Operational and Cleanliness verification of a Lonestar® 3.0 with ATLAS™ Sampling Module 2.x

Issue/Version	Date	Author	Details
AAA	20/11/2015	Céline Lainé	New document
AAB	05/01/2016	Andrew Pauza	Edited with comments - to tie in with OQ procedure etc
AAC	23/02/2016	Céline Lainé	Updated
AAD	27/04/2016	Andrew Pauza	Tidy up formatting, correct some typos.
AAE	28/04/2016	Céline Lainé	Tidy up final graphic and condense 15 pages to 13 pages
001	28/4/2016	Andrew Pauza	Final version

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Notices

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The supplied system is in compliance with international regulations. If this system is used in a manner not specified by Owlstone Ltd, the protection provided by the system could be impaired

Warning Labels

This symbol is used to highlight a section explaining particularly important safety considerations

This warning label indicates danger of electrical shock hazard

This warning label indicates parts of the product that will become hot during use. Please take care.

Introduction

This document details the steps to capture a Lonestar® system blank using a positive pressure supply after the installation and initial operation of the Lonestar® and ATLAS™ Sampling Module. This process will demonstrate that the installed system performs as intended in the anticipated operating range.

Instructions detailed below are divided in three main parts:

- **PART 1 – On-site generation of the Lonestar® cleanliness matrices**

The step-by-step instructions allow the generation of a Lonestar® system cleanliness check by collecting three matrices after on-site installation.

- **PART 2 - Online review of the Lonestar® cleanliness matrices**

Using the online Lonestar® software, a review of the cleanliness check data that has been generated allows us to determine the general cleanliness state of the system.

- **PART 3 - Offline matrices comparison between on-site and Owlstone® FAT cleanliness checks**

The final cleanliness check allows us to confirm the system operates as it did during the Final Acceptance Tests at Owlstone before delivery. To do this we make an overlay of data using the Owlstone® offline DF Review software to compare the on-site cleanliness check with a cleanliness check done during the FAT.

For further details on how to install the Lonestar® system and proceed with initial operation, please consult the following documentation:

CC-900550-PR – Installation of a Lonestar 3.0 with an ATLAS 2.x

CC-900576-PR – Initial operation of a Lonestar 3.0 with an ATLAS 2.x

Set up and Components

Please ensure that you are familiar with the hardware naming before generating the system blank.

Figure 1 shows the final setup of the Lonestar® when used with an ATLAS™ sampling system.

Figure 2 details the Sampling Module Assembly part of the ATLAS™.

