Clinical Safety Case Report – (CSCR) Vitacam

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Authors Rebecca Wilson GPHC: 5027499	**Version issue date**	21/03/23

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	29/03/23	V1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Rebecca Wilson	Principal Clinical Safety Officer	14/03/23	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
3	Clinical Risk Management System	WIP
4	Clinical Risk Management Plan	V1.0
5	Vitacam Hazard Log V1.3	V1.3
6	Software development plan V14	V14
7	System Architecture V19	V19
8	Quality_Manual 1.5.0	V1.5.0
9	Risk management_Triage_Report_08032021	V1.1.0
10	TF-01_V1.3	V1.3
11	Vitacam ER CHECKLIST_V1.1 (1)	V1.1
12	Release Plan V9	V9
13	Requirements for installation V9	V9

Ref	Title	Version
14	EN_EU_DoC_1.1.0 (1)	V1.1.0
15	SOP-002 Management review_v.1.3	V1.3
16	SOP- 003 Risk Management Process V.1.2	V1.2
17	SOP-004 Product development and Design Control_1.4	V1.4
18	SOP-006 Indentification and traceability V.1.1	V1.1
19	SOP-009 Feedback_V.1.2	V1.2
20	SOP-012 Verification & Validation_V.1.2.0	V1.2.0
21	SOP-018 Post market surveillance_V1.3	V1.3
22	SOP-021 Usability_V.1.2	V1.2
23	Vitacam ethical approval letter	n/a
24	Method V1	V1
25	Bland Altman plots	n/a

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

In the UK, manufacturers of health IT systems including software are required to comply with the clinical safety standard DCB0129- Clinical Risk Management: its Application in the Manufacture of Health IT Systems (Ref 1). The standard sets out a framework for clinical safety activities, therefore rigorous and systematic analysis must be completed by any company wishing to provide their product(s) to the market. The technologies which are to be used in the health and social care settings which involve patient information or decision making must be evaluated to ensure there is no increased harm to the patient. Analysis and evaluation must be performed by an accredited clinical safety officer to establish the nature of any potential clinical hazards and the degree of clinical risk that might be introduced by use of the product or software.

This report provides an overview of Vitacam and addresses clinical safety, governance arrangements and provides other additional information which is all used in the analysis of the product. This report collates the evidence required and is presented to support the factors which mitigate any clinical risk(s) which may be associated with the product.

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

1. Clinical Risk Management Plan (ref 4)
2. Hazard Log (ref 5)
3. Clinical Safety Case Report (this document).

Collectively, these three documents support compliance with DCB0129.

It provides the assurances that the application is clinically safe in the context of the NHS Digital clinical safety standards (Ref 1 & 2).

The Clinical Safety Objectives for this Product and associated documentation are:

- To ensure that the safety activities undertaken during the course of the clinical safety process are in line with the risk management plan (ref 4,9,16)
- The design, development and deployment has continued monitoring of the Hazard Assessment / Log
- Ensure the system is clinically safe in the context of its intended purpose or use
- Monitor any change to the system, assess any potential risk and mitigate these
- Identify and assess clinical hazards/risks to ensure patient safety
- Identify safety critical functionality of the system and evidence assurance activities in these areas to mitigate clinical risk

The safety case report aims to provide part of the argument that the application complies with NHS clinical safety standards. As such it is deemed clinically safe and fit for purpose.

Background

NE Device SW was established in 2014 in Oulu, Finland. NE Device SW is a medical device software manufacturer that designs, develops and distributes medical device software. NE Device SW have developed Vitacam.

Vitacam is a Medical Device Software product , it is primarily targeted to Europe, including all countries in the European Economic Area and the United Kingdom. Vitacam is a standalone software for measuring vital signs, including respiratory rate and pulse, by analysis of a video stream or clip from a webcam or smartphone on a dedicated processing server.

While Vitacam is designed to be easy to use by a lay person, it is intended to inform clinical decision-making. Therefore, the intended user is a medical professional.

System Definition / Overview

Vitacam is a Cardiopulmonary physiologic analysis software device, it is registered as a class IIa medical device with the MHRA. It is a 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. Vitacam processes the sequence of video frames of a patient to obtain vital signs measurements (incl. respiratory rate and heart rate). This is done by using a computer server which is referred to as the ‘Analyzer’. This server can be physically located inside a hospital firewall (LAN) or as an instance in either private or public (accessible via internet) cloud infrastructure.

If Vitacam is used for in-person ‘triage’ assessments, a dedicated client application needs to be installed on a third-party personal computer, which allows the user to view the patient and the measurement results in real-time. The live video stream from a digital camera can be viewed on the client application and processed in the ‘Analyzer’, which also sends the measurement results to the client application.

The Vitacam solution has been designed for use mainly in hospitals in a triage situation. End users include hospital personnel such as nurses and other care givers. The Vitacam solutions purpose is to provide vital signs data in a contactless manner from video live feed and therefore to help make clinical decisions in a safe manner. The measurable vitals signs are respiration rate and heart rate.

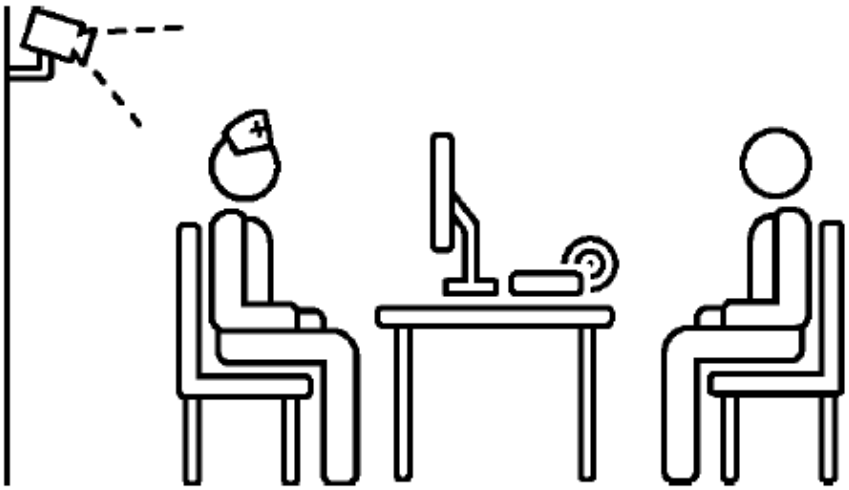
The respiratory rate is measured through optical flow analysis of a video sequence of the chest area. This is a technique of extracting the respiratory rate from the magnitude and frequency of chest movements, by tracking movement of points on the chest area from a video sequence.

