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:

Siemens Medical Solutions Dimension Vista 500 3.X AI

2. DOD COMPONENT NAME:

Defense Health Agency

CyberLOG

3. PIA APPROVAL DATE:

10/24/23

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 Siemens Medical Solutions Dimension Vista 500 3.X (AI) is a medical device (Intelligent Lab System). Externally it is a single large unit (7' in width). Internally it contains one or more analyzers, and an information processing unit (IPU). The Vista 500 can perform a very large number of different blood tests (see https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems/dimension-vista-500-intel-lab-sys/assays), and is generally found in the testing lab of a medical facility.

Additional information can be found at: https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems/dimension-vista-500-intel-lab-sys. The following areas will utilize the medical device: Elmendorf Air Force Base (AFB), Travis AFB, California, Fort Carson, Colorado (CO), United States Air Force (USAF) Academy, CO, Eglin AFB, Florida, Fort Benning, Georgia, Nellis AFB, Nevada, Great Lakes, Illinois, Bremerton, Washington, Camp Lejuene, North Carolina.

The Siemens Medical Solutions Dimension Vista 500 3.X (AI) is a medical device (MDE) that receives information from an external source (Composite Health Care System (CHCS), or its replacement MHS Genesis) and returns to that same source: Name, Medical Record Number and Account Number. This medical device indirectly (via middleware) returns to that same external source: test results (generated from blood samples). Note: test results are protected health information (PHI).

Siemens Medical Solutions Dimension Vista 500 3.X (AI) is owned by the 60th Medical Group, David Grant USAF Medical Center and operated at multiple sites mentioned above. CyberLOG is responsible for the Risk Management Framework (RMF) process, and gaining an approval from DHA J6 Risk Management Executive Division (RMED). Local sites address day to day operations, maintenance, and management of the device. Sites ensure 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 personally identifiable information (PII)/PHI received or returned will be used for mission-related purposes to support the delivery of health care services. The received PII/PHI will be used to ensure the tests results that were generated by the MDE, were generated for the correct individual, and were inserted into the correct medical record.

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.

Individuals do not have the opportunity to object to the collection of their PII because Siemens Medical Solutions Dimension Vista 500 3.X (AI) is not the initial point of collection.

f. Do individuals have the opportunity to consent to the specific uses of their PII? Yes ☒ 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.

Individuals do not have the opportunity to consent to the specific use of their PII because Siemens Medical Solutions Dimension Vista 500 3.X (AI) is not the initial point of collection.

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 ☒ Not Applicable

Siemens Medical Solutions Dimension Vista 500 3.X (AI) does not collect PII directly from individuals. Therefore, no Privacy Act Statement or Privacy 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)*

☒	Within the DoD Component	Specify.	DHA Military Treatment Facilities (MTFs)
☐	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.	
☒	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
☒	Existing DoD Information Systems	☐	Commercial Systems
☐	Other Federal Information Systems		

CHCS
Military Health System 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
☒	Information Sharing - System to System	☐	Website/E-Form
☐	Other *(If Other, enter the information in the box below)*		

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 ☐ No

If "Yes," enter SORN System Identifier EDHA 07

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.

FILE NUMBER: 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 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. 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), as amended.

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 **X** 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 not considered a public information collection in accordance with DoDM 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).