



PTB-M100 Portable Tablet Hardness Testing Instrument Operating Manual



Version 1.0

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The Documentation

This document describes the set-up, operation and general maintenance of the instrument. It should be used by the operators and the technical support staff responsible for the installation and set-up of equipment.

All attached equipment and parts 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. 1 or STOP)**
- Display information
- *Information entries*
- **Select from a menu**
- Note: informs about special use or possibility



Instrument type	PTB-M100
Document name	B-29-006x0_PTB-M100_e.docx
Document version	1.0
Author	Pharma Test Apparatebau AG
Valid from	25.02.2025
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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	28.02.2025	Pharma Test	N	First release

Table 1: Document history

Index Information - Change:

N = New Document

C = Correction

R = Revision

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1. About PTB-M100

Thank you for choosing the Pharma Test PTB-M100 instrument. PTB-M100 is a portable, manual hardness testing instrument for tablets. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia. PTB-M100 is very easy to use. The force and break point are measured by a precise force sensor and the result is immediately displayed on the large color touchscreen. The instrument is solidly built and yet perfectly portable, making it ideal for use in a production department, for example.

The instrument is operated using a 3.5" color touch screen. During a test the hardness value is displayed live in either Newton (N), Kilopond (Kp) or StrongCobb (Sc). The instrument is powered by a rechargeable battery using a standard USB-C charger. The test results can be documented by connecting a ticket printer or by using the Pharma Test PT-Node network adapter. When starting a new test run, a batch number (alpha-numeric) can be entered using a software keyboard.

Then simply place the sample on the testing platform and manually rotate the knob. This moves the jaw and applies force to the sample. The result is immediately displayed. All results of a current measurement run are then shown in a scrollable table. Incorrectly measured samples can be discarded here. These results are still documented on the result report but are not included in the statistics. The results of the latest test run are stored in the instrument memory and can be printed repeatedly. Starting a new measurement run discards the results of the previous run.

The settings menu is password protected. This password can be changed. The instrument keeps date and time (date and time are not lost when the battery is empty) and supports 12- and 24-hour time formats and US and European date formats. All printouts contain date and time of performance and date and time of the printing.

PTB-M100 Intended Use

The PTB-M100 portable tablet hardness testing instrument is intended for testing the hardness of pharmaceutical and medicinal tablets only. It is not permitted for liquids in glass ampoules, non-breakable samples, samples which emit corrosive or toxic substances while breaking or non-pharmaceutical products.



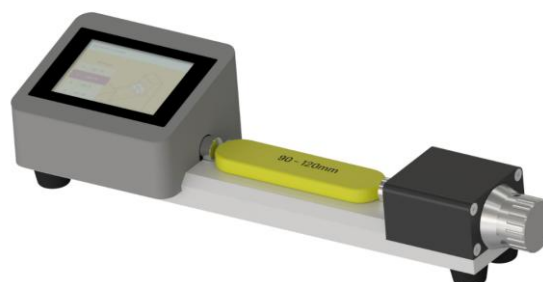
We recommend wearing protective glasses during operation of the instrument.

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PTB-M100 Instrument Variant with Extended Measurement Range

PTB-M100 is also available in an extended measurement range version. In this instrument variant, the mechanics have been extended to be able to test larger samples than the standard model. This is useful for certain veterinary products or other, non-pharmaceutical applications.

PTB-M100 is available with the following extended measurement ranges:



Part No.	Sample Min. Diameter	Sample Max. Diameter	Hardness Max.
29-01660	30mm	60mm	300N
29-01665	30mm	60mm	500N
29-01690	60mm	90mm	300N
29-01695	60mm	90mm	500N
29-01620	90mm	120mm	300N
29-01625	90mm	120mm	500N

Table 2: PTB-M100 variant instruments with extended measurement range

Standard Supply Scope

PTB-M100 comes ready to use with its standard scope of supply:

Part No.	No.	Description
295-0400	1	Calibration support
285-1771	1	Cleaning brush
295-0600	1	Power supply, USB, 5V, 2,4A
34-01173	1	USB-A to USB-C cable, approx. 1m
002-6003	1	Allen key, DIN 911, size 3

Table 3: Standard supply scope

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Optional Items

In addition to the standard scope of supply, the following optional items are available for PTB-M100:

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
	Serial cable to connect PTB-M100

Table 4: 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.



Part No.	Type
29-02200	Epson TM-U220D ticket printer
34-01201	Cable to connect PTB-M100
007-0230	Ink ribbon for Epson ticket printer

Table 5: Ticket printer

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PT-MET Mechanical Tablets for Daily Verification

For daily verification, PTB-M100 is compatible with the Pharma Test PT-MET mechanical tablets. PT-MET are available with four different nominal hardness values (50, 100, 150, 200N). They can be purchased individually or as a complete set. They come with a certificate of calibration, operating instructions and can be returned to us for re-calibration.



Part No.	Type	Nominal value
28-01050	PT-MET50	50N
28-01100	PT-MET100	100N
28-01150	PT-MET150	150N
28-01200	PT-MET200	200N

Table 6: PT-MET mechanical test tablets

PTB-CAL15 Calibration Weight Set

Using the certified PTB-CAL15 weight set, adjustment and calibration of PTB-M100 can be carried out on site and requires only a few minutes. 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.



