Strumentazione Biomedica - Pacemaker

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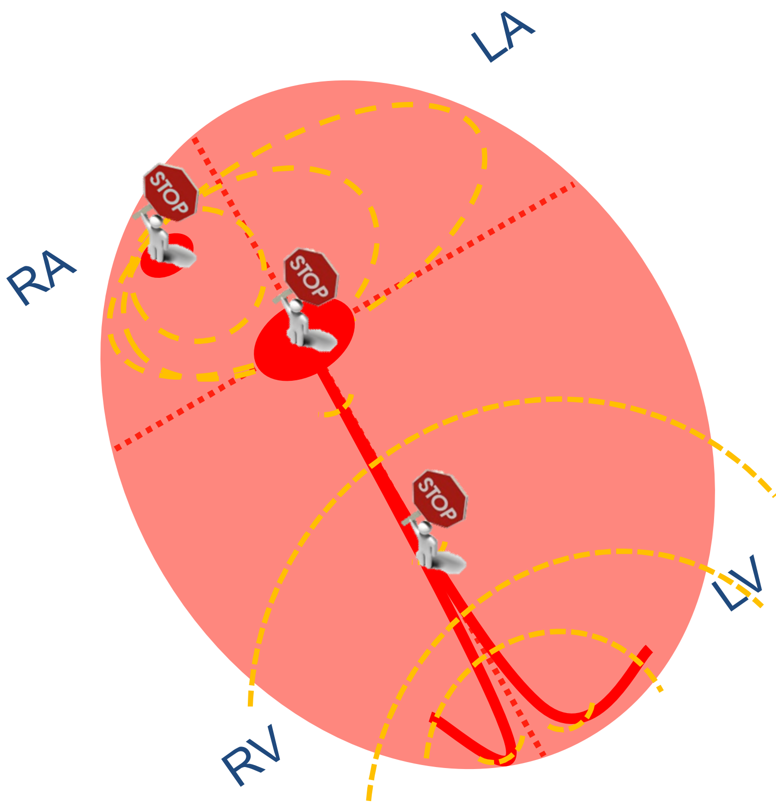
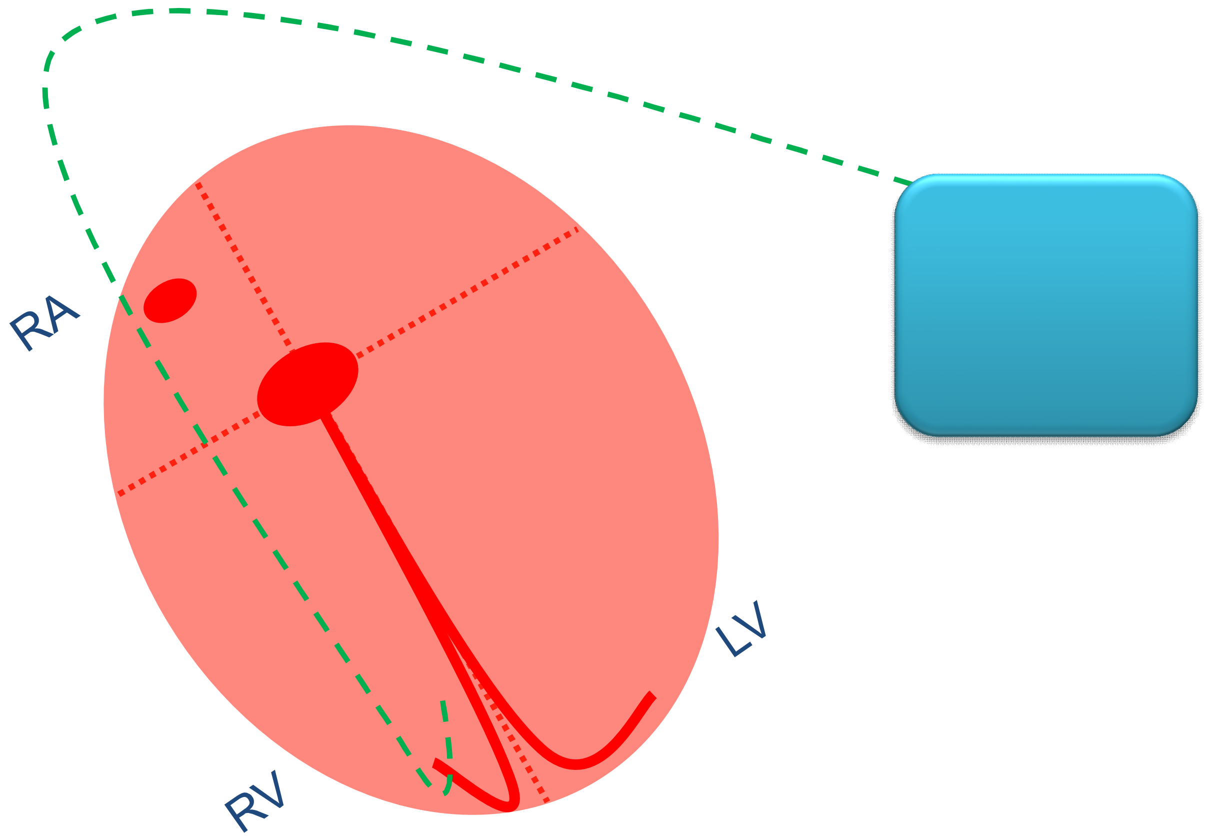
President, *EAMBES* (2021-23)
Secretary General, *IUPESM* (2018-2022)
Treasurer, *IFMBE CED* (2018-21)

