mdi
Membrane Technologies

Data Sheet

AseptiSure® TH

High Temperature Resistant Hydrophobic PTFE Membrane Cartridge Filters

Pharmaceutical and Biopharmaceutical manufacturing involves sterile filtration of air/gases for a multitude of critical processes such as air sparging, bioreactor venting, fermentor exhaust, dry powder filling, WFI tank venting etc.

The critical nature of these processes and associated high costs require the highest degree of reliability for the filter device with regard to its retention efficiency, flow rates, service life and mechanical and thermal stability.

mdi *AseptiSure® TH* cartridge filters are specially designed high temperature resistant PTFE filters which are steam sterilizable at upto 135°C. These filters are validated with liquid microbial challenge test as per ASTM F 838-05 to offer absolute retention even under high moisture conditions.

These are also validated for other key performance parameters such as chemical compatibility, extractable, heat stability, flow rates, blow through and ability to withstand accidental reverse pressure. These are available in a variety of pore sizes to suit specific microfiltration needs in critical and specialized process applications for air as well as liquid.

AseptiSure® TH

High Temperature Resistant PTFE Membrane Cartridge Filters

Datasheet

mdi *AseptiSure® TH* high temperature resistant PTFE membrane cartridge filters are deeply validated for use in Biopharmaceutical applications. These filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Key Features

- Absolute retention
- Heat sealed
- No leaching
- High heat Stability
- Wide chemical compatibility
- Essentially hydrophobic
- Long service life
- Non-toxic material of construction
- Pre-flushed to minimize particulate release after installation
- 100% integrity tested
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

Applications

- Fermentors venting and aeration
- Sterile filtration of API and injectables
- Sterile compressed air for pharma machineries
- Sterile air for dry powder injectables filling
- High temperature WFI tank venting

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filter with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Quality Assurance

Datasheet

mdi quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each cartridge filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiSure® TH* is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

AseptiSure® TH filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

Extractables/leachables from *AseptiSure® TH* filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

AseptiSure® TH filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

AseptiSure® TH bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

AseptiSure® TH filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

AseptiSure® TH filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room process areas.

Other Regulatory Compliance

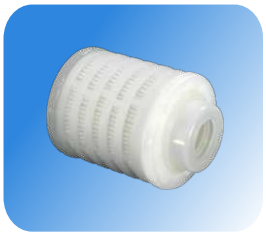
- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics

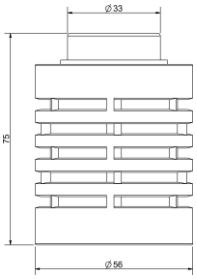
Adapters and Dimensions

Datasheet

2.5" Mini Cartridge Filters

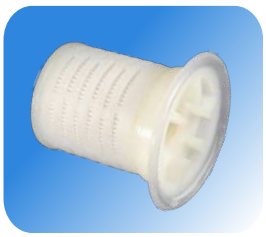
4463 Adapter (E0)

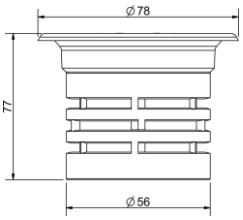




Total Length : 75 mm
Diameter : 56 mm

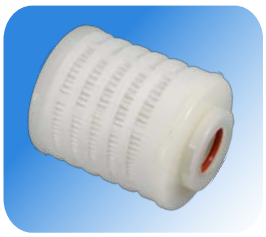
Seal-K Adapter (G0)

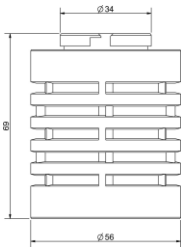




Total Length : 77 mm
Diameter : 56 mm

4463B Adapter (H0)

