Clinical Risk Management Plan (CRMP)- Vitacam

Published 14th March 2023

Document filename: Clinical Risk Management Plan			
Project: Vitacam			
Document Reference: CRMP			
Director: Moyeen Ahmad		**Status: Approved**	
Owner: Moyeen Ahmad		**Version: 1.0**	
Author: Rebecca Wilson **GPHC: 5027499**		**Version issue date**	14/03/23

Document Management

Revision History

Version	Date	Summary of Changes

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Moyeen Ahmad	Director	29/03/22	V1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Rebecca Wilson	Principal Clinical Safety Officer	14/03/22	V1.0

Related Documents

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

Ref	Title	Version
1	DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Specification	4.2
2	DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification	3.2

Glossary of Acronyms	
DCB 0129	Clinical Safety Standard- Clinical Risk Management: its application in the manufacture of Health IT Systems
DCB 0160	Clinical Safety Standard- Clinical Risk Management: its application in the Deployment and Use of Health IT Systems
Clinical Safety Officer	CSO
Clinical Risk Management	CRM
Clinical Risk Management File	CRMF
Clinical Risk Management Plan	CRMP
Hazard Log	HL
Clinical Safety Case Report	CSCR

Contents

Introduction

Vitacam is standalone software for measuring vital signs. It is used to measure the respiratory rate and heart rate of ambulatory patients, for clinical assessment of current condition and deterioration.

Purpose of Document

The purpose of this Clinical Risk Management Plan (CRMP) is to define steps taken for the development and implementation, and any variation of the product, held by Vitacam Ltd.

It describes how Vitacam Ltd will conduct clinical risk management to ensure patient safety with respect to products and services provided and the interrelated and interactive activities that will occur to ensure that the Vitacam product meets the requirements of DCB0129- Clinical Risk Management: its Application in the Manufacture of Health IT System.

This CRMP identifies the means by which the Vitacam product shall be controlled to ensure that the safety work is of high quality, conforms to the requirements of the DCB0129 requirement and any specific product requirements.

This document will be updated when the plan changes in any way as to deviate from what has been committed to deliver. This will be decided by the product team and Clinical Safety Officer (CSO).

This document aligns to the Clinical Safety activities and processes which are in place at Vitacam Ltd.

Background to Clinical Safety standards and requirements

Information standards provide the mechanism for introducing requirements to the NHS, those with whom it commissions services and its IT system suppliers. There are two Clinical Safety Standards related to patient safety described below. These standards can be found at:

DCB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT platforms

DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT platforms

DCB 0129: Clinical Risk Management: its Application in the Manufacture of Health IT platforms

This standard sets clinical risk management standards for manufacturers of Health IT systems including software and apps. It requires the manufacturer to establish a structure within which clinical risks associated with the design and development of a new system or the modification of an existing system are properly managed. It also ensures that outputs are clearly documented to provide evidence of compliance. Compliance with the standard ensures that the manufacturer has instigated a best practice clinical safety during the manufacture of the Health IT system. [Ref 1]. This plan supports safe deployment of the Vitacam product and its associated configurations.

DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT platforms

This standard requires health and care organisations deploying and using new or modified Health IT systems including software and apps to have a structure to manage clinical risks associated with that deployment. Many of the requirements in DCB 0129 are repeated in DCB 0160 for the health and social care organisations [Ref 1 & 2]. Vitacam Ltd is approaching this standard with a proactive, best practice approach to ensure patient safety throughout the product deployment and decommissioning pathway.

ISO 14971: Risk Management: its Application to Software as a Medical Devices

ISO 14971 is an international standard aimed at those products whose intended purpose falls within the scope of the Medical Device Regulation. The scope of the standard encompasses harm not just to patients, but also to healthcare staff, property, and the environment. The Vitacam product is registered as a medical device with the MHRA. It is has a Medical device classification lla according to rule 10 set out in Annex IX of Directive 93/42/EEC. Vitacam Ltd hold a full, creditable and thorough technical file which supported the application and approval process to gain the accreditation.

Managing the CRMP:

This CRMP applies to the Vitacam product. The Clinical Safety Case Report (CSCR) and Hazard Log (HL) accompanies the configuration and has being formulated around the parameters of its intended use defined for the development, deployment and considering potential for misuse.

If there is any deviation in the clinical risk management processes, the CRMP will be updated to reflect this, and approval sought from the Director and appointed CSO to provide assurance of compliance.

