MARKET MONITOR™NOTES
Status of Laboratory Automation

November, 2012

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 taken from the 2012 Laboratory Automation MARKET MONITOR™, published in October, 2012.

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 2012 edition of the Laboratory Automation MARKET MONITOR™ is the fifth 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 eight 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. Some laboratorians still view automated systems as merely "integrated" analyzers that can perform both general chemistry and immunoassay testing on the same instrument.

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' 2012 edition of the Laboratory Automation MARKET MONITOR™, approximately one out of every six 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 three hundred percent in the eight-year period to 832 accounts. The graph to the right illustrates that the market for laboratory automation has enjoyed slow but steady growth over the past eight years.
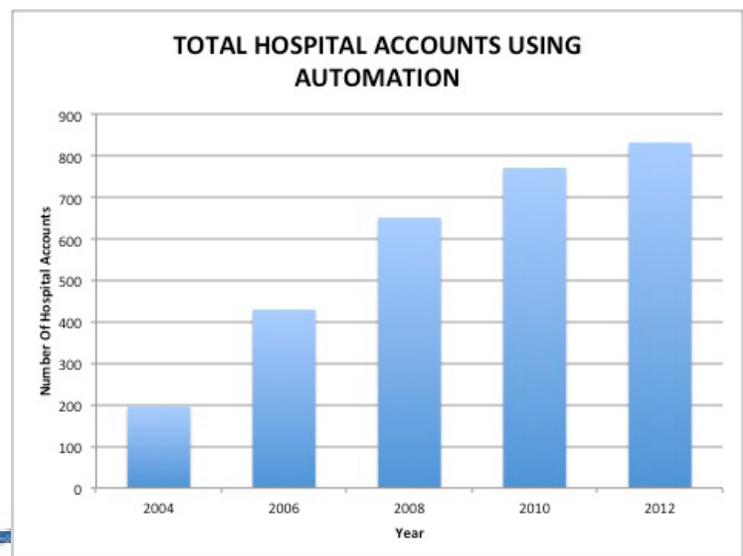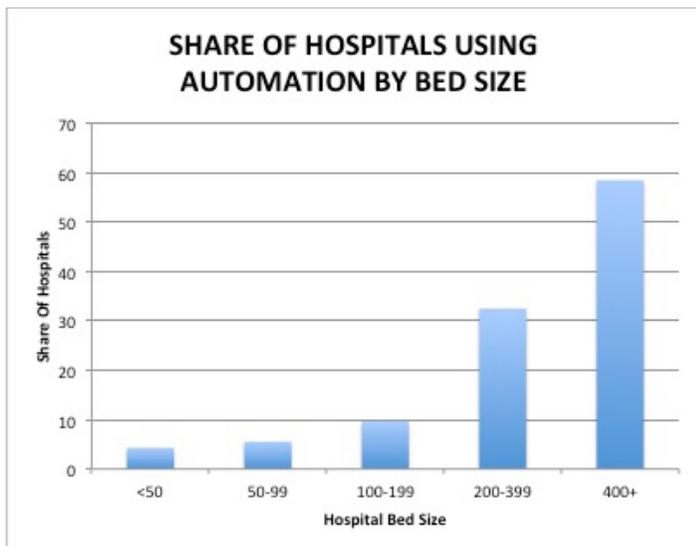
Segmenting the Use of Laboratory Automation

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 2012, as in previous years, the existing market for these automated systems continues to be within the largest hospital bed size segments.

But 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

TOTAL HOSPITAL ACCOUNTS USING AUTOMATION

SHARE OF HOSPITALS USING AUTOMATION BY BED SIZE

(chart: Share Of Hospitals vs. Hospital Bed Size; categories <50, 50-99, 100-199, 200-399, 400+)

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 0.56. In other words, only 31% of the variation between bed size and volume is related. 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 and are as follows:

Low Volume, Basic Menu Performs <250,000 Tests Per Year and is characterized by: Low Volume and/or STAT immunoassay capability (i.e. Cardiac, Thyroid, Drugs of Abuse, TDM); Probably does not have secondary immunoassay analyzers; high send out volume; no outreach
Low Volume, Basic Plus Menu Performs <250,000 Tests Per Year and is characterized by: Some non-STAT and/or low volume immunoassay capability (i.e. Fertility, Tumor Markers, Anemia)
Low Volume, Complex Menu Performs <250,000 Tests Per Year and is characterized by: STAT and non-STAT, high and low volume immunoassay capability plus esoteric testing. Probably requires secondary analyzers; little to no send out volume; capable of large outreach program; increased staffing requirements

