flok health

SD-00001 Patient Information

Doc number	SD-00001
Title	Patient Information
Original Author	Shareta Passingham

Information for patients

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This is regulatory information for patients using the Flok Health Clinical Engine.

Device name and model number: Flok Health Clinical Engine (CELBP2)
Unique device identification: (01)05070002368328(8012) v4.1.0.5a0df99

Device manufacturer Information



Flok Health Ltd
Manufacturer Address:
Lime Tree Barn
Foxes Bridge Farm
Royston Lane
Comberton
Cambridge
CB23 7EE
United Kingdom
Email address: regulatory@flok.health
Telephone number: 0333 3396 052
Website: https://flok.health/



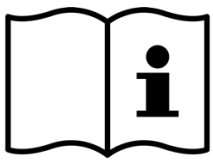
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MedQAIR Services B.V.
Rooseveltlaan 56-2, 1078 NL,
Amsterdam, The Netherlands





flok.health/celbp2/patient-ifu

Device specifications and compatibility

The Flok Health Clinical Engine is only compatible with the Flok Health App v1.0 onwards.

Minimum hardware requirements	Smartphone or tablet
Operating system compatibility	Compatible with the Flok Health app
Internet access requirements	Yes. Minimum 3 Mbps
Minimum screen size	4.7 inches diagonally
Languages supported by the device	British English
Device Lifetime	5 years from manufacture

Intended Purpose

The Flok Health Clinical Engine is a software medical device that delivers a digital pathway designed by a healthcare provider. It is intended to provide diagnostic triage and rehabilitation therapy directly to a patient through a video and chat-based user interface.

The Flok Health Clinical Engine is intended for use by patients in their home environment as primary care without special equipment or instruction.

How the Flok Health Clinical Engine works

A patient watches videos that display physiotherapy content. At the end of each video a patient is asked questions with multiple choice answers. The physiotherapy content that the device delivers to the patient next depends on their response to each question and all the previous responses patients have given.

Indications

The Flok Health Clinical Engine is intended for patients seeking care for musculoskeletal and/or pelvic health symptoms. These symptoms may be acute or chronic, and no clinical screening or examination is required prior to use of the device.

Intended patient population

The Flok Health Clinical Engine is for lay people who are:

- Aged 18+.
- Currently experiencing or experience bouts of musculoskeletal and/or pelvic health symptoms.
- Able to move independently between standing, seated and lying positions (including from the floor).

Device Benefits and Performance Characteristics

The clinical benefits of Flok Health Clinical Engine are a reduced time to triage, reduced time to treatment and guideline adherence.

Residual Risk

The medical device has undergone extensive risk analysis. There are two residual risks which result in an incorrect triage outcome/action due to software failure during triage. The clinical benefits of the medical device outweigh the risk.

Contraindications

The Flok Health Clinical Engine must not be used by patients who:

- Have significant cardiac disease.
- Have a bleeding diathesis, e.g., haemophilia.
- Are pregnant (any gestation).
- Have an underlying chronic neuromuscular disorder that affects their ability to perform light to moderate exercise (unless their doctor has advised that they are suitable).

The Flok Health Clinical Engine must not be used in emergency situations or in the immediate treatment of trauma.

⚠ Precautions

These precautions apply to all patients using the Flok Health Clinical Engine. Please familiarise yourself with these before using the Flok Health Clinical Engine:

- Use the Flok Health Clinical Engine in distraction-free environment as distractions might lead to you accidentally answering a question incorrectly. This could mean that you might not receive appropriate and timely care which could lead to health complications.

- Always use a safe and clutter-free environment for physiotherapy exercises. Make sure you have enough space to move around safely, including being able to lie flat on the floor.

- Use the Flok Health Clinical Engine in a suitably private environment to protect the confidentiality of your personal healthcare information. If you are not in a private environment, there is a risk that you could be overheard or the information on the screen could be overseen.

