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Abstract:

This document aims to define the requirements for a leadless and completely autonomous cardiac therapy system. In this document we focus on the physical, electrical and reliability requirements. And they will be segmented according to two levels. The first one will be a baseline of the state of the art of existing devices and the second describes our expectations for the MANpower device

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Clarification

Nature of the Deliverable

R Report
P Prototype
D Demonstrator
O Other

Dissemination level of Deliverable:

PU Public
PP Restricted to other programme participants (including the Commission Services)
RE Restricted to a group specified by the consortium (including the Commission Services)
CO Confidential, only for members of the consortium (including the Commission Services)

Disclaimer

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List of acronyms/abbreviations used

BAN: Body Area Network
BLE: Bluetooth low energy
EKG: Electrocardiography
DFMEA: Design Failure Modes and Effects Analysis
HBC: Human Body Communication
MHR: Maximum heart rate
PZT: Lead zirconium titanate
RF: Radio Frequency
SiPs: System-In-Packages
SoC: System-on-Chip
WDoD: Wafer Die-on-Die

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Executive Summary

To recover appropriate electrical behavior on heart disease affected patients, an artificial electrical stimulation has to be delivered to one or multiple locations along the conduction path by a so-called pacing-system. Currently, pacing systems are not miniaturized enough to be implanted in a small volume around the stimulation location. Hence, they comprise of two types of elements.

- A pacemaker that is implanted outside the heart where a space is available (typically under the skin on the right side of the chest) and this is the source of the electrical stimulation
- One or more leads that are effectively electrical wires supplying the electrical impulses from the pacemaker through the veins to the stimulation location within the heart.

In the future, we expect all pacemaker components (electronic, sensors, energy source, etc) to fit in a very small volume (>1cm^3). This small size would enable us to fix the pacemaker directly on the endocardium within the heart cavity and without any lead. Hence this is called a leadless pacemaker.

The main advantage of a leadless pacemaker is to remove leads, as they are often highlighted as being the weakest element in a pacing system. Examples of lead problems include: lead dislodgment, lead malfunction, lead infection, lead fraction, etc.

For all these reason and others, the Manpower project was initiated.

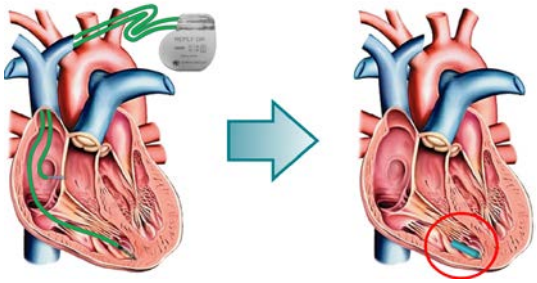


Fig 1. Current pacemaker VS envisioned leadless pacemaker.

This document aims to define the requirements for a leadless and completely autonomous cardiac therapy system.

Each device (capsule) in the system can have different roles in the leadless system and can thus replace the old pacemaker and leads. These devices could be responsible for measuring (sensing and capture) electro-cardiac potentials EGM or delivering electrical stimulations to cardiac tissues. They could also be sensors to measure temperature, pressure, acceleration, etc.

The power source for a capsule will be a harvester module (piezoelectric/ electrostatic) and charge storage gadget (stacked super capacitor of nanowires).

In this document we focus on the physical, electrical and reliability requirements. And they will be segmented according to two levels. The first one (shown in red) will be a baseline of the state of the art of existing devices and the second (shown in orange) describes our expectations for the MANpower device.

1. Physical specifications

1.1 Background of the cardiac system

The circulatory system comprises the heart, the veins and the arteries. Its main function is to carry the agents necessary for the cells metabolism (mostly oxygen), and remove waste products from the cells.

Operating at a temperature range from 37°C (98.6°F) to 41°C (105.8°F), the heart is the muscular organ that constantly pumps blood throughout the body and permits the circulation of components. The heart is composed of very strong cardiac muscle tissue able to contract and relax rhythmically throughout a person's lifetime. The average heart beats 100,000 times per day, and pumps about 5 liters of blood per minute.

