Is not what you do, is how you look doing it---Yocli

BIOMECHANICS OF A PACEMAKER IN THE HUMAN BODY[1]

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Abstract—**The pacemaker is used in the human body to regulate rhythm disorders. This paper presents biomechanics and biomaterials of the pacemaker. The heart is basically a hollow muscle with four chambers – the two atria (this is the upper chamber) and the two ventricles (this is the lower chambers). The heart is divided into a right and a left side and is responsible for pumping blood throughout the body. This is necessary in order for all organs and tissues to be supplied with oxygen. In order for the blood to be collected and pumped out, the heart depends on tiny electrical impulses passed from the upper chambers to the lower chambers. These impulses usually start at the sinus node, which is also known as the natural pacemaker. Thus, the sinus node is the one which coordinates contraction and allows the heart to beat rhythmically. Impulses are then carried from the upper chambers into the lower chambers which then contract. This contraction is what we know as a heartbeat. Different reasons, such as disease or age-related processes, can disturb the natural heart rhythm. Very common disorders are problems in the conduction system or possible blockage of the pathways. As a result, the heart may beat irregularly and/or too slowly. In that case, the body – especially under physical stress – will be insufficiently supplied with oxygen, causing dizziness, feelings of weakness or tiredness. The medical term for these kinds of rhythm disorders is bradycardia. In the case of AV block, the conduction of the electrical signals between the sinus node (in the atrium) and the AV node (in the ventricle) can be partially or totally blocked. With a total AV block, the electrical conduction between the atrium and the ventricle is interrupted. So a different center of the heart will generate a very slow, auxiliary rhythm to ensure life-saving function. In either one of these situations, or in other, even less common cases, the heart can be assisted through the use of an artificial pacemaker.**

Keywords---heart, chambers, electrical impulse, sinus node, blood, rhythm, artificial pacemaker.

INTRODUCTION

Our heart is a pump made of special muscle. It pumps blood to all cells of our body. This is vital, because the blood carries oxygen and nourishment to keep your cell alive and healthy.

Our heart beats because special cells in our heart (the heart's natural pacemaker, called the sinus node or sinoatrial) produce electrical impulses. These impulses cause the heart to contract and pump blood. The impulses travel from the pacemaker cells down certain electrical paths in the muscle walls, causing a contraction. As long as the electrical impulses flow down our heart's walls at regular intervals, our heart pumps at a rhythmic pace. Sometimes, though, something happens to interfere with how the electrical impulses of our heart's natural pacemaker are made or flow down our heart. When this occurs, the natural pacemaker can't do its job and components.

DESCRIPTION OF AN ARTIFICIAL PACEMAKER

1. **A pulse generator** which has a sealed lithium battery and an electronic circuitry package. The pulse generator produces electrical signals that make the heart beat. Many pulse generators also have the capability to receive and respond to signals that are sent by the heart itself.

2. **One or two wires (also called leads):** Lead wires are insulated, flexible wires that conduct electrical signals to the heart from the pulse generator. The leads may also relay signals from the heart to the pulse generator. One end of the lead is attached to the pulse generator. The electrode end of the lead leads may be positioned in the atrium, ventricle, or both, depending on the condition requiring the pacemaker to be inserted. Pacemakers that pace either the right atrium or the right ventricle are called "single-chamber" pacemakers. Pacemakers that pace both the right atrium and right ventricle of the heart and require two pacing leads are called "dual-chamber" pacemakers.

Older pacemakers sent out electrical signals at a constant rate, regardless of the heart's own rate. Pacemaker technology is now much more advanced. Today, pacemakers can "sense" when the heart's natural rate falls below the rate that has been programmed into the pacemaker's circuitry (figure 1).

3. **An atrial arrhythmia** (an arrhythmia caused by a dysfunction of the sinus node or the development of another atrial pacemaker within the heart tissue that takes over the function of the sinus node) may be treated with an atrial permanent pacemaker whose lead wire is located in the atrium.

4. **A ventricular arrhythmia** (an arrhythmia caused by a dysfunction of the sinus node, an interruption in the conduction pathways, or the development of another

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pacemaker within the heart tissue that takes over the function of the sinus node) may be treated with a `ventricular pacemaker whose lead wire is located in the ventricle.

5. It is possible to have **both atrial and ventricular arrhythmias**. There are pacemakers which have lead wires positioned in both the atrium and the ventricle. There may be one lead wire for each chamber, or one lead wire may be capable of sensing and pacing both chambers.

6. **An ICD** has a lead wire that is positioned in the ventricle, as it is used primarily for fast ventricular arrhythmias. The components of a pacemaker are indicate in figure 3. Table 1 reveals typical specification of a pacemaker.

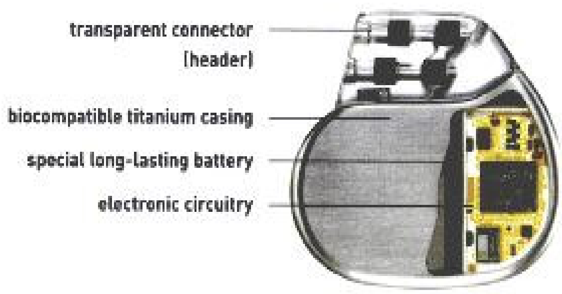


Figure 1. Schematic diagram of the pacemaker [23].

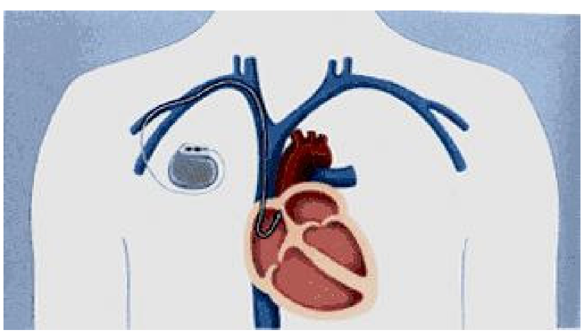
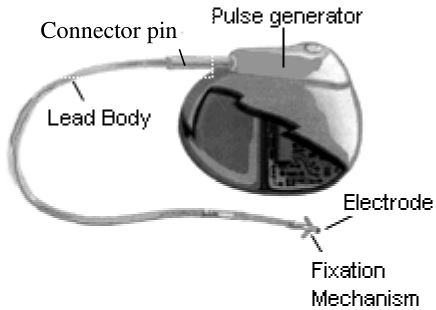


Figure 2. Location of the pacemaker near the heart [23]

Changing physiological needs that occur during running, swimming or gardening, for example, are met by the rate adaptive features of pacemaker.

Furthermore, the latest generation of BIOTRONIK pacemakers can also react to mental changes. Everybody has experienced a sudden rise in pulse or blood pressure while watching an exciting film or if an unexpected event occurs. CLOSED LOOP Stimulation can adapt the pacing rate to both physical activity and emotional stress. BIOTRONIK's wide range of products allows the physician to appropriately diagnose and treat any rhythm disturbance.

