ULTRA-V™

User Instruction Manual

9002 V1/0820

Inivos®

Ultra-V™ User Manual

VERSION 1/0820

ALWAYS READ THE INSTRUCTIONS
IN THIS USER MANUAL BEFORE USE

ULTRA-V™

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Welcome

The aim of this manual is to provide guidance, techniques, best practice and responsibilities for effective use of the Ultra-V™ system.

Please read and understand this manual. This will ensure you are familiar with the individual components and their functions of the Ultra-V™ system. Step by step instructions will ensure optimum performance and results.

All units are tested in our UK manufacturing and test facility by trained technicians. In the unlikely event of a malfunction or error, you should refer to this manual to rectify minor faults yourself. In the unlikely event your Ultra-V™ develops a serious fault, then please contact the relevant 24hr helpline displayed at the bottom of every other page.

Overleaf is a detailed table of contents to help you find your way around this manual quickly. Enjoy using the Ultra-V™ system!

IMPORTANT: Please keep this manual in a safe place.
It contains safety and operating instructions for your Ultra-V™ system.

When you see a bracketed letter in bold (B), it corresponds to the diagram of the Ultra-V™ on the fold out back cover. Please refer to this to see where items are located on the Ultra-V™ system.

Section 1: Essential safety information

- DANGER: Ultra Violet product. These lamps emit high-power UV radiation that can cause severe injury to skin and eyes. Avoid eye and skin exposure to unshielded light. Use only in an enclosed environment which shields users and others from the radiation.
- Only trained and competent operators must use the Ultra-V™ system. Use by untrained personnel can lead to an ineffective decontamination treatment, accidents or personal injury.
- Fully read and follow this user manual and follow provided instructions before attempting to operate the Ultra-V™ system.
- Never attempt to use the Ultra-V™ system for any purpose other than its intended use as a decontamination system.
- Never operate the unit outside an enclosed controlled area.
- Do not operate the Ultra-V™ system in wet conditions.
- Always ensure that the mains cable (D) is fully extended before use.
- Regularly check that the Ultra-V™ system (including its cables and accessories) are free from damage. Do not use the system if damaged, please contact Inivos for repair.
- It is recommended that the Ultra-V™ system should be connected to the mains through a 30mA RCD adaptor.
- The Ultra-V™ unit must be earthed.
- Do not use any other Power Adapter. Using an unapproved Power Adapter may result in system damage. Call Inivos if your supplied adapter is lost or damaged.
- Do not attempt to open the Ultra-V™ system. There are no user serviceable parts inside. Opening the Ultra-V™ system could be dangerous, and will invalidate the warranty.
- Do not attempt to replace the lamps (B) of the Ultra-V™ system, please contact Inivos for service.
- A lamp breaking is extremely unlikely to have any impact on your health. If a lamp breaks, ventilate the room for 30 minutes and remove the parts, preferably with gloves. Put them in a sealed plastic bag and take it to your local waste facilities for recycling. Do not use a vacuum cleaner.
- Do not attempt to defeat the safety systems.
- Avoid placing the Ultra-V™ adjacent to Air-conditioning vents, as this could result in incomplete, or termination of the process.
- Always use supplied door barriers to secure all entrances to the treatment area.
- Never enter a space where the Ultra-V™ system is operating, wait until the process has completed and the process monitor is displaying process finished.
- Always disconnect the system from the mains supply when not in use.
- Do not use harsh or abrasive chemicals to clean the Ultra-V™ system or its accessories. Suitable Solvent free wet wipes or a damp cloth may be used for cleaning. Always test for suitability in a small area first.
- The Ultra-V™ system must be serviced and PAT (Portable Appliance Testing) tested for electrical safety every six months. Note that the system does not have any user serviceable parts.
- Never look directly at the Ultra Violet light source. The system is designed to produce Ultra Violet radiation which can be harmful to eyes and skin if directly exposed.
- Always carry out a site and location specific risk assessment, taking into consideration the hazard analysis and risks reduction identified and implementing suitable control measures to avoid harm or injury to anyone.

Section 2: The Ultra-V™ system

2.1 Ultra-V™ system

The Ultra-V™ system is a bio-decontamination system that emits UV-C light, which is a proven technology for the reduction of biological contamination. The technology used by the Ultra-V™ monitors and adjusts the process to ensure consistent results in the reduction of surface contamination.

The Ultra-V™ system is intended to be used in enclosed areas only. If an area to be decontaminated cannot be enclosed and cordoned then please contact Inivos for further advice.

The Ultra-V™ system consist of three major components:

1. **The Main Unit –** This consists of ten low pressure mercury lamps responsible for the UV-C light emission and the structure for the lamps and the electrical components.
2. **The Process Monitor –** This controls the main unit, starts the process, stops the process in case of an emergency, and informs which stage the process is at.
3. **Spectromes –** There are 6 Spectromes. In use Spectromes must be located at strategic points within the treatment area. They monitor the decontamination process, controlling the amount of UV-C light necessary for an effective decontamination.

2.2 Ultra-V™ Safety measures

UV-C light is an electromagnetic radiation with shorter wavelength than that of visible light, in the range of 100-280nm. This short wavelength is effective in destroying the nucleic acids of the microorganisms so that their DNA is disrupted by the UV radiation, leaving them unable to perform vital cellular functions.

Direct exposure to short wavelength UV-C light can cause sunburn and skin cancer. Direct exposure to the eyes can cause extremely painful inflammation of the cornea and temporary or permanent vision impairment, up to and including blindness in some cases. UV-C light can also damage the retina of the eyes.

1

2

3

2.3 Ultra-V™ Process Safety

In order to avoid these potential risks of the UV-C light the Ultra-V™ system comes with a number of safety and security features that are designed to minimize the potential risk of accidental UV-C exposure:

1. The operator must secure all the entrance/exit points to the treatment area and display visual warning signs at all the entrance points to the space. Use Inivos tape to block any potential UV-C Light leakage.
2. In case of emergency, a “Stop Process” soft button is available during the process on the screen of the Ultra-V™ Process Monitor (BB), pressing it will switch off the lamps immediately and carry out safety checks. Do not enter room while the Process Monitor is performing safety checks.
3. The Ultra-V™ Process Monitor communicates with the Ultra-V™ main unit by Wi-Fi, this communication is checked every 10 seconds, in the case that the communication is lost, Ultra-V™ automatically switches off the lamps.
4. As a last resort, Ultra-V™ units are equipped with a movement sensor system (C) that automatically switch off the lamps when any movement is detected. Therefore, if someone inadvertently enters the treatment area, Ultra-V™ will automatically switch off the lamps to minimise exposure to UV-C light. This safety feature is last resort, putting any person very close to the hazard, and therefore must not be used to switch off the Ultra-V system light.
5. UV-C Light emitting lamps (B) feature a polymer coating sleeve which is designed to safely contain any glass in case of breakage.
6. The lamps of the Ultra-V™ system are provided with special lamp glass that filters out the wave-lengths which produce ozone, therefore the amount of ozone produced during the decontamination is negligible. If possible, allow the room to be ventilated before entering after the decontamination process.
7. Site specific risk assessment must be carried out taking into account hazards identified in this manual and the hazard analysis and reduction report.

