PTB 311E / 311E-500 / 311E-800
Automated Tablet Testing Instruments

Operating Manual

For Firmware 4.0x

Version 4.3

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bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment

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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 have to 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

Differences in Interface

As part of our policy of ongoing product development, we do reserve the right to introduce improvements as and when we see fit to do so. So the interface on your screen and the figures in this document can differ insignificantly.

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Document History

Revision	Valid from (dd.mm.yyyy)	Author	Change	Remark
2.0	15.08.2011	PTAG	N	
3.0	30.10.2017	PTAG	N	General revision of version 2.0, new format, document actualized to actual firmware features
3.1	19.02.2018	PTAG	R	Freeweight protocol added
3.2	15.09.2020	PTAG	R	Section 6.5: Gap harmonized to QC
3.3	06.05.2021	PTAG	C	Section 5.5: Interface parameter corrected
4.0	19.10.2022	PTAG	N	General revision, new format, new parameter (width) and new (CAL) functions added
4.1	01.07.2024	PTAG	R	Correction: "stop a Test series" and revision error codes. Revision Section numbering
4.2	01.08.2024	PTAG	R	New Pictures. Incorrectly results cannot be skipped!
4.3	16.09.2026	PTAG	R	Updated spare part codes

Table 1: Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

Section 1.0 About PTB 311E/ 311E-500/ 311E-800

The PTB 311E/311E-500/311E-800 automated tablet testing instrument is a sophisticated instrument to test the individual hardness (Break Point) and dimensions of solid dosage forms such as tablets, caplets etc.

The measurements for hardness can be expressed in either Newton (N), Strong Cobb (Sc) or Kilopond (Kp). The measurements for thickness, width and diameter can either be expressed in millimeters (mm) or inches (IN).

To calibrate/ adjust the testing station of the instrument, calibrated standards are used. Reference weights are required to calibrate and adjust the hardness test station, which is equipped with an electronically operated load cell (strain gauge). A 10 mm reference block is used to calibrate the thickness, width, and diameter testing station.

The hardness test is performed in compliance to the USP <1017>, and the European Pharmacopoeia EP <2.9.8>. The force rate can be selected for either linear force increase (N/sec.) or linear speed increase (mm/min) with a broad variable range. We recommend using the linear force increase setting (20 N/sec.) as this can be easily validated using a stopwatch. It is also important to highlight the point that his hardness or break point mode more closely resembles the breaking of the sample when manually done.

Section 1.1 Available Instrument Variants

There are three instrument types in the PTB 311E/311E-500/311E-800 series of instruments:

Section 1.1.1 PTB 311E (part no. 29-02860)

This model features a load cell capable of testing the hardness of samples up to 300N. It can measure the thickness and diameter within a range of 2,0 ... 45,0mm. Furthermore, it is equipped with a printer port for the connection of an external parallel A4 printer. Alternatively, it´s possible to connect a serial Epson TM-U220D ticket printer.

Section 1.1.2 PTB 311E-500 (part no. 29-02870)

This model has the same functionality as the PTB 311E, but with an enlarged hardness range up to 500N.

Section 1.1.3 PTB 311E-800 (part no. 29-02875)

This model has the same functionality as the PTB 311E, but with an enlarged hardness range up to 800N.

Section 1.2 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.

Section 1.3 Technical Data

Parameter	Specification
Hardness Testing Range	PTB311E/ 311E-70mm: 5.0 – 300.0 N ± 10 N PTB311E-500: 10.0 – 500.0 N ± 50 N PTB311E-800: 10.0 – 800.0 N ± 50 N
Hardness Accuracy	Better than ±1 N
Hardness Resolution	0.1 N
Thickness Testing Range	PTB 311E/ 311E-500/ 311E-800: 2.00 – 45.00 mm
Thickness Accuracy	Better than ±0.02 mm
Diameter Testing Range	PTB 311E/ 311E-500/ 311E-800: 2.00 – 45.00 mm
Diameter Accuracy	Better than ±0.02 mm
Thickness/ Width/ Diameter Resolution	0.01 mm
Measuring Units	Thickness/ Width/ Diameter: Millimeter (mm) or Inches (IN) Hardness: Newton (N), Kilopond (kp) or Strong Cobb (Sc)
Force Mode	Selectable: linear force increase or constant speed
Total Driveway	Approx. 50 mm
Max. Speed Forward	Approx. 3 mm/sec.
Interface	RS232 serial port to connect a PC, PT-Node or Epson TM-U220B ticket printer; Parallel port for A4 printer connection
Instrument Housing	Stainless steel (304) to meet GLP requirements
Power	115 Volt AC or 230 Volt AC, 50/60 Hz
Current Consumption	0,15 A at 230 V; 0,30 A at 115 V; 35 W
Main Fuse	2 x T1,0 A
Installation Requirements	Ambient Temperature 15-35 °C, Relative Humidity 15-80 %rH Desk with at least 50 kg working load. All around the instrument at least 10 cm free distance to walls or other equipment. Free access to the mains power plug and switch.
Instrument Dimensions	Approx. 26 cm x 50 cm x 26 cm (D x W x H)
Packaging Dimensions	Approx. 31 cm x 66 cm x 42 cm (D x W x H)
Net Weight	Approx. 9,5 kg
Gross Weight	Approx. 12,5 kg (without optional accessories)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

Table 2: Technical Data

Section 1.4 Setting Ranges

Instrument Type	Parameter	Specification	
		MIN	MAX
PTB311E	Nominal Hardness	2.0 N	300N
	Valid Zero Offset	12 Digits	52 Digits
	Linear Force Increase Rate	5 N/sec.	200 N/sec.
	Sample Touch Force	2N	100N
	Breakpoint Detection Force	2N	100N
PTB311E-500	Nominal Hardness	5.0 N	500 N
	Valid Zero Offset	12 Digits	52 Digits
	Linear Force Increase Rate	5 N/sec.	200 N/sec.
	Sample Touch Force	2N	100N
	Breakpoint Detection Force	2N	100N
PTB311E-800	Nominal Hardness	10.0 N	800 N
	Valid Zero Offset	16 Digits	56 Digits
	Linear Force Increase Rate	5 N/sec.	200 N/Sec.
	Sample Touch Force	2N	100N
	Breakpoint Detection Force	2N	100N
General	Linear Speed Increase Rate	5 mm/min.	200.0 mm/min.
	Breakpoint Detection Range	1 mm	10 mm
	Capsule Compression Distance	1 mm	10 mm

Table 3: Setting ranges

Section 1.5 About the instrument

Figure 1 PTB 311E Instrument Overview

Functional Keys

This instrument is equipped with a symbolic and numerical keyboard. Find below a table with the functional keys and their meaning:

Keysymbol	Description	Function
	"Thickness"	Activate/ Deactivate the Thickness measurement station. Activate it by entering a nominal value
	"Diameter/Width"	Activate/ Deactivate the Diameter/ Width measurement station. Activate it by entering a nominal value
	"Hardness"	Activate/ Deactivate the Hardness test station. Activate it by entering a nominal value
	"Cal"	Functional key to have access to multiple functions when combination with number codes
	"Print"	Reprint the last test report including single results and statistics

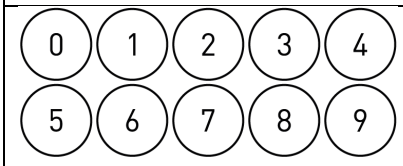
Keysymbol	Description	Function
	"Statistic"	Reprint the last test report with statistics only and without single results.
	"Star"	Used as "Enter"-Button. Confirm an entry by pressing <*>.
	"Point"	Switch between different settings within a menu by pressing <.>
	Numbers	Numbers from 0 – 9 to enter all possible nominal values as well as it is used in combination with <CAL> to enable the instruments functions
	"Auto"	This feature allows the operator to perform consecutive tests without having to push <START> repeatedly. See also Section 4.7.
	"Stop"	Stop a test run.
	"Start"	Start a test run.

Table 4: keys description

Section 1.6 Operation Principle

The operator may select to test either all four or just some of the available testing stations, thickness, width, diameter and hardness. To test the thickness of the samples, exchangeable thickness testing jaws are available to meet the different diameters of the tablets to be tested. As soon as the PTB instrument is switched on a self-check is performed. Once the self-check has been successfully completed, the instrument is ready to be used. In case any fault has been found the instrument will inform with an Error Code (see also section 10.1 Error Codes).

Prior to starting any measurement sequence, you need to select the operational settings, such as force increase rate and units for the results display; we recommend using the factory default settings:

Parameter	Default Setting
Force Mode	Linear Force Increase
Force Increase Rate	20 N/sec.
Breakpoint Detection Range	within 2 mm
Sample Touch Force	PTB311E: ~ 7N, depending on the load cell adjustment; PTB311E-500: ~ 14N, depending on the load cell adjustment; PTB311E-800: ~ 10N, depending on the load cell adjustment;
Breakpoint Detection Force	PTB311E: ~ 14N, depending on the load cell adjustment; PTB311E-500: ~ 26N; depending on the load cell adjustment; PTB311E-800: ~ 18N, depending on the load cell adjustment;
Result Display Units	Newton [N] and Millimeters [mm]

Table 5: Operational Parameters Default Settings

Those settings or the settings you selected are filed and remain valid until the user changes them.

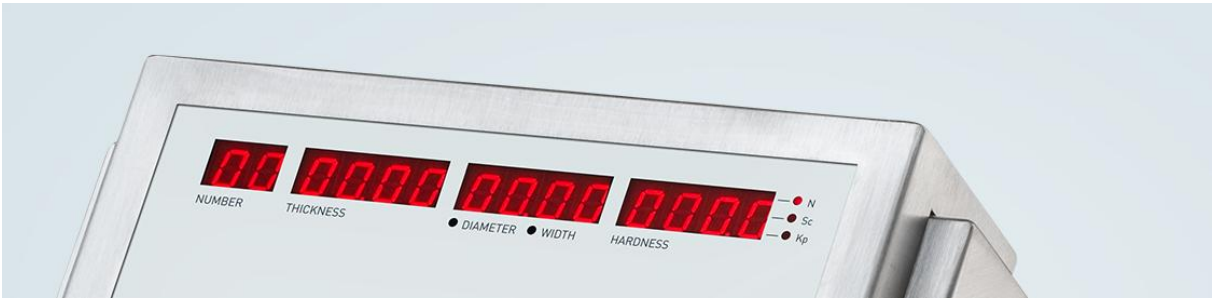


Figure 2: LED Display of the PTB 311E

You have to select which tests are to be performed. The LED display is split into three sections showing the results of Thickness, Diameter/ Width and Hardness and one on the left-hand side which indicates the number of tests performed. The three red diodes at the right-hand side indicate the actual force result selected (N/ Sc/ kp). Use the keyboard to enter any data or confirm the setting. If you wish to switch off a testing station, select the station using the corresponding function key and enter the sequence <0 0 0 0>. To activate a station, select the parameter using the corresponding Function Key and enter a Nominal Value which the sample should read for this measurement. As soon as all data have been entered the test sequence can be started.

The results are immediately displayed and printed (if a printer is connected). The data can be directly transferred to any external PC or to the PT-Node using the RS-232 data interface of the PTB instrument. At the end of a testing series, you need to either print or transmit all results, otherwise they will be erased automatically as soon as the next test has been started. Additionally, the instrument is able to print a hardness curve showing the increase rate and linearity during the test. This feature is used to perform an instrument performance qualification to show the linearity of operation.

Section 1.7 Calculation Factors and Unit Conversions

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

Table 6: Calculation Factors and Unit Conversions

Section 2.0 Available optional equipment

The following equipment is available:

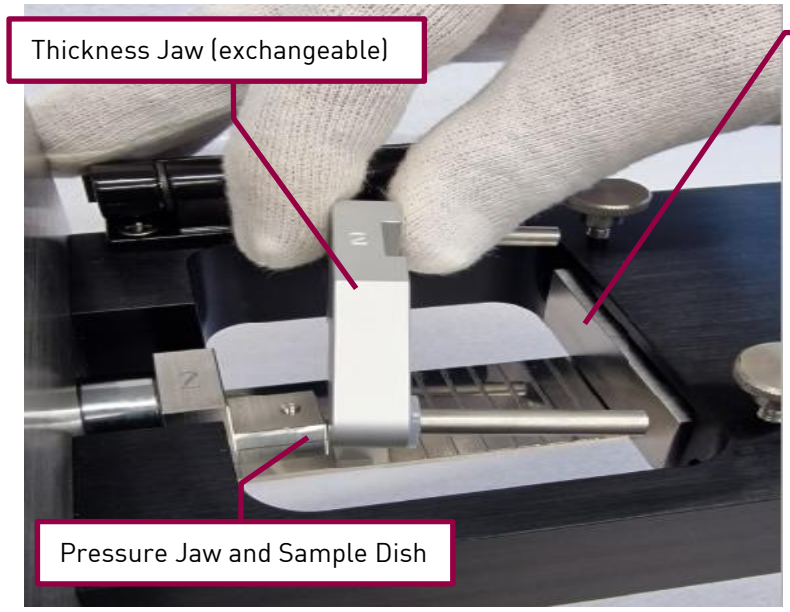
Section 2.1 Thickness Jaw in different sizes

Thickness jaws are available in the sizes:

Size 0: 3 - 5mm	(part no. 29-28530)	**Size 1:** 5 - 8mm	(part no. 29-28531)
Size 2: 8 - 12mm	(part no. 29-28532)	**Size 3:** 12 - 18mm	(part no. 29-28533)
Size 4: 18 - 22mm	(part no. 29-28534)	**Size 5:** 22 - 26mm	(part no. 29-28535)

Table 7: Different Thickness Jaw Sizes

Section 2.1.1 Installation of a Thickness Jaw



Each Thickness Jaw set is made up of 2 parts: the Thickness Jaw which keeps the tablet in a vertical position and the pressure jaw which is used to contact and then to apply force to the sample to measure the thickness, diameter and hardness. The Thickness Jaw is retained by 2 knurled screws while the force jaw is held in place using a push fit assembly with a locating pin.

Figure 3: PTB 311E/311E-500/311E-800 Thickness jaw

The thickness jaw should not contact the load cell. If it does, then the instrument will not start to operate as there would be pressure detected on the load cell and an error code would appear (see section 10.1).

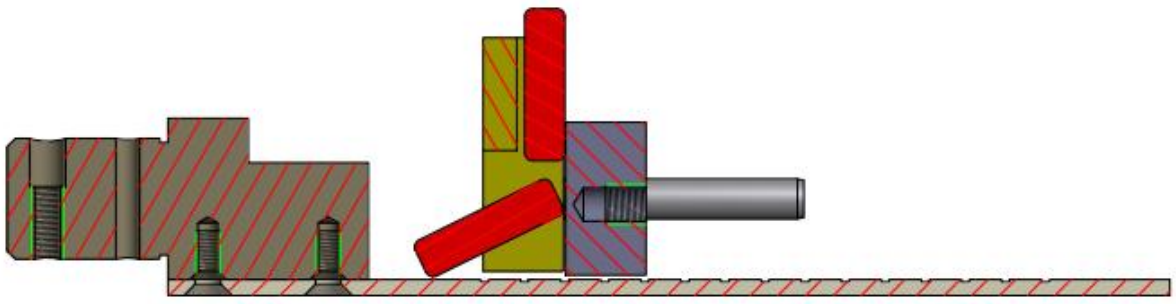


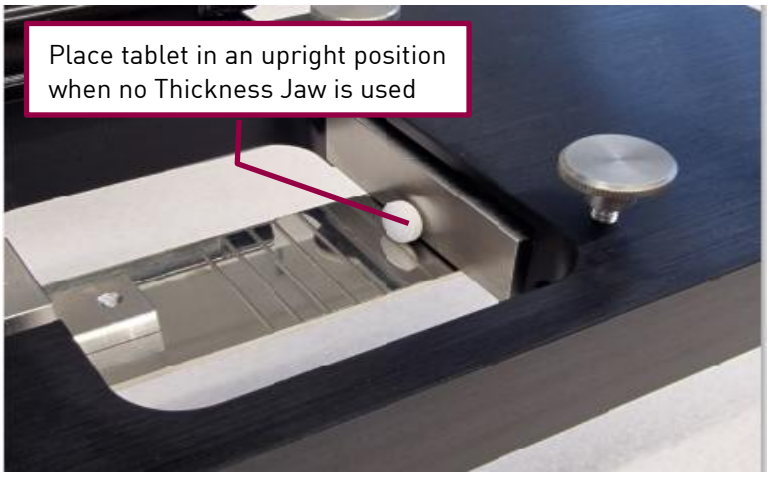
Figure 4: Position of an Oblong after Placing it in the Thickness Jaw

The sample holder is inserted in a way to keep the tablet in a vertical position during the thickness measurement. The space between jaw and sample should be approximately 1-2 mm; if this distance is too small, the sample will not be able to turn into horizontal position to allow diameter and hardness testing.

