KerrisdaleCapital

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iRhythm Technologies, Inc. (IRTC)

Growth Reversal will Leave Investors Heartbroken

We are short shares of iRhythm Technologies, a $2.3bn medical device company trading at over 15x sales despite facing multiple factors that will dramatically cut its revenue growth in the coming years. iRhythm's Zio, developed over a decade ago and accounting for nearly all the company's $150m in sales, is a one-lead heart rate monitor in patch form. This "extended Holter monitor" is worn by patients for up to 14 days, during which the device continuously records heart rhythm data. Each application of a Zio patch costs payors about two to four times what it would cost to use legacy monitoring modalities, but iRhythm claims that the Zio reduces costs for the healthcare system through increased effectiveness and better patient compliance.

A closer look at the circumstances surrounding the reimbursement treatment of the Zio Patch reveals that at the core of iRhythm's revenue base is an exceedingly generous, but increasingly fragile, reimbursement regime. The Zio patch's success in achieving unit-level revenues greater than any other cardiac monitoring method is a function of iRhythm's subtle and skillful maneuvering around the arcane technicalities at the center of the American Medical Association's reimbursement coding process. This has allowed iRhythm to essentially "name its own price" in the Medicare negotiation process, leading to unduly favorable reimbursement from commercial payors as well.

But the price gouging will inevitably be short-lived. The rapid increase in Zio patch utilization has now put a bullseye on its back, increasing the odds that both Medicare and commercial payors will both cut back on reimbursement levels and throttle utilization. In addition, the Zio patch is currently reimbursed under a temporary CPT tracking code that we expect will be transitioned into a permanent code for calendar year 2021. In the process, we anticipate reimbursement levels for the Zio patch will fall by over a third, and potentially more than 50%.

Reimbursement cuts are not iRhythm's only problem. Until recently, the Zio patch was the only product available in a category that it was responsible for creating. But the simplicity of the Zio and its commercial success have attracted competition, and new entrants have both superior devices and more diversified device portfolios. Up to now, iRhythm has successfully used favorable clinical studies and enterprise integration capabilities to win business. But competitors are now promoting the superiority of their own devices, backed by more recently published data that reflects much less favorably on iRhythm. They're also offering more flexible solutions that appeal to a broader array of customers, such as larger enterprises. As a result, iRhythm will find it increasingly difficult to win business with large hospital systems and physician groups. In addition to market share losses, the specter of price competition from these peers looms large.

iRhythm has recently tried to diversify by extending its Zio patch into the real-time cardiac monitoring space with its Zio AT device. But the attempt appears to be too little, too late. Extensive discussions with industry participants and new disclosures in the company's filings indicate that, contrary to iRhythm's attestations in its most recent earnings call, iRhythm has pulled back on the AT. In fact, the product can no longer even be found on the company's website. That leaves iRhythm as a one-hit wonder with a shrinking reimbursement revenue pool and a slew of superior competition. As the only single product company in the cardiac monitoring space, iRhythm has already missed the beat. The results could be fatal.

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I. Investment Highlights

iRhythm faces reimbursement cuts of 30-60% in the near future. Close to all of iRhythm's revenue is derived from its Zio XT Extended Holter patch, and the vast majority of that is not through the sale of the device to physicians and hospitals, but by billing third party payors for the scanning analysis and report, which are performed at an iRhythm Independent Diagnostic and Testing Facility (IDTF). The level of reimbursement for that step of the process, like any medical procedure, is dependent upon the Current Procedural Terminology (CPT) codes under which the procedure is reimbursed. CPT codes are overseen by the American Medical Association (AMA) and medical procedures can be associated with a few different types of CPT codes, depending on the level of recognition they receive from the AMA and the relevant specialty societies.

iRhythm generates almost all its revenue through billing third party payors for CPT code 0297T, the letter "T" indicating that the reimbursement code is a Category III tracking code. The AMA describes Category III codes as "temporary alphanumeric codes for new and developing technology, procedures and services," a description that certainly fit the Zio patch when its temporary CPT code was first approved in July of 2011. But that was 8 years ago. The CPT system provides for automatic sunset of Category III reimbursement codes 5 years after implementation, whereupon they can expire, be renewed for a further five years if they are still "developing," or be transitioned to Category I "permanent" codes if the underlying procedure has become more widespread and supported by literature.

Notwithstanding at least some success on both the utilization and literature fronts in the 2013 to 2015 period, the temporary CPT codes associated with the Zio patch were renewed in February of 2016 and are currently slated to be reconsidered by the CPT Editorial Panel in early 2021. Given the recent explosion in the utilization of extended Holter monitors and the literature supporting their use, the relevant CPT codes will almost certainly be transitioned to Category I codes for use in the 2023 calendar year. Because Category I codes receive special scrutiny from the AMA's Relative Value Scale Update Committee (RUC), reimbursement rates for procedures typically drop by about a third when they move from Category III to Category I, according to several former RUC members we've spoken with.

In the case of the 0297T code, we expect that the reimbursement rate cut will be even more draconian than average, and is closer at hand than 2023. With respect to the magnitude of the reimbursement cut, we expect that the current $311 rate that CMS Contractor Novitas Solutions pays for 0297T in Houston (where iRhythm's IDTF is not coincidentally located) will decline to the $150-200 range in a best case scenario, on par with the Category I reimbursement rate CMS confers upon cardiac Event Monitoring. Novitas accounts for the vast majority of iRhythm's CMS revenue (in a classic case of contractor shopping, iRhythm originally located its diagnostic

and testing facility in the region where it negotiated the most favorable reimbursement). In a worst case scenario, iRhythm could see the reimbursement rate for 0297T fall to $45-50, similar to a Holter monitor reimbursement rate, which is what the vast majority of CMS contractors reimburse for the code at the current time. Commercial payor reimbursement rates, which are typically more generous than Medicare reimbursement rates, tend to use the CMS fee schedule as a reference, and a drop in Medicare reimbursement generally presages a similar magnitude decline in commercial payor reimbursement.

Regarding the timing of the transition to a Category I code, iRhythm competitor BioTelemetry Inc (BEAT) has stated that it wants the extended Holter procedures transitioned to a permanent Category I code as soon as practicable. While there is some specialty society politics that BioTel has to navigate in the course of getting its application to the CPT Editorial Panel, we would expect a 2019 application to be easily approved by the Panel in the current year, implying a 2021 implementation of the newly transitioned code and the inevitable reimbursement reduction. BioTelemetry's extended Holter accounts for less than 5% of its total revenue, and based on conversations with industry participants, management is pushing for a Category I code to exert pressure on iRhythm, its newest competitor. BioTel has also been on the receiving end of a massive reimbursement cut on its MCT monitoring in the past and would like to clarify the long-term pricing for the product in order to assess its own strategic direction in the new vertical.

Finally, even with no action from the AMA on CPT code changes, we expect that iRhythm's extraordinary success in attaining coverage and favorable reimbursement rates from payors is in the process of backfiring. It's worth noting that Category III codes are "contractor priced." In other words, CMS does not set the price in its physician fee schedule, but each Medicare Administrative Contractor (MAC) sets or negotiates a price with the provider. iRhythm, with its IDTF in Houston performing all the scanning and reporting procedures, has benefited from the regional MAC – Novitas Solutions – generously reimbursing the Zio codes. No other MAC in the country reimburses for the procedure as generously, and most MACs have taken the view that not much differentiates the Zio from a traditional Holter monitor beyond the presence of some solid-state memory that can hold 14 days' worth of heart rhythm data (~500MB). As such, in 39 of 50 states, 0297T would be reimbursed at rates 33-89% lower than $311.

While MACs don't fiddle with pricing very much, we've found that large price changes tend to occur following abnormally large changes in procedure utilization. Our discussion with a former Novitas medical director who was involved in the original Zio reimbursement discussions confirmed that the MACs have analytics-based screens meant to flag procedures with abnormally large increases in utilization. Given the 300% cumulative increase in iRhythm's revenues from CMS for the 3 years ending 2018 (3 year utilization changes being one of CMS's primary triggers for review), we would expect that the alarm has already sounded at CMS or Novitas (or both) on a code that is being reimbursed disproportionately well compared to very similar procedures.

Any review of the code at the institutional level is likely to result in reimbursement coming down to a level closer to where the other MACs are. Additionally, Novitas' contract for Jurisdiction H ends in June of this year. If any other contractor wins that contract, iRhythm is almost certain to lose its lush Medicare deal. And of course, commercial payors will follow.

The competition is already beating iRhythm at its own game. The Zio XT is actually a fairly simple device: a sensor that detects cardiac rhythm, some memory, and a patch. As a former iRhythm regional sales manager told us, "you could literally go and find the building blocks in your garage and build it yourself if you're a bit handy." Until the last twelve months, though, there was no real competition for the device, as it had yet to gain traction with physicians until two years ago. But recently, a slew of competitors have launched extended Holters that compete with the Zio, and for the most part, they're making improvements around the Zio's weaknesses, including patch placement, number of sensors, time-to-reporting and rhythm-recording clarity.

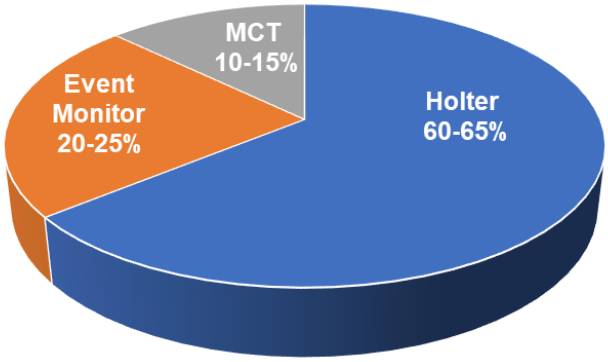
To investors, iRhythm has defended its competitive position as unassailable given that the Zio is "better, proven, and complete." But the literature it uses to show that the Zio is better than other monitoring modalities has now been replaced by literature employing the same testing methodologies but showing that competitors such as Bardy Diagnostics' CAM patch are superior to the Zio on the same endpoints. And though iRhythm claims that its underlying AI tools perform better than expert cardiologists, a careful read of the clinical studies it promotes shows that the Zio's diagnostic capabilities are in certain ways inferior to even the "low-tech" traditional Holter monitor that has been around since 1962.

Finally, discussions with doctors at large hospital networks suggest that iRhythm's one-size-fits-all "complete" enterprise solution can be a competitive disadvantage. Zio customers are forced to use iRhythm's IDTF for scanning and reporting, but many hospitals already employ their own ECG technicians, which makes paying for iRhythm's scanning and analysis service inefficient and costly. New entrants such as Bardy have exploited this weakness by offering more accommodating software tools that allow larger institutions to have their already-employed technicians read and analyze the rhythm recordings. This has the added advantage much faster turnaround time, which aids both physician and hospital workflow.

