

DOC-2026-140 — XyDromatics VNA Research — DICOM Conformance Statement

Document number: DOC-2026-140 **Title:** XyDromatics VNA Research — DICOM Conformance Statement
Version: v4 **Category:** DICOM Conformance Statement **Release version:** 1.0.3.155 **Product:** XyDromatics VNA Research v1.0.3.155 **Classification:** Research Use Only (RUO); non-device software (FD&C Act §520(o)(1)(D))
Owner: Synthology Healthcare Solutions Group (SHSG) **Effective date:** (on approval)

0. Regulatory Notice — Research Use Only

This product is RESEARCH USE ONLY. IT IS NOT A MEDICAL DEVICE. IT IS NOT FDA CLEARED OR APPROVED. IT IS NOT FOR CLINICAL USE, CLINICAL DECISION-MAKING, DIAGNOSIS, TREATMENT, MONITORING, OR ANY OTHER PATIENT-CARE PURPOSE.

Every object passing through VNA Research's ingest SCP is subjected to a non-bypass DICOM PS3.15 Basic Application-Level Confidentiality Profile before persistence. The anonymization pipeline is compile-time enforced and cannot be disabled or weakened by any operator-role user. `/health` reports

`anonymization_enforced: true` as a service-startup invariant.

This Conformance Statement describes what DICOM services VNA Research exposes; it does **not** imply any clinical-use suitability.

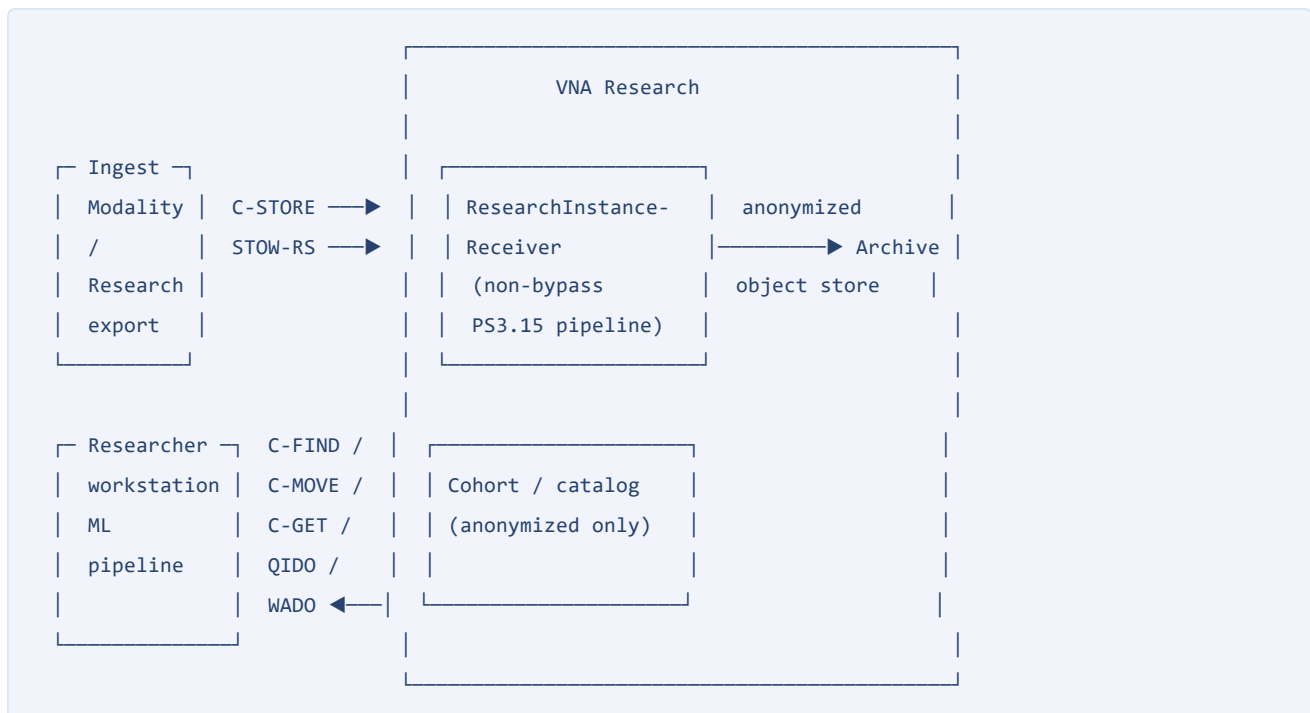
1. Conformance Statement Overview

XyDromatics VNA Research is a research-dataset archive. It accepts DICOM objects over C-STORE or STOW-RS (each object is anonymized before persistence), supports cohort-based query and retrieval via C-FIND / C-MOVE / C-GET / QIDO-RS / WADO-RS, and exports anonymized datasets via `research_export`. It deliberately omits services that would create paths for identifiable data to flow in or out: **no HL7 ingest, no Storage Commitment, no inbound replication, no MWL, no MPPS.**

