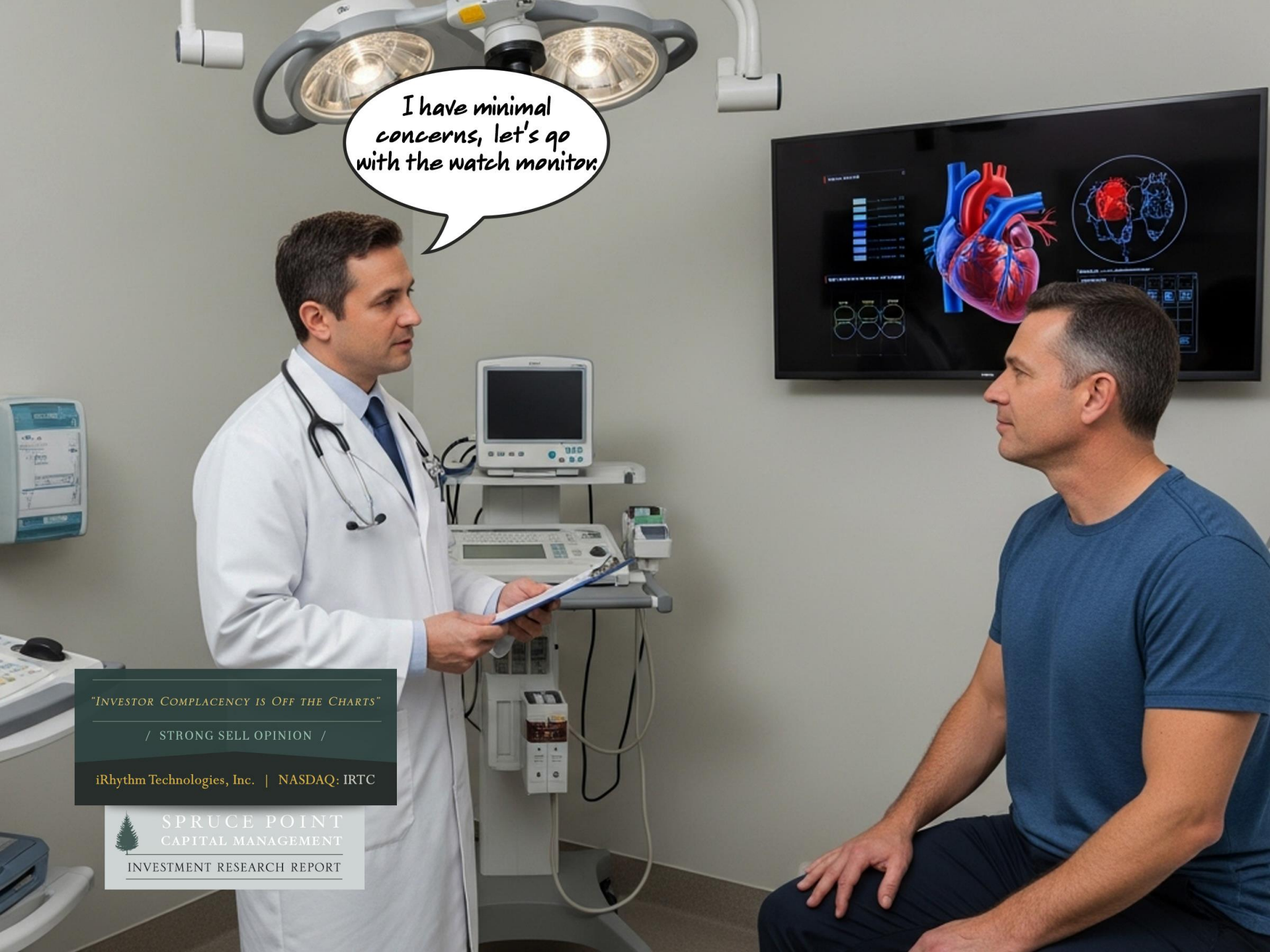

"Investor Complacency is Off the Charts"

/ STRONG SELL OPINION /

iRhythm Technologies, Inc. | NASDAQ: IRTC

SPRUCE POINT
CAPITAL MANAGEMENT

INVESTMENT RESEARCH REPORT

SPRUCE POINT CAPITAL MANAGEMENT

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Spruce Point Has A Track Record With Healthcare Short Activism

Spruce Point has successfully targeted a number of healthcare-related companies benefitting from unreasonably high growth expectations and misunderstood business models.

	stryker	HESKA	progyny	PROCEPT BioRobotics
Report	NYSE: SYK | 4/26/22	Nasdaq: HSKA | 10/25/21	Nasdaq: PGNY | 2/6/23	Nasdaq: PRCT | 1/16/25
Market Cap	$102.8 billion	$2.7 billion	$3.1 billion	$4.7 billion
Company Promotion	Best of breed roll-up acquiror of orthopedic, neuro and medical devices.	A pandemic beneficiary, this equipment distributor wove a story of innovation, diversification, and growth to capitalize on the booming animal health theme.	High-growth fertility benefit manager capitalizing on the war for talent in the wake of COVID.	Innovative new Aquablation treatment can address all patients with benign prostatic hyperplasia (BPH).
Our Criticism	A poor acquiror that has a reputation for overpaying for acquisitions as R&D has failed to deliver product innovation. Recent acquisition of Vocera has handicapped the company into a position of high leverage necessitating debt reduction. Numerous accounting and financial anomalies to portray growth despite signs of financial strain.	We found that HSKA misrepresented its organic growth, market share gains, profitability, subscription trends, product development efforts, and M&A deal contributions while proving to be an ESG nightmare. Despite acquiring low-margin businesses at low single digit multiples, HSKA traded in-line (9x revs.) with industry leader IDEXX.	We identified concerns around revenue and expense recognition, inconsistencies with key disclosures (and thus higher implied churn), an expanding array of growth headwinds, offering commoditization and increasing competition, problematic marketing claims, and conflicts of interest with the structure of the benefit. We also highlighted management's involvement with a past accounting scandal.	We found that the actual addressable market for Aquablation is much smaller than the Company represents because it is not right for "all prostates", that the Aquablation procedure has numerous drawbacks and growth inhibitors (particularly relative to less invasive alternatives), that the cancer market opportunity is likely overstated, and that key metrics either indicated business issues or were problematic.
Successful Outcome	Stryker's Q1 2022 results showed increasing signs of financial strain which our report warned about. Operating cash flow contracted materially to just $203m, down from $452m in the prior. The company has been incapable of responding to our report, and the VP of Investor Relations was reassigned. Shares declined by -30%.	Over the next year (from Q3'21 to Q3'22), revenue from the areas most highly touted for growth by HSKA (consumables, Element AIM, and international), grew 1%, seemingly nil, and -6%, respectively. In the three months after our report, HSKA returned -40% versus a -4% decline in the S&P 500. Mars acquired HSKA for $120/share in 2023, -48% below our unaffected price.	Given Progyny's annual selling cycle and long-term contracts, its business remained stable through 2023 yet underperformed the Nasdaq by nearly 500bps for the year. However, PGNY shares returned -54% in 2024 after the company's growth challenges (including loss of its largest customer), margin disappointments, and increasing competition became apparent.	Over the following three months, PRCT shares returned -33%. We believe more critical views of the Company's claimed growth opportunities and business metric deterioration drove substantial multiple compression. On 7/24/25, PRCT announced the retirement of its CEO, who had been in the role since 2020.

The recommendations shown above are not intended to be exhaustive. A full list of all recommendations made over the past twelve months can be found on our website. Max decline post release is presented as one indication of the potential success of a short research campaign. These movements do not reflect any fund's gain or loss on these securities.

Executive Summary

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Spruce Point Issues "Strong Sell" Opinion On iRhythm Technologies, Inc. (Nasdaq: IRTC)

After conducting a forensic review of iRhythm Technologies, Inc. (Nasdaq: IRTC) ("iRhythm" or the "Company"), including a proprietary survey of 100 practicing cardiologists, we have serious concerns about the safety and competitiveness of the Company's products, the growth potential of the oft-touted asymptomatic market, looming business headwinds (particularly when coupled with the Company's poor profitability), and, perhaps most of all, the credibility of its management team. **We see troubling signs that iRhythm's regulatory problems may yet worsen, as recently unsealed legal filings suggest the Department of Justice (DOJ) is investigating a cover-up by the Company's management.** We believe investors have cut iRhythm management too much slack and have failed to properly acknowledge the magnitude of the Company's failures. U.S. Food and Drug Administration (FDA) evidence suggests iRhythm's own analysis revealed multiple product deficiencies that threatened the lives of patients. Yet, by the time it was first called out by the FDA in 2022, at least three years had lapsed without the Company taking any action to address complaints or warn patients or cardiologists. During this period of inaction, depending on the issue referenced, iRhythm insiders cashed out of approximately $90 to $160 million of Company stock. Based on FDA evidence, we believe iRhythm violated several of the most basic regulatory processes meant to protect patient safety. Investors are acting as though the Company's regulatory risks have been fully remediated and that new market opportunities will be realized, which have driven a 141% increase in its share price over the past year. We disagree and see 40% to 70% downside risk in iRhythm shares.

A Single Product, Single Market, Single Application Company

iRhythm manufactures ambulatory cardiac monitors designed to detect arrhythmias and other cardiac abnormalities that can indicate atrial fibrillation (AFib), which can lead to strokes, heart attacks, or blood clots. The Company's first product was the Zio XT (updated and renamed "Zio Monitor"), which is a wearable long-term cardiac monitor (LTCM) that records a patient's electrocardiogram (ECG or EKG) data for up to 14 days. Following the prescribed wear period, the device is mailed to iRhythm, where it is analyzed by the Company's Zio ECG Utilization Software ("ZEUS") System and certified cardiographic technicians (CCTs), who then send a final report to the cardiologist. The device is generally prescribed by a cardiologist after some sort of patient cardiac event, such as syncope (i.e., fainting) or palpitations. Traditionally, such data was gathered using a Holter monitor, which employed a bulky device with numerous leads/contact points and had a short 1 to 2 day wear period. The Zio XT was one of the first extended wear monitors and has captured a dominant (~70%) share of the market. However, due to the long lag time between prescription and cardiologist receipt of patient results (as long as a month or more), the Zio XT is only appropriate for less serious arrhythmias. In 2019, iRhythm launched the Zio AT, which added a wearable cellular gateway to transmit patient data to iRhythm's ZEUS System. Marketed by iRhythm as a mobile cardiac telemetry (MCT) device, this transmission capability is meant to enable real-time surveillance and notification to doctors of cardiac events for more acute patients.

We Believe iRhythm Products Are Undifferentiated, And The FDA Found They Put Patients' Lives At Risk

Similar to the Zio XT, the device is returned to iRhythm after the wear period for final analysis of patient data. The Zio AT was heralded by the Company as a disruptive product that would incrementally increase iRhythm's addressable market.

We Believe Zio Products Are Undifferentiated as Competitive Threats Emerge

iRhythm's products are relatively low-technology devices, as factors such as strength of adhesive and form factor (within a narrow range) are often noted as distinguishing features (rather than accuracy). In fact, all medical-grade cardiac monitors use the same electrode measurement techniques, and virtually all monitor suppliers use machine learning-developed algorithms to aid patient data interpretation. Although iRhythm claims research supports their statements of product superiority, we find most major competitors can make similar claims, and we question a number of the Company's product marketing claims. Our research shows that cardiologists generally view the monitor as commoditized. More importantly, due to their general distrust of suppliers' analysis of patient data, cardiologists rarely rely on supplier final reports and almost always read the raw strip data to form their own diagnosis. In fact, FDA findings highlight serious shortcomings in iRhythm's artificial intelligence (AI) capabilities and even its ability to perform basic data analysis. More worrying, the cardiac monitoring market has seen an influx of small competitors offering comparable products at lower prices. As we discuss in the context of treating asymptomatic patients, research has shown that smartphone-paired devices and smartwatches offer near-comparable detection abilities. One strategy iRhythm has discussed to differentiate and enter new markets is to expand its breadth of sensor capabilities, yet we believe the Company is already too late, as integrated multi-sensor solutions already exist. While iRhythm plans to launch a new MCT product, we find little to be excited about as the product seems incremental at best in our view, and the MCT market may be smaller than investors assumed.

The FDA Found That iRhythm Products and Practices Put Patients' Lives at Risk

Despite iRhythm frequently touting its products as the "*gold standard*", the Zio AT contained several fatal flaws. As revealed in an FDA Form 483 received in August 2022 and a subsequent FDA warning letter received in May 2023, the Zio AT had been designed with a transmission limit, above which the device ceased transmitting patient data, which prevented the device from meeting the definition of an MCT because doctors could no longer receive real-time alerts for high-risk patients. The FDA found that at least two patients died because of this issue, in part because iRhythm failed to disclose this serious product shortcoming to doctors, patients, or the FDA (as required by law) despite having received complaints for at least three years. The FDA also found that incomplete patient registration could prevent real-time data transmission, an issue iRhythm had known about since 2017, further endangering high-risk patients. FDA evidence shows iRhythm continued marketing the Zio AT as an MCT to high-risk

iRhythm Management's Actions Are Still The Target Of A Department Of Justice Investigation

patients despite these issues. Following a simultaneous inspection of both iRhythm facilities in July 2024, we believe a clear sign of government distrust, iRhythm received two additional Form 483s. Once again, the FDA found that iRhythm jeopardized patient safety, this time by failing to investigate, report, and remediate over 4,000 complaints related to patient data reporting errors and data measurement and algorithm mistakes (which call into question the Company's promotion of its AI capabilities). Alarmingly, subsequent revelations suggested there were systemic issues with iRhythm's results analysis operations, including that technicians were encouraged to delete patient data that highlighted inconsistencies between transmitted and saved readings in order to produce "clean" reports for cardiologists. We believe iRhythm's defense of its actions was troubling, as the Company argued the results analysis activity should be viewed as separate from the monitor product and thus not subject to the typical regulatory oversight. Regulatory consultants we interviewed believe this interpretation was indefensible. While seemingly ignoring these issues, iRhythm has moved to outsource its CCT operations to India and the Philippines. However, in doing so, we find that iRhythm may have used unqualified personnel to interpret patient data, creating additional potential legal liability.

iRhythm Management Has Downplayed the FDA Issues at Every Turn

While the FDA's findings are "known" to many investors today, we believe that reviewing the multi-year fact pattern in totality produces an extremely unfavorable view of management's actions. We believe iRhythm management continually delayed and downplayed its disclosure of its regulatory troubles, perhaps hoping to avoid revealing the true breadth of its violations. For example, CEO Blackford repeatedly characterized the FDA's issues as related to "reporting", "labeling", or other terms that minimized the fact the FDA evidence shows a clear disregard for patient safety. In fact, we believe iRhythm's alleged violations demonstrate a corporate disregard for some of the most basic regulatory tenets meant to ensure consumer safety. Management has repeatedly been forced to backtrack as new revelations emerged or the seriousness of the FDA's findings sank in. For anyone who has read the case record in detail, this is consistent with the Company's defensive and argumentative approach to the government's actions and communications, particularly during its early stages.

Newly Unsealed Court Documents Suggest the Department of Justice is Investigating a Cover-Up by iRhythm Management

In May 2023, iRhythm disclosed it had received a Department of Justice subpoena, the subject of which was later revealed to be the Zio AT issues. As stated in an iRhythm petition, the "*Government issued a Subpoena with thirty-two requests—ranging in subject matter from quality control policies, to scientific studies, to coverage and reimbursement by federal and state healthcare*

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Recently Unsealed Court Documents Suggest The DOJ Is Investigating A Cover-Up By iRhythm

programs, to communications with the FDA—spanning over a decade." Subsequently, the government filed an enforcement action against the Company on July 1, 2024. Due to the sealing of documents and the need to watch videos of court proceedings, some of the legal posturing between iRhythm and the government have been harder to follow, which is why we believe investors may have lost sight of the significant risks entailed. We would make three key observations regarding the DOJ process: (1) the Company sought privilege on potentially damaging internal documents it produced in anticipation of a whistleblower lawsuit by a Senior Regulatory Affairs Specialist, (2) despite management's suggestions to the contrary, the DOJ and FDA remain engaged and focused on the case, and (3) the court recently ruled against the Company on the long fought discovery issue (subsequently appealed), increasing the risks of an adverse ruling against the Company. iRhythm has repeatedly questioned the government's efforts to obtain the internal documents in question by stating the government already knows their contents. However, we believe this line of argument is undermined by their ongoing efforts (including a recent appeal) to avoid their disclosure, as the Company's arguments regarding privilege seems to have weak legal foundation in our layman's opinion. **Most importantly, a recently unsealed government petition suggests that the government is investigating a cover-up by iRhythm management. That is, the government seeks to investigate *"what executives knew at the company and when they knew it."***

Excerpt From Government Petition For Enforcement of Administrative Subpoena
(Case 3:24-cv-03967-AMO document 63-15 filed 6/13/25)

4. The Government has established substantial need for the Consultant Reports

The government has established that it has a substantial need for the Consultant Reports. In *ISS Marine Srvcs*, closely analogous to this matter factually, the court ruled that the respondent had to provide the audit reports to the Government because it needed not only the underlying facts contained within the audit, but what executives knew at the company and when they knew it. 905 F. Supp. 2d at 139. Similarly here, key to the Government's investigation is understanding what specifically iRhythm employees and officer knew about [redacted] when they knew it.

The fact that both sides continue to fight this court battle should be an ominous sign for investors. We believe the trail of evidence is highly unfavorable for iRhythm and that investors have become complacent regarding the associated risks.

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Legal Petitions By iRhythm Counsel Suggest Material Business Downside Risk From The Information Involved

iRhythm requested the court seal portions of its recent order related to discovery. The excerpt below from its motion to seal suggests disclosures related to its regulatory compliance issues could harm its business, which should concern investors.

Excerpt From Joint Administrative Motion to Seal the May 30, 2025 Order
(Case 3:24-cv-03967-AMO document 61 filed 6/13/25)

Specifically, iRhythm requests that the Court seal the identified portions of the Court's Order that relate to iRhythm's confidential regulatory and compliance details. Tahler Decl. ¶ 6. As described in iRhythm's prior sealing motions (*see, e.g.*, Dkt. No 37), iRhythm's internal regulatory compliance investigations are integral to its business strategy and contain particularly sensitive information that could be exploited by competitors in the marketplace. *Id.* ¶¶ 4–6. This type of

Further, public disclosure of these materials would risk competitive harm to iRhythm, including reputational damage, loss of customer confidence, and impairment of its market position. Tahler Decl. ¶ 5. Moreover, iRhythm's competitors and activist investors have already shown an interest in such material and may use the same to continue efforts at exploiting the information to undermine iRhythm's reputation with its customers and engender a loss of customer trust and loyalty, a negative market position, and revenue decline. *Id.* at ¶ 8.

It is difficult to handicap the potential outcomes, but they could range from a settlement accompanied by a material fine, an additional warning letter, or a consent decree, which would prohibit device sales until the government was satisfied that sufficient changes have been made. However, even if the Company escapes major sanctions, we believe iRhythm's actions and communications warrant an indictment in the court of investor opinion. At the very least, we do not believe this extended regulatory episode should be a survivable event for CEO Blackford and perhaps additional executives, which could cause further business disruption.

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We Believe iRhythm's Strategy Of Targeting Asymptomatic Patients Is Flawed

We Believe the Asymptomatic Market Opportunity Will Disappoint

We believe the current market served by iRhythm products is quite small, between 4.5 to 6.5 million patients a year. Already having ~70% market share with its Zio XT/Monitor, iRhythm has had to find a new leg of growth to support its hefty valuation. The Company settled on the opportunity to have primary care physicians (PCPs) proactively prescribe monitors for asymptomatic patients, suggesting there is widespread support because (1) such pre-emptive monitoring can avoid more costly future medical interventions, and (2) doing so can relieve the burden on cardiologists. Of course, the Company excitedly pitches that the asymptomatic market could expand its addressable market by 27 million patients annually. Our research finds that such testing has not been adopted as a standard of care by any credible organization. Moreover, we found that cardiologists are not supportive of asymptomatic testing because they believe PCPs are not qualified to interpret the data. This highlights what we believe is a major disconnect in iRhythm's strategy. In stark contrast to iRhythm's claim of "*99% physician agreement*" with their final reports, our cardiologist survey found materially more frequent disagreements with final reports and a widespread distrust of supplier reports due to the errors made by supplier CCTs (error incidence that is supported by the FDA's findings). In addition, many of the cardiologists we surveyed also believe testing asymptomatic patients will inevitably result in over-testing while doing little to improve outcomes. Moreover, while iRhythm likes to point to the widespread prevalence of arrhythmias, we found that cardiologists believe monitoring is only justifiable when the patient diagnosis involves certain types of strokes, suggesting a much more limited patient population. We also question the ROI on asymptomatic monitoring, as most tests need to be repeated (in part due to PCP errors) and because of short patient coverage duration for a given insurer (making proactive intervention less economical). Insofar as a meaningful asymptomatic market develops, we believe it will be dominated by near-ubiquitous consumer devices. Apple and Samsung smartwatches have the ability to test for arrhythmias with near-comparable sensitivity and specificity at practically zero cost to insurers. We have seen this movie before. Apple is poised to disrupt the hearing aid market with its earbuds, and we expect the same here.

We Question iRhythm's Prospects for Continued High Growth and Improved Profitability

We acknowledge the market's reaction to iRhythm's recent reported results, but we believe these results represent only transitory strength. We see numerous growth headwinds facing iRhythm. Q1 disclosure suggested that, absent referral activity from PCPs, YoY revenue growth was modest at best, and iRhythm failed to disclose the information needed to update this analysis. With increases in "non-contracted" revenue, contractual adjustments, and accounts receivable write-offs, we observe a marked decline in iRhythm's reported revenue quality. We also believe it is possible that revenue has benefitted from inflated reimbursement

We Believe Worsening Headwinds Will Pressure Growth

related to its CCT operations. Reimbursement issues have historically been a negative catalyst for iRhythm shares, and we see risks of continued reimbursement decreases for the Zio AT (or any future MCT product) due to decreasing service delivery costs and alternative solution costs. Importantly, most of iRhythm's recent Q2 outperformance versus expectations came from its core LTCM market, where its high market share limits continued gains, rather than oft-cited new market opportunities. Investors may have missed it, but iRhythm disclosed on its Q2 earnings call that the MCT market opportunity is smaller than assumed. iRhythm has also pitched a massive international opportunity, yet we find that growth in the UK (its largest ex-U.S. market) has been modest, and a recent reimbursement ruling in Japan was a disappointment that we believe management should have foreseen. Given historic preference for traditional Holter monitors and a lack of reimbursement, we question both the topline growth potential and profit prospects for international markets. Our analysis highlights real risks to the Company meeting 2027E revenue expectations. These headwinds are particularly concerning, as we believe the Company has a structurally unattractive margin model. We believe investors also should be concerned that the Company's regulatory issues have been accompanied by a material decrease in business and financial transparency, we believe a harbinger for future financial disappointments.

We Do Not Believe iRhythm Senior Management is Credible: The FDA Actions Should Not be a Survivable Event

We believe the FDA findings are damning and that this should not be a survivable event, even if they are eventually fully remediated. The record shows a massive failure of action to address and properly report serious product safety issues. We believe management has not only violated investor trust, but the evidence presented by the FDA suggests they have also violated the Company's own Code of Conduct. We believe CEO Blackford has a particularly poor track record of forthright disclosure. Management's track record is all the more troubling when viewed in the context of their involvement with other troubled companies. We were concerned to find that nearly every company with which CEO Blackford has been associated has faced scrutiny for questionable practices. And where has the iRhythm Board been? They have adjusted executive incentive compensation to reward management for remediating the troubles they oversaw (effectively compensating them for not endangering patient safety and operating within standard regulatory guidelines) and, curiously, overseen the significant watering down of the Company's Code of Conduct. The Company's executive suite has been a revolving door for years, and we uncovered employee discontent with the actions taken by the "Dexcom crew". The iRhythm Board has also undergone near-complete turnover since coming public, and we are particularly troubled by the recent departure of two longtime directors and their replacement with former industry executives with questionable track records. Importantly, we note that iRhythm insiders have only a small stake in the Company (or exposure to its risks), as stock sales since the receipt of the first FDA Form 483 have totaled about half of current common ownership.

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We See 40% To 70% Downside Risk Potential In iRhythm Shares

We Believe Investors Are Using the Wrong Comparable Companies For Valuation

Despite allegedly endangering patients and the specter of legal liability, iRhythm shares have rallied to near a two-year high. Even Wall Street analysts, who we believe are largely ignoring both the regulatory risks and looming growth headwinds, are having a hard time justifying iRhythm's inflated stock price. Despite all but one of the 13 analysts having a "Buy" rating on iRhythm shares, the average price target represents just 11% upside from current. We view iRhythm as a low-margin supplier of a largely commoditized product, yet the Company is currently trading at an approximate 100% premium to other medical device companies. Arguably, iRhythm is actually a services company, a position clearly endorsed by one of the Company's former CFOs. This is problematic for the stock, since the Company is trading at an approximate 200% premium to medical testing services companies, which we believe more closely approximate iRhythm's CCT operations and thus represent credible comparable companies. Based on our analysis, even assuming iRhythm can meet the Wall Street forecasted revenue range in 2026, we derive a price target range of $43 to $94 per share, representing approximately 40% to 70% downside from current and material risk of underperformance relative to medical device and services industry peers and the broader market.