Due to extensive research, BIOTRONIK pacemakers today are not only technologically advanced but are also safer, smaller, lighter and more streamlined.



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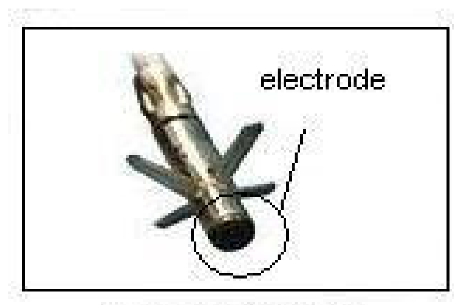

www.pacemakerclub.com

Figure 3. Components of a pacemaker.[23,30]

The Pacemaker and Surroundings

A patient with an artificial pacemaker, should be aware of the surroundings and the devices that may interfere with pulse generators:

1. **Home appliances**

CB radios, electric drills, electric blankets, electric shavers, ham radios, heating pads, metal detectors, microwave ovens, TV transmitters and remote control TV changers, in general, have not shown to damage pacemaker pulse generators, change pacing rates or totally inhibit pacemaker output. Several of these devices have a remote potential to cause interference by occasionally inhibiting a single beat. However, most people can continue to use these devices without significant worry about damage or interference with their pacemakers. Power-generating equipment, arc welding equipment and powerful magnets (as in medical devices, heavy equipment or motors) can inhibit pulse generators. Patients who work with or near such equipment should know that the pacemakers may not work properly under these conditions

Table 1. Typical specifications of a pacemaker [23,30].

Pacemaker	
Dimensions	47 x 64 x 11.5 mm
Mass	38g – 53g
Case Material	Titanium
Pulse Generator : material	
Battery Chemistry	Encasing
Lithium-Carbone monofluoride WG9086	Titanium
Lithium-Iodine WG 8077	upgrade from ceramics
Mercury	epoxy resin with silicone rubber
Electrode : material	
Titanium	
silver alloyed with palladium	
platinum alloyed with iridium	
Tungsten Carbide-Cobal	
Lead Body : material	
Injection molded	
polyether urethane	
polytetramethylene ether glycol and 1,4-butanediol	
Fixation Mechanism	
Nickel-cobalt alloy with silver core helix	
Electrically active platinum-iridium helix	
Titanium alloy screws	

2. **Cell phones**

Cell phones available in the United States (less than 3 watts) don't seem to damage pulse generators or affect how the pacemaker works. Technology is rapidly changing as the Federal Communications Commission (FCC) is making new frequencies available. Newer cell phones using these new frequencies might make pacemakers less reliable. A group of cell phone companies is studying that possibility.

3. **The Pacemaker and the medical equipments**

One should carry a wallet ID card, the doctors and dentists should be told if one has a pacemaker. Magnetic resonance imaging (MRI) uses a powerful magnet to produce images of internal organs and functions. The magnet can interrupt the pacing and inhibit the output of pacemakers. If MRI must be done, the pacemaker output in some models can be reprogrammed. The possible risks and benefits should be discussed with the doctor before undergoing MRI scanning. Extracorporeal shock-wave lithotripsy (ESWL) is a noninvasive treatment that uses hydraulic shocks to dissolve kidney stones. This procedure is safe for most pacemaker patients, with some reprogramming of the pacing. One should be patients with certain kinds of pacemakers implanted in the abdomen should avoid ESWL. Specific case should be discussed with the doctor before and after the treatment. Radiofrequency (RF) ablation uses radio waves to manage a wide variety of arrhythmias. Recent studies of patients with implanted pacing systems measured the units before, during and after RF catheter ablation. These studies showed that most permanent pacemakers aren't adversely affected by radio frequencies during catheter ablation. A variety of changes in pacemaker can occur during and after the treatment. The doctor should carefully evaluate the pacing system after the procedure. Transcutaneous electrical nerve stimulation (TENS) is used to relieve acute or chronic pain. Most studies have shown that TENS rarely inhibits bipolar pacing. It may sometimes briefly inhibit unipolar pacing. This can be treated by reprogramming the pulse generator. Diagnostic radiation (such as X-ray screening) appears to have no effect on pacemaker pulse generators. However, therapeutic radiation (such as for treating cancerous tumors) may damage the pacemaker's circuits. The degree of damage is unpredictable and may vary with different systems. But the risk is significant and builds up as the radiation dose increases. The American Heart Association recommends that the pacemaker be shielded as much as possible, and moved if it lies directly in the radiation field. The electrocardiogram (ECG) should be monitored during the treatment, and the pulse generator should be tested often after and between radiation sessions. Dental equipment doesn't appear to affect pacemakers adversely. Some patients may feel an increase in pacing rates during dental drilling. Electroconvulsive therapy (such as for certain mental disorders) appears to be safe used in patients with pacemakers. Short-wave or microwave diathermy uses high-frequency, high-intensity signals. These may bypass the pacemaker's noise protection and interfere with or permanently damage the impulse generator.

The Implantation of a Pacemaker (Figure 4)

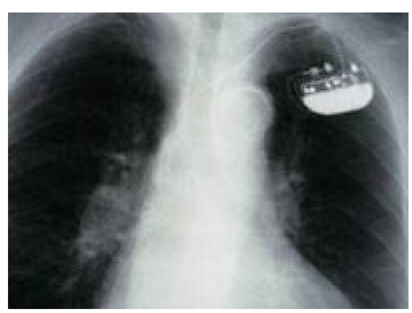

Figure 4. Frontal Chest X-Ray of Dual Chamber Pacemaker [30].

Due to today's technology, pacemaker implantation has become much easier and safer. This common procedure often takes less than an hour. Usually, the physician locally anaesthetizes the region under the collarbone. Then the pacemaker lead is carefully inserted through a vein into the heart. Because blood vessels are not sensitive to pain, no extra anesthesia is needed. In general, X-ray monitoring is used for controlling the correct positioning of the lead within the right atrium or ventricle. Only after the functioning of the lead is tested will it be connected to the pacemaker. The pacemaker itself is implanted just under the skin in a small pocket below the collarbone. Finally, the physician closes the incision with stitches.

General Questions

Can I go through airport security systems or anti-theft detectors?

Yes. BIOTRONIK pacemakers are protected from the influence of external factors (for more information, please ask the physician). However, one must state that one has an implanted pacemaker, because the metal housing may set off the security alarm system. To be on the safe side, inform the airport personnel about the pacemaker and pass through the detector quickly.

Do I feel the pacemaker working?

No. The pacemaker functions at such a low level of electrical current that it only affects the heart and the surrounding tissue. However, should one experiences any symptoms (such as frequent hiccups), he should inform the physician.

How long does a pacemaker battery last?

The exact life for replacement depends on the pacemaker type, medical condition, lifestyle and other factors. In general, most pacemakers last for some years. The physician is the right person to tell.

