CyberLiver Limited

AlcoChange Clinician Dashboard

Instructions for Use

CL-IFU-CD-001 | Version 2.15 | September 2026

Class IIa Medical Device

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Applies to	AlcoChange Clinician Dashboard v2.15 and AlcoChange Patient Care app v2.3.5
Dashboard URL	https://livercare.cyberliver.com
Device	AlcoChange, Class IIa SaMD, Rule 10, UK MDR 2002
UKCA Certificate	GB23/00000054 (SGS UK AB 0120)
Intended users	Registered healthcare professionals: hepatologists, alcohol nurse specialists, gastroenterologists, addiction specialists, GPs
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This eIFU is available at: https://alcochange.com/information-materials.html
Paper copy: available on request, contact info@cyberliver.com

1. Introduction and Purpose

This document is the Instructions for Use (IFU) for the AlcoChange Clinician Dashboard (https://livercare.cyberliver.com), version 2.15. It is addressed exclusively to registered healthcare professionals who prescribe AlcoChange to patients and who use the dashboard to review patient engagement, clinical progress, and therapy compliance.

The Clinician Dashboard is the web-based clinical interface of the AlcoChange digital therapeutic platform. It displays patient-reported and system-generated information for the clinician to review and act upon. The dashboard does not make clinical decisions, does not act autonomously, and does not replace clinical judgement. All clinical decisions remain with the responsible clinician.

Through the dashboard, clinicians can:

- Review patient therapy compliance, alcohol use data, and engagement information
- Review risk information (high, medium) that highlights patients for clinical review
- Access engagement, breath check adherence, cravings, and goal performance information
- View validated health questionnaire scores (GAD-7, K10, PHQ-9, AUDIT, MACE, User Experience Survey)
- Communicate with patients via the secure in-app Communication Desk
- Request breath checks and view historical breath check information
- Review the patient progress calendar and therapy timeline

This document covers the Clinician Dashboard only. Patient-facing instructions are provided in AlcoChange Detailed Instructions for Use v3.2 (IFU-AC-001, August 2026). The Clinician Dashboard Guide referenced in patient IFU Section 2.1 is this document (CL-IFU-CD-001).

1.1 Connected Device

The dashboard displays breath check data for patients who use the ADBII breath alcohol indicator (Model BA6), a separate medical device that connects to the patient's AlcoChange app via Bluetooth. Refer to the patient IFU (Section 11) and the ADBII's own Instructions for Use (CL-REG-ADBII-IFU-001) for device-specific information.

2. Intended Users and Prerequisites

2.1 Intended Users

The AlcoChange Clinician Dashboard is intended for use by:

- Hepatologists and gastroenterologists managing patients with alcohol-related liver disease (ARLD)
- Alcohol nurse specialists and alcohol liaison nurses (ALNs) in outpatient and community settings
- GPs, addiction specialists, and other registered clinicians prescribing AlcoChange under the NIHR RCT (ISRCTN10911773) or in routine clinical use
- Trained clinical support staff assisting with patient onboarding under direct clinician supervision

All users must be trained by CyberLiver or their NHS Trust alcohol care team before using the dashboard independently. Training covers access and setup, patient enrolment, dashboard navigation, risk information handling, data interpretation, and safety-critical workflows.

2.1a Patient App Intended use and Indications for reference

Intended Use

AlcoChange is a prescription-only digital therapeutic intended to support the reduction of alcohol use and the maintenance of abstinence in adults (aged 18 years or over) with established alcohol-related liver disease (ARLD). It is used as an adjunct to standard clinical care, under the supervision of a qualified clinical team, and does not replace standard clinical care. AlcoChange delivers behavioural change interventions and provides information used by the clinical team to monitor the patient's behavioural risk (relapse and disengagement) during treatment.

2.2 Indications for Use

AlcoChange is indicated as a 90-day, prescription-only treatment for adults (aged 18 years or over) with established ARLD who are enrolled in outpatient or community care under the supervision of a qualified clinical team. It provides behavioural therapy based on the CyberLiver Behaviour Change (CBC) Model, using personalised digital behaviour change techniques and behaviour change notifications, and presents behavioural-risk and engagement information, together with validated questionnaire outputs, to the supervising clinician for review.

2.3 Intended Users

- **Patients:** Adults (aged 18 years or over) with established ARLD, high-risk alcohol use, Alcohol Use Disorder, or persistent harmful drinking, who have been prescribed AlcoChange.
- **Clinicians:** Registered healthcare professionals (hepatologists, gastroenterologists, addiction specialists, alcohol nurse specialists, GPs, and mental-health clinicians) who prescribe AlcoChange and review patient information through the clinician dashboard.
- **Trained operators:** Trained clinical support staff assisting with onboarding under clinician supervision.

2.2 Technical Prerequisites

Internet access	Reliable broadband or NHS network connection required
Browser	Google Chrome (recommended), Microsoft Edge, Safari v15+, Firefox, current versions
Screen resolution	Minimum 1280 x 800; 1920 x 1080 recommended for full dashboard view
Account	CyberLiver dashboard account provisioned by CyberLiver or NHS Trust administrator
Dashboard URL	https://livercare.cyberliver.com
Dashboard version covered	v2.15 (displayed bottom-left of all screens)

The dashboard is a web application. It requires no local installation, calibration, or physical maintenance. Software updates are deployed server-side and controlled under the Device Lifecycle SOP (CL-QMS-PROC012).

3. Safety Warnings and Precautions

The Clinician Dashboard displays information for clinician review and decision-making.

The dashboard does not make clinical diagnoses, does not act autonomously, and does not replace clinical judgement.

All clinical decisions, including referrals, treatment changes, and escalation, remain the responsibility of the prescribing clinician.

Data displayed on the dashboard is refreshed periodically, not in real time. Do not rely on the dashboard for immediate crisis detection or emergency management.

AlcoChange does not send emergency alerts to clinicians, emergency services, or any third party on behalf of patients.

3.1 PHQ-9 Question 9 and Mental Health

The PHQ-9 questionnaire, administered at Weeks 5 and 11, includes Question 9 on suicidal ideation. Where a patient's response is anything other than "Not at all", the dashboard highlights this in the patient's Health Questionnaires tab for the reviewing clinician.

