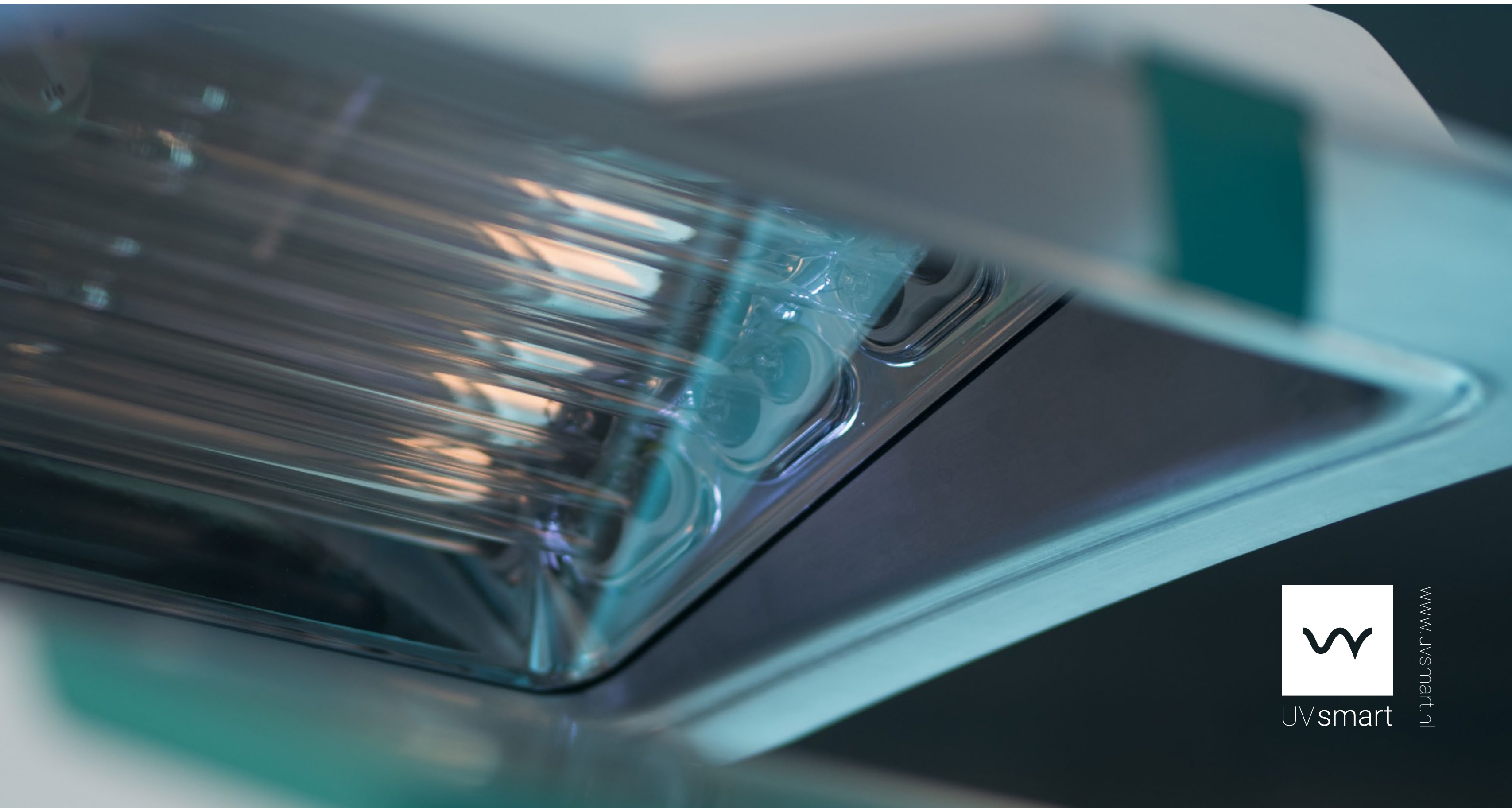


WHITEPAPER UV-C DISINFECTION

Safety, efficiency and practical application



UVsmart

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Traditionally, disinfection of small medical instruments and equipment is done in an autoclave with steam, heat, with chemical substances or disinfectant wipes.

High-energy UV-C light (UVGI) has been used for decades for disinfection of water and air treatment systems of, for example, operating theatres. This technique has been further developed and refined over the years, which opened up possibilities for applying UV-C in the disinfection of medical instruments and equipment.

