

Sterilair PRO BIOLOGICAL AIR TREATMENT

Combatting airborne infections in close contact environments

THE SCIENCE





Sterilair PRO – The Science



This guide offers further information on the technology behind Sterilair PRO and science-based explanations of how it works.

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- Philips UV disinfection and how it works



Sterilair PRO – harnessing the power of UV-C

Sterilair PRO is an innovative Air Biological Treatment System that uses ultraviolet light (UV-C) to sterilise ambient air, killing bacteria, mould, spores, yeast and viruses, including coronaviruses such as Covid-19.

Ultraviolet Germical Irradiation (UVGI) is a well-established method for the disinfection of air, water and surfaces.



Coronaviruses are extremely sensitive to UV-C light. In fact, one passage through the Sterilair PRO chimney is enough to destroy the coronavirus outright.

Sterilair PRO can treat 120m³, with a killing rate of 99.99% and a proven efficacy in real environment of 99.22%. (Eurofins Biopharma Lab Report)

Sterilair PRO does not clean the air – it sterilises it.

Sterilair PRO – harnessing the power of UV-C

Sterilair PRO is CE marked and FDA approved and has been rigorously tested for its efficacy.

Manufacturers TecnoGaz, have issued the results of some of these tests and the theory behind them. Below are some interesting highlights.

Ultraviolet Germicidal Irradiation (UVGI) is a well-established method for the disinfection of air, water and surfaces.

Ultraviolet germicidal irradiation (UVGI) is an electromagnetic radiation that destroys the ability of microorganisms to reproduce causing photochemical changes in nucleic acids. Wavelengths in the UVC range are particularly harmful to cells because they are absorbed by nucleic acids. In particular, it has been shown that UVC radiation causes dimerization of adjacent thymine molecules **preventing DNA replication**.

The germicidal efficacy of the UVC peaks corresponds to the peak of UV absorption by the bacterial DNA.

Steril air PRO is equipped with <u>4 high power</u> (25W) PHILIPS TUV T8 certified lamps operating at 253.7 nm

Microbial susceptibility to ultraviolet light varies between species of microbes. Bacteria, viruses and fungal spores respond to UV exposure at speeds defined in terms of UV rate constants.

Starting from the irradiation (linked to the power of the lamps and the geometry of the machine) from the exposure time and the UV constants of the individual bacteria, it is possible to determine Kr or the percentage of abatement with <u>a single passage of air inside STERIL AIR PRO</u>:

$$Kr = 1 - e^{-k(E_t \cdot I_r)} \tag{1}$$

Where:

k= constant dependent on the bacterium/virus

Et= exposure time (depends on the range and length of the lamp)

I_r= Irradiance (depends on the power of the lamp and the geometry of the chamber)

This percentage is reported for a SINGLE PASS in the Steril Air PRO in the following table. In the case of multiple passages, as happens in continuous operation, the effectiveness is obviously multiplied.

It should be considered that in this calculation the worst theoretical conditions were kept (in reality the results are therefore decidedly better) that is: on each particle only the energy of the closest UVC lamp was considered (ignoring the contribution of the other 3); the energy received was calculated as if all the air passed at the maximum distance from the lamp (while in reality it passes much closer and therefore receives much more energy).

Despite the worsening conditions used for the calculation, the results are very positive: for example for the coronavirus family, the one-passage killing rate is **99.999999%**

Sterilair PRO – harnessing the power of UV-C

	D ₉₀ (2)	K ⁽²⁾	KILLING RATE
Bacillus anthracis	45,2	0,051	91,518171%
B, megatherium sp, (spores)	27,3	0,084	98,281462%
B, megatherium sp, (veg,)	13,0	0,178	99,981794%
B, parathyphosus	32,0	0,072	96,929004%
B, suptilis	71,0	0,032	78,734300%
B, suptilis spores	120,0	0,019	60,114980%
Campylobacter jejuni	11,0	0,209	99,995936%
Clostridium tetani	120,0	0,019	60,114980%
Corynebacterium diphteriae	33,7	0,069	96,449338%
Dysentery bacilli	22,0	0,105	99,377773%
Eberthella typhosa	21,4	0,108	99,461831%
Escherichia coli	30,0	0,077	97,588822%
Klebsiella terrifani	26,0	0,089	98,650698%
Legionella pneumophila	9,0	0,256	99,999582%
Micrococcus candidus	60,5	0,038	84,091852%
Micrococcus sphaeroides	100,0	0,023	67,132265%
Mycobacterium tuberculosis	60,0	0,038	84,091852%
Neisseria catarrhalis	44,0	0,053	92,300376%
Phytomonas tumefaciens	44,0	0,053	92,300376%
Pseudomonas aeruginosa	55,0	0,042	86,890697%
Pseudomonas fluorescens	35,0	0,065	95,691269%
Proteus vulgaris	26,4	0,086	98,439948%
Salmonella enteritidic	40.0	0.05.9	03 05/678%
Salmonella paratynhi	32.0	0,038	96 929004%
Salmonella typhimurium	80.0	0.029	75 412763%
Seratia marcescens	24.2	0.025	98 990633%
Shigella naradysenteriae	16.3	0.141	99 890959%
Shigella sonnei	30.0	0.077	97 588822%
Spirillum rubrum	44.0	0.053	92 300376%
Stanbylococcus albus	18.4	0.126	99 774712%
Staphylococcus aureus	26.0	0.086	98 439948%
Streptoroccus faecalis	44.0	0.052	91 918732%
Streptococcus hemoluticus	21.6	0.106	99,407158%
Streptococcus lactus	61.5	0.037	83,303338%
Streptococcus viridans	20.0	0.115	99,616426%
Sentertidis	40.0	0.057	93,655032%
Vibrio chlolerae (V.comma)	35.0	0.066	95,894752%
Yersinia enterocolitica	11.0	0.209	99,995936%
Bakers' yeast	39.0	0.060	94,512186%
Brewers' yeast	33.0	0,070	96,617021%
Common yeast cake	60,0	0,038	84,091852%
Saccharomyces cerevisiae	60,0	0,038	84,091852%
Saccharomyces ellipsoideus	60,0	0,038	84,091852%
Saccharomyces sp.	80,0	0,029	75,412763%
Hepatitis A	73,0	0,032	78,734300%
Polio virus	58,0	0,040	85,558922%
Rotavirus	81,0	0,028	74,194057%
Cryptosporidium parvum	25,0	0,092	98,832978%
Giardia lamblia	11,0	0,209	99,995936%
Cryptosporidium parvum	25,0	0,092	98,832978%
Giardia lamblia	11,0	0,209	99,995936%
Coronavirus	6,0	0,377	99,999999%
Adenovirus	49,0	0,047	89,707294%
Bacteriophage MS2	5,0	0,424	100,000000%
Coliphage X-174	3,0	0,710	100,000000%
Coliphage T7	7,0	0,330	99,999988%
Coxsackievirus	21,0	0,111	99,534533%
Influenza A virus	19,0	0,119	99,683911%

Sterilair PRO – the process

Sterilair PRO works on the basis of a closed loop forced ventilation system. Boasting an innovative design, Sterilair PRO is the first system dedicated exclusively to biological air treatment. Unlike many of the cheaper units currently available such as air purifiers, this high-performance technology does so much more than simply filtering out micro-organisms. **Sterilair PRO does not clean the air, it sterilises it.**

As well as being considerably more effective than other technologies, the Sterilair PRO is much safer. Due to its patented covering, the Philips UV lamp does not disperse radiation into the room, meaning it can be used continuously in the presence of people without any risk to health. This feature also means the device is substantially safer for the environment.

Other methods of decontaminating air include free ultraviolet radiation and chemical cleaning, but these have a temporary effect and can only be carried out when the room is empty.



Sterilair PRO – the process



No ozone dispersion

Output grille

The treated air is expelled from the outlet nozzle thus reducing the microbial load in the environment.

Irradiation with UV-C rays

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The mercury vapour tubes produce irradiation for maximum germicidal action.

Dust filter for primary purification from coarse pollutants

Sterilair PRO – the process



Solid aluminium construction

Tecno-Gaz Quality

No risk to people

SterilAir PRO can work round the clock because it does not disperse radiation in the environment and is therefore totally safe.

No noise

Operation is in fact noise-free. The forced air circulation is ensured by special silent fans.

No maintenance

SterilAir does not use expensive antibacterial filters but simple dust filters because the germicidal action is guaranteed by the lamps.

> Programmable Thanks to a simple display.

Maximum effectiveness

Tecno-Gaz – committed to quality



Tecno-Gaz manufactures and markets **Sterilair** *since* 1999



Sterilair PRO is designed and manufactured by Tecno-Gaz. Based in Italy, Tecno-Gaz has been producing high-quality medical devices since 1979.

Sterilair PRO has been used extensively and globally by medical professionals since its launch 20 years ago.

Due to the outbreak of Covid-19, this device is now being used in a wide variety of other settings.



CERTIFICATO N. CERTIFICATE N. 9124.TGA2

SI CERTIFICA CHE IL SISTEMA QUALITA' DI WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

TECNO-GAZ SPA

STRADA CAVALLI 4 - 43038 SALA BAGANZA (PR) UNITA' OPERATIVE I OPERATIVE UNITS

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ci kit di primo soccorso e palloni rianimatori. Produzione e commercializzazione di prodotti ed accessori destinati al settori medicale, odontoiatrico e primo soccorso. Gestione della manutenzione, installazione e riparazione di apparecchiature per radiologia, aspiratori chirurgici, riduttori di pressione per l'utilizzo con i gas medicali e riuniti dentali

Design, manufacture and service of sedative analgesia devices. Design, production and testing of small autoclaves. Production and service of first aid kits and resuscitators bags. Production and sale of products and accessories intended for the medical, dental and first aid. Maintenance management, installation and repair of radiology equipment, suction pumps, pressure regulators for use with medical and dental units gas

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione Further clarifications regarding the applicability of ISO :3485:2016 requirements may be obtained by consulting the organization

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BioPharma Product Testing

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Тпсе	SCREENING AIR SANITI CHAMBER AGAINST AN	ZATION TEST USING STERIL A AEROSOL OF E. coli K12	IR PRO IN AN AIRLOCK
50 59	TECNO-GAZ S p A		
	STRADA CAVALLE 4		
SPONSOR	43038 SALA BAGANZA (F	(R)	
	ITALY		
TEST ITEM			
DEVICE IDENTIFICATION	Steril Air Pro		
DESCRIPTION	Indoor air purification device		
BATCH	OEZSA5529	CODE	Not Provided
MANUFACTURING DATE	Not Provided	EXPIRY DATE	Not Provided
ACTIVE INGREDIENT	Not Provided		
PARCEL REGISTRATION N.	IP-LV-2020099-ANY	RECEIVING DATE	08-Apr-2020
MATERIAL ITEM ALIQUOT	LV-MAT-F5PH-20-111-050	2:a	
ANALYSIS STARTING DATE	05-May-2020	ANALYSIS ENDING DATE	14-May-2020
METHOD SET-UP			
Note	A set up phase has been of E. coli K12 inside a 1 m ³ v. The aim of the set up pha time and the experiment microorganisms in the air a Test has been performed in	conducted in order to verify the re- olume air lock chamber. ase is to determine the starting in tal conditions that allow to a after nebulization and verify their non n duplicate.	covery of a nebulization of noculum, the nebulization significant recovery of eproducibility.
TEST STRAIN	Escherichia coli K12	DSM 11250	
INOCULUM CONCENTRATION	1.5 - 5.0 x107 cfu/ml	1.	
NEBULIZATION TIME	30 minutes		
INNER CHAMBER VOLUME	1 m ³		
CONTACT TIME (AFTER NEBULIZATION)	Immediately after nebulizati	on (time 0)	

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	The sterilized Collison nebulizer - filled with bacterial suspension - was connected to the test chamber via a sterilized glass aerosol delivery tube surrounded by thermostatic water, in order to obtain a temperature in the aerosol of 20°C ± 5°C. The Collison nebulizer was connected to the air-flow system. The test chamber and its content were exposed to the spore bacterial aerosol for 30 minutes.
PREPARATION OF THE TEST CHAMBER (FOR EACH NEBULIZATION RUN)	The test chamber surfaces were sanitized with wipes imbibed with 6% H_2O_2 solution before and after each run, then dried with sterile wipes after 30 minutes exposure to H_2O_2 . 6 contact plates were used to verify the microbial contamination after the sanitizing treatment. The contact plates were incubated at 30°-35°C for 2 days and then at 20-25°C for 5 days.
	The level of the environmental contamination after test chamber opening and sanitization were monitored during the experimental phase in order to validate the sanitizing procedure using 6 witness placed outside the test chamber. Plates were insubstant at 30° 35° of cr 2 days and then at 30° 35° of cr 3 days
	A bacterial suspension of <i>E. coli K12</i> showing a concentration of 1.5 – 5.0 ×10 ⁷ cfu/ml has been diluted up to the decimal dilutions 10 ⁻⁵ and 10 ⁻⁵ . Each dilution was pour plated in duplicate. The number of colony-forming units per ml has been determined following incubation for 48 hours at 37°C±1°C and the actual count of the microbial test suspension, expressed as N value, was calculated.
EXPERIMENTAL PHASE	The suspension has been nebulized inside the test chamber for 30 minutes. 8 TSA sterile plates were inserted into the test chamber as sedimental plates and distributed in order to cover the entire surface base area. Plates were opened just before closure of the chamber in order to sample and record bacteria touching the lower chamber surface during the exposure time (considering a sufficiently homogeneous dispersion of the aerosolized inoculum). After 30 minutes the nebulization was stopped and the 8 sedimental plates recovered in order to measure the microorganism contamination. Plates were incubated for 48 hours at 37°C±1°C and the number of CFU/plate (Nc) was determined. This procedure has been performed in duplicate, in order to confirm the reproducibility of the adopted experimental conditions and the homogeneous dispersion of the microbial aerosol.
RESULTS	See Addendum N. 1
Conclusions of Method Set-up	Since the suspension dispersed in the air was not stable enough to allow the measurement of surviving microorganisms through the use of SAS, it has been decided to consider the number of surviving microorganisms recovered from the surface base area after nebulization, that ensure a better and reproducible recovery of <i>E. coli K12</i> in the adopted test conditions. Since recovery is not stable for longer contact times after nebulization, the reduction in viable count of bacteria after the use of the device is calculated in comparison to the recovery at time 0.



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BioPharma Product Testing

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NOTE	A preliminary test has been conducted to verify a contact time of 30 minutes, in order to decide the final contact time of the screening phase. The test has been performed in duplicate.		
TEST STRAIN	Escherichia coli K12	DSM 11250	
INOCULUM CONCENTRATION	1.5 - 5.0 x107 cfu/ml		
NEBULIZATION TIME	30 minutes		
CONTACT TIME (AFTER NEBULIZATION)	30 minutes		
PREPARATION AND COUNT OF THE BACTERIAL TEST SUSPENSION	The bacterial suspension up to the decimal dilution The number of colony-fo for 48 hours at 37°C±1 expressed as N value, we	with a concentration of 1.5 – 5.0 ×10 ⁷ cfu/ml has been diluted s 10 ⁻⁵ and 10 ⁻⁵ . Each dilution was pour plated in duplicate. rming units per ml has been determined following incubation °C and the actual count of the microbial test suspension, as calculated.	
PREPARATION OF THE TEST CHAMBER (FOR EACH NEBULIZATION RUN)	The test chamber surface before and after each rund H ₂ O ₂ . 6 contact plates were us treatment. The contact plates were days. The sterilized Collison nut the test chamber via thermostatic water, in or The Collison nebulizer w its content were exposed The level of the environ sanitization were monitor sanitizing procedure usi Plates were incubated a	es were sanitized with wipes imbibed with 6% H ₂ O ₂ solution n, then dried with sterile wipes after 30 minutes exposure to sed to verify the microbial contamination after the sanitizing incubated at 30°-35°C for 2 days and then at 20-25°C for 5 ebulizer - filled with bacterial suspension - was connected to a sterilized glass aerosol delivery tube surrounded by der to obtain a temperature in the aerosol of 20°C ± 5°C. vas connected to the air-flow system. The test chamber and d to the bacterial aerosol for 30 minutes.	
Assay	The device has been pla delivery tube. Then, a ba test chamber for 30 minu 8 TSA sterile plates we distributed in order to c before closure of the ch lower chamber surfac	ced inside the test chamber with the filter near the nebulization cterial suspension of <i>E. coli K12</i> has been nebulized inside the tes. are inserted into the test chamber as sedimental plates and over the entire surface base area. Plates were opened just namber in order to sample and record bacteria touching the e during the exposure time (considering a sufficiently	
	homogeneous dispersion After 30 minutes the nel contact time of 30 minut were recovered and inco the microorganism conta	n of the aerosolized inoculum). bulization was stopped and the device has been left on for a es. At the end of the set contact time, the 8 sedimental plates ubated for at least 48 hours at 37°C±1°C, in order to measure amination. The number of CFU/plate (Na) was determined.	

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BioPharma Product Testing

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	An untreated control (Nc) the initial microbial contami	nas been performed, without t ination inside the test chambe	he device, in order to measure er.
	A bacterial suspension of E minutes.	E. coli K12 has been nebulize	d inside the test chamber for 30
UNTREATED CONTROL	8 TSA sterile plates were distributed in order to con before closure of the cha lower chamber surface homogeneous dispersion	e inserted into the test char ver the entire surface base imber in order to sample ar during the exposure tim of the aerosolized inoculum)	mber as sedimental plates and area. Plates were opened just ad record bacteria touching the ne (considering a sufficiently
	After 30 minutes the net recovered and incubated microorganism contamina	oulization was stopped and for at least 48 hours at 37°C tion. The number of CFU/plat	the 8 sedimental plates were C±1°C, in order to measure the e (Nc) was determined.
INTERPRETATION OF RESULTS	Vitality reduction has been	calculated at the end of the $R = Nc - Na$	process as follows:
	where: R = % Reducti Nc = number of Na = number of	on of vitality cfu/plate in the untreated cor cfu/plate in the test assay at	trol at time 0 the set contact time
	% of Red	duction after 30 minutes of	contact time
	Microorganism	Replica 1	Replica 2
RESULTS	Escherichia coli K12 DSM 11250	99.35	98.81
	% R Average	99	.08
		See Addendum N. 2	
CONCLUSIONS OF PRELIMINARY TEST	The air treatment with STE 30 minutes of contact time It has been decided to mai	RIL AIR PRO resulted EFFE , in the adopted test conditio ntain 30 minutes of contact t	CTIVE against <i>E. coli K12</i> after ns. ime for the Screening phase.

