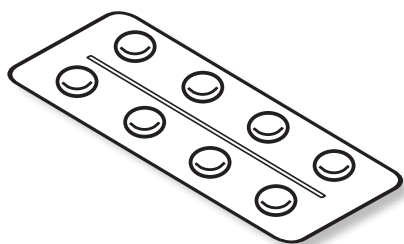


Hardness

INTRODUCTION ►►►



Copley Philosophy

Robust	✓	Reliable	✓
Easy to use	✓	Compliant	✓

Modern day tablets come in a variety of forms – uncoated, coated, dispersible, effervescent, gastro-resistant, modified release, soluble, rapidly disintegrating, slowly disintegrating, etc. Each type places different demands on the formulation concerned.

Manufacturing processes such as coating, printing, packaging and rigours of handling and transport place additional demands on the mechanical integrity of the finished product.

Together with friability testing, the testing of a tablet's **hardness (or more correctly breaking force)** plays a vital role in both product development and subsequent quality control.

In this test method, the tablet is placed between two platens (jaws), one of which is attached to a load cell and the other to a motor which provides the mechanical drive. During testing, the motorised jaw drives forward pressing the tablet against the fixed jaw until such time as the tablet breaks, whereupon the motorised jaw retracts and the load required to break the tablet is recorded.

High hardness values may indicate, for example, increased disintegration times and reduced dissolution values. On the other hand, if hardness is too low then friability, and hence % defective, may well be too high. By exploiting the correlation between hardness, disintegration, dissolution, friability, percentage defective and weight variation, the various parameters can be manipulated to produce a dosage form with optimum characteristics.

Significant advances have been made in the field of tablet hardness testing in recent years. Copley Scientific offers a range of semi and fully automatic electronic testers incorporating these advances and varying in sophistication from simple hand-held units for use on the production floor to fully automatic units incorporating printout and data input/output facilities.

All Copley Hardness Testers feature:

- Simple, easy to use operation ensures that the number of operations required to perform a test is kept to a minimum
- Full supporting documentation (including full IQ/OQ/PQ qualification documentation where applicable)



TABLET HARDNESS TESTER TBF 1000

The Tablet Hardness Tester Model TBF 1000 combines the economy of a simple, easy to use tester with the performance and accuracy of microprocessor controlled data collection.

It was designed in accordance with the specifications as laid down in **Ph.Eur. Chapter 2.9.8 Resistance to crushing of tablets** and **USP Chapter <1217> Tablet Breaking Force**.

Foremost in the design specification were those features that you, the user, identified as being essential to the **"ideal"** hardness tester.

You told us, for example, that the unit must be as **compact** as possible such that it could be used in the confines of the tablet press booth.

Measuring only 283 mm x 235 mm x 160 mm (w x d x h) (including **in-built printer** and **optional keyboard**) and weighing 8.5 kg, the TBF 1000 has the smallest footprint of any hardness tester of its type on the market, making it ideal for this purpose.

You told us that the unit should be **simple to operate** - the TBF 1000 employs just three touch sensitive keys located on the front panel to set up, perform a test and provide a printout of the results, namely <New Size>, <Test> and <Stats>.

At the same time, you asked for a number of **advanced and sophisticated features** - so, we provided them plus a small QWERTY keyboard located in the base of the instrument to access them.

The 4-line on-screen menu leads you through the measuring process. If **diameter** measurements are required, ensure that this option is selected prior to operation.

Attach a balance and/or thickness gauge and the TBF 1000 will collect **weight and thickness data** as well.

On completion of the test, the TBF 1000 automatically prints out the results and **statistical analysis** including time, date, min, max, mean and standard deviation together with the batch number and size.

Finally, you asked us whether it would be possible to **output data** to an external PC or printer - so, on the back of the unit, in addition to the interfaces for balance and thickness gauge, we have provided two further ports, one RS232 and one USB, to satisfy this request.

PRINCIPLES OF OPERATION

The principle of measurement is based on proven electronic load cell technology used in conjunction with a mechanical drive and electronic signal processing.

In practice, the tablet is placed on a platform between two precision ground platens (jaws), one of which is attached to the load cell and the other to a motor which provides the mechanical drive.

During testing, the motorised jaw drives forward pressing the tablet against the fixed jaw until such time as the tablet fractures, whereupon the motorised jaw retracts and the change in the resistance of the strain gauge employed on the load cell (the breaking force) is measured.

