The Pacemaker Formal Methods Challenge

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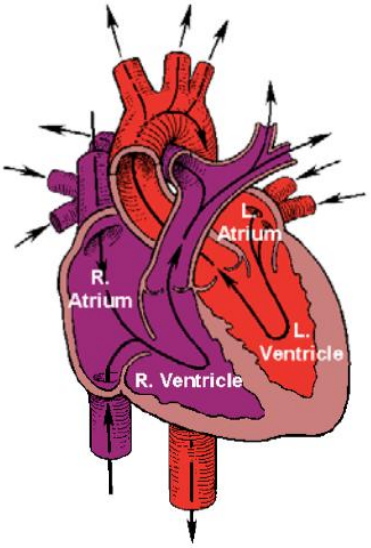
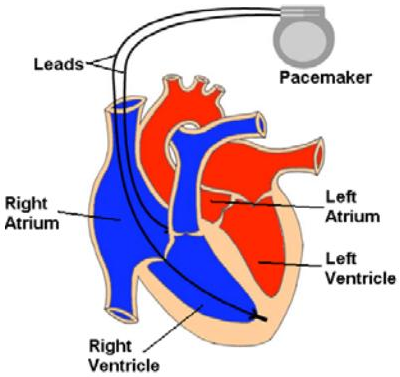
Contents

Background: The human heart



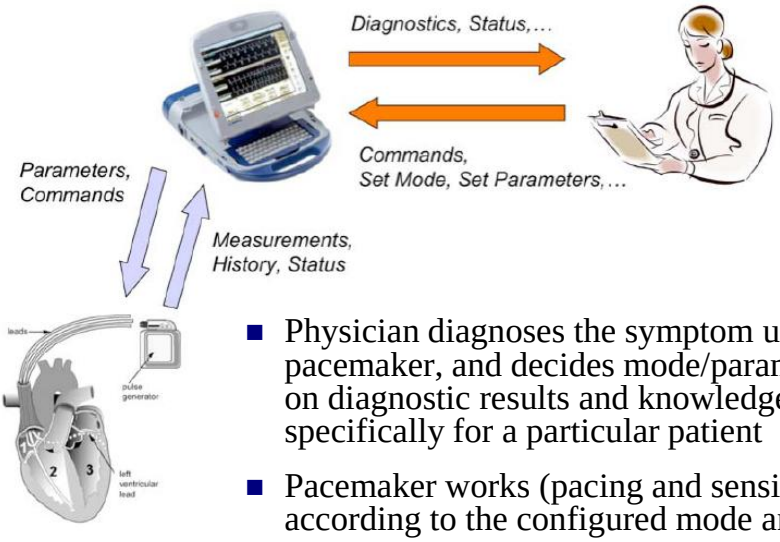
- Four chambers: atria & ventricles
- Electrical stimulus in the right atrium → heart's chambers contract & pump blood → the ventricles do the same
- When this system does not work properly, a pacemaker may be used to regulate the heart rate

Cardiac Pacemaker



- Deliver electrical stimuli, or paces, over leads with electrodes that are in contact with the heart
- May detect natural cardiac stimulations, called senses
- Must satisfy three requirements:
  - The heart rate must not be too fast
  - The heart rate must not be too slow
  - The ventricles must contract at a particular interval after the atria contract

Overall System



- Physician diagnoses the symptom using pacemaker, and decides mode/parameters based on diagnostic results and knowledge/experience, specifically for a particular patient
- Pacemaker works (pacing and sensing) according to the configured mode and parameters.

The Pacemaker Challenge

- The formal method challenge problem issued by the Software Certification Consortium (SCC), hosted by the McMaster University's Software Quality Research Lab (SQRL)
- Boston Scientific has released into the public domain the system specification for a previous generation pacemaker
- The reference hardware platform was developed by a ECE design group at the University of Minnesota.