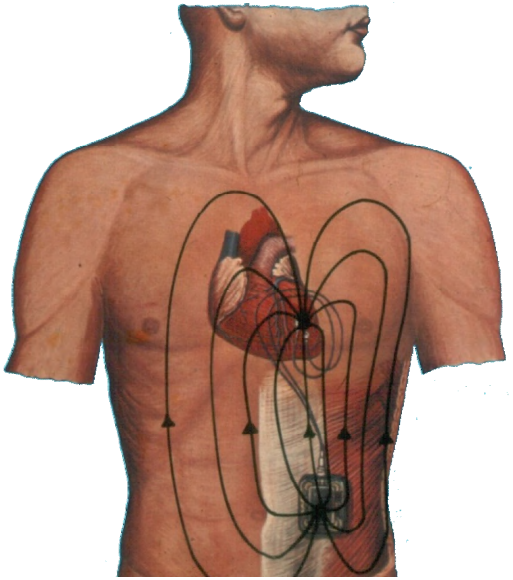
PK action



Implant:
https://www.youtube.com/watch?v=TjW5-pU0nBs

PK action

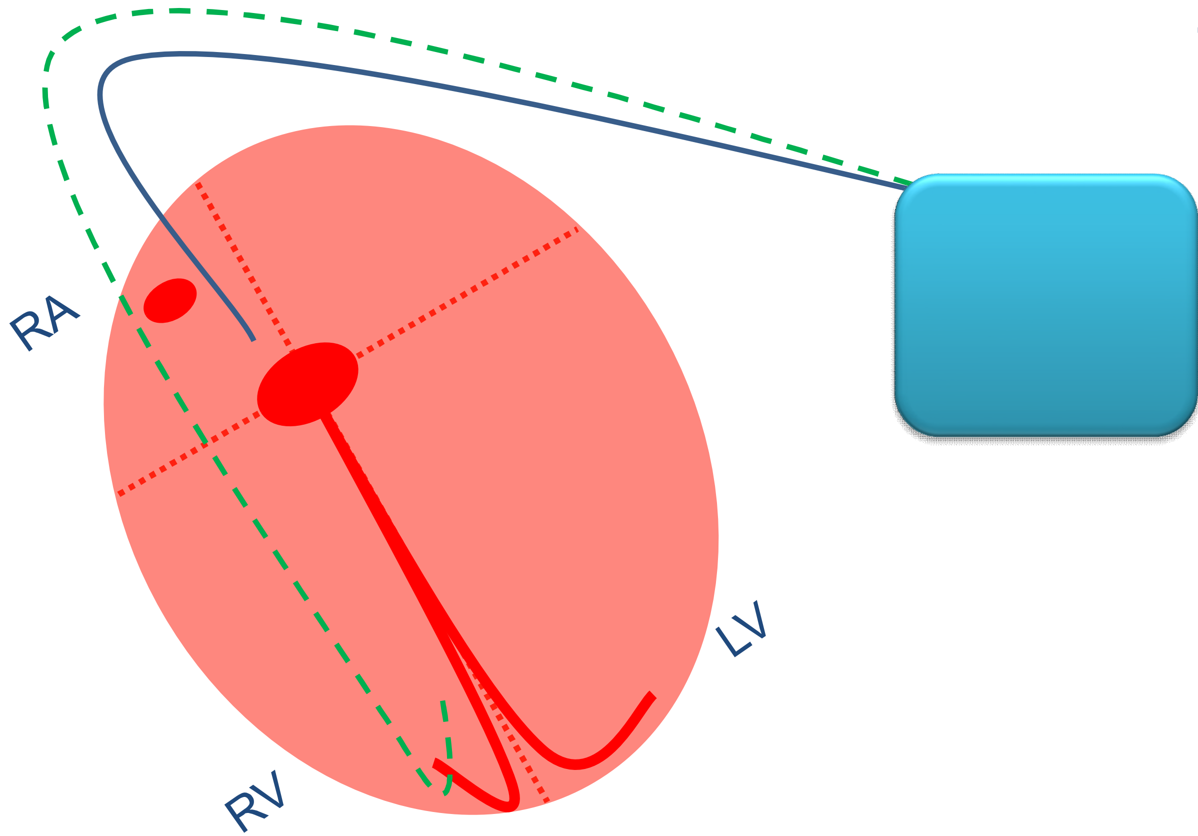


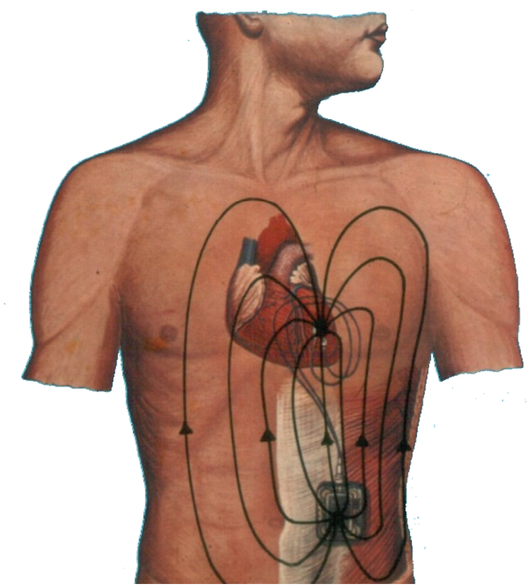


PK Code
VOOOO

PK action

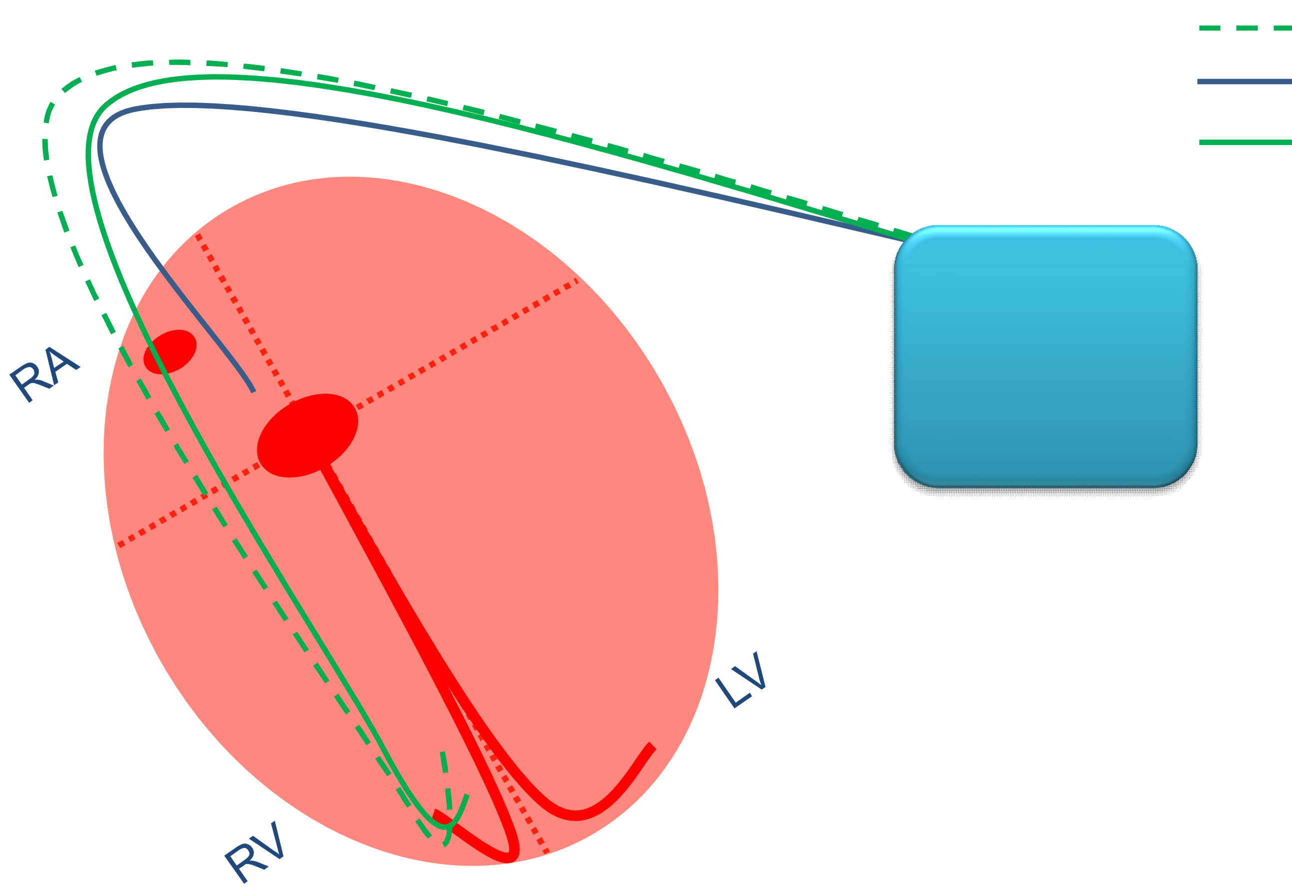
Stimulation (dashed green line)
Stimulation (solid blue line)

