User Manual

carity

Please read this manual carefully before you start using the Carity System.

Product description

1.1. About Carity

The Carity System is a Software as a Medical Device Product designed to be used by a patient during and after a prescribed outpatient rehabilitation program (further referred as rehabilitation program or rehab program) and by the related rehabilitation team and enabling to:

• Collect patients' self-reported psychological and quality of life assessment outcomes

• Collect patients' cardiac biomarkers provided by supported consumer wearables (pulse, HRV, estimated 6-minute walking distance, VO2max)

• Collect patients' workout time and records provided by same wearables

• Compile patients' status and progress for its psychological, workout performance and heart fitness based on the collected data as listed above

• Determine appropriate patient's objectives for its psychological, workout performance and heart fitness for progress tracking

• Monitor the patient's rehabilitation adherence progress

• Access to objective patient psychological, performance and

heart data to support a follow-up consultation by the rehabilitation team or adequate health coaching

The Carity System is suitable for use by all patients who can understand the instructions and control a compatible smartphone and a compatible wearable device. The Carity System is released as an application installed on a mobile device supporting iOS or Android operating system.

Please note that in this document "Carity System" term is used interchangeably with the term "Carity App".

1.2. Intended use

The Carity System is a digital adjunct to a patient rehabilitation program. It collects patients' psychological, exercise performance and heart fitness data using input from questionnaires or provided by supported consumer wearables.

The Carity System uses collected data to compile and track rehabilitation progress against set targets and enables a regular monitoring of psychological, exercise performance and heart fitness status and progress to support a follow-up consultation by healthcare professionals ("HCP") and / or health coaches.

The Carity System is intended to be used for a single patient and is recommended and onboarded during the rehabilitation program by the rehabilitation team at the centre.

The Carity System is intended to be used by healthcare professionals in form of receiving dedicated adherence reports of the treated patient to supporting follow-up consultations.

The Carity System is intended to receive information from

supported consumer wearables or to collect via its interface additional, supplementary patient- and health-related information and to compile such information into health reporting to be sent to HCP or progress indicator shown on its interface.

The Carity System does not compute any data on a dedicated Carity Support API. All data computation happens locally on the patient's mobile device.

1.3. Indication for use

The Carity System focuses in its current version on supporting patients during and after their cardiac rehabilitation, and provides value and useful insights as well for the rehabilitation team as well as health coach or HCP acting after the rehabilitation.

1.4. Who is the Carity App for?

The Carity System is suitable for patients with following characteristics:

- Male or female, aged from 40 years to 80 years, older possible upon HCP discretion if cognitive status enables patient to handle the app and the related wearable device according to the provided training.

- Patient had a past cardiac event, either myocardial infarction or heart failure and is scheduled for an outpatient cardiac rehabilitation program. Exception are patients whose indication prevents regular exercises (e.g. heart failure with ejection fraction <45%, a valve replacement, a heart transplant).

- Comorbidities are acceptable if these do not prevent the patient to handle the app, the related wearable according to the provided training and training exercises itself.

- Patient starting the outpatient rehabilitation program shall receive from its treating HCP the recommendation to use the app and the app is being onboarded and trained at rehab start.

The Carity System is suitable for HCP and health coaches willing to receive a reporting on patients' adherence and workout progress in order to provide insights into the patient's program-related actions and the effects of such actions. Such insights shall serve the HCP to better define the need to further examinations, which would be the basis of any medical decision. Such insights shall serve the health coach to better engage in the exchange with the patient and eventually to recommend patient to seek medical advice.

Contraindications

There are no known contraindications for the use of the Carity System.

Warnings ⚠

- The Carity System is not a permanent live-streaming monitoring system, neither it provides any dashboard to collect permanent data for HCP use outside of Carity System.

- The Carity System is not an emergency system, as collected data may be delayed and do not represent an instant monitoring of the patient, neither the patient is able to use the app for any emergency call or signals to the HCP.

- The Carity System reporting does not replace the HCP's responsibility to examine and assess the patient prior any medical decision, nor the app provides any guidance to the HCP for any medical decision.

