Test Summary
Test File # 237
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U.S. ARMY MEDICAL RESEARCH & MATERIEL COMMAND

TEST BRANCH

ENVIRONMENTAL TESTING: JOINT OPERATIONAL EVALUATION OF FIELD TOURNIQUETS (JOEFT)

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EXECUTIVE SUMMARY

Introduction:

As part of a Joint Operational Evaluation of Field Tourniquets (JOEFT) to determine the most suitable joint product of choice (JPOC), five tourniquet candidates were submitted to the USAMRMC Test Branch for environmental testing. This testing was designed to evaluate each tourniquet's continued ability to perform as designed following exposure to environmental conditions likely to be encountered on the battlefield.

Methods:

Baseline tourniquet performance data was obtained for each of the five submitted tourniquet candidates prior to environmental exposure using the HapMed tourniquet training mannequin. The time required for tourniquet application, the tourniquet pressure exerted on the leg, and the number of windlass turns or ratchets was documented for each application event. Samples of each of the five tourniquets, while in their non-operational configurations, were then subjected to environmental conditions including: high and low temperature, dust and sand, salt fog, immersion, and freeze/thaw. Following environmental exposure, the performance of each tourniquet was assessed using the HapMed mannequin, and these results compared to baseline tourniquet performance.

Results:

The environmental exposures did not adversely affect any of the five tourniquet candidate's ability to continue to operate as designed. None of the devices sustained visible damage, and all the tourniquets successfully performed the post-exposure validation procedure. The time required for tourniquet application, the tourniquet pressure exerted on the leg, and the number of windlass turns or ratchets remained consistent with each tourniquet's baseline data.

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1.0 INTRODUCTION

1.1 TEST OBJECTIVE

The U.S. Army Medical Materiel Agency (USAMMA) requested the U.S. Army Medical Research and Materiel Command (USAMRMC) Test Branch conduct environmental testing on five candidate field tourniquets. This testing was designed to identify the capabilities and limitations of the candidate tourniquets when exposed to conditions encountered in a military environment.

Tourniquets under Test	Tourniquet Type
1) [redacted]	[redacted]
2) [redacted]	[redacted]
3) [redacted]	[redacted]
4) [redacted]	[redacted]
5) Tactical Mechanical Tourniquet	Windlass

1.2 PROGRAM BACKGROUND

Extremity limb tourniquets are a major reason why mortality rates have gone down in current conflicts compared to those from the past. These devices are in the Individual First Aid Kit, Medic Care Bag, Ground and Air Medical Equipment Sets (MES), as well as other MES kits. In order to determine the most suitable joint product of choice (JPOC), a Joint Operational Evaluation of Field Tourniquets (JOEFT) was established. Increasing medical device standardization is intended to increase mission effectiveness, and patient safety, while decreasing procurement efforts and costs.[1]

The USAMMA, as a component of the JOEFT, submitted the five candidate tourniquets to the MRMC Test Branch for environmental testing. Environmental testing is designed to determine the robustness and efficacy of medical devices in their intended environments. It is imperative that reliable, independent Department of Defense (DoD) Test and Evaluation (T&E) be performed on medical devices intended to be used in military field conditions to determine any operational and storage constraints. This includes standard tests such as high/low temperature testing which are outlined in MIL-STD-810G (Environmental Engineering Considerations and Laboratory Tests).

2.0 DESCRIPTIONS OF TOURNIQUETS UNDER TEST

2.1 [redacted]

[redacted]

2.2 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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2.3 [redacted]

[redacted]

2.4 [redacted]

[redacted]

2.5 TACTICAL MECHANICAL TOURNIQUET (Alphapointe™; Kansas City, MO)

The Tactical Mechanical Tourniquet (TMT) is a windlass tourniquet, using a hooking clasp to connect the two ends of the tourniquet, eliminating the need to thread the strap. Once applied, the windlass applies secondary pressure and is secured with a locking clip.

Tourniquet Specifications:

Dimensions, Unpackaged:

- 5.1 cm W x 98.6 cm L (2.0" x 38.8")
- Effective Length: 90.2 cm (35.5")
- Weight: 80.2 grams (2.8 oz.)

