Establishment of manual Knapp test results

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- 2001 – 2004: Technical apprenticeship at Seidenader Maschinenbau GmbH
- 2005 – 2009 Visited University of Supplied Science in Munich.
  Graduated as Dipl.-Ing. (Business and Engineering). Spending one semester in Seidenader's subsidiary "SV Research - Harrisburg/USA" and at the University of Plymouth / England.

- September 2009 – Mai 2015: Area Sales Manager at Seidenader Maschinenbau GmbH in Markt Schwaben, Business Unit Inspection Machines.
  Sales area responsibilities:
  - India
  - France
  - USA, Canada
  - South & Latin America

- Since May 2015: Executive Vice President – Sales with responsibility for the sales and marketing department of the Seidenader Business Unit Inspection Machines.

Agenda

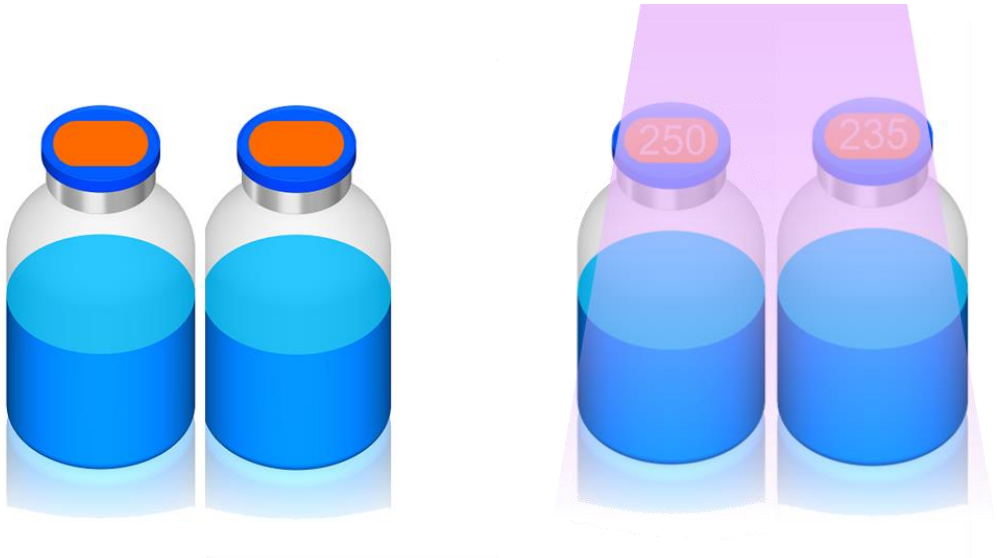
- Preparation and performance of manual Knapp test inspection
- Human behavior / conditions while inspecting a Knapp test set
- Performance of automatic Knapp test inspection
- Evaluation / comparison of manual and automatic inspection results
- Evaluation and reporting of the grey and valid Knapp test results

Knapp test preparation / performance

- Defect selection out of existing defect library
  (Approx 10 per category, do not forget spare)

- Collection of the Knapp test kit. Defects : good samples = 20% : 80%
  Approx. 200 defects / 800 good samples

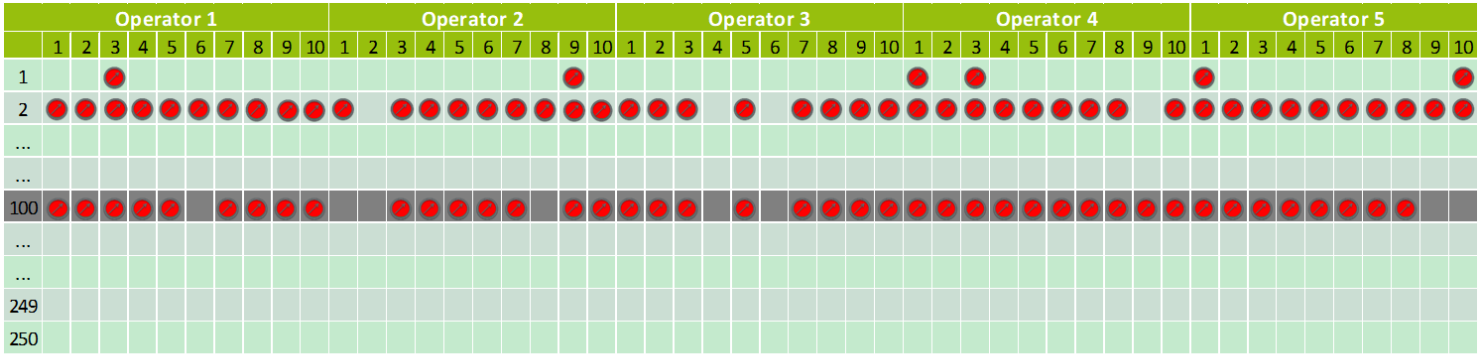
- Preparation of the Knapp test set – mixing / marking invisible



