Good Boost Wellbeing Limited

Clinical Risk Management Plan (#GBP0027)

< Good Boost apps & software >

Last updated: 16/12/2025
Next review due: 16/12/2026

Clinical Safety Officer (CSO): Ben Wilkins

Contents

SECTION 0.0 – References

Reference	Title	Description
1	DCB (0129) Standard Specification	DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification
2	Back up and restore Policy	GBP021 – Good Boost Back-up and Restore Policy.
3	Business Continuity Plan	GBP024 – Good Boost Business Continuity Plan.
4	Data Security and Protection Toolkit	NHS DSPT: https://www.dsptoolkit.nhs.uk/
5	Medical Device Directive	MHRA Medical Device Directive MDD, under biomechanical function analysis/rehabilitation software, reference number 8728
6	MDD technical document and Annex 4	Submitted to MHRA under under biomechanical function analysis/rehabilitation software, reference number 8728
7	Incident Management Process at Good Boost	GBP0025 – Good Boost incidence management process.
8	CSO Competency Evidence	CSO competency evidence for Ben Wilkins.

SECTION 1.0 – Overview

1.0 Overview

This document outlines the procedures, reporting and requirements completed by Good Boost Wellbeing Limited (GBW) to adhere to the requirements presented in the DCB0129. This documents covers the risk analysis, risk evaluation and risk control for GBW's medical-apps and technology services. An overview of the process is displayed below in *Figure 1*.

Potential hazards were identified and mitigation plans adopted and implemented. Al hazards were identified through risk analysis. The consultation process and risk identification, evaluation and control steps involved a multidisciplinary team approach including technical, engineering, clinical and operational staff. This culminates in three deliverables:

- Clinical Risk Management Plan ("The Plan") (this document);
- Hazzard log:
- Clinical Safety Case Report ("the Safety Case")

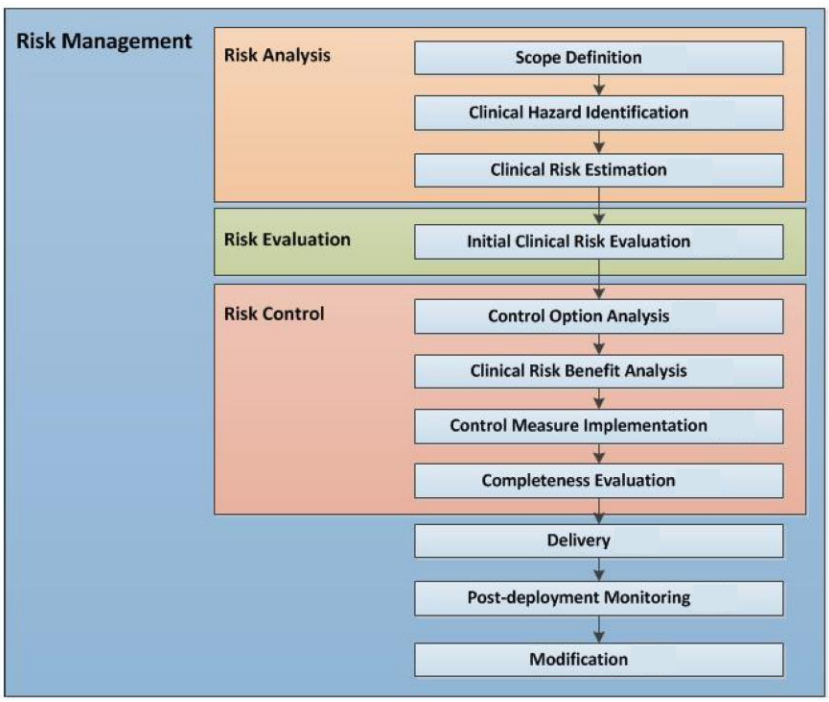


***Figure 1**: Clinical Risk Management Process*
Clinical Risk Management: It's application in the manufacture of Health IT Systems – Specification. NHS, 2018 V4.2

1.1 Scope

The Scope of this Clinical Risk Management plan is for the Good Boost exercise app as defined in Good Boost registration in the Medicines and Health Regulatory Authorities (MHRA) Class 1 Medical Device, reference number 8728 under 'Biomechanical function analysis/rehabilitation'.

1.2 Senior Management Responsibilities

In implementing the clinical risk management process for a given deployment, Senior Management must:

- make available sufficient resources
- assign competent personnel (see section 2.4) from each of the specialist areas that are involved in developing and assuring the Health IT System
- nominate a Clinical Safety Officer (CSO).

Senior Management must ensure that appropriate levels of authorisation for the Health IT System and its safety documentation are defined in the Clinical Risk Management Plan.

1.3 Clinical Safety Officer

Good Boost's Clinical Safety Officer (CSO) is a registered health care professional with sufficient experience and training to conduct and complete the Clinical Risk Management process and monitoring.

The role of a Clinical Safety Officer (CSO) is to review the Clinical Safety Case using his/her clinical experience to judge the appropriateness and effectiveness of the risk management strategies and mitigating actions. The CSO should monitor the execution of the Clinical Safety Case and ensure that clinical safety obligations are being discharged.

1.4 Competencies of Personnel

Personnel must have the knowledge, experience and competencies appropriate to undertaking the clinical risk management tasks assigned to them. Competency and experience records for the personnel involved in performing the clinical risk tasks must be maintained.

1.5 Regular Clinical Risk Management Process Review

This process review is repeated every 6-months and upon the release of any new feature and/or function that changes the intended use and/or audience for the medical device.

1.6 Product Description

Good Boost is a social enterprise that develops digital technology for the purpose of personalised exercise on land and in water that is suitable for people living with musculoskeletal conditions and wider multi-morbidity. The digital device is a native app for iOS and Android and a self-management app to promote exercise that reflects clinical guidelines, research evidence and clinical best practice for people with musculoskeletal conditions and wider multimorbidity. The digital service also provides exercise sessions for people without a musculoskeletal conditions and wider multi-morbidity and seeking exercise activity suggestions for a core training preference (i.e. strength training, aerobic training, neuromuscular training, stretching, relaxation exercises).

Good Boost's mission is:

Creating solutions to better treat, manage and prevent musculoskeletal conditions and wider multi-morbidity through world-leading technology: transforming any space into a therapeutic place.

We want everyone to love looking after their health by moving more, having fun and feeling better.

1.7 System Description

1.7.1 Overview and intended use

The system consists of five components:

1. A native app that is user facing which allow individual to register their details and follow personalised exercises suggested by Good Boost's AI exercise selection system.
2. The Good Boost AI exercise selection system
3. A web-portal for public venues delivering Good Boost that provide a data dashboard overview of the number of users at their venue and aggregate statistics (no individual/personal user data is displayed/accessible)

The service is access by users via a native app either in a community settings (i.e. a leisure centre) on a waterproof tablet computer located in a venue or with their own personal device. Once registered a user can choose whether to follow a exercise sessions from the exercise library (pre-made exercise sessions that are generic, not personalised) or a personalised sessions that includes exercises suggested based on their registered details.

Users have the option to register relevant health details and details about a body part with a musculoskeletal condition. Users do not need to have a musculoskeletal diagnosis to register a body part. Users can register with no musculoskeletal condition but live with other long term health conditions.

The AI exercise suggestion system does not make an diagnosis regarding a users registration details. The system has been designed to filter exercises and suggest exercises based on clinical guidelines, published research and best-clinical practice that are safe and appropriate for the user.

The user can then use the app to follow an exercise programme with instruction (both written and animation videos). User can provide feedback after their exercise session. This include how satisfied they were with the exercise or any difficulties performing the movement. This information is used to adapt the users exercise suggestion for their next session in an on-going feedback loop.

The exercises provided by Good boost include exercises for aqua exercise, land based exercise and ante-natal exercise. There are additional screening and red flag safety netting processes dependant on the exercise environment or exercise/population type.

Further details on the technology is listed in the Annex 4 technical document (*Reference document 6*).

1.7.2 Venues and users supported

Good Boost is designed to be used in community spaces such as leisure centres, retirement villages and gyms in addition to be used in a residential setting. Our community delivery focus is to enable the delivery of personalised exercise programmes in communal spaces that are locally accessible. Additionally, providing the service at these venues makes personalised exercise accessible and affordable, overcoming health inequalities and digital inequalities.

At these venues, Good Boost is pre-installed on waterproof tablet computers and set-up at the venue. Every venues completed a set-up and onboarding process to ensure the tablets computer are correctly connected to a data connection. The venues are provided with certified training, accredited by Active IQ, to be certified to facilitate Good Boost session that safe.

User can self-refer to venues delivering Good Boost. Some venues connect with local social prescribing and primary care services to be part of an integrated community health network.

The principles users of Good Boost app are:
- People living with a musculoskeletal condition(s) who are aged 18 or over
- People without a musculoskeletal diagnosis, but seeking personalised exercise and aged 18 or over

At these venues, the manager or responsible person is provided with a Data Dashboard to review aggregated data of service utilisation at the venue.

The principle users of the venue Data Dashboard are:
- Venue manager or appointed person at the venue (i.e senior fitness instructor)

1.7.3 Clinical Dependency of the system

Should the system fail to operate as intended, a user may receive an exercise suggestion that is not suitable for them or may not receive any exercise suggestion at all. As a result, a user may cause injury to themselves by performing an unsuitable movement or fail to perform any exercise, resulting in inactivity.

The A.I exercise suggestion system has been designed to follow clinical guidelines, published research and best clinical practice to recommend safe and appropriate exercises. On through an on-going feedback loop, work towards an optimal exercise programme personalised for every user.

The risk of an unsuitable exercise being recommended is explored in the Clinical Risk Review of this Plan.

1.7.4 Technology and architecture

The Health IT system is the Good Boost app, a mobile app with a cloud based back end and NOSQL database. The mobile app can be used on phone and tablet device.

The system is written using JavaScript, particularly NodeJS and ExpressJS as a framework for a back end and React Native and React for the front end.

