

**ACCREDITATION SYSTEM FOR TESTING LABORATORY CENTRES
OF THE STATE SANITARY AND EPIDEMIOLOGICAL SERVICE
OF THE RUSSIAN FEDERATION**

**TESTING LABORATORY CENTRE
FEDERAL GOVERNMENT BUDGETARY INSTITUTION
"D.I. IVANOVSKIY RESEARCH INSTITUTE OF VIROLOGY"
OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION**

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December 20, 2013

SCIENTIFIC AND EXPERT REPORT

based on the research findings

"Virucidal activity study of pulsed ultraviolet continuous spectrum radiation"

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of the Russian Ministry of Health

Moscow
2013

1. Research goal. Virucidal activity study of pulsed ultraviolet continuous spectrum radiation for developing the operating modes of pulsed ultraviolet units of “Alpha” series for room surfaces decontamination in healthcare facilities.

2. Research objectives:

1. Efficiency study of viruses’ inactivation on the surfaces under the influence of pulsed ultraviolet continuous spectrum radiation.
2. Surface (virucidal) doses evaluation of pulsed ultraviolet continuous spectrum radiation for viruses’ inactivation with 99.99% efficiency.
3. Developing the operating modes of pulsed ultraviolet units for room open surfaces decontamination in healthcare facilities.

3. Place and time of research performance

The experimental research was performed under the auspices of “D.I. Ivanovskiy Research Institute of Virology” from June 17, 2013 till December 20, 2013 with the equipment provided by SIE “Melitta”, Ltd.

4. Research procedure name, date of its approval

Studying and evaluation of the virucidal activity of the pulsed ultraviolet continuous spectrum radiation were performed in accordance with Methodical Guidelines MY 3.5.2431-08 “Studying and evaluation of the disinfectants virucidal activity”, Moscow, 2010.

5. Materials

The following viruses were used for testing - poliomyelitis virus, adenovirus, hepatitis C virus, human influenza virus (type A), applied on Petri dishes surface (surface samples). The samples set allowed for studying their resistance depending on the genetic material builders (nucleic acid type): genomic RNA (poliomyelitis virus, hepatitis C virus, influenza virus) or genomic DNA (adenovirus), or protein coat type: with protein coat (hepatitis C virus, influenza A virus) or without protein coat (poliomyelitis virus, adenovirus).

The following viruses and biological materials were used for testing

A) Poliomyelitis virus, vaccinal strain, type 1, acquired from the State Institution Research Institute of poliomyelitis and viral encephalitis named after M.P. Chumakov of the Russian Academy of Medical Sciences. Viral titer 6.5 lg TCID50.

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B) Adenovirus, type 5, acquired from the State Viral Specimen Collection of FGBI “D.I. Ivanovskiy Research Institute of Virology” of the Russian Ministry of Health. Viral titer 6.0 lg TCID50.

C) Hepatitis C virus. Culture fluid from hepatitis infected cells of swine embryo kidney during cytopathic events development was used as virus-containing material. Viral titer 7.5 lg TCID50.

D) Influenza A virus. Human influenza virus A/H1N1/Moscow/2009 from the collection of FGBI “D.I. Ivanovskiy Research Institute of Virology” of the Russian Ministry of Health was used as virus source. Viral titer 6.5 lg TCID50.



Picture 1

Cells. The kidney cells' passaged culture of Vero green monkeys was used for work with poliomyelitis virus. The finite cell line of human HeLa cells was used for working with adenovirus. Cell culture of swine embryo kidney was used for working with hepatitis C virus. Dog kidney cells were used for working with human influenza A virus.

The said viruses' choice was determined by:

1. The viruses list, accepted as test viruses' selection for studying and evaluating the disinfectants virucidal activity (MY 3.5.2431-08, Moscow, 2010).
2. Experimental and clinical data on viruses' survivability on surfaces.

6. Equipment

Xenon lamp of “UIKb-01-Alfa” unit is the source of pulsed continuous spectrum UV radiation (Picture 1).

The unit generates light flashes in a broad-spectrum range (200-700 nm) with 2.5 Hz frequency. For each pulse, the bactericidal dose on the treated surface (in 235-285 nm spectral range) is 0.43 J/m². The ultraviolet flow in 200-400 nm range is 5.7 W/m² with pulse power over 2 MW/m².

7. Research procedure

Stage 1. The virus contaminated samples (Petri dishes) (viral suspension applied to Petri dishes surface (5.0 cm)) were placed on 2 meters' distance from the pulsed xenon ultraviolet lamp. The exposure time was from 0.5 to 16 minutes. The treated plastic surface of Petri dishes was located perpendicularly to the lamp light flow, i.e. vertically.

