The Meaning of PACEMAKER

Formal Semantics for Chapter 5 of PACEMAKER System Specification

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Scope and Purpose

This presentation concerns the meaning of English-language text of *PACEMAKER System Specification* (a.k.a. the Spec).

Chapter 5, Bradycardia Therapy was largely re-written to be declarative—to define *what* must happen, not *how* it should be done.

At this time, I was working-out the extension of first-order predicates for time at the same time as re-writing the Spec.

The purpose of this presentation is exhibiting and explaining the temporal logic formulas expressed in the text of the Spec.
Heart rates have easily measured, colloquial meaning:

- 60 bpm is typical resting rate;
- 180 bpm is beating fast;
- Age-Predicted Maximum Heart Rate (APMHR) = 220 - age

But always think in milliseconds:

duration = 60000/rate

60 bpm heart rate = 1000 ms cardiac cycle interval

60 PPM lower rate limit (LRL) = 1000 ms lower rate limit interval
LRL=60 Means

“Heart rate at least 60 bpm.”

“Heart paced if not sensed in previous second.”
LRL can only be certain values

<table>
<thead>
<tr>
<th>Lower Rate Limit</th>
<th>30-50 ppm</th>
<th>5 ppm</th>
<th>60 ppm</th>
<th>±8 ms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50-90 ppm</td>
<td>1 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>90-175 ppm</td>
<td>5 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When I was hired, the company manual had a table, printed inside the back cover, of PPM/ms values for exactly those in the table.

The table was referenced often, until memorized.
Semantic Notation

Meaning is defined with $M$. Subscripts specify context.

$M_t[X] \equiv$ meaning of $X$ evaluated at time $t$

$M[X] \equiv$ meaning of $X$ with time unspecified

$\text{now}$ is the time of the present instant
Meaning of @

@ fixes the moment when its predicate is evaluated.¹

For predicate $q$ and time $s$,

$$ M[q@s] ≡ M_s[q] $$

¹ added $q^i$ for periodic threads post Spec
First Example: VVI Mode

Single, bipolar lead\(^2\) to bottom corner of right ventricle, used for both sensing and pacing.

Only VVI mode: pace ventricle, sense ventricle, inhibit pacing when intrinsic heart rate is faster than LRL.

\(^2\)shielded wires to a contact at the tip, and a ring about 1 cm further up.
VVI Thread Component

Event ports s (ventricular sense) and p (ventricular pace) are connected to the analog front end. Parameters l (LRL interval) and r (Ventricular Refractory Period) are parameters of patient’s electrophysiological prescription supplied by telemetry.

T renames data BLESS_Types::Time;

thread VVI
  features
    s: in event port; --ventricular sense
    p: out event port; --pace ventricle
    n: out event port; --non-refractory ventricular sense
    l: in data port T; --lower rate limit interval
    r: in data port T; --ventricular refractory period
  properties
    Dispatch_Protocol => Aperiodic;
    ...
end VVI;
5.1 Lower Rate Limit (LRL)

The Lower Rate Limit (LRL) is the number of generator pace pulses delivered per minute (atrium or ventricle) in the absence of

- Sensed intrinsic activity.

The Spec says stuff about sensor-controlled pacing, hysteresis, and when the LRL interval starts. Those behaviors will be considered later.
A heartbeat occurred in the previous LRL interval, either an intrinsic contraction electrically sensed, or caused by an electrical pace. Let

- the lower rate limit interval be $L$
- an intrinsic ventricular contraction sensed at time $t$ be $M_t^n$
- a paced ventricular contraction caused at time $t$ be $M_t^p$

then for an arbitrary time $x$, the predicate $LRL(x)$ is defined as

$$LRL(x) \equiv \exists t \in [(x - L) \ldots x] \mid (M_t^n \lor M_t^p)$$

Will attempt to show that $LRL(x)$ is true, for times $x$ of concern, especially, now.
defines a predicate \texttt{LRL} applied to parameter \texttt{x}, where \texttt{n} and \texttt{p} are names of ports, and that \texttt{n}@\texttt{t} means an event occurred on port \texttt{n} at time \texttt{t} and \texttt{p}@\texttt{t} means an event occurred on port \texttt{p} at time \texttt{t}.

The most recent heartbeat occurred within the last LRL interval can be expressed as \texttt{<<LRL(now)>>}, where \texttt{now} refers to the present instant.
All signals are not senses of heartbeats

Electrical chaos follows contraction; device is refractory\(^3\) (unresponsive) to mV heart signals immediately after heartbeats.

### 5.4.1 Ventricular Refractory Period (VRP)

The Ventricular Refractory Period shall be the programmed time interval following a ventricular event during which time ventricular senses shall not inhibit nor trigger pacing.

A ventricular sense will be non-refractory when the most-recent beat, whether intrinsic or paced, was further in the past than the Ventricular Refractory Period.

