

PHARMA TEST

Operating Manual PT-MT3 Electro-Magnetic Test Tablet Version 1.5



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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



Instrument Type	PT-MT3
Document Name	B-29-18050 PT-MT3 v1.5e
Revision No.	1.5
Author	PHARMA TEST Apparatebau AG
Valid from	11.06.2021
Change	R

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Document History

Version	Valid from	Author	Change	Remark
1.0	12.07.2012	PTAG	N	
1.1	14.10.2013	PTAG	R	Added information to adjust load cell offset in trouble shooting
1.2	17.07.2015	PTAG	R	Pictures updated
1.3	12.08.2015	PTAG	R	PTB420 added
1.4	18.02.2019	PTAG	C	New Support for PTB111/311 added
1.5	11.06.2021	PTAG	R	WHT4 and additional information added

Table 1: Document History

Index Information - Change:

N = New Document

C = Correction

R = Revision

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1 About the PT-MT3

This instrument represents a system for calibrating and qualifying the hardness range of Pharma Test and other brands of tablet hardness testers. The PT-MT3 instrument has an electronically controlled magnetically held “finger” made of stainless steel and a load cell attached to it. The finger is held in position by an electromagnet which is always powered with maximum current. The finger is equipped with an electronic load cell which can be calibrated to allow a maximum force of 500N (Newton).

The strike arm or jaw of the hardness tester makes contact with the load cell at the finger and tries to “break” the finger away from the electromagnet holding it in place. The force required to make this “break” can be set from 5 to 500 N. Once the load cell detects the necessary force, the electro-magnet is turned off. The tablet hardness tester will in turn detect a force decrease and interpret this as the breaking of the sample.

The load cells have been calibrated against traceable standards to produce a useful series of equivalent tablet break points. The PT-MT3 can be supplied fully certified.

The system acts as a type of tablet simulator, which once broken can, unlike real tablets, be reset for the next test. At the end of a test it is possible to compare the force reading at the tested hardness tester and the actual setting at the PT-MT3. Both results should be within a specified tolerance and be stable over a number of repeated tests if the hardness tester works well. Also the testing time can be measured, this means the time when the strike arm or jaw of the hardness tester hits the load cell at the finger until breakpoint has been detected. This will allow qualifying instruments which run on a constant speed and force mode. In this case the time needed to break the magnetic finger should always be the same within minor tolerances.

1.1 How is it Different from Other Calibration Media?

In many other types of hardness tester calibration systems, the load cell is qualified by the use of another load cell. This load cell should be calibrated against a traceable standard. However, in operation these cells can be awkward to use and the result is simply a confirmation that the hardness tester load cell and the external load cell read the same force. The PT-MT3 offers an independent means of qualifying the load cell using a system which may be easily fitted into any of the hardness tester jaw areas of the PTB 302, PTB 502, PTB 111E, PTB 311E, PTB 411E, PTB 511E, PTB 420, WHT 3ME, including the ampoule hardness tester, the PTBA 211E and other manufacturers instruments. It is used to qualify the correctness of the break-point detection, linearity of the load cell readings of the hardness tester, and to qualify the correctness of the set force increase rate.

You can already easily calibrate the load cell of the hardness tester and the PT-MT3 using static means, i.e., by the use of a certified calibrated weight. In the case of Pharma Test units this can be achieved by the use of a PTB-CAL15. This is a 15kg calibrated weight which can also be used with individual weights of 5, 10 and 15 kg for instrument qualification. However, this is just a static calibration and does not represent a true picture of what is really a “dynamic” tablet testing system.

The PT-MT3 offers a dynamic validation option for hardness testers. So the operating system may be qualified as a whole rather than in component sections. Calibrating the load cell of the Hardness Tester is fine, but there is no indication as to the way in which the jaw mechanics are operating once it makes contact with the tablet and finally breaks it. With qualification points for the full range from 5 to 500N it covers the hardness range for the bulk of tablets available, the whole instrument’s reaction can be gauged over a realistic hardness test range.

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3 System Overview

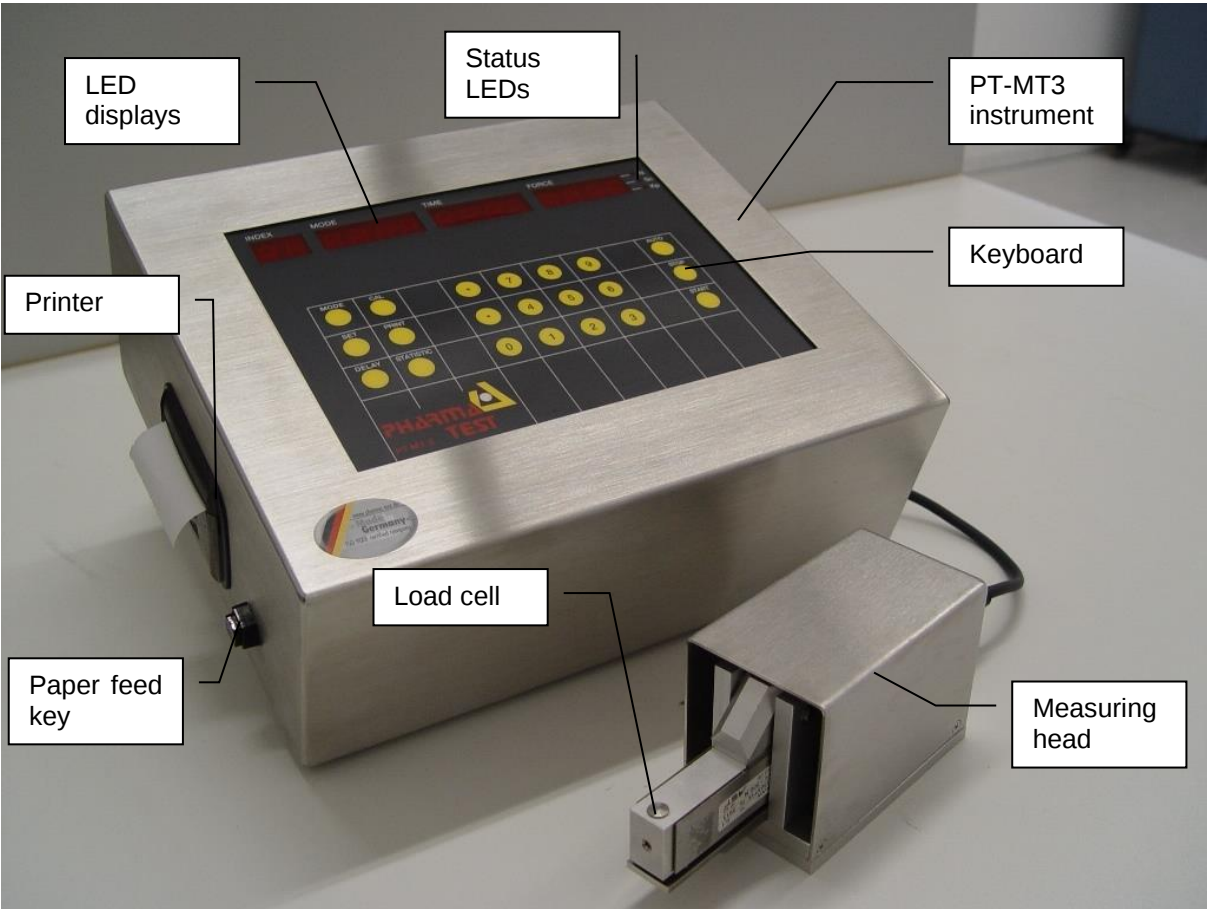


Figure 1: PT-MT3 Front View

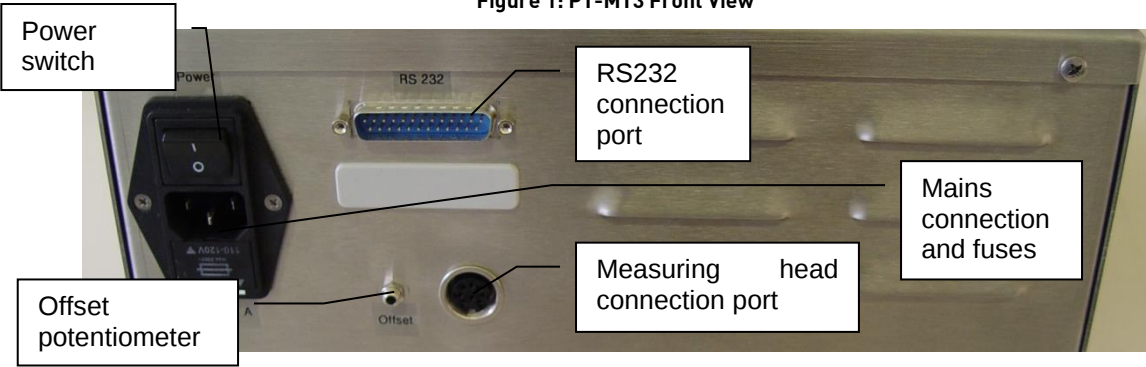


Figure 2: PT-MT3 Back Side Connections

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4 Setting Up the System

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

After the instrument is unpacked, please check the completeness using the supplied packing list, the delivery note, the IQ form and your order copy.

