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14. ABSTRACT This TOP provides the standard for designing and conducting tests estimating penetration of chemical agent vapor simulant through chemical/biological (CB) individual protective equipment (IPE) suit systems while the suits are worn. Methyl salicylate (MeS) is used to simulate a chemical agent vapor challenge. For the vapor tests, personal sampling devices (PSDs), such as passive adsorbent devices (PAD), are used to monitor chemical concentration inside the IPE suits. Test data are analyzed using a Body Region Hazard Analysis (BRHA) model to provide an indication of the protection levels of the IPE suit systems when exposed to vesicant or nerve chemical agents					
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U.S. ARMY TEST AND EVALUATION COMMAND
TEST OPERATIONS PROCEDURE

*Test Operations Procedure 10-2-022B
DTIC AD No.

20 June 2023

CHEMICAL VAPOR SYSTEM-LEVEL TESTING OF CHEMICAL/BIOLOGICAL
INDIVIDUAL PROTECTIVE EQUIPMENT (IPE) SUITS

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1. SCOPE.

1.1 Purpose.

a. This test operations procedure (TOP) provides the standard process for designing and conducting tests estimating penetration of chemical agent simulant vapor through chemical/biological (CB) Individual Protective Equipment (IPE) suit systems while the suits are worn. Further discussion of the purpose of CB protective suits is in Appendix A.

b. This document describes standard procedures for testing complete IPE suit systems of protective clothing worn by test participants (TPs) when exposed to vaporized, chemical warfare agent (CWA) simulants. These procedures test the entire ensemble, including seams, closures, and interfaces at the ankle, wrist, waist, and neck. This testing is known as man-in-simulant testing (MIST) and uses passive, adsorbent samplers to measure breakthrough concentrations of vaporous simulants at the surface of the skin. Additional procedures are also included to address the use of real-time sensors as the samplers.

c. This document describes the specific or range of test parameters required for this testing. Usually, several tests and particular test parameters must be chosen from among those listed herein. The test parameters chosen for a particular test program may change depending upon objectives.

d. This TOP provides information necessary to plan, conduct, and report CWA simulant vapor testing of CB IPE suits and discusses facilities, equipment, procedures, test and experimental parameters, and data obtained from such testing. This document also provides the procedures for characterizing IPE suit performance as a baseline for quality assurance (QA).

e. This TOP will be used as a guide in preparing program-specific test plans. Procedures described in this document may require tailoring to address the particular purpose and requirements of a specific IPE suit.

f. The test procedures described in this document must be referenced or incorporated into a detailed test plan (DTP) or similar document. The DTP will describe the specific test methods and parameters to be used. These methods and parameters will be based on factors such as the concept of operation requirements and hazards to the IPE suit being tested. The procedures may be modified in the DTP to accommodate unique items and materials, or to satisfy testing requirements specified in the system evaluation plan or other acquisition document. Alterations, however, will be made only after full consideration and coordination with applicable parties (customer, system evaluator, etc.) of how the changes may affect the reliability and validity of the data. These alterations, a description of the effect desired by the change, and the changes in the assessment process must be fully described in the DTP.

1.2 Limitations.

a. Data obtained by these procedures cannot be correlated to specific field conditions.

b. This TOP is limited to approved standards and procedures. Developments in practices, equipment, and analysis may necessitate establishing new testing conditions or baselines. Standards of performance must be adjusted with the development of new technologies.

c. This methodology describes system-level testing using simulants, which may not fully represent the physical behavior of chemical or biological warfare agents of concern. The use of simulants is valid for penetration through interfaces or holes in the IPE suit, but permeation of simulants through different IPE suit materials may not provide a direct correlation to chemical agents. It is recommended that an agent-to-simulant correlation be conducted when new IPE materials are tested. It is recommended to perform vapor challenge/vapor permeation swatch testing with distilled sulfur mustard (HD), soman (GD), sarin (GB), and methyl salicylate (MeS) to measure vapor permeation at the MIST test conditions (100 mg/m³ for 30 min, 3,000 mg•min/m³). This correlation can be used to determine if penetration under MIST test conditions is only through the interfaces or holes in the IPE suit, or if it is from permeation through the material. The permeation correlation testing at these conditions will be helpful to address the differences in simulant versus agent permeation so that better health-based assessments using the correlation data between MeS, HD, GD and GB can be made.

2. FACILITIES AND INSTRUMENTATION.

a. Facilities, instrumentation, and safety procedures used for chemical and biological contamination survivability CWA testing are strictly controlled. Testing with simulants has fewer restrictions.

2.1 Facilities.

<u>Item</u>	<u>Requirement</u>
Test chamber.	The test chamber must be able to prevent simulant vapor contact with the environment, or areas of the facility not intended as exposure areas. The test chamber should be large enough to hold at least two TPs simultaneously. Room for on-floor supervisor (TP monitor), or visual monitoring capabilities should be available. The chamber should have sufficient room for any exercise equipment and prescribed physical activity. The chamber must contain fans capable of providing a stable, uniform airflow directed toward the TPs at a variety of wind speeds from 3.2 to 16.1 km/hr (2 to 10 mph). Chamber temperature must be controlled at 21.1° to 32.2 °C (70° to 90°F) and relative humidity (RH) of 50 to 90 percent.
Dressing/undressing area.	An area, apart from the test chamber that is clear of CWA simulant (clean room area) and large enough to hold at least one (preferably two) TPs and two lab technicians. The Clean Room is required for application and removal of samplers to TPs before dressing and after undressing with the IPE suit. The dressing/ undressing area should

<u>Item</u>	<u>Requirement</u>
	consist of a Clean Room area and a Doffing Room area; preferably in separate room areas. Both must be capable of being monitored for CWA simulant levels during the trials.
Chamber airlock.	A protective entryway between the test chamber and other test facility areas (including the dressing/undressing area). The chamber airlock allows for test participants to enter and exit the test chamber without transporting significant amounts of vapor to other building areas, Airlocks usually consist of a small room (like a vestibule) with doors on both sides (side leading to chamber and side leading to the rest of clean building areas), but in some cases the airlock is just a typical doorway. Filtered air can be used with the airlock.
Medical treatment facility.	A medical facility with individuals trained and equipped to treat adverse reactions to physiological stress should be available, as circumstances warrant. A method for measuring heat stress should be available. The test safety officer (TSO) will be present during all CWA simulant test trials. The TSOs will watch for possible adverse physiological responses in TPs and obtain appropriate medical aid whenever necessary.
Chemical laboratory.	The chemical laboratory will provide the general analytical laboratory support needed for work with CWA simulants, including sampler analysis, instrument standardization, and hazardous waste disposal.
Operators area.	The operator's area will be occupied by test conduct personnel who will adjust wind speed, temperature, and RH, and operate the simulant vapor generator and the chemical vapor concentration measuring instruments. This area will also have some means of visually observing the TPs and communicating with the on-floor supervisor.

2.2 Equipment.

<u>Item</u>	<u>Requirement</u>
Vapor generator.	The generator must dispense MeS, as a vapor, at the controlled rate required to maintain vapor concentration at the target specified in the DTP; most testing has been conducted at 100 mg/m ³ vapor concentration. NOTE: It is recommended that compressed nitrogen be used in lieu of air to reduce or eliminate the risk of fire.
Data acquisition system.	Automated data collection system to collect all real-time data.

2.3 Instrumentation.

<u>Parameter</u>	<u>Measuring Device</u>	<u>Permissible Error of Measurement</u>
Chamber simulant concentration.	GasMet™ (or equivalent) Fourier Transform Infra-Red (FTIR) Real time monitors (RTMs) or near-real time monitors (NRTMs).	±15 percent over the range of 0.1 to 1000 mg/m ³ for each instrument.
Vapor concentration in TP's dress and undress areas.	MINICAMS® (or equivalent) NRTM.	±15 percent over the range of 0.01 to 1 mg/m ³ for each instrument.
Vapor concentration underneath the IPE (near the skin).	Passive adsorbent device (PAD) samplers, or real-time sensor (RTS) for monitoring CWA simulant vapor underneath the IPE.	PADs must be able to detect a mass of MeS of at least 25 ng; RTS must be able to monitor MeS concentration levels down to at least 0.05 mg/m ³ .
Vital Signs Monitoring (core body and/or skin temperature and heart rate).	Personal vital signs monitoring system (PVSMS) or equivalent system (if required by test facility/DTP).	±0.5 °C core body or skin temperature.
Chamber temperature.	Thermocouple or equivalent.	±0.5 °C.
Relative humidity (0 to 90 percent).	Hygrometer or other.	±2.5 percent.
Wind speed (0 to 5 m/sec).	Anemometer or other.	±0.1 m/s.
Video.	Video camera.	Adequate to document typical test procedures, details of contamination techniques, and any discrepancies from planned procedures necessitated by operational conditions.
Photographs.	Still, color camera.	Adequate to document typical test procedures, details of contamination techniques, and any discrepancies from planned procedures necessitated by operational conditions.

3. REQUIRED TEST CONDITIONS.

3.1 Experimental Design.

a. The IPE suit configurations worn (especially when comparing suit types) will be balanced to the greatest extent possible among the trials to minimize the effect of any trial-to-trial variation in the overall analysis. The IPE suit configurations will be balanced among test participants to minimize the effects of different TPs. Individual trial matrices will be provided in the DTP.

b. Historical testing has used eight replicates per configuration as a minimum for vapor MIST. This number of replicates was selected to balance data quality and cost.

3.2 Test Planning.

a. The following elements in developing the test plan should be considered:

(1) The entrance order of each TP must be specified for each trial. Rotation into and out of the test chamber will be conducted in a manner that prevents introducing bias (e.g., all TPs wearing one IPE suit type entering the chamber one after another) for any particular IPE suit based on chamber position or rotation order.

(2) Typical exercise stations and activities are found in Appendix B. These may be modified as necessary for the IPE suits tested or for safety.

(3) A safety release approving simulant operations must be in place before testing begins. Each TP will be informed of potential safety and health hazards involved in test conduct and the precautions required to prevent accidents.

(4) A human-use committee (HUC) or equivalent authority must provide approval for testing with human volunteers at the test facility before testing begins unless an exemption is in place.

(5) Ensure all TPs are thoroughly familiar with the ensembles to be tested, test procedures, test exercise protocol, and safety release constraints (if any).

(6) Each TP should submit to a physical examination, be certified by a medical authority for eligibility to perform the assignment, and voluntarily sign an informed consent affidavit (Appendix C) before participating in the test (as applicable for each test facility).

(7) Program requirement documents [Test and Evaluation Master Plan (TEMP), operational test agency evaluation plan (OEP), etc.] should be referenced in the test plan.

(8) Review of previous test reports for similar testing.

3.3 Safety.

Applicable test site safety regulations will be reviewed to ensure compliance during conduct of all test procedures. Special consideration will be given to any applicable protocols for using human TPs.

3.4 Environmental.

All test-site-specific environmental requirements for local, state, and federal approvals for the use of simulants will be reviewed and documented in the test plan.

3.5 Quality Assurance (QA) and Quality Control (QC).

a. A QA plan, as required by the test site, must be prepared for each test program to ensure that all variables that can be controlled are controlled, and that appropriate records are kept throughout the duration of testing. Variables that cannot be controlled must be identified in the test plan. Test variables include but are not limited to: purity and stability of simulants used, calibration and maintenance of instrumentation and disseminators, accuracy and precision of the laboratory instruments, and quality of all test samples.

b. All QC measures will be described in the test plan.

c. The quality of instrument data is assured with appropriate instrument maintenance, periodic calibration, periodic QC checks, and careful documentation of procedures. Calibration will be conducted in accordance with (IAW) the validated calibration protocol of the test facility. Instruments used in the testing should be calibrated as recommended by the manufacturer or according to the specific program calibration requirements. Instrumentation calibration will be recorded as part of the test record, and will include the calibration requirement (yearly, semi-annual, etc.). Calibration records will be maintained for all measuring and test equipment used to collect data. Calibration methods will be traceable to the National Institute of Standards and Technology if possible.

d. Sampler controls of the PAD are outlined in Table 1 and further described below.

(1) Several of the same kind of samplers will be stored with the test samples as storage controls (Table 1). Some samplers will be blank and others will be spiked at the concentration range expected to be measured beneath the IPE suit.

(2) Storage control samples will be analyzed with test samples to determine if any sample degradation or interfering chemicals were introduced during storage.

e. Each trial will have at least four QA/QC controls for PADs, two spiked and two blanks. Controls will be deployed in two ways:

(1) The spiked PAD controls will have known amounts of MeS added. The controls will be transported to the test site and returned to the chemical laboratory with the remainder of the samplers for analysis.

Table 1. Vapor Sampler Controls.

Control Sample Type	Number of Control Samples	Purpose of Control Samples
Blank sampler PADs or MINICAMS®	Two samplers for each set of TPs, or near real-time monitoring (mandatory; either method)	Determine if contamination of background MeS is in the dressing/undressing clean room areas.
Blank sampler PADs	Two samplers per test (mandatory).	Used as background MeS controls.
Spiked sampler PADs	Two samplers per test (mandatory).	To check sample degradation during storage.
Spiked PAD storage controls	Minimum of three (optional).	To check sample degradation or pickup during storage.
Spiked laboratory controls	10 percent of the total number of samples (mandatory).	A check to determine if the chemical analysis is in control.
Blank PADs and MINICAMS®	Determined by test director (optional).	To check the clean rooms for contamination of background MeS before testing begins.

(2) The blank PAD controls will be transported to the test site and returned to the chemical laboratory with the samplers for analysis.

(3) Additional samplers may be placed in the dress and undress areas to monitor the levels of MeS vapor. These PAD controls will be exposed to the clean-room environments whenever PAD samples or RTS units are exposed. A set will be opened during application of PAD samples to the TPs and dressing in the IPE, and then again when the IPE is taken off and the PAD samples are removed from the TPs' body regions. **NRTMs should also be used here.**

f. QA/QC for RTS monitors will include standard calibration procedures with quality controls to ensure reliability of the concentration measurements. Sensor substrate heads will be stored at conditions specified by the manufacturer, and new substrate heads will be used for each test. **NOTE:** RTS technology is evolving and substrate heads may be able to be cleaned and reused in the future.

g. Chemical Analysis.

(1) The chemical analysis procedure will be conducted with an appropriate number of standards, blanks, and analytical controls (10 percent of the samples as a minimum; see Table 1).

(2) These actions will ensure that the analytical procedure is reliable and will document the precision obtained from analysis of each batch of test samples.

(3) Calibration standards need not be at equal concentration intervals; rather, they should be spaced closer together near the low concentration end of the calibration curve.

(4) Results from the analysis of PAD laboratory QC controls (spiked and blank samples) will be reviewed to determine the amount, if any, of background MeS, and cross-contamination that existed during testing (Table 1).

h. If MIRAN[®] units are used as RTMs for chamber concentration monitoring, a five-point calibration will be performed on the chamber concentration monitoring equipment before each test series. GasMet[™] RTMs may be used instead of MIRANs to improve accuracy and reliability. Calibrate Gasmet RTMs when first acquired for MIST testing and verify the calibration. Calibrations will be verified annually thereafter. Daily check shots of GasMet[™] RTMs are not necessary because of the inherent stability of the FTIR detector; zero baselines with nitrogen will be performed to compensate for any variation in the IR source and sample cell.

i. Verification of performance of chamber RTMs can be performed by using additional GasMet[™] RTMs (above the minimum number of two units) or solid sorbent tubes to verify the concentration measurements.

j. Function checks of critical test instrumentation (e.g., the near-real-time MINICAMS monitors used in clean-room areas) will be performed daily to verify that the instrumentation used is operating correctly. Pre-test checks will be performed at levels that the instruments are reasonably expected to measure during the testing.

4. TEST PROCEDURES.

a. Vapor MIST measures the penetration of vaporized CWA simulants through complete CB protective ensembles worn by TPs. The data collected from the vapor MIST will allow testers to determine the level of penetration for complete CB IPE suit systems worn by TPs when exposed to vapor CWA simulants in controlled environments. This TOP is written so that MeS is the CWA simulant and PADs are used as samplers; other simulants or samplers may be used in the future. Additional procedures are also included to address the use of RTS as the samplers.

4.1 Objectives.

a. Collect data to contribute to the evaluation of ensemble effectiveness in protecting Warfighters while wearing the ensemble.

b. Determine protective capabilities of IPE using operationally relevant testing with approved simulants and analysis of potential toxicological results with the Body Region Hazard Analysis (BRHA) model.

4.2 Receipt Inspection.

a. Test items must be inspected for shipping damage and completeness of the ensembles. Any missing components, damage, or other discrepancies will be documented. There should be no visible damage to the systems.

b. Test items should be assigned unique test item control numbers (TICNs) before testing begins. The TICNs can be generated during the receipt inspection as sequential, alphanumeric

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codes that identify the specific test item. The component or the manufacturer's serial numbers may be used as identifiers. The TICNs will be permanently marked on or attached to the test items.

c. Samplers will also be inspected for damage and suitability for testing; if the plastic diffusion layer has cuts or tears it will not be used. Uptake rates for each lot of samplers will be measured and documented (see Section A-4). The samplers will be tracked individually to a test participant and location via the sample chain of custody to track samplers from placement on TPs to sample analysis.

d. Photographic records of items showing damage (with a metric scale and in focus) will be made along with a written record of the damage. This record will show all areas of damage and will be cross-referenced to recorded TICNs.

4.3 Background MeS Interferents

a. Certain personal hygienic materials (such as soaps, shampoos, etc.) may interfere with the detection of the chemicals used during testing. Because MeS, or oil of wintergreen, is in a wide variety of consumer products including certain toothpastes, chewing gum, muscle liniment (BenGay), and chewing tobacco (Skoal), TPs will be instructed to avoid the use of any of these products before testing. TPs who have used any product containing MeS within the past 24 hours will not be allowed to participate in any testing. The test items and the TP may be monitored and tested before participation in the test. The clean room area of the dressing/undressing areas (where PAD samples will be applied and removed) must be free of background MeS and will be monitored to ensure levels are within the acceptable range ($\leq 0.1 \text{ mg/m}^3$; the optimal background level is $\leq 0.05 \text{ mg/m}^3$).

b. It is recommended that TPs shower before participation in each test. This will help to avoid introduction of potential background MeS contamination during sample analysis.

4.4 Calibration and Standards.

The instrumentation that will be used during testing is discussed in Section 2.3 and in Appendix A of this TOP. The calibration standards and requirements are outlined in Paragraph 3.5 (QA/QC) with some additional guidance provided below.

a. The RTMs used to monitor chamber concentrations will be calibrated with MeS by a validated procedure IAW the RTM's user manual or applicable standing operating procedure (SOP). The RTMs will then be installed and checked at the test chamber for correct response before testing begins.

b. The NRTMs used to monitor the clean-room and doffing-room areas will be calibrated with MeS IAW procedures recommended by the manufacturer. NRTM MINICAMS will be checked each morning for correct response before testing begins (check-shot at levels expected to be measured with $\pm 20\%$ response).

c. The instruments for measuring the temperature, RH, and wind speed in the test chamber will be calibrated IAW their user manual or applicable SOP.

d. An instrument logbook will be used to track the record of installation, calibration, maintenance, and any failures.

e. Before beginning each test, the test officer must verify that all calibrations are current and record the calibration dates.

4.5 Vapor MIST Criteria and Conditions.

a. Criteria. No specific criteria are provided in this TOP; criteria for each IPE system will be specified in the DTP or requirements document for each system.

b. Conditions.

Unless otherwise specified in the DTP, the following conditions will be used during performance of all MIST trials. It should be noted that chamber concentrations can be adjusted to meet IPE challenge dosage requirements.

- (1) Chamber concentration: $100 \pm 15 \text{ mg/m}^3$.
- (2) Exposure duration: 30 minutes.
- (3) Chamber temperature: 21.1 to 32.2°C (70 to 90°F).
- (4) Chamber RH: 50 to 90 percent.
- (5) Chamber wind speeds: 3.22 to 8.05 km/hr (2 to 5 mph).

4.6 Pre-Test Instructions.

4.6.1 TP, IPE, and Test Chamber.

a. The IPE suits and masks being worn for testing must be fit to each TP; each TP must also be trained in the correct wearing of the ensemble. Each TP should be quantitatively tested for adequate mask fit and should achieve a fit factor of at least 500.

b. Anthropometric measurements will be taken for all TPs so that the IPE suits used during the testing are sized correctly to each TP according to fit requirements provided by the test sponsor (see guidance provided in Reference 1).

c. Each TP will be measured for adequate fit to include slack measurements taken at the chest, upper arm, lower arm, wrist, hips, thigh, calf, and ankle (as outlined in the DTP).

d. The test chamber and equipment will be set up and checked to ensure the instruments' operational readiness. An operational readiness inspection (ORI) will be conducted before the start of the actual test to ensure that all system components are performing adequately.

(1) The chamber and test instrumentation will be tested by bringing the chamber to operational conditions. These conditions will be monitored for an appropriate length of time to ensure that a complete test trial can be conducted.

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(2) In the case of an active sampling requirement, an independent referee system, such as Gasmeter (Gasmeter Technologies Oy, Helsinki, Finland), or MIRAN, should be used to verify that the concentration of MeS vapor in the chamber is within acceptable limits. A minimum of two RTMs should be used to monitor chamber MeS concentrations.

(3) The operational readiness of the instrumentation to measure MeS vapor concentration in the dress and undress areas will also be checked (MINICAMS pre-test check shots; see Section 4.4 b.). Supplies for application and removal of PAD samplers will be pre-positioned in these clean-room areas.

