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X-on Health

Clinical Risk Management Plan for Surgery Assist

Organisation: X-on Health

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Document Version Control

Version	Date approved	Changes	Approver
1.4	Dec 19, 2025, 14:58	change P Harvey → Technical services lead	Keith Grimes
1.5	Mar 18, 2026, 09:00	Updated for SAv7 (Release 2026.03.R4). Added V7 multilingual scope. Updated CRMF locations from Assuric to Curistica NEXUS. Added translation engine out-of-scope statement.	Keith Grimes
1.3	Nov 24, 2025, 08:19	updated	Keith Grimes
1.2	Nov 23, 2025, 15:48	Updated for SAv6	Keith Grimes

1.1	Oct 17, 2025, 16:49	updated manufacturer	Keith Grimes
0.0.2	Aug 14, 2025, 18:35	No changes were made to the document.	Max Gattlin
0.0.1	Aug 14, 2025, 18:29	Added a new section for the Clinical Risk Management Plan for Surgery Assist V5, including details on its purpose, scope, and various features such as the 'Ask a Question' feature and LLM powered responses. Updated the table of contents and removed previous introductory materials and a section header. Introduced additional details on the Clinical Risk Management File, Resources and Personnel responsibilities, and the Clinical Safety Multi Disciplinary Team (CSMDT) process. Included new appendices on Clinical Ris	Max Gattlin

Version	Date	Description	Author	Approver
0.1	10 May 2025	First draft based on CRMP SAv4	Keith Grimes	Sharon Hanley
1.0	15 May 2025	Final Version SAv5	Keith Grimes	Sharon Hanley
1.1	17 Oct 2025	Manufacturer update	Keith Grimes	Julian Coe
1.5	18 Mar 2026	SAv7 multilingual update	Keith Grimes	Chris Dunscombe

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Introduction

The purpose of the Clinical Risk Management Plan (CRMP) is to define the implementation of, and any variation to X-on Health ltd Clinical Risk Management System.

It describes how the Surgery Assist programme will conduct clinical risk management to ensure patient safety with respect to services provided and the interrelated and interactive activities that will occur to ensure that it meets the requirements of DCB0129 and DCB0160.

In fulfilling this purpose, any variation to the standard practices and procedures to be followed, as defined by the Clinical Risk Management System (CRMS), when performing the activities of the programme are documented here in this document.

This CRMP identifies the means by which the Surgery Assist programme shall be controlled to ensure that the safety work is of high quality, conforms to the requirements of the CSMS and any specific programme requirements.

This document will be updated when the plan changes in any way as to deviate from what has been committed to deliver. This will be decided by the Clinical Safety Multi Disciplinary Team (CSMDT).

Overview and Intended use

Surgery Assist facilitates and supports users to undertake their own administrative healthcare tasks (e.g. bookings, referrals, results checking) instead of it being done by receptionists.

This is accomplished by supporting and facilitating the use of existing or new digital pathways to accomplish the same tasks; surfacing, highlighting and guiding users through the digital journey to achieve the same outcome they intended to accomplish either on the phone or in person.

Services which users can access digitally vary by practice, but usually include online appointment booking, accessing local community and pharmacy services, access (via drop-off) to digital healthcare products (NHS App, online consultations, symptom checkers), all available 24/7.

Surgery Assist is integrated into healthcare providers' cloud telephone systems, websites, and via QR codes displayed on posters and on GP waiting room display screens.

Scope

This CRMP covers Surgery Assist Versions 5.0 and upwards.

Version 5.0 provides further improvement and refinements to the V4.0 experience including UI and UX experiences. Additionally, it introduces several new functions at launch as well as a timeline for further improvements over the product lifecycle:

1. 'Ask a Question' feature allowing users to ask questions in natural language.
2. LLM powered responses grounded in practice reference material provided by X-on Health ltd, client practices, and local service providers.
3. Ability to signpost to practice specific community services and FAQ's.