Regulatory Experts See Real Odds of a Negative Outcome

Spruce Point Interview with Medical Device Regulatory Compliance Consultant, June 2025	*"[if] people are being diagnosed incorrectly, and if that led to a death or if that led to somebody getting treated incorrectly,* ***this is a very serious 483. They could actually get a consent decree, and FDA could walk in and shut them down…it is apparent that it's systemic****…"* *"…to be honest, this would really scare me because they're on the radar of the DOJ. They've kind of upset them…They've got a mess on their hands…****I would truly run away. I wouldn't touch that company with a 10-foot pole****."*

Source: Spruce Point research

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iRhythm Q2 Results Created More Questions Than They Answered

Investors cheered iRhythm's Q2 2025 results, as the Company's shares rallied 18% the day after the earnings release. Based on our review of the results, including information that was conveniently saved for the 10-Q, we question the positive reaction. We believe the Company's disclosures actually call into question several elements of the growth thesis underlying the stock.

Spruce Point Concerns Regarding iRhythm Q2 2025 Disclosures	
A Material Revenue Beat, But…	We believe the $13 million (+7%) revenue beat represented the confluence of multiple transitory tailwinds and was largely a function of management's conservative guidance to start the year.
Increased Seasonality?	iRhythm management guided to what would be its lowest sequential growth for Q3. We have always had a hard time accepting the "vacation" argument for this supposed seasonality given the catalyst for most patch prescriptions is a cardiac event.
Growth / Upside Driven by LTCM Products	We believe investors should be concerned that LTCM products drove upside since they are the most commoditized and face structural barriers to additional share growth.
Lack of Revenue Transparency	iRhythm failed to provide (and analysts failed to ask about) several metrics that could have provided greater insight, including PCP referral, Zio AT, and international percentage of revenue.
MCT Market Smaller Than Perhaps Anticipated	We believe CEO Blackford's disclosure that its MCT offering cannot address an estimated 20% of the market was the first time this issue has been raised. As we discuss later, we believe the threat of data analysis and reporting insourcing may threaten iRhythm's entire business model.
More Suspect Promotion of the Asymptomatic Opportunity	As we discuss later, we believe there are numerous factors that suggest iRhythm's strategy to target the asymptomatic market will disappoint. Thus, we were disappointed to hear CEO Blackford suggest that providers may even seek to test asymptomatic patients annually when testing such patients at all is not the current standard of care and arguably not economical.
Zio Watch is Dead	iRhythm management failed to mention it on the earnings call, but the Company slipped into its 10-Q that it is unlikely to commercialize Zio Watch, is taking an impairment charge, and is seeking to terminate its collaboration agreement with Verily. We believe this represents a major blow to the Company's ability to address the asymptomatic market where we believe such devices will win.

Source: iRhythm Q2 2025 10-Q, iRhythm Q2 2025 earnings call transcript, Spruce Point research

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Twenty Potential Revenue Headwinds And Anticipated Growth Disappointments At iRhythm

1.	Negative cardiologist reaction to potential additional regulatory action
2.	Negative impact of potential management turnover from systemically weak regulatory controls and compliance
3.	Resolution of competitor issue resulting in aggressive re-entry of strong competitor
4.	Share loss to new low-priced competitors
5.	Share loss to consumer devices, especially in asymptomatic market (if it even develops)
6.	Reimbursement decline for telemetry (MCT) products
7.	Commoditization of LTCM products
8.	Limited potential additional share gain due to structural threshold in core LTCM market
9.	New Zio MCT device likely to disappoint due to troubled development history and only minor improvements
10.	Asymptomatic market opportunity fails to materialize due to cardiologist pushback and poor ROI and outcomes impact
11.	International fails to materialize due to lack of reimbursement and bias for short-term Holter monitors
12.	Structural downside share threshold for Holter monitors due to clinical fit for certain cases
13.	Multi-sensor product opportunity fails to materialize due to poor timing and capability set and existing competition
14.	Pressure from potential insourcing of data analysis and final report preparation
15.	Minimal contribution from sleep apnea market given other solutions exist
16.	Reimbursement pressure on CCT operations from potential for reduced IDTF billing for remote CCTs
17.	Realization of customer pressures indicated by revenue quality decline
18.	Pressure from instability of value-based healthcare customers (the *“innovative channel partners”*)
19.	Macroeconomic pressures on cash pay customer demand
20.	Turnover and employee dissatisfaction in iRhythm engineering and product development organizations

Source: Spruce Point research

The FDA Found That iRhythm's Products Put Patients At Risk

SPRUCE POINT CAPITAL MANAGEMENT

The Zio AT Has Long Been Considered A Strategic Product For iRhythm

The Zio AT has long been promoted by iRhythm management as a strategic product because (1) it addressed the risk (marginally) of being a single product company, (2) it increased (marginally) the Company's addressable market, (3) it represented a growth opportunity given iRhythm's low MCT market share, and (4) it received about 4x the reimbursement of the Zio XT/Monitor. However, the record of events should now force investors to re-examine everything they've been told about the product.

The Blackford Pitch vs Reality	
iRhythm CEO Blackford at Investor Day Presentation, 9/21/22	*"We hear about it being talked about all the time. **We have a perfect product** to address putting information into the hands of the patient on a near real-time basis. We checked that box incredibly well."*
iRhythm CEO Blackford at Morgan Stanley Conference, 9/13/23	*"We began **in 2021 to really invest into the whole quality regulatory organization** of the company."*

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iRhythm CEO Blackford at J.P. Morgan Conference, 1/13/25	*"Part of that is our MCT product was sort of a second-generation product that we brought after our original patch. **It's not quite competitive to the degree that we would like it to be**. It's a 14-day patch. Most MCT products are out to 30 days. Physicians want to see monitoring, get beyond at least 20 days based upon the market research that we've done."*
iRhythm CEO Blackford on Q3 2024 Earnings Call, 10/30/24	*"…**I also have a very, very strong point of view that it's just not quite the right product for the market**…"*

*'…based on your marketing materials, website, and other documentation, the Zio AT System is intended for "near real-time monitoring" and "high-risk patients," **even though the Zio AT System is not cleared for these indications**. When used in this patient population, the **Zio AT System may cause or contribute to serious injury or death because life-threatening arrhythmias may not receive timely treatment**."* - **Excerpt from FDA Warning Letter**

Source: Bloomberg, iRhythm Q3 2024 earnings call transcript, FDA Warning Letter dated 5/25/23 (CMS# 643474), Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

The FDA Warned iRhythm That Its Zio AT Product Is Jeopardizing Patient Safety

In both its August 2022 Form 483 and May 2023 Warning Letter, the FDA observed two potentially fatal flaws in iRhythm's Zio AT product and how it is managed: (1) that the device had a maximum event transmission limit after which it ceased transmitting any data to its ZEUS System, and (2) that if the patient registration was incomplete the product would not transmit data as intended. Both of these problems could prevent timely physician notification of potentially life-threatening cardiac events.

Excerpts From FDA Warning Letter Dated 5/25/23 (CMS 643474)

FDA finds the Zio AT has an uncommunicated device transmission limit

"As a [redacted], your firm implemented a transmission limit on how many times the Zio AT System transmits data. As a result, the device is only able to transmit 100 patient-triggered and 500 automatically detected arrhythmia events. Once the transmission limit is reached, the patient's data stops being transmitted for review/reporting. Thus, when the transmission limit is hit, the device can no longer be used for its intended purpose of transmitting patient ECG for reporting. Further, ***when the transmission limit is hit, the device can no longer provide near-real time monitoring for high-risk patients****."*

FDA finds incomplete patient registration can lead to failure to capture patient data

*"…****your firm was aware that when the patient's device registration is incomplete, the patient's ECG information is still collected but cannot be read by anyone****. When the patient's data can no longer be analyzed and reported, the device can no longer be used for the purpose for which it is intended, which is a nonconformance."*

FDA finds that neither issue was properly communicated to patients or physicians

"During our inspection, it was revealed that the labeling ***does not inform the physician of the existence of a transmission limit, when the transmission limit is reached, or include any information about the action a physician should take if the device reaches the transmission limit****…Further, there is no information provided to the patient that a transmission limit exists, no notification to the patient when the transmission limit is reached, and no information provided to the patient about what to do when the transmission limit is reached."*

Shockingly, two patients died while wearing Zio AT devices that had reached their transmission limit and thus failed to notify their physicians.

Source: FDA Warning Letter dated 5/25/23 (CMS# 643474)

SPRUCE POINT CAPITAL MANAGEMENT

Patient Risks Were Magnified Because iRhythm Had Been Marketing The Zio AT For High-Risk Patients

The Zio AT came to market under a 510(k) premarket notification application, a simplified clearance process, as the Company claimed it was substantially equivalent to the existing Zio XT device. However, as the FDA noted in its Warning Letter, the Zio XT *"is not intended for use on critical care patients"*. Seemingly ignoring this fact, iRhythm marketed the Zio AT as a Mobile Cardiac Telemetry (MCT) device capable of *"near real time"* transmission and timely notification of cardiac events to a patient's physician, making it appropriate for *"high risk"* patients. Nor had iRhythm properly reported the transmission limitation as a *"malfunction"*.

Excerpts From FDA Warning Letter Dated 5/25/23 (CMS 643474)

iRhythm did not have FDA approval to market Zio AT as an MCT to high-risk patients

"…your device was cleared under K163512 for long-term monitoring of arrhythmia events ***for non-critical care patients where real-time monitoring is not needed*** *as reporting timeliness is not consistent with life-threatening arrhythmias. However, your marketing materials and other documentation…state that the Zio AT Patch System is intended for "near real-time monitoring" as a "mobile cardiac telemetry monitor," can provide notifications "immediately," and that it is intended for "high-risk patients." The claim that the device is intended as a mobile cardiac telemetry monitor implies this device is intended for high-risk patients and near real-time monitoring…* ***This change could significantly affect the safety or effectiveness of the device*** *because it suggests that the device is intended for a new patient population – high-risk patients."*

FDA finds that iRhythm failed to report the transmission limitation as a malfunction as required by law

"The Zio AT System malfunctioned when the Zio AT System hit its transmission threshold and stopped submitting data that is used to determine potential arrythmias. ***This failure meets the definition of a reportable malfunction****, as defined in 21 CFR 803.3. This malfunction is* ***likely to cause or contribute to death or serious injury*** *for the reasons discussed in #1 above. However,* ***these complaints were coded as unreportable malfunctions and no MDR was filed****."*

For brevity, we do not provide the countless examples of iRhythm making claims regarding the Zio AT, as the FDA clearly stated that such statements were made. As a result, the FDA considered the Zio AT product inappropriate for high-risk patients and thus mislabeled. And despite the FDA alerting iRhythm to its mislabeling concerns in its August 2022 Form 483, the Company continued to market these devices to high-risk patients. While *"mislabeling"* may sound like an innocent offense, the implications were potentially fatal for patients and represent a material violation.

Source: FDA Warning Letter dated 5/25/23 (CMS# 643474)

SPRUCE POINT CAPITAL MANAGEMENT

Shockingly, The FDA Observed iRhythm Knew About These Issues For Years And Failed To Address Them

To make matters worse, the FDA observed that iRhythm knew about the transmission limit and registration issues since 2019 and 2017, respectively. As a result, numerous patients suffered arrhythmias while wearing the Zio AT without their physicians receiving the intended timely notification.

Excerpts From FDA Warning Letter Dated 5/25/23 (CMS 643474)

FDA finds that iRhythm knew of the transmission limit issue in 2019

"Our inspection revealed that your firm knew that the device's transmission limit, which was explained in the previous section, was resulting in data not being transmitted. ***Records reviewed during our inspection indicate that your firm has been aware of customer complaints related to this issue since at least 2019****. Specifically, our inspection found a significant number of complaints regarding this issue, which revealed* ***two deaths as well as significant arrythmias that were not reported to physicians****."*

FDA finds that iRhythm knew of the registration completion issue in 2017

"However, your firm failed to initiate a CAPA when you were aware that patient data, including significant arrythmias requiring physician notification (see Z ticket[3] records [redacted] noting Atrial Fibrillation and [redacted] noting Bradycardia), was being held inaccessible within your Zeus system. Specifically, your firm was aware that when the patient's device registration is incomplete, the patient's ECG information is still collected but cannot be read by anyone. When the patient's data can no longer be analyzed and reported, the device can no longer be used for the purpose for which it is intended, which is a nonconformance. ***Since at least 2017, your firm has been aware of this issue where your clinical care team cannot access the patient's data****. Our inspection confirmed 39 examples from a list of over [redacted] Z tickets where this problem occurred."*

For brevity, we note that iRhythm's initial responses (including that the transmission limit was a *"design limitation"* rather than a *"nonconformance"*) were both deemed inadequate by the FDA. We believe that iRhythm simply couldn't design a product without transmission limitations that also had adequate battery life to accommodate the stated 14-day wear period.

Source: FDA Warning Letter dated 5/25/23 (CMS# 643474)

SPRUCE POINT CAPITAL MANAGEMENT

Subsequent Revelations Suggest Systemic Issues At iRhythm

Subsequent to iRhythm's receipt of the Form 483s in 2024, Capitol Forum revealed additional concerns regarding the Zio AT that suggested the issues at iRhythm were even more widespread and systemic. The issues cited represent serious and harmful corporate practices in service of continuing to sell a troubled product.

Excerpts From Glazing v iRhythm Second Amended Complaint

*"…**further unknown to physicians and patients, the Zio AT failed to consistently provide "near real-time" notifications because it regularly had a "lag time" of around four hours or more**. FE 3—a former iRhythm Zio AT technician from before the Class Period through November 2022—explained that because of this lag time, the Zio AT was not live and did not notify physicians of arrhythmias right away. According to FE 3, **it took four hours for any arrhythmia events transmitted from the Zio AT to show up in a "queue" for technicians' review**. Then, the technicians had to work their way down this queue to analyze the events one by one, which added on additional "lag time" to the four hours it took just for events to make it into the queue. **Worse, on weekends and overnight, the queue built up even more because there were not as many technicians during those shifts**."*

*"These failures of the Zio AT had serious consequences. **Troublingly, FE 3 stated that technicians could see patients dying while wearing the Zio AT monitor. FE 3 stated that many patients should not have been wearing the Zio AT device and should have been monitored live instead.** FE 3 wanted to look at critical and end-of-life arrhythmias first in the queue, but **there was no way to prioritize review of those arrhythmia events**. FE 3 stated that the technicians were always concerned about the additional "lag time" that it took to work through the queue and analyze arrhythmia events. It was a constant discussion among the technicians, but these concerns were never addressed during FE 3's tenure. At the same time, **in stark contrast to the Company's statements throughout the Class Period, FE 3's managers consistently told technicians that the Zio AT was 'not an emergency service' and that they were not here for 'the critical arrhythmias.'**"*

*"One former sales employee stated that he was "completely unaware" of these problems with the Zio AT, adding **'I would have stopped trying to sell the Zio AT as an MCT if I knew it could harm patients.'** A then-current sales employee told The Capitol Forum, 'Here's the deal. **We were never told it was not an MCT. We were never told to not call it an MCT, and we are 100% still selling it as an MCT.'**"*

Source: Case 3:24-cv-00706-JSC Document 43 Filed 10/11/24

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Employee Commentary Supports The Notion Of Product Development Shortcomings

We found the Glassdoor review commentary submitted by an Engineering Lead to be particularly insightful and damning, as it seems to provide perspective on how the engineering and management culture at iRhythm could allow its variety of product-related issues to fester.

Excerpts From iRhythm Employee Commentary on Glassdoor	
Engineering Lead, iRhythm, Glassdoor, 11/14/24	*"Cons:* *-Opaque and seniority-based decision making processes* ***-Poor engineering/technical/management practices*** ***-Uninspiring product pipeline*** ***-No internal experts/expertise*** ***-Little to No Technical Development"*** *"iRhythm has always been cruising on that initial business case while trying to figure out the hardware to support it. Unfortunately, startup management grew the team based on social fit and communication skills - even preventing managers from performing technical evaluations of candidates. As a result,* ***much of the Director level and under "organic" middle-management is technically under-skilled****, and, for the most part, has spent most of their career at iRhythm."* ***"There are very few technical challenges at iRhythm****, but many procedural and political ones.* ***Decision making is terrible. Inconvenient truths are hidden under Directors and hand-waved away to be fixed later - the result is significant technical debt (in my opinion) in the core products while trying to scale.*** *These problems are surmountable, but* ***not with current leadership****, and not without holding middle-management accountable for performance."*

Source: Glassdoor

SPRUCE POINT CAPITAL MANAGEMENT

We Believe The Discovery Process Related To The DOJ Subpoena Suggests iRhythm Is Hiding Something

iRhythm frames its resistance to the DOJ's discovery as protecting its rights. While we are not lawyers, we believe the arguments for its opposition are weak. As the government notes, the fact that iRhythm disclosed the documents in question to an adversary (a potential whistleblower) means they effectively waived privilege. iRhythm has not challenged the legitimacy of the subpoena.

Excerpts From Glazing v iRhythm Second Amended Complaint

- *"On July 1, 2024, the DOJ revealed in court filings that iRhythm had refused to produce certain relevant documents regarding the Zio AT, in response to the same DOJ subpoena that the Company previously disclosed on May 4, 2023. This revealed that the DOJ inquiry was in fact about the Zio AT's failure to timely transmit patient data to doctors, which had not been previously confirmed. This event further revealed to investors the seriousness with which the DOJ was pursuing its investigation, given that it was now seeking court intervention to obtain these documents about the Zio AT over a year after the DOJ inquiry had been disclosed. Specifically,* ***the DOJ was forced to move for enforcement of the subpoena because iRhythm has withheld relevant documents—"over 1,000 documents" concerning "third-party consultant reports"—over the course of months of negotiations.*** *The DOJ filed its motion in the U.S. District Court for the Northern District of California before Judge Martínez-Olguín. In its petition, the DOJ explained that* ***'the Subpoena sought communications and other documents concerning potential issues related to the Company's Zio Systems, including that the Zio Systems were failing to timely transmit patient cardiac data to physicians for review after the occurrence of a cardiac event.'****"*
- *"The DOJ's petition specified that the Company 'has refused to produce three third-party consultant reports assessing the design history of their devices, as well as hundreds of related communications that do not involve an attorney.' DOJ's Petition for Order to Show Cause and Application for Enforcement of Administrative Subpoena, ECF No. 1, 3:24-cv-03967 (N.D. Cal. July 1, 2024).* ***These third-party reports and related communications assess 'whether the Company's cardiac monitoring devices were developed in accordance with the approved design plan,'*** *which the Company is required by federal regulation to maintain."*
- *"The Company moved to seal documents associated with the DOJ's motion from public view…In iRhythm's reply brief in support of that motion to seal, it noted* ***'the immediate negative impact the disclosure of the investigation [the DOJ's administrative motion] may have had on its stock price.'****"*

iRhythm claimed that the three consultant reports were privileged because they were prepared in anticipation of a potential whistleblower lawsuit by a regulatory compliance employee. The court recently ruled in favor of the government on the discovery fight related to the third-party reports, though iRhythm has appealed.

Source: Case 3:24-cv-00706-JSC Document 43 Filed 10/11/24

SPRUCE POINT CAPITAL MANAGEMENT

Our Review Of iRhythm Medical Device Reports (MDRs) Suggests The Transmission Failures Persist

Examining the MAUDE database used to track medical device adverse events and product problems for May 2025 alone, we found six Medical Device Reports (MDRs) related to transmission failures resulting from the transmission threshold. Of note, while iRhythm management has characterized exceeding the transmission threshold as exceptional edge cases, we highlight that the device failures occurred on average on day 10, well within the advertised 14-day wear period.

Excerpts From iRhythm MDRs Related to the Zio AT Filed in May 2025

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 04/23/2025
Event Type malfunction
Manufacturer Narrative

Stopped transmitting on day 13.

The device was returned to irhythm, and the clinical data was downloaded.A review of the clinical data revealed that the device was worn for the full 14-day prescribed wear period.On day 11, the hcp account was notified that the device was approaching the asymptomatic transmission limit, and a replacement device was shipped.The device reached the asymptomatic maximum transmission limit and stopped transmitting asymptomatic events on day 13.Irhythm

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 04/03/2025
Event Type malfunction
Event Description

Stopped transmitting on day 7.

The patient experienced an arrhythmia that met medical doctor notification (mdn) requirements that was not transmitted during the wear period.The investigation confirmed the zio at reached the asymptomatic maximum transmission limit.The hcp account was notified that the device was approaching the asymptomatic transmission limit prior to reaching the limit, according to the standard process, and a replacement device was declined.Additional follow-up was performed, and the healthcare provider (hcp) was immediately notified of the patient's arrhythmia.No adverse events, such as death or serious injury, are known to have occurred.

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 04/13/2025
Event Type malfunction
Manufacturer Narrative

Stopped transmitting on day 10.

The device was returned to irhythm, and the clinical data was downloaded.A review of the clinical data revealed that the device was worn for the full 14-day prescribed wear period.On day 8, the hcp account was notified that the device was approaching the asymptomatic transmission limit, and a replacement device was shipped.The device reached the asymptomatic maximum transmission limit and stopped transmitting asymptomatic events on day 10.Irhythm became

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 03/26/2025
Event Type malfunction
Event Description

Stopped transmitting on day 13.

The patient experienced an arrhythmia that met medical doctor notification (mdn) requirements that was not transmitted during the wear period.The investigation confirmed the zio at reached the asymptomatic maximum transmission limit.The hcp account was notified that the device was approaching the asymptomatic transmission limit prior to reaching the limit, according to the standard process, and a replacement device was shipped.Additional follow-up was performed with the account, and despite several attempts to obtain more information, no additional details were obtained.No adverse events, such as death or serious injury, are known to have occurred.

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 03/28/2025
Event Type malfunction
Event Description

Stopped transmitting on day 8.

The patient experienced an arrhythmia that met medical doctor notification (mdn) requirements that was not transmitted during the wear period.The investigation confirmed the zio at reached the asymptomatic maximum transmission limit.The healthcare provider (hcp) account was notified that the device was approaching the asymptomatic transmission limit prior to reaching the limit, according to the standard process, and a replacement device was shipped.The healthcare provider was immediately notified of the patient's arrhythmia and irhythm learned there were no delays in treatment, and no adverse events, such as death or serious injury, are known to have occurred.

IRHYTHM TECHNOLOGIES, INC ZIO AT; DETECTOR AND ALARM, ARRHYTHMIA — Back to Search Results

Device Problem Failure to Transmit Record (1521)
Patient Problem Unspecified Heart Problem (4454)
Event Date 01/14/2025
Event Type malfunction
Manufacturer Narrative

Stopped transmitting on day 10.

The device was returned to irhythm on day 91, and the clinical data was downloaded.A review of the clinical data revealed the device was worn for the full 14-day prescribed wear period.The hcp account was notified on day 10 that the device was approaching the asymptomatic transmission limit, and a replacement device was shipped.Subsequently, the device reached the asymptomatic maximum transmission limit on the same day and stopped transmitting

These device failures call into question management's claims of a 14-day wear period, as these failures occurred on average on day 10.

Red box for Spruce Point emphasis. Source: MDR report 22096920, MDR report 22002066, MDR report 22001815, MDR report 21962035, MDR report 21950082, MDR report 21950081

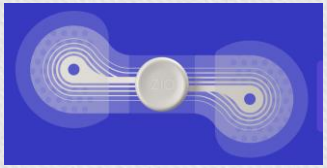
We Believe Zio Is A Commoditized Product In An Increasingly Crowded Landscape

The iRhythm Solution: A Relatively Low-Tech Device Plus A Labor-Intensive Services Operation

We believe the Zio solution is so simple as to make meaningful and sustainable differentiation a challenge. Ultimately, we view the device as highly commoditized and the results reporting activity as persistently labor-intensive. As a result, we would argue that iRhythm is as much, or even more so, a services business as opposed to an innovative medical device company.

The Zio Solution is Pretty Simple

Zio Monitor



Zio AT

Reporting

Advanced AI

We combine a deep-learned, FDA-cleared algorithm with Certified Cardiographic Technicians[11-14] to generate end-of-wear reports with 99% physician agreement.[19]

The Zio patch uses a single-lead, single-channel electrode sensor to measure electrical activity of the heart. The remaining bill of materials is relatively simple: a printed circuit board (PCB) with a standard microcontroller, a small amount of memory, some analog power management circuitry, a light emitting diode, a small battery, and the plastic housing. The Zio AT also contains a Bluetooth chip to transmit data to the gateway device.

Device accuracy would seem to be a major factor, yet most of iRhythm's discussion around accuracy surrounds the post-wear reporting instead. Thus, we do not believe there is material differentiation between the sensors used by different suppliers. Much of the discussion around differentiating features for the patch focus on form factor and the effectiveness of the adhesive used, both of which can directly impact patient satisfaction and thus adherence. Given the simplicity of the device, we do not believe either of these features provide significant or sustainable differentiation.

Much is made of the use of AI to interpret cardiac monitor data, as it clearly presents a logical application of machine learning techniques. However, at this point, we believe that (1) virtually every supplier has an AI capability and the statistical techniques used are all the same, (2) the core machine learning activity here is relatively simple compared to other healthcare applications, and (3) thus the use of these techniques is no longer a meaningful source of differentiation. Tellingly, iRhythm also has certified cardiac technicians (CCTs) analyze all patient data, suggesting they know the AI cannot be relied upon. In fact, as we show later, despite the AI+CCT redundancy, cardiologists generally still do not trust the final reports received from suppliers and still analyze the raw data themselves.

