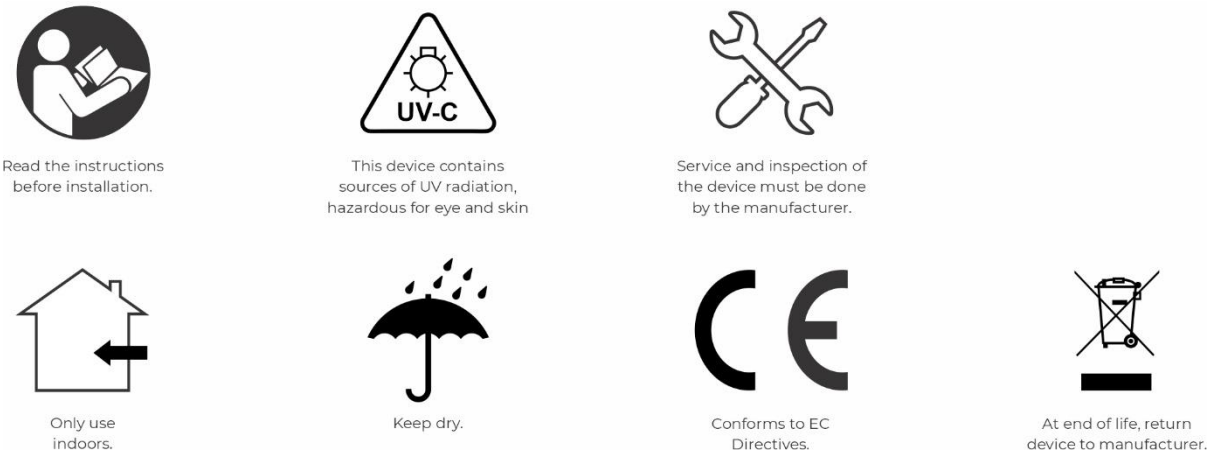
RAY-ONE

USER MANUAL

Product Name:	RAY-ONE
Unique Device ID:	ZA-01-Z-xxx
Date:	8 April 2021
Version:	v0.4

Disclaimers :



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1. QUICKSTART GUIDE.

PRIOR TO ANY USE:

Check for damage in the disinfection chamber, reflector walls and glass plates.
Clean the drawer insides with a damp cloth if dirty.

1.

Make sure the **objects** you want to disinfect are **cleansed** from dirt, blood, saliva...

2.

Disinfect your hands or use the special UVSEETHROUGH bags to put your objects in.

3.

Open drawer and **load your objects**.

4.

Make sure the objects surfaces **do not overlap**. There must be no shadow or coverage, all objects surfaces need to be visible.

5.

Close drawer and wait for the green light. Press the left or right bottom-corner of the touchscreen to navigate to the **next page**.

6.

Select and **start** the programme. A purple light will flash during the cycle.

7.

When light returns to green, the RAY-ONE disinfection **cycle is finished**.

8.

Prior to removing your objects from the drawer, **disinfect your hands** if you chose not to use the UVSEETHROUGH bags.

9.

Take out the objects.
Restart procedure.

1. GENERAL

1.1. INTRODUCTION

Disinfection has become a permanent part of our daily activities; the efficacy of good object surface hygiene is no longer an argument.

It is the responsibility of every medical practitioner to fully understand the characteristics pathogenic germs and strictly implement the most appropriate protective measures to reduce and control the risk of cross infection in applied procedures.

Not all objects being used during a medical consult are suited for thermal disinfection or sterilization. As these objects are also prone to contamination with saliva while being handled, medical practitioners are looking for additional infection control systems.

Traditional cleaning methods with bleach, alcohol and wet wipes cannot always reach the lethal dose required to eliminate nosocomial infections. The emergence of resistance to biocides makes this problem even worse.

The RAY-ONE is a user friendly and secure improvement on daily disinfection procedures. It serves in conjunction with other procedures. The RAY-ONE provides a LOG6 viral reduction on surfaces after their initial manual cleansing, freed from blood and saliva particles.

The approach to disinfection with automated processes without increasing the workload can only benefit biological safety.

