BREATH ALCOHOL INTENANCE BREATH ALCOHOL MAINTENANCE MANUAL

Revision 4

Issue Date: 01/23/2023

Issuing Authority: Quality Manager

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	Procedure for Lifeloc

Revision History

Revision #	Description of Changes
1	Original issue of document
2	Added section 4.2.3, 4.3.2 and 5.2.6. Changes made to section 4.3.4.1
3	Edited/Changes to sections 4.2.2.3, 4.2.2.4, 4.2.3.2, 4.2.3.4, 4.2.4.1.1, 4.3.1.1, 5.2.3.2, 5.2.4 and 5.2.6.3.1
4	Reformatted, added section 4.1.1.4, 4.2.2.3, 4.3.1.2, 5.2.3, and changed 4.2.2.6
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MAINTENANCE OF INSTRUMENTS FOR THE BREATH ALCOHOL DISCIPLINE FOR THE ISPFS

Background/References 1.0

1.1 Background: When an instrument is submitted to the laboratory for calibration services, it is first assessed 'as found' for its performance when it is received. The instrument is then adjusted to a known standard, compared to certified reference materials at several different levels, and a calibration report is issued for that instrument. This is a standardized method employed by the laboratory and has very little variance. If an instrument is submitted and that instrument cannot meet the laboratory calibration standards after it has been adjusted, it is then taken out of service for breath testing and maintenance is performed on the unit to bring it into compliance. The maintenance and service manual of the calibration program is an uncontrolled document that is outside the instrument calibration program for the ISPFS laboratory certification.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- Calibration methods
- Instrument manuals
- Instrument training manuals
 - ISO 17025 and ISO 17034 standards

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2.0 Scope

2.1 Upon failure to meet calibration specifications or the inability to be tested 'As Found', the scientist/analyst has the discretion to troubleshoot the instrument in order to identify, isolate and correct the potential problem or issue with the unit. The analyst may perform maintenance on the instrument in accordance with the section of the manual that they believe will have the most impact or be the most effective at correcting the issues that they have identified through their troubleshooting process. The analyst is expected to utilize the entirety of their knowledge, skills and abilities that they have obtained throughout their training (including returning the unit to the manufacture for repair or part(s) replacement) in order to return the unit to working conditions.

3.0 Equipment/Reagents

- 3.1 Equipment:
 - 3.1.1 Refer to methods, training and individual sections of the manual for all required equipment.
- 3.2 Reagents:
 - 3.2.1 Refer to methods, training and individual sections of the manual for all required equipment.
- 3.3 Reference Materials:
 - 3.3.1 Refer to methods, training and individual sections of the manual for all required reference materials.
- 3.4 Safety Concerns
 - 3.4.1 Chemicals must be handled according to safety guidelines in the Idaho State Police Forensic Services Health and Safety Manual.
 - 3.4.2 Refer to methods, training and individual sections of the manual for all specific safety requirements.

4.0 Procedure for Lifeloc

- 4.1 Lifeloc Troubleshooting:
 - 4.1.1 Low or high response to EtOH.
 - 4.1.1.1 A low response could be from multiple sources. It could be due to the instrument needing the fuel cell gain adjusted, the fuel cell being dehydrated from a lack of use or abuse (improper storage conditions, etc.), or simply the fuel cell needing to be replaced.
 - 4.1.1.2 The scientist should assess the instrument's performance with both wet and dry standards, at low and high concentrations in order to determine if the instrument is responding consistently at all levels or is showing symptoms at certain levels.
 - 4.1.1.3 Responses should be evaluated in accordance with the analysts training and experience.
 - 4.1.1.4 It may be advisable to adjust the gain (up -or- down) if the fuel cell sensitivity to ethanol is non-optimal.
- 4.2 Lifeloc Maintenance and Service
 - 4.2.1 Hydration
 - 4.2.1.1 The fuel cell's primary active component is an aqueous acid. The acid is hygroscopic and absorbs water readily. Coincidentally, the reaction of the fuel cell with ethyl alcohol ultimately produces water as an end product of the reaction. This makes the very act of using the instrument to measure breath alcohol an effective means of keeping the unit hydrated. In order to rehydrate the unit, the analyst may use a simulator to provide several alcohol breath samples to the unit, in succession, and then allow the unit to equilibrate the water (from the alcohol reaction and from the humidity within the breath sample or simulator) into the fuel cell.
 - 4.2.1.2 After hydration of the fuel cell, the unit should be left for a period of time sufficient for equilibration prior to testing to see if the cell has responded to the rehydration attempts.
 - 4.2.2 Gain Adjustment
 - 4.2.2.1 The amplification of the signal to increase the signal to noise ratio above the baseline cutoff levels for the instrument is another metric of the unit that can be adjusted by the analyst in order to improve the instruments performance.
 - 4.2.2.2 If the unit loses sensitivity to EtOH, then the measurement algorithm may become less accurate in its ability to quantitatively measure the analyte of interest. This would necessitate an adjustment of the unit's gain setting to increase the instrument's signal to noise ratio.

