ERWEKA

Instruction Manual

Tablet Hardness Tester TBH 325-425

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ERWEKA

Instruction Manual
Tablet Hardness Tester
TBH 325-425

Table of Contents

1 – Introduction

Thank you for purchasing the ERWEKA tablet hardness tester of TBH 325-425 series!

1.1 – About this instruction manual

This instruction manual supports you in work with your ERWEKA device. It describes the device, its operation and gives you useful tips on its handling. Furthermore, read descriptions of installation and setting as well as detailed step-by-step work operations in the present manual. Pictures facilitate the understanding of processes described here.

NOTICE The instruction manual is a part of the product. Read this manual completely and make sure you understand its content. Keep this manual in a safe place so that it will be available for any questions at a later date. This is important for warranty of permanent and accurate operation of the corresponding device.

Optionally there is the possibility to control ERWEKA tablet hardness testers via MC.NET software and to perform the calibration of the devices with AutoCal. Then for operation of the device the user‘s guides of MC.NET and AutoCal are valid additionally besides this manual.

NOTICE For operation of a TBH 325-425 with MC.NET or AutoCal this instruction manual is valid only in connection with the corresponding user‘s guides!

The editorial team of ERWEKA appreciates your feedback regarding the present manual. Just send an e-mail to *quality@erweka.com* with your topic and “technical documentation” as a subject. Your reply contributes to our high quality level.

1.2 – Service

Contact ERWEKA at *service@erweka.com* to order the spare parts, in case of technical questions or possible repairs. Please supply the following information:

- Type of the device (on the type label)
- Serial number of the device (on the type label)
- Short description of the case

1.3 – Safety instructions and symbols

WARNING indicates a possible hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION indicates a possible hazardous situation which, if not avoided, could result in moderate or minor injury.

HAZARD due to electric shock! Indicates a possible hazardous situation which, if not avoided, can lead to injuries due to electric shock.

This symbol indicates a possible hazardous situation which, if not avoided, can lead to equipment damage.

This symbol emphasizes the information to ensure a smooth work process.

This symbol provides you with additional useful information.

1.4 – Protection of the environment

Note that residues of the test products must be properly disposed of in accordance with the applicable environmental regulations. According to the valid EC directives all the electrical parts (electrical waste) must be disposed of appropriately.

2 – Safety

2.1 – Safety information

To guarantee the health and safety, read the following safety instructions before using the device.

WARNING
Danger of springing fractions! During a test, fractions of samples can spring off.
Wear personal protective outfit and glasses!

HAZARD due to electric shock! Electric devices are to be plugged into safety sockets only! Use the delivered network cable! The voltage of the existing current supply is to be compared to the indications on the type label!
Before installation works always switch the corresponding device off and disconnect it from the rear panel.

CAUTION
Clamping, squeezing!
During a test, parts of the body (e.g. fingers) can be clamped between the jaws. Place the samples always with a pincette or similar appropriate tool. Remove the tablet remains steadily with a brush (delivery scope).

CAUTION
Enwraping, moving parts! Hair and clothes can be entangled in the TBH 425 with thickness measurement station. Tie long hair back. Do not wear any long necklaces, bracelets etc. Wear only the clothes with tightly fitting sleeves.

NOTICE ERWEKA devices should be operated by qualified and trained personnel only!

Pay attention to the on-site safety instructions for work in the laboratory and with the laboratory equipment!

2.2 – Intended use

ERWEKA tablet hardness testers of TBH 325-425 series should be used only for measuring weight, thickness, diameter/length and hardness of solid formulations, e.g. tablets, dragees or oblongs, in the installation environment defined by ERWEKA.

ERWEKA devices should not be used for processing:

- products that are easely flammable or explosive
- products that develop vapours which may create flammable or explosive mixtures in combination with air
- products that release harmful or poisonous substances

The device should be operated and maintained only as it is foreseen and due to the instructions presented in this manual.

3 – Overview

3.1 – Description

ERWEKA tablet hardness testers of the TBH 325-425 series are compact devices for automatic measurement of hardness as well as optionally diameter, weight and thickness of tablets and similar solid dosage forms. The devices habe been developed for the in-process and quality control department.

The hardness measurement of tablets plays an important role in their formulation and production. The hardness measurement on the base of two different measuring principles (constant speed, constant force) can be performed with the devices of the TBH 325-425 series.

As opposed to the TBH 325 series, the TBH 425 devices are equipped with a 10-chamber star magazine for the fully automatic measurement of up to 10 samples. In the devices of TBH 325 series the tablets must be placed for each measurement in the measurement stations manually.

In both device series the nominal hardness values can be indicated with 3 individual plus/minus tolerances (T3 = pass/fail criteria) for up to 50 different products, stored and called for a measurement using the alphanumeric foil keypad. The stored product data can be transferred via a SD card or USB stick to other TBH 325/425 devices.

The calibration is completely menu-guided and can be performed with calibration weights or the electronic ERWEKA AutoCal system (available separately). A printer can be connected via a standard USB printer interface to make hard-copy documentation possible. The LAN/USB interface makes the connection to a computer with the optionally available MC.NET software for external operation possible. At the same time the TBH 425 series is 100% conform to 21 CFR 11 for operation via a PC with MC.NET.

The measurement range corresponds to the general market standard. Up to 100 tablets can be measured per test run. Measurement values and evaluations are shown on the illuminated LC display, can be printed out directly or forwarded to the ERWEKA WinPrint software. It is possible to store up to 50 products.

3.2 – Device types

3.2.1 – Overview

<u>325 series</u>

Function	TBH 325	TBH 325 D	TBH 325 TD	TBH 325 WTD
Hardness measurement	+	+	+	+
Diameter/length measurement	-	+	+	+
Thickness measurement	-	-	+	+
Weight measurement	-	-	-	+

<u>425 series</u>

As opposed to the TBH 325 series, the TBH 425 devices are equipped with a magazine for the automatic measurement of up to 10 samples and in connection with the operation via MC.NET are 100% 21 CFR 11 conform.

Function	TBH 425	TBH 425 D	TBH 425 TD	TBH 425 WTD
Hardness measurement	+	+	+	+
Diameter/length measurement	-	+	+	+
Thickness measurement	-	-	+	+
Weight measurement	-	-	-	+

3.2.2 – Pictures of the device types

TBH 325

TBH 325 TD

TBH 425

TBH 425 TD

TBH 325 D

TBH 325 WTD

TBH 425 D

TBH 425 WTD

3.2.3 – Description of the type features

TBH 325/ TBH 425

The basic devices of this series. The hardness can be measured with them. The series differ in that the devices of the TBH 425 series compy with the 21 CFR 11 (when operating with MC.NET) and are equipped with a magazine for the automatic measurement of up to 10 samples. As opposed to this, in the devices of TBH 325 series a quick validation without conformity is possible. Because in the TBH 325 the samples are placed manually in the measurement station, you can measure the solid formulations of various kinds.

TBH 325 D / TBH 425 D

These devices are similar to the basic devices and additionally offer the possibility to measure and document diameter/length of the sample. You can also verify that the sample was placed in the correct position for the hardness measurement.

TBH 325 TD / TBH 425 TD

TBH 325 TD offers you the possibility to measure the diameter/length automatically and the thickness of the sample half-automatically. For the determination of thickness the sample is placed under the thickness gauge. The thickness measurement station is manually lowered after that. The measurement of the diameter/length as well as the hardness is performed later by placing the sample before the jaw.

The TBH 425 TD offers you additionally to the basic device the possibility to measure the diameter/length and the thickness of the sample by means of a calibrated electronic linear potentiometer fully automatically (full automatic transportation of the samples to the thickness and hardness/diameter measurement stations).

With the TBH 325 TD / 425 TD devices it is possible to print out up to 3 measurement parameters (thickness, diameter and hardness). This can be done with an externally connected printer, the WinPrint software via the network or the MC.NET software. The results can be displayed in N (Newton), KP (Kilopond) and Sc (Strong Cobb) as well as in mm and inch.

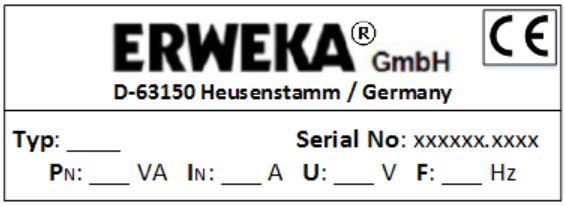
TBH 325 WTD / TBH 425 WTD

The TBH 325/425 WTD devices are similar to the TBH 325/425 TD devices but additionally give the possibility to determine the weight of the sample with an external analytical balance.

There is an analytical balance by Sartorius or Mettler for selection, both are equipped with a windshield (weighing range from 20.00 mg to 64.00 g; accuracy ± 0.1 mg; Sartorius balance with built-in calibration weight). Before the measurement of the other parameters the sample is placed manually on the balance. The weight is measured and transferred to the device‘s electronics. Then the weighed sample is transported in the thickness measurement station (TBH 325 WTD) or the corresponding chamber of the magazine (TBH 425 WTD).

3.3 – Type label

The type label is placed on the rear panel of the device and contains following data:



Typ: Device type
Serial No: Serial number
P_N: Normal output in Watt [W] or Volt Amper [VA]
I_N: Nominal current in Amper [A]
U: Voltage in Volt [V]
F: Frequency in Hertz [Hz]

3.4 – Construction

Pict.: TBH 325 WTD

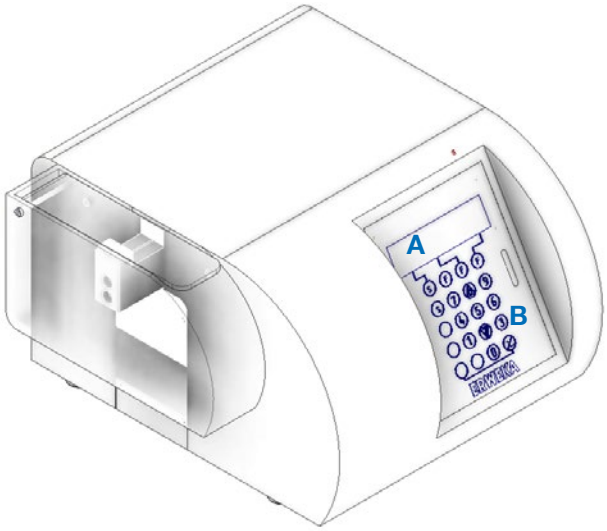
1) Manual thickness gauge
2) Hardness and diameter measurement station
3) Collection container
4) LC display with foil keypad
5) Balance

Various connections as well as mains switch are located on the right of the device and on the rear panel. Read more in *3.5 – Operation elements and connections*.

