

Introduction

Almen Labs is committed to creating pioneering imaging software solutions customizable to a variety of biomedical markets. The company is a leading developer and supplier of comprehensive, easy-to-use and highly innovative software applications, capable of assisting and advancing productivity of image and data processing, computer-aided detection ("CAD"), diagnostic imaging support and image retrieval for a variety of customers and markets. The Company's flagship product is *Image Companion*®, that enhances, filters, sharpens and profiles digital images or Regions of Interest ("ROI") within digital images, as well as detects, counts, measures and searches objects for similar to selected template(s) object(s) or even template image. While equally successful in application to a variety of different types and modalities images, all processing and analysis is independent of the image sources. Enabled with non-scripting Macro Libraries capability and batch processing, this simple-to-use Windows95/98/NT based software facilitates computer-aided detection, "second reading", and biomedical information retrieval automation at the same time reducing operating costs, improving analytical accuracy and easy user barrier to complete automation in clinical lab and hospital information system environment. The company has developed a fully functional statistical package to simplify and at the same time advance post-processing of exported numerical results of image analysis and CAD. All software can be modified to be used in mobile computer configurations, real time imaging and is OEM ready due to its robust framework, detachable user interface, compact size and optimization for speed of performance. The first phase of Internet deployment is complete. The components for use in ASP model are available.

Pioneering example - a conceptual overview of unique image retrieval by-the-content capability

Almen Labs has developed and filed a patent application for its' image-retrieving system that enables search and indexing of desired images in a database. A storage device in the database or dedicated directory stores a plurality of images, additional information for identifying each of the plurality of images and calculated feature data for identifying each of the images. The developed software system inputs additional informational data for identifying a desired image stored in the database. The system selects a first set of candidates as the desired image by comparing the input unique processing information with the stored needed information for each of the stored set of images. The system enables input of a template image or certain elements of the image and then generates output based on the feature data from the input template image. A search or indexing method selects as the desired image one of the candidates whose stored feature data is most similar to the generated feature data of the input template image or its certain components. The system and its core technology may be advanced and enhanced to allow a user specific method for generating a semantically based, linguistically searchable, numeric descriptor of a predefined group of input images. For example, data for an annotation or image number/index can be computed for each image in a set using multi-level iterative convolution filtering, sharpening and segmentation with threshold values supplied as input to each filtering level or calculated automatically. Average and variance vectors, such as collective numeric parameters of all the images in the set, are separately computed across corresponding elements in all the image components for the set. For image retrieval, the descriptor for any set may be then accessed by a textual search through the database using the appropriate linguistic term of the hosting information system. The descriptor is then compared against the accessed feature structures or components for other images in the database in order to index an image, among those stored in the database, that is the most similar to those in the set associated with the template.

Image Processing Functionality Overview:

Preprocessing

- LUT/Enhancing/ROI
- Filtering/Edge Detection
- Sharpening/Dilation
- Editing/Calibrating

Look-up Table Linear, Saw-tooth or Histogram-type transformations allow Inversion, Binarization, Piecewise Contrasting and Histogram Equalization functions to be applied to an entire image or region-of-interest ("ROI"). Sharpening and Filtration functions provide different kinds of Laplacian and Gaussian linear and non-linear, low and high pass filters (variable and fixed kernel dimensions), edge detection and dilation, shading, median filtration with an editable convolution mask and instant preview of transformation in ROI. Customize masks can be saved and retrieved.

The system has a unique preprocessing visualization system when the form and the results of each transformation can be viewed on the same computer screen in real time.

Processing

- Manual Segmentation
- Automatic Single Threshold and Multi-threshold Segmentation
- Measuring/Sorting
- Profiling
- Histograms/Stats

Manual and automatic feature sets: Manual regime of image segmentation through histogram input and shift correction, smoothing control and threshold selection; or automatic regime for "one-button," batch processing. Other features include measurement of objects, statistical analysis, sorting and classification, histogram of statistics, image profiling and calibrating (metric units).