The Zio AT is a failure, leaving iRhythm as a single-product company with a TAM much smaller than it describes to investors. iRhythm's portrayal of its current addressable market is a cardiac monitoring market encompassing approximately 4.5 million monitoring procedures annually, all of which can be addressed by either the Zio XT or the newer Zio AT. iRhythm, with just a "low double digit" percentage of that market at recent year-end, has a long way to go before its penetration will start to slow, or so iRhythm claims.

This narrative is misleading. The market for cardiac monitoring, excluding iRhythm, is trifurcated along approximately the following lines:

Market Share, by volume, of Cardiac Monitoring Modalities 2018



Medicare Pricing Per Procedure		
Holter	$	85
Event Monitor	$	205
MCT	$	970

Source: CMS Provider Utilization and Payment Data, BioTelemetry Inc. Filings and Conference Call Commentary, Kerrisdale analysis

Traditional Holter monitors occupy the low end of pricing but almost two thirds of volumes. Event Monitors are in the middle with ~20-25% of the volume. Meanwhile, mobile cardiac telemetry (MCT), the most expensive monitoring procedure, makes up ~10-15% of volumes. As we heard from several electrophysiologists, the Zio XT cannot reasonably compete with most Event Monitoring procedures and MCT, which make up about a third of the market. These procedures are typically prescribed by electrophysiologists who require real-time attended monitoring, high levels of rhythm-recording clarity, and/or minimal time-to-diagnosis. The Zio XT has no real-time capabilities and takes 3-4 weeks from the start of monitoring to get its report to the doctor. Due to its miniaturized design, it also necessarily skimps on recording clarity. As a result, we believe that at least a third, and potentially up to a half, of iRhythm's claimed TAM is actually off-limits to the Zio XT.

To address the inability of the XT to perform real-time monitoring, iRhythm introduced the Zio AT in mid-2017. The AT was originally billed by iRhythm as "our version of Mobile Cardiac Telemetry" meant to "serve patients who have more critical symptoms such as syncope, pre-syncope and ventricular tachycardia."[1] But the AT has not lived up to iRhythm's initial expectations, which foresaw a timeline of "3 to 4 quarters in order to get full AT contracts." We were unable to find any physicians, at large hospital groups or otherwise, that were using the

[1] Comments by CEO Kevin King at the 2018 JP Morgan Healthcare Conference – January 10, 2018

AT, while multiple competitors indicated that they were under the impression that iRhythm had pulled the product from the market. At the current time, the AT has been pulled from the company's website entirely, leaving iRhythm as a single product company.

Even more potentially concerning is that the presentation of the product was clearly misleading – the Zio AT was apparently never able to provide actual real time monitoring, and the recently filed iRhythm 10-K has noticeably backed away from this claim. In fact, the 510K device application to the FDA specifically states that the device "is not intended for use on critical care patients," who are ostensibly to be treated with actual MCT devices. It's unclear, then, why iRhythm would claim to investors that the AT was a "version of MCT" and intended to compete in that arena.

In a separate attempt at "TAM expansion," iRhythm has been confidently suggesting to investors that the 4.5 million annual monitoring procedures will double over the next few years as monitoring guidelines are rewritten to recommend monitoring asymptomatic but "high-risk" populations. But the actual literature and studies that iRhythm cites, as well as some important literature they ignore, seems to imply the precise opposite. Such an explosion in the monitoring market is nowhere on the horizon, partly because devices like the Zio are simply way too expensive, but also because they're not very effective.

II. Company Overview

iRhythm: Capitalization and Financial Results

Capitalization	
Share price ($)	$ 87.25
Fully diluted shares (mm):	
Shares outstanding	24.4
Dilutive impact of options	1.5
Total	25.9
Fully diluted market cap (mm)	$ 2,260
Less: cash	35
Enterprise value	$ 2,225
EV/revenue (trailing)	15.1x

Financial results ($ mm)	2016	2017	2018
Revenue	$ 64	$ 99	$ 147
EBITDA	(15)	(26)	(41)
EBITDA Margin	*-23%*	*-26%*	*-28%*
Diluted EPS	$ (3.95)	$ (1.30)	$ (2.02)

Source: company filings, Kerrisdale analysis

iRhythm was founded in 2006 by electrophysiologist Uday Kumar to fill a void he identified in the available cardiac monitoring methods that were used to diagnose problematic arrhythmias. Physicians would normally try to diagnose an arrhythmia through a 12-lead ECG (electrocardiogram) or a 24-48 hour-portable Holter monitor, the latter which Kumar considered cumbersome, and which could only monitor for up to 48 hours.

Arrhythmias (abnormal heart rhythms) occur when the electrical impulses that coordinate a person's heartbeats aren't working properly, causing the heart to beat too fast, too slow, or irregularly. An arrhythmia could be a symptom of Atrial Fibrillation, a condition that the CDC estimates affects anywhere between 3 and 6 million people in the United States, and which can be a precursor to stroke. It could also signal more acute and potentially fatal conditions in the case of ventricular tachycardia or ventricular fibrillation (rhythms with dysfunctional electrical impulses originating in the ventricles).

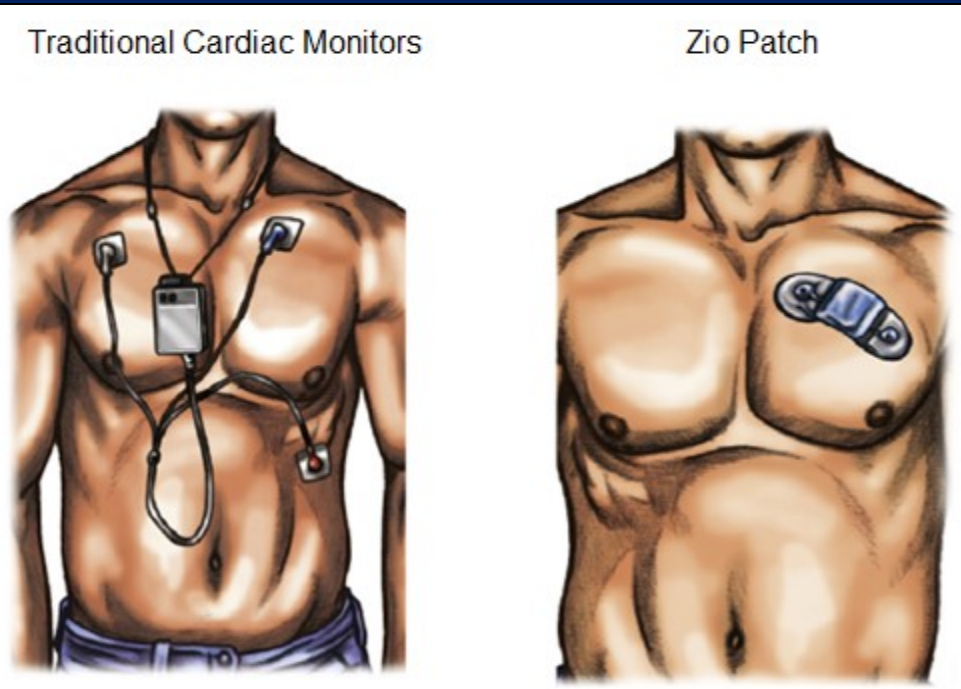
Diagnosing arrhythmias can be tricky. Even in a symptomatic patient, they can occur multiple times a day, but they can also occur less frequently – sometimes just a few times over the course of a month. Before the Zio, physicians had three cardiac monitoring options:

- 24-48 Hour Traditional Holter monitor – A technology that first became available in 1962, a modern Holter typically has 2-5 leads (wires) that are connected to electrodes, which are attached to the patient's chest in strategic locations so as to maximize the precision and clarity of the reading. The leads are attached on the other end to a recorder, which saves the recording onto flash memory. After 24-48 hours, the recording is analyzed by a technician and physician, with the aid of software that eliminates the majority of the dataset made up of "normal" heart rhythms.

- Cardiac Event Monitors – Event Monitors (EM) have at least two leads connected to a recording device similar to a Holter. EMs differ from a Holter in their duration and purpose – they can be worn by patients for up to 30 days, and only offer episodic, rather than continuous, monitoring. If the device senses an arrhythmia, or the patient signals the occurrence of symptoms (by pressing the appropriate button), the rhythm data from the episode is saved and transmitted to a scanning facility. A technician, or the patient's doctor, is immediately able to analyze the episode in close to real time.

- Mobile Cardiac Telemetry – MCT takes all the capabilities of Holters and Event Monitors, and combines them. An MCT device records continuously for up to 30 days and there's always a technician at a scanning facility watching the patient's heart rhythm in real time.

Traditional Cardiac Monitoring Devices vs. the Zio Patch



Source: 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry

All of the monitors were assemblies of wires, electrodes, and external recorders, which required the patient to unhook and then reconnect the device when showering or exercising. Holter monitors were inconsistent in diagnosing infrequent arrhythmias. Event Monitors recorded arrhythmias only episodically, which could theoretically have resulted in missed events. MCT was mostly overkill for patients without potentially life-threatening symptoms, and the constant monitoring was expensive, leading to reimbursement difficulties.

Into that void stepped the Zio patch, a water-resistant device in which all the monitoring components – sensor, lead, recorder – are combined into a small device and attached, on a

patch, to the patient's chest slightly above their heart. The device records the patient's heart rhythm continuously for up to 14 days and saves all of it. At the end of the monitoring period, the patient mails the assemblage to an iRhythm Independent Diagnostic and Testing Facility (IDTF), where an iRhythm technician scans the data and generates a report, with the help of iRhythm's proprietary software. The report is then sent to the physician, whose responsibility it is to review and interpret the report, and then treat the patient appropriately.

The Zio has some significant drawbacks. The turnaround time from the day the patch is applied to when the doctor would review results with the patient is about 4 weeks (which is still a major obstacle to physician acceptance). The Zio also has no ability to transmit rhythm data in real time. Perhaps most significantly, both the patch placement at the top of the chest, and the presence of only one lead, result in rhythm data quality that's inferior to that of any "legacy" monitoring system.

But, in iRhythm's telling, what the Zio lacked in these respects it made up for with simplicity for the patient, workflow enhancement for the doctor, and length of continuous recording. The latter, in particular, is at the heart of the clinical evidence employed by the company to "prove" that the Zio is the ideal monitoring modality with the best record of diagnosing arrhythmias. iRhythm has very effectively parlayed this argument into broad payor coverage for the Zio with generous reimbursement.