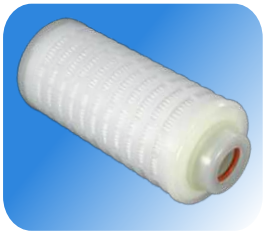


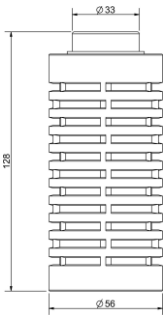


Total Length : 69 mm
Diameter : 56 mm

5" Mini Cartridge Filters

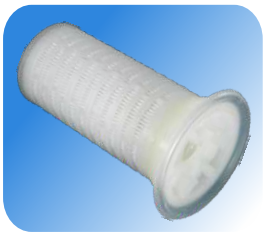
4463 Adapter (E0)

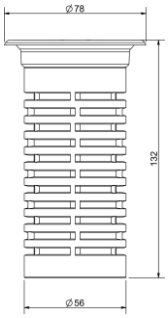




Total Length : 128 mm
Diameter : 56 mm

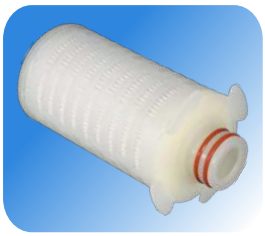
Seal-K Adapter (G0)

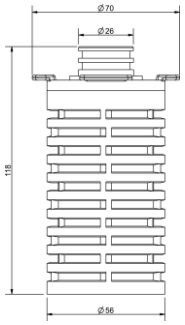




Total Length : 132 mm
Diameter : 56 mm

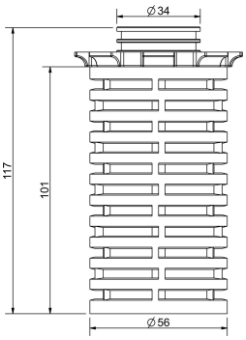
4440 Adapter (U0)





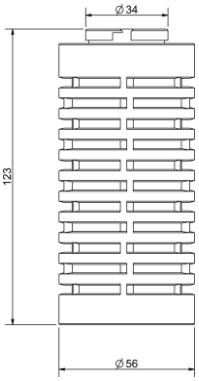
Total Length : 118 mm
Diameter : 56 mm

Seal-O Adapter (F0)



Total Length : 117 mm
Diameter : 56 mm

4463B Adapter (H0)



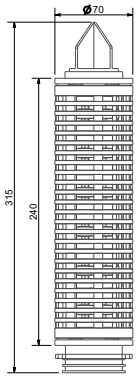
Total Length : 123 mm
Diameter : 56 mm

Adapters and Dimensions

Datasheet

Standard Cartridge Filters

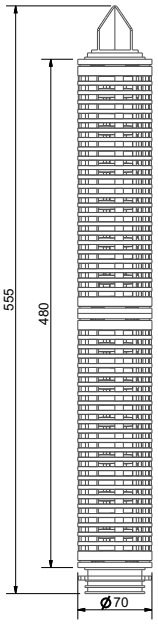
10" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 315 mm

Diameter : 70 mm

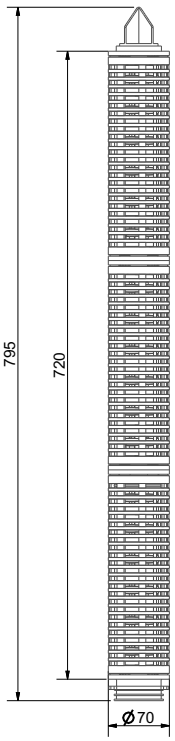
20" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 555 mm

Diameter : 70 mm

30" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 795 mm

Diameter : 70 mm

Adapter and Elastomers Availability Chart

Mini Cartridge Filters		
Adapters	**2.5”**	**5”**
4463	√	√
4463B	√	√
4440	√	√
Seal-K	√	√
Seal-O	X	√
Seal-M	√	√

Mini Cartridge Filters	
Adapters	**Elastomer**
	Silicone
4463	√
4463B	√
4440	√
Seal-K	X
Seal-O	√
Seal-M	√

Standard Cartridge Filters				
Adapters	**5”**	**10”**	**20”**	**30”**
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	X	√	√	√
‘O’	X	√	√	√

Standard Cartridge Filters				
Adapters	**Elastomers**			
	Silicone	Viton	EPDM	FEP Encapsulated Viton
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	√	√	√	X
‘O’	√	√	√	X

Linear Upscaling from Pilot Scale to Production Process

Datasheet

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

mdi offers a wide range of *AseptiSure® TH* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 1000 cm^2 to 18000 cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiSure® TH* filters there by reducing the additional validation cost and time.

