A Study on Identifying the Worst Position within Mixed Clinical Loads to be Sterilized

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- Study Road Map
- Pass Criterion
- Research Method
- Conclusion
- Discussion

Project Background

Two questions we faced during our daily work

Q1:The pre-set sterilization cycles of steam sterilizer in CSSD are designed and tested according to EN 285 with standard and single category material. But it's heavily different to the mixed load in daily practice. Can the default process settings handle the daily mixed load?

Q2:When biological indicator or process challenging device(PCD) are required to be placed at "worst condition" for batch monitoring, is the position above chamber drain appropriate?

A study was performed on the 101 clinical packs in our hospital

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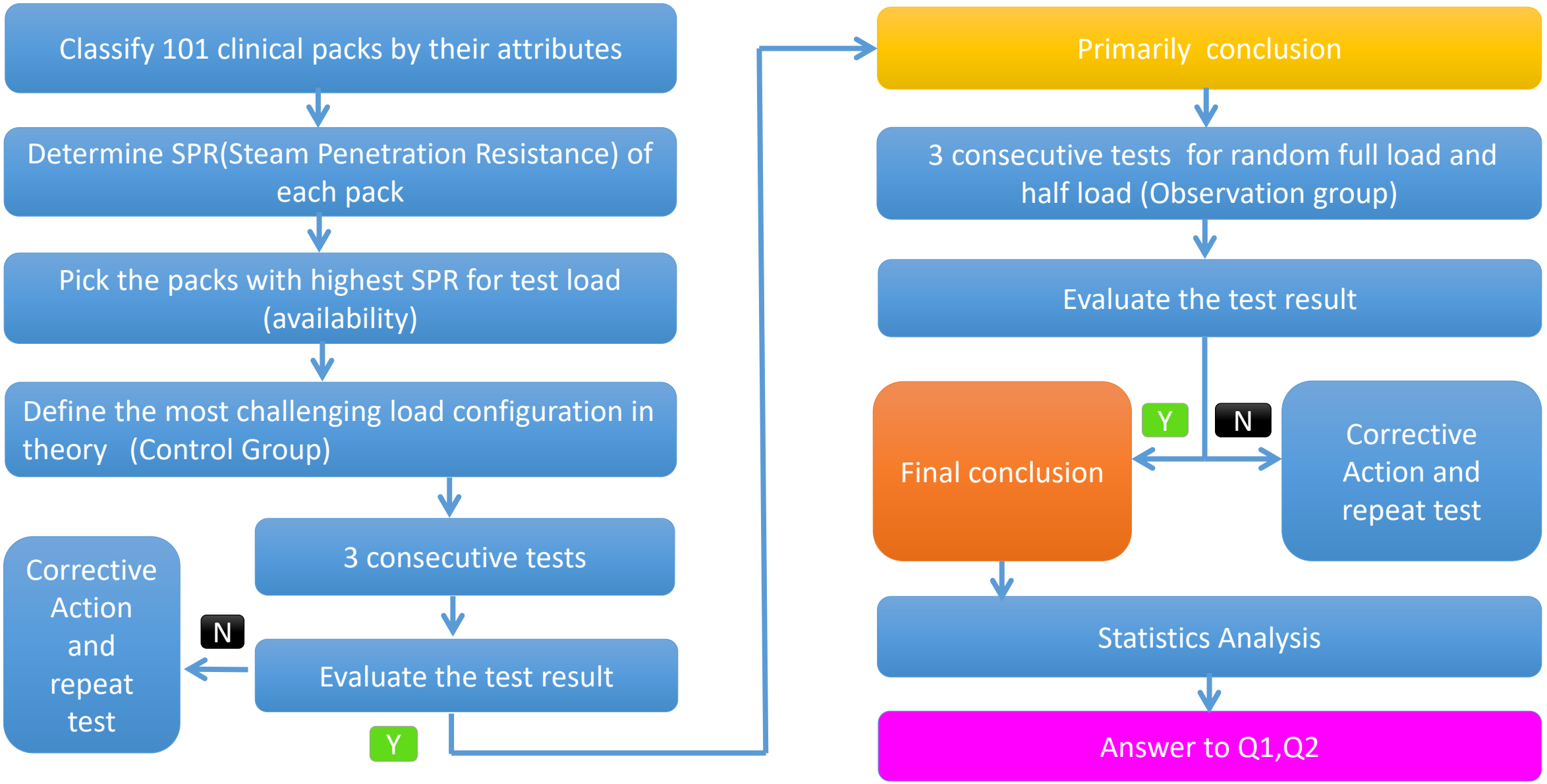
Study Road Map



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Pass Criterion

Criteria	Standards(EN285/GB8599)
Leak rate	≤1.3mbar/min
Bowie and Dick test	The chemical indicator changes color evenly
Equilibration time	≤30s
Sterilization temperature fluctuation	≤2C
Sterilization temperature band	0C ～+3C
Holding time	≥180s
Dryness test	The added weight of the test load after sterilization shall not exceed 0.2% compared to the weight before sterilization

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Classification 101 Type clinical packs by their attributes

Steam penetration resistance---《ISO17665-3：2013》

Challenge to a sterilization process from a medical device， including any sterile barrier/packing system that may delay attainment of process parameter for moist heat sterilization on all parts of the medical device

Table 1 — General attributes

Attribute	Code
Design	a
Weight	b
Material	c
Sterile barrier system	d

Table 6 *(continued)*

MD	Attribute																									Steam penetration resistance (estimated)
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
22					x					x	x	x			x								x			
23					x				x				x	x		x	x	x					x			
24					x					x	x	x				x	x	x					x			
25					x					x			x	x		x	x	x					x			
26						x			x	x			x	x		x	x	x						x		
27						x			x			x	x		x	x	x	x					x			
28						x				x		x			x	x	x	x						x		
29[a]							x		x	x															x	
+																										