Patient-side control (primary): Patients are directly advised in the AlcoChange patient IFU (Section 4, Warning: Mental Health and Suicidal Thoughts) to contact their clinician or Alcohol-Liaison nurse immediately, and to use Samaritans (116 123), NHS 111, or 999 / A&E in a crisis. The patient IFU makes clear that AlcoChange is not a crisis intervention service. Patients are not instructed to wait for a message from the dashboard or from their clinician.

Clinician-side control: On seeing a PHQ-9 Q9 flag, follow your local clinical escalation pathway for patients at risk. Document your actions and outcome in the Review notes.

3.2 Data Currency

Dashboard data is not live-streamed. Always click the Refresh button before conducting a clinical review to ensure you are viewing the most current patient data. The "Last clinical review" timestamp on the daily review panel indicates when the dashboard was last updated, not when the patient last used the app.

3.3 Alcohol Withdrawal, Adjunctive Use and Over-Reliance

Acute alcohol withdrawal is a medical emergency. The dashboard cannot detect alcohol withdrawal and is not a control for it under the AlcoChange risk management file (see FMEA hazard ACC-20, controlled at patient level).

Patient-side control (primary): Patients are directly advised in the AlcoChange patient IFU (Section 4, Warning: Alcohol Withdrawal) to STOP using the app and to call 999 or attend A&E immediately if they experience symptoms of withdrawal (severe tremor, confusion, hallucinations, severe sweating, seizures). The patient IFU makes clear that patients must follow this standard-of-care instruction directly; they are not required to wait for a message, alert, or advice from the dashboard or their clinician before seeking emergency care.

Clinician-side awareness: Because withdrawal is handled at the patient level through the patient IFU, there is no expectation on the clinician to detect or respond to withdrawal via the dashboard. If withdrawal or a comparable clinical concern is raised through another channel (a telephone call, an in-person visit, a referral, or a family member), follow your local standard of care and clinical escalation pathway.

Adjunctive use and over-reliance: AlcoChange is adjunctive to clinical care and does not replace clinical assessment or treatment. Continued patient engagement with the app does not indicate a stable clinical condition. Do not delay clinical assessment or treatment on the basis of information in the dashboard, and do not treat absence of an adverse indicator on the dashboard as reassurance of clinical stability.

4. Accessing the Dashboard

Navigate to https://livercare.cyberliver.com in a supported browser. The sign-in screen displays the CyberLiver dashboard login form alongside compliance certification marks.

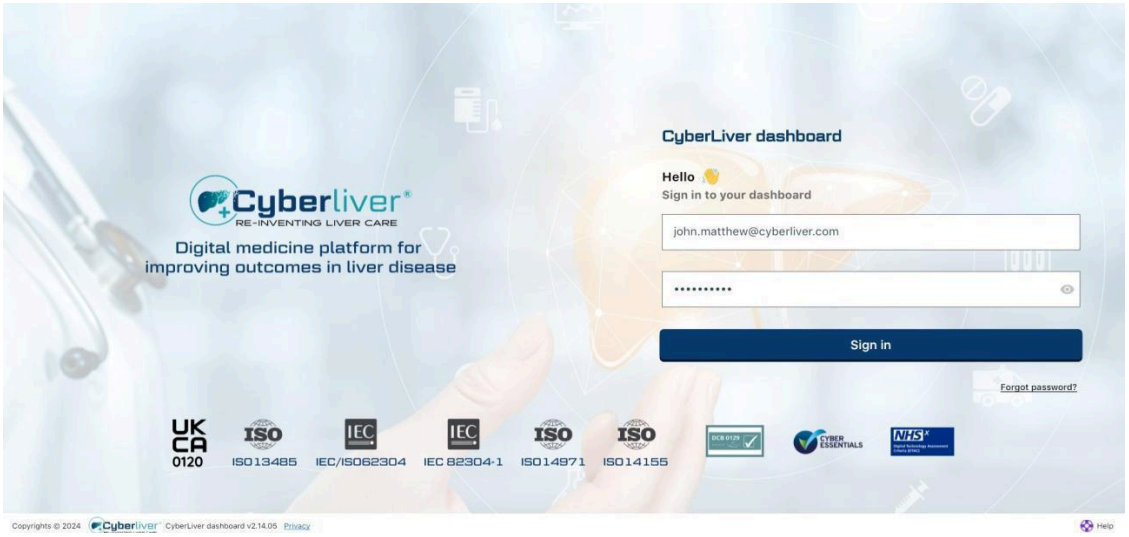

Figure 1: Clinician Dashboard, Sign-in Screen (v2.15)

The sign-in screen shows:

- CyberLiver logo and platform description
- Email and password fields, use your provisioned CyberLiver dashboard credentials
- "Forgot password?" link, use this to reset your password; contact info@cyberliver.com if issues persist
- Compliance marks at the bottom: UKCA 0120, ISO 13485, IEC/ISO 62304, IEC 82304-1, ISO 14971, ISO 14155, DCB 0129, Cyber Essentials, NHS X Digital Technology Assessment Criteria (DTAC)
- Dashboard version number displayed bottom-left (v2.15)

Access and account management

Your account is provisioned by CyberLiver or your NHS Trust administrator and is role-specific (clinician or admin).

Do not share your login credentials. Each clinician must have an individual account to ensure audit trail integrity.

Multi-factor authentication (MFA) is enabled on all clinician accounts. You will be prompted for a second factor at first login from a new device.

For account provisioning or access issues, contact info@cyberliver.com.

5. Daily Clinical Review, Home Screen

After sign-in, the Home Screen provides your daily clinical review overview. The header displays patient counts grouped by risk status, and the main panel shows the daily review summary with filters, therapy compliance, and patients at risk.

