

# DIGITIVA™

## Instructions for Use





# Introducing DIGITIVA

## A tool to manage your heart failure your way.

The DIGITIVA Mobile Application<sup>1</sup> offers a customized program for individuals, age 22 or older, with an existing diagnosis of heart failure or other cardiac conditions. Within DIGITIVA, support is offered to promote, track, and encourage healthy choices that may reduce the risk of, or help individuals to live well with, their cardiac conditions. DIGITIVA is not intended for diagnosis or treatment and does not replace a physician's judgement.

### Is DIGITIVA right for you?

Many people struggle to manage their health conditions or disease state. For example, it may be overwhelming to remember your health care team's advice about medications, food, or exercise. DIGITIVA offers a way to manage your health and connect with your care team.

DIGITIVA is not intended to alert you or your doctor to an emergency condition or substitute for your doctor's advice. If you feel ill, DO NOT use DIGITIVA to check your condition. Call your doctor immediately.

### DIGITIVA, your results, and your health care team

DIGITIVA creates a report that may be sent to your health care team. This allows your health care provider to view your data and gain insights into the challenges that you face between appointments. During your clinic visit, you can discuss your treatment plan.

### System Description

DIGITIVA is a mobile application for use by adults under the supervision of their health care provider. Patients use the mobile application on their mobile devices (Apple iOS or Android). Patients can record health data manually or by connected devices; receive coaching, education, and medication reminders. DIGITIVA shares data with the patient's health care team and can facilitate final review by the health care provider.

### Remote Monitoring Report

The Remote Monitoring Report helps your health care team keep track of and discuss your progress at office visits or between visits. This report includes relevant information entered into DIGITIVA such as:

- Symptom Tracker information
- Weight
- Blood pressure
- Heart rate
- Medication list
- Sleep or activity data
- Heart Health Recordings
- Heart Failure Status Review<sup>2</sup> and
- Engagement data

The Remote Monitoring Report is intended for the display of health data collected from connected medical devices and your input.

**IMPORTANT:** The Remote Monitoring Report is intended to supplement, not replace, medical expertise in the self-management of your heart failure or other cardiac condition. The report provides information that can be used to identify trends to inform treatment decisions. The Remote Monitoring Report is not intended for alarm notification nor is it intended to control any of the devices to which it is connected. The report is intended for physician use only and is not accessible to the patient.

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<sup>1</sup> The DIGITIVA Mobile Application may also be referred to as DIGITIVA throughout this Instructions for Use.

<sup>2</sup> This survey is based on the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) and adapted in DIGITIVA to collect your responses. Spertus JA, Jones PG. *Development and Validation of a Short Version of the Kansas City Cardiomyopathy Questionnaire*. Circ Cardiovasc Qual Outcomes. 2015 Sep;8(5):469-76. doi: 10.1161/CIRCOUTCOMES.115.001958. PMID: 26307129; PMCID: PMC4885562



### Clinical Review Team

The Clinical Review Team is a team of licensed healthcare providers that receives and reviews your Remote Monitoring Report on an intermittent basis. The Clinical Review Team will review this information, assess your progress over the prior 30 days, and organize it for your health care provider as they oversee your heart failure or other cardiac condition self-management.

The Remote Monitoring Report is sent automatically to the Clinical Review Team (and may be forwarded to your health care provider).

### Key Features

- Tracking of manually entered or synced health data (blood pressure, weight, food, medications, activity, sleep)
- Connection to digital stethoscope, blood pressure monitors, weight scales, and activity trackers
- Daily symptom tracker survey
- Coaching messages (blood pressure, weight, and symptoms)
- Medication reminders
- Education and resources (e.g., articles and videos)
- Reports for the Clinical Review Team (Remote Monitoring Report)

### Indications for Use

The DIGITIVA Mobile Application is software that is intended to guide heart failure patients in the self-management of heart failure, including heart failure with preserved ejection fraction (HFpEF) and heart failure with reduced ejection fraction (HFrEF), as well as patients with suspected cardiac diseases or conditions. The mobile application includes functions for the storage and electronic transfer of data collected from connected medical devices. The mobile application provides the patient with an interface to log medication and symptoms as well as provide relevant educational content tailored to a patient's entries.

The DIGITIVA Mobile Application does not diagnose or provide treatment for heart failure. The information presented by the DIGITIVA Mobile Application is only significant when considered in conjunction with health care provider assessment of all other patient data. The DIGITIVA Mobile Application is not a substitute for appropriate medical attention in the event of an emergency and should be used as directed by a physician.



**ATTENTION:** For medical questions, please contact your health care provider.



**ATTENTION:** If you are experiencing an emergency, please dial [911](#).

### Considerations for Use

DIGITIVA is designed for individual use and should not be shared with other individuals. To help prevent others from accessing your data or settings, always use a passcode or the biometrics (fingerprint or image of your face) to unlock your mobile device. Do not leave your mobile device in an area that can be accessed by others.

DIGITIVA is designed for individuals who are able and willing to maintain sufficient self-care skills and visit a health care provider regularly.

**NOTICE:** Users must create a PIN to access the application. Adding a PIN adds a layer of security and protection in the event of theft or loss of the smart phone and avoids unauthorized use which may result in disclosure of your health information.

**IMPORTANT:** Your mobile device's default settings for notifications and Bluetooth® may override any DIGITIVA settings. If the settings such as Bluetooth or notifications are disabled, DIGITIVA may not function as intended. For accurate data tracking and reminders, ensure your mobile device is set to the correct time.

PlatformCatalog Number

Mobile App for iOS

DIGI-001

Mobile App for Android

DIGI-002



Astellas Pharma US, Inc.

2375 Waterview Drive

Northbrook, IL 60062, USA

Patient Services: Ready to Answer Your Questions

Need help using DIGITIVA? Call us at [1-855-348-6069](tel:1-855-348-6069).

Available Monday to Friday 8:00 am – 7:00 pm (CST), except holidays

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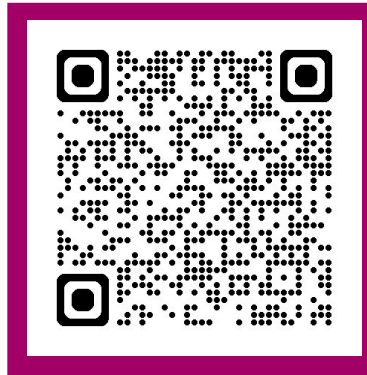


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## Download the DIGITIVA Mobile Application

If you haven't already downloaded the DIGITIVA Mobile Application, scan the QR code for your mobile platform below to download the app to get started.

### Scannable QR Code



*If you have an iPhone, use the App Store:*



1. Find the icon **App Store**
2. Launch the **App Store**.
3. Search for **DIGITIVA**
4. Select **GET** or **INSTALL** or picture of a cloud with a down arrow if it's been installed before.
5. Enter your Apple ID and password to complete the transaction.
  - a. If you do not have an existing Apple ID, go to our website at:  
[www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks) for a resource to help create an Apple ID.
6. Once the install is complete, you will see an icon for the DIGITIVA App.

