



Manual 21 – ECG Patch Results Letter Templates

The following templates are for participant results letters. Physicians will receive a generic cover letter attached to the participant letter, which can be found in the Manual 2 Appendices. Descriptions/interpretations for the abnormal findings and alerts are included at the end of this document, after the letter templates.

Results letter template #1 – Letter to Participant No abnormal findings

[Date]

[Participant Name]
[Address]

Dear [Mr./Ms. Participant Name]:

Thank you for taking part in the ARIC Study. We appreciate your willingness to join us in this important study.

The results of your Heart Patch Monitor examination were within the expected normal range for someone your age. We have attached a detailed report for your records. If you instructed us to send these results to your physician during the ARIC Study visit, we have done so.

Thank you again for being a member of the ARIC Study.

Sincerely,

<Field Center Principal Investigator>

Lin Yee Chen, MD, MS
ARIC Heart Patch Monitor Study
Principal Investigator
University of Minnesota

Enclosure

Results letter template #2 – Letter to Participant Abnormal findings present

[Date]

[Participant Name]
[Address]

Dear [Mr./Mr. Participant Name]:

Thank you for taking part in the ARIC Study. We appreciate your willingness to join us in this important study.

The results of your Heart Patch Monitor examination are detailed in the attached report. The report shows some results that may be considered outside of the normal range. In most instances, such results do not mean that a medical problem exists. However, you may want your physician to review the report and determine whether the results should be studied further.

The findings are: [List below]

If you instructed us to send these results to your physician during the ARIC Study visit, we have done so. ~~We would be glad to assist with an appropriate referral if you do not have a personal physician or other source of health care.~~

Thank you again for being a member of the ARIC Study.

Sincerely,

<Field Center Principal Investigator>

Lin Yee Chen, MD, MS
ARIC Heart Patch Monitor Study
Principal Investigator
University of Minnesota

Enclosure

Results letter template #3 – Letter to Participant Alerts present

[Date]

[Participant Name]
[Participant Address]

Dear [Participant Name]:

Thank you for taking part in the ARIC Study at our Field Center. We appreciate your willingness to join us in this important study.

The results of your Heart Patch Monitor examination are detailed in the attached report. We have identified some findings which are possibly abnormal. We believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

The findings are:

Because the ARIC Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. We encourage you to consult your physician or usual source of medical care to review those results that we have highlighted for verification.

Thank you again for being a member of the ARIC Study.

Sincerely,

<Field Center Principal Investigator>

Lin Yee Chen, MD, MS
ARIC Heart Patch Monitor Study
Principal Investigator
University of Minnesota

Enclosure

Description of abnormal findings and alerts

Abnormality or alert	Description
Atrial fibrillation	This is an irregular heart rhythm. It may feel like palpitations or “racing heart beats”. If you know that you have atrial fibrillation, please follow your physician's guidelines. Otherwise, please share these results with your physician.
Atrial flutter	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”. If you know that you have atrial flutter, please follow your physician's guidelines. Otherwise, please share these results with your physician.
Supraventricular ectopy (SVE) / Premature atrial contractions (PACs) / Supraventricular bigeminy / Supraventricular trigeminy / Supraventricular couplets / Supraventricular triplets	These are heartbeats that come early and originate from the upper chambers of the heart. They may feel like palpitations or “skipping a beat”.
Supraventricular tachycardia	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”.
Ventricular ectopy (VE) / Premature ventricular contractions (PVCs) / Ventricular bigeminy / Ventricular trigeminy / Ventricular couplets / Ventricular triplets	These are heartbeats that come early and originate from the lower chambers of the heart. They may feel like palpitations or “skipping a beat”.
Non-sustained ventricular tachycardia	This is a fast rhythm that originates from the lower chambers of the heart. It may feel like palpitations or “racing heart beats”.
2 nd degree AV block, Mobitz I (AV Wenckebach)	This is an occasional slowing of heart rate due to a drop of a beat in the lower chambers.
Paced beats	These are heart beats that originate from a pacemaker device rather than your heart's own pacemaker.
Wide QRS tachycardia >120 bpm and sustained for >30 seconds (includes monomorphic ventricular tachycardia, polymorphic ventricular tachycardia, ventricular fibrillation)	This is a fast rhythm that originates from the lower chambers of the heart and may feel like palpitations or “racing heart beats”. Please follow up with your healthcare provider as soon as possible.
Complete heart block	This is a slow heart beat due to an interruption in the electrical pathway in the heart. Please follow up with your healthcare provider as soon as possible.