The heart actually consists of two pumps in series:

- The left pump brings oxygenated blood from the lungs to distal organs
- The right pump brings the blood back from the distal organs to the lungs where it is oxygenated

It is to be noted that the heart is always represented with its right side on the left and the left side on the right, as if looking into a mirror.

As the lungs are close to the heart, the right side of the heart is less powerful than the left and the increase in blood pressure has to be about 5 times higher in the left ventricle than the right. Therefore the myocardium (cardiac muscle) is several times thicker on the left ventricle, and the volume of this cavity is also slightly smaller.

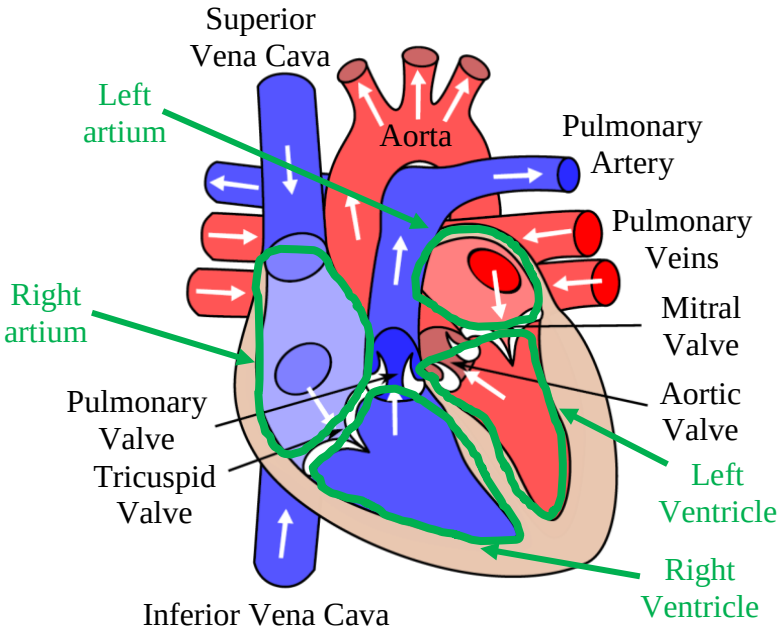


Fig 2. Illustration of the heart anatomy.

The cardiac cycle is composed of two phases: **systole** and **diastole**. The systole corresponds to the contraction of the muscle fibers and hence to the expulsion of blood out of the cavity. On the contrary, the diastole corresponds to the relaxing of the muscle fibers and to the entry of blood in the cavity. A heart beat is composed of a systole-diastole sequence for each of the cavities.

The heart generates its own beating independently. Indeed, the contraction is started by an electrical impulse born in a group of specialized cells located in the sinoatrial node in the heart itself.

The impulse flows through a specialized conduction system made up of a network of cells able to conduct electrical impulses within milliseconds. Through this system the electrical impulses reach each cell of the myocardium, generating a synchronous contraction of the entire cardiac muscular mass.

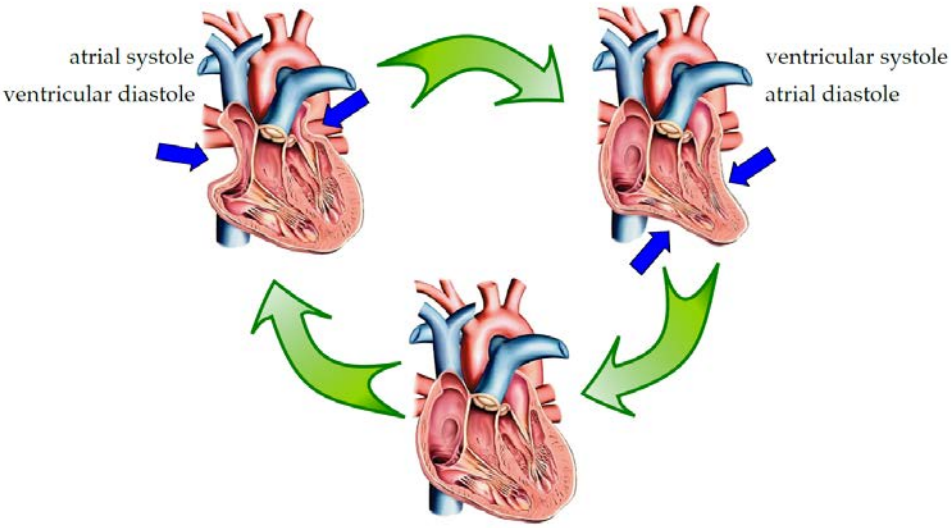


Fig 3. Heart chambers contraction cycle.

