

FROM
QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

PRIORITYMESSAGE RELEASED: 02/06/2012

*****UNCLASSIFIED*****

SUBJ: MMQC-12-1070
PHILIPS HEALTHCARE / INVIVO CORPORATION / PRECESS MRI PATIENT MONITORING SYSTEM / URGENT
MEDICAL DEVICE CORRECTION

PART ONE FOR ALL SERVICES.
PART TWO FOR CONSIGNEES ONLY.
PART THREE FOR ARMY ONLY.

IMAGE ON USAMMA'S WEBSITE.

01. EXCERPT FROM FDA MEDWATCH.

A PROBLEM HAS BEEN DETECTED IN CERTAIN PHILIPS INVIVO PRECESS MRI PATIENT MONITORING SYSTEMS (PRECESS) THAT, IF IT WERE TO RE-OCCUR, COULD POSE A RISK FOR PATIENTS. THIS FIELD SAFETY NOTICE IS INTENDED TO INFORM YOU ABOUT:

- WHAT THE PROBLEM IS AND UNDER WHAT CIRCUMSTANCES IT CAN OCCUR
- THE ACTIONS THAT SHOULD BE TAKEN BY THE USER IN ORDER TO PREVENT RISKS FOR PATIENTS OR USERS
- THE ACTIONS PLANNED BY PHILIPS INVIVO TO CORRECT THE PROBLEM.

THIS NOTICE IS INTENDED FOR PHILIPS INVIVO CUSTOMERS AND END USERS USING CERTAIN PRECESS SYSTEMS. PHILIPS INVIVO HAS DETERMINED THAT IT IS POSSIBLE FOR THE SYSTEM'S ALARM LIMITS AND OTHER DEVICE SETTINGS TO SPONTANEOUSLY CHANGE WITHOUT USER INTERVENTION. PHILIPS INVIVO HAS RECEIVED ONE USER REPORT OF UNPROMPTED CHANGES TO ALARM HIGH AND LOW LIMIT VALUES AND TO THE UNITS OF MEASURE FOR SOME PARAMETERS, BUT NO HARM TO ANY PATIENT WAS REPORTED. OUR INVESTIGATION HAS FOUND THAT THE PROBLEM IS ASSOCIATED WITH INTERMITTENT AND FREQUENT LOSS OF COMMUNICATION BETWEEN THE WIRELESS PROCESSING UNIT AND THE DISPLAY CONTROLLER UNIT.

PRODUCT:

PRECESS MRI PATIENT MONITORING SYSTEM (PRECESS, MODEL NUMBER 3160).

INTENDED USE: THE PRECESS IS INTENDED TO MONITOR VITAL SIGNS FOR PATIENTS UNDERGOING MRI PROCEDURES AND TO PROVIDE SIGNALS FOR SYNCHRONIZATION OF THE MRI SCANNER. THE PRECESS IS INTENDED FOR USE BY HEALTH CARE PROFESSIONALS. THE STANDARD PRECESS CONFIGURATION CONSISTS OF WIRELESS INTERFACED ELECTROCARDIOGRAM (ECG), WIRELESS INTERFACED PULSE

OXIMETRY (SPO2), AND NON-INVASIVE BLOOD PRESSURE (NIBP). OPTIONAL PARAMETERS INCLUDE END-TIDAL CO2 (ETCO2), ANESTHETIC AGENTS, INVASIVE BLOOD PRESSURE (IBP) AND FIBER-OPTIC TEMPERATURE.

FOR SERIAL NUMBERS AND ADDITIONAL INSTRUCTIONS FOR CUSTOMERS AND END USERS, AS WELL THE ACTIONS THAT PHILIPS INVIVO PLANS TO TAKE (SEE IMAGE ON USAMMA'S WEBSITE).

PROBLEM DESCRIPTION:

ALARM LIMITS AND OTHER DEVICE SETTINGS FOR THE AFFECTED DEVICES MAY SPONTANEOUSLY CHANGE WITHOUT USER INTERVENTION. PHILIPS INVIVO HAS RECEIVED ONE USER REPORT OF UNPROMPTED CHANGES TO ALARM HIGH AND LOW LIMIT VALUES AND TO THE UNITS OF MEASURE FOR SOME PARAMETERS, BUT NO HARM TO ANY PATIENT WAS REPORTED. OUR INVESTIGATION HAS FOUND THAT THE PROBLEM IS ASSOCIATED WITH INTERMITTENT AND FREQUENT LOSS OF COMMUNICATION BETWEEN THE WIRELESS PROCESSING UNIT (WPU) AND THE DISPLAY CONTROLLER UNIT (DCU).

