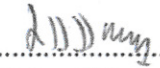
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DOCUMENT APPROVAL


Author's Signature:

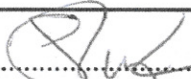
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Print Name	James Drury		
Title	Production Engineer		

Reviewer's Signature:

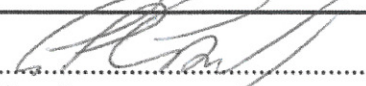
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1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the filter system used on the Purite system for the clean room is maintained in a controlled and consistent manner to assure compliance with ISO 14698 for the required class of operation.

2.0 SCOPE

- 2.1. The scope of this documents covers the methods of working and maintenance of the water purification system used by the clean rooms and associated equipment at Advanex Europe Ltd.

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. ISO 14698 – The International Standard Organisation Specification for Bio contamination control for clean rooms.
- 3.2. CR1 - Clean Room 1, the Upstairs clean room.
- 3.3. CR2 - Clean Room 2, the new Downstairs clean room.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. Within the factory area safety footwear is mandatory.
- 4.2. Within the factory area the use of safety glasses is mandatory.
- 4.3. Water Authority Consent to Discharge Document.

5.0 ASSOCIATED DOCUMENTS

- 5.1. Cleanroom Activity Log (Document Number AEU00496).
- 5.2. Correct Usage of Bins For Non-Hazardous Waste Streams (Document Number AEU00396).


6.0 PROCEDURE

6.1. General Instructions.

Note: The Two Different Clean Rooms Use Different Types Of Purite Systems To Maintain The Water Quality, However The Procedure To Replace the 25µm Filter For CR1 Is The Same As The 0.2µm Filter For CR2.

6.2. Purite System Filter Change For CR1.



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6.2.1. **When to Change the Filter Cartridges.** Change the filter cartridges only if the resistance measured on the resistance meter on the control and as shown in Figure 1: is below the required level, as indicated by the Cleanroom Activity Log (Document Number AEU00496).

Note: Change Both Filter Cartridges And 25µm Filter At The Same Time Or After Cleaning / Replacing The Ultra Violet Filter's Sleeve.

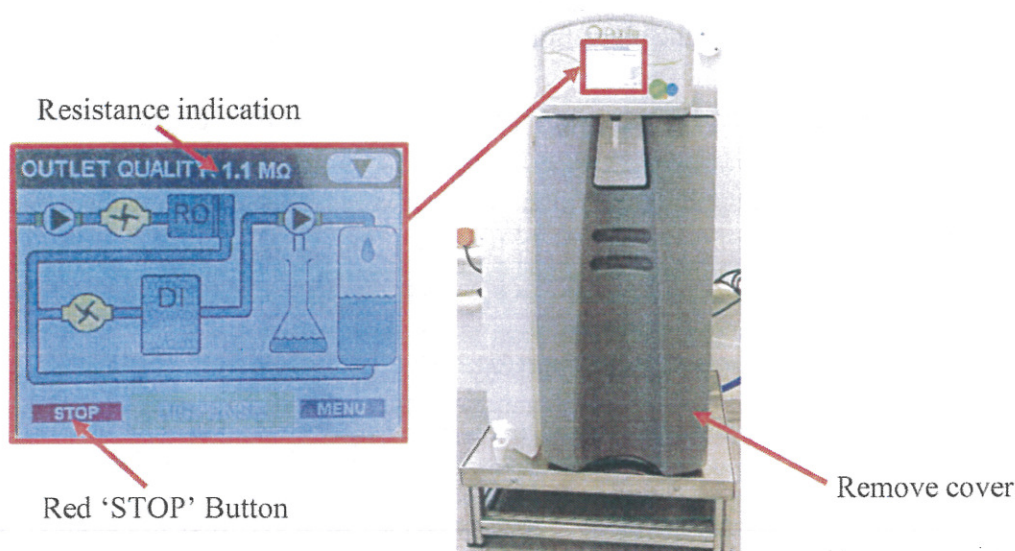


Figure 1: Purite System for CR1, shown with a zoomed in view of the control panel.

