

BioTelemetry, a significant holding within our Bionics certificate and an equally important position in the Biotech and Innovation certificates, has experienced 7 months of extreme derating with its shares trading now at 21.5x FY 2019 PE after having touched a valuation of 40x FY 2019 PE in February of this year. Even if we do not envisage a return to previous valuation, we believe current level is too low for a company that, in our view, will be able to sustain a double-digit top line growth and a constant margin improvement for the next 5 years at least.

The firm has probably experienced, in a relatively short period of time, what Gartner calls in his Hype Cycle, the transition from a "Peak of Inflated Expectations" phase to a "Trough of Disillusionment" phase. After acquiring in July 2017 the Swiss-based company LifeWatch, the numbertwo player in the space, BioTelemetry partnered with Apple (AAPL US) to provide cardiac monitoring services in conjunction with the Apple Heart Study with researchers from Stanford University. The study had the goal to combine the iPhone, Apple Watch, and BioTelemetry's ePatch to screen for heart rhythm abnormalities in the general population. These two events pushed the stock quickly, probably too quickly, to a valuation that was too rich and inflated by the prospect of a possible acquisition of the company by its giant partner. The stock in less than a year tripled helped of course by its ability to deliver constant year-over-year revenues growth. As always happens, after a phase of extreme (and unsustainable) excitement, the stock reached a level in which there were no incremental buyers, M&A appeal started to vanish, and valuation was too high to sustain the price. From there BioTelemetry started to lose ground, overshooting eventually on the downside even if fundamentals did not change at all. The company, in fact, continued to release quarters of double digits top line growth and margin improvements, but that was not enough to regain interest from investors.

When a stock experiences a large derating without fundamental reasons, the street tries to find reasons to blame. Concerns of increased competition (from the likes of **iRhythm** (IRTC US) or privately held companies such as **Applied Cardiac Systems**, **Bardy** and **Preventice**) and possible cuts in reimbursements are by far the two main arguments that we heard over the last few months.

The goal of this report is firstly to go deeply into these two main worries to see if there are some credible threats arising that could negatively affect BioTelemetry's fundamentals and then to refresh our investment case. October 2019

BioTelemetry

Current Share Price: \$37.71 Fair Value (AtonRâ): \$55.50 Upside potential: +47%

BioTelemetry (NASDAQ:BEAT) is the leading provider of remote cardiac monitoring diagnostic services (www.gobio.com)

United States Health Care Providers & Services

AtonRā Partners

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Investment Case

We see digital medicine and Remote Patient Monitoring ("RPM") as a massive market opportunity, even more since the Center for Medicare & Medicaid Services ("CMS") approved three new billing codes for RPM in November 2018. This is one of the most significant incentives to-date in digital medicine in the US.

BioTelemetry's primary revenues – 85% of the total, come from the diagnosis and monitoring of cardiac arrhythmias. Within this business, about 70% of its revenues come from the Mobile Cardiac Outpatient Telemetry (MCOT or MCT), which supplies real-time cardiac monitory services to patients for up to 30 days. The company is also leveraging its expertise in mHealth in other markets and most notably in diabetes monitoring.

The Global Mobile Cardiac Telemetry is a market that is expected to grow at 10% CAGR for the next 5 years driven by increasing awareness about cardiac diseases and by technological innovation. BioTelemetry is, in our view, the best positioned company, on a risk-adjusted basis, to take advantage of this growth thanks to its product portfolio and its unique platform. Even if competition in the space is high, BioTelemetry has **one of the most accurate and diversified product portfolios in the market**. This is an important advantage considering that physicians and electrophysiologists are used to prescribe more than one type of cardiac device and having the same supplier can provide them additional benefits. There are multiple drivers explaining the superiority of their portfolio, e.g. (1) the algorithm used in their MCTs, (2) the possibility to take off the ePatch on their extended Holter and to put on a different patch, or (3) their platform providing the service/technology to physicians to follow more closely their patients – and eventually charging them an incremental fee justified by the quality of the data collected. BioTelemetry's product portfolio can generate the highest diagnostic yields and the fastest turnaround times for more than 30,000 physicians.

As for the other players in the sector, revenue for BioTelemetry is strongly dependent on governmentrelated **reimbursement**; Medicare alone accounts for 34% of the revenues, where **we do not see substantial changes in the short- to midterm**. The MCOT reimbursements fees for 2020 are currently under review with final approval due in November 2019. Based on the indication from the preliminary July guidelines we should not see any cut.

Patients are given MCOT only as a second line diagnostic. A patient suffering from arrhythmia has first gone through Holters and extended Holters (up to 14 days) for some of the payors. If physicians decide that the patient need to go under more prolonged heart surveillance, it will choose longer-term monitoring systems such as BioTelemetry's MCOT or event recording devices which are very accurate in detecting the different types of arrhythmias, unlike the extended Holters. Prolonged duration monitoring such as the extended Holters are replacing conventional Holter monitoring thanks to clinical studies confirming a better accuracy. In 2017, BioTelemetry launched the ePatch service, which is an extended Holter monitoring – 5% of the company's healthcare revenues, and one of the fastest-growing products for the company. ePatch directly competes with iRhythm's products (Zio XT) while Medtronic exited this market in 2018 to focus on monitoring patients for up to three years and where cardiac arrhythmias are less frequent. In September 2019, the American Medical Assocation ("AMA")



decided on the reimbursement code change for extended Holter monitoring such as BioTelemetry's ePatch and iRhythm's Zio XT, which are currently under Category III (temporary code – the highest reimbursement). Their decision is expected to be published in November 2019. The technical piece of the reimbursement has a chance to go down. There is also a chance that it remains the same and a chance that it goes up, but we will be surprised if this happens. This reduction has a very limited impact on BioTelemetry business as of now because is still not a huge part of their business.

Whilst an aggregation with Apple Health remains a possibility, given the strong link between the two companies and the willingness of Apple to become an important player in the healthcare sector, our Investment Case prescinds from this possibility but sees the iWatch ECG functionality a significant driver for the sector. With the increased penetration of iWatch and the consequent increase of heath rhythm abnormalities detection, real-time monitoring device like BioTelemetry extended Holter or MCTs have the potential to significantly reduce its health consequences.

Company description

BioTelemetry (NASDAQ:BEAT, market capitalization of \$1.3bn, 97% free float) provides remote cardiac monitoring, remote blood glucose monitoring, centralized core lab services for clinical trials and original equipment manufacturing that serves both healthcare and clinical research customers. They operate under two main reportable segments: <u>Healthcare</u> and <u>Research</u>.



Diagnosis and monitoring of cardiac arrhythmias or heart related disorders in a healthcare setting The Healthcare segment, which generated 85% of the revenue in 2018, is focused on the diagnosis and monitoring of cardiac arrhythmias or heart rhythm disorders. Since they started focusing on cardiac monitoring in 1999, they have developed a proprietary integrated patient management platform that incorporates wireless data transmission, and the U.S. Food and Drug Administration ("FDA") cleared algorithms, medical devices and 24- hour monitoring service centers. They offer cardiologists, electrophysiologists, neurologists and primary care physicians a full spectrum of solutions, which provides them with a single source of cardiac monitoring services. These services range from the differentiated MCT service, to event, traditional Holter, extended-

wear Holter, Pacemaker and International Normalized Ratio ("INR") monitoring. With over 30,000 unique referring physicians per month, they provide cardiac monitoring and reporting for over one million patients per year.

They market the cardiac monitoring solutions in the Healthcare segment through direct sales. They are the leading member of the Remote Cardiac Service Provider Group ("RCSPG"). The RCSPG collaborates with physician specialty societies as well as the American Telemedicine Association to advocate to the Centers for Medicare and Medicaid Services and Congress for appropriate valuation of remote diagnostic services that the RCSPG members provide.

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The Research segment, which generated 13% of the revenue in 2018, is engaged in central core laboratory services providing cardiac monitoring, imaging services, scientific consulting and data management services for drug and medical device trials.

They market the Research segment services to pharmaceutical companies, medical device companies, contract research organizations and academic research organizations. They are a founding member and the first cardiac core lab to join the Cardiac Safety Research Consortium ("CSRC"). Through the CSRC, they are able to network with key thought leaders and decision makers of major pharmaceutical companies, as well as discuss key cardiac safety issues during the drug development process.



Cardiac monitoring & imaging services for drug trials in a clinical research environment



Remote monitoring and analysis of blood glucose for diabetes population health management



Develops, manufactures and markets medical devices to medical companies, clinics and hospitals The "**Corporate and Other**" category contains their other operating business brands: **<u>BioTel Care</u>** and **<u>BioTel Alliance</u>**, which focus on the sale, manufacturing, engineering and development of non-invasive cardiac monitors and other population health management devices for leading healthcare companies worldwide.

They offer contract manufacturing services, developing and producing devices to the specific

requirements set by customers. They manufacture various devices, including MCT-monitors, cardiac event monitors and digital Holter monitors utilized by their Healthcare and Research segments. Their facilities, located in San Diego, CA and Concord, MA, are responsible for research and product development under FDA guidelines. Manufacturing of devices is performed in part in their Eagan, MN facility.

Key People

As of October 2019, the executive committee is composed of five people. Three other people assume operational leadership of the main business segments (Heart, Care, Research). Among the Executives, the two largest shareholders are the CEO and the CFO: Capper owns roughly 162,000 shares of the company (0.48% of outstanding), and Getz 78,000 (0.23%). Wadwha, Chief Medical Officer, was recently appointed but holds the required qualifications and background to fulfill his duties; he joined the company through the Geneva Health Solutions acquisition. Regarding the board members, the 10 people own an aggregate 2.64% of the outstanding shares of the company.

Joseph H Capper (President/CEO): Prior to joining BioTelemetry, Mr. Capper served as President, Chief Executive Officer and a member of the board of directors of Home Diagnostics, Inc. (HDIX), a leading developer, manufacturer and marketer of diabetes management products, which he joined in

2009. Prior to joining Home Diagnostics, from 2002 to 2009, Mr. Capper was President and Chief Executive Officer of CCS Medical Inc., a private company that is a leading provider of medical supplies in diabetes, wound care, respiratory and other therapeutic categories.

Heather C Getz (CFO/IR): Ms. Getz was appointed Executive Vice President and Chief Financial Officer in May 2017. Ms. Getz joined BioTelemetry in May 2009 and previously served as Senior Vice President and Chief Financial Officer and prior to that our Vice President of Finance. From April 2008 to May 2009, Ms. Getz was Vice President of Finance at Alita Pharmaceuticals, Inc., a privately held specialty pharmaceutical company, where she was responsible for all areas of finance, accounting and information systems. Prior to joining Alita Pharmaceuticals, Inc., from March 2002 to April 2008, Ms. Getz held various financial leadership positions at VIASYS Healthcare Inc., a healthcare technology company acquired by Cardinal Health, Inc. in July 2007, including directing the company's global financial planning, budgeting and analysis, and external reporting functions. From June 1997 to February 2002, Ms. Getz began her career at Sunoco, Inc., where she held various positions of increasing responsibility. Ms. Getz received her undergraduate degree in Accountancy and a Master of Business Administration degree from Villanova University.

Manish Wadhwa (Chief Medical Officer): Dr. Wadhwa joined BioTelemetry in March 2019 as part of the Geneva Health Solutions acquisition. He is an actively practicing, board-certified cardiologist and cardiac electrophysiologist. After interviewing for medical school at the age of 16, Dr. Wadhwa enrolled in Penn State University's Thomas Jefferson Medical College Six Year BSc-MD program. Upon completion, Dr. Wadhwa trained in internal medicine and general cardiology at Thomas Jefferson University Hospital in Philadelphia, PA. He completed his cardiology training with two years of advanced fellowship in cardiac electrophysiology at the University of California at San Diego. Dr. Wadhwa has expertise in both implanted device management and follow-up as well as invasive and non-invasive treatments of arrhythmias. He has been serving the San Diego community in private practice since 2000. Dr. Wadhwa has served on the physician advisory boards of Medtronic, Boston Scientific, Biotronik, St. Jude Medical and Sanofi-Aventis, and is a fellow of the Heart Rhythm Society (F.H.R.S.). Dr. Wadhwa has authored numerous medical papers, lectures on clinical issues in cardiac electrophysiology and continues to be involved with post-market evaluations of commercially available implanted device leads and generators.

Kirk E Gorman (Chairman): Mr. Gorman served as the Executive Vice President, Chief Financial Officer of Thomas Jefferson University, an academic medical center in Philadelphia, from August 2014 until his retirement in June 2016. Mr. Gorman served as Executive Vice President and Chief Financial Officer of Jefferson Health System, a multi-hospital system in Philadelphia, Pennsylvania from September 2003 to August of 2014. Mr. Gorman was also a member of the board of directors and Audit Committee of IASIS Healthcare LLC from February 2004 until September 2017 when the company was sold. From April 1987 to March 2003, Mr. Gorman served as the Senior Vice President, Chief Financial Officer of Universal Health Services, Inc., a hospital management company and President, Chief Financial Officer and a member of the Board of Trustees of Universal Health Realty Income Trust, a real estate investment trust specializing in healthcare and human service related facilities. Mr. Gorman previously served on the board of directors of Health Management Associates, Care Investment Trust and VIASYS Healthcare, Inc.



SWOT Analysis

Strengths

- Extended range of cardiac monitoring services: event and traditional Holter, extended wear Holter, and mobile cardiac telemetry.
- Ease of use and reliability of the products.
- Good quality of algorithms to detect arrhythmias. The high diagnostic yield of MCOT (88%) can be a competitive advantage and encourage physicians to use the device for timely interventions and more effective treatments.
- Reimbursement approved by Medicare and other third-party commercial payors (already in category I for MCOT).
- Despite the increase in long-term debt to finance recent acquisitions, BioTelemetry's balance sheet remains solid. Moreover, free cash flow is expected to increase, and gross margins are high. The company has enough cash to eventually consider other investments.

