SOP

Clinical Trial Protocol (Phase I, II, III) of Innoen® Airborne Infection UV Quarantine® Device

Regulated Under Health Canada

CLINICAL TRIAL PROTOCOL (PHASE I, II, III)
FOR AIRBORNE INFECTION UV QUARANTINE DEVICE

PART I. PHASE I CLINICAL TRIAL PROTOCOL
FOR THE SAFETY OF THE INFECTION UV QUARANTINE DEVICE

PART II. PHASE II CLINICAL TRIAL PROTOCOL
FOR THE EFFECTIVENESS OF THE AIRBORNE INFECTION UV QUARANTINE DEVICE STUDY WITHOUT HUMAN PARTICIPANTS

PART III. PHASE III CLINICAL TRIAL PROTOCOL
EFFECTIVENESS OF THE DEVICE FOR ON-SITE INFECTIOUS AGENT PREVENTION VALIDATION WITH HUMANS PARTICIPANTS

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1.0 Purpose and Scope

The purpose of this document is to describe the clinical trial protocol (Phase I, II, III) of **Innoen® airborne infection UV quarantine® device** (319987HA-D#), the safety & effectiveness of applying this device in hospitals and/or healthcare facilities to stop airborne infectious agents including COVID-19. Phase I and Phase II without human participants, and Phase III fully with human participants.

The scope of this document applies to **Innoen® airborne infection UV quarantine® device** products, implemented by doctors, health practitioners, relevant R&D personnel, QC/QA personnel, and other trained personnel.

2.0 Classification of infection UV quarantine medical device

Innoen® airborne infection UV germicidal lamp (319987UV*#)	Class II
Innoen® airborne infection UV quarantine device (319987HA-D#)	Class II

3.0 Intended usage

- The products are intended use to stop airborne COVID-19 or other infectious agents to transmit in hospitals and/or healthcare facilities, maybe compromised to use in some non-hospital public regions.
- Disease: airborne COVID-19 and equivalent infectious agents
- Prevent method: Create controlled artificial environmental UV radiation in regions follow the definition in document 003 (2.0) and relevant specifications. All people wearing **Airborne Infection UV quarantine® Device** without a helmet lamp in these regions and following the relevant instructions. Alternative convenient way, wear **Airborne Infection UV quarantine® Device** with a helmet lamp in public regions, then all the COVID-19 or other infectious agents can't transmission in the region.

4.0 Responsibilities

These procedures are to be carried out by personnel and participants of clinical trials for airborne infection UV quarantine devices in public regions, monitor by clinical trial monitoring persons.

5.0 Clinical Study:

Phase I: Safety of the device to healthy humans, trial without human participants
Test the UV goggle shielding effective, and the shielding effect of the whole device under UV 253.7nm radiation with strength range from 0-5000 $\mu W/cm^2$. The present product can get a defective rate lower than 10^{-5}, this number can be adapted as the safety rate of the device to healthy humans, much safer than most of the medical devices. Such kind of non-invasive medical devices is quite safer for use. For this type of special medical device, it is reasonable to design the phase I study in this way without human participants.

6.0 Clinical Study:

Phase II: Effectiveness of the device to the infectious agent simulation, trial without human participants.
Use the protocols writing in document 001 (6.0 UV germicidal lamp device sterilization validation for infection stopping function, 6.1 Petri dish Validation Approach, 6.2, Spraying Simulation Validation Approach.) to validate the effectiveness of UV radiation to the infectious agent. UV has been used for disinfection for more than one century, quite effective to kill any infectious agents, under Petri dish or spraying simulation. For this type of special medical device, it is reasonable to design the phase II study in this way without human

participants.