The RAY-ONE uses sustainable LED light sources, reducing the use of mercury as in traditional UVC lamps. The LEDs are contained in a refractive enclosure protected by safety systems, prohibiting UVC radiation to escape, guaranteeing safe use of the RAY-ONE.

1.2. UV-C WARNING

The disinfection inside the RAY-ONE is achieved by use of UV-C emitting LEDs with wavelength 265nm+-5.

Such UV-C light, also known as far UV, is hazardous for skin and eye.

In case of the Ray-One, these UV-C light emitting LEDs are mounted in a device with a fully ‘closed enclosure’, and so the UV-C device does not emit any UV-C light.

1.2.1. UV-C Safety measures

Following safety measures remain important at all times:

- The apparatus can only be activated when the drawer is completely closed.
- The maximum radiation duration is limited to 3mins.
- The device is equipped with safety measures that the device stops all radiation automatically the moment the drawer would accidentally be opened during radiation.
- The Ray-One is designed in such a way that the housing is and remains inert for any degradation by UV-C light, by careful selection of materials.
- Every Ray-One device produced has to pass the Final Quality Check, including a UV-C Light Leakage Test, prior to become available for the market.
- In the highly improbable situation that the housing would get damaged, or that the drawer is not fully closing, do NOT switch on the device, disconnect the power cord and contact Zaparay Customer Service.
- Do not perform any repair or maintenance on the device, other than cleaning of the outside of the housing and the drawer. Please refer to 5.1 for cleaning guidelines.

1.2.2. Statement on Ozon Emission

The UV-C emitting LEDs in this device are narrowband with nominal wavelength 265nm +-5. Only light sources with wavelengths below 240nm might cause ozon emission.

With the Ray-One there is **no such risk.**

1.3. INTENDED USE

1.3.1. Intended Use

The intended purpose of the ZAPARAY RAY-ONE is sustainable UV-C LED disinfection of non-porous outer surfaces of non-invasive, non-critical medical instruments, such as stethoscopes, thermometers, communication systems…

The objects shall not be bigger than the surface of the disinfection chamber. Specific care is required ensuring objects to not overlap. The to disinfect objects should not be shadowed or covered during the disinfection process.

The RAY-ONE is not to be used for re-processing of single-use medical devices, neither for sterilization.

1.3.2. Intended Users

Any operator of the device should first read the safety instructions and the manual prior to activating the RAY-ONE.

Preferably it is only operated by users who received the short training on safety precautions and the working of the device.

At no time a user is allowed to perform any repair or maintenance other than careful cleaning of the outer surfaces and the drawer. For cleaning instructions see §5.1

1.3.3. INTENDED USE ENVIRONMENT

The RAY-ONE is for indoor use only.

It is advisable not to position the RAY-ONE close to heating elements or behind glass in direct sunlight. When the ambient temperature rises above 40°C the device will automatically interrupt the disinfection program and it will not be possible to restart again until the temperature drops back below 40°C.

For the same reason it is advised to assure sufficient air flow around the device to avoid overheating. The RAY-ONE is developed for intensive use. When operating the device with fast consecutive cycles the housing temperature may rise to 10°C above the ambient room temperature.

The RAY-ONE is preferably to be positioned on a table or shrank for easier handling of the drawer and user touch panel. It is not a floor-standing device: it is not meant to climb on top of it and one should not step into the open drawer.

The max. load on top of the RAY-ONE should be limited to 80kg. By that do not stack more than 4 RAY-ONE devices on top of each other. (taking into account that per RAY-ONE a load of 4kg per device is allowed – 5 empty ones would be ok).

To avoid small dust entering the device, and potentially affecting the radiation, it is recommended not to position the RAY-ONE close to printers (toner dust) or ventilators.

The RAY-ONE shall be used in the following environmental conditions:

- Relative humidity: 20%-90% (non condensing)
- Temperature: +5°C to +40°C

1.4. PERFORMANCE CLAIM

The RAY-ONE is intended to reduce micro-organisms by at least a LOG-6 in 3 minutes by using Ultra Violet Germicidal Irradiation generated by UV-C LED light sources.

The RAY-ONE is designed for the following use-cases:

Automated object disinfection
Fast LOG 6 disinfection of viruses.
Consistent object disinfection

1.4.1. Viral Performance

The following viral reductions are claimed:

Laboratory results from the Class III Virology lab at the Ghent University, Belgium.
Tests conducted on August 21st 2020, January 28th 2021 and February 8th 2021.

