

12-0382

STAFF ACTION SUMMARY SHEET <small>For use of this form, see MEDCOM Reg 25-51 and OTSG Reg 25-51</small>						STAFF ACTION FOR: 20 Apr 12 1. <input type="checkbox"/> OTSG 2. <input checked="" type="checkbox"/> MEDCOM	
3. SUBJECT Aeromedical Certification for the Athena GTX Wireless Vital Signs Monitor Aboard All UH/HH-60A/L/M Helicopters						4. SUSPENSE DATE	
						5. DATE 28 Mar 2012	
6. SUMMARY OF ACTION <i>(Briefly describe purpose, discussion/background, and recommendation for the action.)</i> 1. Purpose: To obtain Aeromedical Certification (AC) approval for the Athena GTX Wireless Vital Signs Monitor aboard all UH/HH-60A/L/M helicopters. The USAARL staff review of the supporting document indicates that all approvals and documents are correctly in place and signature by the Commanding General is appropriate as required by AR-40-61, para 3-22. 2. Background: The AC provides the record of approval by the Commanding General to release the aeromedical certification for the subject items and approves their use on all U.S. Army UH/HH-60A/L/M helicopters with the medical limitations contained within the enclosed memorandum. 3. Recommendation: Request the approval from the Commanding General, USAMRMC.							
7. COORDINATIONS							
OFFICE SYMBOL	GRADE & LAST NAME	INI	DATE	OFFICE SYMBOL	GRADE & LAST NAME	INI	DATE
MCMR-AC	Dr. Caldwell	<i>[Signature]</i>	4/19/12				
MCMR-AC	Dr. Bertram	<i>[Signature]</i>	4/26/12				
MCMR-SG	LTC Laurel	<i>[Signature]</i>	25.04.12				
MCMR-ZB	CAPT Daniel	<i>[Signature]</i>	25 Apr 2012				
MCMR-ZC	COL. Starrs	<i>[Signature]</i>	26 Apr 12				
MCMR-ZA	MG Gilman	<i>[Signature]</i>	27 Apr 12				
8. MEDCOM REVIEWS / APPROVALS				9. OTSG REVIEWS / APPROVALS			
	GRADE & LAST NAME	INI	DATE		GRADE & LAST NAME	INI	DATE
BR CH				BR CH			
DIV CH				DIV CH			
DIR/OFC CH				DIR/OFC CH			
SGS				AXO			
DEP CoS				XO			
CoS				ASG			
CG				DSG			
CSM				TSG			
				SACO			
				DISPATCHED			
10. NAME, GRADE, OFFICE SYMBOL, & PHONE NUMBER OF ACTION OFFICER DANA K. RENTA, COI., CDR, USAARL				11. SIGNATURE <i>[Signature]</i>			



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
US ARMY AEROMEDICAL RESEARCH LABORATORY
6901 ANDREWS AVENUE
FORT RUCKER, ALABAMA 36362-0577

MCMR-UAD-A

6 April 2012

MEMORANDUM 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 Athena GTX Wireless Vital Signs Monitor
Aboard All UH/HH-60A/L/M Helicopters

1. References:

a. Memorandum, Aviation and Missile Research, Development, and Engineering Center,
7 March 2012, R-22, Subject: Airworthiness Release (AWR) for UH/HH-60A/L/M Helicopters
Equipped with Patient Movement Items (PMI) (AWR 1330).

b. Airworthiness Test and Evaluation of the Athena GTX, Wireless Vital Signs Monitor,
U.S. Army Aeromedical Research Laboratory Technical Report (in review).

c. Army Regulation 40-61, 28 January 2005, Medical Logistics Policies.

d. Army Regulation 70-62, 21 May 2007, Airworthiness Qualification of U.S. Army
Aircraft Systems.

e. Memorandum of Agreement between USAMRMC and USAAMCOM, "Airworthiness
Release (AWR) Certification for Medical Carry-on Equipment," 18 February 2003.

