WHT 3ME – Fully Automated “4 in 1” Tablet Testing System

Test **weight**, **thickness** (or height), **diameter** (or length), and **hardness** of regular tablets, odd shaped tablets (caplets, oblongs etc.) and other solid samples fully automatically.

Use the WHT 3ME for the fully automated testing of single tablet critical parameters including weight (in compliance to the European and German Pharmacopoeia for uniformity of mass), thickness, diameter and the tablet hardness also according to the European **EP <2.9.8>** and **USP <1217>** Pharmacopoeia. This instrument offers a reliable and reproducible self-contained feeder and measurement station for quality control of samples during tablet production as well as in post-production QC and QA laboratories. The WHT 3ME testing system offers four test parameters of the same sample. The instrument is offered as a stand-alone unit controlled by an external computer system. A single- or multiple-batch feeder may be used to individually file the samples into the testing system for fully automated control of different samples and batches. Using the single feeder WHT-SM1 and direct connection to an existing tableting machine is possible. The multiple batch feeder WHT-SM is used to test up to 10 different products fully automatically and unattended.

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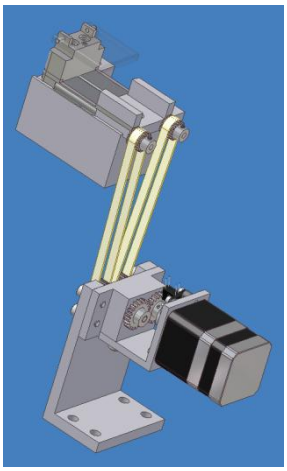
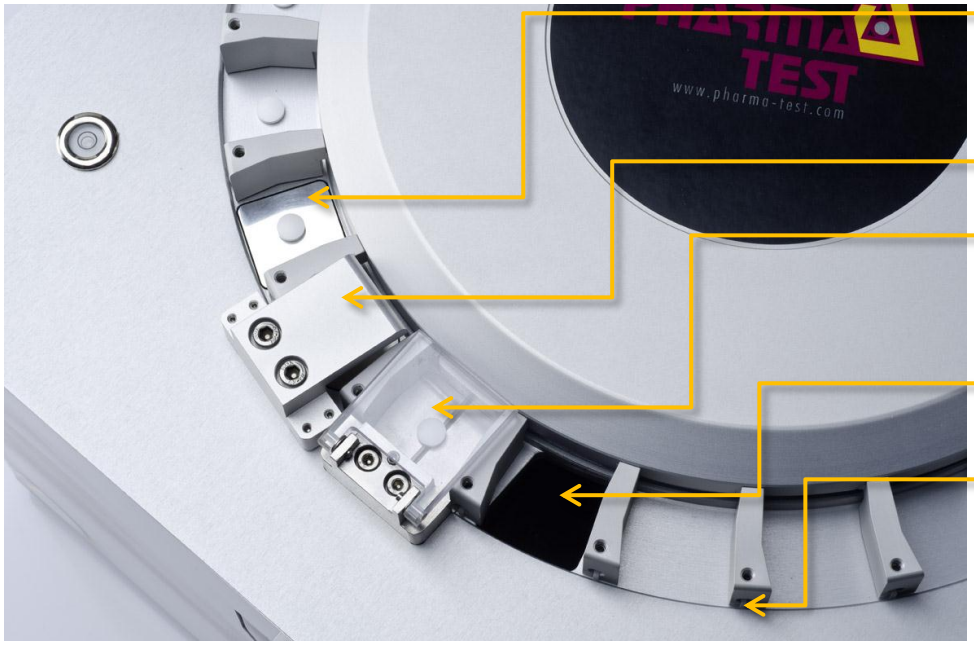
Operating Principle of the Sample Positioning Flaps



Use the WHT 3ME for all regular (round) and most odd shaped dosage forms. Its unique orientation “flap” design aligns automatically incorrectly positioned samples into the correct tip-to-tip hardness test position. The schematic on the right side shows the two flaps of the combined hardness and diameter testing station and the drive controlling the flap movement.

Use the single or multiple batch feeder or place up to 20 samples manually into the individual segments of the sample carousel. Select the valid testing program and start the run.

Below is a top down view of the sample carousel and the four testing stations of WHT 3ME:



- Square balance dish, directly connected to a Mettler-Toledo balance cell
- Thickness testing station
- Combined diameter and hardness testing station with sample orientation “flaps”
- Separate discharge for unbroken samples
- Replaceable Teflon scrapers to clean the balance dish and hardness test station from particles

Operation Principle of the Hardness Measurement

The current monographs of the USP and EP Pharmacopoeia define how a tablet hardness testing instrument should work, but without establishing data of how to increase the applied force and when to detect a sample to be broken. This often causes problems when trying to compare results of the same tablet measured with instruments from different manufacturers. The hardness result is directly influenced by the contact speed and force increase rate of testing instrument. A faster operated test jaw means a lower reproducibility and often higher absolute results. In order to offer the possibility to select an operating mode which will offer you similar results to other instruments you may already use, WHT 3ME allows to set the force mode by selecting between linear force increase or linear speed increase and the set the force rate. When the instrument detects that the sample has been touched, it switches to the measuring mode and starts to increase the force applied to the sample.

