

# Product Manual

## Clinical Trial or Beta Program Spring 2022

Dear Parents,  
Welcome to LittleOne.Care.

We wrote the Beta Manual in a way that allows you simple and immediate use of our solution.

At the same time, please share with us if you need better clarification. Your input will enable us to improve and simplify the Manual for future parents who join the testers in the future.

Enjoy the reading!



### Background

LittleOne.Care is developing a platform that includes a baby's wearable device, a cell phone application for parents, and Artificial Intelligence (AI) technology.

Our testing stages include Pilot (stage one), Alpha (stage two), and Clinical trial or Beta program (stage three). You can participate in the Clinical trial if you registered at Hadassah hospital. You can participate in the Beta program if you came directly through LittleOne.Care. *It is important to note that no difference exists between the products, services, and applications of the two programs.*

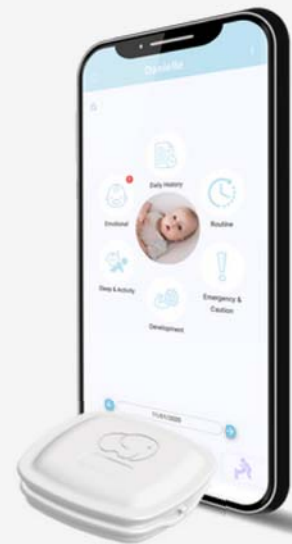
### Participation in the Trials

Participation in the Clinical trial or the Beta program is for the benefit of parents' feedback, data collection, and performance improvement of the algorithms and AI we develop.

### The box you received includes the following items:

- One small wearable device for data collection
- One grip ring for connecting the device to the shirt
- One spare grip ring
- One docking station (only used for charging)
- One USB-C connection cable between the docking station and the power source

We do not provide a power adapter. Any power adapter can be used for charging.





# Application Set-Up

[Click Here to Enter the Application](#)

Use the Chrome browser and click [here](#) to enter the application (app).

## Saving the App on the Home Screen

1. Tap the three dots that appear in the upper right or left corner of your phone screen
2. Look for "Add to Home Screen" (In Hebrew look for הוספה לעמוד הבית)
3. Drag the icon to your cellphone, home screen, or any place that will allow you to quickly access the app

## Classifying the Current Status of the App

Although our "Web App" does not currently exist in the app store, it is similar to any other website you can access. In addition, until further notice, the app may not be accessed from iPhones, only via Android devices or desktops.

## Adjusting the App

During the Clinical trial and the Beta program, the app will undergo many changes according to the testers' feedback, progress in development, and new features. Firstly, some of the changes will be tangible and some will not be tangible. Secondly, some of the changes will follow your comments and some will not. Finally, the pace of changes will be rapid. To keep up with the growing changes, we will use the flexibility of Web App.

## Registering As a "Leading Parent"

The first parent who registers on the app is the "Leading Parent." Only one parent initially registers on the app. The responsibility of the Leading Parent is to manage all other users who will connect to the app later on.

## Adding a New User to the App

1. Enter the burger button in the top right/left corner
2. Look for "Add a User"
3. Follow the instructions to produce a dedicated link
4. Each link can only be used once
5. If the link is not used within 24 hours OR the new user does not accomplish the registration process, the link will close. Then, the Leading Parent must generate and send a new link to the new user

## Removing Users from the Application

At this stage, only LittleOne.Care admin can remove users. To remove users, the Leading Parent who first installed the app needs to submit a written request to remove users. To avoid mistakes, please provide the Leading Parent's registered email, phone number, and baby's name.

## Deletion of the App

Remove the app by long-clicking the LittleOne.Care icon on the home screen and following the removal instructions.

## Removing Data

We are committed to your privacy and operate in the spirit of the General Data Protection Regulation's (GDPR) stringent privacy policy.

If you would like to delete any information (beyond disconnecting the app), contact us and we will delete the file within one working day. This information consists of all accumulated data from the app.

Because we are in a Beta program and ongoing development, we do not have GDPR approval yet. However, we strive to improve our system by following the GDPR spirit and principles.

### **Designing the Device**

The Consumer Product Safety Commission sets clear guidelines for the size and shape of any product or toy that is near or used by infants under the age of three. The size of the device must be large enough to prevent babies from swallowing it. Rest assured that the device you received from LittleOne.Care meets these requirements.

