Appendix-A

MARAA

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Safe-to-Fly Recommendation

DEPARTMENT OF THE AIR FORCE
HUMAN SYSTEMS GROUP (AFMC)
BROOKS CITY-BASE TEXAS

OCT 2 8 2005

MEMORANDUM FOR SEE DISTRIBUTION

FROM: HSG/CD
7980 Lindbergh Landing
Brooks City-Base TX 78235-5119

SUBJECT: Safe-to-Fly (STF) Recommendation for the Sorenson Medical ambIT MARAA (P/N 61755.06) and "Standard" (P/N 220262) PCA Infusion Pump

1. We recommend STF certification of the ambIT MARAA and "Standard" Patient-Controlled Analgesia (PCA) infusion pump on all U. S. Air Force fixed-wing aeromedical evacuation cargo aircraft. Testing demonstrated the equipment will not cause adverse effect to the aircraft or patient. Testing results indicated operational suitability and effectiveness risks as presented in attachment 2. This recommendation is based on completion of testing by the Human Systems Group Aeromedical Testing Branch.

2. The using organization shall assume Operational Safety, Suitability, and Effectiveness responsibility, as directed by AFI 63-1201, Section 2.9. Configuration management resides with the vendor; therefore, the using organization must address future issues with the vendor. The using organization must also address procurement, sustainment logistics and maintenance directly with the vendor.

3. My point of contact is 1Lt Dominic Manaligod at DSN 240-3124, commercial (210) 536-3124 or dominic.manaligod@brooks.af.mil.

BRITT COVINGTON
Deputy Director

2 Attachments:
1. HSG/TFL Technical Report
2. Operational Suitability and Effectiveness Risks for the ambIT MARAA and "Standard" PCA Infusion Pump

C-17 Globemaster III

MARAA

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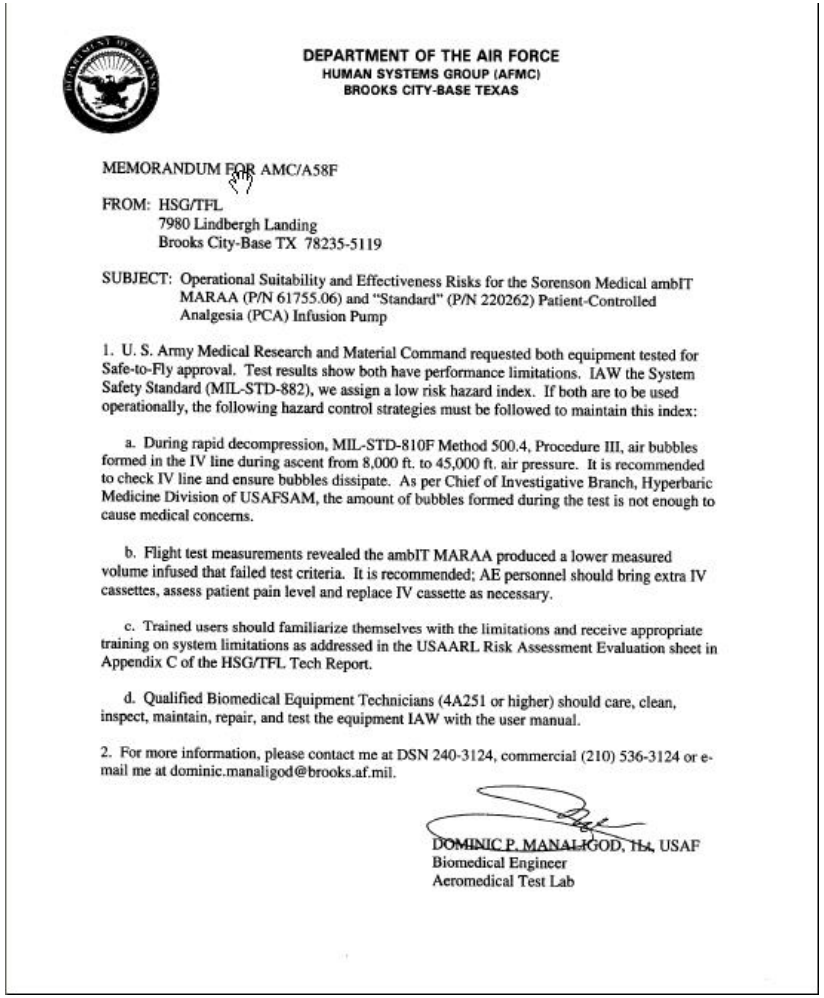
Operational Suitability & Effectiveness Risks:



