INTEGRITY TESTING THEORY AND TROUBLESHOOTING
完整性测试理论和常见问题

Technical Service **技术支持**

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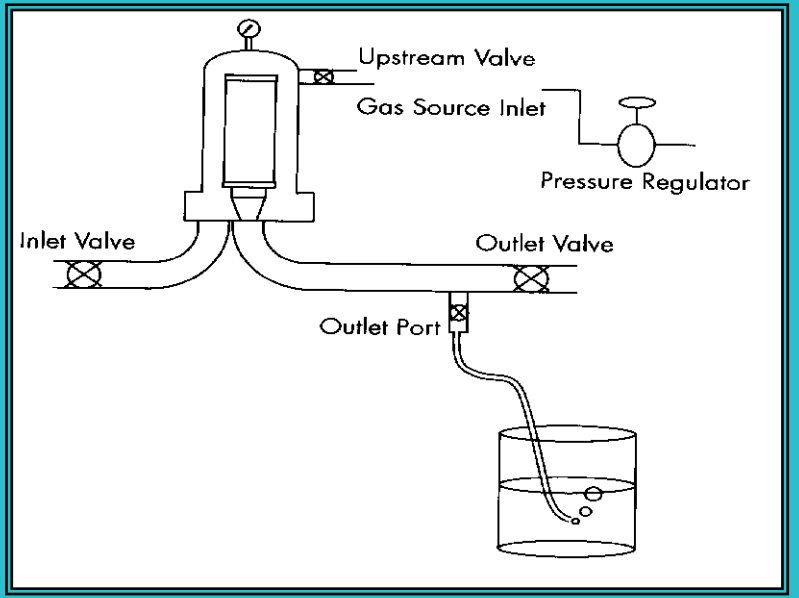
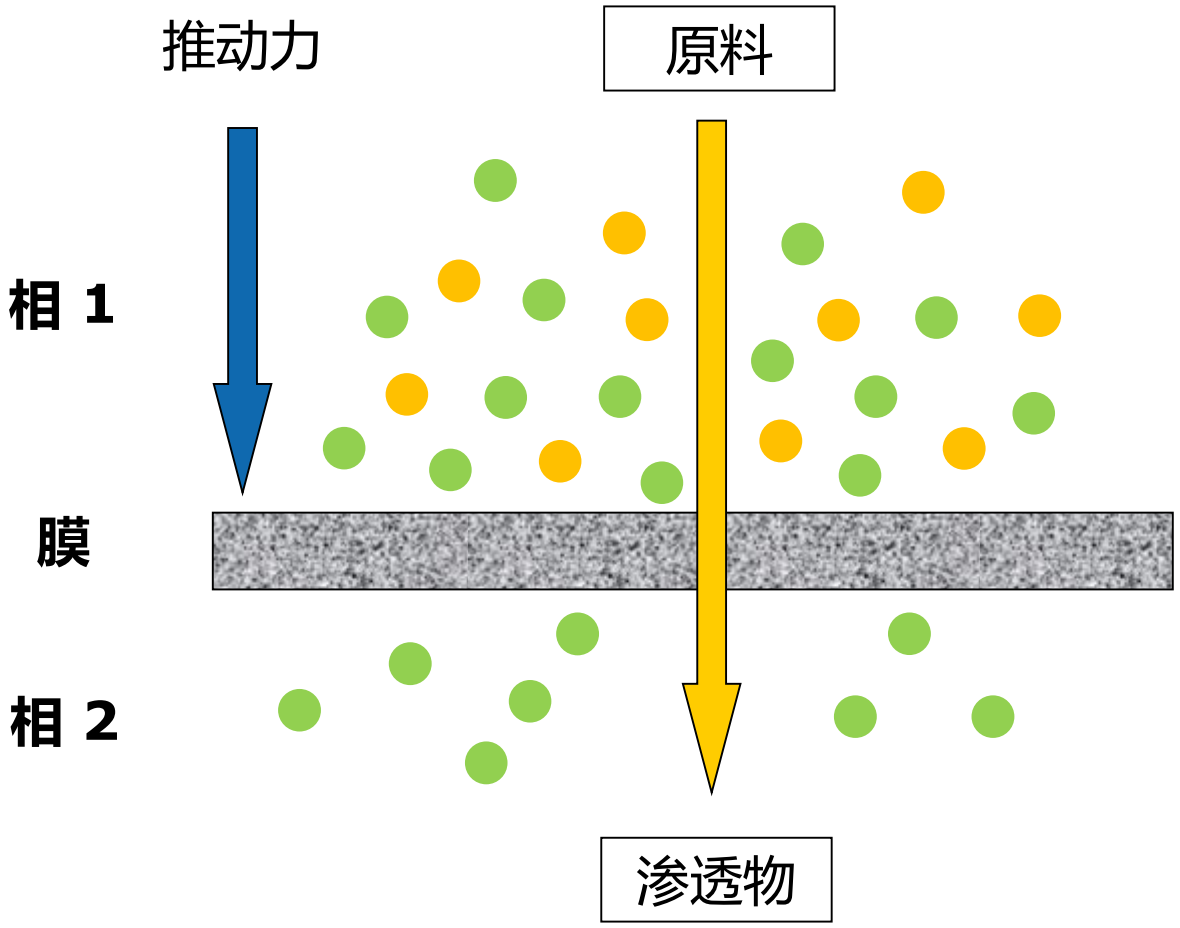
MERCK

Content
目录

INTEGRITY TESTING THEORY
完整性测试的基本原理

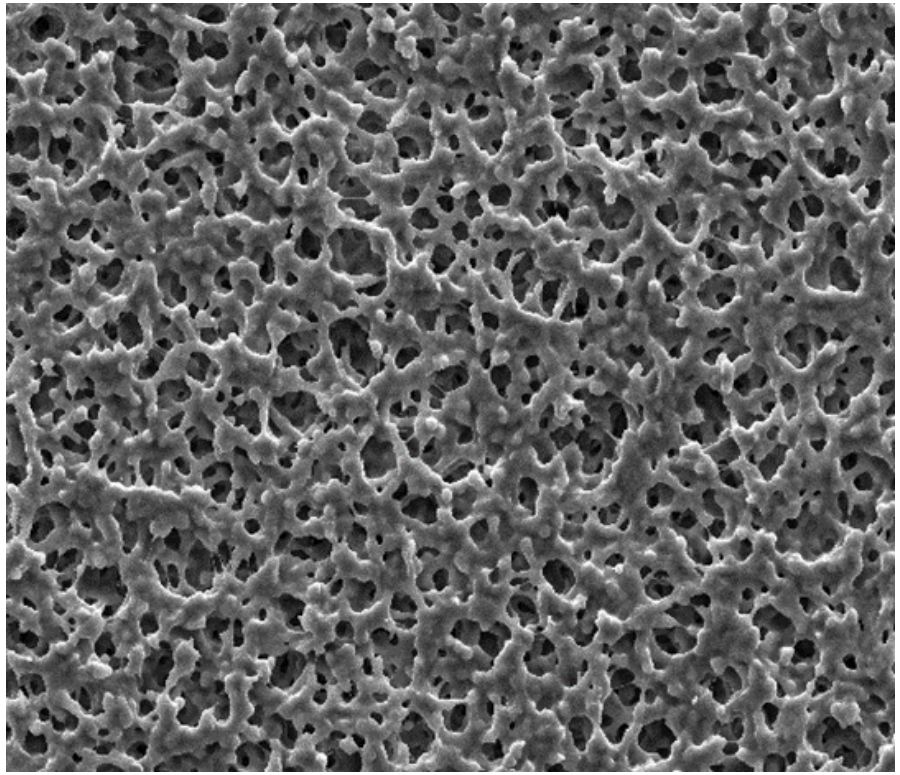


What's the filtration?
什么是过滤?



Membrane Filtration
膜过滤

- Polymeric 聚合物
  - Can be either hydrophilic or hydrophobic
    可以亲水，也可以疏水
- Examples: PVDF, PES, cellulose ester, regenerated cellulose, nylon
  实例：聚偏二氟乙烯、聚醚砜、纤维素酯、再生纤维素、尼龙
- Very thin (100 - 260 µm) 很薄（ 100 - 260 µm ）
- Rated on the size of the smallest particle it retains 按照其截留的最小颗粒尺寸，划分等级



0.22 µm PVDF Surface
0.22 µm PVDF表面

Purpose of Sterile Filtration
无菌过滤的目的

Sterilization 除菌

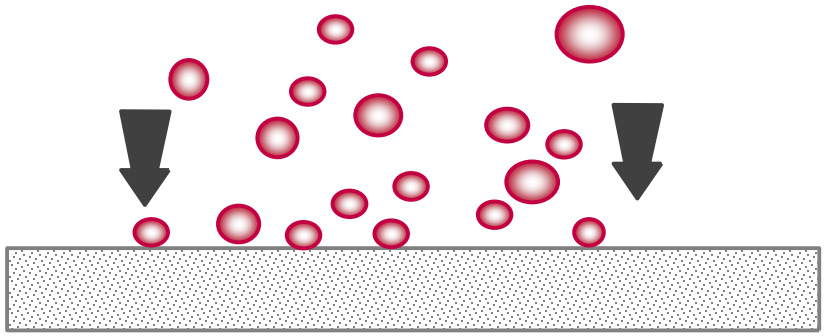
- Removal of bacteria from process fluids 除去工艺料液中的细菌
  - Prevent contamination of the fermentation 防止发酵污染
  - Cell culture media and air 细胞培养基和空气
- Reduction of bioburden in purification process steps
  降低纯化工艺过程中的生物负荷
  - Low bioburden means low endotoxin
    低生物负荷意味着低内毒素浓度
- Sterilization of injectable drugs 可注射药物的除菌
  - Protect the patient from infection 使患者免于感染

What is Membrane Integrity?
什么是膜完整性?

