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August 4, 2023

Washington Association of Prosecuting Attorneys
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Subject: Draeger Alcotest 9510 Software Update

On July 6, 2023, the State Toxicologist approved an update to the software employed by the State's currently deployed evidential breath test instrument, the Draeger Alcotest 9510. The software approval was based on the culmination of work completed by the Breath Test Program and their vendor, Draeger Safety Diagnostics International (DSDI). No changes to the instrument's metrological functions or algorithms were requested and the vendor has provided documentation stating that none were made.

The Breath Test Program is providing the attached document which provides an overview of the changes made to the software the timeline of work, and final approvals. Breath Test Technicians will be updating breath test instruments over one (non-calendar) year.

If additional information is needed, please contact the Impaired Driving Section.

Sincerely,

Lieutenant Jeffrey N. Leonard
Impaired Driving Section

JNL: kna
Enclosure

TO: Lieutenant Jeffrey Leonard, Impaired Driving Section

FROM: Sergeant Susan Harbour, Impaired Driving Section

SUBJECT: Draeger Software Validation

DATE: June 26, 2023

Since the last software update, finalized in 2017, the Washington State Patrol Impaired Driving Section (WSP IDS) identified a need to revise the software employed by the evidential breath test instrument known as the Draeger Alcotest 9510. The requested modifications were cumulative over time and intended to address various user enhancements as well as one legislative change. The requested functionality changes do not affect the instrument's metrological functions or algorithms.

The software approved in February, 2017 from which the new versions were created contained the following components:

- WinCE: 8322797 version 5.11
- M16: 8322798 version 0.9
- Config: 8322796 2.7

The user enhancements included how the instrument handles specific data entry for the observation time, restricting the allowable observation time to a two-hour window preceding the current time displayed on the instrument. Other enhancements include the ability to scan American Association of Motor Vehicle Administrators (AAMVA)-compliant driver licenses and identification cards, addition of a gender X option, and the removal of a default selection for "Subject Ethnic Group." Additional modifications addressed technician processes and how the instrument responds to certain status codes. The legislative change refers to the repeal of 9A.72.085 RCW Perjury and Interference with Official Proceedings/ Unsworn statements, certification-Standards for subscribing to an unsworn statement. The reference to the RCW is no longer on the printed breath test documents.

The following is a synopsis of the changes requested and the work accomplished, including a timeline of events. Attached are additional documents supporting the acceptance of the proposed software version and are offered as exhibits.

On June 29, 2021 Draeger Safety Diagnostics International (DSDI) submitted a software package for validation. The software was delivered in response to a software change order from the WSP IDS. The software revisions were requested to address nine (9) identified areas for improvement. Three (3) additional requests were made during the validation procedure and two (2) of those requests were implemented in the final version of the software. The list of changes is contained in the "Washington State Patrol Alcotest 9510 Functionality Modification List." Validation was performed via a Quality Assurance Procedure (QAP) and by independently verifying that requested changes were delivered.

The software package delivered on June 29, 2021 contained the following components:
- WinCE: 8322797 version 5.12
- M16: 8322798 version 1.0
- Config: 8322796 2.8

On July 22, 2021, four technicians were provided with instructions regarding the installation and testing of the software. Worksheets were provided to record the results. The software was installed on four instruments: ARAH-0094, AREH-0024, ARJN-0047, and ARKA-0043.

Trooper Justin Rumsey performed the QAP and validation on instrument ARAH-0094; Trooper John Axtman performed the QAP and validation on instrument AREH-0024; Forensic Scientist Ruth Cramer performed the QAP and validation on instrument ARJN-0047; Trooper Mike Qunell performed the QAP and validation on instrument ARKA-0043.

When testing the allowable observation times, all four instruments allowed entries outside of the expected two-hour window prior to the current time on the instrument. In addition, contrary to what was requested, all four instruments listed measurement procedure options which do not generate printouts. The software package was therefore rejected. Draeger was notified and revised software was requested.

On September 27, 2021 DSDI submitted new versions of software for validation. Validation was once again performed via a QAP and by independently verifying that requested changes were delivered, if not addressed through the QAP.

The revised software package contained the following components:
- WinCE: 8322797 version 5.13
- M16: 8322798 version 1.0
- Config: 8322796 2.9

The software was installed on four instruments: ARAH-0094, AREH-0023, ARJN-0047, and ARKC-0022.

Trooper Rumsey performed the QAP and validation on instrument ARAH-0094; Trooper Axtman performed the QAP and validation on instrument AREH-0023; Forensic Scientist Cramer performed the QAP and validation on instrument ARJN-0047; Trooper Qunell performed the QAP and validation on instrument ARKC-0022.

Supplemental validation was performed by Trooper Qunell, Trooper Rumsey, and Trooper Axtman to further validate how the instrument handles specific data entry for the observation time. Supplemental validation was also performed by Trooper Qunell and Trooper Rumsey specifically to validate instrument functioning when a disabling code is followed by a non-disabling code.

