Pathology Partners

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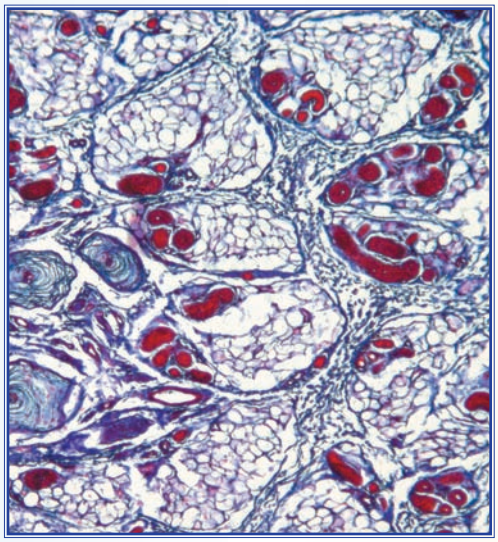
Leica MICROSYSTEMS

Telepathology: Revolution or Evolution?

By Doug Giszczynski, *Leica Senior Marketing Manager*

Many view telepathology as one of the next revolutionary steps in diagnostics workflow; that eventually and inevitably it will do the same for diagnostics as did teleradiology. While few doubt that telepathology is desirable, many wonder if the technology has advanced far enough for mainstream use.



While the principle philosophy is the same, improved workflow to facilitate rapid diagnosis and treatment of a greater number of patients, there are key differences between teleradiology and telepathology:

Specimen Types and Imaging Needs

The higher variability of specimen types and imaging requirements for pathology diagnostics can stress imaging systems designed for standardization and high performance under defined conditions of specimen preparation (thickness, stain, etc.).

a) Radiology diagnostic capabilities are well defined with a select group of tissue types that can be imaged and diagnosed with a standard set of imaging tools, e.g., x-rays and film. The technicians are skilled and can adjust the instruments until the desired image is obtained.

b) Pathology diagnosis encompasses a wide variety of diseases and disease states from all types of specimens, including tissue, fluids, and cells (both macro and micro images may be helpful in diagnosis).

c) By necessity, pathology diagnostics is often an iterative process that requires additional sections, slides, and staining techniques to be performed after review of an initial set of H&E slides.

d) Slide digitizers operate under a number of defined programs. Chances to improve image capture are limited.

Digital Image Data Volumes

There are no commercial slide digitization systems available today that can scan slides as quickly as they are produced in high volume

continued on page 5

Histology Automation and Laboratory Workflow: Is Automation Right for My Lab?

By Andreas Kaepplein, *Leica Marketing Manager*

Over the years, histology processes have evolved to enable the histotechnologist to produce finished slides more quickly than ever before in a safer environment. Today, technology advancements that promote histotechnologist health and safety play a big role, and automation is key in providing safety to laboratory personnel and higher throughput. Many of today's laboratories are contemplating the benefits of automation when it comes time to acquire new equipment. The following discussion is meant to highlight a few of the issues that laboratories take into account when facing this decision.

Lack of Workers

The number one issue facing histology laboratories is the lack of registered histotechnologists/technicians. NSH provides educational opportunities for people interested in the histology profession and actively looks for ways to make the histology laboratory a desirable place to work in order to elevate the histology profession and foster the career advancement of certified histotechnologists/technicians. One main way of addressing this personnel shortage and making the laboratory a safer and more attractive place to work is the implementation of automated solutions.

Rapid Diagnosis

The increasing demand of rapid diagnosis directly impacts workplace health and safety because of the repetitive or awkward motions that can occur during manual workflow and the exposure to hazardous chemicals. Automating processing, slide and cassette

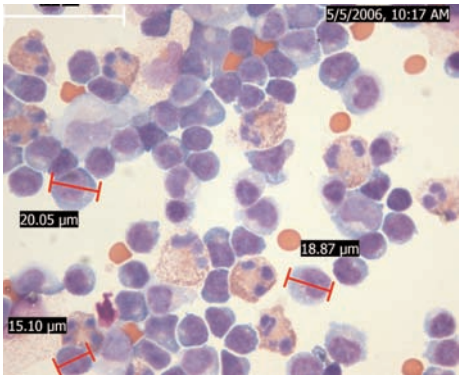
continued on page 6

Contents

Digital Imaging Part 1– Calibration and Digital Measurement

By Rob Kimura, *Leica Product Manager, Digital Imaging*

Image measurement is the discipline of taking quantitative data from an image for the purpose of documentation or analysis. In order to accomplish proper measurement, the microscope, camera, and measurement software must be calibrated with a consistent unit of measure and distance. This applies whether a manual or an automated microscope is used. Having the microscope, camera, software, and the fastest computer does not guarantee accurate measurement results. Only correctly calibrating the system insures accuracy.



