, c, etc.).
	Back and forward keys	Use to move the cursor one character to the left (back) or to the right (forward).
	abc key	Switch the mode of the combined numerical and alpha-numerical keys between small letters, capital letters and numbers
	Special characters key	Enter special characters, such as the "." (dot). Press the button multiple times to cycle through the characters.
	Delete	Delete the character left of the cursor.
	Enter	Save the entry and close the onscreen keyboard.
	Cancel	Close the onscreen keyboard and discard the entry.

Table 6: PTWS 120D/120S/820D/1420 Keyboard Elements

## 4 Logging On to the System and User Management

Before you can work with the instrument you need to log in. This section explains this process and shows how to change the user details from the pre-set factory values.

### 4.1 Pre-Defined Users

PTWS 120D/120S/820D/1420 works with pre-defined users which can be edited. Each of these users has a fixed set of user rights.

The default factory password for all users is:

1234

For security reason we strongly recommend changing all user passwords once the instrument is installed.

The passwords are numeric and can have up to 4 characters.

#### 4.1.1 User 1, User 2, User 3, User 4

These are the basic users which have the lowest level of rights. They can perform tests with the instrument based on pre-defined methods and can perform a quick test.

The names and passwords of these users can be changed.

#### 4.1.2 Edit User

This user has all rights of User 1 to 4 and in addition can edit method descriptions.

The name of this user is fixed. The password can be changed.

#### 4.1.3 Service User

The Service User user is intended to be used by service technicians. The Service User can perform calibration and adjustment procedures.

The name of this user is fixed. The password can be changed.

#### 4.1.4 Administrator

The administrator has the rights to edit the names and passwords for User 1 to 4, he can edit method descriptions and change instrument control settings.

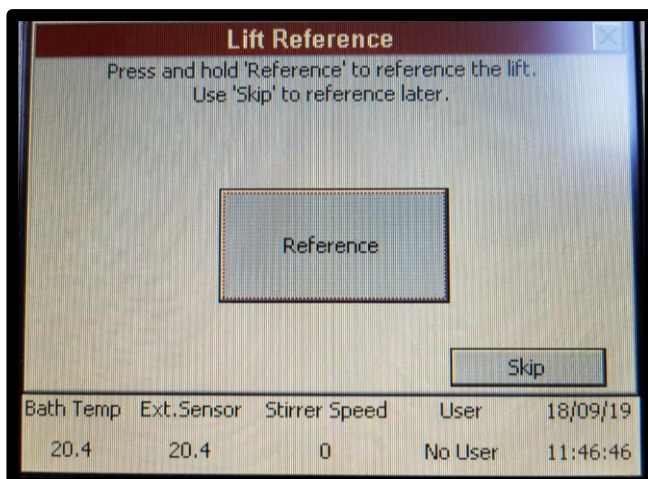
The name of this user is fixed. The password can be changed.

#### 4.1.5 Factory

The Factory user can be used by Pharma Test personnel to access the system for support issues.

The user information of the factory user is not required for the end user.

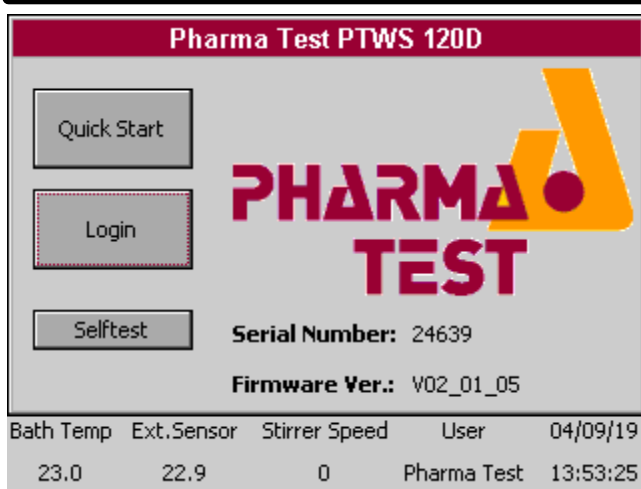
## 4.2 Logging on the PTWS 120D/120S/820D/1420



When you turn on the PTWS 120D/120S/820D/1420 instrument, an automated self-test will be done. After passing this test, you will see a lift reference mask.

The lift must generally be referenced once after turning on the instrument before the lift can be used. You can perform the reference now or "Skip" it and do it later.

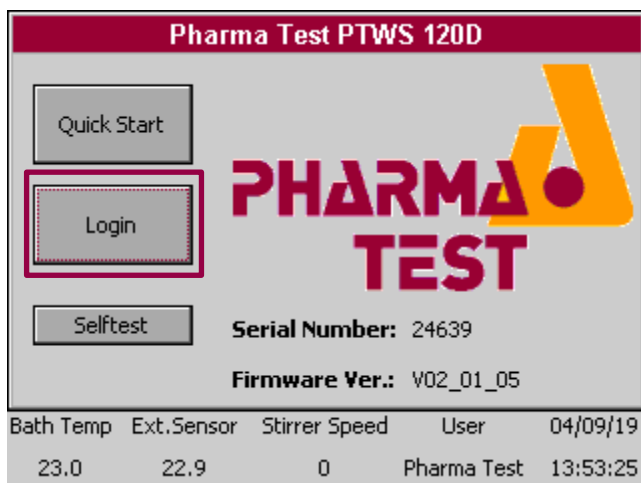
The „Reference“ button must be held until it becomes green.



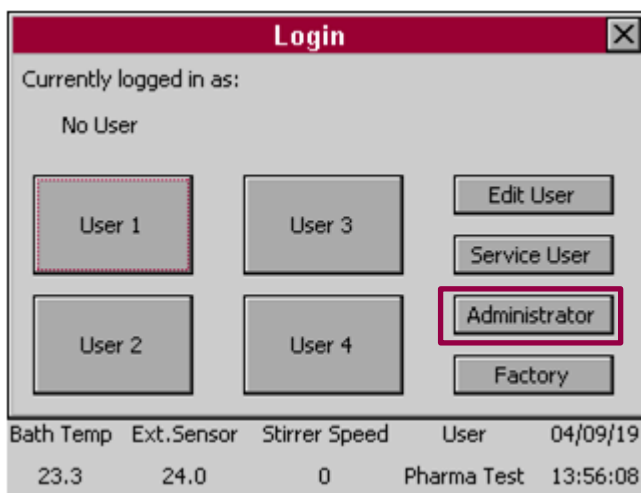
After referencing or aborting with "Skip", the start screen is displayed.

It shows the instrument type, the instrument's serial number and the installed firmware version.

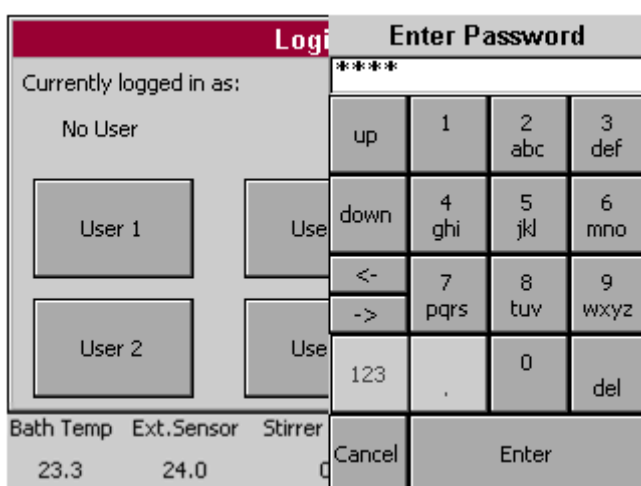
The status line is displayed as well.



Select "Login" to log on to the instrument.



A list of all users present on the PTWS 120D/120S/820/1420 appears. Select the desired user. In this case we select the user "Administrator".

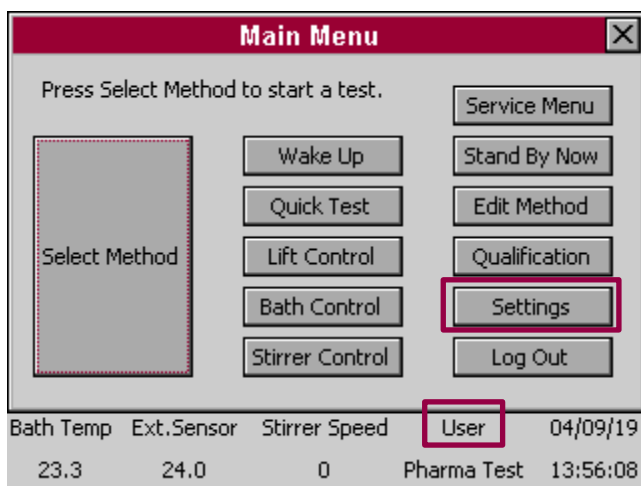


The onscreen keyboard appears. Enter the password for the selected user.

In this case the default password for the Administrator is:

**1234**

For security reason we strongly recommend changing the administrator password once the instrument is installed.



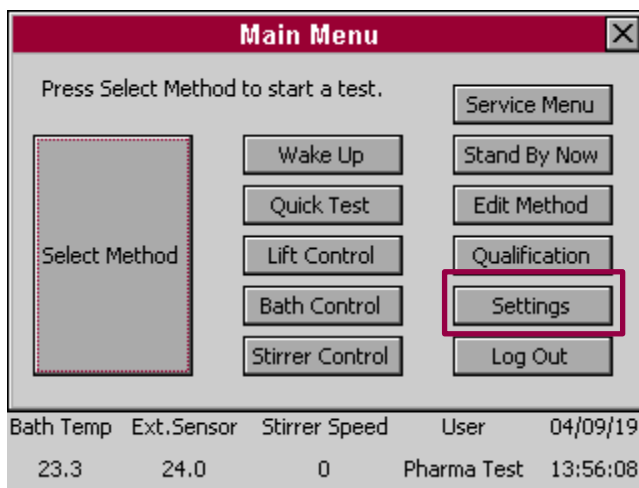
The main menu appears. The last line shows the currently logged in user. To log out again, select "Log Out".

You will then be returned to the start screen and may log in as another user.

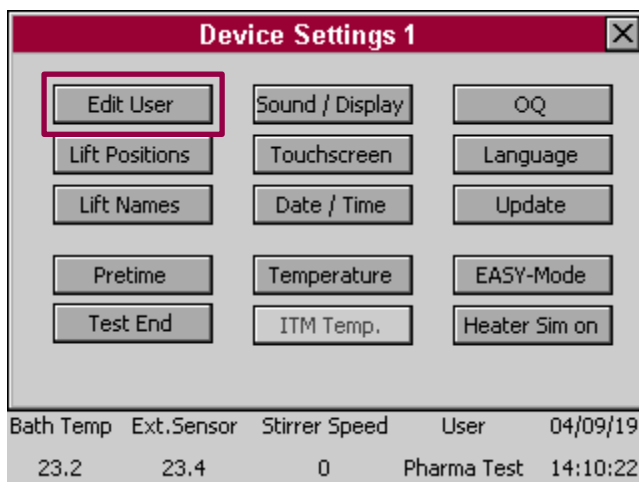
## 4.3 User Management

From the main menu enter the “Settings” menu and there the “Edit User” menu to edit users. Make sure, that you are logged in as the administrator in order to have the necessary rights to edit the users.

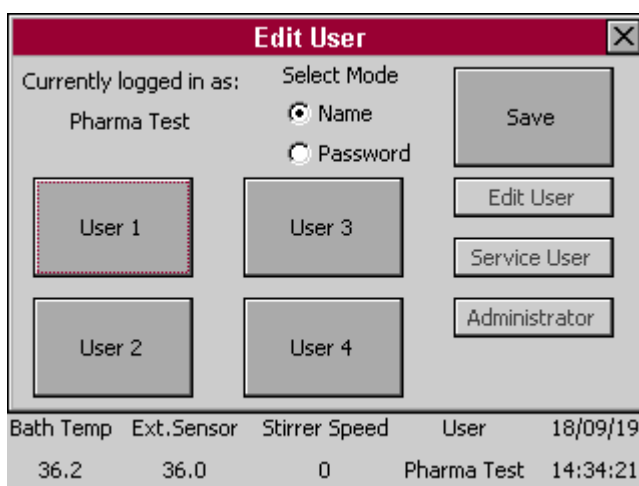
### 4.3.1 Editing a User



From the main menu select “Settings”.



In the “Device Settings” menu select “Edit User”.



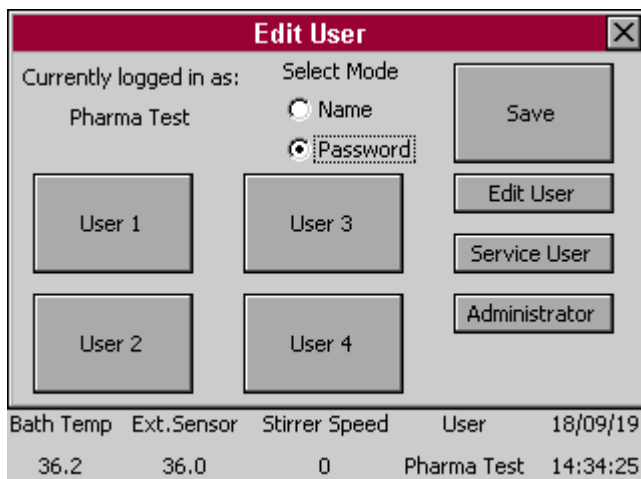
The “Edit User” menu appears. You can see the all users of the PTWS 120D/120S/820D/1420 displayed here as well as which user is currently logged in.

There are two modes of editing the users:

- Name
- Password

Use the selector to switch between these modes.

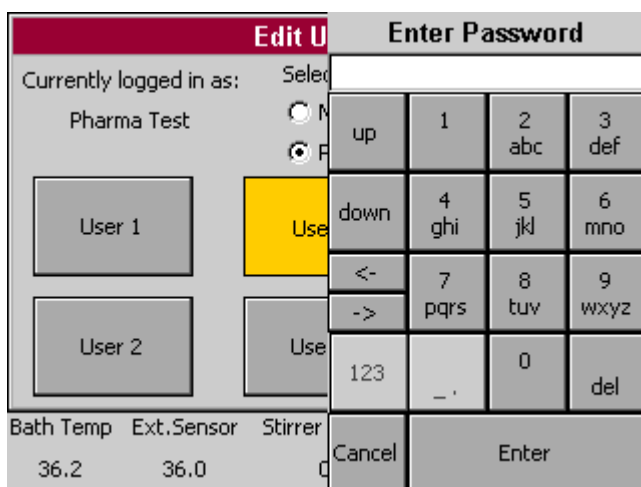
When the name mode is selected, the buttons of the users with fixed names are disabled.



When the password mode is selected, the buttons of the fixed users become active as well.

Touch the button corresponding to the user you would like to edit and enter the new name or password.

When you change the user name, you will see the change reflected directly on this screen.



Here you can enter the password for the corresponding user.

Every password must consist of 4 numbers!

## 5 The PTWS 120D/ 120S/ 820D/1420 Main Menu

After logging on to the PTWS 120D/ 120S/ 820D/ 1420, the main menu appears. This section explains the menu items of the main menu.

### 5.1 Main Menu Items

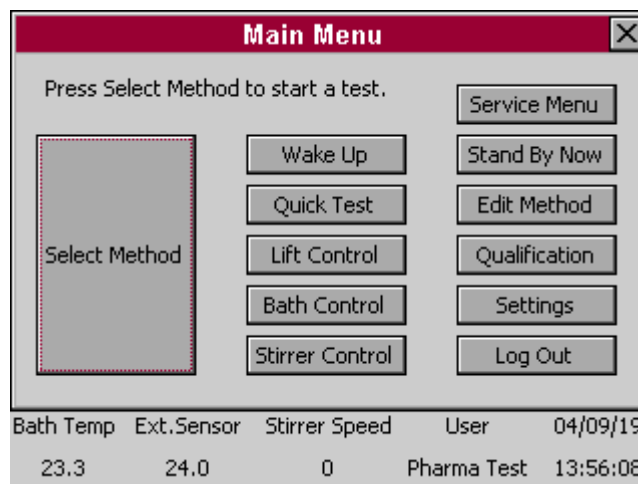


Figure 10: Main Menu

Key Name	Function Description
Select Method	Select a pre-defined method and run a test based on this method description. See the chapter on methods below for more information.
Wake Up	The Wake Up Function is intended to be used in combination with the Stand By Function. Enter the time (hours and minutes) when the instrument should be heated up again and set the requested temperature. The mains power supply must be ON at that time as well. Even if the Wake Up function is activated, you can use the instrument normally anymore. Please read chapter 5.3 for more information.
Quick Test	Perform a Quick Test without creating any method prior to the test. See the chapter on Quick Test below for more information.
Lift Control	Drive the lift up and down or to a programmed position. This is useful for cleaning purposes, for example.
Bath Control	Control the heating function of the water bath. This is useful to pre-heat the water bath before starting a test or to maintain the temperature in the water bath between tests.
Stirrer Control	Turn the rotation of the stirrers on and off and control the stirring speed.
Service Menu	A service screen for trouble shooting purposes – useful to check every single sensor in the instrument individually.

Stand By Now	<p>The Stand By is a function which can be selected in the “Test End”-settings (see chapter 10.3 for more information).</p> <p>After a test is finished (including all “Infinity” steps) you can program the instrument to cool down to a Stand-By temperature to save energy. Additionally you can program a delay time (up to 100 minutes, beginning from the test finish) until the instrument starts the Stand By mode. This is a kind of “automatic” mode.</p> <p>Additionally you can start the Stand By mode immediately by pressing the “Stand By Now”-button. If you confirm the warning message, the bath temperature will be set to the Stand By temperature programmed in the “Test End”-settings.</p> <p>NOTE: the pump (and heater) will start by activating the Stand By mode, because the temperature control can only work with a working pump.</p> <p>A text “Stand By” will be displayed in the lower right corner as long as the Stand By Mode is active.</p> <p>The Stand By Mode will be stopped as soon as you enter the “Bath Control” menu or if the Wake Up function begins.</p>
Edit Method	Create new methods and edit or delete existing methods. See the chapter on methods below for more information.
Qualification	Call up various qualification programs, which assist the user during the operation qualification of the instrument.
Settings	Edit various instrument settings, like date and time for example. See the chapter in settings below for detailed instructions.
Log Out	Log the current user out and return to the start screen.

Table 7: Main Menu

## 5.2 The Status Line

The status line is displayed on the bottom of most screens. It provides important run time information at a glance:

Bath Temp	Ext.Sensor	Stirrer Speed	User	04/09/19
23.3	24.0	0	Pharma Test	13:56:08

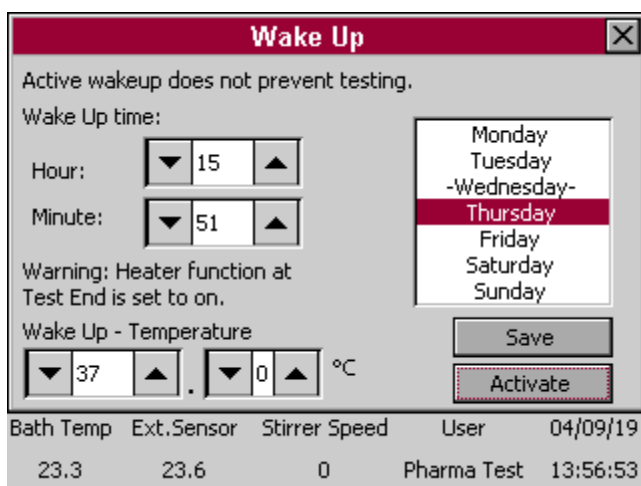
Figure 11: Status Line

Key Name	Function Description
Bath Temp	The actual water bath temperature.
Ext. Sensor	The actual temperature measured by the external hand sensor.
Stirrer Speed	The current stirrer speed.
User	The name of the user currently logged in to the instrument.
Date and Time	The actual date (dd/mm/yy) and time (hh:mm:ss).

Table 8: Status Line



### 5.3 Wake Up-Function



The Wake Up Function is intended to be used in combination with the Stand By Function.

Enter the time (hours and minutes) and the days of the week (marked red – here: Thursday. Multiple selectings are possible!), when the instrument should be heated up again and set the requested temperature. The mains power supply must be ON at that time as well. One hour before the set time is reached, pump and heater will start to work, so the instrument will be prewarmed with reaching the set time.

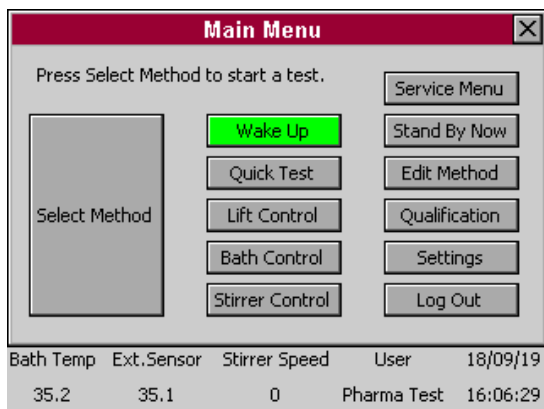
The day of the week with the “-” left and right is the current day, set in the instrument settings. This setting must be correct for a proper function of the Wake-Up mode (see chapter 5.3).

If the heater function in the „Test End Settings“ is set to „ON“ (see chapter 10.3), a warning message will be displayed in the upper right corner.

The Wake Up Function works as follows:

- The Wake Up Time must be set to at least one hour in the future. Otherwise there will be an error message „Check Time“.
- If the function is activated, the button text changes from „Activate“ to „Cancel“.
- If the heater is running while activating the Wake Up Function, the user will be asked if the heater should remain on or be turned off.
- If a Method test is active while the Wake Up Timestamp is reached (one hour before the set Wake Up Time), the Wake Up Function will be refused.
- If the Wake Up Timestamp is reached while a method test is finished and the instrument is waiting for the Stand By (Delay-)Time, the waiting for the Stand By Function will be aborted and the Wake Up Function starts.
- If the heater function in the “Test End Settings” is set to “ON” (see chapter 10.3), a warning message „Warning: Heater function at Test End is set to on” will be displayed in the upper right corner. This is just an information for the user and no error.

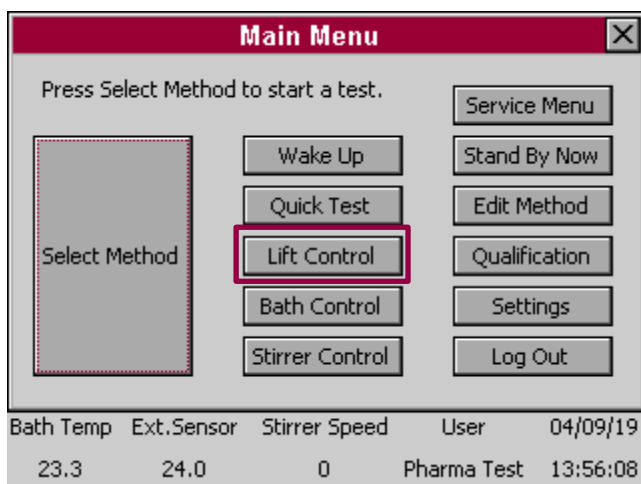
Description: After a method test is finished, with the test end setting „ON“ the heater will continue heating with the method temperature. But if then the Wake Up Time is reached, the bath will be heated to the Wake Up Temperature.



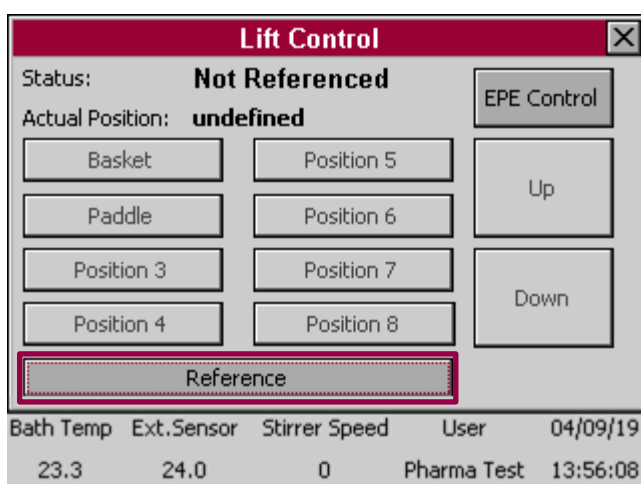
If Wake Up is activated, the button lights green. The instrument can still be operated as normal. The Wake Up function doesn't prevent actual tests.

Example for the time setting: You must set a TIME in the wake up menu, not a SPAN! If it's now 02:00 p.m., you can set the wake up time to 03:10. Then at 02:10 p.m., the unit starts to heat up to the wake up temperature and be prewarmed at 03:10 p.m. If you insert a wake up time to 01:10 because of accidentally thinking it means "in 1 hour and 10 minutes", fact is the wakeup time is set to 01:10 a.m. This means the instrument will start heating up at 00:10 a.m. to be prewarmed at 01:10 a.m.

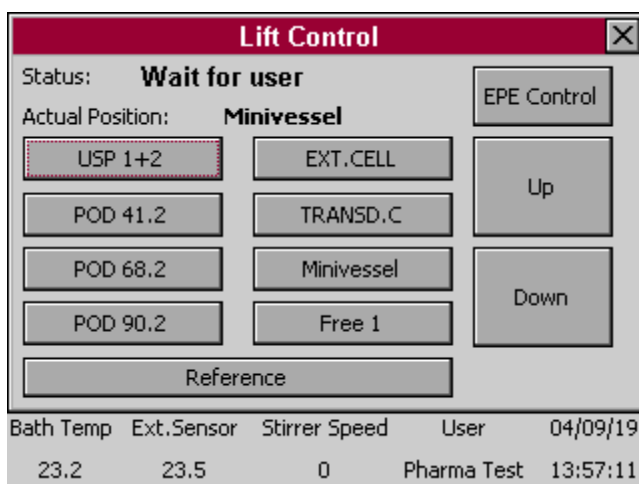
#### 5.4 Lift Control



From the main menu select "Lift Control". The lift of PTWS 120D/120S/820D/1420 only moves as long as the user keeps his finger on the touch screen for operator security reasons.

