

Curio Digital Therapeutics Inc.

100 Overlook Drive, 2nd Floor | Princeton, NJ | 08540

MamaLift Plus™

**PATIENT
INSTRUCTIONS
FOR USE
(MLP Patient IFU)**



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MAMALIFT PLUS™ PATIENT INSTRUCTIONS FOR USE

MamaLift Plus™ is a prescription-only digital therapeutic intended to provide neurobehavioral interventions to patients 22 years of age and older, as an adjunct to clinician-managed outpatient care. MamaLift Plus treats mild to moderate postpartum depression by improving a patient's symptoms of depression.

WHO SHOULD NOT USE MAMALIFT PLUS (CONTRAINDICATIONS)

MamaLift Plus uses Cognitive Behavioral Therapy (CBT), Behavioral Activation Therapy (BAT), Interpersonal Therapy (IPT), and Dialectical Behavior Therapy (DBT). MamaLift Plus is not intended to be used as a stand-alone treatment and may not be appropriate for everyone.

You should not use MamaLift Plus if you have any of the following conditions or disorders:

- Severe depression or anxiety
- Serious Mental Illness (SMI)
- Psychosis
- Thoughts of harming yourself or others
- Patients under 22 years of age

WARNINGS

MamaLift Plus is not for everyone.

- MamaLift Plus is not for emergency use. Please dial 911 or go to the nearest emergency room in the event of a medical emergency.
 - MamaLift Plus should not be used to communicate severe, critical, or urgent information to your Health Care Provider.
 - MamaLift Plus is not meant to be used as a treatment without supervision of a Health Care Provider.
 - MamaLift Plus is not meant to be a substitution for any treatment medication. You should continue to take your medications as directed by your doctor.
- MamaLift Plus contains sensitive medical information. Please protect your information by password-protecting your smartphone and tablet and ensuring no one else may access your device.

Please read and follow the instructions provided in each module and stay with the therapy until the end to achieve the best result with MamaLift Plus. It is important to give honest and accurate answers when answering questions in the program.

DESCRIPTION.

MamaLift Plus is an 8-week Prescription Digital Therapeutic (PDT) for treatment of symptoms of postpartum depression. MamaLift Plus can be used on a mobile device, such as a smartphone or tablet. MamaLift Plus is available by prescription only. A licensed Health Care Provider (HCP) must prescribe MamaLift Plus and use of MamaLift Plus should be undertaken only under the supervised care of a Health Care Provider.

MamaLift Plus delivers digital Cognitive Behavioral Therapy (CBT), Behavioral Activation Therapy (BAT), Interpersonal Therapy (IPT), and Dialectical Behavior Therapy (DBT) for postpartum depression. CBT, BAT, IPT, and DBT are neurobehavioral treatments which focus on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate during postpartum depression.

CBT, BAT, IPT, and DBT for postpartum depression are typically delivered by a specialty-trained clinician

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either 1:1 or in group format. Standard delivery of CBT, BAT, IPT, and DBT for postpartum depression usually occurs in weekly sessions over 8–10 weeks. This can be conceptualized as eight sessions or Modules that deliver proven behavioral and cognitive treatment strategies. MamaLift Plus delivers treatment with the following 8 treatment Modules or Weeks:

- **Week 1:** This Week sets the stage for the therapeutic experience by discussing the science and types of therapy behind the program as well as the difference between postpartum blues and depression. You will understand the relationship between your thoughts and feelings and learn what to do when you find yourself overthinking. The trackers are introduced this week that weave BAT throughout the entire program.
- **Week 2:** This Week is heavily focused on CBT. You will learn about automatic thoughts, negative thoughts, and 10 negative thinking styles. You will learn how to begin shifting their thinking to more healthy, adaptive thoughts by utilizing a Thought Record.
- **Week 3:** This Week is focused on CBT and BAT. You will identify your unhelpful thinking styles, understand alternative constructive thinking methods, learn how to stop overthinking, and practice activities to shift and balance their thinking styles.
- **Week 4:** This Week is focused on CBT. You will continue to work on Thought Records, learn ways to manage feeling overwhelmed, learn sleep management tips that are critical during the postpartum period, and review time management techniques.
- **Week 5:** This Week is heavily focused on IPT as well as DBT. You will learn the science behind IPT and DBT and subsequently learn the DEARMAN technique and tap into your Wise Mind. You will practice social support strategies and learn effective ways to manage interpersonal conflict.
- **Week 6:** This Week you will learn about postpartum anxiety and triggers for your anxiety and unproductive worry. You will practice strategies such as worry postponement, scheduling worry appointments, senses grounding exercises, and progressive muscle relaxation to manage your anxiety and triggers.
- **Week 7:** This Week you will learn about getting back into a routine and coping with worries related to adjusting to the new role of motherhood. You will learn about effective ways to return to work as well as techniques to improve their body image.
- **Week 8:** This Week prepares you for the future with various activities, such as writing in a gratitude journal and writing letters to your future self. You will also learn about the behavior chain and how to apply it. You will also learn self-confidence tips, meditation, and mantras.

