IN-PERSON EXPERT OBSERVATION & ATTESTATION RECORD

Supplementary Peer-Observation Instrument to the IEC-Approved Clinical Protocol
AI-Robotic Surgery in Ayurveda — Phase 1 (Pilot Feasibility Study)

Reference Protocol	QUAASX/TMAE/IEC/2026/001 (IEC-Approved)
This Instrument's Number	QUAASX/TMAE/VAL/2026/001
Version / Date	Version 1.0 | 21 April 2026
Study Title	A Pilot Clinical Study to Evaluate the Safety and Feasibility of the ShalyaMitra AI Surgical Intelligence System in Shalyatantra (Ayurvedic Surgery)
Study Site	Department of Shalyatantra, T.M.A.E Ayurveda Medical College and Hospital, Hospete, Vijayanagara District, Karnataka — 583 201
Sponsor	Quaasx108 Pvt. Ltd. (DPIIT-Recognised Startup)
Purpose of This Instrument	To formally record the in-person observations of independent Ayurveda scholars and medical professionals present at a live surgical session, as qualified peer observation — NOT as a substitute for the trial's own safety monitoring or IEC oversight.
Observation Venue	Mumbai (Bombay), Maharashtra — In-person live observation (this instrument supersedes any remote/livestream observation format)

SCOPE NOTICE — READ BEFORE COMPLETING: This instrument records what a qualified, independent observer directly witnessed at an in-person live surgical session. It is a peer-observation record, not a clinical safety verdict, not an efficacy claim, and not a substitute for the Principal Investigator's cumulative safety reporting to the IEC under Protocol QUAASX/TMAE/IEC/2026/001. Observers should complete only the sections that reflect what they personally and directly observed, and must not attest to matters outside their direct observation (e.g., post-operative outcomes, adverse event causality, or overall trial safety conclusions).

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Not for promotional, marketing, or commercial distribution

PART A — OBSERVER IDENTIFICATION

To be completed in full by every observer prior to the session. Please print clearly.

Full Name	
Qualification(s)	e.g., BAMS, MS (Ayurveda), MD, MBBS, MS (Surgery)
Registration Council & No.	e.g., Central Council of Indian Medicine / State Medical Council
Current Institution / Designation	
Area of Expertise	e.g., Shalyatantra, General Surgery, Ayurvedic Pharmacology
Contact (Email / Phone)	
Relationship to Sponsor or Site	None / Please specify any professional, financial, or advisory relationship
Date of Observation	
Location of Observation	Venue, Mumbai (Bombay), Maharashtra

Declaration of Independence: I confirm that I am providing this observation in my independent professional capacity. I have not been offered, and do not expect, any payment, gift, or benefit in exchange for a favourable observation record.

PART B — SESSION DETAILS

Study Patient Code Observed	De-identified study code only — no patient-identifying information
Procedure Observed	
Operating Surgeon (Name, Qualification)	
Session Start / End Time	
ShalyaMitra Components Present	Surgeon's Eye / Monitor Sentinel / Overhead Sentinel / Voice Agent (Nael) / Theatre Display — circle as applicable
Observer's Physical Vantage Point	e.g., within OT viewing gallery, adjacent monitor feed, direct OT presence

PART C — DIRECT OBSERVATIONS

Mark only what you personally and directly observed. Leave blank or mark “Unable to assess” for anything outside your direct line of sight or expertise.

- ■ The surgical procedure was performed by the qualified operating surgeon named above; I did not observe the ShalyaMitra system physically contact the patient, hold any instrument, or perform any surgical action.
- ■ Classical Shalyatantra technique, as I understand it from my own training/expertise, appeared to be respected during the portions of the procedure I observed.
- ■ The AI system's audible or displayed outputs (voice agent, alerts, Theatre Display), where I could observe them, appeared to function as advisory information rather than as directives overriding the surgeon's independent clinical judgment.
- ■ I did not observe any activity during the session that appeared promotional, commercial, or unrelated to the clinical procedure itself.

■ I observed no event during my period of observation that I would classify as an adverse event or safety concern. (Note: this is not a substitute for the trial's formal AE/SAE reporting process, which the observer is not positioned to conduct.)

Anything observed that gave you pause, or that you could not fully assess (optional, use additional sheet if needed):

PART D — SCOPE-LIMITED PROFESSIONAL REMARKS

Space for the observer's professional remarks, framed strictly as observations from this session — not as a certification of overall trial safety, efficacy, or regulatory readiness, which remain the responsibility of the Principal Investigator and the Institutional Ethics Committee.

PART E — DECLARATION AND SIGNATURE

I confirm that the information recorded in Parts A to D above accurately reflects what I personally and directly observed during the live, in-person session described. I understand that this record:

- is a peer-observation record, limited to matters within my direct observation and professional expertise;
- does not constitute a clinical safety determination, an efficacy finding, or an endorsement of the ShalyaMitra system's overall performance, regulatory status, or commercial claims;
- may be retained by the study site and sponsor as part of the institutional and regulatory record for Protocol QUAASX/TMAE/IEC/2026/001, and referenced (with attribution to me by name) in IEC or CDSCO correspondence strictly as an in-person peer-observation record;
- does not transfer to me any responsibility for trial conduct, patient safety monitoring, or adverse event reporting, which remain vested in the Principal Investigator and the IEC under the approved protocol.

Observer Signature		**Date**	
Name (Block Letters)		**Place**	

For institutional use — countersignature by Principal Investigator

I confirm that the above-named observer was physically present at the study site for the session recorded, and that this record has been filed with the study's master file for Protocol QUAASX/TMAE/IEC/2026/001.

PI Signature (Dr. M.D. Samudri)		**Date**	

This instrument is a supplementary peer-observation record and forms part of the study master file for Protocol QUAASX/TMAE/IEC/2026/001, held at T.M.A.E Ayurveda Medical College and Hospital, Hospete. It does not replace, amend, or supersede the IEC-approved protocol, informed consent framework, or adverse event reporting procedures set out therein.