



Visual Inspection of Injectable Products: Inspection Technologies

John G. Shabushnig, Ph.D.
Insight Pharma Consulting, LLC



johnshabushnig@aol.com
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“I see no more than you,
but I have trained myself
to notice what I see.”

Sherlock Holmes
in *The Adventure of the Blanched Soldier*





Agenda

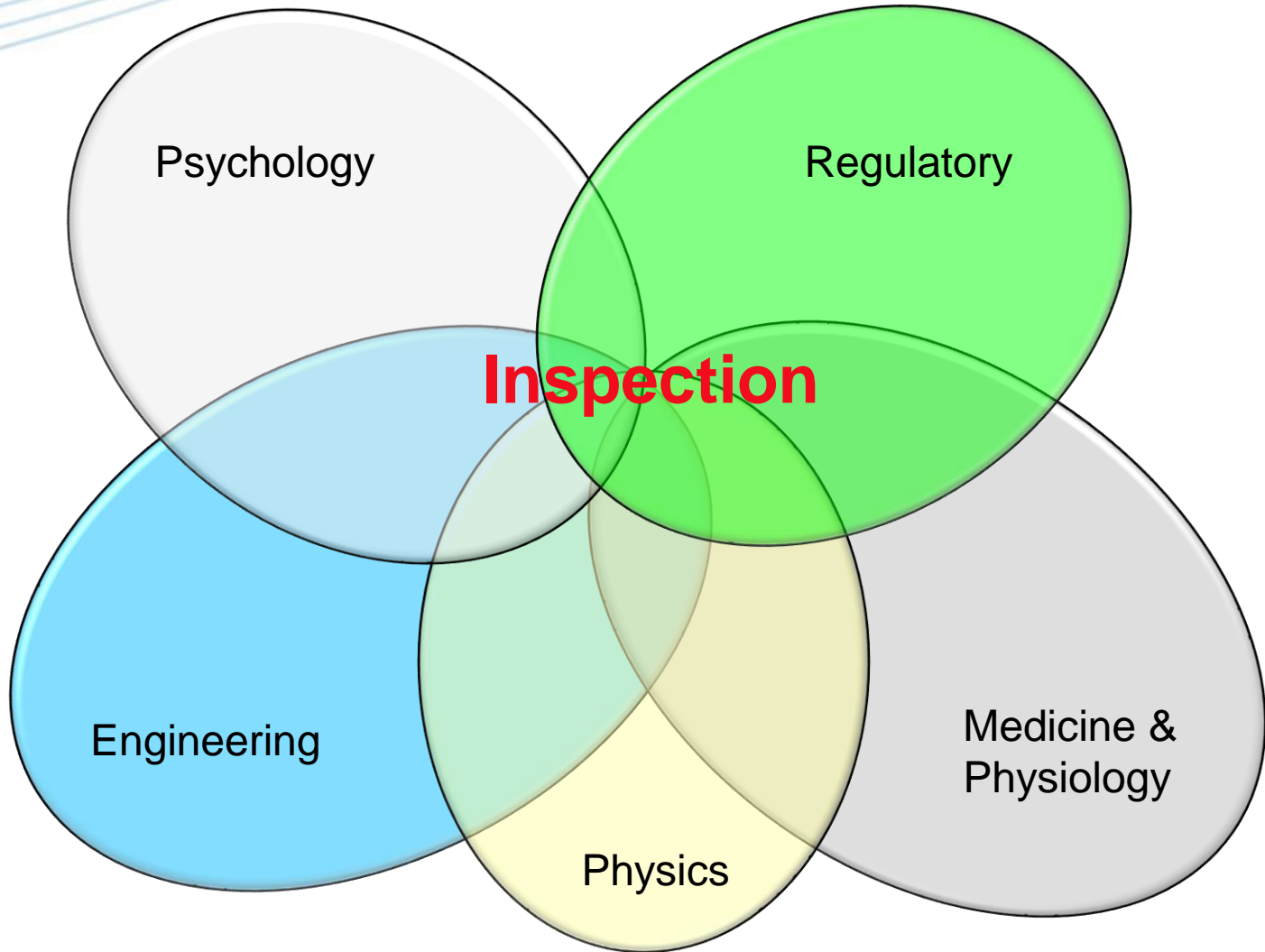
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



