

# PTB 420 Auto

## Fully Automated 4 in 1 Tablet Testing Instrument

The fully automated 4 in 1 tablet testing instrument PTB 420 Auto is a dual test mode instrument to determine the weight, diameter, thickness and hardness of tablets. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.



### Measurement of 4 different parameters

PTB 420 Auto features an integrated Sartorius analytical balance module to determine individual sample weights and a tablet feeder for up to 25 samples. Prior to testing the hardness of the tablet the PTB 420 can measure sample thickness (or height) and diameter (or length). The thickness is detected automatically by an optical system. The samples are automatically positioned by means of the patented movable alignment jaws. The behavior of the jaw's movement is adjustable to accommodate many different shapes of tablets and oblongs. The instrument can be set to either linear force or linear speed increase mode for the tablet hardness test.

### Navigate Through the Menu

PTB 420 Auto features a large, back-lit color LCD. Menu navigation is done by use of a click wheel similar to the ones used in many car navigation systems. This allows the user to rapidly scroll through the menus to make his selections. Quickly create methods by entering the nominal test information for thickness, diameter, hardness and weight via the alpha-numerical keyboard and select the unit to measure (mm/in, Kp/N/Sc).

### Start a Test

It is also possible to use the quick test functionality to work without creating a method first and without entering any nominal values. When creating a method, it is also possible to disable certain measurements, for example to only test the hardness of a tablet. The angle of the operation panel can be adjusted freely to guarantee optimal visibility, whether the user is sitting in front of the instrument or operating it from a standing position. To perform a test with PTB 420 Auto, insert the samples into the tablet feeder. The samples will be weighed and dropped one by one into the unique sample positioning station for automated correct alignment inside the combined thickness, diameter and hardness test station.



### Test Procedure

A class 1 laser beam is used for the touch free measurement of the sample thickness. The beam is used to illuminate a CCD-sensor on the other side of the measurement area. The sample is scanned by the laser beam while simultaneously being moved in front of the CCD-sensor by the moving sample dish. The height of the sample can be determined from the sample's shadow on the CCD-sensor. Thereafter the sample is automatically moved towards the force jaw to measure the diameter and finally the hardness by breaking it.



Once the test is finished and the sample is broken, the sample dish moves backwards to drop the sample fragments into the removable waste container. The results are immediately displayed and may be printed on a connected printer. The print-out includes each individual result as well as product information, date, time, user, instrument serial number and statistics.

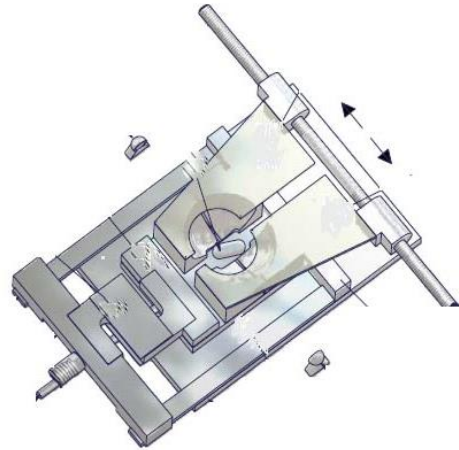
### Operation Principle of the Hardness Measurement

The current monographs of the USP and EP Pharmacopoeia define how a tablet hardness testing instrument should work, but without establishing data of how to increase the applied force and when to detect a sample to be broken. This often causes problems when trying to compare results of the same tablet measured with instruments from different manufacturers. The hardness result is directly influenced by the contact speed and force increase rate of testing instrument. A faster operated test jaw means a lower reproducibility and often higher absolute results. In order to offer the possibility to select an operating mode which will offer you similar results to other instruments you may already use, PTB 420 Auto allows to set the force mode by selecting between linear force increase or linear speed increase and the set the force rate. When the instrument detects that the sample has been touched, it switches to the measuring mode and starts to increase the force applied to the sample. Another adjustable parameter the break detection force to test softer samples as well as gel capsules. Often, samples such as soft gel capsules do not break but become smaller in diameter (deformation). To increase the sensitivity of the instrument and to get a result without just squashing the sample, the total testing distance of the jaw after contact with the sample can be programmed.