The heart rate is measured through remote photoplethysmography (r-PPG) whereby blood volume variations in the microvascular facial tissue are detected from a video sequence. Pulsatile blood causes variation in skin colour that can be detected in Red-Green-Blue (RGB) channels, as used in digital imaging, especially in the green channels. Green light is absorbed better than red light and penetrates deeper than blue light; therefore, green light yields a pulsatile signal with a marked difference between the systolic and diastolic phases. A plane- orthogonal-to-skin colour transformation is applied to exposed skin on the face, whereby changes in the colour channel can be used to extract a pulse signal. The technique is similar to photoplethysmography used in reflectance-based pulse oximetry methods.

There are warnings provided for the end users, which may hinder the correct use of the product, these include:

- A dirty camera lens can impact measurement results. The end user should ensure that the lens is clean before using the application.
- The camera must not be closer than 1.5 metres from the patient.
- Obstacles in the camera view or an incorrectly positioned patient can hinder or prevent measurements. The end user should ensure that the camera view is obstacle-free, and the measuring environment is set up according to instructions.
- Dark clothing can hinder or prevent respiratory rate measurements.
- Insufficient lighting can hinder or prevent measurements. The end user should ensure that the measuring environment is lit up between 360 - 1200 lux and no direct light source is facing the camera or placed within the camera's live view. Spotlights, shadows and other lighting that alters the appearance of the face can hinder or prevent heart rate measurements.
- Near skin tone colours in the background of the measuring environment can hinder or prevent heart rate measurements. A contrasting background should be used when assessing the patient using Vitacam.
- Excessive movement by the patient can hinder or prevent measurements.
- Makeup that significantly alters or covers the base tone of the face can hinder or prevent heart rate measurements.

The Vitacam analyser works whereby a patient is facing towards a camera.



The camera should be mounted securely, e.g. on the back wall. The distance from the camera to the patient can be up to 3 metres.

There are cautions and observations which the end user should be aware of when using Vitacam, these include:

- Excessive movement by the patient can hinder or prevent measurements.
- Respiratory rate lower than 8 breaths a minute may not be detected.

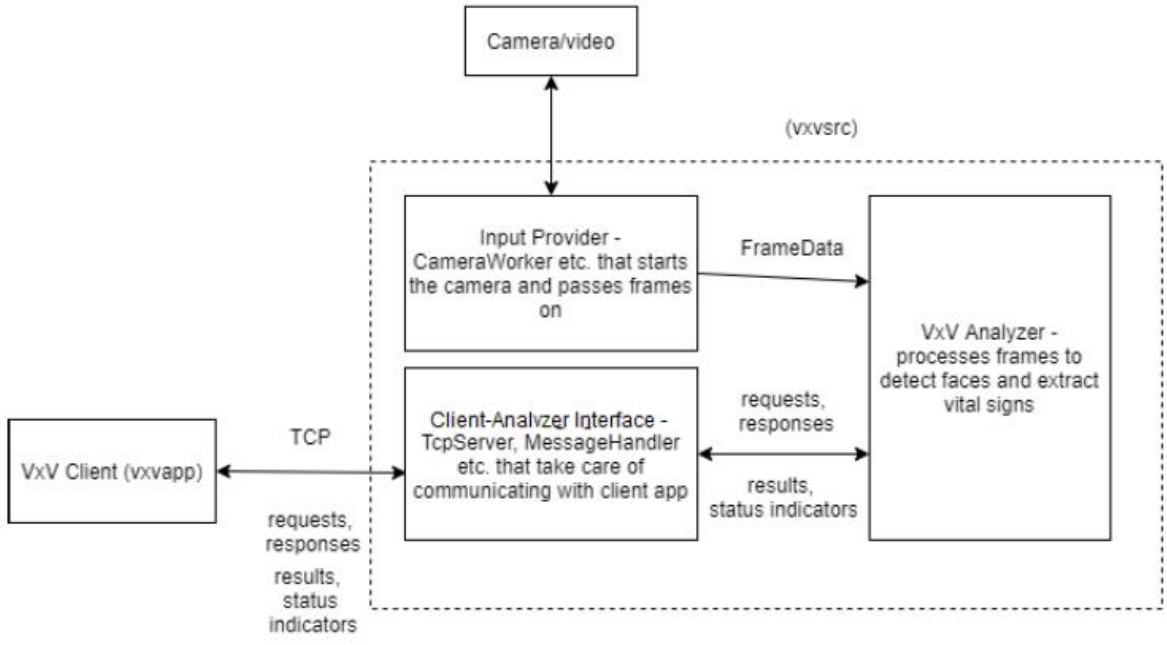
- There can be difficulties in obtaining heart rate measurements from patients with Fitzpatrick skin types 5 and 6, if distance to camera is greater than 2m.
- Vitacam has not been tested with patient with arrythmia, blood pressure disorders or other abnormal heart condition.
- Vitacam has not been tested with patient with lung diseases.
- Vitacam has only been tested on subjects with normal skin temperature.
- Vitacam does not support measurements on patients under the age of 18.

Intended Use and Recommendations of Vitacam are as follows:

- End users should not use Vitacam with a camera that does not fulfil the technical specification (Recommended camera is the Logitech Brio camera.)
- Vitacam should not be used a sole basis for medical decisions.
- Vitacam must be used in conjunction with clinical signs and symptoms.
- Vitacam should not be used on a patient who might be in immediate danger.

