DOC-2026-076 — XyDromatics Pathology Engine: DICOM Conformance Statement

Document number: DOC-2026-076 **Release version:** 1.0.1.116 **Version:** 2 **Product:** XyDromatics Pathology Engine (IPE) v1.0.x **Audience:** Integrating vendors, pathology-lab IT, VNA/PACS vendors **Owner:** Synthology Healthcare Solutions Group (SHSG) **Cross-references:** DOC-2026-051 (IPE DHF); DOC-2026-060 (IPE HW/SW Requirements); DOC-2026-071 (IPE Installation Guide); DOC-2026-075 (VNA Conformance — downstream target).

Structured per DICOM PS3.2 (Conformance) 2024c.

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1. Introduction

1.1 Revision History

Version	Date	Change
1	2026-04-18	Initial release (IPE v1.0.x).

1.2 Audience

Digital-pathology scanner integrators, VNA/PACS vendors configured as IPE's downstream STOW-RS target, and lab-IT personnel deploying IPE alongside a whole-slide scanner.

1.3 Remarks

IPE is a **file-watcher-driven DICOMizer**. Its inputs are vendor- native whole-slide image files (SVS, NDPI, MRXS, VMS, VMU, SCN, BIF, TIFF) placed in an intake folder. Its outputs are DICOM Whole Slide Microscopy Image SOP Instances (SOP Class 1.2.840.10008.5.1.4.1.1.77.1.6) pushed to a downstream DICOMweb STOW-RS endpoint.

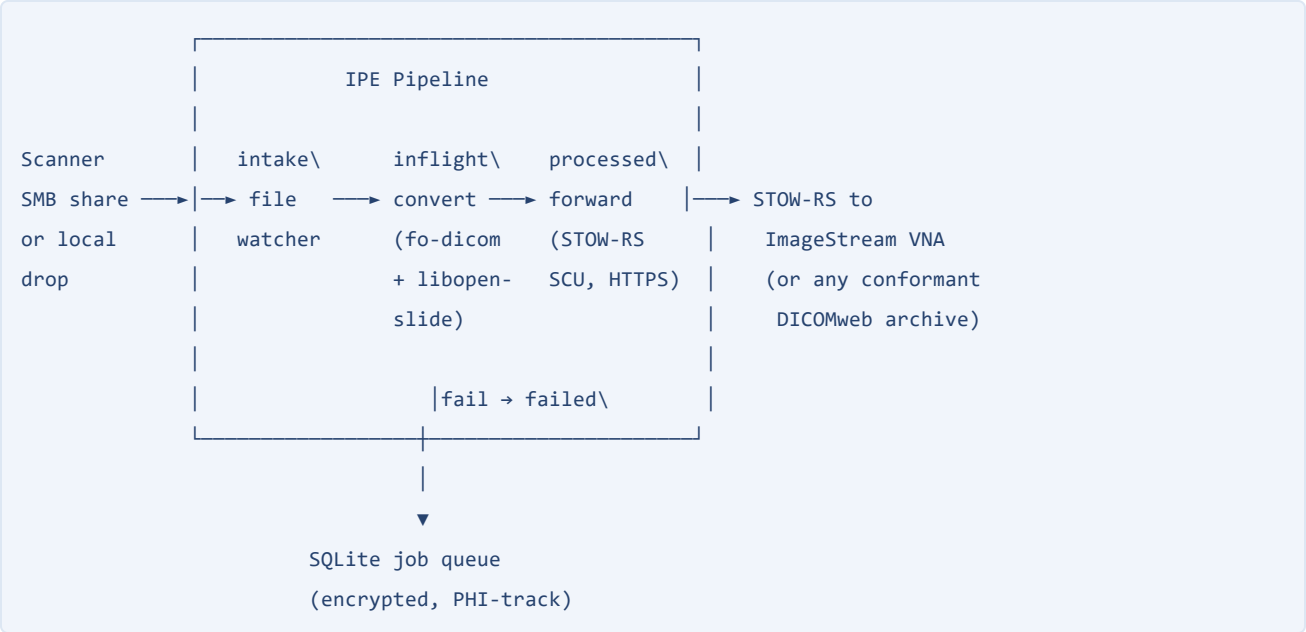
IPE has **no DICOM SCP surface**. It never listens for DICOM associations. It is a one-directional pipeline (file → DICOM → STOW-RS).

