Sterile Air for the Food Industry

Parker Balston Filters Eliminate Food Contamination with Benchmarked Good Manufacturing Practices
We engineer success of our customers around the world, drawing upon nine core motion and control technologies. These technologies enable virtually every machine and process to operate accurately, efficiently and dependably.

As the global leader in motion and control, we partner with our distributors to increase our customers' productivity and profitability by delivering an unmatched breadth of engineered components and value-added services.

We continue to grow with our customers by creating application-focused products and system solutions. A key to our global expansion has been to follow our customers and establish operations, sales and service wherever they are needed. No single competitor matches Parker’s global presence.

Parker’s Motion and Control Technologies

<table>
<thead>
<tr>
<th>Aerospace</th>
<th>Hydraulics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Climate Control</td>
<td>Pneumatics</td>
</tr>
<tr>
<td>Electromechanical</td>
<td>Process Control</td>
</tr>
<tr>
<td>Filtration</td>
<td>Sealing &amp; Shielding</td>
</tr>
<tr>
<td>Fluid &amp; Gas Handling</td>
<td></td>
</tr>
</tbody>
</table>

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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.

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 Pre-requisite 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.
Identifying the risk and potential hazards with compressed air in a food plant is the easy part. Determining Good Manufacturing Practices for air used in a food processing facility are listed below:

### Benchmarking of Compressed Air GMPs

<table>
<thead>
<tr>
<th>Good Manufacturing Practices - Compressed Air In Food Plant</th>
<th>Dew Point</th>
<th>Oil Removal</th>
<th>Particulate Removal (Includes Microbiological particles)</th>
<th>Efficiency</th>
<th>Location of Filtration</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Code of Federal Regulations Title 21CFR, Part 110.40 (g)</td>
<td></td>
<td></td>
<td>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.</td>
<td></td>
<td>Point of use</td>
</tr>
<tr>
<td>FDA Guidance RTE foods²</td>
<td></td>
<td></td>
<td>0.3 Micron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA and the FSMA³ (Food Safety Modernization Act)</td>
<td></td>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-A Standard 694-05-3A⁴</td>
<td>-40° F/C</td>
<td>&lt; 0.01 mg/m³</td>
<td>Point of Use-Contact (sterile air): 99.999%²⁵</td>
<td></td>
<td>Point of Use</td>
</tr>
<tr>
<td>British Compressed Air Society (BCAS)⁵</td>
<td></td>
<td></td>
<td>All other: 99%²⁴</td>
<td></td>
<td></td>
</tr>
<tr>
<td>British Retail Consortium (BRC)⁶</td>
<td></td>
<td></td>
<td>Compressed air used directly in contact with the product shall be filtered.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safe Quality Foods (SQF) 7.1 edition¹</td>
<td></td>
<td></td>
<td>Compressed air used in the manufacturing process shall be clean and present no risk to food safety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SQF Guidance Document for Module 11 May 2013</td>
<td></td>
<td></td>
<td>0.01 Micron</td>
<td></td>
<td>Point of Use</td>
</tr>
<tr>
<td>International Featured Standards (IFS) version 6⁸, Section 4.9.10.2</td>
<td></td>
<td></td>
<td>99.99%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global Red Meat Standard (GRMS)⁹</td>
<td></td>
<td></td>
<td>Compressed air shall not pose a risk of contamination.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO 22000:2005¹ + Prerequisite Program (PRP) like BSI PAS 220:2008¹¹</td>
<td></td>
<td></td>
<td>Hazards relevant to food safety shall be controlled in critical control points (CCP) and/or by GMP measures.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Most discriminating filtration standard:**

- **< 0.01 mg/m³**
- **0.01 Micron**
- **Point of Use-Contact: 99.999%**
- **Point of use**