Source: iRhythm website, iRhythm website, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

Management's Product Marketing Messages For Zio Deserve Closer Scrutiny

We believe iRhythm's, and in some cases the entire industry's, marketing claims are overstated or biased. While iRhythm touts its large amount of supporting scientific literature, we note that much of that is either dated or merely supportive of wearable monitoring rather than Zio specifically. For example, we believe comparisons to traditional Holter monitors are of limited utility.

Review of iRhythm Marketing Claims

Accuracy	As discussed, much of iRhythm's commentary around accuracy is related to the use of AI. While we have no question that AI can provide a useful initial review, our research finds it doesn't come close to alleviating cardiologist concerns about final reporting accuracy. **Importantly, in the FDA Form 483 received in July 2024, the FDA observed that the Zio AT's sensitivity for AFib detection was 88.7%, breaching its threshold.** Moreover, iRhythm markets heavily against the traditional short-term Holter monitor. While there is no question that Holter monitors are a more onerous device, the fact that they have 3 to 12 leads makes them inherently more accurate in gathering cardiac event data, albeit typically over a shorter wear period.
Average Wear Period	iRhythm has recently touted that its Zio AT wear period is better than that of competitors: 13.8 days vs 12.8 days despite being approved for use up to 14 days vs up to 30 days for competitors. We believe this metric is full of noise, as wear periods can end prematurely once enough data for a diagnosis has been captured. Moreover, we believe iRhythm may simply use a stronger adhesive, which increases the probability of negative patient side effects. Our review of the MAUDE database shows numerous cases of seemingly severe skin reactions to the Zio.
Diagnostic Yield	iRhythm pitches its significantly higher "diagnostic yield" versus Holter monitors. However, this is purely a function of longer wear period given the potentially infrequent occurrence of arrhythmias as opposed to any sort of superior detection or analysis capabilities (i.e., it is worn longer).
Form Factor	While the Zio Monitor form factor may compare favorably to some other products, we believe it is not always an apples-to-apples comparison because some competitive products may incorporate more leads for greater measurement accuracy, offer different product options for alternative clinical objectives, implement the telemetry capability differently (such as built-in cellular communications), or incorporate other sensing technologies.

Source: FDA Form 483 dated 7/31/24 (San Francisco), MAUDE database, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's References To Studies Such As CAMELOT Need To Be Qualified

iRhythm frequently references research, much of which it has funded, that it claims supports its assessments of product superiority and value-add. The 2024 CAMELOT study, in particular, is heavily touted. However, we believe the objective review of that study contained in the Aetna Clinical Policy Bulletin on Cardiac Event Monitors contains important qualifications and highlights some of the limitations of that study that investors should understand.

The Oft-Referenced CAMELOT Study Needs to be Qualified:
Excerpts From the Aetna Clinical Policy Bulletin on Cardiac Event Monitors

*"**The authors stated that these findings had several drawbacks**. **First**, the findings were observational and retrospective. This study was carried out in a sample of Medicare beneficiaries; results may not be generalizable to other populations, such as patients who are uninsured, enrolled in commercial or Medicare Advantage healthcare plans, or are aged less than 65 years. **Second**, the choice of ACM was decidedly not random and likely influenced by a number of patient, provider, and system factors, any of which could have served as confounders in this analysis. Although these investigators tried to account for clustering using hospital referral regions (HRRs) cross-walked from the patient's ZIP code, they did not have institutional identifiers to account for differences at the institutional level within the HRR. These researchers were unable to adjust for the duration of monitoring, as the actual wear time for monitors was not available in the claims beyond the minimum duration needed to meet the CPT code reimbursement criteria. **Third**, inherent limitations exist in the use of claims data. Identification of conditions was based on diagnosis codes which requires that they were actually coded. A recorded diagnosis code does not confirm the presence of disease, given that diagnosis codes may be recorded improperly or as a rule-out criterion. However, the authors would not expect disease coding or ascertainment to systematically differ across device types. **Fourth**, these researchers set the analytic start date using claims with CPT codes in part to facilitate the identification of device manufacturer with National Provider Identifier (NPI). The potential time-to-event bias was mitigated by examining only odds of encounter diagnosis yield and ACM re-testing through the 90- and 180-day post-index periods, respectively, rather than a time-to-event analysis. Due to different billing models, it was possible that some brand specific devices could be mis-classified as "LTCM other", although this was expected to be far less common in Medicare or other fee-for-service claims than in a managed care population. **Fifth**, although a difference-in-difference analysis could identify relative differences in utilization and cost trajectories, which was the objective of this analysis, the healthcare resource utilization (HCRU) and cost outcomes were unadjusted. **Sixth**, this study was not designed to examine the mechanism (mediator or moderator) of outcomes. For example, the authors did not examine non-ACM testing (e.g., electrocardiogram, cardiac imaging, stress test) on diagnostic yield, ACM retesting, or utilization. This area is ripe for further investigations."*

Red text for Spruce Point emphasis. Source: Aetna Clinical Policy Bulletin on Cardiac Event Monitors (last reviewed 7/22/2025)

Cardiologists We Surveyed Note Little Competitive Product Differentiation

Spruce Point conducted a proprietary survey of 100 practicing cardiologists regarding their use of cardiac monitors. About half the cardiologists we surveyed viewed cardiac monitors as commodity products, and even industry participants admit that there is little difference between the various suppliers' offerings. Also, 69% of surveyed cardiologists say switching suppliers is not difficult.

Spruce Point Cardiologist Survey Results Related to Product Commoditization and Switching Difficulty

Do you believe there is differentiation between the various monitors or are they a commodity?	
Commodity	48%
Differentiated	52%

Note: n=100

Generally speaking, how difficult would it be for you to switch between suppliers of monitors?	
Extremely Difficult	4%
Somewhat Difficult	27%
Neither Easy Nor Difficult	28%
Somewhat Easy	30%
Extremely Easy	11%

Note: n=100

Tegus Interview with Director at Philips Healthcare, 6/27/24	*"Well, I can give you the marketing answer or I can give you the clinical answer. The marketing answer is they are all very different and unique. Yes.* ***The real clinical answer is there is no difference, none whatsoever, especially in terms of the diagnostic yield, so sensitivity and specificity****."*

Our survey of cardiologists also found that most were already using various types of monitors from a number of different suppliers, likely making it even easier to change the source of these commoditized products.

Source: Tegus, Bloomberg, Spruce Point research

The Cardiac Patch Market Continues To See Competitive Entry

iRhythm competes with both large diversified medical device companies that can leverage broader product lines and institutional relationships as well as numerous smaller focused players and new entrants willing to price aggressively. Our cardiologist survey found that only 16% of iRhythm users solely use Zio products, suggesting low levels of sole sourcing.

Spruce Point Cardiologist Survey Results Related to Monitor Suppliers Used

Which suppliers do you use for mobile cardiac monitors?	
iRhythm Technologies	79%
Philips (Biotelemetry)	52%
Zoll Medical	47%
Boston Scientific (Preventice)	46%
Abbott	27%
Baxter (Hill-Rom, Welch Allyn, Bardy, Mortara)	20%
Biotronik	18%
VitalConnect	12%
ACS Diagnostics	8%
National Cardiac	5%
InfoBionicAI	3%
Other	6%
Note: n=100	

Other Suppliers:
- **Biotricity**
- **Cardiac Insight**
- **HeartBeam**
- **Rhythm Express**
- **Medicomp**
- **Medtronic**
- **TZ Medical**

Tegus Interview with Director at Philips Healthcare, 6/27/24

*"…**new competitors are coming in with more or less the same offering, but with lower prices**…You invested millions of dollars in generating [peer-reviewed articles], in doing the trials, in writing it and publishing it, and now, you're not emphasizing it very much [by referencing research as 'data on file']. Because any of these new guys, like Beat2Phone, CAM patch from Bardy, Bittium, can easily beat you by putting the same thing, data on filing, and reducing the price by 30%... I'm not saying that Philips is in this, **but the smaller ones are definitely very aggressive**, let's put it like this, or the newcomers."*

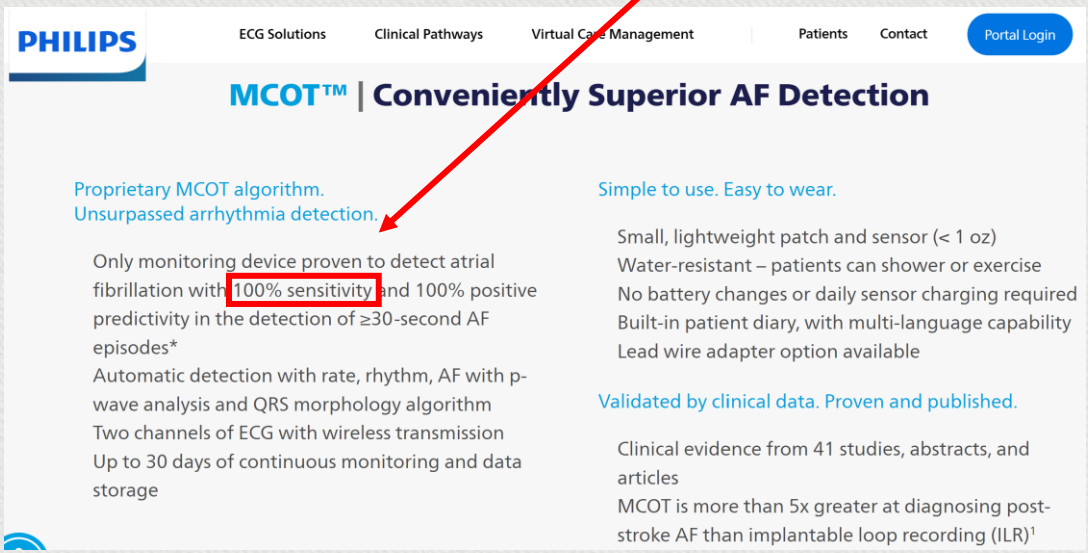
Source: Tegus, Spruce Point research

FDA Evidence Reveals The Zio AT Was Performing At Significantly Lower Sensitivity Than Competitors

While iRhythm frequently refers to its products as representing the *"gold standard"*, that clearly is not the case for the Zio AT. The 2024 Form 483 (San Francisco) revealed that the product breached its sensitivity threshold, delivering materially lower performance than the Philips MCOT device.

Excerpt From FDA Form 483 Dated 7/31/24 (San Francisco) vs Philips Stated MCOT Sensitivity

b) On 06/05/2024, you communicated a new plan/policy of analyzing algorithm functionality data to ensure your devices were performing to specified intended uses, and to determine malfunction reporting requirements under 21 CFR § 803, and you implemented this new plan/policy on or around 07/02/2024. The newly established sensitivity control limit for algorithm sensitivity was breached for the second quarter of CY 2024 in that the algorithm sensitivity rate for detecting Atrial Fibrillation cardiac arrythmia events was determined to be 88.710% (b) (4) the (b)(4)% control limit threshold. However, no corrective and preventive action or health hazard evaluation has been initiated, nor has a related risk analysis been performed. Additionally, you have not included all relevant data inputs for your (b) (4), therefore your resulting calculations are not an all-inclusive quality metric (see Observation 2).



Red box for Spruce Point emphasis. Source: FDA Form 483 dated 7/31/24 (San Francisco), Philips website

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's Discussion Of Its New MCT Device Makes It Sound Incremental At Best

As we show later, iRhythm management has a history of contradictory statements regarding the competitiveness of the Zio AT. Regardless, given the issues identified by the FDA and the hope for market share gain, investors have focused their attention on the coming 510(k) for iRhythm's new MCT device, which the Company expects to submit in Q3 2025. However, after reviewing management's statements, it isn't clear what all the hype is about. Consistent with our view that these products are commoditized and employ minimal "hard" technology, the new MCT product will have a smaller form factor, improve maximum wear period from 14 to 21 days, and still have the transmission limit issue. What about accuracy?

iRhythm Management Commentary About Its Next-Generation MCT Device	
iRhythm CEO Blackford at Goldman Sachs Conference, 6/10/25	*"**Where we've fallen short was on MCT**, right, with the Zio AT product. In our long-range plan, when we put those expectations out, we actually expected to have the new MCT product in the market about 2 years ago. So we're almost 24 months delayed from where we thought we were going to be."* *"Now we will, in our new MCT product, submit for **21-day** wear, which our market intel, market research, we've done a ton of it tells us we need to get beyond 20 days to truly address the entire market."*
iRhythm CEO Blackford at Morgan Stanley Conference, 9/4/24	*"You think about AT, one of the concerns that they had was this max transmission. Well, the new MCT has been designed in a way that **you will hit that in a much, much lower likelihood**, right?...**Skin irritation comes down**, which is another question they were asking us how quickly do we get from AT on to MCT."*
iRhythm CFO Wilson at Citi Conference, 12/4/24	*"And really, that's driven by Zio Monitor, our new form factor that is getting really good remarks in the field and certainly a better patient experience. **That form factor is 72% smaller than Zio XT, 55% lighter, better adhesive in terms of breathability and waterproofing**…Zio MCT will be on the same form factor that Zio Monitor is on…"*

Source: Bloomberg, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Do Not Believe AI Is A Source Of Material Differentiation In Cardiac Data Analysis

We acknowledge that cardiac data analysis is a terrific application for machine learning. It is data after all. And for that reason, just about every monitor supplier and numerous third-party data analysis companies have developed algorithms for detecting arrhythmias.

AI is Coming For iRhythm by Decoupling Results Analysis From Devices and Enabling Competitive Solutions

FDA has now cleared more than 1,000 AI models, including many in cardiology

Dave Fornell | *January 10, 2025* | *Cardiovascular Business* | *Artificial Intelligence*

The U.S. Food and Drug Administration (FDA) has now cleared more than 1,000 clinical artificial intelligence (AI) algorithms to be used commercially for direct patient care in the United States. Cardiology is No. 2 among all healthcare specialties with 161 FDA clearances; some of those are even approved for multiple specialties.

FDA clears new suite of ECG evaluation tools

Michael Walter | *September 03, 2024* | *Cardiovascular Business* | *Electrocardiogr...*

B-Secur, an Irish healthcare technology company funded by Orlando Health Ventures, announced that the U.S. Food and Drug Administration (FDA) has cleared its new suite of algorithms and analytics for evaluating electrocardiogram (ECG) data.

HeartKey Rhythm was designed to assess ECG results and provide heart teams with accurate, efficient data. It runs off the cloud if needed and can communicate with a variety of different existing platforms and devices.

FDA clears heart rhythm AI that turns smartphones into medical devices

Michael Walter | *July 24, 2024* | *Cardiovascular Business* | *Heart Rhythm*

FibriCheck, a Belgium-based healthcare technology company, has gained U.S. Food and Drug Administration (FDA) for its artificial intelligence-powered digital platform that uses smartphone cameras to obtain heart rhythm measurements.

FibriCheck's technology requires a patient to place their finger over a smartphone camera for 60 seconds, with no additional devices required. The company's algorithms then evaluate findings for signs of heart rhythm conditions such as atrial fibrillation (AFib).

Real-world validation of smartphone-based photoplethysmography for rate and rhythm monitoring in atrial fibrillation

Henri Gruwez , Daniel Ezzat , Tim Van Puyvelde , Sebastiaan Dhont , Evelyne Meekers , Liesbeth Bruckers , Femke Wouters , Michiel Kellens , Hugo Van Herendael , Maximo Rivero-Ayerza ... Show more

Author Notes

EP Europace, Volume 26, Issue 4, April 2024, euae065,

This study validated the performance of a PPG-based smartphone application to differentiate between sinus rhythm and AF in an uncontrolled, real-world setting. Photoplethysmography signals were acquired with the cameras of conventional smartphones using the FC application. The FC application automatically runs a machine learning algorithm that analyses PPG signals. The algorithm performance was excellent, with 98.3% sensitivity, 99.9% specificity, 99.6% PPV, and 99.6% NPV. Sufficient quality PPG could be obtained after a single measurement in 89.5% and increased to 96.6% upon repeated measurements (*Figure* 4). Clinicians utilizing PPG for

Validating scientific research.

Red box for Spruce Point emphasis. Source: Cardiovascular Business, Cardiovascular Business, Cardiovascular Business, EP Europace

How Can iRhythm Claim AI Expertise When It Seemingly Cannot Perform Basic Math Correctly?

The FDA Warning Letter is particularly insightful as an indictment of iRhythm's internal product development process and questionable data science capabilities. For example, the FDA found that iRhythm did not accurately calculate a key risk metric related to the potential frequency of patient injury.

Excerpts From FDA Warning Letter Dated 5/25/23 (CMS 643474)

FDA finds iRhythm miscalculated a key risk metric

"We reviewed your firm's response and concluded that it is not adequate. Your response states that your firm's process about when to escalate a CAPA to an HHE [health hazard evaluation] was not clear. As such, CAPA procedural updates were made, and training was performed. Specifically, you updated your CAPA to include the statement, "The issue will be assessed… [in accordance with the Health Hazard Evaluation Procedure], to determine if the criteria for an HHE has been met, and whether field action is required." Your firm also conducted an HHE for the Activation Time Mismatch error, as required by your CAPA procedures. In addition, your firm conducted several other HHEs. It is important that the HHE be performed in accordance with your firm's Risk Management SOP (00010) because the outcome of the HHE is used to determine some of your firm's corrective and/or preventative actions.[4] However, ***based on FDA's own calculations, these HHEs do not appear to be conducted in accordance with your Risk Management SOP (SOP0010). For example, when conducting HHE-[redacted], it appears your firm failed to properly calculate the probability of occurrence of the potential safety issue.[5] Your miscalculation underestimated the likelihood of someone being injured.*** *According to your updated CAPA procedure, the difference in the occurrence rating for HHE-[redacted] would have required an update to your risk documentation and the HHE shows that this was not selected. Further, when conducting HHE-[redacted], your firm failed to apply the Health Risk Table in your Risk Management SOP (SOP0010).[6]* ***This miscalculation is significant because this HHE procedure is used to assess whether or not you will initiate field action****."*

Red text for Spruce Point emphasis. Source: FDA Warning Letter dated 5/25/23 (CMS# 643474)

We View Insourced Data Analysis As A Major Threat To iRhythm

As we show later, cardiologists distrust final reports. To (1) improve accuracy, (2) achieve faster turnaround times, (3) optimize workflows, (4) reduce costs, and (5) leverage increasingly available machine learning technology, cardiology practices are increasingly evaluating the merits of bringing the patient data analysis and reporting activities in-house. We believe this creates a major threat to iRhythm, as taking away the data analysis function reduces the Company to a supplier of commodity products.

Overview of Mayo Clinic Cardiac Monitoring Services: Seemingly Superior to the iRhythm Solution?

Key Elements of the Mayo Clinic Cardiac Monitoring Solution

- Uses the InfoBionic.Ai mobile cardiac telemetry monitor, which is wearable for up to 30 days
- The monitoring platform can be customized by each prescribing physician with personalized alert criteria
- Enables physicians to end service early as soon as clinical diagnosis can be made *"because prolonged monitoring is detrimental to patient care"*
- **Uses in-house Mayo Clinic certified rhythm analysis technicians**
- Alerts are accompanied by a link to the web-based monitoring portal, where physicians can view live monitoring strip data
- Speeds final report generation to within days of monitoring completion

There is a Valid Case For In-Sourcing the Reporting Function:
Excerpt From the Diagnostic and Interventional Cardiology (DAIC) Blog: *Rethinking Traditional ECG Outsourcing*

"Due to staffing shortages and other logistics challenges at IDTFs, ***results reporting can take many days, weeks, or even more than a month before physicians receive patient results****. Diagnostic delays, patient data breaches and fragmented care are often the undesired effects of outsourcing ECG services. Thanks to recent innovations in automated ECG analysis algorithm technology,* ***providers can now bring long-term ECG patch data analysis and draft reporting entirely in-house, streamlining the process and reducing overall time to patient diagnosis. 'Insourcing' rather than outsourcing ECG services can also reduce operational costs and maximize reimbursement for providers****."*

Decoupling the provision of the monitoring device from real-time cardiac event supervision and report preparation would dramatically alter the economics of iRhythm's business, as it would likely result in reduced revenue and effectively relegate the Company to simply supplying a largely commoditized patch product.

Source: Mayo Clinic website, DAIC blog

SPRUCE POINT CAPITAL MANAGEMENT

We Believe iRhythm Acknowledged The Issue Of Data Analysis Insourcing For The First Time On Its Q2 Call

We believe iRhythm management has touted the MCT opportunity for years without clearly acknowledging the risks and addressable market limitations presented by insourced data analysis. Thus, we assume it was "new news" when CEO Blackford commented that about 20% of the MCT market is not addressable by iRhythm since the providers do the data analysis internally. Blackford dismissed it as an issue of "*product market fit*" for that segment of the market, yet we believe it is much more significant: (1) the Company admitted that the MCT addressable market is smaller than many investors may have previously anticipated, and (2) iRhythm is poorly positioned to address such portions of the market. As important is what Blackford did not mention: (1) whether the trend towards insourcing is increasing (we believe it is), and (2) whether insourcing of MCT data analysis could result in insourcing of LTCM results analysis (we believe it will). We believe investors should not dismiss this foreshadowing of a material threat to iRhythm's business.

CEO Blackford Finally Acknowledges Negative MCT Market Dynamics Related to Insourcing

iRhythm CEO Blackford on Q2 2025 Earnings Call, 7/31/25	*"But I also think as we learn more about the AT -- or sorry, the MCT market,* ***there's probably 2 markets within MCT****. There's what we call sort of the buy and build market where customer accounts are buying the device directly from competitor of ours. They put it in their clinic.* ***They're doing the interpretation, the reading right there in clinic, downloading the data. We don't offer that sort of business model.*** *And Zio MCT is something that we're going to have to continue to evaluate how we address that segment of the market.* ***I think that's probably 20% or so of the entire MCT market that we're still probably going to have to think through the right product market fit for how we get after that segment of the market.*** *But there's still 80% of that MCT market that our MCT product, new MCT product is going to go squarely at and I think going to have tremendous success within it."*

We believe CEO Blackford just informed investors that the Company's widely assumed easiest source of growth, increasing share in the existing MCT market, holds at least 20% less potential than previously believed.

Source: iRhythm Q2 2025 earnings call transcript, Spruce Point research

There Are Already Numerous Multi-Sensor Solutions On The Market

iRhythm made a minority investment in BioIntelliSense in 2024 to expand its portfolio of sensor technologies in order to address additional indications, sleep apnea in particular. Despite touting this application as a potential long-term growth opportunity, other companies seem to have already beaten the Company to the punch. In addition, we note that one inherent advantage of smartphone-paired devices is the ease with which they can add additional apps to target new indications.

New Multi-Sensor Product Targeting Cardiac and Sleep Health Supported by Research

Huxley Medical Announces FDA Clearance for Cellular-Enabled SANSA Home Sleep Apnea Test

HUXLEY

Feb 05, 2025, 11:30 ET

SANSA's initial FDA clearance in 2024 validated accuracy against gold-standard polysomnography in a 340-patient clinical trial conducted at seven institutions. The test uniquely combines nine physiological channels—including oximetry, respiratory effort, sleep/wake staging, and a reference electrocardiogram (ECG)—into a single chest-worn patch, enabling expanded insights into cardiopulmonary health.

Multidiagnostic chest-worn patch to detect obstructive sleep apnea and cardiac arrhythmias

Cathy Goldstein, MD, Hamid Ghanbari, MD, Surina Sharma, MD, Nancy Collop, MD, Zak Loring, MD, MHS, Colleen Walsh, Brennan Torstrick, PhD, Emily Herreshoff, Mark Pollock, MD, David S. Frankel, MD, Ilene M. Rosen, MD, MSCE

Published Online: May 1, 2025 • https://doi.org/10.5664/jcsm.11522 • Cited by: 3

RESULTS: SANSA's sensitivity and specificity to detect obstructive sleep apnea ranged from 91–97% and 78–97%, respectively, across all severity levels. SANSA total sleep time correlation with consensus polysomnography total sleep time was 0.83 with a mean difference of 3.8 minutes (limits of agreement: −91.1 to 98.7). Significant arrhythmias were detected in 32% of participants. These participants had a greater apnea-hypopnea index (27.5 vs 15.8 events/h, $P = .003$) and spent nearly twice as long at reduced oxygenation levels (47.5 vs 20.5 minutes under 88% oxygen saturation, $P = .009$).

CONCLUSIONS: SANSA is a promising tool for comprehensive obstructive sleep apnea evaluation, offering the unique advantage of concurrent arrhythmia detection. This dual functionality may improve patient outcomes through early diagnosis and management of both conditions.

As we note later, the Apple Watch sleep apnea monitor received FDA approval in September 2024.

