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Service Lifecycle Management for Medical Devices

The Strategic Role of Service

Executive Overview

Ask an outsider about what makes servicing medical devices challenging. They will probably tell you that—beyond all of the regular challenges in servicing equipment—you probably have to face a lot of extra red tape and regulatory complications. Of course, they will have guessed right. But outsiders don't service medical devices, and managing regulatory requirements is not the whole story about servicing medical equipment.

Servicing medical devices is not the same as servicing a consumer item like a television, a computer, or an entertainment system. Manufacturers in consumer industries can sell their products and then move on to the next piece of business. This is also true for industrial equipment, although often to a lesser extent. Manufacturers in those industries can draw a hard line between manufacturing and service, or even choose to leave service to third parties that they have no relationship with. Although many of these companies are trying to capture the revenue potential available from servicing their own equipment, it is generally a decision that is based on growing the top line. Service in the medical devices industry, however, is not optional. Service is integral to the relationship with the customer and very tightly tied with the success or failure of the company. In the medical devices industry, services are strategic and manufacturers of equipment used in the medical field are held to a higher level of responsibility by their customers.

There are advantages and disadvantages of the closer relationship between medical device vendors and customers. On one hand, companies typically don't have to compete for service contracts with competitors. Because of the complexity of their products and the highly regulated environment, it is often very difficult for uninvited third parties to maintain a manufacturer's equipment. Our outsider might guess that the lack of competition for the service contract means that the cost of maintaining equipment is not an important issue. On the contrary, it means that managing the cost of servicing equipment is frequently more important to the bottom line than in other industries. This contradiction is a result of the lack of competition, and the buyers' knowledge that they don't have flexibility to shop around a service contract. To compensate, the buyers may negotiate the service costs well in advance, often as a part of the equipment purchase. In these cases, service revenue is fixed. Therefore, services profitability can only be impacted by attacking the other side of the profitability equation—cost. Service Lifecycle Management (SLM), coined by industry analyst firm AMR Research, is an approach that allows service organizations to better manage their service-related processes. SLM results in both better service and reduced costs. For medical device companies, it is critical to take advantage of the opportunities that SLM offers to simultaneously enhance the relationship with the customer and keep service costs in control. And yes, compliance is critical to all aspects of the business and shouldn't be minimized in the least.

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Compliance is Critical

Compliance isn't the whole story when discussing medical device service, but it is a big part of the story and one that demands attention from service organizations. Compliance is complicated, and the requirements are pervasive throughout the service processes. The U.S. Food and Drug Administration (FDA), International Standards Organization (ISO) and independent auditors like TUV all demand strict adherence to processes designed to ensure the safety of the patient population. In the medical industry, outside scrutiny is a fact of life. As Jim Cupo, systems support engineer for Diagnostica Stago put it, "Servicing medical devices like our coagulation analyzers is a lot different than servicing a photocopier, you are held under the microscope a lot more."

During an audit, regulators will expect to see specific, detailed information on service reports. This information includes what problem was reported, the serial number of the equipment involved, the time of the service, which technicians were involved, the final resolution, and the inspection criteria and testing data that had to be recorded during the call. "Most of this you would already have, but here it is a must," said Barbara VanHouten, senior product support engineer for automated blood processing systems manufacturer Haemonetics, "If the FDA comes in, the record has to have completeness. Specialty fixtures and testing equipment have to be calibrated, and we have to have records of it. For us—it is mandated."

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- Jim Cupo, systems support engineer Diagnostica Stago***

Some elements of service that are already difficult for any service organization—such as dispatching—are even more challenging in the medical devices industry. While it is always advantageous to dispatch a qualified technician, dispatching a technician that is not certified to perform an operation on a medical device is an ethical—and legal—liability. Employee certifications must be kept current and tracked, and dispatchers must take certifications into account before assigning a technician to a job. Service specifications and procedures take on greater importance as well. "Our engineers are walking into a lab with potentially hazardous material, so they have to wear gloves, eye protection, and a lab coat," Diagnostica Stago's Cupo explained, "They also have to follow OSHA (Occupational Safety & Health Administration) regulations for blood-borne pathogens and receive annual training on procedures." Clearly, regulatory and safety concerns add complexity to managing a service operation.