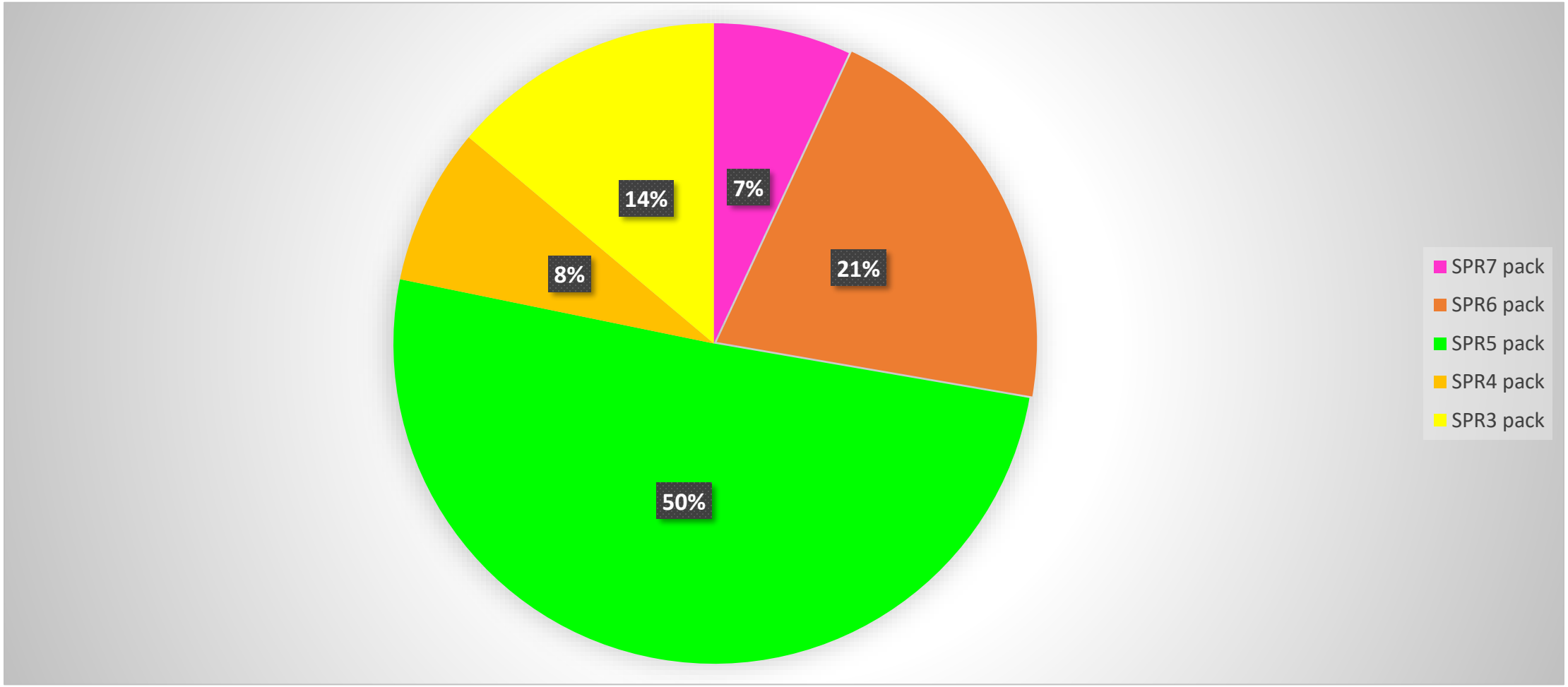
[a] Special - sterilization process should be developed and qualified.

+ New product families that may be identified by the user.

Classification 101 Type clinical packs by their attributes

#	Overview of Pack SPR																									
	Design							Material		Weight of single piece				Sterile barrier system				PF refer to 17665-3:2013	SPR(Estimate)								Estimated SPR
	Solid/Hollow	Pin and Box joints	Lumen	Porous	Tubing,moving parts, tortuous paths	Lumen surrounded by a large mass: >500g	Other	Metal	Non-Metal	< 50g	< 500g	< 2 kg	> 2 kg	None	singel wrapped/pouch	Double wrapped	Combination of two or more systems		1	2	3	4	5	6	7	+	
1	✓	✓	✓	✓				✓	✓				✓			✓		15+12						✓			6
2	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
3	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
4	✓	✓		✓				✓	✓				✓			✓		15					✓				5
5	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
6	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
7	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
8	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
9	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
10	✓	✓		✓				✓	✓			✓				✓		15					✓				5
11	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
12	✓	✓	✓	✓	✓			✓	✓				✓			✓		25					✓				5
13	✓	✓	✓	✓	✓	✓		✓	✓				✓			✓		26							✓		7
14	✓	✓		✓				✓	✓			✓				✓		15					✓				5
15	✓	✓		✓				✓	✓				✓			✓		15					✓				5

Distribution the Degree of Steam Penetration Resistance of 101 Type of Clinical Packs



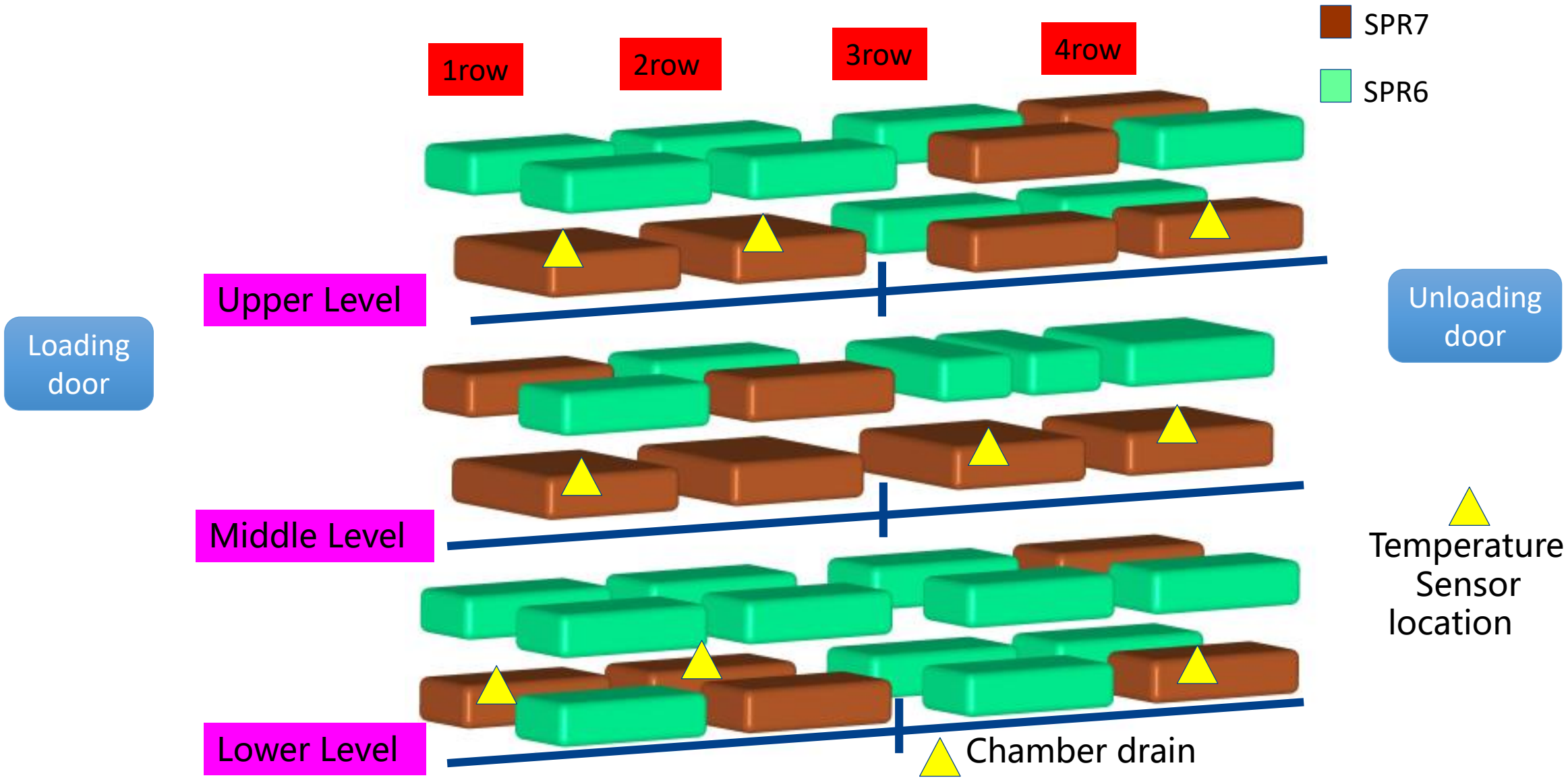
Control Group (CG) --- Theoretical Most Challenging Load