The Pacemaker Challenge

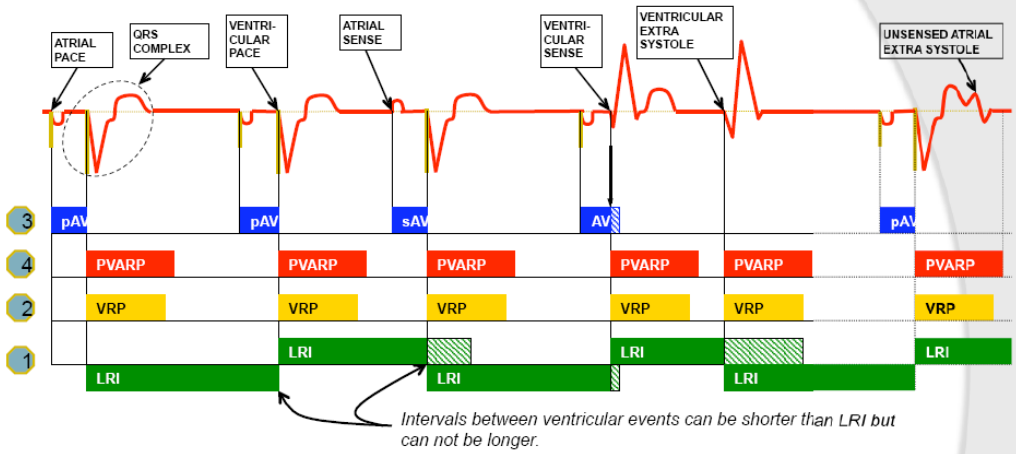
- Requirements Document (Boston Scientific)
- 35 pages, informal natural language (English) and tables
- Domain knowledge has been summarized in a book, "Cardiac Pacemakers Step-by-Step"
- Main areas:
  - System: DCM, leads, pacing pulse, brady modes and state.
  - Diagnostics: monitoring, battery status, etc.
  - Bradycardia therapy: definition of user programmable parameters (e.g. rate limits, delays).

The Pacemaker Challenge

	I	II	III
Category	**Chambers Paced**	**Chambers Sensed**	**Response To Sensing**
Letters	O – None A – Atrium V – Ventricle D – Dual	O – None A – Atrium V – Ventricle D – Dual	O – None T – Triggered I – Inhibited D – Tracked

- Bradycardia operating modes
- 23 programmable pacing modes, e.g.
  - VOO: ventricle paced, no sensing (and no response to sensing)
  - VVI: ventricle paced and sensed. Reaction to sensing a QRS is to inhibit the pace.
  - DDD: both chambers paced and sensed. Sensed P and QRS can inhibit a pace, sensed P can trigger a ventricular pace.

Four Fundamental Timing Cycles

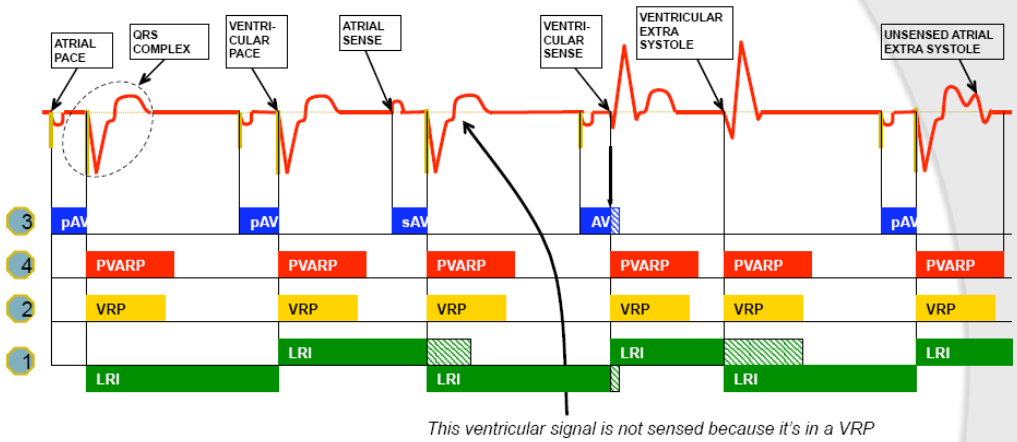


1 LRI = Lower Rate Interval

Longest interval between a paced or sensed ventricular event and the succeeding ventricular paced event with out intervening sensed events.