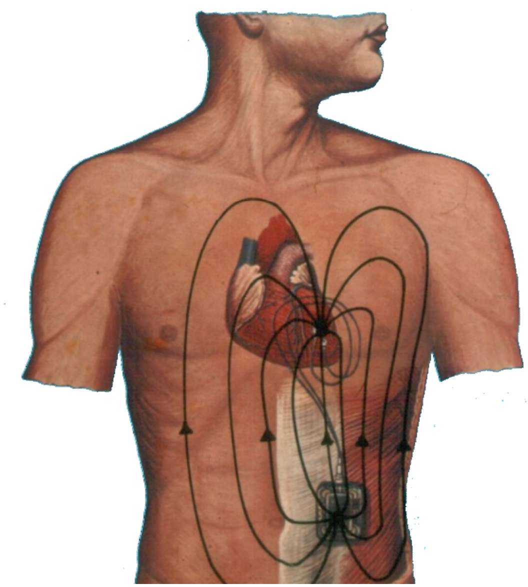




PK Code
VSDOO

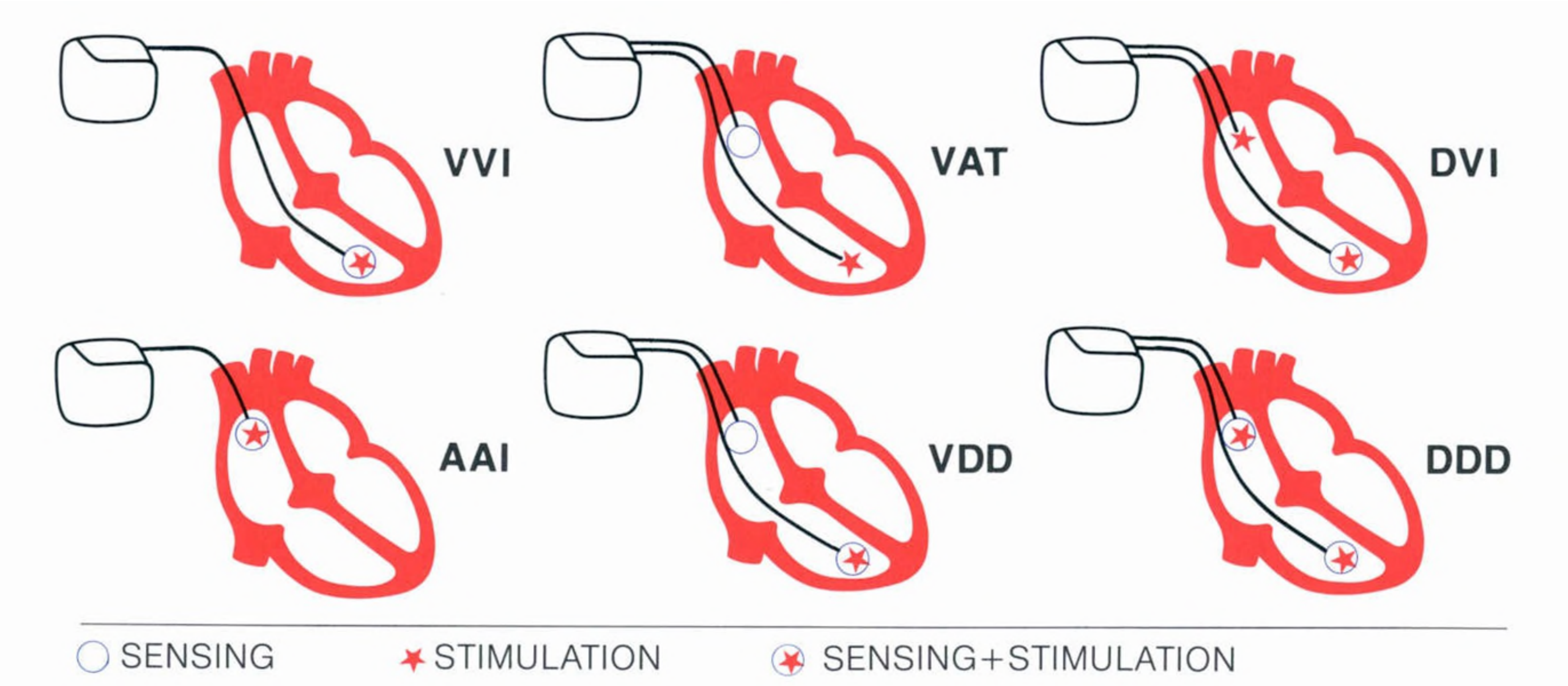
PK action


Stimulation
Atrial Sensing
Vent. Sensing
RA
RV
LV




PK Code
VDDOO

The Heart Contraction

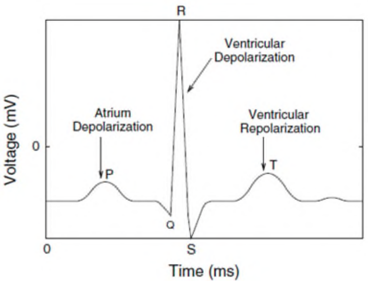


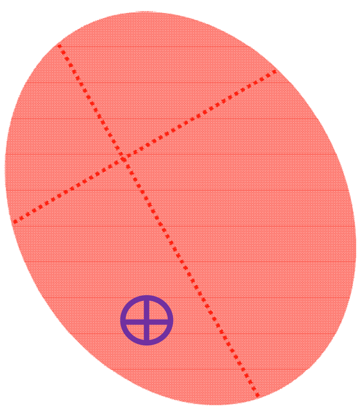
PK code: examples

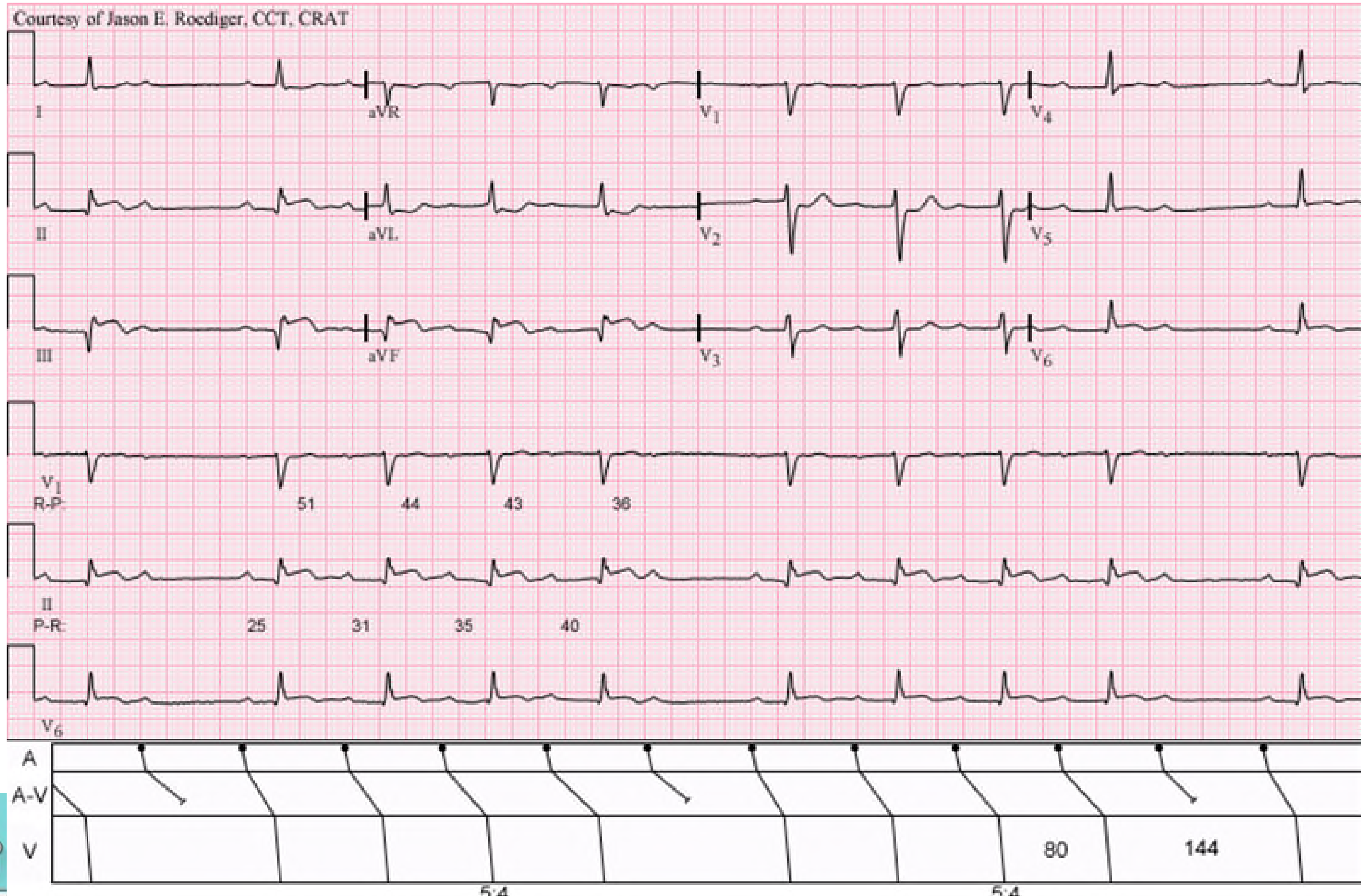
- **VVI** - *ventricular demand pacing* - was prevalent in past years and is still commonly used. It is considered appropriate only when there is no significant atrial contribution to cardiac output.
- **AAI** - *atrial demand pacing* - is appropriate only when A-V conduction is adequate.
- **VDD** - *P-wave synchronous pacing* - senses atrial activity and paces the ventricle. It can also sense the ventricle and inhibit firing in the ventricle if a PVC is sensed.
- **DVI** - *A-V sequential pacing* - units sense only in the ventricle, but pace both the atrium and ventricle.
- **DDD** - *fully automatic* - pacemakers perform physiologic pacing and sense and pace in both the atrium and ventricle. This is the most commonly used dual-chamber pacemaker.
- **DDDR** - *physiologic rate responsive pacing* - is used with patients who "fit the criteria of DDD mode pacing, but who also have evidence of inadequate chronotropic competence of the sinus node." This pacing mode has the capability of increasing or decreasing the pacing rate based upon change in patient activity.

