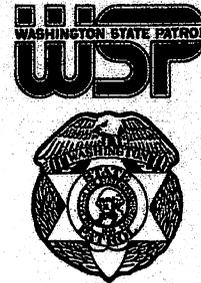


# INTEROFFICE COMMUNICATION

## WASHINGTON STATE PATROL



**TO:** Lieutenant Robert W. Sharpe, Impaired Driving Section  
**FROM:** Sergeant Clark G. Jones, Impaired Driving Section  
**SUBJECT:** Draeger Software Approval  
**DATE:** February 9, 2017      **FILE:**

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On December 21, 2016 Draeger Safety Diagnostics International (DSDI) submitted three new versions of software for validation. The new versions of software were delivered in response to a software change order from the Washington State Patrol. The software revisions were requested to address 19 identified areas for improvement. 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, if not addressed through the QAP.

The software delivered on December 21, 2016 contained three revised software versions:

- WinCE: 8322797 version 5.7
- M16: 8322798 version 0.9
- Config: 8322796 version 2.5

The software was installed on four instruments: ARAF-0030, ARZB-0005, ARJH-0005, and ARJH-0006.

Trooper Hintz performed the validation on instruments ARAF-0030 and ARZB-0005 and Trooper VanDiest performed the validation on instruments ARJH-0005 and ARJH-0006.

When performing the "As Found" test Troopers VanDiest and Hintz discovered the external standard on the printed evidential document, on all four instruments, was 0.000 rather than 0.08 as expected. Trooper VanDiest stopped testing at this point. Trooper Hintz continued testing and noted that he was also unable to enter "00" for the county code or "00-00-0000" for a subject's date of birth, When the instruments were polled some of the polling rules were violated and the polled fields were not properly represented in the database. This software version was rejected. We notified Draeger of the errors and requested revised software.

Revised software was delivered on January 9, 2017. This revision contained two new software versions. The versions are as follows:

- WinCE: 8322797 version 5.8
- M16 8322798 version 0.9
- Config: 8922796 version 2.7



Lieutenant Robert W. Sharpe  
Page 2  
February 9, 2017

This software was installed on four instruments: ARAF-0030, ARZB-0005, ARJH-0005, and ARJH-0006.

Trooper Cam Birman performed the validation procedure on instruments ARJH-0005 and ARJH-0006. Trooper Hintz performed the validation on instruments ARZB-0005 and ARAF-0030. While working through the QAPs it was noted that the technician name was truncated at five characters. It was also noted that the "00" for county code and the "00-00-0000" was still not allowed. Additionally, there was still an issue with the instruments polling. I spoke with DSDI regarding the issues. It was determined that the "00" for county code would be populated in the data set when a technician just leaves the field blank. It was also determined that because of the rules put in place by Microsoft in the Windows CE operating system entering a birthdate of "00-00-000" would not be possible. I informed DSDI that we were satisfied having the blank field for the county code, as long as the data was represented as "00" when polled and that we would forgo the birth date change. The truncated technician name was not satisfactory. This software version was rejected. Draeger was notified of the errors and we requested a new software revision.

Revised software was delivered on January 12, 2017. The revision contained one new software version. The versions are as follows:

- WinCE: 8322797 version 5.9
- M16: 8322798 version 0.9
- Config: 8322796 version 2.7

This software was installed on four instruments: ARAF-0030, ARZB-0005, ARJH-0005, and ARJH-0006.

Trooper Hintz performed the software validation procedures on instruments ARAF-0030 and ARZB-0005. Trooper VanDiest began the procedures on ARJH-0005 and ARJH-0006. While performing the complete breath test step of the QAP three of the four instruments encountered a "Fatal Applications Error" reading, "Application a9510.exe has performed an illegal operation and will shut down. If the problem persists, contact program vendor. Program a9510.exe, Exception: 0x00000005, Address:0003E470." The affected instruments locked up and had to be powered off. This software version was rejected. Draeger was notified of the error and we requested a new software revision.

