Executive Summary

Electrophysiology: Key Metrics in 10 Major Markets

<table>
<thead>
<tr>
<th>Metric</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial flutter (AFL) prevalence</td>
<td>484,893</td>
</tr>
<tr>
<td>Wolff-Parkinson-White syndrome (WPW) prevalence</td>
<td>747,645</td>
</tr>
<tr>
<td>Ventricular tachycardia (VT) prevalence</td>
<td>1,160,995</td>
</tr>
<tr>
<td>Atrioventricular nodal reentrant tachycardia (AVNRT) prevalence</td>
<td>581,947</td>
</tr>
<tr>
<td>Paroxysmal atrial fibrillation (AF) prevalence</td>
<td>4,846,580</td>
</tr>
<tr>
<td>Persistent AF prevalence</td>
<td>1,788,848</td>
</tr>
<tr>
<td>Permanent AF, 2013</td>
<td>2,662,267</td>
</tr>
</tbody>
</table>

Global Electrophysiology Market Revenue, 2013

<table>
<thead>
<tr>
<th>Region</th>
<th>Revenue (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$552m</td>
</tr>
<tr>
<td>5EU</td>
<td>$515m</td>
</tr>
<tr>
<td>APAC</td>
<td>$472m</td>
</tr>
<tr>
<td>South America</td>
<td>$21m</td>
</tr>
</tbody>
</table>

Global Market Revenue by Device Type, 2013

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Revenue (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard diagnostic catheters</td>
<td>$425m</td>
</tr>
<tr>
<td>Advanced diagnostic catheters</td>
<td>$327m</td>
</tr>
<tr>
<td>Standard ablation catheters</td>
<td>$383m</td>
</tr>
<tr>
<td>Advanced ablation catheters</td>
<td>$251m</td>
</tr>
<tr>
<td>Lab systems</td>
<td>$173m</td>
</tr>
</tbody>
</table>

Global Events Affecting the EP Market

<table>
<thead>
<tr>
<th>Event</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE mark approval of AFlx medical ablation catheter in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>510(k) approval of Apama Medical’s ablation catheter in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>510(k) approval of Imricor Vision MR ablation catheter in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>510(k), CE mark and Ninsho approval of Boston Scientific Lesion Assessment Device in 2014</td>
<td>↑↑</td>
</tr>
<tr>
<td>510(k) approval of Imricor Horizon MR recording system in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>CE mark approval of Hansen Medical and Philips Healthcare integrated X-ray and robotic systems in 2015</td>
<td>↑↑</td>
</tr>
<tr>
<td>CE mark approval of SCR lab system in 2015</td>
<td>↑</td>
</tr>
</tbody>
</table>

Forecast Global Revenue by Device Type, 2020

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Revenue (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard diagnostic catheters</td>
<td>$2,493m</td>
</tr>
<tr>
<td>Advanced diagnostic catheters</td>
<td>$1,223m</td>
</tr>
<tr>
<td>Standard ablation catheters</td>
<td>$575m</td>
</tr>
<tr>
<td>Advanced ablation catheters</td>
<td>$460m</td>
</tr>
<tr>
<td>Lab systems</td>
<td>$282m</td>
</tr>
</tbody>
</table>

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK; 10MM = US, France, Germany, Italy, Spain, UK, Japan, China, India, and Brazil; APAC = Asia-Pacific; CE mark = European Conformity; EP = electrophysiology

Electrophysiology Diagnostic and Ablation Technology to Experience Significant Adoption Through 2020

Revenue from the global electrophysiology (EP) market, consisting of ablation catheters, diagnostic catheters, and lab systems, is forecast to increase at a Compound Annual Growth Rate (CAGR) of 9.5% from $1,560m in 2013 to over $2,939 by 2020. This noteworthy market growth will come about as a result of an increasing incidence of arrhythmia, with rising market penetration of diagnostic and ablation catheters in the Asia-Pacific (APAC) and South American regions. Centers supporting ablation are increasingly desirable as the global occurrence of cardiac dyssynchrony continues to rise; it is estimated that roughly 1% of the global population suffers from an irregular heartbeat, although pervasiveness rises to over 20% in elderly people (WHO, 2013). While atrial fibrillation (AF) and ventricular fibrillation (VF) are the most common indications for treatment, heart failure, diabetes, and obesity can all contribute to ongoing rhythm management concerns.