Cable connections are only allowed to be done when all instruments are switched off.

4.1 Connecting the Measuring Head to the Main Instrument

Connect the cable from the measuring head to the measuring head connection port on the backside of the PT-MT3 instrument:

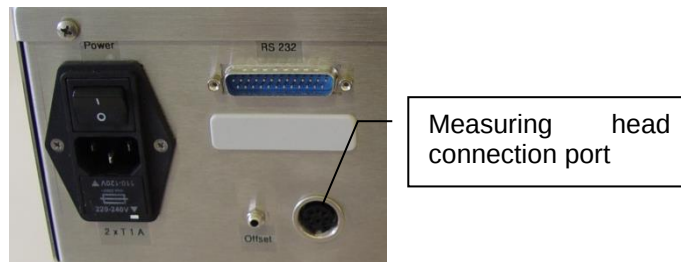


Figure 3: Measuring Head Connection

4.2 Connecting the Measuring Head to a Support

Connect the measuring head of the PT-MT3 to one of the supplied supports suitable to the hardness testing instrument you want to qualify with the PT-MT3. This example shows the support for PTB 302 and PTB 502 but you may proceed accordingly with any other support:



Figure 4: Measuring Head Normal State

The PT-MT3 measuring head in the normal state.

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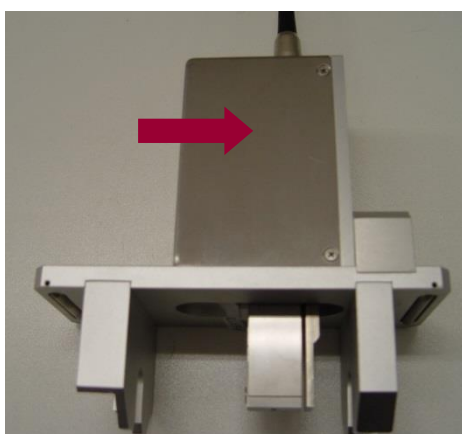
Measuring head, view from the side

Figure 5: Measuring Head Side view



Insert the measuring head from the top into the support.

Figure 6: Measuring Head Inserted



Push the support onto the locking rods thereby connecting it with the support.

Figure 7: Measuring Head Connected

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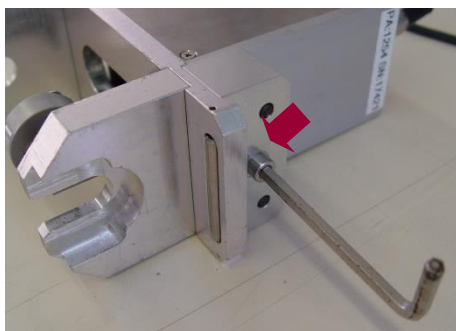


Figure 8: Measuring Head Screwed On

Screw the measuring head to the support.

4.3 Folding out the Instrument Stands

The PT-MT3 features two foldable stands, which can be used to operate the instrument from a more convenient angle:



Figure 9: Stand Folded In

The stands are located on the bottom of the instrument. There are two stands, one on the left side and one on the right side.

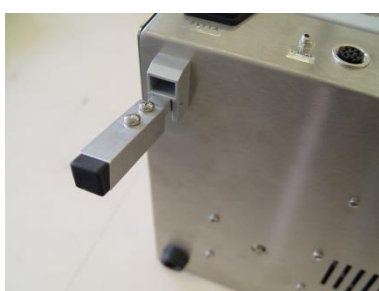


Figure 10: Stand Folded Out

Fold out both stands and turn the instrument over again, so that the stands are on the bottom side.



Figure 11: PT-MT3 Resting on Stands

The instrument rests at an angle on both stands.

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4.4 Connecting the Mains



Figure 12: Type Plate



Figure 13: Mains Connection



Before connecting the mains, make sure the instrument is laid out for the available voltage. You can check this on the type plate on the instrument's back.

Connect the mains cable to the power supply socket at the left side of the instrument's back.

Plug the other end into the power outlet.
You may now turn on the instrument at the mains switch.

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5 Using the PT-MT3

In order to use this testing instrument with the different hardness testing instruments manufactured by Pharma Test, we offer different supports for the PT-MT3 measurement head to use it with PTB 302, PTB 502, PTB 111E, PTB 311E, PTB 511E, PTB 420, WHT 3ME, WHT4 and PTBA 211E (ampoule hardness testing instrument). The supports are listed above in section 2.1.

In addition to the instructions below refer also to the manual of the tablet hardness testing instrument.

We recommend performing 50 tests per testing point with the PT-MT3 with instrument to be qualified. Please note that the first 15 tests of a series should not be used for any statistics or comparison, because it takes time to build up a stable magnetic field. After 15 tests stop the test series and start a new one. This time perform at least 50 tests in order to receive correct statistical information.

The starting frequency may not be shorter than the delay time set up at the PT-MT3. The default delay time setting of the PT-MT3 is 2 seconds; this means every two seconds a new test may be started at the hardness testing instrument. Document all results of the hardness testing instrument and calculate statistics of mean value, absolute and relative standard deviation.

Make sure that there is no pre-load of any kind on the load cell of the hardness testing instrument. To ensure this, push the magnetic tablet to the left or right side (depending on the hardness testing instrument) to relieve it. This can be disregarded when using the PT-MT3 with an ampule breakpoint testing instrument or with the WHT 3ME / WHT4 system, since here the force jaw itself is moved.

On the PTB 302, PTB 502, PTB 111E, PTB 311E, PTB 411E, PTB 511E and PTBA 211E you can set up a re-start time. This re-start time may not be set lower than the delay time set up at the PT-MT3. The test series has to be manually stopped on all of these instruments once the desired number of results has been recorded.

The PTB 420 has a fix time of about 2 seconds between two movements. The DELAY-time in the PT-MT3 must be set to 2 seconds also to match to the PTB420 instrument

To use the PT-MT3 in a WHT3-3ME or WHT4 instrument, the DELAY-time in the PT-MT3 must be set to 1 second because this tablet testers are very fast. See also section 5.7 and 8 about this.

Continue with the section below corresponding the the hardness testing instrument you want to qualify. Usage of the PT-MT3 and evaluating the results is also explained further below.

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5.1 Using the PT-MT3 with a PTB420, PTB420-500 or PTB 420 Auto Instrument

Insert the measuring head into the PTB420-support



Figure 14: measuring head in support

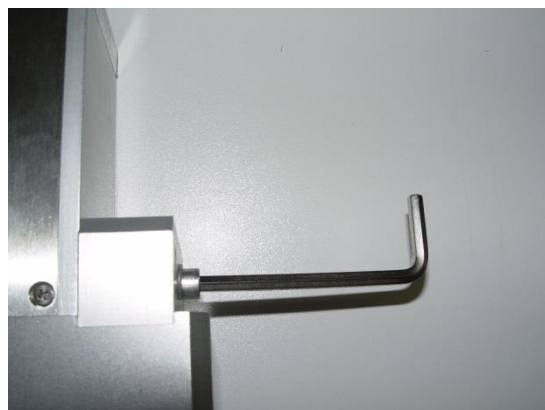


Figure 15: fixing the measuring head

Prepare the PTB420: Remove the black cover plate and set the PTB420 to Calibration: Break Detection