1.4 Conformance References

- DICOM PS3.1–PS3.18, 2024c (esp. PS3.3 Section A.32.8 — VL Whole Slide Microscopy Image; PS3.18 — STOW-RS).
- OpenSlide version as bundled (see `/dicom-tools` → OpenSlide version in the IPE dashboard).

2. Implementation Model

2.1 Application Data Flow



2.2 Functional Definitions

- **Intake watcher** — FileSystemWatcher on configured intake folder.
- **WSI Converter** — reads native WSI via OpenSlideNET; tiles the full image at each magnification level into DICOM WSI frame sequences; emits per-level SOP Instances.
- **STOW-RS SCU** — HTTPS POST of `multipart/related; type="application/dicom"` to the destination archive.

2.3 Sequencing

1. Scanner writes a complete WSI file to `intake\`.
2. IPE's `FileSystemWatcher` fires; the file is moved to `inflight\` (atomically, same-volume).
3. Converter opens the file via OpenSlide, maps the pyramid to DICOM WSI levels, creates SOP Instances, writes to `inflight\<uid>\`.
4. STOW-RS SCU posts each instance to the destination.
5. On 200/202 response, the source file is moved to `processed\` (or deleted per config). On error, moved to `failed\` with a job-level error record.

3. AE / Origin Specifications

IPE has no DICOM AE in the classical sense — it is exclusively a DICOMweb origin. An Implementation Class UID is still assigned for the purposes of tagging generated SOP Instances (see §3.3).

3.1 Network Origins

Origin	Direction	Role
STOW-RS	outbound only	SCU (DICOMweb origin)
Configuration web UI	inbound (5100/tcp)	not DICOM

3.2 STOW-RS Client Profile

3.2.1 Supported Response Codes

- **200 OK** — all instances accepted; job → processed.
- **202 Accepted** — partial success; per-instance warning / failure parsed from `application/dicom+xml` response; fully-failed job → failed, partial → partial-success with per-instance breakdown.
- **409 Conflict** — treated as success for duplicate-UID idempotency.
- **4xx / 5xx** — job → failed, retry per config (default 3 attempts with exponential backoff 30 s / 5 min / 30 min).

3.2.2 Authentication

- Bearer token (configured per destination).
- HTTP Basic (configured per destination; discouraged).
- No-auth (for lab-internal test deployments).

3.3 Generated SOP Instance Tagging

Field	Value
Implementation Class UID	1.2.826.0.1.3680043.10.1443.3
Implementation Version Name	IMAGESTREAM_IPE_1_0
Manufacturer (0008,0070)	Synthology Healthcare Solutions Group
Manufacturer's Model Name (0008,1090)	XyDromatics Pathology Engine
Software Version (0018,1020)	1.0.x (specific at emit time)

3.4 Produced SOP Classes

SOP Class	UID
VL Whole Slide Microscopy Image Storage	1.2.840.10008.5.1.4.1.1.77.1.6

3.5 Transfer Syntaxes — Outbound

IPE negotiates the following on STOW-RS (embedded in the `multipart/ related` DICOM payload): | Transfer Syntax | UID | When used | |—|—|—| | Explicit VR Little Endian | 1.2.840.10008.1.2.1 | Uncompressed (small slides) | | JPEG Baseline (Process 1) | 1.2.840.10008.1.2.4.50 | Default for brightfield | | JPEG 2000 Lossless | 1.2.840.10008.1.2.4.90 | Configurable per use | | JPEG 2000 | 1.2.840.10008.1.2.4.91 | Default for large-tile compression |

Configurable per scanner / per rule.

4. Communication Profiles

HTTPS / TCP IPv4 & IPv6. WSI file intake over SMB or local filesystem. Outbound HTTPS on 443/tcp (or custom port to the VNA). Inbound 5100/tcp is the IPE web UI only (not DICOM).

