BIOZONE PROJECT HEALTHCARE

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Introduction

A brief summary is herein provided of the Geneva Centre for Security Policy of November 2022 and the United States National Biodefense Strategy and Implementation Plan of October 2022. These reports are nearly simultaneously informative, alarming, and shedding clear light on the fact that the International Community will inevitably continue to encounter future serious biological incidents.

Additionally, emphasis is placed on the demonstrably vulnerability of global health security as evidenced with the Covid-19 Pandemic. This still ongoing pandemic has reminded a complacent and naive World of the extremely harmful consequences of hospitalizations, disabilities, psychological trauma, economic and social disruption on a massive scale and death, may result from something other than the nuclear arsenal threat. In fact, pandemic contagious agents have killed vastly more people to date than nuclear weapons.

It is imperative that the United States and the rest of the globe must now chart a new vision for 'Biodefense'. The COVID-19 pandemic illuminated both longstanding and newly discovered limitations in local, national, and international biodefense capabilities, starkly demonstrating that continual investment in, and innovations toward, a biodefense enterprise must be a top priority for the United States. Together with the collective interplay of other developed nations global health security can be achieved but globalization of security and security governance will be required. Sustained investments and transformative improvements in the ability of both the U.S. Government and the international community to assess, prevent, prepare for, respond to, and recover from the next biological incident must be implemented.

Urbanization, climate change, habitat encroachment, economic interdependence, and increased travel, coupled with weak health systems, increase the ability of infectious diseases to spread rapidly

across the globe. Climate change will potentially unearth millions of novel viruses from permafrost and rainforests and change ecosystems.

The earlier SARS, MERS, ongoing COVID-19 pandemic, African Swine Fever, Ug Stem Rust outbreaks, and the 2014, 2018, and 2021 Ebola outbreaks demonstrate that the U.S. Government must be prepared to act swiftly when outbreaks occur. Novel infectious diseases, the resurgence and spread of once geographically limited infectious diseases, zoonotic diseases, and antimicrobial resistance such as with MRSA, VRSA, and most recently Candida Albicans, may potentially overwhelm response capacities and make outbreaks harder to control.

In present time, Virologists can single handedly ignite more pandemics with newer technologies than a century of natural pandemics. With increasing technological advances viruses may be engineered to become more lethal with mutations and viruses spread significantly faster than vaccines can be developed. Even with state-of-the-art equipment and standard biosafety protocols, laboratory accidents re possible due to human error or mechanical failures.

Bioweaponry used from adversarial agents could lead to the release of many contagions simultaneously with lethality rates of 30% or more and any system shown vulnerable to natural pandemics will be significantly more vulnerable to such intentional pandemics.

In the last few decades, the World has developed a biological threat landscape of which the United States must continue a catalytic global leadership role in preparedness to manage the risks posed by natural outbreaks of disease, accidents with high-consequence pathogens, or adversaries who wish to do harm with biological agents. It is now more urgently imperative to lay out objectives to prepare for, respond to, and recover from biological incidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health.

In a world containing viruses such as measles, which typically infects more than 90% of vulnerable individuals exposed to a single case, spreads readily through ventilation systems, and can infect people who

arrive up to two hours after the index case has departed, this is a tall order.

In ‘Preparedness’ for the next epidemic and or pandemic the mentioned reports emphasize that the following items will need implementation:

- Have sustained investments and transformative improvements in the ability of both the U.S. Government and the international community to assess, prevent, prepare for, respond to, and recover from the next biological incident,
- Develop early warning system to mitigate catastrophic biological risks since detection directs decision making with forecasting and risk assessment,
- Recognize conditions and avenues available to achieve these outcomes can be very different Internationally therefore we need a global preparedness and execution management strategy,
- Have establish a layered risk management approach with transparency in communications, data sharing, surveillance, and response efforts
- Develop a common apparatus that networks early warning detection and notification,
- Rapidly and effectively contain biological incidents wherever they occur. The significant viral, bacterial, fungal, and other infectious disease outbreaks and toxin-related illnesses of recent decades impacting human, animal, and agricultural health, including COVID-19, continue to reveal that the financing cycle of panic and neglect must end,
- Ensure domestic and global biothreat detection, biosurveillance, and information systems are coordinated, integrated, and capable of enabling timely bioincident prevention, detection, reporting, assessment, response, and recovery,
- Limit the impacts of bioincidents through information sharing and networking; evidence-driven, coordinated response operations and investigations; effective public messaging; and research,

- Develop a more effective means, single coordinated effort to orchestrate the full range of activity, cutting edge management, biosensors, diagnostics, intervention, and surveillance,
- Develop a 'One Health' collaborative, multisectoral, and transdisciplinary approach working at the local, regional, national, and global levels, with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and the environment. Implementing a coordinated One Health approach is a best practice for understanding, communicating, and mitigating biological threats swiftly and efficiently. Such an approach is necessary to assess, prevent, prepare for, respond to, and recover from biothreats, mitigating potential nationally or internationally significant biological incidents rapidly and effectively,
- Pursue innovative approaches and partnerships to achieve, domestically and globally, the goals articulated in a new generation and cutting-edge strategy,
- Reduce morbidity and mortality and economic livelihood disruption through prevention,
- Assure the strategy recognizes that a collaborative, multisectoral, and transdisciplinary One Health approach to the national biodefense enterprise is necessary to counter biological threats effectively and efficiently,
- Develop the ability to rapidly detect, characterize, report, forecast, and share relevant information (including genetic sequence data), as appropriate, on pathogens that pose a biological threat of national or international significance soon after they emerge in humans, animals, and plants,
- Enhance capacity for rapid analysis, modeling, baselining, forecasting, and reporting to monitor and evaluate the health threat landscape, through a One Health lens,
- Develop and implement a domestic characterization research and development agenda for collaboration between the federal government, academia, and the private sector,

- Maintain and enhance an enduring domestic all-hazards hospital data collection capability, including data reporting and management systems, governance processes, and include other appropriate healthcare facilities and systems to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations,
- Fund basic research, innovation, and the development of tools and technology for suppressing pathogen transmission in the built environment, including antimicrobial and antiviral structures and surfaces, ventilation, filtration, sterilization, and decontamination,
- Continue performance assessment and improvement, prioritize transformational technical and measurable targets, develop better Data Integration and capabilities for more rapid identification of pathogens, prevent the transmission of healthcare-associated infections (HAI) and antibiotic resistant (AR) pathogens,
- Address the proper handling, collection, and disposal of waste streams contaminated with a biological hazard(s) as well as to inform re-occupancy after decontamination and established clearance levels achieved and coordinate Real-Time Research for Response,
- Have a scalable supply alternative to the vulnerability of supply chain and infrastructure exhaustion while considering that a wide array of sectors may be vulnerable to disruption,
- Invest in and incentivize innovations in PPE design, novel material development, advanced manufacturing, and reusable technology capabilities that result in steady state and surge capacities for domestic production of PPE with resilient supply chains and enhanced effectiveness, usability, comfort, affordability, reusability, and fit capabilities to protect against various routes of pathogen transmission, including for use by the general population,
- Have rapid development of pathogen-specific tests to detect spread, point-of-need testing (i.e., near patient use, field use, or pen-side use), including low-resource settings, with a test run time between five and thirty minutes,
- Develop biocontainment or biosafety protocols,

- Have a nucleic acid observatory that performs untargeted metagenomic sequencing of all nucleic acids across relevant human and natural ecosystems to serve as a reliable early warning system, one that neither adversaries nor natural pandemics could evade and then tie into data base. A single nucleic acid observatory monitoring site can only detect a pathogen when the frequency of the sequence fragments in question has detectably risen in an exponential pattern, but a network of sites can detect the same pattern of sequence fragments as it first becomes visible at multiple locations,
- Analyze what equipment will be needed in the event of highly virulent and transmissible pathogens or other biological hazards. Presently, this includes N95 masks, gowns, gloves, reusable respirators (half-face and full-face), reusable full body suits, fully encapsulated Occupational Safety and Health (OSHA) Level A or B boots, Powered Air Purifying Respirators, and sterilization chemicals. Analysis will also assess PPE capacity needs to cover vulnerable populations and a diversity of body types, including children.
- Provide solutions for provider mental and physical health, contagion transmission in facilities, need for popup facilities, the experienced costs of PPE and the disposal thereof, solutions to provider attrition, cost of retrofitting facility rooms versus new equipment, problems with accidental exposure, fit of gear, cleaning of gear and delays of medical care due to the mandate of PPE and the time to dress out delaying care provided to critical patients, environmental and economic impact of pandemic
- Calculate the total environmental and economic impact of the current pandemic
- Facilitate recovery with novel innovation mitigations and countermeasures such as AI system integrations and lung therapy modalities for longer term illness manifestations, and promote resilience with proactive lung therapies and immune modulators,
- Continue Vaccine and Therapeutical drug research and development with potential novel drug delivery systems.

Vertu Medical Technologies LLC (VMT) is now initiating our Global Healthcare Initiative titled 'ICBM' (Initiative for Contagion Biodefense Mitigation) delivering a New Generation of Healthcare Innovations providing a proactive preparedness platform to confront the next epidemic or pandemic. VMT's cutting-edge **BioZone Project** introduces a comprehensive system of mitigants and countermeasure strategies designed to help combat the healthcare provider and facility components of the Geneva Report and the United States National Biodefense Strategy and Implementation Reports.

Furthermore, the **BioZone System** comprises an integrated complement of over forty novel revolutionary Healthcare Innovations applicable to many sectors of the Healthcare Industry. Many of these breakthrough innovations will prove to significantly reduce medical errors, save billions of dollars in healthcare expenses, provide superior analytical, interpretive, and interventional healthcare advancements, deliver Advanced Medical Healthcare Technologies to the underserved populations of the World, provide New Age medical technologies anywhere on land, sea, air, or even space, and most importantly save millions of lives.

The **BioZone Unit,** as presented herein, comprises an integrally functional interoperative medical apparatus unit serving as an early warning counter measure preparedness means and network to combat the next Biothreat, a New Age Biosensor, a means to decontaminate specific areas of healthcare facilites, a mitigant isolation and negative pressure means to address serious or life threatening contagious disease presentations, a novel Pulmonary Drug Delivery and Pulmonary Rehabilitation System, a novel systemmic DNA repair and Nerve Injury Rehabilitation means, a Hybrid all-in-one Emergency and Critical Care delivery system and station with superior medical equipment, a novel means to improve the survivability outcomes of CPR, and a novel means for treating Mental Health and Drug Addiction.


BioZone

THE BIOZONE SYSTEM

I. Executive Summary

A comprehensive and multi-patent pending Healthcare Innovation called the BioZone System and BioZone Unit introduces a synergy of novel and proprietary New Age technologies significantly advancing the evolving fields of Emergency, Critical Care, Infectious Disease, Internal Medicine, Pharmaceutical and Aerospace Medicine and provides a Paradigm Shift approach to an urgently needed comprehensive epidemic and pandemic Biodefense Preparedness.

This 'Hybrid' and fully mobile unit revolutionizes emergency and critical interventional healthcare and in one general aspect, providing an 'all-in-one' state of the art modular treatment, detection, and sterilization and isolation station consisting of a multitude of cooperative breakthrough medical technologies. The plurality of novel innovations provided by the BioZone Unit are integrated into a coordinated complex of synergistic technologies with functional interoperability therein providing vastly superior analytical interpretation of physiological information, detection of Biothreats, unprecedented clinical deduction and management advisement, and a multiplex of avant-garde medical solutions.

The BioZone System, in a general aspect, integrates years of resolute research and development culminating in a unique opportunity to provide an immediate and preemptive mitigation for existing and future life-threatening contagious healthcare crises. In addition to providing state of the art Healthcare Technologies, the BioZone Unit delivers a novel and superior means of contagion detection, eradication, and early warning alerting, and a medical isolation enclosure and novel drug delivery means for the gamut of healthcare facilities in need of such. Medical treatment centers, whether civilian, military, or aerospace in nature, will soon be provided with a Paradigm Shift approach to safely treating a vast number of disease entities including current and future

serious transmittable contagious disease patients. Additionally, the BioZone System Biosensor provisions will provide the means and methodology for early detection of known and novel contagions and Biothreats wherein the BioZone System Activation Protocol will serve to trend, declare, and transmit the data to National and Global early warning Biothreat networks. The BioZone System will play a significant role in the 'One Health' Global Initiative while simultaneously introducing a host of novel treatment modalities for other physiological related diseases and or the manifestations of such.

The Vertu Medical Technologies' ICBM Initiative provides a significant advantage in the utilization of the BioZone Unit causing a Paradigm Shift toward attending patient presentations having potentially serious infectious transmittable diseases.

Conventional approaches have proven to be error prone and to a degree ineffective regarding the disease prevention or transmission objective, extremely costly by burdening global Healthcare Systems with hundreds of billions of dollars of potentially preventable expenses, significantly delay critical care intervention, produce vast amounts of medical waste and costs to dispose of such, are responsible for significant attrition of healthcare providers, overwhelm healthcare facility physical capacities, eliminate the ability for family visitation, overwhelm supply chains, impede assessment and communication with patients, and potentially harm the provider staff in the case of PPE. To date, future pandemic preparedness directives are heading down the same rabbit hole intending to produce more cost-effective pandemic-proof personal protective equipment which has yet to be developed and are part of the problem.

The BioZone Project's assessment and conclusive recommendation is that the healthcare conventional approach to transmittable diseases is inefficient and in need of a complete overhaul. VMT's novel approach recognizes that any true assessment study of healthcare facility disease transmission of infectious contagions would be alarming as to the case number of diseases acquired at such facilities and transmitted to the

public and family members, the cost of treating these acquired infections is exorbitant to the healthcare system, healthcare facility acquired infections have the potential to be multidrug resistant and potentially life-threatening to compromised patients, such acquired infections contribute to significant return visits to already overwhelmed Emergency Rooms, and return visits contribute to overtreatment of viral infections with antibiotics.

The BioZone System provides alternative approaches to infectious disease, immunocompromised, or debilitated patient presentations to healthcare facilities which will significantly reduce healthcare system costs, reduce infectious disease transmission, better secure the safety concerns for protecting the public and healthcare providers, provide an early warning system means for recognizing and reporting serious known or novel contagions, and quite simply save countless lives.

We believe that the BioZone Innovation will soon be recognized as one of the most eminent medical invention projects of the past century. Not only will an immediate paradigm shift be realized in confronting serious contagion presentations worldwide, but an unprecedented number of proprietary and breakthrough technological advancements will be introduced to the medical and scientific communities concurrently.

The following BioZone System presentation will comprehensively detail specific problems known to exist in the Healthcare Industry and shed light on several problems inherent to, but seemingly neglected, and or withheld from public discussion. Subsequently, the component innovations of the BioZone System and BioZone Unit will be presented, the utilities thereof will be discussed, the significant advantages over traditional medical approach will be availed, and regard to the novel technologies provided by the Innovation delivering advancements will be revealed. In the reveal, the BioZone Project will be shown to provide superior solutions to the essence of the 2022 Geneva and United States Biodefense Reports referenced in the introduction section.

Note: VMT proposes a prioritized and phased development of the multifaceted BioZone System and BioZone Unit provisions in order to urgently address the current and future Pandemic Biodefense Preparedness. As stated in the mentioned introduction reports, the immediate necessity for cooperative innovative input from across the spectrum of Governmental Agencies coordinating with the Global Scientific and Healthcare Communities will be required to assure our future National and Global health security.

The VMT Team believes we can provide considerable constructive and meaningful value additions to the Biodefense Preparedness Initiative and will proceed to contribute accordingly. In this aspect, the following BioZone presentation will refer to Vertu Medical Technologies' ICBM Global Initiative in the context of the Healthcare Providers' ability to participate and contribute referencing those associated problems and necessities as outlined in the reports. BioZone Solutions will be provided followed by an elaboration upon the expanded scope of BioZone Unit Innovations as applicable to the broader Healthcare Arena.

II. Other Healthcare Problems Relevant to the Reports

A. Healthcare Facility Infectious Disease Transmission

A scenario is hereby presented wherein a person acquiring a serious bacterial, viral, or fungal infection, whatever the etiology, inevitably presents to or is brought to a Healthcare Setting expecting to be seen, evaluated, and treated by a Healthcare Provider. In the traditional context a person having acquired such serious infection(s) will inevitably and unintentionally expose the transporting person (family member, citizen or ambulance EMT), the facility personnel acquiring the demographical data and chief complaint, potentially all persons temporarily residing in the waiting room of the facility, the triage person assigned to further investigate the presenting complaint and status of the patient to determine a triage priority, the medical tech acquiring the

patient's vital signs, the attending Nurse, Physician, Laboratory personnel, X Ray personnel, EKG personnel, Respiratory Technician, potential consulting Physician(s), admitting Nurse, dietary personnel, admit floor Laboratory techs and X Ray personnel, different assigned Nurses having changed shifts, housekeeping personnel, laundering personnel, admitting and or attending Physician(s) and or consultant Physicians, discharging personnel, and transporting person(s) needed subsequent to discharge. In this single patient presentation, the potential for transmission of a serious or life-threatening contagious infection included around 35 or more 'essential healthcare personnel'. The calculated transmission potential of course excluded any and all people having been exposed to the patient prior to becoming ill enough to need urgent evaluation in the Healthcare Facility.