Part No.	Type	Included weights
28-00295	PTB-CAL15	5, 10, 15kg (not calibrated)
281-2890	Calibration certificate	NA

Table 7: PTB-CAL15 calibration weight set

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Calculation Factors

Hardness: $1 \text{ KP} = 9.81 \text{ N}$ $1 \text{ KP} = 1.43 \text{ Sc}$

Mean value: $\bar{x} = \sum x / N$

Absolute standard deviation: $\sqrt{\frac{\sum (x - \bar{x})^2}{N}}$ [$x = \text{measured value}$]

Relative standard deviation: $\sqrt{\frac{\sum (x - n)^2}{N}}$ [$n = \text{nominal value}$]

Technical Specifications

Parameter	Specification
Display	3.5" color LCD
Data entry	Touch screen
Standard force range	5.0 to approximately 300N (500N optional)
Hardness accuracy	1N
Hardness resolution	1N
Maximum number of tests	100 in one test run
Maximum sample size	28mm diameter (extended measurement range models available)
Battery capacity	2x 1.100mwh NiMH AAA battery cells (approx. 2 hours of working time, can be used and charged simultaneously)
Printer	Serial printer port to connect ticket printer
Interface	RS-232 COM port supporting PT-Node network adapter
Calibration program	3-point calibration program including report
Adjustment program	2-point adjustment program including report
Instrument dimensions	Approx. 27cm x 9cm x 9cm (Length x Width x Height) w/o printer
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

Table 8: Technical data

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

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2. Setting Up the PTB-M100 Instrument

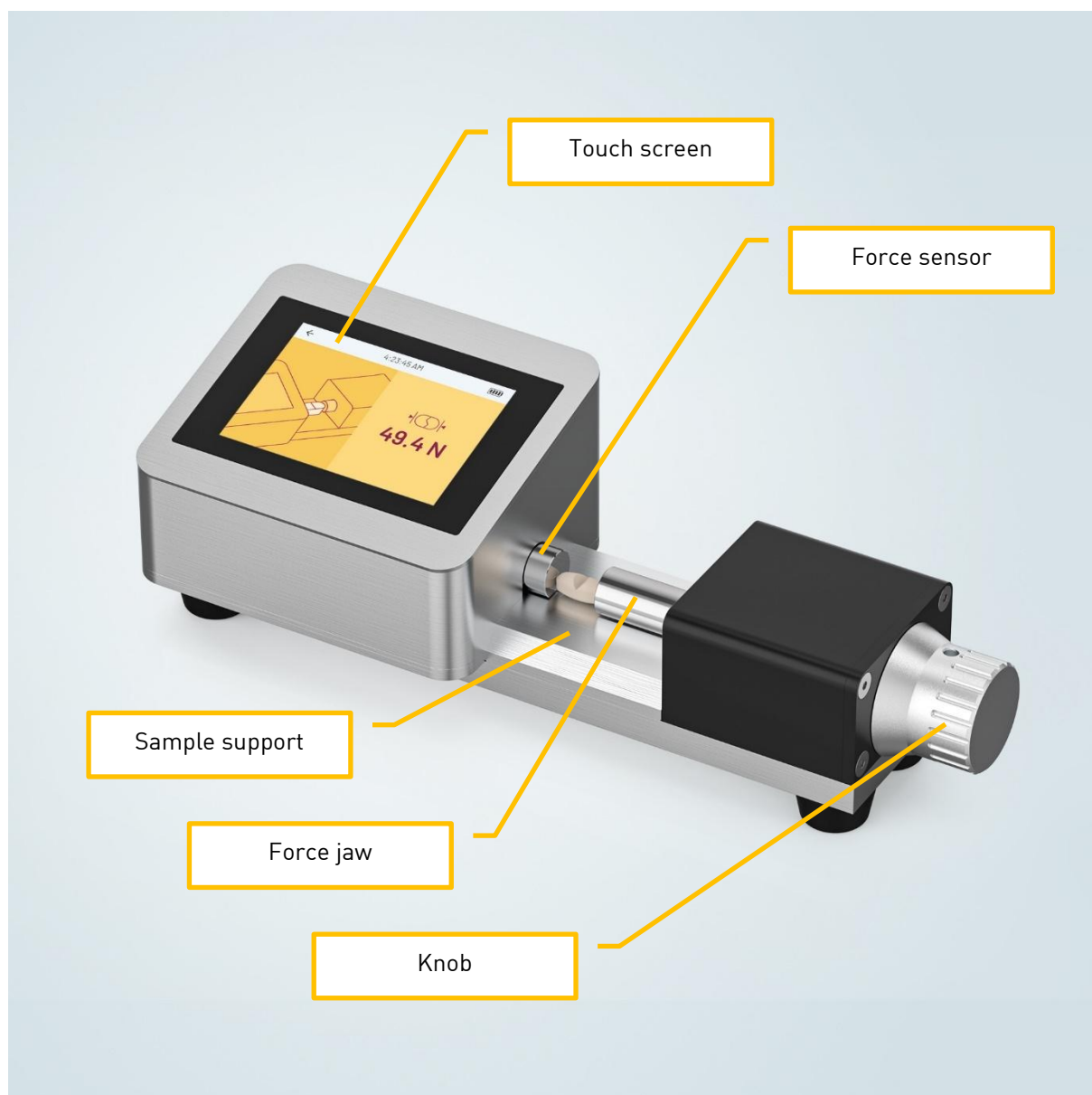


Figure 1: PTB-M100 main components

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Figure 2: PTB-M100 side view ports