### Which Force Mode to Select?

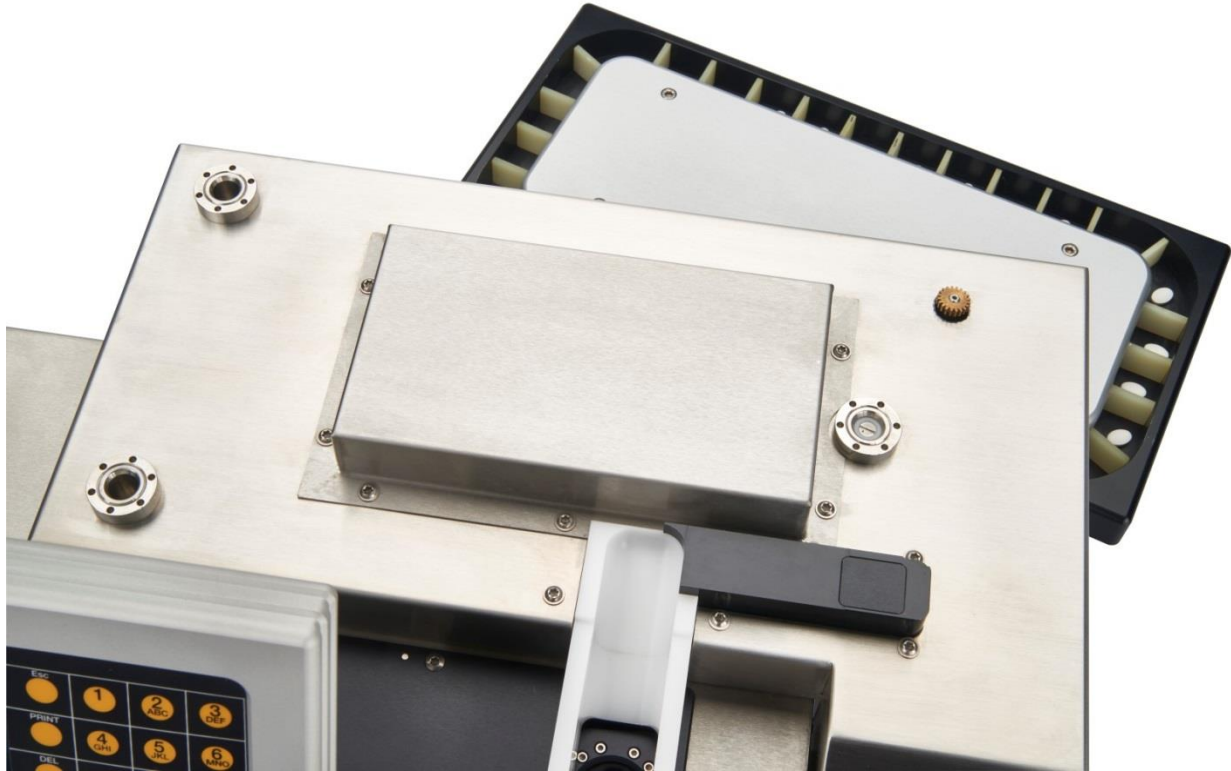
Since more than 10 years ago all Pharma Test tablet hardness testing instruments offer the possibility to select either linear force or linear speed increase. Linear force increase offers the most accurate control, as the rate of increase is directly controlled by the electronic load cell used to read 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 force increase rate. Linear speed increase can also be used; here the driving speed of the stepper motor is kept linear.

Actually, as long as 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 linear speed increase mode are less reproducible than the ones with linear force increase mode. Therefore Pharma Test recommends using linear force increase. The test of "soft" tablets often requires an increase of the standard force setting, otherwise the sample gets deformed only but does not break. We will continue to offer both modes of operation in order to offer the possibility of comparing results of different instruments by setting the same parameters of operation.