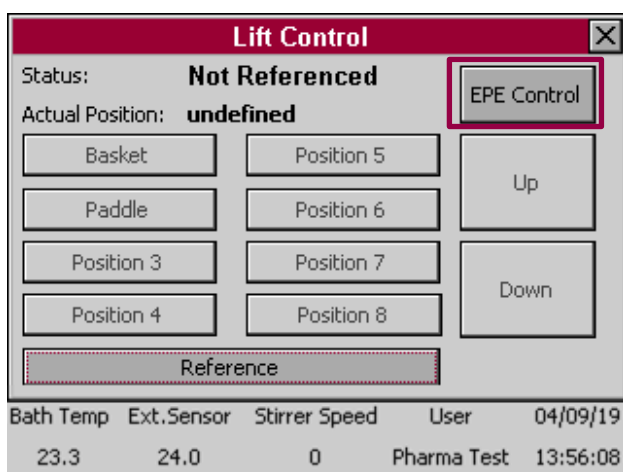


Every time the instrument is turned on, the lift has to be referenced; this means it has to be driven to the upper home position. This can be done from the "Lift Control" menu by pressing the "Reference" button keeping it pressed. Once the lift has reached the upper home position, the "Reference" button turns green and the other buttons become active. If you press the Reference button again after performing a Reference, the actual Reference position will be deleted and you must perform a complete Reference drive again!

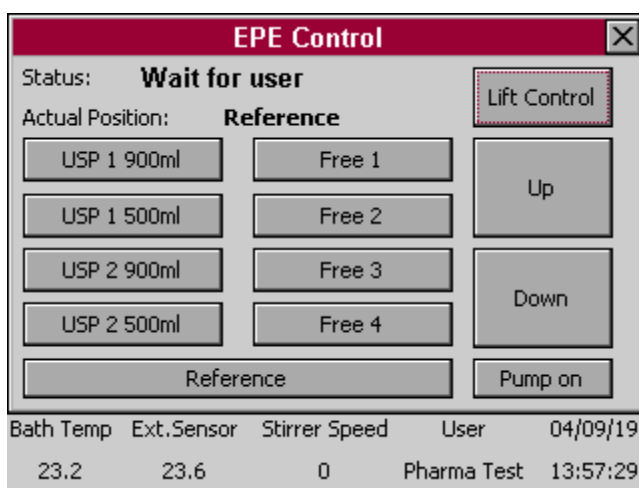


Now you can either move the lift freely by pressing and holding the “Up”- and “Down”- buttons or drive the lift to a programmed position by pressing and holding the position button until the lift automatically stops at the corresponding position.

In the top part the current lift status is displayed and the name of the position the lift is currently at. If the lift is between positions, it is given as “undefined”.



In case the optional EPE system is installed, press the “EPE Control” button to move the EPE manifold in the same manner.



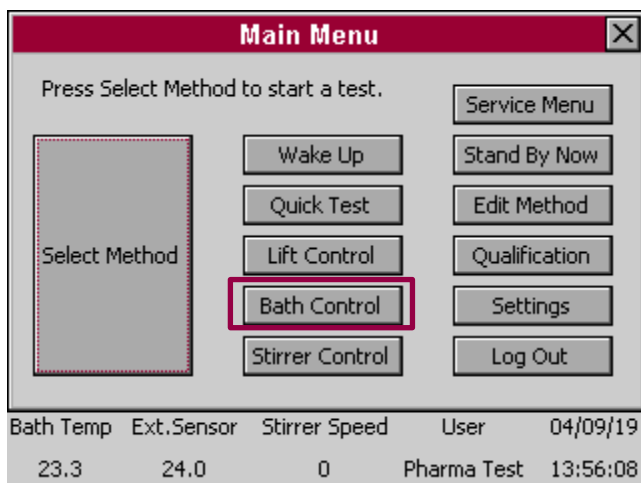
The EPE has to be referenced each time the instrument is turned on. In case of the EPE, this is performed automatically during start-up of the instrument. This step can be repeated here if required.

If you press the Reference button again after performing a Reference, the actual Reference position will be deleted and you must perform a complete Reference drive again!

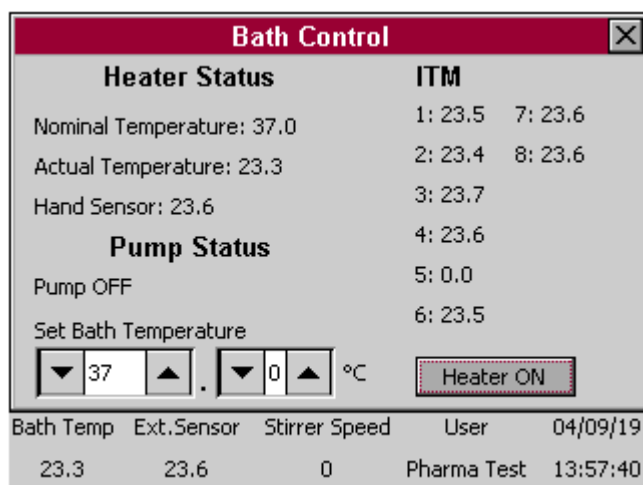
Pressing the “Sample”-button will send the sample signal over the interface. In case the optional ITM system is installed, the temperatures will be read by the ITM sensors as well.

Press “Lift Control” to return to the lift control screen.

## 5.5 Bath Control



From the main menu select “Bath Control”.



The upper left part shows the nominal temperature, actual temperature and the temperature measured by the external hand sensor. Below the actual status of the pump is displayed.

The nominal bath temperature can be set on the bottom of the screen. Either use the up and down button to increment or decrement the setting or click the white box to call up the onscreen keyboard to enter the value directly in a range of 25.0°C to 45.0°C.

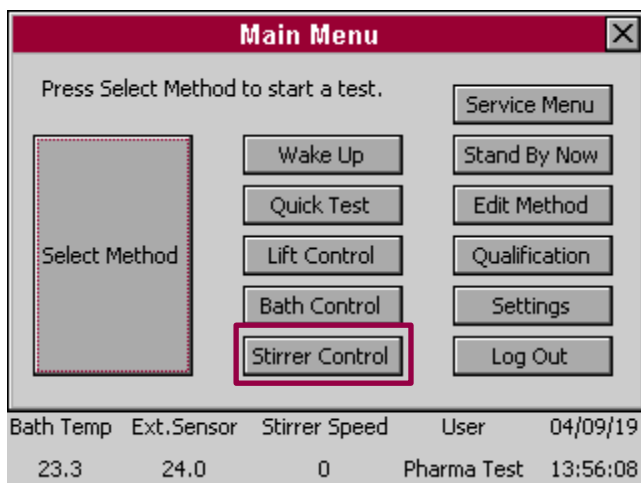
In case the optional ITM is installed, the last temperatures measured by the ITM sensors are displayed here as well.

Press the “Heater On”-button to turn on the heating system. The pump is always turned on automatically as soon as the heating system is activated. In case no pump flow is detected by the system, the heating system will be deactivated to avoid damage to the instrument.

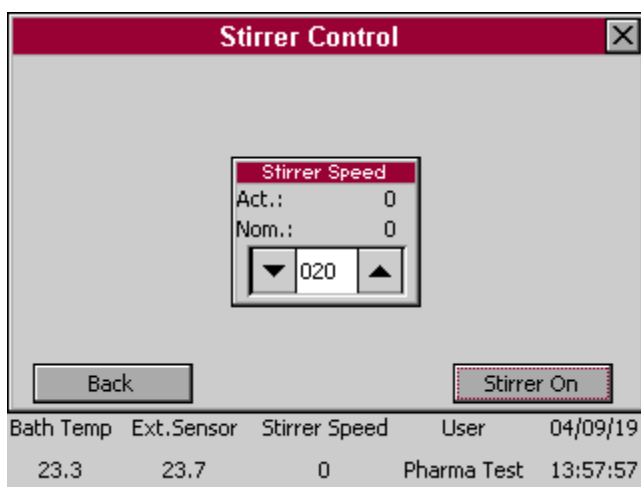
The instrument will heat up the water bath until the nominal temperature is reached. Then it will maintain that temperature.

The “Heater On”-button changes to “Heater Off”. Press it again, to turn the heating system off.

## 5.6 Stirrer Control



From the main menu select “Stirrer Control”.



The box shows the actual and nominal stirrer speed settings.

To change the nominal stirrer speed, either use the up and down button the increment or decrement the setting or click the white box to call up the onscreen keyboard to enter the value directly in a range of 20rpm to 250 rpm.

Press the “Stirrer On”-button to turn on the stirrer rotation. The “Stirrer On”-button changes to “Stirrer Off”. Press it again, to stop the stirrers.

## 6 Method Management

The PTWS 120D/120S/820D/1420 possesses a powerful method management system. The instrument is capable to store a practically unlimited number of methods (only limited by the amount of free space on the user SD card). It is also possible to a method from the SD card of one instrument to the SD card of another instrument.

In order to perform a test run with the PTWS 120D/120S/820D/1420, the user first has to create a method and to configure the procedure. Later the user simply selects the created method from a list to perform further test runs with these settings.

### 6.1 About Methods

This section describes how to create, edit, list and to delete a method. Furthermore the individual parameters of a method are explained. A method stores all data needed for a test. While it is possible to run a test manually using the “Bath Control” and “Stirrer Control” menus it is recommended to run tests using a pre-defined method.

#### 6.1.1 About Sampling Intervals

With the PTWS 120D/120S/820D the user has the ability to program up to ten different sampling interval times that each can be repeated up to 99 times. The sampling interval is announced by a signal from the beeper and a countdown is shown on screen. The interval programming also controls the movement of the EPE in case it is installed. The PTWS 120D/120S/820D/1420 sends a signal to start the sampling.

For example, if you enter the following values:

Interval 1/10  
Hours = 00  
Minutes = 10  
Repeat = 3

Interval 2/10  
Hours = 00  
Minutes = 15  
Repeat = 1

Interval 3/10  
Hours = 00  
Minutes = 20  
Repeat = 2

Intervals 4 to 10/10 are left blank (all values there are set to 0).

In this example, the first sampling interval will occur ten minutes after the test start. The second interval will occur ten minutes later (= 20 Minutes after the test start) and the third interval again will occur ten minutes after the second interval. The first delay time will be repeated three times.

After that, the second delay time will be used once. This means the fourth sampling interval will occur 15 minutes after the third interval. Then the third and final delay time will be used twice. The fifth sampling interval will occur 20 minutes after the fourth and the sixth interval 20 minutes after that:

Start	Sample 1 at 10 Min.	Sample 2 at 20 Min.	Sample 3 at 30 Min.	Sample 4 at 45 Min.	Sample 5 at 65 Min.	Sample 6 at 85 Min.	End
	Interval 1/10			Interval 2/10	Interval 3/10		

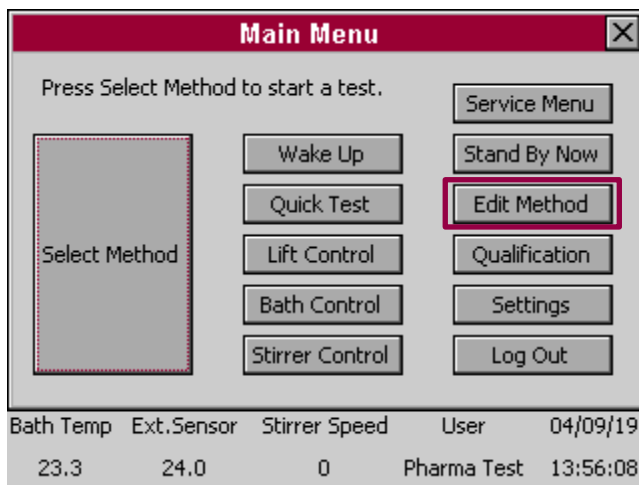
Table 9: Sampling Intervals

### 6.1.2 About the Infinity Test

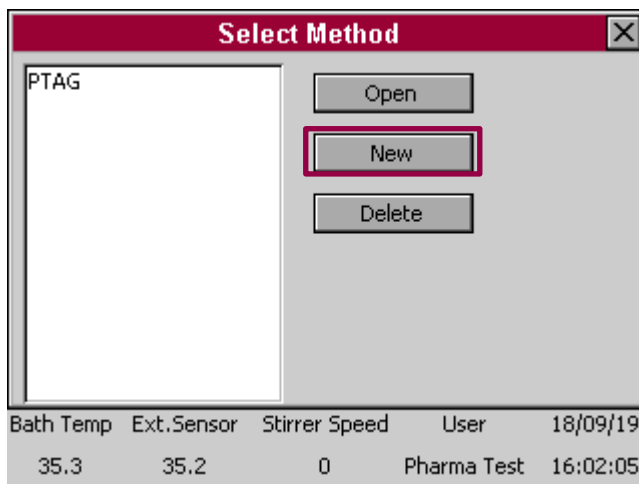
PTWS 120D/120S/820D/1420 offers the possibility to program an infinity test. If this feature is activated, the instrument will continue to stir and heat, after the last sampling interval occurred and the actual test is finished. By means of drawing an infinity sample it is possible to show that at there are no changes between the last sample and the infinity sample to prove, that the dissolution process had concluded at the point of the last sampling. This is especially useful during product development.

It is also possible to set a different stirring speed and temperature for the infinity test. Typically the temperature and stirring speed are increased to maximum levels for this test.

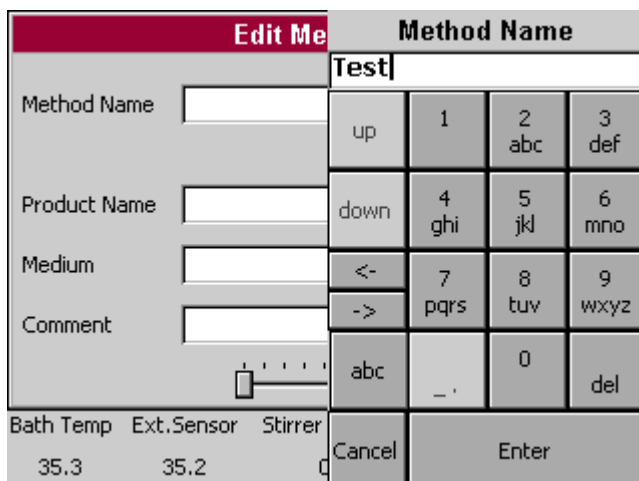
### 6.1.3 Creating a New Method



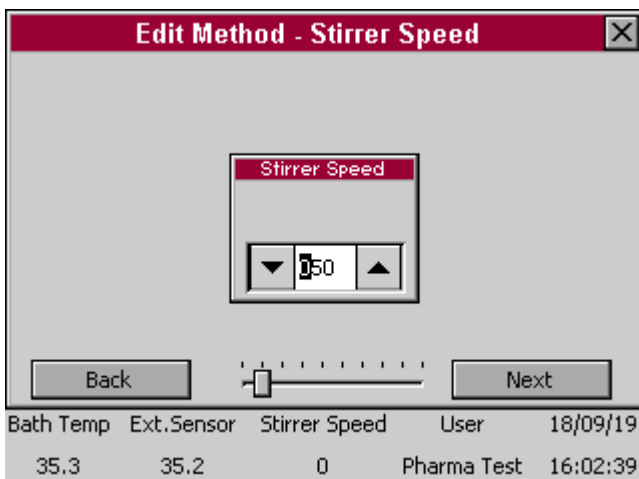
From the main menu select "Edit Method". To store methods, the User-SD-Card (standard supply scope) must be inserted!



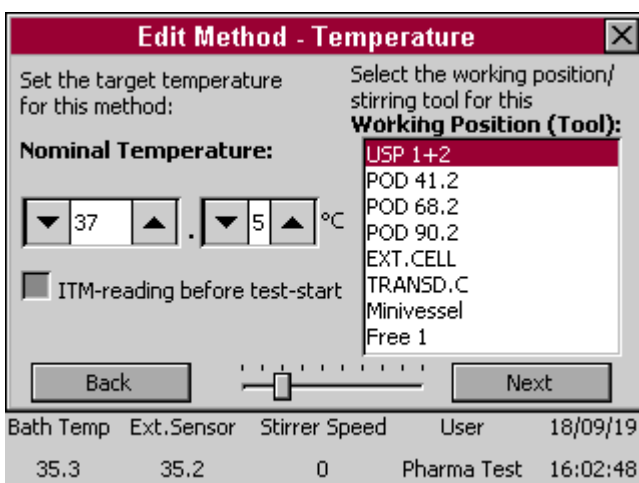
Select "New".



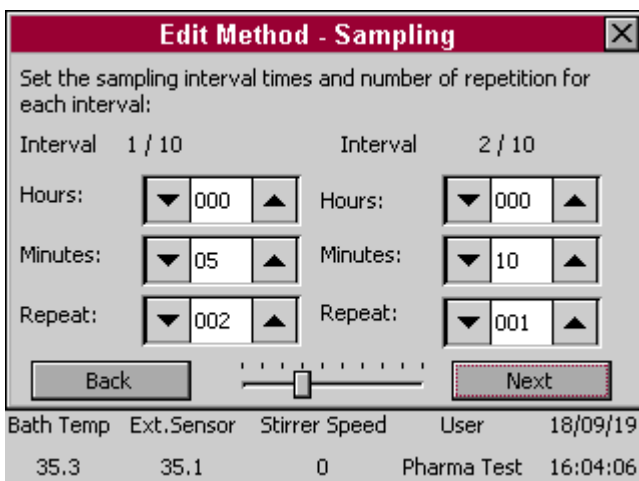
Enter descriptive information for the method in alpha-numeric formats. The method name will also be the filename of the method on the user SD card. Select "Next" to continue.



Set the nominal stirring speed.  
Select "Next" to continue.



Set the nominal temperature for the method.  
Select a working position from the list of pre-programmed working positions on the device.  
Select "Next" to continue.



Set the first and second sampling interval. See above for an explanation on sampling intervals. If an interval is not required for the method, leave all values at 0, thereby disabling the interval.  
The intervals will be polled one after the other. You can, for example, program even interval 1 and 3 and set interval 2 to "0". But Note: Interval 1 must always be used if you use intervals!  
Select "Next" to continue.



**Edit Method - Sampling** [X]

Set the sampling interval times and number of repetition for each interval:

Interval 3 / 10                      Interval 4 / 10

Hours: [▼] 000 [▲]                      Hours: [▼] 000 [▲]

Minutes: [▼] 00 [▲]                      Minutes: [▼] 00 [▲]

Repeat: [▼] 000 [▲]                      Repeat: [▼] 000 [▲]

[Back]                      [Next]

---

Bath Temp    Ext. Sensor    Stirrer Speed    User    18/09/19

35.2            35.1            0            Pharma Test    16:04:14

Set the third and fourth sampling interval. If an interval is not required for the method, leave all values at 0, thereby disabling the interval. Select "Next" to continue.

**Edit Method - Sampling** [X]

Set the sampling interval times and number of repetition for each interval:

Interval 5 / 10                      Interval 6 / 10

Hours: [▼] 000 [▲]                      Hours: [▼] 000 [▲]

Minutes: [▼] 00 [▲]                      Minutes: [▼] 00 [▲]

Repeat: [▼] 000 [▲]                      Repeat: [▼] 000 [▲]

[Back]                      [Next]

---

Bath Temp    Ext. Sensor    Stirrer Speed    User    18/09/19

35.2            35.1            0            Pharma Test    16:04:28

Set the fifth and sixth sampling interval. If an interval is not required for the method, leave all values at 0, thereby disabling the interval. Select "Next" to continue.

**Edit Method - Sampling** [X]

Set the sampling interval times and number of repetition for each interval:

Interval 7 / 10                      Interval 8 / 10

Hours: [▼] 000 [▲]                      Hours: [▼] 000 [▲]

Minutes: [▼] 00 [▲]                      Minutes: [▼] 00 [▲]

Repeat: [▼] 000 [▲]                      Repeat: [▼] 000 [▲]

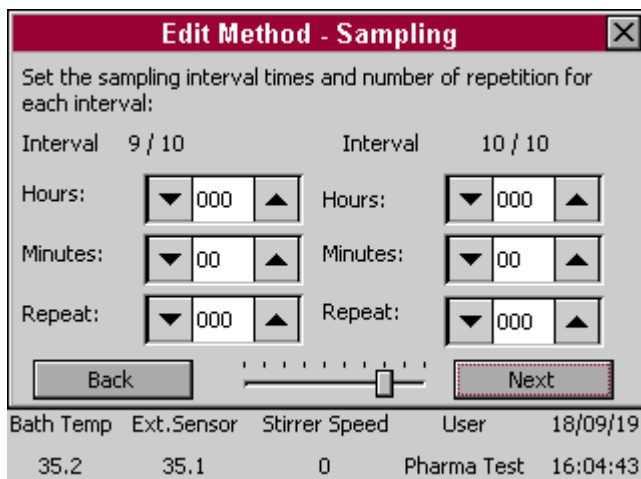
[Back]                      [Next]

---

Bath Temp    Ext. Sensor    Stirrer Speed    User    18/09/19

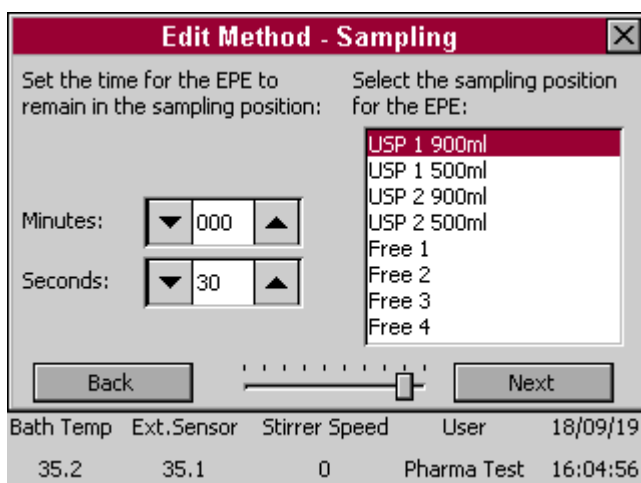
35.2            35.1            0            Pharma Test    16:04:33

Set the seventh and eighth sampling interval. If an interval is not required for the method, leave all values at 0, thereby disabling the interval. Select "Next" to continue.



Set the ninth and tenth sampling interval. If an interval is not required for the method, leave all values at 0, thereby disabling the interval.

Select "Next" to continue.

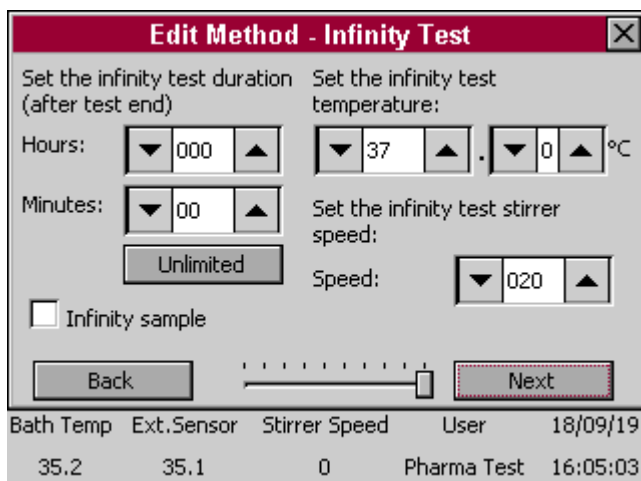


Set the time for the EPE to remain in the sampling position. This time depends on the time the connected pump requires to withdraw the sample.

Then select the sampling position for the EPE.

For systems without the optional EPE systems, the EPE position windows isn't displayed.

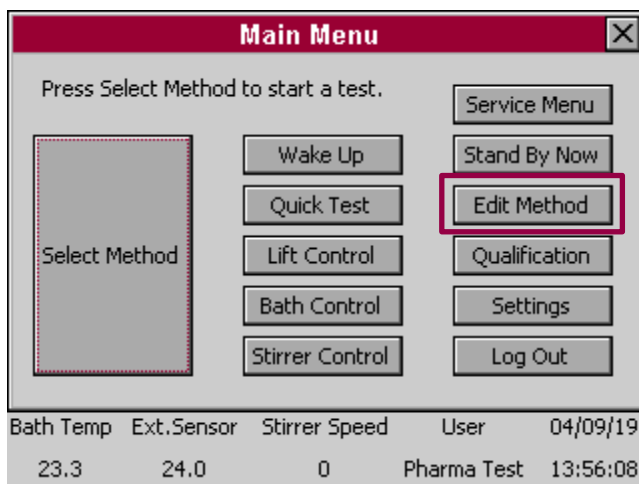
Select "Next" to continue.



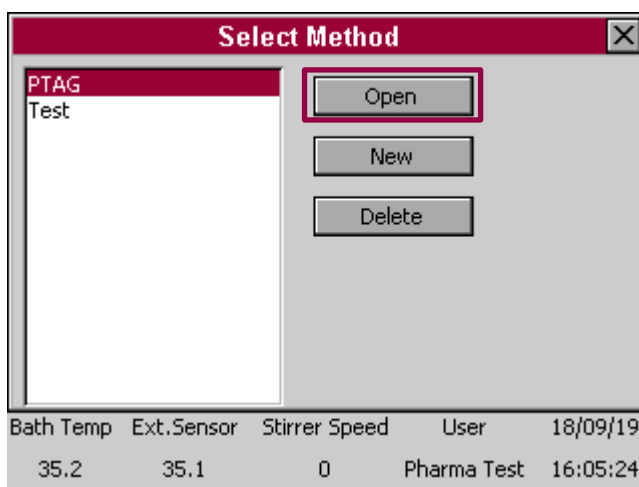
Set the duration of the infinity test or set it to unlimited by pressing the "Unlimited"-button. A temperature and stirring speed may be set as well. In case a last sample at the end of the infinity test shall be taken, activate the "Infinity sample" checkbox (this is not possible in case the infinity test is set to unlimited). Leave the time settings at 0 when no infinity test is required. The test will then end after the last sampling interval.

Select "Save" to create the new method.