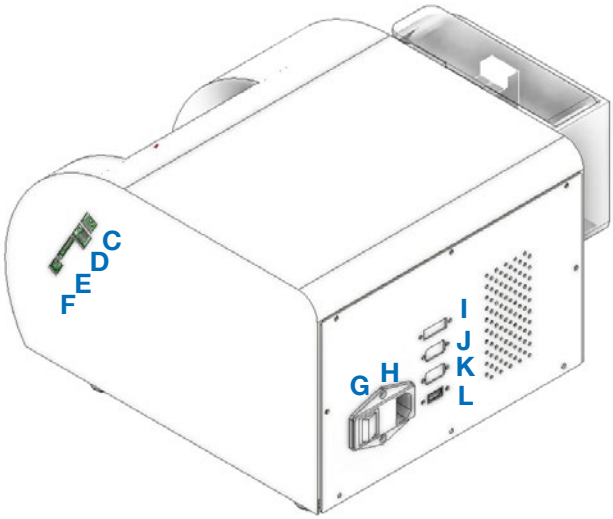
Pict.: TBH 425 TD

1) Thickness measurement station
2) Hardness and diameter measurement station
3) Magazine
4) LC display with foil keypad
5) Collection container

3.5 – Operation elements and connections



Pict.: TBH 325 from the left with the device's front panel,



from the right with the device's rear panel

A) LC display
B) Foil keypad
C) USB B port (PC)
D) LAN port
E) Port for SD card
F) USB A port (e.g. for printer)
G) Mains switch
H) Power supply
I) Port for manual thickness gauge
J) RS 232 interface
K) Port for balance
L) USB A port

3.5.1 – Keypad and display

Pict.: Keypad with LC display

Keys	Description/Function
A - Z, 0 - 9	To enter text and figures
2 8	Arrow keys: To select a menu or an option, to scroll through the menus
␣	To create a space when entering text or figures
CL	To close a menu or window, to clear a wrong entry
ENTER	To confirm the entry or command

Each data input is confirmed with a beep tone.

Example for entering texts on the word „TEST“:

1. Press **8** once ⇨ **T**
2. Press **3** two times ⇨ **E**
3. Press **7** four times ⇨ **S**
4. Press **8** once ⇨ **T**

3.6 – Technical data

	TBH 325 series	TBH 425 series
Dimensions [mm]:		
Width/Height/Depth	350 / 310 / 375	350 / 240 / 375
Weight:		
	10 kg	15 kg
Display/keypad:		
	240 x 64 dot LC display, touch-sensitive alphanumeric foil keypad	
Data storage:		
	50 products, entry of individual ±T1/T2/T3 tolerances, transfer of product data between devices by SD card or USB memory stick	
Measuring priciple:		
	Load cell with wire strain gauge, constant speed or constant force (10 - 200 N/s) with step motor	
with constant speed	0.1 – 3.00 mm/s	0.05 – 3.00 mm/s
Autoposition device:		
		Optional alignment of odd-shaped samples
Throughput:		
	1 – 100 samples per test, preselectable, 6 to 8 samples per minute	
Hardness measurement station:		
	3 – 500 N (optional 1000 N), accuracy: ± 1 N; Newton, Kilopond or Strong Cobb selectable	
Diameter/length measurement (optional):		
	2 – 28 mm (opt. 70 mm), accuracy: ± 0.05 mm; mm or inch selectable	2 – 28 mm, accuracy: ± 0.05 mm; mm or inch selectable
Thickness measurement (optional):		
	manual; 0.10 – 12.00 mm, 0.10 – 25.00 mm, accuracy: ± 0.05 mm; mm or inch selectable	linear potentiometer; 0.10 – 10 mm, accuracy: ± 0.05 mm; mm or inch selectable
Weight measurement (optional):		
	External balance, 20.0 mg – 64.0 g, accuracy: ± 0.1 mg	
Magazine (star shape):		
	—	up to 10 samples Ø max. 28 mm, up to 21 samples Ø max.15 mm (optional), oblong max. 28 mm length
Power supply:		
	100 – 240 VAC ± 10 % / 50 – 60 Hz / 100 W	
Safety protection:		
	IP 21 according to ICE 529	
Fuses:		
	115 V / 250 V, 2 x 3.15 A	
Interfaces:		
	SD card, Ethernet (LAN), RS 232 C (optional), USB A printer interface	
Printer:		
	Compatible printer upon request	
Calibration:		
	Completely menu-guided, calibration weights should be ordered separately (static calibration), optional: AutoCal 2.0 (dynamic calibration)	
Documentation:		
	Available via external printer (USB A), network printer (WinPrint software) or MC.NET	

4 – Installation

4.1 – Storage and transport conditions

The device should not be exposed to punches and vibrations.

Temperature and humidity should not be lower or higher than the values defined by ERWEKA (see *4.3.3 – Required installation environment*).

4.2 – Unpacking and checking

Upon receiving the delivery, check that no physical damage has occurred to the packaging and device during the transportation.

If available, check the tilt indicator label for undue turning of the packaging. In case of 60° inclination the colored quartz sand flows into the display field and is visible there.

If undue transporting or any damage is evident, take a photo of this and send it to our ERWEKA *Service* immediately.

Check the completeness of delivered device with the help of the following list. Ensure that no part fails and all parts are received in working and good condition.

Name	TBH 325	TBH 325 D	TBH 325 TD	TBH 325 WTD
Device	+	+	+	+
Network cable	+	+	+	+
Balance	-	-	-	+
Instruction manual	+	+	+	+
Thickness gauge	-	-	+	+
Calibration device	+	+	+	+

Name	TBH 425	TBH 425 D	TBH 425 TD	TBH 425 WTD
Device	+	+	+	+
Network cable	+	+	+	+
Balance	-	-	-	+
Instruction manual	+	+	+	+

+ available

- unavailable

4.3 – Installation

4.3.1 – Positioning

Position the device on a horizontal, plane, stable surface, e.g. on a laboratory table, and pay attention so that not to displace it during the operation.

For operation and access, when positioning the device, pay attention to the sufficient distance to the walls, cabinets or other fixed components of the facility.

Besides sticking to the requirements for installation environment defined by ERWEKA, avoid the following:

- Heat (heating, insolation)
- Direct draught through open windows, doors or air conditioning and ventilating systems
- Shaking
- Dampness

4.3.2 – Acclimatization

When a cold device is taken into the warm environment, this can lead to the condensation. Therefore, acclimatize the switched off device during approximately 2 hours at the room temperature.

4.3.3 – Required installation environment

Ambient temperature in operation:	+10°C up to +30°C
Storage and transport temperature:	-10°C up to +55°C
Relative humidity:	25-80% no condensation
Max. operating altitude (for balances):	3000 m above NN

4.4 – Connecting the device and its first switching on

Connect the device (on the rear panel) with a safety socket. Use the delivered network cable for this purpose.

HAZARD due to electric shock! Electric devices are to be plugged into safety sockets only!
The voltage of the existing current supply is to be compared to the indications on the type label!

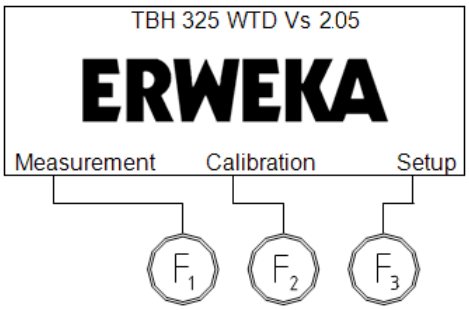
ERWEKA accepts no liability in case of wrong connection!
Defective devices should be opened by the manufacturer or authorized staff only!

If you are using an external printer, connect it with the USB A port of the device.

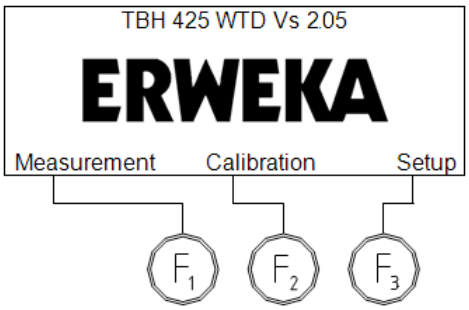
4.4.1 – Switching the device on

For switching on set the mains switch on the device‘s rear panel to I (on).

The start screen is shown.



Pict.: TBH 325 WTD with firmware version 2.05



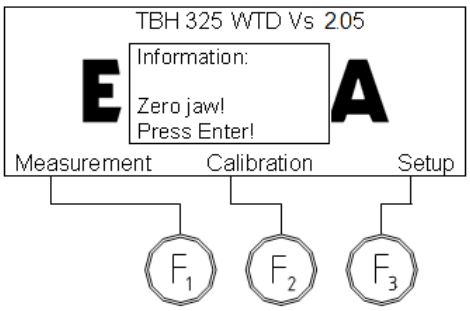
TBH 425 WTD with firmware version 2.05

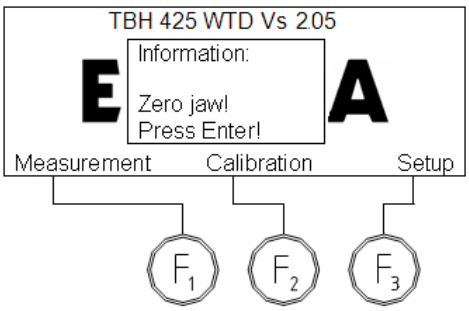
The device type and firmware version installed currently can be seen in the upper part of the screen.

The start screen shows the number of firmware version. Keep this information ready when you contact ERWEKA service department with questions about the device.

4.4.2 – Zeroing

After a second the following message is shown:





Press ENTER on the keypad to start the zero adjustment of the device.

CAUTION
Danger of squeezing!
During the zeroing procedure the jaw is moving. Do not touch the measurement station!

Now the jaws and, if available, the thickness gauge and magazine plate are zeroed. (The movable jaw moves to the fixed jaw, measures the zero point and returns to its initial position.)

In case of dust or inappropriate distance the jaw cannot be zeroed. The following error message appears:

Error:
Zeroing jaw was unsuccessful!
Clean jaw, if necessary justify diameter with START!

Clean the jaw and press START to adjust the diameter. More information you will find in section *7.1.3 – Diameter calibration*.