MamaLift Plus includes daily trackers for Sleep, Mood, and Activities in which you should record information about your sleep, mood, and activities. The Resources section provides selected resources and content from each Module for review. The My Learnings section in Resources is available after the Module is completed.

PATIENT POPULATION

You should only use MamaLift Plus if you:

- Are 22 years or older with postpartum depression
- Are able to read and understand English
- Have regular access to a mobile device (such as smartphone or tablet)
- Are familiar with how to use mobile apps (applications)
- Are able to upload data periodically, i.e., have internet access.
- Are under the supervision of a Health Care Provider

WHY DID MY HEALTHCARE PROVIDER PRESCRIBE MAMALIFT PLUS?

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It is your responsibility to secure your mobile device (smartphone or tablet). If you use an iPhone or iPad, you should use a 6-digit passcode known only to you. If available, Touch ID or Face ID should be used. If you use an Android phone or tablet, you should use a password or 6-digit passcode and enable fingerprint-unlock if available.

It is your responsibility to update your phone or tablet operating system when recommended by the platform vendor (Apple or Google). Important security updates are included in operating system upgrades. The vendor will do this by notifying you on your device that an update is available for download and installation.

ADDITIONAL SUPPORT

For additional support you can contact your Health Care Provider, or email MamaLift Plus support at contact@curiodigitaltx.com.

PATIENT USAGE

You should complete all 8 treatment Modules. Patients who have completed all 8 Modules have shown the best outcomes.

Each module should be completed on a frequency of one module every 7 days. You should complete your Sleep, Mood, and Activity trackers daily.

Your access to MamaLift Plus will automatically discontinue after 10 weeks. The prescription will end automatically based on the start date.

COMPATIBLE DEVICES

MamaLift Plus is compatible with mobile devices (including smartphone and tablet) running:

- IOS version 9.0 or higher
- Android version 5.0 or higher

Please ensure your mobile device is running an Operating System (OS) version matching those above. If not, then please take the time to update your software version before downloading and using MamaLift Plus.

DOWNLOADING MAMALIFT PLUS

Below are instructions to download MamaLift Plus:

To download MamaLift Plus on the iPhone or iPad:

- You will receive an email after the physician has prescribed MamaLift Plus
- The email will contain a link to complete a web registration form, including creating a username and password
- Once you complete the web registration form, you will receive a second email and SMS with a link to download MamaLift Plus from the iOS App Store, as shown in Figure 1 below.
- Tap the App Store icon on the home screen.
- Tap the search icon and type "MamaLift Plus."
- Tap the "GET" button. The patient may need to enter their Apple ID and password or use Touch ID or Face ID to approve the download.
- When MamaLift Plus is downloading, the MamaLift Plus icon will be visible on the home screen. Download progress is indicated within the icon.
- Tap the MamaLift Plus icon to open the app after the download is completed.

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To download MamaLift Plus on an Android phone or tablet:

- Tap on the Play Store app on the Android phone.
- Tap on the search bar and type “MamaLift Plus.”
- Tap “Install”
- When MamaLift Plus is downloaded, tap “Open” in the Play Store
- Or go to the home screen and tap the MamaLift Plus icon.

Dear [Name],

You have successfully completed registration for the ~~MamaLift~~ MamaLift Plus mobile application. Below you will find the verification code and links to download the mobile app for iOS and Android devices.