Manual Inspection

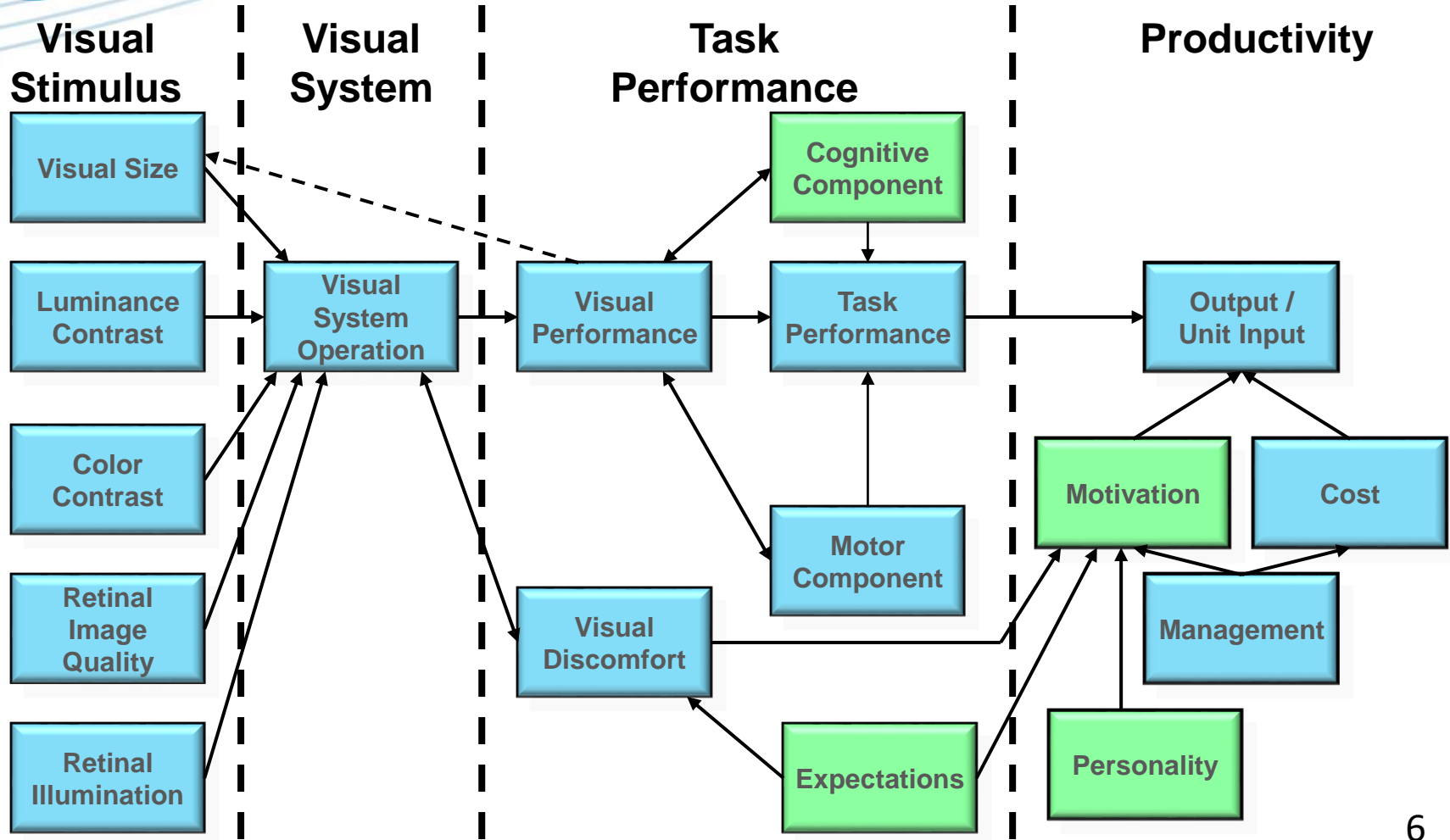


Inspection Influences





Inspection



From G. Salvendy, Handbook of Human Factors and Ergonomics, 2nd Edition

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Manual Inspection



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Manual Inspection



Phoenix Imaging MIB-100



Manual Inspection





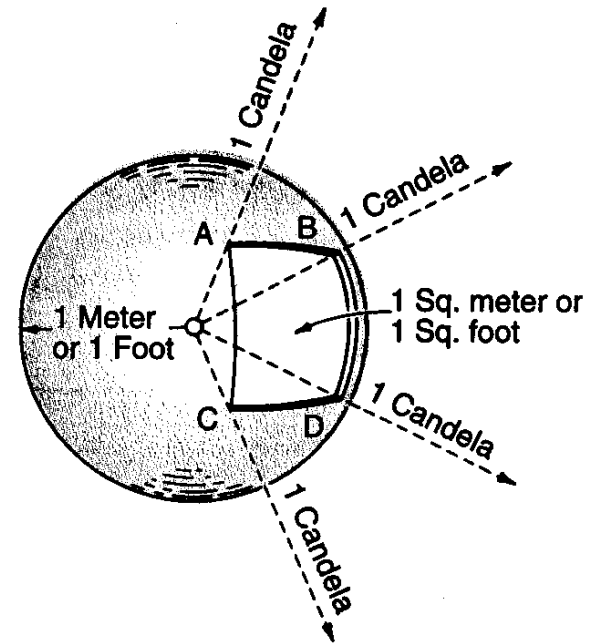
Critical Inspection Parameters

- Lighting
 - Illumination Intensity
 - Uniform, Flicker-free
 - Fluorescent, Incandescent, LED
 - Tyndall (dark-field)
- Background
 - Black / White
- Presentation and Manipulation
 - Swirl and/or invert
- Pace
 - 10 sec / container reference



