

MARKET MONITOR™ NOTES

Status of Laboratory Automation



February, 2015

MARKET MONITOR™ Notes are summary publications that focus on a particular issue or discipline within the clinical diagnostics industry. The data for this MARKET MONITOR™ Notes is from the 2014 Laboratory Automation MARKET MONITOR™, published in November, 2014.

This issue of MARKET MONITOR™ Notes addresses the status of Laboratory Automation within the United States hospital laboratory market. It should be noted that data from non-hospital commercial clinical laboratories is not included in this analysis.

The 2014 edition of the Laboratory Automation MARKET MONITOR™ is the sixth publication of this report, with the first edition being introduced in 2004. These reports provide an in-depth analysis of the status of laboratory automation in the hospital market, it's growth, brand shares, the features and benefits of these systems articulated by current users, and anticipated future implementation among non-users.

What is Laboratory Automation?

The comprehension among laboratorians of what truly is “laboratory automation” is becoming more widespread than when this study was first introduced ten years ago. The concept of an automated laboratory that incorporates any or all of the pre-analytical, analytical and post-analytical processes is gaining widespread understanding and acceptance across most hospital laboratories, although this definition has not yet filtered down to all of the institutions, particularly the smaller hospital based facilities. Still among some laboratorians, the concept of automation is defined, as any analyzer, device or system used in the laboratory that is “not manual”. Particularly among those representing smaller facilities, having an analyzer capable of performing chemistry or immunoassay analyses means that the laboratory is “automated”.

For purposes of this analysis, “laboratory automation” is defined as a stand-alone or connected system that automates the pre-analytical, analytical and/or post-analytical processes involved from specimen receipt to result reporting and specimen storage. It should be noted that this discussion does not focus on those systems designed to process only hematology specimens, but rather those that can potentially incorporate multiple disciplines.

Status of Laboratory Automation

According to the results of Information Dynamics' 2014 edition of the Laboratory Automation MARKET MONITOR™, approximately one out of every five hospital laboratories in the United States uses a laboratory automation system.

The number of accounts employing laboratory automation has risen steadily since first tracking this phenomenon in 2004. At that time, Information Dynamics' data reported a total of 196 accounts using an automated system, and has grown over more than five times to 1,069 accounts. The graph to the right illustrates that the market for laboratory automation has enjoyed slow but steady growth over the past ten years

Segmenting the Use of Laboratory Automation

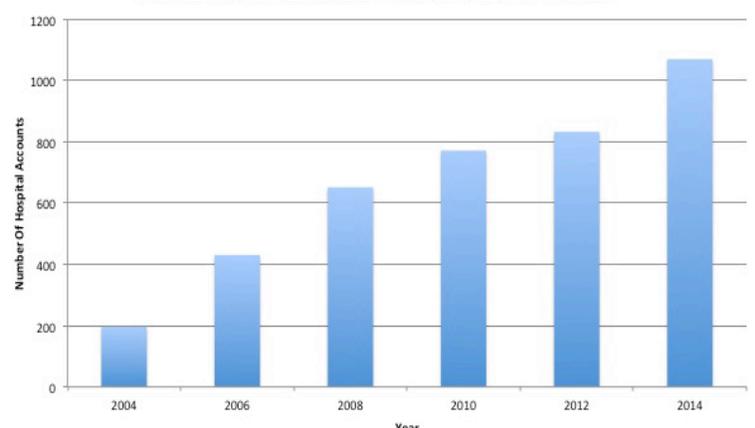
Segmenting markets puts members of a group into categories based on similar characteristics that are of strategic relevance.

Bed size segmentation is important as it allows an accurate projection of information to determine market size and brand shares. Bed size also provides a low cost means of targeting marketing efforts, as information regarding individual hospital bed sizes is readily available through the American Hospital Association and other statistical references.

When examining the status of laboratory automation by hospital bed size, it can be seen that in 2014, the primary existing market for these automated systems is within the largest hospital bed size segments.

