Clinical Safety Case Report
CareConnect – Gamma Telecom Ltd

Version: 1.20

Author: Lisa Simmons

Date: 3rd October 2025

References

Reference	Title	Description
1	DCB 0129 Standard Specification	DCB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification. NPFIT-FNT-TO-TOCLNSA-1792.06. 02/05/18. Version 4.2.
2	CareConnect Hazard Log	CareConnect Hazard Log v1.30.
3	Health and Social Care Act 2012	Health and Social Care Act 2012. https://www.legislation.gov.uk/ukpga/2012/7/contents
4	Health and Social Care Act 2012	Health and Social Care Act 2012. https://www.legislation.gov.uk/ukpga/2012/7/contents
5	Clinical Risk Management Plan	CareConnect - Live Service Clinical Risk Management Plan v1.00.
6	DCB 0160 Standard Specification	DCB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Specification. NPFIT-FNT-TO-TOCLNSA-1793.05. 02/05/18. Version 3.2.
7	Gamma Clinical Risk Management Process	Gamma - DCB 0129 Clinical Risk Management Process v1.10.
8	Medical Device Regulations 2002	Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).
9	CSO Competency Evidence	Competency Evidence for Lisa Simmons, September 2025.
10	Gamma Telecom Limited Test Strategy	Gamma Telecom Limited Test Strategy v1.00.
11	Control Traceability Matrix	CareConnect Traceability matrix for Hazard Log v1.30.
12	CareConnect Test Execution Spreadsheet	CARE CONNECT TEST STATUS - March 2024.
13	Gamma Customer Service Plan	Customer Service Plan v8.0.
14	Horizon Contact Service Description	Horizon Contact Service Description v2.8.1.
15	External Control Spreadsheet	Gamma Ltd CareConnect Hazard Log v1.30 External Controls.
16	Reseller Accreditation Document	Accreditation: Horizon Contact
17	Gamma Safety Incident Management Process	Gamma - Safety Incident Management Process v1.10.
18	DCB 0129 Implementation Guidance	DCB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Implementation Guidance. NPFIT-FNT-TO-TOCLNSA-1300.06. 02/05/18. Version 3.2.

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Executive summary

Gamma Telecoms Limited ("the Company" or "Gamma") have undertaken a formal and structured clinical risk assessment of the CareConnect product pursuant to compliance with Safety Standard DCB 0129 ("the Standard") (Ref. 1). A rigorous and methodical analysis of the products have identified a number of potential hazards. These have been characterised and documented in a Hazard Log (Ref. 2). The Residual Risk associated with each hazard has been evaluated and the risk profile below established:

Residual Risk Category	Number of Hazards
Very High	0
High	0
Significant	0
Moderate	0
Low	7

The evaluated clinical risk has been tested against the Company's risk acceptability criteria (Appendix A). In conclusion the level of clinical risk associated with CareConnect has been found, at this time, to be Acceptable.

Clinical Safety Officer Statement

I, Lisa Simmons, as Clinical Safety Officer for Gamma at the time of drafting, formally approve this Clinical Safety Case Report for CareConnect Version 1.1.3 I confirm that:

- a methodical and systematic clinical risk assessment of the product has been undertaken as required by the DCB 0129 Standard;
- the Safety Claims set out in Section 1.6 are justified and are adequately evidenced by the materials referenced;
- the risk profile set out in Section 7.1 is a true reflection of the clinical risk presented by the product;
- the clinical risk associated with the product under consideration was found to be Acceptable.

At the current time, there are no outstanding actions required to complete this assessment.

Lisa Simmons, Speech and Language Therapist, HCPC registered, MRCSLT
Clinical Safety Officer
Safehand Consulting Limited

1 Introduction

1.1 Document purpose

Health IT systems have the potential to introduce new clinical hazards into the healthcare environment. Manufacturers of health IT systems who intend to deploy products in England are required to comply with Safety Standard DCB 0129 (Ref. 1) as mandated by the Health and Social Care Act 2012 (Ref. 3). Manufacturers of health IT systems who intend to deploy products in Wales should comply with Safety Standard DCB 0129 as recommended by Digital Health and Care Wales (DHCW) (Ref. 4). This calls for a rigorous and systematic analysis of the technology to establish the nature of the potential clinical hazards and the degree of clinical risk that might be introduced.

This report begins by establishing a set of claims regarding the safety of the system under examination. Material is presented to evidence the presence of those factors which mitigate the clinical risk associated with the system. A logical and structured argument is set out to show that the evidence justifies the safety claims.

This document is structured in the following way:

1. Section 2 – Describes the product that is being assessed, the problem it solves and the users who will make use of the product.
2. Section 3 – Sets out the scope of the product which is subject to assessment. This includes the core areas of functionality and architectural components under examination.
3. Section 4 – Describes the methods which have been employed in undertaking the safety assessment and the initial findings.
4. Section 5 – Explains the techniques which have been used to trace risk controls to evidence of their implementation.
5. Section 6 – Presents an overview of the evidence which has been identified.
6. Section 7 – Sets out the outcome of the safety assessment and the significant findings made.
7. Section 8 – Describes how clinical safety will be managed during live service of the application.
8. Section 9 – Sets out what safety activities will be undertaken when changes to the system occur.
9. Section 10 – Describes any outstanding activities which were on-going at the time of issuing this document.
10. Section 11 – Outlines the results of the review to validate that the safety assessment is complete.
11. Section 12 – Sets out the conclusions of the safety assessment.

This report is the third of a series of three deliverables required by the Standard:

1. Clinical Risk Management Plan (“the Plan”) (Ref. 5)
2. Hazard Log (Ref. 2)
3. Clinical Safety Case Report (“the Safety Case”) (this document)

These three documents will be stored within the Clinical Risk Management File and contribute to demonstrating compliance with DCB 0129.

1.2 Intended audience

This document will be made available to all key stakeholders involved in the design, build, test and deployment of the solution in order to inform their own clinical risk management activities. Where the Company contracts with a healthcare organisation which is required to comply with Safety Standard DCB 0160 (Ref. 6), this document, along with the Clinical Risk Management Plan and Hazard Log, will be shared.

1.3 Clinical risk management process

Gamma has formulated and documented a Clinical Risk Management Process (CRMP) (Ref. 7) setting out the clinical risk management activities undertaken for each release of the product. The processes described in the CRMP have been systematically applied to this release. Where the product has been

developed prior to the implementation of the CRMP, assurance activities have been retrospectively conducted as explained in this document.

1.4 Clinical risk management file

The Company have created a Clinical Risk Management File which was established at the start of the project, and this will be maintained for the lifetime of the product. The file will preserve or reference all formal DCB 0129 documents, evidence of compliance and details of any decisions that influence the clinical risk management activities.

As the DCB 0129 assessment project matures and builds, the Clinical Risk Management File will include (but not be limited to):

- Clinical Risk Management Plan
- Hazard Log
- Clinical Safety Case Report
- Traceability matrices
- Incident Management Process
- Change Management Process
- Incident log and issue assessments

1.5 Terms and definitions

All terms used in this document have the same meaning as the Glossary of Terms set out in the Standard.

1.6 Safety Claims

The Safety Case supports and evidences the following claims:

- All foreseeable hazards have been characterised, documented and evaluated by a multidisciplinary team of experts.
- The clinical risk associated with each hazard is either acceptable or has been mitigated to a level which is As Low As Reasonably Practicable (ALARP).

2 Background

This assessment represents a safety analysis of CareConnect Version 1.1.3.

2.1 Project description

CareConnect (CC) was developed to support Primary Care staff in their use of an existing Gamma product - Horizon Contact. Horizon Contact (HC) is a contact centre software product designed to manage the large volumes of phone calls received by GP Practices. A requirement was indicated for an interface connecting HC and GP Practice Electronic Patient Records (ERP) systems, namely EMIS and SystmOne, which could indicate the identity of inbound callers thus potentially improving call handling efficiency. Therefore, Gamma developed a system which integrates Horizon Contact with both EMIS and SystmOne, called CareConnect. It is only this integration system, CareConnect, which is the subject of this assessment.