Section 3: Before using the Ultra-V™ system

3.1 Pre-operation checks

Remove soft cover and stow away safely. Position the system in the room to be decontaminated.

Each Ultra-V™ system is individually tested for full functionality and calibrated before despatch. There is a small amount of machine set up required before use.

Check the Ultra-V™ system for damage after unpacking. Do not connect the electrical supply if any damage is identified. Check each bulb for damage.

Check the spectormes LED’s light up, if not replace the batteries.

3.2 Hazard Analysis and Risk Reduction Report

This document follows a standard risk evaluation and preventative action process to understand hazards and minimise risk to operators and to ensure process efficiency.

Through a process of implementation and audit of standard operating procedures, risk associated with Ultra-V™ Decontamination Process can be minimised independent of operator ability, ensuring safe operation of the Ultra-V™ System within the healthcare setting.

Quantitative Risk Assessment scoring

Likelihood scoring:

1. Rare - Will probably never happen or recur
(unlikely to occur /may happen sometime in 5 to 25 years)
2. Possible (under unfortunate circumstances) - Unlikely - Not expected to happen or recur, but possible (Possible to occur in time; may happen sometime in 2 to 5 years)
3. Possible - Might Happen or recur occasionally (Possible to occur in time; may happen sometime in 2 to 5 years)
4. Probable - Likely - Will probably happen or recur, but is not a persisting issue or circumstance (Probably will occur in time; may happen sometime in 1 to 2 years)
5. Almost Certain - Very Likely - Very likely to happen or recur: possibly frequently (likely to occur immediately or within a short period of time; may happen several times in one year)

Likelihood	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5
		1	2	3	4	5
	Consequence					

	Descriptor	Consequence
1	Very Low	▪ Minor reduction in quality of service ▪ No or minimal effect for customers or patients ▪ Minor Injury, First Aid not required
2	Low	▪ Single failure to meet acceptable standards of quality or service ▪ Low effect for small number of customers / patients if unresolved ▪ Minor Injury, First Aid required
3	Moderate	▪ Repeated failure to meet acceptable standards of quality or service ▪ Moderate effect for multiple customers or patients if unresolved ▪ Injury requires Doctor or hospital attendance
4	High	▪ Ongoing noncompliance with standards of quality or service ▪ Significant effect for numerous customers / patients if unresolved ▪ Major Injury resulting in Disability
5	Very High	▪ Gross failure to meet standards with totally unacceptable levels of quality or service ▪ Very significant effect for a large number of customers / patients if unresolved ▪ Fatality

In the interest of corporate responsibility, Specialist Inivos Will not participate in activities that are categorised as Very High Risk.

3.3 Hazard and Risk reduction associated with personnel

IDENTIFIED HAZARD	EXISTING CONTROLS	Likeli-hood	Impact	Score	PREVENTATIVE ACTION
Exposure to UV-C Light radiation when personnel inadvertently enter the area being treated during the process. Direct exposure to UV-C light. (This is Class 3 equipment as per BS EN 62471:2008 Standard) can cause eye and/or skin damage1. Daily UV-C light exposure limits can be exceeded within seconds.	In case of emergency, a "Stop Process" soft button is available during the process on the screen of the Ultra-V™ Process Monitor. Ultra-V™ UV-C light hazard and caution signs are displayed. Ultra-V™ units are equipped with a movement sensor system that automatically switch off the lamps when any movement is detected. Ultra-V™ radiation will switch off when movement is detected within the Artificial Optical Radiation Directive Guidance limits[2]. Ultra-V™ system is provided with a User Manual. Operators are provided with an accredited training qualification.	3	1	3	▪ The operator must secure all the entrance/exit points to the treatment area using the supplied door barriers and display visual warning signs at all the entrance points to the space. ▪ Never look directly at the Ultra-V™ light source. ▪ In addition to the hazards identified in this report, a Site-specific risk assessment must be carried out. ▪ The Ultra-V™ system is intended to be used in enclosed areas only. ▪ Operator or any other personnel must not enter the room while the decontamination process is in progress.
Leakage of UV-C light during the treatment cycle to adjoining areas	Only trained operators use the Ultra-V™ system. The process can be started only with the unique authorization card which is only issued to trained staff.	3	2	6	▪ All gaps should be blocked using supplied tape.
Strain or injury to the operator during moving and handling of the Ultra-V™ equipment and setting up Ultra-V™ equipment before and after the decontamination process	Secured on four fully steering castors, with a 360-degree handle, allowing Operator to maneuver system without the need for heavy lifting. The center of gravity of the main system unit is very low, which makes it very stable and easy to move. The Ultra-V™ User Manual indicates the correct system maneuvering information. Setting up equipment for the decontamination process does not require heavy lifting and is quick, simple and safe.	2	3	6	▪ Operators of the unit should always maintain an upright posture and avoid lowering their shoulders to push the machine as this can put undue pressure on the lower back area. ▪ Never attempt to lift the Ultra-V™. ▪ Avoid any drops like steps, kerbs and loading bays - do not attempt to wheel the Ultra-V™ down steps. ▪ Always follow best manual handling techniques and practice. ▪ The Ultra-V™ Systems should only be used by trained and competent operators. ▪ Training sessions allow operators to follow the correct room decontamination procedure
The operator is exposed to high electrical voltage.	No exposed live parts are accessible to the operator under normal conditions. The electronics box requires a tool to open and for a service personnel warning label is placed on the electronics box door to warn of the danger.	1	5	5	▪ Operators must carry out standard visual electrical safety checks before using the equipment. The system must not be used if damage to cables or system is identified. ▪ All Ultra-V™ equipment should be periodically serviced and electrically checked in accordance with relevant Electrical Safety Regulations.
Fire	All heat sources are adequately enclosed in metal compartment. Warning signs are present and visible to identify potential heat hazards.	1	3	3	▪ Site specific risk assessment must be carried out taking into account hazards identified in this report. ▪ Ultra-V™ system must not be used in the proximity of flammable or explosive materials.