The data is stored in a MongoDB (NOSQL) database which has replica set.

All passwords are encrypted in the database. All parameters are encrypted in transit over HTTPS. All data is stored on an encrypted disk at rest. Good Boost follows it's policies and protocols to restrict system access to personnel who require it to minimise unnecessary data access. All personal follow the requirements of the Password Policy and Working from Home policy that directs good practice to minimise system compromise.

All data-entry fields are masked to resist the entry of programming code. All parameter data received by application files is treated to strip out tags and characters likely to be used in programming script, before the data is used internally. All multi step database transactions are contained within a single transaction to ensure that changes are automatic.

The Company is compliant with NHS Digital's Data Security and Protection Toolkit (Ref.4).

The servers are hosted by AWS, a reputable hosting provider with experience in the healthcare domain. The architecture is designed to provide a high availability service with a minimum uptime percentage of 99.95% at all times during the service provision time in any month.

Maintenance activity that affects the availability of the solution is performed outside of core working hours. The hosting provider keeps scheduled downtime to a minimum and aims to provide 7 days' notice or the maximum period of notice practicable. During service provision time, the hosting provider proactively monitors the operational state of the network to detect faults. As we use cloud servers, we do not have any equipment that requires an Uninterruptible Power Supply (UPS) for the continual operation of our technology and systems.

The performance of the system is monitored by the Company in live service to ensure it remains performant.

Back up procedures are in place to ensure the source code in the Good Boost application server and the data in the database are backed-up are automatically backed up with replica instances in the cloud system with monthly physical backups. by the hosting provider and stored securely off-site. Routine restores are scheduled periodically and performed to confirm the restore capability works appropriately. Backup and restore procedures are documented in the Company's Back Up and Restore Policy (Ref. 3). The Company also has a Business Continuity Plan (Ref. 4) in place which describes how the Company can recover from an incident that threatens to disrupt its normal operations.

1.7.5 Regulatory position

Good Boost has been evaluated against the scope of the MHRA Medical Device Directive. After undertaking this exercise, it was determined this product is borderline in the requirements of the directive. Following communication with the MHRA, they have also confirmed it is borderline. As a result, we have continued to follow the requirements of the MHRA Medical Device Directive (Ref. 5) to ensure Good Boost's medical device (the Good Boost app) is held to regulatory standards.

Good Boost has been reviewed and certified by NHS Digital Technology Assessment Criteria
Good Boost has been certified by ORCHA medical-app
Good Boost has completed real-word evaluations academic research to evaluate effectiveness and safety.

Details are available here https://www.goodboost.ai/research

1.8 Historical Operation

Good Boost has been delivering a digital exercise service for 7.5 years. The system has supported over 25,000 unique individuals for more than 250,000 exercise sessions. This has been delivered as both a native app pre-installed on waterproof tablets in community leisure centres (300 venues to date) and as a native iOS and Android app for mobile device that has a direct download for use at home.

1.9 Assumptions and Constraints

- Good Boost users are required to complete red flag screening before any personalised exercise session suggested by Good boost system. Users that are unsuitable for physical activity are informed to speak with their physician or relevant health care professional before undertaking any exercise.
- The exercise suggestions are dependant on the user providing accurate, honest and up-to-date information. This is explained to the user upon registration
- Good Boost is not responsible or accountable for the environment where the exercise takes place. For community venues, we provide them with template risk assessment so they can review the suitability and safety of any exercise space. For users in a private space, we inform the user that it is essential they make sure their environment is safe and suitable for exercise.
- Good Boost provides the options and preference before any exercise session for the user to select what training position they are comfortable in (i.e. sitting, standing laying down / shallow-water, deep-water) and what exercise equipment they are happy to use so that the user has control over the training positions and equipment they feel comfortable and competent to perform and use.

1.10 Glossary of Terms

Term	Definition
Clinical Safety Officer (previously referred to as Responsible Person)	Person in a Manufacturer's organisation responsible for ensuring the safety of a Health IT System in that organisation through the application of clinical risk management.
Clinical risk	Combination of the severity 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 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 of harm to a patient and the likelihood 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	Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling clinical risk.
Clinical Risk Management File	Repository of all records and other documents that are produced by the clinical risk management process.
Clinical Risk Management Plan	A plan which documents how the Manufacturer will conduct clinical risk management of a Health IT System.
Clinical Risk Management Process	A set of interrelated or interacting activities, defined by the Manufacturer, to meet the requirements of this standard with the objective of ensuring clinical safety in respect to the development and modification of a Health IT System.
Clinical safety	Freedom from unacceptable clinical risk to patients.
Clinical Safety Case	Accumulation and organisation of product and business process documentation and supporting evidence, through the lifecycle of a Health IT System.
Clinical Safety Case Report	A Report that presents the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at a defined point in a Health IT System's lifecycle.
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 Health IT System.
Health Organisation	Organisation within which a Health IT System is deployed or used for a healthcare purpose.
Health IT System	Product used to provide electronic information for health or social care purposes. The product may be hardware, software or a combination.
Initial clinical risk	The clinical risk derived during clinical risk estimation taking into consideration any retained risk control measures.

1.10 Glossary of Terms

Term	Definition
Intended use	Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer to customers.
Issue	The process associated with the authoring of a document. This process includes: reviewing, approval and configuration control.
Likelihood	Measure of the occurrence of harm.
Lifecycle	All phases in the life of a Health IT System, from the initial conception to final decommissioning and disposal.
Manufacturer	Person or organisation with responsibility for the design, manufacture, packaging or labelling of a Health IT System, assembling a system, or adapting a Health IT System 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	A person who is the recipient of healthcare.
Patient safety	Freedom from harm to the patient.
Post-deployment	That part of the lifecycle of a Health IT System after it has been manufactured, released, deployed and is ready for use by the Health Organisation.
Procedure	Specified way to carry out an activity or a process.
Process	Set of interrelated or interacting activities which transform inputs into outputs.
Release	A specific configuration of a Health IT System delivered to a Health Organisation by the Manufacturer as a result of the introduction of new or modified functionality.
Residual clinical risk	Clinical risk remaining after the application of risk control measures.
Safety incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.
Safety Incident Management Log	Tool to record the reporting, management and resolution of safety incidents associated with a Health IT System.
Severity	Measure of the possible consequences of a hazard.
Third party product	A product that is produced by another organisation and not by the Health IT System manufacturer. Examples include operating systems, library code, database and application servers and network components.
Top Management	Person or group of people who direct(s) and control(s) an organisation and has overall accountability for a Health IT System.

2.0 – Clinical Risk Documents

2.0 Clinical Risk Documents

This document acts as the primary document for the overall identification, evaluation and mitigation of Clinical Risk in the organisation.

Additional documents include:

- Clinical Risk Management File
- Hazzard Logs
- Clinical Risk Management Plan
- Clinical Safety Case
- Clinical Safety Reports
- Safety Incident Management Log
- Red Flag Safety Netting
- Clinical Guidelines and Research evaluation
- Internal Audits
- External Audits
- Retrospective observational data

2.1 Clinical Risk Management Plan

Good Boost will product a Clinical Risk Management Plan, which will includes risk acceptability criteria, for the medical device.

The Good Boost CSO must approve the Clinical Risk Management Plan for the medical device to be used by members of the public.

If the nature of the medical device changes, or key people change, during the development or modification of the technology, then the Clinical Risk Management Plan will be updated.

The Clinical Risk Management will be maintained throughout the life medical device and reviewed 6-monthly.

2.2 Hazzard Log

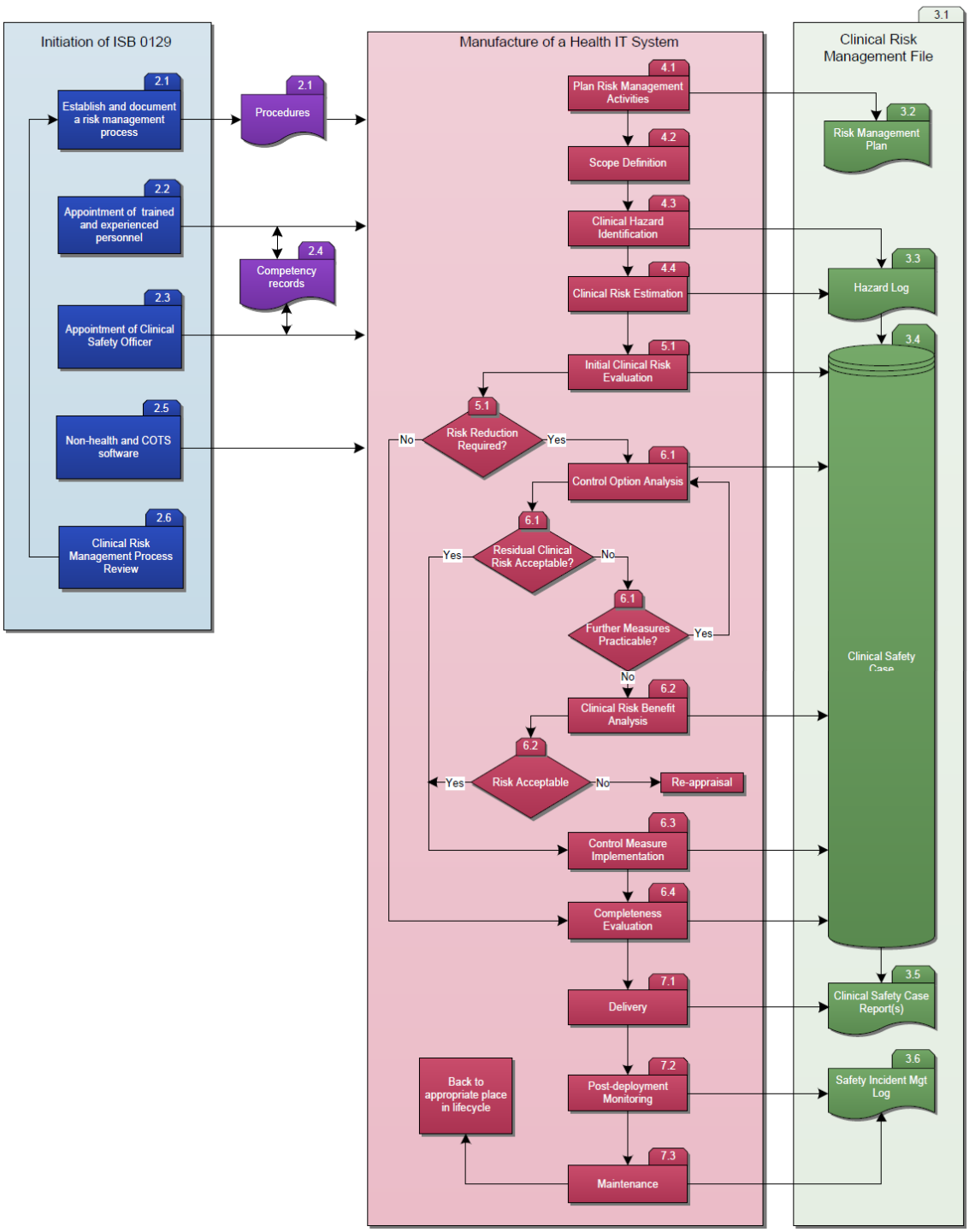
Good Boost will report any hazards related to the medical device in the Hazzard Log.