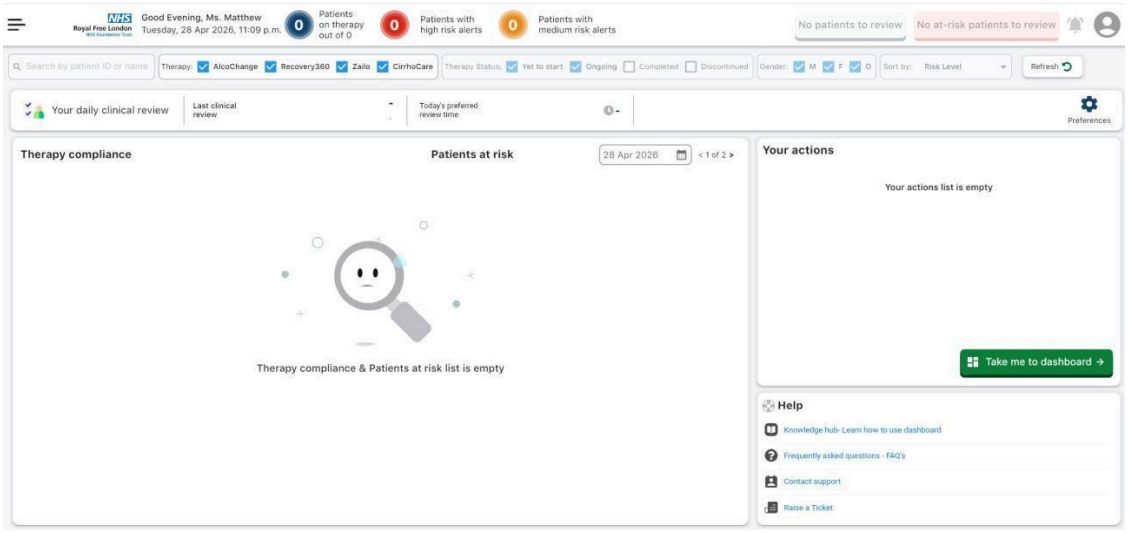

Figure 2: Home Screen, Daily Clinical Review Panel

5.1 Header, Patient Risk Summary

The top header bar shows three patient counts:

Indicator	Colour	Meaning
Patients on therapy out of [total]	Blue	Total patients currently on an active therapy programme
Patients with high risk indicators	Red	Patients with one or more HIGH risk flags requiring clinical attention
Patients with medium risk indicators	Orange/Amber	Patients with medium risk flags requiring review

5.2 Filter Bar

Use the filter bar to narrow your patient list. Available filters: Therapy type, Therapy Status (Yet to start, Ongoing, Completed, Discontinued), Gender, Sort by (Risk Level default), Search by patient ID or name, and Refresh (click to reload dashboard data, always refresh before clinical review).

5.3 Daily Review Panel

The central panel shows Therapy compliance and Patients at risk for today's date. Use the date picker (calendar icon) to navigate to previous days. The "Your actions" panel on the right lists outstanding clinical actions.

6. Patient List View

Click "Take me to dashboard" from the Home Screen, or navigate directly from the header, to access the full patient list. Each row represents one patient, showing a comprehensive clinical summary at a glance.

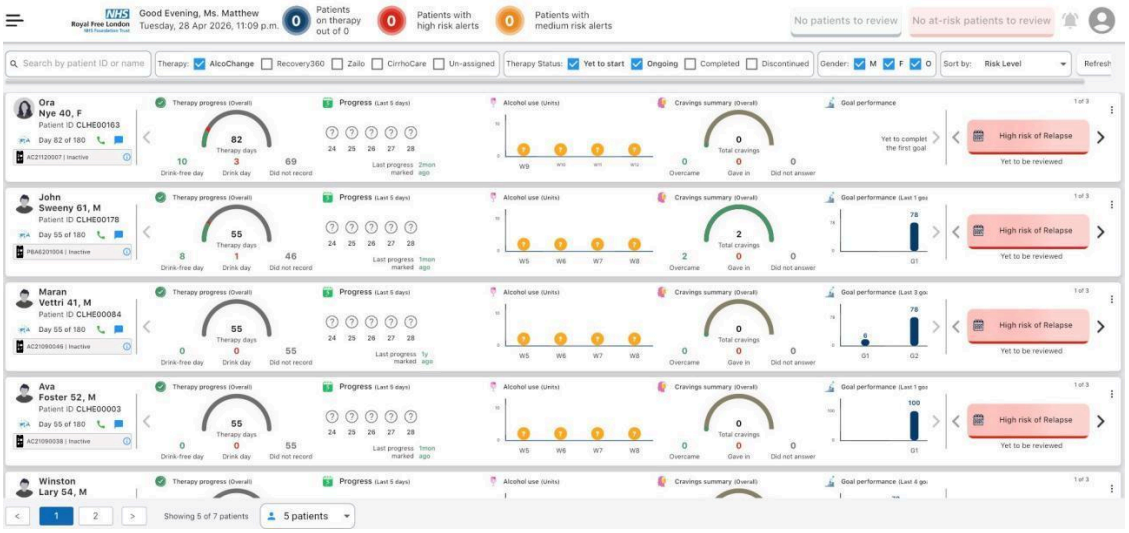

Figure 3: Patient List, AlcoChange patients showing therapy progress, engagement, alcohol use, cravings, goal performance, and risk status

6.1 Patient Row, Data Columns

Patient identity (left)	Photo, name, age, gender. Patient ID (CLHE-xxxxx). Therapy day (e.g. Day 82 of 180). Device/breathaliser ID. Breathaliser status (Active/Inactive).
Therapy progress (Overall)	Semicircular gauge showing overall therapy compliance %. Displays total therapy days, drink-free days, drink days, and "did not record" count.
Progress (Last 5 days)	Daily icons for the last 5 days: tick (drink-free), drink icon (drink day), question mark (not recorded). Shows "Last progress marked" timestamp.
Alcohol use (Units)	Weekly bar chart of alcohol units consumed. Question marks indicate weeks with no recorded data.
Cravings summary (Overall)	Semicircular gauge showing total cravings recorded. Breakdown: Overcame / Gave in / Did not answer.
Goal performance	Bar chart showing abstinence goal completion rate (0-100%) per goal period.
Risk status (right)	"High risk of Relapse", "Medium risk", or "Low risk", coloured red, amber, or green. "Yet to be reviewed" shown until clinician marks as reviewed.