Regulations are not static, so service organizations must stay current. Most recently, the medical profession has had to adapt to new Health Insurance Portability and Accountability Act (HIPAA) rules. Frequently, today's intelligent medical devices contain confidential patient information in their databases. Some service organizations will not remove broken hard drives from the hospital or clinic, preferring not to take the chance that confidential information on the hard drive may accidentally be exposed to being released. Service technicians may also have access to patient information on printouts or on a screen, and must be trained that they can't discuss this information. Regulatory enforcement can also change over time. For example, there is a renewed focus on regulations like 21 CFR Part 11 that describes requirements for electronic signatures in a regulated environment. Although the regulations have been "in the blue book" for years, they are just recently being actively audited and enforced. Service companies must recognize and respond to these changes, ensure that their organization is educated on the new requirements, and provide proof that the processes are being complied with throughout the business.

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Enabling Compliance with Automation

Regulatory compliance is the responsibility of every individual in a regulated environment, it is a core requirement to successful business. In the final analysis, company employees must remain diligent to avoid regulatory problems. Software applications can play a big role in facilitating compliance. By automating processes and data collection, service organizations can institute more consistency and adherence to documented procedures. Many service organizations equip their technicians with handheld devices or laptop computers in order to keep them in touch with the call center and depot, and to help them with their work. Service companies have the opportunity to further leverage mobile devices by embedding standard operating procedures and good service practices into the software applications, allowing these mobile solutions to keep the processes in front of the technician at all times.

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In addition to enforcing compliant processes, mobile service solutions can improve data collection required for medical device service. Information that must be captured can be required before a service ticket is completed—making sure that the data is captured as the service occurs instead of after a paperwork review days or weeks later. By enforcing standardization of data, companies can leverage the system for process improvements, not to mention sales and marketing efforts. Jeff Gaulin, manager of customer service / depot repair for Haemonetics describes one such use. “Because we are FDA regulated, we are required to provide statistical measurements of problems and issues,” Mr. Gaulin commented, “We couldn’t get the data out of the system before implementing our services application.” He went on to describe how standardization and strong application support from their current system—Astea Service Alliance—provides this information readily.

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Having the right information available at the right time is a key element to providing good service. It is also extremely important when facing a regulatory audit. While automation may not be able to make audits fun, it can make them much faster and result in far fewer noncompliance events. Ms. VanHouten describes that at Haemonetics, they can produce a log of transactions during an audit that details who touched the call from the time it was opened all the way until resolution, and that they are able to keep this information easily available for the life of the equipment. “In an audit, we don’t get panicked because we can retrieve the information,” Ms. VanHouten remarked, “In a second we can retrieve the information instead of searching through files—that’s a huge plus.” She described that the software provides strong support for regulatory compliance, commenting proudly that “Astea Service Alliance was one of the first applications that passed Part 11 for our business.”

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Service is Strategic to Customer Satisfaction – and Future Sales

Compliance is critical, but ensuring compliance is not enough to successfully grow a profitable business. Compliance is the minimum requirement for surviving in the medical devices industry. Growth, however, comes from satisfied customers. Service is a key part of keeping a customer happy. For many medical devices companies, servicing equipment is important for more than just retaining the customer's service contract—it is critical to maintaining customers. Because many manufacturers often service their own equipment, the view of the product includes the service. If service is not satisfactory, the entire product experience is impacted. There are many service options in other service industries, so a customer may be satisfied with the product and seek service from a host of third parties. Because of regulatory requirements and complexity of servicing medical devices, the option for service is often limited to the manufacturer and trusted third parties that have been trained on the technology.