But, as we describe in more detail below, a careful study of the evidence reveals that it's much weaker than iRhythm really lets on. That's allowed new competitors, with devices that correct for the Zio's flaws, to design and promote new studies that paint the Zio patch in a more pedestrian light. Those competitors can also successfully claim the same benefits iRhythm does in comparison to other monitoring systems. More ominously, though, a thorough examination of the reimbursement paradigm that underlies the Zio reveals a very precarious foundation for iRhythm's business model that's all but certain to soon change for the worse.

III. iRhythm Faces Reimbursement Cuts of 30-60% in the Near Future

Transitioning the Zio XT procedures from Category III CPT codes to Category I CPT codes will result in a considerable decline of the reimbursement rates

> ***Kevin King (iRhythm CEO):*** *We work very, very closely with the AMA, the ACC, and HRS to determine when do they want us to move this code forward, because it's their code, it's a physician coding system, not an industry coding system. So, they decide when we are ready, and they said that the technology doesn't meet up a run rate now, renew it. So, it's really not a risk from that standpoint.*

…the process that we use for deriving our price, the cost, the relative value units for our code are exactly the same as what is used in the CPT 1 process. So we welcome the opportunity to continue to work with ACC and HRS, we're not fighting it. If they think we're ready, we'll go.

The earliest anything could happen in terms of it being published is 2021. So, if you hit this – if you hit the gas pedal today, pricing would not be effective until 2021. It goes through a very, very long set of cascading steps and so on.

Matt Garrett (Morgan Stanley): *And process has not begun yet…We still got a three-year clock and your view is we get a permanent code, do not believe that code is going to come at a level that is at or below or certainly below where you are today.*

King: *I think it could be higher. I think it could be higher because the complexity of our records, the duration of our work times and the things that we're measuring are more than what was granted to us in 2012.* [emphasis added]

Exchange between iRhythm CEO Kevin King and Morgan Stanley Analyst Matt Garrett
Morgan Stanley Global Healthcare Conference – 9/13/2018

When the FDA initially approved the Zio device in 2009, iRhythm's go-to-market strategy was to sell the device to providers. But according to former iRhythm executives, that didn't work because the procedure didn't quite fit the CPT code descriptions of any of the existing monitoring methods. Submitting the procedure to third party payors therefore required billing an unlisted code along with a detailed justification of the billing amount. Doctors and hospitals simply didn't want to risk having reimbursement claims rejected, so the Zio failed to catch on.

The company responded by applying for a set of Category III, or "temporary", CPT tracking codes from the AMA, for which it received approval in 2011, with an implementation date of January 2012. The code set approved was the following:

Billing for the Zio System "Extended Holter"
(External ECG recording for more than 48 hours up to 21 days by continuous rhythm recording and storage)

CPT Code	Description of codes for services greater than 48 hours
0295T	Global Code (includes recording, scanning analysis with report, physician review and interpretation)
0296T	Recording (includes connection, recording, and disconnection)
0297T	Scanning analysis with report
0298T	Review and interpretation

Source: iRhythm
Note: The CPT code division and respective descriptions for the Zio "extended Holter" monitoring procedures were modeled on the already-existing set of codes for the traditional Holter monitor.

Providers would bill payors for 0295T, the global code, while outsourcing the analysis of the recorded data and summary reporting to iRhythm, which the company included in the price of the device.

But the approval of the codes didn't help the Zio gain traction – Category III codes are considered experimental by payors, and it can be difficult to obtain coverage and contractual reimbursement. That kept providers from buying the device and attempting to bill the tracking code.

Coverage from third party payors for a Category III code faces a chicken-and-egg problem. The provider needs to show that the procedure is worthwhile and that it's being utilized. But to encourage utilization, it helps to have the procedure covered by insurers. Eventually, iRhythm chanced on a strategy that navigated the conundrum: it gave the Zio to doctors for free, and split the billing. iRhythm would bill payors for code 0297T, the scanning and reporting portion of the procedure, also known as the "technical component," while doctors would bill payors for 0296T and 0298T, known as the "professional components" because they are directly performed by the physician.

Providers assumed little risk because they weren't paying for the devices anyway. Meanwhile, backed by more patient venture capital, iRhythm was able to temporarily subsidize any losses resulting from denial of reimbursement for 0297T, while racking up procedure utilization that would help with getting more systematic coverage from Medicare. Obtaining Medicare coverage would then clear the path to favorable coverage decisions from commercial payors.

In an ironic twist, having the Zio procedure linked to temporary Category III tracking codes rather than Category I "permanent" codes turned out to be fortuitous for iRhythm. As we shall see, when approved as Category I, a procedure undergoes an intense evaluation process that is used to determine its reimbursement rate, which is subsequently published in the Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule (PFS). Category III procedures go through no such process. Rather, they are "contractor priced," which means that their reimbursement rate is not set by CMS, but is established on an ad hoc basis by each of the Medicare Administrative Contractors (MACs) in their respective regions.

Because iRhythm's business model was centered on performing procedures through an IDTF, it theoretically needed to secure favorable reimbursement with just one CMS contractor, in whose region they would place the IDTF. That MAC turned out to be Novitas Solutions, which administered Region JH for CMS, and which agreed to a $316 allowable fee for CPT code 0297T (since adjusted to $311). It's very much worth noting that as late as November 2014, iRhythm had one IDTF in San Francisco and another in Lincolnshire, Illinois.[2] The historical fee schedules for the MACs in those regions indicate that, as of 1/1/2015, their allowable fees for

[2] Based on the November 1 archived webpage of iRhythm's various contact locations: https://web.archive.org/web/20141101063058/http://www.irhythmtech.com/company/contact/index.html

0297T were in the $44-48 range. We believe that iRhythm was not able to get the Zio reimbursed at an attractive rate with the MACs in whose regions they already had IDTFs, so they found a more amenable MAC – Novitas – and put an IDTF in Houston, over which Novitas presided.

It took iRhythm 2-3 years to leverage Medicare coverage to attain widespread commercial payor coverage and contracting. By all accounts, the company's success in obtaining such extensive coverage and contracting for a Category III code is an impressive feat. Today, the Zio is covered for nearly every insured person in the US.

But even if *coverage* of the extended Holter monitoring procedures is now permanently secured, the rate of reimbursement for those procedures is set to decline substantially in our view. That's because the family of codes to which the procedures are linked will soon transition from their status as temporary Category III tracking codes to permanent Category I codes. In contrast to the fee schedules for tracking codes, which CMS is generally content to delegate to the MACs, fees for Category I codes are arrived at through a comprehensive evaluation process. The process ultimately concludes with CMS assigning the procedure an exact number of "Resource-Based Relative Value Units (RVUs)." The RVUs, in turn, are directly linked to the dollar values of each procedure on the CMS Physician Fee Schedule (PFS).

According to the AMA, "The Resource-Based Relative Value Scale (RBRVS) is based on the principle that payments for physician services should vary with *the resource costs for providing those services*." Resource costs change over time, though, and given the existence of approximately 10,000 CPT codes, it's hard to expect CMS to continuously monitor the assigned RVUs for every single procedure. Instead, CMS delegates much of the monitoring to the AMA's Relative Value Scale Update Committee (RUC), made up of physicians, which provides relative value recommendations to CMS annually. Historically, CMS has given the RUC's recommendations enormous weight in its own RVU determinations, and about 90% of the time it just certifies the RUC's determination. So it's worth understanding how the RUC reaches those conclusions, particularly on newly approved Category I procedures.

When a new Category I code is established, the RUC starts the process of evaluating the number of RVUs the procedure should be allocated. There's no precise formula for arriving at the "right" number. The RUC surveys physicians in order to assess the "Physician Work" component of a procedure, including "the time it takes to perform the service, the technical skill and physical effort, the required mental effort and judgment, and stress due to the potential risk to the patient." It also asks the relevant specialty societies, such as the American College of Cardiologists or the Heart Rhythm Society, to evaluate the "Practice Expense" component of the procedure, or the practice expenses that could reasonably be allocated to the procedure including staff, materials, office expenses, etc.[3]

[3] AMA RUC RBRVS Overview

Survey responses and cost estimates are compared by the RUC to the values already attributed to existing procedures that are similar. So, for example, in January 2017, the RUC, at the request of CMS, reconsidered the RVUs of the CPT codes covering the evaluation of heart rhythm data from an Implantable Cardiac Defibrillator and Implantable Cardiac Monitor. Unsurprisingly, they used the traditional Holter monitor procedure as the reference case to which they compared the heart rhythm monitoring procedures associated with implantable devices. The survey responses and "crosswalk" comparisons (as they are called by the RUC) are discussed, debated, and merged by the RUC into an official RVU recommendation to CMS.

The 0297T code – the one that accounts for almost all of iRhythm's revenue – has no "Physician Work" component. The entire "procedure" – analysis of the data and encapsulating it into a report – is performed by iRhythm's IDTF. When it becomes a Category I code, there will be no physician survey for 0297T, only an analysis of the appropriate "Practice Expenses" and a comparison to similar codes. Given the array of cardiac monitoring modalities, there are two obviously similar procedures it will be compared to:

Practice-Expense Components of Holter- and Event-Monitoring

CPT Code	Monitoring Modality	Code Description	2019 RVU	2019 CMS National Payment Amount
93226	Holter Monitoring	Scanning Analysis with Report of External ECG Recording by continuous rhythm recording and storage; Up to 48 hours	1.06	$37.12
93271	Event Monitoring	Transmission and Analysis of Patient- and Auto-activated ECG Recording with remote downloading capability; Up to 30 Days; 24-hour attended monitoring*	4.77	$170.10

Source: RUC Recommendations, 2019 CMS Physician Fee Schedule, Kerrisdale Analysis

**CPT® guidelines define attended surveillance as "the immediate availability of a remote technician to respond to rhythm or device alert transmissions from a patient, either from an implanted or wearable monitoring or therapy device, as they are generated and transmitted to the remote surveillance location or center."*

At this point, note iRhythm CEO Kevin King's statement that "the process that we use for deriving our price, *the cost, the relative value units for our code are exactly the same as what is used in the CPT 1 process* [emphasis added]." In our view, that assertion is misleading at best, and disingenuous at worst: $311 would be almost impossible to arrive at in comparison to the existing monitoring modalities. Consider that Event Monitoring a) is performed over a longer period (30 days vs. "up to 21 days" for 0297T), b) requires "the immediate availability" of a technician to respond to rhythm transmissions, and c) entails *real time* analysis of a greater volume of heart rhythm data than that generated by the Zio (even granting imperfect event recording). As such, we expect that the 4.77 RVUs and $170 CMS-determined fee are the absolute *upper bound* for the reimbursement levels that the Zio will achieve through a highly scrutinized Category I code.