3.3 Hazard and Risk reduction associated with personnel

IDENTIFIED HAZARD	EXISTING CONTROLS	Likeli-hood	Impact	Score	PREVENTATIVE ACTION
Injury in case of UV-C lamp breakage.	The UV-C emitting lamps are housed securely in the main unit and feature a polymer sleeve which is designed to safely contain any glass in case of breakage.	1	3	3	• Operators must follow best safe handling practice. • When maneuvering the Ultra-V™ decontamination system, only use the handle. Care should be taken to avoid sharp knocks and bumps particularly on the lamps of the Ultra-V™ system.
Mercury release for Ultra-V™ lamp breakage	All lamps have a polymer sleeve to minimize breakage due to minor knocks. A lamp breaking is extremely unlikely to have any impact on your health.	2	1	2	• Handle Ultra-V™ system with care. • If a lamp breaks, ventilate the room for 30 minutes and remove the parts, preferably with gloves. Put them in a sealed plastic bag and take it to your local waste facilities for recycling. Do not use a vacuum cleaner.
Trip hazards associated with the set-up and use of the Ultra-V™ equipment.	The Decontamination system is equipped with a 4-meter length of cable, which in most cases, will stay with-in treatment area. The process monitor is supplied with 1.5-meter length power adaptor, which could be extended using the supplied extension cable.	3	3	9	• Operators should be trained in cable management. • The cable in most cases, will stay with-in the treatment area. • Routing cables safely and if necessary use of covers. • Decontamination process should not proceed If the unit cannot be used safely.
Injuries or hazards related to misuse and defeat of safety features	The system is designed with several safety features including PIR sensors, software safety and a "one fault should not present a hazardous situation" design rational	2	3	6	• The operator must follow the User manual. Only trained operators should use the system. Trained operators are issued their own time limited operator card to use the system until refresher training is due and in built system reporting helps identify misuse.

Ref 1. Photobiological safety of lamps and lamp systems (BS EN 62471:2008)

RISK GROUP	Maximum Permissible UV Light Effective Irradiance (Eeff) At 20 Cm. 180 Nm – 400 Nm	Mpe Time At 20 Cm For Uprotected Skin And Eye Within An 8 Hour Period Per Day
Exempt	0.001 W/m2	8.33 hours
1 (Low)	0.003 W/m2	2.77 hours
2 (Moderate)	0.03 W/m2	16.66 minutes
3 (High)	> 0.03 W/cm2	< 16.66 minutes

Table 1 Risk group classification

Limitations

Classification is determined by UV light irradiance values at 20 cm distance – relates to the UV light emission of the source rather than characterising the exposure of a person – may not be appropriate for many applications.

Applies to normal operation only – may be not applicable to maintenance, service or abnormal operation (e.g. with broken filter glass). Relates to a single product – doesn't account for accumulative exposure from multiple sources.

Exempt group regarding the un-weighted UV-A limit is based on the ACGIH integration duration of 1,000 seconds – exposure to such lamps at a distance of 20 cm for longer than 16 minutes could lead to exceeding the ICNIRP ELV, where the integration duration is 8 hours.

Ref 2. AORD Exposure Limits for UV-C Disinfector

DISTANCE / meter	Angle Between Emitter & Detector (^{0})	Time To Exceed Aord Limit For Uv-C (Seconds)	L_B ($Wm^{-2}sr^{-1}$)
1	0	5.5	0.0111
2	0	14.3	0.0057
1	90	246.4	0.0027
1	180	797.6	0.0025

Table 2. AORD exposure limit with respect to the UV-C hazard. LB for an 8-hour shift is 100 Wm-2sr-1

The Control of Artificial Optical Radiation at Work Regulations 2010 SI No. 1140. Lower exposure limits may apply to Young persons. Specific young person's risk assessment must be carried out.

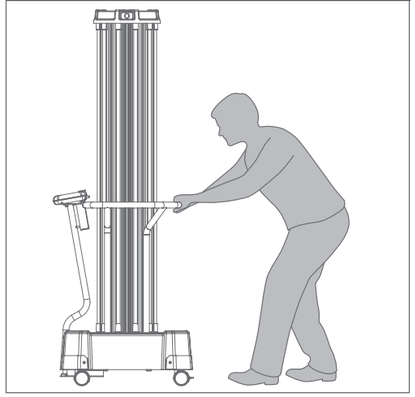
3.4 Manoeuvering the Ultra-V™ equipment

The Ultra-V™ is designed to be operated by a single person. Secured on four fully steering castors with a 360 degree handle (F) the Ultra-V™ unit is very easy to turn left or right. Most of the weight is at the bottom of the unit, which makes it very stable and easy to move, although care must be taken while pushing the Ultra-V™, especially up gradients. Maintain an upright posture and avoid lowering your shoulders to push the machine as this can put undue pressure on the lower back area. Never attempt to lift the Ultra-V™.

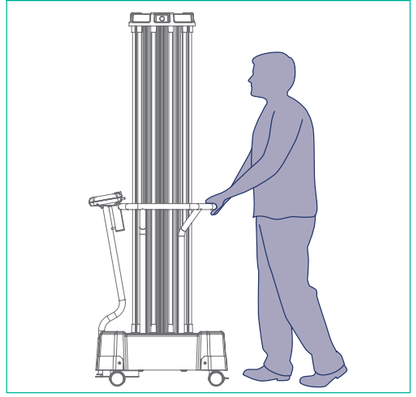
Take particular care when manoeuvring the equipment outside. Avoid any drops like steps, kerbs and loading bays - do not attempt to wheel the Ultra-V™ down steps! Always follow best manual handling techniques and practice.

Care should be taken to avoid sharp knocks and bumps, particularly on the lamps of the Ultra-V™. For your safety, the lamps of the Ultra-V™ (B) are provided with a polymer coating sleeve which is designed to safely contain any glass in the case of a breakage.

BAD POSTURE ✕



GOOD POSTURE ✓



NOTE: When manouvering the Ultra-V™ decontamination system, only use the handle.

3.5 Setting up the treatment area

The system does not require the use of chemicals to disinfect, unlike other technologies. The pre-treatment set up required is therefore minimal compared to other disinfection technologies. However, the use of the Ultra-V™ technology requires you to follow a protocol to ensure the maximum efficiency of the process:

Exposed surfaces - Ensure the maximum number of elements and surfaces are going to be exposed to the UV-C light. The Ultra-V™ technology relies on the UV-C light to reduce the surface contamination, the surfaces that are directly exposed to the UV-C light will receive the highest dose of UV-C light while the surfaces that are exposed to indirect UV radiation will present a lower grade of decontamination.

Cleaning – Ensure the room has been manually cleaned to remove gross soiling, dust and dirt. Dirt and dust interfere in the effectiveness of the decontamination process by shielding the microorganisms and not allowing the UV-C light to directly irradiate the surface to treat.

In this context cleaning is:

- The removal of organic matter
- The removal of adhesive residues and films and spills
- The removal of dust and visible dirt
- Free from waste materials
- Free from loose or compromised surfaces

Block possible UV-C leaking areas – UV-C light must not be transmitted to any adjacent area. In order to avoid this, the operator must ensure that all the openings are closed and gaps are sealed off to block the transmission of UV-C light from one area to another.