- Only you should use your Flok Health Clinical Engine account. Allowing other people to use your account could result in exposure of your personal healthcare data.

- To use the Flok Health Clinical Engine safely, you must have good enough eyesight to see your smartphone clearly and good enough hearing to hear the audio content clearly.

- You must not have any cognitive impairment when using the Flok Health Clinical Engine.

- Do not attempt or continue with rehabilitation exercises that you are unable to do due to the risk of injury.

- You must not use the Flok Health Clinical Engine under the influence of alcohol, illegal drugs or other illicit substances.

⚠ Warnings

These warnings apply to all patients using the Flok Health Clinical Engine. Please familiarise yourself with these before using the Flok Health Clinical Engine:

- To use the Flok Health Clinical Engine, you must be comfortable using smartphone or tablet mobile applications.

- While performing physiotherapy exercises there is a risk of injury due to falls, slips or trips and if you are taking oral anticoagulant therapy, e.g., warfarin, apixaban, rivaroxaban there is a risk of bleeding if you sustain an injury.

- To reduce the risk of falls, slips or trips during physiotherapy exercises, before each session remove all trip hazards from the immediate area around you and make sure you are wearing appropriate clothing and footwear.

- You must answer all questions asked by the device accurately, honestly and to the best of your knowledge. This is to reduce your risk of harm. Inaccurate answers may result in the device delivering an inappropriate treatment or advice.

- If you have an underlying breathing disorder such as asthma or COPD, there is a risk that you may experience an acute episode of breathlessness during the physiotherapy exercises.

- Contact your healthcare provider if you need more information or advice on using the Flok Health Clinical Engine but do not delay seeking further medical advice from an alternative provider if you are concerned about your symptoms.

- If you are concerned about your symptoms at any point while using the Flok Health Clinical Engine, you should seek additional medical advice from a healthcare professional such as a GP or via NHS 111.

- If you stop using the Flok Health Clinical Engine before you are discharged, or you do not do the physiotherapy sessions on a regular basis your recovery may be delayed, and your symptoms may persist longer than if you had completed the programme through to discharge.

- If you have a slow Wi-fi connection or slow mobile data network speed, the Flok Health Clinical Engine might not work properly. For example, videos might not load or play. If this happens, try using the Flok Health Clinical Engine in a different location or on a different Wi-fi connection, or alternatively, seek treatment from another healthcare professional such as your GP or NHS 111.

Side effects

You may experience the following side effects while using the Flok Health Clinical Engine to do physiotherapy exercises. These are the most common side effects, and they could impact your ability to do the physiotherapy exercises or lead to a delay in your recovery.
If you do experience these side effects and you feel able to, you can continue to use the Flok Health Clinical Engine but seek advice from your doctor if you are worried:

- Increased pain (approximately 58 people in 100 people experience this)
- Muscle soreness (approximately 18 people in 100 people experience this)
- Unpleasant sensations like pins and needles or cracking sensations in your back (approximately 13 people in 100 people)
- Headaches (approximately 5 people in 100 people experience this)
- Dizziness (approximately 3 people in 100 people experience this)
- Sleep disturbance (approximately 2 people in 100 people experience this)

Reporting side effects

If you experience any of these side effects or any side effects not listed here, speak to your doctor. You can report side effects directly to the Yellow Card Scheme https://yellowcard.mhra.gov.uk/ or by downloading the MHRA Yellow Card app from the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of using the Flok Health Clinical Engine.

Device disclaimers

These disclaimers apply to all patients using the Flok Health Clinical Engine.

