

# YANCA FITNESS

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# 01. ABOUT US



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# 01. ABOUT US



**Youness Id Lahoucine**

Regulatory



**Ariadna Costas**

Risk Management & quality control



**Ignacio Moragues**

Software and marketing



**Carla Juanes**

Product design



**Ali Abdul Ameer**

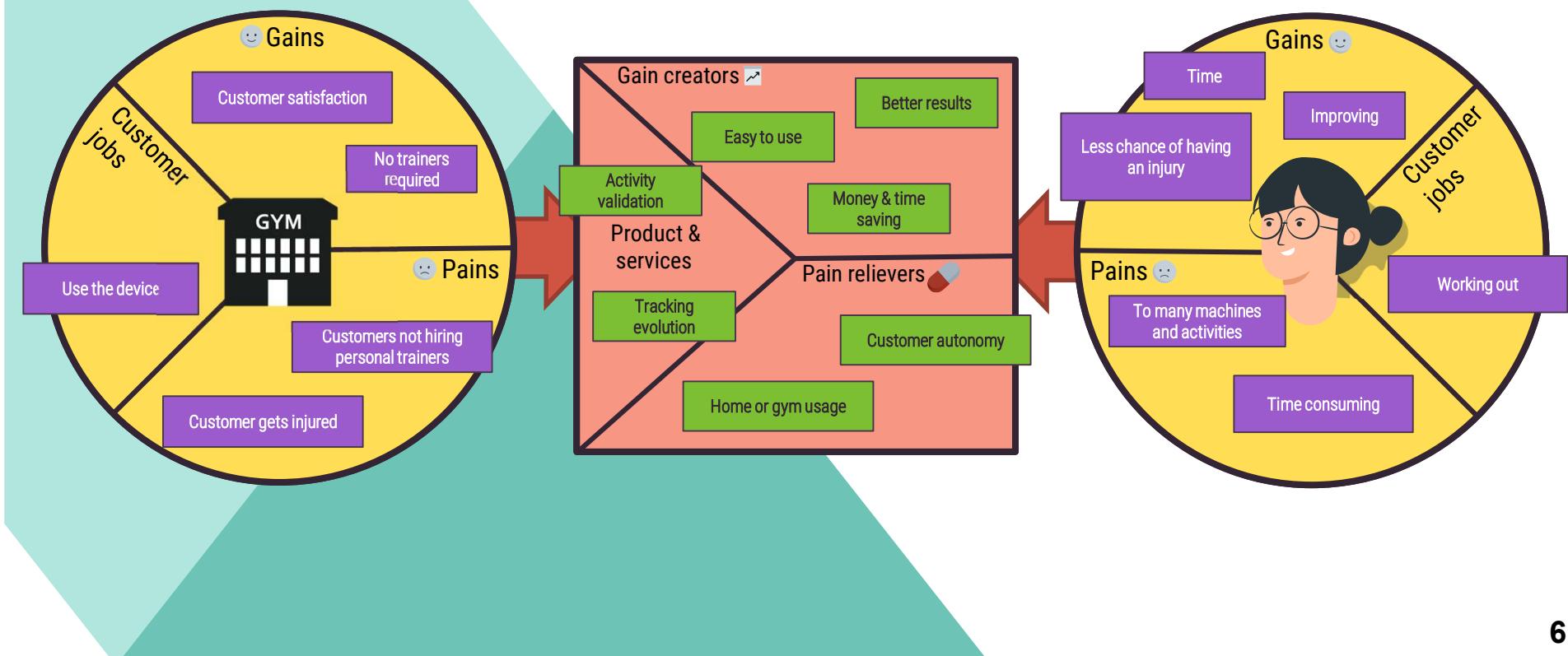