\(^3\)Often confused with a heart being refractory or unresponsive to pacing around 2 V for 0.5 ms
Non-refractory Ventricular Sense

Let

- the time of the most recent heartbeat be \( l_b \) (for last-beat)
- \( M_{lb}[n] \) be an intrinsic heartbeat occurred at time \( l_b \)
- \( M_{lb}[p] \) a paced heartbeat was caused at time \( l_b \)
- \( r \) be the Ventricular Refractory Period
- \( now \) be the present instant

then ventricular senses will be non-refractory, \( NR \), when the last beat occurred earlier than the Ventricular Refractory Period before the present instant

\[
NR(x) \equiv \neg \exists t \in [(x - r)..x] \mid (M_t[n] \lor M_t[p])
\]
\[
NR() \equiv \neg \exists t \in [(now - r)..now] \mid (M_t[n] \lor M_t[p])
\]
5.4.1 Ventricular Refractory Period (VRP)

As Assertion

\[ \text{not exists } t : T \text{ in } [\text{now}-r..\text{now}] \text{ that } (n@t \text{ or } p@t) \]

<<NR: : -- not in Ventricular Refractory Period

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Assertion Properties of Ports

What do you know is true when an event either leaves or arrives at a port?

Events leaving port \( p \) will cause the front end to administer a pace (2 V, 0.5 ms). What should be true when the heart should be paced?

That’s specified by \texttt{BLESS::Assertion properties, VP()} and \texttt{VS()}. 
thread VVI
features
s: in event port; --a ventricular contraction has been sensed
p: out event port --pace ventricle
    {BLESS::Assertion=>"<<VP()>>";};
n: out event port --non-refractory ventricular sense
    {BLESS::Assertion=>"<<(now=0) or VS()>>";};
l: in data port T; --lower rate limit interval
r: in data port T; --ventricular refractory period

properties
    Dispatch_Protocol => Aperiodic;

Component Specification is Port Assertions plus Invariant

\begin{quote}
\textbf{Invariant}
\begin{verbatim}
<<LRL(now)>> --LRL is true, whenever "now" is
\end{verbatim}
\end{quote}

Fundamental effectiveness property is that the most recent heartbeat will always be less than the lower rate limit interval in the past.
Something was sensed, not in ventricular refractory period.

\[ VS() \equiv M_{now}[s] \land NR() \]

<<VS: : --ventricular sense detected, not in VRP

s@now and NR() >>

An event sent out port n means its either commencing operation, or a ventricular sense was detected, not in VRP

n: out event port --non-refractory ventricular sense

{BLESS::Assertion=>"<<(now=0) or VS()>>";};
Pace the heart when there has been no heartbeat in previous LRL interval.

\[ VP() \equiv \neg \exists t \in [now - l, now] \mid (M_t[n] \lor M_t[p]) \]
An event sent out port \( p \) means no heartbeat occurred in the previous LRL interval, so the analog front end should pace the heart.
Show VVI Example

- AADL component
- BLESS behavior
- Correctness proof
Part I

DDD Mode
thread DDD

features

a: in event port; -- atrial sense
v: in event port; -- ventricular sense
ap: out event port -- pace atrium
    {BLESS::Assertion=>"<<AP(now)>>";};
vp: out event port -- pace ventricle, but not too soon
    {BLESS::Assertion=>"<<VP(now) and URL(now)>>";};
as: out event port -- non-refractory atrial sense
    {BLESS::Assertion=>"<<NRAS(now)>>";};
vs: out event port -- non-refractory ventricular sense
    {BLESS::Assertion=>"<<NRVS(now)>>";};

end DDD;
5.2 Upper Rate Limit (URL)

The Upper Rate Limit (URL) is the maximum rate at which the paced ventricular rate will track sensed atrial events. The URL interval is the minimum time between a ventricular event and the next ventricular pace.
Let

- the upper rate limit interval be $u$
- a non-refractory ventricular sense occurring at time $t$ be $M_t[\text{vs}]$
- a ventricular pace caused at time $t$ be $M_t[\text{vp}]$

then the upper rate limit safety property is

$$URL(x) \equiv \neg \exists t \in [(x-u), x] \mid (M_t[\text{vs}] \lor M_t[\text{vp}])$$

Must only ventricular pace when $URL(x)$ is true, when no ventricular event (pace or sense) occurred in the previous URL interval.
5.2 Upper Rate Limit

As Assertion

\[
\text{URL:} \ x: \quad \text{--no } v\text{-pace or sense in previous URL interval}
\]

\[
\text{not (exists } t: T \\
\text{in } x-u,,x \\
\text{that } (vs \ or \ vp)@t \ \rangle \rangle
\]

\[
\text{vp: out event port --pace ventricle, but not too soon} \\
\{ \text{BLESS::Assertion=}"\langle\langle VP(\text{now}) \ \text{and} \ \text{URL(\text{now})}\rangle\rangle"; \};
\]
5.3 Atrial-Ventricular (AV) Delay

The AV delay shall be the programmable time period from an atrial event (either intrinsic or paced) to a ventricular pace.

