

Technovation Systems, Inc

**A Cleanroom Design/Build &
Contamination Control Company**

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Technovation Systems, Inc. – Products & Services

- **Design/Build services:** specializing in Energy Efficient cleanrooms for Life Sciences, Biotech, Pharmaceutical, Hospital and Microelectronics industries.
- **Contamination Control Products:** Advanced energy efficient filtration/air handling equipment.
- **Consulting Services:** expertise in contamination control, cleanroom design, FDA and other regulatory requirements, DQ/IQ and OQ services. (We rely on our advanced knowledge of aerosol & particle science, fluid mechanics, heat transfer and engineering.)

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Clean Room Design/Build Services

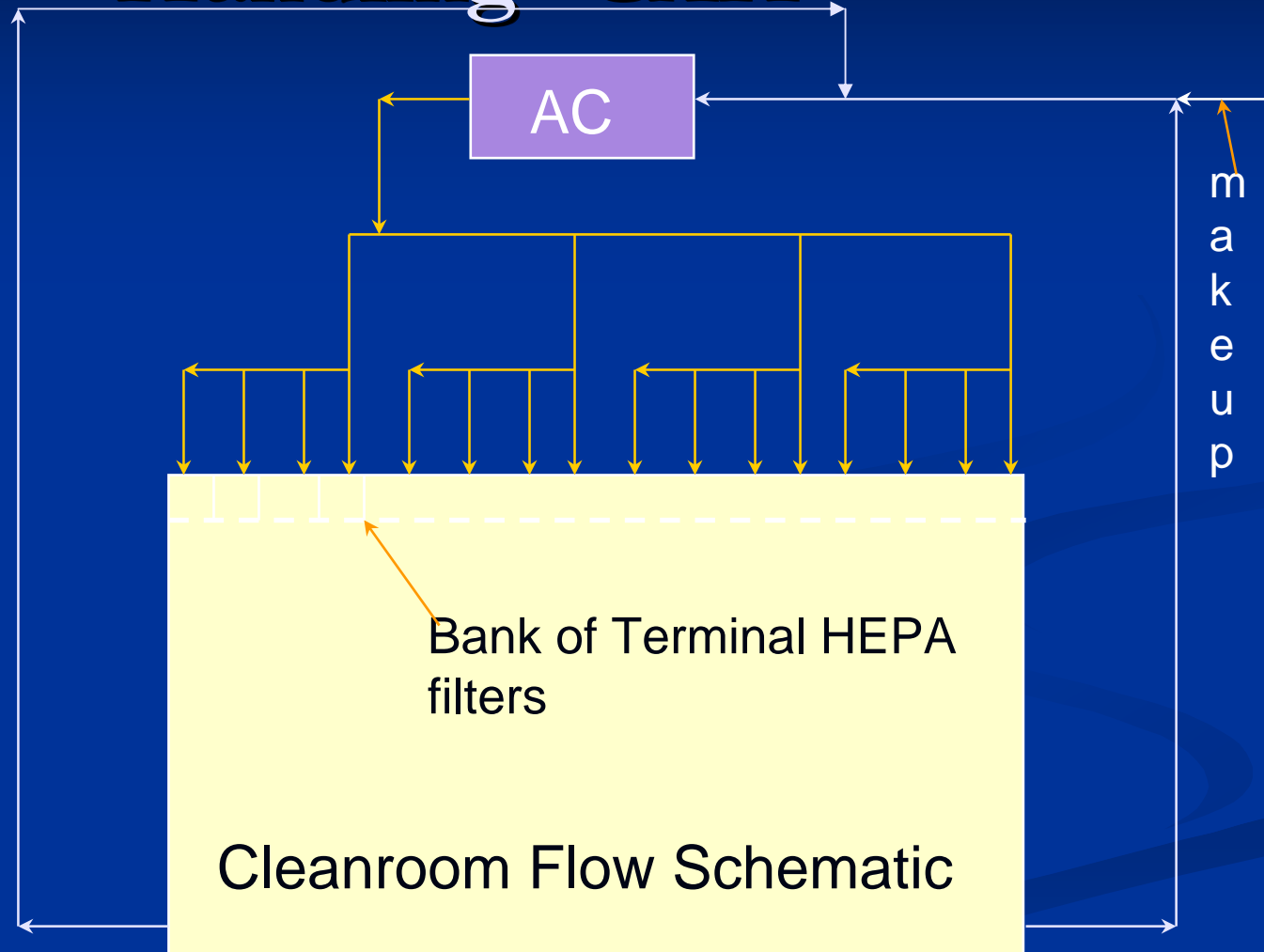
- Technovation **design/builds** Energy Efficient Low bio burden ISO Class 2-9 clean rooms using our innovative Optimized Bypass Distributed Air Handling System.
- **Computer airflow modeling** resulting in higher performance at lower air flow, noise and significant operating cost savings.
- **DQ/IQ/OQ, certification and expert consulting.**
- **Hospital Systems - USP 797 Hospital IV Pharmacy Compliance.**