6.2.2. **Switch Off Filter Unit.** Switch off the filtration unit at the control panel by pressing the red 'STOP' button, as identified in Figure 1:

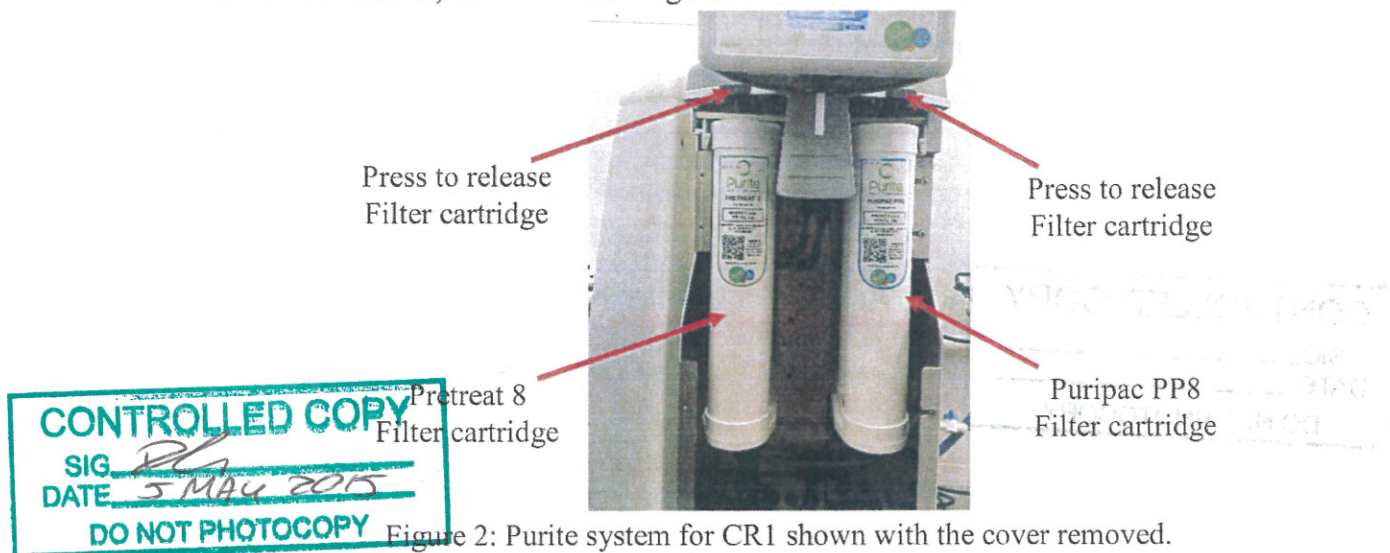


Figure 2: Purite system for CR1 shown with the cover removed.

6.2.3. **Remove Cover.** Remove the cover from the filter system, as shown in Figure 2:

6.2.4. **Remove Old Filter Cartridge.** Press down the dark coloured button above the filter requiring changing, as indicated in Figure 2: Slide the filter out of the filter system.


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Figure 3: Remove the plugs from the water connections of the filter cartridges.

- 6.2.5. **Replace Filter Cartridge.** Ensuring that the replacement filter cartridge is of the same type as one previously removed and using Figure 2: for guidance, remove the plugs from the water connections on the filter cartridge as shown in Figure 3: then slide the replacement filter cartridge into the filter system until it “clicks” into place.

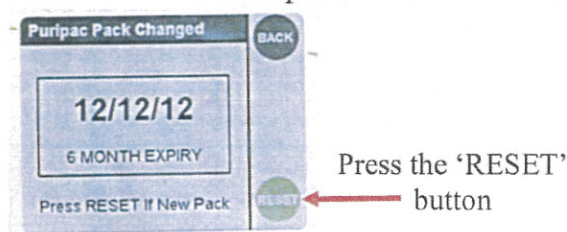


Figure 4: Control panel shown with the reset the filter cartridge life counter screen.

- 6.2.6. **Reset the Filter Cartridge Life Counter.** On the control panel screen that appears when a filter cartridge is replaced, press the ‘RESET’ button to set the date the filter cartridge is replaced on, and then confirm this by pressing the ‘Yes’ button on the screen that pops up.
- 6.2.7. **Replace Second Filter Cartridge.** Repeat steps 6.2.4 and 6.2.6 for the second filter again ensuring that the filter cartridge is replace for one of the same type as identified in Figure 2:

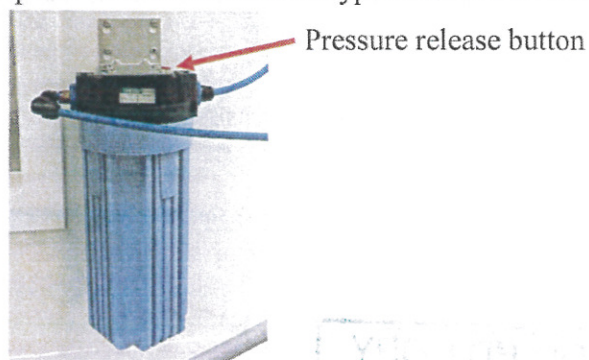
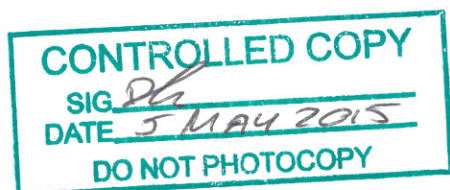



Figure 5: 25µm Filter fitted to CR1.