That is, the lowest allowable rate of ventricular events for normal operation of the heart.

Four Fundamental Timing Cycles

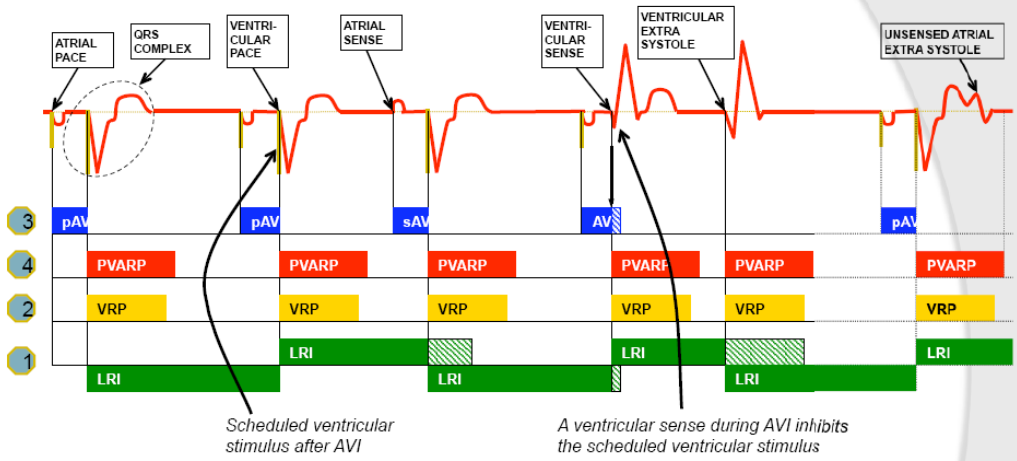


2 VRP = Ventricular Refractory Period

Interval initiated by a ventricular event during which a new LRI cannot be initiated.

After a ventricular event, there are signals (own stimulus, QRS complex, afterpotential, …) which can be identified incorrectly as ventricular events, thus initiate a new LRI. VRP is used to avoid this.

Four Fundamental Timing Cycles



3 AVI = AtrioVentricular Interval

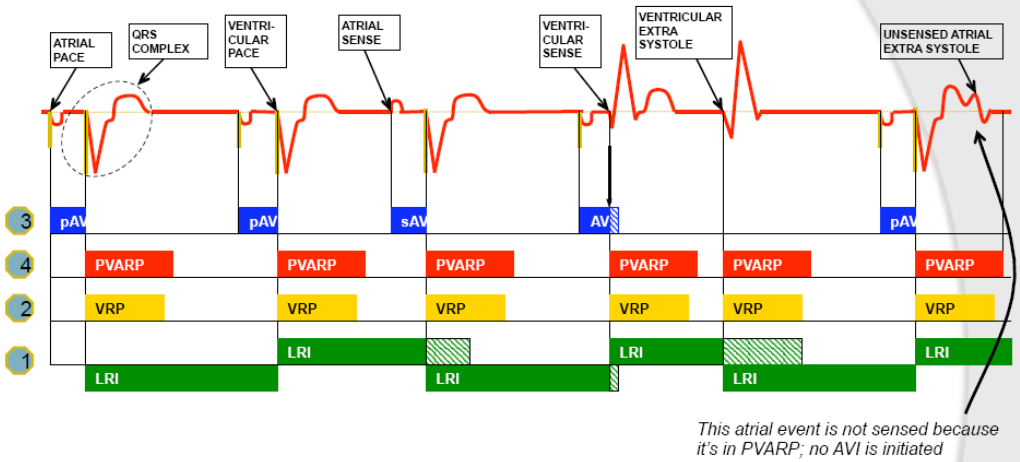
Interval between an atrial event and the scheduled delivery of a ventricular stimulus.

