

Sterile Air for the Food Industry

Parker Balston Filters Eliminate Food Contamination with Benchmarked Good Manufacturing Practices



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Sterile Air for the Food Industry

Safeguarding the Process

Ensuring the safety of food by reducing the risk of contamination is no small task in a food plant. Understanding the potential sources of the contamination can require a lot of detective work. Parker Balston can provide peace-of-mind where compressed air contacts the food by removing all microbial contamination from the air stream.

Know the Potential Risks

Air is not as clean as it appears to be. Untreated compressed air contains many potentially harmful or dangerous contaminants which must be removed or reduced to acceptable levels in order to protect the consumer and provide a safe and cost effective production facility. Along with moisture and particulate matter, inlet air to a compressor generally carries 5 to 50 bacteria per ft³. A 75hp compressor with a capacity of 300 SCFM therefore takes in 100,000 to 1 million bacteria each hour. These bacteria get compressed along with the air and begin their journey through the compressed air system. Introducing this type of microbial contamination to food products is very risky and would be considered a lack of control by the facility. Understanding how to operationalize the treatment of compressed air in a facility will help ward off that risk.

Managing the Risks

Compressor room drying and filtration is good, but it's not enough for a food processing plant. System filtration can do a good job reducing the amount of contaminants that are introduced into the downstream distribution system; however, that alone does not meet the requirements of the published GMPs that address compressed air - nor is it fully effective. In this scenario the risk of food adulteration is still quite high. The warm, oxygen rich environment inside the downstream air reservoirs. piping, fittings, and controls are ideal harborage sites for microbial biofilm growth - especially when fed with food grade compressor oils that inevitably migrate downstream. For this reason a number of the published GMPs call for point-of-use filtration that should be in place for all points where compressed air either directly or indirectly contacts food.

The first line of defense to ward off potential microbial contamination of the food product from compressed air is to use point-of-use sterile air filtration. With a properly designed compressed air system employing the benchmarked GMPs (outlined later in this document) along with welldesigned SSOP (Sanitation Standard **Operating Procedure) maintenance** and monitoring programs – the risk associated with compressed air at points of contact can be mitigated significantly. A system design employing sterile air filtration at point-ofuse puts a physical barrier in the air stream guarding against microbial contamination of the food. Combining this system design with a HACCP Prerequisite Program (PRP) formalizing these GMPs and SSOPs makes a cost effective, efficient, and defensible risk management plan.

Ready-to-Eat Foods (RTE)

RTE foods are at high risk of contamination from sources such as compressed air. Any microbial contamination introduced in the later stages of RTE food processing can stay with the food all the way to the consumer, as few hurdles or barriers are generally in place to eliminate the hazards.



Good Manufacturing Practices – Industry Standards Benchmarked

Identifying the risk and potential hazards with compressed air in a food plant is the easy part. Determining Good Manufacturing Practices for cleaning up the air is not so straightforward. The established, published, and sanctioned Good Manufacturing Practices that relate to compressed air used in a food processing facility are listed below:

Benchmarking of Compressed Air GMPs

Good Manufacturing Practices - Compressed Air in Food Plant	Dew Point	Oil Removal	Particulate Removal (Includes microbiological particles)	Efficiency	Location of Filtration			
FDA Code of Federal Regulations Title 21CFR, Part 110.40 (g)*	Compressed air or other gases mechanically introduced into food or used to clu contact surfaces or equipment shall be treated in such a way that food is not cor with unlawful indirect food additives.							
FDA Guidance RTE foods ²			0.3 Micron					
FDA and the FSMA ¹² (Food Safety Modernization Act)		The FSMA does not introduce any specific regulations related to compressed air. It primarily requires companies under FDA jurisdiction to employ a risk-based (HACCP-like) food safety management scheme.						
3-A Standard 604-05-3A ⁸		P		sterile air): 99.999% ¹⁰				
Section: D6.6.1			All other	r: 99% ¹⁰				
Britsh Compressed Air Society (BCAS) ⁴ Section 6	-40° F/C	< 0.01 mg/m ^a	0.1 - 0.5 Micron					
British Retail Consortium (BRC) ⁹		Compres	ssed air used directly	in contact with the product shall be fil	tered.			
Safe Quality Foods (SQF) 7.1 edition ⁵ . Section(s): 9.5.7; 10.5.7; 11.5.7 ; 13.5.4		Compressed air us	sed in the manufactu	ring process shall be clean and presen safety.	t no risk to food			
SQF Guidance Document for Module 11 May 2013			0.01 Micron	99.999%	Point of use			
International Featured Standards (IFS) version 6 ⁴ . Section 4.9.10.2			Compressed air sha	Il not pose a risk of contamination.				
Clabel Red Meet President (opp.re)7	Hazards relevant to food safety shall be controlled in critical control points (Ci GMP measures							
	15022000:200	5 := Prerequisite Pro		GMP measures.				
Global Red Meat Standard (GRMS) ⁷ ISO 22000:2005 ⁸ + Prerequisite Program (PRP) (like BSI PAS 220:2006 ¹¹)	BSI PAS 220:2 so as to preve	008 Section 6.5 := (Se ent contamination. I	ograms should be in p ummarized) Compre- Requirments for filtr		n 7.2.3.C) nd maintained			
ISO 22000:2005 ⁸ + Prerequisite Program (PRP)	BSI PAS 220:2 so as to preve specified. Fil	008 Section 6.5 := (Se ent contamination. I	ograms should be in p ummarized) Compre- Requirments for filtr	GMP measures. blace to address supplies of air (Section ssed air systems shall be constructed a ation, microbilogy, and humidity (RH%	n 7.2.3.C) nd maintained			
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ISO 22000:2005 ⁸ + Prerequisite Program (PRP) (like BSI PAS 220:2006 ⁵⁵) Most discriminating filtration standard: Balston Product Spec. Applications: Washdown and/or Clean-in-Place	BSI PAS 220:2 so as to preve specified. Fil Element> Stage> 3-3	008 Section 6.5 := (Se ent contamination. I Itration of the air sho < 0.01 mg/m ² BX Stage 2 Balston 6000 Ser Stage Sterile Air Filte BX + DX + SA 1/4" thru 1" Pipe S	ograms should be in p ummarized) Compre Requirments for filtro ould be as close to th 0.01 Micron DX Stage 1 ries er Systems Sizes	GMP measures. place to address supplies of air (Section ssed air systems shall be constructed a ation, microbilogy, and humidity (RH% re point of use as is practicable. Point of Use-Contact: 99,999% SA	n 7.2.3.C) nd maintained) shall be			



Not Specified
 Most critical standard

GMPs/PRPs for Point-of-Use Compressed Air Filtration

Point-of-use filtration is the best line of defense against microbial contamination of food in a compressed air system. Even the best of compressor room system filtration does not eliminate harborage sites and biofilm buildup in the compressed air piping system.

Best Practices

GMP/PRP: System Design Point-of-Use Filtration

Wherever the compressed air comes lin contact with the food – either directly or indirectly - the following 3-stages of filtration will significantly reduce the risk of microbial contamination of the food.



• **Stage 1:** Remove bulk liquid and particulate matter down to 0.01 micron at >= 93% DOP efficiency. Automatic drain in filter.

- Stage 2: Remove oil and water aerosols and smaller particulate matter down to 0.01 micron at >= 99.99+% DOP efficiency. Automatic drain in filter.
- Stage 3: Remove microbial contamination down to 0.01 micron at >= 99.999% DOP efficiency with a sterile air filter.

SSOP: Maintenance of Filters

- **Stage 1:** Change filter element every 6-12 months.
- **Stage 2:** Change filter element every 6-12 months.
- **Stage 3:** Change filter element every 3-6 months – or sooner – as necessary based on point-ofuse air quality test for microbial content. Optional: Steam sterilize stage 3 (provided the filter is designed for CIP sterilization). Follow manufacturer's instructions.

Note: Sterile air filters are designed to capture microbial matter larger than the nominal element rating. Microbial matter will not create a differential in pressure across the element. Therefore, measuring differential pressure across the element will not give an accurate reading of contamination. Air testing and/or regularly scheduled element changes are the best practice.