*If you have an Android mobile phone, use the Google Play Store:*



1. Find the icon **Play Store**
2. Launch the **Play Store** application.
3. Search for **DIGITIVA**
4. Select **Install**.
5. Enter your Play Store ID and password to complete the transaction.
  - a. If you do not have an existing Play Store ID, go to our website at:  
[www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks) for a resource to help create a Play Store ID.
6. Once install is complete, you will see an icon for the DIGITIVA App.

If your download fails, please call Patient Services at [1-855-348-6069](tel:1-855-348-6069) for additional troubleshooting.



## Create Your Account

1. If you are new to DIGITIVA, tap **Get Started** to register
2. Enter your Program ID (find this ID on the front of the Quick Start Guide)
3. Answer the questions based on your health condition(s), as diagnosed by your health care provider<sup>3</sup>
4. Review and agree to Terms of Use and Privacy Policy
5. Enter your personal information
6. Enter your email address and phone number
  - a. Agree to communication consents
7. Create a password
8. Create your PIN

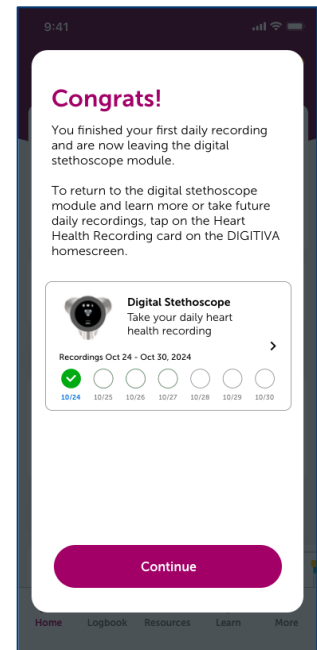
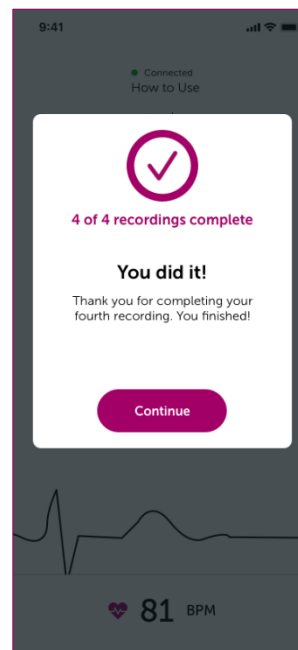
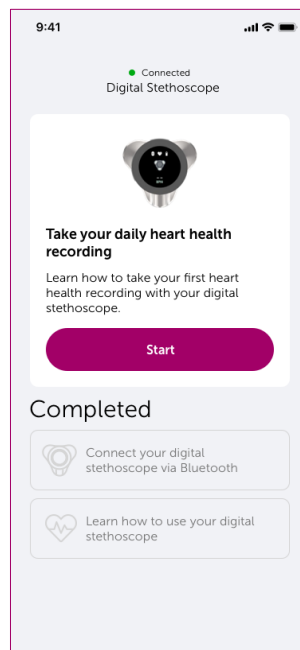
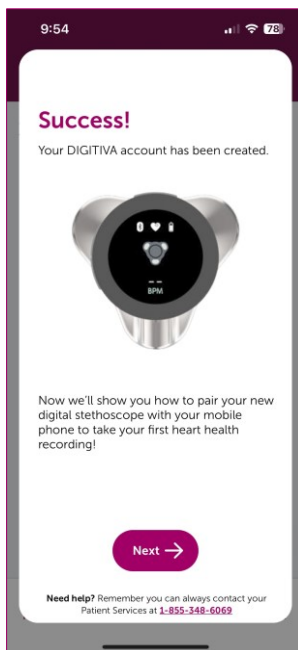
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<sup>3</sup> During registration process, you may be able to tap **Finish Later** to pick up where you left off.

## Onboarding the Digital Stethoscope

To start using DIGITIVA, tap **Next** to complete the prompts to connect your digital stethoscope device via Bluetooth.

1. Unbox and prepare your digital stethoscope device from the kit sent to you
2. Learn how to use your digital stethoscope in the DIGITIVA app (optional)
3. Ensure your phone's Bluetooth is on and tap **Start** to connect your device
4. Once your digital stethoscope device is connected, you are ready to start your recording of 4 locations on your chest, follow the prompts on your phone screen
5. After all 4 recordings are successfully recorded, tap **Continue** to see the Home screen



## Log In

1. Enter your Username/Email and Password
2. Tap **Log In**

Most of the time you will only need to enter your PIN or use Touch ID, Face ID, or Fingerprint (if enabled) to access the app. When you first access DIGITIVA from a new mobile device you will be asked to log in by entering your Username/Email and Password:

1. When re-installing DIGITIVA if you accidentally delete it
2. If you forget your PIN and need to create a new one

## Delete Your Account

Your account can be deleted at any time. Once an account has been submitted for deletion it is no longer recoverable and your account will be deactivated immediately. You will not be able to log in.

1. From the home screen, tap the **profile** icon at the top
2. Tap **Delete Account** at the bottom
3. Tap **Delete** button on the pop-up message
4. Tap **Delete** again to confirm deletion

Your data will be completely deleted and no longer visible to your care team within 7 business days.

## Getting Started

### Track Symptoms

The unique Symptom Tracker tracks user-reported heart failure symptoms of coughing, shortness of breath, swelling, sleep position, gasping at night, activity level, fatigue, and fluid pill (when applicable) on a 3-point scale. Each set of answers are color coded (green, orange, red) to represent the severity of the symptoms.

- **Green:** Good
- **Orange:** Fair
- **Red:** Poor

These symptoms and severity rankings are based on guidance from the American Heart Association. For more information, review the Self-Check Plan for Heart Failure Management found on our website at [www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks).

You can add and edit entries from both the Home screen and Logbook, but you will not be able to delete entries from DIGITIVA.

### Make Entries

Complete all of the questions based on how you are feeling at the time and update your answers if there's a change during the day. From the Home screen or Logbook,

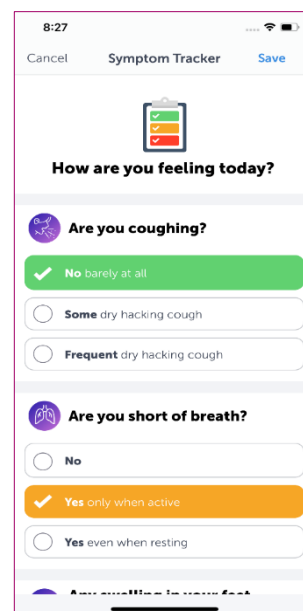
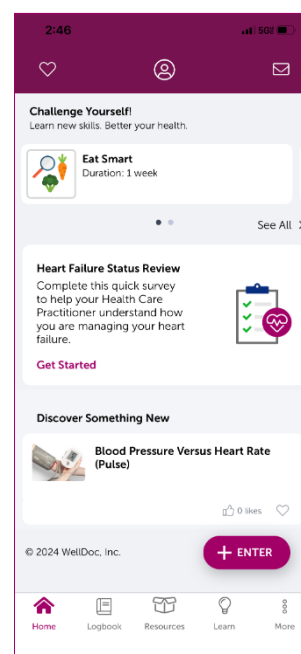
1. Tap **Track Symptoms** and answer according to how you feel.
2. Tap **Save** on the top right-hand corner.