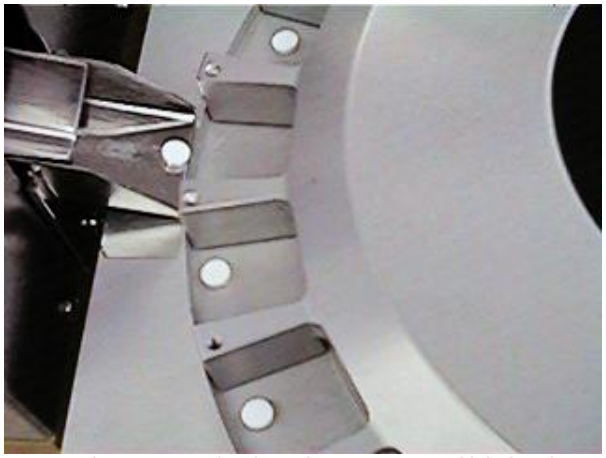
Which Force Mode to Select?

Since more than 10 years ago all Pharma Test tablet hardness testing instruments offer the possibility to select either linear force or linear speed increase. Linear force increase offers the most accurate control, as the rate of increase is directly controlled by the electronic load cell used to read the force. Also it is quite simple to validate the correct and linear operation, as a tablet with, for example 100N hardness, will be broken within 5 seconds, when 20N/s had been set as force increase rate. Linear speed increase can also be used; here the driving speed of the stepper motor is kept linear. Actually, as long as the touching force is kept low, there is not too much difference in the results between the two modes, but validation of this mode is reasonably difficult and requires specific equipment. In general results obtained with the linear speed increase mode are less reproducible than the ones with linear force increase mode. Therefore Pharma Test recommends using linear force increase. We will continue to offer both modes of operation in order to offer the possibility of comparing results of different instruments by setting the same parameters of operation.

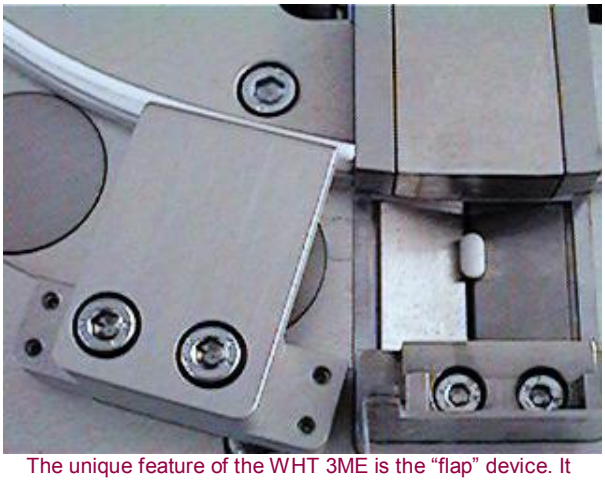
Sample Transportation

For sample transportation a carousel with 20 segments is used. Each of these segments takes one sample. Each segment is equipped with a Teflon scraper to clean the hardness testing jaws from cohesive products and to clean the track of residual particles.

Having a carousel for sample transport, the system can be used without the need of adding a batch feeding system. Simply place one sample into each segment and start the test series. The built-in micro-processor electronics receives the test result from the balance, thickness gauge, load cell and stepper motor and then transfers the information via the RS-232 interface to the WHT32 software program running on a Microsoft Windows PC. The PC itself can be placed anywhere in the laboratory and networking options exist as well.

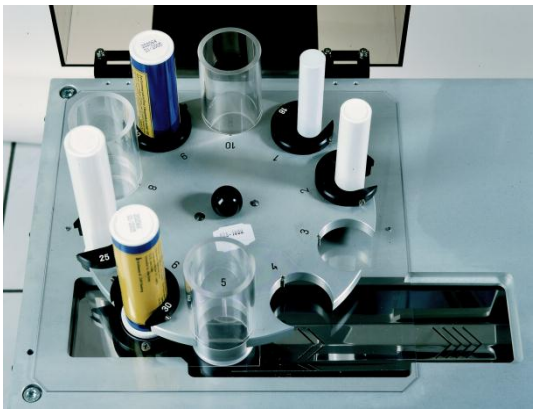


Sample transportation from the WHT-SM multiple batch feeder into WHT 3ME



The unique feature of the WHT 3ME is the “flap” device. It positions the sample precisely in the combined diameter and hardness test station.

Available Batch Feeders WHT-SM1 and WHT SM



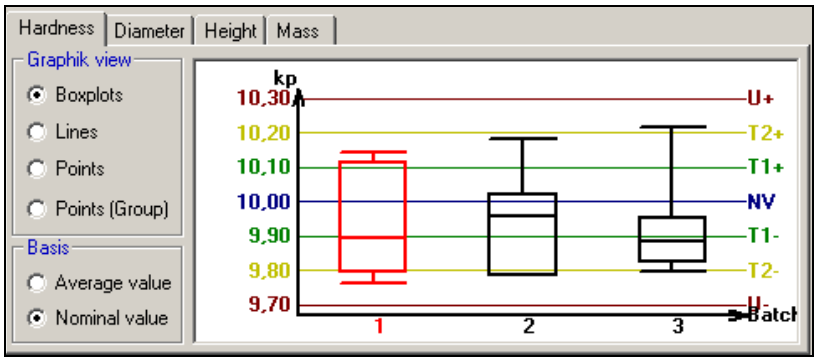
To feed and separate samples automatically use the WHT-SM multi-batch feeder (shown on the left) or the WHT-SM1 single batch feeder (see the picture below). The feeder is controlled by the master WHT 3ME instrument. The sensor controlled separate vibration tracks are self-adjusted to ensure perfect sample separation and transport. The self-adjustment automatically corrects the vibration speed according to the samples weight, shape and size to minimize waste. The corrected speed is filed for the sample tested and automatically used when this sample is tested the next time.