Once you download the app, you will be asked to enter the verification code provided in this email. You will only be required to do this once. After you have entered the verification code, you will be prompted to enter log in credentials. Please enter the email address and password that you entered into your registration questionnaire.

Please contact your study coordinator for any questions related to the study. Thank you for your time and participation in the Curio Digital Therapeutics study!

Registration code: 238566

[DOWNLOAD NOW\(IOS\)](#)



[DOWNLOAD NOW\(ANDROID\)](#)



Sincerely,

Curio Digital Therapeutics

Figure 1

Note: Once commercialized, MamaLift Plus will be available in the iOS App Store and Android Play Store, and the QR codes shown in Figure 1 will be updated accordingly.

INTRODUCTION TO MAMALIFT PLUS

Section A: Daily Playlist

The Daily Playlist is the “homepage” of the mobile application. When you open the mobile application, you will see several features on the Daily Playlist. These features include your Daily Learning, Mood Tracker, Sleep Tracker, Activity Tracker, and Points. We will discuss each of these features in greater detail below.

Part 1: Daily Playlist

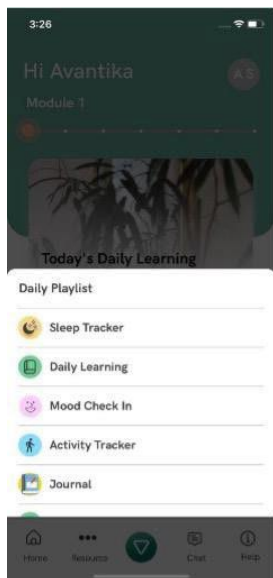
You will be directed to the Daily Playlist. The Daily Playlist is the homepage of the MamaLift Plus mobile app. You can think of it as a hub where you can access all the key features of the device, such as Daily

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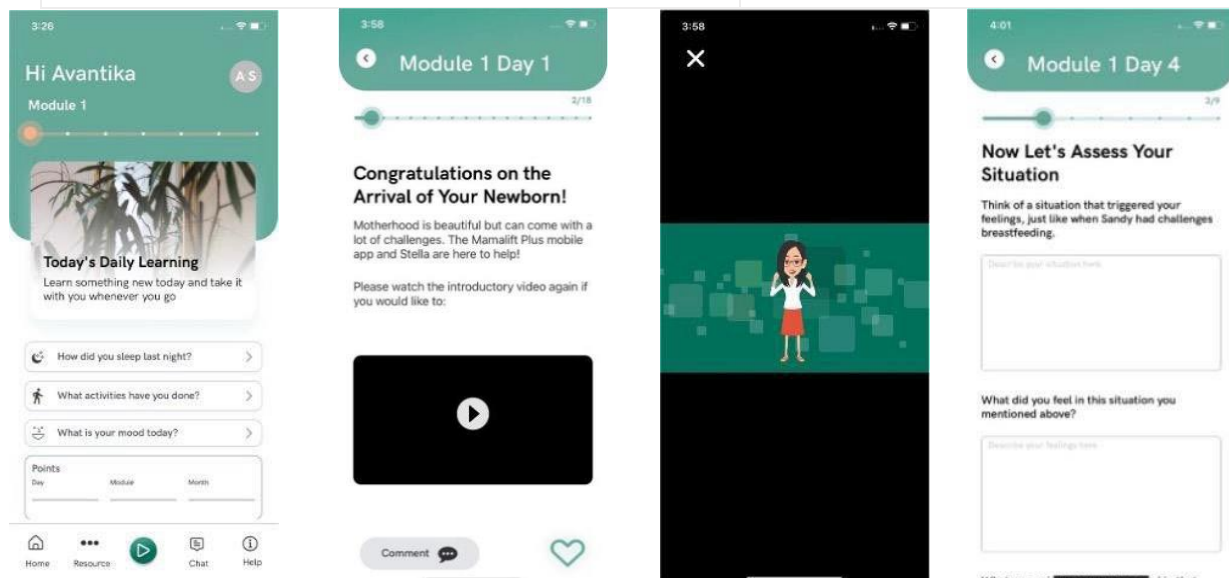
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Learning and Trackers.