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BioPharma Product Testing

EXPERIMENTAL PROCEDURE	- SCREENING AIR SANITIZATIO	W TEST
NOTE	On the basis of the results maintain 30 minutes as co	obtained in the preliminary test, it has been decided to ntact time for the screening test.
TEST STRAIN	Escherichia coli K12	DSM 11250
INOCULUM CONCENTRATION	1.5 - 5.0 x10 ⁷ cfu/ml	
NEBULIZATION TIME	30 minutes	8
CONTACT TIME (AFTER NEBULIZATION)	30 minutes	
PREPARATION AND COUNT OF THE BACTERIAL TEST SUSPENSION	The bacterial suspension v up to the decimal dilutions The number of colony-for for 48 hours at 37°C±1° expressed as N value, was	with a concentration of 1.5 – 5.0 x10 ⁷ cfu/ml has been diluted 10 ⁻⁵ and 10 ⁻⁵ . Each dilution was pour plated in duplicate. ming units per ml has been determined following incubation C and the actual count of the microbial test suspension, s calculated.
PREPARATION OF THE TEST CHAMBER (FOR EACH NEBULIZATION RUN)	The test chamber surface before and after each run H ₂ O ₂ . 6 contact plates were use treatment. The contact plates were in days. The sterilized Collison nel the test chamber via a thermostatic water, in ord The Collison nebulizer wa its content were exposed The level of the enviror sanitization were monitor sanitization were incubated at	s were sanitized with wipes imbibed with 6% H ₂ O ₂ solution , then dried with sterile wipes after 30 minutes exposure to ed to verify the microbial contamination after the sanitizing ncubated at 30°-35°C for 2 days and then at 20-25°C for 5 bulizer - filled with bacterial suspension - was connected to a sterilized glass aerosol delivery tube surrounded by er to obtain a temperature in the aerosol of 20°C ± 5°C. as connected to the air-flow system. The test chamber and to the bacterial aerosol for 30 minutes. Inmental contamination after test chamber opening and ed during the experimental phase in order to validate the g 6 witness plates placed outside near the test chamber. 30°-35°c for 2 days and then at 20-25°C for 5 days.
ASSAY (TO BE PERFORMED IN TRIPLICATE)	The device has been plac delivery tube. Then, a bac test chamber for 30 minute 8 TSA sterile plates were distributed in order to co before closure of the cha lower chamber surface homogeneous dispersion After 30 minutes the neb contact time of 30 minute were recovered and incul the microorganism contar	ed inside the test chamber with the filter near the nebulization terial suspension of <i>E. coli K12</i> has been nebulized inside the es. e inserted into the test chamber as sedimental plates and ver the entire surface base area. Plates were opened just amber in order to sample and record bacteria touching the during the exposure time (considering a sufficiently of the aerosolized inoculum). ulization was stopped and the device has been left on for a s. At the end of the set contact time, the 8 sedimental plates bated for at least 48 hours at 37°C±1°C, in order to measure nination. The number of CFU/plate (Na) was determined.

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BioPharma Product Testing

				Page: 6 of	
	An untreated control (No the initial microbial conta) has been performe mination inside the te	d, without the device, i est chamber.	n order to measure	
	A bacterial suspension o minutes.	f E. coli K12 has bee	n nebulized inside <mark>t</mark> he	test chamber for 30	
UNTREATED CONTROL (TO BE PERFORMED IN TRIPLICATE)	8 TSA sterile plates we distributed in order to o before closure of the cl lower chamber surfac homogeneous dispersio	ere inserted into the cover the entire sur- hamber in order to ce during the exp in of the aerosolized	e test chamber as se face base area. Plate sample and record b oosure time (consid inoculum).	dimental plates and as were opened just acteria touching the ering a sufficiently	
	After 30 minutes the n recovered and incubate microorganism contamin	ebulization was sto ed for at least 48 ho nation. The number o	pped and the 8 sed urs at 37°C±1°C, in o of CFU/plate (Nc) was	imental plates were rder to measure the determined.	
INTERPRETATION OF RESULTS	Vitality reduction has be where: R = % Redu Nc = number Na = number	en calculated at the R = Nc ction of vitality of cfu/plate in the un of cfu/plate in the tes	end of the process as – <i>Na</i> treated control at time st assay at the set cont	s follows: 0 act time	
	% of B	eduction after 30 n	ninutes of contact ti	me	
	Microorganism	Replica 1	Replica 2	Replica 3	
RESULTS	Escherichia coli K12 DSM 11250	99.44	99.02	99.21	
	% R Average 99.22				
		See Adden	dum N. 3		
CONCLUSIONS	The air treatment with ST 30 minutes of contact tin In particular, the treatme the test organism.	ERIL AIR PRO resume, in the adopted te ent determined an a	Ited EFFECTIVE aga st conditions. verage reduction of §	iinst <i>E. coli K12</i> after 99.22% in viability of	

12		
- 	N. 1: RAW DATA ELABORATION – SET-UP PHASE (3 pages)	· · · · · · · · · · · · · · · · · · ·
ADDENDA	N. 2: RAW DATA ELABORATION - PRELIMINARY TEST (4 pages)	
	N. 3: RAW DATA ELABORATION - SCREENING TEST (6 pages)	

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Analytical Report: AAH97546, Eurofins Number: S ADDENDUM N.1

a eurofins	Prova per la valutazione dell'integrità di chiusum di contenitori verso spore nebulizzate		
S.º Curonnis	(Validation of container closure integrity vs aerosolised spore)		
	byčius (poče) 1 \ 3		

Data nizio (Started on):

ID. studio (ID. Study) :

05/05/2020

STULV20AA1791-1

ID. campione (ID. sample) LV-MAT-F5PH-20-111-0502 a

Bacterial Suspension Concentration

Misseemaline test	N (count test suspension)				
wichorganism test	Dil.	r (cluttere)	<"(cfulplate)		
Escherichia coli K12 DSM 11250	10-5	267	284		
	104	25	29		
	Count (CFU/mi)	2.8E+07	VALID		

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Growth observed after 2 Bays (200-3810	Grawth observed after 8 days (20)-15%	(Cruplate)	Pass/Fail
plate 1	11	1	12	PASS
plate 2	7	0	7	PASS
plate 3	8	D	8	PASS
plate 4	5	0	5	PASS
plate.5	0	0	0	PASS
plate 6	8	2	8	PASS

Microbial control of the room during the assay

Sedimental plates	ilopi A18.	enya 430-	Results (CFU)plate)	Pass/Fail
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collison)	0	1	1	PASS
plate 3 (near collison)	1	a	1	PASS
plate 4 (work bench)	0	D	0	PASS
plate 5 (work bench)	0	0	D	PASS
plate 6 (work bench)	0	a	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Grawth alsonned after 2 days @35. 15°C	driveth absorved after 6 draw @28- JPC	Reseits (CFLVplate)	Pass/Fail
plate 1	12	0	12	PASS
plate 2	13	1	14	PASS
plate 3	8	û	8	PASS
plate 4	16	1	17	PASS
plate 5	9	0	9	PASS
plate 6	5	ū.	5	PASS

No - Sedimental plates into the test chamber

Pedimontal states	Nc - control at time 0
Sedimental plates	(cfu/plate)
plate 1	316
plate 2	284
plate 3	296
plate 4	322
plate 5	330
plate 6	298
plate 7	275
plate 8	288
cfu/plate average	301
Log	2.48

Sigla tecnico (Technician signature): SD _191051-20

Data fine (Finished on): 07/05/2020

Data (Date): 07/06/2020

Sigla Approvazione (Approval signature): 34 2052

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N. 1

💸 eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
	(Validation of container closure integrity vs aerosolised spore)
	Pagina (Page) 2/3

Data inizio (Started on)1

ID. studio (ID. Study) :

05/05/2020

STULV20AA1791-1

ID. campione (ID. sample):

LV-MAT-F5PH-20-111-0502 a

Bacterial Suspension Concentration

Mismonism text	N (count test suspension)			
inicrorganism test	Dil.	s (ctubiste)	x' (ctu/plate)	
Escherichia coli K12 DSM 11250	10-5	267	284	
	10-0	25	29	
	Count (CFU/ml)	2.8E+07	VALID	

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Growth observed after 3 Argn @98-151C	Growth observed after 8 days @Strand	Results (CFU/plate)	Pass/Fail
plate 1	5	D	5	PASS
plate 2	9	1. T	10	PASS
plate 3	12	2	14	PASS
plate 4	8	1	9	PASS
plate 5	6	Q	6	PASS
plate 6	2	Ŭ	2	PASS

Microbial control of the room during the assay

Sedimental plates	slays (§35.	107 @28-	Results (CFU/plans)	Pass/Fail
plate 1 (near collison)	1	0	1	PASS
plate 2 (near collison)	â	0	0	PASS
plate 3 (near collison)	0	0	û	PASS
plate 4 (work bench)	0	D	0	PASS
plate 5 (work bench)	1	0	1	PASS
plate 6 (work bench)	1 1	0	1	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Gravits staarval after 2 Anys @01- 15%	Chevella admentered affer 1 dagen (\$15- 15°C	Results (CPUsplate)	Pass/Fail
plate 1	3	2	5	PASS
plate 2	5	2	7	PASS
plate 3	13	0	13	PASS
plate 4	7	0	7	PASS
plate 5	6	1	7	PASS
plate G	4	0	4	PASS

Nc - Sedimental plates into the test chamber

A section control to before	No - control at time 0
Sedimentar plates	(chulplate)
plate 1	300
plate 2	274
plate 3	252
plate 4	269
plate 5	276
plate 6	292
plate 7	304
plate 8	268
clu/plate average	279
Log	2.45

Sigla tecnico (Technician signature) SD 19 05/00

Sigla Approvazione (Approval signature): OH 21/05/20

Data fine (Finished on); 07/05/2020

Data (Date): 07/05/2020

Analytical Report: AAH97546, Eurofins Number: STI ADDENDUM N.1

💸 eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nabulizzate
	(Validation of container cleaure integrity vs aerosolised spore)
	Pagera (Page) 37 3

Data inizio (Started on):

05/05/2020

ID. studio (ID. Study): STULV20AA1791-1

ID: campione (ID: sample);

LV-MAT-F5PH-20-111-0502:a

Bacterial Suspension Concentration

Miccorrection lost	N (cou	nt test susper	(noizr
microrganistii test	Dil.	in Schulphatabi	X*/c%u(phane)
Escherichia coli K12 DSM 11250	10-5	267	284
	10.6	25	29
	Count (CFU/ml)	2.8E+07	VALID

Microbial control of test chamber after sanitizing treatment (before starting the assay)

provide the second data of the second data was a second data and a	and the second	And the second se	and the second se	the second se
Contact plates	Growth advanced after 1 days @56-05*C	Growth observed alter 3 dags (\$29-22%)	Results (CFU/plate)	Pass/Fail
plate 1	3	0	3	PASS
plate 2	7	2	9	PASS
plate 3	10	1	11	PASS
plate 4	5	D	5	PASS
plate 5	9	1	10	PASS
plate 6	4	0	4	PASS

Microbial control of the room during the assay

Sedimental plates	Augo @36-	04ya 900-	Results (CFLiplate)	Pass/Fail
plate 1 (near collison)	1	0	1	PASS
plate 2 (near collison)	1	0	1	PASS
plate 3 (near collison)	1	0	1	PASS
plate 4 (work bench)	0	0	0	PASS
plate 5 (work bench)	0	0	0	PASS
plate 6 (work bench)	0	0	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Grauth allocited after 2 days @30 38*0	Growth attorned after 5 four gibl- arc	Results (CFU/plate)	Pass/Fail
plate 1	12	2	14	PASS
plate 2	11	0	11	PASS
plate 3	9	2	11	PASS
plate 4	17	0	17	PASS
plate 5	5	1	6	PASS
plate 6	6	0	6	PASS

No - Sedimental plates into the test chamber

Redimental eleter	Nc - control at time 0
Secumental plates	(cfu/plate)
plate 1	268
plate 2	242
plate 3	258
plate 4	279
plate 5	282
plate 6	265
plate 7	242
plate 8	267
ctu/plate average	261
Log	2.42

Sigla tecnico (Techvician algnature): 90 19 108/20

Sigla Approvazione (Approval signature): H Zibsha

Data fine (Finished on) 07/05/2020

Data (Date) 07/05/2020

Analytical Report: AAH97548, Eurofins Number: S' ADDENDUM N.2

and eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
S.º Curonnis	(Validation of container closure integrity vs aerosolised spore)
1	Pagins (Page) 1/4
Data inizio (Started on): 06/05/2020	

ID, studio (ID, Study):

dought of the

STULV20AA1791-1

ID. campione (ID. sample):

LV-MAT-F5PH-20-111-0502.8

Bacterial Suspension Concentration

Microsophiem toot	N (count test suspension)			
inicrorganism test	Dil.	x (chuphate)	x* 60fulpfates	
Escherichia coli K12 DSM 11250	10-8	276	251	
	10.4	29	27	
	Count (CFU/mi)	2.7E+07	VALID	

Preparation of the test chamber - No

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Graveth elescrosed after 3 storys @30-28*%	Grewith theory of alter 5 Steps @08.05%C	Results (CFU/plate)	Pass/Fall
plate 1	12	0	12	PASS
plate 2	4	2	6	PASS
plate 3	9	1	10	PASS
plate 4	5	0	5	PASS
plate ő	10	0	10	PASS
plate 6	7	1	8	PASS

Microbial control of the room during the assay

Sedimental plates	daya gao-	4050 (E11-	Results (CFWplate)	Pass/Fall
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collison)	0	D	0	PASS
plate 3 (near collison)	1	1	2	PASS
plate 4 (work bench)	2	D	2	PASS
plate 5 (work bench)	0	D	0	PASS
plate 6 (work bench)	0	0	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Growth electroni after 2 itage gat- 38/C	Growth observed after 5 days gan- 3N°C	Results (CFU/plate)	Pass/Fail
plate 1	11	0	11	PASS
plate 2	8	0	8	PASS
plate 3	7	Э	10	PASS
plate 4	13	0	13	PASS
plate 5	16	2	18	PASS
plate 6	9	1	10	PASS

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N.2

and eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
A. Caronno	(Validation of container closure integrity vs aerosolised spore)
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ID. studio (ID. Study):

STULV20AA1791-1

ID. campions (ID. sample) LV-MAT-F5PH-20-111-0602:a

Preparation of the test chamber - Na

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Geweilen kier von after 1 einpe @19-05%	Growth observed after a days (200-33°C	Results (CFU/plate)	PessiFall
piate 1	5	0	5	PASS
plate 2	9	1	10	PASS
plate 3	10	0	10	PASS
plate 4	8	0	8	PASS
piate 5	6	3	7	PASS
plate fi	7	1	8	PASS

Microbial control of the room during the assay

Sedimental plates	they gos-	ileys 233-	Reveils (CFU)plate)	Pass/Fail
plate 1 (near collison)	4	0	0	PASS
plate 2 (near collison)	0	0	0	PASS
plate 3 (near collison)	3	1	4	PASS
plate 4 (work bench)	0	0	0	PASS
plate 5 (work bench)	Ö	0	Ø	PASS
plate 6 (work bench)	1	0	T.	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	by swith advant web attern 1 data @30- 30*C	Gravella alcorerand, affair 8 daga galai- 1970	Results (CPU/plate)	Pass/Fall
plate 1	13	2	15	PASS
plate 2	15	2	17	PASS
plate 3	12	D	12	PASS
plate 4	9	1	10	PASS
plate 6	11	0	11	PASS
plate 6	8	0	8	PASS

Assay - Sedimental plates into the test chamber

Redimental winter	Nc - control at time 0	Na - test at 30 minutes	
Social praces	(cfu/plate)	(c/u/plate)	
plate 1	288	1	
plate 2	271	1	
plate 3	256	0	
plate 4	269	3	
plate 5	274	5	
plate 6	243	0	
platu 7	259 1		
plate 6	290	3	
cfu/plate average	200	2	
Log	2.43	0.24	
Log R	2,19		
% of Reduction in visbility	99.35		

Sigla tecnico (Technician signature): SD 191051-20 Sigle Approvasionel (Approval signature): Qet 25(1-(1-)

Data fine (Finished on): 08/05/2020

Data (Date): 05/05/2020

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N.2

💸 eurofins	Prova per la valutazione dell'integrità di chiusura di contenito verso spore nebulizzate	
	(Validation of container closure integrity vs aerosolised spore)	
and the second	Pagina (Poger 3 / 4	
Data inizio (Started on): 06/05/2020		

ID. studio (/D. Study): STULV20AA1791-1

ID. campione (ID. sampie): LV-MAT-F5PH-28-111-0002:a

Bacterial Suspension Concentration

Micromaniam tast	N (count test suspension)			
miner or game in test	DII.	x (chalplate)	x'(chulplate)	
Escherichia coli K12 DSM 11250	10-5	254	271	
	104	21	25	
	Count (CPU/mi)	2.6E+07	VALID	

Preparation of the test chamber - Nc

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	trovik observal alter 2 dept @10-32*0	Growth observed attacks down (\$00-21/10	Results (CFU/ptete)	Pass/Fall
plate 1	9	1	10	PASS
plate 2	5	1	6	PASS
plate 3	6	1	7	PASS
plate 4	10	0	10	PASS
plate 5	12	0	12	PASS
plate 6	8	1	9	PASS

