user guide

ember

non-invasive hemoglobin tracking system

Welcome!

We are very excited you have chosen Ember™ to fulfill your training and exercise needs. If at anytime you have questions, please feel free to reach out to us at Cercacor™. We are committed to doing what we can to ensure you become an advocate of Ember and Cercacor technology.

Sincerely,
The Ember Team at Cercacor

Contents

Indication for Use

Ember is intended for use by athletes or their trainers to help measure and track hemoglobin, pulse rate, perfusion index, oxygen saturation, oxygen content, respiration rate or pleth varability index. It is intended to be used by individuals 13 years or older with a finger width of 22mm or less. This product is not a medical device.*

The Ember system consists of the device, sensor, and mobile app. The Ember device requires a smartphone with Bluetooth 4.0 capabilities to operate, running iOS 8.2 or newer. For a list of devices and operating systems that the Ember system works with, please visit www.cercacor.com.

*This product is not intended to monitor or alleviate a physiological condition or disease state. Individuals who need a device to monitor a medical condition should contact their physician. Ember is not meant to replace laboratory measurements nor is it intended for medical use. If you want more accurate hemoglobin assessments, please use invasive methods using properly conducted Cyanmethemoglobin assay or properly conducted and calibrated Coulter Counter testing.


cercacor

Safety

WARNING:

- Reduce possibility of entanglement or strangulation when using and storing sensor cable.
- Explosion hazard. Do not use Ember in the presence of flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- Avoid risk of an electric shock by only plugging in the Ember sensor into the device sensor port. Also, do not plug the Ember sensor into any other equipment except Cercacor devices.
- Only use a UL Listed power adapter that meets LPS or Class 2 limits rated 5V, minimum 0.5A.
- Do not incinerate battery.

CAUTION:

- Do not lift the Ember device by the cable or sensor.
- Discontinue use of the product if it appears to be damaged in any way. Immediately contact customer support.
- Do not attempt to adjust, repair, open, or disassemble the device and/or sensor in order to avoid injury or damage to device.
- Do not submerge device and/or sensor under water or cleaning solution, which will cause severe damage.
- To prevent electric shock, avoid placing device on surfaces with visible liquid spills. Do not soak or immerse the device in liquids, and only use cleaning solutions sparingly.
- The Ember device and sensor should be properly disposed as electronic waste.

Getting Started

Sensor Port: Mini DP 20 Pin

Button

Press once for Battery Status
Press and hold for 3 seconds for Bluetooth pairing
Press and hold for 6 seconds for a Hard Reset

Status Lights

full battery

low battery

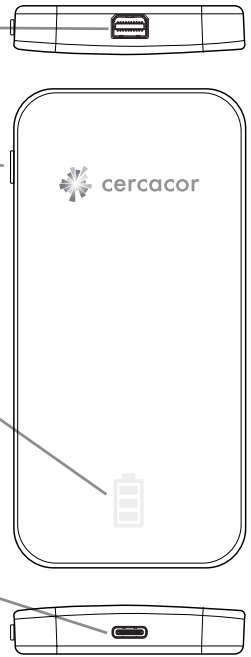
needs charging

bluetooth connecting
(blinking sequence)

bluetooth connected
(displayed for 3 seconds)

Charging Port: USB Type C

Charge the battery by connecting the Ember device to your computer using the included USB Type C cable, or connecting the Ember device to a power outlet using a UL Listed power adapter (LPS or Class 2)



Create an Account (Creating an account is optional, but highly recommended)

- Download the free “Ember by Cercacor” app from the Apple App Store.
- After you open the app, tap the “Sign Up” text at the bottom of the page to create an account. Follow the screen prompts until your account is created.
- Congratulations! You have now created an account. Next let’s connect Ember to your smartphone.

Connecting Ember to your smartphone

- The Ember device is shipped in sleep mode when you first receive it. To wake it up press the button for 3 seconds and then a series of blinking rectangles will appear. Now it is visible to the “Ember by Cercacor” app.

Troubleshooting your connection to the Ember device

- Check your battery level by pressing the button on the side of the Ember device to check if there is sufficient charge.
- Make sure your Ember device is within a close range (approx. 50’) of your smartphone.
- If prior steps do not work, try force quitting the app. To force quit the app, double click the home button on your iPhone then swipe up to close the app.
- If your Ember device does not show within the “find device list”, press and hold the Ember button for 3 seconds until the LED lights blink in a sequence from the center out.

- If prior steps do not work and your Ember device does not connect to the app or is still having trouble taking measurements, then press and hold the button on the side of the Ember device for 6 seconds. This will enable a hard reset of the Ember device.

If problem persists, contact support@cercacor.com. Be sure to include a complete description of the problem.

Taking a Measurement

① Begin by placing the sensor on a finger free of deformities. It is best to use the ring or middle finger of your non-dominant hand. It is recommended to not use nail polish for best accuracy and repeatability of measurements. Blue or green nail polish significantly affect the accuracy of the measurement.