To test the thickness of tablets with different sizes we supply interchangeable thickness jaws. Whenever you change a sample holder set, it is advisable to check the instrument operation prior starting another test sequence.

Section 2.1.2 Appendix to the Thickness Jaw

If you do not want to measure the thickness of the sample, then you do not need to use the sample holder. The force jaw has to be higher than the tablet height in order to be in compliance with the current EP/USP monographs.



Each Thickness Jaw set is made up of 2 parts: the Thickness Jaw which keeps the tablet in a vertical position and the pressure jaw which is used to contact and then to apply force to the sample to measure the thickness, diameter and hardness. The Thickness Jaw is retained by 2 knurled screws while the force jaw is held in place using a push fit assembly with a locating pin.

Figure 5: PTB 311E/311E-500/311E-800 Tablet orientation for Thickness measurement

Depending on the size of the tablet it also may be possible to place the tablet into a vertical position without using the sample holder. After the thickness has been measured, you would need to turn the tablet manually into the horizontal position for further testing.

Section 2.2 Tension Strength Test of Oblongs and Caplets

A special sample holder and force jaw set is available to test the tension strength of oblongs or caplets. This tool set will allow the break force to be concentrated in the middle of the sample (generally along a score line). After the test, both pieces can be weighed to verify that the weight of both pieces is equal. Four sizes of sample holder are available:

12 - 16 mm (part no. 29-28550)	16 - 19 mm (part no. 29-28552)
19 - 24 mm (part no. 29-28555)	24 - 28mm (part no. 29-28553)

Table 8: Different Tension Strength Set

It is also possible to create an individual holder when sending samples to Pharma Test. To install the tension strength jaw set you need to remove the standard force jaw and the force receipt plate:

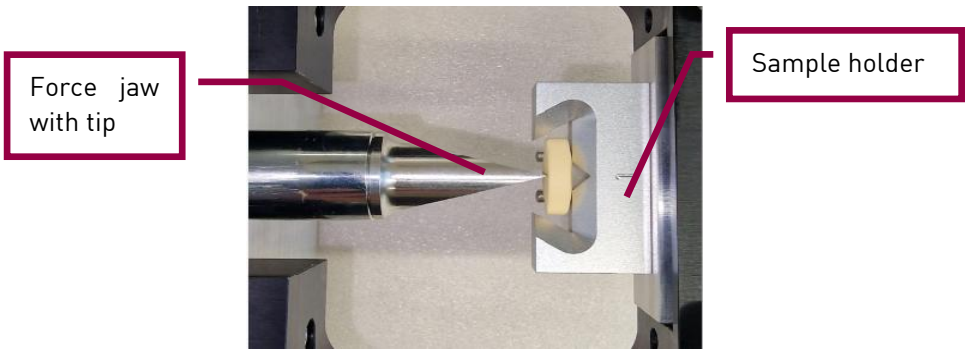


Figure 6: Oblong Tension Strength Test Set

Adjust the sample holder to align the sample in the center of the force jaw.

Section 2.3 PTB32 Software

Note: the PTB32 Software is no longer supported by this firmware version.

For electronic data capturing there´s only the possibility of serial output in Mettler Freeweigh format, breaking curve data in csv-format or the possibility to record the results with the PT Node.

Section 3.0 Installation of the Instrument

The supplied mains (line) cord has to be connected to the mains supply socket in your laboratory and the mains cable socket of the instrument. Prior to any cable connection, the instrument must be switched off.

PLEASE MAKE SURE THAT THE INDICATED VOLTAGE OF THE INSTRUMENT SHOWN ON THE SERIAL NUMBER PLATE IS THE SAME AS AVAILABLE IN YOUR LABORATORY.

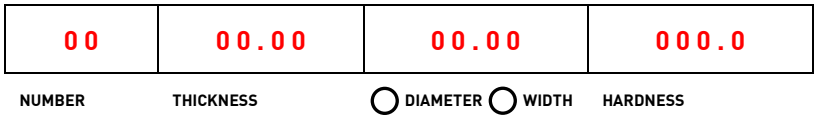
Figure 7: PTB 311E/ 311E-500/ 311E-800 Rear Side

Any cable connection must be done while the instruments are switched off, otherwise damage may occur.

Connect a suitable printer to the port labeled "Printer" on the PTB 311E/ 311E-500/ 311E-800 instrument using a standard printer cable 25 pin D-Sub to Centronix plug (part no. 34-01138). In case using an Epson TM-U220B ticket printer it must be connected to the RS232-port via the "PTB x11 – Epson TM-U220 serial ticket printer" cable (ordering number 34-00312).

On the combined mains socket on the rear side of the instrument, you will find the mains connection and switch to turn on the PTB 311E/ 311E-500/ 311E-800 instrument. As soon as you switch on the instrument, the LED display lights up and the instruments self-check is performed, showing the model and the firmware version. You can abort this test by pressing <STOP>.

As soon as the instrument is ready the 4 LED displays light up and each show < 0 0 0 0 >



In case the display does not light up, check the mains connection and mains fuse (also refer to section 10 – Troubleshooting.

Section 3.1 Set-up and Qualification (IQ)

Refer to the actual IQ-document for PTB311, provided by Pharma Test. The PDF-file is present on the USB flash drive in the instrument folder.

Section 3.2 Warranty Document

The warranty document (yellow!) is present in duplicate in the instrument folder, provided with the instrument. Please fill it manually and send the "COPY" to

Pharma Test Apparatebau AG

Siemenstrasse 5

D-63512 Hainburg

Germany

There are two years of warranty for material- and quality issues from the date of the first IQ/OQ.

Section 3.3 Operation Qualification (OQ)

Refer to the actual OQ-document for PTB311, provided by Pharma test. The PDF-file is present on the USB flash drive in the instrument folder.

Section 4.0 Using the Instrument

Use the keyboard to enter the nominal values for the test stations (thickness, width, diameter and hardness) to activate the station. Nominal value of "0000" means: the respective test station is deactivated. Nominal value of ">0" means: the respective test station is activated,

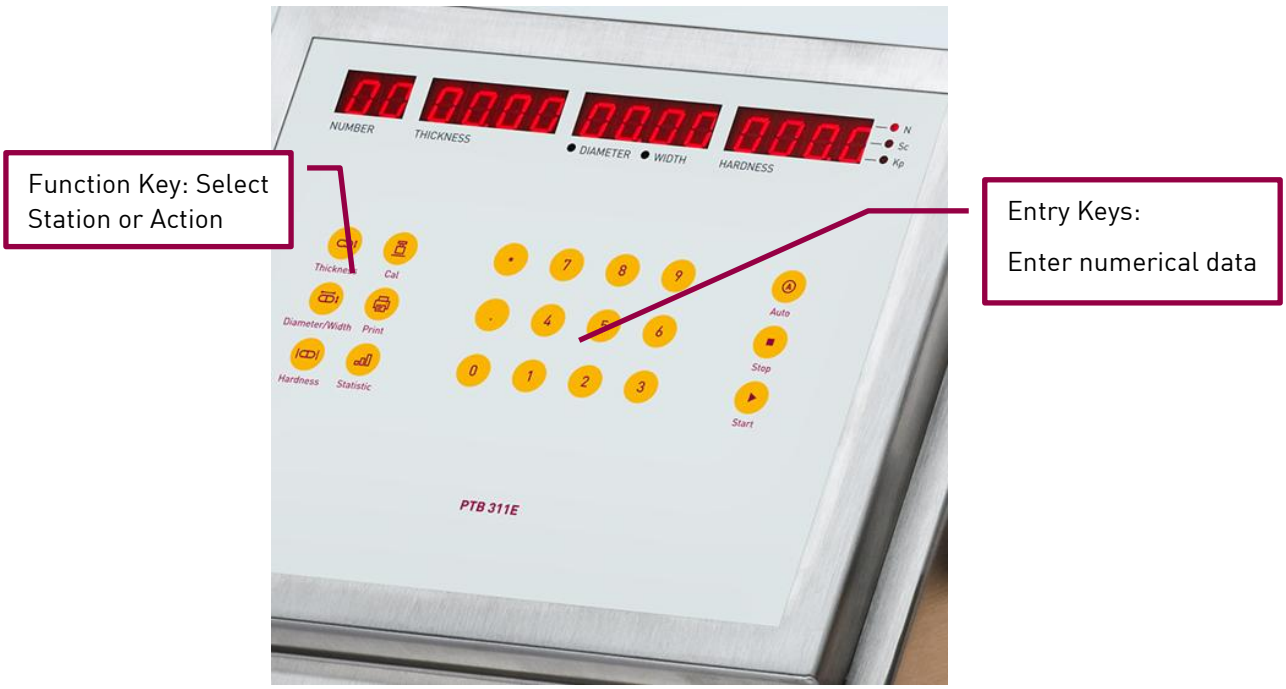


Figure 8: PTB 311E/ 311E-500/ 311E-800 Keyboard

Section 4.1 Example of how to enter Nominal Values and activate the stations

1.Activate Thickness Test	Press the key:	**<Thickness>**
	Enter value, e.g. 3.00 mm:	**<0> + <3> + <0> + <0>**
	Press the key to confirm:	**<*>**
2.Activate Diameter Test	Press the key:	**<Diameter / Width>**
	The red LED shines for the Diameter below the number screen	
	Enter value, e.g. 10.00 mm:	**<1> + <0> + <0> + <0>**
	Press the key to confirm:	**<*>**
3.Activate Width Test	Press the key:	**<Diameter / Width>**
	The red LED shines for the Width below the number screen	
	Enter value, e.g. 10.00 mm:	**<1> + <0> + <0> + <0>**
	Press the key to confirm:	**<*>**
4.Activate Hardness Test	Press the key:	**<Hardness>**
	Enter value, e.g. 100.0N:	**<1> + <0> + <0> + <0>**
	Press the key to confirm:	**<*>**

Table 9: Entering nominal values for a test

All four stations are now activated. At first, the thickness will be measured so make sure the sample is upright within the Thickness Jaw. After this stage, the force jaw will move about 20 mm backwards and turn the sample into a horizontal position. For the width measurement rotate the tablet per hand so that the force jaw will measure the width of the tablet. Afterwards rotate the tablet back for the diameter (or length) and the hardness measurement. When the sample is broken, remove the debris from the support plate by using the supplied brush.

Section 4.2 Deactivate a Testing Station

Deactivate Thickness Station	Press the key:	**<Thickness>**
	Enter 00.00 mm:	**<0> + <0> + <0> + <0>**
	Press the key to confirm:	**<*>**

"no tArGEtS" will appear if none of the 4 stations has an entered, valid numerical value and all are left with the value of: "*0 0 0 0*". Activate at least 1 test station by entering a nominal size or hardness value.

Remember:

If you enter a zero nominal value "0 0 0 0" for the thickness, the station is not activated. It will not print any result. Only the diameter/ width and hardness is shown and printed (if activated). Also the nominal value you enter should be at least as large as the maximum sample size. If you enter a smaller value (smaller than the actual sample), maybe the plunger hits the sample during fast forward movement, the test will be aborted and an error message (>= E177) is shown on the display. If you are unsure of the dimensions then simply enter a larger value and use the first result to set the value for subsequent measurements.

Section 4.3 Start a Test

As soon as all data have been entered you may start the testing series.

Place the sample into the PTB 311E/ 311E-500 /311E-800 thickness test station. As soon as you have placed the sample correctly in the sample holder, start the test using the <**START**> key.

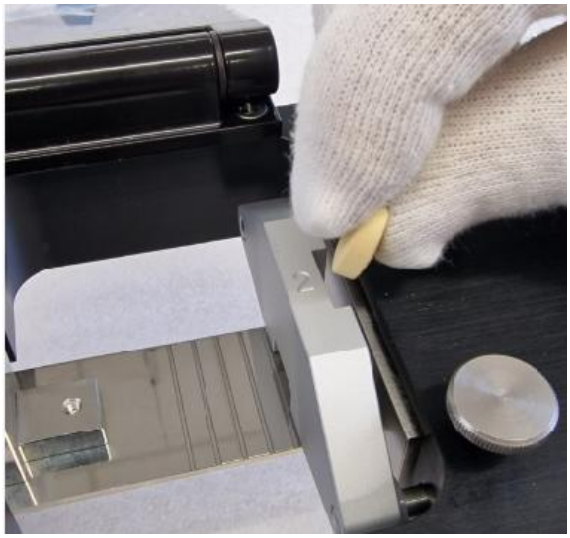


Figure 9: Insert tablet for thickness test

Section 4.4 Entering a Batch Number, Run a Test

After pressing <**START**> once, you are always asked for a Batch number. The batch number can´t be deactivated. It always appears on the printout. After switching on the instrument and pressing <**START**> for the first time, the PTB311E/311E-500/311E-800 shows:

bA	0000	0000	0000
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

This is the default batch number "*0000 0000 0000*". If you don´t enter another batch number, the following printout will show "Batch: 000000000000".

```
   Tablet Testing System PTB311-300
 V04.02E  Instrument Serial No. 029251
-----------------------------------------
Product :
Job     :
Method  :
Operator:
Batch   : 000000000000 Spd: 20.0 N/sec
Time    : 10:50:39  Date: 21.10.2022
Analy.ID: 00000003
Samples :        1    Type: Tablet
-----------------------------------------
        : Thick.: Width : Diam. : Hardn.
        :  (mm) :  (mm) :  (mm) :  (N)
Ref.V.  :       :       :       :  100.0
----------------Results----------------
```

Figure 10: Example printout (test report header) for batch number = 0000 0000 0000

You can enter an up-to-12 digit batch number before every test. If you enter e.g. <**156897**>, the display shows:

bA		15	6897
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

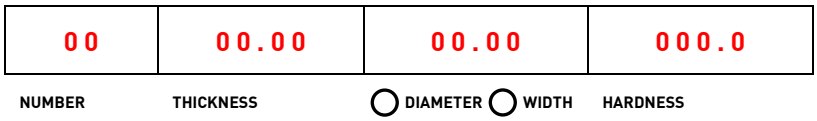
The printout will show:

```
   Tablet Testing System PTB311-300
 V04.02E  Instrument Serial No. 029251
-----------------------------------------
Product :
Job     :
Method  :
Operator:
Batch   :       156897 Spd: 20.0 N/sec
Time    : 10:54:10  Date: 21.10.2022
Analy.ID: 00000004
Samples :        1    Type: Tablet
-----------------------------------------
        : Thick.: Width : Diam. : Hardn.
        :  (mm) :  (mm) :  (mm) :  (N)
Ref.V.  :       :       :       :  100.0
----------------Results----------------
```

Figure 11: Example printout (test report header) for batch number = 15 6897

After entering the batch number, press <**START**> again. The batch number is accepted, and the instrument begins to test the sample immediately.

If you press <**STOP**> instead of <**START**>, the entered batch number is remembered anyway, but no test will be started. You will return to the Start-up display:



When pressing <**START**>, the test begins. In case the thickness station is active, the plunger starts immediately to measure the thickness.

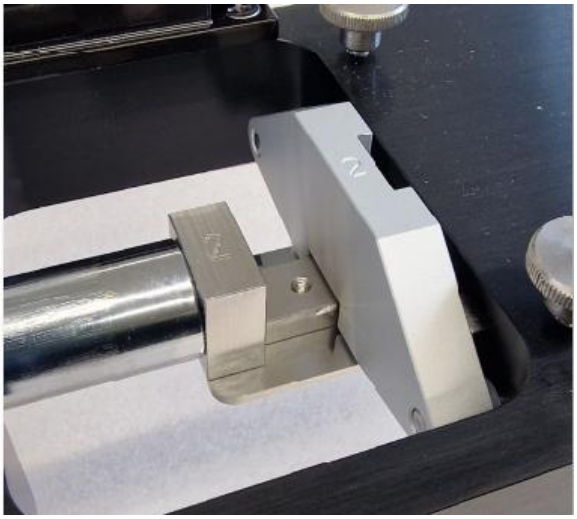
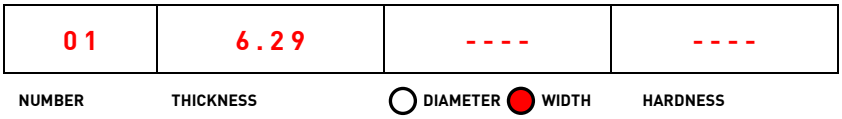


Figure 12: Plunger moves forward for thickness measurement

As soon as the tablet is detected, the plunger stops and the thickness will be recorded. The plunger moves 20mm...45mm (depending on the set width of the sample) backwards, pulling the tablet from its vertical orientation into a horizontal position.