Weaknesses

Threats

- Highly dependent on MCOT (approximately 50% of total revenue)
- In 2018, 34% of total revenue subject to reimbursement from the Medicare program – high dependence on this federal health insurance with restrictive rules and reimbursement rates set nationally, among other constraints (second most important payor represented 6% of total revenue).
- Limited sales channels products are marketed directly to cardiologists, electrophysiologists, neurologists, and primary care physicians in the United States.

Opportunities

- BioTelemetry is one of the leaders in its market but has still room to grow and increase its penetration rate. The market is highly fragmented with many small players.
- Recent acquisitions should increase top-line, e.g. (1) Geneva Health Solutions (cloud-based platform) allows Biometry to expand its footprint into the \$1bn cardiac device monitoring market and to reposition the company as a data management and solutions-oriented firm.
- BioTelemetry also acquired several companies in the Research market. The firm hopes to diversify its service offerings by becoming a global provider in the research market.
- The initial focus of the company has been on arrhythmia diagnosis and monitoring; expansion to new market areas that require outpatient or ambulatory monitoring and management (e.g. commercialization of a wireless blood glucose monitoring system in 2018).
- Demographic factors yielding to additional cardiovascular diseases (ageing population, obesity, etc.)

- The cardiac monitoring services market is competitive. New products and technological advances may affect the company's market share. While BioTelemetry invests into R&D, some competitors devote more resources to R&D.
- Entry of new players into the healthcare market, such as IT companies. BioTelemetry is collaborating with Apple that offers screening tools/apps (and not diagnostic medical devices). This threat could eventually represent an opportunity, as these new players may do some tactical acquisitions (M&A).
- Change in regulations that could lower reimbursement policies or reduce medical prescriptions.
- BioTelemetry's patents expire between 2018 and 2032, potentially exposing the company to more competition. To protect itself, the firm's technology is usually covered by several patents, creating a system of protected technology.



Market

Cardiovascular diseases (CVDs) are the leading cause of mortality worldwide, accounting for 17.3 million deaths per year, a number that is expected to grow to more than 23.6 million by 2030.¹ Arrhythmias (heart rhythm problems) are one of the diseases under the cardiovascular diseases' umbrella. Atrial fibrillation is the most common cardiac arrhythmia globally accounting for 2.7-6.1 million people in the US. That number is estimated to rise to 12.1 million by 2030, mostly because of an ageing population.² Cardiac arrhythmias, such as atrial fibrillation, are often asymptomatic yet are associated with critical adverse outcomes, such as embolic stroke.

According to Research Nester, the global mobile cardiac telemetry market has been expanding at 10-12% per year since 2017 and until 2027. In dollar terms, this market will triple to \$1.5bn from \$0.5bn over the period. BioTelemetry has a solid market share in the United States on this segment, north of 75%. The United States account for the highest market share in 2017 and will account for about 40% of the global market share in 2027. Future revenue growth on mobile cardiac telemetry will come from the organic growth due to an ageing population. Moreover, the company expects to gain market shares on the international markets. Recent acquisitions such as LifeWatch AG and **ADEA Medical AB** pave the way for BioTelemetry to expand to new markets. These companies were headquartered in Switzerland and in Sweden, respectively.

Mobile cardiac telemetry accounts for more than 50% of the revenue of BioTelemetry. The company is also active on Holters, extended Holters, and event recorders. These services are expected to grow at a mid-single digit rate for the next 5 years, within a range of 5-7% per year. However, BioTelemetry is experiencing a growth twice bigger than the market on Holters. The company is gaining market shares.

Finally, we can also note that BioTelemetry acquired in 2018 **Geneva Healthcare Solutions**, a software company that provides a platform to manage data from cardiac devices. This market may potentially represent a \$1bn opportunity. Geneva Healthcare Solutions' sales remain anecdotical for the moment, less than \$10mn, but are expected to grow significantly over the next 5 years, at a CAGR of 53%. By then, the market share of BioTelemetry will represent 5%.

¹ <u>https://www.heart.org/idc/groups/ahamah</u>

public/@wcm/@sop/@smd/documents/downloadable/ucm_470704.pdf

² https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm



Electrocardiogram Products

Alternatives in the market

Cardiovascular diseases are diagnosed using an array of laboratory tests and imaging studies. One of the most common tests used to diagnose cardiovascular diseases include Electrocardiography (ECG or EKG). Electrocardiography is a technology able to detect the electrical activity within the heart to diagnose life-threatening conditions such as ventricular or atrial arrhythmias. People may need a heart rhythm test if they experience symptoms such as angina (chest pain or discomfort), dyspnea, palpitations, and syncope.

Modern heart rate monitors commonly use either electrical or optical methods:

1. Electrical / ECG methods measure the bio-potential generated by electrical signals that control the expansion and contraction of heart chambers.

The current electrical methods of arrhythmia detection are:³

- · 12-lead ECG,
- Ambulatory Electrocardiography (AECG),
 - Holter Monitors,
 - o Event Recorders,
 - External loop recorders,
 - Insertable loop recorders,
 - o Non loop Recorders,
 - o Extended Holter,
 - Outpatient Cardiac Telemetry (MCOT or MCT)

A full description of the various electrical methods of arrhythmia detection can be found in the <u>Appendix 3</u>.

2. Optical / PPG (Photoplethysmography) methods measures the blood volume controlled by the heart's pumping action using photodetectors and light-emitting diodes. By shining a light on a patch of skin with an LED light source, the pulse pressure will cause a measurable difference in the amount of light reflected to a light sensor. The photoplethysmography-based smart devices are used for AF (atrial fibrillation) detection.

The current optical methods use are:

- 1. Smartphone camera and apps, e.g. Cardiio Rhythm (Cardio)
- 2. Smartwatch/band apps, e.g. Apple Watch series 4 (Apple), Simband (Samsung).

These devices are less accurate than electrical methods due to optical noise, skin tone problems, sensors location, false positives, etc. However, PPG-based AF detection can serve as excellent screening tools. These device systems and apps need to be further validated in larger randomized

³ <u>http://mcgs.bcbsfl.com/MCG?mcgId=01-93000-05&pv=false</u>

studies (like those conducted by Apple) in order for wide acceptance among physicians. The current focus of companies in this field is to develop more robust PPG-based algorithms for detection of atrial fibrillation (AF), that will be as accurate as ECG-based algorithms.

VEST BEYOND THE ORDINARY

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BioTelemetry's products

BioTelemetry holds 65 US patents and 134 international patents, and it currently has 56 active patent applications. The firm's products can be grouped into three categories: (1) Mobile Cardiac Telemetry: MCOT Patch, MCT 3 Lead, (2) - Extended Holter: ePatch, and (3) Even Recorder: wEvent.

Mobile Cardiac Telemetry

MCOT Patch

<u>MCOT Patch</u> is an FDA⁴ Class II medical device (cleared in 2016) monitoring up to 30 days of cardiac rhythm. MCOT Patch is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.



The device is comprised of two main components: 1) a patient-worn sensor with no leads and two channels and 2) a monitor.

The device continuously monitors patient ECG, automatically generates an alert triggered by a proprietary detection algorithm, or generates an alert manually triggered by the patient, and transmits the recorded data transtelephonically via Bluetooth to a monitoring center 24 hours a day. When cellular service is unavailable the patient has an option to transmit via a landline telephone. The monitoring center provides the ECG data to the physician for evaluation.

The diagnostic yield (the percentage of patients in whom an arrhythmia is detected) of MCOT Patch compared to Loop Event Recorders is **88%**⁵. The difference in findings is due to the asymptomatic findings captured with the MOCT.⁵

⁴ <u>https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153473.pdf</u>

⁵ <u>https://www.modahealth.com/pdfs/med_criteria/MobileOutpatientCardiacTelemetry.pdf</u>



MCT 3 Lead

MCT 3 Lead is an FDA⁶ Class II device (cleared in 2017) monitoring up to 30 days of cardiac rhythm. MCT 3 Lead is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.



The device is comprised of two (2) main components: 1) a patient-worn sensor with 3 leads and 4 electrodes and 2) a monitor. The device continuously monitors patient ECG, automatically generates an alert triggered by a proprietary detection algorithm, or generates an alert manually triggered by the patient, and transmits the recorded data transtelephonically via Bluetooth to a monitoring center 24 hours a day.

When cellular service is unavailable the patient has an option to transmit via a landline telephone. The monitoring center provides the ECG data to the physician for evaluation. The diagnostic yield of

MCOT Patch compared to Loop Event Recorders is 88%. The difference in findings is due to the asymptomatic findings captured with the MOCT.⁷

Extended Holter

ePatch

<u>ePatch</u> is the Extended Holter developed by BioTelemetry. The device is an FDA⁸ Class II device (cleared in 2017) monitoring up to 14 days of cardiac rhythm. The device is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The ePatch consists of a microprocessor, measuring circuit, memory and data storage, lightemitting diode (trans-illuminates the plastic casing), and contract to the electrode. The recorder is a small, lightweight monitor that records 1, 2 or 3 channels of ECG continuously.

At the end of the recording, the recorder can be plugged into a PC via a USB cable. The patient's ECG is then transferred via the ePatch[®] USB cable to a Holter analysis system for review by physician or other qualified personnel.

ePatch BitTel

⁶ <u>https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170565.pdf</u>

⁷ <u>https://www.modahealth.com/pdfs/med_criteria/MobileOutpatientCardiacTelemetry.pdf</u>

⁸ https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171410.pdf



Event Recorder

wEvent

wEvent offers arrhythmia detection algorithm that detects and automatically transmits asymptomatic and symptomatic events, including atrial fibrillation, tachycardia, bradycardia and pause. Patients will receive timely data sent automatically over a cellular network, or as a backup, through a transtelephonic transmission.





Competition

We've chosen to focus our analysis on two companies that are in our view the most significant BioTelemetry's competitors: **Preventice Solutions** and **iRhythm**

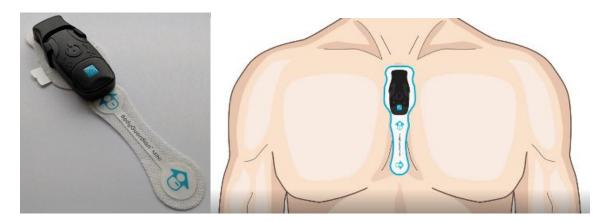
BioTelemetry vs Preventice Solutions

Preventice Solutions is a privately held healthcare company focusing on mobile health solutions and remote monitoring services that connect physicians and patients threatened by cardiac arrhythmias using cloud-based infrastructure, data analytics and machine-learning capabilities. Significant shareholders of the company include (1) Boston Scientific (BSX US), who acts as global sales and marketing representive for Preventice Solutions for cardiology-related diagnostic and monitoring offering, and (2) Merck AG (MRK US), who provided funding to Preventice Solutions through its Merck Global Health Innovation Fund and who was the owner of eCardio, a company that merged with Preventice Solutions in 2014.

Preventice Solutions' products include the PatientCare Platform and the BodyGuardian[®] wearable sensor portfolio. These technologies work together to provide access to detailed data reports showing the types and prevalence of cardiac arrhythmias. Preventice Solution's extended Holter is called BodyGuardian MINI. Preventice Solutions' MCT devices include three different products: BodyGuardian ONE, BodyGuardian Verite, which is comparable to MCT 3Leads, and BodyGuardian Heart, comparable to MCOT Patch.

ePatch vs BodyGuardian MINI

According to the available informations on Preventice Solutions' products, BodyGuardian MINI presents a unique advantage over the ePatch: the smaller size of the device.



Remote heart monitoring System

The Bodyguardian Remote Monitoring System is a technology used by Preventice Solutions' MCT device to detect arrhythmias leveraging Artificial Intelligence (AI) and Machine Learning (ML). BioTelemetry's last Annual Report states that the company has being working on integrating AI and ML in their devices in order to improve cardiac patient management.



In addition, Preventice Soluition' platform is able to calculate the average heart rate every 10 seconds, average respiration rate and average activity level.

MCT 3 Lead vs BodyGuardian ONE / BodyGuardian Verite

BodyGuardian ONE is a one component device. On the contrary, MCT 3 Lead has 2 components; the ECG sensor and the monitor. Having two components instead of one creates more responsibility for the patient to keep track of both devices and maintaining battery power in two devices.



BodyGuardian Verite, contrary to MCT 3 Lead, is a dual modality remote cardiac sensor allowing the transition from a MCT monitor to a cardiac event monitor. We consider this feature to be

quite optional as there is not a huge number of patients which could benefit from the use of both devices.

MCOT Patch vs BodyGuardian Heart

BodyGuardian Heart comes with different adhesive options, able to meet different users' preferences.

We think that Preventice Solutions could be a good fit for BioTelemetry as there is complementarity of products and it could strengthen their presence in the extended Holter market. We do not have detailed information about sales or profitability of Preventice Solutions so it's difficult to estimate its value.



A detailed comparison between BioTelemetry and Preventice Solutions products can be found in the <u>Appendix 5</u>.

BioTelemetry vs iRhythm

iRhythm is a digital healthcare company offering cardiac rhythm monitoring devices to diagnose cardiac arrhythmias by combining wearable biosensing technology with cloud-based data analytics and machine- learning capabilities.

iRhythm' portfolio includes only two products: <u>Zio XT</u>, an extended Holter monitor, and <u>Zio AT</u>, classified by the company as an MCT device.



ePatch vs Zio XT

BioTelemetry's comparable product to Zio XT is ePatch which displays some advantages over Zio XT:

- The ePatch's recorder can be removed and reapplied on a new patch giving the user the flexibility to change the anatomic placement of the device and to continue the recording in case of detachment.
- The ePatch can be put or a traditional device with wires increasing the signal's accuracy (the higher the number of channels and leads the higher the accuracy of the device).



