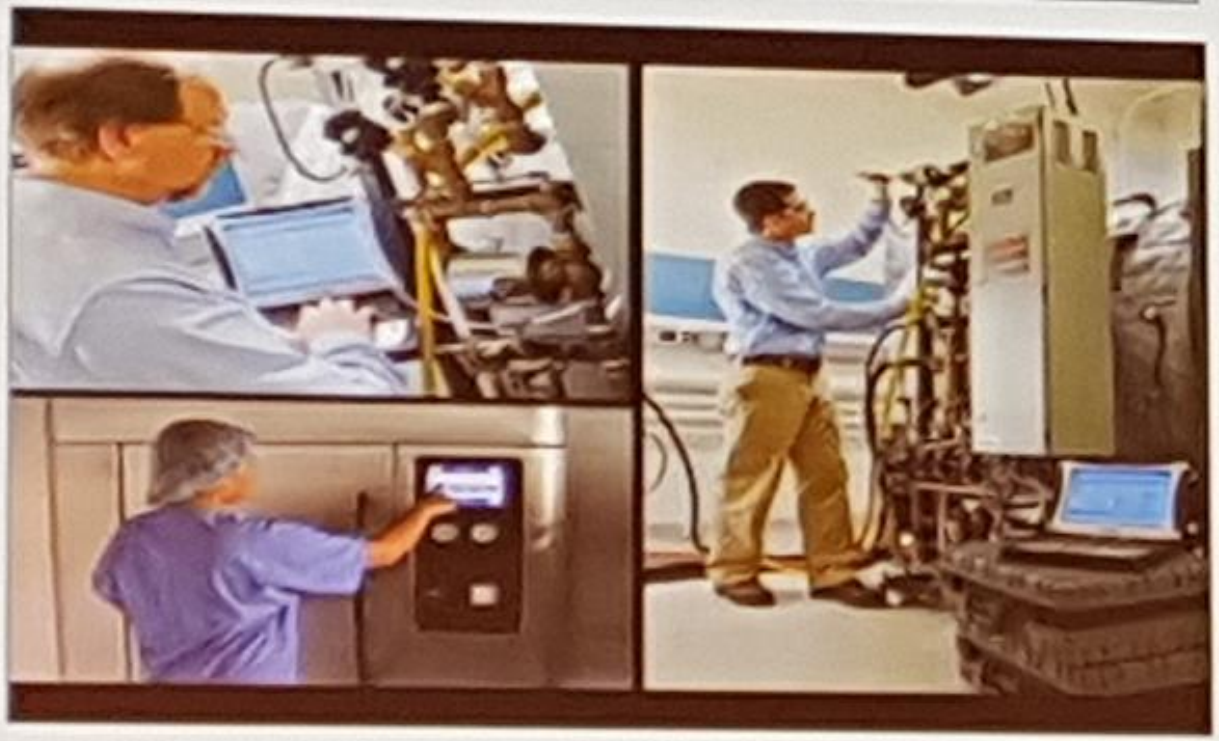
VALIDATION OF STEAM STERILIZERS IN COMPLIANCE TO EN 285 AND ISO 17665

ANNUAL PERFORMANCE REQUALIFICATION



EN 285, the European Large Steam Sterilizer standard [1], is the world's baseline authority for steam quality acceptance criteria. It is referenced in most national standards and in ISO 17665 [2]. With the release of EN 285:2015, the bar has been raised. The acceptance criteria are shown in the following table.

Steam Dryness	Non-condensable gases	Superheat
>0.925 w/w*	≤3.5% v/v	≤25K

AS/NZS 4187:2014 Section 7: Validation

7.4 PERFORMANCE QUALIFICATION	7.5.2.(i)
• Stage of validation: – Exposes the products as specified to the sterilization process – Demonstrates equipment consistently operates in accordance with predetermined criteria – Yields a product that is sterile and meets specified requirements	• Performed using RMDs of each type of product families, if applicable heat penetration studies for each type of load. Further: Successful PQ = can be extrapolated to other loads that that are covered by the reference load.

AS/NZS 4187:2014 Section 7: Validation

7.4.5 STERILIZING PROCESSES

- Demonstrate the attainment of the required sterilizing conditions ON and THROUGHOUT a reusable medical device (RMD) within the specified sterilizer load.
  - Physical performance qualification
  - Microbial performance qualification

- For PQ of a moist heat sterilizing process the penetration time to all parts of an RMD shall be established and added to the sterilization holding time (refer to table 6.2).

AS/NZS 4187:2014: Relevant Parts

Table 6.2

TABLE 6.2

COMMON HOLDING TIMES FOR SATURATED STEAM

Temperature °C	Holding time min
121	15
126	10
132	4
134	3

NOTE: The correct correlation between temperature and pressure is necessary to ensure the presence of saturated steam. For pressure relationships, see Figure 6.1.

PQ for a moist heat must include:

- Establishment of the heat penetration time using the most difficult to sterilize RMD or RMD Set. Penetration time must be added to the holding time of the defined temperature.
- Demonstration of microbial lethality of the process strategically positioned on most difficult to penetrate

ISO 17665 – 3

TABLE 1 – GENERAL ATTRIBUTES	
ATTRIBUTE	CODE
DESIGN	a
WEIGHT	b
MATERIAL	c
STERILE BARRIER SYSTEM	d

TABLE 2 -DESIGN		
STRUCTURE	CODE (A)	EXAMPLE
SOLID, HOLLOW	1	BOWLS/JUG/TRAY/CHISEL
PIN & BOX JOINTS	2	SCISSORS/FORCEPS
LUMEN	3	LAP SUCTIONS
POROUS	4	FILTERS
TUBING/MOVING PARTS/ TORTOUS PATHS	5	POWER TOOL/HOSE/ENT DRILL/DENTAL HANDPICE
LUMEN SURROUNDED - LARGE MASS	6	CANNULATED SCREW DRIVER, OBTURATOR, RACHET HANDLE
OTHER	7	PRE FILLED SYRINGE

TABLE 3 - MATERIALS		
MATERIAL	CODE (B)	EXAMPLE
METAL	1	SS/COPPER BASED ALLOYS/OTHER METAL COMBINATIONS
NON METAL	2	GLASS/PVC/PLYCARBONATE /SILICON