You may receive a real-time feedback message based on your selections, which include information about keeping an eye on your symptom(s) or general education about managing your cardiac condition.

### Heart Failure Status Review

This survey is used to capture important information about your health and how heart failure may affect your life. There are no right or wrong answers; please mark the answer that best applies to you. These surveys will be sent to you at monthly intervals based on information you have entered in the app.

To access the survey, tap **Get Started** within the survey card on the Home screen. Complete the 12 questions in one sitting and submit it for review.

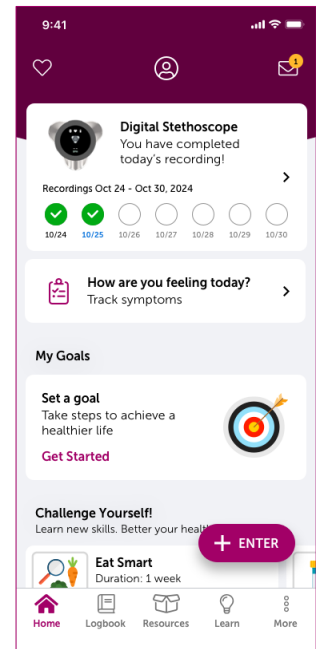



## Set a Goal

From the Home screen, fill in your baseline info and set a goal to achieve a healthier lifestyle. It is a good idea to discuss and confirm your goals with your health care provider. You can customize duration and frequency of your goal and create a reminder within DIGITIVA. Goals help you focus on the following topics:

- Blood pressure
- Healthy body weight
- Daily calories and macros

You can check your progress under **My Goals** on the Home screen or explore other goals in the **Resources** menu.

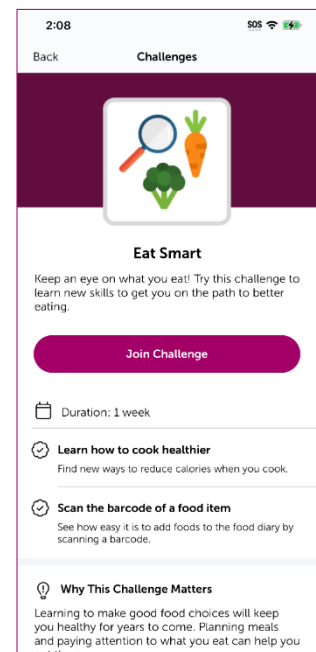


## Challenge Yourself!

You are invited to join a challenge, lasting only a week. Once you commit, your Home screen will display your current challenge progress. You can set challenges such as eating smart and managing your medications. To complete a challenge, you must do all three tasks that are listed for that challenge.

You can only select one challenge at a time, but you can stop any time.

- Under **Challenge Yourself!** on the Home screen, scroll through, and tap on ones that you like to try. Explore more challenges by selecting **See All** or go to the **Resources** menu.
- Tap **Join Challenge** when you find one.
- After you choose your challenge, you can access your challenge and view your days left in the challenge on the **Home** screen.
- Once you have completed the challenge, badge(s) will appear in the Challenge History at the bottom of that challenge. You may repeat challenges as often as you wish.



## Setting Up Your Medication List

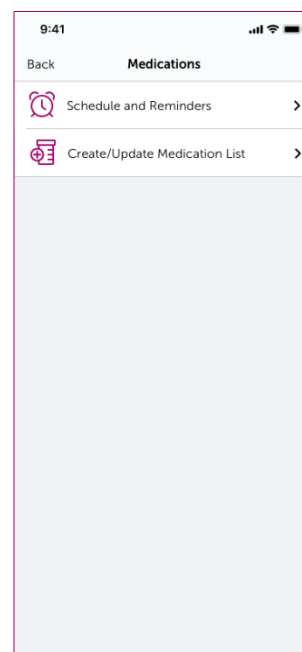
Your Medication List helps you keep a record of your medications and how many times you take them daily. It is important to record all medications you are taking—prescription, over-the-counter, supplements, and vitamins. DIGITIVA will give you reminders about your medications.

**NOTICE:** Confirm your prescription information with your health care provider and continue to take your medications as prescribed.

**NOTICE:** If there are incorrect or missing medications on your medication list, the User should review the “Add Medication” or “Edit Medication” sections below for additional assistance. If you have issues correcting your medication list, please call the Patient Services at [1-855-348-6069](tel:1-855-348-6069).

### Add Medication

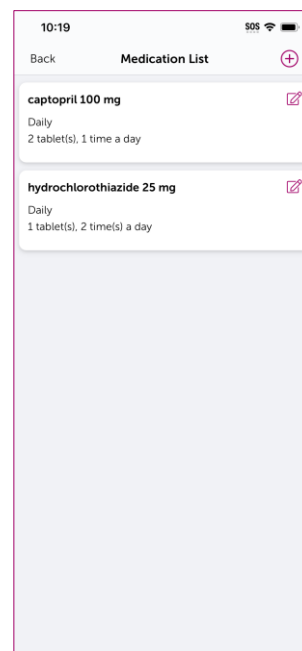
1. From the Home screen, tap the **More** menu and then tap **Medications**.
2. Tap **Create/Update Medication List** and then tap the **Add Medication** button.
3. Enter at least the first 3 letters of the medication name and tap **Search**.
4. Choose the medication name and strength you want to add.
5. Select how often you take the medication.
6. Enter the time and the amount you take and tap **Save**.



## Edit Medication

Any medication information that you have entered can be edited. You can edit your dose, how often you take your medication, or delete the medication from your list.

- Tap the pencil icon next to the medication name.
- Edit how often you take your medication, the amount you take, or the medication strength.
- To delete the medication from your list, tap **Delete this medication**.



## Medication Schedule

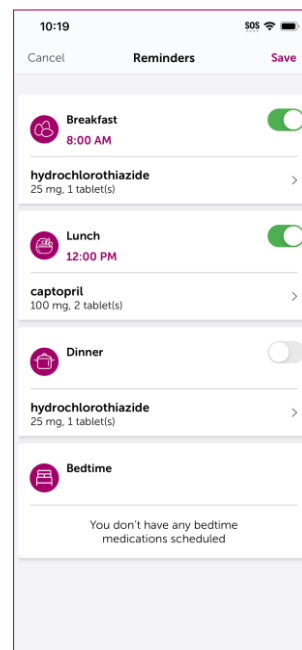
Your medications are scheduled for Breakfast, Lunch, Dinner, Bedtime, or As Needed based on how many times a day you take them.

### Change Your Medication Schedule

1. Select **Schedule & Reminders** from the Medications menu.
2. Tap on the medication you would like to change.
3. Select when you take your medication.