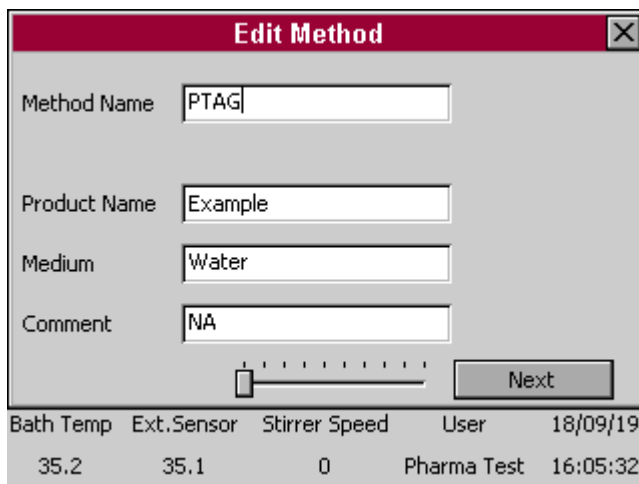
### 6.1.4 Editing a Method



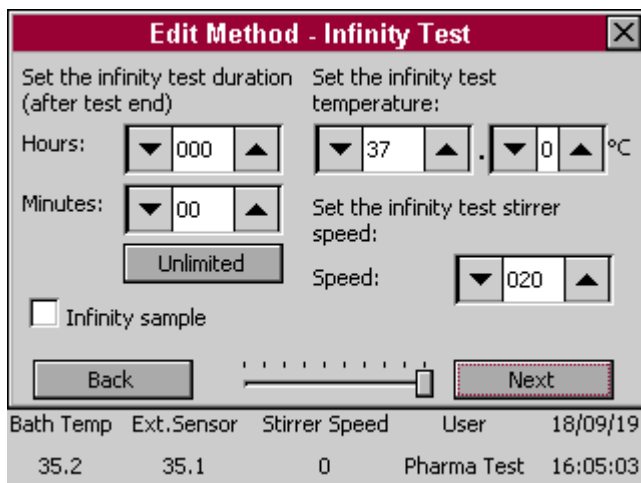
From the main menu select "Edit Method".



Select the method you want to edit from the list on the left.  
Select "Open".

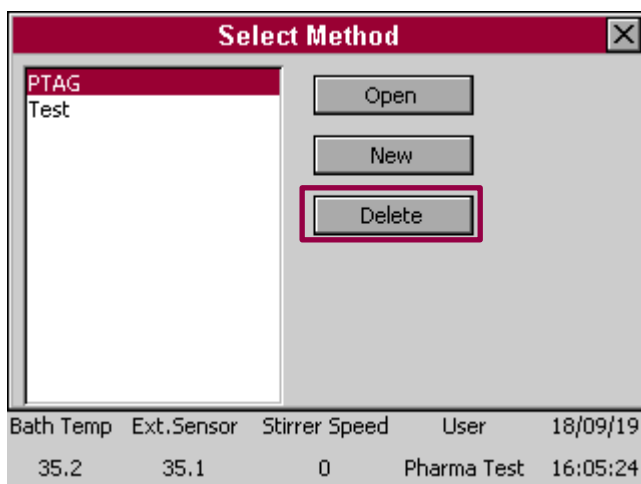


Go through the "Edit Method" screens and perform the required changes.  
The same principle as described above when creating a new method applies to editing an existing method. See the above section for more details.



On the last screen select “Save” to save the changes to the method.

### 6.1.5 Deleting a Method



The user interface of the PTWS allows editing and deleting existing methods. This way any method that is not required anymore can be overwritten with other settings.

We strongly recommend always creating a backup first before deleting anything from the user SD card.

## 7 Running a Test Using a Method

While it is possible to run a test manually using the “Bath Control” and “Stirrer Control” menus, it is recommended to run tests using a pre-defined method. This section explains how to create, edit and delete products as well as how to run a test from a product.

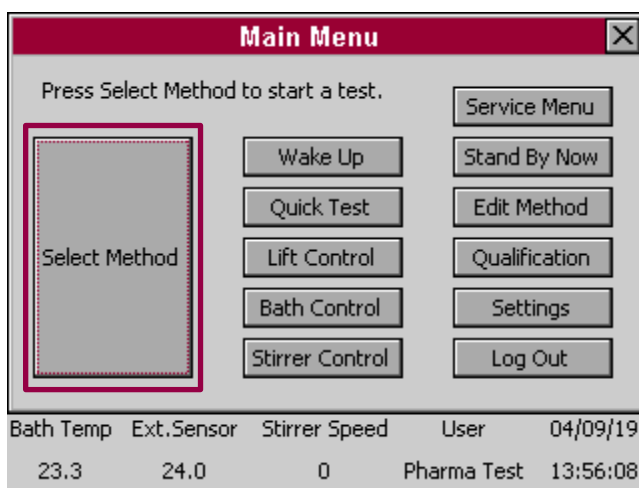
### 7.1 General Dissolution Test Information and Preparation

The actual test should be performed at a media temperature of  $37.0^{\circ} \pm 0.5^{\circ}\text{C}$  or for transdermal drugs at  $32.0^{\circ} \pm 0.5^{\circ}\text{C}$ . In order to keep the media inside the glass dissolution vessels at this temperature you need to adjust the bath temperature to  $37.0^{\circ}\text{C}$  as minimum.

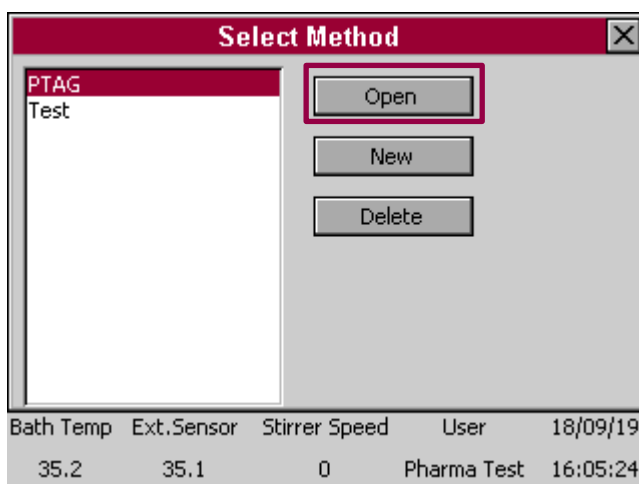
Only when the vessels are covered the temperature of the bath and the media inside the vessels will be within the mentioned limits. If the laboratory temperature is around  $20\text{-}23^{\circ}\text{C}$  you may need to increase the bath temperature to  $37.5^{\circ}$  to get  $37.0^{\circ} \pm 0.5^{\circ}\text{C}$  inside the vessels.

### 7.2 Running a Test Using a Method

This section explains how to run a test based on a pre-defined method.

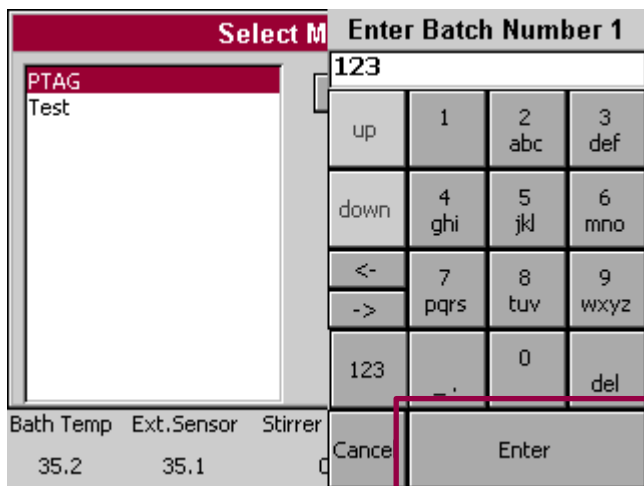


From From the main menu select “Select Method”.

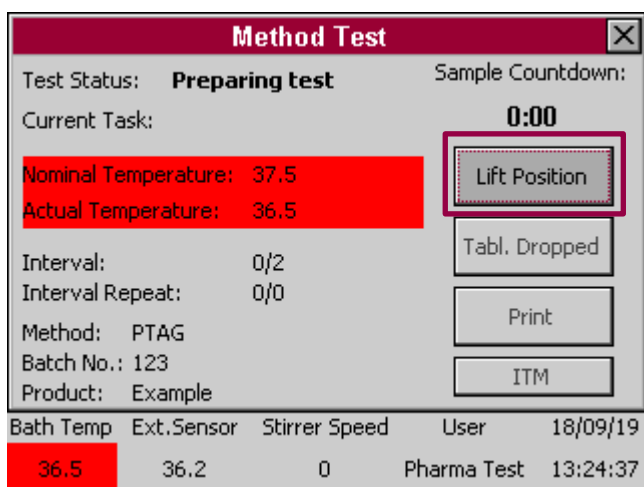


Select t Select the method to use from the list.

Select “Open” to confirm and to proceed.



Enter the batch number and confirm to proceed.



The instrument will now start the heating system to reach the nominal temperature.

In case the head is not yet in the proper position according to the setting in the method file, the instrument will prompt the user to move the head to that position.

Using a method, you must drive the lift to the position programmed in the method.

Press the "Lift Position"-button to move the head. Refer to the Lift Control section for more details on how to move the lift.



The two LEDs on the front of the heater and pump module light up. The green LED on top signals that the pump is currently turned on.

Make sure that the bath control sensor (connected to the pump module, metal hull with thread) is inserted to the water bath!

The red LED on the bottom signals that the heater is currently turned on. It will start flickering when the temperature measured by the control sensor is close to the target temperature. This signals that the heater is now pulsing in order to prevent the water temperature from rising above the target temperature. The pulsing is no error! It will also pulse when maintaining the temperature in the water bath.

**Method Test** [X]

Test Status: **Preparing test** Sample Countdown:

Current Task: **0:00**

Nominal Temperature: 37.5  
Actual Temperature: 36.5

Interval: 0/2  
Interval Repeat: 0/0

Method: PTAG  
Batch No.: 123  
Product: Example

Lift Position  
Tabl. Dropped  
Print  
ITM

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
36.5	36.2	0	Pharma Test	13:24:37

On the display the temperature information changes to a red color to indicate that the heating is active and that the nominal temperature is not yet reached. This is also shown in the status line.

**Method Test** [X]

Test Status: **Preparing test** Sample Countdown:

Current Task: **Drop tablets** **0:00**

Nominal Temperature: 37.5  
Actual Temperature: 37.6

Interval: 0/2  
Interval Repeat: 0/0

Method: PTAG  
Batch No.: 123  
Product: Example

Lift Position  
Tabl. Dropped  
Print  
ITM

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.6	37.3	0	Pharma Test	13:32:18

Once the head is in the proper position and the temperature of the water bath has reached the nominal setting, the instrument will prompt the user to drop in the tablets. Press the "Tabl. Dropped" button as simultaneously as possible while dropping the tablets to confirm, that the tablets have been inserted and to start the stirring.

In case the optional TMA automated tablet magazine is installed, the tablets will be dropped automatically and the stirrers and the time measurement will be started.

**Method Test** [X]

Test Status: **Start** Sample Countdown:

Current Task: **Wait for interval** **4:51**

Nominal Temperature: 37.5  
Actual Temperature: 37.5

Interval: 1/2  
Interval Repeat: 1/2

Method: PTAG  
Batch No.: 123  
Product: Example

Lift Position  
Abort  
Print  
ITM

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.5	37.3	51	Pharma Test	13:32:42

The test is now running and the instrument will count down to the next sampling interval.

**Method Test**

Test Start Time: 13:32:33  
 Test End Time: 13:52  
 Next Sample at: 13:37

**Sample Countdown:**  
**2:08**

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.6	37.5	50	Pharma Test	13:35:25

If you do not touch the display for a period of time, the display will switch to a mode where important information is displayed in an enlarged font. This way the user can keep critical data in view even when he does not stay in front of the instrument during the whole test.

In this screen the test start time, test end time and the time for taking the next sample can be seen.

**Method Test**

Stirrer Nr	Nominal Speed	Actual Speed
1	50	51

**Sample Countdown:**  
**1:18**

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.6	37.4	51	Pharma Test	13:36:15

In this screen the nominal and actual speed is shown as well as the sample countdown time.

**Method Test**

Nominal Bath Temperature: 37.5  
 Actual Bath Temperature: 37.5

Extr. Sensor: 37.4

**Sample Countdown:**  
**0:12**

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.5	37.4	51	Pharma Test	13:37:21

Here you can see the nominal and actual bath temperature as well as the external sensor temperature.



**Method Test**

Test Status: **Start**      Sample Countdown:

Current Task: **Wait for interval**      **1:12**

Nominal Temperature: 37.5  
 Actual Temperature: 37.6

Interval: 1/2  
 Interval Repeat: 1/2

Method: PTAG  
 Batch No.: 123  
 Product: Example

Lift Position  
 Abort  
 Print  
 ITM

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
37.6	37.4	50	Pharma Test	13:36:21

The sample interval has been reached. The instrument informs the user by an audible signal to draw the samples now.

In case the optional EPE sampling system is installed, it automatically starts to move into the vessels before the interval occurs ("Pretime"), to be ready to draw samples at the exact point of the interval. This pre-time can be programmed in the instrument settings. An audible signal announces the pre-time.

The countdown for the sampling time starts 0:30 seconds down to 0:00 seconds.

**Method Test**

Test Status: **Test finished**

Current Task: **No task**

Interval: 2/2  
 Interval Repeat: 1/1  
 Method: PTAG  
 Batch Nr.: 123

**Sample Countdown:**

**0:00**

Bath Temp    Ext. Sensor    Stirrer Speed    User    18/09/19

36.3          36.1          0          Pharma Test    13:38:12

Stand By

The test has been concluded. You can use the print button to print-out the run time report in case the optional PT-RP80 report printer is connected. (only if the printer is activated in the firmware. Activation/Deactivation must be done by the Pharma Test Service!)

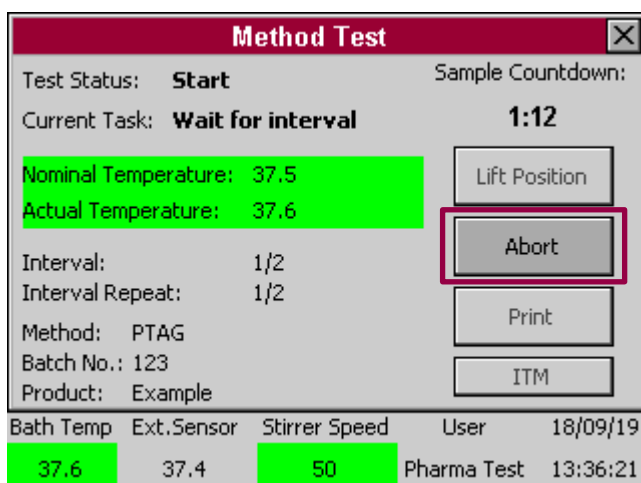
When you leave this screen, the report data is discarded, so make sure you have made all print-outs you require.

### 7.2.1 Example Print Out of Run Time Report

RUN TIME REPORT =====	<u>Explanation of Print Out:</u>
PTWS 820D	Type of the instrument (PTWS 820D)
S/N: 24638	Serial number of the instrument
V: 01.01	Firmware version installed on the instrument
Print Date / Time: 18/07/18 13:52:44	Date (dd/mm/yyyy) and time (hh:mm:ss) of this print out
USER NAME: Pharma Test	Name of the user currently logged in
METHOD NAME: PTAG	Name of the method used for this test
BATCH: 1234	Batch number entered at the start of this test
BATH TEMP NOM: 37.5	Nominal bath temperature from the method for this test
BATH TEMP ACT: 37.5	Actual bath temperature at time of the print out
LIFT POS: USP 1+2	Name of the lift position from the method for this test
DURATION: 0:5	Duration setting from the method for this test
SPEED NOM1: 100	Nominal speed setting from the method for this test
SPEED 1: 100	Actual speed measured at the time of print out
I.-REPEAT1: 1	First interval repetitions
I.-DELAY1: 0:2	First interval delay
I.-REPEAT2: 2	Second interval repetitions
I.-DELAY2: 0:3	Second interval delay
TEST STATUS: NO ERRORS	Current status of the test
START: 18/07/18 13:46	Start date and time of the test
END: 18/07/18 13:52:06	End date and time of the test (if already finished)
-----	
INT.1: 1/1	Occurrence of first interval
03/02/2015 13:49:06	Date and time of first interval
BATH TEMP ACT.: 37.5	Actual bath temperature when first interval occurred
ITM ACT1: 37.5	ITM temperatures (only if ITM is installed)
ITM ACT2: 37.5	
ITM ACT3: 37.5	
ITM ACT4: 37.5	
ITM ACT5: 37.5	
ITM ACT6: 37.5	
ITM ACT7: 37.6	
ITM ACT8: 37.5	
-----	
INT.2: 1/2	Occurrence of second iteration of first interval
03/02/2015 13:52:06	
BATH TEMP ACT.: 37.5	
ITM ACT1: 37.6	
ITM ACT2: 37.6	
ITM ACT3: 37.5	
ITM ACT4: 37.5	
ITM ACT5: 37.4	
ITM ACT6: 37.5	
ITM ACT7: 37.6	
ITM ACT8: 37.5	
-----	
INT.2: 1/1	Occurrence of second interval
03/02/2015 13:55:06	
BATH TEMP ACT.: 37.5	
ITM ACT1: 37.5	
ITM ACT2: 37.5	
ITM ACT3: 37.6	
ITM ACT4: 37.5	
ITM ACT5: 37.4	
ITM ACT6: 37.5	
ITM ACT7: 37.6	
ITM ACT8: 37.5	
.....	
OPERATOR NAME	Space to write down name of the operator
.....	
SIGNATURE	Space for the operator's signature

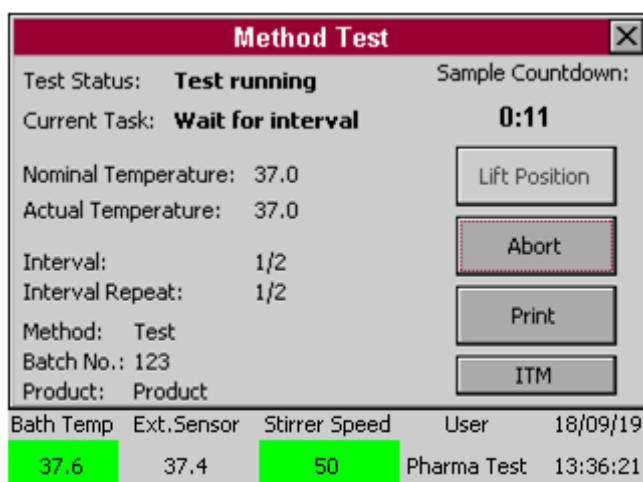
Figure 12: Example Run Time Report

### 7.2.2 Aborting a test before the duration has passed



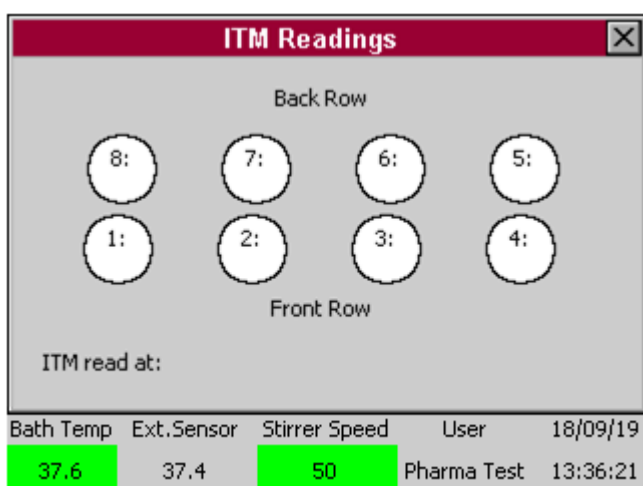
Use the "Abort"-button to terminate a running test. You will have to confirm that you want abort the test before it is finished.

### 7.2.3 Reading the ITM Temperature Results



In case the optional ITM individual temperature monitoring system is installed, the temperature probes automatically read the vessel temperatures during the sampling intervals when the EPE is inside the medium.

Use the "ITM"-button to display the latest temperature results.



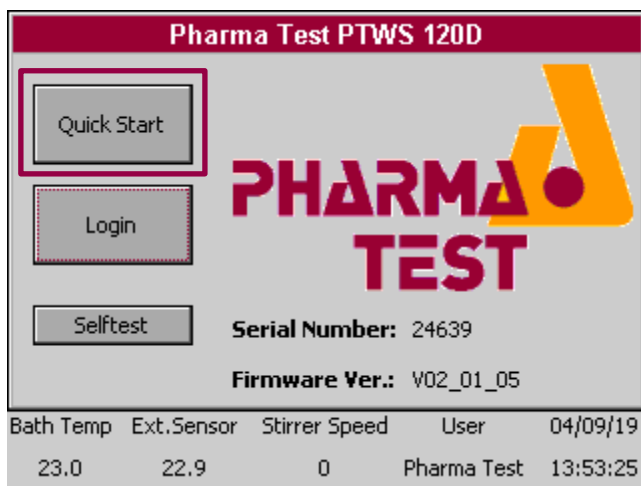
This screen shows the latest ITM temperature results for each vessel and when the values were read.

This information is also included in the run time report.

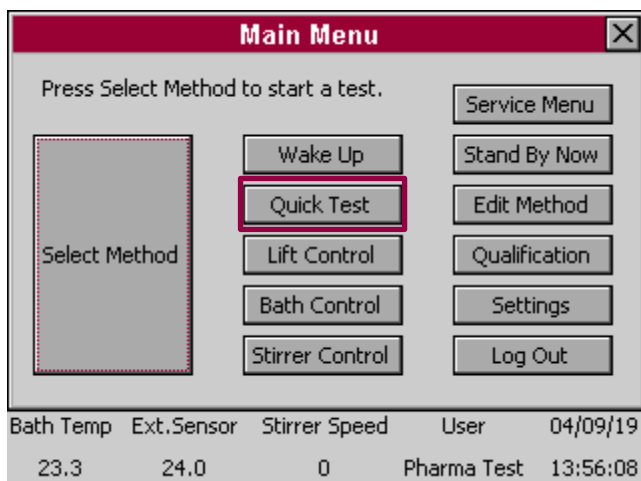
Close the screen to return to the test screen.

## 8 Running a Test Using the Quick Test Function

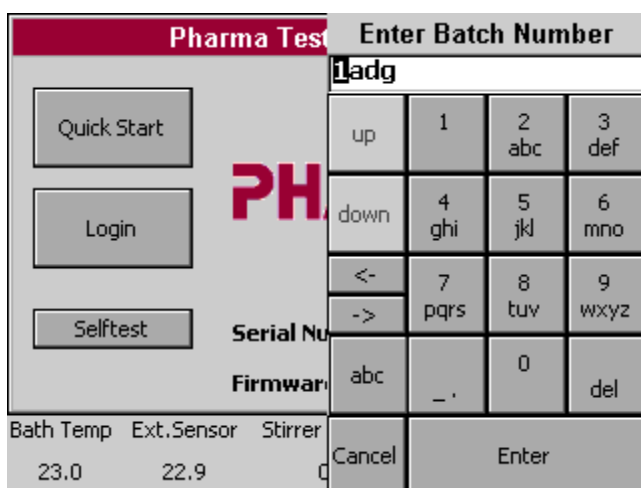
The Quick Test function can be used to run a test without programming a method beforehand. The sampling interval function is not available in Quick Test. Quick Test is designed to be able to be used with only an minimum of data required from the user.



You can select "Quick Start" from the start screen without the need of logging in.

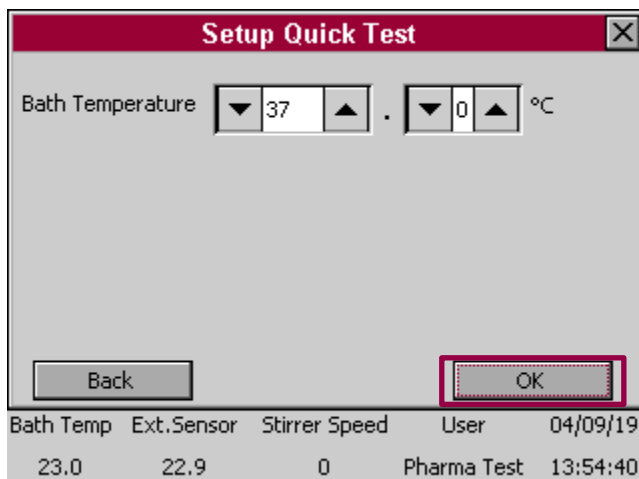


You can also select "Quick Test" from the main menu after logging in.

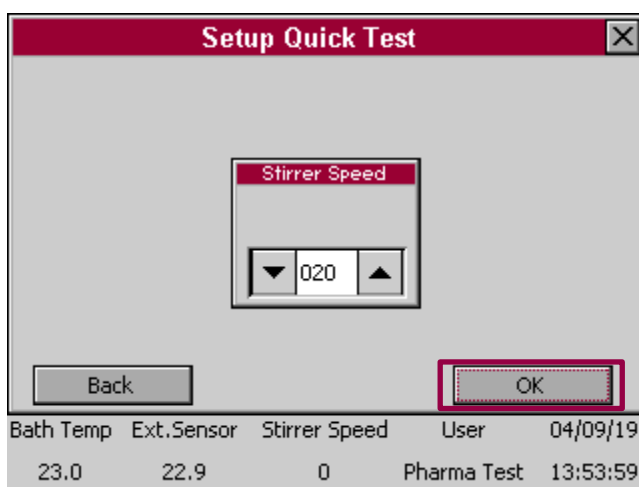


A minimum of data has to be entered in order to start a Quick Test. The date is entered in the same manner as when programming a method. In Quick Test the data is not saved and has to be re-entered for each new Quick Test.

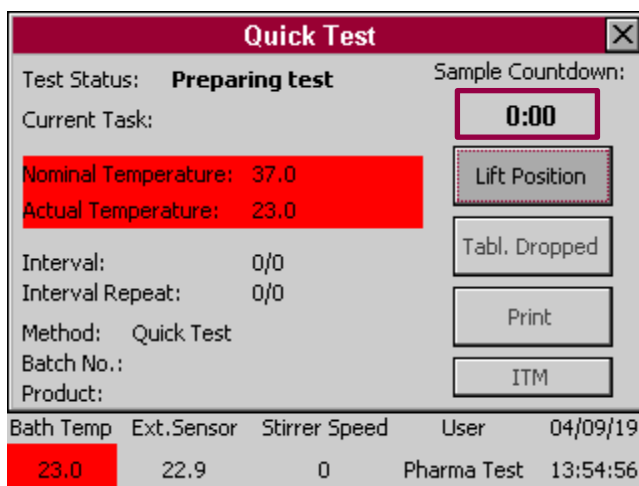
First enter the batch number and confirm to proceed.



Then enter the nominal bath temperature for the test and select "OK" to proceed.



Enter the nominal stirring speed and select "OK" to proceed.