In atrial tracking modes, ventricular pacing shall occur in the absence of a sensed ventricular event within the programmed AV delay when the sensed atrial rate is between the programmed LRL and URL.

AV delay shall either be

1. Fixed (absolute time)

2. Dynamic
5.3.1 Paced AV Delay

A paced AV (PAV) delay shall occur when the AV delay is initiated by an atrial pace.
Let

- the AV delay interval be \( av \)
- an atrial pace occurring at time \( t \) be \( M_t[ap] \)

then the paced AV delay property is

\[
P_{AV}(x) \equiv \exists t \in [(x - av)..x] \mid M_t[ap]
\]

An atrial pace occurred in the previous (paced) AV delay interval.
<<PAV:x:  --there has been A-pace during the AV delay
  exists t:BESS_Types::Time
  in x-av..x
  that ap@t >>
5.3.2 Sensed AV Delay

A sensed AV (SAV) delay shall occur when the AV delay is initiated by an atrial sense.

5.3.4 Sensed AV Delay Offset

The Sensed AV Delay Offset option shall shorten the AV delay following a tracked atrial sense.

Depending on which option is functioning, the sensed AV delay offset shall be applied to the following:

1. The fixed AV delay
2. The dynamic AV delay
Let

- the AV delay interval be \( av \)
- the (negative) sensed AV offset be \( o \)
- the URL interval be \( u \)
- a non-refractory atrial sense occurring at time \( t \) be \( M_t[as] \)
- a non-refractory ventricular sense occurring at time \( t \) be \( M_t[vs] \)
- a ventricular pace occurring at time \( t \) be \( M_t[vp] \)

then the sensed AV delay property is

\[
SAV(x) \equiv \exists t \in [x - (av + o) .. x] | M_t[as]
\]

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An atrial sense occurred in the previous sensed AV delay interval, or the time since the previous ventricular event is greater than URL interval.

\[ \langle \langle \text{SAV}: x : \rangle \rangle \quad \text{--there has been an A-sense during the sensed AV delay exists} \quad t : T \]

\[ \text{in} \quad x - (av + o) \ldots x \quad \text{--SAV offset paces V quicker after a-sense} \]

\[ \text{that as} @ t \gg \]
5.4.2 Atrial Refractory Period (ARP)

For single chamber atrial modes, the Atrial Refractory Period (ARP) shall be the programmed time interval following an atrial event during which time atrial events shall not inhibit nor trigger pacing.

Applies to atrial-only modes: AAI AAIR

With DDD pacing, ARP usually falls in the AV-delay which is refractory to atrial senses anyway.
Let

- the atrial refractory period be \( \text{arp} \)
- an atrial pace occurring at time \( t \) be \( M_t[ap] \)
- a non-refractory atrial sense occurring at time \( t \) be \( M_t[as] \)

then the atrial refractory period property is

\[
ARP(x) \equiv \exists t \in [(x - \text{arp}), x] \mid (M_t[as] \lor M_t[ap])
\]
\[ \langle\langle \text{ARP}:x:} \]
\[\exists \ t:T \]
\[\text{in } x\text{-arp},x \]
\[\text{that } (\text{as or ap})@t >> \]
5.4.3 Post Ventricular Atrial Refractory Period (PVARP)

The Post Ventricular Atrial Refractory Period shall be available in modes with ventricular pacing and atrial sensing. The Post Ventricular Atrial Refractory Period shall be the programmable time interval following a ventricular event when an atrial cardiac event shall not 1. Inhibit an atrial pace. 2. Trigger a ventricular pace.
Let

- the post-ventricular, atrial refractory period be \( p\text{varp} \)
- an ventricular pace occurring at time \( t \) be \( M_t[p] \)
- a non-refractory ventricular sense occurring at time \( t \) be \( M_t[vs] \)

then the PVARP property is

\[
PVARP(x) \equiv \exists t \in [(x - p\text{varp}), x] \mid (M_t[vs] \lor M_t[vp])
\]
Post Ventricular Atrial Refractory Period (PVARP) as Assertion

\[ \text{exists } t : T \text{ in } x - \text{pvarp}, x \text{ that } (\text{vs or vp}) @ t \]
An atrial sense is non refractory when not in ARP, PVARP, or AV Delay.

\[ AS(x) \equiv \exists_x[a] \land \neg ARP(x) \land \neg PVARP(x) \land \neg (PAV(x) \lor SAV(x)) \]

\(<\text{AS}:x>\):
- \(a@x\) -- atrial sense at time \(x\)
- and not \(ARP(x)\) -- not atrial refractory period
- and not \(PVARP(x)\) -- not post-ventricular atrial refractory period
- and not \((PAV(x) \lor SAV(x))\) -- not paced or sensed AV delay
DDD Example

- AADL component
- BLESS behavior
- Correctness proof
Part II

Rate Modifiers

DDD mode is base.

