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### 1.0 Purpose

This procedure describes the testing of filters used in the production processes in the Biopharmaceutical Development Program (BDP) with the Sartocheck 5 Integrity Test System.

### 2.0 Scope

This SOP applies to BDP personnel who will be operating the Sartocheck 5 Integrity Test System.

### 3.0 Authority and Responsibility

- 3.1 The Director, Manufacturing, BDP has the authority to define this procedure.
- 3.2 The Managers and Supervisors, BDP are responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).
- 3.3 BDP Production personnel are responsible for the implementation of this procedure.
- 3.4 BQA is responsible for quality oversight pertaining to this procedure.



## 4.0 Guidelines

- 4.1 All filters used in support of or for final sterile filtration of a product in CGMP production must be tested for integrity.
- 4.2 Filters that are packaged from the manufacturer as sterile will not be tested before use. Filters that are used in an air/gas sterilizing capacity can be tested prior to and after use.
- 4.3 The type of test performed shall be determined by the Master Production Record (MPR), as applicable, or by the Area Supervisor. The Sartocheck 5 Integrity Test System can perform the tests listed below, however the standard test used to verify filter integrity in the BDP is the bubble point test.
  - Diffusion.
  - Water Intrusion.
  - Bubble Point.
  - Diffusion and Bubble Point
  - Volume Measurement
  - Pressure Drop
- 4.4 The filter manufacturer's lot number and serial number shall be the unique identifier used for the purpose of identifying the test filter on the test result.
- 4.5 Filter types that are used on a regular basis may have their testing parameters programmed into the integrity test unit and should primarily be listed by BDP part number.

## 5.0 Instrument Setup

- 5.1 Make connections to the Sartocheck 5 per Figure 1 in Attachment 1, if not already connected.
- 5.2 Make sure the constant incoming gas pressure is  $\geq 60$ psi and  $\leq 115$ psi.
- 5.3 Turn on the power and allow the software to load. Turn on the printer, if desired, or ensure a USB thumb drive is available for result retrieval, if desired.
- 5.4 Log into the system. Each user has their own User ID, in the form of lastnamefirstinitial. Passwords must be changed every 180 days and will be prompted by the unit if expired. User ID and passwords are not shared between users. Passwords must contain at least two of the following and be at least 6 characters long: Upper case character, lower case character, number, or special character (unit will show this requirement when changing the password).
- 5.5 From the menu shown (see Attachment 2), the user can select Run New Test, Repeat Last Test, or Print Last Result.



- 5.6 For consistency of entry and ease of entry, some common or repetitive entry data may be created/printed in barcode format at a computer as applicable and then scanned for entry at the Sartocheck 5.

## 6.0 Filter Preparation for Bubble Point Testing

### 6.1 Air Filters

- 6.1.1 Filters that have been used in a process and are to be tested must be tested in an appropriate housing.
- 6.1.2 The filter must be wetted with 60% IPA or other wetting agent specified by the BPR, or manufacturer instructions. BDP part number, lot number, and expiration should be recorded on the container of 60% IPA.
- 6.1.2.1 The wetting solution should be at ambient temperature.
- 6.1.2.2 The solution must also be stored in a tightly capped container to prevent evaporation.
- 6.1.3 To wet the filter, submerge it into the wetting solution in an inverted position (O-ring side up). Tap the filter gently in order to discharge any trapped air bubbles. Allow the filter to soak while totally submerged for a minimum of 30 minutes.

### 6.2 Liquid Filters

- 6.2.1 After use, flush the filter thoroughly with WFI, or other appropriate solvent per the BPR or manufacturer instructions, to ensure that all residues from filtration are removed.
- 6.2.2 Wet the filter using the appropriate wetting agent (solvent) that is at ambient temperature for the integrity test to be performed.
- 6.2.2.1 Install the filter to be tested into its original housing. Capsule filters can be connected to the wetting solution reservoir with appropriate tubing.
- 6.2.2.2 Connect the inlet side of the filter/housing to the wetting solution reservoir. If wetting reservoir is not pressurized, install a peristaltic pump between the reservoir and the filter.
- 6.2.2.3 Install tubing running from the outlet side of the filter/housing back to the reservoir unless the filter was in contact with a different solution. In which case, the outlet tubing will be directed to drain or a different receiver.
- 6.2.2.4 Open the pressurized source or start the pump and allow the housing to be completely filled with the wetting agent, opening the vents as necessary to remove all air.



