X-on Health ltd

Clinical Safety Case Report

Surgery Assist

Version:	**1.6**
Adopted by:	X-on Health ltd
Date adopted:	18 Mar 2026
Name of Author:	Keith Grimes Youssof Oskrochi Sharon Hanley
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Target audience:	N/A

Contents

Document Management

Revision History

Version	**Date**	**Description of change or amendment**
0.1	10/Sep/24	First Draft
0.2	12/Sep/24	Second Draft

Version	Date	Description of change or amendment
0.3	14/Jan/25	Updated logo, checked product name, uploaded to Assuric
0.4	28/Feb/25	Updated logo, updated fig 1 / fig 2 / Review
1.0	28/Feb/25	Final (images updated)
1.1	14/May/25	SA v5 Update
1.2	21/May/25	SAv5 final version
1.3	17/Oct/25	Manufacturer update
1.4	28/Nov/25	SAv6 Update
1.5	13/Mar/26	Release 2026.03.R4 - Multilingual update. Addition of browser-native translation support for the deterministic chatbot. 15 new causes, 15 new controls, and 12 new evidence items added across 9 hazards. Two controls retired (CTRL-014, CTRL-043). Hazard workshop held 13 March 2026 with post-workshop updates applied 18 March. All residual risk scores confirmed unchanged. Hazard log migrated from Assuric to Curistica NEXUS platform.
1.6	18/Mar/26	Post-workshop updates. Two additional causes (C-ML-014,

Version	Date	Description of change or amendment
		C-ML-015) and one additional control (CTRL-ML-015) added following hazard workshop action completion. HAZ-013 and HAZ-015 reopened. Emergency signposting gap identified for non-English AI input (HAZ-015); "Call 999" button on contact page proposed.

Authors

Name	Title/Responsibility	Date	Version
Keith Grimes	Clinical Safety Officer (Curistica)	28/Nov/25	1.4
Keith Grimes	Clinical Safety Officer (Curistica)	13/Mar/26	1.5
Keith Grimes	Clinical Safety Officer (Curistica)	18/Mar/26	1.6

Reviewers

This document must be reviewed by the following people:

Name	Title/Responsibility	Date	Version
Keith Grimes	Clinical Safety Officer (Curistica)	28/Nov/25	1.4
Keith Grimes	Clinical Safety Officer (Curistica)	18/Mar/26	1.6

Approved by

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Keith Grimes	Clinical Safety Officer (Curistica)	28/Nov/25	1.4
Keith Grimes	Clinical Safety Officer (Curistica)	18/Mar/26	1.6

Executive Summary

This Clinical Safety Case Report (CSCR) outlines the evidence that the safety and documentation requirements of the Surgery Assist application release 2026.03.R4 (V7 - Multilingual), as required by the NHS clinical safety standard DCB0129, are met; as well as our approach to clinical safety risk assessment and the mitigations in place to manage identified risks.

Release 2026.03.R4 introduces browser-native translation support for the deterministic chatbot pathway, enabling non-English-speaking patients to interact with Surgery Assist in their preferred language via Chrome (Google Translate), Edge (Microsoft Translator), and Safari (Apple Translate). The AI-enhanced assistant pathway remains English-only, with language detection via the Microsoft Azure Translator API preventing non-English input from reaching the LLM.

This release required a dedicated clinical safety analysis, including a hazard workshop held on 13 March 2026 attended by the Clinical Safety Officer, Curistica staff, and X-on Health product management, with post-workshop updates applied on 18 March 2026. The analysis identified 15 new causes across 9 existing hazards, introduced 15 new controls (a combination of design, testing, and process controls), and retired 2 controls that enforced English-only access (CTRL-014, CTRL-043). All residual risk scores were reviewed and confirmed unchanged.

Potential hazards have been assessed and documented in our Clinical Safety Hazard Log (CSHL), maintained on the Curistica NEXUS platform, and assigned to a clinical risk category.

Risk Category	Initial Risk	Residual Risk
5: Unacceptable	0	0
4: Mandatory Elimination	1	0
3: Undesirable	8	0
2: Acceptable	17	24
1: Low	2	4

All identified risks have been deemed low or acceptable (either with no follow-up or due to the cost of reducing further) and do not require further supplier-side mitigations.

Last updated: 18 March 2026

Approved by Clinical Safety Officer: Dr Keith Grimes

Relevant Documentation

These documents provide additional information and are specifically referenced within this document.

Ref	Title	Version	Link
1	Clinical Risk Management System (CRMS)	2.2	X-on Health Ltd Clinical Risk Management System CRMS
2	Clinical Risk Management Plan (CRMP)	1.5	Surgery Assist Clinical Risk Management Plan
3	Regulatory Assessment for Surgery Assist V5	1.0	Surgery Assist Regulatory Assessment

Ref	Title	Version	Link
4	Clinical Safety Hazard Log (CSHL)	2026.03.R4	Curistica NEXUS Platform (Product 224)
5	Safety Incident Management Log	1.0	Safety Incident Management Log Surgery Assist
6	Multilingual Change Analysis (NEXUSUPDATEv7)	1.0	Project files
7	Hazard Workshop Minutes (13 March 2026)	1.0	HW-2026-03-13-multilingual-minutes.md

Introduction

A clinical safety assessment for the Surgery Assist software has been conducted in line with NHS Digital safety standard DCB0129.

This Clinical Safety Case Report (CSCR) presents evidence of adherence to DCB0129 requirements throughout the software development lifecycle.

Our clinical risk management approach includes:

- Hazard identification
- Risk assessment
- Implementation of mitigations

Identified hazards are documented in the Clinical Safety Hazard Log (maintained on the Curistica NEXUS platform, Product 224) and classified by risk category. Detailed mitigations for each hazard cause are implemented and documented.

While residual risks may remain, they have been minimised through additional controls and will be managed through ongoing monitoring and safety protocol refinement.

This report demonstrates Surgery Assist's clinical safety for NHS use, reflecting our commitment to patient safety in health IT systems.

Relevant background documentation to this CSCR are:

1. X-on Health Ltd Clinical Risk Management System CRMS
2. Surgery Assist Clinical Risk Management Plan

Intended audience

This CSCR is intended to demonstrate compliance against DCB0129 and also for stakeholders and clients deploying Surgery Assist into their business process, supporting them in meeting their obligations under DCB0160.

To support our clients, we have prepared a template DCB0160 Clinical Safety Case Report based on this CSCR.

Background

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 receptionist staff.

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

The CSCR covers Surgery Assist release 2026.03.R4 (V7 - Multilingual).

Release 2026.03.R4 introduces browser-native translation support for the deterministic chatbot pathway. This enables non-English-speaking patients to interact with Surgery Assist in their preferred language using built-in browser translation capabilities. The key changes in this release are:

- **Browser-native translation support:** The Surgery Assist deterministic chatbot can now be translated by the patient's browser (Chrome via Google Translate, Edge via Microsoft Translator, Safari via Apple Translate). This is a zero-development approach that leverages built-in browser capabilities rather than server-side translation.

