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 UroNav Fusion Biopsy v4.x

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

01/16/25

Walter Reed National Military Medical Center (WRNMMC)

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.)*

- [x] 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.

UroNav is a stereotaxic accessory for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (U/S) images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic Resonance (MR), Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire, grid plate or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. Other software features include patient data management, multiplanar reconstruction, segmentation, image measurements and 2D/3D image registration. UroNav is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. The local MTF's collect the following PII identifiers such as Photographic/ Radiographic images, Test results, Medical record numbers, Device identifiers or serial numbers, and any other unique identifying number, characteristic or code such as date of birth, admission, discharge, etc. PII is only collected by federal employees or contractors. Controls to mitigate risk of exposure of PHI/PII are the use kiosk mode if the UroNav 3 is used as a standalone. In kiosk mode the user has no access to the underlying operating system. If joined to a domain, users authenticate with domain username/ password. After login the UroNav application is launched automatically, and user has no access to operating system. The UroNav internal drives are encypted using bitlocker for data at rest.

UroNav may use MRI images in DICOM format. Institutions performing the prostate MRI exam can encode any personal information in the DICOM tags of the MRI images sent to UroNav. UroNav will store the information as received. If the device is optionally connected to the hospital network any information in the MRI images DICOM tags may be transmitted by Uronav to connected DICOM nodes (e.g. PACS). Can also record Gender, Birthdate.

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 intended use the PII will be for the following :Verification, data matching with our compatible equipment and patient identification purposes; to insure we have the right patient for the right procedure.

e. Do individuals have the opportunity to object to the collection of their PII? [x] 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.

The opportunity for individuals to object to the collection of PII is presented during their initial appointment with the preforming physician.

f. Do individuals have the opportunity to consent to the specific uses of their PII? [X] 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 are asked to provide their PII and have an opportunity to object to the collection of their PII during their initial appointment with the Urology Center for Prostate Disease Research (CPDR) physician. If they choose not to provide the requested information, comprehensive health care services may not be possible, they may experience administrative delays, or they may be rejected from participating Prostate URONAV MRI examination/procedure.

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

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)*

[X]	Within the DoD Component	Specify.	DHA 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.	
[ ]	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.	
[ ]	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

Source of PII is from individuals who complete the questionnaire in person.

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
[ ] Paper
[ ] Fax
[ ] Telephone Interview
[X] Information Sharing - System to System
[ ] Website/E-Form
[ ] Other *(If Other, enter the information in the box below)*

WRNMMC Urology Department questionnaire and procedure consent forms.

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.

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 USC 3013, Secretary of the Army; 10 USC 1071-1085, Medical and Dental Care; 50 USC Supplement IV, Appendix 454, as amended, Persons liable for training and service; 42 USC Chapter 117, Sections 11131-11152, Reporting of Information; 10 USC 1097a and 1079a, TRICARE prime and TRICARE Program; 10 U.S.C 1079, Contracts for Medical Care for Spouses and Children; 10 USC 1079a, CHAMPUS; 10 USC 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTF); 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)

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 within this system is for the diagnosis and treatment of medical disorders and does not collect PHI/PII directly from individuals of the general public; however, the system components, applications, or electronic collections within, in accordance with DoDM 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).