Microbial control of the room during the assay

Sodimental plates	reys @20	20ys (820-	Results (CPUsplate)	Pass/Fail
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collison)	0	0	0	PASS
platé 3 (near collison)	.2	1	Э	PASS
plate 4 (work bench)	0	0	0	PASS
plate 5 (work bench)	3	G	3	PASS
plate 6 (work bench)	3	0	3	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	diasti sisarad shari faya gao 1910	Growth alternised after 8 stays (\$29). 15%	ffemales (CFUIplate)	Pass/Fail
plate 1	9	0	9	PASS
plate 2	12	0	12	PASS
plate 3	18	3	21	PASS
plate 4	16	0	16	PASS
plate 5	7	0	7	PASS
plate 6	20	2	22	PASS

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N.2

🗟 eurofins	Prova por la valutazione dell'integrità di chiusura di contenitori verso epore nebulizzate
Se curonnis	(Validation of container closure integrity vs aerosolised spore)
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ID. studio (ID. Study):

STULV20AA1791-1

ID. campione (ID. sample): LV-MAT-F5PH-20-111-0602-a

Preparation of the test chamber - Na

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Grueth alcorroot after 2 degs @28-0810	Grandt akternet akter å skogn @29-65"C	Results (CFU/plate)	Pass/Fall
plate 1	5	0	б	PASS
plate 2	9	0	9	PASS
plate 3	10	- 4	14	PASS
piste 4	8	1	9	PASS
plate 5	13	1	14	PASS
plate 6	6	1	7	PASS

Microbial control of the room during the assay

Sedimental plates	antes 620	ulays (§23.	Results (CPU/plane)	Pass/Fail
plate 1 (near collision)	0	0	0.	PASS
plate 2 (near collison)	0	1	1	PASS
plate 3 (near collision)	2	0	2	PASS
plate 4 (work bench)	3	2	5	PASS
plate 5 (work bench)	0	0	D	PASS
plate 6 (work bench)	1	0	1	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Growth absenced arter 2 Mays (B32) MPC	Cristik altertool after 1 Bigs gj81- 1970	Pasults (GFU(piste)	Pass/Fail
plate 1	12	0	12	PASS
plate 2	15	-1	16	PASS
plate 3	9	0	0	PASS
plate 4	8	0	В	PASS
plate 5	16	2	18	PASS
plate 6	21	3	.24	PASS
			the second s	and the second se

Assay - Sedimental plates into the test chamber

Codimental elater	No - control at time 0	Na - test at 30 minutes	
Summentar plates	(clw)plate)	(chu/plate)	
plate 1	302	5	
plate 2	274	3	
plate 3	252	6	
plate 4	296	3	
plate 6	283	4	
plate 6	255	2	
plate 7	249	0	
plate 8	267	3	
cfu/plate average	272	3	
Log	2.43	0.61	
Log R	1.92		
% of Reduction in viability	98.81		

Sigia tecnico (Technician signature); 3D 19(05)-20

Data fine (Finished on): 06/05/2020

Sigla Approvazione (Approval signature): OH 21/05/20

Data (Date): 08/05/2020

Analytical Report: AAH97546, Eurofins Number: S' ADDENDUM N.3

a eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
a. curonno	(Validation of container closure integrity vs aerosolised spore)
	Pagna (Fage) 1 / 6
Data inizio (Started on): 12/05/2020	

ID. studio (ID, Study) :

STULV20AA1791-1

ID. compione (ID. sample): UV-MAT-PSPH-20-111-0502.a

Bacterial Suspension Concentration

Sticementing test	N (count test suspension)			
initerorganishi test	Dil.	x (chirphate)	*' (c/tv/plate)	
Escherichia coli K12 DSM 11250	10-5	300	279	
	104	33	28	
	Count (CFU/ml)	2.9E+07	VALID	

Preparation of the test chamber - No

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Cumact plates	Graveth abserved after 2 stays @39-3812	Growth absorved after 5 days @19-26*C	Results (CFU/plate)	Pass/Fail
plate 1	10	1	11	PASS
plate 2	12	0	12	PASS
plate 3	8	0	8	PASS
plate 4	14	3	17	PASS
plate 5	11	1	12	PASS
plate 6	9	0	9	PASS

Microbial control of the room during the assay

Sedimental plates	4482 (\$08-	Heys (200-	Results (CFU)plate(Pass/Fall
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collision)	0	0	0	PASS
plate 3 (near collision)	1	0	1	PASS
plate 4 (work bench)	0	1	1	PASS
plage 3 (work banch)	2	0	2	PASS
plate 6 (work bench)	0	0	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	feys (80) 1870	denn gill- istrc	Measilia (GFWplate)	Pass/Fail
plate 1	11	1	12	PASS
plate 2	8	1	9	PASS
plate 3	9	0	9	PASS
plato 4	5	0	5	PASS
plate 5	12	2	14	PASS
plate 6	14	2	16	PASS

Sigla tecnico (Technician signature): 30 1905/20

Analytical Report: AAH97546, Eurofins Number: STL ADDENDUM N.3

🗟 eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
. curonno	(Validation of container closure integrity vs aerosolised spore)
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ID, studio (ID, Study) : STULV20AA1791-1

ID. campione (ID. sample):

LV-MAT-FSPH-20-111-0502-a

Preparation of the test chamber - Na

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Convects information affine 1 days (\$18-3975	Dreath since on after 5 Mays @38-03°C	Results (CFUIplate)	Pass/Fail
plate 1	5	2	7	PASS
plate 2	7	0	7	PASS
plate 3	10	1	11	PASS
plate 4	12	0	12	PASS
plate 5	9	0	9	PASS
plate 6	6	1	7	PASS

Microbial control of the room during the assay

Sedimental plates	unia Bra-	8445 <u>@</u> 80.	Results (CFU/plate)	Pass/Fail
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collison)	1	0	1	PASS
plate 3 (near collison)	2	0	2	PASS
plate 4 (work bench)	0	1	1	PASS
plate 5 (work bench)	0	0	0	PASS
plate 6 (work bench)	0	D	D	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Crowth observed ofter I Steps 20-	Growth observed attar 5 stays gdo- attra	Results (CFU)glate)	PassiFall
plate 1	B	D.	8	PASS
plate 2	7	2	9	PASS
plate 3	9	0	9	PASS
plate 4	11	1	12	PASS
plate 5	12	0	12	PASS
plate 6	6	0	6	PASS

Assay - Sedimental plates into the test chamber

Redimental elater	No - control at time 0	Na - test at 30 minutes
Secumental plates	(cfu/plate)	(cfu/plate)
plate 1	302	0
plate 2	324	4
plate 3	297	0
plate 4	286	2
plate 5	300	0
plate 6	281	2
plate 7	269	4
plate 8	283	1
cfu/plate average	293	2
Log	2,47	0.21
Log R	2.26	
% of Reduction in visibility	99	.44

Data fine (Finished on): 14/05/2020

Sigle Approvazione (Approval signature); Or ubctuo

Data (Date): 14/05/2020

Analytical Report: AAH97546, Eurofins Number: STI ADDENDUM N.3

💸 eurofins	Prova per la valutazione dell'integrità di chiusura di contenito verso spore nebulizzate		
	(Validation of container closure integrity vs aerosolised apore)		
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Data inizio (Started on) :

12/05/2020

ID. studio (ID. Study) :

STULV20AA1791-1

ID. campione (ID. sample):

LV-MAT-F5PH-20-111-0802:a

Bacterial Suspension Concentration

Microsophism Lost	N (count test suspension)			
microrganism ass	DII.	1)DUSIMB	a transmen	
Escherichia coli K12 DSM	10.8	292	284	
	10 ⁴⁶	29	31	
0.492	Count (CFU/ml)	2.9E+07	VALID	

Preparation of the test chamber - Nc

Microbial control of test chamber after sanitizing treatment (before starting the assay).

Contact plates	Growth observed after 2 days @31 d.F.C	Answitz observed after & mys.(805-200)	Results (CPU/plate)	PassiFail
plate 1	5	0	5	PASS
plate 2	9	0	9	PA38
plate 3	6	2	8	PASS
plate 4	11	0	11	PASS
plate 5	12	1	13	PASS
piate 6	8	1	9	PASS

Microbial control of the room during the assay

Sedimental plates	484 4235-	dins gre.	Roundry (Pringham)	Pass/Fail
plate 1 (near collison)	0	0	0	PASS
plate 2 (near collison)	0	0	0	PASS
plate 3 (near collison)	0	0	0	PASS
plálá 4 (wórk bench)	1	ð	1	PASS
plate 5 (work bench)	0	0	0	PASS
plate 6 (work bench)	0	0	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Grewch winners at after 2 Hoyn gate GPC	Circuit derarises after 3 Bays @20. 2910	Results (CPU/plate)	Pass/Fail
piate 1	9	0	9	PASS
plate 2	6	0	6	PASS
plate 3	8	1	9	PASS
plate 4	14	3	17	PASS
plate 5	16	2	18	PASS
platë 6	7	0	7	PASS

Sigla tecnico (Technician signature): 90 19 1051-26

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N.3

💸 eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate
	(Validation of container closure integrity vs aerosolised spore)
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Data inizio (Started on):

12/05/2020

ID. studio (ID. Study) :

STULV20AA1791-1

ID. campione (ID. sample): LV-MAT-F5PH-20-111-0502:a

Preparation of the test chamber - Na

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Germelle allerer oren arber a darju @30.5810	canada antersea anter p canada antersea anter p	Results (CFU/plate)	Pass/Fail
plate 1	11	1	12	PASS
plate 2	5	0	5	PASS
plate 3	7	0	7	PASS
plate 4	12	1.	13	PASS
plate 5	9	1	10	PASS
plate 6	В	1	9	PASS

Microbial control of the room during the assay

Sedimental plates	days gin.	alays @21-	Results (CFUplate)	Pass/Fail
plate 1 (near collison)	1	0	1	PASS
platé 2 (near collison)	0 U	0	0	PASS
plate 3 (near collison)	0	0	0	PASS
plate 4 (work bench)	2	0	2	PASS
plate 5 (work bench)	0	0	0	PASS
plate 6 (work bench)	з	1	4	PASS

Microbial control of test chamber after sanitizing treatment (after anding the assay)

Contact plates	Growth observed ofter 2 Alget glob- 25%	Growth observed after 8 stays \$32 25%	Results (CPU/plate)	Pass/Fail
plate 1	8	2	10	PASS
plate 2	11	0	11	PASS
plate 3	15	3	18	PASS
plate 4	9	1	10	PASS
plate 5	13	0	13	PASS
plate 6	5	0	5	PASS

Assay - Sedimental plates into the test chamber

Partimental plates	Nc - control at time 0	Na - test at 30 minutes	
aconnentar plates	(crlw/plate)	(cfu/plate)	
plate 1	297	4	
plate 2	258	3	
plate 3	292	6	
plate 4	316	3	
plate 5	279	2	
plate 6	314	1	
plate 7	288	0	
plate 8	305	4	
ctu/plate average	294	3	
Log	2.47	.0.46	
Log R	2	01	
% of Reduction in viability	99	0.02	

Sigla teorico (Technician signature) 80 1965/-26

Data fine (Finished on) 14/05/2020

Sigla Approvations (Approval signature) 04 21/05/20

Analytical Report: AAH97546, Eurofins Number: ST ADDENDUM N.3

a eurofins	Prova per la valutazione dell'integrità di chiusura di contenitori verso spore nebulizzate		
S.º COLOTINS	(Validation of container closure integrity vs aerosol/sed spore)		
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Data inizio (Started on):

ID. studia (ID. Study) ;

12/05/2020

STULV20AA1791-1

ID. campione (ID. sample): LV-MAT-FSPH-20-111-0502.a

Bacterial Suspension Concentration

Micromanian test	N (cou	int test suspension)		
microiganism test	Dil.	n (chulphata)	#" (cfur(okater)	
Escherichia coli K12 DSM 11250	10-8	316	308	
	10*	32	33	
	Count (CFU/mi)	3.1E+07	VALID	

Preparation of the test chamber - No

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	Grant's observed after 2 days @00-38*C	Granth observed after 1 cays (200-2010	Results (CFU/plate)	Pass/Fail
plate 1	13	3	16	PASS
plate 2	5	a	5	PASS
plate 3	16	0	16	PASS
plate 4	8	2	10	PASS
plate 5	9	1	10	PASS
plate 6	8	0	8	PASS

Microbial control of the room during the assay

Sedimental plates	1995 B25	445× @25-	Results (GFU/plate)	Pass/Fail
plate 1 (near collison)	1	t	2	PASS
plate 2 (near collison)	1	0	1	PASS
plate 3 (near collison)	2	0	2	PASS
plate 4 (work bench)	1	0	1	PASS
plate 5 (work bench)	0	0	0	PASS
plate 6 (work bench)	0	0	0	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Contact plates	Greats stoared attor 1 stays gate 18%	Growth statement after 1 Mays @20- 2910	Results (CFUplate)	Pass/Fail
plata 1	9	0	9	PASS
plate 2	8	1	9	PASS
plate 3	16	0	16	PASS
plate 4	8	0	8	PASS
plate 5	17	2	19	PASS
plate 6	5	0	5	PASS

Analytical Report: AAH97546, Eurofins Number: STI ADDENDUM N.3

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Data Inizio (Started on)

12/05/2029

ID. studio /ID. Study) : STULV20AA1791-1

ID. campione (ID. sample): LV-MAT-FSPH-20-111-0602:a

Preparation of the test chamber - Na

Microbial control of test chamber after sanitizing treatment (before starting the assay)

Contact plates	neite Bos-ko.c. Ocomp oppinistist sites 1	Goowth schemined after it 4451 @20-UVC	Resolts (CFU/plate)	Pass/Fail	
siate 1	8	0	8	PASS	
Plate 2	Alate 2 6		6	PASS	
Alate 3	12	2	14	PASS	
plate 4	9	0	9	PASS	
plate 5	14	14 2		PASS	
plate 8	3	0	3	PASS	

Microbial control of the room during the assay

Sedimental plates	4141 S14-	arte Bar-	Results (CFUIplete)	Pass/Fail
plate 1 (near collison)	1	1	2	PASS
pinter 2 (near collision)	(near collision) 0 0		0	PASS
plate 3 (near collison)	1	0	1	PASS
plate 4 (work bench)	0 0		0	PASS
plate 5 (work bench)	i (work bench) 0 6		0	PASS
plate 8 (work bench)	1	0	1	PASS

Microbial control of test chamber after sanitizing treatment (after ending the assay)

Cuntact plates	Grindbabierreitater 1 den @ie- zer:	Crowth absorred after 1 days gam- zint	Results (CPU/yelois)	Pass/Fall	
plate 1	12	1	13	PASS	
plate 2	5	0	5	PASS	
plate 3	9	2	19	17466	
plate 4	6	1	7	PASS	
plate 5	13	0	13	PASS	
plate 6	8	1	9	PASS	

Assay - Sedimental plates into the test chamber

C-dimental plates	Nc - control at time 0	Na - test at 30 minutes (cfu/plate)	
Seduméniai biares	(cfu/plate)		
plate 1	316	0	
plate 2	314	3	
plate 3	279	5	
plate 4	298	0	
plate 5	311	0	
Plate 6	275	4	
plate 7	286	5	
plate 8	319	2	
ciulplate average	300	2	
Log	2.48	0.38	
Log R	2	10	
% öf Reduction in viability	99	0.21	

PRACTICE ARTICLES

The Application of Ultraviolet Germicidal Irradiation to Control Transmission of Airborne Disease: Bioterrorism Countermeasure

PHILIP W. BRICKNER, MD^a Richard L. Vincent, BSc^a Melvin First, ScD^b Edward Nardell, MD^e Megan Murray, MD, MPH, ScD^b Will Kaufman, BSc^a

SYNOPSIS

Bioterrorism is an area of increasing public health concern. The intent of this article is to review the air cleansing technologies available to protect building occupants from the intentional release of bioterror agents into congregate spaces (such as offices, schools, auditoriums, and transportation centers), as well as through outside air intakes and by way of recirculation air ducts. Current available technologies include increased ventilation, filtration, and ultraviolet germicidal irradiation (UVGI)

UVGI is a common tool in laboratories and health care facilities, but is not familiar to the public, or to some heating, ventilation, and air conditioning engineers. Interest in UVGI is increasing as concern about a possible malicious release of bioterror agents mounts. Recent applications of UVGI have focused on control of tuberculosis transmission, but a wide range of airborne respiratory pathogens are susceptible to deactivation by UVGI. In this article, the authors provide an overview of air disinfection technologies, and an in-depth analysis of UVGI—its history, applications, and effectiveness.

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Twenty-first century bioterrorism concerns have created the need for intense review of potential countermeasures.1-9 Our intent is to consider available technologies to protect the occupants of buildings from the intentional release of bioterror agents into indoor congregate spaces through outside air intakes and via recirculation air ducts.¹⁰ Disinfection of air from airborne pathogens can be carried out by means of increased ventilation, filtration, and ultraviolet germicidal irradiation (UVGI). High ventilation rates of spaces occupied by people dilute and remove infectious particles (bacteria, fungi, and viruses). High efficiency particulate air (HEPA) filtration captures and retains particles small enough to be inhaled. UVGI damages the DNA of microorganisms, destroying their ability to replicate and thus rendering them non-infectious.11-12

Although it has long been used in laboratories and health care facilities, UVGI is the air disinfection technology least familiar to heating, ventilation, and air conditioning engineers and the public.^{13–19} UVGI is produced by mercury vapor arc lamps predominately at a wavelength of 253.7 nm, within the UV-C bandwidth of the electromagnetic spectrum (Figure 1). Recent applications have focused on control of tuberculosis transmission, but a wide range of airborne respiratory pathogens are susceptible to inactivation by UVGI. Potential bioterror agents that could be aerosolized maliciously in buildings include those that cause anthrax, ^{5,16-19} smallpox, ²⁰⁻²¹ viral hemorrhagic fevers, ²² pneumonic plague, ²³ glanders, ²⁴⁻²⁹ tularemia, ²⁵⁻²⁷ and drug-resistant tuberculosis.²⁸

Extensive laboratory and model room studies have established that the destructive effect of UVGI on bacterial and viral DNA is related to a combination of two factors: the intensity of UVGI energy to which the infectious particle is exposed, and the duration of the exposure.^{19,29–38} These studies reveal a spectrum of microorganism susceptibility, dependent primarily upon the presence or absence of a cell wall and the thickness of the cell wall (see Table). Since viruses such as smallpox, influenza, and adenovirus lack a cell wall, they are more easily inactivated.³⁴ Common forms of vegetative bacteria are generally intermediate in susceptibility. Spores, such as *B. anthracis* in its usual state outside the body, are most difficult to penetrate by UVGL^{33,36}

As an environmental control technology designed to inactivate micro-organisms, UVGI can be installed through upper room fixtures as well as by placing UVGI lamps inside mechanical ventilation systems. UVGI offers substantial advantages over purging contaminated air by ventilation and collecting contaminants by filtration. These benefits include reduced



Figure 1. Electromagnetic spectrum illustrating UV-C in relation to other UV-bandwidths and visible light.