(4) The integrated team may direct a pilot test to be conducted in place of the pretest if a novel test program, new samplers, or a system with a high potential for interference will be tested. The pilot test will be conducted only if there are sufficient test items available.

4.6.2 Chamber and Dressing/Undressing Area Air Sampling

a. Sampler Setup in the Dressing/Undressing Areas.

(1) Background levels of MeS will be monitored using PADs or NRTMs (MINICAMS or equivalent). PAD mass should be corrected for background levels in the dressing/undressing areas during analysis; however, mass values will be set to one-half of the analytical detection limit if background corrected masses are below the detection limit.

(2) If PADs are used to monitor the background level, then mass on the PADs should be less than the minimum detection limit for the PADs (approximately 25 ng).

(3) If NRTMs are used to monitor the background level, the MeS level should not be greater than 0.1 mg/m^3 . This is an acceptable background level; however, the optimal background level is at or below 0.05 mg/m^3 . If the MeS level in the dressing/undressing area is greater than 0.1 mg/m^3 , then the testing will be stopped because of the excursion into unacceptable levels, and a clearing period will be required until the MeS level drops to levels below 0.05 mg/m^3 . Clearing to these lower levels is required to help ensure that background levels after the excursion will remain in the acceptable region.

b. The test chamber will be set at standard-trial-operating environmental parameters. Chamber sampling with an appropriate number of RTM instruments (2 minimum) will be started to ensure proper operation of the analytical instrumentation.

c. The clean-room area will be set up with appropriate supplies for operation and any ventilation or environmental control systems will be started. Sample the clean-room air using NRTM analytical samplers to determine if there are substantial levels of MeS present and whether they are within acceptable levels ($\leq 0.1 \text{ mg/m}^3$; the optimal background level is $\leq 0.05 \text{ mg/m}^3$).

d. If MeS background is present in the clean-room dressing/undressing area, it must be purged until sampling indicates that the background MeS in the clean-room dressing/undressing area is less than the lower detection limit (LDL) of the analytical sampler being used. In no case

will trials be conducted if MeS levels in the clean-room dressing/undressing area are above acceptable ranges ($\leq 0.1 \text{ mg/m}^3$; the optimal background level is $\leq 0.05 \text{ mg/m}^3$).

4.6.3 System Under Test (SUT) Preparation.

a. Environmental conditioning required by the DTP of the specific IPE (evaluated as the SUTs) will be conducted before testing begins.

b. IPE suits requiring cleaning or laundering before use will be washed IAW the procedures specified in the DTP. Unless otherwise specified in the DTP, the laundering steps and cycles and drying instructions outlined in Field Manual (FM) 42-414 (see Table 2) will be used.

4.6.4 Background MeS Control.

a. The protocol to control background MeS is essential to mitigating inaccurate test data.

b. Before the start of each test series, the test items will undergo sampling for any background MeS present in the ensemble. Background MeS testing may be performed using one of the following two methods:

(1) Test each item before each trial.

(2) If all test items in a population have identical histories (have been taken from the same source, stored together, treated identically, etc.), then a selected number of items representative of each configuration type will be tested as a separate pretest.

c. One complete ensemble (or more) of each type will be placed in an impermeable bag or other suitable container, and the ensemble will be held for at least 2 hours at 32 °C (90 °F).

d. The air in the bag/container will be sampled using one (or more) PAD for a length of time equal to the duration of each trial. MINICAMS NRTMs may be used instead for this sampling.

CAUTION: Sample the empty bag/container for volatile interfering chemicals before sampling the IPE suits. Air supplied to the bag during sampling must be passed through a carbon filter to remove outside MeS before entering the bag.

e. The PAD or MINICAMS NRTM results will be analyzed for MeS to determine whether the IPE suit or bag/container emits a chemical(s) that could give a false positive reading. If positive results are obtained, each component (i.e., suit, hood and mask, boots, and gloves) will be tested separately to determine the source of the MeS background contamination. A determination can then be made to replace the item or subtract the background results from the sample results.

Table 2. Laundering Steps and Cycles.

Step	Laundering Cycles	Water Level	Time (Minutes)	Temperature	Supplies ^a
1	Fill	High	NA ^b	32.2° to 43.3°C (90 to 110°F)	NA
2	Wash	High	5	32.2° to 43.3°C (90 to 110°F)	6-oz laundry detergent PD245
3	Drain	NA	NA	NA	NA
4	Fill	High	NA	32.2° to 43.3°C (90 to 110°F)	NA
5	Wash	High	5	32.2° to 43.3°C (90 to 110°F)	4-oz laundry detergent PD245
6	Drain	NA	NA	NA	NA
7	Fill	High	NA	32.2° to 43.3°C (90 to 110°F)	NA
8	Rinse	High	2	32.2° to 43.3°C (90 to 110°F)	NA
9	Drain	NA	NA	NA	NA
10	Fill	High	NA	32.2° to 43.3°C (90 to 110°F)	NA
11	Rinse	High	2	32.2° to 43.3°C (90 to 110°F)	NA
12	Drain	NA	NA	NA	NA
13	Fill	High	NA	32.2° to 43.3°C (90 to 110°F)	NA
14	Rinse	High	2	32.2° to 43.3°C (90 to 110°F)	2-oz Sour ^c , laundry
15	Drain	NA	NA	NA	NA
16	Extract	NA	3 to 5	NA	NA
Drying ^d	NA	NA	NA	43°C (110°F)	NA

^aAmount of supplies based on a 27.22-kg (60-lb) load.

^bNot applicable.

^cSour is a chemical added during the final washing machine rinse cycle (if needed) to lower the pH of the water and to assist with the removal of detergents and rust stains (as specified in Field Manual 42-414).

^dRemove IPE suits immediately upon completion of the cycle. Avoid over drying.

f. Contamination and background MeS control begins with the TPs; therefore, the following steps will be taken:

(1) TPs will be provided with instructions about foods and products containing MeS that must not be consumed or used within 24 hours before testing begins, or during testing.

(2) TPs will be required to shower with MeS-free soap and dress in MeS-free clothing.

(3) Background sampling of TPs may be conducted to screen for residual MeS and to train TPs in likely areas of contamination.

4.6.5 Simulant Background Analysis.

a. The TP simulant background analysis will be conducted only during the validation and verification of a test chamber or if there is a contamination concern.

b. Two TPs will be fully instrumented with PADs as described in Section 4.7.1.

c. One TP will be dressed in the IPE suit to be tested; the other TP will be dressed in a clean, impermeable suit, such as Tyvek® (Dupont™, Wilmington, Delaware). The TICN of the suit worn by each TP will be recorded.

d. TPs will wear PADs and the suits for the same time as a full vapor MIST trial.

e. PADs will be removed, stored, and analyzed IAW procedures for a standard vapor MIST trial.

f. Results from the PAD analysis will be reviewed to demonstrate that the cleaning and hygiene protocol and the analytical process are operating correctly.

4.7 Test Setup.

a. The chemical vapor generator; temperature, RH, wind speed instruments; and RTMs will be placed at the locations specified in the DTP.

b. The RTMs will be installed and checked at the test chamber for correct response before testing begins. NRTMs will be installed in the dressing/undressing areas (Clean Room and Doffing Room) and their operation will be verified before test start.

c. The control system and data-collection system software will be connected to all equipment and test instruments and checked for readiness and correct operation.

d. If a body core temperature internal sensor or “pill” is used, the pill must be taken one to two hours before the trial starts to become active and stabilize the data telemetry stream. These readings will be monitored in real time. Core body or skin temperature and pulse rate at which TPs will be removed from the test will be established by the test director in coordination with appropriate medical staff before testing begins.

e. A test operator will attach a PVSMS to each TP (if used).

4.7.1 Application of Body Region Samplers and Dressing in the IPE

a. Application of samplers (PADs or RTS) to the TPs will be conducted after chamber concentration levels have been generated and are stable. Background MeS concentrations must not exceed specified levels (see Section 4.3 a.) before sample application commences. TPs and test technicians will enter the clean room of the dressing/undressing area. PADs will be placed

on the bodies of the TPs at the locations described in Table 3 and shown in Figures 1 and 2. Additional PADs may be placed at targeted locations such as behind seams/closures of concern. If RTSs are used, they will be placed on the bodies of the TPs at all practical locations listed for the PAD placement (or as specified in the DTP). If the size of RTS prevent them from being used at the boot (left foot, sample P11), or at the nose cup of the mask (sample P30); alternative sampler location readings will need to be used for these samples. The left lower leg (sample P10) can be used for the boot, and alternative samples for the mask are not necessary since P30 is not used in the BRHA. Alternative sampler locations may be used with agreement from the community and will include documentation about the assumptions used to identify the alternatives. These are highly dependent on the specific ensemble and may change with the configuration. As an example, the lower leg might be appropriate as an alternative for the foot/boot sampler depending on the specific configuration.

TABLE 3. PASSIVE ABSORPTIVE DEVICE (PAD) PLACEMENT LOCATIONS.

Position Number From Figures 1 and 2	Description
P1	Left ear (ensure PAD isn't covered by mask straps)
P2	Chin (anterior neck)
P3	Chest Center
P4	Left Inner upper arm
P5	Left Forearm, volar
P6	Groin/Pubic region
P7	External Genitalia/Crotch
P8	Middle of Back
P9	Left Inner thigh
P10	Left Lower Leg, front (shin)
P11	Left Boot, top (foot)
P12	Scalp
P13	Nape
P14	Left Armpit
P15	Right Outer upper arm
P16	Lower back
P17	Hip point, left lateral (buttocks)
P18	Glove (back of left hand)
P19	Right Forearm, Dorsum
P20	Forehead (outside mask; may need to locate at
P21	Right Cheek (outside mask; above lower strap)
P22	Abdomen (front center)
P23	Right Outer Thigh
P24	Right Lower Leg, back (calf)
P30	Nose cup

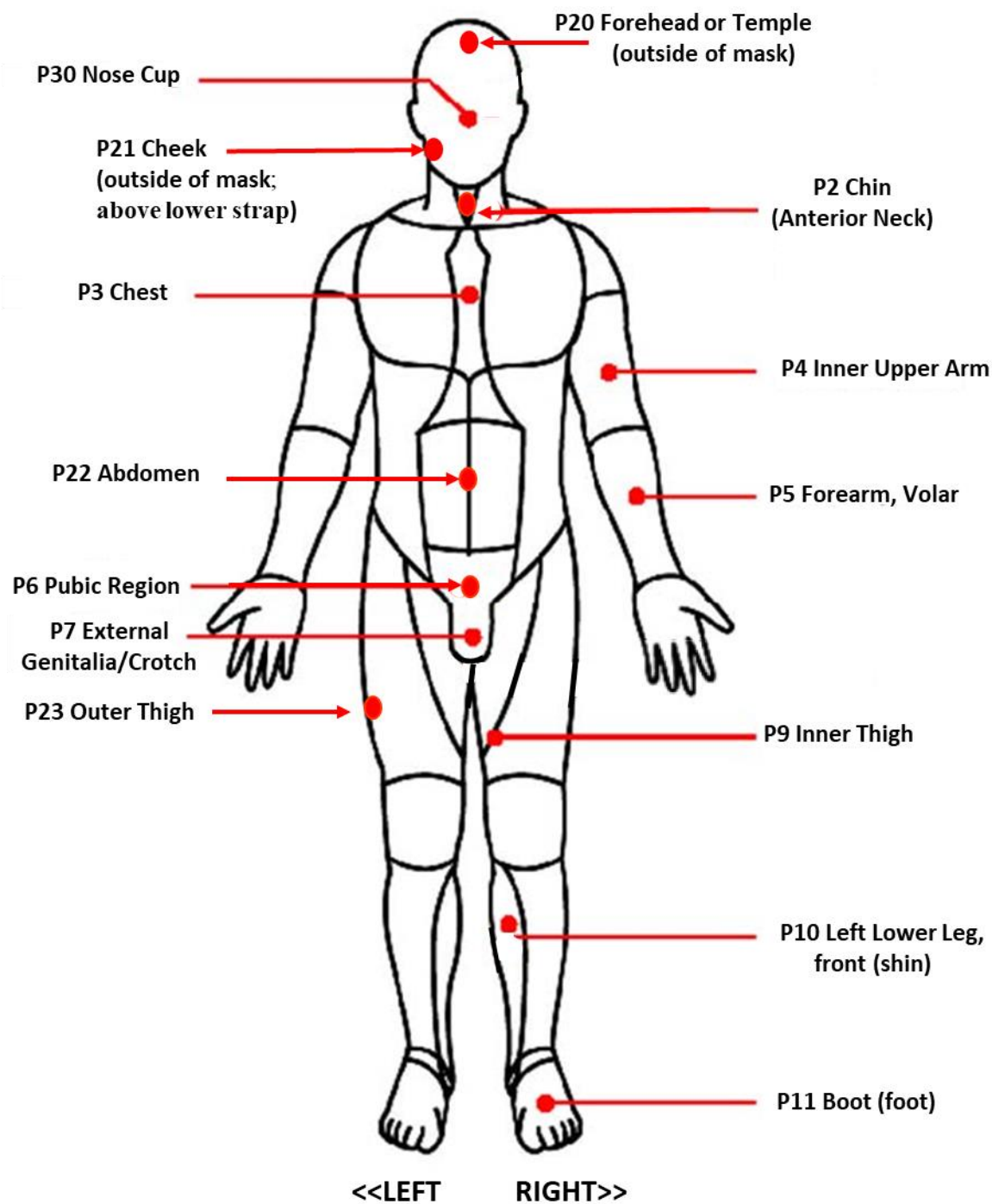


Figure 1. Vapor MIST PADs Sampling Locations (Front).

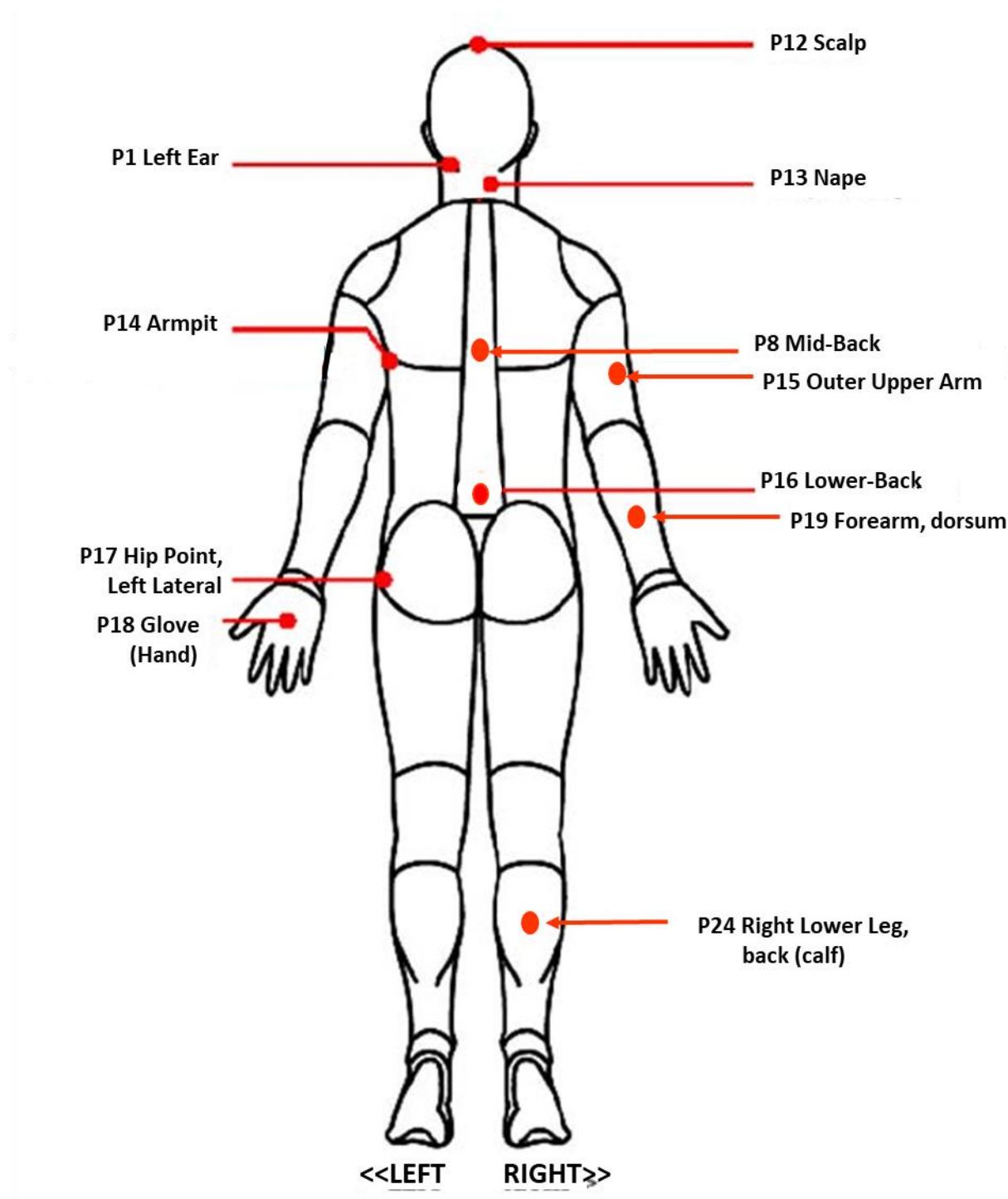


Figure 2. Vapor MIST PADs Sampling Locations (Back).

b. Background PAD samples will be removed from air-tight storage containers and exposed to the air inside the clean-room area before the start of the application of PAD samples; these samples will continue to be exposed to the clean-room environment whenever PAD samples are exposed.

c. All TPs will be sized and fitted with the garments to be tested as outlined in the DTP. TPs will be dressed IAW the procedures specified in the DTP. TPs will also wear specified footwear, gloves, protective mask, and hood.

d. Test operators will assist the TPs in obtaining correct closure of the IPE suit at all locations. Each IPE suit will be inspected to ensure proper wear.

e. As soon as the PAD samples are covered with the IPE, the background PAD samples will be returned to their air-tight container. Background PAD samples will also be exposed after the test is completed during the time when TPs are removing their IPE and the body region samplers are being removed.

f. Photographs will be taken to document the correct fit of each IPE suit and closures.

4.8 Test Procedures.

a. All instruments will be started and the test chamber brought to the required test conditions. The output of all instruments will be recorded by the data collection software. The Clean Room atmosphere (dress/undress areas) will be monitored for 0.5 hour for the presence of any background MeS.

b. The test chamber will be closed and sealed, and a negative pressure established.

c. The MeS vapor generator will be started (before application of PAD samples) to produce a vapor challenge cloud at the required challenge level. Generally, RTMs will be used for chamber control sampling and to determine the total challenge dosage. The RTMs continuously monitor the challenge concentration in the chamber throughout the duration of the trial. They must provide real-time data collection to allow timely adjustments of control devices within their operational limits.

d. Vapor concentration inside the test chamber will be monitored using the average of the RTM readings. The vapor concentration should remain within ± 15 percent of the target value during the test exposure period (minor variations are acceptable) unless otherwise specified by the DTP. Application of body-region samples and dressing in the IPE by TPs (Section 4.7.1) will not commence until steady chamber concentrations have been achieved at the correct levels.

e. After TPs have samples and IPE applied, they will enter the test chamber at a time interval specified in the DTP.

f. Each TP will be continuously monitored for adverse physiological symptoms such as disorientation, hyperventilation, or breathing difficulties during the trial. If such reactions occur, the TP will be removed from the test and given appropriate medical aid. All adverse reactions will be documented. If physiological monitors are used, the physiological signs of the TPs

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(including pulse, blood pressure, and body temperature) will be measured and recorded throughout the chamber exposure and exercise routines [in compliance with personally identifiable information (PII) laws].

g. TPs will follow the protocol of exercises specified in Appendix B (or the DTP). TPs will rotate through each station for a total trial time of 30 minutes, or as specified in the DTP. Generally, the rotation interval is 5 minutes at each station.

h. The activities of the TPs will be visually monitored by the on-floor supervisor, test operators, or video cameras (both human and video monitoring is recommended). If an on-floor supervisor is in the test chamber, they must be in direct communication with the test control room at all times. A means must be provided for the TPs to communicate with each other and the on-floor supervisor. The physiological signs of the TPs will be measured and recorded at the end of the exercise cycle. Physiological signs will include pulse, blood pressure, and body temperature.

