

To Whom It May Concern

Re: Surgery Intellect's Compliance with NHS England AVT Requirements

Surgery Intellect powered by Tortus AI - provides complete Compliance with NHS England AVT Requirements

Executive Summary: Surgery Intellect complies with all NHS England requirements for Ambient Voice Technology laid out in the Priority Notification dated 9th June 2025 from Dr Alec Price-Forbes, National Chief Clinical Information Officer. Surgery Intellect exceeds standards in multiple areas, and we maintain comprehensive governance oversight across all deployments over and above the standards prescribed.

This letter serves as formal confirmation that *Surgery Intellect*, a product of **X-on Health**, powered by **Tortus AI**, fully complies with all NHS standards for Ambient Voice Technology (AVT) solutions. X-on Health, as the contracting entity, ensures full alignment with NHS requirements, underpinned by a strong commitment to clinical safety, data protection, and operational excellence. With robust DPIAs already in place, including a comprehensive overarching DPIA, Surgery Intellect is now being introduced to the market, delivering advanced, voice-enabled clinical support seamlessly into surgical workflows across all care settings.

X-on Health has exclusive rights to offer the Tortus AI AVT solution to primary care in the UK and will be the contracting party with Tortus AI a named sub-contractor. The Tortus AI AVT solution has been approved for deployment in numerous ICBs.

Core Platform Assurance Requirements

Requirement	Tortus AI Compliance	X-on Health Compliance	Compliant
DTAC Ready	Full DTAC compliance achieved across all five pillars. ISO 27001 in progress.	DTAC Ready with all five pillars met. ISO 27001 certified. ISO Certification	✓
DSPT	'Standards Exceeded' status (ODS: O2G5U) DSPT Report	'Standards Exceeded' status (ODS: 8JM42) DSPT Report	✓
Cyber Essentials Plus	Current certification with zero vulnerabilities (8FoldGovernance, Leo CybSec) Cyber Essentials Plus Certification	Current certification (3B Data Security) Cyber Essentials Plus Certification	✓
CREST-approved Pen Testing	Regular CREST-approved testing with zero vulnerabilities Application Retesting Report	Regular CREST-approved testing Penetration Testing Report	✓
Named Clinical Safety Officer	Dr. Dom Pimenta & Nikita Adatia (Named CSOs)	Dr. Imran Khan (Named CSO)	✓
Encryption	AES-256 at rest, TLS 1.2+ in transit, MFA, SSO, RBAC; ISO 27001 in progress	AES-256 at rest, TLS 1.2+ in transit, MFA, SSO, RBAC; ISO 27001 certified ISO 27001	✓
GDPR Compliance	Full GDPR compliance with UK/EU data sovereignty	Full GDPR compliance with UK/EU data sovereignty	✓

No Unsafe Functionality	Aligned with DCB0129 and ISO 14971 standards	Aligned with DCB0129 and ISO 14971 standards	✓
NHS System Integration	Native integration with Epic; Cerner available site-by-site; EMIS/TPP integration supported via X-on; FHIR R4 & HL7 v2 compliant with write-back.	Direct API integration with EMIS and SystmOne/TPP, including write-back; FHIR R4 & HL7 v2 compliant; integration underpins Tortus support.	✓
Translation Accuracy Responsibility	No language translation; full transcription responsibility	No language translation; full transcription responsibility	✓

In addition to the above, X-on Health maintain the following ISO certifications:

- Quality Management System: [ISO 9001:2015](#)
- Environmental Management System [ISO 14001](#)
- Business Continuity Management System [ISO 22301](#)
- Information Security Management System [ISO 27001](#)
- AI Management System [ISO 42001](#)

Enhanced Requirements

Requirement	Tortus AI Compliance	X-on Health Compliance	Compliant
Medical Device Classification	MHRA Class 1 registered; Class 2a application submitted MHRA Registration Certificate	Supports Tortus AI's medical device registration	✓
Data Protection	Automatic deletion of patient session data after 24 hour	Automatic deletion of patient session data after 24 hour	✓

System Integration	Native integration with Epic; Cerner available site-by-site; EMIS/TPP integration supported via X-on; FHIR R4 & HL7 v2 compliant with write-back.	Direct API integration with EMIS and SystmOne/TPP, including write-back; FHIR R4 & HL7 v2 compliant; integration underpins Tortus support.	✓
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Clinical & Operational Threshold Benefits

Requirement	Compliance	Compliant
Evidence of NHS Clinical Validation	Tortus AI AVT is validated via NHS clinical studies: 17,000 17,000-patient study. Early data from our Phase IV study with 473 patient observations shows a 16.9% increase in direct patient care time, while our real-world evaluation spanning 4,890 consultations has achieved a 99% acceptance rate. Clinical satisfaction metrics show that 97% of clinicians report the ability to give full attention to patients, compared to just 67% at baseline, and 82% of clinicians rate their experience as better than previous clinics without AVT.	✓
Economic Justification and Workforce Impact	Tortus AI's economic modelling shows a return on investment of 30-40x through multiple value streams. In Emergency Departments, early data suggests 20% productivity improvements through the largest trial of AVT technology in UK ED settings, enabling increased patient throughput and reduced waiting times.	✓

Commitment to Ongoing Compliance

Surgery Intellect maintains continuous compliance through regular engagement with ICBs, quarterly clinical safety reviews, and proactive regulatory submissions. As the contracting entity, X-on Health ensures that our governance framework not only meets but exceeds NHS requirements, setting a new benchmark for Ambient Voice Technology (AVT) deployment in clinical environments.

We welcome further scrutiny and remain fully available for audit or clarification regarding our compliance framework. Our team is committed to supporting NHS England's vision for safe, effective AVT adoption across all care settings.

Please refer to the following sections for supporting documentation and additional details. If you require further information or would like to discuss any aspect of our compliance framework, do not hesitate to contact our Compliance Coordinator, Sally Harvey (sally.harvey@x-on.co.uk).

Yours sincerely,

Julian Coe
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X-on Health
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Confirmed as an accurate reporting of Tortus AI AVT solution by:

Dr Dom Pimenta MBBS MRCP BSc (Hons)
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