



Operating Manual

PTB 430

Tablet Hardness Testing Instrument



Version 1.0

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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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We reserve all rights.

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

How to Use the Manual

To understand the different information, we use different formatting:

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



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Document History

Version	Valid from	Author	Change	Remark
1.0	15.09.2026	Pharma Test	N	First release

Table 1 Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

1. About PTB 430

Thank you for choosing the Pharma Test PTB 430 tablet hardness testing instrument. PTB 430 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 430 tablet hardness testing instrument

The PTB 430 5-in-1 tablet testing instrument is a dual test mode device designed to measure five distinct parameters of a single sample. It accurately determines the hardness, diameter (or length), thickness, width, and weight of tablets utilizing an integrated analytical balance (optional). Operation is facilitated through a large 7-inch backlit color touch screen.

PTB 430 features a carousel with 20 chambers to transport the samples from the weight station to the thickness station and the combined width, diameter (or length) and hardness testing station. To make manual handling of large samples more convenient, a carousel with 10 larger chambers is available as well. For weight measurement PTB 430 features an integrated Sartorius analytical balance cell (optional).

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).

The instrument is manufactured in strict accordance with EP <2.9.8> and USP <1217> Pharmacopoeial standards.



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

PTB 430 is available with three different maximum force settings for the hardness measurement:

1. PTB 430-300 for measurements of up to 300N for hardness
2. PTB 430-500 for measurements of up to 500N for hardness
3. PTB 430-1000 for measurements of up to 1,000N for hardness

The standard instruments come with a 20-chamber carousel. As an option a 10-chamber carousel is available, to make it easier to perform manual sample alignments in case these are required.

The integrated Sartorius balance is optional. In case this option is not installed, weight measurement is possible using an external balance.

The automated thickness measurement station is optional. In case this option is not installed, thickness can be measured by manually positioning the sample in the hardness testing station.

Otherwise, the instruments are identical, and the contents of this document apply to all the variants whenever PTB 430 is mentioned unless the variant is explicitly mentioned.

Standard Supply Scope

Main Instrument

PTB 430 comes ready to use with its standard scope of supply:

Part No.	No.	Description
288-1005	1	Sample support, with oblong groove
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 430:

Integrated Balance

To measure sample weight PTB 430 is available with an integrated Sartorius analytical balance as an option. The weight testing station is located before the automated thickness measurement station. The integrated balance option includes a clear Plexiglass cover for the instrument to protect the balance and ensure stable readings.



Part No.	Type
288-2200	Integrated balance, 0.1mg with cover

Table 3: Integrated balance

Automated Thickness Measurement

To measure sample thickness, an automated thickness measurement system is available as an option. This station is located between the balance dish and the combined hardness, diameter and width measurement station.



Part No.	Type
288-2100	Automated thickness measurement station

Table 4: Automated thickness measurement

Sample Support Inserts

PTB 430 allows sample supports to be exchanged. The standard instrument includes a sample support with an oblong groove to help align oblongs. Custom supports can also be provided based on customer requirements.

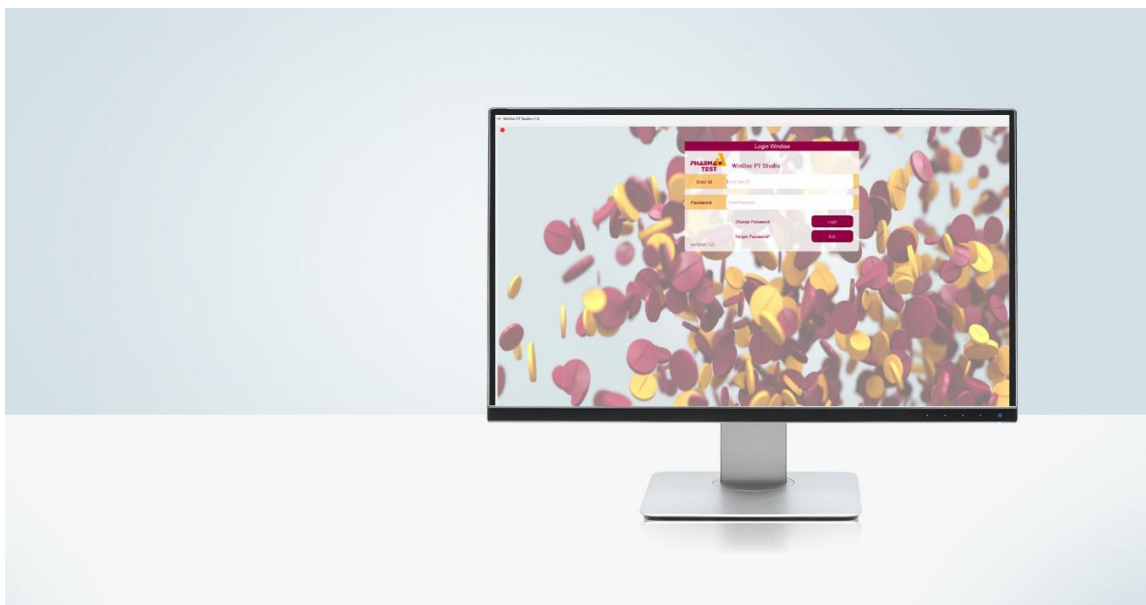


Part No.	Type
288-1000	Sample support, flat
288-1050	Sample support according to customer specification

Table 5: Sample support inserts

WinDoc PT-Studio PC Software with 21 CFR Part 11 Compliance

PT-Studio is an advanced and user-friendly Windows-based platform designed to support precise pharmaceutical testing and robust data management.



Seamlessly integrating with Pharma Test tablet hardness testing Instruments, it offers a comprehensive suite of features that comply with 21 CFR Part 11 regulations. These include secure hardware-bound licensing, detailed instrument control, a complete audit trail, and extensive reporting capabilities. The software is built to optimize workflow efficiency, ensure data integrity, and streamline validation processes, making it an ideal solution for regulated environments where accuracy and compliance are paramount.

Part No.	Type
95-25800	WinDoc PT-Studio PC software with 21 CFR Part 11 compliance
95-28510	WinDoc PT-Studio IQ/OQ documentation, license based

Table 6: PT-Node Network adapter

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 7: 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 430.