### Set Medication Reminders

1. Select **Schedule & Reminders** from the Medications menu.
2. Tap the slider next to the meal to turn on a reminder.
3. Select the time to adjust your reminder time and tap **Done**.
4. Tap **Save**.



## Managing Connections & Devices

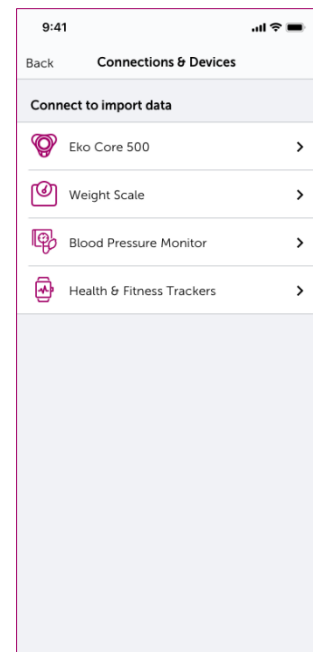
In Connections & Devices, you can customize your DIGITIVA experience with other devices that connect through Bluetooth such as a weight scale, blood pressure monitor, or health and fitness trackers. Tap the **More** menu on the home screen and then tap **Connections & Devices** to do the following:

- Connect your Digital Stethoscope
- Connect Bluetooth Devices

Please visit your device manufacturer's user guide for troubleshooting help.



**ATTENTION:** This document and your Quick Start Guide provide instruction for connecting Bluetooth devices, entry instructions for BP monitoring, exercise, activity, food, weight, and logbook, etc. For any questions or concerns contact Patient Services.



### Considerations for Bluetooth Devices



**ATTENTION:** Make sure you know which Bluetooth device you are connecting with your mobile device.



**ATTENTION:** To ensure that data from your devices (e.g., digital stethoscope, blood pressure monitor) are sent wirelessly to DIGITIVA, you must first connect your device and DIGITIVA.



**CAUTION:** Make sure to NOT use the device while the device is charging.



**CAUTION:** The digital stethoscope should also not be operated near any electronics that can cause the device to lose primary functionality.

**IMPORTANT:** Bluetooth connected devices, such as digital stethoscope, weight scales, blood pressure monitors, and health and fitness trackers, send data to your smart device. To prevent other people's data from being sent to your smart device, do not let anyone else use your connected devices.

**IMPORTANT:** Bluetooth performance varies due to differences in phone hardware and operating systems. DIGITIVA is not recommended for use on Jailbroken or Rooted devices.

**IMPORTANT:** To ensure a secure connection, connect your Bluetooth device with your smart device in a secure area with limited Bluetooth devices in range.

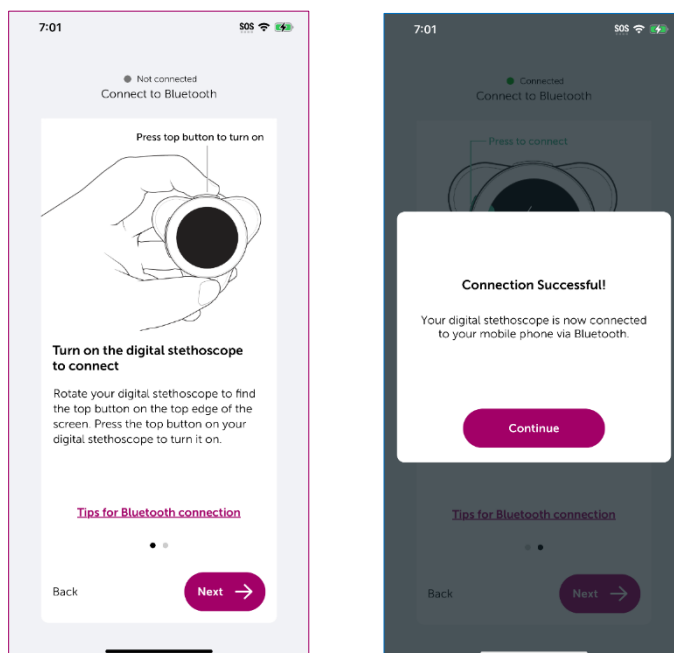


**ATTENTION:** If there are erroneous synced devices, contact Patient Services to assist in deleting the incorrectly synced devices.

## Connect Your Digital Stethoscope

Connecting your digital stethoscope from your mobile device will allow you to wirelessly send your heart health recordings to DIGITIVA via Bluetooth. To connect your Digital Stethoscope after onboarding, turn on Bluetooth on your device, go to **Connections & Devices** and **Eko**. Tap **Start** and follow the prompts.

1. Ensure Bluetooth is turned on and connect your digital stethoscope with your mobile device.
  - a. Check if your device is supported on the Eko Help Center website which may be found at [www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks).
2. Once the connection is successful, go to the Home screen to learn how to use your digital stethoscope and complete your daily recording.
3. **NOTE:** When you are in the Eko CORE 500 screen, look for the “Connected” and online symbol (green dot) at the top of the screen.
  - a. If it shows “Not Connected”, follow the tips for Bluetooth connection on screen.
  - b. If you need additional help, contact the Patient Services at [1-855-348-6069](tel:1-855-348-6069).



## Connect Your Weight Scale

Connecting your weight scale from your mobile device will allow you to wirelessly send your weight readings to DIGITIVA via Bluetooth instead of entering them manually. To connect your weight scale, turn on Bluetooth on your device, go to **Connections & Devices** and **Weight Scale**. Tap **Connect New Scale**, select one of the following weight scales, and follow the prompts.

- A&D (UC-352BLE)
- ChoiceMMed (iChoice S1)
- Pyle Health (PHLSCBT4)
- Welch Allyn® Home™ (RPM-Scale100)

### Sync Your Data

There are three ways to sync your data. You must have Bluetooth turned on to sync.

#### Automatic Sync

1. Turn on your weight scale.
2. Open DIGITIVA.
3. View data being synced automatically from the Home Screen, Logbook, and Weight entry screen.
4. View your synced data in the Logbook.

#### Manual Sync

1. Turn on your weight scale.
2. Open DIGITIVA.
3. Go to the Weight new entry screen.
4. Tap on **Sync with scale** link.

OR

1. Turn on your weight scale.
2. Within the app, go to the Home screen or Weight entry screen.
3. Pull down to sync your data.
4. View your synced data in the Logbook.

## Connect Your Blood Pressure Monitor

Connecting your blood pressure monitor from your mobile device will allow you to wirelessly send your blood pressure readings to DIGITIVA via Bluetooth instead of entering them manually. To connect your monitor, turn on Bluetooth on your device, go to **Connections & Devices** and **Blood Pressure Monitor**. Tap **Connect New Monitor**, select one of the following monitors, and follow the prompts.

- Omron® Evolv™ (BP7000)
- Omron® (HEM-9200T)
- Welch Allyn® (RPM-BP100)
- A&D (UA-651BLE)
- Pyle Health (PHBPB20)
- Omron® 5 Series® (BP7250)
- CVS Health™ Series 800 Blood Pressure Monitor
- Welch Allyn: RPM-BP100/H-BP100SBP
- Omron® 7 Series® (BP7350)

## Sync Your Data

There are three ways to sync your data. You must have Bluetooth turned on to sync.