SOURCE: IESNA Lighting Handbook, 9th Edition; 2000.

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Table. Actinic radiant exposure H at 253.7 nm necessary to inhibit colony formation in 90% (LD90) of organisms (10% survival)

212	(H) Radiant exposure	(K) Decay rate constant	12/10/		Test
Microorganism	$J \cdot m^2$	m² • J ¹	Reference	Type	medium
Bacillus anthracis	45.2	0.051	Sharp 193870	Bacteria	Air
Bacillus anthracis (spores)		0.0031	Knudson 198636	Bacteria	Plates
S. enteritidis	40.0	0.058	Dreyer et al. 193671	Bacteria	Plates
B. megatherium sp. (veg.)	37.5*	0.061	Hercik 193772	Bacteria	Plates
B. megatherium sp. (spores)	28.0	0.082	Hercik 193772	Bacteria	Plates
B. paratyphosus	32.0	0.072	Dreyer et al. 193671	Bacteria	Plates
B. subtilis (mixed)	71.0	0.032	Rentschler et al. 194173	Bacteria	Air
	60.0	0.038	Koller 193974	Bacteria	Air
B. subtilis spores	120.0	0.019	Rentschler et al. 194173	Bacteria	Air
Corynebacterium diphtheriae	34.0	0.068	Sharp 1938 ⁷⁰	Bacteria	Air
		0.0701	Sharp 193975	Bacteria	Plates
Salmonella typhi					
(Eberthella typhosa)	21.4	0.108	Sharp 1938 ⁷⁰	Bacteria	Air
Micrococcus candidus	60.5	0.038	Ehrismann et al. 193276	Bacteria	Plates
Micrococcus piltonensis	81.0	0.028	Rentschler et al. 1941/3	Bacteria	Air
Micrococcus sphaeroides	100.0	0.023	Rentschler et al. 194173	Bacteria	Air
Neisseria catarrhalis	44.0	0.052	Rentschler et al. 194173	Bacteria	Air
Agrobacterium tumefaciens					
(Phytomonas tumefaciens)	44.0	0.052	Rentschler et al. 194173	Bacteria	Air
Proteus vulgaris	27.0	0.085	Rentschler et al. 194173	Bacteria	Air
Pseudomonas aeruginosa		0.2375	Collins 1971 ⁷⁷	Bacteria	Plates
		0.5721	Sharp 194078	Bacteria	Air
	55.0	0.042	Ehrismann et al. 1932 ⁷⁶	Bacteria	Plates
B. pyocyaneus	55.0	0.052	Ehrismann et al. 1932 ⁷⁶	Bacteria	Plates
Pseudomonas fluorescens	35.0	0.066	Ehrismann et al. 1932%	Bacteria	
S. typhimurium	80.0	0.029	Drever et al. 193671	Bacteria	Plates
Micrococcus luteus					
(Sarcina lutea)	197.0	0.012	Rentschler et al. 194176	Bacteria	Air
Serratia marcescens	24.2	0.095	Rentschler et al. 194176	Bacteria	Air
	22.0	0.105	Sharp 193842	Bacteria	Air
	8.3	0.277	Ehrismann et al. 1932 ⁷⁶	Bacteria	
		0.2208	Collins 197177	Bacteria	Plates
		0.214	Riley 197679	Bacteria	Air
		0.4449	Sharp 194078	Bacteria	Air
Dysentery bacilli	22.0	0.105	Drever et al.71	Bacteria	Plates
Shigella paradysenteriae	16.8	0.137	Sharp 193874	Bacteria	Air
Rhodospirillum rubrum					
(Spirillum rubrum)	44.0	0.052	Rentschler et al. 194173	Bacteria	Air
Staphylococcus albus	18.4	0.125	Sharp 193870	Bacteria	Air
	33.0	0.070	Rentschler et al. 194173	Bacteria	Air
	18.4	0.125	Reptschler et al. 194173	Bacteria	Air

(continued on p. 102)

Table (continued). Actinic radiant exposure H at 253.7 nm necessary to inhibit colony formation in 90% (LD90) of organisms (10% survival)

	(H) Radiant Exposure	(K) Decay Rate Constant			Test
Microorganism	J·m ²	m² + J ⁻¹	Reference	Type	Medium
Staphylococcus aureus	21.8	0.106	Gates 1929/1930 ⁸⁰	Bacteria	Plates
80	49.5	0.047	Ehrismann et al. 193276	Bacteria	
		0.0886	Sharp 193975	Bacteria	Plates
		0.3476	Sharp 1940 ^m	Bacteria	Air
		0.0419	Abshire 1981 ⁸¹	Bacteria	Plates
		0.9602	Luckiesh 194615	Bacteria	Air
Streptococcus pyogenes	26.0	0.089	Sharp 1938/3970,75	Bacteria	Air/Plate
(Streptococcus hemolyticus)	21.6	0.107	Sharp 1938 ⁷⁰	Bacteria	Air
		0.6161	Lidwell 1950s2	Bacteria	Plates
		0.1066	Misterlich 198483	Bacteria	Air
Streptococcus lactis	61.5	0.037	Rentschler et al. 194173	Bacteria	Air
Streptococcus viridans	20.0	0.115	Sharp 1938 ⁷⁰	Bacteria	Air
Clostridium tetani	49.0	0.047	Sharp 193975	Bacteria	Plates
Streptococcus salivarius	20.0	0.115	Sharp 193975	Bacteria	Plates
Streptococcus albus	18.4	0.125	Sharp 1939%	Bacteria	Plates
B. prodiaiosus	8.3	0.329	Ebrismann et al. 193276	Bacteria	Plates
Mycobacterium tuberculosis		0.0987	David 1973 ⁸⁴	Bacteria	Plates
		0.4721	Riley 1976 ³³	Bacteria	Air
		0.2132	Collins 197177	Bacteria	Plates
(Tubercle bacillus)	100.0	0.023	Prospeckt Philips ⁸⁵	Bacteria	Plates
Mycobacterium kansasii	100.0	0.0364	David 197383	Bacteria	Air
Mycobacterium avium-intra.		0.0406	David 197384	Bacteria	Air
Escherichia coli		0.0927	Sharp 193975	Bacteria	Plates
		0.3759	Sharp 194079	Bacteria	Air
Haemophilus influenzae		0.0599	Mongold 199284	Bacteria	Plates
Adenovirus		0.0546	Jensen 1964 ³⁴	Virus	Air
		0.0047	Rainbow 197387	Virus	Plates
Vaccinia		0.1528	Jensen 1964 ³⁴	Virus	Air
		0.1542	Galasso 196588	Virus	Plates
Coxsackievinus		0.1108	Jensen 1964 ³⁴	Virus	Air
Influenza A		0.1187	Jensen 1964 ³⁴	Virus	Air
Cryptococcus neoformans		0.0102	Wang 1994 ^{se}	Fundal spores	Plates
Fusarium oxysporum		0.0112	Asthana 1992%	Fungal spores	Plates
Fusarium solani		0.00706	Asthana 1992%	Fungal spores	Plates
Penicillium italicum		0.01259	Asthana 1992%	Fungal spores	Plates
Penicillium diaitatum		0.00718	Asthana 199290	Fungal spores	Plates
Rhizopus nigricans spores		0.00861	Luckiesh 194615	Fungal spores	Air
Cladosporium herbarum		0.00370	Luckiesh 194615	Fungal spores	Air
Scopulariopsis brevicaulis		0.00344	Luckiesh 194615	Fungal spores	Air
Mucor mucedo		0.00399	Luckiesh 194615	Fungal spores	Air
Penicillium chrysogenum		0.00434	Luckiesh 194615	Fungal spores	Air
Aspergillus amstelodami		0.00344	Luckiesh 194615	Fungal spores	Air

Tabular Information adapted from CIE⁵³ and Penn State University Aerobiology.⁵⁷

NOTE: Although data from both air and surface (plate) exposures are intermixed in this table, the LD_{xx} doses for each cannot be compared directly. It is generally much easier to inactivate microbes in the air than on surfaces. In both air and on surfaces the LD_{xx} depends on the exact conditions of each experiment. Susceptibility differences in air between species may reflect differences in the conditions of the study as well as differences proper to the species.

THE APPLICATION OF ULTRAVIOLET GERMICIDAL IRRADIATION \diamondsuit 103

cost, ease of installation and maintenance, and potential effectiveness when used in congregate settings.^{37,38} Applications include commercial and government office buildings, health care institutions, schools, dormitories and barracks, indoor shopping malls, and public transportation facilities, including airplanes.

DISEASE TRANSMISSION THROUGH INHALATION OF DROPLET NUCLEI

Transmission of airborne disease can be understood as a function of the concentration of respirable infectious particles in air. Such particles are called droplet nuclei.39 On average, droplet nuclei are about 3 µm (micrometers) in diameter and, when inhaled, are capable of bypassing the protective mechanisms of the upper respiratory tract and causing infection. Droplet nuclei are thus responsible for human-to-human transmission of many airborne infectious diseases. When a contagious individual coughs or sneezes, sputum droplets containing infectious particles (bacteria, viruses) are released. The larger ones fall to the floor where they adhere to surfaces and dust particles, and are no longer infectious. Smaller particles remain airborne long enough that the moist coating of saliva and mucus evaporates, leaving a residual dry nucleus of the droplet that may include one or more bacteria or viruses.

Inhalation of a single droplet nucleus may be capable of initiating pulmonary tuberculosis in highly susceptible hosts, individuals with AIDS, for instance, whereas more resistant hosts may require larger infectious doses. This implies that there is no specific threshold air concentration below which transmission will not occur. Some bioterrorism agents can be aerosolized and maliciously introduced into congregate settings. Such attacks would present problems for air disinfection technologies that are both similar to and different from those presented by person-to-person transmission. The issues are similar because the control principles are essentially the same, but they differ because the concentrations of infectious agents may be much higher than ordinarily seen with natural infections under usual circumstances.

AIR DISINFECTION TECHNOLOGIES

Building ventilation and directional airflow as protection against airborne infection

A standard engineering approach to the control of airborne infection inside buildings consists of ventilation and directional airflow. Hospital isolation rooms, for example, employ high rates of ventilation to dilute

and remove infectious particles, and directional airflow to prevent them from entering corridors or adjacent rooms. Building codes mandate a range of ventilation rates for various public access buildings, requiring higher rates for schools, for instance, than for department stores. Building ventilation is quantified both as outdoor air volume per unit time per person, and as room air changes per hour (ACH), irrespective of occupancy. After the volume of air entering a room equals the volume of the room, one room air exchange is said to have taken place. In old buildings, natural ventilation occurs through open windows and building leaks. Natural ventilation rates range from as little as one-fourth of an air exchange per hour (0.25 ACH) in a very tightly constructed building to several air exchanges per hour in one less tightly constructed.

Public buildings in industrialized countries are provided with mechanical HVAC systems that usually condition and recirculate most of the returned air, exhausting some and replacing it with outside air to control odors, CO₂ build-up, and air contaminants such as smoke.⁴⁰ Because developers, architects, and engineers are most familiar with these technologies, it is understandable that increased ventilation is often proposed to reduce airborne disease transmission in buildings.¹¹ We will make the case that ventilation is neither the only nor the best method of air disinfection for all airborne threats, including those posed by bioterrorism.

Building ventilation

With a perfectly uniform concentration of particles and uniform mixing of incoming air, 63% of the air and airborne organisms will be removed with each air change.⁴¹ However, under more realistic conditions, when there is an uneven distribution of infectious particles and uneven mixing of fresh air with contaminated air, less than 63% of air and airborne particles are flushed out with each air change.⁴¹ The true decreases per air change that have been measured are in the range of 20% to 60%.⁴²

Another consequence of the uneven distribution of infectious particles in air is that some exposed individuals may inhale multiple infectious doses while others inhale none during the same time period. Mathematical models of airborne infection have been developed to describe the impact of ventilation on the transmission of airborne infectious diseases.^{30,45-45} (See Appendix 1 for an example of applying such a model.)

Building ventilation is often limited by design (capacity of blowers, ducts), comfort (noise, drafts), and by economic consideration (cost of conditioning out-

side air). Whereas an isolation room or intensive care unit may be designed with 12 or more air changes per hour, many public indoor spaces are not. For these reasons, in public indoor spaces where airborne transmission is likely, it is desirable to consider supplementing ventilation with other means of air disinfection, such as air filtration or UVGI. The air-disinfecting effects of these measures have been equated to ventilation for air disinfection purposes only, and termed "equivalent ventilation." That is, when 63% of airborne infectious particles are removed by filtration or inactivated by UVGI, they have produced one "equivalent air change." Particle filters and UVGI do not remove CO₉ or replace O₉, so "equivalency" is limited to air disinfection. Ventilation is still required to serve its usual functions.

Air disinfection by filtration or UVGI follows the same logarithmic clearance relationship described for ventilation. This is a fundamental relationship for all disinfecting processes where a certain percentage of a population of organisms is inactivated with each exposure. One well-mixed air change (produced by ventilation, filtration, or UVGI) inactivates approximately 63% of airborne organisms, a second air change inactivates approximately 63% of the remainder, and so on, producing a logarithmic decay curve. However, because filtered air is recirculated, it may be possible to achieve higher levels of equivalent air changes with filtration at lower cost than by means of outdoor air ventilation, because heating and cooling costs are less. Like ventilation, air filtration requires mechanical airflow and may also be limited by occupant comfort (noise and drafts). UVGI depends on the movement of contaminated lower room air into the irradiated upper room where organisms can be rapidly inactivated. Although low velocity paddle fans have been used to increase air mixing between the lower and upper room, even passive air mixing has been shown to produce useful numbers of equivalent room air changes inexpensively, and without noise or drafts.32.23 For some applications, therefore, UVGI may disinfect air equivalently to high levels of ventilation, but at lower installation and operating costs. Air disinfection in place is especially important for dealing with an unsuspected infectious source, a person, or possibly an attack, where isolation and individual respiratory protection may not be an option.

Air filtration

High efficiency particulate air (HEPA) filters remove over 99.99% of airborne particles that arrive at the filter media.⁴⁵ HEPA filters, often used for infection control, are tested with an aerosol containing monodispersed particles 0.3 µm in diameter, the most penetrating aerodynamic particle size. Filtered recirculated air can be substituted for a portion of outside air. avoiding the cost of heating, cooling, and dehumidifying outside air. Filter technology is used extensively on airliners, where the cost of heating frigid outdoor air at altitude is high. However, as with UV disinfection, HEPA filtration neither removes carbon dioxide nor adds oxygen, so that adequate outdoor ventilation for these purposes is always necessary. The limitations of HEPA filtration for air disinfection are similar to those of increasing building ventilation rates to control transmission of infections diseases, i.e., the need for high levels of progressively less efficient air changes. Also, HEPA filters generate resistance to airflow, necessitating more powerful fans that produce noise and vibration. Filters are costly and must be changed periodically. To be fully effective, HEPA filtration systems must be leakproof. They require careful routine maintenance,10 as do all systems that are counted on to perform a critical function. Another limitation particular to portable air filtration units is the potential to reentrain already filtered air because the unit's intake and exhaust locations are usually necessarily close to one another. This short-circuiting reduces the efficiency of air disinfection by filtration.

Ultraviolet germicidal irradiation (UVGI)

History of UVGI research. Disinfection of air in the upper part of rooms using ultraviolet energy has been studied as a public health strategy to control transmission of airborne disease since investigations by William Firth Wells in the 1930s at the Harvard School of Public Health^{47,48} Dr. Richard Riley and colleagues advanced this work at Johns Hopkins Medical School with a focus on tuberculosis control.^{40,50}

Streptomycin, the first of a series of anti-tuberculosis antibiotics, became available in 1946, followed by isonicotinic acid hydrazide (INH) in the 1960s. It came to be generally believed that the TB problem would be solved by antibiotic therapy, and enthusiasm for ultraviolet air disinfection waned. The sanitarium movement ended in the same period. But in 1985, contrary to predictions, the United States national TB case rate increased for the first time in the 20th century, fueled in part by transmission in homeless shelters, prisons, jails, hospitals, and other congregate settings. One of the results of this upswing in TB transmission was renewed interest in the potential value of UVGI to prevent TB transmission.

Although United States TB case rates are once again in decline, there is growing concern about the spread of the disease, including multidrug resistant strains, in many parts of the world, especially in sub-Saharan Africa, parts of Asia, and in the former Soviet Union. Transmission in hospitals, prisons, refugee camps, and other congregate settings is of greater concern, and practical methods for protecting building occupants are needed. The Tuberculosis Ultraviolet Shelter Study (TUSS), a large clinical trial of the efficacy of UVGI to reduce TB transmission in congregate settings, is being conducted from Saint Vincent's Hospital in New York and the Harvard School of Public Health.⁵¹ The threat of bioterrorism (including multidrug-resistant TB) in this country is a significant reason to reconsider the application of UVGI.