This assessment has been conducted against CareConnect Version 1.1.3 manufactured by Gamma Telecoms Limited.

2.2 System description

2.2.1 Overview and intended Use

CareConnect is a desktop application that establishes a connection to Horizon Contact via HTTP and connects to the Primary Clinical Systems (PCS) EMIS and SystmOne using the Application Programming Interface (API) provided by each PCS supplier. CareConnect has 4 main functionalities –

1. Login
2. Screen pop
3. Click to dial
4. Manual search

The application login process requires the user to sign-in to CC using their Horizon Contact credentials. The CC App then sends an HTTP request to the HC servers, requesting to log in as a user with those credentials. If those credentials match the records in the HC databases and other requirements are met (such as the PCS integration feature being enabled for the user's organisation and the user having the appropriate privileges, etc.), the user will log into Horizon Contact successfully and a WebSocket connection will be established. This WebSocket connection will be used for future requests.

Horizon Contact sends a set of credentials back to the CareConnect App which are required to connect to THE PCS. CC then sends a message to the PCS API to attempt to login on the PCS. If the user has the PCS software running on their machine, the PCS processes those credentials and returns a token that the App will use for future requests.

CareConnect then works by activating the connection to the PCS API at the point that the surgery receives an incoming phone call via Horizon Contact. CC uses this phone number and sends a message to the PCS platform via the supplied API, to obtain details for the patient or patients who are linked to that phone number on the PCS. CC then presents a screen pop to the person taking the call, which includes details of potential matching patients. Upon the user confirming the identity of the caller by clicking the name on the screen pop, the PCS then opens the selected patient's record.

In addition, the system can be used to initiate outgoing calls using the 'click to dial' functionality. The user can navigate to the patient record in the PCS and click on the 'call' button presented on CC which then dials the patient's number using Horizon Contact. This reduces the need to manually input patient phone numbers which can potentially increase efficiency and reduces errors.

The manual search function provides the same functionality as the screen pop but does not depend on Horizon Contact. The user opens CC, clicks 'search' and enters the phone number and the App sends a

request to the PCS. The PCS returns the information, and the matching patients are displayed in a list on CC for the user to select from.

2.2.2 Care settings and users supported

CareConnect is designed to assist staff within a GP Practice more efficiently manage the calls they make and receive each day. It speeds up the process for these two key areas of their job, enabling more calls to be made and answered in a day.

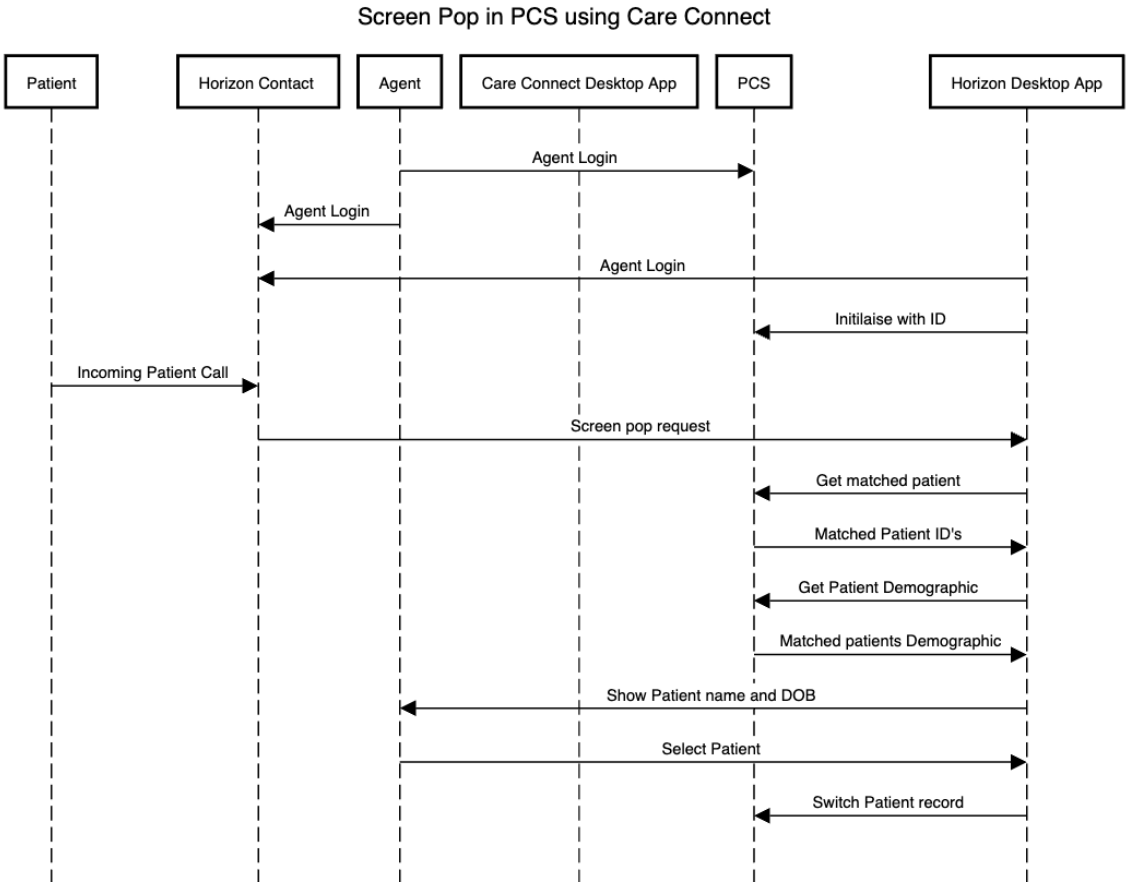
To use the CareConnect App, the user must first log into the PCS to enable connection to the PCS API. Users must then log into Horizon Contact, then log into CareConnect using the same log in details. Once logged in to Horizon Contact, Horizon returns the information that the App requires to establish a connection to the PCS.

2.2.3 Clinical dependency on the system

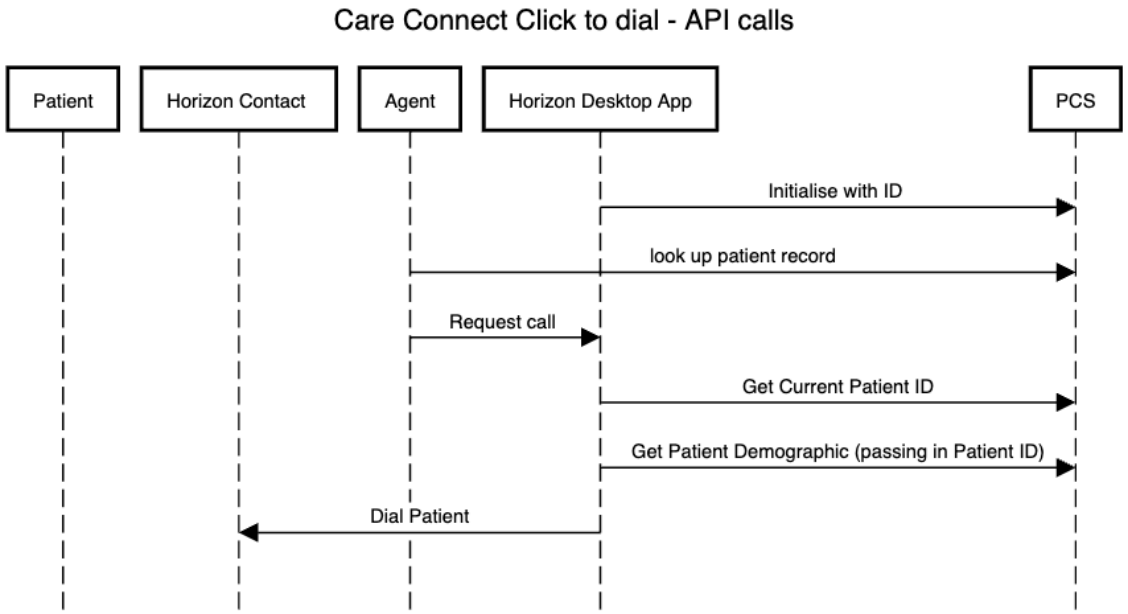
GP Practice staff will rely on CareConnect to manage incoming and outgoing patient phone calls, including accessing patient records in their PCS more quickly with less manual input required. Should the system fail to operate as intended, the incorrect record could be opened in the PCS. As a result, clinical information could be attributed to a different patient than the one intended.