- Flok Health Ltd holds no responsibility for injury to patients should they progress to high level physiotherapy content by not undertaking earlier stage exercises.
- Flok Health Ltd holds no responsibility if patients ignore the clinical advice provided by the Flok Health Clinical Engine e.g., to seek alternate urgent medical provision.
- Flok Health Ltd holds no responsibility if patients fail to complete triage, physiotherapy treatment or withholds medical information such as symptoms from the Flok Health Clinical Engine.
- Flok Health Ltd holds no responsibility for injury, harm or data breach if the Flok Health Clinical Engine is used by a third person other than the registered patient regardless of whether the registered patient gave permission.
- Flok Health Ltd holds no responsibility if the requirements of the appropriate use environment for the Flok Health Clinical Engine for the patient and healthcare practitioner are not followed.
- Flok Health Ltd holds no responsibility if the requirements defined in the intended purpose are not followed.
- Flok Health Ltd holds no responsibility if the requirements for patient and healthcare practitioners are not followed.

How to report serious incidents

For serious incidents with the Flok Health Clinical Engine, please report the issue to Flok Health Ltd (by emailing complaints@flok.health or ringing 0333 3396 052) and to the competent authority of the Member State in which the user and/or patient is established.

You can also post a letter to report a serious incident/adverse event to the manufacturer at:

Flok Health Ltd
Lime Tree Barn
Foxes Bridge Farm

Royston Lane
Comberton
Cambridge
CB23 7EE
United Kingdom

In the UK the competent authority is the MHRA who can be contacted by ringing 020 3080 6000 or emailing aic@mhra.gov.uk. You can also post a letter to the MHRA to report a serious incident/adverse event:

The Medicines and Healthcare products Regulatory Agency
10 South Colonnade
London
E14 4PU
United Kingdom

Patient information

To obtain a hard copy of this patient information, please send your contact details and request from Flok Health Ltd by emailing hello@flok.health, ringing 0333 3396 052, or writing:

Flok Health Ltd
Lime Tree Barn
Foxes Bridge Farm
Royston Lane
Comberton
Cambridge
CB23 7EE
United Kingdom

A copy of the patient information will be posted within 7 days.

Flok Health Ltd is regulated as a healthcare provider in England by the Care Quality Commission:

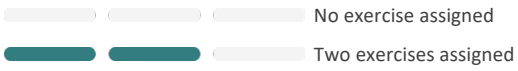
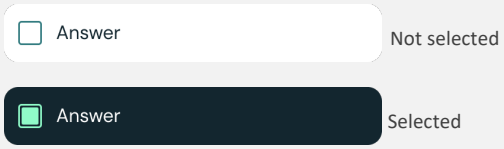
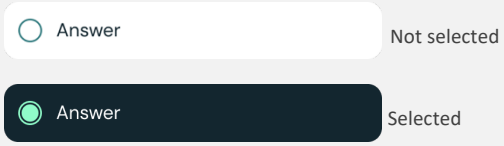
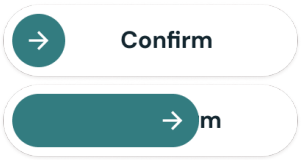
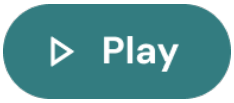
Regulated by CareQuality Commission

Flok Health Clinical Engine is registered with Medicines & Healthcare products Regulatory Agency (MHRA) as a CE-marked Class IIa Medical Device in the United Kingdom.

Icons and symbols

This table provides a list of the symbols used in the Flok Health Clinical Engine and Patient Information document.

Symbol	Meaning of symbol
CE 3022	CE mark indicates that the device complies with Regulation (EU) 2017/745 (EU MDR)
EU REP	Authorised representative in the EU
MD	Medical Device
	Name of manufacturer and the manufacturer address

	Date of manufacture
	An empty bar represents an exercise still to be prescribed. Each filled-in bar represents one prescribed exercise
	Empty square indicates that the answer has not been selected. Filled-in square indicates a selected answer on a multi-select question
	Empty circle indicates that the answer has not been selected Filled-in circle indicates a selected answer on a single-select question
	Slide to submit an answer
	Play video
	Pause video
	Exit video
	The network connection to the device is unstable