

LifeASSURE[®] PB

Cartridge and Capsule Filters for Pharmaceutical & Biological Service

New FlexN[™] Multi-Zone Membrane Design Combined with the Innovative Advanced Pleat Technology[™] Construction



- **Exceptional protection of downstream membranes**
- **High cartridge flow rates for smaller filter assemblies and lower running costs**
- **Superior microorganism reduction**

LifeASSURE® PB Cartridge and Capsule Filters

LifeASSURE PB filter cartridges and capsules are CUNO's latest advance in membrane filter technology. Encompassing two leading-edge processes, FlexN™ membrane manufacture and Advanced Pleat Technology™ (APT) pleating construction, the LifeASSURE PB series of filters offers unmatched protection of final membrane filters, as well as exceptionally long service life. Designed with pleated Nylon 66 membrane in an all- polypropylene cartridge construction, LifeASSURE PB filters are ideally suited for a wide range of prefiltration and clarification applications in the pharmaceutical, biological, and bioprocess industries.

Optimal System Performance

Used as a prefilter, LifeASSURE PB filters protect and significantly extend the service life of CUNO's sterilizing grade SterASSURE™ final filter, as well as other membrane filters. LifeASSURE PB filters will:

- ⇒ increase final filter life substantially, often by 10 times or more,
- ⇒ decrease filter change-outs, greatly reducing filter costs, and
- ⇒ provide superior microorganism reduction

FlexN™ Membrane Technology

LifeASSURE PB filters incorporate CUNO's advanced FlexN membrane technology*. It allows unmatched flexibility in creating a multi-zone membrane that offers the maximum in contaminant holding capacity while maintaining high retention efficiency. The SEM photograph at right shows that the *single layer* LifeASSURE PB membrane consists of an "open" zone on the upstream side of the membrane and a "tighter" zone on the downstream side. In effect, the open zone acts as a prefilter by capturing larger particles and



colloids while the tighter zone provides the retention of smaller contaminants. This multi-zone structure eliminates dual-layer membrane construction to provide a larger surface area, significantly increased contaminant holding capacity, and longer service life. For an in-depth technical presentation of FlexN technology, request CUNO Technical Publication LITTDRC1, or visit www.cuno.com.

Features	Benefits
<ul style="list-style-type: none"> ■ Multi-zone, FlexN Nylon membrane 	<ul style="list-style-type: none"> ■ Maximum membrane protection ■ Increased contaminant capacity ■ Extended service life ■ Lower total filtration costs
<ul style="list-style-type: none"> ■ Advanced Pleat Technology construction for extremely high surface area 	<ul style="list-style-type: none"> ■ Faster flow rates and smaller filter assemblies ■ Lower total filtration costs
<ul style="list-style-type: none"> ■ 100% Integrity tested in manufacturing 	<ul style="list-style-type: none"> ■ Ensures product quality
<ul style="list-style-type: none"> ■ Installation integrity testable by the user 	<ul style="list-style-type: none"> ■ Ensures proper installation and operation
<ul style="list-style-type: none"> ■ True membrane construction 	<ul style="list-style-type: none"> ■ Superior removal of microorganisms
<ul style="list-style-type: none"> ■ Meets USP Class VI Biological Test for Plastics 	<ul style="list-style-type: none"> ■ Safe for product contact

* US patents 6,090,441; 6,264,044; 6,513,666; and 6,280,791.

The Advanced Pleat Technology™ Construction Advantage

LifeASSURE PB filters also feature CUNO's patented* APT construction for extended service life. This design technology maximizes the useful surface area of the filter while maintaining proper flow paths between media pleats. By employing as much as 50% more effective surface area area** than competitive filters (see chart 1), the LifeASSURE PB filter provides lower pressure drops, longer service life and lower overall filtration costs.

Superior Microorganism Removal

CUNO LifeASSURE PB filters consistently exhibit a greater reduction of microorganisms than competitive filters that are constructed of polypropylene fibers, or filters that are constructed with less efficient membranes. For effective prefiltration of pharmaceutical and biological products, microorganism reduction is a critical parameter resulting in economical, reliable filter systems. LifeASSURE PB filters ensure compliance with your GMP requirements to maintain low system bioburden.

In tests with *Brevundimonas diminuta*, (considered one of the smallest bacteria) LifeASSURE PLA020 grade filters exhibited an average log reduction value*** (LRV) of 7.3 and the LifeASSURE PLA045 grade filters exhibited an average LRV of 3.5.