The pressure to the tablet can be applied in two ways. Most modern testers including the TBF 1000 work on the principle of **constant speed** (that is to say, the rate of jaw movement). Other units, mainly earlier models, monitor the rate at which the compressive force is applied i.e. **constant loading**.

Irrespective of which method is employed, it is essential that the uniformity and rate of loading be constant in order to assure comparability of results.

Tab No.	Weight (mg)	Thick (mm)	Hard (kg)
1	379	3.25	5.19
2	379	3.25	5.31
3	380	3.24	5.54
4	380	3.24	5.47
5	379	3.26	5.02
6	378	3.25	4.98
7	381	3.25	5.28
8	380	3.26	5.05
9	379	3.23	4.92
10	380	3.25	5.30

BATCH STATISTICS			

Batch No. 1			
Batch Size: 10			
Min: 4.92 kg			
Max: 5.54 kg			
Mean: 5.21 kg			
Std. Dev: 0.21			
Time: HH:MM DAY DD/MM/YY			
Calibration No: 00004			

Typical Printout ▲

Tablet Debris ►
Collection Tray





Tablet Hardness Tester TBF 1000 ▲

TBF 1000 (with Keyboard Option) ►

TABLET HARDNESS TESTER TBF 1000

In general, the lower the speed or load, the more consistent the results. The **US Pharmacopeia**, for example, suggests a constant platen movement of less than 3 mm per second.

The TBF 1000 offers a choice of speeds between 0.06 and 0.5 mm per second with a default setting at 0.1 mm per second, all of which exceed the pharmacopoeial requirement by a considerable margin.

The standard TBF 1000 has a measuring range of **0 - 520 Newtons (+/- 0.1N)**. Other ranges, for example 50 N and 1000 N are available on request - please consult our technical staff for further details.

The unit will accept tablets up to **36 mm in diameter**.

Results can be expressed in either **kilograms-force (kgf), kiloponds (kp), newtons (N) or pounds (lbs)**. Diameter, if selected, is reported in **mm**.

The TBF 1000 has a **throughput** of approx. 5-8 tablets per minute dependent on the hardness and diameter of the tablets under test.

The TBF 1000 is also available with a **polished stainless steel case**, as an option, for use in a tablet production environment. Please see ordering information for details.

OPERATION

1. Setting up for a new tablet

Press the <New Size>* key - the motorised jaw will retract allowing the operator to insert the new tablet between the jaws before advancing once again to press the tablet lightly against the fixed jaw.

This contact is detected by the load cell electronics, which in turn instruct the motorised jaw to retract to the test position, approx. 5 mm wider than that of the diameter of the tablet.

The **diameter** of the new tablet is printed out on the in-built printer.

The unit is now ready to carry out a test.

2. Carrying out a test

Place a tablet on the test platform, lower the guard and press <Test> twice. The moving jaw will fast forward (2 mm per second) until it reaches a position approx. 0.2 mm from the tablet and then change to the test speed (default 0.1 mm per second).

The increase in load once the moving jaw reaches the tablet is displayed on the LCD display together with the tablet count, the time and date.

** If **diameter** measurements are required, ensure that the diameter measurement option is set to "On every test" at this point.*

Tablet fracture is detected automatically - once detected, the result is printed out and the moving jaw retracts back to the test position ready for the next sample.

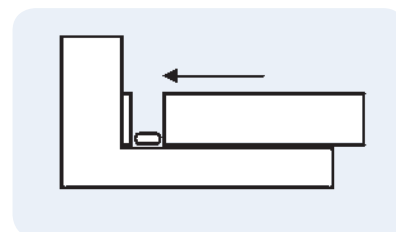
Testing of the next sample can be initiated in two ways depending on the set-up mode: (a) by pressing the <Test> key or (b) by lowering the guard.

The tablet testing position is arranged for horizontal loading and incorporates a removable tray in order to dispose of any **tablet debris**.

3. End of Batch - Statistical Analysis

Ph.Eur. and **USP** recommend that 10 and at least six samples are tested respectively.

At the end of the test, to initiate the printout and re-zero the tablet count, press <Stats>. A further batch of tablets can now be tested.





ADVANCED FEATURES

This outward simplicity disguises the many special sophisticated and advanced features available to the user via the setup menu, which may be accessed through the optional keyboard. This feature is passcode protected to prevent unauthorised changes to operational settings.