The heart electrical stimulation impulses flow sequentially through three main entities.

These three phases can be also seen on an electrocardiography (EKG) that records the electrical activity of the heart over time. The T-wave represents the slow repolarization of the ventricles. The period between two cycles is commonly called the R-R interval.

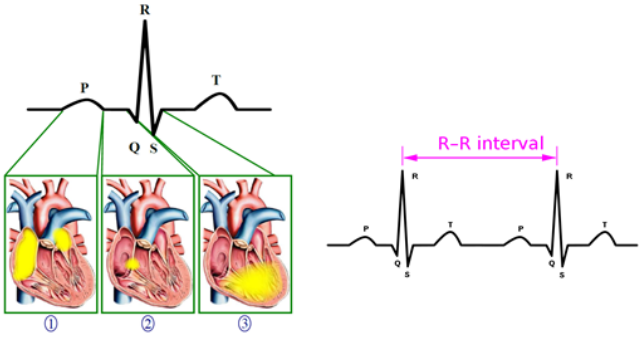


Fig 4. Electrocardiography (EKG)

The heart rate is the number of heartbeat per unit of time. Heart rate differs according to age, the metabolism of the patient and also the body's physical needs. The normal human rate ranges from 60 – 100 bpm (beat per minute) and can reach higher values called Maximum heart rate (MHR= 220 – age).

1.2 Physical requirements

The physical requirements for the capsule are shown in the table below.

	Reference 2013	Typical
Form Factor	Cylindrical capsule	
Material	Titanium	
Volume (cc)	1.36	0.66

1.3 Environment and location effects

The implantation of a leadless pacemaker is more delicate than a conventional pacemaker. The use of a fastening tool seems essential. In this context, we must design and implement a system of fixation and anchoring in the heart for a titanium capsule. More precisely the implant should be on the inner walls of the right ventricle (Apex). This operation will be rapid and will be made by a specialist doctor (electro physiologist).

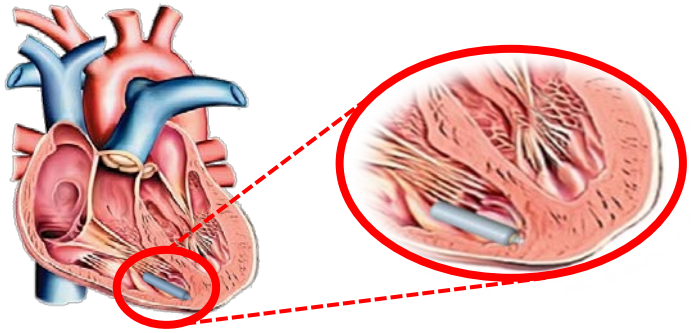


Fig 5. Location of the capsule holding

Such a tool must comply with the standards for implantable devices, in ensuring no damage to the venous system during the implementation phase to the heart; also ensuring a total retention of the capsule and no destruction of muscle tissue; And most importantly, resisting local constraints (heart and blood environmental movement) and must allow one to set and then remove and reattach to another place in a very short time scale.

SORIN has made preliminary measurements of the heart inner wall acceleration in a living pig, and found that the acceleration amplitude (peak to peak) varies from 0.7 to 1.5g.

2. Electrical specifications

The electrical specifications are outlined in this section.

