MailGuard Preventative Maintenance Plan

(Includes BioFlash PM)

v1.00

Items Required for Maintenance:

- Toolkit (screwdrivers, allen wrenches, flashlight, etc)
- Laptop with serial/USB converter, loaded with BioFlash communications apps (GUI, BILT)
- Replacement real time clock battery
- 1 or more unpainted Type-99 disks (for background count checks)
- 1 or more painted Type-99 of a known RLU range (1000-4000 RLU typically)
- 2 or more General Format disks, loaded on channel 9 as per normal positive control usage (optional, not always easily available)
- Test Pallet of at least 8 different disks (each with a valid barcode, should be Type-99)
  - Used for disk lift, barcode, and index hole testing across a variety of disks
- Pre-filled in coefficient setup / firmware version sheet specific to the client installation
- Access to the documents for reference in the field: "BioFlash Device Cheat Sheet", and "BioFlash Serial Protocol"

Customer Site Preventative Maintenance Material Check List

- ☐ On-The-Go Tool Kit consisting of:
  - ☐ Chapman Set
  - ☐ Screwdrivers (assorted)
  - ☐ Allen Wrenches
  - ☐ 1/4" Socket
  - ☐ 11/32" Socket
  - ☐ Long Nose Pliers
  - ☐ Loctite
  - ☐ Electrical Tape
  - ☐ Zip Ties
  - ☐ Adhesive Cable Mounts
- ☐ Motherboard Clock Battery
- ☐ Shutter motors (qty of 2) with PMT cable and air inlet cable attached

- ☐ BioFlash PM Box containing a minimum of 1 paint disc and 7 blank discs
- ☐ Spare paint discs to leave if needed
- ☐ *2 General Format or Two-Agent Format Discs
- ☐ J-Link Dongle
- ☐ Yellow "paint disc" or "disc 99" circular labels
- ☐ PSI Phone Support Decal
- ☐ Ferrite beads (qty of 2)
- ☐ Long (+5") motor controller to spinpit board cable
- ☐ Laser Temperature Gun
- ☐ Cleaning Materials
- ☐ Anemometer
- ☐ PVC pipe

- ☐ Laptop with BioFlash COM apps
- ☐ Serial to USB cable
- ☐ 1/2" Socket
- ☐ Printout of filter log
- ☐ Charcoal filter booth
- ☐ Pre-filters (two types) for booth
- ☐ HEPA cannister filter

- ☐ *Optional Items:*
  - ☐ BioFlash to sub in during service work
  - ☐ Power cord
  - ☐ Soldering iron
  - ☐ Solder
  - ☐ HEPA filter

Preventative Maintenance Tasks Details (Order of Steps IS Important)

1. **Inspect Device for Physical Problems**
   - Photograph any anomalies found
2. **Internal Device Logs Review**
   - Using the BILT tool or other terminal application with logging available perform the following:
     - Issue a "$logerr;" command.
       - Inspect the resulting error log for unexpected reports
     - Issue a "$logalarm;" command
       - Inspect the resulting alarm log for any un-reported agent alarms
     - Issue a "$logtest;" command
       - Inspect the test log and verify the number of tests is in accord with the client scenario.
     - Issue a "$config;" command
       - Note the settings displayed, if any
     - Issue a "$disktype;0", followed by a "$coef;" command
       - Be sure to save these values in the log text file in case of hard reset during later battery change
     - For devices with Firmware 4.04 or newer, reset the logs with a "$resetlogs;" command
   - Save a backup copy of each of the report output logs to the PSI DropBox (Engineering – Hardware/BioFlash/BioFlash Maintenance/Repair and PM Reports), or save to a USB memory stick for later transfer to the PSI data repository.
   - Note any anomalies with any of the logs on the Inspection Report Form
3. **Record Number of disc runs (if available in Firmware) since last inspection**
   - Press Option, then Next, then About to find this number
4. **Replace clock battery**
5. **Firmware Related**
   - Record current firmware on device
   - Flash and record new firmware version (if update available)
   - Ensure Unit ID, and Time setting are correct on the device.
     - Correct using "$datetime;dd-mm-yyyy,hh:mm:ss" command if required
   - Verify correct collection time for customer (collection time can be seen when a valid non-99 type barcoded disk is run)
   - Verify correct shutter open time for device type
   - Verify remaining coefs match device manufacturer by executing the command "$coef;"
   - Ensure 'type' of unit is correct (BioFlash-E, BioFlash-AF etc), shown at device power-on.
   - Note any anomalies with any of the firmware settings on the Inspection Report Form
6. **Air Inlet Shutter Check**
   - Visual Inspection
     - Enter Device Test Mode. Select Disk Lift test.
     - Using the on-screen Inlet +/- button, verify the air inlet shutter opens and closes, resulting in either 100% coverage of the inlet port, or 100% open flow of the air inlet port.
   - Note any anomalies with the above tests on the Inspection Report Form
7. **PMT Shutter Inspection**
   - Visual Inspection
     - With the drawer of the device open, turn off power to the device (to prevent accidental PMT exposure).
     - Visually inspect the state of the PMT shutter. The shutter should be fully closed, with no partial exposure of the PMT lens glass.
   - Audible Inspection
     - Enter Device Test Mode. Verify drawer is closed, and inlet shutter is closed. Select PMT Shutter test.