Abnormality or alert	Description
2 nd degree AV Block, Mobitz II	This is a slow heart beat due to an interruption in the electrical pathway in the heart. Please follow up with your healthcare provider as soon as possible.
Pause >6 seconds	There was no heartbeat for 6 seconds or longer. Please follow up with your healthcare provider as soon as possible.
Bradycardia <40 bpm and sustained for >30 seconds	This is a slower than usual heart rate that lasted more than 30 seconds. Please follow up with your healthcare provider as soon as possible.
Atrial fibrillation/atrial flutter with average heart rate <40 bpm or >180 bpm and sustained for 60 seconds	This is an irregular heart rhythm. It may feel like palpitations or “racing heart beats”. Please follow up with your healthcare provider as soon as possible.
Narrow QRS tachycardia >180bpm and sustained for 60 seconds	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”. Please follow up with your healthcare provider.

Example iRhythm Abnormal Report – Ventricular Tachycardia, Atrial Fibrillation and Pause

Zio XT Final Report for
Report, Patient #16

Date of Birth
12/12/67 (51 yrs)

Patient ID

Gender
Female

Primary Indication (R94.31)
Abnormal electrocardiogram

Enrollment Period
13 days 19 hours

Analysis Time
13 days 19 hours
(after artifact removed)

Prescribing Clinician
Dr. E. Physician

Managing Location
San Francisco

Ventricular Tachycardia (4 beats or more)

Episodes
5
HR Range
116-150 bpm
Avg
132 bpm

Pauses (3 secs or longer)

Episodes
3
Range
3.9-4.9 s

Atrial Fibrillation

AF Burden
37%
Longest Duration
1 d 19 h
HR Range
50-154 bpm
Avg
97 bpm

AV Block (2nd° Mobitz II, 3rd°)

None found

Supraventricular Tachycardia (4 beats or more)

None found

Heart Rate

Overall

Max	154 bpm	09:49am, 03/25
Min	50 bpm	11:59pm, 03/22
Avg	78 bpm	

Sinus

Max	96 bpm	11:14am, 03/24
Min	50 bpm	11:59pm, 03/22
Avg	66 bpm	

Patient Events

Total Triggers: 2 **Total Diaries: 1**

Findings within ± 45 sec of triggered events or diary entries:

	Range	Trigger	Diary
AF	59-126 bpm	✓	✓
Pause(s)	3.9 s	✓	
Sinus	56-73 bpm	✓	
SVE(s)		✓	
VE(s)			✓

Ectopics

	Rare <1%	Occasional 1% to ≤5%	Frequent >5%
Supraventricular Ectopy (SVE/PACs)			
Isolated	Rare	<1.0%	6723
Couplet	Rare	<1.0%	141
Triplet	Rare	<1.0%	9
Ventricular Ectopy (VE/PVCs)			
Isolated	Rare	<1.0%	1716
Couplet	Rare	<1.0%	192
Triplet	Rare	<1.0%	26

Preliminary Findings

Patient had a min HR of 50 bpm, max HR of 154 bpm, and avg HR of 78 bpm. Predominant underlying rhythm was Sinus Rhythm. 5 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 150 bpm, the longest lasting 4 beats with an avg rate of 127 bpm. Episodes of Ventricular Tachycardia may be possible Atrial Fibrillation with aberrancy. Atrial Fibrillation occurred (37% burden), ranging from 50-154 bpm (avg of 97 bpm), the longest lasting 1 day 19 hours with an avg rate of 97 bpm. 3 Pauses occurred, the longest lasting 4.9 secs (12 bpm). Atrial Fibrillation and Pause were detected within +/- 45 seconds of symptomatic patient event(s). Isolated SVEs were rare (<1.0%, 6723), SVE Couplets were rare (<1.0%, 141), and SVE Triplets were rare (<1.0%, 9). Isolated VEs were rare (<1.0%, 1716), VE Couplets were rare (<1.0%, 192), and VE Triplets were rare (<1.0%, 26).