Type:18 Quantity:41,include SPR7:17;SPR6:24

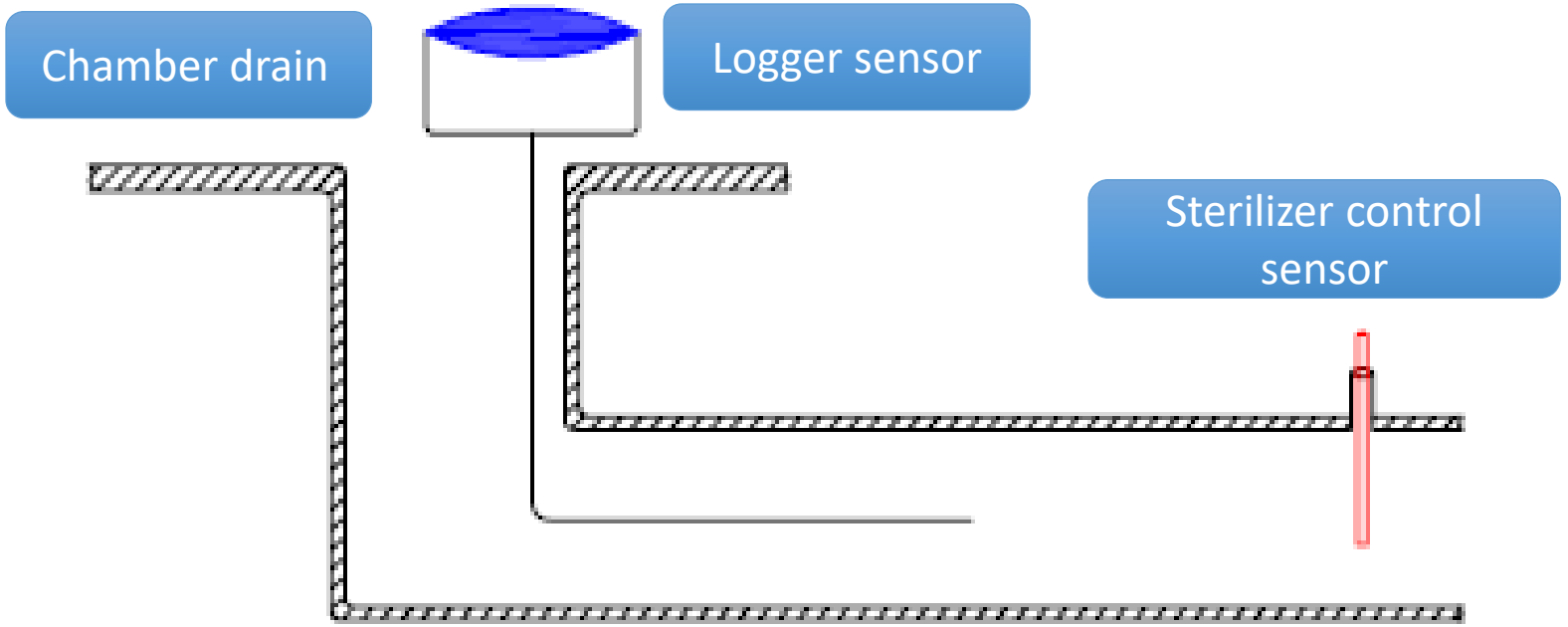
Pass Criteria of Leak rate / BD test/ Dryness test(Metal)

- Leak rate test should be lower than 1.3 mbar/min
- Color change of B-D Test sheet should change evenly
- The Load dryness test for metal shall not exceed 0.2% by weight in comparing to the weight before sterilization.

Control Group (CG) --- Theoretical Most Challenging Load



Reference measurement point



● Take the logger sensor placed at the chamber drain as the reference measurement point

Result Evaluation --- Sterilization Condition in Chamber

parameter	Importance	Criteria	Test	Equilibration Time	Pass/ failure	The location shows longest equilibration time
Equilibration Time	Capability of controlling heat-up accuracy and velocity throughout the chamber	<30s	1#	18s	✔	Upper 1
			2#	13s	✔	Upper 1
			3#	10s	✔	Upper 1
Sterilization temperature band	Capability of controlling temperature precisely throughout the chamber	0℃-3℃	Test	Sterilization temperature band	Pass/ failure	The location of the lowest temperature
			1#	134.03℃ — 135.50℃	✔	Upper1
			2#	134.01℃— 135.49℃	✔	Upper1
			3#	134.13℃— 135.48℃	✔	Upper1
Temperature uniformity	1)Capability of controlling temperature uniformity in the chamber. 2)Capability of adapting steam quality on site	<2℃	Test	Maximum temperature difference at the same moment	Pass/ failure	The location shows maximum temperature difference
			1#	0.96℃	✔	Upper 1
			2#	1.11℃	✔	Middle 2
			3#	0.92℃	✔	Upper 1

Result Evaluation --- Sterilization Condition in Chamber

parameter	Importance	Criteria	Test	Holding Time	Pass/ failure	The location shows lowest temperature at the end of holding time
Holding Time	Capability of stable controlling temperature continuously	≥180s	1#	301s	✔	Upper 1
			2#	308s	✔	Upper 1
			3#	305s	✔	Middle 3

