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:

Beckman Coulter DXC 700 AU Chemical Analyzer 1 V1.X_AI

2. DOD COMPONENT NAME:

Defense Health Agency

CyberLOG

3. PIA APPROVAL DATE:

09/26/23

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.)*

- [x] New DoD Information System
- [ ] New Electronic Collection
- [ ] 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 Beckman Coulter DXC 700 AU Chemical Analyzer 1 V1.X_AI measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) samples, and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, latex agglutination, ion selective electrode and homogeneous enzyme immunoassay.

The data source is an existing accredited hospital information system or health record system within the Department of Defense (DoD). The data collected includes a random number associated with the DoD Identification. The following categories of individuals in which data is collected includes Active Duty Military, Retirees, and their family members. Data is collected from both members of the general public and Federal employees. The Beckman Coulter DXC 700 AU Chemical Analyzer 1 V1.X_AI produces and processes PHI and PII. Data is primarily sourced from primary hospital information systems; this can be Picture Archiving and Communication System (PACS) or Digital Imaging and Communications in Medicine (DICOM) capable systems.

The data is collected from Composite Health Care System (CHCS) or Military Health System (MHS) GENESIS through PACS systems. Cyber Logistics (CyberLOG) is responsible for the Risk Management Framework (RMF) process and gaining an approval from the DHA J6 Risk Management Executive Division (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 approval configurations. Beckman Coulter DXC 700 AU Chemical Analyzer 1 V1.X_AI is owned by DHA CyberLOG and operated by various MTF as needed.

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) collected will be used to match an individual with his/her medical diagnostic reports and to ensure accuracy when these reports are integrated in the medical records for that individual.

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 Beckman Coulter DXC 700 is not the initial point of collection.

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.

Individuals do not have the opportunity to consent to the specific use of their PII because Beckman Coulter DXC 700 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	x	Not Applicable

Beckman Coulter DXC 700 AU Chemical Analyzer 1 V1.X_AI does not collect PII directly from the individual. 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)*

x	Within the DoD Component	Specify.	The data will be shared with health care providers and identified super users within a Department of Defense (DoD) Military Treatment Facilities (MTF) using this device.
x	Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	The PII may be shared with health care providers within Navy and Air Force MTFs.
x	Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	The data may be shared with required and authorized health care providers within other Federal Agencies supporting Army and/or DoD beneficiaries (U.S. Coast Guard, Veterans Administration, Public Health Service, Center for Disease Control).
	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 Manufacturer servicing the device may have access to some data. There may also be contractor radiologists providing radiology support who will need direct access to patient studies. Contracts for Manufacturers and radiologists accessing this device include a standard Military Health System (MHS) Health insurance Portability and Accountability Act (HIPAA) Business Associate Agreement, DoD/HIPAA guidelines, and DHA Information Assurance (IA) guidelines.
	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		

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 information is primarily sourced from primary hospital information systems, this can be Picture Archiving and Communication System (PACS) or Digital Imaging and Communications in Medicine (DICOM) capable systems.

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.

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 Department of Defense Manual (DoDM) 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).