Feasibility Of Point-Of-Wear Patient Satisfaction Surveys To Validate Patient-Centered Product Enhancements: Results From Over 300,000 Patients For Long-Term Ambulatory Cardiac Monitoring

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Background

- Although 14-day patch-based long-term continuous ambulatory ECG monitoring (LTCM) has shown greater diagnostic yield and lower retest rates compared to all other ambulatory cardiac monitoring modalities[1], wear and usability may still be limited by factors related to patient comfort and acceptance.
- Recent advances in patch-based LTCM technology (Figure 1) have improved device performance, specifically longer wear duration, longer analyzable time, fewer reports of skin irritation, and greater arrhythmia diagnostic yield[2,3].
- Rather than rely on data from small, non-generalizable focus groups, post-market patient survey data at point-of-care offered to all patients may be valuable in collecting quality improvement data on product experience and satisfaction.

Objective

- We assessed the feasibility of this approach to compare patient satisfaction associated with the prior generation LTCM to that of a new generation, FDA-cleared LTCM product designed with patient-centered features, including a more breathable adhesive, waterproof housing, thinner profile, and lighter weight.

Methods

- Starting in March 2018, we implemented a survey provided to all patients prescribed Zio® XT LTCM (iRhythm Technologies, San Francisco, CA.
- The survey was completed and returned at end of wear via paper card or digitally via a web address printed on the card (Figure 2).
- The survey included user experience questions regarding ease of use, comfort, ability for normal activity, and willingness to wear the device again.
- Scores of 4 or 5 (i.e., Agree or Strongly Agree) on a Likert scale were considered affirmative responses. To calculate response rates, the numerator was taken as the number of responses of ≥4, and the denominator was the number of patients who responded to the question.
- Beginning in April 2022, the new Zio® Monitor device was launched for use and the same survey method was used.
- We compared survey responses for Monitor and XT prescribed in the US between Jan 1 and Dec 31, 2023.

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Figure 1. Comparison of LTCM Products

Zio XT

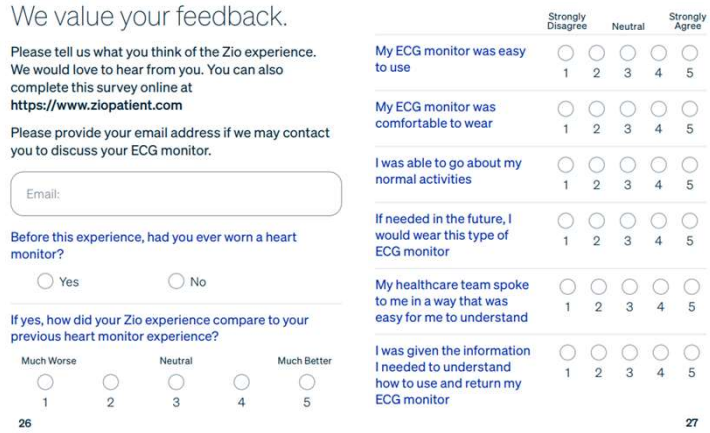
Water resistant (IPX4)
24.5 grams

Zio Monitor

Waterproof (IPX7)
62% lighter (10 grams), 72% smaller, 23% thinner
More flexible and more breathable

Zio XT and Zio Monitor are FDA cleared devices.

Figure 2. Paper Survey With Optional Online Link



We value your feedback.

Please tell us what you think of the Zio experience. We would love to hear from you. You can also complete this survey online at **https://www.ziopatient.com**

Please provide your email address if we may contact you to discuss your ECG monitor.

Email:

Before this experience, had you ever worn a heart monitor?

Yes No

If yes, how did your Zio experience compare to your previous heart monitor experience?

Much Worse 1 2 3 4 5 Much Better

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	Strongly Disagree		Neutral		Strongly Agree
My ECG monitor was easy to use	1	2	3	4	5
My ECG monitor was comfortable to wear	1	2	3	4	5
I was able to go about my normal activities	1	2	3	4	5
If needed in the future, I would wear this type of ECG monitor	1	2	3	4	5
My healthcare team spoke to me in a way that was easy for me to understand	1	2	3	4	5
I was given the information I needed to understand how to use and return my ECG monitor	1	2	3	4	5

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Table 1. Affirmative Responses† by Survey Product Attribute

Survey Question	Zio XT (n=307,337)	Zio Monitor (n=26,717)	Odds Ratio†† (95% CI)	p-value††
Easy to Use (≥ 4)	88.7%	91.3%	1.33 (1.28 – 1.39)	<0.001
Comfortable to Wear (≥ 4)	64.7%	79.1%	2.06 (2.00 – 2.13)	<0.001
Ability for Normal Activity (≥ 4)	83.3%	90.7%	1.96 (1.89 – 2.05)	<0.001
Would Wear Again (≥ 4)	82.6%	89.9%	1.89 (1.81 – 1.96)	<0.001

†Overall survey response rate was approximately 25% estimated from total operational volumes. Among returned surveys, not all patients responded to all survey questions.

††Univariate odds ratios and p-values from Pearson's chi-square were calculated using SAS Enterprise v 8.3 and reflect the ratio of affirmative to negative responses for Zio monitor: Zio XT.

Results

- Among 334,054 respondents, the new LTCM was associated with a greater proportion of affirmative responses across all survey categories (Table 1).
- The new LTCM demonstrated the largest gains in
  - Comfortable to Wear (64.7% vs 79.1%; p<0.001)
  - Ability for Normal Activity (83.3% vs 90.7%; p<0.001)
  - Would Wear Again (82.6% vs 89.9%; p<0.001)

Limitations

- Not all patients responded to all survey questions.
- Analysis was limited to English-language responses from US users.
- Responses to additional survey questions regarding healthcare team interactions, user training, or experience with prior monitoring devices were not included in this analysis.

Conclusions

- Patient survey data for post-market quality assessment is feasible for digital health technologies, in this case leading to over 300,000 total respondents in one year.
- Real-world, patient-reported measures of satisfaction were higher with the new Zio Monitor.
- Findings validate the integrated patient-centered product enhancements and are consistent with post-market data of device clinical performance.

Disclosures

- AJ Battisti, R Santee, A Fan, and R Pinkerton are employees of iRhythm Technologies, Inc.
- Dr. Turakhia has received research grants from Bristol Myers Squibb, American Heart Association, Bayer, Gilead Sciences, and the Food and Drug Administration and has received equity from iRhythm, Connect America, Forward, Evidently, PocketRN, AliveCor, and Hippocratic.ai. Dr Turakhia is an employee and corporate officer of iRhythm Technologies Inc.
- Dr. Mead has received consulting fees from Medtronic and iRhythm Technologies, Inc.

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