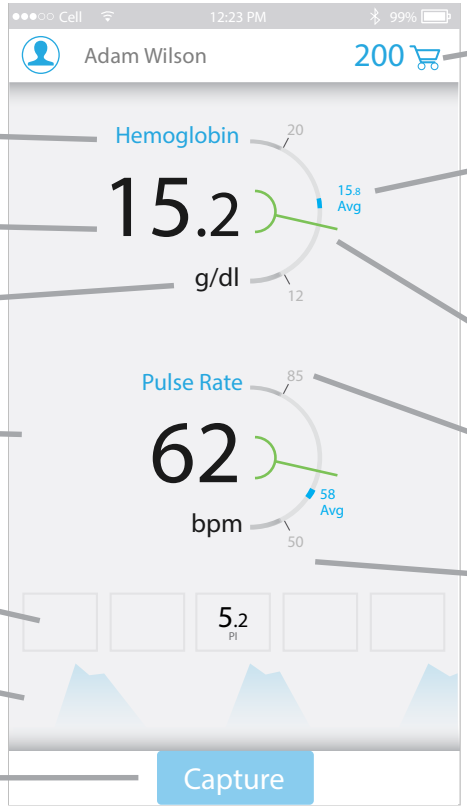
- The cable should be on top of your hand in a straight line as far as possible.
- Always use the same finger for every measurement. Ensure your finger is all the way into the sensor.
- Use the same posture and remain still during measurement.

② Once you are ready, tap the “Start” button within the app. The measurement time varies and can be as fast as 30 seconds. Be patient, the system will ask you to try again if it cannot get a result within 90 seconds.

- Be sure not to move around during the measurement.
- Refrain from talking, coughing, or sneezing during the measurement.
- During the measurement, a question related to the activity will be displayed. Please be sure to answer this question to get more value from your graphs.

③ Your measurement results will be displayed on the screen. When you tap the “Capture” button, the numbers displayed will be saved in your history. The gauge to the right of the display tells you your target range based on your age and biological sex (must have an account for gauges to be enabled). You can customize the target range based on your individual goals by accessing the “Options” tab of the app.

Live Results



Parameter title

Measured value

Units of measure

Parameter display area

Parameter well

Plethesmography waveform (Pleth)

Capture button

Measurement credits remaining

Average value of your measurements for last 30 days with the same activity*

Measurement needle

Upper limit target range*

Lower limit target range*

*Target ranges and averages are only available if you create an account.

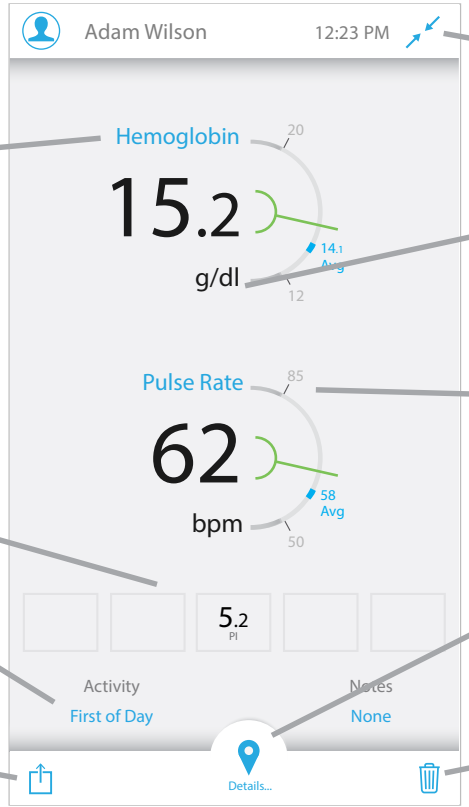
Captured Results

Tap to learn more about the parameter

Tap and hold to rearrange parameters onto the display area

Tap to change or set the type of activity

Tap to share your result



Tap to minimize view and return to the “Measure” tab

Units of measure can be adjusted in the “Options” tab

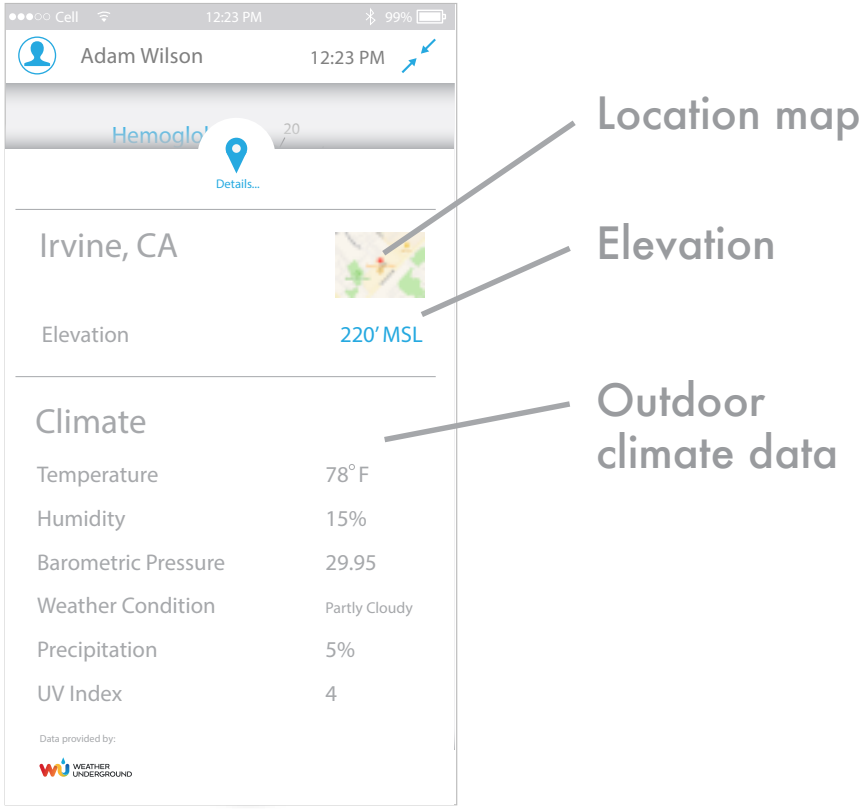
The ranges can be adjusted in the “Options” tab