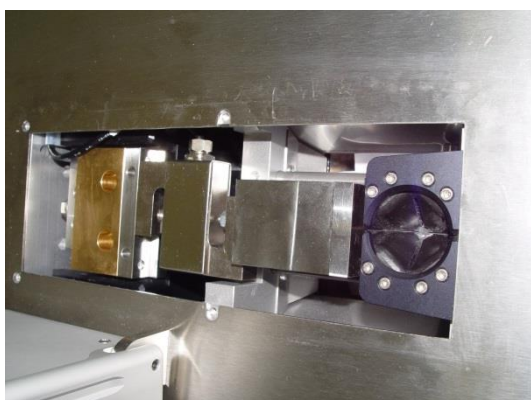


Figure 16: black cover plate removed

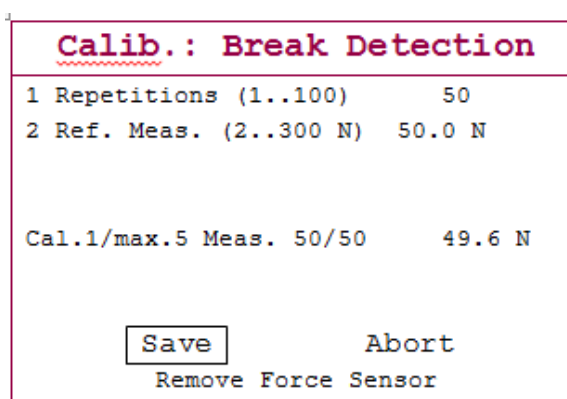


Figure 17: Menu in the PTB420: Calibration: Break Detection

The breaking chamber opens and releases the space for the measuring head. Insert the measuring head to the instrument.

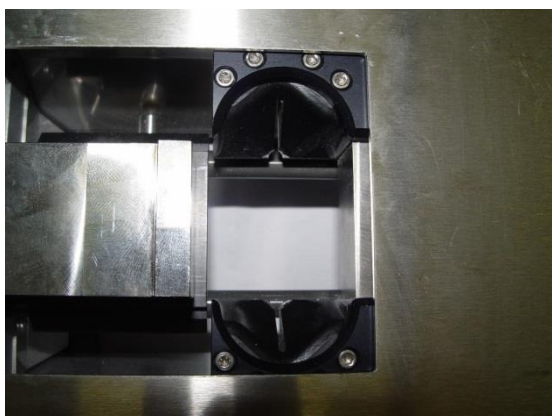


Figure 18: breaking chamber opened



Figure 19: measuring head in the PTB420

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5.2 Using the PT-MT3 with a PTB 302 or PTB 502 Instrument

Insert the measuring head into the support for PTB 302. Flip the testing station cover back. Insert the measuring head inside the support into the testing station of the PTB 302:



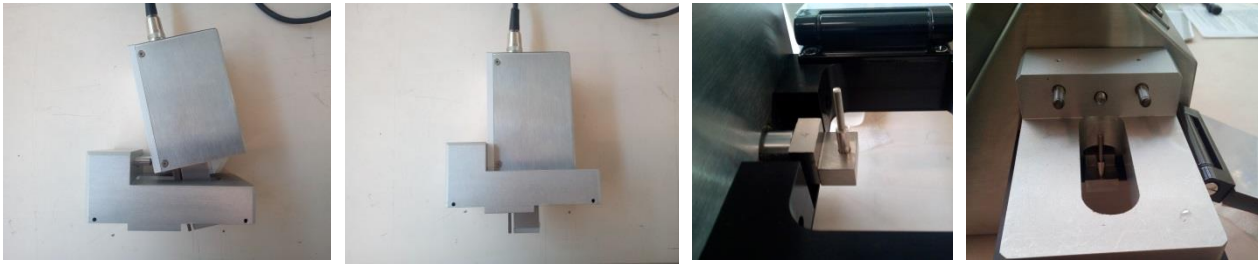
Figure 20: PT-MT3 and PTB 302

Now you can start a test series.

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5.3 Using the PT-MT3 with a PTB 111E or PTB 111EP Instrument

Use a pressure jaw size 4 with carrying rod (285-0017). Insert the measuring head into the support.



Insert the head as shown and fix it with the screw to the left (5mm Allen key).

The rod is to pull the measuring head back from the PTB-loadcell.

Figure 21: PTB111/311/511 support for MT3-usage

You may also remove the waste box to prevent any damage to it. We suggest using a plastic sheet to cover the metal surface of the black hardness test section to avoid scratches and to ease the movement of the electro-magnet when a test series is started.

Connect the measuring head with the corresponding support. Place the assembled head and support into the testing station of the PTB 111E/ EP, so that it is parallel to the direction of the force supply:



Figure 22: PT-MT3 and PTB 111E /EP

Now a test series can be started.

A special return pin is used to pull back the support holding of the electro-magnet of the PT-MT3 from the PTB load cell after a test. This prevents a stroke of the measuring head which could cause irreversible damage.

Set the PT-MT3 to a delay time of appr. 5s!

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5.4 Using the PT-MT3 with a 311E or 511E Instrument

Use a pressure jaw size 4 with carrying rod (285-0017). Insert the measuring head into the support.



Insert the head as shown and fix it with the screw to the left (5mm Allen key).

The rod is to pull the measuring head back from the PTB-loadcell.

Figure 23: PTB111/311/511 support for MT3-usage

You may also remove the waste box to prevent any damage to it. We suggest using a plastic sheet to cover the metal surface of the black hardness test section to avoid scratches and to ease the movement of the electro-magnet when a test series is started.

Connect the measuring head to the corresponding support. Place the assembled head and support into the testing station of the hardness testing instrument, so that it is parallel to the direction of the force supply.



Figure 24: PT-MT3 and PTB 311E

Set the thickness and diameter target values to "0" to turn off these testing stations (no thickness and diameter will be tested). Now a test series can be started.

It is important that after each test the support holding the electro-magnet is pushed backwards towards the moving jaw to release the load cell. If not results will be affected and will be incorrect. With the carrying rod this happens automatically. Set the PT-MT3 to a delay time of appr. 5s!

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5.5 Using the PT-MT3 with a WHT 3ME Instrument

WHT-3ME-instrument only!

To use the PT-MT3 with a WHT 3ME system, the flap movement of the WHT 3ME has to be switched off first. To do this a switch inside the WHT 3ME has to be pushed.

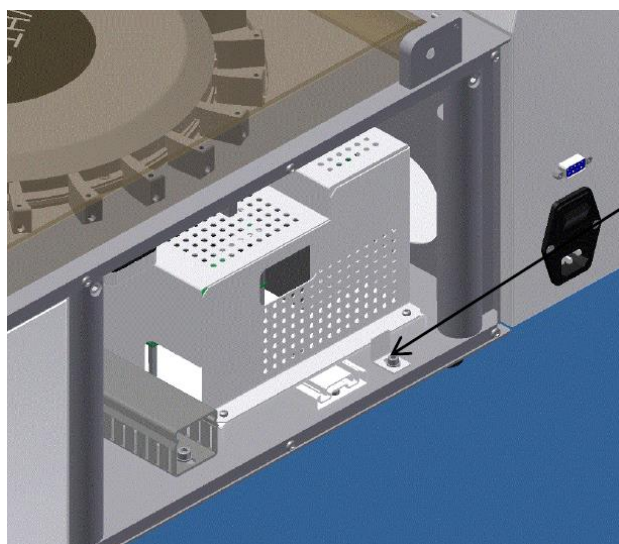
This switch is present in all WHT 3ME instruments with a serial number of 17825 or higher and can be retrofitted in older instruments by a service technician. Contact our technical support to learn more about retrofitting the WHT 3ME flap switch.

Call up the calibration menu in the WHT32 software. Open the flaps of the WHT 3ME by clicking the corresponding button in the software. Follow the steps below to push the flap switch:



Unscrew and remove the screws holding the right side cover of the WHT 3ME.

Figure 25: Remove Side Cover



Remove the movement blocking of the electronics pull out shute.