In case the thickness station is inactive, or the thickness has already been measured, the LED for WIDTH is starting to blink,

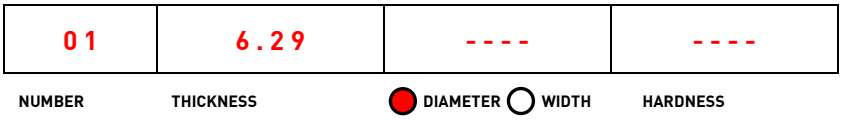


guiding the operator to place the sample into the measuring chamber, oriented for width measurement.

For the measurement of the width the tablet needs to be rotated by hand, so that the jaw will hit the long side of the tablet.

In manual mode (see section 4.7 for more information), the <**START**> button must be pushed once more.

When started again, the jaw will move towards the sample and touch it. The width will be recorded, and the plunger moves 20mm...45mm (depending on the set diameter of the sample) backwards to make clearance for the diameter / hardness measurement. The LED for DIAMETER is starting to blink,



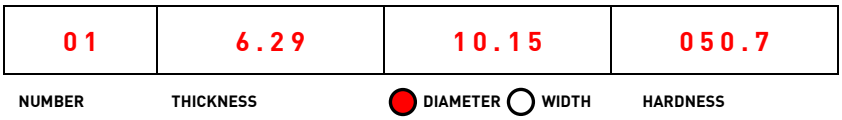
guiding the operator to place the sample into the measuring chamber, oriented for diameter / hardness measurement.

For diameter and hardness measurement the tablet must be rotated by hand, so that the plunger moves forward against the short side of the tablet.

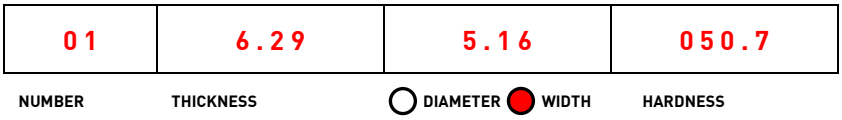
In manual mode (see section 4.7 for more information), the <**START**> button must be pushed once more to make the force piston moving forward again.

As soon as the PTB311E / 311E-500 / 311E-800 detects the tablet (diameter), it switches to the selected force increase mode and rate. The jaw applies force to the tablet until it breaks. When the sample is broken, the plunger returns into home position. After every break, the debris must be brushed into the waste drawer. This one should be emptied frequently.

The display now shows the results, e.g.:



--- alternating ---



For switching between the result of diameter and width the red LED below the display will automatically alternate between diameter (then the result shown is the diameter result) and the width (now the result for the width is shown).

Section 4.5 End a Test Series

A total of 250 tests per test series can be performed. Then sample statistics are automatically calculated, and the series is finished. Of course, you can stop a test series at any time. Simply press <**STOP**> twice. If a printer is connected to the instrument, a printout with the single test results followed by a test statistic will be printed. To reprint the total test report, simply press <**PRINT**>. To reprint the statistics only, press <**STATISTIC**>.

Make sure that the printout is done before you start another test series. With every new test start the previous results are automatically deleted and can´t be restored!

Remember: *A statistic will only be calculated if you have tested more than one sample. If you test only one sample and end the test by pressing <**STOP**>, you will receive only the single result, not a statistic.*

Section 4.6 Printout of Test Report

This test report shows a printout by an Epson TM-U220D ticket printer. The A4 printout looks comparable. You will find an A4 printout below for your reference. All further printouts in this manual are made by an Epson TM-U220D ticket printer.

Printout Test Report	Description of each point
Tablet Testing System PTB311-300 V04.02E Instrument Serial No. 000000	Instrument type Firmware version and Serial number
Product : Job : Method : Operator: Batch : 99999 Spd: 20.0 N/sec Time : 11:17:12 Date: 21.10.2022 Analy.ID: 00000006 Samples : 2 Type: Tablet	Space for user data (Product, Job, Method), Operator ID and comment Batch number and force mode Date & time of test begin Analysis-ID Sample Numbers, Type of Sample
: Thick.: Width : Diam. : Hardn. : (mm) : (mm) : (mm) : (N) Ref.V. : 5.00: 5.00: 10.00: 10.0	Nominal values
Results No. 1 : 6.29: 5.17: 10.47: 46.6 No. 2 : 5.82: 5.92: 10.50: 42.6	Single results
Statistics : Thick.: Width : Diam. : Hardn. : (mm) : (mm) : (mm) : (N) Xmax : 6.29: 5.92: 10.50: 46.6 Xmin : 5.82: 5.17: 10.47: 42.6 Xdif : 0.47: 0.75: 0.03: 4.0 Xmean : 6.06: 5.55: 10.49: 44.6 Xabs : 0.33: 0.53: 0.02: 2.8 Xm Abs. : 1.06: 0.55: 0.49: 34.6 : (%) : (%) : (%) : (%) Xrel : 5.45: 9.55: 0.19: 6.28 Xm Rel. : 21.20: 11.00: 4.90:>+99	Statistics: Maximum values Minimum values Difference between max and min Mean value Standard deviation single results in [N] Deviation Mean to Nominal value in [N] Standard deviation in [%] related to MV Deviation Mean to Nominal value in [%]
Operator: ---------- ---------- Released: ---------- ---------- Name/Signature Date / Time	Signature from operator Signature from supervisor
Printed: Time 11:55:07 Date 21.10.2022	Date & time of printout

Figure 13: Test Report printed with an Epson TM-U220D ticket printer

```
* Tablet Testing System PTB 311E-300 *      Ver. 04.02E  Page : 1/1
  Instrument Serial No: 000000
-----------------------------------------------------------------------
Product   :                      Date      : 21.10.2022
Batch     :         99999        Time      : 11:17:12
Analy.ID  :      00000006        Samples   :   2
Meth.Code:           none        Type      : Tablet
Method    :                      Operator  :
Job       :                      Comment   :
-----------------------------------------------------------------------
          : Thickness:  Width    : Diameter : Hardness : Setting
Ref.V.    :   5.00 mm:   5.00 mm:  10.00 mm:   10.0 N :  20.0 N/sec
-------------------------- Results ----------------------------------
 No.      : Thickness:  Width    : Diameter : Hardness
  1       :   6.29 mm:   5.17 mm:  10.47 mm:   46.6 N
  2       :   5.82 mm:   5.92 mm:  10.50 mm:   42.6 N
-----------------------------------------------------------------------
                    * S T A T I S T I C S *
-----------------------------------------------------------------------
Xmax      :   6.29 mm:   5.92 mm:  10.50 mm:   46.6 N
Xmin      :   5.82 mm:   5.17 mm:  10.47 mm:   42.6 N
Xdif      :   0.47 mm:   0.75 mm:   0.03 mm:    4.0 N
Xmean     :   6.06 mm:   5.55 mm:  10.49 mm:   44.6 N
Xabs      :   0.33 mm:   0.53 mm:   0.02 mm:    2.8 N
Xm Abs.   :   1.06 mm:   0.55 mm:   0.49 mm:   34.6 N
Xrel      :   5.45 % :   9.55 % :   0.19 % :   6.28 %
Xm Rel.   :  21.20 % :  11.00 % :   4.90 % :>+99.99 %

-----------------------------------------------------------------------

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

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

-----------------------------------------------------------------------
Printed:     Time 12:04:35  Date 21.10.2022
```

Figure 14: A4 printout of a Test Report

For explanation of the entries, see Figure 13.

Section 4.7 Automated Re-Start Mode

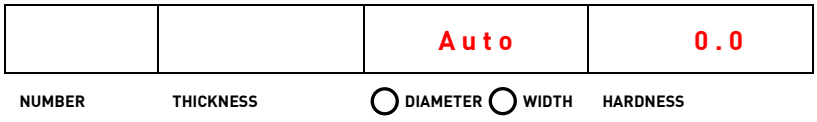
This feature allows the operator to perform consecutive tests without having to push <**START**> repeatedly. To enable automated re-start for the next test, enter a re-start time delay. You can enter any re-start time in the range from 0.1 to 100.0 seconds.

This function expects a connected printer. If no printer is connected, there will be a time delay of about 10 seconds until the first test run starts. In this time the instrument tries to establish a printer communication.

Example of Entering a Re-Start Time Delay

In this example a re-start time delay of 2 seconds is set.

On the main menu press < Ⓐ > to enter the re-start time delay menu:



		Auto	0.0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

Press <2> + <0> to set 2 seconds re-start time delay.

	Auto		2.0

Press <*> (STAR) to confirm the entry.

The auto re-start mode is now active. It´s indicated by a DOT in the lower right corner of the left display:

00.	00.00	00.00	000.0

Place the first sample in the testing station and press <START> twice. The respective next measurement station will be started automatically after the set time (here: 2 seconds) has elapsed. After the test sequence is completed, the jaw will return to its park position and then wait for the set time (here: 2 seconds). The next test will then start automatically. Make sure that by then the subsequent samples are correctly placed in the test station. With <AUTO> + <0> + <1> + <*> the instrument restarts as fast as it can.

To deactivate the automated re-start function, simply press <AUTO> once or set a restart time of 0.0s. The DOT disappears.

Remember: *If the automated re-start mode is inactive (no DOT in the left display!), the operator needs to push <**START**> again and again for every new Width- and Diameter/Hardness-Measurement as well as for every new sample in the test chamber.*

Section 4.8 Pause a Test Series

Press <**STOP**> once to pause a test. You should do this only in the moment after a current test is finished and the results are displayed. Otherwise, your current test run will be aborted, the plunger moves back into home position and the (unfinished) results of this sample are discarded. Press <**START**> again to proceed with the test series.

Section 4.9 Auto Learning Function

If there is a nominal Hardness but no nominal Diameter entered (Hardness activated, Diameter deactivated), the movable jaw will drive forward slowly until it touches the sample to be tested and then proceeds to break it. A second test with the same sample diameter will be faster, because now the system knows the expected sample diameter and the movable jaw moves much faster until it expects the sample.

An error >= *177* will appear if the current sample is bigger than the previous one. Then the movable jaw will again drive slowly to learn the new sample diameter.

Section 5.0 Changing Operation Parameters

With Firmware 4.00 and higher, all instrument settings except the "normal" test entries are password protected. The following settings are only adjustable when logged in as Super User. If not, "no Acc" will be displayed (= "no access")!

Section 5.1 Login

To change the standard operation parameters described in this section, the Super User must login.

Press <**CAL**> + <**0**> + <**1**>. The Display shows:

U	PASS	____	____
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

By default the password is "0 0 0 0 0 0 0 0".

Enter the Super User password. With Entry of the 8th digit, the instrument shows:

U	PASS	EnA	
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

It means: the password has been accepted and the Super User permission is enabled now.

From now on all settings, marked with an **(X)** in the column permissions in section 8.0 are unlocked.

After installation of the instrument, of course the Super User password must be changed to an individual one. Press <**CAL**> + <**0**> + <**2**>. The instrument shows:

CP	PASS	____	____
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

C P = confirm password.

Here the "old password" must be entered. (<**0 0 0 0 0 0 0 0**> by factory default). The display changes to:

E1	PASS	____	____

E 1 = enter password.

Enter a new 8-digit numerical password. The display changes to:

E2	PASS	____	____

E 2 = enter password again.

Repeat the new 8-digit numerical password to confirm it. The display changes to:

E2	PASS	SEt	____

It means: the new password has been accepted.

Remember 1: *There is an even higher permission level available: the Factory User. The key code for login is <**CAL**> + <**0**> + <**0**>. The factory password is alternating and must always be requested anew by sending an alternating 8-digit code to the Pharma Test company. This permission is only necessary for extended service and only shared by demand, together with instructions how to enter the release code.*

Remember 2: *Remember the Super User password well. If the Super User password has been forgotten, press <**CAL**> + <**0**> + <**3**> and tell the shown 8-digit number to the Pharma Test company. Don´t change the display or turn off the instrument, because the number will be different when accessing this menu again. You will receive another 8-digit number which sets the Super User password to <0 0 0 0 0 0 0 0> again. After this, store a new individual password.*

Remember 3: *There is no explicit "Logout"-function. To logout from the Super User permissions (and even from the Factory User permissions), switch off the instrument by the mains switch at the backside and switch it on again. After restart, the standard operator permissions are active again.*

Section 5.2 Changing Units

Section 5.2.1 Changing Hardness unit

You can select between three units Newton [N], Strong Cobb [Sc] and Kilopond [kP]. If you change the unit, your nominal hardness value will always be set to "0" and must be entered anew. It is not possible to get current results printed in different units: after a test series has finished and afterwards the unit has changed, a reprint by pressing <**PRINT**> will remain to the unit the test has been performed with.

The selected unit is shown by the LED right beside the HARDNESS display:

00	00.00	00.00	000.0

N
Sc
Kp

LED "N" is illuminated: the selected unit is "Newton".

Login as Super User. Press <CAL> + <2> + <0>. The display shows:

CA	L 20		Unit

N
Sc
Kp

Press DOT <.>. The hardness changes to Strong Cobb:

CA	L 20		Unit

N
Sc
Kp

Press DOT <.>. The hardness changes to Kilopond:

CA	L 20		Unit

N
Sc
Kp

Press DOT <.>. The hardness changes to Newton again (and so on!):

CA	L 20		Unit

N
Sc
Kp

When the correct unit it selected. Press <*> to confirm. The display returns to the initial screen (all "0"), the selected hardness unit remains.

Now, with pressing <**HARDNESS**>, you can enter a new nominal value (e.g. <**0**> + <**2**> + <**0**> + <**0**> for 20.0[unit]). Press <*****> (STAR) to confirm the entry. The display returns to the initial screen (all "0"). Simply press <**HARDNESS**> and watch the display to check your current nominal value. Leave the display either with <*****> (STAR) or <**STOP**>.

Section 5.2.2 Change Thickness, Width and Diameter unit

You can change between two units Millimetre [mm] and Inches [in]. If you change the unit, your nominal length values will always be set to "0" and must be entered anew. It is not possible to get current results printed in different units: after a test series has finished and afterwards the unit has changed, a reprint by pressing <**PRINT**> will remain to the unit the test has been performed with.

Format "0 0 . 0 0" (two decimals) means, [mm] is selected. In the printout the unit [mm] appears.

0 0	0 0 . 0 0	0 0 . 0 0	0 0 0 . 0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

Login as Super User. Press <**CAL**> + <**2**> + <**1**>. The display changes to:

C A	0 0 . 0 0	0 0 . 0 0	n n

Press DOT <**.**>. The length unit changes to [Inch] (3 decimals):

C A	0 . 0 0 0	0 . 0 0 0	I n c h

Press DOT <**.**>. The length unit changes to [mm] again (and so on!):

C A	0 0 . 0 0	0 0 . 0 0	n n

When the correct unit it selected, press <*> to confirm. The display returns to the initial screen (all "0"), the selected hardness unit remains.

Now, with pressing <**THICKNESS**> or <**DIAMETER / WIDTH**>, you can enter a new nominal value (e.g. <**0**> + <**2**> + <**0**> + <**0**> for 2.00[mm] respective 0.200[in]). Press <***> (STAR) to confirm the entry. The display returns to the initial screen (all "0"). Simply press <**THICKNESS**> or <**DIAMETER / WIDTH**> again and watch the display to check your current nominal value. Leave the display either with <***> (STAR) or <**STOP**>.

Section 5.3 Select the Mode of Operation and the supplied Force Rate

Two different force testing modes (linear force increase or constant speed increase) are selectable in order to meet current and any future monograph (compendial) requirements. At present, none of the pharmacopoeias describe a specified mode or rate of operation. Comparative tests using different instruments and different hardness settings have led to different results. If you ever find such differences arising from the use of two different instrument types, it is always a good point to first check which force setting or jaw speeds are used; they need to be the same.

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 a linear force increase rate of **20 N/s**. This way the load cell adjusts the stepper drive motor to increase the force onto the sample by 20 N every second. This is a very precise instrument control feature. Validation is also quite easy. All you need is a stopwatch and a tablet. Start the stopwatch when 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 more or less equal to your stopped time. (read also "please note" in Section 7.15)

It is also possible to print a graph of the applied force (see section 7.15 force increase curve).

To change the force mode, login as Super user and press <**CAL**> + <**2**> + <**2**>. The display changes to:

C A	L 2 2	dFo	2 0 . 0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

dFo means: the actual force mode is "linear force increase". The actual rate is 20N/s.

