FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELL-BEING

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SCIENTIFIC REPORT

"Evaluation of the disinfection procedures efficacy of pulsed UV units usage in healthcare facilities providing outpatient treatment"

Object of research: Alpha-5 unit (complete analog of Yanex-5 unit)

Manufacturer: Scientific and Industrial Enterprise «MELITTA», Ltd., Russia

Moscow, 2019

APPROVED
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Research aim: verify the effective operating modes of the Alpha-05 pulsed UV unit for air decontamination on the premises of healthcare facilities.

Research Objectives:

1. Verify the application modes of the pulsed UV unit for air decontamination in the pediatric out-patient office.

2. Determine the level of air and surfaces microbial contamination prior to and after 1-minute disinfection procedure with Alpha-05 unit used.

3. Evaluate the antimicrobial efficacy of decontamination of the pediatric out-patient office between patient admissions.

The work was performed under Agreement No. 19/17 dated 26.12.2017

Location and time of the research: FBSI "Central Research Institute of Epidemiology" of Rospotrebnadzor (the Federal Service on Customers Right Protection and Human Well-Being Surveillance).

Materials and methods

Equipment: "Pulsed xenon UV bactericidal unit with a remote control panel and automatic setting of operating time for air decontamination of rooms in categories 1-5, volume of up to 75 m, in the absence of people - "Alpha-05" (henceforth referred to as Pulsed UV unit), designed for disinfection of rooms of all microbial species (bacteria, viruses, fungi), including the drug-resistant forms of microorganisms.

The operating principle of the Pulsed UV unit is based on simultaneous disinfection of air and open surfaces of microorganisms and viruses by high-intensity (25,000 W/cm^2) pulsed continuous ultraviolet irradiation (190-300 nm) generated by a xenon flash lamp. The synergism of the above mechanisms of inactivation of microorganisms (high intensity and photochemical damage to DNA and cell membrane) by pulsed ultraviolet irradiation of continuous spectrum leads to complete destruction of microorganisms with high efficiency (99.9% - 100%) and a minimum operating time period (from 30 s).

Objects of research.

Pediatric out-patient office, total volume of 33.4 m.
(Dimensions: Length: 3 m. Width: 3.6 m. Height: 2.9 m.)

Air samples and surface swab samples
The objects of study were air samples and swab samples collected from the surfaces of various objects in the pediatric office.

Air sampling was carried out at 3 different location points in the office under study:

l.p. 1 - patient admission area;

l.p. 2 - at 1.5 meters distance from the unit and patient (patients' waiting area);

l.p. 3 - at 2.5 meters distance from the unit and patient.

The collection of swabs from the objects' surfaces was performed at 10 various location points, all of which were situated in the range from 50 cm to 2.5 m from the Pulsed UV unit. The test surfaces were the upper (top) surfaces of the couch, the changing table, the doctor's desk, the vertical surface of the pediatric height meter, located in the area of the direct exposure to pulsed UV radiation, the back of the patient's chair, the handle of the antibacterial liquid soap dispenser, the paper towel holder, the inner handle of the front door, cabinet handles.

The algorithm for air and surface swab samples collecting alongside with the disinfection procedure using a Pulsed UV unit included:

- Air and swab sampling of the environmental media immediately after the end of patient admission (Control);
- Irradiation of air of the pediatric outpatient office with a Pulsed UV unit for 1-minute time period;
- Air and swab sampling of the environmental media following the use of the Pulsed UV unit.

The collection of air and surface swab samples was carried out in the following order: initially, the air samples were taken, after that, the swabs were taken from the surfaces of the objects.

The Pulsed UV unit was located in the immediate vicinity of the patient admission area.

Algorithm of disinfection procedures

The room selected for the study was duly cleaned and disinfected in accordance with the protocol abided by in the given healthcare facility (daily cleaning and disinfection of the objects' surfaces prior to the admission of the first patient). All of the related procedures were carried out by the qualified personnel who were appropriately well-equiped with disposable sterile clothing, in order to avoid any possible contamination of the controlled environment.

Method of microbiological research

Air samples were obtained by the aspiration method using a "MERCK MAS-100 Eco" air sampler. The volume of each sample amounted to 100 liters of air. The suspension and isolation of the microbial cultures were carried out in the specially prepared nutrient media: "Columbia Agar with sheep blood" (CBA) – a non-selective medium for isolating most types of clinically significant microorganisms, "Sabouraud Agar" (SDA) with chloramphenicol for the selective isolation of yeast and molds (fungi) colonies produced by "Sredoff ". The bacteria cultivation in CBA medium was conducted at the temperature of 37.0 ° C, for the period of 18-24 hours, fungal culture cultivation in SDA medium - up to period of 96 hours.

