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CHAPTER 1
OVERVIEW

NOTE: The terms Nerve Agent Antidote Delivery System, Multichamber Autoinjector, and Antidote Treatment - Nerve Agent, Autoinjector (ATNAA) used in this report are synonymous.

1.1 PURPOSE. The US Army Medical Department Board (USAMEDDBD) conducted an Initial Operational Test II (IOT II) of the Chemically Hardened Pouch (CHP) during the months of May through July 2001. The purpose of the IOT II was to provide data to assess the durability of two redesigned versions of the CHP (see paragraph 2.1 for background information). The results of this IOT II will be used to support a Milestone In-Process Review for a fielding decision.

1.2 SYSTEM DESCRIPTION. The two versions of CHP included in this IOT II differ only by the types of inks used during the reverse printing process.

1.2.1 The CHPs are fabricated using a 48-gauge polyester film reverse printed with an amber flood coat and a double-coated black underlay area. Devices labeled WBI-1 through WBI-450 are reverse printed using water-based inks, while devices labeled SBI-451 through SBI-900 are reverse printed using solvent-based inks. This is then laminated with an adhesive to a 60-gauge Biaxially Oriented Mylon material. These, in turn, are laminated with an adhesive to a 4-millimeter-density polyethylene modified with a 3-percent ethylvinlacetate material. The 48-gauge polyester film is also imprinted in black on one side with the words "TEAR OPEN AT ANY NOTCH."

1.2.2 The amber ink extends the entire length of the CHP, and the double-coated black underlay area extends 6.5 centimeters (cm) from one end of the package. This provides a light-blocking feature required to protect the atropine from visible and ultraviolet light. It was necessary to include these light-blocking features in the packaging when light exposure studies, performed in accordance with the International Conference of Harmonization, revealed the formation of impurities in the atropine solution. The formulation of these impurities is eliminated or reduced more cost effectively by using the light-blocking feature described above.

1.2.3 In final form, the CHP is constructed of two laminated sheets that are heat sealed on the external margins, approximately 1 cm wide. The outside dimensions are approximately 20 cm in length and 8.5 cm in width. The sealed CHP has reduced interior dimensions of approximately 17 cm by 6 cm.

1.3 TEST CONDUCT.

1.3.1 The IOT II placed emphasis on the field-time durability of the two redesigned versions of the CHP over a minimum of a 30-man-day period. Elements of a Light Infantry Division and an Army National Guard Forward Support Medical Company provided support for this IOT II. Testing was conducted at the Joint Readiness Training Center (JRTC), Fort Polk, Louisiana, and the National Training Center (NTC), Fort Irwin, California.

1.3.2 At the completion of 30-days accumulated time in a field environment, the CHP were visually inspected for signs of failure (holes, tears, or delamination). Details and results of the IOT II are addressed in Chapter 3, Test Results.

1.4 MAJOR RESULTS.

1.4.1 The IOT II addressed one Critical Operational Issue (COI) and two Criteria. The COI was not met.

1.4.2 Neither the solvent-based nor the water-based CHP test articles met the 5 percent or less failure rate. Of the 300 water-based CHP test articles, 268 accumulated at least 30 days of field time and 32 were not deployed. Sixty-five of the 268 exhibited failures, resulting in a 24-percent failure rate. Of the 300 solvent-based CHP test articles, 218 were subjected to at least 30 days of field time and 82 were not deployed. Fifty-nine of the 218 exhibited failures (holes, tears, or delamination), resulting in a 27-percent failure rate. If the 32 water-based and 82 solvent-based CHPs had been deployed and exhibited no failures, the failure rate would have been 20 and 22 percent, respectively.

1.5 RECOMMENDATIONS. Based on this IOT, recommend further studies to find a more durable, CHP that will survive being carried by soldiers in the field for a minimum of 30 days. When a new CHP is developed, a Developmental Test should be conducted to verify that the new packaging durability meets the requirements set forth in the Operational Requirements Document. The new CHP should be retested after the Developmental Test for a minimum of 30 days in an operational environment.

CHAPTER 2
TEST DESCRIPTION

2.1 BACKGROUND. The USAMEDDBD conducted an IOT of the Nerve Agent Antidote Delivery System during the period October 1999 through July 2000 (USAMEDDBD Project 11-99). A Test Report of that event was published in October 2000. As reported, the devices met all the requirements identified in the Operational Requirements Document dated 15 March 1999 with the exception of the CHP, which experienced a failure (holes, tears, or delamination) rate greater than 5 percent. Consequently, the manufacturer developed two versions of the CHP that are the test articles addressed in this report.

