



Buyer's Guide to IDM-enabled Field Service Automation

for Life Sciences and Medical
Equipment Vendors

Table of Contents

- Introduction3
- What is IDM-enabled FSA?3
- Customers Want Proactive IDM-enabled Service.....4
- What Gains Can Vendors Expect from IDM-enabled Service?5
- Better Customer Satisfaction5
- Reagent/calibration problems6
- First visit resolution6
- Technician response time7
- Email and phone support quality7
- A Profitable Service Center.....7
- Turn emergency calls into routine calls7
- Make preventative maintenance calls only as necessary7
- Enable productivity gains for your junior support staff8
- Avoid unnecessary service calls.....8
- Schedule resources economically8
- Improve spare parts ordering8
- Enhance your consumables sales and replenishment process8
- Usage-based billing8
- Evaluation Criteria for Field Service Automation8
- Security8
- HIPAA and 21 CFR Part 11 compliance.....9
- Firewall-friendly network security9
- Modular, configurable deployment9
- Efficient use of device resources10
- Extensible, seamless integration10
- Configurable to support your business infrastructure10
- A consultative partnership approach11
- A track record in the medical industry11
- In Conclusion11
- References12

Introduction

In today's challenging environment, medical equipment vendors need to compete by finding innovative ways to deliver consistently excellent customer service while reducing costs and improving equipment uptime. It is no longer affordable to simply keep adding more staff to the support center to address all service needs.

Whether you manufacture equipment for patient care and monitoring, or the life sciences industries, changes in the healthcare world are putting increased pressure on organizations to deliver more with less, resulting in demands on vendors to increase service efficiency. An overstressed healthcare system means that medical facilities need to have equipment operating for longer hours without compromising reliability. Budget cuts mean that facilities can no longer afford to have their own staff deal with equipment or operational errors, and are offloading the burden onto their vendors' customer support organizations.

Several trends are contributing to an environment for dramatic new service levels. First, new generations of devices for medical imaging, clinical/laboratory testing, diagnostics, and patient care are being designed with increasingly intelligent processors and software to reduce time and complexity for instrument troubleshooting, set-up and calibration. Second, the pervasiveness and competitive cost of high-speed communications allows most hospitals and medical facilities to have ready access to the Internet. Medical device vendors who take advantage of these two factors can increase service efficiency by deploying an intelligent device management (IDM) system that uses the Internet to connect to instruments at customer sites, and integrating it with a state-of-the-art field service automation (FSA) system. The result is what Qestra calls **IDM-enabled Field Service Automation**, an integrated FSA solution that offers the highest levels of service.

This guide provides you with an outline for making informed choices regarding service automation in the medical equipment industry. While every service operation is unique, we've assembled a list of the most common challenges our customers and prospects have shared with us and mapped those against functionality you should expect before selecting an FSA solution with IDM capabilities. This guide discusses how such a solution meets these challenges and reviews the results that can be expected.

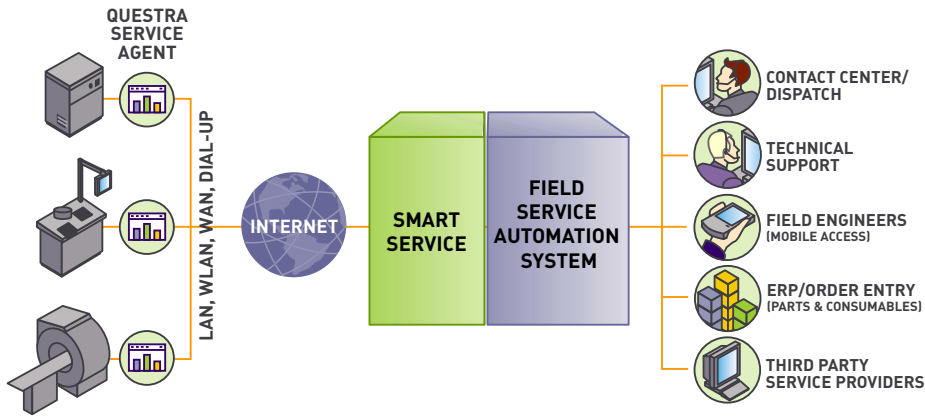
What is IDM-enabled FSA?