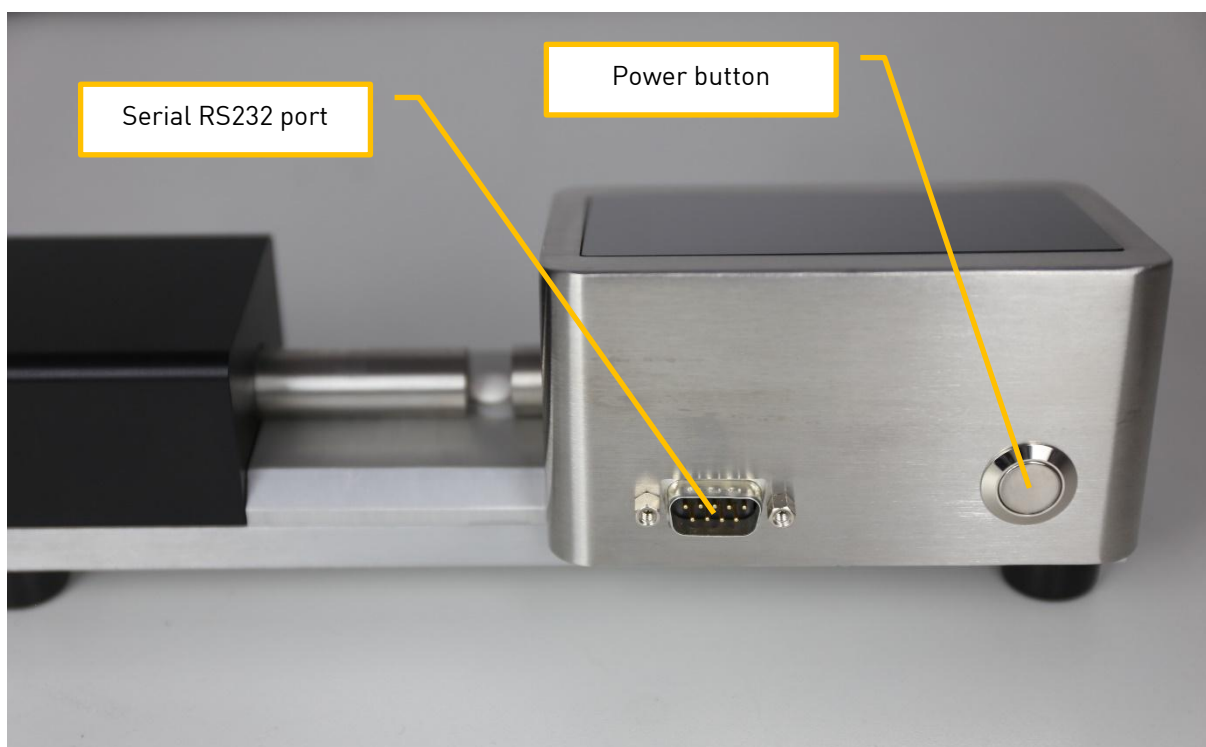


Figure 3: PTB-M100 rear view

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Instrument Connections

Port	Description
USB-A	Currently not used
USB-C	Connect charger to charge the instruments batter and to connect the instrument to a PC to install firmware updates
Serial RS232	Connect a ticket printer to print reports, connect a PT-Node network adapter or capture serial result data

Table 9: Instrument connections

Connecting the Mains

Connect the supplied charger to the mains using an adapter suitable for local power outlet. Connect the USB cable to the charger and to the USB-C port on the side of the PTB-M100 instrument. Press the power button on the backside of the instrument to turn it on.

Using the Rechargeable Battery

PTB-M100 includes a rechargeable battery (2x 1.100mwh NiMH AAA battery cells) providing approximately two hours of working time with the instrument, depending on the brightness setting of the screen. To charge the battery simply connect the instrument to the mains as described above. The instrument can be used while it is charging.

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3. Navigating the User Interface

PTB-M100 is operated using its capacitive touch screen. When you turn on the instrument after a short while the start screen is displayed:

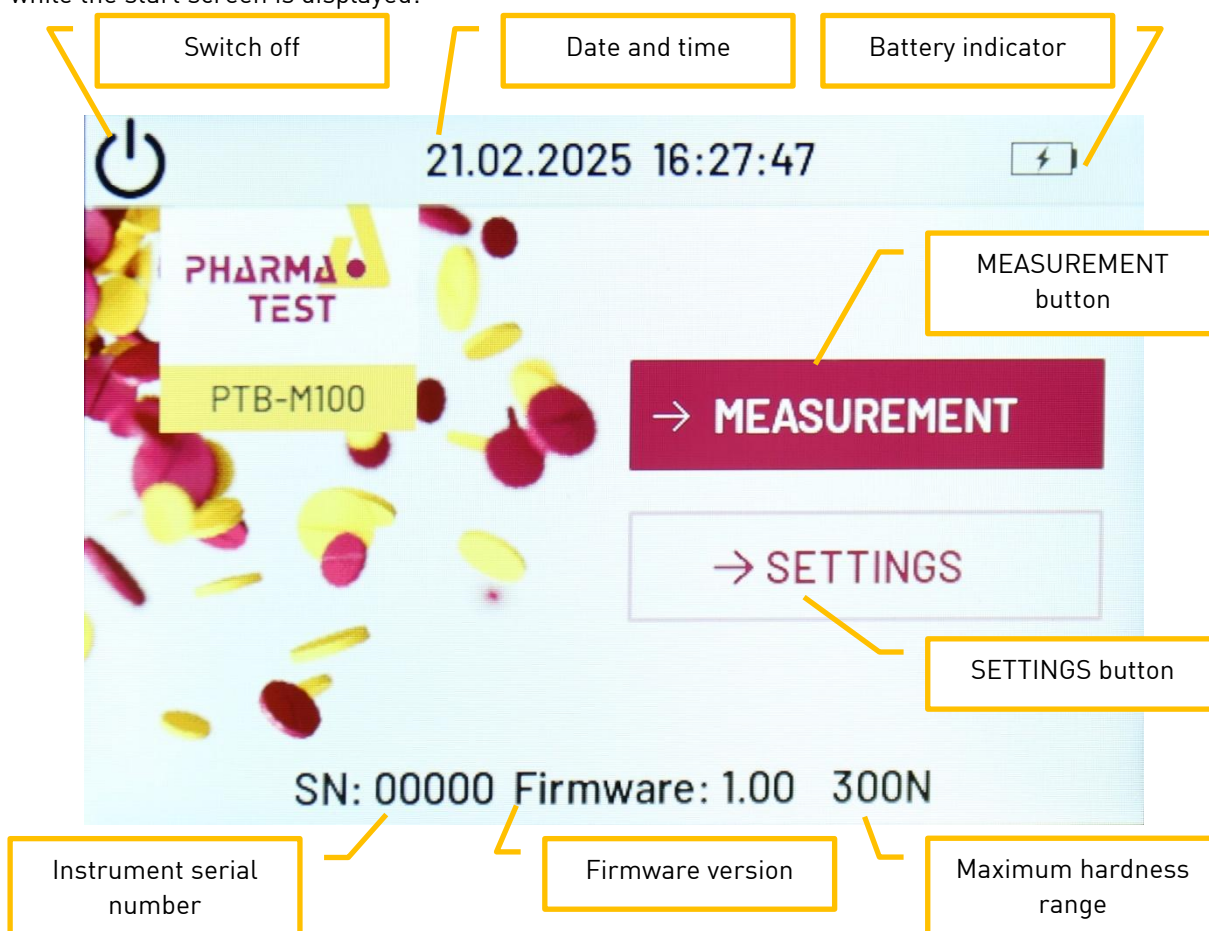


Figure 4: Start screen elements

The start screen contains the following elements:

Screen element	Function
Switch off	Touch this icon to switch off the instrument.
Date and time	Shows the current date and time. PTB-M100 retains date and time in case the rechargeable battery is drained.
Battery indicator	This icon shows the status of the battery:  Currently charging  Fully charged  Half charged  Nearly drained Note that the battery charge indication is only approximate.

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Screen element	Function
MEASUREMENT Button	Touch this button to start a new measurement. See the corresponding chapter below for more details.
SETTINGS Button	Touch this button to enter the settings menu. See the section below for more details.
Maximum hardness range	The maximum hardness range of your instrument, either 300N or 500N.
Firmware version	The currently installed instrument firmware version.
Instrument serial number	The serial number of your instrument
Back arrow	Some screens show a back arrow on the top left corner. Use it to return to the previous menu.

Table 10: Start screen elements and functions

Onscreen Keyboard

Whenever a text entry is required a software keyboard is displayed on screen:

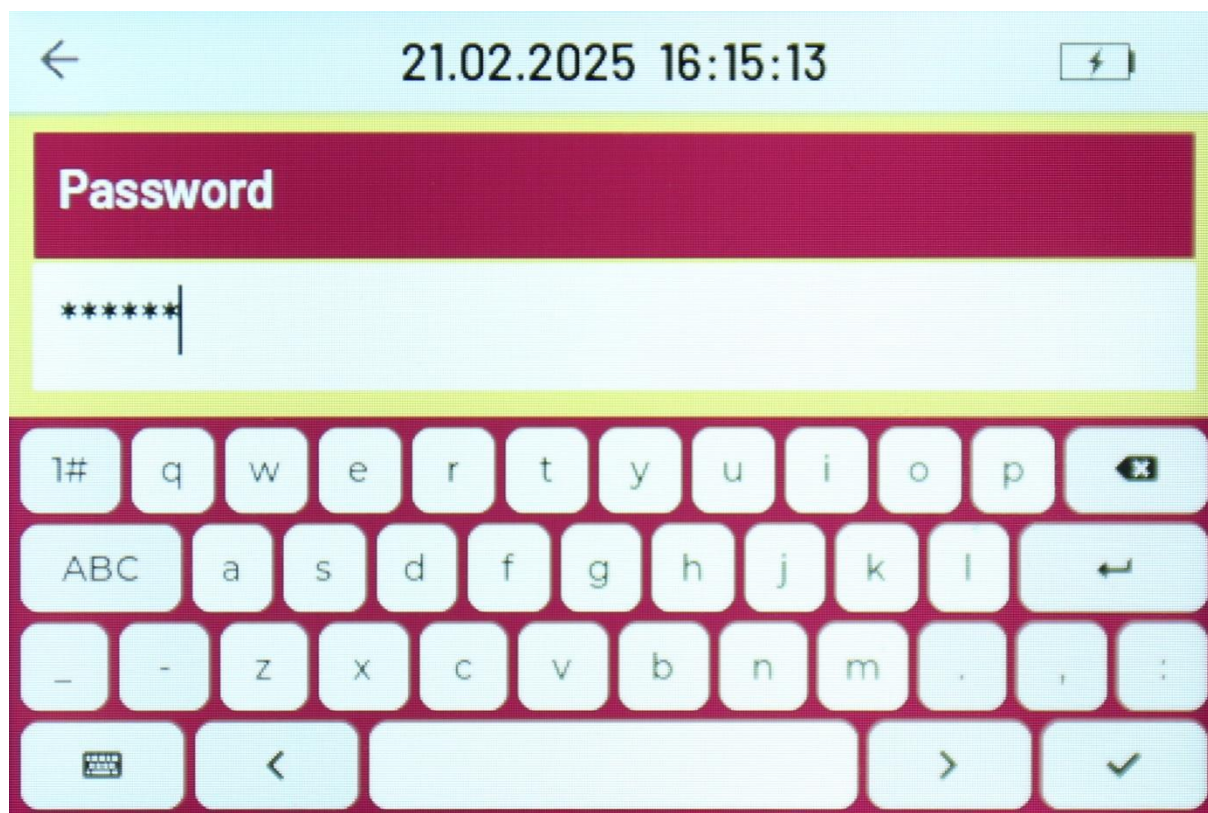


Figure 5: Onscreen keyboard

This keyboard is used to enter a batch number when starting a new measurement and to enter the password to access the settings menu.