***AseptiSure® TH*, 2.5"**
EFA: 1000 cm^2

***AseptiSure® TH*, 5"**
EFA: 2000 cm^2

***AseptiSure® TH*, 5" Large**
EFA: 3000 cm^2

***AseptiSure® TH*, 10"**
EFA: 6000 cm^2

***AseptiSure® TH*, 20"**
EFA: 12000 cm^2

***AseptiSure® TH*, 30"**
EFA: 18000 cm^2

***EFA: Effective Filtration Area**

Specifications

Mini Cartridge Filters

Datasheet

Construction			
Membrane		Hydrophobic PTFE	
Support Layers		Polypropylene	
Plastic Parts		Polypropylene	
O rings		Silicone	
Integrity Testing / Retention			
Pore Size		0.2µm	0.45µm
Bubble Point		22psi (1.52 Bar) with 70% IPA/Water Solution	10psi (0.69 Bar) with 70% IPA/Water Solution
Microbial Retention		LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	LRV >7 for *Serratia marcescens* (ATCC 14756) per cm^2
Water Intrusion Test	2.5″	< 0.3 ml/min @ 2.0kg/cm^2	—
	5″	< 0.6 ml/min @ 2.0kg/cm^2	—

Size		
Size	2.5″	5″
Effective Filtration Area (Nominal)	1000cm^2	2000cm^2

Operational	
Max. Operating Temperature	95 °C @ < 2 Kg/cm^2 (30 psi)
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C
Sterilization	Autoclavable/In-line steam sterilizable at 135 °C for 30minutes, 80 cycles @ Δp= 5psi (0.3kg/cm^2)

Assurance	
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Standard Cartridge Filters

Datasheet

Construction					
Membrane	Hydrophobic PTFE				
Support Layers	Polypropylene				
Plastic Parts	Polypropylene				
O rings	Silicone				
	Viton				
	EPDM				
	FEP Encapsulated Viton				
Integrity Testing / Retention					
Pore Size	0.2µm		0.45µm		
Air Diffusion Flow	≤ 45ml/min @ 16 psi (1.12Kg/cm^2)		≤ 45ml/min @ 8 psi (0.56Kg/cm^2)		
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2		LRV >7 for *Serratia marcescens* (ATCC 14756) per cm^2		
Size					
Size	5″	10″	20″	30″	
Effective Filtration Area (Nominal)	3000cm^2	6000cm^2	12000cm^2	18000cm^2	
Operational					
Max. Operating Temperature	95 °C @ < 2 Kg/cm^2 (30 psi)				
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C				
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C				
Sterilization	Autoclavable/In-line steam sterilizable at 135 °C for 30minutes, 80 cycles @ Δp= 5psi (0.3kg/cm^2)				
Assurance					
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics				
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>				
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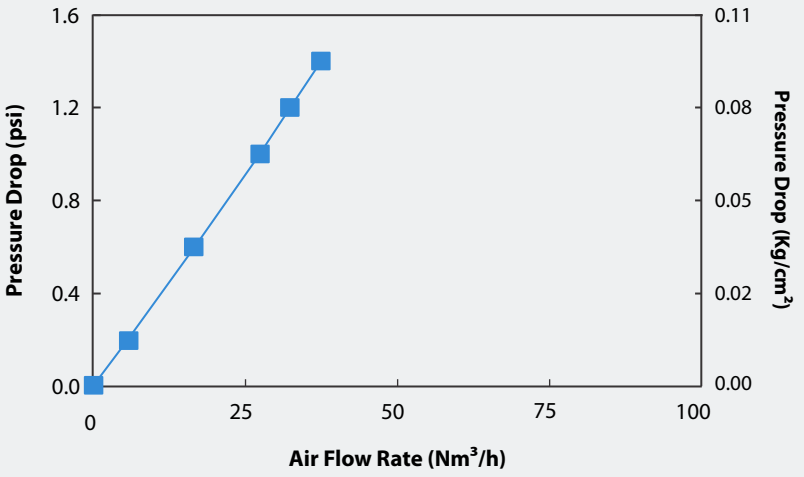
Quality Management System	ISO-9001 Certified				
USFDA	DMF No. 015554				

