# 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:**

Nihon Kohden Family of EEG Neurology & Sleep Devices V.12.x_AA

**2. DOD COMPONENT NAME:**

Defense Health Agency

**3. PIA APPROVAL DATE:**

10/20/2026

NCM MDE Cyber

## 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.**

The Nihon Kohden Polysmith Sleep System_Assessment and Authorization (Polysmith SS AA) is intended to amplify and record physiologic potentials used for Polysomnography (PSG) or Sleep Studies. It comprises patient-facing neurophysiology acquisition systems, review systems, real-time monitoring systems, and server infrastructure for centralized patient information and data storage. Qualified practitioners use the information to score polysomnograms and diagnose sleep disorders. The Live View Panel (LVP) consists of several software components that allow remote viewing of digitized physiological waveforms and general patient information to view PSG or Electroencephalography(EEG) patients in real time or in review. A software module resides on the EEG or PSG device and sends patient data to a remote computer, where another software module displays the data on an array of monitors.

As part of the medical diagnosis and creation of interpretation reports, patient data is collected and typically involves the capture of medical history, medications, personal information, contact information (e.g., address and phone number), responses to clinical questionnaires. Any clinically relevant data a medical practitioner requires in aid of diagnosis, treatment, and maintenance of therapy of a sleep disorder. Note: The Polysmith SS AA has custom and built-in data fields to collect various types of information, but the data type collected is determined by the Department of War (DoW) and medical personnel in accordance with applicable laws and regulations.

Information collected includes: personal information, home/cell phone, address, records, DoW Identification (ID)#/other IDs, sex, medical information, photo, Protected Health Information (PHI), and Personally Identifiable Information (PII). The categories of individual from/ about whom the information is collected include retirees, active duty and their dependents. PII collected includes Medical History "Records" relevant to the patient's condition and treatment, other test results, medication, previous treatments, clinically relevant photographs, and medical questionnaires. Also, PSGs collect nocturnal digital video with audio as a matter of standard practice to aid in the diagnosis and severity of sleep disorders. The digital video with audio is part of the recorded PSG study but is not stored as part of the database. PHI collected includes the Patient ID, which must be a unique identifier such as the Medical ID Number (i.e., the ID is not required to be the DoW ID number).

The Polysmith SS AA is owned and operated by Military Treatment Facility (MTF)s which purchase the device. NCM MDE Cyber is responsible for the risk management framework (RMF) process and gaining approval from DHA J6 Risk Management Executive Division (RMED). Local sites are responsible for day-to-day operations, maintenance, and management of the device. Sites are responsible for ensuring the device is configured to meet NCM MDE Cyber, and RMED approved configurations. This is an Enterprise PIA.

**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)*

PII is collected for identification purposes to match individuals with their medical records and to ensure accuracy when those records are integrated with other records for the same individual. The PII collected will be used for mission-related purposes that 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.

PII is provided by the patient directly or collected by a clinician from the patient and entered into this system. The patient has an opportunity to verbally object to the collection of their PII. If they choose not to provide the requested information, comprehensive health care services may not be possible, they may experience administrative delays, and they may be rejected for service or an assignment. However, care will not be denied.

**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.

PII is provided by the patient directly or collected by a clinician from the patient and entered into this system. The patient has an opportunity to verbally consent to the specific uses of their PII. If they choose not to provide the requested information, comprehensive health care services may not be possible, they may experience administrative delays, and they may be rejected for service or an assignment. However, care will not be denied.

**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

AUTHORITY: Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter 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. Chapter 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of Defense Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities; and DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs.

PURPOSE: Clinical personnel use the Nihon Kohden Family of EEG Neurology & Sleep Devices V.12.x_AA to collect, display, review, record, and store physiologic data and related personally identifiable information and protected health information for polysomnography (PSG), electroencephalography (EEG), sleep studies, diagnostic interpretation, treatment planning, continuity of care, and related clinical documentation and healthcare operations.

ROUTINE USES: In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, these records may specifically be disclosed outside the Department of Defense as a routine use pursuant to 5 U.S.C. 552a(b)(3). These routine uses are identified in SORN EDHA 07.

DISCLOSURE: Voluntary; however, failure to provide the requested information may result in administrative delays, an inability to associate diagnostic data with the correct patient, incomplete clinical documentation, delays in diagnosis or treatment, or other limitations in the provision of healthcare services.

**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. | Defense Health Agency (DHA) MTF |
| ☒ | Other DoD Components *(i.e. Army, Navy, Air Force)* | Specify. | Army, Navy, Air Force and Marine |
| ☐ | 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. | The MTF may utilize contractor services to support this product. DoW 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)*

☒ Individuals
☒ Existing DoD Information Systems
☐ Other Federal Information Systems
☒ Databases
☐ Commercial Systems

Databases used are locally determined by MTFs.

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

☐ E-mail
☒ In-Person Contact
☐ Fax
☒ Information Sharing - System to System
☒ Other *(If Other, enter the information in the box below)*
☐ Official Form (*Enter Form Number(s) in the box below)*
☒ Paper
☐ Telephone Interview
☒ Website/E-Form

Patient Questionnaire as selected by DoW medical personnel relevant to the diagnosis and treatment of patients. Information can be captured on paper and scanned into the Polysmith SS AA or questionnaires can be filled out using the Polysmith AA SS as an electronic form (E-Form).

**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 EDHA 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.

Select NO, IF the system does not collect and maintain records about an individual where the records is retrieved by the individual's name, number or unique identifier IAW the Privacy Act of 1974, as amended. (Chapter 55 of Title 10 USC, §1071 - 1106.)

**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.

Mission Schedules:
- Intermediary Records: GRS 5.2, item 020 (DAA-GRS-2022-0009-0002)

Other Schedules:
- System Access Records: GRS 3.2, item 030 (DAA-GRS-2013-0006-0003),
- Data Administration and Documentation: GRS 3.1, item 051 (DAA-GRS-2013-0005-0003)

(2) If pending, provide the date the SF-115 was submitted to NARA.

(3) Retention Instructions.

Mission Schedules:
FILE NUMBER: 103-14
FILE TITLE: Intermediary Records
DISPOSITION: Temporary. Cut off and destroy upon creation or update of the final record, or when no longer needed for business use, whichever is later.
RM NOTE: Exported patient record information is maintained in the appropriate electronic health record system i.e. MHS Genesis.

Other Schedules:
FILE NUMBER: 1601-02
FILE TITLE: System Access Records - Systems not requiring Special Accountability for Access
DISPOSITION: Temporary. Cut off and destroy when business use ceases.

FILE NUMBER: 1601-12
FILE TITLE: Data Administration and Documentation - Temporary Systems
DISPOSITION: Temporary. Cut off after the project/activity/transaction is completed or superseded, or the associated system is terminated, or the associated data is migrated to a successor system. Destroy 5 years after cutoff.

**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.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter 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. Ch. 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of War (DoW) Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFS); and DoW Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoW 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.

The information collected in this system is for the diagnosis and treatment of medical disorders and is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).