2.2 TEST METHODOLOGY.

2.2.1 The USAMEDDBD Test Team issued three CHPs/ATNAAs and one Convulsant Antidote for Nerve Agent test article to individual soldiers prior to their training exercise. The soldiers were instructed to place the devices in their protective mask carrier where they remained for the duration of the exercise. Soldiers were instructed to turn in the injectors to their immediate supervisors if the devices malfunctioned during the field exercise. At the end of the exercise, the test articles were returned and inspected for any damage by the Test Team. The USAMEDDBD personnel were not permitted access to the soldiers or the field-training site during the JRTC or NTC exercises. The test devices were recovered at the end of the exercises and returned to Fort Sam Houston, Texas, where they were visually inspected for signs of failure.

2.2.2 Emphasis was placed on the durability of the packaging materiel after the test devices were subjected to a minimum of 30 man-days in a field environment. Elements of a Light Infantry Division and an Army National Guard Forward Medical Company provided support for this event. Testing was conducted in two separate exercises at the JRTC, Fort Polk, Louisiana, and at the NTC, Fort Irwin, California.

2.2.3 The data, used for the evaluation of the CHPs, was obtained after the pouches were visually inspected using a high-intensity halogen lamp and subjected to hot- and cold-water baths. The water-bath process consisted of submerging the CHPs in hot water for 5 minutes to expand the air inside the CHPs. The temperature of the bath ranged from 127 to 134 degrees Fahrenheit. The devices were removed from the hot-water bath and immediately submerged in an 80-degree-Fahrenheit water bath for 1 minute to create a vacuum in the packet. After removal from this bath, the CHPs were dried thoroughly and visually inspected under the light of a high-intensity lamp for signs of moisture inside the CHPs.

2.3 TEST LIMITATIONS AND IMPACTS. The following limitations were present in this IOT:

a. The impact of climatic conditions on the test articles was limited to those conditions actually encountered during the IOT II.

b. USAMEDDBD personnel were not allowed to conduct spot checks of the CHPs during the field training exercises.

c. These limitations did not impact on test results.

CHAPTER 3
TEST RESULTS

3.1 COI 1. Is the Multichamber Autoinjector adequately packaged?

3.1.1 Issue Methodology. The CHP was issued to soldiers who carried them in their protective mask carriers during the field training exercises for a minimum of 30 man-days. The CHPs were inspected for damage before and after each training exercise.

3.1.2 Criterion 1-1. The CHP must be moisture proof as long as the package is not opened or damaged.

Results. (Criterion satisfied) CHPs exhibiting no visible materiel failures remained moisture free after being immersed in hot- and cold-water baths.

3.1.2.2 Analysis and Conclusions. Fifty-six water-based and 56 solvent-based CHPs were individually submersed in the water bath. Moisture was not detected in any of the water-based CHPs; however, six of the solvent-based CHPs did have moisture inside the pouch. These six were visually reinspected using the high intensity lamp, which revealed small holes in the material. The CHPs exhibiting no failures appear to be moisture proof.

3.1.3 Criterion 1-2. The CHP will survive after 30 field man-days of field exercise, as demonstrated by returned units with 5 percent or fewer incidents of failures determined by visual inspection.

3.1.3.1 Results. (Criterion not satisfied) Twenty-four percent (65 out of 268) of the water-based CHPs and 27-percent (59 out of 218) of the solvent-based CHPs exhibited failures after being subjected to a minimum of 30 man-days in a field environment.

3.1.3.2 Analysis and Conclusions. The water-based and solvent-based CHPs exceeded the 5 percent or less failure rate, as specified in the criterion. The criterion was not met.

3.2 TEST OBSERVATIONS. Soldiers' comments did not indicate that there was any difficulty when carrying the ATNAA test article in the protective mask carrier, which is the doctrinally prescribed location.

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ACRONYMS AND ABBREVIATIONS

ATNAA	Antidote Treatment - Nerve Agent, Autoinjector
CHP	Chemically Hardened Pouch
cm	centimeter(s)
COI	Critical Operational Issue
IOT	Initial Operational Test
JRTC	Joint Readiness Training Center
NTC	National Training Center
USAMEDDBD	US Army Medical Department Board

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