Energy Efficient Design

- Air Flow Modeling
 - Re-Heat Minimization - Distributed Air Handling System
 - BioPlus® HEPA In Duct filters – Ultra Low Pressure Drop (ULPD) and bactericidal
- Result = significant Cost savings vs. Conventional AH Systems**

Conventional Centralized Air Handling- CAH

- AC flow is the same as the total flow

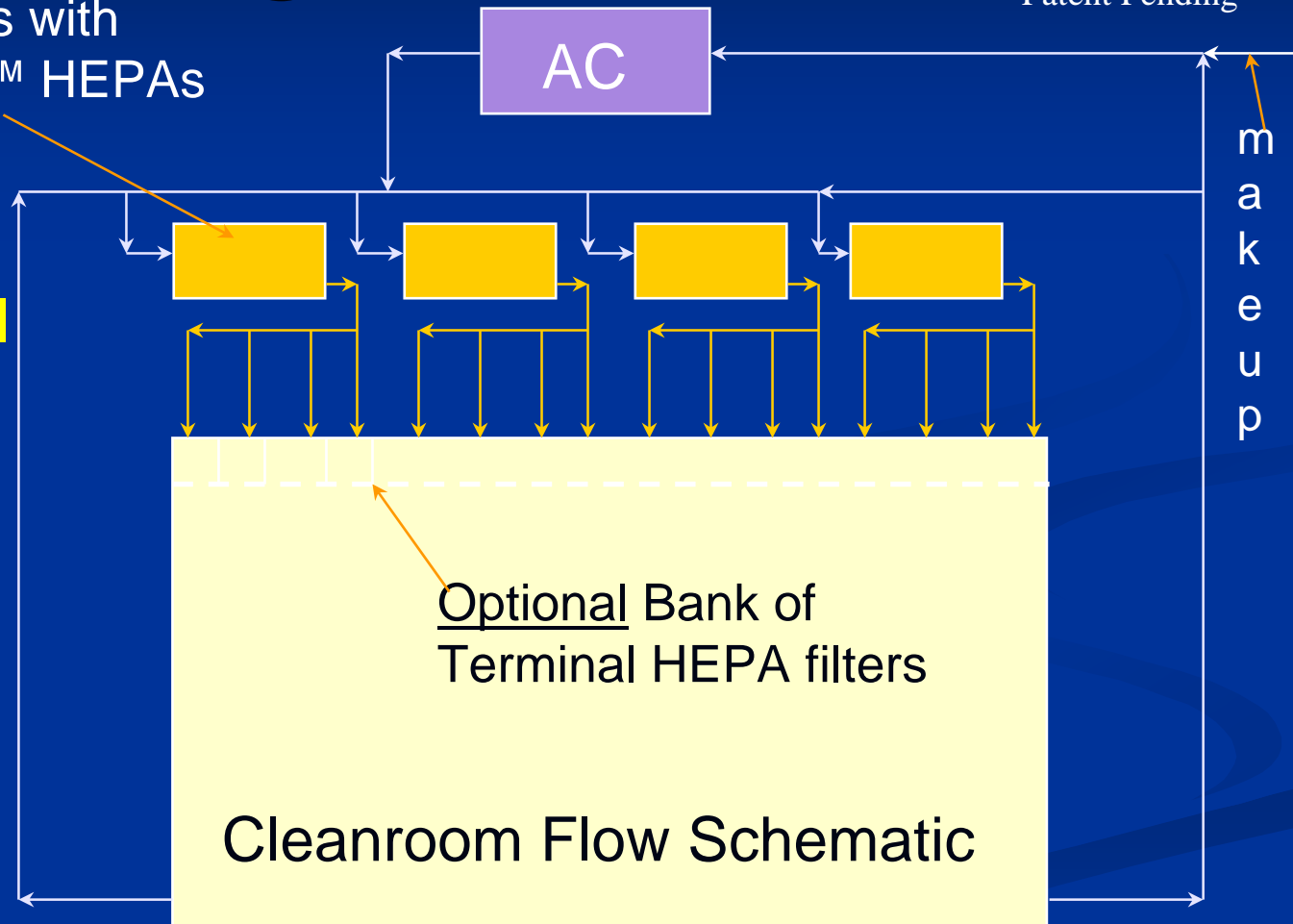


Technovation's Distributed Air Handling System - DAH

In duct fan units with primary ULPD™ HEPAs

Patent Pending

- AC flow is a fraction of total flow
- Flow/ velocity independence



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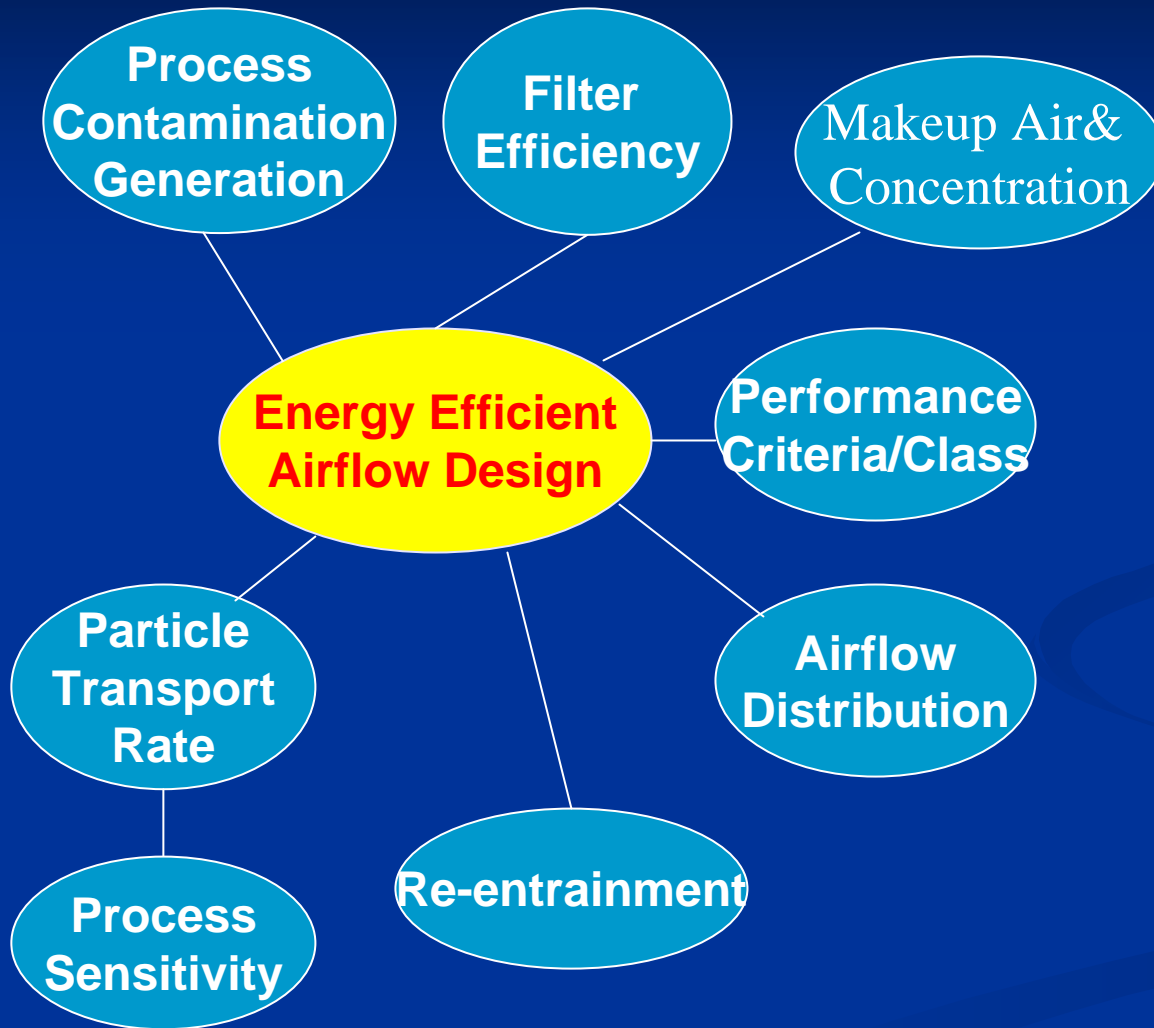
Current Design Methods used by our competition... Charts

Charts recommending Av. Velocity/ Air Changes/hr (ACH) are used. These charts have no technical basis.

| <u>ISO Class</u> | <u>Velocity, fpm</u> | <u>ACH</u> |
|------------------|----------------------|------------|
| 3 | 60-100 | 360-540 |
| 4 | 50-90 | 300-540 |
| 5 | 40-80 | 240-480 |
| 6 | 25-40 | 150-240 |
| 7 | 10-15 | 60-90 |

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Design Variables



- Airflow design depends on many variables.
- Design charts do not take into account the impact of these variables.
- Technovation uses its proprietary Dilution and Transient Analysis Models in conjunction with CFD analysis