Dimensions, Packaged:

- 7.1 cm W x 12.4 cm L x 3.8 cm H (2.8" x 4.9" x 1.5")
- Weight: 85.9 grams (3.0 oz.)

FIGURE 5: Tactical Mechanical Tourniquet

3.0 TOURNIQUET EVALUATION TEST METHODS

3.1 BASELINE TOURNIQUET FORCE MEASUREMENTS

Prior to environmental testing, three samples of each type of tourniquet under test were used to establish each tourniquet's baseline performance.

HapMed Instrumented Leg

The HapMed Instrumented Leg (Figure 6, calibrated 6/29/2015) simulates the actual torque required to stanch bleeding from an extremity wound. Sensors within the device gauge the amount of pressure being applied and LED lights indicate when bleeding slows and occlusion is reached.[3] While using the HapMed, the device's tourniquet application area was marked to ensure consistent and proper placement.

During each tourniquet application event, a tourniquet was placed around the leg IAW its manufacturer instructions, but not tightened. The HapMed's "start" button was then pressed, initiating its tourniquet application timer. In order to apply each tourniquet to the leg with the same initial pressure, an Imada Pound Force Gauge Model DS2-220 (calibrated: 8/1/2014) was attached to the tourniquet strap and the initial tourniquet strap pressure was measured at 40 lbs. prior to engaging the tourniquet's ratchet or windlass.

