Appendix-A

Airworthiness Certification

MARAA

Dedicated to promoting superior pain control for those in harm’s way.
Safe-to-Fly Recommendation

C-17 Globemaster III

MARAA

Dedicated to promoting superior pain control for those in harm’s way.
Operational Suitability & Effectiveness Risks:

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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**MEMORANDUM FOR AMCGASSF**

FROM HSG /TFL
7900 Lindbergh Blvd.
Brooks City Base TX 78235-5119

SUBJECT Operational Suitability and Effectiveness Risks for the Sorenson Medical ambIT MARAA (PIN 61753.06) and "Standard" (PIN 220062) Patient-Controlled Analgesia (PCA) Infusion Pump

1. U.S. Army Medical Research and Materiel command requested both devices tested for Self-Select approval. Test results show both have performance limitations. In the event of decompression, 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-810G Method 500.4, Procedure III, air bubbles formed in the IV line during recent tests from 5,000 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 USAF /SAM, 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 than that of a standard. It is recommended that AE personnel should bring extra IV cassettes, assess patient pain levels, 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 report in Appendix C of the HS0011 Tech Report.

   d. Qualified Biomedical Equipment Technician (4A251 or higher) should clean, maintain, inspect, and replace the equipment IAW with the user manual.

2. For more information, please contact me at DSN 240-3124, commercial (210) 336-3124 or email me at dominic.manalogd@brooks.af.mil.

DOMINIC F. MANALOG, USAF
Biomedical Engineer
Aeromedical Test Lab
Airworthiness Release

MEMORANDUM FOR: 7
US Army Aeromedical Research Laboratory (MCRD-JA), Post Office Box 625577,
Fort Rucker, AL 36362-5577
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 1188)

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 Wotzel, AMSRD-AMR-AE-U, DSN 897-3118,
commercial (256) 311-3118, or e-mail: russ.wotzel@us.army.mil. An alternate POC is Alex
Gallien (Contractor, Cambal Corp.), at DSN 897-8222, commercial (256) 311-3122, or
e-mail: alex.gallien@us.army.mil.

5. Enc) WILIAM D. LEWIS
Director of Aviation Engineering

MARAA
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Aeromedical Certification

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:


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.

MARAA
Dedicated to promoting superior pain control for those in harm’s way.
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

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**NOTE**

There is no backlight on the LCD display. Trained users should be aware of this.

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**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.

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**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.

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7. The Sorenson PCA pumps were not tested with actual patients nor were any pathological conditions simulated to assess the 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 inflight should be reported to the aircraft pilot-in-command and the U.S. Army Medical Materiel Agency via email at USAMMAQUADSERVICEMMQ@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