- 3. The ePatch offers a higher turnaround time providing physicians with the possibility to take a more promptly action on their patients.
- 4. The ePatch seems to have a slightly lower diagnostic yield compared to Zio XT (60% vs 75%). This comparison can lead to misleading conclusions as the diagnostic yield is a parameter that does not have any sense if not tested on the same population, and as of now there are no studies that directly compare Zio AT and ePatch.

MCOT Patch vs Zio AT

To address the inability of Zio XT to perform real-time monitoring, iRhythm introduced the Zio AT in mid-2017.



Not much information is provided by the company about Zio AT as the device is still under development. However, in our understanding, as Zio AT works with the same algorithm as Zio XT, the device is not able to interpret the ECG data in real time and send it to the technicians. For this reason, we believe that, as of today, it cannot be really compared with BioTelemetry's MCT devices.

Extended Holters have the potential to replace traditional Holters, as they are more comfortable to wear, allow their use during sport and shower, and present a higher diagnostic

yield. iRhythm benefits from the first mover advantage as it was the first company to launch extended Holters. However, during last years, BioTelemetry has been able to overcome some limitations encountered by physicians while using Zio XT technology. On top of that they benefit from having a large costumer network already using their vast cardiac monitoring products' portfolio.

We believe that ePatch, thanks to BioTelemetry's already established presence in the cardiac market and proved know-how, has the ability to compete with iRhythm products.

A detailed comparison between BioTelemetry and iRhythm products can be found in the <u>Appendix 5</u>.



Products' Reimbursement

Reimbursements are key for BioTelemetry and all the players involved in the US Healthcare framework. Specifically, the company originates 34% of its revenue (as of 2018 end) from Medicare alone - another 50% are indirectly related to it. Services belonging to the Healthcare segment are billed to government and commercial payors using specific codes describing the services. Every year, such codes determine how much the products will be paid to the producer as well as how much the physicians will be remunerated for related services. A cut or an increase might deeply impact revenue; for instance, the 2013 reduction on remote cardiac monitoring services, effective on 1 January 2014, resulted in a 13.7% decrease to the national reimbursement rate the MCOT service.⁹ Last year reimbursement cut on MCT products, effective on 1 January 2019, eroded around 150-200 bps in revenue growth during the first quarter of the year.

After having discussed with experts and with many companies involved in this market, we do not expect reimbursement cuts to seriously threat BioTelemetry's business over the upcoming years. What we assume in our model is a 0-2% range of reimbursement cut every year, and this is in line with the management's guidance.

The only reduction we would expect may affect the Extended Holter business by 2022, that accounts for low-single-digit revenue in BioTelemetry's statements. A theorethical cut would affect mainly iRhythm as more than 80% of their revenues are coming from this type of service.

A detailed explanation of how the reimbursement work in US is provided in the <u>Appendix 6</u>.

BioTelemetry Acquisitions

Since 2012 BioTelemetry has done 10 acquisitions:

ADEA Medical AB	07/2019	Biomedical Systems Corp	04/2014
Geneva Health Solutions	03/2019	Mednet Technology, Inc.	02/2014
LifeWatch AG	07/2017	cardioCORE Lab, Inc.	08/2012
Telcare Medical Supply	11/2016	ECG Scanning & Med. Services	s 02/2012
ePatch division of DELTA	04/2016	Biotel, Inc.	11/2010
VirtualScopics, Inc.	05/2016	PDSHeart	04/2007
Radcore Lab, LLC	06/2014		

Acquisitions have played an important role in the top line growth of BioTelemetry. Some of them have drastically changed the profile of the company and paved the way for future growth.

⁹ <u>https://www.marketscreener.com/BIOTELEMETRY-INC-13962890/news/BioTelemetry-Inc-BioTelemetry-Inc-Announces-Reduction-to-Medicare-Reimbursement-for-Remote-Cardi-17590930/</u>



LifeWatch's is BioTelemetry's largest acquisition up to date, closed for a total consideration of around \$290mn. The consolidation of its leadership in the MCT market was its primary purpose, as the Swissbased company was offering the MCT 3 Lead, in addition to the Digitrax XT Holter. Geneva Health Solutions, acquired for \$65mn (\$45mn cash plus \$20mn earn-out), is instead the latest step into the implantable device data management, opening up a \$1bn market according to the company's statements.

Here is a brief description of the most important acquisitions made by BioTelemetry:

ADEA Medical AB

ADEA is a Swedish company focused on the delivery of health information in the Nordics. It was founded in 2018. The acquisition offers to BioTelemetry access to the European market. ADEA owns the trademark Rithm¹⁰, now official partner of BioTelemetry. Rithm offers an FDA cleared and CE marked ePatch that provides continuous health monitoring.

On 31 October 2018, BioTelemetry acquired an ownership interest in ADEA for approximately \$0.9mn (23.8% of total stocks). In July 2019, the remaining shares were bought.

Geneva Health Solutions

Geneva Health Solutions is a software company providing a platform for managing data from cardiac devices. Its platform can be used to monitor any implantable device. In 2018, it showed a triple-digit growth in revenue and 30'000 patients being monitored, a four-fold increase from 2017.

The company's acquisition was completed in March 2019 for a total of \$65.0mn, including contingent consideration. The cash amount paid was \$45.0mn plus a \$20.0mn earn-out payable upon achieving certain milestones. Geneva Health Solutions revenue were higher than \$6mn in 2018.

LifeWatch AG¹¹

At the time of the acquisition, LifeWatch AG was a supplier of mobile cardiac monitoring solutions headquartered in Zug (CH) with U.S. operations based in Rosemont, IL. It was listed on the SIX Swiss Exchange (LIFE SW). The company was carrying on operations through operative subsidiaries in the United States, in Switzerland, Israel and Turkey. The full integration of LifeWatch's activities resulted in a surge in expenses smoothed by created synergies (\$0.7mn in headcount related savings, approximately \$5.0mn in sales and marketing, \$2.7mn in R&D).

LifeWatch currently offers two devices: the MCT 3 Lead (MCT 3L) and the Digitrak XT Holter.

The company has been acquired through three timesteps:

 On 12 July 2017, through Cardiac Monitoring Holding Company, LLC, BioTelemetry acquired 97% of the outstanding shares for an aggregate consideration of 3'615'840 shares of BioTelemetry's common stock with a fair value of \$116.8mn and cash in the amount of \$165.8mn. On this date, they acquired control of LifeWatch AG and began consolidating its financial statements;

¹⁰ <u>http://www.rithm.se</u>

¹¹ 10-K 2017

- In September 2017, they purchased 343'525 additional shares for a cash consideration of \$4.8mn and the issuance of 19,806 with a fair value of \$0.6mn;

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<u> lā Partners</u>

- In December 2017, the acquisition was completed for an aggregate consideration of \$2.9mn in cash and 58'786 shares with a fair market value of \$2.0mn, which was settled in early January 2018.

BioTelemetry detains the registered trademark LifeWatch[®]. The company operates under the Healthcare segment and, to a lesser extent, on the Technology one (manufacturing, engineering and development).

Through years, LifeWatch AG showed a surge in revenue, peaking at CHF 112.1mn in 2016. Its gross margins have been ranging in the 40-60% span, approaching 50% in 2016. At the end of 2016, the company was reporting a negative net income of CHF13.2mn.

Telcare Medical Supply, Inc.

Telcare is a diabetes¹² management technology company distinguishing itself for being the first offering an FDA-cleared cellular-enabled Blood Glucose Monitoring ("BGM") system. The wireless BGM system transmits real-time statistics to a cloud-based analytical engine apt at filtering out data and monitoring trends. The company was acquired by BioTelemetry for \$7.0mn in cash and potential performance-based earn-outs of up to \$5.0mn in cash; it was included in the Technology segment, under the BioTel Care name.

The move increased its presence into the large and rapidly growing digital population health management market. In November 2017, the company announced that Telcare entered a strategic collaboration with Onduo¹³, a joint venture created by Verily (an Alphabet company) and Sanofi.¹⁴ Telcare will supply remote blood glucose systems and related data for patients enrolled in Onduo's diabetes management program.

Accreditation granted by the national accreditation organizations on behalf of Centers for Medicare & Medicaid Services certifies that suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") meet quality standards under Medicare Part B. In 2017, the Healthcare Quality Association on Accreditation renewed Telcare accreditation for another three years; the company will undergo the next survey cycle in 2020.

ePatch division of DELTA

On 1 April 2016, BioTelemetry entered into an Asset Purchase Agreement ("APA") with DELTA Danish Electronics, Light, and Acoustics for buying the assets of DELTA's ePatch division. The segment, based in Denmark, was paid a total consideration of \$3.0mn in cash and 244.519 shares of BioTelemetry's common stock valued at \$2.9mn. In addition, the APA outlined the milestones for a performance-

¹² The global economic burden of diabetes is estimated US \$827bn, <u>https://www.gobio.com/news/telcare-a-division-of-biotelemetry-inc-announces-collaboration-with-onduo-in-diabetes-management-program/</u>

¹³ "Onduo is a virtual care program with diabetes tools, coaching and clinical support to help take control of type 2 diabetes", <u>https://onduo.com</u>

¹⁴ <u>https://www.gobio.com/news/telcare-a-division-of-biotelemetry-inc-announces-collaboration-with-onduo-in-diabetes-management-program/</u>



based earn-out up to \$3.9mn. The fair value, including contingent consideration, was \$6.5mn at the acquisition date. ePatch is since then included in the Technology segment.

VirtualScopics, Inc.

VirtualScopics is a provider of clinical trial imaging solutions. The company is headquartered in Rochester, NY (US). VirtualScopics has been acquired through an all cash tender offer commenced on 8 April 2016 and ended on 9 May 2016 for a total consideration of \$15.0mn (net of cash acquired of \$0.8mn). The company is now under the BioTel Research group.

Thanks to VirtualScopics, BioTelemetry currently offers services of oncology imagining, cardiovascular imaging, imaging for metabolic diseases, musculoskeletal imaging and neurologic imaging.¹⁵

Together with Cardiocore, it contributed to more than 12% of total revenue for FY2018. At the end of 2015, the year before being acquired, VirtualScopics showed around \$11.99mn in revenue and a gross margin of 40%. It reported a \$1.04mn net loss during FY2015.

Radcore Lab, LLC

RadCore was an imaging core lab serving the biopharmaceutical and medical device research market; the acquisition completed in June 2014 added new oncology, musculoskeletal and neurological imaging capabilities, supported by a cloud-based analysis platform, to BioTelemetry's Research segment.

The total consideration for the deal included \$400'000 in cash and 22'513 shares of BioTelemetry's common stock, valued at \$200'000 at closing. This minor acquisition was strategical to propel future growth, but has no material impact on the company's financial reports.

Biomedical Systems Corporation

In April 2014, the acquisition of substantially all the BMS's assets regarding cardiac event monitoring, Holter monitoring and mobile telemetry monitoring services, took place. The assets gave access to internally developed Holter software and to established customer relationships.

Approximately \$30.1mn revenue for the FY2014 resulted from the Mednet and BMS acquisitions.

Mednet Technology, Inc.

Mednet's core focus was outpatient cardiac monitoring and contract manufacturing of cardiac monitoring devices. In February 2014, an ongoing litigation against the company was settled by its admission of having infringed on five patents owned by BioTelemetry. The settlement was unusually followed by the acquisition of Mednet and its subsidiaries¹⁶ by BioTelemetry.

¹⁵ <u>https://www.gobio.com/clinical-research/medical-imaging/</u>

¹⁶ Subsidiaries: Heartcare Corporation of America, Inc., Universal Medical, Inc., Universal Medical Laboratory, Inc.



Such move let BioTelemetry gain access to a secondary mobile cardiac telemetry technology marketed as ECAT¹⁷ and expanded its market to wireless and trans telephonic event, Holter and Pacemaker monitoring.

The \$16.0mn acquisition was carried out using \$5.5mn of cash, \$0.8mn of BioTelemetry common stock and an assumed \$9.7 of debt deriving from Mednet entities.

cardioCORE Lab, Inc.

The company offered cardiac testing services, such as centralized ECG, Holter monitoring, ambulatory blood pressure monitoring, ECHO, Multigated Acquisition Scans (MUGA), protocol development, and statistical analysis. Its services were primarily offered to the pharmaceutical sector.

The merger was completed in August 2012 for a total consideration of \$23.5mn. Its inclusion in the Research services segment contributed with revenue of \$6.8mn during FY2012.

ECG Scanning & Medical Services, Inc.

ECG Scanning was acquired in February 2012 for \$5.8mn in cash and up to additional performancebased \$600'000 in cash. It opened the access of CardioNet to established relationships with healthcare providers and payers in the Midwest.¹⁸

Merger with Biotel, Inc. (BTEL.OB)

In November 2010, CardioNet announces a definitive merger agreement with Biotel to acquire all outstanding shares of Biotel for \$11mn. The merger solved the ongoing litigation between the two parties, following by the previous merger attempt which ultimately fell apart in 2009.¹⁹ CardioNet's main focus was cardiac monitoring and wireless communications; in 2002, it received the approval of MCOT and opened its first monitoring center. Biotel was involved in the development, manufacture, testing and marketing of medical devices and related software products. Biotel's subsidiary Braemar was included in the deal, thus offering the entrance to the clinical services market.

PDSHeart

PDSHeart was a Florida-based company providing cardiac event monitors and related services. It provided ambulatory care monitoring of asymptomatic and symptomatic arrhythmia detection via landline, cellular telephone and the Internet. The first Web-based digital Holter monitoring system was offered by PDSHeart.