Part No.	Type
29-02200	Epson TM-U220D ticket printer
34-01224	Cable to connect PTB 430
007-0230	Ink ribbon for Epson ticket printer

Table 8: Ticket printer

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 9: Consumables

Technical Specifications

Parameter	Specification
Number of testing parameters	5 (Hardness, Thickness, Width, Diameter/Length, Weight (by optional integrated Sartorius balance cell))
Sample transport	Carousel, 20 chambers, optional carousel with 10 chambers to handle larger samples available
Hardness testing range	PTB 430-300: 2.0 – 300.0 N PTB 430-500: 5.0 – 500.0 N PTB 430-1000: 10.0 – 1,000.0 N
Hardness accuracy	Better than ± 1 N
Hardness resolution	0.1 N
Thickness testing range	2.00 – 20.00 mm
Thickness accuracy	2.00 – 10.00 mm ± 0.02 mm 10.00 – 35.00 mm ± 0.05 mm
Width & diameter testing range	2.00 – 28.00 mm
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 integrated Sartorius balance cell (optional)
Weight testing range	0.0001g – 200.0000g
Weight resolution	0.1 mg
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. (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
Interfaces	2 x RS-232 serial port to connect a PT-Node network adapter, an Epson TM-U220B ticket printer, 1 x USB-C port for firmware updates, Ethernet
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. Desk with at least 50 kg working load. Clearance of at least 10 cm to walls or other equipment.

Parameter	Specification
Instrument dimensions	Approx. 500 x 500 x 400 mm (Length x Width x Height)
Packaging dimensions	Approx. 650 x 660 x 440 mm (Length x Width x Height)
Net / gross weight	Approx. 25 kg / 30 kg (without optional accessories)

Table 10: 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	$\sum x/N$
Absolute Standard Deviation	$\sqrt{\frac{\sum x^2 - n \times \bar{x}^2}{n-1}} \quad [x = MV]$
Relative Standard Deviation	$\frac{\sqrt{\frac{(\sum x^2 - n \times \bar{x}^2)}{n-1}}}{\bar{x}} \times 100\%$

