

Center Number: ____ Participant Number: ____ Participant's Initials: first middle last ____

Ventricular Ischemia Episode

This report is completed if an episode of ventricular ischemia occurs during the VO₂ max measurement (12 or 24 months). Reporting starts when it is first observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

A Identifying information

1 Date of initial report: ____ / ____ / ____
day month year

2 Name of person making this report: _____

B Date when the ventricular ischemia was observed

3 Date: ____ / ____ / ____
day month year

C Temporary Discontinuation

The CR intervention is temporarily discontinued and a stress imaging study is recommended within two weeks.

4 Was CR temporarily discontinued and a stress imaging study ordered?

No → If No: Indicate the reason CR was not temporarily discontinued: _____

Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section D below.

D Stress Imaging Study

If a stress imaging study confirms presence of ventricular ischemia, the CR intervention will be permanently discontinued and a participant will follow all other study procedures to the study end.

5 Date of study: ____ / ____ / ____
day month year

6 Did the study confirm the presence of ventricular ischemia?

No

Yes

E Permanent Discontinuation

7 Was the participant permanently discontinued from the CR intervention?

No → If No: Indicate the reason CR was not permanently discontinued:

The study did not confirm the presence of ventricular ischemia.

Other (specify): _____

Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

Ventricular Ischemia Episode Report

Center Number: ____ Participant Number: ____ Participant's Initials: first middle last ____

Ventricular Ischemia Episode (continued)

F Please provide details of ECG findings including actions taken:

Study Manager's Signature:

Signature: _____

Date: ____/____/____
day month year