PTB 330

5-in-1 Tablet Testing Instrument

The 5-in-1 tablet testing instrument PTB 330 is a dual test mode 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. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.

Measurement of Five Different Parameters

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.

Changeable Sample Support

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).

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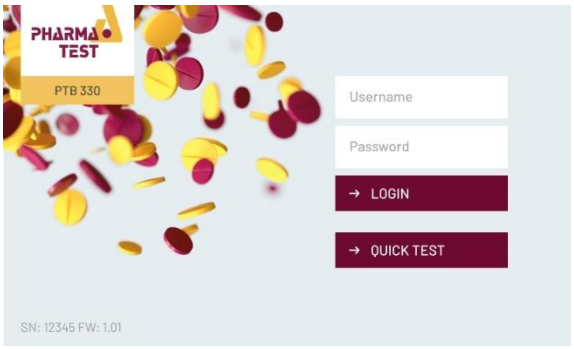
User Interface

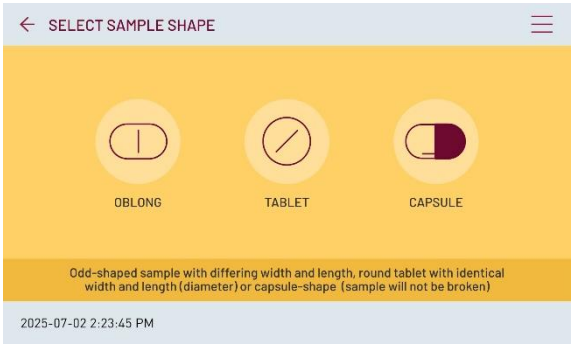
PTB 330 features a large, 7” backlit color touch screen with a state-of-the-art graphic user interface (GUI).

Running a Test



Quick Test or Method

There are two ways to start a test with PTB 330 – start a quick test immediately after powering on the instrument without logging on or login to start a test using a defined method.

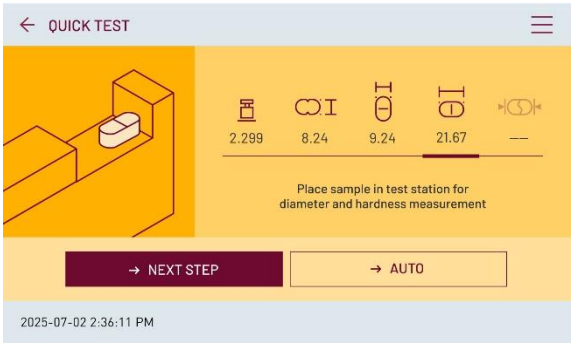


Select Sample Shape

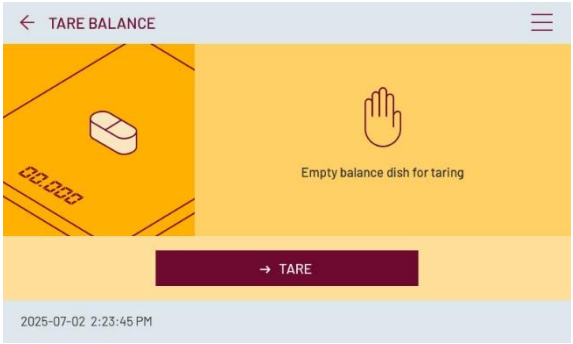
When running a test, you first select the approximate sample shape (round, oblong or capsule). This determines which parameters can be measured subsequently. Afterwards, select which parameters to measure, enter a batch number and start the test.

Insert Sample

Place the tablets one by one into the test station and orientate them according to the parameter to be tested next. The instrument gives clear instructions including pictures to the user at every step.



Test Procedure



Weight Measurement

In case a balance is connected to the PTB 330, the weight of the tablet (or tablets) is measured and directly transferred to the instrument. Take the tablet from the balance dish and place it into the testing station of the PTB 330.