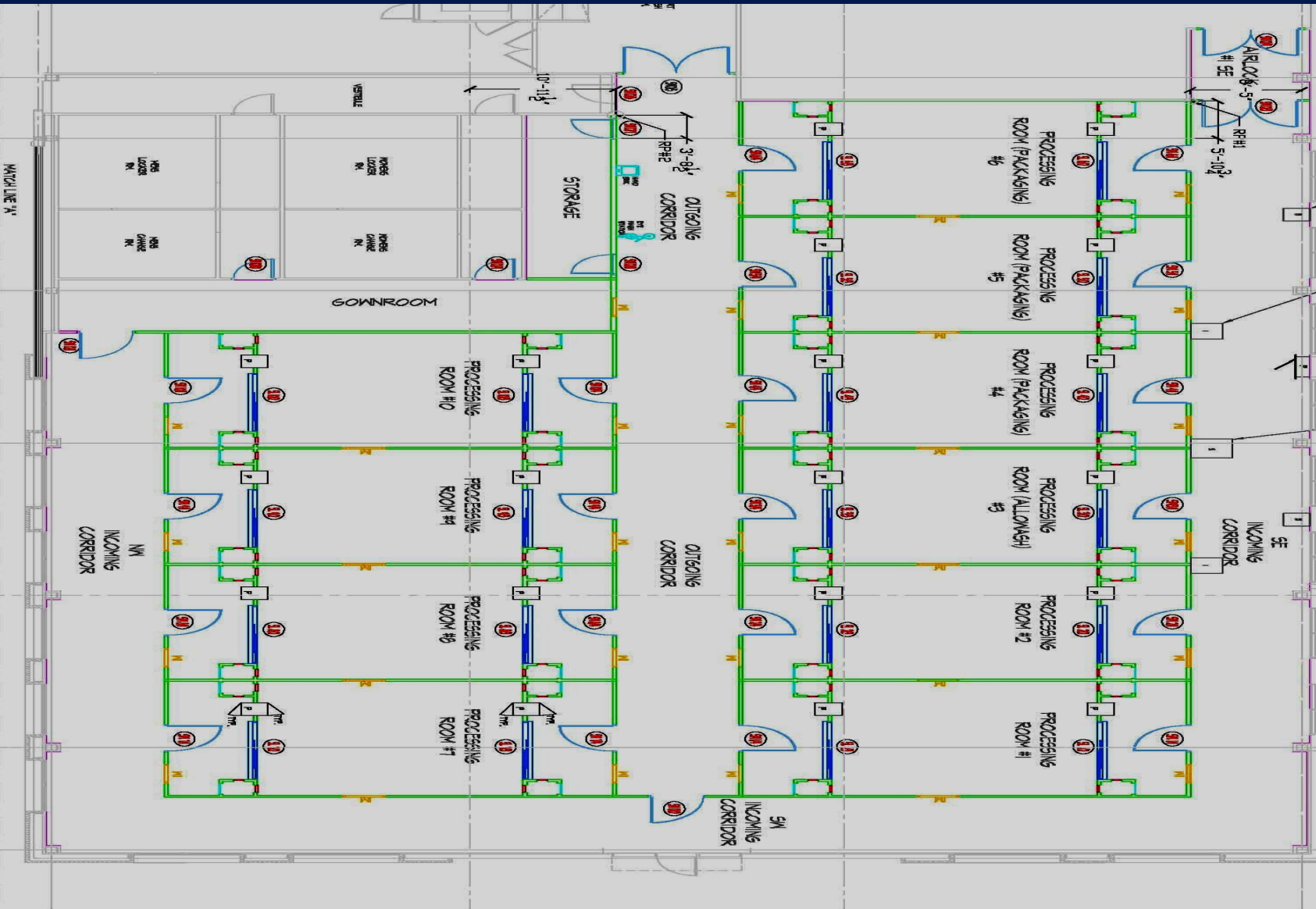
Tissue Processing Facility...



Tissue Processing Facility



Tissue Processing Facility Plan View



Biotech Cleanrooms...@ Encelle



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Sample Cleanroom Installations

- LIFENET – Tissue Processing
- Philip Morris – R&D Labs
- Encelle, Inc - Biotech
- Burlington & TriState – Cleanroom Laundries
- Med Pharmex - Pharmaceutical
- Schwarz-Pharma - Pharmaceutical
- MSHA – US Dept of Labor – Test Lab
- Dow Chemical – Cleanroom Glove packaging
- Beckman Coulter – Medical Devices
- Hollister – Medical Devices
- JM Huber Corporation – Material Science Labs

Technovation Cleanroom Operating Cost Savings

- Distributed Air System vs. Conventional Air System compared for **ISO 5 suite**
- Costs savings per 500 ft² Suite with airlocks

| | Mid-Atlantic | Northeast | CA |
|------------|--------------|-----------|----------|
| Savings/yr | \$30,792 | \$48,131 | \$53,362 |

* Data on file at Technovation Systems, Inc

Technovation Cleanroom Operating Cost Savings

- Distributed Air System vs. Conventional Air System compared for **ISO 7 suite**
- Costs savings per 500 ft² Suite with airlocks