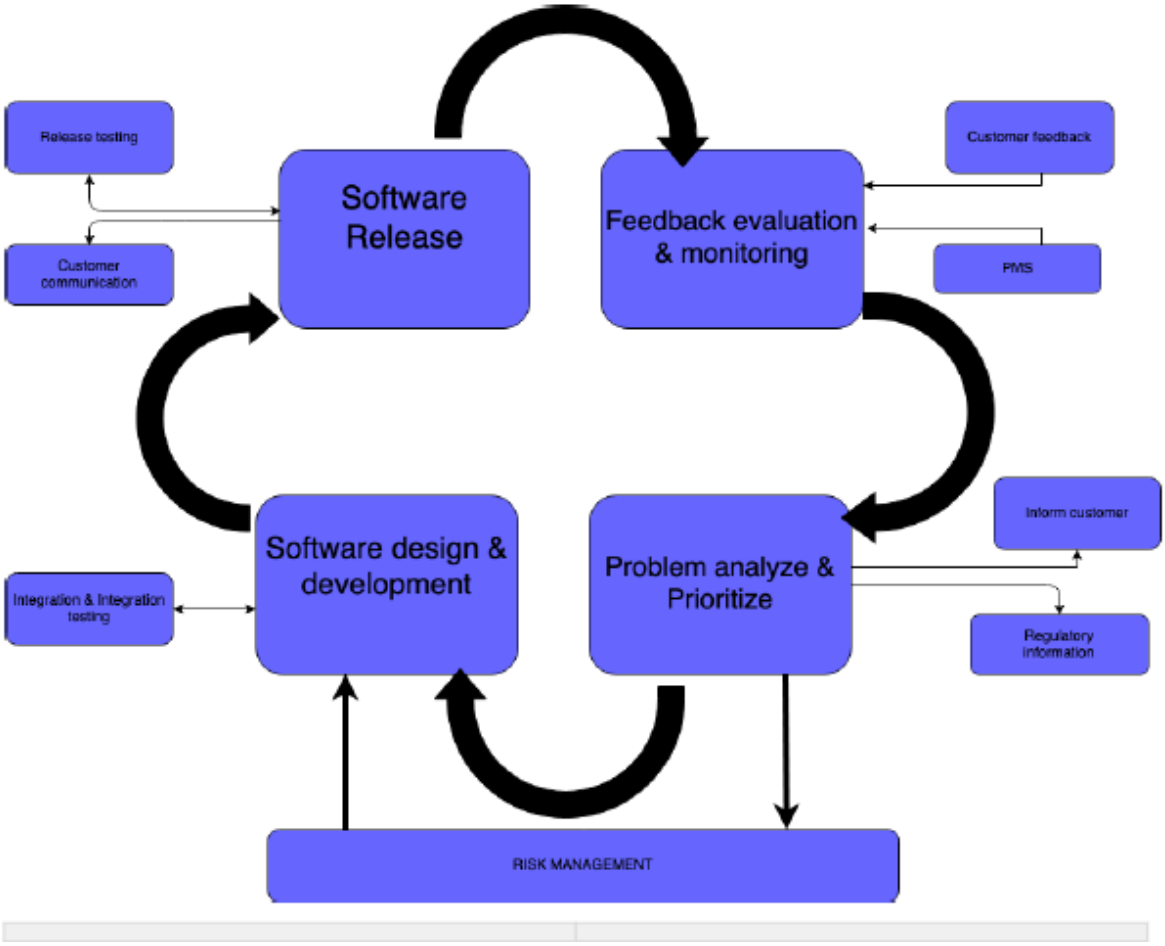
Architecture

Below is a high-level description of Vitacam software architecture



Software Planning

Software design and development happens according to the prioritise and milestone plan within the Vitacam product team. When all the software deliverables are done and integrated for target milestone NE Device SW can release the new software package if release testing is passed which is determined in Release Plan (Triage & Analyser).



The above shows the software design and development plan used for the Vitacam product.

Governance

The responsibility for the clinical safety activities for Vitacam resides with the Project Management team and Clinical Safety Officer.

The Clinical Safety Officer is responsible for ensuring the clinical safety of Vitacam through the application of clinical risk management. The Clinical Safety Officer is a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role.

The DCB 0129 Safety Standard requires that a Clinical Safety Officer (CSO) oversees the clinical risk management deliverables. Vitacam Health have contracted the services of ETHOS LTD who have appointed Clinical Safety Officer Rebecca Wilson GPHC : 5027499 who will undertake the DCB 0129 requirements.

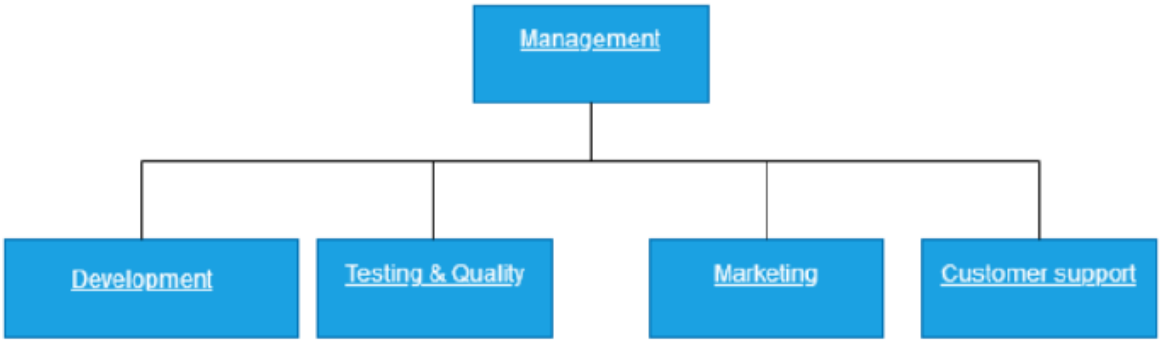
Key responsibilities include:

- approval of the Clinical Risk Management Plan to confirm that the plan is appropriate and achievable in the context of the Health IT System development and modification
- ensuring that clinical risk management activities are completed in accordance with the Clinical Risk Management Plan
- reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Log
- reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report
- provide recommendations where required to the product team
- escalate any unacceptable safety risks