Blood

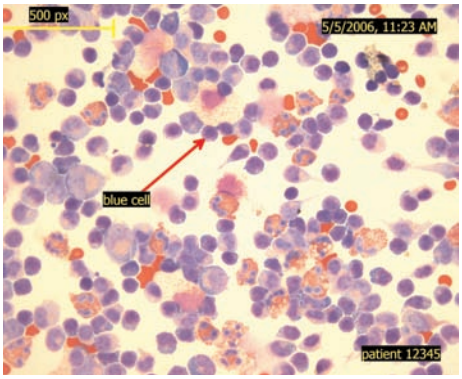
There are two methods of measurement calibration:

- Manual Calibration (most common)
- Automated Calibration (usually requires an automated microscope)

Manual calibration requires a microscope, camera, measurement software, and a stage micrometer.

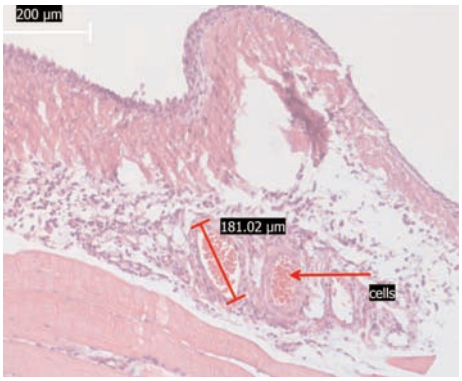
To calibrate a manual system, follow these steps:

1. Place the stage micrometer on the microscope.
2. Take a picture of the stage micrometer, write down the objective magnification and magnification changer setting (if used).
3. Open the acquired image in the measurement software and select the calibration mode. All measurement software has a manual calibration mode.
4. The software will prompt for the unit of measure to be calibrated.
5. Then move the caliper markers over your image. With these caliper markers, measure a known distance from the stage micrometer picture that was just acquired.
6. As you move the caliper markers around the screen, the computer tracks the distance between the two markers by pixel counts; the larger the distance, the greater the pixel count. Once the markers are adjusted to correspond to a set distance, the software asks for the distance to be entered.



Cells

This process is required in both the X and Y axes. However, many cameras now use square pixels in their chips, so the unit of measure for X should equal the unit of measure for Y. For example, if the Y axis is 353 pixels = 1mm, then the X axis is 353 pixels = 1mm. If you are unsure whether or not your camera has square pixels, consult the camera manufacturer. Once the proper X and Y calibration is established, save the results in a chart, and be sure to indicate the magnification used. Follow this process for every magnification scenario used to acquire pictures. Once calibrations are complete, you can begin measuring.



Tissue

(Images: Alan Vitous, Leica Microsystems)

Note: Some software offers an auto calibration mode to acquire pictures. On a manual microscope, the software will ask the user, once the image is acquired, to indicate which calibration magnification to use. Other software requires selection of the calibration magnification in the measurement program. Either way, the process of selecting the right calibration setting is essential. Once you have properly selected the calibration, you can measure the areas of interest.

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Next issue: Using Automated Calibration Systems

Leica Adds Value with First Customer Kaizen

By Pam Jandura, Leica Marketing Specialist

The kaizen team (led by Leica North America President Hank Smith, Vice President George Kennedy, and Marketing Manager Jan Minshew, observe and measure steps in the workflow

Kaizen (Japanese for "change for the better" or "improvement" is an approach to productivity improvement originated by Japanese manufacturers after World War II. The goals of a kaizen include the elimination of waste (defined as activities that add cost but do not add value), just-in-time delivery, production load leveling of quantity and type, standardized work, paced moving lines, and right-sized equipment. Kaizen is a tool that Leica Microsystems' uses as part of its global initiative for continuous improvement, to humanize the workplace, eliminate hard work (both mental and physical), and to teach people to see and eliminate waste in business processes.

Leica Microsystems completed its first Value Stream Mapping (VSM) customer kaizen at Brigham and Women's Hospital in Boston, MA in May 2006. The VSM provided the surgical histology laboratory with a plan to reduce laboratory cycle time by 24%. The kaizen team also identified opportunities to automate the laboratory's current manual operations and reduce laboratory error during the 3-day event. A customer VSM gives Leica the opportunity to understand a customer's spoken and unspoken needs, to help a customer improve workflow, and to find out how Leica's next generation products can meet their needs.

Through participation in the VSM, Leica customer Kathy Mitchell, Technical Director of Surgical Histology, hoped to identify waste in her laboratory's processes, reduce inventory (specimens, tissue blocks, and slides), and flatten workload to gain efficiency. Skeptical at first, Mitchell felt that the VSM model, which to her sounded like a manufacturing tool, could not be applied to laboratory processes. Nevertheless, Mitchell and her team welcomed and supported the kaizen and were forthcoming with information. Mitchell comments, "It is hard to believe that a company would invest the time to come in and help us identify our opportunities to become more efficient."

Brigham and Women's Hospital, affiliated with Harvard Medical School, is an 800-bed hospital that has been listed among the prestigious *U.S. News and World Reports* "America's Best Hospitals" for many years. The surgical histology laboratory processes 900 tissue blocks and 1850 slides per day. The team studied the process from the arrival of specimens into the grossing area to the end of the process; the organization of slides by case into trays for delivery to pathologists for diagnosis. They observed one notable bottleneck that occurs at 3:00 a.m. when all of the specimens are removed from the many Leica ASP300 tissue processors that must be made into blocks for sectioning. "Identifying bottlenecks helps Leica to develop products that address specific problem areas," explains George Kennedy, Leica North America VP of Sales and Marketing–Pathology Diagnostics.

"At the end of the VSM, we reported the current state and the future state maps to the customer," says Jan Minshew, Leica Marketing Manager. The team accurately defined the sequence and timing for all of the histology laboratory steps, and identified eight opportunities to streamline the observed process. Minshew continues, "In the case of a customer VSM, we simply provide suggestions and encourage implementation. The Brigham and Women's laboratory staff were intrigued with the process and found it a valuable exercise."

The team also showed laboratory staff how the integration of automated bar code labeling on a cassette could automatically generate labeled slides with a single scan of a bar code. Printing directly onto slides reduces entry and labeling time, eliminates the necessity to generate and apply paper labels and removes a source of human error. "We are confident that Kathy Mitchell and her team will implement this high level action," says Kennedy. Leica will continue to follow up with the customer to find out which of the eight suggestions will be implemented. "It is amazing that this process reveals the things we have been doing unquestionably for years that may not be necessary," comments David Bowman, Assistant Laboratory Manager.

"This is an exceptional data view of our process," says Mitchell. "Most companies just develop products and throw them at customers in hope that they are a good fit." Leica intends to repeat customer VSMs globally to provide value to customers and help develop next generation product strategy. "We learned that the VSM is absolutely applicable to mapping the processes in a histology lab," sums up Kennedy. "I believe that it is a value-added service that we can use to identify opportunities for laboratory automation and eliminate waste for our customers."

Ask Mari Ann . . .

Dear Mari Ann,

The number of biopsies coming to our lab has steadily increased over the past few years. Our pathologists put a lot of pressure on us to provide the finished slides faster. Do you have any suggestions on how we can cut our processing time for biopsies? Also, is there a way to process our regular tissue faster on the ASP300 tissue processor? – *Pressured in Pennsylvania*

Dear Pressured:

The first thing you can do, if you have the luxury of having two processors, is to dedicate one processor to biopsies. Fix specimens off the processor for a few hours, providing the specimens are no bigger than 2mm. You can schedule a program on the processor to start with 70% alcohol. All stations can be set for a time of 10 minutes.

You can also use a small, countertop, laboratory-grade microwave to fix the biopsy specimens and then place them on the tissue processor with larger specimens and process them that way. I recommend fixing your larger specimens on the microwave also and then placing the biopsies and large specimens together on the processor. This way you will be assured of good fixation for both. You could then reduce the processing protocol to 30 minutes per station. The above process only works if your specimens are no bigger than 5mm. Specimens should never be bigger than the cassette itself because they will not fix well or be properly dehydrated and infiltrated. Fixation is one of the keys to getting proper processing; specimens must be fixed well.