Illuminance

- Luminous Intensity
 - 1 candela = 1/638 W/sr
 - formerly candlepower
- Illuminance
 - 1 lux = 1 lumen/m²
 - 1 foot-candle = 1 lumen/ft²
 - 1 fc = 10.75 lux
- Inverse Square Law
 - illumination = luminous intensity/d²



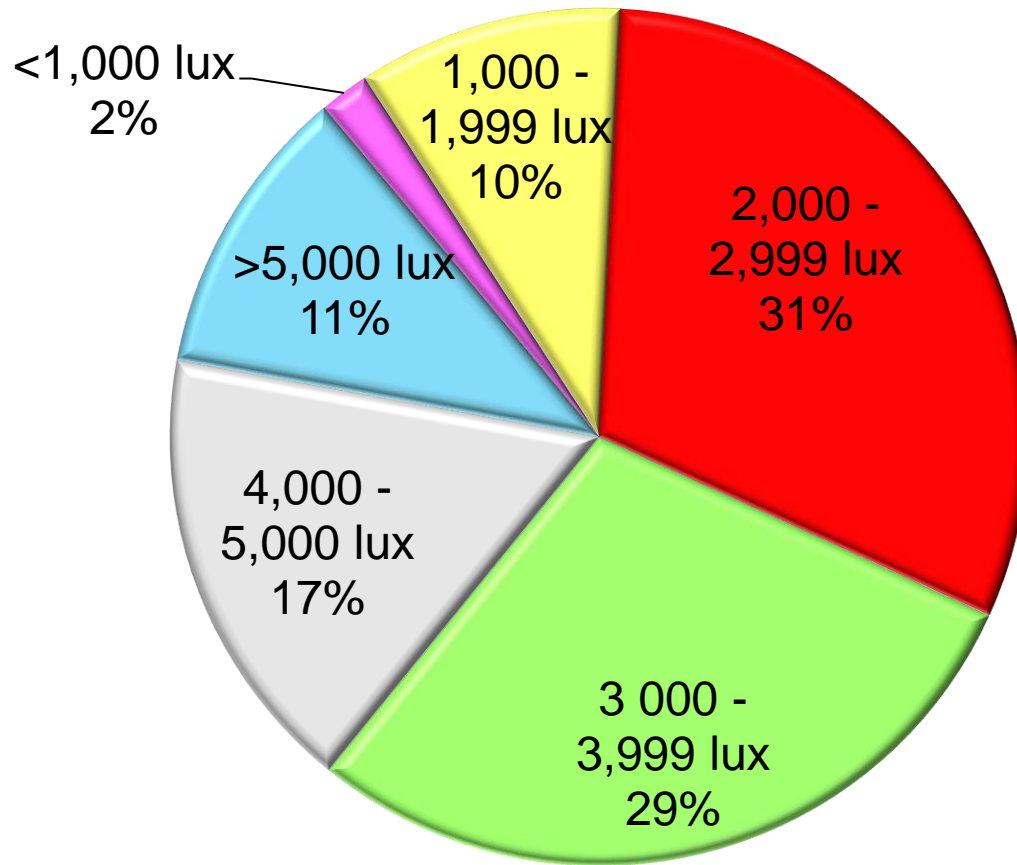


Illumination Intensity

- USP, EP, JP and WHO
 - 2,000-3,750 lux, Higher (e.g., 8,000-10,000 lux for difficult to inspect containers and products)
- ChP
 - 1,000-1,500 lux (clear solutions), 2,000-3,000 lux (colored solutions and glass, plastic containers)
 - 4,000 lux (suspensions, emulsions)
- IESNA
 - “Difficult Inspection”, visual tasks of low contrast and small size. 1,000 lux
 - “Exacting Inspection”, visual tasks near threshold. 3,000-10,000 lux