- 6.2.8. **Replace 25µm Filter.** Following the procedure detailed in steps 6.9.4 to 6.9.8, replace the 25µm Filter.



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Note: There Is No Way To Stop The Water Running Out Of The 25µm Filter Once The Filter Housing Is Open, So Ensure That You Have A Bucket Underneath The Filter And Have The Replacement Filter Ready Before Opening Filter Housing.

6.2.9. **Bleed Trapped Air.** Once the 25µm Filter has been replaced, press the pressure release button identified in Figure 5: to bleed any air trapped inside the filter.



Figure 6: On the control panel, press the green 'START' button to switch on the pump.

6.2.10. **Re-Start Pump.** Switch on the filtration unit at the control panel by pressing the green 'START' button, as identified in Figure 6:

6.2.11. **Check for Any Leaks.** With the pump on, check around the filter cartridges for any sign of leakage, if any leaks are found, Switch off the pump and confirm the correct installation of the filter cartridge effected.

6.2.12. **Replace the Cover.** Once it has been established that there are no leaks, then the cover can be replaced.

6.2.13. **Dispose of Old Filter Cartridges.** Dispose of the old filters and packaging from the replacement filters as general waste in accordance with procedure Correct Usage of Bins for Non-Hazardous Waste Streams (Document Number AEU00396).

6.2.14. **Continue Procedure.** Continue procedure by following instructions from step 6.11.

6.3. Purite System Filter Change For CR2.

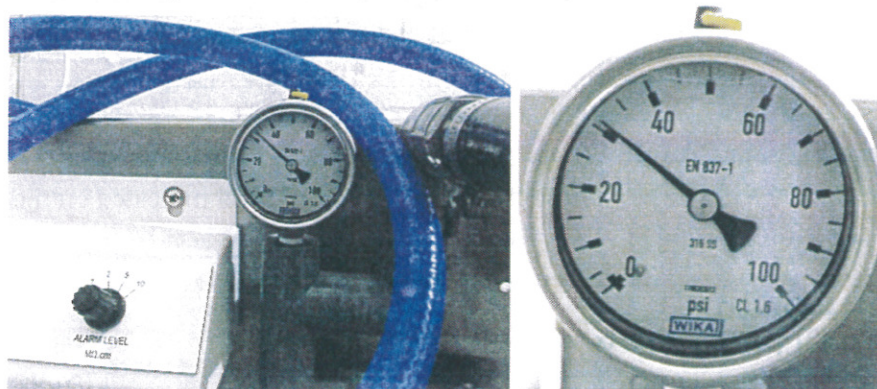



Figure 7: CC9 Filter pressure indicator, location shown in Figure 12:



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6.4. When to Change CC9 Filter. Change the CC9 cylinder filter either if the pressure measured on the pressure indicator shown in Figure 7: is above the required level or the filter cylinder has been in use for more than three months, both are indicated by the Cleanroom Activity Log (Document Number AEU00496).

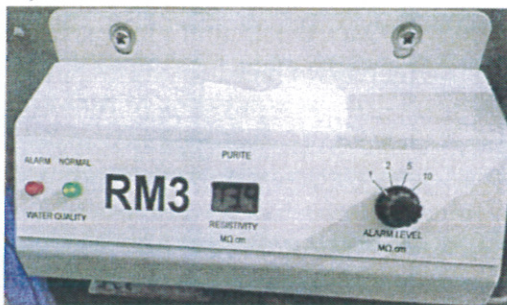


Figure 8: RM3 Resistance meter, the location is shown in Figure 12:

6.5. When to Change DC9 Filter. Change the DC9 cylinder filter only if the resistance measured on the resistance meter RM3 is below the required level, as indicated by the Cleanroom Activity Log (Document Number AEU00496).