It was acquired by CardioNet in April 2007, thus creating the biggest wireless monitoring company in the US at the time.²⁰

¹⁷ <u>http://cardiacmonitoring.com/mobile-cardiac-telemetry/companies/mednet/heartrak-ecat-mobile-cardiac-telemetry-mct-monitor/</u>

¹⁸ <u>https://www.dicardiology.com/content/cardionet-acquires-ecg-scanning-and-medical-services-inc</u>

¹⁹ The deal was valued at \$14mn and was dismissed in July (<u>https://www.biomedreports.com/articles/most-popular/59710-rxnews-recap-for-11-08-10.html</u>)

²⁰ <u>https://www.businesswire.com/news/home/20070313005244/en/CardioNet-Mobile-Cardiac-Monitoring-Innovator-Completes-Acquisition</u>



Apple Heart Study

In late 2017, Apple and BioTelemetry announced a collaboration in a heart study with researchers from Stanford University and telemedicine company American Well. The goal of the study was to combine the iPhone, Apple Watch, and BioTelemetry's ePatch to evaluate the ability of the irregular pulse notification by Apple Watch to identify atrial fibrillation and guide subsequent clinical evaluation of trial participants. On top of that, the objective was to understand (1) how this technology would be received by participants, (2) how participants would interact with virtual study health providers, (3) how effectively the information was conveyed to their primary physicians, and (4) how real-world clinicians responded by measuring healthcare resources that are ultimately utilized.

The Apple Heart Study ("AHS") was performed from 29 November 2017 to 25 February 2019 and enrolled 419'297 Apple Watch and iPhone owners making it one of the largest cardiovascular trials to date.

Among these users, 2'161 (roughly 0.5 percent) received a notification of an irregular pulse. Approximately 57% of all participants who received an alert reported seeking medical attention outside of the study. Should a participant's heart rates trigger a notification, the Apple Heart Study app would prompt the user to schedule a telemedicine consultation with an American Well provider, who would then determine whether to mail BioTelemetry's seven-day ECG monitoring patch to the participant. These patches were sent to 658 participants and returned by 450. By comparing simultaneous Apple Watch and ECG patch readings collected from these 450 users, the researchers found a 71% positive predictive value (positive tachogram reading) for the algorithm. In 84% of these cases, users who received a notification were also experiencing atrial fibrillation at the time of the alert. In addition, 34% of participants whose initial notification prompted an ECG patch delivery were later identified with atrial fibrillation.

Apple has described its Watch as "the ultimate device for healthy life." When interviewed by Fortune magazine, Tim Cook stated that, "medical health activity is the largest or second-largest component of the economy." Apple is clearly focused on the healthcare opportunity, actively building an ecosystem of products that are indispensable in this area.

We do not see this as a threat, but actually as a big catalyst for BioTelemetry and all the other companies involved in the diagnostic medical device market. Apple Watch, as many other instruments that target the consumer health market, is a screening tool, good enough to drive an increased awareness of the population to the importance of cardiac monitoring by alerting asymptomatic, undiagnosed patients of their need for cardiac diagnostics and treatment.

The fact then that BioTelemetry has been selected by Apple as the partner for the Apple Heart Study, validates its position as one of the mHealth leaders. BioTelemetry's expertise across healthcare and clinical research and its product portfolio make the company at the forefront of an expanding cardiac monitoring market.



Valuation

BioTelemetry has been losing market value during the last semester. However, we do believe the market is underappreciating its long-term potential and its expanded platforms offer, while overweighting reimbursement cut risks that are not real. According to our view, the stock shows more than 45% upside with respect to its \$37.71 share price (09/10/19).

We are using a DCF analysis and multiples comparison analysis to frame the situation.

Guidance

BioTelemetry reported earnings for the 2nd quarter 2019 on July 30th. It showed a 10% year-over-year growth in revenue to \$112mn, beating consensus for EPS by 20% even after the 150-200bps lost in revenue increase due to Medicare rate reduction. The guidance for third quarter outlines revenue at approximately \$111mn (+11%) and adjusted EBITDA at about 28%. Throughout recent months, the firm's full-2019 revenue guidance was raised from \$438-\$442mn to \$446-\$450mn.

Base Case Revenue Assumptions

The company ended FY2018 with revenue at \$399.47mn (39.30% YoY growth). Solid organic growth and full Life Watch AG integration helped to drive results. FY2019 will be less impacted in terms of inorganic growth, though the Geneva Health Solutions and ADEA Medical AB acquisition might be a long-term advantage. In our model, we forecast revenue up to 2025 by segment: Healthcare (~85% of 2Q19 revenue), Research (~12.5%), and Corporate & Other (~2.5%).

HealthCare - FY2018 showed an organic 13.4% growth, whereas we expect it to slow down for FY2019 (between 9% and 10%) because of the reimbursement cut effective beginning January 2019. An additional sub-revenue breakdown is provided as of 2Q19, and separate forecast are conducted. MCT (~69% share), event recorder (~14%), total Holter (~11%) and Geneva Health (~6%) are the four subsegments.

- MCT revenue expected growth is kept at 8% for upcoming years, taking into account a 150bps cut in reimbursement rate every year. We think that our assumption is quite conservative as we do not model any geographical expansion outside USA that could accelerate their growth rate.
- Total Holter category includes Holter and Extended Holter. Total Holter inflows are assumed to move at a higher rate (13%) for the first year, reflecting management guidance, then phasing out toward the Holter monitoring market growth over the long-term (5% CAGR). We expect an exception in 2022, when a change in the Extended Holter category reimbursement code will probably cut the product's revenue growth for the year by 20%. This cut has yet to be confirmed and may eventually be less painful. However, if approved, it will not affect the total sub-segment, as the cut relates to Extended Holters only.
- To be conservative, we do not consider any additional market share to be taken by the event recorder sub-segment, which will grow in line with the market (6.80% CAGR).



• Geneva Health Solutions will contribute a low-single-digit percentage in total revenue for the forecast period as guided by the company.

Research, and Corporate & Other - The other two segments will grow at rates consistent with Q1-Q2 growth, then slowing down towards expected market CAGR.

We are not assuming any acquisition in our forecast period even though the company has been really active on that front historically. The company has now a Net Debt/EBITDA of 1.3 and their healthy free cash flow profile allows them to continue looking for external growth opportunities.

Base Case Margins and Expenses

Gross margin has been constantly rising from FY2014 reaching 62.70% during FY2018. We expect it to be close to 65% by FY2025. The EBIT margin reached a 12.47% on revenue in FY2018 and we expect it to steadily grow year over year. The adjusted EBITDA guidance for this year is at about 28%, slightly lower than the 28.4% reached the previous year. We are confident that the company could beat this number as already shown in the first 6 months of the year.

BioTelemetry shows a relatively low R&D expense (considering some R&D expenses were accounted in G&A as well) and this could mean that the company will continue to favor inorganic growth to keep pace with competition and consolidate its leadership. We expect R&D expenses to range from 3% to 4% of total revenue over the forecast period, in line with previous years. We see likely an improvement in the General and Administrative expenses by around 250bps on sales.

The manufacturing capabilities are ready to scale up production as product volume increases, without needing new plants for the production.

Bad debt expense on revenue, almost entirely related to the Healthcare segment, is kept in line with historical percentage (5.00%). Bad debt expense records any adjustment due to patient default to the revenue recognized for contracted payors (including Medicare).

Liabilities

In our view, the company will be able to bear its total financial debt (~34% of assets as of 2018), as the \$57mn free cash flow we expect for FY2019 already embeds the \$45mn acquisition of Geneva Health Solutions closed earlier during the year. We FCFs to exceed the \$100mn from next year onwards and to grow at a high-single-digit rate during FY2020 to FY2022. The most recent injection of mid-term debt was made in conjunction with the LifeWatch AG acquisition in 2017 (\$205.0mn). In that occasion, a term loan to be repaid in quarterly installments beginning January 1st, 2018 was made, with the remaining principal balance repaid on or before July 12th, 2022. Coverage ratio for FY2018 was 5.28.

Bear and Best Case Scenarios

We used multiple scenarios in which revenue growth and perpetual growth rate are differently affected by future events.

Bear Case – We cut revenue by 200 bps per year with respect to the base case and we lower the perpetual growth rate to 1.5% from 3%. The risk of higher reimbursement cuts and market share erosion from the Extended Holters segment are here accounted for. In Fact, the Extended Holter



segment is continuing to take market share from the Holter market and this is driving a better success yield in detecting arrhythmia before physicians have to prescribe an MCT. This is, in our view, the biggest risk at the moment. A slower top line growth will affect profitability as a large part of their costs is fixed. We are modeling in this scenario a 100bps cut in EBIT margin.

Best Case – We add 100 bps per year in revenue assuming a geographical expansion outside USA and keep the perpetual growth rate as for the base case at 3%. We keep profitability at the same level of our base case scenario to be conservative.





Comparison Analysis

Based on our F2019 estimates, BioTelemetry is trading at P/E and EV/S of 20.61x and 4.47x, respectively. Comparable companies – Masimo Corporation (MASI US), iRhythm (IRTC US), and Medtronic (MDT US) - are trading at average multiples of 33.36x and 7.31x, respectively. iRhythm is the closest company to BioTelemetry, in terms of product offering.

			Price to Earnir	ngs	Enter	prise Value t	Earnings per Share growth		
	Market Cap	Current	Forward 2019	Forward 2020	Trailing 12M	Forward 2019	Forward 2020	Forward 2019	Forward 2020
BEAT US Equity	1,342.87	25.86x	20.61x	17.85x	4.29x	4.47x	4.00x	17.12%	15.46%
MASI US Equity	7,929.55	42.51x	47.21x	40.92x	8.23x	7.94x	7.21x	10.76%	16.30%
IRTC US Equity	1,835.07	N/A	N/A	N/A	10.99x	8.84x	6.72x	N/A	N/A
MDT US Equity	145,651.64	25.71x	19.52x	18.18x	5.03x	5.16x	4.92x	33.10%	8.07%
Competitors:									
Median	4,882.31	34.11x	33.36x	29.55x	8.23x	7.94x	6.72x	21.93%	12.19%
Average	39,189.78	34.11x	33.36x	29.55x	8.08x	7.31x	6.28x	21.93%	12.19%

Table 1 Market Cap and Revenue in million USD (data as of 10/07/2019)

Based on this simple multiple comparison analysis, it's clear to us that BioTelemetry is quite cheap. Using the average of competitors' EV/Sales 2020 multiples we arrive at a valuation of \$88.73/share.



Financial model

BioTelemetry, Inc. 10-K, 2018	盦BioTelemetry Inc (XNAS:BEAT)	Scenario	Base	1
10-n, 2018		Forecast Stock Price (\$)	\$ 55.49	
Income Statement		Current Price Delta Target/Current	\$ 37.71 47.15%	
Scenarios: Base				

Bear Best Base scenario + 200bps cut on revenue Base scenario + 100bps added on revenue