7. Patient Record, Insights Tab

Click on any patient row to open their individual record. The patient record contains 8 tabs: Vitals, Insights, Treatment plan, Health questionnaires, Personalization, Communication desk, Breath checks, and Progress calendar. The Insights tab opens by default.

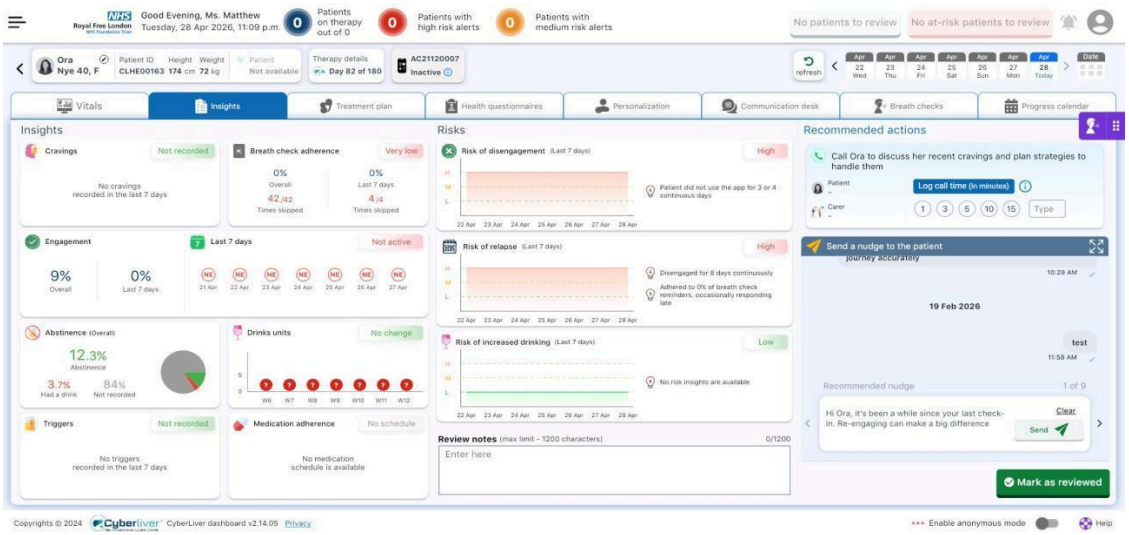

Figure 4: Patient Insights Tab, showing cravings, engagement, abstinence, breath check adherence, risk information, recommended actions, and clinician nudge tools (before review)

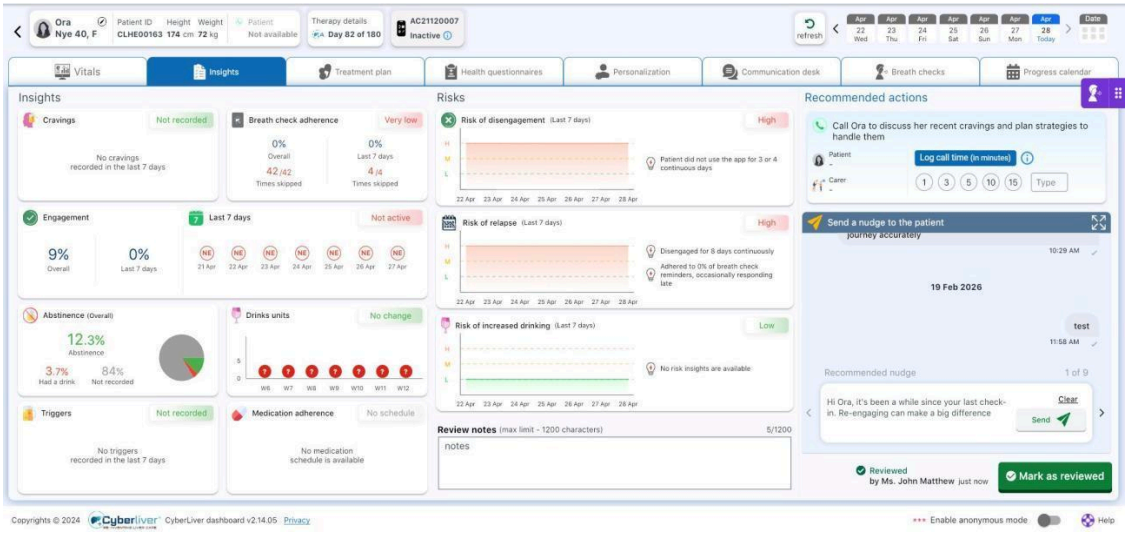

Figure 5: Patient Insights Tab, same patient after clinician adds review notes and marks as reviewed

7.1 Patient Header Bar

The header above the tabs shows: patient name, age and gender; Patient ID; height and weight; therapy prescription details (e.g. Day 82 of 180); breathalyser device ID and status (Active/Inactive); date navigator; Refresh button.

7.2 Left Panel, Insights Widgets

Cravings	Number and status of cravings recorded in the last 7 days. "Not recorded" = patient has not logged any cravings.
Breath check adherence	% of breath checks completed overall and in the last 7 days. Times skipped shown. "Very low" = significant adherence concern.

Engagement	Overall engagement % and last 7 days %. Daily engagement badges (NE = Not Engaged). "Not active" banner = no engagement in last 7 days.
Abstinence	Overall abstinence % with breakdown: abstinence %, had a drink %, not recorded %.
Drinks units	Weekly chart of alcohol units consumed. "No change" = no new drink records in period.
Triggers	"Not recorded" = patient has not logged any drinking triggers in the last 7 days.
Medication adherence	"No schedule" = no medication schedule set for this patient in the system.

7.3 Centre Panel, Risk Information

The Risk panel displays three risk indicators for the last 7 days, each classified High / Medium / Low. These indicators highlight patterns in the patient's data for clinician review; they do not represent a clinical assessment or diagnosis.

- Risk of disengagement: highlighted if the patient has not used the app for 3 to 4 continuous days.
- Risk of relapse: highlighted by combination of disengagement days, breath check adherence, and drink recording pattern.
- Risk of increased drinking: highlighted by increasing alcohol unit records.