Primary Conclusion

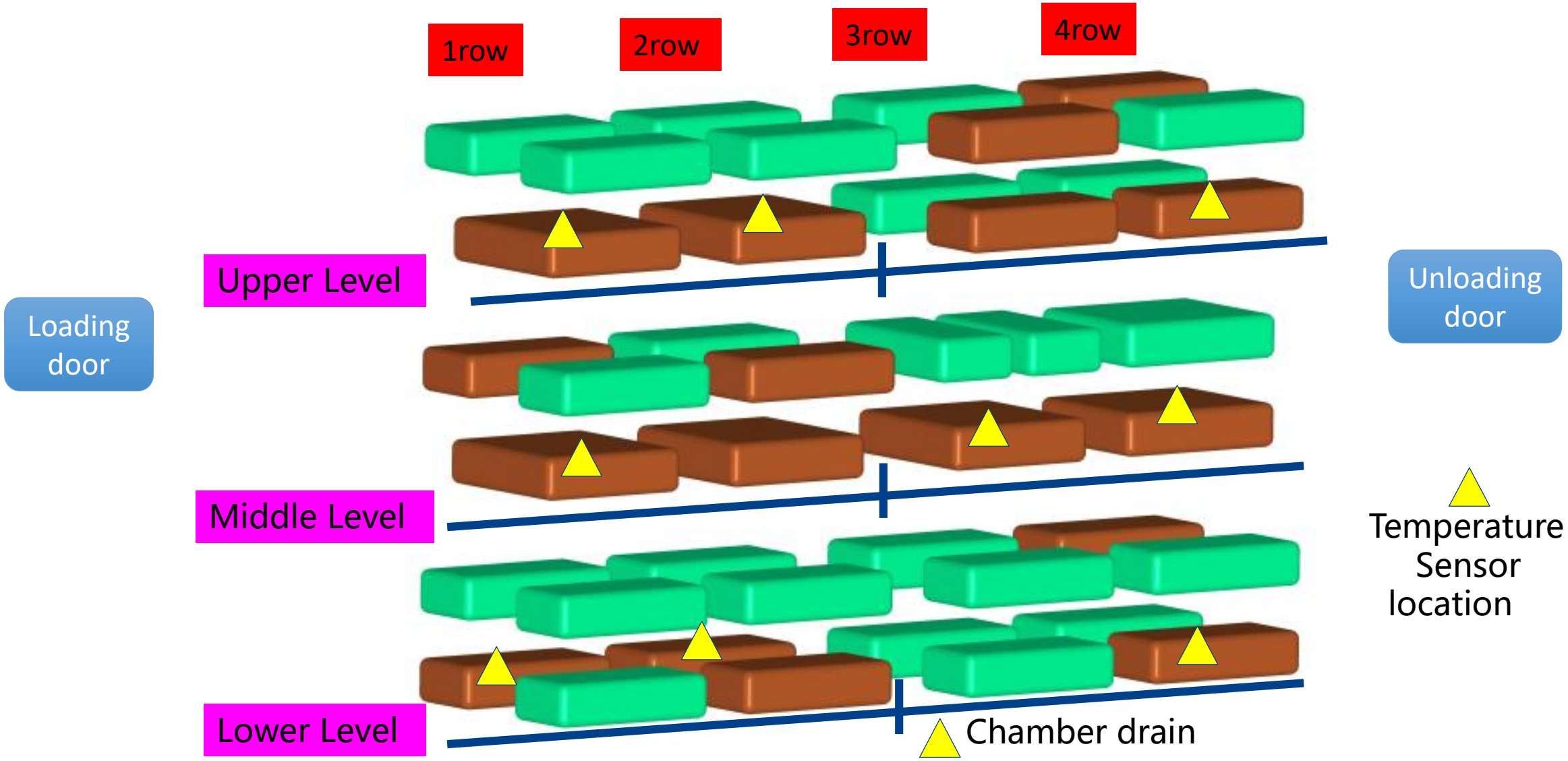
- The pre –set “P1 Instruments 134℃ “ cycle is suitable to sterilize the loads configured by those 101 types of clinical packs, as long as the degree of steam penetration resistance of the clinical packs are not higher than that of Control Group.(SPR6 or SPR7)
- For introduction of any new configuration of clinical set for steam sterilization, process validation is of paramount importance to assure the sterilization efficacy in order to assure patient safety

Observation Group 1 ---daily random packs in full load

- Load Configuration： Random selection of surgical packs within 101 types of clinical packs
- Loading Methods： Full load
- Number of test： 3
- Purpose： Verify the preliminary conclusion

SPR		7	6	5	4	3	2	1	Total number
Control group		17	24						41
Observation Group1	Full load 1			61	46				107
	Full load 2	2	9	35		4			50
	Full load 3	1		56		79			137

Observation Group 1 --- Theoretical Most Challenging Load



Result Evaluation --- Sterilization Condition in Chamber

parameter	Importance	Criteria	Test	Equilibration Time	Pass/ failure	The location shows longest equilibration time
Equilibration Time	Capability of controlling heat-up accuracy and velocity throughout the chamber	<30s	1#	22s	✔	Middle 4
			2#	18s	✔	Middle 4
			3#	13s	✔	Middle 4
Sterilization temperature band	Capability of controlling temperature precisely throughout the chamber	0℃-3℃	Test	Sterilization temperature band	Pass/ failure	The location of the lowest temperature
			1#	134.06℃ —135.55℃	✔	Middle 4
			2#	134.03℃— 135.52℃	✔	Middle 4
			3#	134.07℃— 135.47℃	✔	Middle 4
Temperature uniformity	1)Capability of controlling temperature uniformity in the chamber. 2)Capability of adapting steam quality on site	<2℃	Test	Maximum temperature difference at the same moment	Pass/ failure	The location shows maximum temperature difference
			1#	1.09℃	✔	Middle 4
			2#	1.09℃	✔	Middle 4
			3#	0.77℃	✔	Middle 4