Final Interpretation

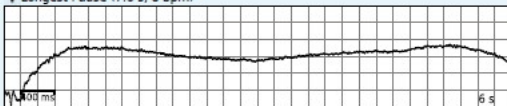
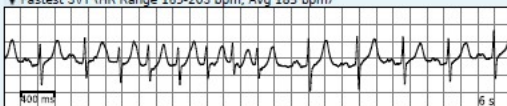
1. Agree with above interpretation
2. Underlying Sinus rhythm with normal rates average =78/min
3. 5 runs of VT some of which could be AF with aberrancy
4. Atrial fibrillation with 37% burden and longest run of 42 hours
5. Pauses of up to 4.9 seconds likely post conversion related
6. Triggered events consistent with AF, Pauses

Electronically signed by Dr. Example Physician 04/12/19 06:18 PM (CT)

SIGNATURE

Example iRhythm Alert Report – Pause > 6 seconds

		Zio XT Final Report for Report, Patient #16		iRhythm Technologies Tel: (888) 693-2401 www.zioreports.com			
Date of Birth 12/12/67 (51 yrs)	Patient ID	Gender Female	Primary Indication (Z13.6) Pause > 6 seconds	Enrollment Period 13 days 19 hours 03/22/19, 05:24am to 04/05/19, 12:40am	Analysis Time 13 days 19 hours (after artifact removed)		
Prescribing Clinician Dr. E. Physician	Managing Location San Francisco						

Pauses (3 secs or longer)		Episodes 1
▼ Longest Pause (7.3 s, 8 bpm)		Range 7.3-7.3 s
		
Supraventricular Tachycardia (4 beats or more)		Episodes 37
▼ Fastest SVT (HR Range 169-203 bpm, Avg 185 bpm)		HR Range 63-203 bpm
		Avg 125 bpm
Ventricular Tachycardia (4 beats or more)		
None found		
AV Block (2nd° Mobitz II, 3rd°)		
None found		
Atrial Fibrillation		None found

Preliminary Findings			
Patient had a min HR of 48 bpm, max HR of 203 bpm, and avg HR of 71 bpm. Predominant underlying rhythm was Sinus Rhythm. First Degree AV Block was present. 37 Supraventricular Tachycardia runs occurred, the run with the fastest interval lasting 6 beats with a max rate of 203 bpm, the longest lasting 25.2 secs with an avg rate of 100 bpm. Some episodes of Supraventricular Tachycardia may be possible Atrial Tachycardia with variable block. 1 Pause occurred lasting 7.3 secs (8 bpm). Isolated SVEs were rare (<1.0%), SVE Couplets were rare (<1.0%), and SVE Triplets were rare (<1.0%). Isolated VEs were rare (<1.0%), VE Couplets were rare (<1.0%), and no VE Triplets were present. Ventricular Bigeminy and Trigeminy were present. MD notification criteria for Pause met - report posted prior to notification per account request (EN).			
Final Interpretation			

Heart Rate			
Overall	Max	203 bpm	02:57pm, 10/22
	Min	48 bpm	02:32am, 10/17
	Avg	71 bpm	
Sinus	Max	139 bpm	10:50am, 10/13
	Min	48 bpm	02:32am, 10/17
	Avg	71 bpm	

Patient Events			
Total Triggers: 2		Total Diaries: 0	
Findings within ± 45 sec of triggered events or diary entries:			
	Range	Trigger	Diary
Sinus	60-111 bpm	✓	