Typical calculations determining the infectivity of an infectious disease refers to the 'Ro' Gauging. Pronounced "R-naught" this number is a mathematical term indicating how contagious an infectious disease is. It's also referred to as the reproduction number since when an infection is transmitted to new people, it reproduces itself. The Ro tells us the average number of people who will contact a contagious disease from one person with the disease and usually applies to a population of people who were previously free of the infection, haven't been vaccinated against the contagious agent, and no way of preventing spread has been enacted. For example, if a disease has a Ro of 16, a person who has the disease will transmit it to an average of 16 other people. The 16 infected people will then transmit the infection to 256 people (16 times 16) and then 256 infected people would transmit it to 4096 people, then 65,536 people, then 1,048,576 people and so on. Of course, this combination of conditions is less feasible today due to advances in modern medicine.

Measles has a Ro of 18 whereas Covid-19 variants such as the current XBB.1.5 Omicron variant has a value approaching 6 which doubled the early estimates of around 2.5. The doubling time for the current Covid strain is around 2.5 days wherein initially it was thought to be 6.5 days. Such is the nature of survival mutagenicity of viruses and with a 5.7 Ro

value at least 82% of the global population would need to be immune to Covid-19 in order to stop its transmission through vaccination and herd immunity. Unfortunately, Covid has defied this expected ratio and odds given the viruses' inherent ability to readily mutate in order to avoid acquired immunity after having the infection and against the vaccines that were developed to combat it. Incidentally, the Spanish Swine Flu of 1918 that killed 50 million people Ro value was estimated to be only between 1.4 and 2.8. When the Swine Flu returned in 2009 the Ro value was 1.5 which was due to the existence of vaccines and antiviral drugs which made the recurrent outbreak much less deadly. Even so it was initially reportedly to have killed 18,449 people which was later believed to be grossly underestimated with the true number ranging between 150,000 to 575,000, according to the various sources quoted.

These representations of viral spread are what the Governments of the World fear. With the present-day and near future technology available to Virologists and the ability to modify and engineer viruses through gain of function, in the wrong hands a real-life similar scenario could manifest across the globe with the potential for tens of millions of deaths. What if an engineered virus was accidentally or intentionally released with a 30% mortality rate, or a 60% mortality rate, and had a Ro value of 25. What if several mutated or novel contagions were accidentally or intentionally released at once. In this case the results would be economically devastating and catastrophic to loss of life.

Specific modifications would be necessary to more accurately calculate a 'Healthcare Facility Ro' given the continued close contact between the healthcare personnel and the patient in order to adequately examine and treat the patient. What about the contamination of the healthcare facility itself including the waiting room, treatment and or admission rooms whereby many serious infectious contagions can survive in the ambient air environment for hours subsequent to the patient being removed. Additionally, essentially no healthcare personnel wear protective garments such as PPE subsequent to known Covid patients leaving the treatment zone. Also, how many patients will be placed in the same triage and exam room as the infected patient just resided, therein

breathing the same infectious contaminated air with no warning of the prior patient's infectious presentation.

In American hospitals alone, the CDC estimates that Nosocomial infections (infections acquired during a hospital stay) account for an estimated 1.7 million infections per year with an associated 100,000 deaths resulting from them. These infections cost the US healthcare system billions of dollars each year. These hospital 'acquired infections' are typically from contaminated environments, airborne transmission of infections in treatment zones, indwelling catheters, or from invasive procedures or surgery complications. Healthcare providers attempt to reduce the number of nosocomial infections by strict adherence to evidence based 'best practices' such as mandated frequent hand cleansing, removing catheters as soon as possible, diligent cleansing and preparation of surgical or procedure sites, and wearing hair covers, masks, gowns and gloves when appropriate.

Healthcare Associated Infections (HAIs) are infections people get while they are receiving health care for another condition but expand to any and all healthcare facilities including clinics, dialysis units, rehabilitation or physical therapy centers, for example. The infections typically include bacteria, fungi, viruses, or other, less common pathogens. What is troubling is the fact that studies revealing the total number of infections acquired by 'all people' entering the gamut of healthcare facilities are not available and would probably be extremely alarming. These individuals would include family members, visiting friends, facility providers and administrative personnel, goods suppliers, vendors, maintenance crews, well patient visits, delivery personnel, or people presenting for outpatient testing such as lab or X Ray, for example. How many of these temporary facility visitors are exposed to waiting room or airborne pathogens that lead to illness may never be known but considering the potential for economic and social disruption such as missed work or necessary visits to healthcare providers after acquiring these infections, the financial impact could be staggering as well as the potential for bad outcomes. What is the Ro number for these infections,

especially considering the potential to be drug resistant infections. One thing undisputable is that healthcare facilities are a haven for contagions to thrive, develop drug resistance, and become a significant source for healthy or debilitated persons to acquire infections from.

It is imperative that better solutions are developed and instilled to reduce the nosocomial, HAI, and incidental infectious disease transmission acquired from visiting healthcare facilities. The ICBM and BioZone System aims to provide countermeasures and mitigant solutions to deter contamination of healthcare facilities through better sterilizing means and better practice guidelines to therein reduce transmission capability.

Healthcare Facility Contagion Transmission Mechanism & Analysis

A 'typical' healthcare facility presentation involves a patient ambulating into or being brought into a common presentation zone inside the facility (possibly having to touch an entry door mechanism, seldom cleaned). Once inside the patient approaches a patient check in area whereby office personnel (usually with no medical training and no adequate protection from the patient) document the reason of the visit and start taking the patient's demographical information such as name, date of birth, address, telephone number, etc., and of course the insurance policy data. There is no means for addressing contagions at this zone. If the patient appears stable the patient is directed to a common area waiting room where they reside until called to be brought to another area. This area has no means of preventing contagion transmission or eradication yet the Covid pandemic might necessitate the patient to wear a face mask (which would provide partial transmission protection) at this point although is allowed to touch all areas of the area. The patient quite often uses the bathroom facilities whereby no efficient transmission policy exists and many viral syndromes have diarrhea symptoms and flushing commodes have been proven to contaminate bathroom areas up to five feet surrounding the commode. The patient may or may not wash their hands after flushing and then returns to the waiting room again touching the arm rests of the chair(s) which could be a different chair this time.

A more unstable patient, or due to the nature of the chief complaint, may otherwise avoid the waiting room phase of the visit and be brought straight to a triage room or directly to the emergency room treatment area. In the stable and unstable patient scenario if residing in the triage room, a triage Nurse further questions the patient of the presenting signs or symptoms while taking their vital signs and assigning a triage level number typically 1 through 5 correlative to the relative urgency to be evaluated by a physician with 1 being the life-threatening assignment and 5 being a condition that will return to the waiting room until the more urgent patients have been evaluated. Many facilities have ER Annex facilities designated as Urgent Care or Minor Care and in the case of level 4 or level 5 patients, often these patients are sent to yet another waiting room again void of infection transmission capabilities.

It is important to note that level 4 and level 5 patients sometimes remain, although ill, many hours in the common waiting room potentially transmitting their illness to the environment. Also note that these level 4 and level 5 patients may be in the early-stage disease manifestation and potentially be a level 2 or level 3 patient the next day and this potentially more serious than first appears scenario must be taken in consideration. In fact, many times the level 4 or level 5 patient becomes a level 2 or level 3 patient during the time waiting to be seen and often complain that they are getting worse to the desk clerk that already saw them. This occurs more frequently in patients with underlying comorbidities such as an Asthma or COPD patient presenting with a cold but develops bronchospasms or wheezing while waiting to be seen. Unfortunately, the vagueness of initial chief complaints lead to inappropriate triage level assignments and patients waiting to be seen collapse and may even die waiting to be seen. This occurs more frequently in the large urban centers where several hundreds of patients are seen daily with waiting times approaching more than half a day or overnight.

In further discussing the waiting room issue, it is relevant to note that more frequently than not, patients sick enough to go to healthcare facility Emergency Departments are usually accompanied by family members, friends, or coworkers that may have serious underlying

medical problems and other known or unknown vulnerabilities themselves. These people are subjected to the same waiting times and contact or airborne contagions as well and if they fall victim to a facility acquired infection it could become life threatening in their case.

Another scenario involves single parents having to bring all the children to the facility waiting room although only one or perhaps two of the children are sick. Also what of the patients that present with RSV and end up catching Influenza or Covid while waiting in a waiting room. The combination of infections or reduced immune response capacity will certainly more threatening to the patient and given the triad of RSV, Influenza, and Covid all presenting to facilities this winter, many patients are now returning with a combination of the infections after being exposed in healthcare facilities.

Whatever the scenario, common initial presentation areas, common waiting rooms, common bathrooms, and triage rooms rarely have an adequate capability to stop the transmission and spread of facility pathogens and these areas have been and continue to be a haven for infectious pathogens and a significant source of facility acquired infections.

The level 1 or level 2 patients are brought immediately back to the ER treating zones as is the case of most ambulance patient arrivals (usually with separate entry portals) so many times the level 3 patients are asked to wait hours in the waiting rooms to be seen also.

All ‘contagious’ patient presentations once entering either the Urgent Care or the ER treatment zones start immediately contaminating these entry zone portals with pathogens by touch and contact of surfaces and with airborne transmission of contagions whether having donned a face mask or not. Patients ready for examination and or acute intervention are next asked to sit on or are placed on department stretchers which are similarly now being contaminated as well. This treatment zone usually has yet another bathroom facility ready for contamination as well. All in all, the entire ER treatment zone is laid siege upon all day and night by pathogenic contamination whether by contact, airborne dissemination, or

body fluid contamination and here is where the real meat of the discussion begins.

Healthcare Facility treatment zones such as ERs vary according to the demographics, physical and geographical location, size of the Community being treated by the facility, financial ‘wellness’ of the facility and population as a business, needs of the Communities being served, and truthfully, by the work ethics and efficiency of the staff member workers and providers, and administrative personnel overseeing the operations. Although we do have National oversight committees and evaluating and credentialing groups to help maintain quality standards but this only usually occurs once every year or so and the rest of the year regard lessens.

For the most part, only the highly subsidized or lucrative healthcare facilities have the operating budgets to more adequately attend prevention of facility contagion transmission as a whole. An exception to this would be the surgical suites since procedural and surgical procedures are so highly scrutinized as to post operative infection rates and facilities can even lose their ability to perform such interventions if their infection rate is through the roof. More often, specific surgeons would more likely be the one to lose operating privileges. Nevertheless, and in consideration of the length of this report, suffice it to say that very few healthcare facilities operate to a standard that would be necessary to ‘significantly’ reduce facility transmission of pathogens and contagions which cost the healthcare system as a whole hundreds of billions of dollars annually, loss of income due to work missed, social and economic manifestations, debilitating physical consequences, and significant loss of life.

This is not a highly publicized issue somewhat like the fact that if every person wanting to participate in athletic sports were required to have an EKG, Echocardiogram, and ‘adequate’ physical examination by providers that actually specialize in sports medicine, many lives would have been saved and will be lost as the consequence that it is simply too expensive to carry out the prerequisite examinations and tests. Hence,

the sudden death occurrence in athletes is in actuality an acceptable loss. If all healthcare facilities were able to provide the necessary infection transmission prevention not many but globally millions of lives would be saved every year. The acceptable loss should simply not be acceptable for mankind and the 'system' must be mandated to change.

Conventional Healthcare Facility Response and Implementation

Healthcare provider attempts utilizing 'best practice' guidelines to reduce facility transmission of pathogens to reduce Nosocomial and HAI associated infections were discussed. Larger hospital facilities that could afford constructed or retrofit some surgical suites to have a negative pressure laminar flow exhaust means intended to continuously remove and or filter the air from the surgical suite. Many of the same facilities utilizing negative pressure surgical suites perform surgery utilizing special PPE and PAPR headgear with filtration airflow which intends to further reduce the chance of postoperative surgical infections. Of course with the Covid pandemic, the use of PPE and PAPR headgear expanded to most of the direct patient care treatment units and were mandated for healthcare providers to comply with. We will further discuss these ramifications shortly.

Emergency Departments, again in those facilities that could afford to, developed at least one infection control room initially intended for patients with known or potential Tuberculosis infections. In this case the special exam room was equipped with ceiling UV germicidal lights which were proven to be most efficacious if installed at the ceiling; having to do with air distribution of pathogens. Very few facilities actually retrofit or built negative pressure means for the rooms due to prohibitive cost outlay.

The next attempt to address treatment zone contagion control was to use HEPA filtration units to filter and decontaminate the air in a certain area and finally, the introduction of vertical mobile low pressure mercury vapor UVC lamps came about. These were promising until it was appreciated that they were costly (initially around 100 thousand dollar each), took considerable time to decontaminate a room; 20 minutes to an

hour, and the process of decontamination with UVC lamps ionized the air to a degree that was felt to be harmful to humans. It was initially recommended to not enter the room for up to an hour which was the icing on the cake considering surgical suites or ER treatment rooms needed quick turnover capabilities. Additionally, the fact that after a single patient was introduced to the room then it was considered contaminated again and theoretically the UVC process had to be performed again. Newer models have undoubtedly become cheaper yet the complications thereof still exist and this is not the sin qua non answer for room decontamination.

With the Covid-19 outbreak the airborne transmission of a novel virus that was actually killing people, inclusive of the providers caring for the patients, created panic and makeshift isolation rooms were created usually using plastic drapes taped to the ceilings and side walls with some kind of makeshift ingress and egress portal. Entire wards of the hospital that treated Covid patients became similarly draped in an attempt to provide safety to the providers and additionally to the non-Covid patients having been admitted to the same ward. Few facilities actually had the spare treatment space to create Covid Wards therefore pop-up Covid Wards began springing up in civic centers, tent cities, cruise ships, for example. These pop-up facilities were also needed because the available facility bed capacity were overwhelmed and there was simply no place to treat the Covid Patients in high case number areas. Additional discussion on this topic will follow in the Covid section forthcoming.

Digressing to the treatment room and equipment decontamination topic, with the Covid manifestation stretchers, treatment rooms, and medical equipment had to be better ‘wiped down’ in order to try to prevent the spread of the Covid virus. Equipment such as ventilators had to be specially cleaned and unable to be used for up to an hour subsequent to use on a Covid patient and as ubiquitously publicized, the ventilator shortage developed. Presently, PPE and face masks mandates have been relaxed and cleaning techniques and policies seemingly have relaxed concurrently and we are pretty much back to pre-Covid conditions

regarding contagion prevention in healthcare facilities. Also presently concurrent is the gradually increasing number of healthcare facility acquired infections given the relaxed standards so here we are trying to determine the next step that must be taken to prepare for either a more serious mutated variation of the Covid virus or heaven forbid, another novel similarly contagious and potentially lethal viral epidemic and or pandemic. Hence, the two reports and this ICBM report.

So the skeletal plan has been laid out in the two reports yet the safety of the healthcare providers as well as routine patients other than more PPE and the consequences thereof, transmissibility of infections in healthcare facilities, biosensor detection of viruses, viral particles, or other viral elements ‘at the facilities’ where most ill patients infected with the viruses go and therefore would be a logical starting place to develop a preparedness program, the tremendous costs needed to retrofit existing facilities with negative pressure rooms, HEPA filtration, UV germicidal lights, more efficient cleaning and sterilization techniques for sensitive medical equipment, for example seem to be missing. One could easily estimate that retrofitting existing treatment rooms and healthcare facility treatment departments would cost in the trillions of dollars and that few Nations would be able to incur such costs nor the fact that emerging and underserved populations of the globe would remain to hope for the scraps, so to say and continue to be neglected and void of advanced medical care. Ironically, these are the areas that may well be the site of origin of the future viruses that have so many worried about. Do we otherwise revise the acceptable attrition of human life due to costs such as with the case of sudden cardiac death in athletes, do we address the Biothreat and Biodefense preparedness alone and accept the hundreds of thousands of global deaths due to healthcare facility acquired infections and the hundreds of thousands of global deaths due to medical error ‘or’ do we integrate the initiatives and address healthcare deaths as a whole. How about that being a better ‘One Health’ mission hereon.