For more details about the standardization of devices used for babies under the age of 3 click [here](#)

### **Mitigating Harmful Transmissions and Radiation**

The design of the device does not emit transmissions when separated from the docking station. However, if the device is attached to the docking station, transmissions may emit. The only way to retrieve data from the device is when the device is physically connected to the docking station. This process occurs when the device is connected to the docking station, the docking station is connected to a power source, and your internet is active.

### **Developing Water Resistance**

The device is not currently waterproof because the device is in the Beta stage and is not yet tested for standardization. Nevertheless, the future device will include water resistance. In addition, the future device will be suitable to handle a baby's dirty environment because of its easy-to-clean design. Until the development of a final waterproof device, in any case, where the device gets wet, stop using the device and report to us. We will replace your device.

### **Testing and Standardization**

The Standards Institute in Israel approved the device for use in LittleOne.Care's Clinical trial. However, the tests performed by the Standards Institute in Israel do NOT include the additional tests required for a commercial product intended for sale. The approval we received for the Clinical trial is NOT relevant for the Beta program, despite that the device is exactly the same.

The product in your possession is NOT a commercial product and may not be sold or transferred to any other user without written approval from LittleOne.Care.

At the end of the Clinical trial and/or Beta program, we ask you to return the wearable device and any other parts you received during the period of the trial to LittleOne.Care's representatives.

### **FCC Compliance Statements**

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined

by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

#### US Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value is measured at a distance of 5mm between the radiator and the body.

#### Read more:

- [Terms of Use](#)
- [Privacy Policy](#)
- [Safety Policy](#)

## Data Collection and Processing

### Data Collection: Motion

The moment the device leaves the docking station it begins to collect any type of acceleration. The accelerations are in different directions and the final outcome is a long and detailed table of numbers. We developed algorithms and AI that learn to analyze these numbers and understand the meaning in terms of the baby's movements.



While charging the device, it uploads the acceleration data to the LittleOne.Care server. The data is processed, analyzed, and sent as your baby's life events and insights to your application. The analysis of the acceleration attempts to identify the number of breaths per minute, quality of sleep, activity, lying position (tummy time), sitting, rolling, and more.

Because of your support and other Beta testers, we are continuing to develop capabilities for automatic detection and decoding of different and unique patterns of baby behavior. These behaviors include rolling, crawling, walking, diaper changing, and unique feeding and breastfeeding patterns.

Our goal is to improve the performance and accuracy of our algorithms for identifying the various situations and activities of the baby.

It is important to note that we continuously conduct various tests to improve performance. Therefore, we do not undertake the responsibility to send reports with accurate or consistent information.

During the Clinical trial and Beta program, the device will also analyze the number of breaths per minute of the baby while they are resting or sleeping. However, we will not include real-time reporting capabilities. These capabilities may include real-time emergencies, such as falls, shaking (SBS), bodily injury, or loss of breath. Any acquired information during the Clinical trial and Beta program cannot be referenced as a valid source to a third party.

### **Data Collection: Sound**

We program our algorithms to detect the crying, laughing, and mumbling of babies. In addition, we program our algorithms to recognize when an adult talks, sings or shouts at the baby.

Please note that our level of accuracy is constantly improving and we do NOT track the content of spoken, sung, or shouted words. Rather, we track the existence of the sound event.

### **Determining the Cause for Crying**

In the next stage, we will analyze the reason for the crying. For the benefit of analyzing the baby's sounds, we collect sound recordings using the sound sensor in the device. In the next stage of the Clinical trial and Beta program, we will analyze the reason for the crying. We will attempt to accomplish this task by recording up to a four-second soundtrack of the baby and their surroundings.

### **Implementing the Four-Second Soundtrack**

We will use the recorded soundtracks solely to improve the algorithms of our solution. We upload the soundtracks and the baby's motion data to the LittleOne.Care server in an encrypted and secure manner. We then convert the sound files into images. Our AI improves the ability to understand the reason for the baby's crying by analyzing image segments of waves and sound energy.

Inside the four-second soundtracks, beyond crying, we may record other sounds that characterize your house or the environment. These sounds can include animal sounds, music from the TV, conversations, and car noises if you are traveling with your baby.

Our goal is to improve our performance in recognizing the baby's murmurs, laughter, and crying as well as the accuracy of recognizing the reason for crying alongside background noises.

The soundtrack processing and crying analysis are automatically performed after the data is uploaded to the LittleOne.Care server and without human involvement.

Rarely, the LittleOne.Care server asks for "help" in sorting the audible sound. In this case, an employee of LittleOne.Care will listen to a random soundtrack of four seconds at most. If this event occurs, the employee of LittleOne.Care will not be able to associate the given soundtrack with any of the program participants.

