Operating Manual

PTB 330
Tablet Hardness Testing Instrument

Version 1.0

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Certificate No FS 529019/0388D

The Documentation

This document describes the set-up, operation and general maintenance of the Pharma Test 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 must be used in compliance with the manufacturer's manuals and papers supplied.

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How to Use the Manual

To understand the different information, we use different formatting:

- **< >Use any key (i.e. <Esc> OR <ENTER>)**
- " " Display information
- *Information entries*
- **[ ] Select from a menu**
- Note: informs about special use OR possibility






Table of Contents

Document History

Version	Valid from	Author	Change	Remark
1.0	28.10.2025	Pharma Test	N	First release

Table 1 Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

1. About PTB 330

Thank you for choosing a Pharma Test PTB 330 tablet hardness testing instrument. PTB 330 is a 5-in-1 tablet testing instrument to measure five different parameters of one sample. Hardness, diameter (or length), thickness, width and the weight of tablets can be determined here. The instrument is operated via a large 7" backlit color touch screen.

Figure 1: PTB 330 tablet hardness testing instrument

PTB 330 features one testing station to determine the thickness, width, diameter (or length) and the hardness of tablets. Furthermore, PTB 330 allows connecting a Sartorius or METTLER TOLEDO analytical balance to measure the weight of the samples as well. PTB 330 offer two modes for the weight measurement: either weigh each sample individually, before placing them in the testing station or weigh all samples together and calculate the average weight.

The sample support of the test station is changeable. You can use version with a groove for optimal positioning of oblongs or other samples which tend to move during the test procedure. The measuring units can be selected from mm or inch and KP (Kilopond), N (Newton) or Sc (Strong Cobb).

PTB 330 is fully compliant with the current EP <2.9.8> and USP <1217> monographs.

If the instrument is used in any other way as described in the manual, the integrated safety features may be affected and there could be the possibility of injuries to the operator.

Instrument Variants

There are three instrument types in the PTB 330 series of instruments, which differ in the maximum force setting for the hardness measurement:

1. PTB 330-300 for measurements of up to 300N for hardness
2. PTB 330-500 for measurements of up to 500N for hardness
3. PTB 330-1000 for measurements of up to 1,000N for hardness

Otherwise, the instruments are identical, and the contents of this document apply to all the variants whenever PTB 330 is mentioned unless the variant is explicitly mentioned.

Standard Supply Scope

Main Instrument

PTB 330 comes ready to use with its standard scope of supply:

Part No.	No.	Description
288-	1	Sample support, flat
283-0420	5	Paper rolls for internal printer
285-1785-3	1	3, 5, 10mm reference block set
285-1771	1	Cleaning brush
34-08400	1	External power supply, 24V/DC, 5A, 120W
34-08500	1	EUR mains cable, or
34-08510	1	CH mains cable, or
34-08511	1	US mains cable, or
34-08512	1	GB mains cable, or
34-08513	1	AR/AUS/NZ mains cable, or
34-08514	1	IN/ZA mains cable, or
34-08515	1	BR mains cable

Table 2: Standard supply scope main instrument

Optional Items

In addition to the standard scope of supply, the following optional items are available for PTB 330:

Sample Support Inserts

PTB 330 allows sample supports to be exchanged. The standard instrument includes a flat sample support, with an optional grooved support for aligning oblongs. Custom supports can also be provided based on customer requirements.

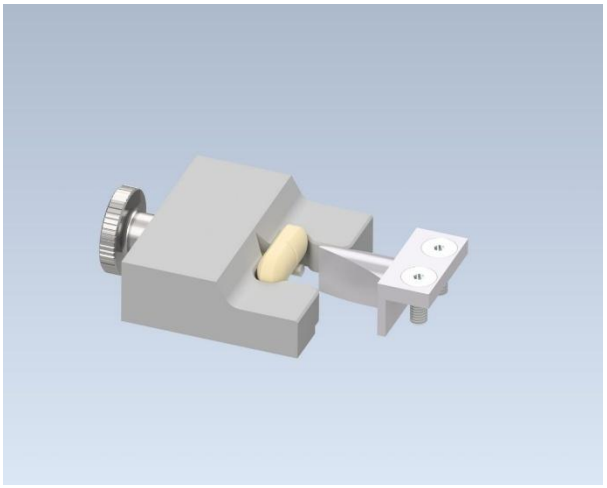
Part No.	Type
288-1005	Sample support with oblong groove
288-1050	Sample support according to customer specification

Table 3: Sample support inserts

Oblong Tension Test Set

To test the tension strength of oblong shaped samples with a break line optional test inserts are available. These inserts are available in different sizes to suit common lengths of oblongs. In case none of these sizes fit your sample, a custom insert based on a drawing of your sample can be offered.

To perform the oblong tension strength test the force jaw below and one or more suitable test inserts are required.



Part No.	Type
288-1300	Oblong tension strength test force jaw
288-1310	Oblong tension strength sample insert, size 1 (16mm)
288-1320	Oblong tension strength sample insert, size 2 (18.5mm)
288-1330	Oblong tension strength sample insert, size 3 (22.5mm)
288-1340	Oblong tension strength sample insert, size 4 (28mm)
288-1390	Oblong tension strength sample insert, custom size

Table 4: Oblong tension strength test set

PT-Node Network Adapter

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

Part No.	Type
24-00100	PT-Node network adapter
34-01205	Standard RS-232 cable, 9:9, female/female

Table 5: PT-Node Network adapter

Ticket Printer

The Epson ticket printer is a robust, high-performance receipt dot matrix printer that is particularly easy to use. It prints on plain paper. This printer can be used as an alternative to the integrated thermal printer of PTB 330.

Part No.	Type
29-02200	Epson TM-U220D ticket printer
34-01224	Cable to connect PTB 330
007-0230	Ink ribbon for Epson ticket printer

Table 6: Ticket printer

Analytical Balance

To measure weight an analytical balance can be connected to PTB 330. See below for more details on how to setup the balance.

Part No.	Type
34-01203	Standard RS-232 cable, 9:9, female/male

Table 7: Analytical balance

Consumables

Part No.	No.	Description
283-0420-10	10	Spare paper rolls for thermal printer, 10 rolls
283-0420-50	50	Spare paper rolls for thermal printer, 50 rolls
283-0420-100	100	Spare paper rolls for thermal printer, 100 rolls

Table 8: Consumables

Technical Specifications

Parameter	Specification
Hardness testing range	PTB 330-300: 2.0 – 300.0 N PTB 330-500: 5.0 – 500.0 N PTB 330-1000: 10.0 – 1,000.0 N
Hardness accuracy	Better than ±1 N
Hardness resolution	0.1 N
Thickness testing range	2.00 – 35.00 mm, expandable to 70mm
Thickness accuracy	2.00 – 10.00 mm ±0.02 mm 10.00 – 35.00 mm ±0.05 mm
Width & diameter testing range	2.00 – 35.00 mm, expandable to 70mm
Width & diameter accuracy	2.00 – 10.00 mm ±0.02 mm 10.00 – 35.00 mm ±0.05 mm
Thickness, width & diameter resolution	0.01 mm
Weight measurement	By external METTLER TOLEDO or Sartorius balance (balance not included in standard supply scope), individual or average weight
Measuring units	Thickness, diameter and width selectable between millimeter (mm) and inches (IN); Hardness selectable between Newton (N), Kilopond (kp) and Strong Cobb (Sc)
Force mode	Selectable: linear force increases or linear speed increase
Force rate	5 – 250 N/sec. (linear force increase); 1 – 5mm/sec. (linear speed increase)
Display	7" color LCD, backlit
Data entry	Touch screen
Number of users	Up to 100
Number of methods	Up to 100
Number of tests per run	Up to 200 tests in one run
Interfaces	2 x RS-232 serial port to connect a PT-Node network adapter, an Epson TM-U220B ticket printer, or a balance, 1 x USB-C port for data export and firmware updates
Instrument housing	Stainless steel (304) to meet GLP requirements
Power	100-240 Volt AC, 50/60 Hz
Installation requirements	Ambient Temperature 15-35 °C Relative Humidity 15-80 %rH Desk with at least 50 kg working load. All around the instrument at least 10 cm free distance to walls or other equipment. Free access to the mains power plug and switch.
Instrument dimensions	Approx. 260 x 500 x 260 mm (Length x Width x Height)
Packaging dimensions	Approx. 310 x 660 x 420 mm (Length x Width x Height)
Net / gross weight	Approx. 9,5 kg / 12,5 kg (without optional accessories)

Table 9: Technical specifications

A Note on Calibration and Nomenclature

In compliance with current compendia requirements, the PTB range of tablet hardness or break point testers feature a three-point calibration routine. Please also note that our nomenclature is in line with current requirements. The older terms "calibration" and "validation" have been replaced with "adjustment" and "calibration". The newer nomenclature is used throughout this manual.

Calculation Factors and Unit Conversions

Unit/Calculation	Factor/Formula	
Hardness Units	1Kp = 9.81N	1Kp = 1.43Sc
Mean Value	∑x/N	
Absolute Standard Deviation	$\sqrt{\frac{\sum x^2 - n \times \overline{x}^2}{n-1}} \quad [x = MV]$	
Relative Standard Deviation	$\frac{\sqrt{\frac{(\sum x^2 - n \times \overline{x^2})}{n-1}}}{\overline{x}} \times 100\%$	

Table 10: Calculation Factors and Unit Conversions

2. Setting Up the PTB 330 Instrument

Check the indicated mains voltage on the external power supply included with the instrument. It must match the mains available locally on your end. If this is not the case, the external power supply must not be connected to this mains supply.

Main Components

This section describes the main components of the PTB 330 instrument.