The tension mounts, but before we get to the VMT (Vertu Medical Technologies) solutions section below we feel it is important to make a couple pertinent assertions and shed light on additional healthcare

facility problems that ‘absolutely’ lead to unnecessary patient deaths which through the means of the VMT solutions, we hope and pray to be able to help mitigate and significantly reduce. In this regard, we will briefly address the Covid concerns and then look at medical errors before the solutions are provided. In this aspect the ICBM Global Preparedness Initiative, the BioZone System, and the BioZone Unit will be realized to be a potential Paradigm Shift breakthrough Healthcare Innovation designed to provide a New Age approach to many aspects of the Healthcare Industry saving billions of dollars and saving millions of lives.

B. The Covid-19 Discussion

In the United States of America alone, we have lost over 1 million people to the Covid 19 virus. In the entire world we have lost over 6.8 million people. Since it had been nearly 100 years since the Spanish Flu pandemic claimed nearly 50 million lives, societies, possessing today’s advanced technologies, complacently depended on a prompt delivery of a vaccine to eradicate any life-threatening novel virus. Additionally, no less than 6 contagions rose from the ashes in the past 20 years with no significant consequence and well Ebola, Malaria and other deadly diseases were for those other countries that we send financial aid to in order to keep those infections out of our country.

So, the world was simply caught with its pants down and the handling of the COVID-19 pandemic in the United States will possibly go down as the worst public health disaster in the history of the country. Over 30 million jobs were affected and beyond grinding day-to-day life to a halt, the pandemic prompted a reckoning throughout the country’s health care infrastructure, shattering decades-old assumptions about how Americans conceive of medicine, the doctors, hospitals, insurance companies, and pharmaceutical manufacturers they pay to provide it.

The full realization of how ill-equipped our country was in terms of personal protective equipment (PPE), intensive care unit beds, and mechanical ventilators quickly became evident. With false delusion, the Covid-19 virus caught the modern world asleep. Everyone had

formulated pandemic strategies, but few countries had actually implemented strategic medical equipment reserves. Biological warfare was something that armed forces trained for but certainly treaties and cruise missiles were an adequate deterrent right? Then came reality, the Covid-19 virus killed people and spread with amazing capacity and for the first time in modern history, although Covid-19 was not supposed to kill young people, young nurses and doctors were dying in the United States. There are many theories as to why this happened, perhaps the best one is the viral load, the mass of Covid-19 inoculum. Because healthcare workers are exposed to the sickest patients, early on initially lacking access to the proper protective equipment, the heavy viral load may have overwhelmed even young clinicians' ability to mount a sufficient immune response to counter the infection.

Nevertheless, healthcare professionals died with the pandemic and for the first time in history doctors and nurses were preparing personal wills knowing quite well that in our profession, we had to put ourselves on the frontline even it meant risking our lives as well as the lives of our families. The documented number of health care workers infected by the coronavirus provided sobering evidence that even in modern times we work in high-risk settings with or without reliable or adequate protection against novel contagions.

Healthcare providers were literally thrown into unchartered waters trying to provide conventional care with the mandated encumbrance of fogged up face shields and PAPR headgear and having to change PPE for every new patient. Donning and doffing the entire shift, throwing plastic sheets over coding patients, trying to provide proper care although many routine treatment modalities had become discouraged due to the possibility of aerosolization of the virus and whole room contamination. Extended decontamination cleaning delayed room turnover. Family members were refusing to bring patients back home afraid to be infected themselves and hospitals were quickly inundated with Covid-19 patients needing ventilatory support with only 1 in 5 patients living through the ordeal.

Designated Covid-19 wards and makeshift isolation enclosures were created in an attempt to protect providers. Pop up facilities were installed in an attempt to isolate uninfected patients from exposure to the virus in hospitals only to quickly become infected as well. Routine clinic visits screeched to an abrupt halt as did the other non-essential medical and dental industry. Many of the dedicated healthcare professionals died unnecessarily yet a far greater toll in numbers was the temporary loss of clinicians to infections and sickness. This is the other poorly recognized exponential growth curve: As each doctor, nurse, respiratory therapist, paramedic, and patient-care person takes care of tens to hundreds of patients at any given time, the loss of even one of these individuals has a dramatic ripple effect on the shortage of professionals trained to care for affected patients, no less the non-COVID-19 usual patient mix.

Treatments such as nebulized breathing treatments, high flow oxygen supplementation, and lifesaving Bipap were discouraged and replaced with low flow oxygen, handheld MDI breathing treatments with a spacer, and sadly enough codes were attended in a much less urgent fashion. Admission criteria were developed so, the eventually admitted patients had to wait to be sick enough to require ventilator assistance to remain alive as the virus ravaged the lung tissue with a cytokine storm of hyperimmune response.

Next the cytokine storm was recognized to be attacking multiple organs and Covid infections were no longer recognized merely as chest discomfort with a dry cough and fever. Vomiting and diarrhea patients, headaches, red eyes, neurological disorders, abdominal pain and many more nonconventional Covid presentations were testing positive. The medical system essentially had to don and doff PPE for almost any presentation for Covid was found to be an asymptomatic presentation as well with nearly 50% of infected patients never having been aware of having the virus.

How many sprained ankles, lacerations, or toothaches were positive for Covid yet being treated without proper attire in medical facilities and Emergency Departments will never be known for sure. One thing for

sure is that the medical system was turned upside down for we were even unable to allow a patient's family member to be inside the facility or even at the bedside of a dying patient. Sadly enough, families and friends had to attend Zoom Meeting funerals and billions of dollars were wasted on PPE which became thousands of tons of medical hazardous waste that had to be properly exposed of.

A tremendous financial burden was placed on the health care system. Surely it is now evident that we can't afford to simply shut down the economy again so we must create a better preparedness. We cannot simply prompt for a dramatic scaling up of the country's disaster readiness workforce for most of the mistakes will simply be repeated. Will Evidence based medicine with double blind randomized clinical trials usually dominating the precedence be ignored again to permit the FDA to once again issue emergency clearances for the use of potentially beneficially medicines. Will the public be trialed once again in an effort to stem the mortality waiting to find out what happens when given partially tested vaccines without adequate testing.

Significant differences in healthcare costs when various proportions of the population got infected showed the value of strategies that could reduce infections and, conversely, the potential cost of simply letting the virus run its course. At first glance, the U.S. health care system appeared to just fail on the margins; however, Covid-19 illuminated that these failures are vast and still growing. The current design of the health care system failed Americans, and the $4 trillion per year question is why.

The coronavirus pandemic also worsened the situation of a shortage of healthcare providers. This placed immense pressure on emergency rooms and intensive care units, highlighting the immense role of nurses, nurse practitioners, and physician assistants. This phenomenon was compounded by a reality that predates Covid-19 by decades: Rural hospitals across America are struggling to stay afloat, and many practices could provide care at lower cost to more patients by leaning more heavily on the nondoctor medical practitioners already on their

payrolls. The problem with this trial-and-error solution once again adds more and more script to the medical error saga.

With no attrition solution in sight, one report by the Association of American Medical Colleges predicted that, due to population growth and specifically growth of the elderly population, the physician shortfall in the U.S. could reach 121,300 by the year 2030. This report was published prior to the Covid-19 pandemic outbreak which will undoubtedly lead to many more early physician retirements thereby exacerbating the existing shortage, and a potential reduction in the already declining medical field interest. Fewer and fewer students are willing to enter an overtaxed profession wherein the education and training alone leads to hundreds of thousands of dollars in accumulated student debt.

With such culmination of massive student debts, aging populations, and combatting potentially lethal infections as with Covid-19 presentations, it is imperative that the healthcare industry undertakes an alternate and proactive intervention. Without such a necessary intervention and radical change, healthcare of the future is destined to evidence an unimaginable critical mass staffing deficit and ultimately a deterioration in the quality of healthcare delivery resulting in significant unnecessary deaths.

So, what have we learned and what have we done to prepare for the next novel life-threatening contagious infection. Will we simply address the exposure prevention with the same bulky and cumbersome outfits. Will we once again create makeshift isolation zones and inadequate enclosure chambers. Will we once again have an exodus of healthcare providers opting for early retirement or occupational changes in order to not have their lives or the lives of their families jeopardized from work exposure and intolerable garment mandates, or will we innovate a paradigm shift in the approach to highly infectious contagions once and for all. Unless we do better with the absolute and inevitable forthcoming confrontations with novel life-threatening contagions, then the die has been cast, for Covid-19 will soon be simply added to the list of acceptable causes of death in our society.

Additionally, what steps have been taken to combat global viruses and bacteria yet to be encountered since we now know that we are actually and unexpectedly vulnerable to worldwide pandemics. What about the million plus speculated viruses that are yet to be encountered from the harvesting and deforestation of the rain forests of the world. What about the permafrost and glaciers that are known to be thawing and melting respectively with viruses over 15,000 years old now being brought back to life with nearly all being previously unencountered. What about continued mutations that are transforming animal viruses into zoonotic human transmissions, many with highly lethal potentials as well as human encroachment on animal habitats. We experimented for decades in gain of function research hoping to be better prepared for an outbreak such as with the Covid-19 virus, but then the pandemic revealed all of this research and money spent was to no avail.

The answer mandates that the complete realm of pharmacological therapeutics should be continued wholeheartedly but novel treatment innovations from the scientific communities must be developed. The vaccine that will save the world is simply untrue as we have verified the Covid-19 to be a rapidly and constantly mutating virus with more than 250 strains already identified. Even now we are experiencing winter spread transition from the BA.5 strain to the new XBB.1.5, BQ.1 and BQ.1.1 variant strains. With such a classically mutating RNA virus a single or even bivalent vaccine will never provide lasting T cell immunity for over 98% of vaccine attempts fail to create long term T Cell memory which is essential for adequate lasting protection. The ‘Covid vaccine(s)’ is now ending up being yet another polyvalent vaccine just as the Influenza vaccine requiring a new vaccine to be formulated on a yearly basis with the CDC eventually having to speculate which strains will be prevalent for the year and formulating the vaccine accordingly. With a vaccine not being the ‘sine qua non’ mitigation for Covid-19 we simply can’t continue to confront the virus with the status quo approach.

It is the exact essence of this BioZone presentation to provide this paradigm shift as well as significantly advancing the field of Emergency

and Critical Care Medicine with novel technologies through the introduction of the ICBM and BioZone System. Any and all resurgences of Covid-19 mutation variants as well as any future novel contagion epidemic or pandemic must have a better proactive mitigation and never again should modern healthcare be caught with its pants down as witnessed the last several years.

The following pictures are reminders of what has been recently tolerated dealing with the Covid-19 pandemic.

C. Medical Errors

According to Johns Hopkins Medicine Center, medical error has been the third leading cause of death in the United States, with only heart disease and cancer killing more Americans. An estimated 250,000 patients die due to medical errors each year, accounting for 10 percent of all U.S. deaths, and researchers believe that deaths from medical errors are under-recognized and under-reported.

In this section we will consider alternative perspectives of medical errors other than what has been commonly recognized. Here we will look at the current Healthcare System itself as being a source for medical errors itself.

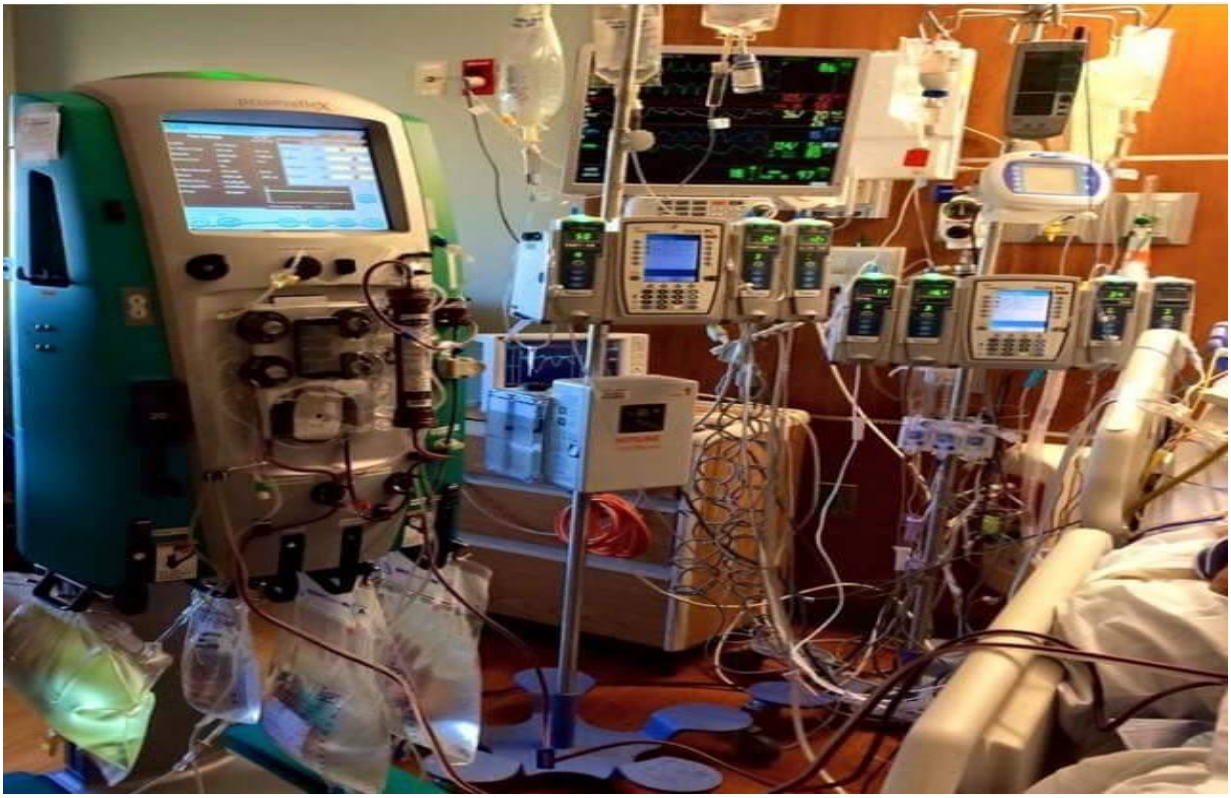


Fig.1 Critical Care treatment room

Fig.1 depicts a cluttered patient care zone utilizing a multitude of machines and medical devices to provide medical care. Of course, this representation is on the absurd side of the spectrum but is shown to

portray just how intense the navigation through the maze of wires and tubes can be for healthcare providers. It is obvious to any provider that this example illustrates certain leads and wires being designed for a specific purposes such as monitoring vital signs or detecting intermittent vital sign recordings. A variety of tubing are intended to administer different fluids, medicines or blood products while other tubes are designated as a means to collect and monitor outputs. Several devices are designed to simply support the machines that are intended to limit the fluid or medication administration to a predetermined and desired flow rate. These devices usually have a rather large base footprint in order to prevent tipping over. Additionally, in a setting such as depicted, there are often bulky devices capable of ventilating a person in need of such or having the capability to cardiovert a patient that develops a life-threatening cardiac rhythm. Trying to get to the head of the bed in order to intubate this patient if so needed can be a task in itself. Trying to be the Nurse provider that has to figure out which of the alarms is alerting staff that something isn't flowing as intended is also difficult. Imagine getting to the patient in the case that CPR is required or try intubating.

While Fig. 1 represents a single treatment room, in reality busy ER and ICU units are designed to provide a number of similar adjacent rooms in a ratio calculated for the critical mass able to support a given size community or referral center. Often there is a number of rooms in the same treatment facility having a number of critical patients that all are in need of such intervention at the same time. Add to the picture that the patient occupying the room may have a life-threatening contagious disease that was previously unencountered that could potentially jeopardize the provider's and their families' lives or the lives of other patients on the ward if exposed.

Previously, and once again recommended in the reports, this scenario would require staff providers to **'correctly**' don and doff bulky and uncomfortable specialized garments and at minimum throw up some sort of semitransparent plastic sheeting surrounding the patient in order that the infectious contagion would not contaminate the entire treatment unit exposing staff and other noninfected patients on the same ward.

Next, the working conditions in this contagion example mandates you cannot wear the same garments that you donned for one patient into the room of another assigned patient so one must '**correctly**' disrobe from the original set of PPE garments, leave the items either inside the room or onto a designated table, where hopefully someone disinfects the items, or in a worst case scenario the same provider has to disinfect their own garments, don a new set of PPE garments to enter a different patient's room and so on and so on all shift long. Of course, the ideal situation provided enough PPE and masks that the provider was able to '**correctly**' dispense of the contaminated items and open a new set right. Imagine the frustration of trying to communicate with a 'compromised' patient that has to look through your face shield or PAPR headgear while yours and the patient's mouth are both covered by a N95 mask. No source for a communication error here right.