4.9 Post-Test Procedures.

a. At the conclusion of the specified exercise cycle, TPs will exit the vapor exposure chamber through the airlock (or other chamber exit), and then proceed to enter the first-stage dressing/undressing area (doffing room) for removal of the IPE and PAD/RTS samplers; the doffing room will be monitored for background MeS vapor. If an airlock is used to exit the chamber, TPs will remain in the airlock for the full purge cycle before exiting to the doffing room. Airlocks are an option that can be used when leaving the vapor exposure area to further reduce vapor transport between the chamber and the dressing/undressing areas during MIST. The purge cycle is generally set to reduce the airborne concentration to levels 1/1000 of the original concentration.

b. Enter the doffing room where operators will remove the protective ensemble from the TP and inspect the PADs and RTS (if used) for any sign of orientation or position shifting on the TP; any discrepancies will be noted. The doffing procedure detailed in the DTP must be followed carefully. The doffing area monitoring PADs (QA/QC samples) will be opened and exposed to the undress area background concentrations during all periods after the IPE is removed and until the PAD samples are removed and sealed in sample containers.

c. The TPs will then enter the second-stage dressing/undressing area (clean room), which is also monitored for MeS vapor.

d. Operators will remove the PADs and RTS (if used), check them for correct identification, and place them in the sealed carrying containers for transfer to the laboratory for chemical analysis. Wrapping the PADs in foil before placing into airtight vials has been shown to be the best practice.

e. Operators must wear new examination gloves (latex, nitrile, or other approved gloves) when handling the samplers, avoid touching the sampling surface, work in a clean environment (preferably a clean box), and use tweezers whenever possible. Any discrepancies must be noted.

f. TPs will then exit the second-stage dressing/undressing area (clean room) and dress in their own clothes.

g. Foil-backed samplers must be placed in individual airtight vials unless the Tenax[®] adsorbent is removed immediately for analysis. Vials must be placed in a refrigerator at $-20\pm10^{\circ}\text{C}$ (14° to -22°F) within 1 hour. The samplers must be analyzed within 24 hours of collection or stored in a freezer for no longer than 30 days.

h. QC personnel will randomly add control PADs spiked with known amounts of MeS to the test PADs before transfer to the laboratory. All spiked control PADs will be properly documented by PAD sample numbers and spike mass quantity to ensure tracking can be verified.

i. Samplers will be analyzed (along with appropriate QA/QC samples) according to approved laboratory procedures at the test site. Instrument detection limits and practical quantification limits of the instrumentation used to perform the analysis of samples will be used to determine the analytical detection limit (see Paragraph E-3 d).

j. The TPs may be interviewed at the conclusion of the test and asked to complete a human factors engineering (HFE) questionnaire concerning comfort and fit, ability to communicate, visibility, and ability to perform the exercise protocol. TPs will be given an opportunity to comment on safety and health hazard issues and to suggest possible improvements to the IPE suit. The HFE questionnaire can be prepared using TOP 1-2-610 Part I³ and Part II⁴ or military standard (MIL-STD) 1472⁵.

5. DATA REQUIRED.

a. The challenge dosage ($\text{mg}\cdot\text{min}/\text{m}^3$) generated during each trial for each TP. This requires an accurate recording of the time (in minutes) each TP spent inside the exposure chamber (entry and exit times), along with precise measurements of the chamber concentrations during these time periods.

b. Actual time (minutes) each TP spent at each activity and any discrepancies.

c. Analytical results (mg) from each PAD for each body region location and each TP with chain-of-custody information. The uptake rate for the lot of PADs used must also be accurately determined (see Section A-4). If RTS monitors are used, the concentration data over time must be collected.

d. The core body or skin temperature, and heart rate for each TP in each trial for the duration of that trial (if required by test facility human use safety review). It should be noted that this type of information represents personally identifiable information (PII) that may be subject to privacy concerns. Any data collected must be safeguarded to ensure compliance with PII laws; alternatively, if this data must be collected or reported, TP identification coding can be used so that no PII that is directly attributable to a specific test participant is recorded or disclosed.

e. Anthropometric measurements from TPs, used mainly to ensure proper fit of IPE on the TP. Because this data constitutes PII, fit data will be anonymized to comply with PII

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requirements. Identification (ID) codes will be used to make data anonymous. All laws governing PII will be followed.

f. Description of adequacy of fit of candidate ensembles to include slack measurements taken at the chest, upper arm, lower arm, wrist, waist, hips, thigh, calf, and ankle (as required by the DTP).

g. Description and photographs of each full IPE system, along with mask quantitative fit factor measurements from TPs.

h. Analytical results of all samples, including control samplers reported as mass of MeS (mg) found in each sample; or concentration for RTS monitors.

i. Analytical results (mg/m³) of RTM and NRTM instruments over time in the test chamber and dressing/undressing areas (respectively).

j. The following chamber environmental data:

(1) Temperature (°C).

(2) RH (percent).

(3) Wind speed (m/s).

k. Trial date, duration, and start and stop times.

l. Operator written observations (especially system openings, mask breaches, and poor fit) along with operator's name (or ID) and any logbooks of test events.

m. TP written observations and HFE questionnaires (as applicable).

n. BRHA output data.

o. The results and precision obtained from the QA/QC analytical controls utilized during the test or added in the laboratory. Calibration documentation must also be available for all analytical instruments used.

p. Results identified by trial number, TICN, and sampler location on each TP.

q. Photographic records documenting the ensemble TICN.

r. Computer files, graphs, and printouts of all recorded real-time test chamber data.

6. PRESENTATION OF DATA.

a. All the anthropometric data and adequacy of fit data related to the TPs will be tabulated. Anthropometric data constitutes PII and will be anonymized to comply with PII requirements before any reporting.

- b. All RTM and NRTM concentration data will be presented as graphs for each trial.
- c. All chamber environmental data will be presented as graphs for each trial.

d. The analytical results from the PADs will be tabulated and run through the BRHA⁶ model. The calculated results of the BRHA analysis will be presented along with a summary of the PAD data results. Missing data points from the PADs will be estimated as the geometric mean of the same body point from all ensembles of the same configuration; values from nearby body regions may also be used (if appropriate). Any data estimations for missing PADs will be flagged as such and clearly marked to be ‘estimates’ when presented; actual methods for any estimation will also be reported with the data estimates.

e. The BRHA model (Appendix E) output is a protection factor (PF) for the entire IPE suit ensemble and exposure dosage effects for each body region.

f. The results from the BRHA will be used to compare IPE suit performance by performing two separate analysis regimes:

(1) Localized Effects.

(a) To evaluate for localized effects, the PF values for each body region are multiplied by the toxicology weighing factor specified in the BRHA for localized effects; the results correspond to the effect of HD. Revised values from the Toxicological Casualty Risk Analysis (TCRA) model have been incorporated into the BRHA (see discussion in Paragraph E-2, d. and References 12 and 13). These revised HD effects values were from a 1945 study at the US Naval Research Laboratory on effects of HD vapor on personnel.

(b) The resulting localized minimum exposure dosage (MED_{HD}) values are compared with each other, and the lowest value is selected as the IPE suit performance value. The localized MED_{HD} for the IPE configuration represents the highest HD agent exposure dosage to which a warfighter wearing the IPE suit ensemble could theoretically be exposed to before the wearer experienced the onset of initial symptoms.

(2) Systemic Effects.

(a) To evaluate for systemic effects, the PF value for each body region is multiplied by a systemic weighing factor for each body region provided by the BRHA (Appendix E). This weighing factor is proportional to the area of each body region and the toxicological dosage that must be adsorbed at each body region to cause end-point nerve agent effects.

(b) The resulting values are summed over all body regions and divided into a summation of the nerve agent/body area weighting factors (uncorrected for body region PF) in order to establish an overall Physiological Protective Dosage Factor (PPDF). The systemic agent Minimum Exposure Dosage (MED_{SYS}) is calculated by multiplying this overall PPDF by the percutaneous nerve agent dosage that causes threshold effects. The MED_{SYS} for the IPE configuration is then calculated for both GD nerve agent and GB nerve agent and these values represent the highest vapor nerve agent exposure dosage to which a warfighter wearing the IPE suit ensemble could be exposed to before the onset of initial symptoms.

g. Any PAD data values that are not typical of standard results will be evaluated with an appropriate outlier test to determine whether those unusual values are valid data or outliers. A number of statistical test methods to identify possible outliers exist and include using an analysis of variance (ANOVA), the Grubbs test, and other statistical methods (available in many statistical software). Graphically analyzing data sets (using boxplots, histograms, scatterplots, etc.) can also be used to identify potential outliers. Full statistical analysis will be conducted on any questionable data that is identified as a possible outlier. Data analysis will include calculation of residuals, the standard deviation of the data set, and studentized residuals. Any data confirmed to be an outlier will be reported as such, along with details of the analysis and the statistical method used.

(1) If necessary, a natural log transformation will be performed on the calculated PAD values.

(2) An outlier will be defined as a point having a studentized residual with an absolute value greater than 3.

(3) A second outlier test will be performed after the outlier analysis is complete to verify results.

(4) If any outliers are identified, those values will be reviewed to determine if there is a discernible cause for each outlier. If there is a discernible cause, the values will be adjusted, if possible, to reflect the true value; otherwise, the value will be replaced with the geometric mean of the same body point from all ensembles of the same IPE configuration. If there is no discernible cause for the outlier, the original value will be used. Any removal of outliers or use of data estimates will be flagged as such and clearly documented. Analysis that verifies data points as true outliers must be provided; methods used for any estimation will be reported along with the data estimates.

h. The PPDF and MED data values will be analyzed to characterize the IPE system under test and to perform comparisons between different IPE suit configurations. The factors used in this analysis will be described in the DTP.

i. If the natural log transformation of any data is performed, the endpoint values will be summarized in terms of geometric means. If the data is not transformed, then an arithmetic mean will be reported. The number of observations, standard deviations, and 95 percent confidence intervals will also be reported.

7. CHAMBER VERIFICATION AND VALIDATION

All verification and validation testing must show that a chamber will perform to the specifications outlined in this TOP. Any verification will need to be reviewed and accepted by the Warfighter Protection Capability Area Process Action Team (WP CAPAT).

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APPENDIX A. BACKGROUND.

A-1. General.

a. To estimate penetration of chemical-protective ensembles by chemical vapor, it is necessary to test the entire IPE suit system, including seams, closures, and the areas of transition to other protective equipment (i.e., areas at the waist, ankles, wrists, and neck).

b. The fit or size of the clothing has an effect on penetration. When worn by a person, clothing is subjected to pressure differentials across the garment from wind, the bellows effect created by movement, breathing, or a combination of the three, all of which may force chemical warfare agent (CWA) vapor through the clothing fabric and closures. Bending and moving stresses clothing, particularly over the joints⁹.

c. The inner sorptive layer/reactive layer may partially remove CWA or simulant vapor that penetrates clothing. Perspiration decomposes the CWA or simulant.

A-2. Human Subjects Versus Mannequins.

a. Static mannequins dressed in protective suits can be tested in CWA-contaminated air but cannot show the effects of physical motion and perspiration. Correlation tests have been conducted using mannequins capable of limited movement with agent. This testing indicates a general agreement in results, but the actual man/system interface can best be tested using actual servicemen and servicewomen wearing the systems. However, this testing can only be conducted using simulants because the use of agents presents significant safety hazards; therefore MIST represents a chosen balance between realistic human motions and TP safety.

b. Test participants (TPs) exercising in approved simulant vapor environments provide data on the effects arising from physical motion, breathing, and perspiration. The level of perspiration underneath the ensemble should be recorded for each TP/IPE ensemble.

A-3. Passive Adsorbent Device (PAD).

a. PADs are small sampling devices designed to evaluate the total dose of simulant received at a specific location. The device is a small packet filled with Tenax[®] adsorbent material backed with adhesive to enable the device to be placed directly on the skin. Ten percent of the total number of PADs used in the test must be available for use as controls.

b. The PAD is a small packet [approximately $3.8 \times 3.2 \times 0.3$ cm ($1.5 \times 1.25 \times 0.125$ in)]. The exposed face of the packet is a 0.025-mm (0.001-in) thick high-density polyethylene film that acts as the diffusion barrier. The back of the packet is an aluminum foil/polyethylene/nylon membrane impermeable laminate. A coating of medical adhesive on the back of the packet allows attachment directly to the skin of the TP. Identical quantities of purified Tenax[®] TA adsorbent (Buchem B.V., Apeldoorn, The Netherlands) are sealed inside each packet. The PADs are sealed inside foil/plastic laminate (impermeable) packages by the manufacturer to prevent exposing the samplers before use.

APPENDIX A. BACKGROUND.

c. Upon receipt, if all of the PADs in the population have identical histories (have been taken from the same source, have been stored together, have been treated identically, etc.), these samplers must be subjected to a lot acceptance test designed to determine if the samplers are suitable for use. Parameters for the lot acceptance test are:

- (1) Sampler area: $3.8 \text{ cm}^2 \pm 25$ percent.
- (2) Mass of adsorbent: $35 \text{ mg} \pm 20$ percent.
- (3) Sampler uptake rate (measured at multiple dosage levels): $\geq 1.0 \text{ cm}^3/\text{min}$; $\leq 25\%$ relative standard deviation (RSD).
- (4) Spike recovery (at one concentration): ≥ 90 percent.
- (5) Chemical cleanliness: $< 25 \text{ ng}$ background MeS.

d. Based on previous lot acceptance tests, most of the criteria defined in the TOP are not attainable and have been an accepted limitation of MIST testing. There is a sole source provider for these PADs, who has not been willing to modify production to meet the requirements set forth by the TOP. However, the BRHA model accounts for PAD uptake rate and normalizes the data relative to challenge concentrations so that local and systemic resultant doses, as well as statistical comparisons between configurations, are unaffected. Comparisons made between ensembles tested in this event and those tested in previous events could lead to confounding and inconclusive results due to variability introduced by several factors, such as the difference in uptake rate between PAD lots.

A-4. PAD Sampler Uptake Rate Determination Procedures.

a. The uptake/sampling rate for each lot of PADs will be determined by exposing a set number of PADs to MeS vapor and back-calculating the uptake rate from the average mass analyzed on these PADs and the total Concentration Time (Ct) challenge dosage the PADs were exposed to. The procedures for uptake rate determination are based on the methods outlined in ASTM Standard F2588-12 for MIST testing¹¹. Once the uptake rate is determined, it can be used to calculate equivalent concentration and dosage levels from the analyzed mass of the PAD samples.

b. PADs will be exposed to MeS either inside the test chamber, or in a vapor exposure container designed specifically for this purpose. It is recommended to use a specific container type using a vapor generation system that produces a well-mixed concentration. A flow-through vapor immersion system with minimum one vapor exchange per minute has also been recommended.

c. The PAD sampler uptake rate testing will be conducted at an MeS vapor concentration range between 0.10 and $3 \text{ mg}/\text{m}^3$ ($\pm 15\%$). This is the expected concentration range the PAD samplers are expected to be exposed to underneath the IPE suit during vapor MIST testing. The uptake rate will be evaluated at a minimum of three concentration dosage (Ct) levels throughout

APPENDIX A. BACKGROUND.

this range; the optimum number of Ct levels for this analysis is five. Vapor concentration will be monitored with real time monitors (i.e., Gasmets, etc.) or near real time monitors (i.e., MINICAMS, etc.). All vapor monitoring instrumentation will be calibrated for MeS between the concentration values used during the PAD uptake rate testing. Environmental conditions for the uptake rate testing will be the same as the conditions used during MIST testing, with a temperature between 70 to 90 °F, and relative humidity (RH) between 50 to 90 percent (recommended conditions are 80±3°F and 70±5% RH). Additional PAD uptake rate trials can be conducted if MIST test conditions are different than the standard test conditions.

d. A minimum of 20 PADs should be tested per lot during testing to determine the uptake rate; it is recommended that more PAD samples are used (i.e., 25), so that the results will be more statistically valid. It is recommended to use PADs from at least three foil shipping packs for the uptake rate testing. The PADs should be mounted in a horizontal position during uptake testing with the Tenax adsorbent distributed as evenly as possible.

e. Place the PADs inside the vapor exposure container after a steady challenge concentration at the desired value has been achieved. Monitor the MeS concentration with Gasmets or other real time, or near real time monitors. Expose the PAD samplers for 60 minutes, and then immediately remove and process the PAD samples to determine the total mass of MeS adsorbed.

f. The PAD samples used during the uptake rate testing will be analyzed on laboratory instrumentation that is calibrated for the range of MeS mass expected to be sampled during the PAD uptake rate testing.

g. The average of the chamber vapor concentration and the actual time of exposure shall be used to determine the uptake rate from the following equation:

$$u = \frac{m}{Ct}$$

Where:

m is the average total mass measured on all of the PADs in mg,

u is the uptake rate in cm³/min, and

Ct is the vapor dosage (in mg·min/cm³) the PADs were exposed to while in the chamber/exposure container as measured during the test.

A-5. Real Time Sensor (RTS).

a. RTSs are miniature real time sensors that were developed for use in MIST testing under the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear (JPEO CBRN) Integration program. RTS are specific for detection of MeS and have the capability to detect momentary leakages of IPE caused by various movements. The RTS have a four-hour battery and are capable of wirelessly transmitting concentration data during testing or downloading the stored data after the test is completed. Alternative RTS developed for use with MIST should have a battery life suitable for a minimum of 2.5-hour testing period.

APPENDIX A. BACKGROUND.

b. The RTS were developed during a research project funded by the Product Director for Cross-Commodity Advanced Threats and Test Infrastructure (PD-CCATTI) from 2018 to 2020. RTS units from various commercial vendors were evaluated early in the project, and the best sensor was selected after initial testing. A final side-by-side evaluation with PAD samplers was conducted during MIST testing in November 2020 to evaluate potential capability for use during MIST. The results were not fully conclusive and more evaluation was recommended.

c. RTS must be calibrated before use and are placed on the same locations as the PAD samplers (except for the boot and nose cup locations). It is hoped to eventually replace the PAD samplers with the RTS, but this is a new measurement device, and the technology is not yet mature enough for complete replacement.

A-6. PVSMS.

a. The PVSMS is a small transistor-based system that relays physiological data about each TP to a computer-based data collection and readout station used in the MIST (if required by safety protocol at the test facility). This system, or another similar system, will allow medical personnel (i.e., emergency medical technicians [EMTs], nurses, etc.) and test control personnel to monitor each TP (in the MeS environment) for heat stress and other physiological signs of distress.

b. The system measures:

- (1) Core body temperature by use of a small, pill-sized monitor (which is swallowed).
- (2) Heart rate by use of a heart monitor strapped around the TP's chest.
- (3) Skin temperature taken by a probe attached to the skin next to the heart monitor.
- (4) Skin temperature taken by a probe attached to the skin on the TP's side next to the IPE suit and the heart monitor harness.

(5) Skin temperature taken by a probe attached to the skin underneath each of the TP's arms.

c. The sensor readings are generally transmitted to the personal data collection instrument package that is attached to the TP's left side, outside the IPE suit (other systems may use different methods for transmitting data). The instrument package will be maintained on the outside of the TP's clothing in a manner that minimizes interference with the test, such as in a garment pocket on the TP's left arm or taped to the upper left arm.

d. A radio-frequency antenna that is mounted inside of the test chamber will transmit the data from the pill receivers to a data-collection system and an auxiliary station inside the control room.

APPENDIX B. EXERCISE STATIONS, EXERCISES, AND INSTRUCTIONS.

Table B.1 shows the standard list of exercise stations, exercises, and instructions. It should be noted that the positions of the stations are rotated so the IPE suit is evenly exposed. The activities may be modified to accommodate safety concerns; especially to accommodate TPs wearing body armor and other IPE with high thermal burden. Table B.2 is a list of other exercise routines used during MIST testing with other ensembles for specific individuals. Other activity routines may also be used if they will more accurately mimic the expected operational routine for the IPE.

TABLE B.1. LIST OF EXERCISE STATIONS, EXERCISES, AND INSTRUCTIONS FOR STANDARD MIST.

Station	Exercise	Instructions
1	Jumping jacks	Test participants (TPs) will perform simulated jumping jacks by repetitively extending arms laterally moving them together above their heads and placing feet approximately 1.5 times their shoulder width apart, then returning the feet heel-to-heel and arms to their sides. Repeat this routine every 6 to 8 seconds.
2	Sitting rest	TPs will be seated with right side facing into the wind.
3	Walking simulation	TPs will walk, facing into the wind, on a treadmill operated at 4.8 km/hr (3 mph) with a 3 percent incline.
4	Sitting rest	TPs will be seated with left side facing into the wind.
5	Lifting weights	TPs will move two 10-kg (22-lb) weights from the top shelf to the middle shelf, to the bottom shelf, and finally back to the top shelf by (1) grasping the weight on the top shelf and moving it to place it on middle shelf; (2) squatting in front of the middle shelf, grasping the weight, and then moving it to the bottom shelf; (3) kneeling on one knee (alternate knees for this portion of the routine), grasping the weight on the bottom shelf and moving it to the middle shelf; and (4) grasping the weight on the middle shelf, and moving it to the top shelf.
6	Taking cover	TPs will assume a prone position, sight the mock weapon into the wind, and stay in that position.
7	Step simulation	TPs will repetitively step up, with back to the wind, onto a 9- to 12-inch-high step with both feet, and then return to the floor. Repeat this routine every 6 to 8 seconds while alternating the leading leg.
8	Reaching simulation	TPs will repetitively extend their arms above their heads as far as possible to touch, grab or replace a designated item. Repeat this routine every 10 to 12 seconds while alternating arms.

APPENDIX B. EXERCISE STATIONS, EXERCISES, AND INSTRUCTIONS.

Table B.2. List of Other Exercise Routines and Instructions for Optional MIST.