DEPARTMENT OF THE AIR FORCE
HUMAN SYSTEMS GROUP (AFMC)
BROOKS CITY-BASE TEXAS

MEMORANDUM FOR AMC/A58F

FROM: HSG/TFL
7980 Lindbergh Landing
Brooks City-Base TX 78235-5119

SUBJECT: Operational Suitability and Effectiveness Risks for the Sorenson Medical ambIT MARAA (P/N 61755.06) and "Standard" (P/N 220262) Patient-Controlled Analgesia (PCA) Infusion Pump

1. U. S. Army Medical Research and Material Command requested both equipment tested for Safe-to-Fly approval. Test results show both have performance limitations. IAW the System Safety Standard (MIL-STD-882), we assign a low risk hazard index. If both are to be used operationally, the following hazard control strategies must be followed to maintain this index:

a. During rapid decompression, MIL-STD-810F Method 500.4, Procedure III, air bubbles formed in the IV line during ascent from 8,000 ft. to 45,000 ft. air pressure. It is recommended to check IV line and ensure bubbles dissipate. As per Chief of Investigative Branch, Hyperbaric Medicine Division of USAFSAM, the amount of bubbles formed during the test is not enough to cause medical concerns.

b. Flight test measurements revealed the ambIT MARAA produced a lower measured volume infused that failed test criteria. It is recommended; AE personnel should bring extra IV cassettes, assess patient pain level and replace IV cassette as necessary.

c. Trained users should familiarize themselves with the limitations and receive appropriate training on system limitations as addressed in the USAARL Risk Assessment Evaluation sheet in Appendix C of the HSG/TFL Tech Report.

d. Qualified Biomedical Equipment Technicians (4A251 or higher) should care, clean, inspect, maintain, repair, and test the equipment IAW with the user manual.

2. For more information, please contact me at DSN 240-3124, commercial (210) 536-3124 or e-mail me at dominic.manaligod@brooks.af.mil.

DOMINIC P. MANALIGOD, Ms, USAF
Biomedical Engineer
Aeromedical Test Lab

1. Air bubbles
   - It is recommended to check IV line and ensure all bubbles dissipate during rapid decompression.
2. Volume infused
   - Recommend AE personnel should bring extra IV cassettes, assess pts pain levels, and replace IV cassette as necessary.

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Airworthiness Release

DEPARTMENT OF THE ARMY
US ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND
AVIATION AND MISSILE RESEARCH, DEVELOPMENT, AND ENGINEERING CENTER
5400 FOWLER ROAD
REDSTONE ARSENAL, ALABAMA 35898-5000

REPLY TO ATTENTION OF

25 Oct 05 | R-3
23 Nov 04 R-2
30 Apr 04 R-1
20 Feb 04

AMSRD-AMR-AE-U

MEMORANDUM FOR

US Army Aeromedical Research Laboratory (MCMR-UAD), Post Office Box 620577, Fort Rucker, AL 36362-0577
Utility Helicopters Project Office, (SFAE-AV-UH), Redstone Arsenal, AL 35898-5000

SUBJECT: Airworthiness Release (AWR) for MEDEVAC UH-60A/L and Search and Rescue (SAR) Configured UH-60L Helicopters (AWR 1158)

1. Scope: This memorandum constitutes an AWR to authorize operation of Patient Movement Items (PMI) on MEDEVAC UH-60A/L and SAR configured UH-60L helicopters. This AWR ensures safety compatibility with the host aircraft. This AWR does not ensure durability and performance of the equipment.