In this document UV Smart collects current backgrounds, scientific studies and practical experiences, to evaluate the safety, effectiveness and practical application of UV-C disinfection in a medical setting.

CONTENT:

1. Mechanism of UV-C disinfection
2. Medical disinfection methods
3. Effectiveness and practical application
4. Applicability and safety of UV-C
5. Experiences in the Netherlands
6. Literature



The compilation of this issue was completed on 6 January 2021. UV Smart expects to be able to regularly supplement this publication with new results from scientific and clinical research. Please consult our website or scan this QR code for updated information.

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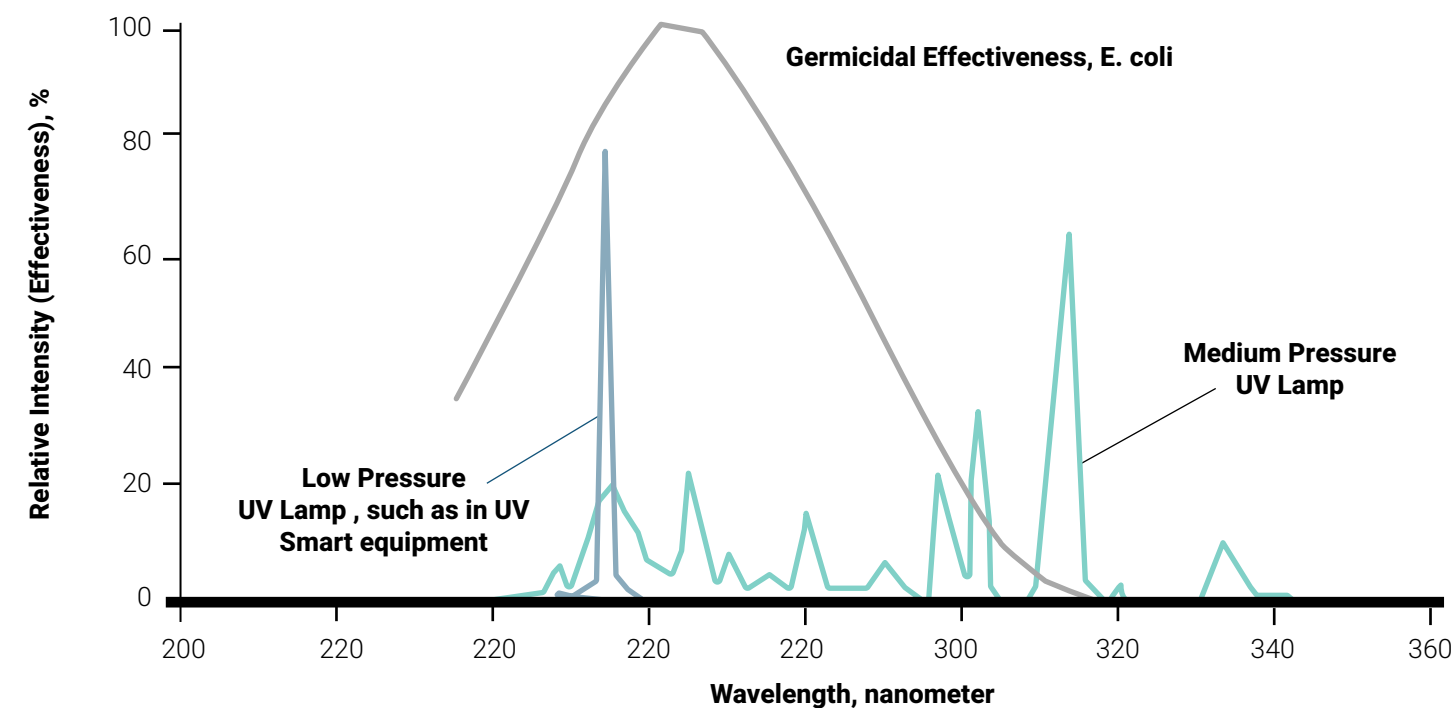
1. Mechanism of UV-C disinfection

UV disinfection responds to an important vulnerability of micro-organisms: the sensitivity to UV-C light from their hereditary material.

Hereditary material (DNA, RNA) of micro-organisms (such as viruses and bacteria) shows an absorption peak for light with a wavelength between 260 and 265 nm, UV-C light. Due to a photochemical process, the DNA “fuses” after only a short exposure time, so that the micro-organisms can no longer multiply and, as a result, die.