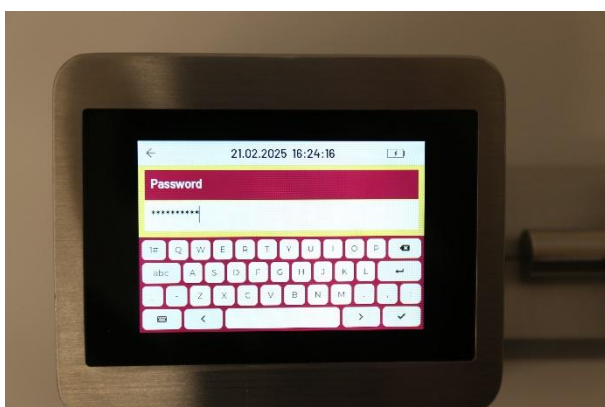
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Settings Menu



From the start screen touch the **SETTINGS button** to enter the settings menu.

The settings menu is protected by a password.



Enter the password using the onscreen keyboard.

The default password is:

PHARMATEST

In case you mistype the password, you are returned to the start screen.

We recommend changing this password as soon as possible. Make sure you note the new password and store at a safe place. In case the password is lost, contact Pharma Test support to help reset the password.



The settings menu consists of two screens. Touch the NEXT button on the bottom of the first screen, to show the second screen. On the second screen touch the SAVE button to save your changed and to exit the settings menu.

Refer to the table below for more details on the individual settings.

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Settings menu item	Screen No.	Function
UNITS	1	Select the force units for the hardness measurement from this drop-down list between: N = Newton kp = Kilopond Sc = StrongCobb
LANGUAGE	1	Select the language for the user interface from this drop-down list between: Deutsch (German) and English
OUTPUT	1	Select the serial output format from this drop-down list between: PRINTER to print result reports and RS232 to send serial result data via the RS232 interface.
DATE	1	Touch this button to change the date. See below for more details.
TIME	1	Touch this button to change the time. See below for more details.
CALIBRATION ADJUSTMENT	1	Touch this button to enter the calibration and adjustment menus. See the corresponding chapter below for instructions on calibration and adjustment of the instrument.
TIME	2	Select the time format from this drop-down list between: 24h for 24-hour format and 12 for twelve-hour format.
DATE	2	Select the date format from this drop-down list between: EUR for dd.mm.yyyy date format and US for mm.dd.yyyy date format.
STDBY	2	Select the standby time from this drop-down list between: 5m for 5 minutes 10m for 10 minutes 15m for 15 and never. After this time has elapsed with any action from the user via the touch screen, the touch screen is dimmed. Setting a shorter time here is recommended to save battery in case the instrument is to be operated regularly without connection to the mains.
OFF	2	Select the automated off time from this drop-down list between: 10m for 10 minutes

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Settings menu item	Screen No.	Function
		20m for 20 minutes 30m for 30 minutes and 40m for 40 minutes. After this time has elapsed with any action from the user via the touch screen, the instrument is switched off. Setting a shorter time here is recommended to save battery in case the instrument is to be operated regularly without connection to the mains.
BRIGHTNESS	2	Use the slider to change the brightness of the screen from 10% (dim) to 100% (bright). Note that increasing the brightness of the screen consumes significantly more battery. Setting a dimmer value here is recommended to save battery in case the instrument is to be operated regularly without connection to the mains.
Change Password	2	Touch this button to change the password for the settings menu. The currently set password is displayed in grey color in the password entry field. Make sure to double check your entry of a new password this way before you exit the settings menu.

Table 11: Settings menu items

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Setting Date and Time



To change the date, simply slide up or down on the touch screen to change the day, month and year.

Touch the **SAVE** button to save the new date.



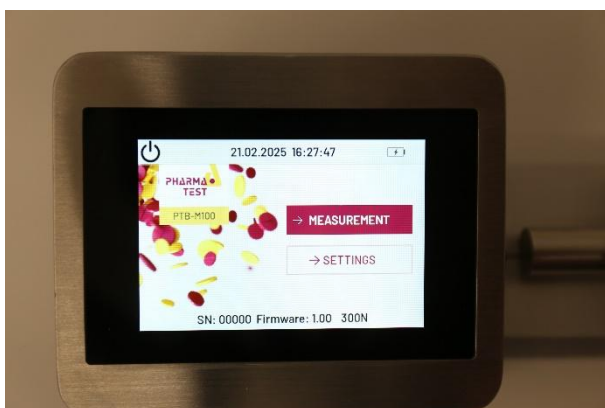
To change the time, simply slide up or down on the touch screen to change the hours and minutes.

Touch the **SAVE** button to save the new date.

Note that PTB-M100 retains the current date and time even in case the rechargeable battery runs empty.

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4. Performing a Measurement with PTB-M100



To start a new measurement run, touch the **MEASUREMENT** button on the start screen.

The instrument saves the results of the latest measurement run. Starting a new measurement run discards the results of the previous measurement run. Before you start a new measurement run, you get the chance to print the results of the previous run.



On the following screen, touch the **MEASUREMENT** button to start the new measurement run.

Depending on whether output is set to printer or RS232 (see "Settings Menu" above) a second button **PRINT** or **OUTPUT** is display. Touch this button to print the result report of the previous measurement or to send the results of the previous measurement through the serial interface.



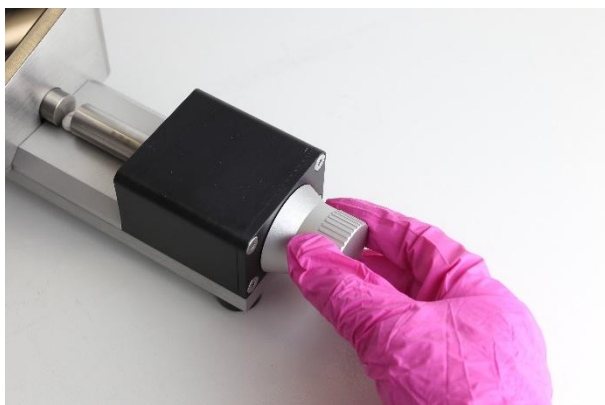
After touching **MEASUREMENT**, the onscreen keyboard is displayed to enter an alpha-numeric batch number. Up to xxx characters can be entered for the batch number.