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

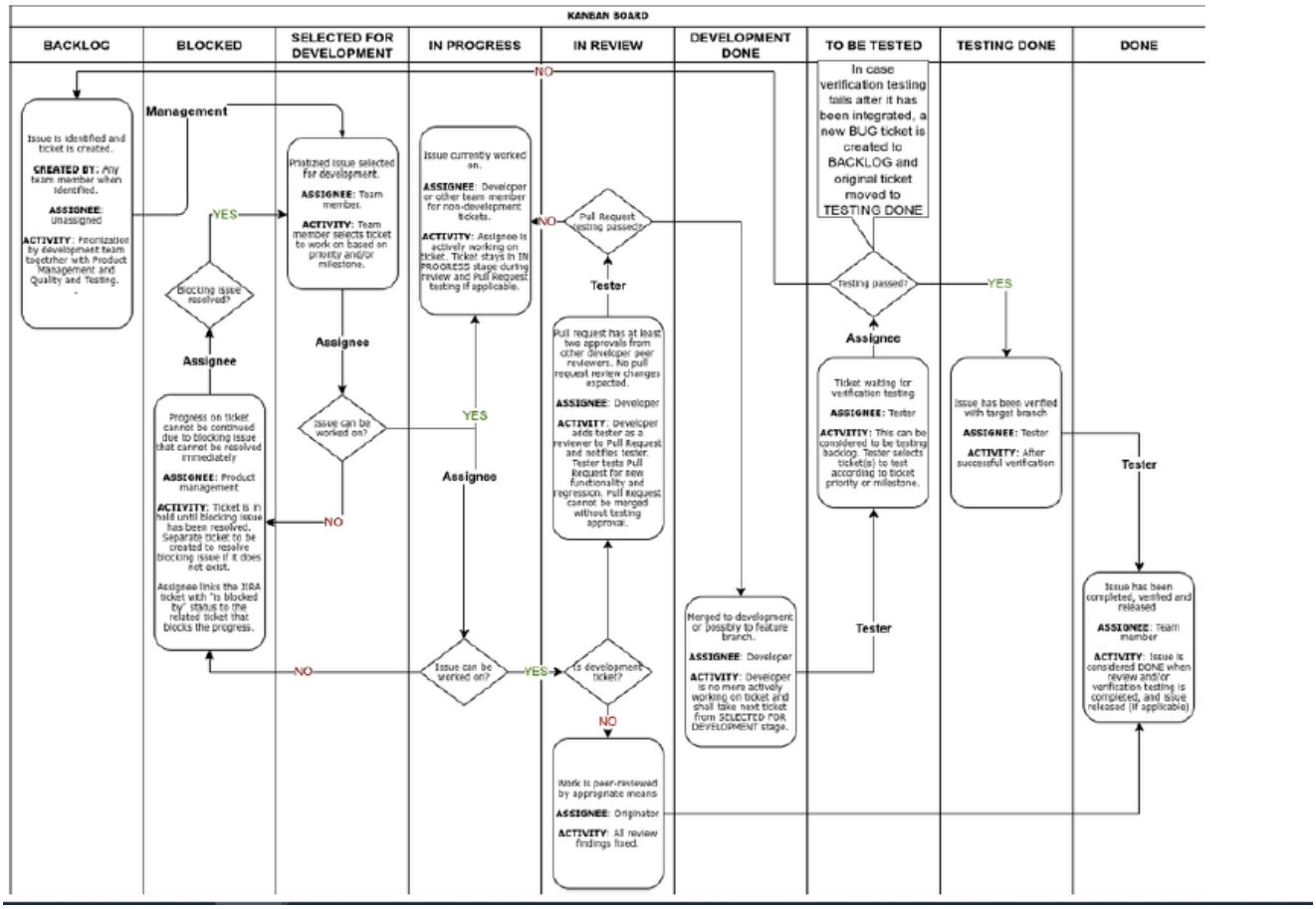
High Level overview of Governance arrangement for the Vitacam Product within NE Device SW. The product has the appropriate level of governance to ensure a through product is designed, developed, tested and deployed for release. The roles outlined above fit into the below diagram and over the development and assurance of the product.



Testing & Configurations

NE device SW use an agile Kanban model for software development and deployment. This involved the relevant testing and any software configurations. The Jira Kanban board is used for:

- Development of tasks and non-development tasks (eg. documentation, UI design, infrastructure changes).
- Problem resolution
- Tracing and tracking for software testing and verification.



Kanban Board Plan used for Vitacam Product.

Test Approach

The following testing is conducted for the Vitacam Product:

- Unit Testing
- Integration Testing
- Product Testing
- Validation Testing
- Verification Testing
- Security / Penetration Testing
- Failover Testing

Vitacam has been tested to ensure that memory does not leak or processing power exceed expected levels during extended continuous use , Verification and validation is completed. (ref 20).

Test Issues

At the time of writing this report they are no known clinical safety test issues.