### **Informing Others of Device Usage**

TO RESPECT THE PRIVACY OF THOSE AROUND YOU, YOU ARE RESPONSIBLE TO INFORM ANYONE IN THE VICINITY OF THE BABY THAT THE DEVICE MAY OCCASIONALLY RECORD FOUR-SECOND SOUNDTRACKS, AND IN SOME CASES, THE RECORDED SOUNDTRACK MAY INCLUDE BACKGROUND NOISES INCLUDING VOICES CLOSE TO THE BABY.

The learning process is an interesting process that is constantly improving itself. The more data we work with, the faster the learning rate and the more accurate the results.

### **Managing the Device's Location**

Please keep the device in a fixed and consistent position and ensure it is balanced whenever possible. This maintenance will improve performance.



# Tagging Baby's Life Events

## Tagging Events Using the App

You can tag significant daily events through the app. To do so, enter the homepage of the app and tap on the icon of the selected event. Once completed, the event will appear on the Daily History page as part of the baby's event day on the date and time the event took place.

## Discussing the Role of the Tagged Events

The baby's daily history automatically displays the baby's sleep, activity time, tummy time, rolling, crying, mumbling, laughing, and any other background noise. Throughout the day, event tagging is designed for you to document and add any other event or status that occurs during the day.

This document will provide you with a better understanding of the sequence of events and the relationships between them. For example, what caused the baby's crying? What contributed to the baby's deep sleep? When did you play or talk with your baby?

## Tagging Accuracy and Insights

Tagging will improve the accuracy of our algorithms. For example, the performance of the feeding stimulus will enable us to teach our algorithms about the baby's sucking movements and to independently identify that type of event.

### Sample Tagged Events

On the homepage of the app, you will find several buttons that enable you to tag different events. The tagged events will be updated according to the number of tags performed, the age of the baby, and our algorithms' needs.

#### We created a list of sample tagged events:

- Diaper change
- Start feeding/breastfeeding
- End of feeding/breastfeeding
- Baby in an adult's hands

#### We also compiled a variety of future tagging requests:

- The baby in the car
- The baby in the stroller
- Talking to/with the baby
- A bedtime story and more ...

The amount of tagging and its exact execution is important to us and will directly affect the quality of the information you receive back. Therefore, if tagging occurs by mistake, you can cancel the tagging immediately or after its establishment by clicking on the cancel button or from the daily history report.

# The Role of the Docking Station

The docking station has three functions:

- 1 **Charging the wearable device:** Each time you connect the device to the docking station it will

1. **Charging the hardware device:** Each time you connect the device to the docking station it will recharge its batteries
2. **Offloading data from the device:** The docking station is responsible for uploading the data from the device to the LittleOne.Care server using your Wi-Fi network to process the data
3. **Updating algorithms on the device:** The algorithm inside the device will be updated from time to time in order to improve its performance.

However, we will not make any functional changes (i.e., emergency reporting) without your prior approval at any point during the Clinical trial or Beta program.

### Charging the Device

The final device is scheduled to operate for approximately three days without the need for recharging. However, during the Clinical trial and Beta program, the device will operate for up to 16-24 hours between charges. We also devote the device charging time to uploading data to the LittleOne.Care server. Therefore, we recommend choosing a fixed time of day to perform the daily charge; for example, while the baby is taking a bath. Once the device completes charging, your app will display a message reminding you to return it to the baby.

### Uploading Data from the Device

To enable a smooth data upload, make sure that the device is attached to the docking station and connected to your Wi-Fi network. If no internet connection is present, you will not be able to upload the data or receive insights into your app. When the data upload process is successful you will receive an update on the app that states the data transfer was accomplished.

If your cellphone is connected to the Internet, you should receive a daily update from your application a few minutes after receiving a notification saying the data has been successfully transferred. Again, if you do not receive a notification that the data has been transferred successfully, your cellphone app will not receive the accumulated daily information and your baby's life events.

## Device Colors

### Terms:

- **Charging:** The specified time to charge the battery
- **Uploading the data to the server:** The specified time to upload the data from the device to the LittleOne.Care server
- **1st time charging:** When you connect the device to the docking station for the first time, the battery is not fully charged.  
After the setup and connection to your wi-fi network process are finished, the device's lighting will be blue.  
We recommend fully charging the device until you get a green indicator indicating that the battery is fully charged.