Result Evaluation ---Sterilization Condition in Chamber

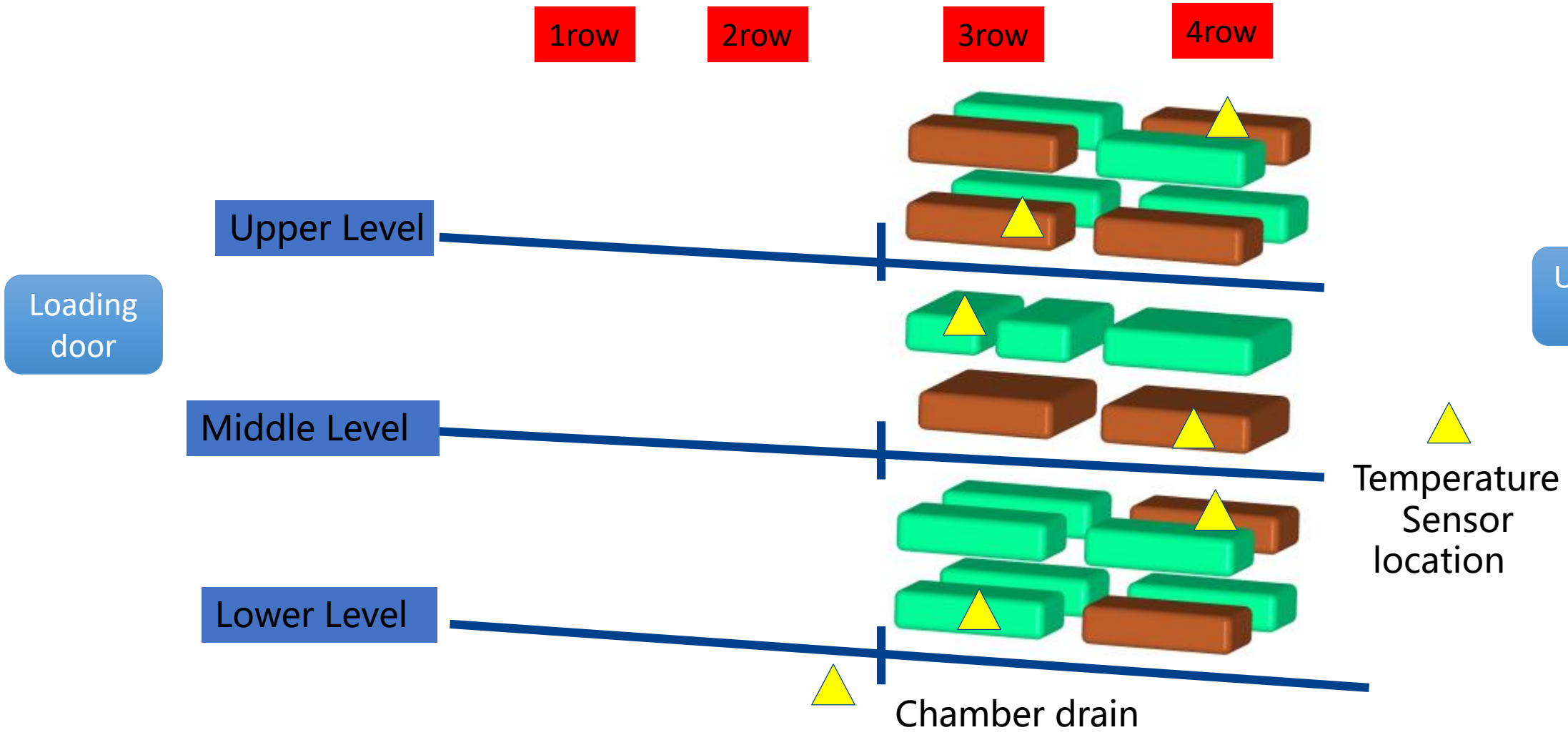
parameter	Importance	Criteria	Test	Holding Time	Pass/ failure	The location shows lowest temperature at the end of holding time
Holding Time	Capability of stable controlling temperature continuously	≥180s	1#	300s	✔	Middle 4
			2#	301s	✔	Upper 1
			3#	305s	✔	Middle 4

Observation Group2--- Daily random packs in half load

- Load Configuration： Random selection of surgical packs within 101 types of packs
- Loading Methods： Half load (according to the actual working practice)
- Number of test： 3
- Purpose： Verify the preliminary conclusion

SPR		7	6	5	4	3	2	1	Total number
Control group		17	24						41
Observation Group 2	half load 1	6	9	5					20
	half load 2	6	9	5					20
	half load 3	6	9	5					20

Observation Group(OG2)--- Daily random packs in half load



Result Evaluation --- Sterilization Condition in Chamber

parameter	Importance	Criteria	Test	Equilibration Time	Pass/ failure	The location shows longest equilibration time
Equilibration Time	Capability of controlling heat-up accuracy and velocity throughout the chamber	<30s	1#	10s	✔	Middle 3
			2#	8s	✔	Middle 3
			3#	9s	✔	Middle 3
Sterilization temperature band	Capability of controlling temperature precisely throughout the chamber	0℃-3℃	Test	Sterilization temperature band	Pass/ failure	The location of the lowest temperature
			1#	134.02℃--135.49℃	✔	Middle 3
			2#	134.07℃— 135.47℃	✔	Middle 3
			3#	134.08℃— 135.51℃	✔	Lower 3
Temperature uniformity	1)Capability of controlling temperature uniformity in the chamber. 2)Capability of adapting steam quality on site	<2℃	Test	Maximum temperature difference at the same moment	Pass/failure	The location shows maximum temperature difference
			1#	1.05℃	✔	Middle 3
			2#	0.8℃	✔	Middle 3
			3#	0.98℃	✔	Middle 3

Result Evaluation – Sterilization Condition in Chamber

parameter	Importance	Criteria	Test	Holding Time	Pass/ failure	The location shows lowest temperature at the end of holding time
Holding Time	Capability of stable controlling temperature continuously	**≥180s**	1#	**303s**	✔	**Upper 4**
			2#	**308s**	✔	**Upper 4**
			3#	**304s**	✔	**Upper 4**

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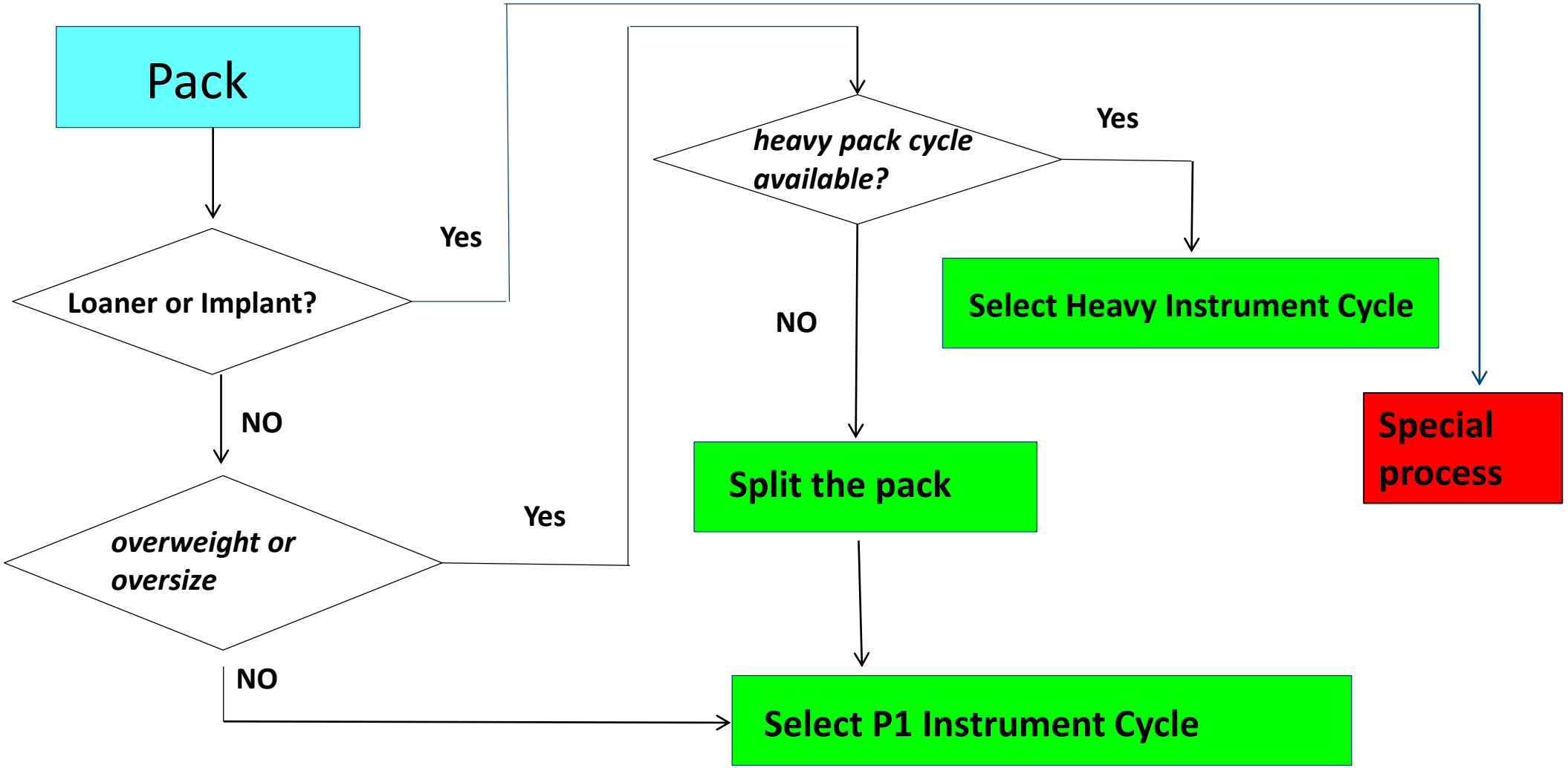
Final Conclusion 1