DICOM Service	v1.0.2.138 Support
Verification (C-ECHO) SCP	Yes
Storage (C-STORE) SCP	Yes — with mandatory ingest-time anonymization
Storage (C-STORE) SCU	Yes (used only for cohort-export outbound forwarding to a research collaborator's endpoint)
Query/Retrieve (C-FIND) SCP	Yes (Study Root + Patient Root)
Query/Retrieve (C-MOVE) SCP	Yes
Query/Retrieve (C-GET) SCP	Yes
DICOMweb STOW-RS (SCP)	Yes — with mandatory ingest-time anonymization
DICOMweb QIDO-RS (SCP)	Yes
DICOMweb WADO-RS (SCP)	Yes
Storage Commitment	Not supported — deliberate RUO design choice
Modality Performed Procedure Step (MPPS)	Not supported
Modality Worklist (MWL)	Not supported
HL7 v2.x MLLP	Not supported and not reserved — HL7 would route identifiable data and is not on the VNA Research roadmap.
Replication (outbound C-STORE / STOW-RS mirror)	Not supported

2. Implementation Model

2.1 Application Data Flow — The RUO Anonymization Boundary



2.2 Anonymization Pipeline

The anonymization pipeline is implemented by `Synthology.Vna.Anonymization.BasicProfileAnonymizer`, which invokes fo-dicom's `DicomAnonymizer` configured for DICOM PS3.15 Annex E — **Basic Application-Level Confidentiality Profile**.

Enforced transformations (non-exhaustive; full tag list per PS3.15 Basic Profile):

- `PatientName (0010,0010)` → empty or replaced with cohort pseudonym
- `PatientID (0010,0020)` → replaced with a randomly generated per-study identifier
- `PatientBirthDate (0010,0030)` → empty
- `PatientSex (0010,0040)` → retained
- `StudyInstanceUID (0020,000D)`, `SeriesInstanceUID (0020,000E)`, `SOPInstanceUID (0008,0018)` → rewritten with fresh UUIDs per invocation; **no persistent source-to-pseudonym mapping is retained**
- `AccessionNumber (0008,0050)` → empty
- `InstitutionName / InstitutionAddress` → empty
- `ReferringPhysicianName (0008,0090)`, `PhysiciansOfRecord`, `PerformingPhysicianName` → empty
- `StudyDate`, `StudyTime`, `SeriesDate`, `SeriesTime`, `AcquisitionDate`, `AcquisitionTime` → retained (research cohorts typically require temporal ordering)
- Private tags → stripped
- `BurnedInAnnotation (0028,0301) == "YES"` → **object rejected at ingest** (cannot be safely de-identified without pixel-level redaction which v1.0.2.138 does not perform)

No `DeidentificationMethodCodeSequence (0012,0064)` is currently written to outbound objects. This is a known gap; a future v1.x will add `(113100, DCM, "Basic Application Confidentiality Profile")` to the sequence.

2.3 Functional Definition

VNA Research is not a medical device. Its functions are: ingest of DICOM objects with mandatory anonymization; cohort-based query and retrieval; export of anonymized datasets for research use. **VNA Research is not a PACS, not a diagnostic viewer, and not for clinical image interpretation.**

3. AE Specifications

3.1 Application Entity Identification

Parameter	Default	Configurable at	Notes
Storage SCP AE Title	XYDROMATICS_RES	MSI + Settings → DICOM	
Storage SCP port	11116	MSI + Settings → DICOM	TCP
Query/Retrieve SCP AE Title	XYDROMATICS_RES	MSI + Settings → DICOM	
Query/Retrieve SCP port	11117	MSI + Settings → DICOM	TCP
Web UI port	5203	MSI	HTTPS
DICOMweb base path	/dicomweb/	Not configurable	On Web UI port
HL7 MLLP port	Not bound	n/a	Research lane does not accept HL7 by design

3.2 Association Policy

Same as VNA Repository §3.2, with one addition: **all ingest associations are subject to ingest-time anonymization; anonymization failure causes the ingested object to be rejected with C-STORE response c000 (processing failure) and the association is allowed to continue for the remaining objects.**

3.3 Storage SCP — Accepted SOP Classes

Accepts any Storage-class SOP class (1.2.840.10008.5.1.4.1.1.*). See VNA Repository §3.3.

