

INTEGRITY TEST - BUBBLE POINT METHOD

(Use Q.I. Medical Tester #PG005)

1. Fill a 10 to 20 mL syringe with approximately 10mL of fresh water.
2. Attach the syringe to the female luer lock on a used Wizard syringe filter.
3. Orient the outlet of the filter in a downward direction and flush the filter with the water.
4. Detach the flushed filter from the syringe and attach filter to the male luer lock on the bubble point tester, #PG005.
5. Fill the syringe with approximately 10mL of air.
6. Attach the syringe to the female luer fitting on the bubble point tester.
7. Immerse the outlet of the filter in a breaker of water.
8. Using the syringe, gradually apply increasing air pressure to the filter. Constantly watch for a steady stream of bubbles from the filter outlet.
9. Stop applying pressure when the gauge reaches 45 psi.
10. The filter passes the integrity test if there is no stream of bubbles before the pressure gauge reaches 45 psi. A steady stream of bubbles before the gauge reads 45 psi indicates that the filter has failed the integrity test.

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SPECIFICATIONS AND OPERATING CHARACTERISTICS

Catalog #	DF010H
Membrane	Polyethersulfone*
Pore Size	0.1 micron
Diameter	25mm
Packaging	50/box
Housing	Modified acrylic
Effective Filtration Area	2.8 cm ²
Typical Fluid Retention	<50 µL
Connections	Female luer lock inlet Male luer lock outlet
Max. Operating Pressure	75 psi
Bubble Point (Water)	>60 psi

*Protected by US patent and other patents.

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0.1 µm Hydrophilic Filter**Sterile • Single Use****Non-Pyrogenic**

- Sterile, single use
- Low protein binding polyethersulfone
- Non-pyrogenic and non-cytotoxic

*Certificate of Compliance

Q.I. Medical, Inc. certifies that the enclosed disposable filters are:

- 1) Sterile, non-toxic and non-pyrogenic
- 2) Sterilized by gamma irradiation
- 3) Biosafe according to USP Class VI-121° Plastics tests
- 4) In compliance with published product specifications
- 5) Will retain >10⁷ *brevundimonas diminuta* on each cm² of upstream filter surface

*Certification does not apply to packaged products that have been opened or damaged by conditions outside the control of Q.I. Medical, Inc.

INSTRUCTIONS FOR USE

- 1) Before filling the syringe with sample, draw approximately 1mL of air into the syringe. This will allow the air to follow the sample out of the syringe. The "air purge" minimizes fluid retention within the filter.
- 2) Fill the syringe with the solution to be filtered. *CAUTION: Use of syringes smaller than 10mL can generate excessive pressure on the filter, which may exceed the maximum operating pressure.*
- 3) Peel the backing from the blister package. Holding the blister in one hand and the filled syringe in the other, secure (without excessive force) the filled syringe to the filter device with a twisting motion.
- 4) Apply gentle pressure to begin filtration (gentle pressure helps assure maximum throughput). *Caution: As the filter removes particulate, filtration will become more difficult (the syringe plunger will be harder to use) as pressure rapidly increases on the filter.* Change filters when resistance becomes excessive. Failure to change may result in housing rupture, which results in particulate contaminating the filtrate.
- 5) These filters are for **SINGLE USE ONLY**.