Figure 26: Remove Movement Blocking

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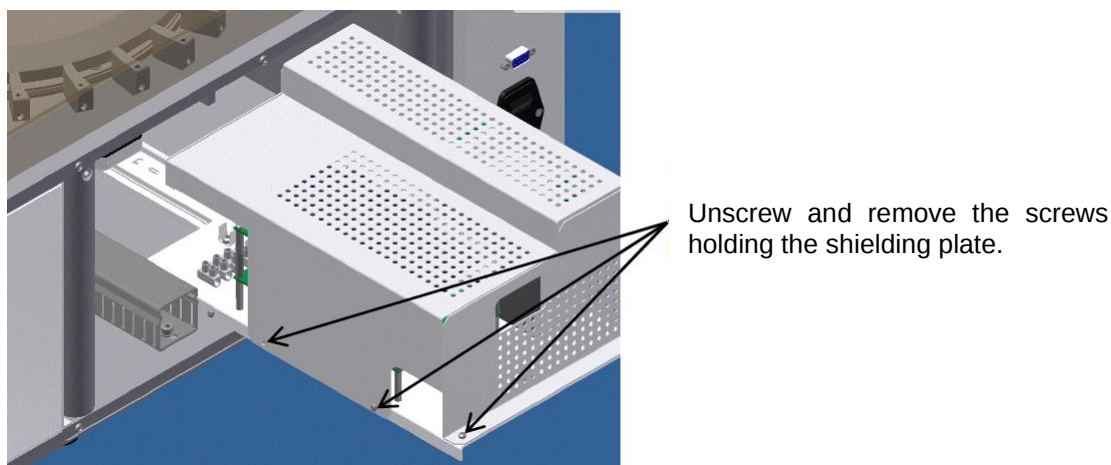


Figure 27: Open Shielding Plate

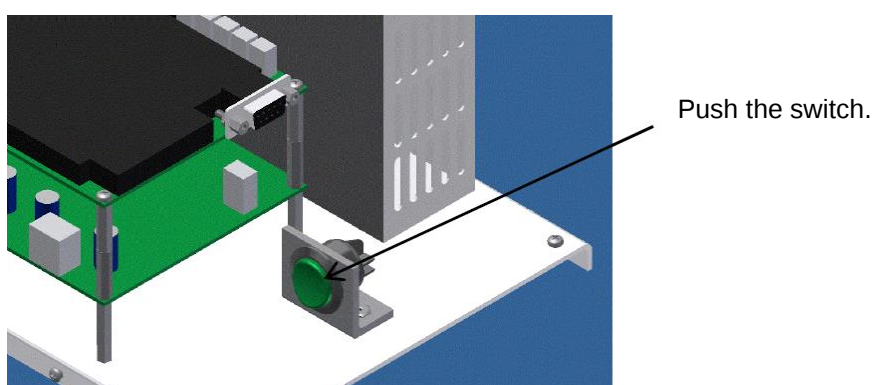


Figure 28: Push Switch

Open the plastic cover and remove the tablet carousel. Place a weight on the safety switch to hold it down. Otherwise an error message will appear on screen.

Continue with 5.7.

5.6 Using the PT-MT3 with a WHT 4 Instrument

Differently to the WHT-3ME system, the flaps needn't to be deactivated as described in section 5.5. The WHT4 doesn't have such a switch and it is not necessary to open the instrument. Just use button in the calibration menu to open the flaps. During hardness calibration procedure the flaps will remain opened.

Open the plastic cover and remove the tablet carousel. Place a weight on the safety switch to hold it down. Otherwise an error message will appear on screen.

Please note: the WHT4 must be initialized prior to any motor control. For this, the carousel must be inserted! So first initialize the WHT4 with(!) carousel on top, afterwards remove the carousel and perform the tests with the PT-MT3.

Continue with 5.7.

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5.7 Common for using the PT-MT3 with a WHT-3ME or a WHT 4 Instrument

Connect the measuring head to the corresponding support. Place the assembled head and support into the combined hardness/diameter testing station of the WHT 3ME / WHT4. Adjust the movable stands of the support that the measuring head doesn't wiggle and that the metal plate behind the load cell is parallel to the mechanical stop of the breaking chamber (the metal block at the left side in Figure 29).

The WHT-3ME and WHT4 instruments are very fast. **You must set the delay time in the PT-MT3 to 1s.** (push <DELAY> + <1> + <0> + <*>). Otherwise you will receive **Error 131** or **Error 133** in the PT-MT3 because the PT-MT3 tries to power the magnet while it is already pushed again by the next forward movement of the WHT.

As consequence of a wrong time setting here, **the WHT** can't detect a break, rises the force up to its maximum hardness, aborts and **reports "Invalid value occurred"**.

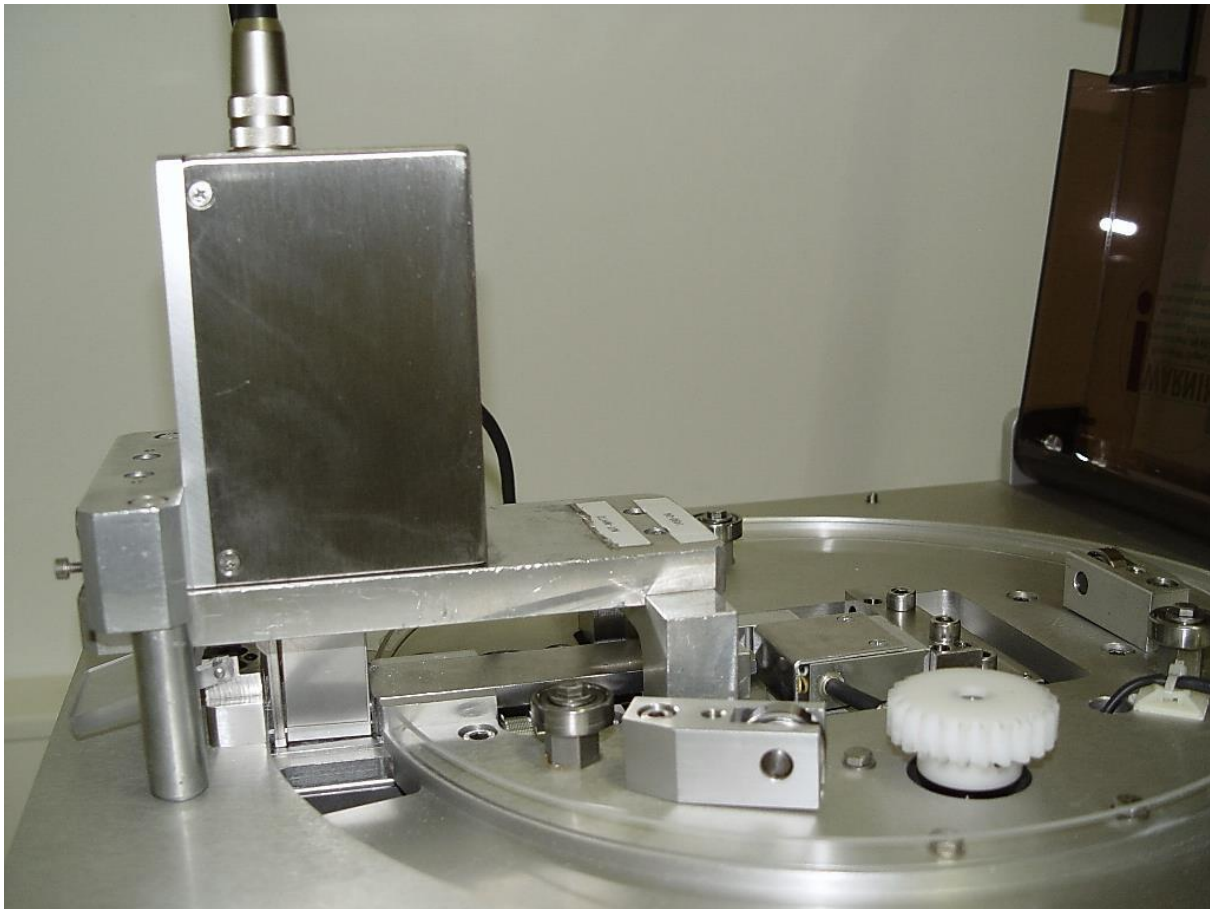


Figure 29: PT-MT3 and WHT 3ME / WHT4

Now you may start the calibration procedure.