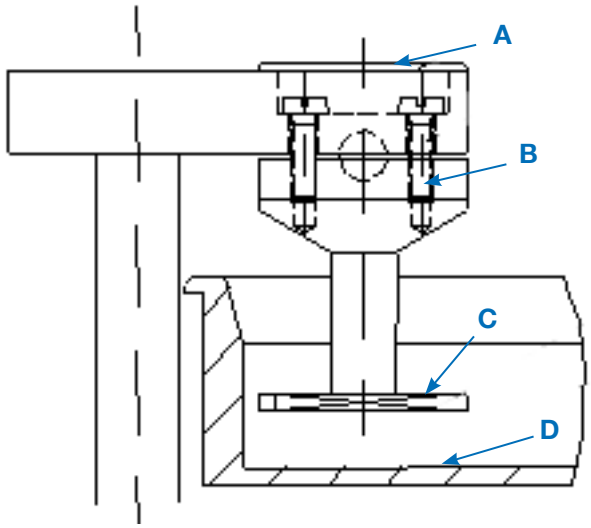
4.4.3 – Switching the device off

For switching off set the mains switch to 0 (off).

4.4.4 – Parallelism of the thickness measurement station

Concerns TBH 425 -TD, -WTD

The transport plate of the magazine and the measurement plate of the thickness gauge must be positioned in parallel to each other.



A) Cover
B) Cylindric screw
C) Measurement plate
D) Transport plate

1. When the thickness gauge moves to the transport plate switch the device off.
2. Check the parallelism with the meter and adjust it, if necessary. The adjustment is performed with 4 cylindric screws (see picture) located beneath the cover.

4.4.5 – Magazine (TBH 425)

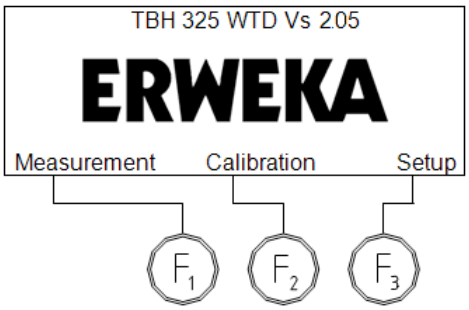
The magazine is applied for the measurement of samples in the TBH 425.

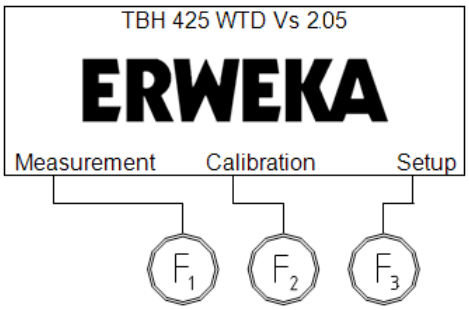
To remove or insert the magazine, release or fasten the middle covering.

NOTICE False measurement values caused by misaligned measurement station! Move the magazine carefully when removing and inserting! At that the magazine should not affect the thickness measurement station!

5 – Main menu

The main menu of TBH 325-425 looks as follows:





Press the function keys **F_1**, **F_2** or **F_3** to enter the corresponding menus:

- **F_1** to the enter the **Measurement** menu
- **F_2** to enter the **Calibration** menu
- **F_3** to enter the **Setup** menu

Menu items of the Measurement menu (F_1)

Menu item	Function
Measurement with general data	Performing measurements with stored products
New direct measurement	Performing measurements with just created products
Direct measurement with last data	Performing measurements with the settings of the previous direct measurement
Show results	Displaying results of the last measurement
Print results	Printing results of the last measurement

Menu items of the Calibration menu (F_2)

Menu item	Function
Calibration	Calibrating the specific measurement stations of the device, checking the calibrations and printing the corresponding protocols
Device check	Checking all calibrations and printing the check protocol
Tolerances	Setting/displaying the measurement tolerances (accuracies)

Menu items of the Setup menu (F_3)

Menu item	Function
General data	Creating, editing, deleting, printing, exporting/importing product data as well as selecting its settings
Units	Specifying units for different types of measurements
Language	Setting the language for the operation and protocols
Date/Time	Setting the date and time
TCP/IP configuration	Specifying the TCP/IP configuration details
Device parameter	Entering the parameters for the measurements
Printer configuration	Specifying the configuration details for the external printer
Service	The Service menu is protected with a password and should be used by qualified personnel only.
Licenses	Entering license numbers for different types of measurements
Password management	Entering passwords for access to the device‘s menus

Please note that the access to the Calibration, Setup menus and the General data, Service, Password management menu items is protected with a password. The access is possible only with a 4-digit code (see *6.1 – Password management*).

6 – Setup

Use the Setup menu to enter device configuration details and manage product data.

To manage the menu:

1. Open the Setup menu by pressing **F_3** in the main menu.
2. Using the **arrow keys** select a menu item and open it with ENTER.
3. Enter your data (input field) or using the arrow keys select an option (selection field).
4. Return to the higher menu level by pressing **CL**.

The specific menu items are explained in the following sections. See an overview of menu items in the chapter *5 – Main menu*.

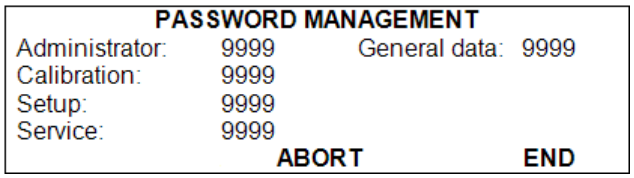
6.1 – Password management

Note that the access to the Calibration, Setup menus and the General data, Service, Password management menu items is protected with a password. The access is possible only with a 4-digit code.

Upon delivery the code previously set by ERWEKA is “9999”. Prior to operating the device the administrator should assign the passwords.

To change the passwords:

1. Select **Password management** from the Setup menu and press ENTER. Following window appears:



2. Enter the passwords in the corresponding fields. Confirm each entry with ENTER.

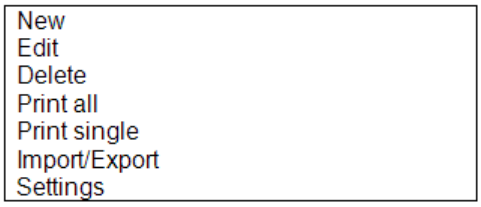
In the Administrator field indicate the password for the Password management menu item.

3. When you are done, press **F_3**.

6.2 – General data

Here you can create new products, edit and delete existing ones, print, import/export the product data as well as specify related settings.

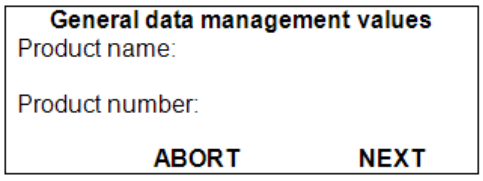
1. Select **General data** from the Setup menu and press ENTER. Following window appears:



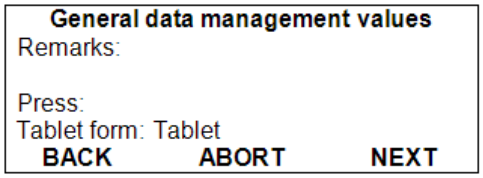
2. Using the arrow keys scroll the list with submenus, which are explained in the following sections.

6.2.1 – Creating new products

1. Select **New** from the General data menu and press ENTER. Following window appears:



2. Enter the product name and number and confirm with ENTER.
3. Press **F_3** to continue. Following window appears:



Field	Value
Remarks	Comments
Press	Press that produces the product
Tablet form *Options:*	*Tablet*, *oblong* or *capsule*.

4. Enter the data and confirm with ENTER.
5. Press **F_3**. Following window appears:

General data management values		
Tolerance mode:	in-house	
Hardness correction:	0.0 N	
BACK	ABORT	NEXT

Field	Value
Tolerance mode *Options:*	*In-house* (manual setting of tolerances), *EP* (European Pharmacopoeia) or *USP* (US Pharmacopoeia).
Hardness correction	Nominal value in N that serves as base for the hardness measurement.

6. Enter the data and confirm with ENTER.

7. Press **F**$_3$. Following window appears:

General data management values			
Weight	Nominal value:	100.0 mg	
Evaluation:	Nominal value	T1+: 10	T1-: 10 %
Number:	10	T2+: 20	T2-: 20
Mode:	relative	T3+: 50	T3-: 50
BACK	ABORT		NEXT

You can enter the data in these fields (and also corresponding in the fields for thickness, diameter and hardness) only if you have selected the in-house tolerance mode in the previous window. If you have selected EP or USP, you can specify only the nominal value and the data for the T3 limits.

Field	Value
Nominal value	Nominal value for product weight
Evaluation *Options:*	*Nominal value* (The measurement results are evaluated based on the nominal value you have entered in the previous field) or *Average value* (The measurement results are evaluated based on the average value received in the measurement).
Number	Number of samples to be measured
Mode *Options:*	*Absolute* (The tolerances are shown in mg) or *relative* (The tolerances are shown in %).
T1+/T1-, T2+/T2-, T3+/T3-	T1 – warning limit, T2 – action limit, T3 – plausibility limit. They are used to set different acceptance criteria. The values outside T3 are shown as fault measurements (FM) in the protocol.

8. Enter the data and confirm with ENTER.

9. Press **F**$_3$. Following window appears:

General data management values			
Thickness	Nominal value:	3.0 mm	
Evaluation:	Nominal value	T1+: 10	T1-: 10 %
Number:	10	T2+: 20	T2-: 20
Mode:	relative	T3+: 50	T3-: 50
BACK	ABORT		NEXT

10. Specify the required data for thickness in this window. See step 7 for the instructions.

11. Press **F**$_3$. Following window appears:

General data management values			
Diameter	Nominal value:	5.0 mm	
Evaluation:	Nominal value	T1+: 10	T1-: 10 %
Number:	10	T2+: 20	T2-: 20
Mode:	relative	T3+: 50	T3-: 50
BACK	ABORT		NEXT

12. Specify the required data for diameter in this window. See step 7 for the instructions.

13. Press **F**$_3$. Following window appears:

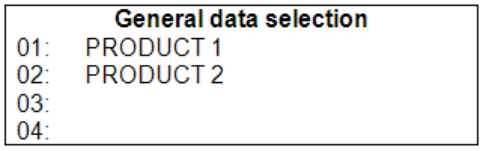
General data management values			
Hardness	Nominal value:	100.0 N	
Evaluation:	Nominal value	T1+: 10	T1-: 10 %
Number:	10	T2+: 20	T2-: 20
Mode:	relative	T3+: 50	T3-: 50
BACK	ABORT		NEXT

14. Specify the required data for hardness in this window. See step 7 for the instructions.

15. Press **F**$_3$ to save all entries. The product data has been saved.

6.2.2 – Editing products

1. Select **Edit** from the General data menu and press ENTER. The list of registered products is shown:

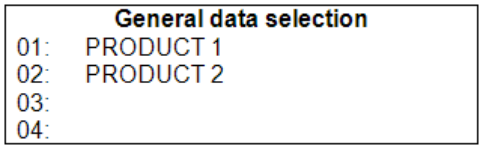


2. Select the product you want to edit and confirm with ENTER. Now you can change the corresponding data.

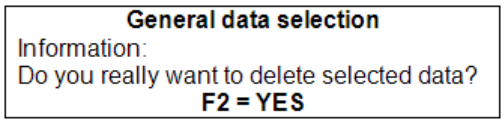
To know how to edit the fields, read *6.2.1 – Creating new products*.