Measurement of Dimensions and Hardness

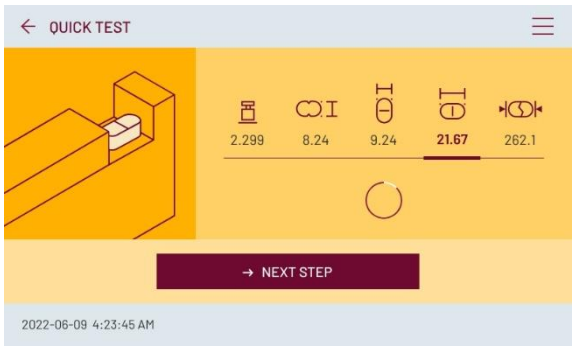
First place the tablet in an upwards position towards the wall and start the thickness measurement. The force jaw moves forward to measure the thickness. Next the sample is rotated for the (optional) width measurement. The sample is rotated a final time for the combined diameter and hardness measurement (breaking force).

Automatic or Manual Restart

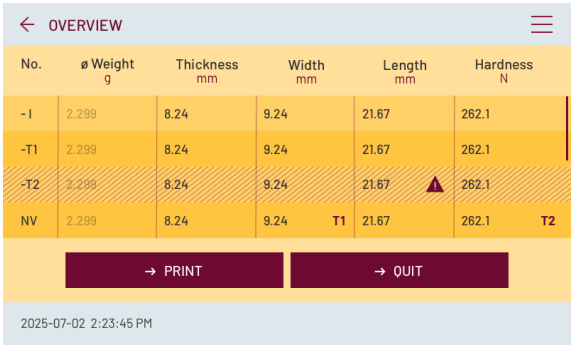
Clear on-screen instruction will lead the user through every step of the test either in an automatic restart mode, where the test procedure continues automatically after an adjustable interval, or manually where the user confirms the correct position of the tablet before each step.

Result Display

All results of the current sample are always displayed during the test. Once the test of one sample is finished, the tablet can be discarded into the removable waste container. Then a result overview of all results obtained during this test run can be displayed.



Once a test run is finished, the results including statistics can be printed directly on the integrated printer, printed on a connected printer or transferred to a LIMS system or other external system via a serial interface.



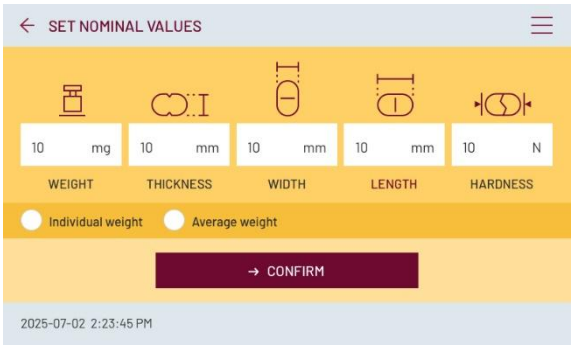
Printing of Results and Statistics

When printing directly via a the internal or a connected ticket printer or a ticket printer the data including each individual result as well as product information, date, time, user, instrument serial number, statistics are added to this information.

PTB 330 features and integrated printer

Test Using a Method

The instrument includes a method management system. In the method the nominal values and number of samples to be tested are defined. It is also possible to define tolerances here, which will be indicated on the result overview on screen as well as in the result reports.



Three Tolerance Levels

PTB 330 supports three tolerance levels: T1, T2 and Invalid. These can be defined as absolute values or in percentages. Performing the actual test then is similar to the procedure described above for the quick test.

Activating or Deactivating Testing Parameters

It is always possible to activate or deactivate separate testing stations. This way it is possible, for example to just test the hardness of a tablet without measuring any other parameters.

A sample in the test station of the instrument

Operating Principle

In the existing USP and EP monographs there is no standard force setting or force increase mode established, but it is recommended to use a linear force increase rate of 20N/s. Different force settings usually cause problems when comparing results received by different supplier's instruments when testing the same tablet. The hardness result is directly influenced by the contact speed and force increase rate.