Sincerely yours,
Mari Ann

Thank you for your question.
Please send your questions to Mari Ann at:
pathologypartners@leica-microsystems.com
Mari Ann Mailhiot, BA, HT(ASCP), Leica product application specialist with over 37 years of experience in the field of histology, will choose one question to answer each issue.

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Upcoming Events

Workflow, Automation, and Patient's Safety
Cerner User Group Meeting November 6-7, 2006, Waltham, MA

American Society for Mohs Surgery
November 8-12, 2006, Sheraton Hotel, San Diego, CA

To find additional exhibitions Leica will attend, visit:
www.leica-microsystems.us and click Company → Events.

Rising to Greater Heights

By Andreas Kaepplein, *Leica Marketing Manager*

NSH Career Day

The 32nd annual symposium/ convention of the National Society for Histotechnology in Phoenix, AZ was held under this year's NSH motto 'Rising to Greater Heights'. As one of the largest booths at the show, which received high marks from our visitors, Leica Microsystems SSP proudly introduced the new ASP300 S tissue processor with RemoteCare™ for real-time, remote diagnostic and service support. The ASP300 S is the successor of the ASP300 tissue processor and features state-of-the-art technology, improved reliability, and last but not least, high-quality processing results and user comfort. Leica Microsystems was a contributor of personnel and equipment at the first annual NSH Career Day for high school students. Students from the greater Phoenix area had the opportunity to meet with histotechnicians and students of the local histology programs to discover the science of histology. After preparing samples, the students then viewed their slides using Leica DM1000 microscopes, captured images of their slides with a Leica DFC420 digital camera, and then took the pictures home.

Students had a chance to get some hands-on experience with Leica microtomes and cryostats at NSH Career Day

Top photo courtesy of Linda Jenkins, HT, Clemson University, Department of Bioengineering.

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www.leica-microsystems.us
Click on "Find Your Local Sales Representative"

Telepathology: Revolution or Evolution?

continued from page 1

histology laboratories. Current communication networks often struggle with the digital image file sizes.

a) Radiology diagnosis is usually performed on a small set of black and white images, and digitizing results in comparatively small data sets that are easier to manage over a LAN network or internet connections.

b) Pathologists routinely review a series of color slides with amazing rapidity and accuracy. To achieve this, they must have a lower magnification scanning view, high magnification for regions of interest, and the ability to "focus through" thicker or unevenly sectioned specimens.

To achieve similar capability, slide digitizers would have to make multiple scans of the same slide and compress images for transmission, but the image would still likely contain terabytes (1000 gigabytes) of information. Typical computers and networks would struggle to manage this much data.

Integration

There are currently a variety of information systems employed by U.S. medical facilities.

a) Teleradiology systems integrate well with existing laboratory information systems to facilitate convenient data communication, storage, case tracking and procedure billing.

b) Most slide digitizers are not yet integrated and do not provide such benefits.

Financial

U.S. medical facilities need to be financially viable and medical testing costs need to be reimbursed. Any changes in workflow that require additional costs must result in those costs being offset by billing, efficiency improvements or both. Financial viability is well documented for teleradiology and is clearly the goal for telepathology, but ROI studies with convincing results are still lacking.

a) The biggest problem so far is that the digitization is an additional step and does not replace the need for any of the current steps. We still need stained slides and need to store them after diagnosis. And the transportation of slides by courier is relatively inexpensive.

b) The digitizers cannot process all stained specimen imaging requirements so the pathologists' microscope is still required. And if the pathologist orders additional sections to be cut or stains applied, he or she will still have to wait (probably longer) for the results.

c) With slide digitizers ranging in cost from ~$35,000 to over $100,000, purchasers must be sure that the system will meet their expectations. Most slide digitizers today are used for reporting, archival, and educational purposes.

Evolution

Through speaking with healthcare professionals about telepathology, Leica has learned that what is really needed is an easy means to consult with colleagues, document results, and communicate diagnosis to others; a device that provides the advantages of a digital format with the flexibility of a traditional microscope. What they describe is an intermediate step between a traditional microscope and a slide digitizer; more of an evolutionary rather than a revolutionary step.