Tap to see your measurement location and environmental data

Tap to delete this measurement

Measurement Details

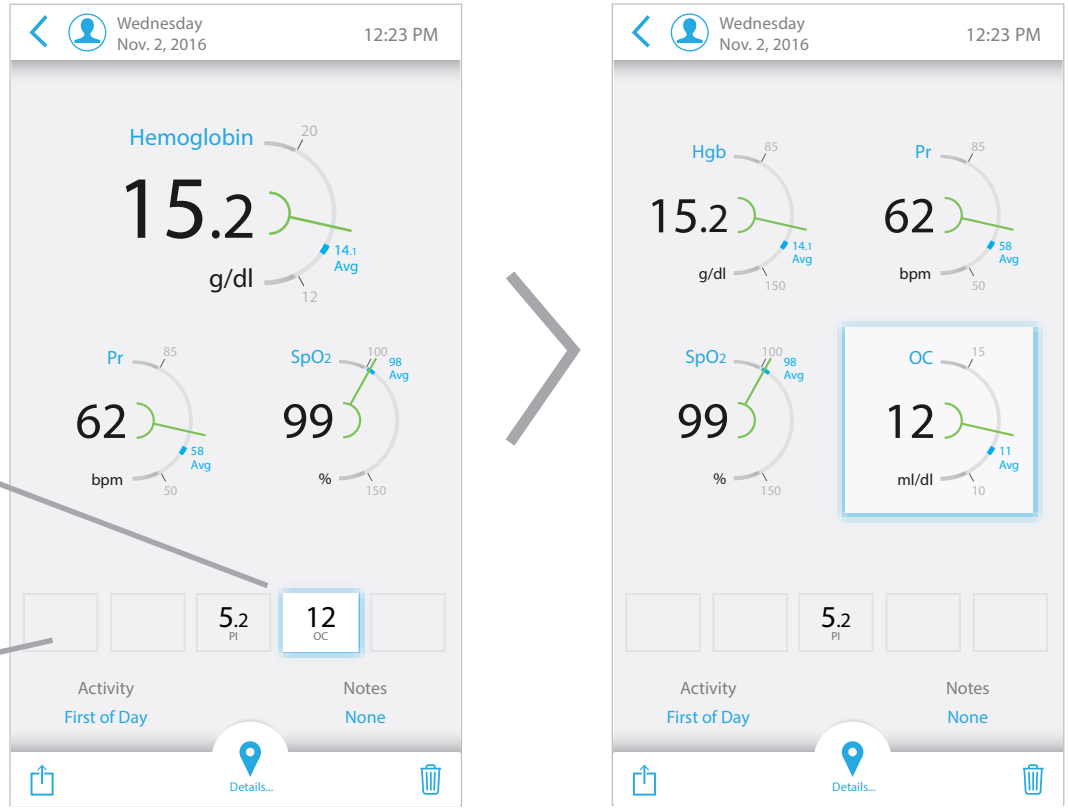
When you enable the Ember by Cercacor app to track GPS location, each measurement you take will log the location and capture the outdoor climatic details where your measurement was taken.



Rearranging Layouts

Tap and hold on any parameter to rearrange its location in the display area or move from the parameter well into the display area

Swipe left or right to reveal more parameters (if installed)



Parameter Descriptions

Your Ember device is capable of measuring numerous parameters depending on your model or the number of parameter upgrades that you have installed.

Hemoglobin (Hgb)

The protein contained in red blood cells that is responsible for delivery of oxygen to the tissues. The range of hemoglobin values can vary based on your age and biological sex. For adults 18 years and over at rest, hemoglobin values can be between 12-15.5 g/dl for females and 13-17.2 g/dl for males. Tracking your Hgb first of day and Pre/Post specific activities such as workouts or hydration may help you understand the intensity of your workouts and the fluid volume shifts and/or recovery times. Additionally, you may be able to learn the extent to which elevation training increases your Hgb and how long the effect lasts after returning to sea level.

Pulse Rate (Pr)

The number of beats your heart takes per minute (bpm) as detected from the pulsation at your finger tip. At rest values range between 50-85 bpm however fit individuals typically have lower resting heart rates. This is because their heart is more efficient and effective with each beat that it requires fewer beats per every minute. Tracking your pulse rate first of day and pre and post work out is a great benefit of using Ember to get an understanding of the intensity of your workouts as well as the impact over time to your fitness level on your first of day pulse rate.

Perfusion Index (PI)

The strength of blood flow/circulation at your finger tip measured as a percentage (%). Values for PI range from 1-20%. When selecting your measurement finger for the first time, it is good to use the ring or middle finger with a higher PI value.