The WHT-SM multi-batch feeder system supports automated testing of up to ten different products or batches. As soon as all testing parameters for the samples have been entered the testing series can be started. The system operates with a speed of 10 to 15 samples per minute (depending on sample hardness). The WHT SM1 can be used instead of the WHT SM in case a single batch is usually tested. It is also possible to collect samples directly at a tablet press and automatically start a test run when a tablet is detected by the WHT 3ME inside the feeder. Unused samples are rejected and pass down a separate collector chute.

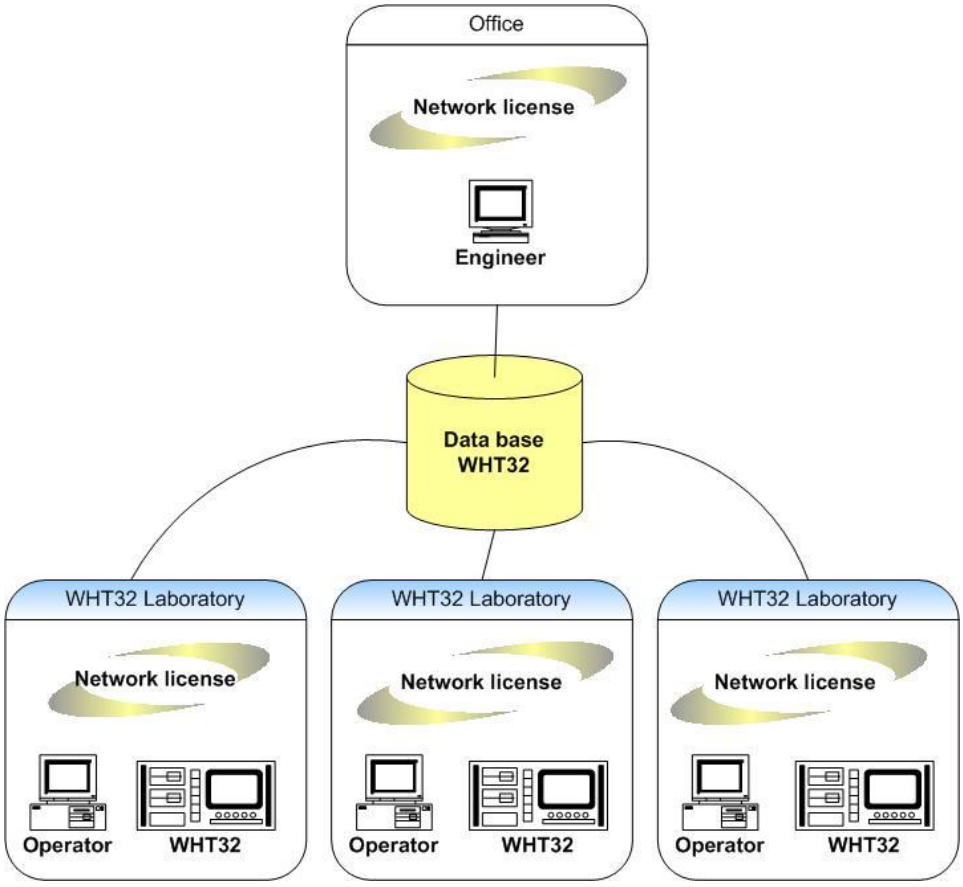
The WHT 3ME Thickness Testing Station

WHT32 Software Package

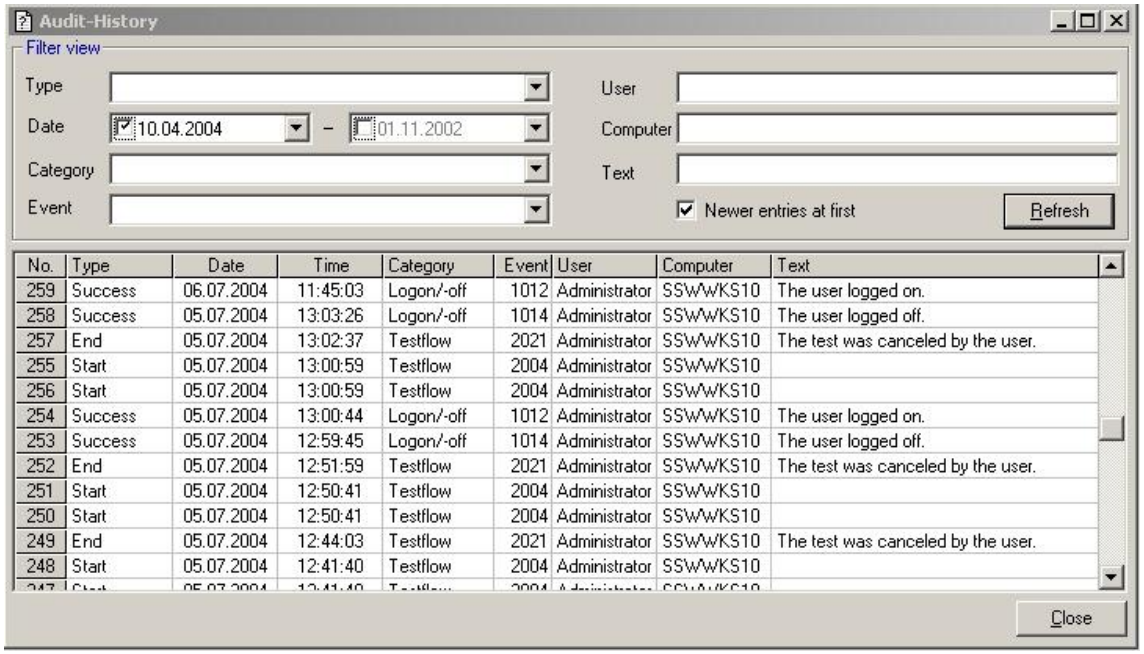
The WHT 3ME instrument is controlled by the powerful WHT32 software package. WHT32 is available with full 21 CFR Part 11 compliance and includes a methods and results data base, validation and calibration programs for all four testing stations, password administration, freely editable print-outs, statistical calculations and graphical print-outs for the performed test run as well as a batch statistical programs. The software is installed under Microsoft Windows NT, 2000, XP or 7 (32bit, GB/US/D language version).



