Version 2.0

[redacted]

Risk Assessment Form

Section 1 – Process Description

DIRECTORATE:	**DEPARTMENT:**
Process/Activity: Use of osseointegration loading frame by patients in their home	

Section 2 – Identifying Risks/Hazards

Risk/Hazard	**Persons at Risk**	**Existing Control Measures**	**Severity (consequences)**	**Likelihood /Frequency**	**Risk Rating SxL**
1. Failure of the lower parallel support bars of the load cell shelf due to bending of the bars	User	The deflections of the bars have been analysed and are within acceptable limits as shown in the attached calculations.	2	1	2
2. Bending or breaking of the load cell shelf resulting in incorrect readings and sense of instability or vulnerability	User	Finite Element Analysis has been done to ascertain the maximum stress likely to occur in the shelf. The results are within the allowable limits. Hand calculations have also been done and are shown in the attached calculations. Testing by normal subjects did cause some deflection of the loading shelf but was not perceivable by the user and during calibration the system was repeatedly accurate.	2	1	2
3. Load cell cable breaks resulting in incorrect display of results, possible over/under loading	User	The cable is attached close to the frame to prevent a trip-hazard occurring and to try and protect the cable. The display will return to the unloaded position or show an overload if this occurs which should be easily identifiable by the user.	1	1	1
4. Injury to user due to slipping on the loading platform	User	The short training prosthesis has rubber grip pad on the base and the loading platform has a rubber surface and all corners and edges of the loading system have been chamfered to reduce the risk of injury.	2	2	4

5. The user cannot see the display clearly therefore over/under loading occurs	User	The display has been modified to show the target area more clearly	1	1	1
6. Failure of the load cell or instrumentation leading to a false or no reading	User	The system has been tested and calibrated and clear instructions are given including actions to take if the readings are questionable	1	2	2
7. The device is not charged therefore cannot be used which affects the patient's rehabilitation	User	The instructions clearly stipulate charging instructions and possible modes of failure if the battery is not sufficiently charged	1	3	3
8. The susceptibility of the system to environmental conditions producing false results or causing malfunction	User	The instructions stipulate that the system should be used indoors therefore it is expected to be within the allowable working conditions which are stated in the instructions as being that the device is suitable for use at room temperature and if subjected to temperatures outside -40 to +100 degrees centigrade the system should be returned for calibration.	1	1	1
9. Incorrect load key inserted resulting in the wrong load target or a similarly shaped key being inserted in the slot resulting in device malfunction	User	The load keys are marked with the corresponding load and instructions on their use is given in the instructions. The user is only issued with the load keys they require at this stage to reduce the likelihood of confusion.	2	2	4
10. The device is not as accurate as claimed, re-calibration is needed	User	The device has been tested to ensure accuracy at the relevant weights required in this instance.	2	1	2
11. Off-axis forces may be applied to the load cell which could affect the results and will not be detected/represented	User	The load cell can withstand certain levels of off-axis loads and these are well above the levels likely to be applied by the user of this system.	1	3	3
12. Unexpected forces are applied to the system such as by sitting on the load cell shelf	User	The system has been designed to withstand likely excess forces and the instructions stipulate loading use. The device has been tested to ensure it is functioning correctly.	1	3	3
13. Misuse of the system due to lack of knowledge	User	The user will be trained in the use of the device and will be issued with a clear	1	2	2

		detailed instruction sheet including telephone numbers to contact the Gait Laboratory with any queries or problems. Training will also be given to clinical staff who may use the device or train the user.			
14. Misinterpretation of the display box controls and lights	User	Controls and lights are clearly labelled on the display box and explained in the instructions.	1	2	2
15. Motion of the system during use, particularly when high loads are being applied or the sound limb is not loaded	User	There are handgrips on the frame which the user can use to stabilise themselves and the instructions highlight the need to use the device on even, level ground.	2	2	4
16. Danger of injury from falling on to the top thread of the load cell when the loading platform is removed	User or nearby personnel	The platform is now attached and should not be removed by the user.	2	1	2
17. The system topples over	User or nearby personnel	Forward stability calculations and practical stability tests have been done as this is the most unstable direction. These calculations are attached. The current stability angle is within the limits set by ISO 11199 Walking Frame Requirements and Test Methods	1	2	2

Complete Action Plan and attach to Risk Assessment form.

Is any employee health monitoring required?	Yes □	No □
Is a more detailed assessment (e.g. COSHH, Manual handling) required?	Yes □	No □
Is further information or investigation required to complete risk assessment?	Yes □	No □

Assessor's Name: Graham Webb	Job Title: Trainee Clinical Scientist
Date of Assessment: 30/01/08	Reassessment Date: January 2009
Assessor's Signature:	Manager's Signature:

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Risk Action Plan

DIRECTORATE: **DEPARTMENT:**

Risk/Hazard	Risk Score	Action Required to Control Risk	Lead Person	Action By	Comments
1-17		Low/Acceptable risk, no action required			

Completed By: Graham Webb

Date: 30/01/08

Manager's Signature: