The Complete Solution for Clean Room Aerosol-Based Disinfection

MINNCARE DRY FOG SYSTEM

Current Methods of Room Disinfection

⇨Surface Wiping
⇨Manual Spraying (with Spray Bottles)
⇨Heating Process (Vaporization)
⇨Cold Process - Wet fogging
- **Dry fogging**

※ Disinfection is NOT a Cleaning Process

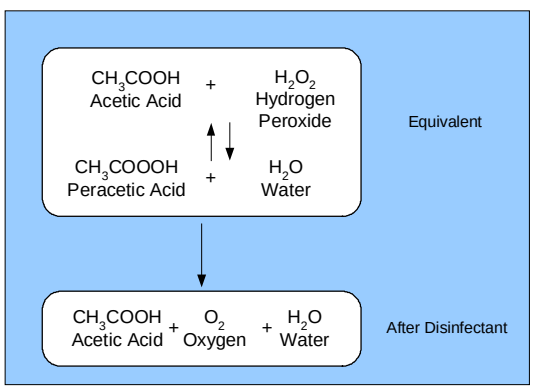
Currently Used Chemical Products

⇨Alcohol based
⇨Formaldehyde based
⇨Gluteraldehyde based
⇨Quaternary Ammonium Compounds
⇨Cocktails of the above

Current Problems

⇨Efficiency (more or less broad spectrum biocide)
⇨Adaptation of the Micro-Organisms
⇨Toxicity of the Chemicals Used
⇨Long Contact Time
⇨Very Long Time for Venting
⇨Neutralization Needed
⇨Corrosion
⇨Variability of Chemical Application
⇨Residuals

Minncare® Cold Sterilant



⇨An alternative solution for room

disinfection in Pharmaceutical,
Biotech, Medical Facilities,...

Benefits of Minncare®

⇨Superior Biocidal Activity
⇨All Components are Ultra-pure, Pharmaceutical Quality
⇨US EPA (Environment Protection Agency) Registered Sterilant
⇨No Heavy Metal Trace Contamination / Stabilizers.
⇨Biodegradable – Decomposes to Acetic Acid, Water and Oxygen
⇨No Toxic Aldehyde Type Vapors, Easy to Vent
⇨Validated Residual Vapor Detection System

Minncare® Applications

⇨Water Systems Disinfection
Tanks, Piping, Resins, Filters, RO Membranes,…
⇨Surface Disinfection (Wiping and/or Manual Spraying)
⇨Fogging

Minncare® Biocidal Activity

Minncare® is a potent antimicrobial agent and is effective against a broad spectrum of microorganisms, including:

⇨Bacteria ⇨Yeast and Molds
⇨Mycobacteria ⇨Bacteria Spores
⇨Viruses

Activities of the most important biocides (Guyader, 1996)

Biocides	Bacteria		Myco-bacteria	Spores	Moulds	Yeasts	Virus
	Gram -	Gram +					
Peracetic acid	+++	+++		++	++	++	++
Alcohols	++	++		0	++	++	+
Alcohol (70?	++	++	0	+	+	++	+
Glutaraldehyde	+++	+++	++	+	+++	++	++
Quat Ammonium	+++	+*	0	0	+	+	+
Chlorine	+++	+++	++	++	++	++	++
Hydrogen Peroxyde	+++	+++		+	+	+	0
Iodine	+++	+++	++	++	++	++	++

** Not active on Pseudomonas*

Minncare® Mechanism of Action

⇨Disrupts Sulfhydrl (-SH) and Sulfur (S-S) bonds in proteins and enzymes Important components in cells and membranes are broken by oxidative disruption.
⇨Impede cellular activity by disrupting chemosmotic function of lipoprotein cytoplasmic membrane transport through rupture or dislocation of cell walls

⇨Denature the properties of protein components by altering the nucleic acid structure of organisms.

⇨Damage vegetative cells by oxidation with hydroxy radicals.

⇨Produces organic radicals that act as reducing agents for spores.