Problems: type I A-V block

Normal ECG







SENSING

STIMULUS

The Heart Contraction

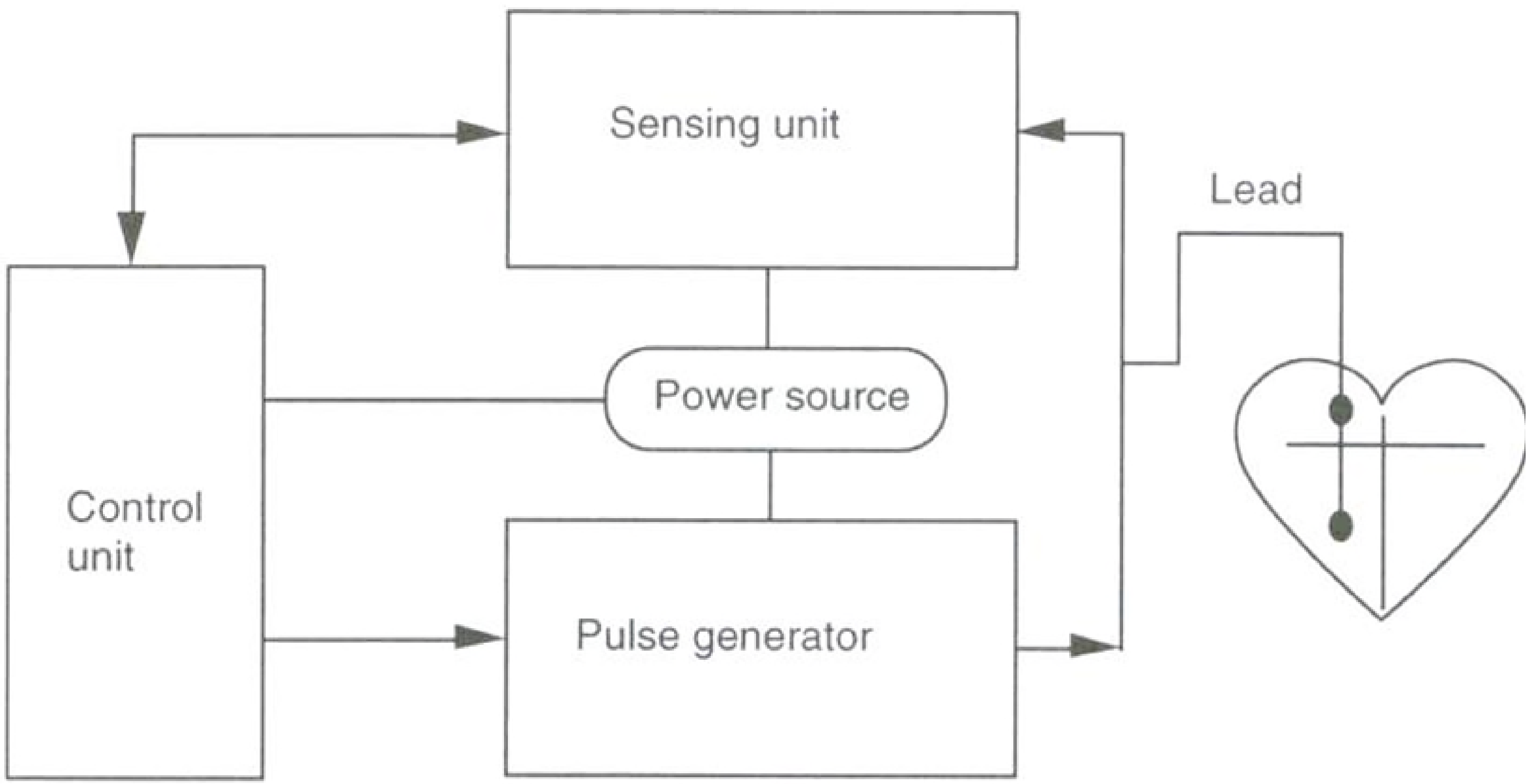
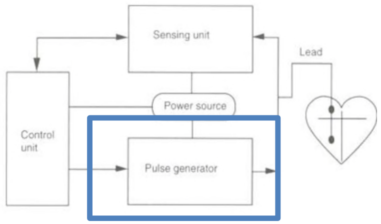
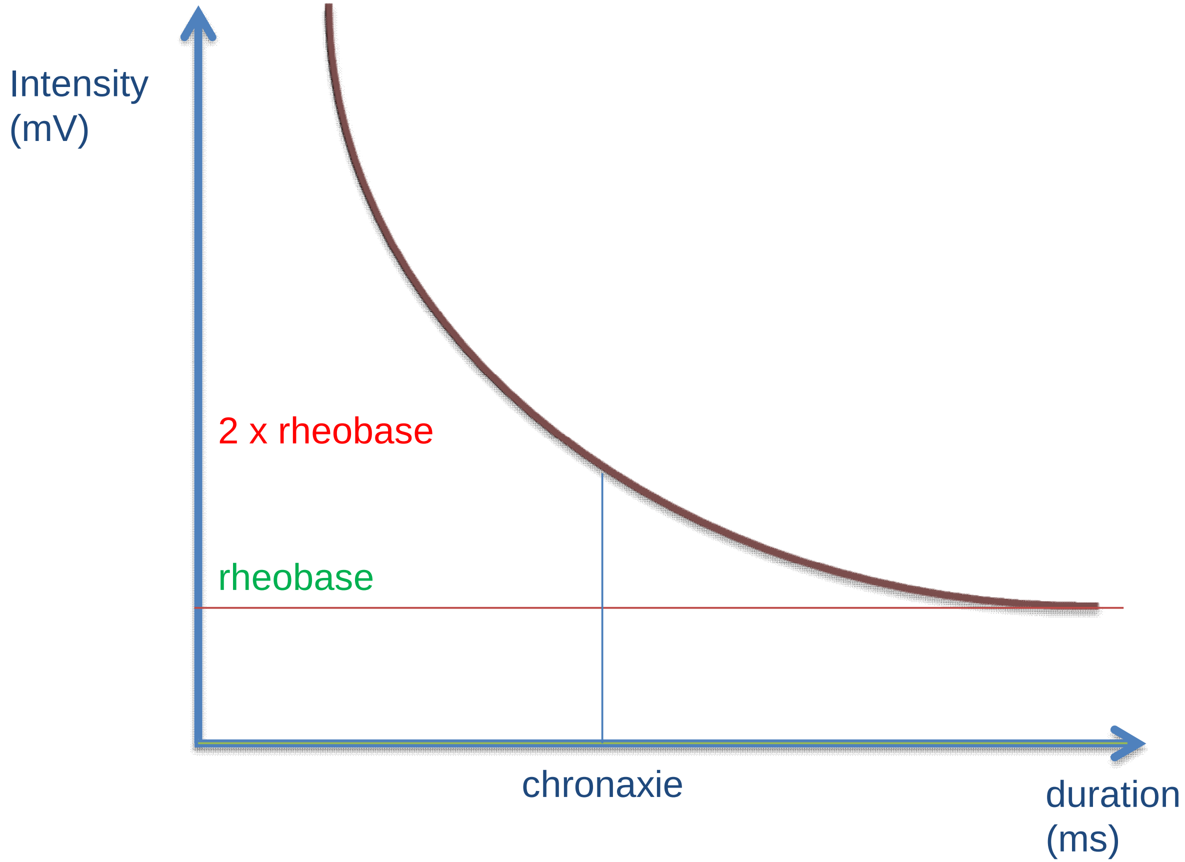


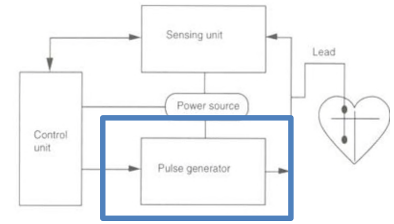
Figure 5.1 A functional diagram of heart and pacemaker.