TABLE 4 - WEIGHT	
WEIGHT GRAMS	CODE (C)
LESS THAN 50	1
50 - 499	2
500 - 1999	3
2000 AND GREATER	4

TABLE 5 - STERILE BARRIER SYSTEM/PACKAGING SYSTEM	
SBS	CODE (D)
NONE	1
SINGLE WRAP/POUCH	2
DOUBLE WRAPPED IN POUCH/DOUBLE WRAPPED CONTAINER TRAY	3
COMBINATION OF 2 OR MORE SYSTEMS	4

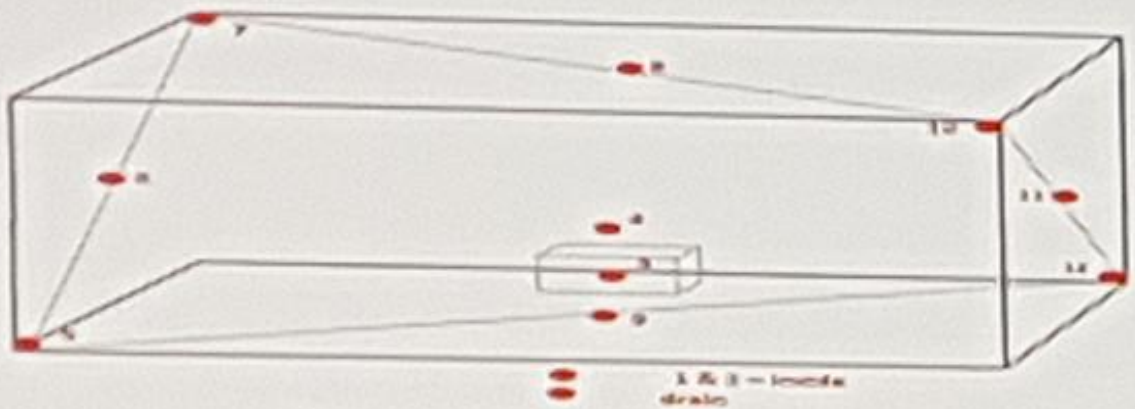
ISO 17665 – PRODUCT FAMILIES IDENTIFIED

PRODUCT FAMILIES					
PF	ATTRIBUTE				STEAM PENETRATION
	A	B	C	D	E
1					
29					

Equipment: 4 X Steam Sterilizers		
Product Family 1	134 C	5 Minutes
Product Family 2	134 C	10 Minutes
Product Family 3	134 C	18 Minutes
Product Family 4	121 C	20 Minutes

AS/NZS 4187:2014 – PQ

Thermocouple placement within the sterilizer chamber is shown in the diagram below.



Thermocouple placement inside chamber

n 1_2 – Heat Distribution Profile:

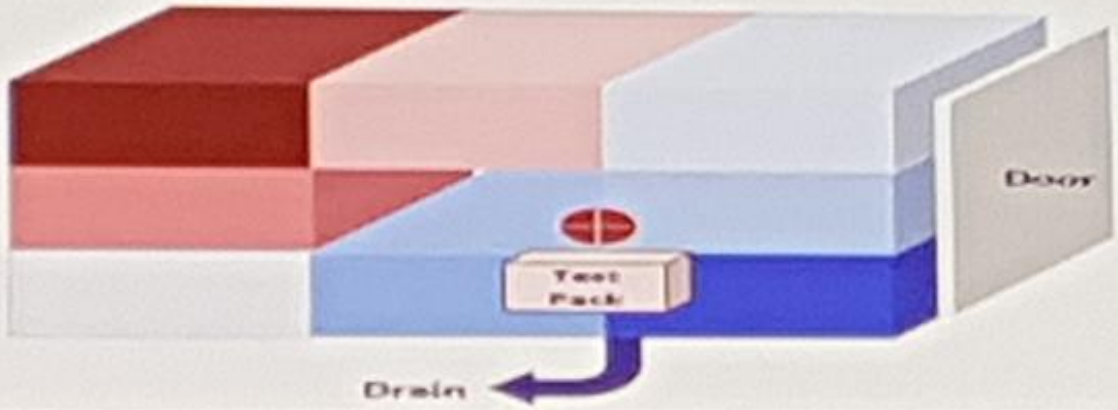


Table 1: Heat Distribution Measurements

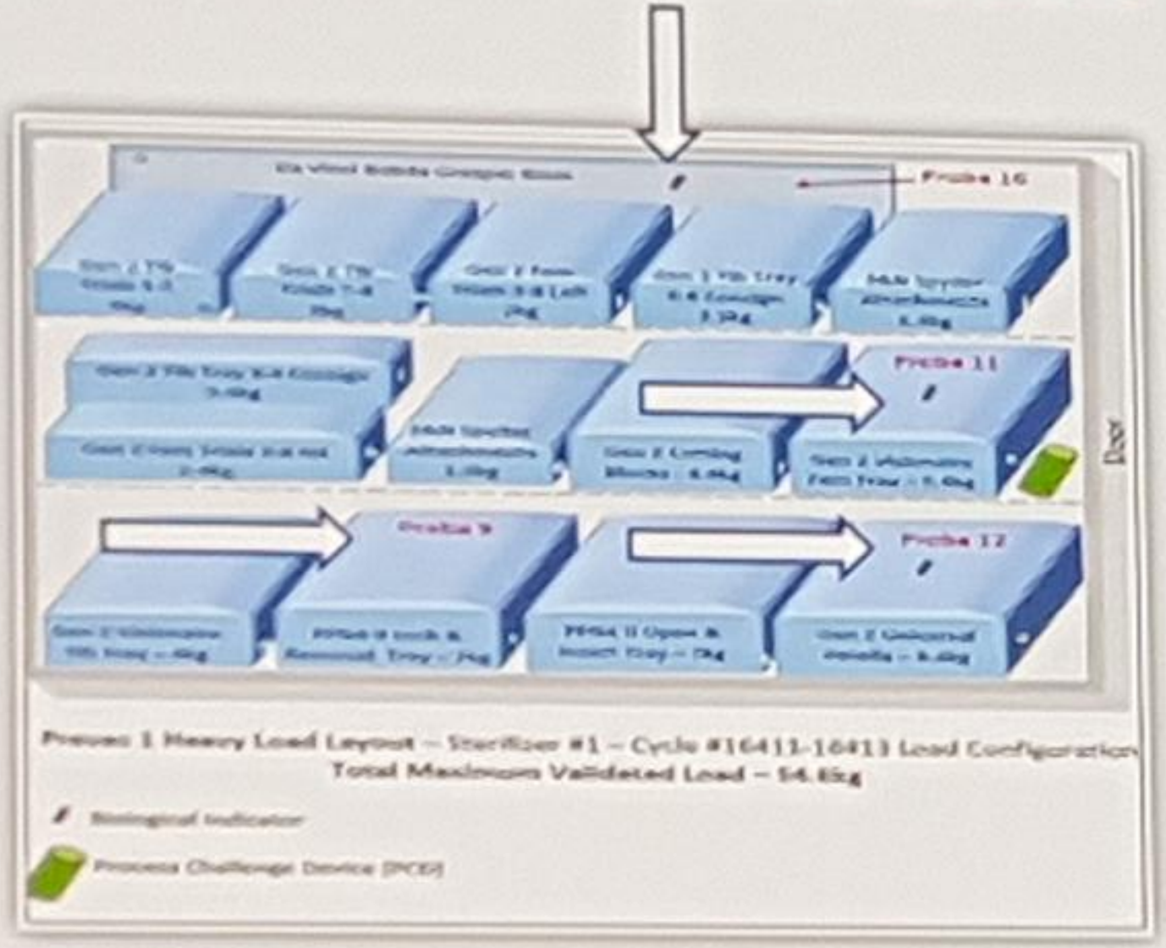
Thermocouple Location	Temp (°C)
1. Drain	135.28
12. Front Lower Right	135.38
9. Centre Lower Centre	135.42
11. Front Centre Centre	135.49
10. Front Upper Left	135.56
5. Rear Lower Left	135.58
3. Pack	135.59
8. Centre Upper Centre	135.60
6. Rear Centre Centre	135.68
4. Above Pack	135.75
7. Rear Upper Right	135.81