HAZARDS INVOLVED:

IF THE PROBLEM WERE TO OCCUR, THE DEVICE COULD POTENTIALLY FAIL TO PRODUCE AUDIBLE OR VISUAL ALARMS AS EXPECTED BY THE USER. IF THE USER OF THE DEVICE RELIES ON ONLY VISUAL OR AUDIBLE ALARMS TO ALERT THEMSELVES TO A POTENTIALLY CRITICAL PATIENT EVENT AND IS NOT ACTIVELY MONITORING THE NUMERICAL DATA OUTPUTTED BY THE DEVICE (WHICH IS ACCURATE), THE NEED FOR MEDICAL INTERVENTION COULD GO UNDETECTED WHICH COULD RESULT IN SERIOUS INJURY.

THE REPORTED UNPROMPTED UNITS OF MEASURE CHANGE IS NOT CONSIDERED TO BE A HAZARD SINCE VITAL SIGN NUMERICAL DATA IS ACCURATELY CONVERTED TO THE ALTERNATE UNITS OF MEASURE (FOR EXAMPLE, IF THE NIBP UNITS OF MEASURE CHANGE FROM MMHG TO KPA, THE DISPLAYED NIBP PATIENT DATA IS ACCURATELY CONVERTED FROM MMHG TO KPA).

TO IDENTIFY AFFECTED PRODUCTS (SEE IMAGE ON USAMMA'S WEBSITE).

THE PICTURES (SEE IMAGE ON USAMMA'S WEBSITE) SHOW THE LOCATION OF THE SERIAL NUMBER ON THE BACK OF THE WPU AND THE BOTTOM OF THE DCU. THE SERIAL NUMBER CAN BE FOUND IN THE AREA THAT IS CIRCLED.

ACTION TO BE TAKEN BY CUSTOMER / END USER:

UNTIL DEVICES CAN BE SERVICED BY PHILIPS INVIVO AS DESCRIBED BELOW, FOLLOW THESE GUIDELINES TO REDUCE THE RISK OF HARM:

- ALWAYS VERIFY GOOD COMMUNICATION BETWEEN THE WPU AND THE DCU PRIOR TO PATIENT USE. IF YOU EXPERIENCE DIFFICULTY IN ESTABLISHING GOOD COMMUNICATION, CONTACT PHILIPS INVIVO CUSTOMER SUPPORT: (877) 468-4861 (OPTION 2) OR YOUR LOCAL PHILIPS INVIVO REPRESENTATIVE.

- IN THE EVENT THAT COMMUNICATION IS LOST AND THEN RE-ESTABLISHED DURING PATIENT MONITORING, RE-CONFIRM THAT ALARM LIMIT SETTINGS ARE APPROPRIATE FOR THE PATIENT BEING MONITORED.

- WHEN THE PROBLEM OCCURS, EVEN THOUGH ALARM LIMIT SETTINGS MAY BE ALTERED, THE DCU CONTINUES TO DISPLAY VALID WAVEFORMS AND ACCURATE NUMERICAL DATA. DO NOT RELY SOLELY ON VISUAL OR AUDIBLE ALARMS TO ALERT YOU TO A POTENTIALLY CRITICAL PATIENT EVENT.

ACTIONS PLANNED BY PHILIPS INVIVO:

PHILIPS INVIVO PLANS TO REPLACE THE RADIOS IN ALL AFFECTED DEVICES. THIS SERVICE WILL BE IMPLEMENTED FREE OF CHARGE BY PHILIPS INVIVO. FOR CUSTOMERS AND END USERS IN ALL LOCATIONS, A PHILIPS INVIVO REPRESENTATIVE CAN VISIT ACTIVITIES IN ORDER TO COMPLETE THE NECESSARY SERVICE. ALTERNATIVELY, IF LOCATED IN THE UNITED STATES, DEVICE CAN BE RETURNED FOR BENCH SERVICE. IF YOU CHOOSE THIS OPTION, A LOANER DEVICE CAN BE PROVIDED FREE OF CHARGE, IF NECESSARY (LIMITED AVAILABILITY). PLEASE CONTACT PHILIPS INVIVO CUSTOMER SUPPORT: (877) 468-4861 (OPTION 2) OR YOUR LOCAL PHILIPS INVIVO REPRESENTATIVE TO REQUEST SERVICE FOR YOUR DEVICE.