What does happen when my pacemaker needs to be replaced?

The pacemaker is removed through minor surgery. The leads are left in the heart, provided they are functioning properly, and are connected to the new pacemaker. Usually a short hospital stay is necessary.

Will the leads also have to be replaced?

During pacemaker replacement, the doctor checks the leads to make sure that these are functioning properly. If these do not need changing, then these will be simply connected to the new pace maker.

Will the pacemaker need adjusting after implantation?

Possibly. Depending on the medical condition and lifestyle, a slight readjustment may be necessary.

Will the pacemaker still be able to provide work as the battery grows weaker?

Yes. The physician can determine how much battery life is felt at the regular follow-up appointments.

How do a heart and a pacemaker react in the case of passing away?

A heart can only function when it is supplied with blood and energy. In the case of death, the small electrical impulses from the pacemaker will have no effect on the heart.

Can I use a mobile telephone?

Yes. One can use the mobile telephone safely, but some precautions should be taken: Check with the physician for specific situation. Be sure not to place the telephone near the pacemaker site (such as in the breast pocket). When phoning, hold the receiver to your ear that is on the opposite side of the body to the site of the pacemaker. Due to differences in telephone technology, please check with the physician.

How often do I have to see my physician for follow-up visits?

The physician will determine your particular follow-up schedule. In general, follow-up appointments are scheduled every 6-12 months.

Can I still use home electrical appliances such as microwaves, dryers, electric blankets, and massagers?

The normally functioning home electrical appliances mentioned above will not damage the pacemaker.

Will my body show allergic reactions to the pace maker materials?

Normally not. Biotronik uses only highly biocompatible materials such as titanium or FDA proven plastics which do not react with bodily fluids.

History and Technology Development of a Pacemaker

1. The Early Years

Early external pacemakers - The first pacemakers of the 1950s were not totally implanted in the body. One end of a small wire, called a "lead," was implanted into the heart. The other end of the lead was connected to an external pacemaker that was AC powered. Mobility of the patient was limited to the length of extension cord. A power failure was a constant concern.

First battery-powered external pacemaker - In 1957 the world's first transistorized, battery-powered, wearable pacemaker was developed. This gave patients mobility and eliminated concerns about a power failure.

2. Sixties

First human implant of a totally implantable pacemaker -The first human implant of a totally implantable pacemaker was in 1960. Its battery life was approximately 12-18 months.

Advances in Pacing Leads - In the mid-1960s, "transvenous leads," leads that could be inserted through a vein leading to the heart, replaced earlier leads that were attached to the outer surface of the heart. Pacemaker and lead implants could now be done without opening the chest cavity or using general anesthesia.

World's First "Demand" Pacemaker –"Demand" pacemakers, introduced in the mid-1960s, sense when the heart is beating on its own and provide pacing only when necessary. Earlier pacemakers continuously paced the heart at a set "fixed" rate. All new pacemakers today are "demand" models.

3. Seventies

Further advances in the 1970s –New lead designs were developed to replace earlier "smooth tip" leads. Still used today, these new "tined" (pronged) leads and "active fixation" (screw-in type) leads provide a more secure attachment to the heart tissue and help prevent the lead from slipping out of place.

Extended battery life and new casing –The introduction of a lithium iodine battery in 1975 greatly extended the pacemaker battery life (10+ years for some models) and replaced the mercury-zinc battery.

Titanium casing was developed to enclose the battery and circuitry. Epoxy resin with silicone rubber previously encased the inner components. The new titanium casing (along with special filters) helps shield the components and greatly reduces outside electromagnetic interference. Patients with these newly designed pacemakers could now safely use microwave ovens and other appliances and equipment found in the home and office.

First programmable pacemakers - With the introduction of programmable pacemakers in the mid-1970s, pacemaker settings could be programmed using radio-frequency signals. This eliminated the need for surgery when/if any pacemaker programming adjustments were necessary.

First dual-chamber pacing –The first programmable pacemaker that could sense and pace the upper (atrium) and lower (ventricle) chambers of the heart was introduced in the late 1970s. Using two leads, dual-chamber pacemakers maintain synchronized timing between the upper and lower chambers of the heart to ensure efficient blood flow.

4. Eighties

First steroid-eluting lead - In the early 1980s, leads were made available that emit a steroid drug from the tip of the electrode. This drug suppresses inflammation of the heart wall.

Rate responsive pacing - Pacemakers with a "rate responsive" feature became available in the mid-1980s. A tiny crystal sensor inside the pacemaker detects body movement and its signals adjust the pacemaker rate up or down according to the wearer's activity.

5. Nineties

Sophisticated devices - In the 1990s, pacemakers like micro-computers, are smaller than earlier devices (1/2 the size), and can last much longer. With the recent introduction of "mode switching," devices can recognize an abnormally fast heart rate in the upper chamber of the heart and react by automatically changing the therapy the pacemaker delivers. This feature allows the pacemaker to deliver the most appropriate pacing therapy.

Adjusting to each person's activity—In the late 1990's, pacemakers can mimic the heart's natural rhythm even more closely by adjusting the rhythm according to a person's activity level.

More useful information—Pacemakers can now collect information and store it until the next clinic visit. Some pacemakers also make follow-up easier by storing patient data directly into the memory of the pacemaker (such as name, diagnosis, doctor).

6. Future Developments

1. Features and capabilities that will enable the pacemaker battery to last longer.

2. Features that make follow-up visits easier and faster.

3. Enhanced features in the pacemaker that monitor the heart's activity and automatically change the therapy delivered by the pacemaker, reducing the number of visits to the doctor.

Some Example of Pacemaker

1. Implantable pulse generator (Figure 5 and table 2) for cardiomyoplasty and aortomyosplasty surgical procedures, include:

-DDD pacemaker.
-Flexible LD channel.
-Work/Rest periods.
-LD inhibition on PVC and UTR.
-Programmable uses of the magnet.
-Friendly programmer.

Figure 5. Ld Pace- II [18].

Table 2. Specifications of a LD Pace- II pacemaker [18].