- **Architectural migration from iframe to native webpage:** To enable browser translation (which cannot operate within cross-origin iframes), Surgery Assist is migrating from an iframe embed to a native webpage integration on practice websites. This is a prerequisite for the translation feature.

- **AI pathway remains English-only:** The AI-enhanced assistant ("Ask a question") pathway continues to operate in English only. Non-English input is detected by the Microsoft Azure Translator API before reaching the LLM, and a translated redirect message is displayed to the patient.

- **Translation RBAC controls:** New role-based access controls in the Surgery Assist Portal allow Owner-level global override and Manager-level per-bot translation enable/disable. Translation is OFF by default for all practices in production and is individually enabled only after the practice has updated its embed code.

- **New hazard causes and controls:** 15 new causes have been identified across 9 existing hazards, with 15 new controls introduced (design, testing, and process controls). Two previous controls enforcing English-only access (CTRL-014, CTRL-043) have been retired.

Previous versions of the CSCR covered Surgery Assist V6.0, which introduced direct appointment booking via Hero Health.

Out of Scope

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

The translation feature relies entirely on browser-native translation engines. X-on Health does not provide, host, or control the translation engines themselves. Translation accuracy is a function of the browser vendor's translation service (Google, Microsoft, or Apple) and is outside the direct control of the manufacturer. Controls have been implemented to mitigate risks arising from translation inaccuracies (see Hazard Profile and Transferred Risks sections).

User Flow

The digital assistant is available on a website only, however users can be informed and directed to it when calling by phone or when attending their healthcare provider's premises:

- **Via telephone:** When a user calls the practice and selects an option, they are informed that a digital assistant is available to carry out their healthcare administrative task online and are offered a choice to switch to it by pressing a key on their phone:
    - If they opt-in and are on a mobile device capable of receiving an SMS, they are then sent instructions and a link via SMS to the practice or Surgery Assist website.
    - If they opt in and have called via a landline, the user is directed to access the practice website.
- **In the practice/in person:** A scannable QR code may be available on posters, on waiting screens or otherwise in the practice and scanning it opens up the practice website.

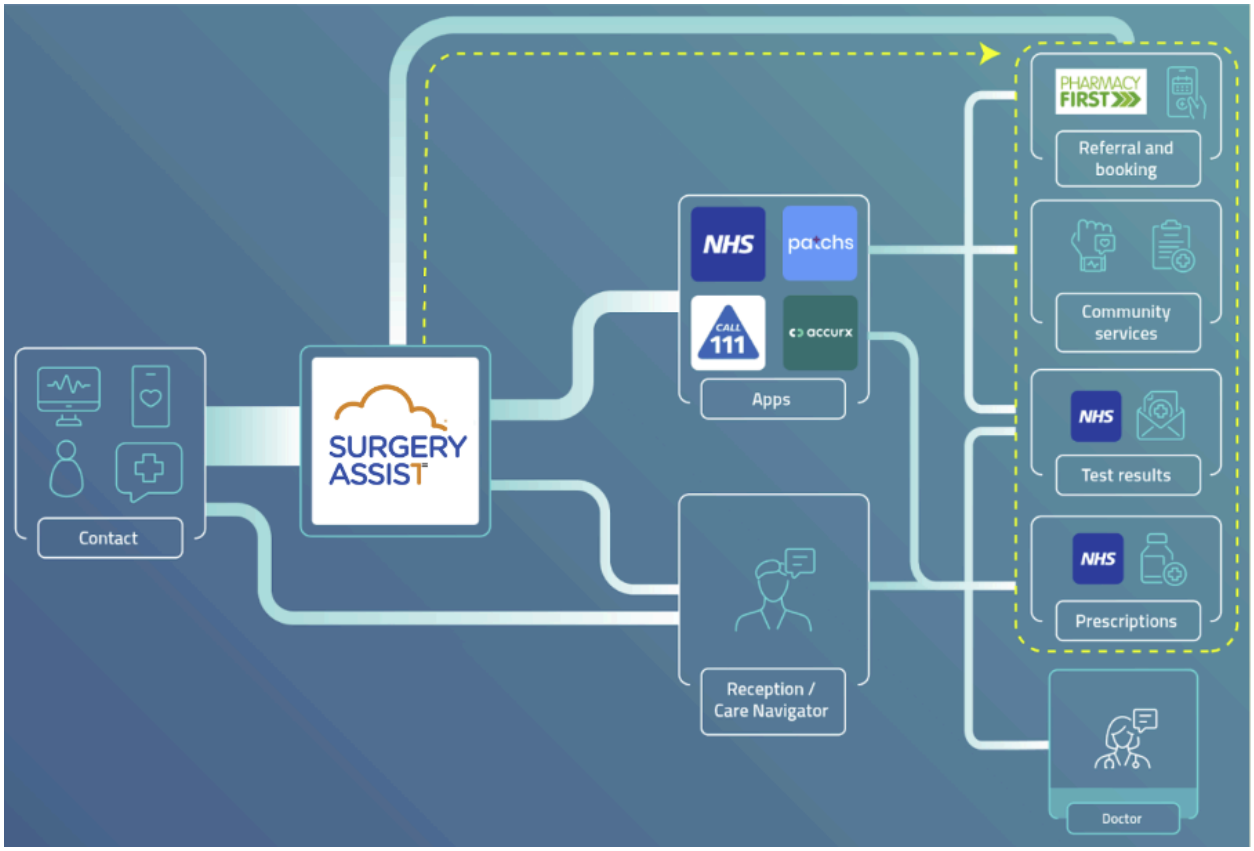
On the practice website, the digital assistant is available as a widget when users load the page. The digital assistant then guides users into completing administrative healthcare tasks they wish. These can include but not be limited to appointment booking, obtaining test results, requesting sick notes or repeat medications and making referrals.

Multilingual user flow (V7): When a patient accesses Surgery Assist via a practice website and their browser is configured for a non-English language, the browser's built-in translation engine may automatically translate the deterministic chatbot content. A disclaimer/banner informs patients that translation is provided by their browser and that clinical accuracy cannot be

guaranteed. If the patient enters free-text input in the AI-enhanced assistant pathway in a non-English language, the Azure Translator API detects this and returns a translated message directing them to rephrase in English or contact the surgery directly. Emergency signposting (including "call 999") is included in this redirect message.

This is demonstrated graphically in Figure 1.