2.2.4 Message flow

The message flow for the screen pop is shown in the below diagram:



The system message flow for click to dial is shown in the diagram below:



2.2.5 Regulatory position

The primary purpose of the system is to provide an integration between one of Gamma's existing products, Horizon Connect, and two EPR systems EMIS and SystmOne (PCS). The product connects HC with the PCS to match patients with their phone number thus enabling healthcare staff to make and receive phone calls quickly and efficiently. Clinical data is subject to simple archive, retrieval, and search. The system makes no attempt to diagnose a patient nor suggest a specific course of treatment. No clinical algorithms, complex scoring systems or other decision-making tools are currently employed. Data is either passed from one component to another in an unchanged manner or is stored and retrieved without modification or enhancement. Information is provided to clinicians for reference purposes to allow them to make clinical decisions using their own knowledge. As such, the product does not have a Medical Purpose.

On this basis, it is the Company's opinion that, at this time, this software application does not fall within scope of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) (Ref. 8). As such, the DCB 0129 Standard alone will form the basis for the risk assessment. The Company will ensure that future enhancements to the product are subject to change control and that any potential implications for Medical Device compliance are considered.

2.2.6 Artificial Intelligence (AI) declaration

The product does not incorporate Artificial Intelligence (AI) or Machine Learning (ML) functionality, either natively or through integration with an API providing such functionality.

2.3 Implementation history

CareConnect has been deployed across live sites since 2024 and currently approximately 1000 users connect to the system on a daily basis.

3 Scope

3.1 Safety-related functionality

The sections below set out the scope of the product functionality and components which has been included in this safety assessment.

3.1.1 Core functional components

The following functionality was included in the scope of the project and has been found to be a potential source of harm to a patient. As such it was further subject to analysis and risk evaluation.

Functionality	Description of functionality	Key reason for identifying as a potential source of harm to a patient and therefore for its inclusion in the assessment
User registration	Allows registration of allocated users on the system. Users can be granted access to a variety of profiles and functionality.	Failure to assign correct permissions and functionality to users could result in a delay to staff accessing patient records thus potentially delaying patient care.
User log in	Allows users to log in to the CareConnect system and Horizon Contact.	Failure of the log in process could result in inbound calls not being attributed to a patient and therefore the patient information not being presented on the user's screen potentially meaning the inbound call is missed.
CareConnect desktop application	Enables users to open the CareConnect system from their local desktop.	Failure of the desktop application to be installed or open correctly would prevent users from accessing the system, potentially resulting in a delay to staff accessing patient records thus delaying patient care.
Matching patient information (name, address, phone number) in the PCS to incoming phone number	Enables users to quickly access the patient record in response to an incoming phone call by matching the phone number to patient information stored in the PCS.	Failure to match the phone number to the correct patient could result opening the incorrect patient record and subsequently attributing clinical information to a different patient than the one intended.
Screen pop	Presents a list of patient/s that match an incoming phone number from which users are able to select the correct patient. For example, one landline phone number may	Failure to present the full list of patients could result in a user selecting an incorrect patient and as such recording information

Functionality	Description of functionality	Key reason for identifying as a potential source of harm to a patient and therefore for its inclusion in the assessment
	match to all members of one family thus the user can identify to whom they are speaking, then select the corresponding name from the list in the screen pop.	in the incorrect clinical record or booking an appointment for an incorrect patient.
Opening patient record in the PCS	Enables users to access the patient record in the PCS once they select the correct patient from the screen pop, therefore negating the need to manually search for the patient record.	Failure to open the patient record in the PCS could result in the user needing to manually search for the patient and potentially selecting the incorrect patient. Additionally, opening the incorrect patient record in the PCS could lead to the user attributing clinical information to a different patient than the one intended.
Click to dial	Allows the user to initiate an outbound call via Horizon Contact from within a patient record in the PCS.	Failure to initiate an outbound patient call could result in a delay in the user contacting a patient subsequently delaying patient care.
Manual search	Enables users to search for a patient based on the patient's phone number and does not rely on Horizon Contact. CareConnect presents potential matching patients for the user to choose from. On selecting a patient in the list, the patient information is then shown in the PCS.	Failure of the manual search functionality could result in the user being unable to identify a patient by their phone number, potentially resulting in a user being unable to find a patient to record a contact thus delaying patient care.

3.1.2 Core architectural components

The following architectural components were included in the scope of the project and have been found to be a potential source of harm to a patient.

Component	Description of component	Key reason for identifying as a potential source of harm to a patient and therefore for its inclusion in the assessment
PCS API	API provided by the PCS supplier which enables CareConnect to communicate with the relevant EPR.	Failure of the API would mean that patient information from the PCS cannot be returned subsequently rendering the CareConnect system unusable.

Component	Description of component	Key reason for identifying as a potential source of harm to a patient and therefore for its inclusion in the assessment
Web API to Contact Centre	Enables the application to monitor the agent status, receive notifications of incoming calls and instruct the contact centre to make an outgoing call.	Failure of the web API would prevent communication with the contact centre rendering the CareConnect system unusable.

3.1.1 Third-party components

The system makes use of some third-party library components which the Company has carefully selected for inclusion. The components include technical elements of the user interface, handling of responsiveness, database connectivity, etc. The library components are not specific to the health domain and have therefore not been subject to assurance under the Standard by their manufacturers. The components are discrete, of a technical nature and are used widely in the app development industry.

Given the envelope of Clinical Risk associated with the system, the Company deemed that a separate safety analysis of the individual components was not justified at this time. However, as the components are an integral part of the product, their function and performance will be evaluated in the course of system testing and any defects associated with the libraries will be examined as part of the normal defect management processes included in the software development lifecycle. The use of any components found to be unreliable would be re-evaluated and subject to clinical risk assessment.

3.2 Non safety-related functionality

The following functionality was included in the scope of the project and has been found not to directly impact clinical care and as such is not a potential source of harm to a patient. As such it was not subject to further analysis and was excluded from this assessment.

Functionality	Description of functionality	Reason functionality is not a potential source of harm to a patient and therefore its exclusion from the risk assessment
User activity	Provides an audit trail of activity on the system within a selected date range and for a variety of action types.	This information does not directly impact clinical care and as such is not a potential source of harm to a patient.

4 Risk Analysis and evaluation

4.1 Personnel and competency

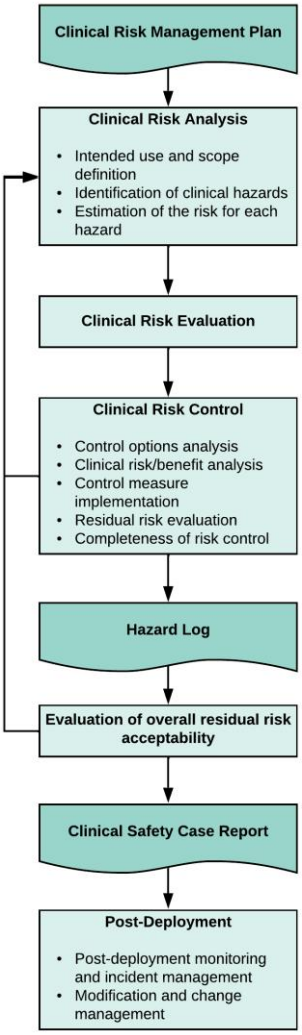
The Standard requires that a Clinical Safety Officer (CSO) is appointed by the Company to oversee and approve the clinical risk management deliverables. The CSO must be a registered clinician who is appropriately trained and experienced in clinical risk management. The Company has chosen to contract with a third-party organisation called Safehand Consulting Limited to advise on safety management and provide an appropriate CSO. A document setting out the competencies of the individual will be included in the Clinical Risk Management File (Ref. 9).