Chart 1. - Surface Area Comparison of 10" Cartridges

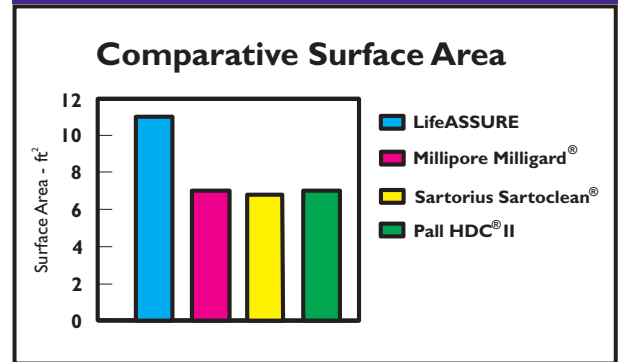


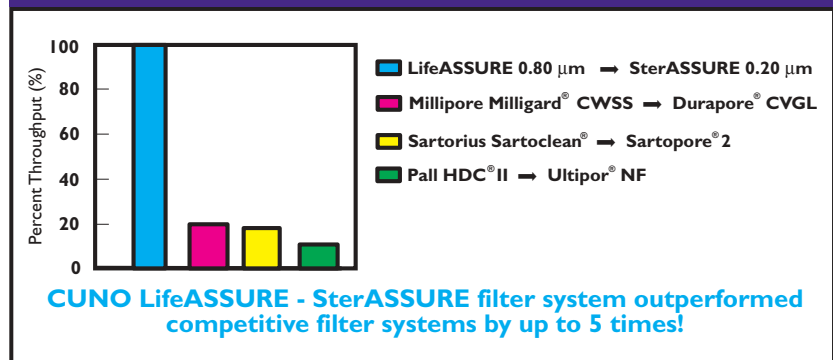
Table 1. - Comparative Log Reduction Values

Products	LRV
LifeASSURE PLA020	7.3
Millipore Milligard CWSS	4.5
LifeASSURE PLA045	3.5
Millipore Milligard CWSC	2.6
Pall HDC J006	0.41

LifeASSURE Prefilter and SterASSURE™ Final Filter System Filtration Advantage

Chart 2 shows the significant throughput advantage of the LifeASSURE/ SterASSURE filter combination compared to competitive prefilter/ final filter selections. The throughput advantage is the result of FlexN membrane construction. LifeASSURE PLA080 (0.8 micron) filters contain an upstream zone of 2.5 micron and a downstream zone of 0.8 micron. SterASSURE PSA020 (0.2 micron) contain an upstream zone of 0.65 micron and a downstream zone of 0.2 micron. The result of this combination is superior system throughput. Finer grades of LifeASSURE prefilters may be required to protect competitive 0.2 micron rated final filters. For best results, please consult CUNO Sales Specialists.

Chart 2. - Prefilter-Final Filter Throughput Comparison Using a Model Contaminant Solution.



For optimum throughput, use LifeASSURE 0.80 µm rated filters upstream of SterASSURE 0.2 µm rated filters, and LifeASSURE 0.45 µm rated filters upstream of SterASSURE 0.1 µm rated filters.

We encourage you to experience the CUNO Performance Advantage by arranging an on-site filter test. For more information about testing and SterASSURE filters (LITZRSTR1) contact your CUNO Sales Specialist or local CUNO Distributor.

*US Patent 6,315,130

** Competitive filter surface area data are from the manufacturer's published literature.

*** LRV = log₁₀ (number of organisms in/number of organisms out).

Milligard® is a registered trademark of Millipore Corporation, Sartoclean® is a registered trademark of Sartorius AG, HDC® is a registered trademark of Pall Corporation.