6.2.3 – Deleting products

1. Select **Delete** from the General data menu and press ENTER. The list of registered products is shown:



2. Select the product you want to delete and confirm with ENTER. Following window appears:



3. Press **F**$_2$ to confirm the deletion of data. The selected product is deleted.

NOTICE The deleted data cannot be restored! Press **CL** to abort the deletion process.

6.2.4 – Data printout

Ensure that the printer is connected to the device appropriately.

<u>To print the information on all products</u>

1. Select **Print all** from the General data menu and press ENTER. Following window appears:

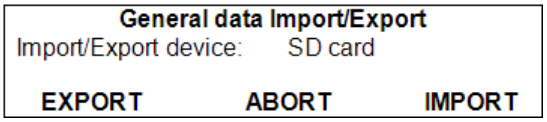
The data of all saved products is printed.

<u>To print the information on a single product:</u>

1. Select **Print single** from the General data menu and press ENTER.
2. Select the required product you want to print the information on and confirm with ENTER. The data of selected product is printed.

6.2.5 – Importing/Exporting

1. Select **Import/Export** from the General data menu and press ENTER. Following window appears:



2. Select **SD card** or **USB device** in the **Import/Export device** field. Press ENTER.

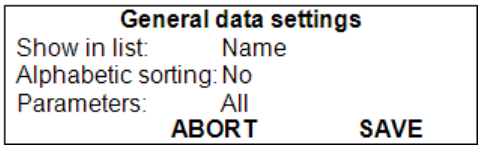
NOTICE Do not forget to connect the corresponding medium (SD card or USB stick) to the device.

3. Now press **F**$_1$ to export data or **F**$_3$ to import data. A corresponding message appears to inform you about the data transfer.

6.2.6 – Settings

Define settings for display and editability of general data.

1. Select **Settings** from the General data menu and press ENTER. Following window appears:



Field	Value
Show in list *Options:*	*Name* (Products are listed by their names) or *Number* (Products are listed by their numbers).
Alphabetic sorting *Options:*	*No* (Products are listed in the order as they were created) or *Yes* (Products are listed in alphabetic order).
Parameters *Options:*	*All* (it is possible to specify all product parameters) or *Device specific* (it is possible to specify only the settings of licensed measurements, e.g. if you have not bought the license to conduct weight measurements, you will not be able to enter the corresponding information).

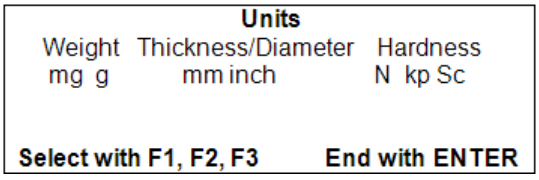
2. Select the required options. Confirm each entry with ENTER.

3. Press **F_3** to save the data.

6.3 – Units

Define the units of measurement parameters.

1. Select **Units** from the Setup menu and press ENTER. Following window appears:



2. Press **F_1** to select „mg" or „g" for the measurement of the weight parameter.

3. Press **F_2** to select „mm" or „inch" for the measurement of the thickness and diameter parameters.

4. Press **F_3** to select „N", „kp" or „Sc" for the measurement of the hardness parameter.

5. When you are done, press ENTER.

> The weight parameter is shown only in the ERWEKA TBH 325 WTD and TBH 425 WTD devices!

6.4 – Language

Select the user language for display and protocol printouts.

1. Select **Language** from the Setup menu and press ENTER.

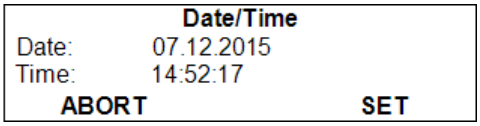
2. Select the required language.

3. Confirm your choice with ENTER.

6.5 – Date/Time

Set the current date and time.

1. Select **Date/Time** from the Setup menu and press ENTER. Following window appears:



2. Press **F_3** to enter the input mode.

3. Specify the current date. Confirm each entry (day, month, year) with ENTER.

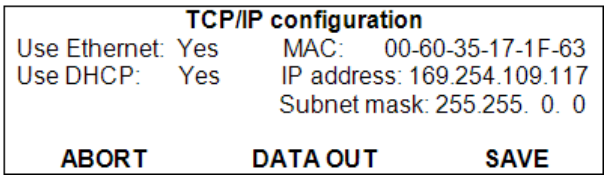
4. Specify the current time. Confirm each entry (hour, minute, second) with ENTER.

5. Press **F_3** to save the entries.

6.6 – TCP/IP configuration

Specify the TCP/IP configuration of the device.

1. Select **TCP/IP configuration** from the Setup menu and press ENTER. Following window appears:



Field	Value
Use Ethernet *Options:*	*Yes* or *No*
Use DHCP *Options:*	*Yes* (to receive the IP address automatically from the server) or *No* (to enter the IP address manually)
MAC	Display of the device's MAC address
IP address	IP address in case you have deactivated DHCP
Subnet mask	Subnet mask
DATA OUT	Device – PC communication via Ethernet. This function must be activated by ERWEKA.

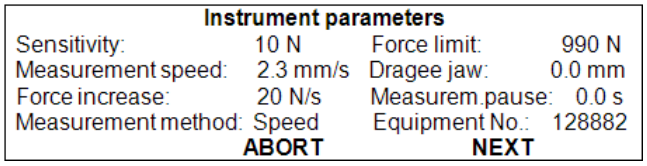
2. Enter the data and confirm each entry with ENTER.

3. Press **F_3** to save your data.

6.7 – Device parameters

Determine the device parameters for your measurements.

1. Select **Device parameter** from the Setup menu and press ENTER. Following window appears:



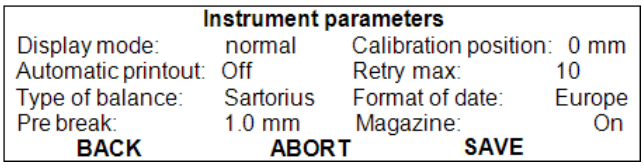
Field	Value
Sensitivity	Sensitivity value in Newton (N). The minimal value is 3 N. The value of 10 N is set by default.
Measurement speed	Measurement speed. The value of 2.3 mm/s is set by default.
Force increase	Extent of force towards the sample. The value of 20 N/s is set by default.
Measurement method *Options:*	*Speed* (The jaw moves with constant speed; the value can be adjusted from 0.05 to 3.00 mm/s) or *Force* (The jaw moves with constant force to the sample; the value can be adjusted from 10 to 200 N/s).
Force limit	maximal force in N that should be used by the jaw on the sample
Dragee jaw	Size of the dragee jaw in mm
Measurem. pause	Interval in seconds between the measurements
Equipment No.	Equipment number or inventory number of the device

On the one hand, the entry of **sensitivity** (sensitivity of the load cell) prevents registering an undesired measurement (e.g. through tablet rests), on the other hand, compressible samples can be easily already „compressed" and in this way falsify the measurement of diameter - then a lower value of sensitivity must be entered.

NOTICE The comparability of test results of a product can be ensured only with the same **measurement method**.

2. Enter the data and confirm each entry with ENTER.

3. Press **F_3** to continue. Following window appears:



Field	Value
Display mode *Options:*	*normal* (white letters on blue background) or *inverse* (blue letters on white background)
Calibration position	Calibration position
Automatic printout *Options:*	*Off* (The test/calibration/check protocol should not be printed after test end) or *On* (The test/calibration/check protocol should be printed out automatically after test end).

Field	Value
Retry max	maximal number of samples to be refilled. E.g. in fault measurements more samples are measured (the measurement happens automatically).
Type of balance *Options:*	*Sartorius* or *Mettler*. The model of balance used with the device
Format of date *Options:*	*Europe* (DD/MM/YYYY) or *USA* (MM/DD/YYYY), valid for all printouts or protocols.
Pre break	The pre break distance in mm.
Magazine *Options:*	*Off* (the test should not be performed with the magazine on the TBH 425) or *On* (the test should be performed with the magazine on the TBH 425).

During the measurement the jaw moves with fast speed to the sample. When reaching the selected sample diameter plus the selected distance the jaw slows down. This distance is indicated as **pre-breaking**.

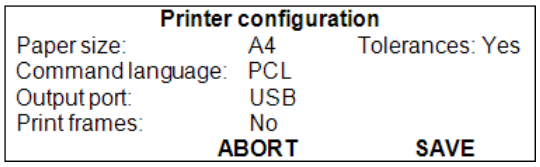
4. Enter the data and confirm each entry with ENTER.

5. Press **F**$_3$ to save the data.

6.8 – Printer configuration

Configure the connected printer.

1. Select **Printer configuration** from the Setup menu and press ENTER. Following window appears:



Field	Value
Paper size *Options:*	*A4* or *Letter*
Command language *Options:*	*PCL* (for a connected USB printer) or *ASCII* (for ERWEKA WinPrint software)
Output port *Options:*	*USB* (for the USB interface) or *ERWEKA WinPrint* (for network printer you can use the ERWEKA WinPrint software)
Print frames *Options:*	*Yes* (you want to have frames shown on your printouts) or *No* (you do not want to have frames shown on your printouts)
Tolerances *Options:*	*Yes* (you want to integrate the set tolerances in the test protocol) or *No* (you do not want to integrate tolerances in the test protocol)

2. Select the required options and confirm each entry with ENTER.

3. Press **F**$_3$ to save your data.

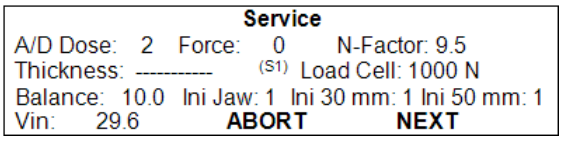
6.9 – Service

NOTICE

No device specific data should be changed in the Service menu!
However, the changes must be made if e.g. the standard jaw is replaced with a jaw for dragees or oblongs. This should be done by authorized personnel only!

