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HUMAN EFFECTIVENESS AND RISK CHARACTERIZATION OF THE ELECTROMUSCULAR INCAPACITATION DEVICE- A LIMITED ANALYSIS OF THE TASER

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14. ABSTRACT
A Human Effectiveness and Risk Characterization for Electromuscular Incapacitation (EMI) reflects the results from three workshops (data gathering/sharing, peer consultation, and independent external review) evaluating two EMI devices: the M26 and X26 TASERs. The intended effect of these devices is electromuscular disruption. Key potential unintended effects included ocular injury, seizures, ventricular fibrillation, or fall injuries. The likelihood of these effects were determined, based on an analysis of the TASER International Database (scrubbed to minimize false positives) and modeling. The probability of inducing a complete EMD ranges from 74% to 52% depending on distance to the target. Probability estimates were up to 0.04% for eye strikes and 0.15% for fall injuries depending on distance to the target. Ventricular fibrillation (VF) is not expected to occur in an otherwise healthy adult population. Key data gaps include the biological basis for TASER effects and appropriate dosimetry. The results support the conclusion that the M26 and X26 TASERs are generally effective for their intended use.

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Human Effectiveness and Risk Characterization; Electromuscular Incapacitation, TASER, Quantitative Estimates, Qualitative Estimates, Dose Response, TASER International Database, Eye strikes, Falls, Ventricular Fibrillation, Seizures, Tetany

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Human Effectiveness and Risk Characterization of the Electromuscular Incapacitation Device – A Limited Analysis of the TASER

Part I – Technical Report


M26


X26

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Human Effectiveness and Risk Characterization of the Electromuscular Incapacitation Device – A Limited Analysis of the TASER

Part I – Technical Report

Submitted by

Advanced Information Engineering Services
A GENERAL DYNAMICS COMPANY

Toxicology Excellence for Risk Assessment (*TERA)*
and
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Graphic on cover adapted from images provided by TASER International (2003).

ABSTRACT

A Human Effectiveness and Risk Characterization (HERC) for Electromuscular Incapacitation (EMI; also referred to as Electromuscular Disruption (EMD) when describing the intended effect of the TASER® products) devices has been conducted in an effort organized by the Human Effects Center of Excellence (HECOE). This HERC reflects the results from a three-workshop process with sequential workshops held for data gathering and sharing, peer consultation, and independent external review of the HERC document. This HERC included two EMI devices manufactured by TASER International, the M26 and X26 TASERs®.

Probability estimates as well as data gaps and uncertainties were characterized for intended and potential unintended effects of the devices. The intended effect of the TASER is electromuscular disruption. During EMD, the individual experiences tetany and is temporarily incapacitated. Key potential unintended effects that were evaluated as part of the process included ocular injury from dart strikes, seizures, ventricular fibrillation, or fall injuries. Numerous other potential effects were evaluated during the process, but these were not further assessed because they were of limited severity (e.g., minor lacerations) or their occurrence was not supported by the available data (e.g., cancer or reproductive effects).

Information developed in the dose-response and exposure assessment was integrated to provide quantitative or qualitative estimates of effectiveness and risk probabilities. The likelihood of various effects were determined, based on an analysis of the TASER International Database (scrubbed to minimize false positives); the probability of inducing a complete EMD ranges from 74% to 52% depending on distance to the target. Severe unintended effects are likely to be of low probability. Probability estimates were up to 0.04% for eye strikes and 0.15% for fall injuries depending on distance to the target.

Ventricular fibrillation (VF) is not expected to occur in an otherwise healthy population, although experimental data are too limited to evaluate probabilities for susceptible populations or for alternative patterns of exposure. No cases of VF have been reported in training or field exposure conditions.

Several key data gaps were identified in the data evaluation. These gaps include the biological basis for TASER effects, appropriate dosimetry, and the impact of environmental and scenario dependent variables on the induction of effects. Available experimental-only data are too limited to adequately quantify possible risks of VF or seizures, particularly in susceptible populations. Limitations in the exposure and incidence data for some infrequent events and the need to rely on a database of case reports compiled by TASER International also generate uncertainty in the results.

Overall, the results support the conclusion that the M26 and X26 TASERs are generally effective for their intended use. However, they may cause several unintended effects, albeit with estimated low probabilities of occurrence.

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ABBREVIATIONS & ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADP	Area Denial to Personnel
AIS	abbreviated injury scale
COE	concept of employment
DoD	Department of Defense
EC	effective concentration
ECBC	Edgewood Chemical Biological Center
ED	effective dose
EMD	Electromuscular Disruption
EMI	Electromuscular Incapacitation
FOV	field of view
HECOE	Human Effects Center of Excellence
HEPAT	Human Effects Process Action Team
HERC	Human Effectiveness and Risk Characterization
HERB	Human Effects Review Board
IERP	Independent External Review Panel
IMC	induce muscular contraction
IPT	Integrated Product Team
JNLWD	Joint Non-Lethal Weapons Directorate
JNLWP	Joint Non-Lethal Weapons Program
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
MDU	Muscle Disruption Units
NLW	non-lethal weapon
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NRC	National Research Council
PSDB	Police Scientific Development Branch
SEV0	severity score assignment 0
SEV1	severity score assignment 1
SEV2	severity score assignment 2
SEV3	severity score assignment 3
TACOM-ARDEC	Tank-Automotive & Armaments Command-Armament Research, Development & Engineering Center
TERA	Toxicology Excellence for Risk Assessment
TI data	TASER International data
U.S. EPA	United States Environmental Protection Agency
VF	Ventricular Fibrillation

FOREWORD

This report is produced for the Joint Non-Lethal Weapons Directorate Human Effects Center of Excellence (HECOE) via contractual agreement between General Dynamics and Toxicology Excellence for Risk Assessment (*TERA*) and its subcontractor LINEA, Inc. This report describes a Human Effectiveness and Risk Characterization (HERC) for Electromuscular Incapacitation (EMI) devices. The evaluation of EMI devices contained in this report utilized a framework for HERC (*TERA,* 2001) developed in a previous contract with Veridian Engineering (General Dynamics) (PO P66050-DSC0142). The assessment and the characterization for EMI devices was reviewed by an Independent External Review Panel (IERP), the HECOE Senior Management, the Area Denial to Personnel Program Manager, subject matter experts and users, in a workshop in December 2003. Their comments and recommendations have been incorporated into this document.

PREFACE

Non-lethal weapons (NLWs) are defined in DoD Policy Directive 3000.3, Policy for Non-Lethal Weapons, dated July 9, 1996, as:

> "... weapons ... explicitly designed and primarily employed ... to incapacitate personnel or materiel, while minimizing fatalities, permanent injury to personnel, and undesired damage to property and the environment."

Accordingly, a major challenge is to develop test and validation processes to assess NLW effectiveness and unintended risks. A secondary task is to fully characterize the performance envelope for various NLWs or payloads in support of joint needs. Meeting these challenges provides users and policymakers confidence to employ these capabilities, insight into fielding and policy acceptability, and data upon which effects-based design or modification of NLWs can proceed. The JNLWP Integrated Product Team (IPT) addressed these issues by formation of a Human Effects Process Action Team (HEPAT) to develop a process-based approach NLW program managers can use in the weapons development process. The HEPAT recommended establishment of a Human Effects Review Board (HERB) to allow independent review of human effects characterization. Also recommended was establishment of a DoD Human Effects Center of Excellence (HECOE) as a central NLW focal point for human effects work to aid NLW program managers to plan, test and analyze all facets of human effectiveness and risk characterization work (Levine, 2002).

On 7 June 2001, the Air Force Research Laboratory (AFRL) and Joint Non-lethal Weapons Directorate (JNLWD) signed an historic Memorandum of Agreement (MOA) at Brooks Air Force Base, Texas, that established HECOE. Upon program review in August 2003, HECOE graduated from a provisional start-up program and was awarded full and permanent program status. Further, the MOA between the JNLWD and AFRL was upgraded and extended in October 2003. The HECOE's joint mission is to formally assist Joint NLW Program Managers (and others with related interests) to accomplish research continuity in human effectiveness and risk characterization. The system or program benefits from this support throughout its life cycle. The objective is to assist decision and policy makers in determining the technical feasibility, likely effectiveness, safe operational use, and policy acceptability of NLWs.

The HECOE accomplishes its mission by scientific, fair evaluation of existing human effects information and develops strategies to collect the additional information needed to complete evaluations. The methods must consider the risk of unintended effects to targets, users, bystanders, and/or other observers, as well as weapon effectiveness, uncertainties, and limits of human effects models. HECOE's Human Effectiveness and Risk Characterization (HERC) process is consistent with National Academies of Sciences and Society for Risk Analysis recommendations and standards.

Three workshops are typically conducted as part of the HERC process. The first, a data sharing workshop, identifies possible sources of relevant data and determines insufficiencies in effectively evaluating the NLW. The second, a peer consultation workshop, outlines potential data gaps, identifies additional sources of data, and provides feedback on preliminary strategies for completing dose-response and exposure assessments. At the third workshop, an Independent External Review Panel (IERP) submits comments and recommendations that are incorporated into the formal HERC document. A final proposed draft may then be reviewed by the JNLWD, the sponsoring program manager(s), HECOE, and the IERP. The product of these three workshops, resultant taskings, and final draft feedback is the HERC for a given payload. The HECOE assessed the effectiveness and risk of M26 and X26 TASERs to support the Hand Emplaced Non-lethal Munition (HENLM) Program Manager's desire to include an Electromuscular Incapacitation (EMI) payload and U.S. Army interest in fielding EMI devices.

The HECOE is also the central repository of human effects data and maintains extensive references for the full gamut of technologies used in NLW developments. The HECOE continues to forge relationships with subject matter experts and NLW-relevant research organizations both within and external to DoD. Please contact us with any questions, comments and/or recommendations.

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We also greatly appreciate the Independent External Review Panel (IERP), which met in December 2003 to review the draft model and evaluation. Their review and advice and many insightful comments strengthened the risk characterization report and the model.

Finally, we thank Dr. Carroll Brown of General Dynamics for his editorial contributions.

EXECUTIVE SUMMARY

The Human Effects Center of Excellence (HECOE) conducted a Human Effectiveness and Risk Characterization (HERC) for Electromuscular Incapacitation (EMI) devices (also referred to as Electromuscular Disruption (EMD) devices when describing the intended effect of the TASER® products), such as the TASER International M26 and X26 TASERs® in support of several Joint Non-Lethal Weapons programs[1]. General Dynamics and TERA assembled a HERC team to address this need. The word "TASER" (Thomas A. Swift Electric Rifle) is a registered trademark of TASER International.

This HERC presents a characterization of the likelihood of intended and unintended effects from the use of primarily the M26 and to a lesser extent the X26 TASER. Overall, the results indicate that the use of the M26 and X26 TASER as intended would generally be effective in inducing the desired EMD effect without presenting a significant risk of unintended severe effects. Although likely to be uncommon, severe unintended effects might occur. In some cases, key data gaps and uncertainties preclude the development of effectiveness and risk probabilities. These overall conclusions regarding effectiveness and risk are consistent with the current experience with the M26 and X26 TASERs in the field, limited empirical data, as well as human effects or safety assessments developed by others. Furthermore, an additional aspect of the analysis is the comparative risk. Analyses provided by law enforcement agencies indicate that increased use of the M26 or X26 TASER may likely decrease the overall injury rate of both police officers and suspects in conflict situations when compared to alternatives in the use of force continuum.

Electrical devices have been designed to induce a variety of physiological effects for medical and other applications. However, these devices are distinct from EMI devices, which are designed to control muscle contractions via externally applied electric fields delivered to the target. There are two delivery mechanisms: tethered and drive-stun. The tethered systems fire two tethered darts that carry the electricity from the device to the target individual. These devices include The Tasertron® TE-76, which contains two dart cartridges (only one of which fires at a time), and two single-shot tethered systems (M26 and X26 TASER®). In drive-stun application, the EMD device is placed directly against the skin of the subject.

This assessment will be limited to two tether-based devices, the TASER International M26 and X26. In addition, the majority of this report will investigate the TASER M26 rather than the X26 since most of the available field data deal with this system and because the exposure potential (based on parameters that impact dart strikes) is similar for these two handheld devices.

Three workshops were conducted: data sharing, peer consultation, and independent external review. The data sharing workshop identified possible sources of relevant data to determine any insufficiencies in effectively evaluating the current Non-Lethal Weapon (NLW) system. The peer consultation workshop uncovered potential data gaps, identified additional sources of data, and obtained feedback on preliminary

[1] The term "Human Electromuscular Incapacitation (HEMI)" is also presently being used in some research efforts, and it may be encountered elsewhere by the reader.

strategies for completing the dose-response[2] and exposure assessments. This workshop also served to review the preliminary concepts being developed for the HERC modeling effort of the EMI devices. The purpose of the final, independent external review workshop was: 1) to review the preliminary HERC that identified the effects of EMI devices, 2) to assess the dose-response for these effects, 3) to assess exposure scenarios, and 4) characterize the effectiveness and risk for the EMI devices. The Independent External Review Panel (IERP) submitted comments and recommendations that were incorporated into this HERC document.

The intended effect of the device is electromuscular disruption. During EMD, the individual experiences tetany and is temporarily incapacitated. A fall resulting from tetany (an unintended effect) can create a wide range of effects from a skin laceration or bruise to a bone fracture or concussion. Additional potential unintended effects evaluated in this report include ocular injury by dart penetration, as well as seizures and ventricular fibrillation induced by the electrical current. Many other unintended effects were considered in this evaluation, but were found to have a low health consequence or low probability of occurrence and were not evaluated in the Dose Response or Exposure Assessment sections of this report.

Five effects of sufficient concern were identified and had adequate data to include in the quantitative dose response assessment (see below table). These effects include electromuscular incapacitation (the intended effect), and unintended effects (ocular injury, seizures, ventricular fibrillation, and fall injuries). The effects are rated by severity level (SEV). Severity Level 1 includes the intended effect and effects that are reversible with no/minimum medical intervention. Severity Level 2 is more severe and would require medical attention for full recovery, while Severity Level 3 refers to acute life-threatening or lethal effects with risk of disability after recovery.

[2] Dose is defined as amount of current acting on the subject per unit of time.

Effects of Concern Evaluated in the HERC		
Effects	**Severity Level**	**Comments**
Intended Effects		
Electrical Effects		
Electromuscular Incapacitation (EMI)	1	Intended effect (anecdotal data, animal studies, data from human volunteers)
Unintended Effects		
Dart-related effects		
Ocular Injury	2-3	Risk based on probability of eye strike (professional judgement, anecdotal data)
Electrical Effects		
Seizure	1	Included in quantitative assessment based on probability of head strike and threshold data for seizures
Ventricular fibrillation	3	Included in quantitative assessment based on animal dose-response data
Other Effects		
Fall injuries (laceration, fracture, chipped teeth, concussion, etc.)	1-3	Included in quantitative assessment based on incidence data from field reports (professional judgement, medical literature, anecdotal data)

The available data on EMI were from human experience, animal studies, as well as comparison to biological let-go thresholds. These data all suggest that when an appropriate EMI device-induced electrical circuit is completed, muscle contraction can occur. Based on these data, EMI device output is assumed to exceed the muscle contraction threshold in all cases where a circuit is established. Whether an induced EMI is fully or partially effective in controlling the exposed subject, however, depends on the location and distribution of the current path. The impact of dart placement on effectiveness is estimated based on observations from experienced users of the TASER and was integrated with hit probabilities in the effectiveness and risk characterization steps of the analysis.

No dose-response data are available to calculate the probability of eye effects of different severities. Thus, any strike to the eye is considered a moderate to severe unintended effect (SEV2 or SEV3). Since eye strikes (although rare) have occurred and have resulted in permanent vision impairment in just one case (Dave Dubay, personal communication, 2004), this approach may be viewed as conservative and health protective. The risk characterization approach for ocular injury is a direct function of the probability of an eye strike from firing the weapon.

Induction of seizures has not been tested experimentally for the M26 or X26 TASERs, although the TASER output is in the range of experimental seizure thresholds. A sensitivity analysis approach provides a 0.7% upper bound estimate of seizure risk.

A key effect of concern for which dose-response data are available is ventricular fibrillation (VF). Experimentally determined VF thresholds in pigs for differing X26

TASER outputs are plotted against body weight (see Section 4.4). The resulting curve is extrapolated for use in assessing human dose-response with the use of uncertainty factors for experimental animal to human extrapolation and human variability. This analysis suggests that healthy adults and larger children would not be at significant risk of VF following exposure to the X26 TASER under normal operating conditions. However, due to assumptions made in selecting uncertainty factors and the absence of specific threshold information in young children, the elderly, individuals with underlying heart conditions, or individuals with concurrent drug use, it is not known whether there are highly sensitive individuals in these groups that could experience VF under normal use of an EMI device. The data are also limited with regard to extrapolation of the data obtained with the M26 to the X26 TASER or future EMI waveforms, or for assessing the impact of different temporal patterns of exposure.

Published data on fall injuries rates are limited. However, TASER International field reports suggest that four moderately severe (SEV2) fall injuries have occurred in more than 1600 deployments that resulted in a complete EMD. These data are consistent with expert judgments from TASER users in the law enforcement community. Based on the data and expert judgments, an injury rate of 1 in 500 (0.2%) fall events is used for the risk characterization.

The use of either of the two TASER devices, the M26 and X26, will result in individuals being exposed to dart lacerations and electrical currents. These exposures occur as a result of the intended use of the devices, and the exposures are required in order for the devices to produce their intended effects. These exposures will occur in the majority, but not all, of the instances where the device is fired. The probability of exposure is influenced by the distance to the target individual and the orientation of the individual (front/back, profile, crouched, or prone position).

The best available data on exposures for the two devices has been collected by TASER International from user reports. These data, while not ideal, provide a good description of the exposures resulting from use of the devices by civilian police departments; in this assessment, we assume that police uses are a reasonable guide for exposures that will occur from military use. Data on exposures to the devices collected by TASER International reflect the range of body position that occurred in actual police use. These data have been sorted by distance to give the following estimates of the probability of exposure to three TASER effects.

Estimates for Field Exposures Resulting from the Use of TASERS at Different Distances					
	Distance (ft)				
	1-3	3-7	7-11	11-15	15-21
Dart Lacerations	84%	87%	84%	76%	57%
Complete or partial EMD	80%	81%	80%	72%	56%

The table indicates dart lacerations occur in approximately 85% of device firings for distances of less then 11 ft (TASER International database). At distances above 15 ft, the probability of the effect drops to approximately 57%. EMD occurs in approximately 80% of the closer shots, and the rates decline to approximately 56% at the longer distances.

Information developed in the dose-response and exposure assessment was integrated to provide quantitative or qualitative estimates of effect and risk probabilities. The likelihood of various effects can be summarized as follows:

- Complete EMD - 74% to 52% (decreasing with distance)
- Partial EMD - 6% to 4% (decreasing with distance)
- Eye strikes - 0.01% to 0.04% (possibly increasing with distance)
- Fall injuries - 0.15% to 0.10% (decreasing with distance)
- Seizure - 0.7% is the upper bound estimate based on head strike probabilities and a worst-case assumption that all head strikes in the region of the brain result in an electrical exposure that exceeds the seizure threshold. No seizure incidents have been reported.
- VF is not expected to occur in otherwise healthy adult populations, although data are too limited to evaluate probabilities for susceptible populations or for alternative patterns of exposure. No cases of VF have been reported in training or field exposure conditions.
- EMI exposures induce other effects of minimal severity (e.g., burns or lacerations) when successfully employed; these effects are not further analyzed.
- Some effects of potential concern are too uncertain or lacked sufficient data to develop probability estimates.

Several areas require further evaluation or data collection before a conclusion can be reached regarding potential effects or risks. Suggestions to address key uncertainties and data gaps include:

- Develop a statistically rigorous database of field incidence exposures (target demographics, TASER International database)
- Develop a common metric for predicting physiological effects of exposure
- Determine the parameter of merit for EMI waveforms (total pulse charge, body current, net charge, charge in positive phase)

- Develop a dosimetry technique to compare existing and future EMI waveforms
- Determine the threshold for ventricular fibrillation/asystole
- Determine the threshold for seizures
- Determine the effect of scale (body size, mass, age, dart location/contact) on EMI response
- Develop a dose response for EMI intended effects (varying pulse amplitude, pulse duration, pulse form, inter-pulse interval)
- Determine the effect of drugs (e.g., ethanol, cocaine, phencyclidine) on the dose response to EMI
- Determine the effect of existing morbidity (e.g., cardiac arrhythmias, epilepsy) on the dose response to EMI
- Determine the effect of increasing the duration of stimulation
- Determine the effect of EMI on respiration
- Develop 3D impedance modeling
- Determine the impact of TASER stimuli on pregnancy & reproduction
- Examine applicability for novel applications such as remote or sensor-activated non-man-in-the-loop devices.

The focus of this report was to address the effects of non-lethal devices that employ EMI technology. However, all data and evaluations in this report specifically relate to the TASER International M26 and X26. These weapons are effective for their intended use, but also may cause several unintended effects. Although sufficient information does not exist to characterize the effectiveness and risk of all potential effects, available data indicate that key effects have been addressed. When data related to the use of these weapons in military operations become available, additional efforts at characterizing the effectiveness and risks would be appropriate.

1 INTRODUCTION

1.1 The Human Effectiveness and Risk Characterization Process

The Joint Non-Lethal Weapons Human Effects Process Action Team (HEPAT) recommended that the Human Effects Center of Excellence (HECOE) develop a risk analysis methodology to quantify the risk to human targets of a non-lethal weapon (NLW) system that takes into account the uncertainties in the models used to predict those effects. The HECOE collaborated with Toxicology Excellence for Risk Assessment (*TERA*) to develop a framework for assessing both the effectiveness against the target and the risks of unintended effects to the target, the user, and any collateral nonbelligerent bystanders. During 2001, *TERA*, with the assistance of an expert panel of risk analysis experts, developed a conceptual framework to evaluate and characterize the effectiveness and risks from use of non-lethal weapons in Military Operations Other Than War (MOOTW). At that time, the panel suggested that the framework be tested with data from one or more non-lethal weapons and be subsequently re-evaluated.

Since the development of the framework (2001), it has been used and revised during the evaluation of several different NLW systems (TERA, 2002; TERA, 2003). During this development phase, the Human Effectiveness and Risk Characterization (HERC) process was refined in collaboration with the HECOE to include a data sharing workshop, a peer consultation, and an independent external review panel (IERP). These workshops build on each other, with the outcome being an independently peer-reviewed report. The Electromuscular Incapacitation (EMI; also referred to as Electromuscular Disruption (EMD) when describing the intended effect of TASER products) HERC used the revised approach.

1.1.1 Data Sharing

The initial workshop in the HERC process is a data-sharing workshop. The attendees at this workshop are weapon system researchers, testing labs, users, and any additional experts that can contribute to the identification of possible sources of human effects, dose-response, exposure, or scenario data. The purpose of the workshop is to identify all possible sources of relevant data to determine any insufficiencies in effectively evaluating the current NLW system. If there is insufficient data to begin the evaluation of the human effects, dose-response or exposure to the NLW system, then the HERC team will recommend additional research or testing. If there are sufficient data, the HERC Team proceeds to review the data and develop a detailed outline of possible human effects, as well as the relevant available dose-response and exposure data.

In July 2003, the HERC team participated in a workshop with researchers, users, and subject matter experts from the Department of Defense (DoD), National Institute of Justice (NIJ), and manufacturers of EMI devices. Prior to the workshop, the HECOE provided *TERA* with several documents on EMI, as well as primary references for some of the major human effects. At the workshop, the HERC team reviewed and discussed what data are available on EMI.

The workshop participants identified a list of potential human effects and discussed what data might be useful for assessing dose response and exposures. The participants then organized the potential effects to humans into three categories: electrical effects, dart-related effects, and secondary effects. The effects identification section describes specific effects identified in each of these categories. Available dose-response data for these effects were examined and discussed at the workshop, with experts identifying the most usable and appropriate data. A discussion of the dose-response data is in Section 4. For the exposure assessment, the workshop participants discussed the nature of a hypothetical individual and how the weapon might be used (i.e., the concept of employment) to enhance the development of the HERC model. The HERC team did not conduct a comprehensive review of the refereed literature, but did conduct additional literature searches to seek further information for some effects and exposure factors, as well as consulting some primary references. Rather, existing review articles and tutorials were used to the extent possible.