Figure 2: PTB 330 front

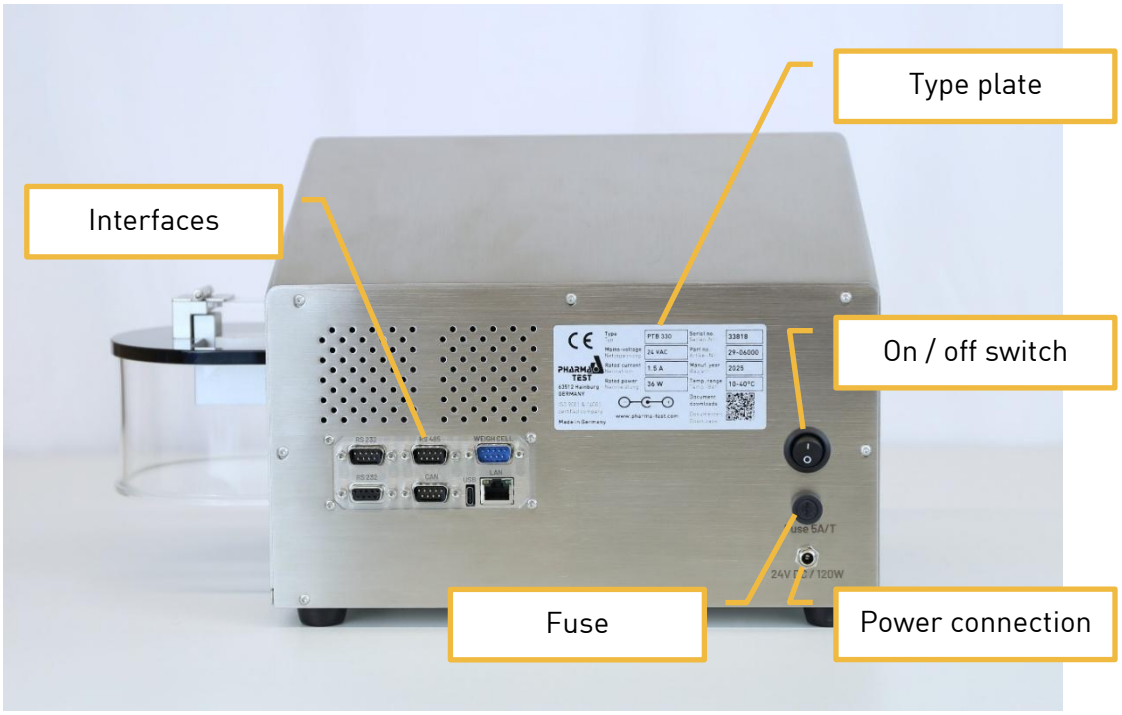


Figure 3: PTB 330 back side

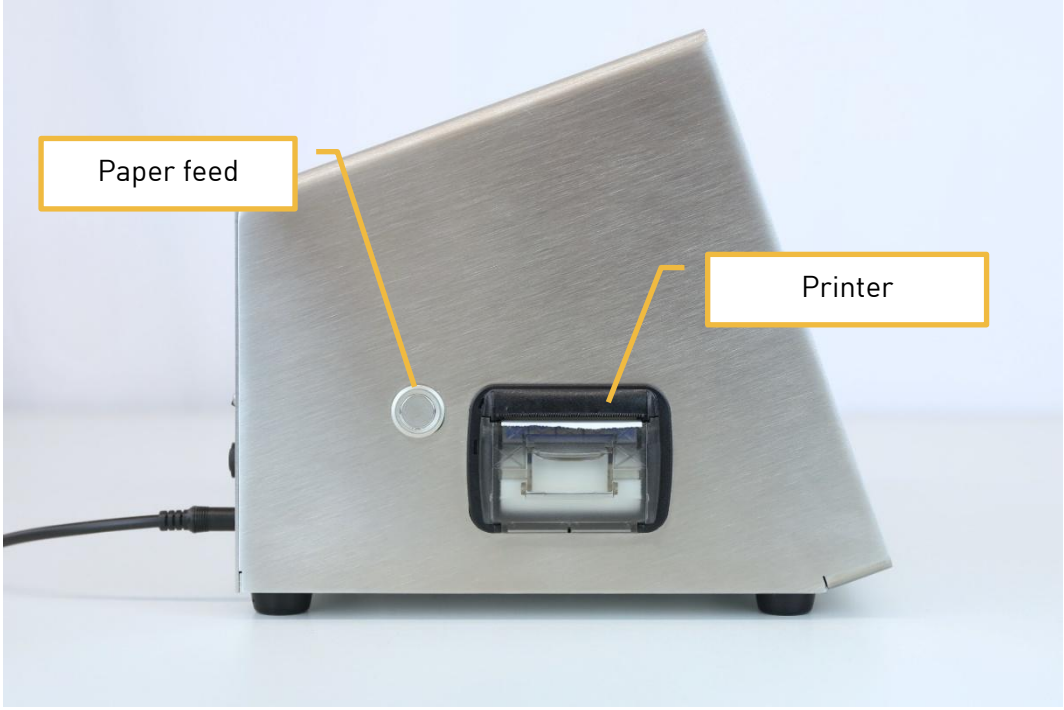


Figure 4: PTB 330 left side with printer

Assembling the Waste Container

Follow these steps to assemble the waste container:

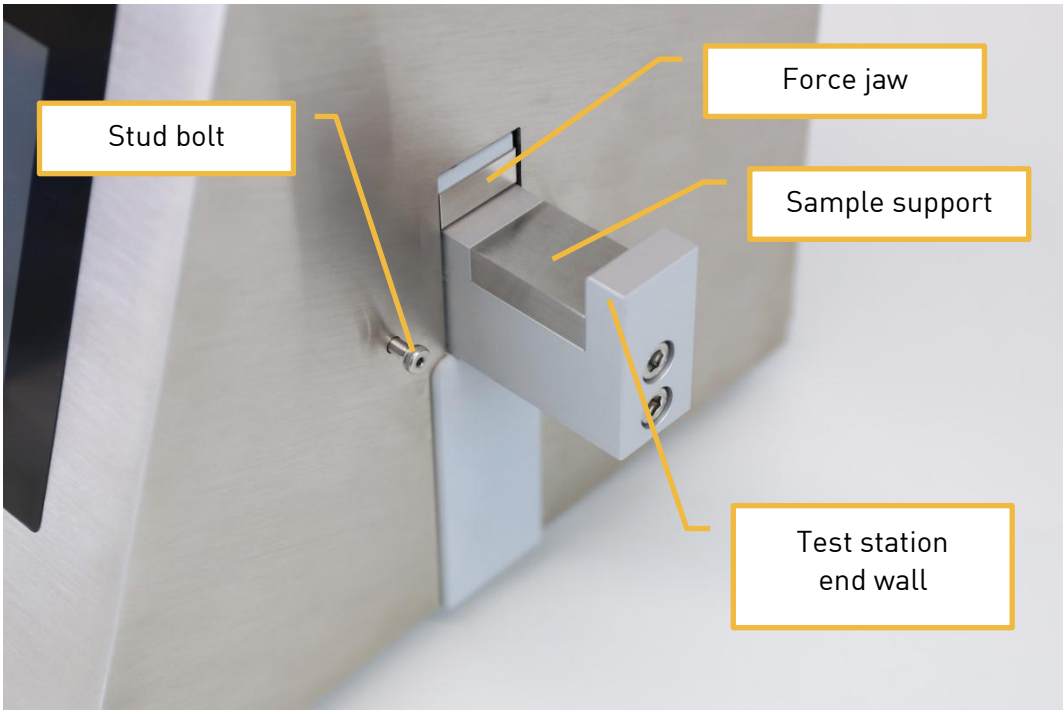


Figure 5: PTB 330 right side

There are two stud bolts on the left and right side of the testing station.

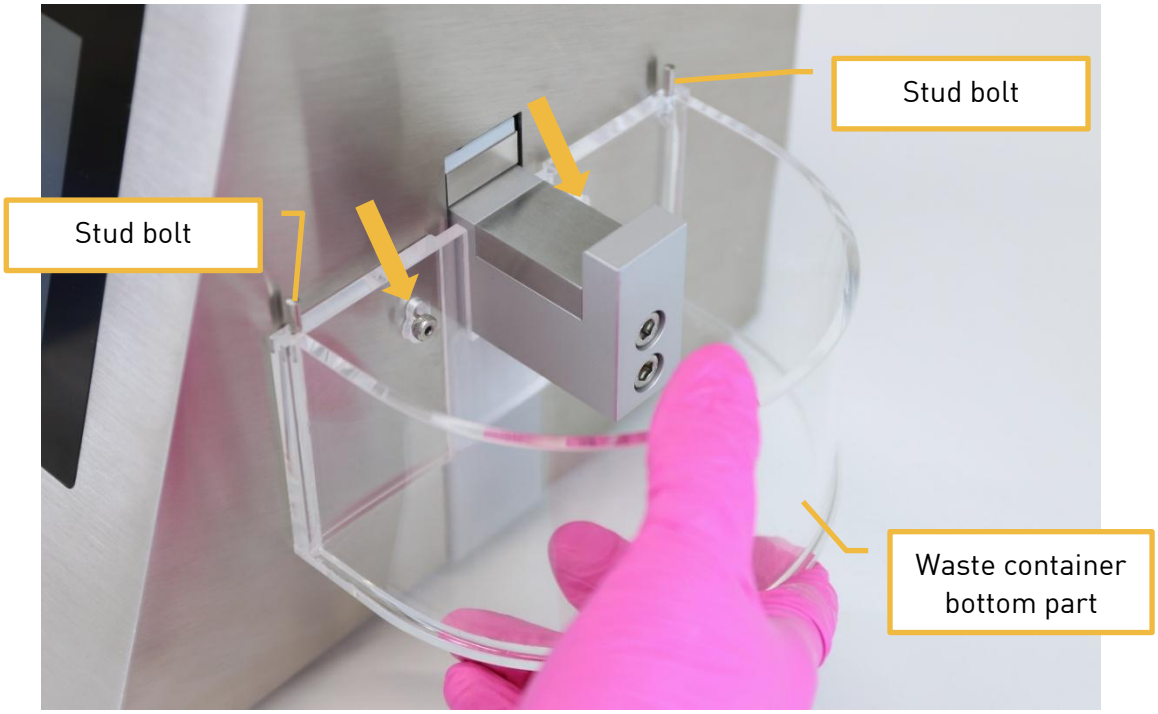


Figure 6: PTB 330 waste container bottom part

Slide in the bottom part of the waste container over the stud bolts on the instrument side and gently push it down. On the top of the waste container bottom part there are also two stud bolts.

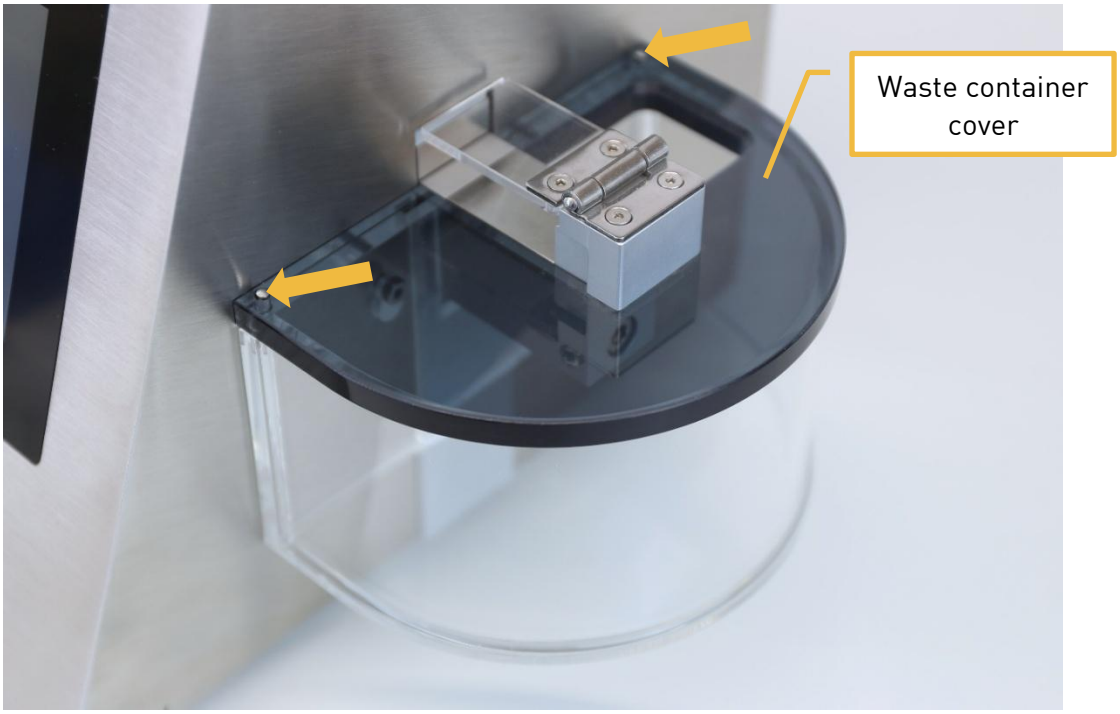


Figure 7: PTB 330 waste container cover

Slide the waste container cover over the testing station and place it on the two stud bolts of the bottom part of the waste container.