- The Carity System shall not be used as primary prevention health tool downloaded and introduced by the patient itself. It cannot be used a first time without at least a prior HCP recommendation.

- The Carity System may be impacted in its accuracy by patients having experiences of Arrhythmia and may only be used for these patients upon HCP discretion.

- The Carity System has generally not yet been tested for

> patients outside of the indications and use cases described above.

- The Carity System does not provide any medical advice on its own, neither it offers an automated coaching service.

Precautions ⚠️

- Make sure to keep the Carity App updated so that you always have the latest version. Carity recommends setting your smartphone to update the app automatically.

- Make sure to turn on Bluetooth in order that your data from wearable is transferred to your mobile device.

- Make sure to enter correct data in the Carity App whenever you are asked to.

- Make sure to stay attentive to your surroundings while exercising and perform app and wearable device actions before and after completing the exercise.

- If you notice that wearable device wrist band causes irritation, try to optimise how tight do you wear it. Too tight or too loose wearing might cause some inconvenience. In case of persisting irritation please contact your Care Team.

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Product instructions

5.1. Pair your wearable device (optional)

This step is only for patients who do not already have a personal wearable device.

- Pairing can be performed **BEFORE** or **AFTER** installing Carity App;

- App is currently compatible with iPhone and Apple Watch. You are encouraged to follow official instructions on the Apple website: www.support.apple.com or request additional materials on www.carity.care;

- If you encounter any difficulties, you can schedule a call with one of our consultants through the Carity App.

After you pair the device, it is recommend to practice recording a workout. We recommend recording 1 minute 'test' workout of any type in order to learn the process:

• Press the side button **(Digital Crown)** to open the menu.

• Open the **Workout app.**

• Turn the **Digital Crown** or swipe down to find the desired workout type.

• Tap on the selected exercise and start your workout.

• Once the workout is finished, **swipe right** and tap **"End"** at the bottom.

• You can also pause your workout by tapping **"Pause"** at the bottom.

5.2. Install your Carity App

The Carity App is available to the general public, but all features remain locked until you receive and scan a QR code from your Care Team (Healthcare Professional).
Your QR code details will be provided to you, either in person or through physical mail, once you have been referred to Carity and your Patient ID has been created.

Step 1: Download the Carity App

If you are a participant in **Clinical Study** install **Carity-P app** from the Apple App Store.

If you are regular patient install the **Carity app** from the Apple App Store .

After installation, please enable notifications, so Carity App can remind you about important events in the app.

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Step 2: Scan the QR-Code

You will receive a QR-code from Carity or your Care Team directly that includes details of your Care Team, selected Carity Plan and the Patient ID.

At the bottom of the Progress Indicator, you will find the "Scan QR Code..." button. Tap on it and grant permission to access your camera – you will need it to scan the QR code;

- Scan the QR-code;

- Follow the on-screen instructions until your profile is complete. Make sure all your entries are correct;

- Upon completion, you will be assigned standard therapy goals based on the ESC Guidelines*, which will be approved by your cardiologist.
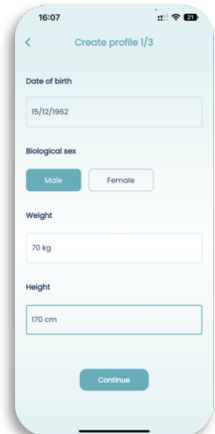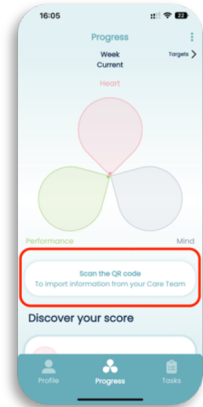
It is **IMPORTANT** to collaborate with a doctor to update your therapy goals at least twice during the rehabilitation program – once after the initial weeks and again shortly before the program concludes.