SSOP: Monitor Purity of Compressed Air

As a baseline - test compressed air at each food contact point periodically in accordance with ISO 8573-7:2003 standards. Determine test interval empirically based upon presence of microbial contamination.

Common Foodborne Contamination Effectiveness of Parker Balston Filters

				Balston Filter Element Grade			
				DX	BX	SA	
				Filte	r Element R	ating	
Organism	Microbial Group	Rod Length µm	Rod or Coccus Diameter µm	93 % Efficiency @ .01 micron 1-log reduction	99.99% Efficiency @ .01 micron 4-log reduction	@ .01 micron 6-log	
Campylobacter	Bacteria	0.5	0.2				
Clostridium botulinum (B)	Bacteria	3.0-8.0	0.5-0.8				
Clostridium Perinngens	Bacteria	4.0-8.0	1.0-1.5				
Clostridium tetani	Bacteria	4.0-8.0	0.4-0.6				
Escherichia coli	Bacteria	1.0-3.0	0.5				
Listeria monocytogenes	Bacteria	1.0-1.5	0.4				
Salmonella enteritidis	Bacteria	2.0-3.0	0.6-0.7				
Salmonella enteritidis	Bacteria	2.0-3.0	0.6-0.7				
Salmonella hirschefeldii	Bacteria	1.0-2.5	0.3-0.5				
Salmonella typhimurium	Bacteria	0.5-1.0	1.0-2.0				
Salmonella typhosa	Bacteria	2.0-3.0	0.6-0.7				
Staphylococcus Aureus	Bacteria	Coccus->	0.8-1.0				
Yeast	Fungi		1.0-50.0				
Mold	Fungi		1.5-20.0				
Mycotoxins (by product of mold)	Fungi		0.1				

See Bulletin:

Parker Balston Validation Studies

...showing the effectiveness of Parker Balston filters in removing submicron particulate and microbial contamination from compressed air.

Useful for food safety scheme audits.





www.balstonfilters.com

CAMTU Compressed Air Microbial Test Unit

Identify Sources of Contamination in Compressed Air and Improve Food Safety

Compressed air is used in a broad range of applications in the food processing industry, such as mixing of ingredients, cutting, sparging, drying of product, transporting/ propelling product through processing systems and packaging of final product. In many of these applications, compressed air is in direct or indirect contact with food product. The impurities in the compressed air may contaminate the food product which can result in change of color and taste and reduced shelf life. In addition, exposure to bacteria and other micro-organisms can result in product recalls.

Compressed air is warm, dark and contains moisture which is the ideal environment to promote the growth of microbes. These microbes migrate through the entire compressed air system and are released at exit points; critical areas at which food, packaging or surface areas come into direct contact.

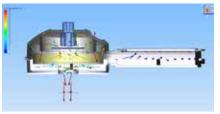
Recently, Safe Quality Foods (SQF) released a 7th edition amendment in sections 10.5.7 and 11.7.5 stating, "compressed air used in the manufacturing process shall be clean and present no risk to food safety." Others have also identified compressed air as a source of contamination and risk to food safety.



- Lightweight and ergonomically designed for ease of use
- Built in timer with indicator lights
- Constructed of durable polypropylene - easily sanitized
- Pre-filled agar plates with specialized tryptic soy or potato dextrose agar designed to hold up to com-

- pressed air flow/pressure
- No electrical supply required
- Quick sampling time -20 seconds
- Complete kit with connection tubing, pressure regulator/metering orifice, shut off valve, timer and agar plates.

New Custom Designed Agar Plate Provides Enhanced Exposure to the Agar



Flow dynamics original CAMTU with standard agar plate

	<u>ie</u>
	a a constant

Flow dynamics new CAMTU with custom agar plate providing more compressed air exposure over the agar plate



CAMTU Compressed Air Microbial Test Unit

British Compressed Air Society has produced a specification for dewpoint (-40F/C), oil removal <0.01mg/m³ and particulate removal (including microbiological particles) 0.1-0.5 microns. (Request white paper by Lee Scott, "Reducing Contamination Risks of Compressed Air in Food Plants".)