DDD Pacemaker	
Modes	VVI,VVT,VOO,AAI, AAT, AAT, AOO, DDD, VDD
Refractory Periods	From 195 to 480 oms
Basic Ratest	From 36 to 120 min
AV Delay	From 55 to 280 ms
Amplitudes	From 0.7 to 5.5 V, unipolar / bipolar
Sensed AV Delay	Shift of 5 to 40 oms
Pulse Width	From 0.1 to 1.5 ms
Adaptive AV Delay	on / off
Atrial Sensitivity	From 0.5 to 4.0 mV unipolar / bipolar
UTR	From 36 to 140 min^{-1}
Ventricular Sensitivity	From 1.0 to 8.0 mV, unipolar / bipolar
UTR Mode	Off, Wenckebach, Fixed Block
Blanking	From 39 to 63 ms
Hysteresis (single chamber)	From 0% to 20%
Non Programmable Parameters	
Independent upper rate limit	180 min^{-1}
PVC Response	The device reverts to DVI mode for a single cycle

Table 2. (continued):

End-of-Service Indicators	
EOL (End Of Life)	When the remaining capacity of the battery is under 5%, the basic rate is decreased by 10 min^{-1} and the ratio is incremented by one.
Latissimus Dorsi Muscle (LD) Pacing Parameter	
Modes	VVI-LD, VVT-LD, VDD-LD, DDD-LD
Ratio	From 1:1 to 1:16
Output to muscle	Off, Ventricular pace and / or sense
Adaptive ratio	On / off, different ratios according to actual heart rate
Amplitudes	From 0.45 V to 7.5 V unipolar / bipolar
Adaptive train	On / off, different ratios according to actual heart rate
Pulse width	From 0.06 to 1.0 ms
Adaptive V-LD Delay	On / off
Pulse interval	From 16 to 133 ms
Work regiment	From 1 to 120 min
V-LD Delay	From 2 to 350 ms
Magnet Uses	No use, turn LD On/OFF, switch Ratio
Magnetic response	
Programmed Magnet response, no use	The presence of a magnet will have no effect.
Programmed Magnet response: off / on	The presence of a magnet will inhibit the muscle channel until the magnet is detected again.
Programmed Magnet response: switch ratio	The presence of a magnet will change the ratio to the programmed night ratio. When the magnet is detected again, the ratio goes back to the programmed Ratio.
Power source	
Battery Chemistry	Liithium-Carbone monofluoride WG9086
Initial Voltage	2.8 V (load 5 kohms)
Maximum Available Capacity	2.5 Ah
Physical Characteristics	
Dimmensions	47 x 64 x 11.5 mm
Mass	53 g
Case Material	Titanium
Cardiac Connectors	IS-1
Muscle Connectors	Special connectors
Service life	
The expected life of the generator, stimulating 100% both, ventricule and lattissimus dorsi at 50 min^{-1} with 2.5 V amplitude, pulse width of 0.488 ms, a burst of 6 pulse and ratio 1:4 is 8 years. (10 years if the ventricle is sensed).	

2. Apex model SSI 3143 (Figure 6 and table 3)

- Coupled stimuli and temporary programming for tachycardia treatment.
- Hysteresis.
- Telemetry information of battery status.
- Marker pulses.
- Automatic access to Data Base.
- Statistic.

Figure 6. Apex model SSI 3143 [19].

Table 3. Specifications of a 'Apex SSI 3143' pacemaker[19].

Programmable Parameter	
Pacing Modes	VVI, VVT, VVO, AAI, AAT, AOO, OFF
Basic Pacing Rates	From 30 to 120 min^{-1}
Pulse Widths	From 0.122 ms to 1.952 ms in steps of 0.122 ms
Refractory Periods	From 203 to 438 ms in steps of 15.625 ms
Sensitivities	From 0.5 to 4.0 mV in steps of 0.5 mV
Hysteresis	From 0 to 20% in steps of 5%
Electrical configuration for pacing	Monopolar/Bipolar
Electrical configuration for sensing	Monopolar/Bipolar
Tachycardia Treatment	
Temporary Programming	From 30 to 400 min^{-1}
Coupled Pacing Delay	395 ms, 410 ms, 426 ms, Off
Maximum Rate	From 60 a 150 min^{-1}
Magnetic response	
Mode	VOO
Rate	At BOL: 80 ms reduction in pulse internal. At ERI: 80 ms. Increase in pulse interval.

Table 3. (continued):

End-of-Service Indicator	
ERI (elective replacement)	When the remaining capacity of the battery is between 4% and 8%, the pulse internal increase 80 ms when a magnet is applied.
EOL (End Of Life)	When the remaining capacity of the battery is under 4%, the pulse internal is increasedby 120 ms.
Power source	
Battery Chemistry	Lithium-Iodine WG 8077
Initial Voltage	2.8 V
Maximum Available Capacity	1.66 A-hr
Physical Characteristics	
Dimensions	47 X 55 X 8.5 mm
Mass	38 g
Case Material	Titanium
Connectors	IS-1
Service Life	
The expected life of the generator, stimulating 100% at 70 min^{-1} with 5 V amplitude and pulse width of 0.488 ms, is 11 years and 4 months	
Telemetry Data	
Parameters	All programmable
Identification	Model and Serial Number
Battery Condition	BOL OK, OK, ERI and EOL.
Statistics	Sensed operations and paced operations.
Protections	
Noise Detection	When the pacemaker senses events with frequency exceeding 11 Hz, it changes to VOO mod

3. External Pacemaker model 196 (figure 7 and table 4)

- 6 Programmable Parameters.
- Tachycardia Treatment.
- Battery Status Indicator.

Figure 7. External Pacemaker model 196[17].

Table 4. Specifications of a external pacemaker model 196.[17].

Programmable Paranmeter values	
Pacing Modes	SSI, SOO, SST
Basic Pacing Rates	From 36 to 163 min^{-1}
Pulse Widths	From 0.170 to 1.850 ms, (12 values)
Pulse Amplitudes	From 0.5 to 5.0 V in steps of 0.5 V, 8 V and 11 V
Refractory Periods	250 and 350 ms
Sensitivities	From 0.5 to 4.0 mV in steps of 0.5 mV
Tachycardia Treatment	
Temporary Programming	Asynchronous stimulation using a rate 4 times greater then the basic rate. It is necessary to press a special button during operation.
Battery Change Indicator	
In normal operation, a green indicator lights following the cardiac rate. When the remaining charge of the batteries is less than 20%, the indicator turns red.	
Power Source	
Type	2 alkaline AAA batteries
Nominal Voltage	3 V
Service Life	
The expected life of the batteries, stimulating 100% at 70 min^{-1} with 5 V amplitude and pulse width of 0.48 ms, is 6 months.	
Protections	
Noise Detection	When the pacemaker senses events with frequency exceeding 11 Hz, it changes to VOO mode
Run Away Limit	The pacemaker includes an antirunaway circuit to avoid the generation of stimuli with a rate over 180 min^{-1}. (except in temporary programming)
Trigger Upper Rate	117 min^{-1}

CHARACTERISTICS OF MATERIALS FOR EACH COMPONENT OF PACEMAKER

1. Casing of a Pacemaker includes:

- Battery
- Electronic circuitry: converts electrical energy to electrical signals and controls timing of the delivery of signals
  - Lithium-Carbone
  - Lithium-Iodine
  - Mercury

Common Casing Materials are:

- Titanium
  - High modulus of elasticity.
  - High resistance to corrosion.
  - High durability.
  - Strong.
  - Noncorrosive.
  - Not degraded.
- Upgrade from ceramics and epoxy resin with silicone rubber.

