

Report Number: 210919JR

DATE: 24/09/2021

Test Certificate

Accredited For Compliance with ISO / IEC 17025 - Testing

Determining compliance to the performance requirements of:

ISO14644-3

CLEANROOM CERTIFICATION

Client: Plasma Shield.

Address: G.D. Pharma Pty Ltd. 46A Beulah Road. Norwood. S.A. 5067.

Location: Clean Room

Technician: Justin Rowe

METHOD OF TEST	REQUIREMENTS	TEST OBSERVATIONS	RESULTS	COMPLIANCE
Air Change Rate. ISO 14644-3 Procedure B.2	Depending on customer requirements	Great than 20 A/hr	16.0 Air Changes per hour – See page 2	Depending on customer requirements
HEPA Filter installation Integrity ISO 14644-3 Procedure B.3. AS1807.6 or AS1807.7	< 0.01 % Penetration		N/A	N/A
Particle Counting ISO 14644-1 Procedure B1	As Per ISO 14644-1 Requirements of ISO	See Report: 210920JR	ISO Class 7 (TGA Class C)	PASS
Air Pressure ISO 14644-3 B5	Depending on customer requirements		See page 2	Depending on customer requirements
Recovery Time ISO 14644-3 B12	Depending on customer requirements	See Report: 210921JR		Depending on customer requirements

Authorised Signatory: 