The safety assessment has been supported by a number of other individuals with a background in user training, software testing, project management and IT implementation. These individuals contributed to the construction of the clinical risk management deliverables and reviewed all output.

4.2 Method

4.2.1 Risk management process

The flowchart below demonstrates the risk management process adopted.



4.2.2 Process steps

The following steps were undertaken:

1. A Clinical Safety Officer was appointed for the project.
2. The key functions of the system were broken down into constituent parts.
3. Business processes and functions were broken down further into individual tasks.
4. Each task was taken in turn and subjected to a Structured What-If (SWIFT) analysis. Consideration was given to normal operating conditions, fault conditions and reasonably foreseeable misuse.
5. The process resulted in a number of candidate hazards, causes and controls being generated. This information was assembled in the form of a Hazard Log.
6. The clinical risk for each hazard was estimated and evaluated based on a combination of the hazard's severity and the likelihood of a patient coming to harm of the stipulated severity.
7. The Company took into consideration the potential effectiveness of the controls identified and reflected this in the clinical risk estimation.
8. The estimated level of Clinical Risk was reviewed for each hazard and evaluated against the Risk Acceptability Criteria set out in Appendix A.
9. Where the clinical risk was considered unacceptable, control option analysis took place to examine opportunities for further mitigation.
10. Where further controls were required, the Company prioritised strategies which were most likely to be effective (i.e. through engineering and design). Only where these measures were deemed to be impractical were less effective means of control (such as information provision) considered.
11. Any additional clinical risk associated with the implementation of new controls was evaluated.
12. Where the proposed controls required the healthcare organisation to take action in order to mitigate the risk these will be highlighted to support their DCB 0160 activities (Ref. 5).
13. Each component, function, screen or business process was worked through systematically. Only when all of the elements had been subject to analysis was the process deemed complete. The documentation has captured the rationale for completeness being achieved.
14. The output material has been preserved in the Clinical Risk Management File.

4.2.3 Executing the assessment

A number of materials were made available for the assessment and were examined in detail. These included (but were not limited to):

- Product Description
- Warranted Environment
- System Architecture Description
- Training materials
- Requirements Management Procedure
- Software development strategy
- Support and helpdesk process
- Defect resolution policy

The system is already built therefore the assessment focussed on examining the application itself in a systematic manner in order to identify potential hazards. Application experts provided a demonstration environment and walked the Clinical Safety Officer through the system. Each piece of functionality was then examined, and a SWIFT technique used to establish potential deviations from normal operation. Hazards, causes and controls were formulated and embodied in a Hazard Log. From time to time questions arose on the precise logic and workflow of the application. In these cases, questions were constructed and passed to the relevant experts for clarification.

The Hazard Log was circulated for review amongst the project stakeholders and comments solicited. In some cases, it was not possible to characterise the precise controls from the initial input materials. Expertise and clarification was therefore sought from other stakeholders and the existing controls formulated and validated.

The preliminary analysis conducted by the Clinical Safety Officer found that a number of hazards could not be satisfactorily controlled based on the initial information provided and the user interface examined. These queries were raised with the software designers and service managers and, in each case, solid design controls were uncovered. These were documented accordingly in the Hazard Log.

4.2.4 Formal analytical methods

A Structured What-If Technique was used to perform the hazards analysis as set out in Section 4.2.4 of the Plan.

4.2.5 Assumptions

The following assumptions were made in conducting the assessment:

- Healthcare professionals and supporting administrative staff will apply judgement when using the system. If professionals have any concerns regarding the correctness or completeness of information communicated by the system, it is assumed that alternative sources of information will be consulted.
- Healthcare organisations will ensure that staff only rely on the system once they have been fully trained in the system's functions and have been supervised to a level where they are able to operate the system independently.
- The Residual Risk stated in this document and in the Hazard Log assume that the External Controls set out in the Hazard Log are implemented by the healthcare organisation.
- Healthcare organisations will conduct their own Clinical Risk Management activities as set out in DCB 0160 (Ref. 5).

4.2.6 Constraints on the analysis

There were no constraints in performing this analysis.

4.2.7 The Hazard Log

The Hazard Log represents the outcome of the analysis and forms the basis of the argument and evidence set out in this report. The Hazard Log will be revisited from time to time as the product changes and more is learnt about the system's characteristics in live service.

The Hazard Log is provided at Ref. 2. It should be noted that the codes associated with Hazards, Causes and Controls are unique identifiers and not sequential numbers.

4.2.8 Assessment workshops

To formulate the original Hazard Log, a dedicated Clinical Risk Management workshop was held on 20th February 2023 and included the Product Owners, Technical Lead, Business Analyst, Lead Developer, and Clinical Safety Officer. The scope of the safety assessment was agreed, and any areas not related to clinical safety were formally excluded from further analysis. The attendees systematically worked through a draft Hazard Log which had been prepared by the Clinical Safety Officer prior to the workshop. The Hazards and Causes identified were validated and additional material added as further failure modes were explored.

Each control was examined in turn to validate its presence and confirm that its character had been articulated correctly. In some areas, the degree of risk control was initially found to be incomplete and the presence of further mitigations was explored by examining in more detail the technical design of the product. Wherever possible, the examination of engineering-based controls was prioritised, and administrative measures were only relied upon as a control as a last resort.

A number of actions and areas of further exploration were documented in the hazard log tool. Following the session, the Hazard Log was updated with the findings and the level of clinical risk re-evaluated.

For the uplift to the Hazard Log for the integration with SystmOne the Clinical Safety Officer met with the Engineering Director and the Product Manager on 8th March 2024 to discuss the changes to the integration. The CSO systematically reviewed each of those changes, noting any updates that would be required to the Hazard Log. The Hazard Log was updated and circulated for review amongst the project stakeholders. Feedback comments as a result of this review were then incorporated into the Hazard Log accordingly.

The Hazard Log was reviewed and updated in September 2025 with minor artefactual updates. The updates to the system have not resulted in the identification of any additional or amended hazards, causes or controls.

4.3 Hazard identification

Analysis of each of the functional areas and product components set out in Section 3.1 resulted in a number of identified hazards. References to those hazards are set out below and full details are presented in the Hazard Log (Ref. 2).

Functionality/Component/Activity	Hazard ID	Hazard Title
User registration	Haz3	System is not available to a user
User log in	Haz3	System is not available to a user
CareConnect desktop application	Haz1	System is unavailable or inaccessible
	Haz2	Incompatible client technology
	Haz3	System is not available to a user
Matching patient information (name, address, phone number) in the PCS to incoming phone number	Haz4	Patient information incorrect or incomplete
	Haz5	CareConnect fails to receive accurate patient information from the PCS
	Haz6	Patient record pertains to a different patient than the one which was intended
Screen pop	Haz6	Patient record pertains to a different patient than the one which was intended
Opening patient record in the PCS	Haz6	Patient record pertains to a different patient than the one which was intended
Click to dial	Haz7	Automatic placement of an outbound call fails
Manual search	Haz6	Patient record pertains to a different patient than the one which was intended
PCS API	Haz1	System is unavailable or inaccessible
	Haz4	Patient information incorrect or incomplete
	Haz5	CareConnect fails to receive accurate patient information from the PCS
	Haz6	Patient record pertains to a different patient than the one which was intended
Web API to Contact Centre	Haz5	CareConnect fails to receive accurate patient information from the PCS
	Haz6	Patient record pertains to a different patient than the one which was intended

4.4 Controls in the clinical environment

The following controls are likely to be present in the context of the clinical environment in which the product is used. In the event that the identified hazards were to be triggered, these measures would likely act to reduce the impact of the hazard on the patient.