During additional testing of the disabling algorithm, it was noted that the instrument did not put itself out of service when a CAL GAS SUPPLY Status Code 3 was encountered. The software package was therefore rejected. Draeger was notified and revised software was requested.

Prior to November 6, 2022, the Washington Administrative Code (WAC 448-16-060) indicated the mean of the four breath samples would be rounded to four decimal places when determining agreement of duplicate breath samples. The algorithm employed by the Draeger truncates the mean. The WSP IDS requested a change to the Draeger's algorithm to reconcile the two methods. Revised software (WinCE: 8322797 version 5.13 - M16: 8322798 version 1.1 - Config: 8322796 3.0) was made available on August 9, 2022.

This version of the software was never accepted, downloaded, viewed, installed, nor tested. The decision was made to revise the WAC to coincide with the algorithm employed by the Draeger software installed on evidential instruments currently in use in Washington State. The change to the WAC was effective November 6, 2022. Draeger revised the software to revert the algorithm employed to verify agreement of duplicate breath samples back to the original method of truncating the mean and included a change to correct the handling of Status Code 3.

The revised software package delivered on September 23, 2022 contained the following components:
- WinCE: 8322797 version 5.13
- M16: 8322798 version 1.2
- Config: 8322796 3.0

The software was installed on six instruments: ARAF-0010, ARAH-0094, ARKA-0041, ARKB-0012, ARKC-0022, and ARKD-0019.

Trooper Darren Wilkes performed the QAP and validation on instrument ARAF-0010; Trooper Justin Rumsey performed the QAP and validation on instrument ARAH-0094; Trooper Chris Hooper performed the QAP and validation on instrument ARKA-0041; Forensic Scientist Shelley Benante performed the QAP and validation on instrument ARKB-0012; Trooper Mike Qunell performed the QAP and validation on instrument ARKC-0022; Trooper Kyle Dahl performed the QAP and validation on instrument ARKD-0019.

During testing of functionality request two listed below, the instruments automatically generated printed documents for CAL GAS SUPPLY Status Code 3, EXT. STANDARD FAILED Status Code 21, and CHECK AIRWAY Status Code 40. In addition, with the addition of the gender X option, the gender was by default "Male." The software was therefore rejected. Draeger was notified and revised software was requested to address the unexpected printing and default settings for both gender and ethnicity selections.

Revised software delivered on November 11, 2022 contained the following components:
- WinCE: 8322797 version 5.14
- M16: 8322798 version 1.2
- Config: 8322796 3.1

The software was initially installed on one instrument (ARKA-0019). A QAP and testing was performed by Forensic Scientist Shelley Benante. Minor modifications and clarifications were made to the validation procedure and technician worksheets. The instrument performed as expected.

The software was then installed on six instruments (ARAF-0010, AREH-0024, ARKA-0072, ARKC-0022, ARKD-0019, and ARJN-0023) and testing was performed by pairs of technicians:
- Trooper Darren Wilkes and Sergeant Pedro Zepeda performed the QAP and validation on instrument ARAF-0010.
- Trooper John Axtman and Trooper Justin Rumsey performed the QAP and validation on instrument AREH-0024.
- Trooper Chris Hooper and Trooper Tanya Wright performed the QAP and validation on instrument ARKA-0072.
- Forensic Scientist Ruth Cramer and Trooper Mike Qunell performed the QAP and validation on instrument ARKC-0022.
- Trooper Kyle Dahl and Trooper Nate Dashiell performed the QAP and validation on instrument ARKD-0019.
- Sergeant Susan Harbour and Trooper Kate LeCount performed the QAP and validation on instrument ARJN-0023.

The instrument performed as expected.

Each requested modification is noted in the "Washington State Patrol Alcotest 9510 Functionality Modification List" documents. A summary and the validation of all changes follows:

1. The parsing functionality was to be modified to support reading Driver Licenses with barcode encoding that comply with the AAMVA DL/ID Card Design Standard from 2020. During data entry, technicians scanned versions of Washington State, Oregon, New York, and Idaho Driver's Licenses. Technicians verified the gender option was correctly identified, verified all data could be altered by the operator, and verified polled data is correct. The change reflects what was requested.

2. A change was requested to modify the manner in which the instrument handles a disabling status code followed by a non-disabling status code. The disabling algorithm is designed to place the instrument out of service based on specific status codes. This change request ensures the instrument is placed out of service if a "disabling" status code is recorded even if a "non-disabling" status code occurs subsequently. After a status code is generated in measurement procedure 1 (Evidential Breath Test) or 2 (Training Breath Test), status codes

generated subsequent to data-logging and prior the conditional disabling algorithm will no longer prevent the instrument from exposing the original status code to the conditional disabling algorithm. The technicians tested the disabling algorithm by eliciting a non-disabling status code after a disabling status code was recorded and verified that the instrument places itself out of service. The change reflects what was requested.