***Service for medical devices becomes strategic not just to service sales,
but to continued product sales***

Even if service is outsourced, the service provider must still live up to a certain level of expectation in order for the customer to feel good about the product. Service for medical devices becomes strategic not just to service sales, but to continued product sales. Poor service can damage the reputation of the medical devices manufacturer—resulting in a difficult selling environment for new products.

Servicing medical devices is a matter of complexity and regulation, but also a matter of trust. Trust is a big issue for servicing medical devices because medical device service can be critically urgent. That urgency places a higher service burden on the company and demands a higher level of service to maintain customer satisfaction. “When a service call comes in, it’s possible that somebody could be on an operating table,” Mr. Cupo said, highlighting the importance of first class service, “We have to have a good knowledge base to get the equipment running as quickly as possible.”

***“Uptime is critical for medical devices”
- Dr. Jane Naish, senior information engineer Optos***

Clearly the impact of an outage can be more significant than the impact of an out of service appliance. “Uptime is critical for medical devices like our retinal imaging and diagnostic equipment,” says Optos senior information engineer Dr. Naish, “In fact, our revenue itself is tied to uptime because we get paid based on usage—so it’s up to us. If our customers can’t use the product, we are losing money.” Although uptime is not always tied directly to revenue as it is with Optos, it is indirectly tied through customer satisfaction when there are no fingers to point.

Making Best Service Practices Standard Operating Procedure

In order to maintain regulatory compliance, service organizations must define and operate under approved, compliant business processes. In order to provide world class service, companies must go beyond compliant process to adopt best practices for service organizations. One of the key areas of improvement for many companies is the communication and coordination between field service, the depot and the call center. Automation can dramatically help in this capacity. Automation—if done properly—provides an integrated view of the customer and the customer’s equipment across organizational boundaries. “At Haemonetics, we can now review a complete service report on the laptop,” Ms. VanHouten remarked, “Everybody has access to the status of calls, inventory and even sales orders for spare parts.” Visibility is important, and provides an opportunity to offer better service to customers.

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“For Optos, we needed better systems to help grow the business—it was as fundamental as that,” Dr. Naish stated, “With automation it becomes easier to track calls and go beyond call-tracking into spares management.” Dr. Naish described that the right system comes with business processes built in that will help improve business performance. “Our driver was to find a service-oriented package, but one that would also protect the integrity of the information for compliance reasons,” Dr. Naish explained, “We were happy to find Astea who offered strong service practices, but also introduced us to other customers that were already FDA validated.”

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Mr. Cupo of Diagnostica Stago commented on the value that automation has offered towards customer service. He described that since his company has implemented Astea, they are completely paperless. Nothing comes in house for filing because everything gets filed electronically. “We now spend our time handling customer issues, which is much more important than tracking down paper that hasn’t come in,” Mr. Cupo stated. The software has also improved efficiency, he explained, because they can manage field staff more efficiently. One other valuable benefit for Diagnostica Stago is that physical inventory has been cut down to two times per year, which according to Mr. Cupo “saves a lot of time and headaches.”

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There are a lot of valuable byproducts of automation as well. By standardizing calls and quality data, it is much easier to identify the top quality issues. “That information surfaces much more quickly than combing through service calls,” says Mr. Gaulin of Haemonetics, “Now that information goes back to R&D and is reviewed every month in our quality meeting. It opens up the loop of data and provides much faster reaction,” he added. As companies implement SLM, they will often discover other valuable benefits. “Our use of the system has grown since we started five years ago,” Ms. VanHouten stated, “As you dive into it more, you find things you can take advantage of and use.”