Configure the service settings.

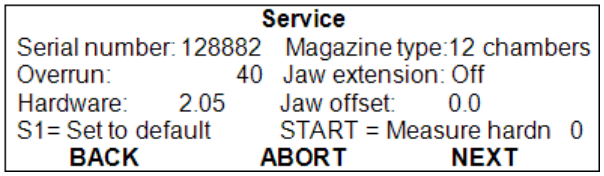
1. Select **Service** from the Setup menu and press ENTER. Following window appears:



In this window the current device settings are shown.

2. Press **F**$_3$ to continue.

Following window appears:



Field	Value
Serial number	Serial number of the device
Overrun	Number of motor steps. The entry range is from 10 to 120 steps.
Hardware	Display of the device's firmware version
Magazine type *Options:*	Three different magazines can be applied. The *12-chamber magazine* is applied by default, *24-* and *30-chamber magazines* are optionally available.
Jaw extension *Options:*	*On* (you want to use the jaw extension for big tablets) or *Off* (you do not want to use the jaw extension).
Jaw offset	The differences between standard jaw and special jaw are cleared. In case of dragees or oblongs enter the value stated on the jaw.

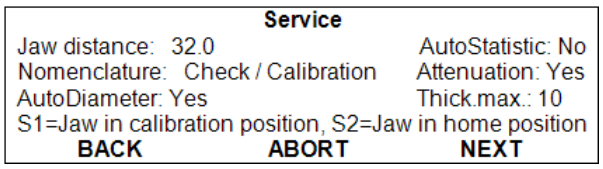
The **Overrun** defines the way through tablet to make its breach more obvious.

NOTICE

By pressing **S**$_1$ the device is reset to the manufacturer's settings. All data entered so far is going to be deleted. This function should be activated in case of emergency only after consulting ERWEKA.

3. Enter the data and confirm each entry with ENTER.

4. Press **F**$_3$ to continue. Following window appears:



Field	Value
Jaw distance	Distance which the jaw should move from its initial position to the zero point
Nomenclature *Options:*	*Check/Calibration* or *Calibration/ Adjustment.*
AutoDiameter *Options:*	*Yes* (activation of the AutoDiameter function for the automatic detection of the nominal diameter during the direct measurement) or *No* (no activation of AutoDiameter function)
AutoStatistic *Options:*	*Yes* (display of the statistical data after a measurement) or *No* (no display of the statistical data after a measurement).
Attenuation *Options:*	*Yes* or *No*
Thick. max.	maximal nominal value of thickness in mm

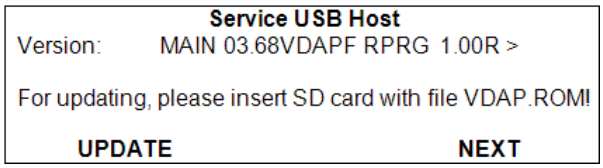
Thick. max.: This entry is foreseen for the manual thickness measurement with a thickness gauge. Specify the maximal thickness according to the thickness gauge (12 or 25 mm). The possible range of setting is 5 – 30 mm.

Jaw distance
By pressing **S**$_1$ the jaw moves from the housing to the calibration position and can be replaced with dragee or oblong jaw.

By pressing **S**$_2$ the jaw moves to its initial position.

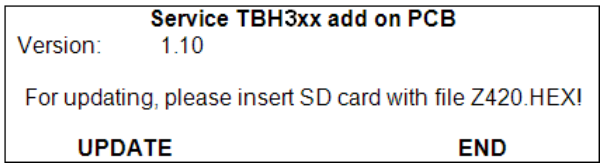
5. Enter the data and confirm each entry with ENTER.

6. Press **F**$_3$ to continue. Following window appears:

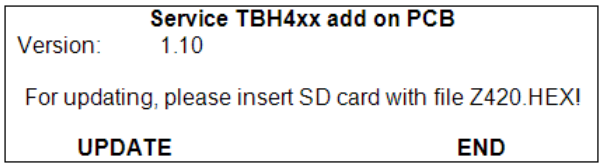


7. Insert the SD card with the VDAP.ROM file into the special port on the device's rear panel and press **F**$_1$.

8. Then press **F**$_3$. Following window appears:



or



9. Insert the SD card with the Z420.HEX file into the special port on the device's rear panel and press **F_1**.

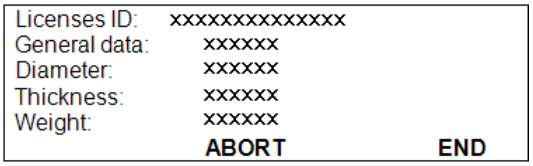
10. Then press **F_3**.

6.10 – Licenses

The licenses are subject to charge and are delivered by ERWEKA only.

Specify the license numbers for different measurements.

1. Select **Licenses** from the Setup menu and press ENTER. Following window appears:



2. Enter the corresponding correct license numbers. Confirm each entry with ENTER.

3. Press **F_3** to save your data.

7 – Calibration

Using the Calibration menu you can perform the calibration of the measurement stations.

You can also perform the calibration with AutoCal 2.0 or MC.NET. For more information read the corresponding instruction manuals.

To manage the menu:

1. Open the Calibration menu by pressing **F_2** in the main menu.

2. Using the **arrow keys** select a menu item and open it with ENTER.

3. Enter your data (input field) or using the arrow keys select an option (selection field).

4. Return to the higher menu level by pressing **CL**.

The specific menu items are explained in the following sections. See an overview of menu items in the chapter *5 – Main menu*.

Calibration intervals

The intervals for the calibration of the device are determined by the user as needed. A calibration should be performed after these intervals or in case of high deviations in measurements.

Printout of the calibration protocols

According to device setting the calibration protocol is printed out.

It can be printed out directly when you leave the Calibration menu item with ENTER on completion of a calibration cycle.

For this purpose activate the function of automatic printout (see *6.7 – Device parameters*) before the calibration and connect a printer.

Otherwise the printout can be prepared manually (see *8.5 – Results printout*).

See also the *Protocol examples* in the attachment of this manual.

7.1 – Calibration

Calibrate the specific stations.

1. Select **Calibration** from the Calibration menu and press ENTER. Following window appears:

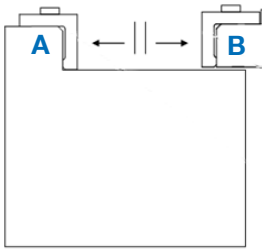
Weight
Thickness
Diameter
Hardness

The list of items in the Calibration submenu depends on the device type as well as the purchased licenses.

Preconditions

Parallelism of the test jaws:

NOTICE Incorrect measurement values in case of false setting of the test jaws. Check the parallelism of the test jaws [A, B] before you begin with the calibration.



Pict.: Hardness measurement station

A) Fixed jaw
B) Movable jaw

TBH 425:

For the calibration of the TBH 425 remove its magazine. The test jaws can be adjusted with the help of screws.

7.1.1 – Weight calibration

Concerns devices with weight measurement (WTD).

NOTICE Before starting the calibration clean the balance thoroughly and prepare the 100 mg, 500 mg and 1000 mg control units.

To perform the weight calibration:

Device with Sartorius balance (internal calibration weight):

1. Select **Weight** from the Calibration submenu and press ENTER. Following window appears:

Calibration Weight
Clean balance! Do not apply anything!
Press "NEXT"!
ABORT **NEXT**

2. Follow the instructions in the window and press **F**$_3$. Following window appears:

Calibration Weight
Balance is being calibrated! Please wait!
When finished, press "NEXT"!
BACK **ABORT** **NEXT**

3. Wait until the balance is calibrated. Read the technical documentation of your balance for more details.

4. Press **F**$_3$ to continue. Following window appears:

Check Weight			
	1	2	3
Nominal value:	100mg	500mg	1000mg
Actual value:	0.00mg	0.00mg	0.0mg
BACK	**ABORT**		**END**

i You should check the weight calibration with the 100 mg, 500 mg and 1.000 mg control units. However, you may apply other control units.

5. Enter the nominal value of the control unit in the first field (digit keys).

6. Position the corresponding control unit on the balance.

7. Press ENTER. The value measured actually is shown in the corresponding field.

8. Repeat the previous three steps (5 - 7) with two other control units.

9. To finish, press **F**$_3$. The weight calibration is completed.

7.1.2 – Thickness calibration

Concerns devices with thickness measurement (-TD, -WTD).

NOTICE

Before starting the calibration clean the thickness measurement station thoroughly and prepare the thickness control units (blocks) of 3 mm and 5 mm.

TBH 425
Before beginning with the calibration of the TBH 425 remove its magazine!

To perform the thickness calibration:

1. Select **Thickness** from the Calibration submenu and press ENTER.

Following message is shown on the TBH 425:

Calibration Thickness		
Clean thickness gauge! Do not insert anything! Press "NEXT"!		
	ABORT	NEXT

2. (TBH 425) Clean the thickness gauge and press **F_3** after the end of procedure. Following window appears:

Calibration Thickness		
Insert 5mm calibration block! Press "NEXT"!		
BACK	ABORT	NEXT

3. (TBH 425) Position the 5 mm control unit in the thickness gauge.

4. (TBH 425) After the end of procedure press **F_3**. The TBH 425 calibrates the thickness gauge.

Then or after step 1 (in TBH 325) following window appears:

Check Thickness			
	1	2	3
Nominal value:	3.0mm	5.0mm	8.0mm
Actual value:	0.0mm	0.0mm	0.0mm
BACK	ABORT		END

You should check the thickness calibration with the control units of 3 mm, 5 mm and 8 mm. However, you may apply other control units.

5. Enter the nominal value of the control unit in the first field (digit keys).

6. Position the corresponding control unit on the measurement station.

7. Press ENTER. The value measured actually is shown in the corresponding field.

8. Repeat the previous three steps (5 - 7) with two other control units.

9. To finish, press **F_3**. The thickness calibration is completed.

TBH 425
After you have finished the calibration:
- install the magazine
- reset the device by pressing **S_1** or starting it again

7.1.3 – Diameter calibration

Concerns devices with diameter measurement (D, TD, WTD).

For calibration position different control units in the hardness measurement station.

NOTICE

Before starting the calibration clean the hardness measurement station and prepare the control units of 5 mm and 10 mm.

TBH 425
Before beginning with the calibration of the TBH 425 remove its magazine!

To perform the diameter calibration:

1. Select **Diameter** from the Calibration submenu and press ENTER. Following window appears:

Calibration Diameter	
Clean hardness station! Do not insert anything! Press "NEXT"!	
ABORT	NEXT

2. Follow the instructions and press **F_3** after the end of procedure.

The hardness measurement station is zeroed and returned to its initial position again.