Intensity duration curve



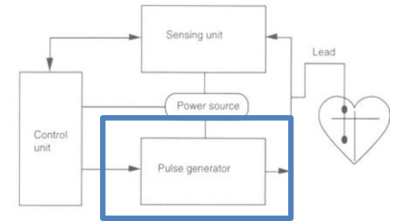


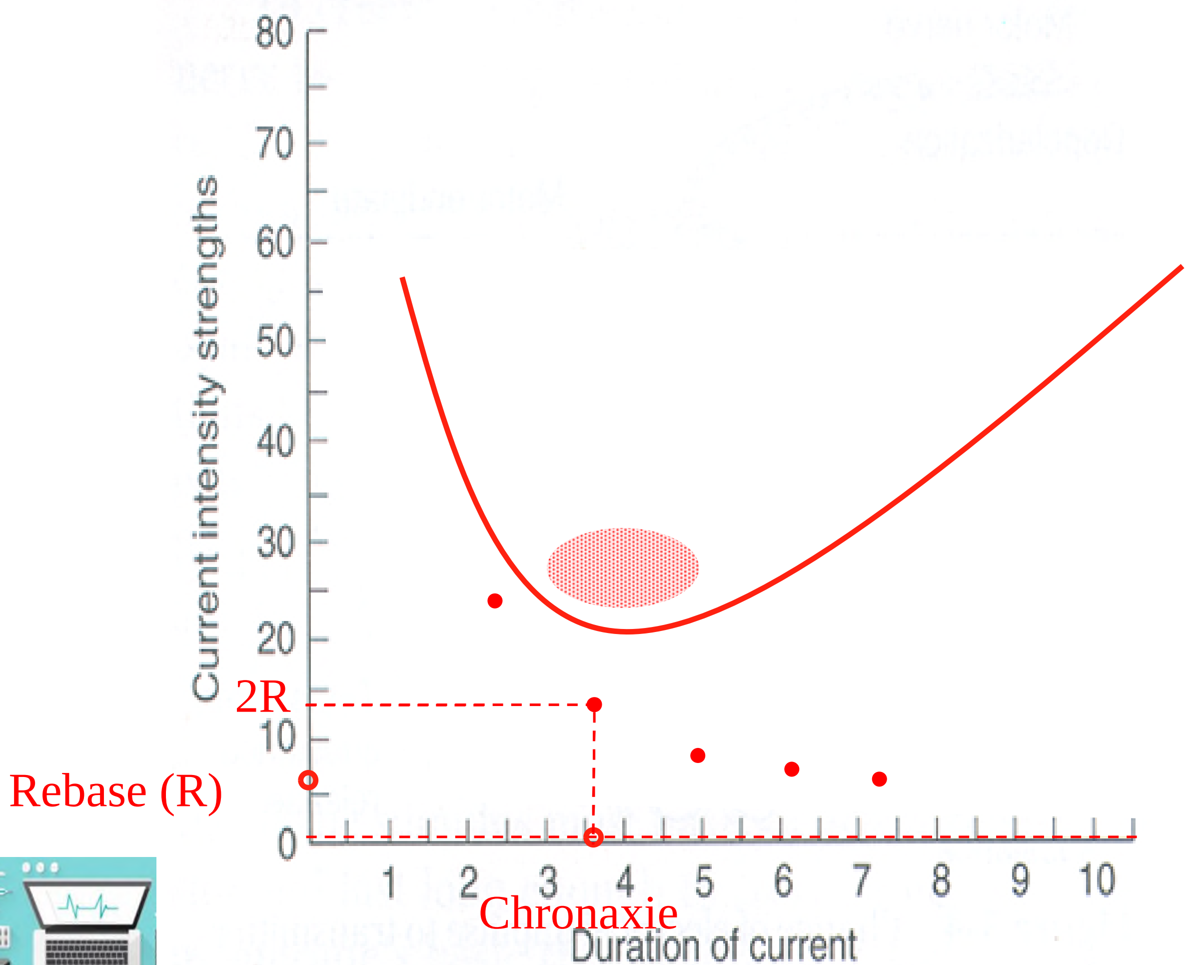
Intensity duration curve



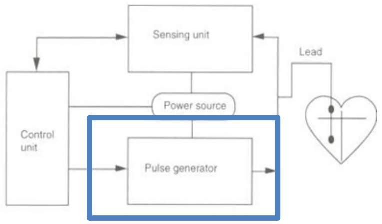
1. Set intensity (I) to 0 Volts
2. Set duration (T) to +∞ (2sec will be sufficient)
3. Increase slowly the intensity until you see contraction (Rebase found)
4. Double this volume and calculate how long it takes before contraction (you have the Chronaxie)
5. Find few more point changing V and I
6. Set the parameter in a ‘safe zone’

Intensity duration curve



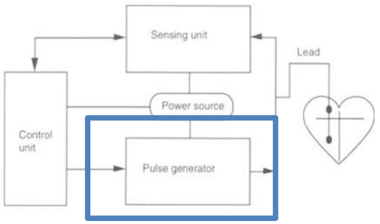


Current effects



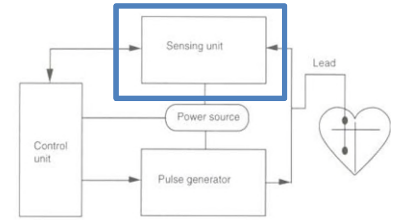
1. Alternating versus direct current
2. Tissue impedance
3. Current density
4. Frequency of wave or pulse
5. Intensity of wave or pulse
6. Duration of wave or pulse
7. Polarity of electrodes
8. Electrode placement

PK code



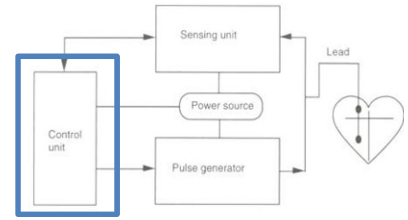
I
Chamber paced
V ***- ventricle*** *A* ***- atrium*** *D* ***- dual (A +V)*** *O* ***- none*** *S** ***- A or V***

PK code



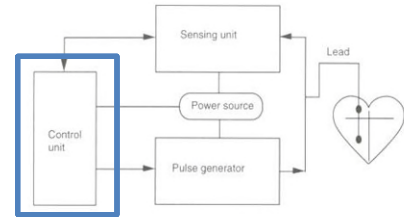
II
Chamber sensed
V - ***ventricle*** *A* - ***atrium*** *D* - ***dual (A +V)*** *O* - ***none*** *S** - ***A or V***

PK code



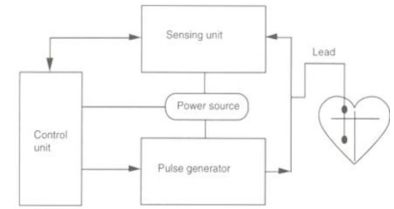
II
Response to sensing
T- triggers pacing ***I - inhibits pacing*** ***D - dual (T +I)*** ***O - none***

PK code



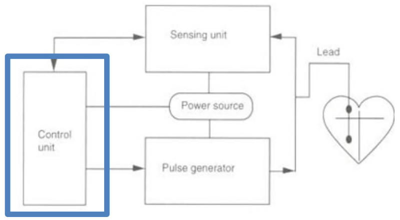
IV	V
Programmable functions, rate modulation	*Antitachyarrhy-thmia function(s)*
P ***- programmable rate and/or output*** *M* ***- multiprogranm-mability of rate, output, sensitivity I etc.*** *C* ***- communicating function (telemetry)*** ***Rate modulation*** *O* ***- none***	*P* ***- pacing (antitachyarrhy-thmia)*** *S* ***- shock*** *D* ***- dual (P+S)*** *O* ***- none***

PK code



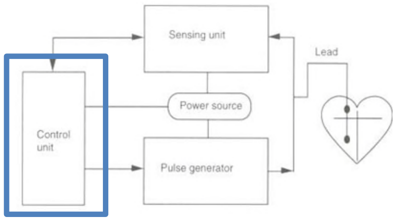
I	II	II	IV	V
Chamber paced	*Chamber sensed*	*Response to sensing*	*Programmable functions, rate modulation*	*Antitachyarrhy-thmia function(s)*
V - ventricle ***A - atrium*** ***D - dual (A +V)*** ***O - none*** ***S* - A or V***	***V - ventricle*** ***A - atrium*** ***D - dual (A +V)*** ***O - none*** ***S* - A or V***	***T- triggers pacing*** ***I - inhibits pacing*** ***D - dual (T +I)*** ***O - none***	***P - programmable rate and/or output*** ***M - multiprogranm-mability of rate, output, sensitivity I etc.*** ***C - communicating function (telemetry)*** ***Rate modulation*** ***O - none***	***P - pacing (antitachyarrhy-thmia)*** ***S - shock*** ***D - dual (P+S)*** ***O - none***