PTB 330 User Interface

This section describes the main components of the user interface and the instrument interface connections.

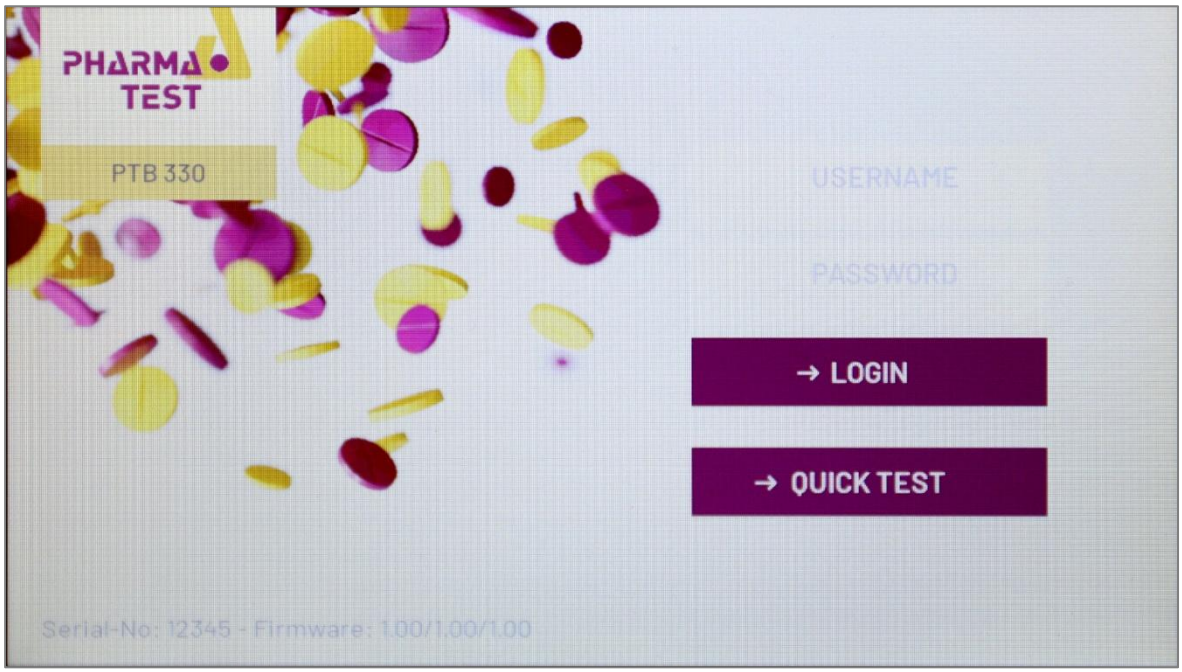


Figure 8: Start screen of the instrument

The touch screen is used to navigate the menus. Touch the screen to select items on screen or to use buttons.

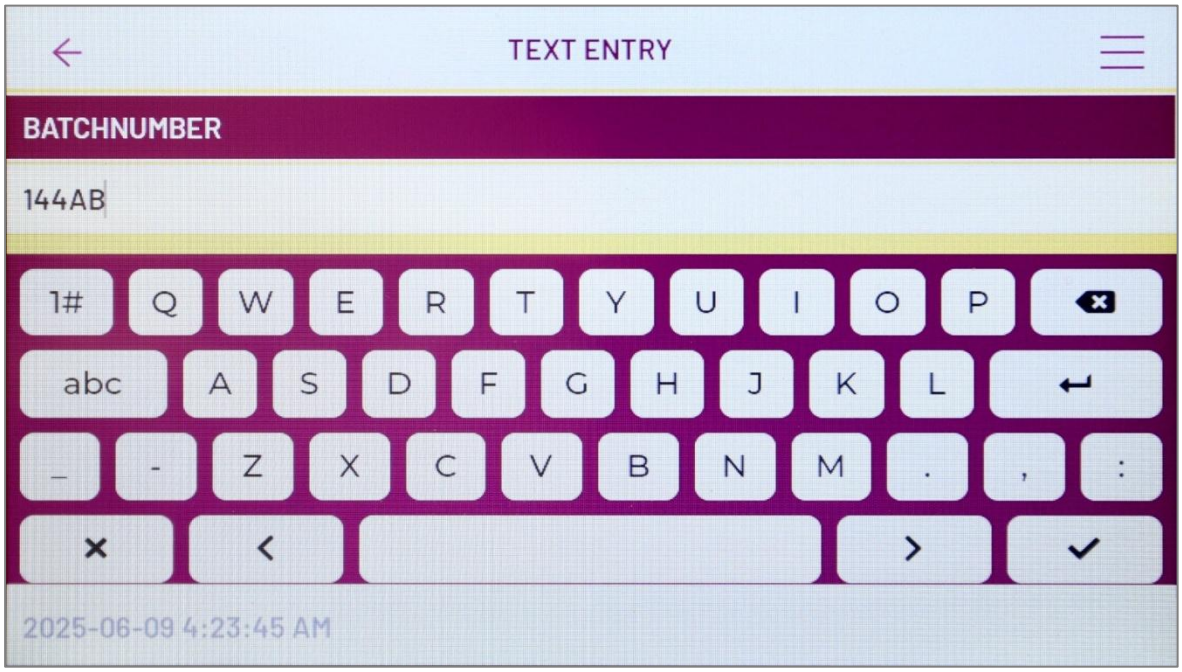


Figure 9: Software keyboard

To make alpha-numeric and numeric entries, a software keyboard is displayed.

On the back side of the instrument there the following interface connections:

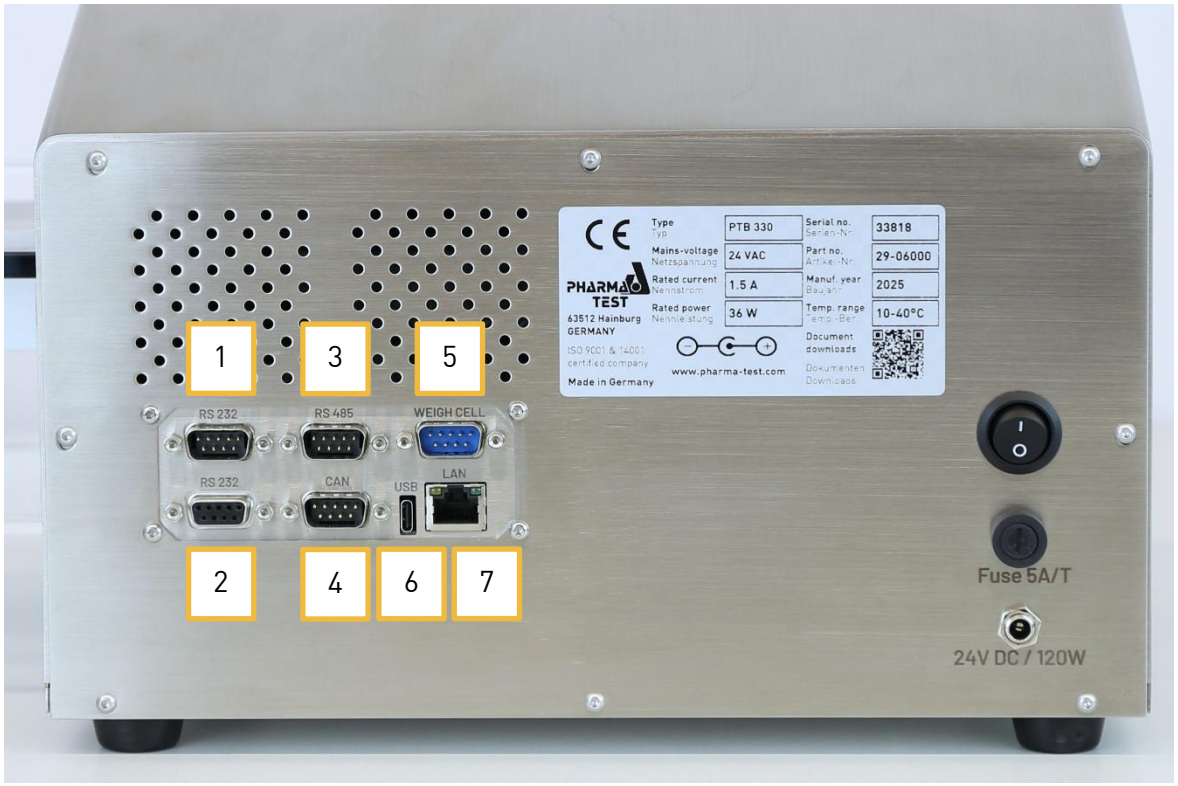


Figure 10: Instrument overview - interfaces

No.	Label	Description
1	RS 232	Serial interface port for printer, PT-Node and PC
2	RS 232	Inactive, for future use
3	RS 485	Inactive, for future use
4	CAN	Inactive, for future use
5	WEIGH CELL	Serial interface port to connect an analytical balance
6	USB	USB-C port to install firmware updates
7	LAN	Inactive, for future use

Table 11: Instrument interfaces

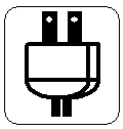
First Steps

Make sure you follow these steps before turning on the instrument for the first time:
NOTE: This instrument requires an electrical installation with a good quality, grounded, interference-free earth ground.

As you unpack your new instrument, please make sure that the package contains all items listed on the packing list and that there has been no damage during transport. Please also check that the details on the serial plate are correct, especially the mains (line) supply voltage. If this is not the case, the instrument should not be released for use.

Place the PTB 330 onto a common laboratory bench. The distance between the instrument and the lab wall should be at least 10cm.

Before Power On



Check that your mains voltage corresponds to the voltage written on the external power supply. Connect the supplied external power supply to your local mains socket. Connect the external power supply to the power port on the instrument. All cable connections must be made while all instruments are switched off. Switch the instrument on. The LCD lights up and shows the start screen.

Installation Qualification (IQ)

It is recommended to follow the IQ protocol for the PTB 330. This document is available free of charge from Pharma Test as a PDF download.

Operation Qualification (OQ)

After completing the IQ, it is recommended to follow the OQ protocol for the PTB 330. This document is available free of charge from Pharma Test as a PDF download.

Warranty Certificate

A warranty certificate (yellow sheet) is supplied in duplicate in the instrument folder. Fill both certificates and return the "COPY" to Pharma Test. Pharma Test grants 24 months warranty for material and quality issues from the date of the first performed IQ and OQ (or 30 months after date of delivery).

3. Using the PTB 330 Instrument

This section explains how to navigate the menus, how to run tests, change settings, and perform calibrations and adjustments.