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5.8 Using the PT-MT3 with a PTBA 211E Instrument

Insert the measuring head into the support for PTBA 211E. Insert the measuring head inside the support into the testing station of the PTBA 211E:

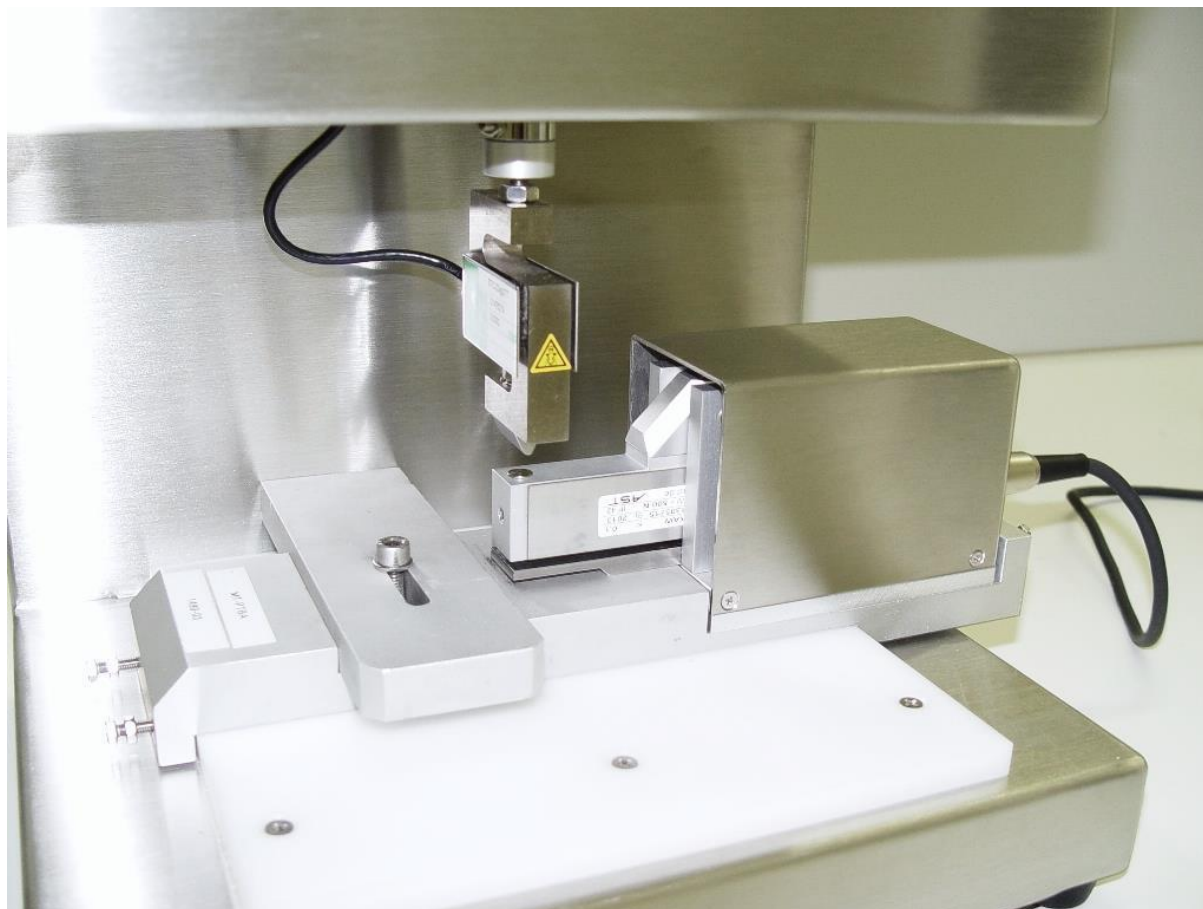


Figure 30: PT-MT3 and PTBA 211E

Now a test series can be started.

5.9 Using the PT-MT3 with another Instrument

To use the PT-MT3 with another instrument, not listed above, in case the instrument is an earlier type of the instruments listed above, follow the instructions for the current version. If you need additional information, contact our technical support.

In case you want to use the PT-MT3 with another brand of instrument, please contact our technical support to find out if a support this particular instrument is already available or if it is possible to design a suitable support.

Instrument Type	PT-MT3
Document Name	B-29-18050 PT-MT3 v1.5e
Revision No.	1.5
Author	PHARMA TEST Apparatebau AG
Valid from	11.06.2021
Change	R

5.10 Navigating the PT-MT3 Menus

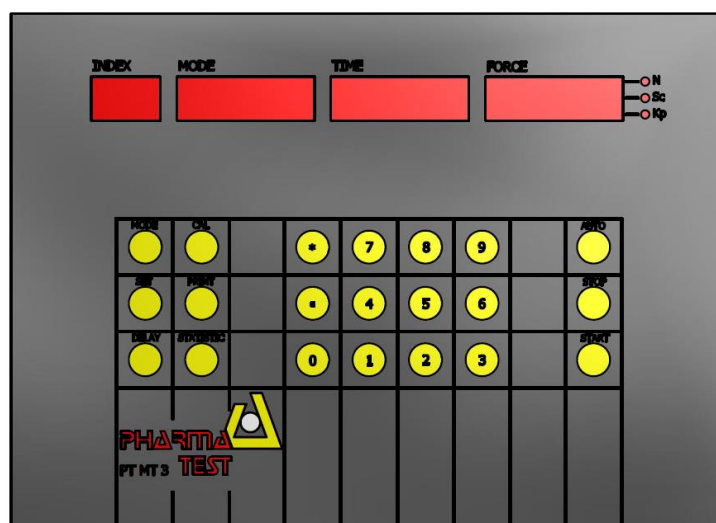


Figure 31: PT-MT3 Display and Keyboard Layout

5.10.1 Main Menu

After turning on the PT-MT3 enters the main menu. On the main menu you may enter commands as listed below.

5.10.1.1 Main Menu Commands

Refer to the table below for explanations on the commands of the PT-MT3 main menu:

Key or Key Combination	Function
<MODE>	Switch between mode A (force limit) and mode B (time limit) If mode A is selected, the MODE display shows: [] [A-F] [] [] If mode B is selected, the MODE display shows: [] [b-t] [] []
<SET>	Enter target value: Mode A – from min. 5.0 to max. 500.0N Mode B – from min. 1.0 to max. 120.0S
<DELAY>	Enter an auto delay value in seconds. When you press <DELAY> the display shows: [] [] [dLY] [xxx.x] “x” is the delay value in seconds. The default setting is 2 seconds.
<CAL>	Enter the setup menu
<PRINT>	Print out measurement results and statistics
<AUTO>	Switch between manual operation mode and remote operation mode via RS232 interface
<START>	Start a measurement run

Table 4: Main Menu Commands

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5.10.2 Setup Menu

From the main menu press <CAL> to enter the setup menu. From there you may enter the commands as listed below or press <CAL> again to return to the main menu.

5.10.2.1 Setup Menu Commands

Refer to the table below for explanations on the commands of the PT-MT3 setup menu:

Key or Key Combination	Function
<2>	Display the current ADC ¹ value and the conversion to the force unit Press <AUTO> to tare respectively switch back to untared raw data
<3> + <1>	Switch on the electro-magnet for testing, calibration or adjustment purposes
<3> + <0>	Switch off the electro-magnet
<4>	Switch between force units
<5> + <0>	Display date. Press <START> to edit date.
<5> + <1>	Display time. Press <START> to edit time.
<5> + <2>	Display qualification interval. Press <START> to edit qualification interval.
<6>	Display serial number
<7>	Enter touch force in digits from min. 48 to max. 999; default setting is 50N
<8> + <1>	Turn on serial output of force readings in 0.1s intervals over the interface; default setting is off
<8> + <0>	Turn off serial output of force readings; default setting is off
<9> + <1>	Turn on graphical print out of force readings in 0.1s intervals; default setting is off
<9> + <0>	Turn off graphical print out; default setting is off
<MODE>	Enter baud rate for RS232 communication Push <POINT> to select Push <STAR> to confirm Default setting is 2400 baud
<SET>	Enter adjustment menu
<DELAY>	Enter calibration menu
<PRINT>	Print out adjustment report
<STOP> + <1>	Serial output of EEPROM data to an external storage device for support purposes
<STOP> + <2>	Serial output of calibration characteristic curve for support purposes

Table 5: Setup Menu Commands

¹ ADC value: analog value from the load cell converted into a digital value

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5.11 Performing a Cycle of Measurement Runs

This section lists and explains the run menu commands and presents the sequence of a measurement run.