However, to date, the only devices capable of sampling compressed air systems for microbes are expensive, very cumbersome, require lengthy sampling times and extensive training. Parker Balston recognized the need for an alternative device that is easily transported throughout the food plant and can provide a quick qualitative analysis of compressed air purity requiring very little training.

The Parker Balston CAMTU (compressed air microbial test unit) is easily transported, weighing less than a pound. It comes complete with connection tubing, shut off valve and a specially designed pressure regulator and metering orifice. These matched components provide the exact amount of compressed air exposure for each sampling. The agar plates are filled with specialized tryptic soy agar designed to hold up to compressed air flow and pressure. TSA is used for the cultivation of a wide variety of microorganisms including most bacteria and mold spores.

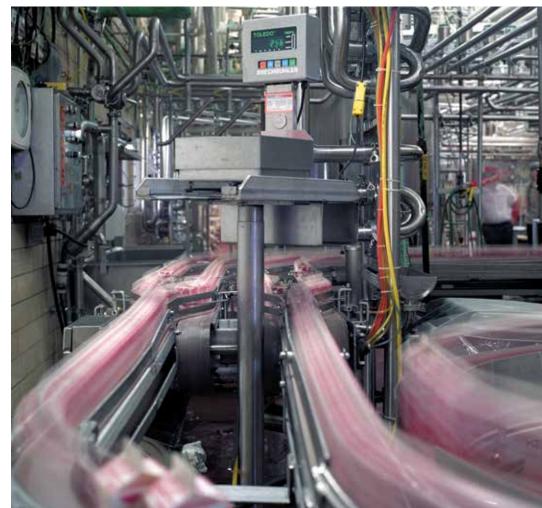
The Parker Balston CAMTU has been validated by Dr. Mclandsborough, head of the Food Science Department of the University of Massachusetts, Amherst



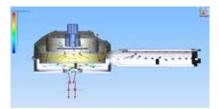
MA. (Request white paper by Dr. Mclandsborough "Comparison of the Compressed Air Microbial Testing Unit (CAMTU) to a standard method of bioaerosol sampling.") To obtain a sample, simply plug the connection tubing into the sample point on the compressed air system, insert an agar plate into the CAMTU, close the CAMTU, open the shutoff valve and expose the agar for 20 seconds. After exposure simply place the agar plate in an incubator for 48 hours or in a controlled environment of at least 68°F and observe for colony forming units (CFUs).



Obtaining a sample using the Parker Balston CAMTU

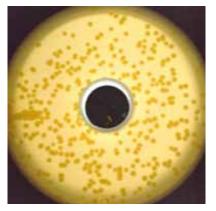


Optimum Agar Plate Design!



Flow dynamics: original CAMTU





Flow dynamics: new CAMTU

Unlike the conventional agar plate, this unique agar plate offers greater dispersion of the compressed air over the agar as a result of an improved air flow path through the center hole in the plate. This provides optimum detection performance and enhanced capture of microbes. This is an ideal device to incorporate into your Good Manufacturing Practices program for monitoring all identified HACCP risk points. For those risk points where microbes were detected, Parker recommends installing Balston 3 stage sterile air filter systems which will remove oil, water, rust, pipescale and all microbes from the compressed air (Request Bulletin FMB09). The CAMTU can then be used to monitor those filter systems for optimum performance.



Balston 6000 Series 3 stage Sterile Air Filter Systems



CAMTU Compressed Air Microbial Test Unit



CAMTU Sampling System



Storage and Carrying Case

Complete Kit: C01-0136	
CAMTU Sampling Device	C01-0135
DFU Assembly	P/N TBD
Tubing ¼" OD	A01-0459
Regulator/Metering Assembly	C01-0125
Sanitizing spray bottle	C01-0124
Shut off valve	C01-0126
Agar Plates (5 total) Tryptic Soy	C01-0143
Agar Plates (5 total) PDA	C01-0134
Petri dishes (5 total) Empty	C01-0133
Dimensions	15.63"w x 13.63"h x 6.38"d
	(40cm x 35cm x 16cm)
Shipping Weight	7 lbs. (3.2 kg)



3-Stage Sterile Air Filter Systems

Safeguard your food processing operation from the contamination hazards of rust, pipescale, water, oil, and microorganisms. In 3 stage pointof-use filtration systems, the first 2 stages are designed to remove contaminants at a very high efficiency up to 99.99% for 0.01 micron particles and droplets. Liquid releases from the filter cartridges to automatic drains as rapidly as it enters the filter. This allows the filters to continue removing liquids for an unlimited time without loss of efficiency or flow capacity.