3. Following window appears:

Calibration Diameter
Calibration block: 10 mm
Insert calibration block! Press "NEXT"!
BACK ABORT NEXT

NOTICE

Before the diameter calibration in TBH 325 devices with installed jaw extension position the 50 mm control unit.

4. Position the 10 mm control unit on the hardness station and press **F**$_3$. Following window appears:

Check Diameter			
	1	2	3
Nominal value:	5.0mm	10.0mm	15.0mm
Actual value:	0.0mm	0.0mm	0.0mm
BACK	ABORT		END

You should check the diameter calibration with the control units of 5 mm, 10 mm and 15 mm. However, you may apply other control units.

5. Enter the nominal value of the control unit in the first field (digit keys).

6. Position the corresponding control unit on the measurement station.

7. Press ENTER. The value measured actually is shown in the corresponding field.

8. Repeat the previous three steps (5 - 7) with two other control units.

9. Press **F**$_3$ after the end of procedure. The diameter calibration is completed.

TBH 425

After you have finished the calibration:

- install the magazine
- reset the device by pressing **S**$_1$ or starting it again

7.1.4 – Hardness calibration

Concerns all devices of the TBH 325 and TBH 425 series.

NOTICE

Before starting the calibration clean the hardness measurement station thoroughly and prepare a calibration device with weight plate and the control units of 10 kg and 20 kg.

TBH 425

Before beginning with the calibration of the TBH 425 remove its magazine!

Information on dynamic calibration with AutoCal 2.0 (optional) you will find in the corresponding instruction manual.

To calibrate the hardness measurement station statically:

1. Select **Hardness** from the Calibration submenu and press ENTER. Following window appears:

Calibration Hardness
Clean hardness station! Do not insert anything!
Press "NEXT" to move jaw in calibration position!
ABORT NEXT

2. Follow the instructions and press **F**$_3$ after the end of procedure.

The jaw moves to the calibration position.

3. Following window appears:

Calibration Hardness
Mount calibration mechanism!
Turn instrument on side. Press "NEXT".
ABORT NEXT

4. Mount the calibration plate:

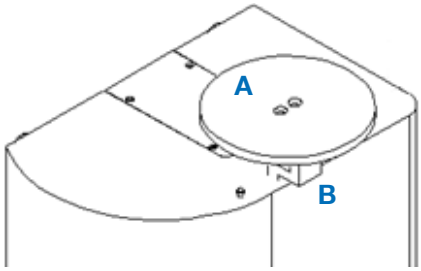
   remove the angle of refraction from the movable jaw [D],

   mount the calibration device [B] with the weight plate [A] in position [D],

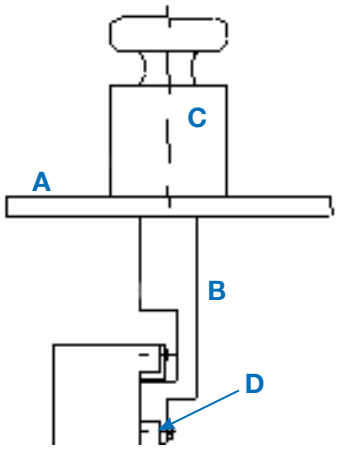
   place the device carefully on the side so that the calibration device points upwards.

See the two following pictures.

Pay attention so that a printer connection is freely accessible if the printer is connected on the side!



Pict.: mounted calibration device



Pict.: mounted calibration device with weight

5. After the calibration plate is mounted correctly, press **F_3** to continue. Following window appears:

Calibration Hardness	
Calibration weight:30.0 kg	Actual value: 0.1 kg
S1 = Zero.	If value is stable press "NEXT".
	ABORT **NEXT**

6. Press **S_1** to zero the system.

WARNING
Insecure positioning of the control units can lead to injuries or damage the device. Be careful when positioning the control units so that they do not fall!

7. Position a 30 kg control unit [C] onto the weight plate [A]. The actually measured value is shown in the Actual value field.

8. When this value is stabilized, press **F_3**. Following window appears:

Check Hardness			
	1	2	3
Nominal value:	30.0 kg	20.0 kg	10.0 kg
Actual value:	0.0 kg	0.0 kg	0.0 kg
	ABORT		**END**

You should check the hardness calibration with the control units of 30 kg, 20 kg and 10 kg. However, you may apply other control units.

9. Enter the nominal value of the control unit in the first field.

10. Position the corresponding control unit on the plate.

11. Press ENTER. The value measured actually is shown in the corresponding field.

12. Repeat the previous three steps (9 - 11) with two other control units.

13. Press **F_3** after the end of procedure. Following window appears:

Check Hardness	
Dismount calibration mechanism!	
To move jaw back, press "END"	
BACK	**END**

14. Dismount the calibration plate and press **F_3**. The hardness calibration is completed.

TBH 425
After you have finished the calibration:
- install the magazine
- reset the device by pressing **S_1** or starting it again

NOTICE
After <u>each</u> static hardness calibration the parallelism must be checked and a diameter calibration must be performed.
See:
7.1 – Calibration
7.1.3 – Diameter calibration

7.2 – Device check

Check the overall calibration of your device.

1. Select **Calibration** with **F_2** in the main menu.
2. Select **Device check** from the Calibration menu and press ENTER. Following window appears:

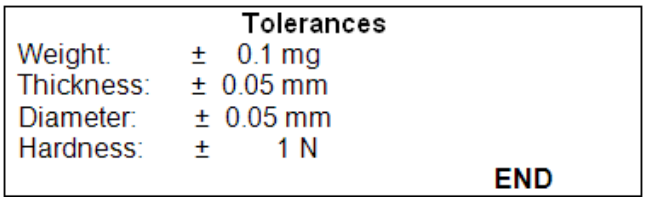
3. Select the required menu item.
4. In opened windows check the calibration results of different measurement parameters (see corresponding calibration).

7.3 – Tolerances

View the ERWEKA measurement tolerances and define own values.

1. Select **Calibration** with **F_2** in the main menu.
2. Select **Tolerances** from the Calibration menu and press ENTER. Following window appears:

3. Select between the *ERWEKA* or *In house* options and press ENTER. After your selection following window appears:



NOTICE

ERWEKA tolerances are fixed. The in house tolerances can be changed. The values of changed tolerances should not be smaller than the ERWEKA tolerances.

4. If needed, change your local values under in house tolerances.
5. At the end of procedure press **F_3**.

8 – Measurements

In the Measurement menu you can perform the measurements as well as display and print the results.

WARNING

Danger of springing fractions! During a test, fractions of samples can spring off. Wear personal protective outfit and glasses!

CAUTION

Danger of clamping, moving parts!
During a test, parts of the body (e.g. fingers) can be clamped between the jaws. Do not touch these areas during the tests! Be careful to avoid injuries!

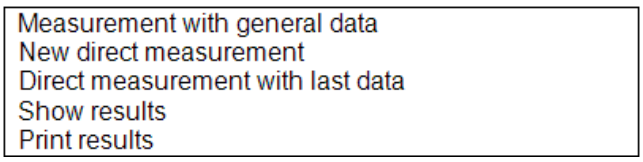
NOTICE

Before performing the measurements ensure that the device is correctly installed, connected, equipped and calibrated. If needed, perform calibrations. Prepare the samples.

If for performing the measurements you use the MC.NET software, read the information for operation of MC.NET in the MC.NET user's guide.

<u>To manage the menu:</u>

1. Select **Measurement** with **F_3** in the main menu. Following window appears:



2. Select a menu item using arrow keys.
3. To open it, press ENTER.

In the following sections the specific menu items as well as different procedures of performing the measurements are explained.

8.1 – Measurement with general data

Measure a product stored in the device memory.

To specify the product and nominal values:

1. Select **Measurement with general data** from the Measurement menu and press ENTER. Following window appears:

General data selection
01: PRODUCT 1
02: PRODUCT 2
03:
04:

2. Select the product to be measured and press ENTER. Following window appears:

Batch/Lot entry		
Batch/Lot:		
Remarks:		
	ABORT	NEXT

3. Enter the batch and comments, if any. Confirm each entry with ENTER.

4. Press **F_3** to continue. Following window appears:

Measurement				
Nominal Diameter	No weight	No thickness	No diameter	No hardness
6.0	10	10	10	10
ABORT		OPTIONS		START

Field	Value
Nominal Diameter	The corresponding value (up to 28.00 mm) from the general data is automatically set in this field.
No weight, No thickness, No diameter, No hardness	The number of samples to be tested for each measurement parameter.

If you need to change the entered nominal value of the diameter, proceed as in the section *6.2.2 – Editing products*.

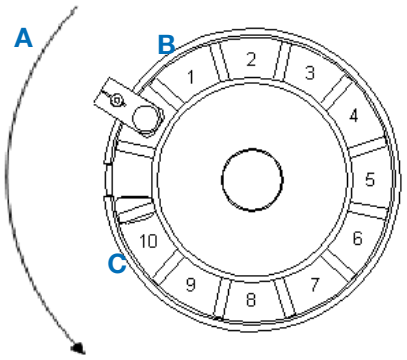
5. Enter the data in the fields and confirm each entry with ENTER.

According to device type fit the magazine (TBH 425), weigh the samples (WTD) or place them and begin with measurement (TBH 325).

The options are explained below.

To fit the TBH 425 magazine without weighing:

6. Place the samples in the magazine, a sample per chamber. Pay attention to the order:

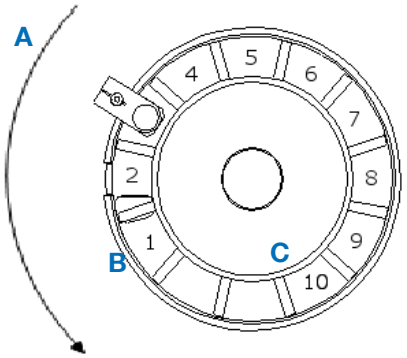


Pict.: TBH 425 magazine, view from above

A) Rotation direction of the magazine during the test
B) Position for placing the first sample
C) Position for placing the last sample (test with 10 samples)

To fit the TBH 425 WTD magazine:

6. Weigh each sample one by one and place them in the magazine, a sample per chamber. Pay attention to the order:



Pict.: TBH 425 WTD magazine, view from above

A) Rotation direction of the magazine during the test
B) Position for placing the first sample after weighing
C) Position for placing the last sample after weighing (test with 10 samples)

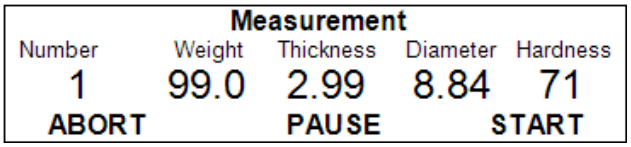
After each weighing process the magazine rotates for a position further. The samples must be placed so that after the end of weighing of all samples the sample weighed first stands in the start position.