3. The requested change would allow the technician to select a specific cylinder during a Supervisor Test. The instrument will respond to input from "Gas Inlet" section in the dialog settings screen, instead of input setting from the "Set Cylinder" function. The technicians verified the active cylinder was 1 (then 2). The technicians set up to run a Supervisor Test and selected cylinder to 2 (then 1) then ran a supervisory test to determine the selected cylinder is accessed during the Supervisor Test. The change reflects what was requested.

4. The requested change was for the removal of all measurement procedure options which do not generate printouts from the Reprint function "Database type" drop-down selection list. The technicians verified the identified measurement options were no longer in the drop-down selection list. The change reflects what was requested.

5. The requested change was to insert one extra vertical line feed between "Officer Signature" line and "Location Signed" line on the Evidential Test external printout. The technicians verified the requested spacing is present on the breath test document.

6. The requested change was to modify the instrument functionality in measurement procedure 1 (Evidential Breath Test) and 2 (Training Breath Test) so instrument displays observation countdown timer when the entered observation start time is between 0 and 15 minutes prior to the current instrument time. The technicians tested several time scenarios to verify a countdown timer was triggered when the observation start time is between 0 and 15 minutes inclusive prior to the displayed time on the instrument. The allowable observation time entry is also restricted to a two-hour window prior to the current time displayed on the instrument. The technicians tested several scenarios to verify the restriction. The technicians verified the instrument performed as expected and the change reflects what was requested.

7. The requested change was for the instrument functionality to be modified in the Reprint menu option. When a search list is populated and a selection is made, the instrument will display a simplified feedback screen. The simplified feedback screen will contain information (including subject last name, subject DOB, and operator last name) for the operator to know that the desired record was selected from the search list. Technicians verified abbreviated information is displayed on the "Reprint screen" after selecting a record to be reprinted and verified the selected document corresponds to the selected

record. The change reflects what was requested.

8. The requested change was to modify the signature block of the Breath Test Document generated by the instrument system during measurement procedure 1 (Evidential Breath Test) or 2 (Training Breath Test) to include an updated Penalty of Perjury Statement and remove the RCW reference. The technicians verified each breath test document has the following penalty of perjury statement and signature block:

>   *I declare under penalty of perjury under the law of Washington that the foregoing is true and correct.*
>
>   Officer Signature _____
>
>   Printed Name _____
>
>   Date _____ Location: City/State _____

The change reflects what was requested.

9. The requested change was for the instrument functionality to be modified so that during manual data entry for Subject Gender, a third gender option is available and no selection is indicated by default. This would be reflected as an "X" in the display, data entry, and data storage of the Subject Gender. Technician verified three gender options were present during data entry and the proper data transmitted during polling. The change reflects what was requested.

10. The requested change was for the instrument functionality to be modified so that the instrument places itself out of service when a CAL GAS SUPPLY Status Code 3 was encountered. The technicians forced the instrument to encounter a Status Code 3 and verified the instrument would place itself out of service in the Evidential Mode. The change reflects what was requested.

11. A request was made to change how the instrument determines sample agreement. The software version implementing this change was not accepted nor tested. The request was made to revert back to the original method of determining sample agreement (truncating the mean of all four results). Draeger engineers verified the proper functioning of the algorithm.

12. While testing software at the Draeger facility, Draeger engineers allowed for printouts to be automatically generated for results other than a Refusal, an Incomplete, or Complete Breath Test. A request was made to automatically generate a document only in the case of a Refusal, an Incomplete or a Complete Breath Test. During the software validation,

technicians monitored the automated printing. The change reflects what was requested.

13. The requested change was for the instrument functionality to be modified so that no selection is indicated by default for "Gender." The technician verified no selection is indicated by default. The change reflects what was requested.

14. The requested change was for the instrument functionality to be modified so that no selection is indicated by default for "Subject Ethnic Group." The technician verified no selection is indicated by default. The change reflects what was requested.

Each of the attached listed changes in this software version performed as expected. The instruments displayed data as expected when polled.

Based on the results of the validation procedure, I recommend the software package containing the following components:
- WinCE: 8322797 version 5.14
- M16: 8322798 version 1.2
- Config: 8322796 3.1

be approved for deployment in all Draeger Alcotest 9510 instruments in Washington State.

The manufacturer has provided documentation regarding the changes requested and implemented. Draeger also provided documentation attesting that the analytical properties of the instrument have not changed due to the software modifications.

Attachment

I have reviewed the software validation documents and recommend approval

6/26/2023

Reviewed + approval recommended
QB 6·27·2023

I have reviewed validation/GAP documents (Software Validation Notebook 2f, dated 06/22/2023) and this summary IOC. The following software versions are approved for use and deployment in all Draeger Alcotest 9510 instruments in Washington State: WinCE 8322797 version 5.14, M16 8322798 version 1.2, and Config 8322796 version 3.1.

Approved 7·6·2023   FIONA COUPER, State Toxicologist