Oxygen Saturation (SpO_2)

The amount of hemoglobin that is saturated with oxygen expressed as a percentage (%). At rest you should be greater than 95% oxygen saturated and after an intense workout you may go less than 85%. The lower your SpO_2 the less effective your muscles and tissues are for performance. Tracking your SpO_2 with specific activities throughout the day with Ember may help you understand the quality of your oxygen exchange.

Oxygen Content (OC)

The total amount of oxygen bound to hemoglobin. This value is derived from your hemoglobin and oxygen saturation levels in millilitres per decilitre of oxygen (ml/dl). At rest values can range between 15.2 - 23 ml/dl. By tracking this number with Ember, you may discover that you have better endurance and performance when your OC is trending higher.

Respiration Rate (RR)

The number of respiratory cycles you complete per minute (rpm). A respiratory cycle is the entire inhalation (breathing in) and exhalation (breathing out) from your lungs. Values can range from 15-20 respiratory cycles at rest. Tracking your RR multiple times per day with Ember may help you understand the impact exercise has on your respiratory cycle and provide feedback on how effective your breathing becomes over time.

Pleth Variability Index (PVI)

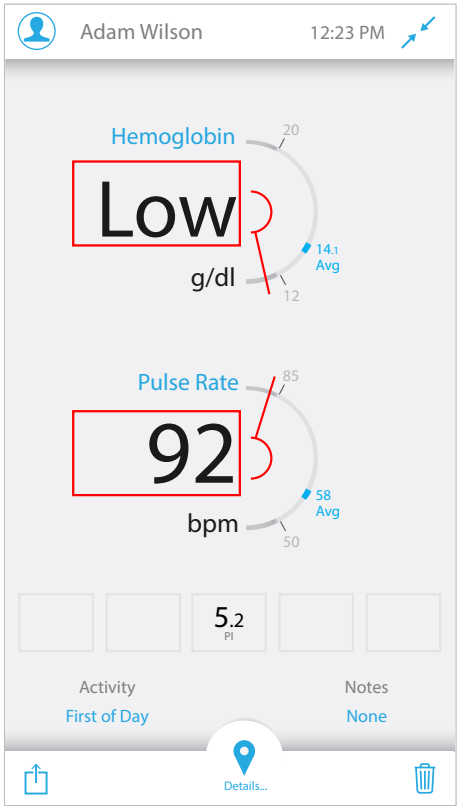
A measure of the dynamic changes in the perfusion index that occur during the respiratory cycle. In mechanically ventaliated patients PVI has been correlated as an indicator for how well patients respond to fluids. If you track PVI multiple times per day we are excited to hear from you how this helps your training, planning or wellness.

It is suggested to establish your baseline PVI by measuring it over several days, at the same time, in the same body position, at the same breathing rate and depth of breathing. An ideal time to measure PVI is in the morning before you get out of bed. An increase in PVI compared to your baseline PVI may indicate increased dehydration, increased breathing effort, or other factors. A decrease in PVI compared to your baseline PVI value may indicate greater levels of hydration, decreased breathing effort, or other factors. Multiple factors other than hydration and breathing effort can affect PVI, including breathing rate, depth of breathing, body position, body movement, vascular tone, blood flow to the finger, and cardiovascular abnormalities.

Out of Range Results

If you take a measurement and receive the phrase "Low" instead of a numeric value for hemoglobin, it indicates that your value was below 10 g/dl and is too low to present a number. If you receive the phrase "High" instead of a numeric value, it indicates that your value was above 24 g/dl and is too high to present a number.

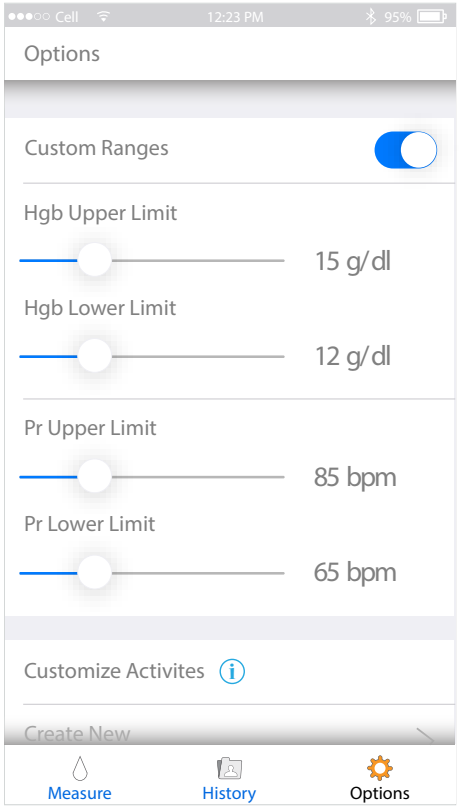
If your measurement value has a red box behind it, the value is out of your set ranges. These ranges can be adjusted to your specific needs in the "Options" tab of the App.



Range Adjustment

The normal ranges displayed on your results screen can be adjusted within the "Options" tab of the Ember app. The default values are from published sources on general population ranges based on biological sex and age.

We recommend you set your own custom ranges based on input from your trainer or your own personal knowledge and goals.