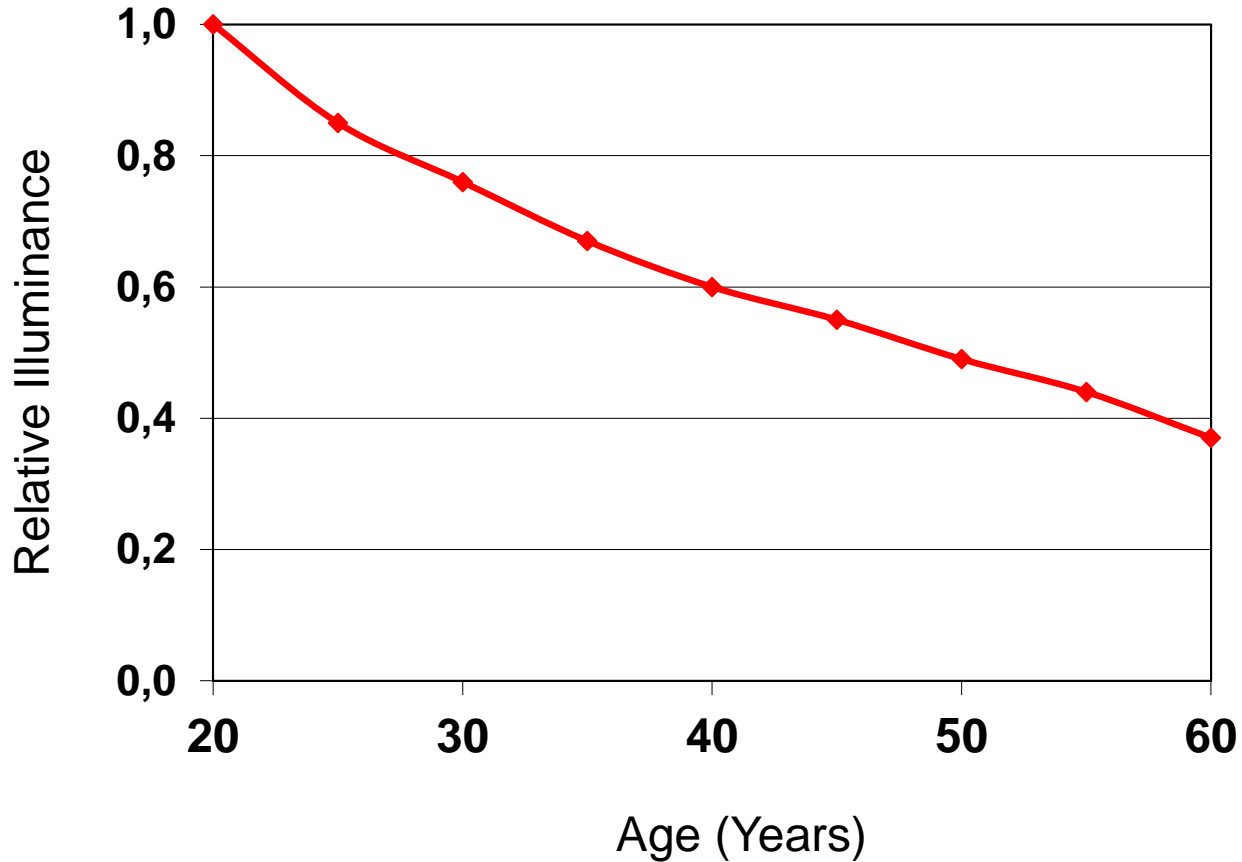


What is the average illumination intensity at the container during manual inspection?





Aging and Relative Illuminance



From IESNA Lighting Handbook, 9th Edition

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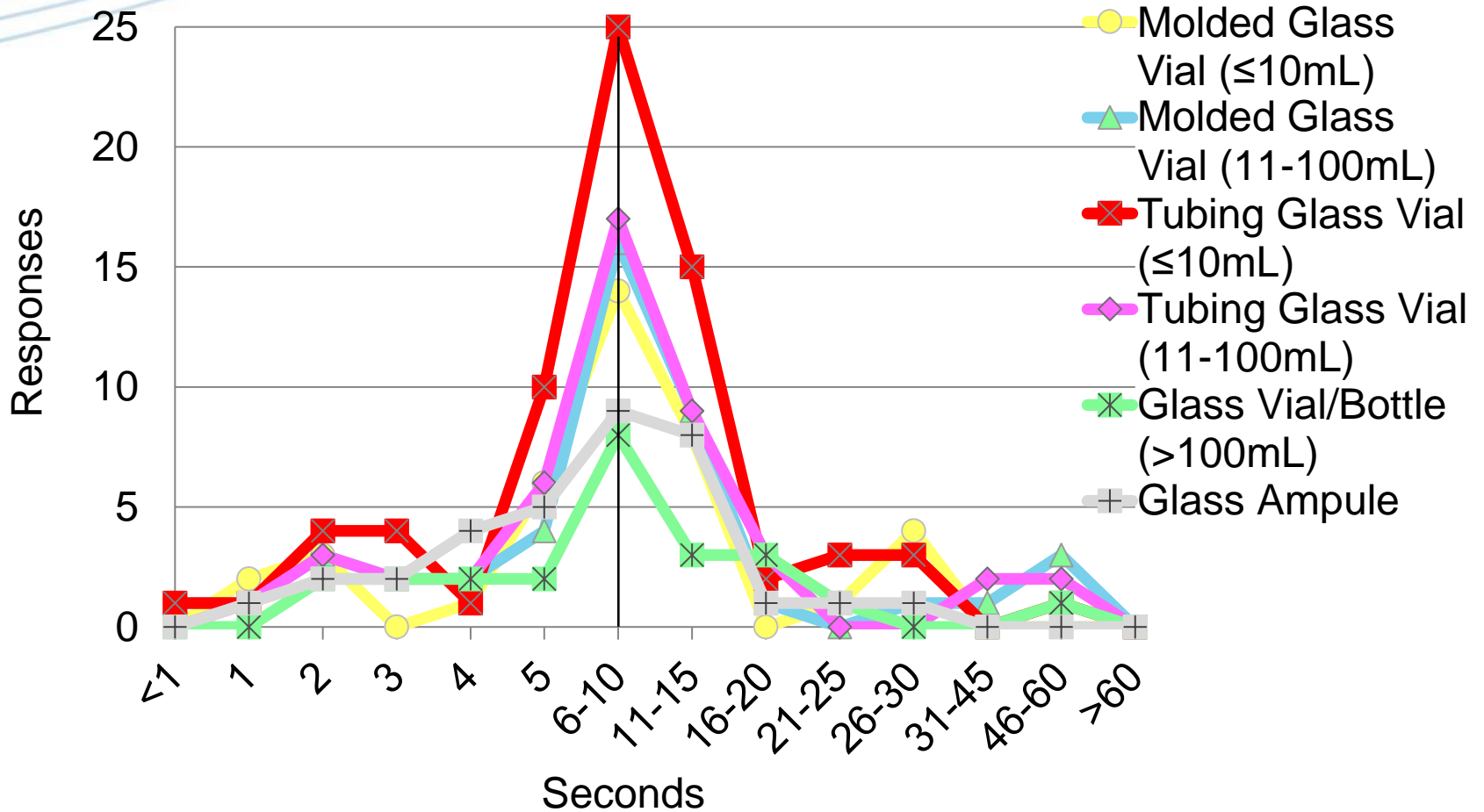