The CSO will review and approved each version of the Hazzard Log.

The issued Hazard Log will accompany the Clinical Safety Case Report.

2.0 – Clinical Risk Documents

2.0 Clinical Risk Documents



2.3 – Clinical Safety Case

A Clinical Safety case is a structured rationale which is supported by a body of relevant evidence that provides compelling, comprehensible and valid case that a system is safe for it's give application in a given operative environment. The Clinical Safety Case provides an explanation of how the supporting evidence can be interpreted as indicating that the Good Boost app and system exhibits an adequate degree of safety, e.g. by demonstrating compliance with requirements or sufficient mitigation of identified hazards

A Clinical Safety Case evolves during the lifecycle of the Good Boost app and system, and is to be reviewed to ensure that it continues to provide sufficient confidence in the safety of the Good Boost medical device.

The safety cases demonstrate that all foreseeable hazards have been characterised, documented and evaluated, with each hazard being either judged to be acceptable or mitigated as far as possible, in line with NHS safety requirements

This document outlines the process and the rationale and justification of the safety of Good Boost medical technology and where there is any risk, where this is acceptable risk where the benefits outweigh the risk.

The following have been undertaken and considered:

- a complete understanding of the medical device system to be deployed and used
- an appropriate awareness of clinical risk management
- an awareness of how clinical risk management aligns with any wider governance processes
- a fully defined clinical risk assessment process which incorporates the application of recognised and rigorous methodologies
- a risk assessment, carried out completely and competently
- the implementation of any required clinical risk control measures
- any residual clinical risks appropriately documented
- appropriate lifecycle management is in place.

2.4 – Clinical Safety Case Reports

A clinical safety case report will be produced for each lifestyle phase of the medical technology. This includes a new Clinical Safety Case for of development or feature release of a technology that sufficiently changes the clinical services delivered by the technology. All technology is subject to a six-monthly review over the lifecycle of the medical technology.

Every Clinical Safety Case Report must be reviewed and approved by Good Boost CSO.

Good Boost will make available the Clinical Safety Case Report to any organisation that required the documentation and process of Good Boost clinical safety governance and mechanisms.

2.5 – Safety Incident Management Log

Good Boost will maintain a Safety Incident Management Process and Log (Ref 7) alongside the Clinical Safety Case Report.

3.0 – Clinical Risk Analysis

In accordance with the clinical risk management process a clinical risk analysis has been undertaken to understands the risks associated with use of Good Boost's digital exercise app. Section 3.0 described the process and methodology in identifying and analysing risks alongside the estimation of the relative risk to users.

3.1 – Clinical Risk Analysis Process

The clinical risk analysis process involves three key steps.

1. Identification of potential risks to users
2. Analysis and scoring of risks
3. Estimation of the clinical risk to users

This process involves a multi-disciplinary group of clinical, engineering and operational staff members that is led by the CSO. The multi-disciplinary process for risk identification, analysis and estimation is to ensure maximum likelihood of identifying risk and collective analysis and evaluation.

The extent of each clinical risk analysis must be proportional to the scale, complexity and level of clinical risk association with the exercise technology and user of the technology.

3.2 – Identification of Hazards to Users

The known and foreseeable hazard to users with respect to the intended use of the digital exercise system in both normal and fault conditions will be identified for analysis and risk estimation.

The process of risk identification follows best practice as recommended by the Health and Safety Executive.

The potential hazards to users in both normal and fault conditions are listed in *Table 3.1*

Table 3.1

System Operating at Normal

1. Harm due to over exercise following a personalised exercise programme
2. Death due to over exercise following a personalised exercise programme
3. Harm due to correct completion of a correct exercise
4. Harm due to incorrect completion of a correct exercise
5. Harm due to correct completion of an incorrect exercise
6. Harm due to incorrect completion of an incorrect exercise
7. Injury due to trip or fall while exercise
8. Death due to trip or fall while exercise
9. Injury due to drowning
10. Death due to drowning
11. Harm due to pregnancy related factor
12. Psychological harm due to viewing user or host curated content

Possible underlying causes:

- User has underlying health conditions that present a risk to any exercise
- User has an underlying health condition that presents a risk to aerobic exercise
- User performs incorrect exercise to exercise shown
- User exercises in an environment with trip hazards
- User exercises in a position they are not confident to exercise in
- User performs an exercise with unsuitable exercise equipment
- User enters incorrect details into the app creating unsuitable exercises
- User progresses in exercise intensity faster that their physiological capacity

Table 3.1

System Operating at Fault

1. Failure of the device to present any exercise recommendation
2. Harm due to performing an exercise that is incorrect personalised for the user
3. Death due to performing an exercise that is incorrectly personalised for the user
4. Harm due to failed pre-screening of the user
5. Death due to failed pre-screening of the user
6. Harm due to failure to send user data to the Good Boost service, resulting in incorrect exercises performed
7. Death due to failure to send use data to the Good Boost server resulting in incorrect exercises performed

Possible underlying causes:

Pre-screening/Red flag safety netting fails

App fails/crashes when collecting user post-exercise feedback

3.3 – Estimation of Clinical Risk

Estimation of clinical risk uses criteria specified below that includes:

- Severity of the hazard
- Likelihood of the hazard
- The resulting clinical risk

To estimate the clinical risk a Clinical Risk Matrix has been applied to quantity the total risk and the risk acceptability definitions suitably evaluate and respond to each risk.

The Clinical Risk Matrix and scoring criteria are displayed below.

Table 3.1 - Clinical Risk Matrix Table

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 3.2 - Likelihood Classification

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible: reasonable 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 3.3 - Severity Classification

Severity Category	Interpretation
Catastrophic	The vulnerability is exposed and exploitable, and it's exploitation could result in severe impacts and of loss of technology system(s) and severe business interruption or failure.
Major	The vulnerability is of moderate concern, based on the exposure of the vulnerability and ease of exploitation could result in considerable exploitation and significant and long-term failure of technology system(s). Relevant controls or remediation is minimally implemented and have limited effectiveness
Considerable	The vulnerability is of moderate concern, based on the exposure of the vulnerability and ease of exploitation could result in moderate exploitation and moderate or temporary failure of technology system(s). Relevant controls or remediation is partially implemented and somewhat effective
Significant	The vulnerability is of minor concern, but effectiveness of remediation could be improved
Minor	The vulnerability is not of concern. Relevant controls or other remediation is implemented, assessed and effective

Table 3.4 - Risk Matrix Score Acceptability Definitions

Overall Risk Matrix Score	Risk Definition	Risk Acceptability > Action
5	Very high	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
4	High	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
3	Significant	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 or impossible without introducing alternative risks.
2	Moderate	Tolerable where further risk reduction is not practical or impractical without introducing alternative risks.
1	Low	Acceptable, no further action required

3.3 – Estimation of Clinical Risk

Following the severity and likelihood classification methodology, each identified risk has been classified with a risk acceptability definition.

Normal functioning of the device:
(N = normal, + # = risk ref number)

Table 3.5 – Normal functioning estimation of clinical risk

Risk	Severity	Likelihood	Risk Definition
N1. Harm due to over exercising while following a personalised exercise	Significant	Medium	2: Moderate
N2. Death due to over exercising while following a personalised exercise	Major	Very Low	2: Moderate
N3. Harm due to correct completion of a correct exercise	Minor	Medium	2: Moderate
N4. Harm due to incorrect completion of a correct exercise	Significant	Medium	2: Moderate
N5. Harm due to correct completion of an incorrect exercise	Significant	Medium	2: Moderate
N6. Harm due to incorrect completion of an incorrect exercise	Significant	Medium	2: Moderate
N7. Harm due to trip or fall while exercising	Considerable	Medium	3: Significant
N8. Death due to trip or fall while exercising	Major	Medium	3: Significant
N9. Harm due to drowning	Considerable	Low	2: Moderate
N10. Death due to drowning	Major	Low	3: Significant
N11. Harm due to pregnancy related factor(s)	Significant	Medium	2. Moderate
N12. Psychological harm due to viewing user or host curated content	Significant	Medium	2. Moderate

3.3 – Estimation of Clinical Risk

Fault functioning of the device:
Fault function is defined as the one or more of the following fails to work as expected.
The Good boost AI logic creates an output that is not as expected,
The output generated by the device is incorrect during transmission
The application presents the exercise recommendations as expected

(F = faulty, + # = risk ref number)

Table 3.5 – Fault functioning estimation of clinical risk

Risk	Severity	Likelihood	Risk Definition
F1. Failure of the device to present any exercise recommendation.	Minor	Medium	2. Moderate
F2. Harm due to performing an exercise that is incorrectly personalised for the user	Significant	Low	2: Moderate
F3. Death due to performing an exercise that is incorrectly personalised for the user	Major	Very Low	2: Moderate
F4. Harm due to failed pre-screening of the user	Considerable	Very low	2: Moderate
F5. Death due to failed pre-screening of the user	Major	Very Low	2: Moderate
F6. Harm due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	Considerable	Low	2: Moderate
F7. Death due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	Major	Very Low	3: Significant

4.0 – Clinical Risk Evaluation

Following risk identification and analysis and evaluation will take place to determine whether the clinical risk is acceptable as defined in the criteria defined in the Clinical Risk Management Plan.