Table 11: Calculation Factors and Unit Conversions

2. Setting Up the PTB 430 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 430 instrument.



Figure 2: PTB 430 front

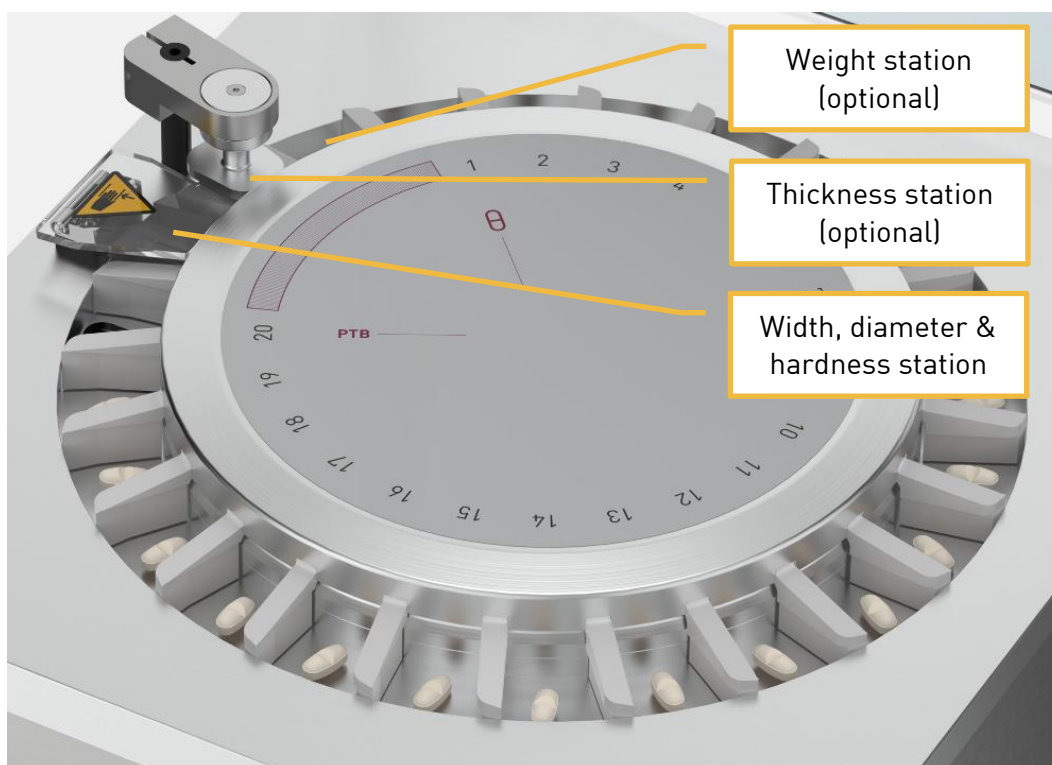


Figure 3: PTB 430 Carousel

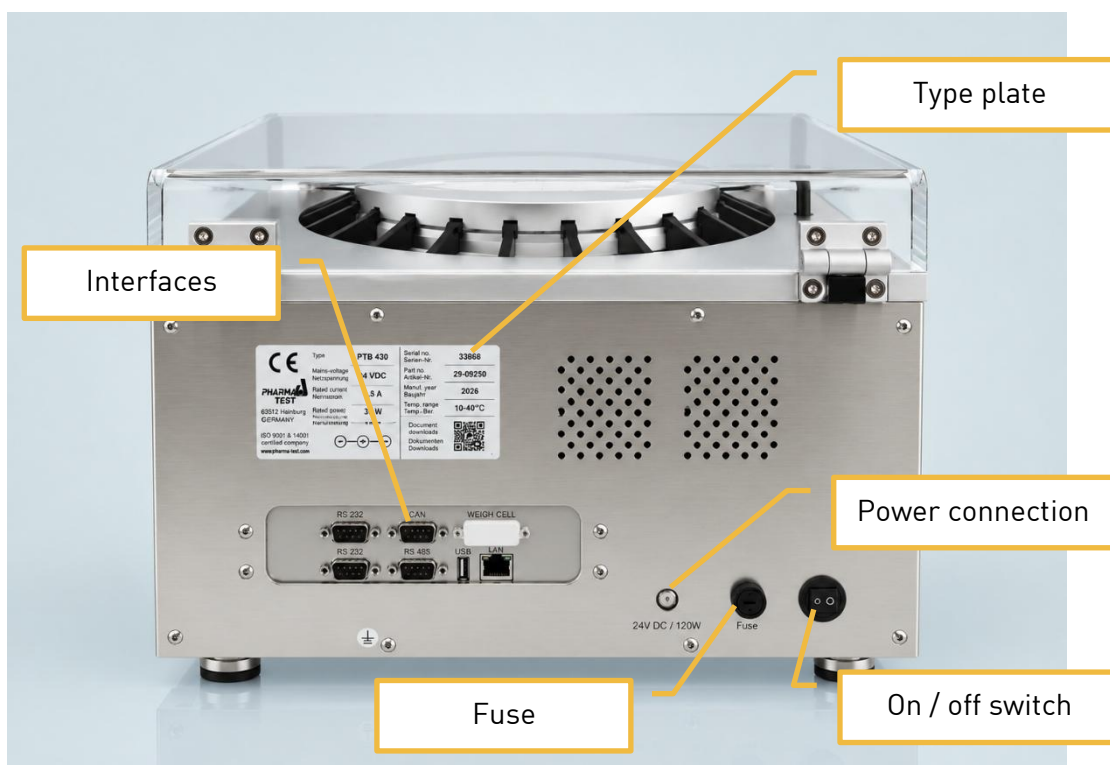


Figure 4: PTB 430 back side

PTB 430 User Interface

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

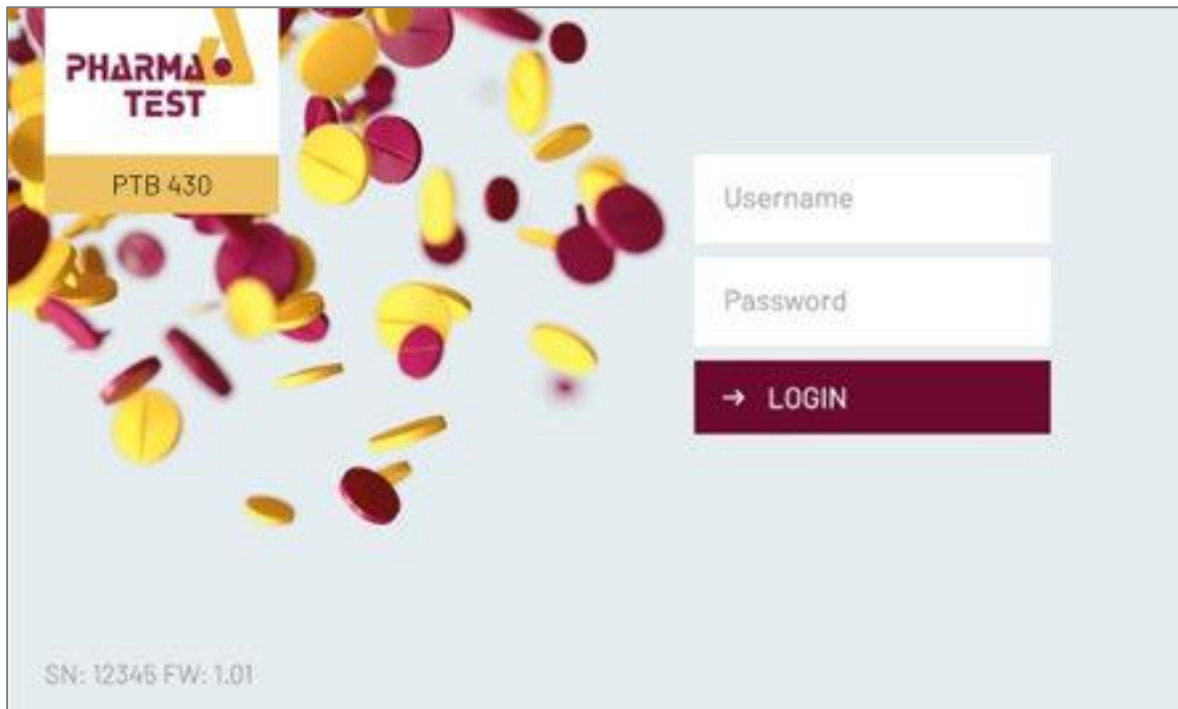


Figure 5: Start screen of the instrument

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

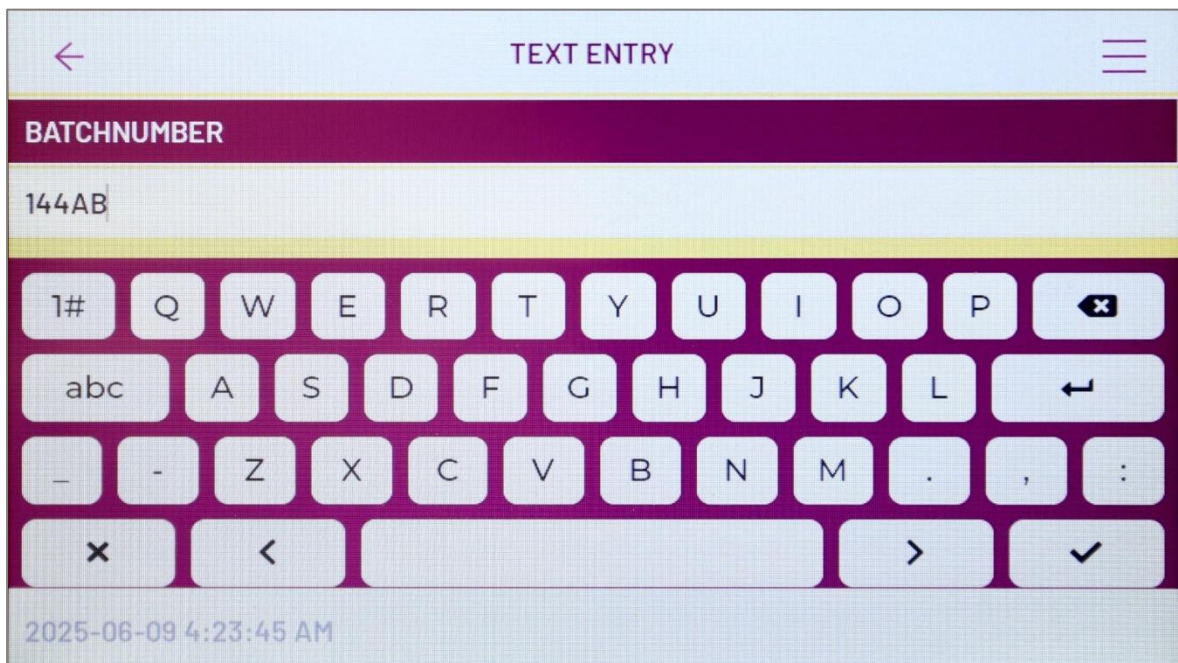


Figure 6: Software keyboard

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

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

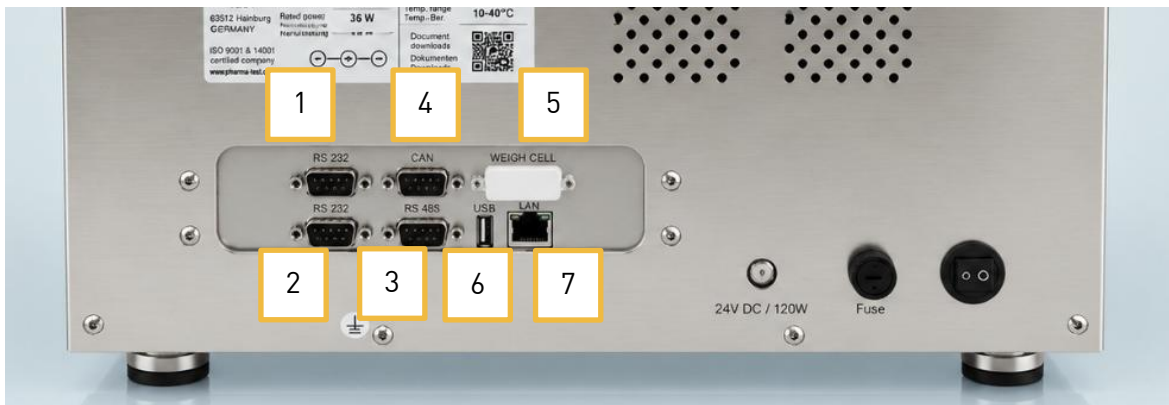


Figure 7: Instrument overview - interfaces

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	Not used in this model