In a normal heart, an atrial event must always be followed by a ventricular event after some delay (AVI) ⇒ AV synchrony.

pAVI for paced atrial events; sAVI for sensed atrial events.

Maybe fixed or rate-adaptive.

Four Fundamental Timing Cycles

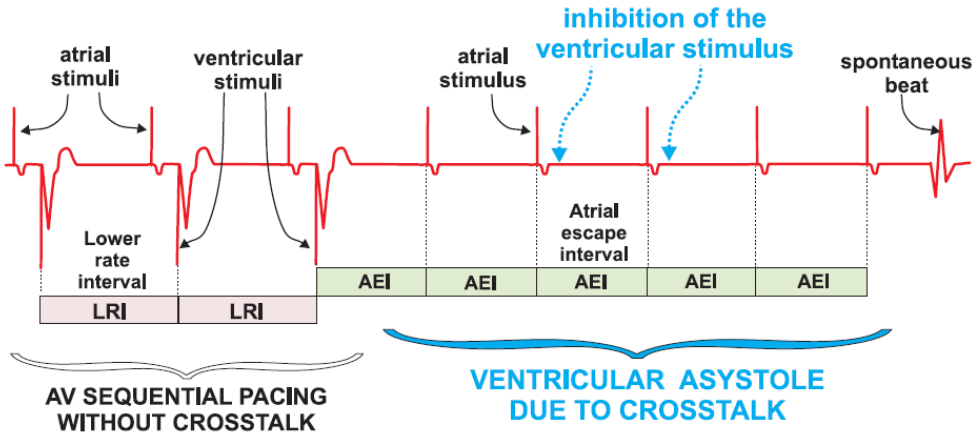


4 PVARP = PostVentricular Refractory Period

Interval after a ventricular paced or sensed event during which an atrial event cannot initiate a new AVI.

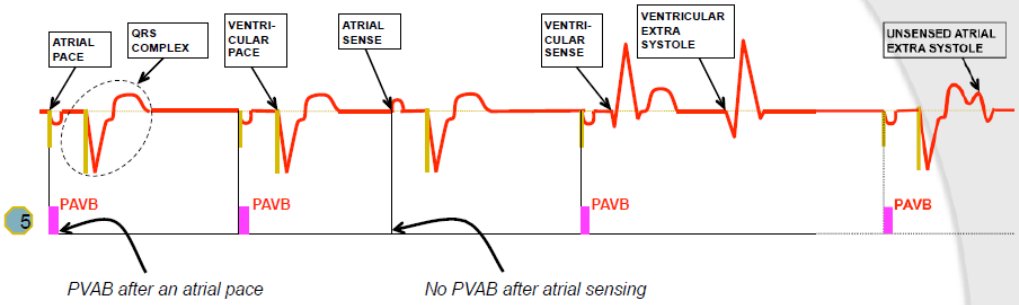
To prevent the atrial channel from inappropriately sensing ventricular events (QRS complex, ventricular stimuli,…) or retrogradely P waves.

AV CROSSTALK



- Sensing of the atrial stimulus by the ventricular channel
- The atrial pacing rate increases

Fifth Timing Cycle to Prevent AV Crosstalk



AV Crosstalk

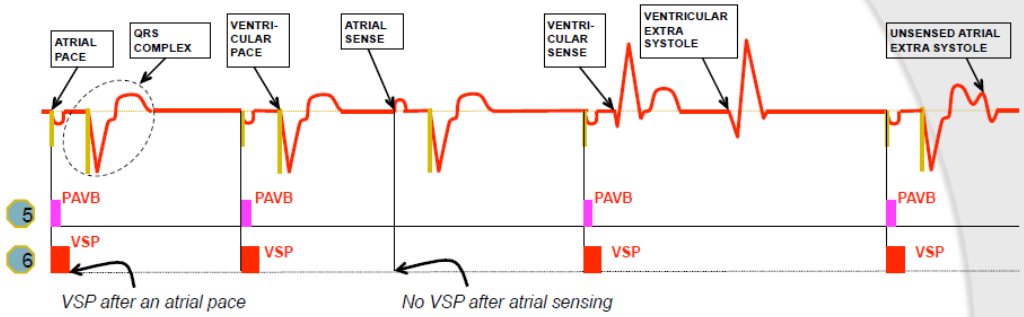
The disturbance caused by an atrial stimulus which, if sensed by the ventricular channel, may cause ventricular inhibition.