To start measurements on the TBH 425:

7. Press **F_3** to start the measurement. The test jaw is zeroed.

8. Follow the instructions on the display. The weight is determined optionally.

Then all next measurements are being performed. Following window appears:

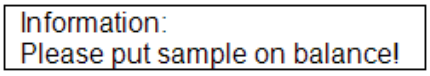


The window shows the measurement results for the actually determined sample.

You can abort the test by pressing **F_1** or pause it by pressing **F_2**.

To start measurements on the TBH 325 WTD:

7. Press **F_3** to start the measurement. The test jaw is zeroed. Following message appears:



8. Weigh the sample and follow the instructions on the display. Then all next measurements are being performed. See below how to start measurements on the TBH 325.

To start measurements on the TBH 325:

7. Press **F_3** to start the measurement. The test jaw is zeroed.

8. Follow the instructions on the display.

9. (TBH 325 -..T..) As soon as „Thickness“ blinks in the window, lift the measuring stick of the manual measurement station and place the sample beneath the small measuring plate. When the value is measured, the blinking disappears and the value is displayed on the screen.

10. (TBH 325 -..T..) Place the sample between the jaws of the hardness measurement station by means of the horizontal movement mechanism, on which the thickness gauge is installed, and release the vertical measuring stick.

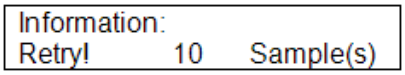
10. Place the sample between the jaws of the hardness measurement station.

The movable jaw measures the diameter (optional) and hardness of the sample.

12. Then clean the measurement station and repeat the procedure with the rest samples.

To refill samples:

If the measurement results are out of the foreseen tolerances, after the end of all measurements following window appears:



In this case 10 new samples must be placed and tested. Perform the test as described above according to device type.

Samples outside the T3 limit are refilled correspondingly. The tolerance limit T3 = plausibility limit is an device specific limit. With it the samples that deviate greatly from the nominal data should be detected and excluded from the statistics. Values outside T3 are indicated as fault measurements (FM) in protocol and, if foreseen, new samples are refilled for measurement.

After the measurement

As soon as all additional samples have been measured, the list of all registered products available for the next measurements appears.

According to device setting the test protocol is printed out.

The test protocol is printed out directly if you have activated the function of automatic printout (see *6.7 – Device parameters*) and the printer is connected.

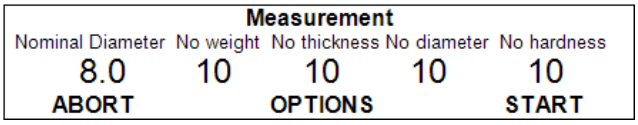
Otherwise the printout can be prepared manually (see *8.5 – Results printout*).

See also the *Protocol examples* in the attachment of this manual.

8.2 – New direct measurement

Measure a product that is not stored in the device memory.

1. Select **Direct measurement** from the Measurement menu and press ENTER. Following window appears:



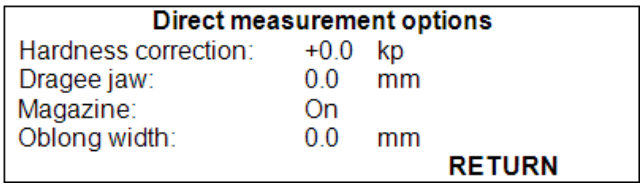
Field	Value
Nominal Diameter	The required value of diameter (necessary only if the AutoDiameter function from the Service menu is disabled).
No weight, No thickness, No diameter, No hardness	The number of samples to be tested for each measurement parameter.

> Information on the AutoDiameter function you will find in section *6.9 – Service*.

2. Enter the data in the fields and confirm each entry with ENTER.

3. (TBH 425) Place the samples in the TBH 425 magazine chambers (see „To fit the magazine“ in *8.1 – Measurement with general data*).

4. Press **F**$_2$ to enter the following test options:



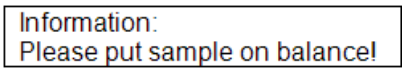
Field	Value
Hardness correction	The required correction value of diameter (necessary only if the AutoDiameter function in the Service menu is disabled).
Dragee jaw	The required value for the size in mm.
Magazine *Options:*	*Off* (the magazine (TBH 425) is not involved in the measurement) or *On* (the magazine (TBH 425) is involved in the measurement).
Oblong width	The oblong width, if needed, for the measurements in mm.

5. Enter the data in the fields and confirm each entry with ENTER. Press **F**$_3$ to return to the previous window.

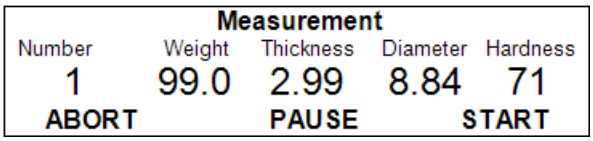
The measurement procedures differ according to applied device type analogically to the measurement with general data.

6. Now press **F**$_3$ to start the measurement. The test jaw is zeroed.

7. (TBH 325 WTD) When using a TBH 325 with weight measurement option the following message appears:



8. Follow the instructions of the display. The weight is optionally determined. The next measurements are being performed. Following window appears:



The window shows the measurement results for the actually determined sample.

> You can abort the test by pressing **F**$_1$ or pause it by pressing **F**$_2$.

9. (TBH 325 -..T..) As soon as „Thickness“ blinks in the window, lift the measuring stick of the manual measurement station and place the sample beneath the small measuring plate. When the value is measured, the blinking disappears and the value is displayed on the screen.

10. (TBH 325 -..T..) Place the sample between the jaws of the hardness measurement station by means of the horizontal movement mechanism, on which the thickness gauge is installed, and release the vertical measuring stick.

11. (TBH 325) Place the sample between the jaws of the hardness measurement station.

(TBH 325) The movable jaw measures the diameter (optional) and hardness of the sample.

12. (TBH 325) Then clean the measurement station and repeat the procedure with the rest samples.

13. When all samples have been measured, the Measurement window (see step 1) appears. Here you can perform following measurements.

According to device setting the test protocol is printed out.

The test protocol is printed out directly if you have activated the function of automatic printout (see *6.7 – Device parameters*) and the printer is connected.

Otherwise the printout can be prepared manually (see *8.5 – Results printout*).

See also the *Protocol examples* in the attachment to this manual.

8.3 – Direct measurement with last data

Measure a product with data of the last direct measurement.

1. Select **Direct measurement with last data** from the Measurement menu and press ENTER.

2. Follow the previous instructions described in the section *8.2 – New direct measurement*.

The values of the last direct measurement are inserted in the fields of the window. However, you can also enter other values here.

8.4 – Results display

Display the measurement results.

1. Select **Show results** from the Measurement menu and press ENTER. Following window appears:

Results (F1=Statistics F3=End)				
01:	99.0	2.99	71	8.84
02:	96.5	3.02	70	8.81
03:	97.2	3.01	71	8.83
04:	98.5	2.96	71	8.84

The window shows the measurement results of the last performed test.

2. Press **F$_1$** to show the statistics for each measurement parameter. The window may look as follows:

Statistics: Diameter			
No Statistics:	10		
Xmin	8.69	Xaverage	8.81
Xmax	8.85	X S	0.05
Xmax-min	0.16	X Srel	0.52
ABORT			NEXT

3. Press **F$_3$** to scroll to the next page. Here you find the statistical information on other measurement parameters.

4. Press **F$_1$** to return to the Results window (step 1).

5. Press **F$_3$** to exit the window and return to the main menu.

8.5 – Results printout

Here you can print results.

1. Select **Print results** from the Measurement menu and press ENTER. Following window appears:

The results of the last performed test are printed out.

Ensure that a printer is connected to the device and the corresponding settings are configured.

9 – Maintenance

9.1 – Cleaning

To guarantee the failure-free operation, it is recommended to clean the device regularly. The device is to be cleaned after each measurement. Spilt liquids must be removed immediately. Read the following instructions thoroughly before you begin with the cleaning.

HAZARD of electric shock when cleaning the electric devices! Disconnect the mains supply for cleaning the electric devices! Switch the device off and unplug it for cleaning! Clean the electrical instruments without liquids.

Note that residues of the test products must be properly disposed of in accordance with the applicable environmental regulations.

Instructions for cleaning

NOTICE

Inaccurate measurement results!
Shaking and vibrations can displace the measuring instruments. Clean the device carefully. Pay attention that no particles collect in the guide rails, grooves and chinks.

For thorough cleaning ERWEKA recommends to exhaust the surfaces or apply a soft brush.

1. Disconnect the mains supply and available network connections.
2. Remove the magazine (if available) and collection container.
3. Clean the surfaces of the measurement stations from dirt and tablet rests.
4. Wipe the device with a soft and slightly dampled cloth.

NOTICE

Do not use an excessively damped cloth but slightly damped one. Do not add any chemical cleansing agents to the cleaning water. For the lacquered housing parts use no cleansing agents which attack this material.

If needed, e.g. in case of serious dirtying, use a damp cloth and blot the cleaned surface dry.

9.2 – Inspection and maintenance

Ensure that the device is regularly inspected and each time is clean.

To ensure a long lifetime of your units and systems, we recommend a regular maintenance performed by our specialized staff.

In longer standstills

If the device is not used for a long time, follow the instructions below:

- Switch the device off and disconnect it from the mains supply.
- Dismount additional components.
- Clean the device thoroughly.
- Store the device, its components and manual under conditions defined for the installation environment.

NOTICE Non-performance of the instructions given above can lead to damages!

9.3 – Spare parts

NOTICE Electronic and mechanical replacements are to be made by the ERWEKA personnel or approved by ERWEKA!

Only original spare parts or components released by ERWEKA should be used. Only repairs or changes on the device performed by the ERWEKA technicians or approved explicitly by ERWEKA are to be made.

Attachment

Protocol examples

Below you will find example protocols that can be printed from the device.

TBH 325 calibration protocol

ERWEKA TBH325 **Vs 2.05 CALIBRATION** **Page : 1**
ID-Number: 00000304913992 Serial number: 130269
Equipment No.: 130269
Date: 23.05.2013 Time: 12:17
Check tolerances: ERWEKA

HARDNESS
last calibration date:23.05.2013 last calibration with: 30.0 kg
Actual : 31.6kg Newtonfactor: 20.03

Calibration NEW
Calibration date: 23.05.2013
Calibrationweight Nominal: 30.0kg Actual:30.0kg
Newtonfactor new: 20.04

Signature:.....