Location of the Spectromes around the treatment area – Spectromes monitor the amount of UV-C light they are receiving from the main unit. This helps them control the process and ensures an effective decontamination process. Therefore, Spectromes must be located around the treatment area (see section 4.6), ensuring that all the surfaces receive a sufficient amount of UV-C light for an effective decontamination.

The Ultra-V™ process lasts for a maximum of 45 minutes. In the case that one or more of the Spectromes have not received enough UV-C light after the 45 minutes of treatment, the process monitor will indicate which areas have not been properly decontaminated, allowing the operator to relocate the Ultra-V™ system and rerun the decontamination process.

Section 4: Using the Ultra-V™ system

4.1 Ultra-V™ user instructions

IMPORTANT: The Ultra-V™ system should only be used by trained & competent operators.

4.11 Identify, Cordon and Secure the area to be treated against general access. Stick "NO ENTRY – decontamination in progress" signs on every access door. Fill all required entries on the Warning sign sheet. Enter the area location, room name, date, time, operator, etc

4.12 Wheel the Ultra-V™ main unit into the centre of the treatment area & apply brakes.

4.13 Unhook the process monitor from the main unit by lifting it and placing it outside the room.

4.14 Take the Spectromes out of the storage tray and place them within the treatment area as far from the Main Unit as possible. Make sure The Spectromes sensor eye is facing the Main Unit. By doing so, the Ultra-V™ unit will automatically calibrate to the size of the treatment area and will ensure that the right amount of UV-C light is emitted. (Refer to Spectrome placing diagrams page 23)

4.15 Fully extend the main cable (D) of the unit by grasping the main plug and pulling. Plug the main cable into a convenient socket, using an extension lead if necessary. If an extension lead is used, it must be in accordance with site rules, approved CE marked 13A extension lead and must be fully unwound, not left in a coil.

4.16 Connect the Process Monitor to the convenient mains socket by using supplied Power Adapter (AA). If required, use supplied Cable Extension for extra cable length. Use ONLY Inivos approved Power Adapters and Cable Extensions.

4.17 Process Monitor will connect to Ultra-V™ System. You will be prompted with the confirming message on the screen (BB).

4.18 Close the door of the area to be treated. Ensure the warning signs are displayed at all entrances to the space. Use Supplied Door barriers to secure all entrances to the treatment area. Block any gaps using Inivos Tape provided.

4.19 When asked - If you are satisfied that it is safe to start the decontamination process then present your key card. (CC). Ultra-V™ Process Monitor will now ask if you are ready to start the decontamination process.

4.20 Check to ensure that the entrance/exit points to the treatment area are closed locked and sealed so that no UV-C light is going to irradiate outside the treatment area, then press "YES (start process)" on the process monitor screen.

4.21 The system will now perform a Baseline calibration.

4.22 Once the Baseline calibration has finished, the process monitor will show the status of each Spectrome. Thumbs up symbol would mean that Spectrome is working and communicating with the system. Thumbs down symbol would mean that Spectrome is not working or communication is lost. Low battery sign would mean that the batteries need replacing. If either of the last two symbols appear, re-enter the room, replace the batteries, or reset the Spectrome by placing it back into the holder. Press ''NO (start again)'' button on the process monitor. Process monitor will reset the system and will repeat the Baseline calibration – Steps 4.17 to 4.22. The Ultra-V™ system can be used with fewer than 6 Spectromes if necessary.

4.23 If all in use Spectromes appear with the thumbs up symbol, Baseline Calibration has been successful. Now, press ''YES (ready to start)'' on the process monitor screen. Decontamination process will start after 30 seconds. You will hear a warning sound prior to the UV-C lamps activating.

4.24 The decontamination process will now run for a maximum time of 45 minutes. The duration time of the process and Spectromes status will appear on the process monitor screen.

4.25 At any time during the decontamination process, the Ultra-V™ process can be Stopped and/or paused.

4.26 Once the process is complete, the process monitor will show the final status of in use Spectrome. Process is considered successful when all in use Spectromes are indicating Thumbs Up. If there are any thumbs down for the in use Spectromes, then the success of the decontamination of the room needs to be evaluated by a competent person. Inivos can provide guidance if necessary.

4.27 Once the Ultra-V™ decontamination process has completed successfully, enter the room, switch off at the wall sockets and unplug the process monitor and the main unit. Give a light pull on the unit's cable to disengage the ratchet and allow the cable to retract. Store process monitor power adapter neatly in the Storage box provided (AA).

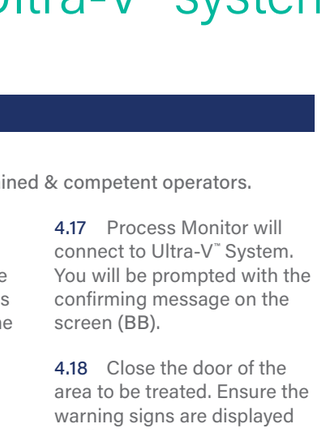
4.28 Collect all Spectromes and place them back in the storage tray (E), stow Process Monitor back on the main unit, and wheel Ultra-V™ system out of the treatment area. When the area is ready for patients, inform the staff involved and ensure the room is clear.

Ultra-V™ warning sign

The Ultra-V™ warning signage is a simple and highly visible single use sign to inform personnel of the Ultra-V™ process.

The sequentially numbered signs come in pads of 50, glued and stitched at the spine and perforated to remove the sign before use. The 'proof of process sign stub' retained in the spine of the book has space to complete process time, date, location and operator details and can be retained as proof of process for later reference. There is space for the operator to complete the predicted process times and contact details in case of emergency.

There is also a handy pre-process checklist on the reverse to ensure all necessary preparations are carried out prior to the process in order to achieve maximum efficacy of decontamination and safety in operation.



Ultra-V™ Door Barrier

You should always ensure that your Ultra-V™ unit is allowed to complete its Decontamination process uninterrupted. Our Ultra-V™ Door Barrier Kit has been specially designed to prevent accidental access to rooms being treated. This is achieved by preventing access to the door handle. The unit features a Telescopic pole, Door Barrier Sign Clip, and a Door Barrier Sign. The telescopic pole has been designed to fit securely into the door frame. The door bar sign is then slotted into the door bar clip, and then this in turn is clipped to the pole at a height which obscures access to the door handle. The barrier also features a write on/wipe clean section for the details of the process running, and of all other emergency and technical helplines.

Ultra-V™ Plug Guard

You should always ensure that your Ultra-V™ unit is allowed to complete its cleaning process un-interrupted. Our Ultra-V™ plug guard has been specifically designed to prevent the accidental removal of the unit's power supply from the mains wall socket . The unit features high visibility warning messages, and is produced in durable non-tear synthetic paper. The plug guard simply fits over the mains plug of your Ultra-V™ unit, creating a highly visual barrier to help prevent the accidental removal of the plug.