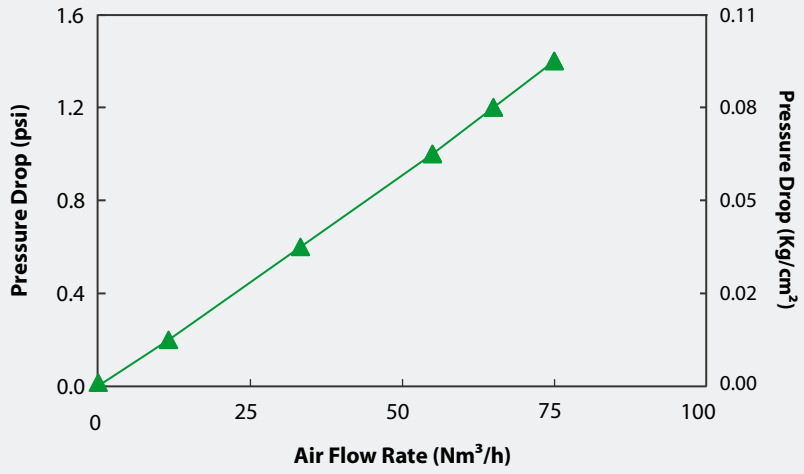
Typical Air Flow Rates
Mini Cartridge Filters

Datasheet

0.2µm *AseptiSure® TH*, 2.5" Mini Cartridge Filters



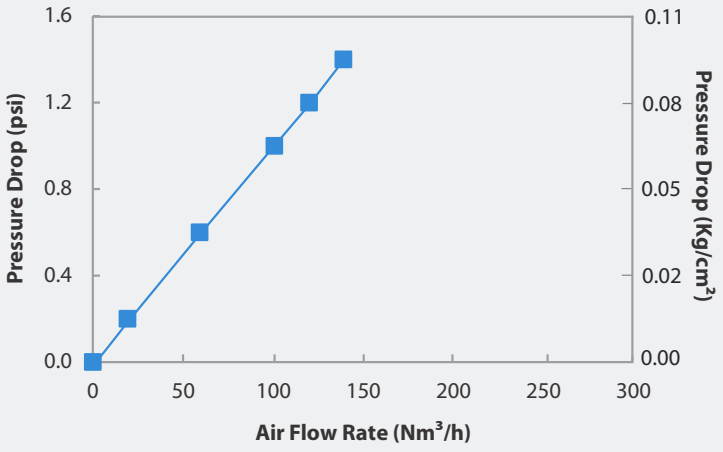
0.2µm *AseptiSure® TH*, 5" Mini Cartridge Filters



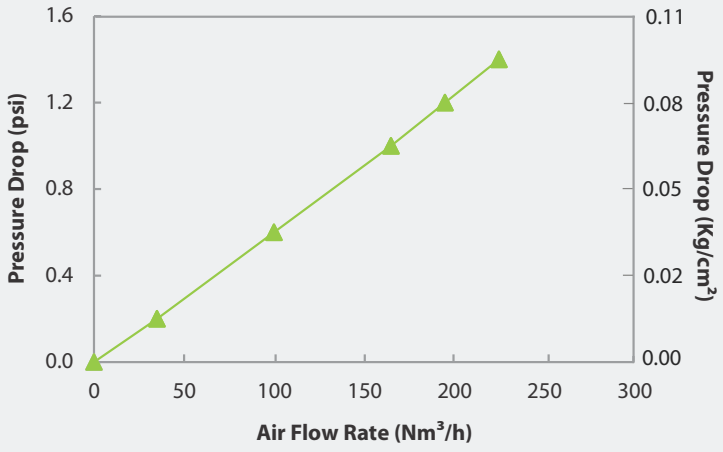
Typical Air Flow Rates
Standard Cartridge Filters