Part 2: Daily Learning

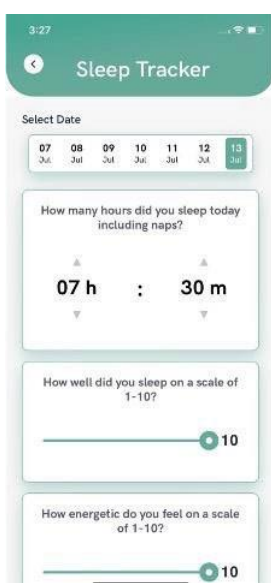
- There is a large square-shaped button in your Daily Playlist that read, “Daily Learning.” Your Daily Learning contains your lesson for the day. Click on this square and try to spend 10-15 minutes per day reading through the lesson, watching the videos, listening to the audio, and completing the activities in your Daily Learning lesson.
- Your Daily Learning lesson is divided into “cards.” You can view the number of cards in the top right corner of your Daily Learning, next to the progress bar. The number on top indicates the number of the card that you are currently on. The number of cards that are recommended for you to read that day. As you progress through your cards, the circular icon on the progress bar will move towards the right, and the numerator of the fraction will increase. Once you have reached the end of the cards, you will receive a pop-up notification that lets you know that new cards will be shared with you the following day.
- You can give a like, comment, or rating on any card that has a comment bar or heart at the bottom of the screen.
- Once you’re finished giving a like, comment, and rating, click on the arrow in the top left-hand corner of your screen to return to the Daily Playlist. If you forget to complete your Daily Learning for one or more days, you can catch up on two days of Daily Learning cards the next time you visit the Daily Learning section.



Part 3: Sleep Tracker

- Click on the Sleep Tracker underneath Daily Learning on the Daily Playlist. You will be directed to a screen that asks you three questions.
- The first question will ask you how much you slept today including naps. Use the drop-down menus to select the number of hours and minutes of sleep that you had today.
- The second question asks you how well you slept on a scale of 1-10. Selecting a “1” means that you did not sleep well at all. Selecting a “10” means that you slept very well. Use the sliding bar to indicate your response.
- The third question asks you how energetic you feel on a scale of 1-10. Selecting a “1” means that you feel very unenergetic. Selecting a “10” means that you feel very energetic. Use the sliding bar to indicate your response. When you are done, click “add tracking.”
- Once you’re done entering your sleep, click on the arrow in the top left-hand corner of your screen to return to the Daily Playlist.
- You can enter your sleep several times a day.

If you forget to complete your Sleep Tracker, you can visit it the next day and enter your sleep data for the prior day.



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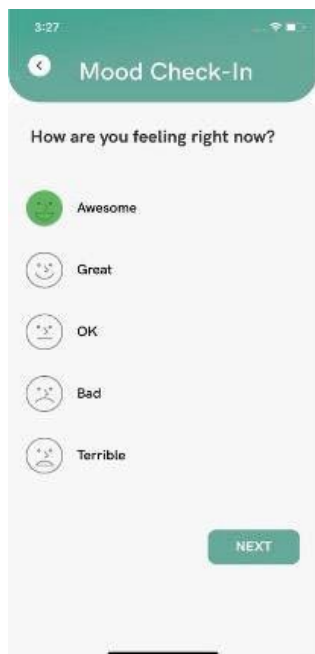
Part 4: Activity Tracker

- Click on the Activity Tracker underneath the Sleep Tracker on the Daily Playlist. You will be directed to a screen that asks you what you have been up to today. Select all the pleasant activities that you have engaged in today.
- You can add an activity not already listed by clicking on the “Add Activity” button. When you click on this button, you will be directed to a search bar where you can search for the activity that you want to add. Once you’ve found it, click save to add it to the list of other activities.
- Click on the Daily Activities tab at the top of the screen. You will be directed to a screen where you can select the activities of daily living that you engaged in today. When you’re done, click “save.”
- Once you’re done selecting your activities, click on the arrow in the top left- hand corner of the screen to return to the Daily Playlist.
- You can enter activities several times a day.