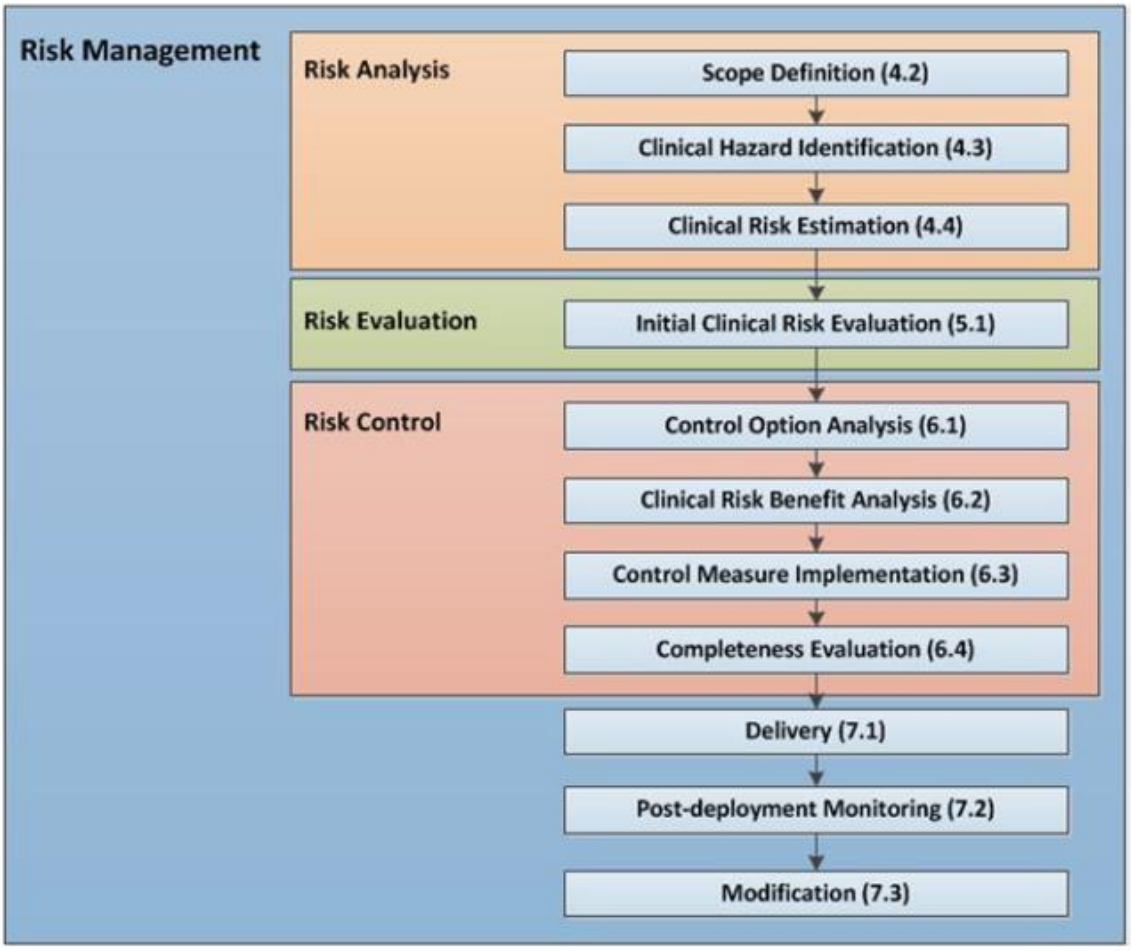
Clinical Risk Management System

Vitacam has a Clinical Risk Management Plan (CRMP) and NE Device SW Clinical Risk Management System is to be completed. However, NE Device SW have a technical file which contains reference 1-25 and more, these documents along with the CRMP and this CSCR provides the structure and governance required to ensure NE Device SW comply with the CRMS requirements. The file contains the risk management processes(s). The CRMP and other relevant documentation is stored within the Clinical Risk Management File (CRMF), Vitacam's Clinical Risk Management activities for the Product include the following areas:

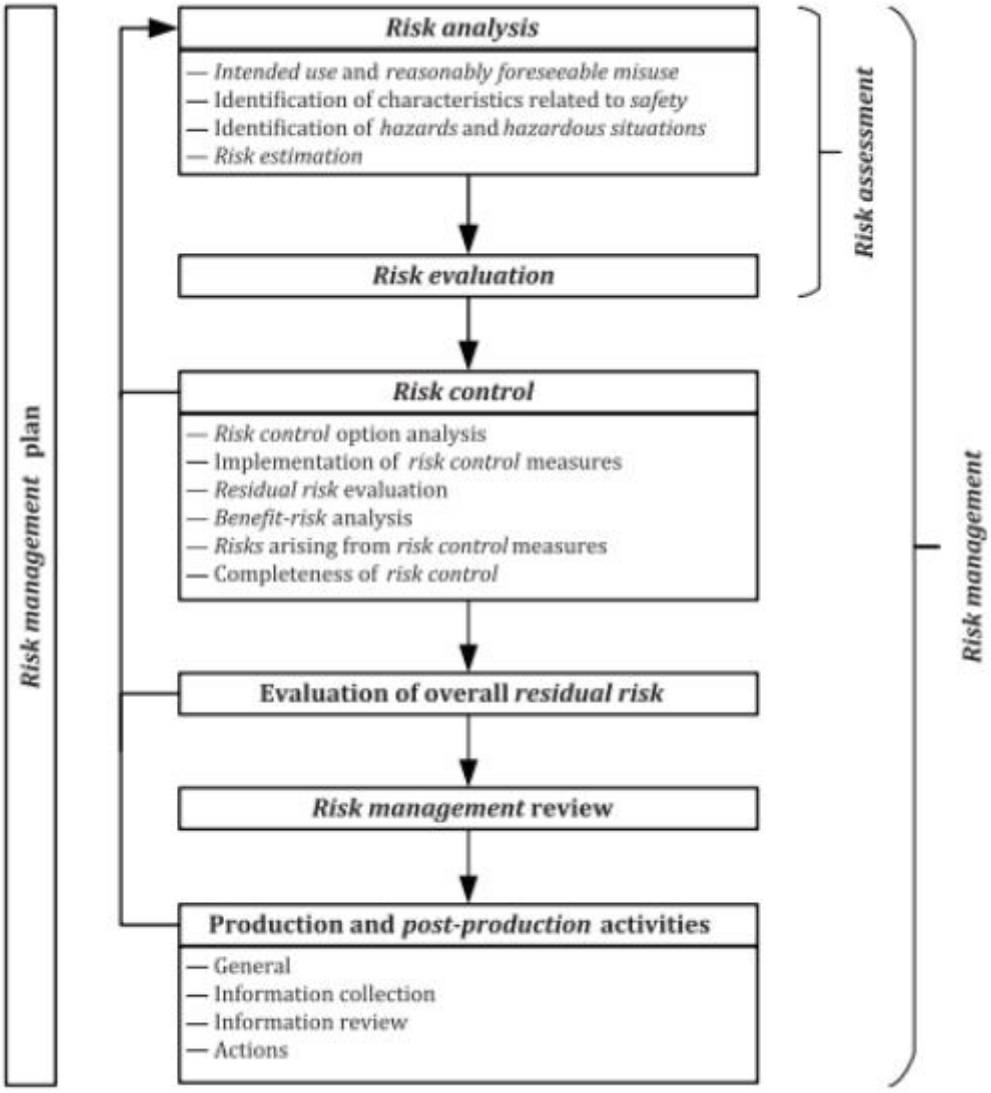
- Risk management including:
    - Risk Analysis
    - Risk Evaluation
    - Risk Control
- Clinical Hazard Identification including:
    - Clinical Hazard workshops
    - Hazard mitigation and control
    - Hazard methodology
- Control Measure Implementation
- Incident Management Process

