# HCHS/SOL-RHYTHM
# SOL-RHYTHM Checklist Form – ZCK
# QxQ

12/07/2022

## Introduction

The SOL-RHYTHM Checklist form is used to track preparation and dispensing of the Zio® XT Monitor, device application, participant follow up, device return, and results reporting.

If a replacement device is issued, use a separate occurrence of this form for each device.

## Question by Question Instructions

For each question, enter or select the appropriate response.

### ADMINISTRATIVE INFORMATION

**Q0a.** Enter the date the form was initially completed.

**Q0b.** Enter the Staff ID of the person completing the form.

### DEVICE PREPARATION AND MAILING

Complete this section after participant consent procedure is completed. Refer to the SOL-RHYTHM MOP for information about registering the Zio® XT Monitor Kit box with iRhythm.

**Q1.** Set Q1=1 once Zio® XT Monitor has been registered with iRhythm. See SOL-RHYTHM MOP for information on registering the device.

**Q2.** Use scanner to scan the bar code on the outside of the Zio® XT Monitor Kit box for the device serial number. If scanning the code does not work, enter the serial number manually.

**Q3.** Use scanner to scan the bar code on the outside of the Zio® XT Monitor Kit box for the USPS tracking number. If scanning the code does not work, enter the tracking number manually.

**Q4.** Select whether Zio® XT Monitor was issued to the participant in the clinic or by mail. If participant withdrew consent or was unable to be reached for device distribution after initially consenting, set Q4=0 “Not issued”.

**Q5.** Set Q5=1 once listed materials are provided to the participant, whether in-person, by mail, or some other method.

### DEVICE APPLICATION

**Q6.** Note whether Zio® XT Monitor was applied to participant and whether it was applied in-clinic by FC Staff or at home by the participant or their proxy.

Refer to the SOL-RHYTHM MOP for instructions on device application.

If participant refuses device application at this stage, set Q6=0 “Refused” and end form. Do not update consent information in ZSB unless participant explicitly withdraws their consent from the study.

If device is not applied for any reason other than participant refusal, set Q6=3, record the reason in the note log, and end form. If appropriate, staff may schedule another time with the participant to redo the device application. However, if a replacement device is needed, enter all information for the replacement device on a new occurrence of the ZCK form.

**Q7.** Record the date of device application.

**Q7a.** Record the ID of the staff member who either applied the device to the participant or who walked the participant through the device application process over the phone.

## REMINDER CONTACTS

Refer to SOL-RHYTHM MOP for 3-Day and 10-day reminder scripts in English and Spanish.

**Q8.** Once the date of Zio® XT Monitor application (Q7) is entered, the click refresh wheel in CDART to display the recommended date of the Day 3 reminder contact.

**Q9.** Record date of Day 3 reminder contact.

**Q9a.** Enabled once a date is entered in Q9. Record the method of Day 3 reminder contact.

**Q10.** At the time of Day 3 reminder contact, indicate whether the participant is still wearing the Zio® XT Monitor. FC staff may learn this information at the time of the Day 3 reminder contact, or earlier if the participant calls to notify the Field Center that they have removed the device or the device has fallen if. If participant was not reached to answer this question, set Q10=2 “Unknown”.

**Q10a.** If participant reports that they are NOT still wearing the device at Day 3 or before (Q10=0), ask participant if they would be willing to wear a replacement device. Indicate their response here.

If participant agrees to wear a replacement device, set Q10a=1 “Yes.” Save and end form. Use a new occurrence for the replacement device.

**Q11.** Click the refresh wheel in CDART to display the recommended date of the Day 10 reminder contact.

**Q12.** Record date of Day 10 reminder contact

**Q12a.** Enabled once a date is entered in Q12. Record the method of Day 10 reminder contact.

## DEVICE RETURN AND PARTICIPANT REPORT

Refer to SOL-RHYTHM MOP for instructions on tracking device return, sending participant feedback reports and alerts, and 3-Day and 10-day reminder scripts in English and Spanish.

**Q13.** Click the refresh wheel in CDART to display the date that the participant is scheduled to remove the Zio® XT Monitor (Day 14). FC staff may edit this field if they learn that the device was removed prior to Day 14.

**Q14.** Record the date the participant mailed the Zio® XT Monitor, either confirmed by the participant over the phone or using the USPS tracking number.

**Q15.** Record date of return reminder contact, if applicable. Update each time a reminder contact is conducted. If no return reminder contact is necessary because participant mailed device within 5 days of scheduled removal, set field status to “N/A”.

**Q15a.** Q15a will be enabled once a date is entered in Q15. Record the method of the most recent return reminder contact.

**Q15b.** Add any comments related to the monitor return status.

**Q16.** Set Q16=1 once the SOL-RHYTHM Reviewer Form (ZBX) is completed.

**Q17.** Record the date the SOL-RHYTHM Participant Feedback Report was sent to the participant. If the participant did not consent to receive results (ZSB12=0 and ZSB12b=0), set field status to N/A.

**Q18.** Add any additional comments or notes.