There is a distinct possibility, though, that the Zio will receive much less than that, and closer to what a traditional Holter gets. While the Zio records 14 days of data compared to the traditional Holter's 2 days, the length of recording doesn't cost very much – a few hundred extra megabytes of flash memory.[4] The analysis, conducted by technicians at iRhythm's IDTF, doesn't take 7 times as long – based on our discussions with competitors (some of whom employ former iRhythm technicians), a traditional Holter requires about 20 minutes of technician time while the Zio requires 40-60 minutes of analysis. And while iRhythm might point to its advanced Artificial Intelligence and Machine Learning algorithms used to identify arrhythmias, that software still underperforms the traditional Holter technology in a head-to-head comparison (i.e., when the two are recording concurrently). It's difficult to understand, then, why iRhythm should be compensated for its "scanning analysis and report" so much more than the same procedural code of a traditional Holter. Indeed, as we shall see, the fee for procedure 0297T at every Medicare contractor besides Novitas is just a bit more than a traditional Holter.

We expect that when the extended Holter codes are transitioned to permanent Category I codes, iRhythm's reimbursement revenue per procedure will fall from $311 to, at most, $170, or a decline of 45%.

The transition from Category I to Category III codes could come faster than expected

The timing of that transition is also closer at hand than iRhythm has indicated. In various statements over the last few years, as well as in its public filings, the company has mentioned that its current tracking codes are valid through the end of 2022 and that it expects that, if a transition to Category I were to occur, it would happen beginning in 2023. We believe that 2023 is the *latest* that the transition to Category I will occur, and that it will most probably happen beginning in 2021. That's because BioTelemetry Inc., the most dominant company in the traditional Holter, Event Monitoring, and MCT spaces, has recently entered the extended Holter space. BioTel has been hinting in various earnings calls and presentations that it's aiming to get the extended Holter codes approved for Category I:

> *[the Zio] was on the market with no competition. And interestingly enough,* ***it still operates under a temporary code, which, I'm sure, as you're aware, means that there is a tremendous amount of inherent risk around reimbursement****. So, that's the thing that kind of gives me a little bit of agita when I think about growing that product category. I can assure you that if it does have viability, if it moves into a permanent CPT code, we will take our fair share of that market.* [Emphasis added]
>
> Joseph Capper, BioTelemetry Inc. CEO
> February 22nd, 2018

[4] iRhythm has stated that the entire 14 days of data amounts to approximately half a gigabyte of data.

> *…this new category, as you know, is still under a temporary code. We will participate in that process as much as we can.* ***I think it's a good thing to get it permanently priced sooner rather than later.*** *I don't want to speculate on where that will end up, but I do think it will be better than traditional Holter…* [Emphasis added]
>
> Joseph Capper
> April 25th, 2018

In our conversations with industry participants, it has become apparent that BioTel isn't simply hinting at the potential for a code change, but is actively working to achieve it. One industry participant also mentioned to us that his company's reimbursement specialists have received guidance from CMS and commercial payors suggesting that the process to convert the Category III codes to Category I will be set in motion in 2019, and that the company should prepare accordingly.

We think that BioTel has two primary motivations in advancing the timeline for Category III conversion. First, as indicated by Capper in BioTel's February 2018 earnings call, there is still significant risk around reimbursement, even for a seemingly well-secured code, when that reimbursement relies on a generous fee arrangement with just one MAC. Capper would know. In 2009, CardioNet, BioTel's predecessor company, was heavily reliant on MCT reimbursement from just one MAC for the vast majority of its revenues. The MAC, Highmark Medicare Services, suddenly announced a 33% reduction in MCT reimbursement in July of 2009, upending CardioNet's business for several years, and causing the company's stock to decline by 65% over the two weeks after the announcement. As we discuss below, we think iRhythm and the Zio codes are at similar risk. Capper probably has no stomach for a rerun of that situation in a new market BioTel is entering.

The second reason Capper seems bent on the Category I transition, according to various industry players we spoke with, is that he's well aware of the reimbursement decline that it will trigger, and the negative impact it would have on BioTel's upstart competitor, iRhythm. The impact on BioTel would be negligible as BioTel's extended Holter product is still in its infancy, but slowing down iRhythm is a key priority for Capper.

Finally, we note that Capper indicates that he thinks the extended Holter reimbursement rate "will be better than the traditional Holter." We're glad to see there are other industry participants who publicly acknowledge that the traditional Holter is very clearly the correct frame of reference for the Zio's reimbursement, and we are confident that the RUC and CMS will view it that way too when they get their chance to decide the matter.

The rapid increase in the Zio's Medicare utilization makes it uniquely vulnerable to a sudden and dramatic reimbursement shock

> *[Reimbursement rates] typically don't change much, though it's when utilization kicks up that you can see galactic price changes.*
>
> Former iRhythm VP of Marketing & Reimbursement

The Category III status of the Zio reimbursement codes, and the resulting reliance on favorable contract terms with Novitas, puts iRhythm in a precarious position. The chart below shows the reimbursement rate for 0297T in all 50 states and the District of Columbia, sorted from the lowest reimbursement rate to the highest.

Medicare Administrative Contractor (MAC) Reimbursement for Zio and Traditional Holter Monitoring, by State

State	MAC	City	0297T	93226	State	MAC	City	0297T	93226
ID	Noridian		$ 33.34	$ 33.34	IL	NGS	Chicago	$ 47.05	$ 38.70
UT	Noridian		$ 34.50	$ 34.50	FL	First Coast		$ 47.20	$ 38.75
KY	CGS		$ 34.95	$ 32.64	CA	Noridian	San Francisco	$ 48.86	$ 48.86
OH	CGS		$ 35.96	$ 34.07	CT	NGS		$ 49.35	$ 41.33
AZ	Noridian		$ 35.99	$ 35.99	MA	NGS	Boston	$ 50.93	$ 43.72
SD	Noridian		$ 36.90	$ 36.90	NY	NGS		$ 51.67	$ 43.96
ND	Noridian		$ 36.95	$ 36.95	WV	Palmetto		$ 171.34	$ 31.97
WY	Noridian		$ 37.08	$ 37.08	AL	Palmetto		$ 183.26	$ 32.89
MT	Noridian		$ 37.35	$ 37.35	TN	Palmetto		$ 185.53	$ 33.31
NV	Noridian		$ 37.71	$ 37.71	SC	Palmetto		$ 187.80	$ 33.72
OR	Noridian	Portland	$ 39.03	$ 39.03	NC	Palmetto		$ 191.59	$ 34.47
IA	WPS		$ 39.25	$ 33.49	VA	Palmetto		$ 201.91	$ 36.57
KS	WPS		$ 39.75	$ 33.71	GA	Palmetto	Atlanta	$ 205.51	$ 37.04
NE	WPS		$ 39.97	$ 33.57	MS	Novitas		$ 267.10	$ 32.11
IN	WPS		$ 40.89	$ 33.92	AR	Novitas		$ 267.99	$ 32.26
AK	Noridian		$ 41.32	$ 41.32	OK	Novitas		$ 269.65	$ 33.10
HA	Noridian		$ 42.35	$ 42.35	NM	Novitas		$ 284.28	$ 34.31
WA	Noridian	Seattle	$ 42.46	$ 42.46	LA	Novitas	New Orleans	$ 304.13	$ 35.97
WI	NGS		$ 42.52	$ 35.30	TX	Novitas	Houston	$ 311.08	$ 37.54
MO	WPS	St. Louis	$ 42.87	$ 35.63	CO	Novitas		$ 312.67	$ 37.80
VT	NGS		$ 44.63	$ 37.53	DE	Novitas		$ 318.85	$ 37.86
MN	NGS		$ 44.71	$ 37.29	PA	Novitas	Philadelphia	$ 336.21	$ 39.98
ME	NGS	Portland	$ 45.37	$ 37.26	MD	Novitas	Baltimore	$ 339.28	$ 40.72
MI	WPS	Detroit	$ 45.72	$ 36.96	NJ	Novitas	North Jersey	$ 365.48	$ 43.71
NH	NGS		$ 46.34	$ 38.79	DC	Novitas	Washington, DC	$ 372.67	$ 44.75
RI	NGS		$ 46.79	$ 38.96					

Source: Medicare Administrative Contractor Fee Schedules, 2019
Note: In states with multiple sub-regions, we used the region with the highest reimbursement rate

The reimbursement for the Zio scanning and report in most states is, in Joe Capper's words, "better than the Holter," but not by very much. The exceptions to this are states managed by

Palmetto, where the reimbursement rate is closer to the rate for Event Monitoring, and Novitas, where the reimbursement rate is about 50% higher than even Palmetto's rates.

How did Novitas end up reimbursing iRhythm at a rate more than 6.5 times the median MAC reimbursement? The decision has to be put in the context of decisions about Category III codes in general. As the AMA describes:

> *Category III CPT codes are a set of temporary codes for emerging technology, services, and procedures. These codes are intended to be used to track the usage of these services, and the data collected may be used to substantiate widespread usage…*

In other words, no contractor expects a Category III procedure to be more than a rounding error. We spoke with a former medical director at Novitas that was involved in the 2015 reimbursement discussions, who confirmed that when the reimbursement decision was made, the Zio "had barely registered on anybody's radar." Since then, though, the Zio has turned out to be larger than anyone expected. Based on iRhythm's disclosures, we estimate that 0297T racked up a little more than $40 million of Medicare utilization in 2018,[5] all of it billed through Novitas. To put that in context, *the entire traditional Holter category* – all 4 CPT codes comprising all the relevant procedures – had about $50M in Medicare utilization last year.[6]

In our discussions with the former Novitas executive, former CMS officials, device company reimbursement experts, and former members of the CPT Editorial Panel and RUC, there was one overarching theme when it came to large changes in reimbursements: they are almost always spurred by massive increases in procedure volumes, known in CMS parlance simply as "utilization." Significant utilization increases almost always raise a red flag somewhere – at CMS, at the MAC level, or at the commercial payors, who will raise the issue with CMS and/or the relevant MAC. As an example, consider that the CMS "high expenditure screen" in 2016 flagged the entire family of CPT codes related to remote monitoring of cardiac defibrillators because the codes had allowed Medicare charges of over $10 million and saw utilization increases of over 50% cumulatively over 3 years. 0297T in 2018 allowed Medicare charges of over $40 million and has seen a cumulative 3-year utilization increase of close to 300%.

The former Novitas director we spoke with was astounded by those numbers. He confirmed that Medicare contractors, including Novitas, have screens with advanced analytics that are supposed to be run in order to flag new technologies with rapid utilization increases. He agreed that there would indeed be risk "of this being flagged and subject to repricing" and was adamant that providers shouldn't "underestimate Medicare – if something is enough of an outlier…it'll get back to them one way or another." He also volunteered that if a group of MAC medical directors were aware of the reimbursement disparities discussed above, they would definitely look into this one.

