Title/Description:

Maintenance and Certification of Bio Dot Enclosure Air Extraction System

APPROVAL

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Approval Stamp (Document Control stamp, initials and date)

	Effective Date:

Revision History

Revision	Summary of Change	Originator	DCO#	Eff. Date
01	New Document	D. Julian	1328	

1. PURPOSE:

To provide for the maintenance and annual certification of the BioDot Enclosure System, including the Air Science Fume Extractor and replaceable filters.

2. SCOPE:

2.1. This procedure is applicable to the plexi-glass enclosure surrounding the BioDot machine, the connected Air Science Fume Extractor QA975, and the replaceable carbon/HEPA air filters the unit requires.

2.2. This procedure does not apply to maintenance of the BioDot machine itself, see 931038 Operations and maintenance of the BioDot AD3200 Dispensing System. This procedure is not to be used for maintenance and certification of large built-in laboratory fume hoods covered in 931030 Operation, Certification, Calibration, and Maintenance of Laboratory Fume Hoods and Associated Monitors.

3. RESPONSIBILITIES:

3.1. It is the responsibility of Quality to have the BioDot Enclosure System certified for minimum air flow annually by an approved calibration service and to have Manufacturing personnel change QA975 Air Science Fume Extractor filters annually. Personnel using the BioDot system are responsible to perform and record unscheduled maintenance as appropriate and to comply with this procedure during routine operations.

4. REFERENCE DOCUMENTS:

4.1. 910026 *Calibration*

4.2. 910024 *Preventive Maintenance*

4.3. 927000 *Nanomix Environmental Safety & Health Manual*

4.4. 931030 *Operation, Certification, Calibration, and Maintenance of Laboratory Fume Hoods and Associated Monitors*

4.5. 931038 *Operations and Maintenance of BioDot AD3200 Dispensing System*

5. DEFINITIONS:

5.1. BioDot Enclosure – Clear, plexi-glass box surrounding entire BioDot machine.

5.2. Air Science Fume Extractor QA975 – Filter box connected to back of BioDot Enclosure via clear ducting. Removes CNT's and other toxins from enclosure around BioDot machine.

5.3. Filter – Filtco carbon/HEPA ASTM-200 filter for Fume Extractor box.

5.4. Front Panels – Two clear, hinged, panels on front of Enclosure that fold up for increased access to inside of BioDot Enclosure.

6. PRECAUTIONS/SAFETY:

6.1. Personnel must follow guidelines established in 927000 *Nanomix Environmental Safety & Health Manual* when operating any equipment.

6.2. Air extraction systems are intended for use with certain chemicals or powdered toxins that can cause serious injury or illness through inhalation or physical contact. While an air extraction system is intended to minimize exposure to certain hazardous chemicals when installed and

operated properly, its performance and the safety of the user is affected by a number of factors. These include the Heating, Ventilation and Air Conditioning (HVAC) system, the specific chemicals and processes being used, proper operation and the condition of the room.

6.3. Prior to using the BioDot Air Extraction System, operators should have trained on 931030 for general fume hood safety practices and 931038 for BioDot procedures,

6.4. Check to make sure the associated Vaneometer QA849 on the inside left of the enclosure is moving in response to inward air flow. This ensures the Fume Extractor is pulling air from the enclosure into the extractor box and filtering it.

6.5. Clean up spills immediately with a mild detergent.

6.6. Avoid placing your head inside of the enclosure. Always work as far back from the front of the enclosure as possible. Keep all chemicals and apparatus 6 inches inside the front of the front plexi-glass.

6.7. Avoid cross drafts and limit traffic in front of the Enclosure. Air disturbances created may draw fumes out of the enclosure.

7. CERTIFICATION:

7.1. QA851 BioDot Air Extraction System is certified for minimum safe air flow annually by an approved external calibration service provider according to 910026, *Calibration*.

7.2. Filter replacement is not part of the air flow certification and is performed by Manufacturing personnel as annual maintenance. Filter replacement is recorded on form 931038-02 Annual Preventative Maintenance for the BioDot Dispensing System, page 19 of 931038. Filter replacement may be performed more frequently if heavy use of the BioDot machine occurs, and can be performed as a scheduled and unscheduled maintenance.

8. OPERATING PROCEDURE FOR ENCLOSURE:

8.1. This air extraction system is not intended to be used with any other process besides operating the BioDot dispensing system.

8.2. Always keep both front panels folded down when operating the BioDot dispenser or when the BioDot machine is running by itself in automated mode.