The 3rd and final stage of filtration removes all viable organisms with an efficiency rating of 99.9999+% at 0.01 microns. Filters are available in 1/4" to 1-1/2" port sizes in either 304 stainless steel or aluminum with a durable powder coating designed to hold up to the dirtiest compressed air systems. The stainless steel filters are also compatible with CIP steam cleaning processes.

2000 Series Aluminum Sterile Air Filters



Flow Rates

Flow Rates

Filter Housing Model	Port Size	Filter Cartridge Grade	Flow rates SCFM (Nm ³ /hr), at 7 psi (0.48 bar) drop at indicated line pressure. Refer to Specification Charts in each product data sheet for maximum pressure rating of each PSIG						
			2 (0.1)	20 (1.4)	40 (2.8)	80 (5.5)	100 (6.9)	125 (8.6)	150 (10)
3B-2002N-3B1	1/4"	DX	9 (15)	19 (32)	39 (87)	51 (107)	63 (107)	76 (129)	90 (153)
3B-2003N-3B1	3/8"	BX	3 (5)	8 (14)	11 (36)	21 (42)	25 (42)	31 (53)	36 (61)
3B-2004N-3B1	1/2"	SA		8 (14)	11 (36)	21 (42)	25 (42)	31 (53)	36 (61)
3B-2104N-3B1	1/2"	DX	19 (32)	41 (70)	65 (192)	113 (233)	137 (233)	166 (282)	196 (333)
		BX	9 (15)	19 (32)	30 (87)	51 (107)	63 (107)	76 (129)	90 (153)
		SA		19 (32)	30 (87)	51 (107)	63 (107)	76 (129)	90 (153)
3B-2206N-3B1	3/4"	DX	37 (63)	78 (133)	123 (364)	214 (440)	259 (440)	315 (535)	371 (630)
		BX	10 (17)	21 (36)	34 (95)	56 (119)	70 (119)	85 (144)	101 (172)
		SA		21 (36)	34 (95)	56 (119)	70 (119)	85 (144)	101 (172)
3B-2208N-3B1	1"	DX	55 (93)	115 (195)	181 (533)	314 (646)	380 (646)	463 (787)	546 (928)
		BX	11 (19)	23 (39)	37 (109)	64 (131)	77 (131)	94 (160)	111 (189)
		SA		23 (39)	37 (109)	64 (131)	77 (131)	94 (160)	111 (189)
3B-2312N-3B1	1 1/2"	DX	98 (167)	203 (345)	319 (941)	554 (1138)	670 (1138)	816 (1386)	963 (1636)
		BX	22 (37)	46 (78)	74 (219)	129 (263)	155 (263)	189 (321)	223 (379)
		SA	16 (27)	33 (56)	52 (155)	91 (187)	110 (187)	134 (228)	158 (223)

