

AlcoChange – Instructions for Use (Brief IFU v2.3.4 | Oct 2025)

Manufacturer: CyberLiver Limited | Website: www.alcochange.com | Email: help@cyberliver.com

Device Type: Digital Therapeutic (Software as a Medical Device – SaMD) | UKCA Class IIa

Prescription-Only Device

1. Purpose of the Device

AlcoChange is a digital therapeutic intended to reduce alcohol use and maintain abstinence in individuals with established alcohol-related liver disease (ARLD). It supports behaviour change through digital behavioural-therapy modules delivered via a mobile app and monitored by a clinician dashboard.

2. Intended Use and Indications for Use

Intended Use

AlcoChange is a digital therapeutic intended to reduce alcohol use and maintain abstinence in individuals with established alcohol-related liver disease (ARLD).

Indications for Use

AlcoChange is intended to increase abstinence and reduce alcohol use in patients with alcohol related liver diseases (ARLD) by providing behavioural therapy based on CyberLiver Behaviour Change (CBC) Model that is designed from a blend of principles from various behaviour change theories in the design of Digital Behaviour Change Techniques (DBCTs), Digital Behaviour Change Interventions (DBCI's) and Personalised Digital Behaviour Change Notifications (DBCN's) that help patients self-monitor, manage cravings, and sustain abstinence..

AlcoChange is intended to provide behavioural therapy as an adjunct to a contingency management system, for patients 18 years of age and older who enrolled in outpatient or community-based alcohol management programmes.

The device may also be used by healthcare professionals supporting patients at risk of relapse or harmful drinking, including individuals with co-existing mental-health or wellbeing needs, under appropriate clinical oversight.

AlcoChange is indicated as a 90-day prescription-only treatment for eligible patients.

3. Contraindications

AlcoChange is contraindicated in individuals unable to provide informed consent, those under 18 years of age, those with severe cognitive impairment, severe psychiatric crises, or without access to a compatible smartphone.

4. How to Start Using AlcoChange

1. Download and Install: Search 'AlcoChange' on Apple App Store or Google Play Store.
2. Register: Use the Patient Access Code provided by your clinician.
3. Complete Baseline Assessment: Your clinician or nurse will guide you through health, AUDIT, and goal-setting assessments.
4. Begin Therapy: Receive daily reminders and digital prompts to track progress.
5. Optional Accessory: Use the Bluetooth Digital Breathalyser if provided as part of your prescription.

5. Safety Information

AlcoChange is not a replacement for clinical care or prescribed medication.

In case of an emergency, contact your clinician or nearest A&E immediately.

Do not share your account or access credentials; enable device security features (PIN or biometrics).

Report any technical or safety issues to help@cyberliver.com or via the in-app support channel.

Serious incidents should also be reported to the MHRA via the Yellow Card Scheme (<https://yellowcard.mhra.gov.uk>).

Warnings

- Not for management of acute withdrawal or detoxification.
- May show delayed data sync if internet connectivity is unavailable.
- Do not rely on breathalyser readings for diagnostic or clinical decision-making.

6. Technical and Compatibility Requirements

iOS 15.0 or later / Android 10.0 or later.

Internet connection required for full functionality.

Data usage may apply as per your mobile plan.

7. Duration of Therapy

Standard digital course: 90 days per prescription, renewable at clinician discretion.

8. Storage and Maintenance

Keep your smartphone secure and updated with the latest OS and app version.

If using the breathalyser, store it in a clean, dry environment.

App updates are applied automatically via the app store.