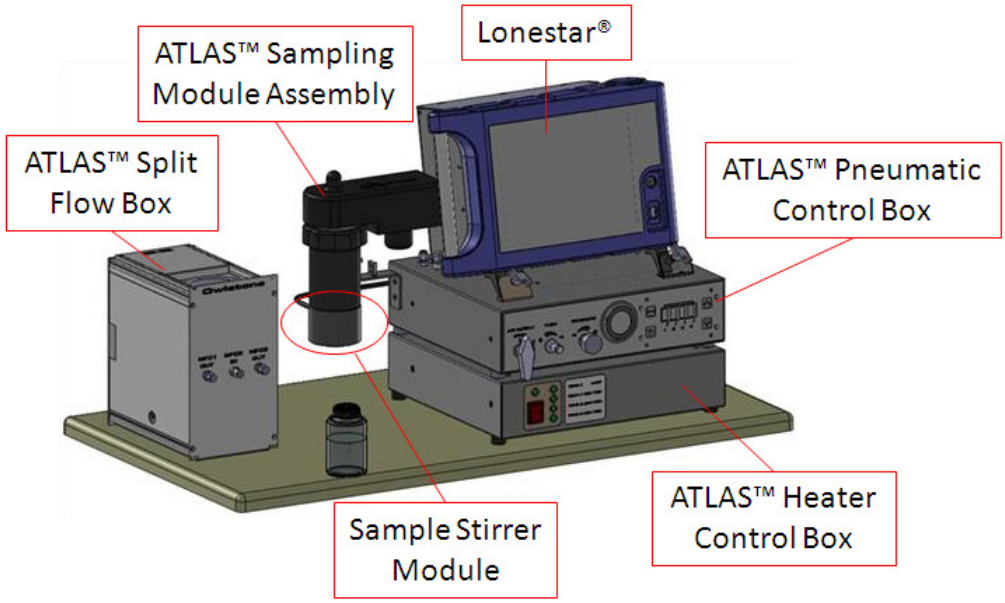


Figure 1 Lonestar® ATLAS™ Split Flow Box installation

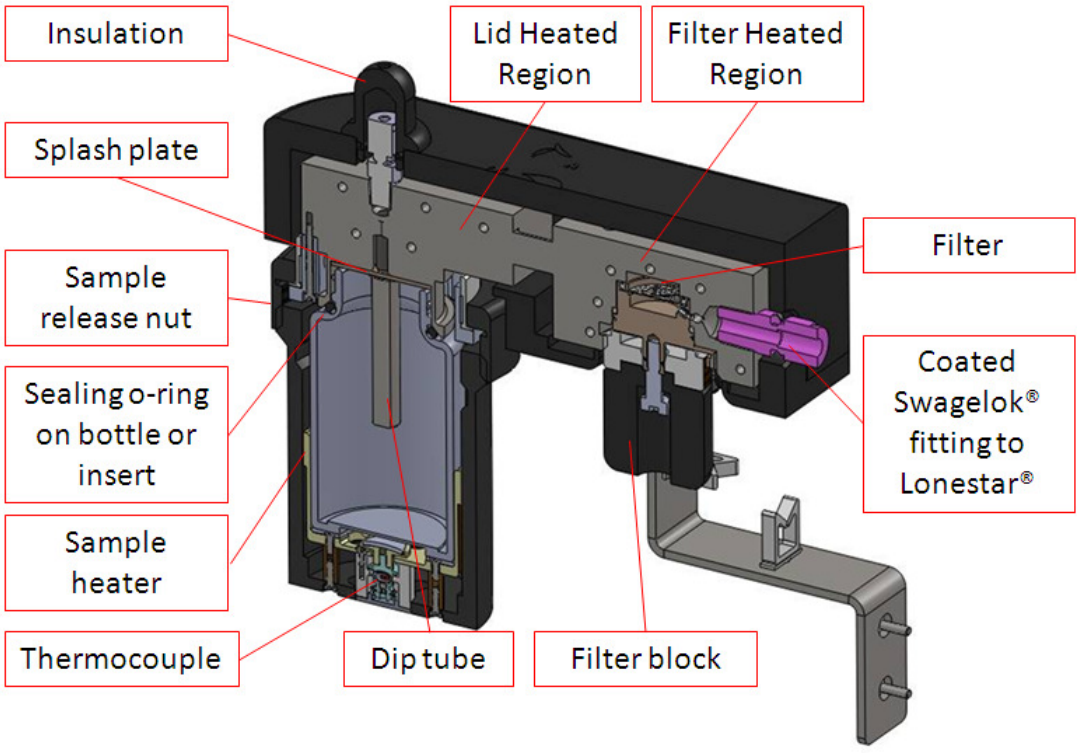


Figure 2 Diagram of components of the ATLAS™ Sampling Module Assembly

Instructions

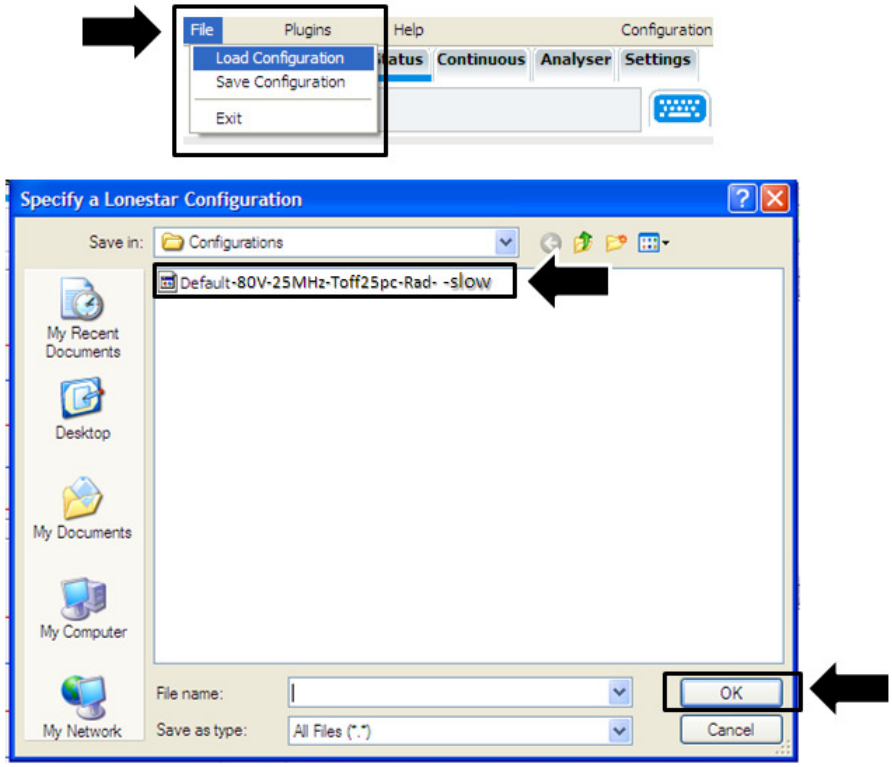
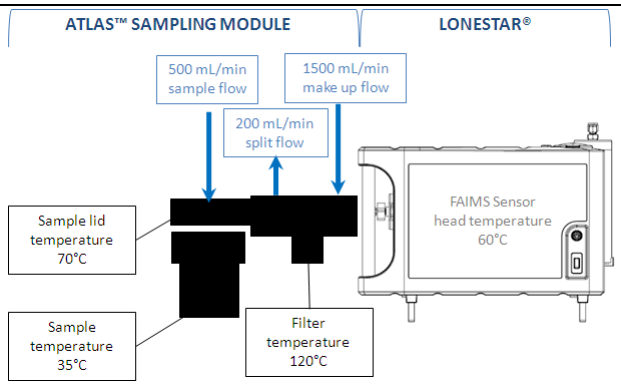
Once the Lonestar® and ATLAS™ system is fully installed and has passed the initial operation, please follow the instructions detailed in the table below to qualify the system operation and cleanliness.