If clarification is required on whether any system/configuration falls within the scope of this CRMP, this should be raised with the Vitacam Health's CSO who will decide. This nominated person provides clinical and organisational leadership on health IT patient safety on behalf of the organisation

Overview

Scope

The scope of the CRMP extends to all static and dynamic functionality, including any operational use and potential misuse of the system in the specific Vitacam configuration, which has the potential to cause harm to patients. This document defines the process of clinical risk management within the company with a focus on its analytical boundaries, and to the role and responsibilities of the personnel tasked to oversee its implementation.

Clinical risk assessment and management applies to all aspects of the Vitacam product and considers any third-party hardware/software being used as part of the deployment, by provider companies.

The configuration adheres to this scope. It takes the following users into consideration:

- Patients

- Carers
- Nurses
- Other allied health care professionals
- Etc.

Product Overview

Governance

The Vitacam Ltd's appointed Clinical Safety Officer (CSO) is responsible for ensuring the clinical safety of the Vitacam configuration through the application of clinical risk management. The CSO is a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role. Vitacam Ltd has appointed external Clinical Safety Specialists to undertake the required work. ETHOS LTD are providing Vitacam Ltd with the Clinical Safety expertise and Clinical Safety Officer(s) and engineers to support clinical safety activities.

Key responsibilities include:

- approval of the information in this plan to confirm that it is appropriate and achievable in the context of the product development and modification
- ensuring that clinical risk management activities are completed in accordance with this plan
- reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Logs and reviews
- reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report (CSCR)
- providing recommendations to Top Management
- escalating any unacceptable safety risks through clearly defined routes of escalation

Vitacam Ltd provide company wide, dedicated resources to support quality management, adhere to appropriate training and communication between all staff and users. Clinical safety culture and awareness raising is currently ongoing and being embedded in new starter onboarding processes.

Table 1 Roles and responsibilities

Project management/ Product owner	CTO, CEO Miikka Kirveskoski, Moyeen Ahmad	Management
Risk analysis	CTO, Miikka Kirveskoski	Management
Algorithm development	Algorithm developers Henri Tikkala, Ahmed Shaheen	Development
UI Development	Software developer Henri Tikkala Aki Huttunen	Development
UI Design	Marketing Designer Laura Niemi	Marketing
DevOps	Software Developer Esa Rauman	Development
SW communication	Software Developer Timo Huttunen	Development
Testing	Testing Manager Mikko Heikura, Emmanuel Etchu	Testing & Quality

Clinical Risk Management File

Vitacam Ltd have a SharePoint Technical file 0.10.1 which contains all relevant clinical safety documentation and will perform the function of the Clinical Risk Management File (CRMF).

This folder will be managed by Vitacam Ltd and the appointed CSO. The CRMF is a live repository, updated contemporaneously and will change and evolve in response to the product lifecycle, personnel change and policy and methodological revisions.

It will be the responsibility of the Product Owner to ensure that the CRMF is current and up to date.

The CRMF will be reviewed in its entirety on an annual basis, and at each phase in the product lifecycle, and will be accessible to all relevant stakeholders internal/external as appropriate.

Individual projects assurance

Issues pertaining to data security and information governance (IG) will not be covered in the CRMF.

Assumptions:

- Each new configuration idea will trigger the Clinical Safety activities outlined in this plan
- Each new configuration/significant alteration to Vitacam will utilise the Clinical Safety process to support effective review and contemporaneous documentation of decisions, kept within the CRMF, for sign off by the CSO.

- Reviews of similar configurations of the Vitacam product can share learning to optimise safety discussions and awareness early in product development cycles
- This CRMP will underpin clinical safety for the project lifecycle including closure/offboarding and potential support with provider decommissioning of the product and be subject to Vitacam Ltd's audit and quality management cycles.

Constraints:

- New configurations compliance with required testing prior to release and review of the hazard log and CSCR.

Clinical Risk Evaluation and Management

The clinical risk matrix, evaluation and management process used is defined below and can also be found in more detail within Appendix 1. The hazard assessment process will follow the standard DCB 0129 Clinical Risk Management System approach [Ref 1].

Hazards may be identified in other ways during the development and use of the Vitacam Product such as:

- Discovery activities during design of a solution
- Testing of amended functionality of the Vitacam product in different configurations
- Ad hoc testing of live service functionality and end user feedback/insights
- Reporting of an incident, near miss or problem within the live service
- Identification by a member of the product team within Vitacam Health, a third-party supplier, or the customer business

For each identified hazard, the following information will be defined and recorded on the Hazard Sheet and summarised on the Hazard Log:

- Hazard number;
- Hazard name;
- Hazard description;
- Potential clinical impact – this will describe the effect of the hazard in the care setting and potential impact on the patient;
- Possible causes – these may be technical, human, error etc. A hazard may have a number of causes; and
- Existing controls – these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation again the hazard, i.e. will be used as part of the initial Hazard Risk Assessment.