Integral Membrane
完整膜

Contaminants larger than pores upstream

污染物大于膜的孔径



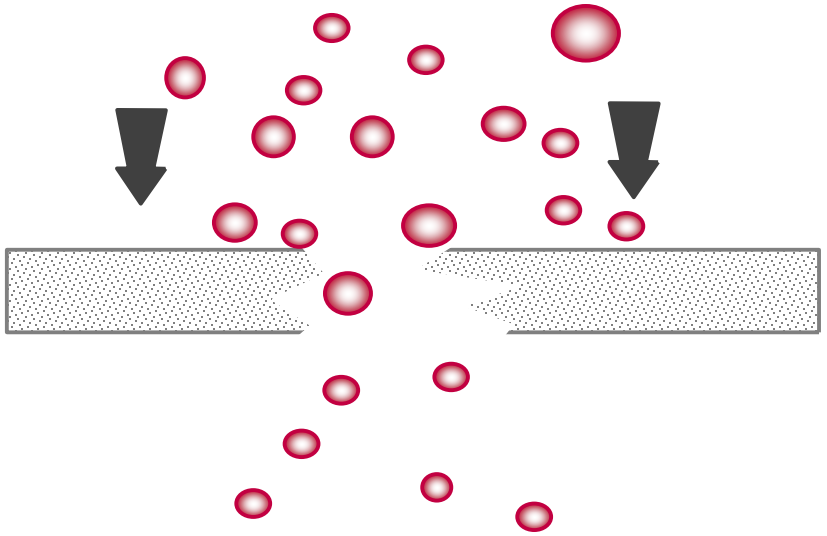
No downstream Contamination

下游无污染

Non-Integral Membrane
非完整膜

Contaminants larger than expected pores upstream

污染物大于膜预期孔径



Downstream Contamination

下游污染

Why Integrity Test?
为什么做完整性测试?

Business Practice 商业惯例

- Government Guidelines & Regulations 法规要求
- Part of corporate standard operating procedure 公司标准操作规程
- Auditing requirement 审计需要

Common Sense 通常理解

- Filtration is often the most critical step in an operation
  过滤通常是操作的关键步骤
- Confirmation of manufacturers specifications
  确认生产商的参数
- Detecting leaks due to O-rings, gaskets, seals
  检测O形圈,垫片,密封圈的泄漏
- Assuring the correct pore size filter
  确保过滤器的正确的孔径
- Assuring integrity before sterilization
  确保灭菌前的完整性
- Assuring integrity after steaming or autoclaving
  确保蒸汽和高压灭菌后的完整性

Regulatory Expectations
法规中对完整性测试的规定

FDA Guideline指南 (2003)

- Whatever filter or combination of filters is used, validation should include microbiological challenges to simulate worst-case production conditions.

对于由一个或多个滤器组成的过滤系统，对它的验证都应该包括在最差条件下进行的微生物挑战试验。

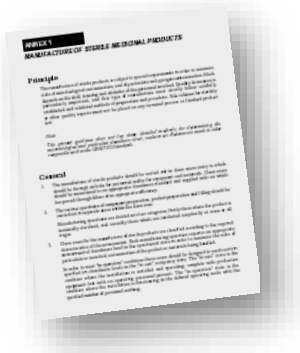
Guidance for Industry

Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory affairs (ORA)

September 2004
Pharmaceutical CGMPs

Regulatory Requirements
法规要求


ANNEX 1
MANUFACTURE OF STERILE MEDICINAL PRODUCTS
Principle
General

EU GMP: The integrity of the sterilised filter should be verified before use and should be confirmed **immediately after use** by an appropriate method such as a bubble point, diffusive flow or pressure hold test

EU GMP Annex 1 for the manufacture of sterile medicinal products, February 2008

US FDA: Integrity testing of the filter can be performed prior to process and **should be routinely performed post-use**.

US FDA Guideline on Sterile Drug Products Produced by Aseptic Processing, 2004


Guidance for Industry
Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

CFDA: **除菌过滤器使用后**，必须采用适当的方法立即对其完整性进行检查并记录。常用的方法有起泡点试验、扩散流试验或压力保持试验。
GMP指南: **在使用前和使用后**对除菌级成品过滤器进行完整性测试是无菌保证的一个至关重要的因素

CFDA Guidelines, 2010

无菌保障：使用后必须进行完整性测试，使用前依地区法规和应用而定

Industry Guidance
行业指南

PDA® TR26:

- Where the claimed purpose of the filter is to sterilize, **pre and post filtration** integrity tests **should be performed**.
- Prefiltration integrity test may be performed prior to sterilization of the filter and, preferably, after sterilization.
- Steps should be taken to ensure that the **downstream side of the system remains sterile** when performing a post sterilization, pre-use integrity test.

PDA® Technical Report 26-2008, pg. 34

ISO® 13408: The filtration system should be designed to permit in-place integrity testing as a closed system prior to filtration.

ISO® 13408, 2003

PDA® 建议使用前后均进行完整性测试

行业指南强调保障生产过程中的无菌性应作为重要考虑因素

There are two types of integrity tests
两种完整性测试类型

Destructive：used mostly by suppliers.

破坏性：主要由供应商使用。

ex：bacterial challenge, aerosol tests, retention test with biological markers, or Dextrans

例：细菌挑战、气溶胶测试、截留测试（使用生物标记物，或葡聚糖）

Non-destructive：used on site to confirm efficiency and used by supplier prior to shipping.

非破坏性：现场使用以确认有效性，以及在运输前由供应商使用。

ex：bubble point, diffusion, pressure hold test

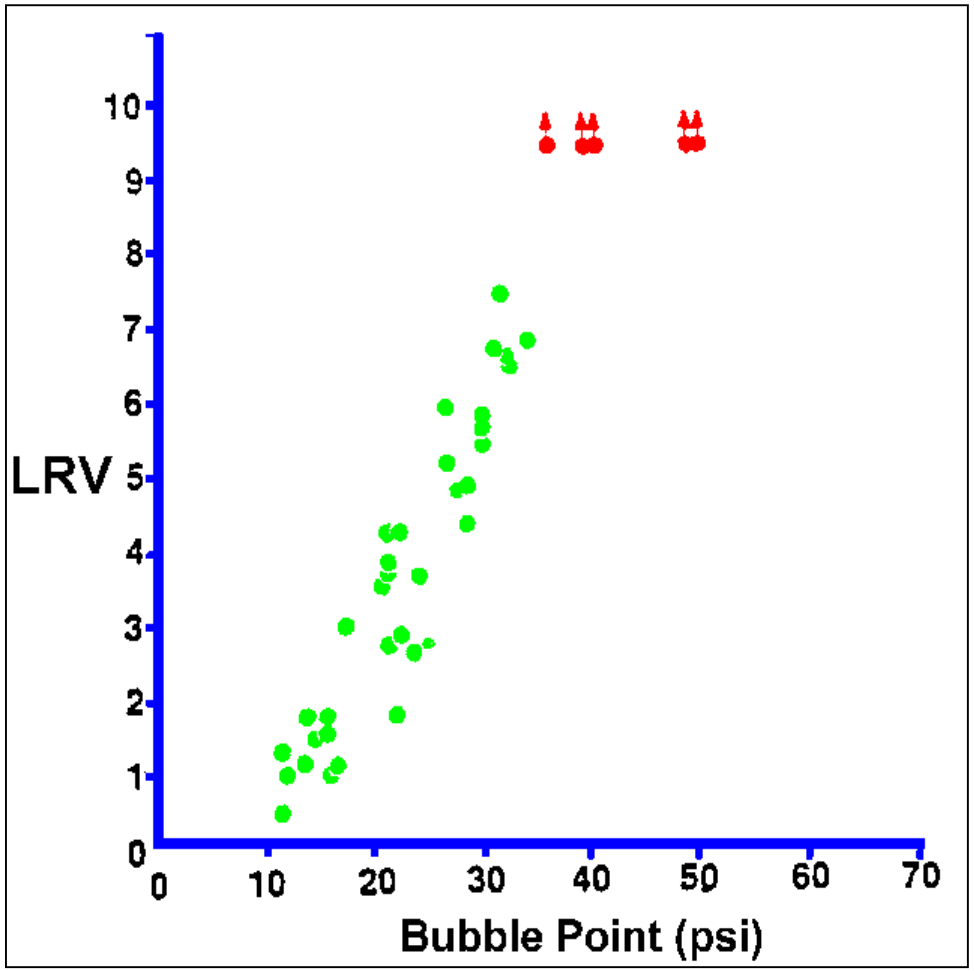
例：泡点、扩散流、保压测试

Destructive vs. Non-destructive Testing
破坏性和非破坏性测试

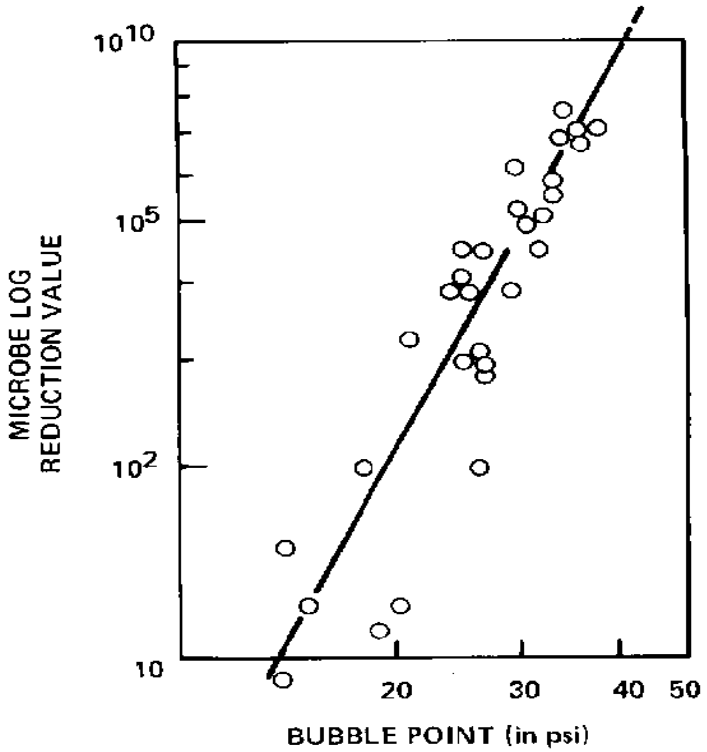
There must be a correlation between a destructive and a non-destructive integrity test.