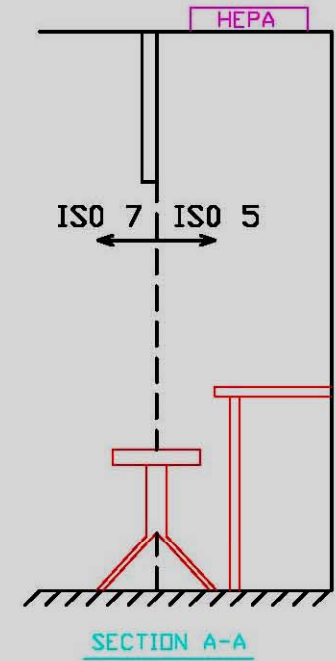
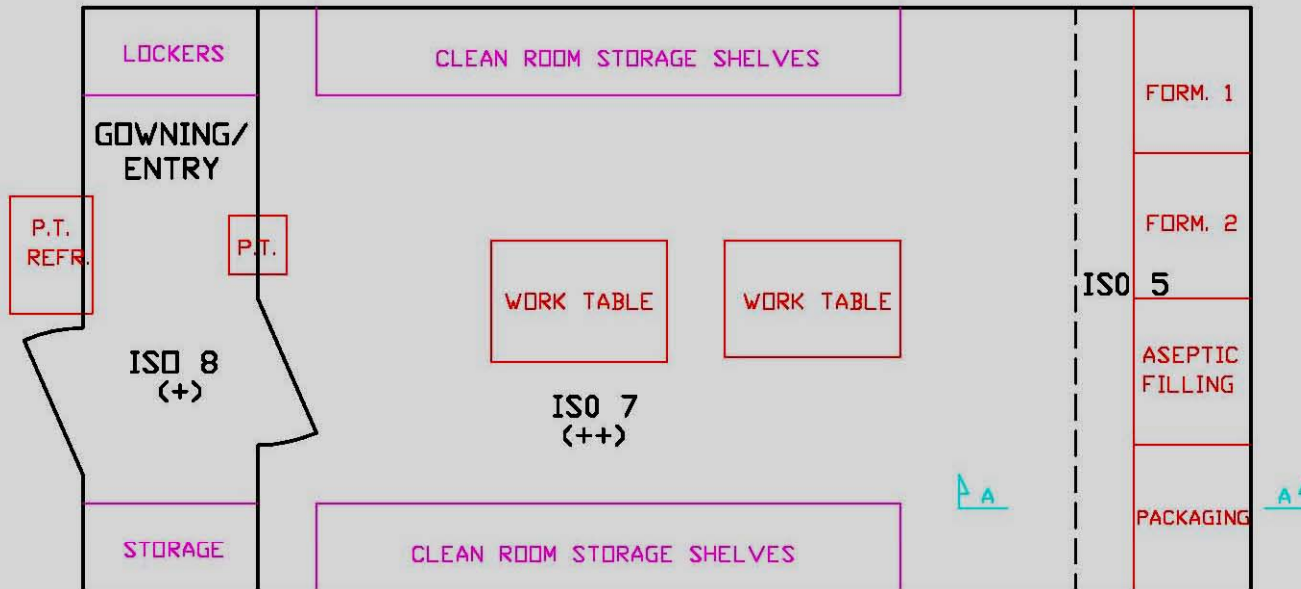
| | Mid-Atlantic | Northeast | CA |
|------------|--------------|-----------|---------|
| Savings/yr | \$3,529 | \$4,856 | \$5,256 |

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Hospital Design/Build Services

- USP 797 Compliance – Design & Build IV Cleanroom
- Isolation Rooms – negative and positive pressure rooms for TB, Oncology, Infectious Disease, Burn Centers etc.
- Operating Rooms and upgrades

TYPICAL IV PHARMACY LAYOUT



TYPICAL IV PHARMACY LAYOUT

ABBREVIATIONS:

- P.T. PASS THROUGH
- P.T. REFR. PASS THROUGH REFRIGERATOR
- FORM. FORMULATION

Technovation's Solution

Features

- Contiguous Class 5 Environmental Zones created in Class 7 Room.
- No Flow Benches are required.
- Positive and Negative Room design.
- Bactericidal BioPlus® HEPA's.
- Energy Efficient Design.

Technovation's Solution's Benefits

- Increase productivity due to ISO 5 zone as opposed to flow benches and better flow of material in work area
- Energy savings
- Low Bio Burden – BioPlus® HEPA's
- No cost penalty for above operational advantages vs. isolators

Technovation's USP 797 Pharmacy

Operating Cost Savings

- Distributed Air System vs. Conventional Air System in a ISO 5/ ISO 7 Work Environment
- Cost savings based on 400 ft² Pharmacy

| | Mid-Atlantic | Northeast | CA |
|------------|--------------|-----------|----------|
| Savings/yr | \$10,345 | \$15,345 | \$17,283 |

* Data on file at Technovation Systems, Inc

Validation Related Services During Design/Build

- DQ – Design Qualification
- IQ – Installation Qualification
- Commissioning
- OQ – Operational Qualification

This documentation becomes part of the Master Validation Plan and also insures high quality design and construction

Process Integration & Consulting

- Cleanroom design cannot be divorced from the process / process equipment.
- Cleanroom equipment must be carefully selected – Technovation provides consulting utilizing our R&D facility. Examples freezers, refrigerators, filling machines etc.
- Material /chemical compatibility is an important issue for process integration.