European Society of Cardiology Guidelines 2021
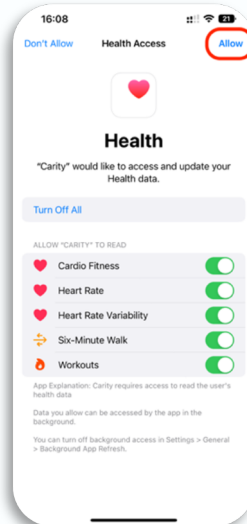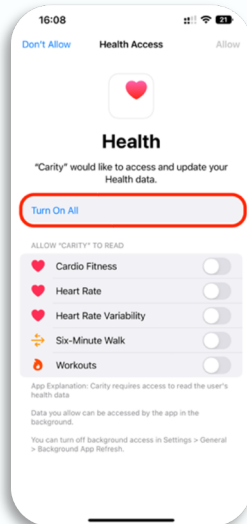
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Step 3: Add your wearable device

If you haven't yet paired your wearable device (see 5.1) Carity App will not be able to fully connect to it. We recommend you pair the device before you start this step.

Now, under the progress indicator, you will find the **"Add Your Device"** button – tap on it and follow the on-screen instructions.
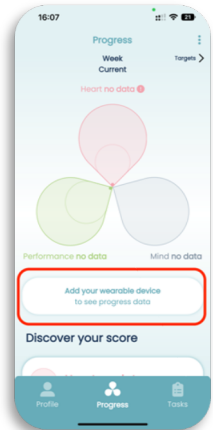
IMPORTANT!

Grant permission to Apple Health Kit when prompted. Otherwise, Carity will not be able to access your health data and calculate your scores.

5.3. Carity Overview

Carity contains 3 simple menus:

Profile Menu contains the patient's basic information, information about the app, therapy goals, Care Team information, supporters and connected devices.
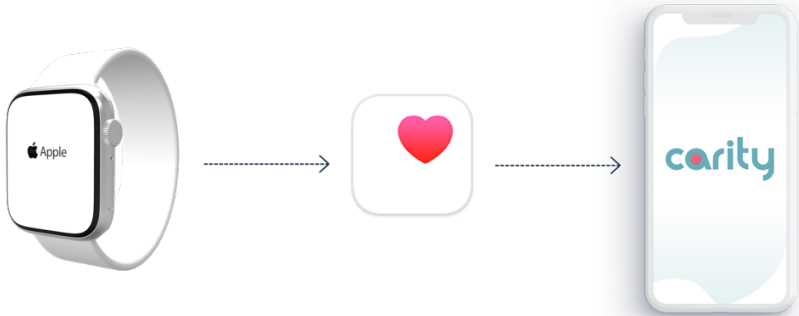
Progress Menu representing your heart recovery through monitoring carefully selected metrics related to heart health, physical activities, and mental state.

Tasks Menu designed to guide you in improving your health. It consists of questionnaires, notifications, guides and collects metrics beyond the wearable device.
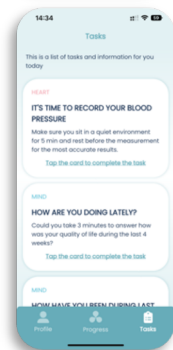
How does it work?

Apple Watch collects Data about your heart, respiratory, activity etc.

Apple Health receives and stores this data.

Carity picks up only relevant data for your cardiac health and presents to you in a simplified form.

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5.4 Profile

View your Profile
Here you can check your personal data.

Edit your therapy targets
Here you can check your therapy goals and modify them.

Information & Feedback
Here you can access more information about Carity , access to all your consents, export all your data , delete your account. Moreover, you can send us your feedback or support request.