Energy management block		
Voltage delivered (V)	**1 - 3**	**1 - 3**
Total average Power required (µw)	**27**	**14**
Stimulation pulse width (ms)	**0.1 to 1 (typical 0.5)**	
Electrodes impedance (mean value) ±50%	**650 ohm**	
Heart Rate range (bpm)	**30 to 180 (typical 70)**	

Scavchip	It will convert the AC voltage source or current source provided by the harvester to DC voltage used by the electronic parts. It can also charge the Super Capacitor/Battery if the available power exceeds the required power. When the harvested power is less than required, Scavchip will switch the power supply source to you the SuperCapacitor/Battery. • Dimensions : 3.8 x 1.6 x 0.4 mm (chip version) • Input Voltage : harvester specific • Output Voltage Range : 2.8V – 3.3V • Output Voltage Typical : Vo = 3V • Accepted ripple = 10% • Output Power Range : 14µW (Typical) • Using inductor is forbidden

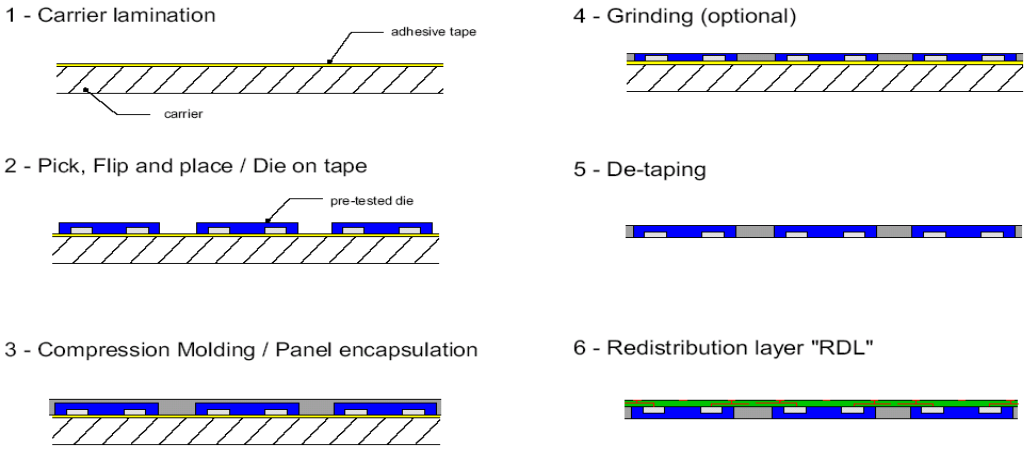
Super Capacitor	• Provide enough energy for 6 months to 1 year • Output voltage= 3V • Current peak= 10mA during 1ms • Leakage current = 100nA • Form factor : Compliant with system integration technologies and several architecture requirements • Dimension < $20mm^3$

3. System integration constraints

3.1 Stacking process (recommendation)

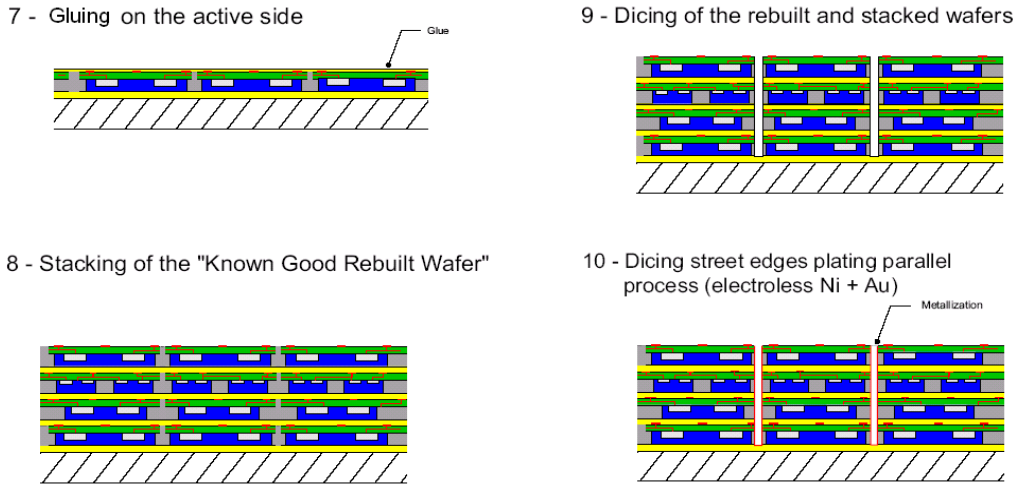
3.1.1. 2D process and constraints

If this process is the one chosen then development of the super capacitor must take account of the stacking method constraints described below. Note that this process is qualified for the stacking of components based on silicon technology.