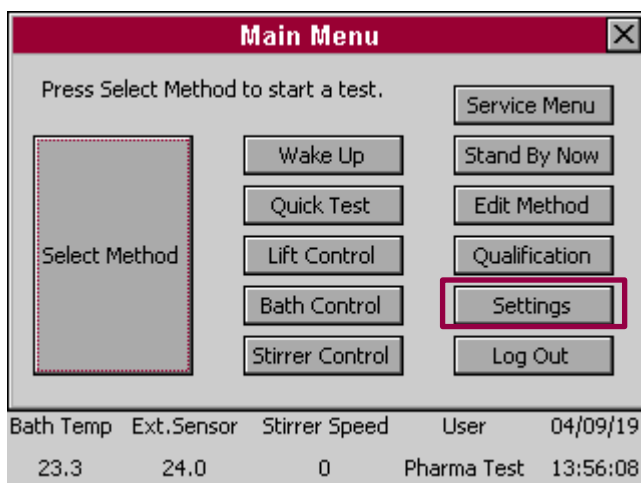
The actual test screen is very similar to the method test screen. Since intervals are not available, instead of a countdown timer the run time will count up. The instrument starts the heating process automatically and as soon as the nominal temperature is reached in the water bath, the tablets may be dropped in.

If an EPE is installed, the button "Lift Position" changes to "EPE". Pressing this button, you will be lead to the EPE positioning window. This window will contain a "Sample"-Button. Pressing this button, you can manually trigger a sampling device connected to the PTWS (pump, fraction collector etc.).

If no EPE is installed, the button "Lift Position" changes to "Sample". Pressing this button, you can manually trigger a sampling device connected to the PTWS (pump, fraction collector etc.). Refer to the method test section for more details on the test procedure.

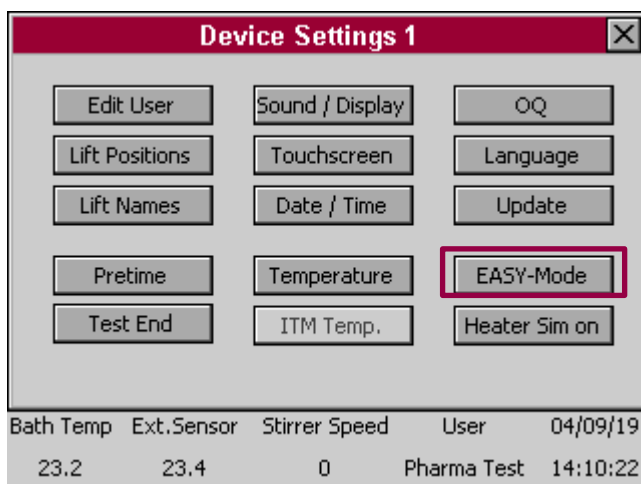
## 9 Easy Mode

The Easy Mode feature is especially relevant for manual instruments like the PTWS 120D. No login or user rights are required to use the new Easy Mode. This mode is reduced to the bare minimum of necessary entries: simply set a rotation speed between 20 to 250 rpm and to start the heating of the water bath a target temperature from 25.0 °C up to 45 °C. The lift can be driven up and down by pressing the corresponding buttons. The stirring rotation can be started at any time and a timer starts to run, no matter which position the lift head is currently. The possible range of the lift head movement in this mode is from the upper reference position and to the USP 1+2 working position. The option to use the Easy Mode can be activated by the administrator in the setup menu of the PTWS instrument.

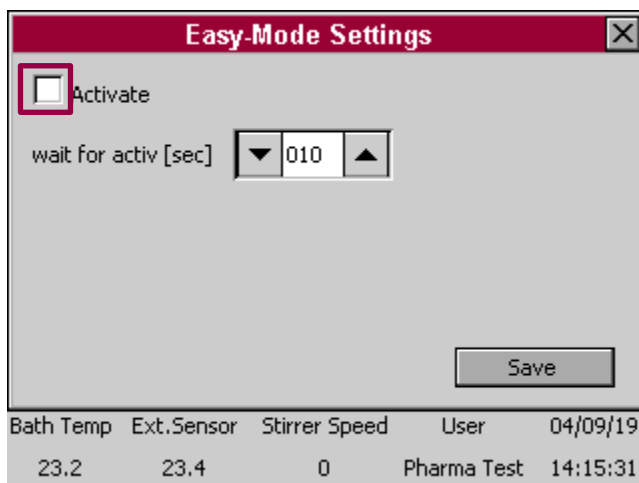


You can select “Settings” from the main menu after logging in.

Please note: You have to be logged in as “Administrator”



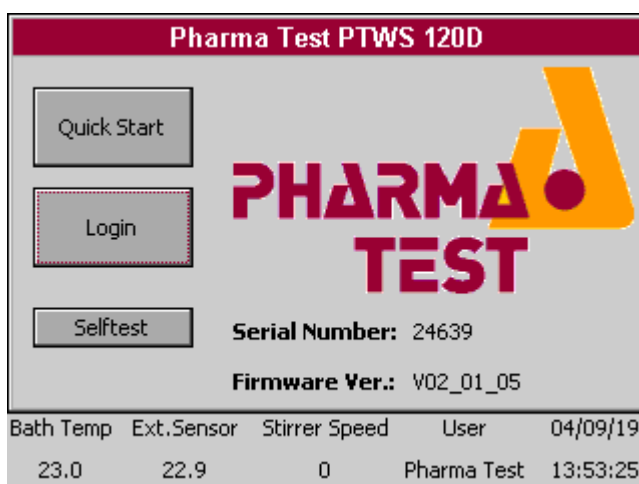
Here you will find the setting “Easy Mode”. Enter the setting by pressing the button.



If you want to activate the Easy-Mode you have to set a hook in the marked field.

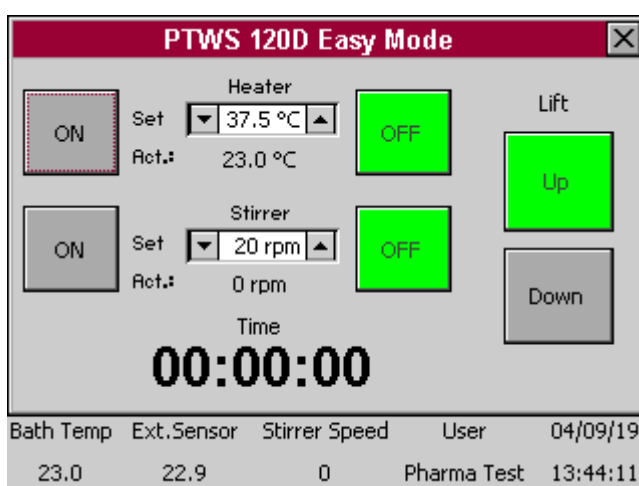
Afterwards you have to choose the aiting time, until the Easy Mode will appear on the start screen. You can choose between 001 – 999 seconds.

Press “Save” to save your current settings.



In the case you activated the Easy Mode you can use it afterwards by entering the start screen.

Now you have to wait the set time in the screen “Easy Mode Settings”.

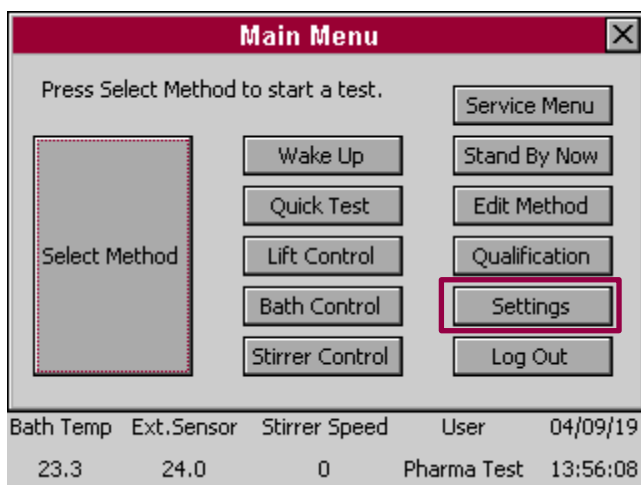


As soon as the time has passed away the Easy Mode will suddenly appear and you will have different options to handle the dissolution tester:

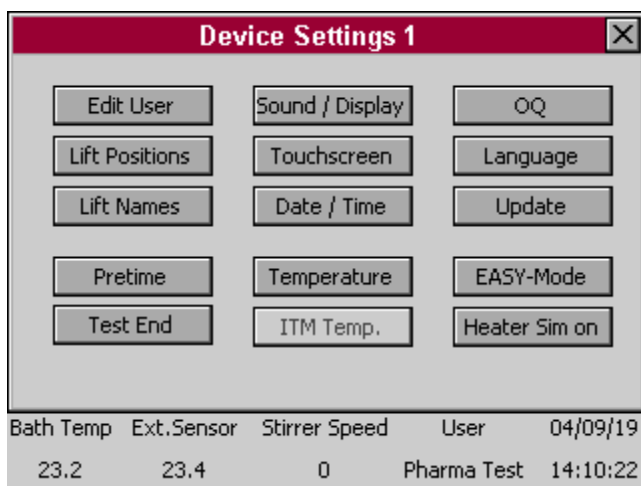
- Set rotation speed between 20 to 250 rpm
- start the heating of the water bath from 25.0 °C up to 45 °C
- lift can be driven up and down
- The stirring rotation can be started at any time and a timer starts to run
- Move the lift head stepless between the upper reference position and to the USP 1+2 working position

You can easily close the Easy Mode by pressing the “x” in the upper right part and continue with a normal method and test sequence or other settings. The screen shown will be the start menu.

## 10 Device Settings



From the main menu select "Settings".



See below for a description of the various instrument settings.



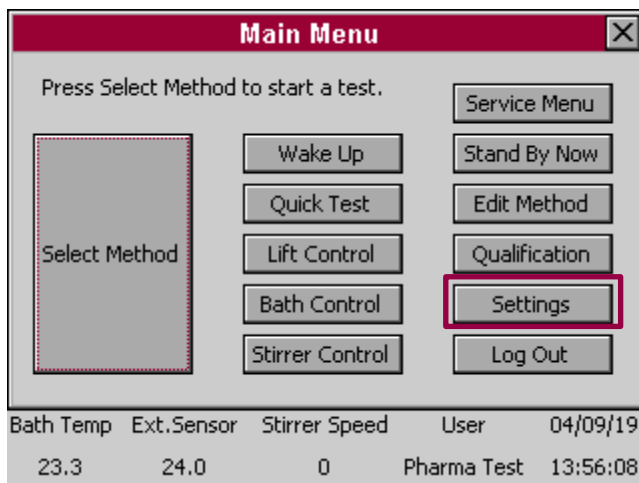
Menu Item	Description
Edit User	Edit user names and password. See the section on user management above for more details.
Lift Positions	Program Lift positions and EPE positions in case the optional EPE system is installed.
Lift Names	Edit lift position names and EPE position names in case the optional EPE system is installed.
Pre Time	<p>This setting determines at how much time before a sampling interval occurs, the EPE manifold starts to move into the sampling position. This is pre-set at the factory and does not have to be changed under normal circumstances.</p> <p>The pre-time is announced by an audible signal. Even for instruments without the optional EPE system installed, this can be useful. This way the pre-time signal would inform the user that he should return to the instrument and to get ready for sampling. Once the sampling interval occurs a second signal sounds. Now the user can start taking the samples.</p>
Test End	Program how the Heating System and Lift should proceed at the end of a test run
Sound / Display	Adjust loudness of the speaker and brightness of the display.
Touchscreen	Calibrate the touch screen.
Date / Time	Edit date and time settings.
Temperature	Adjust the temperature settings. See the section on qualification and adjustment below for more information on this.
ITM Temp.	Adjust the ITM temperature settings in case the optional ITM system is installed. See the section on qualification and adjustment below for more information on this.
OQ	Here you can set the OQ interval and select the relevant tests
Language	Here you can choose between German and English (or another language which could be programmed)
Update	Install firmware updates. See the section below on details about updating the instrument firmware.
Easy Mode	This mode is reduced to the bare minimum of necessary entries: simply set a rotation speed between 20 to 250 rpm and to start the heating of the water bath a target temperature from 25.0 °C up to 45 °C. The lift can be driven up and down by pressing the corresponding buttons. The stirring rotation can be started at any time and a timer starts to run, no matter which position the lift head is currently.
Heater Sim on	<p>This activates a demonstration mode for the heating system. When this mode is active, the heating system is deactivated internally and when it is activated by the user, the instrument reports the actual temperature as equal to the nominal temperature, without actually turning on the heater.</p> <p>This function is useful for demonstration purposes during user trainings for example.</p>

Table 10: Device Settings

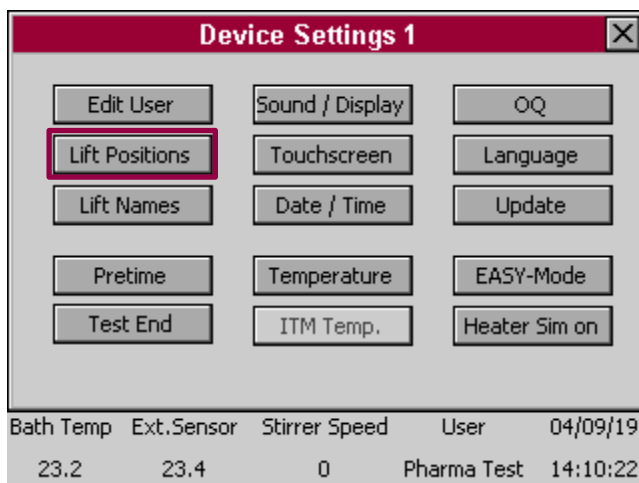
## 10.1 Lift and EPE Positions and Names

To accommodate the height requirements of different tools it is possible to program up to eight positions for the head of the PTWS 120D/120S/820D/1420. Each position also has a freely editable name by which it is identified during method creation. In case the optional EPE system is installed, eight positions can be programmed for it in the same way.

### 10.1.1 Edit Lift Positions

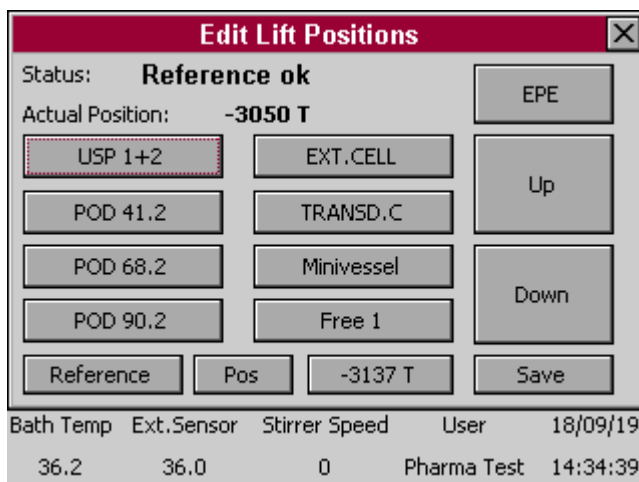


From the main menu select "Settings".



Then select "Lift Positions".

In case the lift had not been referenced since the instrument has been turned on, this can be done by pressing and holding the "Reference"-button until it turns green and the lift has reached its upper home position.

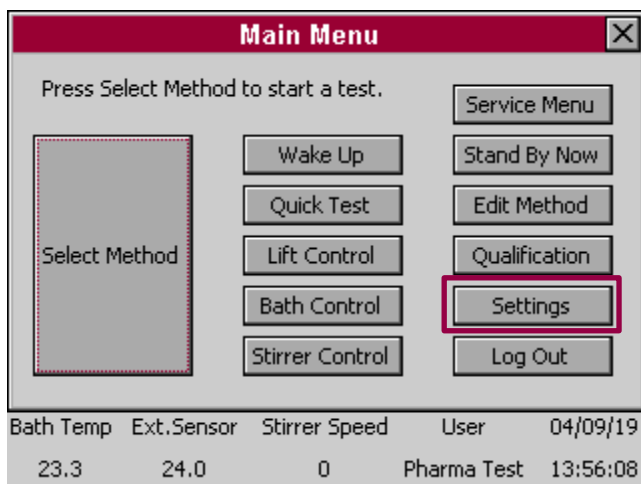


Use the "Up"- and "Down"-key to move the lift to the desired position. The actual position is displayed here in micro steps and counted from the home position (one microstep is ~0.08mm).

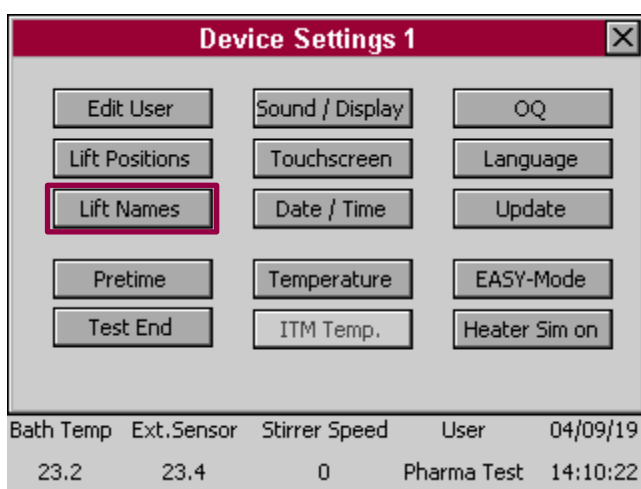
For fine tuning you can enter a discrete position by pressing the (here) "-3137 T" button. Now you can enter any other position and move the lift to this position using the "Pos" button. To save the current position of the lift press and hold the button of the lift position you want to overwrite.

Store the changings by pressing "Save".

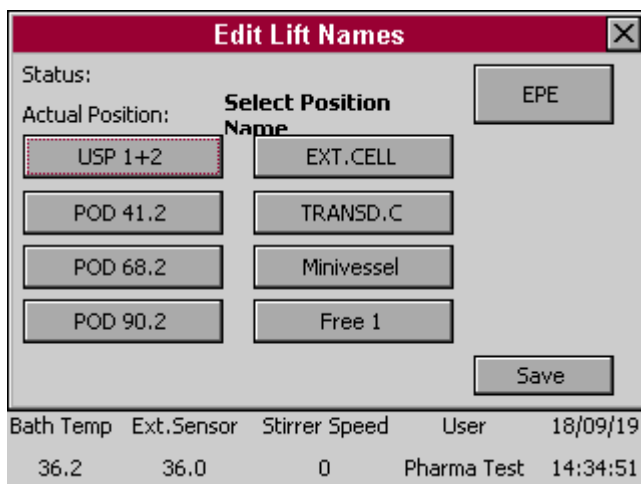
## 10.1.2 Edit Lift Names



From the main menu select "Settings".



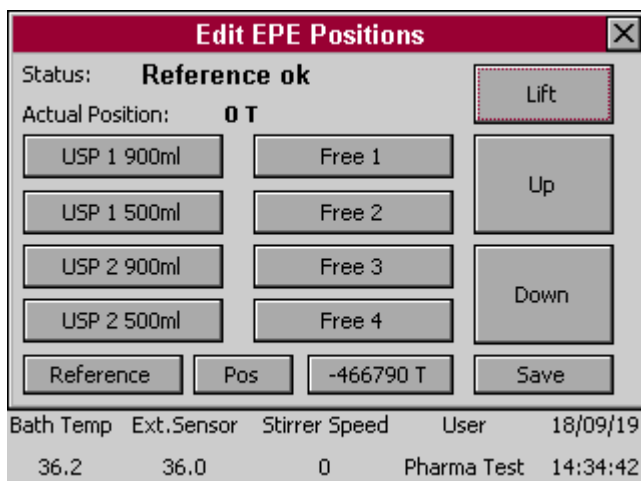
Then select "Lift Names".



Press the button with the lift name you want to change. The onscreen keyboard will appear and you can edit the name. The change will be reflected directly on this screen. These names are shown during method creation and are printed on the run time report.

Store the changes by pressing "Save".

### 10.1.3 Edit EPE Names (only if optional EPE is installed)

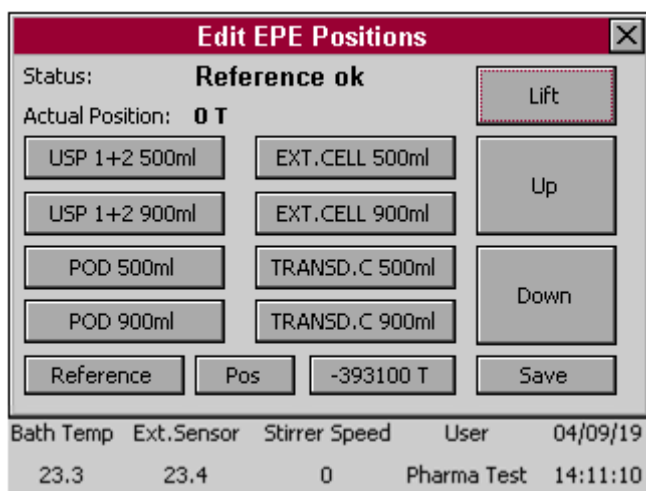


From the “Edit Lift Names” screen select “EPE”.

Press the button with the EPE name you want to change. The onscreen keyboard will appear and you can edit the name. The change will be reflected directly on this screen. These names are shown during method creation and are printed on the run time report.

Store the changes by pressing “Save”.

### 10.1.4 Edit EPE Positions (only if optional EPE is installed)



From the “Edit Lift Positions” screen select “EPE” to access the “Edit EPE Positions” screen. This menu is used the same way the “Edit Lift Positions” menu is used.

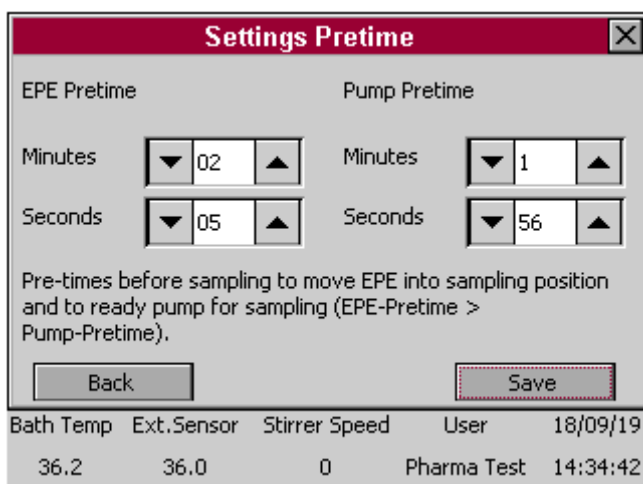
Use the “Up”- and “Down”-key to move the EPE to the desired position. The actual position is displayed here in micro steps and counted from the home position. (1000 microsteps are ~0.3mm).

For fine tuning you can enter a discrete position by pressing the (here) “-393100T” button. Now you can enter any other position and move the lift to this position using the “Pos” button.

To save the current position of the EPE press and hold the button of the EPE position you want to overwrite.

Store the changes by pressing “Save”.

## 10.2 Pretime



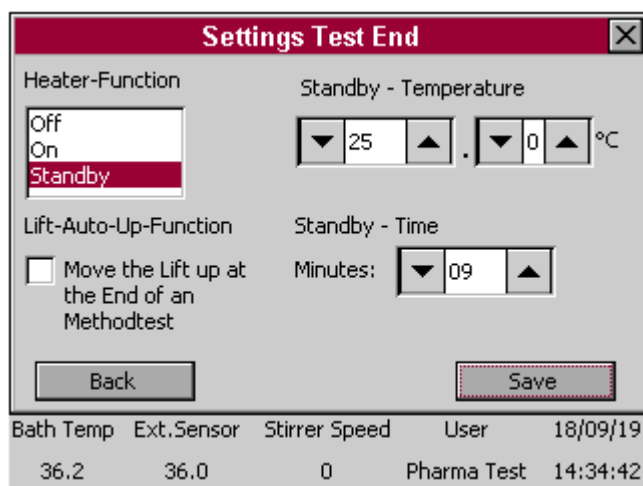
With this setting you set the time the EPE starts to move down into the vessels BEFORE the sampling time is reached. This time is preset to 30 seconds and under normal circumstances it needn't to be changed.

It's sufficient to set the time once to the longest needed moving time at all (normally 30s). For special applications, e.g. a very low immersion depth, the moving time is maybe significant lower. If the user wants the sampling tubes to be inserted to the sampling media as short as possible, he can reduce this time.

Especially syringe pumps (PT-SPx) need some time for preparation (deaerating the hoses, flushing...). This preparation delays the moment for the "real" sampling. To compensate this delay, you can set a "Pump Pretime" which means, the trigger signal to the pump is sent earlier. The concrete time must be measured for every pump individually. Of course, the EPE must be inside the media when the pump is started. So the Pump Pretime is always limited to the setting of the EPE Pretime. We recommend to measure the time for the pump preparation, set the EPE Pretime to the "Preparation time + 15 seconds" and finally set the Pump Pretime to the measured preparation time.

NOTE: if the time set too low, the tubes maybe aren't in their intended sampling position when the sampling starts. In this case the sampling isn't EP/USP-conform. It's in charge of the user / administrator, to exclude this!

## 10.3 Test End

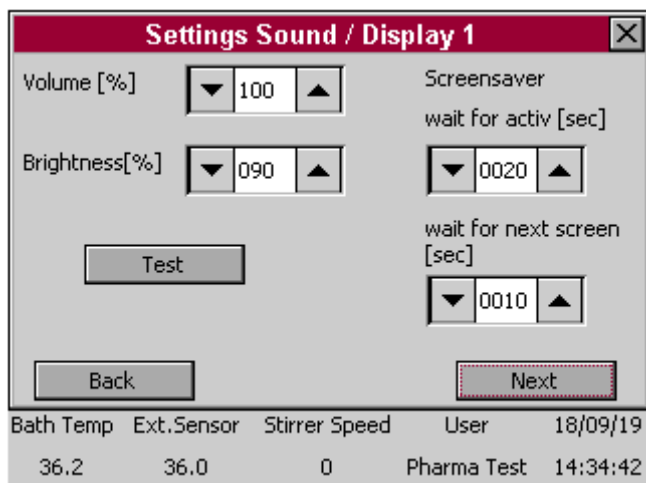


Here you can select the heater behaviour after the end of a method test (incl. all infinity steps). You can select if the heater should be turned "OFF", if it should remain "ON" with the method temperature or if it should heat to a "Standby" Temperature.

The Standby - Time is a (delay-)time in minutes (up to 99 minutes) the heater will continue heating with the method temperature until it will be set to the Standby temperature.

If the Heater-Function is set to „ON“, a warning message will appear in the Wake Up-Display (described in chapter 5.3).

## 10.4 Sound / Display



With „Volume [%]“ you can change the volume of the beeper. With button „Test“ you can check the volume.

With „Brightness [%]“ you can set the brightness of the display.

NOTE: Never set the brightness to „0“ (zero). This will cause a black display and you will have difficulties to rise the brightness again.

After the number of seconds you set at „Screensaver – wait for active“, the display (in test mode only) will start the screensaver if it isn't used anymore.

