The Boston Scientific Pacemaker Challenge

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Pacemaker Formal Methods Challenge

- The first certification 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
  - This offers an opportunity for the formal methods community to propose novel ideas for pacemaker design

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SQRL Websites and Reading

- Challenge information can be found at http://www.cas.mcmaster.ca/sqrl/pacemaker.htm
- Wiki is located at http://www.cas.mcmaster.ca/wiki/index.php/Pacemaker
- Suggested reading: S. Serge Barold, Roland X. Stroobandt, Alfons F. Sinnaeve, *Cardiac Pacemakers Step by Step: An Illustrated Guide* (2004)

System Specification

- Defines functions and operating characteristics of the pacemaker system
- Identifies the system environmental performance parameters of the system
- Characterizes anticipated uses of the system
- Includes
  - System definition
  - System requirements
  - Diagnostics information
  - Bradycardia therapy information

Supporting Documents

- Tutorials
  - Timing Cycles
  - Advanced Timing Cycles
  - Pacing Codes and Mode Concepts
  - These topics will be discussed shortly
- Hardware Platform Design Documents

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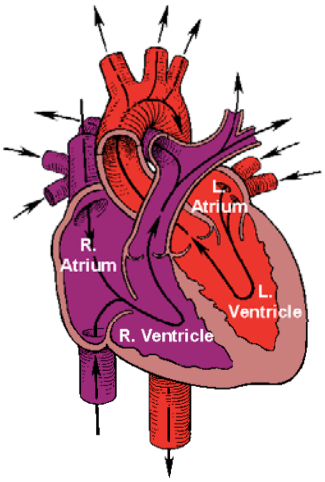
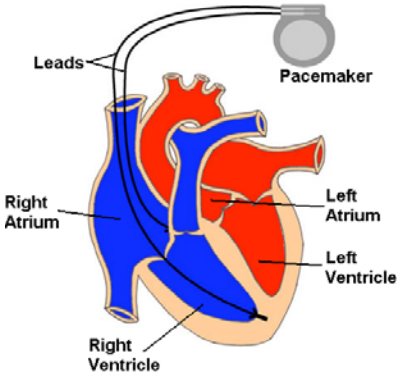
The Human Heart



- Four chambers: right and left atria, and right and left ventricles
- Electrical stimulus is generated periodically in the right atrium, causing the heart's chambers to contract and pump blood. First, the atria are stimulated and contract, then the ventricles do the same
- When this system does not work properly, a pacemaker may be used to regulate the heart rate

Cardiac Pacemaker



- Device implanted into the body to regulate the heart rate by delivering 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:
  1. The heart rate must not be too fast
  2. The heart rate must not be too slow
  3. The ventricles must contract at a particular interval after the atria contract

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System Components: Device

- Detects and provides therapy for bradycardia conditions
- Provides programmable, single- and dual-chamber, rate-adaptive pacing, both permanent and temporary
- May measure physical activity resulting in a sensor indicated rate for pacing the heart
- Provides sensor output data and rate histograms
- Provides diagnostic features including
  - Real-time telemetry markers
  - EGMs
  - P and R wave measurements
  - Lead impedance
  - Battery status tests

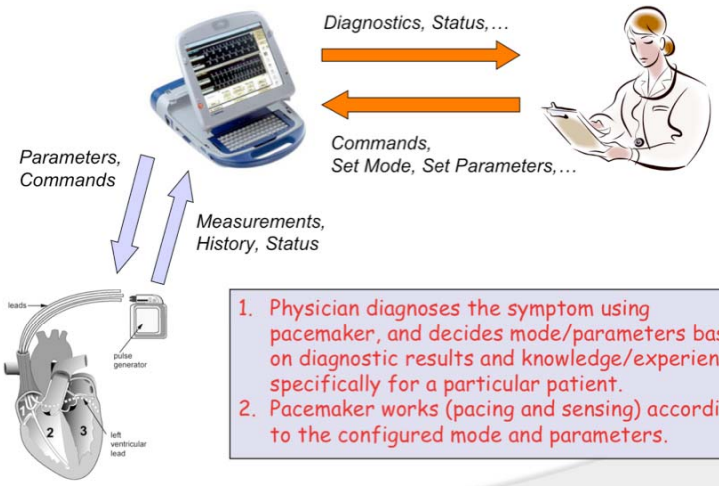
System Components: Device Controller-Monitor

- Primary implant, pre-discharge electrophysiology (EP) support, and follow-up device for the pacemaker system
- Programs and interrogates the device
- Commands delivery of a “Pace Now” pace
- Acquires and shows diagnostics and lead signal measurement information, sensor history and trending information, and multi-channel monitoring
- Monitors battery status