In case you already performed a measurement and did not switch off the instrument in between, the previously entered batch number is displayed in the entry field in light grey. You can directly touch **ENTER** to retain the previous batch number for the new measurement run.

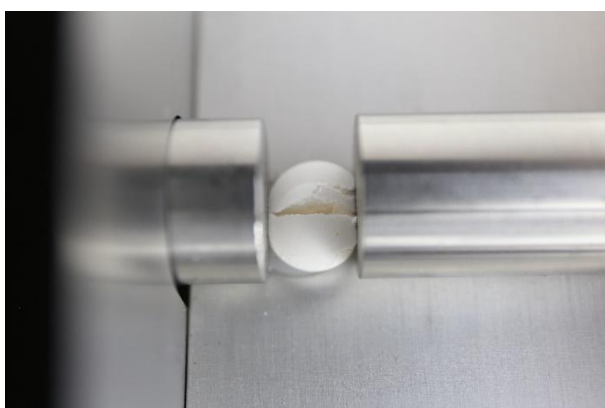
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After confirming the batch number entry, the test screen is displayed. The current reading of the force sensor is displayed.



Insert the first sample onto the sample support. Rotate the knob in counterclockwise direction to move the force jaw towards the sample and force sensor.

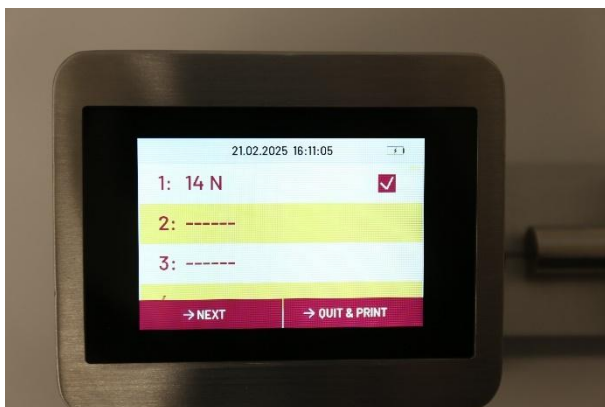


Keep turning the knob until the force jaw touches the sample and ultimately breaks it.

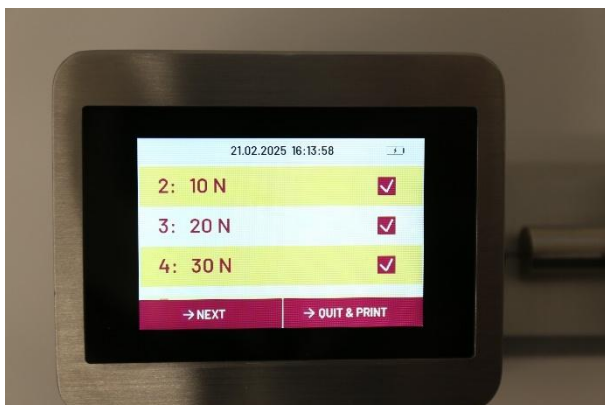


During this process you will note that the force value displayed on the test screen increases. Once the sample breaks, the force sensor will notice a decrease in force and thus detects the break. This is indicated by a green check mark icon.

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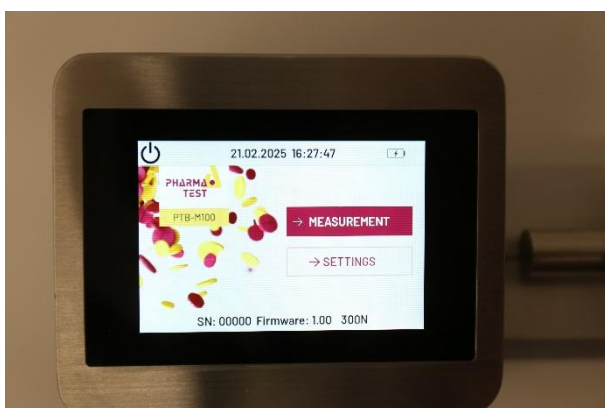


This display then switches automatically to the result table. Swipe up and down on the touch screen to scroll the table. Up to 100 measurements can be performed in one run.



In case of an erroneous measurement, untick the checkbox to the right of the erroneous result. This marks this result as invalid and excludes it from the statistics of the result report.

Touch **NEXT** to perform the next measurement or touch **QUIT & PRINT** to end this measurement run. In case a printer is connected, the result report is printed automatically.



You are then returned to the start screen.

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Example Test Report

```

Pharma Test PTB-M100-300 SN 33402 V1.00

Batch      : 1234abcd
Date       : 19.02.2025   Time: 16:58:04

-----Results-----
No.        1:   99 N
No.        2:   97 N
No.        3:  104 N
No.        4:  101 N
No.        5:   95 N
No.        6:   96 N
No.        7:   95 N
No.        8:   95 N
No.        9:   96 N
No.       10:   94 N

-----Statistics-----
Xmax       :  104 N
Xmin       :   94 N
Xdif       :   10 N
Xmean      :  97.2 N
Xabs       :   3.2 N
Xrel       :   3.3 %

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

Printed   : 20.02.2025   Time: 11:03:49
  
```

Header with instrument serial number and firmware version

Alpha-numeric batch number

Date and time when the test was performed

Individual test results, a test run can contain up to 100 tests

Statistics:

Maximum

Minimum

Mean value

Absolute standard deviation

Relative standard deviation

Space for signatures of operator and second person for release

Date and time when this report was printed

Figure 6: Example test report

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5. Calibration

This section describes how to perform the calibration of the force sensor using certified weights, such as the Pharma Test PTB-CAL15 weight set. The weights must be placed carefully on the force sensor using the supplied calibration support. We recommend performing a three-point calibration with 5, 10 and 15kg weights.