5 PAVB = Post-Atrial Ventricular Blanking

Brief interval (10-60ms) initiated by an atrial output pulse when the ventricular channel is switched off and cannot sense.

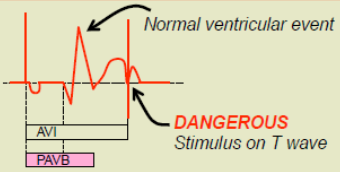
There is no PVAB after an atrial sense since it does not cause disturbance.

Sixth Timing Cycle to Prevent the Consequences of AV Crosstalk



✓If PAVB is too long: normal ventricular event may not be sensed, which may cause stimulus on T wave (DANGEROUS for the heart).

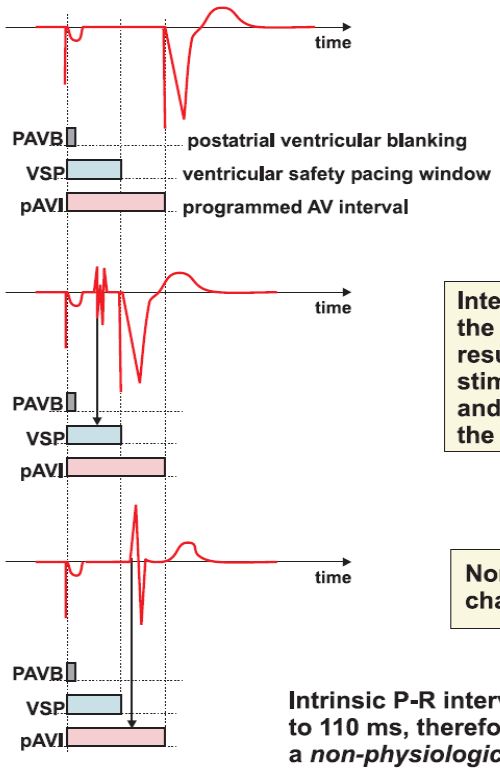
✓If PAVB is too short: crosstalk may still happen.



6 VSP = Ventricular Safety Pacing

First part of AVI (PAVB < VSP < AVI) during which ventricular channel can sense; a signal sensed in VSP but not in PAVB will trigger a premature ventricular stimulus at the end of VSP (thus shorten the current AVI).

VSP does not prevent crosstalk, just prevents its consequences.



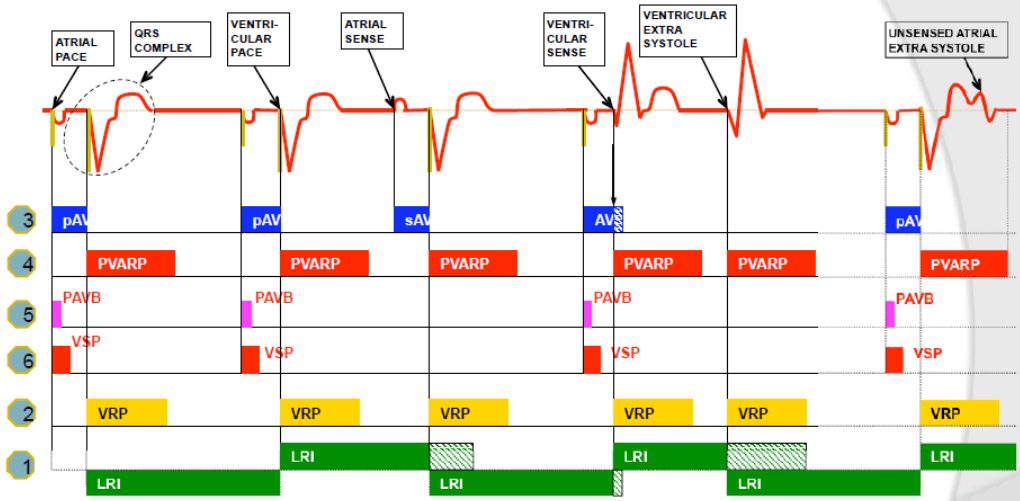
No spontaneous conduction, no crosstalk, no interference : stimulation at the end of the programmed AV interval