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- 4.2.2.3 If the unit's sensitivity to ethanol has increased, it may be necessary to decrease the fuel cell gain in order to prevent the possibility of false positive indications of "external interference" being detected during the acquisition of a breath test.
- 4.2.2.4 Use the manufacturers provided software (ZOC software) and work instructions to set the gain on the instrument to an optimal level.
 - Document the starting gain prior to adjustment
 - Maximum setting is ~30
 - Manual adjustment is possible at the analyst's discretion
 - If the Zoc software requests a large increase in the gain, and visual inspection of the gain increase appears to be too large, manual adjustment may be considered to a lower number.
 - Document the final end gain setting.
- 4.2.2.5 Alternatively, the gain may be adjusted manually using the Zoc command: fgx where x represents the new gain value.
- 4.2.2.6 After setting the gain, the instrument's calibration should be adjusted first using a wet bath simulator solution.
- 4.2.3 Dry Gas Correction Factor (DGCF)
 - 4.2.3.1 Since the main component of the fuel cell is a hygroscopic aqueous acid, and alcohol is extremely soluble in water, the wet samples introduced into the fuel cell will be drawn into the cell with a greater affinity than a dry sample. This necessitates a correction for dry samples to account for this differential due to their lack of water content.
 - 4.2.3.2 Utilizing the manufacturers provided ZOC software, enter the command string (/ff||#) and adjust the correction factor up (for a low dry gas response relative to the wet solution response) from the factory setting of 1.05, to increase the response that the dry gas has when reacting with the fuel cell. Adjust the correction factor down to decrease the dry gas response.
 - 4.2.3.2.1 This adjustment is for the dry gas response in order to correlate the Wet:Dry results for the instrument. If the DGCF is changed, the instrument must be readjusted with a CRM prior to calibration.
 - 4.2.3.3 Enter the command string again without the number to check the DGCF setting.
 - 4.2.3.4 Recommended DGCF settings should be within 0.950 1.050. Maximum DGCF setting for the FC20 is 0.900 1.100.

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4.2.4 Other Maintenance:

- 4.2.4.1 At times, the analyst may employ different techniques to attempt to bring the unit into compliance with the ISPFS calibration standards. These may not be listed within the manual, but the analyst should utilize their training and experience to perform maintenance on the unit.
 - 4.2.4.1.1 Pump Reset: If the instrument pump requires multiple reset attempts, the analyst may open the unit and lubricate the pump drive screw.
- 4.2.4.2 All symptoms and status messages associated with the issue shall be documented on the maintenance worksheet(s).
- 4.2.4.3 Any communications made with the agency about history of instrument or made with the manufacturer about technical assistance issues to help resolve the issue shall be documented on the maintenance worksheet(s).
- 4.2.4.4 A summary of the maintenance performed on the instrument and the steps taken to bring the unit back into conformance with the calibration standards shall be documented on the instrument worksheet(s).

4.3 Documentation:

- 4.3.1 All testing results obtained during maintenance shall also be documented in the records/summary of the maintenance.
 - 4.3.1.1 Gain adjustments may be documented on the Lifeloc calibration form.
 - 4.3.1.2 DGCF adjustment settings may be documented on the Lifeloc calibration form.
- 4.3.2 Raw data and results from maintenance may be kept in logs or electronically but must be referenced on the maintenance form or within the case record.
- 4.3.3 Approval Documentation
- 4.3.3.1 When placing the instrument back into service, it will first need to go through the calibration procedure and meet the ISPFS criteria for evidential testing. The maintenance that was performed on the unit will be recorded on the maintenance form or calibration form and attached to the instrument in the LIMS.
- 4.3.4 Rejection Documentation
 - 4.3.4.1 Should the instrument fail the laboratory's maintenance attempt to return it to acceptable performance, the recommended service will be documented in the LIMS.
 - 4.3.4.2 The instrument should then be returned to the owning agency, to be returned to the manufacturer for service.

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4.4 Work Instructions

- 4.4.1 Equipment: ZOC program, ZOC USB, cable and FC20
 - 4.4.1.1 If you still have version 6.44 on your thumb drive, you will need to load the following files to the thumb drive:

FC20Idaho_REV3v6_50 Aug 26 2015.id. Save this file to the thumb drive in the following folder: \Firmware and software updates\FC Rev 3. Delete the existing .id file dated 12-17-2013

- 4.4.1.2 FC20Idaho_REV3v6_50 Aug 26 2015.mot. Save this file to the thumb drive in the following folder: \Firmware and software updates\FC Rev 3. Delete the existing .mot file dated 12-17-2013
- 4.4.1.3 ReProgram.zrx Save this file to the thumb drive in the following location. Replace the existing "ReProgram.zrx" file.

