PRESS RELEASE

Dear colleagues,

a group of epidemiologists contacted us with a request to clarify the anonymous newsletter they received from the email address <u>chestnyy.epidemiolog@mail.ru</u> with an attached article by M. Nerandzic from Cleveland ("**Evaluation of a pulsed xenon ultraviolet disinfection system for reduction of healthcare-associated pathogens in hospital rooms**"), hereinafter "Article", which supposedly confirms the low efficiency of pulsed ultraviolet (UV) units such as Xenex, USA, when compared with mercury UV units Tru-D, Tru Defense Inc., USA.

This is not our company's way to enter into a discussion with anonymous "experts", but the outrageous comment of an "honest epidemiologist" related to "Melitta" and followed by the link to the "Article" forced us to answer.

- There are <u>16</u> studies published in leading peer-reviewed US medical journals (including "American Journal of Infection Control", "Journal of Infection Prevention", "Infection Control & Hospital Epidemiology", and "BMC Infectious Diseases") that confirm the real efficiency of pulsed UV units for reducing the HAI incidence in hospitals, as well as microbiological studies performed in one of the largest oncological hospitals in the world, MD Anderson, and Harvard Medical School, showing real results of the pulsed UV light use;
- 2. There is a Conclusion from the US Government Accountability Office (US GAO) supporting the decision of the US Department of Veterans Affairs to enter into a non-competitive contract for the supplying mercury-free pulsed ultraviolet disinfection systems. In this Conclusion, the Government Accountability Office commented: "Because the agency's market research revealed only one source for a mercury-free UV disinfecting lamp, and because there is no dispute about the hazards of mercury gas exposure, we conclude that the agency's decision to award the contract on a sole-source basis to the only source of a mercury-free product was reasonable." The US Department of Veterans Affairs' market research revealed 57 suppliers according to the US General Services Administration catalogs, but only one of them offers mercury-free xenon germicidal lamps. This is Xenex Disinfection Services;
- 3. There are Russian studies performed at the accredited test laboratory scientific center of G.N. Gabrichevsky Moscow Research Institute of Epidemiology and Microbiology of Federal Service on Consumer Rights Protection and Human Wellbeing, as well as in other research centers, confirming high biocidal efficiency of pulsed ultraviolet radiation both against resistant clinical strains (VRE, MRSA, and Clostridium difficile spores) and other epidemiologically significant microorganisms Pseudomonas aeruginosa, Acinetobacter baumannii, Proteus mirabilis, and Mycobacterium terrae;
- 4. In the mentioned "Article" the authors recognize the advantages of pulsed UV units. Quotation: "The PX-UV device has some important potential advantages over other UV disinfection devices. First, unlike continuous UV-C devices, xenon flash lamps do not contain mercury. There is therefore no danger associated with mercury disposal or contact. Therefore, there are no safety hazards associated with disposal or exposure to mercury. Second, the manufacturer recommends a relatively brief disinfection cycle (10–20 minutes per room versus up to 45 minutes for spore-killing cycles of some UV-C devices) which may facilitate greater use of the devices.. <...> Moreover, previous studies have demonstrated that optimal killing of C. difficile spores by UV-C is likely to be achieved with longer cycle times. <...> Finally, organic load did not impact the efficacy of the PX-UV device", which is very important in real-life clinical conditions;

- 5. What is more, the very fact of comparing the efficiency of a Xenex unit (820 W, 1 lamp) and a Tru-D unit (2.4 kW, 28 lamps), performed in different hospitals, is debatable for the experts and even the authors of the "Article;.
- 6. Table 1 shows the compared characteristics of the Xenex Germ-Zapping Robot[™] and mercury ultraviolet units which are actively promoted in the US market and have approximately the same power and number of lamps: Tru-D SmartUVC, M20 Wall Mount Unit and Pathogon UV Disinfection system. In Russia, only units with 6 mercury UV lamps are officially registered. It is known that increasing the efficiency and reducing the processing time using mercury UV units is possible <u>only by</u> increasing the lamps length and number. Table 1 clearly shows that the developers and manufacturers of all the mentioned units chose exactly this way. At that, all these units still have the limitations characteristic for monochromatic UV light. Plus, the size and lamps number increase inevitably adds to difficulties related to their transportation, maintenance, disposal and safety;
- 7. There are microbiological studies performed in the Antimicrobial Test Laboratories accredited in accordance with the GLP rules (Good Laboratory Practice Code of International Requirements for Laboratory Research). In 2010, this laboratory confirmed the efficiency of the Alfa-01 unit, manufactured by the Scientific and Industrial Enterprise "Melitta", against Clostridium difficile spores, which until 2012 had been supplied to the US market under the Yanex trademark. In 2012, Xenex entered into a licensing agreement with the Scientific and Industrial Enterprise "Melitta" gaining the right to manufacture pulsed xenon UV units in the United States. In 2014, the same laboratory conducted a similar study, but with the M20 unit manufactured by UVC Cleaning Systems Inc., USA (see Table 1). According to the obtained data, the M20 unit requires 24 minutes to achieve the same efficiency at the same distance, when the Alpha (Yanex) unit requires only 12 minutes. In another study by Dr. Nerandzic, the Pathogon UV Disinfection system (2.4 kW, 24 lamps) was found to be equally efficient with Tru-D.

Obviously, the market penetration of such units by increasing their power, length and number of mercury UV lamps did not create significant advantages (like increasing efficiency and reducing exposure time) when compared with pulsed xenon UV units (820 W - 1 kW, 1 lamp);

8. And finally, there is the Judicial Order of the Bexar County District Court (Texas, USA) dated October 5, 2015. The court has issued a temporary restraining order against Tru Defense Inc., to force the company to stop publishing false and misleading statements about its Tru-D Smart UV disinfection device. The Court found that the Order was necessary because Tru-D has "already made and is continuing to publish false and misleading statements about [Xenex's] product." The Court ordered Tru-D to immediately cease publishing false and misleading statements about [Xenex] and its product.

In conclusion, we would like to quote Morris Miller, CEO of Xenex: "This [temporary restraining order] will force them to be truthful moving forward."

The same words are relevant for the "honest epidemiologist".

Device	Xenex Germ-	Yanex-01	Tru-D SmartUVC	M20 Wall Mount	Pathogon UV
	Zapping Robot TM	(Alfa-01)		Unit	Disinfection system
Dimensions, cm	76.2 x 50.8 x 95.5	50.0 x 40.0 x 93.0	134 x 68.7 x 176.4	53.5 x 53.7 x 154.0	71.1 x 78.7 x 170.2
Weight, kg	68.0	50.0	72.0	56.2	66.0
Capacity	820 W	1 kW	2.4 kW	2.34 kW	2.4 kW
Number of lamps	1	1	28	18	24
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