Example Hazard Description log:

		Hazard Assessment			
		Hazard Description			
No.	Date Added	Effect	Hazard	Harm	Possible Causes

Each Hazard will be discussed by Vitacam Health's team and the appointed CSO and any other appropriate stakeholders/specialists.

Estimation of clinical risks.

For each identified hazard, estimation will be made of the clinical risk. This will include the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process will follow that established by the safety processes defined in DCB 0129/0160. A copy of the risk assessment matrix is provided below, in Appendix 1 and a glossary in Appendix 2.

The method used by the Clinical Safety Officer to determine risk scores is a principle, called the AFAP principle. The principle stands for "as far as possible" and its core is to look at the individual risk and assess how that may be controlled to reduce the likelihood of it occurring through applying mitigations. See diagram(s) below.

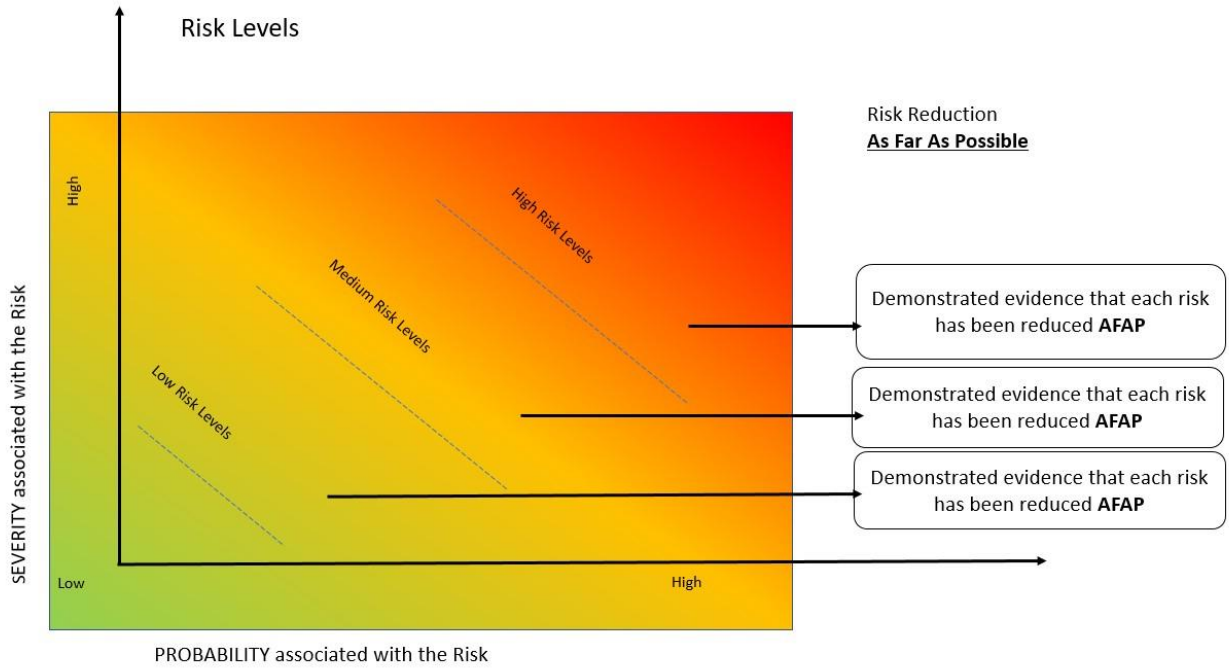

Diagram- 'as far as possible'

Clinical Risk Control

There are a number of activities that provide the diligence in assurance, technical integration, communication, training and clinical governance. The areas of control which are to be covered during the Vitacam product lifecycle are as follows:

- Technical Assurance & Integration where applicable
- Training (provided to users)
- Communication provided to users and patients
- Configuration management process
- Operational Go-Live
- Business Process for users
- Live Service
- Incident Management Process
- Support

The Vitacam product already has a large technical file which contains all the pertinent evidence required for the medical device registration, many of these are transferable for this Clinical risk management plan and all relevant assessment and compliance requirements to satisfy the DCB0129 standard.

Appendix – Risk Classification Matrix

Clinical Risk Management 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
		Consequence				

Risk Matrix key - Severity

5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.

2	Acceptable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required

Hazard likelihood definitions

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

Hazard Consequence definitions

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