[5] As disclosed in footnote 2 of iRhythm's 2018 10-K
[6] Based on CMS utilization data.

The MCT experience that Joe Capper faced when he became CEO of CardioNet, as discussed above, is a particularly ominous precedent for the Zio reimbursement rate, as it bears a striking resemblance to iRhythm's current situation. At the beginning of 2009, CardioNet had just finished two years in which it tripled its Mobile Cardiac Telemetry revenues, with utilization also growing at a similar rate. MCT had just been approved as a Category I code in October of 2008, but as of 2009, CMS kept it as contractor-priced, i.e., dependent on the MAC where the IDTF was placed. Similar to iRhythm now, CardioNet then was "credited with creating the reimbursement codes for MCOT or wireless cardiac monitoring from CMS." The dollar revenues from the relevant MAC increased in 2008 to about $35 million from about $20 million in the prior year (compare iRhythm's revenues from CMS increasing from about $25 million in 2017 to $40.6 million in 2018). Even the management guidance from CardioNet at the time is eerily similar to iRhythm's current reassurances, with then CFO Marty Gavlan saying in the April 2009 earnings call that "candidly the argument is just as strong that we could justify a higher level of reimbursement as there would be any reduction."

Then, on July 13th, Highmark announced that it would cut the reimbursement rate on MCT from $1123 to $754. This was followed, according to CardioNet's 2010 10-K, by "pressure from several commercial payors to renegotiate reimbursement rate contracts." After growing at torrid rates for several years, the company saw three consecutive years of revenue declines, driven by reimbursement cuts and payor throttling of MCT utilization. The latter, we believe, is another risk that iRhythm faces following its rapid growth. If a procedure becomes overused, either because of generous reimbursement or simply convenience, commercial payors are notorious for restraining procedure utilization growth through required preapprovals and administrative hassling. It's unclear, in retrospect, if commercial payors began to be more prudent with MCT reimbursement on the heels of the Highmark decision, or on their own volition after the explosion in MCT volumes from 2006-2008. But the case of MCT clearly demonstrates the risks that can build for a rapidly growing single-product company reliant on a single fee negotiation.

In the end, we believe that even without a move to Category I, iRhythm's Zio reimbursement is in imminent danger of being forced downward by both Novitas and commercial payors. Such rapid revenue growth, at significant total dollar sums, from a single procedural code, is all but certain to call attention to the finer details of the reimbursement arrangements. When Novitas and commercial payors take note of what other MACs are paying, we don't expect them to stand still.

IV. iRhythm Faces Formidable Competition that it has (Over)Confidently Dismissed

So the other patch products that are coming out here are, in my view, not proven in that there are no peer-reviewed publications to validate their effectiveness versus anything. [They] certainly haven't been compared to Zio. Those patches generally are anywhere

from three days to five days... We know that a three to five days of where your diagnostic yield maximally will be about 40%, it won't hit 74%, because you need that long-term duration.

Kevin King
Cannacord Growth Conference, August 9, 2018

From a competitive standpoint, the competition is legacy technology. As I said earlier, about 2.8 million Holter monitors; 1.3 million, 1.4 million Event monitors and less than 0.5 million MCT products. That's how we think of the competition is legacy [sic]. I don't really think of it as a sales process with two companies standing toe-to-toe as much as I see it as the status quo of what's already penetrated.

Kevin King
iRhythm 2018 Third Quarter Earnings Call, October 30, 2018

I don't really see competitive threats in a big way. Our competitive threat is really all about helping customers to change their status quo, as you mentioned earlier in your first comment there. So, it doesn't appear that anything is really immediately on the horizon. And if it were, it would need to be proven clinically. It would need to be as complete as iRhythm is in helping people to understand how to diagnose and manage their patients to the level of effectiveness that we have.

Kevin King
iRhythm 2018 Fourth Quarter Earnings Call, February 12, 2019

Since iRhythm went public in late 2016, the company has been adamant that the only competition they face is the status quo – "legacy technology." The battle against traditional Holters, Event Monitors, and Mobile Cardiac Telemetry is primarily about physician inertia, because the clinical data so obviously favors the Zio over the status quo. Once that inertia is broken, though, there's essentially no alternative to the Zio – it's the only extended Holter patch that has been "proven clinically" and no other patch is "as complete as iRhythm" in enabling doctors to effectively "diagnose and manage their patients."

But our discussions with electrophysiologists and cardiologists, as well as our read of the clinical literature, paint a picture that bears almost no resemblance to iRhythm's portrayal of its competitive position. For one, the legacy modalities retain significant advantages against the Zio that won't soon erode. For another, at least one upstart competitor – Bardy Diagnostics – has been shown in the clinical literature to best the Zio on precisely the metrics that iRhythm uses to demonstrate its superiority. Finally, the Zio's clear weaknesses, and iRhythm's success despite those weaknesses, has spawned a slew of competitors that have focused on taking share through improving upon the Zio's faults.

iRhythm's primary claims regarding the Zio can be summarized as follows:

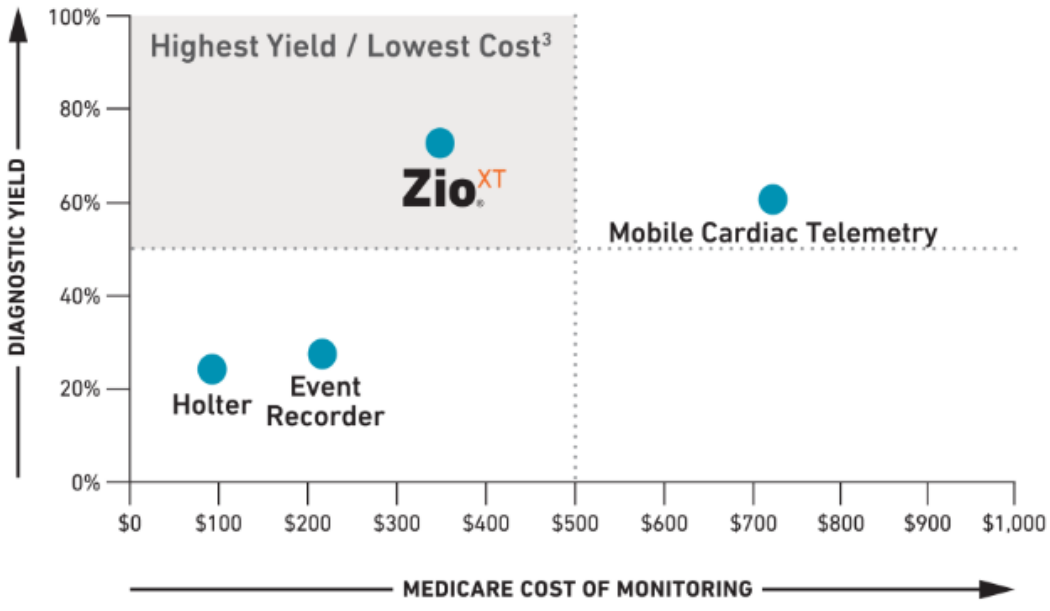
- The Zio's "diagnostic yield" is higher than any of the legacy systems.

- Because of the Zio's higher diagnostic yield, monitoring procedures that need to be repeated with legacy monitoring methods can be performed just once with the Zio, eliminating wasteful procedures.
- The higher diagnostic yield also results in a large number of cases with significantly differing treatment plans when patients use a Zio compared to a legacy monitoring modality.

Diagnostic yield is defined by iRhythm in its recent 10-K as "the percentage of patients in whom an arrhythmia was detected" in a particular group of patients being monitored. In one of the studies iRhythm sponsored, for example, a group of 70 patients with suspected atrial fibrillation were monitored using both a traditional Holter monitor and a Zio. The Zio patch identified arrhythmias in 38 of the 70 patients, for a diagnostic yield of 38/70 = 54% while the Holter identified arrhythmias in only 18 patients for a diagnostic yield of 26%.

In that context, we don't think it's an exaggeration to label the following graph, demonstrating iRhythm's diagnostic yield claims, as deeply misleading, and even deceptive. iRhythm's investor presentation and product webpage present this diagnostic yield comparison among the various monitoring modalities:

iRhythm Presentation of Diagnostic Yield Comparisons



Source: iRhythm Investor Presentation

The problem is that the term "diagnostic yield" has no meaning without context – you can only compare the diagnostic yield of different devices if they're tested on the same patient populations. But in the above graph, iRhythm compares the diagnostic yield of the 4 cardiac monitoring methods in 4 *totally different patient populations, in at least 3 different journal*

articles,[7] *spanning the course of over a decade*. A close reading of even just the abstracts of these papers suggests that iRhythm selectively chose the papers, and even selectively chose which data from the papers to present in the graph. For example, *Rothman et al. (2007)* found that in "a total of 266 patients…***a diagnosis was made in 88% of MCOT subjects compared with 75% of LOOP [event monitor] subjects**." That is very obviously not an inference that could be made from iRhythm's graph, which shows the Event Recorder's diagnostic yield at ~30% and MCT's at ~60%.

iRhythm also posts a selective list of about twenty scientific papers it uses to bolster its argument that the Zio is superior to legacy technology. A detailed look at that literature, though, tells a different story. Of all the studies that iRhythm presents, only two are head to head comparisons against legacy cardiac monitors, and in both cases, the Zio is compared only to a Holter monitor. No comparison against Event Monitoring or Mobile Telemetry seems to exist. Even in those two head-to-heads against the Holter, the root of Zio's diagnostic yield advantage is *not* the superior ability to identify arrhythmias, but the simple fact that the device monitors the patient for longer.

What happens during the first 24 hours of the study, in which the Holter and Zio are both concurrently monitoring? In one of those studies, "over a 24-hour period, there was excellent agreement between the Zio Patch and Holter for identifying AF [Atrial Fibrillation] events," though the study is noticeably silent about which device was superior in capturing non-AF arrhythmias. In the second of the two head-to-heads, the inferiority of the Zio during the period in which both devices are worn is much more obvious:

> *As a secondary outcome measure, the adhesive patch monitor was compared with the Holter monitor for detection of arrhythmia events over a simultaneous 24-hour period.* ***In this period, the Holter monitor detected significantly more of the 6 types of arrhythmia events than the adhesive patch monitor.*** *The Holter monitor detected 61 arrhythmia events compared with 52 arrhythmia events by the adhesive patch monitor (P = .013)* [emphasis added]

Our discussions with several electrophysiologists clarified the matter: The Zio's intrinsic ability to identify arrhythmias can never be as accurate as a Holter's. As a one-lead monitor placed on top of the chest, the Zio will necessarily read P-waves less precisely and will be handicapped trying to record ventricular rhythms (which come from the lower chambers of the heart). The Zio can mostly make up for the lack of precision by recording for longer, but even then, one lead can be only so useful. The ideal solution would theoretically be to have a multi-lead device that can monitor for longer than a Holter.