Higher Flow At A Lower Pressure Drop Reduces Filter Cost Two Ways:

Change-out filters less frequently - For existing applications at a given flow rate, filter cartridges with more surface area per cartridge have a lower flux (flow per unit surface area) than those filter cartridges with less surface area. Since service life is inversely proportional to flux (lower flux = longer service life) in most applications, LifeASSURE PB filter cartridges provide longer service life and require fewer cartridge change-outs. ***This greatly reduces filter costs, disposal costs, CIP/SIP, labor and downtime.***

Use smaller more efficient CUNO Filter Systems - For new applications where filter housing size is selected based on a desired “clean” initial pressure drop, filter cartridges that provide a higher flow rate per cartridge at a given pressure drop will require fewer cartridges, and hence a smaller filter housing, to complete the task. ***This results in a substantial reduction in system costs.***

Benefits of Higher Per-Cartridge Flow Rates

The relative water flow rate performance of LifeASSURE prefilter and SterASSURE final filter cartridges was compared to conventional prefilter and final filter combinations commonly used by pharmaceutical manufacturers. The combined pressure drop of 10-inch LifeASSURE/SterASSURE filter systems for a 3 gallon per minute (11.4 lpm) water flow rate is compared to competitive 10-inch filter systems in Table 2. The results of water flow versus differential pressure testing show a combined system flow rate/pressure drop of less than 1/2 that of competitive filter systems.

Prefilter	Final Filter	Pressure Drop (psid)
CUNO LifeASSURE PLA080	CUNO SterASSURE PSA020	3.25
CUNO LifeASSURE PLA045	CUNO SterASSURE PSA020	3.5
Millipore Milligard CWSS	Millipore Durapore CVGL	7.25
Pall HDC J006	Pall Ultipor NF	7.4

LifeASSURE Prefilter Selection

The table below is provided as a guide to LifeASSURE prefilter selection, although actual process conditions may dictate the use of a more open or tighter prefilter, than specified below. Prefilter selection can be aided by smaller scale pilot tests or flow decay studies using membrane discs or LifeASSURE PB Capsules. Consult CUNO’s Scientific Applications and Support Services (SASS) or your CUNO Sales Specialist for more information.

Grade	Upstream Zone	Downstream Zone	Pre-filter for:
PLA020	0.65µm	0.2µm	Zetapor® 020SP, SterASSURE PSA010
PLA045	0.8µm	0.45µm	Zetapor® 020SP, SterASSURE PSA010, PSA020
PLA065	1.2µm	0.65µm	SterASSURE PSA020
PLA080	2.5µm	0.80µm	SterASSURE PSA020

Chart 3.- Typical water flow rates @ 77°F (25°C) for 10” Cartridges and J Style Capsules

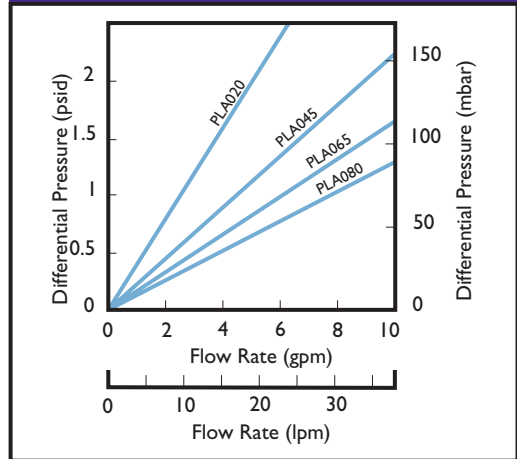


Chart 4.- Typical water flow rates @ 77°F (25°C) for Mini Cartridges and Sanitary Style Capsules with 0.20 & 0.45 µm media**

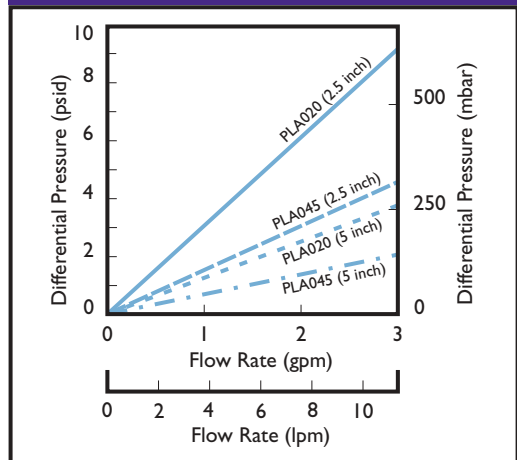
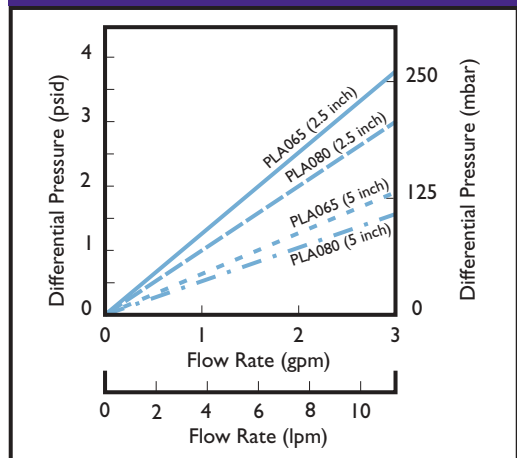


Chart 5.- Typical water flow rates @ 77°F (25°C) for Mini Cartridges and Sanitary style Capsules with 0.65 & 0.80 µm media**



* Millipore Milligard mini cartridges are 4” long, all others are 5”.

