PROMIO

SUIT FOR **PRO**TECTION FROM **MI**CRO-**O**RGANISM
with AUTOMATED DONNING AND DOFFING SYSTEM.

(An alternative to Social distancing, PPE also for the general public)

1. Introduction:

ProMio is a **protective encapsulation designed to safeguard humans** from the potential threat posed by highly contagious biological agents by isolating humans. It also **includes an automated mechanism to easily don and doff** the said protective encapsulation, for minimizing the risk of cross-contamination.

Epidemics, **pandemics**, bio-war, bio-terrorism, or the use of bio-weapons **in the future can't be denied.** With every new outbreak the humanity will face an unknown, mysterious enemy, in the fight towards such invisible enemies, **we rely on developing a vaccine or drug which takes time and resources**, by such time we lose several precious lives. Other methods like social distancing and lockdowns take a toll on the economy and invite poverty. Newer biological agents (specially bacterium, virus, or fungus) will keep emerging as threats **we cannot every time afford to fight with them using lockdown.**

Humans are social animals. Social distancing is like a punishment to them. Enforcing social distancing is difficult through a lockdown and it takes a toll on mental health the people too. **People defy social distancing** as they want freedom and they want an end to uncertainty. (Americans/Israelis took to the streets in several states to protest the coronavirus "lockdowns", or stay-at-home rules.)

Immunity is dynamic it can be strong one day and frail the other day, it cannot be built overnight. Likewise, diseases like **Diabetes, Hypertension, heart disease, COPD, etc cannot be undone** at the arrival of a pandemic.

Why presently available PPE is not recommended to be worn by the general public?

- The people not dealing directly with patients are **considered to be at low risk** therefore, PPE not required.
- PPE has **several components** to it, wearing and removing it in a **particular sequence** is a **cumbersome and time-consuming** procedure.
- **Special training is needed** to don and doff PPE.
- Use and throw make it **expensive** and leaves behind a **high carbon footprint**.
- **Most of the infection** to healthcare workers are found to be **due to deviation in the doffing** procedure, which needs extreme care and adherence to protocol. https://www.psqh.com/analysis/study-finds-major-problems-with-ppe-doffing/
- PPE is too very **uncomfortable**, causes rashes and skin irritation to many.
- The person in PPE **cannot eat, drink, or use the toilet**.

Therefore, the **presently available PPE is not recommended** to be worn by the general public.

In the future too, the threat of bigger pandemic looms us and our future generations. **What is a lasting solution to such challenges?**

2. History:

Humans are known to design & wear outfits as per their needs.

Seasonal:	***Rain:***	***Religious:***	***Safety:***
Winter – Jackets, coats or sweaters	*Rain coat, Umbrella*	*Burqa, Cap, cassock*	*Helmet, Hazmat suit, Sport guards*

Whenever living organisms expect a threat, they cover themselves up as a protective mechanism, as tortoise covers itself. In the same manner, forces wear bulletproof jackets, scuba divers wear a protective suit and the list is endless. Then why not **wear a biological agent proof jacket** to protect oneself and one's family. Yes, it may seem uncomfortable, but then one will have to **choose between comfort and safety**.

In a challenging time, when humanity is presented with the **threat of getting infected by a biological agent in the environment**. To contain such infections the agencies governing such places enforce measures such as **curfew or social distancing**, which causes a far reaching impact on the essential services & economy of the area and even on the world. **Humans need a specially designed outfit to contain and mitigate the risk of infection**, to carry off important socio-economic activities.

3. Solution:

Pandemic / Epidemic causing agents are mostly transmitted through respiratory droplets that get generated when people cough, sneeze, or exhale. These disease-causing agents also get transmitted by touching, by direct touch and through contaminated surfaces or objects and then touching their own mouth, nose, or possibly their eyes.

What is a definitive solution to this challenge?

The **only lasting and effective solution to this challenge is encapsulating/shielding humans** from these biological agents. If the biological agent doesn't reach humans, it cannot infect them and it is no more transmissible. Therefore, encapsulating humans will stop transmission.

For encapsulating humans, **ProMio has been specially designed** PPE (Personal Protection Equipment), keeping in mind the challenges associated with presently available PPE. ProMio is a **single piece of encapsulation with an automated donning and doffing system** to minimize the risk of cross-contamination associated with the presently available PPE.

