

BPT

FILTER INTEGRITY TESTER



MRI COMPATIBLE

Within the pharmaceutical industry there is a growing use of automated techniques and electronic storage of critical batch records.

BPT has been conceived as a specific instrument to perform the filter integrity test, fully compliant to GMP normatives.

It is an extremely versatile device, which is connectable to any filter to be tested (synthesis module, dispenser, quality controls, etc).

The highest reliability and safety of BPT is extremely effective in saving time and operation costs. Data saving and reporting become fast and easy.

Three configurations are available, with different levels of automation:

Pos.	Configuration	WorkFlow	Level of Automation
1	BPT - Stand Alone	Manual connection of the filter to the outlet gas pipe Visual check of the result on the touch control panel Data print out via thermal printer	Data print out No data saving No remote control Output port available
2	BPT - Control PC	Manual connection of the filter to the outlet gas pipe Remote control PC fully management	Data saving and print out Remote control
3	BPT - Control PC - Tema Sinergie Dispenser	Filter is connected through a dedicated plug in the disposable set before production Remote control PC fully management	Data saving and print out Remote control and automatic test performance

BPT is also suitable for MRI application, as it allows to perform fast integrity testing of the filters used in preparation of doses of MRI ¹³C imaging agent with Hyperpolarizers.

BPT tests automatically both vented and not vented filters (previous approval of the filter by Tema Sinergie Tech. Dept. is required)

TEMA SINERGIE
High tech, high care

BPT (Image 1) comes in one single case with:

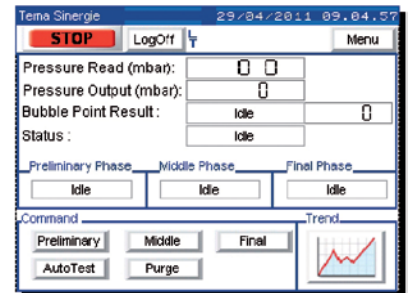
- n. 1 Programmable Logic Controller (PLC)
- n. 1 Operator Panel Touch Screen PC
- n. 1 analogical pressure transmitter
- n. 1 digital pressure transmitter
- n. 1 high precision manometer
- Air or gas inlet and outlet connection
- Ethernet plug to connect the control PC
- Air filter (option) to sterilize the compressed air



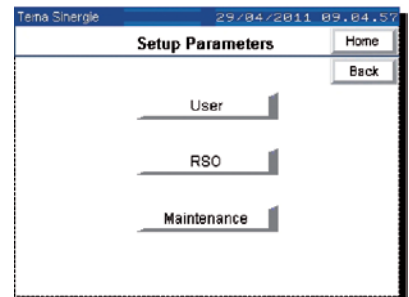
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BPT can minimize any operator involvement, saving time and sensibly reducing any chance of error

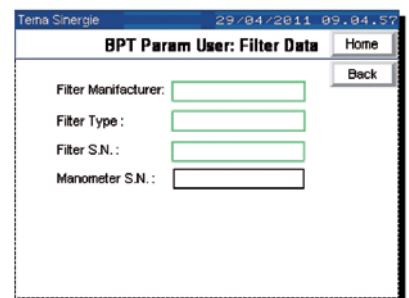
- Direct measurement allows the shortest test times at highest safety and accuracy levels
- Pressure and calibration procedures according to GAMP guidelines (Image 2)
- No time and cost for software development as it is ready to be used in any circumstances
- Easy full parameters configuration (pressure, time, speed)
- Access under password control (Image 3)
- 21 CFR part 11 compliant for data saving when connected to the control PC
- Filter integrity test data can be configured by the PLC or SCADA system to be compliant with 21CFR Part 11 (Image 4)
- Calibration and servicing are performed by specialized Tema Sinergie operators
- Auto test to verify the maximum reachable pressure according to the filter specifications (Image 5)



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DIMENSIONS AND WEIGHT

- 400 (w) x 300 (d) x 150 (h) mm (15,5" x 12" x 6")
- 10 kg (22.4 lb)

SPECIFICATIONS

- Self Test Yes
- Filter Integrity Test pressure range 0 – 5000 mbar (0 – 72.5 psi)
- Pressure Transmitter measurement $\pm 0.25\%$ of full scale
- Power Voltage automatically adjusted between 90 – 230 V AC
- Frequency 50 Hz to 60 Hz
- Power Output (Typically) 70 W
- Fuse 3.15 A inert
- Internal Pressure Transducer 4 – 20 mA (0 – 6 bar / 0 – 87 psi)
- Maximum Gas Supply Pressure 5000 mbar (72.5 psi)
- Splash Proof IP54
- Working Temperature 5 °C to 50 °C (41 °F to 122 °F)
- Calibration validity 2 year
- Quick pre-injection filter test for MRI application yes (<25sec.)

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