The Good and Bad of Servicing a Captive Audience

Medical device service organizations, unlike those that service more commodity products, often service a captive audience. The competition for service revenue in many industries has driven services to a commodity level, with no ability to capture a service premium. “Service contracts can’t really be shopped around in our industry,” said Haemonetics’ Mr. Gaulin, “but they are often negotiated in advance with the sale of the product.” Because purchasing agents know they are committing to not just a product but a source of service, they frequently want to negotiate the entire package in advance. Often, this results in fixed service contracts. With fixed revenue contracts, profit margins depend solely on cost—making aggressive cost control critical.

***Even the time-tested method of maintaining service revenue
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is challenged by a captive audience***

Even the time-tested method of maintaining service revenue—consumables—is challenged by a captive audience. “Our customer is required to pay for and keep stock of halogen lamps, syringes, needles and solutions for washing,” Diagnostica Stago’s Cupo said, “They realize they will need these so they are all signed into a consumable list on the contract and they budget a fixed amount for it.” In this model, customers have negotiated fixed costs in advance so the cost of inefficiencies can’t be passed on and managing cost is really protecting revenue.

Despite defining the service market as a “captive,” medical device companies can’t rely on service revenue always being available. There is still competition for maintaining medical devices—even if it comes from inside the customer. “In the past, customers were always buying service contracts, but they have cut out a big chunk of the budget from service contracts,” says Haemonetics’ Gaulin, “Because of increase equipment reliability, they are more willing to go straight time and materials or take the service work in-house to their own Biomed people—it’s all about cost.”

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- Jeff Gaulin, manager of customer service / depot repair Haemonetics

SLM Drives Superior Service at Optimal Cost

In the medical devices industry, service is highly strategic. Maintaining the customer relationship is critical, and requires companies to offer superior service levels. Service Lifecycle Management offers methods and tools that can help to institute the right processes to achieve and sustain superior service.

***In addition to superior service—and potentially in conflict with that goal—
costs must be actively managed to maintain profitability***

In addition to superior service—and potentially in conflict with that goal—costs must be actively managed to maintain profitability. The challenge is that managing costs requires attention and focus at a very detailed level. The difference between profit and loss can be as simple as missing a manufacturer’s warranty for a replaced component or dispatching an overqualified technician for a particular job. Being smart about service is the difference between profit and loss. Service Lifecycle Management can help by providing a template for best business practices. SLM provides an approach that highlights getting the basics right and focusing on the right details to improve service and manage profitability.

In May of 2003, Tech-Clarity published a white paper titled “The Service Lifecycle Management Approach - Strong Customer Relationships Result In Profits in the Service Industry.” That paper highlighted some practical ways in which companies could adopt SLM concepts into their business and improve profitability in the product aftermarket. The following overview highlights these approaches:

Never Ignore a Call for Help

Every call from a customer is an opportunity to increase customer satisfaction. Many companies can gain value simply by providing their employees with visibility to all of the contacts from a customer—regardless of the source—so they can get a full picture of the customer’s needs. By automating the capture and response to requests through tools such as remote access, workflow, automated escalation and integrated e-mail, companies are ensuring that customer calls are captured and acted on in a timely manner. Even better, by proactively predicting a problem or supply need, customers see value from service contracts through prevention of a problem as opposed to firefighting, and the service company can decrease the need for expensive and disruptive emergency service calls.

Reduce Waste in the Call Center and Office

In order to improve call efficiency, companies are providing shared knowledge of problems, resolutions, occurrence rates and causes to their representatives. By providing information that can be quickly searched for relevant answers, time spent with customers is more productive and provides more value. If a customer can find the answer to their problem or question through self-service, customer satisfaction can come at a significantly reduced cost. Automated web response, if done properly, can also save significant resources and maintain high customer satisfaction levels.