Other modes subsets of DDD behavior.

Rate modifiers (actually duration modifiers) to DDD make parameters dynamic in some way.

LRL, URL, AV delay, PVARP, mode, etc.,
Dynamic Parameters

**MaxCCI** maximum cardiac cycle interval (like LRLi)

**MinCCI** minimum cardiac cycle interval (like URLi)

**DAV** dynamic AV delay

**FB** ATR fall-back: temporarily ignore all atrial senses

**Hysteresis** increases MaxCCI

**Rate Response** shortens MaxCCI during activity
5.4.4 Extended PVARP

The Extended PVARP works as follows:

1. When Extended PVARP is enabled, an occurrence of a premature ventricular contraction (PVC) shall cause the pulse generator to use the Extended PVARP value for the post-ventricular atrial refractory period following the PVC.

2. The PVARP shall always return to its normal programmed value on the subsequent cardiac cycle regardless of PVC and other events. At most one PVARP extension shall occur every two cardiac cycles.
Let

- the extended, post-ventricular, atrial refractory period be \( \text{ex}_p \text{varp} \)
- an ventricular pace occurring at time \( t \) be \( M_t[p] \)
- a non-refractory ventricular sense occurring at time \( t \) be \( M_t[vs] \)

then the extended PVARP property is

\[
\text{ExPVARP}(x) \equiv \exists t \in [(x - \text{ex}_p \text{varp}), , x] \mid (M_t[vs] \lor M_t[vp])
\]

and is used when
5.4.4 Extended PVARP

UseExPVARP(x) ≡ XPEN(x) ∧ PVCinCC(x) ∧ ¬XPlastCC(x)

where

- enabling the extended, post-ventricular, atrial refractory period be \( XPEN(x) \)
- occurrence of pre-mature ventricular contraction (PVC) during previous cardiac cycle be \( PVCinCC(x) \)
- PVARP was extended previous cardiac cycle be \( XPlastCC(x) \)
5.4.4 Extended PVARP

As Assertion

\[ \text{exists } t:T \text{ in } x\text{-ex\_pvarp,,}x \text{ that } (\text{vs or vp})@t \]

\[ \text{UseExPVARP:} x: \text{ XPEN}(x) \text{ and PVCinCC}(x) \text{ and not XPlastCC}(x) \]
Premature Ventricular Contraction (PVC)

“A ventricular sense is deemed to be a premature ventricular contraction if there has been no atrial event since the previous ventricular event.”

PVC occurs when there is a non-refractory ventricular sense at time $x$, with some time $y$ earlier than $x$ with a ventricular event, but no atrial event since.

$$PVC(x) \equiv M_x[vs] \wedge \neg VRP(x) \wedge \exists y : T \mid y < x \wedge (M_y[vs] \vee M_y[vp])$$

$$\wedge \neg \exists t : T \in [y..x] \mid (M_t[as] \vee M_t[ap])$$

<<PVC::x: VS(x) and --non-refractory ventricular sense
(exists y:T in y<x that (vs or vp)@y --with earlier v-event and --with no a-event since
not (exists t:T in [y..x] that (as or ap}@t))>>
Premature Ventricular Contraction (PVC)

PVC in Previous Cycle

\[ \text{PVCinCC}(x) \equiv \exists t : T \in [(x - l), x] \mid \text{PVC}(t) \]

Note: using LRL interval instead of CCI. Would need to set variable for most recent cardiac cycle interval.
**Extended PVARP in Previous Cycle**

\[
XPlastCC(x) \equiv \exists t : T \in [(x - l), , x] \mid \text{ExPVARP}(t)
\]

<<XPlastCC:x: \textbf{exists} t:T \textbf{in} x-l,,x \textbf{that} \textbf{UseExPVARP}(t)>>
5.8 Hysteresis Pacing

When enabled, hysteresis pacing shall result in a longer period following a sensed event before pacing. This encourages self-pacing during exercise by waiting a little longer to pace after senses, hoping that another sense will inhibit the pace.

To use hysteresis pacing:

1. Hysteresis pacing must be enabled (not Off).

2. The pacing mode must be inhibiting or tracking.

3. The current pacing rate must be faster than the Hysteresis Rate Limit (HRL), which may be slower than the Lower Rate Limit (LRL).