"NO CHANCE"For Micro-Organisms to Build a Resistance

Minncare® In Vitro Aqueous Testing

Minncare™ Concentration .5%		
Species	**Count per ml**	**Time for 100% kill in minutes**
Bac. subtilis	6 x10⁶	2.5
Bac: stearothermophilus	6 x 10⁶	2.5
Bac. subtiis NCTC 3610	2.4 x 10⁹	5.0
Bac. mesentericus	1.6 x 10⁹	5.0
Clostr. perfringens	1 x 10⁷	10.0
Clastr. tyrobutyricum	1 x 10⁷	5.0
Sacchar. cereisiae	6 x 10⁷	0.5
Cand. mycoderma	1.4 x 10⁸	0.5
Hansenula anomala	6.4 x 10⁸	0.5
Pichia membronaefaciens	4.8 x 10⁸	0.5
Pen. camerunense	1.7 x 10⁸	2.5
Mucor plumbeus	3 x 10⁶	2.5
Geotrichum candidum	2 x 10⁷	0.5
Byssochlamys nivea	6 x 10⁷	0.5
Staph. aureus	2.6 x 10⁹	0.5
Strept. faecalis	4.6 x 10⁹	0.5
Kleb. aerogenes	2.3 x 10⁹	0.5
Ps. fluorescens	4.6 x 10⁹	0.5
Ps. aeruginosa	2 x 10⁹	0.5
Salm. thyphimurium	2.8 x 10⁹	0.5
Coryneb. rubrum	1 x 10⁷	1.0
Leuconostoc spec.	5.3 x 10⁸	0.5
Lactob. brevis	1.8 x 10⁹	0.5

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A total of 720 tests were performed on three lots of the test chemical. Results of the test are shown on the chart below.

Lot/Organism	Carrier type	Positives/Total
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3 Bacillus subtilis	loop	0/60
3 Bacillus subtilis	cylinder	0/60
3 Clostridium sporogenes	loop	0/60
3 Clostridium sporogenes	cylinder	0/60

Deactivation of Organisms by Minncare® Vapors

Estimated spore concentration of filter suspended 1 inch above	B. subtilis spores/filters
Control: water	
10^3 spores	9.6 x 10^3 CFU*
10^6 spores	> 3 x 10^3 CFU
Minncare® solution (1%)	
10^3 spores	<1 CFU
10^4 spores	<1 CFU
10^5 spores	<1 CFU
10^6 spores	<1 CFU

* Colony forming units

Minncare®Toxicity Assessment Summary

Toxicity summary	Specimen	Results	Reference
Oral toxicity	Male rats	LD_{50} = 2.43 (2.04-2.88) g/kg	Litchfield & Wilcoxon
	Femal rats	LD_{50} = 2.10 (1.92-2.30) g/kg	
Inhalation toxicity	Male rats	Established lethal concentration	
	Female rats	LC = 13,439 mg/cubic meter	
Skin sensitivity	Mice	No reaction	Burkhard's Test
	Humans	No visible effects	
Mucos membranes	New Zealand rabbits	Effects completely gone within 7 days	HH Draize
Dermatological sensitivity qualities	White Guinea pigs	No difference between control and test group	Klugman & Magnusson
Intravenous toxicity	Male rats	LD_{50} = 212 mg/kg	Litchfield & Wilcoxon

Minncare Dry Fog™ - A Best Way for Clean Room Disinfection.

⇨An Integral Part of Modern Clean Room Disinfection Procedures

⇨EPA Registered

⇨Match FDA , PIC/S request.