Manual Inspection Conditions

- 73% control inspection time or the pace of inspection.
 - 46% with Timer
 - 29% by SOP
 - 24% with Conveyor
- 26% use a magnifier.
 - 44% 2X, 25% 3X, 8% 4X, 8% 5X, 14% >5X
- 6% use a polarizer.
- Light Source used:
 - 73% Fluorescent, 19% LED, 18% Incandescent,

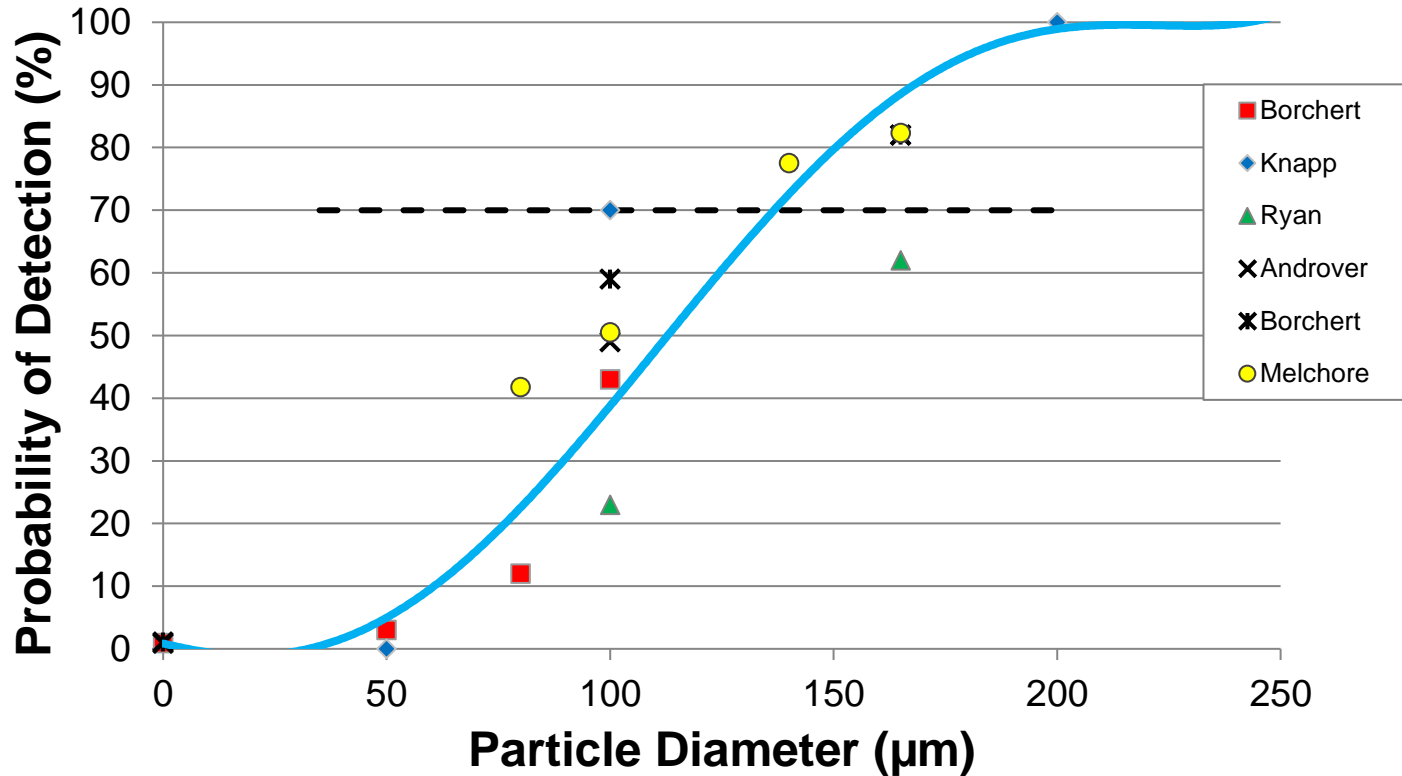


What is the average inspection time for this container type?