Each risk panel shows a trend chart and a plain-English explanation of the contributing factors.

High risk indicators are for clinician review, not autonomous triage

High risk indicators highlight a patient for the clinician's attention. They do not constitute a clinical decision and do not act autonomously.

Review the patient record, form your own clinical judgement, take any action you consider appropriate, and document your action in the Review notes.

If you are unable to contact the patient, escalate per your local clinical pathway or document a follow-up plan.

7.4 Review Notes and Mark as Reviewed

The Review notes field (centre-bottom, max 1,200 characters) allows you to document your clinical review observations. Type your notes and then click "Mark as reviewed" (green button, bottom-right). The dashboard will record the review timestamp and reviewer name.

7.5 Right Panel, Recommended Actions and Nudge Tools

The right panel shows:

- Recommended actions: suggested clinician actions generated from patient data (for example, "Call the patient to discuss recent cravings"). These are prompts for clinician review, not clinical decisions.
- Send a nudge to the patient: pre-populated motivational message suggestions. Review and edit the wording before sending.
- Communication history: prior messages sent to the patient with timestamps.

8. Patient Record, Vitals Tab

The Vitals tab provides a comprehensive overview of tracked clinical parameters for the selected patient over a chosen time period.

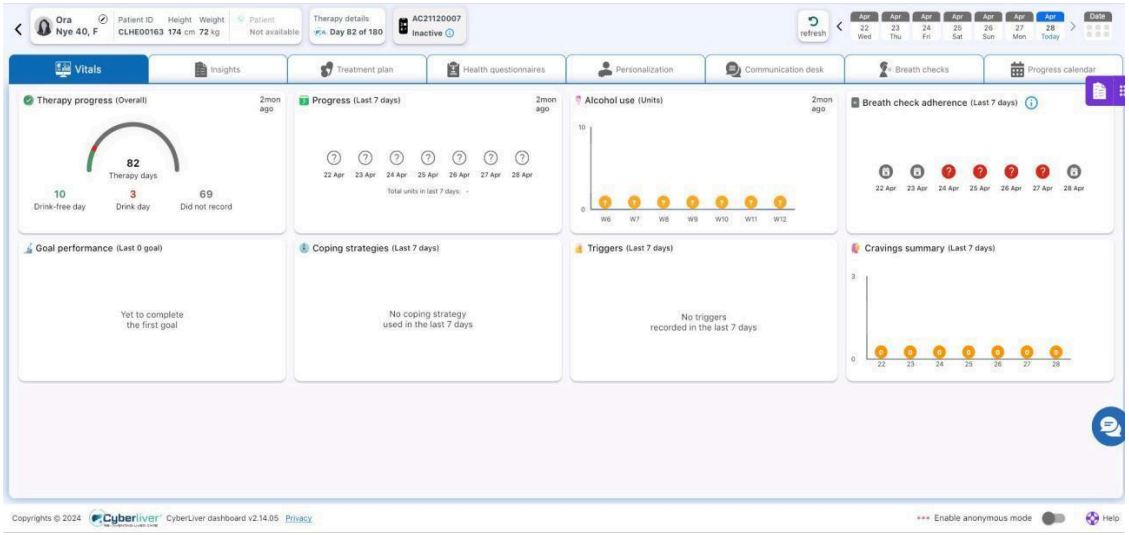

Figure 6: Vitals Tab, showing therapy progress, progress last 7 days, alcohol use, breath check adherence, goal performance, coping strategies, triggers, and cravings summary

Therapy progress (Overall)	Semicircular gauge (0-100%). Shows therapy days, drink-free days, drink days, did not record.
Progress (Last 7 days)	Day-by-day icons for the past 7 days with dates.
Alcohol use (Units)	Weekly bar chart. Question marks on bars = no data recorded for that week.
Breath check adherence (Last 7 days)	Calendar icons for each day: grey check = completed; red question mark = missed/skipped.
Goal performance	"Yet to complete the first goal" shown when no goal periods have been completed.
Coping strategies (Last 7 days)	Lists coping strategies used by the patient.
Triggers (Last 7 days)	Lists drinking triggers recorded.
Cravings summary (Last 7 days)	Bar chart of craving events per day. Stacked by: Recorded / Overcame / Given in / Not answered.

9. Patient Record, Health Questionnaires Tab

The Health Questionnaires tab shows the patient's scheduled and completed clinical assessment questionnaires, mapped to their therapy timeline.

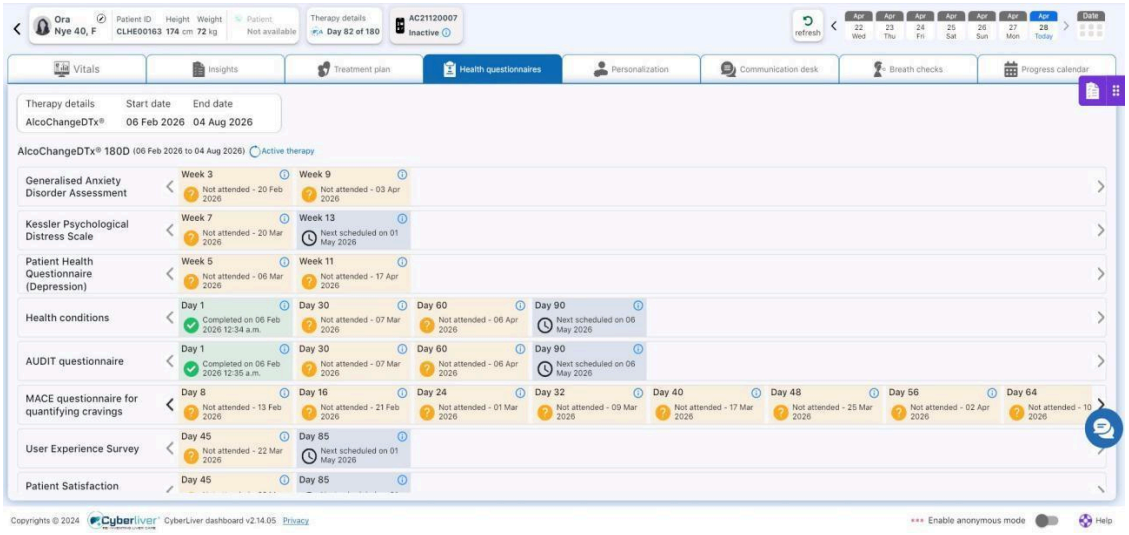

Figure 7: Health Questionnaires Tab, showing AlcoChangeDTx 180D programme schedule with GAD-7, K10, PHQ-9, Health conditions, AUDIT, MACE, User Experience Survey, and Patient Satisfaction questionnaires