6	USB	USB-C port to install firmware updates
7	LAN	Ethernet

Table 12: Instrument interfaces

First Steps

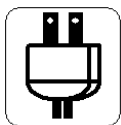
Make sure you follow these steps before turning on the instrument for the first time:

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 430 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 430. 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 430. 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 430 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:

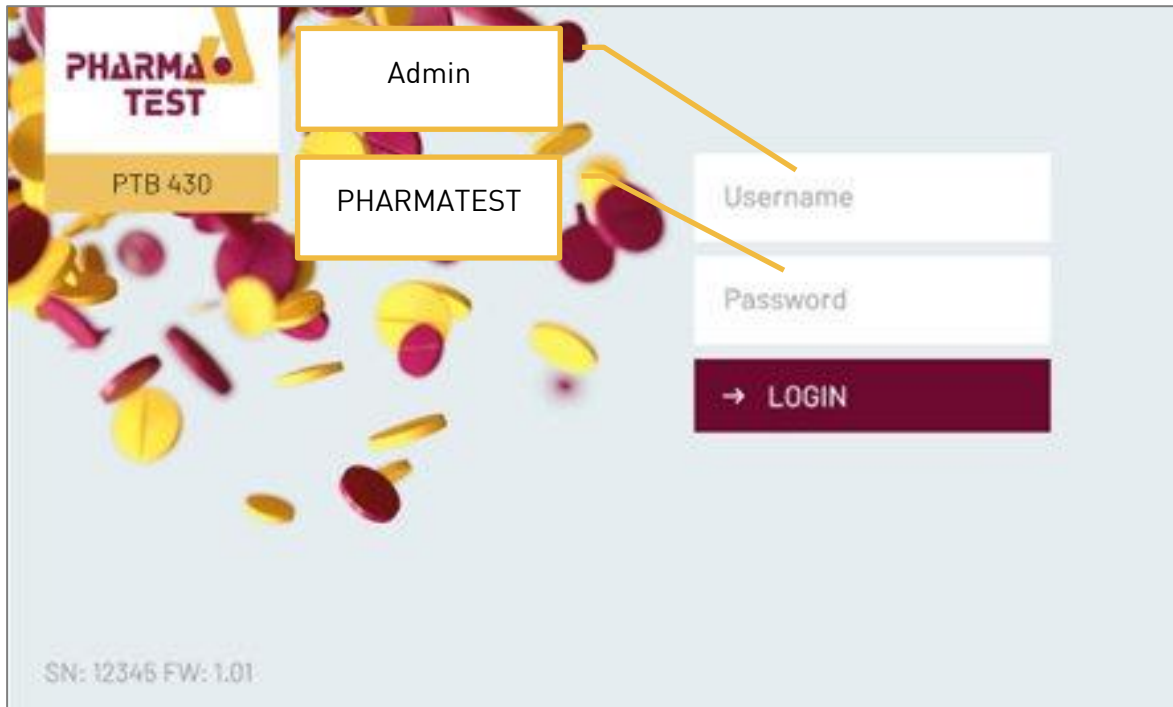


Figure 8: Login

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.

Main Menu

After logging in the main menu appears. This section provides a short overview of each item on the main menu of PTB 430. More details are found in later sections of this manual:

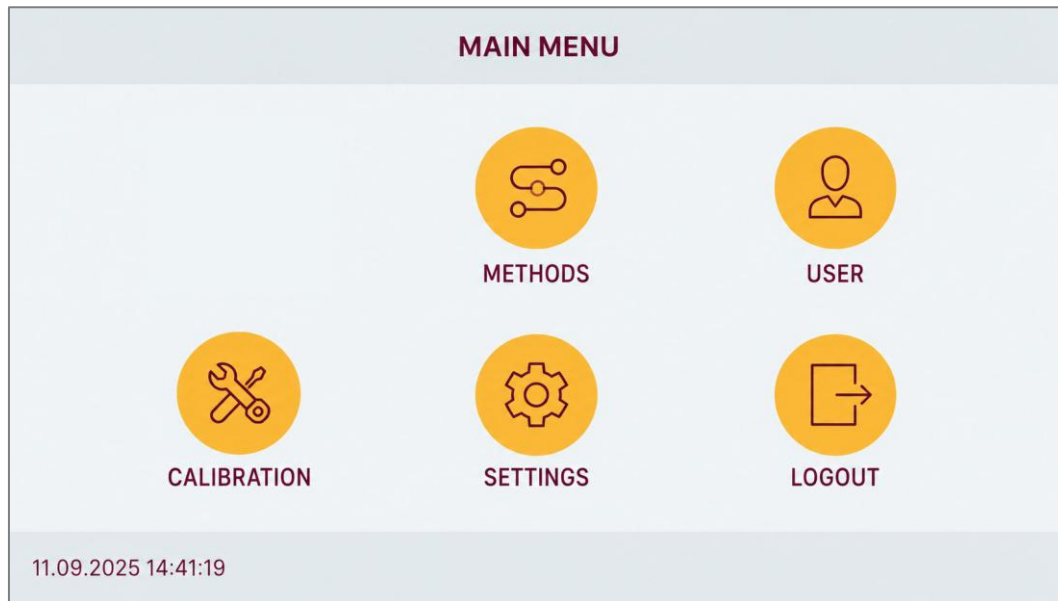


Figure 9: PTB 430 main menu

This is the main menu for PTB 430. 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
METHODS	Perform a test run based on a method View, create, edit and delete methods View and print the last test result	Page 2121
USER	View, create, edit and delete users	Page 3030
CALIBRATION	Perform calibrations of the weight, length and hardness measurements	Page 3332
SETTINGS	View and change settings Perform adjustments of the hardness and length measurements	Page 3939
LOGOUT	Log the current user out and return to the login screen	NA

Table 13: Main menu items overview

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.

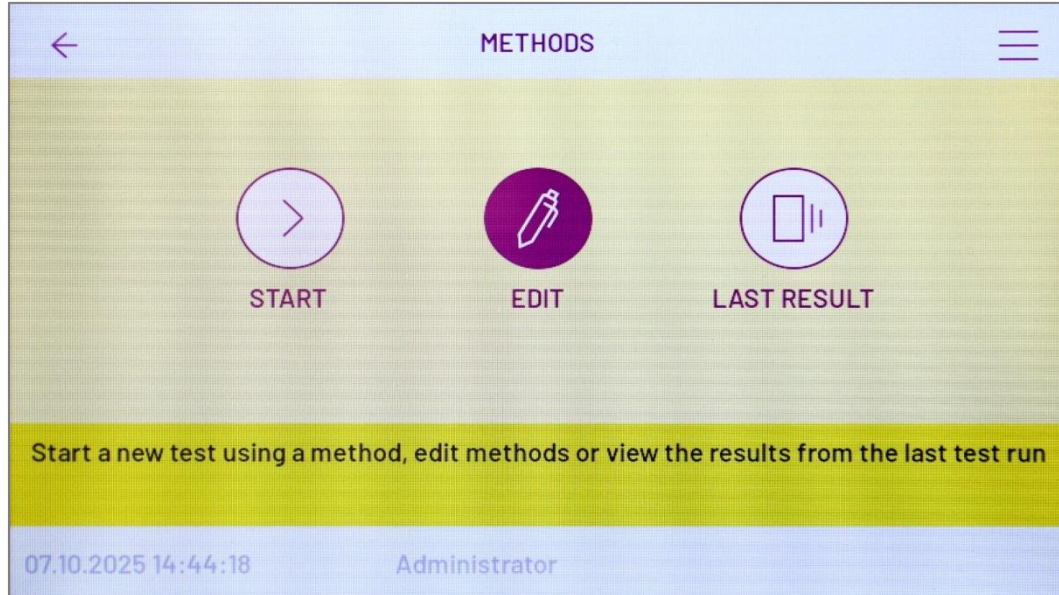
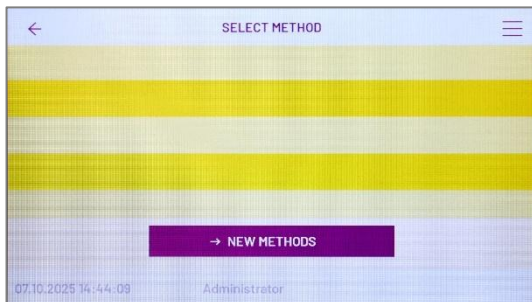


Figure 10: Methods menu

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 430 instrument. Select a method from this list to view and edit it.

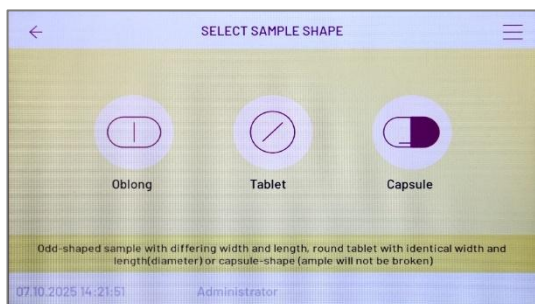
Touch **[→ NEW METHODS]** to create a new method.



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:

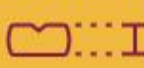
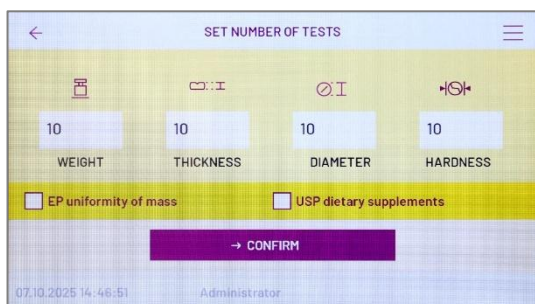
Sample shape	Weight	Thickness	Width	Diameter	Length	Hardness
Oblong	Yes	Yes	Yes	No	Yes	Yes
						
Tablet	Yes	Yes	No	Yes	No	Yes
						
Capsule	Yes	Yes	No	No	Yes	No
						

Table 14: 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 11: 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 12: 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 430 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 15: About Tolerances

The tolerances are arranged in this way:

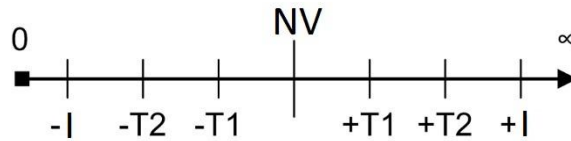


Figure 13: Tolerance Arrangement

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.