2 . Electrode

- Located at tip of lead.
- Delivers electrical energy from pacemaker to heart and information from heart back to pacemaker.
- Common electrode materials are:
- Titanium
  - High modulus of elasticity.
  - High resistance to corrosion.
  - High durability.
- Platinum-iridium
  - Stronger than most steels.
  - Used in steroid-eluting leads.
- May be coated with iridium oxide
  - Prevents nonconductive layers from forming.
  - Reduces local inflammation.
- Stainless steal, silver and cobalt alloys.

3. Lead Body

- Requirements
  - Flexible
  - Durable
  - Noncorrosive
  - Good electrical conductor

Materials of lead body one:

- Insulated with silicone rubber or polyurethane
  - Polyurethanes
- High strength
  - Enables thinner lead to be used
  - Offers greater lead flexibility
- Very low coefficient of friction when wet
  - Silicone rubber
- Not degraded by metal ion-induced oxidation

4. Steroid Eluting Leads

- Electrode emits steroid when exposed to body fluids to suppress inflammatory response of heart wall
  - reduces energy requirements of pacemaker
- Platinum-iridium porous electrode contains silicone rubber matrix
- Silicone rubber matrix contains steroid Dexamethasone sodium phosphate
- Soluble Polyethylene glycol or mannitol capsule placed on electrode tip to facilitate passage of fixation mechanism

5. Fixation Mechanism

- Holds the tip of the lead (electrode) in place in the heart
- Materials currently used :
  - Nickel-cobalt alloy with silver core helix
  - Electrically active platinum-iridium helix
  - Titanium alloy screws

6. Connector pin

- Inserted into connector block
- Permits continuous communication between pacemaker and lead
- Injection molded of polyether urethane
- Composed of polytetramethylene ether glycol and 1, 4-butanediol

Titanium

Titanium is used for casing, electrode and fixation mechanism. The metal was a laboratory curiosity until 1946, when Kroll showed that titanium could be produced commercially by reducing titanium tetrachloride with magnesium. This method is largely used for producing the metal today. Titanium, it has a low density, good strength, is easily fabricated, and has excellent corrosion resistance. It is ductile only when it is free of oxygen. Titanium is as strong as steel, but 45% lighter. It is 60% heavier than aluminum, but twice as strong. (Tables 5 and 6 give characteristics of a titanium)

Table 5. Characteristics of a titanium [24]

Name	Titanium	Symbol	Ti
Atomic number	22	Atomic weight	47.90
Density @ 293 K	4.50 g/cm3	Atomic volume	10.64 cm3/mol
Group	Trans. Met.	Discovered	1791
Physical States			
State (s, l, g)	s		
Melting point	1933.2 K	Boiling point	3558 K
Heat of fusion	15.450 kJ/mol	Heat of vaporization	421.00 kJ/mol
Energies			
1st ionization energy	658 kJ/mole	Electronegativity	1.54
2nd ionization energy	1310.3 kJ/mole	Electron affinity	7.6 kJ/mole
3rd ionization energy	2652.5 kJ/mole	Specific heat	0.52 J/gK
Heat atomization	470 kJ/mole atoms		

Table 5. (continued)

Oxidation & Electrons			
Shells	2,8,10,2	Electron configuration	[Ar] 3d2 4s2
Minimum oxidation number	-1	Maximum oxidation number	4
Minimum common oxidation number	0	Maximum common oxidation number	4
Appearance & Characteristics			
Structure	hcp: hexagonal close pkd	Color	gray
Uses	steel,white pigment(TiO2)	Toxicity	Not known
Hardness	mohs	Characteristics	Max strength/weight ratio
Conductivity			
Thermal conductivity	21.9 J/m-sec-deg	Electrical conductivity	23.81 1/mohm-cm
Polarizability	14.6 A^3		
Abundance			
Source	Ilmenite, rutile(oxide)	Rel. abund. solar system	3.380 log
Abundance earth's crust	3.8 log	Cost, pure	6.1 $/100g
Cost, bulk	$/100g		

Table 6. Mechanical properties of a titanium [24]

Mechanical Properties			
Property	Metric	English	Comments
Density	4.51 g/cc	0.163 lb/in³	Typical
Ultimate Tensile Strength	725 MPa	105000 psi	Typical
Tensile Strength (Yield)	570 MPa	82700 psi	Typical 0.2% Proof Stress
Elongation at Break	16 %	16 %	Typical
Modulus of Elasticity	105 - 120 GPa	15200 – 17400 ksi	Typical
Fatigue Strength	360 MPa	52200 psi	Limit; test specifics not reported
Thermal Properties			
Beta Transus	960 °C	1760 °F	

STAINLESS STEEL (electrode)

Table 7.Typical chemical and physical properties of stainless steel.

Property	304	430	410
Chemical Composition	(Austenitic)	(Ferritic)	(Martenitic)
Max. unless otherwise noted)			
Carbon	0.08	0.12	0.15
Maganese	2.00	1.00	1.00
Phosphorus	0.045	0.04	0.04
Sulfur	0.03	0.03	0.03
Silicon	1.00	1.00	1.00
Chromium	18.00-20.00	16.00 -18.00	11.5 -13.50
Nickel	8.00 -10.50	---	---
Tensile Strength			
Ksi	84	75	70
MPa	579	517	483
Yield Strength (0.2% offset			
Ksi	42	50	45
MPa	290	345	310
Elongation (in 2" or 50.8 mm)			
%	55	25	25
Modulus of Elasticity in Tension			
psi x 10^6	28	29	29
GPa	193	200	200
Modulus of Elasticity in Torsion			
psi x 10^6	12.5		
GPa	86.2		
Density			
Lbs / in^3	0.29	0.28	0.28
kg /$meter^3$	8060	7780	7780
Specific Heat			
Btu/lb/F	0.12	0.11	0.11
32-212ºF (0-100ºC) J/kg.k	503	460	460

Table 7. (continued) [24].

Thermal Conductivity			
Btu/hr/ft/F			
212F (100C)	9.4	15.1	14.4
932F (500C)	12.4	15.2	16.6
W/m.K			
212F (100C)	0.113	0.182	0.174
932F (500C)	0.149	0.183	0.201
Mean Coefficient of Thermal Expansion			
x10^{-6}/F			
32-212F (0-100C)	9.6	5.8	5.5
32-600F (0-315C)	9.9	6.1	6.3
32-1000F (0-538C)	10.2	6.3	6.4
32-1200F (0-648C)	10.4	6.6	6.5
32-1800F (0-982C)		6.9	.
x10^{-6}/ºC			
32-212F (0-100C)	17.3	10.4	5.5
32-600F (0-315C)	17.9	11	6.3
32-1000F (0-538C)	18.4	11.4	6.4
32-1200F (0-648C)	18.8	11.9	6.5
32-1800F (0-982C)		12.4	
Melting Point			
ºF	2550-2650	2600 - 2750	2700 - 2790
ºC	1400-1455	1425 -1510	1485 - 1535

Electrical Resistivity				
Microhm - mm	Type 304	Type 430	Type 410	S13800
68F (20C)	720	600	570	1020
212F (100C)	780	675	640	
392F (200C)	860	770	720	
752F (400C)	1000	925	880	
1112F (600C)	1110	1050	1035	
1472F (800C)	1210	1150	1110	
1652F (900C)	1260			

Cobalt (electrode, fixation mechanism)

Table 8. Properties of a cobalt [24].