### Balston Product Spec.

<table>
<thead>
<tr>
<th>Applications: Washdown and/or Clean-In-Place</th>
<th>3-Stage Sterile Air Filter Systems BX + DX + SA 1/4” thru 1” Pipe Sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balston 6000 Series</td>
<td></td>
</tr>
<tr>
<td>3-Stage Sterile Air Filter Systems BX + DX + SA 1/4” thru 1” Pipe Sizes</td>
<td></td>
</tr>
<tr>
<td>Balston 2000 Series</td>
<td></td>
</tr>
<tr>
<td>3-Stage Sterile Air Filter Systems BX + DX + SA 1/4” thru 1” Pipe Sizes</td>
<td></td>
</tr>
</tbody>
</table>

**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 >= 99.9999% DOP efficiency with a sterile air filter.

  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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Microbial Group</th>
<th>Rod Length µm</th>
<th>Rod or Coccus Diameter µm</th>
<th>93% Efficiency @ .01 micron</th>
<th>99.99% Efficiency @ .01 micron</th>
<th>99.9999% Efficiency @ .01 micron</th>
<th>1-log reduction</th>
<th>4-log reduction</th>
<th>6-log reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>Bacteria</td>
<td>0.5</td>
<td>0.2</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Clostridium botulinum (B)</td>
<td>Bacteria</td>
<td>3.0-8.0</td>
<td>6.5-5.8</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Clostridium Perfrugens</td>
<td>Bacteria</td>
<td>4.0-8.0</td>
<td>6.4-6.5</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Clostridium tetani</td>
<td>Bacteria</td>
<td>4.0-8.0</td>
<td>6.4-6.5</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Bacteria</td>
<td>1.0-3.0</td>
<td>0.5</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>Bacteria</td>
<td>1.0-1.5</td>
<td>0.4</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Salmonella enteritidis</td>
<td>Bacteria</td>
<td>2.0-3.0</td>
<td>6.6-6.7</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Salmonella enteritidis</td>
<td>Bacteria</td>
<td>2.0-3.0</td>
<td>6.6-6.7</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Salmonella typhimurium</td>
<td>Bacteria</td>
<td>1.0-2.5</td>
<td>6.3-5.5</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Salmonella typhosa</td>
<td>Bacteria</td>
<td>2.0-3.0</td>
<td>6.8-6.7</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Staphylococcus Aureus</td>
<td>Bacteria</td>
<td>Coccus-&gt;</td>
<td>0.8-1.0</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Yeast</td>
<td>Fungi</td>
<td></td>
<td>1.0-50.0</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Mold</td>
<td>Fungi</td>
<td></td>
<td>1.5-20.0</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td>Mycotoxins (by product of mold)</td>
<td>Fungi</td>
<td></td>
<td>0.1</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
</tbody>
</table>

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/m³ and particulate removal (including microbio-logical 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 shut off 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
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.
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 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 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