- Users will apply professional judgement in interpreting patient information provided by the system.
- Where data presented by the system appears to be corrupt or otherwise nonsensical, users will treat the data with some suspicion and validate it against other sources.
- Users will typically verify the identity of patients against records in the system and other supporting materials to ensure the information matches the correct patient.
- Users have available to them patient demographic data from other sources such as directly via the EPR system, paper records, or from the patient directly.

4.5 Risk assessment findings

For each hazard, the level of Initial Clinical Risk has been estimated taking into account only those controls provided by the clinical environment. The risk was then evaluated based on the severity of the hazard and the likelihood of harm. Further detail is included in the Hazard Log (Ref. 2).

A summary of the identified hazards is set out below along with the estimated Initial Clinical Risk.

Hazard ID	Hazard Title	Initial Clinical Risk
6	Patient record pertains to a different patient than the one which was intended	Moderate
4	Patient information incorrect or incomplete	Moderate
5	CareConnect fails to receive accurate patient information from the PCS	Low
7	Automatic placement of an outbound call fails	Low
3	System is not available to a user	Low
2	Incompatible client technology	Low
1	System is unavailable or inaccessible	Low

Further controls for the identified hazards were sought and characterised. The impact of these controls on the level of clinical risk and the evidence of their implementation is set out in the subsequent sections of this report.

5 Controls and their implementation

This section sets out the assurance activities which have been undertaken to identify and mitigate Clinical Risk.

5.1 Approach to traceability

The Hazard Log identified a number of controls - these controls were categorised into types, for example, Design, Testing, Training, Architecture, etc. Control types which represented simple statements of fact about the system (such as a comment on the system's architecture) were not specifically traced to formalised evidence when it was clear that the control was present. However, controls in other categories such as Testing were systematically traced to evidence of their implementation. The sections below set out how that traceability was undertaken. Section 6 of this document discusses the outcome of the traceability verification.

5.2 Requirements analysis

At the point of undertaking the risk assessment, the product had been built. On this basis, the risk assessment was undertaken against the built product rather than purely against the product requirements.

5.3 Design assurance

The product has been designed through close co-operation with clinical experts and experienced users of the system. An iterative approach has been taken whereby the Company constructs prototypes of new functionality and validates this with clinicians prior to formally developing the product code.

In constructing the Hazard Log, the identification of controls focused, wherever possible, on design and engineering features. Where features of the product had been included to mitigate clinical risk, these were captured as design controls. Each design control was then passed to the development team to evidence the inclusion of the feature in the product. In many cases, it was not practical to source and reference the original requirements for each individual feature. In these cases, screenshots of the relevant functionality were captured.

The outcome of this activity is set out in Section 6.1.

5.4 Build assurance

The Company has processes in place to validate the integrity of the code developed. Trivial changes are undertaken by the developer and tested as per the processes set out in Appendix B. However, more significant changes are subject to formal peer code review.

During the peer review, the developer makes comments in the code where appropriate, and the code is passed back to the original developer for amendments. The approach the developer has taken is discussed and analysed for consistency, style and technique. Where warranted, the code is formally inspected, and any issues noted and remediated. The aim is not only to update the code, but to educate the developer as part of their professional development and to improve future coding practices. Branches where changes have been made and where defects are found will not be merged until the review has been successfully completed.

5.5 Testing activities

5.5.1 Examination of test approach

The Company's test strategy is set out at Ref. 10 and was made available for review by the Clinical Safety Officer to ensure that it met the expectations of the DCB 0129 assessment process.

The outcome of this activity is set out in Section 6.2.1.

5.5.2 Examination of testing conducted

The examination of the test approach revealed that Regression Testing was the testing phase which most rigorously demonstrated the correct end-to-end functioning of the application. As such, a traceability exercise was conducted to determine the extent to which existing regression test scripts adequately covered the testing controls in the Hazard Log.

The outcome of this activity is set out in Section 6.2.2.

5.5.3 Outcome of testing

The Company's testing processes are constructed to only accept code into the production environment when all significant defects have been resolved. In exceptional cases, defects may be scheduled to be fixed in a subsequent release. As such, the product could, in some cases, be used operationally with known bugs present.

These defects will be subject to examination by the Clinical Safety Officer prior to go-live of the modified code and the level of clinical risk evaluated. In the event that the residual clinical risk presented by these defects was evaluated as Significant or above, the situation will be escalated to senior management. In these circumstances, it is not anticipated that the affected code would go live.

The Clinical Safety Officer examined the output from the most recent phases of testing to determine whether any safety-related defects remained unresolved. The outcome of this activity is set out in Section 6.2.3.

5.6 Assessment of user interface

A high level review of the product user interface was conducted as part of this safety assessment. The Clinical Safety Officer was provided with a demonstration of the system by knowledgeable Gamma representatives to enable a thorough examination of the user interface. A summary of the findings of this activity are set out in Section 6.3.

5.7 Information for users

In formulating the Hazard Log, a number of controls were identified which relied on users of the system operating the product in a particular manner. It is the Company's intention to facilitate the communication of these controls in the form of information provided to users. However, it should be noted that it is the healthcare organisation's responsibility to ensure that this information is disseminated effectively to users as part of their DCB 0160 activities.

The Company conducted a validation exercise to determine whether the existing training materials were adequate to communicate the information controls identified. The outcome of this activity is set out in Section 6.4.

5.8 Operating policy development

A number of Controls set out in the Hazard Log rely on the Company implementing certain processes, procedures and ways of working. Evidence of the existence and implementation of those controls has been sought and the result of this exercise is set out in Section 6.5.

5.9 Assurance by other stakeholders

Where it has been identified that stakeholders external to the Company need to own and implement certain controls, these have been characterised and marked accordingly in the Hazard Log. The outcome of this activity is set out in Section 6.6.

Note that healthcare organisations should not assume that the implementation of these Controls alone will be sufficient to mitigate the Clinical Risk associated with their implementation to acceptable levels. A full hazard assessment must be undertaken as required by DCB 0160.

In addition, the commercial model for CareConnect is such that much of the business for the product is managed by Gamma's channel/ business partners ("resellers"). The responsibilities of the resellers is discussed further in Section 6.7.

6 Review of control implementation evidence

This section sets out the evidence for the implementation of the identified controls.

6.1 Review of design materials

Each design control was passed to the engineering team to evidence the inclusion of the feature in the product.

- Most controls were evidenced by tracing to the ID of a test script which could only pass if the control had been implemented. In such cases, the specific test script ID was captured.
- A small number of the design controls were evidenced via links to videos which evidences the existence of the control.

This validation and traceability exercise was documented in the Control Traceability Matrix (Ref. 11). A total of 21 design controls were identified. Of these, 18 were evidenced by tracing to test scripts. The remaining 3 design controls were evidenced through links to videos. In summary, it was possible to trace all design controls to evidence of their implementation.

6.2 Review of test strategy and materials

6.2.1 Review of test approach

The review of the Test Strategy (Ref. 10) demonstrated that the testing techniques were robust and typical of good practice in the wider health IT industry. In particular the following were noted:

- Both manual and automated testing was conducted offering the benefits of both efficiency and flexibility.
- Testing was conducted against defined acceptance criteria which, themselves, were aligned to requirements.
- Testing was largely scripted providing an opportunity to ensure that controls in the Hazard Log could be demonstrably linked to the scope of the testing.
- A risk-based approach had been employed to scale the extent of testing to the risk presented by the functionality being tested.
- A number of layers of testing had been defined including Unit, Acceptance, and Release/ Regression testing at differing levels of developmental maturity.
- A defect management and priority triage strategy had been defined.
- Suitable test environments had been specified with a requirement for them to be representative of the intended live environment and containing suitable test data.
- User Acceptance Testing was not included and that this was the responsibility of the Healthcare Organisation.
- Criteria were defined which must be met in order for testing to continue into the next phase.

