Plastikos Medical

Erie, Pennsylvania

Our medical business over the last 14-15 years has grown strategically across numerous customers and multiple sub-sectors of the medical device industry; we saw the need to add capacity in order to support existing customers, take on new projects with our existing customers, and to grow our broader medical device OEM customer base.

Philip Katen
President and General Manager

In August 2019, Plastikos opened their new 25,000-square-foot facility dedicated 100% to producing plastic components for the medical industry. After experiencing double-digit growth year-over-year, the executive team decided that it was time to expand their medical product offering in order to meet growing customer demand coupled with advancing its risk-mitigation strategy via a second, stand-alone medical component production facility.

When selecting an air handler unit for the new manufacturing facility it was vital to the team that the products performance would meet the extremely tight indoor air quality tolerances specified by the medical industry, and the rigorous ISO 7 cleanroom classification. With the air handler unit being described as the 'heart of the cleanroom environment', it was important for Plastikos to partner with a company they could trust to meet their strict specifications and project deadlines. Although many options were considered, SolutionAir had the only product and team that Plastikos trusted for the job.

The SolutionAir Precision Control unit is application specific, providing precise humidity and temperature control while limiting the introduction of foreign particles. For Plastikos, environmental control and dependable operation is required all day, every day, throughout the year.

With parts that are very sensitive to variances in temperature and humidity ensuring a fail system was key in selecting a product. We also wanted something that would provide our employees with a comfortable work environment – especially considering they have to wear protective gear from head-to-toe when working in the cleanroom production areas.

Philip Katen
President and General Manager

A control failure can have catastrophic effects on operational capacity, and risks contamination and quality of the manufactured products. The SolutionAir team worked closely with Plastikos to ensure that the Precision Control unit was configured to meet their strict application requirements of ISO 7 classification, +/- 2°F dry bulb temperature control, and a maximum of +2°F above a specified dew point. SolutionAir's Detect + Protect monitoring system oversees unit operation, reporting anomalies in vital components and performance metrics so they can be quickly addressed should they occur. In the unlikely event of a component failure, the unit will automatically change operating parameters to best use the remaining functional components to meet the operating conditions. The unit is housed in SolutionAir's Thermoshield Cabinet. The Thermoshield Cabinet uses a lightweight, low leakage, corrosion resistant marine-grade aluminum design. Material composition and construction minimizes galvanic corrosion greatly improving the integrity and life span of the cabinet, helping to ensure that the stringent ISO 7 air quality requirements are met for years to come.

A big differentiator of SolutionAir is their product expertise and service. We've seen that some of your competitors who didn't step up when a problem or concern arose, whereas the SolutionAir team does – it makes a huge difference. SolutionAir is always available to make adjustments, and work hand-in-hand with our Team to get us over the finish line.

Philip Katen
President and General Manager

With the MFG Precision Control unit successfully running since August 2019, the Plastikos Medical team is excited to start analyzing data collected from the units built in monitoring system to see how they can continue to further optimize the performance of the units to their demanding needs.

ISO 7 Classification Requirements

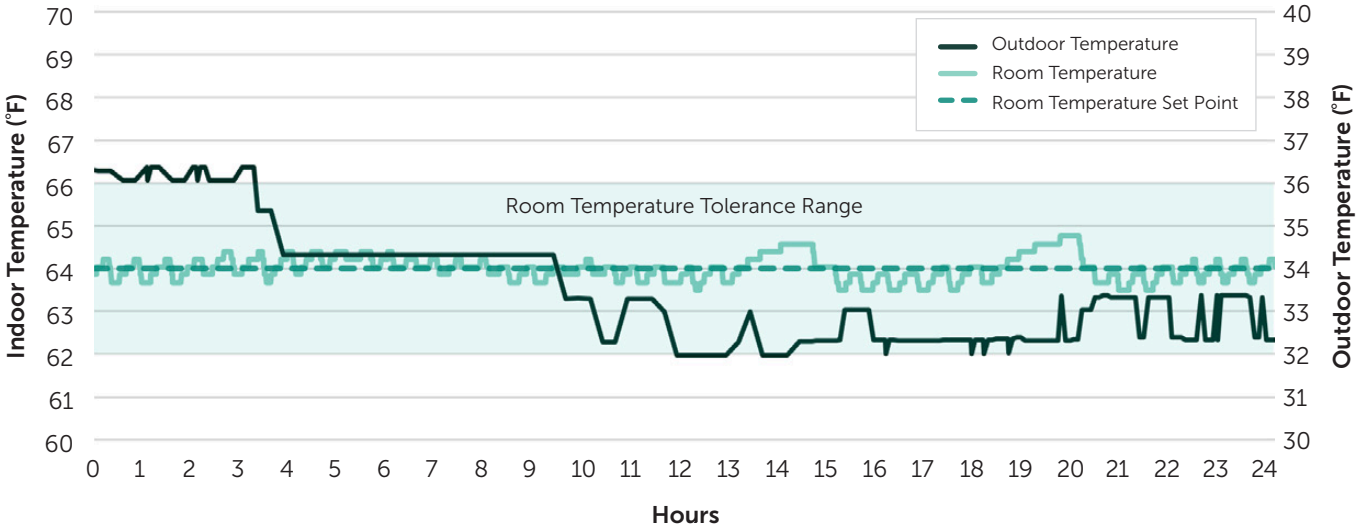
Table shows the concentration of airborne particles and number of air changes in a cleanroom required to meet ISO 7 classification.

Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the sizes shown below			Average number of air changes per hour
≥0.5 µm	≥1 µm	≥5 µm	30 to 60
352,000	83,200	2,930	

For context, the average size of a bacteria is typically between 0.5 µm and 5.0 µm; recommended air changes for an office space is approximately 4 changes per hour.

The following graph shows the operation of one of the Precision Control unit installed at Plastikos over a twenty-four hour period. The room's dry bulb temperature stays well within the +/- 2°F tolerance of the 64°F set point, even as the outdoor air temperature drops to freezing temperatures.

24 Hours of Sensible Temperature (Dry Bulb) Readings



Project Summary

Products

Two 46.5 ton Precision Control units, each delivering 18,000 CFM of supply air.

- Precision control tailored to application requirements
  - +/- 2°F dry bulb temperature
  - Maximum +2°F above specified dew point
- -20°F low ambient cooling capabilities
- Condensate management system
- Detect + Protect monitoring
  - Monitors electronic expansion valves, refrigerant charge, refrigeration cycle, compressors, and blower and condenser motors
- Direct digital controller with BACnet communication
- Remote operable web enabled controls
- Thermoshield cabinet
  - Lightweight, corrosion resistant marine grade aluminum
  - 3.5 in. R14 stone-wool insulation
  - Double thermally broken construction
  - Built to minimize galvanic corrosion
- Factory charged and tested refrigeration system

Project Highlights

Location: Erie, PA, USA

Project Type: ISO 7 Plastic Injection Molding and Manufacturing Cleanroom

Year Completed: 2019

Square Footage: 25,000 sq. ft.

- **Cleanroom Square Footage:** ~10,000 sq. ft.