<table>
<thead>
<tr>
<th>Filter Housing Model</th>
<th>Port Size</th>
<th>Filter Cartridge Grade</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>3B-2002N-3B1</td>
<td>1/4&quot; DX</td>
<td>9 (15) 19 (32) 39 (66) 51 (87) 63 (107) 76 (129) 90 (153) 117 (199) 145 (246)</td>
<td></td>
</tr>
<tr>
<td>3B-2003N-3B1</td>
<td>3/8&quot; BX</td>
<td>3 (5) 8 (14) 11 (19) 21 (36) 25 (42) 31 (53) 36 (61) 47 (80) 58 (99)</td>
<td></td>
</tr>
<tr>
<td>3B-2004N-3B1</td>
<td>1/2&quot; SA</td>
<td>--- 8 (14) 11 (19) 21 (36) 25 (42) 31 (53) 36 (61) --- ---</td>
<td></td>
</tr>
<tr>
<td>3B-2104N-3B1</td>
<td>1/2&quot; DX</td>
<td>19 (32) 41 (70) 65 (109) 113 (233) 137 (233) 166 (282) 196 (333) 257 (437) 316 (537)</td>
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</tr>
<tr>
<td>3B-2206N-3B1</td>
<td>3/4&quot; DX</td>
<td>37 (63) 78 (133) 123 (184) 214 (440) 259 (440) 315 (535) 371 (630)</td>
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<tr>
<td>3B-2208N-3B1</td>
<td>1&quot; DX</td>
<td>55 (93) 115 (195) 181 (302) 314 (440) 380 (440) 463 (787) 546 (928)</td>
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</tr>
<tr>
<td>3B-2312N-3B1</td>
<td>1 1/2&quot; DX</td>
<td>98 (167) 203 (345) 319 (541) 554 (1138) 670 (1138) 816 (1386) 963 (1636)</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Filter Housing Model</th>
<th>Port Size</th>
<th>Filter Cartridge Grade</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>3B-6002N-0A1</td>
<td>1/4&quot; DX</td>
<td>9 (15) 19 (32) 39 (66) 51 (87) 63 (107) 76 (129) 90 (153) 117 (199) 145 (246)</td>
<td></td>
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<tr>
<td>3B-6004N-0A1</td>
<td>1/2&quot; BX</td>
<td>9 (15) 19 (32) 39 (66) 51 (87) 63 (107) 76 (129) 90 (153) 117 (199) 145 (246)</td>
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<tr>
<td>3B-6006N-0A1</td>
<td>3/4&quot; DX</td>
<td>37 (63) 78 (133) 123 (184) 214 (440) 259 (440) 315 (535) 371 (630)</td>
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<tr>
<td>3B-6008N-0A1</td>
<td>1&quot; DX</td>
<td>55 (93) 115 (195) 181 (302) 314 (440) 380 (440) 463 (787) 546 (928)</td>
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<td>3B-6003N-0A1</td>
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<td>19 (32) 41 (70) 65 (109) 113 (233) 137 (233) 166 (282) 196 (333) 257 (437) 316 (537)</td>
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</tr>
<tr>
<td>3B-6005N-0A1</td>
<td>3/4&quot; DX</td>
<td>37 (63) 78 (133) 123 (184) 214 (440) 259 (440) 315 (535) 371 (630)</td>
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</tbody>
</table>

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6. Utility Upon Notification. Seller will, at its option, repair or replace a defective product, or refund the purchase price, at its option.Ệorrent shall neither sell, substitute, repair, or otherwise dispose of field repairs. If replacement is necessary, Buyer's sole and exclusive remedy for infringement of any patent, trademark, copyright, trade secret or other similar rights except as provided in this Section. Seller will defend and indemnify Buyer against any 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 any such allegations of infringement, and Seller having sole control over the defense of any such action or proceeding. Buyer shall give Seller written notice of any infringement as soon as practicable after discovery, but in any event within thirty (30) days after Buyer becomes aware of any such allegations of infringement, and Seller having sole control over the defense of any such action or proceeding. Buyer is liable for all damages, costs, and expenses, including reasonable attorneys' fees, and other expenses associated with defense of any such action or proceeding. Buyer shall cooperate with Seller in any such defense or prosecution. If Buyer is unable to substitute a non-infringing Product, Seller will refund to Buyer the purchase price of the Product, and Buyer will take reasonable steps to defend and settle the action or proceeding. Buyer's obligation to pay any such costs, expenses, or indemnity is subject to Buyer's use of the Product in accordance with Seller's instructions and limitations, and in accordance with all applicable laws. Seller may change product features, specifications, designs and availability with notice to Buyer. Order cancellation fee of 15% may apply.

10. Buyer's Obligation; Rights of Seller. 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 agrees to use reasonable care in the use, possession, and control of the Products and not to alter, modify, misuse, misuse or otherwise dispose of any special tooling or other property or the sole discretion at any time in Seller's possession or control.

11. Improper Use and Indemnity. 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 in connection with 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. Cancellations and Changes. 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 loss, direct and consequential loss or damage. Seller may change product features, specifications, designs and availability with notice to Buyer. Order cancellation fee of 15% may apply.

13. Limitation on Assignment. Buyer may not assign its rights or obligations under this agreement without the prior written consent of Seller. In the future, this agreement will no longer 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 loss, direct and consequential loss or damage. Seller may change product features, specifications, designs and availability with notice to Buyer. Order cancellation fee of 15% may apply.
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