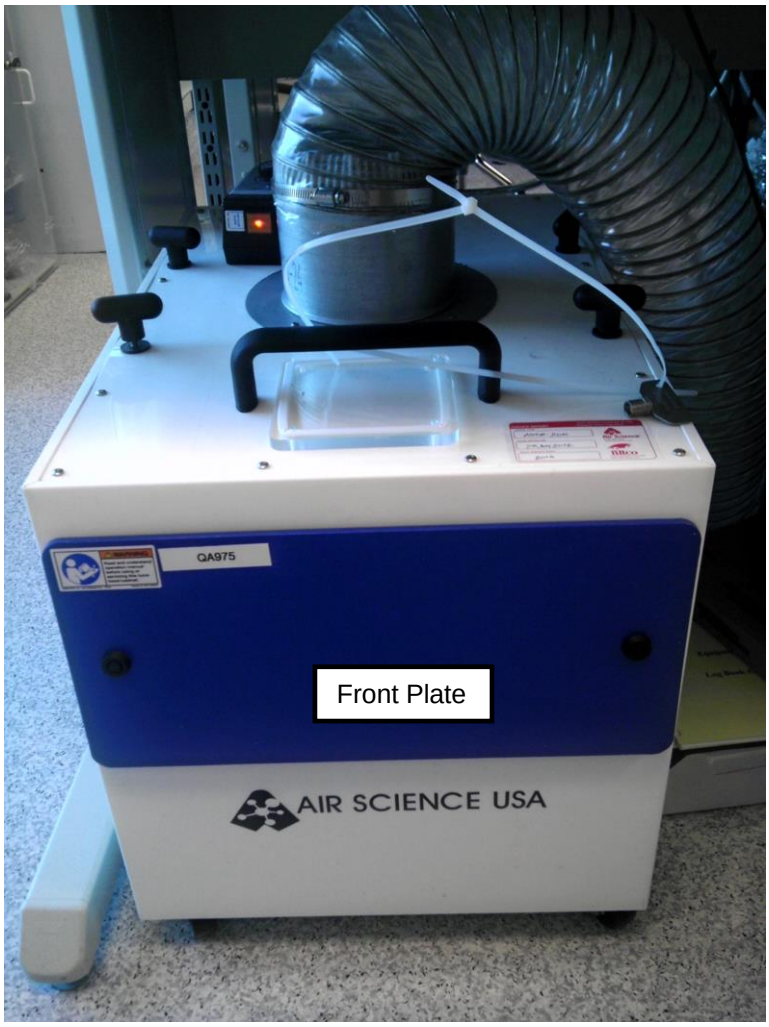
8.3. Turn on the light above the Enclosure for proper illumination of working area.

8.4. Check the associated Vaneometer to make sure air is flowing into the extraction system before using BioDot machine.

9. OPERATING PROCEDURE FOR FILTER CHANGE:

9.1. Turn Air Controller Switch from Low to Off.

9.2. Use attached Key and loosen connectors on both sides of the Front Plate, remove Front Plate and put aside.



9.3. Filter is held in place by four screws on the top of the extractor enclosure. Loosen each screw by turning clockwise several times each. Filter should feel loose enough to pull out.

9.4. Filter has two rounded catch knobs on the back side that secure it into place. Lift the filter up first and then pull out towards opening to release.

9.5. Place used filter in plastic bag that new filter came in. Close filter box and seal with tape.

9.6. New filter has a black rubber gasket on the bottom, this side goes down. Slide new filter into enclosure as far in as it will go. Catch knobs will ensure it falls into place. Make sure label on front of new filter is right side up.

9.7. Screw the four knobs on the top of the extractor enclosure counterclockwise until they are tight and the filter feels firmly in place and will not move.

9.8. Put Face Plate back on, and use key to tighten face connectors until the face plate is flush with the front of the enclosure and does not move.

9.9. Turn Air Controller back on and up to Low.

9.10. Check Vaneometer QA849 in BioDot hood enclosre to make sure it is regeistering air flow. If it shows movement above the zero mark, air is flowing from the BioDot hood enclosure through the filter and the system is functioning properly.

10. TROUBLESHOOTING SECTION

10.1. Room Cross Drafts

10.1.1. Air moving through an open door located adjacent to the Enclosure can cause cross drafts.

10.1.2. An open window or a room air supply located to one side or across from the Enclosure can cause disturbing cross drafts.

10.2. Insufficient Air Flow

10.2.1. If associated vaneometer on the inside left of the Enclosure is not moving inward, check to be sure it is not stuck.

10.2.2. If vaneometer is functioning properly and is moving freely, check to make sure the two air outlets to the clear ducting at the back of the Enclosure have no blockage.

10.2.3. If air is still not moving freely out to the back of the Enclosure and into the ducting, check that QA975 Air Extractor Box is on and that filters are installed correctly and do not need changing.