1 For CRN rated assemblies add a "C" to the Model Number. Example: 3B-C2104N-3B1

6000 Series Stainless Steel Sterile Air Filters



Filter Housing Model	Port Size	Filter Cartridge Grade	Flow rates SCFM (Nm ³ /hr), at 7 psi (0.48 bar) drop at indicated line pressure. Refer to Principal Specification Charts in each product data sheet for maximum pressure rating of each housing PSIG								
			2	20	40	80	100	125	150	200	250
3B-6002N-0A1	1/4"	DX	9 (15)	19 (32)	39 (66)	51 (87)	63 (107)	76 (129)	90 (153)	117 (199)	145 (246)
3B-6904N-0A1	1/2"	BX	3 (5)	8 (14)	11 (19)	21 (36)	25 (42)	31 (53)	36 (61)	47 (80)	58 (99)
		SA		8 (14)	11 (19)	21 (36)	25 (42)	31 (53)	36 (61)		
3B-6004N-0A1	1/2"	DX	19 (32)	41 (70)	65 (110)	113 (192)	137 (233)	166 (282)	196 (333)	257 (437)	316 (537)
		BX	9 (15)	19 (32)	30 (51)	51 (87)	63 (107)	76 (129)	90 (153)	117 (199)	145 (246)
		SA		19 (32)	30 (51)	51 (87)	63 (107)	76 (129)	90 (153)		
3B-6006N-0A1	3/4"	DX	37 (63)	78 (133)	123 (209)	214 (364)	259 (440)	315 (535)	371 (630)	484 (822)	596 (1013)
		BX	10 (17)	21 (36)	34 (58)	56 (95)	70 (119)	85 (144)	101 (172)	131 (223)	162 (275)
		SA		21 (36)	34 (58)	56 (95)	70 (119)	85 (144)	101 (172)		
3B-6008N-0A1	1"	DX	55 (93)	115 (195)	181 (308)	314 (533)	380 (646)	463 (787)	546 (928)	711 (1208)	877 (1490)
		BX	11 (19)	23 (39)	37 (63)	64 (109)	77 (131)	94 (160)	111 (189)	144 (245)	178 (302)
		SA		23 (39)	37 (63)	64 (109)	77 (131)	94 (160)	111 (189)		



Offer of Sale

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2. Price Adjustments: Payments. Prices stated on Seller's quote or other documentation offered by Seller are valid for 30 days, and do not include any sales, use, or other taxes unless specifically stated. Unless otherwise specified by Seller, all prices are F.C.A. Seller's facility (INCOTERMS 2010). Payment is subject to credit approval and is due 30 days from the date of invoice or such other term as required by Seller's Credit Department, after which Buyer shall pa¬¬y interest on any unpaid invoices at the rate of 1.5% per month or the maximum allowable rate under applicable law.

3. <u>Delivery Dates</u>; <u>Title and Risk</u>; <u>Shipment</u>. All delivery dates are approximate and Seller shall not be responsible for any damages resulting from any delay. Regardless of the manner of shipment, title to any products and risk of loss or damage shall pass to Buyer upon placement of the products with the shipment carrier at Seller's facility. Unless otherwise stated, Seller may exercise its judgment in choosing the carrier and means of delivery. No deferment of shipment at Buyer's request beyond the respective dates indicated will be made except on terms that will indemnify, defend and hold Seller harmless against all loss and additional expense. Buyer shall be responsible for any additional shipping charges incurred by Seller due to Buyer's acts or omissions.

4. Warranty, Šeller warrants that the Products sold hereunder shall be free from defects in material or workmanship for a period of 12 months from the date of shipment and covers in-factory repair and parts only. Warranty does not include on site labor, travel expenses, or other expense associated with field repair. Purchaser shall notify Seller of any breach of warranty within 30 days. Upon notification, Seller will, at its option, repair or replace the defective product, or refund its purchase price. Any action for breach of warranty or for failure to deliver must be commenced within 13 months of its accrual. DISCLAIMER OF WARRANTY: THIS WARRANTY COMPRISES THE SOLE AND ENTIRE WARRANTY PERTAINING TO ITEMS PROVIDED HEREUNDER. SELLER DISCLAIMS ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, INCLUDING MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

5. Claims: Commencement of Actions. Buyer shall promptly inspect all Products upon delivery. No claims for shortages will be allowed unless reported to the Seller within 10 days of delivery. No other claims against Seller will be allowed unless asserted in writing within 30 days after delivery. Buyer shall notify Seller of any alleged breach of warranty within 30 days after the date the defect is or should have been discovered by Buyer. Any action based upon breach of this agreement or upon any other claim arising out of this agreement or upon any other claim arising out of this agreement or upon any invoice) must be commenced within 12 months from the date of the breach without regard to the date breach is discovered. If product is returned for refund a 20% restork fee may apply