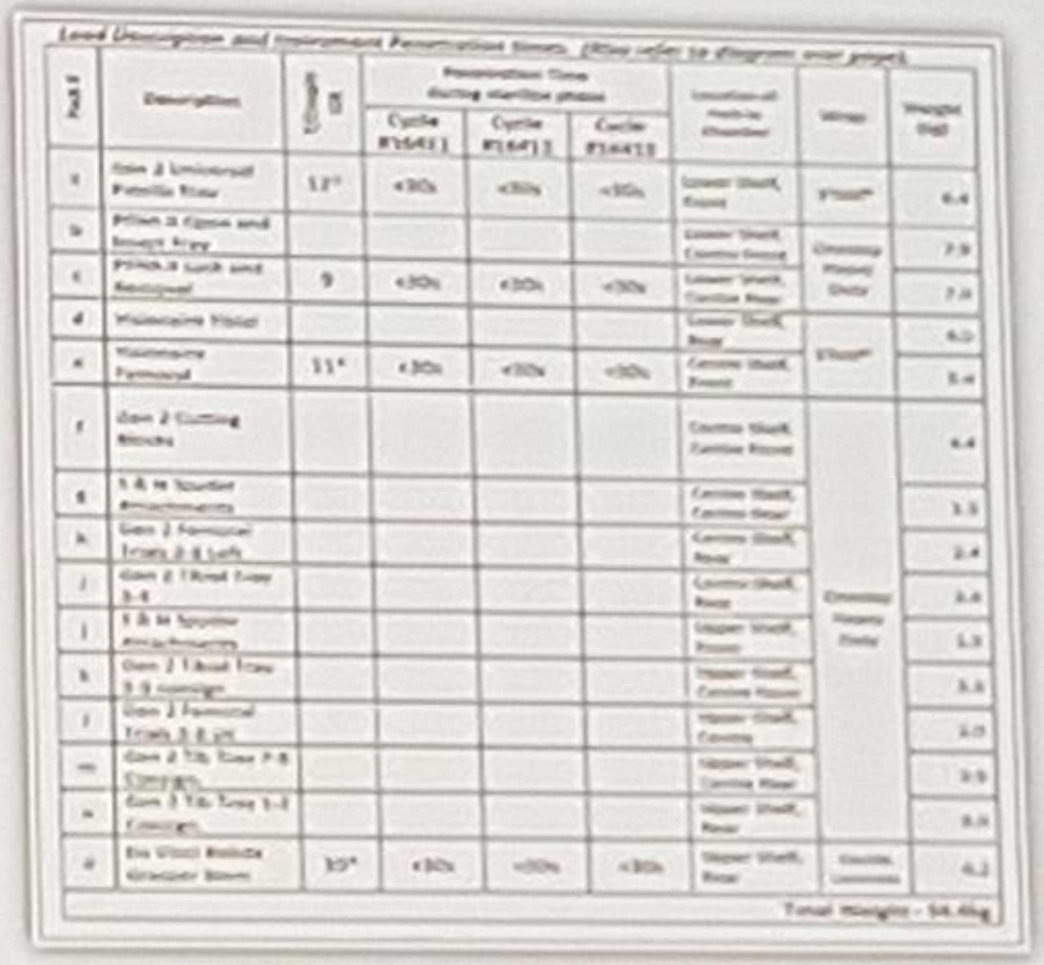
PRODUCT FAMILY 1

GEN 2 Universal Patella Tray

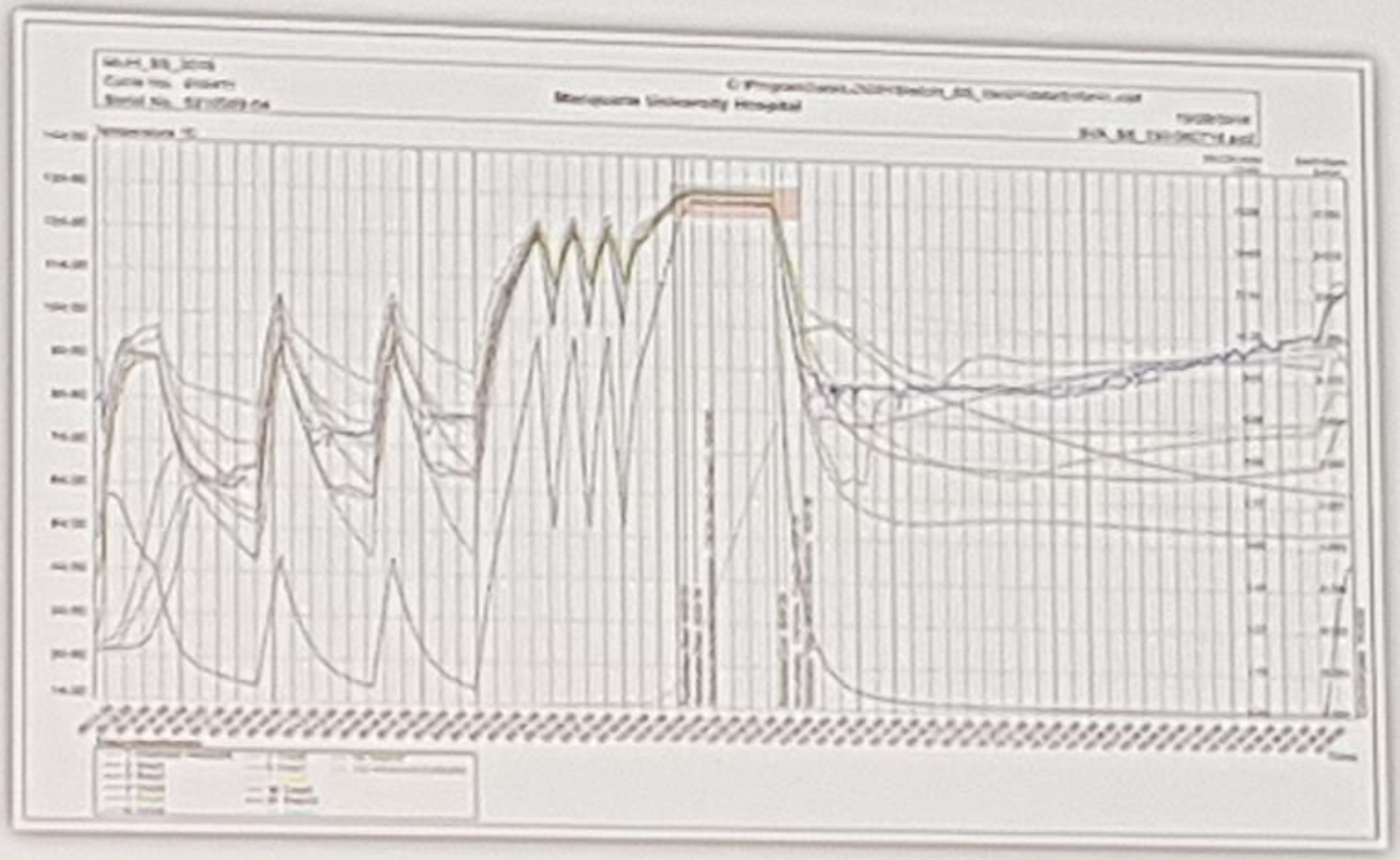
PFNA Lock and Removal Tray I

Reference Load 1/Product Family 1



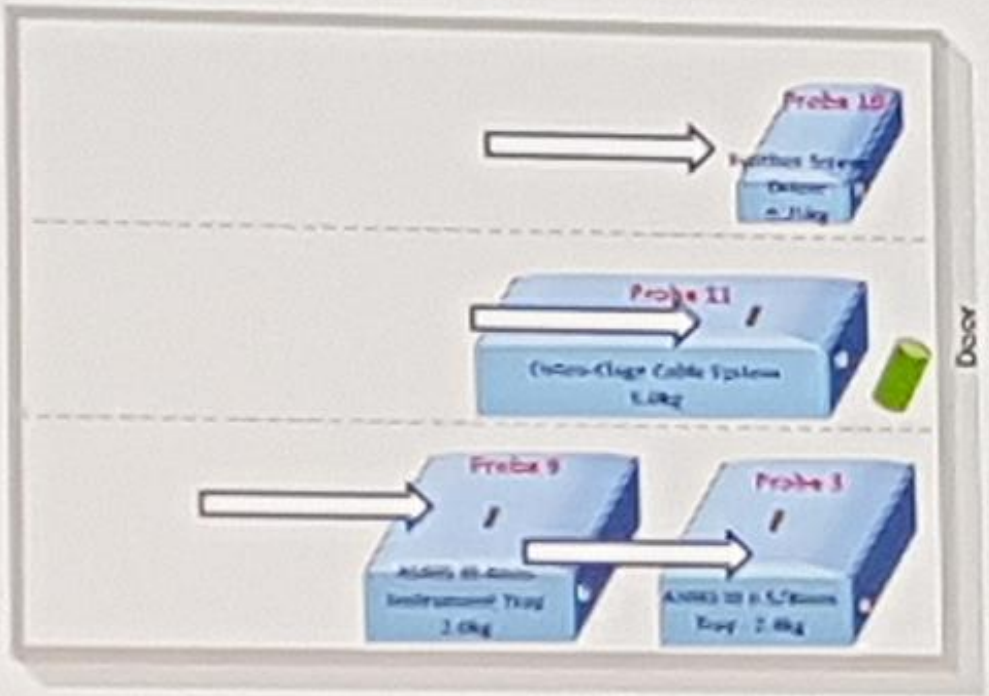


Penetration time graphical data – PF 1



Reference Load 2/Product Family 2

Diagram 1.6



Prevac 2 Complex Instruments Load Layout – Sterilizer #1 – Cycle #16421-16423 Load Configuration

Total Load Weight** – 10.15kg

5.7 Complex Instrument Load Test Results

Program Parameters		Sterilizer Cycle	Test Cycle Sequence	Test Result
Program Name: 'Prevac 5'		#16421	1/3	PASS
Sterilization:	134°C for 18m	#16423	2/3	PASS
Drying:	30m dry	#16423	3/3	PASS

Load Description and Instrument Penetration times. (Also refer to diagram cover page)

Pack #	Description	T/Depth (D)	Penetration Time during sterilize phase			Instrument Place in Chamber	Area	Type (D)
			Cycle #16421	Cycle #16423	Cycle #16425			
a	ASMS III 4mm Tray	3"	1m 52s	<30s	<30s	Lower Shelf, Front	Chamber	3.0
b	ASMS III 6.5/8mm Tray	9"	<30s	<30s	<30s	Lower Shelf, Centre	Chamber	2.4
c	Ortner-Clage Cable Systems	11"	5m	6m 30s	4m 34s	Centre Shelf, Front	Sterilizer	5.0
d	Synthes Cannulated Screwdriver Instrument #314.050	10	<30s	4m 54s	3m 32s	Upper Shelf, Front	Chamber Ambient	0.75