This type of UV can be found in sunlight, but is largely captured by the ozone layer.

However, with a certain type of UV lamp, light of this wavelength can easily be generated in sufficient intensity for disinfection of air, water and irradiable surfaces.



History of UV-C technology (from water to medical).

- 1877** discovery of the disinfection property of sunlight
- 1901** invention gas discharge lamp as a UV source
- 1903** application documented against tuberculosis bacteria on the skin
- 1910** test installation for UV-C disinfection of drinking water, Marseille
- 1929** mechanism of genetic damage by UV-C in microorganisms is described
- 1955** wide use of UV-C disinfection of drinking water in Europe
- 1970** wide application UV-C disinfection wastewater in the USA
- 1990** introduction of UV-C air disinfection in a medical setting

2. Medical disinfection methods

Various disinfection methods can be used in a medical setting. UV-C is one of them.¹

In practice it depends on the required level of disinfection and on the nature of the materials which method of disinfection is recommended².

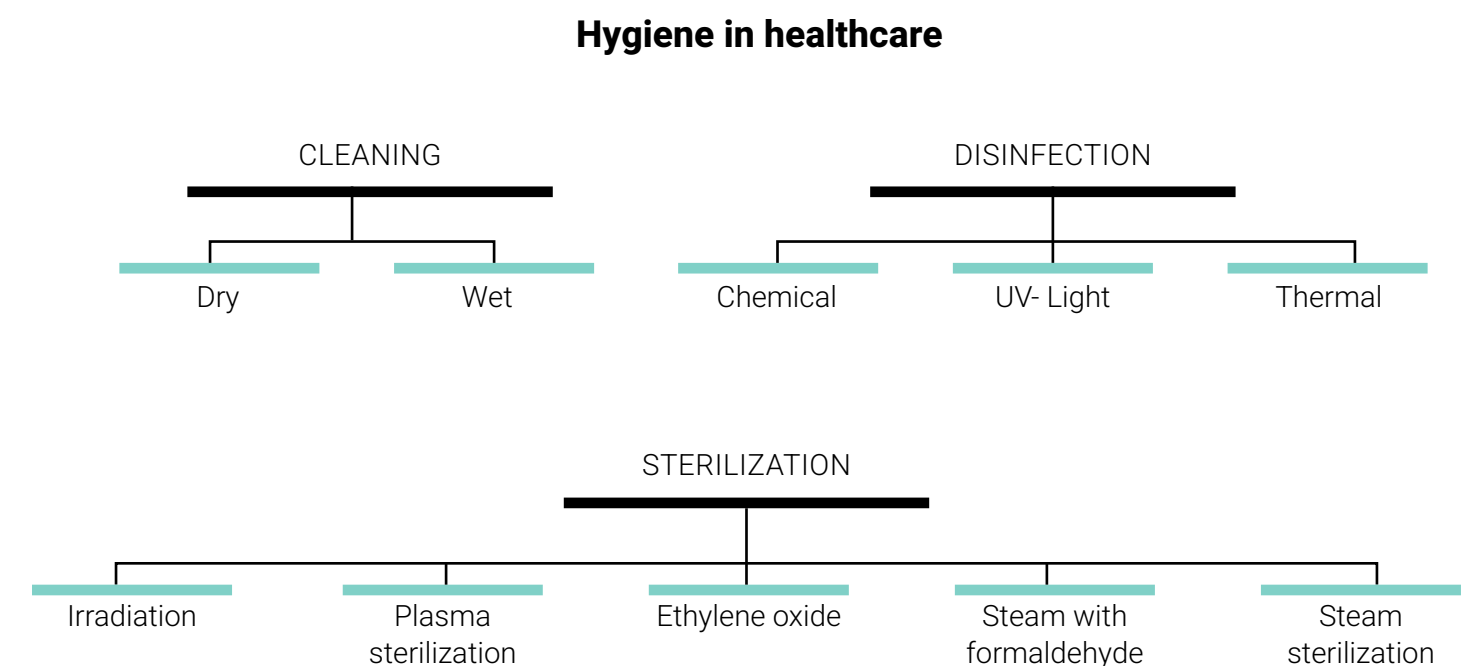
The trend is that methods that do not require manual action (“no-touch” disinfection) are increasingly preferred over manual disinfection with wipes or chemicals³.

