

Mastering AVI

Part2: Introduction to technical principles of automated inspection machines

- Camera systems / light / motion
- Image processing and database system
- Interlinkage of parameters:
 Speed, Rotation speed, Inspection parameters,
 - Detection probability, False reject rate
- Properties, capabilities and limitations of automated inspection systems
- Scope of Automated Visual Inspection Critical design elements



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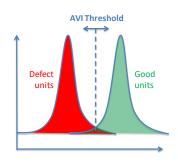




Mastering Automated Visual Inspection

Part 2: Introduction to technical principles of automated inspection machines

- Process / People to master AVI
- Functionality of automated inspection machines
- Camera systems / light / motion
- Image processing and database system
- Interlink age of parameters
 - Speed
 - Rotation speed
 - Inspection parameters
 - Detection probability
 - False reject rate
- Properties, capabilities and limitations of automated inspection systems
- Scope of Automated Visual Inspection









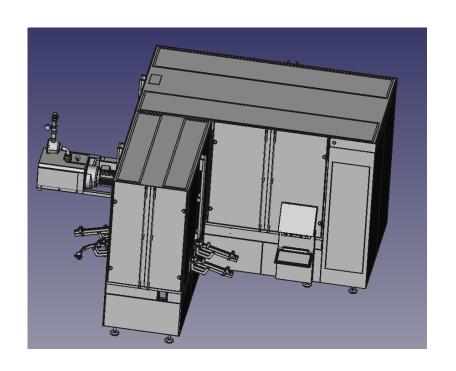


General intro

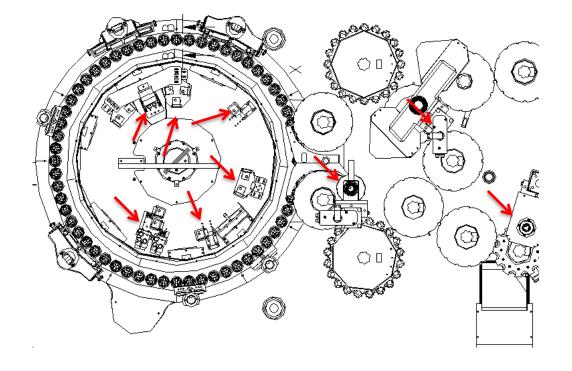




Is it just a black box? Need for transparency / explain ability



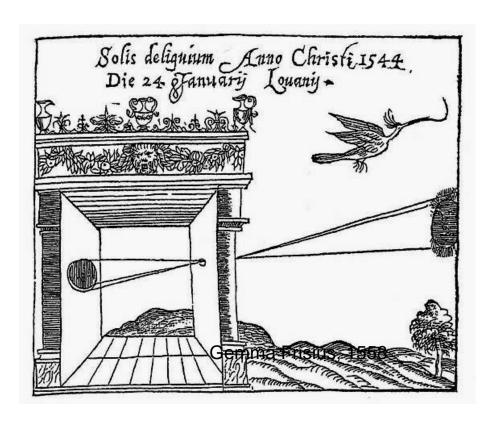
Certainly, no more!!







inspection machines Some milestones



"...and we call invisible, either what is absolutely – as we consider impossible in other cases -,

Or what is visible by its inherent nature, but in fact it may only be hardly visible or invisible »

Aristotle, De Anima, Book 2, 10

Camera Obscura

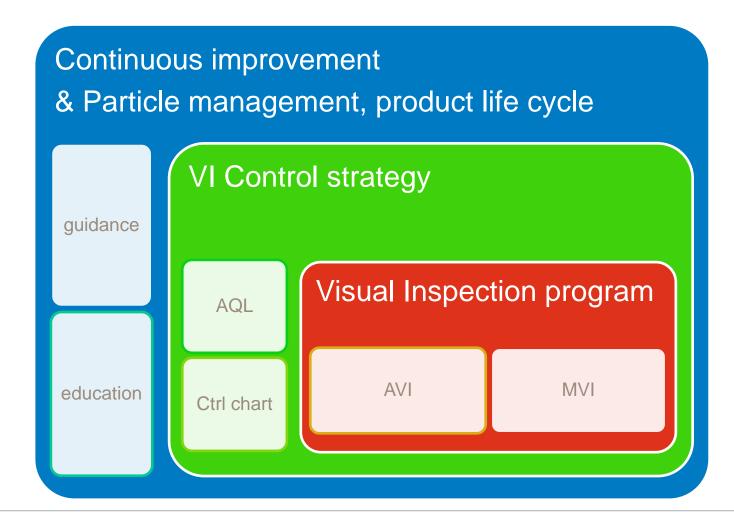
- •Basic principle Aristotle (384-322 BCE)
- •Drawing aid for artists: described by Leonardo da Vinci (1452-1519)
- •.....first industrial CCD camera 1975
- 2022 AVI





Visual inspection program in 3 layers:

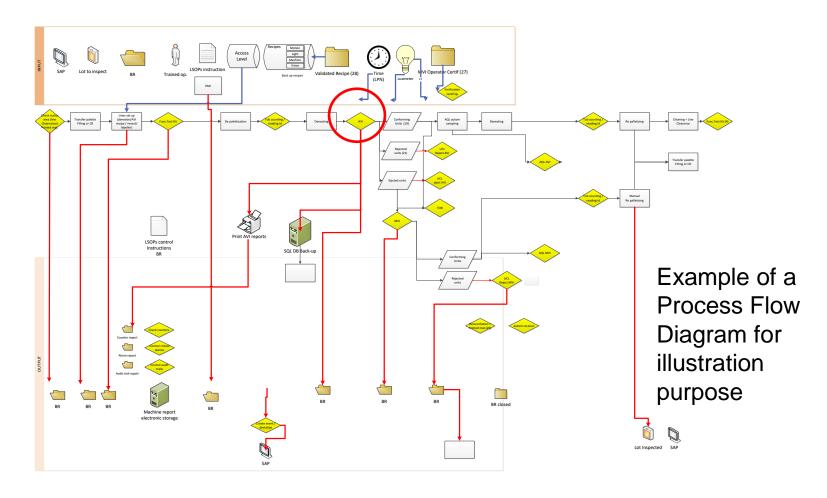
- The Core is AVI/MVI program, with strategy for DML / standard work / certification / validation
- The control strategy with ctrl chart and AQL guarantees that VI is kept under control
- -Continuous improvement is the goal of all VI activities with CAPA management. The Particle management guidance is a key to success with particle control and associated WOW & education, product life cycle approach







AVI is just a small part of the process







For AVI masteryPeople mgnt is a key! Need to have landing conditions for equipment / Process

Best in class organization for VI (People mngt)

Transformation is not only buying a machine, but build a team/organization for VI

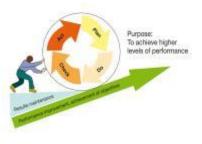
- develop operators / supervisors
- develop maintenance (calib./mech./vision)
- develop automation support
- opportunity to develop vision experts / Ext.
- develop a team to supply kits or externalize
- develop AQL quality team
- develop control chart tools & SPC team
- develop defect id. / externalize



CAPABILITY MNGT IS KEY

And change mindset by generating a feedback loop and involve the filling & Quality department

Loop with USP<1790> ultimate goal of VI is continuous improvement







Let's reflect of Quality attributes?



what are your CQAs / CPPs for VI process ?

Can you list some of them?

- CQAs: Critical quality attributes
 think about USP<1790>....
- CPPs: Critical process parameters
- CDEs: Critical Design elements
- PA Performance Attribute

Some CQAs may be proposed:

Attributes						
CQA	CQA	CQA	CQA	CQA	CQA	PA
Identi	Essentialy free of glass Defect/Particles/Stopper defect/Closure defec. fill level/Empty/Lyo defect	Leak absence	Container Integrity	Stength, Potency	Potency (sheer stress)	Equipment Performance





Core parts of AVI





Why classifying AVI Main block functions?



Motion of units



Light illumination

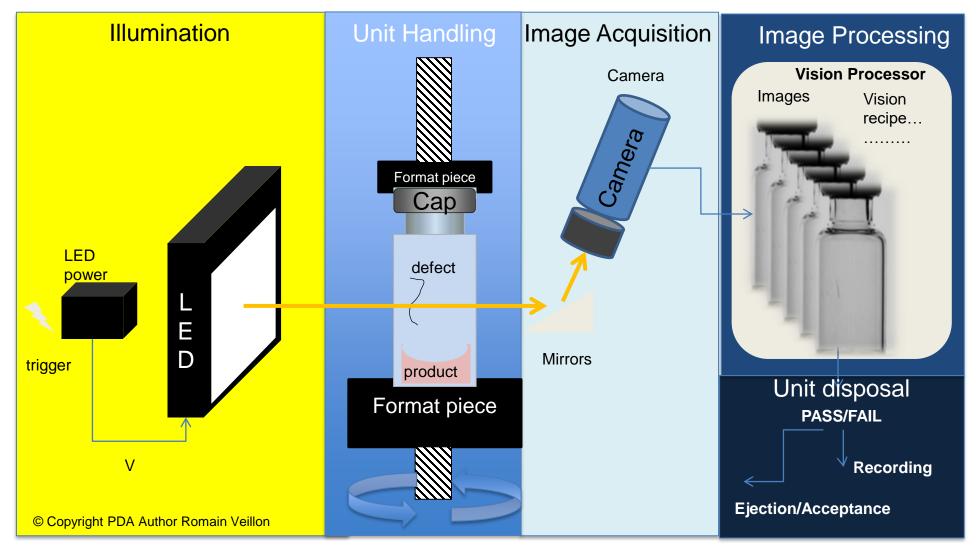


Digital image processing



AVI Main functions









Camera Sensor

- Resolution
- Sensor size
- Mono or color
- CCD or CMOS
- IR / Vis
- Interfaces
- Number image

Machine vision

- Digital image processing
- Speed
- Software
- Vision processing
- Learning type
- Access level
- Image archiving

Lightning

- Shape
- Distance
- Color
- Type illumination
- Intensity
- Alignment XYZ

Optics

- Focus
- Focal length
- Field of view
- Chromatic aberration
- Stability of tuning

Object to inspect

- Size
- Geometry
- Surface
- Material
- Color / transparency
- rheology

AVI machine

- Automation
- Fail safe design
- Enviroment (dust, temperature....)
- Holding time
- Vials/syringe
- Closure design
- Glass suppliers





AVI by block of critical function, proposed approach:

- 1. Unit presentation to camera by mechanical handling
- 2. Unit presentation to camera with product rotation
- 3. Unit presentation to camera with glass & product dependent parameters
- 4. Refeed transport mode
- 5. Lightning to camera
- 6. Image acquisition
- 7. Digital Image Processing
- 8. Result transfer to shift register
- 9. Physical unit ejection
- 10.Inspection result archiving (ex SQL)
- 11.Batch closure and local report creation
- 12. Central reporting & archiving





Object presentation to camera





Unit presentation to camera in many ways

Different ways of conveying:

Intermittent rotary CMP: https://www.youtube.com/watch?v=H55CQj1JsNI

Linear Continuous Heuft: https://www.youtube.com/watch?v=5BCChqQZFac

Bottom gripper Rotary continuous: https://www.youtube.com/watch?v=xC2ed0Tu2NU

handling syringes: https://www.youtube.com/watch?v=GlojLwZeX0o

Side clip conveyor Innoscan: https://www.youtube.com/watch?v=_5oueC3ilxy

Top gripper ATS Lyo: https://www.youtube.com/watch?v=opscAQFk1sM

Brevetti Continous mvt + up and go moving arm: https://www.youtube.com/watch?v=XkiKzsL-bfw

