

INSTALLATION AND USER INSTRUCTIONS – PATIENT INFORMATION

CirrhoCare 2.0



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1 Preface

1.1 Intended use of the product

CirrhoCare is a digital therapeutic intended for the assisted diagnosis, recommendations and therapeutic intervention for managing new complications of decompensated cirrhosis.

1.1.1. Indications for Use

CirrhoCare will be applied for out-of-hospital specialist Hepatology follow-up and intervention of all adult cirrhosis patients, at risk of acute cirrhosis decompensation. Its principal use is foreseen in patients being discharged from the hospital following recovery from acute cirrhosis decompensation for the assisted diagnosis of new complications of cirrhosis and their early intervention. As such, potentially preventable causes of cirrhosis decompensation when diagnosed, such as dehydration or hepatic encephalopathy, would be managed by a prescription digital therapeutic intervention by CirrhoCare. In patients who remain stable on CirrhoCare Management follow-up for up to 6 months, a more standard medium-term outpatient clinical follow-up pathway could be resumed. For those who remain unstable or with signs of frequent new complications, CirrhoCare PDT management would be continued beyond 6 months.

1.2 Users of this manual

Patients enrolled under the CirrhoCare program

1.3 Obtaining documentation and information

1.3.1 Internet

The latest version of the documentation is available at the following address: https://cirrhocare.com/patient-eifu/

1.3.2 Ordering documentation

Documentation, user instructions and technical information can be ordered by emailing CyberLiver Ltd at info@cyberliver.com

1.3.3 Documentation feedback

If you are reading CyberLiver product documentation on the internet, any comments can be sent to info@cyberliver.com

We appreciate your comments.

2 Description of the product

2.1 Purpose of the product

CirrhoCare® is one of a new class of therapeutics called Prescription Digital Therapeutics (PDTs). It is designed specifically for the diagnosis of further cirrhosis complications and/or organ dysfunction for patients at home.

2.2 Product elements

The CirrhoCare HealthKit comes with the CirrhoCare App installed on the smartphone, an ECG monitor, a Blood pressure monitor and a weighing scale.

Specifications for the iOS phones to support the CirrhoCare patient app

iOS Phone minimum requirements:

OS version: iOS 13

Display size: 5.5 inches

RAM: 2GB

Storage: 64 GB

Connectivity: 4G, WiFi, Bluetooth 4.0

Connectivity requirements for wearables & sensors:

Watch: Bluetooth 4.0, Steps calculator, sleep calculator, heart rate calculator, ECG (optional), rechargeable battery

Blood Pressure monitor: Bluetooth 4.0, Systolic & Diastolic BP, Heart rate, ECG (optional), rechargeable battery or replaceable battery

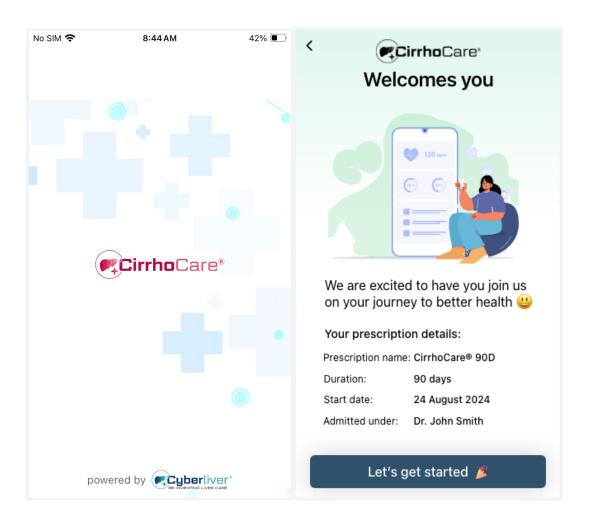
Weighing scale: Bluetooth 4.0, Total weight (kg & lbs), Bio-impedance (optional), rechargeable battery or replaceable battery

Digital Thermometer: Bluetooth 4.0, Fahrenheit & Celsius modes, rechargeable battery or replaceable battery

2.3 Use of the smartphone app

The CirrhoCare App will be pre-installed on your smartphone and ready to use.

The medical personnel will instruct you during your induction on the app usage. Your device will be already connected and "synced" to the app and ready to use.



3 Safety instructions

3.1 How to use the product safely

Follow the instructions that are displayed on the app. Follow each step in the sequence. During usage, please put each element of the HealthKit on a safe, flat surface before use. Make sure the devices are charged as appropriate. Do not mishandle the HealthKit. Do not expose the kit to heat or moisture.

3.1.1 Explanation of safety information on the packaging and product

Read and understand the manual and its safety instructions for each element of the HealthKit, if available, before usage.

4 Operation/Use

4.1 How to use the product

4.1.1 App initiation

Your smartphone will have the CirrhoCare App installed and available for use. You will receive instructions on how to use the app from the medical staff during your induction. The devices will already be "synced" to your smartphone and available for use.