IMPORTANT!
Do not change the targets without prior consultation with your Care Team.
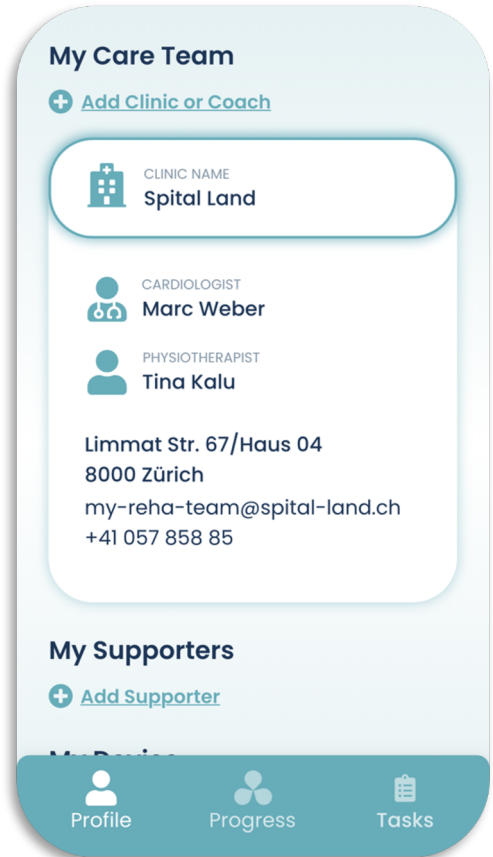
My Care Team

Here you can access basic information about your Care Team.

My Supporters

Here you can add an e-mail of your significant other or friend. Thanks to that they will also receive your PDF-reports.

My Device

This section shows you the data sources for Carity app. "Refresh data manually" button might be helpful in case you see some data missing.

My Care Team

⊕ **Add Clinic or Coach**

CLINIC NAME
Spital Land

CARDIOLOGIST
Marc Weber

PHYSIOTHERAPIST
Tina Kalu

Limmat Str. 67/Haus 04
8000 Zürich
my-reha-team@spital-land.ch
+41 057 858 85

My Supporters

⊕ **Add Supporter**
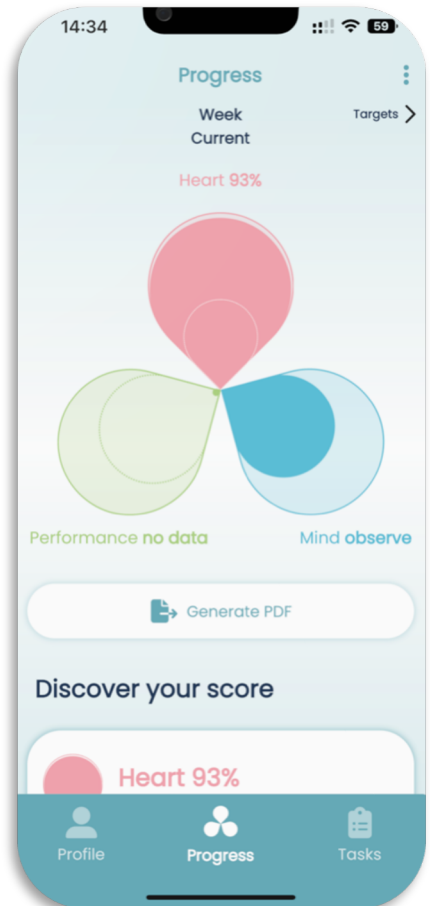
Profile   Progress   Tasks

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5.4 Progress

Main view of the app summarizes your achievements towards a healthy heart on a weekly basis and includes 3 elements:

- Heart
- Mind
- Performance

You can navigate to your previous weeks by tapping **'Previous'** or by swiping.

You can navigate to see your detailed Targets by tapping **'Targets'** or by swiping.

IMPORTANT!

During the first 3 weeks of Carity, some data might be missing in the Heart section, especially if you just started to wear an Apple Watch - the device needs time to calibrate with every new user. Do not be alarmed by this. Keep wearing the watch **at least 2 hours during the day and during physical activities** and your score will get filled with data gradually.