⇨Superior “Dry” Delivery System

⇨Better Dispersion than “Wet” Systems

⇨Effective for Very Large Areas: 20 ~ 1000 M^3

⇨Better for Critical Applications

⇨Less Preparation Work

⇨Less Corrosion

⇨Less Residue

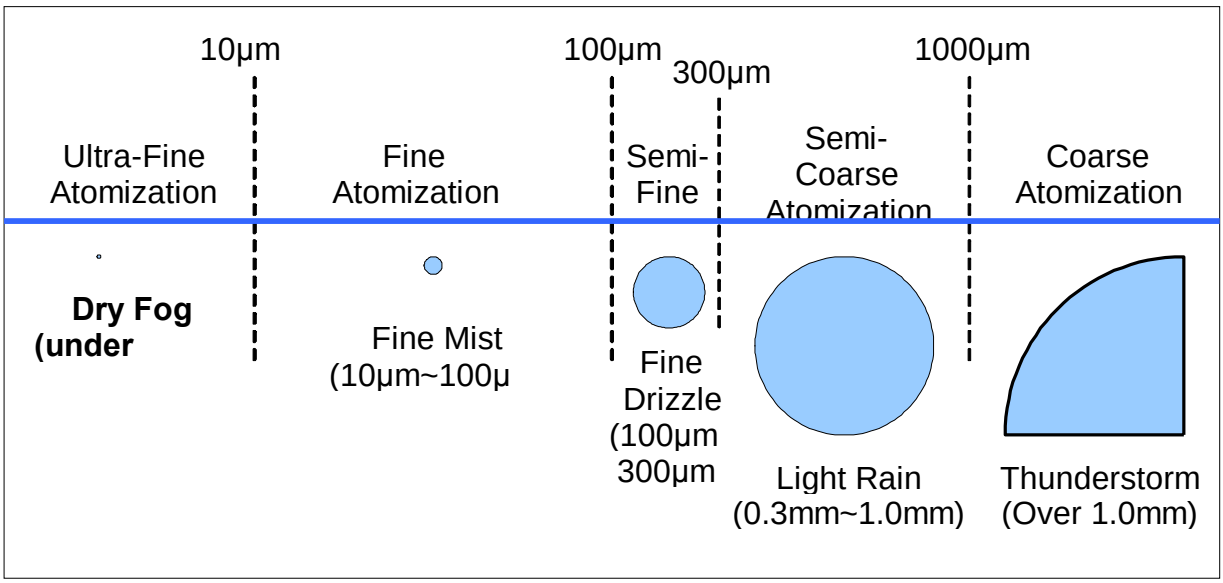
Droplet Size effect

⇨The Minncare Dry Fog System Produces 7.5 μm Droplets

–Droplets Behave Like Gas Particles

•Bounce Off Surfaces •Do Not Wet Surfaces

–Float in the Air Due to Brownian Motion.



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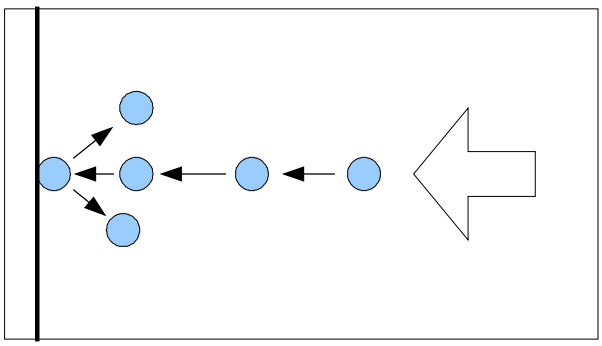
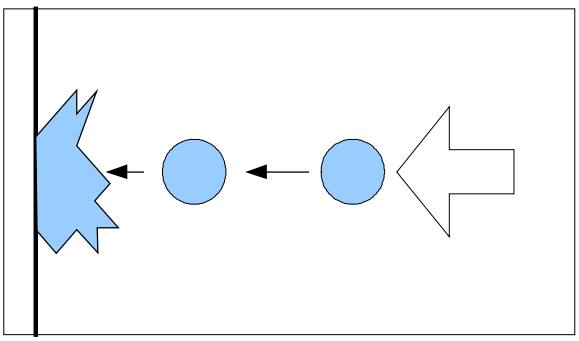


⇨Small droplets bounce and do not burst upon collision.



⇨Large droplets burst and make things wet.

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⇨Minncare Dry Fog Creates a Vapor State, It Disperses Throughout the Room More Completely Than a Liquid Mist.

⇨Better Dispersion Means More Surface Contact.

⇨Even Hard to Reach Surfaces, Like Behind Cabinets, Under Tables.

⇨Less Condensation.

Relative Humidity

⇨Initial Relative Humidity Should Be <50%.

⇨Optimum Activity Between 70 and 80% Relative Humidity.(1)

•Measure Using Optional Cable-Free Thermo Hygrometer.

⇨Maintain Relative Humidity Below 90% to Avoid Condensation

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Room Size

⇨The Number of Nozzles or Machines Required is Dependent on the Size of the Room

⇨Each Nozzle Can Fog Up To 8,750 ft^3 (250 m^3) Efffectively

⇨Each Machine Can Fog Up To 35,000 ft^3 (1,000 m^3) With 4 Nozzles

Machine Positioning

⇨Strategically Place the Machine in the Room

⇨Aim Nozzles Away from Nearby Walls and Equipment

⇨Position the Machines to Allow an Easy Flow of the Fog to All Parts of the Area

General Information

⇨**SETUP**

–Amount of Minncare: 1.5 ml / M^3 of Room Volume

–Total Solution Volume: Function of the Initial RH

–Ideal Initial Relative Humidity: less than 55%

–Ideal Room Temperature: 20-25°C

⇨**PROCESS**

–Fog Dispersion Time: 15 - 120 min

–Exposure Time: 1 hour

–Venting Time: 0.5 - 2 hours

⇨**TOTAL PROCESS TIME: 2 - 5 hours (including venting)**

※Notes:1)All individuals MUST evacuate the room during the process.
Assure Safe Operation with the Dry Fog Remote Control Unit
2)After confirmation of chemical vapor residuals below limits (using the Minncare Dry Fog Vapor Detection System) the room may be returned to service.