Fire Fighter Exercise Routine		
Station	Exercise	Instructions
1	Head Movements	Stand With Arms Hanging Downward Along the Sides of the Body and Move the Head Left to Right, Upward and Downward, and Over Left and Right Shoulders
2	Walking	Treadmill Walking, Level, Moderate Rate (4 mph)
3	Arm Reach	Reach Above Head and Look Upward and Downward Repeatedly
4	Duck Walk	Walk in Semi-squatted Position (the "Duck Walk")
5	Crawling	Crawl on Hands and Knees
6	Drag Rescue	Drag 160-pound Dummy (Under Arm Drag)
7	Rest	Rest for 1 minute
8	Ladder	TPs will climb up a ladder, extend their arms above their heads, and climb down the ladder.
9	Stretcher Rescue	Place a 160-pound Dummy in a Rescue Basket, Lift Basket and Carry.
10	Rest	Rest for 1 minute
Police Officer Exercise Routine		
Station	Exercise	Instructions
1	Standing	Standing; 3 minutes
2	Walking	Slow Walk on Treadmill, Level, Moderate Rate; 2.5 km per hours (1.55 mph); 3 minutes
3	Hand Movements	Traffic Directing Hand Movement; 2 minutes Radio Operation Hand Movement; 1 minute
4	Door Actions	Knocking on Doors/Evacuation Procedures; 3 minutes
5	Running	Running in Place, Treadmill, Fast Rate; 5 km per hours (3.1 mph); 3 minutes
6	Rest	Seated Rest; 3 minutes
7	Hand Movements	Traffic Directing Hand Movement; 2 minutes Radio Operation Hand Movement; 1 minute
8	Arrest Movements	Handcuff Motions; 1 minute Shoulder Firearm; 2 minutes
9	Walking	Slow Walk on Treadmill, Level, Moderate Rate; 2.5 km per hours (1.55 mph); 3 minutes
10	Rest	Seated Rest; 3 minutes

APPENDIX C. SAMPLE INFORMED CONSENT AFFIDAVITS.

INFORM CONSENT AFFIDAVIT FOR
MAN-IN-SIMULANT TEST (MIST) PROGRAMS

PROTOCOL OBJECTIVE: MIST programs are designed to test various chemical/biological personal protective ensembles and equipment for possible adoption to provide military personnel with state-of-the-art protection against known chemical and/or biological hazards.

INSTITUTION:

TEST LOCATION:

TEST EXECUTION RESPONSIBILITY:

TEST OFFICER: A test officer (or equivalent) will be assigned for each MIST program. This individual is responsible for on-site execution of the MIST program. All activities at the MIST site are under direction of the assigned test officer. This individual will be your day-to-day contact for receiving instructions regarding your personal participation. Questions or concerns regarding your participation in the MIST program should be directed to this individual for resolution. This individual will be made known to test participants during orientation briefings.

PROGRAM OBJECTIVES: To obtain sufficient data to characterize the vapor-protective performance of candidate chemical-protective ensembles and equipment. The data from this comparative analysis will support the evaluation of the chemical protection capability provided by the candidate ensembles and equipment in order to further determine acceptance for future military use.

GENERAL NOTICE:

a. This research does not expose you, or any test participant, to any chemical or biological agent.

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APPENDIX C. SAMPLE INFORMED CONSENT AFFIDAVIT

b. All records of this study, including the names and social security numbers of each test participant, will be stored, upon completion of this study, in accordance with Army Regulation (AR) 340-21.

c. There are no hidden experimental procedures within this study.

d. This research has been reviewed for scientific validity, military significance, and ethical concerns. As a volunteer, you will be authorized, under the provisions of AR 70-25, all necessary medical care for injury or disease which is the proximate result of your participation of this study.

e. The complete plan for this study is contained in the detailed test plan for this MIST program. A copy of the detailed test plan will be made available to you upon request.

f. You have been asked to participate in a research study conducted by [Name of the Test Facility]. It is important that you read and understand the following principles that apply to all participants in our studies:

(1) Your participation is entirely voluntary.

(2) You may withdraw from participating in this study at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

(3) After you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

(4) Subjects in this test must be active military, government civilian, or government contractor.

(5) Subjects with the following conditions will be excluded from test participation:

(a) Anyone with a known heart problem.

(b) Anyone with high blood pressure (systolic above 160 or a diastolic above 100).

DESCRIPTION OF STUDY: Detailed information concerning the specific nature of the study in which you have been asked to participate is provided below:

a. **TITLE OF TEST:** [Name of Test].

b. **PURPOSE:** To obtain sufficient data to characterize the vapor-protective performance of candidate chemical-protective ensembles and equipment. The data from this comparative analysis will support the evaluation of the chemical-protection capability provided by the candidate ensembles and equipment in order to further determine acceptance for future military use.

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APPENDIX C. SAMPLE INFORMED CONSENT AFFIDAVIT

c. DURATION: The duration of this program is dependent on the number of protective ensembles to be tested. The current schedule is to test X ensembles per trial day with X test participants in each trial. You will be informed of the number of trial days during the in-brief.

d. CHEMICAL AGENT SIMULANT: The simulant to be used in this program is methyl salicylate (MeS). This chemical is also known as oil of wintergreen which is used in many products that are used internally and externally. A copy of the safety data sheet (SDS) will be provided to you on request.

e. TEST PROCEDURE: Each test participant will be wearing prototype or standard chemical-protective garments during a 2-hour mission scenario.

f. REASONABLE FORESEEABLE RISKS OR DISCOMFORTS: The risks or discomforts that may arise from this study include heat stress caused by moderate to heavy work performed while wearing the standard and prototype garments.

(1) Heat stress may occur during periods of moderate work while wearing the standard garments in hot weather. Water will be made available throughout the test, and participants should drink ample amounts to protect against heat stress. Symptoms of heat stress include: heat cramps of the muscles of the stomach, arms, or legs and heat exhaustion which may cause you to be dizzy, faint, or weak. A test participant experiencing heat stress should notify a buddy, seek shade, drink water, remove outer clothing, lie down, and elevate feet. Although heat stress is not in itself life threatening, if ignored it could lead to a much more serious situation called heat stroke. Heat stress monitoring and egress procedures are incorporated into the MIST to ensure the maximum protection for each individual.

(2) Heat stroke is always life threatening. In heat stroke, the person's temperature-control system that causes sweating stops functioning properly. The body temperature rises so high that brain damage and death will result if the person is not cooled quickly. The main signs of heat stroke are: red or flushed skin; hot, dry skin (although the person may have been sweating earlier); and extremely high body temperature (up to 106°F). There may be dizziness, nausea, headache, rapid pulse, and unconsciousness. If you feel these symptoms or notice a buddy who appears to have these symptoms, immediately notify the on-site floor boss, medical personnel (i.e., emergency medical technicians [EMTs], nurses, etc.), test officer, test data collector, or a buddy. The test participant will be given immediate first aid and evacuated to medical facility.

(3) Medical personnel (i.e., EMTs, nurses, etc.) will be onsite throughout the test. Test participants will have their core body temperature monitored using the PVSMS. The purpose of the PVSMS is to help mitigate the occurrence of heat stress during the trials. You may be requested to swallow a disposable monitor pill and wear a small transmitter on your upper arm. The pill has been used in hospitals and in previous field studies and is considered safe.

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APPENDIX C. SAMPLE INFORMED CONSENT AFFIDAVIT

The pill will measure your core body temperature and transmit the measurement to the transmitter using a low-power transmitter; skin thermistors may be used instead of the pill to monitor skin temperature. You will also be asked to wear heart rate and activity monitors throughout the test, which will also provide safety-monitoring data. The Army Surgeon General's Office and the Human Use Review Board approved the PVSMS for use during this test. The pill is eliminated from your body through normal waste elimination processes. The pill is processed like any other medicine or food except that the pill does not break down or get digested; it goes in and comes out whole. The pill is a little larger than the average medicine capsule and will only be used once and then be discarded. More information is available about the PVSMS upon request.

g. BENEFITS TO SUBJECTS OR TO OTHERS: The subjects who participate in this test will gain a unique training experience in the operation, wear, and maintenance of the newest chemical-protective garments available and other candidate commercial garments. The results (comments and statistical data) will be used as input for upgrading the design and operation of the chemical-protective suits in the future and providing guidance and procedures for safe operation today.

h. ASSURANCE OF CONFIDENTIALITY OF PERSONAL IDENTIFICATION INFORMATION (PII): I understand that this study is affected by the Privacy Act of 1974 (top of the Inform/Consent Affidavit) and have been made aware of the safeguards available to me because of that act. I also understand that the information gained from this study may be analyzed and used as part of a scientific publication, but I will in no way be personally identified. I understand that it may be necessary for representatives of the Surgeon General's Human Subjects Research Review Board to inspect my records concerned with this study in their capacity as reviewing officials.

i. CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: At the discretion of a physician, you may be withdrawn at any time from this study for medical reasons. You will be removed if your core body temperature reaches 38.8 °C (102 °F). You may also be removed, at the discretion of the test officer, if it becomes obvious that continuation in the study is likely to result in injury to you or others in the study.

j. COMMENTS FROM SUBJECTS: Your safety is our primary concern. Any feedback in the form of questions, comments, and criticism is essential to the success of the test. You will be asked to fill out human factors engineering questionnaires and to comment on safety and health hazard issues.

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IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE TEST OFFICER BEFORE SIGNING.

I concur that the use of the PVSMS has been explained to me and is considered an experimental device. I understand that my signature below is an agreement to use the PVSMS and associated pill as a safety monitor.

I have received a copy of the volunteer explanation and volunteer inform/consent affidavit that I may keep.

VOLUNTEER'S SIGNATURE

DATE

VOLUNTEER'S PRINTED NAME

PERMANENT ADDRESS

I was present during the explanation referred to above, as well as during the volunteer's opportunity to ask questions. I hereby witness the volunteer's signature.

WITNESS' SIGNATURE

DATE

TOP 10-2-022B

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APPENDIX C. SAMPLE INFORMED CONSENT AFFIDAVIT

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APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

D-1. STANDARDIZED POSTURE.

The purpose of a standardized test participant posture is to ensure that the differences found in body sizes within a group are not because of variations in body posture. Most body posture descriptions are self-explanatory, but the frequently used phrase “anthropometric standing” requires clarification. For anthropometric standing, test participants are asked to stand erect with their weight evenly distributed on both feet, heels together as much as possible, legs and trunk straight without stiffness, and the head erect and looking straight ahead. The arms are to hang relaxed with the elbows lightly touching the sides with the palms of the hands beside, but not touching the thighs. This posture is similar to that of the position of military attention but without the stiffness and bracing with which it is often associated. A number of dimensions and landmarks require that the participant's head be in the Frankfort plane (also known as the Frankfort horizontal, Figure D.1). This head position is quite similar to having the participant look straight ahead with the head erect. However, when the Frankfort plane is called for, the anthropometrist will position the participant's head so that an imaginary line connecting the drawn landmarks at right tragon and right infraorbital is horizontal.

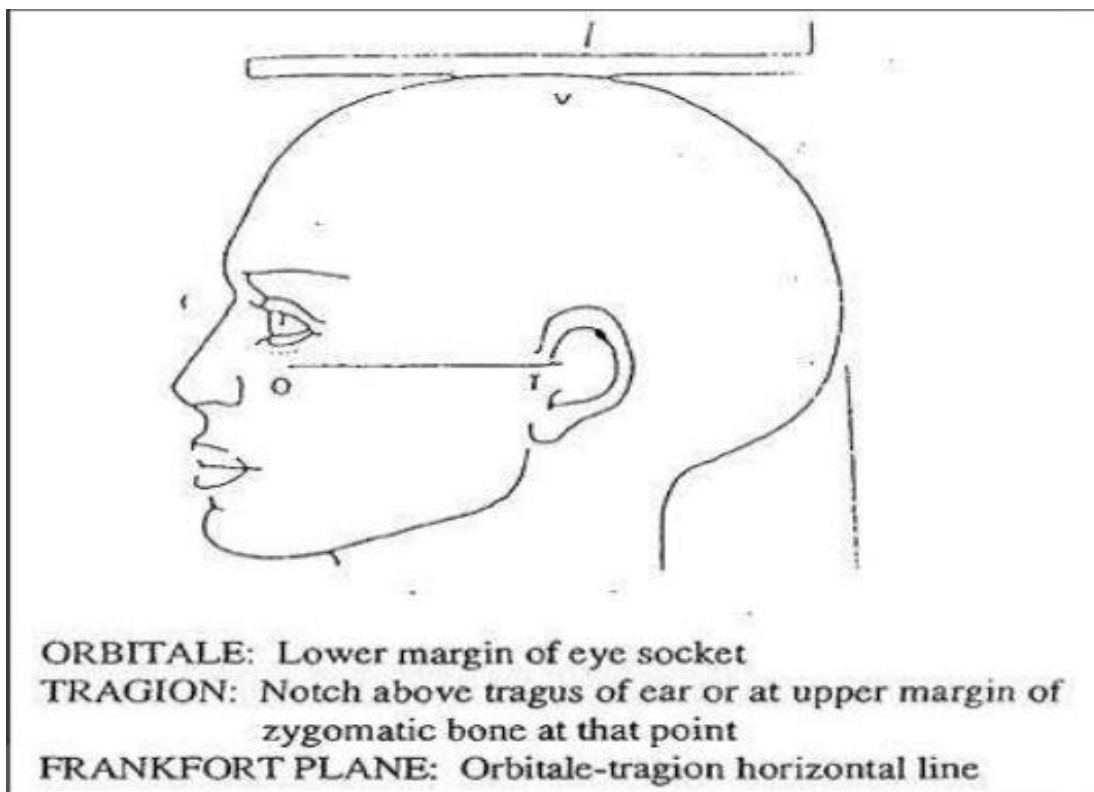


Figure D.1. Frankfort Plane Example.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

D-2. TERMS OF ORIENTATION.

a. Anatomical Position – a standard position of the body to which all anatomical directions (e.g., superior, medial, anterior) are referenced (Figure D.2).

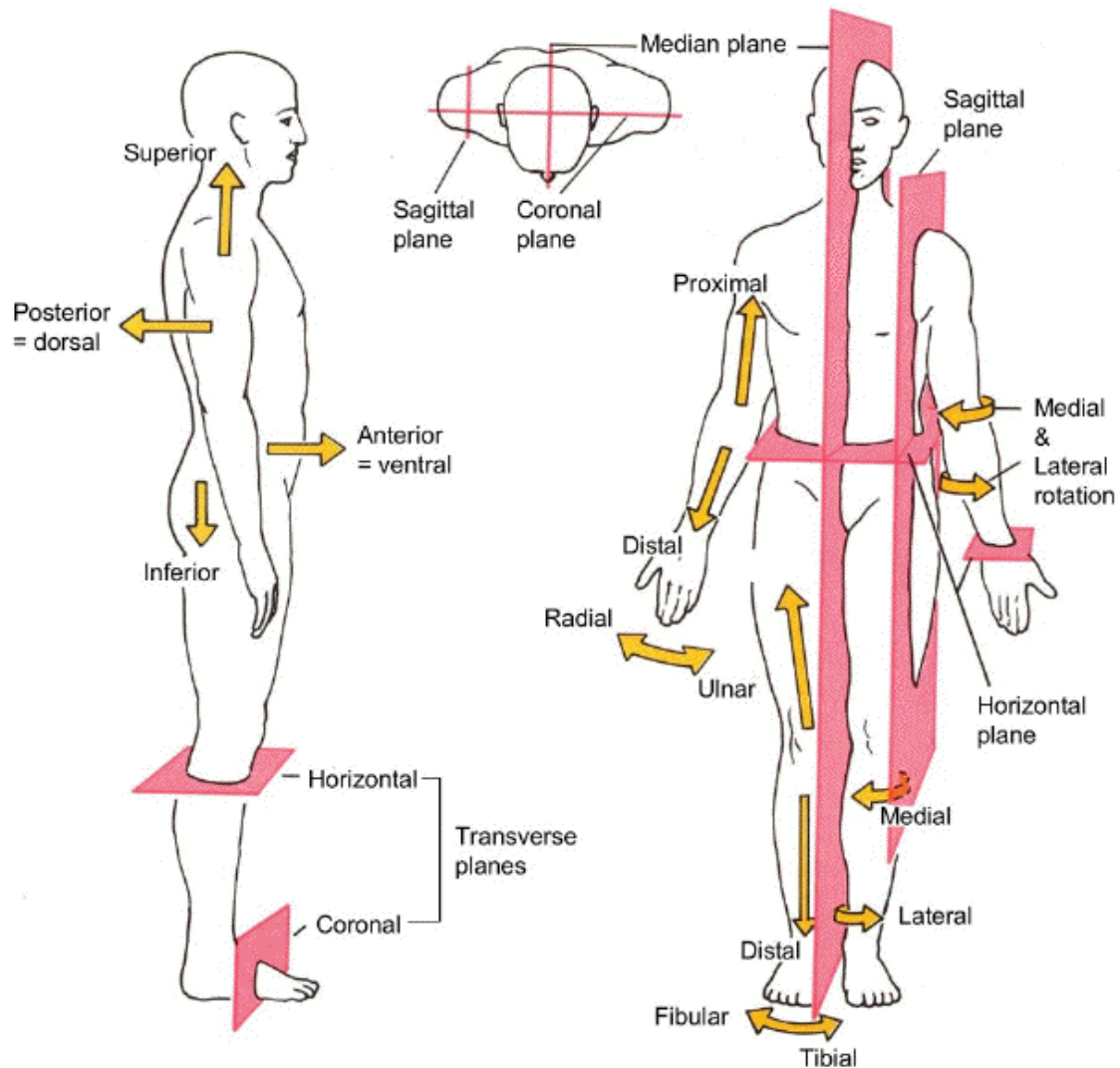


Figure D.2. The Body in Anatomical Position.

- b. Anterior – pertaining to the front of the body as opposed to posterior.
- c. Coronal Plane – any vertical plane at right angles to the midsagittal plane.
- d. Distal – the end of a bone or body segment farthest from the head, as opposed to proximal.
- e. Dorsal – pertaining to the back of the body or one of its parts (on the hand, its top surface as opposed to its palmar surface).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

- f. Inferior – below, in relation to another structure; lower.
- g. Lateral – lying near or toward the sides of the body as opposed to medial.
- h. Medial – lying near or toward the midline of the body as opposed to lateral.
- i. Midsagittal Plane – the vertical plane which divides the body into right and left halves.
- j. Transverse Plane – the horizontal plane which divides the body into top and bottom halves.
- k. Posterior – pertaining to the back of the body as opposed to anterior.
- l. Proximal – the end of a bone or body segment nearest the head as opposed to distal.
- m. Superior – above, in relation to another structure; higher.
- n. Supra – prefix designating above or on.

D-3. Anatomical and Anthropometric Terms.

- a. Anterior superior iliac spine (ASIS) – the anterior terminal point of the iliac crest of the pelvis. It can be located by palpation. A line drawn between the right and left ASIS defines the superior boundary of the pubic region.
- b. Landmark – a landmark (auxiliary landmark or another passive adsorbent device (PAD) location) which is used to determine the position of a given PAD location of interest.
- c. Biceps – the large muscle on the anterior surface of the upper arm.
- d. Femur – long bone of the upper thigh (thigh bone).
- e. Inguinal crease – the crease at the junction of the inner part of the thigh with the trunk.
- f. Mastoid process – lowest bony projection behind and below the ear. The mastoid process can be easily located behind the earlobe.
- g. Omphalion – the navel or bellybutton.
- h. Palpate – to locate or explore an area of the body by touch or feel. They are often used in reference to identification of an underlying bony landmark.
- i. Mandible – the jawbone.
- j. Radius – long bone of the forearm, located laterally (thumb side) when in anatomical standing posture.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

k. Scye – points at the junction of the upper arm and torso. Scye can typically be referred to as anterior or posterior.

l. Tibia – primary long bone of the lower leg (shin bone), located medially (big toe side).

m. Triceps – the large muscle on the posterior surface of the upper arm.

n. Ulna – long bone of the forearm located medially (little finger side) when in anatomical standing posture.

D-4. IDENTIFYING LANDMARKS AND PAD MARKERS.

a. Landmarks are listed in table D.1. Procedures for determining these landmarks are described in this section along with appropriate PAD markers for each sample.

TABLE D.1. LANDMARK CHECKLIST

Landmarks	Anatomic Location
1	Infraorbitale (bony eye socket)
2	Tragion (ear flap juncture)
3	Infrathyroid (bottom point of the Adam's apple)
4	Biceps point, left
5	Elbow crease, left
6	Stylian, left (bony wrist point – thumb side)
7	Wrist, dorsal, left
8	Anterior superior iliac spine (ASIS), right and left
9	Waist (venter of the navel)
10	Left inside knee, flexed knee
11	Fifth metatarsophalangeal protrusion, left
12	First metatarsophalangeal protrusion, left

b. Identify Landmark 1 (Figure D.3).

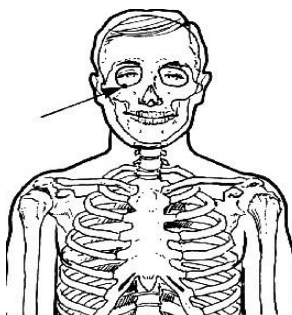


Figure D.3. Infraorbitale.

(1) Infraorbitale, the lowest point on the border of the bony eye socket.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(2) PROCEDURE: Direct the participant to stand, looking straight ahead. Stand in front of the participant and palpate the bony eye socket under the eye to locate its lowest point. Draw a dot on the landmark.

(3) CAUTION: Participants may be apprehensive when you palpate near their eyes. Care must be taken in locating this landmark to reduce the participant's concern.

c. Identify Landmark 2 (Figure D.4).

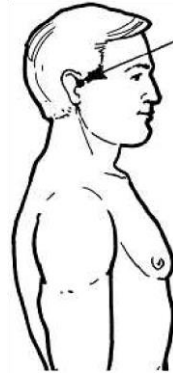


Figure D.4. Tragion.

(1) Tragion left and right.

(2) PROCEDURE: Palpate each tragus to find the upper point of attachment to the head. Place a dot on each landmark. Avoid distorting the soft tissue in this area while drawing the landmark.

d. PAD marker P1.

(1) DESCRIPTION: Point posterior to the ear at the level of tragion (Figure D.5).

(2) LANDMARK: Tragion.