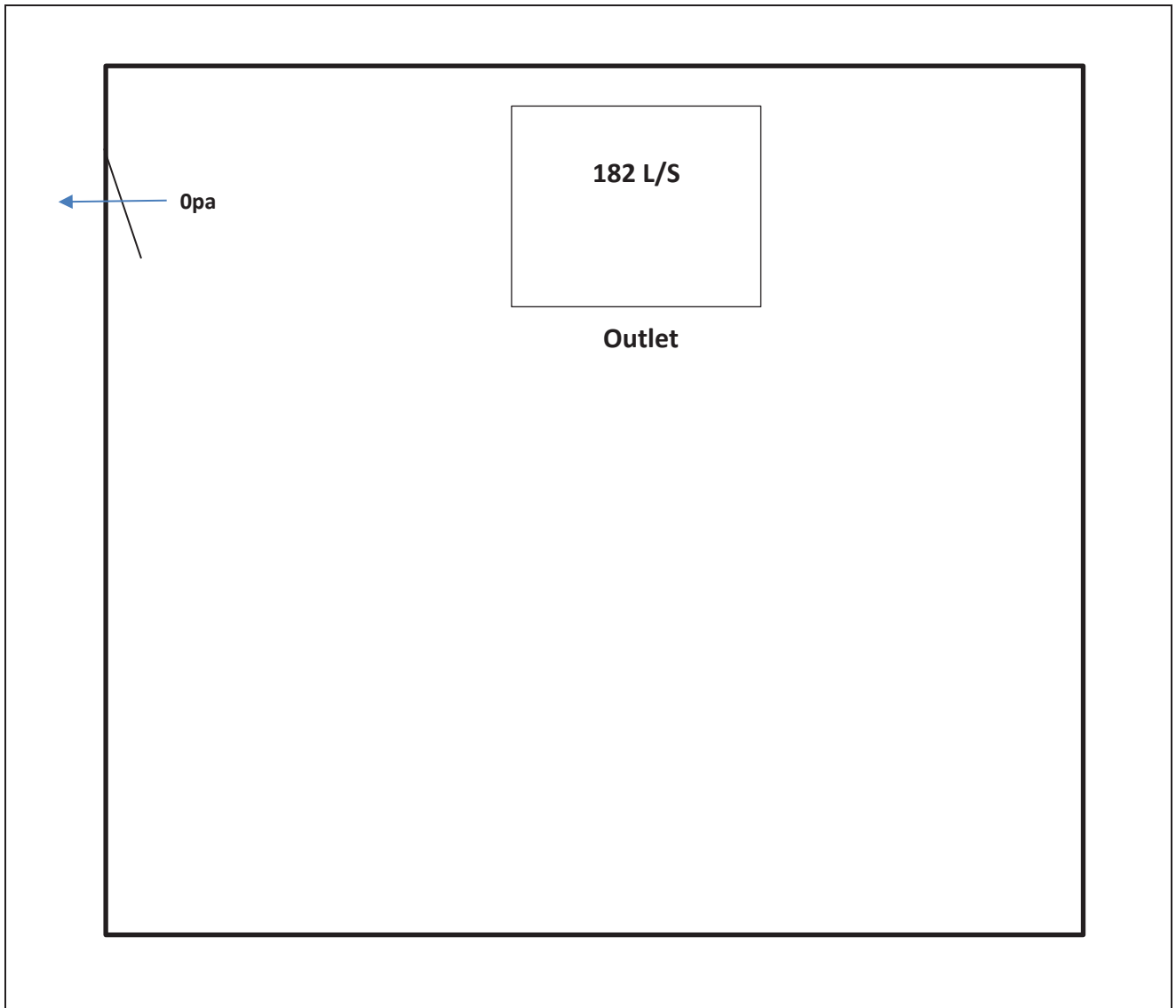
Print Name: Justin Rowe

Issue Date: 27/09/2021

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Sterile Room



AIR CHANGE RATES:

Cleanroom:

Room volume: L X W X H = 40.9 m³

Outlet Supply: = 182.0 L/s

Total Air Quantity: = 182.0 L/s

Air change rate: = $\frac{\text{Total Air Qty} \times 3.6}{\text{Room volume}}$ = 16.0 Air Changes per hour

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Test Instruments Used:

Manometer: T58151541001

Particle Counter: 122729

Flow Hood Serial Number: 70912065

Comments: (Not Covered by NATA Accreditation)