6.2.2.5 Continue flow until no more air bubbles are observed or for at least 15 minutes, whichever is longer.

## 7.0 Performing the Bubble Point Test

- 7.1 Connect the filter/housing using braided tubing and a hose clamp or via sanitary connection and clamp.
  - 7.1.1 For liquid filters, ensure the air flow is in the same direction as when the filter is in use.
  - 7.1.2 For air filters, the flow of air should be directed into exterior of the filter element and through the filter, in the opposite direction of typical usage.
- 7.2 Direct the flow from the downstream side to the drain or other suitable container.
- 7.3 From the program menu, select the desired test program to be run and click the right arrow button. The next screen is a confirmation of the program to be run. Click the right arrow button again once confirming the desired program
  - 7.3.1 The filter must have a program in the Sartocheck in order to test it. If the operator needs to test a filter for which a program does not exist, contact the Equipment Owner to coordinate the creation of a new program.
- 7.4 The next screen is for data entry specific to the filter. The operator should enter the information as follows, via touchscreen or barcode scanner. Once complete, click the right arrow button.
  - Department (Production, Fill/Finish, Purification, Utilities, etc.)
  - Product
  - Product lot (BDP lot number)
  - Filter type will be populated by the program selection in the prior step
  - Filter lot (Filter lot number and serial number)
  - Filter line (description of filter use, e.g., Seed Media, Overlay Filter, etc.)
  - Housing and Wetting medium will be populated by the program selection in the prior step
- 7.5 Press the START button to begin the test.
- 7.6 The test will now commence. If desired, the test can be aborted at any time, just press the STOP button and enter a reason for the abort in the End comment field.



## 7.7 Results

7.7.1 Once the test is complete, the unit will display several screens summarizing the test data. If utilizing the USB printer, the result will print. Record the results in the BPR or other appropriate form. Press the OK button to exit the test.

7.7.2 If an electronic copy of the test result is desired, return to the home screen and press the Administration banner at the bottom of the screen. Select Results, then Results management. Select the desired test, or tests, and press the  $\uparrow$  button at the bottom of the screen. On the next screen, choose usb-1 in the Location dropdown and then check the box for Export as PDF, then press OK. The unit will show the progress of the export and notify the operator when complete. The result can now be saved to a computer, network folder, or printed on a standard printer.

7.7.3 Collect the printout and annotate with the operator's initials and date. Attach the printout to the BPR or store in a location determined by the Area Supervisor.

7.8 Return to the main menu using the back buttons. If additional filters are to be tested, proceed to Section 6.0 for wetting.

7.9 If no additional tests are to be performed, the unit may be turned off via power button at the outlet or it may be left on.

7.10 In the event of a filter test failure, perform the following operations.

7.10.1 Re-wet the filter per Section 6.0.

7.10.2 Visually inspect all sealing surfaces, verify that all connections are tightly sealed. Re-test the filter per Section 7.0.

7.10.3 If the filter fails a second time, notify the Area Supervisor and consult manufacturer-specific troubleshooting procedures.

7.10.4 Record any corrective action taken for the filter failure in the comments section of the BPR or on the printout of the failed filter.

## 8.0 Documentation

8.1 Document the results of the integrity test in the BPR. Attach the test result(s) as necessary. Record in the equipment log the date, time, operator's initials, production lot number, if applicable, and a description of activities performed.

8.2 Any changes to, or additions of, test programs shall be recorded in the equipment logbook. Changes must indicate why the change was made.