Field service automation systems enhanced with IDM deliver the absolute highest levels of service for equipment vendors and service organizations, including advanced, proactive activities that identify problems before they even occur. IDM is the enabling technology that allows the manufacturer to monitor and manage devices in real-time at customer sites over the Internet. Leading providers of field service automation systems have integrated intelligent device management capabilities into their software, allowing their customers to take advantage of real time device data to offer competitive service that traditional FSA systems cannot match. Traditional FSA systems go into action when a service request is logged, initiating an optimized workflow path to respond to the customer call. However, such a system is necessarily reactive, relying on a customer phone call to trigger events. IDM-enabled FSA integrates the FSA solution to an IDM system, creating a proactive solution that enables monitored equipment to initiate service requests or even to flag potential problems before they happen, without requiring any human intervention.

Budget cuts mean that facilities can no longer afford to have their own staff deal with equipment or operational errors.

IDM-enabled Field Service Automation delivers the absolute highest levels of service for customers, including advanced, proactive activities that identify problems before they even occur.

Questa Corporation is the leading provider of IDM software for the medical equipment industry and has partnered with major FSA suppliers in the industry to create a solution that meets data security and HIPAA requirements. An FSA system with IDM capabilities monitors equipment in real time over the Internet and processes the data using business rules to drive the workflow for field service functions such as call center notification, dispatch, usage-tracking, preventative maintenance scheduling, inventory and spare parts management, consumables replenishment and much more. If you are already using an FSA system, Questa can work with your supplier to integrate IDM into your existing service environment. If you are about to purchase FSA software, it is worth adding IDM capabilities to your evaluation criteria.



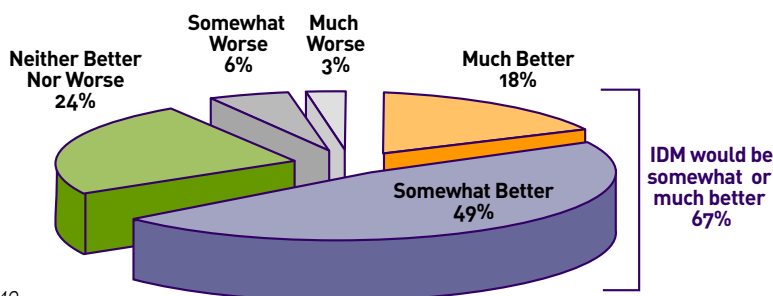
67% of lab managers believe that intelligent device management (IDM) would be an improvement over their current service system.

Customers Want Proactive IDM-enabled Service

A survey by Customer Insights Group in March 2003 reveals that 67% of lab managers believe that intelligent device management (IDM) would be an improvement over their current service system, and expect IDM capabilities to deliver positive results to their business. In this group,

- 40% cited “faster troubleshooting/reduces troubleshooting and repair time” or “easier troubleshooting/describe problem better” as benefits
- 12% liked the “better monitoring/better maintenance/better uptime/better instrument control” it could provide
- 10% said they wanted to “know the instrument requires servicing before it goes down/catch problems before they happen.”

Lab Managers Want to Leverage Network Connectivity of Their Automated Instruments to Improve Uptime



Total Sample n = 140
© 2003 Customer Insights Group

For the remaining one-third who thought IDM would be neither better nor worse than what they currently have,

- 27% of respondents, mostly in basic research, said that "instrument problems are not an issue"
- 13% needed more information

Overall, 40% mentioned security concerns. Security was the single most important concern mentioned by all groups. This is an important evaluation criteria and is covered in the section on Security (page 9).

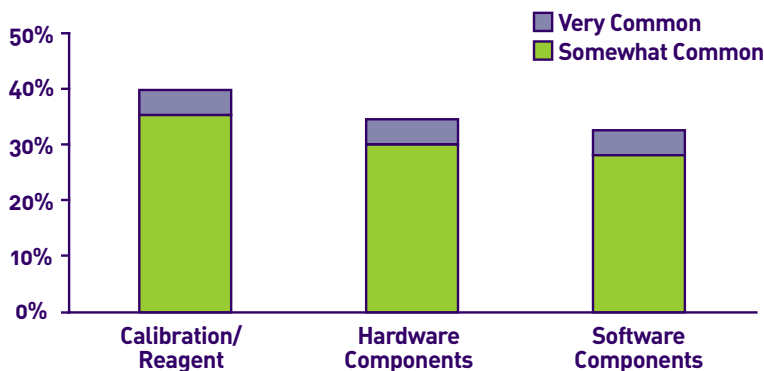
What Gains Can Vendors Expect from IDM-enabled Service?

