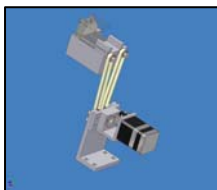


Fully Automated Tablet Testing System 4in1 - Type WHT 3ME



Test WEIGHT, THICKNESS, 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, length (or 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 4 test parameters of the same sample. The instrument is offered as a Stand Alone Unit controlled by an external Computer System. A Single- or Multi-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.



Operating Principle of the Sample Positioning Flaps ...

Use the WHT 3ME suitable for all regular (round) and most odd shaped dosage forms. Its unique orientation Flap design aligns automatically incorrect positioned samples into the correct tip-to-tip hardness test

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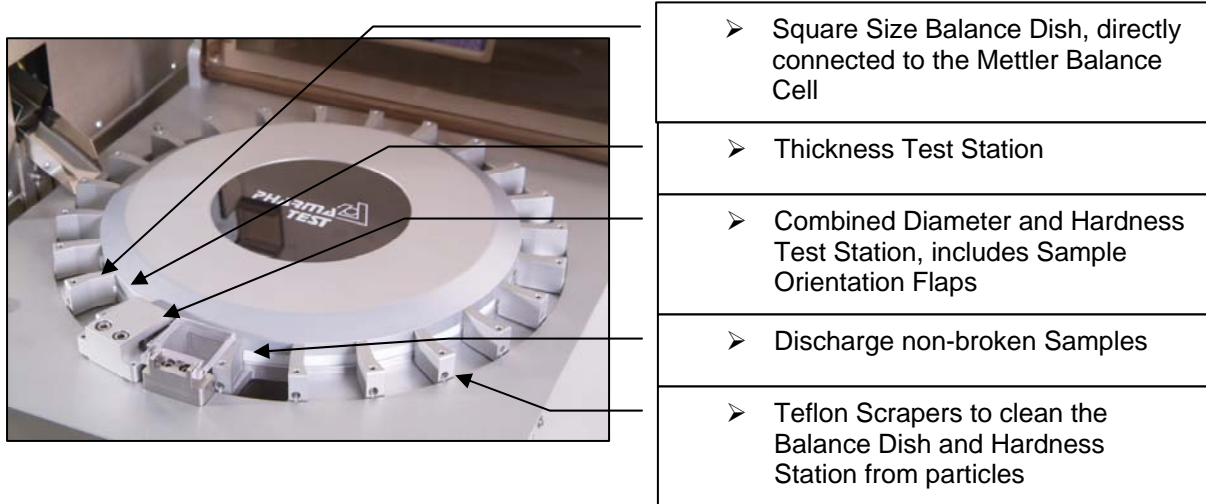


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position. Use a Single or Multiple Batch feeder or place 20 samples manually into the individual segments of the Sample Carousel. Select the valid testing program and start the run.



Which force mode to select ?

Linear force increase certainly offers the most accurate control, as the rate of increase is directly controlled by the electronically load cell used to read the force. Also it quite simple to validate the correct and linear operation as a Tablet of 100 Newton hardness will be broken within 5 seconds if 20N/s had been adjusted.

Linear speed increase can also be used. Here the driving speed of the stepper motor is kept linear. Actually if the touching force is kept low there is not too much difference in results between the 2 systems

System which run on high speed often measure the force while moving forward instead of the breaking of sample. Usually the results of faster operating systems are therefore higher. This can be avoided if slower speed or force rates are selected

Sample Transportation



For sample transportation a carousel is used which has 20 segments, each of which takes a tablet. Each segment is equipped with a PTFE 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 adding a batch feeding system. Just place one sample into each segment and start the test series. The built-in micro processor electronics receives the test from the balance, thickness gauge, load cell and stepper motor and then transfers the information via RS-232 interfacing to a software program installed under Windows™

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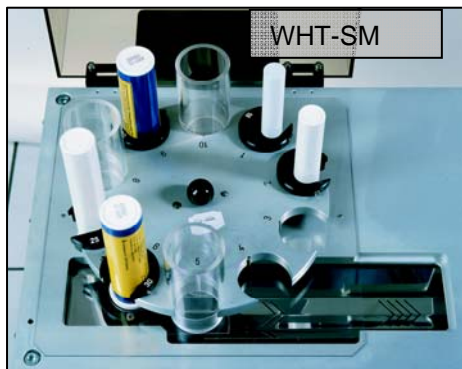
2000/XP (D/GB/US Version) in a suitable PC. The PC itself may be placed anywhere in the laboratory.