The extremely competitive EP market is dominated by several key players who must continue to innovate in the face of mounting pricing pressure and strict regulation, as new entrants battle to gain market share. Up-and-coming technologies in development, including alternative forms of energy such as cryo-, ultrasound-, and laser-ablation, as well as mapping and navigation technologies,
promise to heighten product sales and new account openings, while industry standards continue to develop in regard to ablation strategies for treatment, improving outcomes. Ongoing clinical studies investigating the applicability and appropriateness of varying ablation modalities are expected to further clarify suitable device indications and therapy best practices, while advances in diagnostics as well as adjunctive therapy will ensure improved patient outcomes and lower rates of arrhythmia recurrence.

Key Drivers during the Forecast Period

- Growing incidence of arrhythmia and heart failure.
- Heightened adoption rates in emerging markets.
- New advancements in alternative energy ablation strategies.
- Increased emphasis on early intervention and ablation.
- Strong EP program adoption in hospitals worldwide for new account openings.

Key Barriers during the Forecast Period

- Ever-intensifying EP market competition with limited innovation on the horizon.
- Lacking number of electrophysiologists who can perform ablation, especially using advanced ablation catheters.

Advanced Diagnostic and Ablation Catheter Use on the Rise as New Devices Are Approved

With improvements in reimbursement, training, and physician adoption, the EP market will see continued revenue growth, driven by an increased use of more expensive advanced catheters for diagnostics and ablation. These next-generation devices, offering improved outcomes, generate more revenue for manufacturers, but they are harder to use, and require additional physician as well as hospital staff training, and are not always reimbursed. Depending on the availability of training resources provided by the manufacturer, distributor, hospital, or academic societies, physicians also may or may not gain experience.

![Electrophysiology Market, Global, Revenue ($m), 2012–2020](chart.png)

Source: GlobalData; Interviews with industry experts and key opinion leaders (KOLs).
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with these newer devices. Many physicians do not have an opportunity to try new devices, either because of price barriers or a lack of access to the products. As distribution increases, training improves, and physician awareness grows, GlobalData expects advanced catheter product sales to drive EP market revenue. Currently, advanced catheters are used in only a minority of procedures, but GlobalData expects a shift in this trend, with an increase in advanced catheter use and a leveling out of standard catheter use.

Significant Growth in Target Population

- The population requiring EP diagnosis and therapy continues to grow due to an increasing prevalence of serious risk factors including obesity, diabetes, hypertension, and congestive heart failure (CHF). According to a 2013 briefing published by the World Health Organization (WHO), over 1 billion people suffer from hypertension worldwide, which is a major cause of CHF, a condition common in over 25 million people (WHO, 2013). Similarly, the International Diabetes Federation (IDF) states an estimated 285 million people had diabetes in 2010, which is expected to increase to 438 million by 2030 (IDF, 2013). Additionally, the global obesity population is increasing at a rapid, uncontrolled rate. Lifestyle factors including tobacco, alcohol, and caffeine intake can also greatly increase the risk of arrhythmias.

- With limited pharmacotherapy to treat dyssynchrony, EP devices are expected to remain the go-to option for patients with rhythm management concerns.

Emerging Market Adoption to Increase Sales

- As the US and European Union (EU) markets reach a point of maturation, companies are forced to turn to emerging markets for revenue growth. In particular, Japan has experienced significant EP adoption in the past 10 years and more recently, China, Brazil, and India have initiated many new programs. These emerging markets offer significant potential for companies that are able to establish distribution channels in these regions; however, lacking reimbursement and low costs of living will provide intense pricing pressure for market entrants. With limited financial resources available, current devices are largely unaffordable in these developing countries, and significant price reductions are expected in
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the coming years as manufacturing operations improve and distribution becomes more global.