Part 5: Mood Tracker

- Click on the Mood Tracker underneath Daily Learning on the Daily Playlist. You will be directed to a screen that asks you for your mood. Click on the face that best describes your mood.
- Once you have selected the face that best describes your mood, click “next.” You will be directed to a page where you can view trends in your mood.
- Once you’re done viewing trends in your mood, click on the arrow in the top left-hand corner of your screen to return to the Daily Playlist.

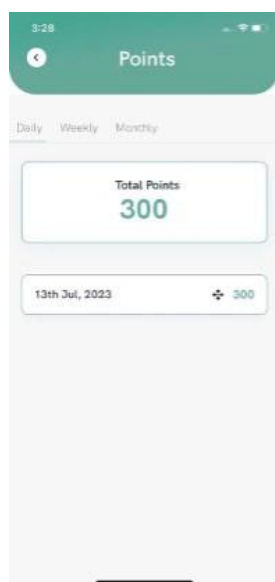


You can enter your mood several times a day.

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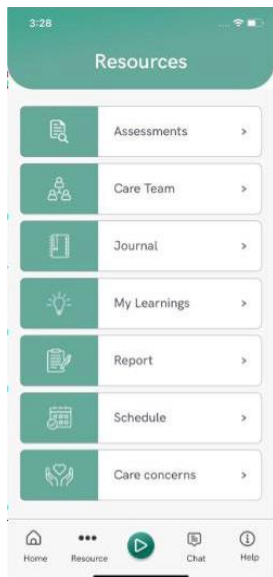
Part 6: Points

- You can earn up to 500 points per day by completing activities in your MamaLift Plus mobile app! You will earn 200 points for completing your Daily Learning, 100 points for completing your Sleep Tracker, 100 points for completing your Activity Tracker, and 100 points for completing your Mood Tracker
- Click on “Points” underneath the mood tracker on your daily playlist.
- You will be directed to a screen where you can view your point totals. Navigate to the “Daily” tab to view your point totals, to the “Weekly” tab view your weekly point totals, and the “Monthly” tab to view your monthly point totals.
- If you forgot to complete your daily learning or sleep tracker, you can always recover a portion of the missed points! When you visit the daily learning section, you will be able to view two days of Daily Learning lessons. You will earn 600 points for completing both days. When you visit the sleep tracker, you can input your sleep information for yesterday and today. You will earn 150 points for completing both days of sleep trackers.
- You can return to the Daily Playlist at any time by clicking on the white arrow in the top left corner of your screen.



SECTION B: RESOURCES

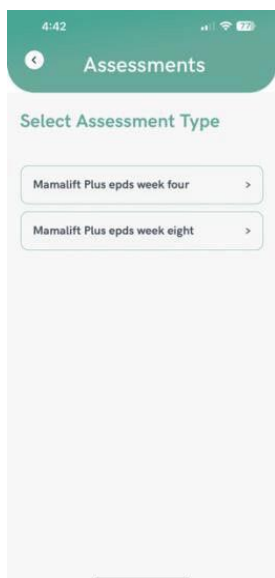
Your MamaLift Plus mobile application offers a Resource List that contains several useful features to enhance your experience with the program. These include Assessments, Care Team, Journal, My Learnings, Report, Schedule, and Care Concerns. Navigate to the Resource List by clicking on the icon of three dots in the white bar at the bottom of your screen. You can return to the Daily Playlist at any time by clicking on the home icon in the white bar at the bottom of the screen.



Part 1: Assessments

There are assessments in the MamaLift app to assess your progress towards your mental health goals.

- Click on the resource button on the bottom of your screen.
- Inside the folder, all assessments that need to be completed will show up.
- Select the assessment you wish to complete and fill out the questions to the best of your ability. When you are ready to submit, hit “SAVE.”
- To exit this screen, tap the arrow in the top left corner.



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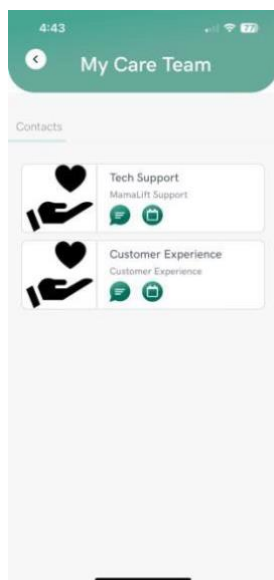
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Part 2: Care Team

Care team allows you to talk to a medical provider while in the MamaLift Plus app.