4. When in AAI mode, a single, non-refractory sensed atrial event shall activate hysteresis pacing.

5. When in an inhibiting or tracking mode with ventricular pacing, a single, non-refractory sensed ventricular event shall activate hysteresis pacing.
5.8 Hysteresis Pacing  As Assertion

Extend LRL when VS

Need to re-define LRL property to have variable maximum cardiac cycle interval (MaxCCI)

\[
<<\text{LRL\_Hy}\!: x \quad \text{--Lower Rate Limit with Hysteresis}\]
\[
\exists t: \text{Time} \quad \text{--there was a moment}\]
\[
in x-\text{HyLRL}(x) \ldots x \quad \text{--within the previous Hysteresis Pacing interval}\]
\[
\text{that } (n@t \text{ or } p@t) \quad \text{--with a pace or non-refractory sense}\]

Make MaxCCI dependent on whether last V event was VS. Use Hysteresis Rate Limit if last V was VS.

\[
<<\text{HyLRL}\!: x \quad \text{--lengthen LRL upon VS}\]
\[
(LAST\_V\_WAS\_VS(x) ?? h : l) \quad \text{--use Hysteresis Rate Limit if last V was VS}\]
Last V was VS

<<LAST_V_WAS_VS:x: exists t:T in x-1..x that
    (vs@t and --v-sense at time t
      not exists t2:T in t,,x that --no vs or vp since
        (vs@t2 or vp@t2)) >>

Set boolean variable each VS or VP:

<<INV: : . . . and (lastVwasVS iff LAST_V_WAS_VS(now))>>
5.8 Hysteresis Pacing

In AAI, Extend LRL when AS

Atrial-only pacing triggers hysteresis pacing when last A was AS.

<<AtrialMaxCCI:x:=\quad--\text{lengthen LRL upon AS}
(LAST_A_WAS_AS(x) \Leftrightarrow \text{hrl : l}) \quad--\text{use Hysteresis Rate Limit in}

<<LAST_A_WAS_AS:x: \textbf{exists} t:T \textbf{in} x-1..x \textbf{that}
(as@t \quad--\text{A-sense at time } t
\textbf{not exists} t2:T \textbf{in} t,,x \textbf{that} \quad--\text{no as or ap since}
(as@t2 \textbf{or ap@t2})) \quad--\text{no as or ap since}

<<\textbf{INV:} : \quad... \quad\textbf{and} \quad\text{lastAwasAS \quadiff \quadLAST_A_WAS_AS(now)})>>
5.3.3 Dynamic AV Delay

If dynamic, the AV delay shall be determined individually for each new cardiac cycle based on the duration of previous cardiac cycles. The previous cardiac cycle length is multiplied by a factor stored in device memory to create the dynamic AV delay.

The AV delay shall vary between

1. A programmable maximum paced AV delay
2. A programmable minimum paced AV delay

Shortens AV Delay when pacing faster.

Fixed AV Delay when tracking/pacing LRL.

Minimum Dynamic AV Delay when tracking at URL.
5.3.3 Dynamic AV Delay

AV Squeeze

Let

- Fixed AV delay be $av$
- Minimum Dynamic AV Delay be $m$
- Lower rate limit interval be $l$
- Upper rate limit interval be $u$
- Dynamic AV delay be $dav$
- Cardiac cycle interval be $cci$

then

$$dav = \left(\frac{av - m}{l - u}\right) \times cci + m$$
5.3.3 Dynamic AV Delay

As Assertion

<<DAV:x:= CCI(x)*((av-dav)/(l-u)) + dav>>

Note: when fixed (av) and minimum (dav) AV delays are the same, then
dynamic AV delay becomes fixed.

<<PAV:x: --dynamic
exists t:BLESS_Types::Time in x-DAV(x)..x that ap@t >>

<<SAV:x: --dynamic, with offset
exists t:T in x-(DAV(x)+o)..x that as@t >>

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5.5 Noise Response

In the presence of continuous noise the device response shall be asynchronous pacing.

Electrical garbage on leads sensed by analog front end.

Independent A and V noise detections.

Suppressing all senses causes asynchronous pacing (AOO VOO or DOO).

Put out “TN” marker on strip-chart, A-channel, V-channel, or both, at onset and repeated some unspecified interval (2 s) if continuous noise.
Add noise term to uses of a and v

Where $tnv$ is the boolean data port\(^6\) value from analog front end indicating noise on the ventricular lead, $tna$ is the boolean data port\(^7\) value from analog front end indicating noise on the atrial lead,

$M_x[a]$ becomes $M_x[a] \land \neg M_x[tna]$

$M_x[v]$ becomes $M_x[v] \land \neg M_x[tnv]$

\(^6\)NOT an event port
\(^7\)NOT an event port
Add extra condition for signal to be a sense

**<<AS:x:**

- $a_x$ -- atrial sense at time $x$
- and not $tna_x$ -- no noise on A-channel
- and not $ARP(x)$ -- not atrial refractory period
- and not $PVARP(x)$ -- not post-ventricular atrial refractory period
- and not $(PAV(x) \lor SAV(x))$ -- not paced or sensed AV delay

**<<VS:x:**

- $v_x$ -- ventricular sense at time $x$
- and not $tnv_x$ -- no noise on V-channel
- and not $VRP(x)$ -- not ventricular refractory period
5.6 Atrial Tachycardia Response (ATR)

The Atrial Tachycardia Response prevents long term pacing of a patient at unacceptably high rates during atrial tachycardia. When Atrial Tachycardia Response is enabled, the pulse generator shall declare an atrial tachycardia if the intrinsic atrial rate exceeds the URL for a sufficient amount of time.