1.1.2 Peer Consultation

The peer consultation workshop is the second workshop in the HERC process. The purpose of this workshop is to communicate potential data gaps, identify additional sources of data, and obtain feedback on preliminary strategies for completing the dose-response and exposure assessments. This workshop also serves to review the preliminary concepts developed for the EMI modeling effort. Feedback from the participants helps to refine the focus of the HERC.

In August 2003, the HERC team participated in a peer consultation with subject matter experts, researchers, users, and program managers from the DoD, NIJ and EMI device manufacturers.

1.1.3 Independent External Review Panel Workshop

The final workshop is an Independent External Review Panel (IERP) meeting. The purpose of this third workshop is to review the HERC that addresses the effects, the dose-response for these effects, the exposure, and effectiveness and risk characterization for the weapon system. An IERP of experts reviews and provides comments on the HERC. The panel's expertise ranges across medicine, decision analysis, exposure assessment, risk assessment, toxicology, and weapon specific knowledge. After the IERP, TERA begins to revise the HERC report by addressing the comments provided by the panel. The final product is an IERP-reviewed technical report on the human effectiveness and risk of a weapon system.

The IERP workshop on the EMI HERC took place 4-5 December 2003. A variety of researchers, weapon developers, weapon users, sponsors, authors, and expert panel attended the workshop. This final document incorporates the IERP's comments and recommendations (see Appendix C for Disposition of Panel Comments).

1.2 Purpose of the Report

The HECOE, through Veridian (now General Dynamics), tasked *TERA* to develop a HERC for EMI devices, including the TASER International M26 TASER® and the X26 TASER®. The word "TASER" is a trademark of TASER International. The remainder of this report will refer to the specific TASER models included in the evaluation simply as the M26 and X26. This report presents the results of this human effectiveness and risk characterization effort.

The NLW HERC framework provides decision-makers with a process for identifying the types of data needed and for organizing these data to support conclusions regarding effectiveness and risk from use of a particular NLW. To facilitate this, the NLW Risk Characterization framework utilizes the National Academy of Sciences (NAS) steps of hazard (effects) identification, dose-response assessment, exposure assessment, and risk characterization. By following these steps, an evaluation of the necessary information assists in making decisions at several levels, including weapons development and deployment.

The four steps organize this report using separate sections for effects identification, dose-response assessment, exposure assessment, and risk characterization. This report does not provide extensive general discussions about the current NLW HERC framework. This report focuses on presenting information on a weapon delivery system and the results. Appendix A contains a brief description of the HERC framework (TERA, 2001) and some definitions of terms used in this report.

2 ELECTROMUSCULAR INCAPACITATION (EMI) DEVICES

Electrical devices have been developed to induce a variety of physiological effects for medical and other applications. However, these devices are distinct from EMI devices, which control muscle contractions via externally applied electric fields delivered to the target. There are two delivery mechanisms that are used for NLW applications: tethered and drive-stun. The tethered systems fire two tethered darts that carry the electricity from the device to the target individual. These devices include earlier TASER designs such as the Air TASER, which contains two dart cartridges (only one of which fires at a time), and newer designs such as the M26 and X26, which are single-shot tethered systems. TASER devices used in drive-stun mode do not fire darts, but have two electrodes that contact with a person to complete the circuit. In addition to differences among these devices in the physical delivery technique for the electrical charge, the electrical waveform of each also differs. For these reasons, comparison of effects data across weapons systems is complex.

This assessment will be limited to the TASER International M26 and X26 tethered devices. The majority of this chapter will investigate the TASER M26 rather than the X26 since most of the available field data deal with this system and because the exposure potential (based on parameters that impact dart strikes) are similar for these two devices. The Dose-Response section discusses the differences in electrical characteristics that impact the human effectiveness and risks. For EMI device comparison purposes, dose is defined as the amount of current acting on the subject per unit of time.

The TASER (Thomas A. Swift Electric Rifle) was invented by John H. Cover and patented in 1974 (U. S. Patent 3803463). This patent describes a number of different ways to generate short-duration, high-voltage, electrical pulses. Until fairly recently, two companies utilized the patent or a derivation of the patent to manufacture a number of different models of the TASER. These companies are TASER Technologies and TASER International (Scottsdale, AZ). In 2003, TASER International purchased TASER Technologies.

The TASER M26 and X26 (Figure 1) are pistol-like devices that shoot two tethered darts. The tethers are insulated wires that carry the charge from the gun to the darts. The penetrating portion (shaft and barb) of the dart is made of stainless steel. The TASER dart has a barb similar to that on the end of a fishhook. TASER International currently has three types of darts for use with either system.

The two systems differ in the nature of the charge delivered by the devices; however, the two systems use the same dart cartridge, targeting system, and procedures for use.

Figure 1. M26 and X26 TASER (adapted from TASER International, 2003)

In both of these devices, the darts strike an individual or the individual's clothing and complete an electrical circuit. The individual's body receives the charge producing the Electromuscular Disruption (EMD). The electrical charges delivered by the TASER create an electrical arc between the dart and the skin to complete the circuit if dart penetration has not occurred. Once the darts strike and a circuit is achieved, the devices provide a series of electrical pulses for 5 seconds. If the tethers remain intact, the user can deliver additional impulses as needed.

The two darts fire at the same time. The orientation of the darts in the M26 and X26 are vertical (one dart is directly above the other). The maximum distance for both of the devices is 21 ft. The length of the two tethers determines the distance. The tethers are copper-clad steel wires with an insulated coating. Reports suggest forceful contact of the subject with the wires during the deployment can either result in an effective stimulation or break the circuit.

The trajectory of the lower dart is 8° below the upper dart. This offset results in a separation of the darts that is proportional to the distance between the user and target. The separation occurs as the lower dart drops in height relative to the upper dart. This separation maximizes the charge dispersal in the target individual and thus enhances the intended muscle contraction. Table 1 shows the theoretical amount of dart separation at different distances between the user and the target. As discussed in Appendix B, the observed separation is slightly less than this table indicates.

Table 1. Theoretical Dart Separation Based on Distance Between User and Target

Target Distance (ft)	2	5	7	10	15	21
Dart Spread (in)	4	9	13	18	26	36

When the darts contact or penetrate the skin, the electric charge can induce the EMD. When clothing prevents direct contact, it is necessary to create an arc between the dart and the skin that will carry the charge and complete the circuit. The manner in which this arc is established varies between the M26 and X26. The M26 uses a simple "blunt" pulse to both generate the arc (if one is required) and the EMD pulse. The pulse has an electrical output of 50,000 volts, an average current of 3.6 milliamps, and 1.76 Joules of energy per pulse. The X26 uses a "shaped" pulse that consists of two portions, a high-voltage low-charge portion to create the arc and a second portion with lower voltage and higher current to cause the EMD. The result is a pulse that has less total energy than the M26. The X26 has an electrical output of 50,000 volts, average amperage of 2.1 milliamps, and 0.36 Joules of energy per pulse.

Pulling the trigger on both the M26 and the X26 automatically delivers five seconds of pulsed current. In the M26, the frequency is 19 pulses per second. For the X26, the first 2 seconds deliver 19 pulses per second; this drops to 15 pulses per second for the remaining 3 seconds.

Holding the trigger down to deliver continuous bursts, the M26 will continue to deliver 19 pulses per second. In the X26, the first 2 seconds will deliver 19 pulses per second and then deliver 15 pulses per second until releasing the trigger.

The electrical stimulus produces an uncontrollable skeletal muscle contraction (referred to as EMD) that causes the targeted individual to lose control of posture and fall. The target suffers no long-term injuries due to the direct effect of EMD. The target remains incapacitated for as long as the electrical pulses are applied. The probabilities of inducing intended and unintended effects are the subject of this report.

3 EFFECTS IDENTIFICATION

3.1 Overview of Effects

The first phase in the HERC framework is the process of identification and discussion of all the possible effects of the weapon, both intended and unintended. After identifying the unintended effects, another possible step is to combine them in a way that allows easy comparison with the intended effects. One approach would be to combine effects of equal severity for a "combined" effect. Another approach would be to select a single "critical" effect, such as the unintended effect that occurs at the lowest dose, to establish a benchmark to compare with other levels of exposure (dose). Where possible, it is helpful to seek data and information that would support these approaches. The quantitative data on the combined effects or the critical effect helps to develop the dose-response curves.

The TASER propels two darts into an individual and transmits short pulses of electrical charge through wires attached to the darts and into the subject causing incapacitating EMD. Optimally, the TASER should safely decrease an aggressive individual's ability to initiate hostile actions, and it should incapacitate the individual without causing acute or long-term injury. Incapacitation occurs when the targeted individual is unable to perform intended tasks for a specific period. Incapacitation is the intended behavioral response.

There are relatively few data about the effects of rapid-rise-time, short-duration, high-voltage (the TASER peak current is high relative to electrostimulation thresholds, but the average current is low) electrical impulses on biochemical, physiological or behavioral responses (Reilly, 1998). There are only a few reports in the refereed literature that deal with the electrical output of pre-M26 model TASERs (Robinson et al., 1990). Electrical waveforms have a significant impact on the physiological effects that are induced. For this reason, data collected directly for the M26 or X26 have a greater weight in the assessment than data collected for other devices that have different electrical properties. The consideration of many other sources of data included effects data and safety standards for other diverse types of electrical devices and published data on effects of other earlier TASER designs. Sources of data were actively sought from subject matter experts at two earlier workshops (July 2003 and August 2003) and during an IERP Meeting (December 2003) sponsored by the HECOE. The effects identification section uses information obtained from comprehensive searches of the biomedical literature and general press, TASER International, and personal communication with subject matter experts.

The HERC process is structured to be comprehensive and based on an attempt to evaluate all potentially relevant physiological effects of EMI devices, even those that would appear to be only remotely possible. The review includes effects (intended as well as unintended) potentially caused by the TASER darts, electrical injuries, as well as likely immediate secondary effects. Table 2 lists the considered effects, assigned levels of effect severity, and comments on the approach used for the effectiveness and risk characterization.

Effects are categorized according to a qualitative severity scale including the following four categories.

SEV0 - The lowest effect severity is defined as severity level 0, which corresponds to a no observed adverse effect level (NOAEL). This category includes exposures that evoked no effects or effects of insignificant severity, such as minor cuts and bruises. Effects that fall in this category would not be expected to incapacitate the target.

SEV1 - The next higher level of severity corresponds to reversible effects that would not normally require medical treatment for full recovery. SEV1 exposures induce discomfort or evoke involuntary mechanisms that incapacitate. Effects in this category will usually include the intended physiological effect.

SEV2 - The next higher severity level includes effects that are more severe and typically require medical treatment, but that are not life threatening nor pose risk of significant disability after recovery. Effects in this category are unintended effects.

SEV3 - The highest severity level refers to severe acute life-threatening effects or lethality or effects that pose risk of significant disability after recovery. Effects in this category are unintended effects of the NLW system.

Table 2. Summary of Considered Effects

Effects	Severity Level	Overall Concern Level for Effectiveness and Risk Characterization
Intended Effects		
Electrical Effects		
Electromuscular Incapacitation (EMI)	1	Effect of concern - Intended effect
Unintended Effects		
Dart-related Effects		
Blunt trauma	1	Low concern - kinetic energy is below threshold
Skin penetration	1	Low concern - primary risk due to secondary infection
Ocular injury	2-3	Effect of concern - risk based on probability of eye strike
Skin burns	1	Low concern - small skin surface
Blood vessel injury	1-2	Low concern - small target area and barb diameter
Testicle Injury	1-2	Low concern - small target area and barb diameter, no evidence of reproductive effect
Electrical Effects		
Discomfort	1	Low concern - minimal effect severity
Changes in blood pressure or heart rate	1	Low concern - available data do not support effect
Peripheral nerve injury	1-2	Low concern - available data do not support effect
Mechanical muscle injury	1	Effect of concern - reported in field case studies, but data inadequate to include in assessment
Bone Fracture	2	Low concern - available data do not support effect
Spontaneous abortion (developmental)	3	Low concern - available data do not support effect, although an effect with remaining uncertainties
Acute respiratory impairment & failure	2-3	Low concern - potential concern only for extended duration stimulation
Rhabdomyolysis	1-3	Low concern – significant concern only for extended duration stimulation
Seizures	1	Effect of concern - limited threshold data available for quantitative risk estimate
Ventricular fibrillation	3	Effect of concern - included in quantitative assessment based on animal dose-response data
Cancer	3	Low concern - available data do not support effect
Other Effects		
Fall related injuries (laceration, fracture, chipped teeth, concussion, etc.)	1-3	Effect of concern - included in quantitative assessment based on incidence data from field reports
Laser-related eye injury	1	Low concern - Laser targeting device compliant with current laser safety standards
Noise-related Injuries	1	Low concern - sound pressure levels below threshold for impulse noise
Interactions with other NLW		Considered a secondary effect (not evaluated)
Flammability/Explosions		Considered a secondary effect (not evaluated)
Drive Stun Effects		
Testicular torsion	1-2	Effect of concern - not evaluated in quantitative assessment

3.2 Intended Effects

In videotapes of TASER exposures, under field conditions or during demonstrations, the target typically shows sudden tonic muscle contraction, becomes rigid and loses upright posture. Post-exposure interviews indicate that the individual maintains a clear sensorium during stimulation. The induction of these muscle contractions is the intended physiological effect. The mechanism of EMI device-induced muscle contraction has not been fully described in the scientific literature. The amount of charge delivered to the body and the time period of charge delivery determine when an EMI will occur. By repetitive pulsing of the current at a sufficient rate, a state of sustained contraction of major muscle groups is induced, which incapacitates the individual. Cessation of the current restores the individual's full motor function and control.

EMI devices have been demonstrated to be useful in subduing targets by law enforcement agencies for approximately 20 years. TASER International collects voluntary reports of field use from police agencies. Based on an analysis of sales records, TASER International concluded that the database represents about 1/5 of the total number of TASER incidents. On examination, it is clear that the majority of available reports come from small to medium cities with limited data being released by large metropolitan areas. It is not clear what biases, if any, occur in this non-random, voluntary sample. See Appendix B for additional discussion of these data.

A second source of field use data on the TASER is from independent analyses provided by some law enforcement jurisdictions. Representatives of several of these larger agencies provided input as subject matter experts during the effectiveness and risk characterization process, while others submitted summary reports. TASER International also maintains a database of exposures that occur under quasi-controlled conditions, where trainers expose police or corrections officials to the effects of the TASER. With the exception of the TASER International databases as supplemented by input from other law enforcement agencies, relatively little is known about the exposure conditions (i.e., number of exposures, location of darts on the body, duration of exposures) that lead to the effective use of the device.

EMI devices of the 1970s, 80s, and 90s were not effective in all subjects. Kornblum and Reddy (1991) reported that the Tasertron TE-76 in use at that time provided some level of control of the exposed subject's behavior about 80% of the time when it was used by the Los Angeles Police Department. There are other anecdotal reports, mostly on the Internet, suggesting that the effectiveness of these earlier TASER designs is as low as 60%. Mr. Rick Smith, CEO of TASER International, reported at the TASER International 2002 Tactical Conference (Las Vegas, Nevada, May 17-19) that individuals could resist and "fight through" TASER effects induced by their earlier TASER, the Air TASER Model 34000. Since the late 1990s, TASER International, using different electrical waveforms, has increased the effectiveness of new TASER devices. These newer TASERs, the TASER International Advanced TASER M26 and X26, are the subject of this assessment.

Two variables that appear to affect the degree of muscle contraction, and therefore, the effectiveness of these devices to incapacitate are spacing of the darts and location of the darts on the body. Based on expert advice during the second workshop (August 2003) the impact of dart spacing and location were characterized. The Effectiveness and Risk Characterization section discusses the application of these considerations.

Animal studies can provide additional information assessing EMI device effectiveness. Muscle tension measurements in animals exposed to TASER output demonstrate that normal output of the M26 or X26 TASER delivered to the skin of pigs (Nerheim et al., 2003) or sheep (Johnson, 2003) induces dramatic tonic-clonic muscle contraction.

Consistent with reports of human experiences with earlier TASER devices, animal experiments have demonstrated variable effectiveness among the different weapons. Coate and Wargovich (1974) found that exposure to the output of a TF-1 TASER Electronic Gun (2-10 pulses/sec. and 0.01 to 0.5 J/pulse) did not disrupt performance of a simple learned task by monkeys.

Sherry et al. (2003a) chose pigs for experiments because pigs are approximately the same size as humans, and their skin is very similar to humans. A similarity exists between pigs and humans in structure and physiology of the neuromuscular pathways including the pyramidal cells in the motor strip of the cerebral cortex, axons, synapse(s) in the spinal cord, the alpha motor neuron, the neuromuscular synapse, and the muscles, including the individual muscle fibers, myofibrils, and sarcomeres (Swindle & Smith, 2000).

Each pig was initially exposed to the output of one of five randomly selected TASER-like devices for 15 seconds. There was a minimum rest period of 45 hours between succeeding exposures (Sherry et al., 2003b). The initial exposures were accomplished while the pigs were pressing a panel for a food reward. After the second exposure, independent of the devices they were exposed to, the pigs refused to approach the bar and food well. Therefore, the test chamber was reconfigured; the panel press apparatus and food well were replaced with a bowl that contained food. After the third exposure, the pigs refused to approach the food bowl and vigorously resisted entering the test chamber. Table 3 summarizes the behavioral effects in pigs while being stimulated by the TASER along with the electrical characteristics of each device.

Table 3. Electrical Parameters and Bio-behavioral Effects of EMI Devices (N=11)

Device	Decreasing Muscle Coordination				Peak Current Amplitude (amps)	Pulse Duration (nanoseconds)
	Circle	Jump Against Wall	Jump Over Wall	Lost Posture		
Jaycor Sticky Shocker	10	4	0	0	11	2500
TASERtron TE 86	7	4	1	0	6	4500
TASERtron HP 95	11	3	1	0	8.5	5500
TASER Int. Model 34000	6	7	0	0	9	4500
TASER Int. Model 44000 M26	10	10	0	7	14	9000

Based on anecdotal information reported by TASER International, anesthetized animals showed minimal physical response when stimulated with the Air TASER Model 34000 (and by implication all previous TASERs, which utilized the same technology). This observation suggests that these stun systems were insufficiently affecting the motor nerves and muscles, although no empirical data to substantiate this conclusion were reviewed in the preparation of this report. TASER International reported the M26 functions by acting on efferent nerves causing involuntary muscle contractions. However, the available data are very limited on the underlying mechanism for EMD induced by the M26 and X26. All of the data in the refereed literature on human safety evaluation deals with pre-M26 TASER-like devices, and therefore may have limited value in assessing the physiological effects of the M26 and X26 TASERs.

TASER International has developed an approach to measure the force of muscle contraction in pigs exposed to various electrical waveforms. The relative strength of a muscle contraction is reported in terms of Muscle Disruption Units (MDUs), where the M26 TASER's 100 MDU is the baseline. According to this measurement approach, the X26 TASER generates 105 MDUs, and thus is as (or more) effective than the M26 in inducing muscle contraction response. For comparison, an earlier TASER design (Air TASER 34000) generates only 20 MDUs. This metric has been suggested as a tool for evaluating the ability of different waveforms (in current and future devices) to induce the intended muscle contraction event. Therefore, it has potential as a tool for comparing the relative effectiveness of different electrical stimuli.

Another measure of physiological effectiveness would be to compare the electrical output of the EMI device to muscle contraction thresholds derived for other electrical devices, such as shock hazards from electrical wires. For example, comparison of TASER outputs to published thresholds for let-go currents were considered. The maximum current a subject can sustain and still release a conductor is commonly called the let-go current. This provides a well-known response that is similar to the EMI effect, where the subject loses control of the voluntary muscles.

Figure 2 shows a statistical distribution of let-go thresholds with 60 Hz current applied through gripped conductors in men and women (Dalziel, 1972). Children appear to have a lower let-go threshold than adults. Let-go currents for three children were in the range of 7 mA (Reilly, 1998). These electrical effects correlate with body weight, and allometric equations have been developed to describe this relationship (Reilly, 1998).

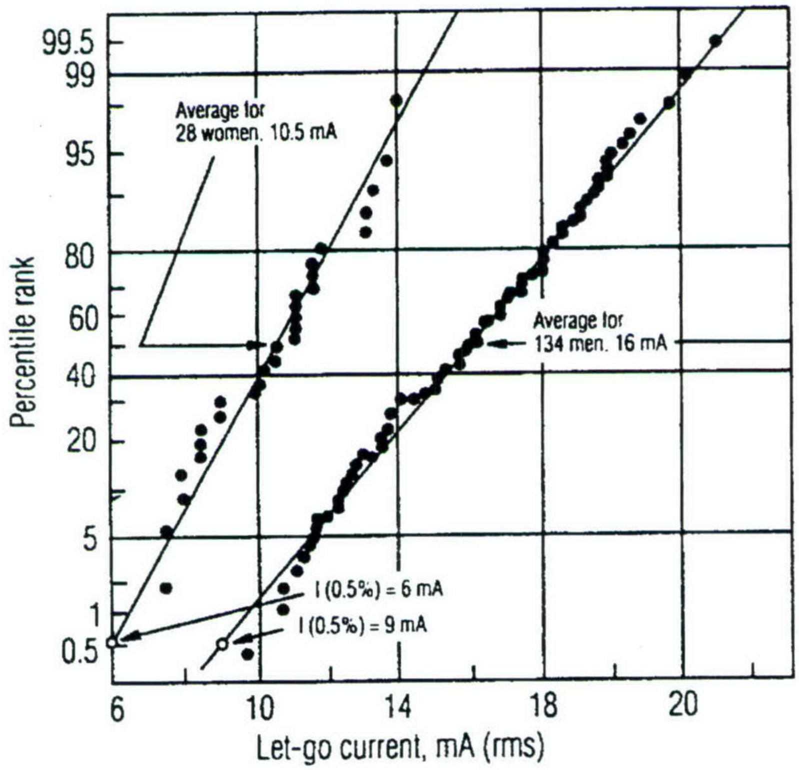

Figure 2. Cumulative Probability Distribution for Let-go Current (60 Hz) by Percentile Rank for Males and Females (modified after Dalziel, 1972)

Although useful, such data cannot be directly compared with EMI current magnitudes because their waveforms differ so radically from the 60 Hz sinusoidal waveforms applying to Figure 2. Consequently, the field use data and controlled animal testing results for the M26 and X26 TASERs are more useful. Nevertheless, Dalziel's let-go data can be useful in describing human variability in response to electrical stimulation. The Dose-Response Section discusses this point.

3.3 Unintended Effects

3.3.1 Dart Related Effects

A summary of the evaluation of several identified dart related injuries is below.

3.3.1.1 Blunt Trauma and Skin Penetration

When launched from the TASER, the top dart moves horizontally, while the lower dart drops at an angle of 8 degrees. When the TASER dart strikes bare skin, the dart penetrates the skin until the flange on the dart stops it. Removing the dart causes a small laceration of the skin. TASER International (TASER International, personal communication, 2003) recommends that removal of the dart is best accomplished by gripping the probe firmly and pulling straight out in quick fashion, using the other hand to brace and stabilize the skin. Disinfection with alcohol or other means should follow. Kornblum and Reddy (1991) reported that superficial puncture wounds are found on TASER shot subjects. Field data for thousands of applications of the M26 and X26 TASERs demonstrate that the darts do not penetrate the skin beyond the length of the shaft up to the flange. The energy of the dart at the muzzle of the TASER is well below the 20 J/cm^2 required for skin penetration of projectiles (DiMaio et al., 1982), although comparison to existing kinetic standards is of limited value since they were not developed for application of pointed projectiles such as the TASER dart.

Due to the limited extent of the skin injury involved, skin penetration wounds are categorized as SEV1 effects. Although the TASER darts themselves are likely to be clean and are not reused or recycled, they could carry bacteria or contaminants from the external environment when they penetrate the skin. Localized skin infection is a potential secondary risk, and is not considered further in the quantitative risk characterization. Possible transfer of biological contamination from target to individual who improperly removes the barb and receives a puncture wound from the barb could be a secondary risk, but is not considered further in this quantitative risk characterization.

