

Acutus Medical, Inc. (AFIB)

Paradigm-shifting technology at a shocking price

We are long shares of Acutus Medical, a small-cap medical device company that we believe will play a central role in changing the treatment paradigm for persistent atrial fibrillation (AF) and other complex arrhythmias. Evidence that catheter ablation successfully treats less advanced forms of AF has been mounting for years, but persistent AF remains intractable: pharmaceutical intervention rarely succeeds and 30-50% of patients undergoing ablation suffer a relapse into AF in less than a year. Because unresolved AF increases the risk of stroke, heart failure, dementia, and other cardiac disease, the unmet need for treating persistent AF is massive.

Into this treatment void has now stepped Acutus. Its AcQMap catheter is the only cardiac mapping tool that can *simultaneously* record the electrical activity of an entire atrial chamber of the heart in high resolution, continuously over multiple heartbeats. Within about 3 minutes, the “playback,” an electrical propagation map of the chamber, can be analyzed by an electrophysiologist performing an ablation. The map allows the EP to visualize the pattern of the heart’s electrical conduction, as well as discern various properties of conduction including amplitude, velocity, breadth, and contiguity. Our discussions with numerous EPs confirmed that AcQMap provides a high-resolution visualization of complex atrial arrhythmias that is unrivaled among other mapping tools, and which helps determine an individualized ablation strategy with a precision that has never been possible before.

Already, initial prospective trials suggest that EPs using AcQMap dramatically increase their success rates in ablation for persistent AF. Notably, the trials achieved these efficacy improvements with primitive versions of AcQMap and rudimentary heuristics to determine ablation strategy. AcQMap has since undergone several iterations of improvement and the heuristics, which had been derived from a combination of legacy theories of AF conduction and early feasibility studies of AcQMap, are adapting to incorporate more real-world experience from AcQMap-guided ablation. As that experience mounts, it will translate into the most robust AF-conduction dataset ever. A rigorous taxonomy of conduction phenomena will enable precision characterization of the severity and prognosis of AF, which will further inform individualized ablation strategy for EPs using AcQMap and lead to better outcomes.

Acutus’s stock came under pressure earlier this year as suspicion arose that its 2021 revenue guidance reduction stemmed more from a lack of customer interest in AcQMap than from transient pandemic-related turmoil. Based on discussions with industry participants, we’re confident the snag in momentum is temporary. For one, the pandemic *did* hit hospital new product procurement especially hard, and that’s reversing now. Additionally, the perceived lack of customer interest in AcQMap is merely a sign that Acutus’s previously indiscriminate approach to sales resulted in AcQMap installations at labs uninterested in precision ablation methods. Acutus’s recently revamped targeted sales efforts are already on track and have already borne fruit in the first half of this year.

As Acutus gains momentum and expands its product offering to RF and pulsed-field ablation catheters, the company will gain substantial share of a now-\$5-6 billion catheter ablation market growing at a mid-teens rate. That market growth rate will also soon inflect upward as faster ablation methods become mainstream and guidelines change to reflect recent evidence of the superiority of ablation as an early-stage therapy to treat AF. We expect Acutus to easily gain over 10% market share in the medium term, by which time the company will be a billion-dollar cardiology juggernaut. Given its current \$480 million valuation, the returns over that time will be electrifying.

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I. Investment Highlights

Acutus's cardiac mapping technology is revolutionary for the field of electrophysiology.

The standard second line treatment for atrial fibrillation (AF), in patients for whom anti-arrhythmic drugs (AADs) no longer work or aren't tolerated well, is cardiac catheter ablation, a procedure in which an electrophysiologist (EP) inserts a catheter into the heart and carefully burns (or freezes) specific areas of tissue. The scarring is meant to block the dysregulated electrical conduction that's responsible for the arrhythmia. For patients with early-stage AF, in which the arrhythmia is sporadic, or "paroxysmal," catheter ablation has a relatively high success rate, with 70-80% of patients remaining arrhythmia-free in the twelve months after the procedure, and 60-70% permanently rid of it over time.

For patients with more persistent forms of AF, or for paroxysmal patients who relapse into persistent AF even after undergoing ablation, the prognosis has not been as constructive. Paroxysmal AF is understood to be the result of errant conduction triggers in the area of the pulmonary veins in the heart's left atrium, which are relatively straightforward to ablate. Persistent AF, on the other hand, has been much more elusive, with no clear cardiac region having been shown to trigger the arrhythmia. Two different approaches within the field of electrophysiology have emerged in response to the low rates of effectiveness in ablating persistent AF:

- Empirical ablation approach – physicians of the empirical ablation school will ablate pre-specified regions of the endocardium, most prominently the posterior wall of the left atrium, but also near the superior vena cava (SVC), the coronary sinus, and other areas. The logic of empirical ablation is that these sites have been shown to trigger AF in some patients, so ablating them will increase the odds of procedural success.
- Mechanism-based approach – physicians of this school will use advanced 3D mapping catheters to detect abnormal electrical conduction across the atrial endocardium and ablate the areas from which they seem to emanate.

For patients with persistent AF, both approaches do improve on the effectiveness of just isolating the pulmonary veins, but not by much. A substantial proportion of patients (a third to a half) will still end up relapsing into AF or other atrial arrhythmias (such as atrial flutter or atrial tachycardia, a category generally referred to as supraventricular tachycardia, or SVT).

We think Acutus's AcQMap, a 3D mapping catheter that was first developed and used in humans in 2013, will revolutionize mechanism-based ablation. Prior to AcQMap, the most cutting-edge mapping technology used in the EP lab has been the CARTO 3D contact mapping system from Biosense Webster. But as our extensive discussions with EPs has impressed upon us, even the best contact mapping systems suffer from significant limitations in painting a picture of the atria's electrical conduction patterns. Contact mapping catheters can only touch the tissue at a few neighboring points at once, which means that the resulting "map" of electrical activation is actually a mosaic of fragmentary electrical measurements taken over the course of

10-40 minutes (depending on the skill level of the physician), and in which the areas that are not directly touched by the electrodes on the catheter are not as accurately depicted. The problem measuring electrical activation this way is that complex arrhythmias – like persistent AF or atrial flutter – are unstable, both temporally and spatially, and stitching up the fragmented measurements results in a necessarily distorted view of the errant electrical conduction. That can sometimes help but, given the current state of mechanism-based ablation, not often enough.

AcQMap, on the other hand, is a non-contact catheter that's inserted into one of the atrial chambers and, using its 48 electrodes and 48 ultrasound transducers, assembles not just a picture, but a *recording* over the span of multiple heart beats, of the *entire* chamber's electrical activation *simultaneously*, and in resolution that is 4-10x higher than the best resolution available from the most advanced contact mapping catheters. The best analogy to explain this, as one EP explained to us, is that the most advanced contact mapping system can only return an HD-quality panorama photo composed of images that were separately photographed over a long enough period of time that the disjointedness is noticeable when closely observed. AcQMap, meanwhile, allows the EP to observe the chamber's electrical activation as a short video recorded and played back in 8K picture quality. AcQMap opens a whole new chapter in observing, researching, and ablating complex arrhythmias like persistent AF.

AcQMap increases the success rate of ablation procedures and improves their safety and efficiency.

The initial studies run using AcQMap have given, in our view, just a small glimpse of what we think the technology will enable. In the UNCOVER AF trial, EPs with no prior experience using AcQMap were trained to use the system to detect three conduction patterns that were identified by investigators running the early feasibility studies on AcQMap. When ablating the sites of these patterns, the clinical success rate of ablation in persistent AF patients was better than any achieved in any rigorous study of empirical or mechanism-based ablation. In a second study, conducted independently by two electrophysiology labs using AcQMap, the EPs adjusted the ablation method that was pioneered in the early Acutus feasibility studies. The modest adjustment was made based on prior research into electrical conduction patterns, and it resulted in one-year effectiveness of ablation that completely blew away anything that has ever been achieved before in any large scale study of ablation for persistent AF.

The iterative improvement in using AcQMap has only just begun. The breadth and depth of data on arrhythmic cardiac conduction that is now obtainable through AcQMap will be used to assemble a rigorous taxonomy of conduction patterns and properties. These will be studied in order to plumb their relationships to clinically relevant observations and outcomes, such as how they affect patient prognosis, how they relate to bio-anatomical phenomena like cardiac fibrosis, and how effective will ablating them be in avoiding any recurrence of arrhythmia. Several prominent EPs, some in conjunction with Acutus and others independently, have already begun this kind of research, and only EPs using AcQMap will be able to exploit the clinical insights of this kind of research.

Beyond the ability of AcQMap to improve clinical outcomes, our wide-ranging discussions with electrophysiologists have made it clear that another critical aspect of AcQMap is its ability to improve procedural efficiency and workflow. EPs using AcQMap can construct an electrical activation map in 3 minutes, which cuts down on the time spent mapping during an ablation procedure. That speed also allows them to get intra-procedure feedback about how the ablation is affecting cardiac conduction because remapping the endocardium can be done multiple times in the same procedure, which is too time-consuming to do with contact mapping. The ability of AcQMap to quickly and easily get a complete and precise activation map is also a boon for most EPs, who don't all have the experience and skill level to handle a contact mapping catheter with the dexterity necessary to get a passable activation map. The advent of a mapping method that makes physicians' tasks easier and more efficient during an intense procedure may be just as important for the success of AcQMap as is its ability to improve patient outcomes.

