CYBATHLON

Risk Management File

Teams are required to submit full documentation of their device for each CYBATHLON event participation separately.

Please indicate below the event for which you are submitting the documentation:

Type of event	**O** CYBATHLON Experience	**O** CYBATHLON Series	**X** CYBATHLON 2020
Name of event	CYBATHLON 2020		
Location of event	Zurich		
Date of event	2/3 May 2020		

Date 28. February 2019
Version V_2019-02-28
Author(s) Lukas Jaeger

Please insert the following information and sign at the bottom of the page

Device name
CYBATHLON Fan
Name and address of company or institution
ETH Zürich Sensory-Motor Systems Lab Tannenstrasse 1 CH-8092 Zürich Switzerland

Responsibility and Approval

Name of responsible person
Prof. Dr. Robert Muster
Role of responsible person within the project
Team Manager
Place and date
Zurich, 28 February 2019

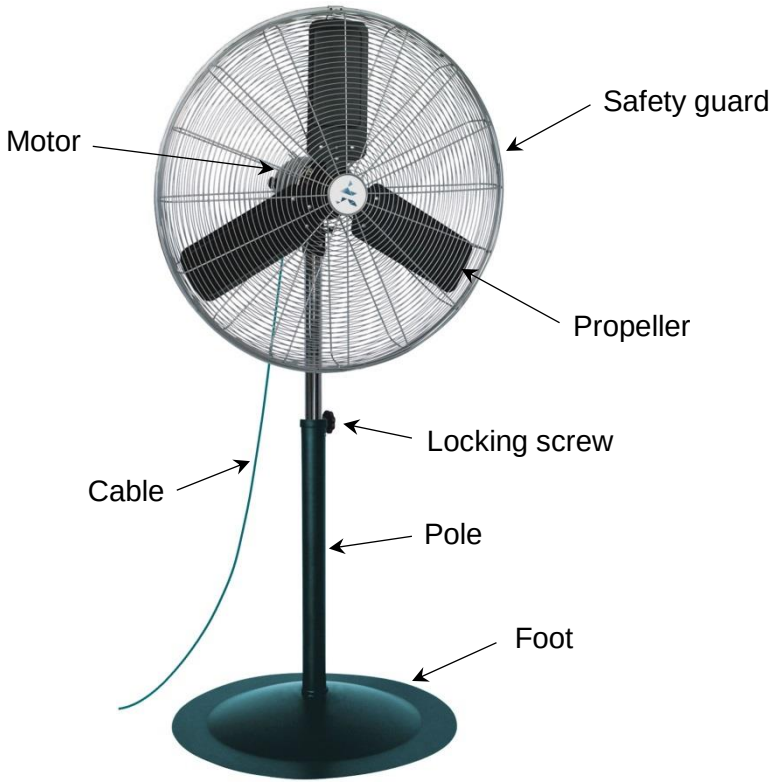
Signature (wet-ink)
 ……

Table of contents

A. Device identification

Description

Describe your device here. What is the purpose, how does it work, what can it do, how does it look like (picture, drawing, etc…).

