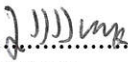
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	Revision.	Date	Supersedes	Page	
	01	06/Mar/2015	N/A	1 of 6	

## DOCUMENT APPROVAL

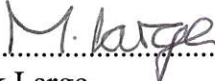
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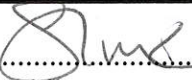
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<b>Signature</b>		<b>Date</b>	06-MAR-15
<b>Print Name</b>	James Drury		
<b>Title</b>	Production Engineer		

### Reviewer's Signature:

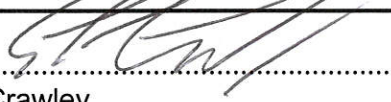
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<b>Print Name</b>	Mark Large		
<b>Title</b>	Team Leader AEUB		

<b>Signature</b>		<b>Date</b>	06 <sup>th</sup> MAR 15
<b>Print Name</b>	Scott Franklin		
<b>Title</b>	Operations Manager AEUB		

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<b>Signature</b>		<b>Date</b>	08 Mar 2015
<b>Print Name</b>	Gary Crawley		
<b>Title</b>	Quality Manager		

	DOC No: AEU00507	TITLE: CLEAN ROOM HEPA FILTER REPLACEMENT			<b>Advanex Europe Ltd</b> 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
	Revision.	Date	Supersedes	Page	
	02		Iss.01/ 01/Jan/20	2 of 6	

## 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 clean room working areas are used and maintained in a controlled and consistent manner to assure compliance with ISO 14644 for the required class of operation.

## 2.0 SCOPE

- 2.1. The scope of this documents covers the methods replacing the HEPA filter to help maintain the validated status of the clean room (CR2) at Advanex Europe Ltd.

## 3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. ISO 14644 – The International Standard Organisation Specification for clean rooms.
- 3.2. Class of Operation – The required standard of clean room based upon the particulates sizes and concentration levels measured in the clean room.
- 3.3. H-VAC – Heating – Ventilation and Air Conditioning, the equipment used to determine the air quality in the plenum.
- 3.4. HEPA - High-Efficiency Particulate Air, the type of filter used to clean air entering the clean room from the plenum.
- 3.5. CR1 - Clean Room 1, the Upstairs clean room.
- 3.6. CR2 - Clean Room 2, the new Downstairs clean room.

## 4.0 HEALTH, SAFETY & ENVIRONMENTAL


- 4.1. Within the factory area safety footwear is mandatory.

## 5.0 ASSOCIATED DOCUMENTS

- 5.1. Cleanroom Testing Procedure (Document Number AEU00505).
- 5.2. Full Clean Down (Document Number AEU00500).
- 5.3. Plenum Clean and H-VAC Filter Check (Document Number AEU00501).

## 6.0 PROCEDURE



	DOC No: AEU00507		TITLE: CLEAN ROOM HEPA FILTER REPLACEMENT		<b>Advantex Europe Ltd</b> 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.advantexeurope.co.uk general@advantexeurope.co.uk
	Revision.	Date	Supersedes	Page	
	02		Iss.01/ 01/Jan/20	3 of 6	

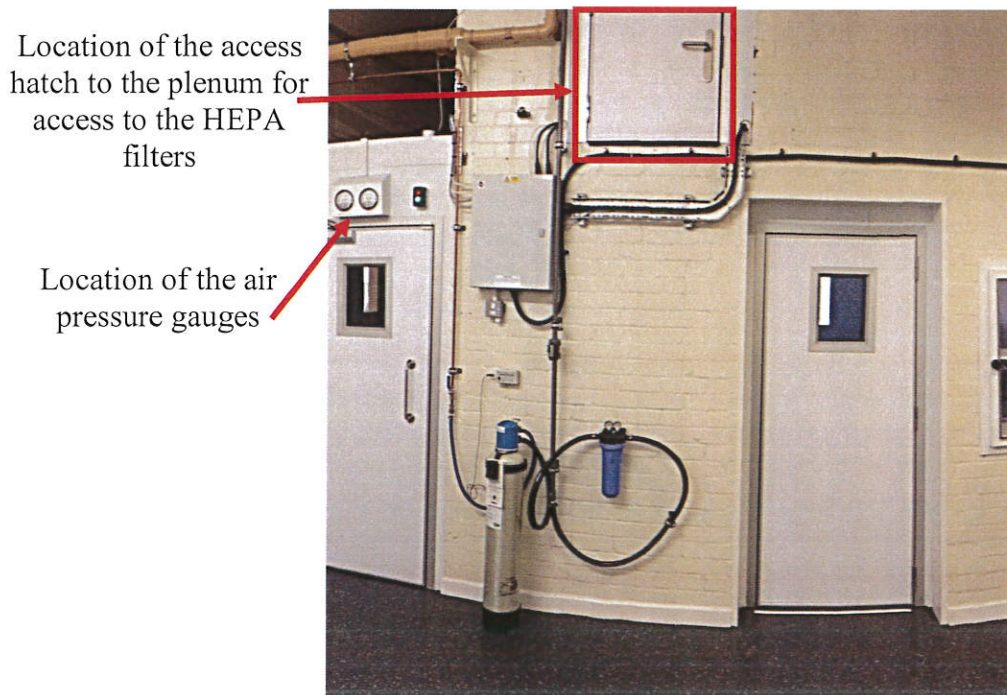


Figure 1: Location of the access to the plenum.