Data in thousands US\$ except for share p			Fo	precast peri	od								
						Year end - December 31,							
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	202	
Revenue	166,578.00	178,513.00	208,332.00	286,776.00	399,472.00	448,124.07	500,448.86	555,280.77	597,955.15	660,411.65	726,894.72	797,163.99	
Yo Y growth		7.16%	16.70%	37.65%	39.30%	12.18%	11.68%	10.96%	7.69%	10.45%	10.07%	9.679	
Base						12.18%	11.68%	10.96%	7.69%	10.45%	10.07%	9.679	
Bear						8.18%	7.68%	6.96%	3.69%	6.45%	6.07%	5.679	
Best						13.18%	12.68%	11.96%	8.69%	11.45%	11.07%	10.67%	
Cost of revenue	73,114.00	71,956.00	78,882.00	114,406.00	148,986.00	163,565.28	181,013.51	199,031.74	212,391.30	232,456.27	253,545.83	279,007.40	
% of Revenue	43.89%	40.31%	37.86%	39.89%	37.30%	36.50%	36.17%	35.84%	35.52%	35.20%	34.88%	35.00%	
Base						36.50%	36.17%	35.84%	35.52%	35.20%	34.88%	35.00%	
Bear						37.00%	37.00%	37.00%	37.00%	37.00%	37.00%	37.00%	
Best						36.00%	35.45%	34.91%	34.38%	33.86%	33.34%	33.50%	
Gross profit	93,464.00	106,557.00	129,450.00	172,370.00	250,486.00	284,558.78	319,435.35	356,249.04	385,563.85	427,955.38	473,348.89	518,156.59	
Gross margin	56.11%	59.69%	62.14%	60.11%	62.70%	63.50%	63.83%	64.16%	64.48%	64.80%	65.12%	65.00%	
Operating expenses													
General and administrative	45,131.00	47,882.00	55,877.00	82,983.00	109,736.00	116,512.26	127,630.44	138,908.37	146,725.50	158,954.53	171,613.29	191,319.36	
% of Revenue	27.09%	26.82%	26.82%	28.94%	27.47%	26.00%	25.50%	25.02%	24.54%	24.07%	23.61%	24.00%	
Sales and marketing	28,805.00	27,936.00	28,636.00	35,322.00	42,849.00	47,241.06	51,849.92	56,541.60	59,839.93	64,953.75	70,263.23	75,730.58	
% of Revenue	17.29%	15.65%	13.75%	12.32%	10.73%	10.54%	10.36%	10.18%	10.01%	9.84%	9.67%	9.50%	
Bad debt expenses	9,347.00	8,047.00	9,931.00	13,291.00	22,222.00	20,165.58	22,520.20	24,987.63	26,907.98	29,718.52	32,710.26	35,872.38	
% of Revenue	5.61%	4.51%	4.77%	4.63%	5.56%	4,50%	4.50%	4.50%	4.50%	4.50%	4.50%	4.50%	
Research and development	7.396.00	7,111.00	8.355.00	11,101.00	11.206.00	13.224.41	15.536.43	18.135.02	20,544.12	23.869.72	27.638.71	31.886.56	
% of Revenue	4.44%	3.98%	4.01%	3.87%	2.81%	2.95%	3.10%	3.27%	3.44%	3.61%	3.80%	4.00%	
Other charges	7,098.00	6,063.00	8,639.00	31,436.00	14.659.00	11,203.10	12,511.22	13,882.02	14,948.88	16,510.29	18,172.37	19,929.10	
% of Revenue	4.26%	3.40%	4.15%	10.96%	3.67%	2.50%	2.50%	2.50%	2.50%	2.50%	2.50%	2.50%	
Total operating expenses	97,777.00	97,039.00	111,438.00	174,133.00	200.672.00	208,346.41	230.048.22	252.454.64	268.966.41	294.006.82	320,397.86	354,737,97	
YoY growth		-0.75%	14.84%	56.26%	15.24%	3.82%	10.42%	9.74%	6.54%	9.31%	8.98%	10.729	
% of Revenues	58.70%	54.36%	53.49%	60.72%	50.23%	46.49%	45.97%	45.46%	44.98%	44.52%	44.08%	44.50%	
EBIT	(4,313.00)	9,518.00	18,012.00	(1,763.00)	49,814.00	76,212.37	89,387.14	103,794.40	116,597.44	133,948.56	152,951.04	163,418.62	
% of Revenues	-2.59%	5.33%	8.65%	-0.61%	12.47%	17.01%	17.86%	18.69%	19.50%	20.28%	21.04%	20.50%	
Base						17.01%	17.86%	18.69%	19.50%	20.28%	21.04%	20.50%	
Bear						16.01%	16.86%	17.69%	18.50%	19.28%	20.04%	19.50%	
Best						17.01%	17.86%	18.69%	19.50%	20.28%	21.04%	20.509	
Otherexpense													
Interest expense	(713.00)	(1,534.00)	(1,830.00)	(4,897.00)	(9,429.00)								
Loss on estinguishment of	(372.00)	(1,004.00)	(1,030.00)	(4,897.00)	(3,423.00)								
Loss on equity method investments	(372.00)		(287.00)	(343.00)	(246.00)								
Other non-operating income	(6,708.00)	(88.00)	(287.00) (125.00)	(2,809.00)	1,365.00								
Total other expenses	(7,793.00)	(1,622.00)	(2,242.00)	(8,633.00)	(8,310.00)	(6,721.86)	(7,506.73)	(8,329.21)	(8,969.33)	(6,604.12)	(7,268.95)	(7,971.64	
	(1,193.00)	(1,822.00) 0.91%	(2,242.00)	(8,633.00) 3.01%	(8,310.00) 2.08%	(0,721.00)	(7,506.73)	(0,329.21)	(0,969.33)	(0,004.12)		(7,971.64	
% of Revenues EBT	(40,400,00)										1.00%		
	(12,106.00)	7,896.00	15,770.00	(10,396.00)	41,504.00	69,490.51	81,880.40	95,465.19	107,628.11	127,344.44	145,682.09	155,446.98	
(Provision for)/benefit from in	2,313.00	(468.00)	37,667.00	(6,747.00)	370.00		17 101 57	00.047.07	00.004.07	00 740 65		00.046	
Tax on income						14,593.01	17,194.88	20,047.69	22,601.90	26,742.33	30,593.24	32,643.87	
Tax Rate	35.00%	35.00%	35.00%	21.00%	21.00%	21.00%	21.00%	21.00%	21.00%	21.00%	21.00%	21.009	

Net operating loss carryforwards												
Beginning of the period						160,000.00	120,000.00	80,000.00	40,000.00	-	-	
Amountused						40,000.00	40,000.00	40,000.00	40,000.00	-		
End of the period						120,000.00	80,000.00	40,000.00	-	-		
EBT after offsetting NOL carryforwards						29,490.51	41,880.40	55,465.19	67,628.11	127,344.44	145,682.09	155,446.98
Paid tax on income						6,193.01	8,794.88	11,647.69	14,201.90	26,742.33	30,593.24	32,643.87
Net Income (loss)	(9,793.00)	7,428.00	53,437.00	(17,143.00)	41,874.00	63,297.50	73,085.52	83,817.50	93,426.21	100,602.11	115,088.85	122,803.11
	-5.88%	4.16%	25.65%	-5.98%	10.48%	14.12%	14.60%	15.09%	15.62%	15.23%	15.83%	15.41%
D&A			14,269.00	28,561.00	40,168.00	45,060.10	48,257.32	51,348.26	53,026.30	56,162.59	59,280.73	59,787.30
% of Revenue			6.85%	9.96%	10.06%	10.06%	9.64%	9.25%	8.87%	8.50%	8.16%	7.50%
n												
EBITDA			32,281.00	68,000.00	113,400.00	121,272.47	137,644.46	155,142.66	169,623.74	190,111.14	212,231.76	223,205.92
% of Revenue			15.49%	23.71%	28.39%	27.06%	27.50%	27.94%	28.37%	28.79%	29.20%	28.00%
Goodwill impairment			-	12,045.00	-							
Stock-based compensation			6,502.00	7,680.00	9,261.00	10,388.91	11,654.18	13,073.55	14,665.79	16,451.95	18,455.65	20,703.38
Costs related to previous acquisitions			100.00									
Taxprovision/(benefit) from released valuation al	lowance		(51,600.00)									
Additional professional fees			-	4,900.00	800.00							
Legal fees			-	1,500.00	1,200.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00
Decrease in considerations for previous acquisit	ions		-	(2,600.00)	1,900.00							
Intangible amotization from LifeWatch			-		7,200.00							
Adjusted EBITDA			(14,959.00)	65,384.93	113,450.05	126,439.51	143,291.90	161,387.00	176.820.21	201.458.98	224.918.47	237,437.66
% of Revenue			-7.18%	22.80%	28.40%	28.22%	28.63%	29.06%	29.57%	30.51%	30.94%	29.79%
			7.1070	22.0070	20.4076	20.2270	20.0370	23.0070	23.51 /0	50.5170	55.5470	23.1370



Healthcare revenue by product

% Healthcare revenue:		7		2019	2020	2021	2022	2023	2024	2025
MCT	69%									
Event recorder	14%		Total Holter	43,414.79	49,058.72	54,984.14	43,987.31	48,386.04	52,881.56	57,640.90
Total Holter	11%		% YoY		13.00%	12.08%	-20.00%	10.00%	9.29%	9.00%
Geneva	6%	1								
			Event Recorder	55,255.19	59,012.54	63,025.40	67,311.12	71,888.28	76,776.68	81,997.50
			% YoY		6.80%	6.80%	6.80%	6.80%	6.80%	6.80%
Holter ECG Monitoring Market	CAGR	5.00%								
Arrhythmia Monitoring Devices Market	CAGR	6.80%	MCT	272,329.16	296,838.78	323,554.27	352,674.15	384,414.83	419,012.16	456,723.26
Cardiac Monitoring and Cardiac Rhythm Mana	CAGR	4.00%	% YoY		9.00%	9.00%	9.00%	9.00%	9.00%	9.00%
			Market dimens	565,539.00	624,920.60	690,537.26	763,043.67	843,163.25	931,695.40	1,029,523.41
Global Mobile Cardiac Telemetry	CAGR	11.30%	10.50% Market share	48.15%	47.50%	46.86%	46.22%	45.59%	44.97%	44.36%
Global Mobile Caldiac Telefitelly	2018	511,800.00								
			Total	370,999.14	404,910.04	441,563.81	463,972.59	504,689.15	548,670.41	596,361.66
			% YoY		9.14%	9.05%	5.07%	8.78%	8.71%	8.69%

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Scenario Base

 \$
 55.49

 \$
 37.71

 47.15%

Forecast Stock Price (\$) Current Price

Delta Target/Current

1

BioTelemetry, Inc. 10-K, 2018

Balance Sheet

Scenarios: Base

Bear	
Best	

Base scenario + 200bps cut on revenue Base scenario + 100bps added on revenue

					Forecast period						
in thousands		2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
ASSETS											
Current assets											
Cash and cash equivalents	_	21,052.00	36,022.00	80,889.00	129,228.81	225,140.07	330,829.92	445,176.83	555,392.86	678,623.13	807,085.71
Healthcare accounts receivable		14,594.00	25,190.00	37,754.00	-	-	-	-	-	-	-
Other accounts receivable		12,261.00	13,296.00	14,874.00	-	-	-	-		-	-
Total accounts receivable		26,855.00	38,486.00	52,628.00	58,980.75	65,867.58	73,084.40	78,701.07	86,921.41	95,671.71	104,920.34
Inventory	•	5,176.00	5,332.00	7,323.00	8,798.46	9,737.03	10,706.26	11,424.90	12,504.23	13,638.67	15,008.29
Prepaid expenses and other current assets		4,477.00	10,268.00	5,820.00	10,734.65	11,988.07	13,301.55	14,323.80	15,819.92	17,412.50	19,095.78
Total current assets		59,560.00	90,108.00	146,660.00	207,742.67	312,732.75	427,922.13	549,626.60	670,638.42	805,346.01	946,110.12
Property and equipment, net		25,823.00	49,194.00	48,377.00	76,519.09	108,520.90	144,677.21	184,322.96	228,909.06	278,879.47	334,680.95
Intangible assets, net		33,472.00	141,707.00	129,653.00	134,162.95	138,300.45	142,565.54	146,962.17	151,494.38	156,166.37	160,982.43
Goodwill		41,068.00	223,105.00	238,814.00	238,814.00	238,814.00	238,814.00	238,814.00	238,814.00	238,814.00	238,814.00
Deferred taxasset		36,636.00	17,681.00	19,975.00	22,407.77	25,024.20	27,765.98	29,899.85	33,022.90	36,347.28	39,860.99
Otherassets		2,425.00	2,767.00	3,322.00	-	-	-	-		-	
Total assets		198,984.00	524,562.00	586,801.00	679,646.49	823,392.30	981,744.86	1,149,625.58	1,322,878.76	1,515,553.13	1,720,448.49
LIABILITIES AND EQUITY											
Current liabilities											
Accounts payable		12.425.00	14.529.00	18.147.00	22,152,86	24.516.00	26.956.34	28,765,73	31,483,28	34.339.59	37,788,04
Accrued liabilities		13.698.00	26,055.00	21,609.00	31,247,81	34,896.43	38,719,88	41,695.57	46,050.68	50,686.56	55,586,46
Current portion of capital lease obligations		152.00	4.023.00	1.652.00	2,388,88	2.667.82	2,960,12	3,187,61	3.520.56	3.874.97	4,249.56
Contract liabilities	•	3.972.00	4,298,00	3.080.00	4,453,85	4,973.90	5.518.87	5,943.00	6.563.75	7.224.52	7,922.92
Current liabilities (excl. acc. payable)		17,822.00	34,376.00	26.341.00	38,090,55	42.538.15	47.198.87	50.826.19	56,134,99	61,786.05	67.758.94
Current portion of long-term debt		1.250.00	2.050.00	5,125.00	5,125,00	5,125.00	5,125.00	5,125.00	5,125.00	5,125.00	5.125.00
Total current liabilities		31,507.00	50,955,00	49.623.00	60,243,40	67.054.15	74,155,21	79,591,92	87.618.27	96,125,64	105,546,98
Long-term portion of capital lease obligations		126.00	1,486.00	117.00	114.44	111.61	108.78	105.92	103.13	100.34	97.56
Long-term debt		23,911.00	197,306.00	193,424.00	188.302.10	183,180,20	178.058.29	172,936,39	167.814.49	162.692.59	157.570.69
Other long-term liabilities	•	4,526.00	25,112.00	33,152.00	37,189,61	41.532.02	46.082.50	49,624.03	54.807.26	60,324.66	66.156.28
Total liabilities		60,070.00	274,859.00	276,316.00	285,849.55	291.877.98	298,404.79	302,258.26	310,343.14	319,243.23	329,371.51
Stockholders' equity											
Common stock	•	28.00	32.00	33.00							
Paid-in capital		281.642.00	409.517.00	426,054.00							
Accumulated other comprehensive income/(loss)		(34.00)	(114.00)	256.00							
Accumulated deficit		(142,722.00)	(158,678.00)	(115,858.00)							
Total BioTelemetry, Inc.'s stockholders' equity		138,914.00	250,757.00	310,485.00	393,796.94	531,514.32	683,340.07	847,367.32	1,012,535.61	1,196,309.89	1,391,076.99
Noncontrolling interests		138,914.00	(1,054.00)		000,700.04	001,014.02	505,540.07	341,301.32	1,012,000.01	1,130,303.09	.,551,070.99
Total equity		138,914.00	249,703.00	310,485.00	393,796,94	531,514.32	683.340.07	847.367.32	1,012,535.61	1,196,309.89	1,391,076.99
Total liabilities and equity		198,984.00	524,562.00	586,801.00	679,646.49	823,392.30	981,744.86		1,322,878.76	1,515,553.13	1,720,448.49
Check					0	0	0	0	0	0	0
T		04.007.00	400 700 00	100 511 00	400 440 00	100 001 00	170 100 00	170 0 11 00	407.040.00	100 701 00	457.000.00
Total long-term debt		24,037.00	198,792.00	193,541.00	188,416.00	183,291.00	178,166.00	173,041.00	167,916.00	162,791.00	157,666.00
% Total assets		12.08%	37.90%	32.98%	27.72%	22.26%	18.15%	15.05%	12.69%	10.74%	9.16%
Total debt		25,439.00	204,865.00	200,318.00	195,930.42 28.83%	191,084.62	186,252.20	181,354.93	176,563.17	171,792.90	167,042.82
% Total assets		12.78%	39.05%	34.14%	28.83%	23.21%	18.97%	15.78%	13.35%	11.34%	9.71%
Not Working Conitol		10.385.00	13.502.00	26.015.00	25.113.19	28.180.25	31.415.99	33.988.47	37.711.60	41.696.73	45.649.91
Net Working Capital											
Change in NWC		10,385.00	3,117.00	12,513.00	(901.81)	3,067.06	3,235.74	2,572.48	3,723.13	3,985.13	3,953.18



Appendix 1 – Conference Call with BioTelemetry's CFO

The interview was conducted on 2 September 2019.