Interference (or early QRS) during the VSP window (beyond the PAVB) results in a committed ventricular stimulus at the end of that window and a characteristic shortening of the AV interval

Normal inhibition of the ventricular channel by a conducted QRS

Intrinsic P-R intervals are usually longer than 100 to 110 ms, therefore the VSP window is often called a *non-physiologic AV delay*

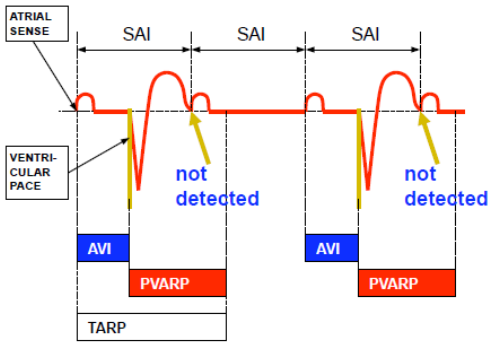
Six Timing Cycles

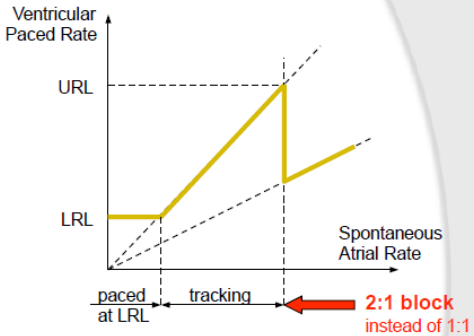


TARP = AVI + PVARP = Total Atrial Refractory Period

Tracking Mode

The ventricular paced rate follows the spontaneous atrial rate (1:1).



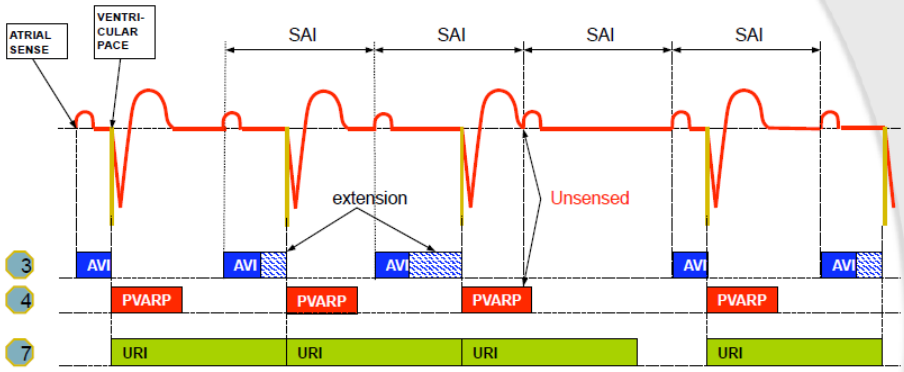


SAI = Spontaneous Atrial Interval

URL = 60,000 / TARP
LRL = 60,000 / LRI

Upper rate limitation by the abrupt development of 2:1 block should be prevented!