Batch Comparison Result Display

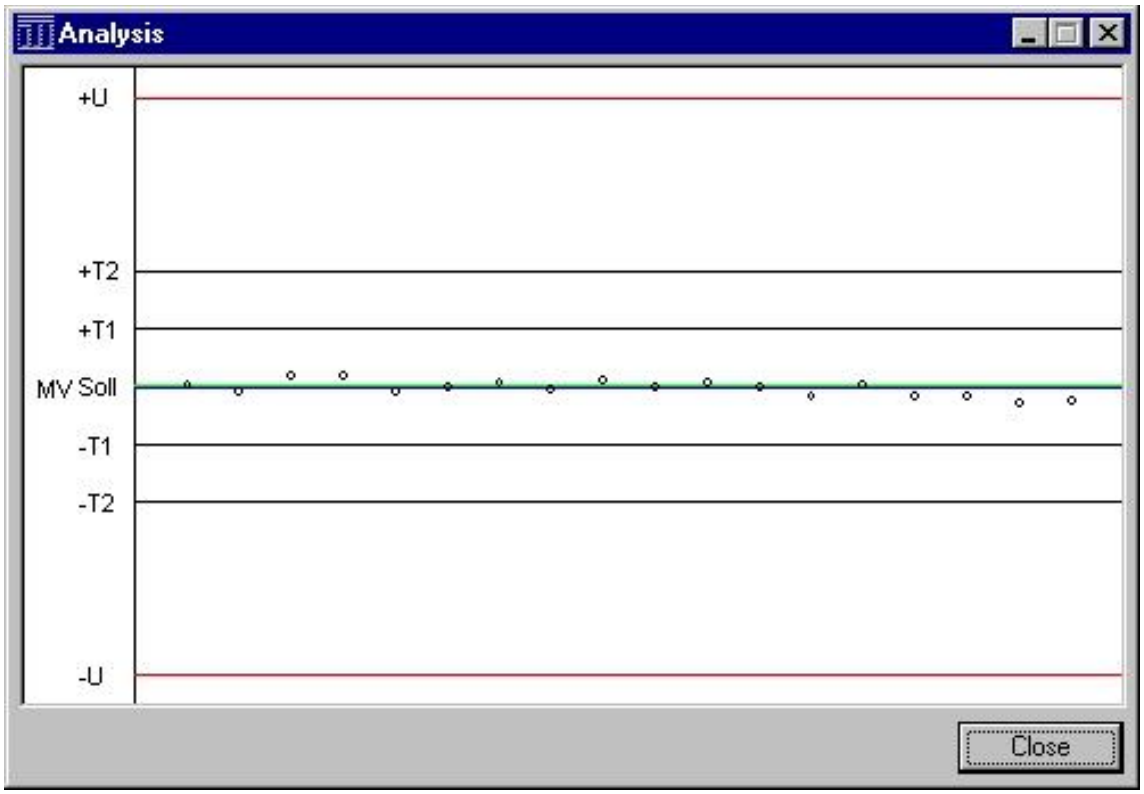


Networking Capabilities

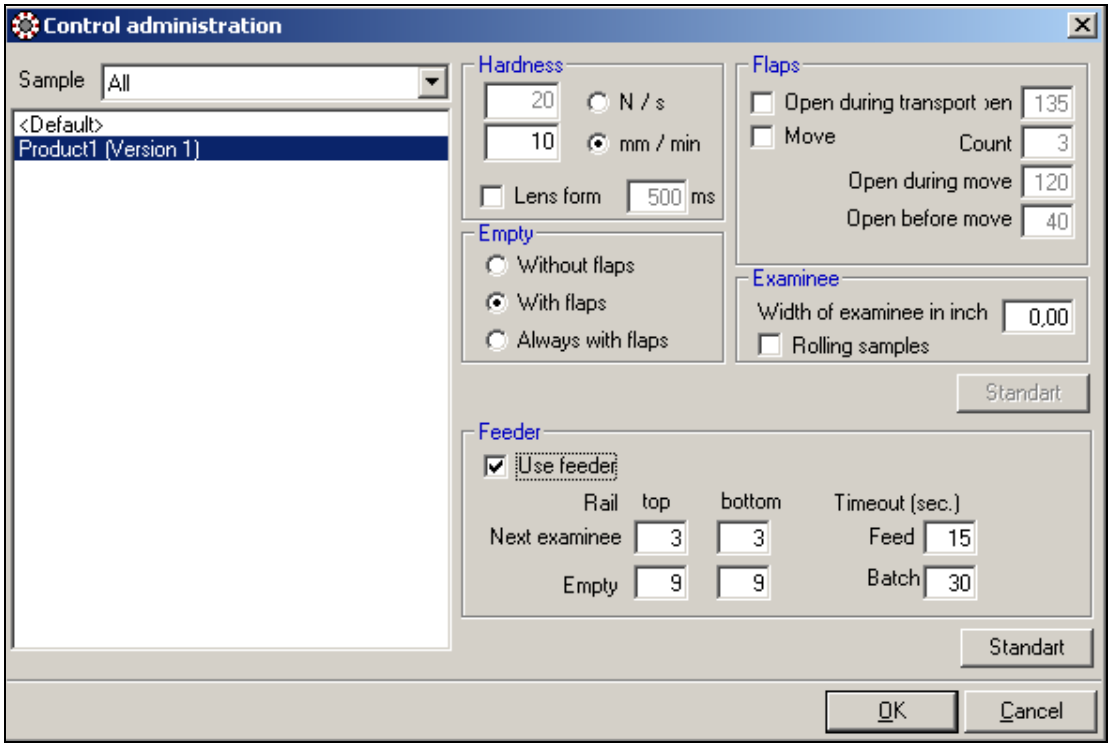


No.	Type	Date	Time	Category	Event	User	Computer	Text
259	Success	06.07.2004	11:45:03	Logon/-off	1012	Administrator	SSWWKS10	The user logged on.
258	Success	05.07.2004	13:03:26	Logon/-off	1014	Administrator	SSWWKS10	The user logged off.
257	End	05.07.2004	13:02:37	Testflow	2021	Administrator	SSWWKS10	The test was canceled by the user.
255	Start	05.07.2004	13:00:59	Testflow	2004	Administrator	SSWWKS10	
256	Start	05.07.2004	13:00:59	Testflow	2004	Administrator	SSWWKS10	
254	Success	05.07.2004	13:00:44	Logon/-off	1012	Administrator	SSWWKS10	The user logged on.
253	Success	05.07.2004	12:59:45	Logon/-off	1014	Administrator	SSWWKS10	The user logged off.
252	End	05.07.2004	12:51:59	Testflow	2021	Administrator	SSWWKS10	The test was canceled by the user.
251	Start	05.07.2004	12:50:41	Testflow	2004	Administrator	SSWWKS10	
250	Start	05.07.2004	12:50:41	Testflow	2004	Administrator	SSWWKS10	
249	End	05.07.2004	12:44:03	Testflow	2021	Administrator	SSWWKS10	The test was canceled by the user.
248	Start	05.07.2004	12:41:40	Testflow	2004	Administrator	SSWWKS10	