Reimbursement

 Center for Medicare and Medicaid in November 2018 approved 3 new billing codes for Remote Patient Monitoring (RPM) services. What is BioTelemetry's take on this new billing codes? These codes impact more the physicians. BioTelemetry installs a single platform in the physician's office where they can get reports and data from the patients' devices (implanted defibrillators, ILR and pacemakers). If the physician reviews those records and takes an action or has to do some research spending a certain amount of time doing an evaluation, he can bill for RPM codes as long as that work/service is uncovered under another code.

BioTelemetry can benefit from these codes in two ways:

- 1. BioTelemetry could benefit from additional services if they enable the physicians to bill these codes,
- 2. Even if physicians do not prescribe BioTelemetry's service, BioTelemetry can still provide with the information that they can use to bill these codes and then charge a per-patient fee directly to the physician.
- 2. Has BioTelemetry any idea of what could be the new reimbursement code and rate for the Extended Holters?

Right now, Extended Holters have temporary codes and there has been recommendation to create a permanent code. If a product or a service does not receive a permanent code in a certain amount of time, there is not a mechanism to get reimbursed. The permanent code is necessary to continue to be paid by Medicare or other insurance companies.

The information about the precise reimbursement rate is not out there yet. BioTelemetry can't disclose anything about the process yet. But from public information, AMA has agreed to review the codes to make them permanent at the September meeting. If the AMA decides to modify the temporary codes into permanent codes, it then refers to a committee that will define how much Medicare will pay for the product according to several factors:

- They gather information from existing technology, and they could decide to nationally price the new reimbursement based on existing technology like the standard Holters. In this case scenario the chance is that the reimbursement will be lower than what it is today. But they can also consider that the difference between what they think the price should be and what it currently has been reimbursed is consistent and increase it. Or they can decide to leave the reimbursement equal to what it is today.
- 2. They could lead the decision to the local carriers during a certain time while they continue to collect information.



- 3. Are we going to see a reduction in all the components of the code (for the physician)? BioTelemetry is not sure about the professional piece, but the technical piece has a chance to go down. There is also a chance that it remains the same and a chance that it goes up, but they will be surprised if this happens. This reduction has a very limited impact on their business as of now because is still not a huge part of their business.
- 4. What is the average reimbursement rates for BioTelemetry's MCT and extended Holter devices, breaking them down into technical and professional components? And, is the firm paid for the device or the service it provides?

They have not given the reimbursement rate for their extended Holter yet, because it is still new, and they are still signing contracts for reimbursement. Medicare reimburses about \$300 that is public information. On the MCT the average reimbursement is about \$800.

For the professional component the MCT is only about \$35, for the Extended Holters is very significantly (about \$50).

5. Who pays BioTelemetry? The hospital or the insurance company?

They are paid by the insurance company. Most of the time they are reimbursed by Medicare or commercial insurance. They are paid for the service and the product in the same code. They provide the technology and they consider that technology enables service. Their fee includes the cost of the technology and service. They supply the device but at the end they get the device back.

6. Does BioTelemetry see any risk of reimbursement reduction for devices in category 3? What brings Medicare to decide to reduce a reimbursement rate for devices in the category 3? There is always the chance. It has been flat during the last years. They already had the preliminary rules in July indicating that it will be flat again next year. In November they will know for sure. When they receive the preliminary decision if they do not agree with the decision, they can appeal it (if they believe that the device does not cost what Medicare is assuming in the formula).

Medicare decides the reimbursement based on cost; however, the formula is a black box, they have indications about the formula, but they do not know for sure.

Technology

1. Do Extended Holters have any chance to replace Holters? Why?

Absolutely, sales of Extended Holters are growing very nicely and BioTelemetry sees that the growth of traditional Holters and event monitors has been flat or has going down. They believe that this is because some of standard Holters' market is going to the extended Holters and some of the event monitoring's market is going to MCT products. Extended Holter is also able to replace the event monitoring devices.



2. Do MCT devices have any chance to replace Extended Holters or maybe the opposite? Why? The MCT was here before the extended Holter. During that time, MCT did not prove to be able to replace the Holters. So BioTelemetry does not see MCT as a replacement for Extended Holters. This is because they are very different products. Moreover, if the physicians directly decide to use a device that records for 30 days without using an Holter before, he will use an event monitor instead of using an MCT.

3. What advantages has the ePatch compared to iRythm's products?

Zio AT is not really in the market. They tried to launch it 3 times and, in their understanding, it does not really compare to an MCT and they do not even know if they are billing it (and if they can because it seems it does not meet the definition of an MCT).

On the Extended Holter they are the first. They created this market. BioTelemetry were able to do some adjustments on the technology in response to the physician's opinion about the Zio patch:

- Once the patch falls off, the device can't be replaced. The devices could fall off because the
 practice of the skin cleaning was not correctly done, or if the patient sweats, or if the patient
 is tired to wear it in a certain place of the skin, or if men's hairs start growing... With
 BioTelemetry's patch they can put the device off and they can put the sensor on another
 patch, so it gives the chance to clean the skin.
- The ePatch device can be taken out of the patch and be put on a traditional device with wires. Some people do not like the patch, do not like the area where it is while with wires, patients have the ability to move the electrodes around. Patients with ePatch do not have to cover the same surface area for 14 days.
- Physicians using ePatch can download the information of the device in the office without having to send back the information to them. So, they have a quicker turnaround time on the device.
- A more general advantage is that they have all the portfolio of products. They also introduced recently the ILR, defibrillators and pacemakers. There is no other company in the market with such comprehensive portfolio. Cardiologists and electrophysiologists do not use just one product.
- Having multiple channels can give more accuracy on the device. It is like looking at a paint from different angle. The more leads and channels the more accurate the diagnose and analysis will be.

4. Has the ePatch real-time monitoring capability or is it planned to introduce this feature, like Zio AT?

It does not make sense for them. The Holter monitoring device just records the information. It does not make sense to stream just data like that. The MCT is recording but also doing analysis on that ECG as has being recorded. It is the information that has been analyzed that gets sent. If the algorithm detects something, then this "something" is sent.



5. Will photoplethysmography devices ("PPG") like the Apple Watch become as accurate as the electrocardiographic devices?

No, PPG is not a diagnostic tool but a screening device. Apple is giving value to the consumer, but they do not want to bill Medicare and commercial payers. The just want more consumers to buy more devices. This feature was introduced to add more value on the device and not as a diagnostic tool. BioTelemetry does not have an intent to do something similar. However, this kind of devices are increasing the market for BioTelemetry and competitors.

From The collaboration with Apple they have different agreements and revenues from this partnership falls into the research part of the business as they are doing validation of the consumer devices.

Market & Financials

1. What is the market dimension and growth you consider for the extended Holter and MCT devices?

They do not have the data specifically, but they believe that Extended Holters' sector is the fastest growing sector. The second is MCT, growing in their business at approximately 10%. They believe that they will continue to take market share on the MCT side because they have shown efficacy. MCT is a much more difficult product and service to provide and thus has higher barriers to enter.

- 2. Do they have access to the data inside the Geneva platform once it is used by physicians? It depends on the agreement with the hospital, because both own the data. BioTelemetry does not have any intent to use these data for now.
- 3. *Bad Debt Expenses* have accounted for about 5% of the total revenue, since at least 2014. Why is this number so high?

The IR/CFO explained that most of these bad debt expenses were related to money owned by patients. Some patients are not fully covered by their insurance company. But in their opinion, this 5%-mark is not worrisome, as per U.S. standards.

4. Similarly, *Research & Development* has represented less than 5% of the total revenue in the past. Is it enough to remain innovative?

BioTelemetry expenses some R&D activities in the *General & Administrative* account. For instance, all the IT development is not included in the R&D. They actual R&D expenses are therefore higher than what is shown in the income statement.



Appendix 2 – Conference Call with iRhythm IR

The interview was conducted on 11th September 2019.

Reimbursement

- Center for Medicare and Medicaid in November 2018 approved three new billing codes for Remote Patient Monitoring services. What is iRhythm's take on this new billing codes? They are not aware about these codes.
- 2. Does iRhythm have any idea of which could be the new reimbursement code/rate for the extended Holters?

AMA Process

The physicians community summitted the request in June to move the code from the temporary to the permanent code. In July, AMA determines the Current Procedural Terminology ("CPT") codes and then, CMS applies the value to these codes. In July AMA accepted the application to move from temporary to permanent codes. They are now on the agenda for September editorial panel meeting which is an AMA member meeting that reviews CPT application and decides whether they should be (1) accepted, (2) denied, or (3) maintained as temporary codes. There are over 80 CPTs that are going to be reviewed in that meeting. This is a quick review, and the results should be released in November. On the July agenda, the application regarding the Extended Holters concerned eight codes.

Today, they are four temporary codes. The first one is the component that the physician gets when he applies the Zio to the patient. The technical fee which is the fee that iRhythm receives, \$320. Thirdly, the physician's interpretation component relates to the fee perceived when the physician receive the data report from iRhythm. The fourth is the global that ties all the other three components.

They are not allowed to say what the eight new codes would mean. But this solution was proposed by iRhythm in the July meeting and they think it is positive as it could eventually increase the total reimbursed amount. Here are the potential outcomes from the September review:

- 1. The AMA approves to move to eight codes;
- 2. The AMA agrees to move to permanent codes from temporary, but maintain four codes rather than eight;
- 3. The AMA denies the application to move forward towards permanent codes and they stay with temporary codes. They can be under temporary codes until 2022 so there will be no change.

Utilization of the device

Over 2 million patients have used iRhythm's services so far. They have over 30 peer reviewed articles, so they feel very comfortable about this process. They were just waiting to have clinical and utilization evidence to move towards permanent codes.



The outcomes from the meeting of September will likely be presented in November. At this moment only, AMA will be able to talk about what happened during the September meeting. If they move forward to permanent codes, CMS will have to determine the new pricing before July 2020. It is only in July 2020 that the new rates will be published in the federal register. iRhythm feel very confident that the rates go up.

3. Are we going to see a reduction in all the components of the code, in particular for the physician?

They did not study too much this part, but they do not believe it will change materially.

- 4. What is the average reimbursement rate breakdown for the Extended Holter device (technical and professional components)? And also, is iRhythm paid for the device or the service provided? And who is paying them? The hospital or the insurance company? The total reimbursement rate for all the components is around \$370. They receive \$320 and the physician gets \$50.
- **5.** And for standard Holters ? They do not have the exact amount, but it is substantially lower than Extended Holters.
- 6. Is the reimbursement for Zio AT the same as for Zio XT? What is the reimbursement code for Zio AT?

The Zio AT and the Zio XT represent two different type of service.

The Zio AT is an MCT device. MCT devices are currently reimbursed under a current category 1 code, which is a permanent code. This code is reviewed periodically, but not every year.

The Zio XT product, launched in 2012, was granted a CPT category 3 code which is a temporary code and that is used to new procedures that do not naturally fall in an existing code. They could have put the device in the existing code of the standard Holters but they considered at that time that Extended Holter was different from the standard monitor. This code is used when you do not have clinical evidence and utilization yet. But the AMA reviews these codes again some years later to determine if there is sufficient clinical evidence and sufficient utilization to then transition to a permanent code.

7. Has the contract with Novitas been renewed? If yes, for how long? For the moment, they still have an agreement with Novitas.

The temporary code from 2012 was renewed in 2017. This code is good until 2022. In case the code is not transitioned to a permanent code, they have another year of temporary code. Discussions regarding the renewal of the the contract with Novitas will only take place once there will be a better visibility on the codes.



Technology

1. Is the Zio AT a real-time monitoring device? What is the advantage compared to MCT? Is Zio AT already in the market? Is the yield of Zio AT the same as Zio XT? What are the market dimension and growth they look at?

Zio AT is a newer product and they are very excited about it. It is very similar to Zio XT but at the same time very different. They look identical, they use the same platform, the same billing system, and the same ordering system. This no-differentiation approach is an added-value in their opinion.

They believe the AT is a better device than existing MCT products. However, they need to generate the clinical evidence to prove it; they have done studies internally that show that their device detects arrhythmias faster than the competing MCT devices. The Zio AT uses the same algorithm as Zio XT so it should be the same diagnostic yield. Zio AT has been in the market for over one year and they are getting feedback from their costumers on the device, making modifications to it. Their sales team has not been trained on the product and it requires 24/7 coverage of the service. They are generating some revenues from Zio AT but not in a material way.

2. Do Extended Holters have any chance to replace Holters? Why?

Yes, Extended Holters only have a 15% penetration rate of the standard Holter market; they see a lot of potential going forward.

3. Which advantages has iRhythm over BioTelemetry in terms of product? In particular, if we compare Zio XT and the ePatch and Zio AT with MCT devices – in terms of yield, reimbursement rate, turnaround time and features like leads or channels.

They have not generated clinical evidence of having better products than BioTelemetry yet. Their MCT, Zio AT, targets people who need faster action. With Zio AT, they can deliver near real-time reports on events that are very similar to the reports used for Zio XT. These reports are different from those generated by the other MCT devices.

4. Could Photoplethysmography ("PPG") devices like the Apple Watch one day become as accurate as the Electrocardiographic devices?

They believe the two types of devices could someday be combined. This is beneficial for iRhythm, as more patients will be inclined to go to a physician, as more anomalies will be detected. iRhythm plans to launch its own device for the early detection of atrial fibrillation. However, there is a long way for these PPG devices to reach the diagnostic capability and atrial fibrilliation is only one out of fourteen types of arrhythmias that can be detected with Zio. The entry of companies like Apple on the market is probably not a risk in the short- to midterm.

