The Pacemaker Project

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Contents

I. Introduction to Pacemaker Challenge
II. Background Information
III. Pacemaker System
IV. Pacemaker Timing Cycles
V. Project Overview

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
  - This offers an opportunity for the formal methods community to propose novel ideas for pacemaker design
- The reference hardware platform was developed by a ECE design group at the University of Minnesota.

The Pacemaker Challenge

- Requirements Document
  - 35 pages, informal natural language (English) and tables
- 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).
- Domain knowledge has been summarized in a book
  - S. Serge Barold, Roland X. Stroobandt, Alfons F. Sinnaeve, *Cardiac Pacemakers Step by Step: An Illustrated Guide* (2004)
- SQRL Websites
  - http://www.cas.mcmaster.ca/sqrl/pacemaker.htm

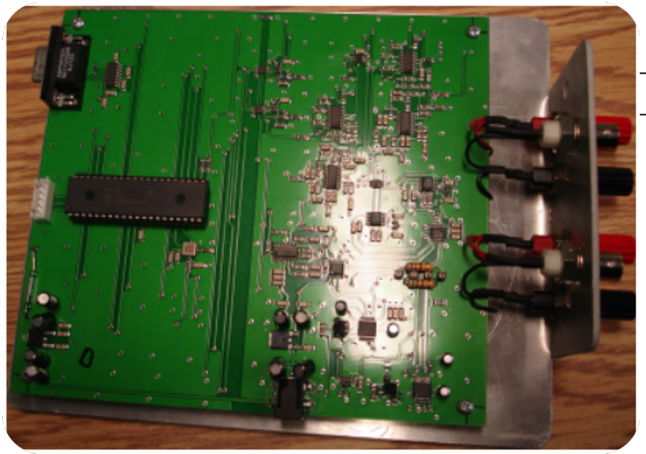
The Pacemaker System Specification

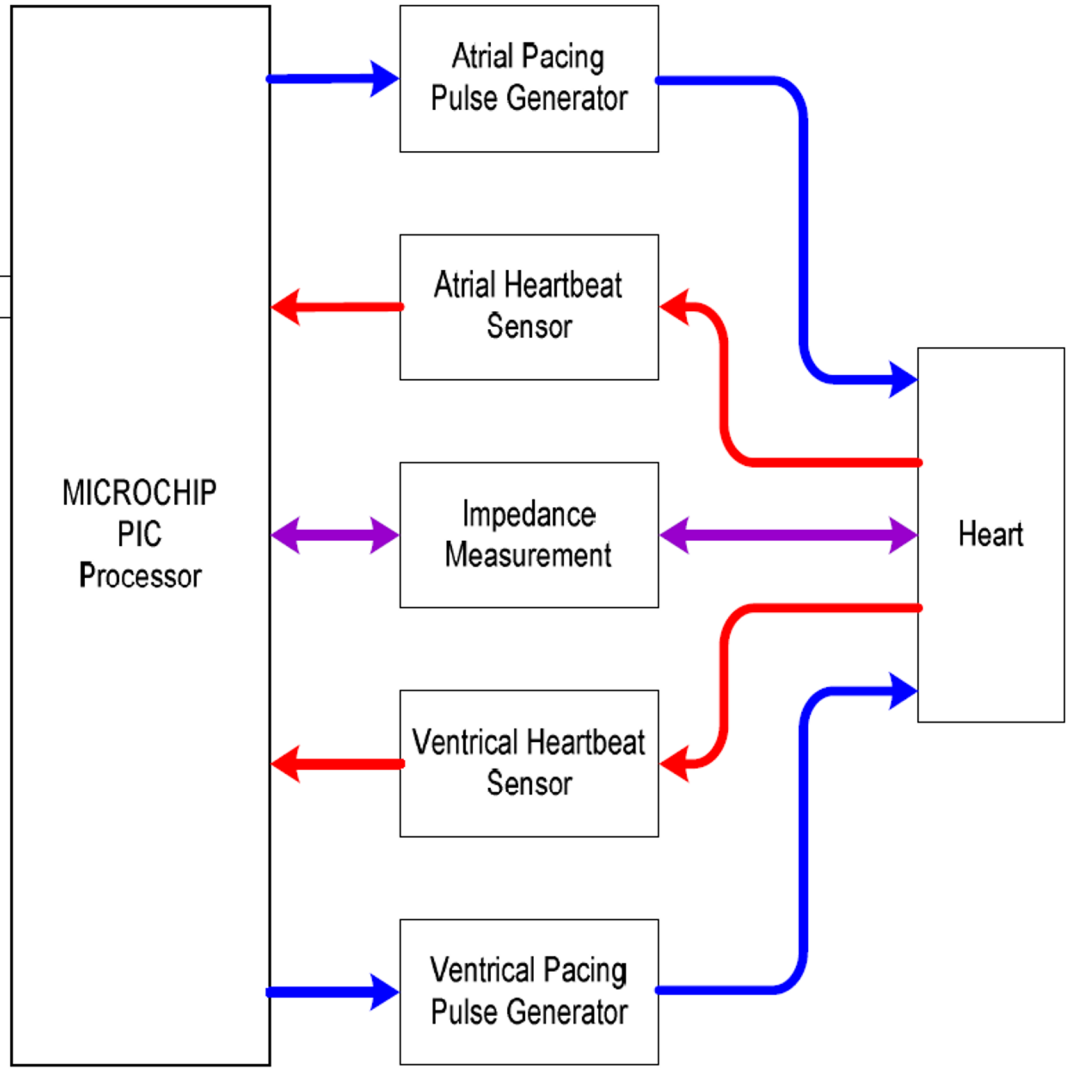
- Defines functions and operating characteristics of the pacemaker system
- Identifies the system environmental performance parameters of the system
- Characterizes anticipated uses of the system
- Includes
  - System definition
  - System requirements
  - Diagnostics information
  - Bradycardia therapy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

The Pacemaker Challenge—Objectives

- Closing the gap between software modeling and code
  - Formal model for the operation of a cardiac pacemaker under useful operating mode. (e.g., VVI and DDD mode)
  - Implementation for the pacemaker device that adheres to the formal models with proper verifications on PIC board.
- The challenge has multiple dimensions
  - Participants may choose to submit a complete version of the pacemaker software
  - may choose to submit just a formal requirements documents - or anything in-between

The Pacemaker Challenge—Target Board





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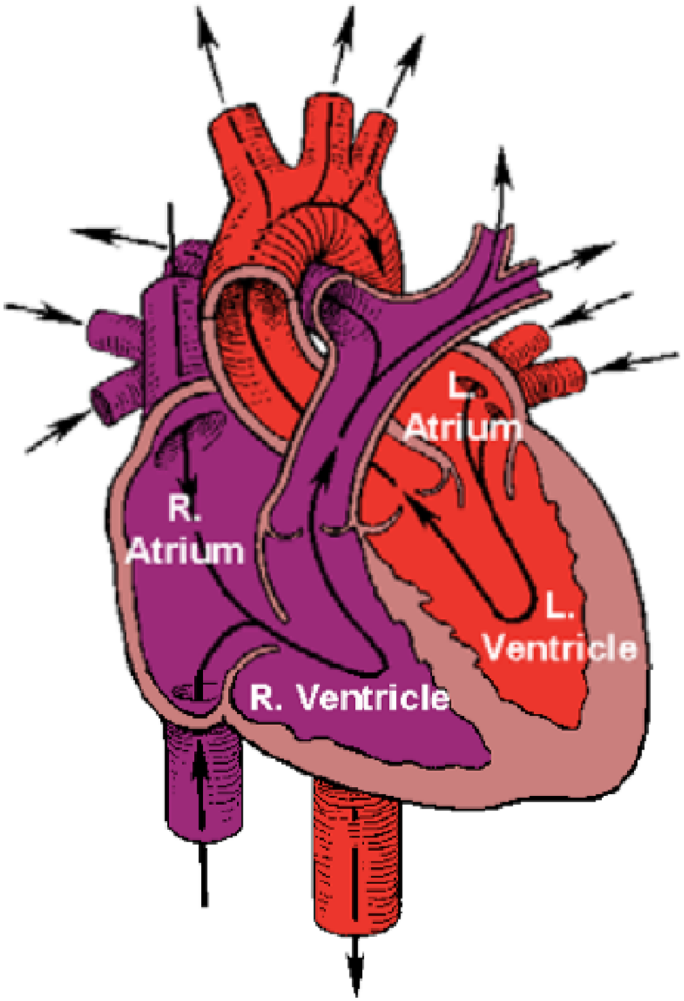
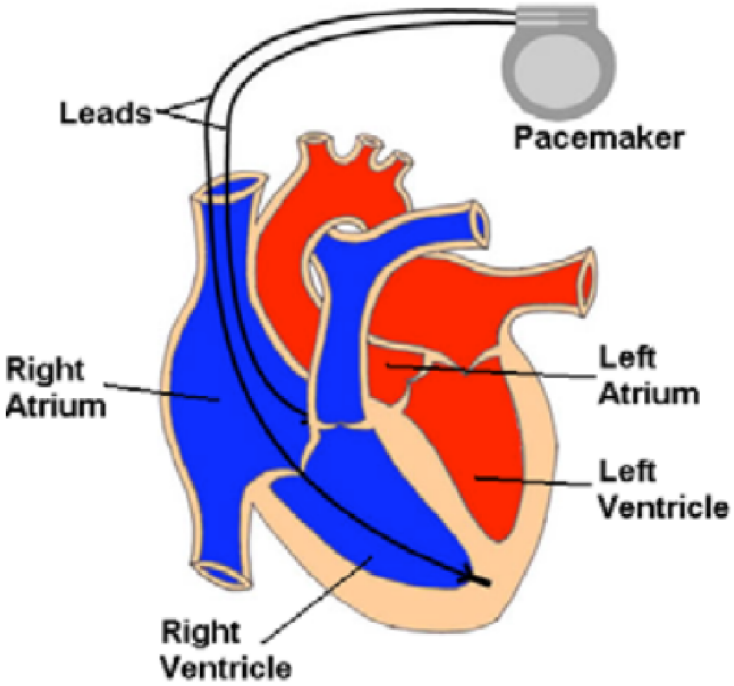
Background: The human heart



