

SPIROMICS - HEART FAILURE ECHO COMPLETION FORM ECH, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-HF Echo Completion Form is to be completed during the participant's SPIROMICS-HF study visit before, during, and after the echo testing.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected or abstracted. Select the date from the pop-up calendar in the CDART data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data, please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Please answer every question on this form.

Baseline Assessment (to be completed prior to echo)

NOTE: Items 1 and 2 will auto-populate. Save and reload the form to display participant height and weight in CDART.

- Item 1. **Height (from ANT form):** Record the participant's height from the ANT form.
- Item 2. Weight (from ANT form): Record the participant's weight from the ANT form.
- Item 3. **Oxygen saturation:** Record the participant's baseline oxygen saturation.
- Item 4. **Heart rate:** Record the participant's baseline heart rate.

Item 5. Omron Blood Pressure

- Item 5a. **Omron systolic blood pressure:** Record the participant's Omron systolic blood pressure.
- Item 5b. **Omron diastolic blood pressure:** Record the participant's Omron diastolic blood pressure.

Item 6. Manual Blood Pressure

- Item 6a. **Manual systolic blood pressure:** Record the participant's manual systolic blood pressure.
- Item 6b. **Manual diastolic blood pressure:** Record the participant's manual diastolic blood pressure.

- Item 7. **EKG Heart Rhythm (approximate based upon echo leads):** Select only one option among the three possible choices.
 - Select 'Normal Sinus Rhythm' if the EKG shows normal sinus rhythm.
 - Select 'Atrial-fibrillation' if the EKG shows atrial-fibrillation.
 - Select 'Other' if the EKG shows something other than normal sinus rhythm or atrial fibrillation.
- Item 7a. Artificial Cardiac Pacemaker: Select only one option among the two possible choices.
 - Select No if the participant does not have an artificial cardiac pacemaker.
 - Select Yes if the participant does have an artificial cardiac pacemaker.
- Item 8. **Supplemental oxygen:** Select only one option among the two possible choices.
 - Select No if supplemental oxygen should not be used during the echocardiogram. [Go to Q9]
 - Select Yes if supplemental oxygen should be used during the echocardiogram.

Item 8a. Record the number of oxygen liters that should be used.

Baseline Echo Findings

- Item 9. Baseline Echo Views: Select only one option among the two possible choices.
 - Select No if all required baseline views were not obtained.
 - Select Yes if all required baseline views were obtained. [Go to Q10]
 - Item 9a. Select only one option from the three possible choices to explain why all required baseline echo views were not obtained.
 - Select 'Participant refused' if the participant refused.
 - Select 'Echo terminated early' if the echo was terminated early.
 - Select 'Technical problems' if there were technical problems.
- Item 10. **Urgent alert:** Select only one option among the two possible choices.
 - Select No if an urgent alert was not suspected. [Go to Q11]
 - Select Yes if an urgent alert was suspected.

Item 10a. Select only one option from the six possible choices.

- Select 'Suspected tamponade' if the urgent alert was suspected tamponade.
- Select 'Aortic aneurysm or dissection' if the urgent alert was aortic aneurysm or dissection.
- Select 'Abscess or obvious vegetation' if the urgent alert was abscess or obvious vegetation.
- Select 'Thrombus or mass' if the urgent alert was thrombus or mass.
- Select 'Pseudoaneurysm' if the urgent alert was pseudoaneurysm.
- Select 'Significant arrhythmia' if the urgent alert was significant arrhythmia.

Item 10b. Record any comments for reviewer about the urgent alert.

- Item 11. Non-urgent alert: Select only one option among the two possible choices.
 - Select No if a non-urgent alert was not suspected. [Go to Q12]
 - Select Yes if a non-urgent alert was suspected.
 - Item 11a. Select only one option from the six possible choices.
 - Select 'Moderate or greater valvular stenosis' if the non-urgent alert was moderate or greater valvular stenosis.

- Select 'Moderate or greater Al or MR' if the non-urgent alert was moderate or greater Al or MR.
- Select 'Severe TR or PI' if the non-urgent alert was severe TR or PI.
- Select 'Severe LV or RV enlargement' if the non-urgent alert was severe LV or RV enlargement.
- Select 'Moderate or greater LVOT obstruction' if the non-urgent alert was moderate or greater LVOT obstruction.
- Select 'Significant pulmonary hypertension' if the non-urgent alert was significant pulmonary hypertension.
- Select 'Low EF or WMA' if the non-urgent alert was low EF or WMA.
- Select 'Moderate or greater pericardial effusion' if the non-urgent alert was moderate or greater pericardial effusion.
- Select 'New atrial fibrillation' if the non-urgent alert was new atrial fibrillation.

Item 11b. Record any comments for reviewer about the non-urgent alert.