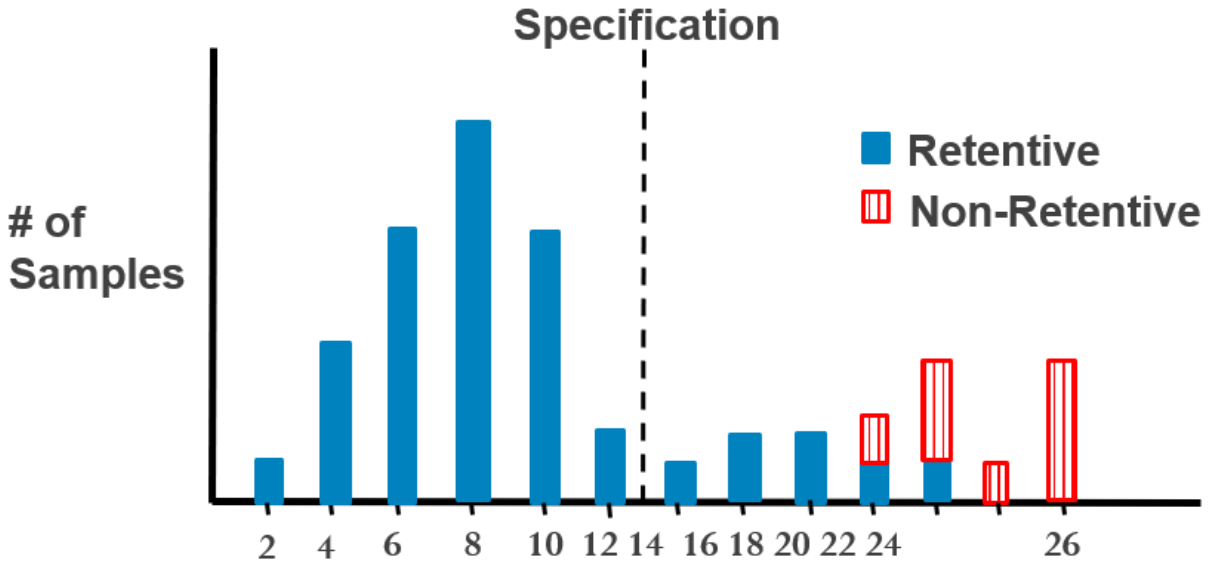
破坏性和非破坏性测试两者必须有关联。

- Regulatory requirement 法规要求
  - FDA Aseptic Guidelines FDA无菌指南
- Validation justification for the use of a test
  验证使用的测试的合理性



Integrity Testing Correlations
完整性测试关联





Bubble point can have a direct correlation

与泡点有直接的关联

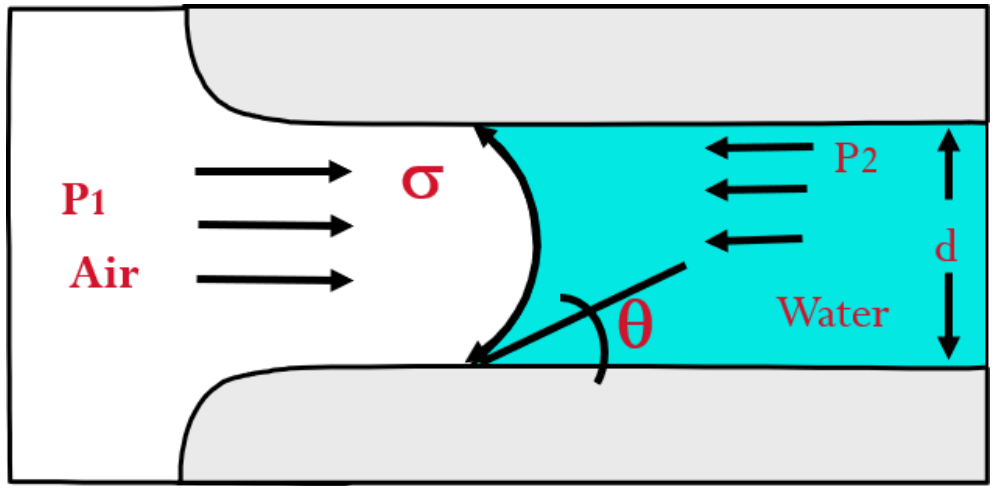
Diffusion & other tests can have an "go - no go" correlation

扩散和其它测试有”通过,不通过”关联

What Non-Destructive Integrity Tests are Available?
有哪些非破坏性完整性测试可用?

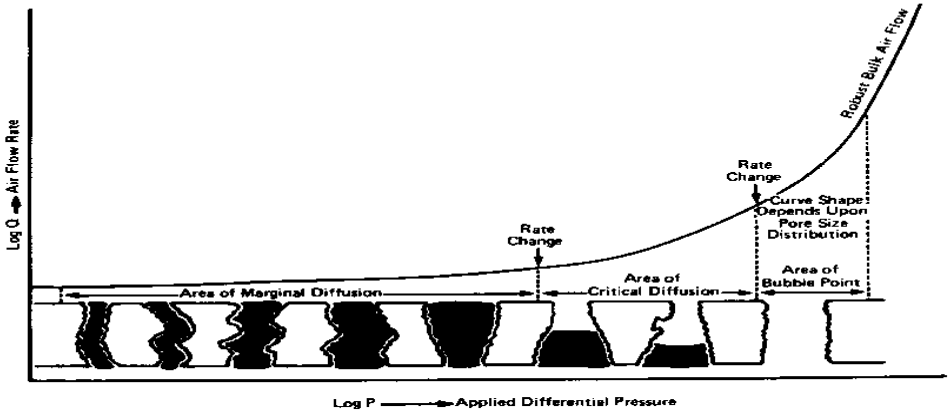
- **Measuring capillary forces**

  测量毛细管力
  - Bubble Point 泡点
  - HydroCorr 挤水法



- **Measuring diffusive gas flow**

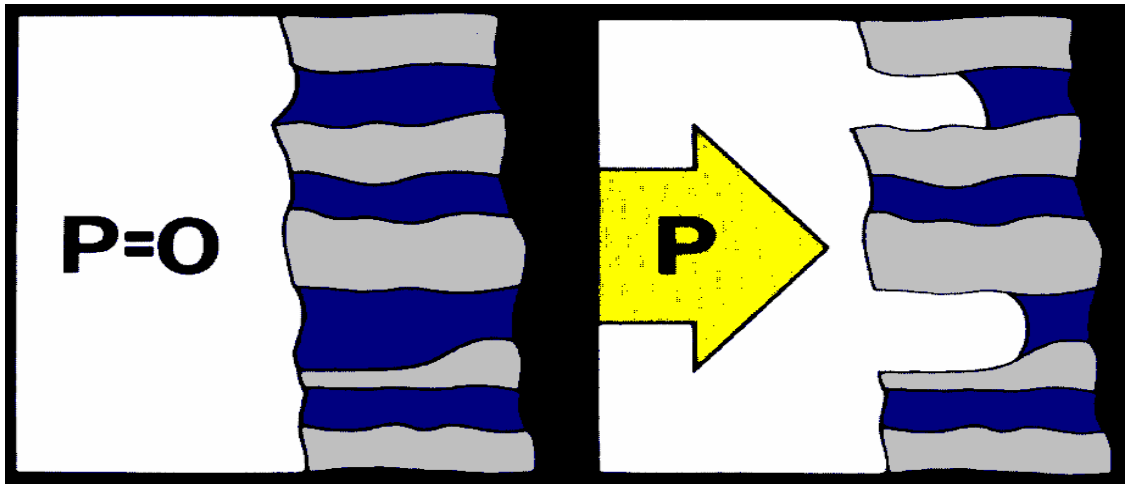
  测量扩散气体流速
  - Diffusion 扩散
  - Forward Flow 前进流
  - Pressure hold / decay 压力保持/衰减



Bubble Point Introduction
泡点介绍

Bubble point is the pressure at which gas displaces liquid from the largest set of filter pores and flows rapidly through the filter.

泡点值是，气体将液体从最大的一组过滤器孔中排出，然后快速流经过滤器时的压力。



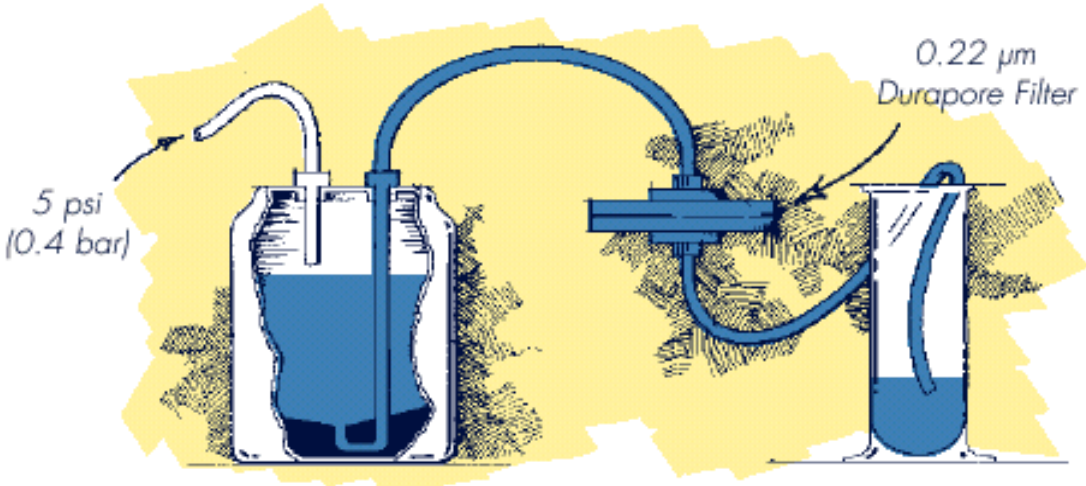
Bubble point indicates the magnitude of the forces holding liquid in the filter structure.

泡点值指示了过滤器结构保持液体的力的大小。

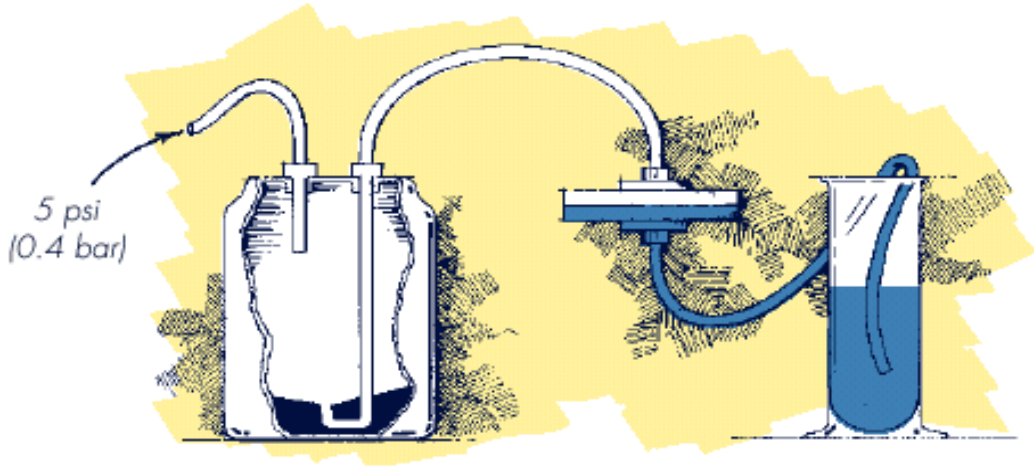
The oldest non-destructive integrity test.

