X-on Health Limited
Surgery Intellect, powered by TORTUS
Clinical Safety Case Report

Software and Version

X-on Surgery Intellect, powered by TORTUS and is compatible with Phonebar version 8.3.3 or above.

Purpose

This document summarises all the elements of the Clinical Safety Case for X-on Surgery Intellect, powered by TORTUS for DCB0129 compliance.

This document should be read in conjunction with the attached supporting documentation: the Clinical Risk Management Plan, the Hazard Log, and the Responsibilities and Resources RACI documentation. Together these documents constitute the Clinical Safety Case for X-on Surgery Intellect, powered by TORTUS.

Scope

Applies to the X-on Surgery Intellect, powered by TORTUS development and delivery.

Document Status	Fist version 1.0
Document Author	Dr Imran Khan/Daniel Grainge/Kirsha Ryland
Document Ratified By	Dr Imran Khan
Date Issued	April 2026
Date to be Reviewed	April 2027

Document history

Amendment History

Version	Date	Amendment history
1.0	April 2026	First draft

Approval

Name	Title/Responsibility	Date	Version
Dr Imran Khan	Clinical Safety Officer	April 2026	1.0

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version in the Clinical Risk Management File is the controlled copy. Any printed copies of the document are not controlled.

Table of Contents

Table of Contents

Introduction

This Clinical Safety Case Report outlines the X-on Surgery Intellect, powered by TORTUS, the Clinical Risks presented by the system, additional control measures put in place to minimise the Clinical Risks, the verification that such controls are in place and the conclusion about the Clinical Safety of the solution.

System Definition and Scope

The scope of this report is for the X-on Surgery Intellect, powered by TORTUS.

Primary Care currently undertakes a large workload via a variety of communication channels in addition to the traditional face to face consultation. These channels include telephone communication and consultation, SMS text messaging, chatbot assistance, video messaging, plus monitoring and reporting. This way of working adds some additional challenges and carries some risks, for example calling the wrong number for a patient, or consulting without visual evidence.

The X-on Surgery Intellect, powered by TORTUS solution, seeks to mitigate a range of these risks by integrating with the practice's phonebar and clinical system. Using ambient voice technology (AVT) to listen, transcribe and code consultations via the X-on Phonebar for both in-person (ambient) and telephone consultations. It reduces the cognitive load for GPs and provides accurate, secure patient consultation notes and letters. Once a clinician has reviewed and approved the generated content, Surgery Intellect, powered by TORTUS, can file this into the patient record, and back to Surgery Connect's patient contact history, for accurate, joined-up patient records.

X-on Health's services can be used as standalone, but they are primarily used as an extension to the core clinical systems used in UK primary care, such as EMIS Web, TPP SystmOne, Vision, and Medicus.

For Surgery Intellect, powered by TORTUS, compliant with all NHSE regulations surrounding AVT, its product updates are covered within these articles:
https://help.x-onweb.com/en/collections/794299-surgery-intellect .

As an enabler for current communication mechanisms which are already established within primary care, which provides no clinical input or direction, the intrinsic risks for this application are very low as is reflected in the risk scoring within the Hazard Log within this clinical safety case.