Exercise Echo Assessment (to be completed prior to exercise echo)

- Item 12. Suspected alerts: Select only one option among the two possible choices.
 - Select No if there were no suspected alerts during the baseline echo assessment.
 - Select Yes if there were any suspected alerts during the baseline echo assessment. [Do not proceed with exercise echo assessment; go to Q24]
- Item 13. **Cardiovascular events or stable angina:** Select only one option among the two possible choices.
 - Select No if there were no cardiovascular events (MI, unstable angina, or HF exacerbation) or stable angina in the last 3 months.
 - Select Yes if there were any cardiovascular events (MI, unstable angina, or HF exacerbation) or stable angina in the last 3 months. [Do not proceed with exercise echo assessment; go to Q24]
- Item 14. Bicycle exercise: Select only one option among the two possible choices.
 - Select No if the participant is not physically able to perform the bicycle exercise. [Do not proceed with exercise echo assessment; go to Q24]
 - Select Yes if the participant is physically able to perform the bicycle exercise.
- Item 15. O₂ saturation > 88%: Select only one option among the two possible choices.
 - Select No if the participant's O₂ saturation is less than or equal to 88% at rest (supplemental oxygen use is allowed). [Do not proceed with exercise echo assessment; go to Q24]
 - Select Yes if the participant's O₂ saturation is greater than 88% at rest (supplemental oxygen use is allowed).
- Item 16. Participant willingness: Select only one option among the two possible choices.
 - Select No if the participant is not willing to do the exercise echo assessment. [Do not proceed with exercise echo assessment; go to Q24]
 - Select Yes if the participant is willing to do the exercise echo assessment.

20 Watt Exercise Echo Assessment (record after 3 minutes of exercise)

- Item 17a. **Manual 20W systolic blood pressure:** Record the participant's manual systolic blood pressure after 3 minutes of exercise.
- Item 17b. **Manual 20W diastolic blood pressure:** Record the participant's manual diastolic blood pressure after 3 minutes of exercise.

- Item 17c. **20W heart rate:** Record the participant's heart rate after 3 minutes of exercise.
- Item 17d. **20W oxygen saturation:** Record the participant's oxygen saturation after 3 minutes of exercise.
- Item 17e. **20W supplemental oxygen:** Select only one option among the two possible choices.
 - Select No if supplemental oxygen was not used. [Go to Q18]
 - Select Yes if supplemental oxygen was used.

Item 17e1. Record the number of oxygen liters.

40 Watt Exercise Echo Assessment (record after 3 minutes of exercise)

- Item 18a. **Manual 40W systolic blood pressure:** Record the participant's manual systolic blood pressure after 3 minutes of exercise.
- Item 18b. **Manual 40W diastolic blood pressure:** Record the participant's manual diastolic blood pressure after 3 minutes of exercise.
- Item 18c. 40W heart rate: Record the participant's heart rate after 3 minutes of exercise.
- Item 18d. **40W oxygen saturation:** Record the participant's oxygen saturation after 3 minutes of exercise.
- Item 18e. 40W supplemental oxygen: Select only one option among the two possible choices.
 - Select No if supplemental oxygen was not used. [Go to Q19]
 - Select Yes if supplemental oxygen was used.

Item 18e1. Record the number of oxygen liters.

- Item 19. **Total exercise time:** Record the total exercise time with minutes in 19a and seconds in 19b.
- Item 20. **Peak wattage achieved:** Record the peak wattage achieved.

Recovery Assessment (record 5 minutes after exercise completion)

- Item 21a. **Manual recovery systolic blood pressure:** Record the participant's manual recovery systolic blood pressure.
- Item 21b. **Manual recovery diastolic blood pressure:** Record the participant's manual recovery diastolic blood pressure.
- Item 21c. Recovery heart rate: Record the participant's recovery heart rate.
- Item 21d. Recovery oxygen saturation: Record the participant's recovery oxygen saturation.
- Item 21e. **Supplemental oxygen during recovery:** Select only one option among the two possible choices.
 - Select No if supplemental oxygen was not used during recovery. [Go to Q22]
 - Select Yes if supplemental oxygen was used during recovery.

Item 21e1. Record the number of oxygen liters used during recovery.

Exercise Echo Findings

- Item 22. Exercise Echo Views: Select only one option among the two possible choices.
 - Select No if all required exercise views were not obtained.
 - Select Yes if all required exercise views were obtained. [Go to Q23]
 - Item 22a. Select only one option from the three possible choices to explain why all required exercise echo views were not obtained.
 - Select 'Participant refused' if the participant refused.
 - Select 'Echo terminated early' if the echo was terminated early.
 - Select 'Technical problems' if there were technical problems.
- Item 23. **Non-urgent alert (there are no urgent alerts for the exercise portion):** Select only one option among the two possible choices.
 - Select No if a non-urgent alert was not suspected. [Go to Q24]
 - Select Yes if a non-urgent alert was suspected.

Item 23a. Select only one option from the three possible choices.

- Select 'New atrial fibrillation during the exercise test' if the non-urgent alert was generated by new atrial fibrillation during the exercise test.
- Select 'New WMA with exercise' if the non-urgent alert was generated by new WMA with exercise.
- Select 'RSVP > 70mmHg during exercise' if the non-urgent alert was generated by RSVP > 70mmHg during exercise.

Item 23b. Record any comments to reviewer about the non-urgent alert.

Item 24. **Echo sonographer:** Enter the name of the echo sonographer.

Item 24a. Enter the date of the echo sonographer's acknowledgement.

Save and close the form.