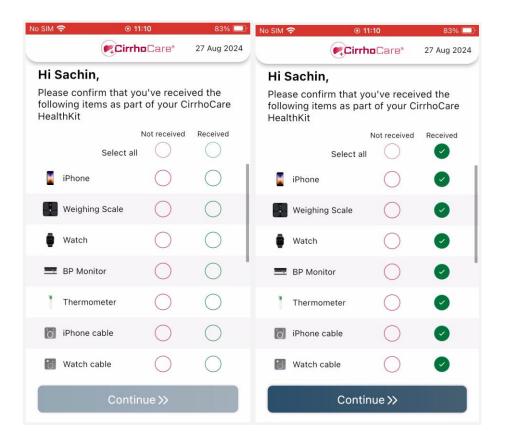
4.1.2 Validating HealthKit receipt

Once your HealthKit is received, you may be asked to cross-check or validated if you received all of the items in the HealthKit depending on your prescription. The mandatory items on the HealthKit are the following, which you will typically receive:

- iPhone
- Apple Watch
- Weighing Scale
- BP Monitor
- Digital Thermometer
- iPhone cable
- Watch cable
- BP monitor cable
- Charging adapter UK plug
- Sim card

There are also a few optional items that you may not receive or may receive at a later date. This will not have any impact on your therapy. They include:

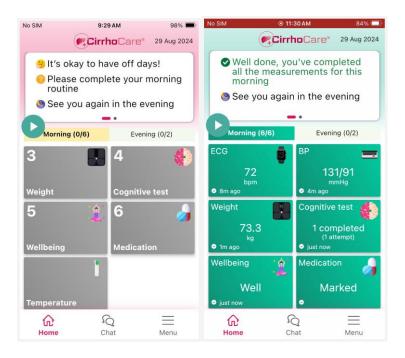
- HealthKit bag
- 3-in-1 spare cable
- User manual
- Spare batteries
- Mobile case



4.1.3 App elements

Your app will be personalised based on your prescription. You will have any or all of these elements on your app according to your prescription.

- ECG (morning)
- Blood pressure (morning)
- Weight (morning)
- Cognitive test (morning)
- Wellbeing (morning)
- Medications (morning and evening)
- Temperature (on clinician request)
- Food & fluid (evening)



4.1.4 Usage timings

The app will automatically trigger morning reminders at scheduled time (07:00 to 11:45 am) personalised for the patient and point to the ECG measurement guide screen.

If you fail to respond to the morning reminder, a follow-up reminder will be sent. If you miss the 2nd reminder, the app will send a 3rd reminder.

If you still fail to respond to the reminder, CirrhoCare will send an alert to the Clinician.

Daily app connection			
	Measurement of your heart rate (ECG), Weight and Blood Pressure (see individual instructions)		
Morning routine (07:00 to 11:45 am personalised)	Answer questions regarding your mood and enter any symptoms and questions/concerns you have for the clinical team on how you feel		
	Perform the Cognitive test as indicated on the app		
	Record your temperature if prompted		

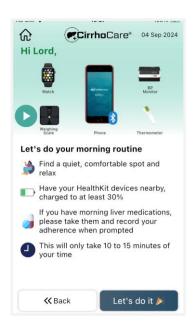
	Record update on morning medications adherence
Evening routine (06:00 to 09:45 pm personalised)	Record update on evening medications adherence
	Record your food & fluid intake for the day

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4.1.5 Morning routine

4.1.5.1 Morning routine initiation

Before beginning your morning routine, find a quiet, comfortable spot and relax. Have your HealthKit devices ready and charged. If you have any morning liver medications, please take them.

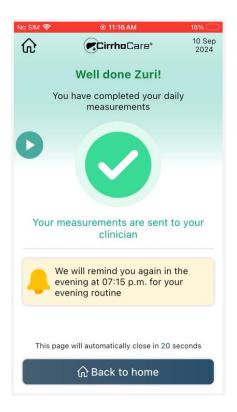


As part of your morning routine, you will be asked to take the following measurements/tests

- ECG
- BP
- Weight
- Cognitive test
- Well-being
- Morning medications adherance
- Temperature (if requested by your clinician)

4.1.5.2 Morning routine completion

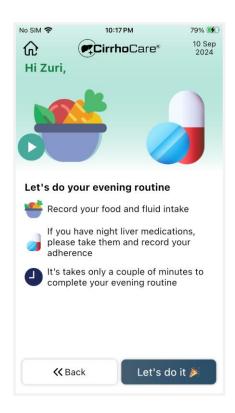
After completing your morning routine, you will see a screen indicating the completion of your routine and displaying the scheduled time for your evening routine. Your measurements will be sent to your clinician.



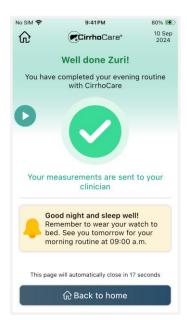
4.1.6 Evening routine

4.1.6.1 Evening routine initiation

As part of your evening routine, you will be prompted to log your afternoon and night medications as well as your food and fluid intake for the day. Your evening routine will only take you 3 to 5 minutes.



4.1.6.2 Evening routine completion



Once you complete your evening routine, your log will be sent to your clinician. Remember to wear your watch throughout the night to aid in tracking your sleep.