Improving product functionality and adding reliability is one way to lower service costs and gain competitive differentiation. But there are significant R&D costs to developing new products or in adding reliability to existing products, and it can take years before the enhanced products are sufficiently deployed to impact service costs. This is why medical equipment vendors are looking for ways to achieve competitive advantage and reduce costs in other ways. Optimizing field service with IDM-enabled FSA turns the service department into a profit center and a valuable adjunct to the sales process.

Better Customer Satisfaction

IDM-enabled FSA leads to increased customer satisfaction because equipment uptime levels can be increased. Equipment downtime is a significant issue and takes a toll on revenues, overtime costs, and productivity. The survey by Customer Insights Group reveals that more than 30% of medical and life sciences equipment users report that downtime due to hardware and software problems are "very common" or "somewhat common".

Manufacturers claim 98+% equipment uptime, while their customers claim downtime is a serious problem.



Total Sample n = 154 to 170 © 2003 Customer Insights Group

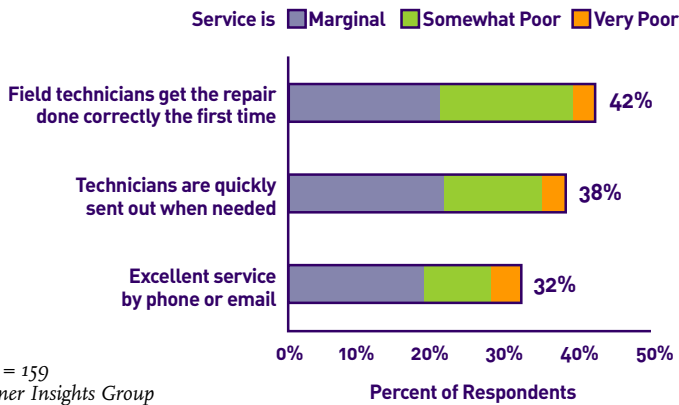
Furthermore, the research revealed that the primary drivers to low satisfaction were:

- Inability to resolve problems on the first visit, resulting in extended downtime, and follow-up visits
- Slow response time by field technicians in getting on site
- Poor quality of support by telephone support staff

More than 30% of medical and life sciences equipment users report that downtime due to hardware and software problems are "very common" or "somewhat common".

With IDM-enabled FSA, alerts are automatically generated and field technicians are instantly notified when equipment problems occur and sometimes even before they occur. Network connectivity to the device allows for an instant response and an improved ability to resolve problems on the first visit.

Field Service Not Meeting Expectations



In this portion of the survey, lab managers were asked about their experiences with the servicing of their automated lab instruments. They were asked a number of questions and given an opportunity to respond on a 5-point scale. The above chart shows that 42% thought the field service they received was marginal to poor on first-time repair resolution. 38% percent had issues with the slowness of repairs and 32% responded that they did not get good telephone service. The implication is that when an instrument is down, it will neither be repaired quickly nor correctly the first time.

Fortunately IDM coupled with FSA directly addresses all of these problems, making some entirely avoidable and the rest far easier to resolve. Here are some examples of improvements that are **visible and valuable** to your customers:

Reagent/calibration problems:

With continuous real-time monitoring, devices themselves will alert your contact center to problems before they happen. Equipment vendors can monitor key operational parameters and set thresholds that will cause the IDM system to notify the FSA system when certain conditions occur. Fluid levels, temperature, number of hours running or number of tests performed are all examples of operational data that can signify a need to check on reagents and other fluids, or on machine calibration. Support center staff can be proactive by calling and/or emailing the customer in advance to warn that fluids are running low or that instrument settings are drifting, and help them take appropriate action. With IDM, these types of downtime problems are easily avoidable, and make your support team indispensable to your customers.