What if this donning and doffing process was simply to reset one of the alarms that was beeping in the previously illustrated picture which more often continues to intermittently and repetitively go off because of some flow impediment such as a patient bending their arm or repositioning themselves. What if the patient codes necessitating the entire response team have to be '**correctly**' outfitted in PPE and PAPRs to enter the patient's room. Certainly, a significant team response delay is destined to happen given these circumstances jeopardizing the patient's life.

So, what is being done to prepare for a similar situation such as with the Covid-19 pandemic in the future. The two reports seem to emphasize we are merely planning to "stock up" with more PPE garments and masks knowing quite well from experience that trying to deliver quality healthcare dressed up in space suits undoubtedly led to an increase in medical errors, patient deaths, and attrition of healthcare providers. Could this be considered malfeasance accepting increased medical errors to be acceptable in the future given a similar situation?

The facility administration and directors will most certainly make sure that an adequate number of rooms and equipment are supplied for a staff of providers to render proper care so their job is done right. Lets' not

even take into account the existing shortage of healthcare providers or the fact that in such a future scenario attrition will repeat itself due to the reluctance of being forced to take more vaccinations to continue working in a healthcare facility, or from workers quitting to protect their own lives, or from becoming burned out and stressed from the unnatural and unconventional PPE mandates, or from simply becoming sick themselves due to the contagion. The entire list will all serve to exponentially exacerbate the problems previously encountered.

Another aspect of the existing healthcare system itself that may be associated with medical error has yet to be communicated in the literature. Traditionally, medical equipment has been purchased individually wherein acquiring an EKG machine means researching what is affordable and efficient and then buying or leasing the machine. Next, qualified ancillary personnel are hired to operate the device. For example, purchasing a ventilator machine or a defibrillator unit or a bedside ultrasound would be done in a similar fashion. Qualified personnel must be hired for these specialty devices according to conventional medicine. Ultimately the Emergency Room or Critical Care Unit ends up with numerous machines and devices cluttered around the treatment zone or secured to various areas with wall mount devices. In the prior discussion we addressed this concern. It is readily appreciable that such a traditional approach most certainly lends itself to the possibility of unintentional medical error and play a contributing supporting role in the Johns Hopkins report.

With the number of infusion devices as illustrated below in Fig. 2 the odds of one or more pharmaceutical solutions being inappropriately administered to a patient at an incorrect rate of infusion is destined for eventual miscalculation or unintentional flow errors. In the same situation, the attending Nurse or Nurses can look forward to a shift with constant beeping indicating that something has gone wrong. When the same Nurse is working an understaffed shift, attending to the annoying infusion alarms can be significantly delayed which might just put the patient’s life in peril.

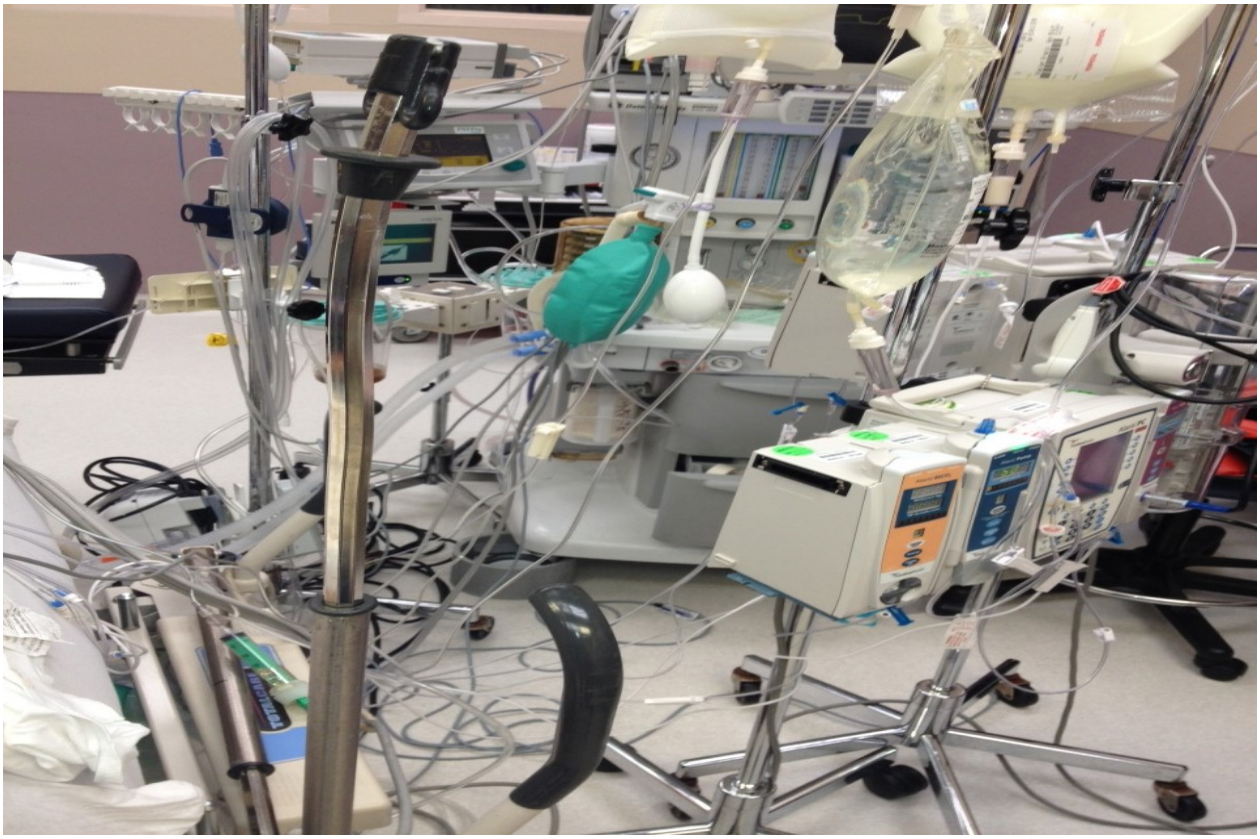


Fig. 2 Infusion Technology

Another consideration for the medical error topic is that ancillary personnel have their job descriptions optimized to validate their salaries so most often a person hired for a specific role is burdened with extracurricular mandates. If the EKG technician is upstairs in a different medical unit performing some expected service while the patient in the Emergency Room presented with an acute coronary event, how long will the EKG evidence be delayed in this scenario before the interventional process is activated. The answer is it depends on what is going on upstairs. The EKG technician might be attending another critical situation and is unable to leave the bedside with the ER patient heart muscle dying in the neighborhood of 50,000 cells per second in the case of an active infarction. The same can be said for the respiratory therapist caught with numerous stat requests at the same time in various areas of the treatment facility. What of the delay in obtaining lab results for the critical bloodwork must be sent to the lab in order for the facility to

charge separately under the auspices of the laboratory department and not the Emergency Department. Consider the patient registration having to be done before any orders can be submitted for surely the EKG, Respiratory Therapist, or X Ray Technician often do not perform their roles unless a patient is registered and an order is documented. Separate departments, separate duties, separate charges, and that is how the modern medical system exists; seemingly yet unfortunately revenue driven instead of proficiency driven. Perhaps we now touch on a totally novel way of defining how patient's lives are jeopardized in order to "leave no charge left on the table". Perhaps an alternative definition of medical error has been touched upon and void of publication.

Additionally, is it possible that the constant well known mismanagement of fluids and medication administrations are affected by the amount of time that healthcare providers are expected to document. Presently around 50% or more of the nursing staff performance occupies chart documentation instead of direct patient care. Of course, documentation is crucial in integrated patient care but having to actually take 8-hour courses in order to understand the complexities of the multitude of electronic medical records is at the least excessive. Again, is the documentation expectation care driven or revenue driven and could more direct patient care result in fewer medical errors and earlier recognition of a deterioration or change in a patient's status.

Yet another costar role in medical error incidence is the fact, as previously mentioned, that there is a shortage of appropriately trained physicians and ancillary healthcare providers. With such a shortage in providers, healthcare facilities ultimately mitigate the problem by substituting inappropriately trained providers expecting one title to be as good as another. Substituting Nurse Practitioners or Physician Assistants for Board Certified Emergency and Critical Care Physicians can't have any negative consequence with patient satisfaction or outcome can it. Taking a department and substituting lesser trained individuals to save money may merit administrative bonuses by reducing overhead but most

In modern times with unprecedented technological advancements why does the healthcare system continue to allow such longstanding problems to continue and why aren't we demanding a change through innovation. Emergency Departments have STAT orders for a reason and the acuity factor saves lives. Our Emergency Departments need to have a better system with faster diagnostic abilities and hospital revenue should not be jeopardized creating a system whereby payors make it nearly impossible to financially survive without playing the revenue games constantly mutating the ICD9 code reimbursements or intentionally denying reimbursement on a percentage of claims just to see how many they can get away with not paying. This is something that the Biodefense preparedness projects should address for if biosensor biothreat detection reimbursement is treated the same way by payors as everything else in the medical industry, then thousands of people will be infected by the time an actual Biothreat detection has gone through the maze of who is permitted to obtain it, who has to bill for it, who has to report it in order to receive the maximum reimbursement, or possibly, who failed to properly communicate the report to the officials.

The ICBM Global Initiative and the BioZone Innovation Project are designed to combat the problems discussed and much more. The ICBM provisions are being fast tracked to mitigate the report objectives and the remaining comprehensive system of cooperative integrated technologies will be phased in. The system has been designed to adopt compliment technologies discussed hereafter and those that will be introduced by global input. In this manner, perpetual modification and improvements will enhance the system capabilities accordingly.

Medical errors such as those described above will be reduced or eliminated and healthcare providers will have more time for direct patient care. The core BioZone unit is configured according to the primary needs of the healthcare center yet the multi-functional software programs will serve to reduce the potential for provider error, mitigate treatment delivery delay and documentation demands, and significantly improves diagnostic and interventional success through the breakthrough technologies that will lead to a new generation of healthcare innovations.

THE BIOZONE UNIT

A **Hybrid BioZone Unit** rendering is shown above with the optional multi-purpose isolation enclosure drape attached. Not shown in the rendering are the BioZone proprietary stretcher-chair, specialized patient PPE garment that seals to the bottom of the enclosure drape therein providing an airtight enclosure chamber, or the bilateral arrays of medical equipment and proprietary devices.

Note: The Healthcare Industry has historically responded to the past Biothreats in a serve and volley, action causing reaction fashion. The Biodefense Initiatives intend to change this approach to get ahead of the problem but in reality this is a formidable task. Perhaps the future will prevail with sophistication and superhero Biosensor detector Apps for our phones or sensing coats whereby anyone walking through smart supermarkets wherein entry will set off alarms if harmful contagious particles are detected.

Realistically, the fact is we are not there technologically therefore we must take a sensible approach as to what is manageable for the near term yet keep our long-term objectives in focus and keep plowing ahead. Sure, one day in the future all hospitals will be constructed with advance Biodetection provisions but the fact is healthcare today is achieved relative to healthcare facilities existing today and therefore we must be pragmatic and realistic in what can be done in the '**next phase**' of reaching sustained global health security. In regard to healthcare facility and healthcare provider interaction with patients the ICBM feasible near future solutions are presented herein.

It is important for the reader to recognize the '**open ended**' strategy built into these projects wherein concept technological advancements in the future will be able to be integrated into the basic countermeasure mitigant solutions provided hereafter. In the meantime, why not clean up some of the other present-day problems as well, get rid of the clutter from redundant and outdated equipment, get rid of the nidus for medical error, get rid of the revenue-based delays in patient care where '**minutes matter**' start getting rid of the untold but realistic healthcare facility acquired infections which are inevitably brought home to our family and friends, and finally, actually do something for mental health and drug addition with a different approach that might just work better.

So, in our quest for pandemic free preparedness and global security we are excited to do our part at VMT but this quest will not be cost free yet it will also not be cost prohibitive. We will need considerable financial assistance but we will not be repeating the mistakes of the past.

III. ICBM and THE BIOZONE SYSTEM

The BioZone System and Unit as a whole will undoubtedly prove itself to be a remarkable breakthrough advancement in the Biodefense and Healthcare System delivery arena. Millions of lives can be saved through the realization and utilization of the BioZone Project integrated with the **ICBM Global Initiative**. The ICBM Global Initiative objective being a Pandemic Preparedness Project utilizes the novel BioZone System and BioZone Innovations to provide countermeasure and mitigant solutions necessary for the Global Health Biodefense security. As the **ICBM Guidelines** are introduced the BioZone Innovations will be discussed correlative to the guideline necessary utilities.

The ICBM Project guidelines start by modifying conventional patient triage presentation practices by introducing an exterior facility **Patient Presentation Annex** (PPA). This PPA facility is presented as a viable option to having to retrofit existing buildings internally with those prior discussed preventative measures addressing contagion transmission in healthcare facilities. The cost of one Annex facility versus the cost of an entire building retrofit at a significantly reduced cost outlay realization.

This PPA Annex facility is recommended for all preliminarily assessments of patient presentations and is designed to have state of the art amenities to prevent the spread of transmissible diseases before entering the main facility. The PPA Annex will have a prescribed continuous laminar flow negative pressure airflow with ceiling germicidal UV lamps that are utilized per scientific advisement criteria. The bathroom facilities will have the same airflow and sterilization amenities and are equipped with **BioZone Commodes** specially designed to prevent contaminant spread with flushing and with smart technology analysis provisions. Partitioned seating areas separate infectious patients from noninfectious patients each with designated bathroom facilities. A separate ambulance entry portal is provided with the same airflow dynamics and sterilization means. PPA furniture provided are SAM coated materials and armless in order to minimize contact transmission from one person to another. N95 masks are made

available and encouraged or mandated for all patients. One area of the PPA waiting room will have specialized **BioZone Chair/Stretchers** in the case a patient does not feel they can remain sitting for a prolonged time. These BioZone specialty chairs have built in telemetry monitor capabilities in the case that the triage personnel feel unsure as to the patient's stability even in the case that the chief complaint doesn't seem to match the appearance of the patient or when the Triage Specialist fails to correctly assess the nature of the complaint. A patient monitor person is staffed to attend to the patient's and accompanying visitor needs and is also trained to recognize a person's deterioration. A novel trained **Triage Specialist** is present an performs a preliminary screening in a specified zone of the PPA. It is the duty of the Triage Specialist to do a first assessment of the patient and document the patient name and chief complaint that is most urgent. Here the Triage Specialist makes a Triage Level determination and enters the patient's name and chief complaint into the integrated electronic medical record software. The Triage Specialist then directs the patient and accompanying person(s) as to which section of the partitioned PPA they are to remain in.

Note that this reverses the previously described system as it exists presently. The ICBM guidelines recommend that all patients receive an initial cursory assessment prior to any investigation process as to the demographics and insurance status of the patient. Additionally, in this manner, patients with contagious entities can be directed away from patients with noncontagious presentations. **BioZone Shoe Sterilizer** means are provided for those patients or guests that desire to sterilize or decontaminate their shoes before leaving and going home.

Subsequent to preliminary screening and Triage Level assignments those patients requiring immediate evaluation and or intervention will be brought directly to the Emergency Department. Those patients with stable triage level determinations will await summoning by the administrative personnel into the patient information portion of the Annex. Hippa confidentiality measures and adequate staff protection is designed for the patient information zone and security doors are

provided for entry into the Emergency Department with staff activation necessary to open the doors. Waiting room monitors are provided as well as a security office section visible to patients or visitors in the PPA waiting areas. Patients immediately brought back to the ER will be conventionally secondarily triaged by ER provider personnel and all patient information will be obtained at the bedside by the ED admissions clerk(s).

Patients not immediately brought back to the ER treatment area and felt to potentially have some form of communicable contagious disease will be summoned to a specialized triage screening area of the PPA wherein an **ICBM Biodefense Screening** will be performed. An **ICBM Scoring Criteria** assessment of these patients will be performed and the attending staff provider will don and doff appropriate zone PPE garments as warranted. Here contagious patient triage rooms are equipped for rapid room sterilization and patient turnover.

A **PPA Anteroom** holding area is provided for those patients with positive ICBM Scoring Indices which warrants preliminary patient **isolation** from common areas of the facility wherein transmission of contagious infections could result. If such isolation is recommended and giving consideration to the patient's appearance and preliminary assessment, the patient could either be placed in a **BioZone Unit** and Zone with only the negative pressure and filtration system activation or brought to the treatment zone within the BioZone enclosure cabinet confinement. The BioZone Unit provides an attached transport mechanism chair and or the proprietary attachable stretcher chair.