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Stage 2. After exposure to irradiation, the sensitive cell culture was infected with the treated virus, incubated and analyzed. The virus propagation in cells was evaluated based on the virus-induced cytopathic effect in several experiments.

8. Research results

The research results are presented in tables 1-4.

Table 1 – Efficiency of *poliomyelitis* virus inactivation by pulsed ultraviolet continuous spectrum radiation

Exposure time, minutes	Poliomyelitis virus titer, lg TCID50			Inactivation grade, lg TCID50
	No. 1	No. 2	m±	
0.0	6.5	6.5	6.5	-
0.5	4.5	5.0	4.8	1.7
1.0	4.7	4.5	4.6	1.9
2.0	4.5	3.5	4.0	2.5
5.0	1.6	1.5	1.6	4.9
10.0	0.0	0.0	0.0	6.5

Table 2 – Efficiency of *adenovirus* virus inactivation by pulsed ultraviolet continuous spectrum radiation

Exposure time, minutes	Adenovirus virus titer, lg TCID50					Inactivation grade, lg TCID50
	No. 1	No. 2	No. 3	No. 4	m±	
0.0	4.0	3.6	4.5	4.5	3.8/4.5	-
1.0	2.9	2.7			2.8	1.0
2.0			2.0	2.0	2.0	2.5
4.0			2.0	2.0	2.0	2.5
8.0			1.0	1.0	1.0	3.5
16.0			0.0	0.0	0.0	4.5

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Table 3 – Efficiency of *influenza* virus inactivation by pulsed ultraviolet continuous spectrum radiation

Exposure time, minutes	Influenza virus titer, lg TCID50					Inactivation grade, lg TCID50
	No. 1	No. 2	No. 3	No. 4	m±	
0.0	5.0	5.2	7.5	7.2	5.1/7.35	-
1.0	2.5	2.0			2.3	2.8
2.0			5.5	5.0	5.25	2.1
4.0			2.0	2.2	2.1	5.25
8.0			0.4	0.5	0.45	6.9
10.0	0.0	0.0	0.0	0.0	0.0	7.35

Table 4 – Efficiency of *hepatitis C* virus inactivation by pulsed ultraviolet continuous spectrum radiation

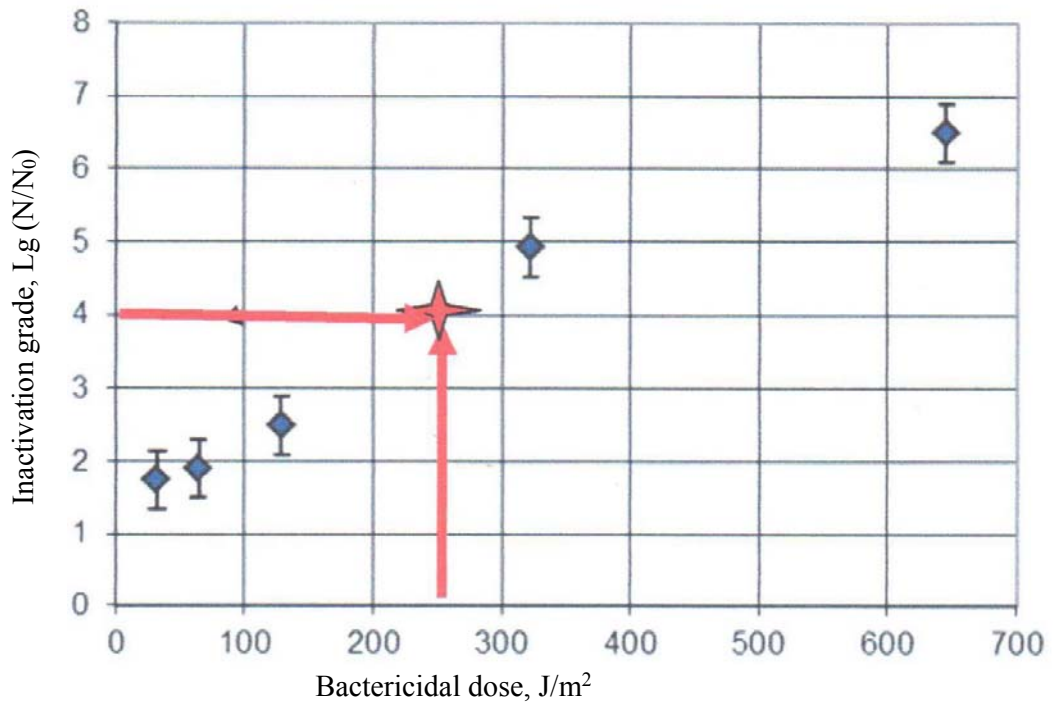
Exposure time, minutes	Hepatitis C virus titer, lg TCID50			Inactivation grade, lg TCID50
	No. 1	No. 2	m±	
0.0	5.5	5.5	5.5	-
1.0	4.2	4.6	4.4	1.1
10.0	1.0	0	0.5	5.0

Irradiating the poliovirus and influenza virus for 10 minutes and the adenovirus for 16 minutes by pulsed ultraviolet continuous spectrum radiation of “UIKb-01-Alfa” unit leads to their complete inactivation (Tables 1-3).