TBH 425 calibration protocol

ERWEKA TBH425 TD Vs 2.05 CALIBRATION Page : 1
ID-Number: 00000304913102 Serial number: 130381
Equipment No.: 130381
Date: 06.06.2013 Time: 14:39
Check tolerances: ERWEKA

THICKNESS
last calibration date:06.06.2013 last calibration with: 5mm

Calibration NEW
Calibration date: 06.06.2013

HARDNESS
last calibration date:06.06.2013 last calibration with: 30.0 kg
Actual : 30.6kg Newtonfactor: 19.42

Calibration NEW
Calibration date: 06.06.2013
Calibrationweight Nominal: 30.0kg Actual:29.9kg
Newtonfactor new: 19.36

DIAMETER
last calibration date : 06.06.2013 last calibration with: 10.00mm

Calibration NEW
Calibration date: 06.06.2013
Calibration gauge: Nominal: 10.00mm

Signature:.....

TBH 325 check protocol

ERWEKA TBH325 Vs 2.05 CHECK Page : 1
ID-Number: 00000304913992 Serial number: 130269
Equipment No.: 130269
Date: 23.05.2013 Time: 12:17

HARDNESS
last calibration date: 23.05.2013
last instrument check: 23.05.2013

Control weight	Nominal: 30.0 kg Actual: 30.0 kg	OK
Control weight	Nominal: 20.0 kg Actual: 20.0 kg	OK
Control weight	Nominal: 10.0 kg Actual: 10.0 kg	OK

Signature:.....

TBH 425 check protocol

ERWEKA TBH425 TD Vs 2.05 CHECK Page : 1
ID-Number: 00000304913102 Serial number: 130381
Equipment No.: 130381
Date: 06.06.2013 Time: 14:39

THICKNESS
last calibration date: 06.06.2013
last instrument check: 06.06.2013

Control gauge:	Nominal: 3.00 mm	Actual: 2.99 mm	OK
Control gauge:	Nominal: 5.00 mm	Actual: 5.00 mm	OK
Control gauge:	Nominal: 8.00 mm	Actual: 7.99 mm	OK

HARDNESS
last calibration date: 06.06.2013
last instrument check: 06.06.2013

Control weight	Nominal: 30.0 kg	Actual: 30.1 kg	OK
Control weight	Nominal: 20.0 kg	Actual: 20.1 kg	OK
Control weight	Nominal: 10.0 kg	Actual: 10.0 kg	OK

DIAMETER
last calibration date: 06.06.2013
last instrument check: 06.06.2013

Control gauge:	Nominal: 5.00 mm	Actual: 5.00 mm	OK
Control gauge:	Nominal: 10.00mm	Actual: 9.99 mm	OK
Control gauge:	Nominal: 15.00mm	Actual: 14.99mm	OK

Signature:.....

TBH 325 test protocol

Measurement method: constant speed (here 2.3 mm/s)

TBH325 Vs 2.05 TEST PROTOCOL Page : 1
ID-Number : 00000304913992 Speed: 2.3 mm/sec
Equipment No.: 130269
Force limit: 500 N Sensibility: 10 N
Check Hardness: 23.05.2013

Date: 23.05.2013 Time: 13:12

Correction value : 0.00
Nominal diameter : 6.5 mm

Number of samples: 0 10 0

M E A S U R I N G V A L U E S

	Hardness
1	76 N
2	63 N
3	74 N
4	70 N
5	74 N
6	74 N
7	68 N
8	74 N
9	69 N
10	81 N

S T A T I S T I C S

No. stat:	10
X min:	63 N
X max:	81 N
X max-min:	18 N
X average:	72.30 N
X S:	4.97 N
X rel:	6.87 %

Signature: .....

TBH 425 test protocol

Measurement method: constant force (here 20 N/s)

TBH425 TD Vs 2.05 TEST PROTOCOL Page : 1
ID-Number : 00000304913102 Increase of force: 20 N/sec
Equipment No.: 130381
Force limit: 500 N Sensibility: 10 N
Check Hardness: 06.06.2013 Diameter: 06.06.2013
Check thickness: 06.06.2013

Date: 06.06.2013 Time: 14:49

Correction value : 0.00
Nominal diameter : 6.5 mm

Product: TEST
Product number: 85
Press:
Remarks:
Batch/Lot: 09
Remarks:

-T3:	1.500 mm	32.50 N	3.000 mm
-T2:	2.700 mm	52.00 N	5.400 mm
-T1:	2.850 mm	58.50 N	5.700 mm
Nominal value:	3.000 mm	65.00 N	6.000 mm
+T1:	3.150 mm	71.50 N	6.300 mm
+T2:	3.300 mm	78.00 N	6.600 mm
+T3:	6.000 mm	130.00 N	12.000 mm
Number of samples:	10	10	10

M E A S U R I N G V A L U E S

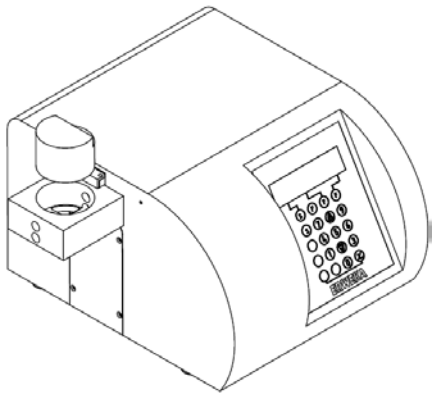
	Thickness	Hardness	Diameter
1	2.91 mm T1	59 N T1	6.02 mm T1
2	2.95 mm T1	58 N T2	6.02 mm T1
3	2.92 mm T1	60 N T1	6.02 mm T1
4	2.94 mm T1	53 N T2	6.04 mm T1
5	2.93 mm T1	55 N T2	6.03 mm T1
6	2.92 mm T1	56 N T2	6.03 mm T1
7	2.92 mm T1	58 N T2	6.02 mm T1
8	2.92 mm T1	55 N T2	6.02 mm T1
9	2.92 mm T1	53 N T2	6.03 mm T1
10	2.92 mm T1	61 N T1	6.03 mm T1

S T A T I S T I C S

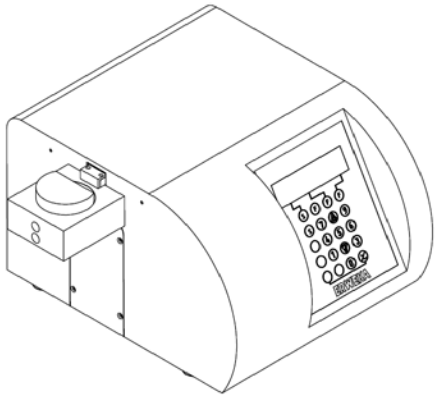
	Nominal	Nominal	Nominal	Nominal
No. stat:		10	10	10
X min:		2.91 mm	53 N	6.02 mm
X max:		2.95 mm	61 N	6.04 mm
X max-min:		0.04 mm	8 N	0.02 mm
X average:		2.93 mm	56.80 N	6.03 mm
X S:		0.01 mm	2.82 N	0.01 mm
X rel:		0.40 %	4.97 %	0.12 %

Signature:.....

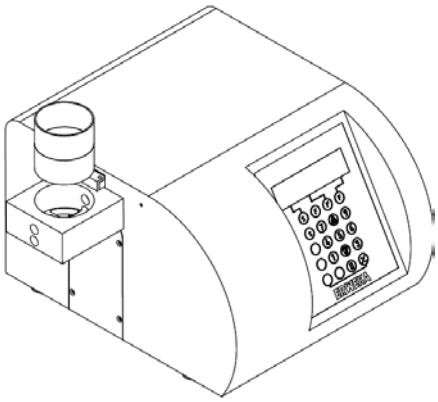
Option: Jaw for Fertilizers (TBH 325)



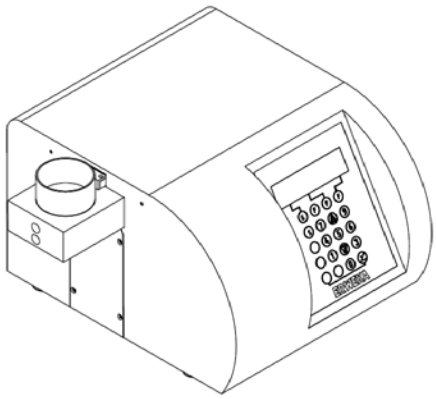
1. Insert the test jaw and align it in parallel to the movable test jaw.
2. Fix the test jaw with screws from the bottom to the holder.



3. Calibrate the diameter.
4. Measure the tablets.



5. Unscrew the fixed test jaw.
6. Insert the rings 1 + 2 with pressed fertilizer.



7. Measure the shearing force of fertilizer.

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Konformitätserklärung für

Tablet Hardness Tester, Type TBH 325 - D / TD / WTD

We, ERWEKA GmbH, declare under our sole responsibility that the product to which this declaration relates is in conformity with the following EU-Directives and harmonized standards:

- Low Voltage Directive (LVD) 2014 / 35 / EU
- Safety requirements for electrical equipment for measurement, control and laboratory use; EN 61010-1
- Electromagnetic Compatibility, (EMC) Directive 2014 / 30 / EU
- Electrical equipment for measurement, control and laboratory use; EN 61326-1

Wir, die ERWEKA GmbH, erklären in alleiniger Verantwortung, dass das Produkt, auf das sich diese Erklärung bezieht, mit folgenden EU-Richtlinien und harmonisierten Normen übereinstimmt:

- Niederspannungsrichtlinie 2014 / 35 / EU
- Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte; EN 61010-1
- Elektromagnetische Verträglichkeit, EMV-Richtlinie 2014 / 30 / EU
- Mess-, Steuer-, Regel- und Laborgeräte, EN 61326-1

Heusenstamm, 07.03.2016

Manfred Koller
-CTO-

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Certificate of Compliance for

Konformitätserklärung für

Tablet Hardness Tester, Type TBH 425 - D / TD / WTD

We, ERWEKA GmbH, declare under our sole responsibility that the product to which this declaration relates is in conformity with the following EU-Directives and harmonized standards:

- Low Voltage Directive (LVD) 2014 / 35 / EU
- Safety requirements for electrical equipment for measurement, control and laboratory use; EN 61010-1
- Electromagnetic Compatibility, (EMC) Directive 2014 / 30 / EU
- Electrical equipment for measurement, control and laboratory use; EN 61326-1

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