Mark each container and use UV - Ink

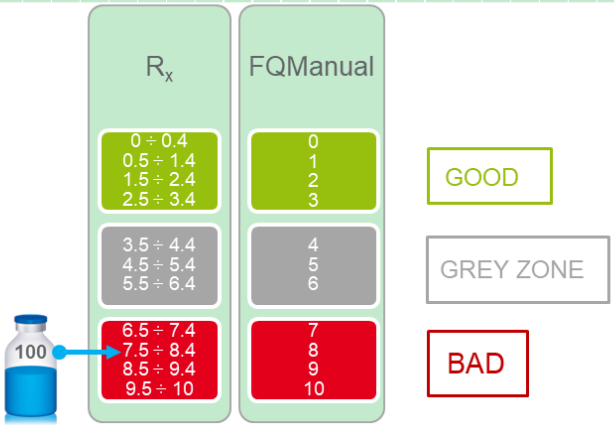
Human behavior while inspecting

- Operators realize that they will be tested, different conditions as in batch mode.
- Knapp set results will be visible in Excel file / personal accuracy gets measured / visible to colleagues
- Every obvious marking or visible marking is soon realized and used as reference for inspection / defect detection (even fingerprints on the defects will be realized).
- Inspection time has to be the same as in production, this needs to be ensured. Sample kit should be inspected 10 times by different operators.



$R_{100} = 9 + 7 + 8 + 10 + 8 = 42$ (out of 50)

$R_{100} = 42/50 * 10 = 84\%$



Performance of automatic Knapp Test Inspection

- After the manual results are established the sample set should be separated in good and defect samples.
- Separate the defects in categories to run them on the final machine configuration in loop / validation mode
- Defects should be tested at a minimum of 10 times in a loop mode function category by category
- Since the machine does not know what is loaded, it is not necessary or useful to mix the samples on the machine. It is only for the human operators as they have to separate the samples. If he realizes a defined arrangement, the result will be falsified.

Evaluation / comparison of manual and automatic inspection results

- Collect and list all manual inspection results for all samples and calculate the average of the different human inspection results from their 10 inspection rounds for good and bad products.
- Collect and record all results of the machine loop mode / validation mode for good and bad products in this list. Define a column where you can directly compare the final results of both validation processes and compare the final results of the defect groups.
- The goal is that the results of the machine must be as good or better than the human inspection result in order to pass the validation. (OQ Vision Performance has already been established with the SAT Vision Performance Test)

FQManual vs. FQAutomatic

$$\sum \text{FQManual} = 9 + 10 + 7 + 8 + 10 + 9 = 53$$

$$\sum \text{FQAutomatic} = 9 + 10 + 8 + 10 + 10 + 10 = 57$$

$$\text{Efficiency} = \frac{\sum \text{FQB}}{\sum \text{FQA}} * 100 = 107{,}5\ \%$$

		FQManual (operators)	FQAutomatic (machine)
	1	1	1
	2	9	9
	3	0	0
*	4	4	10
	5	10	10
	...	...	...
	...	...	...
	97	0	1
	98	7	8
*	99	6	7
	100	8	10
	101	0	0
	102	1	0
	103	1	1
	...	...	...
	...	...	...
	246	10	10
	247	9	10
	248	1	1
	249	3	2
	250	2	0

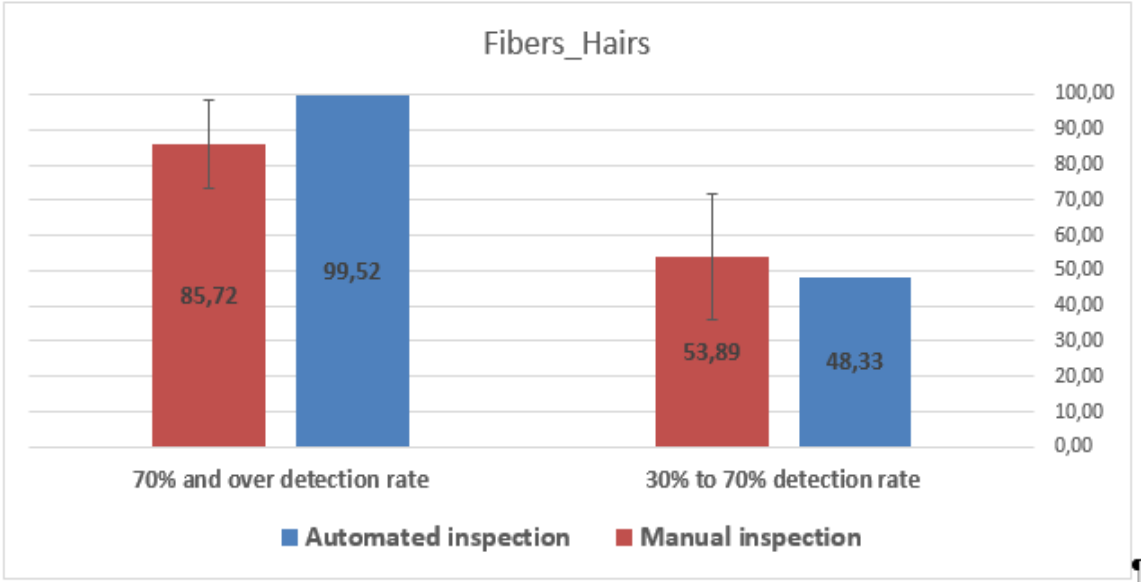
Evaluation / comparison of manual and automatic inspection results

