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:

Radiometer ABL90 Flex Series Version 3.x_AI

2. DOD COMPONENT NAME:

Defense Health Agency

CyberLOG

3. PIA APPROVAL DATE:

03/28/23

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		x	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 Radiometer ABL90 Flex Series Version 3.x_AI (ABL90 Series) is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, potassium, sodium, calcium, chloride, glucose, lactate, neonatal bilirubin, and co-oximetry parameters. The ABL90 FLEX/PLUS analyzer is intended for use in a laboratory environment, near patient or point-of-care setting, by trained technologists, nurses, physicians and therapists.

The ABL90 Series may collect limited Personally Identifiable Information (PII) and may store it on the Internal Processing Unit (IPU). The ABL90 Flex Series obtains PII from the Defense Health Agency (DHA) Laboratory Information System (LIS) to match individuals with the correct medical record. The ABL90 Series collects and feeds the PII to the accredited Picture Archiving Communication System (PACS) to support providers in their diagnosis and treatment of the patient. The PII collected includes demographic information, medical information, and Protected Health Information (PHI). The categories of individuals on which PII is collected include Active Duty Military, Retirees, and their family members.

Cyber Logistics (CyberLOG) is responsible for the Risk Management Framework (RMF) process and gaining an approval from Risk Management Executive Division (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 approval configurations. Radiometer ABL90 Flex Series Version 3.x_AI is owned by DHA's CyberLOG and operated by various Military Treatment Facilities (MTFs) 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 is collected for identification purposes to match individuals with their medical records and to ensure accuracy when those records are integrated with other records for the same individual. The PII collected will be used for mission-related purposes that 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.

Individual do not have the opportunity to object to the collection of their PII as the the Radiometer ABL90 Flex Series Version 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 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.

Individual do not have the opportunity to consent to the specific uses of their PII as the the Radiometer ABL90 Flex Series Version 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	x	Not Applicable

Radiometer ABL90 Flex Series Version 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)*

x	Within the DoD Component	Specify.	Department of Defense Agencies and 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.	
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 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.
x	Other *(e.g., commercial providers, colleges).*	Specify.	Medical Professionals upon referral

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		

Picture Archiving Communication System (PACS)
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.

A SORN is not required because because Radiometer ABL90 Flex Series Version 3.x_AI does not collect PII from individuals to be stored in a system of records and retrieved by a 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 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.

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C., Chapter 55, Medical and Dental Care; 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); Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 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.

Medical devices are purchased using Defense Health Program Funding, which has been designated as for medical use only.