Start-Up and Login

When you switch on the instrument you are presented with the login screen:

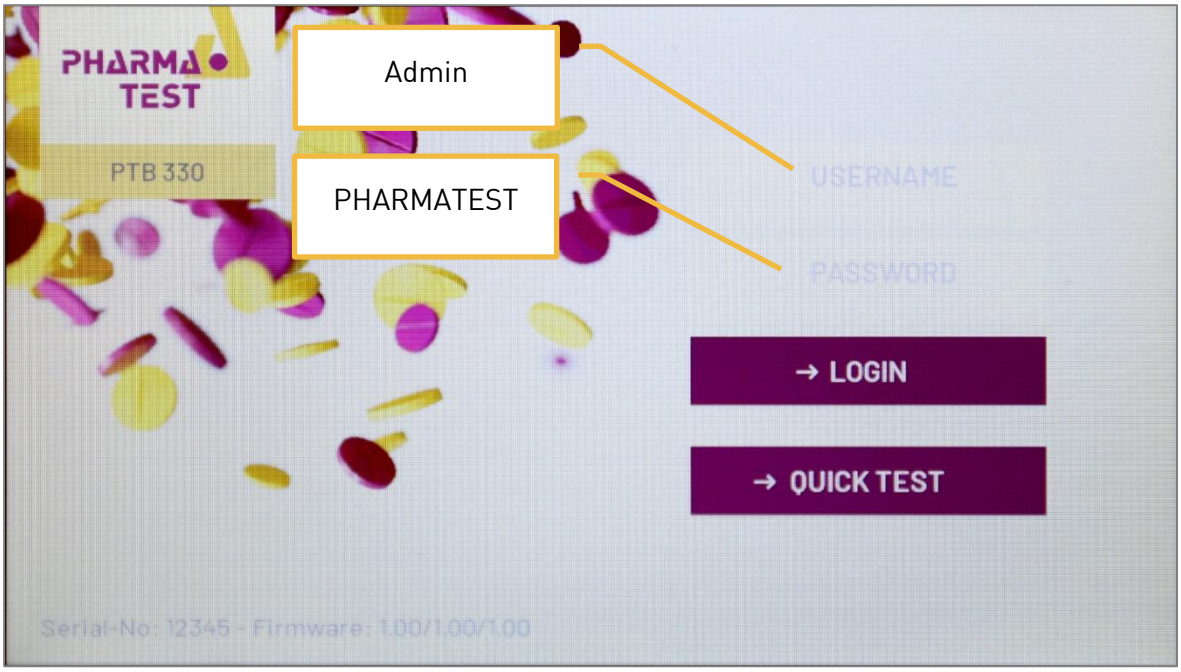


Figure 11: Login and quick test

Here you can enter your username and password and touch **[→ LOGIN]** to log in to the instrument. By default, there is an administrator user available on the instrument with the following username and password:

Username:	**Admin**
Password:	**PHARMATEST**

NOTE: Both username and password are case sensitive.

Alternatively, you can touch **[→ QUICK TEST]** to start a test run without logging in to the instrument first. See below for more details on the quick test.

NOTE: The option of performing a quick test without logging in to the instrument can be deactivated in the device settings. See the section about device settings below for more information.

Main Menu

After logging in the main menu appears. This section provides a short overview of each item on the main menu of PTB 330. More details are found in later sections of this manual:

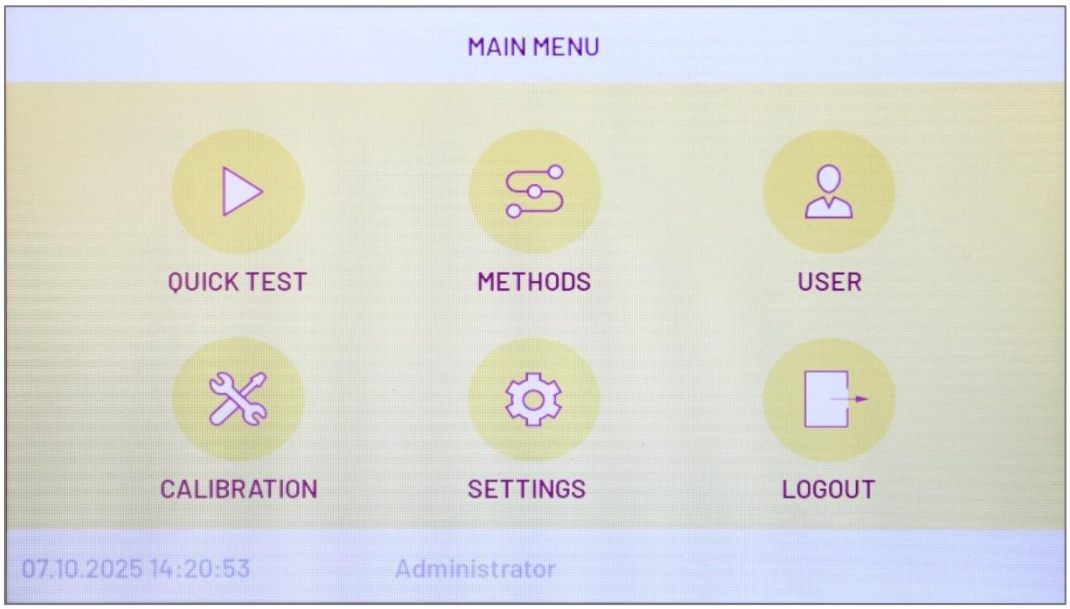


Figure 12: PTB 330 main menu

This is the main menu for PTB 330. By selecting **[LOGOUT]**, the current user is logged out and you are returned to the login screen.

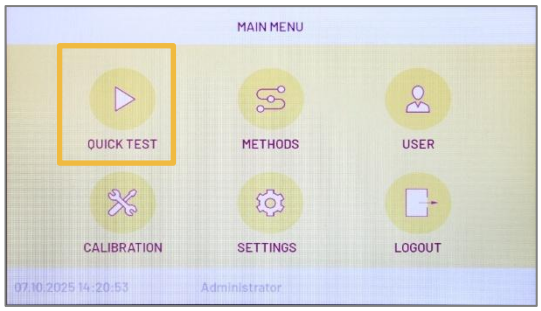
Refer to this table below for an overview of each item on the main menu:

Main menu item	Description	Further details on
QUICK TEST	Perform a test run with default settings and without entering nominal values	Page 20
METHODS	Perform a test run based on a method View, create, edit and delete methods View and print the last test result	Page 26
USER	View, create, edit and delete users	Page 36
CALIBRATION	Perform calibrations of the weight, length and hardness measurements	Page 38
SETTINGS	View and change settings Perform adjustments of the hardness and length measurements	Page 40
LOGOUT	Log the current user out and return to the login screen	NA

Table 12: Main menu items overview

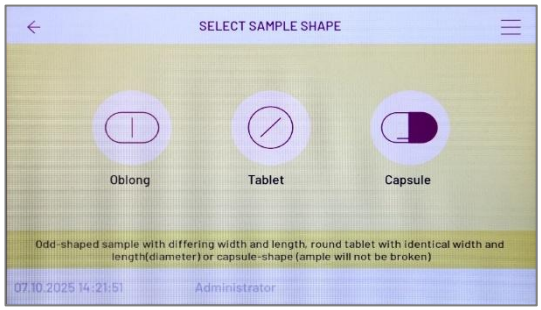
Quick Test

The "Quick Test" function is designed to quickly start a test by entering only minimal data. The quick test uses the break parameter and break mode settings as set in the device settings.



To start a quick test, select **[→ QUICK TEST]** from the login screen or **[QUICK TEST]** from the main menu.

Before the first measurement, the force jaw must be referenced. Make sure that the testing station is empty for this and that the driveway of the force jaw is unobstructed. Touch **[→ CONFIRM]** to start the referencing and wait until it finishes.

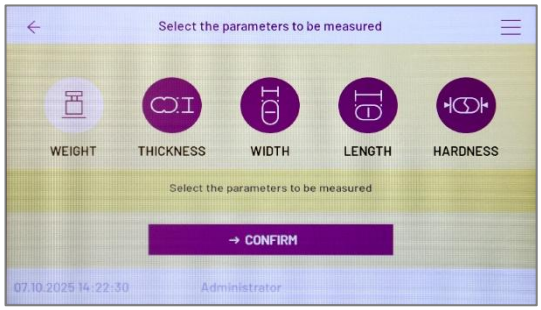


Next the approximate sample shape must be selected. Touch the sample shape to proceed.

The sample shape determines which parameters can be measured:

Sample shape	Weight	Thickness	Width	Diameter	Length	Hardness
Oblong	Yes	Yes	Yes	No	Yes	Yes
Tablet	Yes	Yes	No	Yes	No	Yes
Capsule	Yes	Yes	No	No	Yes	No

Table 13: Test parameters depending on sample shape



Depending on the selected sample shape, you can now select which parameters you want to measure. At least one parameter must be selected. Touch the test parameter icons to select and de-select parameters. Active parameters are displayed in magenta color, inactive parameters are white.

The parameters are displayed in the order they will later be measured in, from left to right.

NOTE: To measure weight an external balance must be connected to the instrument.

Touch **[→ CONFIRM]** to continue.

Here you can enter a batch number. The entry is alpha-numeric. The software keyboard will be displayed when you touch the batch number entry field.

The batch number is included in the printed result report.

When you perform another test after this quick test, the previously entered batch number will be proposed, and you can confirm to keep the same batch number or edit to change it.

Touch **[→ CONFIRM]** to continue.

In case the weight parameter is active, the instrument will now tare the balance. Make sure that the balance connected to the PTB 330 instrument is turned on and that the balance dish is empty.

Touch **[→ TARE]** to continue and wait until the balance has finished taring.