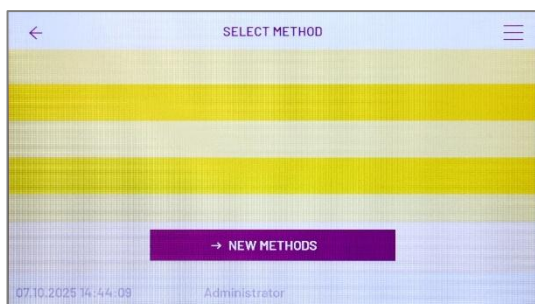
An overview of this method is displayed. Touch **[→ SET INACTIVE]**. This method can now no longer be used for tests. This method is now marked "INACTIVE" on the list of methods. To permanently delete this method, select the method again from the list. Touch **[→ DELETE]** to permanently delete this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

Start a Test

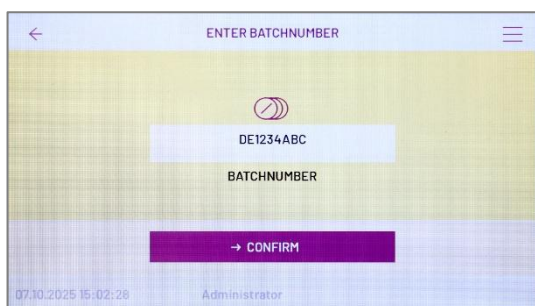
From the methods menu select "START" to perform a test with pre-defined parameters, based on a method. This means, you must create at least one method first.

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.



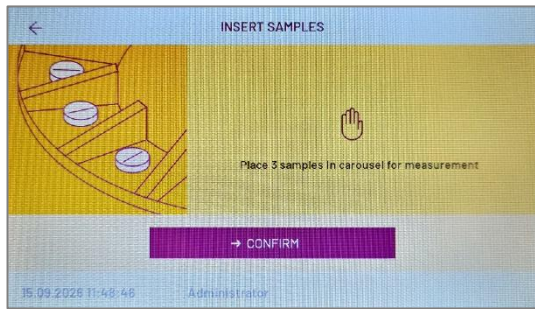
Select a method from the method list.



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.



The instrument will now ask to place a number of samples according to the method in the carousel. In case the method asks for more than 20 samples in total, first 20 samples are placed into the carousel and later the instrument will ask to refill.

Touch **[→ CONFIRM]** to proceed.

Now the overview screen is displayed while the test is running:

No.	WEIGHT mg	THICKNESS mm	DIAMETER mm	HARDNESS N

Once all parameters of one sample have been measured, the results are displayed. You can swipe up and down to scroll the list of results. You can also pause and cancel the current measurement run.

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

No.	WEIGHT mg	THICKNESS mm	DIAMETER mm	HARDNESS N
Max		4.34	9.10	106.7
Min		4.31	9.07	104.2
Dif		0.03	0.03	2.5
Mea		4.33	9.09	105.4

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 16: 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 430-500 SN 12345 V1.00

Header with instrument type, serial no. and firmware version

Method name: DEMO METHOD

Nso: 3 X : 3 X : 3 X : 3 X : 3 X

Number of measurements

Batch No. : 1234567890ABCD

Start date : 12.09.2025 13:47:19

Batch no. and test start date

-----Results-----

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

Results of measurements

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)

Statistics

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

Test end date

Operator : -----

Signature lines

Released : -----

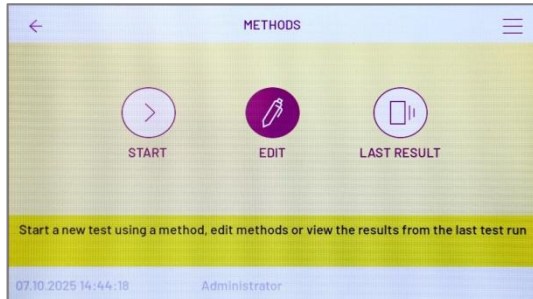
Name/Signature Date/Time

Print date : 12.09.2025 : 13:49:36

Print date of report

Repeat Print of the Last Result

NOTE: PTB 430 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]**.

No.	WEIGHT mg	THICKNESS mm	DIAMETER mm	HARDNESS N
Max		4.34	9.10	106.7
Min		4.31	9.07	104.2
Dif		0.03	0.03	2.5
Mea		4.33	9.09	105.4

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 430 is equipped with a flexible user management system that can handle up to 100 users with different permissions.

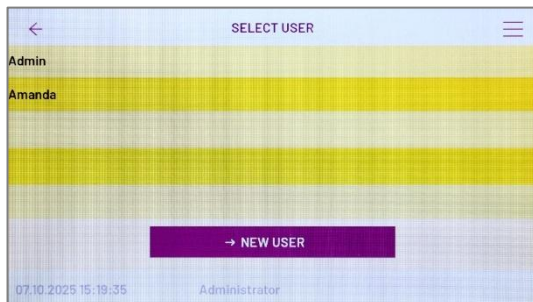
Users can be assigned any combination of the following user rights:

User right	Description
Run tests	Perform test runs based on a method
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 17: User rights

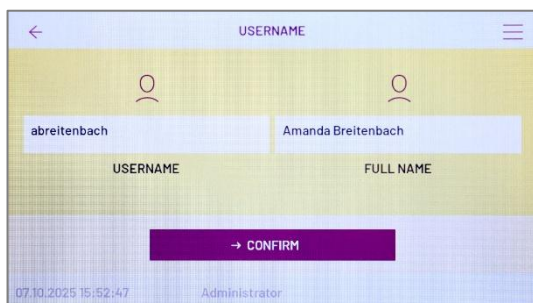
Creating a New User

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



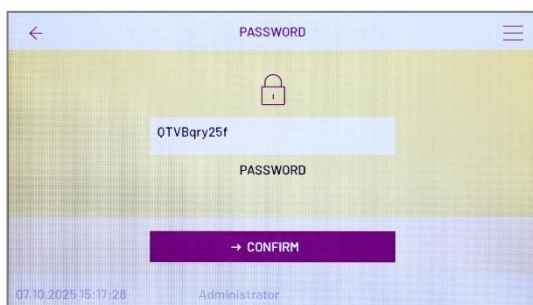
Enter the user menu from the main menu. The list of users will be displayed.

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.