2. Validity: This AWR is terminated upon transfer of the helicopter, changes in configuration of the subject equipment, or upon issuance of a later AWR, whichever occurs first.

3. List of Appendices: This memorandum and Appendix A will be carried in the logbook, and a complete AWR copy with all appendices shall be kept in the aircraft historical record file.

Appendix A. Restrictions and Operating Information
Appendix B. Configuration and Installation Detail
Appendix C. Inspections, Maintenance, and Logbook Instructions
Appendix D. References

4. The point of contact for this AWR is Russ Wetzel, AMSRD-AMR-AE-U, DSN 897-3118, commercial (256) 313-3118, or e-mail: russ.wetzel@us.army.mil. An alternate POC is Alex Gallien (Contractor, Camber Corporation), at DSN 897-3122, commercial (256) 313-3122, or e-mail: alex.gallien@us.army.mil.

Encl

WILLIAM D. LEWIS
Director of Aviation Engineering

DEPARTMENT OF THE ARMY
U.S. ARMY AEROMEDICAL RESEARCH LABORATORY
POST OFFICE BOX 620577
FORT RUCKER ALABAMA 36362-0577

REPLY TO ATTENTION OF

MCMR-UAD

17 October 2005

MEMORANDUM THRU Commander, U.S. Army Medical Materiel Agency, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001

FOR Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZA, 504 Scott Street, Fort Detrick, MD 21702-5012

SUBJECT: Aeromedical Certification for the Sorenson Medical AmbIT® MARAA and "Standard" PCA pumps for the MEDEVAC UH-60A/L and SAR Configured UH-60L Helicopters

1. References:

a. Rotary-Wing Airworthiness Certification Evaluation of the Sorenson medical ambIT MARAA and "Standard" PCA pumps, Part A: Laboratory Testing. U.S. Army Aeromedical Research Laboratory Technical Report (in review).

b. Rotary-Wing Airworthiness Certification Evaluation of the Sorenson medical ambIT MARAA and "Standard" PCA pumps, Part B: Flight Testing. U.S. Army Aeromedical Research Laboratory Technical Report (in review).

2. The U.S. Army Aeromedical Research Laboratory (USAARL) has completed Joint aeromedical testing and evaluation on the Sorenson Medical AmbIT MARAA Patient Controlled Analgesia (PCA) and Sorenson Medical AmbIT "standard" PCA pumps in the laboratory and aboard a JUH-60.

3. The purpose of this memorandum is to list all limitations or restrictions on the use of subject equipment by medical personnel in the U.S. Army UH-60 helicopter. Extensive aeromedical testing is conducted at USAARL to determine if medical equipment functions properly in the aircraft environment. The evaluation includes electromagnetic interference, environmental, and human factors testing in the laboratory as well as in-flight assessments by engineers and medical personnel under a variety of flight conditions.

4. Subject to the limitations in this memorandum and any other restrictions listed in the fleet airworthiness release (AWR), the ambIT PCA pumps are recommended for approval for use by trained medical personnel in the UH-60 helicopters. Medical personnel using these items in-flight should be fully aware of the notes, cautions, and warnings listed in this memorandum.

5. Care providers must be familiar with the instructions and guidance in this memorandum, as well as the contents of the AWR granted by the U.S. Army Aviation and Missile Life Cycle Management Command which may contain additional restrictions that affect aircraft and medical equipment operations.