Avoid the Service Call (or at Least Reduce the Urgency)

By providing customers and customer service representatives with broad access to product and service-related knowledge, many service calls can be avoided. If the problem can be fixed without dispatching a technician, the cost of the technician and related overhead expenses can be saved. By preventing emergency calls with planned maintenance or repair, customer satisfaction can be increased with less need for urgent response. Also, through better scheduling, some service calls can be avoided by taking advantage of the existing service schedule for routine maintenance and meter-reading calls, or combining them with other calls. By providing the technician with the right information about the customer and upcoming service, technicians can often “kill two birds with one stone” and save on the total number of calls required.

Make the Right Calls First

Service calls should be prioritized based on customer need, but also on the value of the customer and the service level that the customer has paid for. Nobody wants to leave a customer in need, but knowledge of the contracted service agreement can allow company representatives to properly prioritize limited resources to the appropriate customer. Customers that continually request urgent responses outside of their service levels can be targeted for an upgrade to their service plan and provide more income for the company. Any service calls that are trending towards an SLA violation or customer service failure can be reported in advance and the appropriate person notified while there is still time to address the problem.

Close the Call the First Time

By closing the call the first time, the number of service calls can be reduced and customer satisfaction can be increased. Fixing the problem the first time requires the right technician, with the right knowledge, the right parts, the right tools, the right customer data and the right product information in hand. By having predefined response lists for problems that outline the appropriate actions, tools and materials required to make the correction, service technicians can show up prepared to get the job done right. Through visibility to the equipment installed, the service history and the call history, the technician can more accurately diagnose and resolve the issue. And closing the call means that the customer signs off that the problem is corrected—as soon as the problem is corrected.

Keep Technicians Productive, not Just Busy

The service technician is critical to resolving customer problems, but also to maintaining service history and providing information for billing. Reducing the amount of time that the technician spends on paper work through automation allows the technician to take more calls, reducing employee expenses from overtime and hiring additional technicians. Mobile technology and self-service capabilities can significantly reduce both the load on the call center from technicians and the amount of time the technician must spend on the phone and away from helping customers. Schedule optimization is also key. Keeping technicians updated—in real-time—of schedule changes is another way that they can be kept productive.

“There is no such thing as a ‘swap jockey’, technicians really have to diagnose the problem and understand what’s going on”

- Jeff Gaulin, manager of customer service / depot repair Haemonetics

Considering the skill level and cost of service technicians, this is even more important for medical devices. This point was highlighted by all of the companies researched for this paper. “A medical device is a lot more technical than a PC and there is lot more logic involved in components and parts,” said Haemonetics’ Gaulin, “There is no such thing as a ‘swap jockey’, technicians really have to diagnose the problem and understand what’s going on.” This increased level of technical skill leads to higher costs and longer training time before a technician or engineer is up to speed. But technical expertise is not all that is required. “Engineers have to understand the clinical use as well as technical use,” explained Mr. Cupo of Diagnostica Stago, “They need to talk intelligently to the customer about the product and they have to understand medical and technical jargon.” “It’s not just field service, it’s also consultancy,” furthered Optos’ Dr. Naish, “technicians have to know how to integrate the product into the customer’s business—from interpreting test results to helping them market the service.” Clearly, the technician’s time must be carefully guarded and its use optimized given the value of these resources.

Turn the Service Call into an Opportunity

Companies with field service personnel trained to spot sales and replacement opportunities can add a significant new source of revenue, provided that it is easy for them to communicate those opportunities back so the order is captured or turned over to Sales. Service technicians that have visibility to contract expirations, upgrade availability and complementary products can increase customer satisfaction as well as sales revenue. A service technician with a piece of equipment to fix will probably not look for another sales opportunity, but if they are proactively notified of the opportunity in the course of their work they can uncover new business for the company.

Turn Service into Cash – Rapidly

Perhaps one of the best ways to increase the profitability of services work is to enable the service technician to create an invoice on the spot, starting the payment cycle immediately. In addition to being paid earlier, the service technician can get approval at the time of the service. Part numbers, time and expenses are much more accurate when captured quickly so nothing is lost. To generate an accurate invoice in the field requires easy access to understandable information on contracts, warranties, service history, call history and customer information. With the right information to generate the invoice accurately and get it approved, the company will have less disputes and credits, and increase cash flow positively. Creating an inaccurate invoice, however, may be worse than delaying the invoice, so attention to the details is required here.

