Title	Date	Author	Approval	Version	Revision	Company
Automated Pre-clean Machine Validation	6th Sept1202 5	Chris Helson	David Ralston	TA 2.1	1.5	Tiny Air Limited

X = Required

0= Not required

IQ= Installation Qualification - OQ= Operational Qualification - PQ = Performance Qualification

Brief Description of test	*Detail Test Ref*	*Factory Internal New*	*IQ Installation CPD or AED*	*Weekly CPD or AED*	*3 Month CPD or AED*	*12 month at Service*	*AUTO*
Device Operation							
Automatic Control test OQ	1.0	x	x	x	x	x	x
Cleaning Efficacy	2.0						
Residual protein Test PQ	2.1	x	0	x	x	x	0
Review of rewash results PQ	2.2	0	0	0	x	x	0
Thermometric	3.0						
Thermal Disinfection							
Chamber walls OQ	3.1	X	0	0	0	x	0
Integrated Thermocouples OQ	3.2	x	0	0	x	x	x
Over temperature cut out OQ	3.3	x	0	0	x	x	x
Water Temperature/ time	3.4	x	x	x	x	x	x
Fluid Emission	4.0						
Wash Cabinet Leaks OQ	4.1	x	x	x	x	x	x

Aerosol Elimination OQ	4.2	x	x	x	x	x	x
Brief Description of test	*Detail Test Ref*	*Factory Internal New*	*IQ Installation CPD*	*Weekly CPD*	*3 Month CPD*	*12 Month at AEDService*	*AUTO*
Wash Cabinet	5.0						
Doors Opening Closing	5.1	x	x	x	x	x	x
Door Interlock	5.2	x	x	0	x	x	x
Loading/Unloading	5.3	x	x	x	x	x	0
Visual Inspection Wash Cabinet interior OQ	5.4	0	x	x	x	x	0
Control System	6.0						
Touch Screen	6.1	x	x	0	x	x	0
Engineering Login	6.2	x	x	0	x	x	0
E-stop test	6.3	x	x	x	x	x	x
Operating Cycle	7.0						
Spray System	7.1	x	x	0	x	x	0
Carriage Position	7.2	x	x	0	x	x	0
Solenoids	7.3	x	x	0	x	x	0
Water pressure	7.4	x	x	0	x	x	x

Automatic Control Test

1.0 Automatic Control Test (ACT): The automatic control test is designed to demonstrate that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the Tiny Air V2.1.

The Tiny Air V2.1 system has an Automatic Monitoring System (AMS), if the system does not run within the limits set out the machine will not run. However, Tiny Air recommends that an Authorised Engineer Decontamination AE(D) or a Competent Person (Decontamination) performs a manual ACT weekly, following the procedure set out below:

ACT Test procedure:

1. Place a test device into a standard DIN basket and place that into the carriage inside the loading door. Using the touch screen start the cycle.
2. Ensure that a traceability record is made of the test. Note, all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage.
3. The test should be considered satisfactory if the following requirements are met:

a. A visual display indicating “cycle complete” occurs.

b. During the whole of the operational wash cycle, the values of the cycle variables are within the pre-determined limits of the programme: full cycle 2 minutes (+/- 15 seconds). Each pass of the carriage x12 8 seconds (+/- 3 seconds).

c. Manually check that the vacuum pump is drawing air from the wash cabinet by lifting the top vacuum tube and placing your hand over the rear pipe.

d. The door does not open until the cycle is complete.

e. Visually check that the inside of the doors and wash cabinet are free from visible contaminants.

e. The Competent Person Decontamination CP(D) conducting the test does not observe any mechanical or other anomaly.

Pre-cleaning efficacy

- 2.1 Residual Protein Test. Tiny Air have worked with Aseptium to develop a bespoke test for specific pre-cleaning challenges, the system uses test plates coated in htm 01-01 compliant artificial soil. The test replicates contaminate trapped between surfaces. The test is designed to reveal cleaning inconsistencies across the full basket from above and below to highlight issues from any of the jets.
  The bespoke test system is available from https://aseptium.com/contact/
- 2.2 Review of rewash results. Where the Tiny Air Automated Pre-clean machine has been included within the SSD/CDU data scanning system, instrument sets should be scanned to monitor rewash rates. Rewash rates should be examined regularly to check for any indication that cleaning efficacy has changed due to Tiny Air machine performance, if a statistically significant change is indicated Tiny Air Engineers should be contacted.