3.3.1.2 Ocular Injury

Deployment of EMI devices requires aiming and firing darts at an individual with imperfect control of dart impact location. Projectile impact in the facial area presents a risk to internal ocular structures. However, for the purposes of this HERC, any eye penetration event would ideally receive medical treatment (SEV2 or SEV3 effect). This categorization encompasses all possible severe eye injuries, including those that result in permanent loss of vision. The probabilities of permanent loss of visual function or ocular injury due to any single eye strike event are unknown. While not contained within the TI database, there is one known case of permanent vision impairment as a result of a dart strike to the ocular region (Dave Dubay, personal communication, 2004). Since field cases of eye strikes are very limited, all eye strikes are severe unintended effects (SEV2 or SEV3) for this risk characterization. The Effectiveness and Risk Characterization section presents the probability of ocular injury based on the probability that a direct hit of the eye may occur. The possibility that ocular injury might occur due to electrical effects resulting from strikes to other parts of the body, rather than direct physical trauma, was also considered. Field reports of TASER use in the TASER International database and thousands of exposures in training exercises did not report any ocular effects. No change in blood pressure was reported in pigs exposed to the X26 TASER (Nerheim et al., 2003) suggesting that under normal use conditions, the TASER output would not induce severe eye effects through systemic blood pressure changes.

3.3.1.3 Skin Burns

Kornblum and Reddy (1991) report examination of early-generation TASER puncture wounds excised at autopsy (see detailed discusson, Section 3.3.2.10.2) in subjects exposed during law enforcement applications. Skin lacerations are superficial and may or may not be surrounded by erythema. A thin zone of homogenously coagulated tissue lines the wound track. The wound margins show sub-epidermal bullous formation and separation of the epidermis from the dermis. Surrounding capillaries are dilated and filled with fluid. Should the dart of the newer TASER fail to contact the skin, the electrical output can arc across approximately 1.25" (3.2 cm) of clothing per dart for a cumulative distance of 2.5" (6.4 cm). This is based on relatively basic laboratory experiments in which maximum arc length was tested by discharging the TASER across various thicknesses of cloth into a piece of meat (TASER International, personal communication, 2003). Photographs presented by TASER International for exposed pigs and humans exposed during training courses show that the arc will damage the surface of the skin, and can generate a visible and persistent mark on the skin. However, due to the superficial nature of these wounds and the very small skin surface area involved, they are considered SEV1 (see Table 2) effects for this characterization and have not been considered further in the quantitative risk characterization.

3.3.1.4 Blood Vessel Injury

Koscove (1985), Ordog et al. (1987), Kornblum and Reddy (1991), and Smith (2003) did not report any incidences of TASER darts penetrating a major blood vessel in individuals who were shot with a TASER during law enforcement activities. Superficial major blood vessels that are vulnerable to laceration by the longest TASER dart include the vessels in the neck and groin (i.e., external carotid artery, jugular vein, femoral artery and vein). Lesser vessels may also be at risk. It is unlikely that the TASER darts would strike the side of the neck or the femoral triangle based on the small surface area these vessels represent. Subject matter experts have suggested that given the barb diameter, significant injury to blood vessels would be unlikely unless the laceration were worsened by improper dart removal. In addition, because only relatively superficial blood vessels could theoretically be reached by the darts, their superficial location would permit rapid and successful tamponade of bleeding. Based on these considerations, blood vessel damage is an effect of low concern, and is not considered further in the quantitative risk characterization.

3.3.1.5 *Testicle Injury*

Within the scrotum, spermatic cords suspend each testicle, which provide a passageway for the sperm and testicular blood supply. When a testicle twists on its cord, the blood supply can be impaired. This results in immediate severe pain, and if unrelieved, infarction and death of the organ, which then requires surgical extirpation. Ordog et al. (1987) reported that one patient in their series developed testicular torsion immediately after being hit with the TASER. The patient denied any pre-existing scrotal pain or swelling. Ordog et al. (1987) could not determine if the torsion was a result of the TASER event or not.

No data were identified for the TASER to evaluate whether dart penetration injuries or electrical effects would have an effect on male reproductive capacity. No documented cases of male reproductive dysfunction were identified for the TASER, although at least one current lawsuit related to a claim of incidence has been noted by TASER International. Scrotal anatomy (protection of scrotal contents by muscle and connective tissue, low blood flow to gonads versus other scrotal contents) and the apparent lack of adverse effects of other electrical devices on male genitals such as in animal husbandry, suggests that this effect would be a low concern (R. Stratbucker, personal communication, 2003). Based on these considerations, functional testicular injuries are an effect of low concern.

3.3.2 Electrical Related Effects

3.3.2.1 *Discomfort*

Discomfort from the EMI stimuli is expected in all cases when an electrical circuit is achieved. Field data and the experience of thousands of subjects in training exercises demonstrate that the perception threshold is routinely exceeded. There is no comparison between the perception thresholds published for some electrical sources (Bernstein, 1991; Dalziel & Mansfield, 1950) and the EMI output because their waveforms differ substantially from those of the current TASER device. However, other experiments with human subjects have tested high-voltage capacitor discharges, which produce brief, but high intensity current waveforms (Reilly, 1998; Reilly & Larkin, 1987). These data show that experimental subjects have reported significant pain at stimulus levels that are much below EMI device outputs.

Anecdotal reports in post-exposure interviews of individuals that have been exposed to the TASER (i.e., dart hit and circuit established) during training did not generally describe the experience as painful, but as an intense throbbing sensation. Induction of pain is not the intended effect (except in drive stun mode), but is considered only a SEV1 response for the effectiveness and risk characterization, since no treatment or longer-term secondary effects would be expected from the perception of the EMI stimuli. This effect is of low concern.

3.3.2.2 Changes in Blood Pressure and Heart Rate

Previous work on a series of stun gun (NOVA XR-5000) devices (Roy and Podgorski, 1989) reported cardiac and blood pressure changes in Yorkshire pigs following exposure. In this study, only the highest power device caused a change in cardiovascular measurements, and this device substantially exceeded the output of the M26 and X26 TASERs. The X26 showed no effect on heart rate in exposed pigs. Blood pressures were marginally decreased during the stimulation (Nerheim et al., 2003). Based on these considerations, the data do not support adverse influence on blood pressure and heart rate, and therefore, these data are not in the quantitative effectiveness and risk characterization.

3.3.2.3 Peripheral nerve injury

Peripheral nerve injury has been reported following high-current electrical stimuli (e.g., in accidents, victims exposed to high power transmission lines or lightning strikes) (Chilbert, 1998). However, no studies were identified that specifically evaluated the potential for EMI-related peripheral nerve injury. No clinical cases of peripheral nerve injury have been reported in subjects who have been exposed to EMI stimuli, although the degree to which these types of effects have been specifically evaluated after EMI device exposure is unclear. Based on the absence of reported effects in field use of EMI devices, peripheral nerve damage associated with functional effects is unlikely. Therefore, in the absence of available data this effect is not in the quantitative effectiveness and risk characterization.

3.3.2.4 Mechanical muscle injury

A muscle strain ("pulled muscle") is categorized as a SEV1 effect. It occurs when excessive use tears some of the muscle fibers. This categorization is not intended to imply that severe muscle strains cannot benefit from medical treatment. Rather, in the hierarchy of effect severities as described earlier in the report, self-limiting effects that heal fully without medical intervention have been categorized as SEV1 responses for the HERC process. No data were identified on the incidence of muscle injury resulting from rapid induction of strong muscle contractions. Searches of the sports medicine literature did not identify relevant data. A subject matter expert relayed an anecdotal account of one such incident. Considering the number of field uses of the TASER, it is reasonable to conclude that this is an infrequent event. These potential effects warrant further empirical investigation. In the absence of reliable data, this effect is not in the quantitative effectiveness and risk characterization.

3.3.2.5 Smooth Muscle

There are no field use reports of involuntary urination or defecation. However, these responses require both a contraction of smooth muscle and relaxation of external sphincters. Therefore, it is not a straightforward matter to make inferences about the ability of the EMI device to stimulate smooth muscles based on the absence of these responses. Due to the lack of reliable data, this effect is not in the quantitative effectiveness and risk characterization.

3.3.2.6 Bone Fracture

No reports were identified that describe bone fractures resulting from rapid induction of strong muscle contraction. Subject matter experts in law enforcement applications of the TASER have reported cases of TASER dart penetration into the sternum with no severe outcomes. Bone fractures are generally SEV2 effects. Based on these anecdotal and field data from subject matter experts and considering the number of field uses of the TASER, it is reasonable to conclude that this is an infrequent event. Limited incidence suggests that bone fracture (other than from falls) is of low concern. This effect is not in the quantitative effectiveness and risk characterization, due to lack of reliable data.

3.3.2.7 Spontaneous Abortion

Only one published report was identified suggesting that being stimulated by a TASER (pre-M26 design) can induce a miscarriage, although one or two complaints have entered the legal system (TASER International, personal communication, 2003). Mehl (1992) reported that a woman who was 12 weeks pregnant began to spontaneously miscarry 7 days after being exposed to an early-model device. TASER International developed a written critical analysis of this study, disagreeing with several of the Mehl study's conclusions (TASER International, personal communication of an in-house TASER International document, 2003). In the literature regarding pregnancy, Einarson et al. (1997) found no difference in the outcome of pregnancy for females accidentally exposed to electric shock and unexposed controls. The majority of seizure-prone women who experience seizures while pregnant have full term infants (Nakken et al., 1999). Electro-convulsive therapy for recalcitrant depression during pregnancy does not appear to compromise the pregnancy (DeBattista et al., 2003; Rabheru, 2001). In addition, current medical practice is to use external defibrillation regardless of pregnancy status. Multiple defibrillation stimuli applied to a pregnant dog did not cause any adverse effect on the viability of pups (R. Stratbucker, personal communication, 2004).

Only limited animal data are available to assess effects on pregnancy or the developing fetus. In an unpublished study with only summary data available for review, TASER International reported that the X26 TASER did not induce miscarriage in either of two pregnant pigs.

One research tool to further evaluate this endpoint would be to use a total body impedance model to determine whether the electrical output of an EMI device can reach the uterus of a pregnant female. The overall risk of developmental effects is probably low. However, in the absence of adequate dose-response information, this endpoint needs further study, but is not evaluated in the quantitative effectiveness and risk characterization.

3.3.2.8 *Effects of prolonged muscle contraction: Respiratory impairment, acidosis, rhabdomyolysis, and nervous system effects*

The M26 and X26 TASER are preset to give an initial 5-second exposure to control the subject's behavior. Subsequent activation of the TASER's trigger will result in an additional 5-second energy delivery, and continuous depression of the trigger can result in a continuous impulse train lasting up to the life of the battery. Battery life for the M26 with 8 Alkaline Energizer AA batteries is approximately 10 minutes at room temperature. The X26 battery is rated for approximately 300 5-sec discharges at room temperature (Mark Johnson, TASER International, personal communication, April 2004). Field experience indicates that in most cases only one or a small number of 5-second activations are needed to achieve and maintain control of the subject (Law Enforcement Officials, personal communication, August 2003). However, repeated or constant activation of the devices can deliver constant electrical output, which results in sustained muscle contraction with little or no muscle recovery period. This is a particular concern in a situation where a human operator is not involved, as might be the case with future tether-less or non-man-in-the-loop devices. If long periods of uninterrupted EMI activation did occur, the risk of unintended adverse effects such as cardiac arrhythmia (see ventricular fibrillation discussion, Section 4.4), impairment of respiration, or widespread metabolic muscle damage (rhabdomyolysis) could be severe.

3.3.2.8.1 Acute respiratory impairment and failure

If placement of the darts induces spasm of the muscles of respiration (diaphragm and intercostal muscles), one can hypothesize that the subject may not be able to breathe. Furthermore, personal observations during animal studies in pigs (Clifford J. Sherry, personal communication, 2003), suggest that the test animals hold their breath while being stimulated with the TASER. If humans respond similarly, one would expect no or minimal normal breathing while being exposed. In an extreme case of several minutes of exposure during which respiration is impaired, acute respiratory failure, which is immediately life threatening, could plausibly develop. Acute hypoxia and CO_2 retention cause acidosis and failure of aerobic cellular energy production in all tissues, with earliest effects seen in the brain and heart.

Respiratory failure or muscle lactate production, or a combination of these may induce acidosis. Any acidosis from sustained muscle contraction will at first be localized to muscle, and would affect systemic pH only if lactate production were prolonged and massive, such as might occur with stimulus durations much greater than the 5 seconds (even without impaired respiration). When acidosis becomes severe, confusion, irritability, or lethargy can occur, followed by syncope (fainting), and if unresolved can be fatal. However, the treatment of acidosis is restoration of gas exchange and cessation of the muscle contraction. Only in severely affected people would support of tissue perfusion be necessary. In a subject who is able to breathe, lactic acidemia stemming from the EMI would be temporary and self-correcting once the muscles are released from spasm. Unconventional use of EMI-type devices that may result in longer duration exposure, may lead to acute respiratory impairment and failure as described above. However, the normal operating conditions for the TASER do not include a stimulus duration longer than 5 seconds without deliberate operator action, so this effect is not in the quantitative effectiveness and risk characterization. Future research will be needed to address longer duration exposures.

3.3.2.8.2 Rhabdomyolysis

Damage to muscle fibers resulting in release of their cellular content into the circulation is known as rhabdomyolysis. Etiologies are many and include direct muscle trauma such as in crush injuries; toxic muscle injury such as in alcohol abuse; and imbalance between energy production and consumption in muscles such as those induced by strenuous physical exercise, struggling against restraints, and drug-induced states of sustained muscle contraction (neuroleptic malignant syndrome and malignant hyperthermia). Accompanying pathologic events in rhabdomyolysis include hyperkalemia due to release of intracellular potassium and cardiac arrhythmia, acute renal injury due to myoglobin breakdown products, and lactic acidosis.

A search of the medical literature did not identify studies that provide quantitative estimates of the degree of muscle exertion required to damage muscle. Ordog et al. (1987) reported that 1% of the subjects subdued by a Tasertron TE-76 in his series had mild rhabdomyolysis, but it was not clear if it was caused by the Tasertron event or the PCP abuse that prompted control by authorities in the first place. It is unlikely that significant rhabdomyolysis would occur due to short duration muscle contractions initiated by EMI device output. However, it is not known if persons with other risk factors for muscle injury such as PCP intoxication, alcoholic myopathy, depleted muscle glycogen or hereditary myopathies would be at more risk for rhabdomyolysis following EMI stimulation. If the deploying force is removed from the loop and the EMI is used to control the behavior of the target for long periods, especially in hot humid environments, it is possible for significant rhabdomyolysis to occur.

Because the normal operating conditions for the TASER do not include impulse train duration longer than 5 seconds without operator input, this effect is not in the quantitative effectiveness and risk assessment.

3.3.2.8.3 Nervous System Effects

Several central nervous system (CNS) effects have stimulatory thresholds well below the output of the EMI devices. However, many of these such as jerky movements and hand or leg contraction are similar to the desired EMI effect and would not be considered an additional concern. There are other effects noted with electrical exposure of the brain. These include headaches and dizziness in humans, and reductions in the rate of learning of mice. These effects are seen with relatively low induced currents – much lower than that of EMI device waveforms, but take some prolonged experimental exposures before they are elicited (Reilly, 2003). More serious neurological effects (e.g., memory loss) are seen with high current exposures (e.g., as reported in lightning strike victims), and would have thresholds greater than that of a seizure.

3.3.2.9 *Seizures*

It is important to note that the muscle contractions associated with an EMI exposure are not a seizure[3]. A limited number of papers in the refereed literature, including both empirical evaluations and models, suggest that the EMI device output exceeds the seizure threshold. It is questionable whether a single dart located somewhere on the head and a second dart located somewhere else on the body could elicit a seizure. The number of head strikes with the M26 is small (<11), with only one case where two darts struck the head, and no seizures have been reported. The absence of seizures is not sufficient to conclude that they would not occur with a larger number of events.

The potential for seizure induction should be investigated further with analytic models (to predict the magnitude and distribution of current in the brain, and the theoretical dependence on waveform features) and controlled animal testing. Since the data are not adequate to determine with confidence whether a head strike with a TASER dart can induce a seizure, this HERC provides a discussion of the uncertainties and presents a sensitivity analysis by calculating the seizure risk, assuming either one- or two-dart hits can induce a seizure event (see Effectiveness and Risk Characterization section). Even if EMI can induce a seizure based on its electrical properties, the risk is likely to be low (SEV1) because the probability of head strikes in the relevant locations is small.

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[3] A seizure refers to uncontrolled spread of electrical activity through the brain that results in loss of normal consciousness and may or may not manifest in the body as abnormal motor activity. Approximately 10% of the population will have one or more seizures during their lifetime. Generally these seizures are self-limiting (i.e., the seizure stops spontaneously, without any treatment) and are not repeated. Seizures can be provoked, that is, caused by many diverse conditions including fever, acute metabolic processes, drugs, systemic illness, etc. Spontaneous recurrence of unprovoked seizures is the main symptom of epilepsy, which occurs in 1% to 3% of the population (Shnecker & Fountain, 2003). Hauser et al. (1990) reports that 33% of those that had an unprovoked seizure had a second seizure and 73% that had a second seizure, had a third. Similar percentages are seen in children (Shinnar et al., 2000). Kindling, which has been extensively studied in animals, is induced by periodic administration of sub-convulsive electrical or chemical stimuli continued until the seizure threshold is decreased and generalized seizures occur (Adamec, 2000).

3.3.2.9.1 Electroconvulsive Therapy

Another source of information that further evaluates the probability and effects of electrically-induced seizures is the literature on electroconvulsive therapy (ECT). The literature dealing with electroconvulsive shock therapy (ECT) does not contain any reference to seizures elicited by one electrode on the scalp or skull and another electrode on some other part of the body. Normally, therapeutic seizures are elicited by contralateral electrode placements (e.g., on opposite sides of the head at the level of the temples) or ipsilateral placements wherein both electrodes are on the same side of the head with one at the temple and one near the midline of the skull. Based on an evaluation of the TASER International database, dart strikes to the head with a single dart occur infrequently (approximately 3% of the time). Dart strikes with two darts to the head have occurred in only one of the documented 1,502 field cases reported in the TASER International database (see Appendix B for discussion of the mining of this database).

Until recently, most therapeutic seizures were elicited using 30 or 60 Hz sine waves, which are not comparable to the current TASERs. However, newly developed ECT technology using brief (0.15 - 1 ms) square or rectangular pulses, where charge is a more useful measure than energy, may have greater relevance to EMI waveforms. Another difference between ECT and EMI stimulation that makes direct comparison uncertain is the surface area of the applied stimulus. However, although the TASER dart has a very small surface contact area as compared with normal ECT practice, the skull has a much lower conductivity to electric current compared with the overlying tissue. Consequently, the charge from a scalp electrode tends to diffuse to surrounding skin areas - creating a larger external area of stimulation on the scalp, than would be predicted based on the barb size itself. Based on this principle, the small dart size would itself not be a sufficient argument against the ability of the EMI to induce a seizure.

The mortality rate associated with ECT is reported to be about 3-4 deaths per 100,000 treatments, or per 10,000 treated patients (Abrams, 1988). About two-thirds of these deaths were cardiovascular in nature. These fatalities are kept to such low numbers due to the routine administration of drugs prior to ECT to prevent such events. It is unclear what the mortality rate would be without such prophylactic measures, or for subjects under the influence of certain drugs. Furthermore, it is not clear whether these cardiovascular events were due to an electrical effect, were secondary to the effects of muscle relaxants normally administered during the procedure, or had some other etiology. Other effects of concern such as tongue bites secondary to the seizure effect have been reported during ECT. The evaluation process for this report did not investigate the potentially serious (albeit low-probability) sequelae that might occur if a EMI-induced grand mal seizure were indeed possible.

ECT-induced seizure has also been associated with memory loss or cognitive impairment, though it now appears such effects are largely transitory (Reisner, 2003). Despite some patient claims of long-term memory loss (Carney & Geddes, 2003), empirical demonstration of persistent cognitive impairment from ECT (across a variety of dosages) was not documented in a single study over a 16-year span (Abrams, 2002).

Further, there is emerging evidence that cortisol hypersecretion (a common response to physiological and psychological stress) may mediate the ECT-memory loss relationship (Neylan et al, 2001). This is relevant given anecdotal comments about short-term memory interference by some trainees exposed to a TASER stimulus (those being trained on the use of TASERs are often offered the opportunity of being exposed to the TASER as part of the training). It is suggested that the stress response (esp. cortisol hypersecretion) in both artificial and real-world situations may be the actual source of any short-term and temporary memory impairment.

3.3.2.10 Cardiac Effects (Arrhythmias/Asystole)

There are only two studies in the refereed literature that deal with morbidity/mortality associated with pre-M26 TASER exposures (Kornblum & Reddy, 1991; Ordog et al., 1987), as discussed in detail below. Briefly, Ordog et al. reported that 38% of 218 patients in his series had an EKG and of these, 3 were in asystole (absence of contractions of the heart). They did not report any incidences of fibrillation. Kornblum and Reddy reported that of 16 deaths that came to autopsy, cardiac related events were the principle cause of death in 5. They reported that 4 had enlarged hearts and one had a mitral valve prolapse and a cardiac arrhythmia (not specifically identified). They did not indicate whether these patients had an EKG test performed and/or ventricular fibrillation or asystole. Roy and Podgorski (1989) found that when the output of a stun gun (NOVA XR-5000) was applied to the chest wall of an anesthetized swine, asystole was induced. Sherry et al., (2003a) reported that a single monopolar pulse[4] caused asystole in an anesthetized swine and normal rhythm could not be restored with appropriate defibrillation. Animal test data with the standard M26 and X26 (TASER International, personal communication, 2003) did not induce asystole, ventricular fibrillation or precursor arrhythmias.

Underwriters Laboratory (1988) and the International Electrotechnical Commission (1984) have published safety limits indicating the amount of current needed to induce ventricular fibrillation. These safety limits are not developed for application to waveform characteristics of the M26 or X26 TASER. Furthermore, neither of these safety limits discuss induction of asystole.

3.3.2.10.1 Controlled Animal Studies

Dose-response data have been collected in pigs using several protocols (Nerheim et al., 2003). A dose-response experiment was conducted in which 13 adult pigs weighing between 92 and 158 pounds were exposed to increasing TASER outputs, which were described as multiples of the normal operating electrical output (in microcoulombs) for a 5-second duration at a pulse rate of 19 pulses per second (pps). The X26 TASER pulses were administered across the thorax using electrode placements that would maximize cardiac effects. The electrical output was increased in

[4] The monopolar pulse was 75 amps for approximately .013 seconds. It is important to note this pulse was not delivered by the standard TASER barbs, but through four-inch square brass plate electrodes (Sherry et al., 2003c).

a stepwise fashion to determine VF thresholds. It is noteworthy that increasing the TASER output not only increased the total energy imparted, but also changed the shape of the electrical waveform. Changes in waveform can have an important impact on potential induction of effects and the implications of the waveform changes in the context of these experiments are explored in detail in the Dose-Response section.

No ventricular fibrillation events were observed in the animals at electrical output values up to 16-fold of the normal operating values of the M26; in fact, no changes in heart rate and blood pressure were noted. Electrical output 20-fold higher than the normal operating output induced ventricular fibrillation in 6 of 12 animals. Slowing the pulse rate by half doubled the electrical output per pulse required to induce fibrillation. The current X26 TASER design uses a 19 pps rate for 2 seconds, which falls to 15 pps for the remaining 3 seconds of the 5-second cycle. Therefore, at the lower terminal pulse rates, an even higher energy output would be required to reach the tentative VF threshold. This level would need to be well above those values cited in the VF experiments. These data identify a Lowest Observed Adverse Effect Level (LOAEL), or in this case the Effective Dose for a 50% response (ED50) of 20-fold the normal TASER electrical output, with a No Observed Adverse Effect Level (NOAEL) of 16-fold in pigs for the X26 TASER.

In a second series of experiments under the same protocol, Nerheim et al. exposed 10 adult pigs (body weights ranged from 66 to 258 pounds) to step-wise increases in electrical outputs of the X26 TASER waveform to identify VF thresholds for each test animal. Individual animal VF thresholds ranged from 15-fold to 42-fold normal TASER output. The variation in the margin of safety was related to body weight with larger animals clearly less sensitive to the externally applied TASER stimulus. These experiments did not evaluate sensitivity based on other anatomical measures (e.g., body fat, skin thickness, distance from the skin surface to the heart, heart size, etc.). Therefore, the relative importance of body weight, as opposed to some other correlate to body weight, is unclear from these experiments. The Dose-Response section discusses this issue in detail. Nerheim et al. (2003) reported that decreases in TASER pulse rate significantly increased the observed margin of safety.