Datasheet

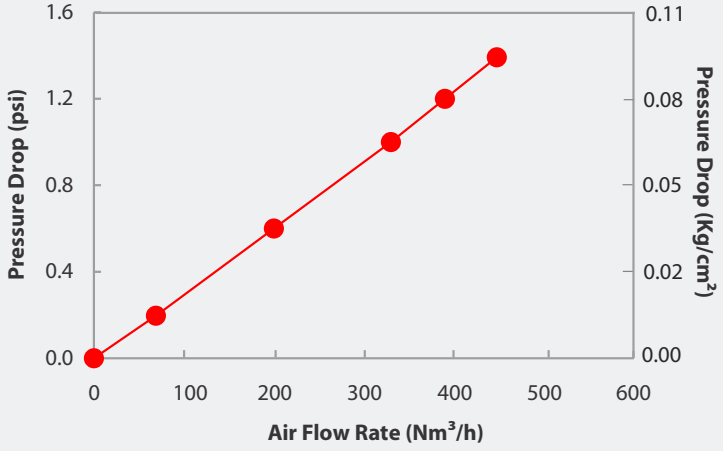
0.2µm *AseptiSure® TH*, 5" Standard Cartridge Filters



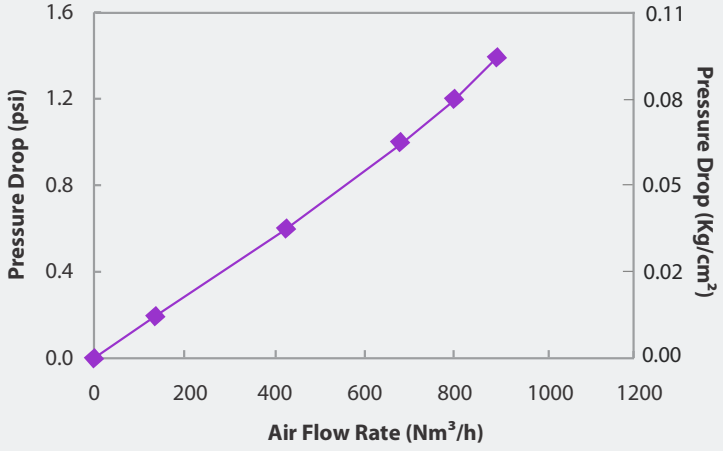
0.2µm *AseptiSure® TH*, 10" Standard Cartridge Filters



0.2µm *AseptiSure® TH*, 20" Standard Cartridge Filters



0.2µm *AseptiSure® TH*, 30" Standard Cartridge Filters



Ordering Information

Datasheet

AseptiSure® TH PTFE Membrane Mini Cartridge Filter

Type	
	Code
AseptiSure® TH	CPTH

Size	
	Code
2.5″	50
5″	53

Pore Size	
	Code
0.2µm	01
0.45µm	02

Adapter	
	Code
4463	E0
4463B	H0
4440	U0
Seal-K	G0*
Seal-O	F0**
Seal-M	J0

Elastomer	
	Code
Silicone	SS

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPTH	50	01	E0	SS	1	01

*G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

**Adapter code F0 is available only in 5″ cartridge filters.

AseptiSure® TH PTFE Membrane Standard Cartridge Filter

Type	
	Code
AseptiSure® TH	CPTH

Size	
	Code
5″*	53
10″	54
20″	55
30″	56

Pore Size	
	Code
0.2µm	01
0.45µm	02

Adapter	
	Code
7P	A0
7P without fin	A1
28 with fin	C0
'O'	D0

Elastomer	
	Code
Silicone	SS
EPDM	SE
Viton	SV
FEP Encapsulated Viton	FV**

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPTH	54	01	A1	SS	1	01

*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**FV is available in adapter code A0 (7P) and A1 (7P without fin) only

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