In the case whereby the patient met the isolation criteria, the contagion protocol is activated, a specialized patient **BioZone PPE Garment** is donned about the patient's upper torso wherein the outer border of the garment is configured to seal to the lower enclosure drape of the BioZone Unit creating an airtight sealed N Class negative pressure isolation cabinet. Having accomplished the isolation seal, the BioZone Unit can now be brought inside the treatment facility without contaminating the treatment areas or exposing healthcare providers to

contagions '**without the need for PPE**'. The VMT proposal addresses the need for a contagious patient to be treated with precautionary isolation and not the entirety of the staff, a **Paradigm Shift** from what was experienced with Covid.

Note: It is relevant to discuss a patient being placed into a Hybrid BioZone isolation enclosure. This is not a discomfort for the patient as the BioZone enclosure has been designed with a predetermined comfort area and volume which is climate controlled, able to supplemented with oxygen, atmospheric pressure controlled, has a communication means to conversate with staff with a translator provision, provides an AI generated holograph image that communicates with the patient in order to obtain critical data such as the history of the present illness, past medical history, review of systems, allergies, social and family history, for example and convert the data into the electronic medical record therein saving considerable provider time and effort, an entertainment mode is controlled by the patient with music or projected media, may provide facial recognition technology, and much more. The proprietary upper torso specialized PPE garment has access portals to attend neck and facial needs, has intervention access in the case airway stabilization is necessary or becomes necessary, the upper section of the BioZone apparatus manually or automatically pivots to a skyward angle of 35 degrees therein lifting the PPE garment off of the body of the patient therein providing direct patient care access to the patient which will be further discussed but basically allows all medical assessment and procedures to be performed without exposing the provider to the infectious contagion, there is a PPE version for a mother and child presentation, there is even a portal whereby the patient may consume food or drink and be able to take oral medication. The following are the advanced provisions of the BioZone Unit apparatus.

Next, a **BioZone Unit BioSensor** is housed in the upper unit section of the BioZone apparatus. Here the integrated plurality of revolutionary breakthrough technologies such as Plasmonic Metamaterial based Biosensors for rapid virus, viral particle and antigen detection and recognition, low-cost point of care testing (POCT) through noninvasive

salivary diagnostic biosensors, geno, optical and electrochemical transducers, contagion resonance frequency detection, and second harmonics of magnetic nanoparticles all together grant a superior means for Biodefense with Detection and Activation provisions.

In this presented case scenario, the BioZone enclosure atmosphere will rapidly analyze the enclosure atmosphere for a specific period determining whether specific identifiable viral particles or antigens can be detected. An '**ICBM Alert**' is enacted if the BioZone AI provision detects and compares the findings to data base libraries thereby objectively identifying potentially serious contagions and or identifying those of which have yet to be recorded. In both cases, immediate notification of the facility healthcare personnel of a potentially serious contagion presentation occurs and simultaneous alerts to the associated National and or Global Biodefense Networks will occur. In this manner, integral data collection, analysis, and transmission at the initial point of care (POC) is provided. In the case that the contagion Biodefense Protocol is activated, the patient will be managed according to ICBM, Department, and Facility and National or Global operational guidelines and policies.

In the case no potentially harmful contagion is identified the patient may be either returned to a common area waiting room or again brought directly to a treatment zone if the urgency is warranted. In this fashion a serious contagion presentation has not entered or contaminated the Healthcare facility and the safety concerns of the healthcare providers was retained.

In the case of ambulance presentations, the **ICBM Scoring Index** will determine whether a BioZone Unit utilization will be necessary upon arrival to the facility ambulance ramp. In the case of an unstable patient ambulance presentation with no available time to evaluate and or prepare a BioZone Unit, the EMT patient report will be the determining factor as to whether a BioZone Unit is immediately required or the stretcher version BioZone Unit may be utilized with isolation provisions if needed.

Next, the **Hybrid BioZone Purifier** devices of the apparatus are themselves a means for decontaminating the treatment areas and or any desired area or zone of healthcare facilities. The unit permanently houses an internal HEPA filtration and UV light sterilization device fed by a fan motor assembly capable of creating a negative pressure laminar airflow. The units may function with or without the enclosure drape component. These decontamination and sterilization provisions were initially designed to treat a 12- foot by 12-foot treatment area but versions are now designed for larger rooms, waiting rooms, hallways, conference rooms, or any dead space of the facility.

In this provision, any designated or dead space zone inside a healthcare facility can become a rapid Covid or **Contagion Isolation Ward**. This advantage may also be a solution to the necessity for pop up facilities wherein additional bed space availability is needed. Simply create an isolation ward in any dead space of the facility. Additionally, the decontamination operation may be safely operated as such when the unit is occupied by patients. When temporarily occupied, the unit comprises an airtight N Class negative pressure isolation cabinet with an additional far left UV excimer lamp capable of safely and rapidly decontaminating the inner confines of the enclosure chamber in seconds which allows rapid and safe patient turnover.

The BioZone Units are designed for the continuity of care permitting a patient to be placed in the isolation enclosure in an ante room, transported to a treatment area whereby the proprietary patient garment permits direct patient care, subsequent transport to an admission floor room, be treated during the entirety of the hospital stay, and finally be transported to the discharge area outside the facility. The contagious patient was housed within the comforts of the BioZone the entirety of the hospital stay while never contaminating any zone of the facility or exposing any staff to the infectious contagion. The same sterilization or decontamination provisions are applicable to the hospital admit room.

Considering the BioZone is configured to provide a proprietary stretcher chair, universally adapt to all conventional stretchers and surgical tables,

the same isolation and decontamination provisions are applicable in surgical suites, obstetrical delivery areas, PICU and Pediatric treatment areas, dialysis units, chemotherapy administration units, observation units, for example.

Basically, in one preferred application the BioZone Unit is a state-of-the-art means for decontaminating healthcare facilities and therefore reducing the pathogen transmission capacity. A BioZone temporarily or permanently residing in an ER treatment room may be programed to intermittently operate and decontaminate the treatment zone air. With several BioZone units strategically placed in the ER the BioZone is designed to decontaminate and sterilize the ambient environment. Note the excimer lamp configured into the upper section of the apparatus may be rotated for a skyward projection limited to the treatment room ceiling area therefore substituting for ceiling germicidal lamps. In this fashion the excimer lamp does not interfere with examinations and or bedside treatments.

Next a mechanized mobile version of the BioZone can be programmed to course a desired facility path robotically in order to decontaminate and sterilize the ambient environment of waiting rooms, hallways, surgical suites, admission rooms, etc. The BioZone Units are designed to fit through all conventional facility doors and elevators and may be programmed to return to a charging station autonomously with a storage mode. Redundant protective means are provided to avoid contact with individuals and or moving or stationary obstacles when being utilized for decontamination of the facility.

As emphasized in the two informative reports, an early warning system to mitigate catastrophic biological risks is urgently needed. Since early Biodefense detection directs decision making with forecasting and risk assessment, it is essential to develop the ability to rapidly detect, characterize, report, forecast, and share relevant information (including genetic sequence data), as appropriate, on pathogens that pose a biological threat of national or international significance.

In doing so we must develop a more effective means through a single coordinated effort to orchestrate the full range of activity, cutting edge management, biosensors, diagnostics, intervention, and surveillance capacities. It was furthermore suggested that a common apparatus that networks early warning detection and notification would be ideal for the Biodefense Initiative.

The ICBM BioZone System and Unit provides such a recommended common apparatus therein providing integral data collection, analysis, and transmission at the initial point of care (POC) of patient evaluation areas within the healthcare facilities. Having such a unified approach would ensure domestic and global biothreat detection, biosurveillance, and information systems are coordinated, integrated, and capable of enabling timely bioincident prevention, detection, reporting, assessment, response, and recovery. In this fashion the Biodefense System is able to maintain and enhance an enduring domestic all-hazards hospital data collection capability, including data reporting and management systems, governance processes, and include other appropriate healthcare facilities and systems to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations. The BioZone Biodefense activation coordinates and notifies all local and regional facilities of a threat detection.

The Vertu Team believes the novel integrated point of care BioSensor detection provision, ICBM scoring criteria, AI integrated software alerting system networked and cooperatively integration with preestablished Biodefense Networks will serve as a valid and meaningful frontline **Early Warning System** application of the Biodefense Initiative and Pre-Pandemic Preparedness means.

The BioZone Unit can be programmed to intermittent scan any ambient environment anywhere in healthcare facilities in order to constantly and proactively search for known serious viral or bacterial pathogens, lethal chemical or gas agents, and or unknown viral or bacterial elements that warrant investigation. The BioZone Units AI technology is designed to communicate with one another during alerts as well as run trial

activations to assure functional interoperability and operational awareness and effectivity. The ability for POC detection and activation of the ICBM guidelines makes the BioZone a valuable asset of the **One Health** System of the future.

Next we will describe additional amazing superior and novel provision technologies planned for the BioZone System and BioZone Unit

IV. BioZone Core Project Technologies

A. CPU Core Element and Logic Development

The first major hurdle that had to be crossed recognized the problems in jointly interactive product realization between multiple parties. With IP theft, litigation for ownership and title, patent dispute, overwhelming costs, and language barriers, for example, we were compelled to 'Innovate a better method to Innovate', if you will. This is what led to the design of the **BioZone Innovation Software**. Utilizing the blockchain ledger documentation and time stamping interface as well as the GitHub strategy of global blockchain design input to better the blockchain implementation for everyone, we designed an analogous software construct for multiple people or groups working on the same medical problem. With expected submission description disputes and multiple options for node-to-node propagation we built in a heavy chain and DAO type governance to impart impartiality and fair algorithmic determinations. Next a system for participation and valid input was designed in order that fair reward distributions could be awarded to participants.

The BioZone Innovation Software Phase I has now been developed to the Minimal Viable Product 'MVP' status with significant additional coding input necessary for full functionality. The maturation of the software will hopefully become a global project such as GitHub exists in the blockchain arena. In this fashion the software would be an open-

source entity designed for perpetual improvement and free to the innovators of the world since the utilities are multifaceted and applicable to various technologies.

The **BioZone Intensive Care Unit** or 'BICU' is a state-of-the-art medical system version functionally configured to provide every aspect of emergency and critical interventional healthcare with a single modular apparatus.

The Phase II BioZone Innovation Software logic flow has been designed to integrate enhanced quality of care with the BioZone 'BICU' as a multifunctional partitioned core CPU or system driver. Phase II of the software is the central brain architecture of the project and will not only provide a unique functional interoperability between proprietary devices but will also interface with AI to assist providers in reducing medical errors, coordinate with a global scoring system and libraries to better patient outcome delivery, link clinical data with remote transmission and telemedicine, and transform such analytical data into an evidence-based matrix. A novel means for patient identification, confidentiality, and record security is introduced as well. Besides primarily saving countless lives, the BioZone Software mission is directed to lowering the cost of healthcare delivery by reducing outdated and redundant ancillary services, technique and equipment errors. The BioZone CPU will coordinate the functional interoperability of the proprietary compliment of BioZone medical devices and systems discussed herewithin.

Medical device interoperability is the ability to exchange and use information among one or more devices, products, technologies, or systems safely, securely, and effectively. This exchanged information can be used in a variety of ways including display, store, interpret, analyze, and automatically act on or control another product.

The BICU is designed to provide a plurality of innovation interoperability through the sharing of global medical healthcare information libraries and a proprietary artificial intelligence interface.

The FDA guidelines established in 2019 support the smart, secure, and safe interaction among different medical devices and information systems. The agency has been collaborating with hospitals, health care providers, manufacturers, standards development organizations, and other interested parties to promote medical device interoperability.

In compliance with FDA guidelines, the BICU System provides a multifunction partitioned CPU technology ensuring partition independence with no unintended interaction. The adaptive processing system's integrated processors and microprocessors utilize a multitasking stack-based architecture. This architectural approach simplifies the overall complexity of the integrated system.

Built in intrinsic partitioning permits hosting several critical applications on the same CPU therefore the BioZone CPU System provides a means for hosting a multiplex of desired medical analytical tools.

The BioZone CPU multiplex includes conventional modules for cardiac and respiratory telemetry transmission, EKG with rhythm and waveform morphology interpretation, pacing and cardioversion, chip technology ultrasound and POC labs, critical care cardiac and pulmonary index interpretations, direct and remote integration with existing electronic medical records, and a controlled environment.

Additional CPU capacity has been preserved for integration with forthcoming BioZone IP technologies such as the proprietary AI interface diagnostic and management software, pharmaceutical infusion and drug delivery management system, critical interventional devices, novel physiological signal detection and analytical data transmission, S.T.A.T. airway system, Summation BEKG, VO2 oxygen saturation detection, and STATUS; a revolutionary means for time saving examination and management documentation.

Even the basic version BioZone CPU provides the ability to be easily reconfigured upgrading rendered technology to meet the growing needs of healthcare facilities.

With current healthcare provider shortages, coupled with reliable model projections predicting even greater shortages forthcoming, the BICU will provide superior clinical detection, processing of acquired information, analytical deduction, and clinical management consultation. The BioZone System and Unit may well be a mitigant to future healthcare provider shortages. Diagnostic acuity will be vastly enhanced while provider medical judgement error will be subject to redundant means for redirection and if needed, correction. The remarkable BioZone System and Unit can be rapidly deployed to any area of the globe thereby immediately providing advanced technological healthcare to all underserved population of the world.

The BICU software provides on demand bedside and remote access brief and or comprehensive tutorials available for users therein providing an immediate instructional compendium of expertise. Video display of procedural tutorial content is accompanied by narration in all languages as is language interpretation for patients. The software additionally provides a streaming informational and entertainment package for the patient being treated.

Forthcoming software programs designed for the BioZone System include a circadian rhythm enclosure ambience, light therapies, proprietary BioZone documentation software designed to interface with conventional electronic medical records, fluid and medicine management program, room and zone sterilization program, AI integrated stroke detection program, real time cardiac event detection and intervention program, obstetrical monitoring program, pain perception and management program, code management with a hyperbaric environment now known to increase survivability, and documentation program, ventilator management program, automatic ER

to ER and provider to ER consultation and transfer management program, overdose management program, to name some examples.

B. The BioZone Modular Apparatus

The globally patents pending BioZone apparatus is designed with a futuristic yet minimalist appearance. The base of the BICU is designed to provide a temporary juxtaposition with conventional stretchers, gurneys, treatment chairs, and hospital beds of all variety. For close approximation, such as positioning the apparatus next to any side of a surgical operating table, the supporting legs fold in at a ninety-degree angle. A counterweight distribution provides the vertical nature of the apparatus to have a sound counter tipping result. The lower section of the apparatus also houses the power transformers, back up battery power sources and the functional CPU system. The wheeled base section of the apparatus provides mobility as well as stabilization. A programmable motorized version of the unit is available wherein the BICU can be automatically summoned or sent to programmed destinations.

The middle horizontal section is called the docking station. This section provides a securing means for multiple pivotable extending arms which support the BICU array of proprietary medical devices designed for the system. These adjustable supporting arms have variable sized rotating table inserts providing a multitude of system equipment support as well as providing a stable means for interventional or procedural platforms. In this fashion the need for bedside Mayo stand trays is usually eliminated. The docking station and extendable tables are designed for supporting the various emergency department and ICU devices such as a ventilator, defibrillation and pacing machines, a Bipap machine, an ultrasound device, for example. A variety of monitors and proprietary devices are affixed to elevated support arms or the lateral aspects of the vertical workstation section wherein the total array provides a meticulously organized ER or ICU means in one system. All wiring is enclosed providing a very organized and neat appearance.

The docking station additionally provides umbilical attachments providing a utility connection means from the CPU unit to the system's medical device array and a temporary securing feature to secure the BICU apparatus to a stretcher or operating table, for example.

The next vertical section is the workstation. This customizable multifunction unit provides the multitude of devices used in emergency and critical care medicine a means for organized access and display. The extrinsic workstation provides a vast number of configurable variations to meet the needs of the facility as well as providing a means for oxygen delivery, suction, power sources, light arrays depicting the functioning mode of the unit, USB ports, IV pole extension trees, function switches and air intake and discharge vents for the intrinsic workstation.

The internal workstation provides a proprietary means for decontamination and sterilization of air as well as the means for providing a desired positive or negative pressure environment to the optional isolation enclosure. The workstation provides the posterior attachment mechanism for the BICU isolation enclosure drape wherein the front section of the workstation becomes an internally situated functioning panel in the BICU isolation mode. Specific utility of the internal panel of the workstation is provided as needed when the isolation unit is operating.