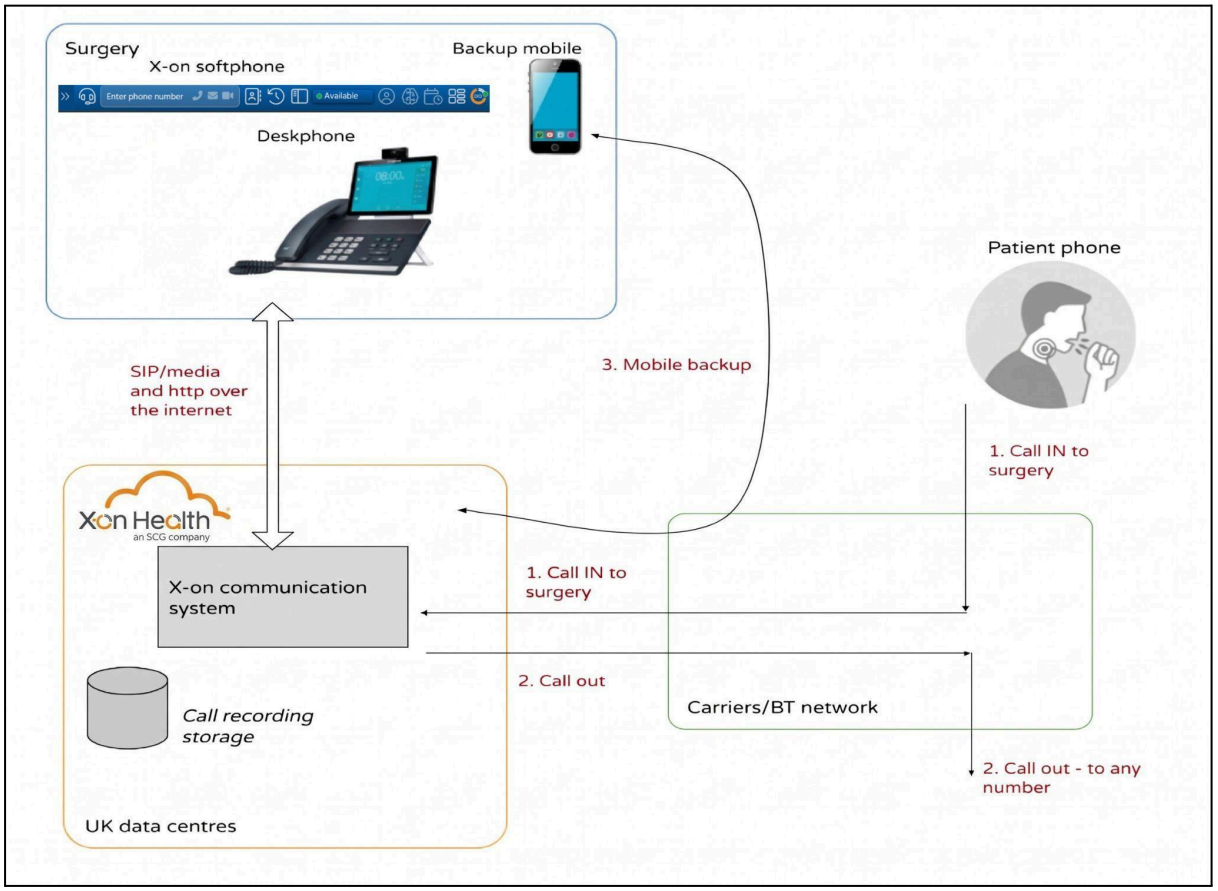
System Architecture as used in Production

The following describes the architecture and core components of Surgery Intellect, powered by TORTUS as deployed in production. Each subsystem has been defined to illustrate its role in supporting safe clinical communication, the points of integration with NHS clinical systems, and the associated risk controls in place. The descriptions that follow provide an overview of the Surgery Connect telephony platform, the Phonebar application and Surgery Intellect.