Batch Feeder WHT SM or WHT SM1



To feed and separate samples automatically use the WHT-SM Multi Batch Feeder or the **WHT-SM1** Single Batch Feeder. Sensor controlled separate vibration tracks are self adjusted to ensure perfect separation and sample transport. The self adjustment automatically corrects the vibration speed according to the samples weight, shape and size to minimise waste. The corrected speed is filed for the sample tested and automatically used when the sample should be tested ever again. The WHT SM1 can be used instead of the WHT SM if single batches shall be tested. It is also

possible to collect samples directly from a Tablet Press and automatically start a Test Run when a tablet is detected inside the Feeder Control.



Automated testing of up to 10 different Products or Batches, using the **WHT-SM** Multi Batch Feeder System which is controlled by the Master Instrument. As soon as all testing parameters for the samples have been entered the testing series can be started. Operate the System with a speed of 10 - 15 samples per minute (depending on samples hardness). Use the WHT-SM1 if samples are collected directly from a tableting machine. On sample arrival the detection sensing system automatically begins the test procedure. Unused samples are rejected and pass down a

separate collector shoot.

WHT32 Software

The 21 CFR Part 11 compliant WHT32 software package includes a Methods and a Results Data Bank, Validation and Calibration programmes for all 4 testing stations, password administration, freely editable printouts, statistical calculations and graphical prints for the performed test run as well as a batch statistical programmes. Install the software under Windows NT, 2000, XP™ (GB/US/D version).

The WHT32 software offers:

- Auto speed adjustment for tablet transportation
- Automated flap control for opening and closing angle (depends on sample size - thickness)
- Adjustable flap operation speed
- Special transport adjustment for "rolling" samples, like caplets
- Special diameter and hardness test program to run deep concave tablets which intend to "stand up" while moved for hardness and diameter testing
- Instrument qualification procedure

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Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

- Station calibration program (requires calibration tools, such as reference blocks, weights etc.)
- User and password administration (21CFR part11)
- User login administration (21 CFR part 11)
- SQL MS Jet data bank (21CFR part 11)
- Audit trail (21CFR part 11)
- Data path selection (21 CFR part 11)
- Batch comparison statistic
- Gel Capsule weight control program
- Excel export (option)
- LIMS export (option)
- Networking
- Software IQ and OQ documentation
- Software controlled display, data entry and calculation facilities
- 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
- Immediate display and filing of all results
- Statistical calculations of mean value, absolute and relative standard deviations, minimum and maximum result
- Graphical display of results either as a chart diagram or variation curve
- Immediate documentation of all results on screen and printer
- Result data transfer via RS-232 data interface
- Calibration and validation procedures for all integrated stations

Special Features:

- Product dependent operation parameters to adjust transportation speed, sample orientation flap, number of tests in each station, T1 and T2 tolerance ranges, selectable testing units

Calibration of the stations

- Calibrate the built-in Mettler Balance Cell using a 50mg calibrated reference weight
- Calibrate Thickness and Diameter Station using calibrated reference blocks, 1-30 mm
- Calibrate the Hardness Testing Station statically using a 10kg certified reference weight

Qualification of the stations

- Qualify the Mettler Balance Cell using certified weights
- Qualify the Thickness and Diameter Station using certified reference blocks 1-30 mm
- Qualify the Linearity of the built-in load cell of the Hardness Test Station using the PTB-CAL3 weight handle, 5, 10, 15 kg
- Qualify the Breakpoint Detection of the Hardness Testing Station using the PT-MT Magnetic Tablet
- Qualify the Force Increase rate using the PT-MT3 Magnetic Tablet

Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

PQ Instrument Qualification

- Use the validation program to qualify all 4 testing stations, including linearity test for the hardness station. A printed report shows all results

Batch Feeding using WHT SM1 or WHT SM

- Sensor controlled, product dependent transportation speed
- WHT SM multi batch feeding of different samples
- WHT SM1 single batch feeding, collect samples from a Tablet Press
- Automatic rejection of unused samples
- Error free sample handling within batch feeder

Technical Data WHT 3ME

Test Stations:	4
Sample Handling:	Semi- or fully automated using batch feeder
Testing Speed:	10 - 15 test per minute (depends on sample hardness)
Testing range weight:	0.0001 to 50.0000 gr. using built-in Mettler Balance Cell
Accuracy:	0.1 mg
Testing range thickness:	2.00 - 15.00 mm
Accuracy:	Better 0.02 mm
Diameter:	2.00 - 30.00 mm - 35 mm optional available WHT 3MEB
Accuracy:	Better 0.02 mm
Hardness:	2.0 - approx. 300 N (Newton) - 500N option available
Accuracy:	Better 1 N
Measuring units diam.:	Selectable in either mm (Millimetre) or In (Inch)
Hardness:	Selectable in either Newton (N), kilopond (kp) or Strong Cobb (Sc)
Force rate:	Adjustable for linear force increase or linear speed increase
Range:	5 - 50 mm/minute or 5 - 50 N/sec.
Number of tests:	250
Calibration Procedure:	Needs 1-30 mm reference blocks, 50g and 5-15 kg PTB-CAL3 reference weight (all certified)
Flap Control:	Flap speed steplessly adjustable - opening angle steplessly adjustable
Validation breaking force:	PT-MT2 magnetic tablet at 50 - 85 and 130 N
Validation linearity:	Different certified weight, eg. 5kg - 10kg - 20kg ..
Validation Thickn.-Diam.:	1-20 mm reference blocks
Validation Balance Cell:	50 g reference weight
Interface:	RS-232 port for PC connection
Instrument Housing :	Stainless steel to meet GLP requirements