Multi-Sensor Product Developed by Vivalink

Comprehensive Data Parameters Captured by Vivalink's Wearable Cardiac Monitor

- ECG rhythm
- Heart rate
- Heart rate variability
- RR-interval
- Respiratory rate
- Skin temperature
- Step count
- Posture
- 3-Axis accelerometer

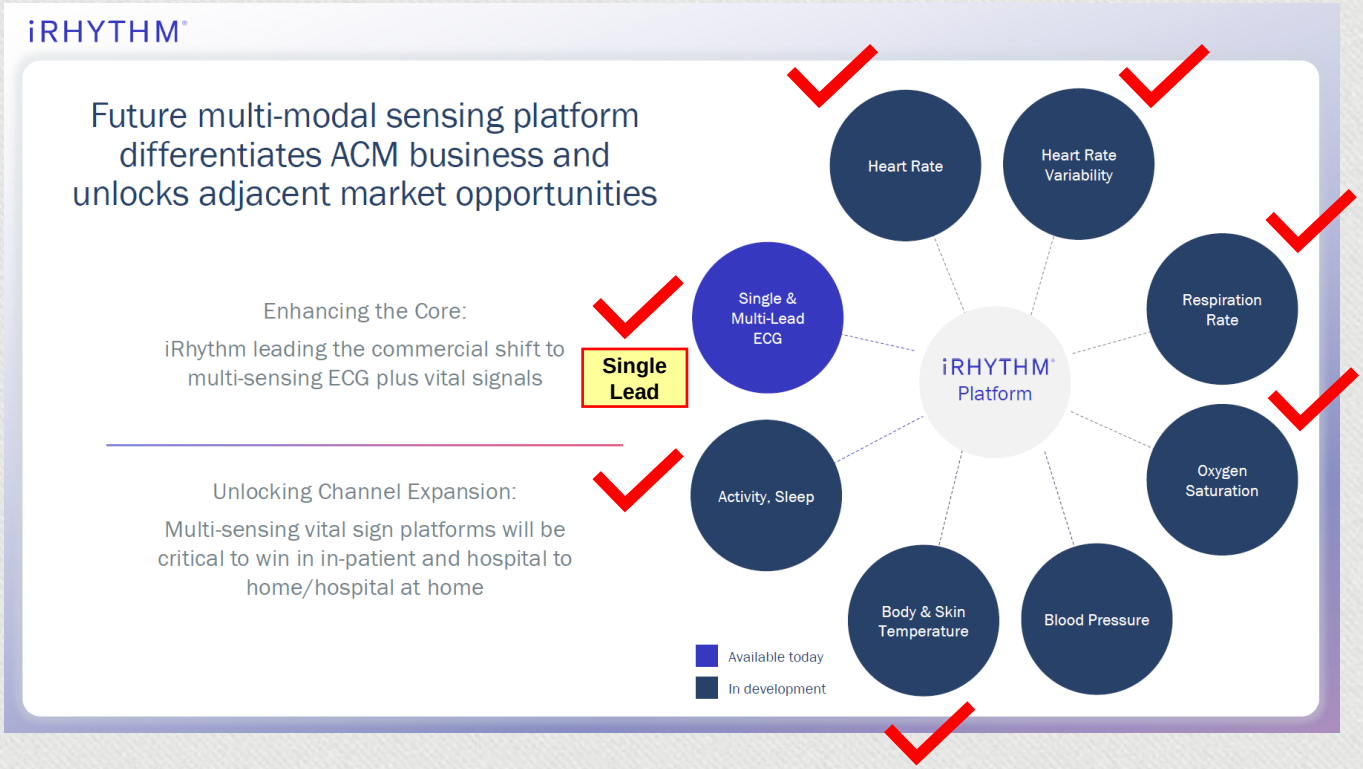
Source: Huxley Medical press release, Journal of Clinical Sleep Medicine, Vivalink

We Believe The iRhythm Vision Of Multi-Sensor Zio Patches Is Already Obsolete

We believe investors should be skeptical of iRhythm's vision of adding additional sensor capabilities. Doing so would inevitably increase its costs, damaging a key selling point. Regardless, multi-sensor solutions are already on the market. As we discuss later, a breadth of consumer devices already combine most of these capabilities into a singe device.

The Apple Watch Already Offers Seven of the Eight Sensor Capabilities on iRhythm's "Roadmap"

Functionality Available on Apple Watch



Red check marks for Spruce Point emphasis. Source: iRhythm William Blair Conference presentation 6/4/25

SPRUCE POINT CAPITAL MANAGEMENT

This Doesn't Sound Like A Company Investing For Innovation And Growth

We find it surprising that employees on Glassdoor have commented about recent layoffs in iRhythm's engineering organization given the Company's representation of its new product development activities. Given the Company's lackluster history of new product development, we do not believe this bodes well for innovation and growth.

Recent Glassdoor Commentary From iRhythm Employees	
Product Designer, iRhythm, Glassdoor, 3/31/25	*"All in all, the layoff was a blessing in disguise.* ***The decision to lay off so many designers and researchers (more than 50%) shows me how much they do not care about design or research…Please investigate the ethical standards of your upper management****."*
Product Designer, iRhythm, Glassdoor, 1/21/25	*"The company had multiple org changes and company layoffs.* ***We went from a 20 people research/design team to a 10 person team to a 5 person team****."*

Source: Glassdoor

We Have Grave Concerns About Patient Data Analysis At iRhythm

SPRUCE POINT CAPITAL MANAGEMENT

The FDA Shows That iRhythm Knew Of Thousands Of Complaints Regarding The Misreading Of Zio AT Data But Failed To Take Action

In its Form 483 (San Francisco) dated 7/31/24, the FDA clearly states that iRhythm failed to properly analyze over 4,000 complaints related to recurring quality issues involving the misreading and/or misclassification of data used for diagnostic purposes. The FDA detailed the ways that iRhythm sought to conceal these complaints and their implications for patient safety.

Excerpts From FDA Form 483 Dated 7/31/24 (San Francisco)

FDA finds over 4,000 complaints related to the accuracy of its data analysis and reporting

*"…your firm received approximately 4,014 complaints related to your Certified Cardiographic Technician (CCT) personnel operations from 05/02/2022 to 07/19/2024, **including issues/ events related to CCT personnel misreading arrhythmia data and providing such misclassified data to end users for diagnosis purposes**."*

FDA finds that iRhythm failed to investigate the complaints

*"You also have **not initiated any corrective and preventive actions to investigate the cause or identify the action(s) needed to correct and prevent recurrence of this quality problem**…You have not evaluated the risk associated with your Certified Cardiographic Technician (CCT) personnel operations to ensure that your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices conform to defined user needs and intended uses."*

FDA notes that iRhythm failed to submit MDR reports despite the potential for patient death

*"you **routinely do not report required information** after becoming aware of events that allege your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices have malfunctioned and **would be likely to cause or contribute to a death or serious injury**, if the malfunction were to recur."*

We believe it is damning that iRhythm failed to submit MDR reports related to an issue that could cause patient deaths given that MDR reporting failures were already an FDA criticism in its 2023 Warning Letter. Collecting, analyzing, and remediating complaints is one of the most fundamental activities of any medical device company.

Source: FDA Form 483 dated 7/31/24 (San Francisco)

SPRUCE POINT CAPITAL MANAGEMENT

Equally Alarming Are Subsequent Revelations Suggesting Broader Systemic Issues At iRhythm

As referenced in a pending shareholder lawsuit (Glazing v iRhythm), following iRhythm's receipt of the additional Form 483s in July 2024, Capitol Forum revealed that former employees of iRhythm accused the Company of directing them to delete patient data from its final reports that was not transmitted (and thus subject to physician notification) during the wear period. If true, this would have deprived physicians of potentially important information used to diagnose their patients' cardiac health.

Excerpts From Glazing v iRhythm Second Amended Complaint

*"Alarmingly, **the Capitol Forum's interviews with former iRhythm CCTs revealed that the Company was directing and training CCTs to provide inaccurate reports to patients and doctors in order to make the final report "match" the reporting transmitted during the wear period**. The report stated, 'Both former iRhythm CCTs said that they were often countermanded by iRhythm when they identified cardiac events that would [have] been classified as arrhythmias at other companies and tried to include them in final reports.' These final reports were issued to doctors once the patient's wear period had ended. One of the CCTs observed that "**we were told that it is 'important that the final report match what the patient experienced during wear time**.'" Thus, if the CCT found "a life-threatening arrhythmia while doing the final report, and said lifethreatening arrhythmia was not found during the wear time . . . I do not mention the life threatening arrhythmia I found on the final report the doctor sees."*

*"According to FE 3, **the Company wanted to show doctors very "clean" reports instead of "ugly" reports because the Company wanted to maintain the appearance that the Zio AT gave perfect data every time**. When a report was "ugly," **technicians were sometimes instructed to "artifact" the data in question—which resulted in deletion of the data, and it would never be seen by the patient's physician in the final report**. Whenever FE 3 asked about a questionable arrhythmia, FE 3 was told not to "post" it for the physician's review. FE 3 stated that providing "cleaner" reports to physicians was prioritized over simply providing the information to the physician for the physician's evaluation."*

"One of the CCTs further explained, "There would be times when during the final report, myself or others would find what we consider to be 3rd degree or complete heart block (for example). We would include it in the final report only for QA leadership to downplay it and say, "That is not complete heart block. That is only first degree with non-conducted pvc,"a much less non-life threatening rhythm."

Source: Glazing v iRhythm second amended complaint (Case No. 3:24-cv-706-JSC document 43)

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Used Its Own Definition Of Its "Product" To Understate Patient Safety Issues To Investors

On the Company's Q2 2024 earnings call during which it first disclosed the receipt of additional Form 483s, CEO Blackford disclosed a core disagreement between iRhythm and the FDA: whether or not the post-wear results analysis and the CCTs who perform/validate that work are "part of the product" being offered. We believe the implications for iRhythm's historical compliance are huge.

Excerpt From iRhythm Q2 2024 Earnings Call Discussing iRhythm's Disagreement With the FDA

iRhythm CEO Blackford on Q2 2024 Earnings Call, 8/1/24	*"…**I think the fundamental issue sort of comes down to whether the IDTF, the CCTs, if you will, the clinical technicians, are they part of the product or are they not? And I think from the beginning of time, we view those as separate items. And I think the FDA has a bit of a different perspective right now that we're working through.** But when you start to think about those 2 things differently, meaning ourselves versus how the FDA may be looking at it, **you start to land in different places, when it comes to complaint handling or reporting or process controls and how you document those controls or how you go about your statistical techniques**. I think it's important to note, like, **there is no conversations in here with the FDA in the course of these inspections around the overall safety or efficacy of our product**."*

We are troubled by Blackford's framing of the issue. The FDA clearly identified life-threatening issues with iRhythm's post-wear results analysis, that CCTs were misreading arrhythmia data. However, because iRhythm did not view these activities as part of its "product", Blackford characterized the Form 483 as not related to product safety. Blackford failed to communicate that the FDA clearly viewed the issues it identified as related to product safety. Viewed another way, iRhythm effectively ignored 4,000 complaints that, among other things, called into question the accuracy of the data it was providing to physicians. Blackford has repeatedly stated or implied that the FDA is trying to "figure out" how it wants to regulate products in the MCT market. The FDA seems to know exactly how it wants to regulate them: the way that best ensures patient safety. That just happens to be inconsistent with the way iRhythm was apparently managing its business. We believe this issue opened an enormous can of worms, as Blackford effectively admitted that iRhythm had not viewed these activities as subject to the same regulatory oversight as the FDA did. This is particularly troubling in light of the various other operational issues that have surfaced around these operations.

Source: iRhythm Q2 2024 earnings call transcript

SPRUCE POINT CAPITAL MANAGEMENT

We Believe iRhythm's Contention That Patient Data Analysis Is A Separate Product Was A Stretch

We believe iRhythm's position that patient data analysis is NOT part of its "product" is difficult to justify and irresponsible. Patient data analysis and provision of a final report to physicians has always been characterized as part of the iRhythm "solution". Moreover, iRhythm's revenue recognition disclosure clearly states that delivery of the final report is the "final step" in its Zio Services and is the point at which the Company bills its customers.

Excerpt From iRhythm IPO Prospectus

Our Solution

Our patented ZIO Patch is a patient-worn biosensor that captures ECG data continuously for up to 14 days. Patients also have the ability to mark when symptoms occur while wearing the ZIO Patch by pressing a trigger button on the device and separately recording contextual data like activities and circumstances in a symptom diary. This allows physicians to match symptoms and activity with ECG data. Following the wear period, the ZIO Patch is returned and data is uploaded to our secure cloud and run through our proprietary, machine-learned algorithms. A concise report of preliminary findings is prepared by our certified cardiac technicians and made available to physicians electronically.

At least as it regards iRhythm's leading Zio Monitor product, it is rendered completely useless without the analysis of patient data.

Excerpt From iRhythm 2024 10-K

"The Zio Monitor System is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. ***The final step in the Zio Services is the delivery of an electronic Zio report to the prescribing physician with a summary of preliminary findings. Our Zio Monitor services are generally billable when the Zio report is issued to the physician****."*

Red box for Spruce Point emphasis. Source: iRhythm 424B filed 10/20/16, iRhythm 2024 10-K, Spruce Point research

Medical Device Regulatory Consultants We Spoke With Were Critical Of iRhythm's Position When Opining On The Company's Actions

We spoke with two medical device regulatory compliance consultants, both of whom believed that, in their opinion, iRhythm's failure to report complaints was indefensible. We believe capturing, tracking, and analyzing complaints to inform assessments of product safety are one of the most fundamental quality control activities of any medical device company.

Regulatory Compliance Consultant Answers to the Question: *"Was iRhythm's Contention That the Results Analysis Activity is NOT Part of Its Product a Credible Position or Should They Have Known Better?"*

Spruce Point Interview with Medical Device Regulatory Consultant, June 2025	*"**They should have known better**. I don't know if it fringes on gross negligence, but I still see it to this day. Even though the FDA has been talking about outsourcing contract operations for a long time…**it's still your responsibility**. So, they should have known better. And **that takes me back to who's running the shop and what's their background, how do they not know, why are they thinking this?** There's always a why; sometimes you might never know what that why is, but **something's off**."*
Spruce Point Interview with Medical Device Regulatory Compliance Consultant, June 2025	*"**So those should have been reported because if it relates to a diagnosis, that tells you that the product is not safe and effective. If the diagnosis is incorrect, that person can be treated inappropriately**…In this case, like I said, all I have really to make my interpretation and my opinion is reading the 483, which appears to be very well documented…**They should have looked at that because the regulations are real clear**, if you go back and read them, they'll tell you what to report… And because they didn't report it, they didn't track it to see how many different complaints they were getting. And in this case, **I would've attacked this right now, if it was my company, I would've attacked that and said, we need to investigate this because you can't have CCT personnel misreading our data.**"*
Tegus Interview with Regulatory Consultant, 2/25/25	*"Now, the fact that companies don't review complaints for MDRs is **sloppiness in how they have their quality system set up** because when we set up quality systems, we have a check off on every complaint if it was MDR-reportable. **It's that easy to do**."*

Source: Tegus, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Employee Commentary On Glassdoor Suggests Results Analysis Quality Issues Are Endemic

Glassdoor commentary primarily from cardiac technicians suggests quality concerns have persisted for years and remain cause for concern. Employees highlight concerns around (1) heavy workloads negatively impacting reporting quality, (2) a general lack of care regarding patient safety, and (3) the implications of continued outsourcing of reporting personnel overseas.

iRhythm Employee Commentary on Glassdoor	
Cardiac Technician Trainer, iRhythm, Glassdoor, 5/6/25	*"Most positions have been or will be outsourced. **Most quality managers have been driven off**."*
Cardiac Monitor Technician, iRhythm, Glassdoor, 1/14/25	*"Everyone in management is responsible for the high turnover, **unrealistic goals and the QA process is a joke**, If you want overwhelming loads work and stress this is the company to be at."*
Anonymous Employee, iRhythm, Glassdoor, 12/19/24	*"**Rushed, unrealistic goals causing many quality issues**…End the secrecy, end the lies, and treat people with the decency and respect they deserve."*
Patch Technician, iRhythm, Glassdoor, 12/16/24	*"**Go big and go fast does not work when it comes to patient care.**"*
Cardiac Technician, iRhythm, Glassdoor, 7/13/24	*"**They forgo quality for quantity**…They Keep **outsourcing jobs to India/foreign countries** and getting rid of jobs in the US."*
EKG Technician, iRhythm, Glassdoor, 5/10/24	*"When the new CEO and his former employees came in, things seemed great at first. Over time the company lost what it was founded on. **Quality before productivity went out the door**."*

Source: Glassdoor

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Employee Commentary On Glassdoor Suggests Results Analysis Quality Issues Are Endemic (Continued)

iRhythm Employee Commentary on Glassdoor (Continued)	
EKG Technician, iRhythm, Glassdoor, 4/2/24	*"They also **push you to crank out numbers, and patient safety is not a concern** at this place. **There have been missed critical rhythms because people are just burnt out and exhausted**. Run from this place as fast as you can. **If you don't get fired the FDA will probably investigate you for even working here**."*
Finance Employee, iRhythm, Glassdoor, 3/13/24	*"**Outsourcing to Philippines was a very bad business investment**."*
Engineer, iRhythm, Glassdoor, 2/25/24	*"when you actually see how management is trying to execute **the action plan is more concerning**…**Ethics violation complaints are not taken seriously**, we got a warning letters and multiple 483 observations, and nothing happen within our quality department, instead they promoted people and started to push more changes that make no sense that can actually affect more the business than before."*
Senior R&D Engineer, iRhythm, Glassdoor, 2/16/24	*"**Failure to follow international regulations** - the organization received multiple correspondence from agencies to fix their processes. Although a small group of people are working toward this, **the majority of the team has no idea what is going on and refuses to change their behavior**."*
Advanced Patch Technician, iRhythm, Glassdoor, 12/26/23	*"iRhythm likes to tout itself as a company that values their employees and puts patient care above all else, but quite frankly, their bottom line is money. **They could not care less about patients**…**Their new motto is "work faster"**, but one must ask themselves, would you want your EKG read fast or read accurately?...**They're outsourcing everything to India and the Philippines**…**The turnover is also alarmingly high**. In the year and a half I've worked at iRhythm more than HALF of the techs on my team have left. It is truly a revolving door."*

We are unable to reconcile repeated employee references to outsourcing with iRhythm management's numerous statements regarding hiring CCTs for its "Center of Excellence" in San Francisco.

Source: Glassdoor

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Touts Its Use of AI To Analyze Patient Data, Yet The FDA Identified Accuracy (And Competency) Issues

iRhythm claims it has developed *"proprietary artificial intelligence, including a deep-learned neural network model"* to analyze patient data and frequently references the Company's past involvement with renowned AI researcher Andrew Ng. However, the 2024 FDA Form 483 (San Francisco) revealed that the Company's internal analysis misstated the accuracy of its algorithm.

Excerpts From FDA Form 483 Dated 7/31/24 (San Francisco)

b) On 06/05/2024, you communicated a new plan/policy of analyzing algorithm functionality data to ensure your devices were performing to specified intended uses, and to determine malfunction reporting requirements under 21 CFR § 803, and you implemented this new plan/policy on or around 07/02/2024. The newly established sensitivity control limit for algorithm sensitivity was breached for the second quarter of CY 2024 in that the algorithm sensitivity rate for detecting Atrial Fibrillation cardiac arrythmia events was determined to be 88.710%, (b) (4) the (b)(4)% control limit threshold. However, no corrective and preventive action or health hazard evaluation has been initiated, nor has a related risk analysis been performed. Additionally, you have not included all relevant data inputs for your (b) (4), therefore your resulting calculations are not an all-inclusive quality metric (see Observation 2).

It's easy to claim your algorithm is accurate when the data used to evaluate its accuracy excludes mistakes. We believe these failures of simple data analytics (far short of anything approaching AI) reflect poorly on iRhythm's internal capabilities and external motivations.

b) You have not included all relevant data inputs for your (b) (4), therefore, it is not an accurate or all-inclusive quality metric. False positive arrythmia events, as well as duplicated algorithm miss events are not included as data input sources for your (b) (4), which you use for algorithm functionality monitoring.

For example,

a. Complaint COMP-2024-8814 created 05/04/2024, Z ticket number (b) (4), and the Visual Timeline document referencing device serial number (b) (4), document that the Zeus System Software medical device misinterpreted/misread the cardiographic data as a Superventricular Tachycardia arrythmia event during patient wear, although it was later confirmed by a CCT to be an Atrial Fibrillation arrythmia event. This algorithm misread event was not included as a data input for your (b) (4) quality metric, dated 01/01/2024-06/30/2024.

b. Complaint COMP-2024-13230 created 06/24/2024, and Z ticket number (b) (4), referencing device serial number (b) (4), document that the Zeus System Software medical device did not detect a Ventricular Tachycardia cardiac arrythmia event during patient wear. This algorithm misread event was not included as a data input for your (b) (4) quality metric, dated 01/01/2024-06/30/2024, due to other Ventricular Tachycardia cardiac arrythmia events being accurately reported during patient wear.

Excerpt From Glazing v iRhythm Second Amended Complaint

"One of the CCTs…recalled that the 'Zio AT has only a single lead, meaning you only get a very narrow view of the heart,' whereas many fellow iRhythm CCTs with previous experience 'found that… ***a regular Holter monitor [has] six leads and gives a much better read of cardiac activity****.' One of these former CCTs 'found* ***missed arrythmias that were not reported to cardiologists in 100% of final reports they analyzed****, which they blamed on the technical limitations of the Zio AT and iRhythm's processes for classifying arrhythmias.'…Thus, the 'initial* ***reports could be inaccurate and require massaging*** *before being submitted to cardiologists.'* ***This CCT stated, 'I found the reports to be inaccurate and alarming as a technician.'****"*

Red box for Spruce Point emphasis. Source: FDA Form 483 dated 7/31/24 (San Francisco), Glazing v iRhythm second amended complaint (Case No. 3:24-cv-706-JSC document 43)

SPRUCE POINT CAPITAL MANAGEMENT

Our Survey Of Cardiologists Found Little Value Placed On AI Or Perception Of Differentiation

In our survey of 100 cardiologists, two-thirds of the respondents stated that the use of AI made no difference or made them less likely to trust a supplier's final report. Moreover, despite iRhythm's efforts to market its AI capabilities, 70% of respondents thought iRhythm monitors were as accurate or less accurate than others. Moreover, as we discuss later, most cardiologists do their own analysis of the raw cardiac data, both because they do not trust the final reports provided by monitor suppliers and because they are the ones ultimately responsible for an accurate diagnosis.

Spruce Point Cardiologist Survey Results Related to the Use of AI and Final Report Accuracy

Does the use of artificial intelligence make you more likely to trust the results in the supplier's final report?	
More Likely	34%
The Same	62%
Less Likely	4%

Note: n=100

In your experience, are iRhythm reports of results more or less accurate than those of others?	
More Accurate	19%
The Same	66%
Less Accurate	4%
I Don't Know	11%

Note: n=100

AI does not seem to garner much physician trust or perception of accuracy.

Source: Spruce Point research

Importantly, iRhythm's Claims Of "99% Physician Agreement" Seem Unsupportable

In our cardiologist survey, 66% to 69% of physicians disagreed with the monitor final report more than 20% of the time. Recognizing our survey has a small sample size and physicians indicated use of multiple brands of monitors (notwithstanding iRhythm's ~70% market share), this makes us question the veracity of iRhythm's claims of *"99% physician agreement"* with its final reports.

Spruce Point Cardiologist Survey Results Related to the Use of AI and Final Report Accuracy

What percent of time would you estimate you disagree with the findings in the final report? (Extended wear monitors, iRhythm users only)	
Less Than 10% of the Time	31%
Between 10-20% of the Time	45%
Over 20% of the Time	24%

Note: n=80

What percent of time would you estimate you disagree with the findings in the final report? (Telemetry monitors, iRhythm users only)	
Less Than 10% of the Time	34%
Between 10-20% of the Time	45%
Over 20% of the Time	21%

Note: n=77

While generally in line with non-iRhythm users, we are surprised by the high level of physician disagreement, particularly given iRhythm's claims of *"99% physician agreement"*.

Excerpts From iRhythm Investor Presentations

From September 2022 investor day presentation, sourced as only "Data on File"

From October 2024 investor presentation, with no source provided

Red underline for Spruce Point emphasis. Source: iRhythm September 2022 investor day presentation, iRhythm October 2024 investor presentation, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Believe Investors May Be Underestimating The Risks Associated With iRhythm's CCT Offshoring

iRhythm must perform monitor results analysis for Centers for Medicare & Medicaid Services (CMS) patients at Medicare-enrolled independent diagnostic testing facilities (IDTFs) that must meet certain performance standards. Based on the Company's comments and our review of Glassdoor commentary, iRhythm has been aggressively offshoring a number of administrative and service delivery functions to both a third-party contractor in India and the Company's owned operations in the Philippines. In its press release announcing a settlement agreement with BioTelemetry regarding CCT offshoring, the Department of Justice noted the company had *"improperly billed Medicare and other federal health care programs for certain cardiac monitoring services — including Holter, event monitoring, and mobile cardiovascular telemetry (MCT) tests — that were performed overseas in violation of federal law that prohibits payment for services furnished outside the United States."* In the Company's SEC filings, iRhythm includes risk factor disclosures related to such potential issues. We note that their disclosures (1) seem to suggest that its overseas facilities are not qualified as IDTFs given the sentence *"Our facilities in Illinois, California, and Texas are enrolled in the Medicare program as IDTFs"*, and (2) the Company only added additional detailed risk factor language regarding billing for tests performed overseas after the BioTelemetry settlement was announced.

Excerpt From iRhythm 2024 10-K
(Text Added in 2023 10-K Highlighted)

"…only recently has CMS initiated changes to the regulations to address IDTFs like iRhythm that furnish "indirect tests" that do not require in-person interaction and involve technicians performing computer analyses offsite or at another location. ***The changes, however, do not address all gaps identified by CMS relating to IDTF operations and the Medicare billing requirements. For example, CMS has not addressed billing for remote diagnostic tests that are performed from one or more IDTF or other remote locations.*** *Our failure to comply with the applicable Medicare regulations, or regulators' disagreement with our interpretation of the regulations as applied to indirect tests, such as the Zio Services, could result in the discontinuation of our reimbursement under the Medicare program, a requirement to return funds already paid to us, civil monetary penalties, criminal penalties, and/or exclusion from the Medicare program."*

Source: iRhythm 2024 10-K, Spruce Point research

Cardiologists We Surveyed Indicated Material Unease With Offshored Results Analysis

Our survey of cardiologists uncovered material unease with the prospect of results analysis being performed outside the U.S. Interestingly, over 80% of these physicians were current users of iRhythm products, suggesting that continued outsourcing overseas could eventually catch up with the Company as the existence of these operations becomes better known.