For future releases, the Clinical Safety Officer will continue to validate that the testing strategy is implemented and that evidence of test execution, including regression testing, is made available for inspection. Any unresolved defects or unexecuted tests will be subject to a risk assessment prior to deployment using the methods set out in this report.

The examination of the test approach set out in Appendix B resulted in the creation of a number of regular tasks for the CSO to conduct on an on-going basis. In summary, the CSO will:

- ensure that the existing test strategy and exit criteria continue to be enforced.
- ensure that all safety-related requirements in Jira are risk assessed to steer the testing rigour.
- check that all bugs raised and scheduled for fixing in a later release are associated with No or Low Clinical Risk.
- check that Functional and Acceptance Testing completed successfully for each major release.

- ensure that those functional areas covered are prioritised based on the testing controls in the Hazard Log.
- review and assess relevant safety-related bugs raised if they remain unfixed at go-live.

6.2.2 Review of testing conducted

The testing controls were extracted from the Hazard Log and passed to the Company's test and clinical experts. Existing regression test scripts were attributed with codes and each testing control traced to a test script. Where a test script could not be identified, a new test was created. Traceability between Controls and test scripts was maintained in a traceability matrix (Ref. 11). The activities involved and were overseen by the Clinical Safety Officer.

This validation and traceability exercise was documented in the Control Traceability Matrix (Ref. 11). A total of 5 testing controls were identified. These were all evidenced by tracing to regression test scripts.

In summary, the resulting regression test scripts were deemed to be sufficient to evidence implementation of the testing controls in the Hazard Log.

6.2.3 Review of testing outcome

A complete execution of all test scripts was undertaken in March 2024. The outcome of each test was documented in a testing spreadsheet (Ref. 12). All tests successfully passed and no defects were noted.

In summary, at the time of drafting, all tests had completed execution and had successfully passed.

6.3 Review of user interface

Review of the user interface by the CSO did not find any potential areas for enhancement.

6.4 Review of training and information controls

The Company has created training materials to accompany the product. Training controls relate to specific points covered within the training materials and information controls relate to information provided to business partners. The training and information controls were extracted from the Hazard Log and were systematically traced to these materials (Ref. 11).

The results of this activity were as follows:

Total number of training controls	3
Total number of information controls	2
Training controls successfully traced to existing training materials	3
Information controls successfully traced to existing materials	2

Gamma provides all of their training and information materials online via the Gamma Portal. Healthcare users and business partners are provided with access to the portal such that the relevant material is always accessible.

In summary, the exercise revealed that the training and information materials were adequate to communicate the training and information controls identified in the course of this assessment.

Note that the potential effectiveness of training and information controls in the target operating environment has been taken into consideration in the degree of risk mitigation claimed.

6.5 Review of operating policies

A number of Controls set out in the Hazard Log rely on the Company implementing certain processes, procedures and ways of working. Those controls are listed below along with the corresponding evidence.

Control ID	Cause ID	Control title	Control description	Evidence
3582	29	The business partner can provide support	Gamma's business partners, who are the initial contact with healthcare organisations, are able to support with resetting passwords if required.	Links to end user facing knowledgebase pages for how users can reset their password: https://agenthelp-contact.unlimitedhorizon.co.uk/knowledge-base/what-to-do-if-i-forget-my-login-password/ https://adminhelp-contact.unlimitedhorizon.co.uk/knowledge-base/resetting-user-passwords/
3586	1364	Installation is the responsibility of the business partner/ reseller	Any issues with the installation of the system should be relayed to the reseller that installed the software.	Customer Service Plan v8.0 (Ref. 13)
3588	1364	The business partner can log into an admin account	If there are any issues with the system after installation and configuration, the business partner is able to log in via their admin account and check the installation and configuration settings and make any necessary amendments.	Link to the channel partner training video uploaded to the Gamma Academy showing how to configure the integration settings: https://vimeo.com/814947708/f85173ce75
3591	1777	Notification regarding new version	Gamma notifies healthcare organisations and business partners of any required updates to the application. Notifications are provided via the Gamma Portal and by email to registered email addresses.	Horizon Contact Service Description v2.3 (Ref. 14)

6.6 Controls to be implemented by other stakeholders

The assessment identified a number of Controls which can only be implemented by the healthcare organisation deploying the system (external controls). As such, ownership of these Controls is formally transferred to the healthcare organisation and should be considered as part of their DCB 0160 activities. In estimating the Clinical Risk associated with each identified Hazard, it has been assumed that healthcare organisations will implement the external Controls stated.

Each Control in the Hazard Log is attributed a type. The following Control types relate to external Controls:

- External Training
- External Policy
- External Validation

- External assumption

The external controls were copied from the Hazard Log and into a separate document (Ref. 15). This document will be made available to healthcare organisations implementing the system in order to inform and facilitate their clinical risk management activities.

6.7 Resellers

Where CareConnect is resold through resellers, certain safety-related responsibilities are transferred to those parties. These responsibilities ensure that installation, support, and incident management processes are carried out in a way that maintains the clinical safety of the system.

6.7.1 Repository and Documentation

- The DCB 0129 Clinical Safety documentation will be stored in a dedicated repository for resellers to access. (The location of this repository is on the Gamma Academy knowledge base).
- Gamma will circulate relevant documents to resellers, including installation guides, best practice instructions, and escalation procedures.
- Updates to documents (e.g., installation testing guidance) will be maintained by Gamma and made available through the Gamma Portal.

6.7.2 Installation and Configuration

- Installation of CareConnect is the responsibility of the reseller.
- Resellers must follow the installation checklist and instructions provided by Gamma.
- Any changes made by resellers during installation or configuration are their responsibility.

6.7.3 Incident Management and Support

- Resellers act as the first line of support for healthcare organisations.
- Resellers must provide assistance with installation issues, password resets, and local troubleshooting where applicable.
- All incidents and issues must be reported to Gamma, even if the reseller is able to resolve the issue locally. This ensures Gamma maintains oversight of clinical safety risks.
- Resellers must escalate unresolved or significant safety-related incidents promptly to Gamma in line with the defined escalation pathway in the reseller accreditation document (Ref. 16).

The specific hazard controls within the CareConnect Hazard Log that apply to resellers and business partners are summarised in the table below.

Hazard	Cause ID	Control ID	Control type/ title	Description
HZ1	CS1364	CT3588	Business partner admin access	Business partners can log into an admin account to check installation/configuration and make amendments.
HZ1	CS1364	CT3587	Installation checklist	Business partners who install CareConnect must follow Gamma's installation checklist.
HZ1	CS1364	CT3586	Installation responsibility	Installation of the system is the responsibility of the business partner/reseller. Any issues should be relayed to them.
HZ1	CS1364	CT3624	Best practice guidance	Gamma provides information to resellers on best practice for downloading/distributing CareConnect (e.g., uncontaminated pen drive, antivirus checks, download from portal).

HZ1	CS1777	CT3591	Notification regarding new version	Gamma notifies healthcare organisations and business partners of required application updates via portal/email.
HZ3	CS29	CT3582	Business partner support	Gamma's business partners (first contact for healthcare organisations) can support with resetting passwords if required.

All of the above controls are supported by documents provided by Gamma which are included in the traceability evidence (Ref.11), including installation guides, best practice materials, and incident management procedures, and are further reinforced within the reseller accreditation.

7 Outcome of the safety assessment

7.1 Hazard assessment summary

The following overall clinical risk profile has been ascertained:

Residual Risk Category	Number of Hazards
Very High	0
High	0
Significant	0
Moderate	0
Low	7

A summary of the identified hazards is set out below. Further detail is included in the Hazard Log (Ref. 2).