Human Inspection Performance



From Shabushnig, Melchore, Geiger, Chrai and Gerger, PDA Annual Meeting 1995

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Inspection Performance

- Human Inspection
 - Visual acuity
 - Fatigue
 - Flexibility
- Probabilistic
 - Especially true for particulate matter due to continuously changing presentation.



Semi-Automated Inspection

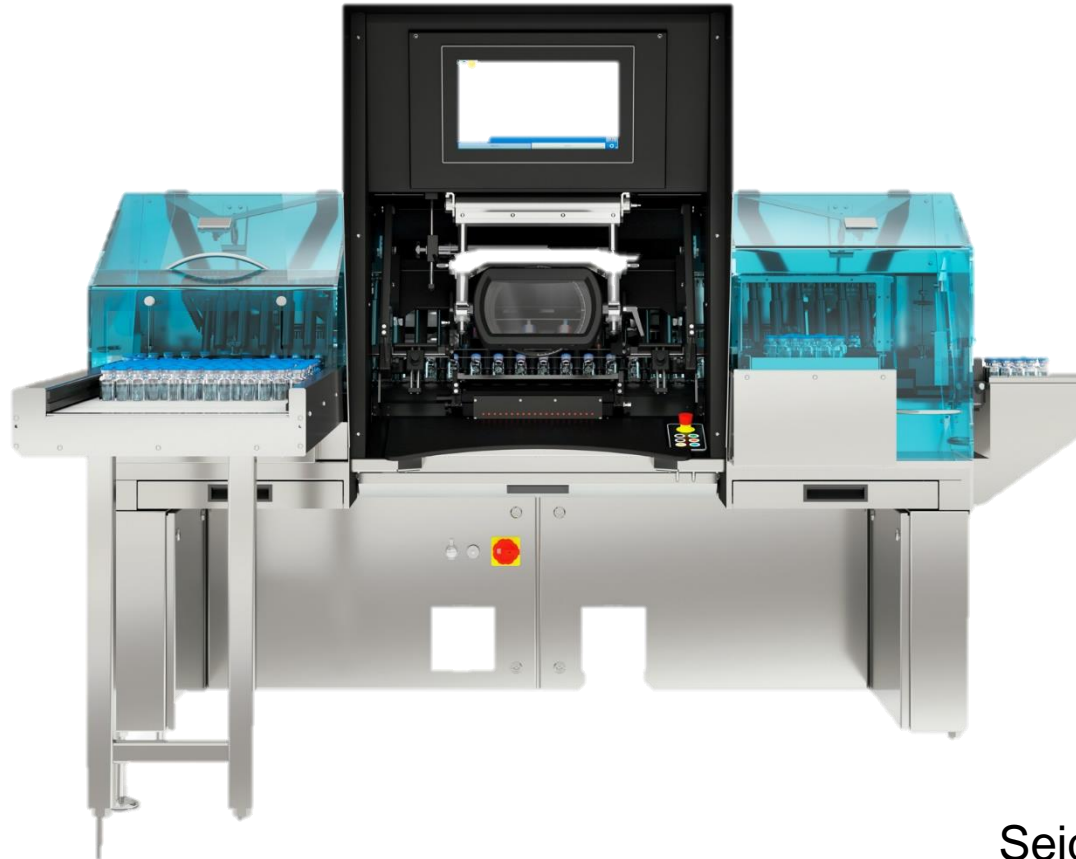


Semi-Automated Inspection

- Machine Material Handling
 - Transport, Spin/Rotation, Traying
 - Consistent lighting and presentation
 - Manual or Machine Rejection
- Human Inspection
 - Quality Decision