Spruce Point Cardiologist Survey Results Related to Outsourcing and/or Offshoring Results Analysis

Does it matter to you if the supplier report is compiled by technicians located outside the US, such as India or the Philippines?	
Yes	**28%**
No	**72%**
Note: n=100	

Commentary

- *"Concerns about training of those individuals"*
- *"Because differences in training standards, time zone challenges, data privacy regulations, and communication barriers can affect report accuracy, turnaround time, and overall quality."*
- *"I prefer techs to be located in the US, as it improves turn around time and communication is easier."*
- *"Training standards are different"*
- *"Prefer US standards and training"*
- *"outsourced "technicians" cannot be verified that they are giving correct information.* ***most doctors mistrust outsourced information especially from these 2 countries****. it is only cheap labor. information must be from US source where there are standards."*
- *"Need to trust results. Don't know standards in those countries"*
- *"Quality clearly worse"*
- *"Would be worried about quality control"*
- *"Because I am concerned about quality control"*
- *"Reliability issues outside USA"*

Source: Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Question Whether iRhythm Has Accurately Characterized Its CCT Operations In The Philippines

On multiple occasions, iRhythm management has characterized its operation in the Philippines as its "Global Business Services Center" that is largely focused on back-office functions as opposed to clinical operations such as patient data analysis using CCTs, which carries some level of customer and regulatory risk if performed offshore. However, when we analyzed LinkedIn profiles, we found 180 iRhythm employees in the Philippines, 70 of which are CCTs and another 13 of which are seemingly in clinical operations. We believe that 39% of employees operating as CCTs is not consistent with what the Company has communicated. We find this inconsistency troubling given the related risks.

iRhythm Management Commentary Regarding Philippine Operations

iRhythm CEO Blackford on Q3 2023 Earnings Call, 11/2/23	*"…we are also thrilled to announce the formal opening of our Global Business Services Center in Manila that took place during the third quarter…**our Manila team now includes almost 150 team members, who are part of iRhythm's global clinical operations, customer care, finance, human resources, information technology, and revenue cycle management functions**."*
iRhythm CEO Blackford on Q4 2023 Earnings Call, 2/22/24	*"The Philippines, we set up that Global Business Services Center **really focused on the back office more so than the clinical ops function, if you will, right? So think about that as finance, HR, IT, customer care, leveraging a bit of outsource capabilities there**. But that's really the intent of the Global Business Services Center…"*

Spruce Point Analysis of iRhythm Philippines LinkedIn Profiles by Job Function

Function	Headcount	Pct. of Total
Clinical Operations		
CCTs	70	39%
Healthcare Professional (Generic)	7	4%
Healthcare Specialist (Respiratory)	6	3%
Sub-Total	83	46%
Customer Operations		
Customer Billing	14	8%
Quality / Compliance	8	4%
Customer Care	5	3%
Sub-Total	27	15%

Function	Headcount	Pct. of Total
Internal Operations		
Human Resources and IT	21	12%
Finance	17	9%
Executive and Managers	13	7%
Operations	5	3%
Sub-Total	56	31%
Other or Not Disclosed	14	8%
Grand Total	180	

Source: iRhythm Q3 2023 earnings call transcript, iRhythm Q4 2023 earnings call transcript, LinkedIn, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Believe It Is Possible That iRhythm Used Unqualified Personnel To Interpret Patient Data

In the Company's 2024 10-K, iRhythm states that after the patient wear period ***"each report is then validated by qualified technicians"*** and that its ***"technicians also notify physicians of potential urgent arrhythmias according to the ordering physician's specified notification criteria."*** However, one vendor iRhythm has used for these services, Techindia Infoway, was found to misrepresent the qualifications of nearly all its "cardiac technicians". Thus, we believe it is possible that iRhythm patient data was also interpreted by unqualified personnel. It remains unclear if iRhythm also billed Medicare and other federal healthcare programs for cardiac monitoring services performed overseas in violation of federal law that prohibits payment for services furnished outside the United States, yet the Company has clearly demonstrated it viewed these operations as not subject to the full weight of regulatory oversight governing the product portion of its offering.

Excerpt From iRhythm 2024 10-K Disclosing the Use of Techindia Infoway

"Beginning in the third quarter of 2022, we engaged Sutherland Healthcare Solutions, Inc. and ***Techindia Infoway Private Limited*** *to support certain customer care and clinical operations of our IDTFs."*

Department of Justice Press Release Related to BioTelemetry False Claims Act Settlement Dated 12/20/22 and Excerpt From Settlement Agreement

Cardiac Monitoring Companies to Pay More than $44.8 Million to Resolve False Claims Act Liability Relating to Services Performed by Offshore Technicians

"Although CardioNet's contract with ***Techindia*** *required Techindia to use technicians who were appropriately certified, Defendants did not audit or otherwise confirm compliance with that provision of the Techindia contract until at least 2017. In fact, of the over 450 Techindia technicians who reviewed Medicare patients' ECG Data in connection with MCT services CardioNet billed to Medicare during the 2013 to 2018 period,* ***less than 3% were certified*** ***by Cardiovascular Credentialing International ("CCI"), the only recognized credentialing body for such cardiovascular technicians****. BioTelemetry's CHC contract did not even require CHC's technicians to be certified prior to beginning work…"*

Source: iRhythm 2024 10-K, Department of Justice press release dated 12/20/22 and accompanying settlement agreement

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's Philippines Operation Seems To Be Repeating An Issue Highlighted In The BioTelemetry Settlement

In its settlement agreement with BioTelemetry, the Department of Justice took issue with its practice of hiring uncertified CCTs to analyze patient data. We note that a current iRhythm job posting for a CCT role in the Philippines only requires the candidate to be able to achieve certification within 120 days of hire. We ask what that potential employee is doing for four months, and what is their involvement with patient data analysis, if they are not required to be certified within that period?

Excerpt From BioTelemetry Settlement Agreement

such cardiovascular technicians. BioTelemetry's CHC contract did not even require CHC's technicians to be certified prior to beginning work; rather, CHC staff that analyzed cardiac data only had to obtain their certifications within six months of the date on which they joined a project. The conduct discussed in this Paragraph D is referred to below as the "Covered Conduct."

Current iRhythm Philippines CCT Job Posting

GBS Cardiac Tech XT Manila iRHYTHM

Apply

About you:
An experienced Certified Cardiac Technician with the following qualifications:

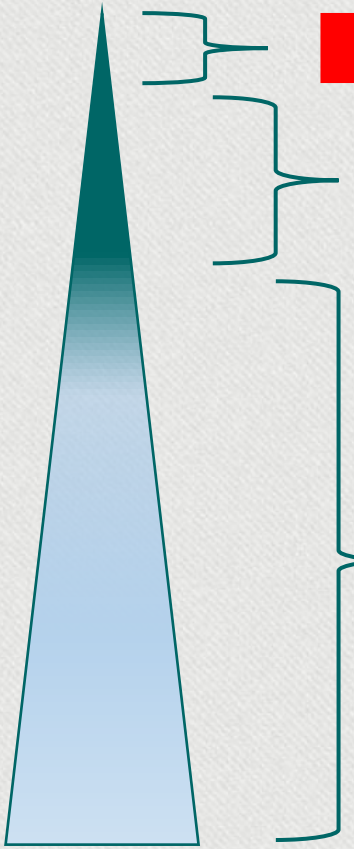
- High School Diploma required; an Associate's degree or two years college course work preferred
- 2+ years' experience as a cardiac telemetry/monitor technician, Holter scanner or other requiring ECG interpretation
- Demonstrated capability in rhythm analysis and interpretation
- You're a Certified Cardiographic Technician (CCT) or able to be certified within 120 days of hire; other related certifications or licenses may qualify (i.e. RN or Paramedic)
- Intermediate level PC proficiency
- Excellent attention to detail
- Positive attitude and team player
- Ability to use critical thinking skills
- Ability to define problems, collect data, establish facts, and draw valid conclusions
- Knowledge of medical terminology specific to Cardiology
- Excellent interpersonal, organizational, and communication skills
- Great work ethic and a desire to provide high quality outcomes (reports) to our clients and patients

Red underline for Spruce Point emphasis. Source: Department of Justice press release dated 12/20/22 and accompanying settlement agreement, iRhythm job posting

Putting iRhythm Complaints In Context

Approximately 1,250 MDRs reported by iRhythm since 2015 are in the FDA's MAUDE database. However, the FDA found that the Company had effectively ignored over 3x that number of complaints related to its patient data analysis operations. Even more staggering, the FDA warning letter noted that iRhythm had received nearly 1 million complaints during just the ~2.5 years between March 2019 and August 2022. Recognizing many of those may not be valid, we still find that to be an extraordinary figure.

Just the Tip of the Iceberg?



1,250 MDRs reported to the MAUDE database.

Additionally, your firm received approximately 4,014 complaints related to your Certified Cardiographic Technician (CCT) personnel operations from 05/02/2022 to 07/19/2024, including issues/events related to CCT personnel misreading arrythmia data and providing such misclassified data to end users for diagnosis purposes.

We reviewed your firm's responses dated September 1, 2022, October 6, 2022, November 4, 2022, December 7, 2022, January 3, 2023, February 2, 2023, and March 1, 2023, and they appear to be adequate. The responses indicate that your firm conducted a retrospective review of a total of 999,328 complaints received from March 1, 2019, through August 6, 2022, for reportability, resulting in the submission of 13 MDRs. Your firm's response dated March 1, 2023, notes that your firm has completed all the planned corrective actions.

Red underline for Spruce Point emphasis. Source: FDA Form 483 dated 7/31/24 (San Francisco), FDA Warning Letter dated 5/25/23 (CMS# 643474), MAUDE database

We Believe The Asymptomatic Market Opportunity Is Overstated

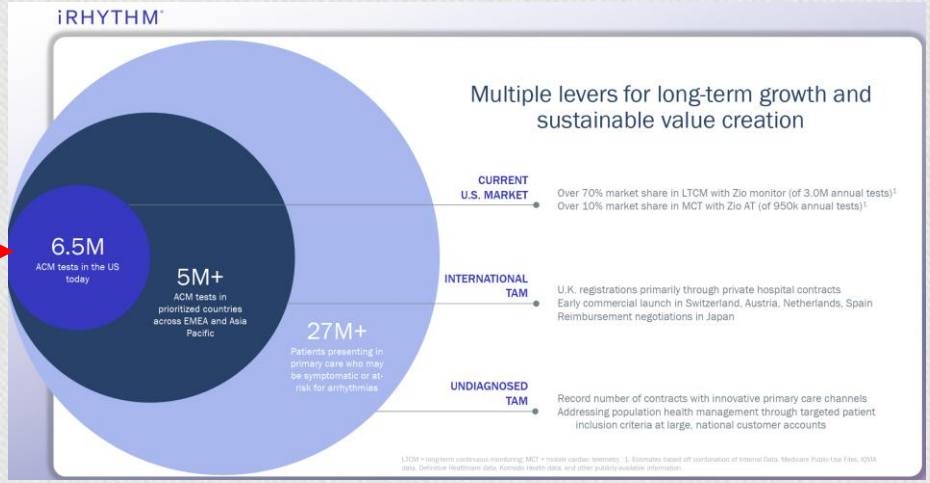
SPRUCE POINT CAPITAL MANAGEMENT

Targeting The Asymptomatic Market Is A Key Pillar Of The iRhythm Growth Strategy

As stated, nearly all prescriptions for Zio monitors come from cardiologists after a patient has demonstrated symptoms of arrhythmia, such as palpitations, dizziness/syncope, or fatigue, among others. Because this is a relatively small market and iRhythm already has ~70% share of the 3 million annual tests performed in the LTCM segment, pitching the Company's prospects for penetrating the asymptomatic (or undiagnosed patient) market is key for investors to perceive an attractive growth story.

Addressable Market Slide From iRhythm William Blair Conference Presentation 6/4/25

iRhythm's current target market is about 4 million annual cardiac monitoring tests. This figure excludes about 2.5 million short-term (24-48 hour) Holter monitor tests. While we acknowledge Holter share is declining, we see a structural floor as the practical reality is that Holter monitors (1) are more accurate as multi-lead devices, and (2) will simply be the more appropriate device depending on certain clinical situations. Thus, iRhythm's promotion of the asymptomatic opportunity is understandable. But is it justifiable?



iRhythm CEO Blackford at Goldman Sachs Conference, 6/10/25

"I think the market is very different than the way folks have thought about this market. ***I think it's very different than the way our competitors even think about the market****, to be honest with you...****The market is not 6.5 million ACM tests being performed each and every year****. The market is further up the care pathway. It has to happen in primary care. You have to do this through population health programs, value-based care.* ***That's right where we're going…And that's why I think the market is 27 million-plus patients by the time we get it opened up****. So we're incredibly bullish about that and feel good about the momentum."*

There is an alternative explanation: maybe iRhythm's competitors are correct that the market is just 6.5 million tests?

Source: iRhythm William Blair Conference presentation 6/4/25, Bloomberg

We Believe iRhythm Overstates The Level Of Support For Monitoring Asymptomatic Patients

If you only listened to iRhythm, you might believe that the entire healthcare system and cardiologists support primary care physicians prescribing monitors to asymptomatic patients. We do not believe that is the case, as such prescriptions are not supported by any credible standard of care or, based on our research, a majority of cardiologists.

iRhythm Statement Regarding Primary Care Prescriptions

iRhythm CEO Blackford at BAML Conference, 5/13/25	*"But more and more expanding into primary care is a big part of the strategy. And it's really encouraging what we're seeing. I believe it's better for patients, better for physicians, better for payers to bring Zio upstream earlier in the kind of the care pathway for patients.* ***And it feels like everyone is supporting that…So cardiologists and electrophysiologists, which are generally the clinical champion when an account is initially opened, they are supporting this move up to primary care****."*

≠

Entities Directly or Indirectly Opposed to Primary Care Prescriptions For Cardiac Monitoring
(See Following Page For Excerpts)

- **U.S. Preventive Services Task Force (USPSTF)**
- **American College of Cardiology (ACC)**
- **American Heart Association (AHA)**
- **American College of Clinical Pharmacy (ACCP)**
- **Heart Rhythm Society (HRS)**
- **The majority of the 100 cardiologists surveyed by Spruce Point**

Source: Bloomberg, USPSTF recommendation (and PDF download) on screening for atrial fibrillation, JACC Journals, Spruce Point research

The Current Standard Of Care Does Not Support Asymptomatic Testing

Key to addressing the asymptomatic market opportunity is getting primary care physicians (PCPs) to proactively prescribe cardiac monitors for patients yet to be diagnosed with arrhythmia symptoms. This is difficult because the U.S. Preventive Services Task Force (USPSTF), an independent body that works closely with the Department of Health and Human Services, as well as the ACC/AHA/ACCP/HRS Guideline, currently does not support proactive screening of asymptomatic patients for atrial fibrillation.

Excerpts From USPSTF JAMA Recommendation Statement on Screening For Atrial Fibrillation (January 2022) and The 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation

Summary of Recommendation

Asymptomatic adults 50 years or older	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for atrial fibrillation.	I

Table. Summary of USPSTF Rationale

Rationale	Assessment
Detection	• Inadequate evidence to assess whether 1-time screening strategies identify adults 50 years or older with previously undiagnosed AF more effectively than usual care. • Adequate evidence that intermittent and continuous screening strategies identify adults 50 years or older with previously undiagnosed AF more effectively than usual care.
Benefits of early detection and intervention and treatment	• Inadequate direct evidence on the benefits of screening for AF. • Inadequate evidence on the benefits of treatment of screen-detected AF, particularly paroxysmal AF of short duration.
Harms of early detection and intervention and treatment	• Inadequate direct evidence on the harms of screening for AF. • Adequate evidence that treatment of AF with anticoagulant therapy is associated with small to moderate harm, particularly an increased risk of major bleeding.
USPSTF assessment	Evidence is lacking, and the balance of benefits and harms of screening for AF in asymptomatic adults cannot be determined.

Abbreviations: AF, atrial fibrillation; USPSTF, US Preventive Services Task Force.

In addition, the *2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation* states: *"It is not yet established that patients at high risk of developing AF by a validated risk score benefit from screening and interventions to improve rates of ischemic stroke, systemic embolism, and survival."*
It also states: *"RCTs have demonstrated that implantable cardiac monitors exhibit the highest sensitivity in detecting AF compared with external ambulatory monitors, likely related to the longer duration of monitoring."*

Source: USPSTF recommendation (and PDF download) on screening for atrial fibrillation, JACC Journals

The Cardiologists We Surveyed Had Numerous Objections To PCPs Prescribing Monitors For Asymptomatic Patients

Cardiologists noted that PCPs are not qualified to interpret monitor results, an important point given the high rates of disagreement with final reports noted earlier. However, it is easy to see why iRhythm is pushing this treatment protocol, as many cardiologists believed it would result in over-testing, although with little to no impact on outcomes.

Spruce Point Cardiologist Survey Commentary on Why PCPs Should Not Prescribe Monitors For Asymptomatic Patients

- *"Over prescribe and don't know how to deal with results from monitors"*
- *"Because interpreting long-term cardiac monitoring data in asymptomatic patients requires specialized expertise to avoid unnecessary testing, misdiagnosis, and inappropriate management."*
- *"The PCP is not proficient to assess these patients and the overall volume of tests ordered will be huge and many patients will be undergoing unnecessary tests."*
- *"PCP do not have the expertise to analyze cardiac rhythm disorders"*
- *"In my experience, I would say almost 100% of the monitors that are chosen by primary care providers are chosen incorrectly. They're either choosing an incorrect duration or incorrect type of monitor for the wrong indications. Asymptomatic people generally shouldn't be monitored at all."*
- *"Not enough training. Too many unnecessary tests will be ordered"*
- *"Primary care physicians should not be ordering monitors. They don't know how to interpret them"*
- *"In general, there is not a role for evaluation of asymptomatic patients with longer term cardiac rhythm monitors."*
- *"PCPs do not know how to interpret the data. Will trigger unnecessary testing and consultation"*
- *"If there's no clinical question some findings will eventually be found like asymptomatic APCs/VPCs resulting in undue patient anxiety and inefficient consults"*
- *"Monitor fatigue, etc are known side effects of their use"*
- *"Inaccurate reading and failure to easily share full data with cardiologist when referring for consultation"*
- *"Too much noise, artifact. Poorly interpreted and inappropriately treated/referred"*
- *"I believe they would over prescribe them. A cardiologist is equipped to understand when it is appropriate to order this test and how to interpret the results."*
- *"Low impact on long term outcomes"*
- *"Asymptomatic patients likely don't need monitoring except for very few nuanced clinical scenarios that should likely be managed by a cardiologist"*

Source: Spruce Point research

Most Cardiologists Do Not Rely Solely On The Final Report, Highlighting A Major Problem With PCP Prescriptions and Undermining iRhythm's Strategy

Our survey of cardiologists uncovered that 74% do not rely completely on the final report provided by the monitor supplier. This supports the frequently noted issue that PCPs do not have the expertise to properly interpret patient data.

Spruce Point Cardiologist Survey Results Regarding Reliance on Final Report Provided by the Monitor Supplier

Do you ever rely completely on the final report provided by the monitor supplier?	
Yes	26%
No	74%
Note: n=100	

Cardiologist Commentary

- *"Always read it myself"*
- *"I have to interpret the data myself to make sure I agree with the report"*
- *"Because relying solely on the supplier's report risks missing subtle abnormalities, data errors, or contextual clinical nuances that require expert interpretation."*
- *"Missing data or errors"*
- *"I want to be 100% confident in the results."*
- *"I always interpret my own studies for any possible missed data"*
- *"I need to review the strips in case of artifact which is common"*
- *"unintentional errors are common"*
- *"I have seen rhythm interpretations that are wrong. And the counts for the number of longest runs of tachycardia have been mistaken in the past."*
- *"Inaccurate. Need to see strips"*
- *"The tech reading the tracings is often incorrect. They will call "VT" when it is clearly aberrantly-conducted SVT. I've seen many bradycardic rhythms also described incorrectly. Clinical context also matters which non-clinicians are unable to integrate."*
- *"Don't completely trust it. Need to look at primary data."*

If iRhythm final reports are not reliable, then PCPs are unable to properly diagnose arrhythmias.

Source: Spruce Point research

Importantly, Not All Arrhythmias Matter

While iRhythm likes to talk about the prevalence of atrial fibrillation as a rationale for asymptomatic screening, the practical reality is that not all arrhythmias are so important as to justify preemptive testing. Many cardiologists view monitoring as most justifiable specifically when cryptogenic stroke is either being evaluated or has occurred. We believe this important point is often ignored in the debate, and it was a major reason a former iRhythm executive was *"never bullish"* on the asymptomatic market opportunity.

A Former iRhythm Executive Spruce Point Interviewed Highlighted the Issue

Spruce Point Interview with Former iRhythm Executive, June 2025	
	*"…**that's the one area of the business [asymptomatic monitoring] that I was never bullish on**, and I'll tell you why…I got versed in [atrial fibrillation] very early on in my career. and I was surprised even then to realize what percent of the population eventually gets AF…But I remember learning early on too that **just because you have AF is not the worrisome part**. It's only if your AF is characteristic of you being at risk for stroke…the feedback that we'd get from cardiologists as well 'I don't care if a patient has AF; I care if they are at risk for something because of their AF'…**screening the whole population for AF only to find out that 70% of your population has it doesn't make sense from a healthcare test perspective. That's asking the wrong question**. And so the reason I was never bullish on the silent AF market and asymptomatic AF was because **when you have companies like Apple and Samsung that have long led this market, there's no point in a company like iRhythm now trying to play catch up**…"*

Several Cardiologists Spruce Point Surveyed About the Asymptomatic Opportunity Reinforced the Point

Cardiologist Commentary on Monitoring Asymptomatic Patients

- *"Unless a cryptogenic stroke is being evaluated there is no role for using a monitor for screening in asymptomatic individuals"*
- *"Unless they have had some type of event I do not know that it's appropriate to look for silent atrial fibrillation"*
- *"For the specific indication of cryptogenic stroke for discovery of pAF"*
- *"Screening for afib post stroke or surgery"*

As stated in the *2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation*, *"Brief episodes of subclinical AF are at low risk of clinical events."*

Source: Spruce Point research, JACC Journals

SPRUCE POINT CAPITAL MANAGEMENT

We Question Whether The Math Makes Sense For Asymptomatic Testing

With asymptomatic testing not the standard of care and cardiologists generally not in favor of PCP prescriptions for monitoring, iRhythm has focused heavily on value-based healthcare organizations that are more open to considering preventive testing today if it can avoid more expensive interventions in the future. However, we question the ROI and impact on outcomes.

Factors Negatively Impacting Value-Based ROI Calculations For Arrhythmia Screening

Not All Arrythmias Matter	As discussed, while atrial fibrillation prevalence seems to suggest an acceptable return on asymptomatic testing, the materially smaller incidence of AFib that "matters" worsens the ROI calculation.
Retesting Effectively Doubles Costs	55% of the cardiologists we surveyed said they were forced to repeat cardiac monitoring for patients already tested and referred by PCPs, which can result from the unavailability of results, insufficient analytic support, or incorrect previous testing methodology or device. Thus, realized upfront costs are higher than often represented.
Insurance Companies Churn Customers at a High Rate	According to one Tegus interview with a former iRhythm EVP of Marketing, the average tenure of an insured individual is just two years. As a result, it can be hard to justify upfront costs meant to avoid more expensive interventions in the future because that customer won't be their "problem" anymore.
Tegus Interview with Director at Philips Healthcare, 6/27/24	*"Stepping into the asymptomatic market and asking for, what, $250, what you said, or $500 or $750, **I think this would be impossible**. If you just say, it's like this, okay, we want to put, let's say, 12 million Zios, everybody will say, okay, forget it...**As much as it sounds great for the company, but it's not realistic**."*

We believe the integration of smart watches and smartphone-paired devices present far more disruptive healthcare cost reduction potential than iRhythm's products.

Source: Tegus, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Are Troubled By CEO Blackford's Recent Attempt To Further Inflate The Asymptomatic Opportunity

As noted, healthcare practitioners clearly question the value of testing asymptomatic patients. However, iRhythm continues to pitch this market opportunity. In fact, on its recent Q2 2025 earnings call, CEO Blackford went so far as to suggest asymptomatic patients should be tested annually. We believe this is a blatant attempt to suggest an even higher unit sales opportunity and irresponsible, as (1) it is not yet the standard of care to test asymptomatic patients in the first place, and (2) it is not even consistent with the standard of care for symptomatic patients, for whom repeat testing is typically prescribed only after cardiac medical procedures, changes in therapy, or the occurrence of new or recurrent symptoms.

CEO Blackford Further Inflates the Asymptomatic Opportunity

iRhythm CEO Blackford on Q2 2025 Earnings Call, 7/31/25	*"I think one of the things that's really encouraging to us as we continue to get closer to these partners of ours is just learning about their prescribing patterns. I think what we're learning is* ***most of these folks expect this to be a repeat monitoring sort of opportunity into the future where whether they're retesting every single year****, their patient population to try to stay ahead of the asymptomatic population that is just completely unaware and avoid those catastrophic downstream events or they're signing up new patients who are coming in all the time.* ***There's going to be a continuous repeat sort of prescribing pattern*** *with these innovative channel partners that excites us."*

The benefits of asymptomatic testing remain questionable, yet CEO Blackford suggests providers will test annually?