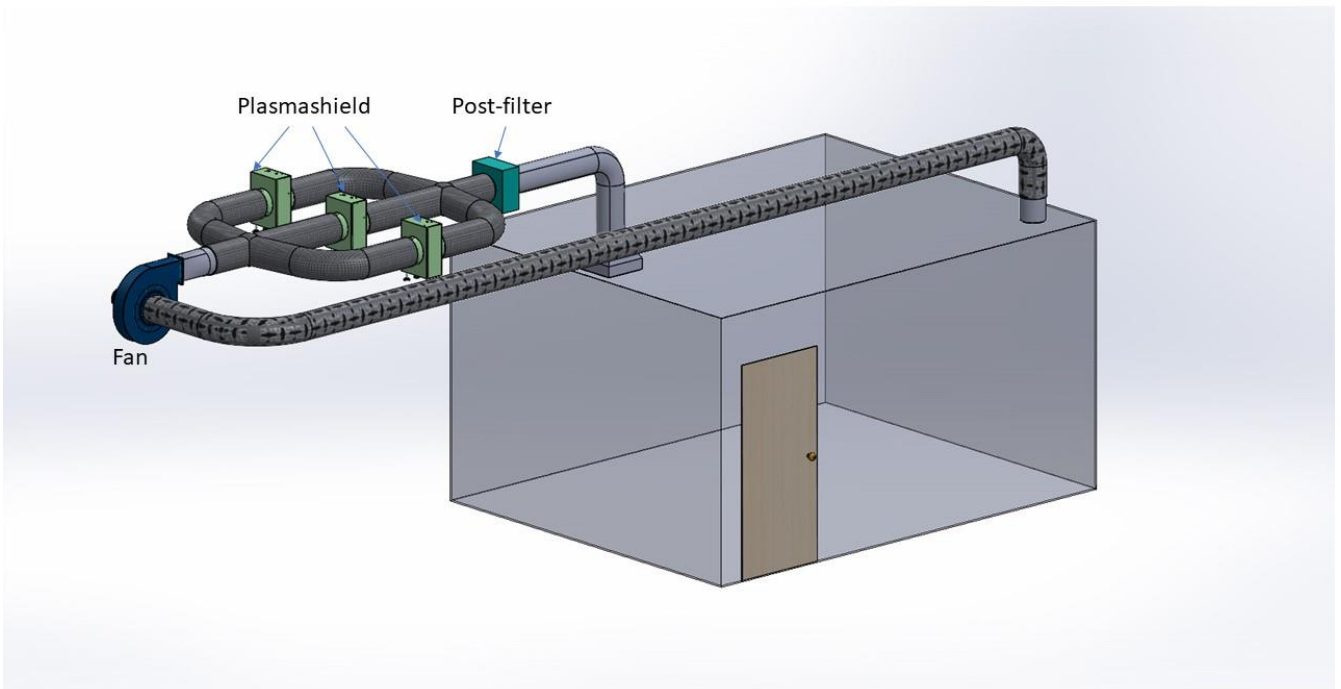
Humidity: 59.9

Humidity Gauge Serial Number: 795451137001

Temperature: 21.1 °C

Temperature Gauge Serial Number: 70912065

F7 (MERV 13)' filter was used as the pre-filter



Comment: Pass and/or Fail decision are based on the estimated probability that the calculated result is within the limited specified in the requirements for **ISO14644-3**. A pass result is reported when the estimated probability is greater than or equal to 95% of the specified limit.

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For determining the classification of air cleanliness to the performance requirements of:
CLASSIFICATION OF AIR CLEANLINESS - ISO 14644.1 - 2017

Client: Plasma Shield.

Equipment: LasAir III

Address: G.D. Pharma Pty Ltd. 46A Beulah Road. Norwood. S.A. 5067.

Model: 350L

Location: Clean Room

Serial Number: 122729

Calibrated: Oct - 2020

Technician: Justin Rowe

Selected airborne particulate cleanliness classes for cleanrooms and clean zones:

ISO Classification Number (N)	Maximum concentration limits (particles/m ³) for particles equal to and larger than the considered sizes shown below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10 ^b	^d	^d	^d	^d	^e
ISO Class 2	100	24 ^b	10 ^b	^d	^d	^e
ISO Class 3	1 000	237	102	35 ^b	^d	^e
ISO Class 4	10 000	2 370	1 020	352	83 ^b	^e
ISO Class 5	100 000	23 700	10 200	3 520	832	^{d, e, f}
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7	^c	^c	^c	352 000	83 200	2 930
ISO Class 8	^c	^c	^c	3 520 000	832 000	29 300
ISO Class 9	^c	^c	^c	35 200 000	8 320 000	293 000

- 1) ISO CLASSIFICATION UNDER CONSIDERATION: CLASS: 7 (TGA Class C)
- 2) PARTICLE SIZE SELECTION TO BE SAMPLED: 0.5 & 5.0
- 3) OCCUPANCY STATE: One Person

Page 2: RESULTS

Page 3: SAMPLE POSITION PLAN

Authorised Signatory: 