The General Procedure

–Unpack & Assemble the System

–Calculate the Needed Water and Minncare Quantity

–Position Fogger

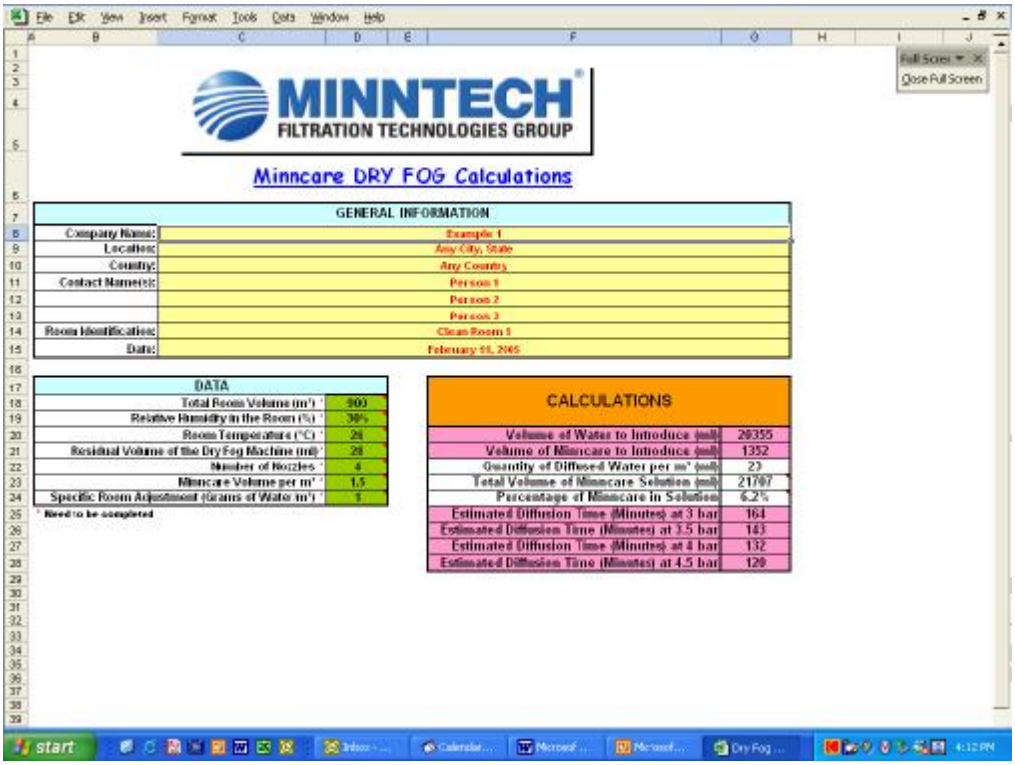
–Add Water

–Connect Pressurized Air Source

–Test System Operation

–Adjust Gauges
–Add Minncare
–Start Spraying

Dry Fog Setup – Software Support-Initial Calculations:



MINNTECH
FILTRATION TECHNOLOGIES GROUP

Minncare DRY FOG Calculations

GENERAL INFORMATION	
Company Name:	Example 1
Location:	Any City, State
Country:	Any Country
Contact Name(s):	Person 1
	Person 2
	Person 3
Room Identification:	Clean Room 1
Date:	February 15, 2005

DATA	
Total Room Volume (m³) *	900
Relative Humidity in the Room (%) *	30%
Room Temperature (°C) *	20
Residual Volume of the Dry Fog Machine (ml) *	20
Number of Nozzles *	4
Minncare Volume per m³ *	1.5
Specific Room Adjustment (Grams of Water m³) *	1

* Need to be completed

CALCULATIONS	
Volume of Water to Introduce (ml)	20355
Volume of Minncare to Introduce (ml)	1352
Quantity of Diffused Water per m³ (ml)	23
Total Volume of Minncare Solution (ml)	21707
Percentage of Minncare in Solution	6.2%
Estimated Diffusion Time (Minutes) at 3 bar	164
Estimated Diffusion Time (Minutes) at 3.5 bar	143
Estimated Diffusion Time (Minutes) at 4 bar	132
Estimated Diffusion Time (Minutes) at 4.5 bar	120

Position & Operate the System

Dry Fog – Air Residuals

⇨Measure Using the Minncare Dry Fog Vapor Detection System

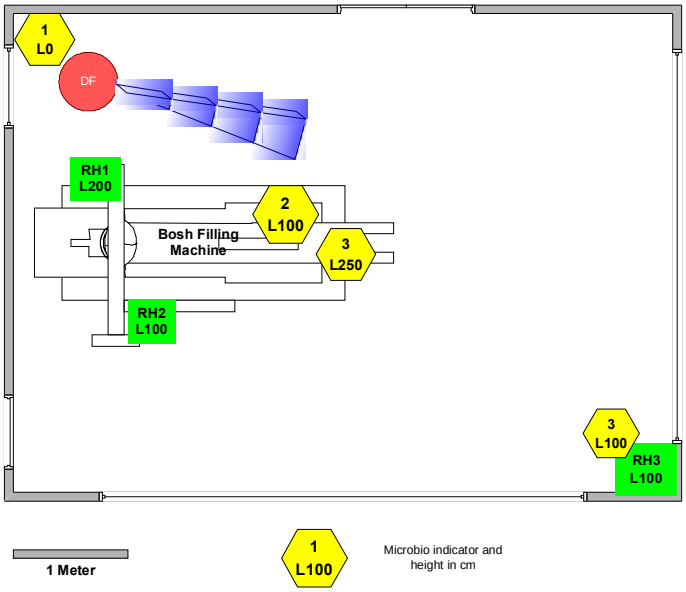
⇨Permissible Exposure Limits (PEL)