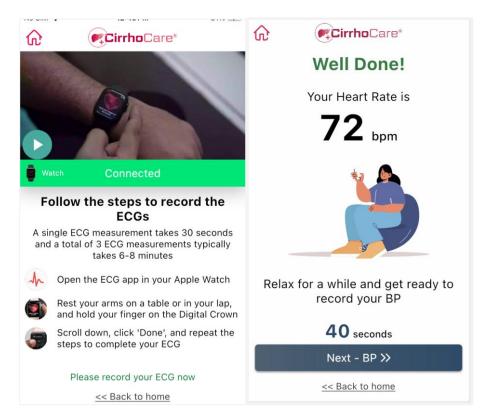
To understand how to take each measurement, please review the sections that follow for detailed instructions.

4.1.7 Measurement of ECG, Blood Pressure and weight

- You will receive a reminder alarm notice on your watch and smartphone at your scheduled every day asking you to perform three very critical liver health status checks: Blood Pressure, ECG, and Weight
- The three gadgets that were provided to you during the induction will be used to measure each of these three parameters
- This will only take 10 to 15 minutes to complete these measurements

4.1.7.1 ECG Measurement

The First measurement you will be ask to take the ECG. You will need your watch and your smartphone.



Procedure:

- 1. Tap on the ECG tile in your CirrhoCare app.
- 2. Each measurement takes 30 seconds, and you'll need to complete 10 measurements.
- 3. Rest your arms on a table or in your lap.
- 4. Open the ECG app on your Apple Watch.

- 5. Place your finger on the Digital Crown. No need to press down; just keep your hands still.
- 6. After each measurement, scroll down on the watch and click 'Done'.
- 7. The app will update the count simultaneously.
- 8. Repeat this process until you've completed all 10 measurements.

4.1.7.2 Blood Pressure Measurement

The second measurement you will be ask to take your blood pressure. You will need your blood pressure monitor and your smartphone.

Procedure:

- 1. Please remain seated in a comfortable position for this test. You need to be at rest for five minutes before taking a measurement.
- 2. Press the 'Start/Stop' button on the BP monitor to connect.
- 3. Wrap the pressure cuff of the Wireless Blood Pressure Monitor around your arm, about 1 inch above the bend in your elbow. Make sure the aluminium tube is at the bicep level.



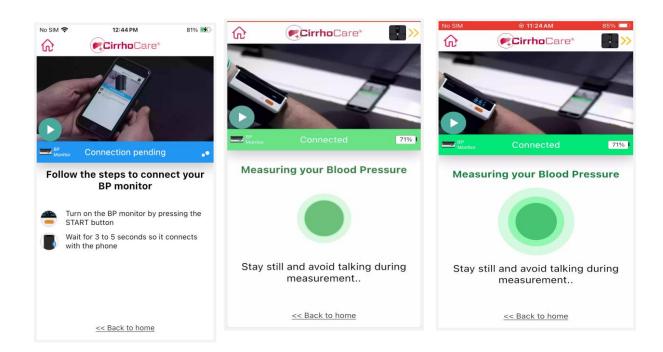
4. Place your arm on a table, slightly bent and at the level with your heart.



5. Press the 'Start/Stop' button again of the Wireless Blood Pressure Monitor device.

- 6. A notification will appear on your smartphone to tell you that the measurement has started.
- 7. Recording your BP typically takes 3 minutes.
- 8. Wait patiently as the cuff inflates and deflates.
- 9. After completion, the reading will appear on the app screen.

Audio Playing in the language choosen by the patient.

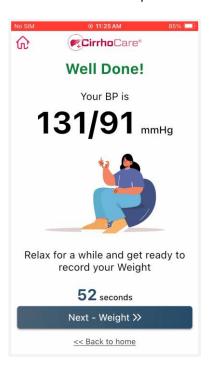


Before Bp Device Connecting

Device connected

Device connected – While Recording measurements

Measurement completed

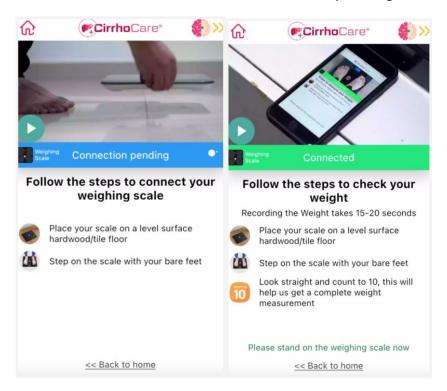


4.1.7.3 Weight Measurement

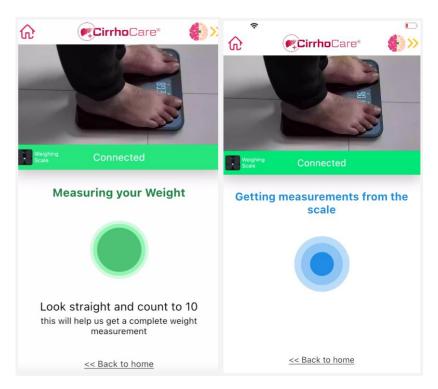
The third measurement you will be ask to take the weight. You will need your weighing scale and your smartphone.