Print Name: Justin Rowe

Issue Date: 29/09/2021

Report Number: 210920JR

Date: 24/09/2021

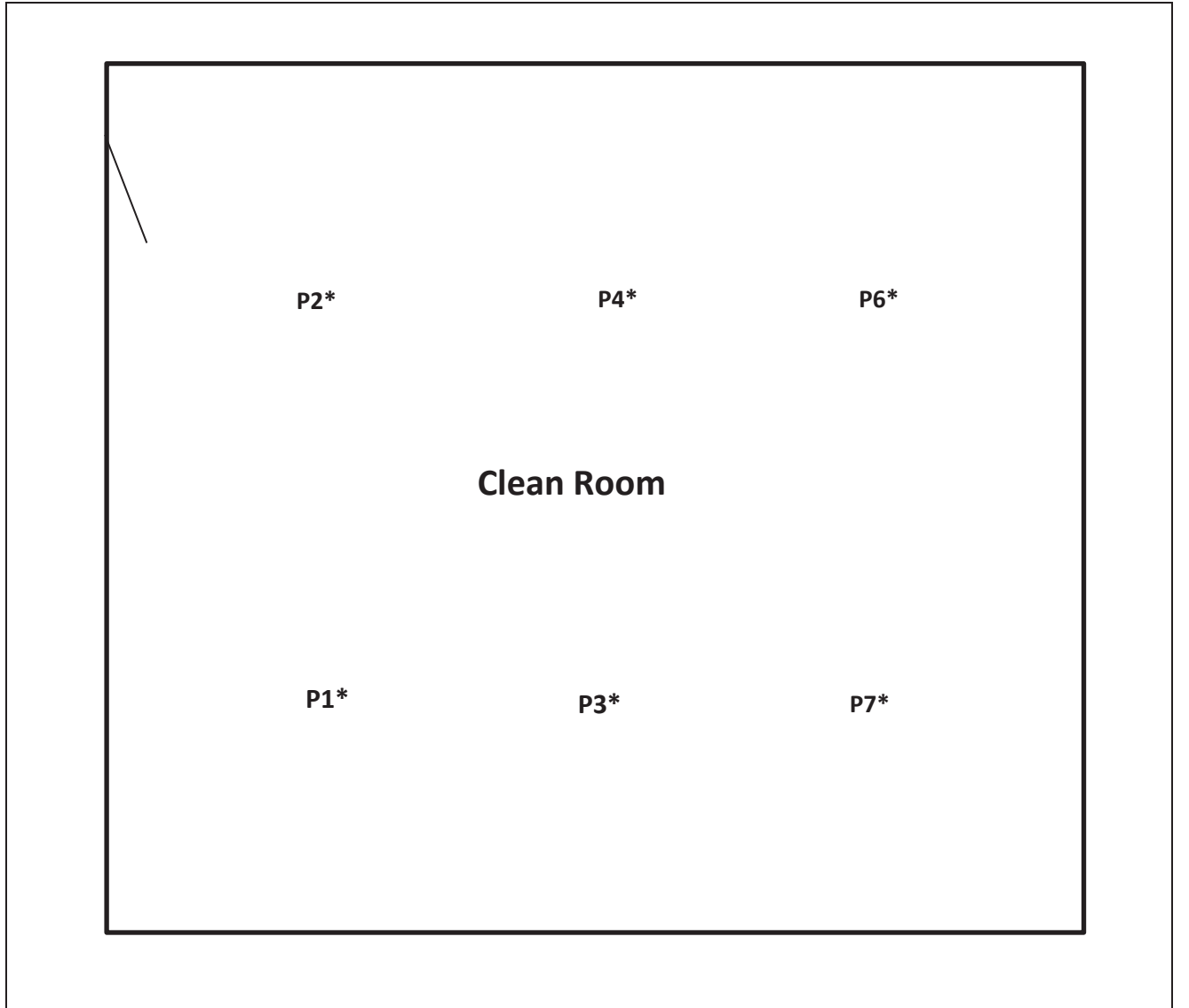
4) **RESULTS:** **Class Achieved: ISO Class 7 (TGA Class C)**
PARTICLE SIZE: 0.5 LIMIT FOR CLASS: 352,000 **LARGEST AVERAGE: 171,785**
PARTICLE SIZE: 5.0 LIMIT FOR CLASS: 2,930 **LARGEST AVERAGE: 2,761**

Test Position	Size = 0.5 Per Cubic Meter	Size = 5.0 Per Cubic Meter	Test Position	Size = 0.5 Per Cubic Meter	Size = 5.0 Per Cubic Meter
POS 1	154808	2761	POS 2	171785	2521
Average	154808	2761	Average	171785	2521
	144291	2421		130568	2441
POS 3	144291	2421	POS 4	130568	2441
	127625	2100		127102	2040
Average			Average		
POS 5	127625	2100	POS 6	127102	2040
Average			Average		

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SAMPLE POSITION PLAN



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For determining the classification of air cleanliness to the performance requirements of:

CLASSIFICATION OF ROOM RECOVERY TIME - ISO 14644.3-2017. Section B.12

Client: Plasma Shield.

Equipment: LasAir III

Address: G.D. Pharma Pty Ltd. 46A Beulah Road. Norwood. S.A. 5067.

Model: 350L

Location: Clean Room

Serial Number: 122729

Calibrated: Oct - 2020

Technician: Justin Rowe

Selected airborne particulate cleanliness classes for cleanrooms and clean zones:

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- 2) PARTICLE SIZE SELECTION TO BE SAMPLED: 0.5 & 5.0
- 3) OCCUPANCY STATE: One Person

Page 2: RESULTS

Page 3: SAMPLE POSITION PLAN

Authorised Signatory: 

Print Name: Justin Rowe

Issue Date: 29/09/2021



Airepure Australia Pty Ltd
 Airepure Technical Services
 Laboratory Accreditation No: 20231
 1/125 Hayward Avenue, Torrensville, S.A. 5031

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4) RESULTS:

Class Achieved: ISO Class 7 (TGA Class C)