Now the test screen is displayed:

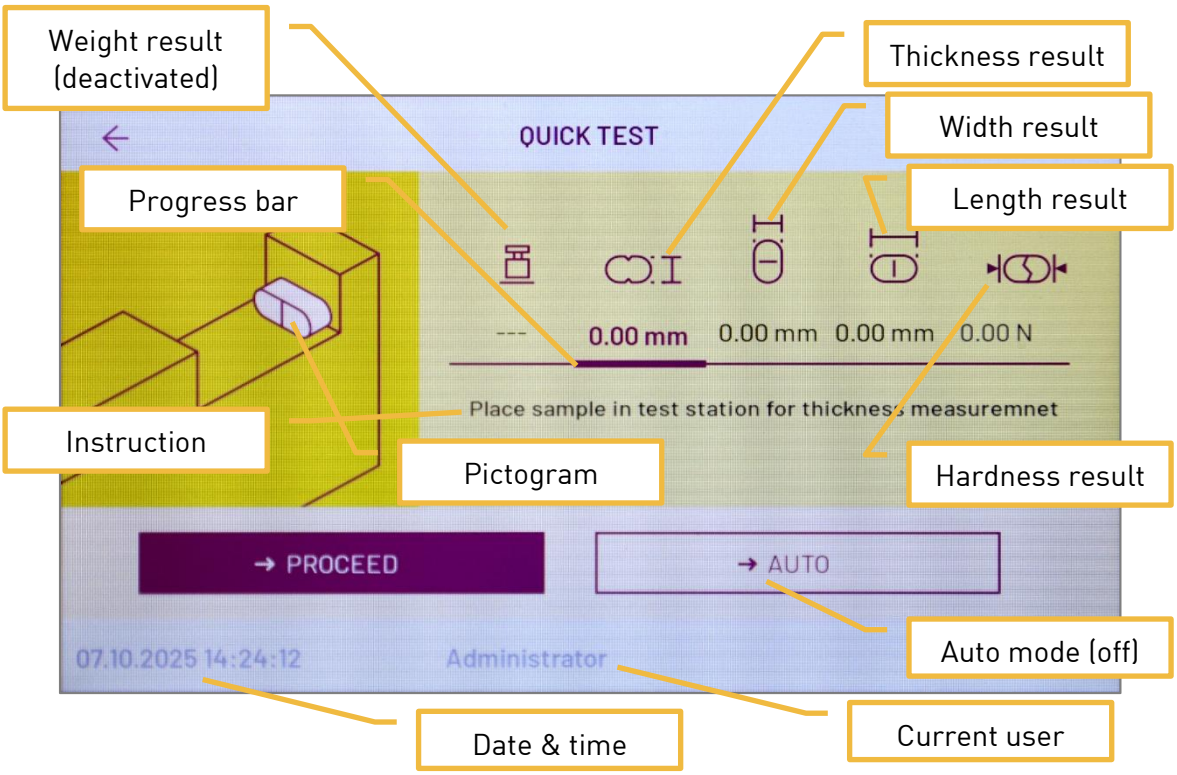


Figure 13: Test screen – Quick Test

Screen element	Description
Results	On the top right side the results for each measurement of the current sample are displayed
Progress bar	This bar moves from left to right an indicates which measurement is currently being performed
Instruction	This text explains what the next step in this test run is, this changes into a circle while the instrument is working
Pictogram	This illustration shows how the sample must be inserted for the next measurement
Auto mode	Use this button to toggle auto mode on and off
Date & time	Actual date and time
Current user	The full name of user currently logged in

Table 14: Test screen elements – Quick Test

Auto Mode

This feature allows the operator to perform consecutive tests without touching **[→ CONFIRM]** to continue each time. To enable the auto start mode touch **[→ AUTO]**. To disable auto start mode touch **[→ AUTO]** again.

The **[→ AUTO]** button turns into solid magenta to indicate that the auto start mode is active. When this mode is active the instrument automatically starts the next measurement once it is ready and the auto start mode delay has elapsed.

By default, the delay is set to 2 seconds. It can be changed in the device settings.

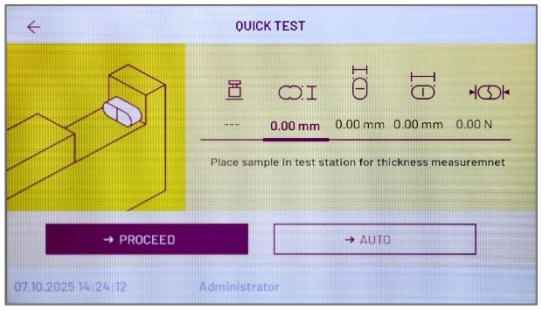
Quick Test with an Oblong Sample

The following instructions assume that all parameters are active. In case a parameter is set to inactive the measurement is skipped.

Follow the on-screen instructions and refer to the picture on the left side.

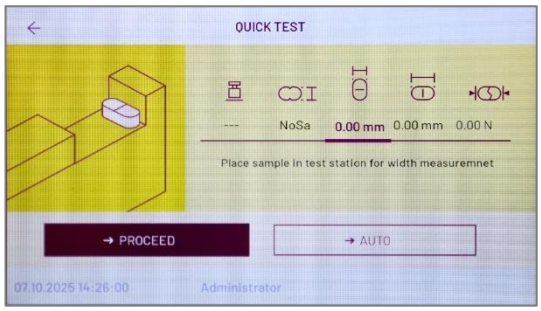
Place the first sample on the balance dish and touch **[→ PROCEED]** to continue and start the weight measurement.

Once the weight measurement is complete, the result is displayed below the weight icon.



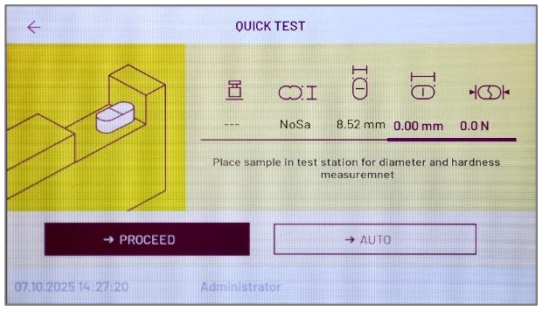
Now place the sample in the test station for the thickness measurement as shown in the picture on the left side.

Touch **[→ PROCEED]** to continue and start the weight measurement.



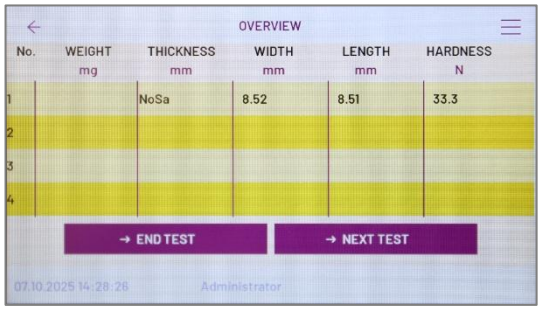
Next place the sample in the test station for the width measurement as shown in the picture on the left side.

Touch **[→ PROCEED]** to continue and start the weight measurement.



Next place the sample in the test station for the length and hardness measurement (length and hardness are measured together in a single process) as shown in the picture on the left side.

Touch **[→ PROCEED]** to continue and start the weight measurement.



Now that all parameters of one sample have been measured, the result overview is displayed. Here you can see all test results obtained thus far. You can swipe up and down to scroll the list of results. This overview is displayed each time all parameters of a sample have been measured.

Touch **[→ END TEST]** to terminate this test run and to display the statistics.

Touch **[→ NEXT TEST]** to continue the current test run with the next sample.

Quick Test with a Round Tablet

The Quick Test with a round tablet is like a test with an oblong sample but there are no length and width measurements. Instead, the diameter of the sample is measured. The test screen uses the appropriate symbols and illustrations for a round tablet instead of the oblong one.

Quick Test with a Capsule

The Quick Test with a capsule too is like a test with an oblong sample but there are no length, width and hardness measurements. For capsules only weight, diameter and length are measured. The test screen uses the appropriate symbols and illustrations for a capsule instead of the oblong one.

Statistics

Once a test run has ended the statistics are displayed. You can swipe up and down to scroll the table. The following statistics are calculated:

Max: Maximum

Min: Minimum

Diff: Difference between maximum and minimum

Mea: Mean value

Xab: Absolute standard deviation

Xrel: Relative standard deviation

Statistics are generated for each of the measured parameters.

Touch **[→ PRINT]** to print out the result report.

Touch **[→ QUIT]** to return to the main menu or login screen. This will discard the results of this quick test. Make sure to print the result report before quitting.

Example Quick Test Report

```
Pharma Test PTB 330-500 SN 12345 V1.00

Method name: Quick Test
-------------------------------------
Batch No.  : 1234567890ABCD
Start date : 12.09.2025 13:47:19
----------------Results--------------

   :Weight:Thick.:Width :Diam. :Hardn.
   : (mg) : (mm) : (mm) : (mm) : ( N)
-------------------------------------

1:    10.0:  4.00:  5.00: 14.00:  30.0
2:    10.0:  4.00:  5.00: 14.00:  30.0
3:    10.0:  4.00:  5.00: 14.00:  30.0
-----Statistics  3 samples-----------

   :Weight:Thick.:Width :Diam. :Hardn.
   : (mg) : (mm) : (mm) : (mm) : ( N)
Max:  10.0:  4.00:  5.00: 14.00:  30.0
Min:  10.0:  4.00:  5.00: 14.00:  30.0
Dif:   0.0:  0.00:  0.00:  0.00:   0.0
Xab:   0.0:  0.00:  0.00:  0.00:   0.0
   :  (%):  (%) :  (%) :  (%) :  (%)
Xre:   0.0:  0.00:  0.00:  0.00:   0.0

End date  : 12.09.2025 :13:48:58

Operator : ---------------------------


Released : ---------------------------

           Name/Signature  Date/Time

Print date : 12.09.2025 : 13:49:36
```

Header with instrument type, serial no. and firmware version

Batch no. and test start date

Results of measurements

Statistics

Test end date

Signature lines

Print date of report

Methods

A method contains the name of the method, an optional comment, the number of measurements to be performed for each parameter, the nominal values for each parameter, tolerances for each parameter, test parameters and which break method is to be used.

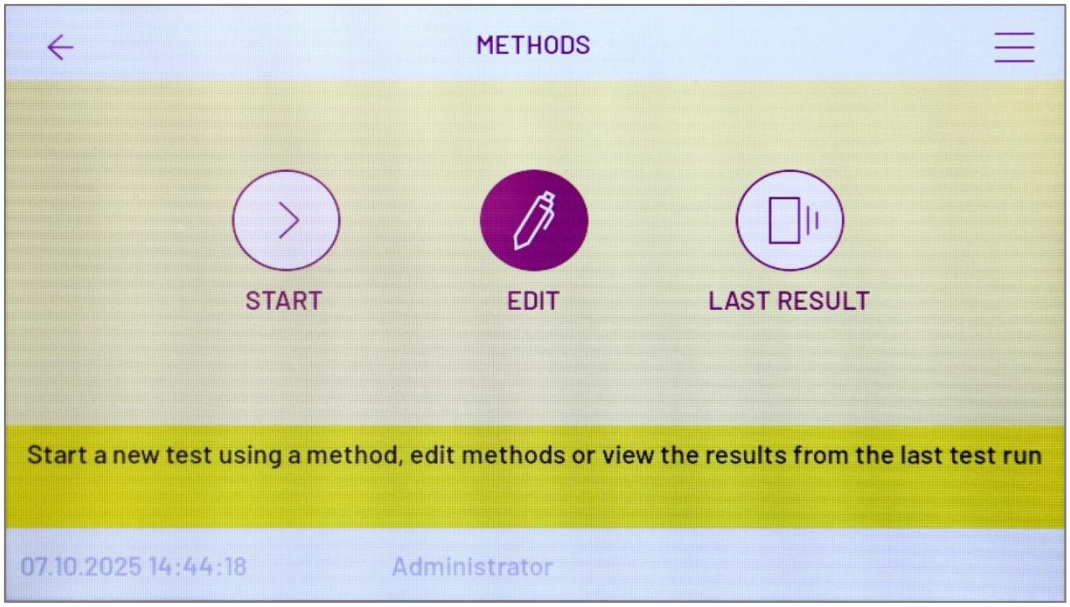


Figure 14: Methods menu

Create or Edit Methods

This section describes how to create, edit (update) and delete methods. From the methods menu select "EDIT".

NOTE: deleted methods cannot be restored. In case you suspect the method may be required again in the future, you can set the method as "inactive" to prevent it from being used for any tests.