The sales growth deceleration at Acutus earlier this year was a function of temporary factors that have already reversed. Acutus's stock price declined markedly earlier this year as the company had to reset its 2021 guidance after two quarters of subpar revenue momentum. We believe Acutus's stumbles have been a function of temporary phenomena that have since reversed:

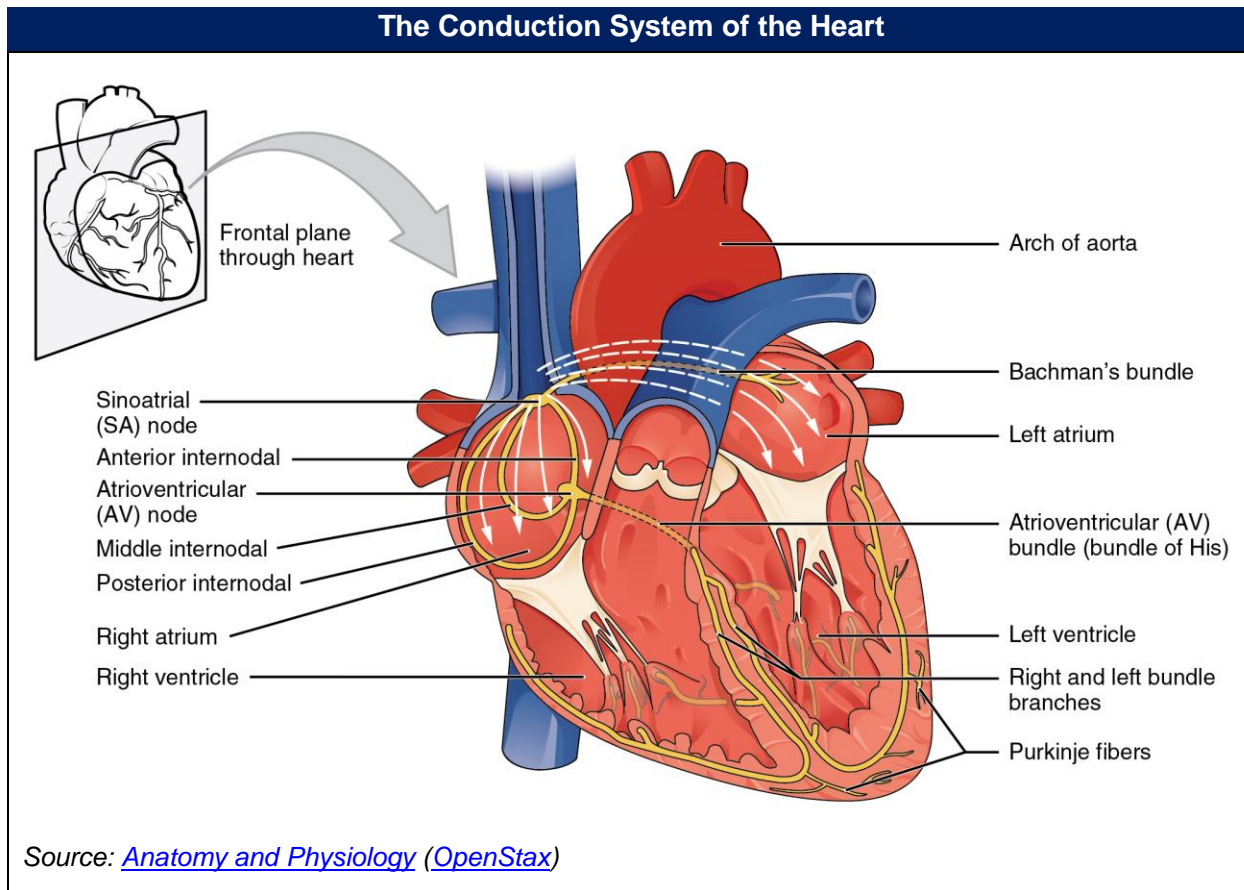
- The Covid pandemic made it difficult for Acutus to train physicians due to the logistical hurdles involved in travel and non-essential close contact, particularly in the medical setting. That led to subpar utilization of AcQMap at the facilities in which the system was installed, and inadequate proficiency on the part of physicians to exploit its capabilities. The pandemic also created crisis conditions in which hospitals discouraged the installation and usage of new technologies in favor of trying to ramp up capacity of existing services wherever possible.
- Acutus's initial marketing message and go-to-market strategy were not appropriately tailored. Early AcQMap marketing focused on the potential for AcQMap to "solve" AF, but after a decade's worth of hollow claims to that effect from other companies, that message fell on deaf ears. Additionally, Acutus sales reps were overly focused on low-barrier system installs instead of targeting the kind of EP that was likely to use the systems once installed.

The pandemic has since eased, with hospitals changing their policies on new technologies, and training logistics improving dramatically. Additionally, earlier this year Acutus recruited Duane Wilder, formerly of [Volcano](#), as Chief Commercial Officer. Wilder has quickly adapted Acutus's marketing message to focus on AcQMap's ability to improve physician workflow and procedural effectiveness. The sales effort has also become markedly more targeted, focusing on EP labs that are both partial to mechanism-based ablation methods, and willing to quickly adopt new technologies that can improve those methods. Given the step-change in capabilities that AcQMap brings to the table, it's no wonder that this year's first half already began to demonstrate renewed momentum, and we expect that to continue in the second half of this year and into 2022.

The total addressable market (TAM) for Acutus’s product offering is massive, and AcQMap is the only product of its kind within that market. The global market for ablation disposables is approximately \$5-6 billion. While that’s grown at a mid-teens percentage rate over the last five years, we expect new technologies – including Acutus’s non-contact mapping and the introduction of pulsed field ablation (PFA) – will make the performance of the procedure faster, safer, and more effective, leading to an acceleration in the growth of the market. In five years, we expect the overall market to exceed \$15 billion globally.

Acutus’s current product lineup, which includes its mapping catheter in the US and Europe, as well as its radiofrequency ablation catheter only in Europe, addresses about 60-70% of the current market. In the next 18-24 months, we expect Acutus’s ablation catheter to be approved in the US, giving it entrée to the rest of the ablation TAM. Beyond that, Acutus is in the process of developing its own PFA catheter optimized to ablate non-PV triggers in persistent AF, and expects trials to begin next year. Given the game-changing nature of AcQMap technology, we expect that Acutus’s market share will easily exceed 10% over time, while reaching much higher levels in the niches of complex arrhythmias like persistent AF, redo procedures, and supraventricular tachycardias. A successful ablation catheter and PFA product will result in even more dramatic market share gains. Acutus may be in the very early stages of commercializing its technology, but its groundbreaking nature will allow it to sustain extraordinary levels of revenue growth for at least the next decade and possibly beyond. At its current \$480 million market capitalization, investors have an extraordinary opportunity to ride that wave of growth at an incredibly attractive entry point.

II. Atrial Fibrillation remains an unresolved problem



The human heart beats approximately 60-100 times per minute, powered by a complex system of electrical activation in which charged ions traverse cardiac conduction cells leading to the contractions of the heart. The electrical impulse begins spontaneously at the sinoatrial node (also called the sinus node) and then travels through the right and left atrium, causing atrial contraction. The electrical impulse then regroups at the atrioventricular node, where it pauses briefly (for ~100 milliseconds) to allow for the complete contraction of the atria to pump blood into the ventricles, and then continues through the various groups of conduction cells in the ventricles that stimulate the ventricles to contract. All this takes place for every heartbeat in less than a quarter of a second, and when it all functions correctly, it results in a normal heart rhythm or “normal sinus rhythm.”¹

An arrhythmia occurs when there’s a problem with the normal *rate* of the heartbeat – it’s either too fast (tachycardia) or too slow (bradycardia) – or its *rhythm* (the beats are irregular), or both simultaneously. Arrhythmias can be caused by changes to the cardiac tissue (which can themselves be a result of lifestyle choices such as smoking and obesity, or age-related alterations rooted in genetics), physiological imbalances (e.g., hormonal or chemical), or even

¹ A good primer on the conduction system of the heart can be found [here](#).

medical treatments like medicines or surgery (some arrhythmias, as we discuss below, can actually be caused by prior treatment of other arrhythmias).

By far the most common arrhythmia diagnosed in the US is atrial fibrillation (AF), with about half a million hospitalizations each year occurring with a primary diagnosis of AF, while the true prevalence is estimated at 3 to 7 million people.² In Europe, the proportional numbers are a bit higher.³ In AF, errant electrical signals in the atria overwhelm the normal sinus node impulse and cause the atria to contract irregularly, usually resulting in a rapid and chaotic heartbeat. AF results in a marked decrease in quality of life and a marked increase in the risk of many adverse health outcomes, particularly stroke and other clotting events, but also dementia, heart attack, heart failure, and even sudden cardiac arrest. Other atrial tachycardias, or supraventricular tachycardias (SVTs), occur less frequently than AF, but are similarly characterized by dysregulated atrial electrical conduction and increased health risks.