Innoscan continuous mvt + fixed VI + oscillating mirror piezo:

https://www.youtube.com/watch?v=mw3UU9wPwKo

Vacuum wheels suckers Seideander: https://www.youtube.com/watch?v=2g4RABopI1k

Pre Spin turret Syntegon: https://www.youtube.com/watch?v=s31mC8rFwZk

Wilco mechanical conveyor: https://www.youtube.com/watch?v=7MiQVALsRCo

Base holder / Gripper / sucker Those are pieces with ageing / regular checks / changes Critical Design Element:

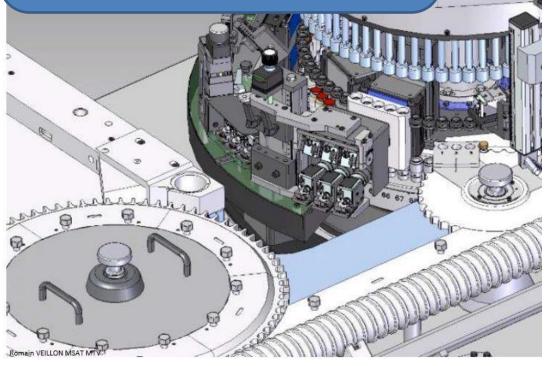
Mechanical stability of AVI Axial Rotation no cavitation Aging parts maintenance





Critical Design Element:

Bottom and top carousel aligned Pressure top caroussel Mechanical fitting bottom ring No loose in X Y No mech. Break to rotation Alarms on rotation ctrl

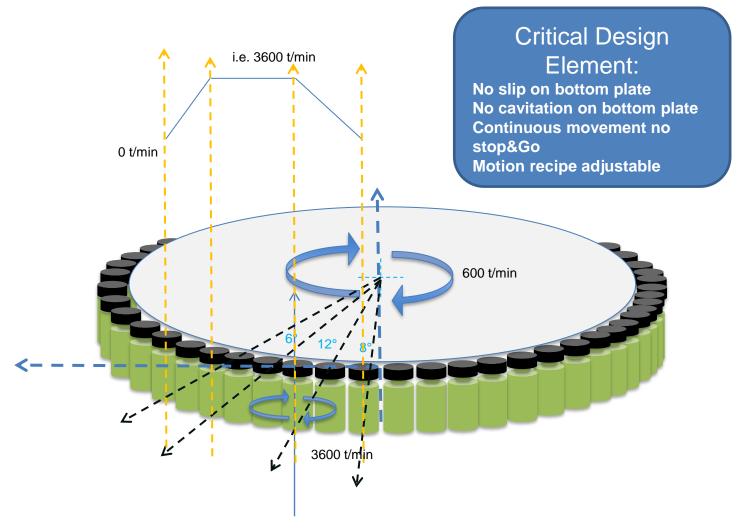








Unit presentation to camera



Key learning: Modern AVI machine is very complex in term of unit motion; Double motion main

- carousel rotation
- each unit individual fast rotation
- + all synchronized to image acquisition every few ms







Unit presentation to camera => Fast spin rotation









600 t/min



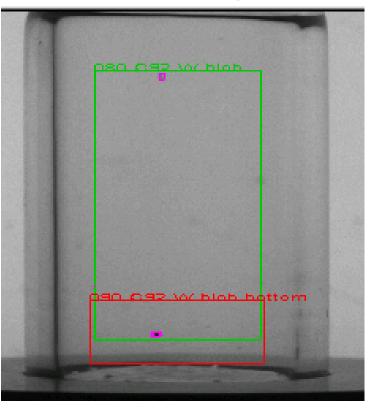
1800 t/min



3600 t/min

How to inspect Automatically a suspension that has a high optical density + scattering?

- = Fast rotation To present liquid in thin layer
 - ⇒ Lower optical path (density beer lambert)
 - ⇒ Minimized scattering effect







Unit presentation to camera => Fast spin rotation

1000 images Conform overlayed



1000 Crack image overlayed



Conform images are clearly shifted to the left and more shaky

Crack images are more stable

Critical Design Element:

Fast spin requires strict mechanical alignment Need to have some periodic control of axial rotation with no cavitation



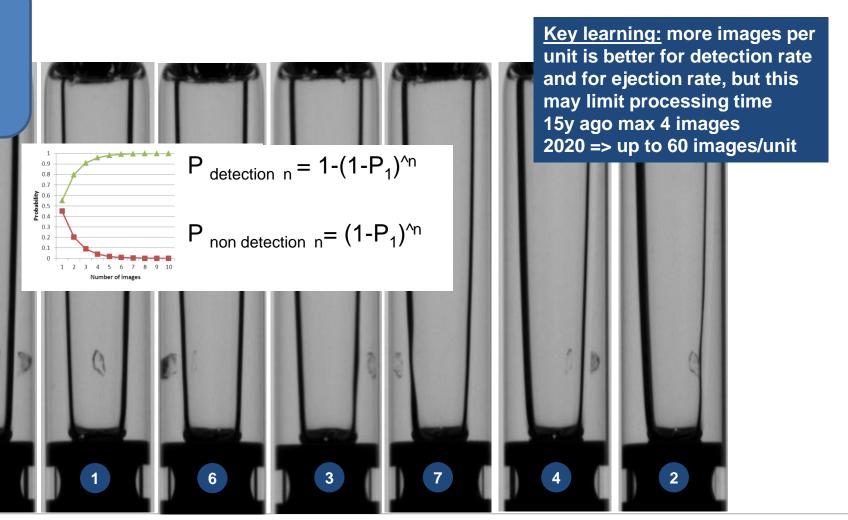


Unit presentation to camera, why multiple images?

Critical Design Element:

More image increase defect detection

Possibility to have image treatment by stack of image





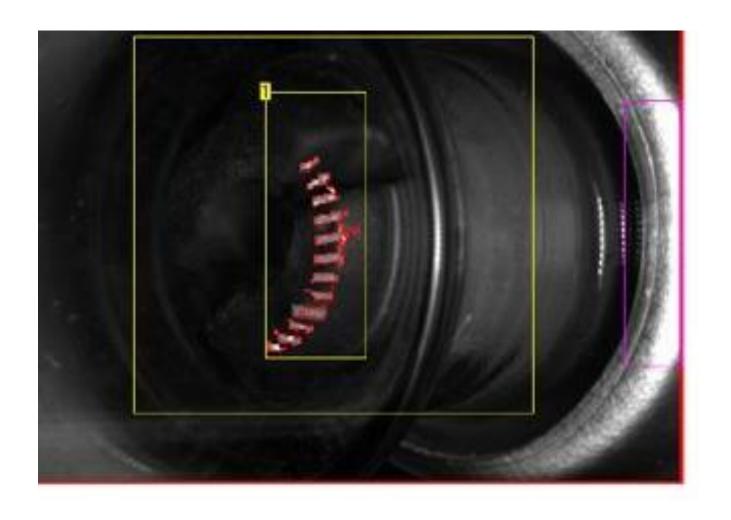


Unit presentation to camera, why multiple images?

Critical Design Element:

More image increase defect detection and lower false reject

Possibility to have image treatment by stack of image







1 Central moving Mirror

1 torque moving arm for LED / cameras

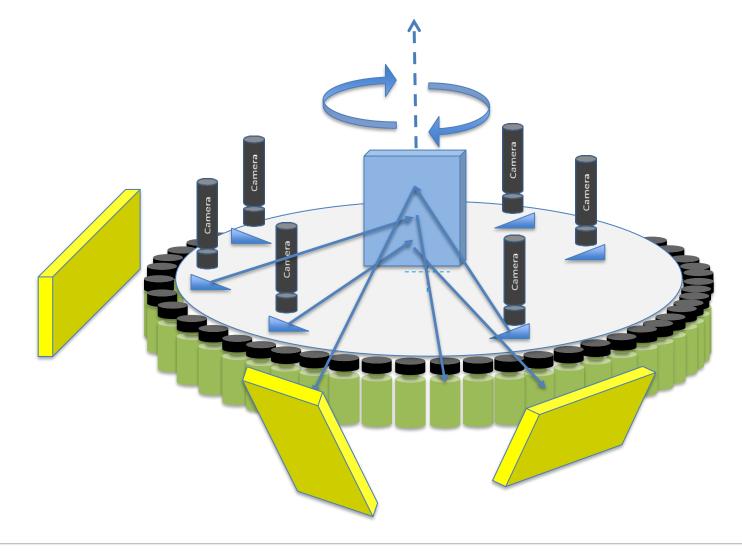
1 piezo oscillating mirror on each camera station

Fixed camera larger field of view





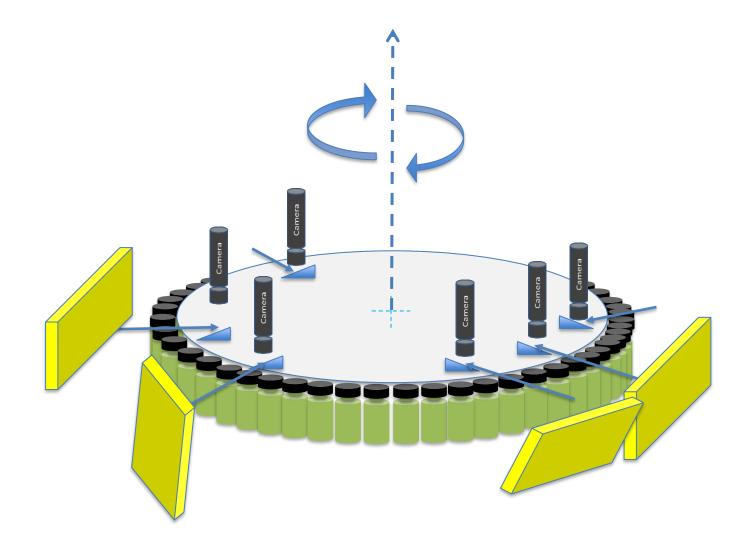
1 Central moving Mirror







1 torque moving arm for LED / cameras







Camera and image acquisition





Camera is converting Photons is digital signal



Photon

Photosite

Electron

- Integration
- Transfert
- Amplification

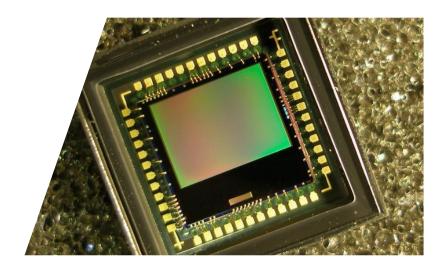
Further Deep Dive: https://www.baslerweb.com/en/vision-campus/



Camera



Matrixial Sensor : X and Y image

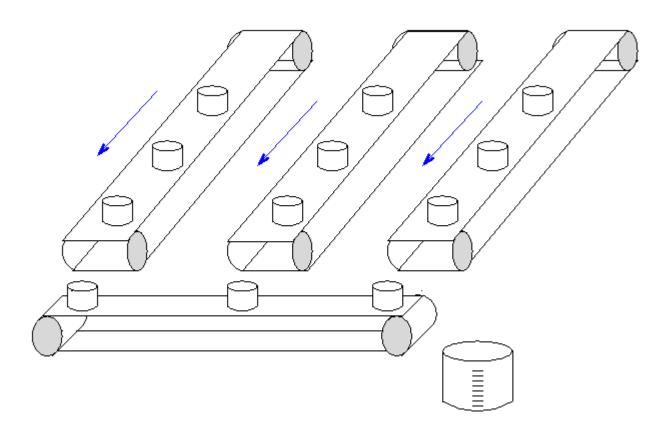


Linear Sensor = Line Scan









https://youtu.be/ZwN0DT_4FhY





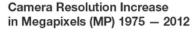


AVI

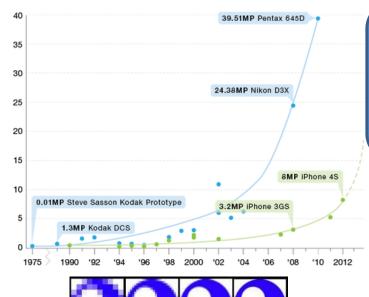
11µm per cone/6^{E6} Cones/ LOD 50-150µm particle

Willing .

2022
2-5 MP
6µm / pixel
48 images
/unit
128FPS

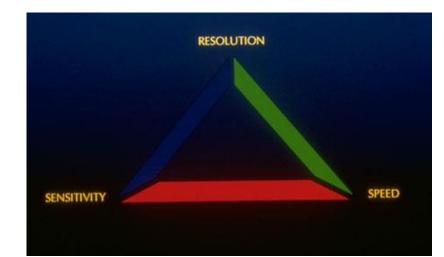


High-end Cameras (Expensive, SLR)
 Low-end Cameras (Cheap, Mobile)



Critical Design Element:

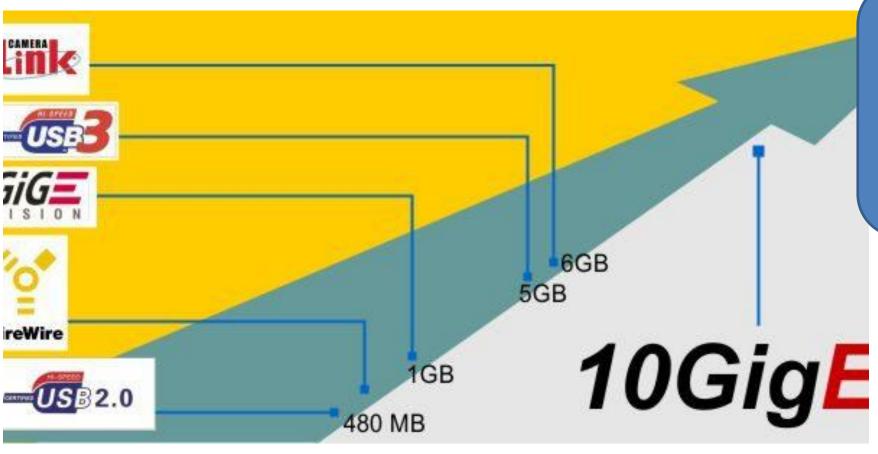
Today compromise between performance / speed Availability on the market sustainability





25 x 25



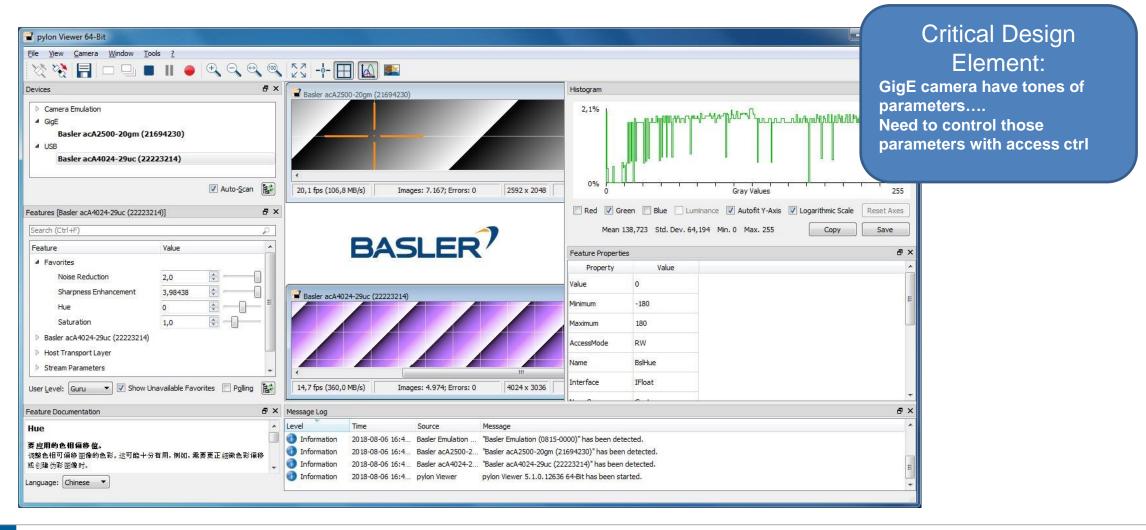


Critical Design Element:

1 GigE bus on a vision computer is limiting for 3 or 4 camera
The design of com card is critical to handle a fast transfer mode
Some camera have now more than 100 FPS









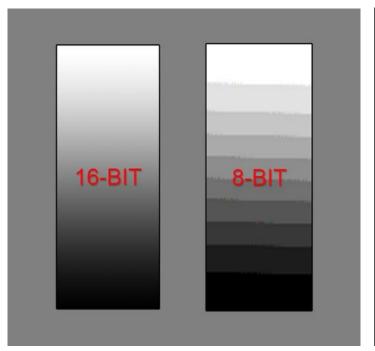


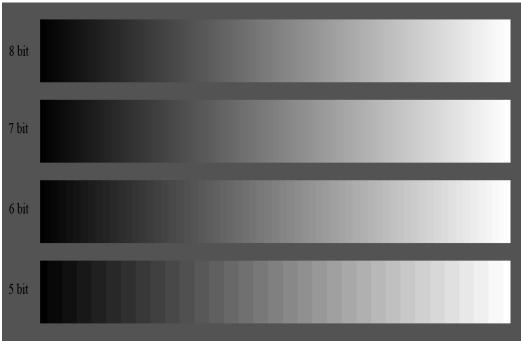
What is Image resolution?

Key learning:

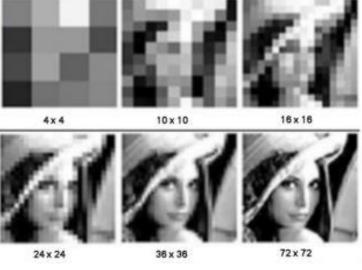
Tonal resolution in bit Spatial resolution in pixel

tonal resolution in bit





Spatial resolution

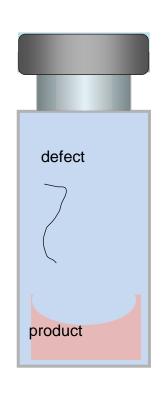


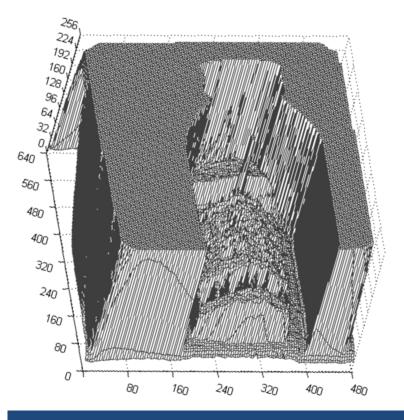




Variable:

- discrete spatially
- discrete quantitatively





Key learning: AVI sees only a matrices of discrete information in X Y and Z for grey levels



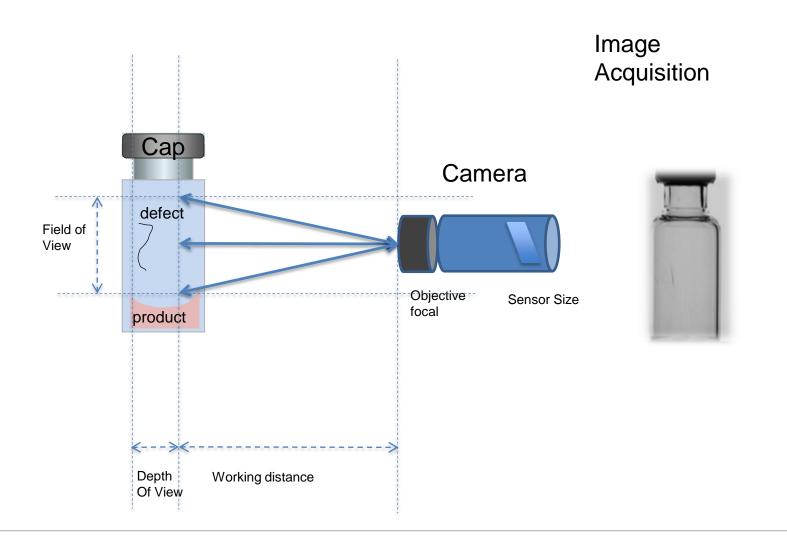


Optic Fundamentals





Image Acquisition = > optic parameters



Critical Design Element:

Optical setup must be masked and locked In case of change possible to come back to pre existing image before validation





Innovation in optics

Ordinary lens



Part of the object's surface may be hidden by surface unevenness



Size of the image changes



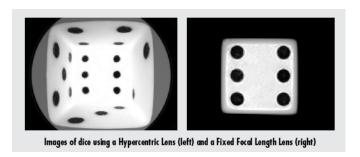
The entire surface of the object is visible



Size of the image remains the same



hyper centric



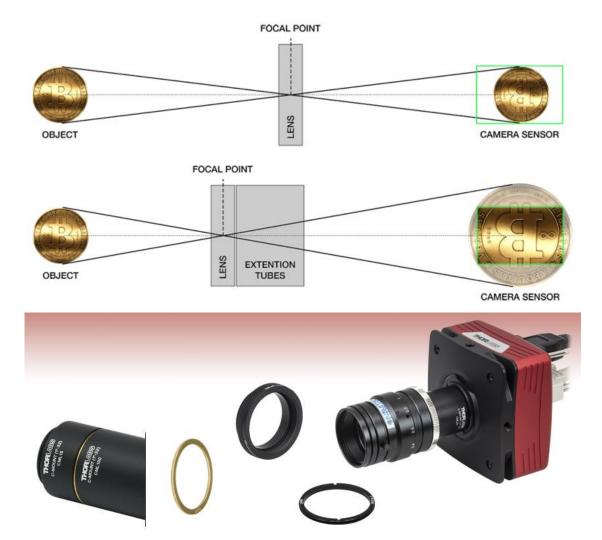
Critical Design Element:

Innovation in optic goes with larger size optics that are difficult to integrate in some AVI design





Optical Rings to reduce focal distance



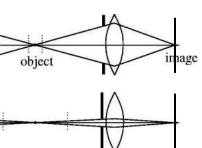
Critical Design Element:

Extension tubes and mirrors are used to cope with lack of space to shorten focal distance
But the depth of view is deeply impacted in some case, to be discussed during design review with suppliers



Depth of field









Critical Design Element:

High Depth of field can allow to see defect from front and back of unit at same time.

To do so we close objective aperture but image are darker

Macro objective can allow large field of view like on the lyo cake below:



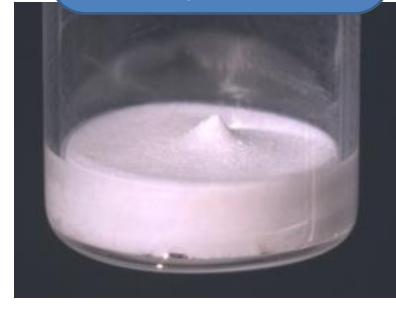
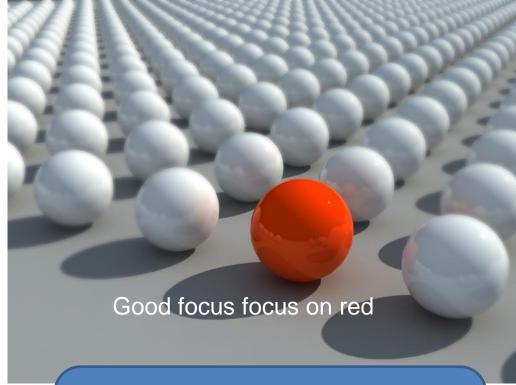




Image Focus





Critical Design Element:

It is critical to have a good focus on the field of view, focus must be locked and graved to be able to come back to pre existing focus



Bad focus

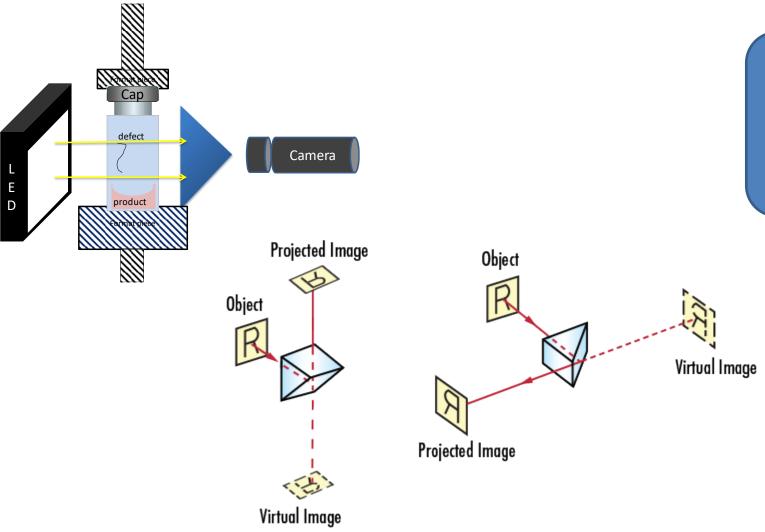
- => poor specificity
- => hard to detect crack vs

dust/scratch



PDA® Parenteral Drug Association

Use of Prism





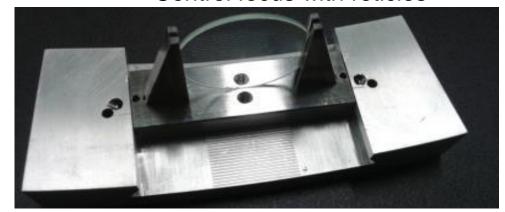
Prism or mirror position and dust may impact image, do periodic check
Can allow to have 2 views with 1 camera





Image Focus control

Control focus with reticles





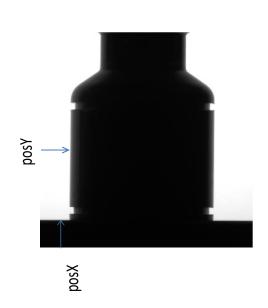


Control focus gauge





How to control Vision mechanical alignment?

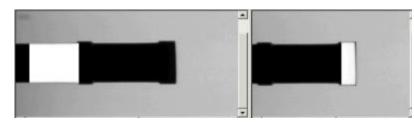


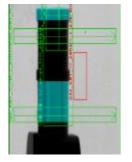


Dummy syringe

Critical Design Element:

There should be tools to control vision alignment to document that vision tools remains within range from initial baseline corresponding to initial PQ Special gauges and vision setup







Adjustment recipe

Dummy vial







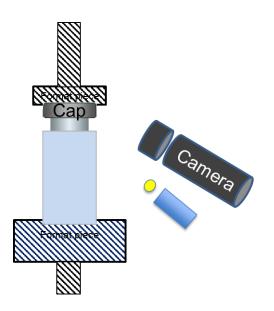
Measuring light intensity and angle





Critical Design Element:

There should be tools to control vision alignment to document that vision tools remains within range from initial baseline corresponding to initial PQ Special gauges and vision setup



Most common light sources are back- and front light.

- The position of Backlight is not that critical, but the light intensity is. This is often reported within the grayscale 0, black, to 255, white
- Directly measuring it through the camera can be done if the image is not oversaturated, so below 255 in theory. Be aware that some cameras are already oversaturated around 240. A reference measurement than can only be done with the aid of a grey filter to reduce light.
- Regarding front light not only the light intensity is critical, but also the angle of the light source.
- The crimp should be shiny to detect distorting of it as one of the aspects. The above example is exaggerated, the center of the light source dropped in the neck.
- So after the initial PQ the angle should be established and documented.





Baseline definition to keep zero alignment

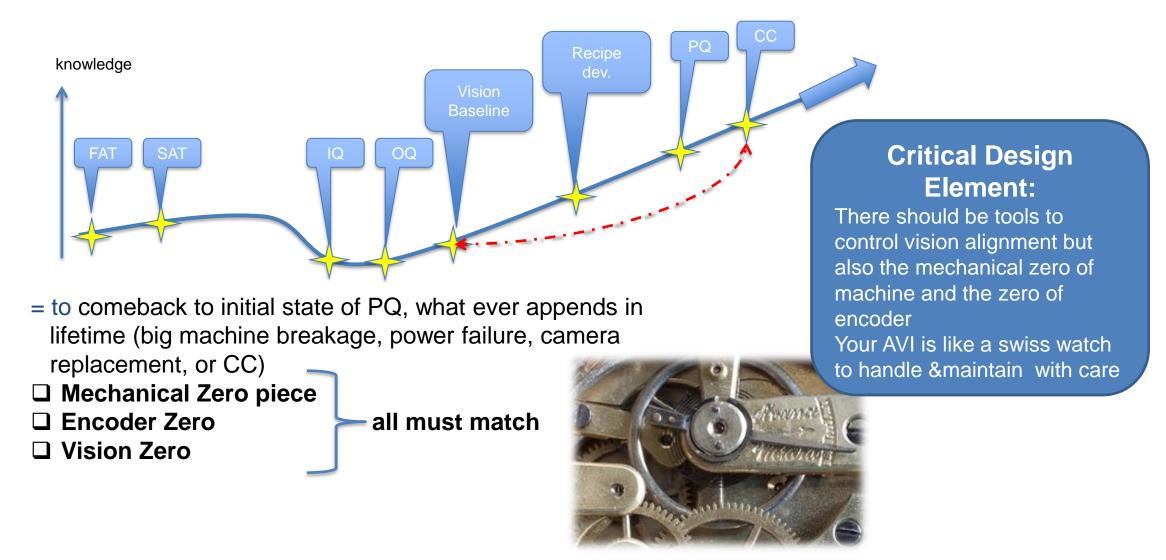
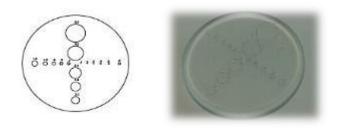






Image correlation pixel to size

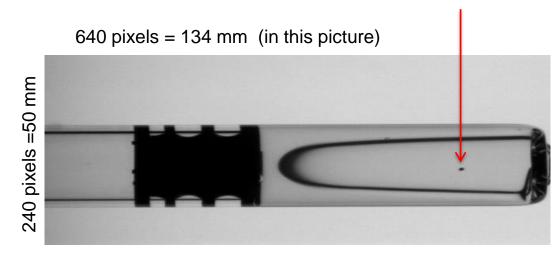


C91 machine B Pixel size measured [Pixel] y = 25,008x $R^2 = 0.9998$ 60 50 y = 25,124x40 Size X $R^2 = 0.9996$ 30 Size Y 20 -Linear (Size X) 10 —Linear (Size Y) 0,5 1,5 2,5 Reticle VWR object diameter [mm]

Critical Design Element:

With reticles that are calibrated, you can correlate pixel to size

1.1 mm = 5.3 pixel

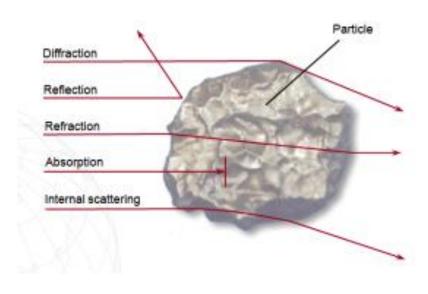


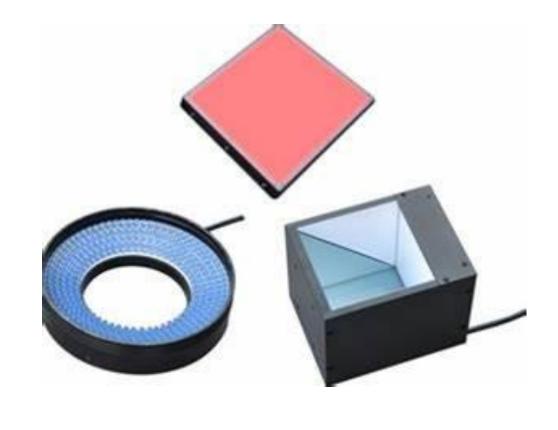
Camera C61 resolution: 0.05 mm per pixel or 5,3 pixel = 0,27 mm





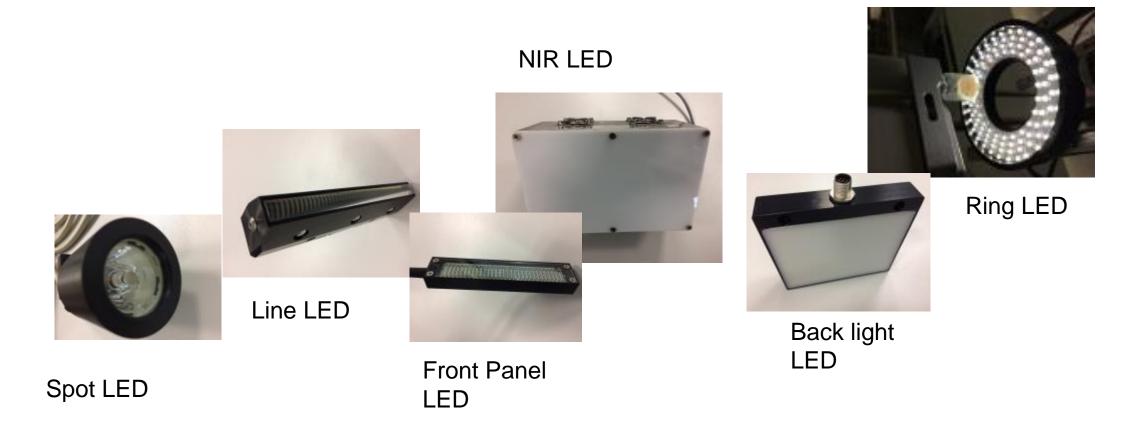
Illumination







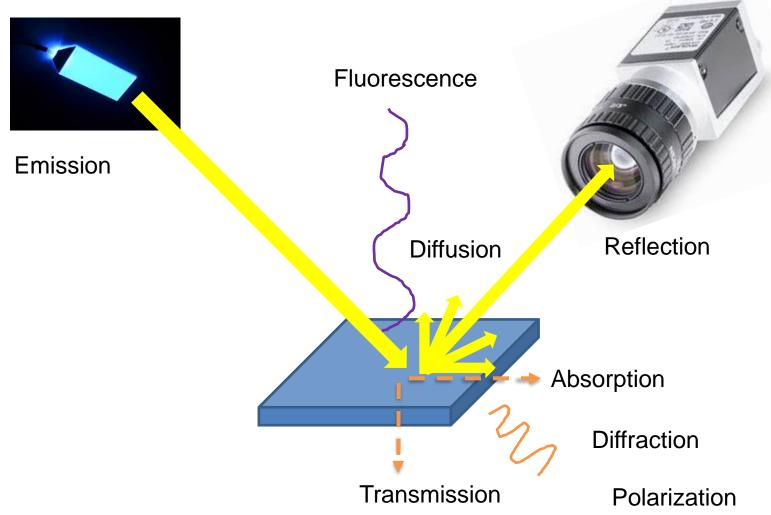








Light interaction paths with an object



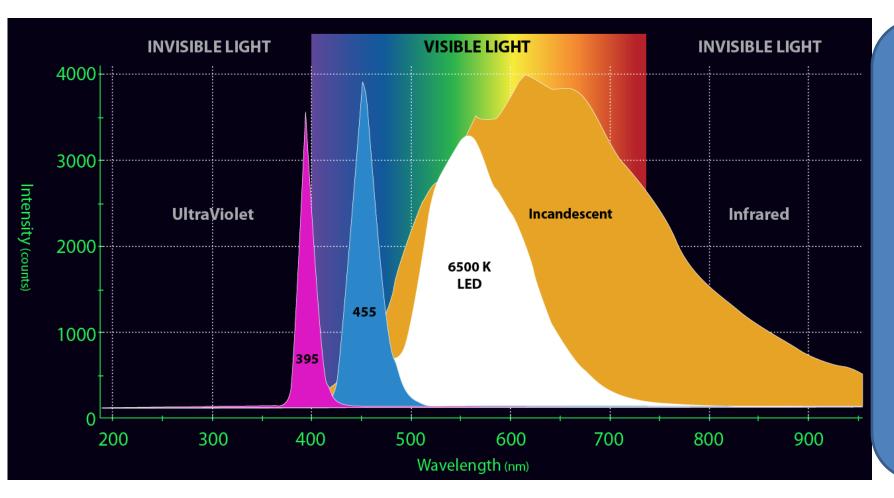
Detection

Critical Design Element:

Every illumination design should take into account interaction with product presentation, It is upmost critical to supply product samples from real production with real primary packaging and fill level during AVI design phase







Critical Design Element:

Spectral wavelength is critical to be studied with supplier,
Most of product will use visible range
Color LED may be optimal for some camera setup
Some emulsion scattering product could use NIR range





Multispectral LED are more used in packaging by now

Conventional color camera



With conventional models, distinguishing between similar targets with little noticeable color difference was difficult.



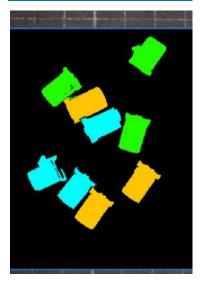
Multi-Spectrum Mode



A different type of cap is extracted virtually as the same color.

330 380 430 480 530 580 630 680 730 780 830 880 930

Multi-Spectrum Mode : Color picking



Slight differences in color are clearly defined.





Color perception impacted by light color





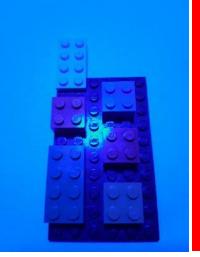


Critical Design Element:

LED color may change defect detection, like to like change is critical **Color camera calibration** is necessary





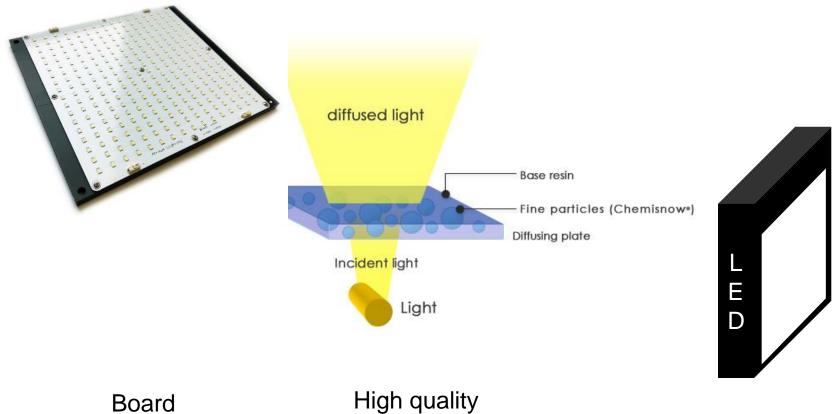




Courtesy of my kids!



Back Light



diffusor

Back Light LED Assembly

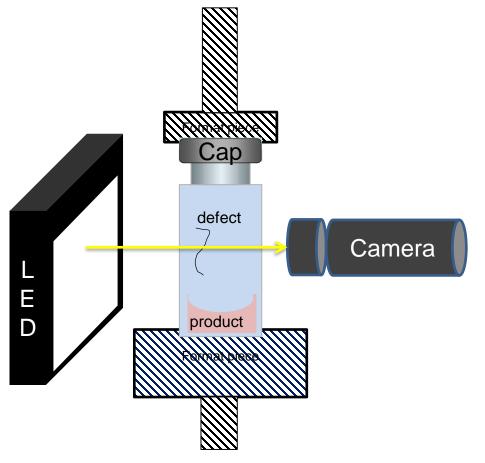
Critical Design Element:

- Back light is easy to place in AVI (very common)
- LED must be replaced like to like or some equivalency studied must be done;
- mind the wire replacement, may impact the luminance



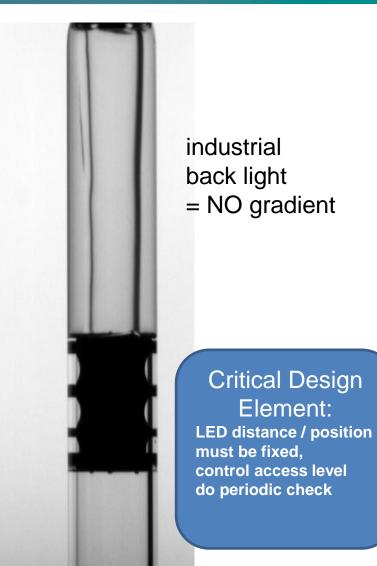


Back Light





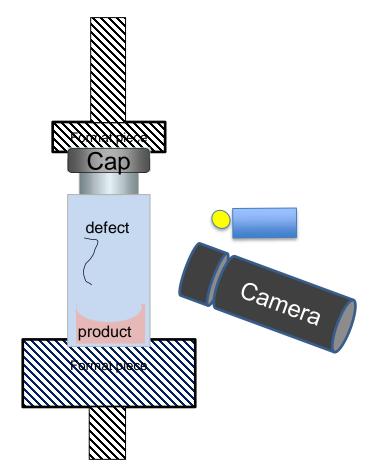
Low cost back light = gradient







Spot LED Light source





Shiny reflects

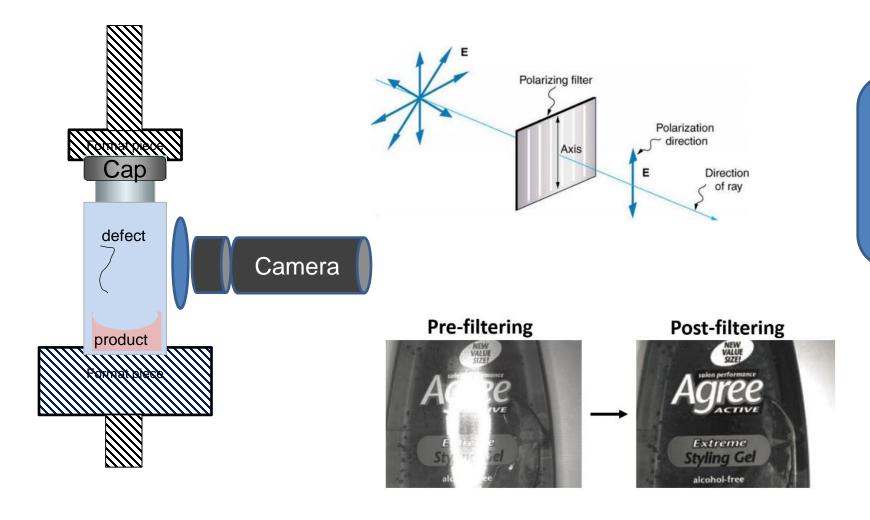
Critical Design Element:

Front spotlight may create reflects, control angle position, limit access and do reg check, use pol filters





Light source + Pol filter



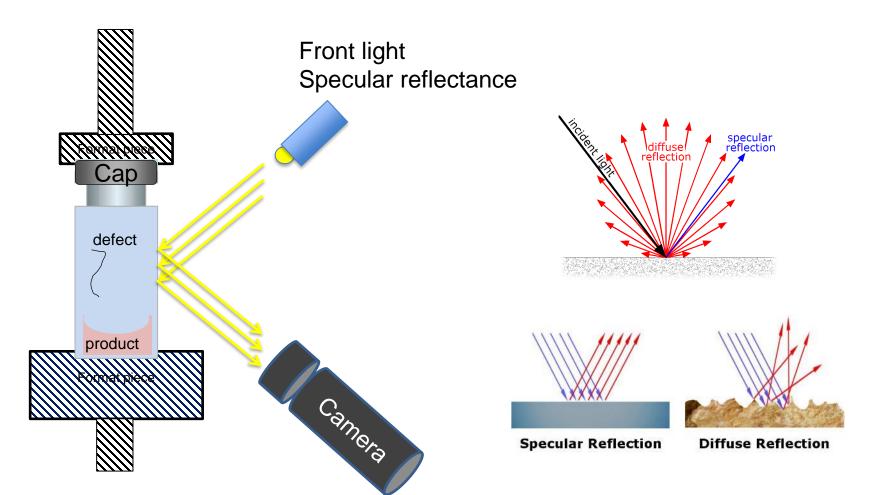
Critical Design Element:

Polarization filter may impact luminance in function to positioning angle, lock and control the angle Powerful to block some glass reflects



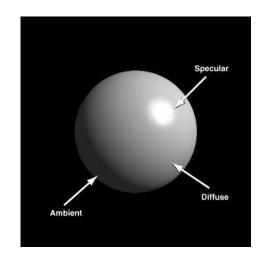






Critical Design Element:

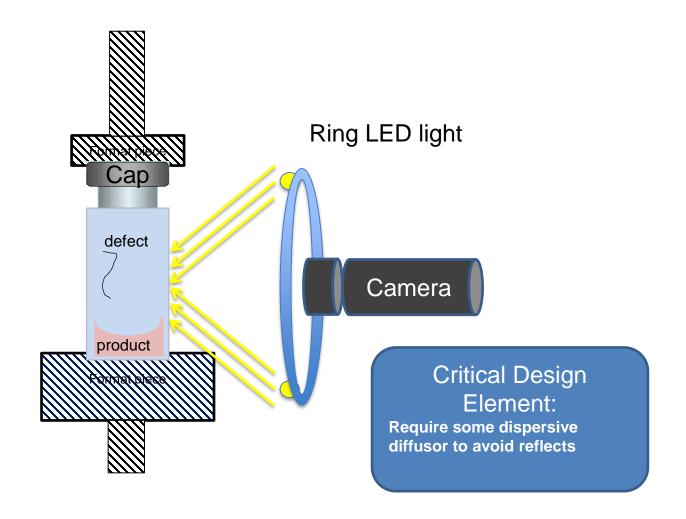
Light position and Angle is upmost critical in term of stability, control access level and do regular check