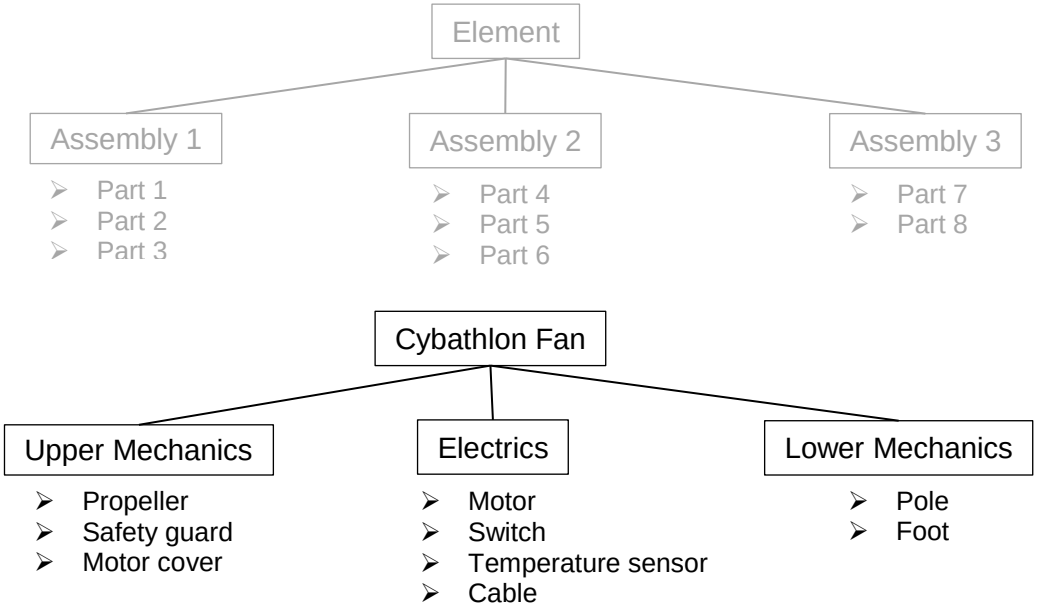


The “Cybathlon Fan” is a machine used to create an airflow, typically applied for personal thermal comfort. The propeller is driven by a motor, which is powered trough a cable from the 230 VAC power socket. Due to the rotation of the propeller, airflow is produced.

The propeller is covered by a safety guard to prevent injury due to touching the moving parts. The motor-propeller unit is placed on a pole that is mounted on the foot, which stands on the floor. The length of the pole is adjustable and locked by a screw.

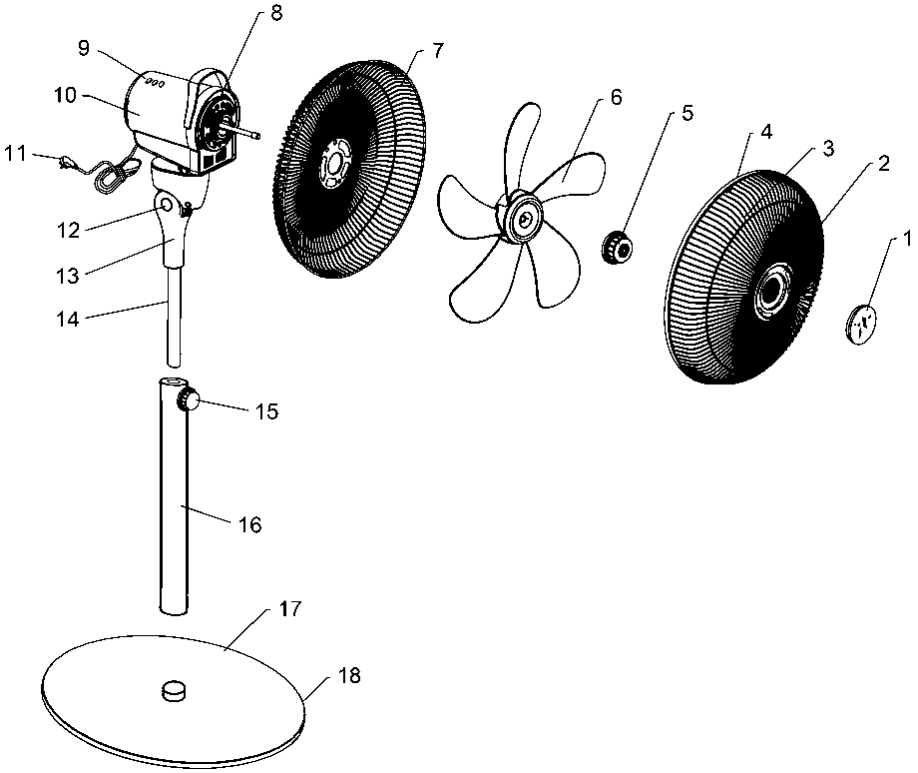
Assembly definition of the element

Describe individual assemblies and components here, suggested format as follows:



Assembly identification

Identify assemblies and parts by images, sketches, etc.



