

## **Hanley Health Ltd Surgery Assist Clinical Safety Case Report**

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# Document Management

## Revision History

Version	Date	Description of change or amendment
0.1	10/09/2024	First Draft
0.2	12/09/2024	Second Draft
0.3	14/01/2025	Updated logo, checked product name, uploaded to Assuric
0.4	28/02/2025	Updated logo, updated fig 1 / fig 2 / Review
1.0	28/02/2025	Final (images updated)

## Authors

Name	Title/Responsibility	Date	Version
Dr Keith Grimes	Chief Digital Health Officer & CSO	28/2/25	0.4
Dr Youssef Oskrochi	CSO (Curistica Ltd)	28/2/25	0.4

## Reviewers

This document must be reviewed by the following people:

Name	Title/Responsibility	Date	Version
Paul Harvey	Build Lead		1.0
Sharon Hanley	Managing Director		1.0
Max Gattlin	Commercial Director		1.0

## Approved by

This document must be approved by the following people:

Name	Title/Responsibility	Date	Version
Dr Keith Grimes	Chief Digital Health Officer & CSO	28/2/25	1.0

## Executive Summary

This clinical safety case report (CSCR) outlines the evidence that the safety and documentation requirements of the Surgery Assist application Version 4 as required by the NHS Digital safety standard DCB0129, are met; as well as our approach to clinical safety risk assessment and the mitigations in place to manage identified risks.

Potential hazards have been assessed and documented in our clinical safety hazard log (CSHL) and assigned to a clinical risk category.

Clinical Risk Category	Number of Hazards
Unacceptable	0
Mandatory	0
Undesirable	0
Acceptable	5
Low	2

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:** 28 Feb 2025

**Approved by Clinical Safety Officers:** Dr Keith Grimes & Dr Youssof Oskrochi

### **Relevant Documentation**

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

Ref	Doc Reference	Title	Version	Link
1		Clinical Risk Management System (CRMS)	0.1	<a href="#">DRAFT CRMS Hanley Health.docx - Google Docs</a>
2		Clinical Risk Management Plan (CRMP)	0.1	<a href="#">DRAFT CRMP Surgery Assist V4.docx - Google Docs</a>
3		Regulatory Assessment for Surgery Assist V4	0.1	<a href="#">DRAFT EDATT V4 Regulatory Assessment.docx - Google Docs</a>
4		Clinical Safety Hazard Log (CSHL)	0.4	<a href="#">EDATT V4 Hazard Log.xlsx - Google Sheets</a>
5		Safety Incident Management Log	1.0	<a href="#">Safety Incident Management Log EDATT - Google Sheets</a>
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## Introduction

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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:

1. Hazard identification
2. Risk assessment
3. Implementation of mitigations

Identified hazards are documented in the [Clinical Safety Hazard Log](#) 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:

- Hanley Health Clinical Risk Management System (Ref 1)
- Hanley Health Clinical Risk Management Plan for Enabling Digital Access Through Telephony (V4) (Ref 2)

## 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

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### 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

The CSCR covers the Surgery Assist Version 4.0.

Version 4.0 provides further improvement and refinements to the V3.0 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 life cycle:

1. The capacity to host forms and questionnaires
2. Ability to signpost to practice specific community services and FAQ's.
3. Free-text search of practice provided documents (e.g. DoCS<sup>1</sup> and FAQ's)

### Out of Scope

Surgery Assist software 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).

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<sup>1</sup> Directory of Community Services





## 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:
  - o 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 website.
  - o 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.

This is demonstrated graphically in Figure 1.