4.4.2 Procedure:

- 4.4.2.1 FIRST TIME WITH A SPECIFIC COMPUTER
- 4.4.2.2 Before inserting cable insert memory stick (thumb drive)
- 4.4.2.3 In the FTDI Driver folder, run *CDM20828_setup.exe* to install cable driver.
- 4.4.2.4 After cable driver installation is complete, insert programming cable
- 4.4.2.5 Computer should find cable. You only have to do this the *first* time you connect the cable on a new computer.
- 4.4.2.6 CLICK ON FC_SERVICE.EXE
- 4.4.2.7 Power on the FC and make sure "Air Blank" is on the display. Connect to programming cable.
- 4.4.2.8 In Zoc, click on the *Communication Setup* button. "Ready for communication".
- 4.4.2.9 At this point you can check unit temperature or software version by clicking on those buttons to verify communications if you like. It is not required.
- 4.4.2.10 CLICK ON THE *REPROGRAM* BUTTON NOW.
- 4.4.2.11 The Zoc program button will query the unit and verify it can be updated. Then the instruction will be displayed in ZOC.
- 4.4.2.12 -Perform steps 1-4.
- 4.4.2.13 IDAHO SOFTWARE UPDATE INSTRUCTIONS
 - 4.4.2.13.1 1. Turn off the unit.
 - 4.4.2.13.2 2. Flip the cable switch to Program Mode. (Towards the prongs on the bottom)

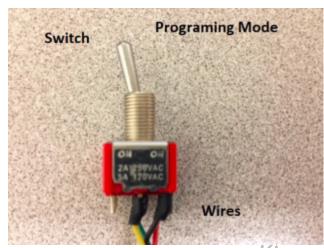
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4.4.2.13.3

4.4.2.13.4 3. Push power on the unit. The display should remain off.

4.4.3 4. Re-program the unit via instructions below

- 4.4.3.1 Be sure to select the current programming option in the menu option.
- 4.4.3.2 Click *Erase and Program*. If an error occurs, remove and replace a battery and try again.
- 4.4.3.3 Upon completion, a read check will run automatically.
- 4.4.3.4 When the unit programming is complete you will see the following screen:
- 4.4.3.5 "Program OK"
- 4.4.3.6 -click OK
- 4.4.3.7 Click on Exit and the following instruction will appear in ZOC.
 - 4.4.3.7.1 1. Flip the cable switch back to Normal Mode
 - 4.4.3.7.2 2. Remove and replace a battery
 - 4.4.3.7.3 3. Turn unit on
- 4.4.3.8 After the unit re-boots it will need to be re-initialized to complete the programming process. Click on OK.

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5.0 Procedure for Dräger

- 5.1 Dual Sensor Troubleshooting
 - 5.1.1 The Dräger Alcotest 9510 employs dual sensor technology (Electrochemical Fuel Cell-EC and Infra-Red spectrophotometry-IR). This allows the instrument to maintain an enhanced specificity to ethyl alcohol. It also requires an increase of adjustments to the instrument and its multiple sensors to deliver the correct signal response for the different sensors to respond to the reference standards.
 - 5.1.2 In order to troubleshoot the Dräger 9510 properly, it is necessary to adjust the instruments EC sensor to match the value of the IR sensor, and then adjust the paired sensors to match that of a reference standard. This process may be conducted through the adjustment of one of many different values within the instrument, or through an automated process.
- 5.2 Instrument Adjustments
 - 5.2.1 Utilizing the following matrix, the instrument may be adjusted to bring the sensors into alignment and adjusted to match that of the different reference standards utilized during the maintenance process.
 - 5.2.2 During maintenance, the unit should be assessed for its response versus both wet standards and dry standards across the expected range of values the instrument is expected to encounter during evidentiary testing in the field.
 - 5.2.3 The analyst may elect to begin their post assessment adjustment from the average setting for the instrument calibrations.

5.2.3.1 Cal Factor EC: 1110 Cal Factor IR: 891

Adsorption: 3% Calgas Inlet Drygas: 2-3% EC drygas offset: 7-8% IR slope multiplier: 13484

EC quadratic correction factor: 12

- 5.2.4 In the event that the response of the unit at the higher values of EtOH is not linear, the instrument may be adjusted using the manufacturer provided software "LinearityFactor.exe" along with a 0.400 ethanol wet bath solution.
 - 5.2.4.1 Utilizing the linearity software and the 0.400 wet bath solution, you can adjust the IR Slope Multiplier and the EC Quadratic Correction Factor to correct the linearity of the instrument calibration.
 - 5.2.4.2 Alternatively, the linearity adjustments may be done manually by adjusting the EC quadratic correction factor and the IR slope multiplier.