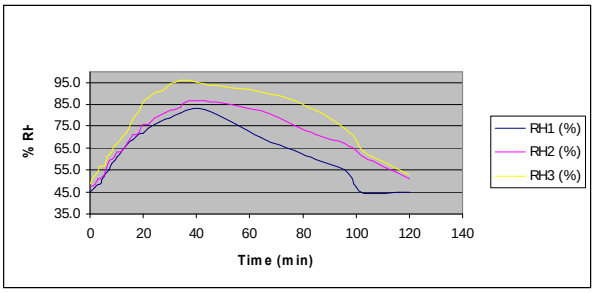
–Hydrogen Peroxide: 1 ppm

–Acetic Acid: 10 ppm

※ Residuals on the surfaces : Much less than 0.00002 ml Acetic Acid / cm²

⇨EXAMPLE - 70 M³

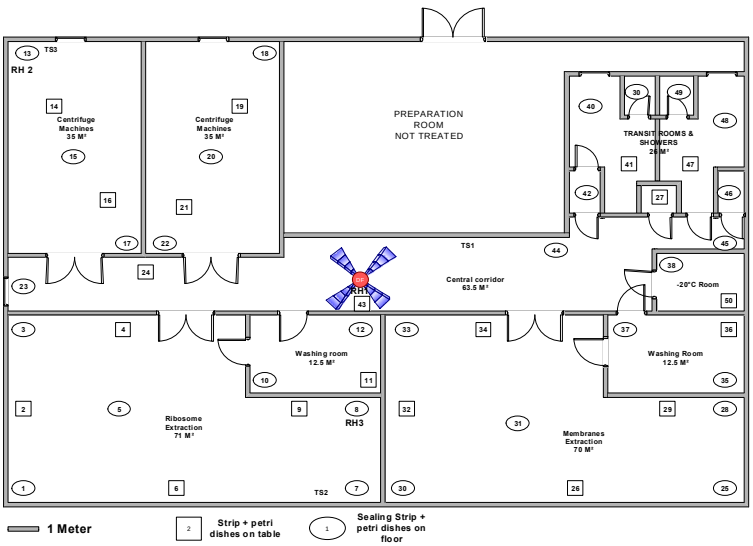


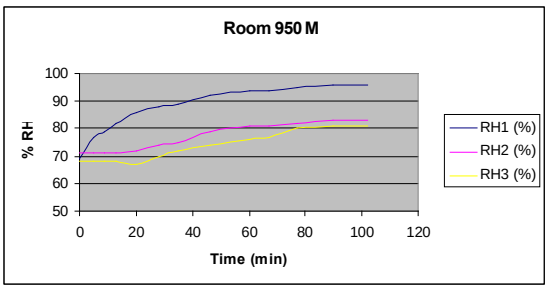


6 log reduction in spore
B. Stearothermophylus
ATCC 7953

Surface control: 0 germ
Air control: 0 germ

⇨EXAMPLE - 950 m³





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Evaluation

Customer Evaluation of Dry Fog

⇨Diffusion Testing

⇨Microbiological Testing

How Do Customers Validate Their Disinfection Process?

⇨Tools

–Spores Strips: Paper, SS, Glass, Plastic

–Inoculated Petri Dishes

–Surface Microbiological Controls

–Air Microbiological Controls

※Cleanroom Disinfection Does Not Need a Specific Method or Specific Microorganisms for Process Validation. Controls Showing LRV Are Sufficient.

⇨Possible Microorganisms for Cleanroom Disinfection Process Validation

–Bacillus trophaerus (subtilis) ATCC 9372

–Geobacillus stearothermophilus ATCC 7953

–Bacilus cereus CIP783

–Anterococcus hirae CIP5855

–Use Caution with B. stearothermophilus ATCC 12980

※Some Versions Packaged for Autoclave Tests (Sealed from Vapor)

