J. Protect Testing Protocol

Version 1.1

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August 10, 2020

Table of Contents

Executive Summary

Recent events brought to the front the problem of environmental hygiene. What used to be the realm of hospitals and healthcare facilities is now a global concern endangering all people and effecting our economy.

Public spaces are a hotbed for contamination… Enclosed areas with high traffic/high touch surfaces and people of all ages and underline health conditions – they have become dangerous.

JUGANU with J.Protect – is offering an efficient, cost efficient and safe, protection solution for public spaces.

Lab test and installations in clinical inpatient environment have shown the intuitive and easy to use solution, with minimal impact on the daily life and minimum changes in operations settings.

The effectivity of the J.Protect solution, the capability to use both modes of operation and a combination of both in a scheduled manner creating a unique capability to disinfect in the most safe and green approach with no side effects and with minimal impact on the day to day lives of organizations and citizens.

ALLEGRO - CONTINUOUS DISINFECTION

- Safe & Continuous protective light with unlimited exposure time for humans.
- Juganu is using the safest zone of the disinfecting range (390nm-400nm) in compliance with IEC62471.
- Lab test proven to be effective for virus and bacteria.
- Self-explanatory, user friendly graphical user interface to achieve safe and easy operation.

PRESTO – ACCELERATED DISINFECTION

- Accelerated mode with UVC (265nm-275nm) disinfecting area in a very short time.
- Lab test proven to be highly effective for wide germicidal spectrum
- Self-explanatory, user friendly graphical user interface to achieve safe and easy operation.
- Operated only after space is checked to be vacant from people presence.

The test protocol in this document is based on the accumulated experience in the different settings including university clinical labs for virology.

Introduction

The use of pseudoviruses-based assays for the measurement of inhibition of infection provide a convenient system in cases of safety issues in using live viruses such as with the current SARS-CoV-2. Results with pseudo corona viruses were demonstrated to be consistent with results with live viruses, and therefore are reliable in determination of inhibition of infection.

It is required to have SARS-CoV-2 Pseudoviruses that are based on retroviruses expressing on their envelop the SARS-CoV-2 spike protein, that mediates entry into host cells. These viruses contain the gene for GFP as reporter. Therefore, infection can be quantitated by detection of GFP positive cell.

Objective

The objective of the test is to define the capability of different irradiation levels of Juganu J.Protect Allegro and Presto light to deactivate the infection capacity of SARS-cov-2 spike pseudovirus in human cells.

Methods

Production of SARS-CoV-2 Pseudoviruses

HEK 293T-cells should be transfected with expression vectors encoding for the viral components for packaging (Gag-Pol), vector containing reported gene (GFP) and a vector encoding the SARS-CoV-2 S protein. Culture supernatant fluids containing pseudovirus should be collected, and pseudoviruses should be concentrated and stored. The titer of pseudoviruses is determined by quantification of the number of GFP-positive cells that represent the number of infectious viruses using IncuCyte® (Live Cell Analysis System), and calculation of transduction unites per 1ml (TU/ml).

Measurement of SARS-CoV-2 Pseudoviruses infectivity

Virus stock should be diluted to 10^3-10^4 infectious viruses in 50ml per well in a 96 well plate. The samples should be placed inside a fume hood. Irradiation will be applied (without a lead) at different modes and then the medium containing irradiated viruses will be transferred to Human HEK293T cells stably expressing the ACE2 receptor that is generated pre-seeded in a 96 tissue culture plate at $1*10^5$ cell/well. At 3 days post infection, the number of GFP-positive cells that represent the number of infectious viruses should be visualized and counted using IncuCyte® (Live Cell Analysis System). The % of infection should be calculated as number of positive infected cells in each treatment compared to number of infected cells in an un-treated control.

Methodology

J.Protect luminaries should be installed according to the defined setup.
According to the different operation times of the different modes samples will be collected to measure the J.Protect radiation effect.

The J.Protect luminaries will be set in two different setups for the test.

- Hanged/set in a 2feet high above the surface.

Facilitators

Observer and Safety person.
Technician – to operate the system
Clinical staff - to run the pathogens test.

Training

The participants will receive an overview of the test procedure, equipment and application.
The training will include dedicated session on:

- Installation and setup of the J.Protect luminaries.
- User application and the operation of the two modes.
- Safety instructions.
- Live session of operating system and go-through the different operation modes.