最早的非破坏性完整性测试方法。

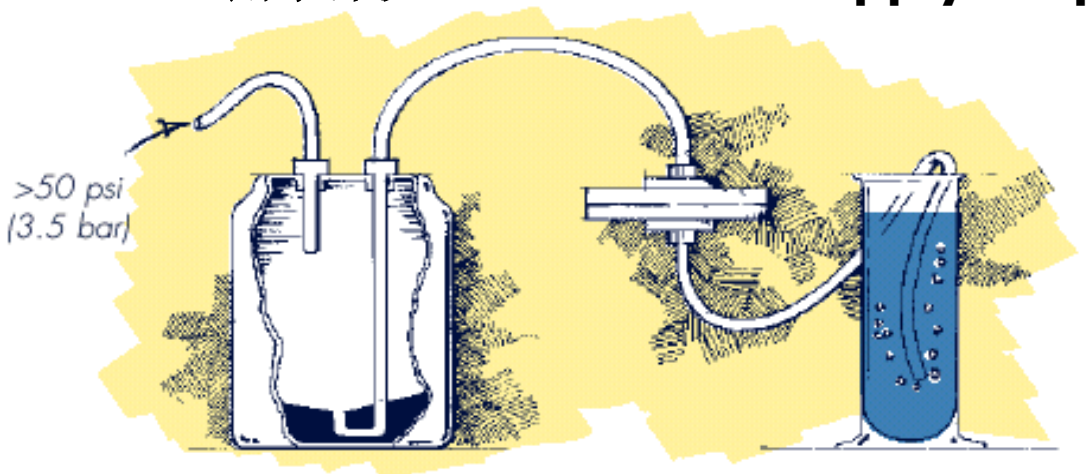
Manual Bubble Point Testing
手动泡点测试



Flush with water用水冲洗



Apply air pressure施加气体压力



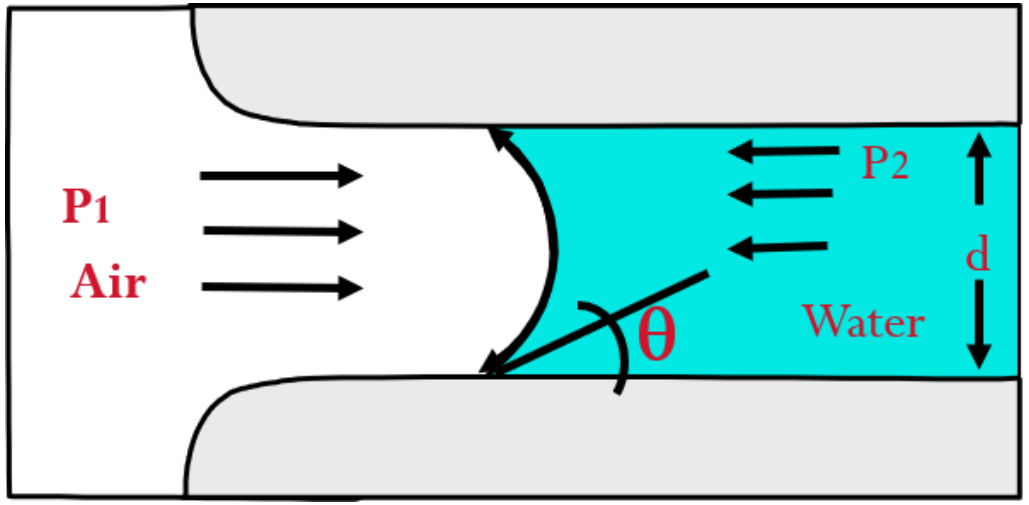
Increase pressure until bubbles are seen downstream
增加压力直到气泡在下游出现

Bubble Point Equation
泡点方程

The bubble point is expressed as:

泡点值可以表示为：

$$BP = \frac{4 \bullet k \bullet \gamma \bullet \cos\theta}{d}$$



Where其中

k = shape correction factor 形状校正因子

γ = surface tension 表面张力

θ = contact angle 接触角

d = pore diameter 孔径

Bubble Point Dependencies
影响泡点的因素

Depends on capillary forces; 取决于毛细管力:

- membrane material, surface tension, contact angle, effective diameter,
  膜材料、表面张力、接触角、有效直径

Bubble point specifications (including the SOP) should include;

泡点值参数（包括SOP）应当包括:

- filter type 过滤器类型
- wetting liquid 润湿液体
- Temperature 温度
- minimum pressure 最低压力

Examples of the Effect of Contact Angle and Surface Tension on Bubble Point Values
接触角和表面张力对起泡点值的影响实例

Two sterilizing grade filters with identical bacterial retention claims and performance have the following minimum bubble point specifications:
两种无菌过滤膜有同样的细菌截留率，有下列最小泡点参数:

- Durapore® PVDF CVGL >= 50 psig
- Charged Durapore® PVDF CCGL >= 40 psig

A sterilizing grade filter has is the following minimum bubble point specifications:
一种无菌过滤膜有下列最小泡点参数:

- Water >= 50 psig
- 70/30% IPA/Water >= 18.5 psig

Higher bubble point test values do not mean better filters
高泡点值并不是意味好的过滤膜

- Check the filter manufacturer's validation guide for the destructive / non-destructive integrity test correlation, integrity testing technique and bacterial challenge method
  检查过滤膜制造商对破坏性/非破坏性完整性测试关联的验证文本,完整性测试技术和细菌挑战的方法

Diffusion Testing Introduction
扩散流测试介绍

Gas dissolves in liquid held in the pores of a fully wetted membrane filter.

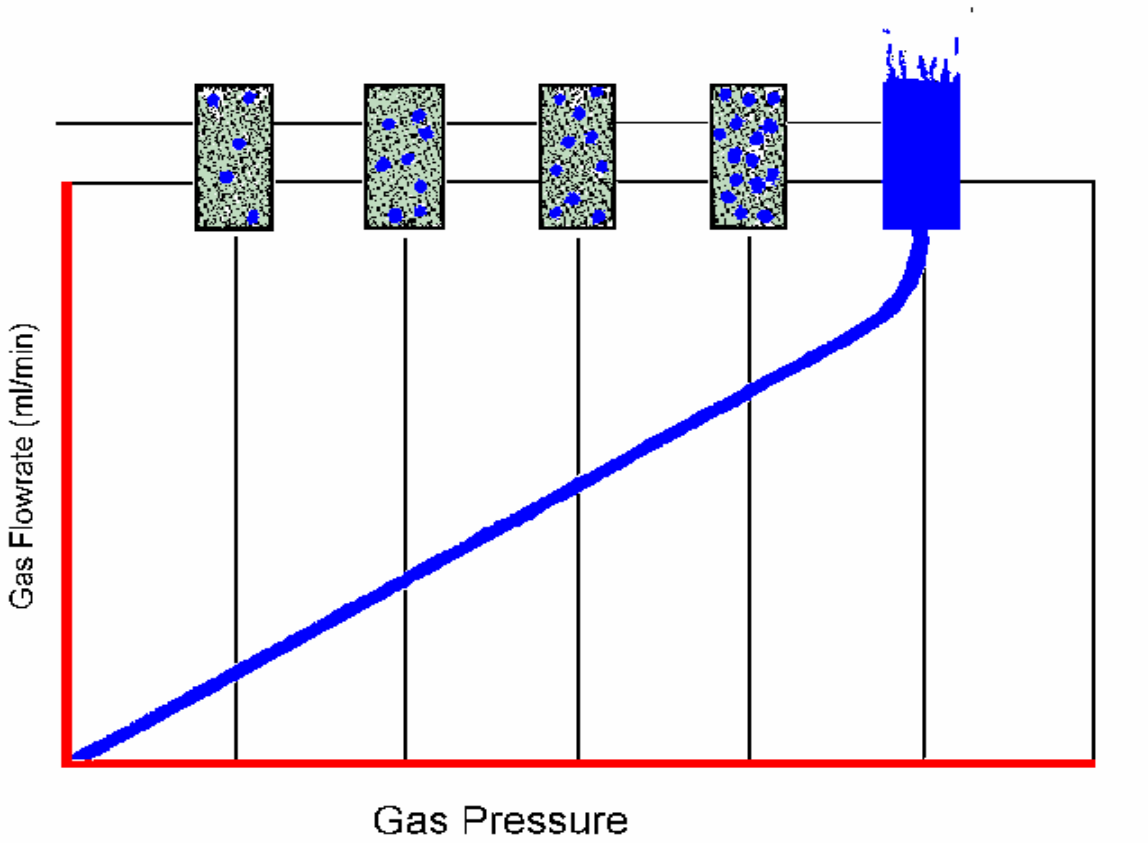
气体溶解于充分润湿的膜过滤器孔中的液体

A pressure differential will give a different gas concentration across the filter.

压差使得过滤器膜两侧的气体浓度不同

Results in gas flow through the liquid dissolved in the filter pores.