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MINNCARE DRY FOG SYSTEM

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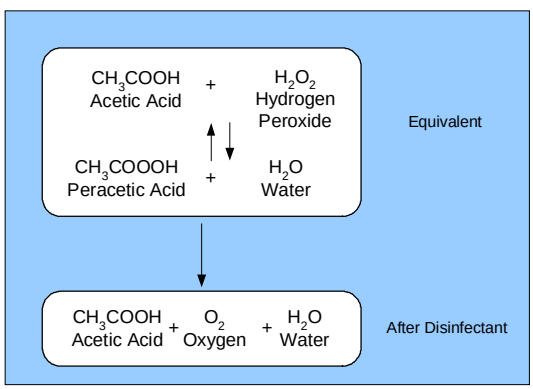

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Alcohols	++	++		0	++	++	+
Alcohol (70?	++	++	0	+	+	++	+
Glutaraldehyde	+++	+++	++	+	+++	++	++
Quat Ammonium	+++	+*	0	0	+	+	+
Chlorine	+++	+++	++	++	++	++	++
Hydrogen Peroxyde	+++	+++		+	+	+	0
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** Not active on Pseudomonas*

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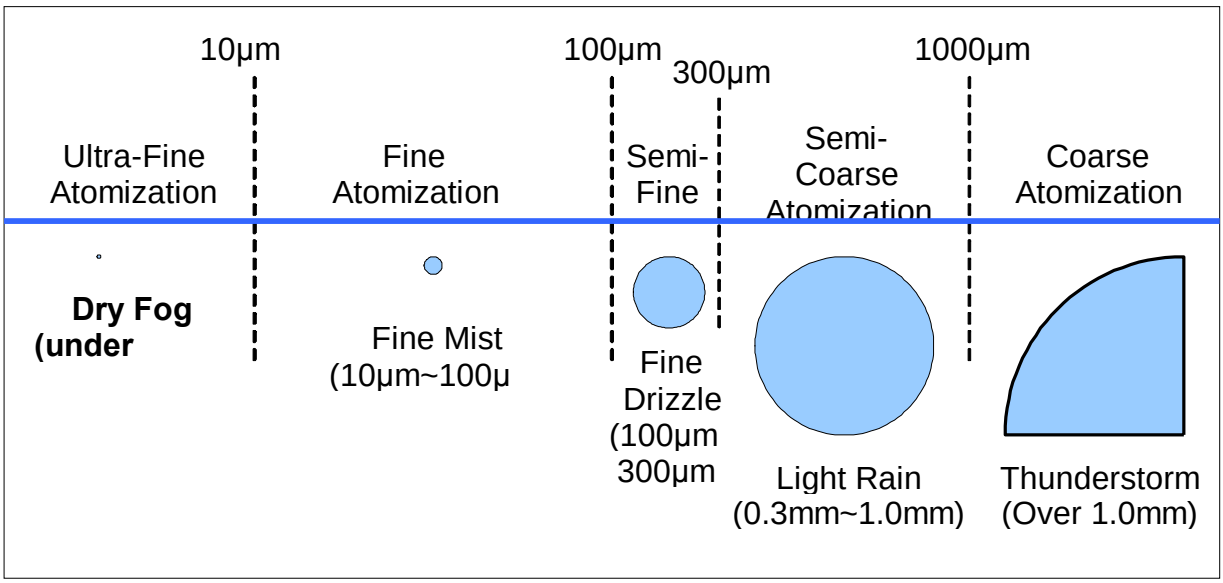

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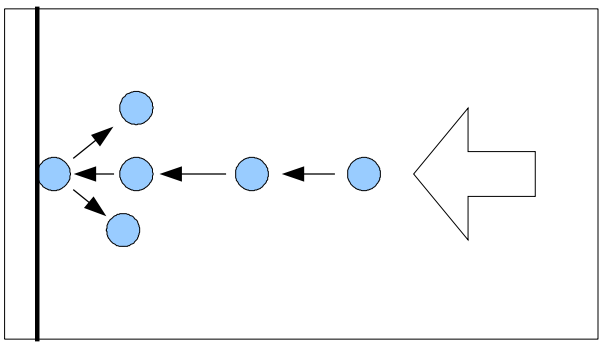

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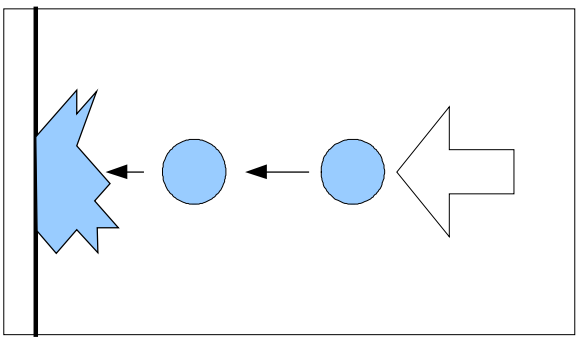