### Automatic Sync

1. Turn on your monitor.
2. Open DIGITIVA.
3. View data being synced automatically from the Home screen, Logbook, and Blood Pressure entry screen.
4. View your synced data in the Logbook.

### Manual Sync

1. Turn on your monitor.
2. Open DIGITIVA.
3. Go to the Blood Pressure new entry screen.
4. Tap on **Sync with monitor** link.

OR

1. Turn on your monitor.
2. Within the app, go to the home screen or Blood Pressure entry screen.
3. Pull down to sync your data.
4. View your synced data in the Logbook.

## Connect Your Health & Fitness Trackers and Devices

If you have an activity tracker such as Fitbit®, Garmin®, Polar®, or Withings; or the Apple Health (iOS devices) or Health Connect (Android devices) app; you can connect it to sync your data.

### Connect Your Activity Tracker

1. Go to **Connections & Devices** and tap **Health and Fitness Trackers**.
2. Select the activity tracker\* to connect.
3. Log in using your Fitbit®, Garmin®, Polar®, or Withings username and password.

The first time you connect an activity tracker, DIGITIVA syncs the last 30 days of lifestyle data including exercise, steps, sleep, height, and weight. After connecting, each time you use or add information to your activity tracker, the information is automatically updated in DIGITIVA.

### Connect to Apple Health or Health Connect

1. Go to **Connections & Devices** and tap **Health and Fitness Trackers**.
2. Select Apple Health or Health Connect.

If you connect to Apple Health, DIGITIVA syncs the last 30 days of blood pressure and lifestyle data including exercise, steps, sleep, weight, and the last 5 years of lab results.\*\* If you connect to Health Connect, DIGITIVA syncs the last 30 days of lifestyle data including exercise, steps, sleep, and weight. After connecting, data will be synced from Apple Health or Health Connect each time you launch DIGITIVA.

*\*The data provided by these monitors are intended to be a close estimation of your activity and metrics but may not be precisely accurate. The data are not intended to treat, cure, or prevent any disease.*

*\*\*This only applies if the user has connected their Apple Health to their Electronic Health Record.*

### View Your Lifestyle Data

1. Go to the Logbook to view all your synced data. The source of your synced data will be indicated with your activity tracker's icon.
2. You cannot change your activity tracker information displayed in DIGITIVA. If you want to change or delete your data, go to your activity tracker application. Your data will re-sync after editing the data within the activity trackers application.
3. If you would like to disconnect your activity tracker, simply select **Disconnect**.

## Settings

To access the Settings menu, tap the **More** menu from the Home screen and then tap **Settings**. You can do the following from the Settings menu:

- Set a reminder for your goals.
- Change your PIN.

## Making Entries

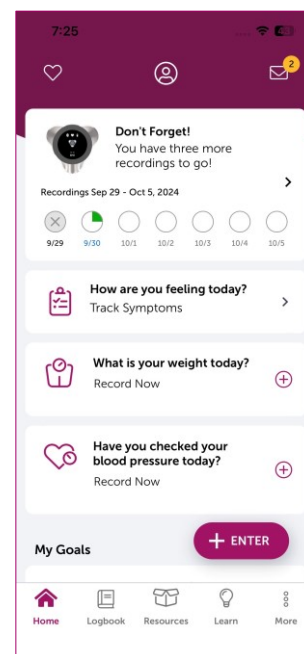
### Home Screen

The Home screen is personalized based on the information you enter. It helps you understand what to do and when.

- Learn how to use your digital stethoscope and take your daily heart health recording.
- Track your symptoms daily.
- Set a goal and review your progress.
- Quickly add your data through specific prompts per your treatment plan.

At the top of the Home screen, you can access favorites, profile information, and messages.

Use the menu along the bottom of the home screen to navigate to other parts of DIGITIVA by tapping on **Logbook**, **Resources**, **Learn**, and **More**.



### Digital Stethoscope (Record and Review Tips)

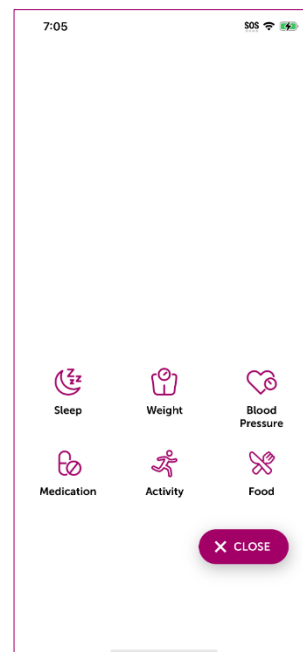
From the top of your Home screen, you can easily see your week's progress on taking your daily heart health recordings. You can also review tips for using your digital stethoscope. You can record 4 recordings once a day. If all 4 recordings were completed for that day, a checkmark within a filled green circle will appear.

1. Tap on the **Digital Stethoscope** at the top of your home screen.
2. Ensure your phone's Bluetooth is on and your digital stethoscope is connected by turning it on.  
**NOTE:** When you are in the Digital Stethoscope screen, look for the "Connected" and online symbol (green dot) at the top of the screen.
3. Tap **Record** to start your recording of 4 locations on your chest, follow the prompts on your screen.
  - a. During the recording process, you will be reminded within 30 minutes before midnight to complete all the recordings for that day.
4. Tap **Continue** to return to the home screen.

If you are unable to finish all 4 recordings in one sitting, tap "I can't finish now" and the recordings you have completed will be saved as partial (e.g. indicated as incomplete circles on your week's progress). Remember to tap on the **Digital Stethoscope** on the home screen and complete the rest of your recording(s) for that day.

### Home Screen: Make Entries

Quickly make entries from the home screen using the **+ ENTER** button. You can view the information you entered in your Logbook.

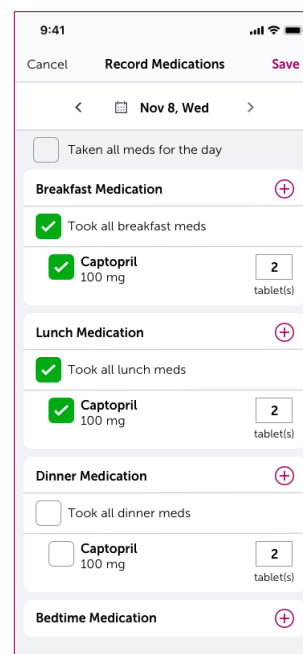


### Record Medications

Your medications are displayed for a day according to your schedule (by Meal or Time of the Day). Tap the **Medication** icon to record your medications.

- You can record one or all of your medications by meal or time of day.
- Tap to check you have taken all your medications for the day, by meal or time of day.
- You can also tap one medication at a time.

You have the flexibility to add a dose of a medication from your list or record a one-time dose of a medication that is not on your list.



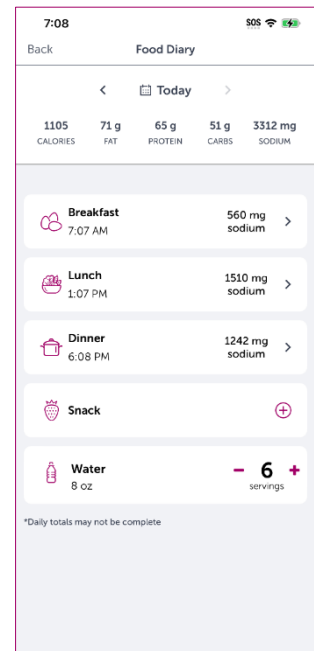
## Add Food

The Food Diary provides an easy way to track your food.

- Tap the **Food** icon to open the Food Diary.
- Tap + next to the appropriate meal (Breakfast, Lunch, Dinner, or Snack).

There are multiple ways to record food.

- To add a food item, you can search, take a photo, scan a food barcode, or add a custom food.
  - After choosing a food item, select the serving size and then **Add Food** to your meal.
  - After entering all foods for your meal, select **Done**.
  - To save multiple food items as a meal, tap the Star icon.
- To just add a photo of your food, select **Photo**, take photo, and then **Save Photo Only**.
- Edit the time of your meal or snack, as needed.



### Add Activity

- Tap the **Activity** icon to log your exercise.
- Select an activity, such as walking or gardening.
- Enter the amount of time you exercised (duration).

### Add Blood Pressure

- Tap the **Blood Pressure** icon to log your blood pressure.
- Enter your systolic and diastolic blood pressure readings and your pulse.
- Add notes related to your blood pressure reading.

### Add Weight

- Tap the **Weight** icon to log your weight.
- Enter your current weight.

### Add Sleep

- Tap the **Sleep** icon to log or edit your sleep.
- Enter your bedtime and wake time to calculate sleep duration.
- Use the sleep slider\* to rate your sleep.
- Add comments in the Notes section about your sleep.
- Connect your activity tracker to sync your sleep data.

*\*The sleep rating is for the previous night's sleep only. Users are able to track sleep for previous days.*

## Sleep Support

DIGITIVA provides multiple ways to help support better sleeping habits by recording your sleep hours and ratings, learning about the importance of sleep, and receiving feedback from your entries.

- Logbook – Track your sleep daily.
- Real-time feedback – Receive feedback on your sleep entries.
- Weekly Report – Review your sleep summary and insights.

From the Home screen, you can access survey and action plans when they are active. You may use the **+ ENTER** button or **Logbook** to record your sleep.

## Logbook

The Logbook displays all your entries. To view your Logbook, select **Logbook** on the Home screen. You can add, change, or delete entries from the Logbook.

### Make Entries

1. Tap an entry type.
  - Symptoms
  - Blood Pressure
  - Weight
  - Food
  - Medications
  - Sleep
  - Activity
2. Tap the entry date to change from current date and time.

### Change Entries

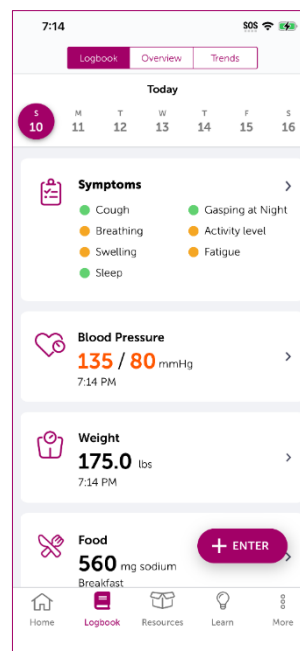
1. Select the day you made the entry.
2. Tap on the entry you want to change.
3. Edit the information.
4. Tap **Save**.

### Delete Entries

1. Select the day you made the entry.
2. Select the entry you want to delete.
3. Swipe left and tap **Delete**.



**ATTENTION:** For Android, press on the Logbook entry until you see a message confirming you want to delete the entry.



## Health Information

Health Information is where you can view and/or update your Medical History, Clinical Results, Preventive Health, and Lifestyle information. From the Home screen, tap the **More** menu and then tap **Health Information**. You need to be connected to the Internet to access Health Information and to add new entries to it.

The Health Information menu includes:

- Clinical Results — Enter your blood pressure readings and lab values.
- Preventive Health — Enter the date of your exams (eye and dental), immunizations, and screenings.
- Medical History — Enter your history of cardiovascular disease and other medical conditions.
- Lifestyle — Add your height and weight. Your body mass index (BMI) will be automatically calculated. You can also enter information about your smoking assessment.

## Remote Monitoring Report Visualizations

The following screens shown on the next pages are only a visual representation of how your data is displayed in the Remote Monitoring Report.

## Sample Remote Monitoring Report (page 1)



Report Sent: Dec 2, 2023

Name: Brahms, Johanne

DOB: Apr 23, 1972

ID: 123465

Gender: Male

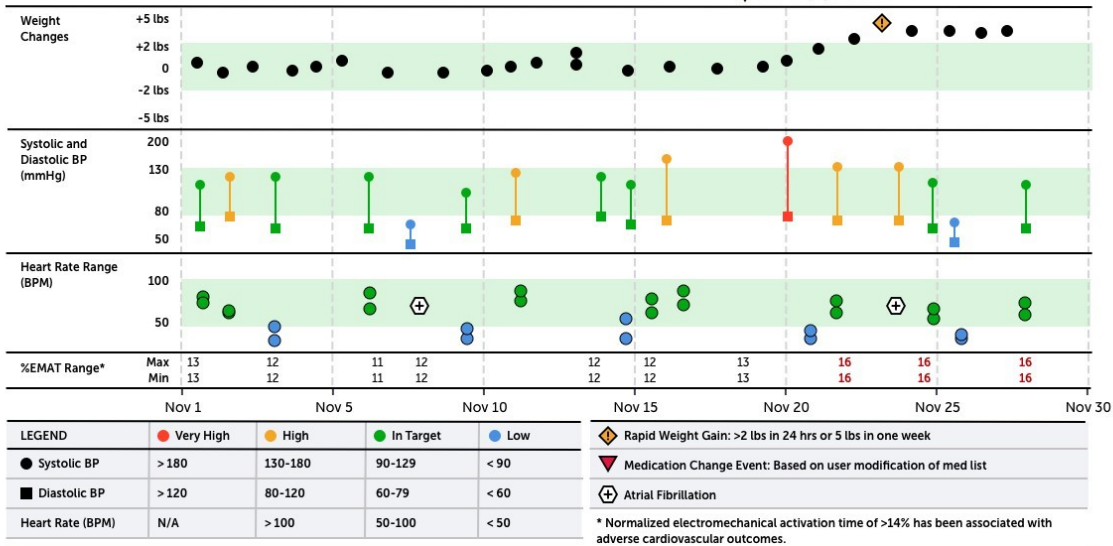
Age: 53

## Astellas Intermediary Review

|                       |                                                                                   |                                                                                   |                                                                                   |                                                                                   |                                                                                   |                                                                                   |                                                                                   |                                                                                   |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Phonocardiogram       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Normal                |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| S3 Suspected          |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| S4 Suspected          |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Weight Increase       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Blood Pressure        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Heart Rate            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| EMAT>13.8             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| New Detection of Afib |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