5. Extensions, Specializations, Privatizations

5.1 Pyramid Synthesis

For scanners whose native pyramids are sparse or misaligned, IPE optionally synthesizes intermediate pyramid levels using ImageSharp + OpenSlide's sub-resolution reads. This is a **lossy** operation documented per slide in `(0020,4000) ImageComments` with the text `SHSG-IPE: level N synthesized from level M`.

5.2 HIPAA Mode (license-gated)

`hipaa_mode` is a license-feature gate, not a runtime toggle (design control per DOC-2026-066 §A.2). When licensed, additional audit records are emitted on every conversion and forward; without the license, the config value is force-reset to `false` at startup.

5.3 No PHI Generation

IPE does not synthesize PHI. Patient demographics must either be (a) present in the source WSI's metadata (vendor-dependent; often absent), (b) present in a sidecar metadata file placed alongside the WSI in `intake\`, or (c) reconciled downstream. IPE's default behavior when source metadata is missing is to emit `(0010,0010) PatientName = ""` and `(0010,0020) PatientID = "UNKNOWN"` plus an ImageComments diagnostic. Customers requiring strict PHI presence should configure IPE's `require_patient_metadata` policy which moves the slide to `failed\` instead.

6. Configuration

Setting	Default	Where
Intake folder	`D:\Synthology\PathologyEngine\intake\`	config.json `intake.folder`
STOW-RS destination URL	(none)	config.json `stow.destination_url`
Default Transfer Syntax	JPEG Baseline	config.json `stow.transfer_syntax`
Web UI port	5100/tcp	config.json `web.port`

7. Support of Character Sets

IPE emits UTF-8 SOP Instances (Specific Character Set `ISO_IR 192`). If source WSI metadata arrives in a non-UTF-8 encoding, IPE transcodes to UTF-8 at emit time. Round-trip integrity is NOT guaranteed for character sets outside ISO-IR 6 / ISO-IR 100 / ISO-IR 192 / GB18030 (see §9.2 Known Quirks).

8. Security

8.1 Network

- STOW-RS to destination should run over HTTPS. IPE refuses plain-HTTP destinations unless `stow.allow_insecure` is explicitly set (default false).
- Outbound HTTPS TLS 1.2 / 1.3; downgrade to TLS 1.0/1.1 not supported.

8.2 Audit

- Job lifecycle records (intake / converting / forwarding / processed / failed) persisted to the SQLite (SQLCipher-encrypted) job store.
- HIPAA-mode audit records (when licensed) include conversion start/end timestamps, DICOM SOP Instance UIDs produced, destination AE, byte counts, and outcome.

8.3 Access Control

Web UI: Admin / Operator / Viewer roles, JWT-Bearer. No DICOM-level access control (IPE has no DICOM surface to protect).

9. Annexes

9.1 Non-Conformances

- Does NOT act as DICOM SCP (by design — file-watcher architecture).
- Does NOT implement DIMSE Storage, Q/R, MPPS, Storage Commitment, or Verification directly over DICOM.
- Does NOT produce Ophthalmic, VL Endoscopic, or other non-WSI photographic SOP Classes; produces VL Whole Slide Microscopy Image exclusively.
- Does NOT consume DICOMweb (no ingestion from WADO-RS).

9.2 Known Quirks

- OpenSlide version dictates which scanner models are convertible. If a slide fails with "Unrecognized file format" and the dashboard shows an older OpenSlide version than the scanner's manufacturing date, request an SHSG-supplied IPE update containing a newer bundled OpenSlide native.
- Synthesized pyramid levels (§5.1) carry an ImageComments diagnostic; viewers may surface this text on hover.

9.3 Produced Attribute Highlights

- `(0020,000D) StudyInstanceUID` — synthesized deterministically from the source WSI filename + MD5 of file bytes unless provided in sidecar metadata.
- `(0020,000E) SeriesInstanceUID` — synthesized per-conversion.
- `(0008,0018) SOPInstanceUID` — per-tile, per-level UID.

- `(0048,0008) SpecimenDescriptionSequence` — minimally populated with the source filename as specimen identifier unless overridden.

Review cycle: 1 year, or on any of: bundled OpenSlide version bump, new WSI SOP Class emission, STOW-RS semantics change, HIPAA-mode gate change, or pyramid-synthesis-policy change. **Next review due:** 2027-04-18.

> **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.