Version 6.0introduces appointment booking capabilities to the Surgery Assist chatbot through integration with Hero Health's Partner API. This will enable patients to view and book appointments directly through the chatbot interface following secure verification.

The proposed workflow:

- The chatbot will use embedded forms to securely collect and verify patient information (either surname and date of birth, or NHS number).
- Following secure verification, the chatbot will interact with Hero Health's API to present available appointment slots.
- Patients will then be able to book directly from within the chatbot interface, making the entire process seamless and efficient.

Further details can be seen on the X-On Confluence Page:
https://x-on.atlassian.net/wiki/spaces/AFR/pages/1033535517/SAD-191+Appointment+Booking+Functionality+Book+Appt+API

Version 7.0 (Release 2026.03.R4) introduces browser-native translation support for the deterministic chatbot pathway. Non-English-speaking patients can interact with Surgery Assist in their preferred language via Chrome (Google Translate), Edge (Microsoft Translator), and Safari (Apple Translate). This is a zero-development approach leveraging built-in browser capabilities rather than server-side translation. The AI-enhanced assistant pathway remains English-only, with non-English input detected by Microsoft Azure Translator API before reaching the LLM. An architectural migration from iframe to native webpage integration is required to enable browser translation. Translation is controlled via new RBAC settings in the Surgery Assist Portal and is OFF by default for all practices in production.

Out of Scope

Surgery Assist platform does not integrate with clinical systems and any interaction or transactions with clinical systems are executed via existing NHS applications (e.g. NHS App) or NHS approved third-party applications (e.g. AccuRX, AskFirst, Anima).

The browser translation feature introduced in V7 relies entirely on third-party browser-native translation engines (Google Translate, Microsoft Translator, Apple Translate) operating client-side. X-on Health does not provide, host, or control these translation engines. Translation

accuracy is a function of the browser vendor's translation service and is outside the direct control of the manufacturer.

Clinical Risk Management File

The Surgery Assist clinical risk management file is located in the internal X-on Health ltdd ocument repository. A description of the components are provided in Table 1.

Table 1. Surgery Assist Clinical Risk Management File components

Item	Definition	Location/link
Clinical Risk Management File (CRMF)	Repository of all records and other documents that are produced by the clinical risk management process.	Internal document repository (Assuric)
Clinical Risk Management Plan (CRMP)	A plan which documents how we will conduct clinical risk management of the Surgery Assist platform.	This document (Assuric)
Clinical Safety Case (CSC)	Accumulation and organisation of product and business process documentation and supporting evidence, through the lifecycle of the Surgery Assist platform	Internal document repository & Curistica NEXUS Platform
Clinical Safety Case Report (CSCR)	A summary of the arguments and supporting evidence that provides a compelling, comprehensible and valid case that the Surgery Assist platform is safe for a given application in a given environment at a defined point in its lifecycle.	Surgery Assist Clinical Safety Case Report (Assuric)
Clinical Safety Hazard Log (CSHL)	A record of the historical and on-going identification and resolution of hazards associated with Surgery Assist.	Curistica NEXUS Platform (Product 224)
Safety Incident Management Log	A record of historical and on-going incidents, including investigation and resolution, which have occurred through the lifecycle of the Surgery Assist system,	Surgery Assist Safety Incident Management Log (Assuric)

Digital copies of the Clinical Risk Management File are available on request.

Resources and Personnel

The Clinical Safety Officer(s) is/are responsible for ensuring the clinical safety of the Surgery Assist platform through the application of clinical risk management.

The CSO's is/are a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role.

Key responsibilities include:

- approval of the Clinical Risk Management Plan to confirm that the plan is appropriate and achievable in the context of the Health IT System development and modification;
- ensuring that clinical risk management activities are completed in accordance with the Clinical Risk Management Plan (this document);
- reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Logs;
- reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report;
- providing recommendation to X-on Health ltd whether the Service is safe to release; and
- escalating any unacceptable safety risks.