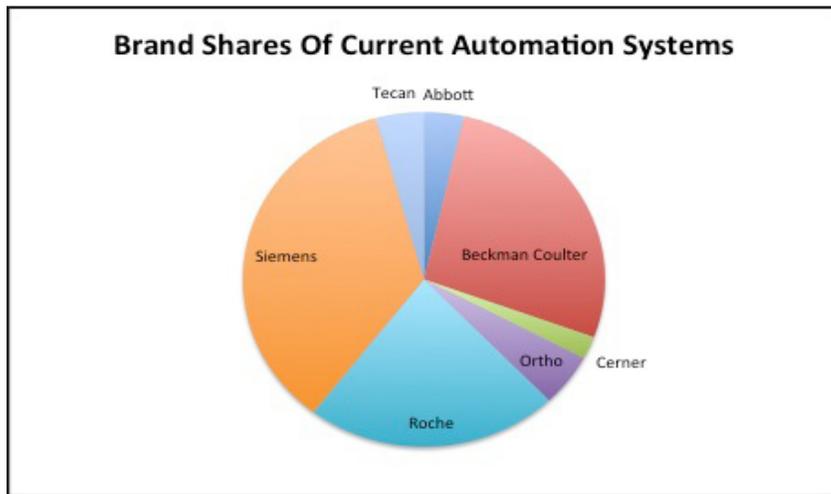
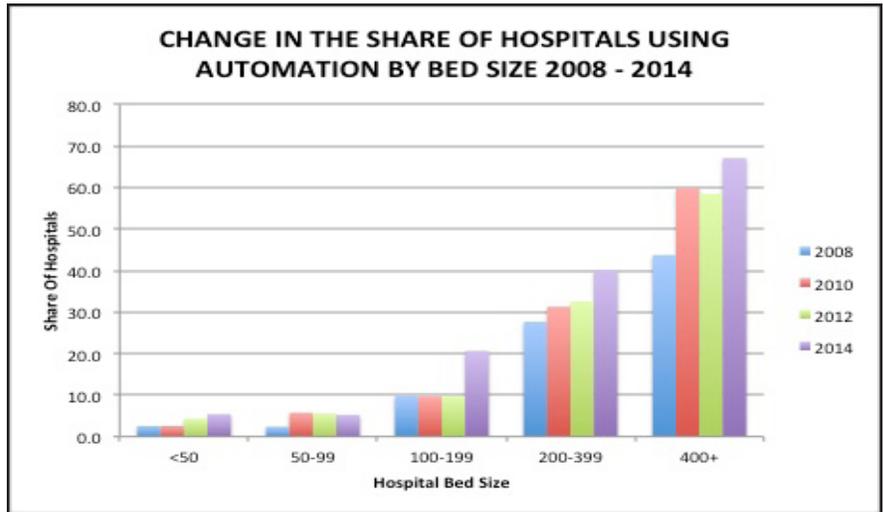
The greatest share of users of laboratory automation continues to be within hospitals having 400 beds or more. The majority of hospitals in this segment use some type of automation. Although most of the hospitals falling within the 200-399 bed size category still do not use a

TOTAL HOSPITAL ACCOUNTS USING AUTOMATION



laboratory automation system, this segment has seen steady growth in use. It is apparent that the use of automation is finally beginning to filter down to those hospitals having 100-199 beds. The share of hospitals in this category using automation has nearly doubled since the 2012 edition of this report was published. Those hospitals falling into the under 100 bed category continue to be very limited users of automation.

The chart to the right illustrates the share of hospitals using automation by bed size over the past six years.



Brand Shares of Current Automated Systems

Which manufacturers have made the most substantial inroads in laboratory automation? Siemens and Beckman Coulter lead the market, followed closely by Roche in the share of total accounts using each brand of automated system, as is illustrated in the pie chart to the left. The share of hospitals using each brand of automation system closely relates to the ranking of manufacturer brands for clinical chemistry systems, according to the data published in the 2014 edition of Information Dynamics' Clinical Chemistry MARKET MONITOR™.

Identifying the Most Likely Automation Adopters

Is hospital bed size alone an accurate predictor of which accounts will choose to automate? Experience has shown that hospital laboratories within the same bed size segment may differ significantly with regard to many variables. Based on data collected in Information Dynamics' most recent edition of the Clinical Chemistry MARKET MONITOR™, the correlation coefficient between bed size and general chemistry volume, for example, is 0.68. In order to further explore the types of accounts that may choose to automate, a segmentation method was developed by Information Dynamics that combines the annual general chemistry result volume as a primary indicator along with menu complexity as a qualifier.

Annual general chemistry result volume is an ideal primary indicator because it has a significant influence on several laboratory management issues. General chemistry test volume directly influences (1) the number of analyzers used, (2) analyzer throughput requirements, (3) staffing issues, and (4) automation/processing. Menu complexity as a qualifier uniquely addresses (1) the selection of immunoassay analyzers, (2) integration of general chemistry and immunoassay, (3) test menu, and (4) outreach and other management issues.