About Dual Force Modes

A faster moving force jaw generally leads to lower reproducibility and often to higher test results. To offer the possibility to select an operating mode which will produce results similar to instruments you may already use, select the same force mode, linear force or linear speed increase and select the same or a similar rate. Also touch and detection force may be altered to suit the sample design specification. When the sample is touched the instrument switches to the selected mode and linear increasing rate. The instrument offers also the option to test capsules with the help of a special procedure, which allows the instrument to just touch the sample, compressing, but without breaking it.

Which Force Mode Should Be Selected?

Since decades all Pharma Test tablet hardness testing instruments offer the possibility to select either linear force increase or constant speed. Linear force increase offers the most accurate control, as the rate of increase is directly controlled by the electronic load cell used to read the force. Also, it is quite simple to validate the correct and linear operation, as a tablet with, for example 100N hardness, will be broken within 5 seconds, when 20N/s had been set as linear force increase rate. Constant speed can also be used; here the driving speed of the stepper motor is kept linear.

If the touching force is kept low, there is not too much difference in the results between the two modes, but validation of this mode is reasonably difficult and requires specific equipment. In general results obtained with the constant speed mode are less reproducible than the ones with linear force increase mode. Therefore, Pharma Test recommends using linear force increase. We will continue to offer both modes of operation to offer the possibility of comparing results of different instruments by setting the same parameters of operation.

User Management

PTB 330 features a user management system. Users can be defined with username and password and a combination of rights can be assigned to them: run tests, edit methods, perform calibrations, perform service and change settings, edit users.

Calibration and Validation

The current USP Pharmacopeia requires the force sensor of a tablet hardness testing instrument to be calibrated periodically over the complete measuring range (or the range used for measuring samples) with a precision of 1N. All Pharma Test tablet hardness testing instruments can be statically calibrated over the complete measuring range using different traceable counterweights. All

instruments support the checking of at least three different points during calibration to prove the linearity of the force sensor.

Weight sets are used to calibrate and adjust the force sensor (load cell) of the instrument over the complete measuring range.

Different weights, like the PTB-CAL15 and PTB-CAL30 weight sets which include 5, 10, 15kg and 30kg (PTB-CAL30) using two additional 10kg weights for total 50kg, may be placed onto the load cell to validate the linearity.

For the thickness, width and diameter (length) station, certified reference blocks are used for both calibration and adjustment.

PTB 330 also supports the PT-MET mechanical test tablets for daily verification of the hardness measuring station. The PT-METs function as a checking device which is used to simulate the breaking of a tablet at defined conditions.