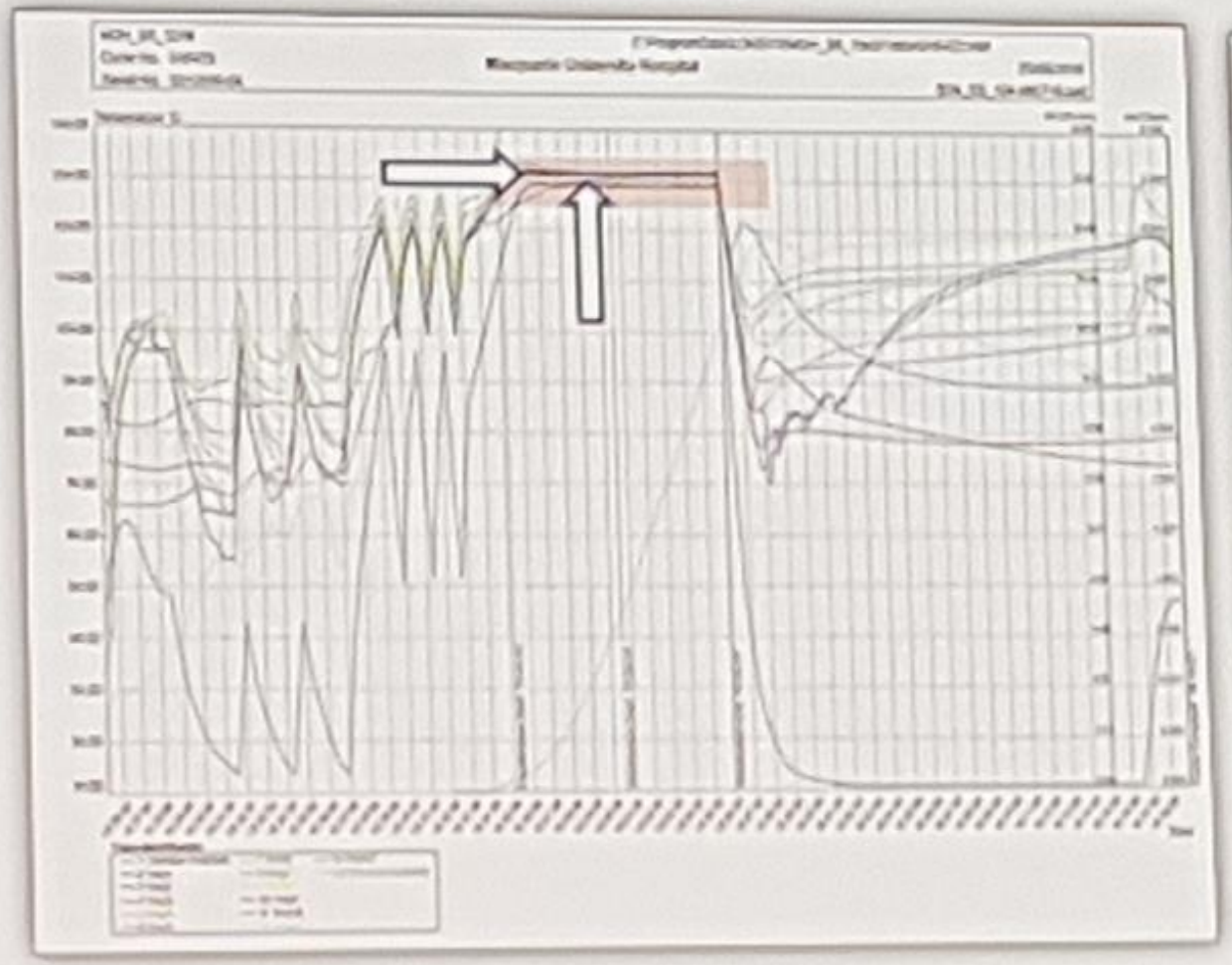
Total Weight: 10.15kg

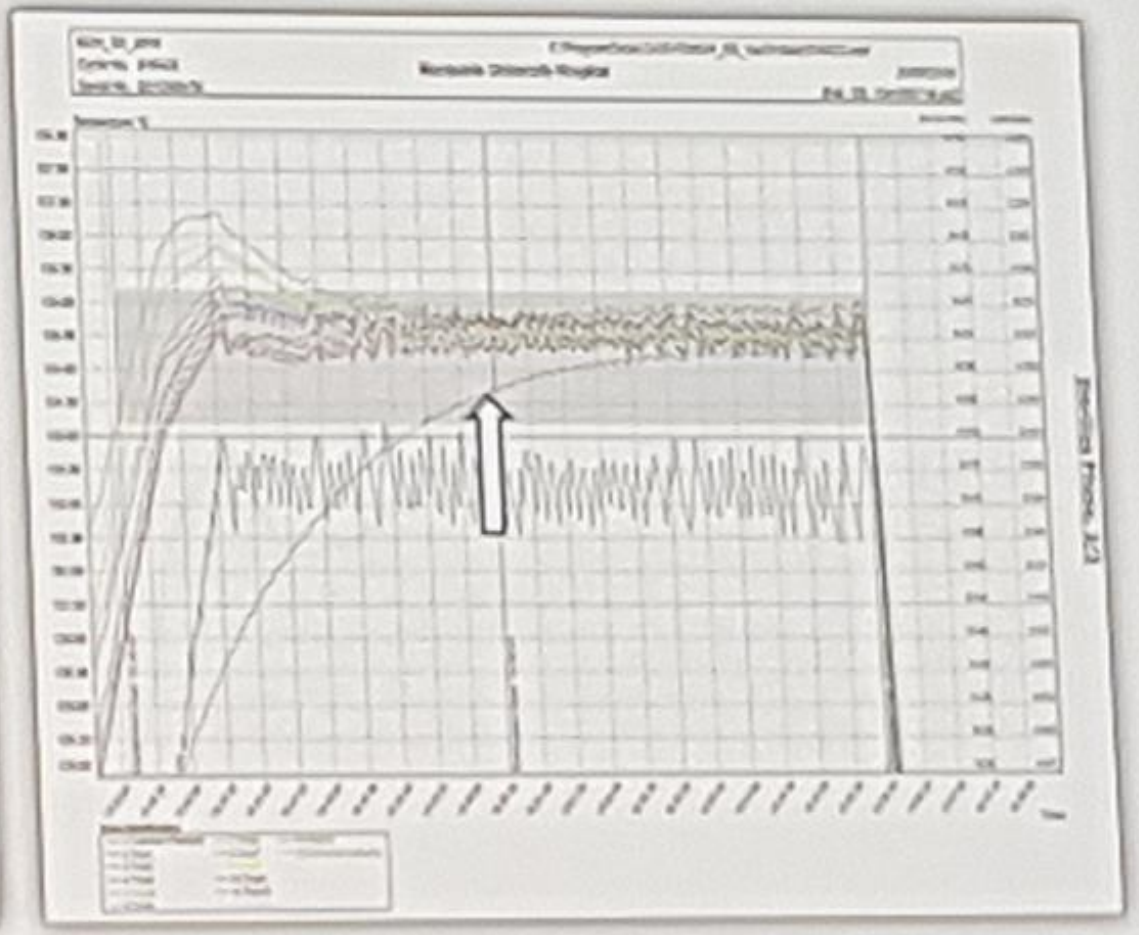
PRODUCT FAMILY 2

Osteo – Clage cable System

Synthes Cannulated Screw Driver

Penetration time graphical data – PF2

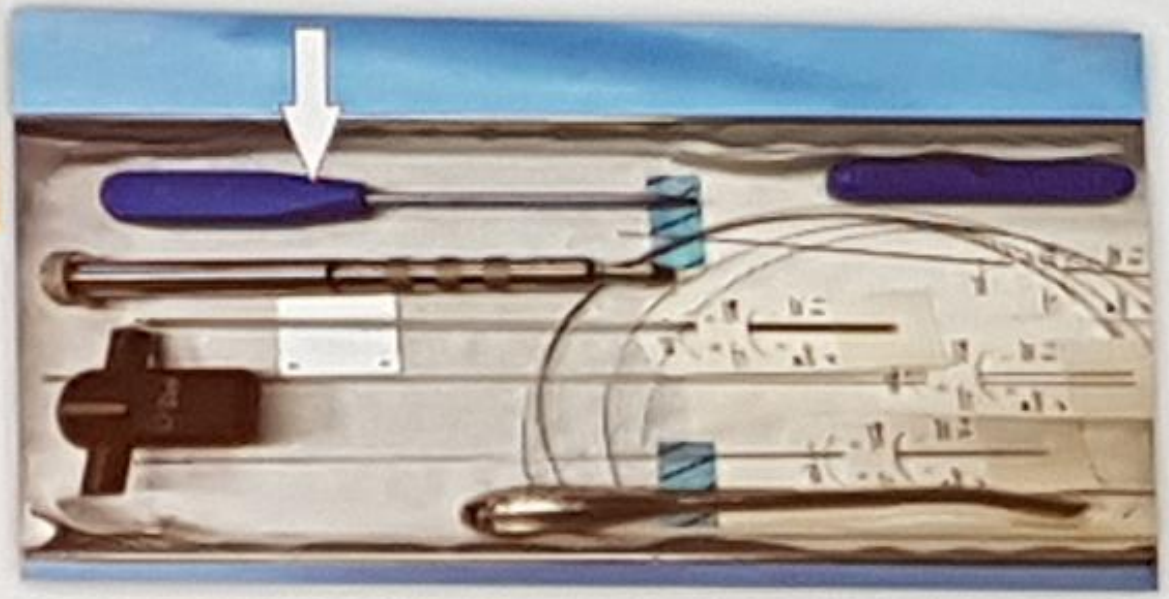




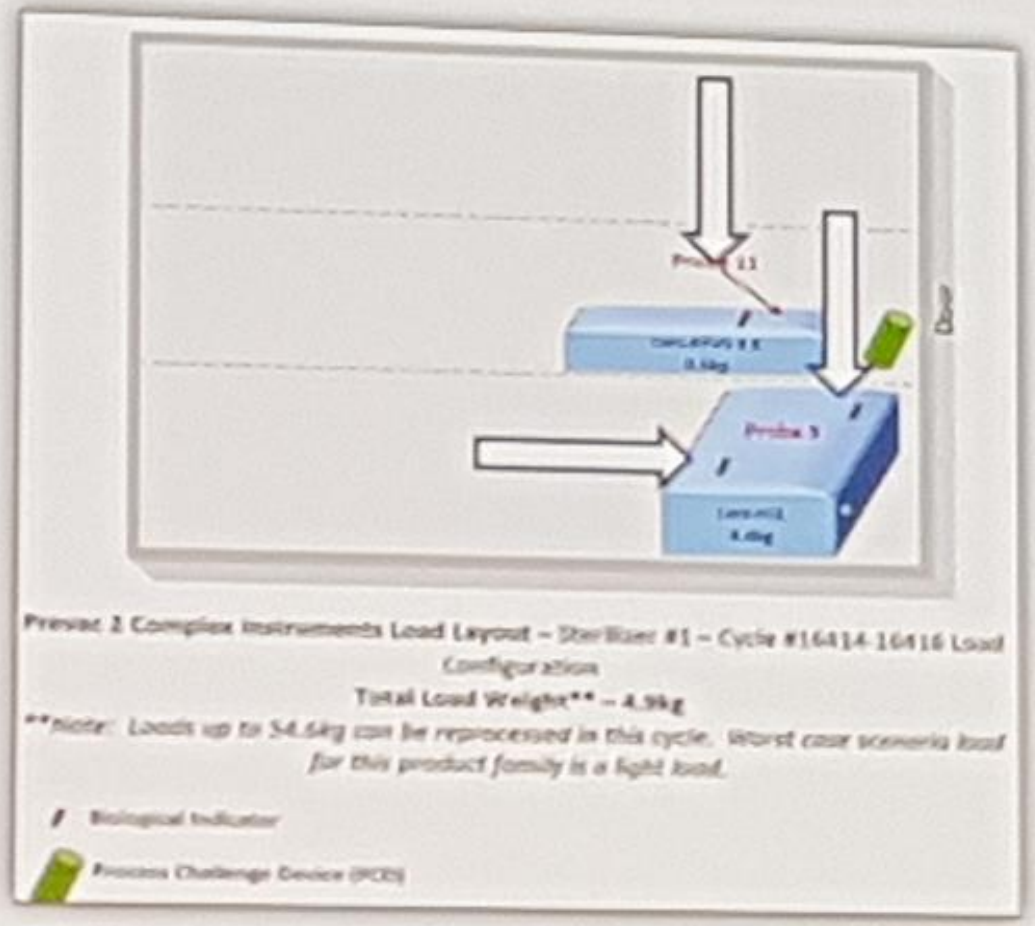
PRODUCT FAMILY 3

LARS ATVS 3.5

LARS ACL Tray



Reference load 3/Product family 3



Prevac 2 Complex Instruments Load Layout – Sterilizer #1 – Cycle #16414-16416 Load Configuration

Total Load Weight – 4.9kg**

***Note: Loads up to 54.6kg can be reprocessed in this cycle. Worst case scenario load for this product family is a light load.*

/ Biological Indicator

Process Challenge Device (PCD)