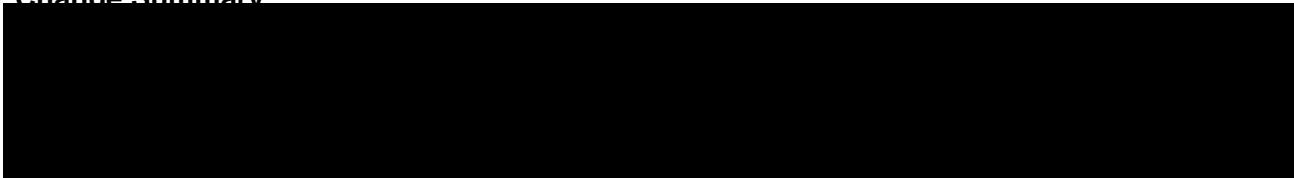
**9.0 Attachments**

9.1 **Attachment 1** Filter Test Station Setup

9.2 **Attachment 2** System Home Screen

9.3 **Attachment 3** Sample Test Result

**10.0 Change Summary**





### Attachment 1

### Filter Test Station Setup

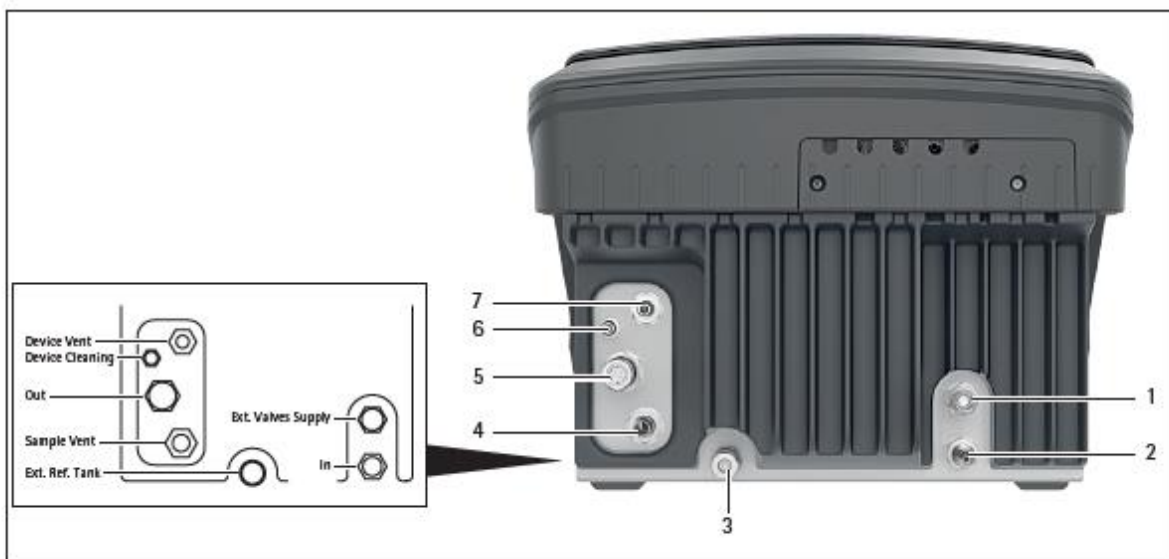


Fig. 3: Supply connections and overview of pneumatic connections (example)

Pos.	Designation	Description
1	Ext. Valves Supply	Gas connection for accessory kits (coupling)
2	In	Connection for gas intake (plug-in nipple); used for the pressure inlet tube
3	Ext. Ref. Tank	Gas connection for an external reference tank (coupling)
4	Sample Vent	Connection for external venting (plug-in nipple); discharges the gas from the sample into the environment or a connected tube (venting tube for sample)
5	Out	Connection for gas discharge (coupling); used for the test tube
6	Device Cleaning	Connection for automatic self-cleaning (plug-in nipple); used for the tube of the accessory kit for cleaning
7	Device Vent	Connection for internal venting (plug-in nipple); discharges the gas from the device into the environment or a connected tube (venting tube for device)

The following pneumatic connections of the device are self-sealing:

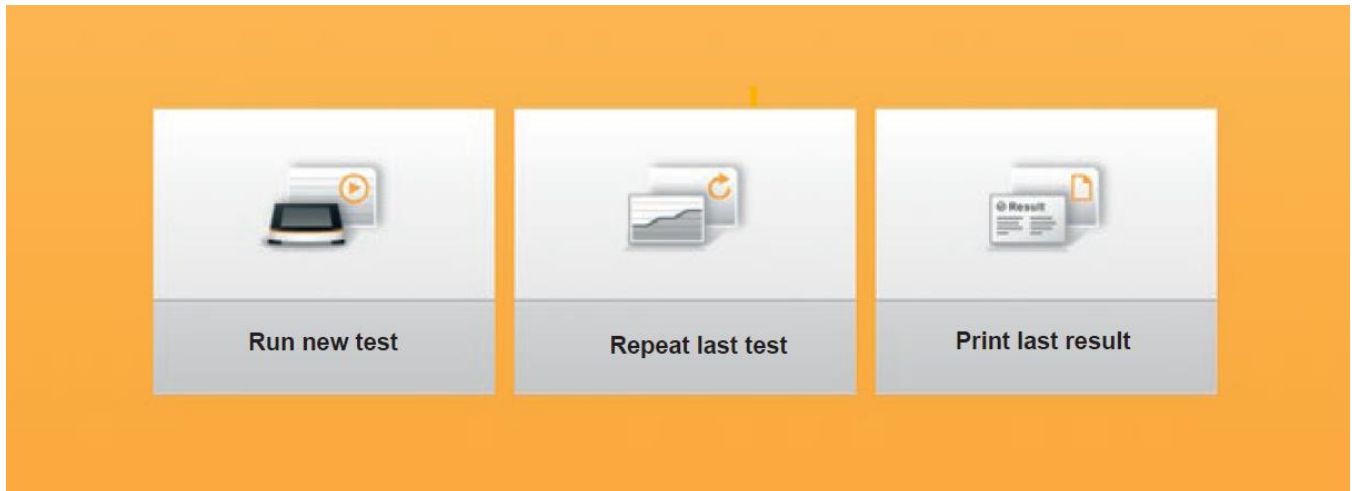
- Ext. Valves Supply
- Ext. Ref. Tank
- Out
- Device Cleaning



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Attachment 2

System Home Screen







Attachment 3

Sample Test Result



sartorius stedim  
biotech

Result

<p><b>General data</b></p> <p>Program name 21911 - Sartopore 2</p> <p>Method <b>Bubble point</b></p> <p>Serial number [REDACTED]</p> <p>Device version 09-04-01.02.04-1.191212</p> <p>Workflow version 0.9.0</p> <p>User ID <b>Admin</b></p> <p>User name <b>Unnamed Administrator</b></p> <p>Number of samples <b>1</b></p> <p>Advanced <b>Yes</b></p> <p>Pressure unit <b>psi</b></p> <p><b>Protocol data</b></p> <p>Filter line <b>7</b></p> <p>Manufacturing site <b>4</b></p> <p>Product lot <b>6</b></p> <p>Product <b>5</b></p> <p>Department <b>3</b></p> <p>Filter lot [REDACTED]</p> <p>Housing <b>8</b></p> <p>Building <b>2</b></p> <p>Gas <b>Air</b></p> <p>Use before date <b>6/23</b></p> <p>Company <b>1</b></p> <p>Wetting medium <b>w</b></p> <p>Water quality <b>wfi</b></p> <p>Comments or Errors ok</p>	<p>Filter type -&lt;S1&gt;5445307H8- 00;024001204;233;U06/2023</p> <p><b>Characteristics and limits</b></p> <p>Acc. kit for venting <b>No</b></p> <p>Volume determination <b>Measurement</b></p> <p>Ext. ref. tank used <b>No</b></p> <p>Tot. max. diffusion <b>150.00 mL/min</b></p> <p>Min. bubble point <b>46.00 psi</b></p> <p>Max. bubble point <b>60.00 psi</b></p> <p>Pressure step <b>0.79 psi</b></p> <p>Accelerated test <b>Yes</b></p> <p>End pressure <b>60.00 psi</b></p> <p>Pre-stabilization time <b>90 s</b></p> <p>Bulk flow criterion <b>240.00 mL/min</b></p> <p>Overprop. criterion <b>30.00 mL/min</b></p>	<p><b>Result</b></p> <p>Result <b>Test passed</b></p> <p>Signature status <b>No signatures</b></p> <p>Start time <b>12/10/2020 12:00</b> [UTC-05:00]</p> <p>End time <b>12/10/2020 12:20</b> [UTC-05:00]</p> <p>Volume <b>250 mL</b></p> <p>Bubble point <b>55.731 psi</b></p> <p>Final diffusion <b>146.35 mL/min</b></p> <div style="text-align: right;"> </div>
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**Signatures**

Role	Responsible	Reviewer	Approver
Name			
Time stamp			
Comment			