System Components: Lead System

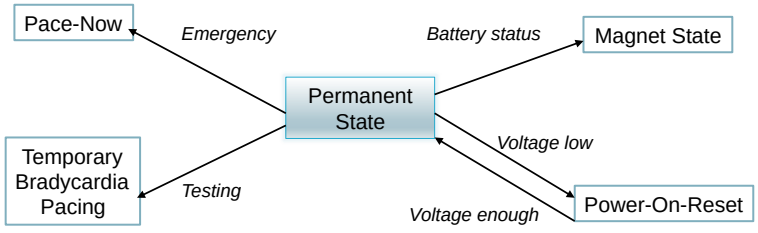
- Implanted in the patient
- Allows the device to sense intrinsic activity of the heart’s electrical signals
- Delivers pacing therapy to the patient’s heart
- Leads are connected to the pulse generator via its header

Pacemaker Usage



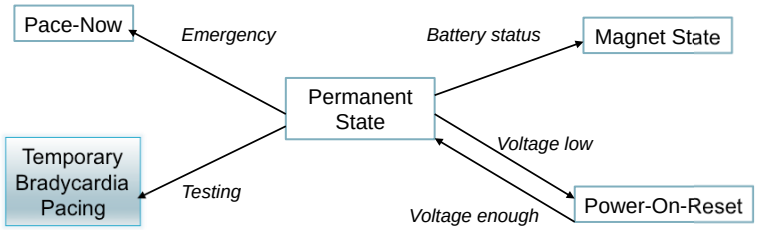
1. Physician diagnoses the symptom using pacemaker, and decides mode/parameters based on diagnostic results and knowledge/experience, specifically for a particular patient.
2. Pacemaker works (pacing and sensing) according to the configured mode and parameters.

Pacemaker Operating States



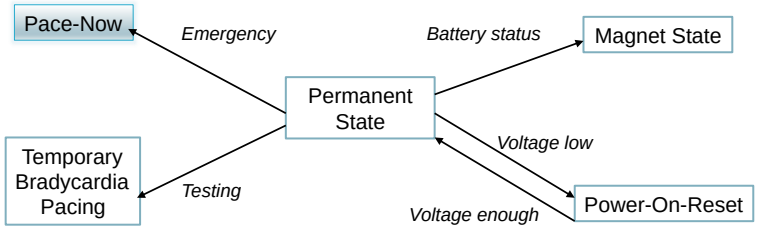
Permanent State: Normal state of operation

Pacemaker Operating States



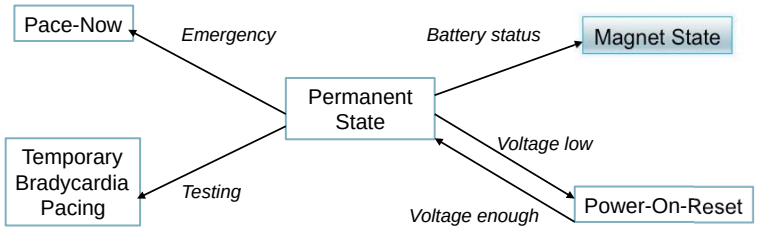
Temporary Bradycardia Pacing: Used to temporarily test various system parameters or provide patient diagnostic testing

Pacemaker Operating States



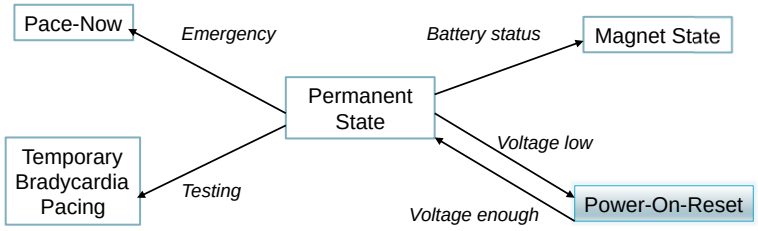
Pace-Now: Emergency pacing, with fixed parameters

Pacemaker Operating States



Magnet State: Used during magnet testing, used to determine battery status of the device

Pacemaker Operating States



Power-On-Reset: Functions are disabled when battery voltage drops below a certain level, and state is resumed when the voltage is restored.

Pacemaker Operating Modes

- There are 10 non-rate-adaptive *modes*, each associated with a 3-letter acronym:
  - The first refers to the chamber(s) paced by the device: V (ventricle), A (atrium), D (dual), or O (neither)
  - The second refers to the chamber(s) in which the device senses, again V, A, D, or O.
  - The third refers to the pacemaker's response to sensing: T (triggers pacing), I (inhibits pacing), D (both), or O (neither).