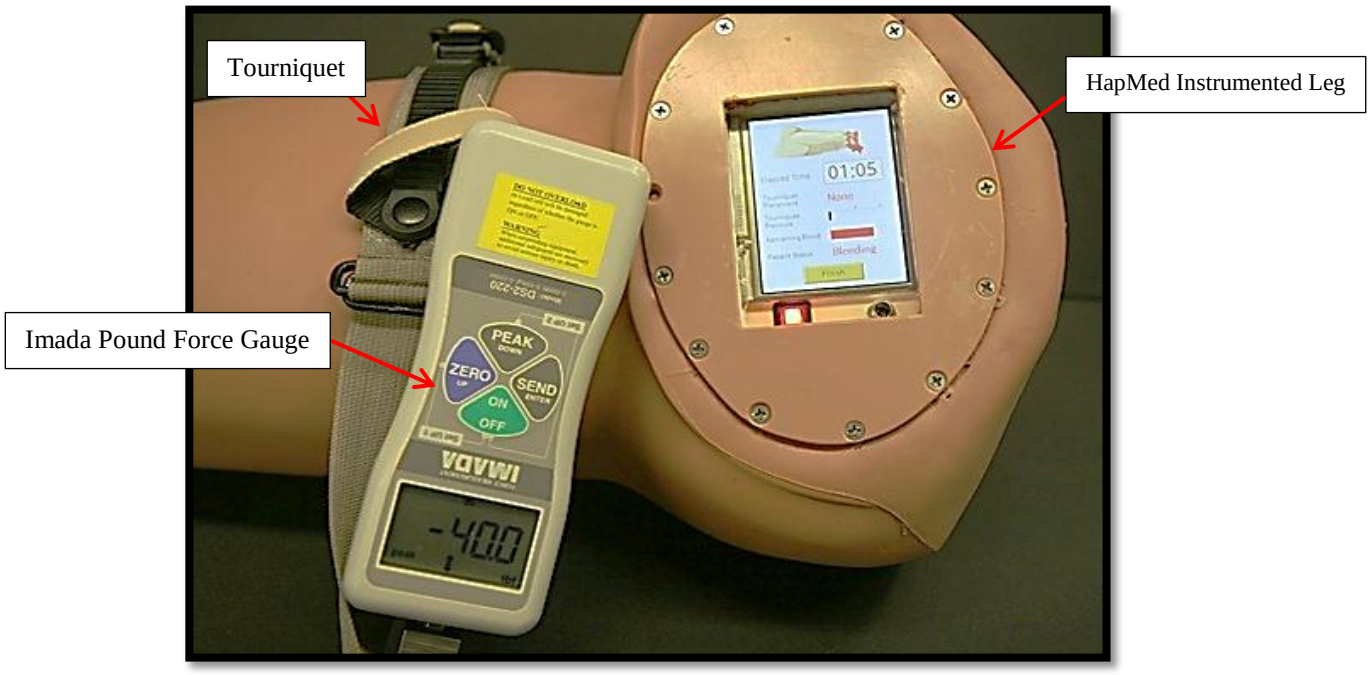

FIGURE 6: Tourniquet Application on HapMed

The tourniquet was then engaged using its ratchet or windlass until the HapMed's touchscreen display indicated the tourniquet placement was "good" and the tourniquet pressure indicator bar turned green (Figure 7). The HapMed was programmed to determine a tourniquet's pressure as "good" when it met or exceeded 250 mmHg within an allotted 330-second tourniquet application time.