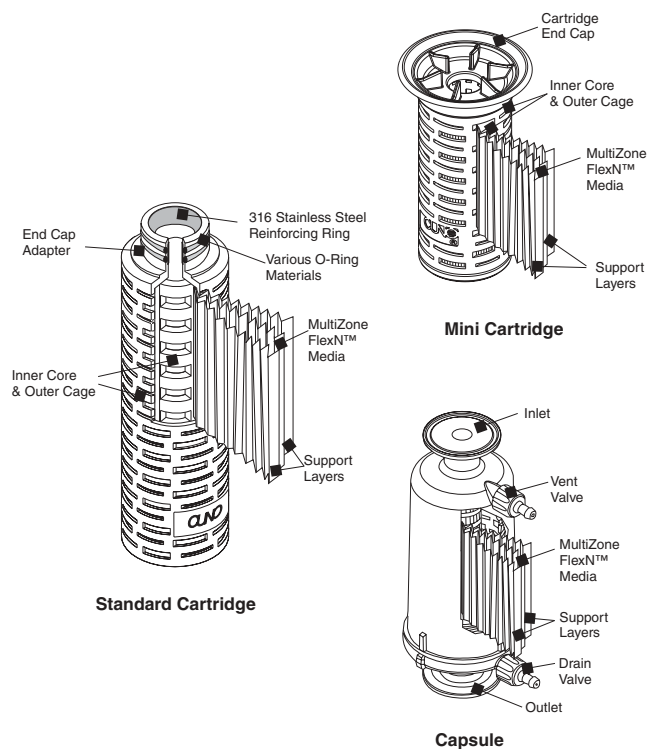
** For capsules with Hose Barb fittings, add 0.36psi @ 2 gpm

LifeASSURE PB Cartridge Construction

LifeASSURE PB filters are constructed of single-layer, patented Nylon 66 microporous membrane pleated with polypropylene upstream and downstream support materials. The cage, core, end-caps and capsule shell are made of polypropylene. All materials of construction are CFR 21 listed and have passed USP Class VI Biological Tests for Plastics at 121°C. Cartridges are manufactured under an ISO 9001 certified quality system using the most advanced thermoplastic welding techniques to ensure filter integrity. LifeASSURE PB filters are 100% integrity tested after manufacture to ensure quality and are supplied with a Certificate of Quality. A regulatory support file (RSF) is available to assist in regulatory control and documentation (request LITRSFLA).

Mini-Cartridges

CUNO's 2.5" and 5" mini cartridges can be installed in Pall Sealkleen housings or the CUNO Mini Cartridge housing (LITZRMCH). The significant LifeASSURE PB flow advantage (Charts 4 & 5) results in greater batch capacity than competitive filters, greatly reducing filter costs.



Disposable Filter Capsules

For critical small-volume applications where convenience and ease of use are desired, LifeASSURE PB filters are available in 2.5, 5, 10, 20, and 30 inch disposable capsules. LifeASSURE PB capsules are supplied with sanitary vent and drain ports, as well as a choice of 1.5" sanitary flange connections or 1/2" (13mm) hose barb inlet/outlet connections (2.5 and 5 inch only).