Inivos sealant tape

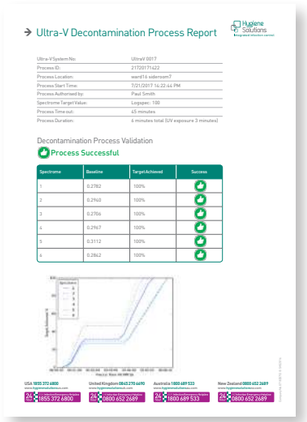
To operate the Ultra-V™ system safely within your organisation, you will require appropriate sealant tapes to prevent possible UV-C light leakage and visually mark the areas during the decontamination cycles for safety reasons. Our branded sealant tapes have been validated for the effective containment of UV-C light during the Ultra-V™ decontamination cycles. These 75mm wide tapes are designed for the easy sealing of doors, windows etc. They are specially developed to ensure successful adhesion without leaving a residue or removing paintwork from surfaces.

4.2 Ultra-V™ Process Log

Each time an Ultra-V™ process is completed, a log file detailing the Date, Time and Operator ID of the process is created. Other process parameters such as the UV-C Light readings from each Spectrome, including their target value and process duration time, will be logged on the same file. The process report file will hold all the relevant information required to validate and track the decontamination process. Any failed attempts to run a UV-C decontamination process will also be logged accordingly.

The Ultra-V™ system can send process validation reports directly to an email address using its internal mobile broadband connection. The service is dependent on a mobile broadband signal. If a WiFi signal is not available, the Ultra-V™ will store reports and send them the next time it is plugged in and a signal is available.

If you would like to enable this service, please contact Inivos using the contact details provided.


Ultra-V Decontamination Process Report

Hygiene Solutions

Decontamination Process Validation

Process Successful

Spectrome	Baseline	Target Achieved	Success
1	0.2782	100%	
2	0.2763	100%	
3	0.2756	100%	
4	0.2767	100%	
5	0.3112	100%	
6	0.2862	100%	

A typical decontamination process report showing that all Spectromes have received the required amount of UV-C light to decontaminate.

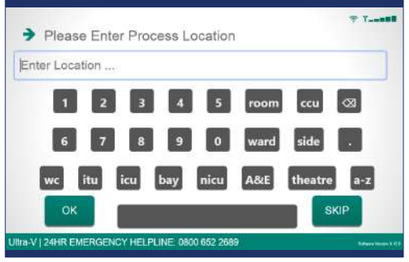
4.3 The Ultra-V™ Process Monitor

The Process Monitor is placed outside of the treatment area, it controls the main Ultra-V™ unit and it is supported by an advanced but easy-to-use piece of software that clearly indicates the steps you must follow in order to carry out the decontamination. It gives continuous on-screen indication of the process progress.

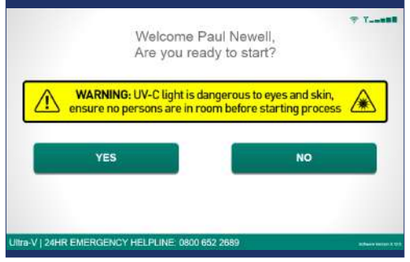
1 UNIT LOADING
Process monitor loads software

2 SPECTROME PLACEMENT
Screen shows optimal placement of Spectromes

3 PROCESS LOCATION
Operator enters location process is taking place

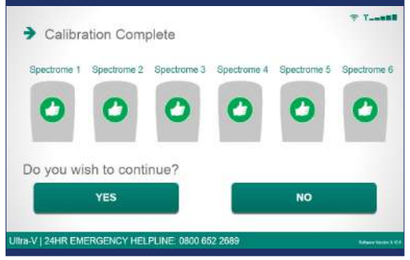


4 READY TO START
Ultra-V™ is ready to commence process. Operator must confirm

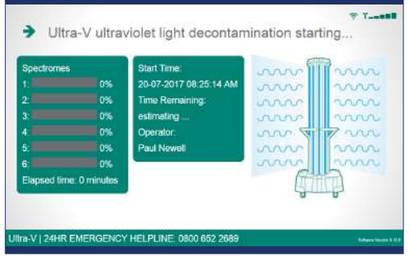


5 PREPERATION
Ultra-V™ is preparing to start the process

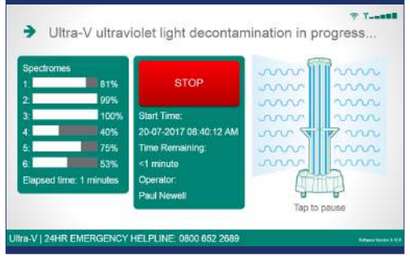
6 CALIBRATION
Ultra-V™ has completed calibration of the Spectromes



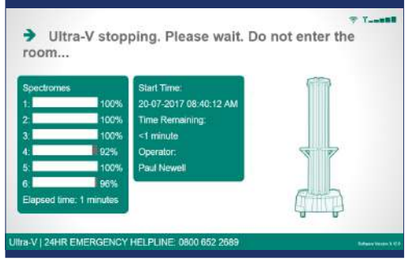
7 DECONTAMINATION STARTING
Monitor displays process information to operator



8 DECONTAMINATION IN PROGRESS
Monitor displays process information to operator



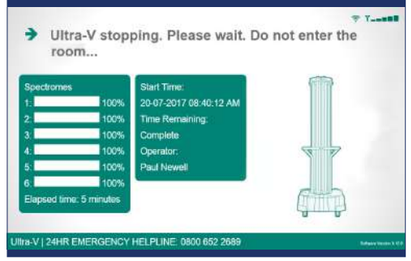
9 DECONTAMINATION STOPPING
Monitor displays process information to operator



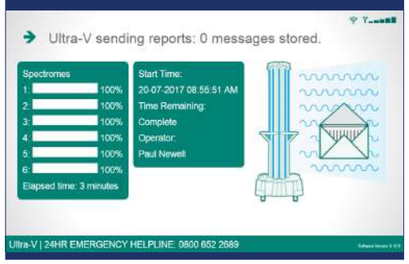
10 RESUME AFTER PAUSE
Operator has option to resume process after pausing

11 RESUME AFTER PAUSE - CONFIRM
Operator has option to resume process after pausing

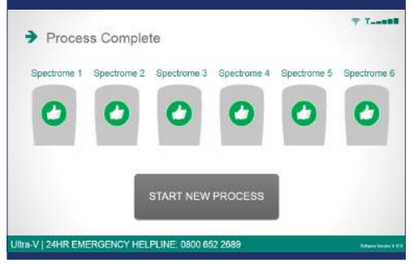
12 PROCESS STOPPING COMPLETE
Ultra-V™ process has ended



13 PROCESS REPORT SENDING
Ultra-V™ process report is sending to the designated recipient



14 PROCESS COMPLETE
Ultra-V™ process has completed



4.4 Method summary

TASK	SEQUENCE	DURATION
Location set up	Position the room contents for optimal decontamination performance Set up equipment Placing warning elements (Door Bar, Door Warning Sign)	Approx. 5 minutes
Decontamination process	N/A	Up to 45 minutes
Post-process requirements	Checking a successful decontamination process Remove Ultra-V™ equipment	Approx. 5 minutes

4.5 Should the power fail during a process

If the electrical supply to the unit fails during a decontamination process, it must be assumed that the decontamination process has not been finished successfully. Entering the room is safe and the system will be automatically reset. The decontamination process should be carried out again once the power has returned.