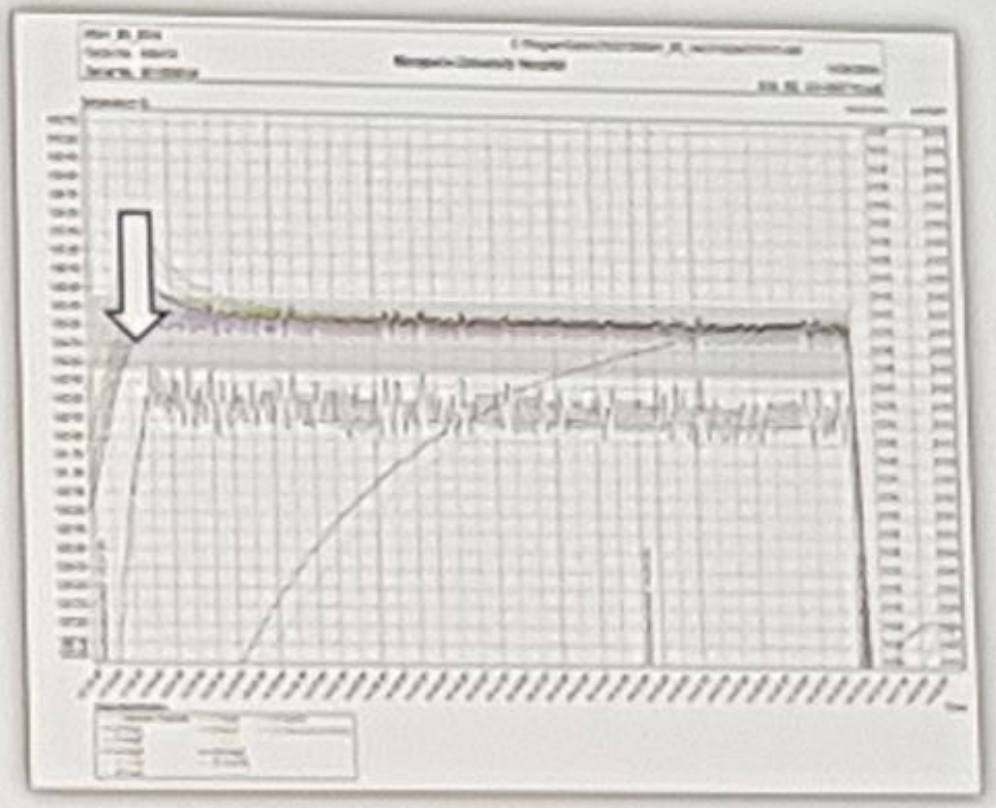
5.5 Ultra Complex Instrument Load Test Results

Program Parameters		Sterilizer Cycle	Test Cycle Sequence	Test Result
Program Name: 'Prevac 2'		#16414	1/3	PASS
Sterilization:	134°C for 18m	#16415	2/3	PASS
Drying:	20m dry	#16416	3/3	PASS

Load Description and Instrument Penetration times. (Also refer to diagram over page).

Pack #	Description	1/2 Double IDI#	Penetration Time during sterilize phase			Location of Pack in Chamber	Type	Weight (Kg)
			Cycle #16414	Cycle #16415	Cycle #16416			
a	Lars ACL Tray	3*	10m 48s	9m 59s	9m 10s	Lower Shelf, Front	Sterilizable*	4.4
b	Lars ATVS 3.5 *(instrument provided by SWA for testing)*	11*	12m 43s	10m 43s	11m 7s	Centre Shelf, Front	Disposable* Sterilizable	0.5
							Total Weight:	4.9kg

Penetration time graphical data – PF3

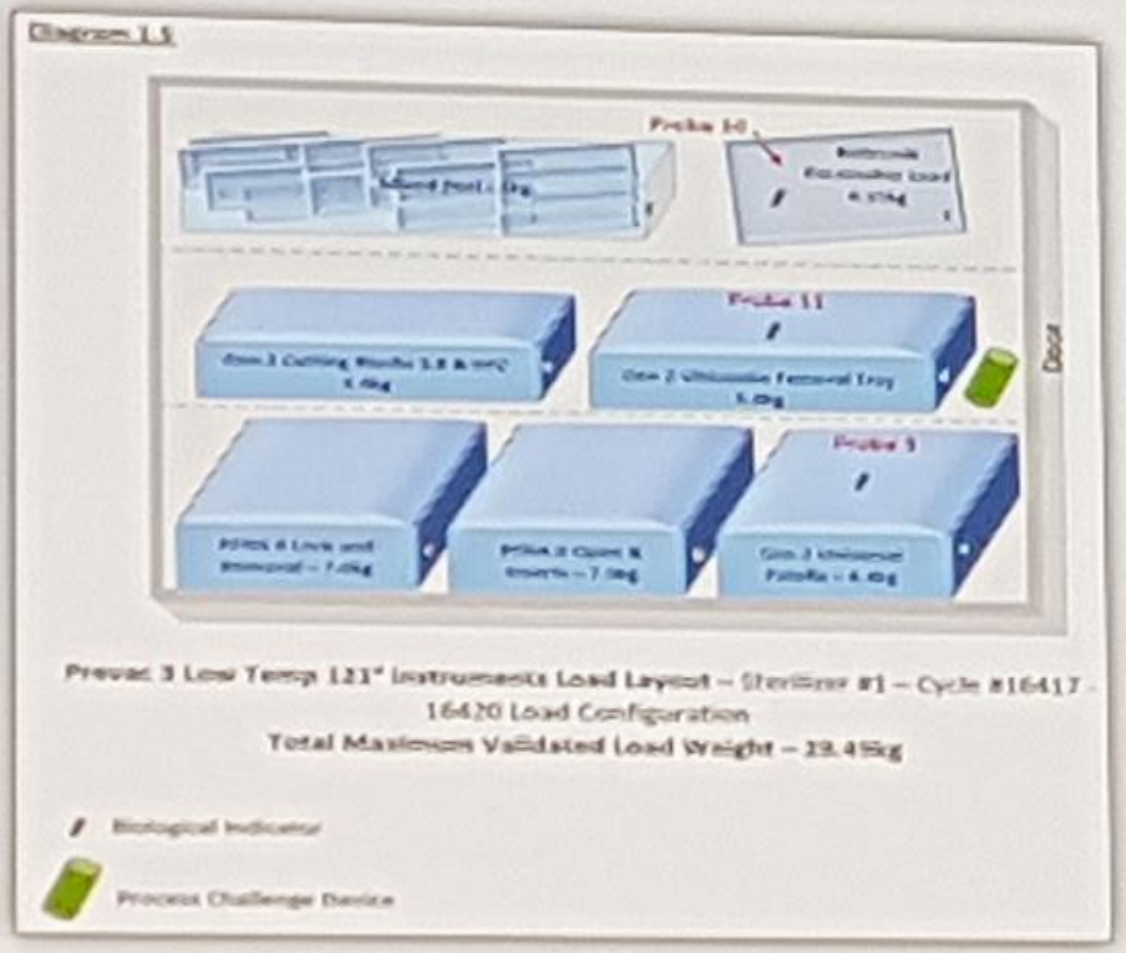


PRODUCT FAMILY 4

Biotronik Pacemaker Lead

GEN 2 Universal Patella Tray

Reference load 4/Product family 4



Prevac 3 Low Temp 121° Instruments Load Layout – Sterilizer #1 – Cycle #16417 - 16420 Load Configuration

