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:

Canon Alphenix Series v9.x_A

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

01/05/24

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 system will be incorporated into CAB 000. The Alphenix-i Series imaging system is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities. The Alphenix-i is comprised of two hardware PC's, a DFP-8000V and Angio Workstation (AWS). The AWS is an optional hardware device and may not be present on all Alphenix-i systems. The Alphenix-i complies with DICOM V3.0 and uses the DICOM services for the import of ePHI, study information, and the export of DICOM data, including images, to the desired locations at the facility. All ePHI is stored locally but is not designed for archival purposes. All ePHI data should be removed as desired at the facilities discretion. Data is acquired from the Flat Panel Detector, preprocessed, and then sent to the digital processor, DFP-8000V for local storage. When image data is sent to remote storage, such as PACS, the images then are sent from the DFP-8000 via a TCP/IP twisted pair Ethernet cable onto the facilities network. The AWS provides post processing functionality as well as a DICOM viewer (Vitrea) for the import and export of DICOM V3.0 images and data. Data may be sent from the DFP-800V to the AWS, depending on workflow of the customer. Applicable System Series: Alphenix BiPlane Alphenix Sky+ Alphenix Hybrid+ Alphenix Sky Alphenix Core+ Alphenix Core Alphenix 4DCT Applicable Model Numbers: INFX-8000V INFX-8000C INFX-8000F INFX-8000H FDA 510K Numbers: INFX-8000V:K181670 INFX-8000C:K181804 INFX-8000H:K182546 INFX-8000F:K182415 XIDF-AWS801:K181415

The Alphenix application complies with DICOM V3.0 and uses the DICOM services for the import of ePHI, study information, and the export of DICOM data, including images, to the desired locations at the facility. All ePHI is stored locally although is not designed for archival purposes. All ePHI data should be removed as desired at the facilities discretion. All ePHI should be archived by the MTF, i.e., PACS. PII: Birth Date, Other ID Number, PHI, ePHI, Device Identifier or Serial numbers, any other unique identifying number, characteristic, or code. A patient's health conditions are captured, which necessarily creates PHI.

The PII in this system is obtained through an interface with the Composite Health Care System and then annotated on the patient's diagnostic images. It is the site's responsibility to purge the PII after the patient's diagnostic images with associated PII are transferred to a Picture Archive and Communication System (PACS) which stores and provides easy and secure access to the images.

Categories of individuals from about whom the information is collected: military patients and their dependents, and retirees.

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 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.

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 ☒ 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 /PHI because this system 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 /PHI because this system 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

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information system or electronic collection, 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.	The data will be shared with health care providers and identified super users within Defense Health Agency (DHA) medical treatment facilities (MTF) using this device.
☒ Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	The PII may be shared with health care providers within the other military services.
☒ 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 DHA 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

☒ Existing DoD Information Systems ☐ Commercial Systems

☐ Other Federal Information Systems

MWL Server in Hospital System (or DoD Information System)

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)*

The information is primarily sourced from primary hospital information systems, this can be PACS, or 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 ☐ No

If "Yes," enter SORN System Identifier EHDA-07

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.

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 1071-1085, Medical and Dental Care; 50 U.S.C. Supplement IV, Appendix 454, as amended, Persons liable for Training and Service; 42 U.S.C. Chapter 117 Sections 11131-152, Reporting of Information; 10U.S.C. 10997a and 1097b, Tricare Prime and Tricare Program; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children; 10 U.S.C. 1079a, CHAMPUS; 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; E.O. 9397 (SSN); DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTFs); DoD Directive 6040.37, Confidentiality of Medical Quality Assurance (QA) Records; DoD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Army Regulation 40-66, Medical Record Administration and Health Care Documentation.

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.

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).