The severity of AF and its classification are dependent upon the length of a patient's episodes, with an episode defined as the detection of AF via electrocardiogram (ECG) monitoring. A patient suffering *paroxysmal* AF has episodes of AF lasting less than 7 days while *persistent* AF describes episodes lasting longer than that. *Longstanding persistent* AF, meanwhile, is the term used to diagnose *continuous* AF that has lasted longer than a year. AF usually (but not always) presents as a progressive disease, starting as paroxysmal and becoming more persistent and continuous over time if left untreated, though even treatment is no guarantee the disease won't progress. Historically, AF was treated with [anti-arrhythmic drugs](#) (AAD) coupled with anticoagulants, but these are successful in maintaining sinus rhythm in only 30-60% of patients, with high rates of AF recurrence and low tolerance of side effects.⁴ Outside of ablation, the disease is basically "managed" with a combination of drugs and lifestyle changes, with the occasional [electrical cardioversion](#), a procedure that also has high rates of AF relapse.

Ablation to treat AF was first pioneered in the context of open-heart surgery by James Cox in 1987. The idea was to create scar tissue in strategic parts of the heart's wall that would physically block the errant electrical signals in the atria from advancing and wreaking havoc on the rest of the electrical conduction of the heart. In 1998, the logic was applied in the electrophysiology lab as radiofrequency (RF) energy was applied via catheter (inserted into the femoral vein and guided into the heart) to burn the relevant tissue and achieve the same kind of electrical blockage.

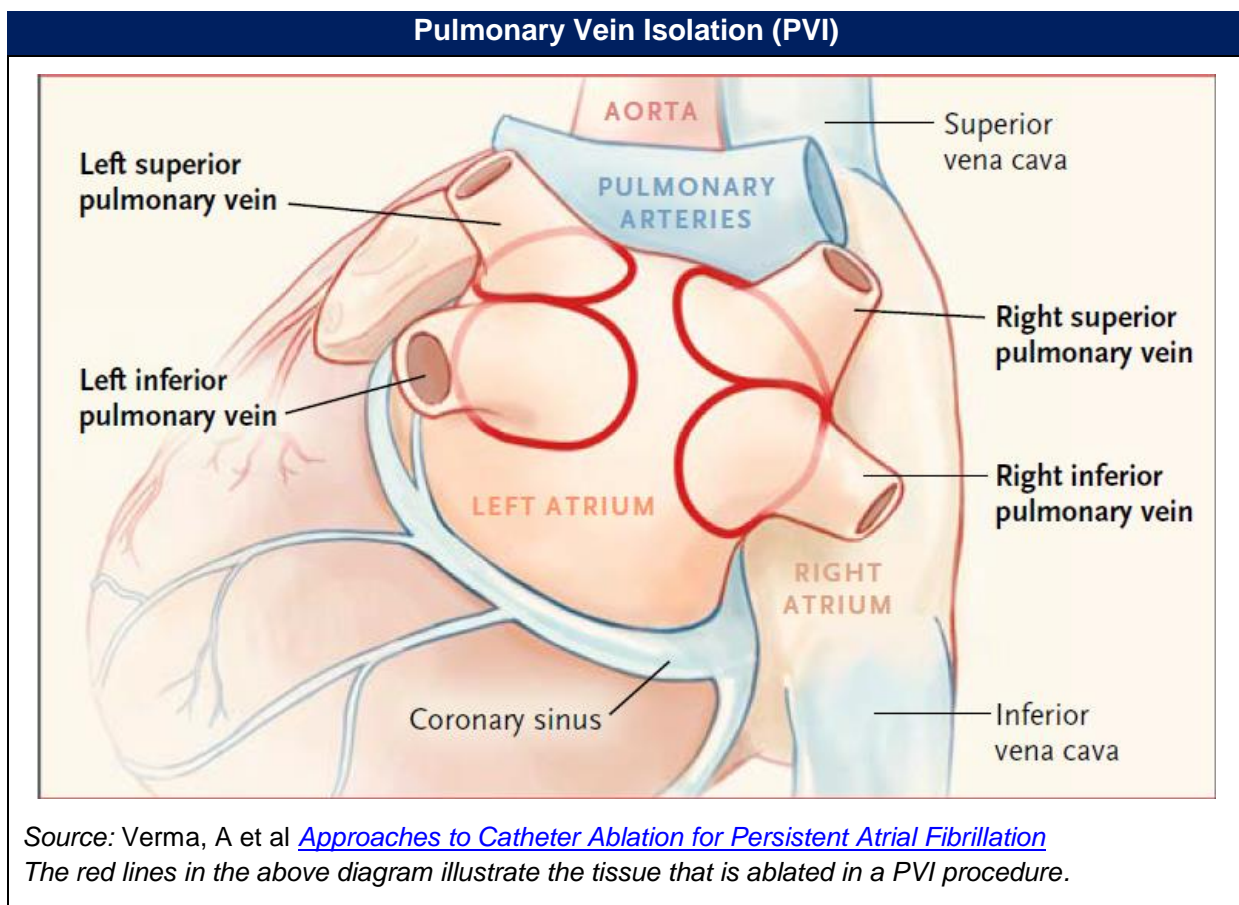
In the ground-breaking study of this method, Michel Haïssaguerre and his colleagues used intracardiac electrocardiography (basically an ECG catheter inside the heart) to reveal that the pulmonary veins were the trigger sites for errant electrical signaling in patients with paroxysmal

² [Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association](#)

³ See Lindberg, T et al [Prevalence and Incidence of Atrial Fibrillation and Other Arrhythmias in the General Older Population: Findings From the Swedish National Study on Aging and Care](#) and Khurshid, S et al [Frequency of Cardiac Rhythm Abnormalities in a Half Million Adults](#)

⁴ Zimetbaum, P [Antiarrhythmic Drug Therapy for Atrial Fibrillation](#)

AF.⁵ They found that patients in AF almost always exhibited signs of abnormal electrical activation at the pulmonary veins. Their solution was to isolate the pulmonary veins by burning (ablate) the tissue connecting them to the rest of the heart, thereby blocking the path into the atrium of any abnormal electrical activation emanating from the veins (see the red lines in the diagram below). This successfully stopped the dysregulated atrial rhythm and returned 36 of 38 patients to sinus rhythm. Months later upon follow-up, 28 of those patients were still completely free of AF.



Pulmonary vein isolation (PVI) remains the mainstay of catheter ablation in the treatment of AF. For patients with paroxysmal AF refractory to or intolerant of AADs, the 2017 [HRS expert consensus statement on ablation of AF](#) makes catheter ablation – specifically PVI – a Class I recommendation (the highest level). Since the Haïssaguerre study, numerous randomized prospective trials have been conducted to measure the effectiveness of treating paroxysmal AF patients with PVI. The consistent result is that 65-70% of patients are free from any atrial arrhythmia and off AADs a year after the procedure, while AADs typically boost that success

⁵ Haïssaguerre, M et al [Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins](#)

rate by 5-10%.⁶ When PVI fails, it's usually because the pulmonary veins have reconnected with the left atrial wall, allowing the AF to recur. PV reconnection can be a result of gaps in the initial ablation line or an ablation scar that did not permeate the tissue deeply enough, or even some tissue remaining viable despite adequate scarring.⁷ Rarely, PVI fails due to AF triggers moving beyond the pulmonary veins, which is usually a precursor to, if not yet a manifestation of, persistent AF.

For persistent AF, PVI is not nearly as effective. Using a similar measure of effectiveness as in the paroxysmal trials, the landmark [STAR AF II](#) trial found that PVI is effective only 40% of the time for patients with persistent AF (50% with AADs).⁸ More recently, two prominent studies have suggested ablation strategies that can raise the effectiveness of catheter ablation for persistent AF. The first is the CONVERGE IDE trial, which we've discussed [previously](#) at length. CONVERGE showed that ablating the entire posterior wall of the left atrium (in the trial this was done surgically) *in addition* to PVI increases the effectiveness of ablation to about 55% (67% with AADs) in patients with persistent or longstanding persistent AF.⁹ The PRECEPT trial achieved a single-procedure rate of effectiveness of about 58% (64% with AADs) using only catheter ablation in persistent AF patients.¹⁰ The novelty in the PRECEPT protocol was that it allowed participating EPs to ablate other areas of the endocardium *at their own discretion* in addition to isolating the PVs.

The common denominator between the CONVERGE trial and the PRECEPT trial was that they both were designed to test ablation of AF triggers beyond the pulmonary veins. Much more frequently than in paroxysmal cases, PVI in persistent AF fails because the PVs are not the only arrhythmic triggers. The CONVERGE response was to surgically burn the entire posterior wall and see if that helped. PRECEPT, on the other hand, had participating EPs who were experienced in using the most cutting-edge technology available – the CARTO electro-anatomical mapping (EAM) system – electrically map the entire left atrium and ablate any non-PV triggers based on identified abnormal electrical activation. Both approaches succeeded to some extent, raising the effectiveness of ablation by 15%.

⁶ Relevant trials include [TOCCASTAR](#) (68% effectiveness), [SMART-AF](#) (73% effectiveness), and [FIRE AND ICE](#) (65% effectiveness). “Effectiveness” is generally defined as freedom from any atrial arrhythmia that lasts longer than 30 seconds in the 12 months post-procedure in the absence of any AADs. The studies enrolled only patients refractory to or intolerant of AADs, so it's plausible that patients would consider the procedure successful if their previously failed AAD was now effective. Effectiveness results *with* AADs in the above studies increase effectiveness by about 5-10% to the ~80% level.