Detection, Duration, Fall-back, and Cessation
5.6.1 Atrial Tachycardia Detection

The atrial tachycardia (AT) detection algorithm determines onset and cessation of atrial tachycardia.

1. AT onset shall be detected when the intervals between atrial senses are predominately, but not exclusively, faster than URL.

2. AT cessation shall be detected when the intervals between atrial senses are mostly, but not exclusively, faster than URL.

3. The detection period shall be short enough so ATR therapy is not unnecessarily delayed nor continued.

4. The detection period shall be long enough that occasional premature atrial contractions do not cause unnecessary ATR therapy, nor cease necessary ATR therapy upon occasional slow beats.

Where is the error?
Count AT and AS

Put out “AT” (atrial-tachycardia) marker when duration since last AS less than URL interval.

AT events are just AS that happen to be fast.

Count AT versus AS. If at least 5 of the last 7 AS\textsuperscript{8} were also AT, then ATR detection is met.

Cease when at most 3 of 7 AS are also AT.

\textsuperscript{8}these are made-up numbers, not those performed by the device
5 (or greater) of 7 fast AS to Detect

For the most recent 7 atrial senses, AS were there at least 5 that were faster than URL?

--at least 5 of 7 lA-events were AT
<<ATR_DETECT:x:
  exists s:T in s<x that --there is an earlier time s
  ((7=num t:T in s..x of as@t) --seven atrial senses
   and (5<=num t:T in s..x of at@t))>> --five or more were faster
3 (or fewer) of 7 fast AS to End

For the most recent 7 atrial senses, AS were there at most 3 that were faster than URL?

--at most 3 of 7 A-events were AT
<<ATR_END:x:
   exists s:T in s<x that --there is an earlier time s
       ((7=num t:T in s..x of as@t) --seven atrial senses
        and (3>=num t:T in s..x of at@t)))>> --three or fewer were faster
5.6.2 ATR Duration

ATR Duration works as follows:

1. When atrial tachycardia is detected, the ATR algorithm shall enter an ATR Duration state.

2. When in ATR Duration, the PG shall delay a programmed number of cardiac cycles before entering Fallback.

3. The Duration delay shall be terminated immediately and Fallback shall be avoided if, during the Duration delay, the ATR detection algorithm determines that atrial tachycardia is over.

Once detection is met (5 of 7), duration continues until programmed CC count, or fast beats fall to 3 out of 7 or fewer.
In ATR Duration

let

- **dur** be the prescribed number of cardiac cycles to stay fast
- met ATR detection (put out “ATR-Dur” marker) on cardiac cycle d

```plaintext
<<ATR_DURATION:d k:  --d and k are cardiac cycle numbers
ATR_DETECT(d) and  --detection met on CC d
(k-d)<dur and  --cc since then is less than needed for fall-back
all j in d..k are not ATR_END(j) >>  --not ended ATR since then
```
5.6.3 ATR Fallback

If the atrial tachycardia condition exists after the ATR Duration delay is over, the following shall occur:

1. The PG enters a Fallback state and switches to a VVIR Fallback Mode.

2. The pacing rate is dropped to the lower rate limit. The fallback time is the total time required to drop the rate to the LRL.

3. During Fallback, if the ATR detection algorithm determines that atrial tachycardia is over, the following shall occur:
   - Fallback is terminated immediately
   - The mode is switched back to normal

4. ATR-related mode switches shall always be synchronized to a ventricular paced or sensed event.
let

- \( \text{dur} \) be the prescribed number of cardiac cycles to stay fast
- \( \text{CC}(x) \) be the cardiac cycle at time \( x \)
- met ATR detection (put out “ATR-Dur” marker) on cardiac cycle \( d \)

\[
\text{FB:} k \ d:\text{FB:} \quad \text{ATR}\_\text{DETECT}(d) \quad \text{and}\quad \quad \text{--detection met on CC } d \quad (k\text{-}d)\geq \text{dur} \quad \text{and} \quad \quad \text{--cc since then is at least needed for fall-back} \\
\text{all } j \text{ in } d..k \text{ are not } \text{ATR}\_\text{END}(j) \quad \quad \quad \text{--not ended ATR since then}
\]
5.6.2 ATR Fall-Back

ATR Fall-Back is one more AS inhibition

--non-refractory atrial sense

<<AS:x:
  a@x  --atrial sense at time x
  and not tna@x  --no noise on A-channel
  and not ARP(x)  --not atrial refractory period
  and not PVARP(x)  --not post-ventricular atrial refractory period
  and not (PAV(x) or SAV(x))  --not paced or sensed AV delay
  and not FB(x)  --not ATR fall-back

>>
5.6.2 ATR Fall-Back

Must slow pacing from URL to LRL over fallback time

Been tracking at or near URL.