Procedure:

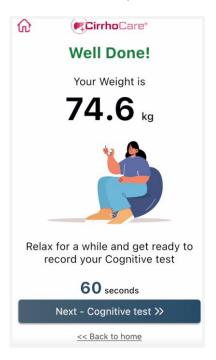
- 1. Place the weighing scale on a hard floor like hardwood or tile. Do not place the scale on a carpeted floor.
- 2. Tap on the weight tile on your CirrhoCare app.
- 3. Tap on the Weight tile within the CirrhoCare app. Once selected, you'll see 'Connection pending.'
- 4. Now gently tap on the weighing scale to activate it or turn it on.
- 5. Upon successful connection, your phone will display 'Connected.'
- 6. Stand on the scale with your bare feet to measure your weight.
- 7. Wait for 10 seconds for the scale to calculate your weight.



Getting Weight and Fluid Weight data from Weighing Scale



Measurement Completed

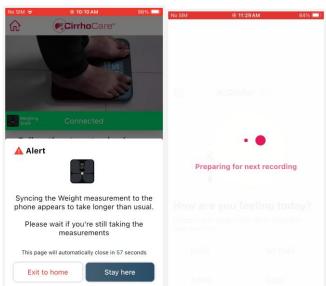


4.1.7.4 Unusual weight recorded

When recording your weight, please ensure that you are barefoot and standing on a flat surface such as tile or hardwood. CirrhoCare maintains a record of your measurements, and if your weight deviates significantly from your usual range due to improper scale placement, stepping on incorrectly, or someone else standing on the scale, you will receive an alert regarding the variation. Your confirmation will be required to proceed







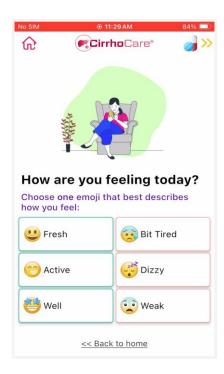
4.1.8 Recording wellbeing

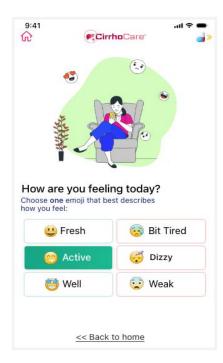
The app will collect your mood and any symptoms you are experiencing. Please try to be as specific as possible because every little thing counts. We want to know how you operate daily, so please be precise.

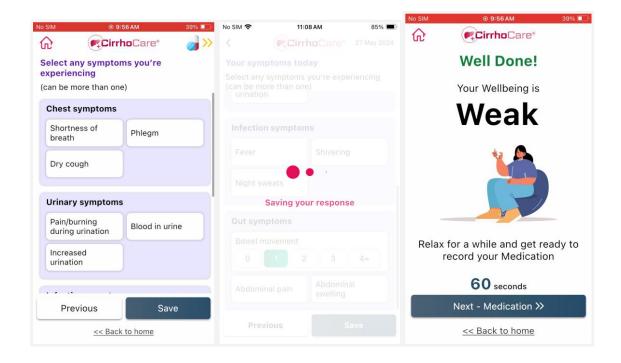
Procedure:

To record your wellbeing:

- 1. Open the Wellbeing recording tile in the CirrhoCare app.
- 2. Emojis represent a range of feelings: Fresh, Active, Well, Bit tired, Dizzy, and Weak.
- 3. Choose the emoji that best represents your current state.
- 4. Once you've marked how you feel, you'll have the option to note any symptoms—this step is entirely optional.
- 5. If you're symptom-free, simply click Save.
- 6. If you do have symptoms, choose one or more from the list, and once you've marked everything, click Save.







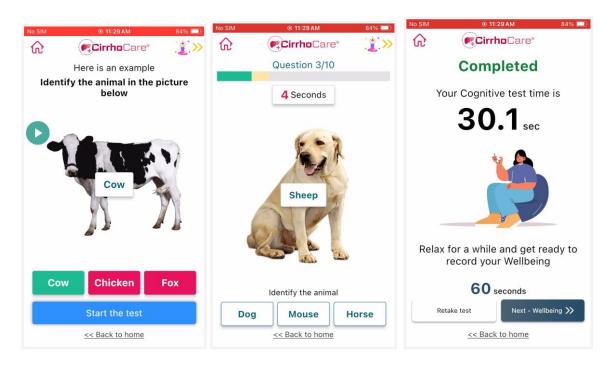
4.1.9 Recording Cognitive test

Cognitive test is a test used to assess your brain function and thinking abilities. The Cognitive Ability Test is a simple yet effective tool for monitoring cognitive health.

Procedure:

- 1. Tap on the Cognitive Ability tile on the CirrhoCare app to open the test.
- 2. You will be presented with an image of an animal and three options to identify it correctly.
- 3. A name of an animal will be displayed above the picture, which may or may not be the correct answer.
- 4. Your task is to correctly identify the animal in the image by selecting one of the three options.
- 5. There are 10 animals to identify, and the time taken to complete the test is calculated.
- 6. If you answer incorrectly at any point, the test is failed. You also have the option to retake the test as needed.