Table 4.1 - Normal functioning of the device risk definition action

Risk	Risk Definition	Action
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N2. Death due to over exercising while following a personalised exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N3. Harm due to correct completion of a correct exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N4. Harm due to incorrect completion of a correct exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N5. Harm due to correct completion of an incorrect exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N6. Harm due to incorrect completion of an incorrect exercise	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N7. Harm due to trip or fall while exercising	3: Significant	Unacceptable 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 or impossible without introducing alternate risks
N8. Death due to trip or fall while exercising	3: Significant	Unacceptable 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 or impossible without introducing alternate risks
N9. Harm due to drowning	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks

4.0 – Clinical Risk Evaluation

Following risk identification and analysis and evaluation will take place to determine whether the clinical risk is acceptable as defined in the criteria defined in the Clinical Risk Management Plan.

Normal functioning of the device:

Risk	Risk Definition	Action
N10. Death due to drowning	3: Significant	Unacceptable 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 or impossible without introducing alternate risks
N11. Harm due to pregnancy related factor(s)	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
N12. Psychological harm due to viewing user or host curated content	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks

4.0 – Clinical Risk Evaluation

Following risk identification and analysis and evaluation will take place to determine whether the clinical risk is acceptable as defined in the criteria defined in the Clinical Risk Management Plan.

Table 4.2 – Fault functioning of the device risk definition action

Risk	Risk Definition	Action
F1. Failure of the device to present any exercise recommendation.	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F2. Harm due to performing an exercise that is incorrectly personalised for the user	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F3. Death due to performing an exercise that is incorrectly personalised for the user	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F4. Harm due to failed pre-screening of the user	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F5. Death due to failed pre-screening of the user	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F6. Harm due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	2: Moderate	Tolerable where further risk reduction is not practical or impossible without introduction alternative risks
F7. Death due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	3: Significant	Unacceptable 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 or impossible without introducing alternate risks

The Clinical Risk Evaluation has identified thirteen moderate risks that require review and controls and four significant risks that require review and controls.

The controls, actions and processes to mitigate risk will be presented in **section 5.0.**

5.0 – Clinical Risk Control

Clinical Risk Control is the combination of the ‘Analysis-Risk-Control’ process. During this process, any risk identified that have unacceptable levels of clinical risk must have an action and monitoring plan to reduce and where possible remove unacceptable risk.

The process of Clinical Risk Control includes:
Clinical Risk Control Analysis: analysis of the measures for each identified risk to reduce risk

Post Control Risk-Analysis: analysis of the impact the controls have on mitigating risk and newly assessed severity, likelihood and risk definition.

Clinical Risk-Benefit Analysis: analysis where the clinical benefit outweighs the risk where further risk control is not practical or possible

Implementation of Clinical Risk Control Measures: the actions and process to implement the clinical risk control measures and process of monitoring

Completeness of Clinical Risk Control Measures: ensuring that the clinical risk from all identified hazard have been considered and accepted.

5.1 – Clinical Risk Control Analysis

Each of the identified risks for the medical device in normal and fault state will be analysed to identify the appropriate control measures to reduce the risk.

Normal functioning of the device:

Normal function is defined as the Good boost AI logic works as expected, the output generated by the device is correct and transmitted without change to the application and the application presents the exercise recommendations as expected

Table 5.1 – Identified Risk and Controls to Mitigate Risk for Normal Functioning

Risk	Risk Definition	Cause	Controls
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	**1. User has a medical condition limiting tolerance to exercise**	**1. Active solutions**. 1. All users are screen initially for known main medical risks to exercise and are advised to discuss with a HCP before starting a good Boost exercise session pop-up warnings. 2. There is a medical screen before starting and GB session, which can also be updated at any point. These re-iterate the warnings plus severity of cardiorespiratory based limitations are asked according to gold standard PROM's and warnings are given accordingly on symptom severity 2**. Future solutions** 1. Before each session a pop-up advising condition specific safety advises e.g. ensure GTN or inhaler is within easy reach or drink/food for diabetic 2. Condition specific exercise programmes that have MSK condition integrated into the creation
		2. Training session is too long in duration	**1. Active solutions** 1. User choses the duration of training they feel they would like to do from 10-60 minutes

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	**2. Training session is too long in duration**	**2. Future solutions** 1. Based on data provided, the app would recommend a certain duration and explain why but would not prevent user using the exercise sessions as they prefer.
		3. Training session is too intensive	**1. Active solutions** 1. Exercise difficulty is controlled by the functional limitations reported by the use. 2. User can request an easier session compared to previous session, but requires a previous session to have been completed 3. User can skip or pause exercises if they dont like them or need a longer rest. **2. Future solutions** 1. AI adjusts the initial programme to a lower intensity 2. Pop-up advising user not to exceed a level of pervieved training intensity (RPE 1-10) according to guidelines 3. If sever symptoms advise on session duration selection and short session to start off with. 4. AI looks at reported RPE after last session as well as other post previous session and pre-current session feedback and controls next session intensity if exceeds expected intensity

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	**3. Training session is too intensive**	5. Improve education on app functionalities and move control to users choice of how much of the recommended programme they complete 6. Session intensity will be adpated according to reported current level of physical activity based on the Interation physical activity questionniare (iPAQ)
		4. User is not expecting post exercise sensations e.g. pain	**1. Active solutions** 1. Post-training messages to inform post training Delyed muscle soreness, short term increase in pain or fatigue are nomal **2. Future solutions** 1. Increase exercise pedagogy in small bite sizes during use of app and whole GB system 2. Develop a FAQ or even chat bot to discuss post exercise pain and assess and re-assure everything is okay. In extreme case recommend going to see and HCP. The difficulty is that many people, especially those with persistent pain, have a multifactorial cause to their pain (Biopsychosocial) and therefore direct cause and effect can be made between exercise and symptoms alone

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	**5. Exercises recommended are too intensive for functional capacity of the user**	**1. Active solutions** 1. Exercise are graded according to level of demand to complete and this is matched with the severity of symptoms and functional limitation reported by user prior to session 2. Internal and external audits of output to match expert expectations 3. User feedback used to improve accuracy of exercise **2. Future solutions** 1. None currently highlighted
N2. Death due to over exercising while following a personalised exercise	2: Moderate	**1. As above**	As above

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N3. Harm due to correct completion of a correct exercise	2: Moderate	**1. Animation may show a movement with range not yet possible for user. Impossible to match the exact ability of user to animation.**	**1. Active solutions** 1. None **2. Future solutions** 1. Warning sign in the app, “Move as you feel comfortable, the animation is just a guide”
N4. Harm due to incorrect completion of a correct exercise	2: Moderate	**1. Animation is unclear**	**1. Active Solutions** 1. Animations are reviewed by the whole teach and approved be fore uploading (new implementation) 2. Animations are reviewed by external reviewers, users and stakeholder and updated as necessary 3. Each exercise has a short and long description for the user to read. Short shows main safety points and how to complete the exercise. Long description has more detail as needed. 4. Employed our own animator to re-do animation, check with users and internal QA and then replace in shortest time frame possible **2. Future solutions** 1. None currently highlighted

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N4. Harm due to incorrect completion of a correct exercise	2: Moderate	**2. Animation is correct but difficult for user group**	**1. Active solutions** 1. Animations are developed to show a ”simplified movement with main movements highlighted”. User is able to imagine themselves doing this exercise 2. User can dislike the exercise so it has lower chance of appearing next session 3. User can select easier or harder exercises compared to previous session **2. Future solutions** 1. “Move as you feel comfortable, the animation is just a guide”
		3. Description is incorrect for the movement	**1. Active Solutions** 1. Descriptions are reviewed by the each team and approved before uploading (new implementation) 2. Descriptions are reviewed by external reviewers, users and stakeholder and updated as necessary **2. Future solutions** 1. None currently highlighted

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N5. Harm due to correct completion of an incorrect exercise; The equivalent is the AI gives them the wrong exercise	2: Moderate	**1. Data enetered incorectly by user**	**1. Active solutions** 1. All questions have been developed with peer review for understanding questions. Using Lay terms and not medical terms throughout the system (ongoing) 2. Both written and visual guides are used in questions 3. User has the ability to update the data for all the data used to create their exercises 4. Data cannot be missing in a working system because the app does not allow progression unless and answer to all questions is provided 5. On going discussion with users about question clarity 6. Information buttons with specific information for difficult questions with extra information is provided **2. Future solutions** 1. Improve dialogue between users and the front end application
		2. The system selects exercises that are too demanding for the user	**1. Active solutions** 1. Demand of exercises are controlled by using user data to estimate severity symptoms and functional limitations and match to exercises (excluding exercise too demanding based) 2. Internal reviews of exercise selected with experts employed by the company