Hazard ID	Hazard Title	Initial Clinical Risk	Residual Clinical Risk	Clinical Risk ALARP?	Risk Acceptability
1	System is unavailable or inaccessible	Low	Low	Yes	Acceptable
2	Incompatible client technology	Low	Low	Yes	Acceptable
3	System is not available to a user	Low	Low	Yes	Acceptable
4	Patient information incorrect or incomplete	Moderate	Low	Yes	Acceptable
5	CareConnect fails to receive accurate patient information from the PCS	Low	Low	Yes	Acceptable
6	Patient record pertains to a different patient than the one which was intended	Moderate	Low	Yes	Acceptable
7	Automatic placement of an outbound call fails	Low	Low	Yes	Acceptable

As no hazards with a Residual Clinical Risk of Significant, High, or Very High were identified and all were assessed as ALARP, no further mitigation of risk was deemed to be required at this time. Nevertheless, the Company will continue to actively manage clinical risk and seek opportunities for further risk reduction through simple design controls.

7.2 Hazards of note

The Hazard Log sets out all of the Hazards identified during the assessment. In this section, some key hazards, their causes and controls are discussed in more detail. These hazards were selected for discussion as they were both assessed as having an Initial Clinical Risk of Moderate.

7.2.1 Hazard 4: Patient information incorrect or incomplete

Hazard description

The patient information in the Principle Clinical System (PCS) e.g. EMIS or SystmOne could be misleading or incorrect.

Harm

It may be difficult for a patient record to be found in the PCS via CareConnect if the affected fields are those which CareConnect or a user would search by. This could delay users being able to identify to patient record to interact with the clinical data needed to support patient care.

Controls

CareConnect provides an integration between the GP Practice EPR system (PCS) and Horizon Contact. The information used by CareConnect is provided by an API query and returns the information captured within the PCS. As such, errors that exist in the PCS could potentially cause difficulty for the user in finding a patient via CareConnect. The controls for this hazard are all external, as errors with patient information within the PCS rely solely on the patient record being updated accurately by the implementing organisation.

Healthcare organisations should ensure that the PCS is kept up to date including registering patients and updating any changed information in a timely manner. Healthcare organisations should have policies in place regarding the registering of patients and updating of patient information within the PCS.

In the instance where a patient record is updated in the PCS incorrectly, for example with a different patient's phone number, this could potentially lead to CareConnect identifying the incorrect patient from an incoming call, or alternatively calling an incorrect patient via click to dial. As such, users should be trained to verify the information they are inputting to the PCS when they are updating patient records. In addition, it is assumed that users will update records with care and ensure that they have the intended patient record open in the PCS before making any updates.

In addition, many of the controls outlined in Hazard 6 (below) also help to mitigate against this hazard.

Clinical Risk

Taking into account the above controls, the Residual Risk associated with the patient information in the patient information being incorrect or incomplete (Haz4) is assessed as:

Severity: Minor
Likelihood: Low
Residual Risk: Low

Recommendations

As the Clinical Risk associated with this Hazard is Acceptable and no other reasonably practicable controls were identified, no further action is required.

7.2.2 Hazard 6: Patient record pertains to a different patient than the one which was intended

Hazard description

The user could believe that they are interacting with a particular patient's record when in fact it pertains to a different patient. They could review the record, input data or transact with it in other ways.

Harm

The user will be misled by the information wrongly believing it to relate to the intended patient. Data inputted could contaminate the record in context, compromising the care of that patient.

Controls

Gamma use the API provided by each PCS supplier which are tested by the suppliers and highly reliable. The integration between CareConnect and the PCS APIs is tested to ensure that the results returned are as expected.

Gamma have also included a number of design controls to support users in selecting the correct patient record when using CareConnect, whether via an incoming call or manual search. Multiple identifiers are displayed within the screen pop enabling the user to check details. In the instance that multiple patients associated with the same phone number also have the same name, alternative checks can be made to validate the identity of the patient. When the patient information is presented in the screen pop, it is presented in a clear way in rows, whereby if there is more than one patient linked to a phone number for an incoming call, the user is presented with all relevant patients and their details to enable them to confirm the patient's identity before clicking the name to open the record in the PCS. In addition, the screen pop remains on screen such that in the instance that the user selects the incorrect patient in the screen pop, they can easily change their selection on the screen pop which will change the open record in the PCS.

Gamma have also produced training materials which are available online for all users via the Gamma Portal. This training covers how to correctly use the screen pop and manual search functions to ensure that the correct patient is selected. Healthcare organisations should ensure that users access the training within the Gamma Portal and encourage staff to refresh themselves on the use of CareConnect on an annual basis or following a long period of absence.

In addition, it is the healthcare organisation's responsibility to ensure that staff are trained to validate the identity of the patient before interacting with the patient record. Users should always validate the identity of the patient when using the CareConnect and Horizon Contact systems including when receiving an incoming call, finding a patient via a manual search, or placing an outbound call via click to dial.

Clinical Risk

Taking into account the above controls, the Residual Risk associated with the patient record pertaining to a different patient than the one which was intended (Haz6) is assessed as:

Severity: Significant
Likelihood: Very Low
Residual Risk: Low

Recommendations

As the Clinical Risk associated with this Hazard is Acceptable and no other reasonably practicable controls were identified, no further action is required.

7.3 Issues of note

There are no significant safety-related issues or defects noted at the time of drafting this document.

8 Post-deployment monitoring and incident management

8.1 Detecting and logging incidents and concerns

The detailed processes and procedures for managing safety related incidents are documented in Gamma's Safety Incident Management Process (Ref. 17). A summary of the process is outlined below.

Gamma will provide second and third line support. First line support will be the responsibility of the Company's business partners.

If the business partner cannot resolve the problem, they will then raise it to Gamma where the steps below are followed:

1. A ticket is raised, then reviewed and resolved by the 'line one' support team.
2. If the 'line one' support team cannot resolve the issue it will be escalated to one of two teams - Provisioning Faults or Technical Support.
    a. Provisioning Faults will handle escalated issues regarding the purchase or assigning of the PCS Integration bolt-on licence.
    b. Technical Support will handle escalated issues regarding the use or setup of the CareConnect Integrator.
3. Where these teams cannot resolve the issue it will be raised as a ticket in Product Board for the Development Team to review and include in the development cycle.
4. If the issue is defined as a bug by the Development Team, it will be resolved by an updated version being released, which is then communicated to the customer via the 'line one' support team.

In live service, the product is supported by an online logging tool managed by the Company. Issues which are found to be related to the product are logged in Product Board by members of the Provisioning Faults or Technical Support teams as outlined above and are prioritised and managed in a similar manner to other product changes.

Where an issue cannot be resolved through advice provision or other simple remedial measures, an issue is created in Jira and the support team will assign the Jira ticket to an appropriate member of the team for review. Where a change to the product is required, this will be scheduled into an appropriate release or hotfix.

The historical Jira tickets, when filtered for those with associated clinical risk, will constitute the Safety Incident Management Log as required by the Standard.

8.2 Assessing and resolving incidents and concerns

Reported issues which have the potential to impact clinical safety will be made available to the CSO for their review. The CSO will attribute a level of Clinical Risk and decide whether the resolution plan and priority are commensurate with the level of risk. Those which have the potential to adversely impact clinical care will be flagged and the fix priority will be reviewed. In the event that the fix priority is inappropriate given the clinical risk associated with the issue, the priority will be re-evaluated. If necessary, the CSO will engage with the healthcare organisation or third-party directly to understand the context of the issue and inform their assessment. The Company will ensure that safety-related incidents and concerns are resolved in a timely manner, commensurate with the clinical risk presented.

Should a serious issue be identified which could impact a number of users across more than one site, measures will be implemented to inform key personnel for dissemination of the issue and any make-safe remedial action required.

Resolved issues will be attributed an appropriate status and comments describing the manner in which the issue was resolved.

For the avoidance of doubt, the Company, in managing the live service, will not differentiate between issues which could be considered bugs, incidents or concerns. The process will remain the same and the remediation activities varied according to the nature of the incident and Clinical Risk attributed.

8.3 Re-evaluating the Safety Case

When new information comes to light as a result of an issue being logged, the CSO will review the Hazard Log and determine whether the issue:

- Represents a new Hazard or Cause previously not identified;
- Changes the level of Clinical Risk associated with an existing Hazard;
- Demonstrates that an existing control is less effective than had previously been assumed.