Press DOT <**.**>. Your force mode changes to:

C A	L 2 2	cSP	1 0 . 0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

cSP means: the actual force mode is "constant speed". The actual rate is 10mm/min.

If the rate is correct already, simply confirm the selected force mode with <*> (STAR).

To change the rate:

First select the wished force mode as described above. After selection, press <**START**>.

Now enter e.g. <**1**> + <**5**> + <**0**> for 15.0 [unit] and confirm with <*****> (STAR).

To check the current setting, also just press <**CAL**> + <**2**> + <**2**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

Section 5.4 Set Touch Force

The touch force is a setting which indicates the force applied to the load cell by the sample. As soon as the load cell measures the set touch force, it switches from "tablet search mode" into "break mode". The factory setting for PTB311E is appr. 7N, for PTB311E-500 appr. 14N and for PTB311E-800 appr. 10N. As soon as this force is applied, the electronics will switch automatically into the selected force mode and rate so as to break the sample.

Testing different samples may require you to change this setting.

Login as Super User. Press <**CAL**> + <**2**> + <**3**>. The display changes to:

C A	L 2 3	t F =	5 . 0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

Now press <**START**> and enter a different touch force. Press e.g. <**1**> + <**0**> + <**0**> for 10.0N.

The input range is 2.0N ... 100.0N. Confirm the entry with <*****> (STAR). The display returns to initial screen (all "0").

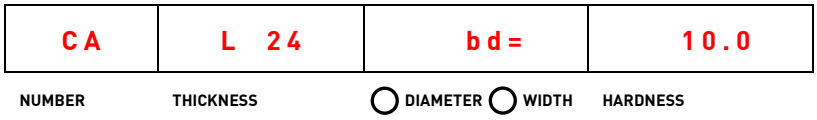
To check the current setting, also just press <**CAL**> + <**2**> + <**3**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

Section 5.5 Set Break Force

The hardness or break point of a sample is detected by the electronics when the load cell registers a lower reading after the previous one. This usually means that the sample is broken. The factory setting for PTB311E is appr. 14N, for PTB311E-500 appr. 26N and for PTB311E-800 appr. 18N. **This is the minimum force drop which must appear to detect a sample as broken!**, The settings above are usually a proper value for a reliable detection. To increase or decrease the sensitivity of the detection, you can change the factory setting. *A lower setting leads to break detections at lower force drops. It may be necessary with soft samples, but there´s a risk that a break is detected too early, for example if a sugar-coated tablet just cracks. A higher setting may be necessary to sort out force drops which are not the final break, for example if sugar-coated tablets crack before they finally break, but there´s a risk that a break isn´t detected at all anymore and the sample becomes crushed completely until the instrument aborts with maximum force.*

Testing different samples may require the operator to change this setting.

Login as Super User. Press <**CAL**> + <**2**> + <**4**>. The display changes to:



Now press <**START**> and enter a different Break Detection. Press e.g., <**2**> + <**0**> + <**0**> for 20.0N.

The input range is 2.0N...100.0N. Confirm the entry with <*****>. The display returns to initial screen (all "0").

To check the current setting, also just press <**CAL**> + <**2**> + <**4**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

Section 5.6 Set Fault Force

This setting is implemented for speed-up reasons, but it affects the operator's safety!

During automated Re-Start Mode (see section 4.7), the force piston starts moving automatically. In case the restart time is short and the piston already started moving towards the tablet although the operator still aligns the tablet in the breaking chamber, the fault force prevents the abortion of the test in case that the operator touches the load cell by mistake during the alignment of the tablet.

This setting is a high pass filter for forces, applied to the load cell during fast forward of the force piston. Forces up to this setting do not lead to an abortion. Only forces above this setting lead to an abortion. This way the instrument becomes less sensitive for unwanted abortions.

The default setting is 25N. To change the setting,

login as Super User and press <**CAL**> + <**2**> + <**5**>. The display changes to:

CA	L 25	FF=	25.0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

Now press <**START**> and enter a different Fault Force. Press e.g., <**5**> + <**0**> + <**0**> for 50.0N.

The input range is 20.0N ... 100.0N. Confirm the entry with <*****>. The display returns to initial screen (all "0").

To check the current setting, also just press <**CAL**> + <**2**> + <**5**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

Be aware: The factory setting of 25N is comparable with a 2.5 kg weight which is slowly put onto your finger, which could also hurt a bit. When rising this setting to e.g. 100N, it is comparable with a 10kg weight put onto your finger. In combination with a sharp edge, it can already lead to a slight injury!

Section 5.7 Set Test Objective and Test Distance

Section 5.7.1 Tablet mode (breaking)

Often, samples become compressed before they break. Usually, they should break within a compression of 2mm, but depending to the size, hardness, and material it is maybe necessary to increase the total way from detection until break from the standard setting of 2 mm.

"*ERR 136*" in mode "constant speed" respective "*ERR 147*" in mode "linear force increase" will appear if there was not a significantly lower signal (broken tablet) recorded within the adjusted range of 2 mm. If this is the case, try a larger range value (the valid range is from 1 to 10 mm, 2 mm is the factory default setting).

Remember:

If the instrument doesn´t detect a break, it´s always a combination of the set break detection force (section 5.5), the force mode (section 5.3) and the distance setting for the break detection (section 5.7.1). So just enlarging your break detection distance maybe doesn´t improve the detection. Make sure there is indeed a significant force decrease during the break of the sample with the selected force mode and set the break detection force accordingly. Only if this doesn´t help, enlarge the break distance.

Login as Super User. Press <**CAL**> + <**2**> + <**6**>. The display will show:

CA	L 26	2.00	tAb
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

In case it shows "C A P" in the right field, just push DOT <.> to switch to "t A b".

Now press <**START**> and enter a different Test Distance. Press e.g., <**3**> + <**0**> + <**0**> for 3.00mm.

The input range is 1.00mm ... 10.00mm. Confirm the entry with <*****>. The display returns to initial screen (all "0").

To check the current setting, also just press <**CAL**> + <**2**> + <**6**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

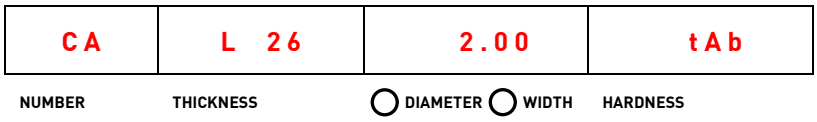
Section 5.7.2 Capsule mode (without breaking)

When testing the hardness of soft gel capsules, they usually should not break (burst) to avoid pollution of the instrument. For this the PTB311(-500 / -800) has a special function for just deform the sample without breaking: the capsule mode.

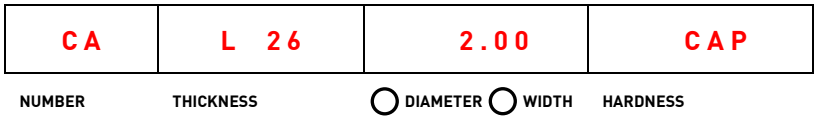
When this feature is active, the control electronics will record the maximum force reading from the load cell over the total movement range (distance) you entered. Within this range a lower force reading doesn´t stop the piston movement as while using the "breaking mode" (Section 5.7.1)

In case of testing soft samples (e.g., capsules) without breaking, the sample will be deformed over a decided distance and the maximum hardness is recorded. After driving the set distance, the force jaw returns to home position.

To select the capsule mode, login as Super User. Press <**CAL**> + <**2**> + <**6**>. The display changes to:



Press DOT <.>. The mode changes to [capsule]:



If the distance is correctly set already (in this example: 2.00mm), simply confirm the selected compression mode with <*> (STAR).

To change the distance:

First select the wished mode as described above. After selection, press <**START**>.

Now enter e.g. <**1**> + <**5**> + <**0**> for 1.50mm and confirm with <*****> (STAR).

The display returns to initial screen (all "0").

To check the current setting, also just press <**CAL**> + <**2**> + <**6**>. Leave the display by pressing <*> (STAR) or <**STOP**>.

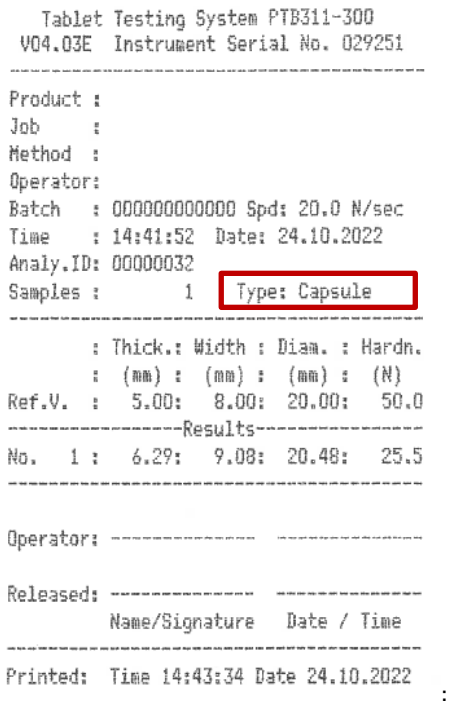
The capsule mode works as follows:

The force piston moves forwards and detects the sample as usual. From the touch position it now moves forwards for the set distance. For this it uses the set force mode and rate. During the forward movement it records the force. After the distance is reached, the movement stops, and the piston returns to home position. The maximum force, recorded during the distance movement is used as hardness value.

Remember:

If the resistance of the capsule rises first and begins to decrease later during deforming, the maximum force will be issued anyway. But if the resistance decreases more than the set "break detection" (Section 5.5) , the sample will be declared as "broken" and an error ("E 254") appears.

The printout will show a mark that this hardness test was done without breaking the sample.



```
   Tablet Testing System PTB311-300
 V04.03E  Instrument Serial No. 029251
-----------------------------------------
Product :
Job     :
Method  :
Operator:
Batch   : 000000000000 Spd: 20.0 N/sec
Time    : 14:41:52  Date: 24.10.2022
Analy.ID: 00000032
Samples :        1    Type: Capsule
-----------------------------------------
        : Thick.: Width : Diam. : Hardn.
        :  (mm) :  (mm) :  (mm) :  (N)
Ref.V.  :   5.00:   8.00:  20.00:   50.0
-----------------Results-----------------
No.   1 :   6.29:   9.08:  20.48:   25.5
-----------------------------------------

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

Released: --------------  --------------
          Name/Signature   Date / Time
-----------------------------------------
Printed:  Time 14:43:34 Date 24.10.2022
```

Figure 15: Test Report mark for Capsule Test

Section 5.8 Use Method Code input -Method definition and identification by a code

Firmware 04.03 allows to select the testing stations by a 4-digit code.

The 4-digit code will be transmitted with the serial result data to assign the results to the relevant method. Those methods must be defined in the customers LIMS system (see "Example" below).

To use this feature, it must be activated:

Login as Super User. Press <**CAL**> + <**2**> + <**7**>. The display will show:

CA	L 27	no	codE
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

Push <.> (dot). The display changes to:

CA	L 27	USE	codE

Push <*> (star) to confirm. The display returns to the initial screen (all "0").

To deactivate this feature, change the setting to "no code" again and the instrument can be used as usual.

When now pushing <**START**>, the display asks you to enter a code.

The first 2 digits define which testing stations are used for this test. The last 2 digits are a subsequent number in a range of 0 ... 99 to differ up to 100 different methods for every combination of testing stations.

The relation of code to testing stations is as follows:

Höhe/Thickness	Durchmesser/Diameter	Breite/Width	Härte/Hardness	Code
•	•	•	•	00
•	•	×	•	10
×	•	•	•	20
×	•	×	•	30
•	×	×	•	40
×	×	×	•	50
•	×	×	×	60
×	•	×	×	70
×	•	•	×	80
•	•	×	×	90
•	•	•	×	11

Figure 16: relation matrix "method code" to "testing station"

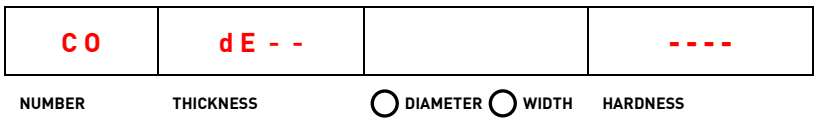
Legend:

• = testing station is active

× = testing station is inactive

Example:

By pushing <START>, the display shows:



Now, for example, you enter the Code <4> + <0> + <0> + <1>.

Explanation: the first two digits "4 0" tell the instrument that the following test will contain only "Thickness"- and "Hardness"-measurement.

It is not possible to enter a nominal value anymore. The instrument will search the respective first dimension automatically by "slow search mode" and then use this dimension as reference driveway for the ongoing tests (identical to Section 4.9 – Auto Learning Function).

When using the "method code input", the statistics calculation and evaluation is done by the LIMS-system. This means, that all nominal values must be present in the customers LIMS system. These values are not relevant for the PTB311 device, which only outputs the results.

Pushing <START> after entering the 4-digit code leads to the input of the batch number. From there the PTB311 instrument works as usual.

To assign the results to the correct method in the LIMS-system, the other two digits are used (here "0 1"). This is just a number; it could also be "9 9" or something in between.

This information is relevant for the LIMS system as it thereby knows:

> "4 0 0 1" means "thickness-" and "hardness-" values will arrive and the nominal values are (for example): thickness = 5.00mm, hardness = 100.0N

The result strings are transmitted via the serial interface port by selection of the "Ser FrEE" function (see section 6.5 for more information) and looks as follows:

```
PTB311E-500 -SN029251-C4001-B        6985-A00000068-DT2024.07.08 09:14:33 -Start
PTB311E-500 -SN029251-C4001-B        6985-A00000068Sample T 001;05.51mm
PTB311E-500 -SN029251-C4001-B        6985-A00000068Sample H 001;109.3N
PTB311E-500 -SN029251-C4001-B        6985-A00000068Sample T 002;05.32mm
PTB311E-500 -SN029251-C4001-B        6985-A00000068Sample H 002;109.1N
And so on…
```

Figure 17: Serial output with Method code

The first line shows:

Instrument type – Serial number – Method code – Batch Number – Analysis ID - "Start"-string to identify a new test run.

The following lines show:

Instrument type – Serial number – Method code – Batch Number – AnalysisID – 1st thickness result

Instrument type – Serial number – Method code – Batch Number – AnalysisID – 1st hardness result

Instrument type – Serial number – Method code – Batch Number – AnalysisID – 2nd thickness result

Instrument type – Serial number – Method code – Batch Number – AnalysisID – 2nd hardness result

And so on…

Because the method code is content of every result string, the results can be assigned to the respective method (in this case method "4001"). With the respective nominal values, stored with this method in the LIMS system, the statistics can be calculated individually.

Section 6.0 General Settings

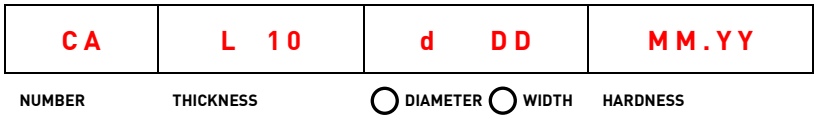
With Firmware 4.00 and higher, all instrument settings except the "normal" test entries are password protected. The following settings are only adjustable when logged in as Super User. If not, "no Acc" will be displayed (= "no access")!

Section 6.1 Login as Superuser to change General Settings

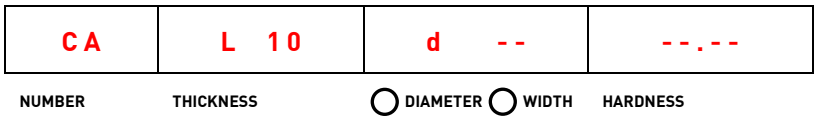
Refer to section 5.1 for information about the Superuser-login.

Section 6.2 Show and Set Date

Login as Super User. Press <**CAL**> + <**1**> + <**0**>. The display will show:



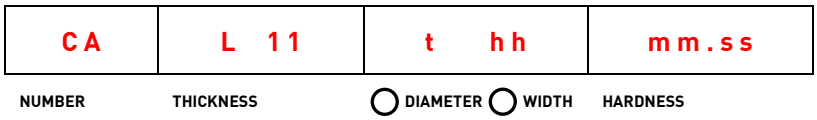
Press <**START**>. The display changes to:



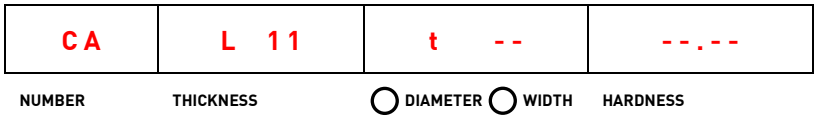
Now enter the actual date in the format <**DDMMYY**> and confirm with <*****>. The date will be accepted and the instrument returns to initial screen (all "0").