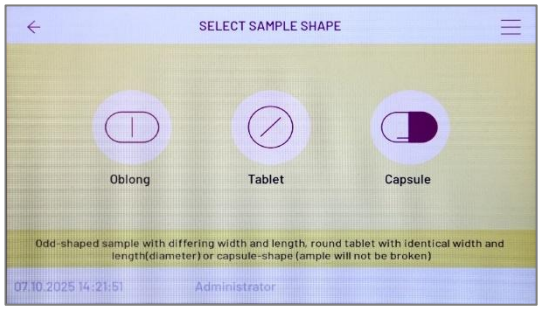
A list of all methods stored on the instrument is displayed. The list is sorted alphabetically. You can store up to 100 methods on the PTB 330 instrument. Select a method from this list to view and edit it.

Touch **[→ NEW METHODS]** to create a new method.

Now you must enter a name for the new method. The name can be alpha-numeric. Touch the entry field to bring up the software keyboard.

You can also enter a comment to describe the method. This may be left blank.

Touch **[→ NEW METHODS]** to proceed.

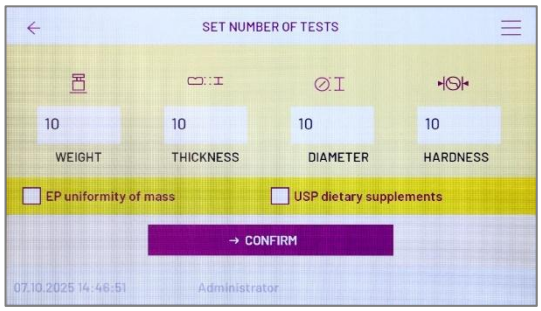


Next the approximate sample shape must be selected. Touch the sample shape to proceed.

The sample shape determines which parameters can be measured:

Sample shape	Weight	Thickness	Width	Diameter	Length	Hardness
Oblong	Yes	Yes	Yes	No	Yes	Yes
Tablet	Yes	Yes	No	Yes	No	Yes
Capsule	Yes	Yes	No	No	Yes	No

Table 15: Test parameters depending on sample shape



On this screen set the number of tests to be performed for each parameter. If you don't want to measure a certain parameter set the number to 0.

NOTE: To measure weight, an external balance must be connected to the instrument.

There are also two checkboxes here: "**EP uniformity of mass**" and "**USP dietary supplements**". Both refer to the weight measurement and the tolerances for it. In case weight is not measured, these checkboxes can be ignored. See further below for more information on tolerances.

There are three monographs in the EP and USP Pharmacopeia that require weight measurement of either 20 or 10+20 tablets/capsules:

- **EP <2.9.5>:** Uniformity of mass: this monograph states, that 20 samples must be weighed/tested
- **USP <2091>:** Weight variation of dietary supplements: test 20 samples
- **USP <905>:** Uniformity of dosage units: weight variation test: prepare 30 samples, then test 10 samples. If the result is outside the tolerance range: test another 20 samples.

EP Uniformity of Mass According to EP <2.9.5>

Activating the checkbox "EP uniformity of mass" sets the number of weight measurements 20 and the weigh mode to individual samples. Furthermore, it sets the T1 and T2 tolerances according to this table:

Shape	Average Mass in mg	T1	T2
Capsule	< 300	10%	20%
	⩾ 300	7.5%	15%
Tablet and oblong	⩽ 80	10%	20%
	> 80 und < 250	7.5%	15%
	⩽ 250	5%	10%

Figure 15: EP uniformity of mass

These settings are derived from the EP monograph <2.9.5> about uniformity of mass.

USP Dietary Supplements According to USP <2091>

Activating the checkbox "USP dietary supplements" sets the number of weight measurements 20 and the weigh mode to individual samples. Furthermore, it sets the T1 and T2 tolerances according to this table:

Shape	Average Mass in mg	T1	T2
Tablet and oblong	⩽ 130	10%	20%
	⩾ 300	7.5%	15%
	⩽ 80	10%	20%
Capsule		10%	25%

Figure 16: USP dietary supplements

These settings are derived from the USP monograph <2091> about dietary supplements.

USP Uniformity of Dosage Units According to USP <905>

Since this test is described as a two-stage test in the Pharmacopeia, testing according to this monograph cannot be performed by using a single checkbox. We recommend creating two methods: The first method with 10 measurements for weight and a T1 tolerance of 15%. The second method with 20 measurements for weight and a T1 tolerance of 15% and a T2 tolerance of 25%.

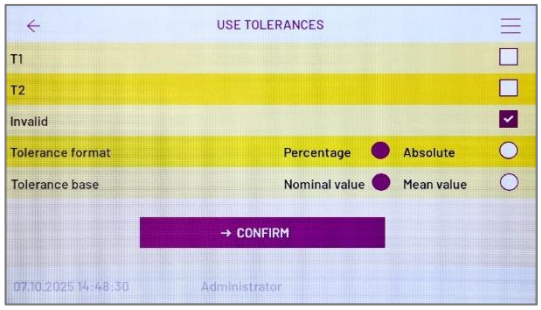
The requirements for dosage uniformity are met if the acceptance value of the first 10 samples tested with the first is within T1. If results are out of T1, test the next 20 samples with the second method. The requirements are met if the results of the 30 samples from both test runs are ⩽ T1, and no measurement of any sample is less than [1 – (0.01)(T2)]M nor more than [1 + (0.01)(T2)]M.

Make sure to consult the latest version of the USP to check if other acceptance values for your samples may apply.

Now set the nominal values for each parameter. For parameters with zero measurements, you can leave the nominal values at the default values displayed with one exception: to measure the hardness, the instrument must know the diameter or length of the sample. There a nominal value must be set.

In case the number of diameter or length measurements are set to 0, no result for diameter or length will be reported.

There are also two radio buttons here which can be toggled between "**Individual weight**" and "**Average weight**". Both refer to the weight measurement. When **individual weight** is active, the samples are placed onto the balance one by one and individual weight results are recorded. When **average weight** is active, all samples are placed onto the balance at the same time, and the average weight is recorded. In case weight is not measured, these checkboxes can be ignored.



Here you can select which levels of tolerance you want to use in this method, how these tolerances should be entered and if they should be based on the nominal values or on the average results.

See below for more information on tolerances.

On the succeeding screens, enter the tolerances values for all active tolerance levels, for all measurements.

NOTE: Only the previously enabled tolerances will be displayed here.

About Tolerances

PTB 330 supports three levels of tolerances:

Parameter	Description
T1	The first lower and upper limit of tolerances.
T2	The second lower and upper limit of tolerances.
Invalid	The upper and lower limit of invalidity. All samples outside these limits are intended to sort out incorrect measurements. These measurement values are not included in statistical calculations. The individual results are still documented in the result report.
Tolerance format	Select whether you the tolerance values should be entered as percentage values or as absolute values.
Tolerance base	Select whether the results should contain a mark for exceeding tolerances based on the nominal values or the average values of the results.

Table 16: About Tolerances

The tolerances are arranged in this way:

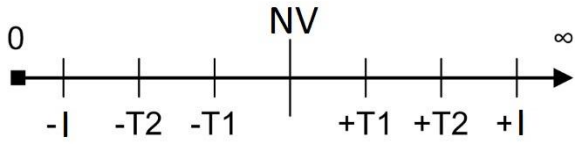
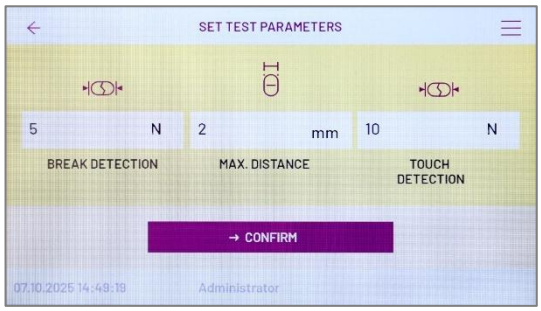
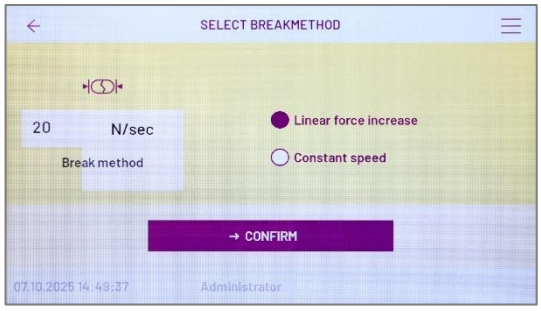


Figure 17: Tolerance Arrangement



Now you can enter the test parameters of break detection, maximum distance and touch detection. By default, these values are displayed as set in the device settings. For most samples it is not necessary to change these values, but they can be set on a per-method basis.

You can find more details about these parameters below in the section about device settings.



Finally, you can select the break method. As with the test parameters, the settings from the device settings are displayed as a default. Pharma Test recommends working with these settings.

See the section about device settings below for an explanation of the break method.

This last screen presents an overview of everything that has been entered for this method.

Touch **[→ SAVE]** to store this newly created method. You are then returned to the methods menu.

Deleting a Method

This section describes how to delete a method from the instrument's internal memory. Deleted methods cannot be restored. In case you suspect the method may be required again in the future, you can set the method as "inactive" to prevent it from being used to perform measurements.

Select the method to be deleted from the list of methods.

An overview of this method is displayed. Touch **[→ SET INACTIVE]**. This method can now no longer be used for tests. This method is now marked "INACTIVE" on the list of methods. To permanently delete this method, select the method again from the list. Touch **[→ DELETE]** to permanently delete this method. This process is irreversible.

Start a Test

From the methods menu select "START" to perform a test with pre-defined parameters, based on a method. This means, you must create at least one method first. Otherwise, if you do not want to work with methods you can use the quick test instead.

This section describes how to run a test from a method. For more details on how to create and edit methods see further down below in this document.

Before the first measurement, the force jaw must be referenced. Make sure that the testing station is empty for this and that the driveway of the force jaw is unobstructed. Touch **[→ CONFIRM]** to start the referencing and wait until it finishes.

Select a method from the method list.

Enter a batch number. The entry is alpha-numeric. The software keyboard will be displayed when you touch the batch number entry field.

The batch number is included in the printed result report.

Touch **[→ CONFIRM]** to proceed.

In case the weight parameter is active, the instrument will now tare the balance. Make sure that the balance connected to the PTB 330 instrument is turned on and that the balance dish is empty.

Touch **[→ TARE]** to continue and wait until the balance has finished taring.