https://surgeryconnect.academy/trust-centre/user-journeys-and-diagrams/

Telephony System - Surgery Connect

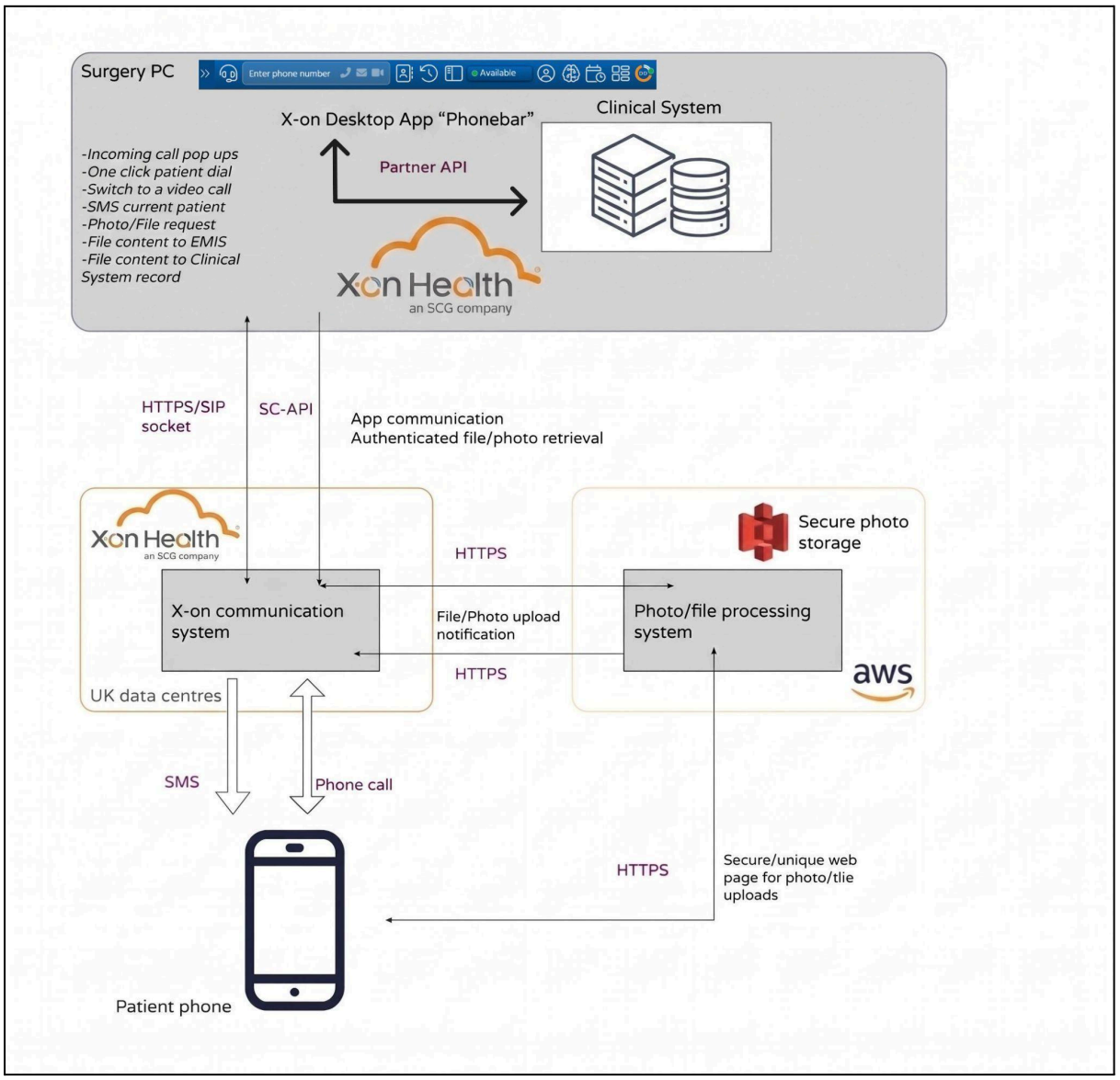
- Cloud based telecoms solution
- Calls delivered over the internet
- Incoming calls to the surgeries
- Users dialling out
- Mobile backup for local connectivity issues
- Remote cloud based failover for critical X-on issues.



