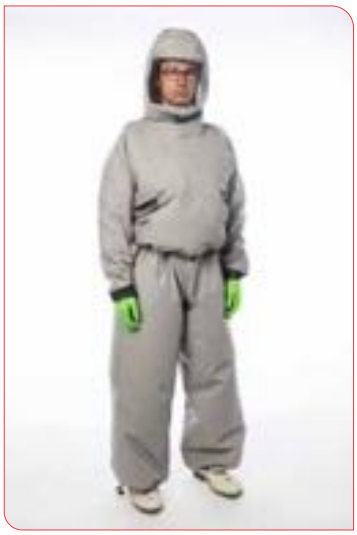
Personal protective equipment suit reusable, ventilated



Country of origin | Switzerland
Primary function | Prevention
Category | Personal protective equipment

Commercial information

List price (USD): $1,000[1]

Development Stage: The development of the suit has reached a design approval stage where performance testing and eventually field tests to validate the robustness and appropriateness for the staff and the existing protocols.[2]

Brand: Ecole Polytechnique Federale de Lausanne (EPFL), Medecins Sans Frontieres (MSF) Switzerland, and Hôpitaux Universitaires de Genève (HUG)[1]

Model: SmartPPE[1]

Health problem addressed

Most of the personal protective equipment (PPE) used during the 2013-2016 Ebola outbreak in West Africa provided unbearable working conditions and restricted empathic relationships with the patients. The primary requirement of the PPE is safety, as the healthcare workers must be protected against any contamination from the Ebola virus. The main improvement is to provide improved working conditions in extreme environments characterized with high temperatures and high humidity.[2]

Product description

The technology is a reusable full body ventilated suit designed to withstand multiple decontamination cycles in a 0.5% solution of chlorine. It is composed of a single-piece garment fully integrating the body except for the hands and the feet allowing use of reusable gloves and standard boots. The suit is equipped with a large face shield. The design simplifies donning and doffing procedures and the internal air flow increases the comfort of healthcare workers allowing for longer shifts in the hot zones.[2]

Product details

Accessories: Full ventilation system with blower and air diffuser headset, indicator cable with LED,storage and charger box, multiple (10) battery charger box, battery, reusable filters.[2]

Lifetime: 0-2 years[1]

Energy Requirements: The system is powered with a 21.6V 70.2Wh Li-Ion battery pack. The autonomy of the ventilated PPE is 4 hours. The charger is plugged on standard 220V outlets.[2]

Contact: Louis Potter | Email: louis.potter@epfl.ch | Telephone: +41764552260 | Website: https://bit.ly/36iaeF5

1 Reported by manufacturer on 19 May 2020
2 Reported by manufacturer on 1 February 2021

WHO ASSESSMENT

WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare against for this type of technology.

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. EPFL, MSF, and HUG should develop their medical device support documentation and data.

Inclusion in the Compendium does not constitute a warranty by WHO of the fitness of any technology or product for a particular purpose, as no rigorous review for safety, efficacy, quality, applicability or cost acceptability was conducted by WHO. WHO will not be held to endorse nor to recommend any technology or product included in the Compendium. WHO disclaims any and all liability whatsoever for any damage of any kind that may arise in connection with the procurement, distribution and/or use of any such technology or product.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact	Innovation
Medical	!	!	
Safety	!	!	
Economy	✗	✗	
Organizational	✗	!	
Legal	→	!	
Social	!	!	
Ethical	!	→	
Green environment	✗	✗	

This PPE is reusable and thus protective. Still it is a prototype and there is no daily life evidence how often it can be reused. Cleaning (inside and outside) is not described and hence the environmental impact is unclear as well as the acceptance by the user. The cost per device is high (USD 1000) and the transferability to LMIC as well as handling after it is no longer used is unclear.

Summary

Transferability	✗	Technology readiness level	5
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	!	Ease of maintenance	→
Ease of Use	→	Infrastructure requirements	!
Positive impact on clinical outcomes	→	Local access to sales support	✗
Affordability	✗	Local access to technical support	✗
Engineering resources minimization	!	Local access to training	→
Cultural and social acceptability	→	Local access to spare parts	→
Environmental conditions	!	Local production	→
Aesthetics	→	Locations of use within target setting	→
Ease of cleaning	!		

Target setting: Public and home settings

This product is a personal protection one-piece suit intended for individual protection in infection sites. The suit is designed with large visibility at the head level between the care provider and patient and a ventilation system that creates airflow away from the face (anti-fogging). Having a design of one garment as compared with conventional shirt and pant suits is an advertised advantage making it easier to don and doff lessening post-procedure infection of the care giver. It is advertised as reusable up to 100 times and easily cleaned. The suit lends itself to facilitate local production and ease of wear, however, its stated cost may be limiting.