Now the test screen is displayed:

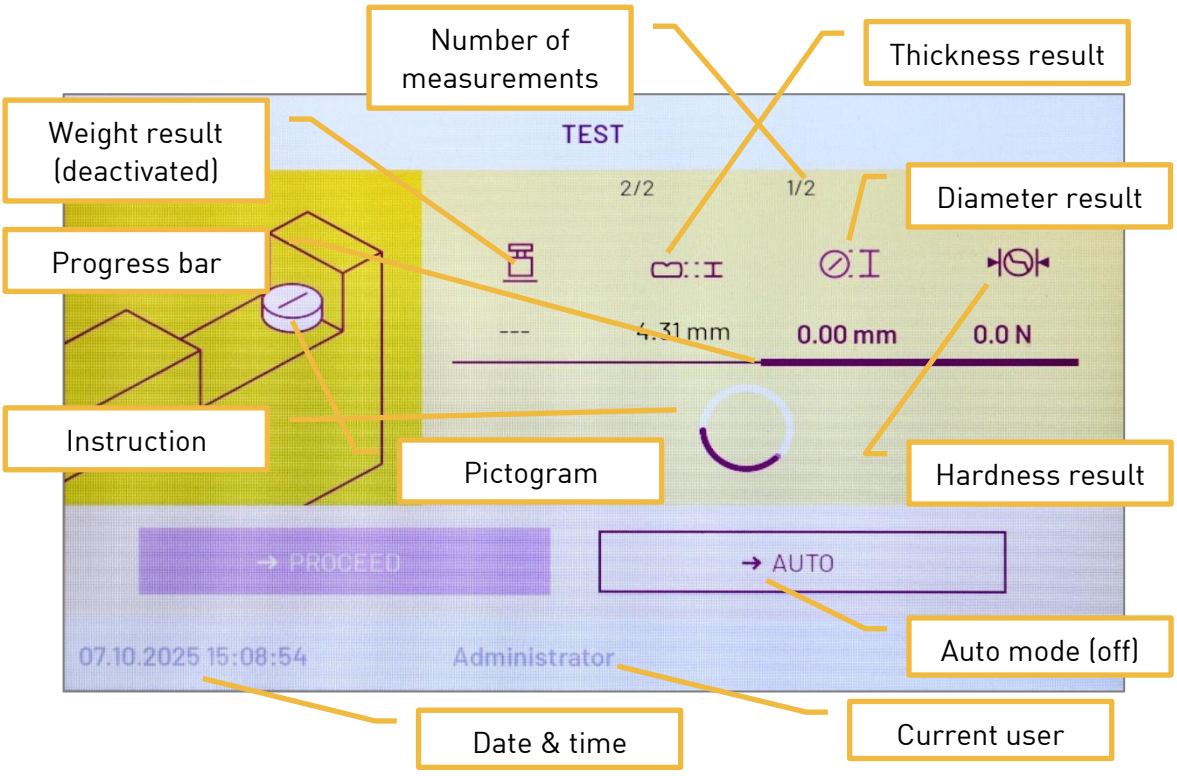
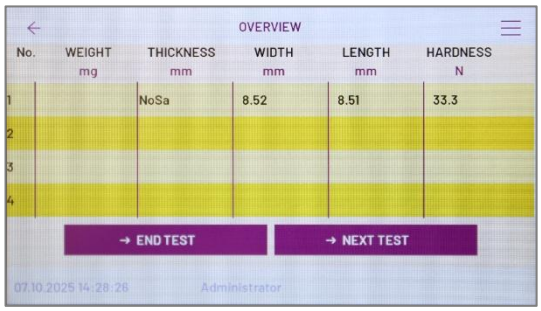


Figure 18: Test screen – Method Test

Screen element	Description
Results	On the top right side the results for each measurement of the current sample are displayed
Number of measurements	The number of measurements already performed and the total number of measurements
Progress bar	This bar moves from left to right an indicates which measurement is currently being performed
Instruction	This text explains what the next step in this test run is, this changes into a circle while the instrument is working
Pictogram	This illustration shows how the sample must be inserted for the next measurement
Auto mode	Use this button to toggle auto mode on and off
Date & time	Actual date and time
Current user	The full name of user currently logged in

Table 17: Test screen elements – Quick Test

Now follow the on-screen instructions and refer to the picture on the left side when inserting the samples.



Once all parameters of one sample have been measured, the result overview is displayed. Here you can see all test results obtained thus far. You can swipe up and down to scroll the list of results. This overview is displayed each time all parameters of a sample have been measured.

In case a measurement lies outside the threshold of a tolerance this is marked accordingly on this table.

Touch **[→ NEXT TEST]** to continue until all measurements as defined in the method have been performed.

Statistics

Once a test run has ended the statistics are displayed. You can swipe up and down to scroll the table.

The following statistics are calculated:

Statistic	Description
Max.	Maximum
Min.	Minimum
Diff.	Difference between maximum and minimum
Mea.	Mean value
Xab	Absolute standard deviation
Xrel	Relative standard deviation

Table 18: Statistics

Statistics are generated for each of the measured parameters. Touch **[→ PRINT]** to print out the result report. Touch **[→ QUIT]** to return to the main menu.

Example Test Report

```
Pharma Test PTB 330-500 SN 12345 V1.00

Method name: DEMO METHOD
--------------------------------------
Nso: 3 X  :  3 X :  3 X :  3 X :  3 X
--------------------------------------
Batch No.  : 1234567890ABCD
Start date : 12.09.2025 13:47:19
---------------Results--------------

   :Weight:Thick.:Width :Diam. :Hardn.
   : (mg) : (mm) : (mm) : (mm) : ( N)
--------------------------------------

1:    10.0:  4.00:  5.00: 14.00:  30.0
2:    10.0:  4.00:  5.00: 14.00:  30.0
3:    10.0:  4.00:  5.00: 14.00:  30.0
-----Statistics  3 samples-----------

   :Weight:Thick.:Width :Diam. :Hardn.
   : (mg) : (mm) : (mm) : (mm) : ( N)
Max:  10.0:  4.00:  5.00: 14.00:  30.0
Min:  10.0:  4.00:  5.00: 14.00:  30.0
Dif:   0.0:  0.00:  0.00:  0.00:   0.0
Xab:   0.0:  0.00:  0.00:  0.00:   0.0
   :  (%):  (%) :  (%) :  (%) :  (%)
Xre:   0.0:  0.00:  0.00:  0.00:   0.0

End date  : 12.09.2025 :13:48:58

Operator : --------------------------


Released : --------------------------

           Name/Signature  Date/Time

Print date : 12.09.2025 : 13:49:36
```

Header with instrument type, serial no. and firmware version

Number of measurements

Batch no. and test start date

Results of measurements

Statistics

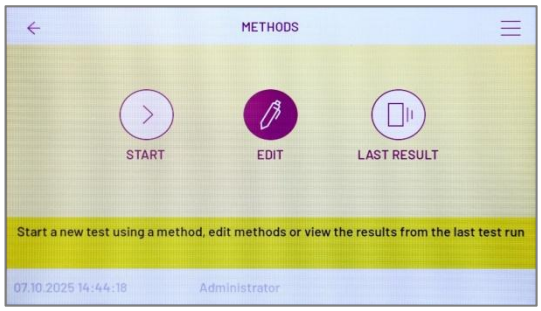
Test end date

Signature lines

Print date of report

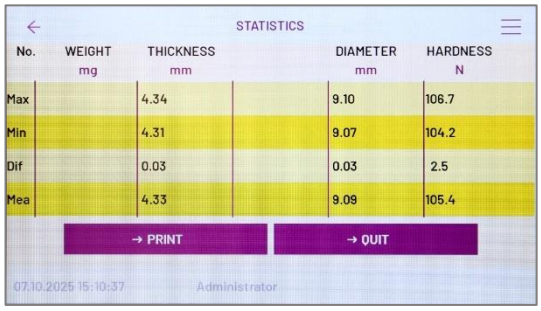
Repeat Print of the Last Result

NOTE: PTB 330 stores the results of the latest test run only! Only this can be re-printed. As soon as a new test is started (even in case this run is aborted), the previous results are irretrievably discarded. So always make sure to print your results immediately or use the repeat print function in case you need to print the last result again (for example in case you reached the end of a paper roll).



From the method menu select "LAST RESULT".

The result overview of the last test run is displayed. Touch **[→ STATISTICS]**.



The statistics of the last test run are displayed. Touch **[→ PRINT]** to print the result report.

NOTE: The print date will always be the actual date when a report has been printed, i.e. this will change with each repeated printing. Test start and test end date will remain unchanged.

Users

This section describes how to add a new user, how to delete users and how to change the user password and permissions. PTB 330 is equipped with a flexible user management system that can handle up to 100 users with different permissions.

Users can be assigned any combination of the following user rights:

User right	Description
Run tests	Perform test runs based on a method or use quick test
Service & settings	Change settings and perform adjustments
Edit methods	Create, edit and delete methods
Edit user	Create, edit and delete users
Calibration	Perform calibrations

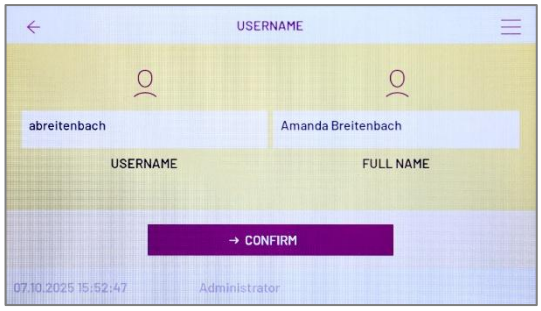
Table 19: User rights

Creating a New User

NOTE: Only users with the user right "edit user" can create or edit users.

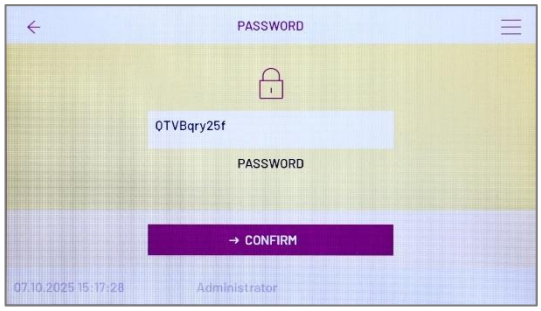
Enter the user menu from the main menu. The list of users will be displayed.

Touch **[→ NEW USER]**.



Enter a short username and the full name of the user. The short username must be entered to login to the instrument. The full name is printed on reports.

Touch **[→ CONFIRM]** to proceed.



Enter the password for the new user. The password is alpha-numeric and must contain at least 8 characters.

Touch **[→ CONFIRM]** to proceed.

On the next screen, confirm the new password you just entered by entering it again.

Touch **[→ CONFIRM]** to proceed.

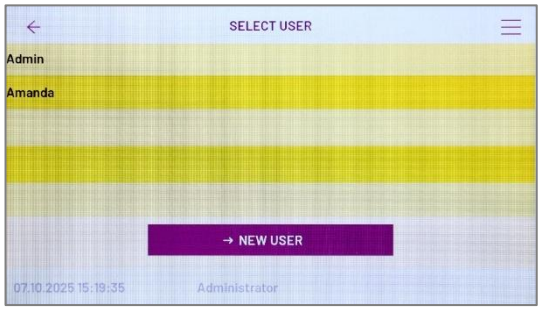
Select the rights the new user should possess. You can select any combination of these rights. Make sure to select at least one right.

Touch **[→ CONFIRM]** to proceed.

The new user is created and shown in the list of users.

Editing a User

NOTE: Only the administrator can edit the "Admin" user and only the password can be changed. The administrator always has all user rights and cannot be set as inactive or deleted.



Select the user to be edited from the list of users.