Burned-In Annotation restriction: objects with `BurnedInAnnotation == "YES"` are rejected at ingest regardless of SOP class (see §2.2).

3.4 Query/Retrieve — Supported SOP Classes (SCP)

Same set as VNA Repository §3.4.

3.5 Transfer Syntaxes

Same set as VNA Repository §3.5. Query/Retrieve responses: ILE / ELE. Compressed pixel data is retained in its ingested transfer syntax; VNA Research does not transcode on ingest or on retrieval.

3.6 Extended Negotiation

Same as VNA Repository §3.6 (no relational queries, no fuzzy matching).

3.7 Character Sets

Same as VNA Repository §3.7.

4. DICOMweb Specification

4.1 STOW-RS

Same routes as VNA Repository §4.1; anonymization pipeline applies identically to STOW-RS ingest.

4.2 QIDO-RS

Same routes as VNA Repository §4.2. Query keys that reference PHI-class tags (PatientName, PatientBirthDate, etc.) are still supported syntactically but will match only the post-anonymization content (typically empty or pseudonymized).

4.3 WADO-RS

Same routes as VNA Repository §4.3.

5. Security

- TLS: same as VNA Repository §5.
- Authentication for DICOMweb: bearer token.
- Authentication for DIMSE: Calling-AE whitelist.
- Audit: ingest anonymization events are logged (source Calling AE, original SOP Instance UID, anonymized SOP Instance UID — note that the source-to-pseudonym mapping is **not** retained in the catalog beyond this audit entry, by design).

6. Character Set and Language Support

Same as VNA Repository §6. Anonymization does not alter character set.

7. Codes and Controlled Terminology

Research cohorts may use arbitrary code systems. VNA Research stores and returns code sequences verbatim after anonymization (code sequences are not PHI).

8. Annexes

8.1 RUO Intent Carried on the Wire

VNA Research publishes RUO markers at two layers:

1. **Service-discovery layer:** `GET /health` returns `regulatory_class: RUO`, `not_for_clinical_use: true`, and `anonymization_enforced: true`. Consumers should check this endpoint before peering.
2. **Web UI layer:** every page renders a persistent RUO banner. The UI cannot be custom-styled to suppress it.

8.2 Objects Rejected at Ingest

The following cause a C-STORE reject (Status `A901 Dataset does not match SOP Class` for SOP-class violations, `C000 Processing failure` for anonymization failure, `A901` for missing required UUIDs):

- SOP classes outside the Storage UUID prefix
- Objects missing StudyInstanceUID, SeriesInstanceUID, or SOPInstanceUID
- Objects with `BurnedInAnnotation == "YES"`
- Objects where the anonymization pipeline raises an exception (logged but contents discarded)

8.3 Deliberate Omissions (Not Reserved)

Unlike VNA Repository and VNA Migration, the following are **not on the VNA Research roadmap** because they would undermine the RUO boundary:

- HL7 v2.x ingest (HL7 carries PHI outside the DICOM anonymization pipeline)
- Inbound replication from a non-anonymized peer
- `storage_commitment` (Research is not an accountable long-term archive for any particular clinical-origin study; the source covered entity retains the accountable archive)
- Any `research_to_clinical` feature (would re-introduce research-lane content into clinical care; prohibited by the EULA annex §A1.2)

8.4 Known v1.0.2.138 Gaps

- `DeidentificationMethodCodeSequence` not written on outbound objects (see §2.2). Workaround: consumers may assume PS3.15 Basic Profile if the object arrives from a VNA Research AE Title.
- No pixel-data de-identification (burned-in annotations cause rejection rather than pixel redaction).

9. Cross-References

- EULA Annex: DOC-2026-135 (XyDromatics VNA Research EULA Annex)
- Hardware & Software Requirements: DOC-2026-130 (XyDromatics VNA Research HW/SW Requirements)
- Anonymization library: `Synthology.Vna.Anonymization.BasicProfileAnonymizer` (wraps `fo-dicom DicomAnonymizer` with PS3.15 Basic Profile)
- Product-family regulatory posture: DOC-2026-114 v3 §8
- Regulatory classification memo: standing rule `regulatory_classification_product_family` (RUO non-device, anonymization-enforced)

Regulatory classification. Non-device software under the FD&C Act §520(o)(1)(D) software exclusion. This statement is published by Synthology Healthcare Solutions Group, LLC as a controlled document; the authoritative version is the approved record in the Synthology quality-management system.