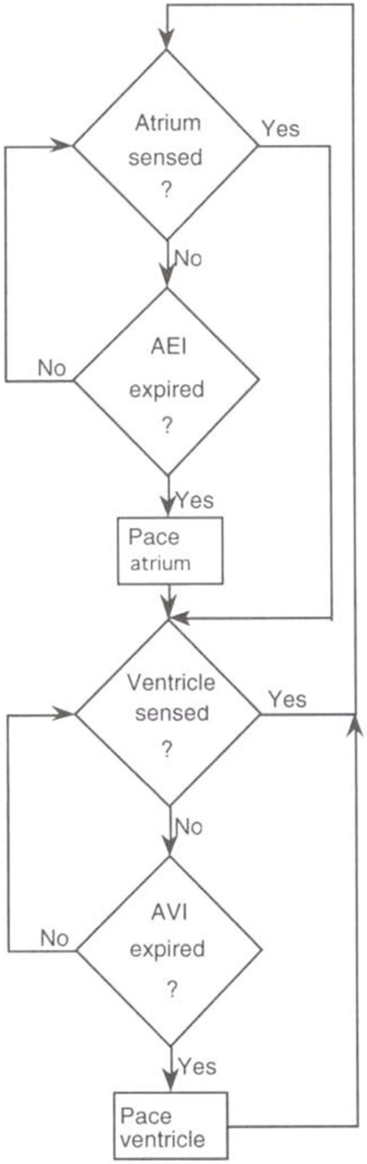
Controlling and timing



- The pacemaker contains a quartz-controlled microprocessor that performs process controlling and timing.
- The most important processes for automatic operation are:
  - recognition of spontaneous electrograms;
  - control of the timing sequence, e. g. reset of the basic cycle and other timing intervals after recognition of a spontaneous excitation or stimulation;
  - initiating a stimulation if the end of the respective time interval is reached without recognition of a spontaneous event;
  - adjustment of the AV-delay;
  - mode-switching;
  - set into operation those parameters like voltage and duration for the stimulus, gain factor for the sensing amplifier etc.
  - become involved in the bi-directional telemetry, i. e. to send on request the pacemaker ID and actual parameter combination to the extracorporeal receiving station, and process the new parameter combination if requested.

Controlling and timing





PK selection

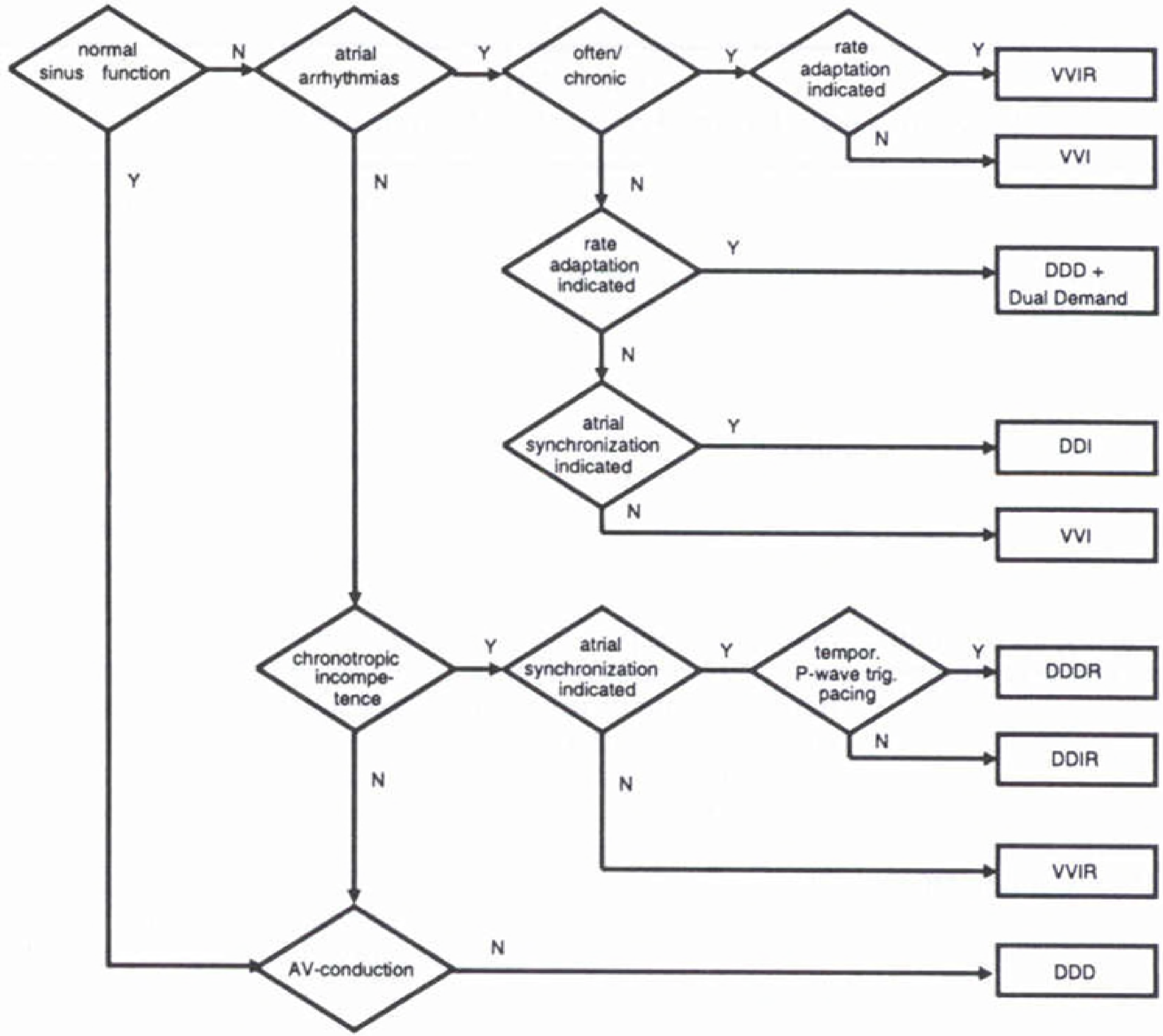
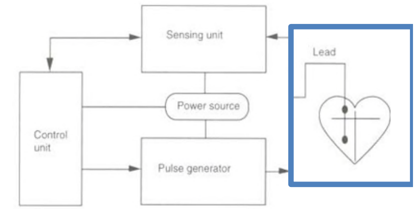


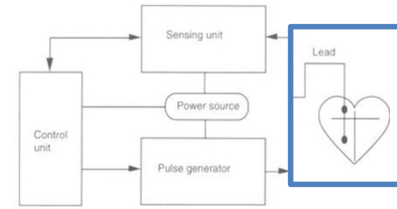
Figure 29. Logic diagram of relationship between rhythm disturbances and therapeutic pacing mode.

Electrodes & Leads



- Electrodes and leads connect the implanted pacemaker with the heart. Usually there is no difference for stimulation and sensing electrodes. Frequently the same electrode is used both for stimulation and sensing. The fundamental requirement is a sufficiently short repolarization time after stimulation.
- It has been found that electrodes with a very large electrically active surface have a very short repolarization time. Typical electrodes of that kind have a porous or fractally coated surface. In case of fractally coated electrodes the electrically active surface can be up to 1000 times that of the geometric projection surface. The effect may be due to the very low current density across the electrode-electrolyte interface. Another advantage of electrodes with large active surface is that they have a very low cut-off frequency.