With „Screensaver – wait for next screen“ you set the toggle speed of the different test parameters.

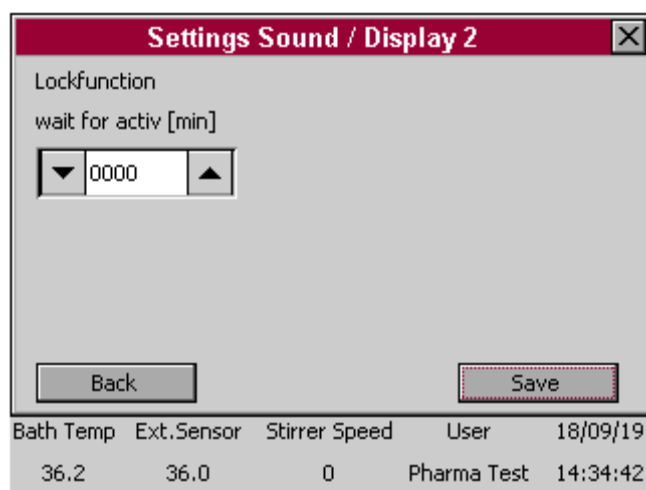
Press „Next“ to call page „2“.

Press „Back“ to return to page „1“.

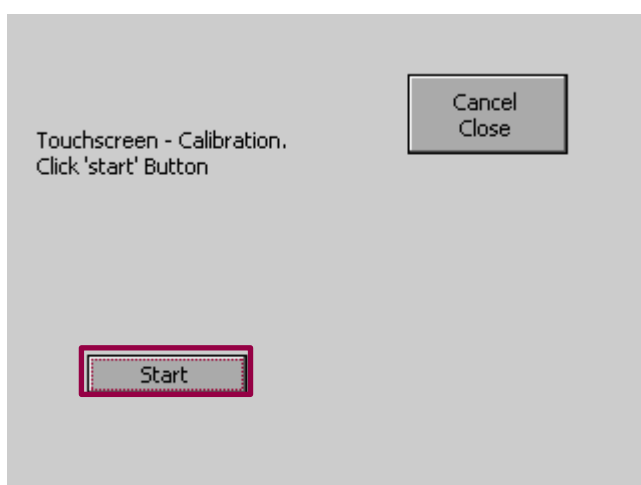
Lockfunktion: Set a time in minutes [min] if you want to lock the display if it isn't used for the set time. The current user logged in must then release the display by entering his password if he wants to use the display again (protection of unauthorized usage).

Set the Lockfunktion to „0000“ if you want to deactivate it (Default setting)

Changes on both pages (Display 1+ 2) will be saved only with pressing the „Save“-Button on page 2!

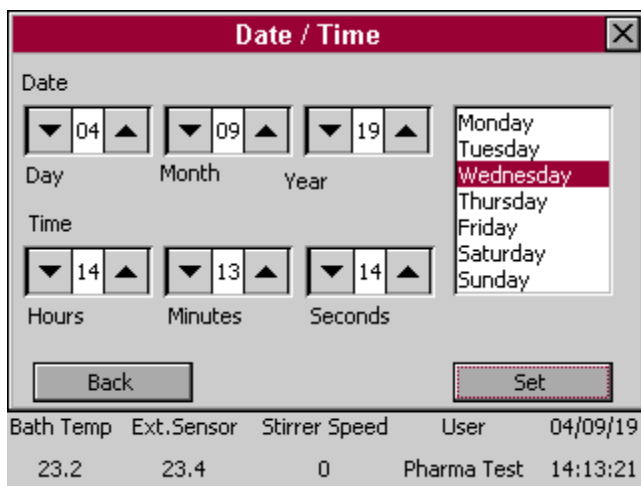


## 10.5 Touchscreen



In the Touchscreen Calibration Menu you can press „Start“ and „Cancel Close“ afterwards to confirm the calibration of the touchscreen.

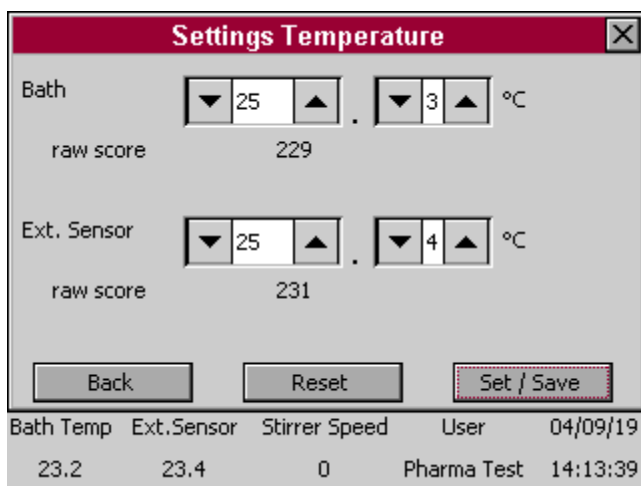
## 10.6 Date / Time



Here you can set the current Date and time and store it with „Save“.

Furthermore: Select the actual “day of the week” in the right table. This setting is important for a proper function of the Wake-Up mode!

## 10.7 Temperature



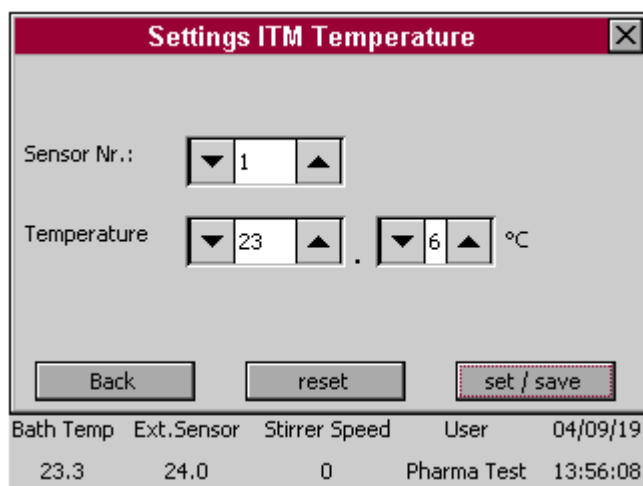
In the temperature settings you can adjust both the „Bath Temp“ (=control) and „Ext. Sensor“ (=hand) -sensor.

User a certified thermometer and set the measured temperature to both probes.

Store the changings by pressing “Save”.

Refer to chapter 13.2.1 for more information.

## 10.8 ITM Temperature



In the ITM-Temperature settings you can adjust the ITM probes

User a certified thermometer and set the measured temperature to every single ITM probe.

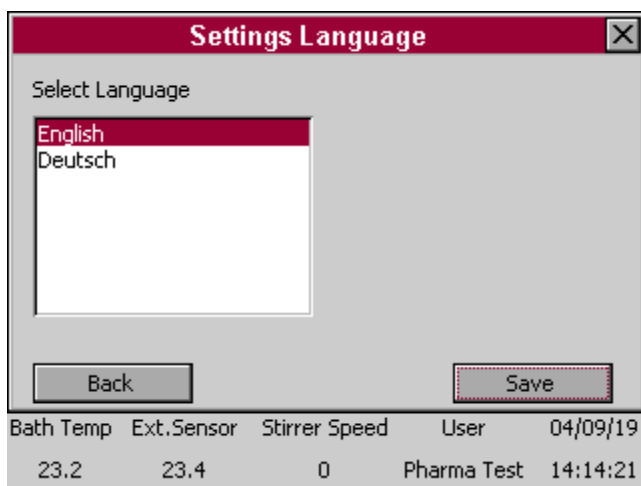
Store the changings by pressing “Save”.

Refer to chapter 13.2.2 for more information.

## 10.9 OQ

See Section 11 Qualification for more information.

## 10.10 Language



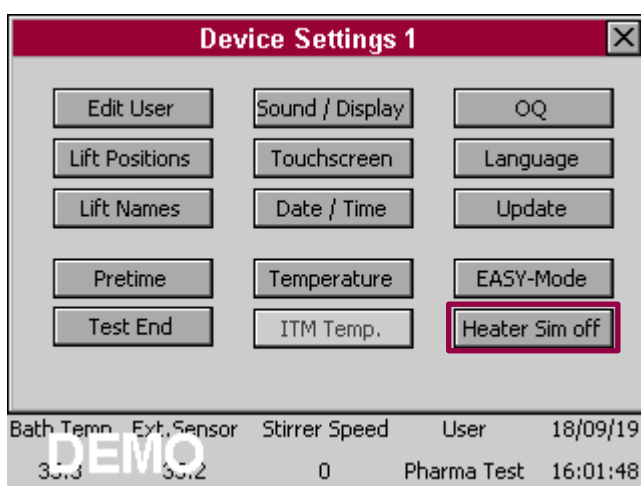
In this menu you can choose between the instruments language "English" and "Deutsch". The chosen language is marked with a dark red color in the back.

Press "Save" to save the current setting.

## 10.11 Update

See Section 16 for more information.

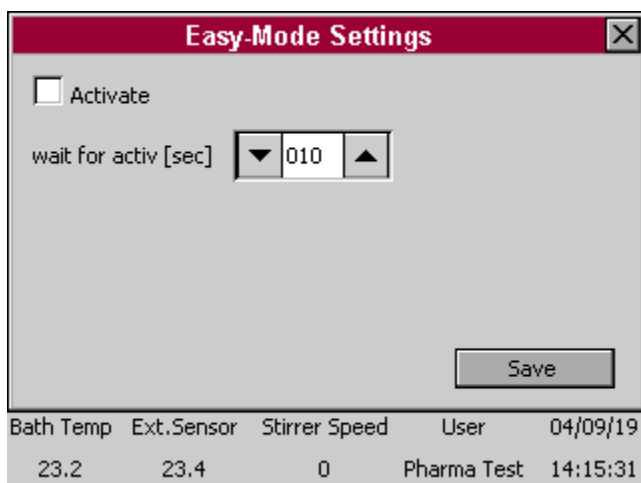
## 10.12 Heater Sim



After activating the Heater Sim, in the left corner the word "Demo" appears. Thereby the lower bar will not react to any temperature changes. The instrument now thinks, that the heater is in its optimal operation temperature.

Press the button again to turn off the Heater Sim again.

## 10.13 Easy Mode

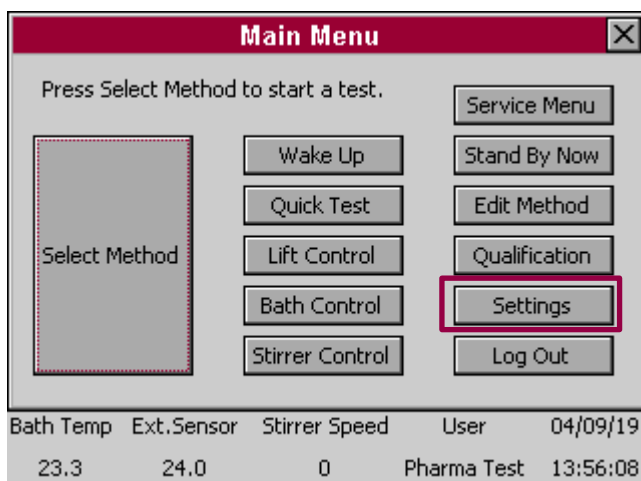


In this setup you can activate or deactivate the Easy Mode by putting a hook in the corresponding field. In addition, the wait time for the screen to appear in the start screen can be set here. Choose between 001 – 999 seconds.

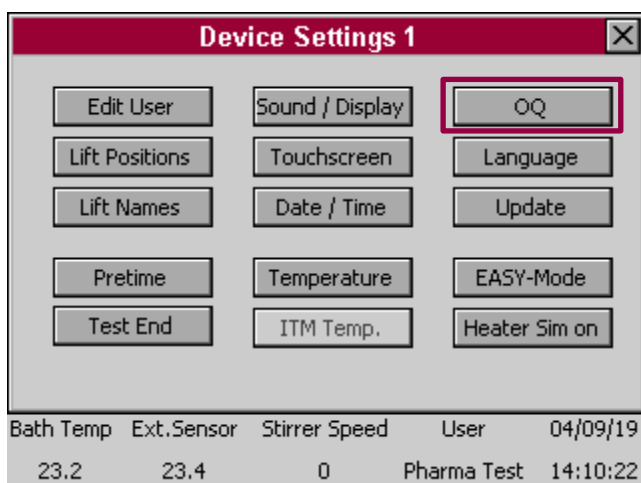
For more information refer to Section 9 "Easy Mode"



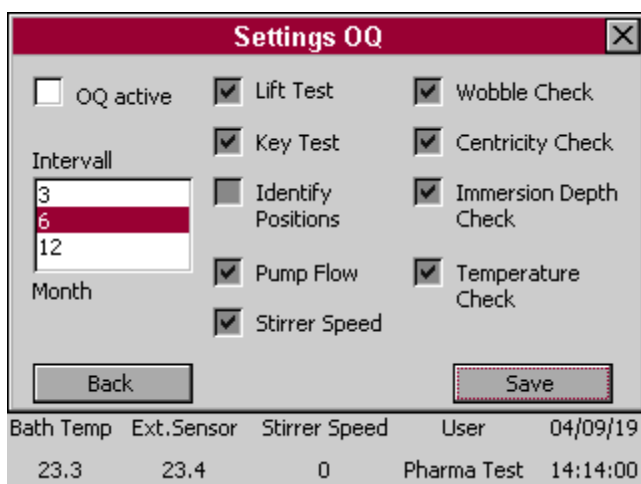
## 11 Qualification



Before the qualification can take place the test which will be performed have to be set. There enter from the main menu the section "Settings".



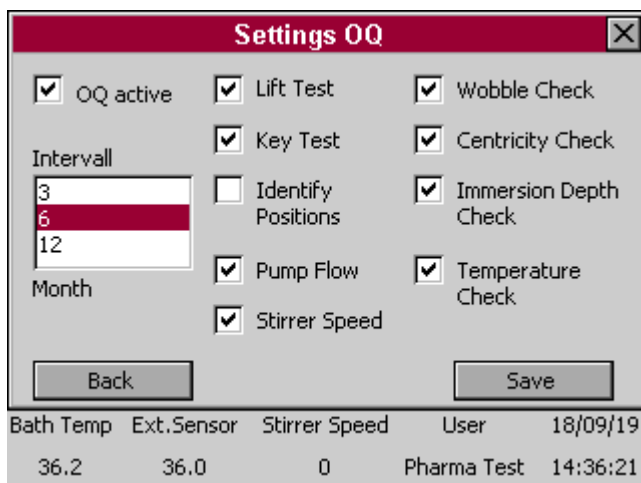
In the Device Settings 1 enter the section "OQ"



Here you can select what should be tested during a OQ procedure. The ticks on the right can be activated/deactivated as soon as the tick "OQ active" on the left is activated.

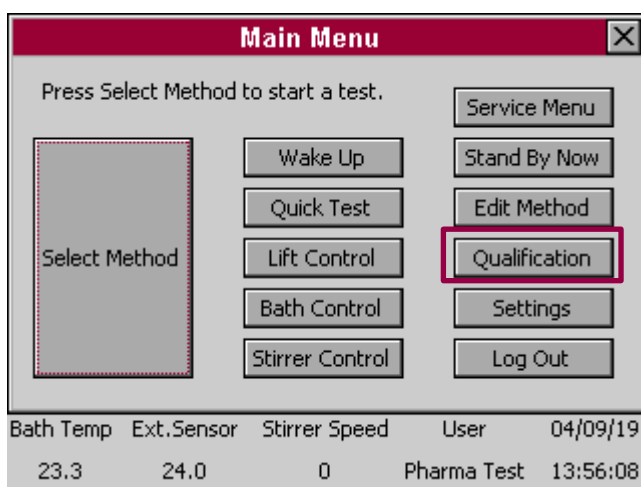
The selected tests can then be performed during a qualification (Using the submenu „Qualification“ called from the main menu). The deactivated tests are locked.

The selected tests remain released, even if you deactivate the „OQ active“ tick again.



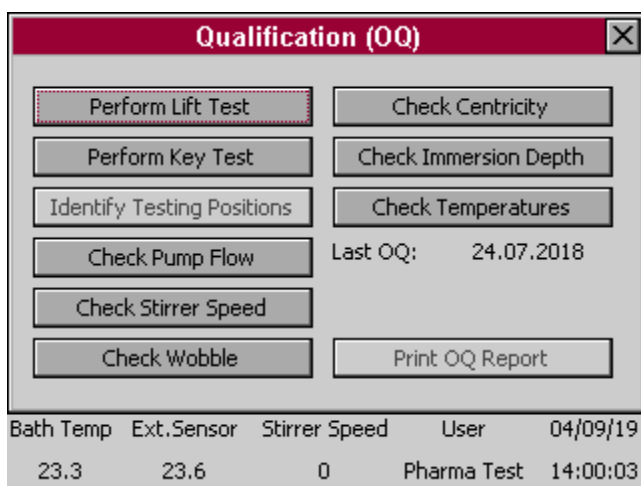
Additional, with the „OQ active“ tick you activate/deactivate the OQ-interval supervision. You can set the qualification period to 3, 6 or 12 month. With the OQ interval elapsed, an error message appears after turning on the instrument, showing that one (some) OQ-interval(s) is (are) due. If you call the submenu „Qualification“ in the main menu the elapsed OQ-tests are coloured red.

After performing the relevant test(s), the interval supervision of this test(s) starts anew. If you want to deactivate the interval supervision, remove the „OQ active“-tick in the settings.



To now perform the relevant qualification steps go back to the main menu and enter the section “Qualification”.

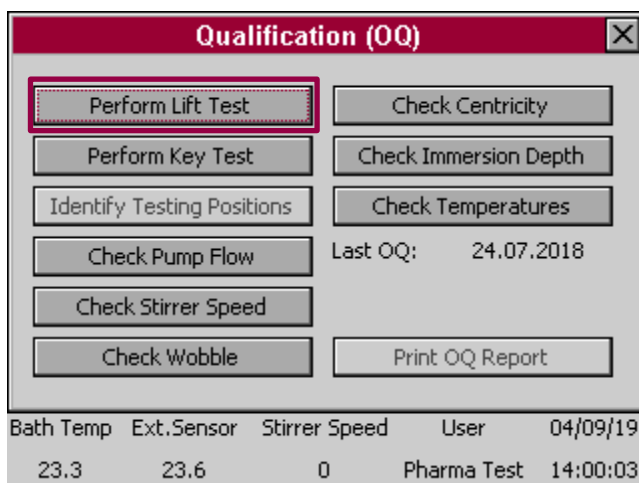
NOTE : It´s intended to perform allways all OQ tests completely and all together. Nevertheless every interal period is calculated separately for every single test.



In the Qualification menu you see the information „Last OQ:“ (here) 24.07.2018. This timestamp allways shows the last performed OQ, no matter what single test it was.

You avoid confusion if you always perform ALL activated tests during a OQ.

## 11.1 OQ Lift

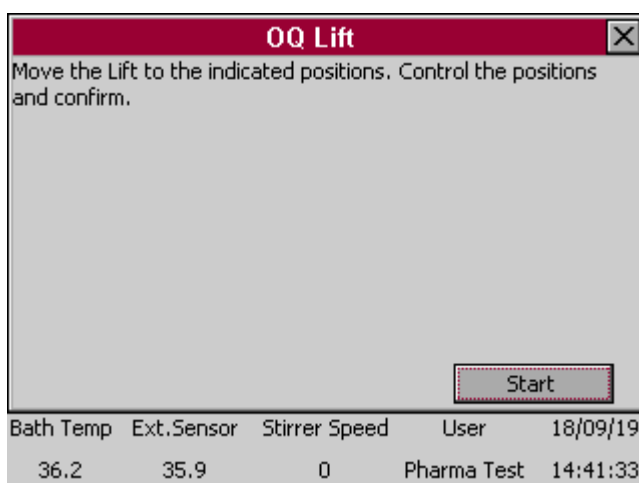


**Qualification (OQ)**

Buttons: Perform Lift Test, Check Centricity, Perform Key Test, Check Immersion Depth, Identify Testing Positions, Check Temperatures, Check Pump Flow, Last OQ: 24.07.2018, Check Stirrer Speed, Check Wobble, Print OQ Report

Bath Temp	Ext. Sensor	Stirrer Speed	User	04/09/19
23.3	23.6	0	Pharma Test	14:00:03

In this section you can check the lift performance.



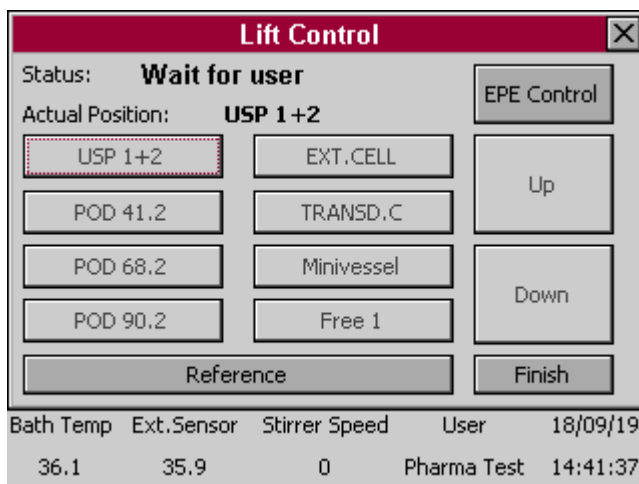
**OQ Lift**

Move the Lift to the indicated positions. Control the positions and confirm.

Start

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
36.2	35.9	0	Pharma Test	14:41:33

Press "Start" to drive to every set lift position and to control the raw data of every position.



**Lift Control**

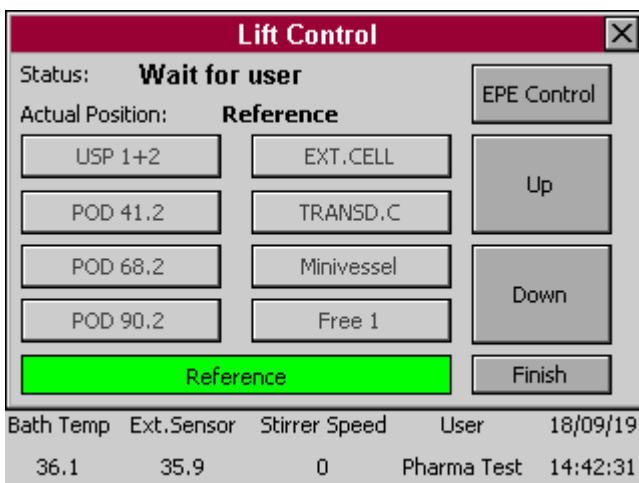
Status: **Wait for user**

Actual Position: **USP 1+2**

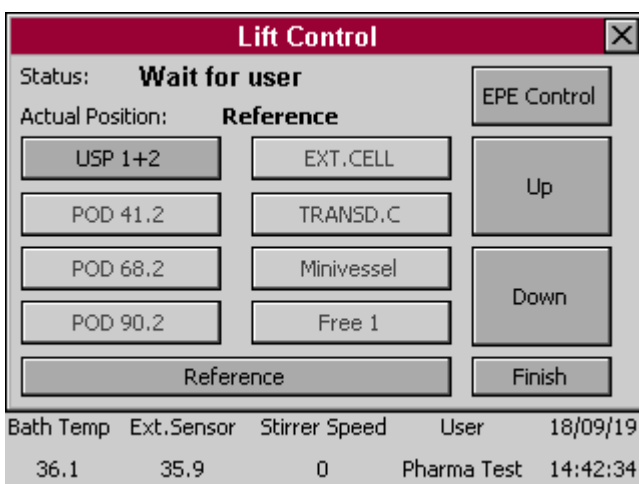
Buttons: USP 1+2, EXT.CELL, EPE Control, POD 41.2, TRANSD.C, Up, POD 68.2, Minivessel, Down, POD 90.2, Free 1, Reference, Finish

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
36.1	35.9	0	Pharma Test	14:41:37

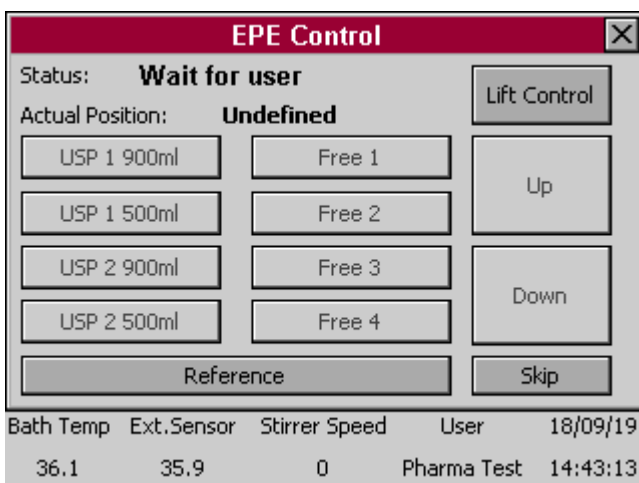
Here you can choose between Lift and EPE Control. In a first step press the button "Reference".



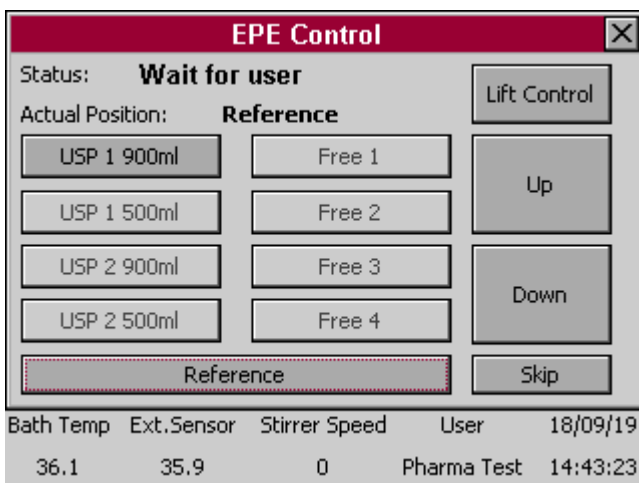
Now you are in the Reference Position.