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Aeromedical Certification

DEPARTMENT OF THE ARMY
U.S. ARMY AEROMEDICAL RESEARCH LABORATORY
POST OFFICE BOX 620577
FORT RUCKER ALABAMA 36362-0577

REPLY TO
ATTENTION OF

MCMR-UAD

17 October 2005

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FOR Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZA, 504 Scott Street, Fort Detrick, MD 21702-5012

SUBJECT: Aeromedical Certification for the Sorenson Medical AmbIT® MARAA and "Standard" PCA pumps for the MEDEVAC UH-60A/L and SAR Configured UH-60L Helicopters

1. References:

a. Rotary-Wing Airworthiness Certification Evaluation of the Sorenson medical ambIT MARAA and "Standard" PCA pumps, Part A: Laboratory Testing. U.S. Army Aeromedical Research Laboratory Technical Report (in review).

b. Rotary-Wing Airworthiness Certification Evaluation of the Sorenson medical ambIT MARAA and "Standard" PCA pumps, Part B: Flight Testing. U.S. Army Aeromedical Research Laboratory Technical Report (in review).

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Aeromedical Certification (cont.)

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Aeromedical Certification (cont.)

Medical notes for subject equipment

MRMC-UAD
SUBJECT: Aeromedical Certification for Sorenson Medical AmbIT MARAA Patient Controlled Analgesia (PCA) and Sorenson Medical AmbIT "Standard" PCA pumps for the MEDEVAC UH-60A/L and SAR Configured UH-60L Helicopters

6. Based on USAARL testing (ref 1a-1b), the following medical notes are listed for the subject equipment. There are no cautions or warnings listed in this memorandum.

NOTE

If the infusion line becomes occluded, the green indicator light will continue to flash as it does in normal operation. If undetected, the patient will experience an interruption of prescribed medication. Trained users must rely on LCD display to identify occlusion alarm.

NOTE

For night operations, the LCD display screen is not visible. Care providers must use ancillary light.

NOTE

Audible alarms cannot be heard during flight. Trained users must rely on visual alarms.

NOTE

Under bright sunlight conditions, the LCD display and green indicator light may be difficult to see. Trained users should be aware of this note.

NOTE

There is no backlight on the LCD display. Legibility is difficult under low-light conditions. Trained users should be aware of this note.

Aeromedical Certification (cont.)

Medical notes for subject equipment

NOTE

There is no backlight on the LCD display. Legibility is difficult under low-light conditions. Trained users should be aware of this note.

NOTE

When the user rotates the battery cap past the detent (off) position, the cap may inadvertently come off. Users should be familiar with pump operation and be properly trained.

NOTE

Laboratory testing indicated that the unit is susceptible to certain high intensity radiated fields (greater than 60 volts per meter). Transient failures could include disruption of normal operation and having to reset the pump. However, no failures caused an increase in infusion rate (fail-safe). These failures have not been duplicated during the limited in-flight testing. For a specific list of the susceptibility events and electromagnetic fields, refer to reference 1b or 1c.

7. The Sorenson PCA pumps were not tested with actual patients nor were any pathological conditions simulated to assess the interactions of any disease state with the flight environment and/or the equipment items. While no significant resultant degradation of device function is anticipated, this cannot be ruled out.

Aeromedical Certification (cont.)

Medical notes for subject equipment

MRMC-UAD
SUBJECT: Aeromedical Certification for Sorenson Medical AmbIT MARAA Patient Controlled Analgesia (PCA) and Sorenson Medical AmbIT "Standard" PCA pumps for the MEDEVAC UH-60A/L and SAR Configured UH-60L Helicopters

8. Any occurrences of medical equipment malfunction or failure during in-flight should be reported to the aircraft pilot-in-command and the U.S. Army Medical Materiel Agency via email at USAMMAQUADSERVICEMMQC@AMEDD.ARMY.MIL or telephonically at (301) 619-7235, DSN 343-7235.

9. Points of contact at USAARL for this memorandum are Dr. Khalid Barazanji and Mr. Robert Eshelman, at (334) 255-6888, DSN 558-6888.

JAMES S. MCGHEE
COL, MC
Commanding