## 30-Day Summary

See next page for details



## 30 Day Symptom Tracker



Signature:

Review Date:

Note that this report contains a combination of automated and self-reported data

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## Sample Remote Monitoring Report (page 2)



Report Sent: Dec 2, 2023

Name: **Brahms, Johanne** DOB: **Apr 23, 1972** ID: **123465**  
Gender: **Male** Age: **53**

## Cardiometabolic Medications as of May 21, 2024

**Farxiga 10 mg** 1 tablet(s), 1 time a day  
**Entresto 97-103 mg** 1 tablet(s), 2 time a day  
**metoprolol succinate 100 mg** 1 tablet(s), 1 time a day  
**spironolactone 50 mg** 1 tablet(s) As Needed

## Medication Change Event: Based on user modification of med list

▼ May 21, 2024

Added: Farxiga, spironolactone, metoprolol succinate, Entresto

## Kansas City Cardiomyopathy Questionnaire Summary

| Scoring*             | 3/20/23 (Baseline) | 9/19/23 | 1/21/24 |
|----------------------|--------------------|---------|---------|
| Total Score          | 76                 | 72      | 62      |
| Physical Limitations | 59                 | 60      | 45      |
| Social Limitations   | 85                 | 82      | 52      |
| Symptom Frequency    | 72                 | 69      | 45      |
| Quality of Life      | 81                 | 83      | 68      |

\*All scores are scaled to 100%. Higher scores indicate better health.

| Very Poor to Poor | Poor to Fair | Fair to Good | Good to Excellent |
|-------------------|--------------|--------------|-------------------|
| 0-24              | 25-49        | 50-74        | 75-100            |

## DIGITIVA 30 Day Engagement Data

| Total Engagement | 219 | Connected Devices (4) |
|------------------|-----|-----------------------|
| Activity         | 19  | Eko Core 500          |
| Sleep            | 9   | Omron 6200 BP Monitor |
| Medication       | 19  | Korescale Gen 2 Scale |
| Blood Pressure   | 17  | Fitbit Charge 4       |
| Weight           | 26  |                       |
| Eko Recordings   | 18  |                       |
| Food             | 47  |                       |
| Education        | 29  |                       |

This report was prepared based on your patient's self-reported health data, in addition to information collected through a cardiac medical device. The patient may also have connected other health monitoring tools. This report is not intended to be a substitute for a physician's judgment nor should it be the sole basis of any decision to start, stop, or modify treatment.

Signature:

Review Date:

Note that this report contains a combination of automated and self-reported data

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## Getting Feedback

### Real-Time Guidance

DIGITIVA supports you with instant feedback about specific symptoms, weight, and blood pressure that are entered in real time and associated with heart failure or another cardiac disease or condition. Any of the entries that are entered within 2 hours of actually checking it are considered “real-time”.

These messages provide:

- Information on nutrition and activity
- Education about heart health, blood pressure, and self-monitoring techniques
- Motivation and inspiration

These messages are for educational purposes. Real-time feedback messages are based on content from the American Heart Association (AHA). For more information, please visit the AHA website which can be found on our website at [www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks).

## Messages

You may receive personalized messages from DIGITIVA regarding weekly reports.

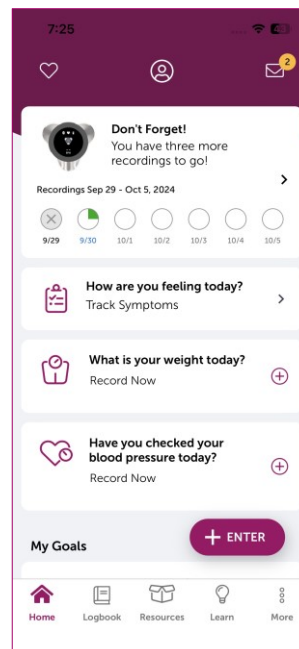
### View Your Messages

Tap the **Messages** icon on the top right corner from the Home screen.

The number displayed in the orange circle shows you how many unread messages are in your inbox.

Your unread messages are displayed first. To see all your messages and choose an individual category, tap **Show** in the top right corner.

**NOTE:** This messaging system is a read-only system. You cannot send or forward messages from it.



## Weekly Reports

Weekly Reports show you how you are doing in a 1-week period. They help you understand how your lifestyle affects your symptoms and what changes may help further improve symptoms.

The Weekly Report has two parts:

- Weekly Summary
- Insights

You will receive a message each week to let you know your Weekly Report is ready for you.

The Weekly Summary shows the entries you have made in a week for:

- Daily Heart Health (digital stethoscope recordings)
- Symptoms
- Weight
- Blood pressure
- Heart rate
- Food
- Medications
- Sleep

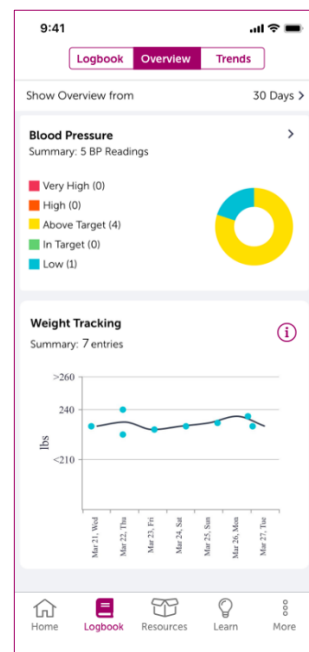
Insights are displayed for sleep and help you understand your data and how to make improvements. Insights in DIGITIVA align with guidelines from the American Heart Association.

## Logbook: Overview and Trends

The Logbook is an overview of your data. You can also view summary information about your blood pressure and weight entries.

To view your Logbook, tap **Logbook** on the home screen.

- To view an overview of your blood pressure and/or weight readings, tap **Overview** in the header.
- To see your blood pressure or weight trends, tap **Trends** in the header.



## Resources

DIGITIVA offers several resources to assist you in learning more about your heart failure.

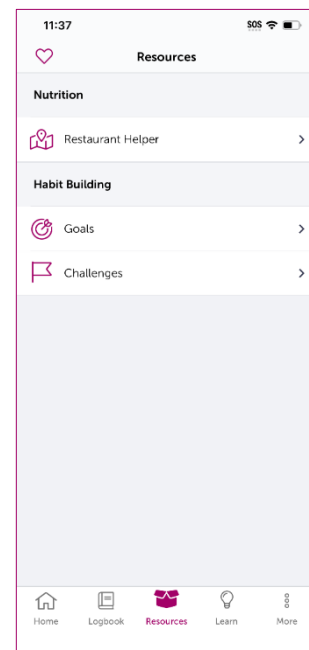
To access Resources, tap **Resources** on the Home screen.

### Nutrition

- Restaurant Helper – Find nearby restaurants based on your location or by zip code.