(3) PROCEDURE: Direct the participant to stand in anthropometric standing position with the head in Frankfort plane. Behind the ear, draw a short horizontal line (the ear landmark line) on the head at the level of tragion. Ensure that the PAD will not be covered by any of the straps from the mask.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure D.5. PAD MARKER P1, Left Ear.

e. Identify LANDMARK 3 Figure D.6.

(1) Infrathyroid (bottom point of the Adam's apple).

(2) PROCEDURE: Direct the participant to stand with the head in the Frankfort plane. Stand in front of the participant and palpate the smooth surface of the thyroid cartilage moving downwards until you locate the bottom point of the thyroid cartilage (Adam's apple) in the mid-sagittal plane. Draw a short horizontal line through the landmark.

f. PAD marker P2.

(1) Chin (anterior neck).

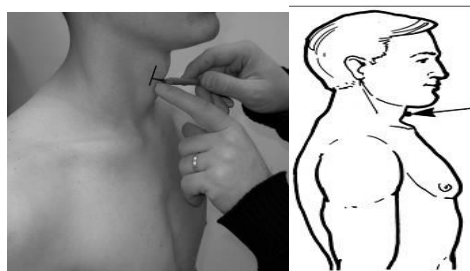


Figure D.6. LANDMARK 3, Infrathyroid.

(2) DESCRIPTION: The front, middle of the neck lateral to the Adam's apple at the level of the neck circumference line (Figure D.7).

(3) PROCEDURE: Direct the participant to stand, looking straight ahead, with the teeth together and the head in Frankfort plane. Stand to the rear of the participant and place the

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

PAD at the center of the neck with the upper edge at the level of the drawn Infrathyroid landmark (bottom of the Adam's apple).



Figure D.7. PAD MARKERS P2, Chin (Anterior Neck).

g. PAD markers P13.

(1) Nape of the neck.

(2) DESCRIPTION: Points on the posterior of the neck (nape) (Figure D.8).

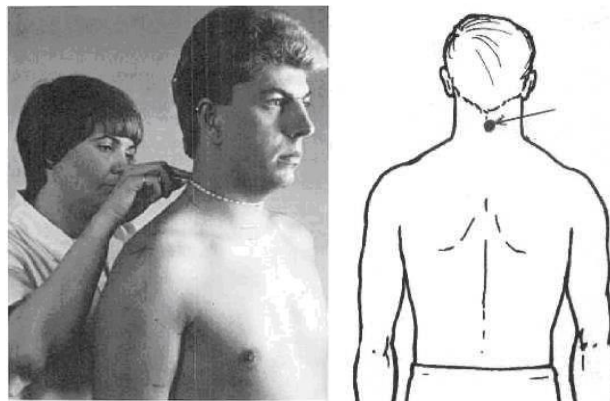


Figure D.8. PAD Markers P13, Nape.

(3) PROCEDURE: Use the same procedure as used in Paragraph g. Now, standing behind the participant, draw a 6-cm, horizontal line along the upper edge of the tape across the back of the neck. At the intersection of the drawn line and the spinal column, draw a short vertical line across the horizontal line.

h. PAD marker P14.

(1) Scye (armpit), left.

(2) DESCRIPTION: Points on the posterior upper arm and torso associated with the armhole of a garment (Figure D.9).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

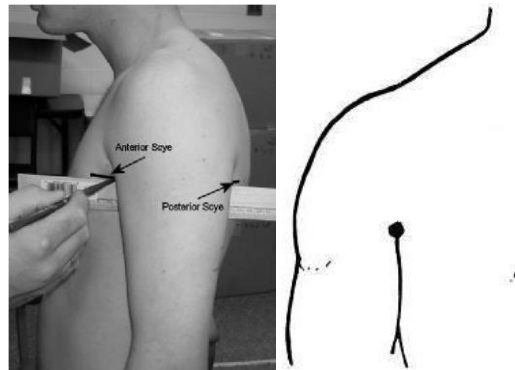


Figure D.9. PAD Marker P14, Scye (Armpit), Left and Right.

(3) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Direct the participant to place the left hand on the hip. Begin by standing in front of the participant and move around the participant as needed. Place the edge of a plastic ruler firmly into the armpit in a horizontal position and then ask the participant to carefully lower the arm to the side, thus clamping the ruler in place. Make sure the ruler is level. Draw a short horizontal line on the torso at the top of the ruler on the anterior and posterior junction where the arm and torso intersect. With the arm hanging naturally to the side, cross this line with a short vertical line at the posterior edge of the arm. Repeat this procedure for the right side.

(4) These are some of the more difficult landmarks to locate accurately and consistently. On some participants, the arms must be held farther away from the body than the hands-on-hips position to place the ruler in its proper position. Be sure that the ruler is level when the arm is lowered to the side. If it is not, begin the process of placing the ruler again. Do not try to level the ruler while the participant's arm is down.

i. PAD marker P3.

(1) Upper chest.

(2) DESCRIPTION: Center of chest at the level of scye (Figure D.10).

(3) PROCEDURE: Place tape horizontally across the torso between the left and right anterior scye landmarks. The tape should be tight against the chest. Align the top edge of the tape with the right and left anterior scye landmarks. Draw a horizontal line along the top edge of the tape at mid-chest. Bisect this line with a short vertical line on the sternum at the midsagittal plane.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

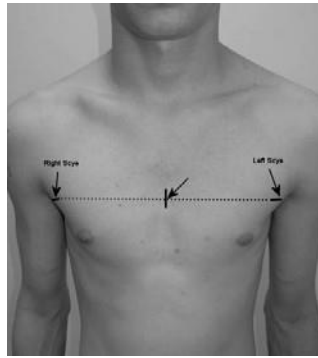


Figure D.10. PAD Marker P3, Chest, Center.

j. Identify LANDMARK 4.

(1) Biceps point, left, the highest point of the left flexed biceps as viewed from the participant's left side (Figure D.11).

(2) PROCEDURE: Direct the participant to stand with the left upper arm extended forward horizontally and the elbow flexed about 90 degrees. The participant's fist will be tightly clenched and held facing the head. Stand to the right of the participant and locate the highest point on the flexed biceps by inspection. Draw a short line perpendicular to the long axis of the upper arm passing through the landmark. Maintain position for next step.

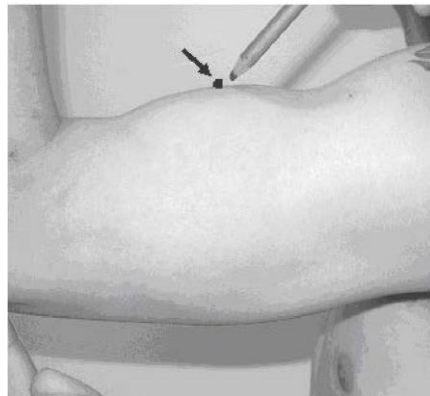


Figure D.11. LANDMARK 4, Biceps Point, Left.

k. PAD marker P4.

(1) DESCRIPTION: Inside of the upper arm between the biceps and triceps muscles at level of biceps circumference, flexed (Figure D.12).

(2) PROCEDURE: Direct the participant to stand with the left upper arm extended forward horizontally and the elbow flexed about 90 degrees. Place a tape around the upper arm (as if measuring biceps circumference) at the level of the drawn biceps point landmark. The fist will be clenched and held facing the head. The participant will be urged to exert maximum effort

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

in “making a muscle.” The tape should be in a plane perpendicular to the long axis of the upper arm. Exert only enough tension on the tape to maintain contact between the tape and the skin. Palpate downward on the biceps along the tape to the groove between the biceps and the triceps brachii muscle. Place a mark at the point where the tape intersects this groove. Maintain tape position for the next step.

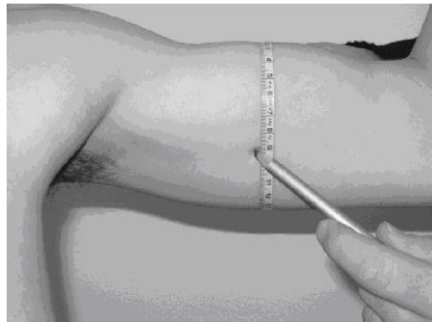


Figure D.12. PAD Marker P4, Inner Upper Arm, Left.

1. PAD marker P15.

(1) DESCRIPTION: Outside of the upper arm at the level of the bicep's circumference, flexed (Figure D.13). Note that sample position P15 is on the right arm; however, this figure shows the left arm. Transpose this same position on the right arm.

(2) LANDMARK: Biceps point, right.

(3) PROCEDURE: Use the same procedure used in Paragraph 1. Place a mark on the right outer upper arm at the most lateral point of the biceps muscle that is crossed by the tape. Place PAD sample P15 on the outer side of the right arm.

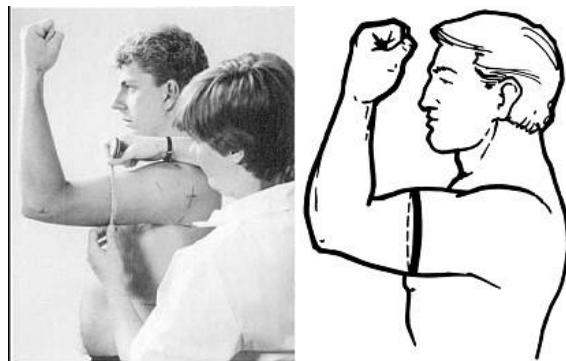


Figure D.13. PAD Marker P15, Outer Upper Arm, Right.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

m. Identify LANDMARK 5.

(1) Elbow crease, left, the skin crease on the inside of the elbow joint when the elbow is flexed 90 degrees (Figure D.14).

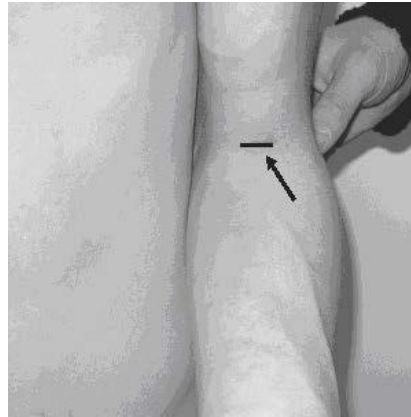


Figure D.14. LANDMARK 5, Elbow Crease, Left.

(2) PROCEDURE: Direct the participant to stand with the upper left arm hanging naturally to the side, the lower arm extended forward horizontally, the elbow flexed about 90 degrees, and the palm of the hand facing upward. Place a horizontal mark along the primary elbow crease.

n. Identify LANDMARK 6.

(1) Stylium, left, the lowest point of the bottom of the radius (Figure D.15).

(2) PROCEDURE: Direct the participant to stand. Stand in front of the participant and grasp the participant's hand. Place your thumb on the thumb side of the participant's hand and palpate up toward the wrist until you locate the end of the radius. Draw a line over the landmark. This area is crossed by tendons so it may be necessary to bend the hand up and down at the wrist to find the landmark.

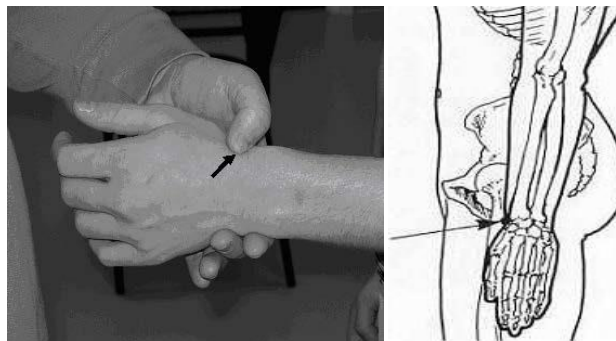


Figure D.15. LANDMARK 6, Stylium, Left, the Lowest Point of the Bottom of the Radius.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

o. Identify LANDMARK 7.

(1) Wrist, dorsal, left (Figure D.16). A line across the back of the wrist originating at the stylium landmark and perpendicular to the long axis of the arm.

(2) PROCEDURE: Direct the participant to stand. Direct the participant to make fists and bring them together as shown in the Figure D.16. With the back of the hand facing outward and the palm sides facing inward, direct the participant raise the arms until they are in a horizontal position roughly parallel to the standing surface. The forearms and fists will be in a straight line. Stand in front of the participant looking directly at the stylium landmark to eliminate errors in sighting. Draw a line across the dorsal (back) surface of the wrist beginning below the stylium. Be sure the line is vertical and that its origin is at the stylium.

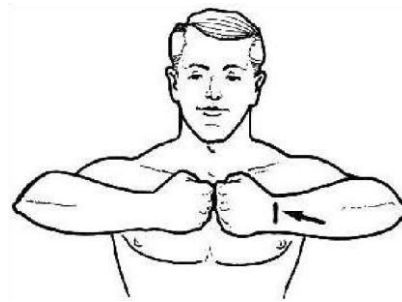


Figure D.16. LANDMARK 7, Wrist, Dorsal, Left.

p. PAD marker P5.

(1) DESCRIPTION: Point centered on the inner surface of the lower left arm at a level midway between the elbow crease and the wrist crease (Figure D.17).



Figure D.17. PAD Marker P5, Forearm, Volar, Left.

(2) LANDMARKS: Elbow crease, wrist, dorsal.

(3) PROCEDURE: Direct the participant to stand with the upper left arm hanging naturally to the side, the lower arm extended forward horizontally, the elbow flexed about 90 degrees, and the palm of the hand facing upward. Mark a line on the arm midway between the

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

elbow crease and the wrist, dorsal landmarks. Visually estimate the point along this line that is midway between the lateral and medial sides of the lower arm. At this point, draw a line that bisects the first line.

q. PAD marker P18.

(1) DESCRIPTION: A point on back of hand midway between the knuckle of the third finger and the back wrist crease (Figure D.18).



Figure D.18. PAD Marker P18, Glove (Hand), Left.

(2) LANDMARKS: Stylium, wrist, dorsal.

(3) PROCEDURE: Direct the participant to rest a forearm on a table while extended forward horizontally, with the hand extended straight with dorsal side facing up. Take a perpendicular measurement from the wrist, dorsal landmark to the first knuckle of the third finger. Mark a point midway along the line.

r. Identify LANDMARK 8.

(1) ASIS, left and right (Figure D19).

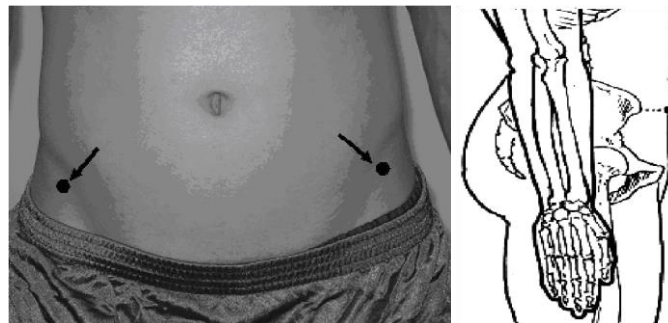


Figure D.19. LANDMARK 8, Anterior Superior Iliac Spine (ASIS), Left and Right.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant. Locate each iliac crest (the top of the pelvis) by palpation, and then bring the thumb to the anterior points of the crests. Mark each landmark. In most cases you will have to ask the participant to lower the waistband of the shorts somewhat to reveal these points. Do not distort the skin when drawing the cross.

s. PAD marker P6.

(1) DESCRIPTION: Point below the navel on a line between the left and right ASIS (Figure D.20).

(2) LANDMARKS: ASIS, center

(3) PROCEDURES: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant. Stretch a tape between the left and right ASIS landmark. Draw a short horizontal line along the tape below the navel. From the center of the navel, visually project a vertical line downward and draw a short vertical line where it crosses the horizontal line. Do not distort the skin when drawing the cross.

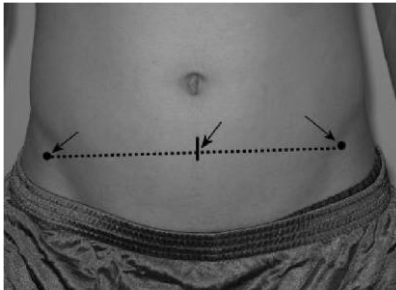


Figure D.20. PAD Marker P6, Groin/Pubic Region.

t. LANDMARK 9, PAD markers P16 Lower Back, and P8 Mid-Back.

(1) Waist (center of the navel, omphalion), posterior (Figure D.21).



Figure D.21. Landmark 9, PAD Marker P16, Waist (center of the navel, Omphalion), Posterior.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant and locate the center of the navel by inspection. Draw a 4-cm horizontal line across navel. Stand in back of the participant. With the top edge of the tape passing over the center of the navel, place tape horizontally around the waist as if measuring waist circumference. Draw a 4-cm horizontal line across the spine of the participant at the upper edge of the tape. Draw a vertical line at the spine that crosses the horizontal line and extends up to the Nape (PAD Marker P13). Draw PAD Marker P16 line in the center of the lower back along the bottom of this vertical line at the waistline. Visually note the distance on the vertical spine line that is halfway between the Nape (P13) and the lower back (P16); mark a cross line at this point. Place PAD Marker P8 line in the center of the mid-back region at this mid-point between the Nape (P13) and the lower back (P16). The landmarks are drawn at the maximum point of quiet respiration. The participant must not tense the abdominal muscles or change body position during location and marking of these points. The tape must be horizontal around the waist.

u. PAD marker P17.

(1) DESCRIPTION: Hip point at the level of the maximum buttock protrusion (Figure D.22).

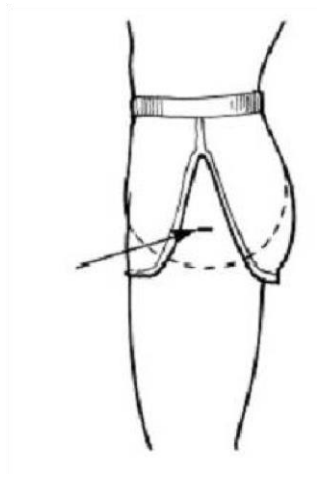


Figure D.22. PAD Marker P17, Hip (Hip Point, Left Side).

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position with the left leg of the shorts hiked above the level of maximum buttock protrusion. Stand to the left of the participant and position the tape loosely around the hips. Sight the point of maximum protrusion of the left buttock (hip point, posterior) and position the tape over the left hip at this point. The tester's assistant will adjust the tape so it is horizontal all the way around the hip region. The tester will place a horizontal line on the left thigh at the lower edge of the tape. The tester will then cross this horizontal line with a short vertical line, visually located along the vertical axis of the femur (upper thigh bone). Be careful because this vertical plane may or may not be located midway between the front and back of the thigh. The posterior and

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

right lateral points of the hip point landmark will not be marked. The participant should exercise care to avoid stretching the soft tissue of the upper thigh when hiking the leg of the shorts.

v. Identify LANDMARK 10.

(1) Left inside knee, flexed knee, inside of the left knee pivot point (medial femoral epicondyle) when the knee is flexed about 90 degrees (Figure D.23).

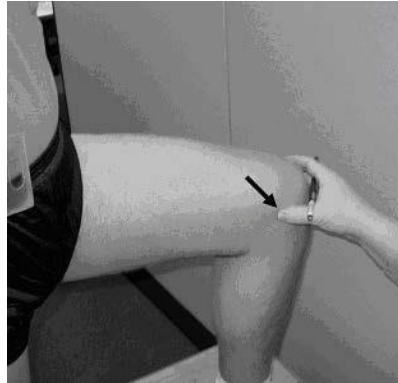


Figure D.23. LANDMARK 10, Left Inside Knee, Flexed Knee.

(2) PROCEDURE: Direct the participant to stand on the right foot with the left foot placed on a low bench so that the left thigh extends forward horizontally and the knee is flexed about 90 degrees. Stand in front of the participant and, with one hand, grasp the bony prominences of the bottom of the femur (femoral epicondyles) located to the left and right of the knee. Direct the participant to flex the knee, if necessary, to help locate the medial epicondyle. When you have located the medial point of the medial femoral epicondyle, use the thumb or index finger of the other hand to mark its place and draw a point on the landmark. Maintain position for next step. This landmark is difficult or impossible to locate accurately in heavily muscled participants. Use your best judgment in these cases.

w. PAD marker P9.

(1) DESCRIPTION: Point on the inner thigh midway between the medial femoral epicondyle and the crotch (Figure D.24)

(2) LANDMARK: Medial femoral epicondyle.

(3) PROCEDURE: Direct the participant to stand erect with the right foot on the floor, the left foot positioned on a low stool so that the left thigh extends forward horizontally, and the lower leg flexes downward approximately 90 degrees. Place an 18-in ruler along the length of the inner thigh with the “zero” end toward the crotch. At the knee, the ruler edge is placed at the medial femoral epicondyle landmark and the ruler is visually aligned with the long axis of the thigh. Ask the participant to slide the ruler up the leg until firm but light contact is

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

made with the crotch. Mark a point on the thigh midway between the crotch and medial femoral epicondyle.

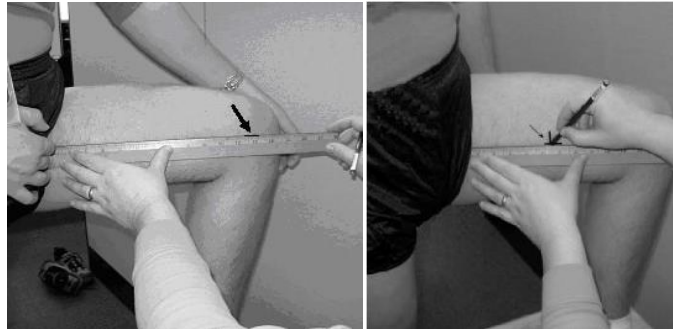


Figure D.24. PAD Marker P9, Inner Thigh, Left.

x. PAD markers P10 and P24.