The next section of the apparatus is called the hood. The hood provides the upper attachment means for an isolation enclosure drape as well as providing sterilization means of the stretcher and room enclosure. The hood is pivotable with the ability to be manually or electronically raised or lowered for desired functions. The lower face of the hood provides vents for treated, heated or cooled air circulation, dome procedural lights and an excimer lamp. The Far-Left Excimer Lamp is provided to rapidly sterilize the isolation enclosure when being utilized either with an occupant remaining inside or for patient turnover. The proprietary excimer sterilization of the enclosure chamber takes but a few seconds to

complete the process and is safe for occupants temporarily residing within the confine. The front section of the hood provides LED light arrays depicting what functioning mode is being operated with the BICU. The top dome section of the hood is where the remote transmission capability of the apparatus is housed as well as a proprietary ceiling treatment area sterilization device is housed.

The Hybrid utility optional isolation enclosure drape is a quadrilateral means for providing an airtight isolation enclosure chamber. Attachment of the enclosure drape to the back side and top of the unit has been mentioned. The front or either side of the enclosure drape has an airtight sealable ingress and egress means. The upper and back attachable securing means provide an easy-on-easy-off attachment mechanism making the isolation function of the BICU a true 'HYBRID' unit. The entirety of the BICU therefore functions as a mobile all in one ER, ICU or Surgical Station, or Drug Delivery (discussed later) apparatus with or without the function of providing an isolation enclosure. The N Class negative pressure means and decontamination and air sterilization functions provided by the BICU will make the hybrid innovation the most rapidly accessible mobile isolation unit available for healthcare facilities. The patents pending proprietary patient garment seals to the bottom of the enclosure drape to provide the base element for the airtight enclosure chamber. The actuator hood can be angled skyward 35 degrees which lifts the patient garment off the patient providing direct patient contact while maintaining the upper torso of the patient within the enclosure chamber. Special provisions are configured into the enclosure apparatus for a provider to intubate, manage the patient's airway, examine the HEENT, provide respiratory treatments, and feed the patient.

Billions of dollars of healthcare expenditures can be eliminated while at the same time providing a revolutionary preemptive and proactive solutions to the life-threatening contagion presentations in need of

surgical intervention anywhere on land, sea, air, space or on the battlefield setting.

The versatility in the design of the modular apparatus permits the healthcare provider or facility to modify the unit easily and incrementally as need be. The internal CPU is initially designed to manage all system interfaces as well as provide the means for an expandable integration of the proprietary forthcoming technologies. For convenience, the BioZone versions have been configured to optimize utility. An operable workstation design format has been pre-configured for each version yet customizable. The build your own version provides the ultimate in preference and specific need, yet the BioZone System has been configured for continuous upgrades without ever needing to replace the core unit with a later version.

C. Utilizations

The BioZone Care Unit is customizable to fit the specific needs of an office or anywhere such healthcare treatment apparatus is needed. The BICU is therefore provided in a core version expandable to:

- A first core **Office Version** is provided to meet the needs of healthcare providers in an outpatient office setting. Whether providing dialysis, phlebotomy, respiratory care, chemotherapy drug delivery or even outpatient surgery, the BioZone can be configured to meet your needs. A positive and or negative pressure isolation enclosure is available whereby direct or indirect patient isolation is provided.
- A second core **Transport Version** is designed for mobility while also providing an isolation negative pressure enclosure. This version allows the safe transport of a contagious patient from an ambulance unit or staging area into a healthcare facility Ante Room. From this location the safe patient transfer of a contagious patient from an Ante Room to a treatment zone is provided therein

preventing the transmission of dangerous contagions within the facility.

- A third core **Intensive Care Version** is the most comprehensive regarding functionality. This version is designed specifically for Emergency and Critical Care Units providing an all-in-one patient care system. This intensive care version is designed to provide an organized immediate access to all conventional critical care equipment. The unit is designed to functionally abut and temporarily secure with all designs and variations of healthcare gurneys, stretchers, hospital beds and operating tables. An isolation enclosure provides the same prevention of contagious transmission while permitting complete access to the patient. The proprietary direct access care provision makes it possible to render any and all conventional interventional applications such as emergency and trauma care, ultrasound, radiological assessment, cardiac care including echocardiogram and angioplasty, and interventional surgery, for example. The BioZone System permits such care without any inconvenience or impedance such as experienced with conventional isolation units. The Intensive Care version is designed to integrate with the revolutionary novel technologies provided with the BioZone System.
- A fourth **Surgical Care Version** is designed in several versions to provide the means for surgical specialties to operate in a sterile environment anywhere on land, sea, air, or space. The surgical care version of the BioZone Unit provides dual excimer lamp sterilization for both the negative pressure isolation enclosure, in the case of a contagious patient presentation, and the surgical intervention treatment zone whereby a means for zone sterilization is provided without sterile field compromise. The conventional BICU UV sterilization, and HEPA filtration system which are configured internally provide the isolation and reverse isolation utilities for a patient temporarily housed within the confines of the

enclosure apparatus. As previously described, the BICU System is able to expand its utility scope to permit an infectious patient to be safely addressed by the surgery provider without risk of infectious exposure to the surgeon, surgical team or surgical treatment zone. A similar yet alternative application of the surgical care version of the BICU may be utilized in the Obstetrical field for infant delivery or serve as a PICU station for caring for the critical newborn or pediatric patient needing isolation or reverse isolation.

Variations of the Surgical BICU are applicable to essentially all surgical specialties and will provide a superior multifaceted advantage over the conventional approaches, reduce treatment space requirements, eliminate treatment area clutter by providing the all in one critical intervention treatment and monitoring apparatus, and provide a new generation of BioZone System Innovations such as AI facilitated administration of anesthetics, real time critical monitoring, improved provider documentation of procedural intervention and data sharing through the electronic medical record interface.

- A fifth **Aerospace Care Version** is designed specifically for employment in air or space. A BioZone Unit has been specifically designed for use onboard aircraft which provide the first aircraft critical care management system. Suffice it to say that not only Air Force One will be equipped with all of the lifesaving unit but all of commercial airliners may be expected or required to follow suit. At the very minimum, commercial airline companies would want to advertise available lifesaving interventional care onboard given the significant number of travelers with existing medical conditions. Even in the absence of a physician aboard the craft the provided interpretive, monitoring, and interventional critical care treatment devices would integrate with the systems provided telemedicine capabilities. At this point, a previously arranged management of

the unexpected critical presentation information can be transmitted and appropriate healthcare management may be continued until transport to a ground facility can be performed. Nothing less should be expected by the customers, the flight crew, and the industry for the future generation of commercial air travel.

In regard to Space Travel, and as the industry continues to expand, a BioZone BICU has been conceptually derived to better the onboard health and wellness of the astronaut crews and or civilian passengers. The Aerospace version is configured with respect to even less available space to occupy yet retains all of the provisions of the comprehensive ground unit version described herein. Given the specialty needs and considerations encountered with prolonged space flight, the utilities provided with this version of the BICU have been generously expanded with solutions to known space travel problems and conditions as well as a complement of novel and proprietary innovations. The considerations for space travel have primary emphasis through the delivery of a proactive means and methodology to better protect the health of the astronauts or cabin occupants through the delivery of a superior onboard healthcare system design. The compact yet comprehensive BICU enclosure component not only provides an onboard positive or negative pressure isolation apparatus similar to the aforementioned versions but addresses specific mental and emotional factors encountered in prolonged space flight by serving as an emotional management station.

The isolation drape enclosure material itself has been well thought through and designed with a proprietary high hydrogen polyethylene content intended to absorb and disperse radiation. Kevlar is integrated in the material as a fire-retardant material and lithium hydride reduces the overall weight of the component.

The BioZone Aerospace Version is exceptional in itself with novel applications specifically applied to space travel. In this aspect as well as for consideration as to the length of this presentation the Aerospace Version is detailed in a separate document with the same title. For those interested in the Aerospace Version please refer to the separate document.

- A Sixth **Submarine or Deep-Water Facility Version** has been designed for the special consideration environment. This version addresses special temporary environmental circumstances with similar regard as with the Aerospace version plus the provisions discussed below.

The BioZone System will provide the central brain power of the unit with elimination of the equipment clutter while providing vastly superior information management. The source for medical error will be drastically reduced and lives will be saved while the Hybrid functionality of the apparatus will provide a direct and reverse isolation enclosure. The need for PPE and bulky inefficient isolation tents or the expensive retrofitting of departments to provide negative pressure treatment rooms will be mitigated and billions of dollars in healthcare costs will be eliminated. From this point forward the future Healthcare Systems of the world will be prepared for any and all existing and future contagious patient presentations. Healthcare providers will be able to immediately return to a conventional work environment and patients and family members will no longer acquire nosocomial exposure to treatment facility pathogens nor be required to wait outside the facility.

There is a BioZone System for every facility need. Medical offices will have the ability to provide unexpected emergency intervention and temporary isolation of a contagious patients. Specialized centers such as Dialysis units or Oncology units will be able to provide life sustaining treatments while protecting the patient from pathogenic exposure or vice

versa protecting other patients and healthcare providers from contagious patients.

Nursing homes will have the ability to provide long term care to their residents with intermittent isolation requirements available and family members will once again be able to visit their loved ones and be by their side during critical moments.

Hospital Emergency Departments will finally have a safe means for the initial acceptance of a potentially seriously ill contagious patient in a designated Ante Room and then be able to isolate the patient in the BICU transport model. From that point on, the patient can be safely transported to a treatment zone, treated and or admitted to the floor while never leaving the isolation enclosure or potentially transmitting the infectious contagion inside the facility.

Patients may continue to receive hospital care of any form inclusive of angiography, surgery, radiology, ventilatory support and even receive CPR with never exposing the staff or facility to contagious transmission. Even a novel means for feeding and providing toilet access has been provided with the BICU system of innovations with similar protective isolation. The BICU is truly a once in a century healthcare innovation with a multitude of forthcoming planned technologies that will redefine medical care as we know it.

The next section of the discussion below will briefly detail numerous additional novel and proprietary methods provided by the BICU System of components.

The following rendering illustrates the basic core unit without the isolation enclosure or laterally housed arrays of conventional and proprietary devices. In the preferred and petitioned configuration proprietary medical devices are situated in arrays to the lateral aspects of the vertical work section. The lever arms and device supporting trays are

extendable anteriorly providing closer approximation to a patient on a stretcher or operating table.

The following options are available and may be incorporated for all versions of the core models.

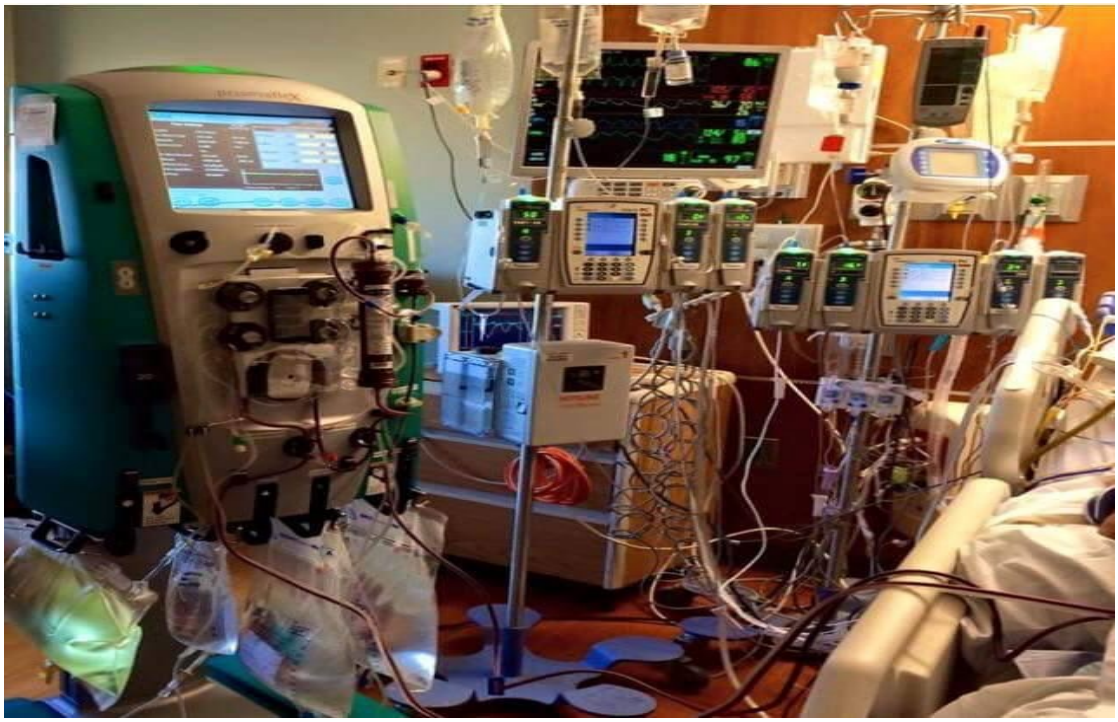
Visuals:

- Custom color packages: Two toned powdered coated paint combinations, pinstripes, decals, seats, bumpers all coordinated to match packages.
- Custom LED light package: multicolored LED light arrays coordinated with apparatus functions. Dimmers included.
- Custom chrome package.

Functional Utility:

- Isolation enclosure curtains
- Enclosure curtain storage unit
- Cooling and heating of isolation enclosure chamber
- Proprietary BioFlow and BioNeb Drug Delivery Device
- Hood dome lights, stationary or directional
- Manual or motorized pivotable hood
- Excimer lamps for sterilization of isolation enclosure
- USB ports
- Intercom
- Language translator
- Proprietary EENT examination unit; includes remote otoscopic, oral and nasal visualization, fundoscopic pressure determination, slit lamp evaluation all with recordable documentation interface
- Entertainment unit for auditory and visual streaming Permits remote video visualization of patient for providers and Telemedicine consultations
- Workstation modules, equipment securing devices
- Multifunction CPU configurations
- Proprietary BioZone medical device array
- BioZone proprietary ventilator
- BioZone proprietary summation KG
- BioZone proprietary Bipap Unit
- BioZone Telemetry and Monitor Unit
- BioZone proprietary S.T.A.T. Airway Management devices
- BioZone Ultrasound on a Chip Unit
- BioZone proprietary pharmaceutical fluids infusion management device
- BioZone proprietary pain management device
- BioZone proprietary vital sign acquisition device
- BioZone proprietary IV placement visualization device
- BioZone ambient lighting and circadian system

- BioZone proprietary exercise and rehab devices
- BioZone Pacer/Cardioversion Unit
- Docking station IV pole trees
- Stretcher securing device
- Pivoting extendable arms and tables
- Built in transport seats and footrests
- BioZone proprietary stretcher/chair
- BioZone proprietary BioSensor
- BioZone proprietary Otoscope
- BioZone proprietary Ophthalmoscope
- Folding base support leg extensions
- UVC and Hepa filtration decontamination devices for Class N negative pressure enclosure environment
- Umbilical unit for oxygen delivery and suctioning
- Oxygen tank holders
- Additional extended life lithium battery power sources



Today's ICU and ER

Future ER and ICU with BICU

BioZone shown decontaminating ICU unit and searching for contagions

The following Fig. (1) rendering of the BICU depicts the operational mode including the isolation enclosure drape. Also depicted is one version of the pivotable extending arms and rotating table supports. This version shows the ingress and egress at the front of the enclosure. The patent pending lower garment section of the enclosure is not shown. A stretcher or gurney, medical treatment chair or hospital bed would be situated between the supporting legs of the base unit. For operating suite utilization, the lower supporting legs will be folded to the middle at ninety degrees. The hood of the unit is shown at the default position and can be tilted superiorly for accessing direct patient care.

Fig. (1) BICU with proprietary negative pressure isolation enclosure attached.

The following fig. (2) rendering is a depiction of a basic core model version of the workstation section of the apparatus. The upper vent is for air intake while the lower vent is for air discharge. The posterior optionally directed vent is not shown. The posterior vent discharge is intended for when the BioZone is being utilized solely as a decontamination and sterilization means.

Fig. (2) BioZone shown with minimal basic requirement workstation

The front face section of the workstation will be inside the isolation enclosure during utilization. The lower ports are ventilator management connectors. Side activation switches are shown in this version with power outlets at the back of the side sections. The workstation can be modelled to nearly any configuration requested for the needs of the facility and updated as needed. This depiction is a basic unit. The slide provisions make the temporary or permanent attachment of desired medical devices a simple task. The BICU provides a full line of accessory emergency and ICU devices designed to complement the appearance and compactness of the apparatus with no visible cords or cables. The interoperability functions provide remote location transmission with formatted data documentation designed to interface

with a proprietary electronic medical record provision. The following fig. (3) BICU Transport model is a rendering of the office or specialty clinic version shown with the optional isolation enclosure. This model provides an enclosed pull-down seat that comes in a variety of designs. Also shown is the hideaway foot support that is adjustable for the comfort of the patient. The transport version is available with a push bar at the back of the unit and or a motorized version that is fully programmable. The transport version is additionally provided a series of proprietary stretcher-chairs that serve as a comfortable dialysis, phlebotomy, respiratory treatment, ER, or chemotherapy chair. These specialty chairs have a C-arm pivotable function wherein the flexed chair extends into a horizontal comfortable stretcher with standard or reverse Trendelenburg capability. In this manner, a patient may be greeted, transported, treated in an upright or horizontal position according to the desired medical intent or placed in an immediate emergency interventional position in the case of seizure, hypotension, vasovagal syncope or cardiac dysrhythmia, for example.