Software and hardware

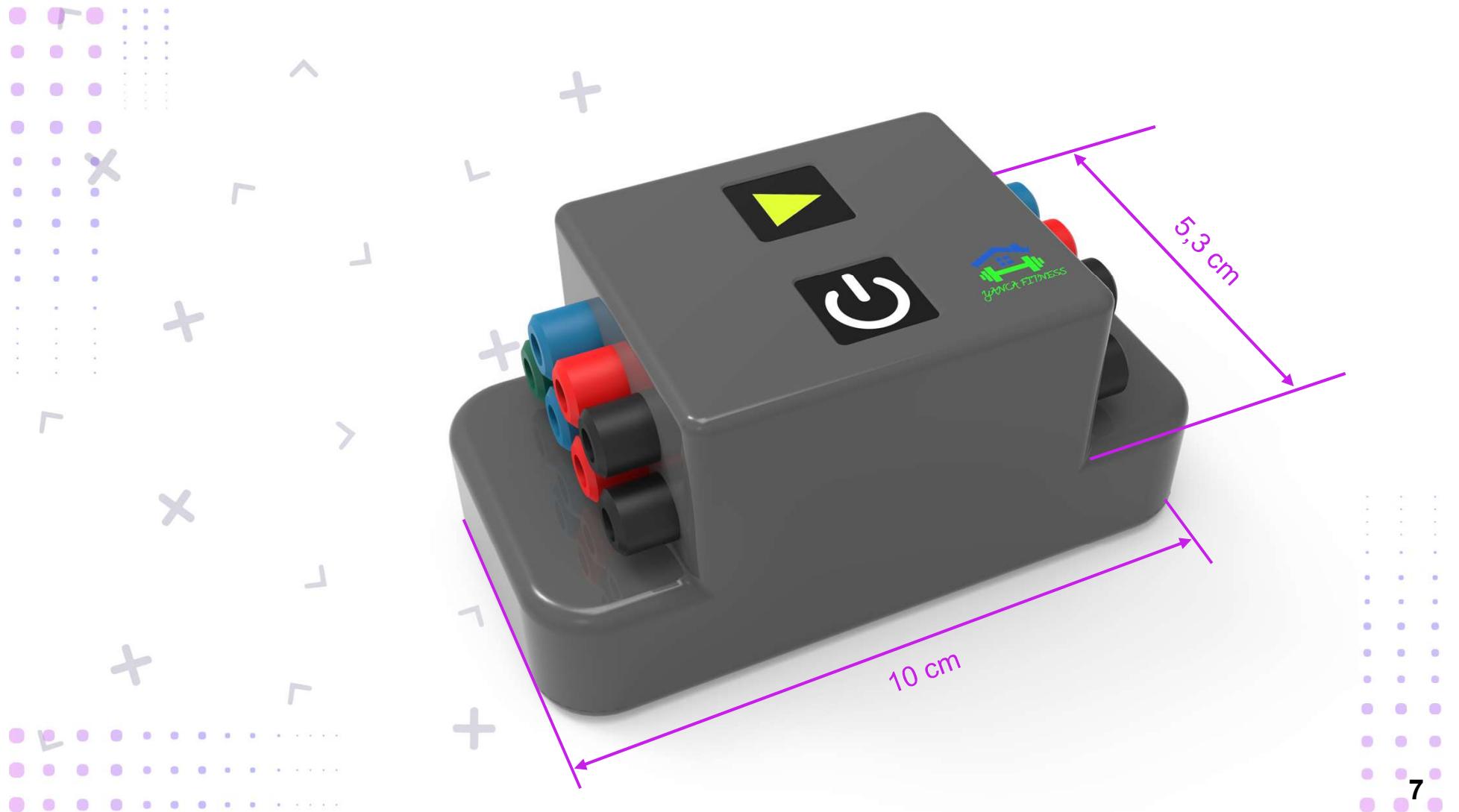


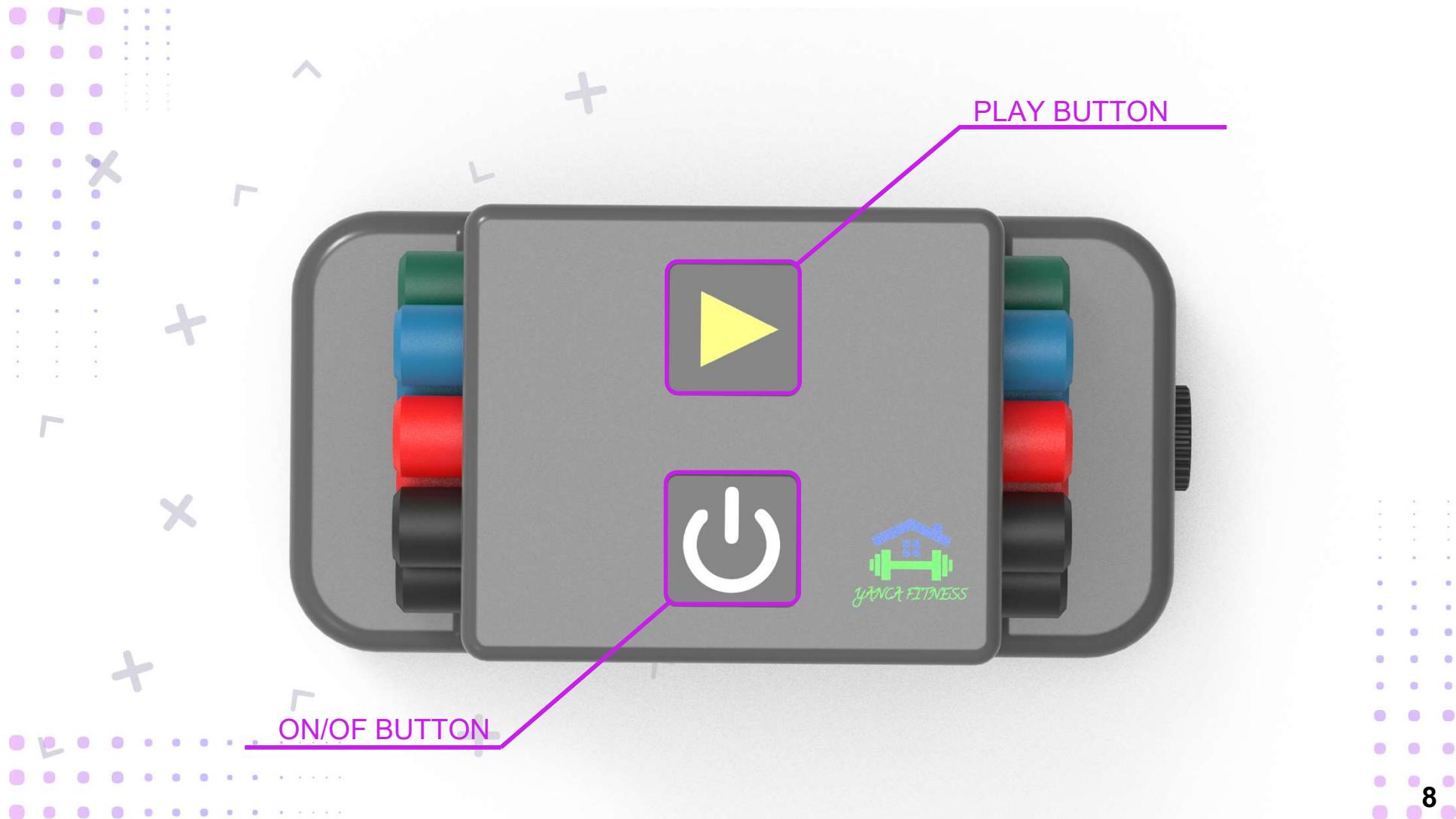
02 DEVICE: DALP

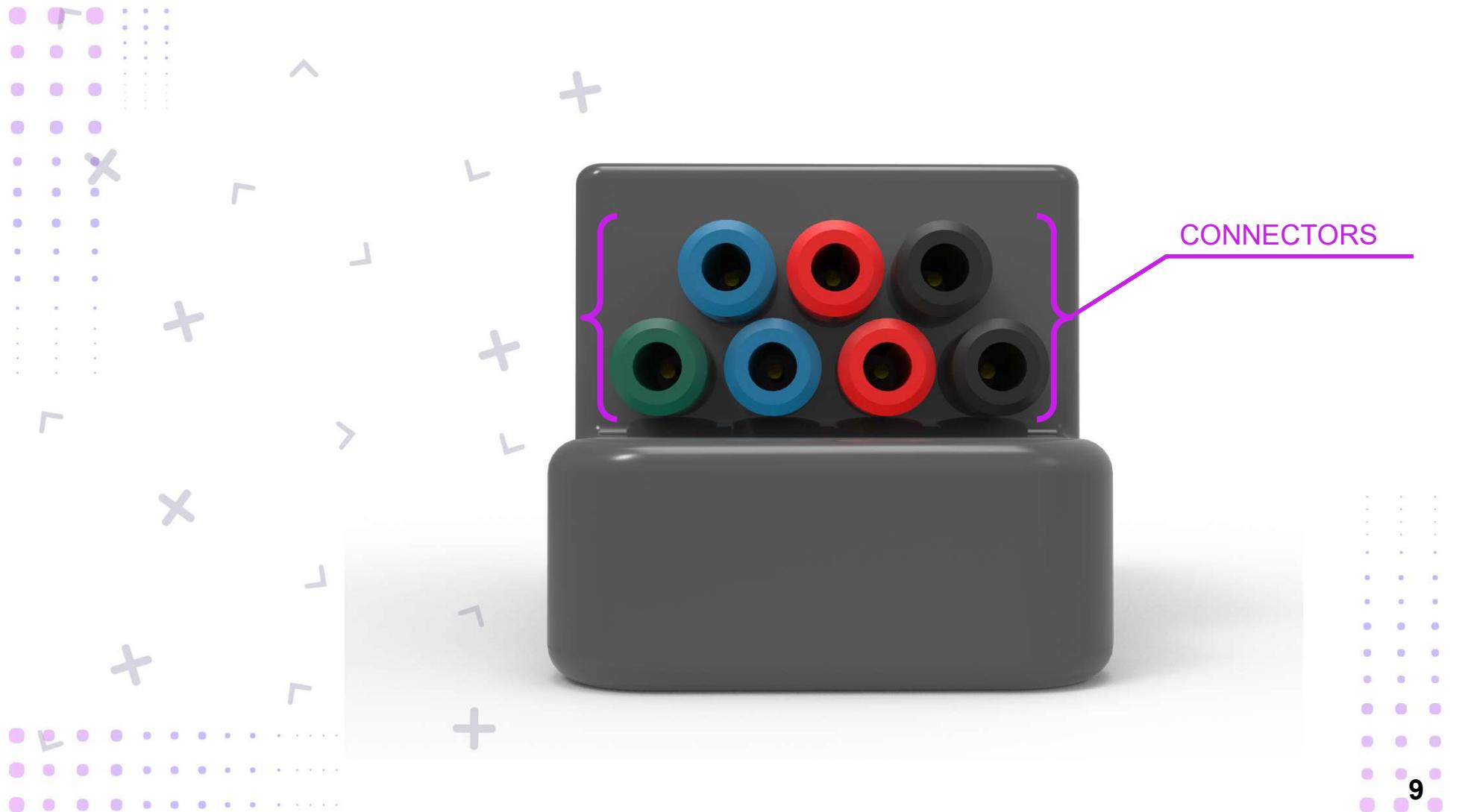


# Value proposition canvas

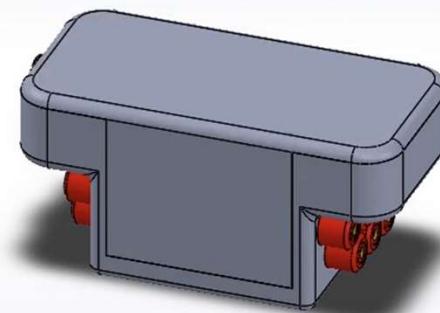