Leica strives to uncover and successfully address the needs of customers. From the valuable feedback we have gathered, Leica incorporated microscope, camera, and PC into a compact device that answers the needs of the pathology market as described in the previous paragraph. The new digital device uses an integrated CCD chip to generate high-resolution digital images with brilliant color fidelity and then displays the images on the integrated LCD screen. A Linux-based computer facilitates rapid acquisition of digital images that can be annotated, e-mailed to colleagues, saved to a network drive, and incorporated into a report or presentation. The large format LCD screen facilitates consultation and resident training, and the data projection port provides a new level of convenience during tumor board reviews. The new product, the Leica DMD108, has been well-received by the pathologists that have seen and used it and, due to the ergonomics of the device, they have said that they "feel better at the end of the day". Leica would like to have your opinion, too, and would be happy to demonstrate the device for you.

For more information click on the link below:
www.leica-microsystems.com/DMD108

Histology Automation and Workflow

continued from page 1

labeling, embedding, sectioning, staining, and coverslipping creates a safer workplace and is also cost-effective from both a labor and operational expense point of view.

What Kind of Automation is Available?

Consider microtomy. In comparison to manual microtomes used in the mid 1980's, automated microtomes represent a giant leap of innovation. More and more histology laboratories automate manual processes to save time and prevent repetitive motion disorders. Automated technology reduces health and safety risks and user error. For example, laboratory automation can prevent repetitive motion disorders such as carpal tunnel. Automation also keeps hazardous material and fumes away from the technician. When manual tissue processing was done in the past with non-enclosed systems, the technician was directly exposed to hazardous materials and fumes. Today's automated tissue processors, stainers, and coverslippers greatly reduce this exposure to hazardous materials.

Automation also improves turnaround time and the quality of results. While automated instruments significantly speed up workflow, they also save cost by reducing manual labor while improving quality due to the elimination of user error. An automated instrument like a motorized microtome always cuts with the same force through any specimen no matter how hard it is, which results in high quality, reproducible sectioning.

As well, automated staining assures uniform quality and intensity by exact incubation times, as opposed to hand staining where there can be inconsistency. Leica's "open" automated staining instruments deliver reproducible results and offer the user the possibility to adjust the staining intensity to a pathologist's needs by adjusting incubation times. The "open" approach also gives laboratories the freedom of choice to use the reagents or consumables of their choice, which can save money.

Integrated Workstations

Faster turnaround time is currently the main driver for automation in today's histology laboratory. Leica Microsystems was the first company to introduce the workstation approach and was the first to integrate two automated systems to create a hands-off staining/coverslipping workstation. The histology laboratory of the future will consist of integrated workstations interfaced with LIS systems, resulting in less user interaction, shorter turnaround time, high-quality results, and a healthier, safer work environment. As well, future automated laboratories will provide higher revenue because of increased workflow.

Cost/Benefit Analysis

When assessing the move from manual to automated histology processes, conducting a cost/benefit analysis of automation vs. manual work steps will help to make the decision. This evaluation provides a strong foundation for laboratory administration to approve appropriate funding. Any cost/benefit analysis should reveal potential labor savings as well as consumables savings and consider the benefits of reduced health issues and increased safety that automation can bring to a laboratory. Expert support and service are always considerations, as well.

How do we get started?

The first step into histology automation is usually the acquisition of a tissue stainer, or better yet, an integrated staining/coverslipping workstation. Microtomy automation is also growing and already well-accepted among histologists. The histology laboratory of the future will be driven by the need for rapid diagnosis, health and safety for laboratory personnel, as well as by the national shortage of trained histotechnologists. Future laboratories will combine integrated workstations with LIS systems. Less technologist interaction with specimens, higher-quality results, shorter turnaround time, better protection of the health and safety of laboratory personnel, and higher revenue will be key in making the decision for automation.

We find that histotechnology professionals already embrace automation. Histotechnologists/technicians take pride in what they do. Their work saves lives, and they realize that higher quality results better serve patients. A large percentage of Leica's customer base has at least one automated instrument in the laboratory. Automation does not yet eliminate every manual step, but this is where Leica sees an obligation and an opportunity and accepts the responsibility to help histologists do an even better job of delivering fast, precise, high-quality results in the future.

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