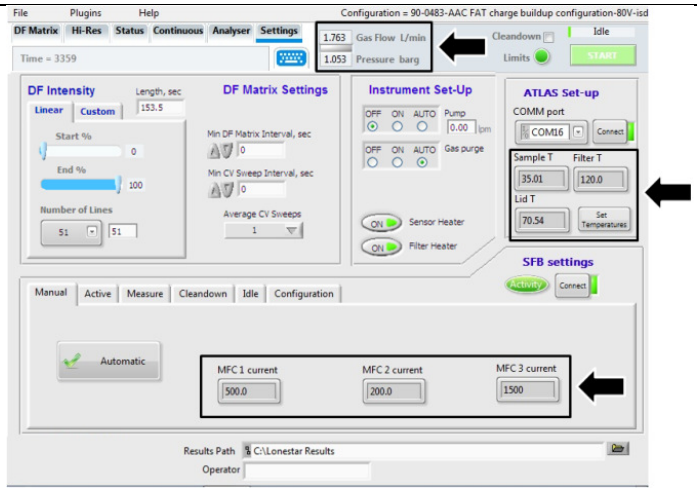
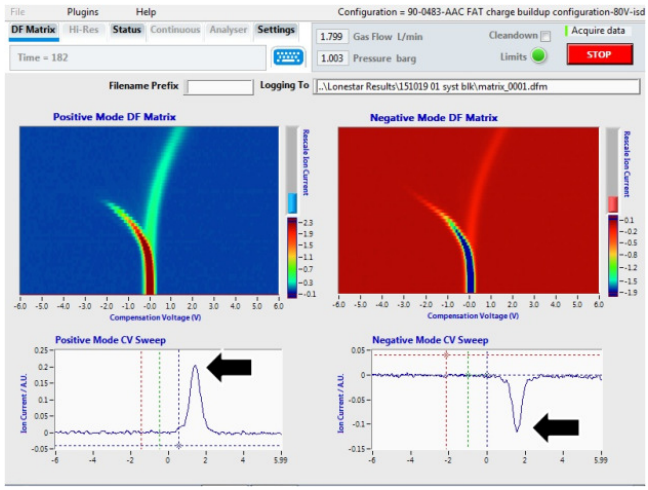
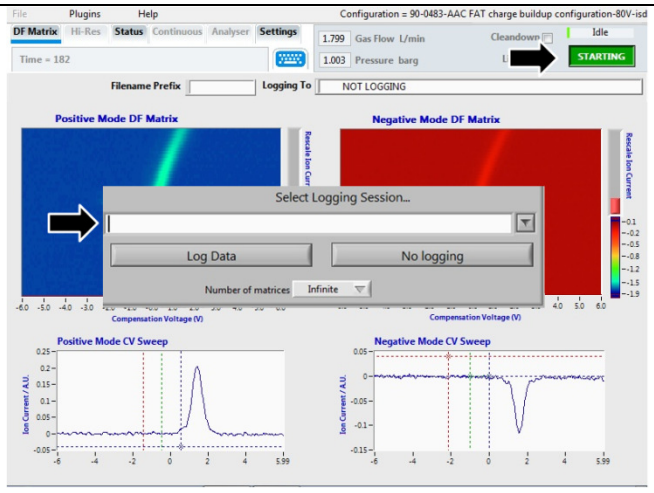
Instructions are divided in three main parts:

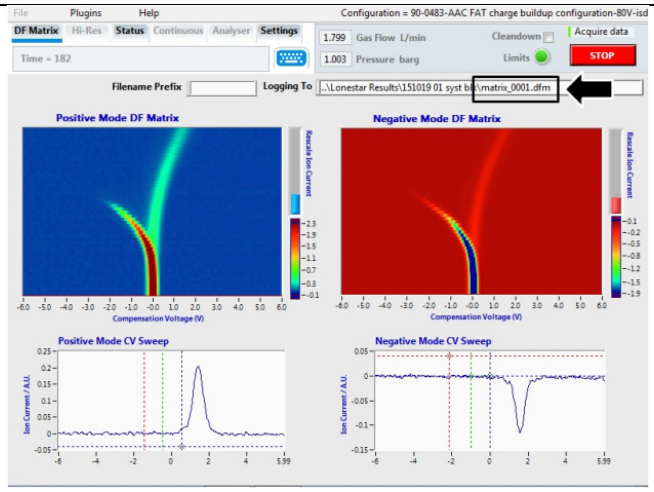
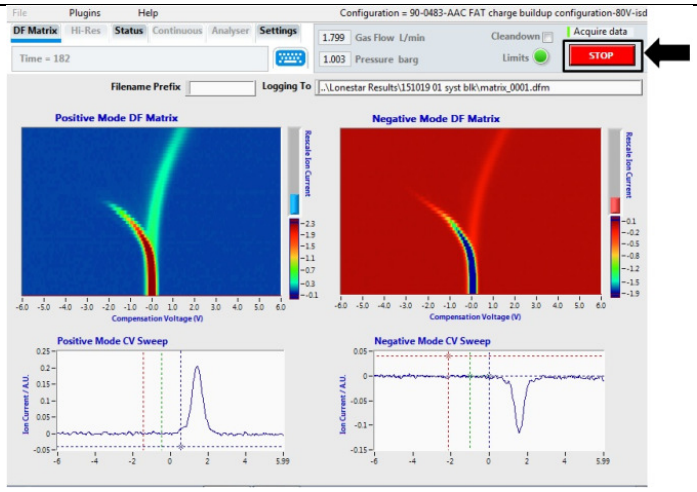
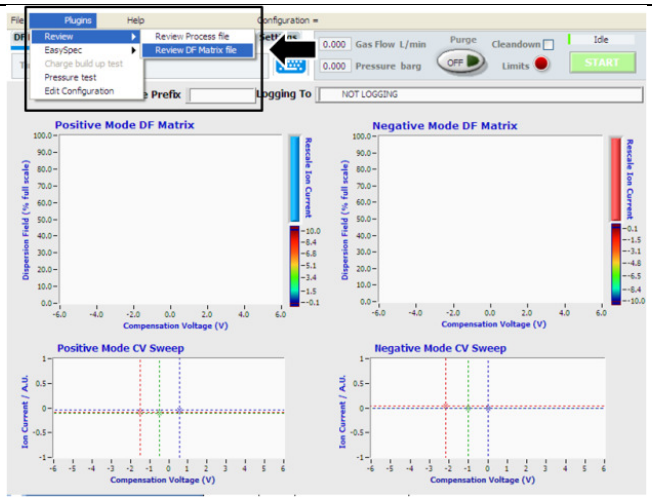
PART 1 – On-site generation of the Lonestar® cleanliness matrices.

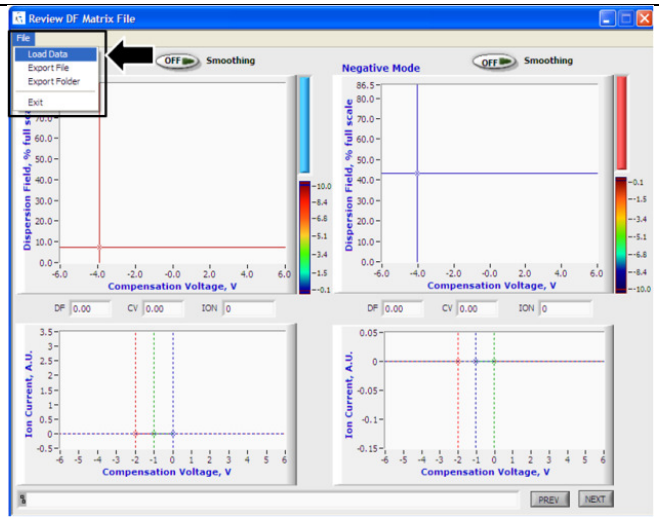
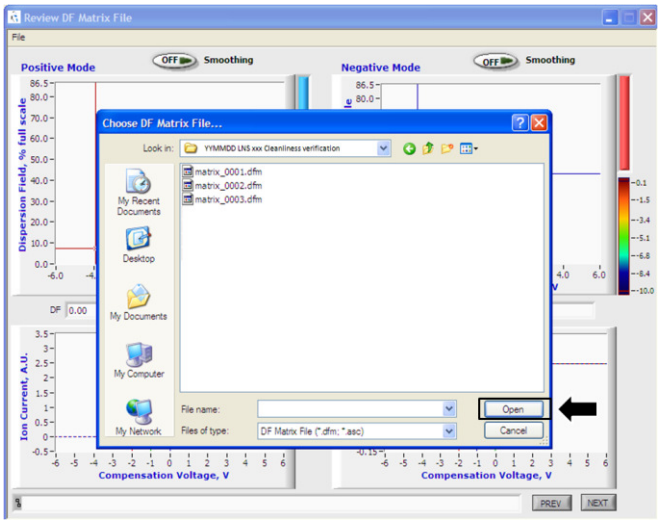
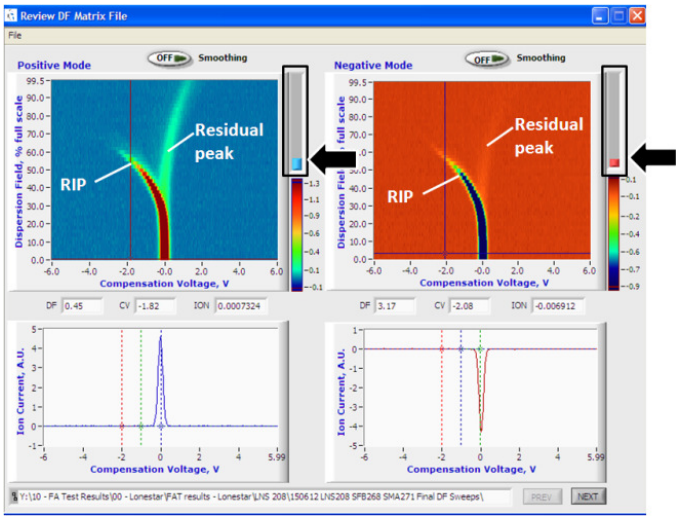
PART 2 - Online review of the Lonestar® cleanliness matrices.