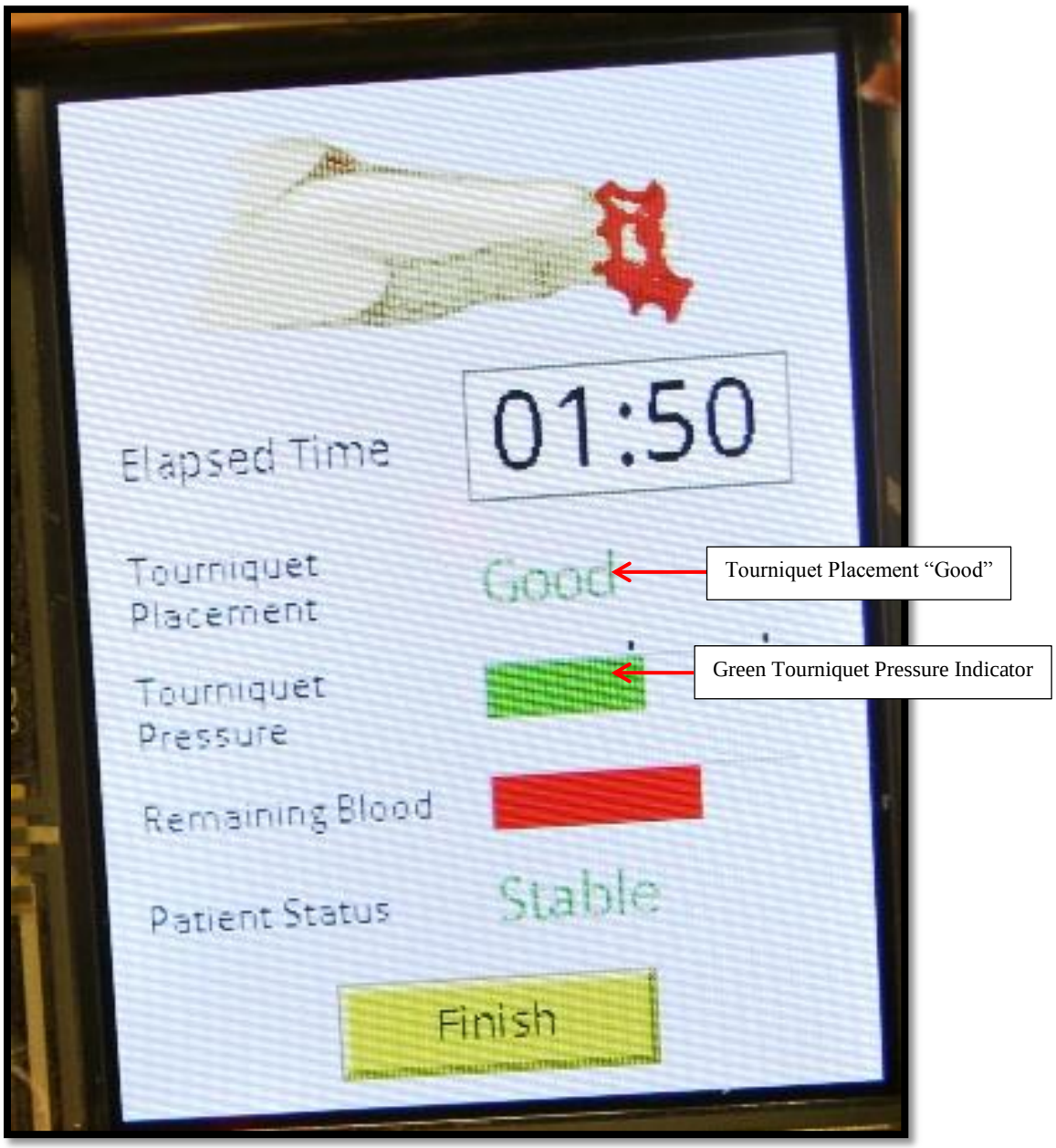

FIGURE 7: "Good" Tourniquet Application on HapMed Display

The "finish" button on the touchscreen was then pressed and the "after action review" screen displayed (Figure 8). This screen displayed the tourniquet pressure in mmHg, and the time elapsed during the tourniquet application event. All "good" tourniquet pressure readings met or exceeded 250 mmHg, within the 330-second application time. The "time to occlude", the tourniquet pressure (in mmHg) exerted on the leg, and the number of windlass turns (in ½ turns) or ratchets was documented for each application event.

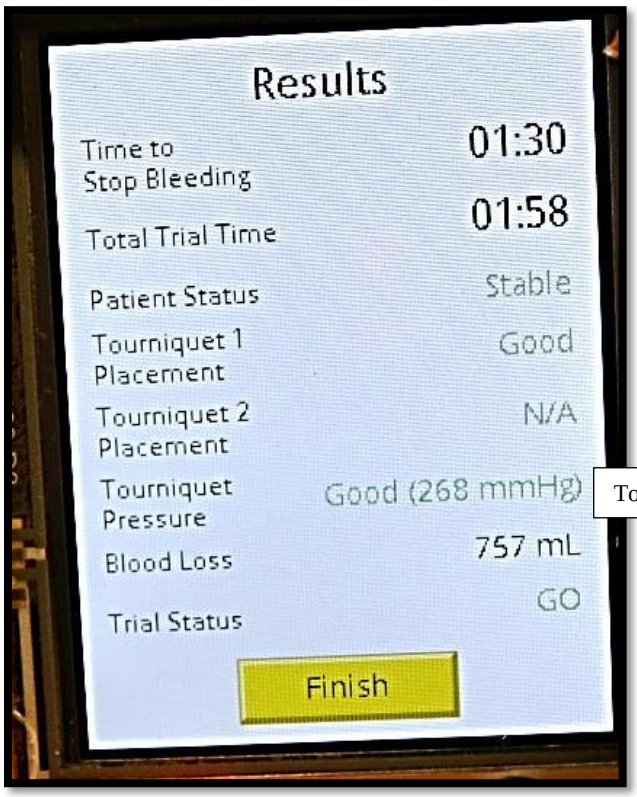

FIGURE 8: HapMed "After Action Review" Screen

Note: The "time to occlude" data, or "time to stop bleeding" by each HapMed tourniquet trial indicated only the time required to tighten each tourniquet around the leg. The HapMed's timer was initiated before the tourniquet was tightened (prior to the Imada pound force measurement) and stopped when the "Tourniquet Pressure" indicator bar on the HapMed's display turned green. The time needed to apply the tourniquet around the leg was not documented, because this time would probably decrease as the tester's application skill increased throughout the test series. Because these times reflected tourniquet tightening only, this "occlusion" data is not meant to be compared to application times obtained during outside testing, only compared to occlusion data obtained during this test.

3.1.1 TOURNIQUET BASELINE TEST RESULTS

The baseline tourniquet force measurement procedure was performed on three of each type of tourniquet while exposed to ambient 21.7˚C (71˚F) conditions. The measurements documented in Table 1 below are the average results of three of each type of tourniquet.

TABLE 1: Baseline Validation Test Results

Device	**HapMed Pressure (mmHg)**	**# of Windlass Turns or Ratchets**	**Time to Occlude** (seconds)
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
TMT	258.0	2.0 (½ turns)	32.7
[redacted]	[redacted]	[redacted]	[redacted]

3.2 VALIDATION PROCEDURE

The validation procedure was intended to evaluate each tourniquet's continued ability to perform as designed following environmental exposure. This process was conducted and documented after each test exposure.