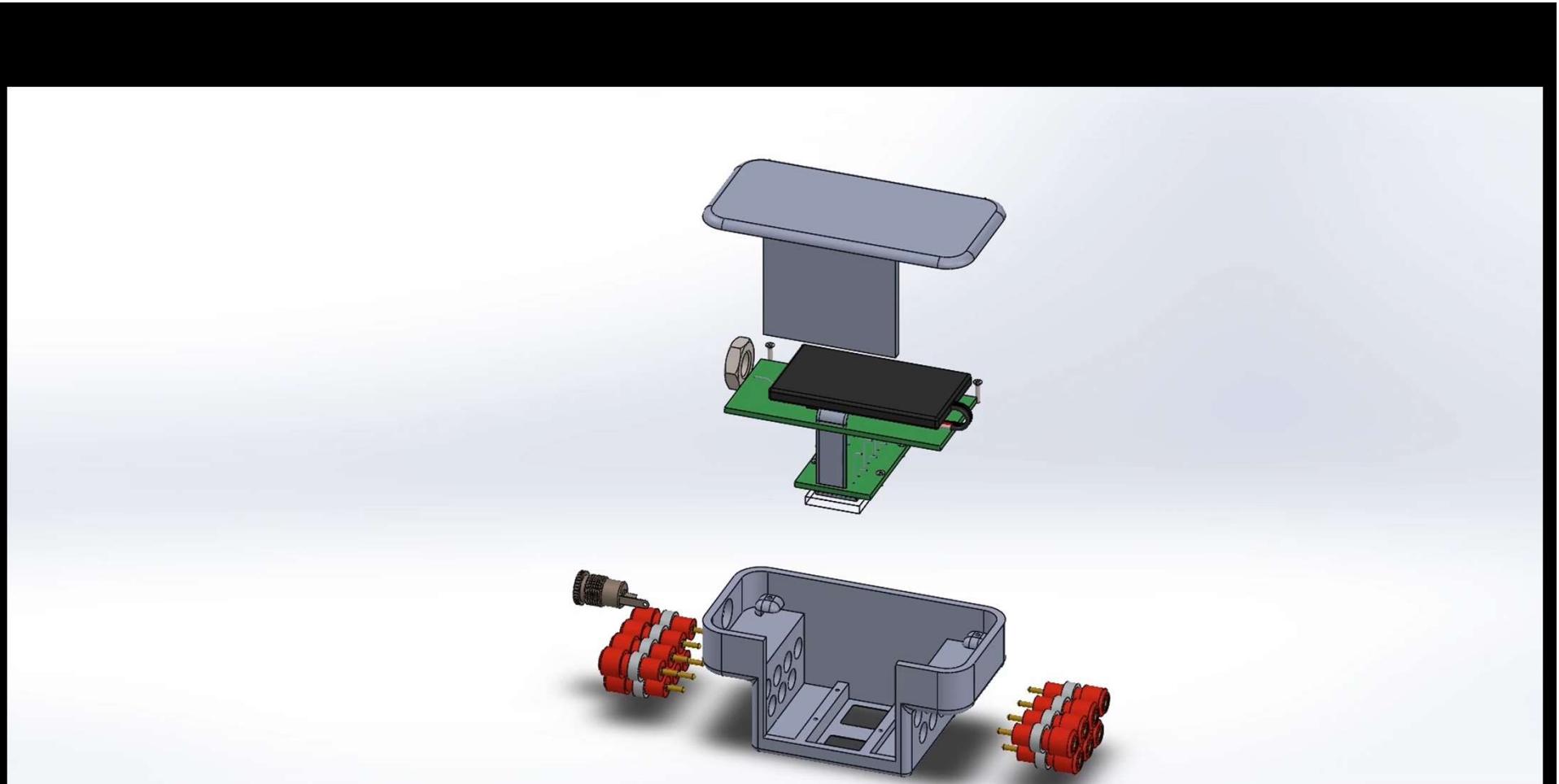


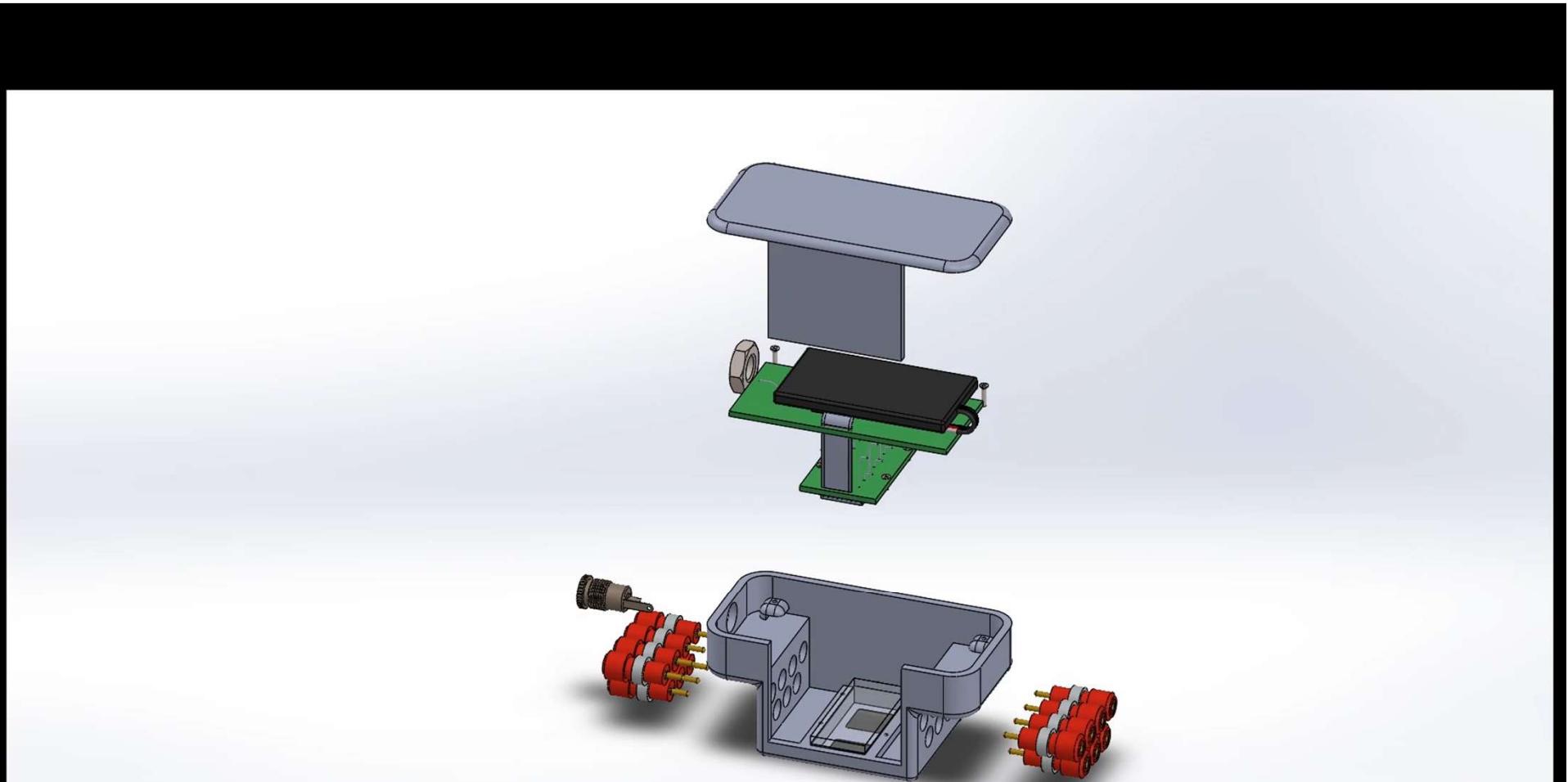


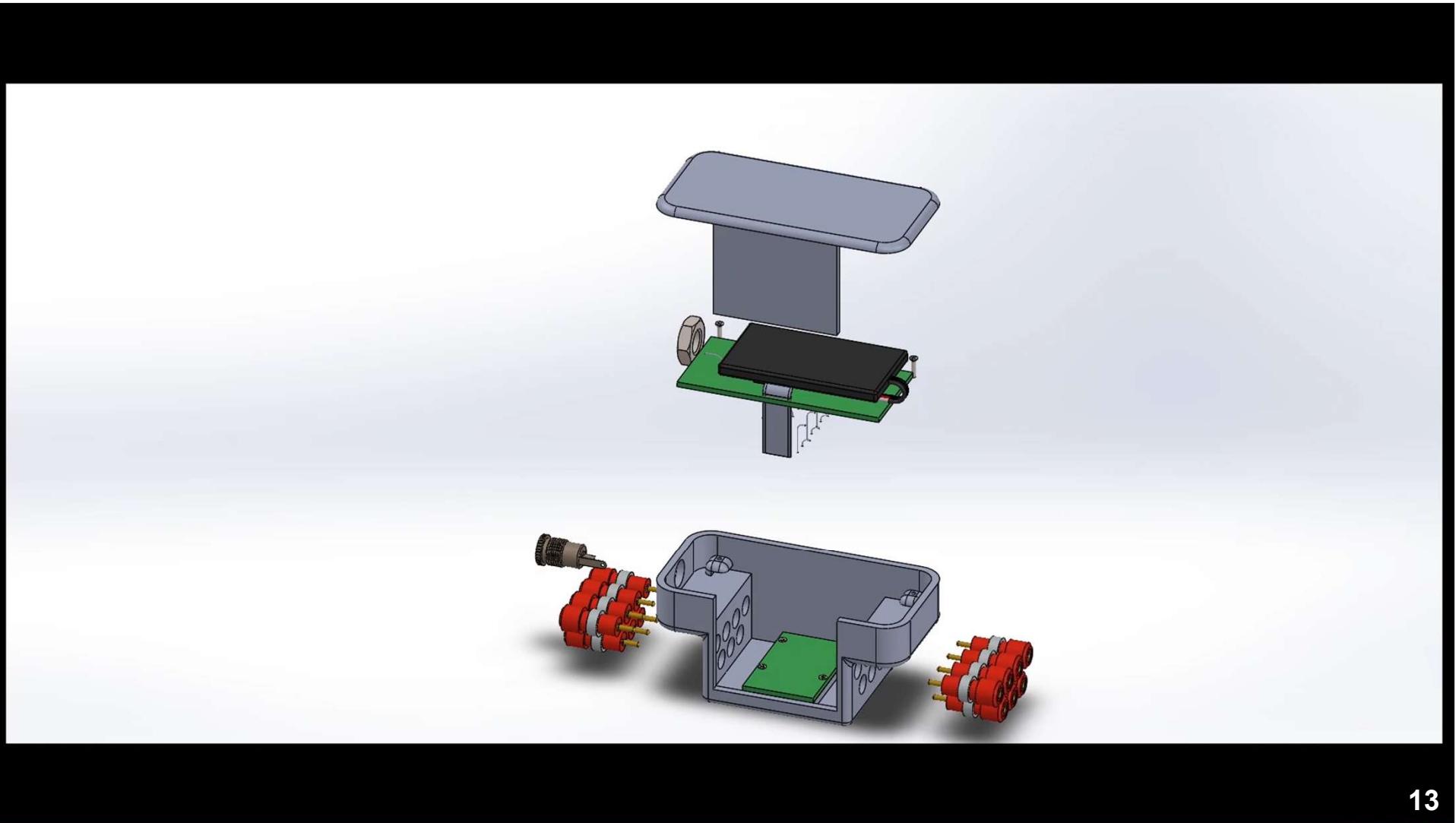


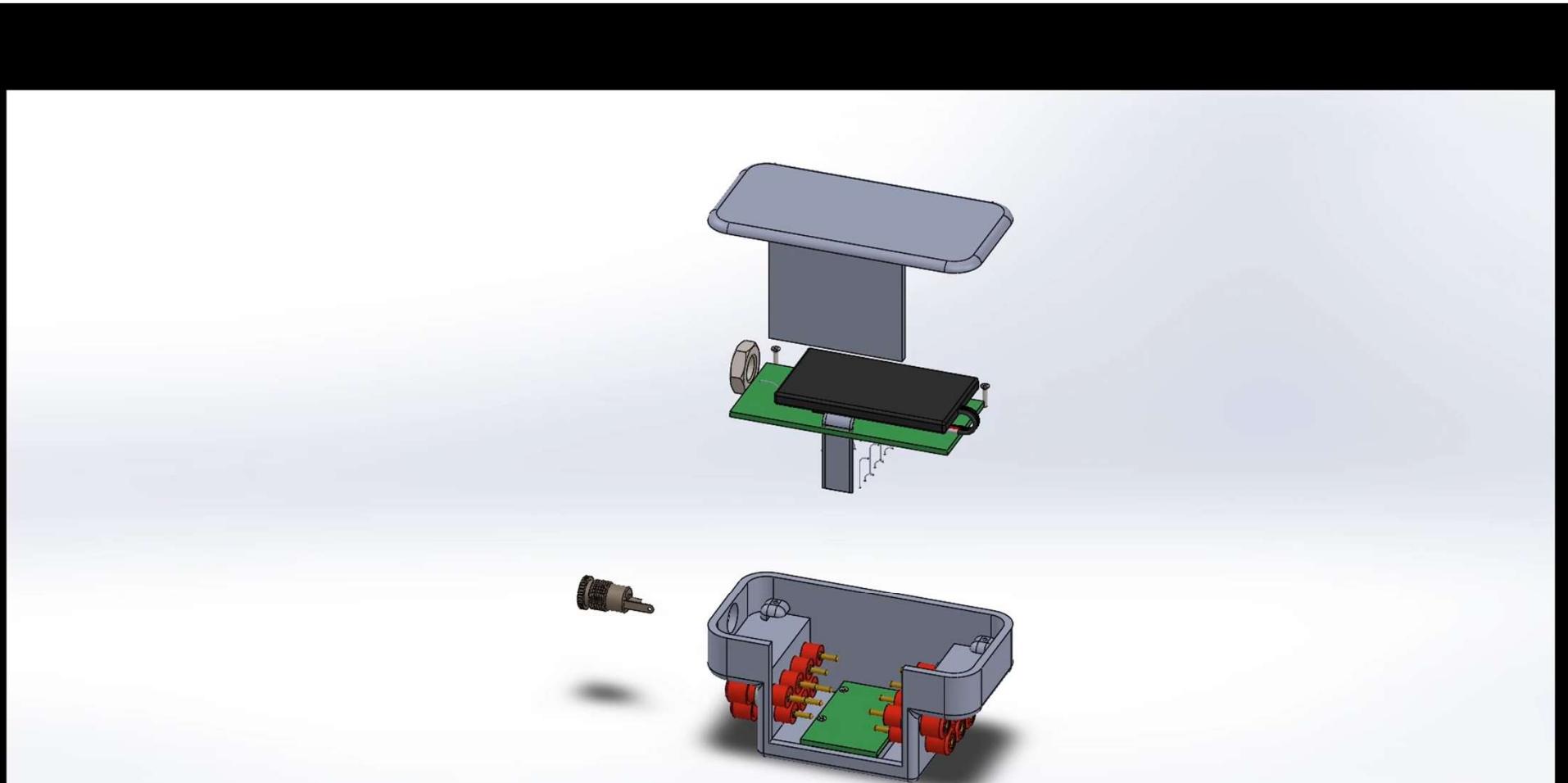