## System architecture

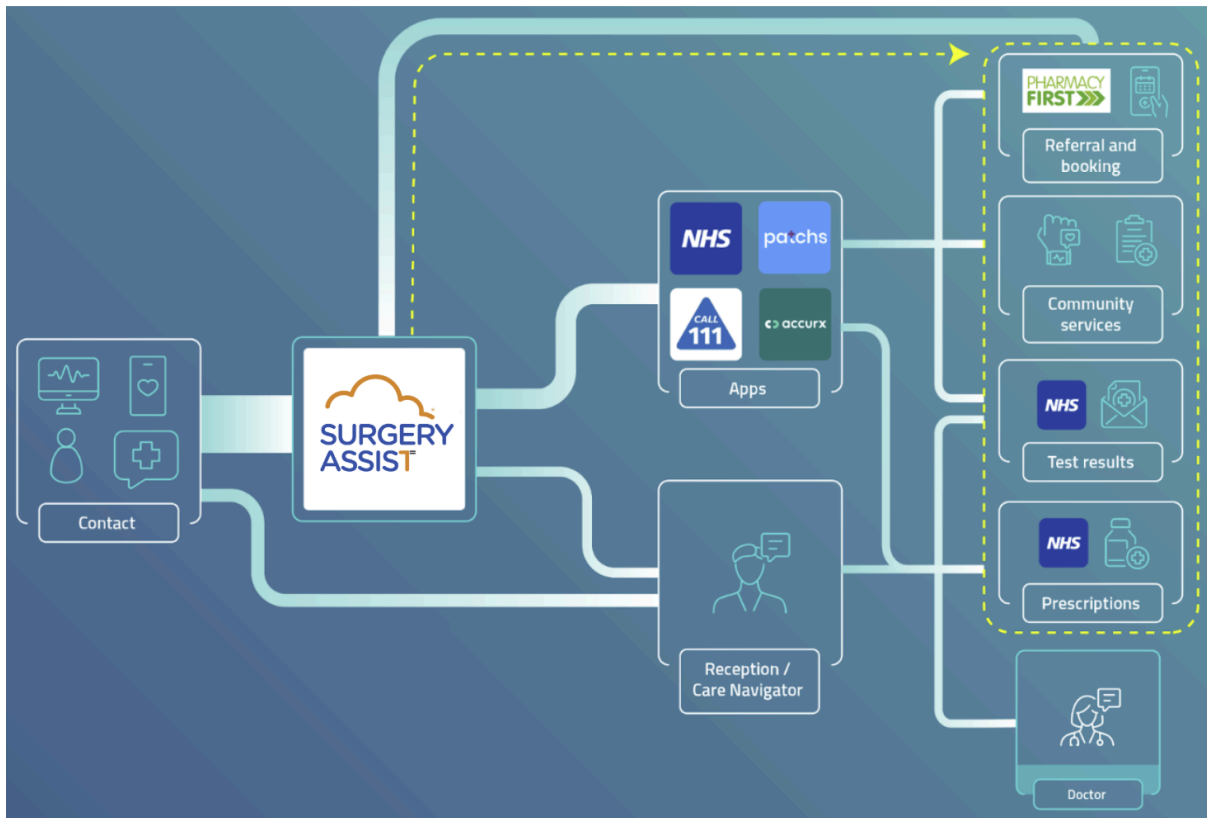
Surgery Assist is hosted on a platform using an Azure Landing Zone integrated with GitHub as a baseline. The landing zone will host multiple Azure services including containerized applications, an application gateway, PostgreSQL, Redis, Storage, Azure Search, Azure Translation, Azure Auto-redaction and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