⁷ Reconnection is explored in further depth by McGarry and Narayan in [The Anatomical Basis of Pulmonary Vein Reconnection After Ablation for Atrial Fibrillation](#)

⁸ Verma, A et al [Approaches to Catheter Ablation for Persistent Atrial Fibrillation](#)

⁹ DeLurgio, DB et al [Hybrid Convergent Procedure for the Treatment of Persistent and Long-Standing Persistent Atrial Fibrillation](#)

¹⁰ Mansour, M et al [Persistent Atrial Fibrillation Ablation With Contact Force–Sensing Catheter: The Prospective Multicenter PRECEPT Trial](#). The PRECEPT investigators determined effectiveness using 5 different endpoints, and we think the single-procedure effectiveness is the most comparable to both CONVERGE and prior trials.

But at ~65% effectiveness (with the aid of AADs), both approaches are still far from perfect in halting persistent AF, and that's not accounting for the risks and consequences of ablating the entire posterior wall as in the CONVERGE trial.¹¹ Further, both PRECEPT and STAR AF II go out further than 12 months in evaluating procedural effectiveness, and both studies show continued patient relapses into AF or other SVT beyond the one-year marker, implying that *long term* effectiveness is even lower than the headline numbers. This is also true for PVI in paroxysmal AF, where long term studies indicate that the ~70-80% one-year effectiveness is whittled down by 10-15% in the 3 years post-procedure.¹²

One approach in paroxysmal patients who relapse into arrhythmia is to redo the ablation. Given the complexity of arrhythmic recurrence, redo procedures aren't as straightforward as initial ablations. Typically, pulmonary veins are checked with EAM for reconnection, and any gaps in the prior ablation are re-ablated. But, as in initial ablations for persistent AF, the problem is not always, or not exclusively, the pulmonary veins, and beyond the PVs, the appropriate (re)ablation route is not always clear. Because of this, *there is currently no consensus standard of care* for ablation of persistent AF, or redo procedures of any kind, beyond PVI.

Since Haïssaguerre, the holy grail of AF research has been finding the non-PV triggers of AF that can be systematically targeted for ablation as in PVI.¹³ Many approaches have been taken and hypotheses offered, all of which have come up short. The [2017 Expert Consensus Statement on Ablation](#), therefore, does not unequivocally recommend ablation for persistent AF or a redo ablation for a paroxysmal patient who relapsed. After surveying many hypotheses and proposed techniques, the statement concludes that “definitive evidence of the benefit or superiority of any of these techniques [beyond re-isolating the PVs] over the others is lacking...Data on current clinical practice confirm the prevailing uncertainty regarding the best reablation technique.” Into this void has stepped Acutus.

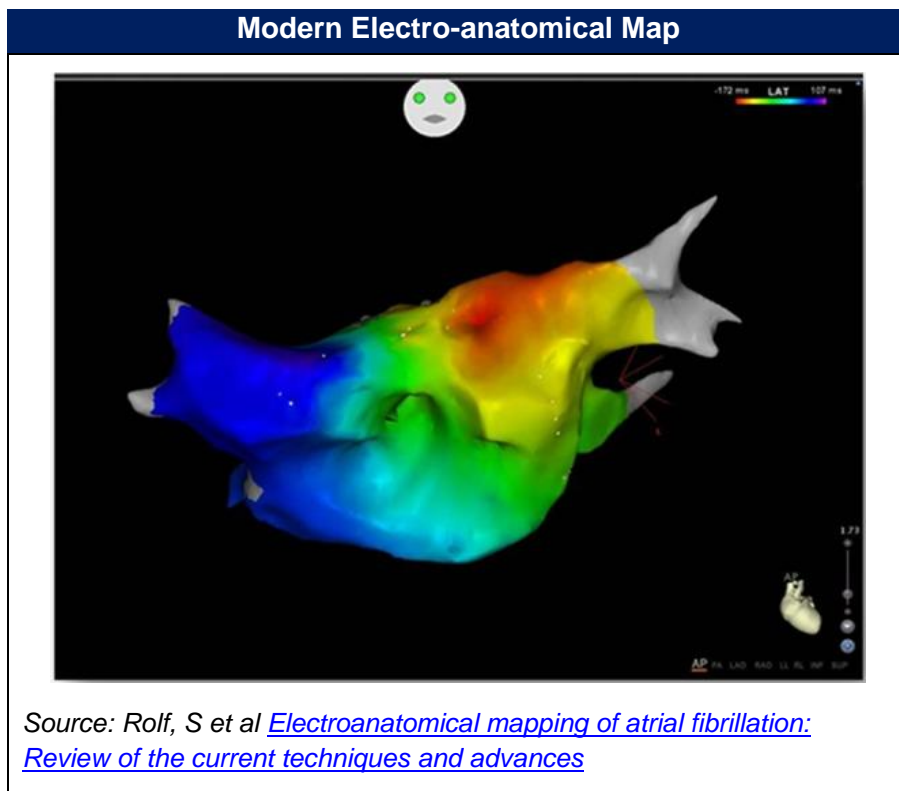
¹¹ It's easy to forget at times that ablation is the attempt to permanently scar cardiac tissue, and the less of that tissue that is permanently destroyed, the better. It has been shown, for example in the STAR AF II trial, that over-ablation can result in *new* arrhythmias developing in the years after the initial procedure.

¹² See Kuck, KH et al [Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation](#), and especially Figure 2A therein.

¹³ We use the term “trigger” in this report loosely to mean sites of arrhythmogenic cardiac tissue, i.e. sites at least partly responsible for the dysregulated electrical conduction that results in arrhythmia. Within the field of AF research, there exists some debate as to the precise classification of arrhythmogenic tissue as “trigger,” which technically is where the errant electrical impulses originate, and “substrate,” which is tissue that allows those impulses to propagate. There's still no widespread agreement as to how to classify trigger vs substrate, or even if the distinction actually exists.

III. Acutus’s cardiac mapping is a massive technological leap from legacy high-resolution mapping modalities

Almost all the research on AF triggers, including the discoveries made by Haïssaguerre on the pulmonary veins, is only possible due to intra-cardiac electrograms (ICE) and the activation mapping they enable. An ICE catheter is a relatively simple device with an electrode at its tip that is inserted into the heart to measure the electrical activation of the spot that it touches in the endocardium, like a precision ECG. It’s impossible to touch an entire cardiac chamber simultaneously, so a separate catheter/electrode is also placed into the chamber as an objective timing reference. The initial ICE catheter is then moved around the chamber to record the timing of electrical activation at multiple points, and the result is an activation “map” of the path taken by electrical impulses in the heart. A modern activation map looks something like the picture below, where the color scheme is used to demarcate different points in time: the electrical activation starts in the area shaded in red and ends in the area shaded in blue.



A detailed activation map can potentially contain information that allows the EP to accurately determine the physical mechanism of the arrhythmia. It can highlight areas of irregular electrical activation, illustrate the probable (or possible) pattern of that electrical activation, and in its most recent iterations, the mapping catheter systems can also be used to simultaneously create a detailed anatomical map of the inside of the heart that can be used by the EP to guide the various other catheters without the need for fluoroscopy and its attendant radiation.

If the holy grail of AF ablation is to find and ablate the non-PV triggers, then electro-anatomical mapping (EAM) is seen as the most likely tool to enable it. The advances in activation mapping over the last 5-10 years have brought about a subtle fissure within the field of electrophysiology: one side of the debate believes that EAM has enabled a new era of “mechanism-based” ablation in which activation mapping can visually reveal the underlying mechanisms of an arrhythmia, which can then be terminated through targeted ablation. The opposing view is that while mechanism-based ablation is theoretically preferable, EAM has so far not been able to supply the kind of information that can systematically improve ablation outcomes. As a result, the optimal course of action is to pursue an “empirical” ablation strategy: PVI for paroxysmal patients, and the additional ablation of the posterior wall in persistent patients. If arrhythmias recur, they can be best managed with AADs or a redo ablation, which in aggregate can result in “clinical success” rates approaching 80%, where clinical success is defined as arrhythmic symptoms under control, even if the arrhythmia has not been fully terminated.

Legitimate rationales underpin both the “empirical” and “mechanism-based” schools of thought. The empirical proponents are undoubtedly right that, while EAM has enabled many hypotheses about the mechanisms of atrial arrhythmias, the best systematic result has been the PRECEPT trial, which merely replicated the success rate of the empirical posterior wall strategy pursued in the CONVERGE trial. Meanwhile, the mechanism-based advocates point out that empirical ablation strategies, particularly posterior wall ablation, burn much more tissue than necessary, which can cause further complications down the road, including potentially setting off SVTs like atrial tachycardia or atrial flutter.

In our view, Acutus’s mapping technology is in the early stages of taking a giant step in the direction of optimizing mechanism-based ablation. The problem with electro-anatomical mapping is that even the most advanced systems are inherently limited by design: they are contact-based and require multiple touches around the chamber. Each touch records activation data of a small portion of the chamber, and the recordings are stitched together into a mosaic of the overall chamber.

That process is inherently flawed for creating an activation map of complex arrhythmias like persistent AF. Each time an arrhythmic electrical impulse makes its way through the cardiac tissue, it completes a cycle, which has a distinct physical pattern. With contact mapping, it’s likely that the pattern will span more than one catheter touch point and will therefore be represented on the mosaic map by multiple snapshots stitched together. But combining two (usually more) snapshots together to get an accurate picture requires that the activation cycle captured by each one is identical in timing and placement. In an unstable arrhythmia, which almost always characterizes AF, the cycle length will change constantly, as will the start and end times, which are determined in relation to a neutral reference catheter.

