

Wearables: Apple Watch For Providers



Specific AIMS

1. Evaluate feasibility of collecting physiologic and activity data from pediatric patients with severe heart failure and VADs using a smart watch application.
2. Describe physiologic and activity data of pediatric heart failure and VAD patients as measured by an Apple Watch.

Inclusion Criteria

Patients between ≥ 12 –19 years old (may be younger if developmentally appropriate at the discretion of the co-investigator) and not in the ICU:

1. With acute decompensated heart failure and enrolled in ADHF ACTION study
2. Supported with ventricular assist device and enrolled in ACTION VAD registry

ACTION DEFINITIONS

Heart failure: *A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection. Cardinal symptoms include breathing difficulty, feeding intolerance, or other symptoms leading to decreased activity.*

Acute decompensated heart failure: *Heart failure severe enough to warrant hospitalization.*

Measures

Initial cohort will be followed for 3 months.

Apple Watch app will collect: Steps covered, distance walked/ran, resting energy burned, number of times fallen, active energy burned, exercise time, stand hours, resting heart rate (HR), walking HR average, HR variability, time in bed, time asleep, respiratory rate while asleep, number and duration of patient-initiated 'Workouts' on the watch.

Prompt patient to perform the following tasks:

- ECG reading once/week
- 6-minute walk test once/month
- Patient entered weight (in lbs or kg) every other day

To correlate with characteristic and event data from:

- ACTION ADHF project forms
- (or)*
- ACTION VAD registry forms

Site Level Enrollment

Pilot sites will receive a batch of 10 watches and wrist bands (5 regular size/ 5 small size)

- Sites can request more watches and/or wrist bands from **ACTION** if needed, by emailing: info@actionlearningnetwork.org

ACTION will keep track of the watches distributed to the sites including:

- Site Name
- Number of Watches
- Address of Site
- Date Shipped
- Date Received
- Watch Serial Numbers

Each site will obtain the ACTION QI ID by enrolling the patient into the Heart Failure (HF) Registry

TIP

Pair Apple Watch(es) with an investigator iPhone ahead of time so the watch OS can be updated. This process takes approximately two hours. Next, unpair the watch from the iPhone. Then, you will have watches available for study patients, making the enrollment process much faster.

Wearables Enrollment and Installation Guide

1. Charge watch FULLY

2. Note serial number (on box) to be entered into Redcap

3. Fill out REDCap and fill in obtained ACTION ID below:

1. Open Heart Failure Registry within REDCap
2. Check to see if patient is already enrolled in the Registry
If yes, » find the patient and open the entry form
If no, » start a new patient record and open the entry form
3. Complete the form, including the Apple Watch section under 'ACTION Studies'
4. Note ACTION ID: _____ - _____ - _____

** If patient is a VAD patient, please still fill out the initial HF form to obtain the ACTION ID. All data will be subsequently entered into Simplified Clinical. Please keep Simplified Clinical up to date. You will receive a prompt at three months (the end of the Apple Watch study).*

Is the patient being enrolled into the Apple Watch Project? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Was the patient consented for ACTION? <small>(Required for Apple Watch, not for Hospitalization Data or Outpatient Medication Titration)</small> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Confirm that the patient was consented for ACTION:	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Date when Apple Watch project began: <small>(Apple Watch given to patient)</small> <small>* must provide value</small>	<input type="text"/> MMDDYYYY	Today M-D-Y
Serial Number on Apple Watch: <small>* must provide value</small>	<input type="text"/>	
Mid-upper Arm Circumference:	<input type="text"/> cm	
Hand Grip Strength:	<input type="text"/> kg	

Enter mid-upper arm circumference and hand grip strength if able, this is **optional**.

4. Indicate if patient will use their own iPhone, or a parent's/caregiver's iPhone below:

Note: Provide corresponding documentation

Check one: Patient's Parent's/Caregiver's

5. Select patient's proper wristband size below:

Check one: Small Wristband Regular Wristband


6. Pair Apple watch

1. Leave watch on charger to initiate setup
2. Turn it on by pressing and holding the side button
3. On iPhone search for 'Apple Watch' application and open.
4. Click 'Pair New Watch'
5. Click 'Set Up for Myself' *(even if using parent's iPhone)*
6. Application should bring up a window to scan Apple Watch face to initialize pairing process
7. Tap 'Set up Apple Watch' then follow the instructions on iPhone and Apple Watch to finish setup. Initial setup will require update of Apple Watch OS will take approximately two hours to complete *(if not previously updated as above)*. If unable to update Watch OS, please contact [ACTION](#) to troubleshoot.


Trouble shooting options:

- Try completing on a different WIFI network if available.
- If unable to pair in the care site/hospital, provider should pair watch with a personal phone outside care site/hospital so the watch OS can be updated. Once updated, unpair and bring back updated watch to pair with patient.

7. For Patients pairing Apple Watch with their Parents/Caregivers iPhone (ONLY)

1. Navigate to the 'Apple Watch application' on the parent's/caregiver's iPhone 
2. Select appropriate Apple Watch assigned to patient
3. Tap 'Notifications'
4. Scroll to applications labeled 'Messages' and 'Phone'
5. Tap 'Custom' followed by 'Notifications Off'
Note: This step can be repeated for any additional applications that the parent may have notifications enabled for.
6. Scroll to section labeled 'Mirror iPhone Alerts From:'
7. Turn off all mirrored alerts

8. Install "My ACTION Tracker" App on Apple Watch

1. To download 'My ACTION Tracker' from the App Store, **Scan QR Code**
2. Open 'My ACTION Tracker' application
3. Input password: 45299 (*easiest to input digits via iPhone*)
4. Input ACTION ID (*14 digits, obtained from HF Registry*)
____ - ____ - _____
5. Allow ALL notifications
6. Under 'Health Access' » click 'Review'
7. Toggle 'All Requested Data below' switch to ON —click 'DONE' at the end of the page
8. Follow prompts to perform a 6 minute walk test
9. Enter weight
10. Obtain an ECG by clicking on the following app on the watch 
This will prompt the user to open the Apple Health app to complete the setup process.
Note: Patient's age should be changed to >22 years old to allow ECG to be performed.
11. Go to Apple Watch app on iPhone » 'Sleep' » turn on 'Track Sleep with Apple Watch'
12. Enrollment is complete.