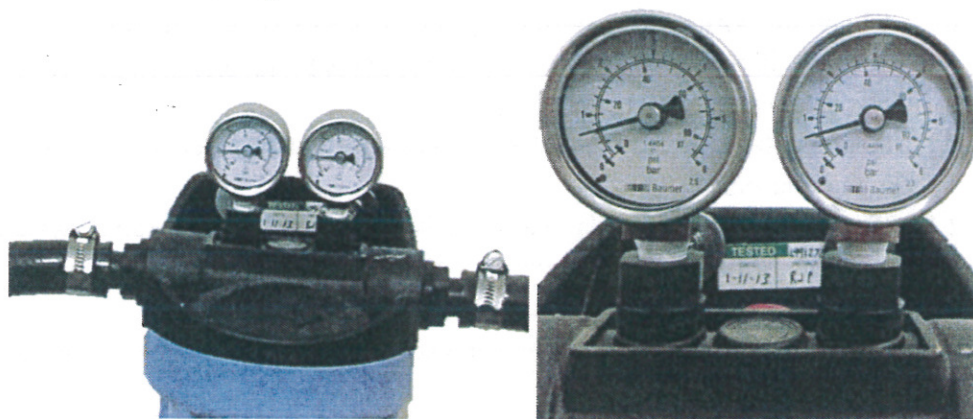



Figure 9: Pressure differential gauges for the 0.2µm filter, the location is shown in Figure 12: for 20" one fitted to filter raft and Figure 16: for the 10" one fitted outside the clean room.

6.6. When to Change 0.2µm Filter. Change the 0.2µm filter only if the pressure indicators shown in Figure 9: show a pressure difference greater than the level indicated on the Cleanroom Activity Log (Document Number AEU00496).



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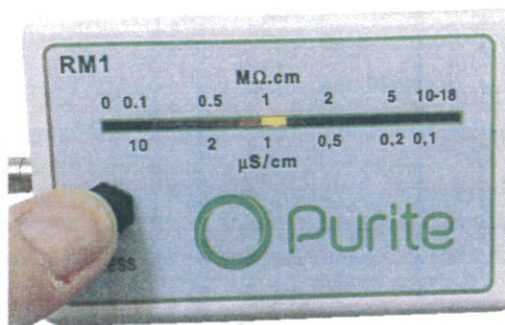


Figure 10: RM1 Resistance meter, shown during test, location is shown in Figure 16:

6.7. **When to Change the DC8 Filter.** Change the DC8 cylinder filter only if the resistance / conductance measured on the resistance meter RM1 is below the required level whilst the water is flowing, as indicated by the Cleanroom Activity Log (Document Number AEU00496).

Note: If The Resistance / Conductance Measured On The Resistance Meter RM1 When The Water Is Not Flowing It Can Give A False Low Resistance Reading.

6.8. Replace CC9 and DC9 Filter.

6.8.1. **Background Information.** The procedure to replace the CC9 and DC9 filters is the same with the exception of the requirement to flush the CC9 cylinder, the DC9 cylinder filter must not be flushed.

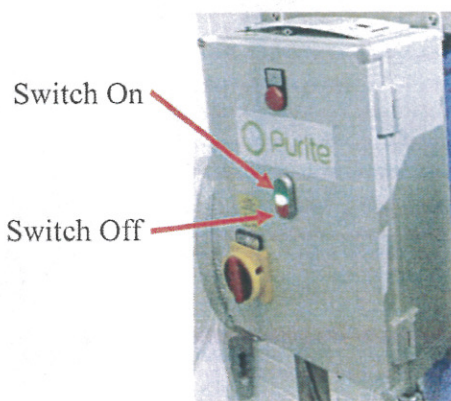



Figure 11: Filtration raft Control Panel, the location is shown in Figure 12:

6.8.2. **Switch Off Filter Unit.** Switch off the filtration raft at the control panel by pressing the red button, as identified in Figure 11:

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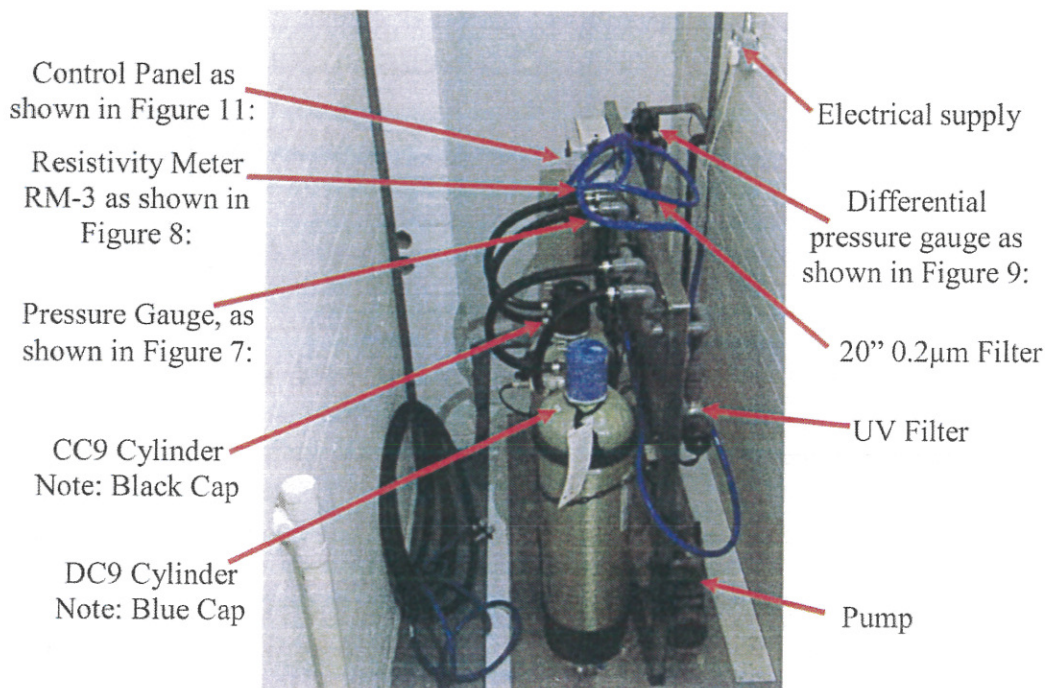


Figure 12: Location of filtration components on the filtration raft.


6.8.3. **Isolate the Electrical Supply.** Switch off and un-plug the electrical supply from the filtration raft, as identified in Figure 12:

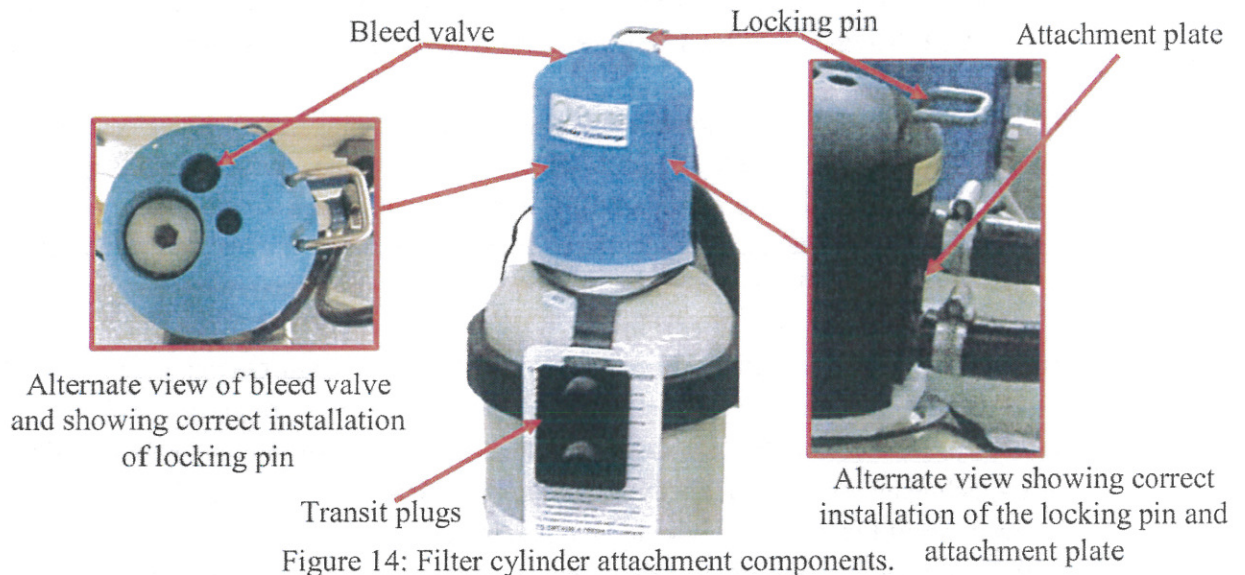


Figure 13: Location of the isolation taps.

