

April 26, 2018

Matthew Gamette Idaho State Police Forensic Services 700 South Stratford Drive Suite 125 Meridian Idaho 83642

RE: Dräger Alcotest® 9510 Instrument Modification

Dear Mr. Gamette,

Kindly please be notified that Dräger has instituted modifications in the production of the Alcotest® 9510. These modifications do not affect the functionality of the Alcotest® 9510 for any applications in the United States, including the State of Idaho.

Beginning with instruments with date code ARKH (July 2017) and later, the following modifications were implemented to the Alcotest® 9510:

- 1. The production facility has changed its solder type. All manual and automatic solder processes are now done with lead-free solder. No changes to the printed circuit board (PCB) were required.
- 2. The PCB is populated with two flow sensors (dual pressure sensor) as opposed to just one. The second flow sensor is required for a few international evidentiary breath alcohol testing (EBT) applications. No changes to the PCB are required since the layout design already allowed placement of the second flow sensor.
- 3. The instrument liquid crystal display has been replaced due to obsolescence. The successor display is from the same manufacturer, has the same mechanical dimensions, and doesn't require any changes to the software.
- 4. Since the new display no longer requires the high voltage module for backlighting, this module is no longer installed in the instrument.
- 5. The bracket for the power supply received a small mechanical modification which allows easier installation of the "glass ethanol reservoir" utilized in a few foreign EBT applications. This ethanol reservoir is not used or installed in United States applications.
- 6. The instrument's WinCE-Image operating system was updated from version 1.6 to version 1.8. No other software changes were necessary.

Draeger, Inc. 1221 S. Beltline Rd., Suite 700 Coppell, TX 75019 Tel +1 972 929-1100



Dräger notified the National Highway Traffic Safety Administration (NHTSA) of these instrument modifications in August, 2017. None of these modifications have any impact on the analytical or metrological functionality of the Alcotest® 9510 in the United States. As confirmation, the NHTSA Volpe Transportation Systems Center received and evaluated an Alcotest® 9510 instrument with the above-listed modifications. In the same way that this device had previously been found to meet the model specifications for EBTs, NHTSA confirmed the Alcotest® 9510 continues to meet the model specifications for EBTs and will continue to be included on the Conforming Products List for EBTs.

This will have no operational impact on your EBT program. The only observable difference is that your technicians may visibly notice some of the above-listed modifications while examining the interior of instruments from date code ARKH and newer, as well as on instruments with repairs affecting the main PCB or display as of the date of this letter and following.

We appreciate your understanding in this process. As always, please let us know how we can support you.

Kind Regards,

Brian Shaffer

Technical Specialist

Encl: Letter from Dr. Randolph Atkins, NHTSA, to Hansueli Ryser, Dräger, dated April 12, 2018





National Highway Traffic Safety Administration

APR 1 2 2018

Hansueli Ryser, Vice President Draeger Safety, Inc. 4040 W. Royal Lane Suite 136 Irving, TX 75063

Dear Mr. Ryser:

This letter confirms that Draeger Safety, Inc. submitted the **Alcotest 9510** evidentiary breath alcohol testing device (EBT) to be evaluated by the Volpe Transportation Systems Center. This device had previously been found to meet the model specifications for EBT devices, and had been included on the conforming products list (CPL) for EBTs. On August 16, 2017, Draeger Safety, Inc. notified NHTSA of the following changes on its device:

- Solder type changed to lead-free solder
- Second sensor added to PCB (not utilized in US applications)
- New LC-Display (the old LCD became obsolete)
- Removal of high-voltage module (was needed with old LCD)
- Modified support bracket for ethanol reservoir for easier installation (this reservoir is not utilized in the US)
- Update Windows CE from version 1.6 to 1.8

This device was evaluated by Volpe. Test data confirmed that these changes had no effect on precision and accuracy. The **Alcotest 9510** was found to meet the model specifications for evidential breath testing devices (EBTs) and will continue to be included on the Conforming Products List (CPL) for EBTs. Enclosed for your convenience is a copy of the test report.

In order for this device to be used as a breath alcohol measuring instrument by workers in the U.S. Department of Transportation workplace testing program, a quality assurance plan (QAP) must be approved by NHTSA, as required by 49 CFR Part 40, "Procedures for Transportation Drug and Alcohol Testing Program" (59 FR 7340). The QAP requires users to calibrate your equipment following your device's instructions, and the instructions provided by the manufacturer of a calibrating unit listed on the CPL for calibrating units. We have reviewed the Quality Assurance Plan (QAP) dated April 11, 2018 for the **Alcotest 9510** breath alcohol testing (EBT) device, submitted in response to 49 CFR Part 40, and we are pleased to inform you that this submission has been approved.

We will place the QAP on file at NHTSA, together with a copy of this letter for interested agencies. A copy will also be provided to the U.S. Department of Transportation Office of Drug and Alcohol Policy and Compliance for their records.

Please be advised that this office is to be notified immediately of any revisions or modifications to the device or the QAP.

If you require further assistance or have any questions regarding NHTSA's quality assurance program in relation to 49 CFR Part 40, please do not hesitate to contact me at 202-366-5597.

Sincerely

Randolph Atkins, Ph.D. Social Science Researcher

Enclosure

CC: Patrice Kelly, OST

Edward Conde, Volpe