The resulting mosaic activation map is a jumble of completely incomparable regional maps that are difficult, often impossible, to interpret. And while arrhythmias are generally spatially stable, that’s not always the case, which can throw another wrench into the mosaic map. The mosaic

map is analogous to a panorama photo of an event composed of disjointed images that were separately photographed over too long an interval, when what's needed is a video recording.

Additionally, though modern 3D contact mapping catheters have multiple electrodes and are designed to touch the endocardium at multiple locations at once, the most precise data will come from the exact locations touched by the electrodes while the data in between is interpolated. Not only does that interpolation exacerbate the already muddled picture assembled from the disparate activation maps, it also results in low (or no) resolution of conduction patterns that are abnormally *small* and have a high proportion of their conduction properties interpolated rather than measured directly.

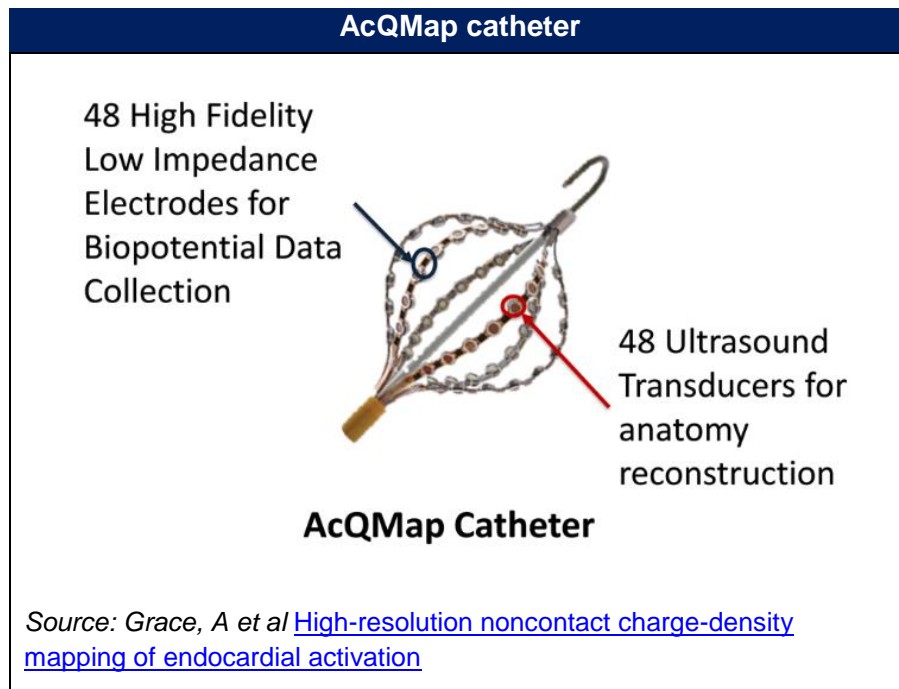
Another issue with contact mapping is the subjectivity of measurement: electrode size, spacing between electrodes, degree of contact with the tissue, and direction of contact with the tissue all impact the voltage measurement, further complicating effective interpretation. On top of all this, consider that after the actual ablation, the chamber is remapped in order to check for conduction blockage, at which point all these problems present themselves again. It's no wonder that as the premier trial showcasing mechanism-based ablation for persistent AF, the results of PRECEPT aren't an especially huge improvement over the just-PVI approach taken in STAR AF II about a decade ago.

Aside from the distorted visualizations produced by contact mapping, maneuvering the mapping catheter through the endocardium to create an informative map takes time and skill. The most skilled EPs can do this in 10-15 minutes, but on average it takes as long as 20-40 minutes. The protracted nature of contact mapping makes iterative remapping within a single procedure impossible, which further compounds the difficulty of identifying arrhythmic triggers. It also makes it impractical to remap and confirm that the ablation achieved the targeted conduction block, particularly in cases of complex arrhythmias that may require ablations in multiple locations.

The limitations of contact mapping also make it incapable of mapping more than one arrhythmia at a time, which makes it ill-suited to help treat SVTs such as atrial flutter or atrial tachycardia. Approximately half of patients with SVTs also have AF, and the presence of multiple arrhythmias can result in either multiple remappings that greatly lengthen procedure times or, more likely, maps that don't clearly delineate the arrhythmias and are thus impossible to correctly interpret and act upon. Complex SVTs can also be difficult to locate with contact maps given their variable locations and transient nature. As a result, EPs will typically forego ablation in favor of low-efficacy AADs or disease "management" to treat these arrhythmias, which leave the patient at greater risk for adverse outcomes over time.

Acutus' AcQMap system, consisting of a catheter, console, and workstation, is designed not only to solve the problems posed by the inherent limitations of contact mapping, but also to advance the field's understanding of the mechanisms of AF. The single-use AcQMap catheter is a *non-contact* mapping catheter that expands into a 25mm sphere formed by six splines (see the depiction below). Each spline has 8 ultrasound transducers interspersed between 8

biopotential electrodes. The transducers measure the distance from the heart's wall and reconstruct the cardiac anatomy, while the electrodes, just like contact electrodes, measure the electric fields in their vicinity.

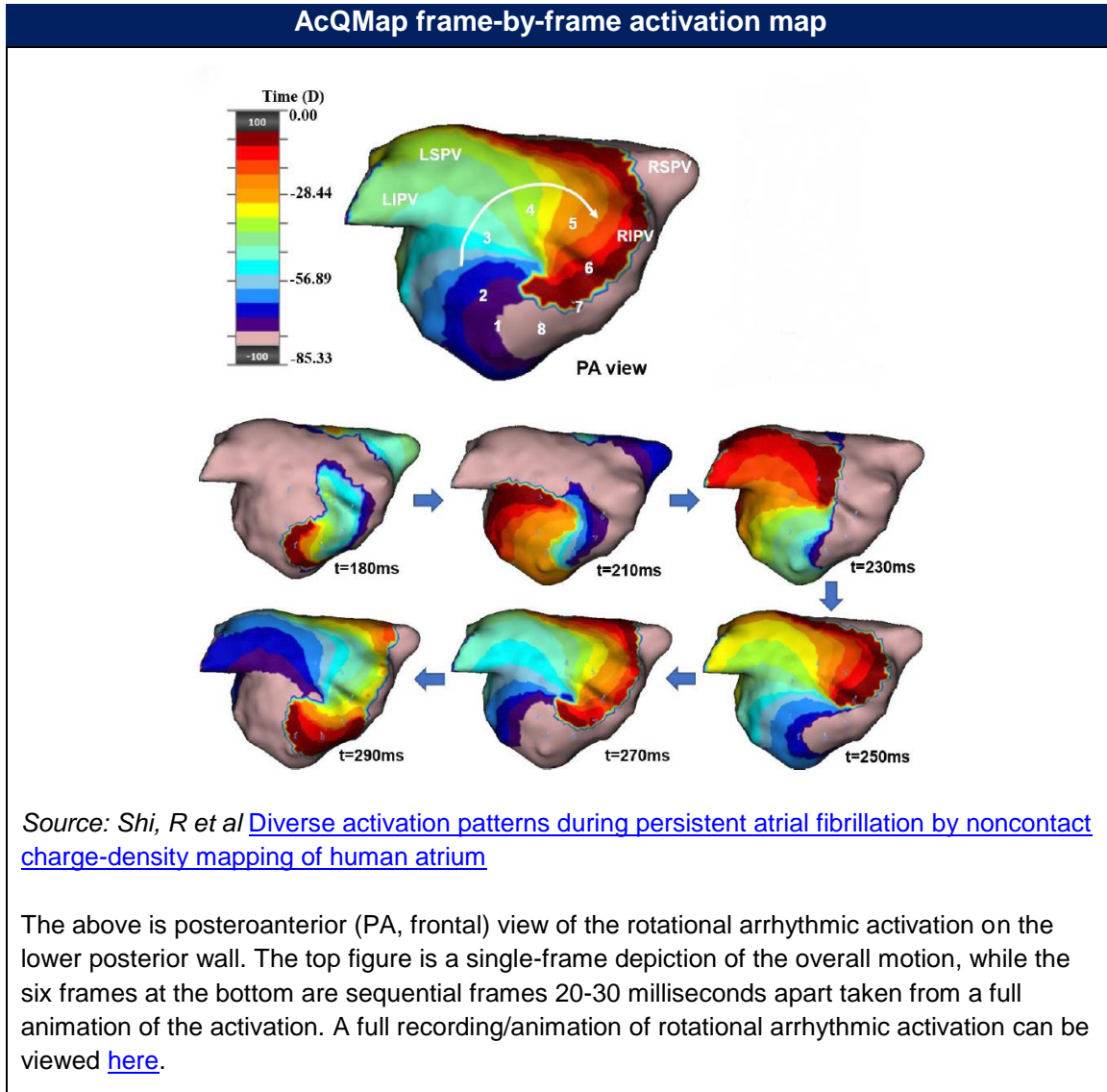


Using the fundamental laws of electrostatics, physicist Gunter Scharf derived a method to infer the charge densities across the endocardium from the electric field measurements of the catheter. Without overcomplicating, “charge densities” are a much smaller unit of electrical activation than “voltage,” which is what’s calculated by contact mapping catheters. The AcQMap activation map denotes the local electric charge at approximately 3,600 discrete sources on the entire chamber’s surface *simultaneously* at a resolution of about 1-2.5mm compared to the approximately 10mm that is standard on the most cutting-edge contact mapping systems.¹⁴ AcQMap records this thousands of times *per second* continuously over the course of multiple heart beats, collecting 9 million biopotential samples per minute to visualize cardiac activation, and 115 thousand ultrasound data points per minute to accurately construct the cardiac anatomy.

