

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:

Dentsply Sirona inLab Family Series Version 20.X_AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

10/24/23

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.

Dentsply Sirona Inlab is a family series of devices. The Inlab family of devices includes Inlab Milling & Grinding Machine (MC X5), INLAB MC XL, INLAB PC, Profire and the inEos X5. This software enables computer-assisted dental restorations from various materials. The Sirona Dental (Computer-Aided Design/Computer-Aided Manufacturing) CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement-retained restorations.

These families of devices are connected via Universal Serial Bus (USB) and Category 5 (CAT5) cables. They connect to the Inlab inEos X5 Scanner with Inlab CAD SW, to the MCX5 Milling unit and Inlab MCXL Milling unit with the Inlab CAM SW connection to the INLAB PC. The family of devices operates as a Peer-to-Peer LAN – it operates in logical isolation but requires the use of networking protocols or RS-232 serial data communications for host-to-host connectivity. Devices transfer PII/PHI in the form of patient name and patient ID to the Inlab PC for use in patient identification. Hardware includes INLAB MC X5, INLAB MCXL, INLAB PC, Profire and the inEos X5.

Categories of individuals about whom the Personally Identifiable Information (PII) is collected: Military members of the Armed Forces and individuals of the general public.

Types of personally identifiable information collected are Names, DoD ID numbers, PHI.

Cyber Logistics (CyberLOG) is responsible for the risk management framework (RMF) process and gaining approval from Defense Health Agency J6 Risk Management Executive Division (RMED). Local sites are responsible for the device's day-to-day operations, maintenance, and management. 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 collected to match an individual with his/her medical diagnostic reports and to ensure accuracy when these reports are integrated into that individual's medical records. The intended use of PII is for mission-related purposes to support the delivery of 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.

Individuals do not have the opportunity to object to the collection of their PII because Dentsply Sirona inLab Family Series Version 20.X_AI is not the initial point of collection.

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.

Individuals do not have the opportunity to consent to the specific uses of their PII because Dentsply Sirona inLab Family Series Version 20.X_AI is not the initial point of 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

Dentsply Sirona inLab Family Series Version 20.X_AI 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)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Within the DoD Component | Specify. DHA Medical Treatment Facility (MTF) |
| <input checked="" type="checkbox"/> Other DoD Components (i.e. Army, Navy, Air Force) | Specify. Army, Navy, Air Force, Space Force, and Marines |
| Other Federal Agencies (i.e. Veteran's Affairs, Energy, State) | Specify. |
| 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 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 |
| <input checked="" type="checkbox"/> Existing DoD Information Systems | Commercial Systems |
| Other Federal Information Systems | |

Armed Forces Health Longitudinal Technology Application (AHLTA); Composite Health Care System (CHCS); and Military Health System (MHS) Genesis/Dentrix.

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 |
| <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.

No PII is retrieved by unique identifier.

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.

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. Chapter 55, Sections 1071-1097b, Medical and Dental Care; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; DoDM 6025.18, Implementation Of The HIPAA Privacy Rule In DoD Health Care Programs; DoD 6010.8-R, CHAMPUS; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities: Foreign Service Care; Third-Party Collection; Beneficiary Counseling and Assistance Co The authorities for this PIA are the same as in F044 F SG E Medical Records SORN.ordinators (BCACs); Pub.L. 104-91, Health Insurance Portability and Accountability Act of 1996; 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 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).