- 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 requirements:
  - The heart rate must not be too low
  - The ventricles must contract at a particular interval after the atria contract

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   i. Components

   ii. Operating Modes

   iii. Parameters

IV. Pacemaker Timing Cycles

V. Project Overview

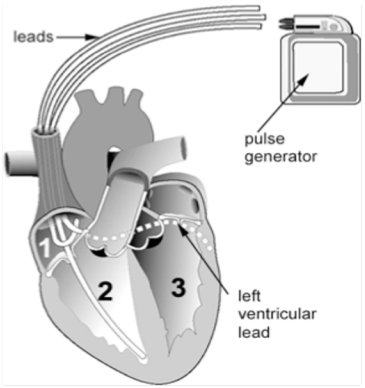
Pacemaker Usage

Diagnostics, Status, …

Commands,
Set Mode, Set Parameters, …

Parameters,
Commands

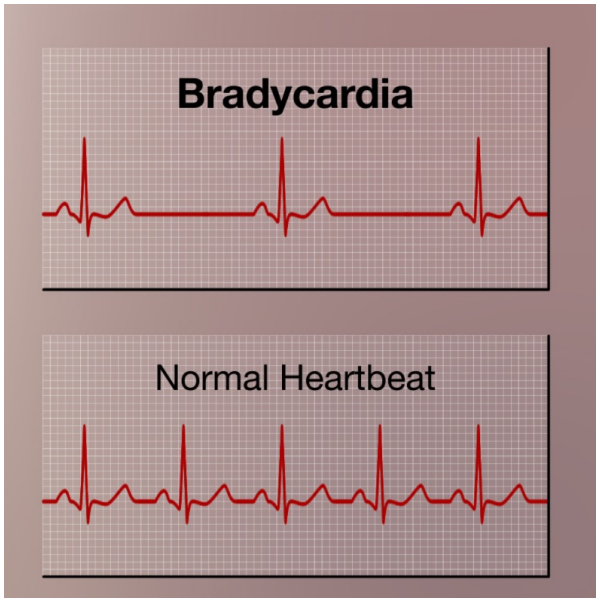
Measurements,
History, Status



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.

System Components for Pulse Generator Device

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

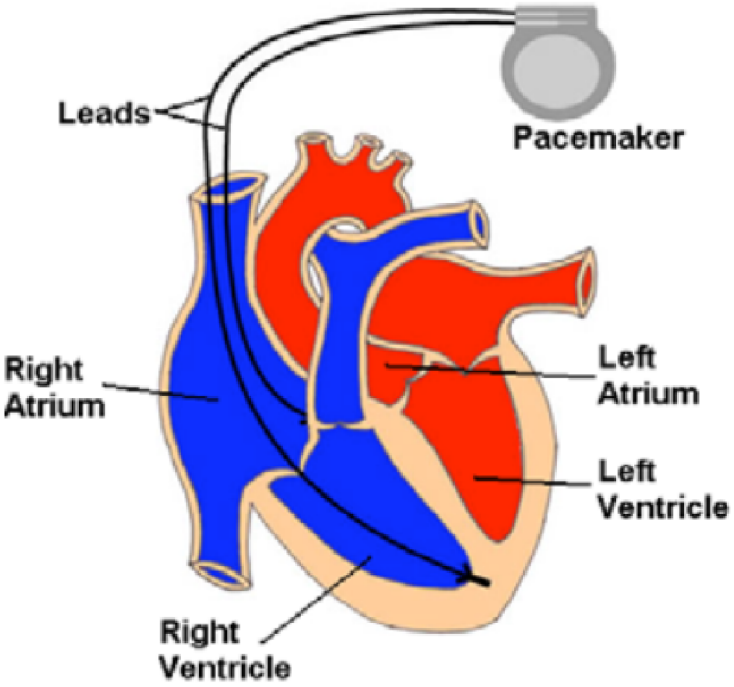


System Components: Device Controller-Monitor

- Used for primary implantation, pre-discharge electrophysiology (EP) support, and follow-up support 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

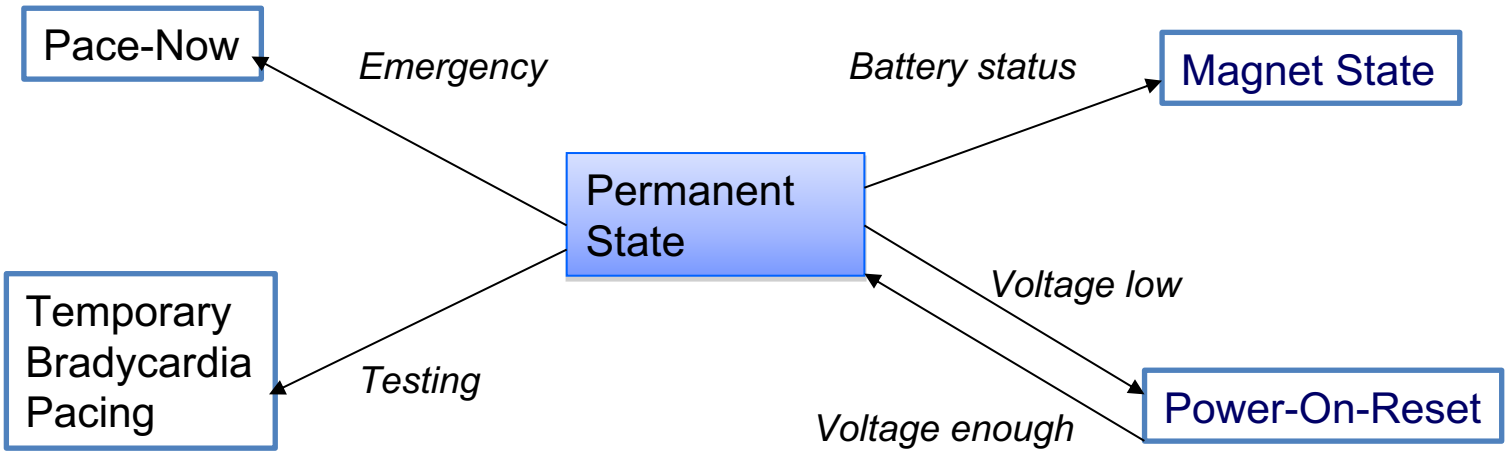
System Components: Lead System

- 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



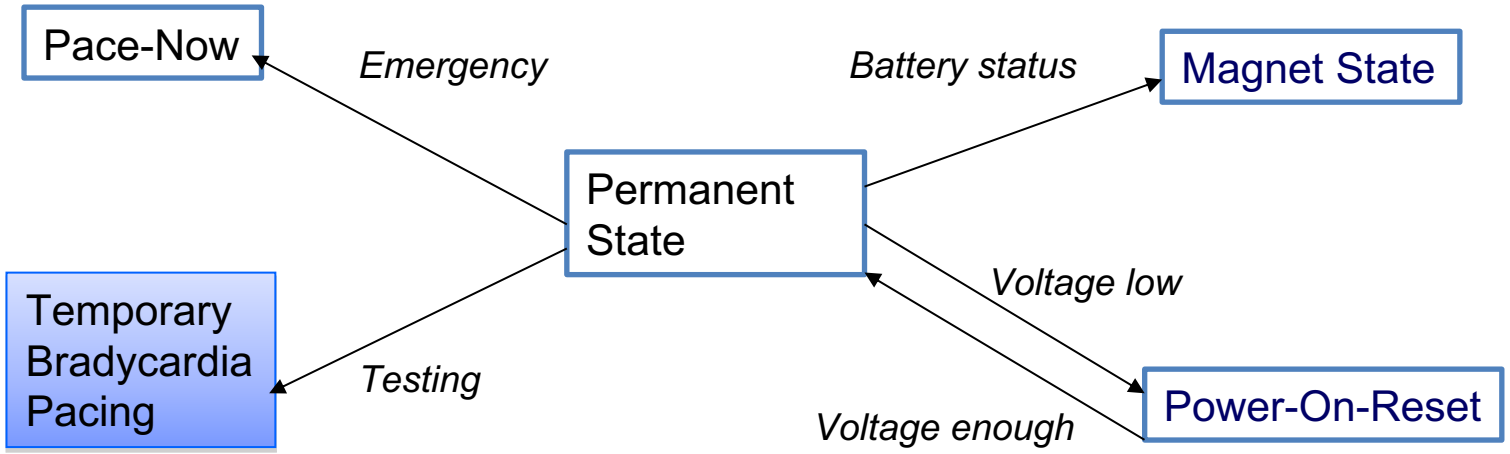
Pacemaker Operating States

Permanent State: Normal state of operation with programmed parameters



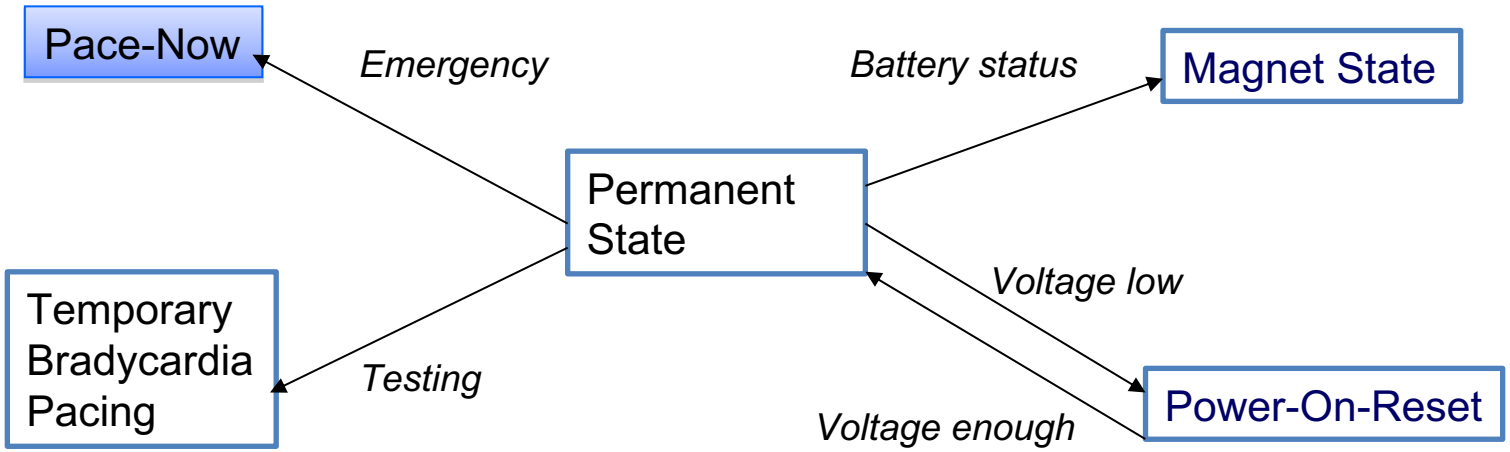
Pacemaker Operating States

Temporary Bradycardia Pacing: Temporarily test various system parameters or provide patient diagnostic testing