Roles

The roles involved in a test are as follows. An individual may play multiple roles and tests may not require all roles.

Trainer

- Provide training overview prior to testing. Trainer will be A Juganu representative.

Facilitator

- Defines purpose of usability testing
- Assists in conduct of debriefing sessions

Ethics

As there is no human interaction or intervention in people there is no need for an ethical committee approval.

Critical Errors

There are two main errors we can foresee and avoid;

- Safety related error
- Measurement related error

For safety related error operator and all other should follow the safety instructions related to the operation of Presto/Mode 2 as it has UVC radiation that harms eye and skin. Protecting gear should be used at all times of Mode 2 operation.

To avoid measurement related errors there should be enough fluid in the petri dish.

Setup and Installation

1. Setup

    a. Setup1:
        1. 2 J.Protect luminaires are installed side by side, 2 feet above the testing surface.
        2. The arrangement should be 4 feet distance between the centers of the luminaries

Required Tools

1. Photometer that measures Irradiance that is sensitive to 200nm – 800nm
   Use this photometer to measure the actual radiance at each mode of operation

2. 2 Black box covers

J.Protect Fixture Operational Tests

1. J.PROTECT fixture

The fixture is operating according to the characteristics of the product Data Sheet and formal documentation

a. User can Turn Fixture ON with Mode 1
b. User can Turn Fixture OFF with Mode 1
c. Mode 2 is NOT Active when only Mode 1 was Turned ON
d. User can activate Mode 2 via Application
e. Mode 2 is Active with RED LED Indicator
f. Mode 2 can be Stopped when User is in proximity to PIR – multiple distances to be checked (with required eye and skin protection) – 3 feet, 10feet, 15feet.
g. Mode 2 is stopped in less than 10 seconds from detection
h. Application provides indication that it was interrupted.
i. Mode 2 can be stopped manually by user
j. Application provides indication that there was a manual stop
k. Mode 2 starts operating and become active only after pre-defined timer was executed. Timer is set to 20 seconds

2. **Operator Application**
   a. Operator can access the app using his Fingerprint
   b. Operator can scan the QR Code
   c. Operator Application get connected to the J.Protect Fixtures in the designated area
   d. Operator Application get Status from PIR Sensor in the designated area
   e. Operator Application is activating Mode 2 in the designated area
   f. Operator Application Timer is working according to the pre-defined operation time
   g. Operator Application get notification of Start/End of Mode 2 Operation

Radiation tests

1. Modes of Operation
   a. Allegro continuous Mode (Mode1) - Continues JMix (light spectrum plus UVA) protection light using Planar D
   b. Presto accelerated deactivation Mode (Mode 2) - Juganu UVC technology.

2. Testing concept
   a. System operation
      After training and after conducting full fixture operation lab test can be started.
3. Efficacy Test

   a. Principal
      1. Operate the J.Protect system in Allegro Mode.
      2. Operate the J.Protect system in Presto Mode.
      3. Operate the J.Protect system in combined mode – First Allegro and then Presto.
      4. Take SARS Cov-2 samples from the testing surface of each exposure condition at the defined schedule.
   b. Exposure Conditions
      1. Control, no light – Covered by black box
      2. Allegro continuous light only - Covered by black box when Presto accelerated Mode operates
      3. Juganu Presto UVC technology only - Covered by black box when Allegro Mode operates
      4. J.Protect Mix (combined Allegro + Presto) – No cover

c. Suggested Testing schedule
This schedule is repeated for at least 3 times in the two different setups.

1. Mode1 - 60min followed by Mode2 – 1min
2. Mode1 - 60min followed by Mode2 – 5min
3. Mode1 - 180min followed by Mode2 – 1min
4. Mode1 - 180min followed by Mode2 – 5min
5. Mode2 – 1min
6. Mode2 – 5min
7. Mode2 – 15min
8. Mode2 – 30min
9. Mode1 – 300min
10. Mode1 – 300min followed by Mode2 – 1min
11. Mode1 – 600min
12. Mode1 Dimmed to 60% – 300min
13. Mode1 Dimmed to 60% – 480min
14. Mode1 Dimmed to 60% – 600min