Event Monitoring exists precisely for that purpose. Indeed, the electrophysiologists we spoke with were uniformly dismissive of the utility of the Zio for their purposes. The Zio might be useful

[7] On its webpage, iRhythm says the data used "diagnostic yields derived from Zio Service Data, Rothman et al. (2007); Tsang et al. (2014) & Rei [sic] el et al. (2005)."

in a cardiology or primary care practice for AF detection, but an EP that sees a patient after a Zio-based referral almost always has the patient monitored again using an Event Monitor or an MCT unit, because the clarity of the rhythm recording may affect treatment choices. Multi-lead is the gold standard in rhythm monitoring, and while iRhythm may claim that the Zio eliminates costly repeat Holter monitoring procedures, it's also true that replacing a traditional Holter with a Zio often necessitates repeat monitoring with an EM or MCT.

To our knowledge, there has not been any head-to-head comparison between the Zio and an Event Monitor, at least none that has been published. The literature on Event Monitors implies that an EM would be superior to the Zio in every respect: even literature from 2003 that compares an EM to a Holter in a head-to-head shows that when both are concurrently monitoring, the EM captures 100% of the AF-related arrhythmias captured by the Holter and greater than 80% of other arrhythmias. And that was using EM technology from 1998 – since then, the arrhythmia detecting capabilities of Event Monitors have gotten much better, and the machines are much more ergonomic and less cumbersome.[8] Event Monitors also have the distinct advantage of transmitting arrhythmia events in real time for physician analysis, while the Zio's results take several weeks to reach the doctor. This latter shortcoming was frequently deemed unacceptable by many of the physicians with whom we spoke. Moreover, as pointed out earlier, EMs are more than 40% cheaper for payors. Given their superiority, we don't expect that payors will allow that disparity for very long.

Beyond the underrated advantages of status quo monitoring modalities, it's fair to say that, by iRhythm's standards, the Zio is not even the best patch-based extended Holter. That distinction probably falls on a relatively new product – the Carnation Ambulatory Monitor (CAM) by Bardy Diagnostics. We've spoken with physicians that have used both the CAM and the Zio, and have reviewed clinical literature comparing the two head-to-head. Briefly:

- In a head-to-head comparison of the CAM with a traditional Holter over a 24 hour period (i.e., a true head-to-head), the CAM had a higher diagnostic yield and showed incremental clarity and precision vs. the Holter monitor, even on arrythmias that were identified by both monitors.

- In a head-to-head comparison (summary here) of the CAM with the Zio, the CAM had a higher diagnostic yield than the Zio, identifying 40% more arrhythmias. Given the CAM's placement, it was also unsurprisingly "ranked higher in clarity compared to the Zio-XT" by the reviewing EPs. Finally, in another data point that iRhythm points to in its comparison with a Holter, "when the managing physician was asked to recommend a specific clinical action based on the findings of each monitor separately, a difference in clinical decision-making would have been made in 12 [of 29] patients."

[8] There isn't much literature on Event Monitors after 2003, and even this systematic literature review in 2010 doesn't find much beyond the early 2000's.

The physicians we spoke with also mentioned that the report that Bardy generates for doctors after the patient's extended Holter usage was as clear, intuitive, and well-designed as the Zio report. The CAM also has the distinct advantage of having the recording of the patient's heart rhythm available to the physician immediately upon receiving the patch from the patient. The physician's staff can easily connect the device to Bardy's software and generate a report in the office without having to send the patch by USPS to Bardy's IDTF (which is also, not coincidentally, located in Houston).

We also spoke to an EP at a large west-coast Integrated Delivery Network (IDN) hospital who confirmed that Bardy also has a distinct advantage relative to iRhythm by allowing more billing flexibility on the customer side. iRhythm does not offer the option of buying the device from them and conducting all the procedures in-house – once the Zio is used, only the iRhythm IDTF can conduct the analysis and reporting. Bardy, on the other hand, offers customers the option of simply buying the device and software, and then conducting all the procedures in-house. This is particularly attractive for large hospital networks that already employ ECG technicians to read traditional Holter and Event Monitor recordings. Their marginal cost structure for using a CAM once they own the device is minimal.

It's also worth pointing out that Bardy is well aware of the pitfalls of being a one-product company. Employees at Bardy have confirmed to us that Bardy is already in the process of moving both up-market and down-market. Regarding the former, the company is working on an Implantable Cardiac Monitor (ICM) that would compete with Medtronic. Down-market, the company has submitted a 510(k) application to the FDA for an over-the-counter extended Holter. The latter effort is a good indication of how rapidly the cost curve is being scaled on extended Holters, and device commoditization is another factor that the Zio, with its high reimbursement levels, will be battling in the near future.

We consider Bardy to be the most formidable challenger to iRhythm, and the CAM patch has already reached 5000 procedures/month according to the Bardy staff (as compared to iRhythm's ~50,000). But there are at least a few other companies that have recently entered the fray, which could make volume growth more difficult to achieve for iRhythm:

- BioTelemetry – BioTel has historically been the most dominant player in Event Monitoring and MCT. Their recent foray into extended Holter monitoring is the ePatch, which has so far been met with a lukewarm reception on the part of cardiologists and EPs. BioTel has been more successful with its recent MCT product introduction which features a multi-lead combined MCT/EM device that is quickly becoming the go-to monitoring device for many EPs given its flexibility.

- Preventice – Preventice has also been historically strong in MCT and Event Monitoring, but it recently introduced the Preventice Mini, which can function as any of the three monitors – MCT, Event Monitor, or extended Holter. Based on discussions with cardiologists, the Mini has generated significant buzz, with all of them intending to try it out in their practice.

Both BioTel and Preventice can take advantage of their ability to sell a full suite of monitoring products to providers, and we think they present, along with Bardy, a significant obstacle to iRhythm's growth rates going forward.

V. The TAM for the Zio is Much Smaller than iRhythm Suggests, and the Effort to Expand its Product Offering through the Zio AT has been a Failure

The Zio XT has a much smaller TAM runway than iRhythm describes

> *If we think about those 4.6 million annual procedures within the U.S., about 60%, close to three million of them are Holter monitors. Those are first line tests. That's a completely addressable market segment for us and there really isn't any innovation in that segment. Event monitoring is either a first line or second line test. We address roughly two-thirds to three-quarters of that market.*
>
> Kevin King
> iRhythm 2016 Third Quarter Earnings Call, December 5, 2016

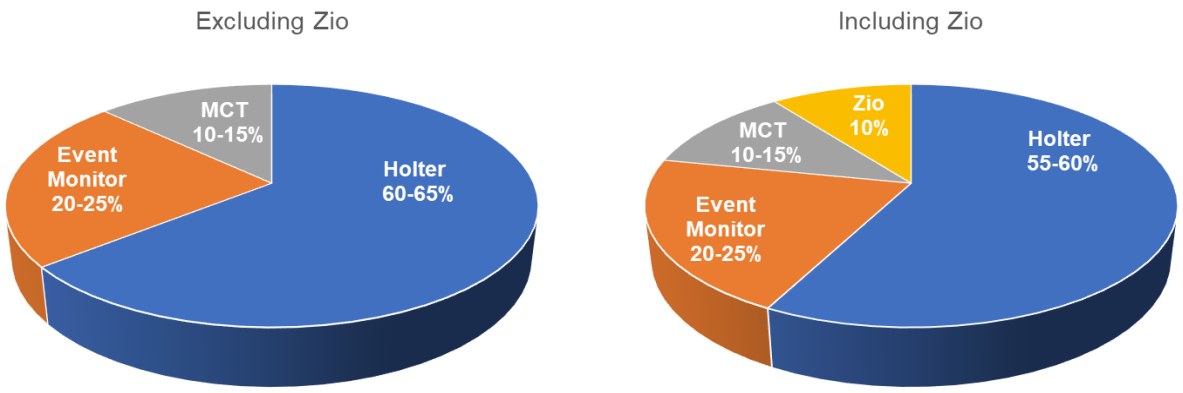
> *Today, the legacy ambulatory monitoring market is primarily focused on the initial diagnosis of symptomatic patients that amounts to over 4.5 million tests per year. We estimate that our share of this existing market is now double digits, as we've broadened our presence and displaced legacy Holter, Event, and mobile telemetries with our XT and AT services.*
>
> Kevin King
> iRhythm 2018 Third Quarter Earnings Call, October 30, 2018

iRhythm would like investors to think that there is a $1.8 billion cardiac monitoring market,[9] and that the company's $147 million revenue is just a small slice of that market. Traditional Holter monitoring makes up the lion's share of the pie and, combined with most Event Monitoring procedures, represents the 85-90% share that the Zio XT can theoretically win. Meanwhile, MCT, at about 10% of the market, is not incredibly relevant. iRhythm, though, is trying to gain a foothold in the space because it allows them to present a more complete product portfolio, thereby improving the prospects for its core Zio XT product.

[9] As per iRhythm's description in Part I of its 2018 10-K

Based on CMS utilization data and commentary by BioTel regarding their share of the MCT space, the volume split in the cardiac monitoring market looks like this:

Unit-Level Market Share of Cardiac Monitoring Modalities 2018



Source: CMS Provider Utilization and Payment Data, BioTelemetry Inc. Filings and Conference Call Commentary, Kerrisdale analysis

Reimbursement considerations aside, we think iRhythm's claim – that 90%+ of the market is up for grabs by extended Holter monitors – is greatly exaggerated because it doesn't account for how the devices are used. MCT and Event Monitoring are almost entirely incapable of being replaced by a Zio patch: Both methods are almost exclusively prescribed by electrophysiologists, most of whom avoid the Zio given its lack of signal clarity and inability to accurately diagnose arrhythmias beyond Atrial Fibrillation. In fact, some of the EPs we've spoken with complained of having received patient referrals after a Zio recording and having to re-monitor with an Event Monitor so that they can get a clear view of the rhythm abnormalities. MCT and Event Monitoring are also generally prescribed because they are real-time monitoring modalities, which has a double benefit. First, it allows the physician to more rapidly make a diagnosis, frequently cutting the procedure short after only a few days, because enough data has already been collected to make an accurate diagnosis. Perhaps more importantly, 24-hour attended monitoring virtually guarantees that a dangerous arrhythmia requiring treatment will get that treatment quickly. The Zio, therefore, has almost no utility for the 35-40% of the market currently served by MCT or Event Monitoring.