5.11.1 Run Menu Commands

Refer to the table below for explanations on the commands of the PT-MT3 run menu:

Key or Key Combination	Function
<SET>	Enter a target value (force or time, depending on mode of operation).
<START>	Start a measurement run
<STOP>	End a measurement run
<*> (STAR)	Confirm an entry
<.> (POINT)	Cancel the current result

Table 6: Run Menu Commands

5.11.2 Sequence of a Measurement Run

Below the sequence of a measurement run is explained:

1. Setting a Target Value

Select the measurement mode by using <MODE>.

Press <SET>.

The display shows:

[] [in] [Put] [yy.yy]

(Mode A constant force) resp.:

[in] [Put] [xx.xx] []

(Mode B constant time)

Use the numeric keys to enter the target value.

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

The display shows:

[] [A-F] [0.0] [100.0]

(Mode A constant Force) resp.:

[] [b-t] [10.0] [0.0]

(Mode B constant time)

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2. Starting a Measurement Run

Press <START>.

The display shows:

[01] [run] [] []

The magnet is turned on and waits until the touch force is reached. Then the run time and current force is displayed. The measurement run ends depending on the operation mode when either the force or time limit is reached. The maximum value is then displayed.

Press <STOP> to end the measurement run, proceed with step 5 otherwise proceed with step 3.

3. End of a Measurement Run

The display shows:

[01] [done] [xxxx] [yyyy]

The run ended after xxx.x seconds with a maximum force of yyy.y N.

Depending on the setting of serial output (<CAL>+<8>) and graphical printout (<CAL>+<9>), the force progression curve is printed and/or the individual force values are sent over the serial interface.

Press <POINT> to cancel the current result. The display shows:

[01] [clr] [xxxx] [yyyy]

Press <STOP> to accept the current result and to show the result report (see step).

After the auto delay has elapsed the next measurement run is started.

4. Result Report

The display shows:

[01] [stat] [xxxx] [yyyy]

The result report is printed out. In case there are at least two results, statistics are printed and the mean value is shown on the display in the format yyy.y N:

[01] [stat] [CAL] [yyyy]

Pressing any key now returns to the main menu.

5. Canceling a Measurement Run

The display shows:

[01] [StoP] [xxxx] [yyyy]

Press <STOP> to proceed with the result report (see step 4).

Press <START> to proceed with the next measurement run (see step 1).

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5.11.3 Sample Result Report

This is an example for a result report in mode A. In this example ten tests with a nominal value of 100N were performed:

RECORD OF MEASUREMENT ----- ADJUSTMENT SYSTEM PT-MT3 Ver. 01.00 E Time 15:18:57 Date 12.07.12 S/N 016289 ----- Operating Mode: Force Limit 100.0N Device under Test: S/N: ----- Results: <table border="0"> <thead> <tr> <th>No.</th> <th>t[s]</th> <th>F[N]</th> <th>No.</th> <th>t[s]</th> <th>F[N]</th> </tr> </thead> <tbody> <tr><td>1</td><td>4.51</td><td>100.1</td><td>2</td><td>4.54</td><td>100.6</td></tr> <tr><td>3</td><td>4.54</td><td>100.3</td><td>4</td><td>4.55</td><td>100.6</td></tr> <tr><td>5</td><td>4.54</td><td>100.3</td><td>6</td><td>4.55</td><td>100.3</td></tr> <tr><td>7</td><td>4.53</td><td>100.3</td><td>8</td><td>4.53</td><td>100.3</td></tr> <tr><td>9</td><td>4.55</td><td>100.3</td><td>10</td><td>4.53</td><td>100.3</td></tr> </tbody> </table> ----- STATISTICS: t[s] F[N] ----- Xmax Maximum 4.55 100.6 Xmin Minimum 4.51 100.1 Xdif Maximum – Minimum 0.04 0.5 Xmean Mean Value 4.54 100.3 Xabs Standard Deviation 0.01 0.16 Xrel relative 0.27% 0.16% ----- Operator: ----- <table border="0"> <tr> <td style="width: 50%;">Name</td> <td>Signature</td> </tr> </table> Released: ----- <table border="0"> <tr> <td style="width: 50%;">Name</td> <td>Signature</td> </tr> </table>	No.	t[s]	F[N]	No.	t[s]	F[N]	1	4.51	100.1	2	4.54	100.6	3	4.54	100.3	4	4.55	100.6	5	4.54	100.3	6	4.55	100.3	7	4.53	100.3	8	4.53	100.3	9	4.55	100.3	10	4.53	100.3	Name	Signature	Name	Signature	The firmware version of PT-MT3. Time, date and PT-MT3 serial no. Mode and nominal value The type and serial number of the hardness tester being used with the PT-MT3 may be entered here Results t[s] = Time in seconds F[N] = Force in Newton Statistics Xmax = Maximum Xmin = Minimum Xdif = Difference between max. and min. Xmean = Mean value Xabs = Absolute standard deviation Xrel = Relative standard deviation Name and signature of the operator. Name and signature of the releaser.
No.	t[s]	F[N]	No.	t[s]	F[N]																																				
1	4.51	100.1	2	4.54	100.6																																				
3	4.54	100.3	4	4.55	100.6																																				
5	4.54	100.3	6	4.55	100.3																																				
7	4.53	100.3	8	4.53	100.3																																				
9	4.55	100.3	10	4.53	100.3																																				
Name	Signature																																								
Name	Signature																																								

Figure 32: Sample Result Report – Mode A

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Author	PHARMA TEST Apparatebau AG
Valid from	11.06.2021
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This is an example for a result report in mode B. In this example ten tests with a nominal value of 5 seconds were performed:

RECORD OF MEASUREMENT ----- ADJUSTMENT SYSTEM PT-MT3 Ver. 01.00 E Time 15:43:15 Date 12.07.12 S/N 016289 ----- Operating Mode: Time Limit 5.0s Device under Test: S/N: ----- Results: <table border="0"> <thead> <tr> <th>No.</th> <th>t[s]</th> <th>F[N]</th> <th>No.</th> <th>t[s]</th> <th>F[N]</th> </tr> </thead> <tbody> <tr><td>1</td><td>4.97</td><td>111.0</td><td>2</td><td>4.99</td><td>110.4</td></tr> <tr><td>3</td><td>5.00</td><td>111.2</td><td>4</td><td>5.00</td><td>110.6</td></tr> <tr><td>5</td><td>5.00</td><td>110.9</td><td>6</td><td>5.00</td><td>110.1</td></tr> <tr><td>7</td><td>5.00</td><td>109.8</td><td>8</td><td>4.97</td><td>110.6</td></tr> <tr><td>9</td><td>5.00</td><td>110.4</td><td>10</td><td>5.01</td><td>110.6</td></tr> </tbody> </table> ----- <table border="0"> <thead> <tr> <th>STATISTICS:</th> <th>t[s]</th> <th>F[N]</th> </tr> </thead> <tbody> <tr><td>Xmax</td><td>Maximum</td><td>5.01 111.2</td></tr> <tr><td>Xmin</td><td>Minimum</td><td>4.97 109.8</td></tr> <tr><td>Xdif</td><td>Maximum – Minimum</td><td>0.04 1.4</td></tr> <tr><td>Xmean</td><td>Mean Value</td><td>4.99 110.6</td></tr> <tr><td>Xabs</td><td>Standard Deviation</td><td>0.01 0.42</td></tr> <tr><td>Xrel</td><td>relative</td><td>0.26% 0.38%</td></tr> </tbody> </table> ----- Operator: ----- <table border="0"> <tr> <td>Name</td> <td>Signature</td> </tr> </table> Released: ----- <table border="0"> <tr> <td>Name</td> <td>Signature</td> </tr> </table>	No.	t[s]	F[N]	No.	t[s]	F[N]	1	4.97	111.0	2	4.99	110.4	3	5.00	111.2	4	5.00	110.6	5	5.00	110.9	6	5.00	110.1	7	5.00	109.8	8	4.97	110.6	9	5.00	110.4	10	5.01	110.6	STATISTICS:	t[s]	F[N]	Xmax	Maximum	5.01 111.2	Xmin	Minimum	4.97 109.8	Xdif	Maximum – Minimum	0.04 1.4	Xmean	Mean Value	4.99 110.6	Xabs	Standard Deviation	0.01 0.42	Xrel	relative	0.26% 0.38%	Name	Signature	Name	Signature	The firmware version of PT-MT3. Time, date and PT-MT3 serial no. Mode and nominal value The type and serial number of the hardness tester being used with the PT-MT3 may be entered here Results t[s] = Time in seconds F[N] = Force in Newton Statistics Xmax = Maximum Xmin = Minimum Xdif = Difference between max. and min. Xmean = Mean value Xabs = Absolute standard deviation Xrel = Relative standard deviation Name and signature of the operator. Name and signature of the releaser.
No.	t[s]	F[N]	No.	t[s]	F[N]																																																									
1	4.97	111.0	2	4.99	110.4																																																									
3	5.00	111.2	4	5.00	110.6																																																									
5	5.00	110.9	6	5.00	110.1																																																									
7	5.00	109.8	8	4.97	110.6																																																									
9	5.00	110.4	10	5.01	110.6																																																									
STATISTICS:	t[s]	F[N]																																																												
Xmax	Maximum	5.01 111.2																																																												
Xmin	Minimum	4.97 109.8																																																												
Xdif	Maximum – Minimum	0.04 1.4																																																												
Xmean	Mean Value	4.99 110.6																																																												
Xabs	Standard Deviation	0.01 0.42																																																												
Xrel	relative	0.26% 0.38%																																																												
Name	Signature																																																													
Name	Signature																																																													