### The device at the docking station:

Yellow: The device activates the connectivity needed from your cell phone. This process is required to set up a Wi-Fi connection

Red: The device encountered a connection failure. Disconnect the device from the docking station for 5 seconds. Try to find a new connection

### Charging and data upload:

Blue: Uploading data and charging are in progress and are not complete yet

Green: Uploading data and charging are complete. The device is ready to use. \*Note that the color change will gradually shift from blue to green. Be aware that the uploading process can take approximately 60 minutes

### The device is attached to the baby shirt:

To determine if the device is on, tap the device once. A single yellow indicator led light will appear

If you see a blinking yellow indicator led light, the device's battery is low and the device must be charged

### Device's sounds and buzzes

Emergency alerts. Not active yet.

## Application Insights

### The "Leading Parent"

The first parent who downloads the app, registers, and connects their application profile with the baby's device is the Leading Parent. Be aware that downloading the application to your cellphone without registering and connecting your application profile is not enough to complete the app setup.

### Other Users

If you do not receive a link from the Lead Parent you will not be able to connect your app with the baby's device.

### Application, Report, and Insights

"Information" and/or "application" refer to data, graphs, lighting, voice alerts, questionnaires, participation in expert lectures, and personal conversations with experts.

We do not undertake to provide continuous or reliable information, and you are not allowed to make any use of the information you received from us.

### Emergency Reports

During the Clinical trial and Beta program, you will NOT receive emergency alerts even if they occur. In the future, the device will help prevent accidents and alert in case of emergencies but do not rely on this functionality during the Clinical trial and Beta program.



If and when we officially activate the emergency alerts, you will receive a dedicated notice that will request your written approval, and even then the responsibility for your baby's life, well-being, health, and quality of treatment is yours alone.

### Expanding the LittleOne.Care Community

LittleOne.Care believes that developing our product within communities of parents as well as diverse baby experts is very important. Parents should have the opportunity to choose their baby's expert.

We trust that in the long run, the insights of our app could be essential for parents' dialogue with their baby experts (i.e., create more productive counseling conversations). Alongside the insights and reports, the app presents bubbles that include quotes and statements from various experts in the field of babies, development experts, psychologists, physiotherapists, and consultants who have participated in designing the AI of the application.

In some cases, the citations also include references and links to academic articles.

### Introducing LittleOne.Care to Your Baby Expert

LittleOne.Care works to establish a community of parents and experts through the app and website. We encourage you to introduce the app to the experts you work with and invite them to join the app.

LittleOne.Care recognizes that different parenting methodologies and diagnosis methodologies exist in the area of baby experts and infant care. We recommend that you, as a parent, follow your preferred expert or specialist instructions.

LittleOne.Care is NOT responsible for the content published by these various experts or their advice. Similarly, the quotes made by these various experts do not make these experts responsible for the insights, units of measurement, and accuracy of the information you receive within our application.

Feel free to directly contact your expert or an expert at any time. Contacting and engaging with experts is considered your responsibility, at your sole discretion, and should not be considered a recommendation on behalf of LittleOne.Care.

### Application Updates

During and after the Clinical trial and the Beta program, the app will undergo many changes in order to expose the testers to a variety of screen design options, report structures, and measurement units. Application updates on your phone will be done periodically.

In cases where any update changes the Terms of Use, we will ask you to confirm the new Terms of Use in order to continue using the application.

At the bottom of each application page, you may find the ability to provide real-time feedback and to add

your detailed comments to each page individually.

**\*WARNING\***

LITTLEONE.CARE'S CLINICAL TRIAL AND BETA PROGRAM ARE DEPENDENT ON THE COMPLETE DEVELOPMENT OF OUR ARTIFICIAL INTELLIGENCE. WE ARE NOT RESPONSIBLE FOR INCONSISTENT OR INCOMPREHENSIVE DATA DURING THESE TRIALS. YOU MAY RECEIVE PARTIAL, INCONSISTENT, OR INCORRECT INSIGHTS.

WE DO NOT AUTHORIZE YOU TO USE ANY OF THE INFORMATION YOU RECEIVE DURING THE COURSE OF THE CLINICAL TRIAL AND/OR THE BETA PROGRAM IN ANY FORMAT. IN ADDITION, WE DO NOT AUTHORIZE YOU TO DRAW CONCLUSIONS OR MAKE ANY DECISIONS BASED ON THE COLLECTED DATA RECEIVED FROM LITTLEONE.CARE.

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