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HEART

Your heart score is calculated from 3 parameters collected through your Apple Watch and post-exercise questionnaire. Find the meaning and values of these parameters by tapping the petal or scrolling down. Tap arrow down for more details.
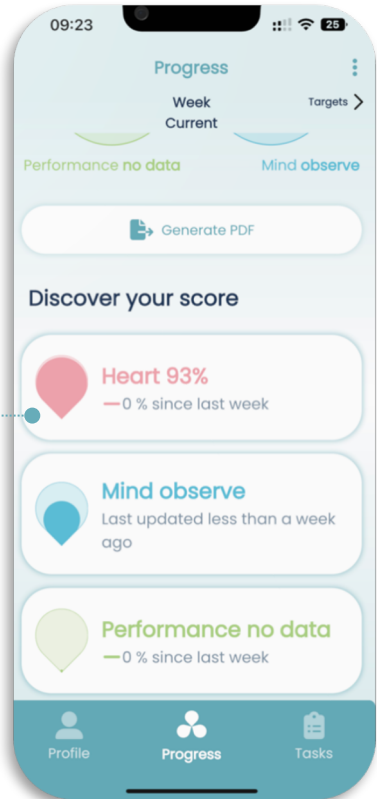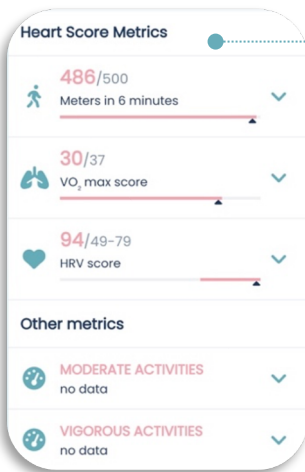
What does the exclamation mean?

If next to the score you see this symbol, it means that there are no data points of this parameter yet or the data is older than 7 days. This can happen during the **first 3 weeks** of using an Apple Watch or if you don't wear a watch regularly or don't exercise.
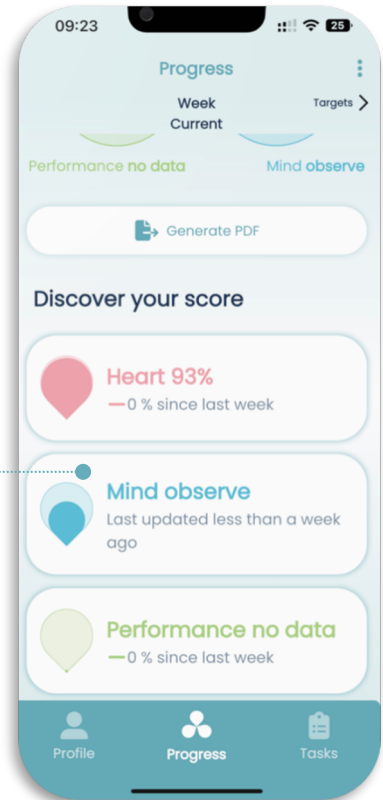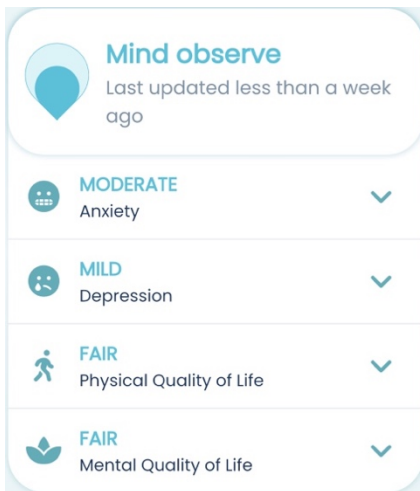
REMEMBER to wear your Apple Watch for at least 2 hours a day, charging it regularly during the night.

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MIND

Your mind status is based on the results of the questionnaires. It includes 3 aspects: **Anxiety, Depression** and **Quality of Life**. You can find your results and general meaning by tapping the petal or scrolling down and tapping each of the elements.


What does 'no data' mean?

It means there is not enough data from the questionnaires to determine your status. Within first week you will receive enough questionnaires to set your status in the app.

REMEMBER to always answer all the questionnaires in the Task section.