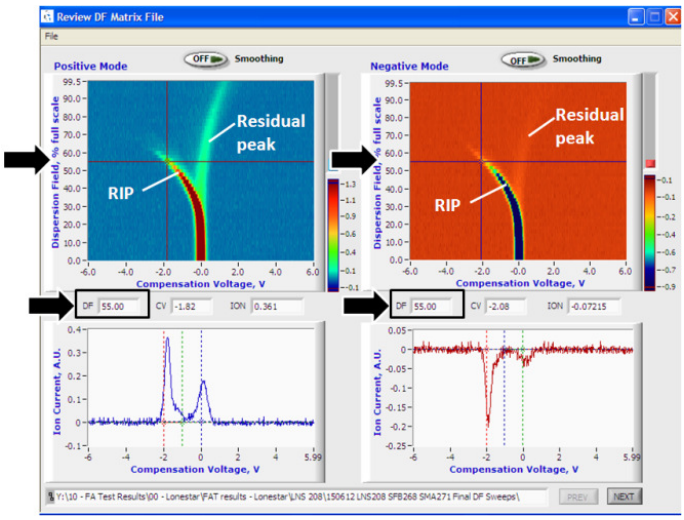
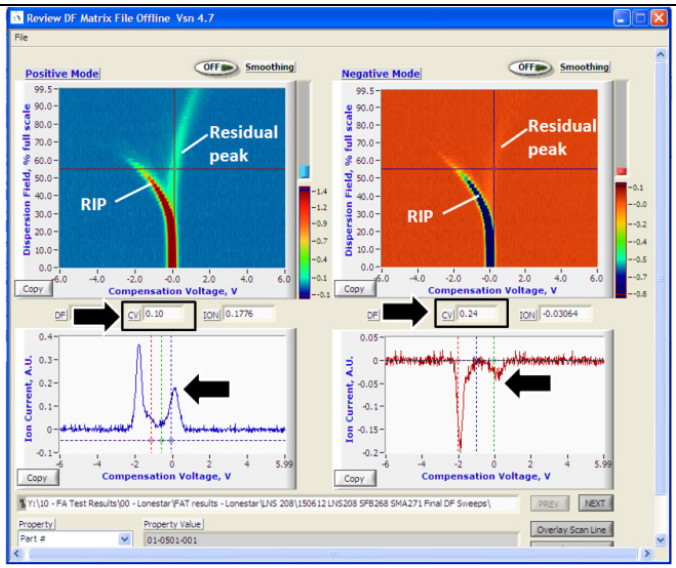
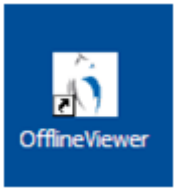
PART 3 - Offline matrices comparison between on-site and Owlstone® FAT cleanliness checks.