导致气体流经过滤器孔隙内的液体



Diffusion Testing Equation
扩散流测试方程

$$\text{Diffusion} = \frac{K \bullet (P1 - P2) \bullet A \bullet \rho}{L}$$

where: 其中:

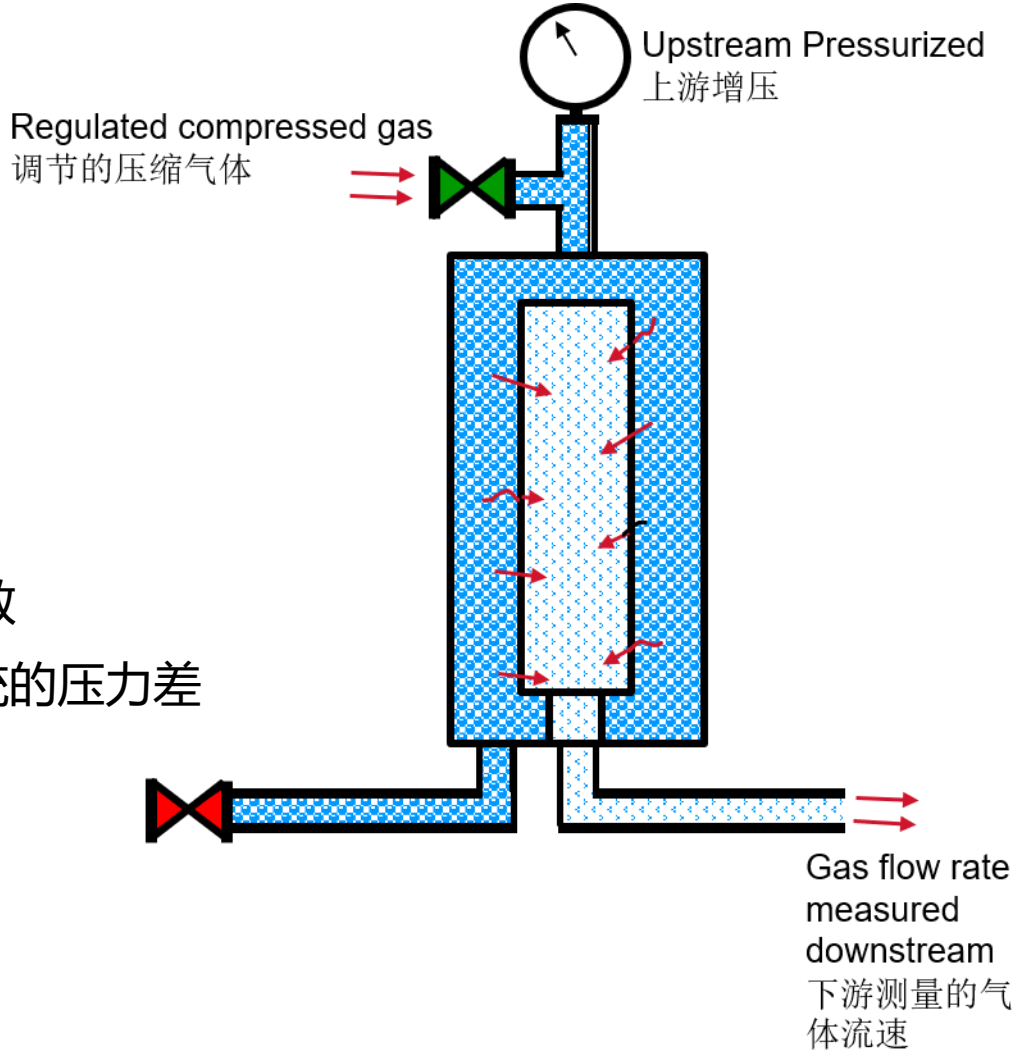
K = Solubility / Diffusivity coefficient 溶解度/扩散系数

P1, P2 = Pressure difference across the system 系统的压力差

A = Membrane area 膜面积

ρ = Membrane porosity 膜孔隙率

L = Effective path length 有效路径长度



Factors Affecting Diffusion Tests
影响扩散流测试的因素

Fluid 流体

- Organic solvents have high diffusion flow rate
  有机溶剂的扩散流速高

Gas 气体

- Carbon dioxide has higher gas flow than air or nitrogen
  二氧化碳的气体流速高于空气或氮气

Temperature 温度

- 80% higher flow rate at 60° C
  在60°C时，流速高80%

Wetting 润湿

- Lower or inconsistent film thickness increases diffusion
  膜厚度较小或不一致，会增加扩散

Example of Effect of Liquid on Diffusional Flow
液体对扩散流速的影响实例

The same filter tested with nitrogen at 18.8 psig (1.3 bar)

用压力为18.8 psig（1.3bar）的氮气，测试相同的滤芯

- Acetone丙酮 <390 mL/min
- IPA异丙醇 <120 mL/min

MESSAGE：信息：

- **The same gas may have different solubility and diffusivity in different wetting fluids**

  在不同的润湿液体中，同一种气体可能有不同的溶解度和扩散系数

- **Changing solvents changes diffusional flowrate**

  溶剂改变，则扩散流速改变

Example of Effect of Gas on Diffusional Flow
气体对扩散流速的影响实例

Hydrophilic filter is tested with both nitrogen and compressed air at 2.8 bar (40psi)

用压力为2.8bar（40psi）的氮气和压缩空气，测试亲水性过滤器

- Nitrogen氮气 < 8 mL/min
- Compressed air压缩空气 < 10 mL/min

MESSAGE: 信息

- **Different gases may have different solubility and diffusivity in the same wetting fluid.**

  在同一种润湿液体中，不同的气体可能有不同的溶解度和扩散系数。

- **Changing the test gas can give a false diffusional flowrate.**

  改变测试气体，可能给出错误的扩散流速。

Example of Effect of Area on Diffusional Flow
面积对扩散流速的影响实例

What is the maximum diffusional flow for a 5 x 30" pleated cartridge filter system?

5 x 30"折叠筒式过滤器的最大扩散流速是多少?

- 10" element < 13.3 mL/min
- 30" element < 39.9 mL/min
- 5x30" elements < 199.5 mL/min

MESSAGE: 信息:

- **Diffusional flow depends on porosity and surface area**
  扩散流速取决于孔隙率和表面积
- **For the same membrane, diffusion is directly proportional to surface area**
  对于相同的膜，扩散流速与表面积成正比

2

HYDROPHOBIC FILTERS INTEGRITY TESTING
疏水过滤器完整性测试

MERCK

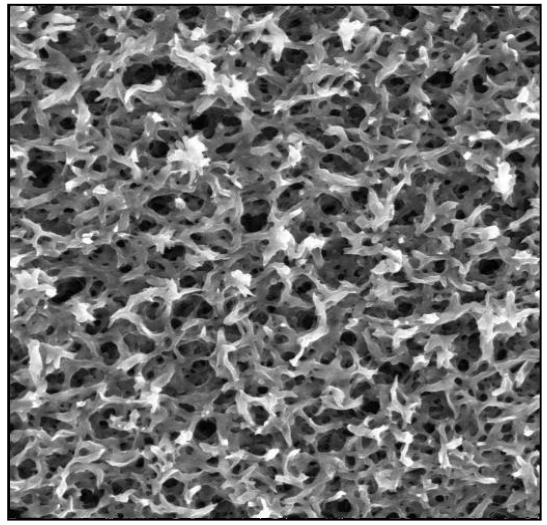
Hydrophobic Filter Materials
疏水过滤器材料

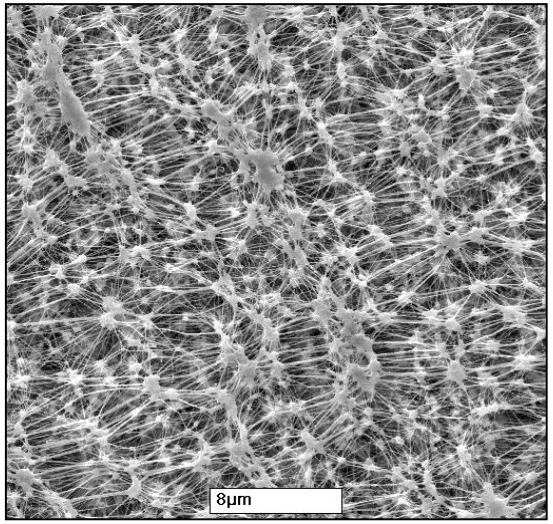
PVDF (Polyvinylidene Fluoride)

聚偏二氟乙烯

PTFE (Polytetrafluoroethylene)

聚四氟乙烯





Advantages 优点

- Naturally hydrophobic 天然疏水性
- Mechanically strong 机械性能强
- Excellent chemical compatibility 优良的化学相容性
- Good thermal tolerance 良好的热耐受性

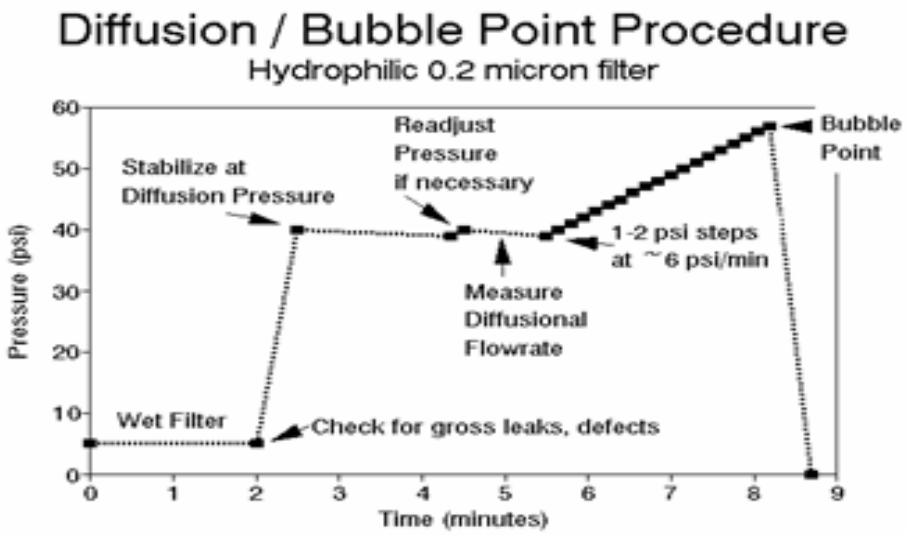
Traditional Testing Principles
传统测试原理

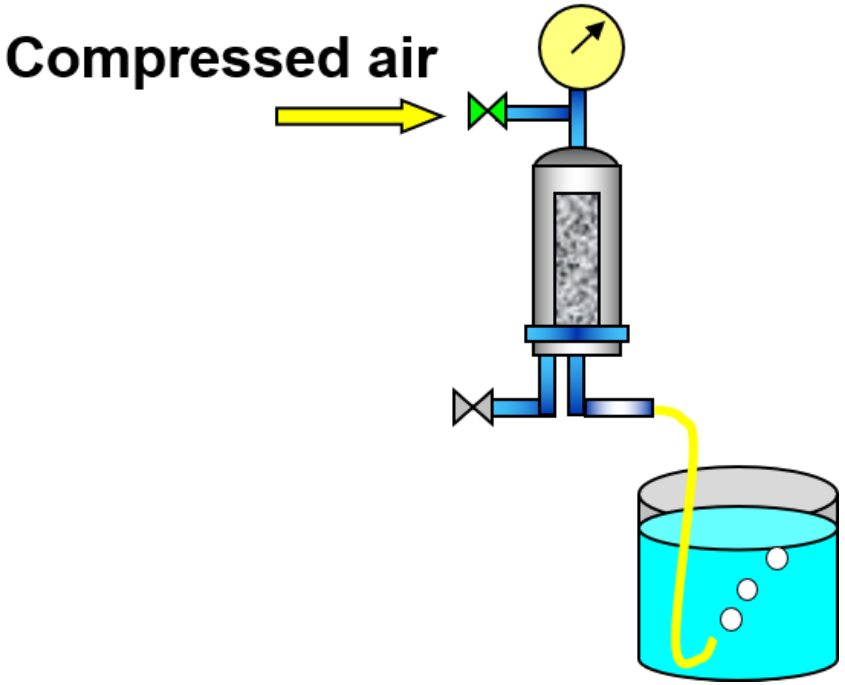
- Typical wetting liquids are Isopropyl Alcohol (I.P.A.), Methanol, Tert-butyl Alcohol, or a mixture of one of these and water