- Use the on-screen buttons to open and close the PMT shutter. There should be an audible indication that the shutter is sliding open and closed, with a slight 'click' heard when the shutter hits its 'closed' hard stop.
  - o Note any anomalies with the above tests on the Inspection Report Form

8. **Blower**
   - o Remove any inlet manifold and install test tube using flanged collar. Make sure that the calculation for air volume is set correctly for the test tube diameter. The correct test tube diameter is 5.1 cm. With a disc in the BioFlash, in the BioFlash's test mode turn on the blower and open inlet valve. Turn the anemometer on and after 30+ seconds insert the probe into the tube's test hole so that the center electrode is maximally exposed to the airflow. Read the volume meter's readout (L/s) and wait for it to stabilize. Multiply by 60 for the airflow in liters per minutes. The airflow should equal **400 +/- 80 L/minute (5.33 – 8.00 L/seconds)**. Record and repeat this on a series of five different discs. If the average airflow rate is not within the stated range, the blower can be adjusted with a thin screw driver. Remove the instrument cover and the port plug on the blower to access the adjusting screw.

9. **Disk Lift, Barcode & Index Hole Check**
   - o Insert each of the Test Pallet of barcoded disks into the BioFlash. Each disk should be recognized, scanned, and result in the LCD on-screen display permitting a test to run.
   - o Run each disk through the entire collection phase.
   - o Verify that each disk makes it to the 'Reading' phase of the test process without any Disk Lift failures.
   - o Note any anomalies with any of the disks on the Inspection Report Form

10. **Measurements**
    - o The disc, sitting on the spindle, should be horizontally flush with the top of the back window mask. If it is not, adjust the spindle height so that the top of the disc and top of the window mask are level.

11. **Drawer Operation**
    - o Perform a minimum of 10 drawer open/close cycles.
    - o Visually and audibly inspect the smoothness of the drawer opening process
    - o Note any anomalies with any of the disks on the Inspection Report Form

12. **PMT Background & Sensitivity Check**
    - o Background counts:
      - Using a non-painted, Type-99 disk, perform a normal test sequence.
      - Using the GUI or BILT tool, verify that the resulting background counts have an average RLU level of < 15.
    - o PMT Sensitivity
      - Use a painted Type-99 disks, perform 2 normal test sequences. (This test can eventually be replaced with a RAD calibration disk)
      - Using the GUI or BILT tool, verify that the resulting curves on the painted channels have an average RLU level that is within the known range of each disk.
    - o Save a backup copy of each of the data output curves to the PSI DropBox (Engineering – Hardware/BioFlash/BioFlash Maintenance/Repair and PM Reports), or save to a USB memory stick for later transfer to the PSI data repository.
    - o Note any anomalies with any of the disks on the Inspection Report Form

13. **Cleaning**
    - o Clean all exterior device services with a damp cloth.
    - o Clean the inside of the device if it is extremely covered in dust
    - o Note any anomalies during the cleaning on the Inspection Report Form

14. **MailGuard Filter Replacements**
    - o Replace the large booth HEPA filter
      - Note down the new serial number on the filter log
    - o Replace the charcoal filter and the prefilter in the downdraft booth
    - o Replace the HEPA cannister filter
    - o Update the filter logs

- o Verify site has purchases/inventory in place for filter changes prior to next PM
  - ▪ 3 charcoal, 3 pre-filters, 1 HEPA cannister filter

15. **Downdraft Booth Operations**
    - o Verify lights work properly in booth
    - o Verify timer for jogger works properly
    - o Verify mail jogger is in good working order & bin is secure
    - o Verify good switch operation for the booth primary power on/off