All process criteria are fulfilled when testing with the most challenging load configuration, randomly packs in full load and half load condition among these 101 routine surgical instrument packs. Therefore the validity of P1 Instruments 134C is proven as long as the sterilization challenge of the batch is not higher than the representative Theoretical Challenging load configuration, namely Control Group (CG). →Answer to Q1

Q1:The factory set sterilization cycles of steam sterilizer in CSSD are designed and tested according to EN 285 with standard and single category material. But it's heavily different to the mixed load in daily practice. Can the default process settings handle the daily mixed load?

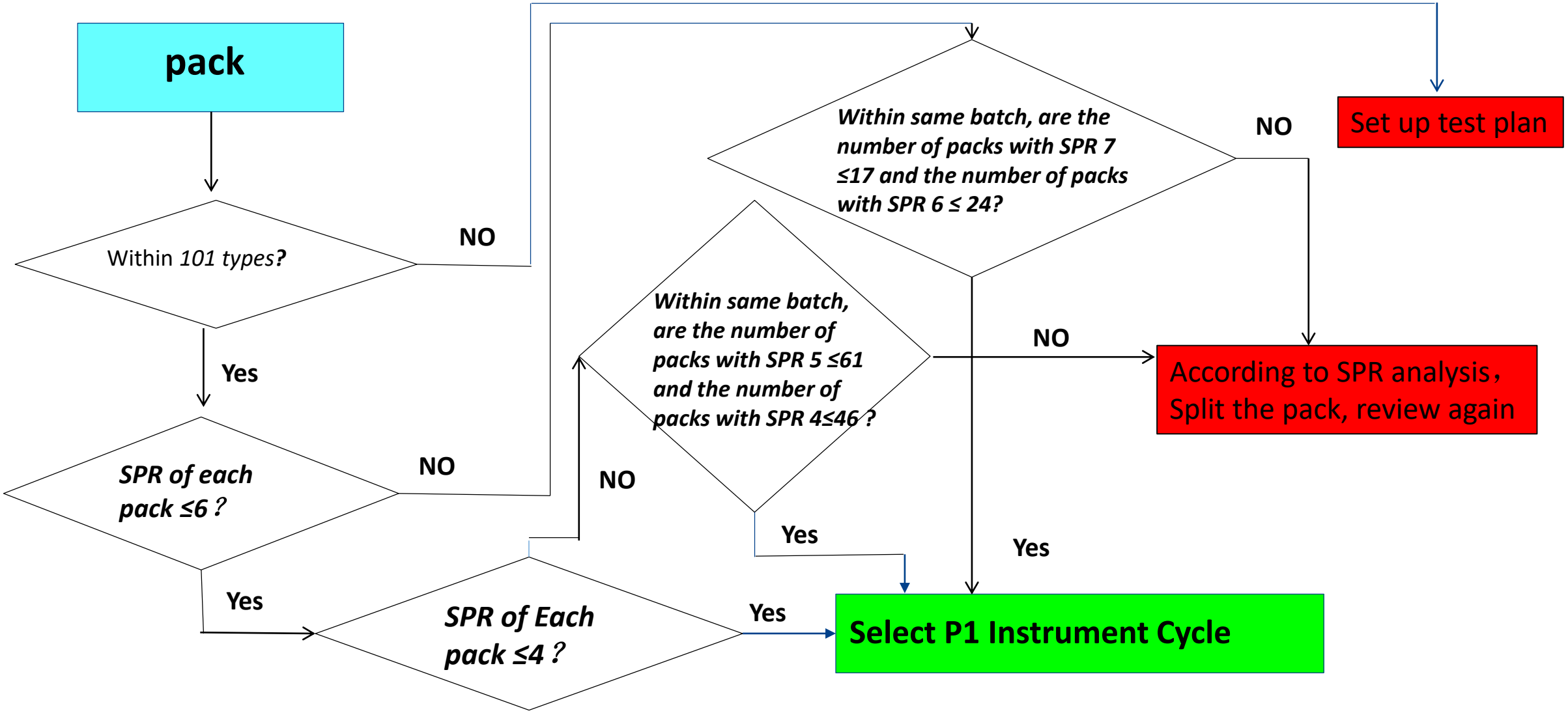
Implementation of Conclusion 1: SOP Updated

