Sterile Air for the Food Industry

Parker Balston Filters Eliminate Food Contamination with Benchmarked Good Manufacturing Practices

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 ft^3. A 75 hp 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 well-designed 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-of-use 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:

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)[1]		Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.			
FDA Guidance RTE foods[2]			0.3 Micron		Point of use
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[3] Section: D6.6.1		Point of Use-Contact (sterile air): 99.999%[10] All other: 99%[10]			
British Compressed Air Society (BCAS)[4] Section 6	-40° F/C	< 0.01 mg/m³	0.1 - 0.5 Micron		
British Retail Consortium (BRC)[9]		Compressed air used directly in contact with the product shall be filtered.			
Safe Quality Foods (SQF) 7th edition[5]. Section(s): 9.5.7; 10.5.7; 11.5.7; 13.5.4		Compressed air used in the manufacturing process shall be clean and present no risk to food safety.			
International Featured Standards (IFS) version 6[6]. Section 4.9.10.2		Compressed air shall not pose a risk of contamination.			
Global Red Meat Standard (GRMS)[7]		Hazards relevant to food safety shall be controlled in critical control points (CCP) and/or by GMP measures.			
ISO 22000:2005[8] + Prerequisite Program (PRP) (like BSI PAS 220:2008[11])	ISO22000:2005 := Prerequisite Programs should be in place to address supplies of air (Section 7.2.3.C) BSI PAS 220:2008 Section 6.5 := (Summarized) Compressed air systems shall be constructed and maintained so as to prevent contamination. Requirments for filtration, microbilogy, and humidity (RH%) shall be specified. Filtration of the air should be as close to the point of use as is practicable.				
Most discriminating filtration standard:		**< 0.01 mg/m³**	**0.1 - 0.5 Micron**	**Point of Use-Contact: 99.999%**	**Point of use**

Balston Product Spec.	Element-->	BX	DX	SA	
	Stage-->	Stage 2	Stage 1	Stage 3	
Applications: Washdown and/or Clean-in-Place	Balston 6000 Series 3-Stage Sterile Air Filter Systems BX + DX + SA 1/4" thru 1" Pipe Sizes				
Applications: Non-Washdown and Non-Clean-in-Place	Balston 2000 Series 3-Stage Sterile Air Filter Systems BX + DX + SA 1/4" thru 1" Pipe Sizes				

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 in 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 >= 99.9999+% 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-of-use 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:

Below are some common foodborne contaminants that threaten the safety of food. Parker|Balston sterile air filtration can ensure that none of these hazards will pass through to the food in the compressed air.

				Balston Filter Element Grade		
Organism	**Microbial Group**	**Rod Length µm**	**Rod or Coccus Diameter µm**	**DX**	**BX**	**SA Sterile Air**
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			

Fully Effective
Moderately Effective
Minimally Effective

See Bulletin:
Parker|Balston Validation Studies
…showing the effectiveness of Parker|Balston filters in removing sub-micron particulate and microbial contamination from compressed air.

Useful for food safety scheme audits.

3-Stage Sterile Air Filter Systems:

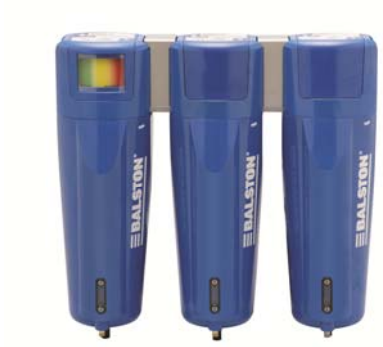
Safeguard your food processing operation from the contamination hazards of rust, pipe scale, water, oil, and microorganisms. In 3-stage point-of-use filtration systems the first 2 stages are designed to remove contaminants at a very high efficiency - up to 99.99% for 0.01 micron particles and droplets. 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[1] 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.

note[1]: larger port sizes are available

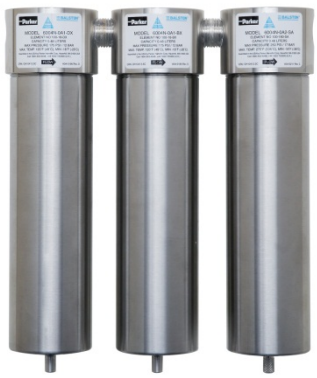
2000 Series Aluminum Sterile Air Filters



Flow Rates

Filter Housing Model	Port Size	Filter Cartridge Grade	Flow rates (SCFM), at 2 psi 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-2002N-3B1	1/4"	DX	9	19	39	51	63	76	90	117	145
3B-2003N-3B1	3/8"	BX	3	8	11	21	25	31	36	47	58
3B-2004N-3B1	1/2"	SA	---	8	11	21	25	31	36	---	---
3B-2104N-3B1	1/2"	DX	19	41	65	113	137	166	196	257	316
		BX	9	19	30	51	63	76	90	117	145
		SA	---	19	30	51	63	76	90	---	---
3B-2206N-3B1	3/4"	DX	37	78	123	214	259	315	371	484	596
		BX	10	21	34	56	70	85	101	131	162
		SA	---	21	34	56	70	85	101	---	---
3B-2208N-3B1	1"	DX	55	115	181	314	380	463	546	711	877
		BX	11	23	37	64	77	94	111	144	178
		SA	---	23	37	64	77	94	111	---	---
3B-2312N-3B1	1 1/2"	DX	98	203	319	554	670	816	963	1254	1546
		BX	22	46	74	129	155	189	223	290	358
		SA	16	33	52	91	110	134	158	206	253

6000 Series Stainless Steel Sterile Air Filters



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			2	20	40	80	100	125	150	200	250
3B-6002N-0A1	1/4"	DX	9	19	39	51	63	76	90	117	145
3B-6904N-0A1	1/2"	BX	3	8	11	21	25	31	36	47	58
		SA	---	8	11	21	25	31	36	---	---
3B-6004N-0A1	1/2"	DX	19	41	65	113	137	166	196	257	316
		BX	9	19	30	51	63	76	90	117	145
		SA	---	19	30	51	63	76	90	---	---
3B-6006N-0A1	3/4"	DX	37	78	123	214	259	315	371	484	596
		BX	10	21	34	56	70	85	101	131	162
		SA	---	21	34	56	70	85	101	---	---
3B-6008N-0A1	1"	DX	55	115	181	314	380	463	546	711	877
		BX	11	23	37	64	77	94	111	144	178
		SA	---	23	37	64	77	94	111	---	---

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