16. **Downdraft Booth Magnehelic**
    - o Recalibrate the magnehelic if necessary
    - o Record the current magnehelic settings on the filter log in the in PM form

    a. Turn the Workstation to the "on" position using the switch on the side of the unit. The needle of the magnehelic gage should clearly register an increase from its "off" position.
    b. Clear the surface and vented back of any blockage (shipping material, tools, mail, etc.) to ensure proper gage reading.
    c. Note the initial reading of the magnehelic gauge while the unit is running.
    d. Use the dial on the gage to establish the **Set Point**. The fixed Set Point is used by operators to monitor the cleanliness of the filters. The Set Point should be established approximately one to two tenths above the initial reading. For example, if the gage initially reads 1.0 the Set Point should be established at approximately 1.15. You may also want to document this value to ensure that if the dial gets inadvertently moved, there will be record of the initial set point.

17. **'Live' Simulated Test (optional, if discs are available)**
    - o Prepare 2 disks, General Format barcoded, loaded with cells and anti-IgM in channel 9 to replicate a positive control channel (00-type barcode, 10-day expiration)
    - o Perform 2 full disk tests, including retrieving of the data via the GUI.
      - ▪ Use 2 'Collect' cycles, followed by 1 'Analyze' for each disc
    - o Review resulting output curves, verify no anomalies in curves or physically in disk
    - o Save a backup copy of each of the data output curves to the PSI DropBox (DATA…/Client Site Logs folder), or save to a USB memory stick for later transfer to the PSI data repository.
    - o Note any anomalies during the cleaning on the Inspection Report Form

18. **Finalization**
    - o Reset all device logs by executing the command "$resetlogs;"
    - o Verify correct $config settings and AF/E type on reboot of device
      - ▪ Includes secondary analysis, twophaseonly config settings
      - ▪ NOTE: If firmware is updated to 7.06 or later, check secondary config definition

19. **Inspection Report Form**
    - o Fill in the report on the general condition of the device, issues found/fixed, etc
    - o Blank form is located in the appendix to this document
    - o Produce "Printout" pages with graphs for PMT background, paint disc, and live tests
    - o Scan and save the report to the Drop Box folder (Engineering – Hardware/BioFlash/BioFlash Maintenance/Repair and PM Reports).

20. **Inform PSI Survey Team that service has been performed and they can now contact the site**

21. **Add PM date to service contracts Smartsheet**

MailGuard Preventative Maintenance Form
Unit #XXXX (Device Name) – Completed XXXX-XX-XX

Customer Information:	PathSensors Information:
	PathSensors Inc. 701 E Pratt Street Baltimore MD 21202 Ph: 443.557.6150

Device Serial Number(s) **BioFlash / Booth:**	
Device 'Name':	
Repair Tech:	
Date Unit Received:	XXXX-XX-XX
Dates of PM Completion:	XXXX-XX-XX

Preventative Maintenance Summary

- Preventative Maintenance Form Results (Attached Below)
- Unit appears to be in good overall condition
- PMT results are within normal parameters

Note on Calibration

The MailGuard device does not require a yearly Calibration. The Positive Control channel on each BioDisc test serves as a continuous calibration/performance check of the BioFlash device. A Preventative Maintenance is suggested once during each calendar year to clean, inspect, and replace BioFlash parts as necessary.

PATHSENS RS
Detecting Pathogens at the Speed of Light

Unit Serial Number: _____   *Unit Location:* _____

Date: XXXX-XX-XX   *Technician:* _____

Step #	Description	Pass/Fail (check = pass)	Notes
1	Physical Inspection	✓	
2	Logs Review		
3	# of Device Runs		
4	Replace Clock Battery		
5	Firmware Settings		
5-1	FW: Current FW Version		
5-2	FW: New FW Version		
5-3	FW: Unit ID		
5-4	FW: Date/Time Correct		
5-5	FW: Misc Coefs		
5-6	FW: Config Settings		
6	Air Inlet Shutter		
7	PMT Shutter		
8	Blower		

9	**Disk Lift, Barcode, Index Hole**		
10	**Measurements**		
11	**Drawer Operation**		
12	**PMT Background & Sensitivity**		
13	**Cleaning**		
14	**MailGuard Filter Replacements**		
15	**Downdraft Booth Operations**		
16	**Downdraft Booth Magnehelic**		
17	**Live Test**		
18	**Finalization**		
--	**Other Notes**		