Previous SOP of Sterilization – Based on Weight and Size



Implementation of Conclusion 1: SOP Updated

New SOP of Sterilization – Based on SPR



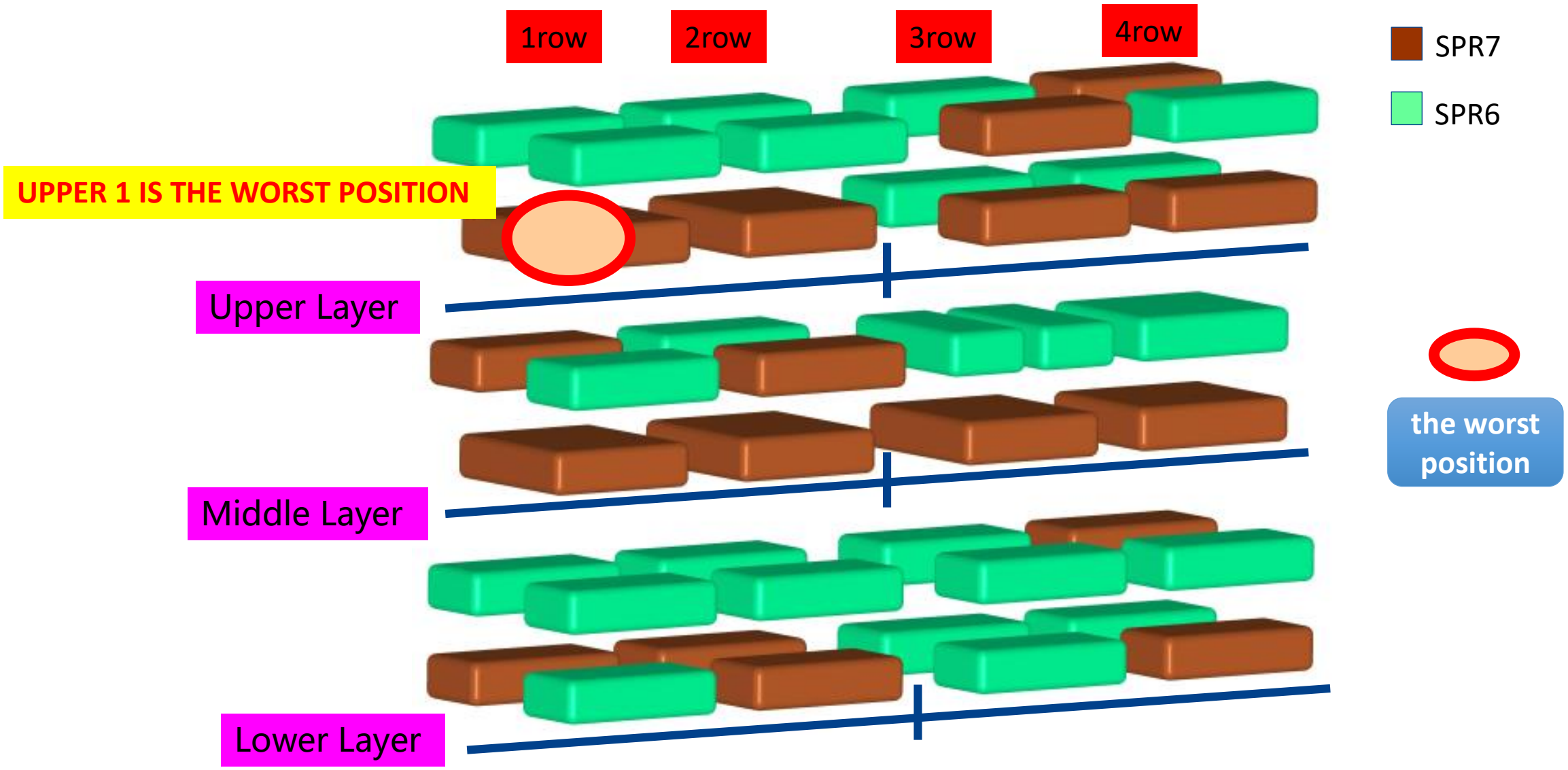
Control group : Where is worst position to be sterilized?

SPR/number of pack	7	6	5	4	3	sum	The place of the maximum equilibration time	The place that show maximum temperature difference	The minimum temperature at the end of holding time	The place of the minimum temperature
Control group 1	17	24				41	Upper 1	Upper 1	Upper 1	Upper 1
Control group 2	17	24				41	Upper 1	Middle 2	Upper 1	Upper 1
Control group 3	17	24				41	Upper 1	Upper 1	Middle 3	Upper 1

In the control group, 10 incidents out of 12 tests (83%) showed the first row of upper level is the worst position. NO incident is above the drain

Control group : the worst position is UPPER 1

Summary- Control Group (CG)



Observation group of full load : Where is worst position to be sterilized?

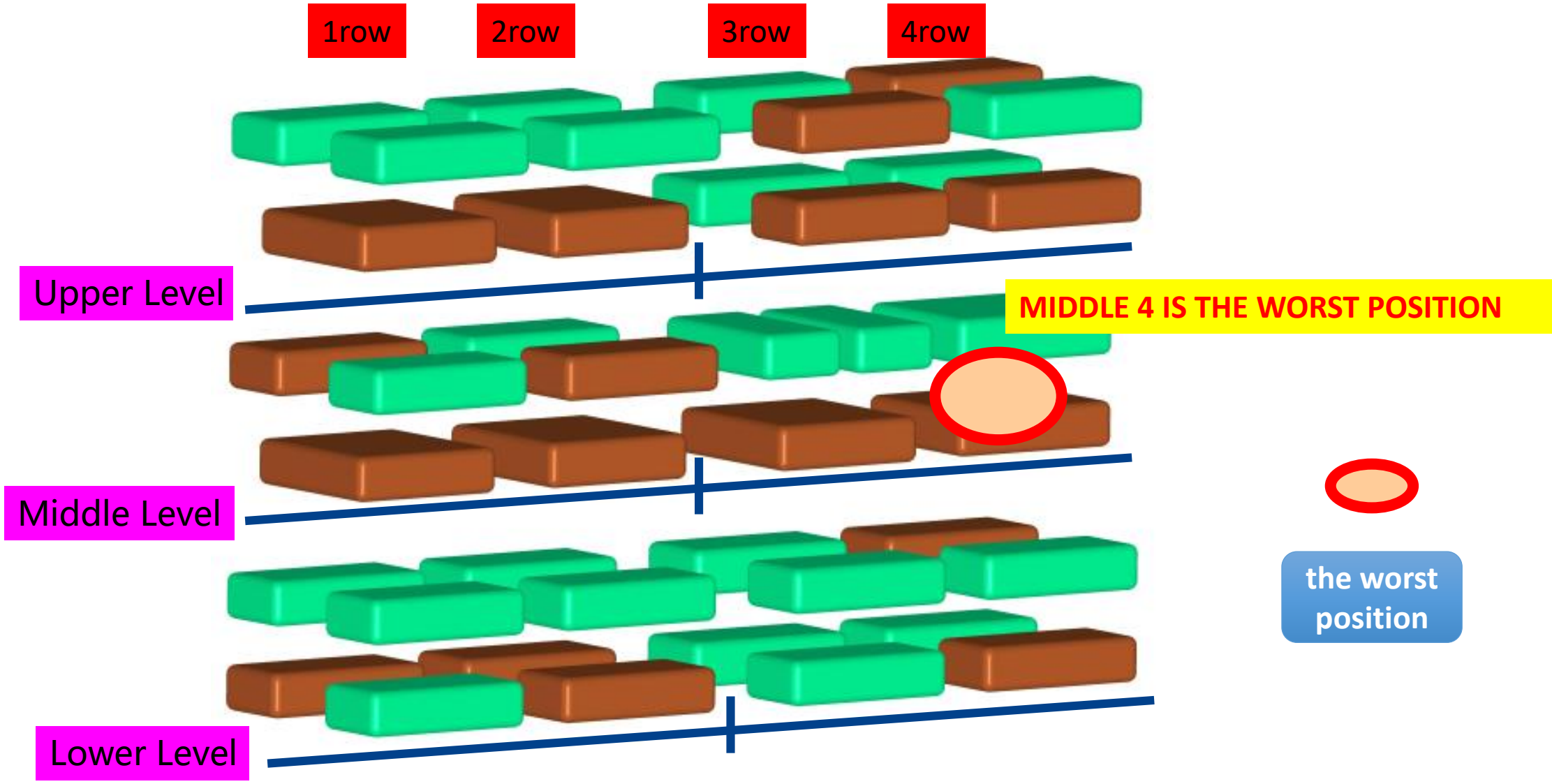
SPR/number of pack	7	6	5	4	3	sum	The place of the maximum equilibration time	The place that show maximum temperature difference	The minimum temperature at the end of holding time	The place of the minimum temperature
OGFL’1			61	46		107	Middle 4	Middle 4	Middle 4	Middle 4
OGFL’2	2	9	35		4	50	Middle 4	Middle 4	Upper 1	Middle 4
OGFL’3	1		56		79	137	Middle 4	Middle 4	Middle 4	Middle 4

For the full load of the observation group, 11 incidents out of 12 tests (91.7%) showed the fourth row of middle level is the worst position.