Source: iRhythm Q2 2025 earnings call transcript, Spruce Point research

Research Has Shown That Consumer Smart Devices Are Comparable To Medical-Grade Devices For Cardiac Monitoring

Extensive research has demonstrated that consumer smart devices are comparable to medical-grade devices for the detection of atrial fibrillation. In fact, smartphone-paired devices offer the real-time monitoring capability only available from the more expensive Zio AT. We believe this data disproves the iRhythm thesis around using Zio patches for asymptomatic patients.

Excerpts From *"Consumer-grade wearable cardiac monitors: What they do well, and what needs work"*, Cleveland Clinic Journal of Medicine, January 2024

Overall, the sensitivity of smart devices for atrial fibrillation detection is remarkably high. A recent meta-analysis found that smartphones detected atrial fibrillation with a sensitivity of 94% and a specificity of 96%, and there was no difference in atrial fibrillation detection between devices that use PPG and single-lead ECG.[11] Another meta-analysis showed that smartwatches were noninferior to medical-grade devices for detecting atrial fibrillation.[12]

OUTLOOK: BETTER DETECTION, BETTER TREATMENT

With comparable sensitivity to medical-grade devices, wearable consumer-grade devices show promise in detecting cardiac arrhythmias, particularly atrial fibrillation. These increasingly common devices can potentially improve the detection of atrial fibrillation and the prescription of therapeutic anticoagulation in appropriate cases, leading to improved patient outcomes. Given the high sensitivity and lower specificity of these devices, absence of atrial fibrillation should be reassuring, while detected atrial fibrillation should

Smartphone-paired devices
Handheld ECG devices are comparable in ease of use with the standard single-lead devices such as Zio patch but have the benefit of real-time monitoring. However, data from the Zio patch can be seen only after it is mailed in.

TABLE 1
Consumer-grade 'smart devices' for detecting cardiac arrhythmias

Device	CE and FDA clearance	Validation	PPG monitoring frequency	Sensitivity, %	Specificity, %
FibriCheck[6] smartphone camera app	Atrial fibrillation	Validated vs standard 12-lead ECG	Not applicable	95.6	96.6
KardiaMobile[10] ECG monitor	Single-lead and 6-lead ECG to detect bradycardia, tachycardia, and atrial fibrillation	Validated vs standard 12-lead ECG	Not applicable	96.6	94.1
Apple Watch Series 6[9]	Irregular heart rhythm notification and ECG monitoring	Validated vs standard 12-lead ECG[a]	Intermittent (every 5 minutes)	85	75
Garmin smartwatch[8]	Garmin Venu 2 Plus model with ECG capability	Garmin Forerunner 945 model validated vs Holter monitoring	Continuous	96.9	99.3
Samsung smartwatch[7]	ECG capability	Active 2 model validated vs BioTech ECG patch	Intermittent or continuous (user defined)	96.9	99.3
Fitbit[9]	Detecting atrial fibrillation, with ECG capability	Fitbit Sense model validated vs standard 12-lead ECG[a]	Continuous in some models (eg, Fitbit Charge 5)	66	79
Withings ScanWatch[9]	Detecting atrial fibrillation using ECG functionality and measuring blood oxygen saturation	Validated vs standard 12-lead ECG[a]	Intermittent (every 10 minutes)	58	75

[a]The BASEL Wearable Study (reference 9) also validated Samsung Galaxy Watch 3 and KardiaMobile against standard 12-lead ECG and demonstrated closely comparable sensitivity and specificity to the Apple Watch, Fitbit, and Withings ScanWatch.

CE = Conformité Européenne; ECG = electrocardiography; FDA = US Food and Drug Administration; PPG = photoplethysmography

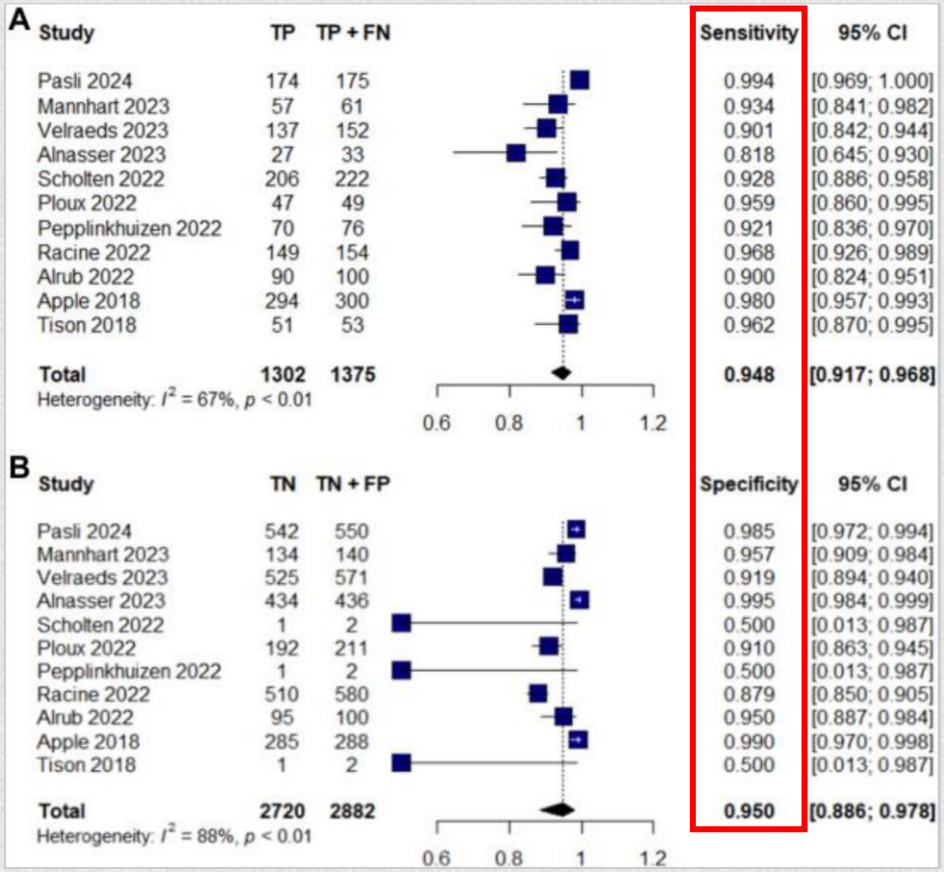
Smartphone-paired devices provide real-time monitoring, unlike the Zio XT/Monitor.

Red box and underline for Spruce Point emphasis. Source: "Consumer-grade wearable cardiac monitors: What they do well, and what needs work", Cleveland Clinic Journal of Medicine, January 2024

Another Recent Study Touted The High Accuracy Of The Apple Watch For Detecting AFib

While the study on the previous page details lower sensitivity and specificity in arrhythmia detection for the Apple Watch relative to several smartphone-paired devices, a recent meta-analysis of 11 studies showed that the pooled results for the Apple Watch were 95% for both metrics, demonstrating high accuracy.

Excerpts From *"Diagnostic Accuracy of Apple Watch Electrocardiogram for Atrial Fibrillation"*, Journals of the American College of Cardiology (January 2025)



Results

The meta-analysis included 11 studies comprising 4,241 participants. Their mean age was 62.56 ± 3.92 years, and 28% of the patients were females. The pooled sensitivity and specificity of the Apple Watch for detecting AF were 94.8% (95% CI: 91.7% to 96.8%; I^2 = 67%) and 95% (95% CI: 88.6% to 97.8%; I^2 = 88%), respectively. The area under the receiver operating characteristic curve was 0.96 (95% CI: 0.92-0.97).

Conclusions

The Apple Watch ECG carries high accuracy in detecting atrial fibrillation, providing a convenient diagnostic option for patients.

We note that the Apple Watch, Samsung Galaxy Watch, and the Fitbit Sense all have ECG capabilities, pulse monitors, and oxygen saturation monitors. Smartwatches generally obtain pulse and pulse oximetry monitoring data through photoplethysmography (PPG). PPG uses a light source and photodetector to determine changes in light intensity on the surface of the skin, correlating to changes in blood tissue volume during different phases of the cardiac cycle.

Red box for Spruce Point emphasis. Source: "Diagnostic Accuracy of Apple Watch Electrocardiogram for Atrial Fibrillation", Journals of the American College of Cardiology (January 2025),, Global Cardiology Science & Practice

The Asymptomatic Opportunity Is Most Exposed To Disruption By Consumer Devices; Are You Betting Against Apple?

According to Statistica, over 450 million people worldwide wear smartwatches, with Apple having 21% market share. Apple received De Novo classification for its Apple Watch ECG app in 2018. Since then, Apple has released highly accurate updates, achieved FDA qualification as a Medical Device Development Tool (MDDT), representing the first time a digital health tool has been qualified for the MDDT program, and broadened its portfolio of sensor technologies.

Excerpt From Apple 2020 510(k) Referencing Updated App Accuracy

Clinical Testing Summary

The ECG app's ability to accurately classify an ECG recording into AFib and sinus rhythm was extensively tested in a pivotal, prospective, multi-center clinical trial of approximately 546 subjects - 305 were enrolled in the Atrial Fibrillation cohort, 241 were enrolled in the normal sinus rhythm cohort. The mean age of enrolled subjects was 58. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the ECG 2.0 app. The ECG app demonstrated 98.5% sensitivity in classifying AFib (HR 50-150 bpm) and 99.3% specificity in classifying sinus rhythm (HR 50-150 bpm) in classifiable recordings. Subgroup analysis indicated sensitivity ranged from 98.3% - 100% across all age groups, and specificity ranged from 99.0% - 100.0%. Specificity and sensitivity estimates were slightly higher for females (99.6% and 99.2%, respectively) than for males (99.1% and 98.3%, respectively). Specificity and sensitivity estimates for subjects identifying as White were 99.1% and 98.5%, respectively, and were 100.0% each for subjects identifying as Asian, Black or African American, and Other.

Apple Achieved FDA MDDT Qualification in 2024

FDA Qualifies Apple Atrial Fibrillation History Feature as an MDDT

The FDA is announcing the qualification of a new tool to assess atrial fibrillation (a type of arrhythmia, or abnormal heartbeat) burden estimates within clinical studies through the Medical Device Development Tools (MDDT) program.

The **Apple Atrial Fibrillation History Feature** is:

- **The first digital health technology** qualified under the MDDT program, providing a non-invasive way to check estimates of atrial fibrillation (AFib) burden within clinical studies.
- **Designed to be used as a biomarker test** to help evaluate estimates of AFib burden as a secondary effectiveness endpoint within clinical studies intended to evaluate the safety and effectiveness of cardiac ablation devices to treat.
- **Designed to be used throughout the clinical study**, both before and after cardiac ablation devices, to monitor a study participant's weekly estimate of AFib burden.

Continued Innovation: Apple 510(k) Submissions

Device Name	Applicant	510(K) Number	Decision Date
Digital Prism Correction Feature (DPCF)	Apple Inc.	K242058	10/21/2024
Sleep Apnea Notification Feature (SANF)	Apple Inc.	K240929	09/13/2024
Irregular Rhythm Notification Feature (IRNF)	Apple Inc.	K231173	07/21/2023
Atrial Fibrillation History Feature	Apple Inc.	K213971	06/03/2022
IRNF App	Apple Inc.	K212516	10/22/2021
ECG App	Apple Inc.	K201525	10/08/2020

Apple Watch AFib feature becomes first-ever digital tool approved by FDA to evaluate medical devices

Michael Walter | May 02, 2024 | Cardiovascular Business | Heart Rhythm

Note that Apple has already received approval for sleep apnea monitoring, one of the new applications iRhythm has been pitching to investors since at least 2019.

Red box and underline for Spruce Point emphasis. Source: Demandsage.com, Apple press release, Apple 510(k) K201525, Apple 510(k) search, FDA Apple MDDT press release, Cardiovascular Business, iRhythm 2024 10-K

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Can't Have It Both Ways: If The Apple Watch Is Good Enough For "Lead Generation", Then It's Good Enough For Asymptomatic Patients

We believe iRhythm downplays the threat posed by the Apple Watch and other consumer devices, particularly high sensitivity/specificity smartphone-paired devices. However, CEO Blackford recently admitted that Apple Watches have been an *"incredible lead generator"* for iRhythm. We view this as an admission that such devices are clearly good enough to perform initial monitoring on asymptomatic people. And if that is indeed the case, why would any healthcare provider pay $250 for a Zio patch?

Historical iRhythm Management Statements Suggest Apple's Technology is More Than Adequate

iRhythm CEO Blackford at Goldman Sachs Conference, 6/10/25	*"I would absolutely agree with it. I think the awareness around cardiac issues is growing, I think, for a couple of different reasons,* ***I think where Apple is a big part of that, I think the Apple Watch has been an incredible lead generator for folks like ourselves*** *that bring patients into see their cardiologists saying, look, I've got an alert alarm that's going off here."*
iRhythm CMO Turakhia at Investor Day, 9/21/22	*"On the right is the Apple Heart Study that I led as a co-PI when I was at Stanford. And the purpose of this is not to talk about wearables, but to really frame what's out there in terms of* ***undiagnosed AFib****. So* ***this study validated the Apple's irregular pulse detection algorithm in 419,000 enrolled patients in the U.S. The overall notification rate was 0.5%. This is a fairly specific algorithm****. So it's a reasonable estimate to assume that, that is the undiagnosed AF population, not just the alert population."*

Source: Bloomberg

A Bad Omen For iRhythm? The Lead Author Of A Seminal Study On Using AI For Arrythmia Detection Now Works At Apple

iRhythm often touts the 2019 Nature Medicine study that demonstrated that AI had the potential to classify a broad range of distinct arrhythmias with performance similar to that of a cardiologist. iRhythm's current Chief Medical Officer Mintu Turakhia and AI pioneer Andrew Ng were co-authors of the report. What is perhaps less well known or promoted by iRhythm is that the lead author of that research paper, Awni Hannun, now works at Apple.

A Premier Research Scientist Who Has Examined Using AI For Arrythmia Detection Now Works at Apple

Letter | Published: 07 January 2019

Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network

Awni Y. Hannun, Pranav Rajpurkar, Masoumeh Haghpanahi, Geoffrey H. Tison, Codie Bourn, Mintu P. Turakhia & Andrew Y. Ng

Nature Medicine **25**, 65–69 (2019) | Cite this article

Research Published in Nature Medicine Demonstrates the Promise of Algorithm-Based Ambulatory Cardiac Monitoring Print

01/07/2019

Collaboration produces advanced artificial intelligence capable of expert-level arrhythmia detection

SAN FRANCISCO, Jan. 07, 2019 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ: IRTC), a leading digital health company focused on the advancement of cardiac care, announced the publication of a new study in the January 2019 edition of *Nature Medicine* showing expert-level detection of cardiac arrhythmias using a new deep learning, or artificial intelligence, approach for electrocardiogram (ECG) analysis across a variety of diagnostic classes. The findings come from a collaboration with the Stanford Machine Learning Group that has resulted in the development of a cutting-edge deep learning model capable of arrhythmia detection at a level comparable to a panel of expert cardiologists for a total of 12 output classes. The study is titled, "Cardiologist-Level Arrhythmia Detection in Ambulatory Electrocardiograms with Deep Neural Networks."

Awni Hannun · 3rd

Research Scientist - Machine Learning

Mountain View, California, United States · Contact info

Experience

Research Scientist - Machine Learning

Apple

Oct 2022 - Present · 2 yrs 9 mos

Red box for Spruce Point emphasis. Source: Nature Medicine, iRhythm press release, LinkedIn

SPRUCE POINT CAPITAL MANAGEMENT

We've Seen This Movie Before

The conventional wisdom on Wall Street is that Apple won't target medical product markets. We find this hard to accept given the powerful health capabilities of the iPhone and Apple Watch and Apple's recent targeting of hearing aids. Perhaps we should listen to Apple's actual statements and recognize that not all disruptive products need to be "medical-grade".

Apple Has Already Demonstrated Its Ability to Target and Disrupt Medical Markets

WIRED

CHRISTOPHER NULL GEAR SEP 11, 2024 11:30 AM

Apple's AirPods Pro Could Soon Disrupt the Hearing Aid Industry

AirPods revolutionized the wireless earbuds category and are poised to do the same for over-the-counter hearing aids.

How Apple just changed hearing aids forever - and the lives of those who need them

Millions of people with hearing loss go without assistive devices for various reasons. However, many of those millions likely now possess AirPods Pro 2 earbuds that can soon function as clinical-grade hearing aids.

Written by **David Gewirtz**, Senior Contributing Editor

Sept. 10, 2024 at 7:18 a.m. PT

ZDNET

Hearing aid makers slip after Apple rolls out hearing aid features, analysts shrug off threat

By **Reuters**

September 10, 2024 2:14 AM PDT · Updated September 10, 2024

Reuters

May 22, 2025

Apple products transform care at Emory Healthcare

At Emory Hillandale Hospital, Apple's ecosystem of products — powered by the suite of Epic healthcare apps — is elevating care delivery and the patient experience

WIRED

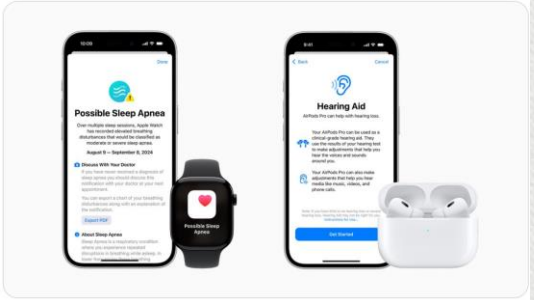
BY STEVEN LEVY THE BIG STORY DEC 4, 2024 3:00 AM

Tim Cook Wants Apple to Literally Save Your Life

Much as the CEO seems awestruck by AI and his just-released Apple Intelligence, he's more convinced that the tech giant's health apps will define the company's legacy.

Tim Cook
@tim_cook

The Hearing Test and Hearing Aid features on AirPods Pro 2 and sleep apnea notifications on Apple Watch are now available in Australia, Indonesia, Taiwan, Vietnam, and more!



11:54 AM · Jul 15, 2025 · **764.1K** Views

Source: Wired, ZDNET, Reuters, Apple press release, Wired, X (Tim Cook), Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

Even The U.S. Government Is Pushing Wearables. Isn't This Bad For iRhythm?

In June, U.S. Health Secretary Robert F. Kennedy Jr. said the Department of Health and Human Services will launch an advertising campaign to encourage Americans to adopt wearable devices, such as those that measure heart rate or blood glucose levels. We believe this is just further evidence that the trend toward consumer-grade wearable health monitors is gaining steam.

The U.S. Government is Pushing Wearables, Which Could Displace Asymptomatic Testing

US Health Secretary Kennedy says HHS to launch campaign to encourage wearable devices

By **Puyaan Singh**

June 24, 2025 3:01 PM PDT · Updated June 24, 2025

Reuters

June 24 (Reuters) - U.S. Health Secretary Robert F. Kennedy Jr. said on Tuesday that the Department of Health and Human Services plans to launch an advertising campaign to encourage Americans to adopt wearable devices, such as those that measure heart rate or blood glucose levels.

"We think that wearables are a key to the MAHA agenda, Making America Healthy Again ... my vision is that every American is wearing a wearable within four years," Kennedy said, speaking before the U.S. House of Representatives Committee on Energy and Commerce's Subcommittee on Health during a hearing on his department's 2026 budget request.

"It's a way of people can take control over their own health ... they can see what food is doing to their glucose levels, their heart rates and a number of other metrics as they eat it," he added.

Kennedy also described the campaign as "one of the biggest" in the agency's history.

Source: Reuters, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

Betting On Zio Watch? Management Failed To Mention On The Q2 Call That It's Dead

iRhythm announced a collaboration in September 2019 with Alphabet unit Verily to develop a watch product. Over the years, iRhythm management pitched its potential, until it simply stopped talking about it. iRhythm last mentioned its Zio Watch product on September 13, 2023, when CFO Wilson told investors to expect commercialization in 2025. Subsequent 10-Ks simply stated: "*The Zio Watch has not been commercially launched.*" We believe investors held out hope that this product could counteract the threat of consumer wearables. Alas, in iRhythm's recent 10-Q filed on July 31st, the Company finally admitted defeat and disclosed it has written off the Zio Watch development. Thus, one of iRhythm's earliest efforts at a new product outside its core monitors has proven a failure. We believe management should have disclosed this on the Company's earnings call.

iRhythm's Last Commentary on the Zio Watch

iRhythm CFO Wilson at Morgan Stanley Conference, 9/13/23	*"Yes, yes. So we continue to work on that product. That is a product that's in collaboration with Verily as you probably know. We've learned a lot in the years that we've been working on that watch and* ***believe that can be potentially disruptive product long term****. As any disruptive product, there may be some market development and reimbursement pathways that need to be worked through in the near term, but I remain excited about that.* ***I expect to get into clinical studies early part of next year on our path to commercialization of the 2025 time frame. So I remain excited about that.*** *I think we've learned a lot about our capabilities in terms of algorithms and how to leverage our clinical back end and the options kind of available to us from a strategy standpoint.* ***So excited about where that's headed****."*

iRhythm's Q2 2025 10-Q Disclosure Regarding the Discontinuation of the Zio Watch Collaboration

"During the three and six months ended June 30, 2025, ***the Company recorded an impairment charge of $2.5 million associated with capitalized internal-use software in development relating to the Zio Watch*** *with the Company's clinically integrated ZEUS system.* ***The Company is not likely to commercially launch the Zio Watch*** *under the Development Agreement. As of June 30, 2025,* ***the Company is actively engaged with Verily to formally terminate the Development Collaboration Agreement*** *dated September 3, 2019, as amended (the "Verily Development Agreement"), between the Company and Verily Life Sciences LLC ("VLS") and Verily Ireland Limited ("VIL", and together with VLS, "Verily")."*

Source: iRhythm press release dated 9/4/2019, iRhythm 2024 10-K, Bloomberg, iRhythm Q2 2025 10-Q, Spruce Point research

We Question iRhythm's Prospects For Continued High Growth And Improved Profitability

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's Core Market Is Small; Even Giving Credit For New Market Penetration Suggests Only Modest Growth Potential

iRhythm's current core LTCM market is only about $750 million, and iRhythm already has ~70% market share. The MCT market is about $1.15 billion, but iRhythm's product issues have resulted in a small share (~10-12%), and it is the segment most prone to reimbursement compression. We estimate the remaining U.S. market for short-term Holter monitors is only about $625 million at the Zio Monitor reimbursement rate. Holter monitors are selected when longer term monitoring is not deemed necessary to achieve a diagnosis, thus the value proposition of Zio monitors is a poor fit here, and we anticipate limited potential penetration. The two additional markets that iRhythm points to, U.S. asymptomatic and international, could add $8 billion to the Company's TAM, but we are highly skeptical of its prospects in both. Assuming (1) maximum likely incremental share gain possible in its core markets, (2) asymptomatic volumes grow to be about 20% of the current LTCM market and that iRhythm can capture 50% share, and (3) iRhythm can achieve 1.5% total global penetration, the Company would fall far short of current 2027E consensus revenue estimates. Stated another way, iRhythm's enterprise value is currently 2.2x its core market, which speaks to overvaluation.

Spruce Point Addressable Market and Potential Incremental Share and Revenue Analysis

Ambulatory Cardiac Monitoring Device / Patient Population	Annual Tests (Millions)	Per Test Reimburse-ment	TAM Revenue (Millions)	Enterprise Value / TAM	Estimated Incremental Share	Incremental Revenue (Millions)
Long-Term Cardiac Monitors (LTCM)	3.0	$250	$750		2.5%	$19
Mobile Cardiac Telemetry (MCT)	1.0	$1,150	$1,150		5.0%	$58
Short-Term Holter	2.5	$250	$625		5.0%	$31
iRhythm Core U.S. Market Total	**6.5**		**$2,525**	**2.2x**		**$108**
Undiagnosed Patients	27.0	$250	$6,750		1.0%	$68
International Patients	5.0	$250	$1,250		1.5%	$19
Additional Market Opportunity	**32.0**		**$8,000**			**$86**
Identified Market Opportunity	**38.5**		**$10,525**	**0.5x**		**$194**

	(Millions)
Current 2025E Street Consensus	$726
Current 2027E Street Consensus	$979
Implied Total Revenue Growth	$253
Estimated Incremental Revenue	$194
Estimated Revenue Shortfall	($59)
Implied 2025-2027E Revenue CAGR	12.6%

Of note, on its recent Q2 2025 earnings call, management noted that its outperformance versus expectations is largely being driven by the legacy LTCM market rather than new products or markets.