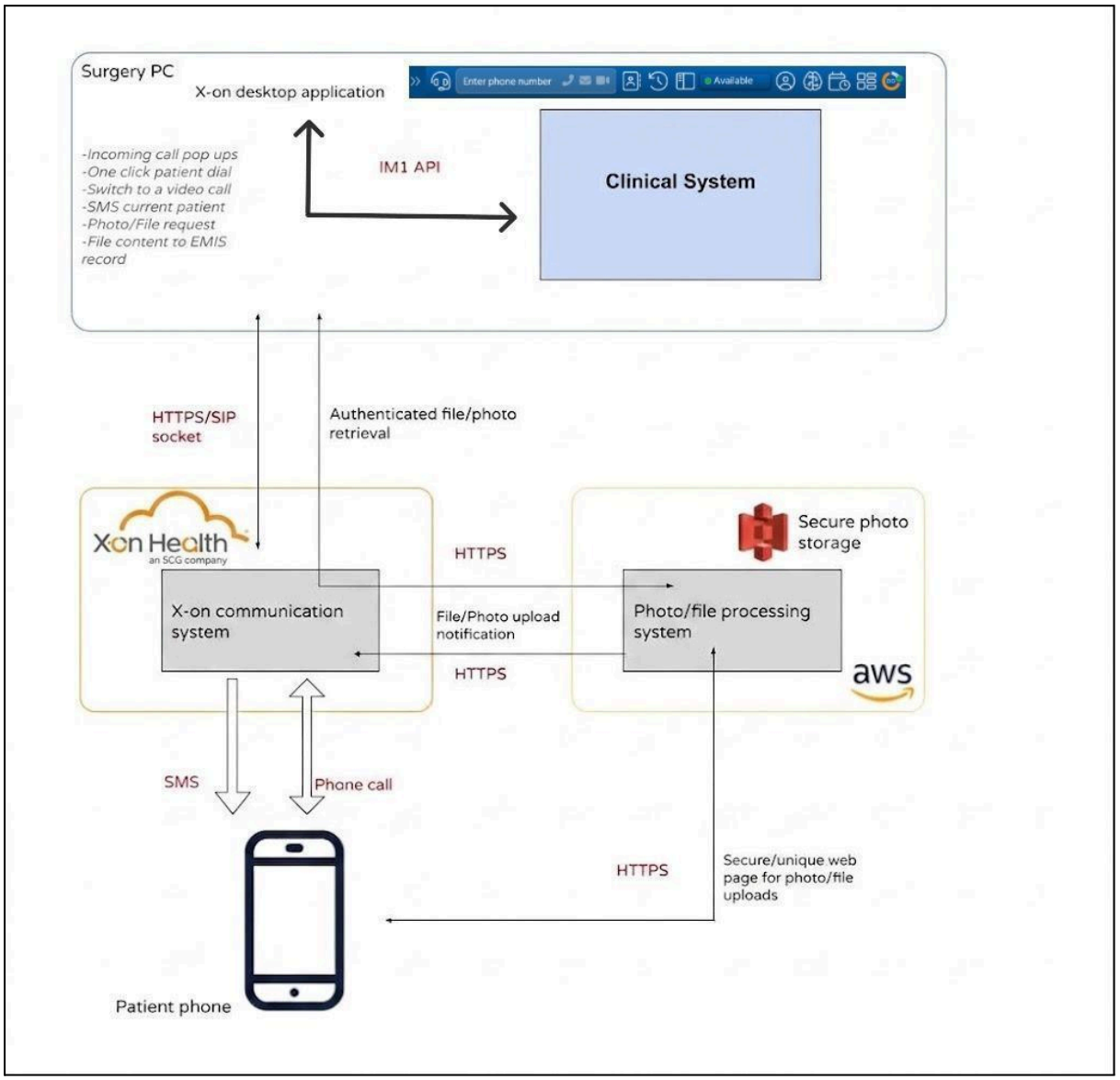
Phonebar Application (EMIS/SystmOne/Vision Integration)

- Connecting the phone system to the surgery records
- Incoming call patient lookup
- One click dialling for current active patient
- SMS to patient
- Photo request for patient
- Switch to video option