Several experiments directly stimulating cardiac tissue with TASER output showed no effect even in the presence of sympathomimetic drugs that sensitize the heart to arrhythmia. Dr. R. A. Stratbucker (Omaha, NE) (personal communication, 2000), a consultant for TASER International, performed a safety test of the Air TASER Model 34000. The output of the power supply was coupled to electrodes attached to an 18.2 kg Hampshire shoat (young pig) that was pre-medicated with atropine (0.02 mg/kg, intra-muscularly or IM) and sedated with Ketamine (10 mg/kg) mixed with Xylazine (2.01 mg/kg) and given IM. The animal was stimulated with output electrodes on the left hindquarter to determine the skeletal muscle response and on the anterior abdomen at the umbilicus to determine the mid-abdominal response. Electrodes were also placed in both the vertical and transverse orientation at the level of the cardiac apex to determine if stimulation caused a change in cardiac rhythm, which was detected by a battery-powered cardiograph. Each stimulus was 5 seconds in duration. There were no ectopic heartbeats and no evidence of myocardial injury. Respiration was briefly arrested during some chest discharges, but returned spontaneously at cessation of stimulation. In all cases, both respiration and heart rate returned to normal within a few minutes.

Dr. Stratbucker and Dr. W. McDaniel of the Division of Cardiothoracic Surgery, University of Missouri (personal communication, 2000), describe a series of tests to determine if external application of the TASER devices could cause ventricular fibrillation in canines. They report that 16 discharges of the Air TASER and 192 discharges of the Advanced TASER (M26 Test Model) through electrodes in multiple configurations resulted in no episodes of ventricular fibrillation. In 3 dogs, they implanted a pair of separated 20-gauge spinal needles through the chest wall to a depth of 2-3 cm so that the sharpened points just contacted the surface of the beating heart. They stimulated these electrodes with the Advanced TASER and did not find any evidence of ventricular fibrillation with 13 stimulations. They gave their subjects sympathomimetic drugs (epinephrine and isoproterenol: doses or route not given) and found that no combination of drugs or doses was associated with induction of ventricular fibrillation. They gave one animal toxic levels of Ketamine (no dose or route reported), which is a close chemical relative of phencyclidine (PCP or angel dust) because PCP toxicity has also been found in a number of deaths in which the subject was subdued by TASER. They reported "no untoward cardiac effects" with repeated external applications of the output of the Advanced TASER. Dr. Stratbucker did not report whether stimulation with TASER-like impulses, either external or internal, caused any other type of alterations in cardiac activity.

Data from an unpublished study (Mark Johnson, TASER International, personal communication, 2003) on the effect of acidosis on cardiac responses to the TASER was provided at the July 2003 workshop. It was reported that application of the M26 TASER to the chest wall or directly on cardiac tissue of presumably acidotic sheep caused no induction of VF (Johnson, 2003).

Data were collected under controlled conditions in an animal-based, safety-related experiment. Roy and Podgorski (1989) used a stun gun (NOVA XR-5000) with high voltage (> 100 kV), short duration (<20 microsecond), pulse output and current limited to less than 3.8 A. Stun gun output applied directly to the chest wall of an anesthetized pig caused asystole. Cardiac effects were reported only for the stun device with the highest electrical output, which exceeded the electrical output of either M26 or X26 TASER devices, and therefore, these results are not inconsistent with the absence of VF induction by M26 or X26 TASERs in field use or in controlled animal studies in pigs and dogs at the normal operation electrical output.

3.3.2.10.2 Human Case Reports and Field Use Data

There is no systematic way to determine morbidity and mortality associated with the use of EMI devices. Information sources are confined to refereed journals and reports in the media. The peer-reviewed open literature contains very limited objective scientific research data on the mechanism of action, efficacy, safety, and acute and long-term effects of these devices. Most reports in the refereed literature deal with post-exposure clinical evaluations or reviews. Only two studies address morbidity associated with EMI devices. Lexis-Nexus and Dialog databases contain several hundred articles on EMI devices in the popular literature such as newspapers and magazines. These deal primarily with issues other than health effects. Both TASER manufacturers have produced studies and databases that are compiled from their websites or other forums. These various sources of information as well as informed expert opinion were considered in identifying the health effects of EMI devices. A comprehensive bibliography of information reviewed for this assessment is provided.

The few published reports on the safety of the TASER address earlier TASER designs that have significantly different electrical waveforms than the M26 and X26 TASERs that are the subject of this report. Ordog et al. (1987) reported the results of all people (n = 218) who were evaluated at the King/Drew Medical Center in Los Angeles after being subdued with a TASER between July 1980 and December 1985. The mean age for the sample was 28 ± 4.8 years (range 15-48). The majority (86%) of the subjects had a history of PCP abuse and 95% were male. The number of darts per individual averaged 2.3 and they were found in anterior chest (4%), posterior chest (39%), scrotum (0.5%), upper limb (6%), gluteus maximus (12%), scalp (2%), anterior abdomen (12.5%), face (1%), and lower limb (23%). The average subject blood pressure was 120/80 mm Hg with an average heart rate of 96 ± 21 beats/min. The exposed patients spent an average of 6.5 hours in the emergency room. Three subjects were admitted in asystole and died; cardiac arrest in these 3 subjects occurred 5, 15, and 25 minutes after the TASER event. High levels of PCP were found in postmortem serum (0.156-0.43 μg/mL in each of 3 deaths); the darts were in the thigh, buttocks, or back. The dart locations associated with these deaths strongly suggest that electrical stimulation was not the cause of cardiac arrest.

Kornblum and Reddy (1991) reported the autopsy findings on 16 young males (20-40 years and of 3 ethnicities) whose deaths occurred in circumstances involving use of a TASER by law enforcement officers in Los Angeles County between 1983 and 1987. However, it must be noted that the TASERs used in this time frame are very different from the M26 in general use today and generally cited in this report. As mentioned before, the X26 utilizes a different waveform and less power than the M26. Without behavioral testing, the X26 is believed to be even more effective than the M26, yet with a higher safety margin. Each person in the Kornblum and Reddy sample was exhibiting bizarre behavior or unusual activity. Cocaine, PCP, or amphetamine were found in 13 of the 16 cases. One to eight TASER dart wounds were found on each body. Kornblum and Reddy (1991) concluded that none of the deaths were caused by the TASER. The deputy medical examiner, assigned to Case 6 of this series, later publicly disputed their conclusion, finding instead that the TASER was a significant factor in the death of Case 6. He further asserted that pathologists in Los Angeles were under pressure from law enforcement officials to exclude the TASER as the cause of death (Allen, 1992).

There are several points that argue against any independent role of the TASER in deaths occurring during arrests. If the TASER stimuli were actually an independent and significant contributing factor to these deaths, then reports of deaths under similar circumstances would have likely appeared in all areas where the TASER was used by law enforcement. In the series cited above, death in each case was attributed to illicit drugs taken by the subjects prior to the TASER exposure. The medical literature reports numerous instances of death occurring during arrests of people under the influence of stimulant drugs no matter what means is used to subdue them. Death also occurs from such drug intoxication in benign environments, and therefore, the risk appears to lie primarily with the drug effect itself. Excessive use of powerful stimulants such as cocaine or amphetamine, or drugs such as PCP, destabilize the cardiovascular system as well as produce non-normative behavior. Agitation, resisting arrest, and fighting restraints may increase the risk. However, sudden death by malignant arrhythmia, heart attacks and strokes have occurred even in the post-arrest period when the individual has quieted (Ordog et al., 1987). It is not known whether avoiding use of the EMI device and substituting traditional physical force to subdue these drug-intoxicated subjects could have altered the occurrence of fatalities.

Contemporary medical opinion supports the view that the drug intoxication itself forms the underlying vulnerability. The very circumstance of bringing the individual under control, if difficult, prolonged, and resisted, may trigger a malignant event in the person made vulnerable by drug ingestion. It is very possible that use of a rapidly effective method to control and subdue such persons will lessen the period of struggle and reduce the risk of death or other serious events. In animal studies by Stratbucker and McDaniel (personal communication, 2000), described above, none of the test animals died because of being exposed to TASER stimulus, even in the presence of isoproterenol or epinephrine, which make the heart more sensitive to arrhythmia. However, intoxicating levels of cocaine, PCP, or amphetamines exhibit somewhat different pharmacological effects, and these were not tested in the animal models. Nevertheless, existing work supports the conclusion that the TASER is not likely to have been a significant factor in fatalities.

TASER International has assembled a database of more than 3,000 records of individual TASER deployments based on field reports submitted by local police departments. Of these records, slightly more than 2,000 report firing darts. Analysis of the location of dart strikes suggests that approximately 21% of these shots, or 400 incidents, would have resulted in current likely passing over the cardiac region. No cases of VF have been reported. Thousands (M26) and hundreds (X26) of police trainees have also been exposed, albeit in semi-controlled situations. These data show no instances of VF under field conditions, suggesting that the risk of this cardiac effect is very low.

3.3.2.11 *Comparison to Existing Standards*

Bernstein (Zylich, 1976) evaluated the safety of the original TASER for the U.S. Consumer Product Safety Commission. This evaluation was based on theoretical analysis, rather than on animal or human experimentation. Bernstein compared the output of the TASER to that obtained from an electric fence controller as described in the Underwriters Laboratories (UL) Standard For Safety Number 69, "Electric Fence Controller" (see also the Underwriters Laboratory Bulletin of Research #14). In addition, other electrical standards are available for the prevention of ventricular fibrillation, including those developed by The International Electrotechnical Commission (IEC, 1984) and Underwriters Laboratory (1988). Comparisons of the M26 and X26 TASER output to these published VF thresholds have been conducted by others. However, these comparisons are not appropriate since the underlying dose metric used in the development of these standards is not directly comparable to the TASER waveform, and such comparisons are outside of the intended use of the published standards. Based on these considerations, comparison of the TASER output to the existing VF thresholds noted above was not included in this HERC.

3.3.2.12 Effect of Extended Stimulus Periods or Repeated Stimuli on VF Risk

The effect of repeated EMI applications or EMI stimuli for extended periods has been less well characterized. There are some data from the general bioelectricity literature to suggest that VF thresholds decrease with greater stimulus durations (see references in Nerheim et al., 2003). Unpublished data developed by TASER International support this general principle for the TASER waveforms. In limited experiments, VF thresholds in pigs decreased from 20-fold to 8-fold above normal X26 TASER output as the stimulus duration increased from the standard 5-second period to 30 seconds. The general biomedical literature also suggests that fibrillation thresholds can decrease nearly to the level of the cardiac excitation threshold when subjected to a period of repeated stimulation below the VF threshold, but above the excitation threshold. It is not clear whether this phenomenon applies to the M26 or X26 TASER because in order for this to occur, the sensitizing stimulus must exceed the cardiac excitation threshold. Data for external use of the TASER do not suggest that this occurs since in the controlled dose-response studies in pigs, no change in heart rate or blood pressure was observed. Secondly, these data on the impact of repeated stimuli were developed for regularly spaced stimulations, rather than the rapid pulse waveforms that characterize the TASER.

Field uses of the TASER (primarily the M26) reported in the TASER International database and examples provided in TASER International's training materials (TASER International, personal communication, 2003) document that there have been cases where subjects have been exposed to multiple shots (multiple cartridges fired from the same TASER) or have been stimulated repeatedly in succession with no unintended effect. However, the TASER International database records do not allow a close examination of the frequency of such events, or specific details regarding the number of simultaneous stimuli or the temporal pattern of stimuli. The effect of multiple simultaneous exposures or sequential exposures needs additional evaluation.

3.3.2.13 Cancer

Data were not identified that sufficiently evaluated whether EMI exposures can cause cancer. The potential for EMI pulses (or related electrical exposures) to induce direct DNA damage has not been well explored. However, any concern for cancer responses for EMI would seem unlikely given the short-term and episodic nature of the exposures, particularly in the absence of evidence that these pulses are mutagenic. This exposure situation is much different from the concerns (still controversial in the scientific literature) that have been raised with other common electrical devices such as cellular telephones, where frequent and long-duration exposures occur.

3.4 Other Effects

3.4.1 Fall Related Injuries

The Web-Based Injury Statistics Query and Reporting System (WISCARS) database of the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention (CDC) report that the number of unintentional nonfatal fall injuries occur at a rate of 2,641 per 100,000 and the number of unintentional fatal fall injuries occur at a rate of 4.84 per 100,000. The CDC report uses original data from the national injury surveillance system of the Consumer Product Safety Commission. Their coding manual advises that reporting hospitals should exclude falls that are identified as related to some sort of consumer product like a ladder or chair, or a handrail. Examples of incidents to include in the database are accidents where no consumer product is involved such as "fell to the ground," "fell on concrete sidewalk," and "fell on curb." In light of this, the data in the surveillance system, and therefore the CDC summaries, are likely biased away from uncomplicated falls to the ground.

Individuals older than 65 years are most likely to experience an unintentional fall as a consequence of seizure, syncope (fainting), dizziness, as well as simple loss of balance. It is reasonable to conclude that a serious nonfatal fall could cause a fracture (e.g., skull, nasal bones, clavicle, and proximal humerus), dislocation (e.g., shoulder) or laceration requiring a suture, while a non-serious nonfatal fall could cause a soft tissue injury.

It is reasonable to assume that fall injuries can occur because of EMI-induced brief spasms of postural muscles, although published data providing incidence rates were not identified. The TASER International database contains four anecdotal reports of fall injuries of moderate severity (2 wrist fractures, a shoulder dislocation, and a concussion) in approximately 3,500 deployment reports (TASER International, personal communication, 2003). As discussed in Appendix B, the number of deployments where a TASER was fired is approximately 2,000 cases. Of these 2,000 cases, it is estimated that a complete EMD would have occurred in approximately 80% of the cases. This roughly suggests a 1:500 rate of injury for the 1,600 uses where a complete EMD occurred. Due to uncertainties in the underlying data as discussed in Appendix B, subject matter experts with experience in law enforcement agencies that deploy TASERs were asked by *TERA* to provide an estimate of fall injury rates for individuals who were hit with the TASER. Their estimates were consistent with fall injuries being relatively uncommon, and supported the use of a fall injury rate of 1:500 for the Risk Characterization.

Since falls to the ground are considered a directly foreseeable consequence of EMI device use and may result in SEV2 injuries (perhaps SEV3 in vulnerable individuals), this effect is evaluated in the quantitative effectiveness and risk characterization.

3.4.2 Laser-Related Eye Injury

The handheld M26 and X26 TASER employs a Class 2 650nm laser site to assist in aiming of the darts. The device which has been manufactured in accordance with published laser safety standards (ANSI 136.1, 1993) and based on the laser classification would not be expected to cause eye injury from incidental or short-duration exposures. Therefore, use of the handheld EMD device according to the Concept of Employment (COE) would not be expected to cause laser eye injuries.

3.4.3 Noise-Related Injuries

Firing of the handheld TASER results in a short-duration report. No data on the sound pressure level associated with this event was identified. Input from subject matter experts who have fired thousands of TASER rounds suggests that the noise is well below impulse noise standards protective of hearing. Therefore, limited uses of the TASER appear to pose no auditory risk.

3.4.4 Interactions With Other Non-lethal Weapons

Ordog et al. (1987) and Kornblum and Reddy (1991) reported fatalities that occurred because individuals were physiologically compromised by stimulant drugs when exposed to TASERs. It is conceivable that individuals similarly compromised by other means would also be at increased risk from active capture and restraint maneuvers. Data on other nonlethal weapon technologies do not exist regarding such interactions with EMI devices.

3.4.5 Flammability/Explosives

If the TASER dart does not contact the skin, but is in close proximity to it (approx. 1.5 inch), the current will arc from the tip of the dart needle to the skin. This arc can ignite flammable and explosive materials. Informal experiments on a mannequin in street clothes where typical riot control agents are dispersed in various solvents have been shown to be ignitable by the current arc. Furthermore, EMI devices used on belligerents carrying flammable or explosive materials would be a risk of concern. It is important to note that aerosolized alcohol-based OC has been shown to ignite if application is concomitant with an EMI device. This effect is not included in the quantitative effectiveness and risk characterization because it is a secondary effect.

3.4.6 Drive Stun Injuries

The TASER International Instructor Certification Course, Advanced TASER M26, Version 10.0, Released June 2003, indicates that the M26 can function in a stun mode if no live cartridge is present. TASER International recommended that the operator remove the cartridge and drive the weapon aggressively against the subject for best results. In this mode, the M26 becomes a self-contained compliance device, which can serve to complete the circuit if one TASER dart misses the target or cannot penetrate air gaps. Training recommends driving the TASER into the carotid/brachial area, the groin (pelvic triangle), or onto the common peroneal nerve on the postero-lateral aspect of the knee. Potential unintended effects of this practice due to the direct forceful trauma might be anticipated, although no reports of adverse effects were identified in existing literature or case reports. Drive stun injuries have not been included in the quantitative effectiveness and risk characterization. This should be further investigated in future efforts.

The carotid artery sinus contains baroreceptors, which help control heart rate and blood pressure. Pressure on the neck in this area could induce reflex cardiac slowing. This maneuver is used therapeutically to abolish certain supraventricular tachycardias. However, symptomatic (fainting) bradycardia or sinus arrest may occur in individuals with preexisting cardioinhibitory syncope. Massage over diseased arteries may dislodge calcified plaque and result in stroke. It is unlikely that EMI energy could temporarily or permanently alter the chemoreceptors or baroreceptors. Blunt trauma to the neck, such as from blows or hyperextension during physical combat, could seriously damage the blood vessels. Since this is related to the circumstance of physical contact and not the TASER stun mode *per se*, it is not further considered.

Driving the TASER against the groin area could injure the male genitals or gonads. In a single anecdotal report, testicular torsion developed following TASER use; thus, some small risk of this may be present. It can be speculated that discharge of an EMI device energy so near to the gonads could alter the production of hormones or sperm, but no information exists to support this speculation.

The common peroneal nerve becomes superficial and, therefore, more vulnerable to trauma at the postero-lateral knee where it wraps around the head of the fibula. If driving or firing the EMI device near the common peroneal nerve damages the nerve, symptoms might include decreased sensation and paresthesia on the top of the foot, as well as weakness of the ankle and foot. Based on these considerations, peroneal nerve damage is an effect of low concern, and is not considered further in the quantitative risk characterization.

3.5 Summary of Effects Identification

The intended effect of the TASER is electromuscular disruption (EMD). During EMD, the individual experiences tetany and is temporarily incapacitated. A fall (an unintended effect) can create a wide range of effects from a skin laceration or bruise to a bone fracture or concussion. Additional unintended effects evaluated in this report include ocular injury by dart penetration, as well as seizures and ventricular fibrillation induced by the electrical current. Many other unintended effects were considered in this evaluation, but were found to have a low health consequence or low probability of occurrence and were not evaluated in the Dose Response or Exposure Assessment sections of this report.

Table 4 lists the identified effects evaluated through the HERC process.

Table 4. Effects of Concern Evaluated in the HERC

Effects	Severity Level	Comments
Intended Effects		
Electrical Effects		
Electromuscular Incapacitation (EMI)	1	Intended effect
Unintended Effects		
Dart-related effects		
Ocular Injury	2-3	Risk based on probability of eye strike
Electrical Effects		
Seizure	1	Included in quantitative assessment based on probability of head strike and threshold data for seizures
Ventricular fibrillation	3	Included in quantitative assessment based on animal dose-response data
Other Effects		
Fall injuries (laceration, fracture, chipped teeth, concussion, etc.)	1-3	Included in quantitative assessment based on incidence data from field reports

Table 5 lists the identified effects that are not evaluated through the HERC process due to a low level of concern based on either very low probability of occurrence, very low health consequence, or lack of data.

Table 5. Identified Effects with a Low Level of Concern.

Unintended Effects	Severity Level	Comments
Dart-related effects		
Blunt trauma	1	Very low health consequence
Skin penetration	1	Very low health consequence
Skin burns	1	Very low health consequence
Blood vessel injury	1-2	Very low health consequence
Testicle Injury	1-2	Very low health consequence
Electrical Effects		
Discomfort	1	Very low health consequence
Changes in blood pressure or heart rate	1	Very low probability
Peripheral nerve injury	1-2	Very low probability
Mechanical muscle injury	1	Very low health consequence
Bone fracture	2	Very low probability
Seizure	1	Very low probability
Fetal development	3	Very low probability
Spontaneous abortion	3	Very low probability
Acute respiratory impairment & failure	2-3	Very low probability
Rhabdomyolysis	1-3	Very low probability
Cancer	3	Very low probability
Other Effects		
Laser-related eye injury	1	Very low probablity
Noise-related Injuries	1	Very low probability
Implanted devices (pacemakers, defibrillators)	1	Very low probability
Interactions with other NLW		Considered a secondary effect (not evaluated)
Flammability/Explosions		Considered a secondary effect (not evaluated)
Drive Stun Effects		
Testicular torsion	1-2	Very low probability

4 DOSE-RESPONSE ASSESSMENT

The second phase in the HERC framework is the dose-response assessment. The dose-response assessment refers to the process of evaluating information on the magnitude or intensity of electrical dose required to produce the physiological effect(s) or the resultant behavioral response of interest. As described above, only five effects were of sufficient concern and had adequate data to include in a quantitative dose response assessment. These effects include electromuscular incapacitation (the intended effect (SEV1)), and four potentially severe unintended effects (ocular injury (SEV2-3), seizures (SEV1), ventricular fibrillation (SEV3), and fall injuries (SEV1-3)).

4.1 Electromuscular Incapacitation (EMI)

Electromuscular Incapacitation (EMI) is the intended effect for this weapon system. The available data (human experience, animal studies, as well as comparison to biological let-go thresholds) all suggest that when an electrical circuit is completed, muscle contraction will occur in all individuals. This does not mean that every shot from an EMI device will be effective. Some fraction of shots will hit the target in ways that fail to establish a circuit, and other shots that do establish a circuit may result in partial EMI. As an alternative to making the simplifying assumption that all or a fixed percentage of dart strikes induce the intended effect, the TASER International database of field reports was analyzed to derive estimates of the probability of establishing a circuit (see the Exposure Assessment, Section 5), and the probability of the circuit being effective in incapacitating the target fully or partially (see the Effectiveness and Risk Characterization, Section 6). Effectiveness may occur without the occurrence of EMD because of psychological factors (e.g., target complies when they become aware that they have been targeted by a TASER or other EMI device).

4.2 Ocular Injury

No dose-response data were available to calculate the probability of eye effects of a given severity with exposure parameters such as distance. Rather, the simplifying assumption for this assessment was made that any strike to the eye would be considered a moderate to severe unintended effect (SEV2 or SEV3). While not contained within the TI database, there is one known case of permanent vision impairment as a result of a dart strike to the ocular region (Dave Dubay, personal communication, 2004). Since dart removal following eye penetration would require medical treatment, this categorization approach is consistent with the severity grading that has been developed for the risk characterization of other non-lethal technologies assessed for the HECOE. Based on these simplifying assumptions, the risk characterization approach for ocular injury is a direct function of the probability that an eye strike will occur. The Exposure section will discuss the estimation of these probabilities.

4.3 Seizures

A limited number of papers in open publications suggest that the EMI device output exceeds the seizure threshold. Data from the TASER International database indicate that head strikes occurred less than 11 times in 1,502 shots or 0.7% of shots resulting in two dart strikes. The TASER International database does not report an instance of seizure, although the number of potential cases (based on head strikes) is very small. In order for a seizure to potentially occur, at least one dart strike must hit the skull. Induction of seizures has not been tested empirically for the M26 or X26 TASERs. Experimental approaches (e.g., targeted animal testing, use of seizure-prone animals or animals with pharmacologically-reduced seizure thresholds) and use of impedance models could be useful to determine with greater confidence the ability of an EMI exposure to induce a seizure. In the event the EMI did result in a seizure, it would not be expected to have any long lasting neurological effects, hence a categorization of SEV1.