Propeller

During operation of the fan, the propeller (6) is rotating on the axis of the motor.

Safety guard

The protective safety guard (3 & 7) covers the propeller. The gaps in the grid are small enough that no finger can get to the propeller.

Foot

The foot (17 & 18) stands on the floor of the room and holds the pole and the propeller-motor unit. Due to its weight, the whole fan is standing stable. It has a rubber bottom to prevent sliding on the floor.

Specification

Specify each element in terms of size, weight, material, power requirement, power in-/output…

Propeller

It is made of lightweight ABS plastic: diameter 50 cm, weight 300 g.

Motor

The actuator (8) is a low cost consumer variable-speed asynchronous motor. It is rated for 230 VAC, 50 Hz supply. The electrical load is specified with 50 W maximum. The motor has three connections for three different rotation speed that can be selected by the user with switches (9) on the motor covering.

Temperature Sensor

The sensor monitors the temperature of the motor and limits its maximal temperature to 50 °C. In normal condition the motor temperature is fairly below this threshold but in case of a mechanical blocking of the propeller or in very hot environments it’s necessary to switch off the energy supply to prevent burning of the motor.

Cable and Connector

The cable is a two wire standard power cable, rated for 250 VAC / 6 A, double isolated. The two pole connector fits into a Swiss power socket.

Involved people

List the main people involved in the development of this device and their tasks in the project:

- Name and Family Name, Mechanical engineer
- Name and Family Name, Electrical engineer
- Name and Family Name, pilot
- …

List the people involved in compiling the risk management file and their tasks in the project (ideally, the risk analysis is conducted by a minimum of two engineers and one person with a clinical background, e.g. physician or therapist):

- User (who wants to feel airflow to cool down)
- Engineer (for installation and maintenance)
- Third party (e.g. cleaning worker, visitors)

B. General safety measures

Describe general precautions made to ensure safety of your device. Consider hardware, e.g. electronics or mechanical components, and software.

In terms of **general safety guidelines** for medical electrical equipment, you may check the following standards:

- IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems*
- IEC 60601-1-2: Ed. 4.0 b:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-1-6: Ed. 3.1 b:2013, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- IEC 62366-1:2015, *Medical devices -- Part 1: Application of usability engineering to medical devices*
- IEC 60601-1-8: Ed. 2.0 b:2006, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.

In terms of safety of **electroencephalographs**, you may specifically check

- IEC 60601-2-26: Ed. 3.0 b:2012, *Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*.

In terms of safety of **FES stimulators** and **bikes**, you may specifically check

- IEC 60601-2-10: Ed. 2.1 b:2016, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- ASTM F2711-08(2012), *Standard Test Methods for Bicycle Frames*.

In terms of safety of **prostheses and orthoses**, you may specifically check the ISO standards catalogue ISO/TC168, *Prosthetics and Orthotics*, in particular:

- ISO 10328:2006, *Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods.*
- ISO 22523:2006*, External limb prostheses and external orthoses -- Requirements and test methods*

Please note that this listing is not intended to be exhaustive.

The device is for indoor use only and has to stand upright on a stable and dry place. The user is asked to read the operator manual before using the fan.

The power socket must be electrically interlocked by a fuse rated maximally 16 A. The cable plug fits only in a standard Swiss socked with a voltage of 230 VAC, 50 Hz. An earth fault current protection switch is recommended for the electrical domestic installation.

The cleaning of the device and the yearly maintenance work is described in detail in the operator manual.