6.8.4. **Isolate the Water.** Isolate the water supply from both sides of the filter raft, using the isolation taps shown in Figure 13:

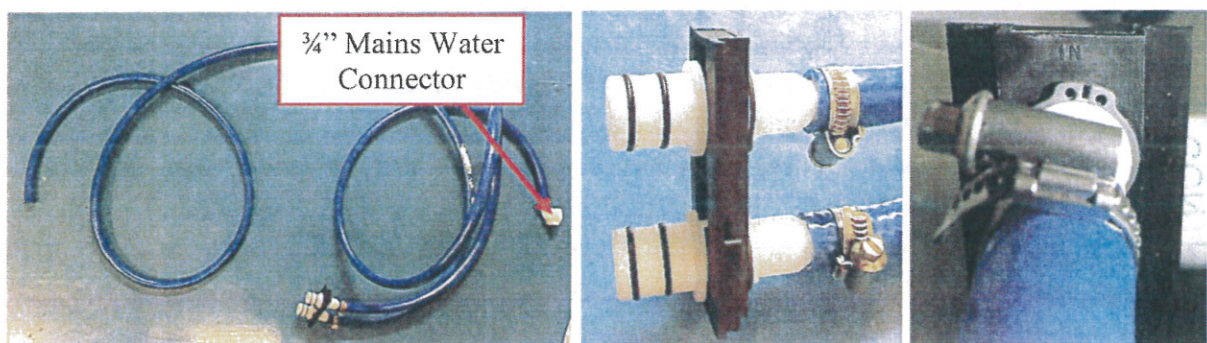


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6.8.5. Prepare CC9 Cylinder For Flushing. If replacing the CC9 cylinder the new cylinder will require flushing before fitting to the filter raft. Take the cylinder to a location that has the required $\frac{3}{4}$ " mains water connector and a drain to take the water from the cylinder. If replacing a DC9 filter cylinder go to step 6.8.8.

Note: Only the CC9 Filter Cylinder Requires Flushing, The DC9 Or DC8 Filter Cylinders Must Not Be Flushed.



6.8.6. Connect Flushing Attachment Plate to New Cylinder. Ensure that the fittings are clean, fully insert the flushing attachment plate into the cylinder ensuring that the 'IN' connector is on the top, as shown in Figure 15: and secure with the locking pin, in the orientation shown in Figure 14:

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Note: If The Locking Pin Is Placed In The Wrong Orientation The Water Will Leak Out When The Filter Is Under Pressure And The Attachment Plate May Warp.

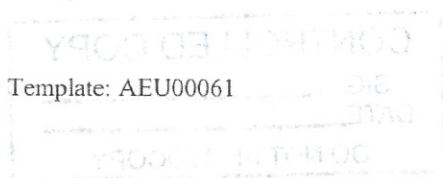
- 6.8.7. **Flush Cylinder.** Connect the inlet hose to the ¾" mains water connector, place the free end of the outlet hose into the drain, open the tap and run water through the cylinder until it runs clear, this will take approximately 10 minutes, once the water coming out of the hose is clear, turn off the tap, disconnect the inlet hose from the ¾" mains water connector, pull the locking pin from the cylinder head to enable the flushing attachment plate to be removed, take the cylinder to the filter raft.
- 6.8.8. **Depressurise the Old Cylinder.** Press the depressurisation button, as shown in Figure 14: to remove any excess pressure from inside the cylinder to be replaced on the filter raft.
- 6.8.9. **Remove Locking Pin On Old Cylinder.** After first ensuring that there is a bucket for collecting any water contained inside the pipes, remove the locking pin from the cylinder head cap of the Filter Cylinder to be replaced on the raft.
- 6.8.10. **Remove the Attachment Plate.** Once the locking pin has been pulled free from the cylinder, the attachment plate can then be removed, ensure any water from the pipework is collected in the bucket sourced in step 6.8.9.
- 6.8.11. **Remove the Old Cylinder.** Open the securing chain and then physically remove the old cylinder.


Note: A DC9 Or CC9 Cylinder Full Of Water Can Weigh Up To 50kg, It Will Require At Least Two People To Remove The Cylinder.

- 6.8.12. **Fit New Cylinder.** Take the replacement cylinder to the filter raft, locate correctly and ensure that the securing chain is replaced.
- 6.8.13. **Connect Attachment Plate to New Cylinder.** Ensure that the fittings are clean, fully insert the attachment plate into the cylinder and secure with the locking pin, in the orientation shown in Figure 14:

Note: The Attachment Plate's Colour Must Match The Cap Fitted To The Filter Cylinder's Colour.

- 6.8.14. **Reinstate Isolation Taps.** Reinstate the all isolation taps, identified in Figure 13: so that they are in line with the pipework.
- 6.8.15. **Bleed Air From Cylinder.** Press the bleed valve, identified in Figure 14: to remove any trapped air from the filter cylinder.
- 6.8.16. **Re-Connect Power Supply.** Reconnect the power supply disconnected in step 6.8.3.
- 6.8.17. **Switch On Controller.** Switch on the Control Panel by pressing the green button shown in Figure 11:



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6.8.18. Make Old Cylinder Ready to Return. Drain the water from the discarded filter cylinder into any available drain then once the filter cylinder has cooled down, if it was warm, replace the transit plugs into the connection plate fittings and take the cylinder to the appropriate place for return to the manufacture for re-cycling.