FURTHER INFORMATION AND SUPPORT:

IF YOU NEED ANY FURTHER INFORMATION OR SUPPORT CONCERNING THIS ISSUE, PLEASE CONTACT YOUR LOCAL PHILIPS REPRESENTATIVE OR THE PHILIPS CUSTOMER CARE SERVICE CENTER AT 877-468-4861 OPTION 2.

02. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, MEDICAL MAINTENANCE, CLINICAL STAFF, MED STAFF, EMERGENCY ROOM STAFF, RISK MANAGER, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

03. AUTHORITY: DODD 5105.22 AND DODD 6025.13. ADDITIONALLY:

A. ARMY: SEE ARMY REGULATION (AR) 40-61, 28 JANUARY 2005, CHAPTER 4, AND THE DEPARTMENT OF THE ARMY SUPPLY BULLETIN (SB 8-75-11) FOR APPLICABLE POLICIES AND PROCEDURES.

B. AIR FORCE: AF ACTIVITIES WILL TAKE ACTION AS PRESCRIBED IN AFI 41-209, MEDICAL LOGISTICS SUPPORT, CHAPTERS 3 AND 9. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES.

04. SERVICE SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);

ARMY: TELEPHONE COM: 301-619-4300, DSN: 343, FAX: 4468,
E-MAIL: QUADSERVICEMMQC@AMEDD.ARMY.MIL

ARMY MEMBERS MAY SUBSCRIBE TO DOD MMQC MESSAGES AND MANY OTHER TOPICS AT THE FOLLOWING WEBSITE:

[HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM](http://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM)

CLICK ON "SUBSCRIBE TO MMQC MESSAGES HERE."

USAMMC-E: TELEPHONE COM: 011-49-6331-86-7118/7181, DSN: 495-7118, FAX: 6218,
E-MAIL: USAMMCE_QA@AMEDD.ARMY.MIL

AIR FORCE: TELEPHONE COM: 301-619-4170, DSN: 343, FAX: 2557
EMAIL: AFMOA.SGALC@DETRICK.AF.MIL

AIR FORCE MEMBERS MAY SUBSCRIBE TO THE DOD MMQC MESSAGES AND RECEIVE EMAIL NOTIFICATIONS DIRECTLY FROM USAMMA WHEN THEY ARE PUBLISHED AT THE FOL WEBSITE: [HTTPS://MEDLOG.DETRICK.AF.MIL/](https://medlog.detrick.af.mil/), GO TO "SITE SETTINGS" AND CHECK "SUBSCRIBE TO MMQC MESSAGES."

NAVY: TELEPHONE COM: 301-619-3085, DSN: 343, FAX: 3087,
EMAIL: MMQC2@MED.NAVY.MIL

NAVY MEMBERS MAY SUBSCRIBE TO RECEIVE DODMMQC MESSAGES AT [HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil)
CLICK ON "SUBSCRIBE TO MMQC MESSAGES."

05. PART TWO FOR FOL KNOWN CONSIGNEES ONLY:

WRIGHT-PATTERSON MEDICAL CENTER, WRIGHT-PATTERSON AFB, OH
BROOKE ARMY MEDICAL CENTER, FORT SAM HOUSTON, TX
LANDSTUHL REGIONAL MEDICAL CENTER, LANDSTUHL, GERMANY
DARNALL ARMY COMMUNITY HOSPITAL, FORT HOOD, TX
EVANS ARMY COMMUNITY HOSPITAL, FORT CARSON, CO
NAVAL MEDICAL CENTER PORTSMOUTH, VA

06. PART THREE FOR ARMY ONLY:

ARMY ACTIVITIES IN POSSESSION OF SUBJECT EQUIPMENT ARE REQUIRED TO REPORT THE STATUS OF THEIR WORK TO THE USAMMA NMP NLT 13 FEBRUARY 2012. THIS CAN BE ACCOMPLISHED BY VISITING THE USAMMA WEBSITE HOMEPAGE ([WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil)) AND CLICKING THE ICON FOR MMQC\MMI MESSAGES. THEN CLICK THE LINK "ARMY MMQC EQUIPMENT STATUS REPORTING," COMPLETE AND SUBMIT THE ON-LINE FORM.
ARMY POINT OF CONTACT: NMPMMQC@AMEDD.ARMY.MIL OR TELEPHONE DSN-343-6648/3170/4464;
COMMERCIAL 301-619-6648/3170/4464.