(1) DESCRIPTION: Point on the inside of the left tibia at the level that maximum calf circumference is measured (Figure D.25).



Figure D.25. PAD Markers P10, Inner Shin, Left.

(2) PROCEDURE: Direct the participant to stand erect with the weight distributed equally on both feet. Wrap a tape around the calf, crossing it at the side, and slide it up and down to establish the maximum circumference of the calf. Be sure the tape is in a horizontal plane. Draw a short horizontal line along the bottom of the tape on the medial side of the calf. Palpate along this line to locate the groove between the calf muscle and the tibia and mark this point on the calf muscle. On some participants, the level of maximum circumference of the calf may extend vertically more than 1 cm. In such cases, the landmark is drawn at the level of the lowest maximum circumference of the calf. Place PAD marker P10 at this location. Perform the same measurements on the right lower leg to determine PAD marker P24, except rotate around to the back of the leg to make the marking. PAD P24 will be placed at this position on the back of the right lower leg, at the calf.

y. Identify LANDMARK 11.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(1) DESCRIPTION: The most lateral protrusion of the left foot in the region of the fifth metatarsophalangeal joint (Figure D.26).

(2) PROCEDURE: Direct the participant to stand on a table with the weight distributed equally on both feet. Stand in front of the participant and, by visual inspection and palpation of the metatarsophalangeal joint, locate the maximum protrusion on the outside of the foot near the little toe. Draw a short vertical line through the landmark. Be sure the mark is placed on or near the joint on the end of the foot and not on the toe.



Figure D.26. LANDMARK 11, Fifth Metatarsophalangeal Protrusion, Most Lateral Protrusion of the Left Foot.

z. Identify LANDMARK 12.

(1) DESCRIPTION: The most medial protrusion of the left foot in the region of the first metatarsophalangeal joint (Figure D.27).



Figure D.27. LANDMARK 12, First Metatarsophalangeal Protrusion, Most Medial Protrusion of the Left Foot.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(2) PROCEDURE: Direct the participant to stand on a table with weight distributed equally on both feet. Stand in front of the participant and, by visual inspection and palpation inspection, locate the maximum protrusion of the inside of the foot near the metatarsophalangeal joint. Draw a short vertical line through the landmark. Be sure the mark is placed on or near the joint on the end of the foot and not on the toe.

aa. PAD marker P11.

(1) DESCRIPTION: Point where the ball of foot circumference intersects the tendon of the second toe (Figure D.28).



Figure D.28. PAD Marker P11, Boot (Foot).

(2) LANDMARKS: First metatarsophalangeal protrusion, fifth metatarsophalangeal protrusion.

(3) PROCEDURE: Direct the participant to stand with the feet about 10 cm apart and the weight distributed equally on both feet. Stand in front of the participant and position a tape as if measuring the circumference of the foot at the drawn first and fifth metatarsophalangeal landmarks on the ball of the foot. At the point where the tape crosses the tendon of the second toe, mark the foot on the side of the tape closest to the ankle; this is the location where PAD sample P11 will be placed.

D-5. PAD PLACEMENT WITH RESPECT TO PAD MARKERS

a. The locations of the PAD placement on the test participant are listed in Table D.2 and are illustrated in Figures D.29 and D.30.

b. Some individuals may experience skin irritation from PAD adhesive following multiple trials. In such cases, varying PAD placement slightly to avoid further irritation is acceptable.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

TABLE D.2. PAD PLACEMENT LOCATION DESCRIPTIONS FOR MIST.

Position Number ^a	Description
P1	Left ear (ensure PAD isn't covered by mask straps)
P2	Chin (anterior neck)
P3	Chest Center
P4	Left Inner upper arm
P5	Left Forearm, volar
P6	Groin/Pubic region
P7	External genitalia/Crotch
P8	Middle of Back
P9	Left Inner thigh
P10	Left Lower Leg, front (shin)
P11	Left Boot, top (foot)
P12	Scalp
P13	Nape
P14	Left Armpit
P15	Right Outer upper arm
P16	Lower back
P17	Hip point, left lateral (buttocks)
P18	Glove (back of left hand)
P19	Right Forearm, Dorsum
P20	Forehead (outside mask; may need to locate at Temple)
P21	Right Cheek (outside mask; above lower strap)
P22	Abdomen (front center)
P23	Right Outer Thigh
P24	Right Lower Leg, back (calf)
P30	Nose cup

^aSee Figures D.29 and D.30.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

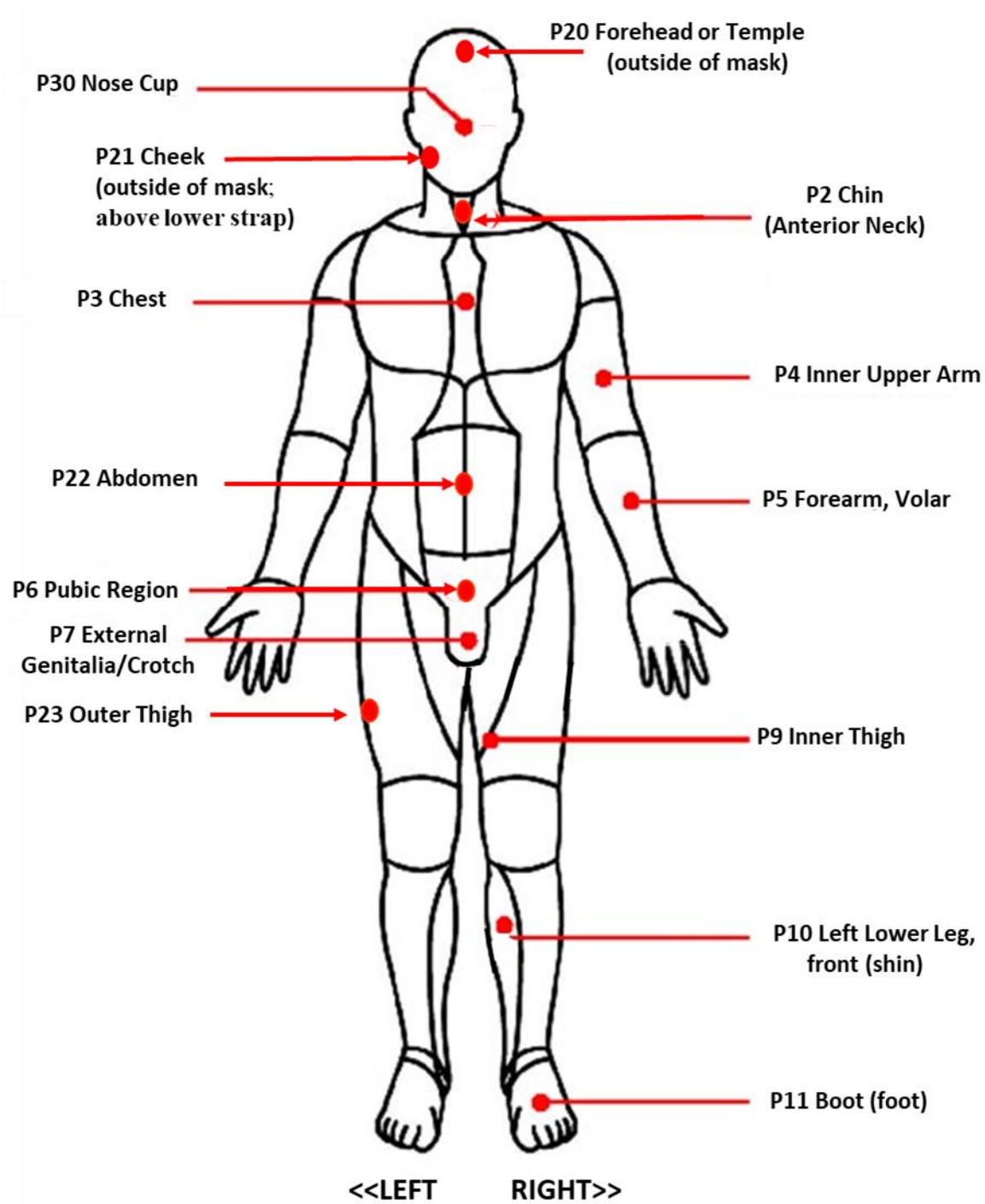


Figure D.29. Passive Adsorbent Device (PAD) Placement Diagram (Front).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

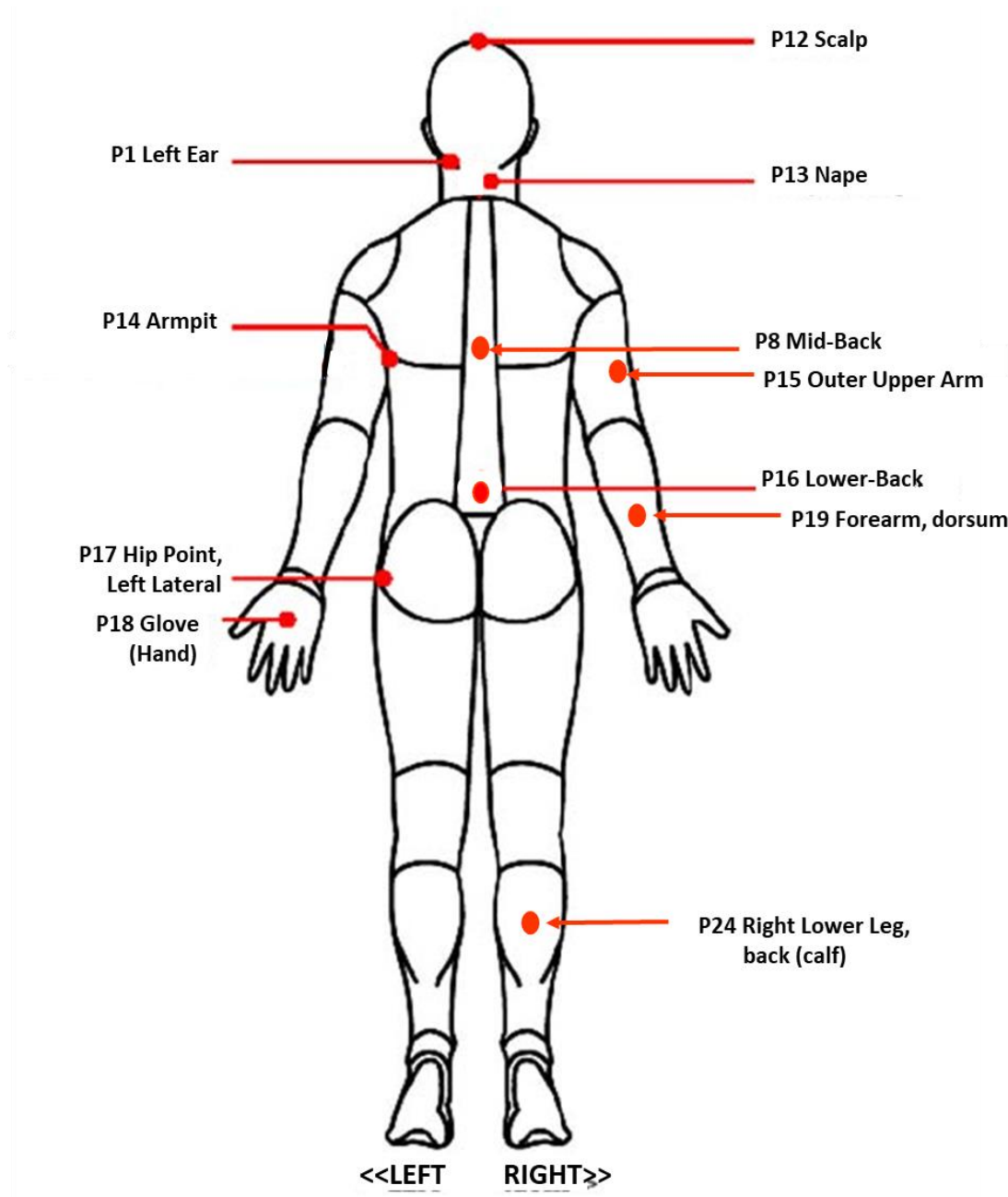


Figure D.30. Passive Adsorbent Device (PAD) Placement Diagram (Back).

c. Left Ear (Position Number P1, Figure D.31).

(1) PAD PLACEMENT: Orient the long axis of the PAD vertically. Align the upper edge of the PAD with the ear landmark line and position the anterior edge of the PAD so it lightly touches the back of the ear at its base. For some individuals and some mask styles, it may be necessary to don the mask before the best location can be determined (so that the mask strap doesn't cover the PAD). Be sure to maintain the vertical orientation of the PAD long axis.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure D.31. Left Ear, Position Number P1.

d. Chin (Anterior Neck, Position Numbers P2, Figure D.32).



Figure D.32. Chin (Anterior Neck, Position Numbers P2).

(1) PAD PLACEMENT: Orientate the long axis of the PAD parallel to the long axis of the neck. Center the PAD vertically over the neck circumference PAD marker line with its anterior edge aligned with the vertical laryngeal prominence line. Place the P2 PAD at the front of the neck, slightly off the center line (either left or right).

e. Chest (Position Number P3, Figure D.33).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

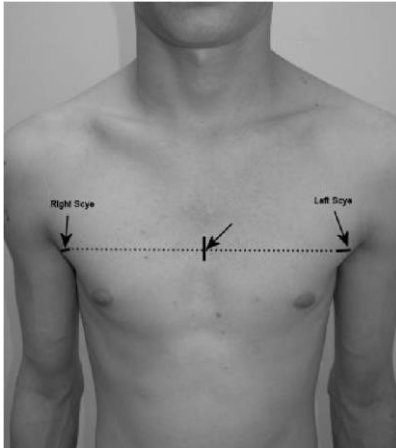


Figure D.33. Chest, Position Number P3.

(1) PAD PLACEMENT: Center the PAD over the P3 PAD marker, at the intersection of the horizontal and vertical lines, with the long axis of the PAD aligned parallel to the long axis of the torso.

f. Inner Upper Arm, Left (Position Number P4, Figure D.34).

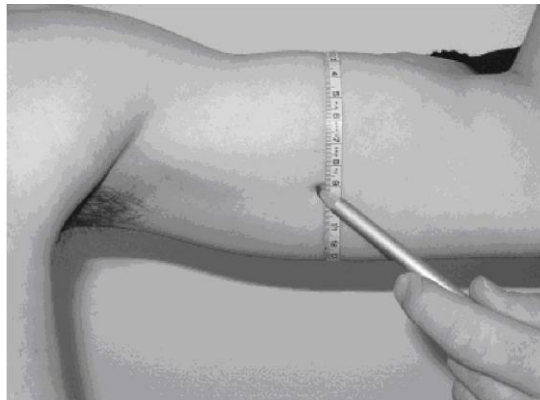


Figure D.34. Inner Upper Arm, Left, Position Number P4.

(1) PAD PLACEMENT: Center PAD over the P4 PAD Marker with the long axis of the PAD running parallel to the long axis of the upper arm.

g. Forearm, Volar, Left (Position Number P5, Figure D.35).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure D.35. Forearm, Volar, Left, Position Number P5.

(1) PAD PLACEMENT: Center PAD over the P5 PAD marker with the long axis of the PAD running parallel to the long axis of the lower arm.

h. Groin/Pubic Region (Position Number P6, Figure D.36).

(1) PAD PLACEMENT: Position P6 in the center of the P6 PAD marker. Align the long axis of the PAD with the vertical axis of the torso. Place the top edge of the PAD along the horizontal line.

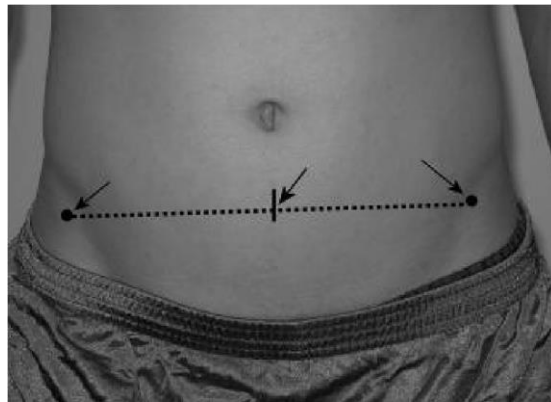


Figure D.36. Groin/Pubic Region, Position Number P6.

i. External Genitalia/Crotch (Position Number P7).

(1) PAD PLACEMENT: Instruct the test participant to make a fist with the hand. Participant will put the fist inside the exercise shorts, on the inner lining in front of the genitalia region. Using the fist as a hard surface, place the PAD on the outer lining of the exercise shorts in the crotch region.

j. Inner Thigh, Left (Position Number P9, Figure D.37).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(1) PAD PLACEMENT: Center the PAD over the P9 PAD marker with the long axis of the PAD parallel to the long axis of the thigh.



Figure D.37. Inner Thigh, Left, Position Number P9.

k. Inner Shin, Left (Position Numbers P10, Figure D.38).



Figure D.38. Inner Shin, Left, Position Numbers P10.

(1) PAD PLACEMENT: Orient the long axis of the PAD parallel to the long axis of the lower leg. Position P10 with its posterior edge aligned with the vertical line on the tibia (shin bone) at the center of the horizontal line. Position the PAD above the footwear.

l. Boot (Foot, Position Number P11, Figure D.39).

(1) PAD PLACEMENT: Place the long axis of the PAD is placed horizontally on the top of the foot so that the lower PAD edge is centered at the P11 PAD marker drawn at the intersection of the second toe tendon and the tape. Align the lower edge of the PAD with the foot circumference line.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure D.39. Boot (Foot), Position Number P11.

- m. Scalp (Top of Head, Position Number P12, Figure D.40).

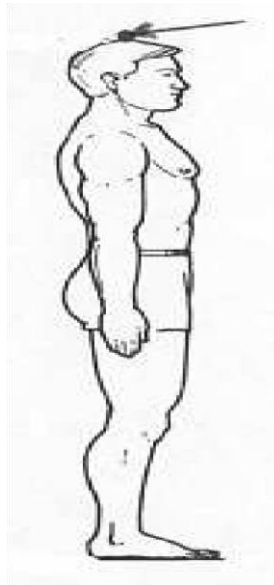


Figure D.40. Scalp (Top of Head), Position Number P12.

(1) PAD PLACEMENT: Direct the participant to stand in the anthropometric standing position with the head in the Frankfort plane. Stand to one side of the participant and palpate the top of the head to determine its highest point. Place PAD at the highest point along the midsagittal plane with the long axis of the PAD oriented from front to back. For some individuals and some mask styles, it may be necessary to don the mask before the best location can be determined. If the mask strap interferes with PAD placement, place the PAD immediately anterior or posterior to the strap along the midsagittal plane. Do not allow the mask strap to cover the PAD. When the PAD is attached to long hair, be sure to secure the hair so the position of the PAD will not move. With certain hair styles in women, it may be necessary to shift the pad location slightly in order to seat the pad securely. If hair becomes an issue with proper placement of the scalp PAD P12, it may be possible to place the PAD on top of the mask strap in the appropriate scalp region.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

n. Nape (Position Number P13, Figure D.41).

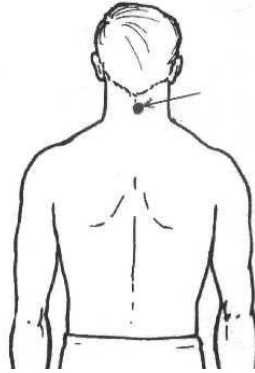


Figure D.41. Nape, Position Numbers P13.

(1) PAD PLACEMENT: Place the P13 PAD in the center of the P13 PAD marker with the long axis of the PAD running parallel to the long axis of the upper neck. Center the PAD vertically on the drawn neck circumference line in back.

o. Back, Middle (Position Number P8, Figure D.42).

(1) PAD PLACEMENT: Place PAD P8 sample in the center of the mid-back region at the mid-point of the vertical line between the Nape (P13) and the lower back (P16).

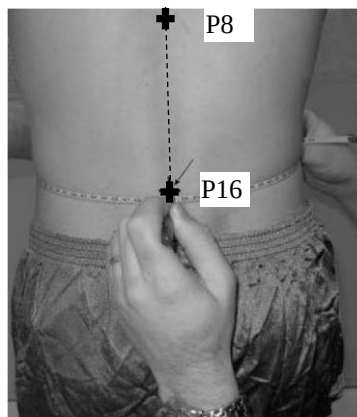


Figure D.42. Middle of Back, Positions P8.

p. Scye (Armpit), Left (Position Number P14, Figure D.43).

(1) PAD PLACEMENT: Long axis of the PAD should be parallel to the long axis of the torso. Position the PAD so that the upper right corner is at the posterior scye landmark.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

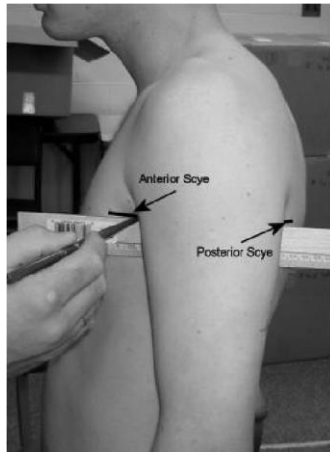


Figure D.43. P14, Scye (Armpit), Left.

q. Outer Upper Arm, Right (Position Number P15, Figure D.44).



Figure D.44. P15, Outer Upper Arm, Right.