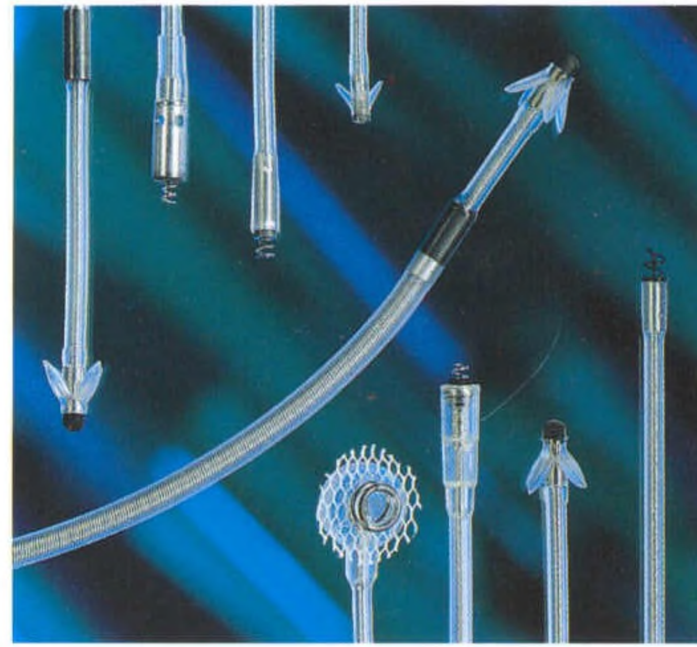
Electrodes & Leads

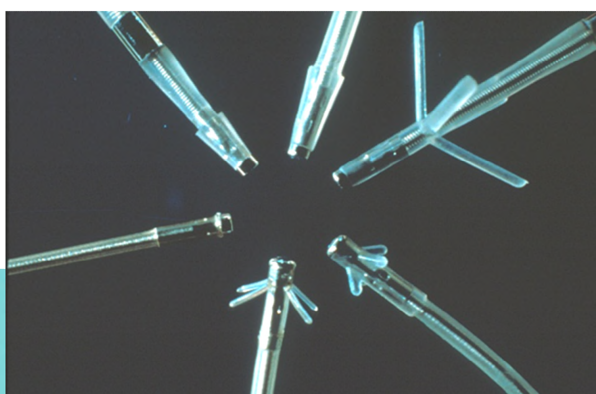


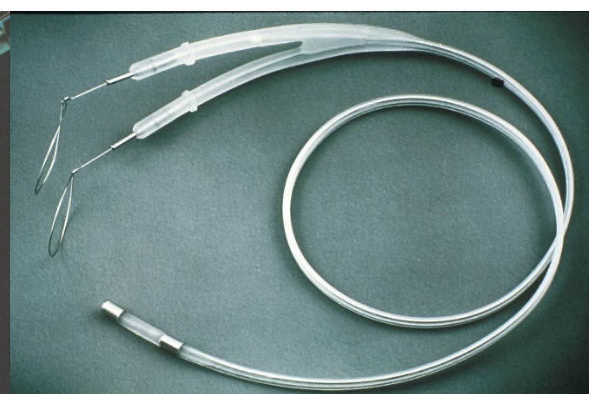
Electrodes can be located in the myocardium by active or passive fixation.

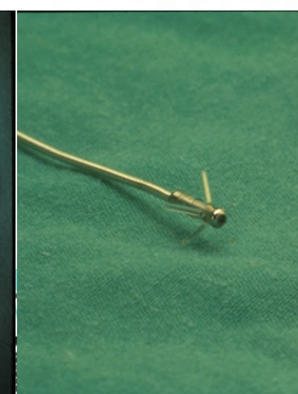
Active fixation is preferred for epicardial electrodes where fixation is realized by a helical (screw-like) form of the electrode tip.

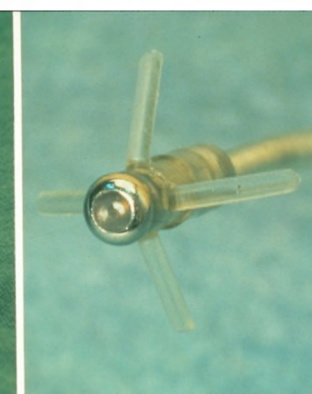
Passive fixation which is now the standard in endocardial position is reached by soft materials (e. g. as wings, crowns, flanges made of silicon rubber) that are arranged behind the electrode tip and promote the encapsulation in the endocardial tissue.