When switching to fall-back, must slowly reduce pacing rate to LRL

Pacing at URL at time when duration met, \( t_d \); pace at LRL prescribed fall-back time later \( t_{fb} \)

For time \( x \) between \( t_d \) and \( t_d + t_{fb} \):

\[
FB_{\text{MaxCCI}}(x) = (x - t_d) \times \left( \frac{l - u}{t_{fb}} \right)
\]

\[<<<FB_{\text{MaxCCI}}:x:= (x-td)*((l-u)/tfb)>>\]
5.7 Rate-Adaptive Pacing

The device shall have the ability to adjust the cardiac cycle in response to metabolic need as measured from body motion using an accelerometer.

Attempt to mimic increase in heart rate with activity.

Fiddle parameters to customize response:

**Max Sensor Rate**  maximum rate based on XL

**Activity Threshold**  minimum milliG for rate increase

**Reaction Time**  minimum time from LRL to MSR

**Response Factor**  how much boost once over threshold

**Recovery Time**  minimum time from MSR to LRL
5.7.1 Maximum Sensor Rate (MSR)

The Maximum Sensor Rate is the maximum pacing rate allowed as a result of sensor control.

The Maximum Sensor Rate shall be

1. Required for rate adaptive modes
2. Independently programmable from the URL

\[ MSR < URL \]

Upper bound of Sensor Indicated Rate (SIR) \[ LRL < SIR \leq MSR \]
5.7.2 Activity Threshold

The activity threshold is the value the accelerometer sensor output shall exceed before the pacemaker’s rate is affected by activity data.

Activity Threshold may be V-Low, Low, Med-Low, Med, Med-High, High, V-High. No specification of how many milliG for each.

My suggestion (in milliG):

<table>
<thead>
<tr>
<th></th>
<th>V-Low</th>
<th>Low</th>
<th>Med-Low</th>
<th>Med</th>
<th>Med-High</th>
<th>High</th>
<th>V-High</th>
</tr>
</thead>
<tbody>
<tr>
<td>milliG</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
<td>35</td>
<td>50</td>
<td>75</td>
</tr>
</tbody>
</table>

25 milliG was cut-off for activity log
5.7.3 Response Factor

The accelerometer shall determine the pacing rate that occurs at various levels of steady state patient activity.

Based on equivalent patient activity:

1. The highest response factor setting (16) shall allow the greatest incremental change in rate.

2. The lowest response factor setting (1) shall allow a smaller change in rate.

No specification of what 1 through 16 mean, just that it’s a greater change in rate.
Response Factor $f$ together with Activity Threshold $th$, lower rate limit interval $l$ and accelerometer $xl$ determine Sensor Indicated Rate interval $\text{SIRi}$. No shorter than maximum sensor rate interval $m$.

For $xl > h$: $\text{SIRi} = \max(m, l - f \times (xl - th))$

Activity to MSR=150 with LRL=60 and “Med” activity threshold (25 milliG)

<table>
<thead>
<tr>
<th>$f$</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>milliG</td>
<td>625</td>
<td>325</td>
<td>225</td>
<td>175</td>
<td>145</td>
<td>125</td>
<td>110</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>$f$</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>milliG</td>
<td>92</td>
<td>85</td>
<td>80</td>
<td>75</td>
<td>71</td>
<td>68</td>
<td>65</td>
<td>62</td>
</tr>
</tbody>
</table>
Response Factor $f$ treated as ms/milliG reduction in interval from LRLi, $l$.

For activity above threshold, $x_l > \text{th}$:

$$SIRI: x := \max(m, l - (f \times (x_l - \text{th})))$$
5.7.4 Reaction Time

The accelerometer shall determine the rate of increase of the pacing rate. The reaction time is the time required for an activity to drive the rate from LRL to MSR.

Sensor Rate (sr) rate smoothed from SIRI.