Section 6.3 Show and Set Time

Login as Super User. Press <**CAL**> + <**1**> + <**1**>. The display will show:



Press <**START**>. The display changes to:



Now enter the actual date in the format <**hhmmss**> and confirm with <*****>. The time will be accepted and the instrument returns to initial screen (all "0").

Section 6.4 Show and Set Calibration Interval

Login as Super User. Press <**CAL**> + <**1**> + <**2**>. The display will show:

CA	L 12	Ci	06
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

The number "0 6" means here that the current calibration interval is set to 6 months. The available intervals are (**in month**!): "OFF" – "1" – "3" – "6" – "12" – "24" – "OFF". You can toggle between the intervals by pressing the <**.**> (DOT) button.

With pushing <***>** (STAR), you set the selected calibration interval from now on. If "OFF" is selected, you will return to the initial screen (all "0") after a few seconds. If an interval is selected, the display shows the calibration elapse date:

For example:

CA	L 12	Ci 15	05.23
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

This display means the calibration is expired in May, the 15th 2023.

After a few seconds the display returns to initial screen (all "0").

As soon as the calibration interval is expired, the PTB311E/311E-500 /311E-800 shows "CAL Int dUE" after startup and a mark on every printout appears. <u>The instrument is still fully usable,</u> but you are remembered to perform a calibration and to restart the calibration interval (<**CAL**> + <**1**> + <**2**> + <***>**).

Printout Test Report

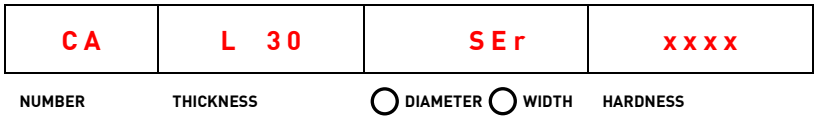
```
   Tablet Testing System PTB311-300
 V04.03E  Instrument Serial No. 029251
-----------------------------------------
Product :
Job     :
Method  :
Operator:
Batch   : 000000000000 Spd: 20.0 N/sec
Time    : 13:13:11  Date: 16.05.2023
Analy.ID: 00000043
Samples :      1    Type: Tablet
-----------------------------------------

        : Thick.: Width : Diam. : Hardn.
        :  (mm) :  (mm) :  (mm) :  (N)
Ref.V.  :       :       : 10.00:  100.0
----------------Results----------------
No.   1 :       :       : 10.65:  105.6
-----------------------------------------

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

Released: --------------  --------------
          Name/Signature   Date / Time
Calibration Due!
-----------------------------------------
Printed:  Time 13:14:09 Date 16.05.2023
```

Mark if calibration interval is expired

Figure 18: Test Report mark for calibration interval expired

Section 6.5 Select the serial output

Login as Super User. Press <**CAL**> + <**3**> + <**0**>. The display will show:



x x x x: Choose between 4 different serial outputs:

- none
- Cdat (CSV Curve Data)
- bonP (Bon Printer)
- FrEE (FreeWeigh Serial Data output)

None: no data will be transmitted via the serial interface

Cdat: only for service- or expert purposes. Here the force readings during the record of a break curve will be transmitted.

bonP: the preferred printout mode by use of the Epson TM-U220B ticket printer. You need the Pharma Test serial interface cable 34-00312 (PTB x11 Epson TM-U220B printer cable) to connect the printer.

Please note: if "bonP" and "parallel printout" (see also Section 6.6) are active simultaneously, only the ticket printer (serial printout) is served!

FrEE: Serial data output.

FrEE is the standard output to be captured by an external LIMS system.

The (constant) serial parameters are: **2400 bit/s, 7 data bits, even parity, 1 stop bit, no handshake.**

Depending whether "Method code input" is activated or deactivated (see section 5.8 for more information), the output format is either:

```
PTB311E-500 -SN029251-C0077-B        6985-A00000068-DT2024.07.08 09:14:33 -Start
PTB311E-500 -SN029251-C0077-B        6985-A00000068Sample T 001;05.51mm
PTB311E-500 -SN029251-C0077-B        6985-A00000068Sample W 001;06.02mm
PTB311E-500 -SN029251-C0077-B        6985-A00000068Sample D 001;10.93mm
PTB311E-500 -SN029251-C0077-B        6985-A00000068Sample H 001;038.0N
```

(in case of "method code input" activated)

or:

```
PTB311E-500 -SN029251 -B       56984-A00000067-DT2024.07.08 09:12:30 -Start
PTB311E-500 -SN029251 -B       56984-A00000067Sample T 001;05.51mm
PTB311E-500 -SN029251 -B       56984-A00000067Sample W 001;06.02mm
PTB311E-500 -SN029251 -B       56984-A00000067Sample D 001;10.93mm
PTB311E-500 -SN029251 -B       56984-A00000067Sample H 001;038.0N
```

(in case of "method code input" deactivated)

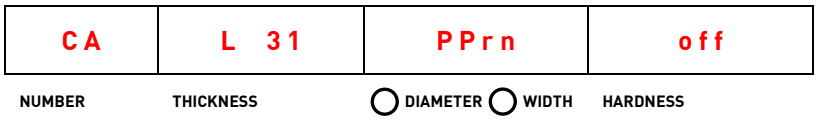
Every string end with CR/LF.

The data is formatted that you can select a "string parser", identify the parameter with the variable "T" (thickness) / "W" (width) / "D" (diameter) / "H" (hardness) at position "54" ("59" if code input is active) and read the values for "T", "W", "D" and "H" at position "60" ("65" if code input is active). Mettler Freeweight ® is able to collect the data this way.

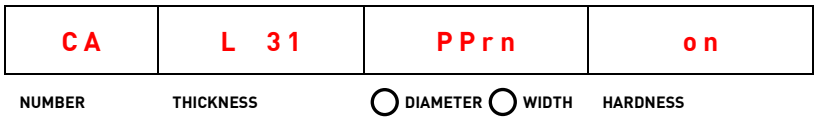
Section 6.6 Select parallel printout

The parallel printer interface can be activated or deactivated.

Login as Super User. Press <**CAL**> + <**3**> + <**1**>. The display will show:



You can change the setting by pressing the <**.**> (DOT) button. The display changes to:



Confirm the setting with <*****>. The display returns to initial screen (all "0").

To use this function, you need a printer with a parallel interface.

You can buy a suitable printer by Pharma Test:

- Epson DOT-Matrix printer (order number 29-02856)

respectively

- Brother Laser Printer (order number 34-28579)

Please note: if "bonP" (see also Section 6.5) and "parallel printout" are active simultaneously, only the ticket printer (serial printout) is served!

Section 7.0 Adjustment and Calibration

The instrument has been adjusted prior to delivery, using traceable calibration tools. The adjustment is certified within the QC/DQ report supplied with the instrument. In the event of incorrect results, the relevant station might be out of the adjustment and a readjustment is necessary.

The following sections describe the required calibration tools needed.

Section 7.1 Equipment Required for Adjustment

Adjust	Tool	Type	Part No.
Hardness	**Optional *):** 10kg reference weight, certified	PTB-CAL15	28-00290
Thickness	10 mm Reference Block, certified	Calibration block	285-1755 (part of set 285-1785-3)
Diameter	10 mm Reference Block, certified	Calibration block	285-1755 (part of set 285-1785-3)
Hardness	**Optional *):** PT-MT3, certified (see section 7.9)	Magnetic Test Tablet PT-MT3	29-18050

Table 10: Adjustment Equipment

Section 7.2 Equipment Required for Calibration

Calibrate	Tool	Type	Part No.
Hardness	**Optional *):** 5, 10, 15kg reference weight set, certified	PTB-CAL15	28-00290
Breaking Detection	**Optional *):** Magnetic test tablet	PT-MT2 or PT-MT3	29-18000 or 29-18050
Thickness	3, 5 and 10 mm Reference Block, certified	Calibration blocks	285-1785-3
Diameter	3, 5 and 10 mm Reference Block, certified	Calibration blocks	285-1785-3

Table 11: Calibration Equipment

*) Explanation of "Optional":

One of the following combinations of calibration tools must be available for the hardness calibration:

- PT-MT3 with PT-MT support for PTB111/311/411/511 and printer: This is the recommended procedure by Pharma Test. Using a PT-MT3, no calibration weight is needed anymore because the PT-MT3 fulfills the hardness calibration completely. Furthermore, the force increase curve must be recorded to check the linearity up to the maximum hardness.
- If the hardness calibration shows a discrepancy, the "Adjustment via PT-MT3" function on the Hardness Tester can be used for correction.
- PT-MT2 with PT-MT support for PTB111/311/411/511, static weights and printer:
  If an obsolete PT-MT2 is available, the usage is valid as long as the certification of the PT-MT2 is valid. Pharma Test recommends the load cell calibration with at least 5kg, 10kg and 15kg static weights, too. Furthermore, the force increase curve must be recorded to check the linearity up to the maximum hardness.

- Static weights and printer: If no electro-magnetic test tablet is available, the Hardness calibration can be done only with static weights. In this case, the PTB311E should be calibrated at least to 15kg, the PTB511E at least to 30kg and the PTB311E-800 at least to 50kg. Furthermore, the force increase curve must be recorded to check the linearity up to the maximum hardness.

Section 7.3 Login as Superuser for Adjustment / Calibration

With Firmware 4.00 and higher, all instrument settings except the "normal" test entries are password protected. The following settings are only adjustable when logged in as Super User. If not, "no Acc" will be displayed (= "no access")!

Refer to section 5.1 for information about the Superuser-login.

Section 7.4 Adjustment of the Hardness Test Station (Load Cell, static Weight)

This section describes the adjustment with static weights. For adjustment via PT-MT3, see section 7.9.

You need to unscrew the load cell retaining bolt from the holder. Place the instrument sideways on to the bench and unscrew the protection cover.

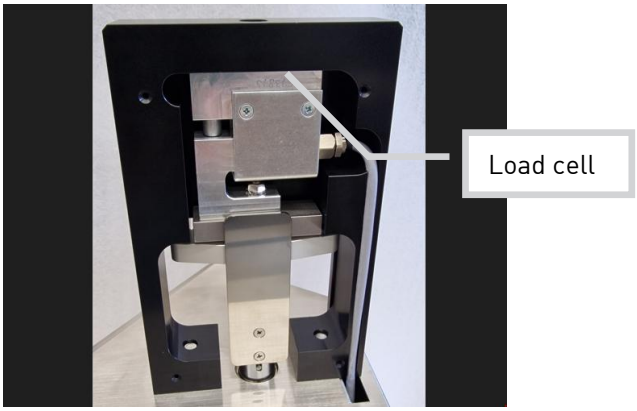


Figure 19: Load cell after cover has been unscrewed

The load cell is tightened only with one screw (5 mm Allen key) from the outer right side (upper side in figure 19). Remove the screw and place the load cell vertically on the bench in a safe manner. Make sure that it has good all-around clearance.

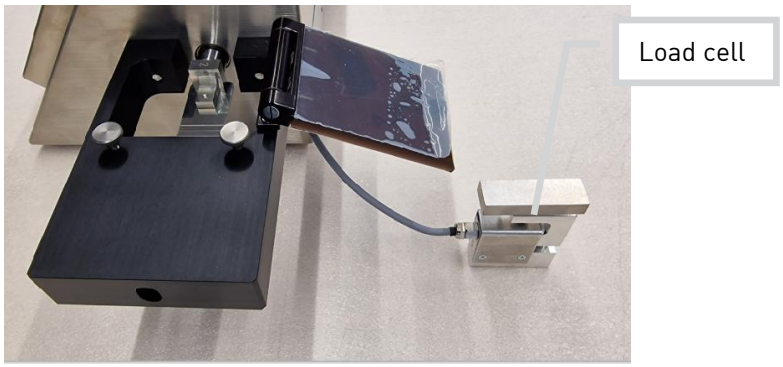


Figure 20: Load cell in upright position - ready for adjustment and calibration

Section 7.4.1 Zero Offset

Login as Super User.

At first the zero offset of the load cell in this position is measured. To read the zero offset of the load cell, press <**CAL**> + <**4**> + <**2**>

The reading for the zero offset value should be within the range of 20 – 60 digits for PTB 311E and 16 – 56 digits for PTB311E-500 and for PTB311E-800. Adjust the offset value with a screwdriver at the back of the PTB 311E/ 311E-500/ 311E-800 to read a value within this range.

Figure 21: Hole to Access Zero Offset Adjustment Potentiometer

Wait until the reading is stable:

C A	h	L = 0	0 0 4 0
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

Confirm the result for zero offset by pressing <*****> (STAR). The value is now stored and fixed. The display shows:

C A	h		d o n E
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

After a few seconds the display returns to initial screen (all "0").

Section 7.4.2 Reference Weight

Now, a 10 kg certified weight is used to adjust a second point for precise measurement. Place the 10kg weight carefully and slowly on top of the load cell and wait until it rests safely.

Figure 22: 10kg Reference Weight On Top Of Load Cell

Press <**CAL**> + <**4**> + <**2**> again to read the adjustment result of the 10kg weight on the load cell,

Wait until the reading is stable:

C A	h	L = 1 0	1 3 3 4
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

The reading for the 10kg reference weight should be within a range of 1240 - 1480 digits for PTB 311E, and 625 - 766 digits for PTB311E-500 and 475 – 555 digits for PTB311E-800.

Confirm the result for the 10kg reference by pressing <*****> (STAR). The value is now stored and fixed. The display shows:

C A	h		d o n E
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

After a few seconds the display returns to initial screen (all "0").

When the adjustment is finished, the load cell should be calibrated. Refer to Section 7.5 - Calibration of the Hardness Test Station.

Section 7.5 Calibration of the Hardness Test Station

The PTB 311E/ 311E-500/ 311E-800 offers a three-point calibration procedure for the load cell used in the hardness test station. So, you will need three different certified weights, e.g. 5kg, 10kg and 15kg. You may order the Pharma Test calibration weight set PTB-CAL15 (part no. 28-00290).

Figure 23: PTB-CAL15 5, 10 and 15kg weight set

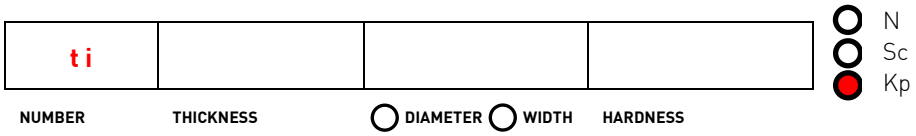
During regular operation qualification (OQ) and every time when a hardness adjustment procedure is performed, you should perform the load cell calibration before you place the load cell back into its housing. Be careful: you handle massive calibration weights up to 15kg. Take care because of hurts and injury!

When the load cell calibration is finished, a calibration report can be printed with the code <**CAL**> + <**5**> + <**4**>, if a printer is connected to the PTB311E/ 311E-500/ 311E-800.

Section 7.5.1 Calibrate the Load Cell Using the First Reference Weight – 5 kg

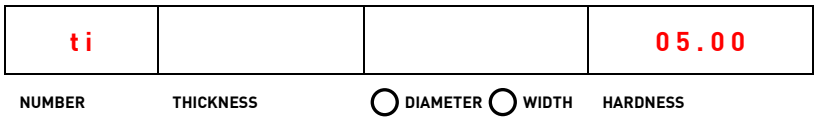
Login as Super User.

To access the load cell calibration program, press <**CAL**> + <**5**> + <**0**>. The display will show:

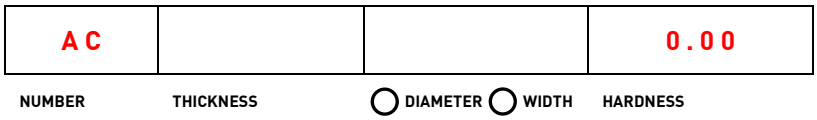


The unit for the hardness calibration switches automatically to Kilopond [Kp] and remains to Kilopond during the complete calibration process. After finishing the hardness calibration, the unit returns to the selected one.