### The Feeder and Balance Module

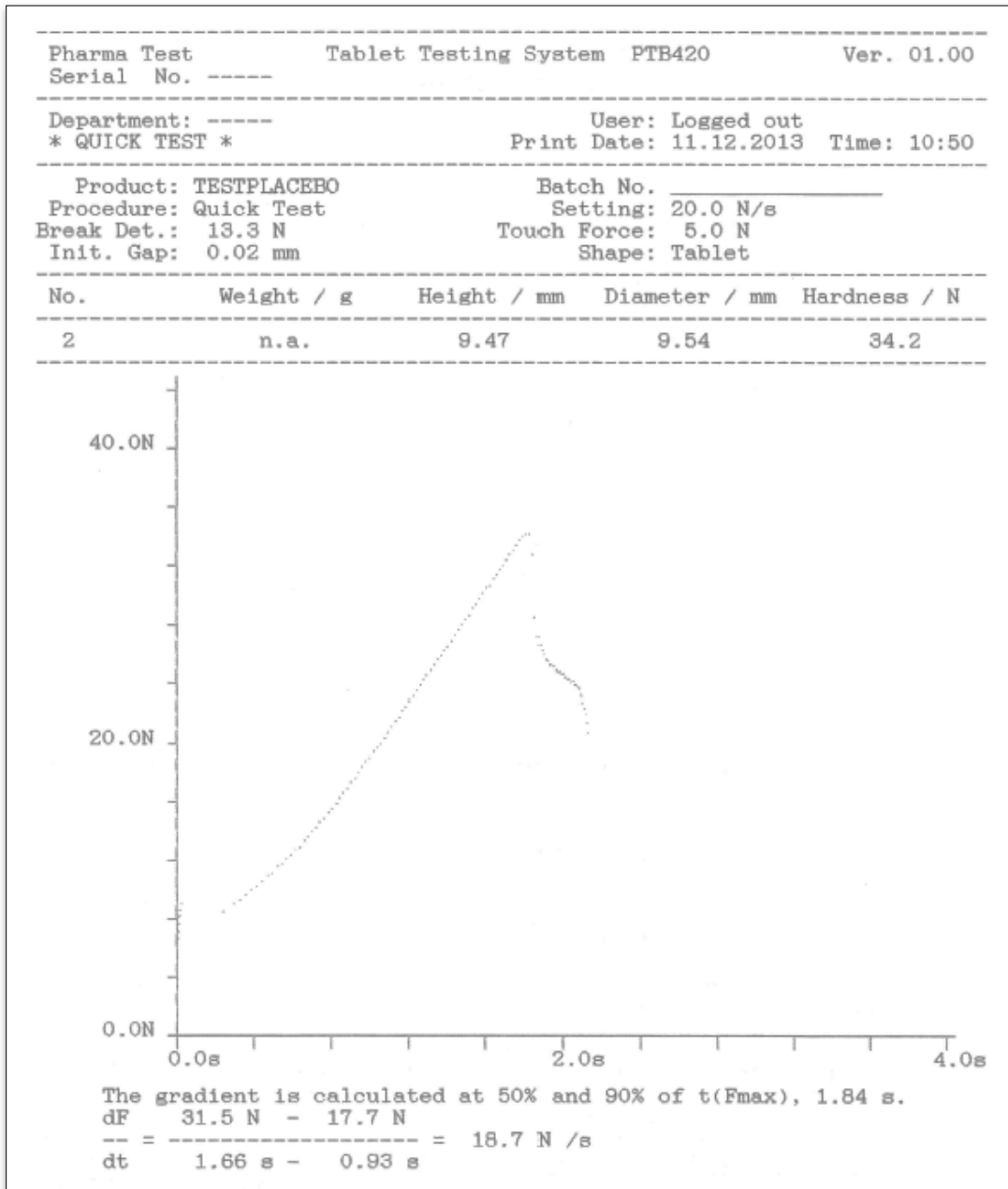
PTB 420 Auto includes a feeder for up to 25 samples and features an integrated Sartorius analytical balance. For tests with more than 25 samples, the instrument prompts the user to refill the feeder once the first 25 samples have been tested.



Before the samples are dropped into the combined thickness, diameter and hardness test station of the PTB 420 Auto, they are transported onto a balance dish integrated into the feeder. There the individual weight of each sample is determined. The feeder can be removed easily for cleaning purposes. The feeder and testing station are covered by a transparent hood. This can be flipped back to easily fill the feeder. It features a detection system to ensure the instrument only runs when the hood is closed.