Seventh Timing Cycle to Avoid 2:1 Block



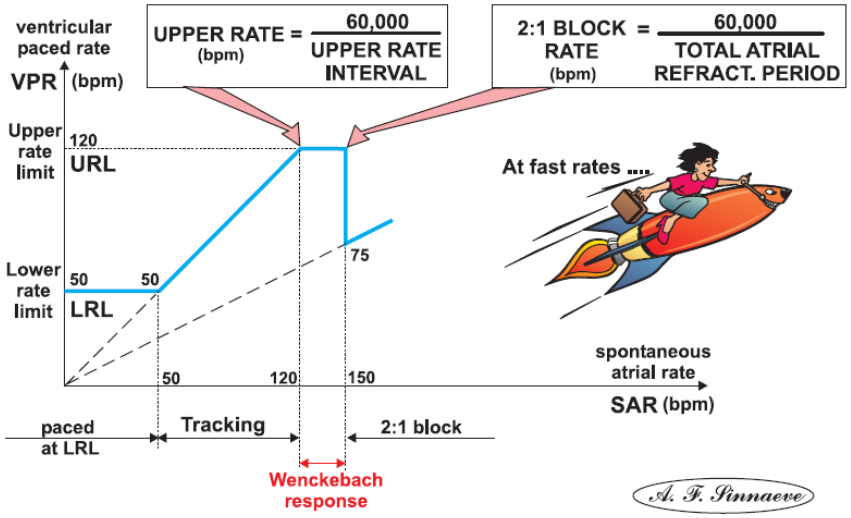
7 URI = Upper Rate Interval (programmable)

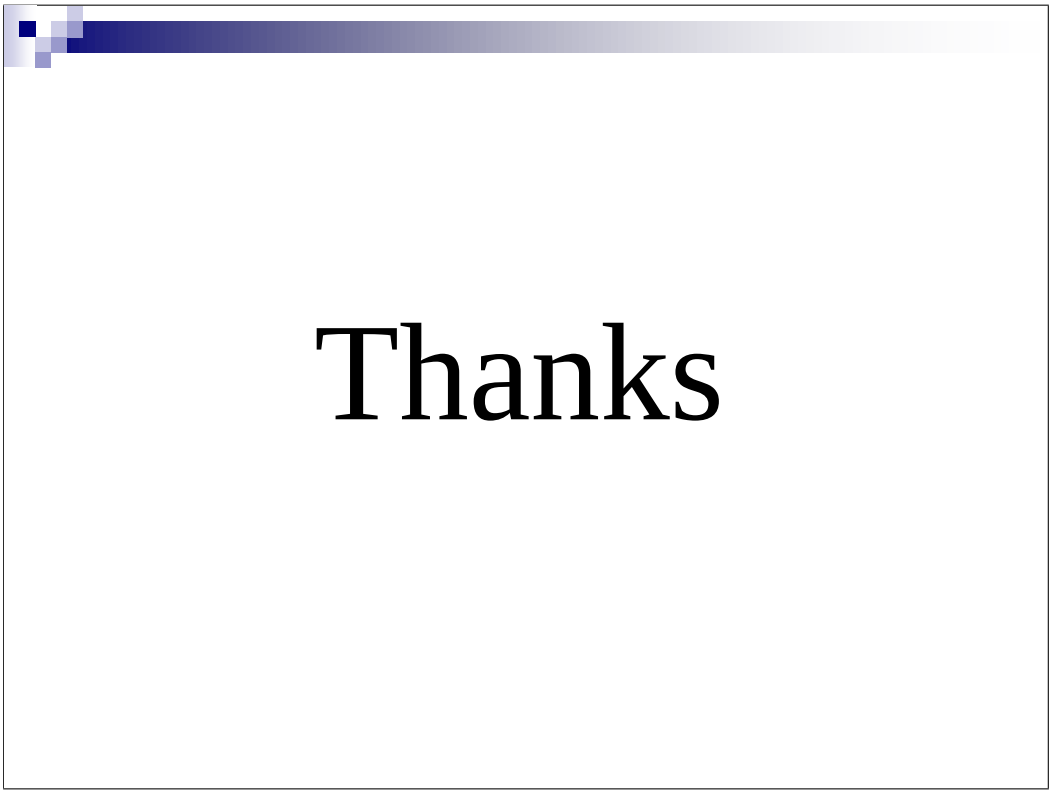
The shortest interval between consecutive ventricular paces.

✓If SAI < URI, AVI may be lengthened.

✓URI must be longer than TARP (AVI + PVARP), otherwise it has no effect.

Wenckebach upper rate response




Thanks