

FLX Health Risk Assessment

Version 2
5 May 2022

Definitions			Acceptance Criteria			Severity			Key:
Probability	Low	Unlikely and rare event	Probability	Negligible	Moderate	Severe	Unacceptable	Acceptable	
	Medium	May happen but infrequently		High					
	High	Likely and frequent		Medium					
Severity	Negligible	No injury or slight	Severity	Low					
	Moderate	Reversible or minor injury							
	Severe	Death, loss of structure or function							

#	Category	Risk	Score			Controls	Final Risk
			Probability	Severity	Score		
1	Safety	User is provided with an exercise regimen that is unsuitable and causes them harm	Low	Moderate	Acceptable	-Subjects undergo robust triage before being provided a pain pathway programme of exercise -Patients with high levels of pain are referred to see a HCP before being allowed to progress on the programme -Patients using the biomechanics pathway are fit and healthy and at low risk of harm from physical therapy -If subjects are limited in their capability they will be unable to perform the exercises to a level that could harm them by the bodies natural pain signals	Acceptable
2	Safety	The lack of a face-to-face relationship with a HCP leads to failure to properly assess the user before they receive their exercises	Medium	Moderate	Unacceptable	-Subjects undergo robust triage to assess their health before using the APP and subjects with high levels of pain or scoring red flags on triage are referred to see a HCP before using the APP -Triage from the APP is actually more detailed than F-2-F to compensate	Acceptable
3	Safety	Subject falls or slips whilst performing an exercise	Medium	Moderate	Unacceptable	-Exercises are standard physiotherapy and are not normally associated with accidents, subjects are screened via triage to uncover any issues that may increase risk -Exercises are provided with detailed instructions and video to help ensure they are performed correctly, minimise risk of accident	Acceptable
4	Safety	An exercise exacerbates an existing injury or biomechanical issue	Medium	Moderate	Unacceptable	-Subjects with injuries are entered onto the pain programme, which takes the user through a series of exercises as part of triage to ensure that they are suitable to receive the exercise programme -They are referred to a HCP if there are issues	Acceptable
5	Safety	A user may override the triage red flags by stating that they have been cleared by HCP when they have not	Medium	Severe	Unacceptable	-Subjects can in fact override the referral to a HCP, but they will be limited in their ability to do exercise if they are in pain which is the bodies inherent mechanism to protect from harm -The exercises are simple physical therapy and unlikely to harm a user in any case, the purpose of triage is to check that issues are not the result of something malignant that needs HCP checking. If this is the case the issue will not be made worse and will eventually be picked up by routine healthcare outside the APP -In the terms of use it is made clear that FLX is not intended to replace a relationship with a HCP, who would be expected to pick up any underlying issues	Acceptable
6	Efficacy	A user may incorrectly carry out the exercise or not comply with the regimen issued, so experience no benefit	Low	Negligible	Acceptable	-Exercises are given in plain English with a high level of detail and are supported by video instructions -In testing we have shown that comprehension is high -Doing exercises with small deviations in technique and compliance will still deliver some level of benefit, and is unlikely to cause harm	Acceptable
7	Efficacy	Completion of the programmes has not fixed issues	Medium	Negligible	Acceptable	-Physical therapy cannot solve all issues but has a high level of success, our programmes are tested and proven with robust supporting algorithms -FLX is not intended to replace any relationship with other HCPs who may be needed to address issues if they remain, FLX is suitable for concurrent use with other musculoskeletal treatments	Acceptable
8	Digital	FLX will not work on my device	Low	Negligible	Acceptable	-FLX requires iOS14.0 or later and works on iPhone and iPad; or Android 6.0 and later. This is standard for digital products and it is not practical to maintain a service that can work on all legacy versions -Users must keep their operating systems up to date and replace devices over time, as is the general consumer practice	Acceptable
9	Digital	I do not have enough storage to use FLX on my device	Low	Negligible	Acceptable	-FLX requires around 30.4 MB of data, users can manage their storage to create space to download the APP is necessary Video content is stored offline to reduce storage issues	Acceptable
10	Data	Data breaches may expose user data	Low	Moderate	Acceptable	-FLX is fully compliant with GDPR and uses secure infrastructure to protect any data in the cloud and on your device -User access requires username and password which may be changed from time to time to increase security, as is standard practice for digital products	Acceptable
11	Usability	Some exercises require equipment that a user may not possess	Low	Negligible	Acceptable	-All equipment is simple, low cost and readily available from high street or online retail outlets in all countries	Acceptable

Overall Risk Statement:

FLX Health is a low risk health application as reflected by its status as a Class I Medical Device. FLX is not meant to replace any relationship a user has with a Healthcare Professional (HCP) and may be used safely alongside other treatments. Users are subject to a rigorous triage and are directed to see a HCP if they score with any redflags before they enter the APP. Exercises are clear, easy to follow with both written and video instruction to aid comprehension and are proven to be safe and effective after tests in over 4500 subjects. Incorrect execution of the exercises is unlikely to cause injury or harm.