PERFORMANCE

Your performance score is based on the minutes of your moderate and vigorous activities. The minutes are collected from your **Apple Health Kit** and in-app **post-exercise questionnaire**. It Is important that you reach your target minutes for each category.
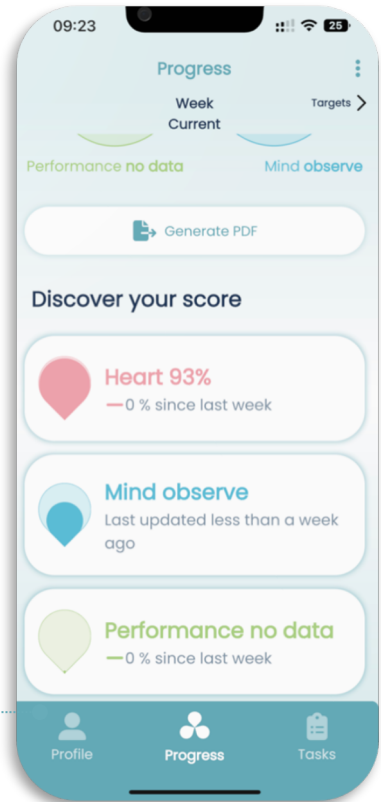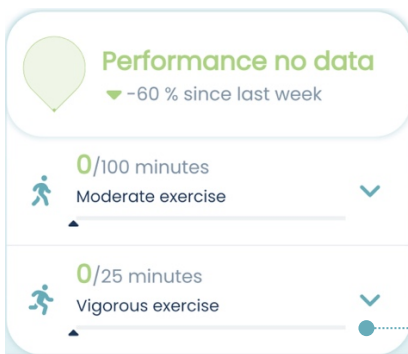
Why did my Performance score suddenly drop to 0%?

Your performance score is calculated on a weekly basis. Every Monday it resets to 0%. Your task is to reach 100% of the activity minutes goal by the end of the week. Every week you start fresh.

REMEMBER to register your exercises on the Apple Watch and answer the post-exercise questionnaire the same day.

If you don't remember how to do read back the section **5.1. Pair your wearable device**.

5.5 Tasks

Daily tasks

Here you will find tasks that will help you to improve your scores. You can expect a minimum of 3 tasks per week, but this number will increase depending on how many exercises you record.

Types of tasks

- **Questionnaires** assessing your state of mind;

- **Post-exercise assessment** after every registered activity, influencing your Heart and Performance scores;

- **Weight and blood pressure check** to monitor changes;

- **Data sharing** of your data with your Care Team - to monitor and follow-up on your progress;

- **Target review and activity planning tasks** helping you set up your more personalized physical goals;

- **Informative tasks** showing you elements of your progress or app management;
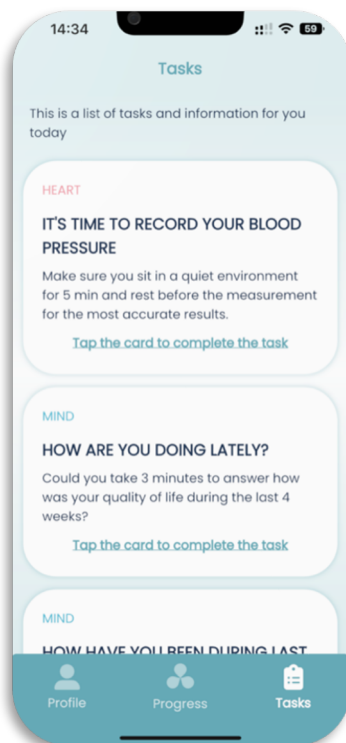
> **IMPORTANT!**
>
> Try to complete all tasks on your list, especially sharing your data with the Care Team during the rehabilitation program. Regularly discuss the report with your Care Team.

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5.6 Frequently Asked Questions

Apple Watch

Search below for the issue at hand to learn how to proceed.

If you need further assistance, contact Apple Support:

https://getsupport.apple.com

1. **If your Apple Watch won't turn on**

   You might need to charge your Apple Watch.

2. **If you are asked for a passcode**

   Your Apple Watch is still paired with another iPhone.
   Contact the Care Team to exchange the Watch.

3. **If an Activation Lock screen appears when first-time set-up**

   Your Apple Watch is linked to another Apple ID. Contact the Care Team to exchange the Watch.

4. **If you can't set up your Apple Watch or you get an error message**

   - Make sure that your iPhone has the latest version of iOS.