9.1 Questionnaire Schedule

Each questionnaire row shows the scheduled assessment points across the therapy timeline. For each scheduled point:

- Green tick + date/time = Completed
- Orange question mark + date = Not attended
- Clock icon + date = Next scheduled (upcoming, not yet due)

Questionnaire	Schedule	Clinical purpose
GAD-7	Week 3, Week 9	7-item validated tool for generalised anxiety disorder screening.
K10	Week 7, Week 13	10-item validated psychological distress scale. Scores 10-50.
PHQ-9	Week 5, Week 11	9-item validated depression screen. Question 9 (suicidal ideation) is flagged for clinician review; follow your local escalation pathway.
AUDIT	Day 1, 30, 60, 90	10-item WHO Alcohol Use Disorders Identification Test.
MACE	8-day intervals	Craving quantification tool.
Health conditions	Day 1, 30, 60, 90	Patient-reported health condition ratings at quarterly intervals.
User Experience / Patient Satisfaction	Day 45, Day 85	Usability feedback and satisfaction rating.

PHQ-9 Question 9 handling

If the PHQ-9 shows any response other than "Not at all" to Question 9 ("Thoughts that you would be better off dead, or of hurting yourself"), the dashboard highlights this in the Health Questionnaires tab.

The patient is separately advised by the patient IFU to contact Samaritans (116 123), NHS 111, or 999 / A&E in a crisis, and to notify their clinician or Alcohol-Liaison nurse. Patients are not required to wait for a message from the dashboard or their clinician before seeking urgent mental-health support.

On seeing the flag, follow your local clinical escalation pathway for patients at risk. Document your action and outcome in the Review notes.

10. Patient Record, Communication Desk

The Communication Desk tab provides a secure two-way messaging channel between the clinician and the patient within the AlcoChange platform.

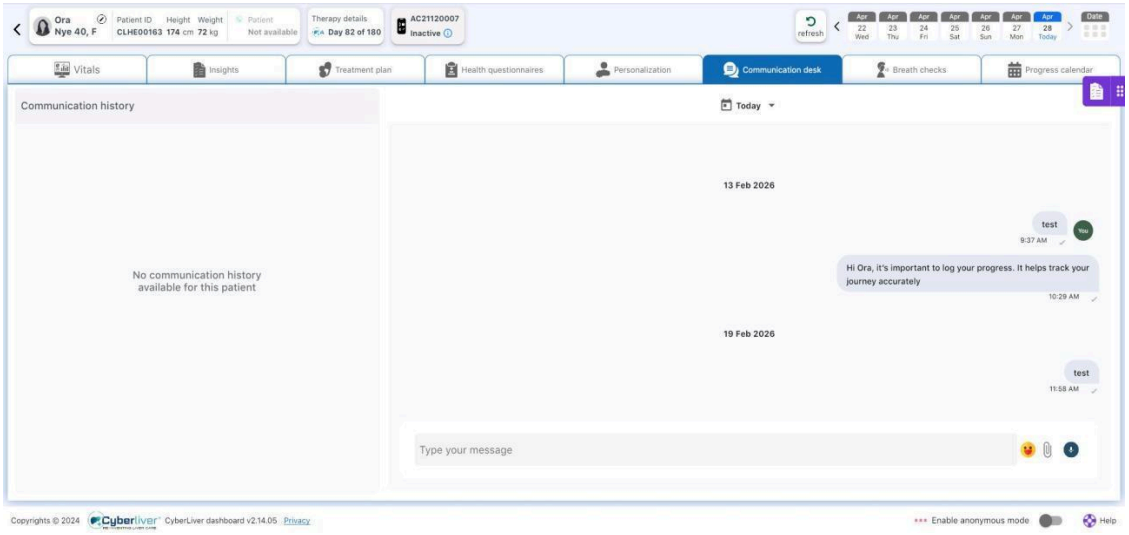

Figure 8: Communication Desk, showing communication history (left panel) and secure messaging thread with patient (right panel)

Communication Desk usage

Use the Communication Desk for routine clinical messages: appointment reminders, engagement encouragement, follow-up after risk indicators.

Do not send clinically urgent information via the Communication Desk. The patient may not read the message promptly.

For urgent clinical concerns, follow your local clinical escalation pathway.

All messages are logged and form part of the clinical record. Write messages professionally and in plain English.

11. Patient Record, Breath Checks Tab

The Breath Checks tab displays the patient's breath check history, including breath check status, face match verification, and location data where enabled.