Ectopics			
	Rare <1%	Occasional 1% to 5%	Frequent >5%
Supraventricular Ectopy (SVE/PACs)			
Isolated	Rare	<1.0%	
Couplet	Rare	<1.0%	
Triplet	Rare	<1.0%	
Ventricular Ectopy (VE/PVCs)			
Isolated	Rare	<1.0%	
Couplet	Rare	<1.0%	
Triplet	0		

Longest Ventricular Bigeminy Episode	2.5 s
Longest Ventricular Trigeminy Episode	3 m 13 s

Example BioTel Abnormal Report – Atrial Fibrillation, Premature Atrial Contractions, Premature Ventricular Contractions



Extended Holter Report
(Tel) 877-593-6421 (Fax) 877-989-0700

Patient Name:

Referring Physician:

Date of Birth: 00/00/0000 (Age: 00)

Ordering Physician:

Gender: Male

Rx Duration: 6 Days

Start Date:

Diagnosis (ICD10):

MRN:

Study Summary

Duration 5d 7h 21m
Rhythm Sinus Rhythm
Min HR 40 bpm 15:51 10/24
Avg HR 81 bpm
Max HR 203 bpm 20:07 10/23
Total Beats 510,481
Diary Entries 0
Pt. Triggers 11

Pause Summary

Pause (≥2.0s) 10
Longest Pause 4.8s 11:30 10/27

AF Summary

AF Burden 30%
AF Events 9
AF HR Range 48 - 80 bpm
Longest AF 0d 13h 38m 2s

Supraventricular Summary

PACs 5,865 1.1%
SVT (≥3 Beats) 0

Ventricular Summary

PVCs 21,439 4.2%
VT (≥3 Beats) 2

Arrhythmias

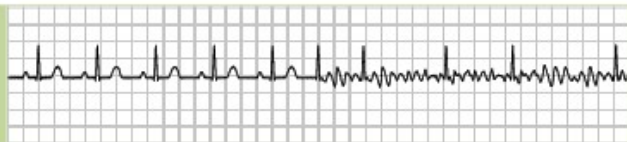
Fastest

AF

80 bpm

11:22

10/25



Fastest

SVT

None Found

Heart

Block

None Found

Longest

Pause

4.8s

11:30

10/27



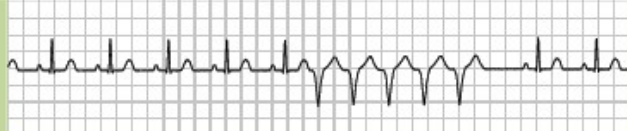
Fastest

VT

152 bpm

15:47

10/24



Preliminary Findings:

- Patient Monitored 4d 7h 21m
- Min HR 40, Avg. HR 81, Max HR 203
- Pause(s) ≥2.0s occurred 10 time(s) with the longest pause 4.8s at 11:30
- 10/27 AF occurred 9 time(s) with a HR range of 48 - 80; Total AF burden = 30%
- SVT did not occur during the monitoring period
- VT occurred 2 time(s) with the fastest run 152 bpm
- 5,865 PACs with PAC Burden of 1.1%
- 21,439 PVCs with PVC Burden of 4.2

Physician Comments:

SIGNATURE

DATE

Example BioTel Alert Report: Atrial Fibrillation with average heart rate >180bpm sustained for >60 seconds

Patient: Holter 14-Day

Patient ID: --

Date of Birth: 01/01/1980 (41 yrs.)

Patient: Holter 14-Day Holter Report

BioTel Heart
Client Services: 877-593-6421
Fax: 877-989-0700
gobio.com



Patient Summary

Date of Birth Sex
01/01/1980 (41 yrs.) Female

Patient ID Pacemaker
-- No

Primary Indication
Chest Pain, Unspecified

Clinician Summary

Analysis by Institution

Report Summary

Recording Length Analysis Length
14d 13d 22h 20min
From 01/25/2021
To 02/08/2021

Date of Analysis Noise Burden
03/03/2021 0.49%

Device ID

bpm at Day 10 / 07:56:28 pm

, fastest rate 156