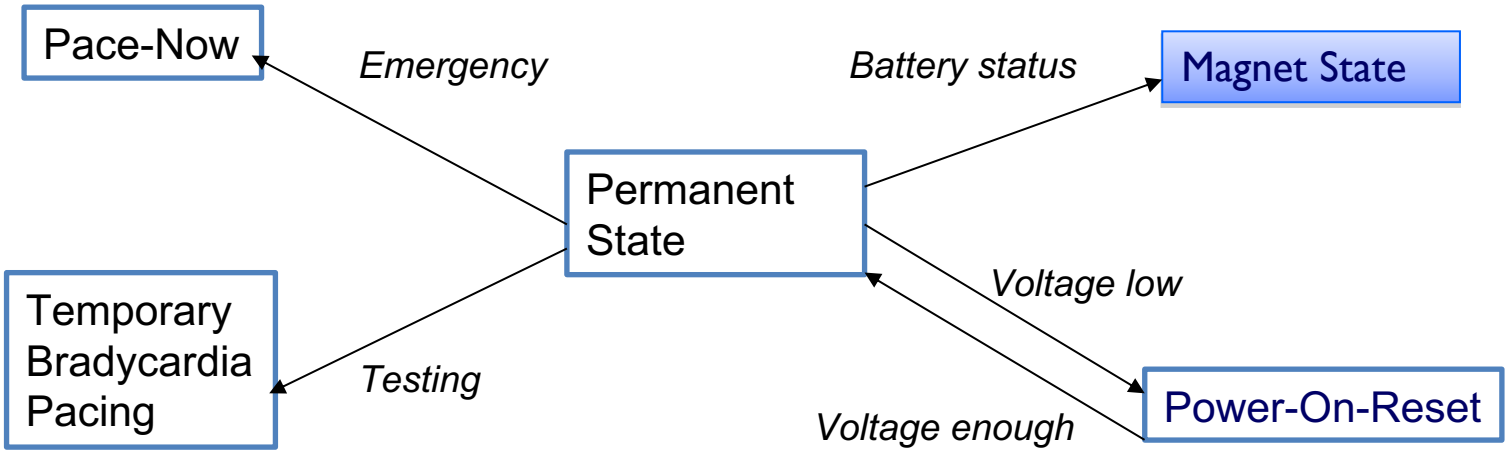
Pacemaker Operating States

Pace-Now : Emergency pacing, with fixed parameters



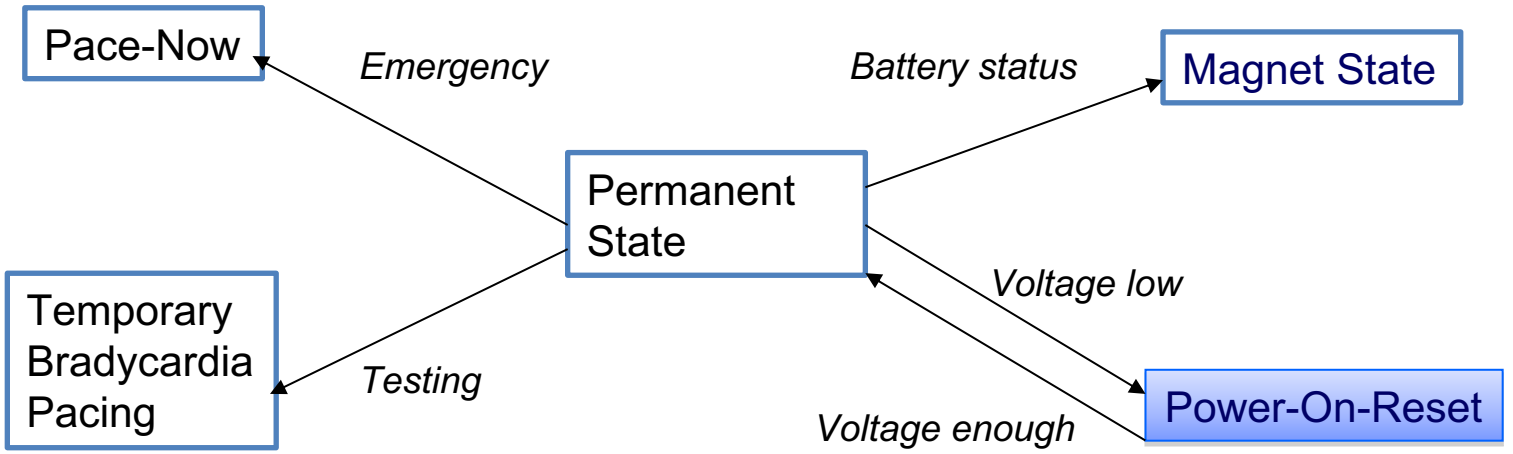
Pacemaker Operating States

Magnet State: Used during magnet testing 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.



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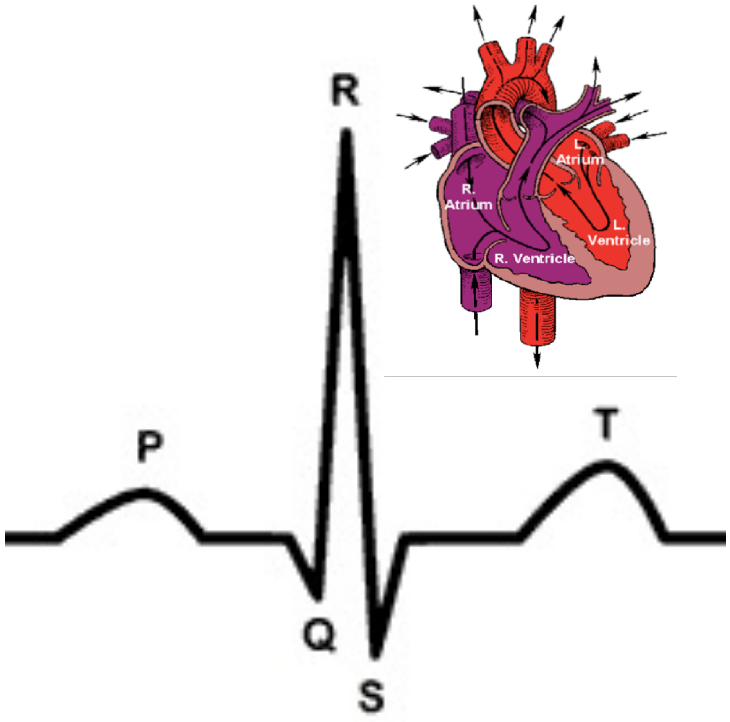
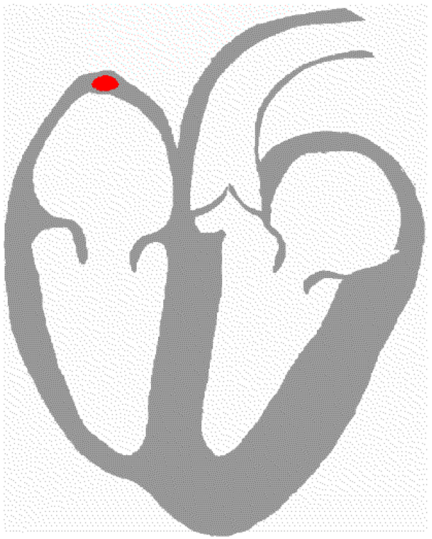
Reading ECG

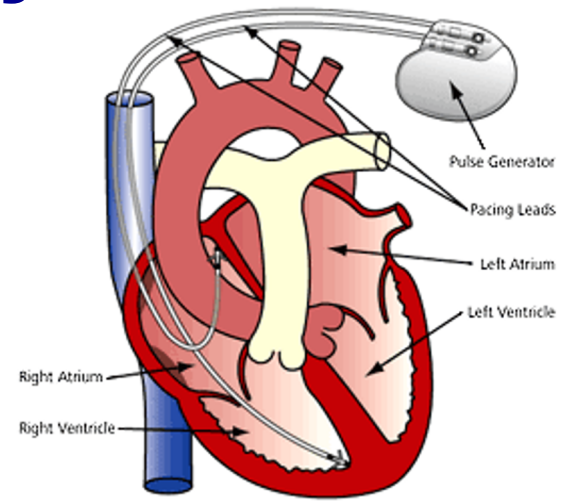


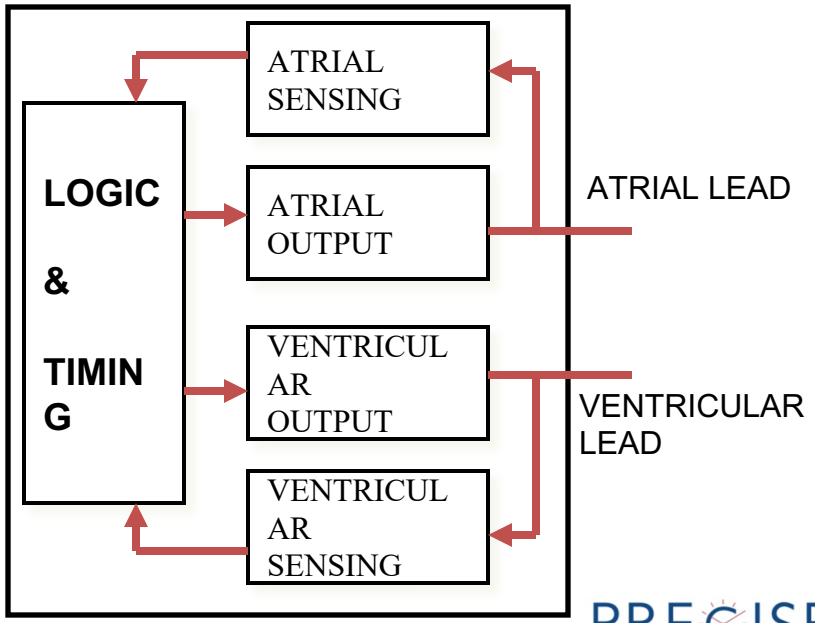


- **P wave**: normal atrial depolarization
- **QRS complex**
  - Depolarization of the right and left ventricles
  - A recording of a single heartbeat on the ECG
- **T wave**: the repolarization (or recovery) of the ventricles.