## 02. DEVICE COMPONENTS AND DESIGN

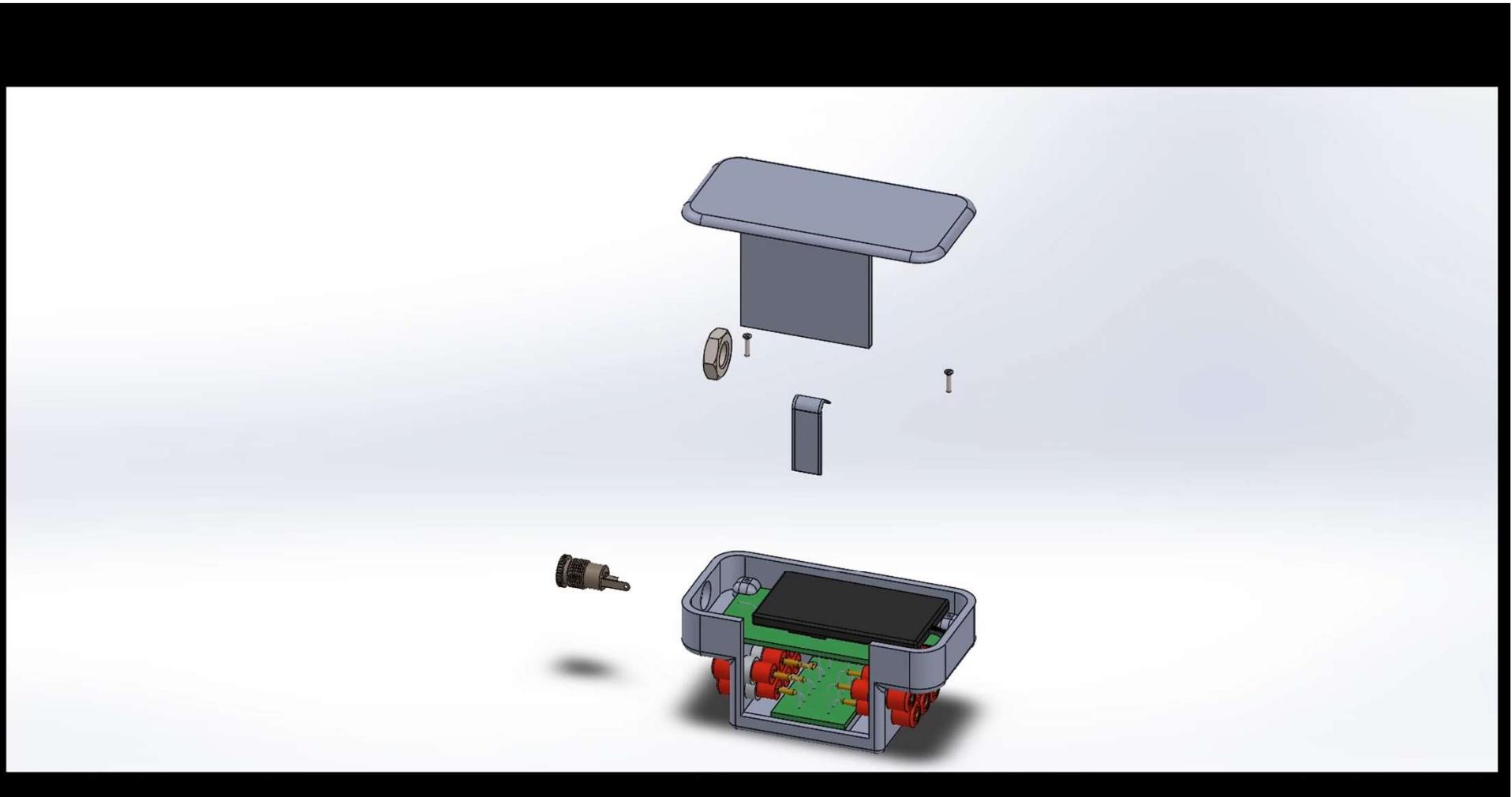


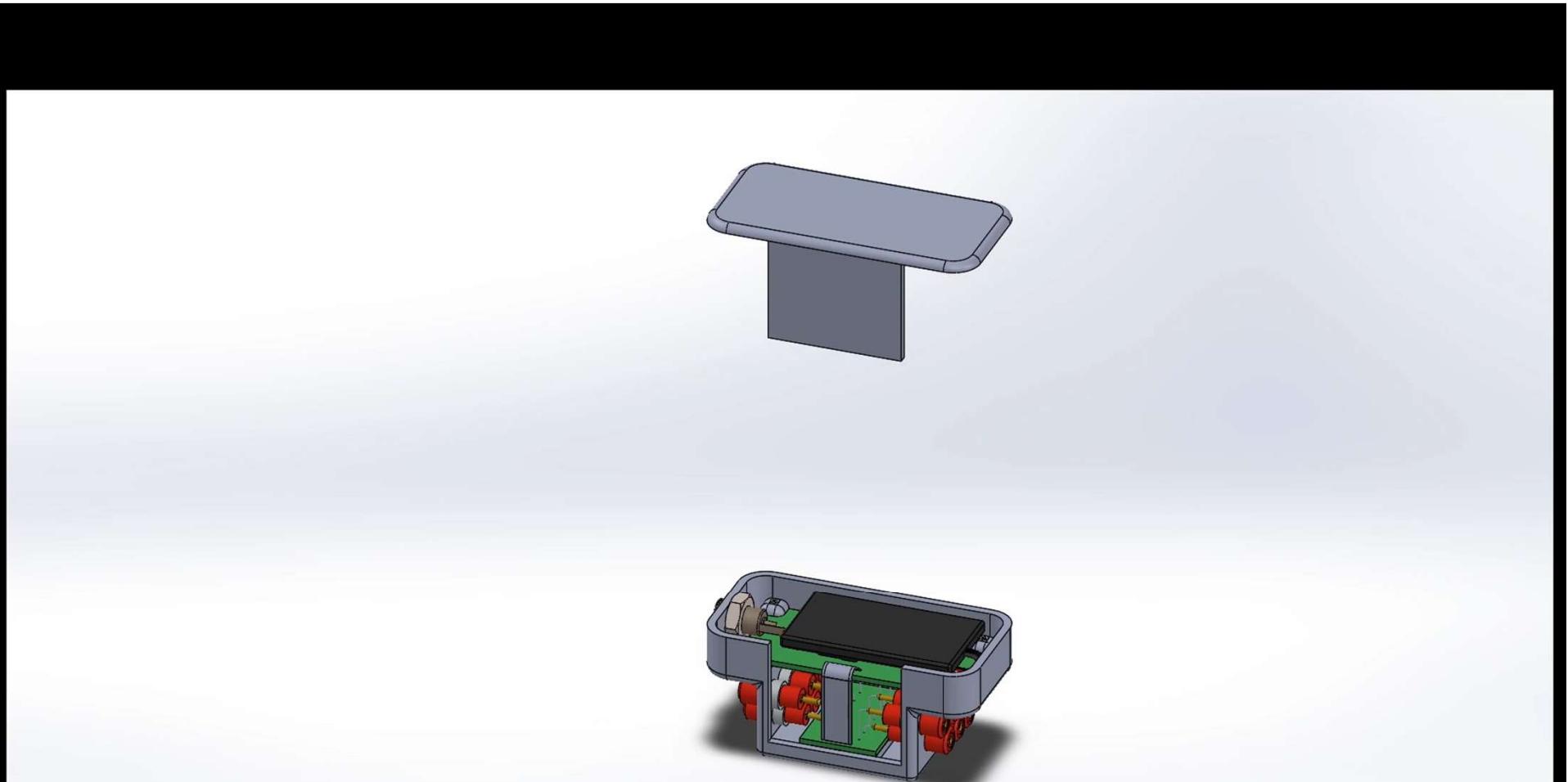
















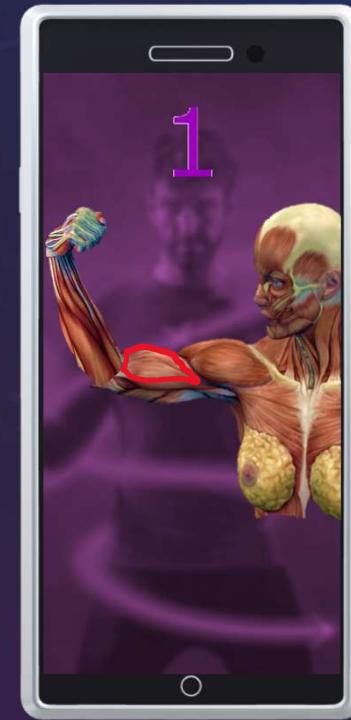
## 02. DEVICE OPERATION AND WORKING MODES