5. What about IRTC's collaboration with Verily, an Alphabet's research organization?

iRhythm's current devices are used to detect symptomatic arrhythmias. However, the asymptomatic population is twice as large as the symptomatic population. It is important to identify these patients quickly, because unfortunately when these people feel symptoms, they are actually having a stroke.

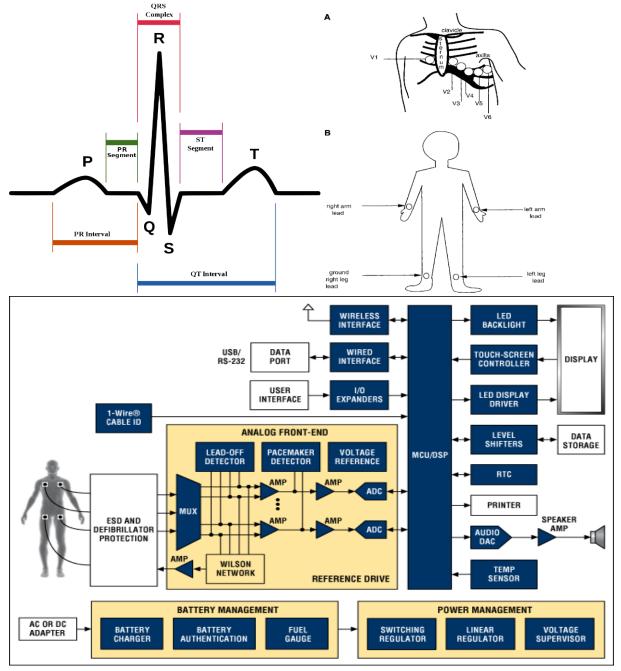


Appendix 3 – Electrical Methods of Arrhythmia Detection

This section provides a full description of the various electrical methods of arrhythmia detection.

1. 12-lead ECG

12-lead electrocardiography remains the gold standard for the diagnosis of an arrhythmia, but its ability to detect atrial fibrillation is limited by the short time frame of recording. In a conventional 12-lead ECG, ten electrodes are placed on the patient's limbs and on the surface of the chest.





2. Ambulatory Electrocardiography (AECG)

AECG devices are non-implantable cardiac monitors intended to provide the physician with documented episodes of arrhythmia, which may not be detected using a standard 12-lead ECG. After a designated time period, the patient will return the monitor to the physician's office. The tape will be played back and analyzed by a technician who forwards a report to the doctor for final interpretation.

2.1. Holter Monitor

The Holter Monitor is a portable device that continuously records heart rhythms continuously for up to 72 hours using several electrodes, stuck on the user's chest. The device has typically a 24% yield due to a limited prescribed wear period and missing data, because patients typically remove the electrodes and disconnect their Holter monitors in order to shower, sleep and exercise.

Typically, a Holter has multiple channels (from 3 to 12) and 3 to 5 electrodes. The device is indicated for people that experience daily to weekly palpitations. If the first 24- to 72-hour Holter monitor test does not give a clear diagnosis, people are referred for further investigations, such as the followingly analyzed devices.

2.2. External Loop Event Monitor

The device is programmed to record the ECG intermittently before, during and after the symptom appears. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. Some models transmit triggered data automatically over a wireless network to a remote monitoring system. The device provides a diagnostic alternative to Holter monitoring for people that experience weekly to monthly palpitations. It includes 3 to 12 leads attached to the chest.

2.3. Implantable Loop Recorder (ILR)

For the evaluation of recurrent unexplained episodes of fainting. The main diagnostic issue with ILRs is that they have ECG storage limits and artefacts can potentially overwrite real arrhythmias.

2.4. Non-loop recorder

The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. The device transmits ECG data telephonically in real-time and is usually used for up to 30 days. These recorders represent old technology.

2.5. Extended Holter

Devices continuously worn and continuously record via one or more leads and store data for a longer period than traditional Holter (14 days) in the following situations:

- In the small subset of members who experience recurrent symptoms so infrequently that a prior trial of other external ambulatory event monitors has been unsuccessful; OR
- In members who require long-term monitoring for atrial fibrillation or possible atrial fibrillation.



Patch Holter monitoring is helpful for monitoring R to R intervals but may be limited in value for complex arrhythmia monitoring due to the presence of only a single vector of ECG and the timeframe of 14 days.

The device provides a diagnostic alternative to Holter monitoring for people that experience weekly to monthly palpitations.

2.6. Outpatient Cardiac Telemetry

This portable device records heart rhythms continuously from external electrodes placed on the body. The standard technology consists of a small sensor attached to the patient's chest by three leads, that the patient wears while continuing his daily activities. Recently, patch MCT devices (with no lead wires) that communicate by Bluetooth to a cell phone-sized monitor have been introduced.

Segments of the ECG data are automatically transmitted to a remote surveillance location by cellular or landline telephone signal. Cardiac events are thus detected even if the patient is asymptomatic. The transmitted events are triggered automatically by preprogrammed algorithms or by the individual during a symptomatic episode. There is continuous, real-time data analysis in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria. Typically, physicians prescribe MCT for patients with higher acuity symptoms such as syncope, or fainting, that require more timely notification and actions.

The device provides a diagnostic alternative to Holter monitoring for people that experience weekly to monthly palpitations. However, Medicare and most insurance companies will cover a Cardiac Event monitor in place of or prior to a Holter Monitor study if the clinician deems the symptoms or arrhythmias too transient to be captured in a 24-hour period. Mobile cardiac telemetry is a cardiac monitoring device system that consists of three to four electrocardiography electrodes, which generate two to three leads. Some of the newer systems consist of only a one lead patch sensor and a monitor.

Event Recording and MCT have similar indications but MCT devices are more effective in detecting cardiac rhythm abnormalities (compared to Event Recorders) while simultaneously lowering the cost of care for these patients. However, Mobile Cardiac Telemetry is perceived to be much more expensive in use as compared to traditional memory loop symptomatic monitoring. The question of whether real-time transmission and interpretation of data has any impact on overall morbidity and mortality is still debated.

Single Channel vs Multi-Channel cardiac devices

The single channel ECG machine contains one amplifier channel and one recording system. Only one lead at a time can be recorded with such type of instrument. The Multichannel ECG consists of several amplifier channels and a corresponding number of recording pens.



Multichannel ECG are probably the most reliable as each channel could confirm the findings of the others (mostly if the artefact is in one or more channels), increasing the accuracy of the diagnosis.

Patch vs multi-lead cardiac devices

Leads represent the electrical potential difference between electrodes. Sometimes the number of leads matches with the number of wires attached to the chest. Patches are easy to use, leadless, minimally intrusive to daily activities, water-resistant, hygienic (i.e., single use only), and they do not require a technician to install the device on the patient. However, patches result in high cumulative consumer costs (due to non-reusability).

One electrode vs multi electrodes cardiac devices

Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex ECG tracings.

Cardiac Monitoring Device	Advantages	Limits
12 leads ECG	✓ Non expensive	✓ Low timeframe
	✓ Largely available	 Non portable
		 Likely to miss most AF
Holter Monitors	✓ Portable	 ✓ Short duration of monitoring
	✓ Longer timeframe than 12 leads	
	ECG	
	✓ Low cost	
	 ✓ Continuous Monitoring 	
External Loop	\checkmark Duration of monitoring up to 1	✓ Intermediate cost
	month	✓ ECG storage limits
	✓ Automatic detection of	
	arrhythmias	
Implantable Loop	\checkmark Duration of monitoring up to 3	✓ High cost
	years	✓ Minimally invasive surgery for
	 Remote monitoring possible 	implantation
	✓ Automatic detection of	 ✓ Non continuous monitoring
	arrhythmias	✓ ECG storage limits
	✓ No external wires	
Non loop Monitoring	\checkmark Duration of monitoring up to 1	✓ Intermediate cost
	month	 ✓ ECG storage limits
	\checkmark The device doesn't need to be	 ✓ Non continuous monitoring
	worn 24 hours	✓ Does not register arrhythmias
		and heart rhythm during
		disabling symptoms that prevent
		patient activating the device
Extended Holter	✓ Portable	✓ Intermediate cost
	✓ Longer timeframe than Holter	✓ Could miss some AF
	 Continuous Monitoring 	 ✓ Patches may require more than 1 device
MCT	✓ Possibility of real time	device ✓ High cost
MCT	 ✓ Possibility of real time intervention 	 ✓ High cost ✓ Devices could be not comfortable
	intervention	
		to wear

Summary of the various electrical methods of arrhythmia detection



Appendix 4 – List of Competitors & Opportunities (M&A targets)

Product Name	Company	Device Category
Reveal XT ICM & LINQ ICM System	Medtronic (MDT)	ILR
Zio XT & Zio AT	iRhythm Technologies (IRTC)	Extended Holter, MCT
CAM	Bardy Diagnostics	Extended Holter
SAVI Telemetry	Medicomp	МСТ
Telesense	ScottCare	МСТ
Mome Kardia	InfoBinic	МСТ
BodyGuardian Verite, Mini, One and	Preventice Solutions	MCT, Event Monitor, Holter,
heart		Extended Holter
Bittium Faros	Bittium (BITTI)	MCT, Event Monitor, Holter,
		Extended Holter
<u>KardiaMobile</u>	AliveCor	Single lead and 6-lead EKG
ECG Check	CardiacDesigns	Single lead EKG
Zenicore ECG	Zenicore Medical	Single lead EKG
AfibAlert	AfibAlert	Event Recorder
ACS Holter Monitoring, ACS cardiac	ACS Diagnostics	Holter, Event Recorder, MCT
event Monitor, ACS MCT Monitor		



Appendix 5 – Comparison by products

Mobile Cardiac Telemetry

MCT 3 Lead / MCOT	Zio AT	BodyGuardian ONE / VERITE / HEART
BioTelemetry	iRhythm	Preventice Solutions
FDA Class II device	FDA Class II device (special controls)	FDA ²¹ class II device and CE Mark
~ 50% of BEAT's revenue	N/A	N/A
Monitoring up to 30 days	Monitoring up to 14 days	Monitoring up to 30 days
Diagnostic yield: 88% ⁵	Estimated diagnostic yield: 75%	N/A
CPT reimbursement group: Category I	N/A	CPT reimbursement group: Category I
Code: CPT 93228 (technical fee)	N/A	Code: CPT 93228 (technical fee)
Code: CPT 93229 (professional fee)		Code: CPT 93229 (professional fee)
2 channels ²²	Single channel	2 to 3 channels
4 leads / 3 leads and 4 electrodes /1 lead	1 lead	4 to 5 leads
The device continuously monitors patient ECG, automatically generates an alert triggered by an arrhythmia detection algorithm, or generates an alert manually triggered by the patient, and transmits the recorded data trans telephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.	While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to- beat information from the entire ECG recording.	The device monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.
Validate for above 6-year old patients.	Validate for above 18-year old patients.	N/A
Conditions where the system should not be used include patients likely to experience primary Ventricular Fibrillation or Ventricular Tachycardia and patients who have other co-morbid cardiovascular conditions where an arrhythmia could be potentially life threatening.	It is not intended for use on critical care patients.	It is not intended for use on critical care patients.
Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.	The device is intended for use by patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light- headedness, pre-syncope, syncope, fatigue, or anxiety.	The device detects and monitors non- lethal cardiac arrhythmias in ambulatory patients
The ECG signals are transmitted via Bluetooth automatically via cellular link. When cellular service is unavailable the patient has an option to transmit via a landline telephone. system has built in cellular telephone that automatically transmits arrhythmic signals to the monitoring center when the patient is away from home.	The wireless transfer of data requires Bluetooth proximity to the Patch and cellular network reception.	Wireless transmission.

²¹ <u>https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121197.pdf</u>

²² Lead is the same as channel and is the electrical potential difference between two electrodes placed on specific points on the body.

AtonRā Partners

Extended Holters

ePatch	Zio XT	BodyGuardian MINI
BioTelemetry	iRhythm	Preventice Solutions
FDA Class II device + CE Mark	FDA Class II device (2009) + CE Mark	FDA Class II device + CE Mark
Less than ~ 5% of BEAT's revenue	90% of IRTC's revenue	N/A
Monitoring up to 14 days	Monitoring up to 14 days. Very occasionally, such	Monitoring up to 14 days
	as with paroxysmal atrial fibrillation, monitoring	01 ,
	for more than 14 days may be needed because	
	events are very intermittent. In this situation 2	
	patches would be worn in succession.	
Continuous recording.	Continuous recording.	Continuous recording.
Diagnostic yield: 60%	Diagnostic yield: 75%	N/A
CPT reimbursement group: Category III	CPT reimbursement group: Category III (transition	CPT reimbursement
(transition to Category I expected for	to Category I expected for 2021)	group: Category III (transition to
2021)		Category I expected for 2021)
Code CPT 02957 (global services,	Code CPT 02957 (global services, encompasses all	Code CPT 02957 (global services,
encompasses all the codes)	the codes)	encompasses all the codes)
Code CPT 0296T and 0297T (technician	Code CPT 0296T and 0297T (technician fee)	Code CPT 0296T and 0297T
fee)	Code CPT 0298T (Professional fee)	(technician fee)
Code CPT 0298T (Professional fee)		Code CPT 0298T (Professional fee)
	Cingle channel	. ,
1,2 or 3 channels	Single channel.	Single or multiple (3) 1 lead
1 lead	1 lead. As the Zio patch offers only 1 lead as	Tiead
	opposed to the multiple channels available with	
	conventional Holter monitoring. It contributes to a	
	lower sensitivity for the detection of events ²³ .	
The device continuously monitors patient	A sensor that detects cardiac rhythm, a memory,	The device monitors and records a
ECG, automatically generates an alert	and a patch. Wireless, single-lead, water-resistant	patient's electrocardiographic (ECG)
triggered by an arrhythmia detection	ECG worn over the heart, used to help diagnose	data, heart rate, respiration rate
algorithm, or generates an alert manually	occasional arrhythmias over periods as long as two	and activity level. The complete
triggered by the patient, and transmits the	weeks.	system consists of components that
recorded data transtelephonically to a		collect data, send the data to a
monitoring center. The monitoring center		remote Preventice computer
provides the ECG data to the medical		server, store the data in secure
practitioner for evaluation.		databases, and present the data for
		review by healthcare professionals.
Intended for use by adolescents 18-21 and	Validate for above 18-year old patients.	Cleared for pediatric and adults.
adults.		
Conditions where the system should not	It is not intended for use on critical care patients.	It is not intended for use on critical
be used: primary Ventricular Fibrillation,		care patients.
Ventricular Tachycardia, other co-morbid		
cardiovascular conditions where an		
arrhythmia could be potentially life		
threatening.		
Intended for use by patients who	The device is intended for use by patients who may	The device detects and monitors
experience transient symptoms that may	be asymptomatic or who may suffer from transient	non-lethal cardiac arrhythmias in
suggest cardiac arrhythmia.	symptoms such as palpitations, shortness of breath,	ambulatory patients
	dizziness, light-headedness, pre-syncope, syncope,	
	fatigue, or anxiety.	
The ECG signals are transmitted via	The wireless transfer of data requires Bluetooth	Transmission via Bluetooth
Bluetooth automatically via cellular link.	proximity to the Patch and cellular network	technology.
	reception. Once completed, the device is mailed for	
When cellular service is unavailable the		
patient has an option to transmit via a	analysis.	