Figure 1. High level overview of Surgery Assist patient flow



System architecture

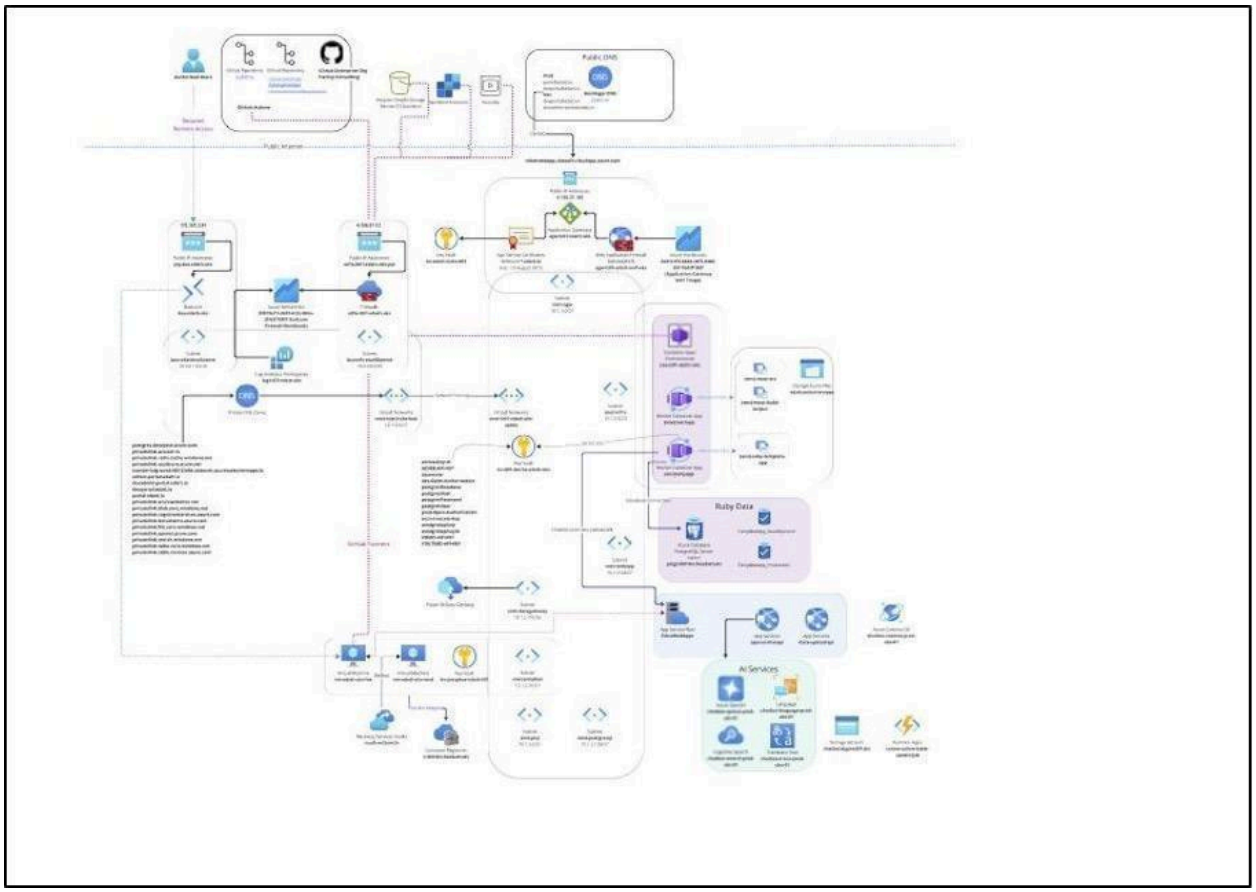
Surgery Assist is hosted on a platform using an Azure Landing Zone integrated with GitHub as a baseline. The landing zone hosts multiple Azure services including containerised applications, an application gateway, PostgreSQL, Redis, Storage, Azure Search, Azure Translation, Azure Auto-redaction and Azure Web Apps.

All egress traffic will be routed through an Azure Firewall to ensure secure and controlled internet access.

Additionally, all incoming traffic will be routed through the application gateway, and a jump-box will be included for managing and deploying to the private environment.

Multilingual architecture (V7): The translation capability for the deterministic chatbot pathway relies on browser-native translation engines (Google Translate, Microsoft Translator, Apple Translate) operating client-side. No server-side translation is performed for the chatbot content. The AI-enhanced assistant pathway uses the existing Microsoft Azure Translator API for language detection on user input. When non-English input is detected, the system returns a pre-defined redirect message (which is itself subject to browser translation) without invoking the LLM.
This is demonstrated graphically in Figure 2.

Figure 2. High level overview of Surgery Assist Technical Architecture



Medical Device Status

The Surgery Assist software itself does not perform any function which may fall under the remit of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended), as such it has been formally assessed and is not deemed a medical device Surgery Assist Regulatory Assessment

Clinical Safety Analysis

Clinical safety activities are led by Dr Keith Grimes, a GMC registered doctor, former General Practitioner, and trained Clinical Safety Officer (CSO) - GMC: 4299088

Further CSO support and input was also provided by Dr Youssof Oskrochi, a trained CSO and GMC registered Public Health Consultant - GMC: 7419290

All clinical safety activities were undertaken via a Clinical Safety Multidisciplinary Team (MDT). Membership of the Clinical Safety MDT is outlined in Table 1. All meetings required at least one CSO and two other members to be quorate.

Table 1. Members of Clinical Safety MDT

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

Methodology

Clinical risk management activities are undertaken by the Clinical Safety MDT through Clinical Risk and Safety Meetings as outlined in the CRMS/CRMP, in summary if any of the following criteria are met, a meeting is convened:

- A new Surgery Assist function or flow is being designed/considered, OR
- An existing Surgery Assist function or flow is being materially changed, OR
- A new Surgery Assist version is being deployed, OR
- a new hazard has been identified, OR
- every twelve months.

Meetings are used to consider newly identified hazards and review/re-evaluate known hazards, consider causes and existing controls, and identify any residual controls that should be introduced. Any controls that require input from the healthcare organisation using Surgery Assist are flagged as such.

The outputs are documented in our Clinical Safety Hazard Log (Ref 4), including an evaluation of the clinical safety risk of each hazard based on the hazard's severity and likelihood of patient harm given the presence of existing and additional controls.

V7 Multilingual Analysis: For release 2026.03.R4, a dedicated multilingual change analysis was undertaken between February and March 2026. This included: structured analysis of the feature specification (SAD-144 / XOF-278); identification of 15 novel causes arising from browser-native translation; design and assessment of 15 new controls; a back-translation testing programme across 5 languages and 3 browser engines (Chrome, Edge, Safari) with automated Gemini scoring (average scores consistently above 94%); and a formal hazard workshop held on 13 March 2026. Workshop attendees included Dr Keith Grimes (CSO, Curistica), Youssof Oskrochi (Curistica), and Chris Duncombe (X-on Health). The workshop reviewed all 9 affected hazards, confirmed all residual risk scores remained unchanged, and agreed 12 actions for ongoing implementation. Post-workshop updates were applied on 18 March 2026, adding two further causes (C-ML-014, C-ML-015) and one further control (CTRL-ML-015) following action completion.