C. Specific risks and failures, detection and preventing measures

Each risk/failure should be listed in the "Detailed Risk Analysis" below. Describe the failure and possible resulting effects, rate the probability of its occurrence, the severity, and the probability to detect the failure. Describe preventing measures and rate the failure again.
The format of this risk/failure table has been adapted from:
http://www.npd-solutions.com/fmea.html,
http://www.harpcosystems.com/articles/Design-FMEA-Ratings-Part1/,
http://www.harpcosystems.com/articles/Design-FMEA-Ratings-Part2/,
http://www.harpcosystems.com/articles/Design-FMEA-Ratings-Part3/

Examples of possible hazards are listed below (based on ISO 14971):

Examples of energy hazards	Examples of biological and chemical hazards	Examples of operational hazards	Examples of information hazards
Electromagnetic energy Line voltage Leakage current ➢ enclosure leakage current ➢ earth leakage current ➢ patient leakage current Electric fields Magnetic fields **Radiation energy** Ionizing radiation Non-ionizing radiation **Thermal energy** High temperature Low temperature **Mechanical energy** Gravity ➢ falling ➢ suspended masses Vibration Stored energy Moving parts Torsion, shear and tensile Force Moving and positioning of pilot **Acoustic energy** ➢ ultrasonic energy ➢ infrasound energy ➢ sound	**Biological** Bacteria Viruses Other agents (e.g. prions) Re- or cross-infection **Chemical** Exposure of airway, tissues, environment or property, e.g. to foreign materials: ➢ acids or alkalis ➢ residues ➢ contaminates ➢ additives or processing aids ➢ cleaning, disinfecting or testing agents ➢ degradation products ➢ medical gasses ➢ anaesthetic products **Biocompatibility** Toxicity of chemical constituents, e.g.: ➢ allergenicity/irritancy ➢ pyrogenicity	**Function** Incorrect or inappropriate output or functionality Incorrect measurement Erroneous data transfer Loss or deterioration of function **Use error** Attentional failure Memory failure Rule-based failure Knowledge-based failure Routine violation	**Labelling** Incomplete instructions for use Inadequate description of performance characteristics Inadequate specification of intended use Inadequate disclosure of limitations **Operating instructions** Inadequate specification of accessories to be used with the device Inadequate specification of pre-use checks Over-complicated operating Instructions **Warnings** of side effects of hazards likely with re-use of single-use medical devices **Specification of service and maintenance**

Critical Risk Priority Number

During the risk analysis, each risk or failure is analyzed and rated with respect to its severity (S), probability of occurrence (O), and detection rate (D). The rating for each of the three aspects ranges from 1 (low security risk/failure, low probability of occurrence, high detection probability) to 10 (severe injuries or death, high probability of occurrence, no/low probability for detection). The product out of these three ratings is called Risk Priority Number (RPN). In case, the RPN is greater than a critical threshold, preventing measures are required in order to reach a final RPN below or equal to the critical threshold by means of reasonable and justifiable security measures.

Define a critical threshold in this section here – we recommend a critical **RPN threshold of 75**.

In case, the risk is greater than the critical threshold the risk **must clearly be mentioned** in the “declaration of agreement” signed by the pilot and involved staff.

Compared with other electrical floor standing fans and out of the experience with previous models a **Risk Priority Number, RPN = 75** seems to be a good compromise between safety, benefit and expense.

Factors of the Risk Priority Number (RPN)

Find below a recommendation how to rate occurrence, severity, and detection. The “Risk Priority Number before” is a mathematical product of the numerical Severity- (S), Occurrence- (O), and Detection-Ratings (D) obtained before applying any preventing measures to reduce the likelihood for dangerous incidents, thus: **RPN before = (S1) x (O1) x (D1)**. This “RPN before” should be set to prioritize items that require additional quality planning or action.

The “RPN after” is a mathematical product of the numerical Severity- (S), Occurrence- (O), and Detection-Ratings (D) obtained after applying the preventing measures to reduce the likelihood for dangerous incidents, i.e. **RPN after = (S2) x (O2) x (D2)**. The “RPN after” has to be equal or below the predefined threshold in order to guarantee safe use of the part/element/device.