## 6.1. General Instructions.

6.1.1. The adjustment of the fan speeds will effect the pressure difference between the clean room, the gowning room and the ambient air pressure measured on the mezzanine, this is displayed on the air pressure gauges shown in Figure 1: the gauges must show the change room pressure with a minimum level of 5Pa (target 10Pa) and the clean room with a pressure difference to the change room of more than 5Pa. The pressure difference between the clean room and the change room is adjusted by use of the louvers in the door between the two rooms.

## 6.2. Procedure.

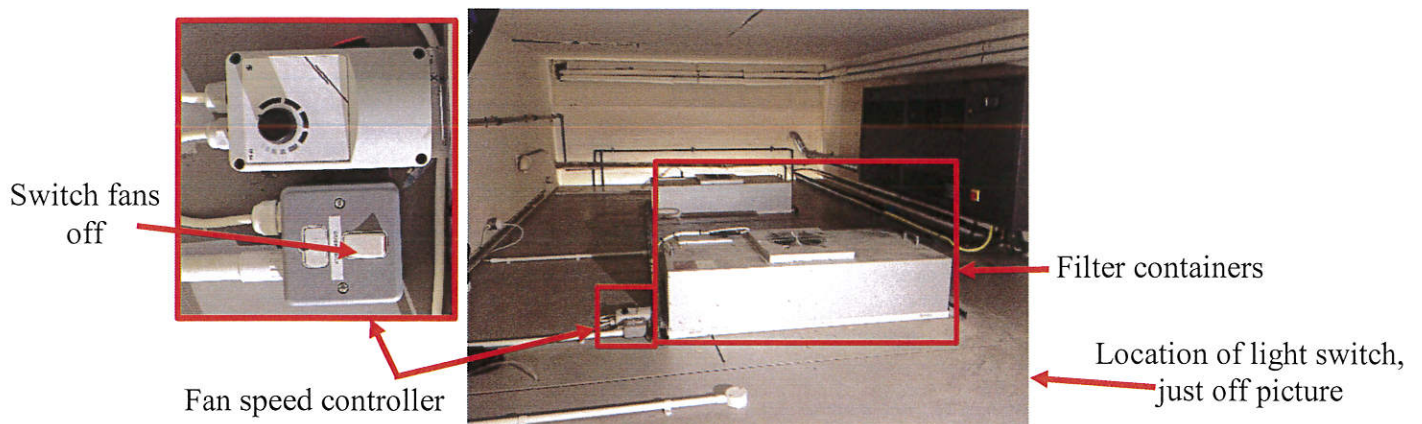



Figure 2: Location of equipment inside the plenum, with a zoomed in view of the Fan Controls.

6.2.1. **Open the Access Hatch.** Open the access hatch, as shown in Figure 1:

 <b>ADVANEX</b>	DOC No: AEU00507	TITLE: <b>CLEAN ROOM HEPA FILTER REPLACEMENT</b>			<b>Advanex Europe Ltd</b> 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
	Revision.	Date	Supersedes	Page	
	02		Iss.01/ 01/Jan/20	4 of 6	

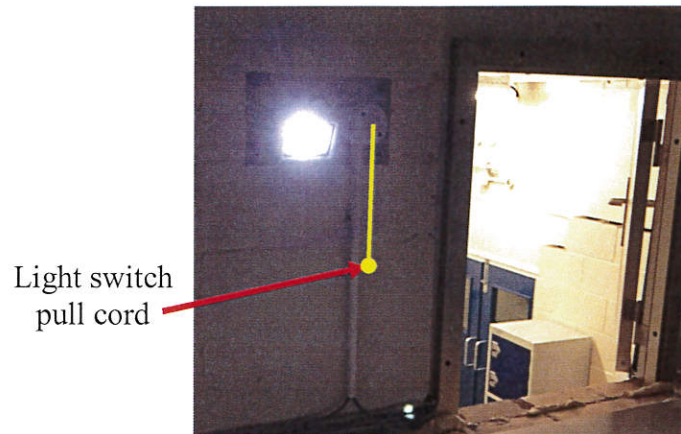


Figure 3: Location of light switch, as seen from inside the plenum, shown with an enhanced pull cord.