Partner API Diagram

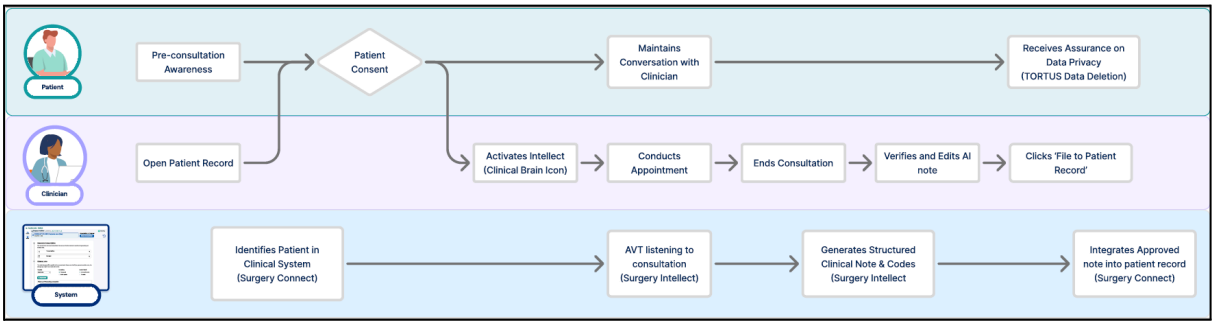


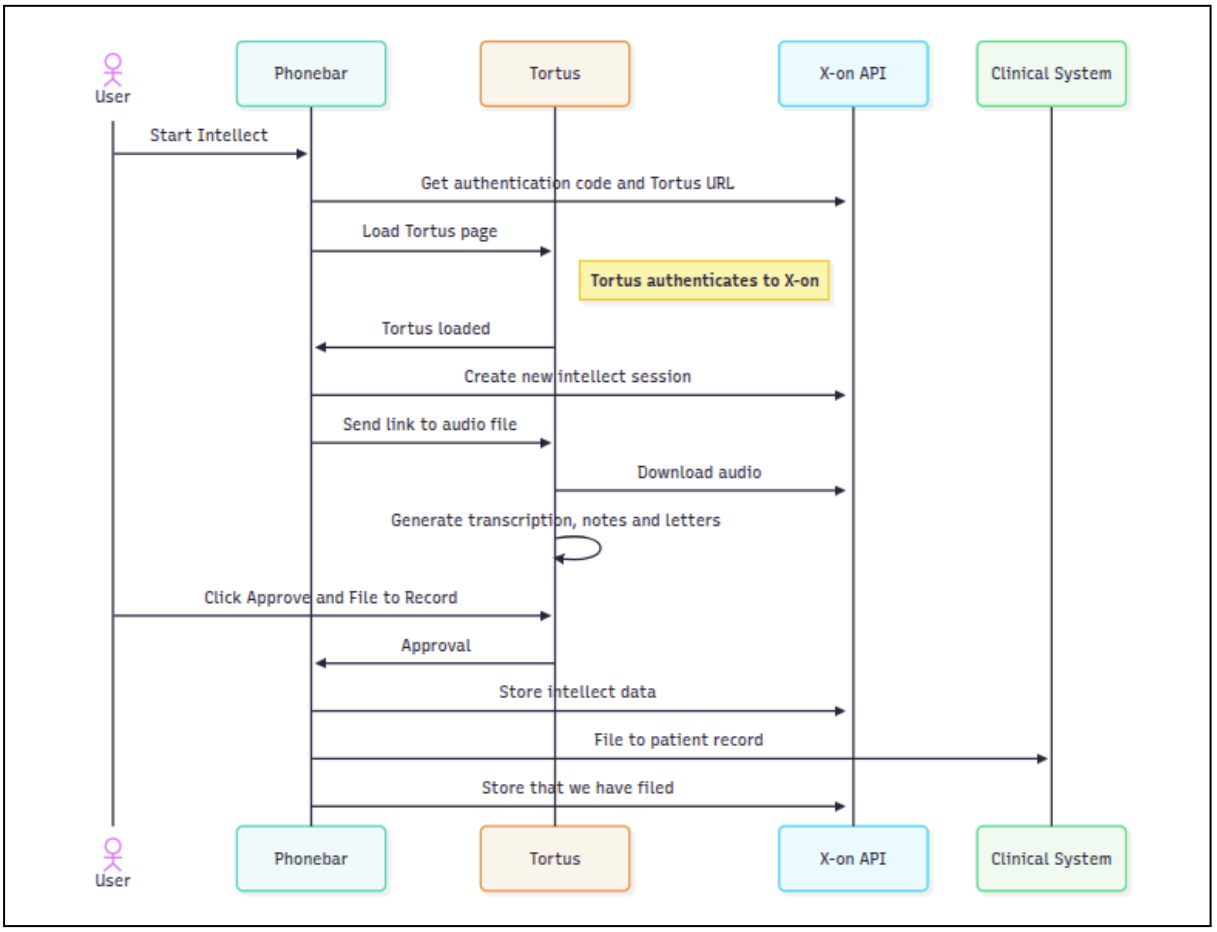
IM1 API Diagram



Surgery Intellect Application - Illustrative Process and Data Flow

- User starting Intellect on the Phonebar
- Loading third-party integration with Tortus
- Creating an Intellect Session
- Audio to Generate Transcript, Notes, and Letters
- Approval and Saving back to Surgery Connect record (TBD Saving to the Patient Record)





Diagrams with expanded detail and for different use cases (ambient consultation - no call recording, launching Intellect during a call, etc.) are available upon request

Third-Party Product Assessment

X-on Health Limited has undertaken an assessment of all third-party products integrated within the Surgery Intellect, powered by TORTUS solution, that may influence clinical safety. This includes software components developed and maintained by external organisations but incorporated into the solution to deliver core functionality.

All third-party components identified as safety-relevant (i.e. those that could directly or indirectly impact patient safety) have been assessed using the same clinical risk management process defined in the Clinical Risk Management Plan.

All third-party software and components have been assessed in line with DCB0129 requirements. For each safety-relevant third-party component, hazards have been identified, appropriate controls have been implemented, and residual risks evaluated. These assessments are maintained in the Clinical Risk Management File and are subject to review during periodic risk audits. These end to end risks are included and referenced in the hazard log.

Significant Third-Party Products utilised

The following third-party components are currently in use:

Tortus AI Ltd, act as a third-party processor for Surgery Intellect, where the TORTUS ambient voice technology (AVT) has been integrated into Surgery Connect, allowing GPs to utilise the AVT scribing to summarise patient consultations and generate clinical notes, patient letters, and SNOMED coding that once approved by the clinician, can be saved back to the Surgery Connect record (this will be saved directly to the patient record within the clinical system once X-on have authority to do so). Tortus AI are fully compliant with DCB0129 requirements and their clinical safety documentation is available here:

https://trust.tortus.ai/. X-on Health has assessed the end-to-end risks of Surgery Intellect, these hazards are available within the X-on and TORTUS Hazard Logs.

Medical Device Assessment

Medical Device Assessments are routinely undertaken to assess whether X-on's products and features fall under the Medicines and Healthcare product Regulatory Agency (MHRA) classification of a medical device for standalone software and applications placed on the Great British marketplace (England, Wales, and Scotland). The assessments are completed by walking through the MHRA device determination flow chart (available here) and determining where our product is situated.

X-on's Surgery Intellect, X-on's ambient voice technology (AVT) Scribe, TORTUS AI, X-on's third party delivery partner for Surgery Intellect, is a Class I UKCA-marked medical device, and is soon to be pursuing Class IIa. This is because TORTUS' scribe solution supports clinicians by generating notes and clinical codes in real time, to help reduce the admin

burden in clinical workflows to ultimately support individual patient care and medical professionals decision making about diagnosis, care, or patient referrals. In terms of how this impacts X-on, under UK MDR (Medical Device Regulations 2002), X-on is considered as a third-party integrator (critical supplier) of Surgery Intellect. More information on Surgery Intellect can also be found on the NHSE AVT self-certified supplier registry.