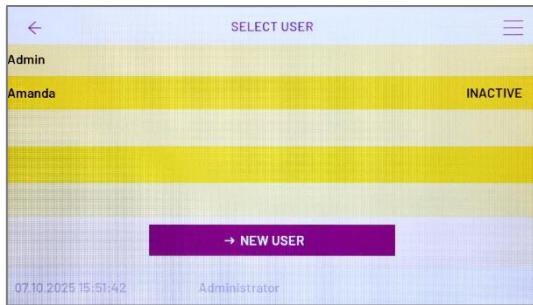
An overview for this user is displayed. Touch the parameter you want to edit. From there the process is the same as creating a new user.

Deleting a User

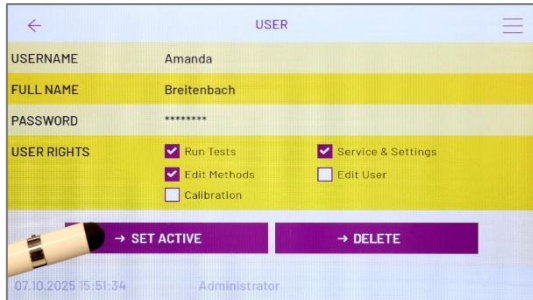
This section describes how to delete a user from the instrument’s internal memory. Deleted users cannot be restored. In case you suspect the user may be required again in the future, you can set the user as “inactive” to prevent him from being able to login to the instrument.

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 430 uses a three-point calibration procedure for the weight, length and hardness test stations. We recommend using the following reference tools, but PTB 430 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
Thickness	Reference block set 3, 5, 10mm, certified	285-1755-3
Length	Reference block set 3, 5, 10mm, certified	285-1755-3
Hardness	Reference weight set 5, 10, 15kg, certified	28-00290
	Calibration support with felt	288-1200
	Calibration support for weights	288-1210

Table 18: Tools required for adjustment



Figure 14: PTB-CAL15 5, 10, 15kg weight set

PTB 430 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.

From the calibration menu select the test station you want to calibrate. The date and time below the icons show when the last calibration for this test station has been performed. Performing one of these calibrations resets the date and time to the actual date and time. In case a PQ interval has been set in the device settings, it is compared to these dates and times here.

Weight Calibration

In case a balance is connected to the instrument, you can perform a three-point calibration of this balance here. Enter three reference weights and how often you want to weigh each reference weight. Then follow the on-screen instructions. Once the calibration is completed you can print the calibration report:

Pharma Test PTB 430-500 SN 12345 V1.00

Header with instrument type, serial no.
and firmware version

Calibration protocol weight

Calibration date: 12.09.2025 13:47:12

Date and time the calibration was
performed

-----Measurements-----

No	Nominal	Actual	Deviation
1/ 1	10 g	10.013 g	0.0013g
1/ 2	10 g	10.000 g	0.0000g
1/ 3	10 g	10.000 g	0.0000g
Meanvalue		10.004 g	0.0004g

Measurements with actual results and
deviation from the reference

Mean value from above measurements

No	Nominal	Actual	Deviation
2/ 1	20 g	20.013 g	0.0013g
2/ 2	20 g	20.000 g	0.0000g
2/ 3	20 g	20.000 g	0.0000g
Meanvalue		20.004 g	0.0004g

No	Nominal	Actual	Deviation
3/ 1	50 g	50.013 g	0.0013g
3/ 2	50 g	50.000 g	0.0000g
3/ 3	50 g	50.000 g	0.0000g
Meanvalue		50.004 g	0.0004g

Operator : -----

Signature lines

Released : -----

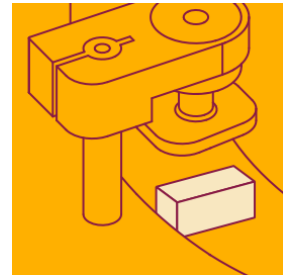
Name/Signature Date/Time

Printed : 12.09.2025 : 13:49:36

Print date of report

Thickness Calibration

The thickness calibration covers all thickness measurements performed using the automated thickness measurement station. You can perform a three-point calibration of these measurements here. Enter three reference block dimensions and how often you want to measure each reference block. Then follow the on-screen instructions and place the reference block in the center of the testing station, as shown in the illustration and on screen.



Once the calibration is completed you can print the calibration report:

Pharma Test PTB 430-500 SN 12345 V1.00

Header with instrument type, serial no. and firmware version

Calibration protocol thickness

Calibration date: 12.09.2025 13:47:12

Date and time the calibration was performed

-----Measurements-----

No	Nominal	Actual	Deviation
1/ 1	2 mm	2.12 mm	0.12mm
1/ 2	2 mm	2.00 mm	0.00mm
1/ 3	2 mm	2.00 mm	0.00mm
Meanvalue		2.04 mm	0.04mm

Measurements with actual results and deviation from the reference

Mean value from above measurements

No	Nominal	Actual	Deviation
1/ 1	10 mm	10.12 mm	0.12mm
1/ 2	10 mm	10.00 mm	0.00mm
1/ 3	10 mm	10.00 mm	0.00mm
Meanvalue		10.04 mm	0.04mm

No	Nominal	Actual	Deviation
1/ 1	20 mm	20.12 mm	0.12mm
1/ 2	20 mm	20.00 mm	0.00mm
1/ 3	20 mm	20.00 mm	0.00mm
Meanvalue		20.04 mm	0.04mm

Operator : -----

Signature lines

Released : -----

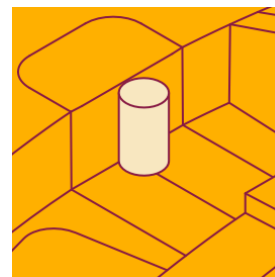
Name/Signature Date/Time

Printed : 12.09.2025 : 13:49:36

Print date of report

Length Calibration

The length calibration covers all width, length and diameter measurements performed with the instrument. You can perform a three-point calibration of these measurements here. Enter three reference block dimensions and how often you want to measure each reference block. Then follow the on-screen instructions and place the reference block in the center of the testing station, as shown in the illustration and on screen.