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

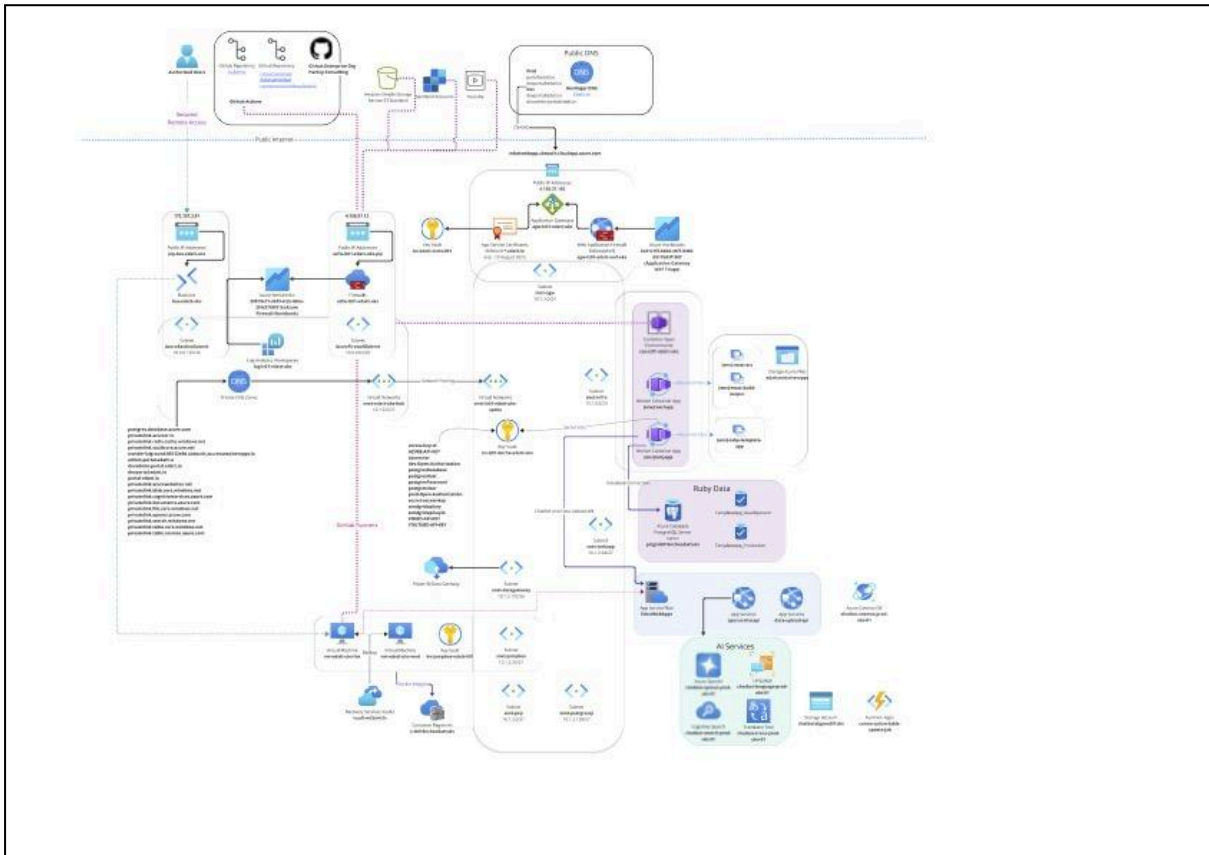
Additionally, all incoming traffic will be routed through the application gateway, and a jump-box will be included for managing and deploying to the private environment.

This is demonstrated graphically in Figure 2.

**Figure 1. High level overview of Surgery Assist patient flow**



**Figure 2. High level overview of Surgery Assist V4 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 (Ref 3).

### Clinical Safety Analysis

Clinical safety activities are led by Dr Keith Grimes, the Chief Digital Health Officer, a registered clinician and trained Clinical Safety Officer (CSO). Further CSO support and input was also provided by Dr Youssof Oskrochi, a trained CSO and registered clinician.

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
Sharon Hanley	Managing Director	Hanley Health
Dr Keith Grimes	Chief Digital Health Officer & CSO	Hanley Health
Paul Harvey	Build Lead	Hanley Health
Max Gattlin	Product Owner	Hanley Health
Dr Youssouf 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:

- 1) A new Surgery Assist V4 function or flow is being designed/considered, OR
- 2) An existing Surgery Assist V4 function or flow is being materially changed, OR
- 3) A new Surgery Assist V4 version is being deployed, OR
- 4) a new hazard has been identified, OR
- 5) 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.

Full methodology and process is outlined in the CRMP and CRMS.

### 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 control.

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.

**Table 2. Summary of the Clinical Safety Hazard Profile for Surgery Assist V4**

Hazard	Severity	Likelihood	Risk
Digital assistant is not available for users to use.	Significant	Low (<1%)	2. Acceptable
Digital assistant unable to successfully accomplish its task despite correct use by the user.	Minor	Low (<1%)	1. Low risk
Users are unable to use the digital assistant to accomplish their task.	Significant	Med (1-10%)	2. Acceptable
Digital assistant successfully completes the task but provides incorrect outputs or outcomes despite correct use by the user.	Considerable	Low (<1%)	2. Acceptable
Inadvertent breach of confidential, user identifiable, and/or special category data.	Major	V. Low (<0.1%)	2. Acceptable
digital assistant being used beyond its scope.	Major	V. Low (<0.1%)	2. Acceptable
Bugs and errors cannot be reported by the user.	Significant	Low (<1%)	1. Low risk

### **Risk management in live service**

Hanley's 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.

### **Support and business continuity**

Hanley's 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, Hanley Consulting 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 Hanley 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, Hanley 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.

Full details are outlined in the CRMS/CRMP.

### **Safety claims**

As part of the CSCR we make the following assertions:

1. All foreseeable hazards relevant to DCB0129 are known, have been evaluated and documented by an MDT and are at low or acceptable level of risk
2. Robust post-market surveillance mechanisms are in place to ensure continued compliance and product safety in the live service environment, allowing early identification and response when necessary.