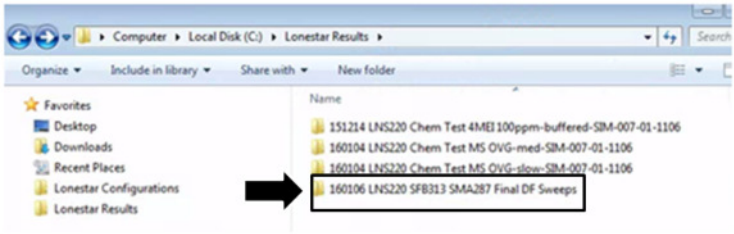
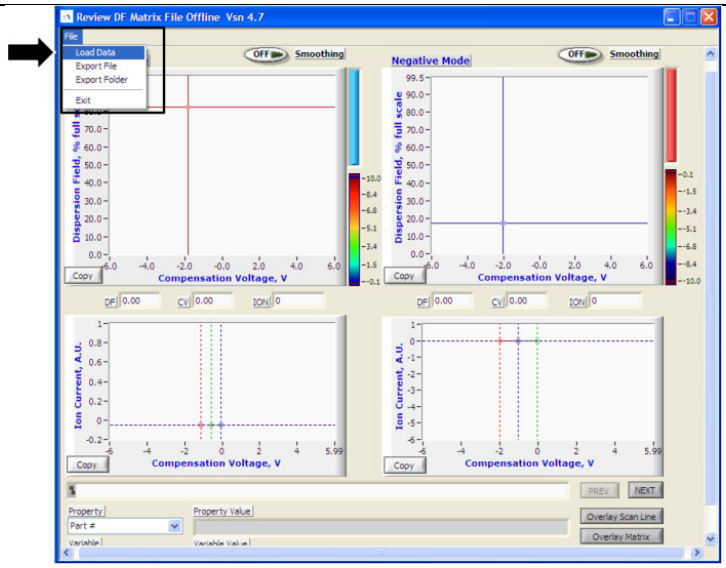
Step #	Instructions	Pictures
PART 1 – On-site generation of the Lonestar® cleanliness matrices		
1	Load the configuration saved by Owlstone® FAT Department before delivering the Lonestar® system: In the top task bar of the Lonestar® software, select File/Load Configuration. This opens a separate window named **Specify a Lonestar® Configuration**. Select the **Default-80V-25MHz-Toff25pc-Rad- -slow** configuration saved on the Lonestar® disk and press OK.	
2	The selected configuration sets flows and temperatures of the Lonestar ®system as summarised in the diagram on the right.	

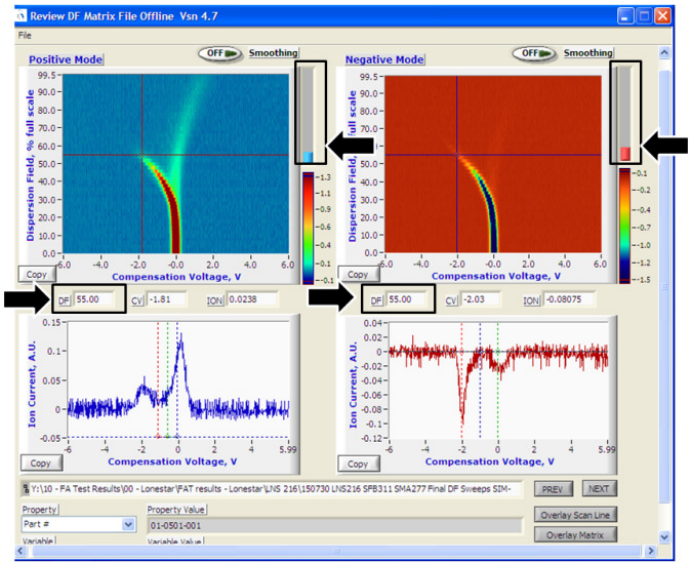
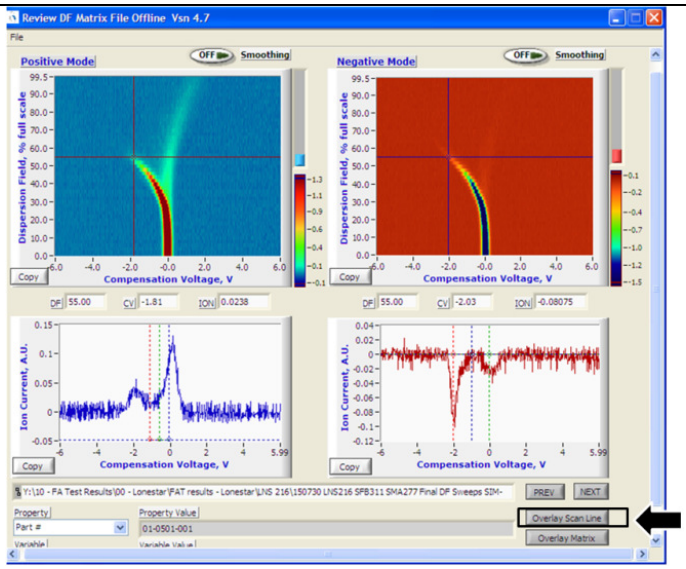
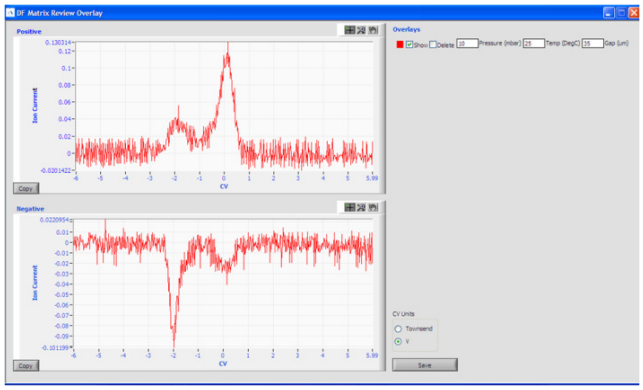
3	To verify that the Lonestar® system responds to the selected configuration, check that the flows and temperatures stabilise at the values specified by the software configuration.	
4	After the flows have been off briefly, wait about 15-30 minutes for the Lonestar® system to clean down again. A clean Lonestar® system shows positive (blue) and negative (red) modes background with a right hand side residual ion current below 0.2 A.U. at DF 55 %.	
5	Record the Lonestar® cleanliness check to validate the system installation and operational conditions. To do so, press **START**. This opens a separated window named **Select Logging Session**. Type a filename and use the **Log Data** button to start the record.	 *Note : Please choose a filename specifying the date and Lonestar® serial number following this kind of format:* ***YYMMDD LNS xxx Cleanliness verification***