Revised software was delivered on January 18, 2017. The revision contained one new software version. The versions are as follows:

- WinCE: 8322797 version 5.10
- M16: 8322798 version 0.9
- Config: 8322796 version 2.7

The software was installed on four instruments: ARAF-0030, ARZB-0005, ARBE-0087 and ARJH-0006. Trooper Hintz performed the Quality Assurance Procedures on ARAF-0030 and ARZB-0005. Trooper Birman performed the Quality Assurance Procedures on ARBE-0087 and ARJH-0006. Trooper Hintz completed the software change validation on instruments ARAF-0030 and ARZB-0005. Trooper Birman completed the validation on ARJH-0006 and Trooper VanDiest completed the validation on ARBE-0087.

Each of the 20 criteria are noted in the "Washington State Patrol Alcotest 9510 Functionality Modification List" document. They are also noted in each of the "Draeger Alcotest 9510 Software Validation" worksheets. A summary of the changes and the validation of the changes follows:

1. The requested change directs that a cylinder change not reset the QAP date in the instrument, as it had previously been doing. The step was performed after the QAP had been done on all four instruments. At least one calendar day after the QAP was performed the technicians performed a cylinder change. After a cylinder change was performed on all four instruments the instruments reflected the correct QAP due date. This change reflects what was requested and it was verified as acceptable during testing.
2. This change requested the ability to print a supervisory test on the external printer, rather than the internal printer. The technicians performed four supervisory tests and the test results were printed on the external printer. This change reflects what was requested and it was verified as acceptable during testing.
3. This change requested the "shutdown" button be moved from the main screen. On all four instruments the "shutdown" button was moved to a menu, and once pressed it prompts a message advising that the instrument requires WSP authorization to shut down. This change reflects what was requested and it was verified as acceptable during testing.
4. This change requested a 15 minute observation period default be added to the training mode. The prior iteration would allow a user to "power cycle" in the training mode and all defaults would restore to the evidential mode except the 15 minute observation period. After switching between training and evidential modes on all four instruments the instruments retained the default 15 minute observation time. This change reflects what was requested and it was verified as acceptable during testing.
5. This request seeks to have the race field mirror that which is currently in our DataMaster instruments, removing "African American" and leaving "Black" as an option. During a complete breath test on all four instruments the race options were "White", "Black", "Asian", "East Indian", "Native American", "Hispanic",

- “Pacific Islander”, and “Other”. “African American” has been removed from the list. This change reflects what was requested and it was verified as acceptable during testing.
6. This change requests the removal of the option of entering alpha characters into the “PBT Results” field. The technicians tried populating the “PBT Results” field with alpha characters. The instruments wouldn’t allow alpha characters. This change reflects what was requested and it was verified as acceptable during testing.
  7. This change reflected our desire to populate the county code field with “00”. DSDI created a blank field that doesn’t show “00” on the instruments but does show “00” when the instruments were polled. This change reflects what was requested and it was verified as acceptable during testing.
  8. This request seeks an optimization of the drinking location code search process. With the change in place technicians were able to enter partial names and counties and the instruments showed corresponding drinking locations. This change reflects what was requested and it was verified as acceptable during testing.
  9. This change optimizes the “reprint” function to make it more intuitive. When the “reprint” function is selected the instrument now displays “database type” and “search text only”. The “preview” mode has been removed. This change reflects what was requested and it was verified as acceptable during testing.
  10. This change allows the scanning of driver’s licenses when “Scan DL/Operator card” is displayed. This function worked as expected on all four instruments. This change reflects what was requested and it was verified as acceptable during testing.
  11. This change requested the colon (: ) on the virtual keyboard be replaced with an asterisk (\*). This change reflects what was requested and it was verified as acceptable during testing.
  12. This request was to optimize the refusal process and eliminate the countdown timer. On all four instruments, when a refusal was selected, the instrument proceeded immediately with the refusal. This change reflects what was requested and it was verified as acceptable during testing.
  13. This change reflected our desire to have the instrument show tests in the “reprint” function in order of last test performed to oldest test in the instrument storage. On all four instruments the tests were displayed in chronological order from last test run to the oldest test. This change reflects what was requested and it was verified as acceptable during testing.
  14. This change requested the ambient fail threshold be set to .005. There was no way for the technicians to introduce ambient air at a .005 threshold. They were however able to induce an ambient fail using hand sanitizer (ethanol) on all four instruments. The instruments then displayed the appropriate ambient fail

