Another Set of Eyes: Machine Vision Automation Solutions for In Vitro Diagnostics

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Outline

- Microscan at a Glance
- In Vitro Diagnostics Market Introduction
- Machine vision system development
- Key Challenges
- Lessons Learned
Founded in 1982 and a Spectris company since 1995

100+ technology patents

Our technology focus today ranges from precision barcode reading & verification to complex vision inspection.

Our products boost manufacturing efficiency and quality control.

We help customers reduce costs, monitor quality, and increase production flow.

The healthcare industry is a key focus, where standardization and automation reduce error rates and allow for higher throughput.
In Vitro Diagnostics Market
In Vitro Diagnostics Overview

- In Vitro Diagnostics (IVD) is a subset of the medical devices market focused on providing a means to diagnose medical conditions and diseases
  - Clinical Chemistry – bodily fluid analysis
  - Immunoassay – detect/measure a molecule
  - Molecular Diagnostics – analysis of genome
  - Point of Care – testing near the patient
  - Laboratory automation systems
• ~$50B global market
• >5% growth expected over the next 5 years
• Double digit growth in China
Automation in the Clinical Laboratory

• Technical advances and standards development allowed for the rapid adoption of automation in the laboratory setting
• Higher throughput and results turnaround
• Reduce Error Rates
  • Error rate for automated devices < 1 in 3,000,000
  • Error rate for human operators ~ 1 in 300
• Streamline and Standardize Tasks
  • Log sample ID and other information
  • Communicate with equipment to initiate additional processes
  • Enable traceability of samples throughout analysis
Machine Vision System Development
Machine Vision Migration

Performance  Ease of Use  Size  Price

Time

Identification  Inspection  Measurement  Guidance
Machine Vision Applications

Must Have Clear Understanding of Requirements Upfront
Product Challenges & Questions to Ask

1. Lack of tight dimensional control
   • Are system level specifications available?
   • Are design changes still an option?

2. System must exceed a 1 in 10,000 error rate
   • What are use cases … acceptance criteria?
   • How do we know when we are done?

3. Any failures must “fail safe”
   • What should response be on a failure?
Measurement and analysis vision tools need a robust method to locate regions of interest

Need consistent lighting for absence/presence and color applications

**Solution 1:** Calibration method for positioning and grayscale

- Discuss tradeoffs of potential options
- Clear understanding with customer that changes, however small they might seem, are not to occur without testing the vision system
Challenge 2: System Reliability

- Understand what consequence a system error may have
  - Manual intervention – $
  - Missed/Incorrect testing – $$
  - Instrument damage – $$$
  - Misdiagnosis – $$$

- Discuss how you will determine the reliability and design for it

- Agree on who is responsible for each phase of the testing
  - Error rate cannot be accurately measured without a large image set for development and testing
Image Library

• **Solution 1**: Collaborate with customer to build an image library that can be used during development and future testing

• Agreement on who is responsible for collecting images, owner of the images, data sharing methods, timeline, cost

• Include all valid test cases, as well as common error cases
  - Labels too high/low, poor print, missing tubes, caps, labels
  - Collect images across multiple instruments and cameras

• Define image naming convention – must know what image is without opening each up
• Customer Example
  • Large IVD instrument manufacturer
  • Analysis of test tube size, type, cap color, label data
  • 70,000 image in library, expect 100,000 when complete
  • Every change checked against full image set
    • Vision inspection improvements
    • Customer design changes
  • >24 hours each iteration across multiple cameras
  • >1 year for development and testing
Challenge 2: System Reliability

• **Solution 2:** Design in features to support the testing process

• Smart camera has been programmed to receive images from a host PC in addition to capturing locally

• Custom code on camera to check output is valid
  • Camera output is XML – data check confirms the combination of image analysis measurements is a valid use case
  • Test software developed for PC also validates the XML is correct and verifies the results against image name
Challenge 2: System Reliability

- **Solution 3:** Use of statistics and visualization methods to track performance
  - Use of a confusion matrix to show performance at each iteration

![Confusion Matrix](http://www.dataschool.io/simple-guide-to-confusion-matrix-terminology/)

<table>
<thead>
<tr>
<th>Actual:</th>
<th>Predicted:</th>
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Challenge 3: Fail Safe Design

• Unlike some applications, a vision system for healthcare cannot guess

• Incorrect diagnostic testing could occur, or equipment downtime due to equipment damage
  • Downtime unacceptable in clinical laboratories analyzing important patient samples, some of which are time sensitive

• **Solution**: the machine vision software starts with the “safe” assumption until proven otherwise
  • Example: sample tube always reported as being capped until image analysis can prove otherwise, to prevent equipment damage
Lessons Learned
Lessons Learned

• Open communication and agreement on design and test strategy required up front

• Documentation of all possible use case combinations
  • If scope increases, revisit to determine if additional design/test needed

• Define the workflow for each use case including potential error situations

• Develop a naming convention early with all use case details in the image name

• Run long term projects like a program with milestones and regular program meetings and reviews
Resources

- https://www.embedded-vision.com/applications/medical
- FDA In Vitro Diagnostics Overview: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm
- Clinical and Laboratory Standards Institute: http://clsi.org/
Backup Material
Complete line of high-performance, precision technology to meet any need to acquire data, verify data and part quality, and control automated operations.

<table>
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<th>Machine Vision</th>
<th>Auto ID</th>
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<tr>
<td>Inspection &amp; Measurement</td>
<td>Barcode Traceability &amp; Off-Line Verification</td>
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<td>Lighting</td>
<td>Solutions</td>
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<tr>
<td>Enabling Readability</td>
<td>Engineered &amp; Industry Focus; Off-Line &amp; In-Line Verification</td>
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FEATURES

- Total scalability from integrated solutions to PC-based components
- Feature-rich machine vision software platforms
- Broad range of capabilities, including identification, inspection, measurement, and robotic guidance
- Gigabit Ethernet software and compact cameras
- Extensive collection of image processing tools and powerful GUI
**MicroHAWK® Platform**

**MicroHAWK** is a modular family of auto ID imagers and machine vision smart cameras engineered to be the world’s smallest, most intuitive, and most powerful devices in their class.

Simply Incredible.