Inaccurate readings can be caused by:

User Factors

- Using the sensor on a deformed finger or placing it incorrectly.
- Moving or talking during a measurement.
- Electromagnetic Interference (EMI) from items such as computer displays and/or LCD TVs.
- High intensity lights (including pulsating strobe lights or sunlight) directed on the sensor.
- Externally applied coloring (such as nail polish).

Other Factors

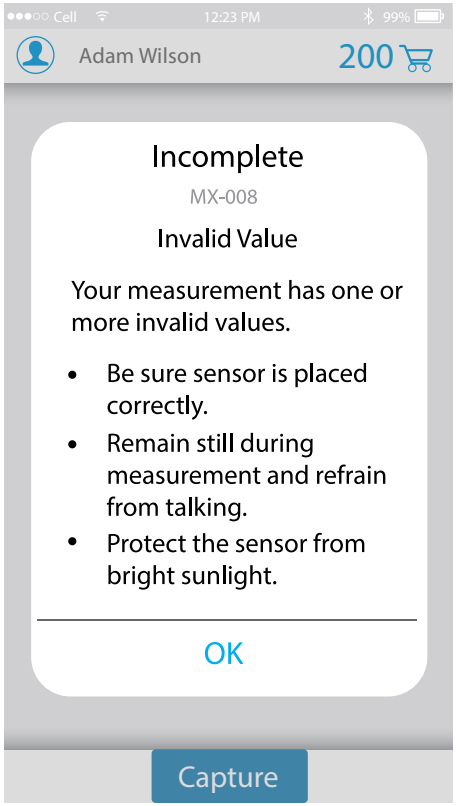
- Hemoglobin synthesis disorders, Hemoglobinopathy, or Vascular disease.
- Elevated Bilirubin, Carbon Monoxide and/or Methemoglobin.
- Low arterial perfusion or low arterial oxygen saturation levels.

Note: Some of these may cause incomplete measurements see pg. 27.

Incomplete Measurement

If you take a measurement and receive the "Incomplete" pop-up dialogue, please check the following and try your measurement again.

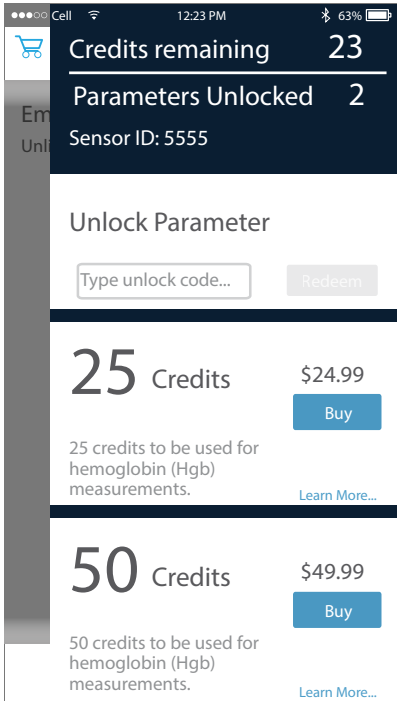
- Reduce excessive motion or interference to the device and sensor during measurement.
- Check sensor placement, reduce ambient light, and remove nail polish if present.
- Use a finger with no deformities or nail abnormalities and always use the same finger.
- Make sure your hands are not cold by rubbing your hands together vigorously for 10 seconds.



In App Purchase and Unlocking Parameters

Hemoglobin requires a per use charge. Each Ember device comes preloaded with 200 hemoglobin credits. Credits are iOS device specific so if you are buying credits they are only applicable on that specific iOS device and they can not be transferred or replaced if your device is lost, damaged, or stolen.

Credits are used immediately after each measurement and cannot be saved for use at a later date. If you run out of credits, your Ember device will still measure all other parameters except hemoglobin and oxygen content. Both hemoglobin and oxygen content will only display when you have sufficient hemoglobin credits.



Unlocking Parameters

Depending on the Ember model you have, you may need to unlock parameters to enable more measurement values. If you would like your Ember to measure additional parameters the unlock code can be purchased online at www.cercacor.com.

When you purchase an unlock code, a one-time-use code will be sent to you to unlock the additional parameters. The code used to unlock additional parameters is specific to your Ember sensor and not your iOS device. This means that the new measurement parameters once unlocked are available anywhere that your Ember sensor is used. As long as the iOS device has sufficient measurement credits then Hemoglobin and oxygen content will display as well.

Reviewing Features

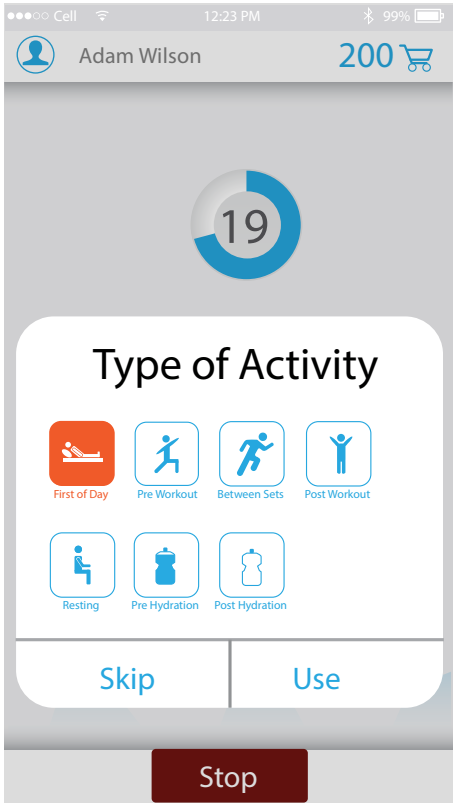
A very exciting feature about the Ember device is the ability to review your historical data in different ways. The more you participate, by measuring frequently and choosing activities associated with each measurement, the more powerful your graphs become. We recommend you measure 3 times per day using these activities: First of day, Pre Workout, and Post Workout.