2. The U.S. Army Aeromedical Research Laboratory (USAARL) has completed aeromedical
testing and evaluation on the Athena GTX Wireless Vital Signs Monitor in the laboratory and
aboard a HH-60M helicopter.

3. The purpose of this memorandum is to list all limitations or restrictions on the use of subject
equipment by medical personnel in U.S. Army H-60 helicopters. Extensive aeromedical
testing is conducted at the USAARL to determine if medical equipment functions properly in the
aircraft environment. The evaluation includes electromagnetic interference and compatibility
(EMI/EMC), 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. The Athena GTX Wireless Vital Signs Monitor is recommended for approval provided all
limitations in this memorandum and any other restrictions listed in the fleet airworthiness release
(Ref 1a) are considered acceptable by the procuring agency. Medical personnel using this item

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during flight should be fully aware of any warnings, cautions, and notes 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 Aviation and Missile Research, Development, and Engineering Center (AMRDEC), which may contain additional restrictions that could potentially affect aircraft and medical equipment operations.

6. Based on USAARL testing (Ref 1b) and the AWR, the following medical limitations and restrictions are listed for the subject equipment:

WARNING

In accordance with AWR 1330 (Ref 1a), the wireless interface feature of the Athena GTX Wireless Vital Signs Monitor was not tested and shall be restricted from use.

WARNING

Auditory alarms could not be heard in the noisy flight environment. Care providers must rely on visual indications from the screen display to determine if there is an alarm condition or system malfunction.

CAUTION

The Athena GTX Wireless Vital Signs Monitor may be susceptible to heavy moisture. Testing revealed that exposure to rain may cause the Nonin SpO₂ sensor to become inoperative. Recommend care providers protect the device when exposure to rain is anticipated.

CAUTION

Climatic testing revealed the Athena GTX battery would not charge to its full capacity below 0 and above 40°C. At -26°C, the battery reached 60% of its charging capacity. At 60°C, the battery reached 45% of its charging capacity. To reach full capacity, the battery should always be charged between the temperature ranges of 0 to 40°C.

CAUTION

During the extreme cold climatic battery test, the Athena GTX battery life at -26°C was six hours and fifty four minutes. The average battery life under

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ambient laboratory conditions (24.4 °C) was eight hours and twenty minutes. Care providers should be aware battery life is shortened when operated below 0°C.

CAUTION

During electromagnetic susceptibility testing, it was discovered that there were responses at certain frequency ranges. Some of the responses included loss of SpO₂ and pulse rate. At 200 volts per meter, the SpO₂ readings were not displayed over large frequency ranges. Other observed responses included shut-down requiring restart, loss of blood pressure readings, distortions of the ECG trace, and display anomalies. These responses were not experienced during USAARL flight testing. For a specific list of susceptibility events and electromagnetic fields, refer to Ref 1b. Trained users should be aware of these findings.

NOTE

In-flight human factors testing revealed screen legibility from different angles was difficult due to the small screen. When possible, care providers should position the Wireless Vital Signs Monitor for better viewing.

7. The Athena GTX Wireless Vital Signs Monitor was neither tested with actual patients nor were any pathological conditions simulated to assess the ability to detect any disease state in the flight environment. While no significant resultant degradation of device function is anticipated, this cannot be ruled out.

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 (USAMMA). Customers may fill out a Product Quality Deficiency Report online at <https://dmonline.dsdp.dla.mil/PORTAL/Customer/PqdrInstruction.aspx>. Customers may also contact USAMMA directly by calling (301) 619-4344 or DSN 343-4344.

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9. The USAARL points of contact for this memorandum are Mr. Robert Eshelman at (334) 255-6954 or DSN 558-6954, robert.eshelman@us.army.mil and Dr. Khalid Barazanji at (334) 255-6888 or DSN 558-6988, khalid.barazanji@us.army.mil.



DANA K. RENTA
COL, MC
Commanding

Approved/~~Disapproved~~



JAMES K. GILMAN
MG, MC
Commanding General