Clinical Risk Management System

Documentation under X-on's Clinical Risk Management Framework, namely the complete CRMF (Clinical Risk Management Framework) documentation as well as the CRMP (Clinical Risk Management Plan), is currently available upon request or via X-on Health's Trust Centre.

For TORTUS AI, all documentation in relation to the Clinical Safety Case Report, Clinical Risk Management Plan and Hazard Log can be found within the Trust Centre: https://trust.tortus.ai/

Clinical Risk Management System

X-on's approach to Clinical Risk is detailed in the attached Clinical Risk Management Plan, section 2.3.

Clinical Risk Management Plan

Key Personnel, Roles and Responsibilities are detailed in the attached X-on Clinical Risk Management RACI matrix.

Clinical Risk Assessment

X-on Clinical Risk Assessment records are stored in a repository in Jira and can be exported as a Hazard log spreadsheet.

Hazard Identification & Description of Patient Safety Impact

The method of Hazard Identification is explained in the Clinical Risk Management Plan.
SWIFT methodology was applied to the current list of software features.
Identified hazards are presented in the Hazard Log. Descriptions of potential patient safety impacts and the possible causes of the identified hazards are likewise presented in the Hazard Log.

Clinical Risk Evaluation

Clinical Risk Evaluation has been undertaken following the methodology detailed in the Clinical Risk Management Plan (section 2.3.2). The risks have been stratified according to the Risk Matrix, presented in the Hazard Log.
The Initial Clinical Risk Evaluation for each identified clinical risk is detailed in the Hazard Log.

Clinical Risk Control

Where Clinical Risk Evaluation shows a risk above the defined risk appetite threshold, therefore requiring the application of additional controls, such controls have been considered and applied. As described in section 2.3.4.
The further control measures are outlined for each Clinical Risk cause in the Hazard Log.

Evaluation of Residual Risks

Following the application of additional control measures, the residual Clinical Risks have been analysed using the same methodology as that used for initial Clinical Risk Evaluation, as detailed in the Clinical Risk Management Plan (section 2.3.2). The same Risk Matrix and associated risk appetite/acceptance criteria have been used to assess and stratify residual risk values.
Residual clinical risk after the application of all relevant controls are presented in the Hazard Log.

Cost/Benefit Analysis of Residual Risks

Where residual risks are greater than the lowest score on the Risk Matrix, further analysis has taken place to determine whether further controls are desirable and/or practicable weighted against the impact and likelihood of the risk itself. This analysis is presented in the worksheet section of the Hazard Log, entitled 'Risk/Benefit Analysis' and documented in column R of the exported Hazard Log

Verification of Risk Controls

All risk controls have been audited to ensure that they are both present and functioning as intended. The verification that these risk controls are operating correctly is presented within the Hazard log.

The X-on Product Process outlines the five stages of our product feature development process; concept generation, feature request submission, requirements, development, and deployment. The Clinical Safety Review occurs during the product requirements stage in order to ensure that any hazards that are raised can be realised, considered, and effectively controlled by design in the development stage and then can go through quality assurance testing, to ensure that the product feature and its controls pass staging and pre-live testing procedures. The entire product feature development process is tracked, from individual development tasks, to product requirement documentation and raised clinical safety hazards, with X-on's Atlassian Jira platform. This includes all execution reporting that details all test runs completed and each individual item tested and their pass/fail status. Our Clinical Safety tickets raised in Jira are tracked through to verification testing and delivery (go-live).

Many of the Clinical Risk Controls, particularly in terms of business processes, were audited at the same time as wider and more general Information Security controls through a defined Internal Audit process aligned to the ISO27001:2013 Standard (forming part of X-on's ISO27001:2013 Certification). The ISO 27001 certification is attached.