Explore and enjoy graphs by using pinch to zoom, pan and even rotate your device to take advantage of landscape view. Graphs can be shared via SMS, email, and popular social networking sites to share your progress with friends, coaches, trainers, and teammates.

Activities

Every time you take a measurement, the app will ask you to associate an activity. By using the same finger, same posture, same time of day, and associating the measurement to a specific activity you will have a more powerful and precise historical review of your data. Consistency is important to get reliable trends in hemoglobin.

We recommend measuring the first thing every day before you get out of bed. We also recommend measuring 5 minutes before a workout and then within 1 minute after you wrkout for the best comparison of exercise on your baseline.



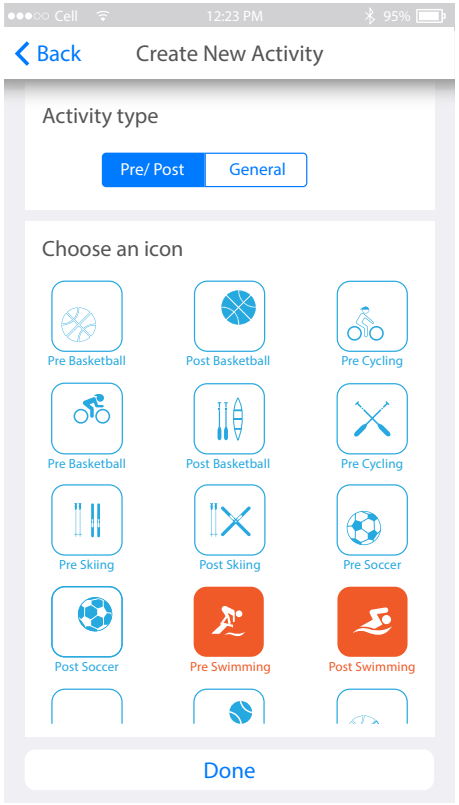
First of Day		This should be performed when you first wake up before your feet touch the ground.
Pre Workout		Select this activity for measurements taken within 5 minutes before you begin a workout.
Bewteen Sets		Select this activity if you are between any sets or intervals of your training.
Post Workout		Select this activity for measurements that are taken within 1 minute after you stop your workout.

Resting		Select this activity for measurements at rest, where you have not exercised or hydrated for at least an hour.
Pre Hydration		Select this activity within a few minutes before you drink at least 6 oz. of fluid or have a meal.
Post Hydration		Select this activity when you take a measurement 30 minutes after drinking at least 6 oz. or eating a meal.
End of Day		Select this activity for your last measurement of the day. Be sure to measure this in a consistent posture and around the same time each day.

Custom Activities

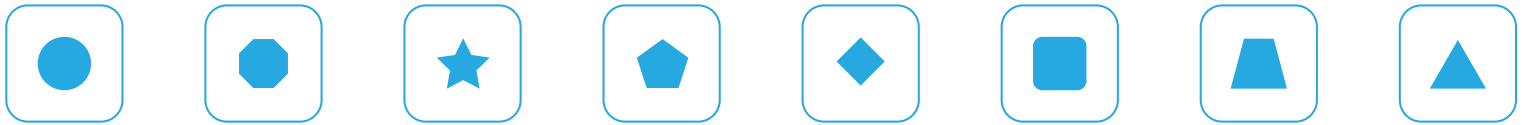
If you want to create specific custom activities you can do so in the “Options” tab. New activities can be General or they can be a Pre/Post combination.

Pre/Post activities are designed for measurements where you want to track your Ember results before and after a sport or training activity. For example you may want to track how swimming impacts your hemoglobin. Pre/Post combinations are available to be viewed within the Daily Ranges graph to see comparisons throughout the day while General activities can not. All other graphs support filtering of General or filtering of Pre/Post custom activities.



The available choices for General and Pre/Post custom activity icons.