Reflectance ring LED light





No dispersive filter = Reflect on glass

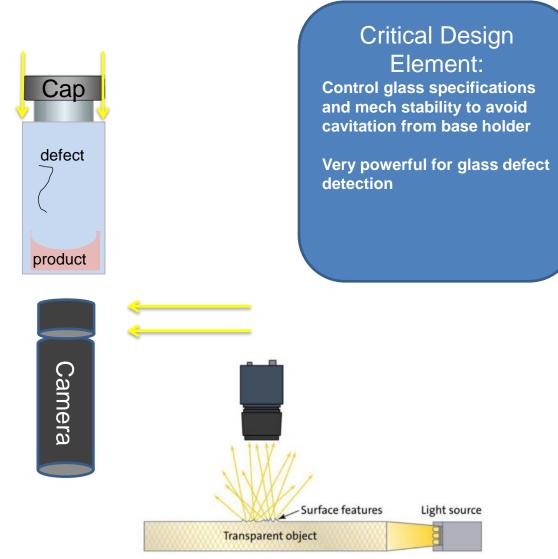


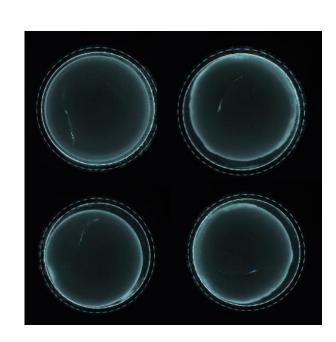
Reflect on glass



Transmissive illumination LED channeled via glass walls





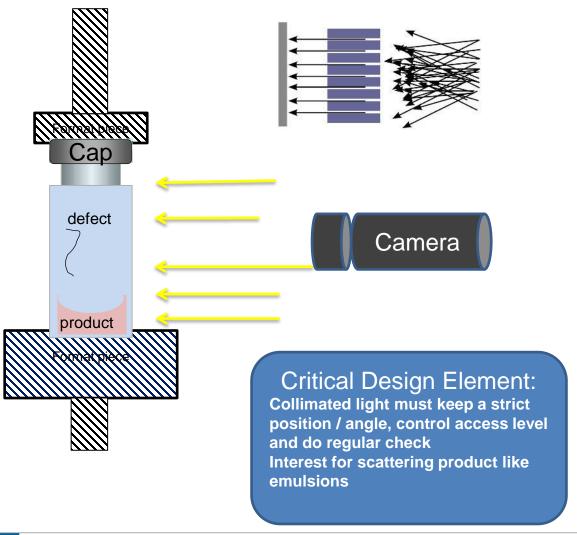


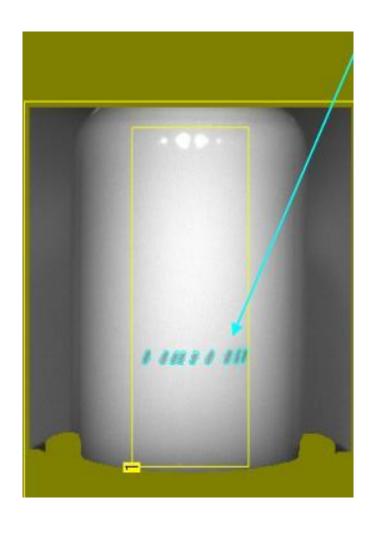




Parenteral Drug Association

Collimated light

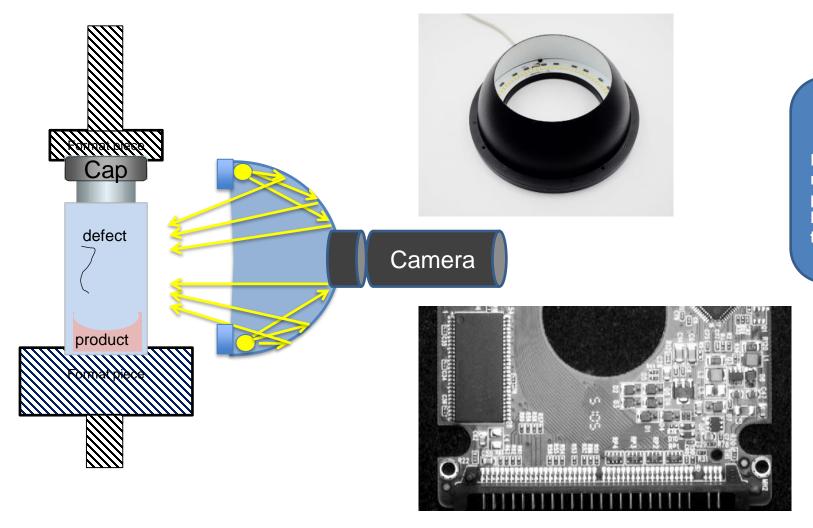












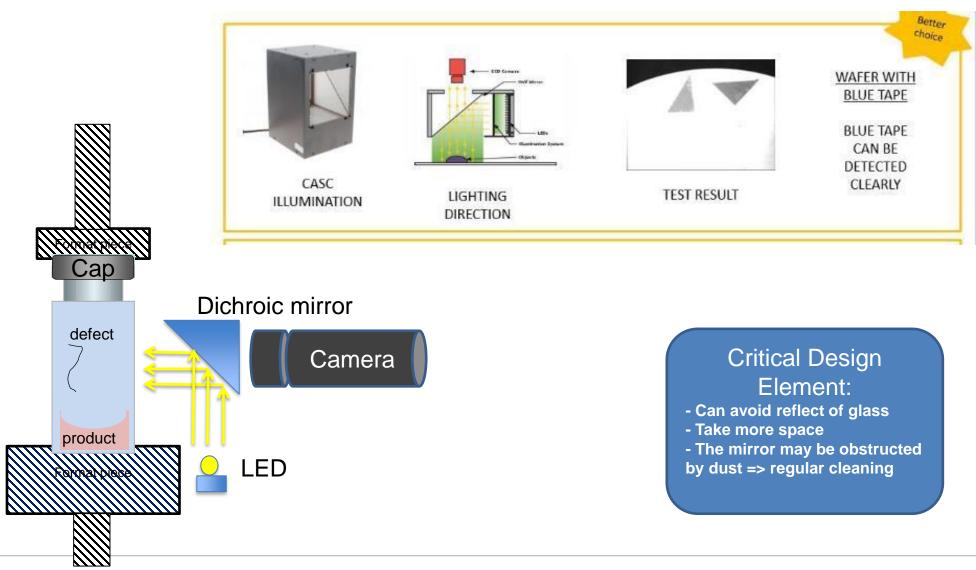
Critical Design Element:

Dome takes some space => mind stability of angle / position fixing Multiple angle light, interest for glass defect detection





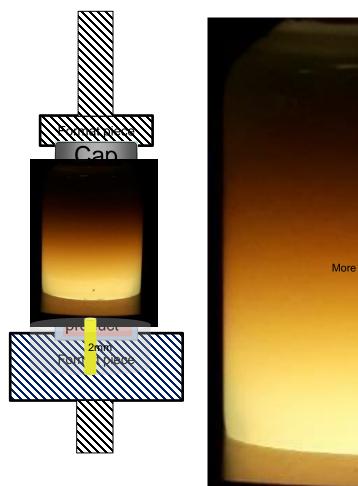








Light source with product as illuminator





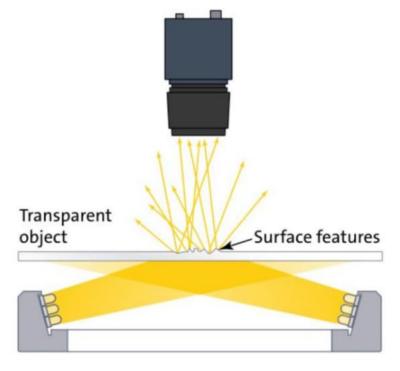
Critical Design Element:

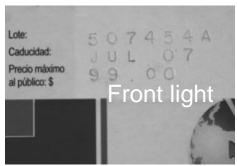
Light from bottom vial may diffract light and burn the image, need to have a small diameter beam light

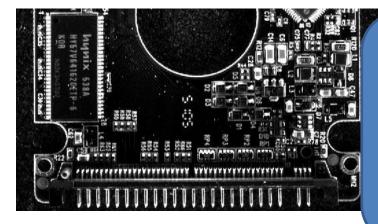


Dark field









Critical Design Element:

Dark field is very sensitive to powder on side walls => extra care in vial handling before AVI

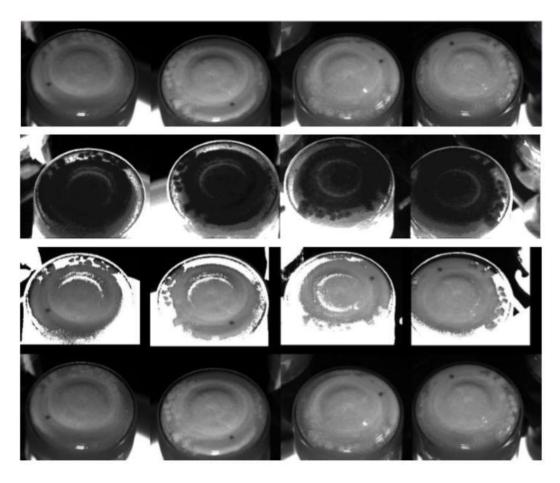
Darkfield can enhance surface defects







Combination of lightLight source



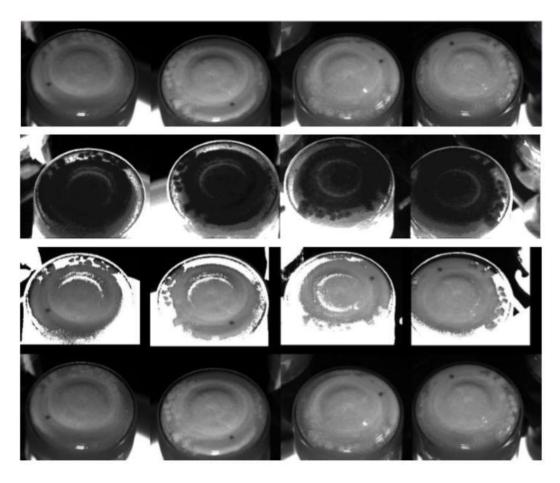
Critical Design Element:

Check no interference of LED from 1 station to other Sequential strobing





Combination of lightLight source

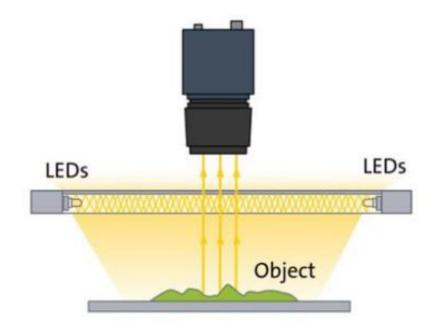


Critical Design Element:

Check no interference of LED from 1 station to other Sequential strobing

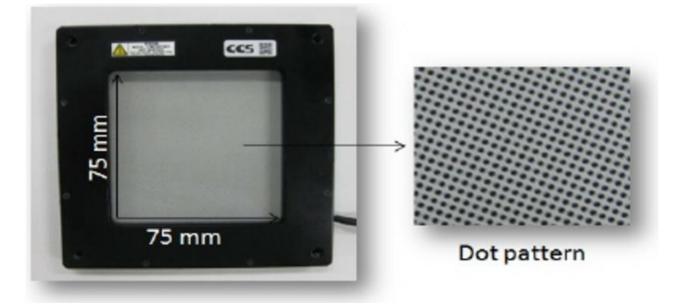






Critical Design Element:

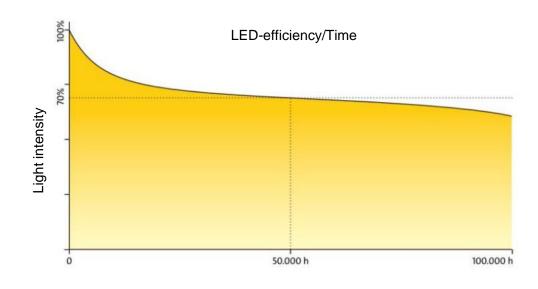
Very powerful with on axial light to avoid reflects Fragile surface with microscopic dots on glass







LED risks

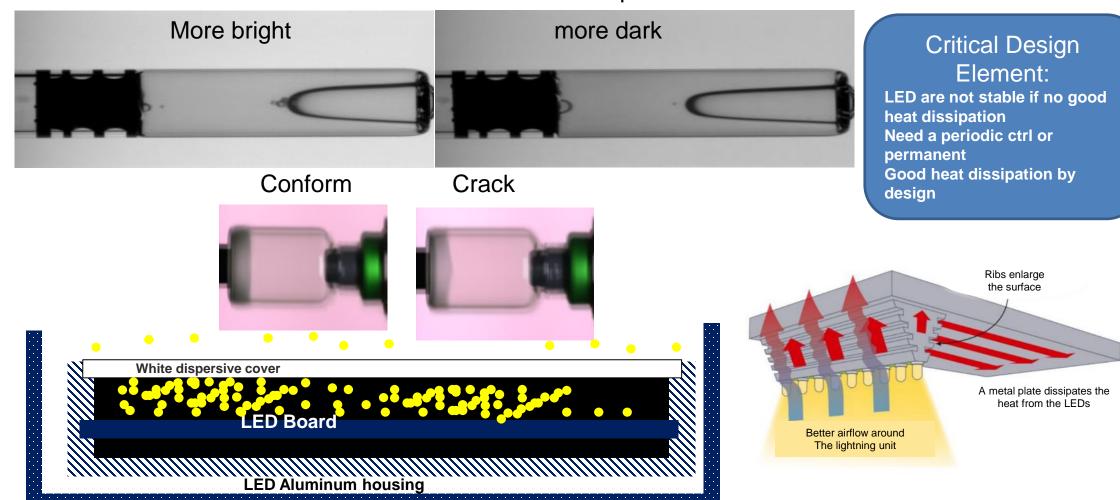






LED Heat Dissipation Risks

LED are more stable butbeware of heat dissipation



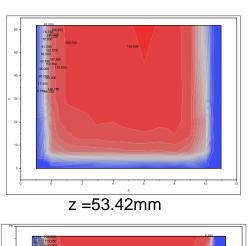


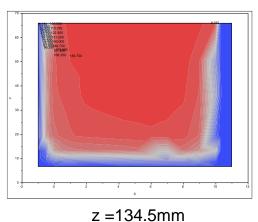


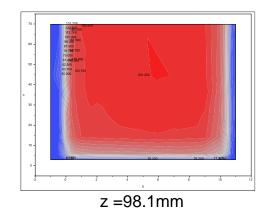


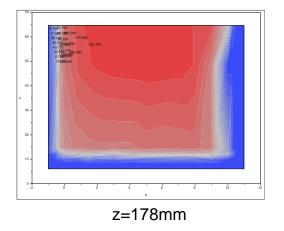
Mapping of
Luminance
Level in X and Y
position
And Z position

=> Very
Homegeneous
in area of use









Critical Design Element:

LED have a border effect Working area should be not so close from border Need to have sufficient sized LED





Digital Image processing

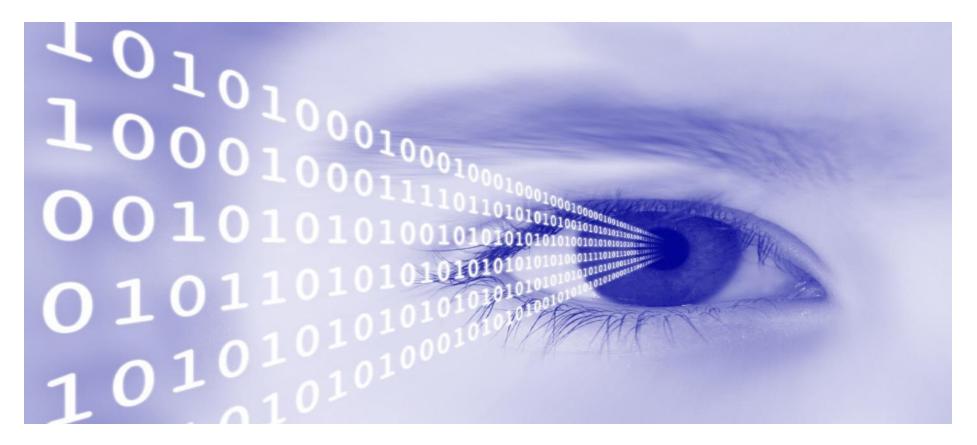
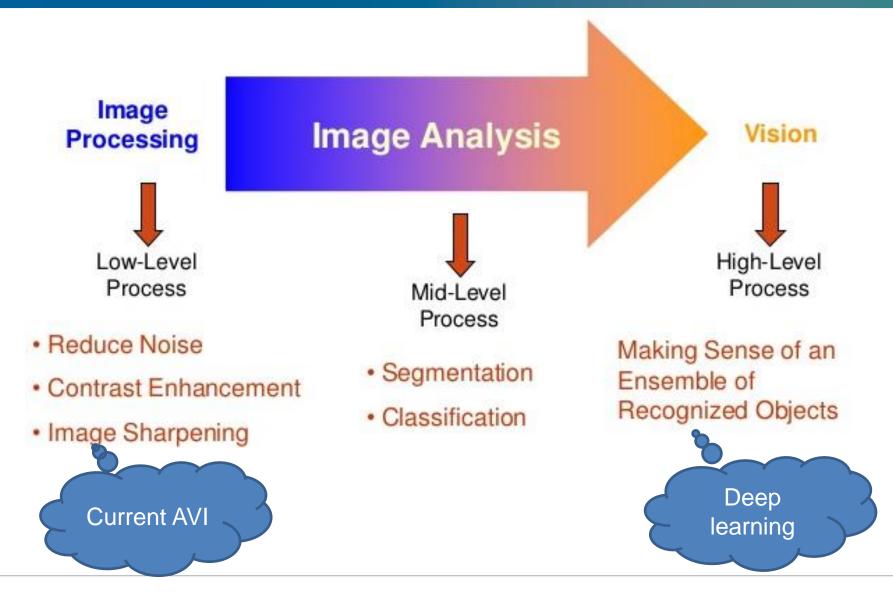






image processing level







A data reduction, a feature extraction







Main steps in image processing

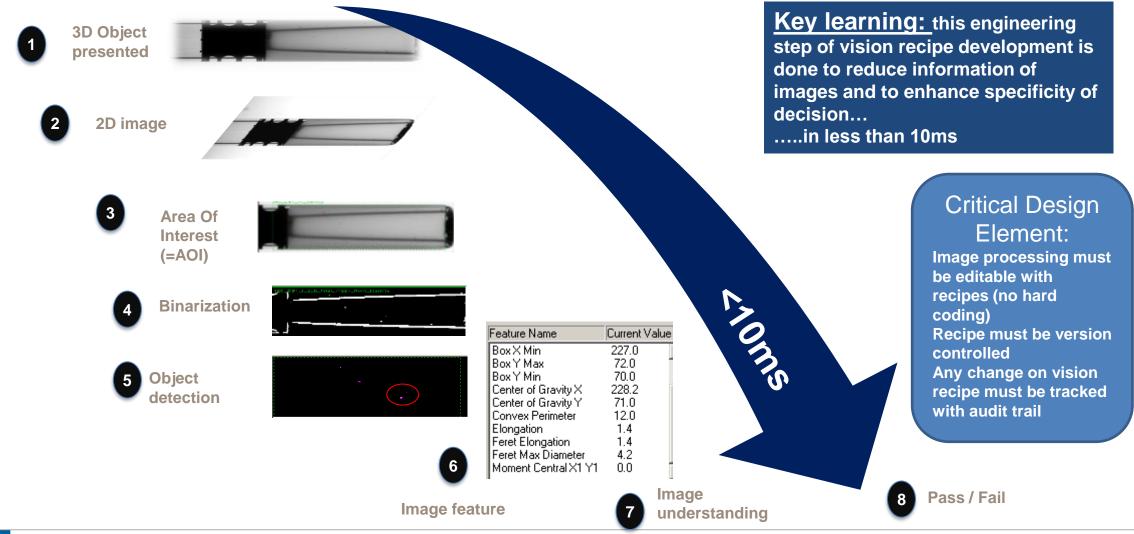
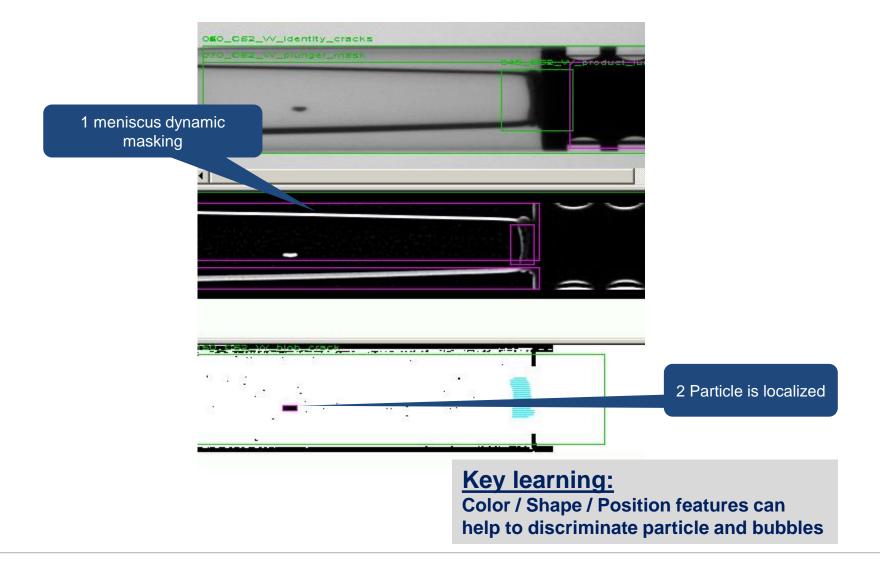