Figure 33: Sample Result Report – Mode B

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Author	PHARMA TEST Apparatebau AG
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5.12 Interpreting the PT-MT3 Results

To interpret the results of the PT-MT3, compare them to the results of the hardness testing instrument. The PT-MT3 is a tool to qualify the reproducibility of the break detection. This means the standard deviation of the results is the most important information here.

We recommend the following acceptance criteria and tolerances:

1. The standard deviation of the hardness testing instrument and the PT-MT3 is equal to or less than 1N for all testing points.
2. The difference between the mean values of each testing point of the hardness testing instrument and the PT-MT3 lies within a maximum deviation of:
 - a. 5% with nominal values of 30N to 100N
 - b. 3% with nominal values of over 100N to 500N

If the test results are outside the mentioned range you need to calibrate and possibly adjust the hardness testing instrument. For that consult the user manual of the hardness testing instrument. Also make sure that the mechanics to drive the force jaw is correctly moving with no detectable stops in between.

Repeat the qualification of the hardness testing instrument with the PT-MT3 after successfully completing the calibration and adjustment of the hardness testing instrument.

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6 Calibrating the PT-MT3

Turn on the PT-MT3 and let the instrument rest for approx. 30 minutes before you start the calibration. Do not activate the magnet of the PT-MT3 within this time.

The PT-MT3 calibration procedure is flexible and enables the user to freely enter the values of his reference weights and to decide how many calibration measurements should be performed. For the Pharma Test recommendation on which reference weights should be used see the OQ document provided with the PT-MT3 instrument.

6.1 Calibration Procedure

Permanently switch on the magnet by pressing <CAL> + <3> + <1> from the main menu.

To start the calibration of the PT-MT3 press <CAL> + <DELAY> in the main menu.

The display shows:

[CA] [tyPE] [reF] [xx.xx]

Enter the weight of the reference weight in the format xx.xx by using the numeric keys. For example when using a reference weight of 10kp enter <1> <0> <0> <0>. The display now shows:

[CA] [tyPE] [reF] [10.00]

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

The display then shows:

[CA] [10.00] [tarE] [xxxx]

This shows the digits being tared. Afterwards the display automatically changes to:

[CA] [10.00] [ACt] [00.00]

It shows the actual value measured by the load cell. Place the load cell on the load cell support:

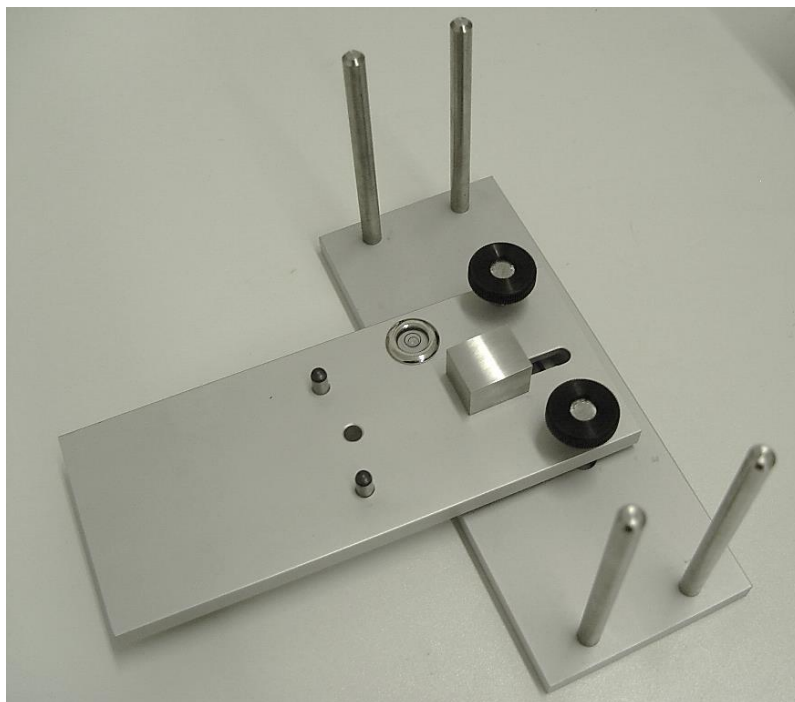


Figure 34: Load Cell Calibration Support

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Carefully place the reference weight on the load cell. Avoid dropping the reference weight on the load cell as this may cause damage to it. Lower the weight slowly and make sure that the reference weight rests on the tip of the load cell:

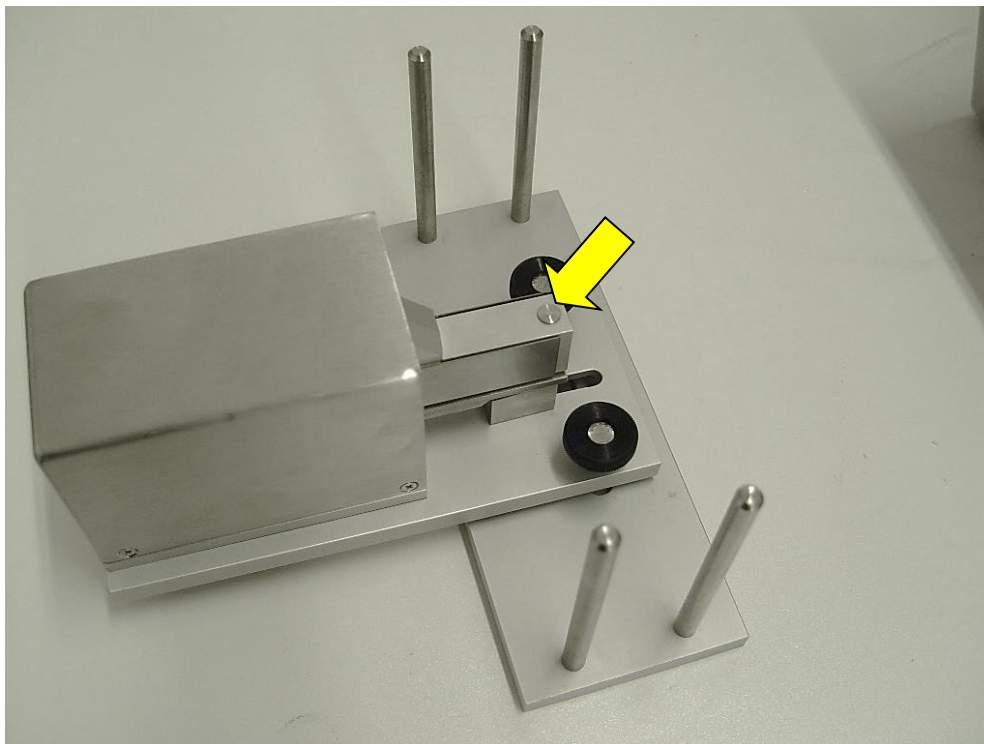


Figure 35: Load Cell on Calibration Support

If you use a certain form of the weight it is may necessary to increase the height of the calibration support to prevent any parts of resting on the table. The fully weight has to be on the load cell.

The display changes again to show the new value measured by the load cell with the weight placed on it. Press <START> to accept this calibration result.

Remove the calibration weight.

Press <START> to proceed the calibration with a new reference weight. Repeat the previous described steps for the new reference weight.

