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 DXI600 & DXI800 V5.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 DXI600 & DXI800 V5.X_AI device helps laboratories run 40,000-80,000 tests per year meeting peak workload demands with throughput of up to 200 tests per hour and up to 60 samples on board. The DXI600 & DXI800 are immunoassay analyzers used to test, detect, and measures analyte; for the purpose of diagnosing diseases, and testing for presence of substances.

This system collects Personally Identifiable Information (PII), including identification numbers, medical information, and Protected Health Information (PHI). The categories of individuals with records in this system are Department of Defense (DoD) health care beneficiaries to include Military members of the Armed Forces, Military retirees, and their family members; DoD Civilian employees; Foreign Nationals; members of the U.S. Coast Guard and Public Health Service; cadets and midshipmen of the military academies; and other categories of individuals who receive medical treatment at DoD treatment facilities/activities.

Cyber Logistics (CyberLOG) is responsible for the Risk Management Framework (RMF) process and gaining an approval from 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. DXI600 & DXI800 is owned by DHA's 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 PII collected is 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. The PII collected will be used for mission-related purposes to support the delivery of health care services.

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.

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information system or electronic 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.

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information system or electronic

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 DXI 600 & DXI 800 does not collect PII directly from an individual; therefore, a Privacy Act Statement or Privacy Advisory is not 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 DoD medical 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.	
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 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		

The information is primarily sourced from primary hospital information systems, this can be Picture Archiving and Communication System (PACS), Health Layer Seven (HL7), Digital Imaging and Communications in Medicine (DICOM) capable systems, or Laboratory Information System (LIS)

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)*		

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.

Beckman Coulter DXI 600 & DXI 800 ("Beckman Coulter") does not retrieve personally identifiable information ("PII") based on unique personal identifier.

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 lastmodified. (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.

10 U.S.C. § 136, Under Secretary of Defense for Personnel and Readiness; Public Law 104-91, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C. Chapter 55, Medical and Dental Care; 10 U.S.C. 1073c, Administration of Defense Health Agency and Military Medical Treatment Facilities; DoD Instruction (DoDI) 6025.18, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs; DoD Manual (DoDM) 6025.18, Implementation of Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs; DoDI 6040.45, DoD Health Record Life Cycle Management; 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).