Vitacam have collaborated with users of the product and also clinical safety experts. Establishing these links has allowed the product to be developed and built not only to the user's needs but also ensuring clinical safety is considered throughout.

The figure below shows the touchpoints where the CSO is involved in the clinical risk activities.



NHS Standard risk management process



The above diagram shows the risk management process the Vitacam product has adopted.

Clinical Risk Identification and Analysis

Hazard Identification and assessment has been performed using the Structured What If Technique or the 'Swift' method. The CSO assessed the Vitacam product and all relevant and available documentation. This enable hazard identification, effect, harm and causes to be recognized. These were documented and then reviewed by the product team, current controls have been reviewed and documented. The hazard log has been approved. (Appendix C).

The structured 'what if' technique (SWIFT) and the patient safety risk assessment approach used carefully considered:

- What could go wrong? (Consequence and likelihood)
- Possible main causes (Why?)
- Most likely Clinical Safety consequences for patients

- Current controls in place to prevent or mitigate error
- Recommendations to improve patient safety

Although the assessment has been completed, further hazards may be identified in other ways during the future development and use of the product such as:

- Discovery during the design of a configuration by third party, end user or product team
- Testing of amended functionality
- Ad hoc testing of live service functionality
- Reporting of an incident or problem within the live service

This will initiate a reassessment of the product and safety position.

For each identified hazard, the following information has been defined and recorded on the Hazard Log:

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

A total of 16 hazards have been identified as having potential to introduce a risk to patient safety for the deployment of the product. Each potential hazard has been assessed for causes and consequences and taking account of existing mitigations an initial risk grading allocated.

Where hazards are assessed as having a risk score of 2, no further controls were required but further recommendations provided for end users. Recommendations have been suggested and recorded in the hazard log (ref 5 and Appendix C). These recommendations should be assessed by the deploying organisation(s)/End Users and where possible the recommendations and further controls applied where applicable.

Clinical Risk Estimation and Evaluation

All identified hazards were evaluated from the perspective of patient safety consequences using a Cause, Effect, Hazard, Harm approach to explore potential consequences. Contributary factors were also considered, in addition to identifying existing mitigating controls from a health IT design, end user training and business process were also considered.

The clinical risk associated with each hazard was scored based on two factors; the severity of harm (if the hazard were realised) and the likelihood of occurrence of that harm. For each

of these factors the presence or otherwise of existing mitigation was considered. The criteria used for assessment is provided in Appendix A- The clinical risk matrix, evaluation and management process.

This enabled the initial risk score to be defined. Applying further recommendations led to the Clinical Risk Analysis Process, leading to each of the hazards been reassessed and ensuring that the residual risk ratings are accurate and justified.

Table 1 below outlines the number of identified hazards and their respective residual risk ratings following the initial risk score and by applying recommendations. These will continue to be evaluated and further mitigation will be applied as the risk management process dictates during the ongoing risk assessment.

Evaluation of initial level of risk of each identified hazard using pre-defined criteria.

Identification of hazards and risks is a continuous activity and occurs at all times in the product's lifecycle. Hazard identification has been conducted by the CSO and review by the CEO.

Residual Risk Ratings						
Application/Process	Risk Rating 1	Risk Rating 2	Risk Rating 3	Risk Rating 4	Risk Rating 5	**Totals**
Vitacam	**6**	**8**	**2**	**0**	**0**	**16**

Clinical Risk Control

Despite all risks associated with the product being broadly acceptable, it was agreed that the further risk control measures should be implemented. This is in line with the As Far As Possible (AFAP) approach. This method assesses the individual risk and how that may be controlled, to reduce the likelihood of it occurring through applying mitigations.

This principle is where DCB 0129 & DCB 0160 draws its foundation from.

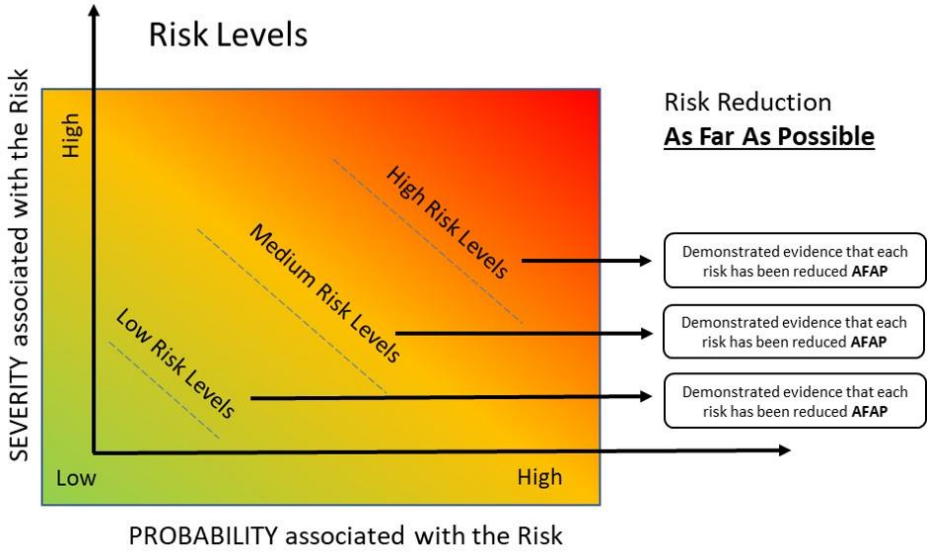


Figure 6 - As Far As Possible (AFAP) approach.

