

Terumo Sterile Connection Device Filtration System

Background

The TSCD-II from Terumo BCT makes sterile connections between plastic tubing in blood banking & cell therapy manufacturing environments. Particles are generated when a heated copper wafer cuts through PVC tubes, which must be minimized in a cleanroom environment.

Particle Size (μm)	0.5	1	5
Maximum # of Particles in the Air (per m^3)	352,000	83,200	2,930

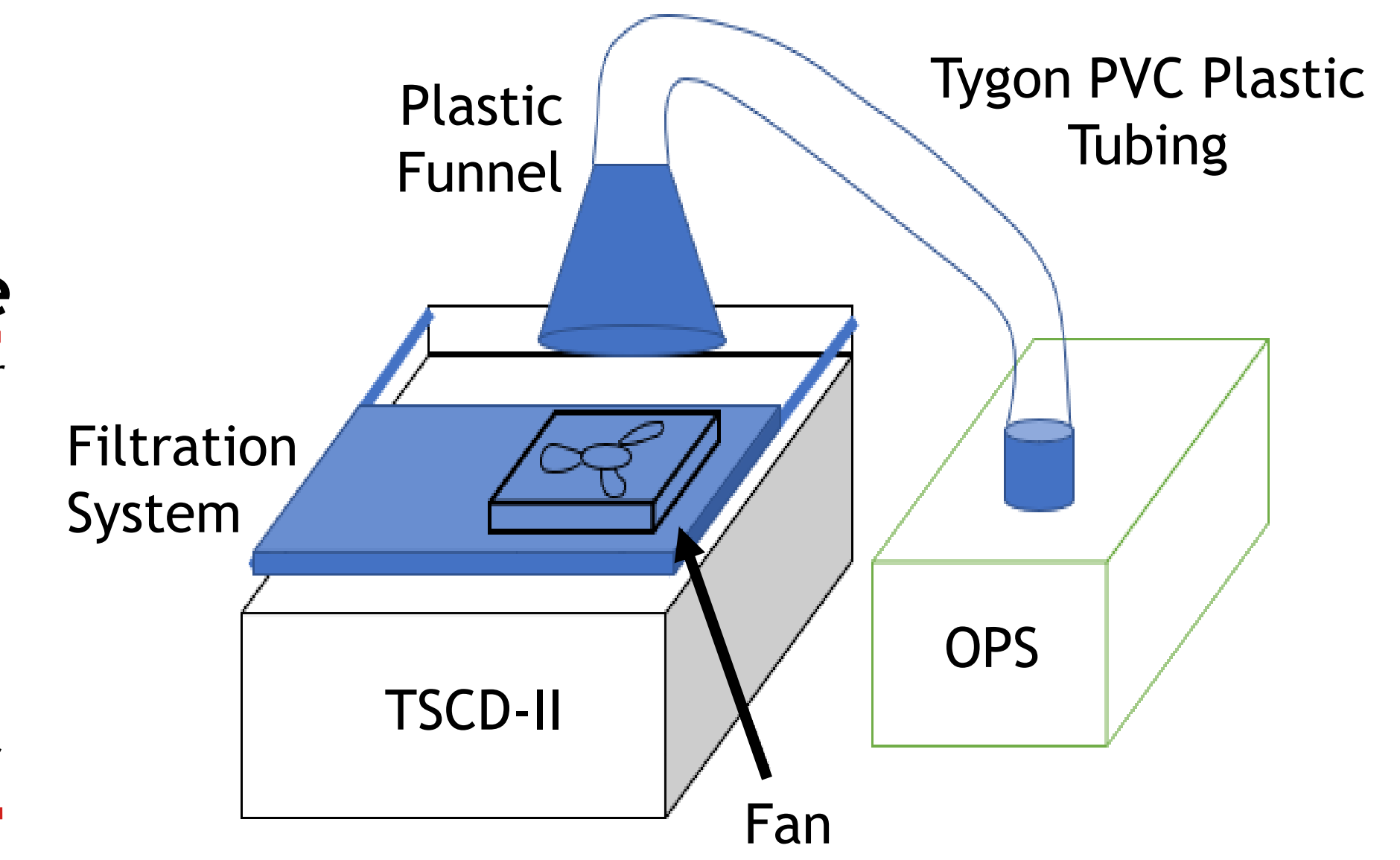
ISO7 Cleanroom Standards

The Device Shall:

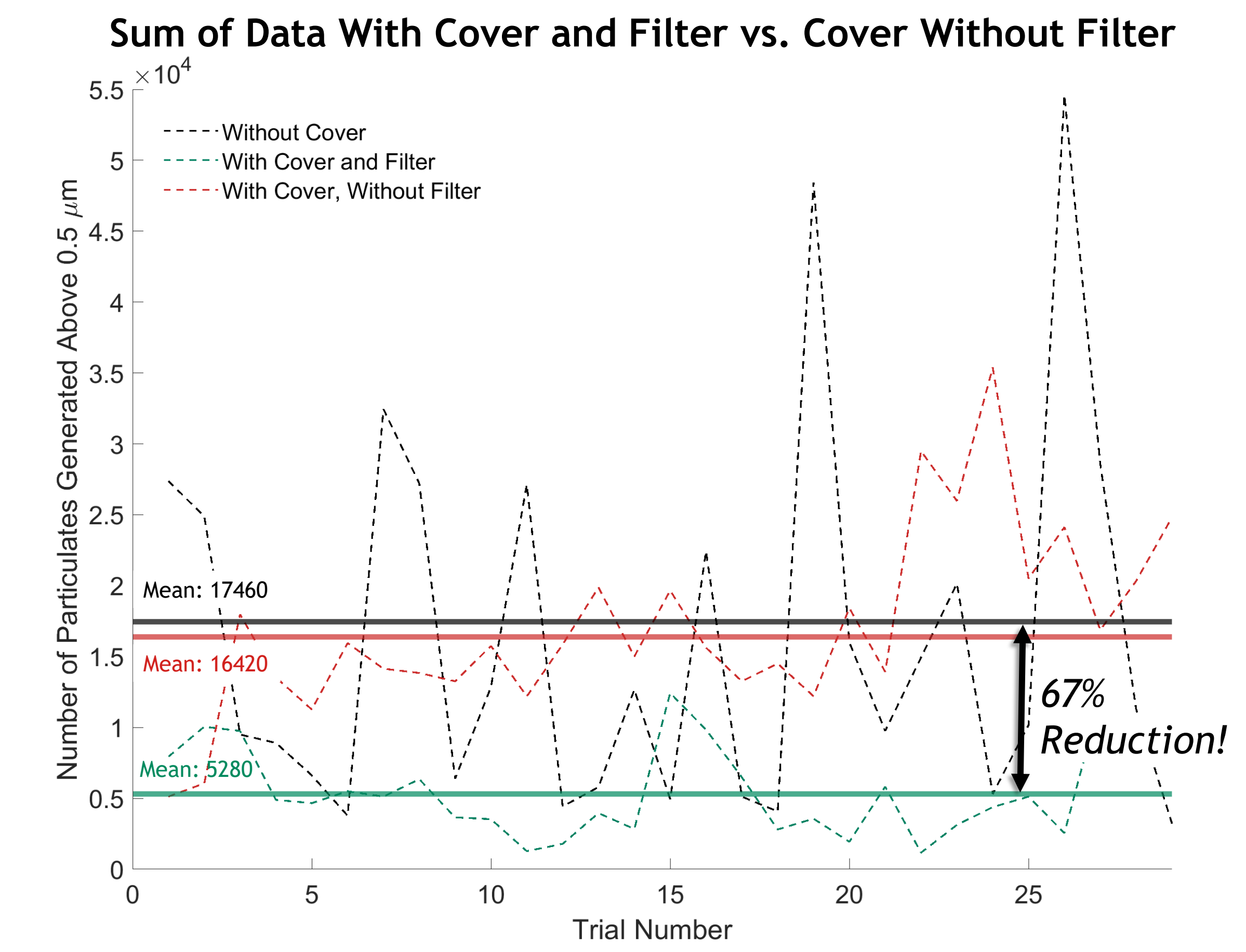
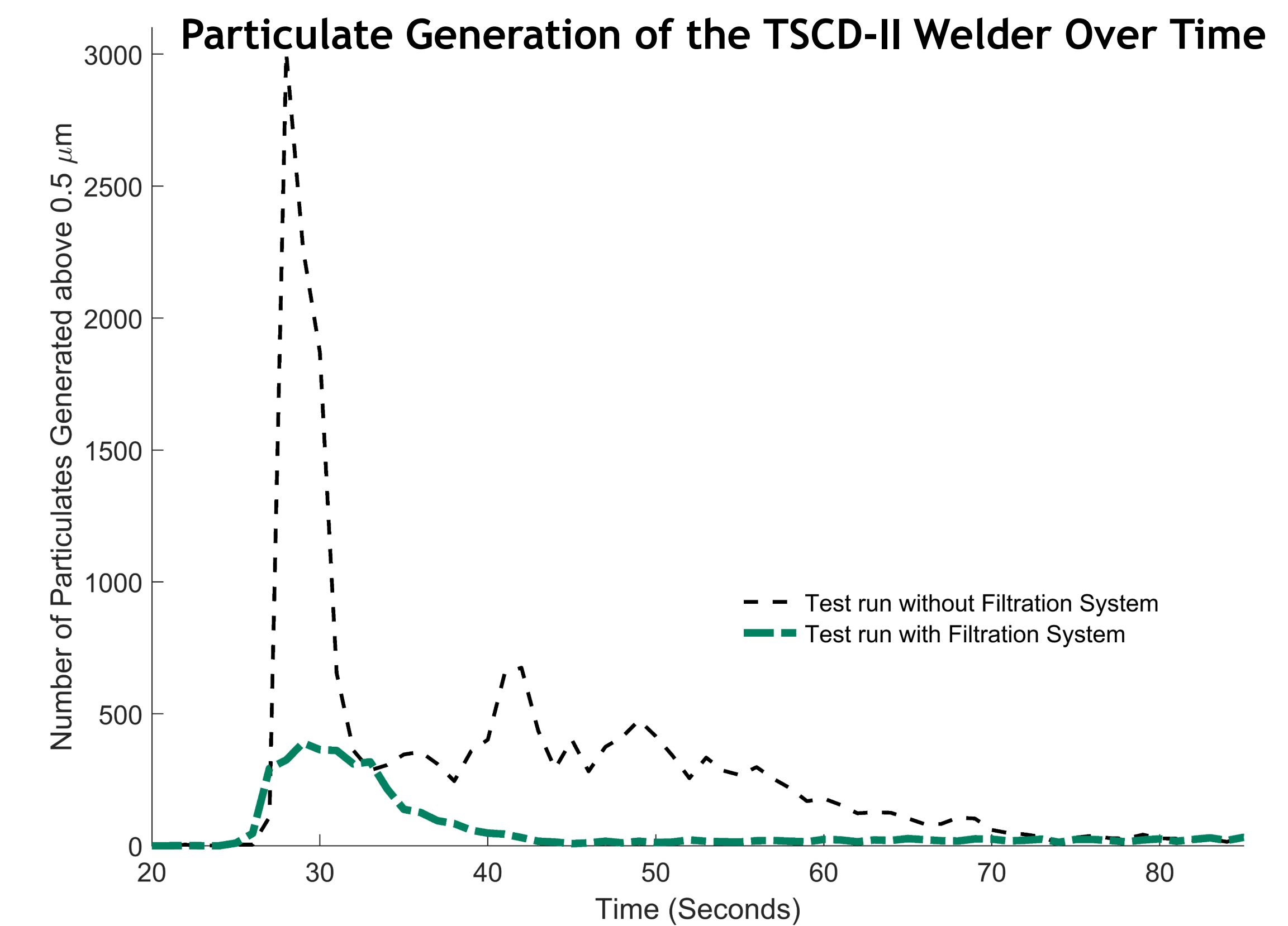
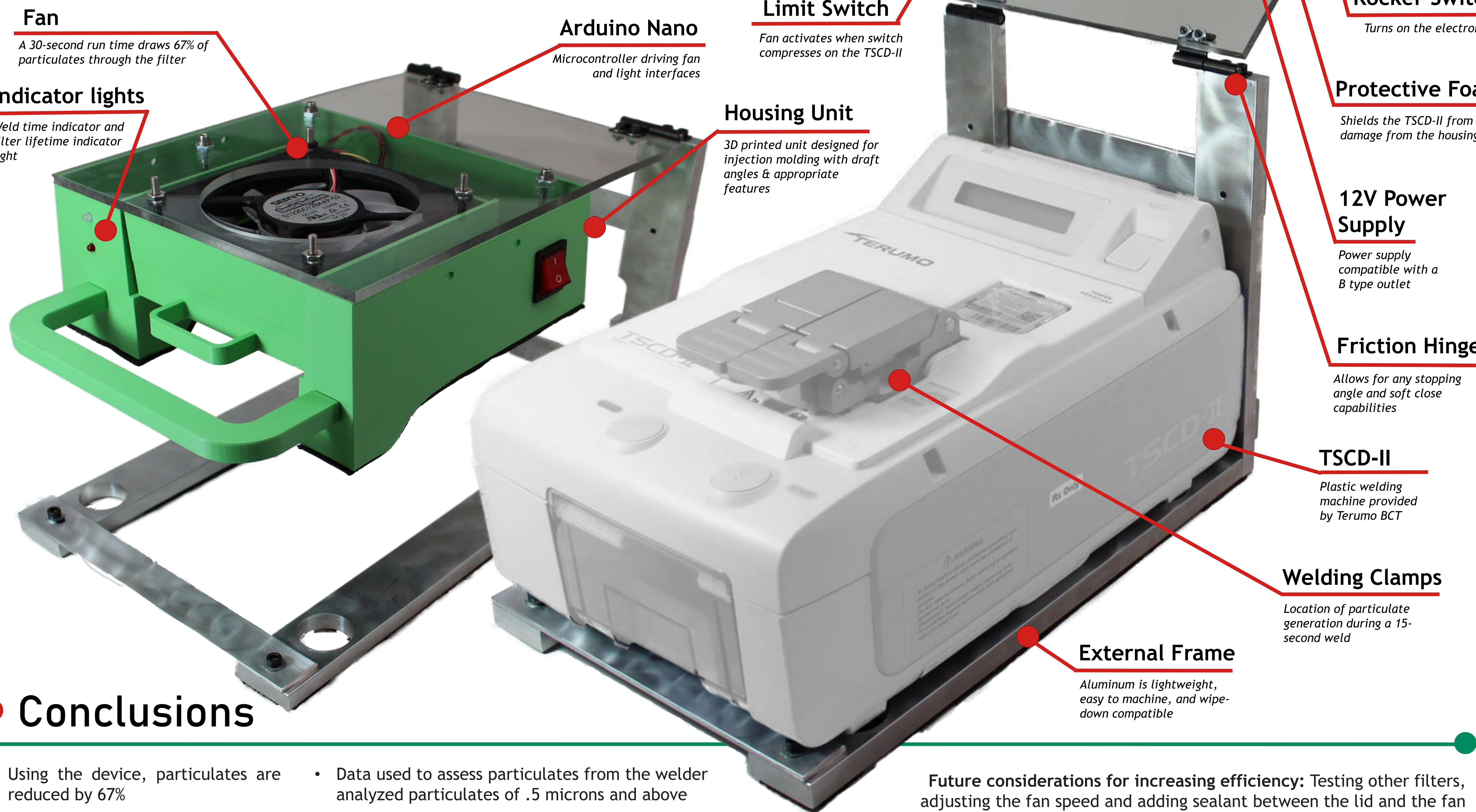
- ✓ Conform to ISO7 cleanroom Standards by filtering particles of 0.5 microns and above
- ✓ Reduce the percentage of particulates emitted by the machine
- ✓ Have a filter lifetime indicator
- ✓ Not complicate or impede the welding process
- ✓ Not use materials prone to degradation upon contact with cleanroom solvents
- ✓ Use an external universal power supply that can be plugged into multiple types of outlets and deliver approximately 12V DC
- ✓ Filter/collect particulates without modifying the TSCD-II
- ✓ Have a maximum height of up to 6 inches above the welder & the length and width dimensions shall not exceed the body of the TSCD-II by more than 1 inch

Testing Setup

The Optical Particle Sizer Spectrometer (OPS) will run tests over the welding clamps and at the exhaust of the filter to determine the percent reduction in particulates emitted.



Data Analysis



Conclusions

- Using the device, particulates are reduced by 67%
- Compatible with 66 welds per hour in a 1 m^3 room
- The device costs \$193 in materials
- Data used to assess particulates from the welder analyzed particulates of .5 microns and above
- Device adds two additional steps to the welding process
- The device can be easily removed from the welder

Future considerations for increasing efficiency: Testing other filters, adjusting the fan speed and adding sealant between the lid and the fan

Future considerations for manufacturing and design: Use injection molding for housing, duct, create a clear panel in the back of the housing unit

Special thanks to Geoff Uhl, Robert DuBois, Daria Kotys-Schwartz, Julie Steinbrenner, Shelly Miller, Victoria Lanaghan, Pat Maguire, Lauren McComb, Greg Potts, Chase Logsdon, Andy Kain, Mark Eaton, Jenn Boggs and Lauren Darling