

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:

Philips DigiTrak XT Recorder- Holter System Version 3.X AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

03/21/23

CyberLOG

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 Philips DigiTrak XT Recorder- Holter System Version 3.X_AI (DigiTrak XT) is a battery-operated solid state recorder which is designed for up to 168 hours continuous recording of Ambulatory electrocardiograph (AECG) Data which monitors the heart. The DigiTrak XT is an Association for the Advancement of Medical Instrumentation (AAMI) Type I device and part of a conventional AECG monitoring system where an Electrocardiogram (ECG) is recorded in Multi Media Card (MMC) memory within the recorder. After the recording is complete, the DigiTrak XT recorder is connected via the docking station to a Universal Serial Bus (USB) port on the Military Treatment Facilities' (MTFs') computer that runs the Holter software.

The Personally Identifiable Information (PII) and Protected Health Information (PHI) collected includes Admission, discharge, death, and all ages over 89 [and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older], name, date of birth, ID number, and medical record number. The categories of individuals from whom PII is collected include Active Duty Military, Retirees, their family members, and Federal employees.

CyberLogistics (CyberLOG) is responsible for the Risk Management Framework process and gaining an approval from Defense Health Agency's Joint Risk Management Executive Division (DHA J RMED). The MTFs/clinics are responsible for day-to-day operations, maintenance, and management of the DigiTrak XT recorder. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations. This system is owned by CyberLOG Enterprise and operated by various 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 collected is for identification and mission-related use. PII is intended to be used for supporting Ambulatory Health Care 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 because Philips DigiTrak XT Recorder- Holter System 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 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 because Philips DigiTrak XT Recorder- Holter System 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 Not Applicable

Because Philips DigiTrak XT Recorder does not request information directly from an individual, 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)

Within the DoD Component Specify. DHA Medical Treatment Facilities

Other DoD Components (i.e. Army, Navy, Air Force) Specify.

Other Federal Agencies (i.e. Veteran's Affairs, Energy, State) Specify. Department of Homeland Security
US Coast Guard

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 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. DigiTrak XT recorder support staff will access during the on-site installation. Support staff are required to follow DoD personnel security policies when granted access to sensitive information. Contract language states: DigiTrak XT recorder agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of th electronic protected health information or personally identifiable information that it creates, receives, maintains, and transmits in the execution of their Contracts.

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

Existing DoD Systems: Picture Archiving and Communication System (PACS)

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

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.

A system of records notice ("SORN") is not necessary because Philips DigiTrak XT Recorder – Holter System Version 3.X (hereinafter "Philips DigiTrak XT Recorder") does not collect information directly from an individual for inclusion in a System of Record, thus, individuals may not receive a Privacy Act Statement. Although the definition of a system of record is not dependent on the source of collection of personally identifiable information ("PII"), Department of Defense ("DoD") policy states that "information obtained without a Privacy Act Statement shall not be incorporated into any system of records." As such, a SORN is not required.

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.

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. Ch. 55, Medical and Dental Care; 32 CFR Part 199, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); DoDI 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs; DoDM 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs.

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 directly collected from members of the public.