Hazard Log

This includes the following components:

- Hazard identification
- Description of patient safety consequences
- Explanation of hazard causes and contributory conditions
- Identification of existing mitigating controls
- Estimation of clinical risk
- Identification of participating personnel

The hazards were scored and then the residual risk scored. The hazards are transferable between Vitacam and the end users of the product, therefore these should be considered in each individual care setting and controls applied.

Hazard scorings:

The hazard scorings are intended to provide a baseline indication of the product safety risk reduction, provided both the 'manufacturer' NE Device SW and the deploying organisation have fully implemented the advised safety requirements (mitigation).

The scorings are caveated as follows:

- Provided all product design related mitigations are met, the initial risk rating scorings for this hazard are determined as indicated.
- Provided product deployment related mitigations are met, the residual risk rating scorings for this hazard are determined as indicated.

The scorings cannot be considered definitive for the deploying organisations without the local consideration of their own individual risk. It is expected that there will be 'localised' risk assessment based on the product and NHS requirements. This is dependent on end users conducting appropriate staff training, implementing changes to business processes and updating to operating procedures.

The Vitacam product team have collaborated with clinical safety experts and safety engineering consultants. They have established links with industry experts in order to provide clinical safety input representative to the risk the application presents and balanced by the commercial position of the company.

The hazard log can be found in Appendix C.

Hazards Overview

Top Level Hazard: Users of the Product inappropriately uses the product and views data either intentionally or unintentionally which leads to a clinical decision.
Resulting in: A clinical judgement being made on information presented by the product.
Effect: The user could base their decision and treatment on the information provided through the product. Missing, Incorrect or conflicting information could lead to patient harm or even death if the presented results in a user acting up on it.

Medical Device Regulatory Assessment

As Vitacam is a standalone software that meets the definition of a medical device it is considered an active medical device. As it is software intended to be used for medical purposes that perform these purposes without being part of a hardware medical device, it can also be referred to as Medical Device Software (MDSW). According to rule 10 of Directive 93/42/EEC (the MDD), active devices intended for monitoring of vital physiological processes are Class IIa medical devices.

Vitacam is classified as a IIa medical device. The classification was also checked according to the Medical Device Regulation 2017/745 (Annex VIII) and Medical Device Coordination Group's (MDCG) 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 –MDR.

This classification does not change under MDR. According to MDR 2017/745, Annex VIII Rule 11, software intended to monitor vital physiological processes is classified as class IIa, except where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

The product complies with the following standards:

- EN ISO 13485:2016 Medical devices --Quality management systems --Requirements for regulatory purposes
- SFS-EN ISO 14971:2019 Medical devices. Application of risk management to medical devices
- IEC 62366-1:2015 Medical devices –Part 1: Application of usability engineering to medical devices
- IEC 62304:2015 Medical device software –software life cycle processes
- SFS-EN ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied.

Quality Assurance & Configuration Control / Management

Vitacam operates a Quality Management System that is complimented by operational processes and the clinical risk management plan which is aligned to NHS clinical safety standards. All documentation used to support compliance positions are reviewed and approved by the Vitacam product team and NE Device SW including subject matter experts as required. Documentation is stored in the Clinical Risk Management File. Vitacam also have an Incident management process in situ as well as a business continuity plan and many internal policies.

The Vitacam product endures a quality assurance process, any documents created and held in relation to this product are approved by CEO and the clinical safety officer (where applicable) and stored in the clinical risk management file.

To support clinical safety activities undertaken during any deployment phases of a product, project or programme of work the following documentation will be required to form a part of the overall approval process:

- Product plan
- Clinical Risk Management Plan
- Test scripts with testing results
- Hazard log – reviewed and amended (where applicable)
- Any other assurance documentation
- Etc.,

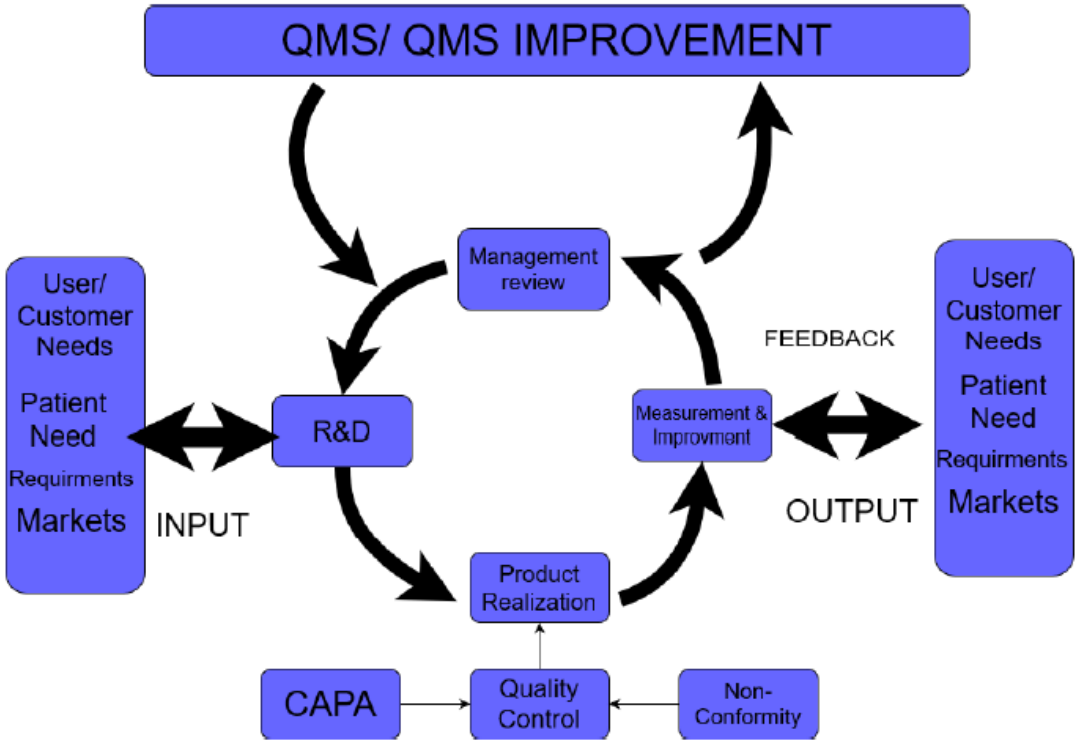
Go/ No Go decisions for releases are dependent upon a release checklist and release compliance with management process when changes are planned to be made to the Product this will be reflected in the clinical management plan. The product team work together to map the changes, record any issues and detail the fixes. An agile methodology has been adopted therefore, regular meetings are held when appropriate to discuss the changes and implementations planned.