Press <STOP> after accepting the calibration result to end the calibration procedure. The calibration report is now printed automatically.

Finally switch off the magnet by pressing <CAL> + <3> + <0> from the main menu.

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6.2 Sample Calibration Report

```

** CALIBRATION REPORT **
-----
ADJUSTMENT SYSTEM PT-MT3 Ver.01.00.00 E
Time 14:46:23 Date 10.11.11 S/N 016289
-----
No  Ref Value  Act Value  Deviation
-----
1  10.00 kp   9.99 kp   -0.01 kp
    695 dig   694 dig   -0.10 %
-----

Operator:

-----
      Name      Signature
-----

Released:

-----
      Name      Signature
-----

```

The firmware version of PT-MT3.
Time, date and PT-MT3 serial no.

Nominal value, measured valid in Kilopond
and digits as well as deviation (absolute and
relative)

Name and signature of the operator.

Name and signature of the releaser.

Figure 36: Sample Calibration Report

In case the calibration results are outside the acceptable tolerances, the instrument has to be re-adjusted. The acceptable tolerance can be taken from the OQ document included in the supply scope of the PT-MT3.

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7 Adjusting the PT-MT3

Please note that a wrong adjustment leads to wrong measurements. Follow the below instructions completely and ensure that you are familiar with the use of the instrument.

The PT-MT3 supports a multiple point adjustment with up to five points.

In a first step permanently switch on the magnet by pressing <CAL> + <3> + <1> from the main menu.

Press <CAL> + <SET> on the main menu to start the adjustment of the PT-MT3. The display shows the current adjustment point in the following format:

[Cn] [xx.xx] [yyyy] [zzzz]

“n” is the number of the current adjustment point from 1 to 5. “xx.xx” is the adjustment point value in kg, “yyyy” is this value in digits and “zzzz” is the current ADC value.

In case the current adjustment point is free the display shows the following:

[Cn] [Fr.EE] [CAL] [zzzz]

Again, “zzzz” stands for the current ADC value.

7.1 Adjustment Menu Commands

Refer to the table below for explanations on the commands of the PT-MT3 adjustment menu:

Key or Key Combination	Function
<0>	Delete the currently displayed adjustment point. The remaining adjustment points will be sorted again. Free adjustment points are moved to the end of the list.
<1> ... <5>	Select the adjustment point from 1 to 5.
<CAL>	Set the currently displayed adjustment point which has to be free.
<POINT>	Display the next adjustment point
<AUTO>	Tare, i.e. calculate the offset (for testing purposes).
<STOP>	Finish the adjustment process.

Table 7: Adjustment Menu Commands

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Author	PHARMA TEST Apparatebau AG
Valid from	11.06.2021
Change	R

7.2 Sample Adjustment Report

** ADJUSTMENT REPORT **		

ADJUSTMENT SYSTEM PT-MT3 Ver.01.00.00 E		The firmware version of PT-MT3.
Time 14:12:36 Date 10.11.11 S/N 016289		Time, date and serial no. of the PT-MT3

Specification Setting Cell Mounted		

Act. Offset 45 Dig 12.. 52 Dig		Load cell offset
Touch Detect 50 Dig		Touch detection force

No Weight Adjustment Cell Upright		

1 5.00kg 344 Dig 331.. 404 Dig		Adjustment values of the used weights in digits, as well as the range of accepted values as evaluation criteria
2 10.00kg 694 Dig 662.. 809 Dig		
3 15.00kg 1018 Dig 993..1214 Dig		
4 20.00kg 1389 Dig 1324..1619 Dig		
5 25.00kg 1695 Dig 1656..2024 Dig		

Operator:		

Name	Signature	Name and signature of the operator.
Released:		

Name	Signature	Name and signature of the releaser.

Figure 37: Sample Adjustment Report

7.3 Setting a New Adjustment Point

Select a free adjustment point or delete an existing one. Then press <CAL> to set the currently selected adjustment point. The display shows:

[cn] [ty.PE] [reF] [zz.zz]

Enter the reference weight value in the format zz.zz within the unit kp. The range is from min. 1kp to max. 50kp. The new adjustment point has to differ at least 1kp from all other existing adjustment points, otherwise the following error message is displayed and the instrument returns to the start of the adjustment menu:

[Cn] [Err] [uSEd] [reF]

Otherwise the display shows:

[Cn] [xx.xx] [tArA] [zzzz]

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Tare the weight of xx.xx Kg to calculate the offset of zzzz. In case the offset is too high or too low, the display shows:

[Cn] [xx.xx] [tArA] [tooH] in case the offset is too high or:

[Cn] [xx.xx] [tArA] [tooL] in case the offset is too low

The instrument then returns to the start of the adjustment menu.

Otherwise the following step is the weighing of the adjustment weight. The display shows:

[Cn] [xx.xx] [reF] [zzzz] in case the adjustment weight is in the acceptable range.

In case the the adjustment weight is outside the acceptable range the display shows either:

[Cn] [xx.xx] [tooL] [zzzz] in case the adjustment weight is too low, or:

[Cn] [xx.xx] [tooH] [zzzz] in case the adjustment weight is too high.

Press <STOP> at this point to cancel the weighing of the adjustment weight and to return to the start of the adjustment menu.

Press <START> to accept the weighing result of the adjustment weight if it is inside the acceptable range. The display then shows:

[Cn] [xx.xx] [zzzz] [done]

This means the new adjustment point has been set. Any key leads to a return to the start of the adjustment menu.

In case a proportionality error is detected (i.e. a heavy weight has a low ADC value) by the instrument, the display shows:

[Cn] [Err] [no] [ProP]

Any key returns to the start of the adjustment menu and the new adjustment point is cancelled. Finish the adjustment procedure with pressing <STOP> twice.

The display shows [] [CAL] [SurE] [0]

Press <1>: display shows [] [CAL] [SurE] [1]

Press <*>: the display shows [00] [0000] [0000] [0000], indicating that you are in the main menu again.

Finally, permanently switch off the magnet by pressing <CAL> + <3> + <0> from the main menu.

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Revision No.	1.5
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Change	R

8 Trouble Shooting and Error Messages

Refer to the section below for explanations on error messages displayed by the instrument and for general trouble shooting information. Please read this section carefully in case of any troubles with the instrument and before contacting our support.

8.1 Error Messages

In case an error occurs during a measurement run, the run is cancelled and the error message is displayed in the following format, where yyy stands for the error number:

[01] [StoP] [Err] [yyy]

If an error message is display, press <STOP> to proceed with the result report or press <START> to proceed with the next measurement run.

Refer to the table below for explanations of the individual error numbers:

[„ADC“ = „Analog-Digital-Converter“; Description: measurement of the loadcell value]

Error Number	Explanation
128	ADC timeout during offset measuring
129	ADC internal electronic failure
130	ADC offset too low (<12)
131	ADC offset too high (>52)
132	ADC maximal value reached
133	Measuring mode A: force limit reached Measuring mode B: max. measurement time of 120 seconds exceeded

Table 8: Error Messages

8.2 Trouble Shooting

Error	Solution
The PT-MT3 does not turn on.	1.) Mains connection is faulty Check is main connections is present and properly connected
	2.) The fuse is blown Check the fuse and replace it if necessary

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The PT-MT3 keeps displaying error number 131.	This error message means that the offset of the instrument's load cell is too high. Turn on the instrument. <u>Make sure that the PT-MT3 load cell is not loaded somehow, e.g. because the measuring head "stands" upright on the load cell.</u> Press <CAL> + <2>. The current load cell offset is displayed. This should be between 12 and 52. If the displayed value is outside of this range, proceed with the next step. If the value is within this range and still the error code is displayed the CPU board may be defective. Use the potentiometer on the back side of the instrument to set the offset to ~32:  Figure 38: Adjusting the load cell offset Check the performance of the instrument.
While using the PT-MT3 in a WHT instrument, after the first break it shows error number 133.	Set the delay time to 1s (see section 5.7)
The PT-MT3 shows "no CAL dAtA" when being started and the magnet can't be switched on.	Follow to the service instruction "PT-MT3: Reactivation - all adjustment points deleted"

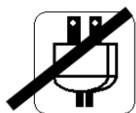
Table 9: Trouble Shooting

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9 Safety Information



Before you open the Instrument always remove the mains cord from the mains socket. Only authorized personnel 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

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