Technovation with its strong background in research & process contamination control is able to better provide these services to the end user.

Technovation Project Management

- Establishment of proper **Cleanroom Construction Protocols** (CCP), will prevent major cost and time overruns. E.g. isolating dust sources and preventing contamination of duct work; utilizing rigid controls when doing dry wall is ridiculous.
- CCPs based on “**probability**” (requires contamination control expertise) rather than “**possibilities**”, will save dollars\$\$\$\$. E.g. understanding migration of dust from outer areas; lower level CCPs are sufficient while applying wall finishes / floors.

Successful Design/Build Services

This requires expertise in:

- Basic Engineering – mechanical, HVAC, structural, electrical, plumbing, safety.
- Contamination Control – aerosol science, associated instrumentation and fluid mechanics, process integration.
- Validation related expertise– DQ/IQ/OQ.

Further, the Designer must be capable of **partnering** with End User to translate process requirements into design specifications.

Technovation Filtration Products: Award Winning Filtration Technology

- 1997 R&D 100 AWARD WINNER

This worldwide award recognizes the 100 technologically significant new products processes of the year.

- 1996 MICRO PRODUCT ALL STAR

- 1995 NASA TECHNOLOGY 2005 SBIR AWARD WINNER - applied to Nuclear Biological and Chemical Protection Systems, US Army.

MAIN BENEFITS OF BIO PLUS® EEF FILTERS

- Bactericidal - This means zero to insignificant airborne burden in cleanrooms. Customer tests show that a Class 1K room w/ BIO PLUS filters has less bio burden than a Class 100 room!
- Higher Flow or Lower Pressure Drop - in the smallest industry package! This enables using double HEPA filtration.
- Lower operating and initial costs - No plenums - enables use of standard A/C system

Ultra Low PD (ULPD) BioPlus® HEPAs

Technovation's 1997 R&D 100 Award winning filters are used in our distributed air handling systems.

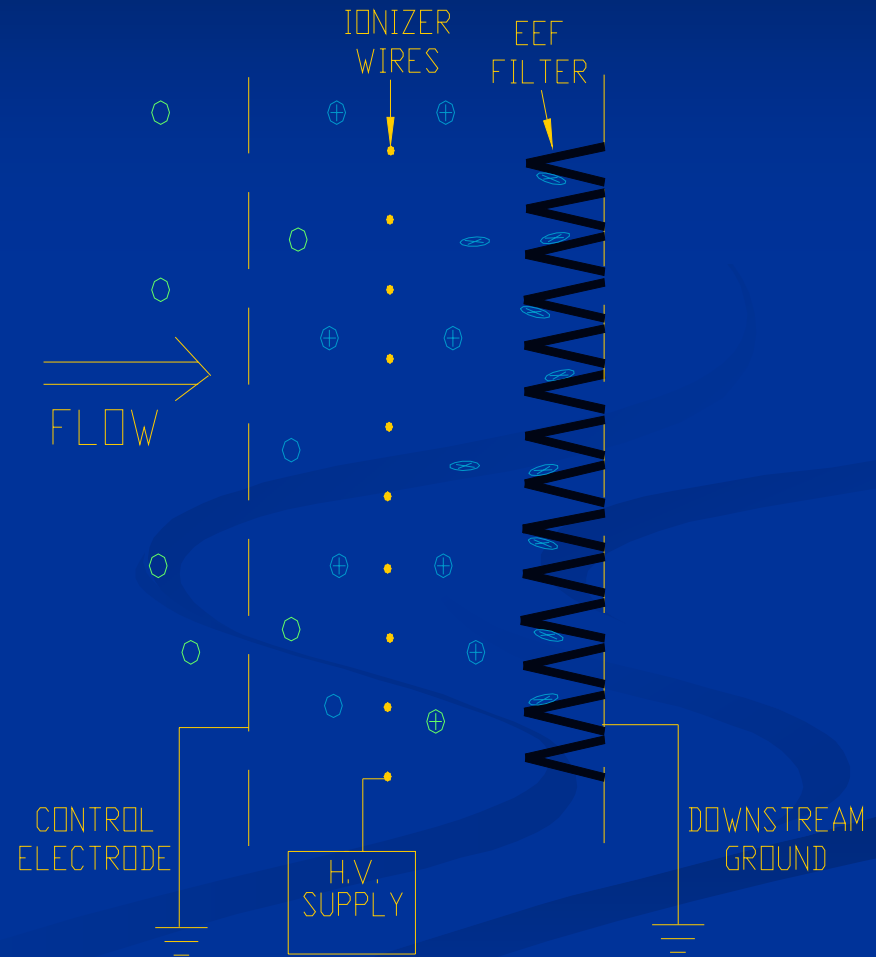
- 0.6" WC @ 2400 scfm – 2'x2'x12" deep! 40% lower pressure drop than conventional HEPA.
- ~ 3 times higher dust holding capacity due to lower PD and formation of porous dust deposits –lower filter maintenance costs.
- Estimated savings of ~ \$900 per year per filter vs conventional HEPAs.
- Used in central and distributed air handling systems.