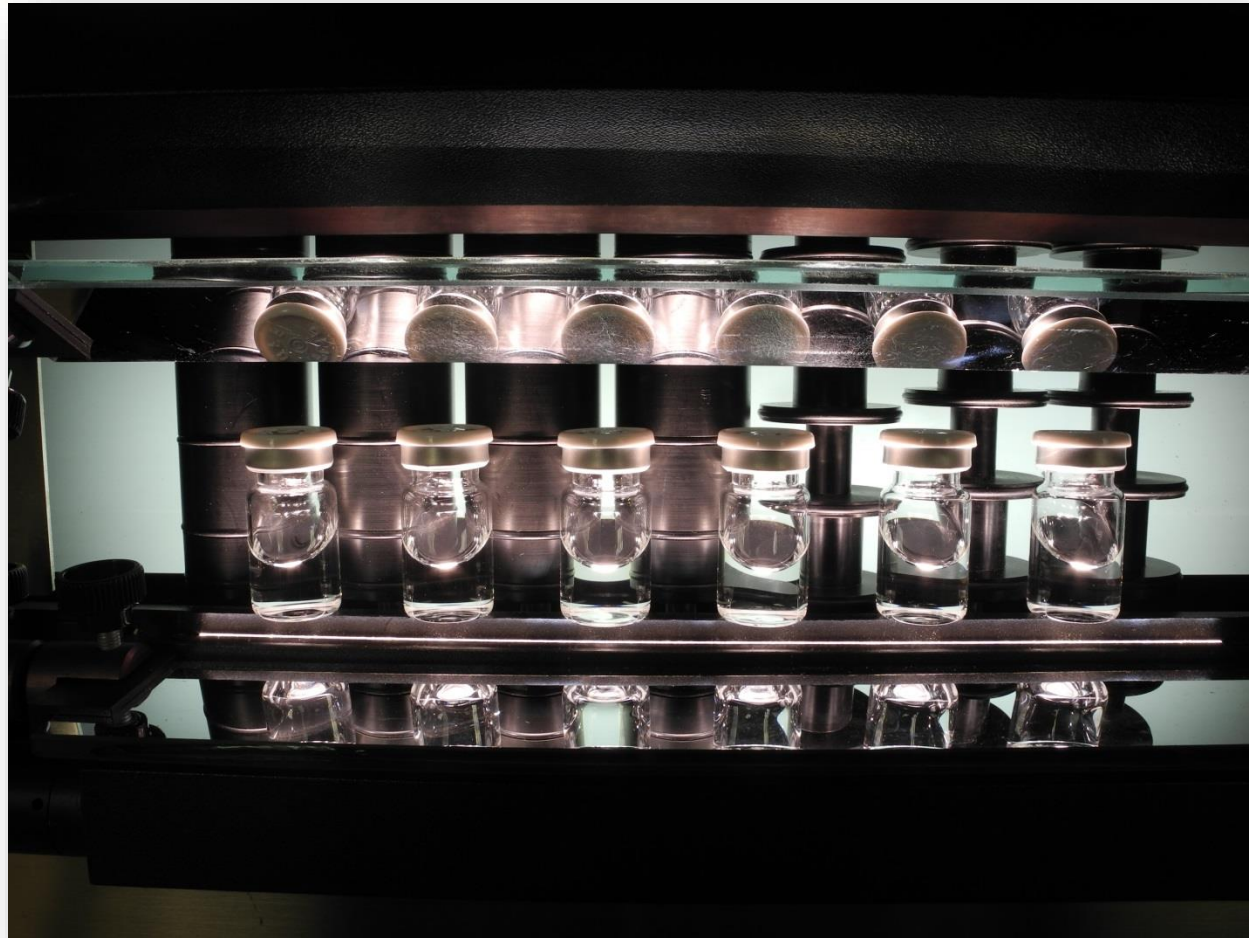
Semi-Automated Inspection



Seidenader



Semi-Automated Inspection



Seidenader



Inspection Performance

- Semi-Automated
 - Similar to manual
 - May have poor sensitivity for heavy particles
 - Particles stop moving before inspection
 - Improved ergonomics
 - Improved throughput



Automated Inspection



Automated Particle Inspection

Light Source

Product

Linear Detector



Bosch Static Detection (SD)



