PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to system.

1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:

IRadimed 3880 MRI Patient Monitoring System_A&I

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

11/28/23

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: *(Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)*

From members of the general public	From Federal employees
x from both members of the general public and Federal employees	Not Collected *(if checked proceed to Section 4)*

b. The PII is in a: *(Check one.)*

New DoD Information System	New Electronic Collection
x Existing DoD Information System	Existing Electronic Collection
Significantly Modified DoD Information System	

c. Describe the purpose of this DoD information system or electronic collection and describe the types of personal information about individuals collected in the system.

The 3880 MRI Patient Monitoring System, also referred to as the 3880, is a multi-parameter vital signs monitor designed for use in the Magnetic Resonance (MR) environment by trained healthcare professionals. The 3880 is a portable non-magnetic monitor used to acquire and display all vital sign measurements and is designed to travel with the patient between the MRI and their care unit. The 3880 processes and displays multiple parameters, waveforms, measurement numeric values and alarms. The device is powered by either AC line power or its internal battery. It is lightweight making it a practical intra-department patient transportation monitor for use within the MRI suite. The device can be carried by its handle, mounted to a wheeled cart/stand, or patient bed.

Hardware is comprised of one patient monitor and one remote base station also containing IRadimed proprietary software for the monitor, tablet and base station. The IRadimed 3880 utilizes custom hardware and software developed by IRadimed for MRI applications. The IRadimed 3880 can be connected via serial RS-232 as well as RJ-45 network connectivity.

The device collects personally identifiable information (PII) to include names, patient ID numbers, and Protected Health Information (PHI) in the form of vital signs. The system will be used for anyone who is eligible for care within the Military Health System (MHS) to include active duty personnel, retirees, and dependents.

IRadimed 3880 is owned and operated by the DHA sites that purchase the workstation. Cyberlog is responsible for the RMF process, and gaining an approval from DHA J6 RMED. Local sites are responsible for day to day operations, maintenance, and management of the device. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations.

d. Why is the PII collected and/or what is the intended use of the PII? *(e.g., verification, identification, authentication, data matching, mission-related use, administrative use)*

The PII is collected for monitoring patient vital signs during MRI procedures and transmits this data via LAN using Health Level 7 (HL7) to the hospital's Electronic Medical Record System (GENESIS). The intended use of the PII is to monitor patient vital signs during MRI procedures.

e. Do individuals have the opportunity to object to the collection of their PII? Yes x No

(1) If "Yes," describe the method by which individuals can object to the collection of PII.

(2) If "No," state the reason why individuals cannot object to the collection of PII.

The information the system receives, uses and collects is not collected directly from the individual. The system collects the data from MHS GENESIS which is responsible for insuring that the patient have the opportunity to object to the collection of PII.

f. Do individuals have the opportunity to consent to the specific uses of their PII? Yes x No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

The information the system receives, uses and collects is not collected directly from the individual. The system collects the data from MHS GENESIS which is responsible for insuring that the patient has the opportunity to object to the collection of PII.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. *(Check as appropriate and provide the actual wording.)*

Privacy Act Statement	Privacy Advisory	x	Not Applicable

IRadimed 3880 does not collect PII directly from individuals. Therefore, no Privacy Act Statement or Advisory is required.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? *(Check all that apply)*

x	Within the DoD Component	Specify.	Defense Health Agencies (DHA) Medical Treatment Facilities (MTF)
	Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	
	Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	
	State and Local Agencies	Specify.	
x	Contractor *(Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)*	Specify.	The military treatment facilities (MTF) may utilize contractor services to support this product. DoD policy requires such contracts include language to safeguard PII including FAR clauses: 52.224-1, Privacy Act Notification; 52.224-2, Privacy Act; and FAR 39.105, Privacy. When the contractor has access to PHI, a HIPAA Business Associate Agreement is also required.
	Other *(e.g., commercial providers, colleges)*.	Specify.	

i. Source of the PII collected is: *(Check all that apply and list all information systems if applicable)*

	Individuals		Databases
x	Existing DoD Information Systems		Commercial Systems
	Other Federal Information Systems		

MHS GENESIS

j. How will the information be collected? *(Check all that apply and list all Official Form Numbers if applicable)*

	E-mail		Official Form (*Enter Form Number(s) in the box below)*
	In-Person Contact		Paper
	Fax		Telephone Interview
x	Information Sharing - System to System		Website/E-Form
	Other *(If Other, enter the information in the box below)*		

The IRadimed 3880 captures the patients vital signs at the patient bedside. IRadimed connects to MHS GENESIS to allow effective communication of patient vital signs information during critical/non critical sedated studies

k. Does this DoD Information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

Yes x No

If "Yes," enter SORN System Identifier

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or http://dpcld.defense.gov/Privacy/SORNs/

or

If a SORN has not yet been published in the Federal Register, enter date of submission for approval to Defense Privacy, Civil Liberties, and Transparency

Division (DPCLTD). Consult the DoD Component Privacy Office for this date

If "No," explain why the SORN is not required in accordance with DoD Regulation 5400.11-R: Department of Defense Privacy Program.

l. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?

(1) NARA Job Number or General Records Schedule Authority. GRS 5.2, item 020 (DAA-GRS-2017-0003-0002)

(2) If pending, provide the date the SF-115 was submitted to NARA.

(3) Retention Instructions.

103-14
DISPOSITION: Temporary. Delete no more than 7 years from the date last modified. (See DoD DTM 22-001 on default disposition policies and OSD Records Manager guidance which file number to associate).

m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statue or Executive Order.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.
(2) If a SORN does not apply, cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply).

(a) Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If direct statutory authority or an Executive Order does not exist, indirect statutory authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

(c) If direct or indirect authority does not exist, DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component must be identified.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter Ch. 55, Medical and Dental Care; 10 U.S.C. 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 U.S.C. 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 U.S.C. 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 U.S.C. 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 42 U.S.C. 290dd, Substance Abuse Among Government and Other Employees; 42 U.S.C. 290dd-2, Confidentiality Of Records; 42 U.S.C 42 U.S.C. Ch. 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of Defense (DoD) Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFS); DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs; and E.O. 9397 (SSN).

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (OMB) Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information. This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

Yes ✕ No Pending

(1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.
(2) If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, " DoD Information Collections Manual: Procedures for DoD Public Information Collections."
(3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected in this system is for the diagnosis and treatment of medical disorders and does not collect PHI/PII directly from individuals. It is not the initial point of collection for any PHI/PII and is not considered a public information collection IAW DoDM 8910.01, V2, Encl 3, paragraph 8b(5).