Total Maximum Validated Load Weight – 29.45kg

Biological Indicator

Process Challenge Device

Program Parameters		Sterilizer Cycle	Test Cycle Sequence	Test Result
Program Name: "Prevac 3"		#16417	1/3	PASS
Sterilization:	121°C for 20min	#16419*	2/3	PASS
Drying:	30min dry	#16420	3/3	PASS

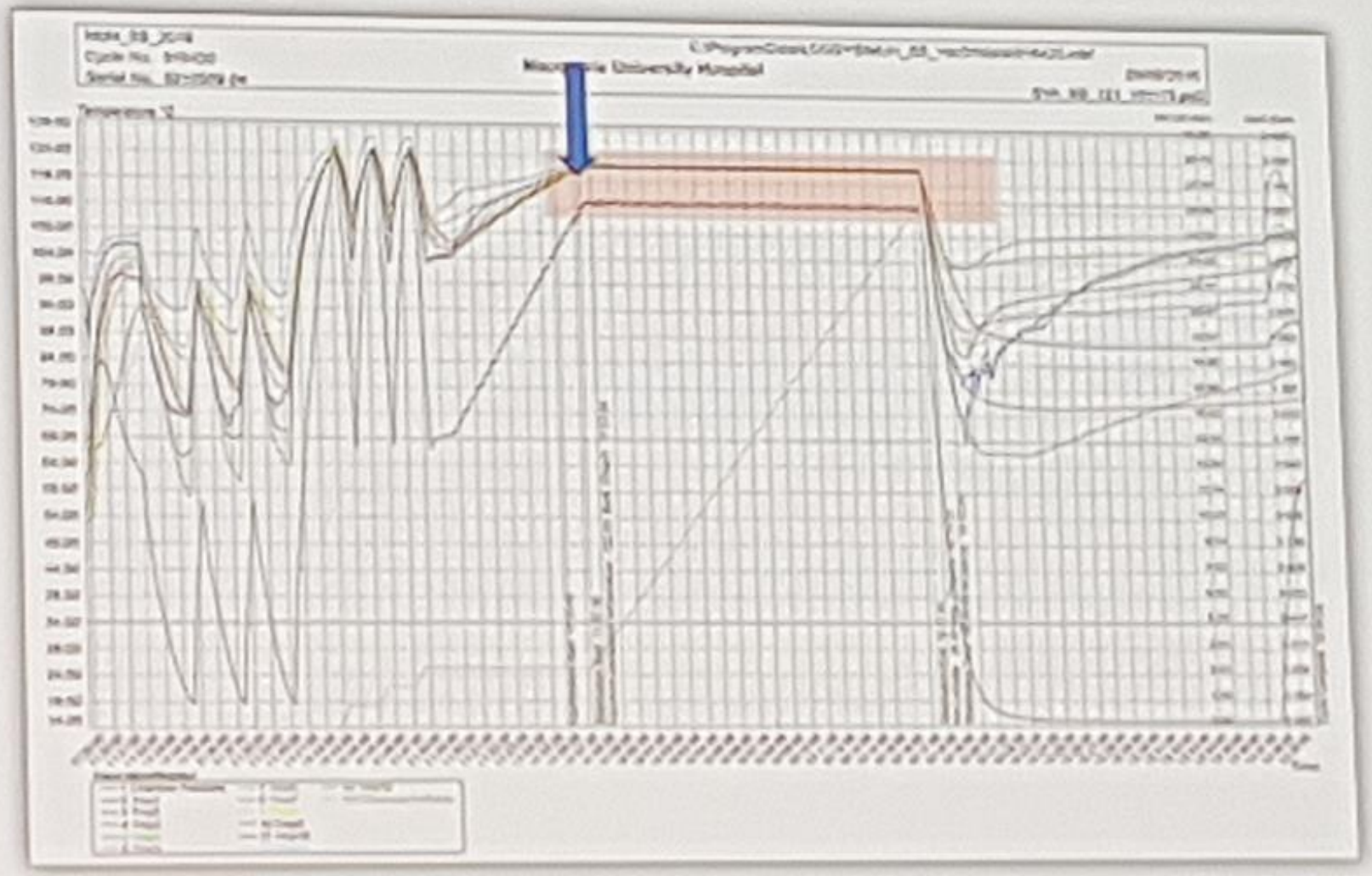
*Cycle 16418 – Logger not ready, test sequence restart not required.

Load Description and Hydrogen Penetration times. (Also refer to diagram next page)

Probe	Description	Weight (kg)	Penetration Time during cycle phase			Location of Probe in Chamber	Tier	Weight (kg)
			Cycle #16417	Cycle #16419	Cycle #16420			
	Gen 3 Universal	3*	<30s	<30s	<30s	Lower Shelf, Front	Instrument	6.4
b	PFISA 8 Open and Inserts					Lower Shelf, Centre		7.0
c	PFISA 8 Lock and Removal					Lower Shelf, Rear		7.0
	Gen 3 Universal	11*	<30s	<30s	<30s	Centre Shelf, Front	Instrument Set	5.4
e	Gen 3 Cutting Blocks 3.8 & OEC					Centre Shelf, Centre		4.6
	Facilitator Lead	19*	<30s	<30s	<30s	Upper Shelf, Front	Lumen/Flexible Lead	0.15
d	Mixed Instruments					Upper Shelf, Rear		4.0

Total Weight = 29.45kg

Penetration time graphical data – PF4



IN CONCLUSION

Compliance to standards is necessary to maintain product realization. In this case, RMDs must be reprocessed according to its specific requirements of exposure to predetermined values necessary to attain lethality and meet minimum sterility assurance level.