Once the calibration is completed you can print the calibration report:

Pharma Test PTB 430-500 SN 12345 V1.00

Header with instrument type, serial no.
and firmware version

Calibration protocol length

Calibration date: 12.09.2025 13:47:12

Date and time the calibration was
performed

-----Measurements-----

No	Nominal	Actual	Deviation
1/ 1	2 mm	2.12 mm	0.12mm
1/ 2	2 mm	2.00 mm	0.00mm
1/ 3	2 mm	2.00 mm	0.00mm
Meanvalue		2.04 mm	0.04mm

Measurements with actual results and
deviation from the reference

Mean value from above measurements

No	Nominal	Actual	Deviation
1/ 1	10 mm	10.12 mm	0.12mm
1/ 2	10 mm	10.00 mm	0.00mm
1/ 3	10 mm	10.00 mm	0.00mm
Meanvalue		10.04 mm	0.04mm

No	Nominal	Actual	Deviation
1/ 1	20 mm	20.12 mm	0.12mm
1/ 2	20 mm	20.00 mm	0.00mm
1/ 3	20 mm	20.00 mm	0.00mm
Meanvalue		20.04 mm	0.04mm

Operator : -----

Signature lines

Released : -----

Name/Signature Date/Time

Printed : 12.09.2025 : 13:49:36

Print date of report

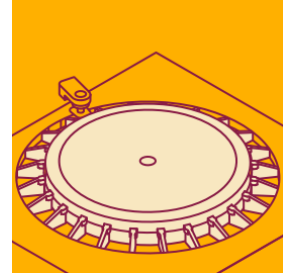
Hardness Calibration

You can perform a three-point calibration of force sensor used for the hardness measurements here. PTB 430 supports static hardness calibration by weight and a dynamic calibration using the Pharma Test digiCAL calibration tool (in preparation). Performing either of these hardness calibrations resets the calibration date and time for hardness.

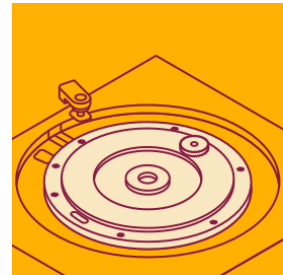
Hardness Calibration by Weights

Enter three reference weights and how often you want to measure each weight. To perform this calibration, the following steps must be performed:

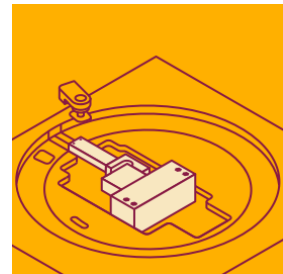
First remove the carousel:



Then remove this coverage:



You now can access the force sensor and its support. Unscrew the support and place it in an upright position.

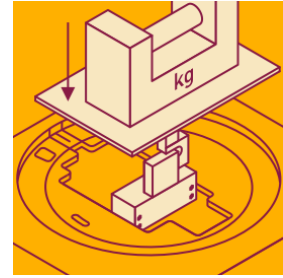


To safely place the weights Pharma Test offers this weight support:



Figure 15: PTB 430 calibration support for weights, part no. 288-1210

This support is screwed to the force jaw of the instrument. Once the support is safely screwed to the force jaw, follow the instructions on screen and carefully place the weights:



Once the calibration is completed you can print the calibration report:

Pharma Test PTB 430-500 SN 12345 V1.00

Calibration protocol hardness

Calibration date: 12.09.2025 13:47:12

-----Measurements-----

No	Nominal	Actual	Deviation
1/ 1	5 kg	5.12 kg	0.12kg
1/ 2	5 kg	5.00 kg	0.00kg
1/ 3	5 kg	5.00 kg	0.00kg
Meanvalue		5.04 kg	0.04kg

No	Nominal	Actual	Deviation
1/ 1	10 kg	10.12 kg	0.12kg
1/ 2	10 kg	10.00 kg	0.00kg
1/ 3	10 kg	10.00 kg	0.00kg
Meanvalue		10.04 kg	0.04kg

No	Nominal	Actual	Deviation
1/ 1	15 kg	15.12 kg	0.12kg
1/ 2	15 kg	15.00 kg	0.00kg
1/ 3	15 kg	15.00 kg	0.00kg
Meanvalue		15.04 kg	0.04kg

Header with instrument type, serial no. and firmware version

Date and time the calibration was performed

Measurements with actual results and deviation from the reference

Mean value from above measurements

Operator : -----

Signature lines

Released : -----

Name/Signature Date/Time

Printed : 12.09.2025 : 13:49:36

Print date of 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 19: 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. 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: use an external printer such as the Epson ticket printer Network Printer: use a PCL capable network printer, enter the printer IP address here RS232 block: send all result data via the serial interface at the end of a test series using the [->PRINT] button

RS232 line by line: send each result of one sample as one line while the test series is running; this setting can be activated independently of the other printer settings

QUICK TEST	Not relevant for this model	Not relevant for this model
Auto Start	Not relevant for this model	Not relevant for this model
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
PQ interval	The instrument will log the date and time when a calibration has been performed. You can set this PQ interval to create a reminder once a calibration as elapsed this period.	off 3 Month 6 Month 12 Month
Ethernet	Connect the instrument to a network using ethernet.	See below
Align balance	Use this screen to check the levelness of the instrument.	NA

Table 20: 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.

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 430 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 430 is 10 N. Testing very soft samples may require you to change this setting.

Ethernet Connection and Network Printer

You can connect the instrument to a network using a standard ethernet cable. The instrument needs to be assigned an IP address. You can either use a static IP address or DHCP to automatically assign the IP address. Which method to use depends on your network settings. Consult your IT department about this.

The following settings can be made concerning the ethernet connection:

- **Use DHCP:** activate to have the IP address for this instrument automatically be assigned by the network or deactivate to assign a static IP address
- **Actual:** once the instrument is connected to the network, its actual IP address is displayed
- **Fix IP:** in case DHCP is deactivated, enter the static IP address here; consult your IT department which IP address should be used here
- **MAC:** displays this instrument's unique MAC address; your IT department might need this address to allow this instrument to connect to your network
- **Fix Subnetmask:** enter the subnet mask of your network; consult your IT department for this
- **Fix Gateway:** enter the gateway of your network; consult your IT department for this

Once the instrument is connected to the network, the reports can be printed using a PCL compliant network printer. From the output settings select network printer and enter the IP address of the printer there. Make sure that the instrument is in a part of your company network, that can access the printer.

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 430.

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

Table 21: Tools required for adjustment

PTB 430 offers adjustment programs for thickness, other 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 22: 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 430 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 23: 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.
UnFI	= "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 24: 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.