Source: iRhythm SEC filings, S&P Capital IQ, iRhythm Q2 2025 earnings call transcript, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We See A Number Of Revenue Headwinds On The Horizon

We believe iRhythm has benefitted from a number of transitory tailwinds. We see a plethora of emerging headwinds and potential investor disappointment in the coming year.

iRhythm Revenue Headwinds	
Risk of Further Government Regulatory Action	We believe further regulatory action against the Company is likely, which could harm market demand. In our survey of cardiologists, nearly 60% revealed that iRhythm's receipt of an FDA warning letter negatively impacted their demand for the Company's products.
Benefit From Competitor Disruption Fading	As confirmed by management, iRhythm benefitted from a customer disruption in Q3 and Q4 2024 that was resolved heading into early 2025. As CEO Blackford stated at the recent BAML conference, *"they were back on the market aggressively in Q4 and into Q1."*
Reimbursement Pressures	We believe cardiac monitoring will continue to see reimbursement pressures given the declining cost of service delivery and proliferation of low-cost alternatives.
Zio MCT Likely to Disappoint	We question why investors have been so excited and focused on the new Zio MCT product given the small market size and management's admission that the category will be flat over time.
Cash Pay Customer Pressures	Out-of-network or cash-pay patients are likely to see headwinds due to the increasing prevalence and awareness of low-cost alternatives and macroeconomic weakness.
International Likely to Disappoint	iRhythm has been consistently overconfident on its ability to penetrate international markets where there is both a preference for short-term Holter monitors and a lack of reimbursement.
New Applications Likely to Disappoint	iRhythm invested in BioIntelliSense to gain access to additional sensor capabilities required to target new markets such as sleep apnea. However, as stated, there are multiple solutions, both medical-grade and integrated into consumer devices, that already combine the requisite breadth of sensor technologies. We believe iRhythm is starting from behind in a market that management expects won't begin to contribute revenue until 2026 at the earliest, and iRhythm's offering is likely to garner below-Zio reimbursement and margins.

Source: Bloomberg, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

Adjusting For PCP Contribution, Core Growth Seems To Have Stalled

Our skepticism regarding iRhythm's ultimate prospects for success in the asymptomatic market could materially impact the Company's growth profile. Based on management disclosures and our estimates, we calculate that YoY revenue growth from non-primary care prescribers was in the low-single-digits in Q1 2025. While some of these patients may have eventually made their way to a cardiologist, that is most likely to occur as a result of a potential cardiac event at some indeterminate point in the future. Of note, iRhythm did not update this figure on its recent Q2 earnings call.

Analysis of Revenue Growth by Referral Source

($ in millions)	Q1 2024	Q1 2025	YoY Growth
Revenue (A)	$132	$159	20%
iRhythm Commentary on PCP Contribution (1) (B)	22%	33%	
Estimated PCP Referral Revenue (C=A*B)	$29	$52	80%
Implied Non-PCP Referral Revenue (D=A-C)	$103	$106	3%

(1) Management commentary referred to "volume" rather than revenue. Q1 2024 based on Spruce Point estimate and subsequent management disclosure and Q1 2025 based on management comment at BAML conference in May 2025.
Source: iRhythm SEC filings, Bloomberg, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Believe iRhythm Revenue Quality Is Declining

We believe multiple signs indicate that iRhythm's reported revenue quality has substantially declined over the past two years. First, the percent of revenue derived from non-contracted payors has increased. Second, iRhythm estimates the amount of revenue it will collect from contracted parties, with the difference between gross and net revenue represented by a contractual allowance. That contractual adjustment as a percent of "contracted" revenue has increased markedly since 2021. Third, iRhythm DSOs remain elevated. Fourth, iRhythm's provision for credit losses shrank to 17% of gross accounts receivable despite write-offs as a percent of gross accounts receivable reaching a six-year high in 2024. Finally, iRhythm is recognizing more revenue earlier as Zio AT revenue increases as a percent of total because, in contrast to the Zio XT/Monitor that is billed upon the delivery of the final report, Zio AT revenue is recognized under two performance obligations, during the patient wear period and the delivery of the final report. We believe the aggregate impact of all these trends and changes has resulted in a worsening of revenue quality.

iRhythm Revenue Quality Metrics 2019 to 2024

($ in millions)	2019	2020	2021	2022	2023	2024
Revenue	$215	$265	$323	$411	$493	$592
Non-Contracted Third Party Payor Revenue	$11	$15	$27	$24	$32	$43
"Contracted" Revenue	$204	$250	$296	$387	$461	$549
Non-Contracted Third Party Payer Revenue / Total	5.0%	5.8%	8.3%	5.9%	6.5%	7.2%
Contractual Adjustments	$9	$15	$17	$31	$41	$53
As a Percent of "Contracted" Revenue	4.6%	6.0%	5.9%	8.0%	8.9%	9.6%
Accounts Receivable, Net	$24	$30	$46	$50	$61	$80
Days Sales Outstanding	37.1	37.0	43.2	42.8	41.3	43.6
Provision For Credit Losses	$9	$13	$14	$18	$20	$16
Accounts Receivable, Gross	$33	$43	$60	$68	$82	$96
Provision / Accounts Receivable, Gross	27%	30%	23%	27%	25%	17%
Write-Offs For Credit Losses	$7	$7	$8	$13	$15	$27
Write-Offs / Accounts Receivable, Gross	22%	17%	14%	19%	19%	28%

iRhythm acknowledges in its risk factors that some patients fail to return their device, which prevents the Company from being able to produce and bill for the final report. Since iRhythm has already recognized some portion of revenue for Zio AT services, we believe some recognized revenue is never actually received.

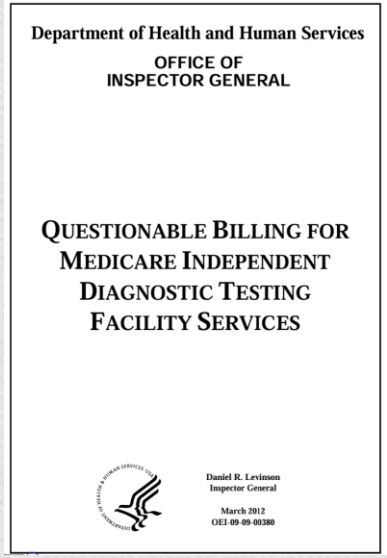
Source: iRhythm SEC filings

SPRUCE POINT CAPITAL MANAGEMENT

Is iRhythm Committing Medicare Billing Violations Related To Its IDTFs?

iRhythm must perform results analysis activities for CMS patients at Medicare-enrolled independent diagnostic testing facilities (IDTFs) that must meet certain performance standards. The Company's facilities in California, Illinois, and Texas (Houston) are approved IDTFs. CMS patients accounted for 24% of 2024 revenue. However, based on our analysis of LinkedIn, we estimate that 63% of iRhythm CCTs are located in remote locations outside the three IDTF metropolitan areas, and, triangulating on several data points, we estimate that only 17% of total global CCTs are located in the three IDTFs. While CMS regulations approve the use of remote CCTs, the reimbursement rates sought by iRhythm must match the costs incurred where the data was actually analyzed. We assume that the Company's facilities in California (San Francisco) and Illinois (Deerfield) are much higher cost (and thus receive higher reimbursement) than most remote CCTs. Therefore, iRhythm may be overbilling CMS for CCTs that are actually located in low-cost locations. IDTF billing violations are an area of historic focus for the U.S. Department of Health and Human Services (HHS). At least one employee highlighted this practice by iRhythm on Glassdoor. If true, this would suggest that iRhythm revenues are inflated and that the Company is at risk of additional regulatory sanctions.

HHS Has Focused on IDTF Billing Issues



Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

QUESTIONABLE BILLING FOR MEDICARE INDEPENDENT DIAGNOSTIC TESTING FACILITY SERVICES

Daniel R. Levinson
Inspector General

March 2012
OEI-09-09-00380

iRhythm Employee Claims Medicare Billing "Scam"

Advanced Patch Technician, iRhythm, 4/10/24, Glassdoor	*"Cons* ***Scams Medicare*** *… Created a program to capitalize on Medicare by scanning the majority of their scans in a state where Medicare pays more."*

Based on our review of LinkedIn and other sources, we believe a large volume of CCTs in the US are located in remote locations. Not only does this suggest the opportunity for questionable reimbursement practices on the part of iRhythm, but we believe it also calls into question iRhythm management's numerous claims related to the build-out of its CCT "Center of Excellence" in San Francisco. Importantly, as indicated by Glassdoor reviews presented earlier, current and former CCTs located in San Francisco bemoaned the negative impacts of increased outsourcing of CCTs from that location to offshore locations. We are unable to reconcile this inconsistency.

Source: HHS, Department of the Inspector General, Glassdoor, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

We Question The Sustainability Of iRhythm's Cardiac Monitoring Reimbursement Rates

We believe the costs associated with several elements of the iRhythm solution, as well as potential substitutes, have declined and are likely to decline further. Therefore, it is reasonable to expect a continued decrease in reimbursement rates, a risk highlighted in iRhythm's 10-K and confirmed on the Company's Q4 2024 earnings call. We believe the Zio AT is particularly susceptible, as the cost to deliver the incremental telemetry capability likely does not justify the ~4x reimbursement rate. This is supported by management commentary of an 8% Medicare price decline for 2025.

Reimbursement Language From iRhythm's 2024 10-K and Disclosure on Q1 2025 Earnings Call

*"**Because remote cardiac monitoring technology, including the Zio System, is rapidly evolving, there is a continuing risk that relative value units assigned, and reimbursement rates set, by CMS may not adequately reflect the value and expense of this technology and associated monitoring services, and CMS may reduce these rates in the future, which would adversely affect the Company's financial results**."*

iRhythm CEO Blackford on Q1 2025 Earnings Call, 5/1/25	*"…[the] MCT category is going to be **slightly flat over time**. I think that there continues to be a nice healthy market there, but we know that **price has been under a bit of pressure from CMS for the last 2 years. I suspect that will continue to be the case**…"*

Anticipated Cost Declines For Service Delivery and Potential Substitutes May Pressure Reimbursement

Device Costs: Device bill of materials is relatively simple and should benefit from scale economies.

CCT Costs: Industry outsourcing overseas should reduce the labor cost related to data analysis.

AI Efficiencies: The use of AI should reduce data analysis time required and the related labor burden.

Cost of Substitutes: Why will payers reimburse for expensive specialized devices when consumer device marginal costs are minimal?

Source: iRhythm 2024 10-K, iRhythm Q4 2024 earnings call transcript, iRhythm Q1 2025 earnings call transcript, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's International Growth Prospects Look Dim

iRhythm has been preparing investors for the take-off of its UK business for almost eight years. As of 2023, revenue had flat-lined due to a lack of reimbursement. We believe the Company's UK track record is instructive for assessing its prospects in more recent new markets entered such as Switzerland, Austria, the Netherlands, and Spain.

iRhythm United Kingdom Metrics Compared to Management Commentary

(£ in millions)	2020	2021	2022	2023
Turnover	£3.9	£8.5	£10.4	£10.4
YoY Growth		*120%*	*22%*	*0%*
Employees	21	42	50	51
YoY Growth		*100%*	*19%*	*2%*

iRhythm CEO King at Morgan Stanley Conference, 9/12/17	*"You know, David, it's identical to U.S. with the caveat that the vast majority of outside U.S. countries are single-payer systems. So **we've had an initiative underway in the United Kingdom for the better part of, I guess, 18 months going on…[2 years].**"*
iRhythm CEO King on Q3 2020 Earnings Call, 11/5/20	*"…we achieved an important funding award in the United Kingdom **that will not only drive increased utilization of ZIO in the near term but also lays the groundwork for wider adoption**."*
iRhythm CEO Coyle on Q1 2021 Earnings Call, 5/6/21	*"We also saw **very strong volume growth in the United Kingdom**, which outpaced overall company growth."*
iRhythm CEO Blackford at J.P. Morgan Conference, 1/13/25	*"We're in the U.K. today, **having great success in that market**, continuing to work on getting public reimbursement established for the public system. But we're having great success **from a unit volume traction perspective**, also growing in the private sector."*
Director, iRhythm, 12/29/24, Glassdoor	*"**An attempt at an international launch has stalled and has been largely abandoned**."*

Source: Companies House, Bloomberg, iRhythm Q3 2020 earnings call transcript, iRhythm Q1 2021 earnings call transcript, iRhythm Q4 2021 earnings call transcript

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm's Recent Setback In Japan Provides Another Proofpoint For International Friction

iRhythm has pointed to Japan as a major growth opportunity for well over three years. Over that time, iRhythm has missed deadlines and been proven incorrect in its assessment of the "premium" pricing it could achieve. We believe the recent adverse decision by the Japanese government should have been anticipated by iRhythm management.

iRhythm Management Commentary Regarding Japan Market Entry	
iRhythm CEO Blackford on Q4 2021 Earnings Call, 2/23/22	*"[We] plan to submit for Shonin approval in Japan **later this year**…We have also accelerated our efforts into Japan where we are moving forward with an application for regulatory approval. Japan is the second largest ambulatory cardiac monitoring market in the world, where reimbursement has historically been very good and physicians have been expressing strong interest in our technology."*
iRhythm CEO Blackford on Q2 2023 Earnings Call, 8/3/23	*"In Japan, we are thrilled to announce that we were granted High Medical Needs designation by the Japanese Ministry of Health and Welfare or the MHLW in early July…Following this designation, **we submitted our Shonin application for regulatory review in July**. Importantly, the designation enables priority review for marketing authorization by the Japanese Pharmaceutical and Medical Device Agency, or the PMDA, and **it also paves the way for potential premium pricing, specifically for Zio in Japan**."* **At least 7 months late.**
iRhythm CEO Blackford on Q4 2023 Earnings Call, 2/22/24	*"…we have identified our distribution partner for Zio in Japan. We are actively collaborating with them to prepare for the **launch in early 2025**…Japan, pricing is yet to be set, but we know they generally use a reference pricing model with the U.K. and the U.S. and in other countries. And so that ought to be a **pretty attractive price point** as well that we're looking forward to."*
iRhythm CEO Blackford on Q1 2025 Earnings Call, 5/1/25	*"…a recent decision by the Japanese Ministry of Health, Labor and Welfare to **reimburse Zio at the established Holter monitoring rate**. While this initial reimbursement decision is **not ideal**, we understand the necessity of demonstrating superiority against existing market products…**a bit disappointed in where the rate got set**…But to be specific, **we don't have head-to-head sort of comparable data in the local Japanese market, and it's clear that that's what they're looking for to differentiate sort of reimbursement**."* **Delayed launch at lower rate.**

Source: iRhythm Q4 2021 earnings call transcript, iRhythm Q2 2023 earnings call transcript, iRhythm Q4 2023 earnings call transcript, iRhythm Q1 2025 earnings call transcript

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Has Demonstrated Little Operating Leverage Since 2016

iRhythm has grown revenue by almost 10x, or $528 million, since 2016. However, over that period, Company gross margins have increased by only one percentage point. What little operating leverage the Company has achieved has come from SG&A, yet those expenses remain at 71% and 61% of revenue (GAAP and non-GAAP, respectively). In addition, we suspect much of that improvement has come from the outsourcing overseas of CCTs and various administrative functions. Of note, close peer BioTelemetry was significantly more profitable at similar revenue scale. Thus, we question iRhythm's financial management.

iRhythm Revenue and Profit / Expense Margins From 2016 to 2024 and Comparison to BioTelemetry Operating Profitability at Similar Revenue Scale

iRhythm Technologies ($ in millions)	2016	2017	2018	2019	2020	2021	2022	2023	2024	Change 2016-24
Revenue	$64	$99	$147	$215	$265	$323	$411	$493	$592	$528
Gross Margin										
GAAP	*67%*	*72%*	*74%*	*76%*	*73%*	*66%*	*69%*	*67%*	*69%*	*1%*
Non-GAAP	*67%*	*72%*	*74%*	*75%*	*73%*	*66%*	*68%*	*67%*	*68%*	*1%*
SG&A Expense / Revenue										
GAAP	*81%*	*86%*	*91%*	*84%*	*74%*	*85%*	*78%*	*78%*	*71%*	*(10%)*
Non-GAAP	*78%*	*78%*	*82%*	*74%*	*62%*	*71%*	*67%*	*66%*	*61%*	*(17%)*
R&D Expense / Revenue										
GAAP	*11%*	*14%*	*14%*	*17%*	*16%*	*12%*	*11%*	*12%*	*12%*	*1%*
Non-GAAP	*11%*	*12%*	*12%*	*15%*	*13%*	*10%*	*10%*	*10%*	*10%*	*(1%)*
Operating Margin										
GAAP	*(24%)*	*(28%)*	*(31%)*	*(26%)*	*(16%)*	*(31%)*	*(21%)*	*(23%)*	*(14%)*	*10%*
Non-GAAP	*(21%)*	*(18%)*	*(20%)*	*(14%)*	*(1%)*	*(15%)*	*(8%)*	*(9%)*	*(2%)*	*19%*

BioTelemetry ($ in millions)	2015	2016	2017	2018	2019
Revenue	$179	$208	$287	$399	$439
GAAP Operating Profit	$10	$18	-$2	$50	$53
GAAP Operating Margin	*5%*	*9%*	*(1%)*	*12%*	*12%*
Excess Margin vs iRhythm GAAP	**36%**	**34%**	**16%**	**43%**	**33%**
Excess Margin vs iRhythm Non-GAAP	**26%**	**23%**	**0%**	**28%**	**20%**

Source: iRhythm SEC filings, S&P Capital IQ

SPRUCE POINT CAPITAL MANAGEMENT

We Question The Margin Implications Of The Company's Supposed New Compliance Infrastructure

iRhythm has long been highly unprofitable, and that was with a compliance and quality infrastructure that was clearly deemed woefully inadequate by the FDA. We expect continued requisite investments in this area to be a source of negative operating leverage.

CEO Blackford Comments About Remediation Costs and New Quality Infrastructure Costs

iRhythm CEO Blackford at BAML Conference, 5/13/25	*"I'm sure we're going to talk about FDA remediation activities. There is incremental $15 million of spend going towards those activities.* ***Ideally, we're wrapping those up by this year, and that will fall off and be a nice source of leverage for 2026.****"*

iRhythm CEO Blackford on Q3 2024 Earnings Call, 10/30/24	*"…we have made significant resource investments in our regulatory and quality organizations* ***from roughly 20 people two years ago to more than 100 individuals today****."*

iRhythm Has Already Been Wildly Optimistic on Regulatory Cost Projections

iRhythm CFO Wilson on Q2 2024 Earnings Call, 8/1/24	*"…we believe that $8 million to $10 million is the appropriate way to think about it for 2024…. As of now,* ***I don't see any indication that this is going to extend meaningfully longer.*** *Now, should something creep into 2025, we'll certainly talk about that."*
iRhythm CFO Wilson on Q3 2024 Earnings Call, 10/30/24	*"We now expect incremental expenses related to these activities to be approximately $11 million to $13 million in 2024 and* ***a $15 million run rate per year going forward with these expenses continuing into 2025****."*

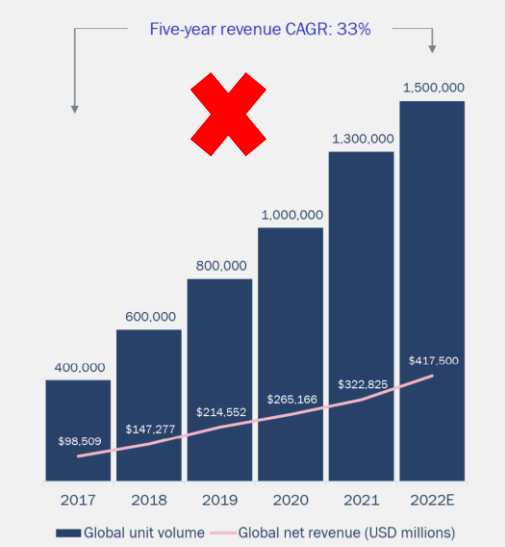
To the extent our concerns about CCT operations necessitate a re-shoring to comply with government regulations, or even customer preferences, it would represent another profitability headwind for the Company.

Source: Bloomberg, iRhythm Q2 2024 earnings call transcript, iRhythm Q3 2024 earnings call transcript

iRhythm Disclosure Is Becoming More Opaque

We believe investors should be worried when companies reduce business and financial transparency. While iRhythm has long avoided disclosing metrics commonly discussed in the medical device industry as well as important underlying accounting assumptions, we are alarmed by the decline in transparency over the past year.

iRhythm No Longer Discloses Even Heavily Rounded Test Counts



Inconsistent, Decreasing, or Absent Disclosures

- **Inconsistent/decreasing disclosure of revenue sources, growth, and average selling prices**
- **Inconsistent disclosure of revenue by product family**
- **No longer disclose gains in covered lives, exact employee count, or number of sales reps**
- **Inconsistent disclosure of international revenue metrics**
- **Does not disclose specifics around PCB amortization and write-offs**

iRhythm No Longer Discloses the Impact of Pricing on Revenue in the Reported Period

	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025
Average Selling Price Disclosure	increased	?	improved	improved	slight decline	stable	-slightly yoy	-400bps yoy	steady	slight improved	?	?	?	?

In addition, iRhythm has ceased providing annual fiscal year guidance for gross margin (since 2024) and adjusted operating expense (since 2023).

Source: iRhythm September 2022 investor day presentation, iRhythm earnings call transcripts, Spruce Point research

We Have Serious Concerns About iRhythm's Management And Governance

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Management Has A History Of Delaying, Understating, Or Deflecting Its Disclosure Of Bad News

iRhythm's practice of slowly leaking out increasingly serious regulatory sanctions resulted in a gradual crescendo of bad news that we believe was orchestrated to soften the blow on the Company's stock price.

iRhythm's History of Questionable Disclosure Surrounding the Government Probes

Delays Disclosure of Initial Form 483 and Recall	iRhythm received the Form 483 on 8/12/22, initiated a voluntary recall on 9/1/22, and issued a Customer Advisory Notice on 9/28/22 but did not disclose these until early November 2022. In the interim, weeks after the Company submitted its response to the FDA privately admitting to the *"hazardous situation"* posed by the transmission limit, iRhythm touted the Zio AT's capabilities at its September 2022 investor day. Disclosure was spread across the earnings press release, conference call, and 10-Q filing, with it characterized as a *"near-term"* headwind.
Says Zio AT Issues Behind It?	On 2/23/23, CEO Blackford stated *"we've made all the updates in the labeling that we need to do and in the packaging that we need to do"*. The Warning Letter came three months later.
Delays/Deflects Disclosure of DOJ Subpoena	iRhythm received the DOJ subpoena on 4/4/23 yet did not disclose it to investors until 5/4/23, with Blackford saying its *"too early to speculate on the precise motivations"*.
Understates the Seriousness of the Subsequent Form 483s	On the Company's Q2 2024 earnings call, Blackford repeatedly downplayed the new 483s as related to *"reporting"* and having nothing to do with product safety, when the FDA clearly viewed the issues as threatening patient safety.
An "Industry" Issue?	iRhythm has repeatedly implied that the FDA's actions are part of a broader review of the industry and that the FDA was trying to *"figure out"* how it wanted to regulate the industry.
Representations of FDA and DOJ Satisfaction	We believe the actions of the FDA and the detailed back and forth between Company counsel and the DOJ suggest a palpable lack of trust and frustration despite the Company's updates characterizing the process as one of full cooperation and positive feelings among all parties.

Source: Glazing v iRhythm second amended complaint (Case No. 3:24-cv-706-JSC document 43), iRhythm Q4 2022 earnings call transcript, iRhythm Q1 2023 earnings call transcript, iRhythm Q2 2024 earnings call transcript, Bloomberg, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

The DOJ Case Record Suggests The Real Reason Behind iRhythm's Foot-Dragging On Discovery

iRhythm has consistently positioned its resistance to the DOJ's discovery request as a noble fight to defend the concept of legal privilege. Yet iRhythm's own legal submissions suggest the Company simply wanted to defend against the release of information it may have suspected would harm its stock price.

iRhythm CEO Blackford on Q3 2024 Earnings Call, 10/30/24

"In July, the DOJ filed a petition for order to show cause, an application for enforcement of administrative subpoena, seeking the production of certain documents that the company has withheld on the basis of legal privilege. The company disagrees with the DOJ's attempt to invade the attorney-client privilege and the protection afforded to attorney work product. In partnership with our top tier outside counsel, we determined that it is in the best interest of the company to continue to maintain our position that certain documents are privileged, ***not only as it pertains to this case, but for the precedent it sets in other outstanding and future matters****."*

Excerpt From iRhythm Motion to Seal Government's Petition For Order to Show Cause (Case 3:24-cv-03967-AMO document 4 filed 7/3/24)

Disclosing this information has already harmed iRhythm competitively. Indeed, since the filing iRhythm's stock has dropped over 10% in just two days and the Petition has been cited in third party analyst reports in assessing the cause of the decline. Courts have repeatedly found it appropriate to seal documents that contain "business information that might harm a litigant's competitive standing," as is the case here. *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 590-99 (1978); *see also Nutratech, Inc. v. Syntech (SSPF) Intern., Inc.*, 242 F.R.D. 552, 555 (C.D. Cal. 2007). Moreover, iRhythm's competitors or activist investors such as short sellers may exploit this information to undermine iRhythm's reputation with its customers, which could manifest loss of customer trust and loyalty, negative market position and revenue decline. Tahler Decl. ¶ 11. Thus, good cause exists to seal portions of the Petition and exhibits thereto.

For brevity, we note that the government eviscerated this defense (see Case 3:24-cv-03967-AMO document 5).

Red underline for Spruce Point emphasis. Source: iRhythm Q3 2024 earnings call transcript, Case 3:24-cv-03967-AMO document 4 filed 7/3/24

We Believe CEO Blackford Has Been A Particularly Unreliable Messenger

We believe CEO Blackford has too frequently been shown to sugar coat or, frankly, be incorrect about key issues related to both the Company's business prospects and the regulatory processes, in particular.