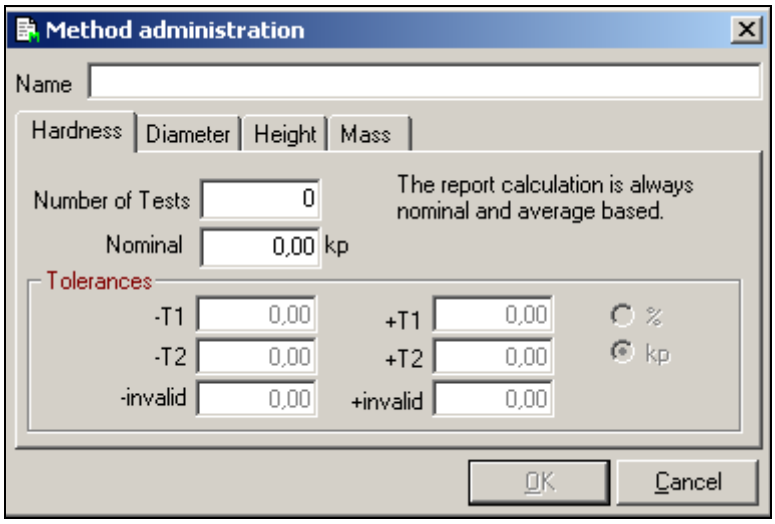
Audit Trail



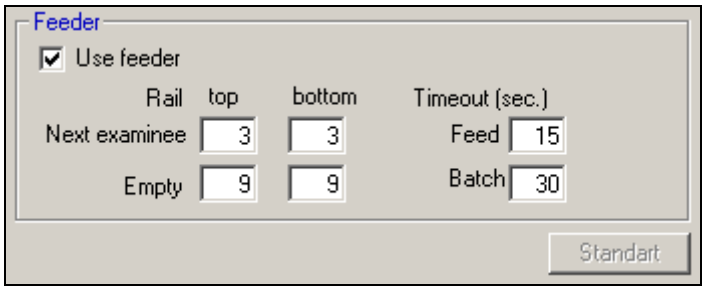
Analysis of Results



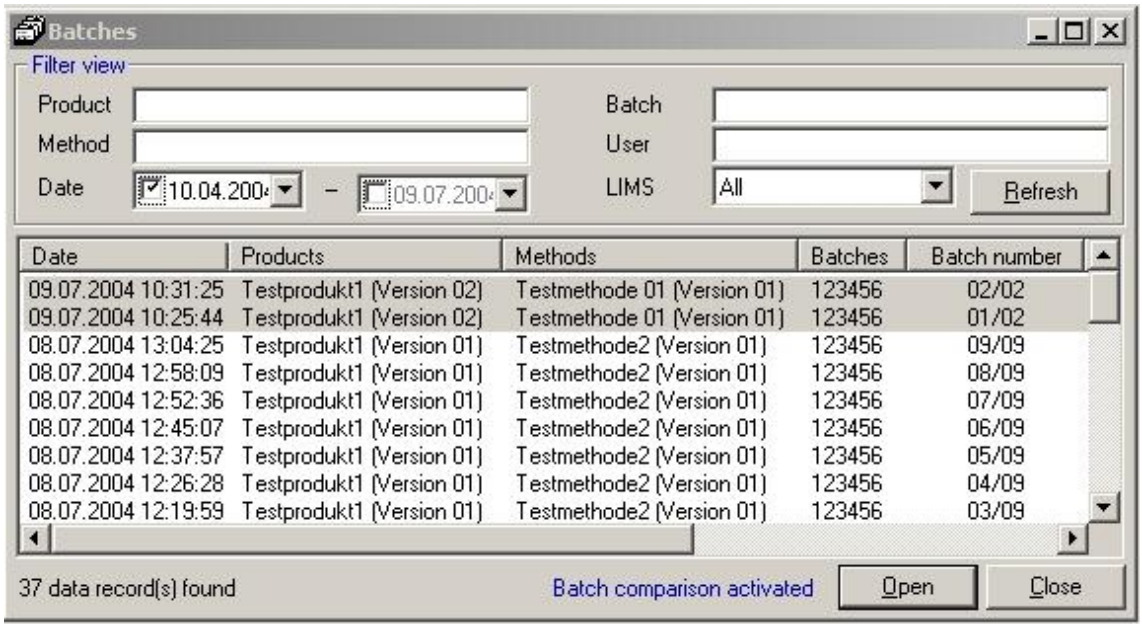
Product Specific Handling (Control) Parameters



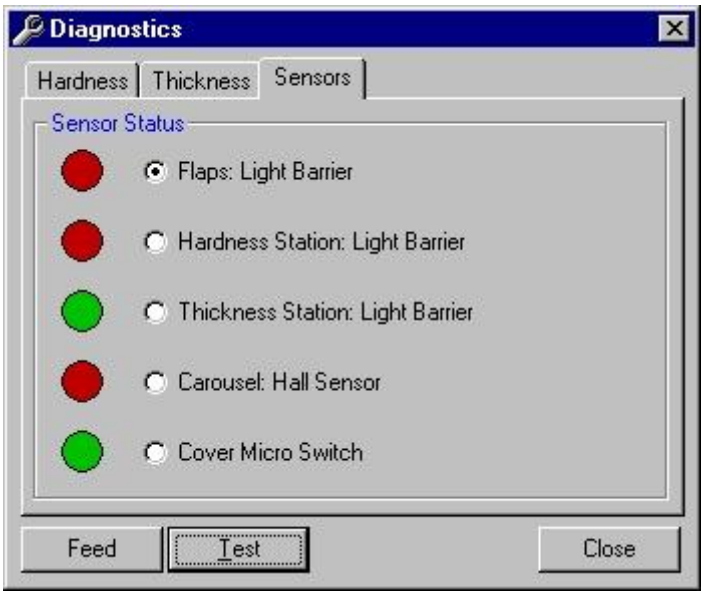
Test Method Administration



WHT SM/WHT SM1 Feeder Vibration Control Parameters



Batch Administration



Integrated Diagnostics to Help Trouble Shooting

PHARMATEST Test System WHT/2 - S/N: 010889

Batch:	**Test 4 4**	Date:	19.04.2002
Product:	Muster	Time:	10:51
Method:	Test	User:	Administrator

	Weight mg		Thickness mm		Diameter mm		Hardness N	
1.	207,8		2,90		8,08		138,30	>T1
2.	201,2		2,85		8,18	>T1	119,50	
3.	206,0		2,89		8,09		124,20	
4.	199,3		2,85		8,08		115,50	
5.	212,7		2,93		8,11		131,00	
6.	205,8		2,90		8,07		138,90	>T1
7.	204,7		2,88		8,12		125,40	
8.	208,7		2,92		8,10		140,30	>T1
9.	203,5		2,87		8,11		128,90	
10.	202,9		2,84	<T1	8,12		123,90	
11.	204,4		2,89		8,11		119,20	
12.	200,9		2,82	<T1	8,10		109,00	<T1
13.	208,1		2,89		8,10		137,50	>T1
14.	203,6		2,85		8,13		120,60	
15.	207,4		2,89		8,13		129,50	
16.	204,1		2,87		8,12		116,30	
17.	203,3		2,85		8,12		119,10	
18.	205,6		2,88		8,10		127,40	
19.	208,0		2,89		8,09		117,40	
20.	204,7		2,95	>T1	8,09		129,90	