  典型的润湿液是异丙醇、甲醇、叔丁醇或它们与水的混合物

- Uses same principles as a hydrophilic test

  使用与亲水性滤膜测试相同的原理





Alcohol Testing Advantages
采用有机溶剂测试的优点

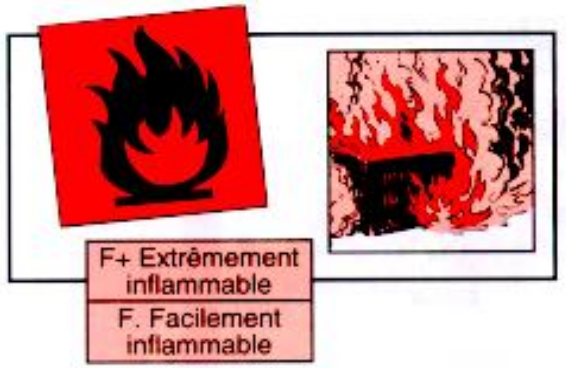
- No special equipment required 不需特定的设备
- Follows similar procedures to hydrophilic membranes 可以采用与亲水性滤膜类似的步骤
- Operator training time is reduced 减少操作者的培训时间
- Traditional 是传统的方法
- Widely accepted 广泛被接受
- Well understood 很好理解
- Correlated to bacterial challenge 与细菌挑战有相关性
- Can be performed easily & quickly 能非常容易及快速的进行测试

Alcohol Testing Issues
采用有机溶剂测试的问题

- Alcohol / Water mixtures are often used due to:

  醇/水的混合物使用经常会导致
  - Cost 成本高
  - Flammability 易燃
  - High diffusion 高的扩散流
- Secure areas and equipment needed

  需要额外的区域及设备
- Can be difficult to perform in-situ 很难在线操作
  - Some concerns with residual test solution remaining in filter holder / pipework after testing 在测试后,测试液体会残存在过滤器/管路中
  - Residual solution should be removed before filter sterilization 灭菌前需要去除残存的液体



Alternatives to Alcohol Based Integrity Testing
代替有机溶剂进行完整性测试

- Needed primarily due to: 改变的主要原因是
  - Issues with alcohol contamination of processes residues 醇残留的问题
  - Risks inherent with the use of solvents 使用有机溶剂的潜在风险

- Water-Based Integrity Tests have been developed to overcome these issues
  基于水的测试可以克服以上问题
  - Ease of validation 容易验证

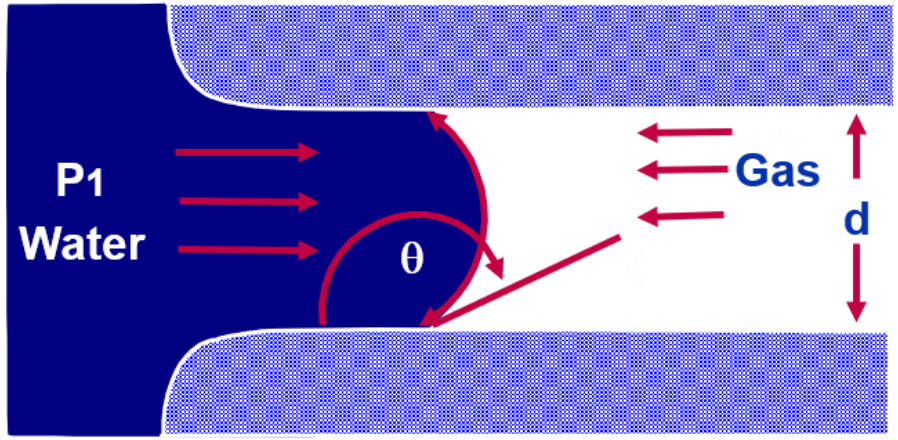
Hydrophobic Filter Water-Based Integrity Test Theory
疏水过滤器用水作完整性测试的原理

- Hydrophobic polymers repel water

  疏水膜抗拒水
- Pleated structures compact under pressure

  在压力下,折叠式结构进一步压缩
- Water Intrusion Pressure is the minimum pressure necessary to force water into the largest pores of a hydrophobic membrane.

  水侵入压的定义为:把水挤入疏水性膜最大孔的最小压力



$$IP = \frac{-4 \cdot k \cdot \gamma \cdot \cos\theta}{d}$$

Where其中

k = shape correction factor 形状校正因子

γ **= surface tension** 表面张力

θ **= contact angle** 接触角

d = pore diameter 孔径

Water Based Testing (HydroCorr / WIT Test)
基于水的测试（ HydroCorr / 水侵入测试)

Test Principles 测试原理

- Capillary forces are strong for integral filters and small pores

  对于完整的过滤器和小孔，毛细管力很大

- Hydrophobic polymers repel water at low pressures (~2600 mbar)

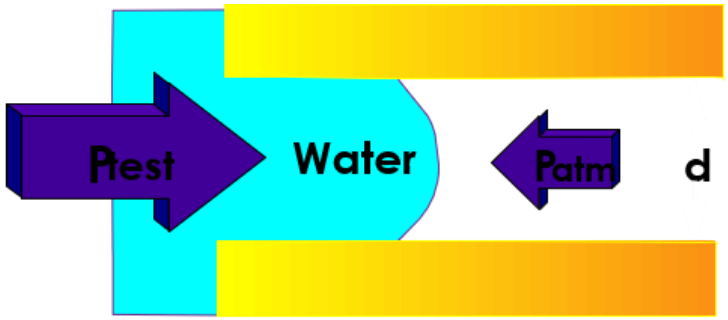
  在低压力下疏水聚合物是排斥水的

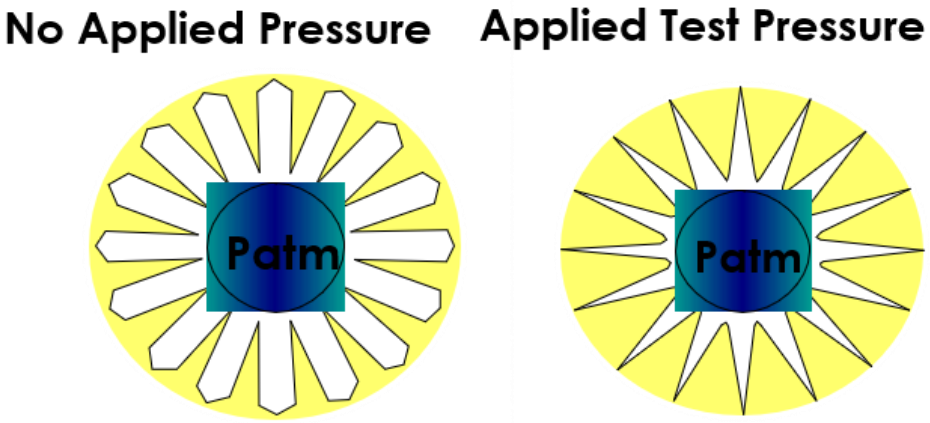
- Pleated structures compact under pressure until pleat pack stabilizes

  折叠结构在压力下会被压缩直到折叠结构稳定

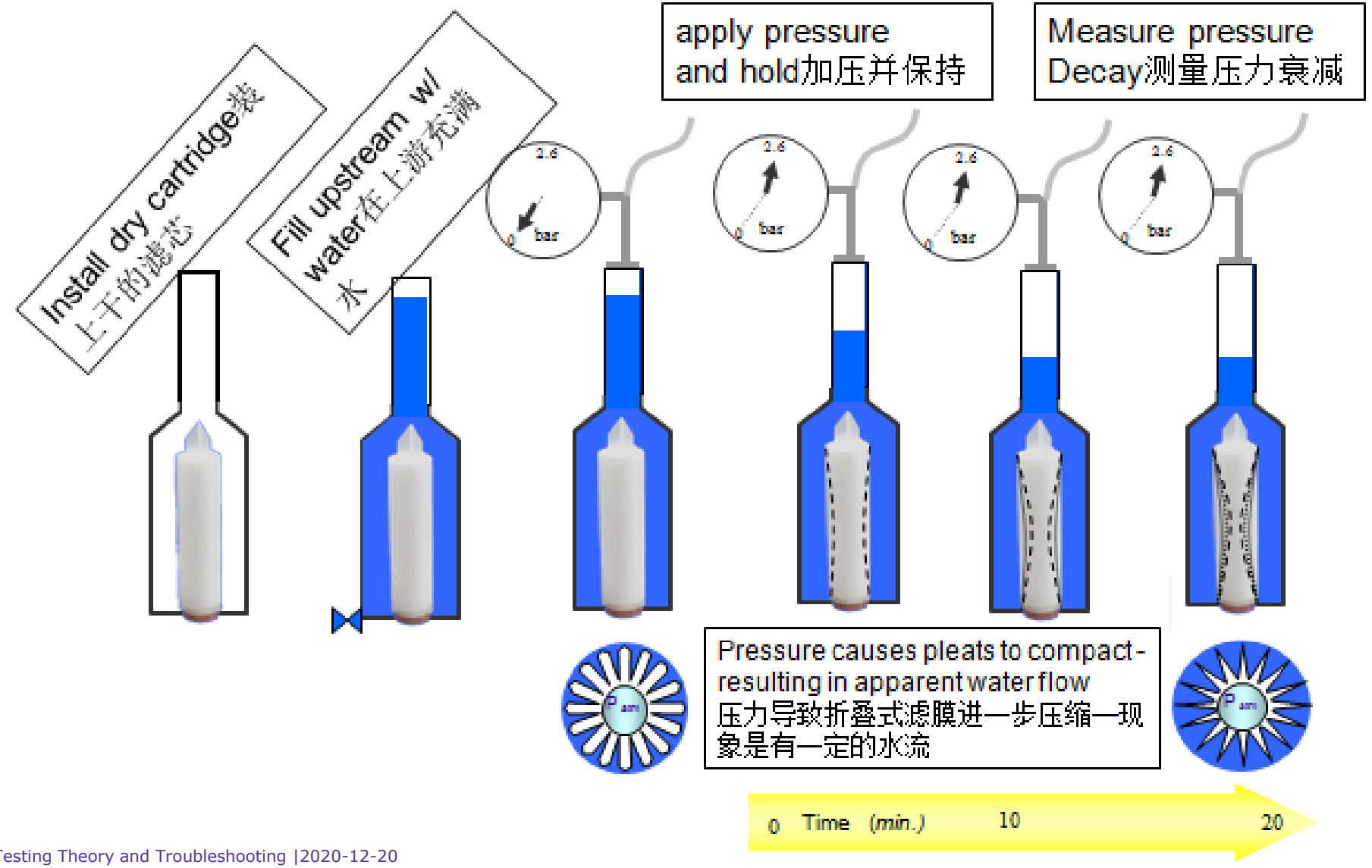
- Measurements are on upstream side

  在上游进行测量





HydroCorr Test - Resistance to Water Intrusion
HydroCorr测试 - 阻挡水侵入



Performing HydroCorr Tests
进行水侵入法测试

Manually手动操作

- Use a flow meter to measure actual upstream water displacement
  使用流量计来测量上游水的水流