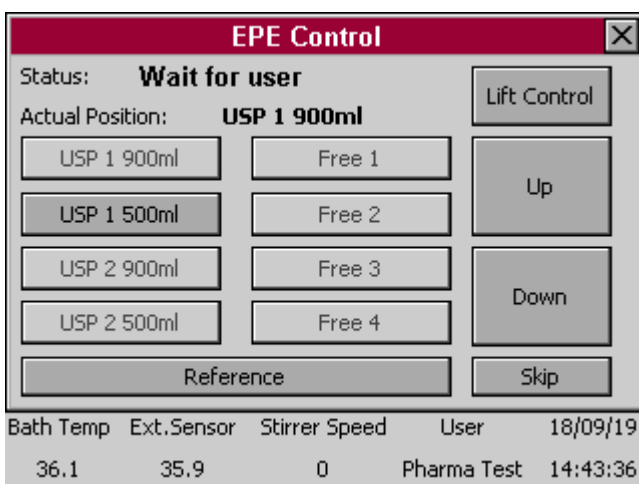
As you are now in the Reference position it is possible to use several buttons like the USP 1+2 button and the Up and Down button.



Here you can see the EPE Control. It is also necessary to first drive into the Reference position before you can check any other position.



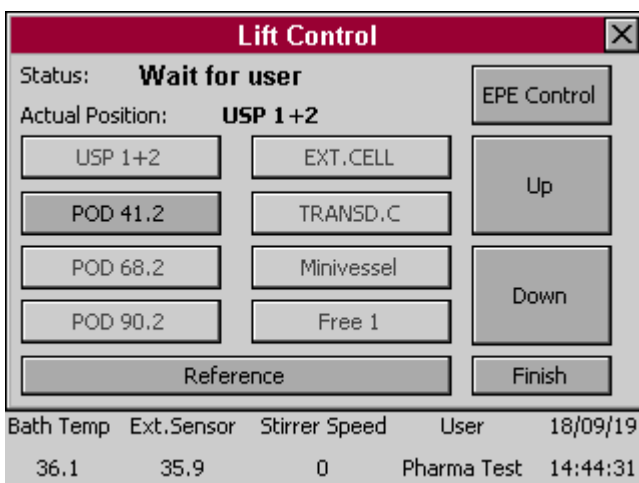
As soon as you are in the reference position you can drive to position "USP 1 900ml".



Now you are in the upper position. You are just able to press the next button "USP 1 500ml".

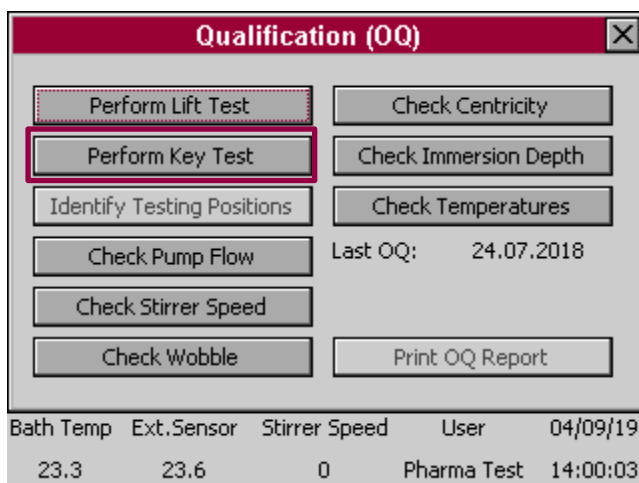
This way all different EPE positions will be hit one after the other.

You have the possibility to skip this screen to come back to the Lift Control.



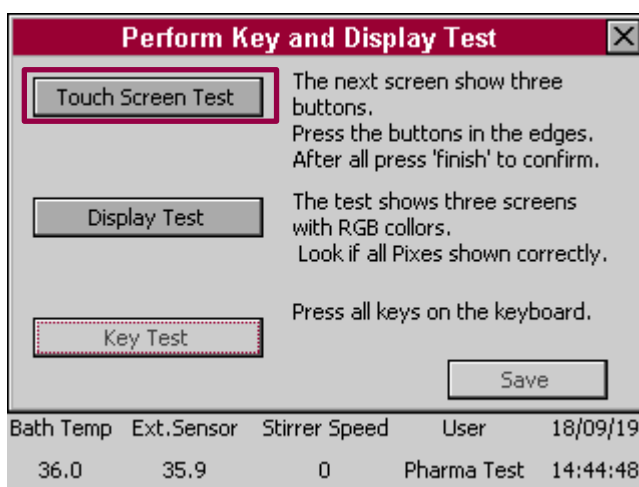
Here you can proceed further to the next positions in the Lift Control, here "POD 41.2".

## 11.2 Perform Key and Display Test

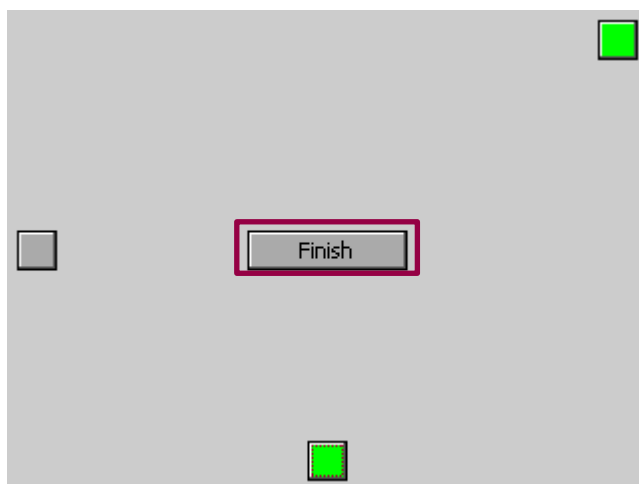


This section is valid to perform touchscreen and display tests.

Press "Perform Key Test" to continue.

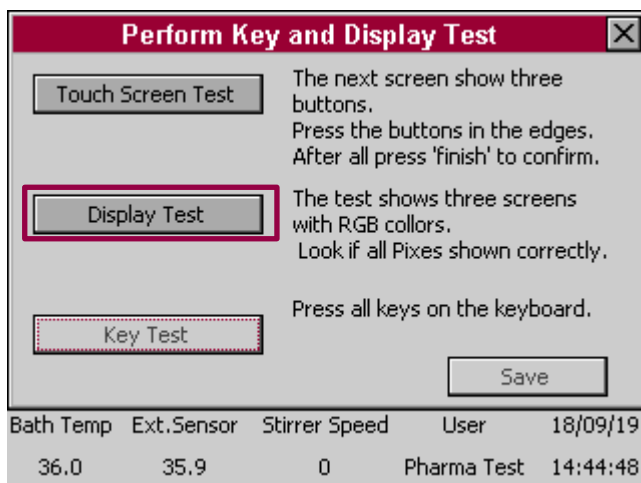


In a first step perform the touch screen test.



You have to press all three buttons in the upper right side, on the middle of the left side and in the middle of the bottom.

Afterwards press "Finish" to continue.



Now you can continue with the display test.



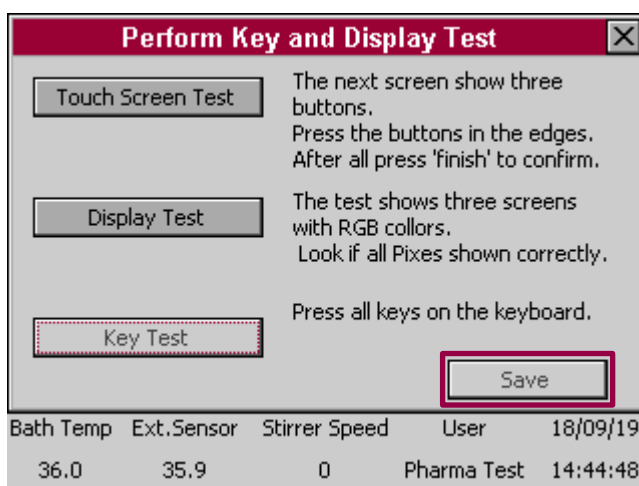
A red screen appears. Please check of the complete screen is absolutely red and that there is no pixel whitout colour. Press the display to continue.



A green screen appears. Please check of the complete screen is absolutely green and that there is no pixel whitout colour. Press the display to continue.



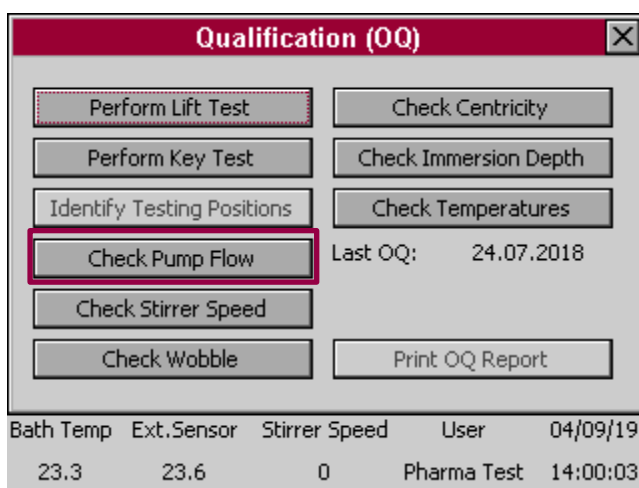
A blue screen appears. Please check of the complete screen is absolutely blue and that there is no pixel whitout colour. Press the display to continue.



The key test is only valid for the PTWS 620, PTWS D620 as well as the PTWS 1220 which habe integrated keyboards.

For this reason the test is deactivated here. Save all test results with pressing "Save".

### 11.3 OC Pump Flow



In this menu you can check the pump flow. Press "Check Pump Flow" to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).



**OQ Pump Flow**

Start Pump

Seconds: 030

Start Pump

0 sec

Enter the collected volume of water:

Milliliters: 00000

The flow rate is: 0.00 l/min

Save

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
36.0	35.8	0	Pharma Test	14:45:15

In this menu you can check the current pump flow.

Here you can set the runtime of the pump on seconds (001 – 999 seconds) and start the pump flow with the corresponding button.

Afterwards you can enter the milliliters the pump forwarded. You can save the result by pressing the button "Save".

**OQ Pump Flow**

Start Pump

Seconds: 28 sec

Start Pump

Enter the collected volume of water:

Milliliters: 00000

The flow rate is: 0.00 l/min

Save

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
36.1	35.8	0	Pharma Test	14:45:20

Usually 30 seconds are entered here. After setting the time you can press the button "Start Pump". Now the counter runs down to 0 seconds.

**OQ Pump Flow**

Start Pump

Seconds: 030

Start Pump

0 sec

Enter the collected volume of water:

Milliliters: 02000

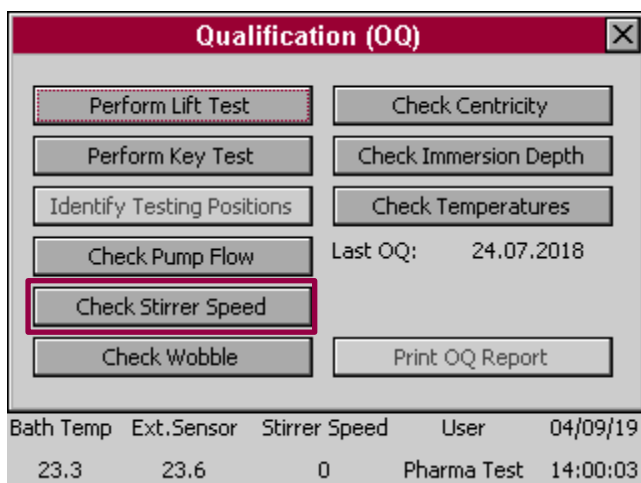
The flow rate is: 4.00 l/min

Save

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
36.0	35.6	0	Pharma Test	14:45:58

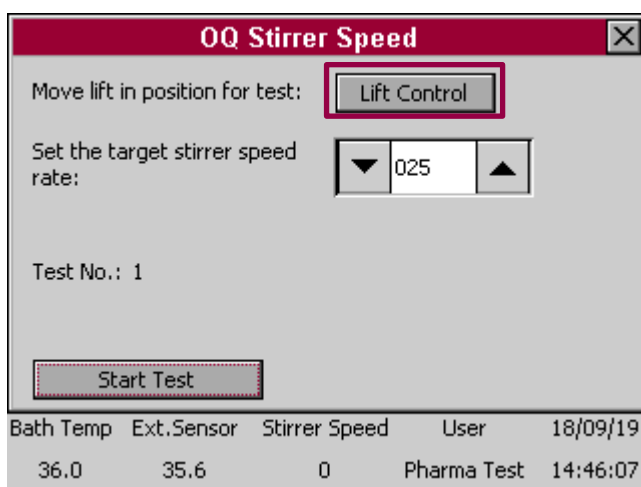
After 30 seconds you can enter the collected volume of water and additionally press "Save".

## 11.4 OC Stirrer Speed



Press "Check Stirrer Speed" In this menu you can check the stirring speed to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).

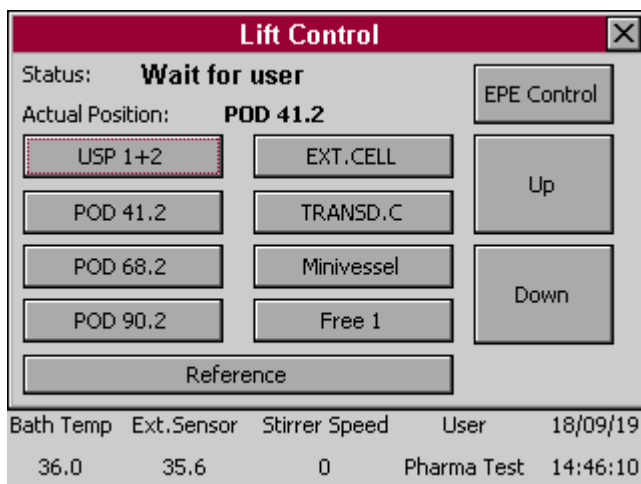


In a first step position the lift in an adequate position via "Lift Control".

Afterwards you can set the target speed you want to measure. Choose between 20 rpm – 250 rpm.

Below you can see "Test No.: 1". This means that you can do several speed tests after each other with different speed settings.

Press "Start Test" to measure the stirrer speed.



Here you can see the usual Lift Control screen after pressing „Lift Control“ to drive into the necessary lift position.

**OQ Stirrer Speed** [X]

Move lift in position for test:

Set the target stirrer speed rate:

Test No.: 1

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.9	35.6	0	Pharma Test	14:46:20

Press „Start Test” to start the stirrer speed test with the set stirrer speed. You herewith start test run no. 1.

**Enter Speed Rates (RpM)** [X]

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.8	35.6	19	Pharma Test	14:46:26

The stirrers start to run and you can now enter the stirring speed for each of the six (PTWS 120S/D), eight (PTWS 820D) or fourteen (PTWS 1420) positions.

Press “Next” to save your entries.

**OQ Stirrer Speed** [X]

Move lift in position for test:

Set the target stirrer speed rate:

Test No.: 2

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.9	35.7	23	Pharma Test	14:47:11

Now you are back in the previous menu. You can see that the Test Number changes to “2”. Change the target stirrer speed and start the test again.

**Enter Speed Rates (RpM)**

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Clear

Next

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.9	35.7	37	Pharma Test	14:47:19

The previously set speed rates are taken by the set target stirrer speed. Enter the real speed rates and confirm with "Next".

**OQ Stirrer Speed**

Move lift in position for test:

Set the target stirrer speed rate:

Test No.: 3

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.9	35.7	0	Pharma Test	14:47:32

Now you are back in the previous menu. You can see that the Test Number changes to "3". Change the target stirrer speed (here 75 rpm) and start the test again.

**Enter Speed Rates (RpM)**

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Clear

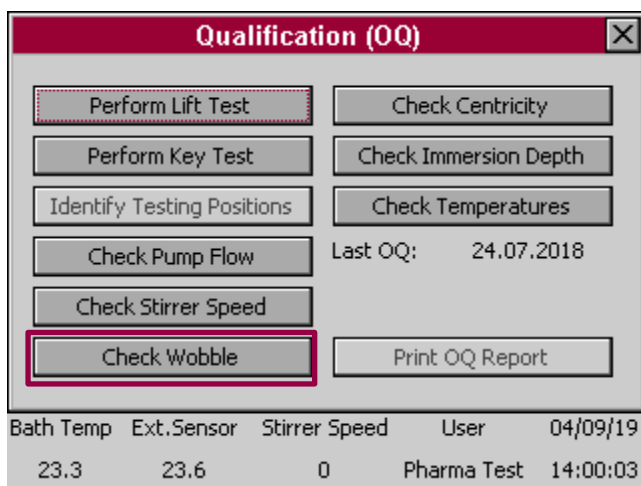
Next

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.9	35.7	20	Pharma Test	14:47:37

The previously set speed rates are taken by the set target stirrer speed. Enter the real speed rates and confirm with "Next".

Confirm as often as you need to test the speed rates. All done tests will be saved.

## 11.5 OQ Stirrer Wobble



**Qualification (OQ)**

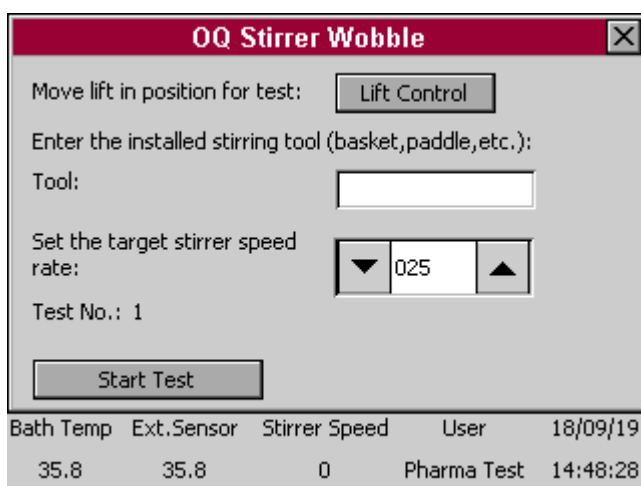
Buttons: Perform Lift Test, Check Centricity, Perform Key Test, Check Immersion Depth, Identify Testing Positions, Check Temperatures, Check Pump Flow, Last OQ: 24.07.2018, Check Stirrer Speed, Check Wobble (highlighted), Print OQ Report

Bath Temp	Ext. Sensor	Stirrer Speed	User	04/09/19
23.3	23.6	0	Pharma Test	14:00:03

In this menu you can check the wobble of the stirrer.

Press "Check Wobble" to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).



**OQ Stirrer Wobble**

Move lift in position for test:

Enter the installed stirring tool (basket, paddle, etc.):  
Tool:

Set the target stirrer speed rate:  025

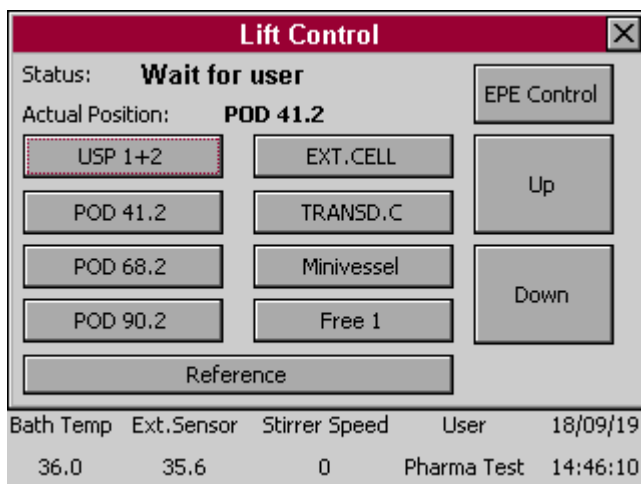
Test No.: 1

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
35.8	35.8	0	Pharma Test	14:48:28

In a first step position the lift in an adequate position via "Lift Control". Now enter the used tool like basket, paddle, and so on. Afterwards you can set the target speed at which you want to measure the stirrer wobble. Choose between 20 rpm – 250 rpm.

Below you can see "Test No.: 1". This means that you can do several wobble tests after each other with different speed settings or tools.

Press "Start Test" to measure the stirrer wobble.



**Lift Control**

Status: **Wait for user**

Actual Position: **POD 41.2**

Buttons: USP 1+2, EXT.CELL, POD 41.2, TRANSD.C, POD 68.2, Minivessel, POD 90.2, Free 1, Reference, Up, Down, EPE Control

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
36.0	35.6	0	Pharma Test	14:46:10

Here you can see the usual Lift Control screen after pressing "Lift Control" to drive into the necessary lift position.

**OQ Stirrer Wobble** [X]

Move lift in position for test:

Enter the installed stirring tool (basket,paddle,etc.):

Tool:

Set the target stirrer speed rate:  025

Test No.: 1

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.8	35.8	0	Pharma Test	14:48:43

Enter the installed stirring tool e.g. paddle or basket and the target stirrer speed.

Now press "Start Test" to start Test No. 1.

**Enter Wobble (mm)** [X]

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.8	35.7	50	Pharma Test	14:50:34

Now you can enter the measured wobble in mm. Thereby you are free in setting the number of decimal digits, depending on your requirements and used calibration tools. Enter your measurements and press "Next" to confirm.

**OQ Stirrer Wobble** [X]

Move lift in position for test:

Enter the installed stirring tool (basket,paddle,etc.):

Tool:

Set the target stirrer speed rate:  075

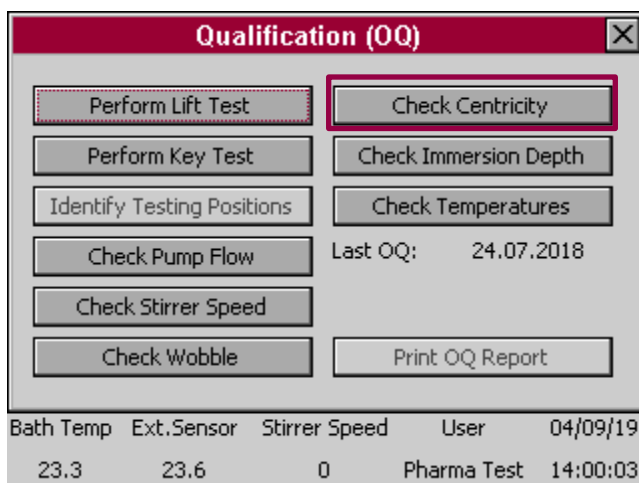
Test No.: 3

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.8	35.7	0	Pharma Test	14:50:55

Enter the installed stirring tool e.g. paddle or basket and the target stirrer speed. You can change both at anytime, independent which test number you are currently.

Now press "Start Test" to start Test No. 1.

## 11.6 OQ Centricity



**Qualification (OQ)**

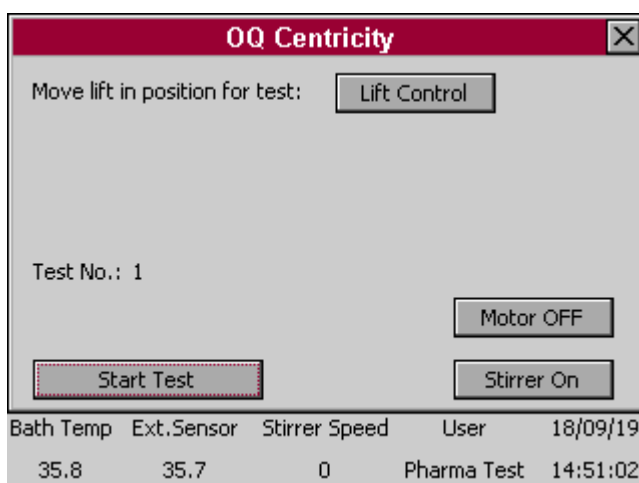
Buttons: Perform Lift Test, Check Centricity, Perform Key Test, Check Immersion Depth, Identify Testing Positions, Check Temperatures, Check Pump Flow, Last OQ: 24.07.2018, Check Stirrer Speed, Check Wobble, Print OQ Report

Bath Temp	Ext. Sensor	Stirrer Speed	User	Date/Time
23.3	23.6	0	Pharma Test	04/09/19 14:00:03

In this menu you can check the centricity of the stirrer.

Press "Check Centricity" to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).



**OQ Centricity**

Move lift in position for test: Lift Control

Test No.: 1

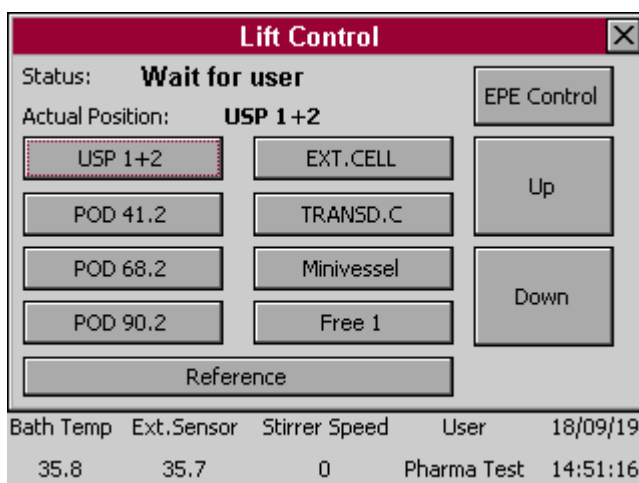
Buttons: Motor OFF, Start Test, Stirrer On

Bath Temp	Ext. Sensor	Stirrer Speed	User	Date/Time
35.8	35.7	0	Pharma Test	18/09/19 14:51:02

In this screen you can check the Centricity of each stirrer. You can change the lift position in "Lift Control".

You can turn the motor on and off as well as the stirrer on and of. Depending on the setting th different centricity positions can be checked during rotation and resting.

Press "Start Test" after choosing the optimal test configuration.