- 6.2.2. **Switch Light On.** Use the pull cord shown in Figure 3: to switch on the light inside the plenum.
- 6.2.3. **Enter The Plenum.** Carefully enter the plenum taking the new filters and bags for the old filters along with tape into the plenum at the same time.
- 6.2.4. **Switch the Fans Off.** Using the control switch shown in Figure 2: switch the fans off.

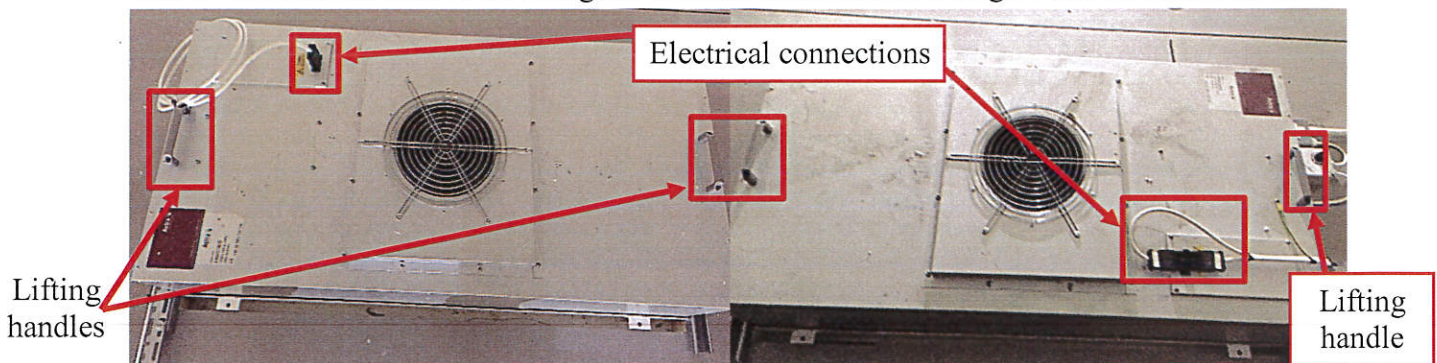


Figure 4: Fan housing equipment.


- 6.2.5. **Disconnect the Electrical Connections.** Unplug the electrical connection from the fan housings.

**Note: The Electrical Connections Have Been Designed To Limit The Possibility Of Being Reconnected In The Wrong Orientation.**

- 6.2.6. **Open the Filter Housing.** Lift off the filter housing and place on the plenum floor next to the filter housings normal location.

**Note: This Is A Two Person Lift Due To Access Limitations.**



	DOC No: AEU00507		TITLE: CLEAN ROOM HEPA FILTER REPLACEMENT		<b>Advanex Europe Ltd</b> 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
	Revision.	Date	Supersedes	Page	
	02		Iss.01/ 01/Jan/20	5 of 6	

6.2.7. **Clean the Filter Housing.** With the filter housing removed it is to be cleaned with a lint free cloth.

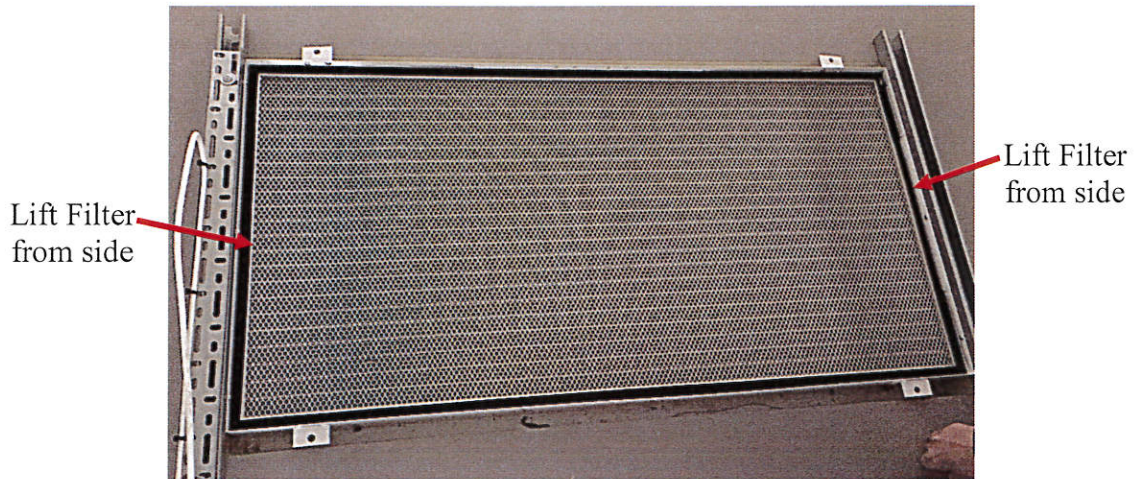


Figure 5: Fan cover removed showing filter exposed.