Examples of contactless methods are gaseous or vaporous disinfectants (e.g. ozone or hydrogen peroxide vapor), and physical methods (e.g. high temperature or germicidal radiation such as UV-C).

In March 2017, the Workgroup Infection Prevention (WIP) on behalf of RIVM (the Dutch National Institute for Health and Environment) issued a Guideline⁴ about disinfection in a medical setting.

The WIP also advises against manually executed processes, and emphasizes the importance of validated equipment and processes.

The possibilities with UV-C are not yet discussed in the WIP guideline report; this is expected to be addressed in the next version of the report⁵, because in the meantime several solutions have been researched, developed and introduced that make use of this technology.



Photochemical effect UV-C on hereditary material¹

- A low-pressure gas discharge lamp emits UV-C light
- This causes chemical bonds in the DNA or RNA chains
- A moderate intensity already causes extensive damage
- This effectively inactivates the virus, after a few seconds of exposure

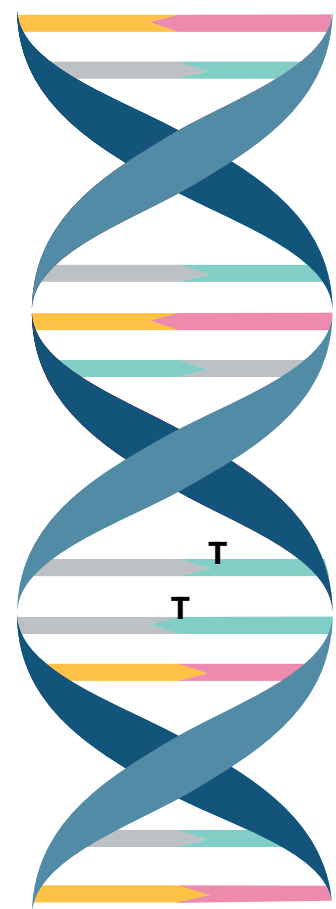
3. Effectiveness and practical application

Standards for medical disinfection are perfectly achievable with UV-C.

The effectiveness of disinfection is expressed as the percentage of microorganisms destroyed by it⁶. If that is 99.999%, then we speak of a Log5 reduction; 99,99 is Log4. In the healthcare sector, document EN 14885:2018⁷ specifies the European Standards to which products have to conform in order to support the claims for microbicidal activity. It is applicable to products for which activity is claimed against the following microorganisms: vegetative bacteria (including mycobacteria and Legionella), bacterial spores, yeasts, fungal spores and viruses (including bacteriophages).

DNA structure change

Before UV-C:



UV-C light breaks DNA/RNA:
When two Thymine are next to each other, the UV-C light binds them to each other instead of to the opposite base in the DNA/RNA molecule.

After UV-C:



Recent research of Boston University shows that UV-C radiation can inactivate SARS-Cov2 virus completely: a dose of 22mJ/cm² results in a reduction of 99.9999% in 25 seconds.⁸

The Centers of Disease Control in the US (comparable to RIVM for the Netherlands) recently published a comprehensive review of the disinfection options for personal protective equipment (see table below). UV-C emerged from this as one of the recommended methods⁹.

Summary of decontamination method antimicrobial efficacy

| Method | Treatment level | Microbe tested | Antimicrobial efficacy |
|---|---|--|------------------------------|
| Vaporous hydrogen peroxide (VHP) | 10 min conditioning phase, 20 min gassing phase at 2 g/min, 150 min dwell phase at 0.5 g/min, and 300 min of aeration. OR Room concentration = 8 g/m ³ , 15 min dwell, 125-min total cycle time. OR 10 minute conditioning phase, 30–40 min gassing phase at 16 g/min, 25 min dwell phase, and a 150 min aeration phase. | Geobacillus stearotherophilus spores T1, T7, and phi-6 bacteriophages | >99.999% |
| Ultraviolet germicidal irradiation (UVGI) | 0.5–950 J/cm ² | Influenza A (H1N1) Avian influenza A virus (H5N1), low pathogenic Influenza A (H7N9), A/Anhui/1/2013 Influenza A (H7N9), A/Shanghai/1/2013 MERS-CoV SARS-CoV H1N1 Influenza A/PR/8/34 MS2 bacteriophage | 99,9% for all tested viruses |
| Microwave generated steam | 1100–1250 W microwave models (range: 40 sec to 2 min) | H1N1 influenza A/PR/8/34 | 99.9% |
| Microwave steam bags | 1100 W, 90 sec (bags filled with 60 mL tap water) | MS2 bacteriophage | 99.9% |
| Moist heat incubation | 15–30 min (60°C, 80% RH) | H1N1 influenza A/PR/8/34 | 99.99% |
| Liquid hydrogen peroxide | 1 sec to 30 min (range: 3–6%) | Not evaluated | Not evaluated |
| Ethylene oxide | 1 hour at 55°C; conc. range: 725–833 mg/L | Not evaluated | Not evaluated |