- message. This change reflects what was requested and it was verified as acceptable during testing.
15. This change reflects our desire to have the default number of external printouts set to two. The technicians set the number of printouts to one on all four instruments, turned off the instruments, and then powered on the instruments. Each of the instruments printed out two copies, when prompted. This change reflects what was requested and it was verified as acceptable during testing.
  16. This change increased the purge time. After a purge time each of the four instruments successfully produced blank samples. This change reflects what was requested and it was verified as acceptable during testing.
  17. This change requested adding the option for technicians to access the "Int-t" function of the instrument to assess fuel cell performance. All four instruments allowed technicians to access this function. This change reflects what was requested and it was verified as acceptable during testing.
  18. This change requested the "S" and "W" season codes be removed from the instrument for the sake of polling data. All four instruments were polled and the polled data showed no seasonal codes. This change reflects what was requested and it was verified as acceptable during testing.
  19. This change reflected our desire to display "Operator Certification is Expired" instead of an "X" when an expired operator attempted to run a test. The technicians attempted to run a test on all four instruments using an expired operator card. All four displayed the desired message. This change reflects what was requested and it was verified as acceptable during testing.
  20. This change optimizes the algorithm when switching from Daylight Savings Time to Standard Time and vice versa. It wasn't possible to test this change during the validation procedure. This change reflects what was requested and it was verified as acceptable during testing.

Each of the listed changes in this software version performed as expected. The instruments displayed data as expected when polled. Based on the observed changes in this validation procedure I recommend WinCE: 8322797 version 5.10, M16: 8322798 version 0.9 and Config: 8322796 version 2.7 be approved for deployment in all Draeger Alcotest 9510 instruments in Washington State.

The manufacturer has provided written documentation indicating that the analytical properties of the instrument have not changed due to the software modifications.

On January 31, 2017 DSDI notified the WSP Impaired Driving Section that they discovered an issue with the new coding for the transition from daylight saving

time to standard time and vice versa. DSDI provided a new version of software for evaluation. The versions are as follows:

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

The software was installed on four instruments: ARJH-0006, ARBE-0087, ARAF-0030 and ARZB-0005. Trooper Cam Birman completed the validation on ARJH-0006 and ARBE-0087. Trooper Dave Hintz completed the validation on ARAF-0030 and ARZB-0005.

The items to be validated are listed in the attached "Washington State Patrol Alcotest 9510 Functionality Modification List". Items 1-19 tested exactly the same as the previous iteration. Item number 20 was the only change in this modification. It worked as expected. Troopers Birman and Hintz induced the time change by manually adjusting the instrument clock and date. The time change was observed for standard time and daylight saving time.

Each of the listed changes in this software version performed as expected. The instruments displayed data as expected when polled. Based on the observed changes in this validation procedure I recommend WinCE: 8322797 version 5.11, M16: 8322798 version 0.9 and Config: 8322796 version 2.7 be approved for deployment in all Draeger Alcotest 9510 instruments in Washington State.

The manufacturer has provided written documentation indicating that the analytical properties of the instrument have not changed due to the software modifications.

Correction -  
WinCE: 8322797 version 5.11  
is approved (and not version  
5.10). FC 2-24-17

CGJ/cgj  
Attachments (2)

I HAVE REVIEWED THE SOFTWARE VALIDATION  
DOCUMENTS AND RECOMMEND APPROVAL  
FORWARD TO QA MANAGER.  2-10-17

I have reviewed the validation documentation and  
recommend approval of this version of the software (latest  
version).  2/21/17

I have reviewed all the validation/GAP documents and the summary  
IOC's. The following software versions are approved for use and deployment  
in all Draeger Alcotest 9510 instruments in WA State: WinCE: 8322797  
version 5.10<sup>FC 2-24-17</sup>, M16: 8322798 version 0.9, and Config: 8322796 version  
2.7.  State Toxicologist, dated 2-24-17.