Automated Particle Inspection



Eisai AIM-288

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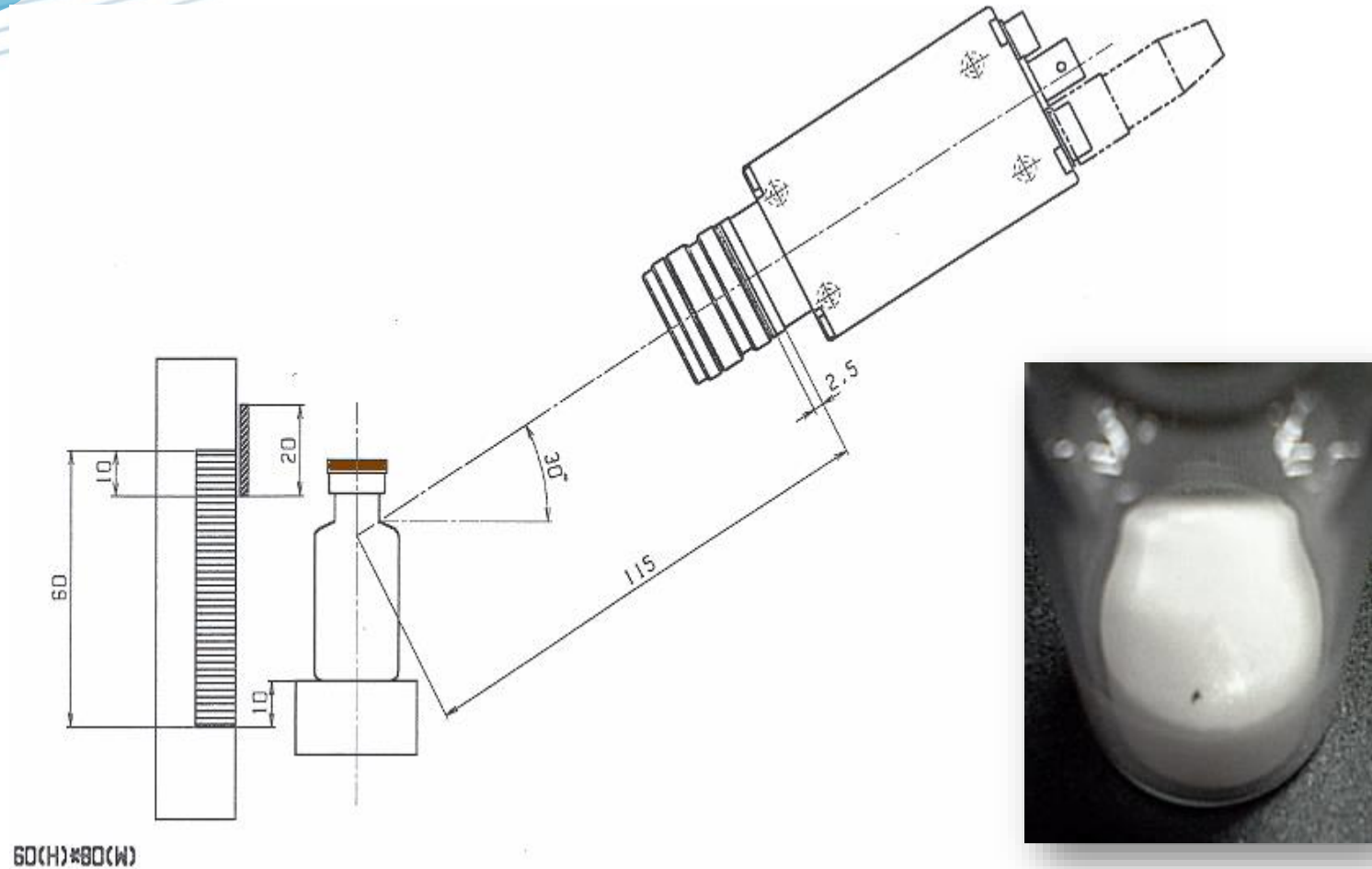
Automated Inspection



Eisai EIS-596



Automated Inspection



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Inspection Performance

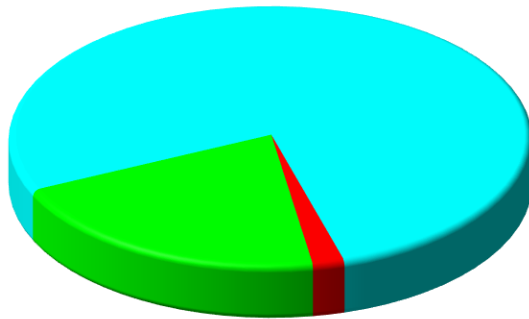
- Machine Inspection
 - Adjustable Sensitivity
 - Increased sensitivity must be balanced with increased false rejection rates.
 - Often product dependent
 - viscosity, surface tension, container design and variability
- Improved Reproducibility
- Improved Throughput
- High Initial Investment



Machine Inspection Performance

Human

Inconclusive

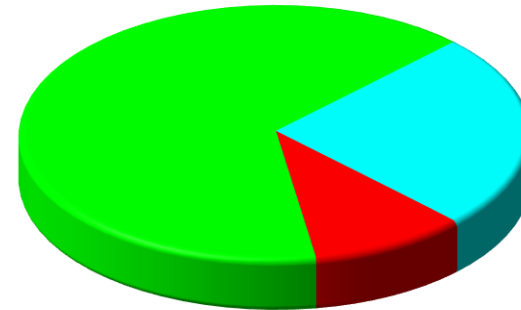


Good

Reject

Machine

Good



Inconclusive

Reject

A set of 250 vials was inspected 20 times by each method. Any vial not classified consistently 20 of 20 times was classified inconclusive.



What technique is used for inspection for / of ...

	2014	2008	2003	1996
Particles				
Manual	49%	33%	46%	33%
Semi-Automated	17%	24%	19%	20%
Automated	33%	43%	35%	42%
Container/Closure				
Manual	54%	36%	63%	48%
Semi-Automated	18%	26%	15%	42%
Automated	28%	39%	20%	5%



Does your firm have plans to replace manual inspection with automated inspection?

	2014	2008	2003	1996
Shift to Automated Inspection	50%	67%	50%	68%
Justification				
Quality	85%	75%	92%	92%
Productivity	87%	92%	92%	100%
Other	5%	0%	8%	17%



Inspection Standards



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How frequently do you challenge or retest automated inspection equipment?

	2014	2008	2003	1996
Never	1%	0%	0%	15%
Each Shift	1%	8%	13%	8%
Start of Lot	46%	42%	75%	38%
Start and End of Lot	8%	ND	ND	ND
Daily	15%	25%	19%	23%
Weekly	2%	0%	0%	8%
Monthly	2%	ND	ND	ND
Quarterly	1%	ND	ND	ND
Annually	19%	ND	ND	ND

ND = No Data, question not asked in survey from this year

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Questions?

**BEAUTIFUL,
BUT OBSOLETE.**