4.4 Ventricular Fibrillation (VF)

To determine ventricular fibrillation (VF) risk, TASER International has developed dose-response data for the X26 waveform utilizing modified X26 capabilities to exceed the output of the standard X26 by up to 48 fold. A regression fit to these data establishes a relationship between VF threshold in pigs and body weight (Figure 3). In this figure, the black dots are the X26 data plotted as a multiple of electrical currents relative to the unmodified standard X26 TASER, which is required to induce ventricular fibrillation; the horizontal axis is the body weight. For example, for the pig that weighed 66 pounds, it took 15 times as much current as the normal X26 TASER output to induce VF. The thick solid black curve represents predicted median responses for the pig VF thresholds, and the thin black curve represents the estimated 95^{th} (upper) and 5^{th} (lower) percentiles (confidence levels) of the response in pigs. Polynomial, log-transformed, or power models did not significantly improve the fit of the regression. Since the linear fit was adequate over the range of body weights evaluated, this simpler equation was used, although other mathematical relationships such as the power curve would be appropriate for extrapolating to the extremely low or high body weights.

The fifth percentile on the predicted pig VF threshold curve was considered as the most appropriate basis for further extrapolating VF risk in humans, consistent with dose-response assessment practice in environmental risk assessment. VF is considered a SEV3.

VF Threshold versus Body Weight

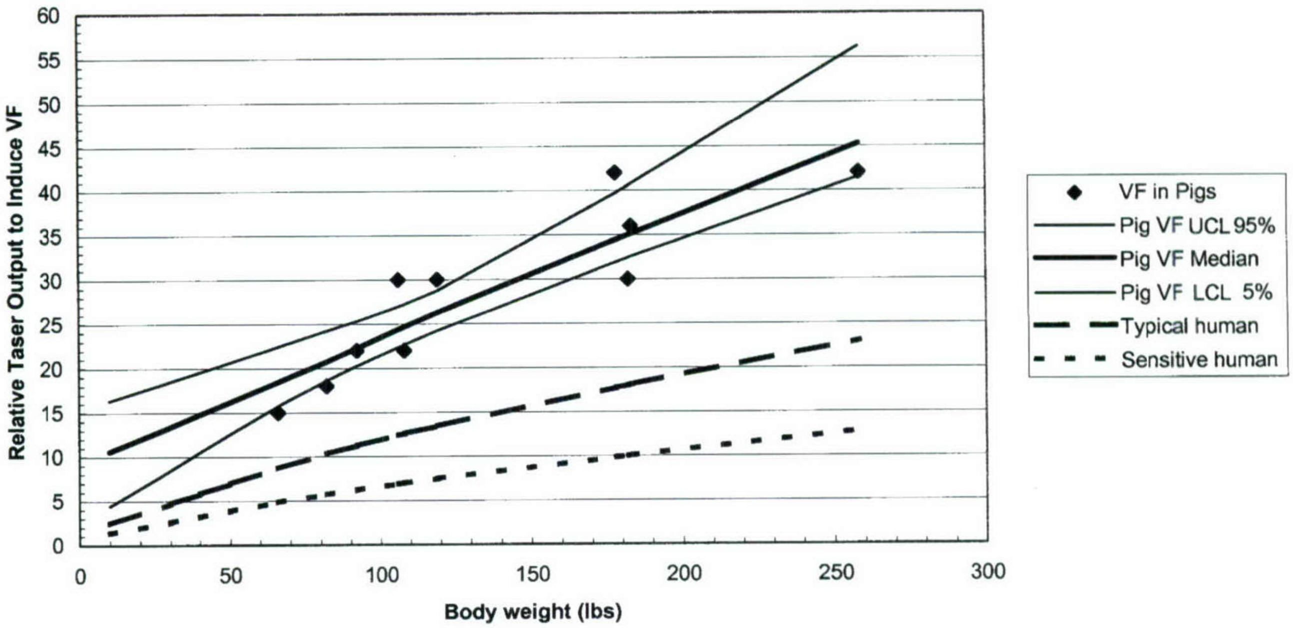

Figure 3. Relationship Between VF Threshold in Pigs and Body Weight

This dose-response approach of using relative TASER output for the X26 as the dose metric was judged reasonable for assessing cardiac effects. The waveform for the X26 high output test (48x the normal X26 output) is reasonably similar to its normal TASER output and pulse duration (the duration increased as a function of relative TASER output). Nevertheless, the TASER pulse remained sufficiently short to be within the integration time for cardiac effects. Note that the same type of direct use of the relative output data would not be appropriate for effects of neuromuscular excitation (e.g., the intended EMI effect); due to the shorter critical integration time for this type of tissue stimulation, relative efficacy on the stimulation of muscle contractions would not increase linearly with increased TASER output.

Based on waveform tracings provided by TASER International, the X26 waveform is relatively insensitive to environmental scenarios (different resistance loads, ground conditions, presence of air gaps), although some quantifiable changes do occur. As compared to the scenario used for the cardiac safety testing used to derive the dose-response, these alternative conditions reduced the total charge per pulse, and therefore, would likely be less apt to induce cardiac effects. On the other hand, reductions in efficacy may also occur for some conditions (e.g., arcing to dry ground) where the reduction in delivered charge is substantial. These conclusions cannot be extrapolated directly to the M26, since the M26 waveform is very different in character from the X26 waveform.

Qualitative estimation of charge in the positive phase for the waveforms suggest that the X26 exceeds the M26 by roughly 30%, even though it has much smaller peak amplitude. Based on these data, it is hypothesized that the X26 would be more effective at inducing an EMI, and have a higher probability of cardiac excitation. The former assertion is borne out by TASER International test data with pigs, in which they found stronger muscle reactions with the X26 as compared with the M26. Although no dose-response data were available for the M26 TASER, based on estimated charge in the positive phase, one would expect the X26 to have a greater potential for exciting the heart. This expectation needs to be examined experimentally.

To be pertinent to this study, the animal data in Figure 3 must be related to human thresholds. Extrapolation of adverse reaction data from animals to humans has parallels in other disciplines. For instance, in toxicology risk assessment, it is customary to apply a conservative factor of one-tenth dose (i.e., an uncertainty factor of 10) to extrapolate from animals to humans if no data exist on the relative sensitivity between the two species. If data on the interspecies relationships do exist, then other extrapolation factors are common. Because the data are somewhat uncertain, these adjustments are usually made in half-log increments. The usual factor of 10 is applied in the absence of any agent-specific data. When a dosimetry adjustment based on a measurable physiological parameter is available (body weight in this case), a factor of 3 ($10^{0.5}$) is often used. When additional evidence suggests that humans and animals have similar susceptibility, the factor may be reduced by another half log, resulting in a factor of 1.8 ($10^{0.25}$). This approach was used since there are several reasons (described below) to conclude that humans are no more responsive than pigs, which were used in the experiments to derive the dose-response.

For the data in Figure 3, values from the estimated 5th percentile were divided by a factor of 1.8 to estimate the human equivalent dose-response as shown by the large dashed curve in Figure 3. This line represents a VF response threshold for the average human with an appropriate animal-to-human safety factor. A factor of 1.8 ($10^{0.25}$) was used, rather than the default 10-fold factor that is often used in risk assessment in the absence of information to extrapolate from animal data to human data, for the following reasons:

- There is general agreement that the pig is a good model for assessing cardiac effects in humans due to relative size, function, and placement of the pig heart in the chest cavity (Reilly, 1998). Furthermore, pig's skin is often used as a model for human skin effects, which is important since skin impedance is a factor in response variability.

- Data for VF in animals, as well as many bioelectric effects in people suggest that body weight is the primary source of response variability and the dose-response already controls for this factor.

- Bioelectric response is a basic physiological response and would be expected to be subject to less interspecies variability than chemical toxicity, which uses a default factor of 3 after making dosimetry adjustments.

- Animal dose-response based on the fifth percentile of the pig VF threshold estimate is used for extrapolation - this increases likelihood that the selected factor of 1.8 is protective.

Estimating any individual's threshold, however, further requires accounting for inter-individual variability around this human equivalent dose-response curve (the small dashed curve in this figure). Thus, an additional factor of 1.8 (see discussion above for the basis for this approach in risk assessment) is used to predict the threshold response in a sensitive human. This factor was selected rather than the default 10-fold factor that is often used in risk assessment in the absence of data to extrapolate from average to sensitive humans, for the following reasons:

- The ratio of human median to first percentile response has been determined for a wide variety of bioelectric effects in healthy adults (male and female), including perception and let-go thresholds, skin impedances, etc. For adult male and female data, median to sensitive ratios fall within factors of 2.0 to 3.0 without adjusting for body weight for most bioelectric effects studies. One study of fibrillating currents in valve replacement patients found electrical sensitivity of the cardiac tissue was approximately a factor of 4 from the median to 5th percentile responder (Watson et al., 1973), but at least some variability was attributed to electrode placement and no data on subject body weight was available for our review. Other than this study, no published data on inter-individual variability in cardiac responses to electric stimuli were identified. Individual fibrillation thresholds are determined routinely in cardiology practice for fitting pacemakers; however, published summaries of these data were not identified. Furthermore, since the electrical devices used for this procedure are not the same as EMI devices, the resulting data would still be subject to uncertain application for estimating human variability to an EMI stimulus.

- The variation in human response to electrical effects has been found to correlate well with body weight in adults (the limited data for responses in children also support this relationship). A number of users have reported that highly obese individuals tend to be somewhat more resistant to the EMI effect. No specific data on the correlation of body weight and fibrillation thresholds in humans was identified. The contribution of body weight is accounted for directly in the dose-response assessment, suggesting it is appropriate to use a minimal factor for human variability. No specific VF data were identified for children and the dose-response curve extrapolates outside the range of the observed data for small body weights, which generates uncertainty in estimating human thresholds in this region. However, in small animals (e.g., cats and dogs) the VF threshold for 50 or 60 Hz currents is lower than for larger animals, consistent with the expected body weight relationship. Furthermore, linear extrapolation to low body weights in humans may be protective since some data suggest that smaller heart sizes (as in children) are less vulnerable to VF than larger hearts. Together these data suggest that the body weight adjustment would account for at least a portion of the possible differences in susceptibility in children. Furthermore, the normal operating TASER output has not been shown to induce VF in smaller animals such as sheep or dogs, or in pigs that have approximate weights of older children and adolescents. This is consistent with the dose-response predictions.

Some uncertainty in assessing the degree of human variability remains. The body weight adjustment does not account for all the variability in response to electrical effects. Furthermore, the relative importance of body weight as opposed to some other correlate to body weight is unclear from the available data. It is not known what specific anatomical features (e.g., body fat, skin thickness, distance from the skin surface to the heart, heart size, etc.) are responsible for changes in cardiac effects from the EMI. The degree of correlation among these various parameters in human populations was not evaluated in this analysis, since the critical predictors were unknown.

No specific data were identified for elderly populations or for comparison of sensitivity between healthy adults and individuals with underlying heart conditions or abnormalities in the physiologic environment within the body such as hypoxia, acidosis, electrolyte abnormalities, and cardiac-sensitizing medications or chemical exposure. In extremes of these conditions, the arrhythmogenic threshold can become so low that malignant arrhythmias including ventricular fibrillation can arise spontaneously. Animal data suggest that the normal operating TASER output does not induce VF in pigs given drugs that sensitize the heart, although this is a quite limited subset of all of the possible known variables.

The issue of whether individuals with implanted electrical devices, and in particular cardiac pacemakers, might be at risk due to failure of these devices during a TASER stimulus was considered. Since pacemakers are designed to withstand a shock from a defibrillator, it would seem unlikely that this would be a concern. However, TASER output is not identical to defibrillator outputs; accordingly, this issue needs to be empirically explored.

Based on this analysis, and assuming that the TASER dart hits and a circuit is established that crosses the heart, the VF threshold (relative to the X26 TASER output) can be calculated from the dose-response curves for normal persons without potentially sensitizing conditions and is shown in Figure 3. Predicted thresholds for typical (50^{th} percentile) and sensitive (5^{th} percentile) humans at a given body weight are provided in Table 6.

Table 6. Predicted Threshold for Ventricular Fibrillation Above Normal X26 TASER Output

Body Weight (pounds)	Predicted Threshold for Ventricular Fibrillation[a]	
	Typical human	Sensitive human
10	2.4	1.5
20	3.6	2.1
40	5.8	3.5
60	8.1	4.8
80	10	6.1
120	13	8.1
160	16	10
200	19	11
240	22	13
280	24	15

a. Values are calculated from the regression equations plotted in Figure 3. The value shown represents the fold increase in X26 TASER output (total electrical current) above normal operating output to exceed the VF threshold for typical or sensitive humans of a given body weight.

Based on these threshold estimates one would conclude that for large children and adults, even those who might be sensitive responders, the risk of inducing VF is very small, since a large margin of safety exists. For example, the VF threshold for a 40-pound child is expected to be 3.5 times greater than the normal X26 operating output to induce ventricular fibrillation, if the darts are placed on the chest above and below the heart. For very small children, however, where the margin is limited (e.g., approximately 1.5 times above normal output), the data are insufficient to conclude that there would be no VF risk.

In summary, due to assumptions made in selecting uncertainty factor adjustments and the absence of specific threshold information in young children, the elderly, individuals with underlying heart conditions, or individuals with concurrent drug use, it is not known whether there are highly sensitive individuals that could have a VF response at the intended EMI output. These results from the dose-response data are consistent with the existing field use data, in which no documented ventricular fibrillation event has occurred in any individual that has been exposed to a M26 or X26 TASER stimulus (in some cases repeatedly). This is the expected result for the population represented by the field experience (mostly adult healthy males).

4.5 Fall injuries

Fall injuries were considered relevant effects for the assessment. Sources of data for possible use in the quantitative dose response include medical literature for epileptics or the elderly, safety engineering literature, and sports medicine literature. Frequency data from the TASER International database suggested that 4 fall injuries of moderate (SEV2) severity have been reported in approximately 3500 documented deployments, approximately 1600 of which are estimated to have resulted in a complete EMD (and thus would be eligible for EMI-induced fall injury). The injuries observed included wrist fractures, joint dislocations, and concussions. These data are consistent with expert judgments from TASER users in the law enforcement community who were asked by *TERA* to estimate fall injury rates. Based on data mining from the TASER International database and input from several jurisdictions, 1 in 500 (0.2%) fall events are classified as a SEV2 effect resulting from TASER use and considered appropriate for the risk characterization.

4.6 Dose-Response Assessment Summary

Five endpoints were identified of sufficient concern and had adequate data to include in the quantitative dose response assessment. These effects include electromuscular incapacitation (the intended effect), and unintended effects (ocular injury, seizures, ventricular fibrillation, and fall injuries).

The available data on Electromuscular Incapacitation (EMI) were from human experience, animal studies, as well as comparison to biological let-go thresholds. These data all suggest that when an electrical circuit is completed, muscle contraction will occur. Based on these data, TASER output is assumed to exceed the muscle contraction threshold in all cases where a circuit is established. Whether an induced EMD is fully or partially effective in controlling the exposed subject, however, depends on the location and distribution of the current path. The impact of dart placement on effectiveness is estimated based on observations from experienced users of the TASER and was integrated with hit probabilities in the risk characterization step of the analysis.

No dose-response data are available to calculate the probability of eye effects of different severities. Thus, any strike to the eye is considered a moderate to severe unintended effect (SEV2 or SEV3). While not contained within the TI database, there is one known case of permanent vision impairment as a result of a dart strike to the ocular region (Dave Dubay, personal communication, 2004). The risk characterization approach for ocular injury is a direct function of the probability of an eye strike from firing the weapon.

Induction of seizures has not been tested experimentally for the M26 or X26 TASERs, although the TASER output is in the range of experimental seizure thresholds. A sensitivity analysis approach provides an upper bound estimate of seizure risk. Using this approach, any head strike that established a current path in the region of the brain is assumed to be sufficient to induce a seizure (i.e., exceed the seizure threshold). The hit probabilities for dart impacts in the head are used as the basis for the risk characterization of this effect.

A key effect of concern for which dose-response data are available is ventricular fibrillation (VF). Experimentally determined VF thresholds in pigs for differing TASER outputs are plotted against body weight. The resulting curve is extrapolated for use in assessing human dose-response with the use of uncertainty factors for experimental animal to human extrapolation and human variability. This analysis suggests that healthy adults and larger children would not be at significant risk of VF following exposure to the X26 TASER under normal operating conditions. However, due to assumptions made in selecting uncertainty factors and the absence of specific threshold information in young children, the elderly, individuals with underlying heart conditions, or individuals with concurrent drug use, it is not known whether there are highly sensitive individuals that could experience VF under normal EMI exposure conditions. The data are also limited with regard to extrapolating the results to the M26 TASER or future EMI waveforms, or for assessing the impact of different temporal patterns of exposure.

Published data on fall injuries rates are limited. However, TASER International field reports suggest that four moderately severe (SEV2) fall injuries have occurred in approximately 1600 or more deployments that resulted in a complete EMD. These data are consistent with expert judgments from TASER users in the law enforcement community. Based on the data and expert judgments, an injury rate of 1 in 500 (0.2%) fall events is used for the risk characterization.

Table 7 lists the identified effects evaluated in the dose-response assessment and the type of data used to evaluate them.

Table 7. Types of Data Used to Evaluate the Identified Effects

Effects	Type of Data
Intended Effect	
Electromuscular Incapacitation	Anecdotal data, animal studies, biological let-go thresholds, data from human volunteers
Unintended Effects	
Dart-related Effects	
Ocular Injury	Professional judgment, anecdotal data in humans
Electrical Effects	
Seizure	Anecdotal data and threshold data in humans
Ventricular Fibrillation	Dose-response data in experimental animals
Other Effects	
Fall Injuries	Professional judgment, medical literature, anecdotal data in humans

5 EXPOSURE ASSESSMENT

The third phase of the risk characterization framework is the exposure assessment. The goal of the exposure assessment is to define the interaction between EMI devices or technologies employing TASER-like payloads and the user, the target individual, and bystanders. The exposure assessment follows the Effects Identification and Dose Response sections since the exposure assessment must specify the information necessary to characterize the intended and unintended effects (defined in the Effects Identification section) using the dose metrics and the response information (defined in the Dose Response section).

In EMI devices, the mechanism inducing the intended effect is electrical excitation of nerve and muscle. These effects have a number of desirable characteristics as a basis for non-lethal weapons. First, the dose of electricity (delivered charge and current, frequency, and duration) largely depends on the electrical design of the weapon system.

Second, many environmental factors that affect other non-lethal systems have no effect on the delivered dose from the EMI device. For example, environmental factors such as wind, temperature, and precipitation do not affect the dose of electricity delivered since the electricity flows through insulated wires. The delivered charge is also independent of the distance between the target and the user (provided the individual is within the 21 ft range of the devices addressed in this report).

Third, when environmental factors affect the dose, they reduce rather than increase the intensity of the dose. This reduction can occur if materials outside of the individual's body conduct the current, such as through a ground connection. When the current passes through a ground connection (or some other partially conducting media), the dose is reduced rather than increased.

Fourth, the dose is limited to individuals who are in contact with one or both darts; this minimizes the risk to the user and to bystanders. The charge is delivered only to the individuals struck by one or both darts. The charge does not reach individuals who are only in contact with the struck individual (bystanders, hostages, or warfighters restraining the individuals). In order for others to be affected, they must be in contact with one or both darts, breaks in one or both of the wires, or they must compress both wires forcefully (TASER International, personal communication, 2003).

Fifth, equipment failure (damage or battery failure) is likely to reduce the dose rather than increase it. Because of these characteristics, EMI devices deliver an electrical charge with a well-defined upper bound of exposure.

The internal dose (i.e., electrical charge reaching specific organs) delivered by EMI devices is less well understood. The effective dose does vary depending on physiological characteristics of the target. As discussed in the Effects Identification section of this report, the intended and unintended effects associated with electrical effects are affected by the size of the individual and the location of darts on the individual's body.

The exposure assessment begins with the specific devices included in the assessment (the M26 and X26) and the uses of the devices. The use of a device is defined in terms of one or more concepts of employment (COE). The COE defines the following elements in the use of a non-lethal weapon (NLW):

- The nature of the user;
- The conditions under which the NLW is used;
- The target(s);
- The tactical goals for the use.

Based on the COE, factors are identified that determine the interaction of the target and the individual and allow the assessment of the weapons' effectiveness and the occurrence of unintended effects.

5.1 Concept of Employment (COE)

The COE for the use of the M26 and X26 handheld devices by DoD warfighters is expected to be similar to the historical use of the devices by law enforcement and correctional facility personnel except that the DoD may encounter child soldiers in some situations (see Section 6.5). The devices will be part of a force continuum for personnel to control the behavior of individuals or small groups of individuals while minimizing risks to bystanders or themselves. The number of devices used will be one per warfighter and can be used by one warfighter or by small groups of warfighters, each equipped with a device.

The devices will be used for close encounters where the distances will be less than 21 ft. According to law enforcement users and TASER International, purposes for using the device include:

- Distraction of individual(s);
- Rendering individual(s) incapable of performing an activity;
- Controlling individual(s) as a prisoner(s);
- Denying access to hostile crowds;
- Directing a crowd's movement (channelize or isolate a crowd); and
- Area Denial

The use of the TASER is described in the training provided by TASER International for law enforcement officials. It is assumed that similar training practices will be part of DoD use. Under this training, the user aims the TASER using the sights located on the top of the TASER or laser sighting. This aiming directs the location of the dart strike for the upper dart. The user is instructed to aim at the center of mass of the torso and to avoid the face. Preference is given to shooting at the back over the front of the torso.

The orientation of the grip of the TASER is held parallel to the body of the target individual. This is achieved by instructing the user to aim at the center of the torso and to keep the butt of the pistol grip pointed toward the buttocks of the target individual.

Since the user directs the top dart at the center of the chest or back, both darts should strike the target individual below the face and neck. This is done to minimize the potential for face and neck strikes. In addition, this targeting increases the likelihood of having both darts striking the person since the torso is a larger target than the head. Finally, it maximizes the effectiveness of the devices by increasing the chance that the current will pass over nerve-rich and muscle dense areas and result in complete EMD.

In this assessment, the intended targets for use of the handheld EMI device by DoD are assumed similar to the target population represented by current law enforcement applications (i.e., heavily weighted to males between the ages of 18 and 40). This assumption allows for the application of the exposure and risk data collected from law enforcement uses to warfighter applications. However, this assumption implies that the EMI devices are never used on small children (less than eight years of age) or the elderly. As a result, the exposure and risk characterization sections of this report do not explicitly consider exposures to very small children or the elderly. The implication of this assumption is discussed in Section 6.5 of this report.

5.2 Accuracy and Trajectory of Darts

The United Kingdom's Police Scientific Development Branch (PSDB) of the Home Office has evaluated the accuracy of the M26 (PSDB, 2002). The PSDB reported that in trials the location of the upper dart in the test was reported to be lower and to the left of the laser sight. This deviation increased with distance. A similar deviation occurred with the lower dart. Figure 4 presents the trajectory of the darts. These deviations are the result of the relatively low velocity of the darts and the influence of gravity on the darts' movements.

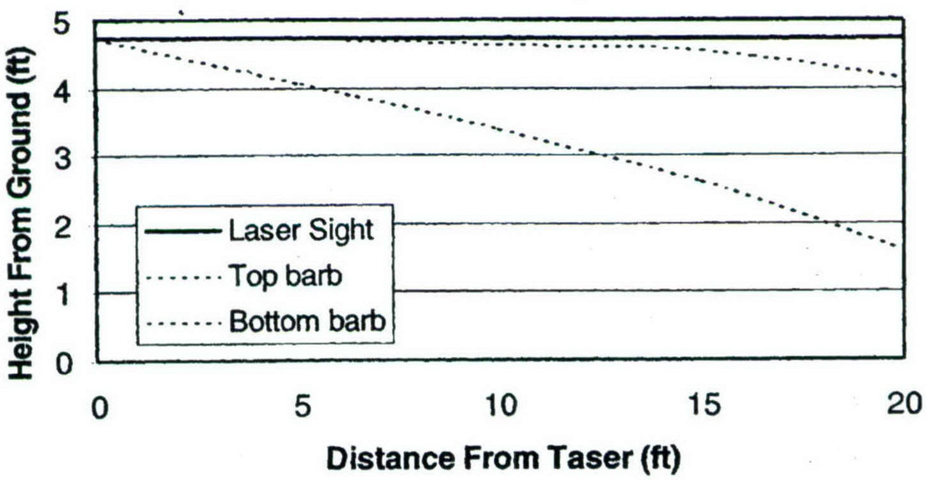

Figure 4. Trajectory of Standard Darts Fired from M26/X26 Cartridge (PSDB, 2002)

In the M26, the location of the lower dart is determined by the location of the top dart, the distance to the target individual, and the orientation of the grip of the weapon. The influence of distance occurs from the 8° angle between the darts. The four panels in Figure 5 present the scatter in the dart locations when the laser pointer is placed on aim point (0, 0), the grip orientation is vertical and the M26 is fired from various distances. Since the M26 is held in identical position for each shot, the data is a measure of the accuracy and precision of the device.