(1) PAD PLACEMENT: Center PAD over the P15 PAD marker with the long axis of the PAD running parallel to the long axis of the outer side of the upper right arm (Note that Figure D.44. shows the left arm; use right arm instead).

r. Lower-Back (Position Number P16, Figure D.42).

(1) PAD PLACEMENT: Place the P16 PAD in the center of the P16 PAD Marker (referenced on Figure D.42) with the long axis of the PAD running parallel to the long axis of the torso. Center the PAD vertically on the horizontal line that was drawn through the PAD Marker.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

- s. Hip Point, Left (Position Number P17, Figure D.45).



Figure D.45. P17, Hip Point, Left.

(1) PAD PLACEMENT: Center the PAD over the left lateral hip point P17 PAD marker such that the long axis of the PAD is vertical.

- t. Glove (Hand, Position Number P18, Figure D.46).

(1) PAD PLACEMENT: Center pad over the P18 PAD marker with long axis of the PAD parallel to the long axes of the hand and arm.



Figure D.46. P18, Glove (Hand).

- u. Forearm, Dorsum, Right (Position Number P19).

(1) PAD PLACEMENT: Locate the same position on the right forearm using the measurements for locating PAD position P5 (Forearm, Volar, Left; reference Figure D.35). Center the P19 PAD on the back of the right forearm at the point on the outer arm that is midway between the elbow crease and the wrist, with the long axis of the PAD running parallel to the long axis of the lower arm.

- v. Forehead, (Position Number P20, Figure D.47).

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

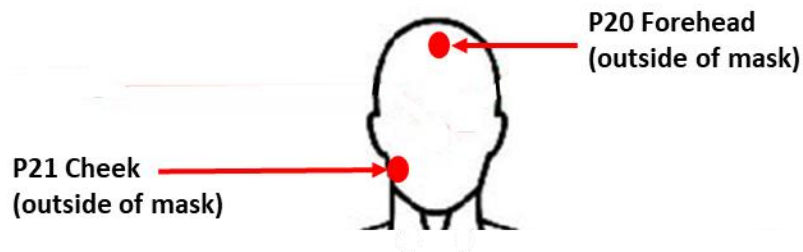


Figure D.47. Forehead, Position Number P20; and Cheek, Position Number P21.

(1) PAD PLACEMENT: Center PAD at the top of the forehead (outside of the mask) as noted in Figure D.47. The mask should be donned to determine the best location so that the edge of the mask face sealing piece doesn't cover the PAD; it may be necessary to place P20 on the sides of the upper face in the temple area (either right or left).

w. Cheek, (Position Number P21, Figure D.47).

(1) PAD PLACEMENT: Center PAD at the right lower side of the cheek (outside of the mask and above the lower mask strap) as noted in Figure D.47. The mask should be donned to determine the best location so that the edge of the mask face sealing piece doesn't cover the PAD.

x. Abdomen, front center, (Position Number P22, Figure D.48).

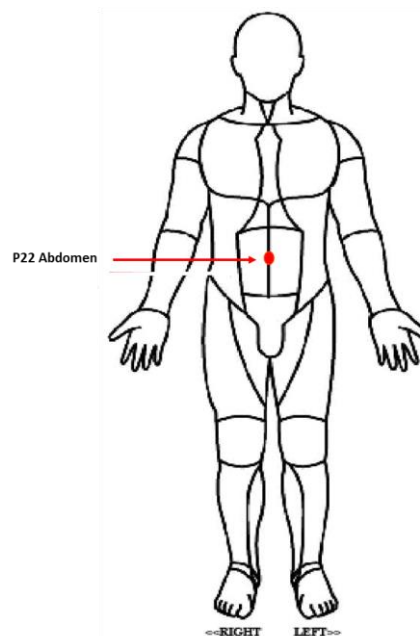


Figure D.48. Abdomen, Front Center, Position Number P22.

(1) Position PAD sample P22 in the center of the abdomen (as noted in Figure D.48) at a location that is approximately two inches above the navel.

APPENDIX D. PASSIVE ADSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

y. Outer Thigh, Right (Position Number P23, Figure D.37).

(1) PAD PLACEMENT: Position the PAD similar to PAD sample P9 (Inner Thigh, Left; reference Figure D.37) except place the PAD on the outside of the right thigh.

z. Right Lower Leg, back (calf) (Position Numbers P24, reference Figure D.38).

(1) PAD PLACEMENT: Orient the long axis of the PAD parallel to the long axis of the lower leg, as shown in Figure D.38, except position sample P24 with its posterior edge aligned on the back of the right lower leg (calf) at the center of the lower leg. Position the PAD above the footwear.

aa. Nose Cup (Position Number P30, Figure D.49).

(1) PAD PLACEMENT: Place PAD inside the mask, in the nose cup area such that there is no interference with breathing or chaffing during wear. It should be noted that this PAD sample is a supplemental sampler only; PAD position P30 (nose cup) is not used in the BRHA analysis. Therefore, the nose cup sample is not really required and may be eliminated for vapor MIST.



Figure D.49. Inside View of M40 Mask, P30 PAD Location.

APPENDIX E. BODY REGION HAZARD ANALYSIS (BRHA).

E-1. OVERVIEW.

a. The BRHA⁶ is a model that determines the protective performance of protective clothing ensembles against percutaneous hazards for various configurations of Individual Protective Equipment (IPE) tested in the vapor Man-in-Simulant Testing (MIST).

b. The main input to the model is the amount (mass) of methyl salicylate (MeS) collected on the standard Passive Adsorbent Devices (PADs) at each body region underneath the IPE system. MeS concentration data measured by Real Time Sensors (RTS) at each body region may also be used as input to the model. These inputs are used in conjunction with the MeS challenge dosage that the IPE system is exposed to during the MIST trial to determine the protection provided at each body region.

c. There are three standard outputs from the BRHA: 1. An overall PF of the IPE system against nerve agent exposure; 2. A Minimum Exposure Dosage (MED) of nerve agent that personnel may be exposed to before systemic nerve agent effects occur (MED_{SYS}); and 3. An MED of blister agent that personnel may be exposed to before localized skin reactions to mustard (HD) blister agent effects occur (MED_{HD}).

d. The overall PF for the IPE system is the capability of the IPE system to protect the wearer against nerve agent effects that may occur through percutaneous adsorption of nerve agent vapor by the skin over the entire body surface. The overall PF has been referred to as the Physiological Protective Dosage Factor (PPDF) by Dr. Paul Fedele (author of the BRHA) and is a systemic summation of nerve agent effects caused by adsorption through any and all body regions. Nerve agent effects are based upon cumulative dosage adsorbed; when enough agent is accumulated in the body that causes sufficient depression of cholinesterase, effects occur (no matter what part of the body the agent was adsorbed at). Blister agent effects are localized (not cumulative); if the skin at a specific body region is exposed to a dosage that causes effects, that body region experiences those effects, but other skin areas will not be affected unless sufficient dosage to cause effects has been adsorbed at that body region also.

e. The MED values theoretically represent the highest agent dosage to which personnel dressed in the IPE configuration could be exposed to before 50 percent of the population experiences the onset of nausea and vomiting (for systemic nerve agents), or skin burns and blisters (for blister agents). However, the correlation between the output and true protection is not known. Therefore, the outputs are used to rank and compare IPE configuration performance. Because the MED outputs theoretically represent the challenge dosage the IPE system protects against, higher MED values are better. The MED_{SYS} systemic nerve agent MED value and the MED_{HD} localized blister agent MED are distinct in both the way they are calculated, and in the way personnel may be affected.

(1) The MED_{SYS} value uses the body region sensitivities and the body region areas to calculate the ability of the configuration to protect against systemic nerve agents; nerve agent adsorbed at each body region add up to cause a cumulative effect. This value can be thought of as a type of weighted average of performance over the entire body.

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(2) The MED_{HD} value compares all the body regions and chooses the region that is most susceptible to the outside challenge based on the protection in the region and the sensitivity of the region to agent. This means that the most susceptible region may not necessarily be the region with the most breakthrough. It could be a region that had less breakthrough but is more sensitive to agent. Typically, the regions of IPE suit ensembles most likely to have leakage are around openings and closures (gloves/wrist interface; pant legs/boot interface, and the mask/hood/suit interface). The most sensitive regions of the body are in the head and neck regions, and in the crotch/groin region.

f. Additionally, optional outputs can be produced that are like the MED_{HD} value. For instance, a program for investigating closures may want to look specifically at the closure areas (wrists, ankles, waist, neck, etc.). Localized exposure dosages are produced for 27 different body regions that can all be reported as desired. Past specialized outputs include minimum exposure dosages for the glove interface (MED_{GLOVE}), boot interface (MED_{BOOTI}), and crotch (MED_{CROTCH}) which are calculated from the clothed effective PF for the body regions in each of these interface regions.

E-2. SKIN TOXICITY VALUES USED IN THE BRHA.

a. An integral part of the BRHA is the sensitivity estimate of the body region to the agent. The historical BRHA⁶ estimates were based on ED₅₀ values (i.e., the amount of a substance required to produce a specific effect in 50 percent of the test subjects) of the persistent nerve agent VX (O-ethyl S-(2-diisopropylaminoethyl) methylphosphonothiolate; CAS Number: 50782-69-9) from a 1962 study by Sim⁷.

b. The 50 percent exposure dosage (ED₅₀) values for VX represent the mass of liquid VX that would cause a 70 percent depression in red blood cell cholinesterase in a 70-kg human. Each body region included in the BRHA model has an associated VX ED₅₀ value. The specific ED₅₀ values for VX at each of the 27 body regions in the BRHA model are included in Table E-1, along with the skin area measurements for each specific body region. It should be noted that these ED₅₀ values are taken from Sim (see reference 7) and are used for comparisons only; they do not represent a safe level of exposure to VX.

c. The historical BRHA used the assumption that the ratio between the sensitivities of different regions of the body is the same for liquid VX, vapor VX, vapor GB, vapor HD, etc. In other words, if one region is twice as sensitive as another to liquid VX, it is assumed that the region will also be twice as sensitive to other agent challenges. This assumption and the idea of using liquid VX data for analysis of vapor hazards has been criticized.

Table E-1. BRHA ESTIMATES OF BODY REGION SENSITIVITIES.

Body Region	Area* (cm ²)	VX ED ₅₀ ^a (mg/Individual) ⁷
Scalp	350	0.76
Ears	50	0.46
Cheeks and neck	100	0.48
Chin and neck	200	0.36

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Body Region	Area* (cm ²)	VX ED ₅₀ ^a (mg/Individual) ⁷
Nape	100	1.72
Abdomen	2,858	2.23
Back	2,540	2.65
Axillae	200	2.07
Inner upper arm	488	2.80
Outer upper arm	706	6.57
Elbow fold	50	2.09
Elbow	50	2.25
Forearm, volar	487	2.80
Forearm, dorsum	706	6.57
Hands, dorsum	200	2.91
Hands, palmer	200	9.24
Buttocks	953	4.26
Groin	300	1.22
Scrotum	200	0.11
Thigh, dorsum	2,845	6.57
Thigh, plantar	1,422	4.26
Knee	200	7.14
Popliteal spaces	100	2.09
Shins	1,897	6.57
Calves	948	2.80
Feet, dorsum	500	6.60
Feet, plantar	300	7.14

^aExposure dosage required to produce a specific effect in 50 percent of the test subjects.

NOTE: Some of the historical surface areas from the original BRHA are suspect and may require future updating/refining.

d. Additional body region sensitivity data for vapor HD was uncovered in a study¹² conducted by J. H. Heinen, (et al) of the Naval Research Laboratory in 1944-1945. The results from this study were analyzed¹³ at the Combat Capabilities Development Command Chemical, Biological Center (CCDC CBC) and localized Exposure Concentration Time that would cause 50% effects (ECT₅₀) values for HD were determined for almost all of the body regions used in the BRHA. The revised ECT₅₀ toxicity values for HD (see Table E-2) were determined for two distinct environmental conditions: these are labeled L/L (low temperature/humidity ambient conditions and low amounts of sweating) and H/H (high temperature/humidity ambient conditions and high amounts of sweating). These tables denote the temperature and humidity conditions under which the Heinen tests were run. The analysis report recommended to use the L/L value if the temperature is less than 84° F and personnel are not appreciably sweating, and to use the H/H value if the temperature is above 84° F and personnel are sweating. However, it is more appropriate to use the H/H values for the BRHA since it is unknown what environment the IPE will be operated in; in addition, using these values for the localized BRHA analysis provides

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a safety factor if the IPE is not worn in a hot, humid environment and profuse sweating does not occur.

Table E-2. BRHA REVISED DISTILLED MUSTARD (HD) TOXICITY VALUES.

Body Region	Revised ECT ₅₀ ^a (mg·min/m ³) Low/Low	Revised ECT ₅₀ (mg·min/m ³) High/High
Scalp	613 ^b	277 ^b
Ears	613 ^b	277 ^b
Cheeks and neck	1,439	443
Chin and neck	1,015	312
Nape	1,179	363
Abdomen	3,446	760
Back	2,116	466
Axillae	613	277
Inner upper arm	4,257	938
Outer upper arm	4,004	882
Elbow fold	1,798	396
Elbow	6,468	1,426
Forearm, volar	4,300	948
Forearm, dorsum	4,300	948
Hands, dorsum	3,386	749
Hands, palmer	6,468 ^c	1,426 ^c
Buttocks	2,871	633
Groin	567	266
Scrotum	350	164
Thigh, dorsum	3,473	766
Thigh, plantar	3,732	823
Knee	3,533	779
Popliteal spaces	3,485	768
Shins	4,925	1,085
Calves	4,382	966
Feet, dorsum	3,386 ^c	749 ^c
Feet, plantar	6,468 ^c	1,426 ^c

^aExposure concentration time required to produce a specific effect in 50 percent of the test subjects.

^bValues for these areas were not available from the Heinen report; data from axillae was used.

^cValues for these areas were not available from the Heinen report; it has been agreed to use data from elbow for the hands (palmer) and the foot (plantar), and data from hand (dorsum) for foot (dorsum).

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e. The revised localized (HD) ECT₅₀ values provide greater accuracy in the determination of the protection of the IPE against skin effects from exposure to HD. It should be noted that the HD values in the original BRHA model were overly conservative (to provide an added safety factor to the calculated results) and generally predicted less protection while using the IPE than we truly have with the more accurate HD values.

f. Further discussions with the ECBC report author Doug Sommerville and Dr. James Madsen from the United States Army Medical Research Institute of Chemical Defense (USAMRICD) concluded that the following HD ECT₅₀ values are appropriate to be used in the BRHA for body regions where no HD ECT₅₀ values were available from the Heinen data: the value for axillae is appropriate for the scalp and ears body regions, the value for the elbow is appropriate for the hands (palmer) and the foot (dorsum) body regions, and the value for the hands (dorsum) is appropriate for the foot (dorsum) region.

g. A combined listing of the systemic (VX) ED₅₀ values and the revised localized (HD) ECT₅₀ values (Heinen level 4 effect: Erythema with edema; maceration of axillary skin; dry scaling of the scrotum) is included below in Table E-3 along with other data parameters for calculations with the BRHA.

E-3. BODY REGION PFs.

a. The results from each of the samples collected at the various body regions are used to calculate an individual PF for each specific body region utilized in the BRHA model. Each body-region PF (i.e., PF_{BR}) is then used with the ED₅₀ exposure dosage values for nerve agent to calculate the overall PPDF and the systemic MED; the PF_{BR} values are also used with the ECT₅₀ exposure dosage for blister agent to calculate the localized MED values.

b. A complete data set for each IPE ensemble tested is required to perform the BRHA calculations. PAD or RTS samples are collected from 24 body region locations underneath the IPE to obtain the data set that is used in BRHA model calculations. The nose cup PAD results are not included in the BRHA because they apply only to percutaneous effects, not inhalation or ocular effects. It should be noted that RTS samples aren't collected at the boot or nose cup areas because of difficulties attaching the RTS at these locations (PAD samples will be used for the foot region).

c. Missing values are estimated as the geometric mean of all other PADs from the same location for the individual configuration tested. This applies because PADs sometimes fall off during testing and cannot be used for analysis. Results from PADs at close proximity to the lost PAD may also be used during that test. The use of estimates based upon PADs from other TPs may induce errors because of differences in fit and variations in the ensembles. Calculation with these estimates should be compared with the results of calculations performed without using the missing PAD data. Both results should be reported, along with details of the missing PAD sample location and any estimates used.

d. The PAD analytical detection limit will be determined experimentally at the MIST test facility using standard QA/QC methods. The most recent value for the detection limit of MeS on

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PADs is approximately 25 ng. PAD mass values below the analytical detection limit will be set at a value that is one-half of the pre-determined measured PAD analytical detection limit. PAD mass values should be corrected for background MeS levels by subtracting the results of the clean-room/doffing-room monitoring PADs; however, mass values will be set to half of the analytical detection limit if background corrected masses are below that value.

Table E-3. CALCULATION VALUES FOR BRHA MODEL.

	Body Region	Area (cm ²)	VX ED ₅₀ ^a (mg/Individual)	Area/Nerve Dosage (A/D) Factor	HD ^b ECT ₅₀ ^c (mg·min/m ³) High/High Revised
1	Scalp	350	0.76	460.53	277 ^d
2	Ears	50	0.46	108.70	277 ^d
3	Cheeks and neck	100	0.48	208.33	443
4	Chin and neck	200	0.36	555.56	312
5	Nape	100	1.72	58.14	363
6	Abdomen	2,858	2.23	1,281.61	760
7	Back	2,540	2.65	958.49	466
9	Inner upper arm	488	2.80	174.29	938
10	Outer upper arm	706	6.57	107.46	882
11	Elbow fold	50	2.09	23.92	396
12	Elbow	50	2.25	22.22	1,426
13	Forearm, volar	487	2.80	173.93	948
14	Forearm, dorsum	706	6.57	107.46	948
15	Hands, dorsum	200	2.91	68.73	749
16	Hands, palmer	200	9.24	21.65	1,426 ^e
17	Buttocks	953	4.26	223.71	633
18	Groin	300	1.22	245.9	266
19	Scrotum	200	0.11	1,818.18	164
20	Thigh, dorsum	2,845	6.57	433.03	766
21	Thigh, plantar	1,422	4.26	333.8	823
22	Knee	200	7.14	28.01	779
23	Popliteal spaces	100	2.09	47.85	768
24	Shins	1,897	6.57	288.74	1,085
25	Calves	948	2.80	338.57	966
26	Feet, dorsum	500	6.60	75.76	749 ^e
27	Feet, plantar	300	7.14	42.02	1,426 ^e

^aExposure dosage required to produce a specific effect in 50 percent of the test subjects.

^bExposure concentration time.

^cDistilled mustard (blister) agent.

^dValues for these areas were not available from the Heinen report; data from axillae was used.

^eValues for these areas were not available from the Heinen report; it has been agreed to use data from elbow for the hands (palmer) and the foot (plantar), and data from hand (dorsum) for foot (dorsum).

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e. The PAD analytical results (mass) are normalized (see Equation 1) to correspond to a standard 3,000 mg·min/m³ challenge concentration × time (Ct). This is the dosage that the PAD will be challenged with using 100 mg/m³ of MeS during a 30-minute trial duration. The PAD masses will be normalized to correspond to the standard (or alternative) Ct dosage (mg·min/m³) value used during the MIST test. Many of the historical MIST tests used a 2-hour trial (12,000 mg·min/m³ dosage), but other MIST testing of IPE such as Level A suits and firefighter protective gear (where Self-Contained Breathing Apparatus [SCBA] is used) could only be conducted for the new 30-minute MIST exposure time because the capacity of the SCBA limits the wear time to 60 minutes. Other specialized MIST testing programs may use concentration exposure levels different than the standard 100 mg/m³ level; for these tests the standard Ct dosage used would be based upon the target concentration and target exposure duration time for those tests.

Equation 1.

$$mass_{normalized} = mass_{original} \times \frac{Standard\ Ct}{Challenge\ Ct}$$

Where:

$mass_{normalized}$ = normalized mass (ng).

$mass_{original}$ = mass (ng) of MeS reported for PAD.

$Standard\ Ct$ = 3,000 mg·min/m³, or alternative Ct (based upon challenge concentration and exposure time)

$Challenge\ Ct$ = measured dosage of MeS (mg·min/m³) during that trial.

f. Regions not measured directly by PADs are estimated using nearby or surrounding PADs (e.g., the elbow is estimated using masses from the upper and lower arm). A total of 27 body regions are included in the model; 18 are directly measured, and the other 9 are estimated using a combination of PAD masses and/or RTS sampler data near that body region (see Table E-4). The mass/concentration for each body region is calculated using the equations in Table E-4. If dosage values are required for each body region, the uptake rate and total exposure duration will be used with the normalized mass analyzed from each PAD to calculate these dosage values; then the equations listed in Table E-4 are used with the dosage values (instead of mass).

g. The local body region PF (i.e., the PF_{BR} for each body region) is then calculated for each of the 27 body regions by comparing the amount of MeS on the outside of the ensemble (in the test chamber) to the amount on the inside of the ensemble. The previous method used a historical estimate of 200,000 ng for the mass on the outside of the suit during a two-hour trial in a 100 mg/m³ challenge. The use of this historical estimate has been questioned and is no longer considered valid for current testing. In addition, this value cannot be used because the standard test duration has changed to a 30-minute exposure time. A new value for the external mass should be measured directly at each MIST test facility by using chamber monitoring instrumentation (i.e., Gasmeter FTIR real time monitors, solid-sorbent tubes, etc.) to measure actual values. The revised method for calculating each PF_{BR} using external challenge dosage and the internal dosage measured at each body region is outlined in paragraphs h., i., and j. below.

