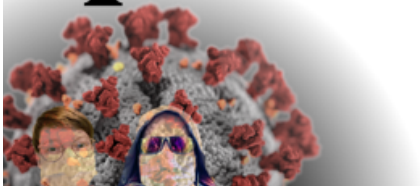


# open.PAPR



## Requirements

### 01 Authorization

Role	Name	Date	Version	Signature
Author	Ralph Lawrence Wunderlin	20200415	01	
Reviewer	Paul Kindt	20200415	01	

### 02 Change Log

Version	Author	Date	Reason
01	Ralph Lawrence Wunderlin	20200414	First revision 🐻❤️🌟

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## 03 Introduction

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### 03.1 General

This document describes the requirements for the open.PAPR projects product - the open.PAPR.

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### 03.2 Why open.PAPR?

- **What the users wear today is defined by availability, not by what would be realistic requirements**
- **Because we must protect our medical professionals from SARS-CoV-2**
- **Because the more medical professionals we loose, the heavier the strain on resources**
- **Because a hood with full face protects eyes, nose and mouth due to the slight overpressure in it - SARS-CoV-2's main entry points**
- **Because handling simple hygienic masks and FFPx-protective equipment is a risk of infection**
- **Because the users can shower or be wiped down with wet-wipes to decontaminate them, when they leave the red-zone**
- **Because handling simple hygienic masks and FFPx-protective equipment is a risk of infection**
- **Because the hood can be used in future epidemics and pandemics**
- **Because all the parts except the filters shall be re-usable**
- **Because the whole system shall be protected against water**
- **Because we can**
- **Because an open system can use nearly any filter that is available on the local market**
- **Because the patients that don't make it are alone. They die alone, without their relatives. The only people who can hold their hand in their last moments are the nurses and doctors working in the hospitals - but they must have the time to do that.**

## 04 Overview

### 04.1 Unit Overview

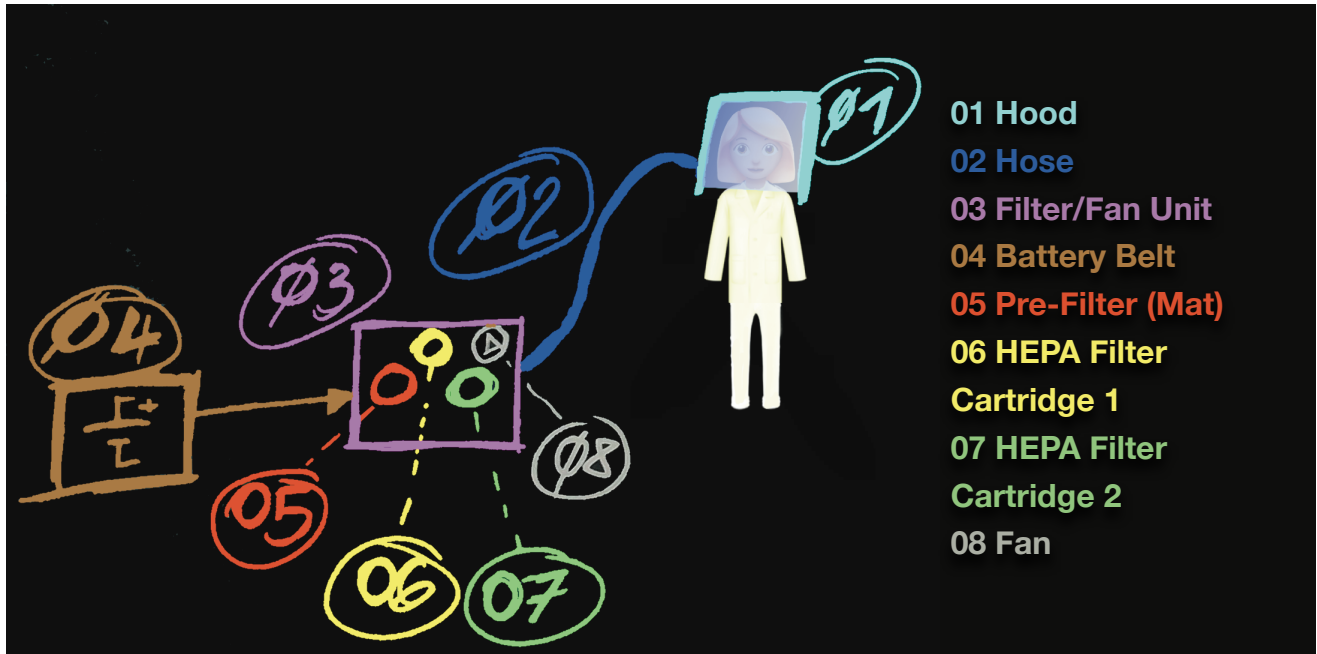


Figure 01: Unit Overview

### 04.2 Preliminary description

**This preliminary description is not part of the requirements, as it must be finalized in the FS (functional specification)**

The Hood is placed over a single-use textile/plastic hood that covers hair and neck.

The hose is connected to the fan and filter unit. This unit, either mounted on a belt or in a light rucksack supplies the hood with a constant flow of filtered air. The air is sucked through a pre-filter (very simple mat, only dust-protection), then through two HEPA filters (these can be of different sizes, ideally small box-filters. An integrated muffler part reduces the noise of the fan.