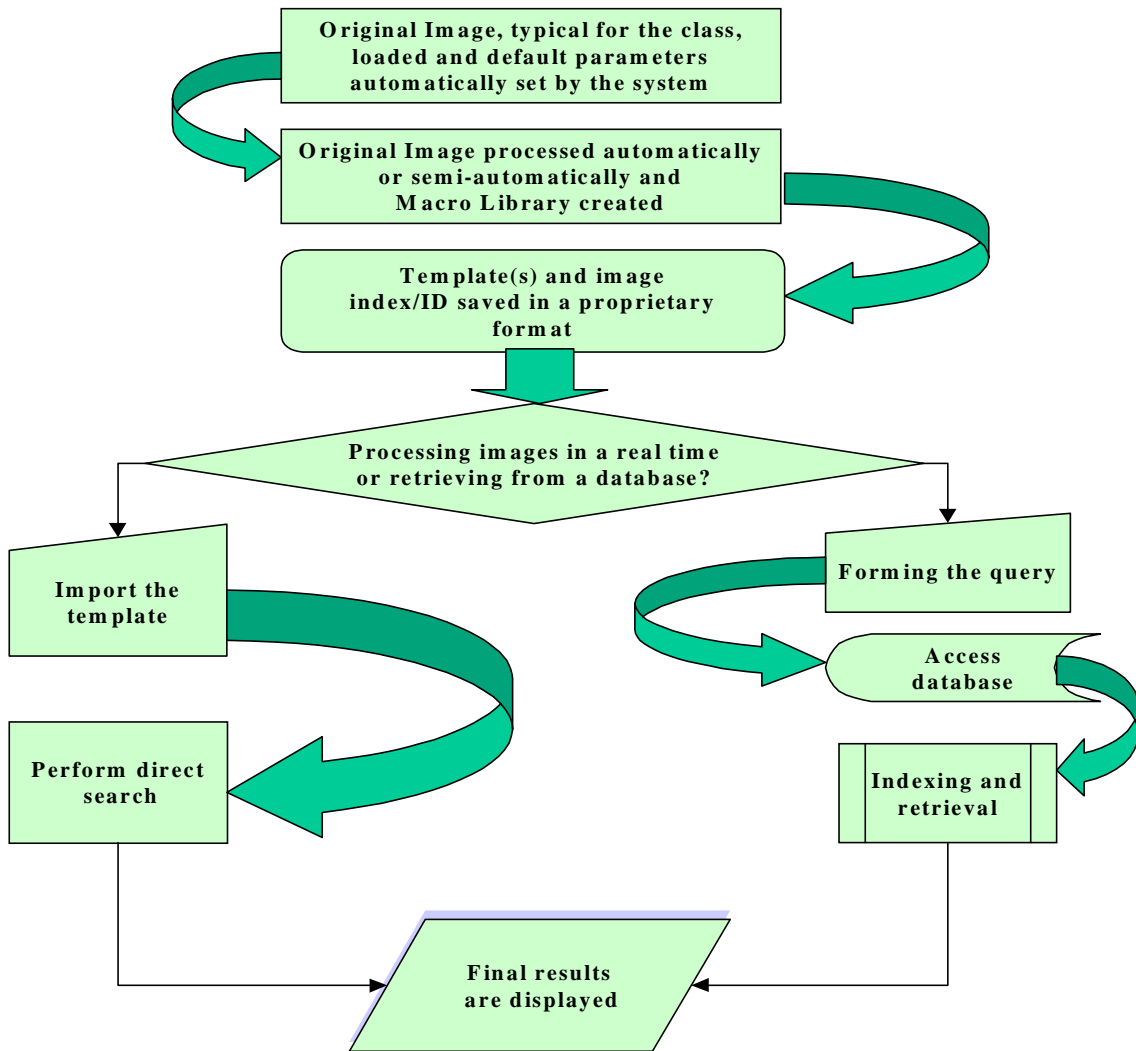
Postprocessing

- Search for object(s) or image(s), including Search with Multi-component Templates
- Import/Export templates
- Single-component and Multi-component Template Support
- Generic Export to Excel or other wordprocessing application
- Macro Library processing and support

The software offers unique search-for-objects capability with the ability to save templates or to import pre-existing templates for search. System supports single-component or multi-component template search.

Functionality includes macro capability (including Library creation, Group Macro and batch execution (no scripting required for Macro creation or execution)), export to Excel or any other desktop application, and generic export for mathematically unique statistical analysis.