**Example Print-Outs**

Pharma Test Serial No. 24xxx	Tablet Testing System PTB420 Auto			Ver. 4.0
Department: -----	User: ADMINISTRATOR			
* TEST REPORT *	Print Date: 16.11.2017		Time: 12:00	
Product: TABLET	Batch No. 12345			
Procedure: LIN. FORCE	Setting: Break, 20.0 N/s			
Magazine: YES	Weighing: Single			
No.	Weight / g	Thickness / mm	Diameter / mm	Hardness / N
1	0.5290	3.88	9.03	62.1
2	0.5298	3.87	9.04	64.4 + T1
3	0.5321	3.84	9.03	61.3
4	0.5278	3.90	9.05	56.8 – T1
5	0.5291	3.87	9.06	58.5
6	0.5309	3.88	9.03	60.2
7	0.5276	3.92	9.02	63.9 + T1
8	0.5301	3.82	9.03	60.3
9	0.5278	3.87	9.05	53.7 – T2
10	0.5281	3.86	9.04	61.0
* Statistics *				
Range	Weight: n	Thickness: n	Diameter: n	Hardness: n
+ l	25.0 %: 0	25.0 %: 0	25.0 %: 0	25.0 %: 0
+T2	20.0 %: 0	20.0 %: 0	20.0 %: 0	20.0 %: 0
+T1	10.0 %: 0	10.0 %: 0	10.0 %: 0	10.0 %: 2
nominal	0.5200 g: 10	3.80 mm: 10	9.10 mm: 10	50.0 N: 6
-T1	10.0 %: 0	10.0 %: 0	10.0 %: 0	10.0 %: 1
-T2	20.0 %: 0	20.0 %: 0	20.0 %: 0	20.0 %: 1
- l	25.0 %: 0	25.0 %: 0	25.0 %: 0	25.0 %: 0
val./total	10/10	10/10	10/10	10/10
	Weight / g	Thickness / mm	Diameter / mm	Hardness / N
min / max	0.5276/ 0.5321	3.82/ 3.92	9.02/ 9.06	53.7/ 64.4
max - min	0.0045	0.10	0.04	10.7
average	0.5292	3.87	9.04	60.2
SD (avg.)	0.0015	0.0281	0.0123	3.22
SD (nom.)	0.0410	0.1230	0.0661	4.77
Performed by: ADMINISTRATOR	Date: 16.11.2017		Time: 12:00	
Confirmed by: .....	Date: 16.11.2017			
Approved by: .....	Date: 16.11.2017			
				Page 1



### Calibration and Adjustment

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 instrument can be statically calibrated over the complete measuring range by the use of different traceable counterweights. All instruments support the checking of at least three different points during calibration to prove the linearity of the force sensor.



Furthermore, Pharma Test offers the PT-MT3 magnetic tablets to calibrate the breakpoint detection of the whole tablet hardness testing instrument (force sensor and mechanics of the instrument). All Pharma Test tablet hardness testing instruments are fully compliant to the requirements of the current USP Pharmacopeia.

PTB 420 Auto features an access controlled calibration and adjustment program for the three testing stations. For the thickness and diameter station, certified reference blocks are used for both calibration and adjustment. Weight sets are used to calibrate and adjust the force sensor (load cell) of the instrument over the complete measuring range. For the two point adjustment (zero and reference) of the load cell inside the hardness station a certified reference weight of 10 kg is used. For validation purposes the use 5 up to 50kg certified weights is recommended. The latest calibration and adjustment results are stored on the instrument and can be printed and signed. To prove the linearity of the built-in load cell during a hardness test, the operator can program a print-out of the force curve recorded during a test. This will show the linear increase of the adjusted force mode.





## Advantages

- » Test up to 25 samples fully automatically by using the integrated feeder; feeder can be refilled at all times for more than 25 samples in one test
- » Automatically determine the individual sample weights using the integrated Sartorius analytical balance
- » Automated positioning of samples in the testing area by unique alignment jaws
- » Touch-less measurement of sample thickness
- » Sophisticated user and method management system included
- » Quick start functionality to start testing with minimal preparation
- » Quick menu navigation by using a large color LCD and a click wheel
- » Select either linear force or linear speed increase (dual mode selection)
- » Entry of time and date
- » Enter a 12 digit batch number
- » Dual point adjustment of the load cell for the hardness test station
- » Multiple point validation (calibration)
- » Hardness testing in compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia
- » IQ/OQ documents included free of charge

