

# PORECHECK IV

The perfect choice for the pharmaceutical industry



Parker domnick hunter, in conjunction with the pharmaceutical industry has reviewed the limitations and benefits of current integrity test equipment. This review has led to the development of the PORECHECK IV integrity test system which has been specifically designed with the needs of routine production users in mind.

The PORECHECK IV is configured for water intrusion testing, pressure decay and bubble point testing.

The PORECHECK IV comes in two versions:

**'P' Pharmaceutical (CFR)**

- allows traceability and audit tracking capability

**'C' Certified**

- comes with password level protection

This market leading system incorporates a range of design features unique to the PORECHECK IV bringing true portability, enhanced ease of use, flexibility and reliability in challenging environments. All this within an instrument fully compliant with 21 CFR Part 11.

- Designed to 21 CFR Part II and Annex II compliant environments
- Automatic compensation when used on housings located 10 metres above instrument
- Maintains resolution and accuracy regardless of filter system size 0.1 to 150 litres
- Highly portable and mains independant
- Configurable to automatically flush and drain filters
- Robust waterproof stainless steel casing
- Direct attachment to test disposable capsules
- 100 storable test programs defined in blocks



## Physical Parameters

|                               |  |
|-------------------------------|--|
| Instrument Material.....      | Stainless Steel 1.4301 (AISI 304)  |
| Instrument Size.....          | 200 mm x 300 mm x 155 mm : 7.9" x 11.8" x 6.1"                           |
| Weight.....                   | 8.6 Kg : 20 lb   |
| Ingress Protection Class..... | IP54   |
| Power Supply.....             | Re-chargeable Battery (12V / 3.8 Ah) & Mains (90 - 230 VAC : 50 / 60 Hz) |
| Keyboard.....                 | Remote Infrared - Alpha Numeric & Instrument Keypad - Numeric            |
| Inlet Pressure Required.....  | 6.5 - 8.0 barg (94 - 116 psig)   |
| Test Pressure Range.....      | 350 mbar to 6 barg (87 psig)   |
| Pneumatic Connectors.....     | Stäubli RBE 0.3 Style : Stainless Steel 1.4404 (AISI 316L)               |
| Storage Temperature.....      | 2 - 50 °C (35.5 - 122 °F)  |
| Ambient Humidity.....         | 1 - 80% RH   |
| Display.....                  | LCD - 20 Character x 4 Lines - Back Lit                                  |
| Printer.....                  | Internally Housed Impact Dot Matrix , 24 Characters per Line             |
| Languages.....                | English, French, German, Spanish, Italian & Danish                       |
| Software Protection.....      | Stored in Flash - EPROM  |
| Storable Test Programs.....   | Up to 100 (in Flash - EPROM) Stored in 10 Blocks of 10 Programs          |

## Test Accuracy

|   | Standard      | High Pressure                                     |
|---|---------------|---|
| Water Intrusion Measurement Range (ul / t).....     | 100 - 99999   |   |
| Resolution (ul).....                                | 5             |   |
| Accuracy (for a 10" cartridge @ 4000 ul / min)..... | 3%            | 6%  |
| Test Pressure (mbar).....                           | 350 - 4000    |   |
| Stabilisation Time.....                             | 60 - 999 secs |   |
| Test Time (t).....                                  | 30 - 999 secs |   |
| Hardware Volume (ml).....                           | 1 - 32000     |   |
| Diffusional Flow Measurement (ml / min).....        | 1 - 999       |   |
| Resolution (ml / min).....                          | 0.1           |   |
| Accuracy (for a 10" cartridge @ 16 ml / min).....   | 3%            | 6%  |
| Test Pressure (mbar).....                           | 350 - 4000    | 350 - 7000  |
| Stabilisation Time.....                             | 60 - 999 secs |   |
| Test Time (t).....                                  | 30 - 999 secs |   |
| Upstream System Volume (ml).....                    | 1 - 32000     |   |
| Bubble Point Measurement Range (mbar).....          | 450 - 3900    | (min. 100 mbar above DF test pressure) 450 - 7900 |
| Resolution (mbar).....                              | 1             | 2   |
| Accuracy.....                                       | 1 & FS        |   |

## Instrument Options

|                            | 'P' Pharmaceutical               | 'C' Certified                   | Documentation                                   |
|----------------------------|----------------------------------|---------------------------------|---|
| Storable Test Records..... | 40                               | No                              | Installation, Operating & Maintenance Manual    |
| USER Accounts.....         | 25                               | Unlimited                       | Checklist of Supplied Components                |
| Access USER.....           | Access Password & PIN            | Open Access                     | Calibration & Pressure Vessel Certification     |
| Access PROGRAMMER.....     | Access Password & PIN            | Access Password                 | CE Declaration of Conformity                    |
| Access ADMINISTRATOR.....  | Access Password & PIN            | Access Password                 | Operational Qualification Support Documentation |
| Record Output.....         | Printed Records & RS232 Transfer | Printed Record Test Result Only | Laboratory Qualification Results                |
| Audit Trail Record.....    | 256 Event Audit Trail            | No                              | Suggested OQ Test Protocol                      |