4.6 The Spectrome

Ultra-V™ system includes 6 Spectromes that are designed to monitor the decontamination process while actively responding to the amount of UV-C light they receive. Spectromes are responsible for the verification of necessary UV-C light exposure for an effective decontamination process.

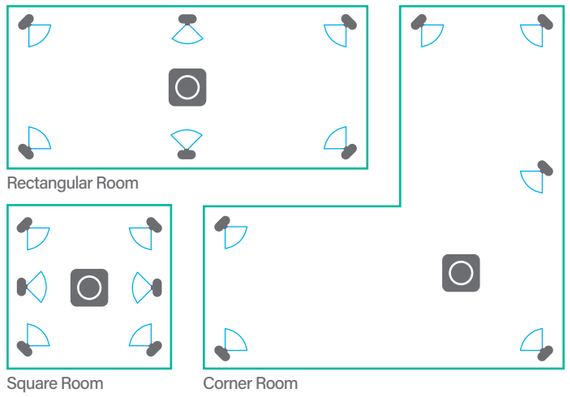
In order to get best results and a complete successful decontamination process, Spectromes must be located at strategic points within the treatment space, ensuring that all surfaces receive the right amount of UV-C light. Always make sure that the Spectromes sensor eye is clean and free from debris, and is facing the Main Unit. By doing so, the Ultra-V™ unit will automatically calibrate to the size of the treatment area.

Spectromes placing diagrams:

Key

Spectrome

Ultra-V™ Main Unit



Rectangular Room

Square Room

Corner Room

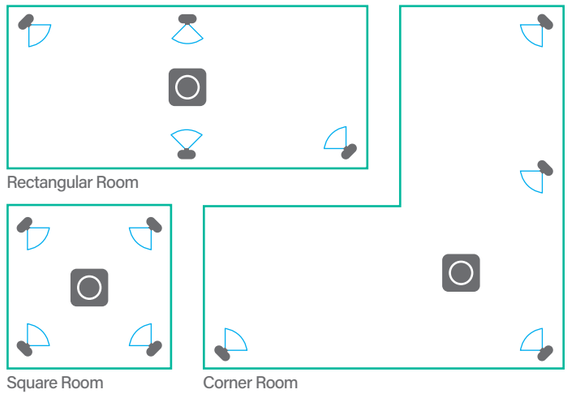
We advise using all 6 spectromes, however if necessary less spectromes may be used. In this case the spectromes used needs to map out the room space at the furthest points.

Spectromes placing diagrams:

Key

Spectrome

Ultra-V™ Main Unit

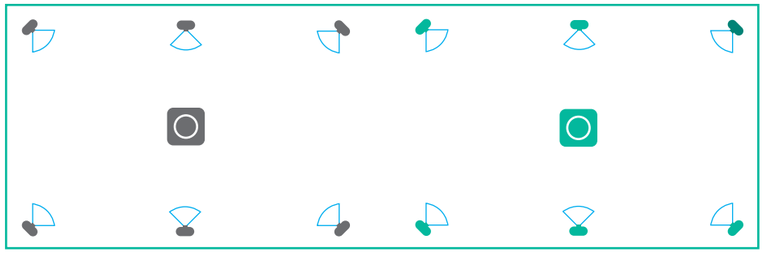


Rectangular Room

Square Room

Corner Room

For larger areas, such as bays, communal areas, corridors etc, you can use two or more separate systems at the same time. You would still follow the same treatment area setup procedure and deploy Spectromes as you would when using one Ultra-V™ unit.



4.7 Process Pause

Process Pause summary:

If you observe on the process monitor screen that the Spectromes are not receiving enough UV-C light you may also wish to pause the process to re-configure the room set up and placement of the Ultra-V™ Main Unit it may be that some of the Spectromes are in shadowed areas. Pressing the 'Tap to Pause' Icon on the process monitor screen will allow you to deactivate the Ultra-V™ and enter the room safely to change the position of the Ultra-V™ Main Unit. In some instances your Spectromes and Ultra-V™ may be in optimum positions for the room layout, in this case you may find it easier, where possible, to re-configure the furniture. Never change location of the Spectromes as this will not guarantee the required UV-C Light exposure to surrounding surfaces.

4.8 Ultra-V™ System message - Process Stop

Any time during the process you can stop the unit by pressing the 'Stop Process' Icon on the process monitor screen. You should only use in the case of an EMERGENCY or for stopping a process.

4.9 Ultra-V™ System message - Communications lost

This message is triggered when communication between Ultra-V™ main unit and Process Monitor has been lost. For safety reasons the Process Monitor of the Ultra-V™ checks the communication with the Ultra-V™ main unit every ten seconds. If the communication is lost the decontamination process is automatically stopped and displayed on the Process Monitor screen.

4.10 Ultra-V™ System message - Safety sensor triggered

This message is triggered when the sensors placed on the Ultra-V™ main unit (C) detect movement. For safety reasons the Ultra-V™ will automatically switch off, it does this in the event that someone may have inadvertently entered the room.

The sensors are passive infra red and will detect heat movement. Air conditioning systems and electronic equipment which change the heat patterns within the decontamination room will also trigger the sensors resulting in the process requiring a restart.

When the safety sensors are triggered, for safety reasons, the decontamination process cannot be restarted for 60 seconds.

4.11 Ultra-V™ System Message - Faults

When a faulty Lamp(s) is displayed on the Process Monitor, the Ultra-V™ Main Unit will continue to operate, but the time taken to achieve a successful decontamination, can be longer. The Ultra-V™ system lamps are not user replaceable parts and Inivos, service Engineer must be contacted.

Any other messages are due to a system fault and a Inivos service Engineer must be contacted.