In about 3 minutes, the result is not just an activation *map* but an activation *recording* that can play back the entire chamber’s electrical conduction patterns, in ultra-high resolution, beat-by-beat, across multiple heart beats (see below). This is completely different from the product of contact mapping, which is 4-10x lower resolution, only touches the endocardium at a few discrete sources, and can only take snapshots of the chamber one region at a time. The fundamental weaknesses of contact mapping – the clunky combination of maps, the potentially

¹⁴ Biosense Webster claims a 1mm ultra-high resolution for its CARTO 3 mapping catheter, but that’s only at the exact point at which the catheter touches the endocardium, with the radius around that point interpolated.

misleading interpolations, the subjective and inconsistent voltage measurements, and the time-consuming nature of the process – are all obviated with AcQMap. One prominent EP with whom we spoke likened 3D contact maps to a high-definition picture whereas the Acutus map was like “watching a video clip in 4K or 8K.”



Acutus is also continuously improving and adding to the capabilities of the AcQMap system. It has already begun to push out software that will help EPs by *automatically* identifying some predefined arrhythmia patterns. It’s also in the process of improving the AcQMap catheter in ways that would allow it to provide real time data on tissue thickness, which would help EPs titrate the energy they deliver in the course of ablation based on the thickness of the tissue they’re ablating. The more use the system gets, the more feedback Acutus will have in improving it, and our impression from EPs is that the company has been very responsive in rapidly adding product features based on physician feedback.

While there's no question that AcQMap is a step change in activation mapping capabilities, its commercial success depends upon its ability to improve either the ablation process – for example, by speeding it up or simplifying it for the EP – or, much more significantly, the ablation outcome by increasing its effectiveness. As we discuss below, it's already doing both, and more.

IV. AcQMap increases the success rate of ablation while improving the efficiency of the procedure

Early prospective trials show that AcQMap can substantially increase the effectiveness of ablation, which will get even better over time

A year before FDA approval of the first generation AcQMap catheter, Acutus began the [UNCOVER AF](#) trial, a prospective multi-center study designed to assess the safety and effectiveness of ablation for persistent AF when aided by AcQMap. From October 2016 to April 2017, 129 patients suffering persistent AF and who had never previously undergone an ablation procedure were enrolled in the trial, with 121 evaluable at 12 months (8 were lost to follow up or withdrew from the trial). All patients underwent an ablation procedure using an ablation catheter chosen by the physician but guided by the AcQMap mapping catheter. Before the procedures, the physicians participating in the trial were briefly trained to use AcQMap to recognize 3 broadly defined abnormal conduction patterns that were initially identified in early AcQMap feasibility studies. The trial protocols had physicians isolate the PVs and ablate any of these abnormal patterns if, and when, identified.¹⁵

A year after the procedure, 56% of patients were free from all atrial arrhythmias off AADs, and 69% were arrhythmia-free with AADs. In other words, the single-procedure effectiveness was better than that achieved in the PRECEPT trial despite the use of the rudimentary first-generation version of AcQMap, the lack of any prior experience with AcQMap on the part of the EPs participating in the trial, and the use of more advanced contact-force ablation catheters in the PRECEPT trial.¹⁶

Like the PRECEPT trial, UNCOVER allowed for a redo ablation for patients in whom the atrial arrhythmia was not sufficiently under control. Including redo procedures and usage of AADs, 86% of patients were free from all atrial arrhythmias at 12 months, a bit higher than the low-80-percent range reached by the PRECEPT trial's clinical success metric, which also included redo procedures. It's worth noting, though, that in PRECEPT, clinical success was defined by the

¹⁵ Willems, S et al [Targeting Nonpulmonary Vein Sources in Persistent Atrial Fibrillation Identified by Noncontact Charge Density Mapping: UNCOVER AF Trial](#)

¹⁶ While the incremental efficacy enabled by contact force catheters has not been convincingly demonstrated in clinical trials, most EPs are adamant that the technology has increased the effectiveness of their procedures. Additionally, the [TOCCASTAR](#) trial results (Figure 4) strongly suggest that procedural effectiveness is directly proportional to the familiarity of the EP with the mapping system used.

lack of *symptomatic* arrhythmic recurrence, while UNCOVER more rigorously defined this secondary effectiveness endpoint by excluding both symptomatic *and* asymptomatic recurrences.

Beginning at approximately the same time as the UNCOVER trial, a separate independent study led by Timothy Betts and Tom Wong, electrophysiologists at John Radcliffe Hospital in Oxford and Royal Brompton Hospital in London, respectively, was also designed to measure the effectiveness of the first generation of AcQMap. The study was conducted in the two aforementioned institutions and enrolled 40 patients suffering persistent AF who had not previously undergone ablation. The patients in the study were substantially sicker than those enrolled in either UNCOVER or PRECEPT, with 6 suffering from longstanding persistent AF, and a relatively high proportion of them objectively at high risk for stroke and/or suffering from heart failure.

The participating EPs were more adept at using AcQMap than the EPs participating in UNCOVER, and the ablation protocol in the trial beyond PVI was slightly different: instead of requiring just the ablation of abnormal conduction targets that fit the same 3 patterns as in UNCOVER, EPs were required to burn a line from the core ablation target to the nearest “boundary” of the region in which the target was identified, with the aim of more robustly blocking the errant electrical impulse. This was characterized by the study authors as “core to boundary” ablation.¹⁷

The patients were followed by the investigators for two years. The effectiveness results of the study were far superior to the results of UNCOVER. At the end of the first 12 months, *75% of patients were free from any atrial arrhythmia off AADs after just one procedure*. At the end of 24 months, 68% of patients were free from atrial arrhythmia off AADs, also after just one procedure. AcQMap, in combination with greater operator experience and a more rigorous ablation protocol, even in the context of sicker-than-average patients, seems to be able to bring the effectiveness of a single ablation procedure in persistent AF to the same level, or better, as PVI in paroxysmal AF.

While the core-to-boundary study enrollment was small, the leap in both procedural effectiveness and the duration of that effectiveness (for 2 years or longer) are indicative of the potential revolution in ablation that we believe AcQMap can help achieve. There’s good reason to expect that UNCOVER and the core-to-boundary studies are just scratching the surface of what’s possible with the capabilities that AcQMap brings to understanding AF. The current research paradigm on the conduction mechanisms underlying AF is still grounded in theories propounded 100 years ago.¹⁸ The research that followed has never been able to categorically

¹⁷ Shi, R et al [Individualized ablation strategy to treat persistent atrial fibrillation: Core-to-boundary approach guided by charge-density mapping](#). The “boundary” in the study was defined as “the nearest nonconducting boundary such as the PVI lesion set...”

¹⁸ The 2017 HRS consensus on catheter ablation: “All three of these classical mechanisms [of AF] were proposed in the early 20th century and continue to underlie much of the contemporary thinking about AF mechanisms.”

confirm or reject these hypotheses, and beyond PVI, little of this understanding has translated into practical knowledge that can be used in ablation. Even modern 3D electro-anatomic mapping has been unable to advance the field's understanding very much, with the 2017 HRS consensus statement concluding of AF activation that "the specific mechanisms and determinants remain to be elucidated, along with their implications for therapy."

AF researchers with whom we spoke were excited about the potential for AcQMap to break this logjam given its ability to produce a recording of an entire chamber's simultaneous electrical conduction over the course of multiple heartbeats. Some of the initial AcQMap feasibility studies have shown that over a cross section of patients with persistent AF, many do in fact manifest some of the errant conduction patterns that have been theorized in the past, but that those patterns are just a small subset of abnormal conduction patterns observed. Additionally, while abnormal conduction is frequently displayed in the posterior wall, the anterior wall and the septum are also frequently the sites of arrhythmic conduction, which would explain why posterior wall ablation still leaves plenty of persistent AF patients in the lurch. Perhaps more intriguing is the fact that different patients can exhibit different patterns, while some patients can exhibit more than one pattern. Thus, initial studies using Acutus technology have been able to more precisely characterize and quantify conduction phenomena that have been, at best, difficult to evaluate in the past.

But AcQMap can go further and detect patterns that have simply never been proposed before because past research has been limited by the tradeoff between resolution, simultaneity, and chamber-wide perspective. Current research enabled by AcQMap is focused on building a rigorous taxonomy of AF conduction focused on both patterns and properties of that conduction. The latter include not just the amplitude of electrical activation at different locations in the atria, but also the velocity of conduction, the contiguousness of the patterns, and the physical breadth of activation. Relating these properties to each other, and then with the array of different conduction patterns that are displayed in persistent AF, can begin to answer questions that have always been out of reach: what kinds of conduction patterns should be ablated, and how? What combination of factors is associated with progression of AF? Is there a relationship between the patterns and properties of AF conduction and patient prognosis?

This taxonomy of patterns and properties of conduction can then be related to bio-anatomical properties such as tissue composition and cardiac fibrosis. Eventually, this information would be related to molecular and genetic markers that could result in prophylactic interventions. But all of this can only be done with a rigorous and robust characterization of the actual mechanisms of conduction, which is simply impossible with even the most cutting-edge contact mapping technology.