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N5. Harm due to correct completion of an incorrect exercise: The equivalent is the AI gives them the wrong exercise	2: Moderate	**2. The system selects exercises that are too demanding for the user**	3. External review of outputs with experts in field of exercise prescription. All new solutions/products reviewed before distribution. Yearly reviews for previoulys approved solutions 4. User can request easier exercises compaared to previous session 5. User can ”dislike” and ”like” exercises in recommended session´s thus decreaseing or increasing likihood of getting that exercise, respectively 6. All exercise given risk falgs (low, moderate, high) for body parts and are excluded under different clinical situations i.e. Severe symtptoms or acute pain onset) 7. Refresh button so user can change the whole programme prior to start (with make easier/harder option) **Future solutions** 1. Machine learning to take over current logic to improve accuracy
		3. The system selects the incorrect exercise for the users weightbearing ability	**1. Active Solutions** 1. Weightbearing questions are asked during registration 2. Weightbearing data can be updated at anytime by the user to reflect changes 3. Weightbearing logic has been excessively test before implementation 4. If user reports limited weightbearing they are recommended to consult a HCP for advise

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N5. Harm due to correct completion of an incorrect exercise: The equivalent is the AI gives them the wrong exercise	2: Moderate	**3. The system selects the incorrect exercise for the users weightbearing ability**	5. User selects, in land, the training position they would like to train in 6. Training positions that expose the user to weightbearing above there reported limits are blocked and therefore add an additional safety barrier
		4. The exercises require range of motion the user either can't or should not perform	**1. Active Solutions** 1. If user responds they have a movement restriction they are advised to consult their HCP and use the expert area until unlimited movement is facilitated 2. If the user has severe pain or and acute injury, exercises that require extreme range of motion or high loading of the joint are excluded. **2. Future solutions** 1. Use more specific question when there is a movement restriction to the type and direction of limitation and link to safe exercises 2. Use Computer vision to estimate actual functional range user has and match to exercises.
		5. User registers two body parts but selects to train the body part with less severe symptoms or higher weightbearing status	**1. Active solutions** 1. The risk ratings from the user most severely affect body are applied **2. Future solutions** 1. Not currently, but this reviewed frequently

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N5. Harm due to correct completion of an incorrect exercise The equivalent is the AI gives them the wrong exercise	2: Moderate	**6. User select two body parts to train with different levels of symptoms and functional ability**	**1. Active solutions** 1. The risk ratings from the user most severely body part affected, is applied to exercise calculation 2. The difficulty/demand level for the more limited/severely symptom body part is applied to all body parts **2. Future solutions** 1. Not currently, but this reviewed frequently
		7. The user has a complaint not covered by the Good Boost exercise solutions	**1. Active Solution** 1. The user is advised that we are unable to adapt according to diagnosis BUT the exercise solution will still be adjusted according to symptoms and functional limitations. The user can continue at their own risk 2. In case of someone having surgery (except knee and hip arthroplasty) they advised to consult their HCP until they can exercise without limitation. In cases where the user still continues to a session, they are given a very easy session suitable for most people post-operation for the reported body part. This is because they could just go down the “normal exercise” line. They are told to continue at their own risk. **2. Future Solution** 1. Continually develop exercise prescription to suit the co-morbidities and/or additional MSK problems not currently covered by the AI

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N5. Harm due to correct completion of an incorrect exercise: The equivalent is the AI gives them the wrong exercise	2: Moderate	**7. The user has a complaint not covered by the Good Boost exercise solutions**	2. Add exhibition programmes that can be selected for specific complains which the user then take responsibility to complete 3. The user is advise to get a HCP to prescribe a session using the expert area (to be created in the next 12-months)
N6. Harm due to incorrect completion of an incorrect exercise	2: Moderate	**1. Incorrect exercise as above**	1. As above
N7. Trip or fall while exercising	3: Significant	**1. Unsafe training environment in Centers delivering community based Good Boost solutions**	**1. Active Solutions** 1. In leisure centres, the location and not Good boost is responsible for providing a safe environment. Training is provide to the centres on safety but a level of internal control in safety is assumed
		2. Unsafe training environment in users own location e.g. home	**1. Active Solutions** 1. None specific 2. Pop-ups advising a safe environment and making user acknowledge they have created themselves a safe environment
		3. User has balance issues	**1. Active Solutions** 1. User can select training position which includes supported standing, seated or lying. It is the responsibility of the user to select the correct training position

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N7. Trip or fall while exercising	3: Significant	**3. User has balance issues**	**1. Future solution** 1. Better communication and training of how to use the position selection 2. Give recommendations on training position that would be suitable for that user 3. Block specific training position selection if felt appropriate 4. Use AI to select sitting or supported standing exercise for those with assumed balance issue with a unacceptably high level of falls risk. This is something that could also compromise effectiveness of the exercise programmes and requires further review and investigation.
N8. Death due to trip or fall while exercising	3: Significant	**1. As above**	1. As above
N9. Harm due to drowning	2: Moderate	**1. User reports having a higher level of water confidence than their actual water confidence**	**1. Active solutions** 1. AI selects exercise that require water confidence at an equal or lower than user reports 2. 2 Questions are asked on users water confidence and final water confidence is calculated using 2 questions allowing fo variation in understanding oif both questions 3. To prevent wrong interpretation of the questions the user is told of importance in answers accurately.

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N9. Harm due to drowning	2: Moderate	**1. User reports having a higher level of water confidence than they actually have**	4. For each level fo water confidnce a specific question style was developed to allow for a more indepth dscription to appear before selection of answer 5. Filtering system reviewed by internal experts 6. All leisure centers are advised to have life savers on pools side and take respinsibility for pool safety. This included in training given to leisure centers before starting to deliver good boost solutions in their leisure center 7. In home solutions, the user reminded of risk of aqua exercise in pre-exercise pop-up and to exercise with supervision and never perform exercises beyond their ability – disclaimer agreed 8. User can update water confidence question in the application at anytime and these are updates in the AI immediately 9. All events are loged and investigated by Good Boost Wellness **2. Future solutions** 1. Filters reviewed by external aquatic exercise experts 2. Users and stakeholders/customers asked for feedback on water depth training preferences 3. Customer reporting low confidence have an additional pop-up reminding them to be aware of the potential risks

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N9. Harm due to drowning	2: Moderate	**2. AI select exercises that require water confidence higher than the user has reported**	**1. Active Solutions** 1. Internal review of each exercise and strict rules for filtering water confidence 2. Regular review of filtering in production version continue to filter appropriately **2. Future solutions** 1. No immediate solutions needed
N10. Death due to drowning	3: Significant	**1. As above**	**1. Active solutions** 1. As above 2. Drowning is a serious consequence of participating in aquatic activities. I is assumed the user is willing to participate in aquatic exercise by voluntarily starting with the aquatic exercise solutions provided by good Boost Wellness. We are able to reduce the likelihood but severity is still considerable therefore risk remains significant **2. Future solutions** 1. No immediate solutions needed
N11. Harm due to pregnancy related factor(s)	2: Moderate	**1. User is not screen out of exercises sessions due to pregnancy related yellow or red flag**	**1. Active Solutions** 1. Pregnancy specific screening questions for every new ante-natal user 2. Specific screening question at every log-in 3. If it the users first pregnancy, increased risk for higher anxiety and the exercises are reduced in difficulty for first session until further post-exercise feedback gather to indicate exercise tolerance. **2. Future solutions** 1. No immediate solutions needed

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N11. Harm due to pregnancy related factor(s)	2: Moderate	**2. User follows unsuitable exercise due to due date / trimester stage (i.e. larger bump, more limits in certain functional movements such as rotation and open chain exercises (i.e. jumps)**	**1. Active Solutions** 1. Due date data gathered at registration and any new future pregnancies (user can update details) 2. Exercises adapted based on trimester/proximity to due date **2. Future solutions** 1. No immediate solutions needed
N11. Harm due to pregnancy related factor(s)	2: Moderate	**3. User experiences harm due to additional load (foetal/pregnancy weight)**	**1. Active Solutions** 1. Due date data gathered at registration and any new future pregnancies (user can update details) 2. Exercises adapted based on trimester/proximity to due date and calculation of projected increase in foetal/pregnancy weight 3. User asked as registration if they have twins/triplets/more which would increase load – exercises adjusted **2. Future solutions** 1. No immediate solutions needed
N11. Harm due to pregnancy related factor(s)	2: Moderate	**4. User experiences harm due to hypermobility and moved beyond end of safe range of movement (increased risk due to release of hormone: relaxin)**	**1. Active Solutions** 1. User asked at registration if they are 'hypermobile' – exercise that involve exercise that put movement to the limits of end of range **2. Future solutions** 1. No immediate solutions needed

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
N12. Psychological harm due to viewing user or host curated content	2: Moderate	**1. User post inappropriate message on the message board or chat function**	**1. Active Solutions** 1. Filter mechanism for all text to filter for profanities and inappropriate language 2. Hosts and admin have the ability to delete messages in the event a message is able to be posted without being filtered **2. Future solutions** 1. No immediate solutions needed
N12. Psychological harm due to viewing user or host curated content	2: Moderate	**2. Host uses inappropraite language or delivers inappropriate content**	**1. Active solutions** 1. Hosts are selected by group admins, who are leisure, health or charitable organisations with their own staff and volunteer recruitment process 2. Host complete certified training course 3. A ‘report’ function in the app for user to report any unsuitable activity directly to Good Boost to investigate **2. Future solutions** 1. No immediate solutions needed

5.1 – Clinical Risk Control Analysis

Faulty functioning of the device:

Faulty functioning is defined as the one or more of the following fails to work as expected.