Experimental evidence of UVGI effectiveness. The scientific development of UVGI began with research on the intrinsic susceptibility of microorganisms to ultraviolet energy. Ample experimental data exist concerning the quantity of UVGI energy needed to inactivate microorganisms in the air, on surfaces, and in water.52 Our discussion is concerned only with UVGI applications for air disinfection. Laboratory and model room experiments have compared the clearance rate of microorganisms by UVGI alone to the number of additional room air changes required to produce the same effect. Both early and recent studies indicate that properly installed UVGI lamps in the upper portion of a normally ventilated room can disinfect air of aerosolized mycobacteria in the range of 10 to 20 ACH equivalents.23,41

Species susceptibility to UVGI

The range of susceptibility for bacteria extends from streptococcus species, the most susceptible; to Mycobacterium tuberculosis (MTb), the agent for tuberculosis, moderately susceptible; to the spore forms of bacteria (such as anthrax outside the human body), the least susceptible. Although effective UVGI doses have been established for a wide range of microbial species, many of these doses were determined for organisms on surfaces rather than in aerosolized form (see Table). Thus the results of these studies may overestimate the dose needed, because it is far easier to inactivate airborne organisms than those bound to surfaces. MTb is both moderately susceptible to UVGI and a significant human pathogen, and therefore has often been used as a reference organism when UVGI exposure requirements are determined for individual pathogens. For example, a dose of UVGI that inactivates MTb will be more than adequate to inactivate respiratory viruses, such as measles, influenza, and presumably smallpox.

To destroy all the infectious particles in a quantum of airborne organisms by UVGI exposure requires a much higher dose than to destroy, for example, 90% of the pathogens, in part because of biological variation in susceptibility. For each microbial species, an experimental dose-response curve varies with environmental exposure conditions such as humidity, temperature, and particle size. Fractional survival of bacteria exposed to UVGI is described in a mathematical expression detailed in Appendix 2. This expression is used to estimate UVGI effectiveness for the destruction of specific airborne infectious organisms in a range of ventilation and UV energy settings.

To summarize, current data indicate that the incident UVGI radiant quantity required to inactivate infectious particles relates to the:

- Microbial species and its ability to recover from damage induced by UV radiation;
- Presence of sufficiently high radiant exposure dose over time;
- Degree of relative humidity.

Accurate data on the impact of these factors are essential for planning UV air disinfection, but exist for only a limited number of species of interest for naturally transmitted infection, and for even fewer agents with bioterrorism potential.

To develop practical application of UVGI in highrisk settings, Riley conducted bench-scale studies during which he exposed both virulent and non-virulent bacillus Calmette-Guérin (BCG), tubercle bacilli, and other organisms to UVGI energy of known intensity and duration under conditions of controlled temperature and humidity.38 These studies demonstrated a 90% lethal dose (LD₉₀) for virulent TB and for BCG of 12 seconds exposure at 50 µW/cm², or 60 seconds at 10 µW/cm2.35 It is relatively easy in practice to produce UVGI intensity in the 10 to 50-µW/cm2 range in the upper room using available UVGI fixtures and lamps. Because rapid overexposure could occur at these intensities, guidelines for maintenance and safe operation of UVGI systems require deactivation when people are at work in the overhead disinfection zone. From these experiments, Riley and other investigators began testing the effectiveness of UVGI in model rooms where neither the average dose nor duration of exposure for test organisms could be estimated a priori.

Model room studies

Evidence that upper room UVGI energy provides useful air disinfection is derived from experiments in model rooms.^{20,32,53-85} Test organisms have been aerosolized into these spaces and their disappearance rates with and without UVGI measured by quantitative air sampling. A characteristic study used BCG aerosolized
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into a naturally ventilated 18.6 m² (200 ft²) room.³³ A single 17-watt UVGI lamp irradiating the upper part of the room added the equivalent of 10 ACH to the ambient ventilation of two ACH. Two UVGI lamps producing a total of 46 watts irradiating the upper room added the equivalent of 33 ACH to the ambient ventilation of 4 ACH (see Figure 2).

Model room experiments with other test organisms have shown that air disinfection in the lower room can be improved by increasing the dose of UVGI in the upper room.³⁵ This effect has been amplified further by increasing air mixing, either through the use of fans or by increasing temperature gradients between the upper and lower room, which also improves air flow. Air mixing is essential for effectiveness of UVGI air disinfection, because the infectious particles must be transported to the irradiated zone.22,56,57 A source of heat in the room increases convection currents and air mixing. It should be noted here that heat flows from an adult human being at the equivalence of a 100-watt incandescent light bulb.58 This finding is based on studies revealing that humans emit 400 BTU per hour during light activity, a well-established figure from physiologic studies, and that an incandescent bulb emits 3.41 BTU-per-watt rating.

Figure 2. Disappearance of aerosolized bacillus Calmette-Guérin (BCG) from room air with and without upper room ultraviolet (UVGI) irradiation using one suspended fixture with one 17 W lamp.



AC/hr - air changes/hour

Y-axis – vlable colonies remaining in air X-axis – duration of exposure to UVGI

SOURCE: adapted from Riley.34

APPLYING UVGI

Upper room application of UVGI in congregate settings

The rationale of UVGI applications is that germicidal irradiation (UVGI, 253.7 nm) placed in the upper part of occupied spaces will safely and effectively interrupt the transmission of certain airborne human infectious disorders, e.g., such common diseases as influenza, adenovirus infection, measles, and tuberculosis. Depending on the UV susceptibility of the organisms and the mode of transmission, agents of potential bioterror concern are assumed to respond in a similar way. Inactivation of microorganisms occurs when they reach the UVGI zone. Vigorous upflow of air rapidly brings infectious particles into the upper room. The more vigorous the upflow, the shorter the stay of the particles per pass within the zone, but the more passes per unit time. For a fixed UVGI intensity there is a theoretical optimal duration of UVGI exposure that will maximize the inactivation of organisms in a room. The optimal duration can be computed from knowledge of UVGI lamp (bulb) energy output, fixture (lamp holder) configuration and placement, room geometry, and ventilation/air circulation patterns. In practice, this computation is seldom made because the duration of exposure required for lethal effect using current UVGI technology is so short that room air mixing is the rate-limiting factor.

UVGI systems are designed so that fixtures generate a controlled zone (Figure 3) of radiation in the space well above occupant's heads. Fixtures are distributed in rooms to provide coverage of as much of the below-ceiling area as is practical. Infectious particles are brought into the UVGI beam by air currents

Figure 3. Section view of wall-mounted UVGI fixture irradiating the upper room space over a hospital bed

Arrows Indicate convection currents.

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generated by body heat, ventilation systems, occupant motion, fans, and other factors. When infectious particles enter the beam, UVGI energy damages the DNA, interfering with replication, and thereby rendering the microorganism noninfective.

The application of UVGI faces practical limits related to old building structures, but new construction can be planned to accommodate UVGI placement. For example, building plans can be modified to adjust floor-to-ceiling height and to optimize space utilization so that UVGI can be installed in conjunction with HVAC designs. These factors demand careful planning of UVGI fixture placement in relation to room geometry and ventilation mode to secure maximum inactivation of infectious agents. This must be achieved while maintaining safety in concordance with daily threshold limitation values for human UVGI exposure.

As noted, the effectiveness of UVGI can be compared to ventilation in terms of equivalent air changes, and can be estimated, although not readily measured for each application, as exposure of test organisms requires. As an example, in a room normally ventilated by six air exchanges per hour, adding an upper room UVGI system might achieve the air-cleansing equivalent of approximately an additional 10 to 20 ACH.

A model of upper room UV air disinfection has been constructed that takes into account both air mixing and upper room inactivation of organisms, based on experimental data. For the purposes of this discussion, we will assume that a minimum number of 10 lower room air volumes pass through the upper room UVGI exposure zone per hour. With the following assumptions, the required exposure time for inactivation of an infectious airborne particle can be calculated: (a) the room height is 2.4 m (8 ft.); (b) the lower 1.2 m (4 ft.) of air circulate vertically through the upper 1.2 m (4 ft.); (c) the average height from which the lower 1.2 m (4 ft.) of air rises is two feet above the floor (the midpoint of the lower 1.2 m [4 ft.] air layer); (d) an amount of air equivalent to 20 times the lower room volume circulates through the upper room each hour (to provide the equivalent of 10 complete upper room volume air changes); (e) the irradiation zone is the upper 0.7 m (2 ft.) of the room.

Based on these assumptions, air travels 1.8 m (6 ft.) up and 1.8 m (6 ft.) down 20 times per hour, or at the velocity of 1.2 m (4 ft.) per minute. Air is in the UVGI zone for two feet during travel up and two feet during travel down for each air turnover through the upper zone. For infectious particles in the air, this is the equivalent of a one-minute exposure to a minimum of Figure 4. Placement of UVGI lamps in air ductwork (section view) with UVGI lamps placed perpendicular to the airflow



10 µW/cm² of UVGI, an exposure time-intensity product that corresponds to Riley's experimentally determined dose for 90% kill rate. This calculation is conservative in that it neglects horizontal travel of air within the upper 0.7 m (2 ft.), the irradiation zone.

UVGI in-duct systems

TB control guidelines recommend the use of the induct systems strategy for disinfection of air (see Figure 4).11 Currently, however, no public or private database exists for designing applications of UVGI within air ducts and ensuring "kill" rates adequate for the proposed use. Several recent studies have developed methods to predict the rate of air stream disinfection produced by in-duct UVGI systems.59,60 These studies allow better understanding of the physical location of UVGI lamps (whether in the supply duct near the coil or in the return duct near the filter) and the radiation densities required, given the multiple reflections that occur within the duct when common ductwork materials are used.59 Ongoing studies are being conducted by the heating, ventilating, air conditioning, and refrigeration industry to map UVGI intensity distribution within ductwork, UV lamp and ballast characteristics, air velocity impact on time in the "kill" zone, and the impact of temperature and humidity on effectiveness.61 Other factors under study include the susceptibility of microorganisms to UVGI coupled with photocatalytic in-duct coatings used to remove air contaminants. While much information exists, it is not as yet integrated into a whole building systems approach.

TECHNICAL OBJECTIVES

Engineering aspects of UVGI

For most purposes, upper room UVGI is applied using long-established guidelines based on early experiments. Usually no attempt is made to quantify either the equivalent air changes produced or the contribution

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of ventilation to air mixing. However, these measurements can be made for research purposes and for critical applications using a mathematical UV effectiveness index.62 A detailed evaluation of UVGI air disinfection requires qualitative and quantitative descriptions of the ventilation systems in buildings. This information is obtained by on-site measurements of air change rates and air mixing factors determined from tracer gas techniques. If mechanical ventilation is present, exhaust and supply airflow is measured using a flowhood, such as an Alnor Balometer, room dimensions and population density, photographs, and other relevant descriptors. The influence of open windows and doors on interior airflow patterns must also be evaluated with respect to air change ratios, mixing factors, and UVGI exposure intensity and duration. Although the latter will change with climatic conditions, so will mechanical ventilation conditions, for example, between heating and cooling periods of the year.

Upper room UVGI could be more effective if it were feasible simply to flood the space with very high levels of UVGI energy. However, this cannot be done because of human safety issues related to external eye irritation (keratoconjunctivitis) and skin erythema. UVGI fixtures are designed for maximum upper room irradiation while limiting exposure to room occupants. Current fixture designs rely on deep louvers to prevent overexposure at eye level or excessive reflection from low ceilings. However, louvers absorb a large fraction of potentially useful UV energy, rendering current UVGI fixtures inefficient. In the future, more efficient fixture designs are likely to utilize precise parabolic reflectors to direct UV beams from powerful, pencil-thin sources.

Among the factors that determine UVGI fixture placement are the characteristics of the ventilation system, safety considerations, occupancy patterns, existing structural limitations, cost, and maintenance. Placement of UVGI fixtures is not practical in some spaces. A minimum ceiling height of 2.4 m (8 ft.) is required to assure that direct UV irradiation is above eye level. The higher the ceilings, the better for UVGI air disinfection purposes, from both the safety and efficacy perspectives. For spaces with lower ceilings, UVGI duct irradiation devices must be employed.11 Also, there may be features of a room or its furnishings, such as podia or bunk beds, that can effectively raise the eye level of occupants above 1.8 m (6 ft.). UVGI applications inside of air ducts may be particularly appropriate in such spaces.

Practical and safe use of UVGI energy sources

Human safety is always the prime consideration, and modern UV systems are designed to recognize this concern. Two side effects are known to occur following human overexposure to UV-C energy. These are skin reddening (erythema, akin to sunburn) and photokeratitis (external eye inflammation).

UVGI lamps emit 90% of their radiant energy as UV-C at 254 nm and 10% at other UV and visible wavelengths. UV-C is "short-wave" radiation, almost totally absorbed by the stratum corneum of the skin. Therefore, it does not produce a significant degree of sunburn even after inadvertent extensive skin exposure, although it can cause a mild erythema. However, the cornea of the eye is very sensitive to UV-C and, with overexposure, a painful photokeratitis can occur. This effect is well known, for instance, among arc welders not properly protected. UV photokeratitis clears in 24 to 48 hours, without sequellae. UV-C energy does not penetrate the cornea, and therefore adverse effects on the lens and retina are not possible in reallife scenarios, even for those who have had their eye lenses removed during cataract surgery (aphakia). In consideration of safety issues, it is important to remember that human exposure to UV from sunlight when outdoors is several orders of magnitude greater than exposure indoors from upper room UV in the lower part of the room. Sunlight contains longer wavelength UVA and UVB, known to be responsible for skin cancer and some forms of cataracts63,64 (Personal communication, DH Sliney, October 3, 2002).

Correctly installed UVGI does not produce photokeratitis or skin erythema. The Tuberculosis Ultraviolet Shelter Study (TUSS), for example, has placed UVGI in 12 shelters in five cities, and has noted no eye or skin complaints since TUSS started in 1997, despite periodic questionnaires soliciting such symptoms.

In current UVGI applications, the fixtures are placed well above eye level (>2m). Thus there exists little potential of UV overexposure for room occupants. Maintenance staff who may need to work in the upper portion of the space (such as for painting the ceiling or changing bulbs) must be trained to turn off the UV system during that time (and then must remember to turn it on again!).

We recommend UVGI fixtures designed to contain UVGI lamps that produce intensities of at least 50 μ W/cm² at a 1 m (3 ft.) distance and at least 10 μ W/cm² (centerline) at about 3 m (10 ft.) from the UVGI lamp. Depending on the room configuration, wallmounted fixtures containing one or two 17-watt lamps per 20 m² (200 ft.²) of ceiling space are usually approTHE APPLICATION OF ULTRAVIOLET GERMICIDAL IRRADIATION | 0 109

priate. Suspended fixtures are often used for larger areas with high ceilings because wall-mounted fixtures may be too distant from the central air space. Some suspended fixtures contain lamps that distribute UVGI horizontally over 360 degrees.

The American Conference of Governmental Industrial Hygienists (ACGIH) has issued guidelines on the safety exposure limits for UV-C that are currently used by the National Institutes for Occupational Safety and Health (NIOSH).⁵⁵ ACGIH recommends threshold limit values (TLVs®), under which most persons can work consistently for eight-hour periods without adverse effects. The TLV® for UV-C exposure is 6.0 mJ/cm2 for an eight-hour exposure. Exposure above 6.0 mJ/cm2 during an eight-hour period may result in erythema of the skin and photokeratitis. Despite this safety threshold, estimating the actual exposure of room occupants is not simple. If eye and skin exposure were uniform and continuous, one would reach a total dose of 6.0 mJ/cm² at an irradiance of 0.2 µW/cm². For many years, this value was inappropriately applied as an upper limit for UVGI intensity at eye level in rooms where upper room UVGI was in use. In reality, however, blinking of eyelids, shading from brows, turning of the head, and numerous other factors normally limit human eye exposure to the maximum irradiance in the lower room with UVGI to a small fraction of the time that a person spends in the room. These same factors normally protect human beings out of doors from photokeratitis due to sunlight exposure.

Louvers on many current commercial UVGI fixtures are designed to prevent exposure of more than 0.2 µW/cm² at eye level. This design, however, reduces UVGI output and sacrifices upper room efficacy in order to achieve unnecessarily low levels in the lower room. Personal monitoring of UV exposure using miniature UV meters has shown that individuals occupying rooms with eye level irradiance several fold in excess of 0.2 µW/cm¹ actually receive only a small fraction of the eight-hour TLV^{9,66}

Where should UVGI be applied today?

UVGI should be considered as a component of emergency preparedness plans for existing public buildings and a wide range of congregate settings. Illustrations of UVGI application are shown in an excerpt from an architectural plan (Figures 5a and 5b). All of these areas could be covered by commercially available upper room UVGI equipment, and would be more practical for air cleansing than installation of costly filtration or separate air handling systems. Guidelines for upper room UVGI placement have been published.^{37,38} Less well understood is where to place UVGI lamps within ductwork. CDC 1994 Guidelines for TB control can be used as a starting point.⁵³

WHAT WORK NEEDS TO BE DONE?

An unrecognized opportunity exists to integrate UVGI as a subsystem within existing buildings and those under design post-September 11, 2001. Upper room UVGI can be easily installed in vulnerable areas within buildings at a small fraction of the cost of installing high efficiency filtration. Additionally, there is a need to establish quality control measures to assure that each of the strategies (filtration, dilutional ventilation, and UVGI) function as intended. These measures require an initial commissioning process and continued maintenance and monitoring. Training will be necessary to bring design and application tools to developers, engineers, and architects.

Bioterrorism concerns have caused an enhanced interest in the development of UVGI in indoor public spaces and large buildings. Additional studies will focus on UVGI efficacy in defined structures, definitive testing for the UVGI dose required to inactivate a wide range of specific pathogens, dosimetry, personal UVGI monitors, standardization of methods to test UVGI system components (lamps, fixtures, ballasts), and the development of design guidelines and computer programs for UVGI applications in high-risk settings.

The integration of ventilation, filtration, and UVGI technologies is the wise approach to airborne disease mitigation for entire buildings, based on the range of infectious agents to be neutralized. The final intention is to achieve energy-efficient and biologically effective control. Basic principles are understood and now require development into guidelines for manufacturers, developers, architects, and engineers.

APPENDIX 1. APPLICATION OF INCIDENCE OF INFECTION MODELS

In these models, the incidence of infection (λ) at time t is a function of the prevalence (Pr) of infectious cases at time t, the average pulmonary ventilation rate per person (p), the duration of the exposure (d), the outdoor air ventilation rate (v), and the number of doses of airborne infection added to the air per unit time by each infectious person (q).