- 150ul porcine respiratoir coronavirus (PRCV 91V44 surrogate for SARS-CoV-2).
- Titre of 10 exp 8,5TCID50/ml.
- After radiation collection of drops and titred on ST cells. 10 fold
- Sample dillution and applied in fourfold on ST cells in a 96-well plate (50ul/well).
- CPE was followed during 4 days.
- Titre measured with Reed & Muench method.

TEST TIME RESULT RAY-ONE February 8th 2021	TIME		RESULT (10exp)	REDUCTION
1. 6-well control sample	300 sec	no UV-C	8,0	0
2. RAY-ONE - center position	5 sec	UV-C	5,6	2,4log10
3. RAY-ONE - center position	10 sec	UV-C	2,8	5,2log10
4. RAY-ONE - center position	15 sec	UV-C	<0,8	>7,2log10

TEST TIME RESULT RAY-ONE January 28th 2021	TIME		RESULT (10exp)	REDUCTION
1. 6-well control sample	300 sec	no UV-C	8,0	0
2. RAY-ONE - center position	30 sec	UV-C	<0,8	>7,2log10
3. RAY-ONE - lateral position	30 sec	UV-C	<0,8	>7,2log10
4. RAY-ONE - front position	30 sec	UV-C	<0,8	>7,2log10
5. RAY-ONE - special reusable bag in center position	30 sec	UV-C	<0,8	>7,2log10

TEST TIME RESULT PROTOTYPE August 21st 2020	TIME		RESULT (10exp)	REDUCTION
1. Fused silica plate control sample	300 sec	no UV-C	8,6	0
2. UVC LED TYPE K - top + bottom	60 sec	UV-C	<0,8	>7,8log10

1.5. WARNINGS

The RAY-ONE shall not be used in case:

- The use is non-intended.
- The device is damaged
- The support glass plate is broken
- The objects to disinfect are not pre-cleansed from blood and saliva
- Alien objects or pollution is present inside the disinfection chamber
- The objects to disinfect are organics, textile object surfaces or hollow tubes.

The RAY-ONE is not suited to disinfected infants nor animals, especially no guinea pigs should be inserted.

The RAY-ONE uses UV-C LEDs with monochromatic radiation at ~265nm. It is safe for the majority of plastics and UVA/UVB curing products, as most photo initiators do not react to the UVC wavelengths.

UVC LED radiation does not overcure UV-glue used in electronics, seen the monochromatic radiation there is less risk of plastics to become brittle or fall apart as with conventional UVC discharge lamps or with UV light outdoor.

Few studies have been published on the effect of monochromatic UV-C radiation on plastics. Potentially and depending on the nature of the plastic, as from 3000 disinfection cycles onwards, some plastics might start showing some discoloration.

It is advised to check UV-C compatibility with your devices manufacturer's guidelines.

2. PRODUCT OVERVIEW

2.1. SUPPLIED CONTENTS:

- RAY-ONE UV-C Surface Disinfection Unit
- Power cable
- User Manual
- Test report
- One RAY-PROOFER : your UV-C dose tester

2.2. FEATURES AND DIMENSIONS

Dimensions (W x D x H)	430mm x 430mm x 175mm
Weight	16,75kg
Voltage Rating	230 VAC
Frequency	50 Hz
Amperage Rating	max 2A
Power Consumption	68W
Power Consumption standby	0,5W
Protective Circuit	2 doorswitches and 5 sec. screen activation
Overvoltage Category	2
Pollution Category	2
Environmental Conditions	Indoor only
Maximum Altitude	2000m
Operating conditions: Temperature Relative Humidity	 5°C to +40°C 20% - 90% (non-condensing)
Transport and Storage Conditions: Temperature Relative Humidity	 -20°C to +50°C 20% - 90% (non-condensing)
Max weight of object to disinfect	4kg
Max size of object to disinfect (W x D x H)	255mm x 353mm x 85mm
Disinfection cycle	3min
Product Life Time	6 years @100cycles/workday
Average Service cycles	6months

3. FIRST TIME USE

3.1. lifting the device

The device is heavy (16,75kg) and by that you might want someone to help you lifting and carrying the device.