Timing Cycles

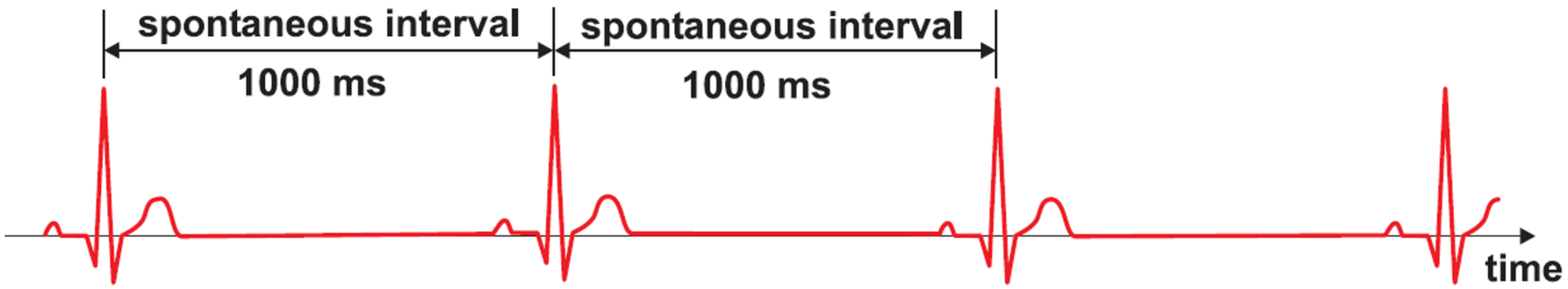
- Pacemaker senses and paces in both atrium and ventricle
- Synchronization between atrial and ventricular sensing and pacing
- Interference from atrial stimuli to ventricular channel and vice-versa.



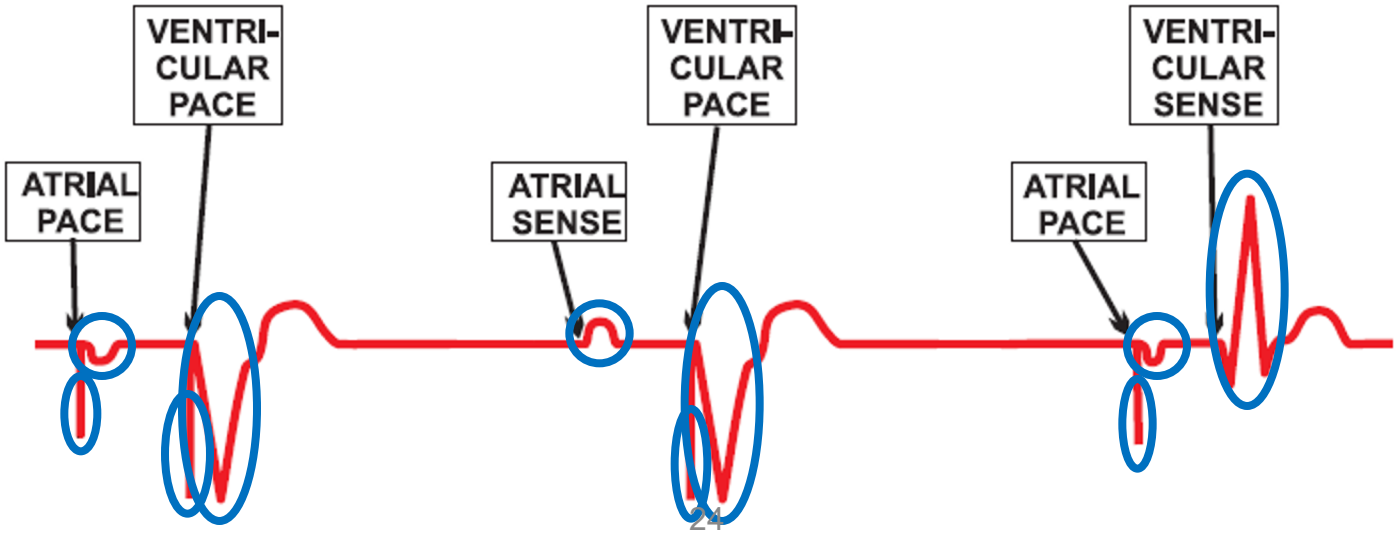


Reading ECG

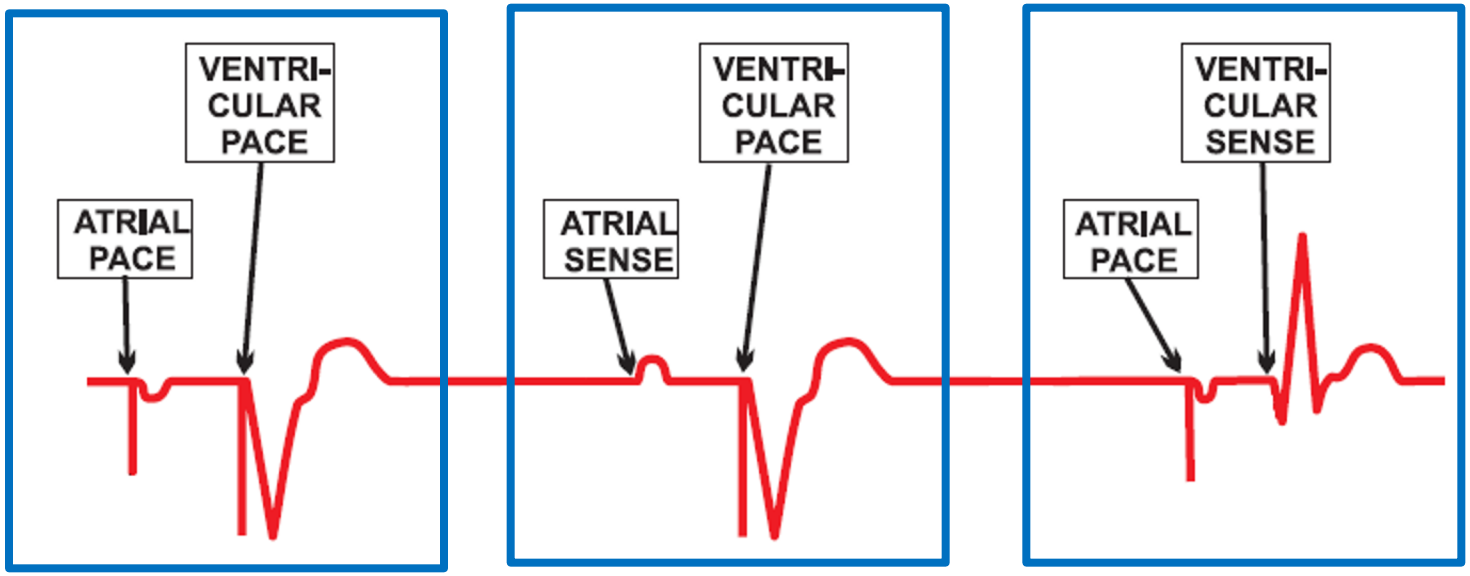
Normal Heart



Heart with problems



Reading ECG



- **No Sensing**: pacemaker delivers both atrial and ventricle signals
- **Atrial Sensing**
  - Atrial sensing inhibits scheduled atrial pacing
  - Pacemaker delivers ventricle pacing
- **Ventricle Sensing**: ventricle sensing inhibits scheduled ventricle pacing

Pacemaker Operating Modes

In the following slides and the project, we are concerned with the VVI pacemaker. Where VVI stands for **V**entricle being paced if the **V**entricle activity sensed is **I**nhibited.