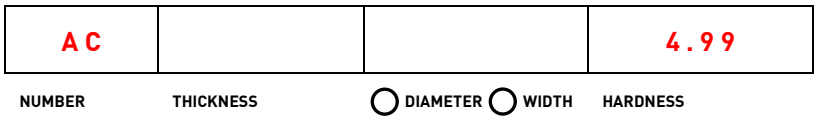
Enter the value of the first reference weight you want to use in four digits, e.g. for a 5 kg certified weight, press <**0**> + <**5**> + <**0**> + <**0**>. The display will then appear as follows (do not load any weight at this point yet):



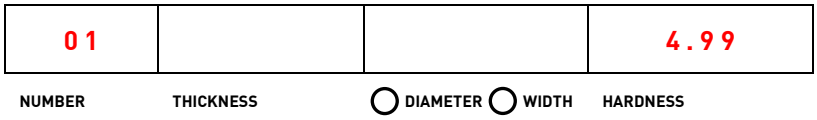
If this is correct, confirm the data by pressing <*****> (STAR). The display will now change and tare the load cell to zero. The display shows:



Now place the certified 5kg weight carefully onto the load cell and wait for a stable reading, e.g.:



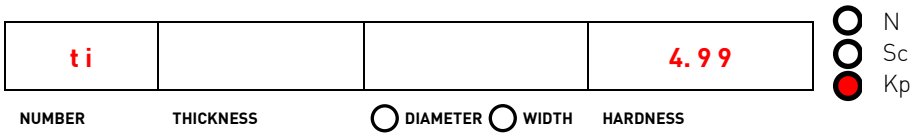
Once the reading is stable, press <**START**> to store the result. The display remains with the last result, e.g.:



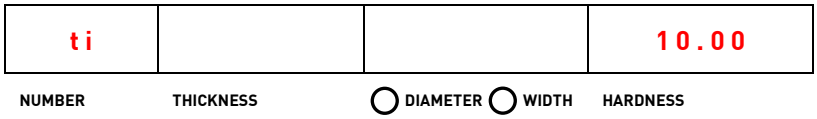
You are now requested to use a second calibration weight, for example 10 kg.

Section 7.5.2 Calibrate the Load Cell Using the Second Reference Weight – 10 kg

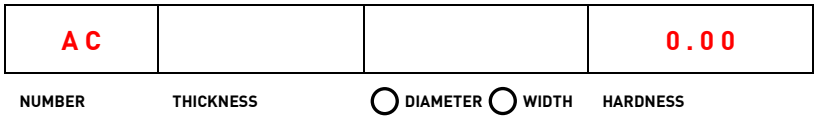
To continue the calibration using a second reference weight, press <**START**>. The display will still show:



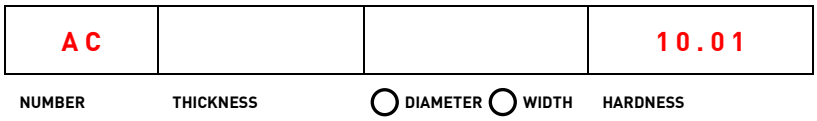
Enter the value of the second reference weight you want to use, in four digits, e.g. for a 10 kg certified weight, press <**1**> + <**0**> + <**0**> + <**0**>. The display will then appear as follows (do not load any weight at this point yet):



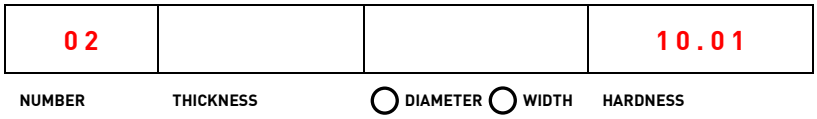
If this is correct, confirm the data by pressing <***>(STAR). The display will now change and tare the load cell to zero. The display shows:



Now place the certified 10kg weight carefully onto the load cell and wait for a stable reading, e.g.:



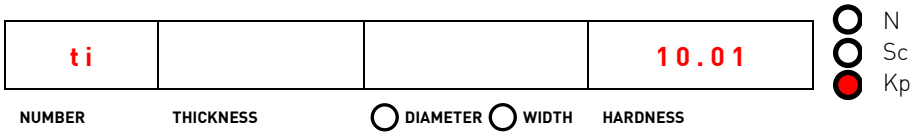
Once the reading is stable press <**START**> to store the result. The value is now stored and fixed. Remove the weight from the load cell. The display remains with the last result, e.g.:



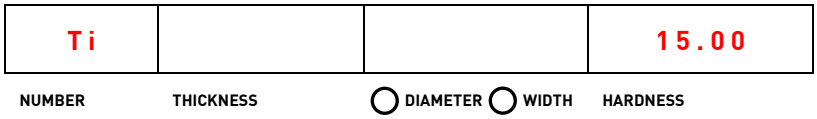
You are now requested to use a third calibration weight, for example 15 kg.

Section 7.5.3 Calibrate the Load Cell Using the Third Reference Weight – 15 kg

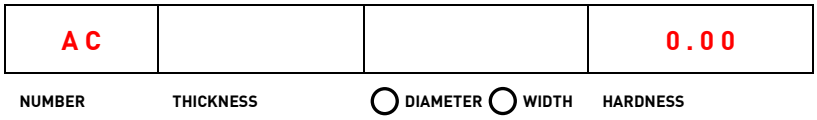
To continue the calibration using a third reference weight, press <**START**>. The display will still show:



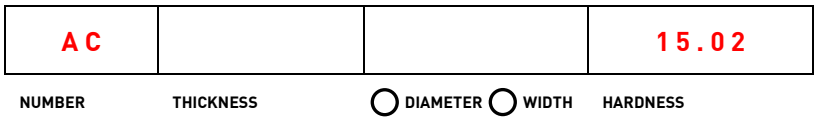
Enter the value of the third reference weight you want to use, in four digits, e.g. for a 15 kg certified weight, press <**1**> + <**5**> + <**0**> + <**0**>. The display will then appear as follows (do not load any weight at this point yet):



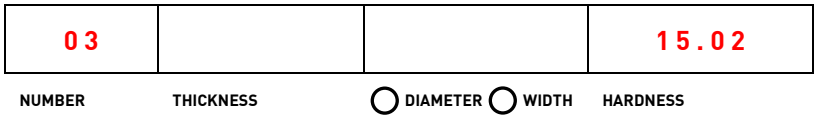
If this is correct, confirm the data by pressing <*****> (STAR). The display will now change and tare the load cell to zero. The display shows:



Now place the certified 15kg weight carefully onto the load cell and wait for a stable reading, e.g.:



Once the reading is stable press <**START**> to store the result. The value is now stored and fixed. Remove the weight from the load cell. The display remains with the last result, e.g.:



You can do 5 of this calibrations in total. The value of the weights can freely be decided. Simply proceed with the button <**START**>. Of course, you are allowed to end the calibration program at any former point by pressing the <**STOP**> button. However, Pharma Test recommends to perform at least the three calibrations shown above.

After the fifth calibration, the calibration program ends automatically and the device returns to initial screen (all "0").

Section 7.5.4 End Load Cell Calibration Program

To end the program, press <**STOP**> after the last calibration instead of <**START**>. The display returns to initial screen (all "0").

Section 7.5.5 Print the calibration report

Press <**CAL**> + <**5**> + <**4**> to print a calibration report on the selected printer.

Section 7.6 Reinstall the Load Cell

Insert the load cell back to its operating position and tighten it with the screw from the outer right side (5mm Allen key).

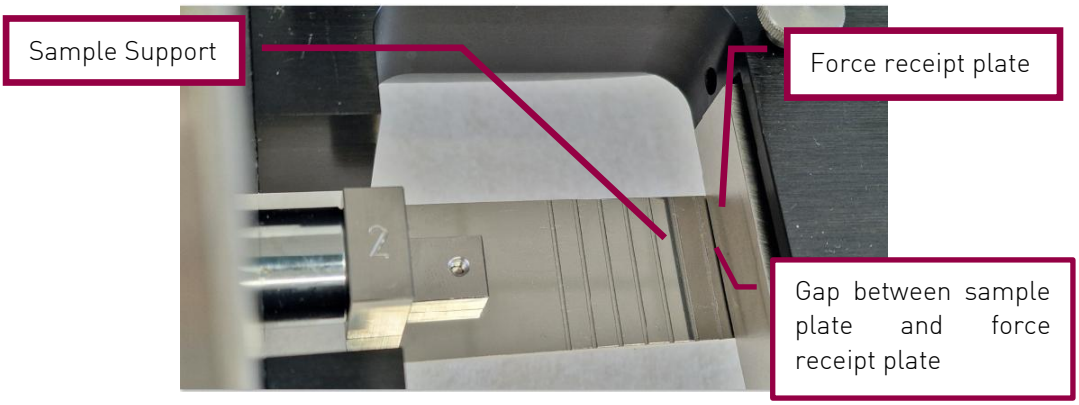


Figure 24: Sample Support Plate Assembly

The load cell (force receipt plate) and sample plate must be absolutely parallel. The gap between the force receipt plate (which is attached to the load cell) and the sample support plate should be 0.3 – 0.5 mm over the complete movement. Screw the cover plate back into position and return the instrument back to its working position on the bench.

Section 7.7 Hardness Calibration Report

The calibration report ("Linearity Validation") must be printed as hardcopy. A serial transmission is not possible.

A printout can be triggered by pressing <**CAL**> + <**5**> + <**4**>, even by the standard user.

```
----------------------------------------
  *** LINEARITY VALIDATION REPORT ***
----------------------------------------
   Tablet Testing System PTB311-500
 V04.03E  Instrument Serial No. 029251
----------------------------------------
Validation Time 15:34:49 Date 16.05.2023
----------------------------------------
No. Ref. Value  Act. Value  Deviation
    [kg   Dig]  [kg   Dig]  [kg    rel]
 1   5.00  242   5.62  272   0.62  12.4%
 2  10.00  484  11.36  550   1.36  13.6%
 3  15.00  726  16.78  812   1.78  11.9%
----------------------------------------

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

Released: --------------  --------------
          Name/Signature   Date / Time
----------------------------------------
Printed:  Time 15:35:42 Date 16.05.2023
```

You can see here:

- Your entered nominal weights.

  In [kg] and the corresponding [digits]
- Your measured actual weights.

  In [kg] and the corresponding [digits]
- The deviation between nominal and actual values.

  Absolute (in [kg]) and relative (in [%])

If the actual values are out specification, a readjustment is necessary!

Figure 25: Example printout of a linearity validation report

Section 7.8 Calibration of the Breakpoint Reproducibility (with PT-MTx)

A Pharma Test standard calibration procedure of a hardness tester instrument always includes a test of the breakpoint reproducibility using a magnetic tablet PT-MT2 or PT-MT3.

For this test, no special program is implemented. A "normal" test run must be executed. Thickness -, Width- and Diameter measurement must be deactivated (nominal value "0000"), the nominal hardness must be set to the intended magnetic tablet hardness and the automatic restart function should be activated.

Refer to the operation qualification (OQ) document of the hardness test instrument and to the manual of the magnetic tablet for more information.

Section 7.9 Adjustment via PT-MT3

As an alternative to the adjustment of the hardness station with static weights, you can adjust the hardness station using a magnetic tablet PT-MT3. This adjustment can be used for correction of the hardness reading.

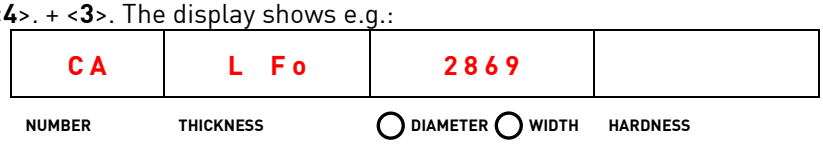
Be careful doing the adjustment this way because the magnetic tablet PT-MT3 is the "reference" for the adjustment of the PTB311E/ 311-500/ 311E-800, equivalent to the 10kg weight during "normal" adjustment in section 7.4! Do the adjustment only with a validly calibrated magnetic tablet PT-MT3 and if you are familiar with the procedure.

Insert the PT-MT3 to the PTB311E/ 311-500/ 311E-800 using the calibration support 29-18003 (PT-MT3 support for PTB x11). Take care that both the PTB311E/ 311-500/ 311E-800 and the PT-MT3 are pre-warmed sufficiently. In a PTB311E/ 311-500/ 311E-800, the PT-MT3 must be inserted that the PT-MT3 load cell is placed face-to-face to the PTB load cell. So, the support must be prepared and placed correctly.

Login as Super User.

Now perform a test series with the PT-MT3. Set the PT-MT3 nominal hardness close to the maximum nominal hardness of the PTB311E/ 311-500/ 311E-800. We recommend performing at least 20 tests to have a representative mean value. After this test series you get a mean value from the PT-MT3 (printout) and from the PTB311E/ 311-500/ 311E-800.

Press <**CAL**> + <**4**>. + <**3**>. The display shows e.g.:



The value "2869" shown in the diameter display shows the PTB hardness mean value of the finished test (It is not a diameter value! At this point it is the hardness! In this example it means: the mean value of the former hardness test was 286.9N!). You can now enter the mean value of the magnetic tablet PT-MT3 (which is the reference for this adjustment) in the hardness display using the number keys. After pressing <*> (STAR) twice, the mean value of the hardness tester is corrected to the mean value of the PT-MT3.

Example: The PTB shows a hardness mean value of 255.0 N and the PT-MT3 shows a mean value of 250.0 N. If you now enter the PT-MT3 value of 250.0 N, the adjustment of the PTB will be raised for 5 N related to 250 N which corresponds to 2%. After the correction, all hardness readings will be 2% lower.

The correction can be done in a range of ± 10% from the PTB mean value. If the discrepancy is higher, an adjustment with calibrated weights is necessary. The correction is valid until a new correction value is entered in the same way or a "normal" hardness adjustment with weights is performed again. The adjustment report (section 7.12) doesn´t change during this correction. Verify the correction by performing a breakpoint reproducibility calibration (Section 7.8) again!

Section 7.10 Adjustment of the Thickness Station

After the load cell adjustment and calibration has been successfully completed, it may be necessary to adjust the thickness testing station as the load cell has been removed from its housing and its position may have changed during re-installation. A certified 10 mm reference block is required for the 2-point adjustment. The built-in stepper motor will measure the range.

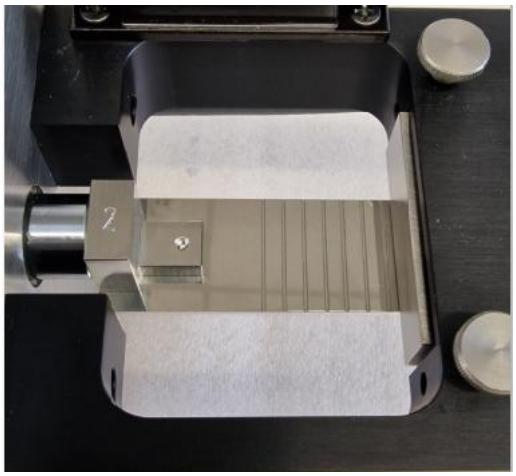


Figure 26: The empty tablet compartment

Login as Super User.
To enter the thickness adjustment mode, press the keys <**CAL**> + <**4**> + <**0**>. As soon as these 2 keys have been pressed, the jaw will start to move forward towards the force receipt plate. Make sure that there is nothing on top of the sample support plate as the total distance between the jaw and the force receipt plate will be measured. The display shows:

CA	t		
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

When the jaw touches the force receipt plate it will stop and automatically return to its home position. The display shows e.g.:

CA	t 0	003	3400
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

This means: a total driveway of 33400 steps is done for the movement from home position (left) to the force receipt plate (right). The valid range is from 30500 to 33500. The instrument identifies this number of steps automatically to the "zero" value for the thickness ("t 0").

Press <*****> (STAR) to store the value.

Now place the certified 10 mm calibration block in the middle and in front of the driven jaw.

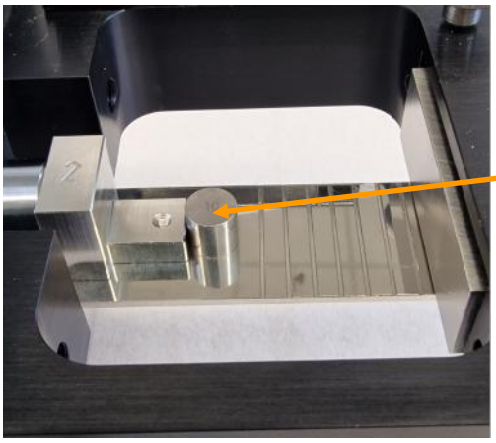


Figure 27: Tablet compartment with 10mm calibration block

To start the reference point adjustment mode, press the keys < **CAL**> + <**4**> + <**0**> again. The jaw will start moving towards the force receipt plate until the 10 mm reference block touches the plate. The display shows again:

CA	t		
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

When the jaw, carrying the calibration block, touches the force receipt plate it will stop and automatically return to its home position. The display shows e.g.:

CA	t 10	002	4700
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

This means a total driveway of 24700 steps is done for the movement from home position (left) to the 10 mm position in front of the force receipt plate (right). The valid range is from 23500 to 26500. The instrument identifies this number of steps automatically to the "10 mm" value for thickness ("t 10").