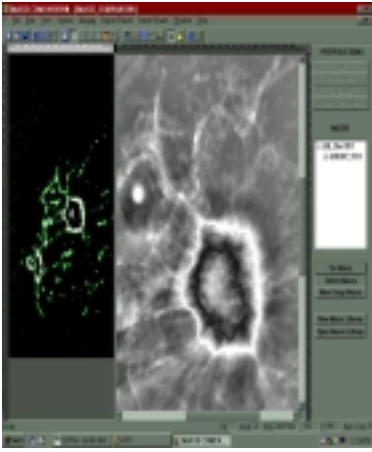
Conceptual Diagram¹ of developed search and retrieval method²



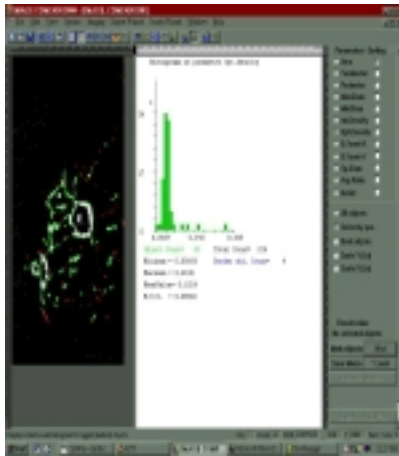
¹ Patent pending.

² The company does not develop or support database access methods. However the software is fully modular and can be embedded into a DBMS or information hosting system such as HIS/LIS or PACS through standard APIs.

Benchmark Results on a sample radiological image³

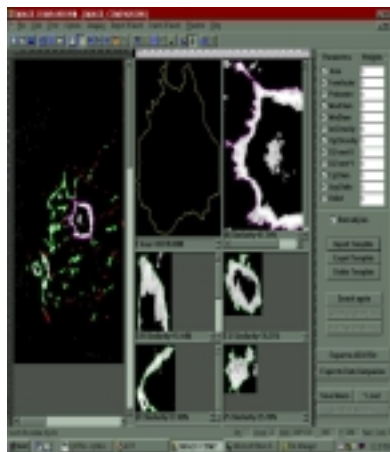
<i>Name of the screenshot result file</i>	<i>Description of the screenshot</i>	<i>Comments</i>
	<p>Original image is acquired and loaded</p>	
	<p>Original image loaded, preprocessed, segmentation and object detection are completed. Area of interest is automatically identified, marked and enhanced for verification. Macro Library is saved.</p>	<p>It took approximately 7-8 minutes for inexperienced non-medical operator to adjust for accuracy automatically calculated by the system default user parameters</p>

³ **Please note that none of the internal, system, algorithmic or user set of parameters were tailored or adjusted to the given class of images.**



General statistics for all identified objects is calculated, numeric filters to sort out erroneous or useless objects are set and applied. Macros are added to the Macro Library.

It took approximately 3-4 minutes for inexperienced non-medical operator to set and apply numeric filters to sort out erroneous or useless objects



Search with imported template from different mammography case is performed and results are displayed. Similarity index is calculated.

According to the search results the system has automatically identified some dense tissue area next to the nipple as the closest match to the stored template. The correctness of the results is verified by medical practitioners⁴.

⁴ The results of *Image Companion*® accuracy and applicability to different modalities are verified by independent sources in application to mammography, ultrasound, microscopy and some cases of CT. Some results of suspicious area detection for breast ultrasound are considered to be unique by independent medical institution.

Conclusions

1. Almen Laboratories, Inc. has a developed software system, which enables the user to highly automate image processing and search/retrieval for different classes of images.
2. According to our beta sites⁵ radiologists the mammography benchmark results have proven applicability and viability of the approach and technology in different radiological cases.
3. This break-through result should be taken in light of the fact that none of the internal system, algorithmic or user set of parameters were tailored or adjusted to the given class of images. The benchmark used only one template and one Macro Library created from the file with no adjustments to different geometries, densities or other morphometric or textural parameters of the targeted objects and areas of images.
4. The same core technology and processing functionality are equally successful with other medical applications such as MRI, CT scans, ultrasound images with distinct objects or areas, etc.

⁵ **UCSD Medical Center, La Jolla, California** – one of the leaders in Hospital Information Systems, Radiology and Ultrasound; **Veterans Administration Medical Center, San Diego, California** - clinical base for product validation and known leader in ultrasound image processing and analysis; **Tri-City Hospital Ultrasound Lab, Vista, California** - one more clinical base and testing facility for product validation; **Crump Institute for Biological Imaging, Imaging Science Division, UCLA School of Medicine, Los Angeles, California** - one of the nation's leading medical imaging research institutions; **Beyond Basic Imaging, Inc. Vascular Lab of the Anaheim Hospital, Anaheim, California** - a recognized leader in vascular testing and diagnostic imaging