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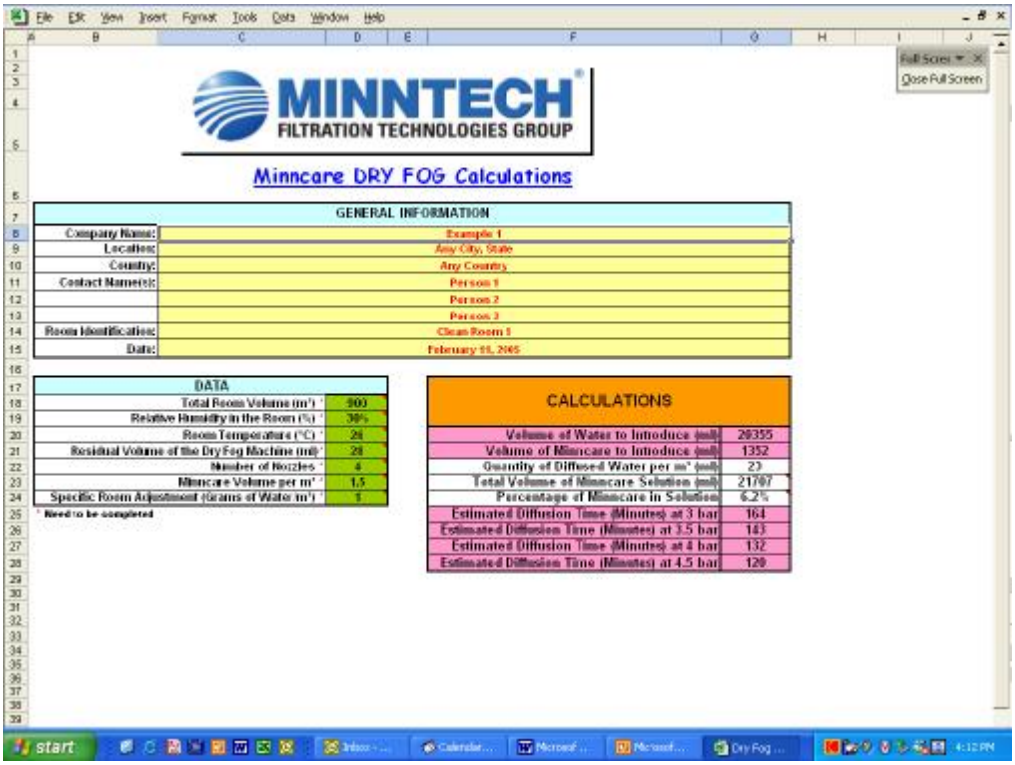
–Add Water

–Connect Pressurized Air Source

–Test System Operation

–Adjust Gauges
–Add Minncare
–Start Spraying

Dry Fog Setup – Software Support-Initial Calculations:



MINNTECH
FILTRATION TECHNOLOGIES GROUP

Minncare DRY FOG Calculations

GENERAL INFORMATION	
Company Name:	Example 1
Location:	Any City, State
Country:	Any Country
Contact Name(s):	Person 1
	Person 2
	Person 3
Room Identification:	Clean Room 1
Date:	February 15, 2005

DATA	
Total Room Volume (m³) *	900
Relative Humidity in the Room (%) *	30%
Room Temperature (°C) *	20
Residual Volume of the Dry Fog Machine (ml) *	20
Number of Nozzles *	4
Minncare Volume per m³ *	1.5
Specific Room Adjustment (Grams of Water m³) *	1

* Need to be completed

CALCULATIONS	
Volume of Water to Introduce (ml)	20355
Volume of Minncare to Introduce (ml)	1352
Quantity of Diffused Water per m³ (ml)	23
Total Volume of Minncare Solution (ml)	21707
Percentage of Minncare in Solution	6.2%
Estimated Diffusion Time (Minutes) at 3 bar	164
Estimated Diffusion Time (Minutes) at 3.5 bar	143
Estimated Diffusion Time (Minutes) at 4 bar	132
Estimated Diffusion Time (Minutes) at 4.5 bar	120