Fig. (3) BioZone coursing clinic with sterilization option engaged

The following fig. (4) rendering depicts the pivotable function of the hood component which is manually or automatically operated. The hood range of motion is at any point in a positive or negative 45-degree arc from the horizontal default plane.

The BICU is in this case is shown with the hood elevated for easy access for the patient into the isolation enclosure. The superior angulation of the hood component is vital for direct patient access care when combined with the proprietary lower isolation enclosure patient garment component.

Fig. (4)

The following fig. (5) rendering is a depiction of medical facility dead space utilization. Any hallway, meeting room, waiting room or dead zone of the facility can easily be utilized as a critical care or isolation treatment zone. With fully independent operable ability and power source the BICU is an ideal mitigation for any urgent demand for additional treatment capacity. In this aspect, the BICU may eliminate the need for pop up hospital treatment facilities yet lends itself to being just that. A remote location deployment of a number of BICU units into a disaster or war zone can be rapidly provide a complete emergency or intensive care unit with surgical intervention capability. This remote utility will be an exceptional option for naval vessels and military bases.

Fig. (5) BioZone Contagion Ward in previous dead space of facility

The final fig. (6) rendering depicts the BICU in a storage mode requiring a mere 3.5 feet by 3.5 feet area for inactive storing. An optional GPS module is programmable therein permitting BICU units to be remotely summoned and or sent back to a storage mode location.

Fig. (6) BioZone automatically returning for storage and recharging

The BioZone Intensive Care Unit is the mitigation for healthcare facilities to prevent contagious transmission of virulent pathogens such as the Covid-19 virus. The virtual ICU in a single apparatus project was fast tracked with the onset of the pandemic whereby the basic core

models including the negative pressure isolation enclosure can be manufactured and readily available.

This immediate Covid-19 mitigation is only part of the overall superior advancements to the Healthcare System that the BICU brings. Hundreds of billions of dollars in healthcare savings will be realized by the introduction of the BICU into the healthcare system. The ability to reduce contagion transmission in medical facilities, the elimination for the need for expensive PPE gear that is only thrown away becoming tons of medical hazardous waste products, and the reduction in medical error are a few examples.

Additionally, revolutionary proprietary technologies in the fields of Cardiology, Emergency and Critical Care Medicine, Artificial Intelligence and unprecedented documentation solutions are now entering development stages. These disruptive technologies are designed to integrate with the BICU making the BioZone System of innovations one of the most significant advances in medical history.

IV. BIOZONE ADVANCED TECHNOLOGIES

A. Pulmonary Drug Delivery System; BioFlow and BioNeb Technologies

An unprecedented and proprietary technology device is provided for the BioZone Intensive Care Unit isolation enclosure chamber. The novel treatment enclosure was initially developed specifically for Covid-19 patients with inflammatory pulmonary involvement requiring intervention and was next expanded to address similar lung injury and inflammatory conditions from many other mechanisms. The utility of the enclosure chamber functioning as an isolation and negative pressure chamber has been discussed. With prevention of intubation and ventilator assistance having been a forefront consideration in treating

Covid-19 patients, the BioZone System provides a unique means to prevent respiratory insufficiency progression. The specific sized enclosure chamber has been calculated for the prolonged comfort consideration of a hospitalized Covid-19 patient as well as providing an ideal internal treatment area and volume. The BioZone isolation chamber is applicable to all existing and future serious contagions. The transportable BICU delivers an isolation enclosure designed to provide a decontaminated negative and or positive air circulation unit function designed for **prolonged occupancy**.

Next, the utility of the BioZone enclosure chamber was expanded with another novel function and objective being the provision of a proprietary Pulmonary Drug Delivery System Compliment.

The BioZone '**Pulmonary Drug Delivery System**' (PDDS) has been designed to cooperate and coordinate with the pharmaceutical industry technologies and not compete with them. Alternatively, the provisions of the BioZone PDDS mitigates many of the impediments encountered by the industry with drug delivery through the respiratory system and provides a combined system with significantly greater efficacy.

A proprietary **BioZone BioFlow** and **BioNeb** device is under development to integrate with the PDDS apparatus wherein pharmaceutical agents can be microsized and aerosolized into an invisible atomized cloud therapy which is infused into the enclosure apparatus in a desired laminar flow through the BioFlow provision. The BioNeb provides a '**Smart Nebulizer**' for drug delivery. The BioFlow laminar circulation, creating the '**Bio-Atmosphere**' and the individualized BioNeb drug delivery infusion therapy is designed for prolonged total lung therapy with far superior diffusion and saturation into the lung tissue than what has been delivered with conventional respiratory therapies.

The BioFlow and BioNeb internal enclosure's Bio-Atmosphere has been designed to specifically address the need to better perfuse lung tissue, facilitate pulmonary drug delivery, mitigate inflammatory responses, reduce the harmful debris accumulation, and prevent progression of

respiratory insufficiency and thwart crossover organ damage. The technology provided by the BioZone System's AI software provides an analysis of an individual's respiratory function, disease status, and pharmaceutical drug to be administered and then automatically determines and modifies the specifics of the BioAtmosphere treatment environment. For the first time in modern medicine technology will integrate biometrics, biosensing, functional signal detection and analysis, with artificial intelligence designed to continuously specify treatment allocations for pulmonary drug delivery.

Multiple novel medical devices are designed for the Bio-Atmosphere in order to achieve the primary objectives. One device delivers olfactory stimuli designated to lessen the protective mucociliary reactionary defenses of the lungs. Cycled pressure gradients are provided in order to affect the macro and microcirculatory pulmonary systems, temperature gradients are varied accordingly as well as upper and lower body pressure gradients. Ionization facilitation is applied according to the pharmacokinetics of the pharmaceutical agents and vibratory and audio synesthesia promotes better absorption. Dithermal chest stimulation stimulates the autonomic nervous system in a preferred fashion and hormonal and pheromonal stimuli is utilized as well. Magnetized directional drug delivery targeting influence is provided and assisted by ultrasonic wave coupling. Cycled humidification is provided as well as harmonically resonated frequencies promoting better absorption at the respiratory membrane. Acoustics are utilized within the BioZone enclosure with specific desirable euphonic interactions with the Pulmonary barriers. Finally, novel respiratory maneuvers increase the pharmaceutical-pulmonary interface duration while electrostatic applications reduce the upper airway drug adherence and precipitation.

The considerations and applications of the complete BioZone PDDS provisions have the following pulmonary objectives:

- Provide a set of inhaled respiratory maneuvers that better facilitates ventilation and drug delivery to the terminal airways of the respiratory tract.

- Provide a predetermined mixture of gases to better promote gas exchange.

- Maximize the gaseous tidal flow exchange and lung tissue absorption area.

- Reduce the molecular adhesion and particle trapping in the conducting zones of the respiratory tract, slow the mucociliary escalator clearance,

- Stimulate Type I and Type II alveolar epithelial cells to enhance gas and microparticle absorption in the respiratory zones while reducing the alveolar membrane permeability barrier through Phospholipid and Apoprotein modulation.

- Modulate the macro and microcirculation and lymphatic flow of the lung tissue.

- Modulate oxygen-hemoglobin affinity and dissociation in a desired fashion.

- Facilitate controlled release drug delivery and systemic bioavailability of proteins, micro, nano, and macromolecules.

- Modulate enzymatic activity

- Promote targeting of pharmaceutical to specific lung regions

- Facilitate lower drug doses with enhanced efficacy.

- Temporary inhibition of Macrophage activity and proteolytic degradation.

- modulate pH-value, electrical charge, solubility, aerodynamic particle behavior and stability of the inhaled substances.

- Preferably alter pharmaceutical dimensions and particle stiffness to facilitate absorption and reduce enzymatic degradation.

- Modulate inertial deposition, sedimentation, Brownian diffusion, interception and electrostatic precipitation of drug carriers.

- Preferrable modulation of mucus generation, steric absorption, adhesion, viscosity, and elasticity. Modulate interaction forces between

mucus and nanoparticles through including hydrogen bonding, van der Waals interactions, polymer chain interpenetration, hydrophobic forces, and electrostatic/ionic interactions or a combination thereof.

- Increase the permeability of the lungs to peptides and macromolecular drugs without the need for absorption enhancers or promoters.

- Reduce drug visibility to reticuloendothelial system.

- Modulate pore size, optimize margination, and particle accumulation and interaction to vascular endothelium.

- Modulate particle trajectory.

- Enhance the mucus penetrating particle speed transit time.

- Reduce the speed and incidence of cellular apoptosis.

- Impede vascular endothelial damage and proinflammatory environment caused by ischemia.

- Provide virus shape configuration of micro and nanoparticles to avoid mucoadhesion and facilitate cellular recognition and absorption.

- Provide charged cations to promote specific cellular absorption, activation and or deactivation of enzymatic processes.

- Modulate high density surface charges to create a hydrophilic surface charge and dissuade hydrophobic mucus entrapment.

- Stimulate mucolytic processes through dithermal regulation, charge manipulation and temperature and pressure gradients.

- Enhance and facilitate drug delivery kinetics and loading efficiency.

- Modulate decoupling of particle and carrier at desired PH, temperature or pressure gradients.

- Facilitate neutralizing monoclonal antibody delivery through lungs.

- Develop Nanovehicles devices powered by biocompatible external energy, such as light, electricity, sound, and chemistry energies provided by the BioZone devices that can convert different forms of energy or

fuel into kinetic energy and are increasingly used in drug delivery, catalysis, environmental monitoring, and biosensing.

- Develop magnetically driven Nanovehicles.

- Facilitate the pulmonary bioavailability of biological drugs.

- Stabilize the aerosolization of biological drugs.

- Modulate the role of endocytosis/transcytosis in transepithelial trafficking of inhaled biologics.

- Reduce inflammatory immunogenicity and amyloid production.

- Prolonged drug residency in the pulmonary environment with mucus saturation.

- Decreased protein aggregation, denaturization of molecules and unfolding at the air-liquid interface during the process of atomization of drugs by means of rapid preparation at site of delivery.

- Smart BioNeb nebulizer utilizing AI to provide unique personal inhalation parameters therein dissociating delivery efficiency and pulmonary functions.

- Modulation of pulmonary clotting manifestations.

- Modulation of cancer vascular architecture endothelial pore size through vasomotor stimulations providing vascular targeting macromolecular agent therapeutics.

- Provide a safe rapid turnover means to deliver potentially harmful drugs through the pulmonary system (example; cancer treatments).

A BioZone technical analysis document has been provided in order to better understand the underlying principles of the body's responses to those stated various injuries, inflammations, ischemia, and irradiation. The intricacies of these physiological and immune cascading responses have been detailed and the BioZone System's technological advancements have been engineered to beneficially intervene in each of the described detrimental physiological processes in the report. In one aspect of the BioZone System Technologies, the novel Pulmonary

Pharmaceutical Drug Delivery System is introduced and discussed herein. In another aspect the BioZone enclosure, BioAtmosphere, BioFlow, and BioNeb provides a means for enhanced pulmonary conducting flow, increased respiratory zone gas exchange, desired microcirculation and endothelium effectors, cardiopulmonary baroreceptor modulation, intervention in effector cells and proinflammatory cytokine release and Cytokine Storm initiation, deactivation of activated Leukocytes and Platelets and free-radical generation, feedback mechanism alteration, selectin secretion inhibition, pseudo-sequestration and alteration of specific cells with detoxification chelator provisions and receptor active drugs and immunosuppressants, and injured cell sequestration and endothelium repair and rejuvenation.

The BioZone Bio-Atmosphere's BioFlow and BioNeb treatment modalities will provide another Paradigm Shift in the ability to better treat those injuries, inflammations, ischemic and irradiation consequences itemized in the report.

Additionally, with the introduction of the BioZone System's Bio-Atmosphere provisions and proprietary Pulmonary Drug Delivery System into the Healthcare Industry, a means and methodology to better intervene into the acute and long-term consequences of Myocardial Infarction and Cerebrovascular accidents will become the standard of care. At VMT we envision the day when a child only has to temporarily reside within the comfort of the Bio-Atmosphere in order to receive chemotherapy or when a stroke or MI patient can undergo immediate and noninvasive treatment to minimize the damages sustained of the event. The investigation of the potential applications of the Bio-Atmosphere are only in early-stage investigation. It is exciting for the Healthcare Industry to have a novel means and methodology to deliver breakthrough technologies by means of the Bio-Atmosphere.

The following itemization reveals additional promising areas whereby the BioFlow and BioNeb delivery system may be utilized accordingly. The petitioned BioZone Bio-Atmosphere discussed herein may treat and/or prevent any inflammatory condition, including primary

inflammatory diseases arising within a subject and/or secondary inflammatory disorders arising as a response to a medical procedure (e.g., dialysis or cardio-pulmonary bypass). Examples of applicable inflammatory conditions, including inflammatory diseases and/or disorders, include, but are not limited to, systemic inflammatory response syndrome (SIRS), polyarteritis, Wegener's granulomatosis, autoimmune vasculitis, anti-neutrophil cytoplasmic antibody (ANCA) vasculitis, extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass syndrome, acute respiratory distress syndrome (ARDS), acute lung injury (ALI), chronic obstructive pulmonary disease (COPD), sepsis, rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, multiple sclerosis (MS), psoriasis, allograft rejection, asthma, acute renal failure, chronic renal failure (CRF), end stage renal disease (ESRD), cardiorenal syndrome (CRS), chronic heart failure (CHF), stroke, myocardial infarction (MI), hepatorenal syndrome, cirrhosis of the liver, diabetes mellitus (type 2 diabetes), and acute organ failure from ischemic reperfusion injury to myocardium, central nervous system, liver, kidney, or pancreas.

Additional examples of inflammatory conditions include, but are not limited to, transplant (such as organ transplant, acute transplant, xenotransplant) or heterograft or homograft (such as is employed in burn treatment) rejection; ischemic or reperfusion injury such as ischemic or reperfusion injury incurred during harvest or organ transplantation, myocardial infarction or stroke; transplantation tolerance induction; arthritis (such as rheumatoid arthritis, psoriatic arthritis or osteoarthritis); respiratory and pulmonary diseases including but not limited to chronic obstructive pulmonary disease (COPD), emphysema, and bronchitis; ulcerative colitis and Crohn's disease; graft vs. host disease; T-cell mediated hypersensitivity diseases, including contact hypersensitivity, delayed-type hypersensitivity, and gluten-sensitive enteropathy (Celiac disease); contact dermatitis (including that due to poison ivy); Hashimoto's thyroiditis; Sjogren's syndrome; Autoimmune Hyperthyroidism, such as Graves' Disease; Addison's disease (autoimmune disease of the adrenal glands); Autoimmune polyglandular

disease (also known as autoimmune polyglandular syndrome); autoimmune alopecia; pernicious anemia; vitiligo; autoimmune hypopituitarism; Guillain-Barre syndrome; other autoimmune diseases; glomerulonephritis; serum sickness; urticaria; allergic diseases such as respiratory allergies (hay fever, allergic rhinitis) or skin allergies; scleroderma; mycosis fungoides; acute inflammatory and respiratory responses (such as acute respiratory distress syndrome and ischemia/reperfusion injury); dermatomyositis; alopecia areata; chronic actinic dermatitis; eczema; Behcet's disease; Pustulosis palmoplantaris; Pyoderma gangrenosum; Sezary's syndrome; atopic dermatitis; systemic sclerosis; morphea; trauma, such as trauma from a gun, knife, automobile accident, fall, or combat; and cell therapy, such as autologous, allogenic or xenogeneic cell replacement. The addition of Radiation Induced Lung Injuries and the manifestations thereof has now been added to this itemization.