First visit resolution:

IDM also means that when an instrument develops a problem, your call center technicians can view data about the error on line and in real time, analyze it against historical performance data and diagnose the problem without having to go on-site. If a technician is required for on-site service, this means that the right technician is sent with the right information, the right diagnosis and the right tools and spare parts, dramatically increasing the odds of a successful first visit – and your customer satisfaction scores.

With field service automation, alerts are automatically generated and field technicians are instantly notified when equipment problems occur and sometimes even before they occur.

Technician response time:

Customers can give a service technician secure remote access to the equipment, eliminating travel time from that first response call. Depending on the actual problem, the support center technician may be able to reset and restart the machine or change device parameters that allow the machine to continue operating until a technician arrives on-site. IDM changes your entire notion of response time, and gives you a competitive edge against vendors who do not support a remote monitoring and access capability.

Email and phone support quality:

Telephone and email support are challenging because troubleshooting is via second-hand information. Support personnel depend on the customer to describe the situation accurately and to follow instructions exactly. IDM changes all that, providing your support center with operational performance data directly from the device. With secure remote access, support staff can even share control of the instrument with the customer and walk together through the steps needed to get the machine running again. IDM saves time and reduces stress for both the customer and your support center.

A Profitable Service Center

IDM-enabled FSA offers compelling economics which are critical to your success as a profit center, but which are often less apparent to your customer base. Research conducted by the Center for Intelligent Maintenance Systems (IMS) found up to a 51% reduction in costs of servicing equipment with prognostics and diagnostics capabilities when compared to those without.

- Emergency repair costs went down to a more manageable 9% of the overall costs, while in systems without, this was responsible for 45% of costs spent servicing equipment.
- The cost of routine inspections went from 40% down to 15% of overall costs, a reflection of inspection schedules driven by actual equipment condition and usage rather than by a fixed time schedule.

Using IDM to enhance your service operations can add up to dramatic savings for your organization. Here are some areas where you can expect to achieve cost reductions when you implement an IDM-enabled field service automation solution.

Turn emergency calls into routine calls:

Continuous proactive monitoring allows you to see when problems are developing, so that you can schedule service calls in advance to prevent problems instead of responding to emergencies after they happen.

Make preventative maintenance calls only as necessary:

Instead of service schedules based on fixed time intervals (i.e. once every six weeks), field technicians can now make service calls based on equipment usage, fluid levels or other indicators of actual need.

Enable productivity gains for your junior support staff:

Keep your most senior technicians in reserve for the more advanced or complex cases. When less experienced technicians go on site, they can accomplish more when there is support from the call center in the form of supervision, support and training through remote access and diagnostics.

With field service automation, customers can give a service technician secure remote access to the equipment, eliminating travel time from that first response call.

Avoid unnecessary service calls:

Significantly reduce the cost of dispatching technicians and engineers through lowered service downtime and the ability to resolve issues remotely.

Schedule resources economically:

Use actual device data to assist in forecasting service demands and allocating resources to meet service level agreements in the most economical manner.

Improve spare parts ordering:

With actual usage data at hand, improve your spare parts consumables forecasting and ordering processes to eliminate unnecessary inventory.

Enhance your consumables sales and replenishment process:

Collecting device data automatically from the equipment to FSA systems allows equipment vendors to anticipate in advance of demand, while providing full visibility and control of your inventory. For many medical equipment manufacturers, equipment consumables represent a significant and recurring revenue stream. Inventory for test kits, reagents and serums, disposables, dialysates and other supplies all need to be managed. An IDM-enhanced FSA system allows you to track usage trends and pass the data on to sales, manufacturing and inventory, allowing them to take appropriate proactive action.

Usage-based billing:

In order to win equipment and service contracts, some medical device vendors are moving to bill-per-use models because it is becoming increasingly difficult for medical facilities, especially in patient care, to secure large capital investments. Usage-based billing helps customers work around budget constraints; some vendors track equipment usage manually during site visits or rely on the honor system. Continuous monitoring of medical equipment means that the IDM system is able to provide data to the FSA system on various usage properties such as cost-per-reportable, ensuring that usage-based billing happens in a timely and accurate manner.

In summary, the benefits of IDM-enabled FSA don't end at the service center. Once you have a system in place to collect real time device data and bring it into your organization, it becomes possible to leverage that data to support other areas of your business.