Position & Operate the System

Dry Fog – Air Residuals

⇨Measure Using the Minncare Dry Fog Vapor Detection System

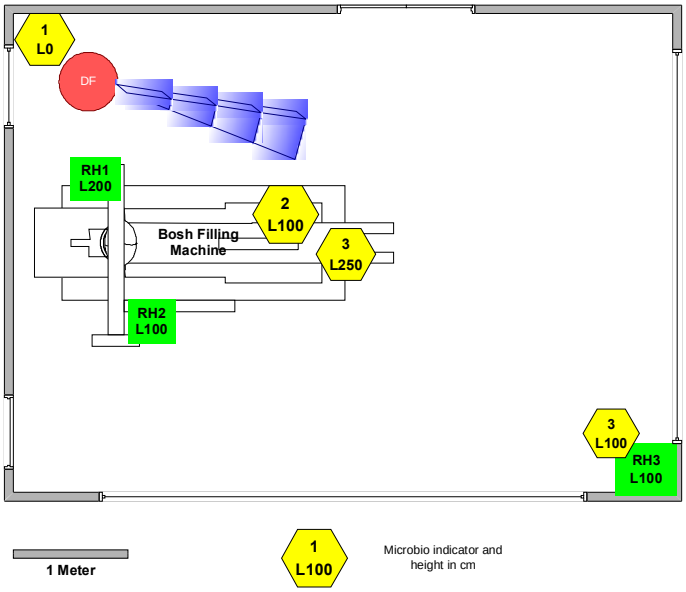
⇨Permissible Exposure Limits (PEL)

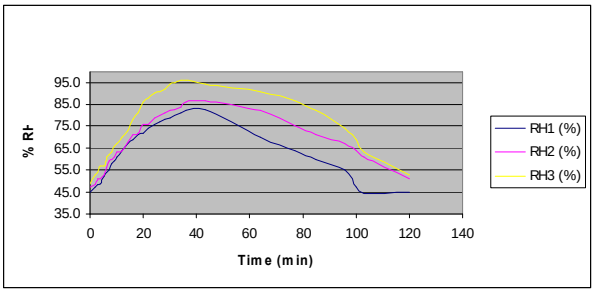
–Hydrogen Peroxide: 1 ppm

–Acetic Acid: 10 ppm

※ Residuals on the surfaces : Much less than 0.00002 ml Acetic Acid / cm²

⇨EXAMPLE - 70 M³

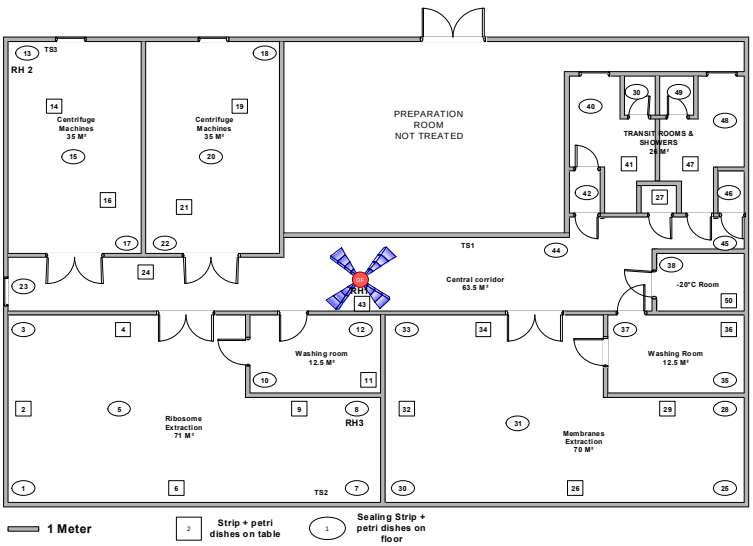


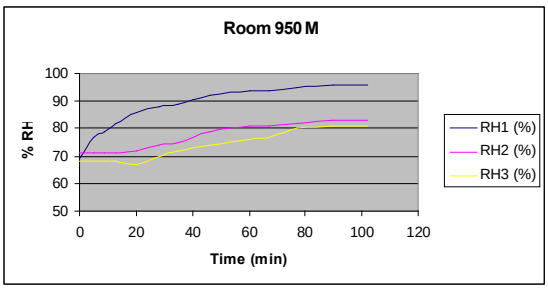


6 log reduction in spore
B. Stearothermophylus
ATCC 7953

Surface control: 0 germ
Air control: 0 germ

⇨EXAMPLE - 950 m³





6 log reduction in spore
B. Stearothermophylus
ATCC 7953

Surface control: 0 germ
Air control: 0 germ

Evaluation

Customer Evaluation of Dry Fog

⇨Diffusion Testing

⇨Microbiological Testing

How Do Customers Validate Their Disinfection Process?

⇨Tools

–Spores Strips: Paper, SS, Glass, Plastic

–Inoculated Petri Dishes

–Surface Microbiological Controls

–Air Microbiological Controls

※Cleanroom Disinfection Does Not Need a Specific Method or Specific Microorganisms for Process Validation. Controls Showing LRV Are Sufficient.

⇨Possible Microorganisms for Cleanroom Disinfection Process Validation

–Bacillus trophaerus (subtilis) ATCC 9372

–Geobacillus stearothermophilus ATCC 7953

–Bacilus cereus CIP783

–Anterococcus hirae CIP5855

–Use Caution with B. stearothermophilus ATCC 12980

※Some Versions Packaged for Autoclave Tests (Sealed from Vapor)