I	II	III	IV
Chamber(s) **paced**	Chamber(s) **sensed**	**Response** to sensing	**Rate adaptive**
O = none	O = none	O = none	O = none
A = atrium	A = atrium	I = Inhibited	R = rate adaptive
V = ventricle	V = ventricle	T = Triggered	
D = dual	D = dual	D = dual	

VVI mode: if natural R wave is not sensed, pacemaker has to pace
Extra Credit Examples: VDD, DDD, VDDR, VVIR, VDDR, DDDR

Pacemaker Operating Modes

I	II	III	IV
Chamber(s) **paced**	Chamber(s) **sensed**	**Response** to sensing	**Rate adaptive**
O = none	O = none	O = none	O = none
A = atrium	A = atrium	I = Inhibited	R = rate adaptive
V = ventricle	V = ventricle	T = Triggered	
D = dual	D = dual	D = dual	

23 programmable pacing modes

- 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.
- AAT: atrium paced, atrium sensed, pace triggered when atrium is sensed

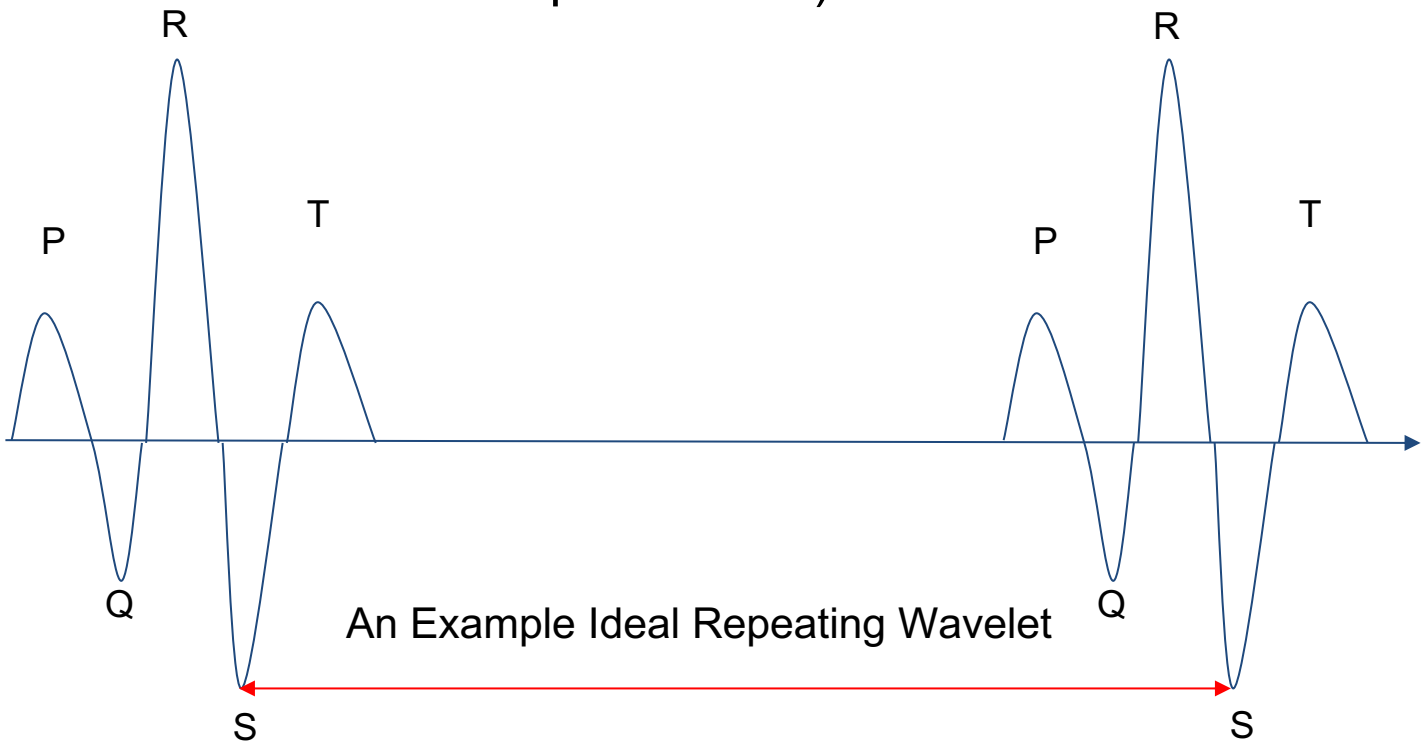
Pacemaker Operating Modes

- 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 (tracked pacing), or O (neither).
    - T: During triggered pacing, a sense in a chamber shall trigger an immediate pace in that chamber.
    - I: During inhibited pacing, a sense in a chamber shall inhibit a pending pace in that chamber.
    - D: During tracked pacing, an atrial sense shall cause a tracked ventricular pace after a programmed AV delay, unless a ventricular sense was detected beforehand.

The VVI mode Pacemaker

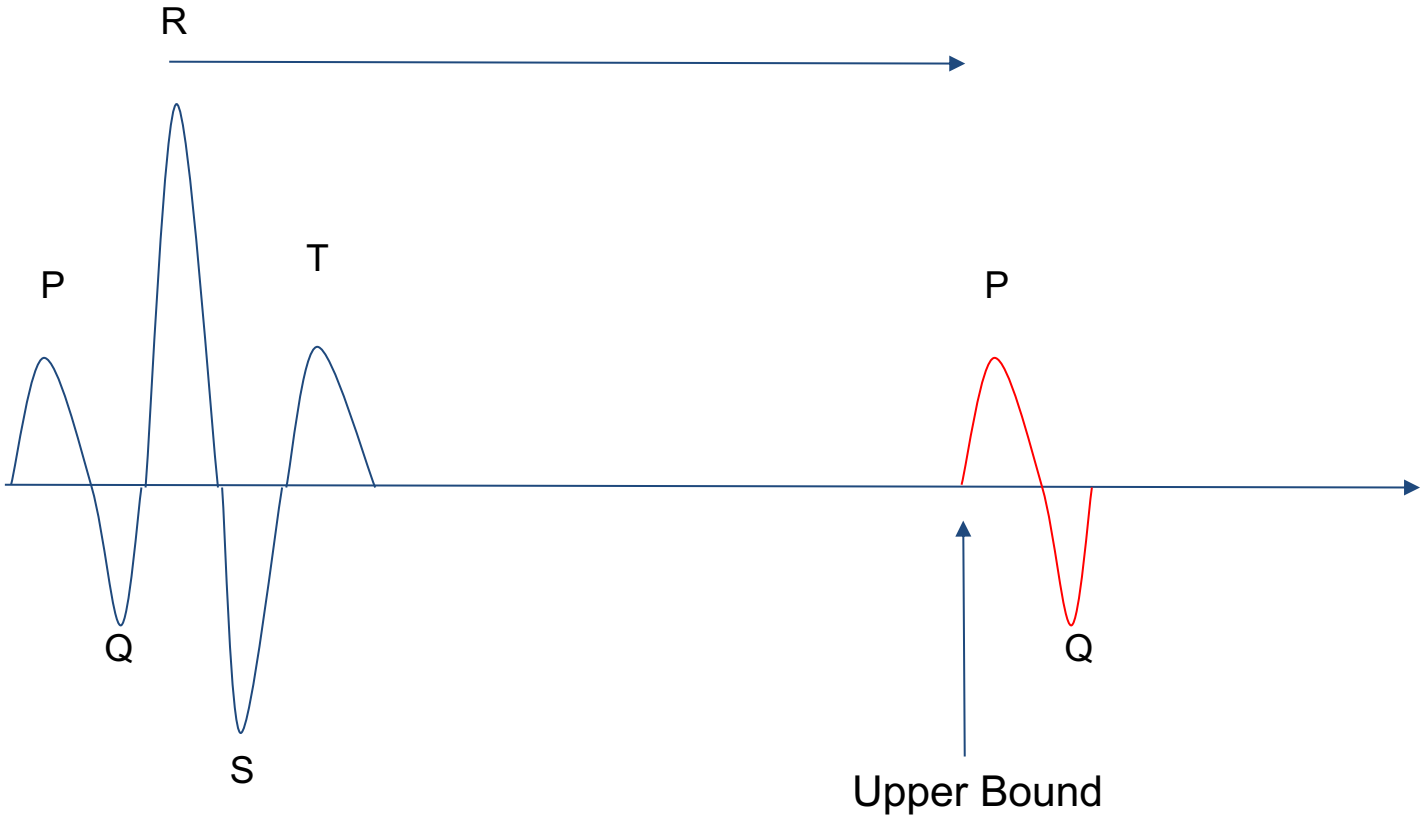
The pacemaker should be inactive for a healthy ECG signal.

(The PQRST waves in the following slides and in the project have been simplified for ease of understanding the workings of a VVI mode pacemaker)



The VVI mode Pacemaker

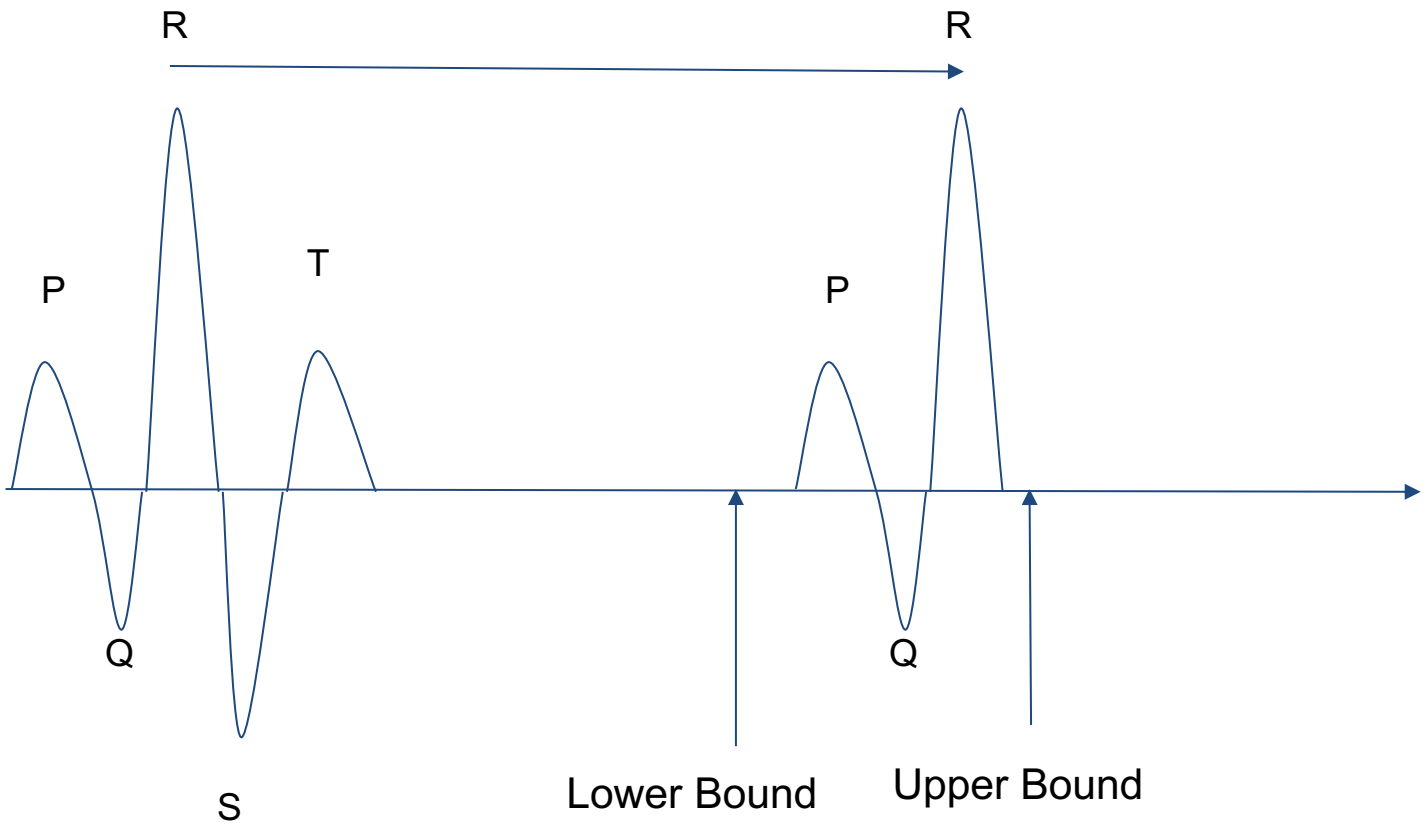
The pacemaker should pace if the R-R interval exceeds an upper bound



Pacemaker paces here to force-restart RandomHeart.