Stop Revenue Leaks

Revenue leaks occur when customers are not billed for services they should pay for. The goal is to give the customer everything they are entitled to—but nothing more—or the service company is leaving money on the table. Without easy access to the proper information it is often unclear if expenses are billable or not, so they are typically not billed. Revenue leakage is difficult to identify after the fact, because it occurs in small but frequent occurrences, and requires access to detailed history and account knowledge. Similarly, supplier warranty information must be readily accessible and easy to understand in order to track returnable or refundable items. A systematic approach can provide significant benefit by recouping out of pocket expense and lost revenues by providing visibility and eliminating guess work.

Enhance the Customer Relationship

Customer satisfaction is extremely important to building long term relationships, and it is good business because it leads to greater profitability through customer retention and repeat business. Moving from a break/fix relationship to one of trusted advisor and value-added service provider results from handling problems proactively, ideally fixing the problem before the customer realizes there is one. To move from “break/fix,” a company does more in the way of preventive maintenance, remote equipment monitoring, failure analysis for retrofit and future design improvements. In this way, the customer is receiving something that they value more than a fast repair call: continuous availability.

Grow Revenue by Restarting the Service Lifecycle

The first step in selling additional products is identifying the opportunities. By mining the information already captured about customers and their equipment, effective marketing campaigns can be developed to target customers for additional products based on accurate, detailed information. Because campaigns can be targeted based on real customer knowledge, they can be very focused on real, specific needs of the customer.

Turn to Proactive Management

Through increased visibility in the service business, companies can gain better control, find bottlenecks and make better management decisions. With better information and tools, they can switch to proactive management through alerts and real-time information, as opposed to reactive management from reports that show history after the fact. Better management results in higher revenue and reduced costs, improving profitability from both income and expense directions.

Summary

From a distance, our outsider was able to see that servicing medical devices demands compliance. But from the outside, it is not as clear to see that service is more strategic to long-term success for medical device companies. Whether service is performed directly or through a third party, the quality and reliability of service reflects directly on the value and reliability of the product—and the company that offers it. The manufacturer's reputation and future sales are based on maintaining long-term relationships and a high level of trust. Service Lifecycle Management can provide needed compliance, but also go much further by improving service levels at a reduced cost. Profitability from today's product relies on cost management and compliance. Revenue from future products relies on strong service. SLM provides an approach that—when coupled with strong compliance capabilities—provides the medical devices company the tools needed to succeed today and into the future.

Recommendations

- Get compliance right. Compliance is mandatory, and noncompliance events are expensive in terms of direct cost and reputation damage
- Get the basics of SLM right. Managing medical devices requires excellent service, but at managed costs
- Be passionate about servicing your customers. Service satisfaction directly impacts your customers' view of your company and your products
- Recognize that service is much more strategic to medical devices, it is integral to the medical device value proposition
- Focus on cost at a very detailed level. The difference between profit and loss is in the details
- Get the inventory out. Service organizations of any kind can't afford to have excess inventory
- Optimize technician time. Service technicians for medical devices are valuable and expensive, their time should be used as efficiently as possible

About the Author

Jim Brown has over 15 years of experience in management consulting and application software focused on the manufacturing and service industries. Jim is a recognized expert in software solutions for manufacturing and service and has broad experience in applying enterprise applications such as Product Lifecycle Management, Supply Chain Management, ERP, and CRM to improve business performance. Jim began his professional experience at General Electric before joining Andersen Consulting (Accenture), and subsequently serving as an executive for software companies specializing manufacturing and service solutions. Jim is the president of Tech-Clarity, a research and consulting firm dedicated to making the value of technology clear to business.

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