- In response to significant cost-concerns, many companies are developing value-tier platforms, and are looking to offer both standard and advanced catheter products. As physician use and adoption continues to increase in these regions, significant market expansion is expected.

Improved Mapping Systems to Drive Ablation Volumes

As next-generation mapping and navigation systems emerge, promising better diagnosis and improved ablation accuracy, catheter enabled intervention volumes are expected to increase. Currently, physician experience and skill can be a limiting factor in EP diagnosis and ablation, especially in patients with an arrhythmia that is difficult to treat. Doctors must know where the catheter tip is during the entire procedure, but with limited information in terms of heart anatomy and device position, this can be difficult. As advanced lab systems are commercialized and approved, such as the Carto 3, physicians will have a greater ability to perform both easy and difficult diagnostic and ablation procedures, with faster procedure times, improved accuracy, and better outcomes. Several lab systems in development, in particular, the integrated X-ray system with a robotic catheter being developed by Hansen Medical and Philips, could add great value to hospitals EP labs, and are expected to drive procedural volumes.

Lack of Clear Answer to Inhibit Adoption

While EP diagnosis and ablation has greatly improved over the last 15 years, much is still unknown about arrhythmia such as how it progresses, and where it originates in various patients. What is now widely understood is that there is a much greater complexity than originally thought, and that despite significant advances in treatment strategies including lesion targeting and focused ablation, the recurrence of cardiac dyssynchrony is still common, and complications still also arise. Moreover, there are limited efforts in terms of establishing registries on an international basis, and the EP field is still very much in its infancy. Guidelines will improve and best-practices will advance as researchers learn more about the cause of arrhythmia, which will be accelerated by technological improvements in lab systems as well as carefully conducted clinical trials. However, with many questions still unanswered, presently performed complex ablations can often be ineffective, and until more is learned about cardiac dyssynchrony, this lack of efficacy is not expected to change.
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Advantages of Ablation over Implantation of a Cardioverter Defibrillator

While EP has historically been a smaller market than cardiac rhythm management (CRM) devices which include pacemakers and implantable cardioverter-defibrillators (ICDs), the EP market is seeing a noticeable increase in revenue as physicians increasingly look to utilize ablation over device implantation. In general, antiarrhythmic drugs (AADs) were the first-line treatment for arrhythmia, but with failing pharmacotherapy and lacking alternatives, device use and implantation is the next go-to option. Previously, there had been increased emphasis on implanting a device, partly because of the development of various technologies, but also based on patient, physician, and hospital preference; hospitals can make more money by implanting a device.

Limited Manufacturer’s Support as Cost-Saving Measures Reduce Compensated Services

Currently, vendors provide support staff for their hospital customers; individuals who know their products well can help physicians to use the products while providing on-site consultation and advice for EP practices. As of now, many of these services are provided free of charge in an effort for vendors to establish strong relationships with hospitals while keeping a representative in the hospital to provide support. These skilled individuals are trained and paid for by the vendor, and allow for a faster integration of new systems at hospitals, including physician and support staff training time, as well as an allotment of resources to support new lab devices. As hospitals and purchasing groups put increased pressure on vendors in terms of pricing, it is expected that some of these compensations will decrease or disappear entirely, as vendors will need to cut services and programs in order to stay profitable. Without this support staff, it is unclear what hospitals will have to do in order to manage their device use and training.

Electrophysiology Market by Country (%), 2013

Source: GlobalData
Executive Summary

**What Do Physicians Think?**

The EP industry has been slow to take off, especially compared with the implantable CRM device industry. As a result, EP has significant catching up to do in terms of revenue. That said, the EP market has been growing quickly, faster than the rate of growth for implantable CRM devices.

“EP ablation is the largest growing sector [within cardiac rhythm management]; faster growing than ICDs, pacemakers, and CRT [cardiac resynchronization therapy].”