Programmable Parameters

Parameter	AAT	VVT	AOO	AAI	VOO	VVI	VDD	DOO	DDI	DDD
Lower Rate Limit	X	X	X	X	X	X	X	X	X	X
Upper Rate Limit	X	X	X	X	X	X	X	X	X	X
Fixed AV Delay							X	X	X	X
Dynamic AV Delay							X			X
Sensed AV Delay Offset										X
Atrial Amplitude	X		X	X				X	X	X
Ventricular Amplitude		X			X	X	X	X	X	X
Atrial Pulse Width	X		X	X				X	X	X
Ventricular Pulse Width		X			X	X	X	X	X	X
Atrial Sensitivity	X			X					X	X
Ventricular Sensitivity		X				X	X		X	X
VRP		X				X	X		X	X
ARP	X			X					X	X
PVARP									X	X
PVARP Extension							X			X
Hysteresis				X		X				X
Rate Smoothing				X		X	X			X
ATR Duration				X		X	X			X
ATR Fallback Mode							X			X
ATR Fallback Time							X			X

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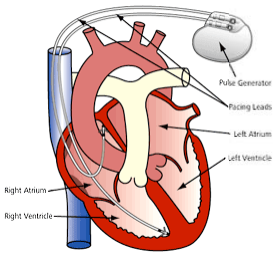
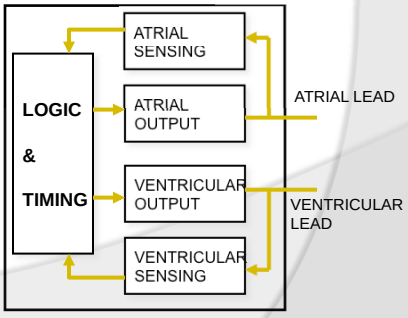
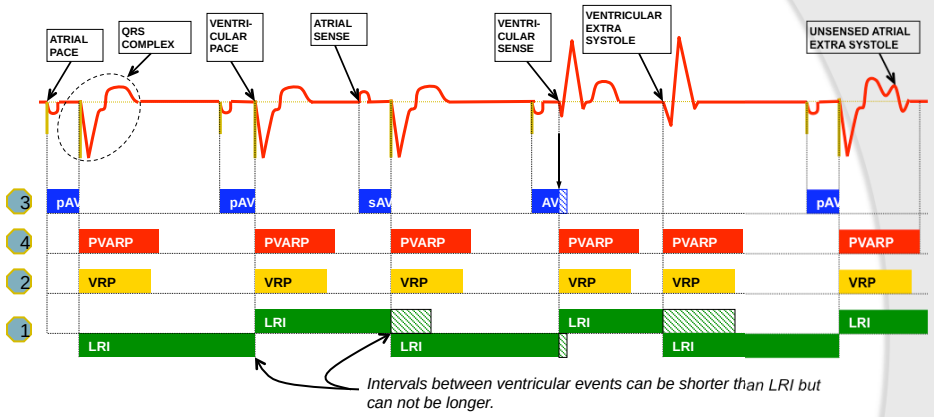
Example: DDD Mode

- Pacemaker senses and paces in both atrium and ventricle
- Synchronization between atrial and ventricular sensing and pacing
- Interference from atrial stimuli to ventricular channel and vice-versa.