Medium Volume, Basic Menu Performs from 250,000 to 999,999 Tests Per Year and is characterized by: Low Volume and/or STAT immunoassay capability (i.e. Cardiac, Thyroid, Drugs of Abuse, TDM); Probably does not have secondary immunoassay analyzers; high send out volume; no outreach
Medium Volume, Basic Plus Menu Performs from 250,000 to 999,999 Tests Per Year and is characterized by: Some non-STAT and/or low volume immunoassay capability (i.e. Fertility, Tumor Markers, Anemia)
Medium Volume, Complex Menu Performs from 250,000 to 999,999 Tests Per Year and is characterized by: STAT and non-STAT, high and low volume immunoassay capability plus esoteric testing. Probably requires secondary analyzers; little to no send out volume; capable of large outreach program; increased staffing requirements

High Volume, Basic Menu Performs 1,000,000+ Tests Per Year and is characterized by: Low Volume and/or STAT immunoassay capability (i.e. Cardiac, Thyroid, Drugs of Abuse, TDM); Probably does not have secondary immunoassay analyzers; high send out volume; no outreach
High Volume, Basic Plus Menu Performs 1,000,000+ Tests Per Year and is characterized by: Some non-STAT and/or low volume immunoassay capability (I.e. Fertility, Tumor Markers, Anemia)
High Volume, Complex Menu Performs 1,000,000+ Tests Per Year and is characterized by: STAT and non-STAT, high and low volume immunoassay capability plus esoteric testing. Probably requires secondary analyzers; little to no send out volume; capable of large outreach program; increased staffing requirements

| Menu/Volume Complexity Category	Universe Of Hospitals	Total Users of Laboratory Automation	Share of Lab Automation Users	Share of Universe
Low Volume, Basic	328	23	2.8	7.0
Low Volume, Basic Plus	1,146	24	2.9	2.1
Low Volume, Complex	282	6	0.7	2.1
Medium Volume, Basic	228	25	3.0	11.0
Medium Volume, Basic Plus	1,076	104	12.5	9.7
Medium Volume, Complex	648	100	12.0	15.4
High Volume, Basic	122	-	-	-
High Volume, Basic Plus	378	73	8.8	19.3
High Volume, Complex	970	477	57.3	49.2
Total	5,178	832	100.0	16.1

So, 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.

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.

Brand Shares of Current Automated Systems

Which manufacturers have made the most substantial inroads in laboratory automation? Beckman Coulter and Siemens lead the market in the total installed base of automated systems, as is illustrated in the pie chart.

With the exception of the closeness in rankings of Beckman Coulter and Siemens for automation, the status of each brand for automation closely resembles the ranking of manufacturer brands for clinical chemistry systems, according to the data published in the 2012 edition of Information Dynamics' Clinical Chemistry MARKET MONITOR™. In fact, over three-quarters of study participants admit that they would prefer to acquire automation systems manufactured by their general chemistry instrument vendor.

Brand Shares Of Current Automation Systems

Tecan 4% — Abbott 3% — Beckman Coulter 38% — Ortho 7% — Roche 16% — Siemens 32%
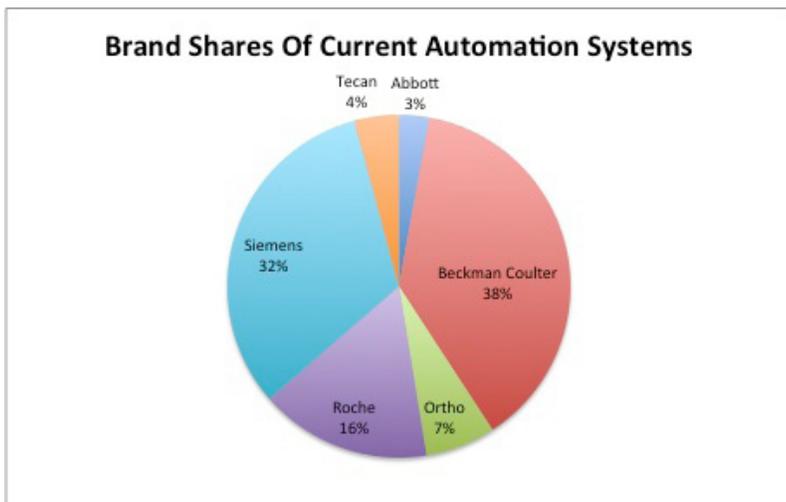
Identifying the Next Segment of Automation Adopters