1) The Good boost AI logic creates an output that is not as expected,
2) The output generated by the device is incorrect during transmission
3) The application presents the exercise recommendations as expected

Risk	Risk Definition	Cause	Controls
F1. Failure of the device to present any exercise recommendation.	2. Moderate	**1. Lack of wifi in environment** **2. 2. Data is completely missing for user**	**1. Active Solutions** 1. There are some basic exercise programmes hard wired which can be used without WiFi or logging in. There is a pop-up transferring responsibility to user if continues as they are not nor can be specific for that user **2. Future solutions** 1. None at present
F2. Harm due to performing an exercise that is incorrectly presented/built and given to a user. (AI logic as been performed as expect and output is correct)	2: Moderate	**1. Error in extracting link for media and or details thus reciving wrong combination of media and description.** **2. This is an error in building the output sent from the AI to the Good Boost app**	Knowing that an exercise or more have been incorrectly presented by the application in the tablet requires feedback from the users. Users possibly could see difference between session overview and those exercises actually played in the session. The user may well notice the exercises do not focus on the request body part. This applies to all the causes under this hazard. **1. Active solutions** 1. Centers can report error in exercise directly 2. Ongoing quality assurance testing throughout development team 3. User can send feedback to the team at the end of the session **2. Future solutions** 1. Button in exercise screen to report a broken exercise 2. Warning message to complete exercise to a comfortable level, if unsure skip and give feedback at the end of the session

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F2. Harm due to performing an exercise that is incorrectly presented/built and given to a user. (AI logic as been performed as expect and output is correct)	2: Moderate	**2. Failure of application to play correct animation, display details or wrong exercise as a whole**	**1. Active solutions** 1. Centers can report error in exercise directly 2. Regular quality assurance testing throughout development team 3. User can send feedback to the team at the end of the session **2. Future solutions** 1. Button in exercise screen to report a broken exercise 2. Warning message to complete exercise to a comfortable level, if unsure skip and give feedback at the end of the session
		3. Error in linking exercise to users details/impact sets i.e. Ai does not extract exercises as expected even though all aspects of the AI logic have been fulfilled	**1. Active solutions** 1. Centers can report error in exercise directly 2. Regular quality assurance testing throughout development team 3. User can send feedback to the team at the end of the session **2. Future solutions** 1. Build a button in exercise screen to report a broken exercise 2. Warning message to complete exercise to a comfortable level, if unsure skip and give feedback at the end of the session
		4. Error or incomplete data in / output sent from the Good bost AI to the App/Device	**1. Active solutions** 1. If the exercise output is incorrect the exercise will not play **2. Future solutions** 1. None at present

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F2. Harm due to performing an exercise that is incorrectly presented	2: Moderate	**5. failure of front end app to present correct exercises: Fault in Good Boost app**	**1. Active Solutions** 1. Ongoing app internal QA and review process 2. Users and facilitator can highlight this issue and it is investigated **2. Future development** 1. Training for facilitators to identify these and give specific feedback to GB
F3. Death due to performing an exercise that is incorrectly presented	2: Moderate	**1. As above**	1. As above
F4. Harm due to failed pre-screening of the user	2: Moderate	**1. Missing data required by AI to make exercise recommendations and exercise programme**	**1. Active Solutions** 1. User cannot start a personalised session if the have not completed a joint specific question flow. The questions are all mandatory and all data is transferred to the database once completed in whole. 2. If the data is missing the response sent from the Good Boost API will not contain any specified body part. Therefore, the application will not allow the user to continue to request a body part specific programme

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F4. Harm due to failed pre-screening of the user	2: Moderate	**1. Missing data required by AI to make exercise recommendations and exercise programme**	3. If data is missing from the body part flow questions, the AI has to receive back from the user the body part they want to train. If the data is missing the user is provided a programme consisting of generic exercise from the requested body part. The exercises are graded as lowest intensity and user still control training position for safety. **1. Future solutions** 1. Add the following to the default training programme 1. Pop-up in the event of an error and to suggest an interim generic program or program from exercise library 2. Add filter of low loading risks to neck, spine, hip and shoulder 3. Add filter of low water confidence = standing near the wall 4. Ensure weightbearing calculation can occur, if not no exercise program to be delivered 2. Ask to re-fresh request and see if data can be found 3. Develop a warning system to highlight whenever this error happens so it can be investigated along with the causes for resolution.
		2. Failure of app to send user pre-screening data to server	**1. Active Solutions** 1. The Good Boost AI is unable to make an exercise programme recommendation without minimal data. Minimal data required is:

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F4. Harm due to failed pre-screening of the user	2: Moderate	**2. Failure of app to send user pre-screening data to server**	1. Requested body part to train 2. Environment for training (land or water) 3. Duration of training session The Application will not present the ability to chose a body part if there is no data for that body part to be found in the data base for that user. The application will request registering at least one body part before allowing the user to start any body part specific program. 2. Data for a body is only transmitted from the application when the user presses complete at the end of the set of questions for that body part. No data is transmitted when the question set is incomplete or left half completed. It is impossible to get to the end of the question set without answer all the questions 2. If data for water confidence or weightbearing status the application will again request completion of the data and will navigate the user to the questions automatically. 2. **Future solutions** Currently none
		3. Failure of app to send user pre-screening data to server. Failure of user to complete the feedback questions	**Active solutions** 1. The previous details are used and no adjustment is made. 2. **Future solutions** 1. Use pre-screen data to asses i.e. minimal data needed 2. Improve UI and application functionalities to motive user to complete feedback and ensure it is sent.

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F5. Death due to failed pre-screening of the user	2: Moderate	**1. As above**	1. Above
F6. Harm due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	2: Moderate	**1. Failure of app to send user pre-screening data to server**	**1. Active Solutions** 1. The Good Boost AI is unable to make an exercise programme recommendation without minimal data. Minimal data required is 1. Requested body part to train 2. Environment for training (land or water) 3. Duration of training session 2. The Application will not present the ability to chose a body part if there is no data for that body part to be found in the data base for that user. The application will request registering at least one body part before allowing the user to start any body specific program. 3. Data for a body is only transmitted from the application when the user presses complete at the end of the set of questions for that body part. No data is transmitted when the question set is incomplete or left half completed. It is impossible to get to the end of the question set without answer all the questions 4. If data for water confidence or weightbearing status the application will again request completion of the data and will navigate the user to the questions automatically.

5.1 – Clinical Risk Control Analysis

Risk	Risk Definition	Cause	Controls
F6. Harm due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	2: Moderate	**1. Failure of app to send user pre-screening data to server**	**Future solutions** 1. Create an error log when data is missing 2. Enhanced Quality control for app testing
F7. Death due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	3: Significant	**1. As above**	1. As above

5.1.1 – Post Control Risk Analysis

A post control risk analysis is to identify the new risk definition of each identified risk in normal and fault state of the system.

The severity, likelihood and risk definition ('Risk Def') will use the same criteria as in section 3.3. Each definition will be represented by a letter and the corresponding colour.

Severity	
Catastrophic	Ca
Major	Ma
Considerable	Co
Significant	S
Minor	Mi

Likelihood	
Very High	VH
High	H
Medium	M
Low	L
Very Low	VL

Risk Definition	
Very High	VH
High	H
Significant	S
Moderate	M
Low	L

Table 5.3 – Post control risk analysis at normal function

Risk Description	Pre-Control			Proposed Risk Mitigation	Post-Control			Acceptable Risk Level?
	Severity	Likelihood	Risk Def		Severity	Likelihood	Risk Def	
N1. Harm due to over exercising while following a personalised exercise	S	M	M		S	L	M	Yes
N2. Death due to over exercising while following a personalised exercise	Ma	VL	M		Ma	VL	M	Yes
N3. Harm due to correct completion of a correct exercise	Mi	M	M	.	Mi	VL	L	Yes
N4. Harm due to incorrect completion of a correct exercise	S	M	M		S	L	M	Yes
N5. Harm due to correct completion of an incorrect exercise	S	M	M		S	VL	L	Yes

5.1.1 – Post Control Risk Analysis

Table 5.3 – Post control risk analysis at normal function… continued

Risk Description	Pre-Control			Proposed Risk Mitigation	Post-Control			Acceptable Risk Level?
	Severity	Likelihood	Risk Def		Severity	Likelihood	Risk Def	
N6. Harm due to incorrect completion of an incorrect exercise	S	M	M		S	L	M	Yes
N7. Harm due to trip or fall while exercising	C	M	S		C	L	M	Yes
N8. Death due to trip or fall while exercising	Ma	M	S	.	Ma	VL	M	Yes
N9. Harm due to drowning	C	L	M		C	VL	M	Yes
N10. Death due to drowning	Ma	L	S		Ma	VL	M	Yes
N11. Harm due to pregnancy related factor(s)	S	M	M		S	L	M	Yes
N12. Psychological harm due to viewing user or host curated content	S	M	M		S	VL	L	Yes

5.1.1 – Post Control Risk Analysis

Table 5.4 – Post control risk analysis at fault function

Risk Description	Pre-Control			Proposed Risk Mitigation	Post-Control			Acceptable Risk Level?
	Severity	Likelihood	Risk Def		Severity	Likelihood	Risk Def	
F1. Failure of the device to present any exercise recommendation.	Mi	M	M		Mi	L	L	Yes
F2. Harm due to performing an exercise that is incorrectly personalised for the user	S	L	M		S	VL	L	Yes
F3. Death due to performing an exercise that is incorrectly personalised for the user	Ma	VL	M	.	Ma	VL	M	Yes
F4. Harm due to failed pre-screening of the user	C	VL	M		C	VL	M	Yes
F5. Death due to failed pre-screening of the user	Ma	VL	M		Ma	VL	M	Yes
F6. Harm due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	C	L	M	.	C	VL	M	Yes
F7. Death due to failure to send user data to the Good Boost server resulting in incorrect exercises performed	Ma	VL	S		Ma	VL	M	Yes

5.2 – Clinical Risk-Benefit Analysis

Where a residual clinical risk is deemed unacceptable and further clinical risk control is not practicable, the CSO will determine if the clinical benefits of the intended use outweigh the residual clinical risk.

If the clinical benefits do not outweigh the residual clinical risk, then the clinical risk remains unacceptable and the project/device should be re-appraised.

The post control analysis of risks for the system at normal and fault, represented in Table 5.3 and Table 5.4, demonstrate that post-control application, there are no clinical risks in medical device higher than Moderate following the application of the Active controls.. In total, there are 13 moderate and 4 low clinical risks. In accordance with the Section 3, Risk Matrix Score Acceptability Definitions (Table 3.4), the Moderate risks are “tolerable without further risk reduction that is not practical or impractical without introducing alternative risks.”