But even the share currently occupied by traditional Holter monitoring will become increasingly difficult for iRhythm to capture. First, that's because some Holter procedures are repeated after an initial monitoring that was inconclusive. We estimate that's at least 5% of traditional Holter procedures.[10] But much more significantly, while a Holter is frequently used because it's the simplest first-line monitoring modality, it's also often used because the patient presents as

[10] Based on CMS utilization data, which includes both total number of procedures as well as the total number of unique beneficiaries for each procedure.

symptomatic on a frequent basis. In that case, not only does the traditional Holter remain the best monitoring method due to its recording clarity and precision, but also because a diagnosis is required without delay. The multi-week waiting period for a Zio procedure will always remain unacceptable for such patients, and we estimate that's another 15-25% of Holter share that will not be captured by any kind of patch monitor.

From the perspective of unit volumes, iRhythm's addressable market is therefore best described as the traditional Holter monitoring procedures performed not by electrophysiologists, but by cardiology and primary care practices, where time is not of the essence, and the quality of the rhythm recording is not relevant. That's perhaps up to half of the size of the cardiac monitoring market as a whole, and it means the Zio is much more penetrated than the company admits.

The attempt to expand clinical cardiac monitoring to asymptomatic patients is unrealistic and bound to fail

> *Sitting above our currently addressable market in the funnel lies the opportunity for detection of asymptomatic atrial fibrillation in patients with risk factors such as age, hypertension, diabetes or prior stroke. Following the publication of our mSToPS study in JAMA, we've spent considerable time with clinical thought leaders, payors and the pharma community to understand this market. And we've grown even more excited about its potential. Based on the inclusion criteria of mSToPS, we now estimate a market of greater than 10 million high-risk patients who could be potentially benefit from screening for AF. In order to fully access this market, we will need to show positive data on clinical outcomes and we expect such data to be available from mSToPS and other studies over the next few years…That data is a three-year endpoint, so it should be coming out sometime in the 2020, maybe 2021 timeframe.*
>
> Kevin King
> iRhythm 2018 Third Quarter Earnings Call, October 30, 2018

The shorter-than-acknowledged runway for the Zio is why iRhythm is so invested in expanding the potential patient population for cardiac monitoring. The current 4.5 million-procedure monitoring market is comprised entirely of symptomatic patients, i.e. people who have arrhythmia symptoms and are subsequently tested through ambulatory cardiac monitoring. There are millions of people, though, who have no arrhythmia symptoms but are still considered at high risk of stroke from atrial fibrillation.[11] The opportunity that iRhythm has highlighted to investors is the mass monitoring of this asymptomatic population – by a Zio of course.

The trial that iRhythm has been consistently emphasizing on earnings calls and presentations is the mHealth Screening to Prevent Strokes (mSToPS) clinical trial. The trial design is as follows:

[11] The simplest measure of this is known as a $CHADS_2$ score, which is used by the mSToPS study

- Two cohorts were formed from a group of at-risk-but-asymptomatic patients: the "actively monitored" cohort is initially monitored by a Zio patch while the "observational control" cohort is left alone and observed.
- The actively monitored cohort is itself split, with half being monitored by a Zio in the first two weeks of the trial ("immediate monitoring") and the other half only getting the Zio monitoring after 4 months have elapsed ("delayed monitoring").
- All those in the actively monitored cohort are monitored by a Zio *twice*. So first, they wear the Zio patch for two weeks, and then they wear it again (also for two weeks) 3 weeks after the first patch is removed.

Among other questions, the study seeks to document any variance between the groups in the proportion of AF diagnoses, percentage of population initiating anticoagulant therapy, amount of healthcare utilization (as defined by doctor visits), incurred medical costs, and, most importantly, medical outcomes.

The trial is set to last 3 years, with a full analysis to be published in late 2020 or 2021. But an analysis of some of the data at the 1-year mark was published in JAMA in July of 2018, and iRhythm hailed it (see the comments by King above) as a precursor to changes in official treatment guidelines that would endorse expanded monitoring, potentially doubling the Zio's addressable market. We examined the analysis, as well as multiple published responses. While the interim-analysis study is clearly indeterminate regarding the utility of mass screening, the evidence presented in the paper would seem to argue strongly against screening with a Zio.

The primary endpoint of the 1-year interim analysis compared the two halves of the actively monitored cohort – the immediate monitoring half and the delayed monitoring half – during the first four months of the trial. The study found that the number of AF diagnoses in the immediate monitoring group was significantly higher than in the delayed monitoring group. This is wholly unsurprising – if you look for something, you're more likely to find it than if you're not looking for it. That doesn't have much bearing, though, on whether mass screening is useful. As the JAMA editorial published alongside the study remarked:

> *… before the findings of mSToPS can be incorporated into clinical practice, 2 major questions must be considered with regard to structured AF screening: (1) does earlier or more sensitive detection of AF improve clinical outcomes? (2) And if so, is it cost-effective?*
>
> *Among **symptomatic** patients who are candidates for rhythm control, both medical (antiarrhythmic) and interventional approaches (ie, catheter ablation) have consistently demonstrated more favorable outcomes among patients with intermittent AF (and less advanced disease). **The net clinical benefit of stroke prevention for patients with lower-burden…or subclinical AF is more complicated**…Data from randomized trials are necessary to test whether the benefits of treatment with oral anticoagulation outweigh the risks in patients with subclinical or low-burden AF.*

> *Whether screening for AF is cost-effective is a more complex question and depends on the target population, local practice patterns, screening approach, and the effects on outcomes. While several studies have suggested various screening protocols to be cost-effective in different health systems, these studies have been based largely on assumptions regarding stroke risk reduction in these patients, which will require additional trials to confirm.* [emphasis added]

In other words, mSToPS will not be the last word on the two critical questions regarding expanded monitoring – namely, is there an associated net benefit and is it cost effective?

The secondary endpoint of the interim analysis, which is actually more relevant to the determination of whether there's a net benefit to mass screening, simply compared the number of AF diagnoses at the 1-year mark in the actively monitored cohort vs. the observational control. The results are incredibly revealing about the utility of screening with a Zio:

> *In the observational study, over 12 months of follow-up, 190 new cases of AF were detected, 109 of 1738 (6.7 per 100 person-years) in the actively monitored cohort and 81 of 3476 (2.6 per 100 person-years) among observational controls (absolute difference, 4.1 [95% CI, 3.9-4.2]).*
>
> *In the actively monitored cohort, 65 individuals were first found to have AF by ECG patch (43 with first patch and 22 only with the second patch). In this cohort, 44 individuals received a clinical diagnosis of AF either prior to monitoring (n = 12) or after monitoring was completed without any findings of AF during monitoring (n = 32).*

So AF was diagnosed much more frequently in the actively monitored cohort compared to the observational control (6.7 diagnoses per 100 person-years vs. 2.6). But note the distribution of the 109 AF diagnoses in the actively monitored cohort:

- 43 were made by the Zio patch the first time it was applied
- 22 were made by the second application of the Zio patch (remember, every patient used the patch twice)
- 44 were made by a doctor *completely independent of the Zio patch*, either because the diagnosis was made before the patch was applied (12 patients), or because *the Zio did not properly identify AF* (32 patients).

In other words, 66 of 109 AF diagnoses in the actively monitored cohort were due to *either the application of a second patch, or a visit that the patient paid to the doctor because they were part of the study*. If you take those away, the number of diagnoses per 100 person-years is *exactly the same*. So the way the Zio would be used in the real world – simply applying it once when a high risk but asymptomatic patient went for a check-up – would provide *nothing* in the way of incremental AF diagnoses.

Additionally, regarding the primary endpoint, which found a 3.9% AF diagnosis rate in the immediate monitoring group vs. the delayed monitoring group, JAMA's editorial had this to say:

> *The population in the current study may be most similar to that of the Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation (REHERSE-AF) Study, in which at-risk patients were recruited in the United Kingdom and instructed to self-record their rhythm 1 to 2 times weekly (and with symptoms) using a hand-held device.* ***This monitoring strategy resulted in a 3.7% rate of AF diagnosis at 12 months, which is similar to that of the mSToPS detection rate at 4 months (3.9%)****…*[emphasis added]

Left unsaid is that self-monitoring using the AliveCor device is 70% cheaper than using a Zio. We also discussed the mSToPS study with a prominent electrophysiologist who is deeply involved in writing cardiac monitoring guidelines, including the 2017 Expert Consensus Statement on Ambulatory ECG. His view was that:

> *…surveillance for patients at high risk of stroke if they have AF is a very legitimate area of inquiry now. To be fair, it is an area that is as yet unsettled…and at the present time it's the conclusion of all the experts that there's insufficient data to warrant sub-population screening with ECG recording systems. I would say that in the asymptomatic, not previously diagnosed patients, it is highly unlikely that it will be an iRhythm-type device that will be used, because that's way too cumbersome and expensive.*
>
> *What* ***has*** *been used are handheld ECG recorders and the Apple Watch, for example, so smartphone-based ECG recorders…not heart rate systems, but actual ECG recording…that may lead to more substantive and comprehensive ECG recording [in a clinical setting].*
>
> *The big objection to doing this in mass screening is the expense, and that was based on using far less expensive products [than the Zio], because obviously when you start employing this in a not-insignificant portion of the older population, the costs add up quite quickly. Even doing the Apple Watch or the AliveCor, that's only $100, but…even if it's $25 or $50, it adds up, and then you have the downstream expenses. You're going to probably have to do some additional monitoring…it opens Pandora's box in terms of expenses. The bottom line is I do believe that mass screening at some point will become accepted, but there's a lot of work to be done to define which type of populations, which type of screening…*
>
> *And then, does it predict stroke? Just because you pick up an incidental AF on one ECG, does it have the same implications for stroke as an AF event that is presented to your office or in the Emergency Room? My guess is it may not…So I think we really have to prove association with stroke.*

Worth noting is that about a month after the mSToPS 1-year analysis was published in JAMA, the journal published the US Preventive Services Task Force statement on screening for AF with ECG in asymptomatic adults older than 65. The task force reviewed seventeen studies and concluded:

> *Although screening with ECG can detect previously unknown cases of atrial fibrillation, it has not been shown to detect more cases than screening focused on pulse palpation. Treatments for atrial fibrillation reduce the risk of stroke and all-cause mortality and increase the risk of bleeding, but trials have not assessed whether treatment of screen-detected asymptomatic older adults results in better health outcomes than treatment after detection by usual care or after symptoms develop.*

It's delusional to think that mass screening of asymptomatic high-risk patients with expensive, clinical-grade cardiac monitors will ever become the standard of care.

