

## Manual Ampoule Breakpoint Test Instrument - Type PTBA 211E



The **PTBA 211E** Ampoule Breakpoint tester is design and manufactured in compliance to the DIN/ISO 9187 standard. According to the DIN/ISO standards Ampoule Breakpoint has to be tested in order to control the quality during production.

### ***Principle of Operation...***

The testing jaw is moved by means of a stepper motor into the neck of the ampoule to be tested. The ampoule is placed onto a DIN/ISO compliant support. As soon as the jaw meets the ampoule the instrument increases the force in a linear speed mode until the sample breaks, the usual force rate is 10 mm/min. As soon as the ampoule is broken, the maximum force will be displayed and printed. The test jaw moves back to the home position ready for the next test. As the operator can enter an automatic re-start time, the next test will be performed immediately after a new sample has been placed onto the ampoule support.

A movable tray holds the ampoule support, a Plexiglas (Perspex) screen protects the operator. A built-in lamp illuminates the handling area to ease the correct positioning of the ampoule at the support.

Exchangeable ampoule supports allow the test of all kinds of ampoules from 1-30 ml.

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## Calibration and Validation



To validate the hardness test station the PT-MT magnetic tablet is used. Select a force, for example 50, 85 or 130 N, and run a test series, the resolution of the results should be within 1.0N. The PT-MT instrument works like an ampoule, it withstands force and than “breaks”.

For the 2 point calibration (adjustment) of the hardness station a certified reference weight of 10 kg is used. All calibration and validation results can be printed and countersigned. To qualify the linearity of the built-in load cell the use of 3 different certified weights is recommended, we offer a PTB-CAL3 weight handle which includes 5, 10 and 15kg.

To prove the linearity of the instrument, the operator can program a print-out of the force curve recorded during a test. This will show the linear increase of the adjusted force mode. Using the standard RS-232 interface, all results can be transmitted to a computer system.

## Validation Report

Specification	Comment	Result	Limits
<b>Hardness Calibration</b>			
Zero-Value 0kg:	Loadcell vertical	00010 Digits	5 - 15 Digits
Ref.-Value 10kg:	Loadcell vertical	00309 Digits	285 - 315 Digits
Range 0kg-10kg:		00299 Digits	280 - 300 Digits
<b>Hardness Validation</b>			
Zero-Value 0kg:	Loadcell vertical	— . — kg	0.1 - 0.4 kg
Ref.-Value 10kg:	Loadcell vertical	— . — kg	10.1 - 10.4 kg
Range 0kg-10kg:		— . — kg	9.9 - 10.1 kg
Max. Force:	Hardness on block	— . — N	300.0 - 360.0 N
Measured time:	to max. force	— . — Sec	15.0 - 18.0 Sec
Act.Offset-Value:	vertical downward	00004 Digits	3 - 13 Digits
Touch detection:		00012 Digits	
Hardn. detection:	hardness decrease	00033 Digits	
Act.force setting:		010.0 mm/Min	
Max.hardness path:	hardness test within	02.00 mm	2.0 - 10.00 mm
Opt.Startposition:	Start from home position		(Select use CAL + 7 +1)
Diameter Calibration (Diff. steps: C0-C1= 6666 +-13 = OK)			
Zero-Value 10 mm:	Full range: >20667	21751 Steps	C0 in No display = OK
Ref.-Value 20 mm:	Refer.20mm: <20667	15096 Steps	C1 in No display = OK

Instrument calibrated AT: \_\_\_\_\_

Calibration operator : \_\_\_\_\_ O Factory: \_\_\_\_\_

Signature \_\_\_\_\_ O PHARMA TEST  
(printed with keys <CAL>+<Print>)

## The microprocessor controlled PTBA 211E instrument offers the following features:

- Enter and Print Date and Time to the report
- Enter a 12 digit Batch Number
- Selectable force increase rate, 5-200.0 N/sec
- Selectable speed increase rate, 5-200 mm/min (standard setting 10 mm/Min.)
- Use automatic re-start facility to speed up the testing sequence
- Documentation of all results using a separate Printer
- OQ and Calibration program for all 3 measurement stations

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- Ampoule testing in compliance with the DIN/ISO 9187 standard
- Programmable print-out of force increase curve
- Built-in printer connection port to connect any Dot-Matrix or PCL5 printer
- Built-in RS-232 COM port
- Calibration menu for the hardness test station
- Reproducible results
- LED display and keyboard
- Statistical calculation of results
- Print-out of PQ result data
- Exchangeable ampoule supports

### Technical Data

Display:	LED Display for No. of samples, thickness, diameter and hardness results
Keyboard:	Numerical and function keys
Hardness:	5.0 - approx. 300 N (Newton)
Accuracy:	Better 1 N
Measuring units:	Hardness selectable in either Newton (N), kilopond (kg) or Strong Cobb (Sc)
Force rate:	Adjustable for linear force increase or linear speed increase
Range:	5 - 200 mm/minute or 5 - 200 N/sec.
Number of tests prior to statistic:	Up to 250
Dual Point Calibration Procedure:	Needs 10 mm reference block and 10 kg reference weight (certified)
Validation linearity load cell:	PTB-CAL3: 5,10, 15 kg
Validation breaking detection:	PT-MT Magnetic Tablet
Validation force setting:	PT-MT3 Magnetic Tablet
Interface:	RS-232 COM port Parallel printer port for Dot-Matrix or PCL printer connection

### Weights and Dimensions

Net weight:	19 kg
Gross weight:	24 kg
Packaging:	450 mm x 450 mm x 650 mm

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