²³ <u>https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.114.009024</u>



Appendix 6 – US reimbursement framework

The US medical device industry is heavily dependent on reimbursements. Although the FDA approval process is much less burdensome than for drugs, the uncertainty regarding products coverage by Medicare and private payors severely affect companies' outlook.

Medicare is the federal health insurance program for:

- People who are 65 or older ;
- Certain younger people with disabilities ;
- People with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD)"²⁴.

Medicare Part A covers inpatient	Medicare Part B covers certain	Medicare Part D adds prescription		
hospital stays, care in a skilled nursing	doctors' services, outpatient care,	drug coverage to:		
facility, hospice care, and some home	medical supplies, and preventive	- Original Medicare		
health care.	services.	- Some Medicare Cost Plans		
		- Some Medicare Private-Fee-for-		
		Service Plans		
		- Medicare medical savings		
		account plans		
Medicare Part C (a.k.a. Medicare Advantage) is an "all in one" alternative to Original Medicare. It includes Part A, Part B				
and, usually, Part D.				

Medicare usually pays for medical devices indirectly by bundling the average cost of medical devices into its overall payment rate for healthcare services. The reimbursement rates are set by Medicare and are typically less than the amount that a private insurance company would pay. However, Medicare's coverage decisions have particular weight since private insurances tend to use the CMS fee schedule as a reference. A drop in Medicare reimbursement generally presages a similar magnitude decline in commercial payor reimbursement.

Medicare reimbursement process includes the following steps:

- 1. The physician performs the service
- 2. The physician documents the service into the patient medical record
- 3. The information is transferred to a billing/coding department
- 4. The department selects the appropriate diagnosis and procedures codes
- 5. The physician and the facility submit separate claims through the submission of a billing form to the Medicare Administrative Contractor (MAC)
- 6. The payers review the coding and the physician documentation
- 7. Payers pay claims to hospitals or/and physicians (if the service is deemed medically necessary)²⁵

²⁴ <u>https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare</u>

²⁵ <u>https://www.bostonscientific.com/content/dam/bostonscientific/Rhythm%20Management/portfolio-group/MedEd/Physician-Primer.pdf</u>



Reimbursement consists of three main elements: Coding, Coverage, and Payment.

1. *Coding* is the sequence of letters and numbers that identifies the service or procedure.

There are several types of codes, depending on where the procedure is performed (inpatient, outpatient, etc.), who is performing the procedure (physician, nurse, technician), and what equipment is involved (durable, consumable, new technology).

Service / Procedure	Reimbursement codes	Diagnosis / Procedure / Technology codes
For hospital Inpatient procedures	MS-DGR - Diagnosis Related Group	ICD-9-CM Diagnosis ICD-9-CM Procedure
For Hospital Outpatient Care (<i>e.g.</i> ambulatory surgery center)	APC - Ambulatory Payment Categories	ICD-9-CM Diagnosis CPT-4 C-Codes
For physician services	CPT - Current Procedural Terminology	ICD-9-CM Diagnosis CPT-4
Covers other services, products, and supplies not found in CPT codes (ambulance services and durable medical equipment, prosthetics, orthotics, and supplies when used outside a physician's office)	HCPCs – Healthcare Procedure Coding System	

2. Coverage represents the criteria by which the service is paid.

Coding	Payment system	Description
MS-DGR	Medicare Inpatient Prospective	This payment is intended to cover all hospital expenses
	Payment System	(overhead, capital equipment, supplies, etc.) with the exception
		of physician labor.
APC	Medicare Outpatient Prospective	This payment is intended to cover all facility expenses
	Payment System	(overhead, capital equipment, supplies, etc.) with the exception
		of physician labor.
СРТ	Medicare Physician Fee Schedule	These payments are usually based on the physician's time, the
		complexity of the case, and other factors.

Medical device companies can apply for Medicare coverage of new devices that do not fit into an existing service code by requesting either a national coverage determination ("NCD") from CMS or a local coverage determination ("LCD") from a Medicare administrative contractor ("MAC") for the procedure that involves the device. NCDs apply nationwide, while an LCD applies only to the states within the jurisdiction of the MAC that issued it. CMS and the MACs make coverage decisions by determining whether the available evidence for a device supports the requested coverage.

3. Payment *is the amount paid to a hospital/facility, physician for service or a procedure.*



Let's take a closer look at the American Medical Association's reimbursement coding process related to cardiac monitoring devices, the technology used to assess a patient's cardiac arrhythmias.

Technology	Coding
Holter Monitors	CPT codes 93224, 93225, 93226, 93227
External Loop Recorder	CPT codes 93268, 93270, 93271, and 93272
Implantable Loop Recorder	CPT codes 33282, 33284, 93285, 93291, 93297, 93298, 93299, E0616
Extended Holter	CPT codes 0295T, 0296T, 0297T ²⁶
Mobile Cardiac Telemetry (MCOT)	CPT codes 93228 and 93229 ²⁷

CPT codes are divided into three Categories:

- Category I most commonly used by healthcare providers to report medical and professional services and procedures. Five-digit numeric code updated on an annual basis with changes effective January 1 of the next calendar year (exception of vaccine codes)
- Category II optional, used by an incentive-based program developed by CMS to provide performance measurement for certain medical conditions. They can be used in conjunction with Category I codes and are released three times a year (effective three months after the publication date). They are alphanumeric with the letter "F" in the last position.
- Category III temporary codes for emerging technology, services and procedures, updated twice a year on Jan 1 and July 1. They are alphanumeric but with the letter "T" in the last position. Physician who embraces new technology, are probably quite familiar with Category III CPT codes.

Category III reimbursement codes expire 5 years after implementation but can be renewed for a further five years if they are still "developing," otherwise they will be transitioned to Category I permanent codes if the underlying procedure has become more widespread and supported by literature. When procedures move from Category III to Category I, reimbursement rates typically drop by about a third.

CPT reimbursement payment is based on the Physician Fee Schedule, a complete listing of fees used by Medicare to pay doctors or other providers/suppliers on a fee-for-service basis. CMS develops fee schedules for physicians, ambulance services, clinical laboratory services, and durable medical equipment, prosthetics, orthotics, and supplies.²⁸

The Physician Fee Schedule with comment period for 2019 has been placed on display on 12 July 2018. On 1 November 2018, the 2019 Medicare Physician Fee Schedule Final Rule was placed on display at the Federal Register (this is the definitive fee schedule, a product of refinements on the Physician Fee Schedule with comment normally proposed during the summer). Such a final rule updated payment policies, payment rates, and other provisions for services furnished under the Medicare Physician Fee

²⁶ <u>https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/e/external-electrocardiographic-recording.pdf</u>

https://www.paramounthealthcare.com/assets/documents/medicalpolicy/PG0039_Cardiac_Event_Monitors_ and_Detection.pdf

²⁸ https://www.cms.gov/medicare/medicare-fee-for-service-payment/feeschedulegeninfo/index.html



Schedule (PFS) on or after 1 January 2019. For 2019 and 2020, it finalizes several documentation policies to provide immediate burden reduction, while other changes to documentation, coding, and payment would be implemented in 2021.

Having a look at the reimbursement model for the specific category of devices called MCOT, it consists of two components:

The reimbursement rate changes according to the type of provider. There are two distinct types of providers:

- A 'Par provider' is a doctor who accepts assignment.
- A 'Non-Par' provider is a doctor who does not accept assignment.

Typically, a Par Provider bills Medicare directly an amount equal to the Medicare 'Par Fee'. Medicare pays the provider directly for 80% of the "Par Fee". The patient is then responsible for paying the provider the 20% co-insurance amount (which may be covered by a secondary policy if the patient purchased such coverage).

A 'Non-Par' provider bills Medicare directly an amount called the Medicare Limiting Charge. The Limiting Charge is set at 15% higher than the Non-Par Fee. The Non-Par Fee is 5% less than the Par Fee. Typically, Medicare will pay the patient directly for 80% of the 'Non-Par Fee'. The patient is then responsible for passing on the Medicare payment to the provider, plus paying for the 20% co-insurance on the 'Non-Par Fee' as well as the 15% difference between the 'Non-Par Fee' and the 'Limiting Charge' (portions of which may be covered by a Secondary Policy if the patient purchased such coverage).

1. Professional Component: the reimbursement goes to the interpreting physician.

CPT code 93228 is the professional component within a course of up to 30 consecutive days of cardiac monitoring and includes review and interpretation of each 24-hour cardiac surveillance as well as 24-hour availability and response to monitoring events.

CPT code	Description	Medicare Physician Fee Schedule
		Payment
93228	External mobile cardiovascular telemetry with	Around \$35 for a 30 days monitoring
	electrocardiographic recording, concurrent computerized real time	service (in facility rate, 2019)
	data analysis and greater than 24 hours of accessible ECG data	
	storage (retrievable with query) with ECG triggered and patient	Around \$35 for a 30 days monitoring
	selected events transmitted to a remote attended surveillance	service (in office rate, 2019) ²⁹
	center for up to 30 days; review and interpretation with report by	
	a physician or other qualified health care professionals.	

²⁹ <u>https://www.gehealthcare.com/-/media/63de206c936a43748ad38420ec512d71.pdf?la=en-us&hash=4848CADC74FE605ED4DF954E215F9106</u>



2. Technical Component: *the reimbursement goes to the service company.*

CPT code 93229 is the technical component within 30 consecutive days of cardiac monitoring. It includes:

- Patient hook-up and patient-specific instruction and education,
- Transmission and receipt of ECG o Analysis of ECG by non-physician personnel,
- Medical chart documentation including daily report,
- Patient and/or physician interaction and response,
- Summary report at the end of the monitoring episode,
- Equipment maintenance,
- All supplies necessary for completion of the monitoring.

Schedule	Fee S	Physician	Medicare				ı	Description	CPT code
			Payment						
	ity) ³⁰	00 (non-fac	Around \$8	CG data patient eillance on and rsis and	of accessible EC triggered and attended surv ort for connectiveillance, analy	cardiovascular cording, concurrent ter than 24 hours of th query) with ECG nitted to a remote ays; technical suppor r use, attended sur d emergent data rep	sis and grea trievable wi vents transn up to 30 da tructions for	data analys storage (re selected ev center for patient ins	93229
				eillance on and sis and	attended surv ort for connectiveillance, analy ports as prescrib	nitted to a remote ays; technical suppor r use, attended sur	vents transn up to 30 da tructions for on of daily an	selected ev center for patient ins transmissic	

3. Professional Component: *the reimbursement goes to the interpreting physician.*

Medical professionals will bill for the in-office hook-up (0296T) and the final interpretation of the results (0298T).

CPT code	Description	Medicare Physician Fee Schedule
		Payment
0298T	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data	Around \$50 (in facility rate, 2019) Around \$50 (in office rate, 2019) ³¹
	storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professionals.	

³⁰ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-

Provider-Charge-Data/Physician-and-Other-Supplier.html

³¹ <u>https://www.gehealthcare.com/-/media/63de206c936a43748ad38420ec512d71.pdf?la=en-</u>us&hash=4848CADC74FE605ED4DF954E215F9106



4. Technical Component: *the reimbursement goes to the service company.*

iRhythm Technologies will bill the patient's insurance for the technical component (0297T).

CPT code	Description	Medicare Physician Fee Schedule
		Payment
0296T and	External mobile cardiovascular telemetry with	Around \$320 (non-facility) ³²
0297T	electrocardiographic recording, concurrent computerized real time	
	data analysis and greater than 24 hours of accessible ECG data	
	storage (retrievable with query) with ECG triggered and patient	
	selected events transmitted to a remote attended surveillance	
	center for up to 30 days; technical support for connection and	
	patient instructions for use, attended surveillance, analysis and	
	transmission of daily and emergent data reports as prescribed by a	
	physician or other qualified health care professionals.	

Under the current service model, the referring physician is only compensated for the professional (interpretation) component which requires 24-hour availability and response each day for up to 30 days to monitor cardiac events. Because of the low reimbursement rate bound to physicians, Mobile Cardiac Telemetry, despite its proved technological value³³, is highly underutilized.

³² <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-</u>

Provider-Charge-Data/Physician-and-Other-Supplier.html

³³ <u>http://cardiacmonitoring.com/mobile-cardiac-telemetry-mct-reimbursement/</u>



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