Tub#/ Syringe	Defect typ / Blanks	Defect description / size	Particle size	Defectkategory	Kritikalität	correct inspected	wrong inspected	%DR	Accept	Grey Zon	Reject	correct inspected	wrong inspected	% DR	Manual comment after machine inspection runs	Single Defect Comparison
1/35	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	25	8	75,76			X	30	0	100,00	Particle in movement	Machine = > Human
1/85	Z	Kunststoff (farblos)	175-225µm	6.6 Particle defect	Major	10	23	30,30		X		30	0	100,00	Particle in movement	Machine = > Human
1/127	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	33	0	100,00			X	30	0	100,00	Particle sticking on stopper	Machine = > Human
1/157	Z	Metall	800-1200µm	6.6 Particle defect	Major	30	3	90,91			X	14	16	46,67	Particle in movement	Human > maschine
2/68	Z	Metall	800-1200µm	6.6 Particle defect	Major	27	6	81,82			X	27	3	90,00	Particle sticking on stopper	Machine = > Human
2/160	Z	Glas	800-1200µm	6.6 Particle defect	Major	30	3	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
3/48	Z	Metall	800-1200µm	6.6 Particle defect	Major	18	14	54,55		X		30	0	100,00	Particle sticking on stopper	Machine = > Human
3/56	Z	Glas	800-1200µm	6.6 Particle defect	Major	29	3	87,88			X	30	0	100,00	Particle in movement	Machine = > Human
3/89	Z	Metall	800-1200µm	6.6 Particle defect	Major	29	3	87,88			X	28	2	93,33	Particle in movement	Machine = > Human
4/66	Z	Glas	800-1200µm	6.6 Particle defect	Major	29	4	87,88			X	30	0	100,00	Particle in movement	Machine = > Human
4/76	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	30	3	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
5/144	Z	Glas	175-225µm	6.6 Particle defect	Major	11	21	33,33		X		9	21	30,00	Particle sticking on sidewall	Human > maschine
6/57	Z	Glas	175-225µm	6.6 Particle defect	Major	5	27	15,15	X			11	19	36,67	No particle visible	Machine = > Human
6/60	Z	Glas	800-1200µm	6.6 Particle defect	Major	28	4	84,85			X	30	0	100,00	Particle in movement	Machine = > Human
6/82	Z	Kunststoff (farblos)	175-225µm	6.6 Particle defect	Major	5	27	15,15	X			30	0	100,00	Particle in movement	Machine = > Human
6/131	Z	Metall	800-1200µm	6.6 Particle defect	Major	29	3	87,88			X	26	4	86,67	Particle in movement	Human > maschine
6/147	Z	Glas	800-1200µm	6.6 Particle defect	Major	27	5	81,82			X	30	0	100,00	Particle in movement	Machine = > Human
6/149	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	30	2	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
7/17	Z	Glas	175-225µm	6.6 Particle defect	Major	7	25	21,21	X			30	0	100,00	No particle visible	Machine = > Human
7/19	Z	Glas	175-225µm	6.6 Particle defect	Major	28	4	84,85			X	30	0	100,00	Particle in movement	Machine = > Human
7/35	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	29	3	87,88			X	30	0	100,00	Particle in movement	Machine = > Human
7/46	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	32	0	96,97			X	30	0	100,00	Particle in movement	Machine = > Human
7/52	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	30	2	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
7/137	Z	Metall	800-1200µm	6.6 Particle defect	Major	22	10	66,67		X		22	8	73,33	Particle in movement	Machine = > Human
7/143	Z	Glas	800-1200µm	6.6 Particle defect	Major	27	5	81,82			X	11	19	36,67	Particle sticking on stopper behind Grading	Human > maschine
7/152	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	29	3	87,88			X	30	0	100,00	Particle in movement	Machine = > Human
8/46	Z	Kunststoff (farblos)	175-225µm	6.6 Particle defect	Major	20	12	60,61		X		23	7	76,67	Particle sticking on stopper	Machine = > Human
8/137	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	30	2	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
8/143	Z	Metall	800-1200µm	6.6 Particle defect	Major	26	6	78,79			X	26	4	86,67	Particle in movement	Machine = > Human
8/149	Z	Metall	800-1200µm	6.6 Particle defect	Major	26	6	78,79			X	23	7	76,67	Particle in movement	Human > maschine
8/156	Z	Kunststoff (farblos)	800-1200µm	6.6 Particle defect	Major	30	2	90,91			X	30	0	100,00	Particle in movement	Machine = > Human
9/26	Z	Glas	800-1200µm	6.6 Particle defect	Major	29	2	87,88			X	30	0	100,00	Particle in movement	Machine = > Human

Evaluation and reporting of the grey and valid Knapp test results

>70% Valid samples

30 -> 70% Grey samples



Q&A