Example Test Report

```
Pharma Test PTB 330-1000 SN 23456  V1.00

Method name: Aspirin
Comment    : my first method
Weight mode: Ind.   Sample sh.: Oblong
Touch det. : 50.0N  Break det.: 50.0N
Max. dist. : 50.0mm Force inc.: 200N/sec

-------------Nominal Values------------
   :Weight: Thick.: Width.: Diam. :Hard.
   : (g)  : (mm)  : (mm)  : (mm)  : (N)
- I:2.0000:  8.00 : 18.00 :  7.00 :150.0
-T2:2.1000:  9.00 : 19.00 :  8.00 :200.0
-T1:2.2000: 10.00 : 20.00 :  9.00 :250.0
---------------------------------------
 NV:2.320 : 11.25 : 21.64 : 10.23 :285.5
---------------------------------------
+T1:2.4000: 12.00 : 22.00 : 11.00 :300.0
+T2:2.5000: 13.00 : 23.00 : 12.00 :350.0
+ I:2.6000: 14.00 : 24.00 : 13.00 :400.0
---------------------------------------
Nos: 20 X : 10 X  : 10 X  : 10 X  : 10 X
---------------------------------------
Batch No. :  12345ABCDEFG
Start Date:  16.06.2025 11:04:47
---------------Results-----------------
   :Weight: Thick.: Width.: Diam. :Hard.
   : (g)  : (mm)  : (mm)  : (mm)  : (N)
---------------------------------------
  1:2.3200: 11.25 : 21.64 : 10.23 :285.5
  2:2.3200: 11.25 : 21.64 : 10.23 :366.0
   :      :       :       :       :(+T2)
  3:2.3200: 11.19 : 21.70 : 10.22 :299.5
--------Statistics 20/20 Samples--------
   :Weight: Thick.: Width.: Diam. :Hard.
   : (g)  : (mm)  : (mm)  : (mm)  : (N)
Max:2.3200: 11.25 : 23.02 : 10.23 :366.0
Min:2.1990:  9.82 : 21.64 : 10.23 :285.5
Dif:0.0000: 00.00 : 00.00 : 00.00 :000.0
Mea:0.0000: 00.00 : 00.00 : 00.00 :000.0
Xab:0.0000: 00.00 : 00.00 : 00.00 :000.0
   : (%)  : (%)   : (%)   : (%)   : (%)
Xre:00.00 : 00.00 : 00.00 : 00.00 :00.00
---------------------------------------
End Date  : 16.06.2025 11:05:33


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

Released: --------------  --------------
          Name/Signature   Date / Time

Print date : 17.06.2025 08:16:13
```

Header with instrument serial number and firmware version

Details about the method used for the test

Tolerances and nominal values defined in the method

Numbers of tests to be performed

Bath number and test start date and time

Individual test results including marks for tolerances

Detailed statistics
Space for signatures of operator and second person for release

Test end date and time

Room for signatures

Date and time the report was printed

PT-Node Network Adapter for Printing and Data Transfer

PT-Node is an adapter that connects up to two Pharma Test instrumentsimultaneously 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. PT-Node supports PTB 330.

Advantages

- Select either linear force increase or constant speed (dual mode selection)
- Stepless adjustment of the force or speed increasing rate
- User and method management system
- Entry of time and date
- Quick start to start testing with minimal preparation
- Automatic re-start facility to speed up the testing sequence
- Directly connectable to LIMS or other external systems
- Validation and calibration program for the measurement station
- Dual point adjustment of the load cell for the hardness test station
- Multiple point calibration (calibration)
- Test program for soft gelatin capsule testing

Features

- Tablet hardness testing in full compliance to USP <1217> and EP <2.9.8> Pharmacopeia
- 5 results of the same sample: thickness, width, diameter (length), hardness and weight (via connected external analytical balance)
- Dual force mode instrument with linear speed increase and linear force increases modes
- Statists including mean value, absolute and relative standard deviations, minimum and maximum
- Easy to use graphical touch screen user interface with clear operator instructions
- Multiple point validation procedure built-in
- Set to test tension strength of oblongs and caplets available

Standard Scope of Supply

The PTB 330 comes ready to use with the following standard scope of supply:

- Broken sample collector
- Integrated printer
- Comprehensive documentation folder including:
  - User manual
  - QC/DQ testing certificate
  - IQ documentation
  - OQ documentation
  - Conformity Declaration
  - CE/EMC Declaration
  - Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- 500N (PTB 330-500) and 1,000N (PTB 330-1000) extended force range
- Full range of certified validation tools available
- Different splints for tablet guidance in test station via exchangeable bottom plates
- Set of recommended spare parts

Technical Specifications

Parameter	Specification
Hardness testing range	PTB 330: 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	Better than ±0.02 mm
Width & diameter testing range	2.00 – 35.00 mm, expandable to 70mm
Width & diameter accuracy	Better than ±0.02 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)
Break modes	Selectable: linear force increases or constant speed
Force rate	5 – 250 N/sec. (linear force increase); 1 - 5mm/sec. (constant speed)
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
Interface	2 x RS-232 serial port to connect a PC or Epson TM-U220B ticket printer, 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)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.