Physical Properties			
	Metric	English	Comments
Density	8.8 g/cc	0.318 lb/in³	
Mechanical Properties			
Hardness, Brinell	125	125	
Hardness,Vickers	253	253	
Tensile Strength, Yield	225 MPa	32600 psi	
Modulus of Elasticity	211 GPa	30600 ksi	
Poisson's Ratio	0.32	0.32	
Shear Modulus	82.6 GPa	12000 ksi	
Electrical Properties			
Electrical Resistivity	6.24e-006 ohm-cm	6.24e-006 ohm-cm	
Magnetic Permeability	Max 245	Max 245	
Magnetic Permeability	68	68	Initial
Curie Temperature	1121 °C	2050 °F	
Thermal Properties			
Heat of Fusion	259.6 J/g	112 BTU/lb	
CTE, linear 20°C	12.5 µm / m-°C	6.94 µin / in-°F	over the range 20-100ºC
CTE, linear 250°C	14.2 µm / m-°C	7.89 µin / in-°F	at 200°C
Heat Capacity	0.44 J/g-°C	0.105 BTU / lb-°F	
Thermal Conductivity	69.21 W / m-K	480 BTU-in/hr-ft²-°F	
Melting Point	1493 °C	2720 °F	
Optical Properties			
Emissivity (0-1)	0.13	0.13	500°C unoxidized, total spectrum
Reflection Coefficient, Visible (0-1)	0.37	0.37	200 nm
Reflection Coefficient, Visible (0-1)	0.675	0.675	1060 nm

Cobalt-Base Alloys (electrode, fixation mechanism)

Table 9. Properties of Co-Ni alloy [24].

Component	Wt. %		
B	2	---	---
C	0.6	---	---
Co	46.9	---	---
Cr	16.2	---	---
Fe	1.3	---	---
Ni	23.5	---	---
Si	1.9	---	---
W	7.6	---	---
	Metric	English	Comments
Density	9.06 g/cc	0.327 lb/in³	---
Mechanical Properties			
Hardness, Rockwell C	41 – 46	41 – 46	---
Processing Properties			
Melt Temperature	1140 °C	2080 °F	fusing temperature
WALLEX 50 – Cobalt-Nickel Alloy			
Component	Wt. %		
B	3.4	---	---
C	0.8	---	---
Co	45.05	---	---
Cr	19	---	---
Fe	1	---	---
Ni	18	---	---
Si	2.75	---	---
W	10	---	---
Density	9.1 g/cc	0.329 lb/in³	---
Mechanical Properties			
Hardness, Rockwell C	56 – 61	56 – 61	---
Processing Properties			
Melt Temperature	1090 °C	2000 °F	fusing temperature

Table 9. (continued):

WALLEX 60 - Cobalt-Nickel Alloy			
Component	Wt. %		
B	2.3		
C	2.3		
Co	36.25		
Cr	12.35		
Fe	0.65		
Ni	9		
Si	1.75		
W	35.4		
Density	11.9 g/cc	0.43 lb/in³	
Mechanical Properties			
Hardness, Rockwell C	Min 58	Min 58	
Processing Properties			
Melt Temperature	1110 °C	2030 °F	fusing temperature

Polyurethane (lead body, connector pin)

Table 10. Properties of a polyurethane [24].

	Metric	English	Comments
Density	1.09 - 1.12 g/cc	0.0394 - 0.0405 lb/in³	Average = 1.1 g/cc; Grade Count = 4
Linear Mold Shrinkage	0.006 cm/cm	0.006 in/in	Grade Count= 3
Melt Flow	11- 26 g/10 min	11 – 26 g/10 min	Average = 17.7 g/10 min; Grade Count=3
Mechanical Properties			
	Metric	English	Comments
Hardness, Shore A	92	92	Grade Count = 1
Tensile Strength, Ultimate	16 - 35.2 MPa	2320 - 5110 psi	Average = 26.6 MPa; Grade Count = 4
Tensile Strength, Yield	12 - 35.2 MPa	1740 - 5110 psi	Average = 24.5 MPa; Grade Count = 4

Table 10. (continued):

Elongation at Break	180 - 320 %	180 - 320 %	Average = 250%; Grade Count = 4
Elongation at Yield	16 - 50 %	16 - 50 %	Average = 31.3%; Grade Count = 3
Tensile Modulus	0.0827 - 0.745 GPa	12 - 108 ksi	Average= 0.44 GPa; Grade Count = 3
Izod Impact, Notched	NB	NB	Grade Count=3
Izod Impact, Notched Low Temp	3.74 - 13.9 J/cm	7.01 - 26 ft-lb/in	Average = 8.4 J/cm; Grade Count = 3
Charpy Impact, Unnotched	NB	NB	Grade Count = 3
Charpy Impact, Notched Low Temp	4.15 - 12 J/cm²	19.8 - 57.1 ft-lb/in²	Average = 7.7 J/cm²; Grade Count = 3
Charpy Impact, Unnotched Low Temp	NB	NB	Grade Count = 3
Charpy Impact, Notched	Min 11 J/cm²	Min 52.4 ft-lb/in²	Average = 11 J/cm²; Grade Count = 3
Taber Abrasion, mg/1000 Cycles	4	4	Grade Count = 1
Thermal Properties			
CTE, linear 20°C	88 – 104 µm/m-°C	48.9 - 57.8 µin/in-°F	Average = 94 µm/m-°C; Grade Count=3
Heat Capacity	1.5 J/g-°C	0.359 BTU/lb-°F	Grade Count = 1
Thermal Conductivity	0.19 W/m-K	1.32 BTU-in/hr-ft²-°F	Grade Count = 1
Maximum Service Temperature, Air	44 - 63 °C	111 - 145 °F	Average = 54.7°C; Grade Count = 3
Deflection Temperature at 0.46 MPa (66 psi)	57 - 78 °C	135 - 172 °F	Average = 68.7°C; Grade Count=3

Table 10. (continued):

Deflection Temperature at 1.8 MPa (264 psi)	44 - 63 °C	111 - 145 °F	Average = 54.7°C; Grade Count=3
Vicat Softening Point	101 - 102 °C	214 - 216 °F	Average = 100°C; Grade Count = 3
Optical Properties			
Gloss	72 - 87 %	72 - 87 %	Average = 78.3%; Grade Count = 3

Polyethylene glycol (steroid eluting leads)

Table 11. Properties of a polyethylene glycol [24].