1) Each tourniquet device was first visually inspected.
2) HapMed Leg Test:

   Each tourniquet was then applied to the HapMed leg and the tourniquet pressure exerted on the leg was measured.

   - *"Successful" Validation Description*: A tourniquet application was documented as "successful" when the pressure exerted met or exceeded 250 mmHg within the 330-second allotted programmed HapMed trial time. The time required for tourniquet application, the tourniquet pressure (in mmHg) exerted on the leg, and the number of windlass turns (in ½ turns) or ratchets was documented for each successful application event.
   - *"Unsuccessful" Validation Description*: A tourniquet application was documented as "unsuccessful" if the HapMed results screen displayed the tourniquet pressure did not meet the 250 mmHg threshold within the programmed 330-second allotted application time. In this case, the tourniquet was classified as having "failed" the validation procedure and the tourniquet pressure achieved (if any) within the 330 second timed attempt was documented.

4.0 ENVIRONMENTAL TEST SERIES

Three tourniquets of each type were subjected to each environmental exposure, no tourniquet was reused or subjected to more than one environmental test (n=3).

4.1 TEMPERATURE TESTING

Temperature tests were conducted because the test item may potentially be used in geographic areas where climatic conditions induce high or low temperatures within the test item. These tests determine if the test item can survive extreme variations in temperature during transportation and storage without experiencing physical damage or deterioration of performance. High and low temperatures can temporarily or permanently impair the performance of the test item by changing the physical properties or dimensions of the material(s) from which it is made. High temperature exposure may cause discoloration, warping or cracking of organic materials while low temperature exposure may result in materials becoming hard or brittle and condensation and freezing of water inside the test item.

4.1.1 HIGH TEMPERATURE, 71˚C, NON-OPERATIONAL TEST

The Environtronics Thermal and Humidity Test Chamber Model EH-18-2-2 (calibrated: 10/7/2014) was set to 71˚C (160ºF), and the unpackaged candidate tourniquets placed in the chamber, exposed to the high temperature, for 48 hours. Following the test exposure, the tourniquets were removed from the test chamber, stabilized at room temperature, visually inspected, and subjected to the post-test validation procedure.

FIGURE 9: High Temperature, Non-Operational Test

4.1.2 HIGH TEMPERATURE, 71˚C, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 2 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 30.3 – 43.0 seconds, well under the 330-second allotted application time.

TABLE 2: High Temperature, 71˚C, Non-Operational Test Results

Device	**HapMed Pressure** (mmHg)		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	High Temp. Average	Baseline Average	High Temp. Average	Baseline Average	High Temp. Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	283.3	258.0	2.3 (½ turns)	2.0 (½ turns)	43.0	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.1.3 LOW TEMPERATURE, -18˚C, NON-OPERATIONAL TEST

The Freezer Link Model 34-15A Laboratory Freezer (calibrated: 9-12-2014) was set to -18˚C (0^{o}F), and the unpackaged candidate tourniquets placed in the chamber, exposed to the low temperature, for 48 hours. Following the test exposure, the tourniquets were removed from the test chamber, stabilized at room temperature, visually inspected, and subjected to the post-test validation procedure.

FIGURE 10: Low Temperature, Non-Operational Test

4.1.4 LOW TEMPERATURE, -18˚C, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 3 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 27.7 – 41.3 seconds, well under the 330-second allotted application time.

TABLE 3: Low Temperature, Non-Operational Test Results

Device	**HapMed Pressure (mmHg)**		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	Low Temperature Average	Baseline Average	Low Temperature Average	Baseline Average	Low Temperature Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	263.7	258.0	2.0 (½ turns)	2.0 (½ turns)	41.3	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.2 DUST AND SAND TESTING

The Dust and Sand Test Method applies to all medical items that may be exposed to the effects of a sand and dust-laden atmosphere. This procedure was performed to ascertain the ability of test items to resist the effects of sand and dust particles which may penetrate test items and cause adverse clogging or other malfunctions.