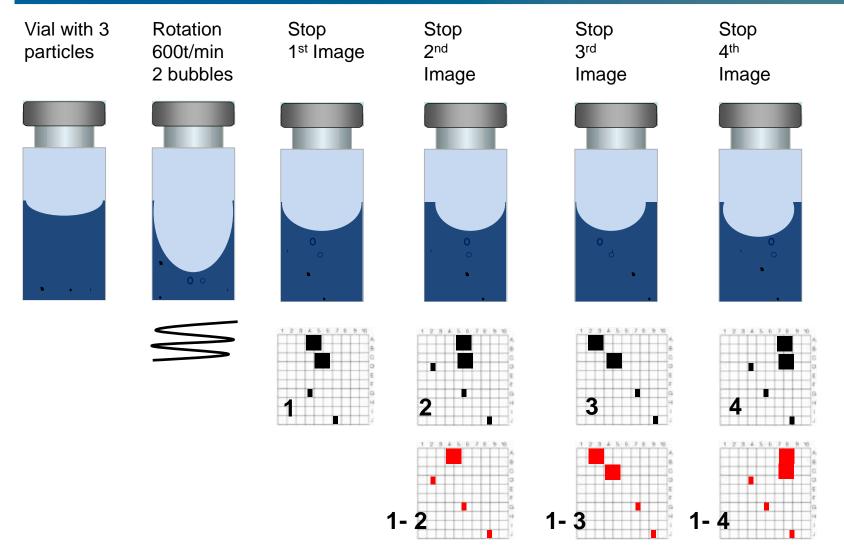
Image processing example







Particle Detection strategies: image subtraction an old approach



Above liquid SENSITIVE NOT SENSIT

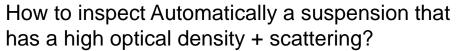
Key learning: Image Subtraction is not very sensitive for particle detection in small suspension unit + no detection above liquid + no detection of fixed particles



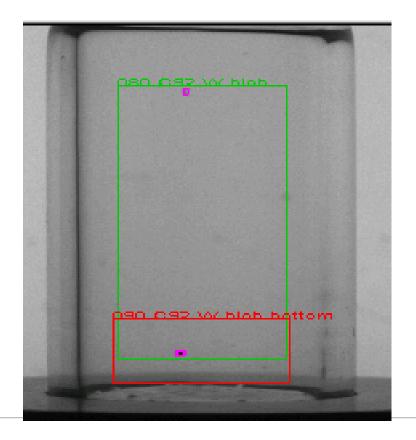
PDA® Parenteral Drug Association

Particle Detection strategies : Fast rotation





- = Fast rotation To present liquid in thin layer
 - ⇒ Lower optical path (density beer lambert)
 - ⇒ Minimized scattering effect











0 t/min

600 t/min

1800 t/min

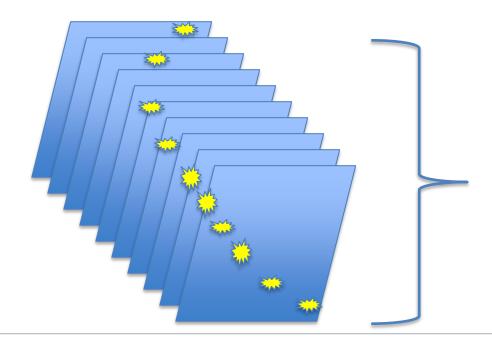
3600 t/min



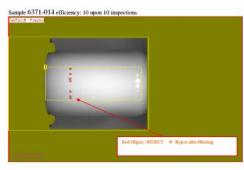


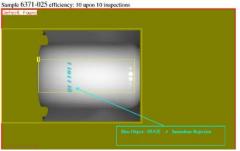
Particle Detection strategies : Particle tracking

- With modern vision machine more images are available
- Images can be treated not only 1 by 1 individually but in stack of images
- Rendering particle trajectories analyzed
- And differentiation to artifacts like bubbles



Analyze of 1 stack of 10 to 60 images all at once to track particle trajectories







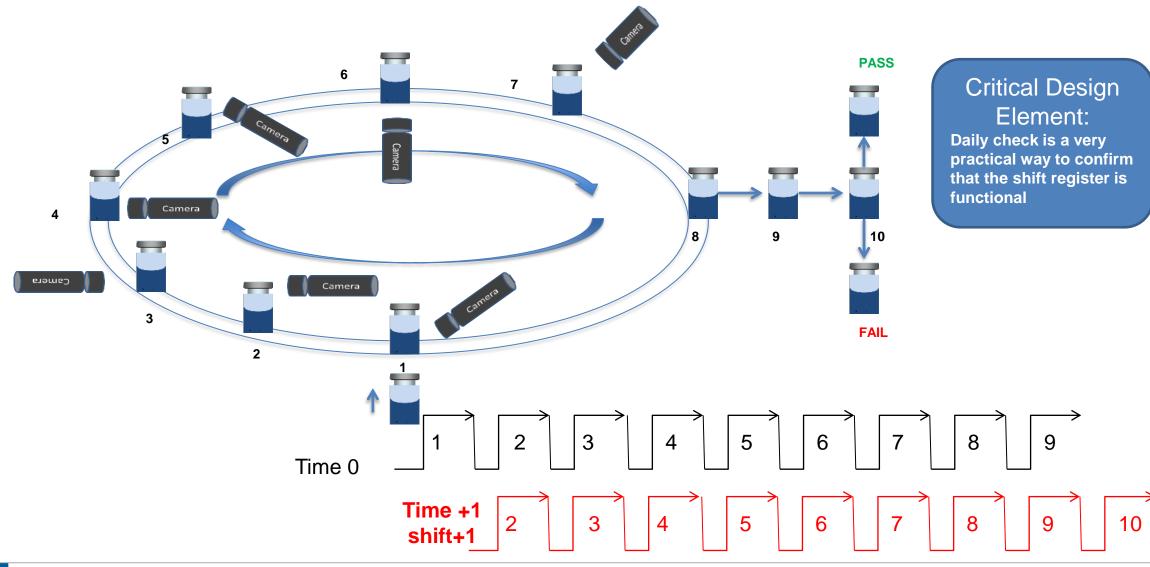


Automation principle of shift register



PDA® Parenteral Drug Association

Automation basic concept / shift register

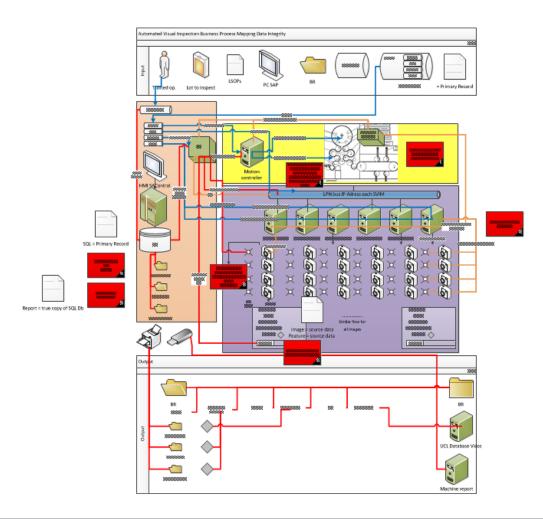






Automation business mapping

move forward to elaborate a fully transparent flow of information inside AVI



Automation

Mechanic

Vision

Critical Design Element:

Drawing a business process mapping for information flow inside your AVI is a way to share knowledge between experts, supplier and QA and end user





Concept of collaborative cameras





multiple images, multiple cameras => probabilistic behavior

Pcam5

P cam2

P cam3

Pcam6

P cam7

P cam4

Multiple camera on AVI machines

2 collaborative Cameras for a specific area i.e. = Syr. flange

> 4 collaborative Cameras for a specific area i.e. = Syr. Body for particle or cracks



Pcam9

Pcam10

A & B mutually exclusive $P_{11+12}=P_{11}+P_{12}$

2 Camera specific for a defect area i.e. = Syr. closure

Camera specific for a defect family i.e. = Fill level



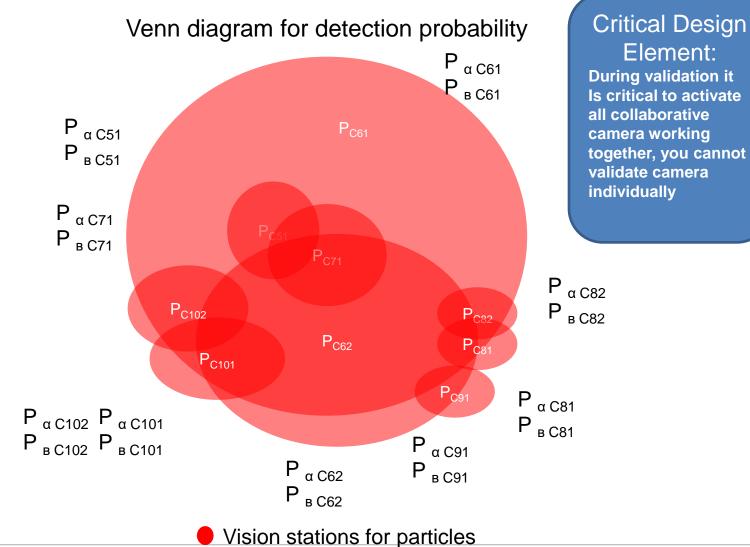


multiple images, multiple cameras => probabilistic detection



Key learning: Automated Inspection machine may be compared to an orchestra: each camera may be compared to an instrument group contributing to an overall particle detection. Each image may be compared to a individual player. We have up to 15 cameras and from 32 images to 150 images per unit







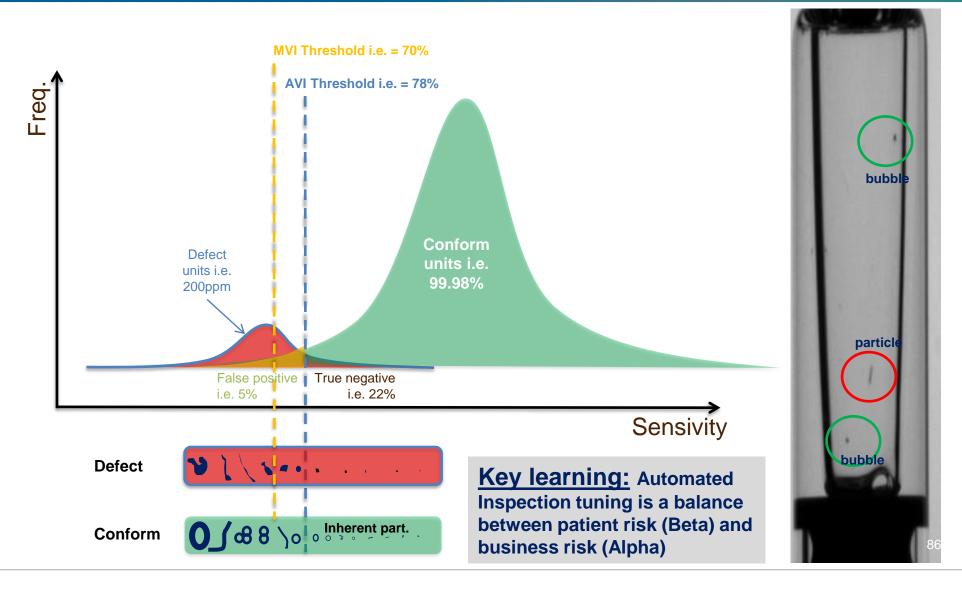


False reject True reject





False reject / balance patient vs business risk







	Actual Value (as confirmed by experiment)		
		positives	negatives
Predicted by the test)	positives	TP True Positive	FP False Positive
	negatives	FN False Negative	TN True Negative

Critical Design Element:

Control of false reject could be considered as a validity criteria

Unit used for this test should be first inspected.

Binomial law shows that min 3300 units can give an accuracy of +/-1% of False reject rate

100 to1000 units for evaluation of False reject has a poor accuracy







You have learnt

AVI

- CQAs, CPPs
- critical design elements
- Core part of AVI
- Sequence images
- Mechanical presentation
- Camera
- What sees AVI
- LED
- Computer vision
- Automation
- False reject



AVI

- What CDEs, CPPs, CQAs
- Why is capability management key
- What are the core parts of AVI
- What tools do you need to keep AVI in validated state
- Do you validate per camera or the whole