Table 3.4 - Risk Matrix Score Acceptability Definitions

Overall Risk Matrix Score	Risk Definition	Risk Acceptability > Action
5	Very high	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
4	High	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
3	Significant	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 or impossible without introducing alternative risks.
2	Moderate	Tolerable where further risk reduction is not practical or impractical without introducing alternative risks.
1	Low	Acceptable, no further action required

Section 5.1 has identified the active controls in place in addition to future controls suggested. The future controls are in development and will be implemented once they are completed, tested and reviewed. For each review of the Clinical Risk Management Plan, when a future control becomes an active control, this will be updated as re-analysed for control risk analysis.

The current system represents a low or moderate risk to users. There are risks of harm for people with musculoskeletal conditions taking part in physical activity and exercise, and risk mitigation actions are required to minimise those risks Jones et al, 1994, MacAuley, 2002, Stathokostas et al, 2013). However the clinical benefit of physical activity and exercise for people with musculoskeletal conditions is considerable, and the risks of sedentary behaviour and inactivity, far outweigh the moderate and low risks that remain in the medical device system Lewis et al, 2019,Moreno-Agostino et al 2020, Rodrigues et al, 2014. Furthermore, from our preliminary clinical audit data (appendix 1), we have demonstrated that Good Boost users report a meaningful improvement in pain, function and quality of life, in a population living with musculoskeletal conditions, where the majority we previously physically inactive.

As a result, the clinical risk evaluation of the Good Boost app, demonstrates that the clinical benefit outweighs the risk. Nonetheless, the system is under continual review to minimise risk.

5.3 – Implementation of Clinical Risk Control Measures

The clinical risk control measures identified in section 5.1 must be implemented except where these are to be implemented by another organisation or the Clinical Risk Benefit analysis in 5.2 has demonstrated the clinical benefit outweighs the residual clinical risk.

Every clinical risk control measure implemented must be verified and documented. The controls are codified as the risk number (i.e. N1), the cause number (i.e. 2) and the active or future solution number. The first active control listed in Table 5.1 would be: N1-1-1-1 (the Control Number), which is initial red flag screening, as shown by the red dots in the example below.

Table 5.1 – Identified Risk and Controls to Mitigate Risk for Normal Functioning

Risk	Risk Definition	Cause	Controls
N1. Harm due to over exercising while following a personalised exercise	2: Moderate	**1. User has a medical condition limiting tolerance to exercise**	**1. Active solutions.** 1. All users are screen initially for known main medical risks to exercise and are advised to discuss with a HCP before starting a good Boost exercise session pop-up warnings.

The approval for the controls are Ben Wilkins (BWi) (CSO) and Ben Waller (BWa), Clinical Director.

Table 5.5 – Implementation status of clinical risk control measures – Normal function

Control Number	Control Activated?	Approval
N1-1-1-1 – initial screening	Yes	Yes – BWi. Yes – BWa.
N1-1-1-2 – pre-exercise screening	Yes	Yes – BWi. Yes – BWa.
N1-1-2-1 – pre-exercise pop-up guidance	Yes	Yes – BWi. Yes – BWa.
N1-1-2-1		Yes – BWi. Yes – BWa.
N1-2-1-1 – user dictates exercise duration	Yes	Yes – BWi. Yes – BWa.
N1-2-2-1 – active suggestion of duration	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
N1-3-1-1 – exercise controlled by function limitation reported by user	Yes	Yes – BWi. Yes – BWa.
N1-3-1-2 – User can request easier session	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N1-3-1-3 – User can skip or pause exercise	Yes	Yes – BWi. Yes – BWa.
N1-3-2-1 – auto adjusting intensity	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
N1-3-2-2 – RPE pop-up suggestion	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N1-3-2-3 – symptom session advice	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
N1-3-2-4 – RPE informed session intensity calculation	Yes	Yes – BWi. Yes – BWa.
N1-3-2-5 – in-app education of intensity	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
N1-3-2-6 – IPAQ informed session intensity calculation	Yes	Yes – BWi. Yes – BWa.
N1-4-1-1 – Post-exercise education messages	Yes	Yes – BWi. Yes – BWa.
N1-4-2-1 – Additional post-exercise education	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N1-4-2-2 – FAQ on post-exercise soreness	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N1-5-1-1 – Graded exercises matched to user	Yes	Yes – BWi. Yes – BWa.
N1-5-1-2 – Internal and external audits of exercise suitability	Yes	Yes – BWi. Yes – BWa.
N1-5-1-3 – User feedback used to improve exercises	Yes	Yes – BWi. Yes – BWa.
N3-1-2-1 – Pop-up in app advising movement	Yes	Yes – BWi. Yes – BWa.
N4-1-1-1 – Animation internal review process	Yes	Yes – BWi. Yes – BWa.
N4-1-1-2 - Animation external review process	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N4-1-1-3 – written exercise description	Yes	Yes – BWi. Yes – BWa.
N4-1-1-4 – internal animator QA process	Yes	Yes – BWi. Yes – BWa.
N4-2-1-1 – easy to understand animations	Yes	Yes – BWi. Yes – BWa.
N4-2-1-2 – exercise preference function	Yes	Yes – BWi. Yes – BWa.
N4-2-1-3 – exercise intensity preference	Yes	Yes – BWi. Yes – BWa.
N4-2-2-1 - Pop-up in app advising movement	Yes	Yes – BWi. Yes – BWa.
N4-3-1-1 – animation whole team approval	Yes	Yes – BWi. Yes – BWa.
N4-3-1-2 – external review of descriptions	Yes	Yes – BWi. Yes – BWa.
N5-1-1-1 – peer review of question terminology	Yes	Yes – BWi. Yes – BWa.
N5-1-1-2 – both visual and written instructions	Yes	Yes – BWi. Yes – BWa.
N5-1-1-3 – user can updated data to inform exercise selection	Yes	Yes – BWi. Yes – BWa.
N5-1-1-4 – full data required to recommend exercises (no missing data exercise)	Yes	Yes – BWi. Yes – BWa.
N5-1-1-5 – ongoing co-design on question terminology	Yes	Yes – BWi. Yes – BWa.
N5-1-1-6 – information buttons for additional question clarity	Yes	Yes – BWi. Yes – BWa.
N5-1-2-1 – chat box function for app	Yes	Yes – BWi. Yes – BWa.
N5-2-1-1 – user severity exercise matching	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N5-2-1-1 – user severity exercise matching	Yes	Yes – BWi. Yes – BWa.
N5-2-1-2 – Internal review of exercise by HCPs	Yes	Yes – BWi. Yes – BWa.
N5-2-1-3 – External review of exercises	Yes	Yes – BWi. Yes – BWa.
N5-2-1-4 – User can request easier session	Yes	Yes – BWi. Yes – BWa.
N5-2-1-5 – User preference for future exercises	Yes	Yes – BWi. Yes – BWa.
N5-2-1-6 – Exercise flag risk applied to user criteria	Yes	Yes – BWi. Yes – BWa.
N5-2-2-1 – pre-session exercise refresh button	Yes.	Yes – BWi. Yes – BWa.
N5-2-2-2 – ML to be implemented to improve exercise selection	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N5-3-1-1 – Weightbearing questions	Yes	Yes – BWi. Yes – BWa.
N5-3-1-2 – able to update weightbearing status	Yes	Yes – BWi. Yes – BWa.
N5-3-1-3 – Weightbearing log tested	Yes	Yes – BWi. Yes – BWa.
N5-3-1-4 – User recommended to consult HCP with weightbearing	Yes	Yes – BWi. Yes – BWa.
N5-3-1-5 – user preference over land training position	Yes	Yes – BWi. Yes – BWa.
N5-3-2-1 – auto blocking of training position based on weightbearing status	Yes	Yes – BWi. Yes – BWa.
N5-4-1-1 – users advise to consult HCP	Yes	Yes – BWi. Yes – BWa.
N5-4-1-2 – exclusion of exercises on high pain	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N5-4-2-1 – greater functional questioning	Yes	Yes – BWi. Yes – BWa.
N5-4-2-2 – Computer-vision to track functional ROM	To be activated in next 18-months.	Yes – BWi. Yes – BWa.
N5-5-1-1 – Risk rating from user most affected body part applied	Yes	Yes – BWi. Yes – BWa.
N5-6-1-1 - Risk rating from user most affected body part applied	Yes	Yes – BWi. Yes – BWa.
N5-6-1-2 – application of most limited body part to exercise calculation	Yes	Yes – BWi. Yes – BWa.
N5-7-1-1 – exercise led by reported functional capability, rather than diagnosis.	Yes	Yes – BWi. Yes – BWa.
N5-7-1-2 – in higher risk users, advised to consult with HCP	Yes	Yes – BWi. Yes – BWa.
N5-7-2-1 – Gradual exercise adjustment, designed around co-morbidities	Yes	Yes – BWi. Yes – BWa.
N5-7-2-2 – Add pre-made exercise library for condition specific exercises	Yes	Yes – BWi. Yes – BWa.
N5-7-2-3 – User to ask HCP to manually create an exercise program	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N7-1-1-1 – leisure center venues required to complete risk assessment of exercise environment.	Yes	Yes – BWi. Yes – BWa.
N7-2-2-1 – pop-up advising environment checks	Yes.	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N7-3-1-1 – user can select training position	Yes	Yes – BWi. Yes – BWa.
N7-3-2-1 - enhanced education on training position	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N7-3-2-2 - recommendation on training position	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N7-3-2-3 - block certain training positions	Yes	Yes – BWi. Yes – BWa.
N7-3-2-4 – auto selection of training position based on user data	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
N9-1-1-1 – selection of exercise at or below user water confidence level	Yes	Yes – BWi. Yes – BWa.
N9-1-1-2 – two questions on water confidence	Yes	Yes – BWi. Yes – BWa.
N9-1-1-3 – user reminded of importance of water confidence questions	Yes	Yes – BWi. Yes – BWa.
N9-1-1-4 – specific question style to convey water confidence	Yes	Yes – BWi. Yes – BWa.
N9-1-1-5 – exercise filtering system internal review	Yes	Yes – BWi. Yes – BWa.
N9-1-1-6 – Public pools advise to have lifeguards	Yes	Yes – BWi. Yes – BWa.
N9-1-1-7 – At home, user reminded of risks of aqua exercise and not to perform unsupervised.	Yes	Yes – BWi. Yes – BWa.
N9-1-1-8 – User can update water confidence	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N9-1-1-9 – All events logged and investigated	Yes	Yes – BWi. Yes – BWa.
N9-1-2-1 – Filters reviewed by external aquatic experts	Yes	Yes – BWi. Yes – BWa.
N9-1-2-2 – User and stakeholder to advise on water confidence preferences	Yes	Yes – BWi. Yes – BWa.
N9-1-2-3 – additional low-water confidence pop-up	Yes	Yes – BWi. Yes – BWa.
N9-2-1-1 – Internal reviews of water confidence filters	Yes	Yes – BWi. Yes – BWa.
N9-2-1-2 – Review of production app water confidence filtering	Yes	Yes – BWi. Yes – BWa.
N11-1-1-1 - Pregnancy specific screening questions	Yes	Yes – BWi. Yes – BWa.
N11-1-1-2 - Specific screening at each log in	Yes	Yes – BWi. Yes – BWa.
N11-1-1-3 – user updates it's first pregnancy	Yes	Yes – BWi. Yes – BWa.
N11-2-1-1 – Due date gathered	Yes	Yes – BWi. Yes – BWa.
N11-2-1-2 – Exercises adapted base on due date	Yes	Yes – BWi. Yes – BWa.
N11-3-1-1 – Due date gathered	Yes	Yes – BWi. Yes – BWa.
N11-3-1-2 – Exercises adapted based on due date and project load change	Yes	Yes – BWi. Yes – BWa.
N11-3-1-3 – User asked if twins/triplets more and exercise/load risk adapted	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
N11-4-1-1 User asked if hypermobile and exercises adapted	Yes	Yes – BWi. Yes – BWa.
N12-1-1-1 – Automatic filters for inappropriate text language	Yes	Yes – BWi. Yes – BWa.
N12-1-1-2 – Host/admin can delete message/remove user from virtual session	Yes	Yes – BWi. Yes – BWa.
N12-2-1-1 – Hosts recruited by reputable organisations	Yes	Yes – BWi. Yes – BWa.
N12-2-1-2 – Host complete certified training course	Yes	Yes – BWi. Yes – BWa.
N12-2-1-3 – Report function for user to report inappropriate behavior	Yes	Yes – BWi. Yes – BWa.