Thermometric

- 3.1 Chamber walls: Thermal disinfection wash cabinet shall be deemed to have been achieved if, when tested in accordance with 6.8.2 and the relevant subsequent parts of ISO 15883, the specified minimum temperature of 85 degrees centigrade for 10 minutes, or the equivalent lethality (A0, see Annex B EN15883), is achieved on all surfaces which are required to be disinfected. Completed by Tiny Air service engineers at 12 monthly service.
- 3.2 Integrated Thermocouples: There are two integrated thermocouples that monitor daily disinfection cycles. These are located close to the doors on the wash cabinet. They are part of the automatic validation system, if they are outside of the required parameters the machine will cease to operate. Any errors can be seen within the engineering section of the HMI (Human Machine Interface) touch screen. Calibration of thermocouples completed by Tiny Air service engineers at 12 monthly service.
- 3.3 Over Temperature Cut-out: The integrated thermocouples monitor the disinfection cycle and provide information to the programmable logic controller to prevent the disinfection water temperature exceeding 90C. Additionally there is a built-in thermocouple in the water heater which controls the temperature of the water in the disinfection cycle this is part of the automatic validation system. Over temperature will e-stop the system and an over temperature will be shown on screen.
- 3.4 Water Temperature /Time Test. Contingent on ambient temperature and water temperature the disinfection cycle runs for approx. 30 minutes. Once the disinfection programme is activated water fills the bottom of the wash cabinet until the float switch

activates the pump and heater. Water is circulated through the spinning nozzle and heated. Once the temperature reaches 90C the heater cycles for 10 minutes maintaining a temperature of at least 85C at all times. Log into the engineering panel to watch the cycle data in full.

Fluid Emission

- 4.1 Wash Cabinet leak proof testing: Any water leaks within the machine are managed automatically, float sensors trigger solenoids to cut off the water supply, initiates e-stop and provides an error message on the screen to report the issue. External leaks from the doors should be monitored by the users, note the door seals are designed to drip into the narrow tray below the doors when open, the bottle and tray should be emptied and cleaned regularly. A visual inspection around and under the machine should be completed to ensure there are no leaks.
- 4.2 Aerosol eradication: Contaminated aqueous aerosols generated during the cleaning cycle are eradicated at the end of each cycle by air extraction through an h13 Hepa filter. The doors crack open as the extraction pump switches back on. The aerosol extraction continues while the doors open.

Wash Cabinet

- 5.1 Doors Opening Closing. The doors can be tested by running a cleaning cycle. The doors at both ends should close in sync at start of the cycle, they should crack open for a few seconds and then fully open in sync automatically at the end of the cycle. The doors can be opened manually by turning the power off at the isolator.
- 5.2 Door Interlock. The doors are held closed by stepper motors during wash and disinfection cycles, they should be tested to ensure that the doors are not easily/ accidently opened during a wash or disinfection cycle, they should not be forced.
- 5.3 Loading/Unloading. The machines are configured for the users to load either from the left or right. Pressing the carriage home button on the touch screen should move the carriage to the correct end for loading.
- 5.4 Visual Inspection of Wash Cabinet. Internal cabinet walls, floor, ceiling and doors should be free of any visible debris or contamination. The drain strainer should be clear of debris.

Control System

- 6.1 Touch Screen. Check that the touch screen functions correctly. If the system displays a PLC error for more than 2 minutes contact the Tiny Air technical team. If the system displays an e-stop error investigate the cause based on the error message, if the error cannot be rectified and the e-stop reset fails, contact the Tiny Air technical team. If the touch screen displays a message saying that the memory isfull press close and continue to use as normal.
- 6.2 Engineering Login. Test the engineering login. To login enter username : eng select enter, then enter the password: 123 and select enter, choose engineering to enter the detailed engineering page. Remain logged in to test the Operating Cycle 7.0-7.4. Log out after full validation is complete.

- 6.3 E-stop test. To test: run a cleaning cycle and press the emergency stop button during the cycle. The system should stop running and a warning will appear on the touch screen. Pressing the e-stop reset on the touch screen should not fix the issue. Turn the emergency stop button to release the lock and then attempt the e-stop reset on the touch screen, which should fix the issue. The machine should then, drain, vent and open the doors.

Operating Cycle

- 7.1 Spray System. Visually check the nozzles within the wash cabinet nozzles to ensure there are no obstructions or anomalies.
- 7.2 Carriage Position. When logged into the engineering screen run a cycle and watch the carriage position indicator to ensure that the carriage is moving correctly though the cycle. The carriage should move 12x in total left and right. The engineering screen shows that the carriage is moving the full length of each pass.
- 7.3 Solenoids Operating. When logged into the engineering screen run a cycle and watch the visual indicator correlates with the solenoids switching between nozzles sets.
- 7.4 Water pressure. When logged into the engineering screen run a cycle and check that the pressure is 150 Bar +/- 15 Bar. If one set of nozzles is out of this range, contact Tiny Air Technical Team. Log out after the full validation is complete.