6.9. Replace 0.2 Micron Filter.



Figure 16: Location of the 0.2µm Filters and DC8 Filter.

- 6.9.1. **Switch Off Filter Unit.** If replacing the 20" 0.2µm Filter, switch off the filtration unit at the control panel by pressing the red button, as identified in Figure 11:
- 6.9.2. **Isolate the Electrical Supply.** If replacing the 20" 0.2µm Filter, switch off and un-plug the electrical supply from the filtration raft, as identified in Figure 12:
- 6.9.3. **Isolate Water Supply.** Isolate the water supply by use of the isolation taps either side of the filters, as shown in Figure 16:
- 6.9.4. **Place a Bucket Underneath Filter Housing.** Place a bucket or plastic box underneath the filter housing to collect the split water.

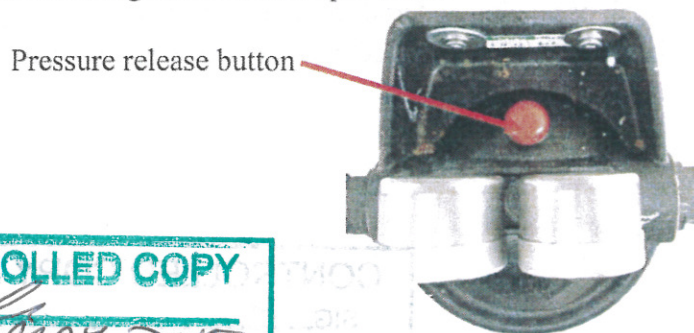



Figure 17: Pressure release button.



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6.9.5. **Remove Any Excessive Pressure.** Press the red button on the top of the filter connector to release any residue pressure.



Figure 18: Removing the filter housing.

6.9.6. **Remove Cover.** Unscrew the blue cover of the filter and remove the filter, place the old filter at a location any trapped water can drain off appropriately, as shown in Figure 19:

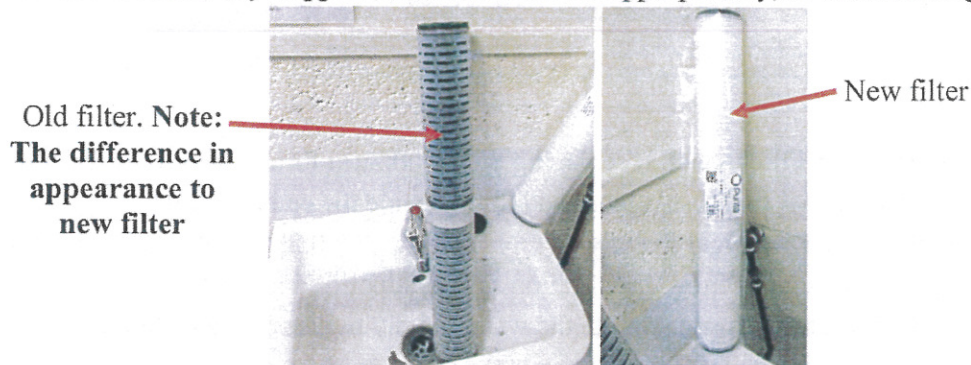
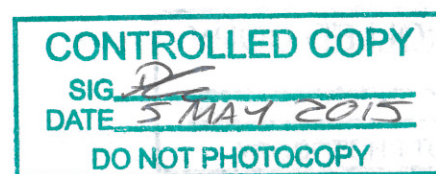

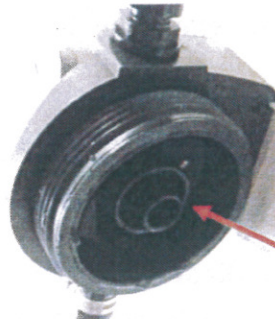
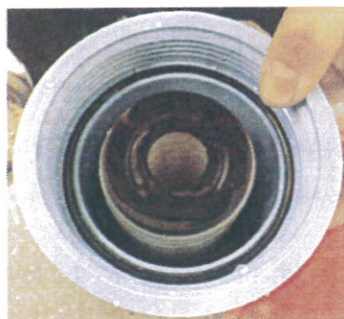


Figure 19: Old filter shown draining and new filter shown in it's packaging.