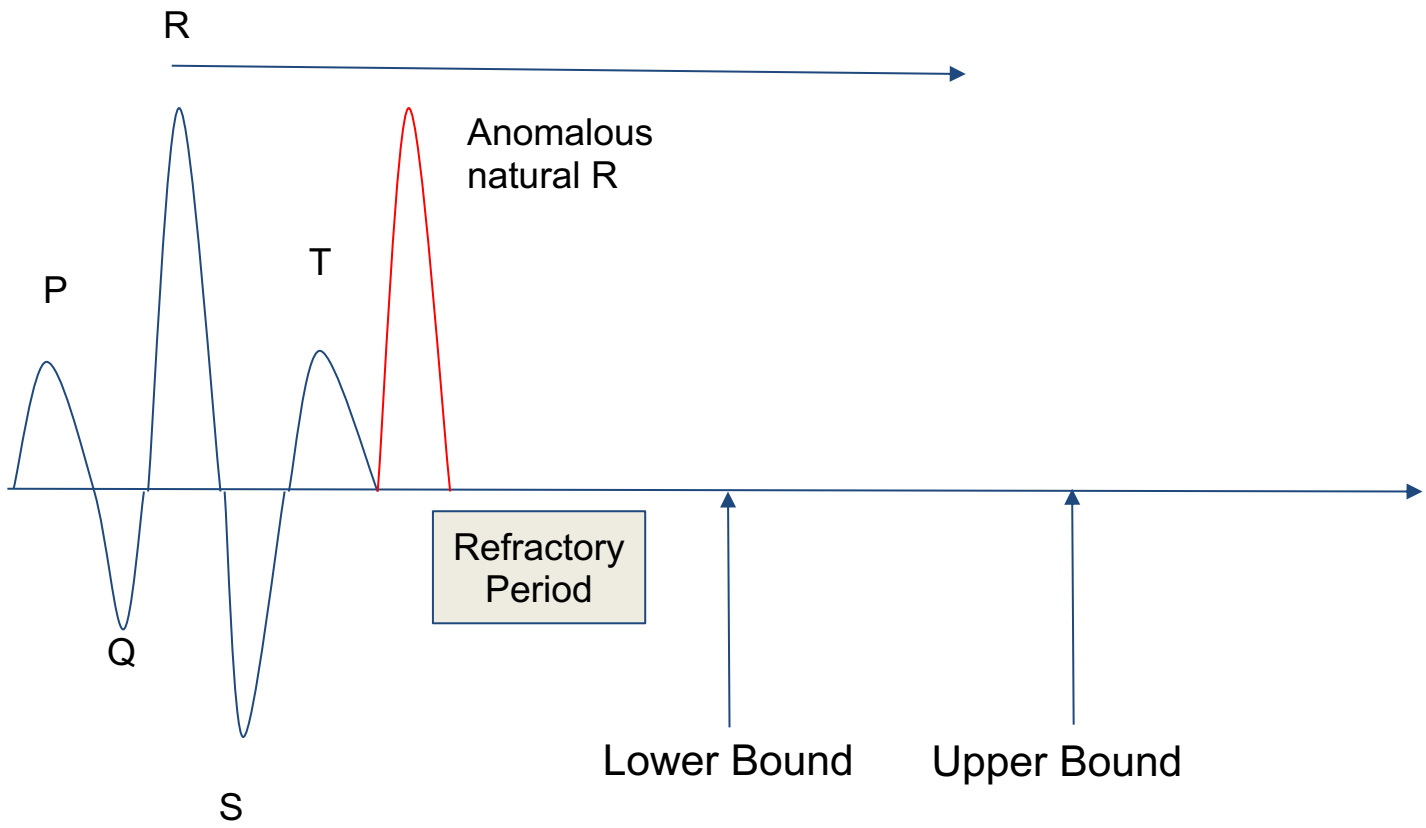
The VVI mode Pacemaker

The pacemaker should not pace if a natural R wave occurs at an R-R interval greater than the lower bound



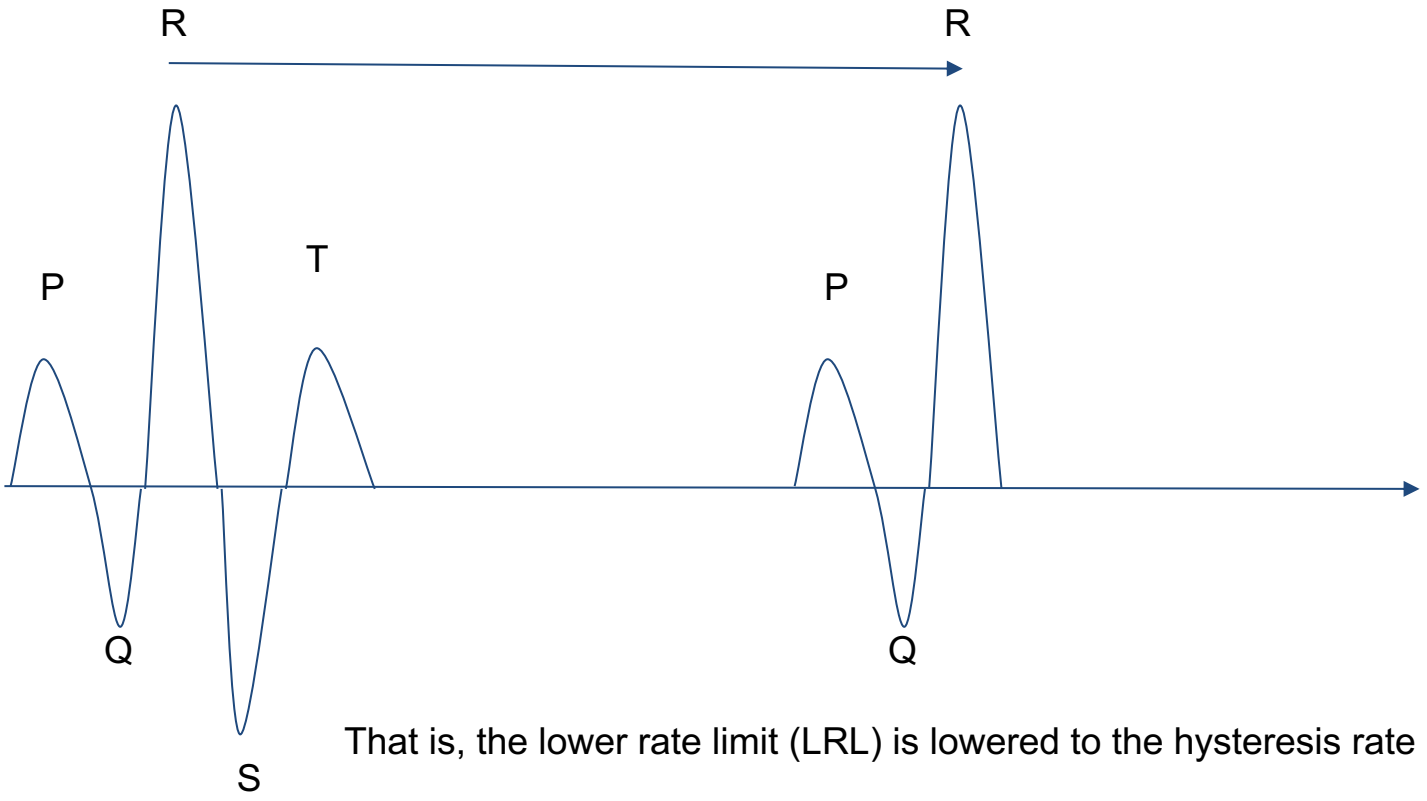
The VVI mode Pacemaker

If an anomalous R wave occurs within the VRP (ventricular Refractory Period) after a PQRST, said R wave should be ignored. The R-R interval needs to still be calculated from the earlier R wave.