Do carry the device by lifting it at the bottom; do not carry it by holding the front drawer, or by opening the drawer and putting your hands inside.

3.2. Installing the device

The unit is delivered ready to use. It comes with a grounded plug and IEC connector and a power cord (250V AC, 10A).

Place the unit on a firm, level surface and plug the power cord in a standard mains socket.

Make sure that the drawer is smoothly opening and closing. The drawer is only fully closed if there is no gap between the front of the drawer and the housing. The resistance you notice at the start of opening and end of closing is a safety in the drawer slider to avoid that it would accidentally move open.

If the device was stored for a longer time in a cold environment, allow some time for conditioning prior to powering up. Do NOT power up if you would notice condense inside the device but wait until it is evaporated. Keeping the drawer open during this time will speed up this process.

In the drawer you will find a safety instruction leaflet, as well as UV-SEE-THROUGH radiation bags and one RAY-PROOFER UV-C dosimeter.

Remove all these items except for the RAY-PROOFER prior to start using the device.

Warning:

Do not place any objects near or in contact with to the outer surface of the unit so as to allow free air flow. Obstructing the air flow may cause overheating. The recommended maximum total weight of items disinfected at one time is 4 kg. The glass plate can become damaged by heavier loads or by sharp edged metallic items which are dropped careless on the glass surface.

Warning:

In case you would notice some loose or missing parts or observe any other damages to the device like the front of the drawer is deformed, and not fully closing, do not power it on. Contact ZAPARAY at +32 9 251 13 23 or welcome@ZAPARAY.com

3.3. First time use of the device

Make sure that the drawer is empty before loading your objects into the RAY-ONE.

The main power switch is at the back of the unit. The unit will automatically display the main menu when it is turned on. It takes just a few seconds for the device to be ready for use. During this startup phase the edge light might blink red for a few times.

During the radiation cycles a certain smell might be observed; this smell is not toxic, it is the result of UV-C radiation on organic materials present in the disinfection chamber like fingerprints or small amounts of dust.

4. USE OF THE RAY-ONE

4.1. Using the device

When the power is switched on, RAY-ONE automatically displays the main menu.

Before starting a disinfection cycle with the RAY-ONE, make sure to remove all visible soiling (eg saliva, blood, dirt, …) from the surfaces of your object.

Open the drawer and put your object(s) inside the drawer in such a way that there is no 'shadowing' and that the different parts of the object are not touching or overlaying each other. For instance, arrange a stethoscope in such way that parts are not touching each other, and unroll the cuff of a blood pressure monitor.

For an optimal disinfection, place the surface that is most likely micro-biological contaminated faced down on the glass of the drawer.

Keep in mind that the disinfection is realised by means of UV-C radiation: the more direct the radiation, the more efficient the radiation.

As a result, only non-hollow objects and objects with non-porous surfaces should be disinfected by means of the RAY-ONE: inner sides of (hollow) objects will not be sufficiently radiated as the UV-C radiation follows always a direct line of sight.

The unit is controlled with the touch screen in front of the device.

Upon powering up the RAY-ONE the display shows the product label if the drawer is closed.

To start a disinfection cycle, open the drawer and load your object, the screen backlight will start to blink a red light whilst the drawer is open.

After closing the drawer the 'start' menu becomes visible for 5 seconds and the background color will turn to solid green.

To start the 3-minute radiation cycle, push 'start'.

In case the start button was not pushed after 5 seconds, open the drawer and close it.

The start menu will appear for 5 seconds.

When the radiation cycle is activated, the background color will blink purple for the entire duration of the cycle. After 3 minutes the radiation will stop and the display will return to a green light.

If you open the door while the program is running, the device will interrupt the program.
The background color will start to blink red.

4.2. Using UV-SEE-Through bags

If you use UV-SEE-THROUGH radiation bags to contain your objects, make sure that these are not folded over your item to disinfect: 1 layer of the specific plastic will not affect the radiation dose inside the bag, but a double layer of plastic will reduce the efficiency of the disinfection.

For the same reason, be very attentive if you would place multiple bags inside the drawer for simultaneous disinfection: make sure that neither the objects nor the plastic bags are overlaying

each other. The bags are re-usable after radiation and should only be replaced when damage is visible upon inspection.