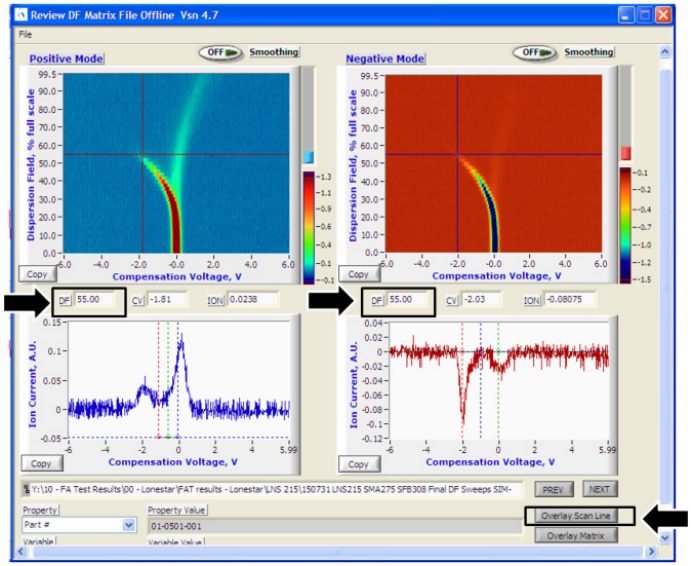
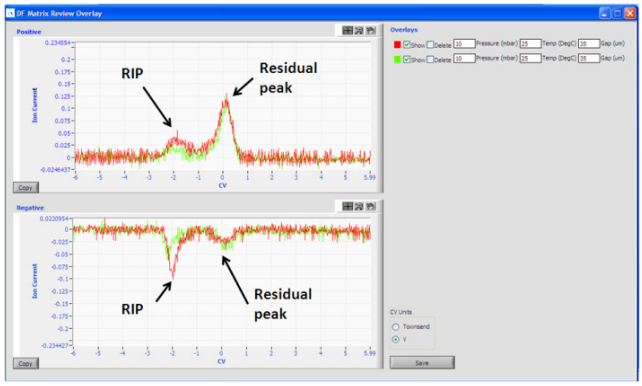
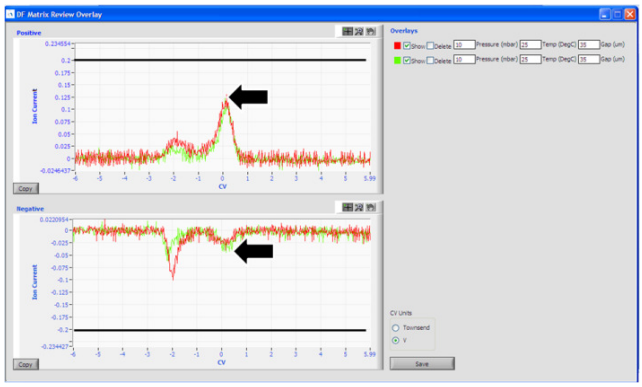
6	Leave the Lonestar® system running for three matrices. The matrix number is automatically incremented at the end of the filename while the Lonestar® system is running.	
7	After saving three matrices press **STOP** to stop the cleanliness verification record.	
PART 2 – On-line review of the Lonestar® cleanliness matrices		
8	To review the cleanliness check record, select Plugins / Review / Review DF Matrix in the Lonestar® software.	