Assuming that the number of infectious cases is constant, the cumulative incidence (CI) of infection is:

$$CI = S(1 - e^{\lambda t}) = S(1 - e^{P_T * q * p * d/z})$$



Figures 5a and 5b. UVGI fixture placement for circulation corridors and congregate settings (dining area) in plan view

In this expression, the incidence rate (λ) is equivalent to the total number of doses per unit volume of air per unit of time. Note that the terminology used in this expression, the Wells-Riley equation, reflects current epidemiology convention and differs slightly from that used to describe the probability of airborne infection in earlier publications.^{41,67} Dividing through the equation by *S* (susceptibles) yields an expression for the fraction infected among those exposed, or the probability of infection, $(1 - e^{2h \cdot q \cdot p \cdot d/q})$. Plotting the probability of infection as function of ventilation with outside air (v) in volume per unit time for various values of Pr, *q. p.* or *d.* generates a family of logarithmic decay curves.

Figure 6 shows two examples of such curves derived from two actual tuberculosis exposures.^{68,69} The two labeled points, "ICU" and "Office building" reflect the probability of infection $(1 - e^{\frac{n}{2} e \frac{n}{2} e^{\frac{n}{2} e \frac{n}{2} e^{\frac{n}{2} e^{\frac{n$ the figure. Assuming that all other factors (Pr, q, p, d, and S) remain constant, the curves represent the theoretical probability of infection predicted for increasing or decreasing ventilation (v) above or below the actual values.

Although plotted on the same axes, the curves cannot be compared directly to one another because the actual ventilation rate per occupant and the room air changes resulting from the ventilation rate in each exposure were very different. The purpose of their juxtaposition is to illustrate one circumstance, the ICU exposure, where actual room total outdoor air ventilation was well below recommended levels and where easily achievable increases in ventilation from the actual value are predicted to result in substantial decreases in risk. The exposure conditions result in a data point high up on the vertical limb of the curve, where small changes in ventilation result in large changes in risk. In contrast, in the office building, Figure 6. Probability of infection as a function of ventilation. These curves are the result of modeling actual exposures, using the Wells-Riley mass-balance equation. In the intensive care (ICU), baseline ventilation was poor, and modest increases would result in marked reductions in transmission. In the office building, baseline ventilation was much better, and major increases would still leave many occupants unprotected.



SOURCE: Nardell EA, Keegan J, Cheney SA, Etkind SC. Airborne infection. theoretical limits of protection achievable by building ventilation. Am Rev Respir Dis 1991;144:302-6:

exposure ventilation was only slightly below national standards. Achievable increases are relatively modest and, therefore, result in a smaller decrease in risk. In this case, the actual data point is near the bottom of the vertical limb of the curve, where each additional infection averted requires a larger and larger increase in ventilation.

A simple way to think of the relationship between risk of infection and ventilation is that each doubling of ventilation reduces the remaining risk by approximately half. The ICU exposure was brief (2.5 hrs during a bronchoscopy and intubation), but intensive (i.e., gestimated at 250 infectious doses generated per hour), during which 10 of 13 (80%) exposed individuals were infected. Ventilation was so low (150 cfm) that it would be realistic to double it, and even double that value again and again, resulting in protection of almost all of the exposed susceptible occupants. However, the office building exposure was longer (30 days), but much less intensive (q estimated at 13 infectious doses generated per hour), resulting in infection of 27 of 67 (40%) exposed workers. In this case, increasing ventilation from the existing 15 cfm outdoor air per occupant (1450 cfm) to the currently recommended 20 cfm would be possible, but is predicted to protect only a few of the 27 workers infected. Even doubling ventilation to 2900 cfm (30 cfm per occupant-highly unusual

for an office building-would have protected only about half of those infected, according to the equation.

APPENDIX 2. MICROORGANISM SUSCEPTIBILITY TO UVGI EXPOSURE

The fractional survival of microorganisms exposed to UVGI is expressed in the relationship shown in the equation below. While this equation gives a straight line in semilogarithmic representation, many microorganisms show deviations at the end, e.g., tailing.

$$\frac{N_s}{N} = 10^{-k \cdot H_0}$$

where

N_a = number of bacteria exposed

N = number of bacteria surviving after an

exposure to UVGI

 $H_0 = fluence, J/m^2$

K = decay rate constant (microbe susceptibility factor), m²/J

This relationship was used to develop Table 1.

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UV Disinfection - Application Information

Perfection Preserved

by the purest of light



PHILIPS

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PREFACE

Polution of the macro and micro environment has caused concerns for decades and in recent times the macro consequences have been subjected to agreed international protocols, aimed at reducing pollution. Additionally, national and international laws now exist to limit the existence of micro-organisms, particularly those which affect human, animal and bird health in the environment and the food chain, A consequence of this concern has been that pollution reduction is now an industry, covering areas such as changing technologies to reduce primary and consequential pollution and chemical, biological and physical cleaning, included in these techniques is disinfection using ultraviolet C radiation (UV-C), which has the benefits of being both efficient and arguably the most energy effective technology.

UV-C disinfection has a long and honourable history in cleaning room air. However, growth in other applications such as high tech volume liquid treatment and domestic ponds has expanded growth, whilst surface treatment of food has been used to extend shelf life in supermarkets, resulting in less waste food and lower stockholdings.



Whilst UV-C can be used as the exclusive solution in some applications, it is often used in tandem with other techniques. It follows that a single technology solution approach is unlikely to be ideal. It also follows that since UV-C is so simple and energy effective, it is perhaps wise to consider this option first.

Philips Lighting has been closely associated with progress in this field by developing, manufacturing and marketing lamps generating UV-C and continues to research new lamp configurations. This brochure is the fourth survey of information to be aimed at production and technical staff in organisations where micro-organisms present problems. Micro-organisms such as bacteria, moulds, of free radicals, which are often highly labile and yeast's and protozoa can be destroyed or which can react together to produce an inert end product. For disinfecting these effects are produced by wavelengths below 320nm, photolytic effect whereby the radiation with the optimum effect occurring at around 260nm. The phenomenon whereby so that it can no longer multiply.

For DNA it does this by causing adjacent thymine bases to form a chemical bond thus creating a dimer and if sufficient of these are created DNA cannot replicate. Some micro-organisms can repair themselves by absorbing UV-A. In other cases UV-C (and indeed UV-A or UV-B) can cause bond splitting in a molecule resulting in the creation

of free radicals, which are often highly labile and which can react together to produce an inert end product. For disinfecting these effects are produced by wavelengths below 320nm, with the optimum effect occurring at around 260nm. The phenomenon whereby micro-organisms can be disfigured or destroyed is independent of host state (fluid or solid) and indeed pH or temperature, the important feature of the action is that radiation can reach the organism; this means that a bacterium shadowed by another or by a particle will escape attack. Unlike other techniques, UV-C photolysis rarely produces potentially dangerous by-products.



I. Micro-organisms

GENERAL

Micro-organisms are primitive forms of life. Their small dimensions not only constituted the original reason for classifying them separately from animals and plants but are also relevant to their morphology, the activity and flexibility of their metabolism and their ecological distribution. They include protozoa, bacteria and moulds.

Cellular death in the case of micro-organisms refers to the loss of the ability to grow and to multiply, or in practical terms, to the loss



Fig I. The main components of a typical bacterial cell.



Fig 2. Some examples of bacteria varieties.

of the ability to cell divide. Sterilization means that all micro-organisms are killed.

Pasteurization or the use of preservatives lead to reduction of the total amount of micro-organisms. Disinfection may be achieved through moist heat, dry heat, filtration, chemical agents and UV radiation.

I.I BACTERIA AND BACTERIAL SPORES I.I.I BACTERIA

Bacteria is the name given to a large group of organisms, which can be both uni and multicellular; they have a simple nuclear mass, and multiply rapidly by simple fission. The structure of typical bacterial cell is shown in Fig. 1 and examples of their shapes are given in Fig. 2.

Bacteria occur in air, water, soil, rotting organic material, animals and plants. Saprophytic forms (those living on decaying organic matter) are more numerous than parasitic forms; the latter include both animal and plant pathogens. A few species of bacteria are autotrophic, i.e. able to build up food materials from simple substances.

. . 2 BACTERIAL SPORES

Bacterial spores are resistant to extreme conditions, such as high temperatures and dryness; for instance some bacterial spores, can stand a temperature of 120°C without losing their capability for germination. Viable spores of bacillus subtilis have been found in earth that has been dry for hundreds of years, thus demonstrating their ability to survive under extremely unfavourable conditions.

.2 MOULDS AND YEASTS



Fig 3. Brewer's yeast (Saccharomyces cerevisiae) in various stages of development: a Various forms b. Yeast cel with spores c. Yeast spores d. Yeast spores after germination.

1.2. MOULDS

The variety of moulds is immense and they are found everywhere. Many are saprophytic, causing food spoilage resulting in enormous damage; some are pathogenic (parasitic). Eig 5. Life cycle' of spore formers.



Fig 4. Mould culture, as seen through the microscope, showing the fungus mycelium with spores forming as beads at the extremities. These spores detach as the result of the formation of further spores pushing from behind. In the photograph many spores have aready become detached and begun to move away freely.

Amongst the diseases caused by moulds, the most frequent are fungal infections of the skin and diseases of the mucous membranes.

Certain kinds of mould form antibiotic substances; these have given rise to the highly important antibiotics industry. Penicillin and streptomycin are early examples. A mould (see figs. 4 and 5) consists of a mycelium and special structures, (sprorangia and conidiophores, for example), which result in the formation



mould spore germinates and a mesh of fine the particular organic substrate, for filaments (hyphae) is formed. The filaments together form the mycelium, which takes up food and water from the surface on which the spore has germinated. Spores, and the manner, in which they are formed, play a considerable part in the classification of moulds.

1.2.2 YEASTS

Yeasts are unice ular moulds. They differ from the other moulds in the way that they propagate. Yeasts (Fig. 3) multiply by means of budding or sprouting, A selection of yeasts are used in various industries, the most important of these being those where fermentation produces wine, beer, vinegar and bread, The action of fermentation



of spores. In a favourable environment, a is the enzymatic transformation of instance the alcoholic fermentation of carbohydrates. Some yeasts are pathogenic.

3 VIRUSES

Viruses are a group of biological structures with extremely small dimensions (Fig. 8) which are obligatory parasitic. Viruses are so small that bacterial filters do not retain them, neither do they precipitate in normal centrifuges. They can be observed by using an electron microscope (Fig. 7). Viruses are unable to grow and multiply by division, they can only grow in living cells, so by their multiplication they kill the host cell. The



Fig 7. One of the types of influenza virus as seen enlarged 3600 times by means of an electron microscope. This virus occurs in the form of filaments and globules having a diameter of approximately 0.1mm.

same process can take place in adjacent cells and eventually whole cellular complexes can be destroyed. Tissue damage is a way of recognising the presence of a virus.

Viruses have been identified as the causative agent of disease in humans, animals, plants and bacteria themselves (bacteriophage). In human beings they are the cause of diseases such as chickenpox, mumps, measles, warts, poliomyelitis, the common cold and influenza (Fig. 6).

In animals, foot-and-mouth disease, Newcastle disease and fowl pest are amongst the diseases caused by viruses.

Plants are also subject to many mosaic diseases caused by viruses. An interesting case is that of 'parrot' tulips. Formerly these were regarded as a separate variety, because of their feathery looking petals and their combinations and patterns of colour. It has now been shown that the colour pattern and shape of the petals results from a virus, which has no destructive effect on the tulip itself, or its reproductive powers. The attractive colours and patterns of the petals are the symptoms of the 'disease'.



Fig 8. Relative sizes of different types of micro-organisms.

2. Ultraviolet radiation

GENERAL

Ultraviolet is that part of electromagnetic radiation bounded by the lower wavelength extreme of the visible spectrum and the upper end of the X-ray radiation band. The spectral range of ultraviolet radiation is, by definition between 100 and 400nm (1nm=10-⁹m) and is invisible to human eyes. Using the CIE classification the UV spectrum is subdivided into three bands:

UV-A (long-wave)	from 3 5 to 400 nm
UV-B (medium-wave)	from 280 to 315 nm
UV-C (short-wave)	from 00 to 280 nm

In reality many photobiologists often speak of skin effects from the weighted effect of wavelength above and below 320 nm, hence offering an alternative definition.



Fig 2. Ultraviolet radiation Threshold Limited Values (TLV) according to ACGIH 1999-2000 (Ref I).

	Perm	issible	Ultraviolet	Exposures
--	------	---------	-------------	-----------

Duration of exposure per day	Effective irradiance Eeff (µW/cm³)
8 hours	0.2
4 hours	0.4
2 hours	0.8
hour	
30 mins.	3.3
5 mins.	6.6
0 mins.	0
5 mins.	20
min	00

Table I. Permissible 254 nm Ultraviolet exposures, according to ACGIH.

A strong germicidal effect is provided by the radiation in the short-wave UV-C band. In addition erythema (reddening of the skin) and conjunctivitis (inflammation of the mucous membranes of the eye) can, also be caused by this form of radiation. Because of this, when germicidal, ultraviolet-radiating lamps are used, it is important to design systems to exclude UV-C leakage and so avoid these effects.

Self evidently people should avoid exposure to UV-C. Fortunately this is relatively simple, because it is absorbed by most products, and even standard flat glass absorbs all UV-C. Exceptions are quartz and PTFE. Again fortuitously, UV-C is mostly absorbed by dead skin, so erythema can be limited. In addition UV-C does not penetrate to the eye's lens; nevertheless,



Fig 10. Germicidal action spectrum.

conjunctivitis can occur and though temporary, it is extremely painful; the same is true of erythemal effects.

Where exposure to UV-C radiation occurs, care should be taken not to exceed the threshold level norm, Fig. 9 shows these values for most of the CIE UV spectrum. In practical terms, table I gives the American Congress of Governmental and Industrial Hygienist's (ACGIH) UV Threshold Limit Effective Irradiance Values for human exposure related to time.

At this time it is worth noting that radiation at wavelengths below 240 nm forms ozone (O_3) from oxygen in air. Ozone is toxic and highly reactive; hence precautions have to be taken to avoid exposure to humans and certain materials

2.1 GENERATION AND CHARACTERISTICS OF SHORT-WAVE UV RADIATION

The most efficient source for generating UV-C is the low-pressure mercury discharge lamp, where on average 35% of input watts is converted to UV-C watts. The radiation is generated almost exclusively at 254 nm, viz, at 85% of the maximum germicidal effect (Fig. 10). Philips' low-pressure TUV lamps have an envelope of special glass that filters out ozone-forming radiation, in this case the 185 nm mercury line. The spectral transmission of this glass is shown in Fig. 11 and the spectral power distribution of these TUV lamps is given in Fig. 12

For various Philips germicidal TUV lamps the electrical and mechanical properties are identical to their lighting equivalents.



Fig 1. Special transmission of gasses (1mm).

This allows them to be operated in the same way i.e. using an electronic or magnetic ballast/starter circuit.

As with a low-pressure lamps, there is a relationship between amp operating temperature and output. In low- pressure amps the resonance line at 254 nm is strongest at a certain mercury vapour pressure in the discharge tube. This pressure is determined by the operating temperature and optimises at a tube wall temperature of 40°C, corresponding with an ambient temperature of about 25°C. For example, a TUV amp operating in still air at + 0°C will produce about 80 per cent of the UV-C radiated at +25°C (See Chapter 5.2, Fig 28). It should also be recognised that amp output is affected by air currents (forced or natural) across the amp, the so called chill factor, The reader should note that, for some amps, increasing the air flow and/or



Fig 2. Relative spectral power distribution of TUV amps in green Effective germicida.

decreasing the temperature can increase the germicidal output. This is met in "High Output" lamps viz. lamps with higher wattage than normal for their linear dimension. (Fig. 29)



Fig 3. Relative spectral power distrubution of HOK and HTK Jamps. In light blue: Effective Germicidal.

A second type of UV source is the mediumpressure mercury lamp, here the higher pressure excites more energy levels producing more spectral lines and a continuum (recombined radiation) (Fig. I3). It should be noted that the quartz envelope transmits below 240 nm so ozone can be formed from air. The advantages of mediumpressure sources are:

- · High power density
- High power, resulting in fewer lamps than low pressure types being used in the same application.
- Less sensitivity to environment temperature.
 The lamps should be operated so that the wall



Fig 14. Survival of micro-organisms depending on dose and rate constant k.

temperature lies between 600 and 900°C and the pinch does not exceed 350°C. These lamps can be dimmed, as can low pressure lamps.

2.2 GERMICIDAL ACTION

The UV radiation emitted by a source is expressed in watts (W) and the irradiation density is expressed in watts per square metre (W/m²). For germicidal action dose is important. The dose is the irradiation density multiplied by the time (t) in seconds and expressed in joules per square metre (J/m²). (1 joule is [W.second).

From Fig. 10 it can be seen that germicidal action is maximised at 265 nm with

reductions on either side. Low-pressure lamps have their main emission at 254 nm where the action on DNA is 85% of the peak value and 80% on the IES curve. For wavelengths below 235 nm the germicidal action is not specified, but it is reasonable to assume that it follows the DNA absorption curve.

Micro-organisms effective resistance to UV radiation varies considerably. Moreover, the environment of the particular microorganism greatly influences the radiation dose needed for its destruction. Water, for instance, may absorb a part of the effective radiation depending on the concentration of contaminants in it. Iron salts in solution ware well known inhibitors. Iron ions absorb the UV radiation.

The survival of micro-organisms when exposed to UV radiation is given by the approximation:

$N_t/N_0 = \exp(-kE_{eff}t)$I Hence In $N_t/N_0 = -kE_{eff}t$2

- N_t is the number of germs at time t
- N_{Ω} is the number of germs before exposure
- k is a rate constant depending on
- the species
- E_{eff} is the effective irradiance in W/m²

The product E_{efft} is called the effective dose H_{eff} and is expressed in Ws/m² of J/m².

t follows that for 90% kill equation 2 becomes

2.303 = kH_{eff}.