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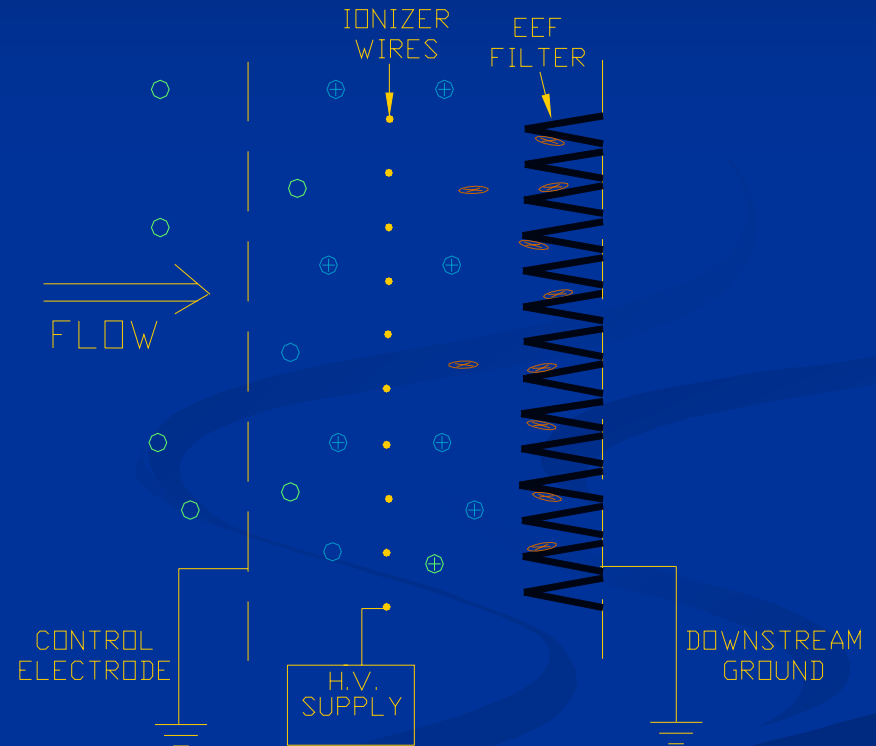
Principle of Operation-EEF Technology

Flow enters first high intensity ionizing field.



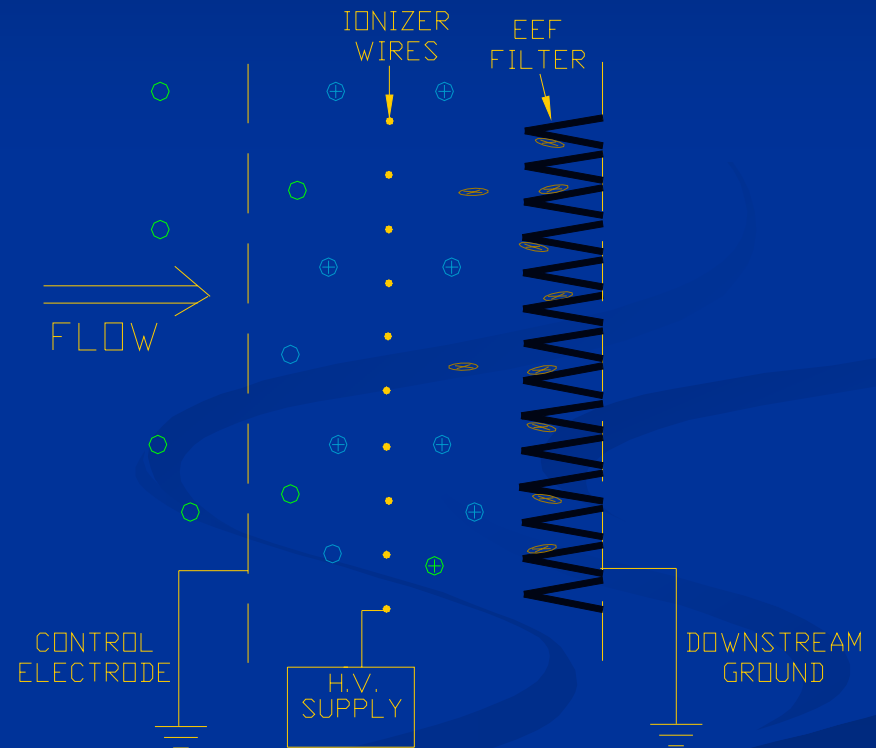
EEF Technology continued.....