4.2.1 SETTLING DUST AND SAND, NON-OPERATIONAL TEST

The unpackaged tourniquets were placed in the Bemco Model AF-27 Dust Chamber. All-purpose sand #1152 was added to Fuller's Earth and the 50% to 50% mixture dispersed around the test items at 70 psi for one minute. After dispersal, the dust/sand mixture was allowed to settle for one hour. The test items were then brushed off, visually inspected, and subjected to the post-test validation procedure.

FIGURE 11: Settling Dust and Sand, Non-Operational Test

4.2.2 SETTLING DUST AND SAND, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 4 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 32.3 – 43.3 seconds, well under the 330-second allotted application time.

TABLE 4: Settling Dust and Sand, Non-Operational Test Results

Device	**HapMed Pressure** (mmHg)		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	Dust & Sand Test Average	Baseline Average	Dust & Sand Test Average	Baseline Average	Dust & Sand Test Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	286.0	258.0	2.0 (½ turns)	2.0 (½ turns)	42.7	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.3 SALT FOG TESTING

The Salt Fog Test is conducted to determine the effectiveness of protective coatings and finishes on materials. It is also used to determine the effects of salt deposits on the physical aspects of materiel. The Salt Fog Test method is applicable to test items which may be exposed to salt-laden environments.

4.3.1 SALT FOG, NON-OPERATIONAL TEST

The unpackaged tourniquets were placed into the Singleton Model 22 Salt Fog Chamber (calibrated: 9/25/14). The chamber was prepared with a 5% salt solution @ 90^{o}F. The rate of salt fog production was 6 gallons (over 48 hours) and the air source regulated to 15 psi and 50 CFM. The duration of the test was 48 hours. Following the test, the test items were removed from the chamber, visually inspected, allowed to dry for 48 hours, and subjected to the post-test validation procedure.

FIGURE 12: Salt Fog, Non-Operational Test

4.3.2 SALT FOG, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 5 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 31.3 – 43.3 seconds, well under the 330-second allotted application time.

TABLE 5: Salt Fog, Non-Operational Test Results

Device	**HapMed Pressure** (mmHg)		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	Salt Fog Test Average	Baseline Average	Salt Fog Test Average	Baseline Average	Salt Fog Test Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	261.7	258.0	2.3 (½ turns)	2.0 (½ turns)	43.3	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

4.4 IMMERSION TESTING

The immersion test was performed to determine if materiel can withstand immersion or partial immersion in water (e.g., fording), and continue to operate as required.

4.4.1 IMMERSION, NON-OPERATIONAL TEST

The unpackaged tourniquets were submerged in one meter (3.3 feet) of water for a 30-minute immersion period. Following the test, the test items were removed from the immersion tank, visually inspected, and subjected to the post-test validation procedure.

4.4.2 IMMERSION, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 6 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 30.0 – 43.0 seconds, well under the 330-second allotted application time.

TABLE 6: Immersion, Non-Operational Test Results

Device	**HapMed Pressure** (mmHg)		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	Immersion Test Average	Baseline Average	Immersion Test Average	Baseline Average	Immersion Test Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	253.7	258.0	2.7 (½ turns)	2.0 (½ turns)	38.3	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.5 FREEZE/THAW TESTING

Freeze/Thaw testing was performed to determine if materiel can withstand being moved from a warm environment to a cold environment (freeze) and then back to the warm environment, inducing condensation (free water).

4.5.1 FREEZE/THAW, NON-OPERATIONAL TEST

The unpackaged tourniquets were placed in the Environtronics Thermal and Humidity Test Chamber Model EH-18-2-2 (calibrated: 10-7-2014) that has been pre-conditioned at standard ambient temperature 22˚C (72˚F) and a relative humidity of 90 ± 5%. These conditions were maintained until the test item's temperature has stabilized for one hour. The test items were then transferred to the Freezer Link Model 34-15A Laboratory Freezer (calibrated: 9-12-2014) that was pre-conditioned at -10°C (14°F). The test item's temperature was then stabilized at this temperature for one hour. Following the test exposure, the tourniquets were removed from the test chamber, stabilized at room temperature, visually inspected, and subjected to the post-test validation procedure.