LifeASSURE PB Specifications								
Material of Construction	Cartridges	Mini Cartridges		Capsules				
		2.5" Length	5" Length	2.5" Length	5" Length	10" Length	20" Length	30" Length
Cage, Core, End-Caps, Capsule Shell, and Media Support Layers	Polypropylene							
Membrane	FlexN Nylon 66							
Adapter Support Ring (full length cartridges only)	316 Stainless Steel	NA						
Dimensions								
Filtration Surface Area (ft ² / m ²)	11 / 1 per 10" Element	1.4 / 0.13	3.4 / 0.3	1.4 / 0.13	3.4 / 0.3	11 / 1	22 / 2	33 / 3
Outside Diameter (inch / cm)	2 3/4 / 7 nominal	2 1/4 / 5.7	2 1/4 / 5.7	3 1/8 / 7.9				
Length (Nominal inches / Nominal cm)	5, 10, 20, 30, and 40 / 13, 25, 50, 75, and 100	3 1/8 / 7.9	5 1/2 / 14.0	1.5" Sanitary Inlet/Outlet				
				5 1/8 / 13.0	7 5/8 / 19.4	12 3/16 / 30.9	22 1/16 / 56	32 / 81.3
				1/2" Hose Barb Inlet/Outlet				
				5 1/2 / 14.0	8 / 20.3	NA	NA	NA
Operating Parameters								
Maximum Operation Temperature	176°F (80°C)			104°F (40°C)				
Maximum Differential Pressure	Forward:	80 psid (5.5 bar) @ 77°F (25°C) 25 psid (1.7 bar) @ 176°F (80°C)		75 psid (5.2 bar) @ 104°F (40°C)				
	Reverse:	50 psid (3.4 bar) @ 77°F (25°C)						
Steam Sterilization	30 minutes @ 259°F (126°C)			Do Not <i>in situ</i> steam				
Autoclave Sterilization				30 minutes @ 259°F (126°C)				
Installation Integrity Test Methods	Consult CUNO for appropriate values for the specific filter and housing in use.							

¹ Sealkleen is a registered trademark of Pall Corporation.

Applications

LifeASSURE cartridges are designed for a broad range of aqueous based pharmaceutical, biological and bioprocess prefiltration and fine particle removal applications, including:

- 0.2 µm final sterilizing filter protection
- Parenterals (SVP, LVP)
- Reagents & Buffers
- Particulate & Bioburden Reduction
- Ophthalmics
- Cell Culture Fluids
- Fermenter Feed Streams
- Solvent Filtration
- Orals & Topicals
- Serum & Blood Fractions
- Vaccines
- High-Purity DI Water and WFI Systems

Safety and Regulatory Compliance

Installation Integrity Test

Unlike other prefilters, LifeASSURE PB filter cartridges are 100% tested for integrity in manufacturing prior to shipment. Additionally, LifeASSURE PB filter cartridges are installation integrity testable *in situ* by the user. The installation integrity test is a non-destructive measurement of a filter's ability to function as intended. Conducting an installation integrity test assures the user that the filter is installed and sealed correctly in the filter housing and is ready for service. This is of particular value where LifeASSURE PB filters are employed in intermediate process steps not requiring a sterilizing grade final membrane filter.

For installation integrity test procedures and values, please consult CUNO document LITDCC04.

Automated Integrity Test - CUNOCheck® 2

The installation integrity test can also be performed with the CUNOCheck2 automated integrity test device. The CUNOCheck 2 integrity tester provides fast, reliable and accurate automated installation integrity testing of LifeASSURE PB cartridges, capsules and mini cartridges. For more information, see CUNO document LITCCC2.



CUNO Final Filters

SterASSURE™ Filters - Employed as the final filter in critical applications, SterASSURE series filter cartridges and capsules are constructed with proprietary FlexN nylon 6,6 membrane and polypropylene components (see CUNO document LITCZRSTR1).

SterASSURE sterilizing grade filters are qualified for complete retention ($>10^7$ CFU/cm²) of *B. diminuta* following ASTM methodology. SterASSURE filters are supported with a CUNO Validation Guide (LITVGSTR).



Validation Support Services

CUNO offers specialized support to the pharmaceutical and biotechnology industry through our **Scientific Application Support Services (SASS) Group**. SASS routinely provides end-users with:

- Validation and Regulatory Support
- Extractable and Compatibility Analysis
- Filter System Optimization Studies
- CUNOCheck 2 Integrity Tester Validation.

For more information regarding CUNO's Validation Support Services, please contact CUNO Technical Service.



CUNO Filter Housings

A specialized range of filter housings are available to meet the needs of the pharmaceutical, biological, and bioprocess industries. They provide easy access for filter change-out and the greatest assurance that LifeASSURE PB filter cartridges are sealed securely, thus eliminating the possibility of fluid bypass. All housings are constructed using 316L stainless steel to maximize corrosion resistance. Internal surfaces of the housings are polished to limit microbial adhesion and provide easy cleaning.