Hysteresis

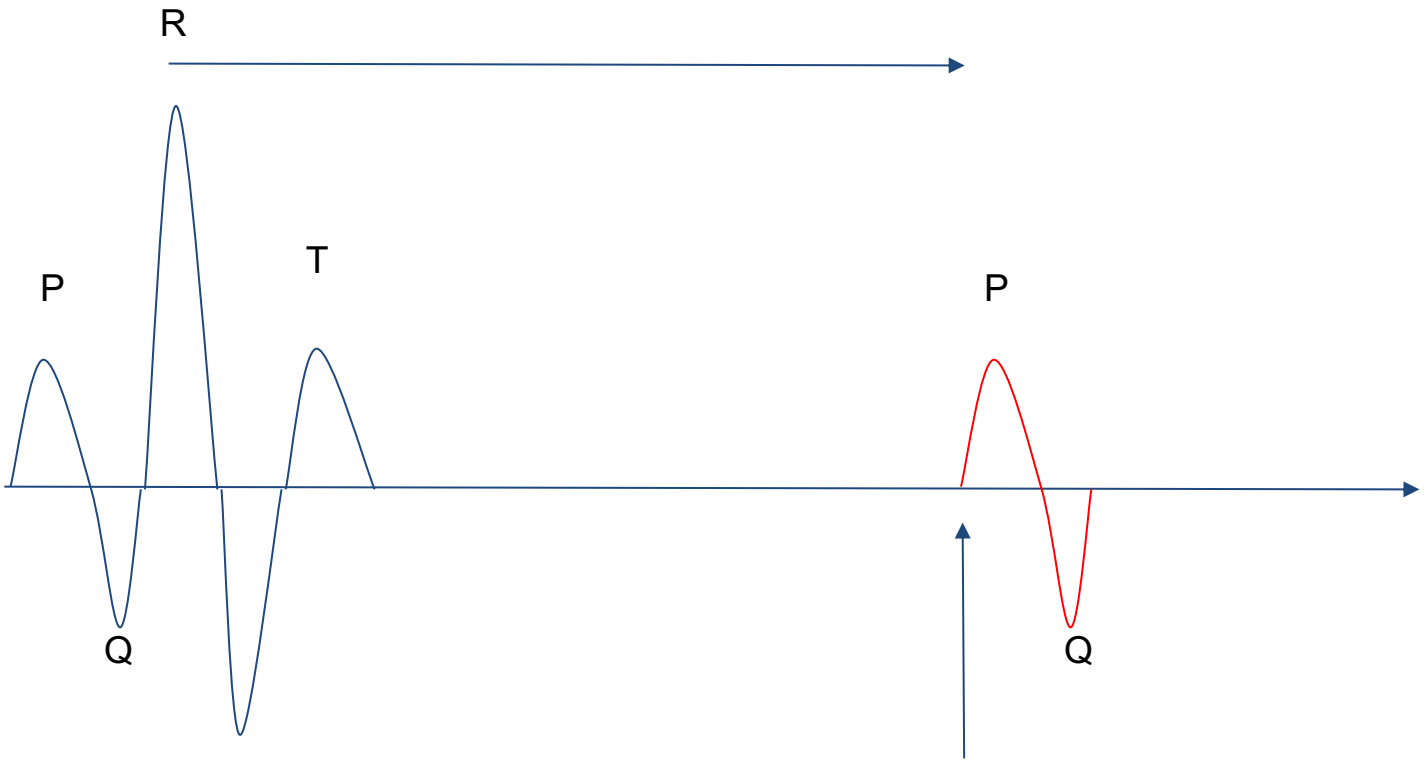
Hysteresis tries to encourage the heart to beat naturally (without pace). In the following situation, when the heart beats naturally, hysteresis is enabled and the pacemaker allows for a longer interval after sensing an R wave to pace the heart. Otherwise, hysteresis is disabled.



That is, the lower rate limit (LRL) is lowered to the hysteresis rate limit (HRL).

Hysteresis

But if the upper limit is reached, the pacemaker paces.



We can have more cases

The Heart can combine the previously discussed cases. Pacemaker should consider all timing constraints carefully.

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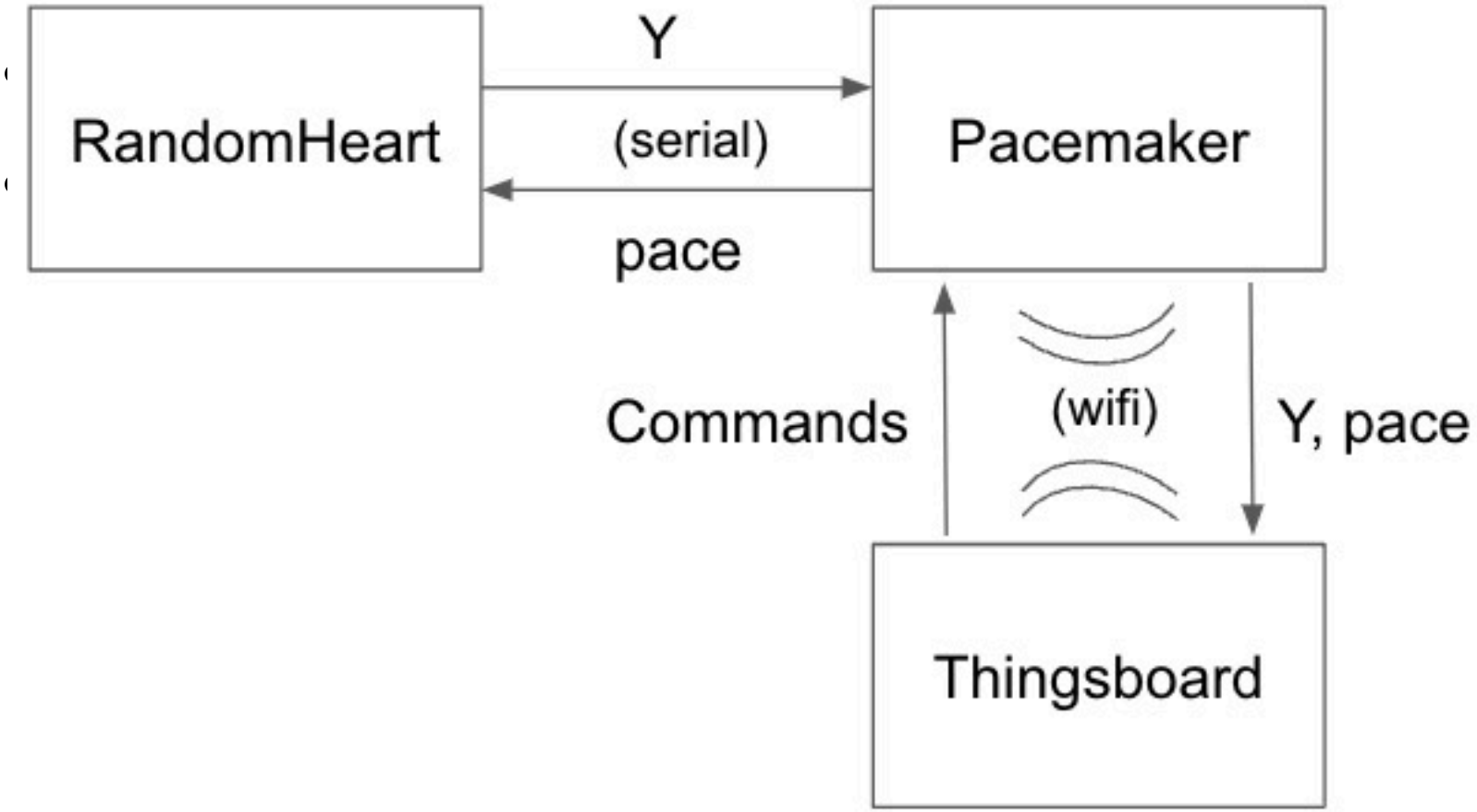
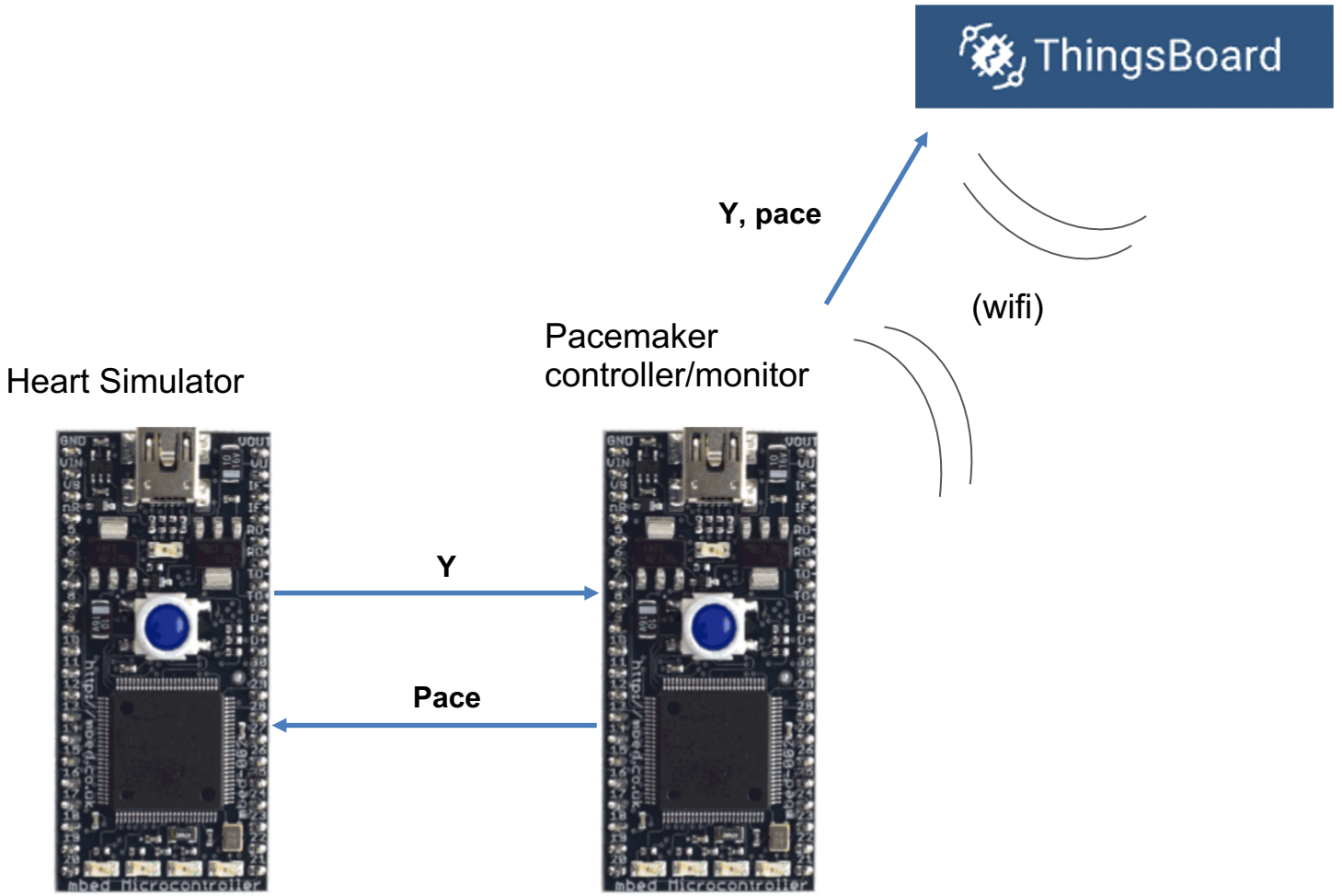
Milestones