Full methodology and process is outlined in:

X-on Health Ltd Clinical Risk Management System CRMS

Surgery Assist Clinical Risk Management Plan

Clinical Safety Hazard Profile

Table 2 provides a summary of the current clinical safety profile of the Surgery Assist application, after consideration of existing and additional controls.

All hazards are deemed to be low risk (risk score 1, no further action) or acceptable (risk score 2, acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical) and therefore no further mitigation is required at this time.

Full details of the Hazards, Causes, Controls & Evidence may be seen in the Surgery Assist hazard log, which is maintained on the Curistica NEXUS platform (Product 224) and available on request, or via the X-on Trust Centre.

Appendix A provides the Risk Matrix for reference.

Changes in release 2026.03.R4: Nine existing hazards received new multilingual-related causes: HAZ-003, HAZ-004, HAZ-005, HAZ-006, HAZ-008, HAZ-013, HAZ-015, HAZ-ADMIN-001, and HAZ-CONFIG-001. All residual risk scores were reviewed at the hazard workshop on 13 March 2026 and confirmed unchanged, with post-workshop updates applied on 18 March 2026. Two controls were retired: CTRL-014 ("English only" restriction on the deterministic chatbot, replaced by CTRL-ML-001 browser translation disclaimer and CTRL-ML-005 translation accuracy testing) and CTRL-043 ("English only" restriction on the AI section, replaced by CTRL-ML-004 Azure Translator API language detection and CTRL-ML-014 notranslate protection on the AI output container).

Table 2. Summary of the Clinical Safety Hazard Profile for Surgery Assist

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
HAZ-001	User is unable to use the phone assistant to switch to the	Significant	Low	2	Closed	--

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
	digital pathway					
HAZ-002	User is disconnected from telephone queue and link sent to their phone	Significant	Low	2	Closed	--
HAZ-003	Users may or may not be able to access the digital assistant	Significant	Low	2	Transferred	+1 new cause (C-ML-001: iframe-to-webpage migration)
HAZ-004	Users are unable, due to personal circumstances/abilities, to complete the task	Minor	Low	1	Closed	+2 new causes (C-ML-002, C-ML-003: translation of dynamic variables and accessibility controls). CTRL-014 retired.
HAZ-005	Users unable to complete task	Significant	Low	2	Closed	+2 new causes (C-ML-004, C-ML-005:

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
	despite correct use of digital assistant					non-English free-text input trap, translation of form validation).
HAZ-006	Users complete task but do not achieve expected outcome	Considerable	Low	2	Transferred	+5 new causes (C-ML-006 to C-ML-010: translation-induced clinical errors, emergency dilution, back-translation failures, cross-browser variability, proper noun corruption).
HAZ-007	User identifiable information recorded in insecure or	Significant	Low	2	Closed	--

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
	inappropriate area					
HAZ-008	Service provides signposting to ineligible users or collects inappropriate data	Significant	Low	2	Closed	+1 new cause (C-ML-011: translated eligibility criteria misunderstood).
HAZ-009	Users do not know how/where to report bugs or issues	Minor	Low	1	Closed	--
HAZ-010	Users may not be able to access LLM enhanced digital assistant	Significant	Low	2	Transferred	--
HAZ-011	Users may not be able to access LLM enhanced digital assistant (accessibility)	Minor	Low	1	Closed	--

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
HAZ-012	Users may not access LLM enhanced assistant correctly	Significant	Low	2	Closed	--
HAZ-013	Users may not access LLM enhanced assistant correctly (data quality)	Significant	Low	2	Closed	+1 new cause (C-ML-015: browser translation alters AI response content). Reopened.
HAZ-014	User spends long time trying to get LLM to respond appropriately	Significant	Low	2	Closed	--
HAZ-015	LLM doesn't recognise medical emergency or urgent help request	Significant	Low	2	Closed	+1 new cause (C-ML-014: non-English emergency symptoms bypass AI detection).

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
						Emergency signposting gap identified; "Call 999" button on contact surgery page proposed. Reopened.
HAZ-016	User identifiable information recorded in insecure area (LLM)	Significant	Low	2	Closed	--
HAZ-017	LLMs respond to broad inputs without proper alignment/ guardrails	Significant	Low	2	Closed	--
HAZ-ADMIN-001	Incorrect appointment type configuration in Surgery	Significant	Low	2	Transferred	+1 new cause (C-ML-012: RBAC misconfiguration of

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
	Assist Portal					translation toggles).
HAZ-ADMIN-002	Appointment types fail to synchronise correctly with Hero Health API	Minor	Low	1	Transferred	--
HAZ-DET-001	Patient verification fails to correctly match patient to medical record	Major	Very Low	2	Transferred	--
HAZ-DET-002	Patient selects clinically inappropriate appointment slot type	Considerable	Low	2	Transferred	--
HAZ-DET-003	System timeout/API failure during booking process	Significant	Low	2	Closed	--

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
HAZ-AI-001	AI chatbot misinterprets query and directs to wrong appointment type	Considerable	Low	2	Closed *	--
HAZ-AI-002	AI chatbot provides inappropriate clinical advice during booking	Considerable	Low	2	Closed *	--
HAZ-AI-003	Patient enters sensitive information into AI chat interface	Considerable	Low	2	Closed *	--
HAZ-CONFIG-001	Hero Health integration not correctly configured in EMIS/SystmOne	Significant	Low	2	Transferred	+1 new cause (C-ML-013: incorrect embed code during iframe-to-webpage migration).

Hazard ID	Hazard Description	Residual Severity	Residual Likelihood	Residual Risk Score	Status	V7 Changes
HAZ-CONFIG-002	Unregistered patient appointments not properly monitored by practice staff	Considerable	Low	2	Transferred	--
HAZ-SYSTEM-001	Surgery Assist booking integration becomes unavailable (service outage)	Significant	Low	2	Transferred	--

* HAZ-AI-001, HAZ-AI-002, and HAZ-AI-003 relate to ai-facilitated appointment booking features currently disabled in production (March 2025). Risk scores reflect the disabled state with controls in place for re-enablement.

Transferred Risks

In accordance with DCB0129 and DCB0160, certain clinical safety risks are appropriately transferred to deploying organisations where effective controls can only be implemented by the healthcare provider. This reflects the recognised principle that practices retain clinical governance authority, infrastructure ownership, and regulatory obligations as registered healthcare providers.

X-on Health Ltd supports deploying organisations in managing transferred risks through comprehensive documentation, template DCB0160 materials, training guidance, and ongoing Clinical Safety Officer consultation. Risk transfer represents shared responsibility, not abandonment of manufacturer safety obligations.

The eight categories of transferred risks below specify:

- Exactly what is transferred (specific hazard, cause, and control)
- Why the practice is the appropriate owner
- What the practice needs to do (actionable requirements)
- How the manufacturer supports the practice in meeting its obligations

1. Information & Content Management

Surgery Assist displays practice-specific content including opening hours, contact details, service descriptions, questionnaires, and informational pages. This content is either provided directly by the practice or sourced from NHS and third-party systems. If this information is inaccurate, outdated, or incomplete, patients may make decisions based on incorrect information.