6.2.8. **Remove And Bag the Old Filters.** With the filter housing removed the old filter can be lifted out, this is to be done by two people from the shorter sides, once the filter is free from the locating recess it is to be placed into a bag and sealed with tape before being removed from the plenum.

**Note: It Takes Two People To Lift The Filters And Remove Or Install Them Due To The Requirement That The Filters Are Lifted Vertically Up.**

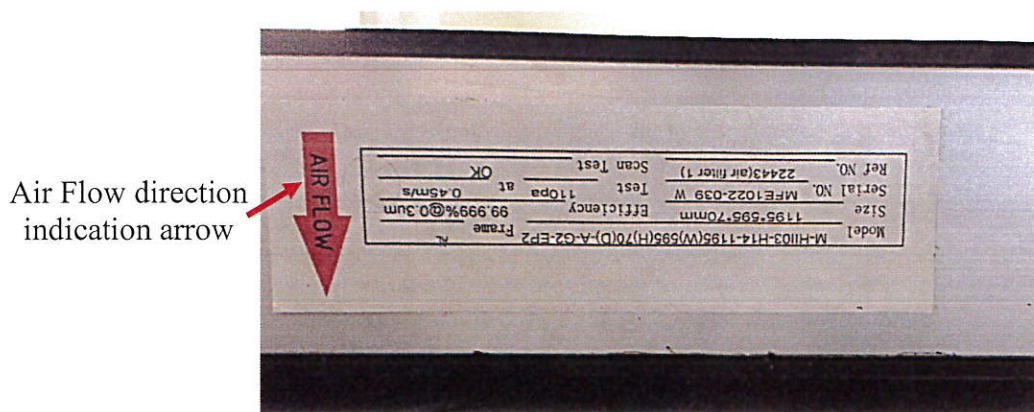


Figure 6: An example of the label on the HEPA filter showing the air flow direction arrow.

6.2.9. **Fit the Replacement Filter.** Unpack and fit the replacement filter ensuring that the replacement filter is fitted with the air flow indication arrow pointing into the clean room, as shown in the example in Figure 6:

6.2.10. **Replace the Filter Housing Over the Filter.** Replace the filter housing in a reverse of the process used in step 6.2.6

	DOC No: AEU00507	TITLE: CLEAN ROOM HEPA FILTER REPLACEMENT			<b>Advanex Europe Ltd</b> 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
	Revision.	Date	Supersedes	Page	
	02		Iss.01/ 01/Jan/20	6 of 6	

**Note: This Is A Two Person Lift Due To Access Limitations.**

6.2.11. **Reconnect the Electrical Connections.** Reconnect the electrical connections removed in step 6.2.5.

6.2.12. **Repeat For Second Filter.** Repeat procedure from step 6.2.5 for the second filter container.

6.2.13. **Switch the Fans Back On.** Using the switch shown in Figure 2: switch the fans back on.

### 6.3. Task Completion.

6.3.1. **Remove All Waste and Equipment from Plenum.** Once all tasks have been completed remove all waste items and equipment from the plenum.

6.3.2. **Clean the Plenum.** Clean the plenum as described in the relevant steps in the procedure Plenum Clean and H-VAC Filter Check (Document Number AEU00501).

6.3.3. **Leave the Plenum.** Upon leaving the plenum, switch the light off and close the plenum access hatch.

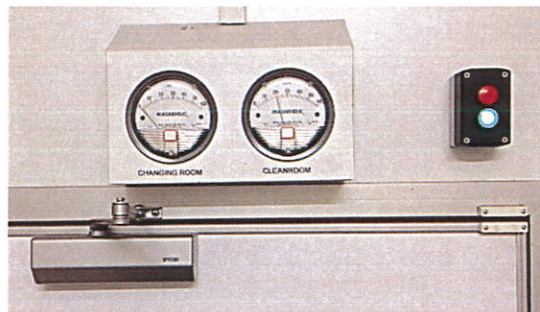


Figure 7: The air pressures gauges.

6.3.4. **Monitor the Air Pressures.** After 10 minutes to allow for settling time, monitor the air pressures inside the clean room and the changing room, these may require adjusting, this is done by use of the fan speed controller shown in Figure 2: or as described in step 6.1.1.

6.3.5. **Full Clean Down Of Clean Room.** A Full clean down of the clean room will be required as described in procedure Full Clean Down (Document Number AEU00500).