General Activity Icons



Pre Activity Icons

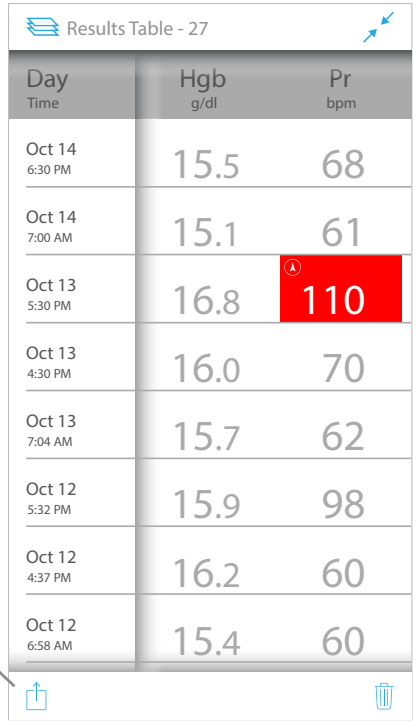
Post Activity Icons

History

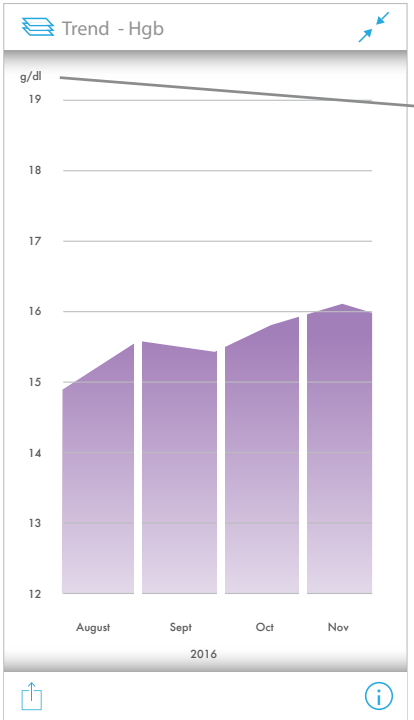
A list view of all measurement results. Swipe to the left to reveal more data.

Tap share icon to export all measurements as a csv file.

Results Table



Trend Graph



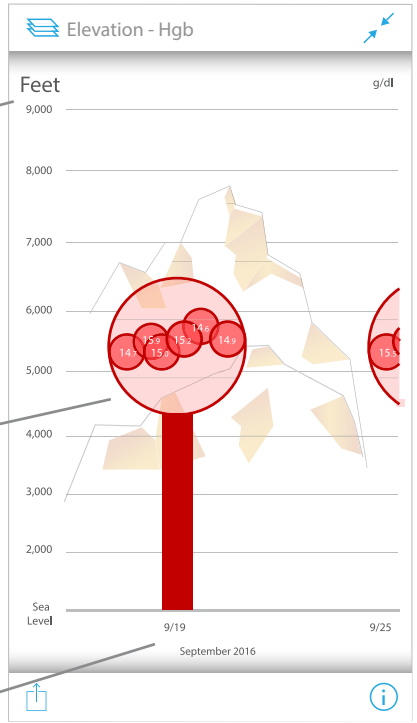
Vertical (Y-axis) displays the units of measure for the parameter you are viewing.

Elevation Graph

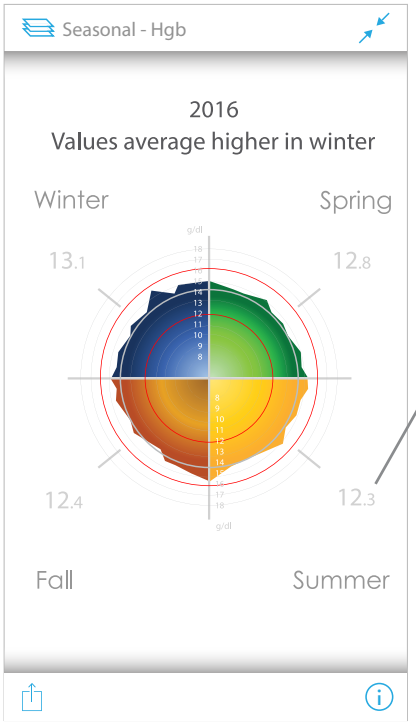
The vertical, Y-axis, represents the elevation.

Each large bubble contains about a week of measurements.

The horizontal (X-axis) represents time.



Seasonal Graph



This graph reads like a clock.

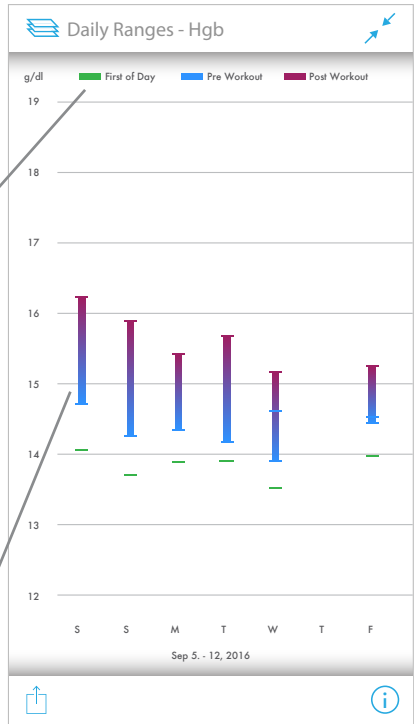
Each degree is about one day of measurements.

The seasonal quadrants have an averaged value presented.