Included within the function of the additional regard with the date breach is discovered. If product is returned for refund, a 20% restock fee may apply.
6. <u>LIMITATION OF LIABILITY.</u> UPON NOTIFICATION, SELLER WILL, AT ITS OPTION, REPAIR OR REPLACE A DEFECTIVE PRODUCT, OR REFUND THE PURCHASE PRICE. IN NO EVENT SHALL SELLER BE LIABLE TO BUYER FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF, OR AS THE RESULT OF, THE SALE, DELIVERY, NON-DELIVERY, SERVICING, USE OR LOSS OF USE OF THE PRODUCTS OR ANY PART THEREOF, OR FOR ANY CHARGES OR SUPENSES OF ANY NATURE INCURRED WITHOUT SELLER'S WRITTEN CONSENT, EVEN IF SELLER HAS BEEN NEGLIGENT, WHETHER IN CONTRACT, TORT OR OTHER LEGAL THEORY. IN NO EVENT SHALL SELLER'S LIABILITY UNDER ANY CLAIM MADE BY BUYER EXCEED THE PURCHASE PRICE OF THE PRODUCTS.

7. User Responsibility. The user, through its own analysis and testing, is solely responsible for making the final selection of the system and Product and assuring that all performance, endurance, maintenance, safety and warning requirements of the application are met. The user must analyze all aspects of the application and follow applicable industry standards and Product information. If Seller provides Product or system options, the user is responsible for determining that such data and specifications are suitable and sufficient for all applications and reasonably foreseeable uses of the Products or systems.

8. Loss to Buyer's Property. Any designs, tools, patterns, materials, drawings, confidential information or equipment furnished by Buyer or any other items which become Buyer's property, will be considered obsolete and may be destroyed by Seller after two consecutive years have elapsed without Buyer ordering the items manufactured using such property. Seller shall not be responsible for any loss or damage to such property while it is in Seller's possession or control.

9. Special Tooling. A tooling charge may be imposed for any special tooling, including without limitation, dies, fixtures, molds and patterns, acquired to manufacture Products. Such special tooling shall be and remain Seller's property notwithstanding payment of any charges by Buyer. In no event will Buyer acquire any interest in apparatus belonging to Seller which is utilized in the manufacture of the Products, even if such apparatus has been specially converted or adapted for such manufacture and notwithstanding any charges paid by Buyer. Unless otherwise agreed, Seller shall have the right to alter, discard or otherwise dispose of any special tooling or other property in its sole discretion at any time.

10. <u>Buyer's Obligation: Rights of Seller.</u> To secure payment of all sums due or otherwise, Seller shall retain a security interest in the goods delivered and this agreement shall be deemed a Security Agreement under the Uniform Commercial Code. Buyer authorizes Seller as its attorney to execute and file on Buyer's behalf all documents Seller deems necessary to perfect its security interest.

11. <u>Improper use and Indemnity.</u> Buyer shall indemnify, defend, and hold Seller harmless from any claim, liability, damages, lawsuits, and costs (including attorney fees).

whether for personal injury, property damage, patent, trademark or copyright infringement or any other claim, brought by or incurred by Buyer, Buyer's employees, or any other person, arising out of: (a) improper selection, improper application or other misuse of Products purchased by Buyer from Seller; (b) any act or omission, negligent or otherwise, of Buyer; (c) Seller's use of patterns, plans, drawings, or specifications furnished by Buyer to manufacture Product; or (d) Buyer's failure to comply with these terms and conditions. Seller shall not indemnify Buyer under any circumstance except as otherwise provided. **12. <u>Cancellations and Changes.</u>** Orders shall not be subject to cancellation or change

12. <u>Cancellations and Changes</u>. Orders shall not be subject to cancellation or change by Buyer for any reason, except with Seller's written consent and upon terms that will indemnify, defend and hold Seller harmless against all direct, incidental and consequential loss or damage. Seller may change product features, specifications, designs and availability with notice to Buyer. Order cancelation fee of 15% may apply.

13. <u>Limitation on Assignment</u>. Buyer may not assign its rights or obligations under this agreement without the prior written consent of Seller.