Four Fundamental Timing Cycles

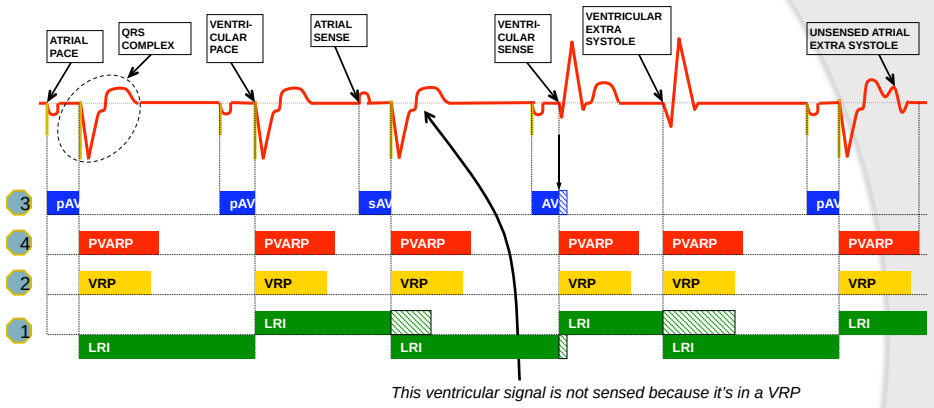


1 LRI = Lower Rate Interval

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

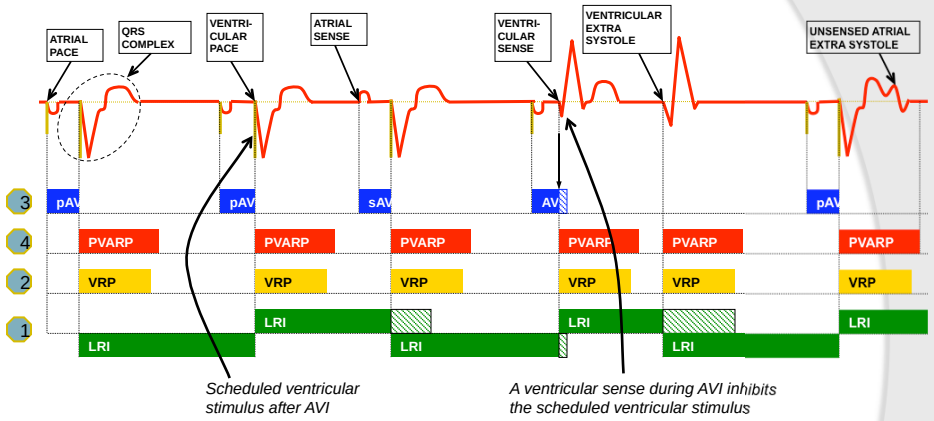


2 VRP = Ventricular Refractory Period

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

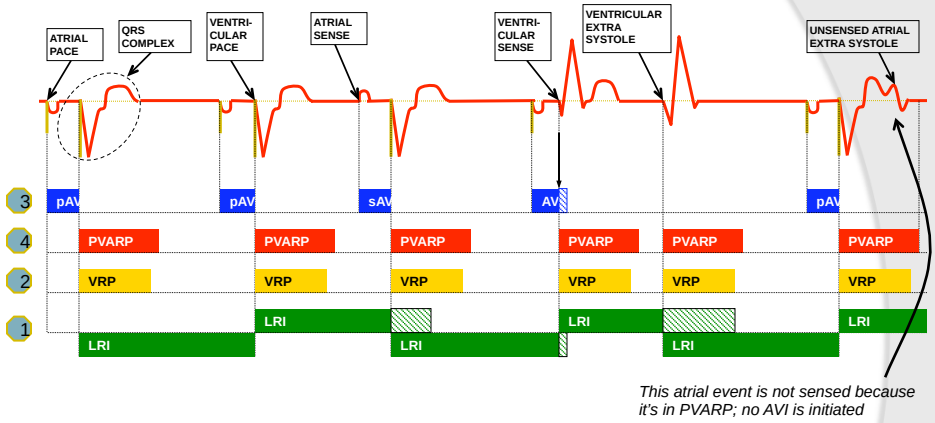
Interval between an atrial event and the scheduled delivery of a ventricular stimulus.

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

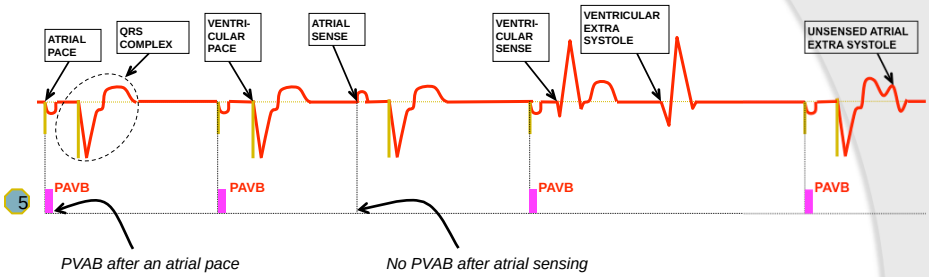


4 PVARP = PostVentricular Refractory Period

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.