General chemistry volume is an easy concept to understand – it is basically the annual volume of general chemistry tests performed in the core laboratory. However, menu complexity deals with the types of assays performed as well as the volume of those tests. Combining the general chemistry volume categories with menu complexity, a total of nine different market segments were established.

How can the users of these automated systems be profiled? When analyzed according to these menu/volume complexity categories, it can be seen that the majority of current users of laboratory automation tend to be those offering a more complex menu and also those processing a higher volume of results. See chart at top of next page.

Even though the share of laboratory automation users has increased in the two years since the previous report publication, most of the newer adopters come from segments that perform a higher volume of tests and offer a more complex menu. The goal for manufacturers, therefore, should be to convince laboratorians from the lower volume performing labs and those with a less complex menu of the utility and benefits of automation.

Automation users by Menu/Volume Complexity Categories

Menu/Volume Complexity Category	Universe of Hospitals	Total Users of Lab Automation	Share of Lab Automation Users	Share of Universe
Low Volume, Basic	528	46	4.3	8.7
Low Volume, Basic Plus	931	49	4.6	5.3
Low Volume, Complex	198	8	0.7	4.0
Medium Volume, Basic	277	14	1.3	5.1
Medium Volume, Basic Plus	1,101	97	9.1	8.8
Medium Volume, Complex	496	166	15.5	33.5
High Volume, Basic	252	6	0.6	2.4
High Volume, Basic Plus	535	136	12.7	25.4
High Volume, Complex	876	547	51.2	62.4
Total	5,194	1,069	100.0	20.6

Identifying the Next Segment of Automation Adopters

The current status of the automation market data suggests that larger hospitals recognize the need for automation and many have already implemented such systems. For the first time since this report was published, however, the use of automation has finally made some inroads within mid sized hospitals (100-199 beds).

Two out of every three of the largest hospitals currently use some level of laboratory automation. The next question that needs to be addressed is which market segments will be the next most likely adopters of their first automated system? Based on those hospitals that have not yet become “automated” the following table illustrates the majority of those from all but the smallest bed size segment will eventually become automated.

Share of Automation Non-Users

Anticipated Year of First Acquisition	Total	Hospital Bed Size				
		<50 Beds	50-99 Beds	100-199 Beds	200-399 Beds	400+ Beds
Within Next 4 Years	19.6	11.4	16.2	29.7	23.9	54.4
Beyond 4 Years	35.1	35.7	35.1	30.3	44.4	19.0
Never	45.3	52.9	48.7	40.0	31.7	26.6
Total Current Non-Users of Automation	4,125	1,612	943	831	581	158

Acquisition of Replacement and Additional Automation System

The vast majority of current automation users expect to eventually replace their current system. Two out of five users expect to replace their current system within the next four years. A slightly higher share expects replacement to occur beyond the next four years, while another 14 percent never expect to replace the current system.

Regarding the acquisition of an additional system, half of current users do not expect to expand their automation line beyond what they currently have. What is the next most likely scenario for automation adoption in the near term? Based on the data as outlined above, the largest market for automation continues to be within the current non-user segment. If approximately one out of five hospital accounts intends to adopt automation for the first time in the next four years, that translates to more than 800 accounts acquiring an automated system. Adding to that the two out of five accounts that intend to replace their current system yields approximately 400 more automated systems. Finally, including those who intend to add another system equals approximately 200 additional systems. The most optimistic view therefore is that another 1,400 automated systems will be placed in both new and existing accounts within the next four years.

Which Brands Will Be Selected for the Next Automation System?

Approximately 36 percent of those accounts that are in the market for laboratory automation have selected Siemens as their first choice for automation, followed by Beckman Coulter, with 21 percent of anticipated adopters selecting this brand as number one. The pie chart on the next page illustrates the share of potential accounts mentioning each brand as their first choice for automation.

