

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:

Medtronic StealthStation S8 AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

12/01/23

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 Medtronic StealthStation™ S8 surgical navigation system allows the clinician to precisely track the location of surgical instruments throughout a procedure. This system is comprised of a platform, clinical software, surgical instruments, and a referencing system (which includes patient and instrument trackers) for neurosurgery and other medical specialties. The StealthStation™ S8 system introduces the most advanced version of Stealth technology which includes a combination of hardware, software, tracking algorithms, image data merging, and specialized instruments to help guide the clinician during surgical procedures. The system tracks the position of instruments in relation to the surgical anatomy, known as localization, and then identifies this position on preoperative or intraoperative images of a patient. Advanced visualization 3D-imaging and powerful multitouch-enabled interactions provide surgeons and clinicians the tools necessary to improve patient outcomes.

The categories of individuals with records in this system are DoD health care beneficiaries to include Military members of the Armed Forces, Military retirees, and their family members as well as other categories of individuals eligible for medical care at DoD treatment facilities/activities.

The types of PII/PHI collected include: Patient Image, Name, Date of Birth, Gender, Medical Information, Medical Record Number, and Device Identifier.

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.

The PII in this system is obtained through an interface with the Composite Health Care System; is annotated on the patient's diagnostic images; and purged when the patient's diagnostic images are transferred to a Picture Archive and Communication System (PACS) which stores and provides easy access to the images.

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.

The opportunity for individuals to object to the collection of PII is specific to the method used to collect PII in the respective system component and is addressed in the sub-system's PIA.

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.

The opportunity to consent is only available at the source system where the PII was initially collected.

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

The LAN infrastructure does not collect PII directly from individuals; however, system components, applications, and electronic collections within the enclave might collect PII. Refer to the respective system component, application, or electronic collection PIA for additional information.

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)

- | | | |
|---|----------|--|
| <input checked="" type="checkbox"/> 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. |
| <input checked="" type="checkbox"/> Other DoD Components (i.e. Army, Navy, Air Force) | Specify. | The PII may be shared with health care providers within the other military services. |
| <input checked="" type="checkbox"/> 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. | |
| <input checked="" type="checkbox"/> 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 Cybersecurity 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 |
| <input checked="" type="checkbox"/> Existing DoD Information Systems | Commercial Systems |
| Other Federal Information Systems | |

The information is primarily sourced from primary hospital information systems, this can be PACS (picture archiving and communication system), HL7 (Health Level 7 Standard) or DICOM (Digital Imaging and Communications in Medicine) capable systems.

j. How will the information be collected? (Check all that apply and list all Official Form Numbers if applicable)

- | | |
|--|---|
| <input type="checkbox"/> E-mail | Official Form (Enter Form Number(s) in the box below) |
| <input type="checkbox"/> In-Person Contact | Paper |
| <input type="checkbox"/> Fax | Telephone Interview |
| <input checked="" type="checkbox"/> 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.

The system does not collect and maintain records about an individual where the records are retrieved by the individual's name, number, or unique identifier IAW the Privacy Act of 1974, as amended.

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.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter Ch. 55, Medical and Dental Care; 10 U.S.C. 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 U.S.C. 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 U.S.C. 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 U.S.C. 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 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 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); DoDI 6025.18; and E.O. 9397 (SSN).

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).