Preventing measures are mechanisms that prevent the cause of the failure mode from occurring or that detect the failure and stop the application before an incident can happen. It could also reduce the severity by e.g. designing softer and rounder edges. Preventing measures could include specific inspection, testing or quality assurance procedures; selection of other components or materials; de-rating; limiting environmental stresses or operating ranges; redesign of the item to avoid the failure mode; monitoring mechanisms; performing preventative maintenance; or inclusion of back-up systems or redundancy.

S – Severity

Rating S	Criteria: Severity of effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Life-long medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Life-long medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fracture, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay
6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay
5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulant treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulant treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

O – Occurence

Rating O	Criteria: Probability of occurrence
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs in 1 of 50 sessions (less than once half a month)
5	Occurs in 1 of 100 sessions (less than once a month)
4	Occurs in 1 of 500 sessions (less than once half a year)
3	Occurs in 1 of 1000 sessions (less than once per year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

D – Detection

Rating D	Criteria: Likelihood of detection by design control
10	No chance of detection
9	Very remote chance of detection
8	Remote chance of detection
7	Very low chance of detection by indirect methods (hardware or software)
6	Low chance of detection by indirect methods (hardware or software)
5	Moderate chance of detection by indirect methods (hardware or software)
4	High chance of detection by indirect methods (hardware or software)
3	High chance of detection by direct or indirect methods (hardware/software)
2	Direct and indirect detection: Hardware or software
1	Direct detection: Hardware or safe software (category 4, performance level e)

D. Detailed Risk Analysis

Propeller

Assembly	Failure & Effect	S1	O1	D1	RPN before	Preventing measures	S2	O2	D2	RPN after
Propeller blade	Crack due to production failure. Blade falls off during operation at full speed and hurts person seriously. Heavy cuts and loss of eye-sight possible.	8	3	8	**192**	Quality control during production. A stable safety guard is covering the propeller. In case of failure, it prevents the propeller blade from falling away.	2	2	8	**32**
	Crack due to aging. Blade falls off during operation at full speed and hurts person seriously. Heavy cuts and loss of eye-sight possible.	8	1	10	**80**	Using nonaging ABS plastic polymer for the propeller. A stable safety guard is covering the propeller. In case of failure, it prevents the propeller blade from falling away. Checking the blade during yearly maintenance. Operation manual lists the danger of imperfect material and the need of shutting down the fan in such a case.	2	1	5	**10**
	Imbalance of propeller. Strong vibration and acoustic noise.	2	2	10	**40**					**40**
Shaft	Loose mounting on the motor axis. Whole propeller falls off the axis to the ground. Human leg or feet may hurt (cuts, contusions)	4	2	9	**72**	A stable safety guard is covering the propeller. In case of failure, it prevents the propeller from falling down. Checking the mounting during yearly maintenance.	2	2	8	**32**
	…									
	…									
Cybath-lon label	Label drop down the shaft. No harm.	1	2	9	**18**					

Motor assembly

Assembly	Failure & Effect	S1	O1	D1	RPN before	Preventing measures	S2	O2	D2	RPN after
Motor	Overheating of the motor due to mechanical blocking of the propeller. Electricity heats up the motor assembly up to self-burning and melting plastic and metal parts. Serious burn of person and home till death.	10	7	10	**700**	The safety guard is covering the propeller to prevent mechanical blocking due to external parts. Temperature switch turns off electricity at temperatures above 50 °C. Motor and motor cover tested for flammability according to UL 94-HB.	9	3	2	**54**
Temperature Switch	Switch is welded and cannot turn off the electricity. In case of overheating of the motor burning and melting plastic and metal parts possible. Serious burn of person and home till death.	10	2	10	**200**	Redundant, second temperature switch (one-way fuse), that turns off the motor permanently if 60 °C are reached. If temperature fuse is burned, the whole fan must be repaired by a qualified service provider.	10	2	2	**40**
…	…									

Assembly …