B. Critical Care Oxygen Saturation Detection

Oxygenation occurs when oxygen molecules (O2) enter the tissues of the body. For example, blood is oxygenated in the lungs, where the oxygen molecules travel from the air and then into the blood. In medical terminology, oxygenation is commonly used to refer to oxygen saturation. Again, in medical common use oxygen saturation (SO2) is commonly referred to as “sats”, which is the measurement of the percentage of hemoglobin binding sites in the bloodstream occupied by oxygen. A Pulse Oximeter is a device that relies on the light absorption characteristics of saturated hemoglobin to give an indication of oxygen saturation, calculates the peripheral oxygen saturation of a person and indirectly monitors the oxygen saturation of a person or patient’s blood without having to take a direct sample from the blood. The oxygen saturation changes with blood volume in the skin and the pulse oximeter device is often attached to medical monitors so staff personnel can always see a patient’s oxygenation. The intermittent or continuous evaluation of a patient’s oxygenation is a crucial asset in determining the patient’s need for oxygen supplementation and whether a patient is

improving or worsening during their treatment regarding sufficiently oxygenating tissues. Portable pulse oximeters are available for monitoring of blood oxygen. Home pulse oximeters are typically used to monitor the respiratory status of patients with advanced lung or heart pathology or to detect sleep apnea in the infant, for example. The documentation of a patient's O2 saturation is now considered the fifth vital sign added commonly in clinic and hospital settings to a patient's blood pressure, pulse, temperature and respiratory rate. The pulse oximeter has had wide adoption in the United States since the late 1980's.

A pulse oximeter is useful in any setting where a patient's oxygenation is unstable, including intensive care, operating, recovery, emergency and hospital ward settings, pilots in unpressurized aircraft, for assessment of any patient's oxygenation, and for determining the effectiveness of or need for supplemental oxygen. Assessing a patient's need for oxygen is the most essential element to life; no human life thrives in the absence of oxygen and therefore we establish medical algorithms for serious medical presentations, assessing the airway and breathing before any other parameter is inspected. Because of their simplicity and speed, pulse oximeters are of critical importance in emergency medicine and are also very useful for patients with advanced cardiac or respiratory disease, especially COPD or CHF, and as mentioned to facilitate diagnosis of sleep apnea and hypoventilation during sleep.

Having briefly discussed the mechanism and manner of the common use of pulse oximetry we must consider those medical situations whereby pulse oximetry readings are jeopardized and negatively affected. In the hypothermic patient for instance the patient's peripheral blood flow has been constricted to protect the vital structures and organs through enhanced macrocirculation. The diversion of peripheral blood flow, changes in local PH and temperature effects on the oxygenation dissociation curve also negatively affect the ability of pulse oximetry to accurately measure oxygen saturation. Another situation negatively affecting pulse oximetry readings is any condition causing shock in a patient. In this situation, the blood flow volume is reduced peripherally,

and the resulting acidosis and temperature changes negatively affect the accuracy of pulse oximetry readings. Yet another medical presentation with adverse effects on pulse oximetry is a patient in respiratory extremis with the inability to adequately oxygenate the blood from peripheral circulatory collapse, direct hypoventilation restricting phenomenon, or cardiac compromise as with acute myocardial infarction or cardiac decompensation from congestive heart failure, all adversely affecting oximetry readings with common device application. The BioZone Project addressed these, and other clinical presentations where pulse oximetry readings are 'compromised' and solved the problem in each, and every example stated here. Through the patent petitioned breakthrough technologies in pulse oximetry detection and readings, significantly enhanced patient oxygen saturation monitoring can be provided to the patient presentations where conventional pulse oximeters fail to obtain valid results. The technologies will save lives in the acute setting as well as save considerable health care expenses by avoiding the need for more invasive procedures providing the same results as non-invasive pulse oximetry.

C. Airway Management Technologies

The BioZone Project's patent petitioned Secured Tracheal Airway Technologies or 'S.T.A.T.' airway management system improves endotracheal tube inserting precision, tube stabilization and airway management to reduce errors, obtains vital physiological data transmittable through a responsive networked support system, improves patient outcomes, and minimize damage from intubation.

Methods and devices are provided for, but not limited to; perform airway intubation. In practicing the subject methods, trained individuals are provided significantly improved methods and devices to intubate an airway, secure the endotracheal tube components provided to a patient's perioral region utilizing unique gripping components, verify correct anatomical placement of endotracheal tube components, provide supplementary ventilation for a patient in a non-interfering manner, and gather and analyze pertinent physiological data from the patient.

Additionally, methods and devices are provided for trained personnel to investigate, intervene and alter specific conditions identified through present invention's integrated system and provide continuous and or interrupted monitoring of specific human physiological parameters in a multitude of settings. Provided elastomeric circuitry permits software and hardware to acquire and analyze gathered physiological data from an intubated patient. The Petitioned invention will be shown to significantly remediate a multitude of prior art's inabilities and complications well known to the medical industry and significantly expand the scope of endotracheal tubes.

D. Prevention of Sudden Cardiac Death

The BioZone Project initially addressed cardiac death in athletes. The petitioned devices allow for rapid static and real time evaluations of an heart electrical signals and physiological structure in the form similar to conventional cardiogram, X Ray and Echocardiogram. A.I. determined thresholds determine if a person is within the safe zone or potentially susceptible to an undesirable cardiac event.

Methods and devices to facilitate identification of cardiac abnormalities are provided for, but not limited to, individuals seeking medical clearance physical examinations for athletic participation and or the general public. In practicing the subject methods, any individual desiring to participate in organized sports is provided the opportunity, means and devices to provide expanded data for present invention's capability to detect cardiac abnormalities. The petitioned invention's unique methods and devices provide a 'cost permissible' means to gather data from athletes and integrally communicate the input and output with software and devices provided with the device and system. A means is provided for the acquired data to be gathered and analyzed, inclusive of athlete's acoustical heart sounds, electrocardiograph signals and or echocardiogram information. Additionally, the invention provides the means to record and analyze output and input data to detect cardiac abnormalities utilizing system's comparison libraries. By methods unique to the present invention, software and hardware are provided to

‘further’ enhance detection of underlying cardiac abnormalities in athletes or general population by simultaneously comparing acoustical, cardiac electrical signals and echocardiogram information relationships in spatial and chronological parameters to present invention’s reference libraries provided. Another means unique to present invention is a scoring criterion applied to gathered and analyzed data permitting an objective means to establish a novel ‘determinant’ for coordinated recommendations and guidelines for all providers granting medical clearance examinations, as example. Present invention will be shown to be a solution to the previously cost prohibitive comprehensive cardiac screening necessary to adequately detect underlying cardiac disorders in individuals of all ages.

E. Revolutionary Summation EKG Technologies

Another BioZone Project revolutionizes conventional electrocardiogram signal detection and clinical interpretation, integrates A.I. analysis resulting in more accurate diagnosis while providing a globally responsive networked support system to modernize conventional diagnostic libraries.

The petitioned invention provides for methods and devices for a trained individual to detect gather and transmit for analysis; the physiological cardiac emissions of a mammal. In practicing the subject method(s), trained individuals are provided a novel apparatus that is temporarily introduced near the esophagus of a mammal wherein inventor’s apparatus comprises a series of elastomeric sensors and electrodes integrally configured onto the outer surface of a longitudinal tubular component wherein a vertical axis electrode and sensor array is provided. With the cooperation of related submissions of inventor(s), a horizontal sensor array apparatus is situated tangentially across the chest wall of said mammal wherein the plurality and integration of invention’s components; as a system, provide a multi-planar temporal relationship of sensors and electrodes in the x, y, and z planes. Software unique to present invention permits user(s) to detect electrical, acoustical and

ultrasound information from a mammal's cardiac emissions in a multitude of manners novel to the applied field(s) of medicine.

The present invention's unique methods and devices provide significant advancements over conventional cardiac diagnostic modalities in regard to sensitivity and specificity of cardiac disorders and additionally, through present invention's means for coordinating transmission of data through networks provided herein, a global database can be created to encourage continual improvements and system learning features significantly advantageous to the healthcare industry. Such applications of petitioned invention to be integrated with Artificial Intelligence interpretations to better determine abnormalities and or acute cardiac events in the different regions of the heart more specifically than traditional EKGs.

F. Variable Frequency UV Light Sterilization

Yet another BioZone Project Technology eliminates static and airborne pathogens using a non-toxic, non-chemical, rapid, improved ultra-violet exposure system.

Means, methodology and devices are provided for incapacitating airborne life forms; with or without potential properties of pathogenicity, in specific designated arenas by the use of either precalculated fixed frequency, variable cyclical interval frequency, and or predetermined oscillating varying frequency ranges of UV light radiation. Methods and devices are provided to incapacitate, to a desired degree of efficacy, the survivability and pathogenic potential of micro and macro airborne life forms in specific locations wherein airborne contact with any portion of a mammal with said potentially pathogenic organisms may cause disease to said portion or entity of a mammal as a whole.

In practicing the subject methods, present invention devices utilizing ultraviolet light generators; specifically, those emitting ranges of UV light radiation; such as permitted with excimer generator sources; for example, are incorporated and configured to be temporarily or permanently housed in specific pertinent atmospheric arenas. An example of such pertinent arena could be the atmospheric environment

within health care facilities or solely provided on BioZone Units. The current invention is designed to emit varying ranges of UV light emissions in fixed wavelengths, varying wavelengths, and or harmonically oscillating ultraviolet radiation to a determined atmospheric volume. Present invention design permits function in a single mode or any combination of mentioned alternatives designated by inventors as Harmonic and Non-Harmonic Phases. Alternative embodiments of the present invention are provided using adjunctive cooperation with sound wave frequencies and directional ultrasonic coupling of said sound wave frequencies to avoid damage to sensitive equipment while encouraging continual improvements and artificial intelligence system learning features significantly advantageous to the healthcare industry

G. Summation Technologies Applied to Physiological Data Detection

An Intercalated System of integrated and cooperative Methods, Devices and Software is petitioned to identify, interpret, analyze, store and remotely transfer physiologic data from a mammal. Input and output data may be individually and or simultaneously and cooperatively integrated and compared in invention's novel summation format and software permitting a significantly enhanced sensitivity and specificity in identification of specific abnormalities and disorders of a mammal. Such integrated and simultaneous comparison of certain physiologic parameters will significantly advance Health Care Specialists' ability to detect underlying cardiac abnormalities. For example, detect symptoms that were undetectable with prior art and science, and give new understanding as to which identified abnormalities are clinically significant. Invention provides a means to develop and create new diagnostic scoring criterion to be utilized and expanded on in the fields of Cardiology, Critical Care and Emergency Medicine; to name a few, both in the acute and critical phase as well as with routine testing. Extrapolated data provided by methods and software here within will be utilized to create novel databases and libraries of clinical determinations of normal, normal variance and or significant abnormalities which will greatly assist health care providers' diagnostic abilities and acuity.

H. Feminine Hygiene Technologies:

The petitioned inventions provide for methods and devices for female individuals to cleanse the internal intraluminal mucosal cavities and or external genitalia. The novel devices are provided for an individual to perform personal hygiene cleansing of their genitalia discreetly and rapidly and or the genitalia of other individual(s) including; but not limited to, the vaginal vault and vulva, perineum and perianal area, anus and rectal chamber, pubic mons and groin region, and or any portion of an individual's penis and scrotum. The present invention may also provide a means of introducing internally and or externally, a variety of solutions with varying properties to be utilized for purposes such as; but not limited to spermicidal agents, water, soaps, glycerin, mineral oil, antimicrobials, antifungal agents, antiviral agents, hormones, medicines, PH buffering agents, deodorant agents, other lubricating agents, aroma agents and or any combination of said agents. Present inventions provide said functions by means of a novel hygienic device with a plurality of components. Present invention is additionally inexpensive, dispensable, and biodegradable and intended for a one-time use and intended to reduce the number of hospital acquired nosocomial urinary tract infections.

I. Biophasic Sensory Stimulation Technologies

Devices and technologies are provided for novel treatment modalities in a variety of medical fields such as pain management, collagen stimulation, wound and bone healing, edema, migraines, seizures, concentration as well as natural athletic performance enhancement and addiction management.

The petitioned technologies provide a revolutionary biophasic sensory stimulation modality wherein various systems of a mammal react in such a manner previously unutilized in modern medicine. Such breakthrough technology provides a disruptive novel means and methodology for applied medicine to integrate the petitioned stimulatory devices in virtually every field of science and medicine. The proprietary technology will potentially provide a paradigm shift in treatment

applications and adjuncts such as acute and chronic pain management, wound and bone healing, collagen formation, edema treatment, vascular insufficiency, migraine headache control, seizure prevention and abatement, natural athletic performance enhancement and recovery, concentration and recall, biofeedback and relaxation and addiction management, for example.

J. Infant Environment Technologies

Petitioned invention intends to reduce infant deaths from preventable causes while in a crib, while providing a controlled stimulus environment that enhances both the psychological and physical health of infants. A dynamic controlled atmosphere, sensory mattresses and linens, A.I. integrated software, and advanced monitoring systems ties to a responsive networked support system.

The BioZone Project provides comprehensive and patent petitioned proprietary means and methods for the prevention of adverse outcomes in the infant and early childhood years. Through years of dedicated research and investigations our proprietary innovations and technologies will soon serve to reduce, if not eliminate, preventable causes of sudden infant death syndrome and other well documented adverse outcomes encountered with neonates.

K. Expanded Scope

The complete scope of the BioZone Project includes a multitude of additional technologies that for the length of this presentation's sake will simply be listed but nor expounded on:

1. ENHANCED VITAL SIGN DETECTION SYSTEM

2. BIOFLUID REGULATION DEVICE

3. IV INSERTION ASSIST DEVICE

4. BICU RAPID LAB ON A CHIP TEST ANALYSIS DEVICE

5. AI ENHANCED AUSCULATORY DEVICE FOR HEART AND LUNG SOUNDS

6. ZONE AND FACILITY STERILIZATION DEVICE

7. BLADDER STIMULATOR DEVICE

8. OBSTETRICAL MONITORING DEVICE

9. PROPRIETARY STRETCHER TECHNOLOGIES INCLUDING SELF CLEANING STRETCHERS

10. EXCREMENT ELIMINATION SYSTEM

11. PROPRIETARY IN BED PATIENT EXERCISE AND REHAB SYSTEM

12. CONSCIOUS SEDATION MANAGEMENT

13. FAST ALERT ALLERGY DETECTION DEVICE

14. COMPARTMENT SYNDROME DETECTION DEVICE

15. REAL TIME ACUTE CORONARY SYNDROME DETECTION

16. MODIFIED PAPR HEADGEAR

17. PHARMACEUTICAL ASSISTANCE PROGRAM

18. BIOMEAL TARGET SPECIFIC NUTRITIONAL PROGRAM

19. FECAL IMPACTION REMOVAL SYSTEM

20. INCISION AND DRAINAGE SYTEM

21. IMPROVED INSTRUMENT DEVICE STAND

22. RAPID SPLINT SYSTEM

23. DVT PREVENTION SYSTEM

24. ORTHOPEDIC TRACTION DEVICES

25. MIGRAINE TREATMENT SYSTEM

26. TREATMENT PROTOCOL REFERENCE SOFTWARE

27. AI INTEGRATED ANESTHESIA DELIVERY SYSTEM AND SOFTWARE

28. HYPERBARIC AND HYPOTHERMIC CPR PROVISIONS

V. Summary

The ICBM, BioZone Project and the BioZone Intensive Care, Surgical Care, and Pharmaceutical Drug Delivery System provides disruptive and novel technologies which will add significant meaningful value in the healthcare systems. The project is intense and comprehensive and will be challenging yet manageable if approached in an organized and systematic fashion. Having researched and conceptualized with development to the stage of patent petitions and Minimal Viable Product prototypes with proof of concepts established, significant strides have been accomplished.

It is the intent of this presentation to introduce the petitioned technologies to the Healthcare Industry, invite collaborative joint

venture participation, and to seek the funding assistance that is obviously beyond that which can be expected of any single individual.

In this regard, I respectfully and sincerely appreciate your interest and desire to develop and Early Warning Biohazard Biodefense, better patient outcomes, reduce Healthcare Costs, and initiate a Paradigm Shift in the medical field through New Generation Innovations provided with the BioZone Global Initiative. A virtuous commitment and a laborious critical review of the problems existing in the Healthcare Industry has been accomplished. Considerable groundwork has paved the path to provide the solutions that will save countless lives and better the working environment for those of us that have dedicated our lives to healing.

Years of dedicated application and perseverance will be needed to see this project realized to full implementation but in the end this BioZone Team of virtuous providers and healthcare related institutions will be remembered best for what was done for others. I represent the VMT Team am we are humbled to be able to serve this global initiative and cause and have dedicated thousands of hours and considerable personal funding in conceptualizing what has been introduced herewithin. We are eager and pray to be able to experience that which can be accomplished given the gracious funding and the collective intellectual input that will ensue from those that will find it in their hearts and soul to board our train.

Respectfully submitted,

Dennis

Dr. Dennis J. Morris, M.D.

Inventor of the BioZone System and Unit Technologies