The air must be sucked in on the lower side of the box, the dust filter shall be clamped to it with stainless steel mesh or some other simple solution. The HEPA-Filters can be of different makes and sizes thanks to the use of adapters. The filter and fan unit (FFU) is compact and can only be opened with tools. It must be easily serviceable nonetheless. There may be additional sensors in it (differential pressure measurement, flow rate, etc). Two filters shall be installed in the unit, DEHS sampling (verification of aerosol retention) shall be prepared and used

No display is required, but there shall be a well audible alarm if a measured value of these optional sensors breaches the alarm limit. There shall be one RGBW-LED and one switch

as user interface. The switch is for on an off, the RGBW-LED displays in a very simple manner if the unit is operational.

The hose must be light-weight and flexible. Couplings must be sturdy, but not heavy and with a safety latch or equal precaution.

## 05 Unit breakdown & Requirements

### 05.1 Hood and Hose

No	Category	Requirement	Traceability/ Check
H-1	Business	The hood shall be re-useable	
H-2	Business	The hood shall be durable	
H-3	Ergonomy	The hood shall be lightweight	
H-4	Ergonomy	The see-through shield shall be as wide and high as possible	
H-5	Hygiene	The material must withstand water, soap water, Cl-based disinfectants, optionally peroxide resistant	
H-6	Ergonomy	Doesn't impair hearing too much	
H-7	Ergonomy	The users voice is audible	
H-8	Ergonomy	No strain on shoulders or neck	
H-9	Hygiene	The airflow shall be controlled, no draft	
H-10	Ergonomy Safety	The hose shall not constrain movement or be a risk	
H-11	Hygiene	Food-grade or better material, re-useable, lightweight, withstands alkaline/acidic washing media	
H-12	Safety	Do not use washing media containing peroxides in silicone tubing as it can accumulate in the silicone	
H-13	Ergonomy Hygiene	Airways in the mask shall distribute air evenly. No draughts, verification of this is to be executed with vaporised vegetable glycerine. These channels must be easy to clean.	

Table 01: Hood Requirements

## 05.2 Filter and Fan Unit

No	Category	Requirement	Traceability/ Check
F-1	Safety Business	Two HEPA Filters in Series is optional IF certified capsule filters can be used.	
F-2	Business	Preferred filter type: HEPA boxed AND/OR HEPA capsule filters	
F-3	Safety Hygiene	The pre-filter is a simple mat filter, cut to size	
F-4	Hygiene Safety	Air-intake must be from the bottom of the device so that a decontamination shower from the top is possible	
F-5	Ergonomy	The device must be as quiet as possible, with internal muffling.	
F-6	Ergonomy	It must be light-weight (think small ruck-sack) and not restrict a users radius of action	
F-7	Business	First devices shall only have an alarm for low battery	
F-8	Safety	Off-line DEHS-testing of each unit must be performed before use (this may enable the use of HEPA-filters for vacuum cleaners to be safely utilised)	
F-9	Business	Future models shall have delta-P switches to detect clogged filters/ closed airway to hood	
F-10	Business	Future models shall have a constant flow control and also a high and low flow switch alarm	
F-11	Hygiene Safety	Air intake must be easy to wipe and closely fitting plug (with seal) must be available for all units	
F-12	Hygiene	There must be plugs with a seal available for the outlet	
F-13	Hygiene	Silicone seals must be used internally, all food-grade	
F-14	Hygiene Safety	An optional plastic cover shall be considered	
F-15	Business	Self-test could be implemented in later models	
F-16	Hygiene Safety	Either IP67 capacitive switch or magnetic switch to enable/disable the unit	
F-17	Safety Business	The units must have one RGBW-LED (preferably inside with POF-fibre sealed in casing) to show operational status	
F-18	Business	Future models may have a terminal for diagnostics	
F-19	Safety	No WLAN, no Bluetooth. Must be tested for electrical interference (motor)	
F-20	Safety	The power consumption of the fan must be monitored, if it is too high, an alarm must be activated	
F-21	Safety	Alarms can only be de-activated outside the red zone by means defined in F-16	

F-22	Ergonomics Hygiene	Textile carrier bands should not be used, They must be adjustable to the user and the unit could be detachable from the harness or belt	
F-23	Business	Future models may have a cumulating timer function to monitor how long the filters have been in use	
F-24	Business	Future models may log measurement data.	
F-25	Safety Hygiene	Off-line integrity testing (leak rate of whole unit, etc) must be implemented	

Table 02: Filter and Fan Unit Requirements

### 05.3 Battery Belt/Pack

No	Category	Requirement	Traceability/ Check
B-1	Business	18650 or better 21700 rechargeable cells are to be used	
B-2	Safety	The batteries must be encapsulated so that a pack can be dropped from 2m without damages	
B-3	Safety	For the first devices: Cells with internal over/undercharge and over temperature protection shall be used - these cells can be removed from the pack and charged in a standard charger	
B-4	Safety	Only genuine Samsung OR Panasonic cells are to be used (or equal quality)	
B-5	Safety	The batteries used in one pack must be of the same lot	
B-6	Business	The batteries could be integrated in to the Filter and Fan Unit	
B-7	Business	Future models shall have a safe charging circuit built in	
B-8	Safety Hygiene	Connectors and wiring is to be reduced to the absolute minimum. Every electrical plug must have a safety mechanism to prevent accidental unplugging	
B-9	Safety Hygiene	The battery packs must be, if not integrated in to the „FFU“, graded IP65 or better and withstand decontamination procedures (shower)	

Table 03: Battery Belt/Pack requirements



## 05.4 General requirements

No	Category	Requirement	Traceability/ Check
G-1	Business	Only European standards („EN“) apply to this project	
G-2	Business	EN64624 must be used for instrumentation	

Table 03: General requirements