14. <u>Force Majeure.</u> Seller does not assume the risk and shall not be liable for delay or failure to perform any of Seller's obligations by reason of circumstances beyond the reasonable control of Seller (hereinafter "Events of Force Majeure"). Events of Force Majeure shall include without limitation: accidents, strikes or labor disputes, acts of any government or government agency, acts of nature, delays or failures in delivery from carriers or suppliers, shortages of materials, or any other cause beyond Seller's reasonable control.

15. <u>Waiver and Severability</u>. Failure to enforce any provision of this agreement will not waive that provision nor will any such failure prejudice Seller's right to enforce that provision in the future. Invalidation of any provision of this agreement by legislation or other rule of law shall not invalidate any other provision herein. The remaining provisions of this agreement will remain in full force and effect.

16. <u>Termination</u>. Seller may terminate this agreement for any reason and at any time by giving Buyer thirty (30) days written notice of termination. Seller may immediately terminate this agreement, in writing, if Buyer: (a) commits a breach of any provision of this agreement (b) appointments a trustee, receiver or custodian for all or any part of Buyer's property (c) files a petition for relief in bankruptcy on its own behalf, or by a third party (d) makes an assignment for the benefit of creditors, or (e) dissolves or liquidates all or a majority of its assets.

17. <u>Governing Law.</u> This agreement and the sale and delivery of all Products hereunder shall be deemed to have taken place in and shall be governed and construed in accordance with the laws of the State of Ohio, as applicable to contracts executed and wholly performed therein and without regard to conflicts of laws principles. Buyer irrevocably agrees and consents to the exclusive jurisdiction and venue of the courts of Cuyahoga County, Ohio with respect to any dispute, controversy or claim arising out of or relating to this agreement.

18. Indemnity for Infringement of Intellectual Property Rights, Seller shall have no liability for infringement of any patents, trademarks, copyrights, trade dress, trade secrets or similar rights except as provided in this Section. Seller will defend and indemnify Buyer against allegations of infringement of U.S. patents, U.S. trademarks, copyrights, trade dress and trade secrets ("Intellectual Property Rights"). Seller will defend at its expense and will pay the cost of any settlement or damages awarded in an action brought against Buyer based on an allegation that a Product sold pursuant to this Agreement infringes the Intellectual Property Rights of a third party. Seller's obligation to defend and indemnify Buyer is contingent on Buyer notifying Seller within ten (10) days after Buyer becomes aware of such allegations of infringement, and Seller having sole control over the defense of any allegations or actions including all negotiations for settlement or compromise. If a Product is subject to a claim that it infringes the Intellectual Property Rights of a third party. Seller will be control over the defense of any allegations. Notwithstanding the foregoing, Seller shall have no liability for claims of infringement based on information provided by Buyer, or directed to Product sellowarce for depreciation. Notwithstanding the foregoing, Seller shall have no liability for claims of infringement based on information provided by Buyer, or infringement based on information provided by Buyer, or infringement based on information provisions of this Section shall constitute Seller's sole and exclusive remedy for infringement of any Product sellever's sole and exclusive remedy for infringement of Intellectual Property Rights.

19. Entire Agreement. This agreement contains the entire agreement between the Buyer and Seller and constitutes the final, complete and exclusive expression of the terms of sale. All prior or contemporaneous written or oral agreements or negotiations with respect to the subject matter are herein merged.

20. Compliance with Law, U.K. Bribery Act and U.S. Foreign Corrupt Practices Act. Buyer agrees to comply with all applicable laws and regulations, including both those of the United Kingdom and the United States of America, and of the country or countries of the Territory in which Buyer may operate, including without limitation the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act ("FCPA") and the U.S. Anti-Kickback Act (the "Anti-Kickback Act"), and agrees to indemnify and hold hamless Seller from the consequences of any violation of such provisions by Buyer, its employees or agents. Buyer acknowledges that they are familiar with the provisions of the U.K. Bribery Act, the FCPA and the Anti-Kickback Act, and certifies that Buyer will adhere to the requirements thereof. In particular, Buyer represents and agrees that Buyer shall not make any payment or give anything of value, directly or indirectly to any governmental official, any foreign political party or official thereof, any candidate for foreign political office, or any commercial entity or person, for the purpose of influencing such person to purchase products or otherwise benefit the business of Seller.



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