Acutus is in the very early days of amassing this data. More ablation procedures conducted with AcQMap, and more data collected by Acutus, will eventually allow AcQMap the capability to incorporate algorithms into its software that can ably guide EPs in their ablation. With the newfound capacity to collect orders of magnitude more information than legacy contact mapping

systems, we expect Acutus will be in the pole position to capitalize on a new era of mechanism-based ablation.

Aside from improved results, electrophysiologists report a variety of procedural improvements enabled by AcQMap

The potential for AcQMap to revolutionize the understanding and treatment of AF is compelling. But a central theme of our wide-ranging conversations with dozens of electrophysiologists was the seemingly more prosaic ability of AcQMap to improve the efficiency and workflow of their ablation procedures. The process improvements most often cited by physicians were mapping speed and informative visualization, which changed the way they treat complex arrhythmias.

An activation map of the atrial chamber with a contact mapping catheter takes about 10-15 minutes for a highly skilled EP to construct, and 20-40 minutes for a more typical physician. Contact mapping also requires a certain level of strategic planning to determine the ideal catheter touch points, and physical dexterity to be able to get the catheter to touch the endocardium at those points. AcQMap requires neither the skill and effort, nor the time, that contact mapping does. The catheter is inserted into the chamber and moved around without touching any tissue at all, and in just 3 minutes results in a chamber-wide anatomical map and a high-resolution recording of cardiac activation that's superior to a contact map. This allows the average EP to access a quality map that has historically only been accessible to the top echelon of practitioners.

Another advantage of rapid mapping we heard about often is that it allows for multiple remappings in the same procedure. An EP can ablate, and then *immediately* assess the impact of the ablation on the arrhythmic conduction. That might be possible once or twice with contact mapping, and only in the hands of a more skilled EP, but several prominent high-volume EPs told us that AcQMap has allowed them to remap six or seven times in just one procedure, which has helped them treat complex arrhythmic circuits in an iterative and patient-specific way that would have been impossible without AcQMap. In complex cases of atrial flutter, for example, the location of the arrhythmia can migrate intra-procedure as a consequence of ablation, and AcQMap allows for remapping within a minute whereas a contact map would require a whole new set of touches.

Some of the more prominent EPs with whom we spoke explained that a difficult case of flutter or tachycardia could take hours to track down and ablate using contact mapping, but could be achieved in less than an hour, and sometimes even less than 30 minutes, using AcQMap. The shortened procedure times also reduce complication rates, enhancing the safety of the procedure.

The *quality* of the AcQMap visualization was also a pervasive theme in our discussions with EPs. It was widely agreed upon that complex arrhythmias like persistent AF and atrial tachycardias simply cannot be accurately visualized by even the most advanced contact mapping systems. That's certainly not the impression one gets from the clinical literature or the

sales reps at Biosense Webster. EPs who were high-volume AcQMap users agreed that the high-resolution activation recording allows for better results in complex arrhythmias because the conduction patterns are just much clearer and more identifiable.

Several EPs observed that PVI is the kind of relatively simple procedure in which AcQMap resolution is overkill, but that in redo ablations and persistent AF, AcQMap can be indispensable. In redo cases, for example, EPs explained that prior ablation can frequently create scar tissue that makes arrhythmic conduction even harder to identify, and AcQMap's visualization avoids that problem. Redo cases that are performed after PVI can also leave an EP with the difficult puzzle of where to even begin looking for errant conduction if the PVs are properly isolated, and AcQMap rapidly points the physician to the appropriate site.

Several EPs explained that the ease, rapidity, and quality of the mapping is a crucial advantage in the context of the increasing pervasiveness of cryoablation. Cryo has made it possible for less skilled EPs to perform PVIs, but it doesn't solve for the difficulty of contact mapping. For the initial PVI, high-resolution contact mapping is not a necessity. But the PVI itself frequently results in scarring that causes other SVTs, which require detailed activation maps to ablate. When patients come back to ablate these, AcQMap allows the EP to rapidly and accurately find and ablate the arrhythmia without requiring a high degree of skill. EPs trained on cryo are unlikely to have the handling skills necessary to maneuver a contact mapping catheter with the dexterity it requires, and so AcQMap can be crucial to the success of their redo procedures.

In persistent AF, like in redo cases after an initial PVI, AcQMap is an effective guide for where in the chamber to focus. As one physician explained to us, an EP treating persistent AF knows they need to do more than a PVI. "There's always a desire to burn off more [tissue], and Acutus can cater to that desire by really pointing to what should be further ablated." Too much ablation will result in unnecessary lesions that can lead to atrial flutter, and AcQMap can help avoid those.

Aside from procedural improvements, several EPs explained that as the older generation of practitioners retires, younger practitioners will be much more apt to want to only work off the highest possible resolution activation maps, and no one can provide that like Acutus. Acutus has also endeared itself to the so-far niche segment of the EP community that has adopted AcQMap by being nimble and responsive to their requests: the second generation AcQMap is a huge improvement over the first in both its capabilities as well as its physical build, mostly because the company has been willing to rapidly incorporate physician feedback into their engineering process.

In sum, the feedback we received from practitioners with first-hand knowledge of AcQMap did more than confirm the impressive ablation effectiveness AcQMap enabled in the clinical literature. It also impressed upon us that AcQMap's successful commercialization will be significantly enhanced by its ability to improve physician workflow and procedural efficiency, and respond to physician feedback in ways that legacy med-tech companies cannot.

V. Acutus will be a major player in the massive catheter ablation market, which is rapidly growing at an accelerating rate

Acutus: Capitalization and Financial Results					
Capitalization		Financial Results			
Share price (\$)	\$ 13.44	2019	2020	TTM	2021E 2022E
Fully diluted shares (mm):		Revenue	\$ 3	\$ 9	\$ 14 \$ 26 \$ 76
Shares outstanding	34.4				
Dilutive impact of options/RSUs	1.2				
Total	35.6				
Fully diluted market cap (mm)	\$ 479				
Debt	46				
Less: cash	164				
Enterprise value	\$ 360				
EV/revenue (trailing)	25.8x				
EV/NTM Revenue	6.7x				

Source: company filings, Kerrisdale estimates and analysis

We estimate that approximately 350-400 thousand atrial ablation procedures will be performed in the US in the current calendar year, and approximately the same number in Europe.¹⁹ The per-procedure cost of disposable products is approximately \$3-10 thousand in the US and a bit lower in Europe, resulting in a total developed ablation market size of approximately \$5-6 billion.

Based on Medicare and European ablation registry data, we believe that the *current* Acutus product line addresses approximately 60-70% of procedures in the US and almost 100% of procedures in Europe. In the US, the addressable procedures include initial ablation on patients with persistent AF, redos after a failed PVI, and cases of other atrial arrhythmias such as tachycardia and flutter (i.e., supraventricular tachycardia). Acutus's opportunity is about 75% of the disposables in each of these procedures, primarily the AcQMap mapping catheter, but also sheaths, transseptal access devices, and other minor tools. That puts the US addressable market for Acutus at about \$1-1.5 billion. In Europe, where Acutus's AcQBlate contact force ablation catheter is approved for use, Acutus products can address 100% of the disposables

¹⁹ Our estimate for the size of the US ablation market is based on the combination of Medicare utilization data for 2018 (the latest year available) as well as commentary on market size and growth from major participants, including J&J's Biosense Webster, Abbott, Boston Scientific, and Medtronic. Our estimate for the size of the European market is based on data from the [European Heart Rhythm Association](#), including its 2017 [white book](#), which includes ablation statistics for 2017, and growth rates reported by the major electrophysiology companies.

consumed in each ablation procedure, putting the total addressable market in Europe at about \$2-2.5 billion. In total, we estimate Acutus's current TAM to be in the \$3-4 billion range, with the lack of an ablation catheter line in the US the only major gap in its product portfolio.

But that gap will soon be filled. Acutus recently began enrolling patients in an IDE trial in the US that is designed to verify the safety of its AcQBlate contact-force catheter. Given the full CE-mark approval the device already secured in Europe at the end of last year, we expect full device approval by the end of 2022, or early 2023 at the latest. At that point, not only will the entire ablation disposables market become fair game for Acutus, but we expect that market share gains will accelerate with the shift to a comprehensive atrial ablation product line in which the components are all seamlessly compatible with each other.

If that weren't enough, Acutus is also in the process of developing its own in-house pulsed field ablation (PFA) technology. We have discussed PFA [previously](#) as another game-changing technology in the field of ablation, which will allow extremely rapid and safe ablation through the power of electroporation rather than either RF or cryo, which are the standard energy modalities used to ablate cardiac tissue. Underdiscussed has been how the current PFA startups have focused on so-called "one-shot" catheter ablation to execute PVIs. Like cryo catheters, none of the PFA catheters currently being trialed are specifically designed for non-PVI ablation. But Acutus's PFA research program has been honing its AcQBlate contact force catheter to also deliver pulsed field energy. AcQBlate is already designed to deliver RF energy to non-PVI arrhythmic triggers, and Acutus has been optimizing its pulsed field generator as well as the various pulsed field parameters (waveform, electric field magnitude, and applied voltage) to reengineer AcQBlate as a non-PV-focused PFA catheter as well.

Acutus has recently said that it expects first-in-man studies of its PFA technology later this year, and the enrollment of an IDE trial next year. Acutus's focus on PFA technology within the specific context of persistent AF ablation would put it in the unique position of having not just the most complete ablation product line focused on complex arrhythmias, but also by far the most technologically advanced. Consider that Farapulse, one of the PFA startups focused on one-shot PFA, was recently acquired by Boston Scientific at a valuation of about \$800 million without having yet generated a dollar of commercial revenue. Acutus's PFA program, if successful, would be synergistically combined with the only mapping catheter capable of advanced diagnostics of complex arrhythmias. Its ability to capture share within the booming catheter ablation market would be materially enhanced.