The manufacturer has implemented controls to ensure content accuracy where it is within the manufacturer's control (automated NHS data feeds, content validation processes, version-controlled questionnaires). However, content that originates from the practice, is maintained by the practice, or is subject to practice-specific clinical decisions cannot be validated by the manufacturer.

Practice Responsibilities:

Deploying organisations must:

- **Content Governance:**
    - **Regular review schedule** for all practice-specific content displayed through Surgery Assist (recommended: monthly review of opening hours, contact details, service descriptions)
    - **Designated staff member** responsible for verifying Surgery Assist content accuracy
    - **Change notification process**: promptly inform X-on Health or update the Surgery Assist Portal when practice information changes (e.g., new opening hours, staff changes, service additions/removals)
- **Questionnaire Management:**

  - **Clinical review** of any questionnaires or forms displayed through Surgery Assist before deployment
  - **Version control**: ensure the Surgery Assist version of any questionnaire matches the currently approved clinical version
  - **Withdrawal process**: notify X-on Health immediately if a questionnaire is clinically withdrawn or superseded

- **Controls Required:** CTRL-021

Hazard	Cause	Control
HAZ-005: Users unable to complete task despite correct use	**CS-030:** Previously uploaded forms/documents no longer available	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-006: Users complete task but do not achieve expected outcome	**CS-037:** Hosted forms/questionnaires out of date	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-006: Users complete task but do not achieve expected outcome	**CS-038:** Information provided by practices is out of date	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes

2. Configuration & Unregistered Patient Management

Surgery Assist allows practice administrators to configure appointment types, booking resources, and service availability through the Surgery Assist Portal and Hero Health. Incorrect configuration could result in patients being offered inappropriate appointment types or booking slots that don't match clinical needs.

Additionally, patients who are not registered at the practice (or whose details cannot be matched) may still be able to book appointments. While the manufacturer has implemented controls to flag unregistered bookings, the practice must manage these patients appropriately.

The manufacturer has implemented configuration validation, default safe settings, and administrative audit trails. However, the clinical appropriateness of appointment type

configurations and the management of unregistered patients are practice-level clinical governance decisions.

Practice Responsibilities:

Deploying organisations must:

- **Configuration Governance:**
    - **Clinical approval** for all appointment type configurations before going live
    - **Regular configuration review** (recommended quarterly) to ensure appointment types match current clinical service provision
    - **Change management process** for appointment type additions, modifications, or removals
    - **Testing** of booking flows after configuration changes
- **Unregistered Patient Management:**
    - **Daily monitoring** of unregistered patient bookings (Surgery Assist Portal and/or clinical system reports)
    - **Clear practice protocol** for handling unregistered patients (verify identity, offer registration, manage appointment appropriately)
    - **Staff training** on the unregistered patient pathway and associated risks
- **Controls Required:** CTRL-ADMIN-001c, CTRL-ADMIN-003a, CTRL-ADMIN-005b, CTRL-CONFIG-005a, CTRL-CONFIG-005b, CTRL-CONFIG-005c, CTRL-CONFIG-005d

Hazard	Cause	Control
HAZ-ADMIN-001: Admin user incorrectly configures appointment types	**C-ADMIN-001a:** Admin user creates incorrect appointment type mapping	**CTRL-ADMIN-001c:** Admin audit trail for all configuration changes
HAZ-ADMIN-001: Admin user incorrectly configures appointment types	**C-ADMIN-001c:** Admin user does not test configuration changes before going live	**CTRL-ADMIN-003a:** Testing protocol required before configuration changes are published

Hazard	Cause	Control
HAZ-ADMIN-001: Admin user incorrectly configures appointment types	**C-ADMIN-001d:** Multiple admin users make conflicting configuration changes	**CTRL-ADMIN-005b:** Practice admin governance SOP for managing Surgery Assist Portal configuration
HAZ-CONFIG-002: Unregistered patient appointments not properly monitored	**C-CONFIG-002a:** Practice staff not aware of unregistered patient bookings	**CTRL-CONFIG-005a:** Practice SOP for monitoring and managing unregistered patient appointments
HAZ-CONFIG-002: Unregistered patient appointments not properly monitored	**C-CONFIG-002b:** Practice does not have process to verify unregistered patient identity	**CTRL-CONFIG-005b:** Practice identity verification protocol for unregistered patients
HAZ-CONFIG-002: Unregistered patient appointments not properly monitored	**C-CONFIG-002c:** High volume of unregistered bookings overwhelms practice staff	**CTRL-CONFIG-005c:** Practice escalation process if unregistered booking volume is unmanageable
HAZ-CONFIG-002: Unregistered patient appointments not properly monitored	**C-CONFIG-002d:** Practice staff incorrectly registers unregistered patient in clinical system	**CTRL-CONFIG-005d:** Practice staff training on correct patient registration process

3. Patient Verification & Identity Management

Surgery Assist offers patient verification using surname and date of birth (DOB) or NHS number before completing appointment bookings through Hero Health. This verification matches against the practice's clinical system (EMIS Web or SystmOne) via the Hero Health API.

While the manufacturer has implemented matching algorithms and validation controls, certain identity management risks remain practice responsibilities because they relate to clinical system data quality and practice registration processes that are outside the manufacturer's control.

Practice Responsibilities:

Deploying organisations must:

- **Data Quality:**
    - **Regular audit** of patient demographic data quality in clinical system (recommended: annual data quality audit)
    - **Duplicate record management**: active programme to identify and merge duplicate patient records
    - **Data entry standards**: staff trained on consistent data entry (capitalisation, formatting, preferred name vs legal name)
- **Patient Communication:**
    - **Information** to patients about what details are needed for Surgery Assist verification
    - **Alternative verification**: clear pathway for patients who cannot verify online (phone call to practice)
    - **Failed verification support**: guidance to patients on what to do if verification fails
- **Controls Required:** CTRL-DET-001a, CTRL-DET-002a, CTRL-DET-004a, CTRL-DET-005a

Hazard	Cause	Control
HAZ-DET-001: Patient verification fails to correctly match patient	**C-DET-001a:** Patient enters incorrect surname spelling or DOB	**CTRL-DET-001a:** Practice patient communication about verification requirements
HAZ-DET-001: Patient verification fails to correctly match patient	**C-DET-001b:** Clinical system contains incorrect/outdated patient demographics	**CTRL-DET-002a:** Practice data quality programme for patient demographic data
HAZ-DET-001: Patient verification fails to correctly match patient	**C-DET-001c:** Multiple patients with identical surname and DOB in practice population	**CTRL-DET-004a:** Practice duplicate record management and NHS number verification
HAZ-DET-001: Patient verification fails to correctly match patient	**C-DET-001d:** NHS number entered incorrectly or transposed	**CTRL-DET-005a:** Practice guidance to patients on NHS

Hazard	Cause	Control
		number retrieval (NHS App, previous correspondence)

4. Appointment Type Appropriateness

Surgery Assist guides patients through a deterministic menu-driven flow to select and book appointments. While the manufacturer has designed the booking flow to present clinically appropriate options based on practice configuration, the ultimate clinical appropriateness of appointment types available to patients depends on practice-level decisions about which appointment types to offer via the digital channel.