Attention: The operator must handle static weights of up to 15kg. Only qualified personnel should perform the calibration. The operator himself is responsible for his safety, concerning dropping the weights in case of carelessness. Use gloves and wear safety shoes to avoid injuries.

Make sure that the battery is charged before you start the calibration, as the charger must be disconnected from the instrument.



Enter the settings menu, then touch the **CALIBRATION ADJUSTMENT** button.



On this screen you can start a new adjustment, a new calibration or print the report of the previous adjustment or calibration.

Note, that performing a new adjustment or calibration discards the values of the previous adjustment or calibration.

Touch **CALIBRATION** to proceed.

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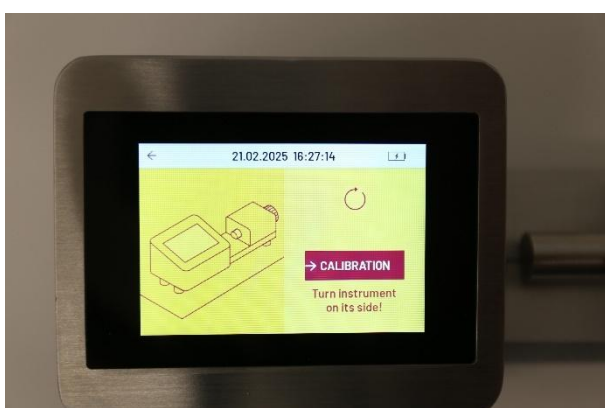
On this screen you can select three reference weights to be used for the three-point calibration. You can also select how many calibration measurements for each reference weight you want to perform.



Use the drop-down lists to select your reference weights from 5 to 50kg. We strongly recommend performing calibration with 5, 10 and 15kg weights.



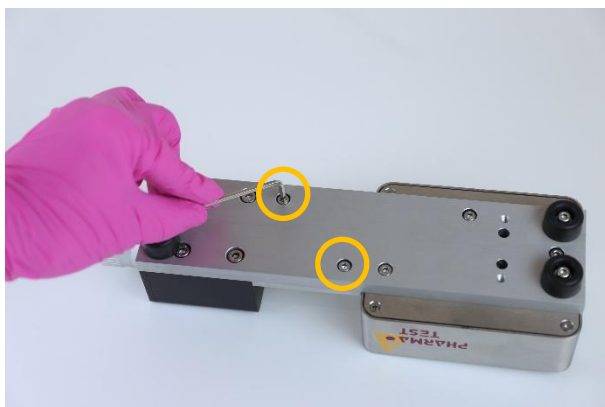
Then select the number of measurements per reference weight from this drop-down list. You can perform from one up to five calibration measurements.



To place the calibration weights onto the force sensor, the instrument must be turned on its side. For this any USB cable must be disconnected from the PTB-M100 first.

Use the knob to move the force jaw all the way to right, away from the force sensor.

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Change	N



Unscrew the sample support from the bottom using an Allen key size 3 and remove it.



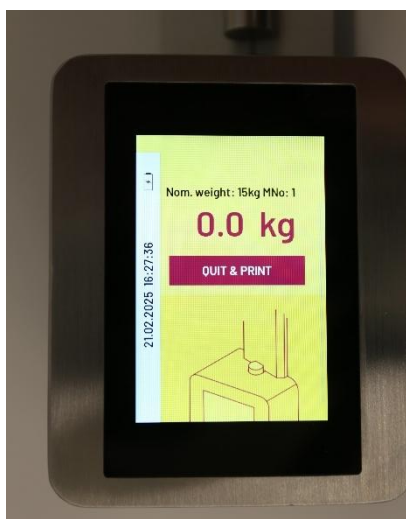
Place the calibration support onto the force sensor.



Then carefully place the first calibration weight as written on screen onto the force sensor. Wait until the reading has stabilized and touch **OK** to store the calibration result and to proceed with the next measurement.

Proceed in the same manner for all reference weights and all measurements.

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Once you have reached the last measurement, the **OK** button changes to **QUIT & PRINT**. Touch this button to end the calibration. In case a printer is connected the calibration report is automatically printed.

Remove the last weight from the force sensor. Remove the calibration support from the force sensor. Insert the sample support and fasten the screws.

Example Calibration Report

Pharma Test PTB-M100-300 SN 33402 V1.00				
Calibration protocol				
Date : 25.02.2025 Time: 11:22:44				
-----Measurements-----				
No	Nominal	Actual	Deviation	
1/01	05 kg	5.0 kg	-0.0 kg	
1/02	05 kg	5.0 kg	-0.0 kg	
1/03	05 kg	5.0 kg	-0.0 kg	
Meanvalue		4.99 kg	-0.01kg	
2/01	10 kg	10.0 kg	-0.0 kg	
2/02	10 kg	10.0 kg	-0.0 kg	
2/03	10 kg	10.0 kg	-0.0 kg	
Meanvalue		9.97 kg	-0.03kg	
3/01	15 kg	15.0 kg	-0.0 kg	
3/02	15 kg	14.9 kg	-0.1 kg	
3/03	15 kg	15.0 kg	-0.0 kg	
Meanvalue		14.99 kg	-0.01kg	
Operator: -----				
Released: -----				
Name/Signature			Date/Time	
Printed : 26.02.2025 Time: 08:45:16				

Header with instrument serial number and firmware version

Date and time when the calibration was performed

Individual calibration results with nominal values, actual values and deviation between them. Also mean values for actual results and deviation are printed here.

Space for signatures of operator and second person for release

Date and time when this report was printed

Figure 7: Example calibration report

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Document name	B-29-006x0_PTB-M100_e.docx
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Author	Pharma Test Apparatebau AG
Valid from	25.02.2025
Change	N

6. Adjustment

Only a trained service technician should perform adjustments to the instrument. Certified calibration tools should be used for the adjustment.