The number of ablation procedures in that market has been growing rapidly, doubling over the last five years. We expect that the mid-teens growth rate of ablations will accelerate over the next five years. First, new technologies, including AcQMap but also the commercialization of pulsed field ablation (PFA), will help reduce the current procedure times of atrial ablations substantially. AcQMap, for example, has already been used to cut down by hours the ablation times of difficult-to-isolate atrial arrhythmias, and has shown that mapping time for persistent AF

procedures can be reduced to just 3-5 minutes from 15-60 minutes using contact mapping modalities. PFA will allow EPs to blast targeted tissue in minutes rather than the 1-2 hours that is currently standard in complex ablation procedures. The shortened procedure times and increased safety enabled by new technology will allow for a much larger number of procedures to make their way through EP labs.

Meanwhile, just as the bottleneck on ablation procedures will be lifted by new technology, the demand for these procedures is set to accelerate. The ability to clearly visualize and safely and easily target difficult arrhythmias will mean that EPs more often refer patients for ablation, particularly those they may have hesitated to refer in the past due to the underwhelming odds of success in persistent AF or intractable SVTs. As AcQMap increases those odds, procedure growth will accelerate.

If recent data is any indication, referrals for ablation will also increase as evidence continues to build in support of earlier and more frequent ablation. One recent [study](#) suggested that patients suffering paroxysmal AF who are treated with AADs are about ten times more likely to progress to persistent and longstanding persistent AF than paroxysmal patients undergoing ablation. Another set of studies showed that ablation is [two thirds more effective](#) than AADs at eliminating AF recurrence in paroxysmal patients, and [twice as effective](#) in persistent patients. The various studies, all discussed at the [AF Symposium](#) earlier this year, are encouraging many prominent EPs to begin considering ablation as an option earlier in the course of disease, and in the case of persistent AF, much more frequently than has been the case prior. Of course, given the current length and intensity of an ablation procedure, it will be hard to grow the number of ablations much more than 15-20% annually, but technologies like AcQMap and PFA will enable an acceleration of that pace, both by increasing EP lab capacity *and* stimulating demand.

We expect the number of atrial ablation procedures in the developed markets of the US and Europe to grow at more than 20% annually through 2026 reaching approximately \$15 billion. Given Acutus's game-changing technology, we expect that it will be able to reach 10% of the overall market, though attaining much higher share in the not-so-niche subsegments comprised of persistent AF and supraventricular arrhythmias. Its share will be even higher if, as we expect, it introduces an effective PFA catheter by then. At any reasonable valuation, the value of Acutus at that point will be many multiples of the company's current \$480 million market capitalization.

The sales growth deceleration at Acutus in early 2021 was a result of temporary problems that are already in the process of reversing

Acutus came public at a valuation of \$500 million in August of 2020, with the high hopes for its unique technology quickly bringing that to almost \$1 billion. But in the process of ramping up its initial commercialization efforts, the company's sales momentum began to stall at the end of last year, culminating in a guidance reset earlier this year from which the stock has not yet

recovered. Based on extensive conversations with EPs and hospital procurement managers, we believe Acutus's stumbles stem from a temporary but unlucky combination of pandemic-driven purchasing and training hurdles, excessively broad early sales targeting, and a strategically misguided initial marketing message from which Acutus has since successfully pivoted.

One mistake Acutus made early on in its commercialization efforts was to take a shotgun approach and get its system hardware installed in as many high-volume electrophysiology centers as possible. The thinking was that AcQMap was so good, system installations would be inexorably followed by increasing utilization of AcQMap in ablation procedures. But that's not what happened. Instead, at many labs, utilization dropped to almost nothing after the first few procedures. Partly, this was due to inadequate initial physician training on the part of Acutus, which was itself very much driven by the logistical difficulty of setting up training centers, inviting EPs to Acutus's central training facilities, or providing on-premises close-contact training *in the middle of a raging pandemic*. Another issue was that Acutus reps didn't discriminate in their push to rack up system installs, and many centers that were philosophically oriented towards empirical ablation methods ended up with an AcQMap system that's a lot less useful for EPs who know exactly which tissue they're going to ablate even before they insert their catheters.

Marketing in the first year of AcQMap's commercialization was also a factor in subpar utilization. Acutus's strategy was to focus on the "holy grail" aspects of AcQMap, namely the ability of the EP to use the technology to find the triggers of AF in complex cases and subsequently ablate them. While it's true that AcQMap has proven its ability to increase the effectiveness of an ablation procedure, there were two problems with the marketing approach. The first was, again, training: the pandemic made it difficult for Acutus to adequately train EPs to exploit AcQMap's advanced capabilities to improve procedural outcomes.

More importantly, though, is that EPs have been subjected to numerous new technologies over the last decade with the promise of finally finding the physical sources of AF. The most spectacular of these failures was Topera, which originally promised that it could map the entire atrial chamber simultaneously over multiple heart beats in real time, which sounds a lot like what AcQMap does. A year and a half after Abbott acquired Topera for \$250 million in late 2014, a controversial RCT was published that showed that Topera's mapping catheter could not demonstrate improved outcomes in persistent AF patients. Never mind that Topera's mapping catheter was an extremely low resolution contact mapping system that relied on extremely questionable algorithms to identify non-PV triggers. The Topera experience, and other less memorable failures, have taught EPs to be skeptical of any technology that claims to be able to identify the sources of AF.

All of the above obstacles – lack of rigorous physician training, overly broad sales focus, and misguided marketing – have been resolved by Acutus over the last few months. As the pandemic has ebbed, the logistical restrictions on training have fallen and, at the same time, Acutus's new Chief Commercial Officer – Duane Wilder – has both expanded the training regimen and bulked up the training and mapping staff to assist physicians in making the workflow and procedural changes that are entailed in the adoption of AcQMap. The new training

program also involves Acutus's training staff doing on-site training during live procedures to aid physicians in understanding how and when to use all the capabilities that AcQMap can bring to their practice.

Wilder, at the direction of CEO Vince Burgess, has also scaled back the aggressive focus on system installs, instead emphasizing installations at EP labs that are comfortable with mechanism-based ablation approaches and are eager to adopt new technologies that can improve their outcomes. The new sales approach is centered on ramping up utilization once the system is installed rather than assuming that installs equal success. Finally, Acutus has been subtly altering its marketing to focus on the capabilities of AcQMap and the ways in which it can improve not just procedural effectiveness, but also procedural workflow, safety, and efficiency. We've spoken with several prominent EPs that are jaded with the claims they've heard over the years of finding the physical sources of AF, but also use AcQMap in all of their redos and complex arrhythmia ablations because there's no other tool that lets them survey the activation landscape of the atria like AcQMap does. There's a subtle, but we believe critical, distinction between claiming to have solved the problem and claiming to provide the tools that can help solve the problem, and this distinction is particularly important in marketing to EPs given the recent history of the field.

It's also worth pointing out that aside from the obvious difficulties the pandemic posed for training, sales, and procedural volume, there was also a significant impact on hospital procurement policies. In the words of one hospital official with whom we spoke, "hospitals have been looking to increase their capacity, not their capabilities" during the pandemic. At least in its adoption phase, AcQMap is a new system that requires time to learn and adjust, and hospitals were not interested in new technology adoption in the context of the chaotic effect the pandemic has had on their business and workflow. That has mostly run its course by now, and we expect that the barriers to new adoption will have fallen completely over the next few months.

While Acutus's sales efforts hit a wall earlier this year, we believe that the problem was temporary with disproportionate effects given the early stage of the company's commercialization efforts. We also think that the problems have either abated or have been largely corrected, and that Wall Street's expectations seem overly pessimistic for the next few quarters.

VI. Conclusion

AF remains difficult to treat primarily because surprisingly little progress has been made in understanding the dysregulated electrical conduction that characterizes it. Even more than 20 years after the first significant advances were made in treating AF with ablation, the properties and patterns of the abnormal conduction are not even close to being rigorously distilled. The long term promise of Acutus lies in solving the still mysterious problem of arrhythmic conduction. In the near term, though, Acutus has shown that even without necessarily "solving" AF, its novel

non-contact mapping technology can change the ablation paradigm – dramatically increasing procedural effectiveness, and making the procedure faster, simpler, and more efficient for its practitioners.

Despite operating in a multi-billion dollar market growing at high double digit rates, Acutus trades at about 8x the next twelve months' consensus revenue estimates, and at just 5x our 2022 estimate of \$76 million in revenues, a valuation on par with mega-cap medical device companies like Boston Scientific and Medtronic, and a steep discount to more rapidly growing upstarts. Atricure, the only other public company exclusively dedicated to ablation devices, trades at more than 11x consensus estimates for its 2022 revenues despite the fact that its surgical ablation end markets are growing much more slowly than the catheter ablation market, and its core products are existentially threatened by catheter ablation advances. At Atricure's valuation, Acutus shares would be worth \$28, more than double their current price, and still offer the prospect of multiplying several times over as AcQMap becomes the standard of care in complex arrhythmias. Acutus's singularly unique offering in the context of its \$480 million market cap presents an investment opportunity that can aptly be described as electric.

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