The management review, Internal audits and Corrective and preventive actions (CAPA) are some of the methods used to ensure that both the operation and control of the processes are effective within the product.

Maintenance plan

NE Device SW maintain Vitacam software by handling feedback from customer and doing post market surveillance. All the Feedback from

customers are handled by customer care according to SOP-009 (Ref 19) and post market surveillance feedback is handled by the Quality manager. Feedback is always evaluated to against intended use and design outputs to determine that if feedback could consider as issue in software. All the issues are fed to problem resolution process for further analysis and prioritising according to chapter 6.1 project management process. NE Device SW will inform customer and regulatory authorities if software changes are substantially and any fixing which may take time.



The above shows the Quality Management System Process used for the Vitacam Product.

Summary Safety Statement

The Vitacam product is registered as a class IIa medical device with the MHRA. The product has already undergone thorough assessment for the classifications. NE Device SW currently has a thorough technical file for the product. This includes the required policy, process and SOP's. NE Device SW has a clear and well defined Quality Management System as well as other risk management processes and software design and deployment methods. The product has clear guidelines for use and recommendations in relation to cameras, patients and what may interfere with the results. It is intended to be used by professionals, whom must ensure they use their own judgement when assessing patients. The product has been through testing cycles and also user led research with proven results. (ref 23-25). End users can feedback to the manufacture using their Maintenance Plan and any issues identified reported. Using all the information which has been provided and assessed I am satisfied that the Vitacam product is safe for its intended use.

Recommendations and Assumptions.

- It is assumed that users will not use this application as an alternative to any clinical or professional medical advice or judgement.
- Standard Operating Procedures should be developed by end users which should include workflow process, Incident management aligned to the Vitacam process, Issue logging etc.
- Fall back Solution should be in situ in case the Product fails
- Care should be taken by the end users when selecting appropriate patients
- Usual vital signs process(s) should be adopted where a patient is not fit and well

- The System should be used in addition to clinical practice and usual processes should be used to obtain the relevant information required.
- Frontline Health and Care users will use this as a tool and continue to document patient information within their own primary clinical system and patient medical records.
- Any organisation deploying the system are responsible for the mandated Clinical Safety Standard DCB 0160.
- Incidents should be reported using local and agreed process and any relating to Vitacam reported to NE Device SW.
- End users should familiarise themselves with the intended use, limitations and recommendations for use.
- It is the individuals professional responsibility to ensure they use the product appropriately and within its remit.

Appendices

Appendix A

Hazard Assessment Matrices used.

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				

Table 6 Risk Acceptance Matrix

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

Table 7 Likelihood Definitions

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

	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term	Multiple
	Significant psychological trauma	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence	Single

Table 8 Severity Definitions

5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level
3	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	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

Table 9 Risk Acceptance definitions

Appendix B

Glossary of Terms

AFAP	As Far As Possible – The level risk acceptability criteria as per Clinical Safety Standards
Clinical Risk	Combination of the severity (consequence) and likelihood (probability) of harm to a patient and the likelihood of occurrence of that harm.
Clinical Risk Analysis	Systematic use of available information to identify and estimate a clinical risk.
Clinical Risk Control	Process in which decisions are made and measures implemented by which clinical risks are reduced to, or maintained within, specified levels.
Clinical Risk Estimation	Process used to assign values to the severity (consequence) of harm to a patient and the likelihood (probability) of occurrence of that harm.
Clinical Risk Evaluation	Process of comparing a clinical risk against given risk criteria to determine the acceptability of the clinical risk.
Clinical Risk Management (CRM)	Systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, and controlling clinical risk.
Clinical Safety	Freedom from unacceptable clinical risk to patients.
Clinical Safety Officer	NHS Digital accredited clinician responsible for ensuring the safety of the product through the application of clinical risk management as set-out in the NHS Digital DCB 0129 Standard requirements.
Clinical Safety Case Report (CSCR)	A report that presents the arguments and supporting evidence that provides a compelling, comprehensible, and valid case that a Product is safe for intended use.
Harm	Death, physical injury, psychological trauma and / or damage to the health or well-being of a patient.
Hazard	Potential source of harm to a patient.
Hazard Log	A mechanism for recording and communicating the on-going identification and resolution of hazards associated with a Product.
Initial Clinical Risk	The clinical risk derived during clinical risk estimation.
International Organisation for Standards (ISO)	The organisation that develops and publishes International Standards. Link at: https://www.iso.org/home.html
Intended Use	Use of the product in accordance with the specifications, instructions and information provided (the Manufacturer) to its clients for its intended use.
Likelihood (Probability)	Measure of the occurrence of harm.
Manufacturer	Being Vitacam, with responsibility for the design, manufacture, packaging, or labelling of a Product, assembling of such a Product, or adapting a

	Product before it is placed on the market and / or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.
Patient Safety	Freedom from harm to the patient.
Residual Clinical Risk	Clinical risk remaining after the application of risk control measures.
Severity (Consequence)	Measure of the possible consequences of a hazard.

Appendix C

Hazard Log

Vitacam Hazard Log V1.3 .xlsx