Following the identification of a safety-related issue, the impact on the on-going validity of the Safety Case will be considered. If the issue materially changes the Clinical Risk associated with the product or challenges assumptions made in undertaking the risk assessment, it may be appropriate to update and re-issue the Hazard Log and the Clinical Safety Case Report for the system or construct a suitable addendum. This will include a re-evaluation of the residual risk and its acceptability. These materials will be communicated to customers accordingly.

9 Modification and Change Management

Where new features and improvements are implemented, those which are safety-related will be made available to the Clinical Safety Officer for their review.

Where the level of Clinical Risk associated with a requirement is evaluated as Moderate or above, the Clinical Safety Officer may choose to document further requirements and/or validation criteria to ensure that the requirement is implemented in a safe manner and is validated to a level commensurate with the risk.

Where new requirements introduce new Hazards, Causes or Controls or where a requirement has the potential to impact existing Hazards, Causes or Controls, the Hazard Log will be updated and will be made available to healthcare organisations. Where there are material changes to the overall safety profile or for larger enhancements, the Clinical Safety Officer will update the Hazard Log and re-issue the Safety Case or create a suitable addendum to the Safety Case.

If no updates are made to the Safety Case during a period of 12 months, a routine update of the document will be performed.

10 Outstanding activities

At the time of drafting, there are no outstanding activities to completing this assessment.

11 Review of completeness

A review was undertaken on 16th September by the Clinical Safety Officer, Product Manager, and Business Analyst, to determine whether the safety assessment was complete.

The Clinical Risk Management Plan, Hazard Log and Clinical Safety Case Report were reviewed and discussed with regards to content and completeness.

The review concluded that:

- The activities set out in the Clinical Risk Management Plan (Ref. 4) had been executed to completion.
- All foreseeable hazards have been identified and documented in the Hazard Log.
- Sufficient evidence has been gathered to verify the implementation of the controls set out in the Hazard Log.
- An appropriate strategy is in place to monitor and manage clinical risk in live service.
- All hazards have been mitigated to As Low As Reasonably Practicable.

12 Conclusion

A methodical assessment of CareConnect Version 1.1.3 has been undertaken to determine where there is potential for clinical risk to be introduced by the system. The Company has appointed an experienced Clinical Safety Officer to advise and oversee the assessment activities and approve the resulting documentation. A Hazard Log has been formulated and the Residual Risk associated with each hazard evaluated. The supporting evidence has been set out in this report to justify the safety claims.

A Clinical Safety Officer has reviewed this Safety Case against the Clinical Risk Management Plan (Ref. 4). All intended activities have been completed.

All identified Hazards have been mitigated to As Low As Reasonably Practicable and, in conclusion, the clinical risk associated with CareConnect was found to be Acceptable.

13 Appendix A – Risk matrix and acceptability criteria

The following risk matrix, adapted from the example provided in the DCB 0129 Implementation Guidance v3.2 (Ref. 18), will be applied to this clinical risk management assessment.

13.1 Severity classification

Severity Classification	Interpretation	
	Severity	**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

13.2 Likelihood classification

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

13.3 Risk matrix

Likelihood	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

13.4 Risk acceptability criteria

5	Very High	Unacceptable level of risk. Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level.
4	High	Unacceptable level of risk. Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level.
3	Significant	Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Moderate	Tolerable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical.
1	Low	Acceptable, no further action required.

14 Appendix B – Company test strategy

14.1 Test phases

The following phases of testing are routinely conducted:

- Unit testing
- Acceptance testing
- Release testing

14.2 Test activities

The following activities are conducted in testing the application for each phase.

Test Phase	Unit testing
Test objective	Test the functions that make up the application are working as expected.
Pre-conditions	Unit tests can be run by the developer in the development environment (Visual Studio).
Personnel	The developer working on the application is responsible for maintaining and running these tests as part of the development process.
Test Environment	Unit tests mock all data.
Test Data	The unit test return data defined in the tests. Given the limited data returned, the do reflect the data quite accurately.
Test Scripts	Test scripts are encapsulated in the source code. Owned by engineering.
Method and tools	The tests can be executed within visual studio.
Defect Management	Defects raised by the unit tests will be fixed by the developer as part of development.
Exit criteria	All unit tests must pass successfully. Code coverage must be maintained after new development.
Post-conditions	App is passed on to QA to release test.
CSO engagement	CSO to ensure that this test strategy and exit criteria continue to be enforced. CSO to ensure that all requirements in Jira are risk assessed to steer the testing rigour.

Test Phase	Acceptance test
Test objective	Ensure that the application meets the criteria, including behaviour under error conditions.
Pre-conditions	The tester must have a Horizon Contact account that is licensed for use with the PCS, the app installed, and currently, be logged into the PCS.
Personnel	QA Engineer.
Test Environment	Tested in our test environment. This is a fully functioning environment that is refreshed at least once per day. An automated test suite is run at least once per day.
Test Data	Gamma utilises the PCS sandbox test data.
Test Scripts	Tests are captured as Jira tickets, using X-Ray. They are maintained jointly by development and QA. QA is responsible for ensuring the tests fully cover the functionality, based on the User Stories that were provided by the business.
Method and tools	The tester places calls into Horizon Contact to check they are delivered correctly and looks up Patients in the PCS to ensure they are dialled from Contact.

Defect Management	Defects are raised as Jira tickets. All tickets raised are triaged by the product owner, the business analyst, and a representative from engineering. Tickets are assigned a priority and a target sprint. P1 tickets are system affecting and are fixed under the escalation procedure. They are fixed as a priority and the fix released under the emergency patch procedure. P2 tickets or bugs introduced but not yet released will be assigned to the next sprint and must be fixed and tested as part of the next release. P3 tickets and lower are not considered gating and are fixed in a future maintenance release. Regarding clinical considerations, the main consideration is to ensure that the application is returning the correct patient, is screen popping the selected patient, and is dialling the correct patient.
Exit criteria	The tester must be satisfied that the acceptance criteria have been met, and the test cases executed cover all error scenarios.
Post-conditions	Once the acceptance testing is completed, the user story or fix being tested is marked as ready for release and will be included in the candidate for the next release.
CSO engagement	CSO checks that all bugs raised and scheduled for fixing in a later release are associated with No or Low Clinical Risk. CSO checks that Functional Testing completed successfully for each major release.

Test Phase	Release/ regression test
Test objective	Integration test to ensure that the final release candidate does not suffer from issues introduced during the final merge of all components.
Pre-conditions	All code for the release must be checked in, and all changes passed acceptance testing. The automated test suite must have passed.
Personnel	QA.
Test Environment	Gamma have a staging environment in the lab that exactly matches the last release. This is updated with the candidate release following the standard upgrade procedure. The QA engineer will use the latest installer for CareConnect to upgrade the application on their desktop. A full release test is then carried out on this environment.
Test Data	From the CareConnect perspective, as this is a release of Horizon Contact (HC), Gamma are concerned about the API between CareConnect, that HC is working correctly, and that API calls are being successfully sent to the PCS.
Test Scripts	The release test is a set of X-ray tests that are deemed to cover the core functionality.
Method and tools	For CareConnect the tester will log into Horizon contact, CareConnect and the PCS, if available.
Defect Management	Defects are raised as Jira tickets. All tickets raised are triaged by the product owner, the business analyst, and a representative from engineering. If a defect is a regression or is deemed service affecting, the release test is halted until it is resolved. P3 tickets that are not regressions are not considered gating and will be fixed in a future maintenance release. Regarding clinical considerations, the main consideration is to ensure that the application is returning the correct patient, is screen popping the selected patient, and is dialling the correct patient.
Exit criteria	The release test is completed, all failures have been documented in Jira tickets. All issues considered gating have been resolved.
Post-conditions	The release is ready to ship.

CSO engagement	CSO to ensure that those functional areas covered are prioritised based on the testing controls in the Hazard Log. CSO to review and assess relevant safety-related bugs raised if they remain unfixed at go-live.