Table 5.6 – Implementation status of clinical risk control measures – Fault function

Control Number	Control Activated?	Approval
F1-1-1-1 – No WiFi pop-up, unable to use	Yes	Yes – BWi. Yes – BWa.
F2-1-1-1 – reporting of errors to Good Boost	Yes	Yes – BWi. Yes – BWa.
F2-1-1-2 Ongoing QA of exercises	Yes	Yes – BWi. Yes – BWa.
F2-1-1-3 – user can send feedback direct through the app of errors	Yes	Yes – BWi. Yes – BWa.
F2-1-2-1 – in-exercise 'error' button	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F2-1-2-2 - pop-up to exercise to a suitable level	To be activated in next 6-months.	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
F2-2-1-1 – user can send feedback direct through the app of errors	Yes	Yes – BWi. Yes – BWa.
F2-2-1-2 – in-exercise ‘error’ button	Yes	Yes – BWi. Yes – BWa.
F2-2-1-3 - pop-up to exercise to a suitable level	Yes	Yes – BWi. Yes – BWa.
F2-2-2-1 – in-exercise ‘error’ button	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F2-2-2-2 - pop-up to exercise to a suitable level	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
F2-3-1-1 – user can send feedback direct through the app of errors	Yes	Yes – BWi. Yes – BWa.
F2-3-1-2 – in-exercise ‘error’ button	Yes	Yes – BWi. Yes – BWa.
F2-3-1-3 - pop-up to exercise to a suitable level	Yes	Yes – BWi. Yes – BWa.
F2-3-2-1 – in-exercise ‘error’ button	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F2-3-2-2 - pop-up to exercise to a suitable level	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
F2-4-1-1 – exercise will not play if output is in error	Yes	Yes – BWi. Yes – BWa.
F2-5-1-1 – Ongoing app QA review process	Yes	Yes – BWi. Yes – BWa.
F2-5-1-2 – reporting process by user	Yes	Yes – BWi. Yes – BWa.
F4-1-1-1 – Cannot start session without mandatory questions answered	Yes	Yes – BWi. Yes – BWa.
F4-1-1-2 – If missing data, API will not output exercise	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
F4-1-1-3 – If missing data, lowest difficulty exercise suggested – user still select training position for safety	Yes	Yes – BWi. Yes – BWa.
F4-1-2-1.1 – Error pop-up	To be activated in next 6-months.	Yes – BWi. Yes – BWa.
F4-1-2-1.2 – Filter of low loading risks	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F4-1-2-1.3 – Filter of low water confidence	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F4-1-2-1.4 – Weightbearing calculation at minimum	To be activated in next 6-months	Yes – BWi. Yes – BWa.
F4-1-2-2 – Refresh data request	To be activated in next 6-months	Yes – BWi. Yes – BWa.
F4-1-2-3 Warning system to flag this event/error	To be activated in next 6-months	Yes – BWi. Yes – BWa.
F4-2-1-1- No exercises without data	Yes	Yes – BWi. Yes – BWa.
F4-2-1-2 –incomplete data, no exercises	Yes	Yes – BWi. Yes – BWa.
F4-2-1-3 – No data, no exercises	Yes	Yes – BWi. Yes – BWa.
F4-2-1-3 – No weightbearing or water confidence data, no exercise	Yes	Yes – BWi. Yes – BWa.
F4-3-2-1 – Use pre-screen data to assess minimal data needed for exercises	To be activated in next 12-months.	Yes – BWi. Yes – BWa.
F4-3-2-2 – Improve UI/UX to encourage data feedback	Yes	Yes – BWi. Yes – BWa.
F6-1-1-1 – No data, no exercise	Yes	Yes – BWi. Yes – BWa.

5.3 – Implementation of Clinical Risk Control Measures

Control Number	Control Activated?	Approval
F6-1-1-1 –incomplete data, no exercises	Yes	Yes – BWi. Yes – BWa.
F6-1-1-2 – No data, no exercises	Yes	Yes – BWi. Yes – BWa.
F6-1-1-3 – No weightbearing or water confidence data, no exercise	Yes	Yes – BWi. Yes – BWa.
F6-1-2-1 – Error log	To be activated in next 6-months	Yes – BWi. Yes – BWa.
F6-1-2-2 – Enhanced quality assurance and testing	To be activated in next 6-months	Yes – BWi. Yes – BWa.

5.4 – Completeness of Clinical Risk Control

Good Boost will ensure that the clinical risk from all identified hazards have been considered and accepted.

The Good Boost team record and document all the controls listed in the active controls. All future controls suggestions are under development within specific timescales. Once the controls are complete, tested and implemented, they will be documents and updated on the Clinical Risk Management Plan.

6.0 – Delivery Overview

Good Boost undertakes a formal review of the Good Boost app and medical device system prior to it's delivery to ensure that all the requirements of this standard and the clinical risk management have been implemented and addressed in full.

All testing and delivery of risk mitigation control measures are documented.

6.1 – Delivery

Good Boost has processes in place that are supported by DCB 0160 so that any safety incidents can be raised and tracked accordingly and, if required, safety communications can be shared with both clinical and appropriate administrative staff.

Within Good Boost, where software bugs are reported, these are tracked and maintained within Good Boost's internal systems, and the CSO or designated CRM assesses the level of clinical risk, escalates as appropriate, and documents further requirements and validation criteria to ensure that the fix is implemented in a safe manner.

Where it is identified that new requirements introduce or impact hazards, causes or controls, the Hazard Log is updated and communicated to relevant parties without delay. Where there are material changes to the product's overall safety profile, or in the instance of a significant product enhancement, the CSO will update and re-issue the Safety Case or create a suitable annex. If no updates are made to the Safety Case during a period of 12 months, a routine update of the document will be performed.

6.2 – Monitoring

Good Boost document and maintain the collection of all reported safety concerns and safety incidence for the Good Boost app in the Hazzard Log.

Each reported and documents log will be assessed and invested, any control measures required to remove or reduce risk will be completed and documented. The impact of any such changed will be reviewed against the on-going validity of the Clinical Safety Case.

Where any such event or evidence is assessed to undermine the safety case, the Good Boost CSO will take appropriate corrective action in accordance with the Clinical Risk Management Plan and document it in the Clinical Safety Case Report.

All safety related incidents reported will be review and assessed within 72 hours of their reporting. Good Boost will resolved the incident within 10 working days. In the event the safety incident represents major-catastrophic risk to a user, the application/function will be removed to remove all risk until resolved.

6.3 – Review Process & Modifications

Good Boost will apply their clinical risk management process to any modifications or updates of the deployed Good Boost app/Medical Device.

The application of this process will be proportional with the scale and extent of the change and the introduction of any new clinical risks.

Good Boost will issue a Clinical Safety Case Report to support any modification to the IT System/medical device that changes its clinical risk. Good Boost must maintain an audit trail of all versions and patches released for deployment.

Clinical Risk Management Sign-off by CSO

I, Ben Wilkins, Clinical Safety Officer for Good Boost Wellbeing Limited, approve this Clinical Risk Management Plan for the delivery of the Good Boost app.

Name: Ben Wilkins

Signature: 

Date: 16th December 2025

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