Upon completion, your results will be displayed, showcasing the time taken to identify all the animals correctly.



Cognitive Test Result Screen

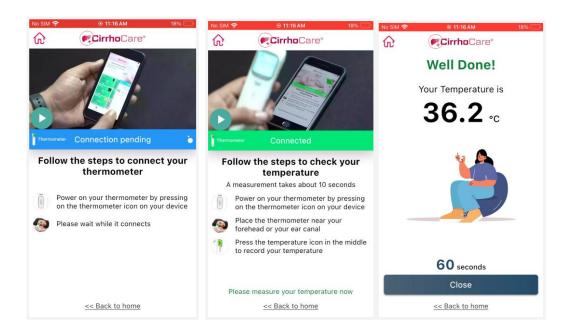
4.1.10 Recording temperature

Occasionally, the app will ask you to take your temperature using a thermometer if you feel poorly. You can measure your temperature if you are developing a cough or urinary symptoms or if your ECG and blood pressure measures alert the clinical team to a suspected new infection.

Procedure:

- 1. Wait for a notification or prompt from your clinician on the CirrhoCare app requesting you to record body temperature.
- 2. Tap on the temperature tile on your CirrhoCare app. You will see "Connection pending" on your phone.
- 3. Now turn on your Digital Thermometer by pressing the temperature button in the middle of the device. You will see "Connected" on your phone.
- 4. Place the thermometer's sensor against your forehead or in your ear and press the temperature button again. It is often preferred to use the ear method for more accurate readings, but the forehead method can be more comfortable and convenient.

- 5. Wait until the thermometer beeps, indicating it has finished taking your temperature.
- 6. The temperature reading will be displayed on the thermometer's digital screen and the CirrhoCare app.



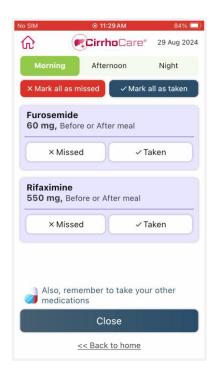
4.1.11 Recording medication intake

Please take your liver medications according to the schedule and record the adherence on the app.

Procedure:

To record your medication adherence:

- 1. Open the "Medications" tile in the CirrhoCare app.
- 2. You will see a list of your liver health-related medications scheduled for the current session (Morning, Afternoon, and Night).
- 3. For each medication, select "Taken" if you have taken the medication. If you did not take the medication, select "Missed".
- 4. Record your morning medications along with your morning measurements. For afternoon and night medications, you can record when you log your food and fluid as part of your evening routine.



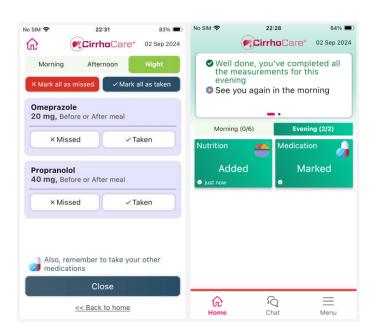
Save: The 'Save' button becomes enabled as soon as you record medication adherence for at least one medication during each session.



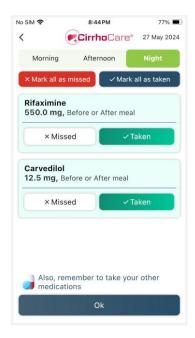
Save & Continue: The 'Save & Continue' button becomes active after recording adherence for all medications in a session. Clicking on it allows you to proceed to the next session



Save & Close: The 'Save & Close' button becomes active after recording adherence for all medications in all sessions. Clicking on it takes you back to the home page. Upon recording medication adherence, the tile will turn green.



Close: After recording adherence for all medications, you will find the 'Close' button upon clicking the medication tile again



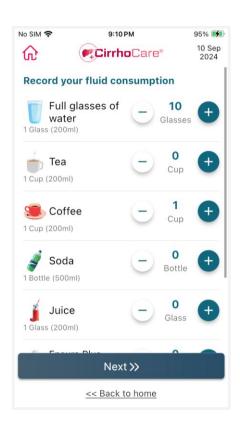
4.1.12 Recording Food & Fluid

As part of your evening routine, you will be able to record your food & fluid intake for the day.

Procedure:

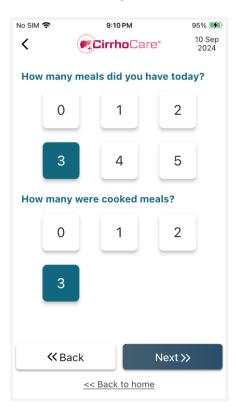
To record your fluid intake:

- 1. Open the Food & Fluid Recording tile in the CirrhoCare app.
- 2. You'll see a list of drinks to record your fluid intake.
- 3. Select the drink you had and add the number of drinks against each.
- 4. You can add more than one category of drinks.
- 5. Once you've recorded all your drinks for the day, click on 'Continue'.