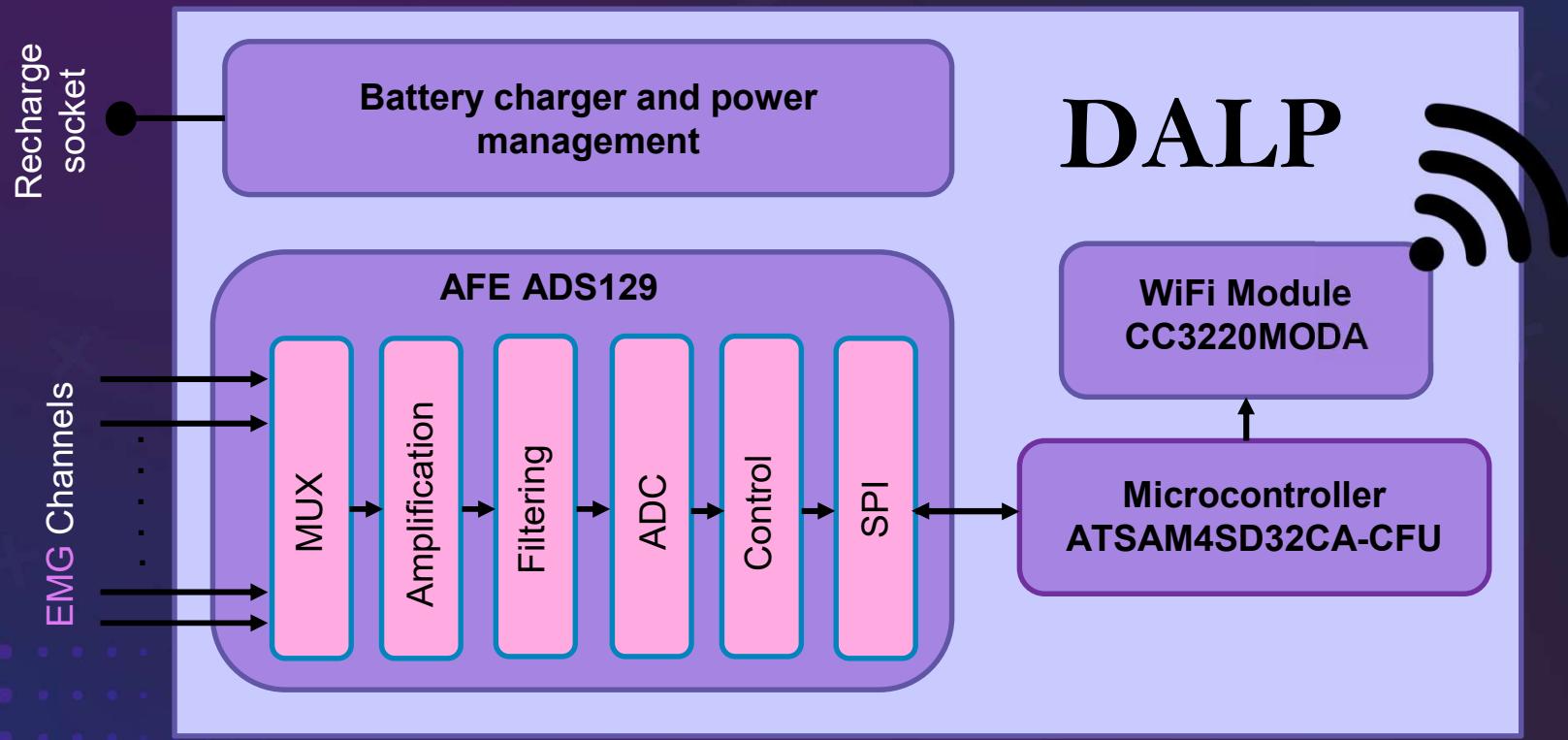
## 02. DEVICE OPERATION AND WORKING MODES