4.3. Correct use

This UV-C surface disinfection unit may only be used for the purpose indicated in this manual. All other uses or modification of the device for some other purpose is prohibited in order to avoid danger and damage.
RAY-ONE's can be used for disinfection of hard, non-porous outer surfaces (glass, plastics, metal) of solid objects, like electronic devices, tablet

ZAPARAY is not liable for any direct or indirect damages resulting from misuse of the device. The device is meant for indoor use only.

Avoid opening the door while the disinfecting program is running. If the door is opened while the program is running, the program will terminate and reset. In that case the required dose for optimal disinfection is not given, a restart of the cycle is recommended. It is the sole responsibility of the user to interrupt the radiation cycle before the display returns to a solid green state. ZAPARY's germicidal claims are only valid whilst having provided the full 3 minute cycle radiation.

When sliding the door into its closed position,, the user's fingers can get caught between the door and frame of the device. Use only one hand when closing the door.

Make sure to close the drawer properly, the display must be green lit in order to start the disinfection cycle.

The device may give off an odour after its 3 minute radiation cycle. This mild odour is the result of the UVGI (UltraViolet Germicidal Irradiation) on organic substances like fingerprints and other small particles, like dust, remaining in the drawer.

4.4. Preventing damage

The electrical safety of this device is guaranteed only when it is plugged in a correctly installed and grounded electrical outlet. Grounding is absolutely necessary for the safe operation of the device. Consult a qualified electrician when in doubt about the specification of your electrical sockets.

Do not place the UV-C unit in a space where explosive substances or oxygen enriched gasses are stored or where it can be exposed to freezing.

A damaged device can be a safety hazard. If the device is damaged, contact ZAPARAY customer service. Service and inspection of the device may only be carried out by ZAPARAY. Unauthorised repairs can result in danger to the user. Our contact details can be found on the last page of this manual.

4.5. Malfunctions and service

In the case of malfunction, restart the device by means of the mains switch at the back of the device. If the malfunction persists, contact ZAPARAY.

Do not use chemicals or water to clean the device. If necessary, wipe the unit with a damp cloth. See further under § 5

Note! The manufacturer is not liable for any direct or indirect damage to property or persons caused by use of the device contrary to instructions for use or safety instructions or other improper use of the device.

ZAPARAY's service contract extends the standard 24 months to 60 months and is highly recommended.

5. MAINTENANCE of the RAY-ONE

5.1. Cleaning

Prior to performing any cleaning, make sure that

- the device is switched off by means of the mains switch at the back of the device
- the power cord at the back of the RAY-ONE is disconnected.

The outer surfaces of the RAY-ONE can be cleaned with a damp cloth and / or antiseptic wipes. Do not use aggressive cleaning agents like bleach, paint thinner, acetone or acids.

To clean the inside of the drawer, use a damp cloth (not wet !) to run over the glass and side reflectors of the drawer.

After cleaning, keep the drawer of the RAY-ONE open to vent for at least 1 minute prior to loading new objects.

Do not use spray aerosols like disinfectants into the drawer or close to the user display of or at the mains power connection.

5.2. TOUCHSCREEN CLEANING MODE:

Pressing the top left or top right diagonal for more than 5 seconds will activate the display cleaning mode. During 15 seconds the screen will circular flash white light and a cleaning agent icon will be shown. Whilst this white LED backlight is present the display screen can be cleaned and no other functions can be activated. If a radiation cycle was ongoing, this will continue without any effect of the cleaning mode.

5.3. Transport

Prior to moving the RAY-ONE, make sure that

- the drawer is fully closed
- the device is switched off by means of the mains switch at the back of the device
- the power cord at the back of the RAY-ONE is disconnected.

Do not lift the RAY-ONE by the drawer handle. Always lift from the bottom.

5.4. Disposal

This device is compliant to the European regulation regarding the Waste of Electrical and Electronic Equipment (WEEE):

At the end of its useful life, the RAY-ONE is not to be treated as household waste, but need to return to ZAPARAY for further disposal and recycling.

Please contact ZAPARAY for further information.