Appendix 1: Declaration of Conformity

Appendix 2: UV-C Light

- Exposure to UV light occurs from both natural and artificial sources. The sun is the principal source of UV light. Solar UV undergoes significant absorption by the atmosphere. UV is one of the non-ionizing radiations in the electromagnetic spectrum and lies within the range of wavelengths 100 nm to 400 nm, and is invisible to human eyes. UV can be classified into UV-A (315 - 400 nm), UV-B (280 - 315 nm) and UV-C (100 - 280 nm) regions, although other conventions for UV-A, UV-B and UV-C wavelengths bands are in use.
- A strong germicidal effect is provided by the Light in the short-wave UV-C band. UV-C works using a photolytic effect whereby the radiation destroys or inactivates the micro-organism so that they can no longer multiply. For DNA, it does this by causing adjacent thymine bases to form a chemical bond, thus creating a dimmer. If a sufficient number of these are created, DNA cannot replicate.
- The most efficient source for generating UV-C are the low-pressure mercury discharge lamps. The radiation is generated almost exclusively at 254 nm viz. at 85% of the maximum germicidal effect. Lamps used with the Ultra-V™ system have an envelope of special glass that filters out ozone-forming radiation, in this case the 185 nm mercury line.
- Self-evidently, people should avoid direct exposure to UV-C. Fortunately this is relatively simple as it is absorbed by most products, even standard flat 4mm glass blocks all UV-C. However, you should take every necessary action to prevent direct UV-C light exposure to your skin and eyes.
- Direct UV-C light exposure to eyes could cause serious eye damage which may result in permanent loss of sight.
- Direct UV-C light exposure to skin could cause solar erythema, “sunburn”, which, if severe enough, may result in blistering and destruction of the surface of the skin with secondary infection and systemic effects, similar to those resulting from a first or second degree heat burn.
- In the unlikely event of being exposed to UV-C light, DO NOT look directly at the UV-C light source. Close, or shield your eyes and leave the area immediately and seek medical advice.
- The Ultra-V™ unit has three layers of safety and security to prevent accidental UV-C exposure, which are designed to automatically deactivate the unit should it sense a change in its operational environment. The residual risks are detailed in the Ultra-V™ Hazard analysis and risk reduction report.

Ref: Environmental Health Criteria 160, World Health Organisation Geneva 1994

Appendix 3: Ultra-V™ study

Evaluation of Ultra-V™ decontamination as an adjunctive to manual cleaning at Barnsley Hospital

Denise Gibson, Dr Jyothi Rao, Susan Burns, Lynn Wright

Section 1 – Objectives

Barnsley Hospital NHS Foundation Trust has been using a hydrogen peroxide vapour (HPV) system to decontaminate the environment. However, this introduces a significant downtime of several hours which the Trust is working to reduce. This has led to an evaluation of UV-C decontamination as a new technology to reduce environmental contamination. The purpose of this evaluation was to assess the efficacy of UV-C decontamination (Ultra-V™) on surfaces both directly and indirectly exposed to UV-C radiation, using a Total Viability Count (TVC) method to culture aerobically forming colonies.

Section 2 – Materials and Methods

The resources used in this study where:

- Ultra-V™ decontamination System
- Rodac Agar Plates x300 - Pro-Tect TWI (Contact Plate) - Product Code PO0678D
- List of Surface Sampling Points for each room
- Sterile Gloves

Testing was carried out in the following steps:

1. On discharge of a patient, 5 samples were taken from the room prior to cleaning from the following locations: inside of chair arm; under bed; windowsill; mattress; and door handle. See 'Method of Sampling' below.
2. The room was then cleaned and allowed to dry.
3. Samples were taken from the same locations post-cleaning
4. The Ultra-V™ decontamination system was then deployed and the process time recorded.
5. Another 5 samples were taken from the standard sample sites

Section 3 – Method of Sampling

1. The agar plate was numbered with an indelible marker
2. The agar was placed on the surface to ensure contact.
3. The plate was lifted from the surface and lid replaced
4. The plate was placed in an insulated box.
5. The plate number and surface contacted were recorded in the table
6. The process was repeated at all sample sites through all stages

Sterile gloves were worn and care was taken not to contaminate the samples at any point.

Section 4 – Results

Mean average process time of 21.4 minutes. Range 12-30 minutes.

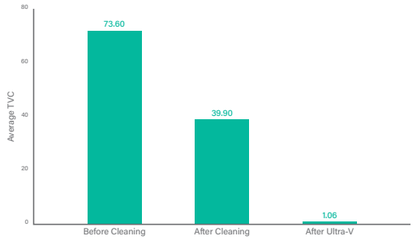


Figure 1. Average Total Viability Count (TVC) by Stage

Discussion

Figure 1 shows the averages from the sample sites, and the corresponding total viability counts cultured at the varying stages of the process. This showed on average, cleaning led to a reduction in the overall bio-burden, (73.6 - 39.902), but with a significant level of contamination still remaining. The introduction of Ultra-V™ decontamination led to a further reduction in the total count (39.902 – 1.06). It should be noted that these results from UV-C are from sites both directly and indirectly exposed to the UV-C rays.

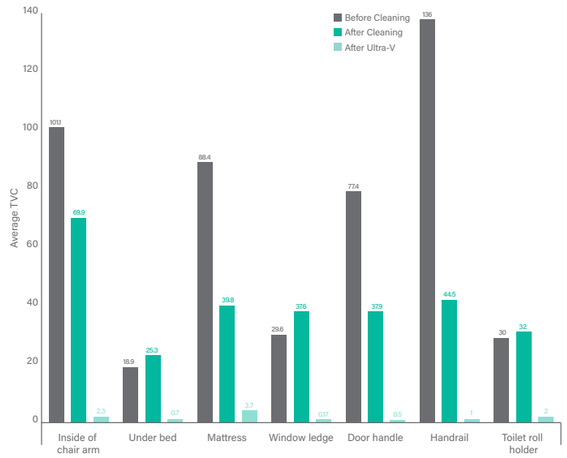


Figure 2. Average TVC by Site at Each Stage

Discussion Continued

Figure 2 shows the average total viability counts at each stage of the process, at the different sites that were sampled around the room. The patient hand rail was the site on which most contamination was found, with the average before and after counts of 136 and 44.5 respectively. However, after Ultra-V™ it had an average colony count of only 1. The Inside of Chair Arm, Mattress and Door Handle were all identified to be sites with high contamination both before and after cleaning, suggesting that manual cleaning as a process still leaves significant risk to the next patient. This clearly highlights that manual cleaning alone does not fully remove the risk of environmental organisms to our patients. However, after Ultra-V™, all of these sites showed low levels of contamination (2.3, 3.7 and 0.5 on average respectively), significantly reducing that risk. The data also shows us that although there is generally a reduction after cleaning, a significant bio-burden is still detected in the room (average 39.902 Figure 1), but after Ultra-V™ there were consistently low counts, even on sites in the en-suite which we would not expect to be directly exposed to the UV-C rays due to obstructions in the direct line of sight.

Conclusion

Owing to the fact that the Ultra-V™ requires no vapour-impermeable sealing and is a rapid process, this technology may be particularly suited to high-pressure environments for example ED, ICU and theatres and would enhance any bed management programme. Pressure to release beds for new patitents is a continual concern and needs to be balanced with providing a safe and clean environment. The Ultra-V™ could be an integral part of securing patient safety whilst optimising bed flow.