### Habit Building

- Goals – Set goals to build healthy habits.
- Challenges – Helps you learn easy skills to be healthier.



## Restaurant Helper

Restaurant Helper helps you find nearby restaurants based on your location or by zip code.

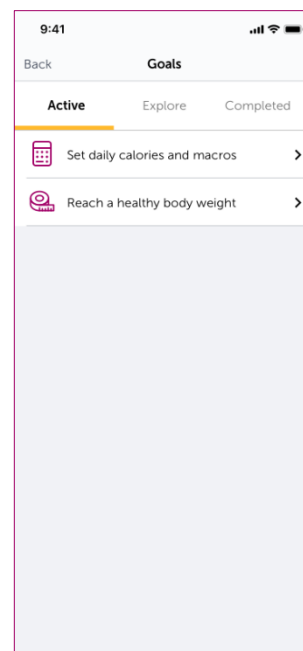
- From the home screen, tap **Restaurant Helper**.
- A list of restaurants will be displayed based on your current location. Tap **Only with Menu** to view restaurants with menus.
- Select a restaurant.
- Every restaurant on the list will have a phone number, website, and ability for you to get directions.

Restaurants that have a menu icon display a list of the menu items with sodium, calories, and serving size. You can add menu items directly to your Food Diary.

## Goals

Guided support messages are offered when you work on your goals. You can create a new goal at any time.

- Tap **Goals** under Habit Building.
- View your Active and Completed Goals.
- Explore new goals that you may want to set.



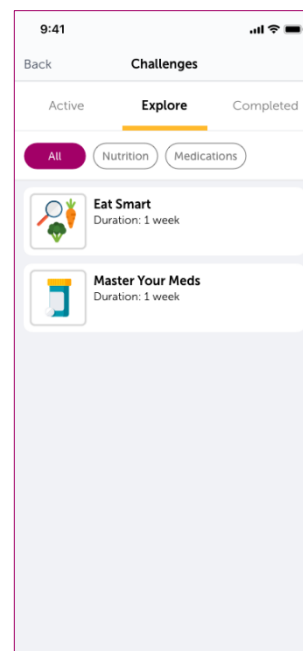
## Challenges

Challenges assist you to create healthy habits based on condition(s). You can only join one Challenge at a time.

- Tap **Challenges** under Habit Building.
- View your Active and Completed Challenges.
- Explore new challenges that you may want to join using the filters.

Categories of challenges include the following:

- Nutrition
- Medications



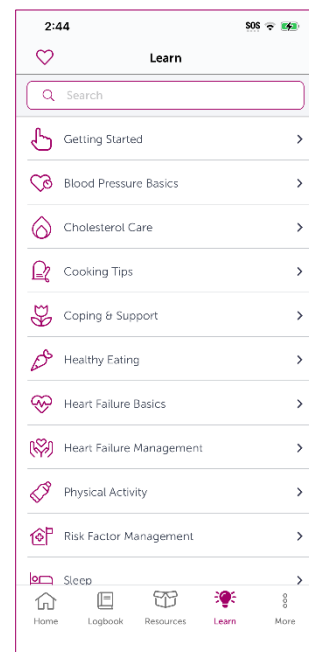
## Learn

DIGITIVA offers tailored education to help you learn about your heart health. All of this educational information is sourced content from the American Heart Association (AHA). For more information, please visit our website at [www.digitiva.com/resources/usefullinks](http://www.digitiva.com/resources/usefullinks) to access more information about the AHA.

To access the Learn section, tap **Learn** on the Home screen and select the category that you want to explore or search for a specific topic by entering at least the first 3 letters in the search bar. Tap the **Heart** icon to add lessons, videos, and articles that you like to My Favorites.

Find resources, such as:

- Tailored heart failure courses and lessons
- Educational videos
- Articles





## Outside of App Communication

When you are not using DIGITIVA, you can stay connected on your mobile device in the following ways:

### Notifications

- Receive notifications when you have a message from DIGITIVA, a scheduled reminder for medication or weight tracking, and to introduce DIGITIVA features.
- Enable or disable notifications in your device's settings.

### Text Messages

- Receive engagement-based text messages from DIGITIVA.
- Reply "STOP" to discontinue the text messages.

## Help

DIGITIVA offers several help topics to assist you.

To access Help Topics:

- Tap the **More** menu on the Home screen.
- Tap **Help**.

Help Topics include:

- Frequently Asked Questions
- Instructions for Use
- Contact Us — Patient Services

## Security & Technology

To ensure security, it is recommended that mobile users keep the OS (Operating System) up-to-date and not install DIGITIVA on Jailbroken or Rooted devices.

Minimum OS Versions:

- iOS operating system: 15
- Android operating system: 11

Verified against OS Versions:

- iOS operating system: 15 and above
- Android operating system: 11 and above

Devices that do not meet the above criteria are not compatible with DIGITIVA.

The DIGITIVA Mobile Application requires internet connectivity to sync data with the application (database). The mode of connectivity can be Wi-Fi or cellular. If you attempt to use a feature that requires internet connectivity while offline, you will be informed that internet connectivity is required. Some functions are still available while offline, such as:

- Access DIGITIVA via PIN or face/fingerprint recognition
- Connect/sync Bluetooth devices
- Manually enter data and receive real-time feedback
- Access Help

**IMPORTANT:** Your smart device must have enough memory storage (at least 120 MB) or DIGITIVA will not be able to be installed. You may need to delete files or apps from your smart device.

## Appendix A: Icons and Symbols Glossary

| Symbol/Icon                                                                         | Title               | Definition/Action                                                                  |
|-------------------------------------------------------------------------------------|---------------------|------------------------------------------------------------------------------------|
| <b>A</b>                                                                            |                     |                                                                                    |
|    | Activity            | Record physical activity                                                           |
|    | App Store           | Where to download iOS version of DIGITIVA                                          |
|    | Attention           | Alerts the user to a risk of possible misuse or important information for DIGITIVA |
| <b>B</b>                                                                            |                     |                                                                                    |
|    | Blood Pressure (BP) | Record BP                                                                          |
| <b>C</b>                                                                            |                     |                                                                                    |
|    | Caution             | Important safety information                                                       |
| <b>E</b>                                                                            |                     |                                                                                    |
|    | Edit                | Make edits to a field or entry                                                     |
|  | Eko CORE 500™       | Eko CORE 500™ Digital Stethoscope                                                  |
| <b>F</b>                                                                            |                     |                                                                                    |
|  | Food                | Record food                                                                        |
| <b>M</b>                                                                            |                     |                                                                                    |
|  | Medication(s)       | Record medication(s)                                                               |
|  | Messages            | View messages in your inbox                                                        |
| <b>P</b>                                                                            |                     |                                                                                    |
|  | Play Store          | Where to download Android version of DIGITIVA                                      |
| <b>S</b>                                                                            |                     |                                                                                    |
|  | Sleep               | Record sleep (rating for sleep)                                                    |
| <b>W</b>                                                                            |                     |                                                                                    |
|  | Weight              | Record weight                                                                      |