Sterile Air for the Food Industry

Parker Balston Filters Eliminate Food Contamination with Benchmarked Good Manufacturing Practices

aerospace
climate control
electromechanical
filtration
fluid & gas handling
hydraulics
pneumatics
process control
sealing & shielding

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Corporate Headquarters in Cleveland, Ohio.

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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 ft^3. 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 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:

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)[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]			
Britsh 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) 7.1 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.			
SQF Guidance Document for Module 11 May 2013			0.01 Micron	99.999%	Point of use
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**	**0.01 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**				

= 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 |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 >= 99.99+% 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-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

				Balston Filter Element Grade		
				DX	BX	SA
				Filter Element Rating		
Organism	Microbial Group	Rod Length µm	Rod or Coccus Diameter µm	93 % Efficiency @ .01 micron	99.99% Efficiency @ .01 micron	99.9999% Efficiency @ .01 micron
				1-log reduction	4-log reduction	6-log reduction
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.

www.balstonfilters.com

CAMTU Compressed Air Microbial Test Unit

Identify Sources of Contamination in Compressed Air and Improve Food Safety

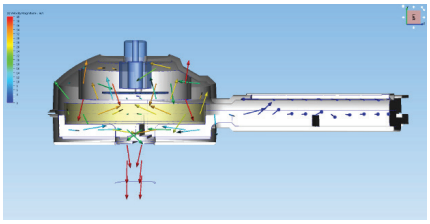
Compressed air is used in a broad range of applications in the food processing industry, such as mixing of ingredients, cutting, sparging, drying of product, transporting/ propelling product through processing systems and packaging of final product. In many of these applications, compressed air is in 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.

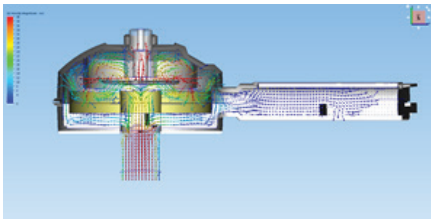
- Lightweight and ergonomically designed for ease of use
- Built in timer with indicator lights
- Constructed of durable polypropylene - easily sanitized
- Pre-filled agar plates with specialized tryptic soy or potato dextrose agar designed to hold up to compressed air flow/pressure
- No electrical supply 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



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/m^3 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.

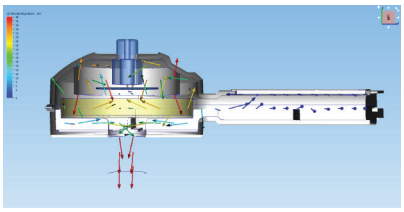
The Parker Balston CAMTU (compressed air microbial test unit) is easily transported, weighing less than a pound. It comes complete with connection tubing, shut off valve and a specially designed pressure regulator and metering orifice. These matched components provide the exact amount of compressed air 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.”)

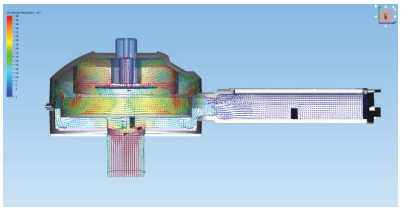
To obtain a sample, simply plug the connection tubing into the sample point on the compressed air system, insert an agar plate into the CAMTU, close the CAMTU, open the shutoff valve and expose the agar for 20 seconds. After exposure simply place the agar plate in an incubator for 48 hours or in a controlled environment of at least 68°F and observe for colony forming units (CFUs).

Parker Balston

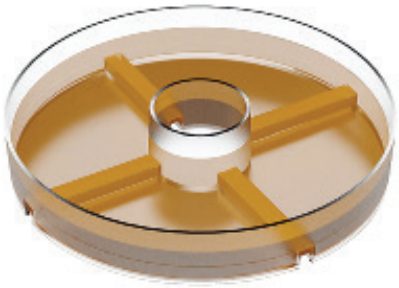
Optimum Agar Plate Design!

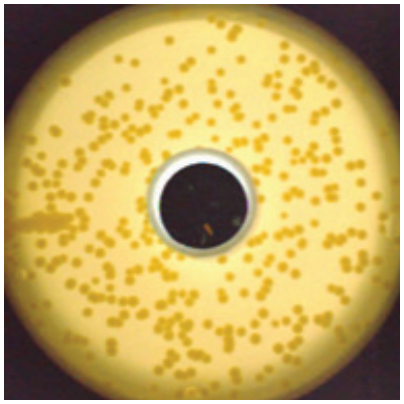


Flow dynamics: original CAMTU



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 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.

Sterile Air Filter Systems
Balston 6000 Series

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)

Printed in U.S.A. Bulletin CAMTU-B 04/2015

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 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.

2000 Series Aluminum Sterile Air Filters

Flow Rates

Filter Housing Model	Port Size	Filter Cartridge Grade	Flow rates SCFM (Nm³/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 (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

Flow Rates

Filter Housing Model	Port Size	Filter Cartridge Grade	Flow rates SCFM (Nm³/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)	---	---

Worldwide Filtration Manufacturing Locations

North America

Compressed Air Treatment

Industrial Gas Filtration and Generation Division
Lancaster, NY
716 686 6400
www.parker.com/igfg

Haverhill, MA
978 858 0505
www.parker.com/igfg

Engine Filtration

Racor
Modesto, CA
209 521 7860
www.parker.com/racor

Holly Springs, MS
662 252 2656
www.parker.com/racor

Hydraulic Filtration

Hydraulic & Fuel Filtration
Metamora, OH
419 644 4311
www.parker.com/hydraulicfilter

Laval, QC Canada
450 629 9594
www.parkerfarr.com

Velcon
Colorado Springs, CO
719 531 5855
www.velcon.com

Process Filtration

domnick hunter Process Filtration
SciLog
Oxnard, CA
805 604 3400
www.parker.com/processfiltration

Water Purification

Village Marine, Sea Recovery, Horizon Reverse Osmosis
Carson, CA
310 637 3400
www.parker.com/watermakers

Europe

Compressed Air Treatment

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Gateshead, England
+44 (0) 191 402 9000
www.parker.com/dhfns

Parker Gas Separations
Etten-Leur, Netherlands
+31 76 508 5300
www.parker.com/dhfns

Hiross Airtek
Essen, Germany
+49 2054 9340
www.parker.com/hzfd

Padova, Italy
+39 049 9712 111
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Engine Filtration & Water Purification

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Parker | Balston

State of California ONLY
WARNING: Proposition 65
The products described herein can expose you to chemicals known to the State of California to cause cancer or reproductive harm.
For more information: www.P65Warnings.ca.gov