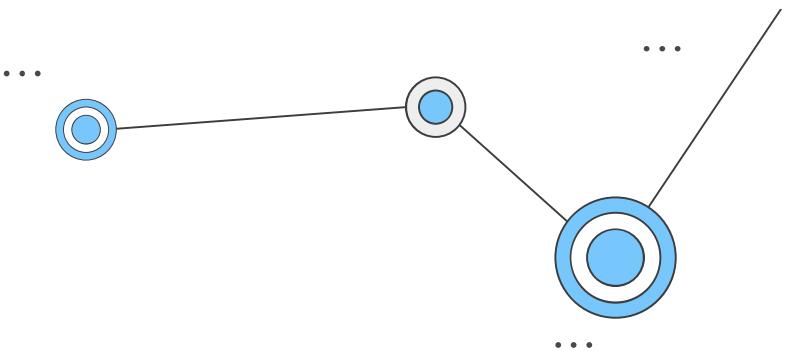


## 02. DEVICE OPERATION AND WORKING MODES



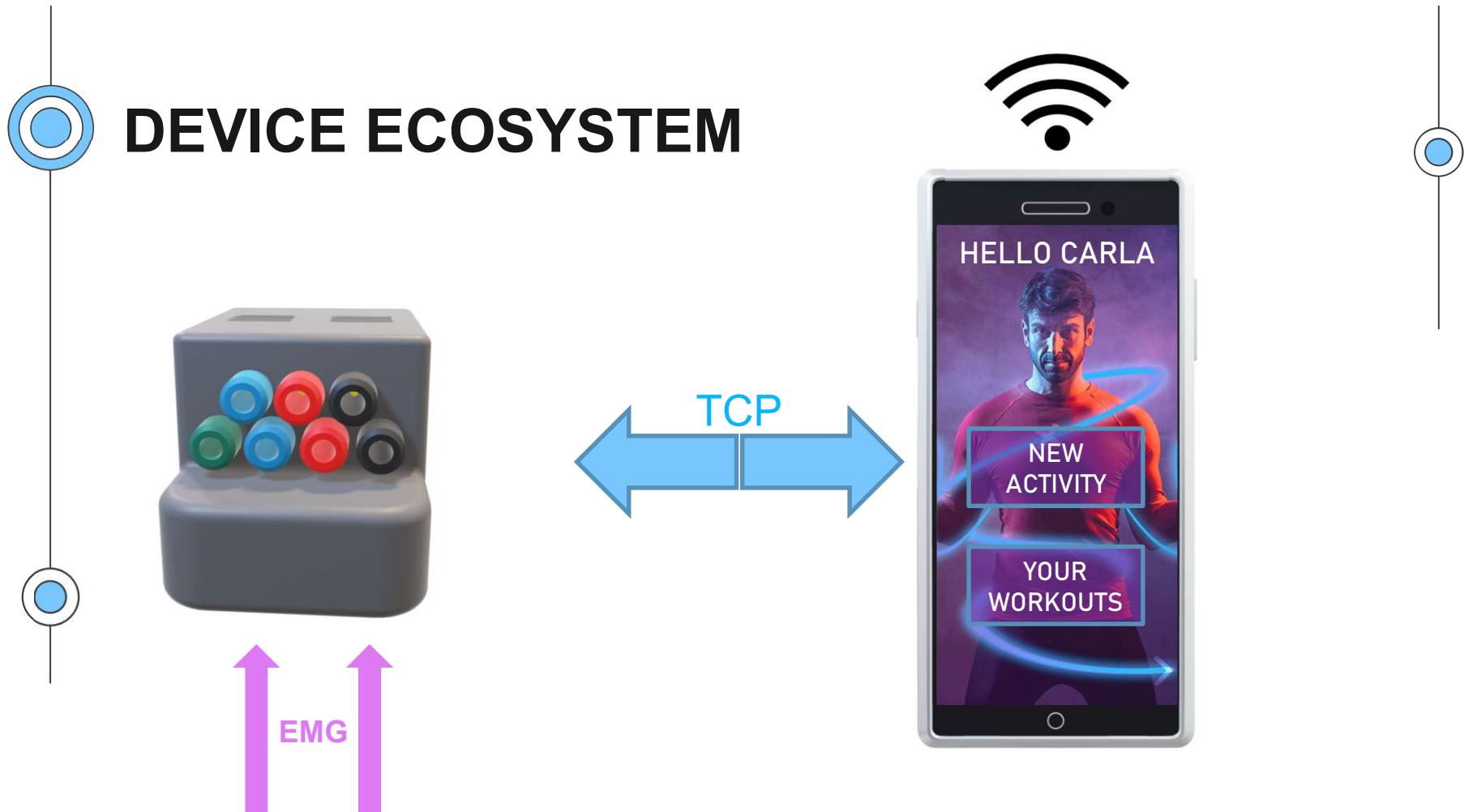
## 02. DEVICE SCHEME OF THE DEVICE



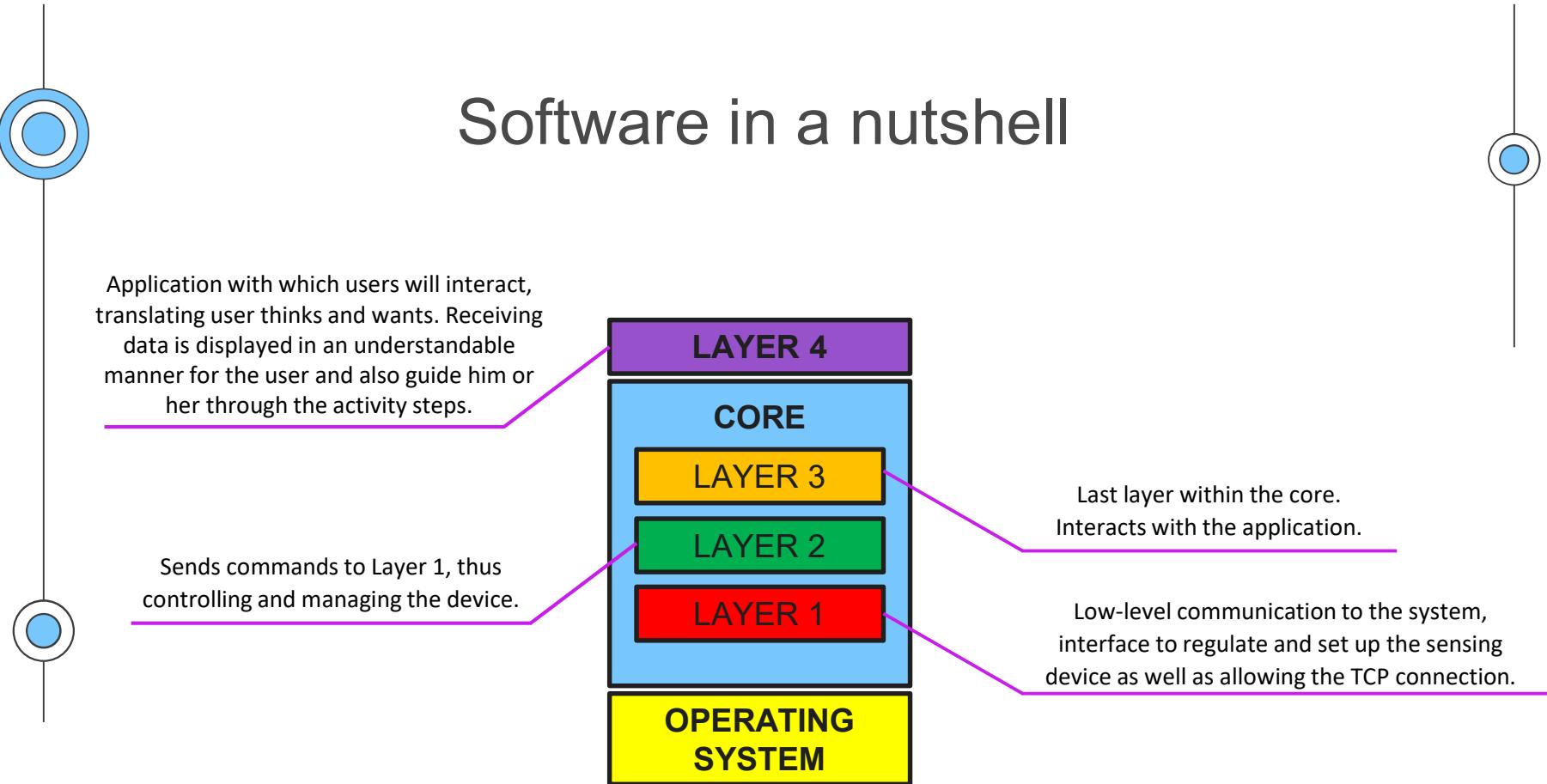


## 03. SOFTWARE

The user is what  
matters



# Software in a nutshell



# 04. ECONOMIC COSTS

The total approximate price of manufacturing one unit of DALP device is **216.84 €** including DALP Shirt, DALP hardware and their accessories.

For data storage, YANCA FITNESS will provide a Server Database (Amazon Aurora Server, model db.t3.small), at a cost of **332,71 €/ year**.

COMPONENT	MARCH AND MODEL	PRICE
DALPCORE hardware device		
White Capacitive Touch Switch	CSMS15CIC04	5.63 €
Green Capacitive Touch Switch	CSMS15CIC05	5.91 €
Capacitive Touch Overlay ON - OFF	CTHOVERLAYONOFF	1.28 €
Capacitive Touch Overlay ARROW	CTHOVERLAYARROW	1.28 €
Rechargeable Lithium-ion Polymer Battery	LP-503562-1S-3	19.63 €
DC Power Connector	163-4021	3.80 €
Black Touch Protected Panel-mount Terminal (4x)	65.333-21	10.8 €
Red Touch Protected Panel-mount Terminal (4x)	65.333-22	10.8 €
Blue Touch Protected Panel-mount Terminal (4x)	65.333-23	11.08 €
Green Touch Protected Panel-mount Terminal (2x)	65.333-25	5.54 €
PCB	PCB JLCPBCB	20 €
Wireless MCU module	CC3220MODA	12.32
Microcontroller	ATSAM4SD32CA-CFU	8 €
Analog Front-End for Biopotential Measurements	ADS1298	33.66 €
Screws (6x)	M1.6x5	1.08 €
Case	3D printed	~ 5 €
<b>TOTAL</b>		150.18 €
DALP T-shirt		
Customized T-shirt	COLDASY	~36 €
<b>TOTAL</b>		36 €
OTHER COMPONENTS AND ACCESSORIES		
Power supply	iCreatin 18650	6,73€
Adapter Plug	Lewis N. Clark, E106	3.30€
Electrodes (28x)	H124SG Covidien	7.90 €
Black Electrode Wire DIN42802 1.5ø (4x)	HBEC001-1	5.56 €
Red Electrode Wire DIN42802 1.5ø (4x)	HBEC001-1	5.56 €
Blue Electrode Wire DIN42802 1.5ø (4x)	HBEC001-1	5.56 €
Green Electrode Wire DIN42802 1.5ø (2x)	HBEC001-1	2.78 €
<b>TOTAL</b>		30.66 €

## 05. APPLICABLE REGULATION

Biocompatibility	
ISO 10993-1: 2009	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
ISO 10993-5: 2009	Biological Evaluation of Medical Devices - Part 5: Test for In Vitro Cytotoxicity
ISO 10993-10: 2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electromagnetic Compatibility and Emissions	
UNE-EN 60601-1-2:2008 CORR:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
UNE-EN 61000-4-3:2007/A2:2011	Electromagnetic compatibility (EMC)- Part 4-3: Testing and measurement techniques- Radiated, radio-frequency, electromagnetic field immunity test
CISPR 11:2015 + A1:2016	Radio-frequency Emissions
UNE-EN 61000-3-2:2014	Harmonic Emissions
UNE-EN 61000-3-2:2013	Voltage fluctuations/flicker emissions