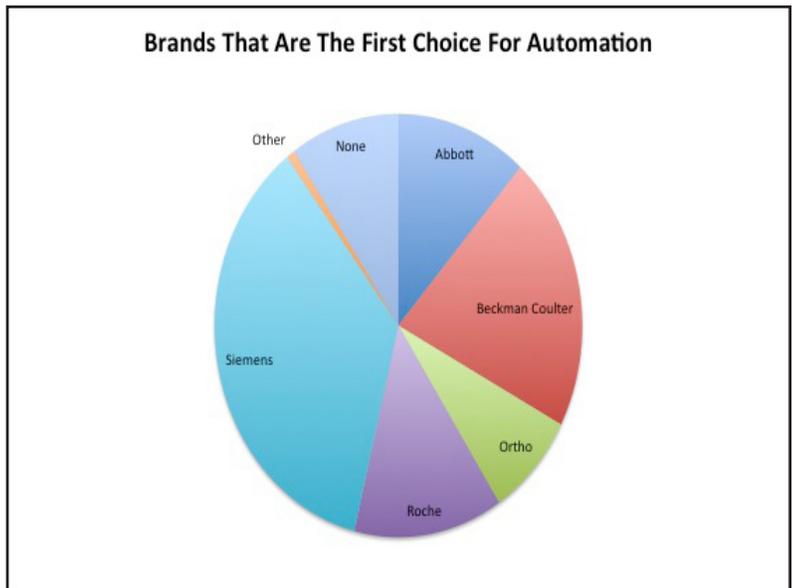
Issues That Need to be Addressed for Future Automation Adopters

What should manufacturers do to convince laboratorians from the next group of potential adopters that they need laboratory automation? Laboratory decision makers who are seeking automation mentioned several factors motivating this need. The three most widely recognized drivers of automation are the desire to reduce errors, increase the productivity of the laboratory personnel and improve test result turnaround time. The discussion of the impact of error reduction should be viewed in the context of the laboratory process. Human errors are the everyday headaches of the laboratory and

a recognized cause of serious disruptions in service to the clinical staff. Automation in the view of some laboratorians has the potential to significantly reduce these errors. In order to increase productivity, these laboratorians have a strong desire to increase the number of test results generated per skilled FTE. Laboratorians see increased productivity as the answer to the immediate problem of “doing more with less” and the continuing labor crisis faced in the laboratory. Clinicians are constantly demanding quicker result reporting, and automation is viewed as a possible solution to these demands.

The most frequently mentioned drivers of the implementation of automation include:

- Error reduction
- Increased employee productivity
- Improved result turnaround time
- Reduced labor costs
- Accommodate growth without increasing workforce
- Improved operator safety



Awareness of the features of automated systems among laboratorians has grown substantially since Information Dynamics' benchmark Laboratory Automation MARKET MONITOR™ was published in 2004. Most of the potential users are aware of some of the features that can be offered by automated systems. There are a number of features that both current users and those in the market consider as essential for any laboratory automation system. The following nine features were mentioned by the majority of this group as being essential components of any automated system.

(1) STAT Prioritization, (2) Linked interface, (3) Re-run, dilution and reflex and/or add-on, (4) Specimen integrity check, (5) Automated input /accessioning, (6) Decapping, (7) STAT centrifugation, (8) Volume detection, (9) Pre-Analytical sorting

Manufacturers would be wise to incorporate and promote as many of these features as possible in their automated systems in order to appeal to the widest range of potential customers.

Similarly, there are some negative perceptions about automation that need to be neutralized before optimum market penetration can occur. Among those not currently using automation, the cost of these systems is one of the most frequently mentioned perceived hindrances to adoption of automation. The views of non-users are in contrast to those of current users, as this group fears that significant remodeling, expansion and facility redesign would be necessary in order to implement automation. Manufacturers need to devise a promotional program and possibly offer different acquisition options to neutralize the objections of cost and the size of the system footprint. Additionally, the majority of current non-users do not see automation as a solution to staffing problems, so this often promoted feature may need to be downplayed in initial introductions of current non-users to the concept of automation.

The integration of automation within hospital laboratories is increasing steadily, and is finally making an entrance in the mid-sized hospital market. Manufacturers need to offer solutions to the objection of the cost of such systems by illustrating a reduction in errors and improved turnaround time for testing. A feature/benefit package that addresses the issues of most importance to laboratorians could help in the decision to acquire automation.

**For more in-depth information on the status of Laboratory Automation within the United States hospital laboratory market
Contact Information Dynamics to purchase the 2014 Laboratory Automation MARKET MONITOR™**

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Information Dynamics has been the major source of tracking data for the clinical diagnostics industry for three decades regarding behaviors and attitudes of clinical laboratorians.

All reports prepared by Information Dynamics include in-depth knowledge of all areas of the US clinical laboratory marketplace. All reports include custom analysis of data provided free of charge by our expert staff. Customer service and data support from Information Dynamics is timely, accurate and second to none.

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