	Metric	English	Comments
Specific Gravity	1.22 g/cc	0.0441 lb/in³	ASTM D792
Linear Mold Shrinkage	0.005 - 0.006 cm/cm	0.005 - 0.006 in/in	1/8 inch (3.18 mm) section; ASTM D955
Mechanical Properties			
Tensile Strength, Ultimate	31 MPa	4500 psi	ASTM D638
Elongation at Break	Min 10 %	Min 10 %	ASTM D638
Modulus of Elasticity	1.38 GPa	200 ksi	ASTM D638
Flexural Modulus	1.38 GPa	200 ksi	ASTM D790
Flexural Yield Strength	49.6 MPa	7200 psi	ASTM D790
Izod Impact, Unnotched	10.7 J/cm	20 ft-lb/in	1/8 in (3.18 mm) section; ASTM D256
Izod Impact, Notched	0.801 J/cm	1.5 ft-lb/in	1/8 in (3.18 mm) section; ASTM D256
Electrical Properties			
Electrical Resistivity	1e+009 - 1e+010 ohm-cm	1e+009 - 1e+010 ohm-cm	ASTM D257
Surface Resistance	1e+010 - 1e+011 ohm	1e+010 - 1e+011 ohm	ASTM D257
Static Decay	Max 2 sec	Max 2 sec	FTMS-4046.1

SILICONE RUBBER INSULATION (lead body, steroid eluting leads)

Silicone Rubber Sheet

Table 12. Properties of silicone rubber sheet [24].

Standard Size :	1M X 2M (Width by Length)		
Width :	1.22 M(48inch)		
Length :	Any length longer than 2m		
Thickness :	From 1 mm to 25 mm		
Standard Color :	Translucent (other colors are available for request)		
Specification :	Test Method	Units	Test Results
Specific Gravity	ASTM D792	g/cm3	1.2
Hardness	ASTM D2240	Shore A	50+-5
Tensile Strength	JIS K6301	kfg/cm2	100
Elongation	JIS K6301	%	390
Breakdown Voltage	UL94HB	KV	24
Volume Resistively	UL94HB	.cm	1 x 1015
Aging Properties, 100oC, 72 hours	Hardness Change		-7 shore A
	Tensile Strength Change		-26%
	Elongation Change		-7%
Oil Resistance Properties, test by JIS #3 test oil, under 150oC, 72 hours	Hardness Change		-17 shore A
	Tensile Strength Change		-35%
	Elongation Change		-6%
	Volume Change		+35%

Silver (electrode)

Table 13. Properties of silver [24].

	Metric	English	Comments
Density	10.491 g/cc	0.379 lb/in³	
Mechanical Properties			
Static Decay	Max 2 sec	Max 2 sec	FTMS-4046.1

Table 13. (continued):

Hardness, Vickers	25	25	Annealed
Tensile Strength, Ultimate	140 MPa	20300 psi	Annealed
Modulus of Elasticity	76 GPa	11000 ksi	
Poisson's Ratio	0.37	0.37	Annealed
Poisson's Ratio	0.39	0.39	Hard drawn
Shear Modulus	32 GPa	4640 ksi	Calculated; Annealed.
Electrical Properties			
Electrical Resistivity	1.55e-006 ohm-cm	1.55e-006 ohm-cm	
Magnetic Susceptibility	2e-007	2e-007	cgs/g
Thermal Properties			
Heat of Fusion	105 J/g	45.2 BTU/lb	
CTE, linear 20°C	19.6 µm/m-°C	10.9 µin/in-°F	over the range 20-100ºC
CTE, linear 250°C	19.9 µm/m-°C	11.1 µin/in-°F	over the range 0-250ºC
Thermal Properties			
CTE, linear 500°C	20.6 µm/m-°C	11.4 µin/in-°F	over the range 0-500ºC
CTE, linear 1000°C	22.4 µm/m-°C	12.4 µin/in-°F	over the range 0-900ºC
Heat Capacity	0.234 J/g-°C	0.0559 BTU/lb-°F	
Thermal Conductivity	419 W/m-K	2910 BTU-in/hr-ft²-°F	
Melting Point	961.93 °C	1760 °F	
Optical Properties			
Emissivity (0-1)	0.055	0.055	700ºC
Reflection Coefficient, Visible (0-1)	0.9	0.9	

316LS Stainless Medical Implant Alloy(Annealed)

Table 14. Properties of a stainless steel 316Ls [24].

	Metric	English	Comments
Density	7.95 g/cc	0.287 lb/in³	
Mechanical Properties			
Hardness, Rockwell B	88	88	
Tensile Strength, Ultimate	586 MPa	85000 psi	
Tensile Strength, Yield	434 MPa	62900 psi	0.2% Offset
Elongation at Break	57 %	57 %	
Reduction of Area	88 %	88 %	
Electrical Properties			
Electrical Resistivity	7.4e-005 ohm-cm	7.4e-005 ohm-cm	Electrical Resistivity
Thermal Properties			
CTE, linear 20°C	18.5 µm/m-°C	10.3 µin/in-°F	0-649°C
CTE, linear 250°C	18.5 µm/m-°C	10.3 µin/in-°F	0-649°C
CTE, linear 500°C	18.5 µm/m-°C	10.3 µin/in-°F	0-649°C
Heat Capacity	0.5 J/g-°C	0.12 BTU/lb-°F	

Table 15. Composition of mechanical properties of biomaterials [24].

Property	units	STAINLESS STEEL 316	Titanium	Cobalt	Silver
Tensile Strength Ultimate	MPa	579	725	420	140
Tensile Strength Yield	MPa	290	570	225	269
Elongation at Break	%	55	16	45	2

Table 15. (continued):

Modulus of Elasticit y	GPa	193	105 - 120 105 - 120	211	76
Density	g/cc	8.08	4.51	8.8	10.49 1
Poisson's Ratio	g/cc	0.305	0.33	0.32	0.37
Shear Modulus	GPa	10.7	90	82.6	32

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GLOSSARY

Atria the upper heart chambers.

Biocompatible: The property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue.

Bradycardia relatively slows heart action whether physiological or pathological.

Chambers An enclosed space in the body of an organism; a cavity.

Diathermy therapeutic generation of local heat in body tissues

Electronic circuitry equipment that involves the controlled conduction of electrons.

Electroconvulsive producing, or involving a convulsive response to a shock of electricity.

Electrode a conductor used to establish electrical contact with a nonmetallic part of a circuit.

Frequencies the number of individuals in a single class when objects are classified according to variations in a set of one or more specified attribute, the number of repetitions of a periodic process in a unit of time.

Hysteresis the lagging of an effect behind its cause, as when the change in magnetism of a body lags behind changes in the magnetic field.

Leakage the unwanted discharge of a fluid from some container, the quantity of electricity thus wasted.

Microwave a comparatively short electromagnetic wave one between about 1 millimeter and 1 meter in wavelength.

Node a pathological swelling or enlargement, a discrete mass of one kind of tissue enclosed in tissue of a different kind, a point, line, or surface of a vibrating body that is free or relatively free of vibratory motion.

