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

MICROSCAN®

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Outline

- Microscan at a Glance
- In Vitro Diagnostics Market Introduction
- Machine vision system development
- Key Challenges
- Lessons Learned

Microscan at a Glance

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

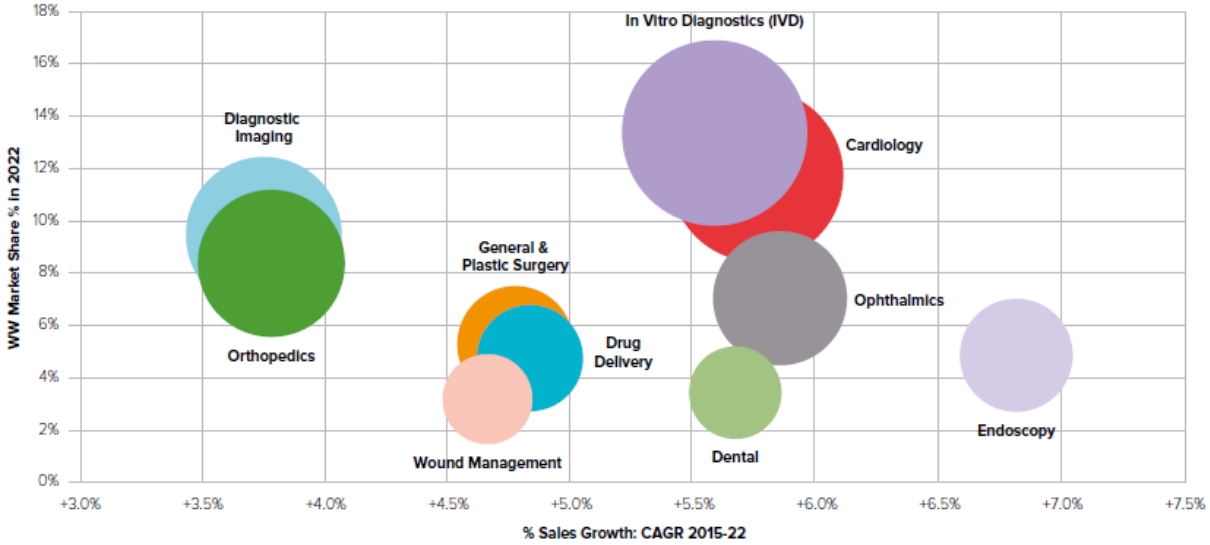
In Vitro Diagnostics Overview

- 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

In Vitro Diagnostics Overview

Analysis on Top 10 Device Areas in 2022, Market Share & Sales Growth (2015-22)

Source: EvaluateMedTech® September 2016



Note: Size of Bubble = WW Sales in 2022

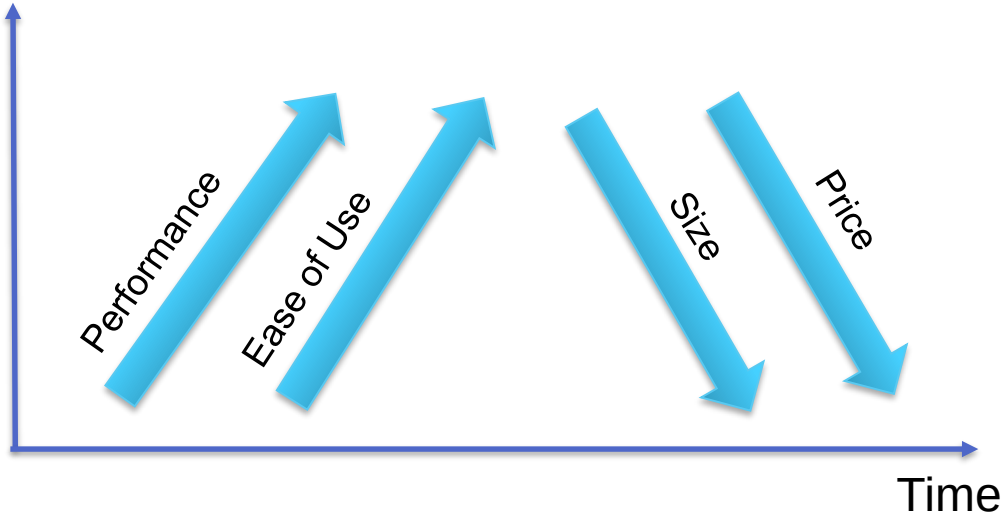
- ~$50B global market
- >5% growth expected over the next 5 years
- Double digit growth in China

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

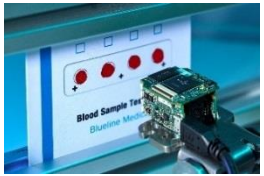
Machine Vision System Development

Machine Vision Migration



Identification → Inspection
Measurement
Guidance

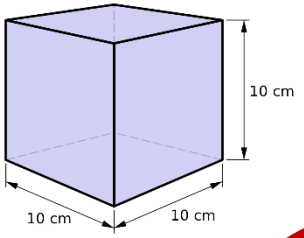
Machine Vision Applications



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?

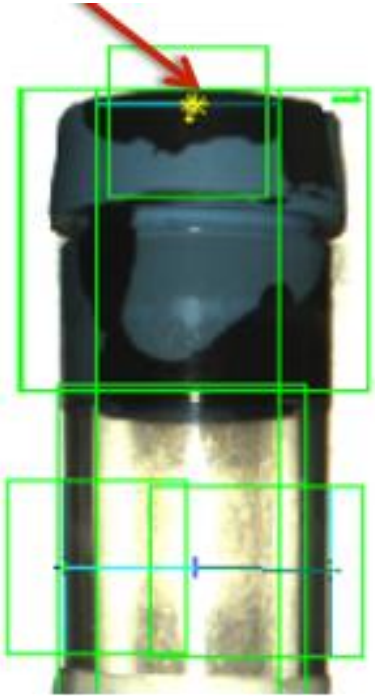


2. System must exceed a 1 in 10,000 error rate
   - What are use cases … acceptance criteria?
   - How do we know when we are done?

3. Any failures must “fail safe”
   - What should response be on a failure?

Challenge 1: Position Tolerance

- 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

Image Library

- **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

n=165	**Predicted: NO**	**Predicted: YES**	
Actual: NO	TN = 50	FP = 10	60
Actual: YES	FN = 5	TP = 100	105
	55	110	

Image source: http://www.dataschool.io/simple-guide-to-confusion-matrix-terminology/

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
- http://www.microscan.com/en-us/products/machine-vision-systems
- Evaluate Group MedTech Outlook: http://www.evaluategroup.com/public/Reports/EvaluateMedTech-World-Preview-2016.aspx
- FDA In Vitro Diagnostics Overview: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm
- Clinical and Laboratory Standards Institute: http://clsi.org/
- Data School Simple Guide to Confusion Matrix Terminology: http://www.dataschool.io/simple-guide-to-confusion-matrix-terminology/

Backup Material

Microscan Products and Solutions

- Complete line of high-performance, precision technology to meet any need to acquire data, verify data and part quality, and control automated operations

Machine Vision

Inspection & Measurement

Auto ID

Barcode Traceability & Off-Line Verfication

Lighting

Enabling Readability

Solutions

Engineered & Industry Focus; Off-Line & In-Line Verification

Machine Vision: Inspection, Measurement, Guidance

Integrated Smart Cameras

Machine Vision Software

GigE Solution

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.