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Table E-4. Body Region Mass Calculations from PAD/RTS for PF.

BRHA Body Region		PAD/RTS Samples/ID numbers used	Body Region Mass Calculation Equation
1	Scalp	P12 Scalp; P20 Forehead	$M_{BR1} = (P12 + P20)/2$
2	Ears	P1 Behind Left Ear	$M_{BR2} = P1$
3	Cheeks & Neck	P21 Right Cheek (outside mask); P1 Behind Left Ear; P2 Chin (Anterior Neck)	$M_{BR3} = (P21 + P1 + P2) / 3$
4	Chin & Neck	P2 Chin (Anterior Neck)	$M_{BR4} = P2$
5	Nape	P13 Nape	$M_{BR5} = P13$
6	Abdomen	P3 Chest Center; P22 Abdomen; P6 Groin/Pubic Region; P14 Left Armpit	$M_{BR6} = [P3 + P22 + (P6/2) + (P14/2)] / 3$
7	Back	P8 Middle of Back; P16 Lower Back; P13 Nape; P14 Left Armpit	$M_{BR7} = [P8 + P16 + (P13/2) + (P14/2)]/3$
8	Axillae	P14 Left Armpit	$M_{BR8} = P14$
9	Upper Arms, medial	P4 Left Inner Upper Arm	$M_{BR9} = P4$
10	Upper Arms, lateral	P15 Right Outer Upper Arm	$M_{BR10} = P15$
11	Elbow folds	P4 Left Inner Upper Arm; P5 Left Forearm, Volar	$M_{BR11} = (P4 + P5) / 2$
12	Elbow	P15 Right Outer Upper Arm; P19 Right Forearm, Dorsum	$M_{BR12} = (P15 + P19) / 2$
13	Forearms, volar	P5 Left Forearm, Volar	$M_{BR13} = P5$
14	Forearms, dorsum	P19 Right Forearm, Dorsum	$M_{BR14} = P19$
15	hands dorsum	P18 Back of Left Hand (glove)	$M_{BR15} = P18$
16	hand, palmer	P18 Back of Left Hand (glove)	$M_{BR16} = P18$
17	Buttocks	P17 Hip Point, Left Lateral (buttocks)	$M_{BR17} = P17$
18	Groin	P6 Groin/Pubic Region; P7 External Genitalia/Crotch	$M_{BR18} = (2/3 * P6) + (1/3 * P7)$
19	Scrotum	P7 External Genitalia/Crotch	$M_{BR19} = P7$
20	Thighs, anterior	P9 Left Inner Thigh	$M_{BR20} = P9$
21	Thighs, posterior	P23 Right Outer Thigh	$M_{BR21} = P23$
22	Knees	P23 Right Outer Thigh; P10 Left Lower Leg, front (shin)	$M_{BR22} = (P23 + P10) / 2$
23	Popliteal Spaces	P9 Left Inner Thigh; P24 Right Lower Leg, back	$M_{BR23} = (P9 + P24) / 2$
24	Shins	P10 Left Lower Leg, front (shin)	$M_{BR24} = P10$
25	Calves	P24 Right Lower Leg, back	$M_{BR25} = P24$
26	Feet Dorsum	P11 Left Boot, top (foot)	$M_{BR26} = P11$
27	Feet Plantar	P11 Left Boot, top (foot)	$M_{BR27} = P11$

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Equation 2.

$$PF_{BR} = \frac{Mass_{external}}{Mass_{body\ region}}$$

Where:

PF_{BR} = the protection factor for the given body region.

$Mass_{body\ region}$ = mass (ng) of MeS reported/calculated for each body region.

$Mass_{external}$ = mass (ng) of MeS measured on the outside of the IPE in the test chamber.

NOTE: The $Mass_{external}$ of MeS (ng) that would be collected on the outside of the ensemble will be calculated directly from RTM instruments in the test chamber during the test trial.

h. An alternative method for calculation of the body region PF is to use dosage values outside the IPE divided by dosage values inside the IPE (see ASTM¹¹ Standard F2588-12). This data is easily determined from concentration data collected with RTS samplers (multiplied by the exposure time during each test). Concentration values can also be calculated for PADs by dividing the corrected mass for each body region by the product of the uptake sample rate (see Section A-4) and the exposure duration in the test chamber (see Equation 3). Note that mass values will be set to one-half of the analytical detection limit if corrected masses are below the analytical detection limit.

Equation 3:

$$C_{Mes} = \frac{M_{PAD}}{F_{PAD} * t}$$

Where:

C_{Mes} = the average concentration of MeS measured by PAD during the exposure duration time (mg/m³).

M_{pad} = normalized mass (ng) of MeS measured by PAD (background corrected).

F_{pad} = flowrate/sample uptake rate (ml/min) of PAD.

t = exposure duration time (minutes) in test chamber.

i. Dosage values for the RTS samplers (or PADs), and in the test chamber are calculated by multiplying the concentration by the exposure duration in the test chamber (see Equation 4).

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Equation 4:

$$Dosage (Ct) = C * t = \frac{M_{PAD}}{F_{PAD} * t} * t = \frac{M_{PAD}}{F_{PAD}}$$

Where:

Dosage (Ct) = the total exposure dosage (mg·min/m³) for RTS/PADs (*Ct_{body region}*), or in the test chamber (*Ct_{outside}*).

C = concentration (mg/m³) of MeS measured by RTS or PAD (body region) or by chamber monitors (outside).

t = the exposure time in the test chamber.

M_{pad} = normalized mass (ng) of MeS measured by PAD (background corrected).

F_{pad} = flowrate/sample uptake rate (ml/min) of PAD.

j. The body region PF values (based on dosage values) for each of the 27 body regions are calculated by dividing the dosage measured outside the IPE suit ensemble by the dosage measured at the skin body region locations inside the ensemble. **NOTE:** use dosages (instead of mass values) calculated at each body sample location with formulas in Table E-4 to calculate dosage values for each body region. Equation 5 lists the dosage body region PF calculations.

Equation 5.

$$PF_{BR} = \frac{Ct_{outside}}{Ct_{body region}}$$

Where:

PF_{BR} = the protection factor for the given body region.

Ct_{outside} = dosage (mg·min/m³) of MeS measured by chamber monitors.

Ct_{body region} = dosage (mg·min/m³) of MeS reported by RTS or PAD samples.

E-4. OVERALL SYSTEMIC PPDF CALCULATION.

a. The body region PFs and agent skin sensitivity values (Table E-3) are used to calculate the overall PPDF, the MED_{sys}, and the MED_{HD} values. A detailed description of the methods and equations used to calculate the overall PPDF and the MED values using the BRHA process is presented below.

b. The overall PPDF is determined by using the BRHA process developed by Fedele and Nelson⁶, which is based upon the amount of agent that must be absorbed percutaneously (through the skin) in each of 27 different body areas to produce mean end-point reactions for nerve agent. In the model, the mean end-point reaction is the symptom that occurs in 50% of individuals exposed to the agent dosage. For exposure to nerve agent, the first significant symptom is headache; this is followed by nausea and vomiting. Erythema, or reddening of the skin (similar to severe sunburn) is the first mean end-point reaction for exposure to the blister agent, mustard (HD).

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c. For nerve agent, the overall PPDF is based on the body region PF values (PF_{BR}) and sensitivities for the 27 individually defined body regions. This approach is used because nerve agents produce a systemic rather than a localized response in the individual. The BRHA process uses the dosage known to be required at each body region to cause a systemic nerve agent effect (end-point reaction). These dosages, referred to as the "VX dose" are the VX ED_{50} values listed in Table E-3. The VX dose for each body region divided into the skin area of that region ("area") is called the Area/Nerve Dosage "A/D" Factor (also listed in Table E-3). The A/D factor represents the relative sensitivity of each body region to nerve agent exposure. The overall PF (PPDF) of the IPE suit is calculated from the local PF_{BR} for each body region and the A/D factor (skin area and associated VX dose) for each body region as shown in Equation 6.

Equation 6:

$$PPDF = \frac{\sum \left(\frac{area_i}{VX ED_{50i}} \right)}{\sum \left(\frac{area_i}{VX ED_{50i} \times [PF_{BR}]_i} \right)} = \frac{\sum \left(\frac{A}{D} \right)_i}{\sum \left[\left(\frac{A}{D} \right)_i \div (PF_{BR})_i \right]}$$

Where:

$PPDF$ = Physiological Protective Dosage Factor for entire IPE ensemble (overall systemic PF)

$area_i$ = local surface area (cm^2) of the i th body region.

$VX ED_{50i}$ = local VX ED_{50} (mg/individual) for the i th body region

$(A/D)_i$ = the Area/Nerve Dosage (A/D) Factor for each body region $i = 1, 2, \dots, 27$, and

$(PF_{BR})_i$ = the protection factor calculated for each body region $i = 1, 2, \dots, 27$.

d. Equation 6 is based on the assumption that the response of the population to agent exposure can be characterized as a function of dose, and that the response curve follows a lognormal distribution. A detailed derivation of Equation 6 is found in References 8 through 10.

E-5. SYSTEMIC NERVE AGENT MINIMUM EXPOSURE DOSAGE CALCULATIONS

a. The Overall systemic PPDF is used to determine the Minimum Exposure Dosage (MED) of nerve agent that somebody wearing that IPE must be exposed to before effects will occur in the body. The MED_{SYS} is a cumulative effect summed over all the 27 body regions. The MED_{SYS} from the original BRHA was a function of the ED_{50} of VX, the local body region PF, and the local surface area for each body region. These factors are used in the calculation of the overall systemic PPDF for the ensemble (see Equation 6 above).

b. It has been noted that using the ED_{50} of VX to calculate an MED_{SYS} of nerve agent that a warfighter in a specific IPE suit must be exposed to to incur effects from exposure to nerve agent is not valid because VX is not a battlefield vapor hazard. Therefore, the percutaneous dosages (ECT_{50} values) of the nerve agents Soman (GD) and Sarin (GB) that cause effects should be used instead (see reference 14) as they are the more realistic battlefield hazard. The percutaneous nerve agent dosage of GD that causes threshold effects is 300 mg-min/m^3 ; the GD dosage that causes severe effects is $2,000 \text{ mg-min/m}^3$. The percutaneous nerve agent dosage of

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GB that causes threshold effects is $1,200 \text{ mg}\cdot\text{min}/\text{m}^3$; the GB dosage that causes severe effects is $8,000 \text{ mg}\cdot\text{min}/\text{m}^3$. The reference source¹⁴ notes that for percutaneous dosage values the “threshold refer to slight Cholinesterase inhibition” (i.e., severe headache followed by nausea and vomiting), and “for organophosphate nerve agents, severe effects are systemic, similar to lethal effects”.

c. The systemic PPDF is multiplied by $300 \text{ mg}\cdot\text{min}/\text{m}^3$ to calculate the threshold GD MED_{SYS} for the ensemble and is multiplied by $1,200 \text{ mg}\cdot\text{min}/\text{m}^3$ to calculate the threshold GB MED_{SYS} for the ensemble. The 300 and $1,200 \text{ mg}\cdot\text{min}/\text{m}^3$ values are the challenge dosages of GD and GB nerve agent (respectively) that would cause threshold effects (usually severe headache followed by nausea and vomiting) for unprotected individuals (Reference 14) through the effects of percutaneous adsorption of the nerve agent through the skin. The systemic MED_{SYS} value for threshold effects is the value reported during MIST testing and represents the maximum vapor exposure dosage that warfighters wearing the IPE can be exposed to before nerve agent effects occur.

d. The systemic PPDF could be multiplied by the ECT_{50} dosage values for severe effects ($2,000 \text{ mg}\cdot\text{min}/\text{m}^3$ for GD, and $8,000 \text{ mg}\cdot\text{min}/\text{m}^3$ for GB) to calculate MED_{SYS} values that warfighters wearing the IPE ensemble would have to be exposed to before lethal effects would occur. However, lethal effects are beyond safe effects estimates that should be used when evaluating the safety of IPE with MIST.

E-6. LOCALIZED BLISTER AGENT MINIMUM EXPOSURE DOSAGE CALCULATIONS

a. Vapor MED_{HD} . The initial effects of HD are localized to specific body regions because the skin reacts directly to the HD dosage. The PF for HD is expressed as a localized MED_{HD} . This was calculated by multiplying the PF for each body region (PF_{BR}) by the dosage which is known to produce mean end-point skin reactions at each of those body regions. The lowest calculated MED_{HD} value, along with the skin area affected, characterizes the protective capability of the IPE suit and areas of susceptibility to HD. A detailed description of the methods and equations used to calculate the MED_{HD} values using the BRHA process is presented below.

b. The revised HD agent toxicology figures from the Heinen data are used as the HD ED_{50} for each body region in the revised BRHA. The only body regions where insufficient HD skin sensitivity data was available from the Heinen data were at the scalp, ears, hands (palmer), and the feet (plantar and dorsum). HD skin sensitivity data from the axillae was used for the scalp and ears regions, because these body regions have similar sensitivity. It has been agreed to use data from the elbow for the hands (palmer) and the foot (plantar), and data from the hand (dorsum) for the foot (dorsum). The toxicology values for these areas appear to be appropriate for the body region areas that did not have values from the Heinen report.

c. The revised skin ratios for HD blister agent toxicological values have been a great addition to the BRHA model.

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d. The ECT_{50} exposure dosage values determined for HD mustard are used to evaluate the local agent MED_{HD} value for the IPE system. The HD mustard ECT_{50} values is the chemical dosage that each specific body region must be exposed to in order to cause erythema (similar to bad sunburn) with edema maceration of axillary skin, dry scaling of the scrotum (level 4 Heinen effect) of the skin at that body region. For example, the chin and neck would start to have effects from agent at a dosage of $312 \text{ mg}\cdot\text{min}/\text{m}^3$ ($HD ECT_{50} = 312 \text{ mg}\cdot\text{min}/\text{m}^3$) but the outer upper arm would not see effects until the dosage reached $882 \text{ mg}\cdot\text{min}/\text{m}^3$. The MED_{HD} clothed effective values for each body region (MED_{HD-BR}) are calculated by multiplying the PF_{BR} by the ECT_{50} values for HD listed in Table E-3. Equation 7 shows this process for a given body region.

Equation 7.

$$MED_{HD-BR} = PF_{BR} \times HD ECT_{50}$$

Where:

MED_{HD-BR} = minimum exposure dosage ($\text{mg}\cdot\text{min}/\text{m}^3$) for a given body region (1, 2, ... 27).

PF_{BR} = the protection factor calculated for each body region (1, 2, ... 27).

$HD ECT_{50}$ = HD blister agent dosage ($\text{mg}\cdot\text{min}/\text{m}^3$) that causes severe burns on a given body region in hot, humid weather.

e. The MED_{HD} is the vapor challenge dosage a warfighter wearing the IPE ensemble must be exposed to before the bare skin in a given body region experiences erythema (similar to bad sunburn) with edema maceration of axillary skin, dry scaling of the scrotum (level 4 Heinen effect). For each body region, this represents the challenge Ct outside the protective ensemble that would cause burns on the skin at that body region. Since HD blister agent produces localized effects on different skin regions (unlike the cumulative effects of nerve agent), the MED_{HD} values are calculated for each of the 27 body regions in the BRHA model (MED_{HD-BR}). The body region with the lowest MED_{HD-BR} is then reported as the skin region most vulnerable when wearing that IPE suit ensemble.

f. The minimum of all the clothed effective MED_{HD-BR} values is reported as the MED_{HD} for the IPE suit ensemble. This represents the challenge Ct outside the protective ensemble that would cause burns on the skin in 50 percent of the population at the most susceptible body region of the ensemble.

g. Additional local summary values can be calculated from these clothed effective MED_{HD-BR} values by taking the minimum value from the body regions in question. For example, MED_{GLOVE} is calculated as the minimum clothed effective Ct dosage that the forearm and hand body regions must be exposed to before skin blistering effects occur there.

APPENDIX F. ABBREVIATIONS.

AD No.	accession number
A/D	area/dosage
AEHA	US Army Environmental Hygiene Agency
ANOVA	analysis of variance
AR	Army Regulation
ASIS	anterior superior iliac spine
ATEC	US Army Test and Evaluation Command
BRHA	body region hazard analysis
CB	chemical and biological
DEVCOM CBC	Combat Capabilities Development Command Chemical and Biological Center
Ct	concentration $\times$ time
CWA	chemical warfare agent
DTIC	Defense Technical Information Center
DTP	detailed test plan
ECT ₅₀	Exposure concentration time: amount of a substance required to produce a specific effect in 50 percent of the test subjects
ED ₅₀	amount of a substance required to produce a specific effect in 50 percent of the test subjects
EMT	emergency medical technician
FM	field manual
FTIR	Fourier-Transform Infra-Red
GB	Sarin (Isopropyl methylphosphonofluoridate; CAS no. 107-44-8)
GD	Soman (O-Pinacolyl methylphosphonofluoridate; CAS no. 96-64-0)
HD	distilled mustard (bis(2-chloroethyl) sulfide; CAS no. 505-60-2)

APPENDIX F. ABBREVIATIONS.

HFE	human factors engineering
H/H	high temperature/humidity
HUC	human use committee
IAW	in accordance with
IPE	Individual protective equipment
LDL	lower detection limit
L/L	low temperature/humidity
MED	minimum exposure dosage
MED _{BOOTI}	minimum exposure dosage for the boot interface
MED _{CROTCH}	minimum exposure dosage for the crotch
MED _{GLOVE}	minimum exposure dosage for the glove interface
MED _{HD}	minimum exposure dosage of HD
MED _{HD-BR}	minimum exposure dosage of HD for each body region
MED _{SYS}	systemic nerve agent minimum exposure dosage
MeS	methyl salicylate
MIL-STD	Military Standard
MINICAMS [®]	Miniature chemical agent monitoring system
MIRAN [®]	Miniature Infrared Analyzer
MIST	man-in-simulant test
NA	not applicable
NRTM	near real-time monitor
OEP	operational test agency evaluation plan
ORI	operational readiness inspection
PAD	Passive adsorbent device
PD CCATTI	Program Director for Cross-Commodity Advanced Threats and Test Infrastructure

APPENDIX F. ABBREVIATIONS.

PF	protection factor
PII	personally identifiable information
PPDF	Physiological Protective Dosage Factor
PVSMS	personal vital signs monitoring system
QA	quality assurance
QC	quality control
RH	relative humidity
RSD	relative standard deviation
RTM	real-time monitor
RTS	real-time sensor
SDS	safety data sheet
SUT	system under test
TCRA	Toxicological Casualty Risk Assessment
TEMP	Test and Evaluation Master Plan
TICN	test item control number
TOP	test operations procedure
TP	test participant
TSO	test safety officer
USAMRICD	US Army Medical Research Institute of Chemical Defense
VX	O-ethyl S-(2-diisopropylaminoethyl) methylphosphonothiolate; (CAS Number: 50782-69-9)
WP CAPAT	Warfighter Protection Commodity Area Process Action Team

APPENDIX F. ABBREVIATIONS.

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APPENDIX H. APPROVAL AUTHORITY.

CSTE-CI (73-1jj)

20 June 2023

MEMORANDUM FOR

Commander, U.S. Army White Sands Missile Range
Executive Director, U.S. Army Evaluation Center
Commander, U.S. Army Operational Test Command
Commander, U.S. Army Yuma Proving Ground
Commander, U.S. Army Dugway Proving Ground
Commanders, U.S. ATEC Test Centers
Director, U.S. ATEC Tropic Regions Test Center
Director, U.S. ATEC West Desert Test Center

SUBJECT: Test Operations Procedure 10-2-022B

1. Test Operations Procedure (TOP) 10-2-022B, Chemical Vapor System-Level Testing of Chemical/Biological Individual Protective Equipment (IPE) Suits (MIST), has been reviewed by the U.S. Army Test and Evaluation Command (ATEC) Test Centers, the U.S. Army Operational Test Command, and the U.S. Army Evaluation Center. All comments received during the formal coordination period have been adjudicated by the preparing agency.
2. Scope of the document. This TOP provides the standard for designing and conducting tests estimating penetration of chemical agent vapor simulant through chemical/biological (CB) individual protective equipment (IPE) suit systems while the suits are worn.
3. This document is approved for publication and has been posted to the Reference Library of the ATEC Vision Digital Library System (VDLS). The VDLS website can be accessed at <https://vdls.atec.army.mil/>.
4. Comments, suggestions, or questions on this document should be addressed to U.S. Army Test and Evaluation Command (CSTE-CI), 6617 Aberdeen Boulevard-Third Floor, Aberdeen Proving Ground, MD 21005-5001; or e-mailed to usarmy.apg.atec.mbx.atec-standards@army.mil.

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(A) Director, Capabilities Integration

APPENDIX H. APPROVAL AUTHORITY.

Forward comments, recommended changes, or any pertinent data, which may be of use in improving this publication to the Policy and Standardization Division (CSTE-TM), US Army Test and Evaluation Command, 6617 Aberdeen Boulevard, Aberdeen Proving Ground, Maryland 21005-5055. Technical information may be obtained from the preparing activity: Commander, West Desert Test Center, U.S. Army Dugway Proving Ground, ATTN: TEDP-WD, Dugway, UT 84022-5000. Additional copies can be requested through the following website: <http://itops.dtc.army.mil/RequestForDocuments.aspx>, or through the Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Fort Belvoir, VA 22060-6218. This document is identified by the accession number (AD No.) printed on the first page.