Clinical Safety MDT

As outlined in the CRMS, X-on Health ltd undertakes Clinical Risk and Safety Meetings using a clinical safety multidisciplinary team (CSMDT) approach.

Membership of the Clinical Safety MDT is outlined in Table 2. All meetings require at least one CSO and two other members to be quorate.

Table 2. Members of Clinical Safety MDT

Name	Title/Responsibility	Organisation
Julian Coe	Managing Director	X-on Health
Keith Grimes	CSO	Curistica Ltd
Chris Duncombe	Product Manager	X-on Health
Paul Harvey	Technical Services Lead	X-on Health
Youssof Oskrochi	CSO	Curistica Ltd

Members of the Clinical Safety MDT are responsible for considering clinical safety in their respective roles in design, implementation, roll out, support and monitoring of the system.

In conjunction with the clinical safety officer they ensure that every release of the software undergoes a formal review to ensure all requirements of the standard have been met.

This approach ensured that the MDT had the full breadth of understanding and experience required to properly undertake the safety analysis.

Clinical Risk Evaluation and Management

The Surgery Assist project will follow the hazard identification and assessment process laid out in the CRMS, a summary of which is provided below and visualised as a flowchart in Figure 1.

Figure 1 - Clinical Risk Management process flow chart

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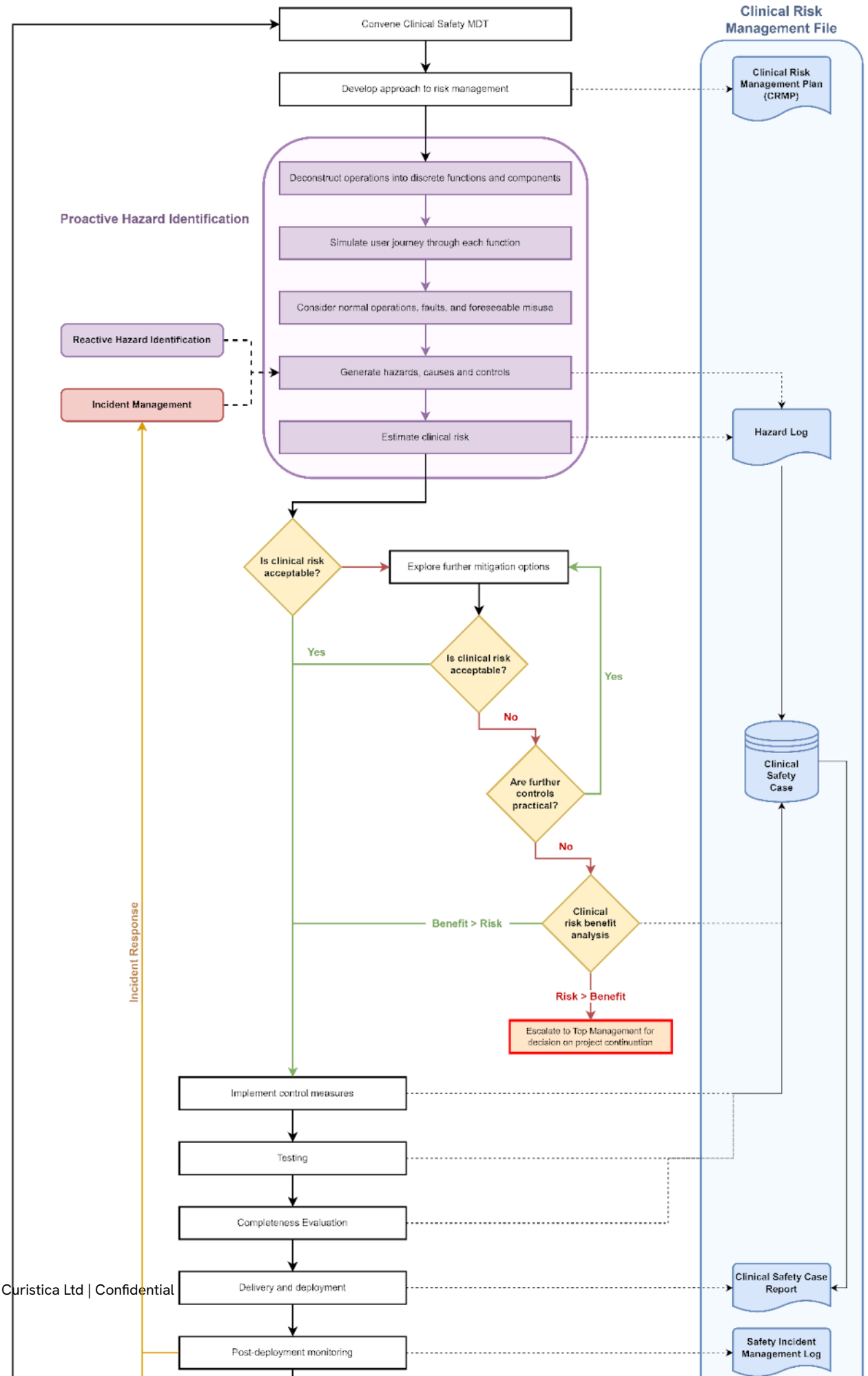

