

# **Process Filtration From Pure to Sterile**

### **Membra-Check**

#### **MAIN FEATURES & BENEFITS:**

- Integrity test of hydrophilic membrane filters
- Integrity test of hydrophobic membrane filters
- Hardware and Upstream volume measurement
- Pressure gauge calibration test
- GMP/GLP compliant version available



#### **INDUSTRIES:**



Food and Beverage



Chemical Industry



Pharmaceutical Industry



Biotech



Environmental Industry

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Donaldson Ultrafilter

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#### PRODUCT DESCRIPTION

The Donaldson "Membra-Check" is a handy filter integrity test unit for both hyrdrophilic and hydrophobic membrane filters. Beside all integrity tests this unit can be used as a calibration pressure gauge (0 – 6 bar) and is capable to check unknown volumes (e.g. the upstream volume of a filter housing; 0.1I – 32I). Besides the integrated software a GMP/GLP compliant version is available. A printer is included for on-site testing without a PC connection or as stand alone.

# Additionally the Membra-Check carries out:

Volume Checks from 0,1l to 32l

# This instrument is designed to run the following membrane filter integrity tests:

- Diffusion Test (Forward Flow)
- Pressure Drop
- Diffusion and Bubble Point
- Diffusion Tests with automatic filter wetting
- Water Intrusion Test (WIT)
- WIT on huge housings (150l)
- WIT with automatic filter drying
- WIT with automatic housing cooling



#### **PRODUCT SPECIFICATIONS**

Product Specification			
Cabinet material:	Stainless steel 1.4301		
Cabinet dimension:	• 200x300x155mm		
Weight:	• ca. 8,6 kg		
Protection class:	• IP 55		
Power supply:	<ul> <li>Rechargeable Battery 7.2V-4Ah or mains 220 V/110V</li> </ul>		
Keyboard:	Infrared- alpha numeric		
Software Protection:	Stored in Flash EPROM		
Matrix Printer:	Normal paper, 24 characters/ line		
Storable Test Programs:	• up to 100 Prg. (in Flash EPROM)		
Storable Test Records:	• 40 (in Flash EPROM)		
Pneumatic Connectors:	Stäubli RBE 03 / Stainless Steel 1.4404		
Pressure Sensors:	• 1x internal: 0-4 bar / 0-58 psi ; Cl 0.5		
	• 1x external: 0-4 bar / 0-58 psi; Cl 0.5 (Stainless Steel)		
	• 1x barometric 800-1090 mbar / 11,6-15,8 psi; Cl 0.5		
CPU-Board:	HC12 (Motorola)		
Program Language:	• C		
Display:	4- lines illuminated		
Possible Languages:	German, English, French, Italian, Spanish, Danish (Further		
	languages on request)		
Pressure units :	• bar/psi		
Interface:	Serial bus RS 232		

#### MAINTENANCE AND HANDLING RECOMMENDATIONS

Cleaning of Pneumatic Parts:

- The sensor can be steamed (121 °C for 20 min)
- The filling and vent valve can be cleaned with water (80°C with usual cleaning detergent)

Recommended Temperature: 5°C – 40°C

Recommended Humidity: 0 - 80%



#### **SOFTWARE**

A software (Windows 98/->XP) for the central administration of filter test programs is available

#### **Internal Software Version "CFR":**

The integrity tester stores up to 40 test records. All features for the acceptance of the FDA guideline 21CFR 11 are implemented: audit trail, electronic signature, different password levels etc. The instrument is compliant with the FDA guideline 21 CFR 11. It can be used, where 21 CFR 11 is necessary.

#### **Internal Software-Version "G":**

The integrity tester stores up to 40 test records. The instrument is not compliant with the FDA guideline 21CFR 11. It can only be used, where 21 CFR 11 is not necessary.

#### **DELIVERY SCOPE AND ACCESSORIES**

- Donaldson Membra Check
- Infrared Keyboard
- Paper Roll and Colour Ribbon
- Pressure Sensor with Stäubli Connection
- Reference Vessel for Volume Measurement
- Manual
- Short Manual
- Data cable
- Software
- Power Supply and Battery Charger
- Inlet tube with pressure reducer
- Outlet tube

Additional Accessoires on request.

#### **Accessories**









#### **EXAMPLE 1: WATER INTRUSION TEST**

#### Measurement limits, resolution and uncertainty

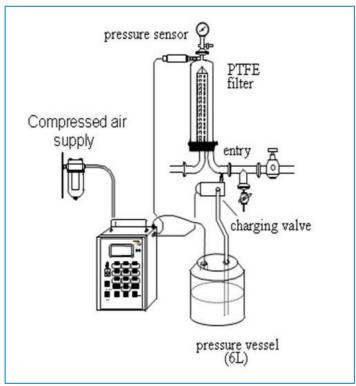
Measuring range (input limits): • 100 - 99.999 µL/measuring time

Resolution: • 5 μL (for Mini cartridge - system)

Measuring uncertainty: • 3 % of measured value ≥ 0.4 ml/min)

#### General limits for water intrusion test WIT for programming

Parameter	Entry limits	General values for Donaldson (P)-PF-PT, 0,2 μm (as an example)
Test pressure:	350 -4000 mbar	2200 mbar
Stabilising time:	60- 999 s	600 s
Test time:	30- 999 s	300 s
Hardware volume:	1-32.000 ml	2629ml (for PF-EG0150)
Max. water flow:	100- 99.999 µl/t	27.000 μl / 5 min



Installation for Water Intrusion Test



#### **EXAMPLE 2: BUBBLE POINT TEST**

#### Bubble point measurement (in conjunction with diffusion measurement):

Measuring range: • 450 - 4000 mbar

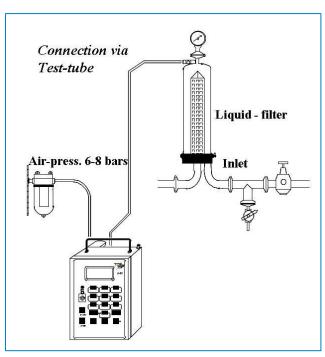
Test pressure range (diffusion test): • 350 - 3500 mbar

Resolution: • 1 mbar

Measuring uncertainty: • 1 % F.S.

#### General limits for bubble point / diffusion tests for programming

Parameter	Entry limits	General values for Donaldson (P)-PF-BEV W, 0.2μm (as an example)
Test pressure:	350 -4000 mbar	2200 mbar
Stabilising time:	60- 999 s	600 s
Test time:	30- 999 s	300 s
Net volume: (upstream volume)	1-32.000 ml	10.625 ml (for PF-EG 0150)
Max. diffusion	1- 999 ml/min	25 ml/min for 10"



Installation for Bubble Point Test

#### Technical alterations reserved 04/2009

 For further information on this test equipment or additional test services, please contact your Donaldson Sales Engineer and visit our website at www.donaldson.co.za (Rev02 – 07/10)