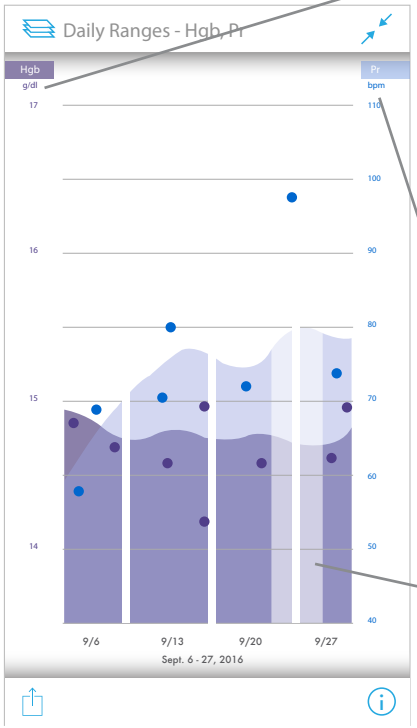
Daily Ranges

View the legend for First of Day, Pre and Post Workout.

Pre and Post Workouts are connected to show any impact workouts have.



Multiparameter



The left vertical, Y-axis, is blue and represents your first parameter.

The right vertical, Y-axis, is purple and represents your second parameter.

Trend color fades when no data present.

Collected Data

All measurements are stored locally on your iOS device. We recommend you create a Cercacor account so that your data is safely backed up and stored in the cloud automatically when your phone is connected to the Internet.

Since your physiology is affected by environmental factors, your measurements will automatically capture various details based on your location, for example, the weather and elevation.

Note: The Cercacor privacy policy can be viewed online at http://privacypolicy.cercacor.com or within the Cercacor app under the “Options” tab.

Cleaning

The outer surface of the device can be cleaned with a soft cloth dampened with a mild detergent and warm water solution or isopropyl alcohol.

- Do not allow liquids to enter the interior of the device.
- Do not soak or immerse the device or sensor in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the device or sensor and cause damage to internal components.
- Do not touch, press, or rub, the Ember device or sensor with abrasive cleaning compounds, such as: devices, brushes, or rough-surface materials.
- Do not use pertroleum-based or acetone solutions, or other harsh solvents, to clean the Ember device. These substances erode the device's materials and device failure can result.

Specifications

Ember Device

Battery Type	3.7V nominal, 500mAh
Hours of Operation, Charging Time	120 measurements, 2.5 hours
Standby Power Mode	20 days
Storage Temperature Range	-40° to 149° F (-40° to 65° C)
Operating Temperature Range	41° to 113° F (5° to 45° C)
Operating Humidity Range	20 - 95% (non-condensing)
Dimensions	115mm x 56mm x 12.9mm
Approx. Weight	75g

For more information on Regulatory and Safety Notices open the “Options” tab in the Ember app and then go to “Regulatory”section.

Parameter Specifications

Hemoglobin

Display Range	10 - 24 g/dl (grams/deciliter)
Accuracy	1 g/dl at 1 SD (Standard Deviation)
Trend	0.7 g/dl at 1 SD
Precision	0.4 g/dl at 1 SD

Note: For further information on Hgb accuracy, trend, or precision, please see page 18-19 or visit http://accuracy.cercacor.com.

Pulse Rate

Measurement Range	25 - 240 bpm (beats per minute)
Accuracy	3 bpm at 1 SD

Note: For further information on pulse rate accuracy, please see page 20.

Perfusion Index

Measurement Range	0.05- 20 %
Accuracy	+/- 10 % of the displayed value

Oxygen Saturation

Measurement Range	0 - 100 %
Accuracy (between 70 - 100%)	2 % at 1 SD

Oxygen Content

Measurement Range	0 - 35 ml/dl
Accuracy	Dependent on Hgb and SpO_2

Respiration Rate

Measurement Range	0 - 150 rpm (respirations per minute)
Accuracy	< 1 rpm at 1 SD

Pleth Variability Index

Measurement Range	0 - 100 %
Accuracy	Not applicable

Accuracy notes:

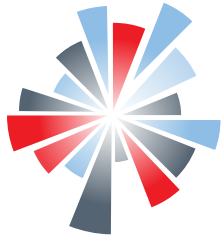
The accuracy of Ember in measuring Hgb has been shown in controlled studies to be 1 gram per deciliter (g/dl) at one standard deviation. This means that under the specific controlled conditions of those studies, 68% of the Hgb values measured on the Ember device fell within +/- 1 g/dl when compared to a calibrated and properly used invasive laboratory reference method used to measure Hgb. The protocols for the accuracy testing of the device are available from Cercacor. Please note that such testing isolates, as well as possible, the accuracy of the device from other sources of error.

Usability and repeatability are separate measures from accuracy, but are frequently confused with accuracy, and the error contribution from these other measures can create an impression about device accuracy that does not reflect actual device accuracy.

An internal study was conducted to evaluate the effectiveness of non-invasive Hgb to detect changes in Hgb and the precision of measurements from the device. The trend accuracy in this study, defined as its ability to detect changes in Hgb values was shown to be +/- 0.7 g/dl at one standard deviation. The precision, defined as the closeness of two or more measurements to one another, was shown to be +/- 0.4 g/dl at one standard deviation. This was a controlled study designed to isolate measure

ment of the trend accuracy of the device, rather than measures of usability and repeatability.

The accuracy of Ember in measuring pulse rate in the range of 25 – 240 beats per minute is +/- 3 beats per minute at one standard deviation, under no motion condition. This accuracy is for plus or minus one standard deviation, which encompasses 68% of the measurements. This accuracy was measured using bench top testing against a Biotek Index 2 simulator. This does not reflect testing on people or in a user setting.



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