Press <*> (STAR) to store the value.

At this point the adjustment for the thickness station is already finished.

Section 7.11 Adjustment of the Diameter and Width Station

After the thickness adjustment has been successfully completed it may necessary to adjust the diameter (length) and width testing. A certified 10 mm reference block is required for the 2-point adjustment. The built-in stepper motor will measure the range.

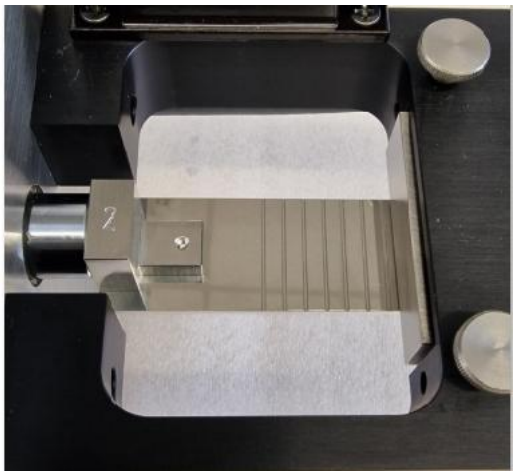


Figure 28: The empty tablet compartment

Login as Super User.
Press the keys <**CAL**> + <**4**> + <**1**> to enter the diameter/ width adjustment mode. As soon as these 2 keys have been pressed, the jaw will start to move forward towards the force receipt plate. Make sure that there is nothing on top of the sample support plate as the total distance between the jaw and the force receipt plate will be measured. The display shows:

C A	d		
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

When the jaw touches the force receipt plate it will stop and automatically return back to its home position. The display shows e.g.:

C A	d 0	0 0 3	3 4 0 0
NUMBER	THICKNESS	○ DIAMETER ○ WIDTH	HARDNESS

This means a total driveway of 33400 steps is done for the movement from home position (left) to the force receipt plate (right). The valid range is from 30500 to 33500. The instrument identifies this number of steps automatically to the "zero" value for the diameter ("d 0").

Press <*****> (STAR) to store the value.

Now place the certified 10mm Calibration Block in the middle and in front of the driven jaw.

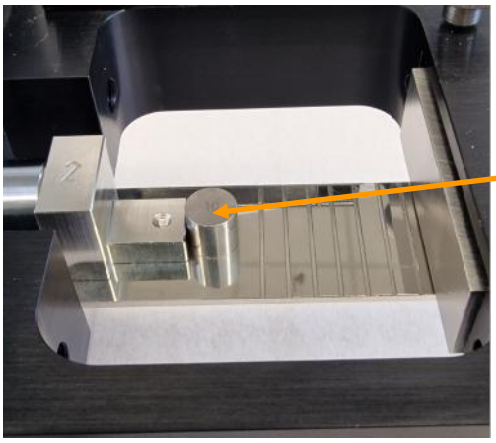


Figure 29: Tablet compartment with 10 mm calibration block

To start the reference point adjustment mode, press the keys <<**CAL**> + <**4**> + <**1**> again. The jaw will start moving towards the force receipt plate until the 10 mm reference block touches the plate. The display shows again:

C A	d		
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

When the jaw, carrying the calibration block, touches the force receipt plate it will stop and automatically return to its home position. The display shows e.g.:

C A	D 1 0	0 0 2	4 7 0 0
NUMBER	THICKNESS	◯ DIAMETER ◯ WIDTH	HARDNESS

This means a total driveway of 24700 steps are done for the movement from home position (left) to the 10mm position in front of the force receipt plate (right). The valid range is from 23500 to 26500. The instrument identifies this number of steps automatically to the "10 mm" value for diameter ("d 10").

Press <*> (STAR) to store the value.

At this point the adjustment for the diameter / width station is already finished.

Section 7.12 Printout the Adjustment Report

Press <**CAL**> + <**4**> + <**4**> while a printer is connected. The adjustment report will be printed.

Print-Out Test Report	Description of each point
*** ADJUSTMENT REPORT *** Tablet Testing System PTB311-300 V04.03E Instrument Serial No. 029251 Adj. Date 17.05.2023 Time 08:56:48	Headline: Adjustment report Instrument identification and date & time of the last adjustment.
Hardness Adjustment (Cell Upright) Zero-Value 0kg 0017 20 - 60 Dig Ref-Value 10kg 1301 1240 - 1480 Dig Range 0kg-10kg 1284 1180 - 1460 Dig	Hardness adjustment ⇨ Zero value [digits] ⇨ 10kg reference value [digits] ⇨ Range between 10kg and zero value [digits]
Thickness Adjustment Zero-Value 0mm 31956 30500 - 33500 Step Ref-Value 10mm 23812 23500 - 26500 Step	Thickness adjustment ⇨ Zero Value [steps] ⇨ 10mm reference value [steps]
Diameter/Width Adjustment Zero-Value 0mm 31952 30500 - 33500 Step Ref-Value 10mm 23814 23500 - 26500 Step	Diameter adjustment ⇨ Zero Value [steps] ⇨ 10mm reference value [steps]
Operator: ---------- ---------- Released: ---------- ---------- Name/Signature Date / Time Printed: Time 08:56:59 Date 17.05.2023	⇨ Signature from operator ⇨ Signature from supervisor ⇨ Date & time of printout

Figure 30: Printout of the adjustment report

Section 7.13 Calibration of the Thickness, Width and Diameter Station

To calibrate the 3 stations for thickness, width, and diameter measurement a "normal" test has to be started but the hardness measurement should be turned off. You may use any suitable reference block within 2 to 30 mm. Print the calibration report immediately after finishing the test.

Start the Calibration of the Thickness, Width and Diameter Test Station

All 3 stations are calibrated at the same time. Select a suitable size of the reference blocks, for example 10 mm, and place it directly in front of the driven jaw. Use the keyboard to enter the nominal value of the reference block you are going to use, e.g., 10 mm. The hardness test station must be switched off for this test.

Press <**THICKNESS**> and enter: <**1**> + <**0**> + <**0**> + <**0**> + <***>.

Press <**DIAMETER/WIDTH**>, when the red LED Diameter shines enter: <**1**> + <**0**> + <**0**> + <**0**> + <***>.

Press <**DIAMETER/WIDTH**>, when the red LED Width shines enter: <**1**> + <**0**> + <**0**> + <**0**> + <***>.

Switch off Hardness, press <**HARDNESS**> and enter: <**0**> + <**0**> + <**0**> + <**0**> + <***>.

Start the test series by the key <**START**> as often as you want to repeat the measurement. If a printer is connected to the PTB311E/ 311-500/ 311E-800, immediately the results will be printed. Usually, 5 tests are sufficient. Stop the test series, push the key <**STOP**> (push the key <**STOP**> twice if you use the automated re-start function). A test report with statistics should be printed as reference for the calibration results.

Repeat the test using a different Reference Block, for example 5 mm:

Press <**THICKNESS**> and enter: <**0**> + <**5**> + <**0**> + <**0**> + <***>.

Press <**DIAMETER/WIDTH**>, when the red LED Diameter shines enter: <**0**> + <**5**> + <**0**> + <**0**> + <***>.

Press <**DIAMETER/WIDTH**> and when the red LED Width shines enter: <**0**> + <**5**> + <**0**> + <**0**> + <***>.

Switch off Hardness, press <**HARDNESS**> and enter: <**0**> + <**0**> + <**0**> + <**0**> + <***>.

Start the test series by the key <**START**> as often as you want to repeat the measurement. If a printer is connected to the PTB311E/ 311-500/ 311E-800 the results will be printed directly. Usually, 5 tests are sufficient. Stop the test series, push the key <**STOP**> (push the key <**STOP**> twice if you use the automated re-start function). A test report with statistics should be printed as reference for the calibration results.

You can repeat this test as often as you need to confirm the precision of the 3 measuring stations. Pharma Test recommends performing the calibration always with at least 3 calibration blocks existing of 3 mm, 5 mm and 10 mm.

If the actual values are out specification, a readjustment is necessary!

Please note: the calibration block set (285-1785-3) from the standard supply scope are uncalibrated if not ordered calibrated explicitly. For calibration/ adjustment only calibrated blocks are allowed.

Section 7.14 Blank Calibration Form

The Pharma Test operation qualification (OQ) documents contain detailed calibration procedures. Nevertheless, the instrument can print a blank calibration sheet you can use additional or if no original OQ document is available.

Press <**CAL**> + <**5**> + <**3**> while a printer is connected. The calibration report will be printed.

Print-Out Test Report	Description of each point
*** CALIBRATION REPORT ***	Headline: calibration report
Tablet Testing System PTB311-300 V04.03E Instrument Serial No. 029251	Instrument identification
Hardness Setting (Cell Normal Pos) Act. Offset 0017 12 - 52 Dig	Actual instrument setting ⇨ Actual load cell offset
Hardness Calibration (Cell Upright) Zero-Value 0kg _____ 0.1 - 0.4 kg Ref-Value 10kg _____ 10.1 - 10.4 kg Range 0kg-10kg _____ 9.9 - 10.1 kg	Hardness calibration ⇨ Here you can note the loadcell readings without the calibration program: zero load [kg] ⇨ 10kg reference load [kg] ⇨ Range between 10kg and zero load [kg]
Thickness Calibration Zero-Value 0mm _____ 0.00 - 0.02 mm Ref-Value 10mm _____ 9.98 -10.02 mm	⇨ Thickness calibration ⇨ Zero Value ⇨ 10mm reference value
Diameter/Width Calibration Zero-Value 0mm _____ 0.00 - 0.02 mm Ref-Value 10mm _____ 9.98 -10.02 mm	⇨ Diameter calibration ⇨ Zero Value ⇨ 10mm reference value
Operator: _____ _____ Released: _____ _____ Name/Signature Date / Time Printed: Time 08:57:29 Date 17.05.2023	⇨ Signature from operator ⇨ Signature from supervisor ⇨ Date & time of printout

Figure 31: Printout of the calibration report

Section 7.15 Linear Force Increase Curve

For calibration or service purposes, the PTB311E/ 311-500/ 311E-800 offers the possibility to print a linearity curve of the force increase. This curve can only be printed by a DOT- matrix printer or the Epson TM-U220D ticket printer, not by a PCL-printer used with a parallel/USB adapter!

This curve is useful to check the maximum hardness, the correctness of the internal controller (force increase rate and linearity) and the safety stop when the maximum force is reached (to avoid damaging the load cell).

To activate the printout of the force, increase curve, press <**CAL**> + <**3**> + <**2**> + "ON" + <*****>.

Make sure that a suitable printer is connected to the PTB311E/ 311-500/ 311E-800.

Enter a nominal hardness (>0.00 [unit], the real value doesn´t have influence to the measurement) and deactivate thickness and diameter (both "00.00").

Start a test without sample by pressing <**CAL**> + <**5**> + <**1**>. This means: the force jaw will drive against the force receipt plate, raising the force with the set rate until it reaches the maximum hardness and stops the test. After the test, the reading of the maximum hardness is displayed and printed with the force curve.

Use a stopwatch and measure the time from the contact of the driven jaw to the force receipt plate until stop. Divide the displayed maximum hardness by the time you stopped. The result shows the force increase rate the PTB311E/ 311-500/ 311E-800 used. See Figure 32:

Please note: The rate according to the time you measured manually by a stopwatch will always differ a little from the one the instrument will show on the printout. If the values match exactly, this will be by chance. Remember that you check an in-circuit controller using a stopwatch which is influenced by human reaction time and a subjective assumption of start and stop of the force increase. This check is simply to verify that the internal clock works correct overall. The rate calculated by the instrument is generally more exact than the manually calculated one.

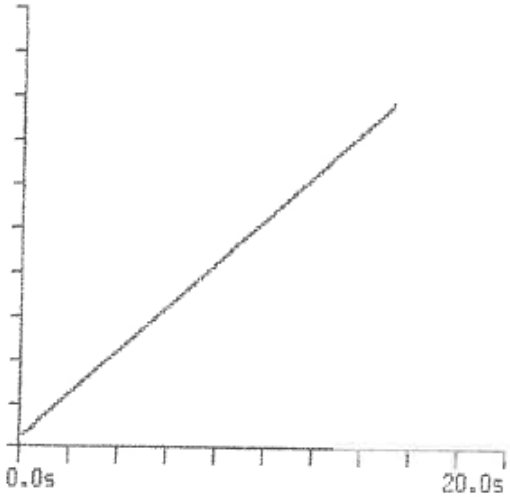
Print-Out Test Report	Description of each point
* LINEARITY AND Fmax VALIDATION REPORT * Tablet Testing System PTB311-300 V04.03E Instrument Serial No. 029251 Setting 20.0 N/s	Common test header Instrument identification Actual setting of the force increase (here: 20N/s)
400 N  0.0s 20.0s Fmax = 311.4N / t = 15.13s Gradient = (279.9N - 157.9N) / (13.62s - 7.57s) = 20.2N /s	Force increase curve If this curve doesn´t show a straight linear curve, the controller can´t raise the force constantly. Either there is a mechanical slippage or the load cell / controller is damaged. Maximum hardness until end and total time for the force increase. Calculated gradient (force increase rate). The values are taken from 90% and 50% of the time for the total force increase.
Operator: ---------- ---------- Released: ---------- ---------- Name/Signature Date / Time	⇨ Signature from operator ⇨ Signature from supervisor
Printed: Time 09:17:01 Date 17.05.2023	⇨ Date & time of printout

Figure 32: Printout of the force increase curve

Don´t forget to deactivate the curve printout again after finishing this test. Press <**CAL**> + <**3**> + <**2**> + "OFF" + <*****>.

Section 8.0 Summary of all CAL-functions

Key Sequence			Type	Action	Comment	Permission: Normal User	Super User	Factory User	See Section:
CAL	0	0	Setup	Unlock Factory Settings	Requests for Factory Activation Code			X	5.1 Remember 1
CAL	0	1		Unlock USER Settings	Requests for User Password		X		5.1
CAL	0	2		Change Password	Input: Old / New / New Password		X		5.1
CAL	0	3		Reset Password to 0000 0000	Requests for User Activation Code			X	5.1 Remember 2
CAL	0	4		Initialize EEPROM	Factory Setting			X	
CAL	0	5		Enter SN	Factory Setting			X	
CAL	0	6		Set AID = 0	Factory Setting			X	
CAL	0	7		Select Force Range (300/500/800)	Factory Setting, dot to toggle, star to save			X	
CAL	0	8		Show SN		X	X	X	
CAL	1	0	Date/ Time	Show / Enter Date	not for normal user		X	X	6.2
CAL	1	1		Show / Enter Time	not for normal user		X	X	6.3
CAL	1	2		Show / Enter Cal.Interval	off/1/3/6/12/24 month		X	X	6.4
CAL	2	0	Measurement Parameters	Select Force Unit	[N], [Sc], [kp]		X	X	5.2.1
CAL	2	1		Select Length Unit	[mm], [Inch]		X	X	5.2.2
CAL	2	2		Set Mode, Speed	Const. Speed [mm/min], dForce [N/s]		X	X	5.3
CAL	2	3		Set Touch Force	Current Force Unit		X	X	5.4
CAL	2	4		Set Break Detection	Current Force Unit		X	X	5.5
CAL	2	5		Set Fault Force	Current Force Unit		X	X	5.6
CAL	2	6		Set Test Object Type, Test Distance	Tablet/Capsule, Length Unit mm		X	X	5.7
CAL	2	7		Use Method Code Input			X	X	5.8
CAL	3	0	Data Output	Select Serial Output	none,Cdat(= CSV Curve Data), BonP (=Bon Printer), or Free (=FreeWeigh)		X	X	6.5
CAL	3	1		Select Parallel Output	Centronix Parallel Printer off/on		X	X	6.6
CAL	3	2		Enable/Disable Printer Graphics (Curve)	Graphics off/on		X	X	7.15
CAL	4	0	Adjustment	Adjustment of Thickness			X	X	7.10
CAL	4	1		Adjustment of Diameter (and Width)			X	X	7.11
CAL	4	2		Force Adjustment (Hardness)			X	X	7.4
CAL	4	3		Force Adjustment by PT-MT3			X	X	7.9
CAL	4	4		Print Last Adjustment Report	to Std.Printer or Bon Printer		X	X	7.12
CAL	5	0	Calibration	Force Linearity Calibration (max. 5 points)		X	X	X	7.5
CAL	5	1		Max. Force Calibration (Drive up to Fmax)		X	X	X	7.15
CAL	5	2		Show Weight [digit,act. unit]	dot to tare/untare	X	X	X	
CAL	5	3		Print Calibration form	to Std.Printer or Bon Printer	X	X	X	7.14
CAL	5	4		Print Lin.Calibration Report	to Std.Printer or Bon Printer	X	X	X	7.7

Table 12: CAL-functions

Section 9.0 Cleaning and Maintenance

The spare parts consistent of acrylic glass should be cleaned every day. Never use solvent-containing cleaning supplies like alcohol, ethanol, etc., they are able to destroy the acrylic glass. Please use exclusively soaps containing cleaning supplies with lukewarm water or cleaning cloths. Do not use the dishwasher to clean acrylic parts.