In May 2020, RIVM published a literature review on disinfection of mouth masks. Steam sterilization, hydrogen peroxide and UV-C are listed as the main suitable options. It would be good if more research was conducted into these methods in Dutch healthcare institutions, RIVM states.¹⁰

Furthermore, the effectiveness of disinfection with UV-C has been demonstrated for medical instruments, equipment and, for example, handheld devices such as tablets (which doctors use every day in the care process), in research by a.o. UMCG¹¹, Radboudumc¹², Streeklab Haarlem¹³ and EurofinsLab¹⁴.



Here is an example of the impact of UV-C light on microorganism, with UV Smart's D25.

Micro organisms tested | D25

| | | Medical requirement (NEN-EN-14885:2018) (surfaces and instruments) | Results UV Smart | Research Center |
|--------------------------------------|---|--|---------------------|---------------------|
| Bactericidal | Staphylococcus aureus (ATCC 6538) | ≥ Log 5 | ≥ Log 6 | Streeklab Haarlem |
| | Pseudomonas aeruginosa (ATCC 15442) | ≥ Log 5 | ≥ Log 6 | Streeklab Haarlem |
| | Enterococcus hirae (ATCC 10541) | ≥ Log 5 | ≥ Log 6 | Streeklab Haarlem |
| | Escherichia coli (ATCC 10536) | ≥ Log 4 | ≥ Log 7 | Streeklab Haarlem |
| Sporicidal | Bacillus cereus (ATCC 12826) | ≥ Log 3 | ≥ Log 6 | Streeklab Haarlem |
| Yeasticidal & Fungicidal | Candida albicans (ATCC 10231) | ≥ Log 4 | ≥ Log 7 | Streeklab Haarlem |
| Fungicidal | Aspergillus brasiliensis (ATCC 16404) | ≥ Log 4 | ≥ Log 6 | Streeklab Haarlem |
| Yeasticidal | Candida auris (DSM 21092) | ≥ Log 4 | ≥ Log 7 | Streeklab Haarlem |
| Mycobactericidal | Mycobacterium avium (ATCC 15769) | ≥ Log 4 | ≥ Log 7 | Streeklab Haarlem |
| Mycobactericidal & Tuberculocidal | Mycobacterium terrae (ATCC 15755) | ≥ Log 4 | ≥ Log 7 | Streeklab Haarlem |
| Virucidal | Poliovirus type 1, LSc-2ab | ≥ Log 4 | ≥ Log 4 | Eurofins Biolab Srl |
| | Adenovirus Type 5, strain Adenoid 75 (ATCC VR-5) | ≥ Log 4 | ≥ Log 4 | Eurofins Biolab Srl |
| | Bovine coronavirus type 1 | ≥ Log 4 | ≥ Log 4 | Eurofins Biolab Srl |
| | Polyomavirus SV40, Stam 777 | ≥ Log 4 | ≥ Log 4 | Eurofins Biolab Srl |
| | Murine Norovirus, strain S99 Berlin | ≥ Log 4 | ≥ Log 4 | Eurofins Biolab Srl |

Source: Validation study: Microbiological efficacy of UVC-disinfection with UV Smart D25
Analytical Report: AAH00216 EuroFins

4. Applicability and safety of UV-C

Closed UV-C systems are inherently safe.

Due to potential health damage, the disinfection guidelines urge caution with the chemicals or hot steam used.¹⁵ Caution is of course also important with UV-C disinfection. The high-energy light is not only harmful to microorganisms, but also to humans. It can potentially cause eye damage, burning, or skin cancer.