## Features

- » Tablet hardness testing in full compliance to USP <1217> and EP <2.9.8> Pharmacopoeia
- » 4 results of the same sample: thickness, diameter, hardness and weight (via integrated Sartorius analytical balance)
- » Dual force mode instrument with linear speed increase and linear force increase modes
- » Stepless adjustment of the linear force or speed increase rate
- » Document all results on external printer
- » Multiple point validation procedure for all measurement stations built-in
- » Programmable print-out of force increase curve

## Standard Scope of Supply

- » PTB 420 Auto instrument including feeder and balance module
- » A set of 3, 5 and 10mm reference blocks
- » 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:

- » Extended hardness range of up to 550N (PTB 420 Auto-500 model)
- » Extended hardness range of up to 990N (PTB 420 Auto-1000 model)
- » Adapter to connect USB PCL5 printers

## Technical Specifications

Parameter	Specification
<b>Hardness Testing Range</b>	2.0 – 300.0N (optional 5.0 – 500.0N and 10 – 1000N)
<b>Hardness Accuracy</b>	Better than 1N
<b>Thickness Testing Range</b>	2.00 – 12.00mm
<b>Thickness Accuracy</b>	Better than $\pm 0.05$ mm
<b>Diameter Testing Range</b>	2.00 – 30.00mm without magazine
<b>Possible Sample Size</b>	22.00 mm x 33.00 mm
<b>Diameter Accuracy</b>	Better than $\pm 0.05$ mm
<b>Weight Measurement</b>	has an integrated Sartorius balance
<b>Weight Testing Range</b>	0.0001g – 99.9999g
<b>Measuring Units</b>	Thickness and diameter selectable between millimeter [mm] (factory setting) and inches [In] Hardness selectable between Newton [N] (factory setting), Kilopond [kp] and Strong Cobb [Sc]
<b>Force Mode</b>	Selectable between linear force increase and constant speed
<b>Force Rate: lin. force</b>	5 – 200 N/sec
<b>Force Rate: constant speed</b>	5 – 250 mm/Min
<b>Display</b>	Back-lit color LCD
<b>Keyboard</b>	Alpha-numeric keypad and click wheel
<b>User Settings</b>	Memory for user defined settings:
<b>User / Passwords</b>	up to 50
<b>Methods</b>	up to 200
<b>Procedures</b>	up to 100
<b>Products</b>	up to 100
<b>Feeder</b>	Tablet magazine for 25 samples (integrated)
<b>Laser Type</b>	Class 1
<b>Interface</b>	<ul style="list-style-type: none"> <li>» RS232 serial port to connect a Mettler-Toledo or Sartorius balance</li> <li>» Parallel port for printer connection</li> <li>» RS232 port for PC connection</li> <li>» USB port for firmware updates</li> <li>» All interface ports match the SELV- (save extra low voltage) codes. All additional instruments (printer, balance...) plugged to the PTB 420 Auto must also match the SELV-codes.</li> </ul>
<b>Instrument Housing</b>	Stainless steel (304) to meet GLP requirements
<b>Power</b>	110/230 Volt AC, 50/60 Hz

<b>Current Consumption</b>	0,25A at 230V; 0,5A at 115V; 60W
<b>Main Fuse</b>	2 x T2,0A
<b>Grade of Pollution</b>	2
<b>Operational Altitude</b>	0 – 2000 m; 0 – 6500 ft
<b>Installation Requirements</b>	<ul style="list-style-type: none"> <li>» Ambient Temperature 10-40°C</li> <li>» Relative Humidity 20-90%rH</li> <li>» Desk with at least 50 kg working load. All around the instrument at least 10cm free distance to walls or other equipment. Free access to the mains power plug and switch. No special ventilation necessary.</li> </ul>
<b>Use of Corrosive Materials</b>	0,1 NHCL approved, no other solvents permitted, see cleaning instructions. Possible residues must be removed immediately (see “Cleaning Instructions”)
<b>Instrument Dimensions</b>	approx. 400 x 530 x 400 mm (Length x Width x Height)
<b>Packaging Dimensions</b>	approx. 500 x 590 x 440 mm (Length x Width x Height)
<b>Net / Gross Weight</b>	approx. 20 kg / 30kg (without optional accessories)
<b>Certification</b>	All components certified to USP / EP requirements
<b>CE / EMC Certification</b>	All CE / EMC Certification provided
<b>Validation</b>	All IQ & OQ documents included

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