The Zio AT does not meet the criteria for Mobile Cardiac Telemetry, and it has been a failure

> *We were pleased to receive FDA clearance in June for Zio AT, our next-generation offering aimed at increasing our served market with the addition of timely data transmission capabilities to serve patients who have more critical symptoms such as syncope, pre-syncope and ventricular tachycardia.*
>
> Kevin King
> iRhythm 2017 Second Quarter Earnings Call, August 2, 2017

> *On the AT side, we've message that this is more like a three to four-quarter ramp. I think the question came on our last call, was this like a 2 to 4 or was this an 8 to 10 quarter ramp, and we guided kind of more towards the lower end of the 3 to 4 quarters in order to get full AT contracts… we came out of the box pretty strong here. And so, we're feeling good about the status or the position that we're at right now.*
>
> Kevin King
> iRhythm 2017 Third Quarter Earnings Call, November 1, 2017

> *The rollout of Zio AT provides another meaningful opportunity to gain share by enabling us to offer a full portfolio of ambulatory cardiac monitoring services on a single platform to our customers…*

> *Most accounts have Holter monitors, Event monitors and to some degree some usage of MCT. They may have it in different mix configurations…It really depends upon the physician preference. The important thing here is that Zio now has the ability to replace*

everything that's there. And that's what we're increasingly doing. Prior to AT, we were taking share, if you will, from the legacy markets of Holter and Event; and to some extent, MCT where the patients were getting prescribed MCT for the purposes of longer duration, but not necessarily the life critical nature of the arrhythmias that they may have underlying.

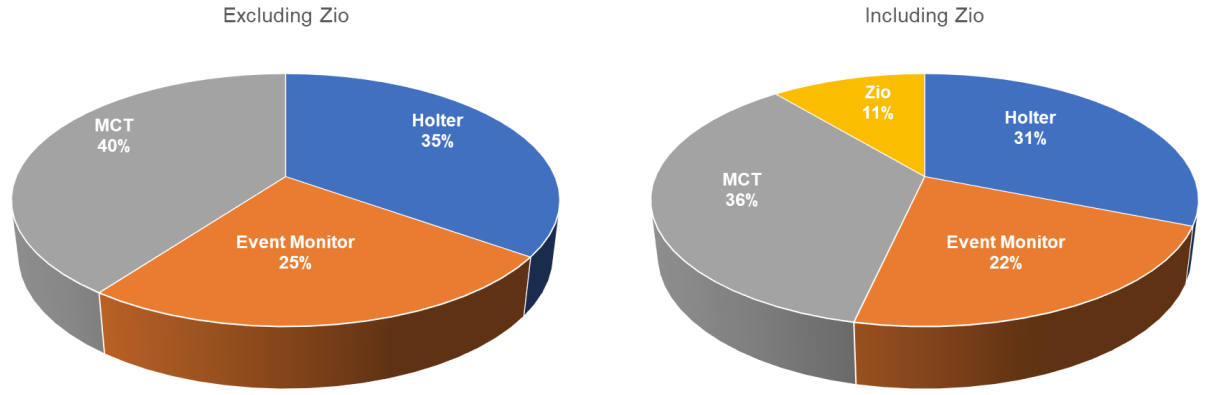
Kevin King
iRhythm 2018 Third Quarter Earnings Call, October 30, 2018

It's worth reiterating the primary reason for our phased roll-out of Zio AT is that the number of possible contracted lives for Zio AT is significantly less than that of Zio XT. Many health plans continue to have negative MCT coverage decisions, stating that the technology is either still unproven or too costly compared to alternatives… We expect to have completed our initial contracting efforts by the first half of this year and will then more aggressively expand Zio AT into the market at that time.

Kevin King
iRhythm 2018 Fourth Quarter Earnings Call, February 12, 2019

In addition to attempting to influence treatment guidelines and expand the addressable patient population, iRhythm has tried to expand its TAM by adding a second product line. The Zio AT, approved in June of 2017, is iRhythm's Zio for the MCT market. It's understandable that iRhythm would want to break into that market. After all, by dollar share, Mobile Cardiac Telemetry, dominated by BioTel, is the largest piece of the cardiac monitoring market:

Dollar Market Share of Cardiac Monitoring Modalities 2018



Source: CMS Provider Utilization and Payment Data, BioTelemetry Inc. Filings and Conference Call Commentary, Kerrisdale analysis and estimates

But iRhythm's portrayal of the Zio AT to investors has been somewhat misleading. When first introducing the product to investors in August of 2017, management described it as similar to the Zio XT flagship product, but with "timely data transmission capabilities to serve patients who have more critical symptoms." As recently as this past October, King stated that the AT allowed

iRhythm to monitor patients and the "life critical nature of the arrhythmias that they may have underlying." The device's application and approval with the FDA, though, explicitly mentions that critical care is contraindicated as the device "is not intended for use on critical care patients."

In our discussions with electrophysiologists around the country, we couldn't find anyone that had used the device, or even knew of someone that had used the device. Industry participants we contacted told us that they were under the impression that the AT did not have the ability to monitor in real time, which is required for an MCT device, and several mentioned that they understood that iRhythm had pulled the device from the field because it wasn't performing up to MCT standards. Indeed, the recently released 2018 10-K has made several significant revisions to the company's descriptions of the Zio AT compared to prior filings, which imply that the device was not successfully deployed as a real-time monitor:

- While historical filings have referred to the AT as "capable of real time monitoring," the recently filed 10-K for Fiscal 2018 describes the AT as "offer[ing] the option of timely transmission of data."

- In its 2017 10-K, iRhythm explained that "we received FDA clearance for the Zio AT monitor in June 2017 and this addition to our product portfolio seeks to address the segment of the patient population who require real-time notification of critical arrhythmias through wireless transmission capabilities during the wear period." The 2018 10-K instead says that the "Zio AT offers the additional capability of transmissions during the wear period to assist physicians to diagnose and treat the small percentage of the population requiring more timely action. During the wear period, physicians will receive notifications if there are significant events that meet pre-determined arrhythmia detection criteria." That capability doesn't even meet the "attended monitoring" standard required to bill under the Event Monitoring codes.

- In the 2017 10-K, the AT is described in iRhythm's "Business Strategy" section as appropriate for "the smaller percentage of the population that requires *outpatient telemetry*." Telemetry, of course, is a clinically relevant term, but the words "outpatient telemetry" are replaced in the recent 10-K with the words "timely notification."

Explicit references to the Zio XT in the 10-K have also been replaced simply by references to the "Zio Monitor," and in the beginning of the 10-K, the company writes "[w]e refer to both the Zio AT monitor, and the Zio XT monitor herein as our Zio monitor(s), unless otherwise specified." In general, in the new SEC disclosures the Zio AT is described more as a sort of Zio XT with some extra features rather than a different monitoring modality.

It's also curiously impossible to find anything on the iRhythm website that mentions the Zio AT. Under "Products & Services," only the Zio XT appears, and in information for healthcare

professionals, there are detailed instructions for the reimbursement codes of the Zio XT, but nothing to be found about the Zio AT.

While iRhythm had originally guided to a 3-4 quarter ramp in getting the AT contracted with third party payors, almost 2 years after approval, the company still does not have significant AT revenues to speak of. For context, bear in mind that for the AT to be 10% of iRhythm's total revenues, the point at which they've implied that they would break out its revenues separately, it would need to have been performed just about 3,500 times over the course of a quarter. That's only about 2.5% of MCT volumes and less than 0.3% of total cardiac monitoring volumes – numbers the Zio XT reached in less than two quarters after receiving a reimbursement agreement with Novitas.

In their February earnings call, the company subtly acknowledged the AT's lack of uptake and said that the "phased rollout," a term they never previously applied to selling the AT, was because of commercial health plans having "negative MCT coverage decisions." But, as per CMS as well as iRhythm's own estimates of the market size, just under half of MCT procedures are performed through Medicare, which shouldn't require any success contracting with commercial payors.

We believe that the Zio AT simply doesn't work as an MCT device, and as a result, does not meet a need in the cardiac monitoring space. It's worth pointing out that even if the AT *did* work, it's hard to imagine that it would get much traction. Recall that MCT is prescribed almost only by electrophysiologists not just for the real-time monitoring ability, but because they require the clarity and precision of a multi-lead monitor, which the Zio AT just can't provide.

VI. Valuation

There aren't many publicly traded companies that are comparable to iRhythm. Perhaps the most similar company is BioTelemetry Inc, which dominates the MCT space with 50-60% market share. We value iRhythm below by estimating its potential revenues at market maturity (as MCT is currently), generously assume a BioTel-like market share, and apply a BioTel-like multiple to those revenues, discounting that back to today.

Valuing iRhythm like BioTelemetry Inc.

(in mm, except for per-share figures)	
Approximate Annual Holter & Extended Holter Procedures:	3.00
Extended Holter Share as a %:	65%
Total Extended Holter Procedures:	1.95
iRhythm Market Share of Extended Holters:	65%
Total iRhythm Procedures:	1.27
Reimbursement Revenue per Procedure*:	$ 193.80
Total iRhythm Revenues at Market Maturity:	$ 246
EV/Revenue Multiple:	4.50x
iRhythm Fair Value at Extended Holter Maturity:	$ 1,105
Years to Extended Holter Maturity:	4
Implied iRhythm Enterprise Value**:	$ 755
Net Cash:	$ 35
Per Share:	**$ 30.50**
Downside:	-65%

**Assumes 30% of procedures through Medicare at the Event Monitoring rate of $170 and 70% of procedures through commercial payors at a 20% premium to Medicare*

***Assuming a 10% discount rate*

Note: 4 years to Extended Holter Maturity implies a unit growth rate for IRTC of 27%

The above might even be a bit generous as BioTel's current valuation embeds at least some optimism that the company will be successful in capturing share from iRhythm. Even assuming an equivalent reimbursement rate as Event Monitoring (as we do in the above table, though we believe there is substantial downside risk to that), it's difficult to imagine iRhythm being worth anything close to its current value.

In this context, it makes sense that in all the insider transactions since iRhythm's IPO, there hasn't been one instance of insider purchasing, with every options exercise that has occurred being accompanied by a sale of the shares acquired.

VII. Conclusion

iRhythm fancies itself a technology company, and investors have bought into the narrative, awarding the company a 10x EV/NTM Revenue multiple. But with no pricing power or customer lock-in, looming drastic price cuts, and a limited TAM, iRhythm's circumstances couldn't be more different than its San Francisco neighbors. iRhythm's narrative has been portrayed as one of rapid revenue growth, no competition, and a huge TAM opportunity. But the TAM is a mirage, and as the company hurtles towards a looming reimbursement cliff and a step change in the competitive environment, the end of the story will be heart-stopping.

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