The surface swabs were taken in accordance with the Guidelines 4.2.2942-11 "Methods of sanitary-bacteriological studies of environmental, air and sterility control in medical institutions". The taking of surface swabs was performed with the use of sterile wet swab sponges from the surface areas of approximately 100 cm^2 (a square

of 10 cm x 10 cm). To allow the detection of the microorganisms the initial seeding was performed: 0.2-0.3 ml of the washed-off solution was inoculated in the liquid nutrient media with a volume of 5.0 ml. The inoculated tubes were incubated at 37°C for the period of 24±2 h, after which they were seeded into the solid nutrient media.

Subjected to measurement in 1 m^3 of air (CFU / m^3):

- total microbial count (TMC);
- number of S. aureus;
- number of streptococci: S. mitis, S. parasanguinis, S. oralis, S. sanguini, S. salivarius, S. Vestibularis – members of the normal microbial flora of the mucous membranes of the human upper respiratory tract;
- number of coagulase-negative staphylococci (CoNS): S. hominis, S. epidermidis, S. caprae, S. haemolyticus, S. capitis, S. warneri - members of the normal microbial flora of human skin and mucous membranes;

<u>On the objects' surfaces</u> (CFU / m^3):

- S. aureus, S. lugdunensis - causative agents of infections of the skin and soft tissues, human systemic infections;
- E. faecalis - an opportunistic infection able to cause purulent infections.

The species affiliation of microorganisms was confirmed by the matrix assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF-MS).

The disinfection efficiency (DE) of the procedures, expressed as a percentage, which indicates the reduction of microbial contamination of the air or the surfaces as a result of exposure to the Pulsed UV unit, was calculated as the ratio of the number of dead microorganisms to the total initial number of microorganisms present before exposure.

Results

Table 1 shows the results of the efficiency study of disinfection of total bacterial contamination of the test facility air with the use of the Pulsed UV unit.

Table 1. The dynamics of the total microbial contamination of test facility air before and after exposure to the Pulsed UV unit.

Sample	Treatment stage	CFU/ m^3			Total value (x ± σ)	DE*, %
		l.p. 1	l.p. 2	l.p. 3		
1	Before exposure	280	280	240	266,66±18,85	75,0
	After exposure	70	70	60	66,67±3,33	
2	Before exposure	300	180	350	276,66±71,33	82,9
	After exposure	20	70	60	50,0±15,27	
3	Before exposure	530	670	370	523,33±122,56	91,2
	After exposure	50	70	20	46,67±14,53	
4	Before exposure	780	510	410	566,66±156,27	90,6
	After exposure	90	40	30	53,33±18,56	
5	Before exposure	200	200	60	153,33±65,99	84,8
	After exposure	50	10	10	23,33±13,33	
6	Before exposure	670	760	480	636,66±116,71	90,6
	After exposure	60	70	50	60,0±5,77	
7	Before exposure	410	750	360	506,66±173,26	75,7
	After exposure	120	140	110	123,33±8,82	
8	Before exposure	430	440	450	440±8,164	96,2
	After exposure	10	30	10	16,67±6,67	

A decrease in TMC in the air was observed at all treatment stages, while the DE of the room air disinfection varied considerably, ranging from the minimum value of 75.0% to the maximum value of 96.2%.

By relying on the high variation coefficients of the air contamination in different location points, used for sampling, before and after the treatment with the Pulsed UV unit, it is possible to assess the uneven distribution of microorganisms constituting the bioaerosol of the facility.

Table 2 shows the results of the efficiency study of disinfection of test facility air with the use of the Pulsed UV unit against various microbial strains.

Table 2. Disinfection efficiency of test facility air contaminated with Streptococcus sp. and coagulase-negative staphylococci (CoNS) with the Pulsed UV unit.

Sample	Treatment stage	Streptococcus sp.		CoNS	
		Total value ($\overline{x} \pm \sigma$)	DE*, %	Total value ($\overline{x} \pm \sigma$)	DE*, %
1	Before exposure	NF	-	43,33±32,99	92,3
	After exposure	NF		3,33±1,6	
2	Before exposure	40,0±32,66	100,0	103,33±24,94	95,2
	After exposure	NF		5,0±1,6	
3	Before exposure	296,7±89,93	98,8	76,66±16,99	94,8
	After exposure	3,4±1,71		4,0±2,16	
4	Before exposure	210,0±37,41	87,3	116,66±52,49	88,6
	After exposure	26,66±11,1		13,33±4,94	
5	Before exposure	100,0±14,14	93,3	63,33±32,99	94,8
	After exposure	6,66±2,42		3,33±1,65	
6	Before exposure	226,66±81,78	98,5	150,0±50,99	92,0
	After exposure	3,33±1,28		12,0±8,16	
7	Before exposure	243,33±146,36	97,3	73,33±4,71	95,5
	After exposure	6,66±5,06		3,33±1,65	
8	Before exposure	176,66±16,99	96,3	63,33±9,42	94,8
	After exposure	6,66±9,42		3,3±1,65	

Note: NF = not found.