The Blackford Pitch vs Reality: Very Often Too Aggressive or Wrong	
iRhythm CEO Blackford at J.P. Morgan Conference, 1/13/25	*"Japan is a massive opportunity for us. Today, Holters are reimbursed at a higher rate in Japan than what they are reimbursed in the U.S.* ***I think that bodes very well for the reimbursement rate we're likely to see get established in the Japanese market*** *for long-term patching."*
iRhythm CEO Blackford on Q1 2025 Earnings Call, 5/1/25	*"…a recent decision by the Japanese Ministry of Health, Labor and Welfare to* ***reimburse Zio at the established Holter monitoring rate****. While this initial reimbursement decision is* ***not ideal****, we understand the necessity of demonstrating superiority against existing market products…"*
iRhythm CEO Blackford on Q2 2024 Earnings Call, 8/1/24	*"But our expectation is that we continue to get Zio MCT on file before the end of the year."*
iRhythm CEO Blackford on Q3 2024 Earnings Call, 10/30/24	*"Considering the substantial efforts to accelerate the transformation of the quality organization while undertaking the remediation efforts and redefining the standards with which we engage the FDA,* ***we will be voluntarily delaying our regulatory submissions for the Zio MCT system****…"*
iRhythm CEO Blackford on Q2 2024 Earnings Call, 8/1/24	*"…I think the fundamental issue sort of comes down to whether the IDTF, the CCTs, if you will, the clinical technicians, are they part of the product or are they not? And I think* ***from the beginning of time, we view those as separate items****."*
iRhythm CEO Blackford at Morgan Stanley Conference, 9/4/24	*"…****we couldn't have been more clear with the agency and our response to them that we hear you. We see your point of view, we agree with your point of view, acknowledge it, and we are going to remediate the entire quality system to address that****."*

Source: iRhythm Q1 2025 earnings call transcript, iRhythm Q3 2024 earnings call transcript, iRhythm Q2 2024 earnings call transcript, Bloomberg, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

How Could Blackford Downplay Labeling Violations After His Experience At NuVasive?

CEO Blackford was employed by NuVasive from 2009 to 2017. In March 2013, while Blackford served as EVP of Finance and Investor Relations, NuVasive received an FDA warning letter for marketing its Affix Spinous Process Plate System for uses not approved by the FDA. Later, NuVasive faced a qui tam lawsuit brought by the DOJ (*United States ex rel. Kevin Ryan v. NuVasive, Inc.*) for marketing its CoRoent System for unapproved uses as well as paying kickbacks to physicians. NuVasive paid a $13.5 million fine to settle the case in July 2015 when Blackford was the Company's CFO. In addition, iRhythm's CFO from 2022 to 2024 Bobzien also worked at NuVasive from 2013 to 2017.

NuVasive 2013 Warning Letter

Our inspection revealed that the Affix Spinous Process Plate Systemis adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/Device

NuVasive 2015 DOJ Settlement

Medical Device Manufacturer NuVasive Inc. to Pay $13.5 Million to Settle False Claims Act Allegations

Thursday, July 30, 2015

California-based medical device manufacturer NuVasive Inc. has agreed to pay the United States $13.5 million to resolve allegations that the company caused health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company's CoRoent System for surgical uses that were not approved by the U.S. Food and Drug Administration (FDA), the Justice Department announced today. The settlement further resolves allegations that NuVasive caused false claims by paying kickbacks to induce physicians to use the company's CoRoent System.

"The Justice Department is committed to holding medical device manufacturers accountable, which includes requiring that they follow all laws designed to ensure that medical devices are safe and effective," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "It is also imperative that manufacturers not improperly influence the selection of medical devices in order to ensure that these decisions are based on the needs and interests of patients, not on a physician's own financial interests."

The United States alleged that between 2008 and 2013, NuVasive promoted the use of the CoRoent System for surgical uses that were not approved or cleared by the FDA, including for use in treating two complex spine deformities, severe scoliosis and severe spondylolisthesis. As a result of this conduct, the United States alleged that NuVasive caused physicians and hospitals to submit false claims to federal health care programs for certain spine surgeries that were not eligible for reimbursement.

We believe Blackford's communications and iRhythm's actions are very concerning given his 25-year career in the medical device industry, including employment at another company that received an FDA warning letter for misbranding.

Red underline for Spruce Point emphasis. Source: Biospece, Department of Justice press release

SPRUCE POINT CAPITAL MANAGEMENT

We Are Troubled By Blackford's Frequent Involvement With Questionable Companies

Sometimes executives find themselves in the wrong place at the wrong time or were not in positions of influence at troubled companies, perhaps making such associations excusable when limited in number. However, in the case of CEO Blackford, we find that nearly every company he has been involved with at the senior executive or Board Director level has faced controversies.

CEO Blackford: Troubling Proximity to Questionable Behavior	
Paragon 28 (FNA) Board of Directors 2022-Present	• Admitted in August 2024 that the Company had understated losses, overstated inventory, and identified material weaknesses in its financial reporting.
Alphatec (ATEC) Board of Directors 2017-Present	• Accused by short seller Bonitas Research in July 2022 of undisclosed related party transactions, undisclosed product recalls, and various accounting red flags.
AxoGen (AXGN) Board of Directors 2019-2022	• Accused of making false and misleading statements to investors regarding its business prospects in 2017 and 2018 and accused by Seligman Investments in 2018 of channel stuffing and questionable revenue recognition practices.
Dexcom (DXCM), COO, CFO 2017-2021	• Highlighted by Spruce Point in March 2019 for emerging competitive threats, commoditization, imminent growth slowdown, and declining financial transparency.
NuVasive (NUVA), CFO, VP Finance 2009-2017	• Accused by short seller GlassHouse Research in September 2017 of stuffing the channel, pulling forward revenue, pushing out expenses, and using non-GAAP exclusions to inflate earnings. • Paid a $13.5 million fine in July 2015 to settle a qui tam lawsuit brought by the DOJ (United States ex rel. Kevin Ryan v. NuVasive, Inc.) for marketing its CoRoent System for unapproved uses as well as paying kickbacks to physicians. • Received an FDA warning letter in March 2013 for marketing products for unapproved uses.

Source: LinkedIn, Bloomberg Law, Bonitas Research, Courthouse News Service, AxoGen investigation press release, GlassHouse Research, Department of Justice press release, BioSpace

SPRUCE POINT CAPITAL MANAGEMENT

We Believe The Evidence Documented By The FDA Represents Clear Violations Of iRhythm's Code Of Conduct

We do not understand why the iRhythm Board has been so forgiving of senior management. When the FDA delivers a Form 483, the agency's investigators have gathered information that they believe would meet an evidentiary standard in court. Thus, we find the Board's willingness to entertain such behavior as highly troubling.

FDA Evidence Suggests Clear Violations of iRhythm's Code of Conduct

QUALITY POLICY

At iRhythm Technologies, the patient is at the heart of everything we do. Each of us has the responsibility to contribute to quality through collaboration, innovation, and passion.

We incorporate quality in everything we do by:

- Operating with integrity and in compliance with applicable laws and regulations
- Continuously improving our products, processes, and services
- Identifying and preventing issues before they arise

To ensure the quality of our products and the safety of our patients, be sure to keep the following in mind:

- Recognize potential product complaints and adverse events
- Gather as much information as possible to report potential complaints and adverse events
- Report potential complaints and adverse events as soon as you discover them to the Quality and Regulatory

Criminal Fraud ?

Knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program; or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody of, any healthcare benefit program. This violates criminal law.

Waste

Overutilization of services or other practices that, directly or indirectly, result in unnecessary costs to the Medicare & Medicaid Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

Abuse ?

Includes action that may, directly or indirectly, result in unnecessary costs to the Medicare & Medicaid Program. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

MEDICAL DEVICE LAWS

Our devices are regulated by governmental agencies, health ministries, and other regulatory authorities around the world. Regulatory requirements include marketing approvals, product registrations, clinical study parameters, good manufacturing practices, design controls and labeling and advertising controls, among others. We all have a responsibility to understand and comply with these requirements and to contact, as applicable, Legal, Quality and Regulatory, or the Ethics & Compliance Services Department for guidance or to report any acts that violate regulations.

We do not believe the regulatory failures of the past three years should be a survivable event for Blackford and others.

Red marks for Spruce Point emphasis. Source: iRhythm 2022 Code of Conduct

SPRUCE POINT CAPITAL MANAGEMENT

The Board's Actions Have Not Reflected Well

Seemingly unlike iRhythm's Board, we do not believe the same management team that resided over a systemically flawed quality and compliance system should receive extra incentive compensation just to remediate their shortcomings, obey basic medical device laws, and cease endangering patients. We are also surprised the Board oversaw the softening of the Code of Conduct.

Excerpt From iRhythm 2025 Proxy Statement

- Updated 2025 executive compensation annual goals to include achievement of remediation activities tied to ongoing regulatory challenges

Comparison of the iRhythm 2022 vs 2024 Codes of Conduct

2022	2024
KEEP IN MIND: WE HAVE A LEGAL AND ETHICAL DUTY TO PROVIDE TRANSPARENT PRICING INFORMATION. THE SUBMISSION OF INACCURATE PRICING INFORMATION OR FRAUDULENT CLAIMS TO THE GOVERNMENT COULD RESULT IN HARM TO OUR COMPANY.	We must maintain complete and accurate records and recommend and/or use correct billing and reimbursement codes.
Our Quality Policy is core to deliver a quality service, focus on patient safety, and maintain transparency with regulatory Medical Device Reporting to the appropriate regulatory agencies.	Our Quality Policy is to deliver safe and effective cardiac monitoring devices and services to our patients, make quality a competitive advantage for growth, and to always comply with the law.
We all have a responsibility to understand and comply with [medical device regulation] requirements and to contact, as applicable, Legal, Quality and Regulatory, or the Ethics & Compliance Services Department for guidance or to report any acts that violate regulations.	We must follow all quality processes and safety requirements set forth in our Quality Management System (QMS) and comply with all applicable standards and regulations on the development of our products and services
The word "criminal" appears 10 times	The word "criminal" appears 0 times
The word "misconduct" appears 7 times	The word "misconduct" appears 2 times
The words "fraud" and "fraudulent" appear 15 times	The words "fraud" and "fraudulent" appear 0 times
The word "regulatory" appears 17 times	The word "regulatory" appears 7 times
The word "laws" appears 56 times	The word "laws" appears 25 times

Red underline for Spruce Point emphasis. Source: iRhythm 2025 proxy, iRhythm 2022 Code of Conduct, iRhythm 2024 Code of Conduct

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Has One Of The Least Stable Executive Suites In The Industry

We view the iRhythm executive team as relatively unstable. More troubling, the Company has cycled through four CFOs since its IPO. Similarly, the iRhythm board has seen significant turnover during its life as a public company. The recent departure of two long-tenured directors and the backgrounds of their replacements are particularly troubling.

Management Turnover Since IPO

	CEO	CFO	COO
2016	Kevin King	Matthew Garrett	
2017			
2018			Karim Kartl
2019			
2020			
2021	Michael Coyle	Doug Devine	
2022	Quentin Blackford		Doug Devine
2023		Brice Bobzien	
2024			Merv Smith
2025		Daniel Wilson	

Status of Board Directors at IPO

Non-Employee Directors

Tiba Aynechi(2)(3)
Casper L. de Clercq(1)(2).
Christopher M. Grant(4)
Joshua L. Green(4)
Vijay K. Lathi(2)
Mark J. Rubash(1)
Raymond W. Scott(2)(3)
William N. Starling, Jr.(4)
Abhijit Y. Talwalkar(1)(3)

We are particularly troubled by the July 3rd resignations of both Mark Rubash (former Audit Committee Chair) and Ralph Snyderman.

We believe investors should be concerned about their replacements. Karen McGinnis presided over Mad Catz's decent into bankruptcy as CFO and CEO, and Kevin O'Boyle was Chair of the Audit Committee at Nevro when short seller Scorpion Capital accused the company of numerous questionable research and business practices.

Source: iRhythm SEC filings, iRhythm 8-K dated 7/7/25, LinkedIn, LinkedIn, Scorpion Capital, Spruce Point research

SPRUCE POINT CAPITAL MANAGEMENT

Actions Under The New Management Regime Seem To Have Been Unpopular

While some reviews on Glassdoor need to be taken with a grain of salt, we find relatively consistent messaging regarding the popularity, perceived integrity, and decision-making of the team installed by Blackford, many of which were former associates from Dexcom.

Excerpts From Glassdoor Regarding the "Dexcom" Team	
Director, iRhythm, Glassdoor, 9/5/24	*"The leadership is a group of **entitled, immature, self-serving individuals**. They are all friends from past professional life who are patting each other's back. So many poor decisions in recent year."*
Anonymous Employee, iRhythm, Glassdoor, 10/19/23	*"I arrived at iRhythm after a significant executive leadership shakeup. The consistent message I heard from coworkers there longer than I had been was, "This is not the iRhythm I joined." **The executive leadership revolving door takes away any air of stability.** All the new leadership comes directly from Dexcom or has strong ties to the people from there. **They are running a Dexcom playbook that is, quite simply, failing iRhythm**… There is also a new culture of outsource and offshore. Customer Service, Clinical Operations, HR, Talent Acquisition, Accounting, Finance, and IT are all actively being moved out."*
Director, iRhythm, Glassdoor, 10/18/23	*"C-suite inserted from Dexcom seems to ram an agenda that **will not fit the acute cardiac monitoring space**. **Rampant nepotism, and unethical behavior going unchecked from every member of c-suite**. C-suite does not seem competent to lead and protect investor value… **Corporation's revised strategy viewed widely as a failure**...**Unless the FDA steps in with a heavy hand, iRhythm's c-suite will not make any substantial changes** to rescue this technology platform."*
Mid-Level Management, iRhythm, Glassdoor, 9/1/22	*"Executive leaders have no morales; **lie incessantly; and will do anything to replace all leaders with their Dexcom buddies**…The C-Suite has no integrity at all… literally nearly everyone who built the company was dumped by this CEO and his crew."*

Source: Glassdoor

SPRUCE POINT CAPITAL MANAGEMENT

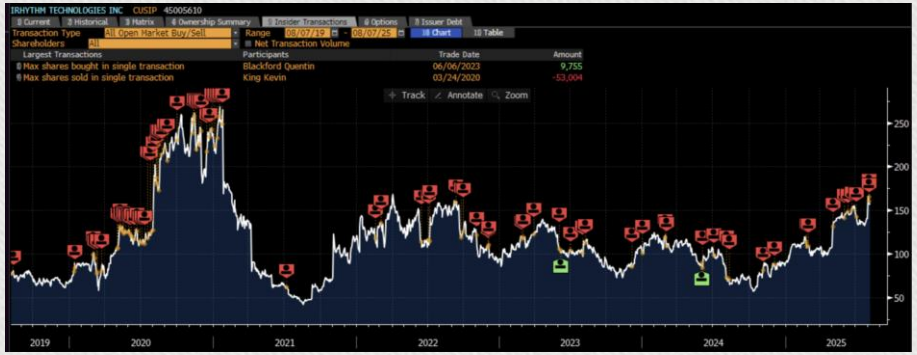
iRhythm Insiders Have Little Stake In The Company's Success…Or Exposure To Its Risks

According to the FDA, iRhythm has been aware of at least one of the potentially fatal flaws of its Zio AT device since 2017. By our calculation, iRhythm insiders have sold nearly $190 million of stock since the beginning of 2018. Today, iRhythm insiders have very little stake in the future of the Company, or exposure to the risks it faces due to its questionable behavior. In fact, we find that current insiders hold less than 1% of common shares outstanding and continue to be opportunistic sellers into any strength.

Common Share Ownership of Current iRhythm Insiders (Excluding Former Executives and Departing Directors)

Holder	Common Stock Held	Ownership	Market Value ($Millions)
Quentin S. Blackford, CEO	102,848	0.32%	$16.5
Daniel G. Wilson, CFO	40,307	0.13%	$6.5
Sumi Shrishrimal, EVP & CRO	34,685	0.11%	$5.6
Patrick Michael Murphy, CBO	29,342	0.09%	$4.7
Abhijit Y. Talwalkar, Chairman	18,941	0.06%	$3.0
Chad M. Patterson, CCO	15,448	0.05%	$2.5
Minang P. Turakhia, CM/SO	15,338	0.05%	$2.5
Bruce George Bodaken, Director	11,280	0.04%	$1.8
Karen L. Ling, Director	8,210	0.03%	$1.3
Cathleen Noel Bairey Merz, Director	7,615	0.02%	$1.2
Marc Rosenbaum, Senior VP & CAO	2,870	0.01%	$0.5
Brian B. Yoor, Director	2,641	0.01%	$0.4
Mervin Smith, EVP of Bus. Opns.	2,239	0.01%	$0.4
Total	**291,764**	**0.91%**	**$46.9**

Stock Sales by iRhythm Insiders



We highlight that iRhythm management rushed to sell stock immediately after its recent Q2 results. $4.8 million of the $5.8 million in stock sales came from CEO Blackford.

Source: BamSec, S&P Capital IQ, Bloomberg

We See 40% To 70% Downside Risk In iRhythm Shares

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Trades At A Premium Valuation Despite Slowing Growth

iRhythm trades at a $5.4 billion market capitalization and mid-to-high-single-digit revenue multiples despite an anticipated deterioration in revenue growth, which we believe may even prove optimistic. We also believe Wall Street expectations for improved profitability are likely to disappoint. Despite this, iRhythm shares have gained 78% year-to-date.

iRhythm Public Market Overview

Valuation ($ millions, except per share figures)	
Stock Price (as of 8/15/25)	$160.58
Shares Outstanding	32
Dilutive Shares (1)	2
Fully Diluted Shares Out.	34
Market Capitalization	**$5,450**
Less: Cash (2)	($546)
Plus: Debt (3)	$735
Enterprise Value	**$5,639**

Historical and Consensus Financials and Multiples (FYE Dec; $ millions)	2021	2022	2023	2024	2025E	2026E	2027E
Revenue	$323	$411	$493	$592	$726	$847	$979
YoY Growth	*22%*	*27%*	*20%*	*20%*	*23%*	*17%*	*16%*
Non-GAAP EBITDA	($90)	($11)	($5)	($8)	$59	$100	$148
Margin	*(28%)*	*(3%)*	*(1%)*	*(1%)*	*8%*	*12%*	*15%*
GAAP Net Income	($101)	($116)	($123)	($113)	($54)	($18)	$41
Margin	*(31%)*	*(28%)*	*(25%)*	*(19%)*	*(7%)*	*(2%)*	*4%*
EV / Revenue Multiple				**9.5x**	**7.8x**	**6.7x**	**5.8x**

Notes:
(1) Includes 0.283m options with an average $41.32 exercise price and 1.6m non-performance based RSUs as of 2024 10-K
(2) Includes $236.4 million of marketable securities
(3) Includes $86.7 million of operating lease liabilities
Estimates from S&P Capital IQ consensus as of 8/15/25
Source: iRhythm 2024 10-K, iRhythm Q2 2025 10-Q, S&P Capital IQ

SPRUCE POINT CAPITAL MANAGEMENT

iRhythm Is Trading At Near Its Two-Year-High Revenue Multiple, And Analysts See Little Upside

iRhythm has seen a dramatic expansion back to a two-year-high revenue multiple despite a lack of resolution of its regulatory troubles and a deteriorating growth outlook. Even Wall Street analysts are having trouble seeing much upside in iRhythm shares, as the current consensus price target is just 11% above the current price despite near unanimous "Buy" recommendations.

iRhythm Public Market Overview and Historical NTM EV / Revenue Multiple

Since 2/1/25, iRhythm has increased its 2025E revenue guidance by 6.6%, yet its stock price has climbed 43%.

Wall Street Recommendations and Price Targets For iRhythm

Firm	Recommendation	Target Price
Morgan Stanley	Overweight	$195.00
BTIG	Buy	$190.00
JP Morgan	Overweight	$190.00
Wolfe Research	Outperform	$185.00
Baird	Outperform	$180.00
Needham	Buy	$180.00
Wells Fargo	Overweight	$180.00
Truist Securities	Buy	$175.00

Firm	Recommendation	Target Price
Oppenheimer	Outperform	$175.00
Canaccord Genuity	Buy	$170.00
Citi	Buy	$167.00
Goldman Sachs	Neutral	$158.00
William Blair	Outperform	-
Average		**$178.75**
Current Price		**$160.58**
Implied Upside		**11%**

Source: S&P Capital IQ, Bloomberg

SPRUCE POINT CAPITAL MANAGEMENT

Our Comparable Company Analysis Suggests iRhythm Is Trading At Least At A 100% Premium

Wall Street analysts often compare iRhythm to leading medical device companies. By contrast, we believe iRhythm's products (1) employ highly commoditized technology (electrical sensors), (2) are not R&D intensive, as they have targeted a single product for a single indication the entire life of the Company, (3) are only attached by adhesive on the surface of the patient's skin, which represents a lower threshold for safety compared to a device being inserted into the body, and (4) are very low-priced wearables as opposed to products consisting of, or accompanied by, a high-priced piece of capital equipment. In addition, the Company's tests are simply not as scientifically rigorous as services such as genetic testing. Based on business similarities, we believe there is a strong case that iRhythm should be valued in-line with other outpatient testing and services companies, which trade at materially lower multiples. While investors may protest that iRhythm's high multiple is justified by its anticipated revenue growth, we note that iRhythm is experiencing declining revenue growth, which is often associated with multiple contraction.

iRhythm Comparable Company Analysis

($ in millions) Company	Stock Price	1-Year Return	Enterprise Value	LTM Revenue	LTM Gross Margin	LTM EBITDA Margin	CY25-26 YoY Rev. Growth	CY2026E EV/Rev
Medical Devices								
ResMed Inc.	$284.89	25%	$41,354	$5,146	60%	36%	7%	7.2x
DexCom, Inc.	$80.95	12%	$31,395	$4,301	59%	21%	16%	5.9x
Zimmer Biomet Holdings, Inc.	$102.75	(7%)	$27,528	$7,834	71%	33%	6%	3.2x
Insulet Corporation	$321.27	65%	$22,893	$2,360	70%	20%	18%	7.4x
Penumbra, Inc.	$253.02	34%	$9,664	$1,280	66%	14%	14%	6.2x
Masimo Corporation	$153.87	27%	$8,852	$2,154	49%	7%	8%	5.4x
Globus Medical, Inc.	$60.57	(12%)	$8,072	$2,626	67%	28%	8%	2.6x
Teleflex Incorporated	$120.68	(49%)	$7,171	$3,041	56%	30%	10%	2.0x
Integra LifeSciences Holdings Corporation	$14.19	(35%)	$2,868	$1,622	58%	19%	4%	1.6x
LivaNova PLC	$53.72	16%	$2,822	$1,309	69%	19%	6%	1.9x
Inspire Medical Systems, Inc.	$87.77	(54%)	$2,328	$861	84%	6%	14%	2.3x
AtriCure, Inc.	$35.45	48%	$1,721	$500	75%	(3%)	12%	2.9x
Tandem Diabetes Care, Inc.	$10.82	(75%)	$870	$1,002	53%	(8%)	9%	0.8x
Median		**12%**	**$8,072**	**$2,154**	**66%**	**19%**	**9%**	**2.9x**
Testing Services								
Labcorp Holdings Inc.	$270.38	20%	$28,441	$13,484	28%	14%	5%	1.9x
Quest Diagnostics Incorporated	$179.77	20%	$26,285	$10,522	33%	20%	3%	2.3x
Median		**20%**	**$27,363**	**$12,003**	**31%**	**17%**	**4%**	**2.1x**
iRhythm Technologies, Inc.	**$160.58**	**141%**	**$5,639**	**$657**	**70%**	**(7%)**	**17%**	**6.7x**

Source: S&P Capital IQ

SPRUCE POINT CAPITAL MANAGEMENT

We See Approximately 40% To 70% Downside In iRhythm Shares

iRhythm's former CFO acknowledged that the Company is a "services" business, justifying testing services company multiples for the low end of our valuation. We also believe iRhythm should trade at a discount to frequently referenced medical device comparables given those companies' dramatically superior profitability. Thus, even if we assume iRhythm can achieve the low end to consensus of Wall Street analyst revenue estimates for 2026, which we doubt, applying a more appropriate 2x to 4x revenue multiple range yields approximately 40% to 70% stock price downside and material underperformance risk.

Spruce Point Price Target Derivation

($ in millions, except per share data)	Low	Consensus
Street Low / Consensus 2026E Revenue	$828	$847
Target Revenue Multiple	2x	4x
Implied Enterprise Value	$1,655	$3,387
Less Debt	($735)	($735)
Plus Cash	$546	$546
Implied Market Capitalization	$1,466	$3,198
Fully Diluted Shares Outstanding	34	34
Implied Price Per Share	$43.20	$94.24
Current Price	$160.58	$160.58
Upside/(Downside) From Current	(73%)	(41%)

iRhythm CFO Garrett at Morgan Stanley Conference, 9/10/19	*"And I think this is a really important note because it talks about how difficult or challenging it is for us because **we're not a medical device. We're a service.**"*
iRhythm CFO Garrett on Q2 2019 Earnings Call, 7/31/19	*"We once again take this opportunity to remind investors…that **we are a services business** that faces material summer seasonality."*

Source: Bloomberg, iRhythm Q2 2019 earnings call transcript, S&P Capital IQ

Rationale For Multiple Compression

- **Deteriorating revenue growth and declining revenue quality**
- **Structurally poor profitability**
- **Inability to operate effectively within the most basic norms of the medical device industry**
- **Lack of management candor or credibility**
- **Poor product development execution**
- **Very small addressable market**
- **Major new market thrust into asymptomatic market not supported by product-market fit, cardiologists, or stated standards of care**
- **Dim international prospects that continue to disappoint**
- **Declining financial transparency**
- **Likely future reimbursement declines**
- **Increasing competition, particularly from already ubiquitous consumer devices that already incorporate multiple sensor technologies and that are more cost-effective for both patients and payers**
- **Adverse business model impact from insourcing patient data analysis and reporting**
- **Overhang of additional legal and regulatory risks**