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:

Ambu aView2 Advance_V1.X_A&I

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

01/01/24

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
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	New Electronic Collection
x 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 Ambu aView2 Advance is a medical device to be placed and utilized in various clinical locations within healthcare facilities. The device is an endoscopic visualization device (imaging processor), which generates images and videos via Ambu single-use endoscopes. The Ambu aView2 Advance must interface with the applicable Ambu aScope endoscopes, utilizing a proprietary multi-pin interface for communication between the video processing unit itself and the Ambu aScope endoscope(s), in order for the device to be used clinically in patient examinations, procedures, treatments, and/or studies. The Ambu aView2 Advance provides additional interface options via directional video feeds (3G-SDI and HDMI) that are intended to connect with external medical grade monitors; medical recorders; and image capture workstations. When utilized in this manner, no additional connectivity is necessary. It is possible for the generated imaging files to be transmitted directly to PACS via a private/local adjacent network or through USB approved drive. Personally Identifiable Information (PII) and Protected Health Information (PHI) entered does not stay on device or with file. Communication on the network can be accomplished via LAN with communications exclusively relegated to PACS utilizing the DICOM protocol.

Department of Defense (DoD) personnel working within the Medical Treatment Facility (MTF) may have general user capabilities to use the device in a clinical environment. They may also have administrative access as deemed by the vendor.

The PII collected includes personal information and PHI. The PII is entered from patients' current medical records and only the DoD ID number, gender, DOB and name can is entered. The PII is not required to generate photos or videos file for transferring to records. The aView2 can attache the video or photos from the device and the information entered and save to an approved USB or sent directly to PACS to patients' records. The information entered is NOT saved in aView2, it is immediately deleted once the file is moved to PACS or USB.

The categories of people PII is collected from includes: Active Duty Service Members, Retirees, Veterans, and their families, the general public and Federal employees and/or contractors.

The Ambu aView 2 Advance is owned and operated by DHA CyberLOG. CyberLOG is responsible for the risk management framework (RMF) process, and gaining approval from DHA J6 Risk Management Executive Division (R MED). Local sites address day to day operations, maintenance, and management of the device. Sites ensure 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 not collected for data matching, but can be added to video or photos to transmit through to PACS or USB exclusively. Reports are integrated in the medical records for that individual. The intended use of the PII is for transmission only to PACS, it is not saved to the instrument or instrument file.

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.

Ambu aView2 Advance_V1.X_AI receives PII from individual or individuals' records in hand; therefore, the opportunity to object is only available at the source system.

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.

Ambu aView2 Advance_V1.X_AI receives PII from individual or individuals' records in hand; therefore, the opportunity to consent to specific uses is only available at the source system.

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

The Ambu aView 2 Advance does not collect PII directly from individuals or individuals' records in hand; 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.	Defense Health Agencies' Military Treatment Facilities
[x]	Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	Army, Air Force, & Navy
[x]	Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	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 military treatment facilities (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)*

[x]	Individuals	[ ]	Databases
[x]	Existing DoD Information Systems	[ ]	Commercial Systems
[ ]	Other Federal Information Systems		

Existing DoD Information Systems:
(PACS)
(HL7)
(DICOM)_capable systems

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)*
[x]	In-Person Contact	[x]	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 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 system of records notice (SORN) is not required because the Ambu aView 2 Advance is not a system of records as it does not retrieve collect or store information, if any, by an individual's unique 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 Personnel and Readiness; 10 U.S.C. Ch. 55, Medical and Dental Care; Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 42 U.S.C. 290dd, Substance Abuse Among Government and Other Employees; 42 U.S.C. 290dd-2, Confidentiality Of Records; 42 U.S.C. Ch. 117, Sections 11131-11152, Reporting of Information; 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 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 entered into this system is for the diagnosis and treatment of medical disorders and is not considered a public information collection in with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).