Fifth Timing Cycle to Prevent AV Crosstalk



AV Crosstalk

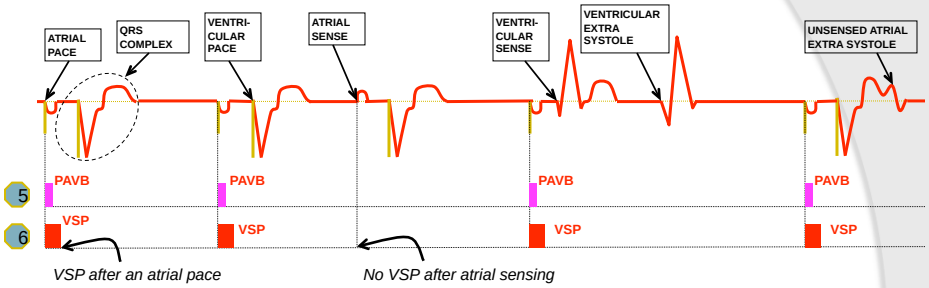
The disturbance caused by an atrial stimulus which, if sensed by the ventricular channel, may cause ventricular inhibition.

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.

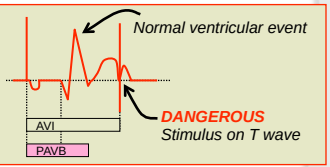
There is no PVAB after an atrial sense since it does not cause disturbance.

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.

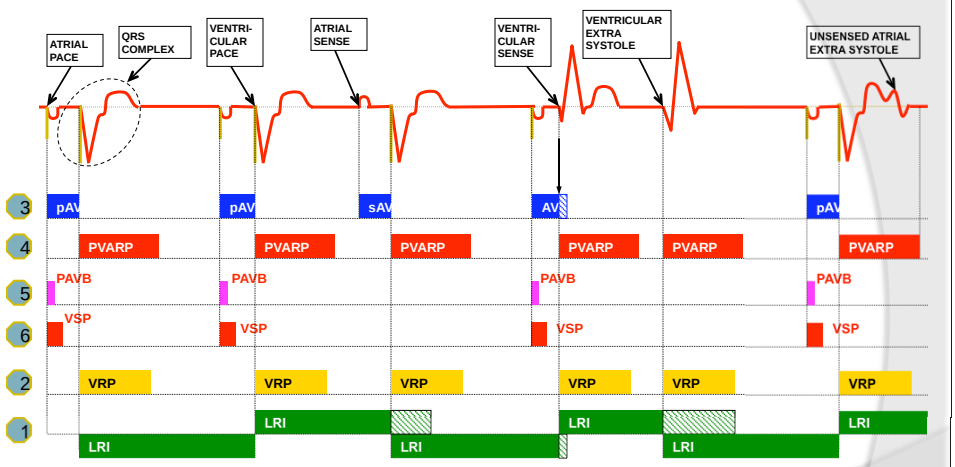


6 VSP = Ventricular Safety Pacing

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.

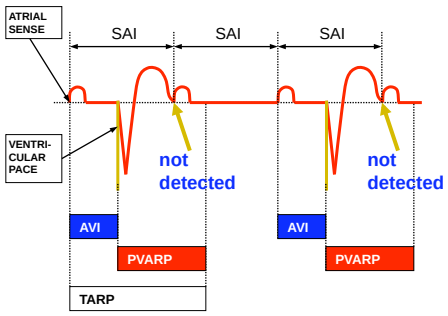
Six Timing Cycles



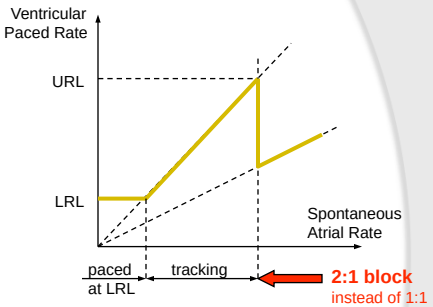
TARP = AVI + PVARP = Total Atrial Refractory Period

Tracking Mode

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



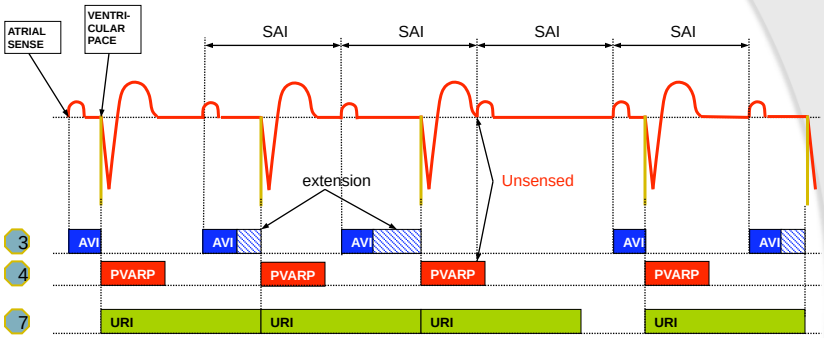
SAI = Spontaneous Atrial Interval



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.