Adjustment Guide: 5.2.5

	STEP 1 WET IR	STEP 2 WET EC	STEP 3 PAIR DRY RESULTS	STEP 4 MATCH DRY TO WET
Goal	Match the Wet IR results to the target (0.080)	Match the Wet EC results to the target (0.080)	Match the Dry EC results to Dry IR results	Match the Dry (EC/IR) need to the target (0.080)
Action	Adjust IR Cal Factor to target (0.080)	Adjust EC Cal Factor to target (0.080)	Adjust EC Drygas Offset % to match Dry gas IR Results	Adjust Calgas Inlet Drygas % to match target results (0.080). (Note: This will change both Dry IR and EC, which is the goal)
Result	Wet IR results should now read 0.080	Wet EC results should now read 0.080	Dry EC and Dry IR results should now match. If they do not read 0.080, proceed to step 4.	All Wet/Dry (EC/IR) results should now be on target.

		wet	wet	dry	dry		
Type of adjustment:	Relation	ir	ec	ìr	ec	low	high
Adsorption	Direct	X	X			X	X
Calgas Inlet drygas %	Direct	. (S ,	X	X	X	X
IR Slope Multiplier	Inverse	X	200	X		X	XXX
EC quadratic correction factor	Direct	Y	X		X	X	XXX
EC drygas Offset %	Direct				X	X	X
Cal Factor EC	Direct		X		X	X	X
Cal Factor IR	Direct	X		X		X	X

^{*}The EC quadratic and IR slope multiplier effect the high end more than the low end.

- 5.2.6 Care should be taken to not fatigue the fuel cell during the adjustment and service process, which may lead to issues in the calibration of the instrument.
- 5.2.7 Software upgrade:
 - 5.2.7.1 With the instrument powered on, insert an ISPFS USB Tech key with the current software version loaded onto the root folder of the USB drive.
 - 5.2.7.2 Navigate the settings menu to the Communications Hub.
 - 5.2.7.3 Enter the IP address 164.165.246.11 and send the instrument data using port 9513 to the ISP Draeger Database server.
 - 5.2.7.3.1 If the server is not available, download all of the instrument databases, utilizing the database management menu, to a USB drive.
 - 5.2.7.4 The files (.txt) can be opened/saved as semicolon delineated excel files (.xls). All files should be returned to the instrument agency. Once the data retention has completed, document all of the instrument calibration settings.
 - 5.2.7.5 Navigate to the Maintenance menu and proceed through the WinCE application, the measurement system firmware, and the configuration files menus to check for the latest versions. Follow the onscreen instructions to completion, if updates are needed.
 - 5.2.7.5.1 The external USB drive utilized for external data storage may now be removed.
 - 5.2.7.6 Reboot the instrument and return the settings to their preupdate conditions.
 - 5.2.7.7 Perform cylinder changes as necessary to set the performance verification standard target values at their needed evidential levels for calibration.
- 5.2.8 Other Maintenance:
 - 5.2.8.1 At times, the analyst may employ different techniques to attempt to bring the unit into compliance with the ISPFS testing standards. These may not be listed within the manual, but the analyst should utilize their training and experience to perform maintenance on the unit.
 - 5.2.8.2 All symptoms and status messages associated with the issue shall be documented on the maintenance worksheet(s).
 - 5.2.8.3 Any communications made with the agency about history of instrument or made with the manufacturer about technical assistance issues to help resolve the issue shall be documented on the maintenance worksheet(s).

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- 5.2.8.4 A summary of the maintenance performed on the instrument and the steps taken to bring the unit back into conformance with the calibration standards shall be documented on the maintenance worksheet(s).
- 5.2.8.5 All testing results obtained during maintenance shall also be included in the records/summary of the maintenance.

5.3 Documentation

- 5.3.1 Approval Documentation
- 5.3.1.1 When placing the instrument back into service, it will first need to go through the calibration procedure and meet the ISPFS criteria for evidential testing. The maintenance that was performed on the unit will be recorded on the maintenance form and attached to the instrument in the LIMS.
- 5.3.2 Rejection Documentation
 - 5.3.2.1 Should the instrument fail the laboratory's maintenance attempt to return it so acceptable performance, the service will be documented on the maintenance form and attached in the LIMS.
- 5.3.2.2 The instrument should then be returned to the owning agency, to be returned to the manufacturer for service. ISPFS may, in coordination with the owning agency, return the instrument directly to the manufacturer for the required service.