**Lift Control**

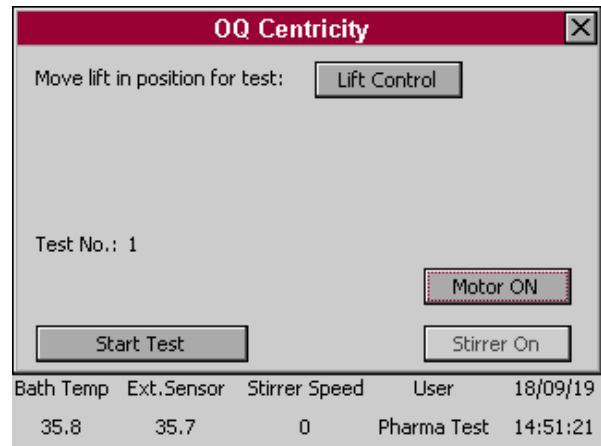
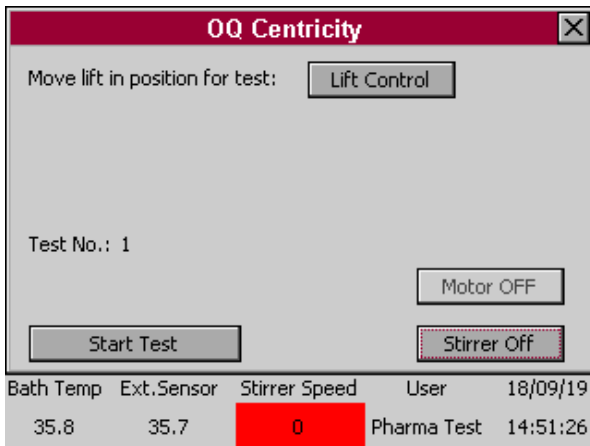
Status: Wait for user

Actual Position: USP 1+2

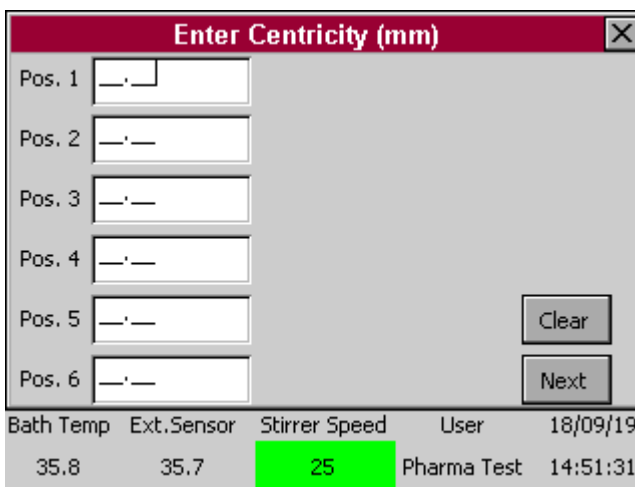
Buttons: EPE Control, USP 1+2, EXT.CELL, Up, POD 41.2, TRANSD.C, Down, POD 68.2, Minivessel, Reference, POD 90.2, Free 1

Bath Temp	Ext. Sensor	Stirrer Speed	User	Date/Time
35.8	35.7	0	Pharma Test	18/09/19 14:51:16

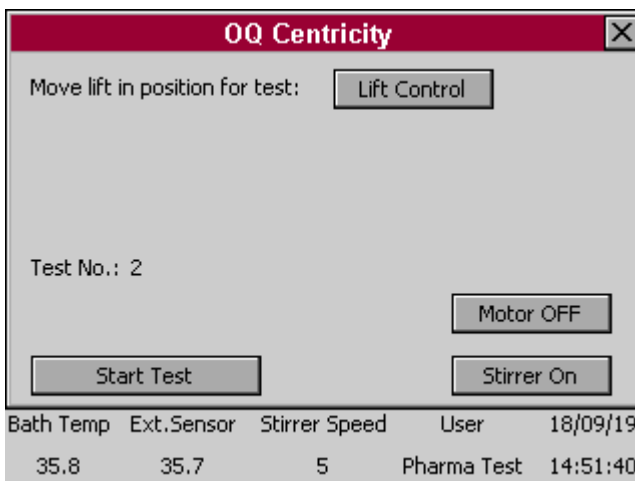
Choose "Lift Control" to move the lift into the necessary position.



When the stirrer is on you cannot turn off the motor and when the motor is off you cannot turn on the stirrer. Press "Start Test".



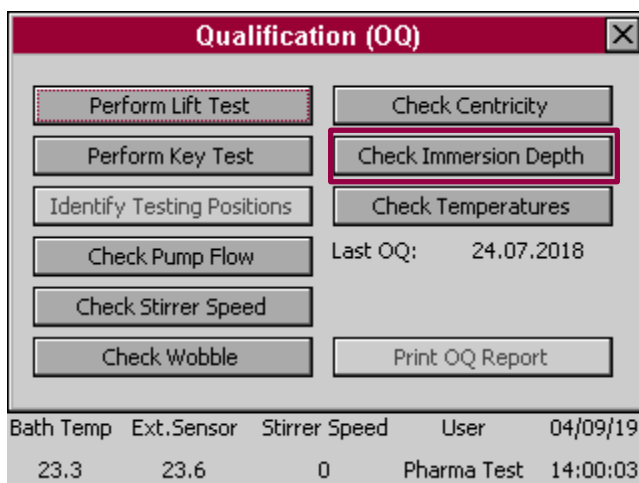
Now you can enter the centricity in mm for each Position. Press "Next" to confirm your entries.



Back in the main screen from the "OQ Centricity" you can run additional checks or quit the test.



## 11.7 OQ Immersion Depth



**Qualification (OQ)**

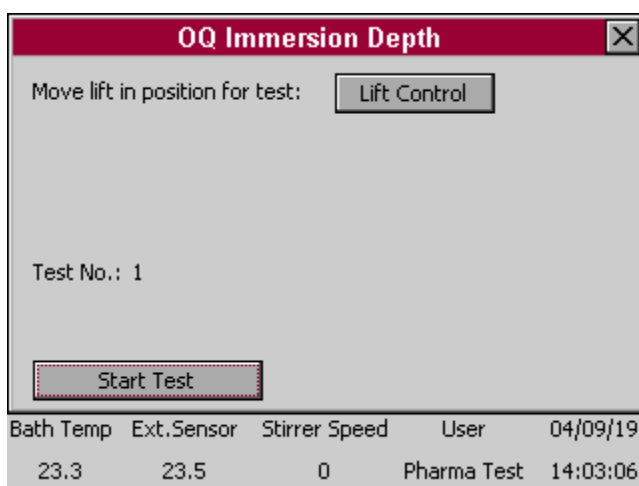
Buttons: Perform Lift Test, Check Centricity, Perform Key Test, **Check Immersion Depth**, Identify Testing Positions, Check Temperatures, Check Pump Flow, Last OQ: 24.07.2018, Check Stirrer Speed, Check Wobble, Print OQ Report

Bath Temp	Ext. Sensor	Stirrer Speed	User	04/09/19
23.3	23.6	0	Pharma Test	14:00:03

In this menu you can check the immersion depth of the stirrer.

Press "Check Immersion Depth" to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).



**OQ Immersion Depth**

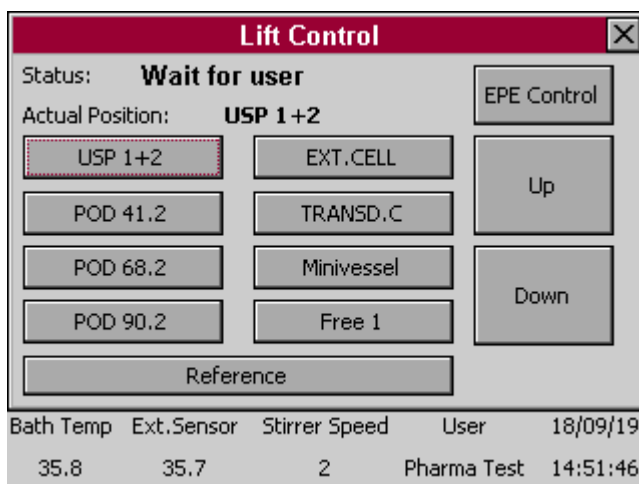
Move lift in position for test: **Lift Control**

Test No.: 1

**Start Test**

Bath Temp	Ext. Sensor	Stirrer Speed	User	04/09/19
23.3	23.5	0	Pharma Test	14:03:06

Choose the necessary lift position



**Lift Control**

Status: **Wait for user**

Actual Position: **USP 1+2**

Buttons: USP 1+2, EXT.CELL, EPE Control, POD 41.2, TRANSD.C, Up, POD 68.2, Minivessel, Down, POD 90.2, Free 1, Reference

Bath Temp	Ext. Sensor	Stirrer Speed	User	18/09/19
35.8	35.7	2	Pharma Test	14:51:46

Choose "Lift Control" to move the lift into the necessary position.

**OQ Immersion Depth**

Move lift in position for test:

Test No.: 1

Bath Temp	Ext.Sensor	Stirrer Speed	User	04/09/19
23.3	23.5	0	Pharma Test	14:03:06

Press "Start Test" to check the immersion depth of the stirrer.

**Enter Immersion Depth (mm)**

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
35.8	35.7	0	Pharma Test	14:51:51

Now you can enter the immersion depth in mm for each position. Press "Next" to confirm your entries.

### 11.8 OQ Temperature

**Qualification (OQ)**

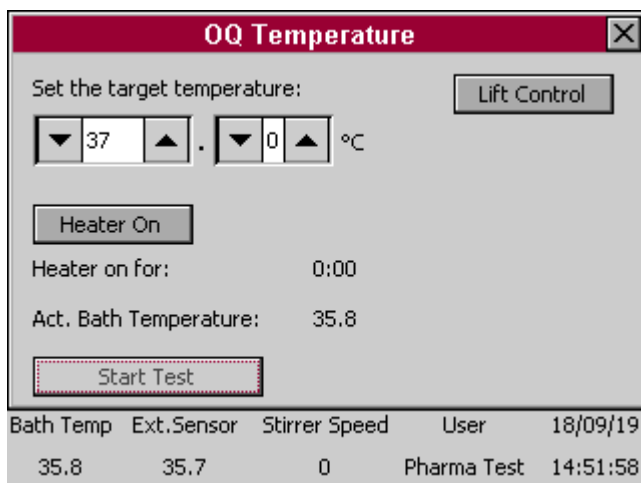
Last OQ: 24.07.2018

Bath Temp	Ext.Sensor	Stirrer Speed	User	04/09/19
23.3	23.6	0	Pharma Test	14:00:03

In this menu you can check the temperature.

Press "Check Temperatures" to continue.

This procedure is used for the qualification described in OQ and QC (for the concrete procedure, set values and positions take a look at the corresponding documents).

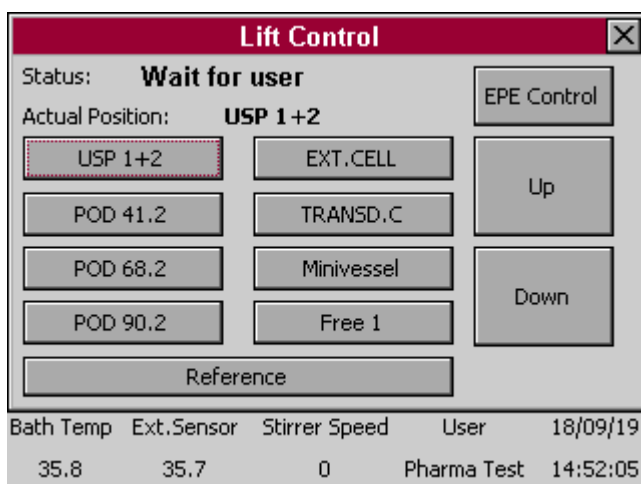


In a first step position the lift in an adequate position via "Lift Control".

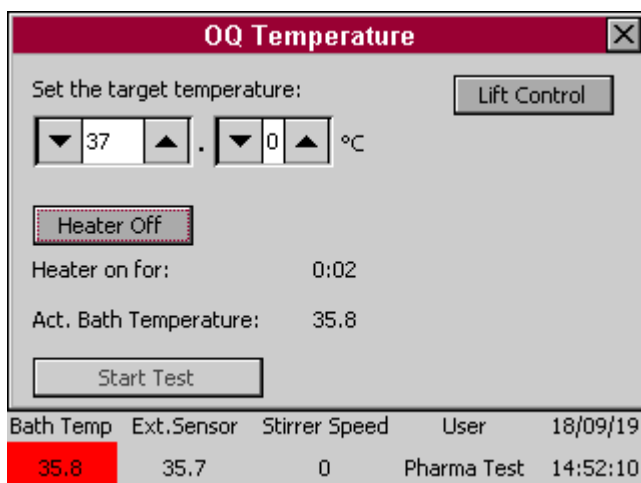
Afterwards you can set the target temperature you want to measure. Choose between 25.0 °C – 45.0 °C.

Now you can start the upheating process with "Heater On". Below you see a line where the time is shown for which the heater is already on now as well as the actual bath temperature.

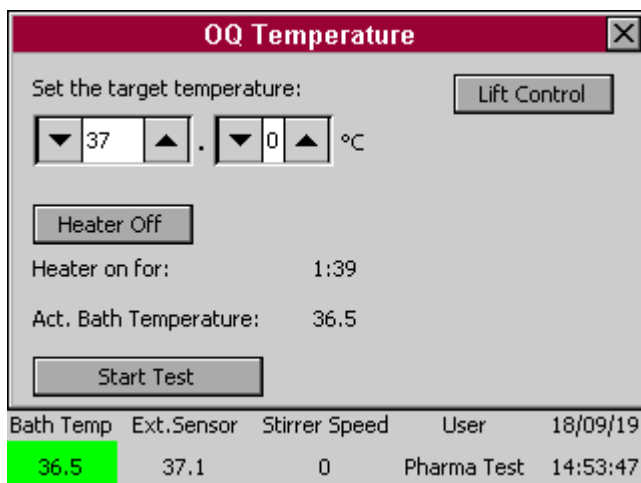
Press "Start Test" to measure the current bath temperature.



Choose "Lift Control" to move the lift into the necessary position.



Set the target temperature and press "Heater On". Then the time starts "Heater on for:" until the actual bath temperature heated up to the target temperature.



**OQ Temperature**

Set the target temperature: Lift Control

▼ 37 ▲ . ▼ 0 ▲ °C

Heater Off

Heater on for: 1:39

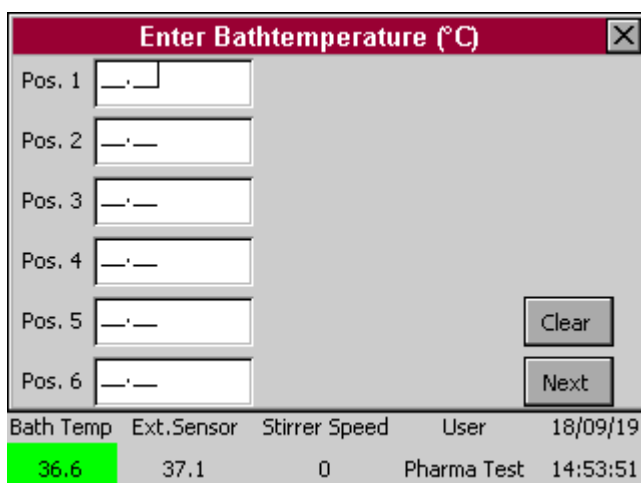
Act. Bath Temperature: 36.5

Start Test

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
36.5	37.1	0	Pharma Test	14:53:47

As soon as the target temperature is reached ( $\pm 0.5$  °C) it is possible to press "Start Test". Make clear that the lift is in its optimum position for the temperature test.

For the "OQ Temperature" you have to determine the Bath- and Vesseltemperature.



**Enter Bathtemperature (°C)**

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

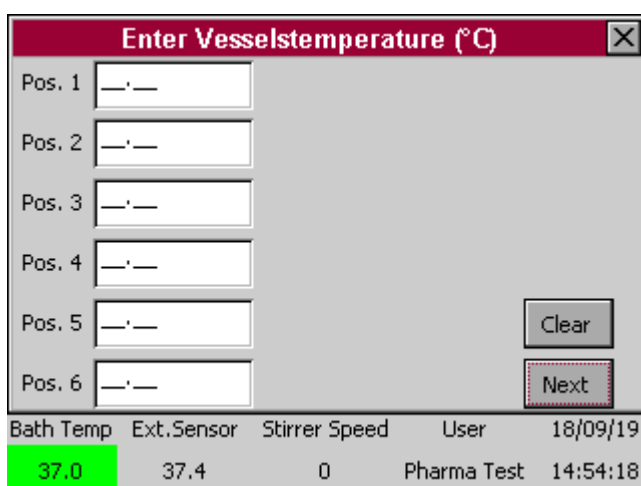
Clear

Next

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
36.6	37.1	0	Pharma Test	14:53:51

Enter the bathtemperature at each of the six vessel positions.

For die concrete OQ instruction, please take a look at the operation qualification document.



**Enter Vesselsttemperature (°C)**

Pos. 1

Pos. 2

Pos. 3

Pos. 4

Pos. 5

Pos. 6

Clear

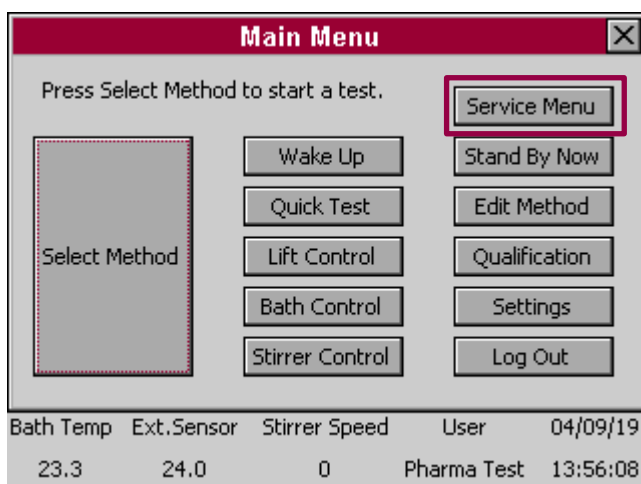
Next

Bath Temp	Ext.Sensor	Stirrer Speed	User	18/09/19
37.0	37.4	0	Pharma Test	14:54:18

Enter the vesseltemperature of each vessel.

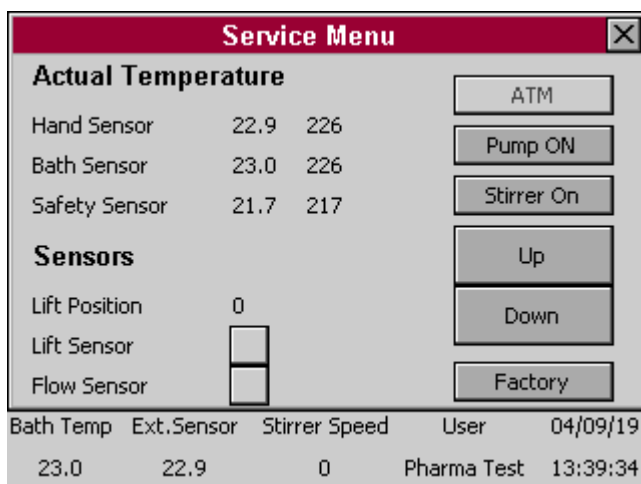
For die concrete OQ instruction, please take a look at the operation qualification document.

## 12 Service Menu



The "Service Menu" is used for instrument specific settings, which are usually locked for safety reasons.

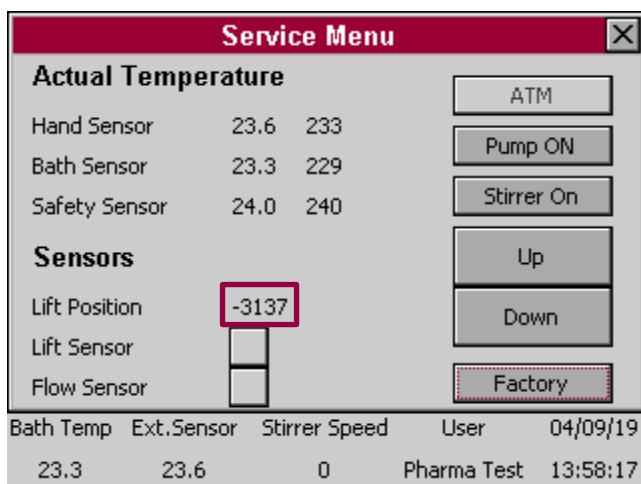
You can only enter this menu as PTAG user as the instrument can be damaged by wrong handling!!!!



This is the main screen of the Service Menu. You have several options for the following settings:

- ATM: open and close it
- Pump: turn it on and off without heating and safety switch off
- Stirrer: turn it on and of
- Lift "Up" and "Down"

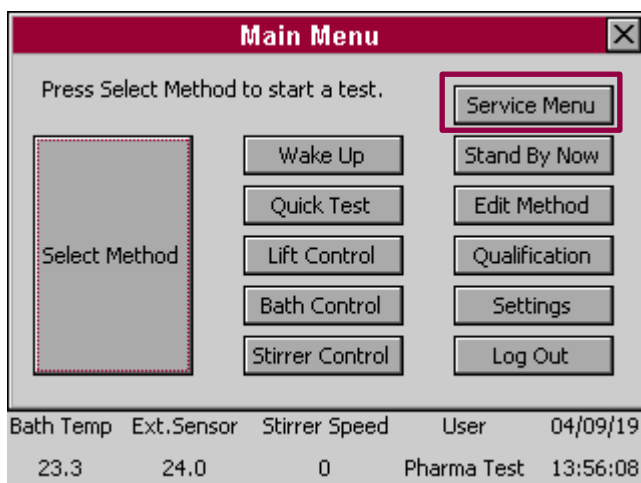
The last button is "Factory". Press it to enter the factory settings.



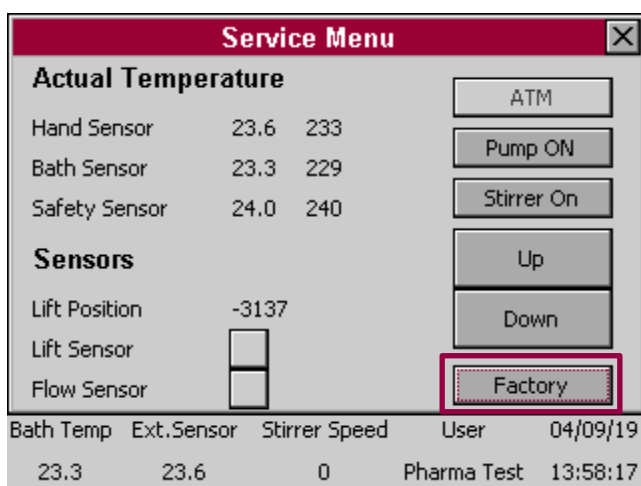
In addition to the button settings you have different displayed sensors here:

- Actual Temperature: Hand Sensor, Bath Sensor, Safety Sensor
- Sensors: Lift Position (raw data of the lift position), Lift Sensor (in reference position or not) and Flow Sensor (activated or not)

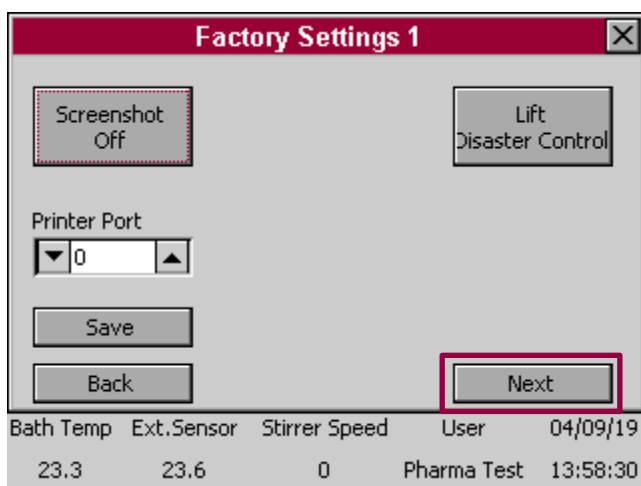
## 12.1 Factory Setting



Enter the "Service Menu".



In the service menu enter the setting "Factory".



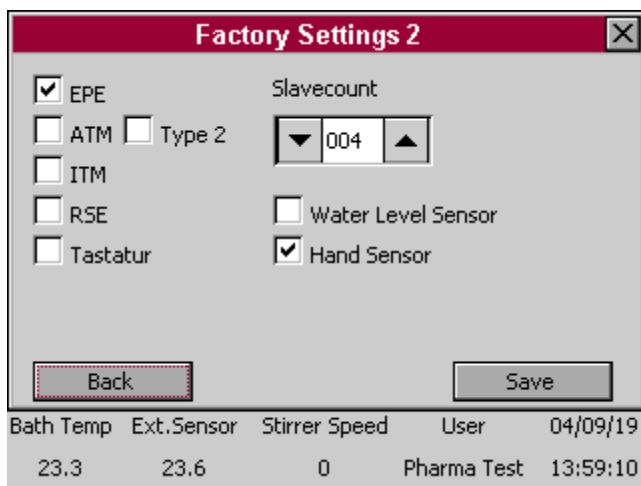
In the first window you have different options:

- Activate or deactivate the screenshot mode
- Set the printer port: 1 or 2 depending on the used port for printer connection, 0 deactivates the printer
- Lift Disaster Control – see Section 12.2 for more information

If you did any changes in the window here press "Save". Press "Next" for the second factory setting window.

NOTE: PTWS620/1220/D620 have a build-in printer which is always connected to Port "1"!

If the PTWS120D/120S/820D/1420 is connected with an optional printer PT-RP80, the printer is always connected to Port "2"!



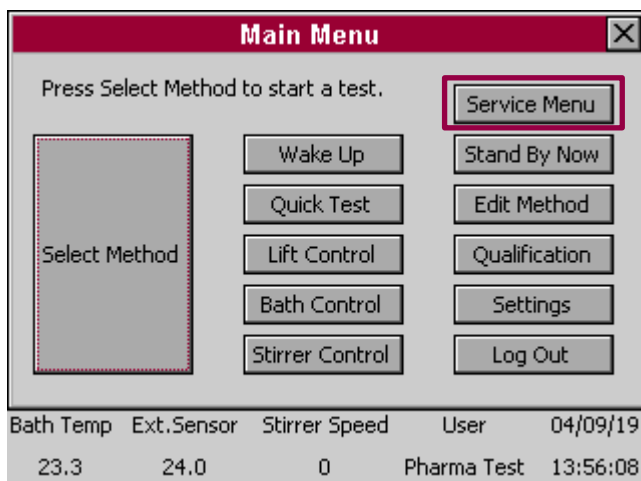
In the second window you can set some basic instrument configurations. Activate or deactivate the following configurations:

- EPE
- ATM, ATM Type 2
- ITM
- RSE
- Tastatur
- Water Level Sensor
- Hand Sensor

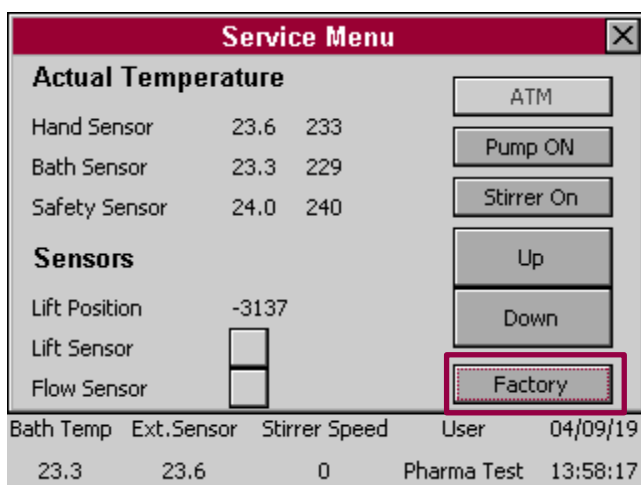
In addition you can change the "Slavecount" counts from 001 to the present number of slaves..