The regularity of the mass in compliance with Ph./Eur. (EP)

Statistics

	Weight	Thickness	Diameter	Hardness
Last Adjustment on:	12.04.2002	12.04.2002	11.04.2002	11.04.2002
Count:	20	20	20	20
Nominal	210,0 mg	2,90 mm	8,08 mm	125,00 N
MV:	205,1 mg	2,88 mm	8,11 mm	125,59 N
Min:	199,3 mg	2,82 mm	8,07 mm	109,00 N
Max:	212,7 mg	2,95 mm	8,18 mm	140,30 N
Tolerances based on Average				
s:	3,1 mg	0,03 mm	0,02 mm	8,75 N
Vc:	1,5147 %	1,1063 %	0,2964 %	6,9666 %
Tolerances based on Nominal				
s:	5,9 mg	0,04 mm	0,04 mm	8,77 N
Vc:	2,7997 %	1,2975 %	0,4587 %	7,0162 %

Signatures:

Pharmatest WHT/2 - V2.06 - 16.01.2002 - 1.2.6 - 1.1.8 - 9 - Z - 010889

Example of a Typical Results Report

Calibration and Adjustment

PT-MT3 Magnetic Test Tablet

The current USP Pharmacopeia requires the force sensor of a tablet hardness testing instrument to be calibrated periodically over the complete measuring range (or the range used for measuring samples) with a precision of 1N. All Pharma Test tablet hardness testing instrument can be statically calibrated over the complete measuring range by the use of different traceable counterweights. All instruments support the checking of at least three different points during calibration to prove the linearity of the force sensor.