Stainless steel parts should be cleaned immediately in case solvents or test solutions (like acidulous substances etc.) are detected on the surface. Wipe away the solutions with a cloth and protect the surface through the use of stainless-steel cleaning oil, which is handed out with the delivery.

The waste drawer should be emptied regularly. We recommend to do this after 50 samples latest, or even earlier depending on the size of the samples.

Sticky residues on the stainless-steel parts (force piston, load cell) should be removed immediately by a plastic or wooden scraper (non-abrasive tool) to protect the surfaces from scratches.

The device does not include any other spare parts, which should be maintained by the user. Any repairs are exclusively allowed to be done via the PHARMA TEST Service or any other authorized service partner.

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

Section 10.0 Service and Support

Section 10.1 Error Codes

Several error codes are used in order to assist our service department in the identification of any operational problems or to inform the user of any incorrect key stroke entries in either a function or operation mode.

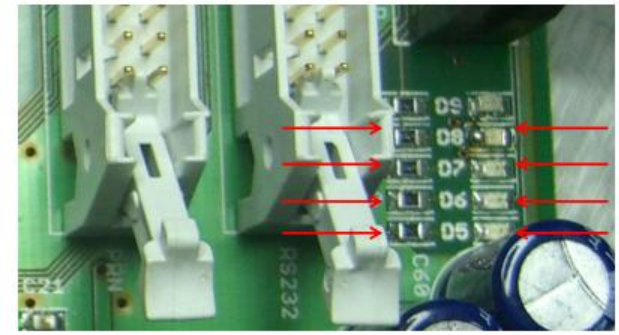
The table will highlight information concerning these codes and advise as to which action should be taken:

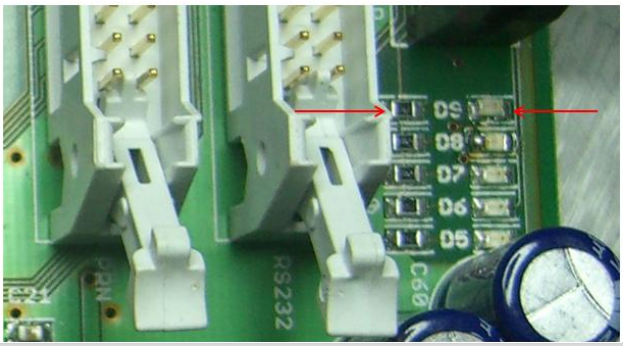
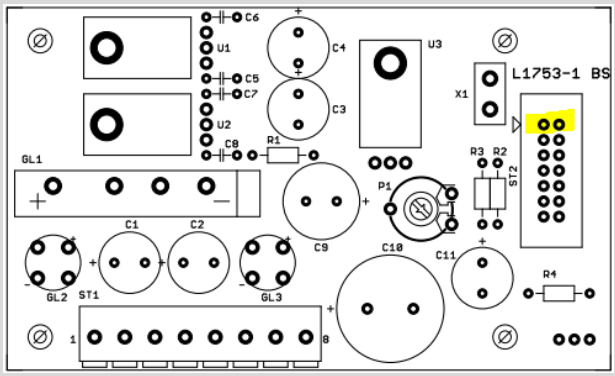
Error Code	Problem	What to check	How to Solve
136 or 147	Sample does not break within the adjusted Breaking Detection Distance	Value of "bF" Speed/force rate Break detection distance	Correct the Detection parameters (see section 5.7)
no tArGEtS	No nominal value is entered.	Press keys <**Thickness**>, <**Diameter/Width**> and <**Hardness**>. Display always shows "0 0 0 0"	Enter at least one nominal value > 0 (see section 4.1)
128... 147	Positioning errors	-Is the driven jaw and the force receipt plate installed correctly? -Check the on-board voltages as described in troubleshooting section, item 2	Check power supply and the <**CAL**> + <**5**> + <**2**> value. See also Troubleshooting. Replace power supply if necessary.
148... 153	Incorrect load cell values	---	Replace main board
154	Load Cell Offset too low	<**CAL**> + <**4**>+ <**2**> shows the actual Offset (see section 7.4.1)	1. Adjust Offset (section 7.4.1) 2. Replace Load Cell
155	Load Cell offset too high	<**CAL**> + <**4**>+ <**2**> shows the actual Offset (see section 7.4.1)	1. Adjust Offset (section 7.4.1) 2. Replace Load Cell
156	Sample too hard: hardness outside of the instrument range	Value of "bF" Speed/force rate Break detection distance	-Correct the Detection parameters (see section 5.7) -Use softer samples -Upgrade the instrument to a load cell with higher maximum force
157... 176	Optical reference switch errors	-Check the operation of the reference switch: troubleshooting, item 3 -Check the on-board voltages as described in troubleshooting section, item 2	Check power supply and the <**CAL**> + <**5**> + <**2**> value. See also Troubleshooting. Replace power supply if necessary.

Error Code	Problem	What to check	How to Solve
177-191	Unexpected hardness reading		Enter correct (larger) nominal value for Thickness and/or Diameter
	Some Force is already applied to the Load Cell	Sample forces the load cell already at test start	1. Use smaller sample 2. Correct installation of the Thickness Jaw
	Sample support plate is touching the Force Receipt Plate		Adjust sample support plate for approx. 0.5mm clearance from load cell force receipt plate.
	Some broken Residue forces the Load Cell		Remove sample holder and clean it.
254	Break detected in Capsule mode	<**CAL**> + <**2**>+ <**6**> setting	Reduce the compression distance.
No printout of a force curve	A curve is only printed using a DOT Matrix Printer or an Epson TM-U220D.		

Table 13: Error Codes

Section 10.2 Trouble Shooting

Error	Solution
The PTB311E/311E-500/311E-800E/EP does not turn on	Check if main connections is present and properly connected Check the fuse and replace it if necessary
The motor doesn´t move, even if no error message is displayed. or an error message E128...E147 is shown	Check the supply voltages. All 4 LEDs D5-D8 must be illuminated. Measure the voltage at the indicated points: D5: 22...32 Volt DC D6: 5.15...5.35 Volt DC D7: 10...13 Volt DC D8: -10...-13 Volt DC 

Error	Solution
The driven jaw moves only backwards or an error message E157...E176 is shown	Check the operation of the light barrier. An illuminated D9 indicates the drive is in home position. As soon as the flap is driven out of the light barrier, D9 must be off. 
The instrument aborts immediately after starting a test showing various error messages. The load cell reading <CAL> + <5> + <2 shows a fluctuation (unit [kP]) > ± 0,1kP.	Ground and Earth must be connected by a solder bridge on the power supply PCB. Call PTAG Service for more information. 

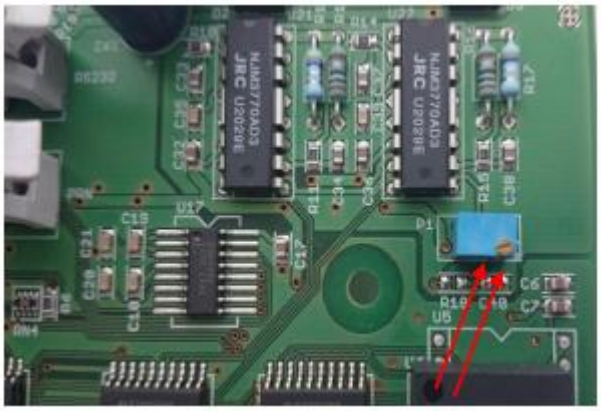
Error	Solution
The driven jaw blocks during fast forward movement and gives a loud beep sound.	Check the motor driver voltage: Measure the Voltage on the solder pads 'C40'. Be informed that you have to start a measurement with your hardness tester to start the movement, otherwise you cannot read the necessary voltage. It should between 4,0 and 4,3 Volts DC. We recommend 4,15 Volts DC.  Check the gear belt tension: If the belt has the right tension, you will be able to twist it about ~90 degrees sideways without much force. Be sure that you cannot twist it much more than 90 degrees.
It is impossible to adjust the zero offset value to be within the ranges in section 7.4.1 using the offset potentiometer.	The load cell is broken and needs to be replaced.

Table 14: Trouble Shooting

Section 11.0 Spart Part Codes

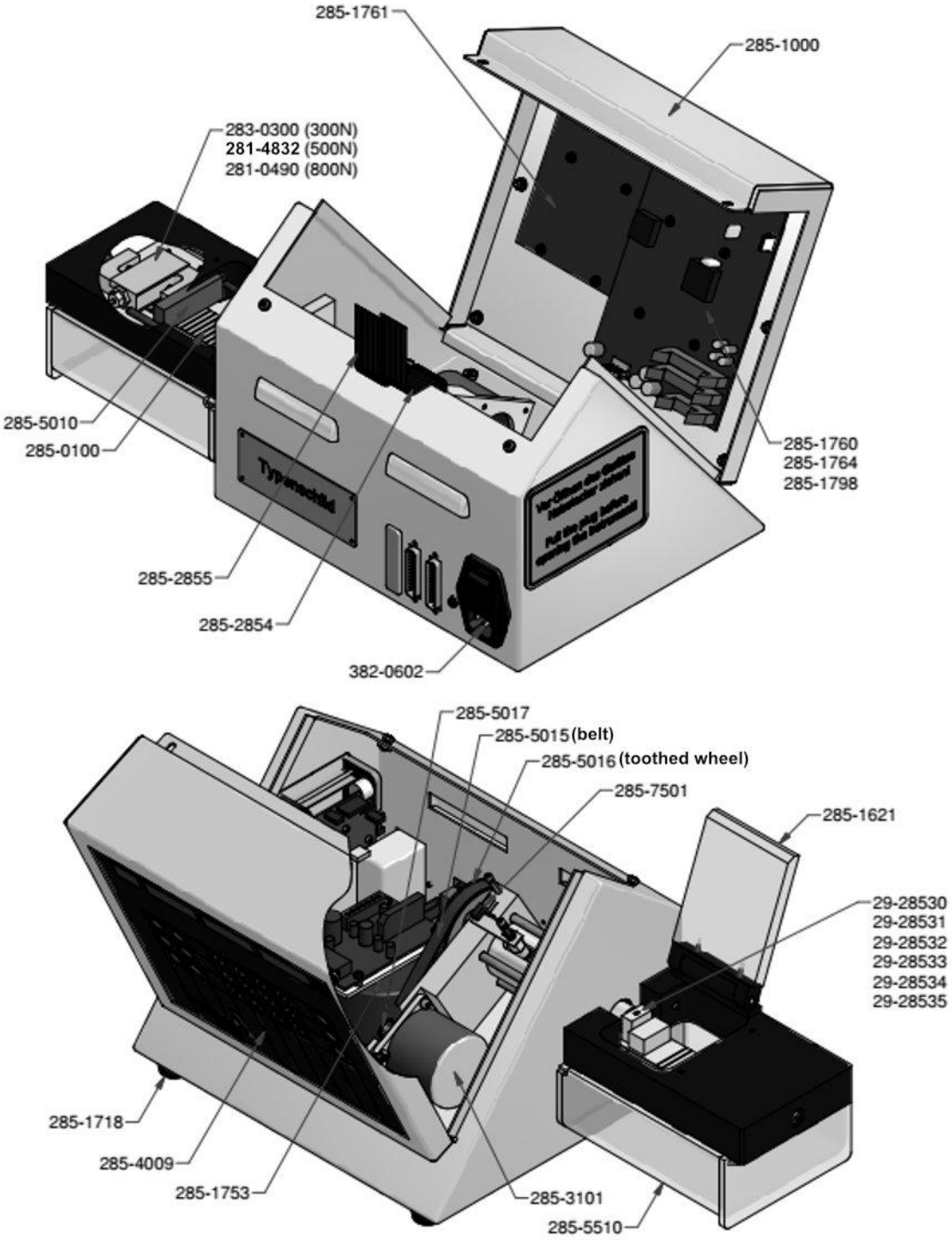


Figure 33: spare part codes

Section 12.0 Electrical Wiring Scheme

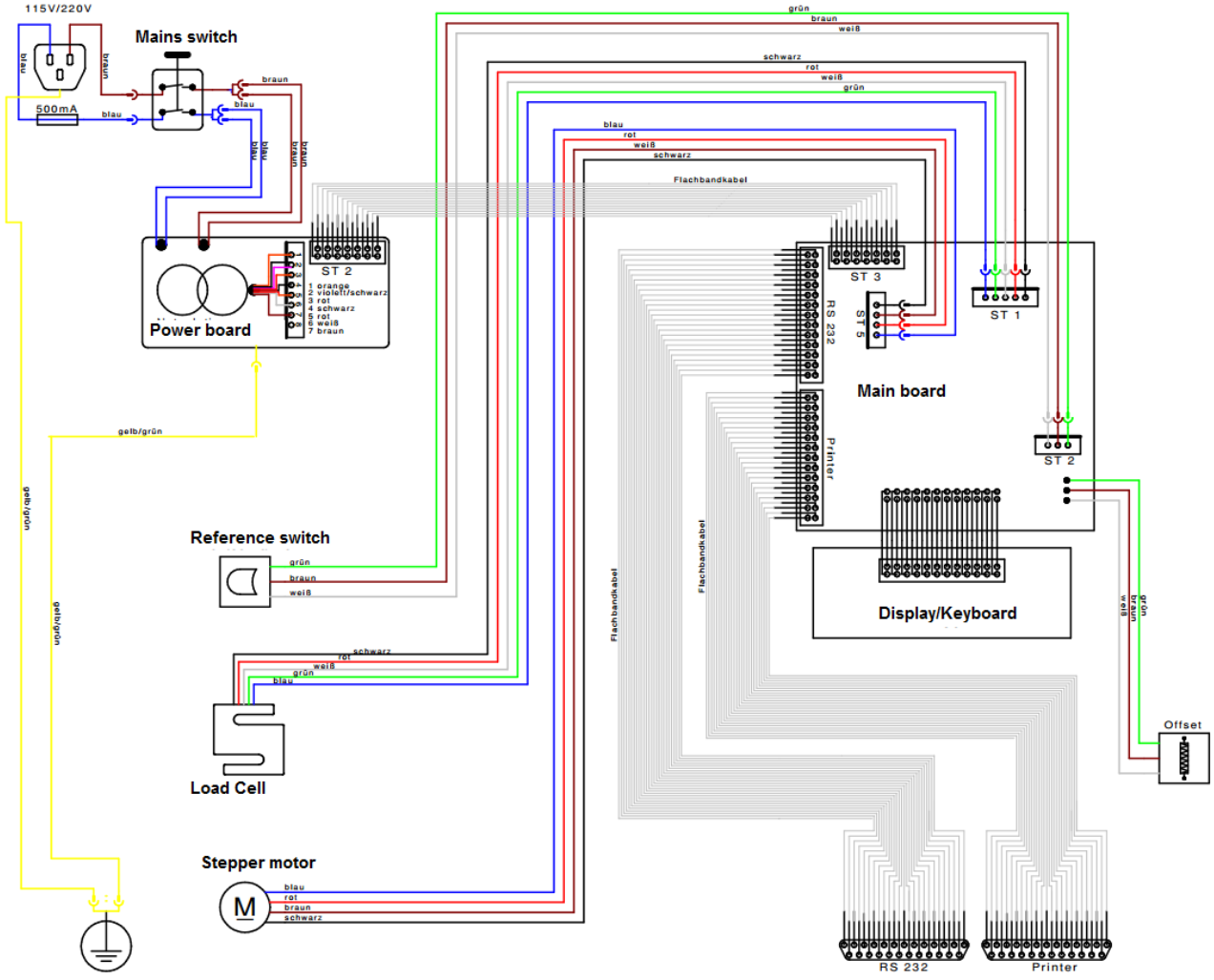


Figure 34: electrical wiring scheme

Section 13.0 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 loading hatch 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 loading hatch. Use the plastic lid to cover the hatch while a test runs. Don´t hold eyes and head in direct closeness to the test sample while breaking or use protective glasses.

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

For further technical support or questions about usage contact your local Pharma Test Service Partner,

or directly:

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