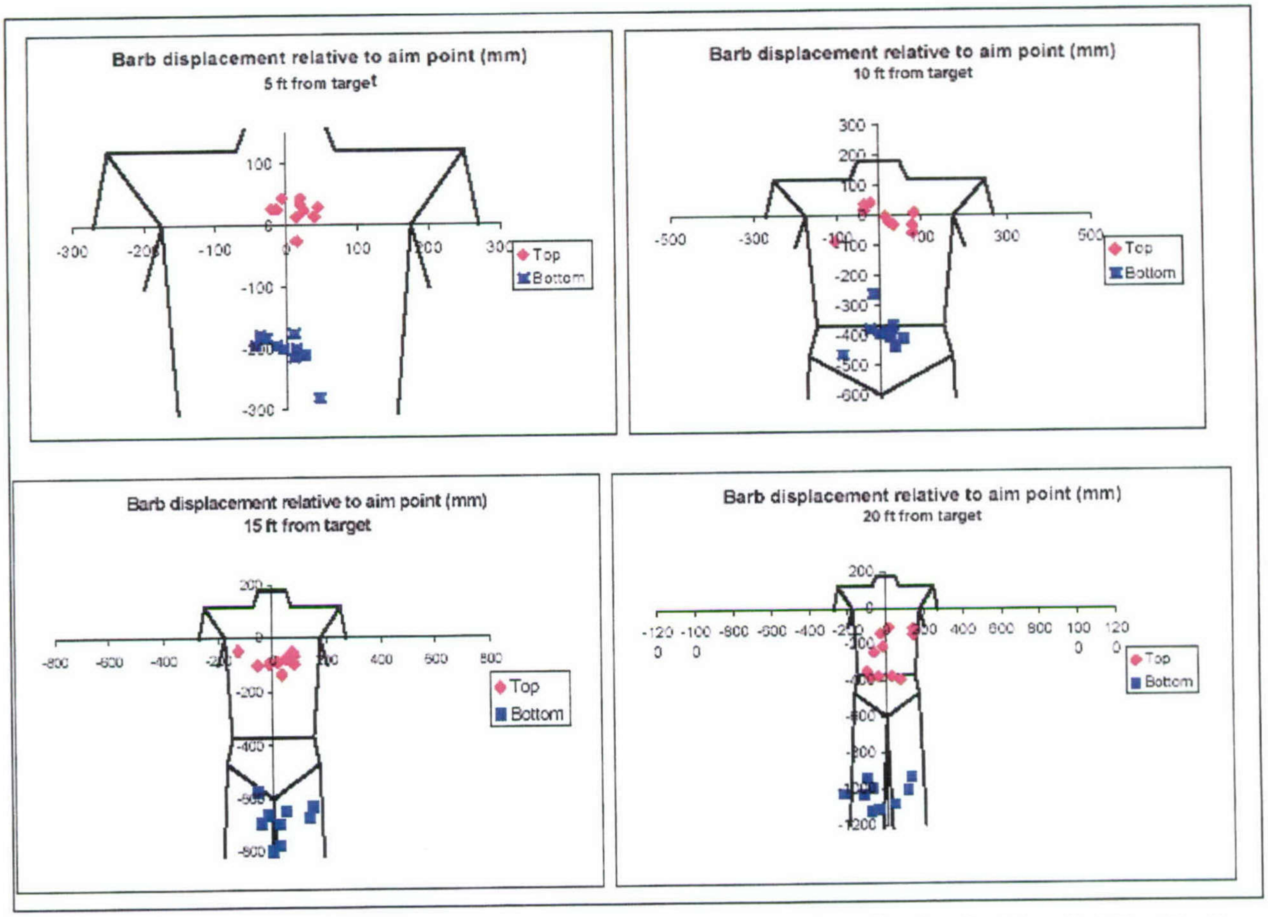

Figure 5. Accuracy of Dart (Barb) as a Function of Distance When Device is Aimed at the Center of the Chest (PSDB, 2002)

The orientation of the grip also plays an important role. If the grip is held in a line parallel to the orientation of the target individual, the second dart will strike the target individual immediately below the first dart. If the grip is not oriented parallel, then the lower dart will fall below and to the left or the right of the upper dart. If the orientation is sufficiently out of line, the lower dart may miss the target individual. The effect of grip orientation on the location of the lower dart will increase with distance.

As discussed in Appendix B and in the PSDB report (PSDB, 2002), the M26 can be easily aimed and users have the ability to place both darts on a target individual. However, it is less easy to do this when the target is distant, prone, or in profile. Individuals who are prone are more difficult to strike since the TASER must be held sideways. If a person turns in profile, the width of the target is decreased, which increases the number of misses for the darts. PSDB data for the M26 indicates the number of shots resulting in two dart hits decreased in prone and profile targets. In addition, head strikes are higher for prone targets (PSDB, 2002). This suggests that holding the devices sideways also affects the ability to aim the upper dart.

5.3 Effects Supported by the Exposure Assessment

An exposure assessment seeks to define the data necessary to determine when and if effects will occur as a result of the use of the device. Thus, the exposure assessment is determined by the effects associated with the EMI (see Table 5). As described in the Effects Identification section of this report, the effects for the EMI devices can be divided into three categories: dart-related, electrical, and fall-related effects. Dart-related effects are those effects associated with the penetration of the barb into an individual. These include minor effects such as lacerations of the skin or genitals and the more significant eye strikes. The electrical effects fall into two categories: the intended effect, EMI, and the unintended effects. Of the unintended effects, the potential induction of ventricular fibrillation is of primary investigative interest. Burns are categorized as a minor (SEV1) effect. Several other potential effects of exposure to the electrical output of the EMI device (e.g., fetal development, and effects associated with longer duration exposures) are evaluated qualitatively. Moderate to severe fall-related effects such as fractures, joint dislocations, and concussions are also considered.

5.4 Specific Exposure Assessments

5.4.1 Dart-Related Effects

The types of exposure information required to estimate dart effects are the location of dart strikes and the effect of clothing. There are two types of darts available for the M26 and X26 that differ in weight and length of barb. However, as discussed in the Effects Identification section, neither type of dart is expected to cause an effect that is greater than a SEV1. Dart injuries to skin and soft tissues, while all SEV1 effects, vary with the location. Lacerations of the face or genitals could be a greater concern relative to lacerations to the chest or back, but would still be regarded as SEV1. This exposure assessment will separately evaluate dart effects for the face and the groin area. In contrast to these SEV1 effects, a dart strike to the eye is categorized as resulting in a SEV2 or SEV3 injury. The exposure assessment will determine the probability that a dart will strike the eye. Dart strikes that do not result in skin penetration because of clothing will not result in injuries. Therefore, the exposure assessment will also estimate the impact of clothing.

5.4.2 Electrical Effects

Electrical effects occur when a circuit is achieved. Therefore, the exposure assessment will estimate the probability that a shot establishes an electric circuit. Electrical effects of the M26 and X26 are also influenced by dart location. EMI device shots that are too close together or strike an area with low nerve density can result in a partial, rather than complete, EMD. The risk of VF and seizures are also influenced by dart location. Based on these considerations, the exposure assessment will investigate the distance between dart strike and locations on the body where they occur.

The key issue for determining exposure to the electrical charge is whether there has been a completion of an electrical circuit. A series of events must successfully occur for a circuit to be completed. Both darts must fire and one or both must either strike a person's skin, or penetrate the person's clothing. The wires must remain intact and the dart(s) must remain in contact with or in close proximity to the person for the duration of the contact. Maximizing the probability that these events occur is the main goal of the design of EMI devices.

If two darts penetrate the skin, they will complete the circuit[5]. If two darts penetrate the individual's clothing, a circuit may or may not occur depending on the characteristics of the clothing. Clothing, braces, or casts can affect the completion of the circuit. If one of the darts becomes lodged in a nonconductive object (plastic brace or plaster cast), then the circuit will not be complete. If one or both darts strike a dense or metallic object (button or rivet) and fail to penetrate, they can fall to the ground and the circuit may not be completed. If both darts strike a conductive material, the circuit may pass through the material (a short circuit) and not reach the body. Finally, a dart can strike loose fitting clothing that can keep the dart away from the body and prevent the formation of an arc. TASER electrical output can arc across approximately 1.25" (3.2 cm) of clothing per dart for a cumulative distance of 2.5" (6.4 cm), based on relatively basic laboratory experiments in which the maximum arc length was tested by discharging the TASER across various thicknesses of cloth into a piece of meat (TASER International, personal communication, 2003). PSDB (2002) reported that in order to have a 50% chance of forming an arc, the air gap must be less than 3.5 cm. Loose clothing such as a heavy coat, robe, or cloak may result in separations greater than these distances.

If a single dart strikes an individual, the circuit can be completed in two ways. First, if the second dart falls to earth and the ground is sufficiently conductive, then the ground can complete the circuit. In these instances, an arc will occur across the person's shoe or, if the shoe is wet, through the shoe. Second, if the wire from the second unit falls over the individual, the arc can form through the insulating coating of the wire (TASER International, personal communication, 2003). This can occur if the upper barb goes over the head of the targeted individual. In this case, the trailing wire can drape over the individual. As discussed in Appendix B, the potential for either of these two scenarios appears to be greatly increased if the dart that strikes the individual penetrates the skin rather then merely penetrating the clothing.

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[5] Assuming that the wires are not broken and the device has not malfunctioned.

If both darts miss an individual, it is unlikely that a circuit will occur. However, individuals coming into contact with the insulated portions of both wires could receive a stimulus if the wires are compressed forcefully (TASER International, personal communication, 2003).

The current flows between the darts, but does not pass through to individuals who are in contact with only the target individual. As a result, individuals in contact with the target individual (e.g., warfighters restraining the individual, children, hostages, or bystanders) will not be affected unless they come into contact with both darts and or wires.

5.4.3 Effects of Falls

Severe fall-related effects (SEV2 or SEV3 as described in the Effects Identification section) include fractures, joint dislocations, and concussions. Fall-related effects occur when an EMI device shot is fully effective and the stimulus is sufficiently strong that the individual can no longer maintain a standing position. These endpoints will be modeled as occurring when EMD is complete.

5.5 Summary of Exposure Factors that are Considered in this Section

The following are the aspects of exposure that are modeled:

- Dart strike locations;
- Dart penetration locations;
- Distance between dart strikes;
- Effect of clothing; and
- Completion of a circuit.

In the case of the M26 and X26 TASERs, data on the physiology of the individual affect the exposure because they determine the size of the targets and the distance between the dart strikes (see below). Therefore, height of the targets will be considered.

Site-specific factors that influence risk are limited to the distance between the user and the target individual. In informal studies, TASER darts have been shown to be relatively insensitive to wind speed (TASER International, 1999). Since the tether wires are insulated, the presence of rain or moisture are believed to also have little effect. TASER International reports that the devices have been used successfully on individuals swimming in lakes.

The distance to the target does have a significant effect on dart location. The M26 and X26 TASERs are aimed by individuals, and thus, would be expected to be less accurate at greater distances. The location of the lower dart strike location will be influenced by distance to the target. Finally, with increasing distance, the kinetic energy in the dart declines and the probability that clothing will stop the dart increases.

Finally, body weight may impact probabilities of inducing electrical effects. A number of users have reported that highly obese individuals tend to be somewhat more resistant to the electrical effects. Obesity is related to the demographics of the targets (age and gender).

5.6 The TASER International Database

The basis for the assessment of exposures to the M26 and X26 are the data collected by TASER International using the Use Report submittal form on the TASER International Web Site (http://www.TASER.com/pages/le/usereport.asp). A description and an analysis of the database are given in Appendix B. The database (as of September 2003) includes reports on more than 2,035 firings of a device. Approximately 98% of the data in this database are on the M26. This reflects the long history and current market share of this device. These reports include information on the location of dart strikes, dart penetration, and the user's determination whether the use was "successful" or "unsuccessful." The reports specify the location of the darts using the grid given in Figure 6. In addition, the gender, age, height, and weight are reported for the target individual.

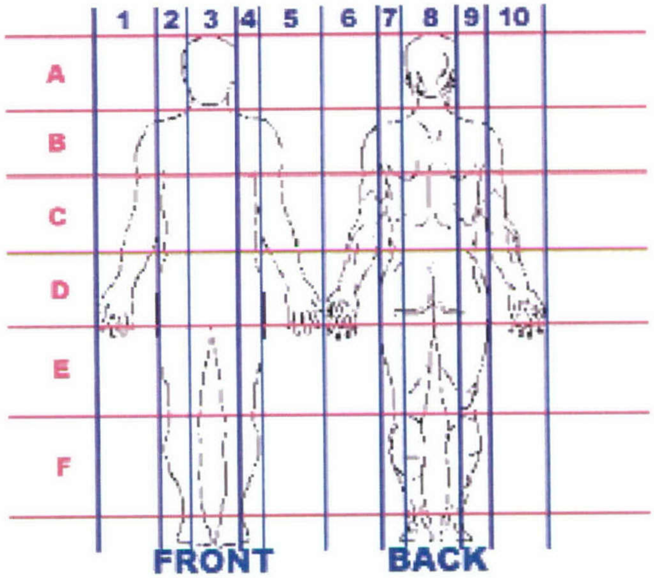


Figure 6. Grid Used to Report Dart Locations in TASER International User Reports (TASER International, 2003)

The data indicate that 57% of the upper darts that strike the target individual strike in row B (Figure 6). A similar percentage of the lower darts hit in row C. The majority of the shots result in two dart hits. Figures 7 and 8 present the fraction of shots resulting in 0, 1, or 2 hits and 0, 1, or 2 penetrations of the skin as a function of distance to the targeted individual. These estimates are based on the 1,666 records that 1) report data on strikes and penetration, 2) report a distance between the target and the user, and 3) only report firing a single shot. Appendix B contains additional data on dart strike location and the effect of distance on dart strikes and penetrations.

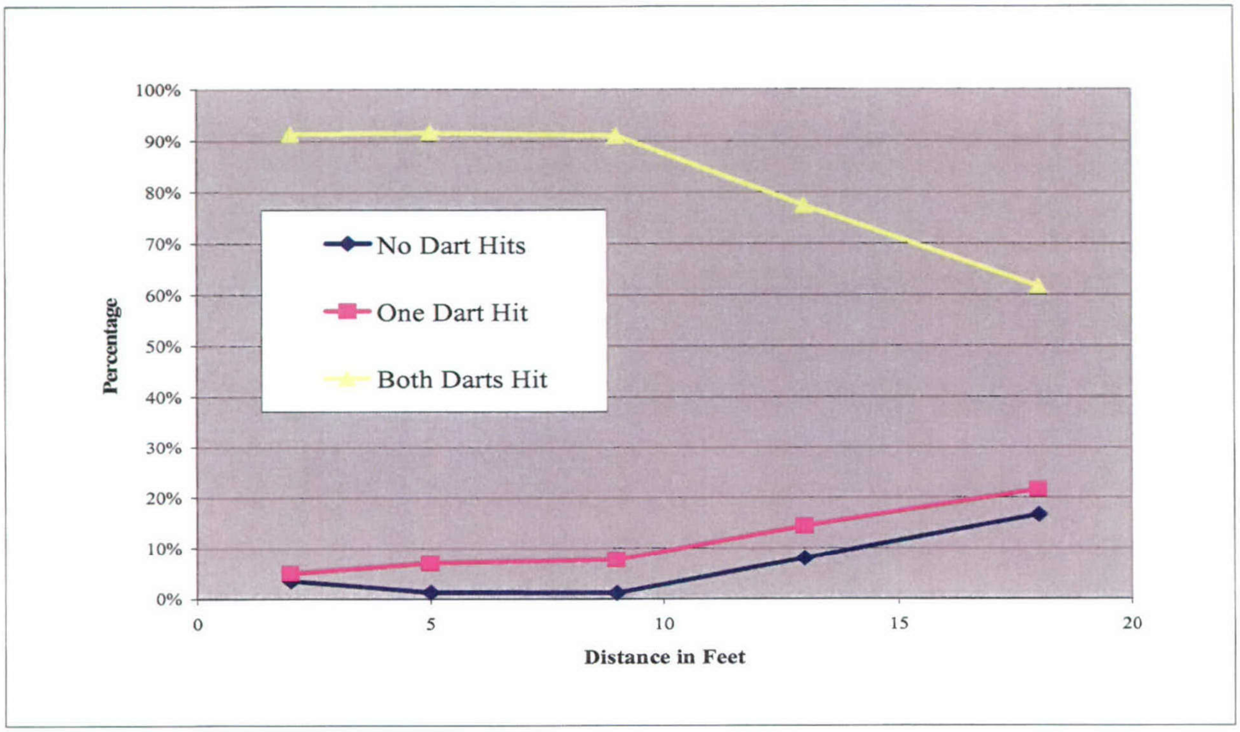


Figure 7. The Effect of Distance Between the User and the Target on the Percent of Shots Resulting in 0, 1, or 2 Darts Hitting an Individual

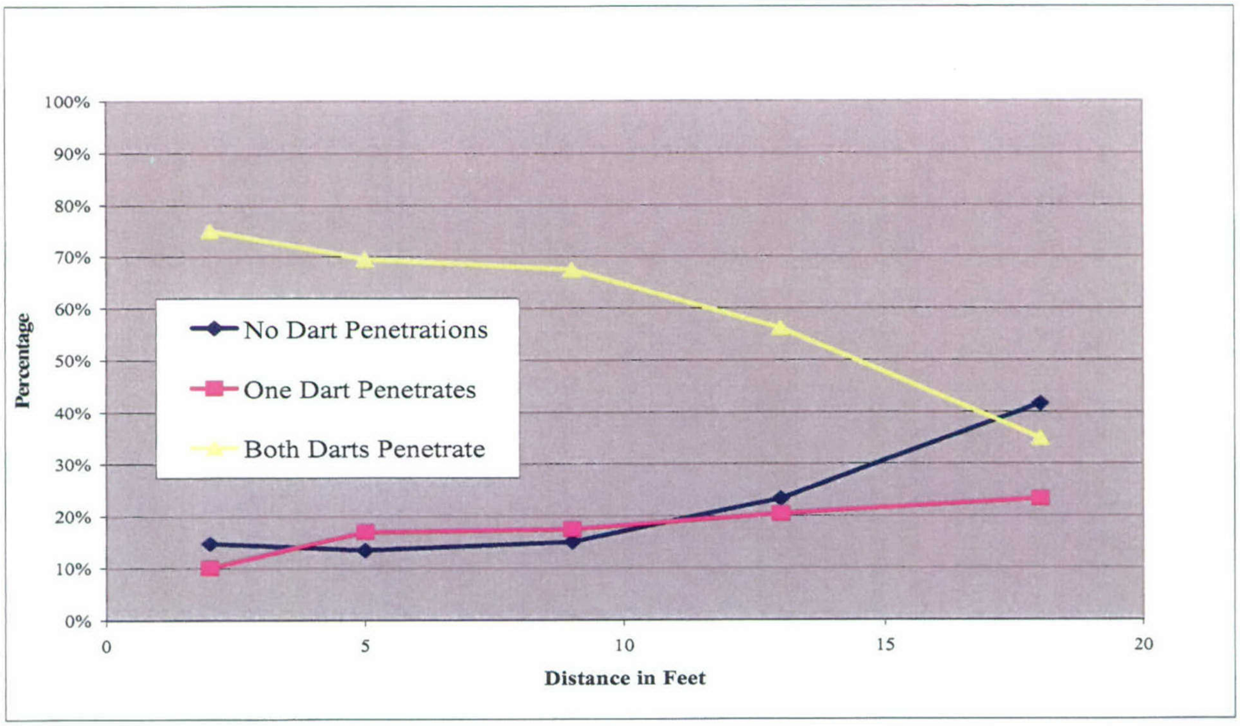


Figure 8. The Effect of Distance Between the User and the Target on the Percent of Shots Resulting in 0, 1, or 2 Darts Penetrating the Skin

Based on these data, for distances under 11 ft, the percentage of shots delivering two darts to a person are 80% and the percentage of the shots having both darts penetrating the skin is 65%. However, there is a drop off in the percent of shots that result in two darts hitting a person and penetrating the skin at distances beyond 11 ft. This finding is understandable given the expected decrease of the kinetic energy of the darts as a function of distance.

The percentage of shots resulting in two-dart strikes is lower than the number of hits reported by PSDB (2002) for standing front profile targets. This is reasonable since the data from TASER International are derived from actual use in the field and not trials using immobile artificial targets.

The distance between darts was modeled based on the dart strike locations (as reported from grid locations in Figure 6) reported in the database and the target's reported height. The estimates were plotted against the distance between the user and the target individual. The result is reported in Figure 9.

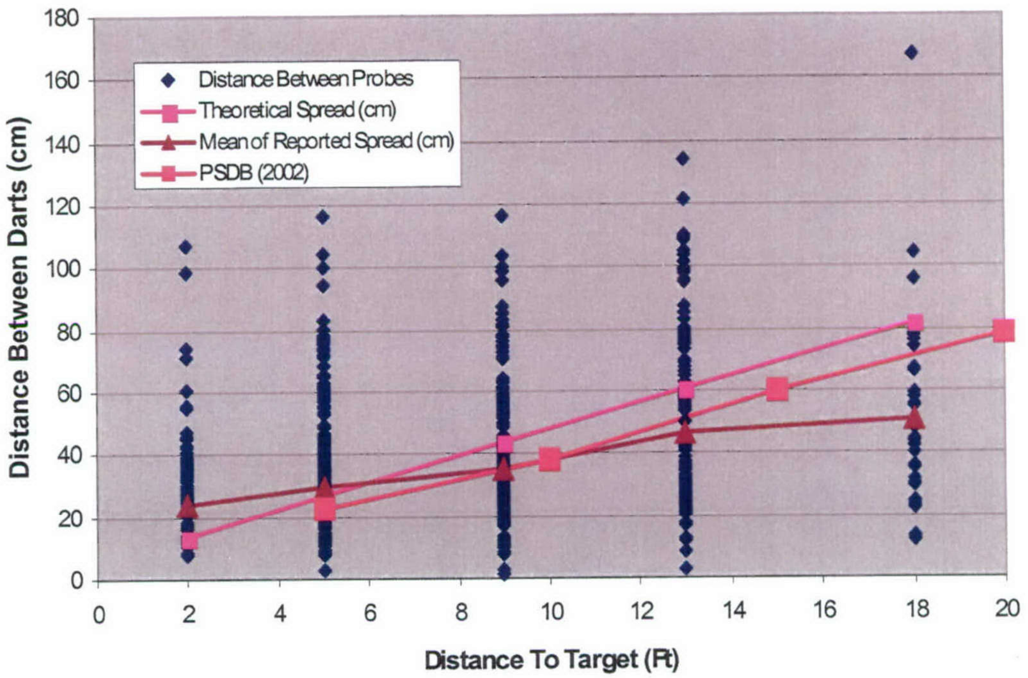


Figure 9. The Effect of Distance Between the User and the Target on the Reported Distances Between the Impact Locations for the Darts

It is not entirely clear why there is such a large range in the separation distance between the darts. While the mean of the separation does increase with distance, the range in dart separation values is similar for the data collected at all five of the distance ranges. One explanation may be that individuals may be crouching or sitting when shot. Such positions would bring the upper portion of the body closer to the legs and result in a wider separation of the strike locations on the body. In addition, if the person is not standing at a right angle to the TASER (such as laying in a prone or partially prone position), the distances between the darts would also be increased. It is not clear how the shorter distances occurred. These may be due to errors in entering the data or the imprecision of using a grid.

Finally, the mean of reported dart separation from each distance range is consistently smaller than the theoretical estimates of separation based on the dart separation angle of 8°. This finding is similar to the PSDB (2002) findings on the M26. The estimates of separation from their trials are also smaller than the theoretical estimates.

5.7 Evaluating Successful EMI Circuit Connections

The survey instrument used to create the data did not ask the user whether a circuit had been achieved. However, it did allow the user to report a subjective finding of whether the use of the weapon was "successful" or "not successful." The reported success rate was very high. Even in the cases where neither dart struck a person, a large number of the records reported the use as successful.