Furthermore, Pharma Test offers the PT-MT3 magnetic tablets to calibrate the breakpoint detection of the whole tablet hardness testing instrument (force sensor and mechanics of the instrument). All Pharma Test tablet hardness testing instruments are fully compliant to the requirements of the current USP Pharmacopeia.

WHT32 features an access controlled calibration and adjustment program for the four testing stations. For the thickness and diameter station, certified reference blocks sets are used for both calibration and adjustment. Weight sets are used to calibrate and adjust the force sensor (load cell) of the instrument over the complete measuring range. For the two point adjustment (zero and reference) of the load cell inside the hardness station a certified reference weight of 10 kg is used. For validation purposes the use 5 up to 50kg certified weights is recommended. The latest calibration and adjustment results are stored on and can be printed and signed. Calibrate the built-in Mettler Toledo balance cell using a 50mg calibrated reference weight.

PTB-CAL15 5, 10, 15kg adjustable weight set

Advantages

Some of the highlights the WHT 3ME instrument offers are:

- Fully automated operation
- Unique flap mechanism to precisely position samples for hardness and diameter test
- No change of tools necessary to handle different tablet shapes
- Stainless steel housing to fit well into a production area
- Standard version of WHT32 software package included in the standard supply
- IQ/OQ documents included free of charge

Some of the highlights the WHT32 software package offers are:

- Integrated instrument qualification procedure
- Automated flap control for opening and closing angle and adjustable speed (depends on sample size and thickness)
- Automated speed adjustment for tablet transportation
- Special transport adjustment options for “rolling” samples, like caplets
- Special diameter and hardness test program to run deep concave tablets which tend to ”stand up” while moved for hardness and diameter testing
- Software controlled display, data entry and calculation facilities
- Gel Capsule weight control program
- Immediate display and filing of all results
- Graphical display of results either as a chart diagram or variation curve
- Immediate documentation of all results on screen and printer
- Calibration and validation procedures for all integrated stations

Separate Waste Container for Broken and Unbroken Samples

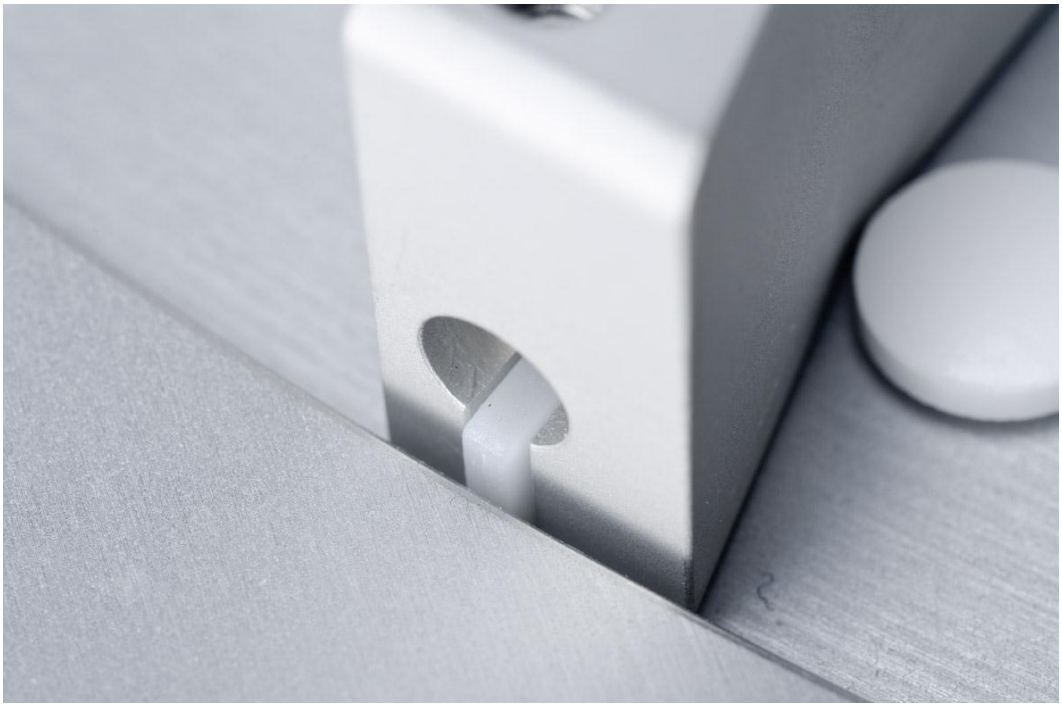
Features

The main features of the WHT 3ME instrument are:

- Tablet hardness testing in full compliance to USP <1217> and EP <2.9.8> Pharmacopeia
- 4 results of the same sample: thickness, diameter, hardness and weight (via internal balance)
- Dual force mode instrument with linear speed increase and linear force increase modes
- Multiple point validation procedure for all measurement stations built-in

The main features of the WHT32 software package are:

- Product dependent method description including number of tests to be done within each testing station, T1 and T2 tolerance classification, plausibility rejection, selectable measuring units and adjustable measuring parameters
- Statistical calculations of mean value, absolute and relative standard deviations, minimum and maximum result
- Batch comparison statistics
- Networking capabilities (optional)
- Features a robust SQL MS Jet database
- User and password and login administration (21CFR part11 option)
- Audit trail and data path selection (21CFR part 11 option)
- Calibration programs for each testing station (requires calibration tools, such as reference blocks, weights etc.)
- Result data transfer via RS-232 data interface
- Microsoft Excel and LIMS export functionalities (optional)
- Software IQ and OQ documentation available