To record your food intake:

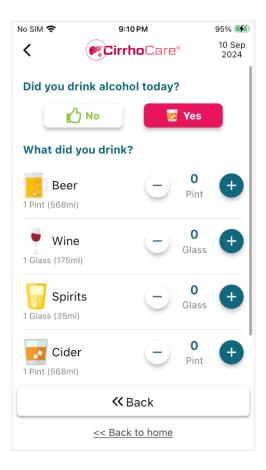
- 1. Choose the number of meals you've eaten for the day.
- 2. Select how many of those meals were cooked.
- 3. Once you've recorded the number of meals, click on 'Continue'.



To record your alcohol intake:

- 1. Choose 'No' or 'Yes' depending on whether you had a drink.
- 2. If 'Yes', choose the alcoholic drink and the number of pints or glasses.
- 3. You can add more than one type of drink.
- 4. Once you've recorded all your alcoholic drinks for the day, click on 'Continue'.

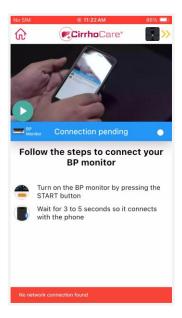
Remember, record all the food and fluids you've consumed for the day as part of your evening routine.



4.1.13 Internet connection issue indication

Your app requires an active internet connection to work. Make sure your phone has an active internet connection at all times. Please do not turn off your internet.

• If you experience any internet issues during the functioning of your app, you will see a screen as shown below on whatever screen you are on.



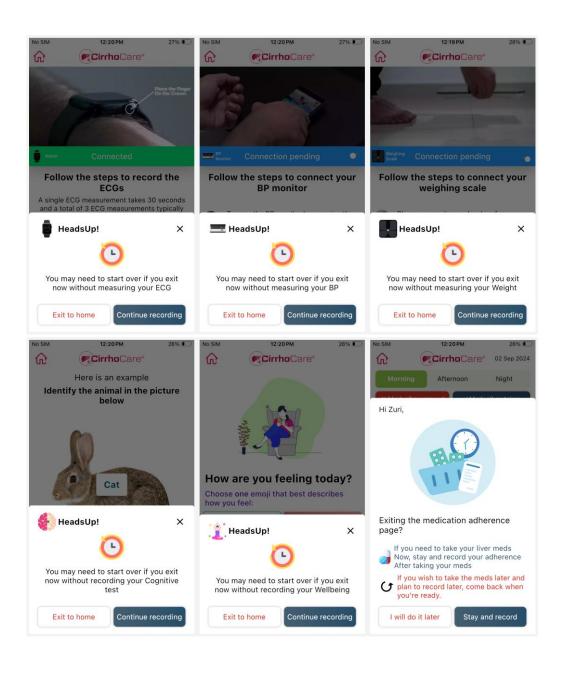
• If you encounter any internet issues while opening the app, you will see a screen as shown below.



• In either case, please ensure that your internet connection is working properly to ensure the proper usage of the app.

4.1.14 Ensure an uninterrupted measurement flow

We recommend that you finish your measurements in a single sitting. If you break the measurements in between, you may have to restart the particular measurement from the beginning. Therefore, settle yourself comfortably and have all your devices next to you before starting the measurements.



4.2 The in-app CirrhoCare Patient guide (E-Learning module)

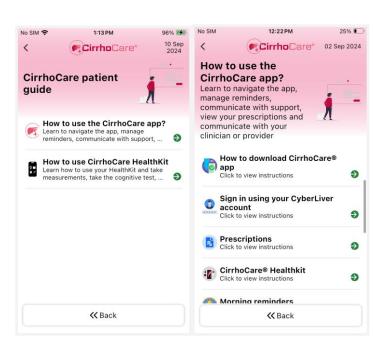
The in-app guide will help you learn how to use the app and the HealthKit. The guide will be a step-by-step on-screen manual to use the app and the HealthKit with the help of images, illustrations and videos. The guide will also be available to the you anytime on demand. This guide is divided into 2 segments.

- How to use the CirrhoCare app?
- How to use the CirrhoCare HealthKit?

4.2.1 How to use the CirrhoCare app

This section helps you with the following:

- Viewing your prescriptions
- Viewing components of your HealthKit
- How to check your morning and evening reminders
- How to log your symptoms
- How to access notifications or messages from your clinician
- How to send a message or communication to your clinician

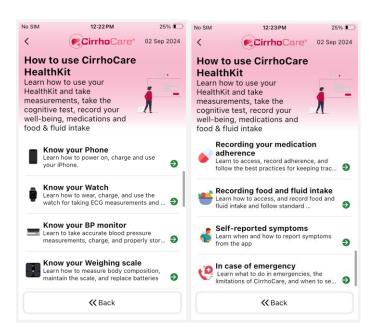


4.2.2 How to use the CirrhoCare HealthKit

This section helps you with the following with detailed step-by-step instructions, images, illustrations and videos on how to use each of your HealthKit devices and how to do each recording. To ensure the proper functioning of your HealthKit, follow the guidelines for

safe storage, charging, and usage for each device (shown in detail in the guide). You can access the following:

- How to use your phone
- How to use your watch
- How to use your BP monitor
- How to use your weighing scale
- How to use your Digital Thermometer
- How to take a Cognitive Ability Test
- How to record your well-being
- How to record your medication adherence
- How to record your food & fluid



4.3 How to charge your HealthKit

4.3.1 How to charge your phone

- Ensure your Phone remains charged daily, especially when prompted by CirrhoCare.
- Insert one end of the charging cable into your Phone.
- Connect the other end of the charging cable to the power adapter.
- Power the adapter by plugging it into a power source.
- Your phone is now charging.