Practice Responsibilities:

Deploying organisations must:

- **Clinical Governance:**
    - **Clinical review** of all appointment types offered through Surgery Assist, including triage requirements
    - **Regular review** of appointment type appropriateness (recommended: quarterly clinical governance review)
    - **Patient safety net**: process to identify and manage inappropriate bookings that slip through
- **Staff Training:**
    - **Reception/admin staff** trained to review Surgery Assist bookings for clinical appropriateness
    - **Clinical staff** aware that Surgery Assist bookings may require verification of appointment type suitability
- **Controls Required:** CTRL-DET-006a, CTRL-DET-006b

Hazard	Cause	Control
HAZ-DET-002: Patient selects clinically inappropriate appointment type	**C-DET-002a:** Patient misunderstands appointment type descriptions	**CTRL-DET-006a:** Practice review and approval of appointment type descriptions displayed to patients
HAZ-DET-002: Patient selects clinically inappropriate appointment type	**C-DET-002b:** Practice offers inappropriate appointment types via Hero Health	**CTRL-DET-006b:** Practice staff training on appropriate appointment type configuration in Hero Health
HAZ-DET-002: Patient selects clinically inappropriate appointment type	**C-DET-002c:** Appointment type no longer clinically appropriate but not removed	**CTRL-DET-006a:** Practice review and approval of appointment type descriptions displayed to patients

5. Appointment Synchronisation & Conflict Management

Hero Health integration with EMIS Web and SystmOne involves bidirectional appointment synchronisation. While the manufacturer has implemented robust synchronisation mechanisms, certain conflict scenarios require practice-level management because they involve practice-side actions (manual appointment modifications, double-booking management) that occur outside the Surgery Assist system.

Practice Responsibilities:

Deploying organisations must:

- **Conflict Management:**
    - **Defined process** for handling appointment booking conflicts reported by patients
    - **Communication protocol** for contacting patients promptly if appointments need rescheduling
    - **Escalation pathway** if conflicts cannot be resolved quickly
- **Manual Override Management:**

  - **Staff training** on the risks of manually modifying Hero Health-enabled appointment slots in the clinical system
  - **Preferred practice**: Cancel via Hero Health portal where possible rather than direct clinical system modification
  - **Documentation** when manual overrides are necessary and notification to affected patients

- **System Outage Management:**

  - **Monitoring** of Surgery Assist/Hero Health availability (manufacturer provides status page)
  - **Fallback procedures** if booking integration is unavailable: revert to telephone booking, NHS App, walk-in
  - **Patient communication** during outages (website banner, telephone message update)
  - **Post-outage audit** of appointments booked during problem period to identify any that need reconciliation

- **Controls Required:** CTRL-ADMIN-006c, CTRL-ADMIN-007a

Hazard	Cause	Control
HAZ-ADMIN-002: Appointment types fail to synchronise correctly with Hero Health API	**C-ADMIN-002b:** Two patients attempting to book same appointment slot simultaneously	**CTRL-ADMIN-006c:** Practice SOP for handling concurrent booking conflicts reported by patients
HAZ-ADMIN-002: Appointment types fail to synchronise correctly with Hero Health API	**C-ADMIN-002c:** Practice staff manual appointment changes in EMIS/SystmOne not synchronised	**CTRL-ADMIN-007a:** Practice to develop/deploy protocol to resolve conflicts

6. Infrastructure & Business Continuity (SystmOne Practices)

SystmOne practices require a unique technical architecture for Hero Health integration: a **dedicated gateway PC** located within the practice network that maintains persistent connectivity to Hero Health services. This is a TPP (SystmOne vendor) architectural requirement, not a Surgery Assist design choice.

The manufacturer has:

- **No physical access** to the gateway PC (it's on practice premises)
- **No remote access** to practice network infrastructure
- **No visibility** of gateway PC status or uptime
- **No ability to remediate** hardware failures or network issues at the practice

The gateway PC is **practice-owned infrastructure**, equivalent to the practice's clinical PCs, network switches, or internet connection. Just as the practice is responsible for maintaining their clinical system infrastructure, they are responsible for maintaining the Hero Health gateway PC.

If the gateway PC fails (hardware failure, network disconnection, power loss), patients cannot book appointments via Hero Health until the practice resolves the issue. This represents a **practice infrastructure dependency** that must be managed through practice IT support arrangements.

Practice Responsibilities:

- Deploying organisations (SystmOne practices only) must:
    - **Gateway PC Infrastructure Management:**
    - **Dedicated hardware** meeting TPP specifications for Hero Health gateway PC
    - **Appropriate environment**: secure location, reliable power supply, network connectivity
    - **Maintenance schedule**: included in practice IT infrastructure maintenance plan
    - **Hardware replacement**: budget allocation for gateway PC replacement when end-of-life (typically 3-5 years)
- **Monitoring and Support:**
    - **Regular checks** of gateway PC status (recommended: daily visual check, weekly connectivity test)
    - **Defined responsibility**: designate practice staff member or IT support contractor for gateway PC monitoring
    - **IT support arrangements**: ensure IT support contract covers Hero Health gateway PC

    - **Escalation pathway**: process for contacting X-on Health support if issues appear software-related vs hardware-related

- **Business Continuity Planning:**

    - **Document** in practice business continuity plan: "If Hero Health booking unavailable, revert to telephone booking and NHS App"
    - **Spare hardware** consideration: some practices may wish to maintain spare gateway PC for rapid swap if primary fails
    - **Communication plan**: how to inform patients if Hero Health booking is temporarily unavailable

- **Network Dependencies:**

    - **Network reliability**: gateway PC requires stable internet connectivity
    - **Firewall configuration**: ensure practice firewall permits Hero Health traffic (TPP provides specification)
    - **Backup connectivity**: consider mobile broadband backup if practice internet is unreliable
    - **EMIS Practices:** These requirements do **not** apply to EMIS Web practices, which use a cloud-based integration that does not require practice-side gateway infrastructure.