Adjustment should only be performed after a calibration has been performed previously and that this calibration failed to achieve results within the given tolerance. You may refer to the supplied OQ protocol for the expected results and tolerances for the calibration.



Attention: After performing an adjustment, a calibration must be performed subsequently to prove that the adjustment has been successful and that the instrument is capable to produce correct results.

In case a subsequent calibration fails, contact the Pharma Test support to receive further information. Make sure to include a copy of the latest adjustment and calibration reports.

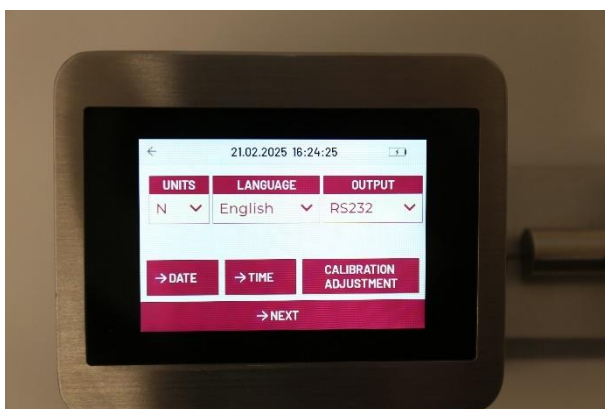


Please Note: Incorrectly performed adjustments can lead to the instrument being unable to produce correct measuring results. Before attempting an adjustment make sure you are familiar with the instrument and the adjustment process.



Attention: The operator must handle static weights of up to 10kg. Only qualified personnel should perform the adjustment. The operator himself is responsible for his safety, concerning dropping the weights in case of carelessness. Use gloves and wear safety shoes to avoid injuries.

Make sure that the battery is charged before you start the adjustment, as the charger must be disconnected from the instrument.



Enter the settings menu, then touch the **CALIBRATION ADJUSTMENT** button.

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On this screen you can start a new adjustment, a new calibration or print the report of the previous adjustment or calibration.

Note, that performing a new adjustment or calibration discards the values of the previous adjustment or calibration.

Touch **ADJUSTMENT** to proceed.



Use the drop-down list to select your adjustment weights from 5 to 20kg. We strongly recommend performing adjustment with a 10kg weight.



To place the adjustment weight onto the force sensor, the instrument must be turned on its side. For this any USB cable must be disconnected from the PTB-M100 first.

Use the knob to move the force jaw all the way to right, away from the force sensor.



Unscrew the sample support from the bottom using an Allen key size 3 and remove it.

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Place the calibration support onto the force sensor.



Then carefully place the 10kg adjustment weight onto the force sensor. Wait until the reading has stabilized and touch **ADJUST** to store the adjustment result.

Then touch **QUIT & PRINT** to leave the adjustment menu. In case a printer is connected the calibration report is automatically printed.

Remove the weight from the force sensor. Remove the calibration support from the force sensor. Insert the sample support and fasten the screws.

Example Adjustment Report

Pharma Test PTB-M100-300 SN 33402 V1.00	
Adjustment protocol	
Date	: 26.02.2025 Time: 08:40:04
Adjustment with 10kg weight	
Factor old:	4.93 new 4.92
Operator:	-----
Released:	-----
	Name/Signature Date/Time
Printed	: 26.02.2025 Time: 08:45:16

Header with instrument serial number and firmware version

Date and time when the adjustment was performed

Reference weight used for adjustment

Old and new adjustment factors

Space for signatures of operator and second person for release

Date and time when this report was printed

Figure 8: Example adjustment report

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Author	Pharma Test Apparatebau AG
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Change	N

7. Cleaning and Maintenance

Cleaning

Depending on the type of the tested sample it may be necessary to clean the sample support, force sensor and/or force jaw after a test. You may use the supplied cleaning brush or a similar tool for this.

Maintenance

The instrument does not include any parts which the user can maintain or repair. Repair work should be done by authorized service agents only.

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



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

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8. Safety Information



Before you open the instrument always disconnect the power supply from the mains socket. Only authorized personnel should open the instrument. Before any repair work is to be performed, always first remove the batteries after opening the instrument.



Do not use the instrument in case:

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



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 unpacking, to avoid bruising hands and fingers.



While breaking a tablet or capsule, parts can bounce out of the testing area. Use protective glasses and do not bring your eyes and head in direct closeness to the test sample while breaking.



In case any spare parts are required, only use original Pharma Test parts.

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9. Instrument Firmware Updates

Over time Pharma Test may release firmware updates for your instruments to add new functionality, introduce improvements or to fix bugs. PTB-M100 can be updated using a PC and a standard USB-C cable. The update software tool, update files and change release documents are provided by Pharma Test to our distributors worldwide.

Contact your local Pharma Test distributor to find out if a firmware update for your instrument is available.

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10. Contact Details and Support

To serve the needs of our customers on a global scale, Pharma Test has established over the decades a worldwide network of qualified distributing partners. Now our strong distributor network has over 100 partnering companies all over the world. Happy to be of help.

For our international customers technical support is provided on a local level this worldwide distributor network. We carefully select our distributors based on their abilities to provide technical services at a quality level you expect – including reaction time and cost. We ensure a steady level of service quality by performing regular distributor trainings.

When making a support inquiry, make sure to include important information such as:

- Model of instrument
- Instrument serial number
- Instrument firmware version
- Your contact details including company name and location
- Description of the issue
- Any recent events such as repairs, adjustments or updates

You can check our website to find the details of the official Pharma Test distributor for your country here:

www.pharma-test.de/en/contact/distributor-contacts/

If you cannot find your country or if you want to contact the Pharma Test headquarters in Germany directly, these are our details:

Pharma Test Apparatebau AG
Siemensstrasse 5
D-63512 Hainburg / GERMANY

T: +49 6182/9532-600
 F: +49 6182/9532-80
 Email: support@pharma-test.de
 Web: www.pharma-test.com

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