

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:

Baxter ELI 380 Resting Electrocardiograph (ECG) v2.X_AI

2. DOD COMPONENT NAME:

Defense Health Agency

Cyber Logistics

3. PIA APPROVAL DATE:

07/05/23

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

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

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 Baxter a/k/a Welch Allyn Resting ELI 380 ECG AI with ERGO swivel and touchscreen display is designed to make the total electrocardiography (ECG) experience more efficient by decreasing the time required to perform the procedure, increasing the accuracy and security of the data acquired, and enhancing the overall patient care experience. The family of devices supports up to a 12 lead resting diagnostic ECG with display capabilities of acquiring, viewing, transmitting, printing, and storing resting ECG test data. It also provides Mortara Critical Test results to help quickly identify high-risk patients. These devices have bi-directional local area network support with ELI-LINK server software and can be configured with wireless connectivity and Digital Imaging and Communications in Medicine (DICOM) Modality Work List (MWL) with synchronization of physician orders with date and time as well as encrypted transmission of the ECG.

Personally Identifiable Information (PII) collected includes personal identifier, demographic data, and medical information including Protected Health Information (PHI). PII is collected from the following categories of individuals to include DoD's Health Care Beneficiaries such as Military Members of the Armed Forces, Military Retirees, and their family members as well as other individuals eligible for medical care at DoD's Military Treatment Facilities (MTFs)/Activities. In addition, PII is collected from both members of the general public and Federal employees.

Mortara ECG Family devices maintains, uses, and disseminates PII/PHI. The studies are retained on the device (500 capacity) and are available for retrieval, viewing, or printing. When the 500 study capacity is reached, the studies will be purged on a "First-In and First-Out" basis. Welch Allyn Resting ECG AI is owned and operated by Defense Health Agency's Cyber Logistics Center Of Excellence.

The Welch Allyn Resting ELI 380 ECG AI is owned and operated by Military Treatment Facility (MTF)s which purchase the device. Cyberlog is responsible for the risk management framework (RMF) process and gaining 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 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 identification purposes to match an individual with their medical diagnostic reports and to ensure accuracy when these reports are integrated in the medical record for that individual. The PII is used for mission-related purposes to support the delivery of healthcare services.

e. Do individuals have the opportunity to object to the collection of their PII? Yes 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 and/or PHI because Welch Allyn Resting ECG 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 uses of their PII and/or PHI because Welch Allyn Resting ECG 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

Welch Allyn Resting ECG 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's Medical 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 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

Composite Health Care System (CHCS)
Armed Forces Health Longitudinal Application (AHLTA)

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://dpcl.d.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.

I. 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 statute 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; 10 U.S.C., Chapter 55, Medical and Dental Care; 32 CFR Part 199, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 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 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.

This system does not require OMB approval since information is not being collected directly from members of the public.