6. PROBLEM SOLVING

6.1. Colour codes & related error modes

Colour	Explanation
RED (blinking)	The drawer is open; radiation cannot be started or was interrupted due to opening of the drawer during a disinfection cycle. There is NO UV-C radiation present.
ORANGE (blinking)	The ambient temperature is too hot: the disinfection process (if running) was interrupted and the device needs to cool down prior to restarting a disinfection cycle. Open and close the drawer to be able to re-start a disinfection cycle once the background light has returned to a green state.
PURPLE (blinking)	Disinfection cycle is ongoing; UVC radiation is present inside the device
GREEN (solid)	The device is ready to start a disinfection cycle: the device's power switch is switched on. The drawer is closed properly.
WHITE (cycling)	Display cleaning mode is activated. The unit will return to is previous state after 15 seconds.

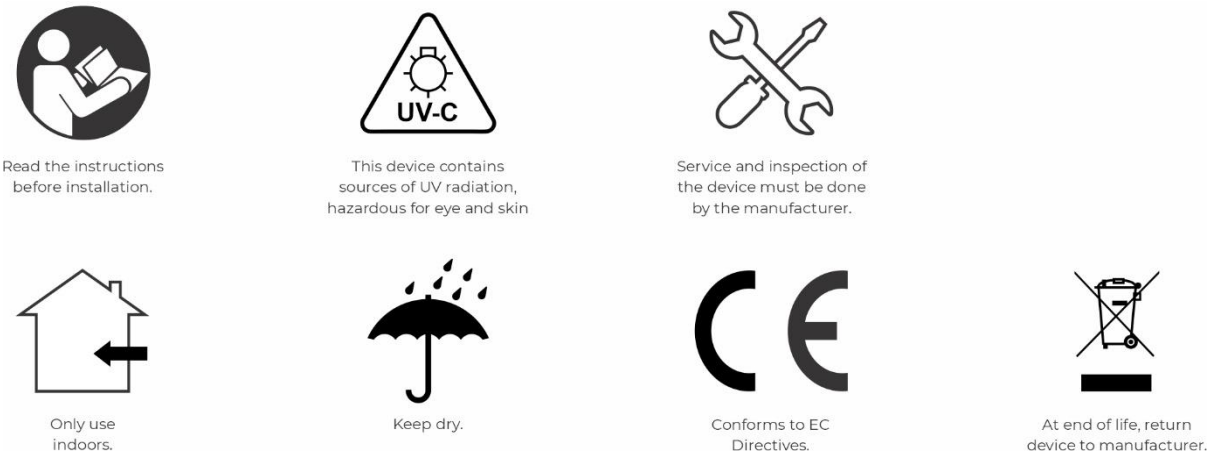
6.2. Undescribed behaviour:

In case the display would act in a different way than the above-described error modes, one can execute following steps to restore proper functioning:

1. Shut down and switch back on the power by means of the power switch at the back of the device. Note: the disinfection program was potentially interrupted and should be re-started. During the first 30 seconds after powering up the device, the touchscreen might blink a few times red, this is a message the processor is re-booting.
2. If above does not help: use a different wall socket to connect the device: disturbances present in the power circuits of the room might cause display malfunctioning. Also in this case, the disinfection program should be re-started.
3. If the problem persists, contact your ZAPARAY Customer Service

7. SPECIFICATIONS

7.1. SYMBOLS



7.2. WARANTY

The product has a 24-month warranty that covers defects in materials and manufacture. In case of problems, contact the manufacturer.
This warranty can be extended to 60 months by signing up for the service contract on the date of purchase. This service contract provides a bi-annual check-up and internal cleaning.

The warranty does not cover normal wear, or damage or malfunction caused by improper use. The product may not be opened or repaired by anyone except the manufacturer.

The warranty is voided if the device is not used in accordance with the instructions in this manual. ZAPARAY will under no circumstances be liable for any direct or indirect damages caused by the product.

If you have any questions concerning the device, do not hesitate to contact us:

8. CONTACT DETAILS

ZAPARAY is a registered trademark from Eledricity bv.

The RAY-ONE is produced in Belgium.

Technical files are stored in the company's headquarters:

Stooktestraat 2 - 9230 WETTEREN - BELGIUM
welcome@ZAPARAY.com
+32 9 251 13 23