Summary of control status (April 2026)

7 Identified Hazards - across the Hazard Log

Status Summary	
Open	0
Transferred	4
Approved/Accepted	2
Closed	0
N/A - No Clinical Impact	1

The hazard status is ‘Open’ if X-on hasn’t completed all actions, ‘Transferred’ if X-on has completed their actions but the Health Organisation needs to have the processes/mitigations in place as outlined, ‘Approved/Accepted’ if X-on has completed their actions, fixed the issue, and any remaining residual risk is small enough to be acceptable, ‘Closed’ when all actions are completed and ‘N/A - No Clinical Impact’ if there was no identified clinical safety risks.

The below table outlines the Initial Risk and Residual Risk summary. This showcases the total Initial Risk assessment scores and Residual Risk assessment scores across the Hazard Log, to showcase the overall likelihood and severity ratings.

Initial Risk (1-5)	*Initial Risk - Likelihood*					
Initial Risk - Severity	Very High	High	Medium	Low	Very Low	
Catastrophic	0	0	0	0	0	0
Major	0	1	1	0	0	2
Considerable	0	0	1	1	0	2
Significant	0	0	0	0	0	0
Minor	0	0	0	1	1	2
Total	0	1	2	2	1	**0**
Residual Risk (1-5)	*Residual Risk - Likelihood*					
Residual Risk Severity	Very High	High	Medium	Low	Very Low	
Catastrophic	0	0	0	0	0	0
Major	0	0	0	0	2	2
Considerable	0	0	0	0	2	2
Significant	0	0	0	0	0	0

Minor	0	0	0	0	2	2
Total	0	0	0	0	6	**0**

Controls requiring action from the client

Where risk controls are transferred (requiring action from the client) these are fully detailed in the deployment and training materials.

User Training Controls and Links

Training provision is incorporated as part of the overall deployment of the solution. A range of training is provided, including a "Train the Trainer" model, administrative training, and end-user training. This training is further supported by an extensive library of user guides and materials on all aspects of the X-on Intelligent Care Navigation solution which is made available to end-user customers for review outside of established training sessions. Training courses and associated materials are typically built around a specific feature to ensure relevance to trainees.

These courses and materials are often mentioned in the X-on Health Hazard Log, as where required, the X-on Academy Courses platform and Help guides are updated to reflect the identified Hazards - furthering the user's visibility of these and the controls required. Links to these platforms and materials are found below:

X-on Health Academy & X-on Health Help Centre.

Hazard Log

The Hazard log contains a relatively small number of hazards and at low risk levels, This reflects the low clinical risks inherent in the scope of the X-on Intelligent Care Navigation System.

Test Issues

There are currently no outstanding Test issues. X-on is currently working in GP Practices across England. We have no outstanding issues, and no clinical safety issues, specifically.

Summary Safety Statement

X-on Surgery Intellect, Powered by TORTUS represents an enhancement to clinical safety for a variety of practice communication channels with patients, where there are risks, these are acceptable and significantly out-weighed by the benefits.

Having reviewed the evidence supplied in the attached Hazard log, clinical risk management plan, software development change management and ISO 27001 documentation, it is clear that deployment of this solution has acceptable risk attached and delivers a significant benefit for patients.

I am fully satisfied that the X-onSurgery Intellect, Powered by TORTUS system is compliant with DCB0129 and is a clinically safe solution for healthcare organisations to adopt and deploy.

Dr Imran Khan,
PhD, B.Eng, MBBS, MRCGP, MBCS
GMC Reg 7278705

Quality Assurance

Section 4 of the Clinical Risk Management Plan outlines the frequency within which X-on's Clinical Risk Management activities will be formally reviewed. Said reviews, as well as any interim amendments or updates, will be documented within the X-on document review log in line with ISO27001 policies.
All materials presented in this Clinical Safety Case Report have been examined for DCB0129 compliance by the Clinical Safety Officer.

Configuration Control / Management

We ensure that our solution is designed, tested, and deployed in partnership with the practices who will use them. Any changes are clearly documented, and only implemented with prior agreement with those practices wanting them.