- **Controls Required:** CTRL-533

Hazard	Cause	Control
HAZ-CONFIG-001: Hero Health integration not correctly configured	**C-CONFIG-001e:** Gateway PC hardware failure (SystmOne practices only)	**CTRL-533:** S1 PRACTICES: Internal policies for ensuring gateway PC uptime & monitoring
HAZ-CONFIG-001: Hero Health integration not correctly configured	**C-CONFIG-001f:** Gateway PC network connectivity failure (SystmOne practices only)	**CTRL-533:** S1 PRACTICES: Internal policies for ensuring gateway PC uptime & monitoring

7. Service Availability & Business Continuity

Surgery Assist is a **digital convenience channel** for administrative tasks (appointment booking, accessing information). It is **not the sole method** of accessing practice services. Patients always retain access to:

- **Telephone booking** (traditional practice phone system)
- **In-person booking** (attending reception desk)
- **NHS App booking** (for GP Connect-enabled practices)
- **Emergency care pathways** (111, 999, walk-in centres, A&E)

If Surgery Assist becomes unavailable (manufacturer infrastructure failure, third-party dependency outage, internet connectivity issues), patients experience **inconvenience** but not **inability to access care**. This is analogous to a practice website being temporarily down: patients can still phone or attend in person.

However, practices must ensure:

- **Alternative access routes remain available** during Surgery Assist outages
- **Patients are informed** of alternatives if Surgery Assist is unavailable
- **Business continuity procedures** are documented and staff are trained

The manufacturer commits to high availability (target: 99.5% uptime) and proactive monitoring, but **cannot guarantee 100% availability** due to dependencies on:

- Azure cloud infrastructure
- Hero Health platform availability
- NHS Login service availability
- Internet connectivity (practice-side and patient-side)
- Third-party APIs and services

Practice Responsibilities:

Deploying organisations must:

- **Business Continuity Planning:**
    - **Document** in practice business continuity plan: procedures for Surgery Assist outage

  - **Ensure** traditional access channels (telephone, in-person) have capacity to absorb digital channel failures
  - **Staff training** on recognising Surgery Assist outages and directing patients to alternatives
  - **Regular testing** of fallback procedures (e.g., annual BC exercise including digital channel failure scenario)

- **Patient Communication:**
  - **Practice website** includes information on alternative booking methods
  - **Telephone greeting message** mentions multiple booking options (not solely Surgery Assist)
  - **Waiting room posters** display multiple access routes
  - **During outages**: update website banner, telephone message, and social media to inform patients

- **Service Level Expectations:**
  - **Monitor** manufacturer status page for scheduled maintenance and incident updates
  - **Escalate** to X-on Health support if outages exceed expected duration
  - **Participate** in post-incident reviews if significant outages occur
  - **Extended Outage Protocols (>4 hours):**
  - **Activate** formal business continuity procedures
  - **Increase staffing** on telephone lines if needed to handle booking volume
  - **Consider** temporary appointment slot increases if digital channel unavailable for extended period
  - **Patient communication**: proactive contact to patients who may have been attempting to book during outage period

- **Practice Website Resilience:**
  - **Separate hosting** for practice website (so Surgery Assist widget failure doesn't take down entire site)
  - **Contact information** always visible even if Surgery Assist widget fails to load
  - **IT support arrangements** to resolve practice website issues independently

- **Controls Required:** CTRL-025, CTRL-SYSTEM-001D

Hazard	Cause	Control
HAZ-SYSTEM-001: Surgery Assist booking integration becomes unavailable	**C-SYSTEM-001A:** Infrastructure or network failure affecting service availability	**CTRL-SYSTEM-001D:** Documented business continuity procedures ensuring patient access during extended outages (>4 hours)
HAZ-SYSTEM-001: Surgery Assist booking integration becomes unavailable	**C-SYSTEM-001B:** Third-party service dependency unavailability	**CTRL-SYSTEM-001D:** Documented business continuity procedures ensuring patient access during extended outages (>4 hours)

8. Multilingual and Translation

NEW IN RELEASE 2026.03.R4

Release 2026.03.R4 introduces browser-native translation support for the deterministic chatbot. While the manufacturer has implemented controls to mitigate translation-related risks (disclaimer/banner, translation accuracy testing, language detection on AI input), certain translation-related risks require practice-level management because they relate to patient population characteristics, local language needs, and practice-specific clinical content that varies by deploying organisation.

Browser translation is a patient-facing convenience feature that relies on third-party translation engines (Google Translate, Microsoft Translator, Apple Translate) operating client-side within the patient's browser. The manufacturer does not provide, host, or control these translation engines. Translation accuracy varies by language, browser, and content type. The manufacturer has conducted structured translation testing (back-translation with automated scoring) across 5 languages and 3 browser engines, with average scores consistently above 94%. Low-scoring items were reviewed by the CSO and confirmed not to relate to emergency or red-flag pathways.
Following the hazard workshop, a gap was identified in emergency signposting for non-English-speaking patients using the AI pathway (HAZ-015, C-ML-014). When a patient types emergency symptoms in a non-English language, the Azure Translator API language detection redirects them to “contact the surgery” without emergency-specific signposting. A “Call 999 –

Emergency" button on the "contact the surgery" options page has been proposed and accepted by X-on Health for implementation. This will provide a language-independent emergency escape route visible to all patients, including those whose browser-translated emergency input bypasses the AI language detection. The corresponding control will be added to the hazard log upon deployment confirmation.

Practice Responsibilities:

Deploying organisations that enable the translation feature must:

- **Migration Management:**
    - **Update embed code** from iframe to native webpage integration when instructed by X-on Health, following the provided migration instructions
    - **Verify** that Surgery Assist loads and functions correctly on the practice website after migration
    - **Report** any issues to X-on Health support during the migration period
- **Patient Communication:**
    - **Inform patients** that browser translation is available for Surgery Assist content
    - **Communicate** that translation is provided by the browser and is not a certified medical translation
    - **Ensure** patients understand that for complex or urgent clinical matters, they should contact the practice directly by telephone
- **Content Awareness:**
    - **Review** practice-specific content (service descriptions, questionnaire text, opening hours descriptions) for translation-friendliness where possible (short sentences, simple vocabulary, avoidance of colloquialisms)
    - **Be aware** that browser translation may not perfectly render clinical terminology, appointment type descriptions, or local service names
    - **Report** to X-on Health any patient-reported translation issues or inaccuracies that may affect clinical safety
- **Controls Required:** CTRL-ML-008 (migration plan)

Hazard	Cause	Control
HAZ-003: Users may or may not be able to access the digital assistant	**C-ML-001:** Incorrect or incomplete iframe-to-webpage migration breaks Surgery Assist on practice website	**CTRL-ML-008:** Documented iframe-to-webpage migration plan with practice-by-practice rollout
HAZ-CONFIG-001: Hero Health integration not correctly configured	**C-ML-013:** Practice implements incorrect embed code during migration to native webpage	**CTRL-ML-008:** Documented iframe-to-webpage migration plan with practice-by-practice rollout

Shared Responsibility Controls (XON/PRACTICE)

These controls require collaboration between X-On Health and practices:

Hazard	Cause	Control
HAZ-005: Users unable to complete task despite correct use	**CS-030:** Previously uploaded forms/documents no longer available	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-006: Users complete task but do not achieve expected outcome	**CS-037:** Hosted forms/questionnaires out of date	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-006: Users complete task but do not achieve expected outcome	**CS-038:** Information provided by practices is out of date	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-012: Users may not access LLM enhanced assistant correctly	**CS-071:** Model generates overly specific responses (overfitting)	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes

Hazard	Cause	Control
HAZ-013: Users may not access LLM enhanced assistant correctly	**CS-065:** Model responds using outdated training data	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-013: Users may not access LLM enhanced assistant correctly	**CS-066:** Model generates response based on incorrect source data	**CTRL-021:** Client owned documents/forms - manufacturer relies on practices to notify changes
HAZ-DET-002: Patient selects clinically inappropriate appointment type	**C-DET-002b:** Practice offers inappropriate appointment types via Hero Health	**CTRL-DET-006b:** Practice staff training on appropriate appointment type configuration in Hero Health
HAZ-DET-002: Patient selects clinically inappropriate appointment type	**C-DET-002d:** Practice enables all appointment types without clinical governance approval	**CTRL-DET-006b:** Practice staff training on appropriate appointment type configuration in Hero Health

Summary Statistics

- **Total Hazards:** 28
- **Total Causes:** 144
- **Total Controls:** 138
- **Total Evidence Items:** 65
- **Risk Distribution:**
    - Risk Score 1 (Low): 4 hazards
    - Risk Score 2 (Acceptable): 24 hazards
    - Risk Score 3+ (Undesirable or above): 0 hazards
- **Average Residual Risk Score:** 1.86
- **Control Types:**
    - DESIGN: 85 controls
    - PROCESS: 38 controls
    - TRAINING: 9 controls
    - TESTING: 2 controls
    - OTHER: 4 controls
- **Total Practice Responsibility Controls:** 15

- **Total Shared Responsibility Controls:** 2 (CTRL-021, CTRL-DET-006b)
- **Hazards with Transferred Controls:** 11

- **V7 Multilingual Changes:**

    - New causes added: 15 (across 9 existing hazards)
    - New controls added: 15
    - Controls retired: 2 (CTRL-014, CTRL-043)
    - New evidence items: 12
    - Residual risk score changes: 0 (all confirmed unchanged at workshop)

Risk management in live service

X-on Health ltd commitment to safety continues once Surgery Assist has been deployed through post-marketing surveillance and continual proactive and reactive hazard identification mechanisms, as outlined in the CRMS/CRMP. This has been extended as detailed in:

Surgery Assist Post-Market Monitoring and Incident Management Process

Support and business continuity

X-on Health ltd approach to system availability, integration monitoring and issue resolution is outlined on our application support and service level agreements (SLAs) page. Where there are issues with using Surgery Assist, X-on Health ltd offers a manned service desk available between 9am-5pm Mon-Fri which offers a resolution pathway for issues. If the issue cannot be resolved and the Surgery Assist service needs to be taken offline, the standard practice access routes by phone, in person or through the NHS App are still available and unaffected.

Incidents and identifications of new hazards

A post-market surveillance and engagement programme with healthcare organisations which use Surgery Assist is also in place, allowing X-on Health ltd and deploying organisations to both continuously monitor existing hazards but also identify and investigate potentially novel/previously unknown hazards as they evolve.

Safety related incidents and identifications of new hazards irrespective of source (user, client, X-on Health and its employees, provider platform, external) are managed with involvement of the CSO and where appropriate lead to an appropriate response including reviewing the CSCR and CSHL and updating them as required.

A monthly independent review of Surgery Assist performance data (post-market surveillance data) is undertaken by New Cloud Metrics under CSO oversight. This review covers chatbot interaction quality, user journey completion rates, and any anomalies that may indicate emerging safety concerns.

Decommissioning and end-of-life

In the event that Surgery Assist is withdrawn from service at one or more deploying practices, or if the product reaches end-of-life, X-on Health Ltd will follow a structured decommissioning process to ensure patient safety is maintained throughout the transition.

Notification and communication. X-on Health Ltd will provide deploying organisations with a minimum of 90 days' written notice of any planned withdrawal or end-of-life decision. This notice will include the rationale for withdrawal, the proposed decommissioning timeline, and guidance on transitioning to alternative patient access routes. Practices will be supported in communicating changes to their patient population, including updating website content and reception messaging.

Transition period. During the notice period, Surgery Assist will continue to operate with full clinical safety controls in place. X-on Health Ltd will work with each affected practice to ensure that standard patient access routes (telephone, in-person, NHS App) are clearly signposted and functioning before the digital assistant is removed. Where practices use Hero Health appointment booking via Surgery Assist, a transition plan will be agreed to maintain booking continuity.

Data handling. Upon decommissioning, all practice-specific configuration data, content, and interaction logs held by X-on Health Ltd will be handled in accordance with the existing Data Processing Agreement and DPIA. Conversation data will be retained for the period specified in the data retention schedule and then securely deleted. Practices will be notified of the data deletion timeline and given the opportunity to request any data they are entitled to receive before deletion occurs.

Safety case archival. The Clinical Safety Case Report, Clinical Safety Hazard Log, and all supporting evidence will be archived by Curistica Ltd on behalf of X-on Health Ltd for a minimum period of 10 years following decommissioning, in accordance with DCB 0129 requirements. This ensures that the safety record remains available for any future regulatory inquiry or incident investigation.

Emergency withdrawal. In the event that a safety concern necessitates immediate withdrawal of Surgery Assist from service (either at individual practice level or across the entire deployment), X-on Health Ltd retains the ability to disable the service remotely via the deployment configuration. The incident management process described in this report and the CRMS/CRMP would apply, with the CSO involved in the decision to withdraw and any subsequent reinstatement.

Safety claims

Based on the Clinical Safety Assessment conducted, Surgery Assist application release 2026.03.R4 (V7 - Multilingual) is a non-clinical system that supports administrative healthcare tasks. The application has been subjected to a thorough clinical safety assessment, and all identified risks have been mitigated to an acceptable level.

The multilingual feature introduced in this release has been assessed through a dedicated change analysis, structured translation testing programme, and formal hazard workshop, with post-workshop updates applied 18 March 2026. All residual risk scores remain unchanged from the previous release. An emergency signposting gap for non-English AI pathway input (HAZ-015) has been identified and a mitigation accepted by the manufacturer for implementation.

The Residual Risk Rating for all identified hazards is Risk Score 2 (Acceptable) or below. There are no hazards with a residual risk score of 3 (Undesirable) or above.

Full details of all identified hazards, their causes, the controls in place, and supporting evidence can be found in the Surgery Assist Clinical Safety Hazard Log, maintained on the Curistica NEXUS platform (Product 224).

Date: 18th March 2026

Clinical Safety Officer: Dr Keith Grimes
Organisation: Curistica Ltd
GMC Registration: 4299088

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