In this analysis, we assumed that the success rate was a function of two processes: those processes that required an EMI effect (either partial or complete EMD) and processes that do not (fear at being fired at, fear of an additional EMI exposure, or fear of the use of other types of force). The probability of a circuit being completed is determined based on the assumption that if a circuit is completed, the user will always report the use as "successful," and if a circuit is not completed, then the user will report the use as "successful" X% of the time.

As discussed in Appendix B, the value of X can be estimated from the records where the individual is not struck by either dart. For these records:

$$X\% = SR / TR * 100$$

Where,

TR = total number of records for a specific combination of dart strikes and penetrations

SR = total number of records for a specific combination of dart strikes and penetrations reported by users as successful

The derivation of the value of X is presented in Appendix B and is based on data from records where either both darts missed the target individual or one dart struck but failed to penetrate the skin. These data were taken from the records where either one shot was taken or from the initial shot in cases where a user took two shots. The value of X obtained from the analysis is 41%.

Once the value of X is determined, the percent of records where a circuit is established (PC) can be determined for the remaining records. As detailed in Appendix B, the percentage can be estimated using the following equation:

$$PC = ((TR - ((TR - SR)/(1 - X/100)))/TR) * 100$$

Table 8 presents the estimated probability of connection (established a complete circuit) for each of the combinations of dart hits and penetration. This analysis suggests that a connection is achieved more than 88% of the time when two darts hit the target person and both penetrate the skin, and more than 78% of the time when two darts hit but only one penetrates. In evaluating Table 8, it is important to note that these estimates are for a single shot. In actual use, if an initial shot fails, users will often fire a second set of darts. This increases the overall effectiveness of the devices.

Table 8. The Effect of Number of Dart Hits and Penetration on the Percent of TASER International Records Reporting "Success" and the Estimate of the Percent of the Records Where an Actual Stimulus Occurred

Dart Hit	Dart Penetration	Single Shots		Multiple Shot Records	Total Records	Reported Percent Successful	Percent of Records Where Circuit is Completed*
		Number of Successful Records	Number of Unsuccessful Records	Number of Records Where First shot is Unsuccessful			
0 or 1	0	56	27	54	137	41%	0%
1	1	106	17	12	135	79%	64%
2	0	176	29	15	220	80%	66%
2	1	162	5	19	186	87%	78%
2	2	1146	34	53	1233	93%	88%

* Equation used for calculation: $PC = ((TR - ((TR - SR)/(1-X/100)))/TR) *100$

5.8 Exposure Assessment Summary

The use of either of the two TASER devices, the M26 and X26, will result in individuals receiving dart lacerations and electrical currents. These effects occur as a result of the normal and intended use of the devices, and the exposures are required in order for the devices to produce their intended effects. These exposures will occur in the majority, but not all, of the instances where the device is fired. The probability of the occurrence of the effects is influenced by the distance to the target individual and the orientation of the individual (front/back, profile, crouched, or prone position).

The best available data on exposures for the two devices have been collected by the manufacturer from user reports. These data, while not ideal, provide a good description of the exposures resulting from use of the devices by civilian police departments. In this assessment, we assume that police uses are a reasonable guide for exposures that will occur from military use. An exception is parts of the world where child soldiers comprise a significant portion of combatants. Data on exposures to the devices collected by TASER International reflect the range of body positions that occurred in actual police use. These data have been sorted by distance to give the following estimates of the probability of exposure to two of the TASER effects.

Lacerations are assumed to occur whenever a record indicated that skin penetration occurred for 1 or both darts and electrical stimulus is based on the estimates of when an electrical circuit had been achieved.

Table 9. Estimates of the Percent of TASER Shots Resulting in Laceration or EMD at Different Distances Between the User and the Target

	Distance (ft)				
	1-3	3-7	7-11	11-15	15-21
Dart Lacerations	84%	87%	84%	76%	57%
Complete or partial EMD	80%	81%	80%	72%	56%

Table 9 indicates dart lacerations occur in approximately 85% of the firings of the devices for distances of less then 11 ft. At 18 ft, the probability of effect drops to approximately 57%. EMD occurs in approximately 80% of the shots for the closer shots and the rates decline to approximately 56% at the longer distances. Lacerations would occur whenever darts pierce the skin. With the presence of thick clothing, an arc would develop between the tip of the dart and the skin causing a small discoloration or burn, but no laceration.

6 EFFECTIVENESS AND RISK CHARACTERIZATION

6.1 Comparative Risks

All NLW systems are associated with intended effect(s) and unintended effects. If the severity and probability of occurrence for each of the intended effects are favorable in comparison to those of the unintended effects, then the NLW system will likely have utility as well as greater public and policy acceptance. A comparison of the relative frequency of the intended and unintended effects from the use of the chosen NLW system/payload to other NLW systems/payloads, or even to the use of lethal force, or not employing any alternatives, can assist in the determination of the value of a weapon system.

This report highlights the probabilities of intended and unintended effects from the use of the M26 and X26. However, an additional aspect of the characterization of risks associated with the devices is comparison of the risk of adverse effects from the use of other non-lethal or less-than-lethal technologies and the effect of adopting the M26 or X26 as part of the force continuum on these risks. A number of authors have reported the impact of the introduction of the M26 and X26 on injury rates for police officers and suspects from conflict situations. These reports indicate a significant reduction of injuries to both individuals. Fisher (personal communication, 2002) reported that the suspect injury rate during arrests before TASERs were issued to Phoenix police officers was 82%; after the introduction, the suspect injury rate was 27%. For officers, the injury rate prior to TASERs was 9.5%; afterwards, the injury rate was 7%. An 80% drop in the annual injury rate to police deputies also occurred in Orange County, Florida, with the introduction of TASERs (Ripple, personal communication, 2003). Finally, there is some anecdotal evidence now being reported by investigative journalists that increased TASER use by police departments is associated with a decline in the number of police shootings (Andrews, 2004).

These results are preliminary, but indicate that the use of TASERs is likely to decrease the overall injury rate of both police officers and suspects in conflict situations. Additional study is needed, however, to further support these initial comparisons.

6.2 Characterizing Risks and Effectiveness of the TASER M26 and X26

Exposure to the two EMI devices occurs as a series of events. Depending on which events occur, one or more of the three types of effects occur (dart related, electrical, and fall related). Figure 10 presents a flow chart that describes the events and the resulting effects.

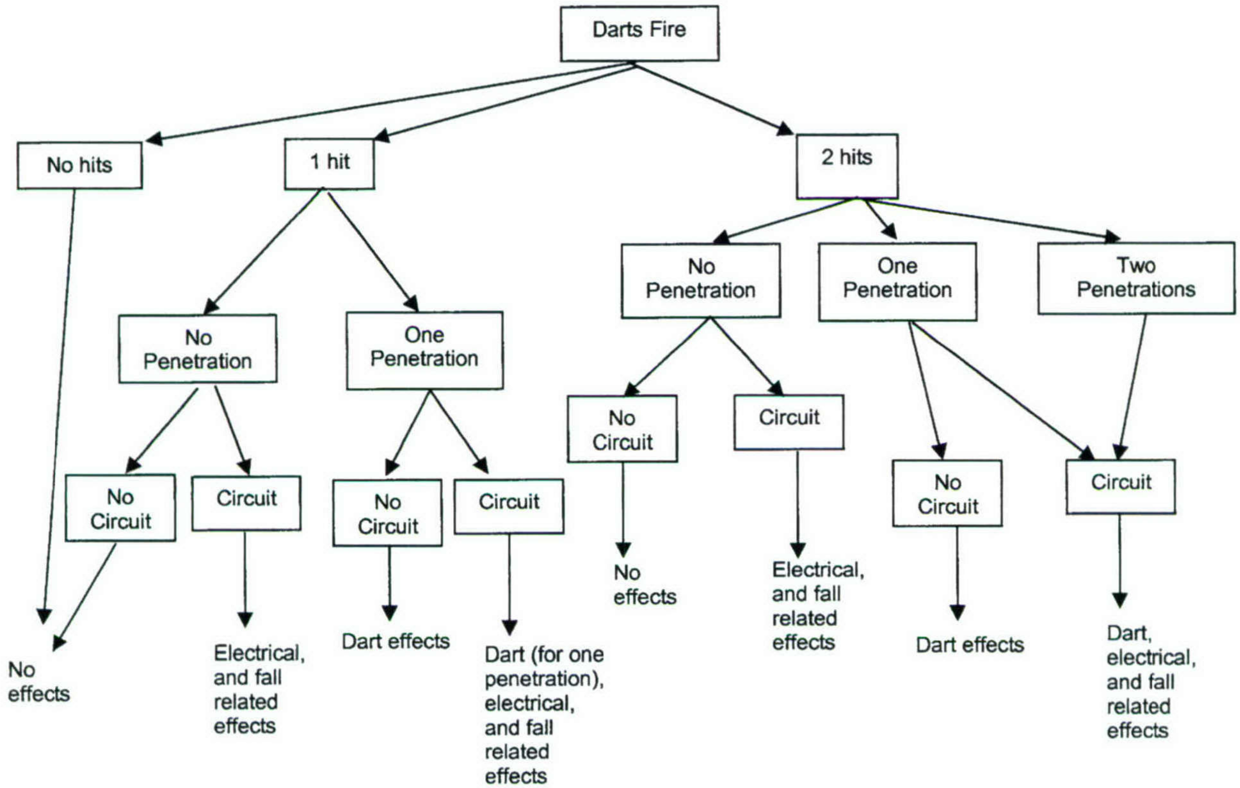


Figure 10. Event Tree for Intended and Unintended Effects as a Function of the Number of Dart Hits and Dart Penetrations of Skin

As Figure 10 indicates, the determination of electrical and fall-related effects requires an evaluation of whether a circuit is achieved. The probability of a circuit forming is a function of the number of dart hits and the number of darts that penetrate the skin. The distance between the user and the target individual affects the probability that darts will strike and penetrate the skin of the target individual.

In the Exposure Assessment section, the probabilities of the occurrence are determined for dart strikes, dart penetration of skin, location of strikes, and establishment of a circuit. In the following sections, these data are used to determine the contingent probabilities (i.e., the probability that a given event will occur given that prior events have occurred) for each of the intended and unintended effects. Once this is completed, a Monte Carlo model of the event tree is used to estimate the frequency of the occurrence of the intended and unintended effects as a function of distance between target and user.

6.2.1 Characterizing Risk of Face and Eye Strikes

As discussed above, the design of the M26 and X26 and the training for the use of the devices are designed to minimize the chance of face and eye strikes. Koscove (1985), Ordog et al. (1987), and Kornblum and Reddy (1991) did not report any incidences of eye damage due to a TASER dart. While not contained within the TI database, there is one known case of permanent vision impairment as a result of a dart strike to the ocular region (Dave Dubay, personal communication, 2004).

In this assessment, the risk of eye strikes was estimated based on information in the TASER International database on the location of dart strikes (TASER International, personal communication, 2003). This estimate is developed in a two-step process. First, the probability of a dart hitting the face is determined. Then the probability of an eye strike is estimated based on the ratio of the size of the eyes and face. The effect of eyeglasses as a possible mitigating or contributing factor in eye injuries was not considered.

The facial area is identified in the location grid used in the database as A3. The database reports that there were 16 records of the upper darts striking in location of A3. This indicates that a face strike will occur in slightly more than approximately 1% of instances where one or more darts strike an individual. This estimate is consistent with field experience of the Los Angeles Police Department (Ordog et al., 1987). In addition, PSDB (2002) reported that in controlled trials 2% of the shots resulted in one barb striking the head or neck.

The cross-sectional area of an eye is 0.00052 m^2 (Dr. Paul Vinger, personal communication, July 8, 2002); thus, the cross-sectional area of two eyes is 0.00104 m^2. The median of the surface area of the total head (not including the neck) is 0.13 m^2 for adult males (U.S. EPA, 1997). Assuming one third of the head area is the face ($0.13\ m^2)/3 = .04329\ m^2$), this results in a relative area of the two eyes of 0.024 (.00104/0.04329). This suggests that if the dart strikes are evenly spread across the face, then 2.4% of the face strikes will be eye strikes.

The risk of an eye strike is the product of 1) the probability that one or more darts will strike the person, 2) the probability of a face strike, and 3) the probability that a face strike will hit the eyes. Table 10 presents the data on head strikes as a function of distance. If one or more darts strike the individual, the risk of an eye strike is 0.025%. This estimate suggests that an eye strike should occur on average every 4,000 successful shots (i.e., one or more dart strikes occur). This is consistent with the finding that the current database (2,035 records of instances where one or both darts struck the individual) does not include an instance of an eye strike. While the role of distance was investigated, the number of facial hits is too small to give a reliable estimate of the effect of distance on the risk of an eye strike.

Table 10. Estimates of the Percent of TASER Shots that will Result in a Dart Striking the Face or Eye at Different Distances Between the User and the Target

	Distance of the Shot				
	1-3 ft	3-7 ft	7-11ft	11-15 ft	15-21ft
Number of Records With Dart Location for the Upper Dart and a Distance to Target	185	603	503	222	46
Number of Records with Upper Dart Location of A3 and a Distance to Target	1	8	3	3	1
Percent of Records With A Reported Dart Location of A3 and a Distance to Target	0.54%	1.3%	0.60%	1.4%	2.2%
Percent of Shots Resulting in an Eye Strike Assuming that Strikes are Evenly Distributed Across the Face*	0.013%	0.032%	0.014%	0.032%	0.052%

* % Location A3 multiplied by 2.4% (e.g., 0.0054 x 0.024 = 0.00129 (0.013%))

6.2.2 Characterizing the Occurrence of Lacerations

Lacerations will occur whenever dart penetrations occur. The probability of dart penetration is determined in the Exposure Assessment section of this report.

6.2.3 Characterizing the Occurrence of Burns

Erythema and minor burns may occur when the intended EMI effect occurs. These skin changes are superficial and will dissipate without medical intervention (SEV1).

6.2.4 Characterizing the Occurrence of Lacerations in the Groin Area

Injuries to the genital organs could occur because of strikes to cells E3 and E8 of the grid given in Figure 7 of the Exposure Assessment section. The total number of reported strikes to these grid locations from either the top or the bottom dart is 30 (TASER International, personal communication, 2003). Of these strikes, four did not penetrate the skin; in addition, clothing may have stopped as many as 10 of the remaining hits.

Table 11 presents the number of shots and fraction of total shots that are reported to occur in E3 or E8. This analysis did find a statistically significant increase in the number of groin hits with distance (comparing the number of hits at distances less than 11 ft to the number at distances greater than 11 ft). The four panels in Figure 5 show that at increased distances, the general area where the lower dart strikes moves from the abdomen to the groin area.

Table 11. Estimate of the Percent of TASER Shots that will Result in a Dart Striking the Groin Area at Different Distances Between the User and the Target

	Distance of the Shot					
	1-3 ft	3-7 ft	7-11 ft	11-15 ft	15-21 ft	All Distances
Number of Records With at Least 1 Dart Location and a Distance to Target	185	603	503	222	46	1,667
Number of Dart Strikes to E3 or E8	3	11	6	7	3	30
Percent of Records With A Reported Dart Location That Reported E3 or E8	1.6%	1.8%	1.2%	3.2%	6.5%	1.8%

6.2.5 Characterizing the Occurrence of Electromuscular Disruption (EMD) and Other Electrical Effects

The health endpoints associated with electrical effects only occur when the circuit is complete. The desired effect is EMD and the unintended effects are ventricular fibrillations, seizures, and burns.

6.2.5.1 *Electromuscular Disruption (EMD)*

The ability of the TASERs to produce the intended effect of EMD requires that a number of separate events occur. These are:

- One or both of the darts must strike the target individual.
- An electrical circuit must be formed.
- The dart placement must be sufficiently separated to allow good current dispersion across the skeletal muscles.

The probability of inducing a complete or partial EMD is determined using a multi-step approach. First, the probability of a shot resulting in a completed circuit is determined. This probability is determined in the Exposure Assessment section of this report and is based on the data on "effectiveness" reported by the user. The probability of a circuit being completed is influenced by the number of dart strikes and dart penetrations, which is influenced by the distance between the user and the target individual.

Once the circuit is completed, the current must be sufficiently dispersed to affect the major skeletal muscles. If this does not occur, then the induced muscle contractions may be limited to one portion of the body and the target individual may be able to continue to move in a limited fashion. The dispersion of the current is a function of the locations of the two darts. At the August 2003 workshop, experts in the use of the TASER provided estimates of the probability of complete versus partial EMD as a function of dart placement. Different probabilities for partial or full EMD were assigned to dart strikes based on dart separation and placement on the front or back of the body. The values presented in Table 12 reflect the collective input of subject matter experts experienced in TASER deployment. These values reflect practical experience of users as communicated during a workshop held in August 2003 and are consistent with postural implications of muscle group stimulation across varying areas of the body.

Table 12. Effect of Dart Placement on the Probability of Partial and Complete Electromuscular Disruption (EMD)

Dart Separation (in.)	Partial EMD	Complete EMD
	Front of the Body	
<4	0.25	0.75
4-12	0.1	0.9
>12	0.01	0.99
	Back of the Body	
<4	0.15	0.85
4-12	0.05	0.95
>12	0.01	0.99

The probability of a shot falling into each of the above six categories was estimated based on the dart separation data discussed in Sections 5.2 and 5.6 and location data from the TASER International records. Based on these data it is possible to determine the fraction of the records at each distance that meet the criteria given in Table 12 for assigning a probability of a complete EMD. The percent of shots that fall into each of the five distance categories is given in Table 13. For example, there is a 99% probability of achieving complete EMD if the darts' strike locations occur 12 inches apart. For shots that occur between 1-3 feet, 23% of the shots result in dart spacing that are greater than 12 inches apart. The distribution of shots that fell into each of the categories varied with distance. At a distance of 15 - 21 ft, the percentage that were 12 inches apart increased to 65%. This increase is understandable since the spread between darts increases with distance.

Table 13. Modeled Probability of Complete Electromuscular Disruption (EMD) at Different Distances Between the User and the Target

Dart Placement* & Separation (inches)	Fraction of Shots Causing Complete EMD	Distance (Feet)				
		1-3	3-7	7-11	11-15	15-21
Front & Back, >12	0.99	23%	32%	45%	59%	65%
Back, 4-12	0.95	34%	24%	24%	18%	16%
Front, 4-12	0.90	41%	42%	30%	22%	19%
Back, <4	0.85	1%	1%	1%	0%	0%
Front, <4	0.75	1%	1%	1%	1%	0%

*Front or back of body

The available data indicate that a circuit can also be completed when one dart strikes the individual (the ground completing the circuit). In this case, the distance between the darts cannot be determined since only one dart strikes the individual. However, in these instances, the current flows through one or both legs and up to the dart. Thus, the effective separation distance is expected to be very large in most cases (except in the limited cases where the single hit would be in the lower extremities). Because of this distance, this assessment will assume that 100% of the shots where a single dart strike results in a completed circuit will cause a complete EMD.

6.2.5.2 *Characterizing Risk of Ventricular Fibrillation (VF)*

As shown in the Dose Response section of the report, VF is not expected to occur in otherwise healthy adult populations from the use of the M26 or X26. The dose-response for VF risk was derived based on controlled studies in pigs using the X26 waveform. Although similar dose-response information was not available for the M26 TASER, it has a lower pulse charge, and could be hypothesized to present less cardiac risk than the X26, although this would need to be determined experimentally.

The observed results in animal studies are consistent with field experience with the TASER, in which no verified cases of VF have been reported. In evaluating the field reports from the TASER International database, the shots that result in dart placements on each side of the cardiac region were the only cases thought to be relevant for evaluating VF probabilities, since other dart placements would not involve a circuit path across the heart. The probability of this dart placement occurring was calculated from the dart strike location information in the data (Appendix B). Three hundred-twenty three (323) records were found to have appropriate dart locations. Since there are 1,502 records where two darts strike an individual, the percentage of shots that result in a potential for an electrical dose reaching the heart is 21.5% (i.e., 323 shots across heart / 1,502 shots with two dart hits). This suggests that if the TASER could cause VF, then the rate must be very low, since a significant portion of shots would induce a current path across the heart. However, no documented VF cases have been reported from field uses.

VF risk is considered minimal for large children and healthy adults due to the large margin of safety identified from the dose-response assessment (see the Dose-Response section). This judgment refers to sensitive, but not hypersensitive individuals (e.g., those with existing heart conditions, cardiac sensitizing drug co-exposure, etc.). The margin of safety based on body weight extrapolations for very small children is sufficiently small to result in significant uncertainty regarding the cardiac safety of a TASER stimulus. If the COE for military and law-enforcement use of the handheld TASER includes avoiding deployment against small children, no significant VF risk is expected.

6.2.5.3 Characterizing the Risk of Seizures

As discussed in the Dose Response section of this report, seizures are considered an effect of potential interest, albeit one that has significant uncertainties based on the magnitude of published seizure thresholds relative to the EMI charge, and the limited amount of applicable field case reports. An analysis was conducted to determine an upper bound for the probability of seizure events from the use of the devices. Seizures are assumed to occur if the locations of the darts will result in a current through the brain and if the electrical charge is greater than the seizure threshold. However, it must be noted that there are no empirical data to support this supposition.

Head strikes are a rare occurrence in the data. One of the 1,502 records report that both darts struck an individual's head (grid location A8). No seizure was reported. In addition, there is no expectation that a single dart striking the head and a second dart striking some other point on the individual's body can induce a seizure. None of these field reports where head strikes occurred reported the induction of a seizure. Even if the EMI output could induce a seizure, the low probability of the darts striking the head indicates that the overall risk of seizures is of limited concern and the risk of permanent effects of a single seizure is low and is considered a SEV1.

6.2.6 Characterizing the Occurrence of Fall Related Injuries

The remaining effects to be modeled are the injuries that occur as a result of falling. Fall injuries will be modeled based on the frequency of a complete EMD. In this assessment, a fall is assumed to occur every time that a complete EMD occurs. As discussed in the Dose Response section of this report, the percent of falls that result in SEV2 or SEV3 effects is estimated to be 0.2%.

6.3 Modeling the Probability of Intended and Unintended Effects for the TASER

The material in the Exposure Assessment section presents the information on the probabilities of each set in the event tree. These probabilities are used in a Monte Carlo model assessment of the intended and unintended effects. In this model, the distance between the user and the target is used to determine: the probability that one or more darts will strike and/or penetrate the skin of the target individual, the distance between the darts, and the location of the dart strikes. Measures of performance (MOP) information is used to determine the probability of the intended and unintended effects. The simulation model was repeated 50,000 times to assure that stable estimates of the probabilities would be obtained. The results of the analysis are given in Table 14 and Figures 11, 12, and 13.