Some k value indications are given in table 2, where they can be seen to vary from 0.2 m²/] for viruses and bacteria, to 2.10-3 for mould spores and 8.10-4 for algae. Using the equations above, Fig. 14 showing survivals or kill % versus dose, can be generated.

Bacteria	Dose	k
Bacillus anthracis	45,2	0.05
B, megatherium sp. (spores)	27,3	0,084
B. megatherium sp. (veg.)	13.0	0. 78
B. parathyphosus	32,0	0,072
B, suptilis	71,0	0,032
B. suptilis spores	120,0	0.019
Campyobacter jejuni	11.0	0,209
Clostricium tetani	20,0	0,0 9
Corynebacterium diphteriae	33,7	0,069
Dysentery bac	22,0	0, 05
Eberthelia typhosa	21.4	0.08
Escherichia coli	30,0	0,077
Klebsie a terrifani	26,0	0,089
Legionella pneumophila	9,0	0,256
Micrococcus candidus	60,5	0,038
Micrococcus sphaeroides	0.001	0.023
Mycobacterium tuberculosis	60,0	0,038
Neisseria catarrhalis	44,0	0,053
Phytomonas tumefaciens	44.0	0.053
Pseudomonas aeruginosa	55,0	0,042
Pseudomonas fluorescens	35,0	0,065
Proteus vulgaris	26,4	0,066
Samone a enteritidis	40,0	0,058
Samonela paratyphi	32.0	0.072
Samonela typhimurium	80,0	0,029
Sarcina utea	97,0	0,012
Seratia marcescens	24.2	0.095
Shige a paradysenteriae	16.3	0,14
Shige a sonnei	30,0	0,077
Spinilum rubrum	44,0	0,053
Staphylococcus albus	8,4	0, 26
Staphylococcus aureus	26.0	0.086
Streptococcus faecalis	44,0	0,052
Streptococcus hemoluticus	2 6	0, 06
Streptococcus lactus	615	0.037
Streptococcus viridans	20,0	0,115
Sentertidis	40,0	0,057
Vibrio chlolerae (Vcomma)	35,0	0.066
Yersinia enterocolitica	11.0	0,209

Yeasts	Dose	k
Bakers' yeast	39	0,060
Brewers' yeast	33	0,070
Common yeast cake	60	0.038
Saccharomyces cerevisiae	60	0,038
Saccharomyces elipsoideus	60	0,038
Saccharomyces sp.	80	0.029

Mould spores

Aspergilus flavus	600	0,003
Aspergilus gaucus	440	0.004
Aspergilus niger	320	0.0014
Mucor racemosus A	70	0.0 3
Mucor racemosus B	70	0.013
Oospora actis	50	0,046
Penici um digitatum	440	0,004
Penicilium expansum	30	0,018
Penicium roqueforti	30	0,0 8
Rhizopus nigricans	0	0,002

Virus

73	0,032
36	0.064
86	0.012
58	0,040
81	0,028
	73 36 86 58 8

Protozoa

Cryptosporidium parvum	25	0,092
Giardia lamblia	П	0.209

Algae

Blue Green	3000	0.0006
Chlore a vulgaris	20	0.0 9

Table 2. Doses for 10% survival under 254 nm radiation (j/m-) and rate constant k (m+j), Ref 2, 3, 4, 5, 6 and 7

Disinfection by means of Ultraviolet Lamps

GENERAL

In practice, germicidal applications and design factors are governed by three main factors:

A. THE EFFECTIVE DOSE (Hett)

Effective dose is the product of time and effective irradiance (the irradiance that makes a germicidal contribution). However, dose is severely limited by its ability to penetrate a medium. Penetration is controlled by the absorption co-efficient; for solids total absorption takes place in the surface; for water, depending on the purity, several 10s of cm. or as little as a few microns can be penetrated before 90% absorption takes place.

B. THE POSSIBLE HAZARDOUS EFFECTS OF SUCH RADIATION

Germicidal radiation can produce conjunctivitis and erythema, therefore people should not be exposed to it at levels more than the maximum exposure given in Fig. 9. It follows that this needs to be taken into consideration when designing disinfection equipments.

Germicidal applications can be and are used for all three states of matter; viz, gases (air), liquids (mainly water) and solids (surfaces) with greatest technical success in those applications where the absorption coefficient is smallest. However, some notable success has been achieved in applications where, despite a disadvantageous absorption, "thin film" or dosed circuit (recycling the product) design techniques have provided effective solutions,

C. LAMPS

Five Philips ranges of lamps are available for disinfection purposes:

- Classic T5 and T8 TUV lamps
- High output TUV amps
- PL-S and PL-L twin-tube compact TUV lamps
- and the newest addition: XPT amalgam "Very High Output" germicidal lamps in T6 and T10 diameters.
- All of these are based on low-pressure mercury technology. Increasing the lamp current of low-pressure lamps produces higher outputs for lamps of the same length; but at the cost of UV efficiency (UV watts/input watts); this is due to higher self-absorption levels, and temperature influences. The application of mercury amalgams, rather than pure mercury, in the lamps corrects for the latter.
- HOK lamps, which are of the mediumpressure mercury type, mainly characterised by a much higher UV-C output than low pressure options, but at much lower efficacies.

The choice of the lamp type depends on the specific application. In most cases the lowpressure types are the most attractive. This is because germicidal lamps are highly efficient in destroying micro-organisms, hence there is limited need for high wattage lamps. For water disinfection, low and medium-pressure are both used, although the choice is not necessarily based on UV-C efficacy. Initial total systems costs, including metalwork and space limitations, can be the driving factor rather than efficacy.

3. AR DISINFECTION (Ref. 2, 3)

Good results are obtained with this form of disinfection because air has a low absorption coefficient and hence allows UV-C to attack micro-organisms present. In addition, two other beneficial conditions are generally present, viz. random movements allowing bacteria etc. to provide favourable molecular orientations for attack and high chances of "closed circuit" conditions, that is second, third and more recycle opportunities. From this, it is evident that air disinfection is an important application for UV radiation.

Even in the simplest system (natural circulation) there is an appreciable reduction in the number of airborne organisms in a room. Thus the danger of airborne infection, a factor in many illnesses, is considerably reduced. However, it should be remembered that disinfected air is not, in itself, a disinfecting agent.

Presently, there are five basic methods of air disinfection using ultraviolet lamps viz: a. Ceiling or wall mounted TUV lamps

- b.TUV lamps (in upwards-facing reflectors) for upper-air irradiation.
- c.TUV lamps (in downwards-facing reflectors) for irradiation of the floor zone (often in combination with b.).
- d.TUV lamps in air ducts sometimes in combination with special dust filters.
- e. TUV lamps, incorporated in stand-alone air cleaners with a simple filter.

3.1.1 CEILING-MOUNTED TUV LAMPS

This method is used in those cases where either the interior is unoccupied or where it is possible for the occupants to take protective measures against radiation. These protective measures entail covering the:

Face:	glass spectacles, closefitting
	goggles or plastic face visors.
Hands:	gloves (for long exposure,
	special plastic is preferable
	to rubber)
Head and neck:	head cover
Note:	
Normal glasses and pl because they transmi are special UV glasses	astics can be used to give protection, t little or no UN4C; some exceptions s cuartz and certain PTFEs

3. 2 TUV LAMPS FOR UPPER-AIR IRRADIATION USING UPWARD FACING REFLECTORS

This method of disinfection can be used to combat bacteria and moulds; it also has the advantage that it can be used in occupied interiors without the occupants using protective clothing. The lamps should be mounted in suitable reflectors and aimed to emit no radiation below the horizontal.

The reflectors should be mounted more than 2.10m above the floor, the lower air is thus entirely free of any direct ultraviolet radiation. Air above the 2.10m level maintains a low germ level, because it is subject to direct UV-C radiation.

Free convection of air without forced ventilation causes air movements of about 1.5 - 8 m³ per minute, thus producing exchanges between the upper treated and lower untreated parts of the room. The process reduces air contamination to fractions of that before the TUV lamps were activated. As an indication for general applications in a simple room, or enclosure, it is advisable to install an effective UV-C level of:









b. Upwards facing reflectors.



c. Downwards facing reflectors.

3. J. 3 TUV LAMPS FOR IRRADIATION OF THE FLOOR ZONE USING DOWNWARD FACING REFLECTORS

This method is for use in those cases where it is important that the entire room air, even at floor level is rendered as sanitary as possible. In this case, lamps supplementing those irradiating the upper air should be fitted in downward-aimed reflectors at about 60 cm above the floor.

In methods 3.1.1, 3.1.2 and 3.1.3 person detectors/systems can be used to deactivate TUV lamps, if necessary.

3.1.4 TUV LAMPS IN AIR DUCTS

In this method, all the conditioned air is subjected to radiation prior to entry. The injected air can be disinfected to a specified killing level, depending upon the number of lamps installed and the dwell time, that is the time spent in the effective killing region of the lamp(s); by definition this takes the dimensions of the air duct into consideration.

Such systems have a controlled flow rate and their performance can be predicted theoretically.

Certain aspects should be borne in mind, however

. These installations are only suitable for



Fig. 16. Basic arrangement of TUV lamps in an air duct for room disinfection.

bacteria; most moulds have higher resistances to ultraviolet, so the air flow rate is not likely to allow a sufficient dwell time to produce a high enough effective dose.

- Dust filters should be installed to prevent the lamps from becoming soiled and hence seriously reducing their effective emission.
- The number of lamps required in an airdisinfecting chamber in an air duct system is dependent on the required degree of disinfection, the airflow rate, the ambient temperature, the humidity of the air and the UV-reflecting properties of the chamber walls.

The advantage of disinfecting air prior to it entering a room is that there is then no limit to the maximum permitted radiation dose, since humans are totally shielded. Designing duct systems needs to account for as already expressed on page 10: practical issues, such as large temperature and humidity variations caused by exterior weather variations, if only because air is often drawn from outside, then released into a room after a single pass over the amps, Recycling part of the air will allow multiple passes, hence improving system efficiency.

Lining the UV lamps section with aluminium, also increases efficiency. The lamps and the wa of the duct should be easily accessible to permit regular cleaning and easy maintenance, another reason for a modular design.

Micro-organisms exposed to UV, experience a normal exponential decrease in population,



Fig 7. Meta surfaces.

a. Evaporated auminium	
b. Aluminium feil	
c. Chromium	

- d. Nicke e. Silver
 - f. Stainless steel

$$N_t/N_0 = \exp(-ke_{eff}t)$$

The rate constant defines the sensitivity of a microorganism to UV radiation and is unique to each microbial species. Few airborne rate constants are known with absolute certainty.

n water based systems. Escherichia coli are often used as test organism. It is however not an airborne pathogen. For aerosolization tests, often the innocuous Serratia marcescens is used.

POINTS TO REMEMBER WHEN CONSTRUCTING TUV LAMP INSTALLATIONS IN AIR DUCTS:

- . The surface of the chamber walls should have a high reflectance to UV 254 nm, for example by using anodised aluminium sheet (reflectance 60-90 per cent).
- . The lamps should be so arranged that there are no 'shadow' areas.
- · Lamps should be mounted perpendicular to the direction of the airflow.
- · Lamps and the inner (reflecting) walls of the chamber should be cleaned frequently using a soft cloth.
- · Lamps should be changed after the nominal ifetime; an eapsed time meter will help.
- · An external pilot light should be used to indicate that the lamps are functioning,

REFLECTANCE OF VARIOUS MATERIALS TO UV 254 NM

The graphs shown across give the spectral reflectance of various metals (Fig. 17) and organic substances (Fig. 18) to radiation of different wavelengths. These graphs demonstrate the importance of determining a material's 254 nm reflectance. As can be seen, high reflectance to visible radiation is not consistent with high reflectance to short-wave ultraviolet radiation.



Fig 18. Organic substances a. Bleached cotton c. Unen b. White paper d. White wool

Materials with a high reflectance to 254 nm are used to construct reflectors for both direct and upper-air irradiation. Material with a low reflectance to 254 nm are used where ultraviolet radiation has to be absorbed after performing its function.

This latter is necessary to avoid the consequences resulting from the unwanted 254 nm reflections, so ceilings and walls should be treated with a low reflectance material for people comfort and safety factors.

3.1.5 TUV LAMPS IN STAND-ALONE UNITS Recently this method has gained commercial favour by meeting a growing need for a better indoor air quality.

Closed stand- alone devices are safe, simple and flexible. In essence the units consist of TUV lamps, mostly PL-L types driven by high frequency ballasts, mounted inside a "light trap" container. The unit incorporates a fan that firstly draws air across a filter, then across the lamp(s). Single and multiple lamp options can be built into a small outer using either single or double-ended lamp options. For maximum design flexibility, PL-L and PL-S lamps offer the best solutions, because their dimensions are compact, so reducing unit size and because their single ended configuration allows more mounting options.

The units have the benefits of portability and hence more mounting positions viz wall, floor or ceiling mounted in either permanent or temporary options. A feature of their design is that cleaning and lamp and filter replacement is easy.

Additionally their portability can be used to produce immediate results. Variation in UV-C dose can be achieved both by varying the number of lamps and their wattage (see also dimming below). As an example, it is possible to use the same physical design dimensions for PL-L lamps with a nominal wattage range between 18 and 95W "HO",

Materia	Reflectance %
Auminium:untreated surface	40-60
treated surface	60-89
Sputtered on glass	75-85
ALZAK-treated aluminium	65-75
DURALUMIN'	16
Stainless steel/Tin plate	25-30
Chromium plating	39
Various white of paints	3-0
Various white water paints	10-35
Alluminium paint	40-75
Zinc oxide paint	4-5
Back ename	5
White baked ename	5-0
White plastering	40-60
New plaster	55-60
Magnesium oxide	75-88
Calcium carbonate	70-90
Linen	17
Beached woo	4
Bleached cotton	30
Wallpapers ivory	31
white	21-31
red printed	3
ivery printed	26
brown printed	18
White notepaper	25

Table 3. Reflectance of various materials to UV-254 nm radiation.

in single and multi lamp variants. Commercial products are known for as few as I × PL-L I8W and as many as 4 × PL-L 95W HO lamps inside the same container, giving a unit capable of producing a 25-fold difference in effective dose.

PL-L lamps are more flexible; they have readily available and competitively priced electronic regulating (dimming) ballasts to vary UV output in a simple reliable fashion. Ballasts can be single, double and in the case of 18W, four lamp versions. This adds to the flexibility of portable units.

3.2 SURFACE DISINFECTION

Surface disinfection generally requires high-intensity short-wave ultraviolet radiation. Mostly this means TUV lamps are mounted close to the surface requiring to be kept free from infection or to be disinfected.

The success of surface disinfection depends largely on the surface irregularity of the material to be disinfected, because UV radiation can only inactivate those micro-organisms that it hits with a sufficient dose. Thus disinfection can only be successful if the entire surface is exposed to UV radiation. Micro-organisms sitting in "holes" in a surface are not likely be overcome by reflections from the hole walls, as can be deduced from the reflectances shown in table 3.

In practice, solid surfaces, granular material and packaging (whether plastic, glass, metal, cardboard, foil, etc.) are disinfected or maintained germ-free by means of intensive, direct irradiation. Additionally, disinfected material can be kept largely germ-fee throughout its further processing by irradiating the air along its path,

3.3 LIQUID DISINFECTION

Germicidal energy radiation is capable of penetrating liquids with varying degrees of efficiency From a treatment view, liquids can be regarded as similar to air so the further the UV radiation is able to penetrate the liquid, the more efficient is its action. The degree of efficiency thus greatly depends on the liquid and more particularly its absorption coefficient at 254 nm (table 4). As an example, natural water's transparency to 254 nm may vary by as much as a factor of 0 or more from place to place. Polluted industrial water often needs purification followed by disinfection; here UV-C is growing with many thousands of systems in use in North America and Europe, each with a multitude of lamps, Often UV radiation may supplement or replace conventiona chlorination measures (see later).

UV-C has advantages over chlorinating techniques, because it produces far fewer noxious by-products and is it unaffected by the pH of the water or its temperature. The reader should note that the latter comment refers to the radiation, not to the lamp, or its environment as described earlier.

Micro-organisms are far more difficult to kill in humid air, or in a liquid environment, than in dry air. This is because they limit transmission of 254 nm radiation.

In more quantitative terms liquids decrease the germicidal intensity



Fig |9. UV "cascade" surface disinfection of spices.

exponentially according to the formula

$E = E_0.e^{-\alpha(x)}$ E_0 incident intensity E intensity at depth (x)

 $\boldsymbol{\alpha}$ absorption coefficient

Liquids with a high α can only be disinfected when they are exposed as thin films. A rough indication to estimate penetration depth is $1/\alpha$, at this depth the irradiation level will have fallen to 1/e or to 37%.

To overcome wall effects where liquids are notoriously static, turbulence or rigorous stirring is necessary for better disinfection, agitation helps orientate micro-organisms hidden behind particles.

Iron salts (as well as other inorganic salts) and suspended matter in liquids will decrease the effectiveness of germicidal radiation. Additionally, it is feasible that organic compounds, in particular, those susceptible to bond fissure under UV radiation, can change the texture and taste of the liquid being treated.

Hence experimentation is needed. In round terms the effective depth of penetration for a 90% kill may thus vary from 3m for distilled water, down to 12cm for normal drinking water and even less in wines and syrups (2,5mm) See table 4.

The penetration depths cause more special techniques to be applied to allow 254 nm radiation to penetrate sufficiently, these include generating "thin films" and or slow speed presentation to the radiation, so that a sufficient dose can be applied.

If an UV lamp has to be immersed in a liquid, it should be enclosed in a quartz or UV-C transparent PTFE sleeve.

Installations for disinfecting liquids may have the following forms:

 One or more lamps enclosed in a quartz container or one of similar material (with a high transmittance at 254 nm), which is surrounded by the liquid to be disinfected, A multiple of such configurations can be used inside one outer container.