4.3.2 How to charge your watch

Your watch's average battery life is 24 to 30 hours on a single charge

To ensure uninterrupted use, follow these guidelines:

- Charge your watch daily when the battery level is low or when prompted by CirrhoCare.
- Use the original charging accessories provided with the watch
- To charge, connect the charger to the watch and a power source
- A complete charge usually takes around 2 hours

4.3.3 How to charge your BP monitor

- Utilize the provided USB to C-type cable.
- Connect one end of the cable to the charging port on the monitor and the other end to a power source.
- Allow the BP monitor to charge until the battery reaches full capacity (usually 2 hours).
- The battery life of your BP monitor can last up to 200 measurements on a single charge.

4.3.4 How to change batteries on your weighing scale

Your Weighing Scale is powered by four AAA batteries, provided with the scale upon receipt. These batteries are sufficient to power the scale throughout your prescription duration.

Here's how you can ensure the scale has an adequate battery for use:

- If the CirrhoCare® app indicates a low battery, it's time to replace it.
- Turn the scale upside down to replace the batteries and open the battery compartment.
- Remove the old batteries and replace them with new AAA batteries. Ensure proper alignment of the positive and negative terminals as indicated inside the compartment.
- Close the battery compartment securely.

4.3.5 How to change batteries on your digital thermometer

- Your Thermometer is powered by two AAA batteries provided when you receive
 it. These batteries are sufficient to power the thermometer throughout your
 prescription duration.
- Here's how you can ensure the thermometer has an adequate battery for use:
- If the thermometer's digital screen indicates a low battery, it's time to replace it.

- Turn the thermometer to access the battery compartment. Remove the old batteries and replace them with new AAA batteries. Ensure the batteries are inserted correctly, aligning the positive and negative terminals as indicated inside the compartment.
- Close the battery compartment securely.

4.4 How to safely store your HealthKit

4.4.1 How to safely operate and store your phone and watch

- Avoid submerging it in water for extended periods.
- Keep it away from extreme temperatures.
- Use gentle cleaning materials, avoiding abrasives.
- Prevent dropping it from significant heights.
- Refrain from exposing it to direct sunlight and harsh chemicals.
- When storing, keep it in a cool, dry place, away from extreme temperatures, in a clean environment, and with the battery charged around 50%.

4.4.2 How to safely store your BP monitor

- Keep it in a cool, dry place away from direct sunlight.
- Avoid exposing the monitor to extreme temperatures or humidity.
- Ensure the cuff is neither twisted, folded, nor soiled when stored.

4.4.3 How to safely store your weighing scale

- Keep it in a cool, dry place away from direct sunlight.
- Avoid exposing the scale to extreme temperatures or humidity.
- Ensure the scale's surface is clean and dry before storing.

4.4.4 How to safely operate and store your digital thermometer

- Keep the Digital Thermometer in a cool, dry place away from direct sunlight.
- Avoid exposing the thermometer to extreme temperatures or humidity.
- Ensure the thermometer is clean and dry before storing.

4.5 What to do in emergency and exceptional situations

4.5.1 Emergency situation

In case of an emergency situation:

If you have a health emergency, immediately go to the nearest A&E or urgent care.

4.5.2 Exceptional situations

In case of an exceptional situation, where you have issues with your HealthKit, contact your hospital or doctor for further steps.

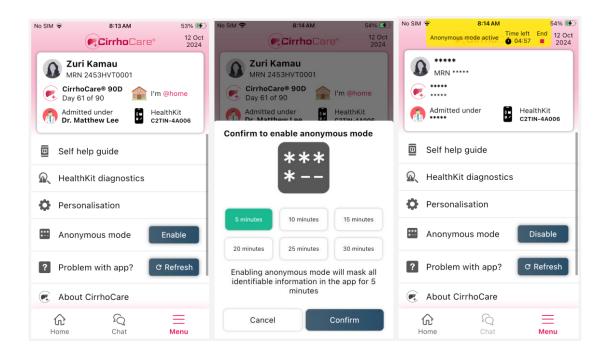
4.5.3 On-boarding Feedback Questionnaire

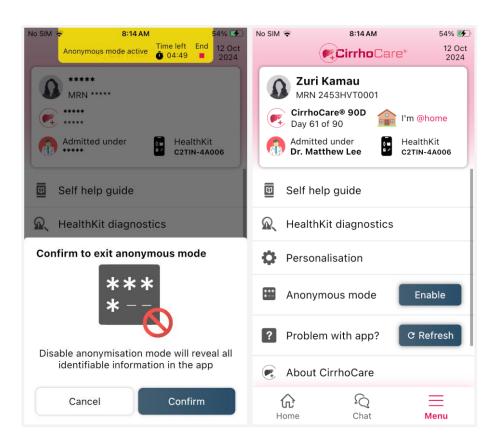
- Users are prompted to complete a short questionnaire after the app setup
- This questionnaire includes two questions designed to evaluate the ease of installation and onboarding with the CirrhoCare app.
- Response options for both questions: Strongly Disagree, Disagree, Agree, or Strongly Agree.