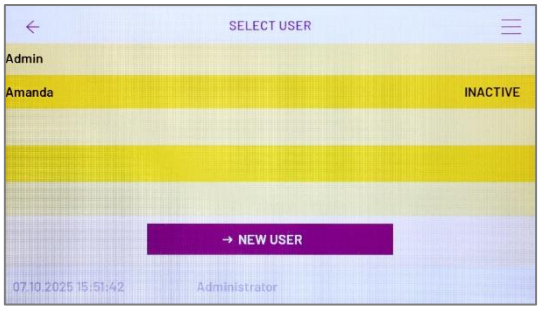
An overview for this user is displayed. Touch the parameter you want to edit. From there the process is the same as creating a new user.

Deleting a User

This section describes how to delete a user from the instrument's internal memory. Deleted users cannot be restored. In case you suspect the user may be required again in the future, you can set the user as "inactive" to prevent him from being able to login to the instrument.

Select the user to be deleted from the list of users.

An overview for this user is displayed. Touch **[→ SET INACTIVE]**. This user now cannot login anymore.



This user is now marked “INACTIVE” on the list of users. To permanently delete this user, select the user again from the list.

Touch **[→ DELETE]** to permanently delete this user. This process is irreversible.

Calibration

PTB 330 uses a three-point calibration procedure for the weight, length and hardness test stations. We recommend using the following reference tools, but PTB 330 allows entering the reference values, so that other tools may be used as well:

Test station to calibrate	Tool	Part no.
Weight	Reference weight 10g, certified	412-0245
	Reference weight 20g, certified	412-0240
	Reference weight 50g, certified	412-0209
Length	Reference block set 3, 5, 10mm, certified	285-1755-3
Hardness	Reference weight set 5, 10, 15kg, certified	28-00290

Table 20: Tools required for adjustment

Figure 19: PTB-CAL15 5, 10, 15kg weight set

PTB 330 offers calibration programs for weight measurement, length measurements and hardness measurement. The procedure is similar in each case: enter up to three reference values and set how many measurements of each value you want to perform during the calibration. From there the instrument will guide the user through the process by on-screen instructions and illustrations. Each calibration concludes with the print-out of a calibration report.

Settings

The settings menu is divided into locale and device settings. Furthermore, you can enter the adjustment menu via the settings menu.

Locale Settings

Locale settings cover all settings related to where the instrument is installed. This means instrument language, date and time settings as well as date and time formats.

Parameter	Description	Settings
Language	The language for the user interface and for the printed reports.	Deutsch, English
Time/Date	Set the current time and date and select the format for time and date.	EUR (dd.mm.yy) or US (mm/dd/yy) format for date 24 hour or 12 hour AM/PM format for time

Table 21: Locale Settings

Device Settings

Device settings cover all settings related to the usage of the instrument and performing of tests.

Parameter	Description	Settings
Units	Select the units for the measurements	Milligram (mg) or Gram (g) for weight measurements Millimeter (mm) or Inch (In) for length Newton (N), Kilopond (kp) or Strong Cobb (Sc)
Break Parameters	Set the default break parameters. These parameters are used as defaults for new methods and for the quick test. See below for more details about the break parameters.	Break detection in N, kp or Sc Max. distance in mm or In Touch detection in N, kp or Sc
Standby	Select after what time of inactivity the display should be dimmed. Select "never" to always keep the display at full brightness.	5 min 10 min 15 min never
Output	Select over which interface the reports should be transmitted.	internal Printer: use the integrated printer external Printer: RS232:
QUICK TEST	Select whether the Quick Test should be accessible from the login screen without logging in or not.	Yes: Quick Test available from login screen and main menu

		No: Quick Test only available from main menu
Auto Start	Set the delay for the auto start mode for tests and quick tests.	Delay in seconds
Break method	Select the break method and set the break method parameter. See below for more details on break methods.	Linear force increase in N/sec or Constant speed in mm/sec

Table 22: Device Settings

About Break Parameters and Break Methods

This section describes the two break methods available on the instrument and the other parameters which affect the hardness measurement.

NOTE: These parameters can be set in the device settings menu. The settings there are then used as defaults when creating a new method but can be changed other values in each method. The Quick Test always uses the settings as they are set in the device settings menu.

About Linear Force Increase and Constant Speed Break Methods

Two different break methods (linear force increase or constant speed) are selectable to meet current and future compendial requirements. Currently, none of the pharmacopoeia describe a specified break methods or force rate. Comparative tests using different instruments with different break method settings will lead to different hardness test results. If you ever find such differences arising from the use of two different instrument types, first check which break method and force setting the two instruments are using. They must be identical to receive comparable hardness test results.

All Pharma Test hardness testing instruments will offer the same reproducible results if they are set up in the same way. The factory default setting is **linear force increase** with a rate of **20 N/sec**. This way the force sensor adjusts the drive motor to increase the force applied to the sample by 20 N every second. This is a very precise way to control the instrument. Validation is also quite easy, as you only need is a stopwatch and a sample. Start the stopwatch as soon as the force jaw touches the sample and stop the watch when the sample is broken. Divide the displayed hardness result by 20 and the result should equal the total time for the test.

The second break method is “constant speed” which sets the drive motor to move at a constant speed. This mode is very difficult to validate. When breaking a sample, the jaw will drive forwards, hit the sample and try to maintain its constant driving speed until the sample is broken. Some competing hardness testing instruments use this break method at different force settings. This mode is offered here to provide comparability with such instruments working in this mode.

About Break Detection

The hardness or break point of a sample is detected by the instrument when the force sensor registers a lower reading after the previous reading. This usually means that the sample is broken. The factory setting for PTB 330 is 5 N, which is usually a sufficient drop off to indicate the sample did break. To increase or decrease the sensitivity of the break detection, you can change this setting. A lower setting increases, and a higher setting decreases sensitivity. Testing very soft samples may require you to change this setting.

About Max. Distance

Usually, samples get compressed before they break. Most samples break within a compression of 2 mm, but depending on the sample size, hardness and material it may be necessary to increase the total distance from touch detection until break detection from the default setting of 2 mm.

About Touch Detection

The touch detection setting or touch force determines the force applied to the force sensor by the sample for the instrument to recognize that the force jaw made contact with the sample. As soon as the force sensor measures this set touch force, it switches from "sample search mode" into "testing mode". The default setting for PTB 330 is 10 N. Testing very soft samples may require you to change this setting.

Adjustment

The instrument has been adjusted prior to delivery, using traceable calibration tools. The adjustment is certified with the QC/DQ report supplied with the instrument. In the event of incorrect results, the relevant test station might be out of adjustment, and a readjustment may be necessary. This section describes how to adjust the testing stations of PTB 330.

Test station to adjust	Tool	Part no.
Hardness	Reference weight, certified A 30kg weight is recommended for adjustment, but lower weights may be used as well.	28-00300 PTB-CAL30 30kg weight or 28-00290 PTB-CAL15 5,10, 15kg weight set
Length	10 mm reference block, certified	288-1755 (part of the set 285-1755-3)

Table 23: Tools required for adjustment

PTB 330 offers adjustment programs for length measurements and hardness measurement. The procedure is similar to calibration. The instrument will guide the user through the process by on-screen instructions and illustrations. Each adjustment concludes with the print-out of a calibration report.

NOTE: An improperly performed instrument adjustment will lead to incorrect measurement results on the instrument. Only trained service personnel should perform adjustments.

Settings of the Built-In Printer

In case that after any change or repair work, the print layout of the built-in printer is in some way incorrect (for example, the print-out does not fit the paper anymore, shows larger symbols, additional line feeds, etc.), check and correct the internal printer settings:

Parameter	Setting
Printer emulation	PLUS
RS232 baud rate	9600 bps
RS232 data length	8 bits/chr
RS232 parity	None
RS232 handshaking	Xon/Xoff
Busy condition	RxFull
USB address number	0
Print mode	Reverse
Autofeed	CR Disabled
Chars / inch	A=22 B=17 cpi
Columns 22 cpi	40 columns
Code table [num]	00
Font type	International
Speed / quality	Normal
Notch / b. mark position	Disabled
PaperEnd Buffer Clear	Disabled
Power off command	Disabled
Print density	0%

Table 24: Integrated pinter settings

4. Troubleshooting and Error Codes

In case your instrument does not behave as expected refer to this section.

Troubleshooting

Error	Solution
The PTB 330 instrument does not turn on	1.) Mains connection is faulty: Check that the mains connection is present and properly connected to the external power supply and in turn to the instrument. 2.) The fuse is blown: Check the fuse and replace it if necessary.
Letters are displayed instead of a result during a test	See the list of error codes below.

Table 25: Troubleshooting

Error Codes

Error code	Description	Solution
OvLi	= "Over Limit": the maximum force limit has been reached without a break	Check that the correct sample has been inserted.
NoSa	= "No Sample": the force jaw has driven all the way, and no sample has been detected	Check that the correct sample has been inserted. Check that the diameter/length has been set correctly for this sample.
UnFl	= "Unexpected Force Increase": the force jaw has detected a force increase before touching the sample was expected	Check that the force jaw can move freely and that the path is not obstructed by anything. Check if the force jaw is clean from any sample debris.
NCom	= "No Communication": the external balance does not reply	Check that the external balance is connected using the proper cable and that the cable is connected to the correct ports. Check that the balance is turned on. Check that the balance supports the correct communication protocol and that the parameters are set correctly in the balance.

Table 26: Error Codes

5. Cleaning and Maintenance

Only trained and qualified personnel should clean and maintain the instrument.

Remove fragments using the supplied brush.

The Plexiglas parts should be cleaned daily. **Never use solvent-containing cleaning supplies like alcohol, ethanol, etc., they will destroy the acrylic glass.** Use exclusively soaps containing cleaning supplies with lukewarm water or cleaning cloth. Do not use the dishwasher to clean the desiccator or parts containing Plexiglas.

Clean the sample support after each hardness test using the supplied brush. Broken samples are swept into the waste box which slides into a slotted holder. When removing the waste box, please remove it carefully. Use a dry towel to clean out the tablet remnants.

If tablet remnants adhere to the fixed stainless-steel jaw, use a sharp piece of plastic (non-abrasive) and remove the remnants without scratching the polished surface.

Clean the stainless-steel parts using specialized cleaning oil, which is included with the shipment. The oil is in compliance with the German Pharmacopoeia monograph DAB 7.

Stainless steel parts must be cleaned immediately in case liquids are spilled onto the surface. Wipe away the liquid with a cloth.

The instrument does not include any other spare parts, which should be maintained by the user. Any repairs are exclusively allowed to be performed by a certified Pharma Test service partner.

In case the instrument cannot be operated anymore without the possibility of damaging or harming anybody, it must be stopped from operation immediately. This is always the case when:

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

6. Safety Information

Before you open the Instrument always remove the mains cord from the mains socket. Only authorized personnel (electrician, Pharma Test service technician) 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

Be aware of potential hurts and injuries caused by crushing fingers in the stroke area during operation of the instrument.

Before transporting the instrument, make sure that it is cleaned and emptied from any test substances.

Always use gloves while moving the instrument, even while unpackaging, to avoid bruising hands and fingers.

While breaking a tablet or capsule, parts can bounce out of the testing station. Use the plastic lid to cover the testing station while a test runs. Do not hold eyes and head in direct closeness to the test sample while breaking or use protective glasses.

In case any parts are needed, please use only Pharma Test Apparatebau AG original parts.