STEP	CONTRAINTS FOR CAPACITORS
1	No constraints
2	Must be able to be manipulated by Pick and Place equipment (mechanical stability, alignment marks)
3	Must support temperature above 150°C and pressure Must be compatible with epoxy resin molding (adapted CTE, low outgassing, good behavior with solvents)
4	Mechanical stability and brittleness must be sufficient in order to support back grinding (inside epoxy resin, not inside capacitors)
5	Before detaping, the active surface is in contact with thermal release tape. Then, capacitor materials must be convenient with this tape and must support release temperature of 150° to 200°C of the thermal tape.
6	RDL (Redistribution Layer) process : 1. Photodielectric deposition and curing Capacitors must support chemical interaction with this dielectric Capacitors must support dielectric curing temperature of 150°C to 200°C Topology of capacitors must be low in z-axis Except connexion pads, capacitors must be covered with passivation 2. Photodielectric photolithography Capacitors connexion pads must be covered with aluminum or gold metal. 3. Seed-layer deposition Capacitors must have physical behavior compatible with PVD process (low outgassing, process temperature of 150°C) 4. Photoresist deposition and photolithography No constraints 5. Copper electroplating No constraints except mechanical robustness 6. Photoresist stripping and seed layer etchning No constraints

3.1.2. 3D process and constraints



STEP	CONTRAINTES FOR CAPACITORS
7	No constraints
8	Capacitors must support mechanical pressure and temperature 150°C
9	No constraints
10	No constraints

4. Reliability/ testability specifications

4.1 Mechanical reliability

The mechanical reliability requirements of the harvester and supercapacitor are shown here.

	Harvester + Super Capacitor	
Heart beat cycle	**$2x10^8$**	**$4x10^8$**
Capsule Lifetime (year)	**10**	**20**
Fatigue	**Environment in constant movement**	
Temperature	**During transport & sterilization** **37°C in operation**	

4.2 Reliability methods

- Mechanical, vibration, shock and thermal testing of MANpower device materials and components (this will include design and construction of a test rig).
- Failure analysis of MANpower device structures and components (microsectioning, microscopy).
- Multiphysics simulation of MANpower device structures and components.
- MEMS reliability simulation and testing.
- Sorin will deliver its integration constraints in the next update of the specifications.

4.3 Reliability criteria

		Protection
EN 45502-1	1	from unintentional biological effects being caused by the active implantable medical device
	2	from harm to the patient or user caused by external physical features of the active implantable medical device
	3	from harm to the patient caused by electricity
	4	from harm to the patient caused by heat
	5	from ionizing radiation released or emitted from the active implantable medical device
	6	from unintended effects caused by the device
	7	of the device from the aging effects
	8	of the device from damage caused by external defibrillators
	9	of the device from changes caused by high power electrical fields applied directly to the patient
	10	of the active implantable medical device from changes caused by miscellaneous medical treatments
	11	of the active implantable medical device from mechanical forces
	12	of the active implantable medical device from damage caused by electrostatic discharge
	13	of the active implantable medical device from damage caused by atmospheric pressure changes
	14	of the active implantable medical device from electromagnetic non-ionizing radiation
	15	Compliant MRI, EDS

4.4 DFMEA conception

Each partner in the design and characterization of the device must also develop its DFMEA.

5. Biocompatibility requirement

All components are inside the capsule, so they are not affected by biocompatibility constraints due to water tightness of the capsule.

However, the capsule must satisfy all the standards in force:

- EN 45502-1
- ISO10993-1

Partner (KU-LEUVEN) responsible for biocompatibility testing will provide the methods selected.