Irradiating the hepatitis C virus by “UIKb-01-Alfa” unit for 10 minutes inhibits the virus propagation 5 lg TCID50 (Table 4).

An example of virucidal doses calculation for pulsed ultraviolet continuous spectrum radiation for 99.99% efficiency (inactivation grade 4 lg TCID50) is given in Picture 2 (for poliomyelitis virus). Picture 3 demonstrates the virucidal operating mode (exposure time) of pulsed UV units for achieving the efficiency of 99.99%

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Picture 2 – Dependence of the poliomyelitis virus inactivation efficiency on the virucidal dose of the pulsed UV radiation (235-285 nm).

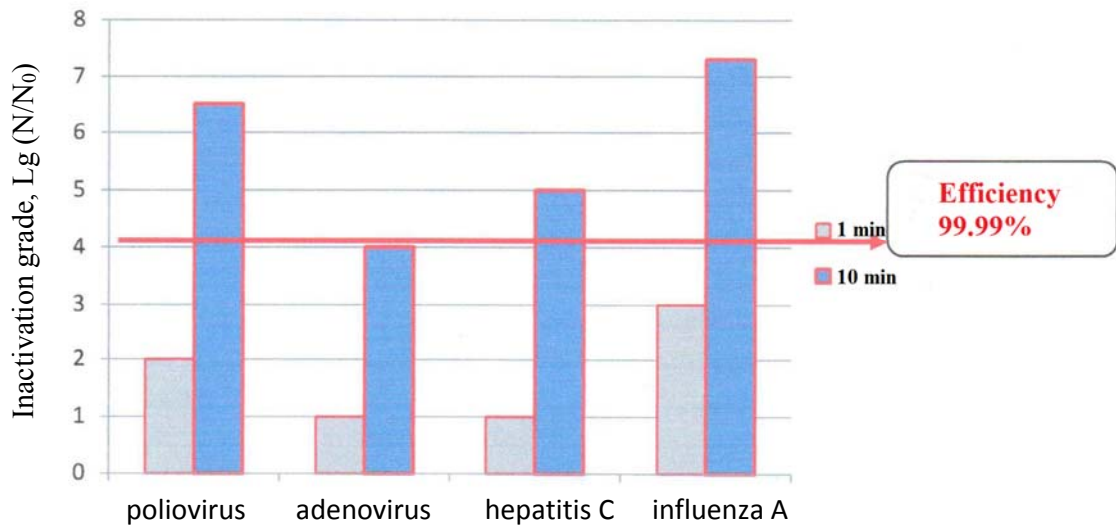


Table 5 shows the virucidal doses values and the required operating time of “UIKb-01-Alfa” unit to achieve the 99.99% virus inactivation efficiency at 2 meters’ distance.

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Table 5 – Surface doses of virucidal radiation, ensuring the 99.99% inactivation efficiency and corresponding time of “UIKb-01-Alfa” unit operation at 2 meters’ distance.

Virus	Efficiency 99.99%	
	“UIKb-01-Alfa” unit operating time, min	Virucidal dose, J/m ²
Poliomyelitis	4.0	250
Adenovirus	9.5	600
Hepatitis C	8.0	520
Influenza A	3.5	200

9. Conclusions:

1. High efficiency (99.99%) of virus inactivation (adenovirus, hepatitis C virus, human influenza A virus, poliomyelitis virus) under impact of pulsed ultraviolet continuous spectrum radiation has been shown by experiments.

2. We have deduced the surface virucidal doses of pulsed ultraviolet continuous spectrum radiation, required for the studied viruses’ inactivation (DNA-, RNA-containing, with and without protein coat) with the efficiency over 99.99%.

3. The experimentally obtained surface dose values for virus inactivation can be used for developing the pulsed UV units’ operation modes, as well as room (open surfaces) treatment procedures.

10. EXPERT JUDGEMENT

1. Pulsed ultraviolet continuous spectrum radiation has a high virucidal activity and can decontaminate surfaces with the efficiency up to 99.99%.

2. Pulsed ultraviolet “UIKb-01-Alfa” unit inactivates viruses with the efficiency over 99.99% within 10 minutes (most studied viruses) and inactivates adenovirus within 16 minutes in 2 meters’ radius.

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3. We can recommend the use of pulsed ultraviolet units of “Alfa” series in healthcare facilities rooms during the complex preventative and anti-epidemic procedures.

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