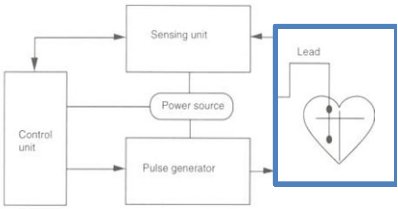


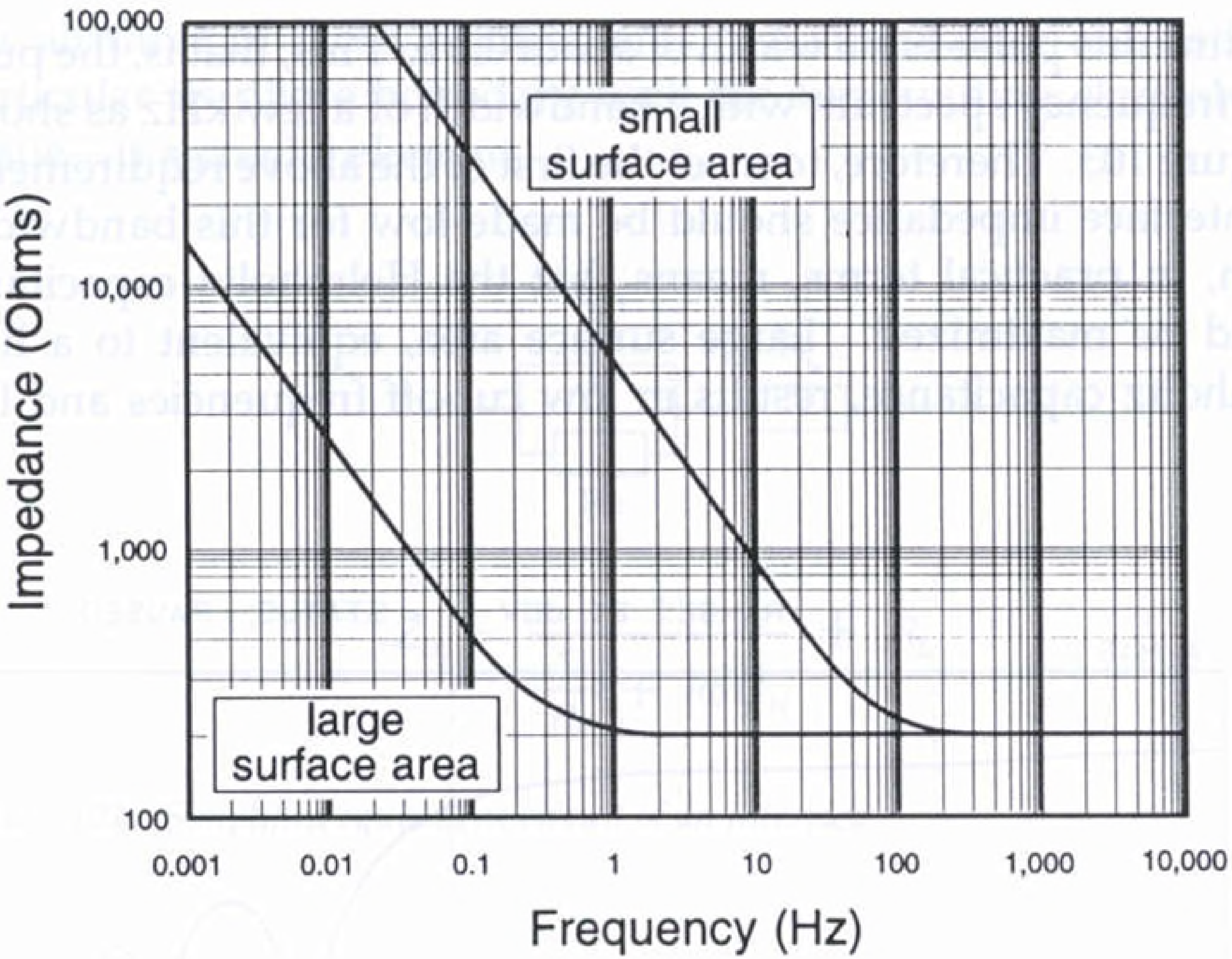




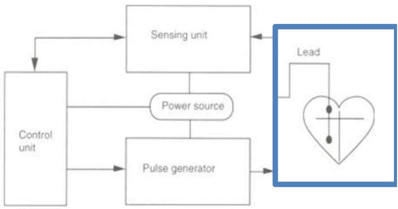


Electrodes & Leads



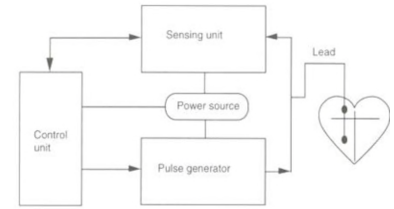


Electrodes & Leads

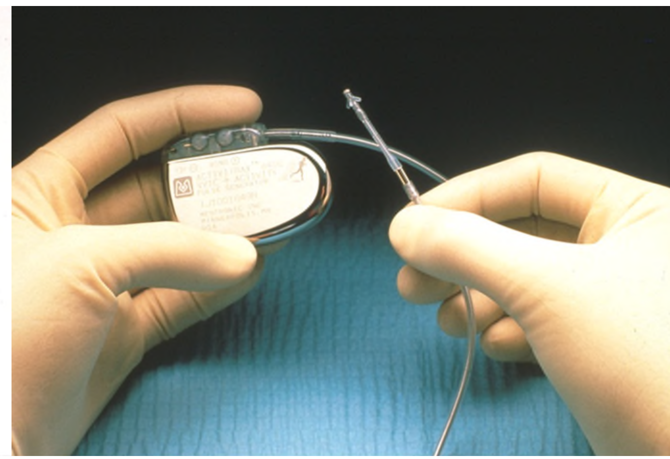


- Electrodes and leads have to be biocompatible. For transvenous access this request is even stronger in order to avoid blood clotting. Usually the electrode is recognized as body foreign material and causes inflammation. This provocation leads to the building of a growing fibrous capsule around the electrode tip with non-excitable tissue. As a consequence both the voltage of the sensed signal will decrease and the threshold for stimulation will increase. This behavior might require re-adjustment of the respective parameters after some time. Steroid-eluting electrodes have been developed that diminish the inflammatory impact.
- The leads have to follow each movement of the heart. Leads have to be sufficiently flexible for bending. Those movements may result in up to 100.000 alternations of load per day or 300 Millions during the expected life time of 8 years.
- Among the not satisfactorily solved problems are:
  - removal of electrodes after some years when the implant has to be exchanged;
  - electrodes for small children since electrodes do not grow simultaneously with the children.

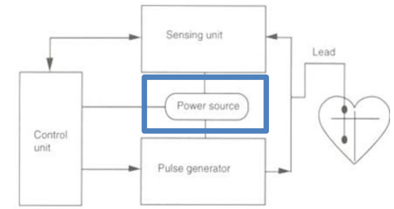
PK


Sensing unit
Lead
Power source
Control unit
Pulse generator


MINIX



Battery

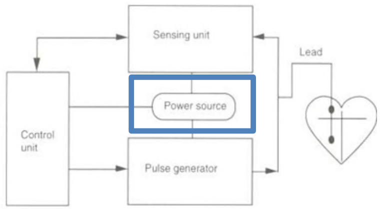


- Modern pacemakers demand a very small power.
- However, the actual power consumption depends on:
  - the mode in which the pacemaker is operated (single/dual chamber?)
  - how frequently the "demand" mode with stimulation is activated
  - stimulus parameters.

  A considerable part of the power is consumed for the service provided by the microprocessor, including "computational service". On average the "no-load"-current is approximately 7 µA, the "mean-load"-current 30 µA.

- With a battery capacity of 2 Ah the "load"-operation can be supplied for nearly 8 years. Battery production has to be performed under extreme high quality standards in order to guarantee comparable capacities and discharge characteristics. However, due to the "individual" load this discharge time is only a rough estimation and needs to be confirmed by measurement.

Battery



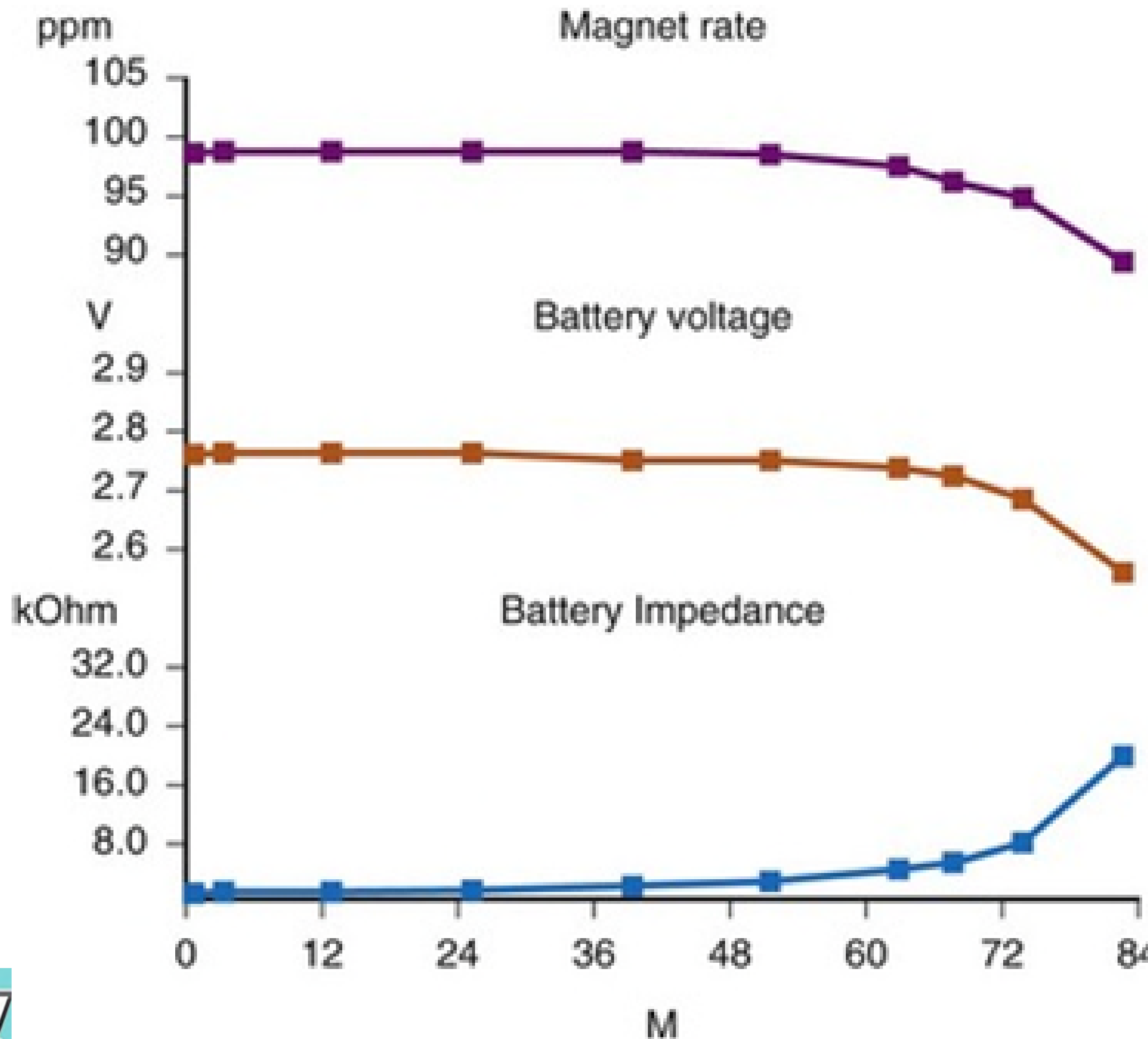
- The most common batteries for pacemakers today are based on **lithium technology** with lithium iodine as preferred material, i.e. lithium is the anode and iodine the cathode. The major advantages of this battery are the high power density (i. e. small volume with regard to the capacity) and its very stable voltage during discharge up to about 90%.

- Rechargeable batteries, although frequently considered for pacemakers, have no relevance at present.

PK follow-up

- Periodic visits aiming to control:
  - Cardiovascular conditions
  - Battery life
  - Electrodes/leads displacements

Follow-up: battery



Safety aspects

Safety is one of the most important requests for all medical devices and products, however even more for life-supporting active implants like pacemakers. The basic measures for providing safety are:

- design and specifications: e. g. self-check procedures, fail-safe mechanisms, redundant circuitry, employment of non-critical technology and components. Only the last aspect can effectively be realized in pacemakers. Fail-safe mechanisms change the operational mode to A00, V00 or D00 in case of serious noise on the sensing channel or reduce the power consumption in case of nearly discharged batteries to the actually life-sustaining functions.

- production: Each step of the production is exactly defined and has to be recorded. Each component must have its own documented “curriculum vitae”. The employees must be well trained, motivated and informed about the possible risks. The manufacturer should have an accredited total quality assurance system. Statistically relevant tests, e. g. accelerated life tests based on the ARRHENIUS-equation, must be used to confirm the calculated “FITs = Failures In Time”.

Safety aspects

- maintenance and repair: This aspect is only of minor relevance for implanted devices. Programming, however, offers an additional possibility to compensate for some deficiencies in individual cases.

- market surveillance: This is a very important aspect and emphasized by the establishment of the EU vigilance system for medical products, especially for active implantable devices.