Particles and bacteria are charged due to ion flux in this ionizing field - some of the bacteria are killed here.



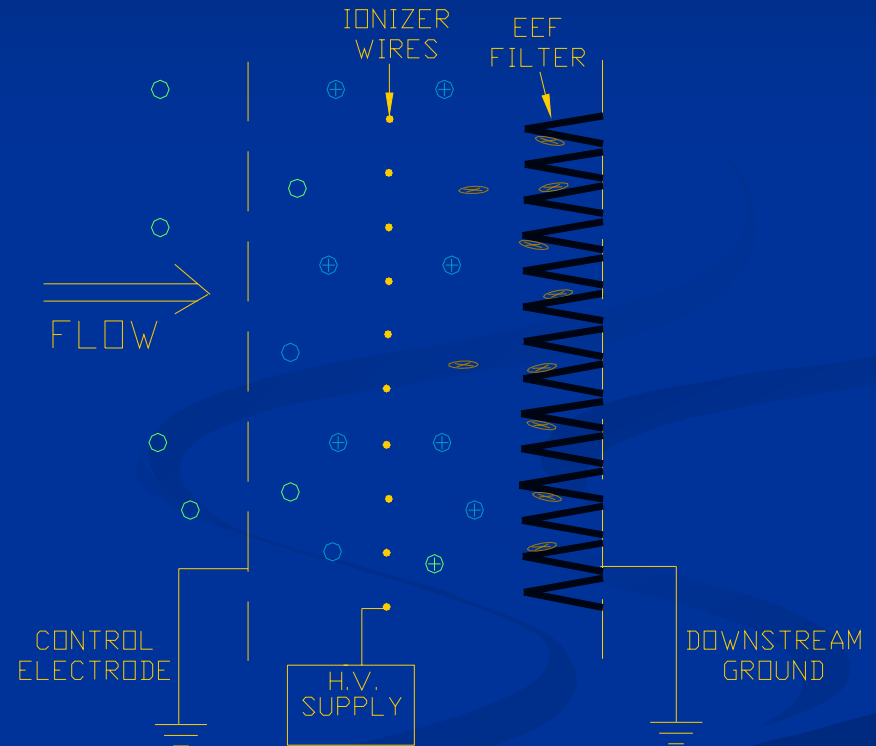
EEF Technology...continued

The charged particles and bacteria are highly efficiently filtered - up to 1000 times lower penetration than conventional filters with the same pressure drop and flow rate.



EEF Technology...continued

Bacteria caught on the filter are subjected to a continuous dose of ionizing radiation and are thus killed.



Lab Results – Bactericidal Properties of EEF (*Staph. Epi.*)

| <u>FILTER</u> | <u>EXPOSURE TIME</u> | <u>AV. CFUs</u> | <u>COMMENT</u> |
|-------------------|--------------------------|---------------------|----------------------|
| control or EEF | hours | #/sq inch | |
| control | 4.00 | 1.00E+06 | No Additional Growth |
| control | 4.00 | 1.02E+05 | After 24 Hours |
| EEF | 4.00 | 0.00E+00 | 100% KILLED |
| EEF | 4.00 | 3.44E+02 | 99.93% KILLED |
| EEF | 4.00 | 0.00E+00 | 100% KILLED |

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Application of BIO PLUS® filter systems

The BIO PLUS® is an in-duct filter used as follows:

- For Class 2-5 it is used as a primary HEPA with terminal ceiling HEPA's - *4 terminal filters for each Model 3001B or 2002B.*
- For Class 6 and above, the BIO PLUS® filter is capable of providing the required clean air - *there is no need for terminal ceiling HEPA's.*
- Ideal for use in Make Up System – *due to low pressure drop it can provide HEPA performance without having to upgrade air handlers.*

Bio Burden / Energy Implications

- EEF bactericidal filters result in significantly lower (negligible) bio burden. E.g.. Encelle's class 1K room meets the USP requirements for class 100.
- Pharmacies must achieve USP Standards for maximum airborne bio burden levels.

Why Chose Technovation?

- Design/Built ~ 100 Cleanrooms
- Specialize in Cleanroom Environments
- Dedicated Team
- USP 797 Expertise
- Energy Efficient and Functional Design
- Bactericidal BioPlus® HEPA's
- Expert Design Build Services, DQ,IQ,OQ and consulting services

Statement of Customer Satisfaction

Technovation prides itself in our record of *100% customer satisfaction* as evidenced by the amount of repeat business we have achieved. References testifying to our unparalleled record customer satisfaction are available.