6.9.7. **Replace Filter.** Remove all packaging material from the replacement filter, place the new filter of the appropriate size into the blue coloured housing, ensuring that the filter sits on the spigot in the bottom of the housing.



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Locating spigot

Figure 20: Lining up the filter on the spigot.

- 6.9.8. **Replace the Cover.** Replace the cover ensuring that the filter correctly aligns with the spigot on the head unit and secure.
- 6.9.9. **Reinstate the Water Supply.** Reinstate the isolation taps either side the filter, as identified in Figure 16:
- 6.9.10. **Bleed Trapped Air.** Press the pressure realise button identified in Figure 17: to bleed any air trapped inside the filter.
- 6.9.11. **Re-Instate the Electrical Supply.** If replacing the 20" 0.2µm Filter, replace the plug and switch on the electrical supply from the filtration raft, as identified in Figure 12:
- 6.9.12. **Re-Start Filtration Unit.** If replacing the 20" 0.2µm Filter, switch on the filtration unit at the control panel by pressing the green button, as identified in Figure 11:
- 6.9.13. **Repeat Procedure for Second Filter, If Required.** If the pressure difference gauges indicates the other 0.2µm Filter requires replacement, repeat process from step 6.9.1.
- 6.9.14. **Dispose of Old Filter.** Dispose of the old filter and packaging from the replacement filter, as general waste in accordance with procedure Correct Usage of Bins for Non-Hazardous Waste Streams (Document Number AEU00396).


6.10. **Replace DC8 Deionisation Filter.**

Note: The DC8 Filter Cylinder Must Not Be Flushed.

- 6.10.1. **Isolate Water Supply.** Isolate the water supply by use of the isolation taps either side of the filters, as shown in Figure 16:
- 6.10.2. **Depressurise the Cylinder.** Press the depressurisation button, as shown in Figure 14: to remove any excess pressure from inside the cylinder.
- 6.10.3. **Remove Locking Pin On Old Cylinder.** After first ensuring that there is a bucket for collecting any water contained inside the pipes, remove the locking pin from the cylinder head of the Cylinder to be replaced.
- 6.10.4. **Remove the Attachment Plate.** Once the locking pin has been pulled free from the cylinder, the attachment plate can then be removed, ensure any water from the pipework is collected in the bucket sourced in step 6.10.3.

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 ADVANEX	DOC No: AEU00497	TITLE: CLEAN ROOM - PURITE SYSTEM FILTER REPLACEMENT			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎ 00 44 (0) 1636 815555 00 44 (0) 1636 817725 Bilborough Site ☎ 00 44 (0) 115 9293931 00 44 (0) 115 9295773 Video Conference IP 80 176 189 113 www.advanexeurope.co.uk general@advanexeurope.co.uk
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6.10.5. **Remove the Old Cylinder.** Open the securing chains and then physically remove the old cylinder.

Note: A DC8 Cylinder Full Of Water Can Weigh Up To 28kg, It Will Require At Least Two People To Remove The Cylinder.

6.10.6. **Fit New Cylinder.** Take the replacement cylinder to the location identified in Figure 16: position the filter cylinder correctly and ensure that the securing chains are replaced.

6.10.7. **Connect Attachment Plate to New Cylinder.** Ensure that the fittings are clean, then fully insert the attachment plate into the cylinder and secure with the locking pin, in the orientation shown in Figure 14:

6.10.8. **Reinstate Isolation Taps.** Reinstate the all isolation taps, identified in Figure 16: so that they are in line with the pipework.

6.10.9. **Bleed Air From Cylinder.** Press the bleed valve, identified in Figure 14: to remove any trapped air from the filter cylinder.

6.10.10. **Make Old Cylinder Ready to Return.** Drain the water from the discarded filter cylinder into any available drain then once the filter cylinder has cooled down, if it was warm, replace the transit plugs into the connection plate fittings and take the cylinder to the appropriate place for return to the manufacture for re-cycling.

6.11. **Task Completion.**



Figure 21: Topping up the Ultrasonic tanks.

6.11.1. **Top Up Level In Ultrasonic Tanks.** If any of the Filters on the filtration raft have been replaced, the water level in the Ultrasonic tanks inside the clean room will require checking and topping up to the required level by use of the topping up guns or bottles of sterile water as appropriate and as shown in Figure 21:

6.11.2. **Drain Any Buckets Used.** Drain the water from any buckets used into any available drain then dry the bucket using a lint free cloth.

6.11.3. **Record Tasks Completed.** Record work completed on the Cleanroom Activity Log (Document Number AEU00496).