Therefore, during an epidemic general population can wear ProMio so that **people can carry out their day to day indoor/outdoor essential activities** like offices, maintenance, services, businesses, food, agricultural services, etc.

4. Benefits & Rationale of use:

In a pandemic, **non-infected humans run the risk of confronting & contracting an infection** from other infected humans carrying and shedding the infection. **As of now, the only way** to cut the human to human transmission is by the way of **social distancing and hygiene practices**. This is **difficult to enforce** in the general public and runs the risk of outbreaks, where these preventive measures fail and **come with severe loss and disruption of life (mental & physical) and economy**.

Humans wearing ProMio (shield) are in a safety zone and thus the infection can't reach them. On the other hand, **infected people wearing ProMio are in a mobile quarantine zone** and can't infect other people. With ProMio **people can move around freely and do their day to day business**. When the virus doesn't find and humans (covered by ProMio) to replicate, it will no longer multiply and can't spread any further. It will thus break the chain and bring an END to PANDEMIC/EPIDEMIC.

It will prove to be **more effective than social distancing** which needs strict measures by enforcing agency, public support & public education.

Thus, an effective alternative to social distancing. The **cost of ProMio is meager** when compared to not using it.

It may definitely not be very comfortable to wear and carry on tasks, but, it surely **will help and ensure sustainability & continuation of essential socio-economic activities**. As safety cannot be compromised, fashion and comfort take a back seat, at least till such time when the threat of spread of infection is over.

Pandemic/Epidemics bring unemployment, poverty, food crisis, economic crisis, education disruption, transportation, businesses every walk of life is affected. To support all these activities let us **use**

ProMio so that essential services and economic activities can go on and the uncertainly and the panic in the society can be brought to an end.

Comparison of presently available PPE & ProMio:

PRESENTLY AVAILABLE PPE	PROMIO
PPE has **several components**[2], wearing and removing in a **particular sequence** is a **cumbersome and time-consuming** procedure.*	Single piece, no sequential wearing, very easy to wear, can be worn in no time.
Special training is needed to don and doff PPE.	No training required.
Use and throw make it **expensive** and leaves behind a **high carbon footprint**.	Re-usable, environment friendly.
Most of the infection to healthcare workers are found to be **due to deviation in the doffing** procedure, which needs extreme care and adherence to protocol.	Automated donning & doffing, therefore, no deviation.
PPE is too very **uncomfortable**, causes rashes and skin irritation to many.	Comparatively comfortable.
The person in PPE **cannot eat, drink, or use the toilet**.	Can eat, drink, or use the toilet.

**CDC Demonstration of Doffing (Taking Off) Personal Protective Equipment (PPE) https://www.youtube.com/watch?v=PQxOc13DxvQ*

ProMio design is more of gown type (Safety concerns):

Center of Disease control CDC USA in Design of Protective Clothing: Gown vs. Coverall says "Unfortunately, **no clinical studies** have been done **to compare the efficacy of gowns vs. coveralls. Both have been used effectively** by healthcare workers in clinical settings during patient care." [3]

Coverall

Gown

US Food and Drug Adminstration says[4]

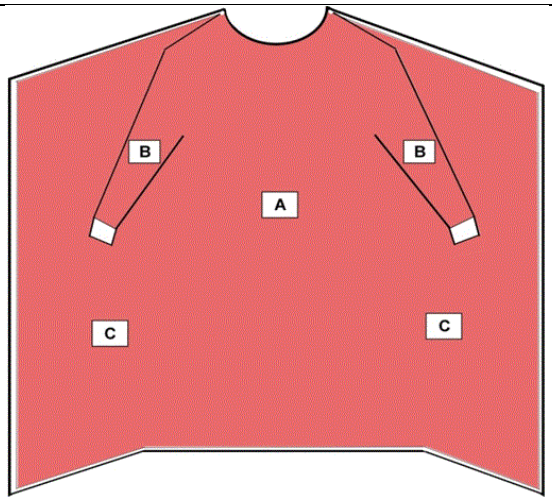
Level 1: **Minimal risk**, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit.

Gowns are examples of personal protective equipment used in health care settings. They are used to **protect the wearer from the spread of infection** or illness if the wearer comes in contact with potentially infectious liquid and solid material. They may also be used to help **prevent** the gown

wearer from transferring microorganisms that could harm **vulnerable patients, such as those with weakened immune systems**. Gowns are one part of an overall infection-control strategy.