   - Turn off your iPhone and turn it back on.

   - Turn off your Apple Watch and turn it back on.

5. Is Apple Watch waterproof? Can I swim with the Apple Watch?

When you start a swimming workout, the Apple Watch automatically locks the screen with the 'Water Lock' feature to prevent accidental taps. When you finish, either press and hold the side wheel (*Digital Crown*) or, if nothing happens, rotate the Digital Crown down to unlock the screen and remove the water from your Apple Watch. A series of beeps will play to remove any water remaining in the speaker.

To manually remove water from your Apple Watch, swipe up on the Watch face to open the Control Centre, then tap "Water Lock" and then press and hold the Digital Crown to unlock the screen and remove the water from the speaker.

Digital Crown/
Home-Taste

Seitentaste

Carity App

1.   Something doesn't feel right, what should I do?

If you notice a strange behaviour of the app, please send us feedback within 24 hours. You can do it from PROFILE menu - information screen. ℹ️

If by any chance you can not open the app - please contact your <u>Care Team</u>.

2.   How often do I need to wear the Apple Watch?

Ideally, it is recommended to wear the Apple Watch throughout the day, but we understand if you don't want to. In that case, it would be beneficial if you wear the Apple Watch at least 2 hours a day and during your physical activities.

3.   I forgot to record my exercise - what can I do?

Unfortunately, if you forget to record your workout on Apple Watch, it will not count towards your scores. However, be mindful to avoid overcompensating forgotten minutes with additional exercise.

4.   The screen is not moving, I can't do anything.

Try to close the app completely as you usually do on iPhone and reopen it again. If that does not help, contact technical support.

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5. **Why am I never getting moderate or vigorous minutes added to my score?**

Do you remember to record exercise on your wearable device? **If not,** please record each exercise directly on your wearable device via Workout app. **If yes,** then continue reading.

In order to grow your performance score, you need to achieve a certain level of heart rate in order to match moderate and/or vigorous exercise intensity.

> **We recommend consulting your Care Team if there is a need to adapt your targets.**

You may try slightly increase or reduce the intensity during the next exercise and observe how your scores are behaving. After each exercise carefully read the **workout summary** (after completing post-exercise questionnaire). At the same time remember to listen to your own body and do not cross your **maximum heart rate** set by your Care Team.

Additional Information

6.1. Help & Support

If you have any problems using the app, speak to your Care Team who will be able to help.

Please report any serious incident that has occurred in relation to the Carity System with no delay to your Care Team.

6.2 Supported platforms

The Carity System can be used with:

- iOS smartphones running on iOS 16.0 or higher.
- Apple Watch running with WatchOS 9.0 or higher.

6.3. Environment for Use

There is no specific environment of use. However, the Carity App can be used wherever a smartphone and wearable device can be used. Only use the app in a secure environment. In public WIFI, connect to secured networks whenever possible.

6.4. Symbol glossary

Symbol	Meaning
▲▲	Manufacturer
⚠	Caution
carity	Carity App logo
📖ⓘ	Consult Instruction For Use
MD	Medical Device
UDI	Unique Device Identifier

6.5. Regulatory and safety notices

This product is currently undergoing testing and the process of obtaining CE marking. As of this version of User Manual (May 2023) this product has NOT yet been granted the CE mark, which signifies its conformity with European Union health, safety, and environmental protection standards. Until the CE marking is obtained, this product should be considered as being under evaluation and must not be used or treated as a certified product.

We are actively working to complete the necessary testing and certification processes to obtain the CE mark. Once the product has successfully completed these processes and the CE mark is granted, we will update the relevant documentation and product labelling accordingly.

Please note that it is essential to follow all guidelines,

instructions, and safety precautions provided with the product, even during its evaluation phase. The use of this product without the CE mark is at your own risk and discretion.

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Carity AG
Herbergstrasse 16, 9524 Zuzwil, Switzerland

UDI Not available. Carity is still an investigational device.

Date of release: August 2023

Device name: Carity System

Model: Carity & Carity-P

MD 📖 ⚠️

www.carity.care