## 05. APPLICABLE REGULATION

Electrical Performance	
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
UNE-EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
UNE-EN 60601-2-40:2019	Medical Electrical Equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
UNE-EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-11: 2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

# 05. APPLICABLE REGULATION

Symbols, labelling and information by manufacturer	
UNE-EN ISO 15223-1:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
UNE-EN 1041:2009+A1:2014	Information supplied by the manufacturer of medical devices
Risk management	
UNE-EN ISO 14971:2020	Medical devices - Application of risk management to medical devices
Other standards and testings	
Software verification and validation testing per IEC 62304 and FDA Guidance	Product specification compliance tests: ➤ Bandwidth ➤ Sampling Rate ➤ Input Referred Noise ➤ Dynamic Range ➤ Operating Hours ➤ Resolution ➤ Input Impedance
Disinfection testing	
Compatibility of electrodes with DALP system	

# 06.QUALITY CONTROL



## 06. QUALITY CONTROL

### ACCURACY

Comparison of the EMG measurement with a recognised system (e.g. Biopac)

### CORE'S RESISTANCE

Check the resistance of the core to impacts

### BATTERY

Battery life and charging speed

### APP'S USABILITY

Testing of the app by external people

## 06. QUALITY CONTROL

### DATA PROCESSING

Test the counter for different speeds

### WATER RESISTANCE

Check if the core is water resistant and the shirt is water proof

### DATA VISUALIZATION

Test if the data is displayed correctly in the app

### EXTREME CONDITIONS

Check the functioning in extreme conditions of temperature, pression and humidity

# 07.RISK ANALYSIS



## 07. RISK ANALYSIS

Failure							
Item	Function	N	Mode	Causes	Effects	P	S
<b>Label</b>	Shows information about the product and precautions	1	Non-existing labelling	The product doesn't contain any label	Precautions are not followed	1	10
		2	Incorrect labelling	The product contains a label without some information	Precautions are not followed	1	10
<b>User manual</b>	Explains how to use the product and precautions	3	Non-existing user manual	The product doesn't contain any manual	Incorrect use, precautions are not followed	2	10
		4	Missing pages	The manual is incorrectly printed, some pages are missing	Incorrect use	1	8
<b>Electrode</b>	Transmit de EMG signal	5	Noise	High skin impedance	Data acquired is incorrect	5	4
		6	Poor adherence	The electrodes have been reused	Data acquired is incorrect	5	5

## 07. RISK ANALYSIS

Failure							
Item	Function	N	Mode	Causes	Effects	P	S
<b>Shirt</b>	Contains electrodes and the core	7	Uncomfortable	The shirt is too big/too small for the user	User dissatisfaction	2	6
		8	Electrodes are misplaced	Error in wire/shirt sizes	Data acquired is incorrect	3	7
<b>Core</b>	Data acquisition	9	Doesn't acquire any data	Bad use (submerge it...) / manufacturing or assembly error	Non-system operation	2	10
		10	No connection to the electrode	Electrodes are wrong connected	Data is not acquired or is incorrect	4	7
	Control when data acquisition starts	11	Led doesn't light up	Fused led	User don't perceive if the device is recording or not, dissatisfaction	3	9
		12	Buttons don't work	Damaged or broken	Data can't be recorded	1	10

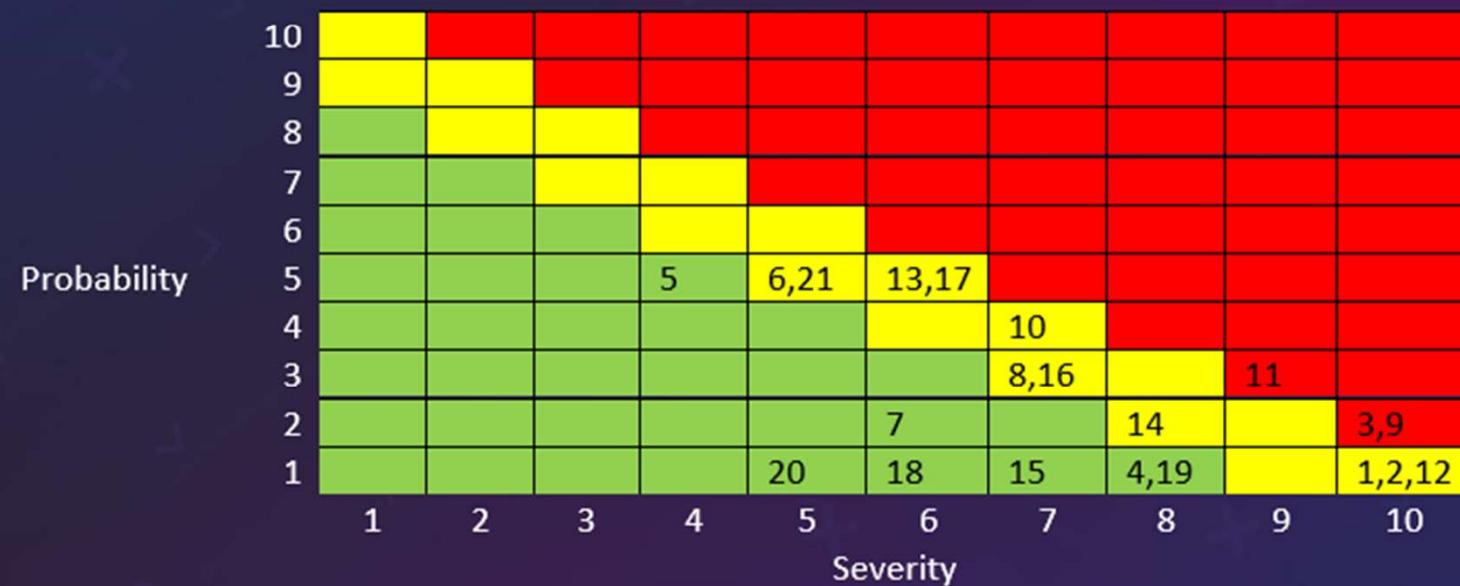
## 07. RISK ANALYSIS

Failure							
Item	Function	N	Mode	Causes	Effects	P	S
<b>Core</b>	Send data to the app	13	No connection to the app for a short period	Not connected to WiFi	User can't have the data on the app at the same time of exercise	5	6
		14	No connection to the app for a long period	Not connected to WiFi	User can't have the data on the app, data is lost	2	8
<b>Battery charger</b>	Charge the battery of the core	14	Charger is damaged	Bad use / defective	Core can't be charged	2	8
		15	Charger is damaged	Bad use	Possibility of little electric shock (not dangerous)	1	7
		16	Charger can't be connected to a plug	The plug is different from plugs in the consumer's country	Core can't be charged without an adapter	3	7

# 07. RISK ANALYSIS

Failure							
Item	Function	N	Mode	Causes	Effects	P	S
App	Receive data from the core	17	No connection to the core	Not connected to WiFi	User can't have the data on the app	5	6
	Data processing	18	Incorrect processing	Bad design of the software	User see incorrect data	1	6
	Data visualization	19	Data is not displayed	Bad design of the software	User can't see the data	1	8
		20	Data displayed doesn't correspond to current exercise	Bad design of the software	User see incorrect data	1	5
	Data storage	21	No more data can be stored	Lack of storage space on the device	Old data is removed	5	5

## 07. RISK ASSESSMENT



## 08. FUTURE VERSIONS

New functionalities and options to enhance the assistance and physical exercise or training:

- Bluetooth connection.
- Software compatible with computer (Windows and Mac).
- Incorporation of accelerometer providing acceleration, velocity and position.
- Measurement of pulse.
- Measurement of ECG.
- Measurement of environmental and corporal temperature.
- Measurement of heart and breathing rate.
- Verification of the optimal conditions for his training or exercise.
- Expanding the back up memory with a MicroSD card.
- Calories consumption

DALP device for physical rehabilitation and clinical research, to provide assistance and monitoring strain and exertion levels, especially on muscles that are struggling to heal.





DALP,  
WHERE  
SMARTHEALTH  
STARTS