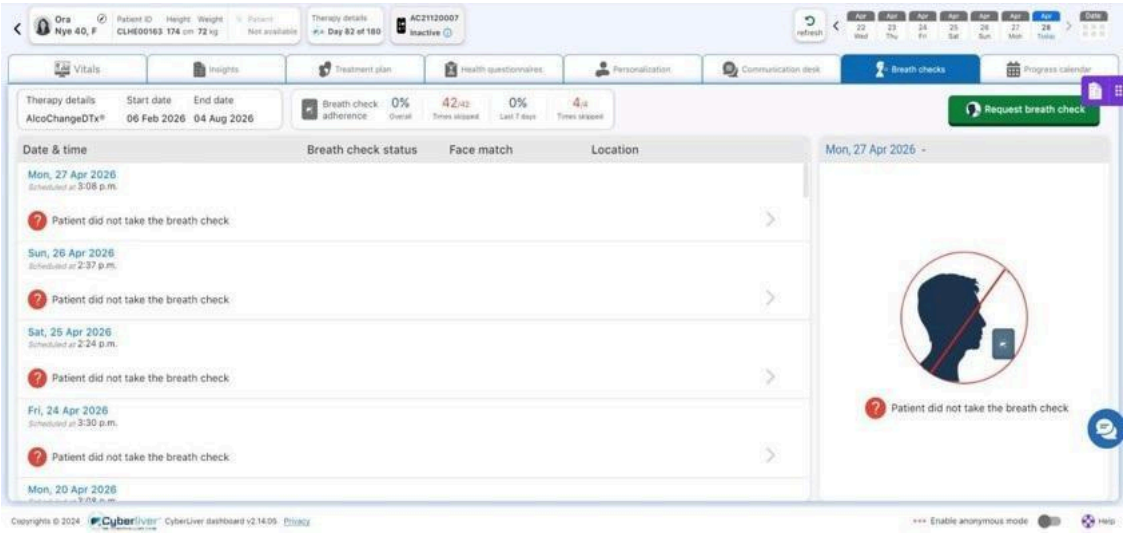

Figure 9: Breath Checks Tab, showing breath check adherence summary, historical check log, and a "Request breath check" function

The summary bar shows: breath check adherence (Overall % and Last 7 days %), times skipped, and a "Request breath check" button (sends a push notification to the patient requesting an immediate breath check).

Interpreting breath check data

Breath check adherence of 0% does not necessarily indicate active drinking; it may reflect device connectivity issues, patient disengagement, or the breathalyser being inactive.

Breath check indications are for patient self-monitoring and clinical trend review. They are not validated as forensic or diagnostic breath test results.

Consistently missed checks alongside deteriorating engagement should be treated as a risk of disengagement or relapse indicator for clinician review.

12. Patient Record, Progress Calendar

The Progress Calendar provides a longitudinal view of the patient's therapy journey with a month-by-month calendar display, goal performance data, cravings summary, and trigger tracking.

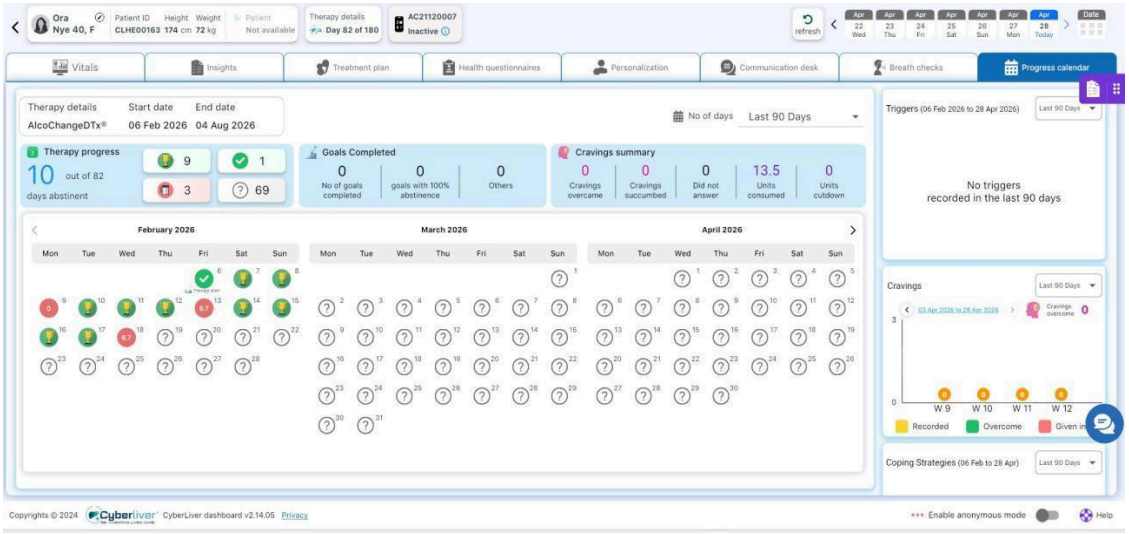

Figure 10: Progress Calendar, showing calendar with drink-free days, drink days, and non-recorded days; therapy progress, goals completed, cravings summary, and triggers panel

Each day is marked as drink-free (trophy icon), drink day (red circle with units), or not recorded (grey circle with question mark). Use the "No of days" dropdown to change the period.

13. Risk Information Handling and Clinical Escalation

The table below summarises the risk information the dashboard presents and the clinician actions to take on review. All actions remain a matter of clinical judgement; the dashboard does not act autonomously.

Indicator	Highlighted by	Clinician action
High risk of relapse	Disengagement, missed breath checks, drink recording pattern	Review the patient record. Take clinically appropriate action and document in Review notes. Mark as reviewed.
High risk of disengagement	Patient has not used the app for 3 to 4 continuous days	Review the patient record. Send a nudge, make direct contact, or assess continued therapy per clinical judgement.
Medium risk	Partial disengagement or moderate increase in drink recording	Review at your next clinical opportunity. Document review and plan.
PHQ-9 Q9 flagged	Patient selects any answer other than "Not at all" to Q9	Follow your local clinical escalation pathway. Document actions.
Elevated GAD-7 / K10	Scores in moderate or severe range	Review scores. Consider follow-up per clinical judgement.

After reviewing a patient and documenting your assessment in the Review notes field, click "Mark as reviewed". This records your name, the date and time of review, and your review notes.

14. Intended Performance and Residual Risks

AlcoChange is intended to support reduction in alcohol consumption compared to baseline after 90 days, increased abstinence rates, and sustained patient engagement with behavioural therapy. Clinical performance evidence is documented in the Clinical Evidence Report (CER002 v5.3) and the pilot study (Mehta et al., JHEP Reports 2024). Zero serious adverse events (SAEs) have been reported across all clinical investigations and post-market surveillance (total n=384 patients, 14+ months).