This emphasis is reflected in the setup menu. In addition to basic settings such as diameter selection, time and date, units (kgf, kp, N or lb), test speed (4, 6, 10, 16 or 30 mm/min), PC interface (RS232 or USB) and LCD backlight functions, the user can also configure the way in which the unit actually operates: the print format, the way in which the unit interfaces with other peripherals and the calibration of the instrument.

During a test, the load cell constantly monitors the increasing force applied to the tablet. The breaking point of the tablet is said to have been reached when the force falls to a set % (the fracture detect percentage) of the maximum (peak) load reached during that particular test. The default setting for this percentage is 70% - it can however be adjusted, if circumstances dictate, between 30 and 90%.

Peripheral and calibration settings allow the user to connect the hardness tester to a balance and/or a micrometer for measuring thickness and to calibrate the instrument, respectively.

The TBF 1000 incorporates an automatic load check routine that runs automatically every time the unit is switched on.

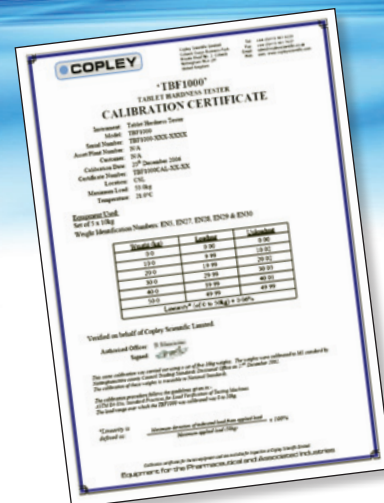
A difference of > 0.1 kg, for example, would suggest a potential problem and the need for recalibration (see below).

All tablet hardness testers should be calibrated on a periodic basis, for example, monthly or quarterly.

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▲ Weight and Thickness Measurement



Calibration Certificate ▲

TABLET HARDNESS TESTER TBF 1000

The user is guided through the passcode protected calibration process by a series of prompts from the in-built software accessible from the setup menu.

A full report is printed out at the end of the calibration process.

An individual calibration number is generated on each occasion the unit is calibrated and reiterated on subsequent test printouts - this ensures that any test printout is traceable to a specific calibration certificate.

IQ/OQ/PQ QUALIFICATION DOCUMENTATION

Analytical Instrument Qualification is no doubt an essential element of your quality control procedures. The following documentation is available to help you to meet these obligations:

- **Certificate of Compliance to USP/Ph.Eur.:** Included with each unit. Written statement that the product, by design, complies with the current pharmacopoeial specifications.
- **IQ/OQ/PQ Qualification Documentation:** (option)
Comprehensive documentation to guide the user through the installation, operating and performance checks of the

equipment, in its operating environment, using specified test protocols. It provides a comprehensive record of the suitability of the equipment to perform its specified task, to be completed and archived.

WEIGHT & THICKNESS MEASUREMENT

The versatility of the TBF 1000 does not end with the measurement of hardness and diameter (optional) - simply add a balance and/or a Mitutoyo micrometer for measuring thickness and you have a complete system for measuring the hardness, diameter, weight and thickness of tablets with the same capabilities as many of the more sophisticated systems that are commercially available.

A list of compatible balances (by make and model) may be found in the setup menu - please consult our technical staff for further details.

Weight and thickness measurements are conducted in a similar manner to that of hardness and diameter (see section on OPERATION on Page 56).

If, for example, both weight and thickness are enabled, then at the start of the test the LCD display will show Weight - the operator should then place the tablet on the balance, wait for the weight to stabilise and then press <Test>. The weight of the tablet will now be displayed and the LCD will show Thickness to request a thickness measurement. Remove the tablet from the balance pan, place it in the micrometer and press <Test>. Repeat the exercise for diameter and hardness (f required).

At the end of the individual tests, the results relating to all three parameters are printed out.

Cat. No. Description

2501	Tablet Hardness Tester Model TBF 1000
2501A	Tablet Hardness Tester Model TBF 1000 (with polished S/S case)
2502	Compact Keyboard (optional)
2503	Calibration Rig
2504	Set of Calibration Weights for TBF 1000 (4 x 10 kg, 2 x 5 kg)
2510	Other Qualification Tools
2505	IQ/OQ/PQ Documentation Pack
2506	Pack of 10 Paper Rolls
2511	Re-Calibration Certificate
2507	Sartorius Balance Model Quintix 224-1 CEU (including cable)
2508	Mitutoyo Thickness Measuring Gauge