The current status of the automation market data suggests that the message regarding the need for automation is coming though loud and clear to hospitals meeting the profile of:
- Large hospitals (400 beds or more)
- High volume of both general chemistry and immunoassay requests, offering a complex menu of a variety of tests, probably including some of the more esoteric tests

Assuming that most hospitals having a large bed size, relatively high test volume and fairly complex menu will eventually adopt automation, the next question that needs to be addressed is which market segments will be the next most likely adopters of automation? Based on those hospitals that have not yet become "automated" the following table illustrates that those most likely in the market for near term adoption are those having 100 or more beds. When comparing the results with the data reported two years ago, the share of anticipated automation near term adopters in the 100-199 hospital bed size category has nearly doubled.

Share of Automation Non-Users						
		Hospital Bed Size				
Anticipated Year of First Acquisiton	Total	<50 Beds	50-99 Beds	100-199 Beds	200-399 Beds	400+ Beds
Within Next 4 Years	30.5	21.4	23.6	41.4	39.9	50.2
Beyond 4 Years	38.0	37.0	50.9	32.1	34.6	22.9
Never	31.6	41.6	25.5	26.5	25.5	26.9
Total Current Non-Users of Automation	4,346	1,564	954	963	664	201

Which Brands Will be Selected for the Next Automation System?

Approximately 38 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 23 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 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
- Improved result turnaround time
- Increased employee productivity
- Improved employee satisfaction
- 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:

- STAT Prioritization
- Re-run, dilution and reflex and/or add-on
- Volume detection
- Decapping
- Pre-Analytical sorting

- Linked interface
- Specimen integrity check
- Automated input/accessioning
- STAT centrifugation

Share Of Accounts Selecting Each Brand As Their First Choice For Automation

Other 0%, None 3%, Abbott 10%, Beckman Coulter 23%, Ortho 12%, Roche 14%, Siemens 38%

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 two most frequently mentioned barriers to adoption include the fear of the need to remodel or significantly expand the laboratory's workspace and the cost of automation. Particularly within smaller hospitals, these are the primary deterrents to the adoption of 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 in order to be successful in expanding the market for automation.

The integration of automation within hospital laboratories is increasing steadily, albeit at a slow pace. 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.
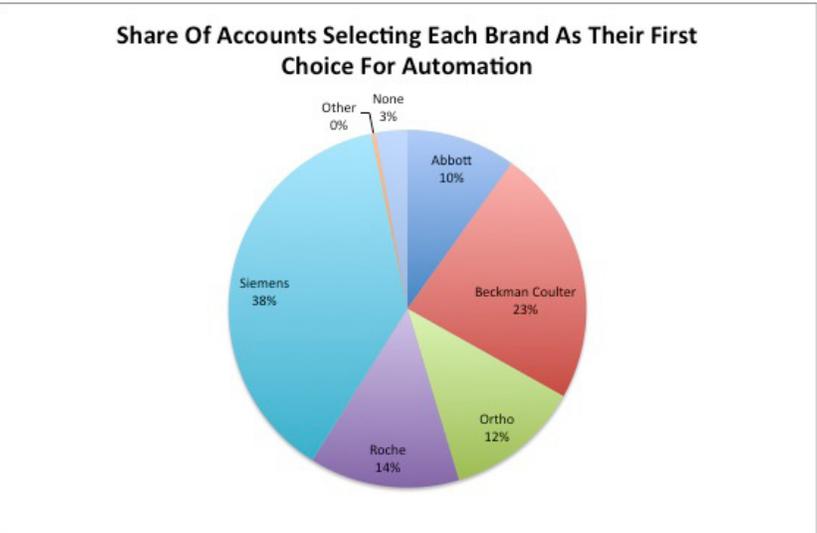
**For more in-depth information on the status of Laboratory Automation within the United States hospital laboratory market
Contact Information Dynamics to purchase the 2012 Laboratory Automation MARKET MONITOR™
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Information Dynamics is a marketing information development company serving manufacturers within the healthcare device and diagnostic markets. We are recognized as the most reliable and accurate company for tracking data among the major diagnostic instrument manufacturers.

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.