Exchangeable Teflon Scrapers Help Cleaning the Carousel and Testing Stations

Standard Scope of Supply

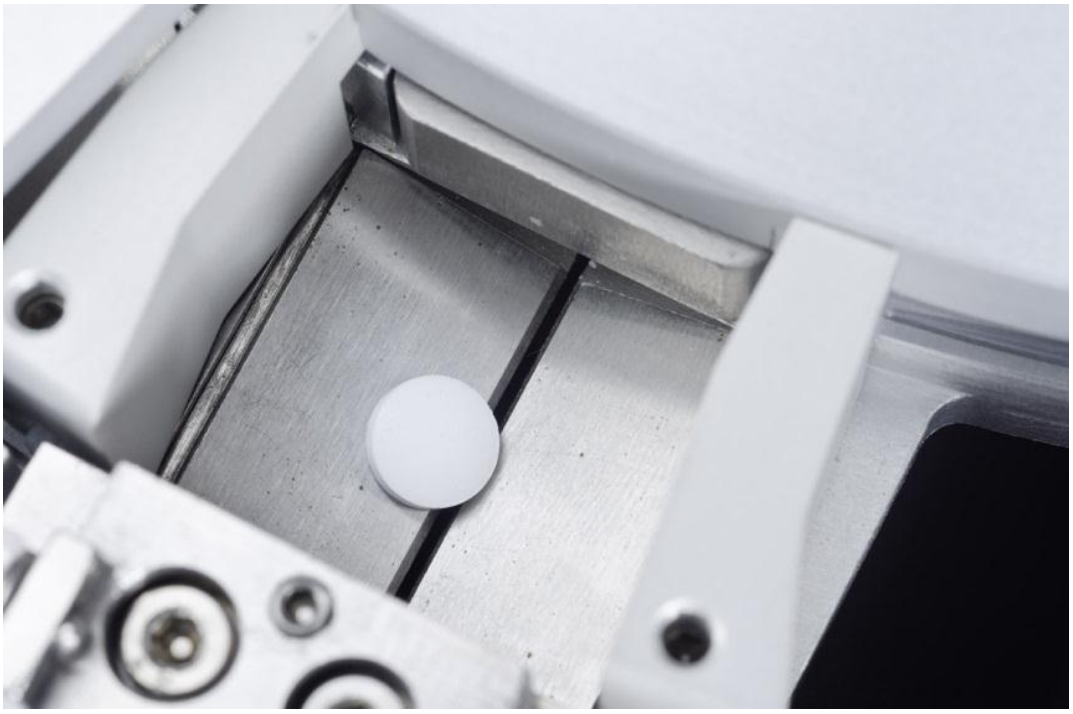
The WHT 3ME comes ready to use[1] with the following standard scope of supply:

- WHT 3ME instrument
- WHT32 software package (standard version)
- A set of 3, 5 and 10mm reference blocks
- Comprehensive documentation folder including:
  - User manual
  - IQ documentation
  - OQ documentation
  - Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- Extended hardness range of up to 500N
- WHT32 21 CFR software update for audit trail, user administration and more
- WHT32 LIMS data transfer module
- WHT32 Network license



Unique flap mechanism to precisely position the samples

[1] A suitable PC running Microsoft Windows has to be provided and is not included with purchase of the instrument. Please ask for the latest system requirements document.

Technical Data

Parameter	Specification
Number of Testing Stations	4 (Hardness, Thickness, Diameter and Weight)
Hardness Testing Range	2.0 – 300.0N (optional 5.0 – 500.0N)
Hardness Accuracy	Better than 1N
Thickness Testing Range	2.00 – 15.00mm
Thickness Accuracy	Better than ±0.02mm
Diameter Testing Range	2.00 – 30.00mm
Diameter Accuracy	Better than ±0.02mm
Weight Measurement	By internal Mettler-Toledo balance cell
Weight Testing Range	0.0001g – 50.0000g
Weight Accuracy	0.1mg
Sample Handling	Semi- or fully automated using single or multi-batch feeder
Testing Speed	10 to 15 tests per minute depending on sample hardness
Flap Control	Flap speed and opening angle steplessly adjustable
Number of Tests	Up to 250 tests in one test run
Measuring Units	Thickness and diameter selectable between millimeter (mm) and inches (IN) Hardness selectable between Newton (N), Kilopond (kp) and Strong Cobb (Sc)
Force Mode	Selectable between linear force increase and linear speed increase
Force Rate	5 – 200N/sec. (linear force increase) or 5 – 200mm/Min. (linear speed increase)
Calibration Procedure	Using certified 1-30 mm reference blocks, 50g (for balance) and 5 to 50kg (for load cell) reference weights
Break Force Validation	Using the PT-MT3 magnetic tablet at 10 to 480N
Interface	RS232 serial port for PC connection
Instrument Housing	Stainless steel (304) to meet GLP requirements
Power	110/230 Volt, 50/60 Hz
Packaging Dimensions	Approx. 90cm x 65cm x 75cm (D x W x H); approx. 118cm x 76cm x 70cm incl. WHT SM
Net Weight	Approx. 45kg; approx. 73kg incl. WHT SM
Gross Weight	Approx. 70kg; approx. 105kg incl. WHT SM
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

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