Sanitary-indicative microorganism *S. aureus* was detected in one sample taken on l.p. 1 and l.p. 3 in an amount of 20 CFU / m^3 before the exposure of the facility to the Pulsed UV unit and was not detected at the location points for air sampling after the exposure.

The greatest bactericidal efficiency (up to 100%) to be exhibited by the Pulsed UV unit was observed against various species of streptococci, and against CoNS – within the range of 88-95%.

Furthermore, a positive correlation between bactericidal efficiency of air decontamination with the use of Pulsed UV unit and the relative weight of streptococci in the initial TMC in the air before the start of irradiation procedures was identified ($R = 0.9$; $p < 0.02$).

Table 3 shows the results of the efficiency study of disinfection of test facility surfaces with the use of the Pulsed UV unit.

Table 3. Disinfection efficiency of the test facility surfaces with the use of the Pulsed UV unit.

Sample (№)	Treatment stage	*CFU/m²*		
		S.aureus,	*S.lugdunensis*	*E. faecalis*
1	Before exposure	**200**	NF	NF
	After exposure	**0**	NF	NF
2	Before exposure	NF	NF	NF
	After exposure	NF	NF	NF
3	Before exposure	NF	**100**	NF
	After exposure	NF	**0**	NF
4	Before exposure	NF	NF	NF
	After exposure	NF	NF	NF
5	Before exposure	NF	NF	NF
	After exposure	NF	NF	NF
6	Before exposure	**100**	NF	**100**
	After exposure	**0**	NF	**0**
7	Before exposure	**200**	NF	**100**
	After exposure	**0**	NF	**0**
8	Before exposure	NF	NF	NF
	After exposure	NF	NF	NF

Note: NF = bacteria not found, the impossibility to evaluate the bactericidal efficiency was admitted.

As can be seen from the data presented, there was observed the 100% reduction in bacterial contamination of the various test surfaces, namely, the doctor's desk and the back of the patient's chair (S. aureus from 200 to 0), the changing table, the automatic dispenser handle and the couch upper (top) surface (E. faecalis from 100 to 0)

CONCLUSIONS

Based on the results of the research work on the topic: “Evaluation of the disinfection procedures efficacy of pulsed UV units usage in healthcare facilities providing out-patient treatment" carried out by the FBSI “Central Research Insitute of Epidemiology” of Rospotrebnadzor (Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing) during the period from January to April 2018, there was determined a high bactericidal efficiency of the Pulsed UV unit for purposes of facilities’ air and surfaces disinfection.

The research results show:

1. High bactericidal efficiency (75.0-96.2%) of disinfection of the facility air with the Pulsed UV unit, both in relation to the total microbial count (TMC), including 100% efficiency against a sanitary-indicative microorganism S.aureus, and 100% efficiency against various types of streptococci (S. mitis, S. parasanguinis, S. oralis, S. sanguini, S. salivarius, S. Vestibularis) and 95% efficiency against coagulase-negative staphylococci (S. hominis, S. epidermidis, S. caprae, S. haemolyticus, S. capitis, S. warneri).

2. High bactericidal efficiency (100%) of disinfecting the facility surfaces exposed to the Pulsed UV unit, against sanitary-indicative S.aureus and E.faecalis.

3. For air and surfaces disinfection of the facility with a Pulsed UV unit, 1-minute operation period is sufficient.

Consequently, the Alpha-05 portable pulsed ultraviolet unit can significantly reduce the risks of infections developing among patients and personnel, that are related to the provision of medical care.

Practical recommendations for healthcare facilities

In order to reduce the risk of occurrence in patients and personnel of the infections, that are related to the provision of medical care, in medical organizations providing primary medical care (polyclinics, ambulant clinics, outpatient offices constituting parts of hospitals, dispensaries, antenatal clinics, health centers, feldsher-obstetric centers) in accordance with the "Procedures for the provision of medical care to the population", approved by the Ministry of Health of the Russian Federation, it is recommended to:

- use "Alpha-05" portable pulsed ultraviolet unit for room decontamination with operation period of 1-2 minutes.

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