9	A new window called **Review DF Matrix File** opens on the screen. Select File / Load data.	
10	In the window called **Choose DF Matrix File…**, follow the path below to access to the Lonestar® cleanliness check that has been saved on the disk: C:/Lonestar Results/ YYMMDD LNS xxx Cleanliness verification/matrix 3 Select the file named matrix_003.dfm and press **Open**.	
11	The Lonestar® cleanliness verification matrix appears on the Review DF Matrix File screen. To observe all peaks, lower the contrast bars on the right-hand side of the positive mode and negative mode detection window.	

12	To pass the cleanliness check, the residual peak ion current has to be below 0.2 A.U. at 55 % Dispersion Field (DF). To read the residual peak value, type 55 in the DF box. This moves the cross of the positive and negative mode detection screens to DF 55 %.	
13	Read the ion current value at 0.1 V compensation voltage (CV) in the positive mode and 0.24 V in the negative mode. The residual peak value has to be equal or below 0.2 A.U. at DF 55 % to pass the cleanliness check.	
PART 3 – Offline matrices comparison between on-site cleanliness check and Owlstone® FAT cleanliness check		
14	The data comparison consists with a data overlay that will be realised by using the **Offline Viewer** Lonestar® software. This piece of software can be downloaded from the Owlstone®	

	website to the user's computer.	Link to Owlstone® website: http://support.owlstonenanotech.com/categories/6685-Lonestar-and-FAIMS-PAD
15	Copy both data folders from the Lonestar® disk to the user's computer: the cleanliness check folder that has just been generated and the Owlstone® FAT cleanliness check folder. The Owlstone® FAT cleanliness check is located in the Lonestar® Results folder and is called something similar to "YYMMDD LNSxxx SFByyy SMAzzz Final DF Sweeps".	 *Please note that data can be moved from the Lonestar® to the user's computer using an external USB disk or the on-site network.*
16	On the user's computer, open the **Offline Viewer**. In the **Review DF Matrix File Offline** window, load the on-site cleanliness check data by selecting File / Load data.	

17	The on-site cleanliness check matrix appears on the screen. To observe all peaks, lower the contrast bars on the right-hand side of the positive and negative mode detection windows. To display ion currents at 55 % DF type 55 in the DF box.	
18	To begin the data overlay, open the overlay window by pressing **Overlay Scan Line** located in the right bottom corner.	
19	A separated window called **DF Matrix Review Overlay** opens. It shows the compensation voltage (X axis) and ion current (Y axis) at the selected 55 % DF.	

20	To complete the overlay, come back to the **Review DF Matrix File Offline** window. Load the Owlstone® FAT cleanliness check matrix called YYMMDD LNSxxx SFByyy SMAzzz Final DF Sweeps by selecting File / Load matrix. Make sure the DF value remains at 55 % and press **Overlay Scan Line.**	
21	The Owlstone® FAT cleanliness check matrix (green) is now overlaid to the on-site cleanliness check matrix (red). Both positive (top) and negative (bottom) modes show the RIP at CV -2 V and the residual peak at CV 0 V.	
22	To validate the cleanliness check: -both cleanliness check matrices should overlay and -the residual peak ion current at CV 0 V should read 0.2 A.U. or below.	

✓ Cleanliness check passed	✘ Cleanliness check NOT passed
• Overlay validated • Lonestar® system installation okay • Operating conditions okay  Lonestar® ready	• Overlay not validated • Leave the Lonestar® system cleaning for two more hours and perform another overlay check • Consult the troubleshooting guide on the Owlstone® website: http://support.owlstonenanotech.com/forums/300976-6-Troubleshooting-Guides-and-Maintenance • Send a request to Owlstone® support: http://support.owlstonenanotech.com/anonymous_requests/new

About Owlstone®

Owlstone® develops and commercializes innovative new technologies to address the critical need for compact, dependable and cost-effective chemical and biological detection solutions for a wide range of markets.

Owlstone® was formed through the recognition of the opportunities created by the application of micro- and nano- technology to develop improved sensing solutions.

Owlstone® is focused on the innovation of detection technologies to address unmet needs, developing solutions that are flexible enough to target a range of markets with the potential for growth by enabling new application opportunities.

From homeland security to home safety, Owlstone® is working with leading manufacturers and integrators across a range of markets to develop products incorporating our microchip chemical sensing solution.

Owlstone® is headquartered in the United States and has laboratory facilities in the United Kingdom. Owlstone® Ltd was founded in 2003 with a seed investment of two million dollars from Advance Nanotech, Inc., a New York based company specializing in the investment in and commercialization of nanotechnologies.