NO incident is above the drain

Observation group of full load :the worst position is MIDDLE 4

Summary- OG1 (full load)



Observation group of half load : Where is worst position to be sterilized?

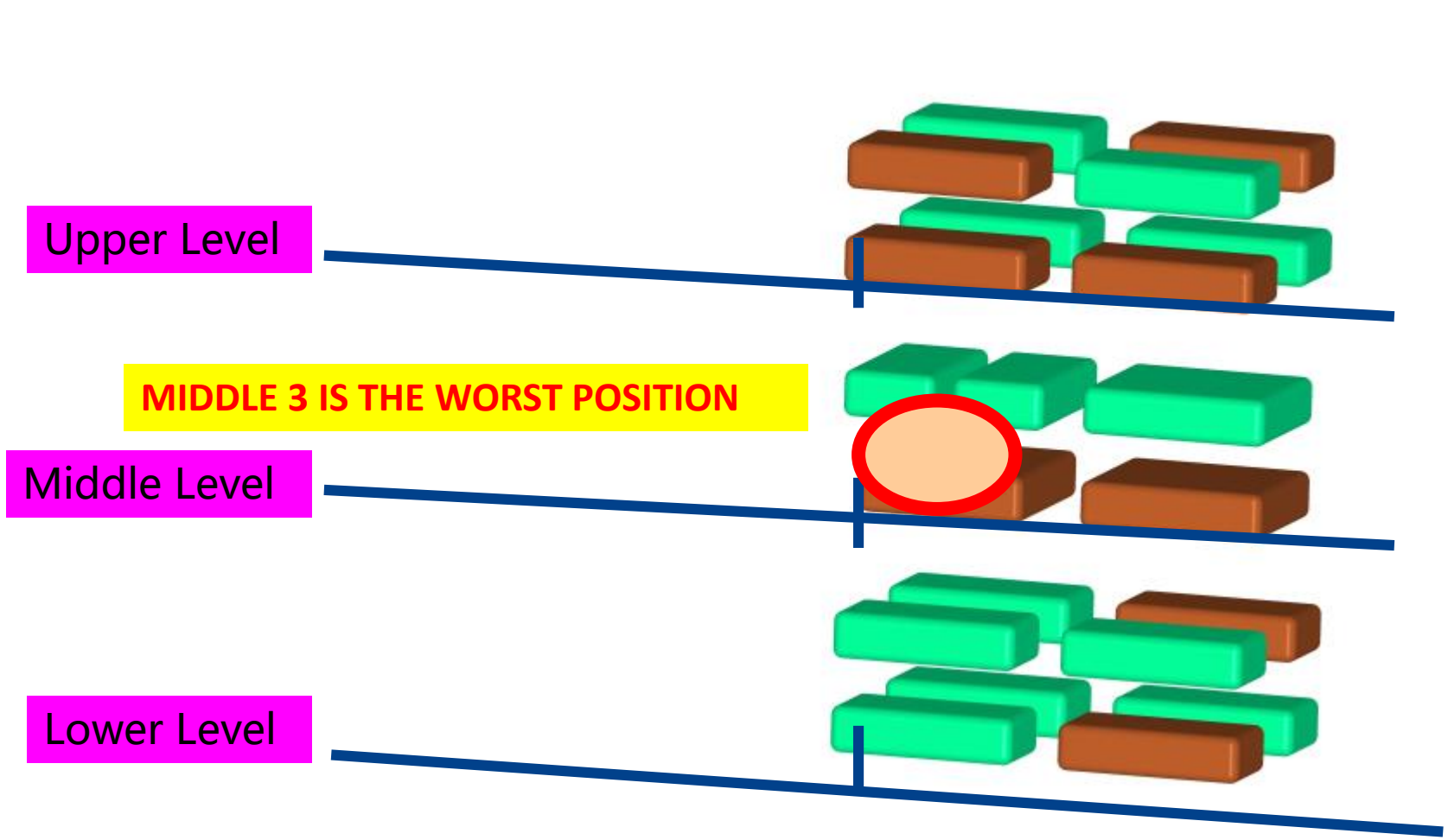
SPR/number of pack	7	6	5	4	3	sum	The place of the maximum equilibration time	The place that show maximum temperature difference	The minimum temperature at the end of holding time	The place of the minimum temperature
OGHL’1	6	9	5			20	Middle 3	Middle 3	Upper 4	Middle 3
OGHL’2	6	9	5			20	Middle 3	Middle 3	Upper 4	Middle 3
OGHL’3	6	9	5			20	Middle 3	Middle 3	Upper 4	Lower 3

For the half load of the observation group, 7 incidents out of 12 tests (58.3%) showed the third row of middle level is the worst position. NO incident is above the drain

Observation group of half load :the worst position is MIDDLE 3

Summary- OG2 (half load)

1row 2row 3row 4row



the worst position

Final Conlusion 2

- All 9 batches fulfill the requirements of EN285, which means they pass in general.
- Tests on control group, namely the theoretically most challenging load, containing 17 packs with SPR degree 7 and 24 packs with SPR degree 6 show that 1st row of top level is the worst place to be sterilized.
- Test on observation group, namely the random mixed full loads and half loads show the 4th row of middle level and the 3rd row of middle level are the worst place for steam sterilization respectively →Answer to Q2

Q2:When biological indicator or process challenging device(PCD) are required to be placed at “worst condition” for batch monitoring, is the position above chamber drain appropriate?

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Discussion

- The position above the chamber drain was never detected as the worst place compared to the other test locations. To place the BI or batch PCD at this position may not be appropriate.
- The sterilizer is normally loaded either in full or half condition thus we included these situations during the study. The repeatability of tests in full load condition is better than that of in half load, probably because the load density inside the chamber is much better. These gave rather concrete evidence to CSSD to set up the SOP.
- Hospitals shall try to identify the “worst position” among the daily load configurations for sterilization processes, using a well-designed test plan. Acting on assumptions is not recommended.
- The study acts as a good reference for future validation of load configurations, introducing new instruments in our hospital. Even though the test results and conclusion may not be fully perfect, the study aim is to discover feasible and practical approach for CSSD management to identify the worst position to be sterilized when daily mixed instrument packs are sterilized in every hospital CSSD.

Thanks To Our Team

Thanks for your attention!

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Five Goats Sculpture