Automatically自动操作

- Use a pressure transducer to measure upstream gas pressure loss
  使用压力传感器来测量上游气体压力的损失

Both need long stabilization & test time 都需要长时间的稳定及测试时间

- Typically, 10 minutes stabilization & 10 minutes test
  一般需要10分种的稳定时间及10分钟的测试时间

3

TROUBLESHOOTING INTEGRITY TESTS
完整性测试常见问题分析

Potential Test Results
可能测试结果

- Specifications are 参数是

  ≥ 50 psi bubble point 泡点

  ≤ 13.3 cc/min diffusion rate at 40psi 扩散流速

- Result 1 - 54 psi b. pt. and 11.0 cc/min diffusion

  结果1：54 psi 起泡点 和 11.0 cc/min 扩散率

  Test pass 测试通过

- Result 2 - < 5 psi b. pt. or very high diffusion flow

  结果2：< 5 psi 起泡点 或者 很高的扩散流

  Gross Failure 一般失败

- Result 3 - 47 psi b. pt. or 18 cc/min diffusion

  结果3：47 psi 起泡点 or 18 cc/min 扩散率

  Marginal failure 边缘失败

- Result 4 - > 70 psi or "0 cc/min" diffusion

  结果4：> 70 psi 起泡点or "0 cc/min" 扩散率

  Test procedural problem 测试过程问题

Review Test Relationships
回顾测试关系

- Wetting solution（湿润液体）
- Membrane material（膜材料）
- What is on the pore（孔上残留物）
- Pore diameter（孔径）
- Temperature（温度）
- Test Gas（测试气体）
- Test Pressure（测试压力）
- Differential pressure（压差）
- Membrane area（膜面积）
- Porosity（孔隙率）
- Wetted thickness（润湿厚度）

$$BP = \frac{4 \cdot k \cdot \gamma \cdot \cos\theta}{d}$$

where 其中

k = shape correction factor 形状校正因子

γ = surface tension 表面张力

θ = contact angle 接触角

d = pore diameter 孔径

$$\text{Diffusion} = \frac{K \cdot (P1 - P2) \cdot A \cdot \rho}{L}$$

where: 其中:

K = Solubility / Diffusivity coefficient 溶解度/扩散系数

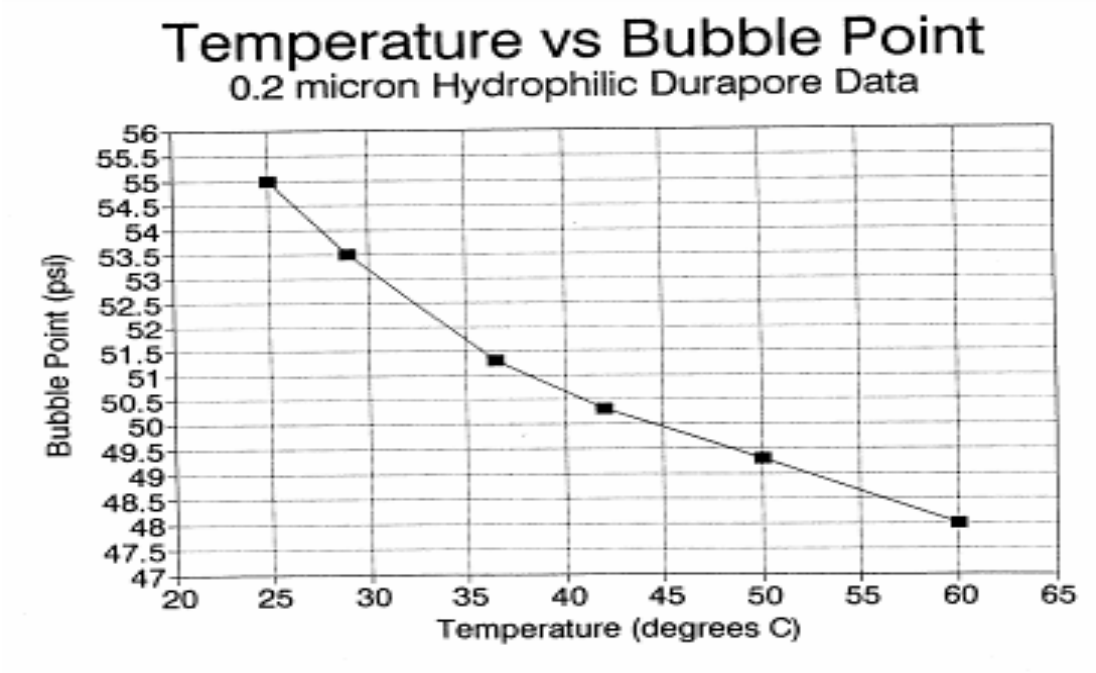
P1, P2 = Pressure difference across the system 系统内的压力差

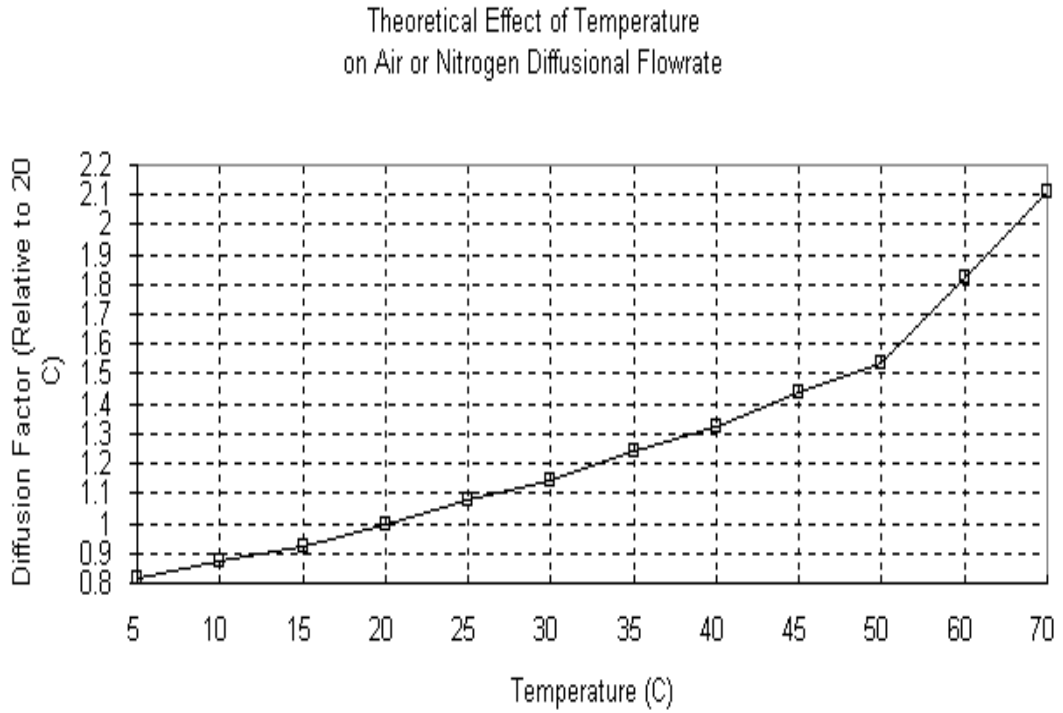
ρ = Membrane porosity 膜孔隙率

L = Effective path length 有效路径长度

A = Membrane area 膜面积

Effect of Temperature Changes
温度变化的影响





Manual bubble point test : ~20%

Manual diffusion test : ~80%

Automatic testers : very dependent

手动的泡点测试： ~20%

手动的扩散测试： ~80%

自动的检测器：有相关性

Standardize test temperature and record test temperature at the start & finish

标准化测试温度，在开始时& 结束时记录测试温度

Effect of Temperature on Automated Testing
温度对自动测试的影响

Temperature CHANGES during a pressure decay test will have MAJOR impact on test results.

