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:

Vyaire Sentry Suite 3.20 AA

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

05/20/24

CyberLOG

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 Vyntus/SentrySuite Product Line is intended to be used for measurements, data collection and analysis of lung function (PFT) and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation purposes. The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance - no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities). A qualified physician has to reassess all Vyntus/SentrySuite measurements. An interpretation by Vyntus/SentrySuite is only significant if it is considered in connection with other clinical findings. The Vyaire Sentry Suite v3.20 family of devices consist of: Vendor provided Windows10 MobileCart/Workstation, Vyntus APS/Masterscreen, Vyntus BODY, Vyntus Spiro Laptop w/ Printer, Vyntus WALK Tablet, Vyntus ONE, Vyntus CPX and a MTF Hosted Application and SQL Server. This system does contain PHI/PII, is scannable via Nessus, and complies with Endpoint Security requirements. The baseline for this package is Landstuhl RMC, Germany.

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 the individual with his/her medical diagnostic reports and to ensure accuracy when these reports are integrated in the medical records for that individual.
- The intended use of PII is 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 [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.

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; however, the source system may provide the individual the opportunity to object to the collection.

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.

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; however, the source system may provide the individual the opportunity to object to the 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

Vyaire Sentry Suite 3.20 does not collect PII directly from individuals. Therefore, no Privacy Act Statement or 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 PII will be shared with authorized personnel within the MTF using this system.
☐ 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.	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)*

☐ Individuals ☐ Databases

☒ Existing DoD Information Systems ☐ Commercial Systems

☐ Other Federal Information Systems

The source of the PII collected in this system is the DoD Electronic Health Record (EHR)

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)*

This system obtains the individual's PII through an interface with the DoD EHR.

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://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-2022-0009-0002)

(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., Chapter 55; Pub.L. 104-91, Health Insurance Portability and Accountability Act of 1996; DoD 6025.18-R, DoD Health Information Privacy Regulation; 10 U.S.C. 1071-1085, Medical and Dental Care; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; 10 U.S.C. 1097a 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, 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; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTFs); DoD 6010.8-R, CHAMPUS; 10 U.S.C. 1095, Collection from Third Party Payers Act; 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 is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).