Instrument Options

- Extended hardness range up to approx. 550 N
- Extended sample transportation to 35 mm to run vitamin tablets etc.
- Special Batch Feeder for soft tablets like vitamins

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Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

Software Options

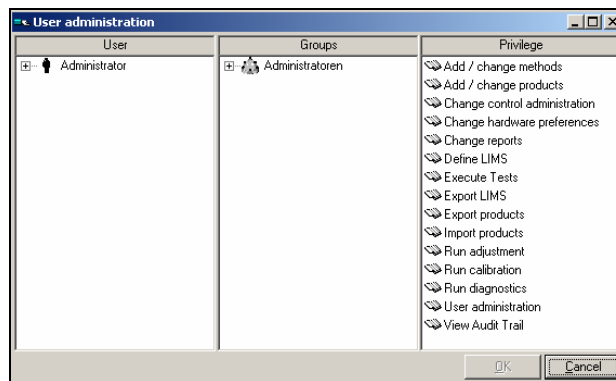
WHT 32 CFR software update for CFR21 Part11 compliant operation. This package includes among others:

- User and User Group password administration
- User Login Administration
- SQL MS JET data bank
- Audit Trail
- Data Path Selection
- WHT 32 LIMS Data Transfer Module
- WHT 32 Network licence

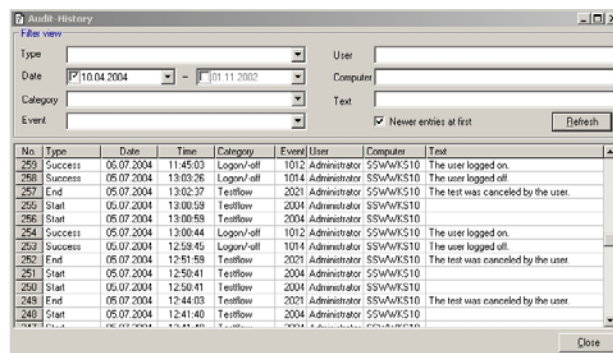
We reserve the right to make technical changes without any prior notice

WHT32 Software Information

WHT 32 User and Password Administration



Audit Trail



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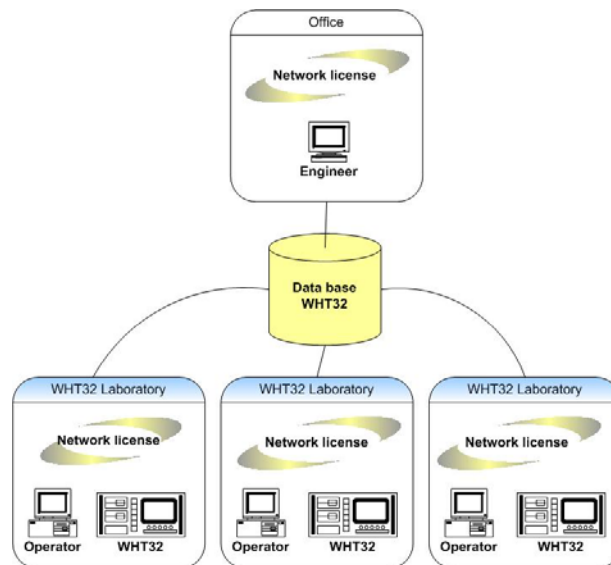


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Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

Networkability (needs Network Software Licence)



Product Specific Handling (Control) Parameters

The screenshot shows the 'Control administration' software interface. It features a 'Sample' dropdown menu set to 'All' and a list of products, with 'Product1 (Version 1)' selected. The interface is divided into several sections for parameter configuration:

- Hardness:** Includes input fields for '20' and '10', radio buttons for 'N / s' and 'mm / min', and a 'Lens form' field set to '500 ms'.
- Empty:** Includes radio buttons for 'Without flaps', 'With flaps' (selected), and 'Always with flaps'.
- Flaps:** Includes checkboxes for 'Open during transport' (checked), 'Move', 'Open during move', and 'Open before move', along with numerical input fields for '135', '3', '120', and '40'.
- Examinee:** Includes a 'Width of examinee in inch' field set to '0,00' and a 'Rolling samples' checkbox.
- Feeder:** Includes a checked 'Use feeder' checkbox and a table for timing parameters:

	Rail	top	bottom	Timeout (sec.)
Next examinee	3	3	3	Feed 15
Empty	9	9	9	Batch 30

The interface also includes 'Standart' buttons for the Examinee and Feeder sections, and 'OK' and 'Cancel' buttons at the bottom.

Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

Test Method Administration

Method administration

Name

Hardness | Diameter | Height | Mass

Number of Tests The report calculation is always nominal and average based.

Nominal kp

Tolerances

-T1 +T1 %

-T2 +T2 kp

-invalid +invalid

WHT SM/SM1 Feeder Vibration Control

Feeder

Use feeder

Rail top bottom Timeout (sec.)

Next examinee Feed

Empty Batch

Batch Administration

Batches

Filter view

Product Batch

Method User

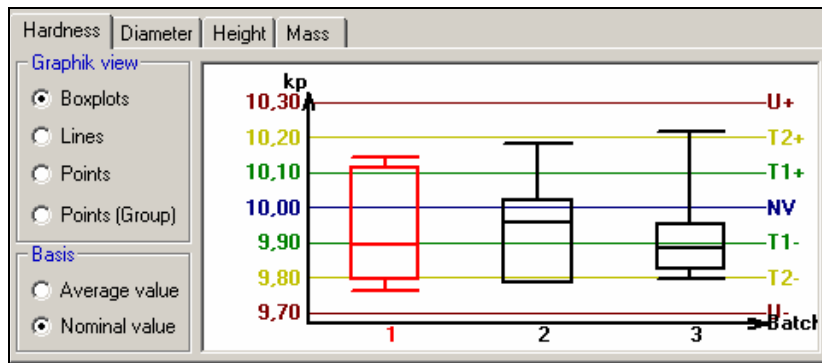
Date - LIMS

Date	Products	Methods	Batches	Batch number
09.07.2004 10:31:25	Testprodukt1 (Version 02)	Testmethode 01 (Version 01)	123456	02/02
09.07.2004 10:25:44	Testprodukt1 (Version 02)	Testmethode 01 (Version 01)	123456	01/02
08.07.2004 13:04:25	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	09/09
08.07.2004 12:58:09	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	08/09
08.07.2004 12:52:36	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	07/09
08.07.2004 12:45:07	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	06/09
08.07.2004 12:37:57	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	05/09
08.07.2004 12:26:28	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	04/09
08.07.2004 12:19:59	Testprodukt1 (Version 01)	Testmethode2 (Version 01)	123456	03/09

37 data record(s) found Batch comparison activated

Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

Batch Comparison Result Display



Typical Result Printout

PHARMA TEST 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
2.	201,2	2,85	8,18	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
7.	204,7	2,88	8,12	125,40
8.	208,7	2,92	8,10	140,30
9.	203,5	2,87	8,11	128,90
10.	202,9	2,84	8,12	123,90
11.	204,4	2,89	8,11	119,20
12.	200,9	2,82	8,10	109,00
13.	206,1	2,89	8,10	137,50
14.	203,6	2,85	8,13	120,60
15.	207,4	2,89	8,13	128,50
16.	204,1	2,87	8,12	116,30
17.	203,3	2,88	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	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 %	0,2064 %	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

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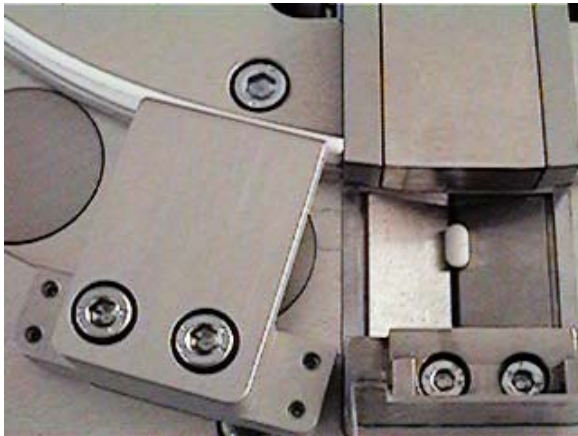


Fully Automated Tablet Testing System 4in1 - Type WHT 3ME

Weights and Packaging

WHT 3ME	Net weight:	45 kg	Gross weight:	70 kg
	Packaging:	900 mm x 650 mm x 750 mm		
WHT 3ME and WHT SM	Net weight	73 kg	Gross weight:	105 kg
	Packaging:	1180 mm x 760 mm x 700 mm		

Unique Features of the WHT 4in1 System



The unique feature of the WHT 3ME is the movable FLAP device. It positions precisely within the Length/Hardness test station.



Sample transportation from the Multi-Batch into the WHT 3ME sample track.

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

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