*Key Opinion Leader*

Despite slower growth than the CRM market, EP device sales continue to increase and competition in the EP market is on the rise globally. As more manufacturers commercialize catheter and lab system products, operations become increasingly global and emerging markets drive sales. Competition is only expected to increase in the currently underpenetrated EP market worldwide, which offers significant opportunity for growth.

“The competition in EP diagnostic and ablation is huge; it’s a very wide-open market.”

*Key Opinion Leader*

Guidelines and best-practices are slowly evolving in favor of device use, with less emphasis on AADs and other pharmaceuticals. Limited clinical evidence of efficacy, combined with high costs and compliance issues, has reduced drug treatment popularity, especially with the introduction of next-generation ablation systems that promise improved patient outcomes.

“It used to be about the drugs until everybody realized that drugs don’t do much at all, especially if you have a serious arrhythmia problem. Drugs are general are pretty gross in their attack on arrhythmias. As EP began to specialize, from the 1990s when RF [radio frequency] ablation came into its own, the EP field began to take off.”

*Key Opinion Leader*

While the EP field has been slow to grow, it has been successful as a whole and has generated significant revenue for hospitals. Compared with other practices in cardiology, EP ablation has lower rates of complication and procedures can often greatly improve patient quality of life (QOL) and life expectancy. In terms of success rates and revenue generated from strong reimbursement, EP practices have generally done well, and this success is expected to drive procedural volume.

“If you look backwards from where we are today, electrophysiologists are the most successful cardiologists in the hospital.”

*Key Opinion Leader*
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While advancements in best practices have improved patient outcomes, physician skill can frequently still be a limiting factor, especially for complex ablations using advanced catheter systems. As next-generation devices emerge that offer robotic assistance and steerability improvements, physician ability will matter less, and patient outcomes will improve.

“It's clear that not every physician has gifted dexterity. Sometimes the smartest guys don’t have the best hands. And one of the things that is really clear about the dotting technology is that you have to be incredibly talented to do it. So, there is a large group of physicians that are not up to that task”

Key Opinion Leader

Despite advances in technology and practice, many barriers still remain, and even the best technology can see slow adoption if physicians are not willing to change their practices.

“Most physicians have confidence in what they are currently doing, and it's hard to change that behavior.”

Key Opinion Leader
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Introduction

2 Introduction

2.1 Catalyst

Still in its infancy, the electrophysiology (EP) device market has seen significant adoption; as more physicians become experienced in diagnostic and ablation techniques, increasing numbers of hospitals purchase supportive equipment, device price-points fall, and efficacy improves. This continued growth is also driven by technological advancements including the emergence of next-generation ablation technologies, improvements in catheter diagnostics, and advancements in lab systems. Further, as imaging modalities improve, patients are exposed to less radiation than ever before, which will only further drive diagnostics. Growth in emerging markets is also expected to drive sales as developing countries look to implement new EP programs, and hospitals adopt ablation techniques. Lastly, published studies, clinical evidence, and patient awareness will all contribute positively to EP market growth and will provide further evidence of the effectiveness of cardiac catheter ablation.

The EP market is dominated by several key players, with the biggest markets being in the US and European Union (EU). With improvements in reimbursement worldwide, as well as advancements of global distribution channels, devices are being sold in more hospitals and ever, and this is only expected to increase. With only a few key players currently in the market, competition remains high as industry leaders fight for valuable market share.

2.2 Related Reports

- MediPoint: Cardiac Rhythm Management Global Analysis and Market Forecasts, November, 2013, GDME0180MAR
- MediPoint: Cardiac Assist Devices Global Analysis and Market Forecasts, March, 2013, GDME0175MAR
# Appendix

## 11.6 About MediPoint

MediPoint is the flagship product for GlobalData’s Medical team. Each MediPoint report is built from the ground-up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading key opinion leaders (KOLs). Running throughout each report in the series, “What Do Physicians Think” quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

## 11.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in medical device research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India, and Singapore.

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