Section 5 – Further Work

This evaluation assesses viable aerobically-forming organisms and does not evaluate efficacy against spores

Appendix 4: Ultra-V™ maintenance

A4.1 Regular care

Once a week wipe down the case, lamps (B) of the Ultra-V™ system, the Process Monitor, and the Spectromes to remove any dust. Never use any wet substance to clean the parts of the system.

Regularly check the mains lead and the Process Monitor for damage, paying particular attention to the points where they emerge from the connectors. The wheels of the Ultra-V™ system (A) should be periodically cleaned.

A4.2 Machine servicing

The lamps of the Ultra-V™ system have a working life of 9000 hours and begin to reduce their intensity and performance after this time, therefore they will need to be changed. The lamps must be changed by Inivos, failure to change the lamps after 9000 hours may lead to longer process times and frequent process failures.

When Spectrome status appears with a low battery sign, all four batteries should be replaced with new AA size Alkaline batteries. The Ultra-V™ system must be serviced every 6 months for optimum performance. There are no user serviceable parts.

Moreover, the Ultra-V™ system must be PAT (Portable Appliance Testing) tested for electrical safety. Inivos can provide this service. The system will flash up a warning message for 30 seconds at power up every six months when this service is due.

8.1 FAQs

Q: How Does Ultra-V™ Work?
A: Ultra-V™ system emits UV-C light, which destroys the nuclei acids of the microorganism, leaving them unable to reproduce.

Q: Is UV-C light dangerous to people?
A: Yes, direct exposure to UV-C light can cause serious damage to skin and eyes.

Q: Would simple glass filter the UV-C light?
A: Yes, UV-C light is absorbed by most products.

Q: Can I replace the bulbs by myself?
A: No, call Inivos for service

Q: How long does the process take?
A: Average side room would normally take 20 min to complete.

Q: How do I stop the process?
A: Process can be stopped by pressing ‘Process Stop’ button on the screen.

Q: What is Spectrome?
A: Spectromes monitor decontamination process to ensure the right UV-C light exposure.

Q: How do I start the process?
A: Process can be started by using a unique key card.

Q: Do I need to have any training to use Ultra-V™ system?
A: Yes, only trained operators can use the Ultra-V™ system.

Q: Should the room be cleaned before using the Ultra-V™ system?
A: Yes, room has to be manually cleaned to remove gross soiling, dust and dirt.

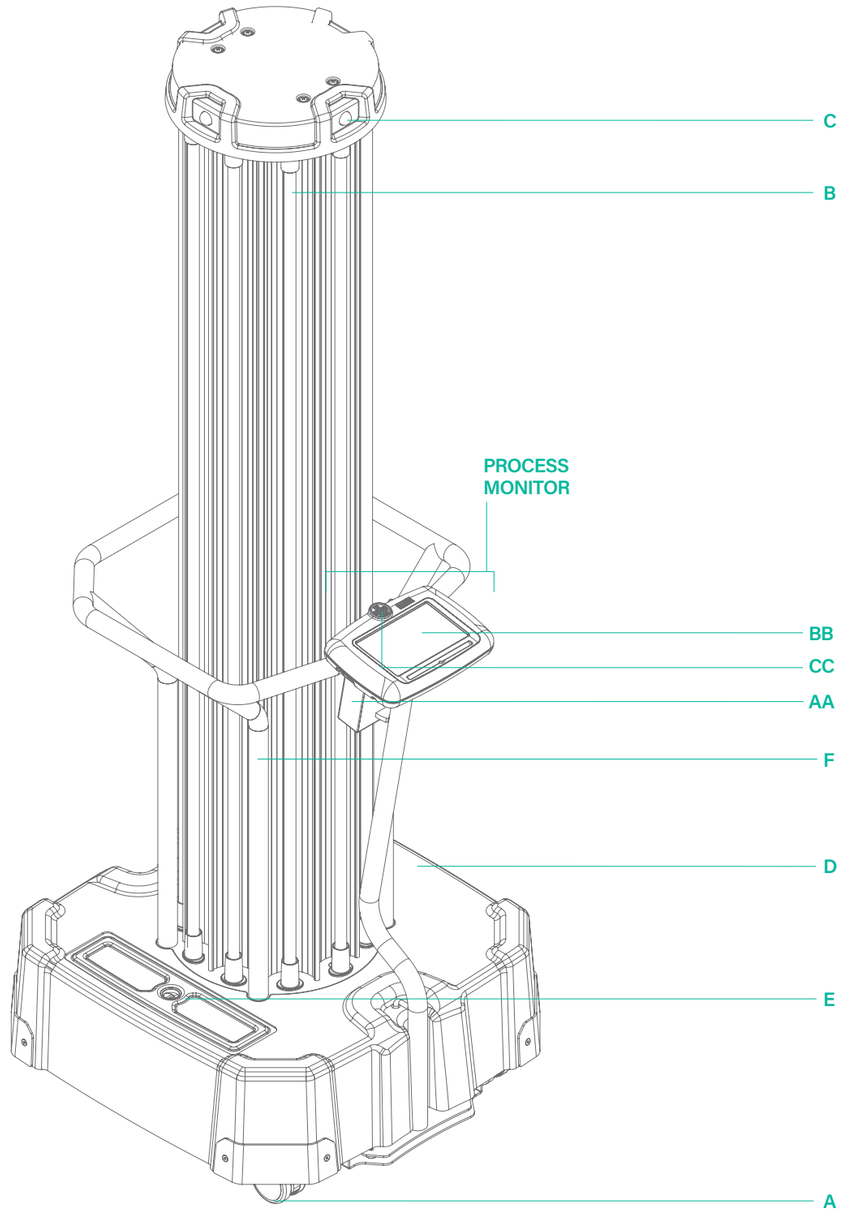
Appendix 5: Information

External dimensions (mm)
1880·660·610 without Process Monitor
1880·660·720 with Process Monitor

Operational temperature range	0-30°C
Operational humidity range	0-95% RH
Power consumption	1430W @ 230V
Supply voltage range	220-240V AC
Supply frequency	50Hz
Plug fuse	13A

The Ultra-V™ unit

Diagram 1



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307 Euston Road,
London NW1 3AD,
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Netherlands

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Het Poortgebouw 54-62,
1119 PW Schiphol, Netherlands

24 HOUR RAPID RESPONSE 035 5336072

USA

1740 Broadway, 15th Floor,
New York, 10019,
USA

24 HOUR RAPID RESPONSE 1855 372 6800

Australia

Australia Square Plaza,
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Australia

24 HOUR RAPID RESPONSE 1800 689 533

New Zealand

6 Clayton Street,
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1023, New Zealand

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