Governance

The Clinical Safety MDT will convene and undertake a Clinical Risk and Safety Meeting if any of the following criteria are met:

1. A new Surgery Assist function or flow is being designed/considered, OR
2. An existing Surgery Assist function is being removed, OR
3. An existing Surgery Assist function or flow is being materially changed, OR
4. A new Surgery Assist version is being deployed, OR
5. A new hazard has been identified, OR
6. Every twelve months.

As a Large Language Model (LLM) is part of the product system architecture, Clinical Safety MDT will also convene at any time the model is being changed. This maps to criteria 4.

Hazard Identification

Undertaken throughout the lifecycle of the product using both proactive and reactive mechanisms as appropriate.

Risk Analysis

The estimation process will follow that established by the safety processes defined in DCB0129 through consideration of hazard

severity (magnitude of harm) and likelihood (probability of occurrence). See Appendix A for further detail.

Risk Evaluation

The same risk thresholds are to be used in the Surgery Assist project as outlined in the CRMS.

Risks evaluated as “Low” or “Very Low” will be deemed as not requiring further mitigating measures (Appendix B).

Risks assessed as being “Moderate” or above will require implementation of further residual risk controls.

Appendix A - Clinical Risk Management Matrix

Likelihood	V. High (100%)	3	4	4	5	5
	High (10-99%)	2	3	3	4	5
	Med (1-10%)	2	2	3	3	4
	Low (<1%)	1	2	2	3	4
	V. Low (<0.1%)	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

Likelihood Category	Interpretation	Probability
Very high	Certain or almost certain; highly likely to occur	100%
High	Not certain but very possible; reasonably expected to occur in the majority of cases	10-99%
Medium	Possible	1-10%
Low	Could occur but in the great majority of occasions will not	<1%
Very low	Negligible or nearly negligible possibility of occurring	<0.1%

Severity Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term	Multiple
	Significant psychological trauma	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence	Single

Appendix B - Clinical Risk Severity Scale

Risk Level	Acceptability	Action Required
5 - Very High	Unacceptable	Do not release; implement controls to reduce risk or discontinue feature/product
4 - High	Unacceptable without exceptional justification	Escalate to senior management; require explicit clinical benefit justification; implement additional controls or suspend deployment
3 - Moderate	Tolerable with justification	Demonstrate ALARP; document risk-benefit analysis; consider additional controls
2 - Low	Acceptable	Document controls and maintain effectiveness
1 - Very Low	Acceptable	Monitor and review at scheduled intervals

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