Residual risks documented in the AlcoChange Risk Management Report (RMR v3.4) that a clinician using the dashboard should be aware of:

- Missed relapse detection (FMEA CLI-04): the dashboard highlights risk of relapse based on engagement and self-reported data; low or absent data may reflect disengagement rather than clinical stability.
- Patient over-reliance / delayed help-seeking (FMEA CLI-16): AlcoChange is adjunctive. Reinforce standard clinical pathways at each contact and do not treat continued app engagement as evidence of clinical stability.
- Undetected mental health deterioration (FMEA CLI-17): PHQ-9, GAD-7 and K10 are administered at scheduled points; interim deterioration between scheduled assessments may not be visible. Baseline and mid-programme mental health assessment remain a clinical responsibility.
- Progressive cognitive impairment (FMEA CLI-18): patients with worsening hepatic encephalopathy may self-report inaccurately; the dashboard may display apparently valid but unreliable data.
- Breath check confounded by acute withdrawal (FMEA ACC-20): a breath test taken during withdrawal may record apparent abstinence. Withdrawal is handled by the patient IFU as described in Section 3.3.

Anticipated adverse effects reported by patients (from the patient IFU; all non-serious):

Category	Possible effects	Management
Psychological (mild)	Increased anxiety from therapy use; guilt or shame when recording a drink; disappointment with slow progress; motivational pressure from notifications	Clinician or Alcohol-Liaison nurse support. Notification settings can be adjusted.
Technology-related (mild)	Frustration with app crashes, sync delays, or breathalyser connectivity issues; occasional incompatibility with older phone models	In-app Help or info@cyberliver.com. Average technical support response time is less than 4 hours.
Social (mild)	Privacy concerns using the breathalyser in public; worry about others seeing the app; perceived stigma	The app is designed to be discreet. Breathalyser use is optional.
Physical	None identified. No physical adverse effects have been reported.	N/A

15. Preferences and Settings

Click the gear icon (Preferences) in the top-right of the Home Screen to set your preferred daily clinical review time. This configures when the dashboard surfaces your daily review queue.

Use the filter bar on the patient list to customise your default view. Contact your NHS Trust dashboard administrator or info@cyberliver.com to update your account profile, reset your password, or modify patient assignment settings.

16. Troubleshooting and Technical Support

Cannot sign in / credentials not recognised	Use "Forgot password?" on the sign-in screen. If still unable to access, contact info@cyberliver.com with your institution name.
Dashboard data appears stale or out of date	Click the Refresh button. If data is still not updating, check your internet connection and try again.
Patient list is empty despite active prescriptions	Check therapy and status filters. Reset filters to default and refresh. Contact support if issue persists.
Risk indicators not appearing for at-risk patients	Ensure "Yet to start" and "Ongoing" therapy status filters are ticked. Refresh the dashboard. If still absent, raise a support ticket.
Cannot see breath check data	Confirm the patient's breathalyser is Active (shown on patient row and in Breath checks tab). If Inactive, the patient's device is not linked or is powered off.
Dashboard is slow or unresponsive	Check internet connection. Try a different browser (Chrome recommended). Clear browser cache. If persistent, contact info@cyberliver.com.
Message not delivered to patient	Confirm patient has notifications enabled in their app settings. Messages are delivered via push notification.

For urgent technical issues affecting patient safety, contact CyberLiver support immediately: info@cyberliver.com. In a medical emergency, call 999. Do not wait for a technical response before escalating clinical concerns.

17. Support and Contact Information

Technical support email	info@cyberliver.com
Dashboard URL	https://livercare.cyberliver.com
Knowledge hub	Available via Help in dashboard
FAQs	Available via Help in dashboard
Raise a support ticket	Available via Help, Raise a Ticket in dashboard
Paper copy of this IFU	Request via info@cyberliver.com, provided free of charge within 7 calendar days
Manufacturer	CyberLiver Limited, Devonshire House, 582 Honeypot Lane, Stanmore, HA7 1JS, UK
UKCA Certificate	GB23/00000054 (SGS UK AB 0120)

18. Safety, Risk and Compliance Standards

The AlcoChange Clinician Dashboard forms part of the AlcoChange digital therapeutic platform, regulated as a Class IIa Software as a Medical Device (SaMD), Rule 10, under UK MDR 2002 (as amended). UKCA marking: GB23/00000054 (SGS UK AB 0120).

The following standards and technical specifications have been applied:

- BS EN ISO 13485:2016+A11:2021, Quality Management Systems
- BS EN ISO 14971:2019+A11:2021, Application of Risk Management to Medical Devices
- IEC 62304:2006+A1:2015, Medical Device Software Lifecycle Processes (Class B)
- IEC 82304-1:2016, Health Software Safety
- EN 62366-1:2015+A1:2020, Application of Usability Engineering to Medical Devices
- BS EN ISO 14155:2020+A11:2024, Clinical Investigation of Medical Devices for Human Subjects
- DCB0129:2018, Clinical Risk Management for Health IT
- EN IEC 81001-5-1:2022, Health Software and Health IT Systems Safety, Effectiveness and Security
- IEC 80001-1:2021, Application of Risk Management for IT-Networks Incorporating Medical Devices
- IEC TS 81001-2-2:2025, Guidance for the Disclosure and Communication of Medical Device Security Needs
- ISO/IEC 27002:2022, Information Security Controls
- Commission Regulation (EU) No 207/2012, Electronic Instructions for Use (as applied under UK MDR 2002 Regulation 4J)

This eIFU is available at https://alcochange.com/information-materials.html. A paper copy is available free of charge on request within 7 calendar days, contact info@cyberliver.com.

19. Document History

Version	Date	Author	Summary
2.15	September 2026	Anu Balaji	UKCA conformity mark with AB number 0120 added to cover and regulatory header (CAR 43k-1-1). Classification corrected to Rule 10 (CAR C.6-3-2). Manufacturer address updated. Intended performance and residual risks section added. Installation and maintenance statement added (ER 13.6(d)). Safety warnings reframed: dashboard displays information for clinician review and decision-making, does not decide or act autonomously. Aligned to patient IFU v3.2.

2.14	28 April 2026	Anu Balaji	Covers AlcoChange Clinician Dashboard v2.15 (livercare.cyberliver.com)
1.0	22 October 2023	Anu Balaji	Initial version

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