Non-surgical gowns are **Class I devices (exempt from premarket review)** intended to protect the wearer from the transfer of microorganisms and body fluids in low or minimal risk patient isolation situations. Non-surgical gowns are **not worn during surgical procedures**, invasive procedures, or when there is a medium to high risk of contamination.

Like surgical isolation gowns, non-surgical gowns should also cover as much of the body as is appropriate to the task. As referenced in below iamge, all areas of the non-surgical gown except bindings, cuffs, and hems are considered critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. All seams must have the same liquid barrier protection as the rest of the gown.



Critical Zones for Surgical Isolation Gowns and Non-Surgical Gowns

The entire gown (areas A, B, and C), including seams but excluding cuff, hems, and bindings, is required to have a barrier performance of at least Level 1.

Looking at the above details from MoHFW[1], USCDC & USFDA it becomes clear that ProMio design fulfills all the requirements for prevention of spread of infection. In areas of suspected higher risk optionally shoe covers can be worn for added protection.

A prepared nation will easily tide over such future threats.

5. Who can use it?

The government and health organization recommendation for protective measures and the risk profile in the health care setting is as below:

Sl. No.	Risk	Recommended protection	Remarks
1.	Low	• Triple-layer medical mask • Gloves	A minimum distance of one to two meters needs to be maintained.
2.	Moderate	• N-95 masks • Gloves	
3.	High	• A full complement of PPE	When aerosol-generating procedures are anticipated.
4.	Nil	• No PPE	A minimum distance of one to two meters needs to be maintained.

So, the presently available PPEs are only recommended for high-risk healthcare workers. ProMio can seem to be an over protection. But, **what is the harm in over protection**?

ProMio Ideal for:

Only for people with Low or No Risk. And as extra care for hospital settings.

- For travel
- For going to the workplace.
- For going into public places.
- For Hospital visits as an attendant.
- Not for use in high air pressure areas.

ProMio as extra care for:

1. Health care Point of Entry.
2. Hospital Setting
    - Out-Patient Department (Respiratory Clinic / Separate screening area).
    - In-patient Services.
    - Emergency Department.
    - Pre-hospital (Ambulance) Services.
    - Other Supportive/ Ancillary Services.
3. Health Workers in Community Setting.
4. Quarantine facility.

6. Ideal ProMio:

- Easy to wear - Easy to remove & requires minimal or no training
- Single piece for preventing cross-contamination
- Breathable - Proper ventilation
- Reasonably Comfortable and fashionable
- Tear, water, flame resistant
- Reusable

7. Parts and components:

Although the ProMio is a single unit, it has several parts continuous to each other seamlessly. Refer to Figure No.1, 2, 3 & 4.

1. **Cassock:** is a 360-degree cover of the torso, arm, forearm, thigh, and leg. The cassock is designed to protect the body of humans from a biological agent in the environment. It is open at the bottom with provision to fasten with buttons/Velcro. Provided with external pockets for keeping handy items like keys. High-quality zipper with cover in the front for male urination, High-quality zipper with cover in the back for female urination and defaecation. As the virus doesn't jump, entry from below is unlikely unless high-pressure air/wind blows in a way to force particles upwards inside the cassock.
2. **Breathable Headcover:** headcover that covers the head and neck made of breathable material of triple-layer mask (fluid-resistant) which is also reusable. The face shield is fused with headcover, a clear material giving a free and maximum field of vision. Anti-glare, non-fogging. These ventilated head cover provide ventilation & protection to the wearer from droplets of infectious material emitted during coughing/sneezing/talking.
3. **Gloves:** Rubber coated extension of cassock sleeves, starting at the level of the wrist with elastic band in the sleeve. When a person touches an object/ contaminated surface and then touches his own eyes, nose, or mouth, he may get exposed to the biological agent.
4. **ProMio Donner and doffer:** is a 4 piped structure with a rectangular 4-sided piped structure connecting them at the top. The 4 piped structure holds strings with hooks on the end via a pulley. When the bottom of the cassock with rings is hooked with the string, the rotation of pulley (manual or motorized) will pull the cassock on all four corners and lift it vertically. So, the human wearing it can move outside of the structure without touching it. In the same manner, the human can also wear ProMio by standing below the structure while ProMio is shrunk at the top by relieving the pulley.