7.0 Clinical Study

Phase III: The basis for the effectiveness of phase III clinical trial is the **placebo group infection rate.**

7.1 Controlled **placebo group infection rate** set up

Table 1. Controlled **placebo group infection rate** set up of healthy and infected participants in the trial to acquire

experiment set up	No. of infected participants	No. of healthy participants	**Placebo group infection rate**
3-day-50% placebo infection rate trial	50 in 100 participants	50 in 100 participants	50%
3-day-90% placebo infection rate trial	90 in 100 participants	10 in 100 participants	90%
3-day-99% placebo infection rate trial	99 in 100 participants	1 in 100 participants	99%
30-day-50% placebo infection rate trial	50 in 100 participants	50 in 100 participants	50%
30-day-90% placebo infection rate trial	90 in 100 participants	10 in 100 participants	90%
30-day-99% placebo infection rate trial	99 in 100 participants	1 in 100 participants	99%

7.2 Minimum controlled **placebo group infection rate** set up

A minimum 50% **placebo group infection rate** is required for phase III clinical trial of **Innoen® Airborne Infection UV Quarantine® Device** or commonly called **UV Mask**:

7.3 Experiment procedure and requirements:

(Generally, 20cm to 2-meter), assure all the participants in the trial, no matter healthy people or infected people wearing the device at all the time in these three days. In the two 14-day quarantine periods before and after the 3-day trial period including the trial period, participants can do various public life activities; however, mandatorily required and monitored as follow:

- Set up participants from **Table 1** to get enough **placebo group infection rate**. 50% **placebo group infection rate** is the minimum requirement for sustaining the effectiveness of the products for public use under most social conditions. Healthy people not only need nucleic acid test negative but also need physical quarantine for 14 days. Infected people also need to be confirmed by blood tests.
- All the participants wearing **COVID-19 Airborne Infection UV Quarantine Devices** with helmet UV (319987HA#), or commonly to call as **UV masks**, to stay in the region to perform lower than social distancing activities. (In the eight-hour daytime meeting, monitoring people will assure a substantial time of the distancing between healthy and infected people must lower than 20cm. This distancing is a guarantee to cover all the social public life or a higher **placebo infection rate** for transmission. Once the device can guarantee to stop transmission for so tight a distancing or so high a **placebo infection rate**, and then no infectious agents can escape the control of the device.)
- The ventilation system of the trial room should be UVC radiation control (319987UVD# or equivalent) to avoid accidental infection from this source. While people take a shower, or something is accidentally wrong with the device mounted UV germicidal lamp, the ventilation system is the riskiest factor.
- the washroom which participants used must be equipped with our washroom UV lamps (319987UVW# or equivalent 319987UVD#), this is to assure no accidental infection or cross-infection from the washroom.
- For the eating or drinking behaviors of participants must inside UV radiation boxes (walls) enclosed space and no two persons can share such as space. Also, before the experiment, all the public spaces need a 30 min protocol. This is to assure no infected human respiratory air in the space, generally performed by the combinations of 319987 UVD#, 319987UVM#, 319987UVW#, etc.) No participant can use a dinar table without UV radiation protection.

(This is the strict clinical trial procedure. In actual use of devices 319987HA#, HC#; there is a compromised code of practice for people who can't strictly follow the trial procedure in less infected regions. For example, on the same dinner table, no two participants can open the device simultaneously, eating or drinking must in turn. For the eating or drinking behaviors of participants, the time of each opening of the device should be as little as possible to less than 1 second, and the interval between each opening will be not less than 10s, etc.)

- If participants want to take a shower in the trial or quarantine period, the showing room must be dealt with a 30 min UVC disinfection protocol before each use (generally by 319987 UWM#, or 319987UWD#), also the ventilation is strictly controlled, under such condition can the shower user can temporarily put down his or her airborne UV quarantine device while washing. It is not allowed two participants to use one shower room during these periods.
- Our devices are specifically for airborne infection. Therefore, it still needs to avoid any non-airborne infection transmission route, such as blood transfer or any social activities that exchange any kind of body fluids, etc., the efficiency of UVC to sterilize these liquid-borne infections is lower than that of airborne. All participants need to get enough training before the clinical trial.