Save your current setting with "Save".

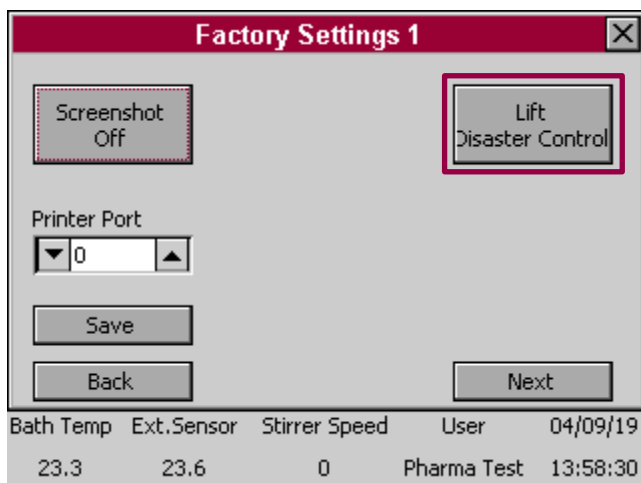
## 12.2 Lift Disaster Control



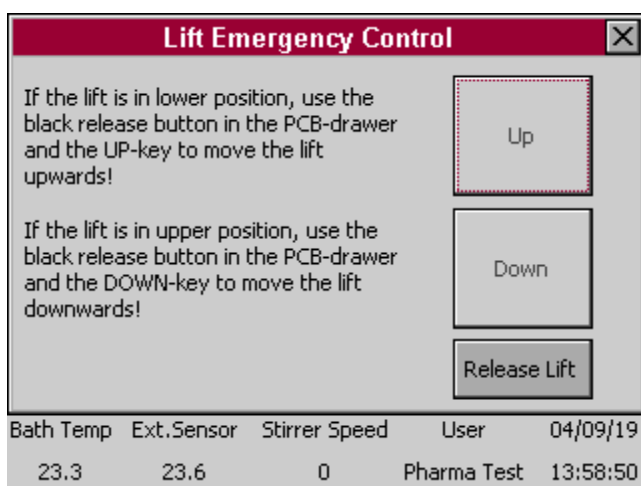
Enter the "Service Menu".



In the service menu enter the setting "Factory".



Here choose the setting "Lift Disaster Control".



In the lift emergency control you can move the lift of the dissolution tester, independent of the current lift position or the error messages.

Please take care, you can crush the instrument in this menu if you drive the lift in the wrong direction!!!!

If the lift is in upper position do not use the button "Up"!!! If the lift is in the lowest position do not press the button "Down"!!

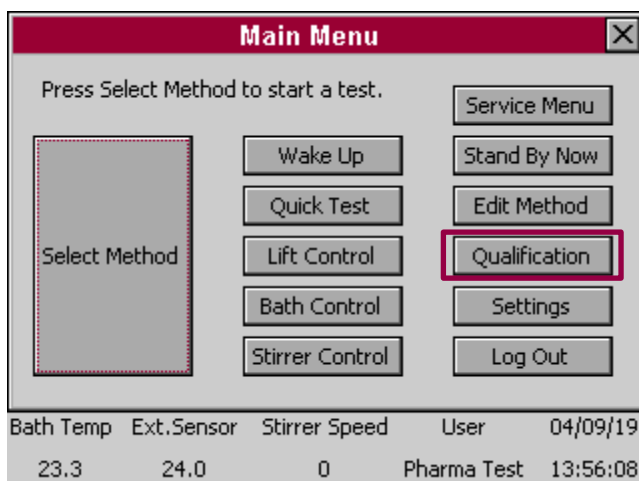
"Release Lift" makes it possible to move the lift even if its not possible under usual circumstances anymore. Often the lift can drive into its reference after this movement.



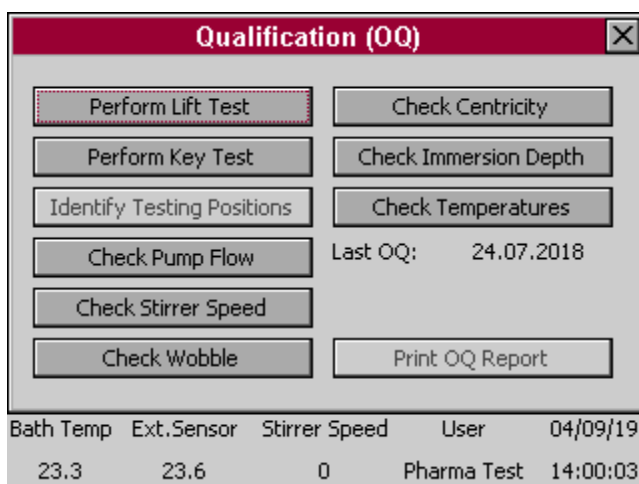
## 13 Qualification and Adjustment

This section describes how to qualify the operation of the instrument using the OQ programs and how to adjust the temperature sensors.

### 13.1 Qualification

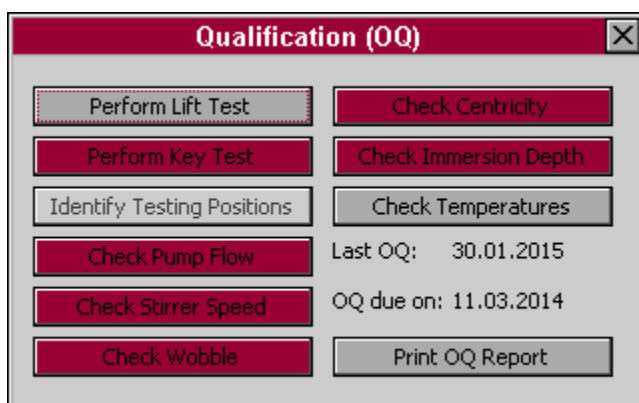


From the main menu select "Qualification".



This menu contains a set of programs to assist the user during operation qualification (OQ). Refer to the provided OQ form as well.

The instrument stores the completion date of each OQ test separately. The latest date is displayed here. The OQ due date is calculated from the OQ interval selected in the settings menu.



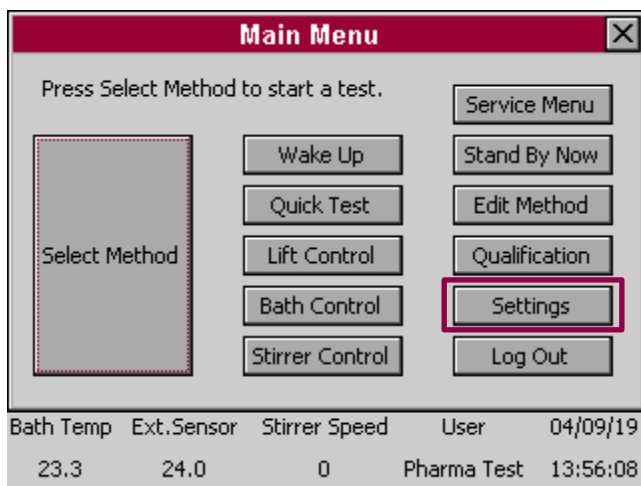
In case the OQ interval for a test has expired, the corresponding button turns red. Perform this OQ test, to reset the interval and turn the button grey again.

Tests disabled in the settings are greyed out here and cannot be selected or performed.

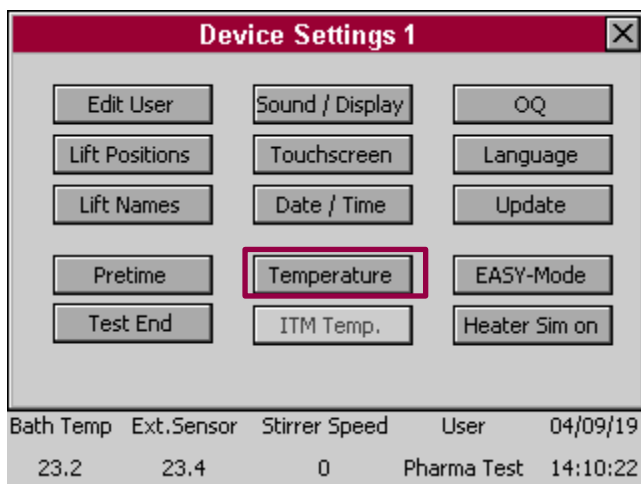
## 13.2 Adjustment

### 13.2.1 Bath- and Hand- Sensor

Adjustment should only be performed in case a calibration showed that the temperature sensors are giving incorrect results.

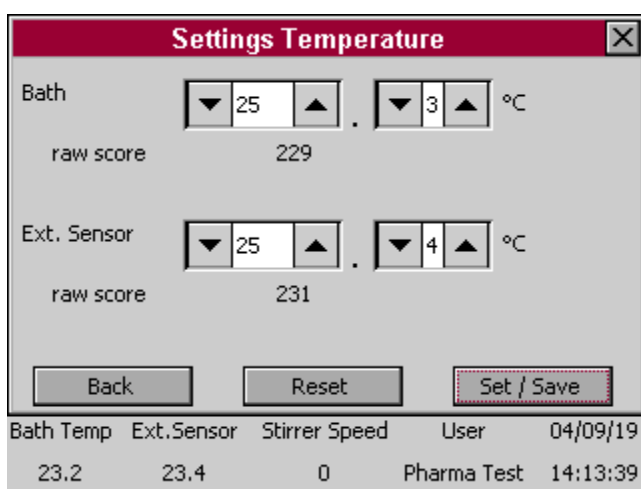


From the main menu select "Settings".



From the device settings menu select "Temperature".

On the temperature adjustment screen, the temperature readings of the bath and external hand sensor can be corrected.

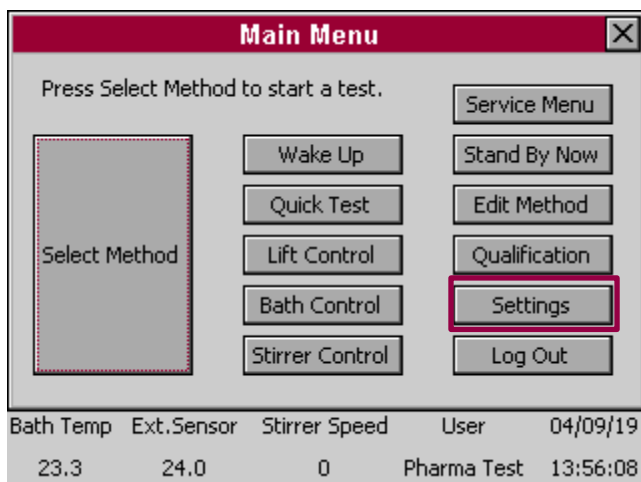


To find the correct value, place the two probes of the PTWS and a certified external thermometer close together into the prewarmed water bath and wait until all 3 temperatures are stabilized. First of all check the temperature display on the instrument. Then compare the displayed value to the actual value measured by an external thermometer. If, for example the instrument is now showing 37.5°C when in reality the temperature is 37.0°C you should enter the correct value of 37.0°C on the temperature adjustment screen.

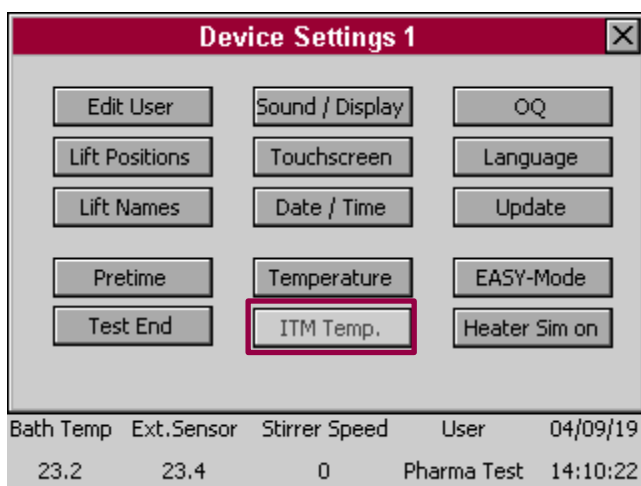
Press "Set/Save" to store the temperatures for both probes.

### 13.2.2 ITM-Probes

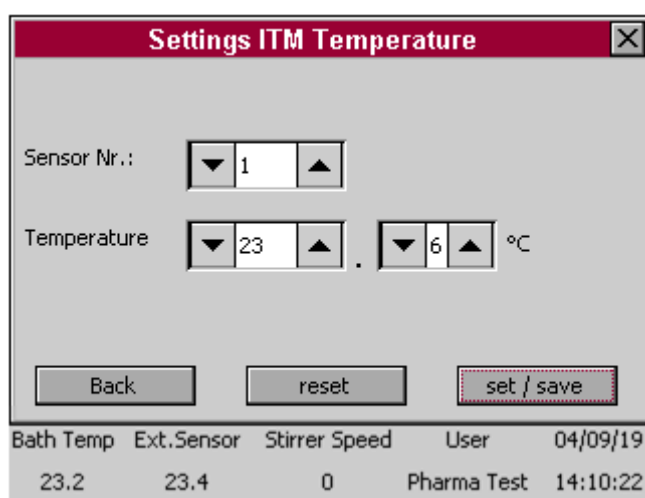
Adjustment should only be performed in case a calibration showed that the temperature sensors are giving incorrect results.



From the main menu select "Settings".



From the device settings menu select "ITM Temp.".



On the ITM Temperature settings screen, the temperature readings of every single ITM probe can be corrected.

Place a certified external thermometer close together to the relevant ITM probe inside the prewarmed vessel. Don't perform an adjustment using a temperature less than 35°C to avoid inaccuracy.

Wait until both temperatures are stabilized and enter the temperature of your certified thermometer at the relevant sensor.

Repeat this procedure for every single ITM probe-..

Press "Set/Save" to store the temperatures for all ITM-probes.

## 14 Error Messages and Trouble Shooting

A number of error codes and messages are used to assist the user and his service department in the identification of any operational problems or to inform the user of any incorrect entries in either a function or operation mode.

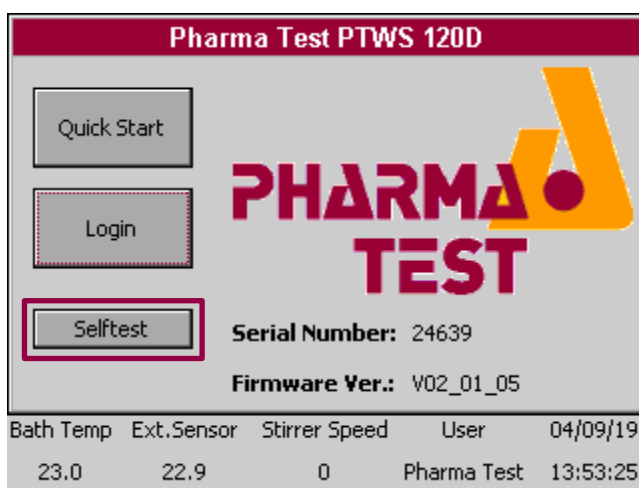
The following list mentions these codes and contains advice as to which action should be taken in response to the error. Make sure to thoroughly go through this list before contacting our technical support.

### 14.1 Status Line Error Information

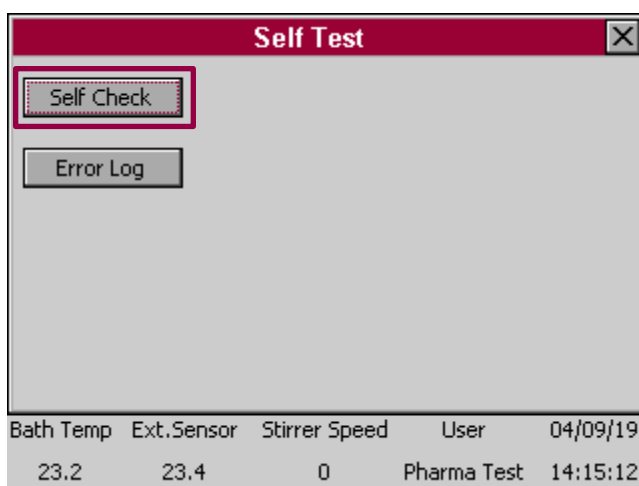
In case the instrument encounters any errors during the self-test on power up or during operation, the status line turns red:

Bath Temp	ext.Sensor	Stirrer Speed	User	17/09/14
21.7	23.1	0	Factory	17:40:45

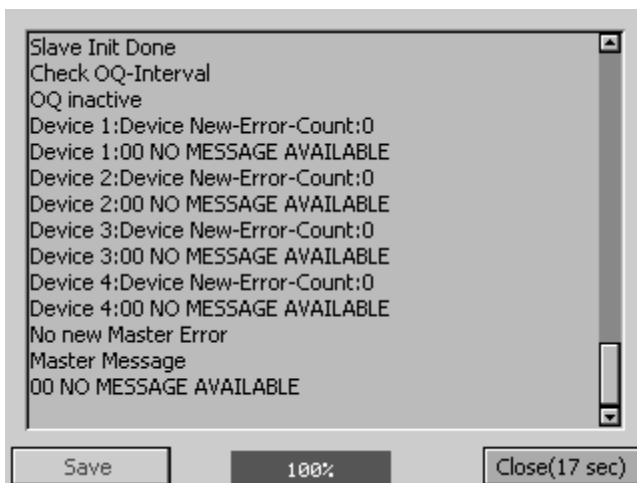
Figure 13: Status Line – Errors Encountered



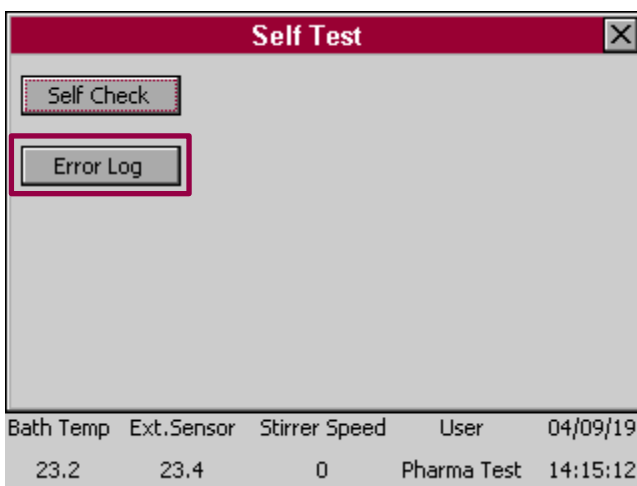
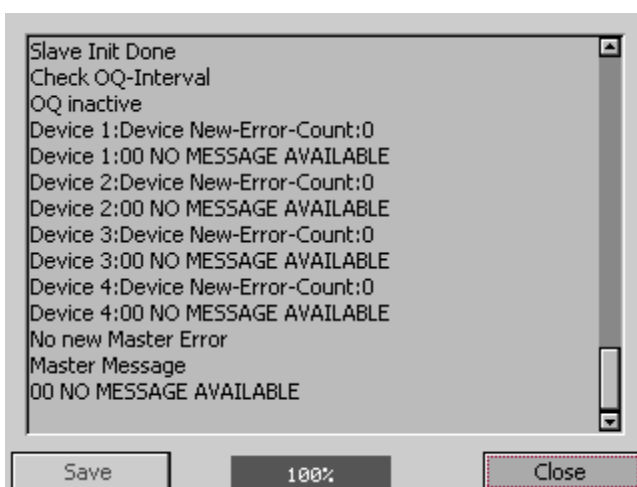
To find out the details of the encountered error, enter the self-test menu from the start screen.



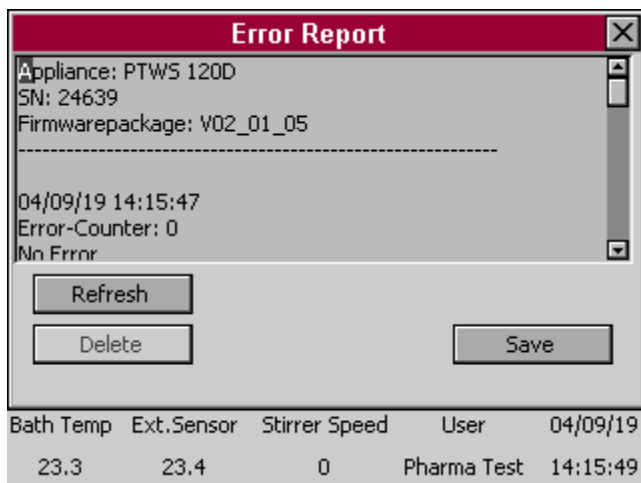
Select "Self Check" to repeat the self-check the instrument performs during start up.



At start up this process is performed in the background and the user is only informed about it in case any errors are encountered. By selecting it here the process can be observed which is useful for trouble shooting purposes. This report can be saved to the user SD card by selecting "Save". You can send this file to Pharma Test support to help solve any issues you might encounter.



The instrument logs all errors that occur during its operation. By selecting "Error Log" the log can be viewed.



This log is also used for trouble shooting purposes. Select "Save" to save it to the user SD card.

This log too can be send to Pharma Test support to receive help.

## 14.2 Error Messages

Messages will be inserted in following revisions of the manual

Error No.	Error Message	Error Description and Solutions

Table 11: Error Messages

## 14.3 Trouble Shooting

Fault	Possible Reasons and Solutions
The pump goes off shortly after being turned on.	<ul style="list-style-type: none"> <li>▪ Check if there is air in the system.</li> <li>▪ Remove the air by opening the fill/drain tap until all the air is gone from the system.</li> <li>▪ Always fill up the PTWS 120D/120S/820D/1420 using the fill/drain tap. This way you can make sure that there gets no air into the heating system.</li> </ul>

Table 12: Trouble Shooting

## 15 Cleaning and Maintenance

All Plexiglas parts should be cleaned daily. Please do not use any 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.

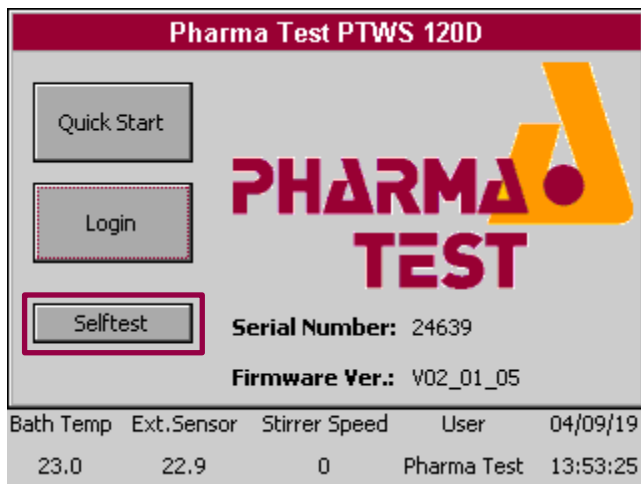
In case the instrument cannot be operated without the damage to property or personnel, it has to be switched off and withdrawn from operation immediately. This is valid always when:



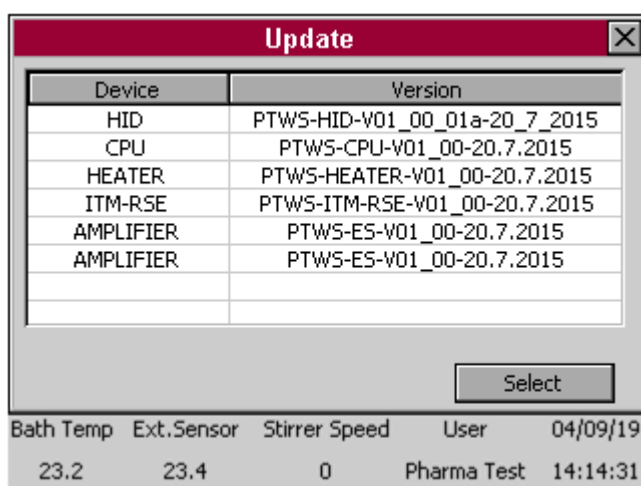
- The instrument mains cable or socket shows visible damages
- The instrument shows visible damages or does not work
- Any cable shows visible damages

## 16 Firmware Updates

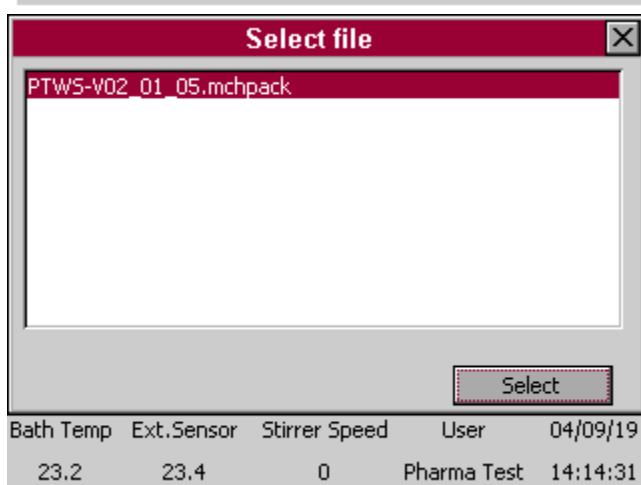
Over time Pharma Test may release new versions of the firmware of the PTWS 120D/120S/820D/1420 to implement new features or to eliminate bugs. Please contact Pharma Test or your local agent to find out if there is a firmware update available for your machine.



You can see the version of the firmware currently installed on your instrument on the start screen of the PTWS 120D/120S/820D/1420.



Or in the table of updateable electronic components (Settings -> Update)





## 16.1 Equipment Needed to Perform Firmware Updates

To perform a firmware update for a PTWS 120D/120S/820D/1420 you will need:

- PTWS 120D/120S/820D/1420 instrument
- User SD card of the instrument
- PC with Microsoft® Windows™ operating system and a SD card slot or adapter
- Firmware update data

## 16.2 Performing the Firmware Updates

To install a firmware upgrade, the upgrade files have to be copied to the user SD card. When the user SD card is inserted into the instrument and contains a firmware upgrade, it can be installed directly from the instrument itself without the need of any external devices.

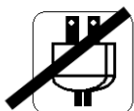
Detailed instructions on how to install a firmware upgrade will be provided together with the update files. Before attempting the firmware update read through the information provided with the update file and make sure you understand every step.

A firmware update should only be performed by a qualified service engineer. A failed firmware update can lead to an unusable machine. Therefore make sure that the user SD card is firmly inserted, that no power failure occurs during the update process and do not interrupt the update process until it is completely finished.

## 17 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