Reaction time (10, 20, 30, 40, 50 sec) is how long from LRL to MSR upon maximum G.
Determine the fixed number of ms to shorten CCI, $z$, such that the time between CCI=$l$ and CCI=$m$ takes Reaction Time seconds, in $k$ cardiac cycles. Each of the $k$ cardiac cycles is $z$ shorter than the previous; $k$ cardiac cycles shorten CCI from $l$ to $m$ in Reaction Time $rt$ ms.
5.7.4 Reaction Time

\[ rt = \sum_{j=0}^{k} l - z \times j = (k + 1) \times l - z \times \sum_{j=0}^{k} j = (k + 1) \times l - z \times \frac{k^2}{2} \]

such that \( l - m = k \times z \) or \( k = \frac{l-m}{z} \)

Substituting for \( k \)

\[ rt = \left( \frac{l-m}{z} + 1 \right) \times l - z \times \frac{(l-m)^2}{2} \]

\[ rt = \frac{(l-m) \times l}{z} + l - \frac{(l-m)^2}{2 \times z} \]

\[ rt - l = \frac{(l-m) \times l - \frac{(l-m)^2}{2}}{z} \]

\[ z = \frac{(l-m) \times l - \frac{(l-m)^2}{2}}{rt - l} \]
5.7.4 Reaction Time

As Math

\[ z = \frac{(l - m) \times (l - \frac{l-m}{2})}{rt - l} \]

\[ z = \frac{(l - m) \times (\frac{l+m}{2})}{rt - l} \]

\[ z = \frac{(\text{change in CCI} \times \text{average CCI})}{(\text{Reaction Time} - l)} \]

When \( SIRi < CCI \) sensor indicated rate interval is shorter than previous cardiac cycle interval,

\[ \text{MaxCCI} = \max((CCI - z), SIRi) \]
\[ Z := \frac{(l-m) \times (l+m)}{2 \times (r_t-l)} \]

\[ \text{MaxCCI}: x := \max((\text{CCI}(x) - Z()), \text{SIRi}()) \]
5.7.5 Recovery Time

The accelerometer shall determine the rate of decrease of the pacing rate. The recovery time shall be the time required for the rate to fall from MSR to LRL when activity falls below the activity threshold.

Recovery Time is down-rate smoothing after exercise.
Let $y$ be the maximum increase in CCI to recover from maximum sensor rate interval $m$ to lower rate limit interval $l$, in recovery time $ct$, 

\[
y = \frac{(l - m) \times (\frac{l+m}{2})}{ct - l}
\]

When $SIRi > CCI$ sensor indicated rate interval is longer than previous cardiac cycle interval,

MaxCCI = \text{min}(\text{CCI} + y, SIRi)
5.7.5 Recovery Time

As Assertion

\[
Y := \frac{(l-m)(l+m)}{2(ct-l)}
\]

\[
\text{MaxCCI: } x := \min((\text{CCI}(x)+Y()), \text{SIRi}())
\]
5.9 Rate Smoothing

Rate Smoothing shall limit the pacing rate change that occurs due to precipitous changes in the intrinsic rate.

Two programmable rate smoothing parameters shall be available to allow the cardiac cycle interval change to be a percentage of the previous cardiac cycle interval:

1. Rate Smoothing Up
2. Rate Smoothing Down

The increase in pacing rate shall not exceed the Rate Smoothing Up percentage.
The decrease in pacing rate shall not exceed the Rate Smoothing Down percentage.

Up- and down-rate smoothing may be set independently.

May interfere with sensor rate if too strict (3%).
MaxCCI and MinCCI within percent of CCI

Let the up-rate smoothing (percent) be $urs$, (.03, .06, ..., .25) and the down-rate smoothing (percent) be $drs$

Next CCI will only slow $drs$ percent

$$cci \leq MaxCCI \leq cci \times (1 + drs)$$

Next CCI will only quicken $urs$ percent

$$cci \times (1 - urs) \leq MinCCI \leq cci$$
5.9 Rate Smoothing

As Assertion

--down rate smoothing CCI gets longer

\[
\begin{align*}
\text{DOWN:} x &:= CCI(x) \times (1.0 + \text{drs}) \\
\text{MaxCCI:} x &:= \min((CCI(x) + Y()), \ SIRI(), \ \text{DOWN}(x))
\end{align*}
\]

--up rate smoothing CCI gets shorter

\[
\begin{align*}
\text{UP:} x &:= CCI(x) \times (1.0 - \text{urs}) \\
\text{MinCCI:} x &:= \max((CCI(x) - Z()), \ SIRI(), \ \text{UP}(x))
\end{align*}
\]

Like bracketing CCI with LRLi and URLi.
Putting it all together

DDDR with
- extended PVARP
- rate smoothing
- hysteresis pacing
- dynamic AV delay
- sensed AV delay offset
- atrial tachycardia response
Fundamental Effectiveness Property: $\text{LRL}(\text{now})$

$$<<\text{LRL}:x: \exists t:T \text{ in } x-1..x \text{ that } \text{vp}@t \text{ or } \text{vs}@t>>$$
Fundamental Safety Property: V-pace only when

\[ URL(\text{now}) \]

\[
\llangle \text{URL:x:} \quad \text{--no v-pace or sense in previous URL interval} \\
\text{not (exists } t:T \\
\text{in } x-u,,x \\
\text{that } (\text{vs or vp)}@t) \gg
\]