- To access this feature, go to the “Resources” tab at the bottom of the screen. There is a folder titled “Care Team.”
- Once in the Care Team folder, there is a list of names under “Contacts.”
- Under each name there is a chat button in the shape of a speech bubble.

Press the chat button under the selected person’s name. You will be brought to a chat log where you can type out a message to send to a person on your Care Team.



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Part 3: Journal

- Click on the Journal bar in your Resource List. You will be directed to a screen where you can select a journal. The journal will give you a prompt and encourage you to write about your day.
- When you are done writing about your day, click on the arrow in the top left-hand corner of the screen to return to the Resource List.



Part 4: My Learning

- Click on the My Learning bar in your Resource List. You will be directed to a screen where you can re- visit lessons that you previously covered in the Daily Learning section. Select the week and day associated with the lesson you would like to see and click “Proceed.” Read through the lesson, watch the videos, listen to the audio, and complete the activities in this section.
- When you are done re- visiting this lesson, click twice on the arrow in the top left-hand corner of your screen to return to the Resource List.



Part 5: Report

- Click on the Report bar in your Resource List. You will be directed to a screen where you can view trends in your sleep, mood, activities, and points earned
When you are done viewing these trends, click on the arrow in the top left- hand corner of the screen to return to the Resource List.



Part 6: Schedule

You can schedule appointments with doctors from the MamaLift app.

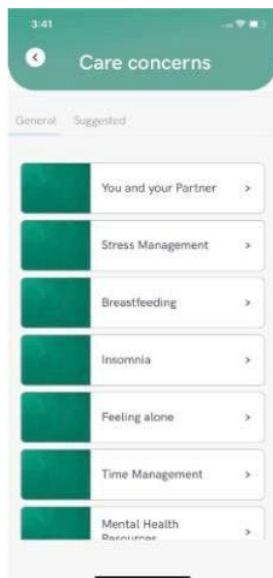
- If you wish to schedule an appointment, tap the “Resources” tab at the bottom of the screen.
- Navigate to the folder labeled “Care Team.”
- Under your Care Team contact(s) select the calendar button.
- You will be allowed to choose a date (up to 6 preferred days) and check off the type of session you would like (regular appointment, 1 on 1 session, or group session). Once you have selected a date/dates and type of session, tap the button that says “BOOK” to confirm your appointment.



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Part 7: Care Concerns

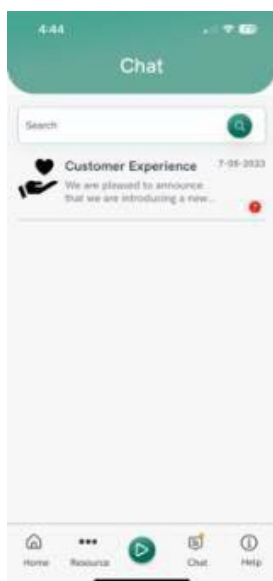
- Click on “Care Concerns” bar in your Resource List. You will be directed to a screen where you can choose to learn more about additional topics of interest. Select the topic you are interested in and read through the article.
- Once you are done reading through the care concerns article, click on the arrow in the top left - hand corner of the screen to return to the Resource List.



SECTION C: CHAT

There is a shortcut to accessing the chat box with your care team member.

- At the bottom of the screen, select the tab labeled “Chat.”
- You will be brought to a list of all care team members you have talked to and are able to access those chats, as well as talk to the provider 1 on 1.



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SECTION D: HELP

You can access additional help by clicking on the information icon in the white bar at the bottom of the screen. Here you will find helpful videos and documents about the MamaLift Plus mobile app. You can return to the Daily Playlist or Resource List anytime by clicking on the home icon or the three dots in the white bar at the bottom of your screen.

- Click on any video that you want to watch to better understand your MamaLift Plus mobile app.
- Click on the Documents tab at the top of the screen to view help documents, the privacy policy, and other helpful documents.
- When you are done viewing this help section, click on the home icon or the three dots to return to the Daily Playlist or the Resource List.