Nourishment to provide with food or other substances necessary for life and growth; feed.

Pacemaker electronic devices used to stimulate or regulate contractions of the heart muscle.

Pulse generator a generator of single or multiple voltage pulses, usually adjustable for pulse rate.

Strain an act of straining or the condition of being strained a force, influence, or factor causing such tension one resulting from a wrench or twist and involving undue stretching of muscles or ligaments, deformation of a material body under the action of applied forces.

Stress force exerted when one body or body part presses on, pulls on, pushes against, or tends to compress or twist another body or body part, the intensity of this mutual force commonly expressed in pounds per square inch the deformation caused in a body by such a force.

Tachycardias: A rapid heart rate, especially one above 100 beats per minute in an adult.

Tensile pertaining to extension as, tensile strength, capable of extension, ductile, tensible.

Urethane a crystalline compound $C_3H_7NO_2$ that is the ethyl ester of carbamic acid and is used especially as a solvent and medicinally as an antineoplastic agent carbamate.

Ventricle a chamber of the heart which receives blood from a corresponding atrium and from which blood is forced into the arteries, one of the system of communicating cavities in the brain that are continuous with the central canal of the spinal cord.

APPENDIX I :EXERCISE

1. An operated ankle (figure 8) is connected with a bolt. The bolt diameter is 18 mm a strut thickness connected to the ankle is 1 cm. The jumps to get a rebound and he arrives to the floor. During this action he exerts a compressive force of 2 KN to the ankle. What is the bearing stress between the bolt and the bone?

$\sigma_b = P/A$

$\sigma_b = 2KN/\ 2*(18mm)*(1\ cm)$

$= 2KN/\ 2*(.018m)*(.01\ m) = 5555.56\ KPa$
$= 5.56\ MPa$

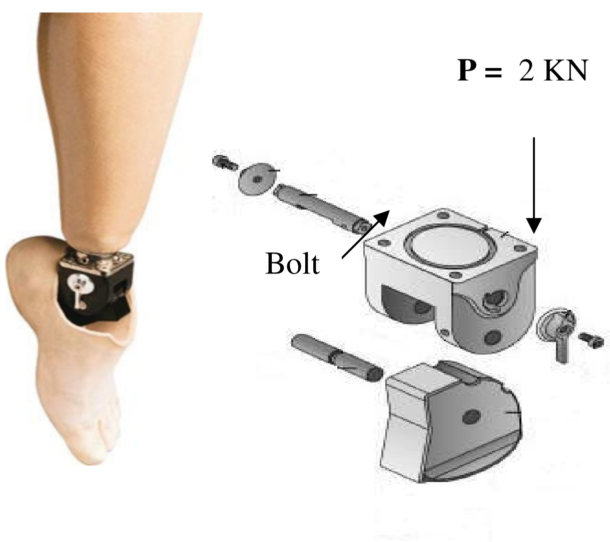

Figure 8. [29].

2. A student with a leg prosthesis (figure 9) is making squats in the gym. When the student is lifting 5 kN, his prosthesis broke having a cross sectional area A= 110 mm² . Determine the stresses acting on the section cut through the prosthesis at an angle θ = 20º.

$\sigma_x = P/A = 5\ kN/110\ mm^2 = -45.5\ Mpa$

$\sigma_\theta = \sigma_x\ \cos^2\theta = (-45.5\ Mpa)(\cos 20^\circ)^2 = 42.7\ MPa$

$\tau_\theta = -\sigma_x\ \sin\theta\cos\theta = (45.5\ MPa)(\sin 20^\circ)(\cos 20^\circ)$

$= 14.6\ MPa$

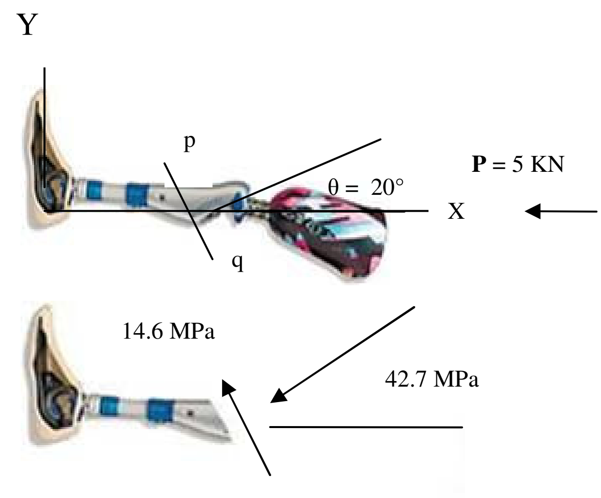

Figure 9. [29].

3. A man with a bar of stainless steels (figure 10) on his hip turn to right without moving his legs applying a torsion of 5 N-m. If the diameter of the circular bar is, 5 cm determine τ_{max} of the bar.

$\tau_{max} = 16T/\pi d^3$

$= [(16)(5\ N\text{-}m)]\ /\ [(\pi)(0.005m^3)]$

$= 2.04 \times 10^8\ N/m^2$

$= 204\ MPa$

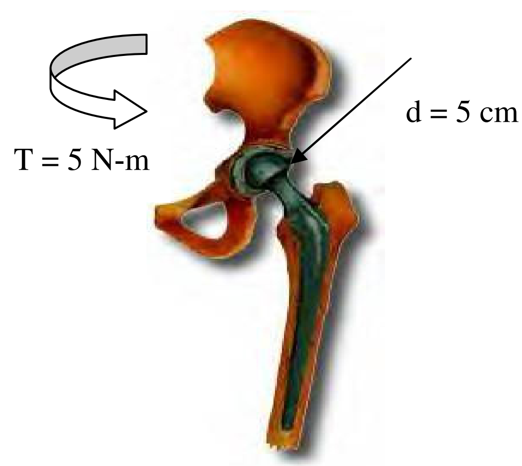

Figure 10. [29].

4. A man with arm prosthesis (figure 11) is supporting a distributed load linearly varying intensity. The maximum intensity of the load occurs at the fixed support and is equal to 5 N. Find the shear force V and the bending moment M at distance 0.4 m from the free end of the beam if the total distance is 0.7 m.

$V = qoX^2 / 2L$

$= (5*0.16) / (2*0.7) = 0.57$ N

$\Sigma M = 0$

$M + 1/2 (qoX/L)*X*(X/3) = 0$

$M = - qoX^3 / 6L$

$= (5*0.64) / (6*0.7) = 0.76$ N-m

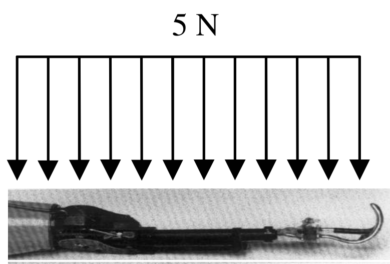

Figure 11. [29].