PARTICLE SIZE: 0.5 LIMIT FOR CLASS: 352,000 RECOVERY TIME: 19 minutes

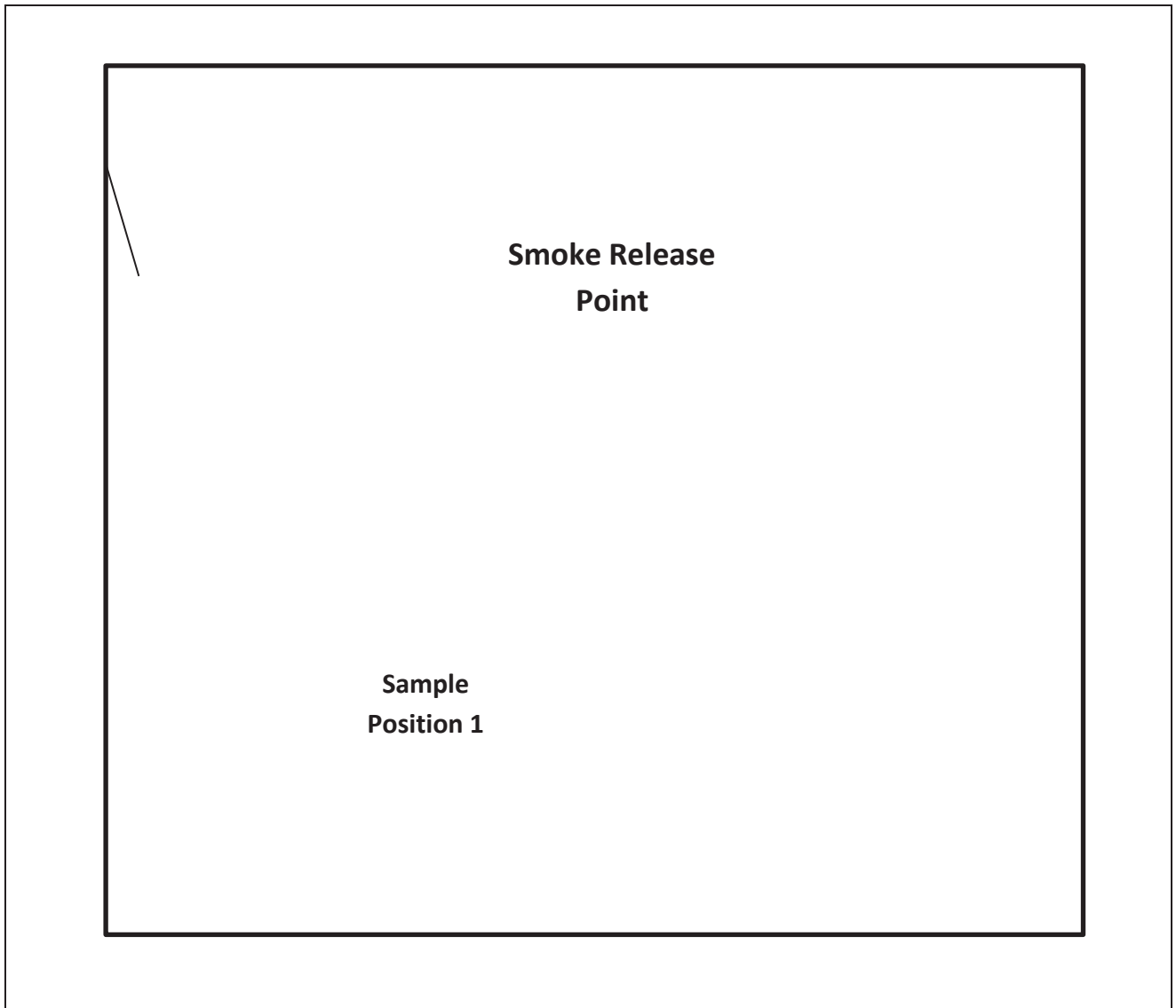
Test Position	Size = 0.5 Per Cubic Meter	Size = 5.0 Per Cubic Meter	Test Position	Size = 0.5 Per Cubic Meter	Size = 5.0 Per Cubic Meter
POS 1					
Before smoke release					
1 minute sample	154808				
POS 1					
100 x Class C					
Time: 2.36pm	36,901,204				
POS 1					
First reaches Class C					
Time: 2.55pm	325,938				

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SAMPLE POSITION PLAN

Clean Room



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