4.5.2 FREEZE/THAW, NON-OPERATIONAL TEST RESULTS

The tourniquets under test successfully completed the post-test validation procedure. None of the tourniquets were visibly damaged during the test exposure. The average test results for each tourniquet type are documented in Table 7 below.

Every tourniquet application event:

1) Produced tourniquet pressure results over 250 mmHg,
2) Produced "green" tourniquet pressure indicator readings,
3) Produced times to occlude between 29.0 – 40.0 seconds, well under the 330-second allotted application time.

TABLE 7: Freeze/Thaw, Non-Operational Test Results

Device	**HapMed Pressure** (mmHg)		**# of Windlass Turns or Ratchets**		**Time to Occlude** (seconds)	
	Freeze/Thaw Test Average	Baseline Average	Freeze/Thaw Test Average	Baseline Average	Freeze/Thaw Test Average	Baseline Average
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TMT	271.7	258.0	2.0 (½ turns)	2.0 (½ turns)	40.0	32.7
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.0 References

1) Proposal Title: **"**Joint Operational Evaluation by U.S. Military Servicepersons for Extremity Tourniquet Use in Simulated Out-of-Hospital Care, Mr. Greggory J. Housler, Proposal ID Number: D6.7_14_C2_I_14_J9_1087.

2) MIL-STD 810G, Subject: Environmental Engineering Considerations and Laboratory Tests, October 2008.

3) Naval Medical Research Unit San Antonio, "Joint Operational Evaluation of Field Tourniquets (JOEFT) – Phase II, NAMRU-SA REPORT #2014-09**,** Rene Alvarez, PHD, D. Duane Cox, and Roy Dory, MS.