• 5. Anonymous mode

This feature ensures user privacy while still allowing the support team to assist with resolving technical issues.

- User can enable **Anonymous Mode** from the app menu when requesting remote support to protect their privacy.
- While Anonymous Mode is active, identifiable information is hidden from the support representative during issue diagnosis and resolution.
- Users can select the duration for Anonymous Mode, after which it will automatically end.
- Anonymous Mode can also be manually turned off at any time if the user chooses.





Once confirmed all the patient identifiable information will be hidden with ****.

• 6. Terms of Service and Privacy Policy:

This feature allows users to easily review the terms they agreed to during their initial setup.

- Users can view the **Terms of Service** and **Privacy Policy** at any time through the menu option within the CirrhoCare app.
- These documents were acknowledged by users during the onboarding process, along with the date of acknowledgment being recorded.
- This ensures transparency and user awareness of their rights and the app's privacy practices.



• 7. Menu Overview

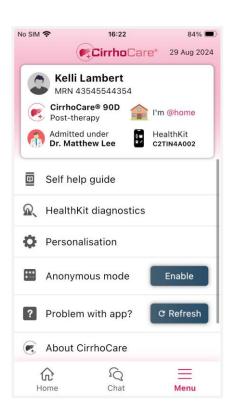
The CirrhoCare app provides an easy-to-navigate menu where users can access important features and manage their personal details. Below is a screenshot of the menu, followed by descriptions of the key functionalities available:

User Details:

- Name: Displays the patient's name.
- MRN: The patient's unique medical record number (MRN).
- CirrhoCare Programme: Indicates the therapy duration and progress.
- Admitted under: Shows the doctor managing the patient's care.
- Location: Displays the patient's current status (e.g., I'm @home).
- HealthKit: Information related to the patient's HealthKit.

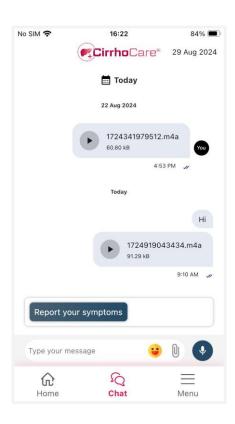
Menu Options:

- Self-help guide: Access guides to resolve common issues and learn more about the app's functionality.
- **HealthKit diagnostics**: Diagnose and manage HealthKit devices to ensure they connect and transfer data to the app seamlessly.
- Personalisation: Adjust the app language and instruction audio language to match your preferences for a customised experience.
- Anonymous mode: Activate Anonymous Mode to hide identifiable information during remote support. Users can set the mode duration, which will either automatically end or can be manually disabled.
- **Problem with app?**: Refresh the app if you encounter any issues.
- **About CirrhoCare**: View the app version and update date. Access links to important documents and resources, including warnings, Instructions for Use, additional information on the CirrhoCare website, and regulatory details.
- Data & privacy: Manage data settings and review the app's privacy policy and terms of service, which were acknowledged by users during onboarding.



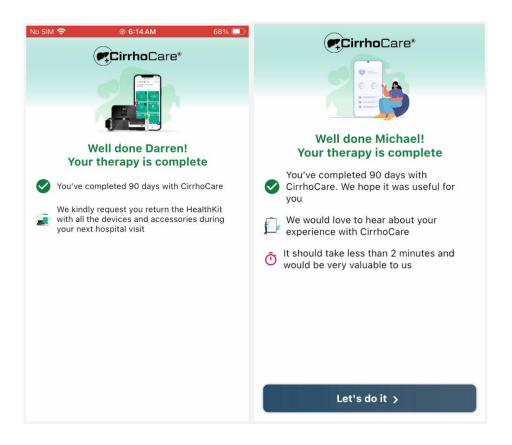
8. Chat with clinician

- Chat in real-time with your clinician.
- Report any symptoms you are experiencing through the chat window.
- New messages from the clinician will appear on the landing page.
- The chat icon will show an indication for new messages.



• 9. Therapy Completion

- After the therapy ends, you will be asked to provide CirrhoCare Usability Feedback.
- You can choose to continue taking measurements for up to 14 days post-therapy or return the HealthKit to the hospital.
- After 14 days post-therapy, the app will no longer be accessible for use and will only prompt you to return the HealthKit.



• 10. Baseline Measurement:

- The clinician will request baseline measurements during the patient's onboarding process.
- These baseline measurements are used to compare with daily measurements taken by the user.
- They help monitor and alert the clinician to any significant changes in the user's health data from the time of discharge.