Housing Model	ZMS Mini	ZMS	ZWC	ZWB	ZVS	Mini-Housing	
	For 5" Cartridge	For 10, 20, 30, and 40 inch cartridges				For 2.5 inch Mini Cartridges	For 5 inch Mini Cartridges
Basic Part Number / Cartridge Capacity	70236-02 / 1	70220 / 1	70180 / 4	70269 / 4	70221 / 1	70235-02 / 1	70235-01 / 1
			70189 / 8	70270 / 8			
			70190 / 11	70271 / 11			
			70191 / 21	70272 / 21			
Housing Style	T-line Sanitary type connection				Sanitary type in-line		
Equivalent Cartridge Lengths	5 inches	10, 20, 30, and 40 inches			2.5 inches	5 inches	
Materials of Construction	316L Stainless Steel						
Pressure & Temperature Ratings	150 psi (10 bar) @ 300°F (149°C)	* 75 psi (5 bar) @ 200°F (90°C)	150 psi (10 bar) @ 200°F (90°C)	150 psi (10 bar) @ 300°F (149°C)	150 psi (10 bar) @ 300°F (149°C)	150 psi (10 bar) @ 300°F (149°C)	150 psi (10 bar) @ 300°F (149°C)
Literature #	LITZRHZMS2	LITZRH.104	LITZRH.106		LITZRH.104	LITZRHMCH	

* 21ZWC rated at 68 psi



CUNO's offering of sanitary style filter housings accommodate from 1 to 21 LifeASSURE filter cartridges in 10" through 40" lengths.



CUNO's Mini Cartridge filter housings provide the user with low product hold-up volume for critical small scale applications.

LifeASSURE PB Cartridge Ordering Guide

Cartridge Grade	Configuration	Length (Inches)	End-modification	Gasket/O-ring Material
PLA020 - 0.2 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	B - Pleated Configuration	01 - 10" 02 - 20" 03 - 30" 04 - 40" 50 - 5" *	B - 226 O-ring & Spear (Code 7) C - 222 O-ring & Spear (Code 8) D - Double open end (10" Length) E - Double open end (9 3/4" Length) F - 222 O-ring & Flat Cap (Code 3) J - 226 O-ring & Flat Cap	A - Silicone B - Fluorocarbon C - EPR D - Nitrile

* Not Available with D or E end-modification.

LifeASSURE PB Mini Cartridge Ordering Guide

Cartridge Grade	Configuration	Nominal Length (inches)	End-modification	Packaging Option
PLA020 - 0.2 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	M - Mini Cartridge	01 - 2.5 02 - 5	A - Standard	6 - 6 Cartridges

LifeASSURE PB 2.5" & 5" Capsule Ordering Guide

Cartridge Grade	Configuration	Nominal Length (inches)	End-modification	Packaging Option
PLA020 - 0.2 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	C - Capsule	01 - 2.5 02 - 5	A - Sanitary Flange B - Hose Barb	1 - Single Capsule 3 - 3 Capsule

LifeASSURE PB 10", 20", & 30" Capsule Ordering Guide

Cartridge Grade	Configuration	Length (inches)	End-modification	Vent/Drain O-ring Material	Packaging Option
PLA020 - 0.2 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	J - Capsule	01 - 10 02 - 20 03 - 30	A - Sanitary Flange	A - Silicone B - Fluorocarbon C - EPR	01 - Single Capsule

WARRANTY

Seller warrants its equipment against defects in workmanship and material for a period of 12 months from date of shipment from the factory under normal use and service and otherwise when such equipment is used in accordance with instructions furnished by Seller and for purposes disclosed in writing at the time of purchase, if any. Any unauthorized alteration or modification of the equipment by Buyer will void this warranty. Seller's liability under this warranty shall be limited to the replacement or repair, F.O.B., point of manufacture, of any defective equipment or part which, having been returned to the factory, transportation charges prepaid, has been inspected and determined by Seller to be defective. THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, AS TO DESCRIPTION, QUALITY, MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR ANY OTHER MATTER. Under no circumstances shall Seller be liable to Buyer or any third party for any loss of profits or other direct or indirect costs, expenses, losses or consequential damages arising out of or as a result of any defects in or failure of its products or any part or parts thereof or arising out of or as a result of parts or components incorporated in Seller's equipment but not supplied by the Seller.

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