7.4 Result evaluation:

After a 3-day or 30-day trial period, check how many healthy people get infected. The monitoring of using the device must be on a 24/7 basis for all the visit regions to assure no chance of accidental infection. For every 100 healthy persons in 3-day or (30-day) trial under a **placebo infection rate** over 50% environment and following above requirements. Record the infection rate of healthy participants and record the **placebo infection rate** for the trial**.** If the final infected people < 1 of 100 healthy participants, means the medical device can meet the designing standard of 99% effectiveness based on a higher than 50% **placebo group infection rate**. If the final infected people between 1-10, just record and calculate the effectiveness and perform root cause analysis and procedure improvement. The trial generally needs more than 300 cases of study.

- 30-day-trial: same requirements with those of 3-day trials, only extend the 3-day trial period into 30 days if feasible.

8.0 **Accidental Airborne Infection,** assist other clinical trials by our devices and protocols to avoid accidental airborne infection interference for their clinical trial

There are a lot of medical devices, drugs, vaccines, etc., intended to stop or mitigate COVID-19 spreading, which need three phases of clinical trials. However, protocols specifically designed for airborne infection or considering the airborne interferences are rare. A successful drug or device will easily fail clinical trials due to **Accidental Airborne Infection**. We should clearly realize that no matter how the clinical trials are designed, all the healthy participants do need certain periods that totally free from the **Accidental Airborne Infection** that comes from accidentally inhaling SARS-CoV-2 viruses. **Accidental Airborne Infection** is defined as people who are transmitted COVID-19 from **infected human respiratory air** in a public region no matter patients who issuing the **infected human respiratory air** present or not present on-site. **Infected human respiratory air** is defined as respiratory air exhaled by an infected person who enough to infect half of the healthy people that inhale this air. (COVID-19 infection while using a public washroom is a typical accidental airborne infection.) The proper combinations of our products:

Airborne Infection UV Quarantine® Devices, 319987 HA#, 319987 HB#, 319987 HC#, 319987 HD#
Airborne Infection UV Germicidal Lamps, 319987UVD#, 319987UVH#,319987UVV#, 319987UVM#,319987UVW##

Can effectively avoid accidental infection in the clinical trial processes of other products intended for COVID-19. We can provide design, protocols, and devices while other people or entities like to trial their products. Simply make an application and send to: service@innoen.org

9.0 Related Documents

Document #	Title
001	Innoen® airborne infection UV germicidal lamp specification
002	Innoen® airborne infection UV quarantine medical device

10.0 References

- GB/T 19258-2012 Ultraviolet germicidal lamp
- GB/T 17262-2011 Single-capped fluorescent lamps – Performance specification
- GB/T 10682-2002 Double-Capped Fluorescent Lamps–Performance Specifications
- GB 28235-2011 Safety and sanitary standard for ultraviolet appliance of air disinfection
- GB 21551.3-2010 Antibacterial and cleaning function for household and similar electrical appliances-particular requirements of air cleaner
- GB 50073-2013 Code for design of clean room
- GB/T 17263-2013 Self-ballasted lamps for general lighting service – Performance requirements
- Lai, Y. Y. Quarantine of UV-Shine Itself Instead of Quarantine Infectious Agent as a Physical Control Method is the only Ever-Known Effective Method for Stopping the Spreading Potential of 2019-nCoV in China and Later Possibly Disseminate to the Global. *IJSR,* **9(3)**, 27-28 (2020). DOI : 10.21275/SR20228084927
- http ://www.innoen.org/
- https ://clinicaltrials.gov/
- https ://www.fda.gov/medical-devices

11.0 Revision History

Revision	CCF #	Description of Changes
0		New Document, Jan. 14, 2020
1		Add phase III monitoring requirement. August 23, 2020
2		Change some sentences. August 30, 2020.
3		Use standard terminologies for UV lamps. September 14, 2020
4		Revise the phase III protocol. Sept. 26, 2020
5		Add assist the clinical trial of other products, Sept. 29, 2020
6		Update the **placebo group infection rate** of the trial, Nov. 9, 2020
7		Set up different **placebo group infection rates**, Nov.20, 2020