5.0 POINTS OF CONTACT

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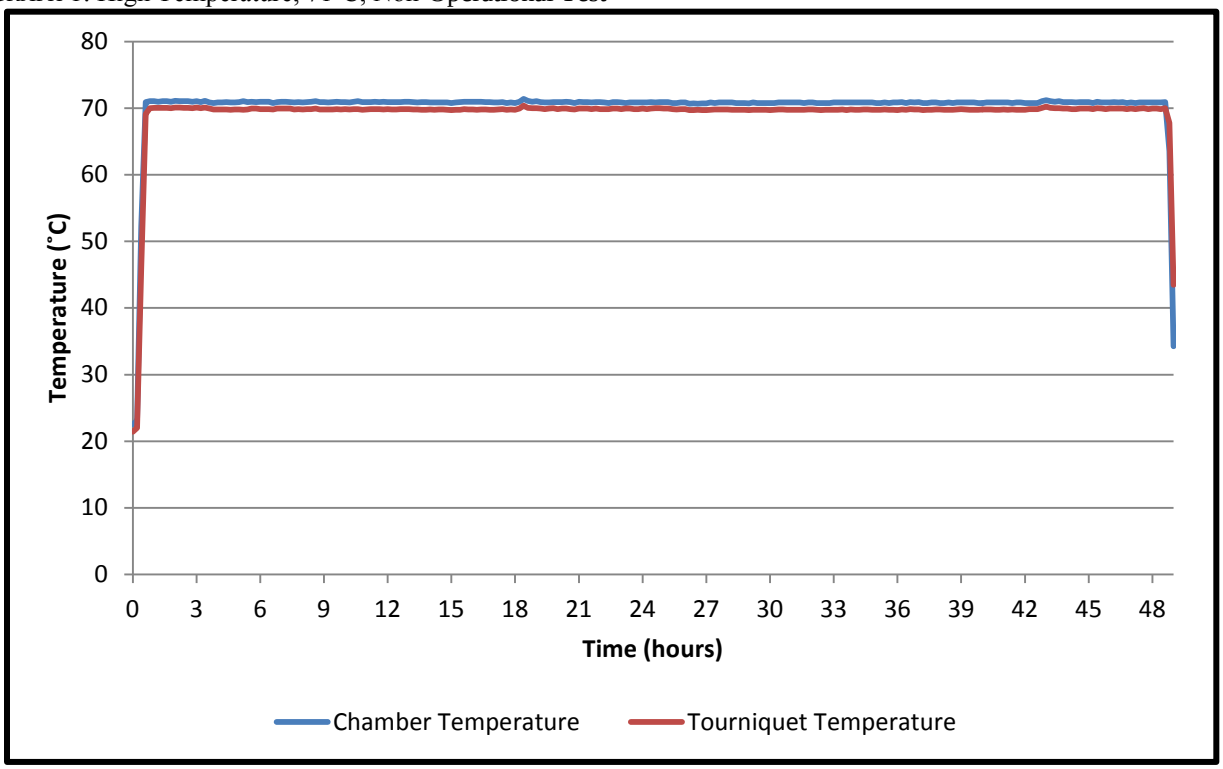
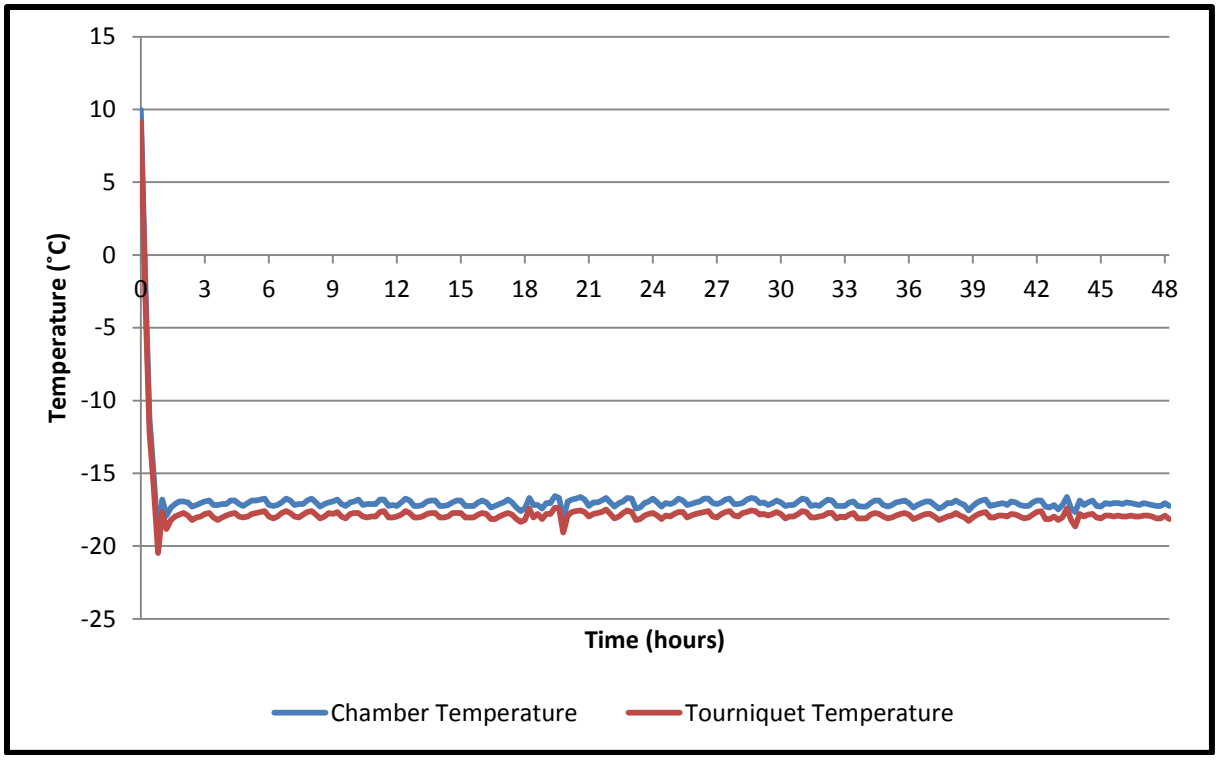
APPENDIX A:

THERMAL TEST GRAPHS

GRAPH 1: High Temperature, 71˚C, Non-Operational Test



GRAPH 2: Low Temperature, -18˚C, Non-Operational Test



GRAPH 3: Freeze/Thaw, Non-Operational Test