压力衰减试验期间，若温度变化，会对试验结果有重大影响。

- Ideal Gas Law - PV = nRT 理想气体定律 – PV = nRT
- As temperature increases pressure increases 随着温度升高，压力升高
- As temperature decreases pressure decreases 随着温度下降，压力下降

If the temperature changes even 1oC. during the test, the pressure change WILL NOT be solely due to gas flow。

测试期间，温度哪怕只改变1℃，气流也将不再是压力变化的唯一原因

- Additional pressure loss or pressure gain are test error
  额外的压力损失或压力增加引起测试错误

Low bubble point
低泡点

REASON 原因

- Poor wetting 较差的湿润
- Different wetting fluid than recommended

  与建议的湿润液体不同
- Product residue 产品残留
- Higher test temperature

  测试温度过高
- Very soluble test gas confusing diffusion for bubble point

  易溶的测试气体高扩散流代替泡点错误
- Pipe/Housing Leak

  管路连接/套筒泄漏

ACTION 措施

- Rewet the filter 重新润湿过滤器
- Flush with manufacturers test fluid

  用生产厂建议的湿润液体冲洗
- Flush with desorbing fluid then wetted with specified fluid

  冲洗掉原来液体，再用指定液体润湿
- Standardize test temperature

  标准化测试温度
- Equilibrate temperature to manufacturers conditions 使温度与生产厂要求的条件相符合
- Check gas and change to manufacturers test gas

  检查气体并且改变到生产厂要求的气体
- Identify fault and replace 识别故障并替换

High bubble point
高泡点

REASON 原因

- Different wetting fluid than recommended
  不同于推荐的湿润液体
- Lower test temperature
  过低测试温度

ACTION 措施

- Wetted with manufacturers test fluid OR flush with desorbing fluid then wetted with specified fluid

  用生产厂推荐的液体润湿或者用先用液体进行冲洗，再用指定液体润湿
- Standardize test temperature OR Equilibrate temperature to manufacturers condition

  使温度与生产厂要求的条件相符合

High diffusional flow rate
高扩散率

REASON 原因

- Poor wetting 较差的湿润
- Product residue 产品残留
- Hydrophobic areas 存在疏水区域
- Different wetting fluid than recommended

  与建议的湿润液体不同
- Different test gas than recommended

  与建议的测试气体不同
- High test temperature.
  高的测试温度
- Pipe/Housing Leak

  管路连接/套筒泄漏

ACTION 措施

- Rewet the filter 重新润湿过滤器
- Wetted with manufacturers test fluid OR flush with desorbing fluid then wetted with specified fluid

  用生产厂推荐的液体润湿或者用先用液体进行冲洗，再用指定液体润湿
- Standardize test temperature;

  标准测试温度
- Equilibrate temperature to manufacturers conditions.

  使温度与生产厂要求的条件相符合
- Check gas and change to manufacturers test gas

  检查气体并且改变到生产厂要求的气体
- Observe / check / certify/technique 观察/检查/证明/技术

Low diffusional flow rate
低扩散率

REASON 原因

- Membrane tested after ~100% blockage.
  膜100%堵塞后测试测试
- Lower test temperature
  过低的测试温度
- Wrong connect to the test machine
  与测试仪器的错误连接
- Short stabilization time
  较短的稳定时间
- Poor testing technique
  较差的测试技巧

ACTION 措施

- Confirm blockage with clean fluid during a water / product flowrate test
  评估水或者产品的流速确认是否有堵塞
- Standardize test temperature or Equilibrate temperature to manufacturers conditions
  标准化测试温度或者使温度与生产厂要求的条件相符合
- Check the connect 检查连接
- Increase stabilization time 增加稳定时间
- Observe / check / certify technique
  观察/检查/证明/技巧

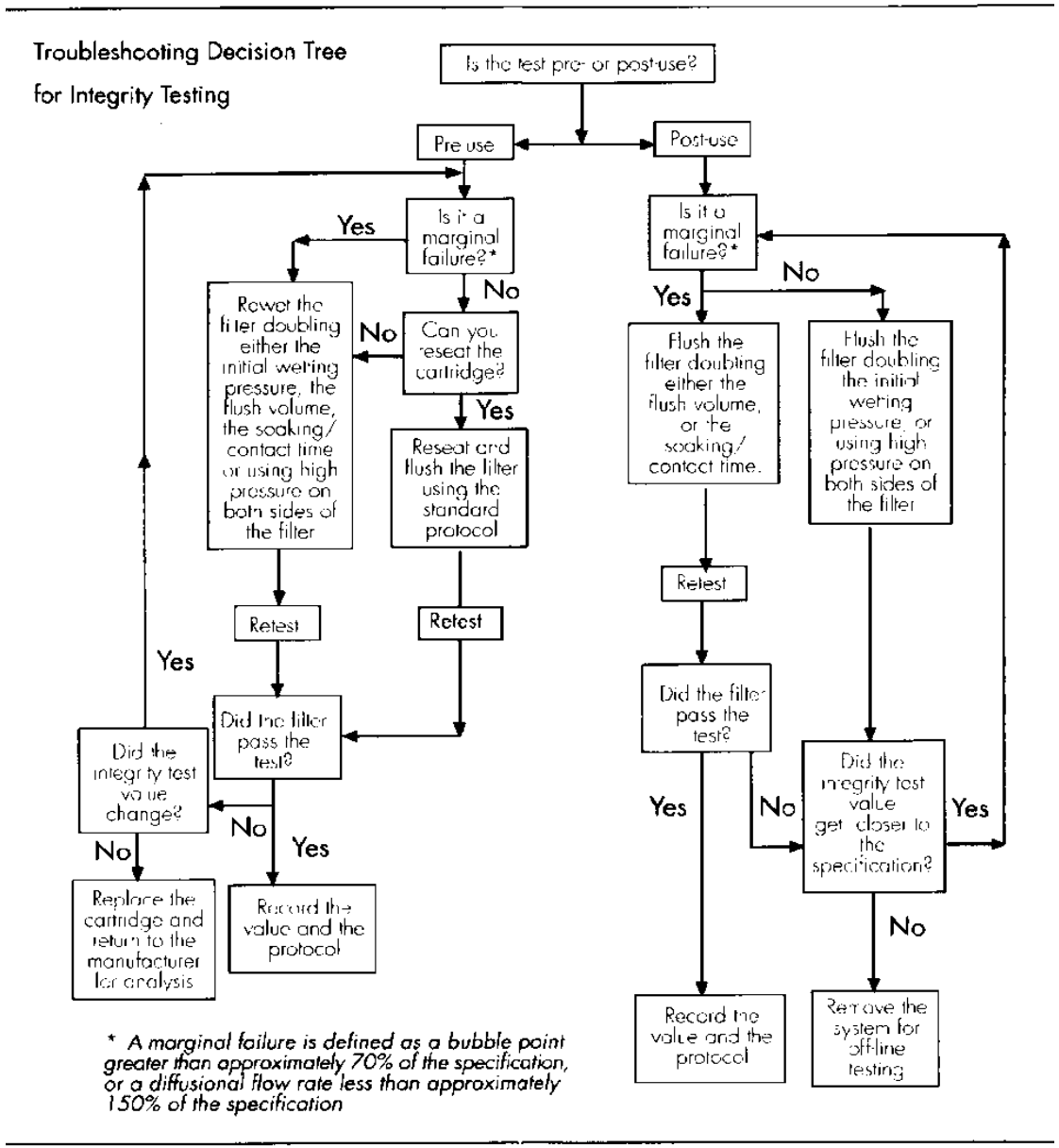
Use a Wetting Guide
使用湿润指南

Wetting Instructions

for Filter Units
and Cartridges with
Durapore® Membranes

Millipore recommends using this wetting procedure prior to conducting an integrity test to achieve optimal results. Please refer to the Millipore catalog for appropriate specifications for the filter and housing to be tested.

MILLIPORE



MERCK

Wetting Suggestions
湿润建议

- Repeat wetting

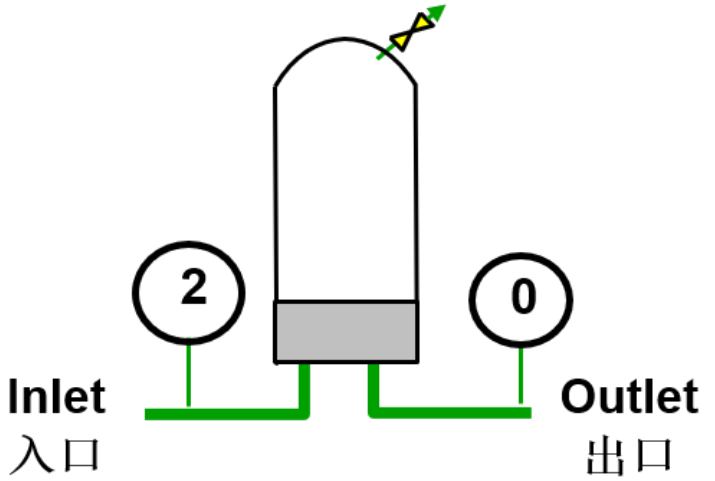
  再湿润
- Use longer wetting

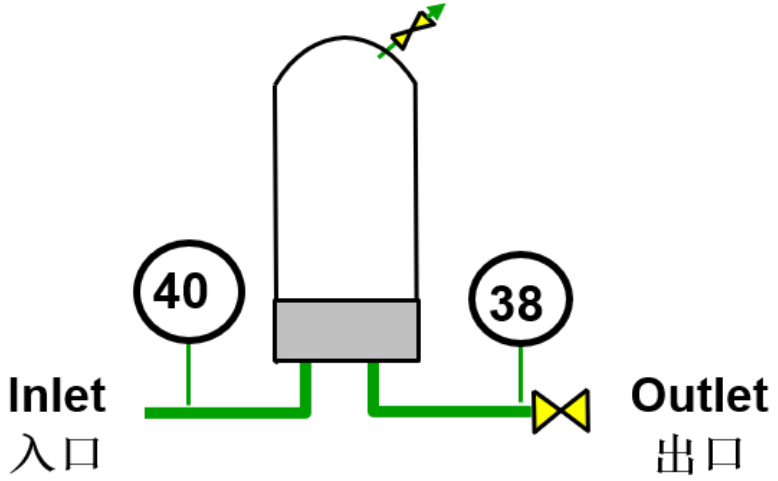
  使用更长的时间湿润
- Use higher pressure

  使用更高的压力湿润
- Use higher temperature

  使用更高的温度湿润
- Replace static soak with dynamic flush

  用动态的冲洗取代静态的浸透





Rewetting
再湿润

- Overcome initial non-optimum wetting procedure

  克服初次非最优化湿润程序的不足
- Increase contact time for partially wetted filters

  增加部分被湿润过滤器的接触时间
- Flush out product 彻底冲洗出产品
- Flush out contaminating wetting solution 冲洗掉被污染的润湿液
- Intrude hydrophobic areas

  进入到不易被水沾湿的疏水区域
- Notice 务必注意
  - A standardized wetting protocol 一个标准化的湿润方案
  - To increase a parameter: pressure, time, volume/flowrate, temperature

    增加规定的参数：压力，时间，体积 / 流速，温度

Re-testing Techniques
再测试技术

- Identify the probable cause 鉴别可能的原因
  - Housing 套筒
  - cartridge 过滤器
  - Machine 仪器
  - Test Method/Process 测试方法/过程
  - Operator 操作员
  - Environment 环境

- Refer to SOP to know: 查阅标准操作程序:
  - How to re-wet 怎样再湿润
  - How to re-test 怎样再测试
  - And how many times to re-test 并且需要重复多少次测试

谢 谢 ！

技术支持：

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