Evaluation Criteria for Field Service Automation

When comparing vendors to provide a field service automation solution for your enterprise, it is important to review these key areas: security, ease of deployment, device resource efficiency, ease of integration with your existing systems and rapid configurability. In addition, ideal vendors will provide a consultative approach to solving your business problem, rather than a one-size-fits-all approach, and have domain expertise and experience in healthcare.

Security

The medical industry has its particular requirements, with privacy and security topping the list of customer concerns. Vendors also express concerns about deployment, the impact of monitoring on equipment performance, and integration with existing and future enterprise applications. Here are the two key security issues to evaluate:

When comparing vendors to provide a field service automation solution for your enterprise, it is important to review these key areas: security, ease of deployment, device resource efficiency, ease of integration with your existing systems and rapid configurability.

HIPAA and 21 CFR Part 11 compliance

An IDM system that is polling devices needs to be configurable to selectively monitor and transmit device data. For customers with the highest security concerns, for example, IDM systems should be configurable to gather only instrument usage and performance data such as voltages, pressures and calibration curves, alleviating concerns that sensitive patient data might be collected and transmitted. There should also be audit trails for data, network and application access by user ID, date and time.

The Qestra solution is designed to support HIPAA with full logging and audit trails, and bi-directional certificates*, and is compliant with CFR 11 requirements. For more details on this, see Qestra's White Paper, *The HIPAA Challenge for Medical Device Monitoring and Data Security*.

**Note: this is not a HIPAA requirement, but is an option under HIPAA guidelines, and so should be included.*

Firewall-friendly network security

Deploying IDM for field service automation should not entail making the customer change their network or opening up a special port to give you access. All proactive IDM systems employ an agent, or embedded software that resides on the device or on the PC connected to the device. The agent is responsible for monitoring and transmitting data, and should leverage the existing firewall by initiating all communications with the enterprise. In other words, the vendor's enterprise IDM software cannot go through the customer's firewall, the communications session must start from behind the firewall, initiated by the agent. Both the agent and enterprise software should communicate using encrypted data sessions so that there is no risk of outsiders impersonating a device, and all users on the IDM system should be authenticated, with specific access privileges that are centrally managed.

Qestra's IDM solution supports all of the security strategies and technologies described above, acting as a secure intelligent data feed to the FSA system. In addition, Qestra's remote access capabilities allow the end customer to have complete control over network access from outside, by user, by application and by session.

Modular, configurable deployment

For most medical device vendors, deployment needs to happen in stages and therefore the solution should be modular, not monolithic. There is no point in paying for features that won't be implemented right away, and ROI should track deployment costs as closely as possible. This means software should be possible to implement in stages as a subset of the full product, or be scalable from pilot system to full enterprise edition. Alternatively, there can be flexible pricing that scales on a per-device basis with a growing implementation.

The Qestra Smart Service Solution gives customers and FSA vendors easy steps and options for IDM. Some customers may be ready to deploy the full enterprise solution with application connectors and extensive reporting capabilities.

For some customers, Qestra TotalAccess™ software is a convenient way to improve customer response time and troubleshooting without changing their current business practices. Remote desktop access to customer equipment and the ability to run hardware diagnostics remotely simply means eliminating unnecessary travel costs.

Qestra has designed products to support HIPAA with full logging and audit trails, and bi-directional certificates, and are compliant with CFR 11 requirements.

Questra SmartStart is a quick 30-day implementation of full, proactive IDM that gets the project started. When your support center is ready, upgrading to the full Questra Smart Service Solution, which provides proactive, continuous device monitoring and automated alerts, is completely seamless.

Efficient use of device resources

Continuous monitoring should consume the minimal amount of system resources, allowing your medical equipment to operate at its optimal level. There should be no impact on machine performance and only minimal impact on network traffic when implementing an automated Xtreme Service solution.

The Questra Service Agent™, responsible for monitoring, communications and alarm notification, is extremely efficient in its use of system resources and yet is feature-rich. It can be configured to poll for data at intervals as often as once per second. Yet it can be set to transmit data only when a significant event or error occurs, minimizing the amount of data being sent across the network.