Dated publications about safety precautions at UV-C usually discuss the use of open light boxes, which can be placed in a fixed place or mobile in a room.¹⁶ It is important to realize that nowadays a closed box is used for the disinfection of small medical equipment. That kind of solution is provided by the UV Smart D25. The materials to be disinfected in the D25 lies thereon on a glass plate with reflective material all around and is irradiated both from below and above. For safety, the UV-C source in the box can only handle when the valve is completely closed, so the design of these types of devices is inherently safe.

The correct use of the equipment is of course also important. The international trade association recently published a recommendation on this¹⁷.

In addition to checking the technical aspects of disinfection, in practice it is always about the correct application. To maintain an effective and valid process, it is important to train care staff and monitoring their results.¹⁸

It is also interesting to know whether the UV-C light does not damage the materials that are disinfected with it. This has been investigated for oral masks, among other things. Only after very high doses does the strength of the material decrease¹⁹, and the effect of the filter in FFP-2 masks remained unchanged after 8 cycles²⁰. This is consistent with research in air treatment systems: even 10 years of exposure to UV-C does not affect plastic filters and pipes²¹.

Damage to medical instruments such as endoscopes has also not been reported²².

Rigorous testing showed that 100 double cycles of UV-C disinfection does not affect integrity of medical grade ABS or polycarbonate plastic materials, as often used in medical devices. Just a slight yellowing was observed, as also known from exposure to sunlight of plastics.²³

Not even damage to sensitive electronics is to be expected - that's why NASA applies UV-C in their clean rooms, and it's also included in the strict disinfection protocols in interplanetary space travel²⁴.

In practice, this method of disinfection is easy to fit into the care process. The D25 is ready to be used when it is plugged in within reach of the department ("point-of-care" device). In the Netherlands, LUMC, Arijne, Ikazia, ADRZ, Martini and Spaarne Hospital have drawn up a protocol for application to ICs.



5. Experiences in the Netherlands

UV-C technology in practice

In the Netherlands, Radboudumc, Martini Hospital, LUMC, Spaarne Hospital, Zorgcentrum St.Jacob and Alrijne Hospital recently used UV-C technology from UV Smart for disinfection of small medical instruments and equipment.

Here a selection of their experiences.

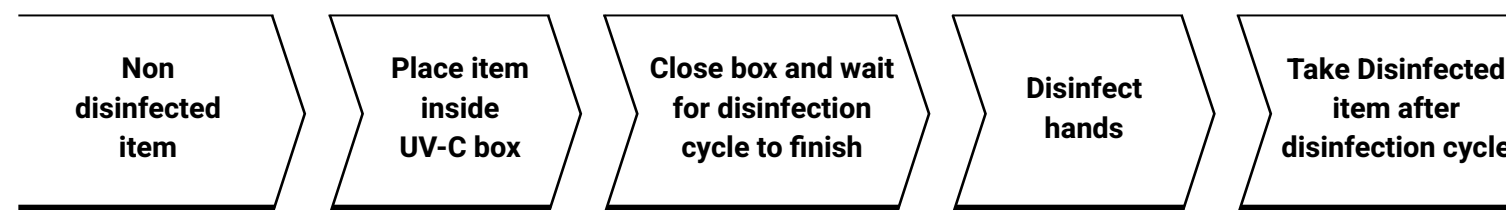
PROFESSOR HARRY VAN GOOR,

“The UV boxes have been purchased for the disinfection of medical devices, such as wrist cabinets and cables, to continuously monitor patients for vital signs. Also patient-bound tablets, smartphones, and VR glasses, smartphones and stethoscopes of employees can be disinfected in this way. This is a huge asset in reducing the virus load and the chance of transmission of the corona virus..”

MICROBIOLOGIST JAYANT KALPOE,

“UV-C has, if you apply it in a proper method and if you implement it in a proper method, it can help us make hospital environment safer for patients.”

Basic workflow UV-C disinfection in institutional care



Would you like to know how UV Smart applies this UV-C disinfection method in healthcare, among others?

Request the brochure for the D25 now via [this link](#).

6. Literature

Below is an overview of relevant literature.

More sources, and overprinting of relevant publications, are available on request from UV Smart. For technical specifications and further information / demos of UV Smart equipment, you can also visit the [website](#).

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- 13 Euser, s (2019, December 23). Validation study: Microbiological efficacy of UVC-disinfection with UV Smart D25. Data on file, Streeklaboratorium voor de Volksgezondheid Kennemerland, Haarlem. Consulted from: <https://www.medrxiv.org/content/10.1101/2020.04.01.20048496v1>
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