5. **ProMio Sanitizer:** Sprinklers at the 4 piped structure can sprinkle disinfectant on ProMio or alternatively it can be washed or disinfected with the help of appropriate wavelength of UV light or fumigation.
6. **ProMio Quality check:** By inflating the ProMio from the bottom, if the air is not freely escaping from its 360-degree surface then it is ready to be worn.

8. Specification:

a) Cassock (excluding back of headcover)
   I. Impervious Material - Impermeable to fluids/droplets (feature film laminate, poly-coated spunbond / casement cotton fabric).
   II. Flame resistant.
   III. Re-useable.
   IV. Changes color on wetting/spraying with sanitizing solution for identification of non-sanitized patches.
   V. Multi-colored but Light colors are preferable to detect possible contamination
   VI. Quality compliant with the following standard:[1,2]

   Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

   [Fabric that cleared/passed 'Synthetic Blood Penetration Resistance Test' (ISO 16603) and the garment that passed 'Resistance to penetration by biologically contaminated solid particles (ISO 22612:2005)] Other:

   Tensile strength ISO 13934-1 (MD/CD) 1 to 2
   Tear Resistance EN ISO 9073-4 1 to 2
   Puncture resistance EN 863 1 to 2
   Abrasion resistance EN 530 Method 1 to 6
   Basis weight 41 gsm to 69 gsm
   Seam strength EN ISO 13935- 2 to 3

b) Face Shield sealed with cassock
   I. Made of clear plastic and provides good visibility to both the wearer and the onlooker.
   II. Fog resistant & scratch (preferable)
   III. Air sealed with the cassock.
   IV. Maybe re-usable (made of a material that can be cleaned and disinfected).
   V. Indirect venting through cassock should reduce fogging.
   VI. Quality compliant with the below standards, or equivalent: [1,2]
      1. EU standard directive 86/686/EEC, EN 166/2002
      2. ANSI/SEA Z87.1-2010

c) Back headcover Ventilation –fluid-resistant triple-layer mask material.

9. Precautions:

1. PPEs are not an alternative to basic preventive public health measures such as hand hygiene, respiratory etiquettes which must be followed at all times.
2. Should not be subject to continued use if damaged, heavily soiled, or compromised.
3. Not for use in areas with high air pressure, heavy machinery, flames, etc.
4. Always follow the laid down protocol for sanitizing/disposing off PPEs as detailed in infection prevention and control guidelines available on the website of MoHFW/WHO.

10. As per Recommendations of

1. WHO REFERENCE NUMBER: WHO/2019-nCoV/DCPv3/2020.4 https://www.who.int/publications-detail/disease-commodity-package---novel-coronavirus-(ncov)
2. Ministry of Health and Family Welfare, Directorate General of Health Services [Emergency Medical Relief] https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf
3. USCDC https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html

4. USFDA https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns

11. Inventors Contact

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12. Figures:

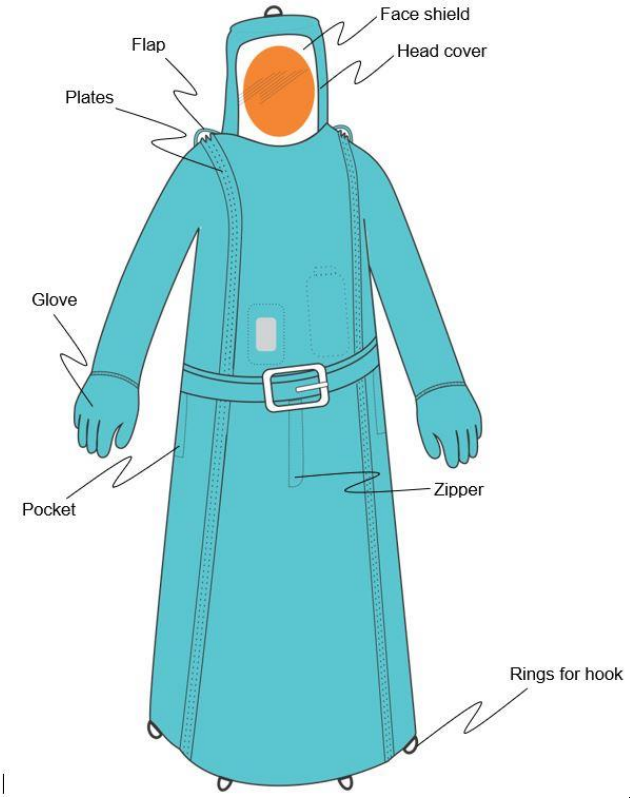

Figure 01

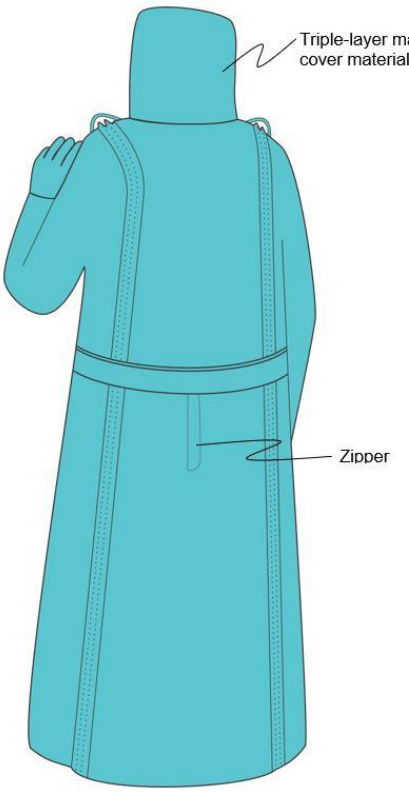

Figure 02

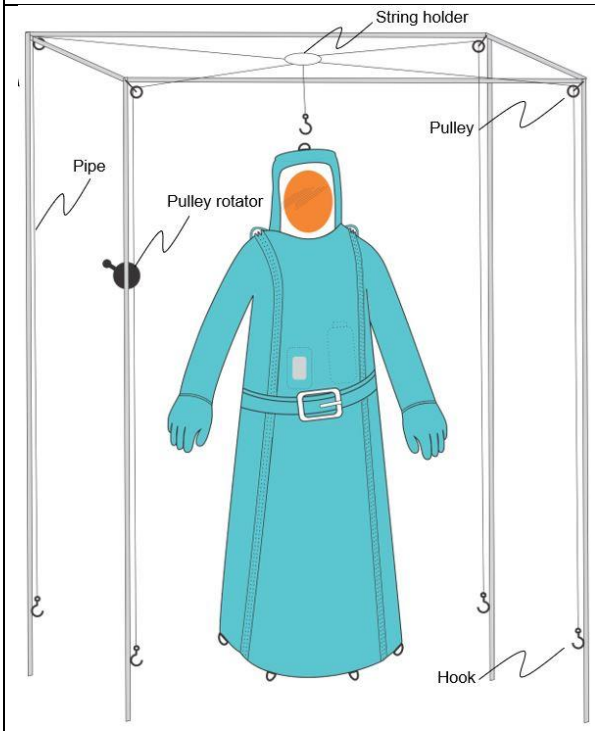

Figure 03

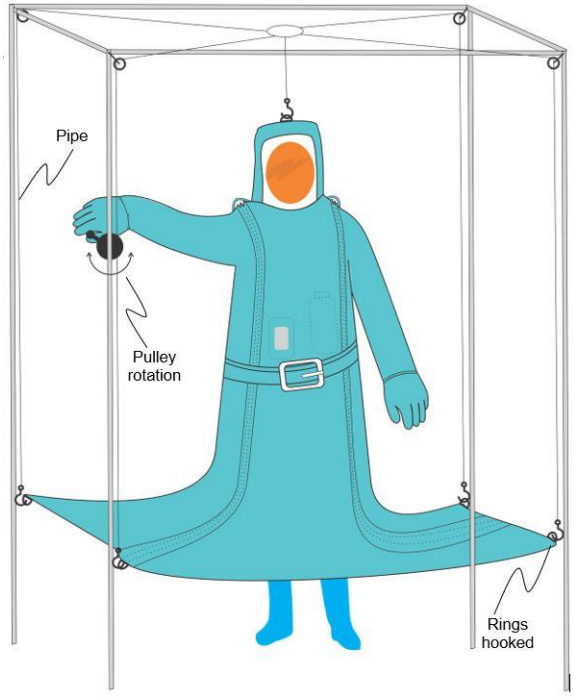

Figure 04