Fig 20. Volume of disinfected water V as a function of the absorption coefficient α (for disteed water $\alpha = 0.007$ -0.0 l/cm, for drinking water $\alpha = 0.02$ -0. l/cm) with respect to different degrees of disinfection (in terms of Escherichia col).

- 2.A quartz tube (with high transmittance at 254 nm) transporting liquid surrounded by a cluster of lamps in reflectors or by an integral reflector TUV lamp e.g. TUVIISW VHO-R.
- 3. Irradiation by means of lamps installed in reflectors or integral reflector TUV lamps e.g. TUVIISW VHO-R mounted above the surface of the liquid.

Liquid	α
Wine, red	30
Wine, white	10
Beer	0-20
Syrup, dear	2-5
Syrup, dark	20-50
Mik	300
Distilled water	0,007-0,01
Drinking water	0.02-0.

Table 4.Absorption coefficient (a) of various liquids to UV4254 nm per cm depth.

Philips – UV Disinfection and how it works

4 Applications

GENERAL

The main application areas for UV germicidal lamps may be briefly classified below, a though there are many other areas, where the lamps may be employed for various purposes.

- Air disinfection
- HVAC cooling coils
- · Residential drinking water
- ndustria drinking water
- · Process water (beverages)
- Waste water
- · Semiconductor and IC manufacture
- · Pools, spas, aquaria, fish ponds.

4.1 AIR DISINFECTION

ndoor air is trapped, often re-circulated and always full of contaminants such as bacteria, viruses, moulds, mildew, pollen, smoke and toxic gasses from building materials. ncreasing levels of such contaminants act as triggering mechanisms for a variation of diseases of which asthma is the most prominent.

For offices and in industrial environments, so called HEPA (High Efficiency Particulate Air) filters are installed in HVAC ductwork, Very fine fibres, pressed together, form a structure for indoor air quality has lead to new with openings, too small for most particulate contaminants, Such filters are effective, but always will give rise to considerable drop in air pressure. In recent days, growing concern against airborne pathogens.





measures. Application of UV in air ducts for ventilation, heating and cooling purposes has proven to provide adequate protection



For domestic use some very different basic types can be considered:

- Fiber mesh filters, generally designed for a particle size of 25 microns or larger.
- Activated carbon filters, which will neutralize some gasses, smoke and odours.
- Electronic air deaners, which charge particles such as dust, pollen and hair. The charged materials are attracted by a series of opposite polarity charged metal plates.
- · Ozone and ion generators
- UV light, the only treatment, truly lethal to micro-organisms

With patients and visitors bringing in pathogens that cause diseases such as tuberculosis, wards, clinics, waiting and operation rooms and similar areas should be protected against the risk of infection in personnel and patient populations, if possible at a reasonable cost!

Common traditional disease controlling methods in hospitals are:

- Ventilation: dilution of potentially contaminated air with uncontaminated air
- Negative pressure isolation rooms
- HEPA (High Efficiency Particulate Air) filtration

UV germicidal irradiation provides a potent, cost effective solution to upgrade protection against infection. (Ref. 12, 13)

Especially upper air disinfection has proven to be very effective to supplement existing controls for TB and other airborne diseases (Ref. 8). Many disease-causing organisms circulate on air currents in "droplet nuclei", I to 5 micron in size, that are expelled with a cough, sneeze or even with speech. These droplet nuclei can be inhaled, spreading infections.

It is estimated that up to 99% of airborne pathogens are destroyed with adequate air circulation and UV exposure.

4.2 COOLING COILS

Air conditioner cooling coils are almost always wet and dusty and thus can serve as an ideal breeding ground for moulds, a known allergen. Coil irradiation with UV drastically reduces or prohibits growth of moulds. At the same time heat exchange efficiency is improved and pressure drops decrease. As the coils are constantly irradiated, only a modest UV irradiance is required.

4.3 WATER PUR FICATION (Ref. 7, 4)

A wide variety of micro-organisms in the water can cause disease, especially for young and senior people, who may have weaker immune systems, UV light provides disinfection without the addition of chemicals that can produce harmful by-products and add unpleasant taste to water. Additional benefits include easy installation, low maintenance and minimal space requirements.

UV has the ability to inactivate bacteria, viruses and protozoa. Each type of organism requires a specific dose for inactivation. Viruses require higher doses than bacteria and protozoa. Understanding the organisms to be neutralised will help to determine to size of the UV system that will be required. For example, to kill 99,9% of E.coli, a UV dose of 90 J/m² or 9 mW.sec/cm² is required.

UV installations are suitable for industrial, commercial and residential markets,

The quality of the water has an important effect on the performance of UV systems. The common factors that have to be considered are iron, hardness, the total concentration of suspended solids and the ultraviolet transmittance. Various organic and inorganic compounds can absorb UV.

When there is uncertainty about what may be present in the water, the UV transmittance should be tested. Most drinking water supplies have UV ' transmittances between 85% and 95%.

Separate treatment technologies often are required to improve the water quality before disinfection:

- Sediment filters, to remove particles that "shadow" microbes or absorb UV
- Carbon filters, which remove organic compounds and undesirable odours.
- · Water softeners to reduce hardness.

UV is often used in conjunction with Reverse Osmosis (RO) applications. Disinfection prior to the RO systems increases the durability of the RO membrane by reducing the accumulation of bacterial biofilms. The reactor of a UV disinfection device must be designed to ensure that all microbes receive sufficient exposure of the UV.

Most manufacturers of UV equipment use low-pressure mercury lamps. High output (HO) versions are rapidly becoming popular. High capacity drinking water and waste water systems feature medium pressure mercury technology.

The temperature of the lamp surface is one of the most critical factors for UV reactor design. The UV efficiency of the lamp (UV output per consumed electrical Wattage) strongly depends on the bulb temperature. (See Fig.28)

The diameter of the protective quartz sleeve should be carefully adapted to the specific power of the lamp (Watts per unit of arc length), as well as temperature and velocity of the water flow.

As the lamp ages, the UV output declines due to solarization of the lamp (glass or quartz) envelope. The quoted dose for a specific unit is the minimum dose that will be delivered at the end of the lamp's life. Most manufacturers offer electronic power supplies, that are more efficient (up to 10%) and operate at lower temperatures. Such ballasts normally withstand wide fluctuations in supply voltage, still providing a consistent current to the lamps.

Factors, that should be considered, when, choosing the right size of UV equipment, in order, to achieve the desired disinfection objectives are peak flow rate, the required dose and the UV transmittance of the water.

Theoretical calculations should be validated by bioassay tests, for a variety of conditions that include flow rates and variable water quality.

4.3. RESIDENTIAL DRINKING WATER

Classic Point of Use (POU) / or Point-of-Entry (POE) UV disinfection systems consist of a low-pressure mercury UV lamp, protected against the water by a quartz sleeve, centred into a stainless steel reactor vessel.

The UV output is monitored by an appropriate UV sensor, providing visual or audible indicators of the UV lamp status. To improve taste and odour of the water POU systems are often used in conjunction with an active carbon filter.

Philips – UV Disinfection and how it works

The new ANSI/NSF Standard 55 (Ultraviolet Microbiological Water Treatment Systems) establishes the minimum requirements a manufacturer will need to become certified for a Class A or B UV system.

Class A POU/POE devices are designed to disinfect micro-organisms, including bacteria and viruses, from contaminated water to a safe level. Waste water is specifically excluded from being used as feed-water. As of March 2002 the UV system has to produce a UV dose of 40 mJ/cm².



Fig 21. POU residential drinking water UV Disinfection device.



Fig 22. Basic sketch of TUV amp operated water-disinfecting unit for general use.

Class A devices are required to have a UV sensor, alarming when the proper dose is not reaching the water.

Class B POU systems are designed for supplemental bacterial treatment of treated and disinfected public drinking water. Such devices are not intended for disinfection of microbiologically unsafe water. The systems are capable of delivering a UV dose of at least 16 mJ/cm² at 70% of the normal UV output or alarm setpoint.

The 2002 version of Standard 55 clarifies all requirements for component certification. For instance, a 15-minute hydrostatic pressure test is needed.
4.3.2 INDUSTRIAL (MUNICIPAL) DRINKING WATER

Disinfection of drinking water by UV light is a well-established technology in Europe. Hundreds of European public water suppliers have by now incorporated UV disinfection. The driving force in Europe was to inactivate bacteria and viruses, but avoid use of chlorine. Recent studies regarding potential negative health effects of disinfection byproducts have led to a critical view on chlorine.

A few fatal waterborne outbreaks of cryptosporidiosis in North America have proven the fact that existing disinfection and filtration technologies could not guarantee to eliminate cryptosporidium occysts from the water.

Cryptosporidium parvum is a human pathogen, capable of causing diarrhoeal infections, sometimes even leading to death. The organism can be shed as an environmentally resistant form (oocyst) and persists for months.

Cryptosporidium is almost completely resistant against chlorine. Ozone can be effective, but the water quality and temperature play a significant role. Its small size makes it difficult to remove by standard filter techniques.



Fig 23. UV drinking water plant 405.000 m² per day, Tollyaytti (Russia)

Recent studies have verified that UV can achieve significant inactivation of cryptosporidium at very modest doses. Exposures as low as 10 mJ/cm² will result in a more than 4- log reduction of concentration.

The effectiveness of UV for cryptosporidium removal, together with stricter limits on disinfection by-products will pave the way for UV disinfection in North America.

Due to their high UV efficiency, low-pressure high-output lamps will certainly find their way in many municipal UV drinking water facilities. However, as space always will be a problem, the high intensity medium pressure lamps will be favourite, especially when existing drinking water plants have to be upgraded with a UV extension.



Fig 24. Waste water system.

4.3.3. WASTE WATER

Chlorine has been used to disinfect waste water for over a century. However, while chlorine is very effective, it is also associated with environmental problems and health effects. Chlorination by products in waste water effluents are toxic to aquatic organisms, living in surface waters. Chlorine gas is hazardous to human beings.

UV irradiance has proven to be an environmentally responsible, convenient and cost-effective way to disinfect public waste water discharges. UV disinfection is much safer than waste water systems that rely on chlorine gas, as it eliminates transport and handling of large quantities of this hazardous chemical. More than 2000 waste water installations all over the world rely on UV disinfection these days. The required UV dose levels depend on the upstream processes, and range, taking into account flow rates and UV transmittance of the water, between 50 and 100 mJ/cm².

4.3.4. WATER COOLERS, DISPENSERS

Water vending machines store and dispense water that is non-chlorinated. The machines must be licensed by local health service departments. One of the requirements for the license is that the vending machine is equipped with a disinfection unit to reduce the number of bacteria and other micro-organisms.

Bottled water coolers, which also dispense non-chlorinated water, are not required to contain a disinfection unit.

However, without an active disinfection system, also bottled water cooler reservoirs are subject to biofilm growth. Such biofilms act like a breeding place for bacteria, protected by the gel-like substance. Bacteria contamination, regardless of whether it is non-harmful or even beneficial, is not a quality to be associated with drinking water. To avoid biofilm growth often simple UV reactors are being introduced.



4.3.5 COOLING TOWERS

Cooling towers and re-circulating loops are often dirty, warm and rich in bio-nutrients. They are perfect breeding places for micro-organisms.

Chemical compounds, like chlorine or ozone, are fed into the system in regular intervals, to control the rate of biological growth. UV will substantially decrease the costs of disinfection, without any safety or environmental issues.

4.3.6 SEMICONDUCTORS PROCESS WATER

Organic compounds, present in the rinse water; can affect production yields and product quality in the semiconductor industry. The total organic carbon (TOC) contamination level is specified to be less than one part per billion (ppb) for ultrapure water, used for this application. Ultraviolet light represents a powerful technology that has been successfully introduced in the production of ultrapure water for semiconductor, pharmaceutical, cosmetics and healthcare industries. Its powerful energies can be applied, not only for disinfection, but also TOC reduction and destruction of ozone and chlorine.

Two different UV wavelengths are employed, 254 nm and 185 nm. The 254 nm energy is used for disinfection. It can also destroy residual ozone, present in the water. The 185 nm radiation decomposes the organic molecules. It carries more energy than the 254 nm and is able to generate hydroxyl free radicals from water molecules. These hydroxyl radicals are responsible for oxidizing the organics to carbon dioxide and water molecules.

185 nm radiating lamps are made of special quartz, with high transmittance for the lower wavelengths. Typical dosage requirements range from 100 to 500 mJ/cm². Philips XPT amalgam lamps in a 185 nm version, but also HOK and HTK medium pressure lamps can provide excellent solutions.

4.3.7 SPAS AND SWIMMING POOLS

TUV amps are used to supplement the traditional methods of water treatment. mportantly, with UV-C as a supplement, chlorination methods need less chlorine for the same result. This is welcome both for those with a ergies and those with a distaste for chlorine. The reason that UV-C is not suitable for sole use is that swimming pool water circulation has to take into consideration solids, inorganic compounds, hence filtration and chemical processes are also needed. A standard technique is to circulate part of the water through a continuous flow UVC device, thus creating a partial dosed loop system; this in tandem with the chlorinator produces effective disinfection, it can lower the chlorine dose up to 50%.

4.4 REDUCTION OF ALGAE IN FIISH PONDS

Fishponds owners are often troubled by phototrophic micro-organisms. These are typical water organisms widely distributed in both fresh and salt water. Phototrophic bacteria contain photosynthetic pigment and hence they are strongly coloured and appear as dense suspensions of either green, olive, purple-violet, red, salmon or brown. Seasonal effects may lead to massive growth ('flowering of the water') as light helps chlorophyll synthesis.



Fig 25. Schematic representation of a water purification system for a private swimming pool E=U.V. radiator F=filter H=heating P=pump S=fresh water supply.

If algae are to be destroyed or their growth inhibited, either a high dose of UV 254 nm radiation is needed or a long irradiation time, These conditions can be met relatively easily by creating a closed loop system whereby the water is presented to the UV-C source a number of times per day. The lamp is encased in a quartz tube. In practice, it has been found that, for instance, a TUV PL-S 5W amp in series with a filter can keep a 45K litre (1,000 UK gallons) pond dear. For larger pond or pool volumes higher output lamps are needed on a pro rata scale. The process is thought to be that algae are split, recombine to form larger molecular chains, which can be removed by the filter, or are so large that they sink to the bottom of the pond.



4.5. AQUAR UMS

Aquariums present two problems: one is that they become swamped with algae; the second is that parasites may cause fish diseases. Both can occur in either freshwater or marine aquariums; warm water provides an excellent condition for micro-organisms and the lighting features used also promotes algae growth. The same system as used for ponds is advocated, using no more than a TUV PL-S 5W lamp for a private aquarium. A low pump speed will create a long dwell

time across the lamp, so helping both bacteria kill rate and algae agglomeration. Using UV-C in ponds and aquariums is also beneficial because it can destroy parasites introduced by new fish; the latter can be catastrophic in many cases. UV-C treatment provides an effective solution particularly for suspended zoospores. Multiplication does not take place and aquariums can be free of parasites within a very short time. Even affected fish soon cease to display symptoms of morbidity.

4.6 PHILIPS GERMICIDAL LAMPS

AND THE R APPLICATION

UV DISINFECTION	TUV T5 mini (+HO)	TUV T8	TUV TI2 (*R)	TUV TS (+HO)	TUV PL-S	TUV PL-L	TS LP I8Snm ¹	Amalgam TUY XPT	HOK/HTK/HTQ
Water		8			e 17				6
Domestic water									
Utra pure water				•			•		
Waste water				•				3.*-	•
Process water									
Industrial drinking water		-		•					•
Fish ponds		•			•				
Aquaria									
Swimming poo		1 8							
Agricultural recycling									
Air									
Space/upper air		•							
Forced air/airco		•		•	•				
Cooing cols		+				•			
Dish dryer etc.		•		8					
Surfaces		1		-	-				
Food processing				•					
Packaging			•						

I. Not in current range

5.Lamp Data

GENERAL

product data brochures.



Fig 26 and 27. Demonstrate the variation of UV irradiance with the distance to the lamps.

5. UV RRAD ANCE VALUES.

The irradiance E on a small surface in point P on a distance a from an ideal linear radiation source AB of length | amounts to:



q is the total radiation flux (in W). This formula is taken from: H, Keitz, Light

For a complete survey, see separate calculations and measurements, Philips Technical Library, MacMillan and Co Ltd, 1971. For a large distance to the lamp we get:

$$\mathsf{E}=\underbrace{\quad \textcircled{}}_{\pi^2,\mathbf{a}^2}\cdots\cdots\cdots\cdots(\alpha^{>>}\mathbf{I})\cdots\cdots\cdots(2)$$

At shorter distances the irradiance is proportional to

$$E = \frac{\varphi}{2\pi.a.l} \dots (\alpha < 0.5 l) \dots (3)$$

For a variety of low-pressure mercury TUV amps, the irradiance values at | metre distance are expressed below.

µW/cm ¹
9
4,5
2
22.5
21.5
48
33
69
00
45
50
220
330
800
920
9,5
22
32
55
05
120
60
300
40
240
240
460

Table 6. Fradiance values TUV lamps at a distance of 1.00 meters.

5.2 INFLUENCE OF TEMPERATURE ON 5.3 LAMP LIFE UV OUTPUT

The UV efficiency of low-pressure lamps is (TUV) depends on: directly related to the (saturated) mercury pressure. This pressure depends on the lowest - lamp current temperature spot on the amp.

Optimum UV efficiency is achieved when this temperature is approximately 40°C, see Fig 28.

Moving air has a strong impact on the tube wall temperature. The cooling effects of air streams (and lower ambient temperatures) can be compensated by over-powering the lamps. Fig. 29 shows this effect, comparing standard TUV PL-L 36W Jamps with "High Output" 60W versions, having the same dimensions.



Fig 28. Temperature Dependence of Mercury Lamp.



Fig 29. UV vs Windch Factor.

The life of low-pressure mercury amps

- electrode geometry
- noble-gas filling
- switching frequency
- ambient temperature
- circuitry

The choice of ballast should match the application.

Electronic preheat type of ballasts provide the best conditions for a long amp life, especially when amps are switched frequently.

Frequent on/off switching will significantly influence the lamp life.



Fig 30. Lamp life.

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