Table 14. Probabilistic Results of Monte Carlo Simulation of TASER Employment (50,000 iterations)

Distance in Feet	Effectiveness of TASER		Severity Level 1 Effects				Severity Level 2 & 3 Effects	
	Complete EMD	Partial EMD	Minor Burns	Any Laceration	Laceration (Face)	Laceration (Groin)	Falls (Major)	Eye strikes
1-3	74%	6%	80%	84%	0.4%	1%	0.15%	0.01%
3-7	75%	6%	81%	87%	1%	2%	0.15%	0.03%
7-11	75%	5%	80%	85%	1%	1%	0.15%	0.02%
11-15	67%	5%	72%	76%	1%	2%	0.15%	0.03%
15-21	52%	4%	56%	57%	1%	3%	0.10%	0.04%

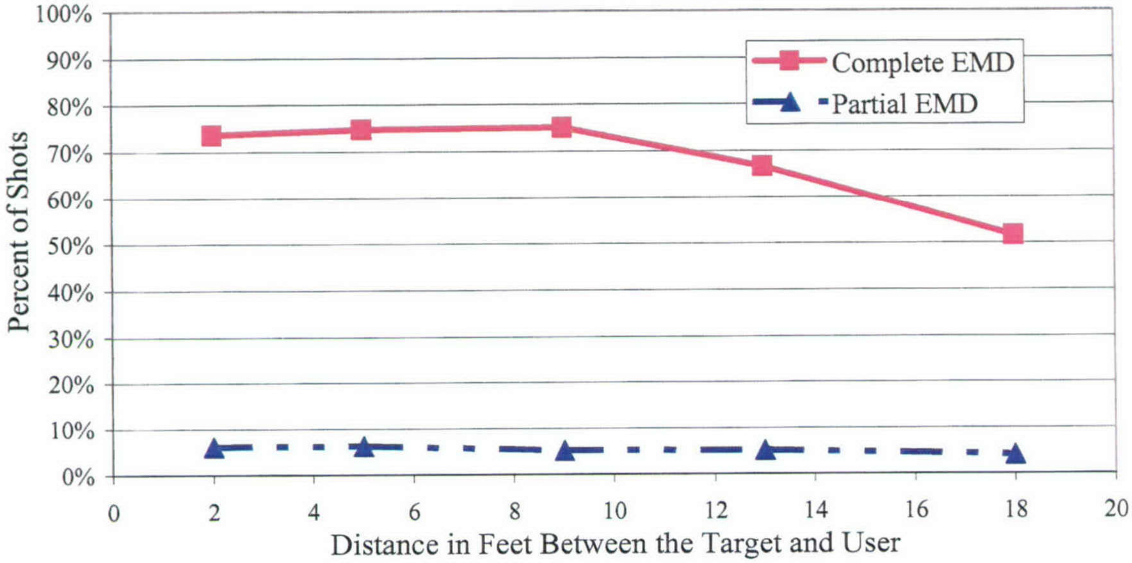


Figure 11. Probability of Complete and Partial Electromuscular Disruption (EMD) at Different Distances Between the User and the Target Individual

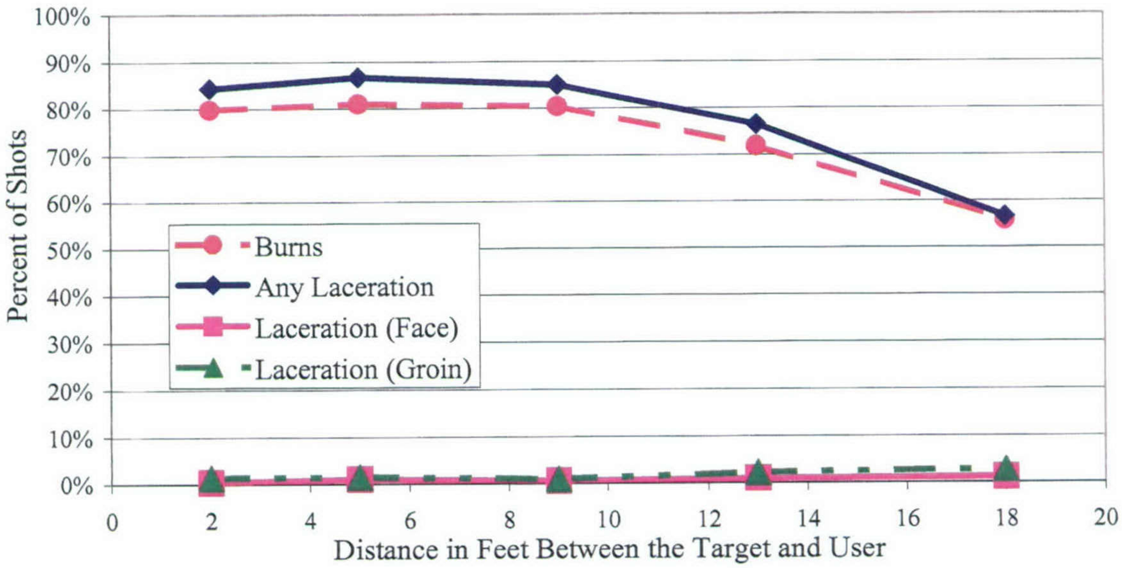
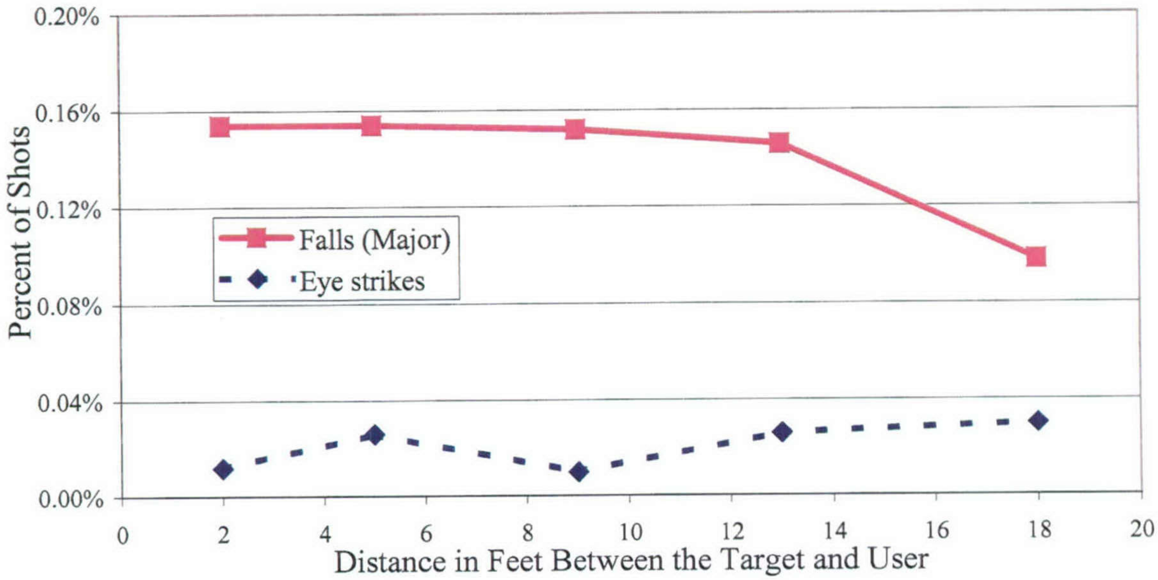


Figure 12. Probability of Unintended Effects (Severity 1) at Different Distances Between the User and the Target Individual



Please note the scale change for the percent of shots when compared to Figures 11 and 12.

Figure 13. Probability of Unintended Effects (Severity 2) at Different Distances Between the User and the Target Individual

As Table 14 and Figures 11, 12, and 13 indicate, a single use of the TASER at distances of less then 11 feet results in approximately a 75% chance of causing complete EMD and an additional 6% chance of causing partial EMD. This drops to approximately 50% and 4% at longer distances. Historically, the use of TASERs by law enforcement and correctional facility personnel have achieved considerable success without firing or if fired without actually causing the EMD. This can be seen in the fact that 41% of instances where both darts missed the target, the weapon was judged by the user as "successful." The mechanisms for achieving this include the psychological effects of having the weapon fired at them, fearing a second shot, or fear of the use of additional (and perhaps lethal) force. It is unknown if these mechanisms for success will also occur in DoD use. If they do not, and if the complete or partial EMD is required, then the effectiveness of a single shot from a TASER is not likely to exceed 75% for distances of less than 11 ft (3-4 m) and could decline to < 52% at distances beyond 18 ft (6 m). This suggests that, with current technologies, EMI devices will have a short standoff distance. These estimates are for single shots from an EMI device. Since the user has the ability to reload and fire a second shot, the actual effectiveness of the EMI device will be higher than the table and figures indicate.

The probability of minor effects, small lacerations and small burns, is very high for the EMI devices and, in fact, such effects must occur for the intended effect of the weapon to occur. More severe effects such as eye strikes and severe fall related effects are expected to occur much less frequently. The frequencies of these effects are estimated to be between one in a 1,000 and one in 10,000 shots.

The initial indications that the M26 and X26 can greatly reduce risks to police officers and suspects also implies that reductions in risks to users and targets are likely to occur when the devices are used by the DoD. However, because of potential difference(s) in how weapons will be used, it is not possible to predict these benefits.

6.4 Effectiveness and Risk Evaluations on the EMI Devices Developed by Other Organizations

The human effects of EMI and related devices have been evaluated previously. For example, human effects or safety assessments have been completed for early EMI devices (Zylich, 1976) as well as for the sticky shocker (HEAP, 1999). However, the electrical dose characteristics and delivery mechanisms of these other devices differ from the M26 and X26 TASERs. Therefore, these earlier assessment reports cannot be used directly to make conclusions about the human effects of M26 and X26 TASER exposures. More recently, a detailed human effects assessment has been done for modern TASERs, including the M26 and X26. This evaluation (referenced in Appendix A of the PSDB's report (PSDB, 2002)) provides the abstract and executive summary from a Defense Science and Technology Laboratory (Dstl) report on the medical effects of TASER use in self-defense and restraint scenarios. A copy of the Dstl report was not available for review for this HERC, but key points from the Executive Summary of the Dstl report (PSDB, 2002) are presented below. It should be noted that the Dstl review was conducted in 2001 and 2002, and may not reflect all of the data available for the current assessment. Nevertheless, in general most of the key points raised in the Dstl review are consistent with the findings of this HERC.

Key conclusions from the Dstl report:

- Data on the distribution of EMI currents in the body are lacking and are needed for understanding potential EMI effects.
- Proposed mechanisms of the desired effect remain speculative, although likely explanations have been developed.
- The data on effects of EMI on pacemakers and implanted medical devices are contradictory and often based on inadequate empirical data. However, the incidence of pacemaker use is low.
- Assessment of EMI impulses cannot rely on direct comparison to U.S. standards based on ventricular fibrillation thresholds (since these standards were derived for different types of electrical devices).
- Experimental work regarding the ability of high-powered EMI devices to induce cardiac arrhythmias is minimal and too limited when considered alone to develop an opinion on cardiac safety. Based on the manufacturer's records of exposures, "it is difficult to judge the incidence of adverse effects from the data but it appears to be very low." (Note: in the Dstl report the term "high-powered TASERs" refers to the M26 and X26). Based on the limited historical data (for "the high-powered TASER") and the limited experimental data, "the high-powered TASERs"

cannot be classed, in the vernacular, as safe." Note: the Dstl report suggests that a precautionary approach be used regarding deployment and indicates that ongoing data collection efforts will strengthen the database for a reassessment regarding cardiac safety.

- "Guidance to TASER users should reflect the likely increased susceptibility to life-threatening cardiac effects in susceptible (i.e., those with acidosis or with concurrent drug use) individuals." Experimental investigations are recommended to resolve the issues, since the data reviewed did not provide adequate evidence for or against an effect of pro-arrhythmic factors on increased susceptibility to EMI devices.
- "There are few reported injuries associated with TASER use. Even falls seem to be controlled and the risk of head injury or long-bone fracture will be low. Ocular trauma is a serious hazard with a low risk and should be controlled with guidance to users. The burns at the current injection point are localized and evidently heal without complication."

6.5 Data gaps, Uncertainties and Research Needs

6.5.1 Effects Identification and Dose-Response

6.5.1.1 Lack of Electrical Dosimetry Approach

It is clear that the electrical properties of a device have a dramatic impact on its physiological effects. Magnitude of the electrical charge, pulse duration, frequency, and other waveform characteristics all impact the spectrum and magnitude of physiological effects. For electrical stun and EMI devices, this fact is clear from comparative studies such as comparative behavioral tests in pigs (Sherry et al., 2003b). The importance of these factors is also evident by the decrease in observed VF thresholds for different pulse repetition rates (Nerheim et al., 2003). Basic understanding of the physiological mechanisms that underlie response to EMI device outputs, as well as the electrical parameters that predict response, are lacking. Therefore, establishing a common metric for predicting physiological effects across varying waveforms is a current research need. The absence of this understanding increases uncertainty in the current assessment. For example, the dose-response data used for estimating human VF thresholds was derived from pigs exposed to the X26 waveforms modified to produce larger currents with electrodes placed directly on the skin. This dose-response approach of using relative TASER output for the X26 as the dose metric was judged reasonable for assessing cardiac effects, since the waveform for the high output test (48x the normal X26 output) is reasonably similar to the normal TASER output. The pulse duration, although increased as the tested multiple was increased, nevertheless, remained sufficiently short to be within the integration time for cardiac effects. This same argument would not hold for assessment of other EMI effects based on nerve stimulation. Furthermore, based on waveform tracings provided by TASER International, the X26 waveform is relatively insensitive to environmental influences (different resistance loads, ground conditions, presence of air gaps), although some quantifiable changes do occur. As compared to the scenario used for the cardiac safety testing used to derive the dose-response model, these alternative conditions reduced the total charge per pulse, and therefore, would likely be less apt to induce both cardiac effects and the intended EMI.

While the dose-response data for VF are available only for the X26, most of the existing human field data used for this assessment reflects use of the M26 TASER waveform. Highly precise predictions of the VF risk of the X26 versus the M26 and under different field conditions cannot be made from the available data. Furthermore, extrapolating the results of this assessment to other waveforms (earlier stun devices or next generation EMI devices) or waveforms as modified by environmental conditions (e.g., spark mode versus dart penetration mode) cannot be completed without further development of the dosimetry. As a result, the comparison of the TASER to existing electrical safety limits was considered of little value for this assessment, and identified the need for a systematic safety standard for EMI devices (see discussion in Nerheim et al., 2003).

6.5.1.2 Temporal and Duration Effects

The quantitative impact of extended periods of continuous stimulation, repeated stimuli, and multiple simultaneous stimuli on the induction of effects is not well characterized. The assessment as presented is most appropriate for evaluating the normal operating mode of the handheld EMI device (single or well-separated serial 5s-duration stimulation periods). As one extrapolates the results to uses that differ greatly from this baseline case, uncertainty is increased. The data are adequate to provide some degree of bounding estimates for temporal responses. For example, as discussed in the dose-response and risk characterization, for large children and adults (other than those that may be especially sensitive), normal output of the EMI devices examined herein is appreciably below expected VF thresholds. However, based on test data in animals, increasing the duration of constant stimulus decreases these thresholds significantly. Increasing the stimulus duration from 5 seconds to 30 seconds (reported as unpublished data from TASER International, personal communication, 2003) reduced the VF threshold by more than half. Without additional data, a quantitative duration-response relationship cannot be derived. Some field cases have involved constant exposures of this duration that did not result in a human VF response, but the number of cases is too small to make conclusive judgments about human safety under these conditions. As an upper bound, it is reasonable to conclude that constant stimulus durations that exceed a minute or two are likely undesirable since they would enhance risks related to impaired respiration and increased risk of rhabdomyolysis. Data are not adequate to determine the required number and duration of break periods to minimize these risks when extended periods of control are needed. Additional duration-response data in controlled animal studies would be desirable to answer these questions.

6.5.1.3 *Human Variability in Sensitivity to VF Response*

The degree of human variability in sensitivity to EMI waveforms has not been directly measured. In the absence of these data, information on human variability of responses to electrical stimuli was used to make these judgments. As discussed above, the VF risk to large children and adults is likely to be very small or non-existent given the margin between normal EMI device operating output and charges that induce VF in pigs of comparable body weight. However, relative sensitivity of very small children, the elderly, and individuals possessing potentially mitigating factors such as underlying heart disease or drug intoxication, for example, is uncertain. Data collection in these populations would enhance assessment certainty.

6.5.1.4 *Effects on Reproduction and Development*

Current data are not sufficient to determine whether exposure during pregnancy can cause abortion or other developmental toxicity. Exposures during pregnancy do not appear to cause abortion/miscarriage based on the totality of the admittedly meager evidence. No data for the M26 or X26 were available to determine whether direct exposure of the testes would have any effect on male reproductive capacity (spermatogenesis), but based on physiological principles and use of other electrical devices, no effect is expected. No data were available to determine whether exposure to EMI could affect the fetus early in pregnancy. Based on the presumption that the electrical output in EMI would need to reach the uterus to induce abortion or adverse fetal effects, it is important to understand the current paths of the EMI current. A recommended tool to answer this question would be to employ a whole body impedance model to characterize the EMI current path with varying dart placements. This research approach would also be helpful in evaluating the plausibility of cardiac and seizure risks.

6.5.1.5 *Seizure Potential Review*

Data are inadequate to determine whether an increased risk of seizure exists following EMI device impacts to the head. Only limited field incidents have been reported (none of which resulted in a confirmed seizure). Published thresholds (reviewed in Reilly, 1998) for this effect are lower than the electrical output of the EMI devices, suggesting that there may be some potential for seizure induction. However, it is important to note that the seizure threshold data reviewed different waveforms. In addition, other neuronal stimulation events in the brain have lower thresholds than the seizure induction threshold. Repeated stimulation above these excitation thresholds may further modify subsequent thresholds for seizures or affect central functioning, to include memory and other cognitive processes. Furthermore, some seizure-prone individuals may have greater susceptibility to impacts of secondary stimuli. No direct testing data for seizure potential or central impairment were identified, and are a key research need.

6.5.1.6 Absence of Independent Injury Incidence Data

Several key effects can best be harvested from field incidence data, rather than from estimation from first principles. These include incidence rates for severe fall injuries and eye strikes. For key effects such as fall injuries and eye strikes where published probabilities were not identified, expert judgment supplemented with database mining from TASER International's database was used to estimate these risks. However, for these effects, other approaches such as estimations based on dart strike probabilities or input from subject matter experts provided results that were consistent with each other.

6.5.2 Exposure Assessment

There are several key sources of uncertainty in the exposure assessment for the EMI HERC that are described below.

6.5.2.1 Demographics of the Target Population

The assessment assumes that the target population characteristics will be the same as the population that historically has been targeted for EMI as part of domestic law enforcement operations. This population is predominately male and includes very few children under the age of 18 and no children under the age of 9. If the target population is younger, the risks may be different. In many parts of the world (especially Asia, sub-Saharan Africa, and parts of Latin and South America), military use will have to anticipate child soldier targets. In some ongoing conflicts, for example, as many as 20% of combatants are child soldiers.

6.5.2.2 Use of Data from TASER International

The analysis relies on the data collected by TASER International. The TASER International database contains a large number of records from a wide variety of users (TASER International, personal communication, 2003). However, the records are not a statistically representative sample and are potentially influenced by a number of sources of bias. For example, the data are voluntary, and thus reflect those individuals who were disposed to respond. This could lead to an over sampling of individuals who were positively disposed to the device and thus introduces a bias toward positive results. This could also lead to an over sampling of individuals who had a problem and were motivated to complain and thus result in an over reporting of problems. It is unclear which of these or other potential biases have the greatest impact on the reports. The completion and reliability of the individual entries in the survey form are also affected by the voluntary nature of the survey. Individuals are more likely to answer questions that are easy to answer (e.g., number of darts fired) than those that require additional effort or are more susceptible to cognitive error and uncertainty (e.g., distance to target).

TASER International has a program of providing a free cartridge in exchange for each report. This will result in a bias to those police departments that place a higher value on obtaining free cartridges than those that do not. Finally, the data are censored by the decision of certain large police departments not to release the data requested in the survey.

Because of these sources of bias, the results of the survey must be viewed with some caution. Factors related to success of use are of concern since these factors are most likely to be influenced by bias.

6.5.2.3 Probability of Completing Circuit

While the report attempts to derive an estimate of the probability of completing a circuit based on the user report of "successful use" from the TASER International database, the estimate of completion of a circuit remains uncertain. However, the data suggesting the induction of the intended physiological effect (muscle contraction) is consistent with the reported field effectiveness data.

Another source of uncertainty is the lack of data on the distribution of dart strike locations on the face. In this analysis, the locations of strikes were assumed to be randomly distributed. If the locations occur more frequently at the lower portion of the face, then the risk of eye strikes and seizures may be greatly overestimated by the approach used in this HERC.

6.5.2.4 Research Data Gaps and Future Needs

The following table (Table 15) is a summary of the research data and future needs.

Table 15. Research Data and Future Needs

• Develop a statistically rigorous database of field incidence exposures (target demographics, TASER International database) • Develop a common metric for predicting physiological effects of exposure • Determine the parameter of merit for EMI waveform (total pulse charge, body current, net charge, charge in positive phase) • Develop a dosimetry technique to compare existing and future EMI waveforms • Determine the threshold for ventricular fibrillation/asystole • Determine the threshold for seizures • Determine the effect of scale (body size, mass, age, dart location/contact) on EMI response • Develop a dose response for EMI intended effects (varying pulse amplitude, pulse duration, pulse form, inter-pulse interval) • Determine the effect of drugs (e.g., ethanol, cocaine, phencyclidine) on the dose response to EMI • Determine the effect of existing morbidity (e.g., cardiac arrhythmias, epilepsy) on the dose response to EMI • Determine the effect of increasing the duration of stimulation • Determine the effect of EMI on respiration • Develop 3D Impedance modeling • Determine the impact of TASER stimuli on pregnancy & reproduction • Examine data applicability and needs for novel applications such as remote or sensor-activated non-man-in-the-loop devices

6.6 Risk Characterization Summary

This HERC presents a characterization of the likelihood of intended and unintended effects from the use of the M26 and X26 TASER. Overall, the results indicate that the use of the M26 and X26 TASER as intended would generally be effective in inducing the desired EMD effect without presenting a significant risk of unintended severe effects. Although likely to be uncommon, severe unintended effects might occur. In some cases, key data gaps and uncertainties preclude the development of effects and risk probabilities. These overall conclusions regarding effectiveness and risk are consistent with the current experience with the M26 and X26 TASERs in the field, limited empirical data, as well as human effects or safety assessments developed by others. Furthermore, an additional aspect of the analysis is the comparative risk. Analyses provided by law enforcement agencies indicate that increased use of the M26 or X26 TASER may likely decrease the overall injury rate of both police officers and suspects in conflict situations when compared to alternatives along the use of force continuum.

Information developed in the dose-response and exposure assessment was integrated to provide quantitative or qualitative estimates of effectiveness and risk probabilities. The likelihood of various effects can be summarized as follows:

- Complete EMD - 74% to 52% (decreasing with distance)
- Partial EMD - 6% to 4% (decreasing with distance)
- Eye strikes - 0.01% to 0.04% (increasing with distance)
- Fall injuries - 0.15% to 0.10% (decreasing with distance)
- Seizure - 0.7% is the upper bound estimate based on head strike probabilities and a worst-case assumption that all head strikes in the region of the brain result in an electrical exposure that exceeds the seizure threshold.
- Ventricular fibrillation - VF is not expected to occur in otherwise healthy adult populations, although data are too limited to evaluate probabilities for susceptible populations or for alternative patterns of exposure.
- EMI device exposures induce other effects of minimal severity (e.g., burns or lacerations) when successfully employed. These effects are of minimal severity and not further analyzed.
- Some effects of potential concern are too uncertain or lacked sufficient data to develop probability estimates.

Several areas require further evaluation or data collection before a conclusion can be reached regarding potential effects or risks. Key uncertainties and data gaps include:

- Better understanding of the biological basis for EMI effects, appropriate dosimetry, and the impact of environmental variables on the induction of effects are needed to predict response probabilities under varying conditions, when temporal patterns of exposure change, and for assessment of risks for new EMI waveforms.
- Available data are too limited to adequately quantify potential risks of ventricular fibrillation in susceptible populations, or for seizures, cognitive, reproductive, or developmental effects.
- Incidence data for some infrequent events are limited. In many cases effect probabilities relied on a database of reports compiled by TASER International. This database is not a statistically representative sample and is potentially influenced by a number of sources of bias. Furthermore, in some cases the design of the report forms did not result in the collection of all the relevant information needed for the exposure assessment (e.g., whether a circuit was established and specific dart strike locations on the head were not generally available).
- The assessment assumed that the target population for the use of EMI devices will be the same as the population that historically has been controlled by EMI devices as part of law enforcement. This population is

predominately male and includes very few children under the age of 18 and no children under the age of 9. The frequency of child soldiers in conflicts around the world is expected to increase, and accordingly, there will need to be a better understanding of the biological mechanisms and risks of EMI devices and other NLWs (Lt Col Drummond, personal communication, 2004).

The focus of this report was on EMI technology that may be incorporated into non-lethal weapons developed or new COTS products, and specifically, the TASER International M26 and X26. These weapons are effective for their intended use, but also cause several unintended effects. Although sufficient information does not exist to characterize the risk of all potential effects, available data indicate that key effects have been addressed. Additional efforts at characterizing the risk of these key effects with scenarios related to the use of these weapons in military operations would be most helpful as these weapons gain additional use, visibility, and public interest/concern.

7 Other EMI Implications

The evaluations presented herein specifically address the TASER M26 and X26 handheld units. Safety concerns and effectiveness issues will be different for applications that are triggered remotely or by sensors in stand-alone devices that have no man in the loop. Trajectories will be different, duration of on/off time will require further investigation, and information on the COE and associated risks will need to be established. To the extent future systems use present technologies (darts, for example), some effects are likely to remain quite similar (lacerations, for example). In any case, such future EMI devices will drive the need for focused human effectiveness and risk characterization and research.

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