Extensible, seamless integration

While some vendors view IDM as a point solution benefiting only the service department, others see device data being leveraged by multiple business units and departments across the company. So it's important that both the IDM and FSA systems should have integration points and be based on open standards and databases so that vendors can integrate seamlessly with other enterprise applications. Such applications include CRM, SCM, billing systems, ERP, predictive maintenance and expert systems. Many vendors envision taking hard data about how the equipment works in the field and building a database on product performance that assists their new product development efforts.

On the FSA side, software must support and coexist with other areas of your IT environment. An FSA solution must reside in environments where exchange of data is paramount. Other systems must access the FSA database and the FSA system must be able to access information from other databases if all your IT investments are to be maximized. All this should occur in the most convenient, least disruptive way possible – while minimizing the resources needed to enable information exchange.

Questra has worked extensively with FSA vendors that use Web-based technologies and therefore can integrate easily to these solutions via XML. Most applications nowadays use Web Services for communications, which allows devices to speak what is rapidly becoming the native language of business systems. When software products have XML-based enterprise connectors, integration becomes a matter of bidirectional sharing of information between the IDM and FSA solutions and any other existing enterprise application that can benefit from FSA and IDM information.

Configurable to support your business infrastructure

For a simple remote access application, an off-the-shelf solution may work, but an enterprise business application must be extensible to fit the business process and workflow of your organization, not the other way around. A rigid solution that makes your organization fit the product is not practical.

Questra and its FSA partners have extensive consultative experiences in enterprise implementations and these have reinforced our belief that one set of specifications will not

The Questra Smart Service Solution™ gives customers easy steps and options for IDM.

accommodate all ongoing customer needs and processes. So, while it is certainly possible to use an IDM-enabled FSA solution right out of the box, it still needs to be highly configurable so that the solution can be implemented and customized to meet your changing business requirements.

Architecturally, Questra assumes the need to tailor business rules and applications, and supports flexible administrative views of device populations that match the way you segment your supported instruments – by product type, by region, by customer, or by service technician.

A consultative partnership approach

IDM and FSA solutions bring value to a service organization – however, the solution provider(s) should also bring value to the table by taking a consultative approach, bringing options, knowledge and clarity to the discussion. Plus, they need to be willing to be involved on an ongoing basis to ensure that you get maximum value and usage from your system.

Questra professional services operate as a team with the FSA vendor and your own team. Our project leaders come from consulting backgrounds that cover IDM and FSA systems, with extensive experience in deploying enterprise business applications. We propose solutions only after understanding customer needs. Together we create implementation plans that recognize your business goals and constraints.

A track record in the medical industry

Although most medical equipment vendors feel that solution providers for IDM and FSA do not need to be experts in life sciences or patient care devices, it is important for them to have reference customers who are in the medical industry. Please ask Questra for customer references in the healthcare industry.

In Conclusion

Device management and automation is rapidly moving from a "nice to have" to a "must have" by market leaders, who are driven by the need to deliver proactive service, increase customer satisfaction and gain competitive positioning. IDM is truly the "killer app" for the connected business world. There is also recognition that the coming generation of doctors, researchers, lab technicians and other medical practitioners are far more computer literate than previous generations, and will expect higher levels of automated services and networked connectivity.

Talk to Questra or your FSA vendor and ask how you can quickly transform your service operations from reactive to proactive through IDM. IDM-enabled FSA is no longer a solution for early adopters. Leading medical equipment manufacturers have already transformed their support environments by integrating device alerts to service requests and dispatch, field service operations to SLA management, parts and consumables inventory management to equipment usage and replenishment. The benefits you gain from Field Service Automation can turn your service organization into a profit center for your company.

A field service automation solution by itself brings value to a service organization – however, the solution provider(s) should also bring value to the table by taking a consultative approach, bringing options, knowledge and clarity to the discussion.

References

- *The HIPAA Challenge for Medical Device Monitoring and Data Security: New Security Measures for Patient Privacy.* Qestra Corporation.
- *Intelligent Device Management For Life Sciences.* Qestra Corporation
- *The Impact of Lab Equipment Downtime in Life Sciences.* Customer Insights Group



Qestra Corporation
333 Twin Dolphin Drive
Suite 220
Redwood City, CA 94065

info@qestra.com
www.qestra.com
650.632.4011