1. Implementation of the Smart Pacemaker
   a. Heart and Pacemaker MBEDs (20%)
   b. Thingsboard and Remote Control (10%)
2. Verification and Security of the Smart Pacemaker
   a. Verification (20%)
   b. Security (20%)
3. Validation, Demo, and Final Report
   a. Validation with Assurance Cases (20%)
   b. Teamwork and Member Contribution (5%)
   c. Demo (5%)

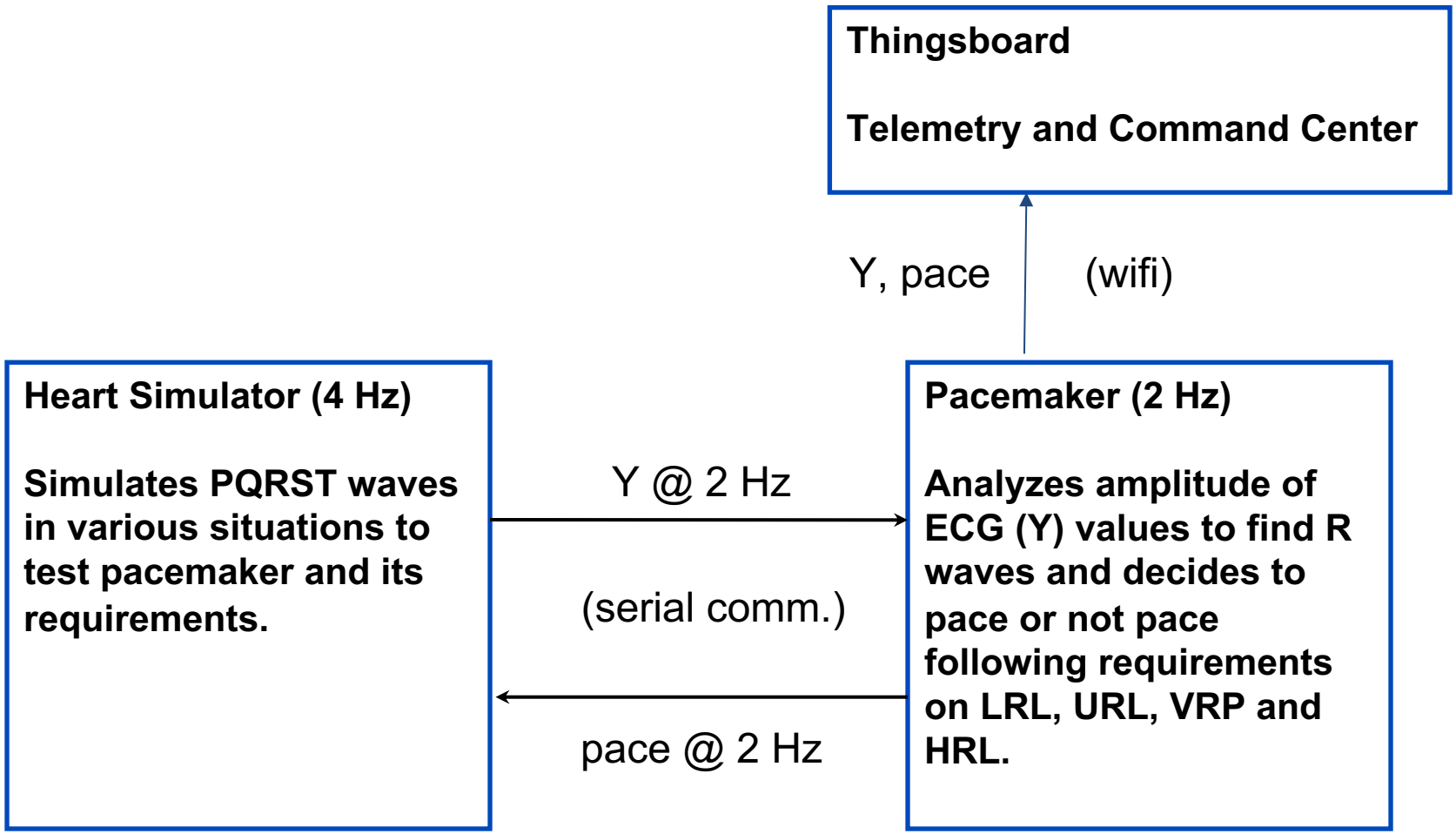
Milestone 1: Implementation of the Smart Pacemaker



Implementation Scheme



Overview (is there chat?)



Milestone 2: Verification, and Security of the Smart Pacemaker

1. Verify Pacemaker Properties to make sure the Design is Conceptually Correct
    1. UPAAL- an integrated tool environment for modeling, validation and verification of real-time systems
2. Secure the Thingsboard Communication Layer
    a. Existing MQTT Security
    b. Cryptographic Protocol(s)

Milestone 3: Validation, Demo, and Final Report

1. Develop assurance case to argue the correctness of your system
2. Final Report
    1. Implementation Architecture
    2. Design Models and Correctness Properties
    3. Assurance Cases
3. In-Class Demo

Smart Pacemaker Project

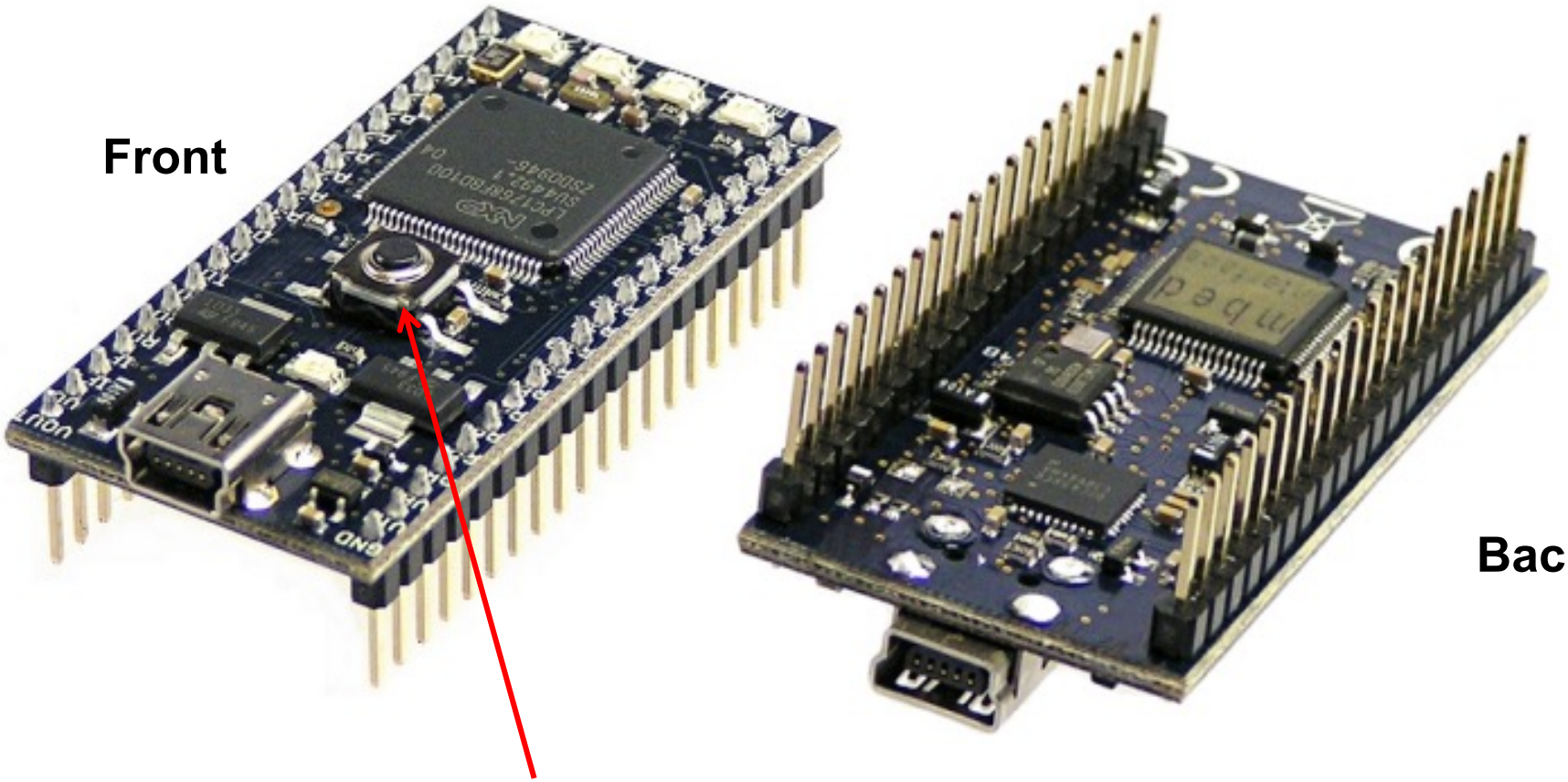
- Team project
- Based on the pacemaker challenge problem
- Project phases
  - Milestone 1: Implementation
  - Milestone 2: Verification and Security
  - Milestone 3: Demo and Final Report

Acknowledgements

- Slides Created By:
  - Kausthubh Sridhar

Introduction to MBED

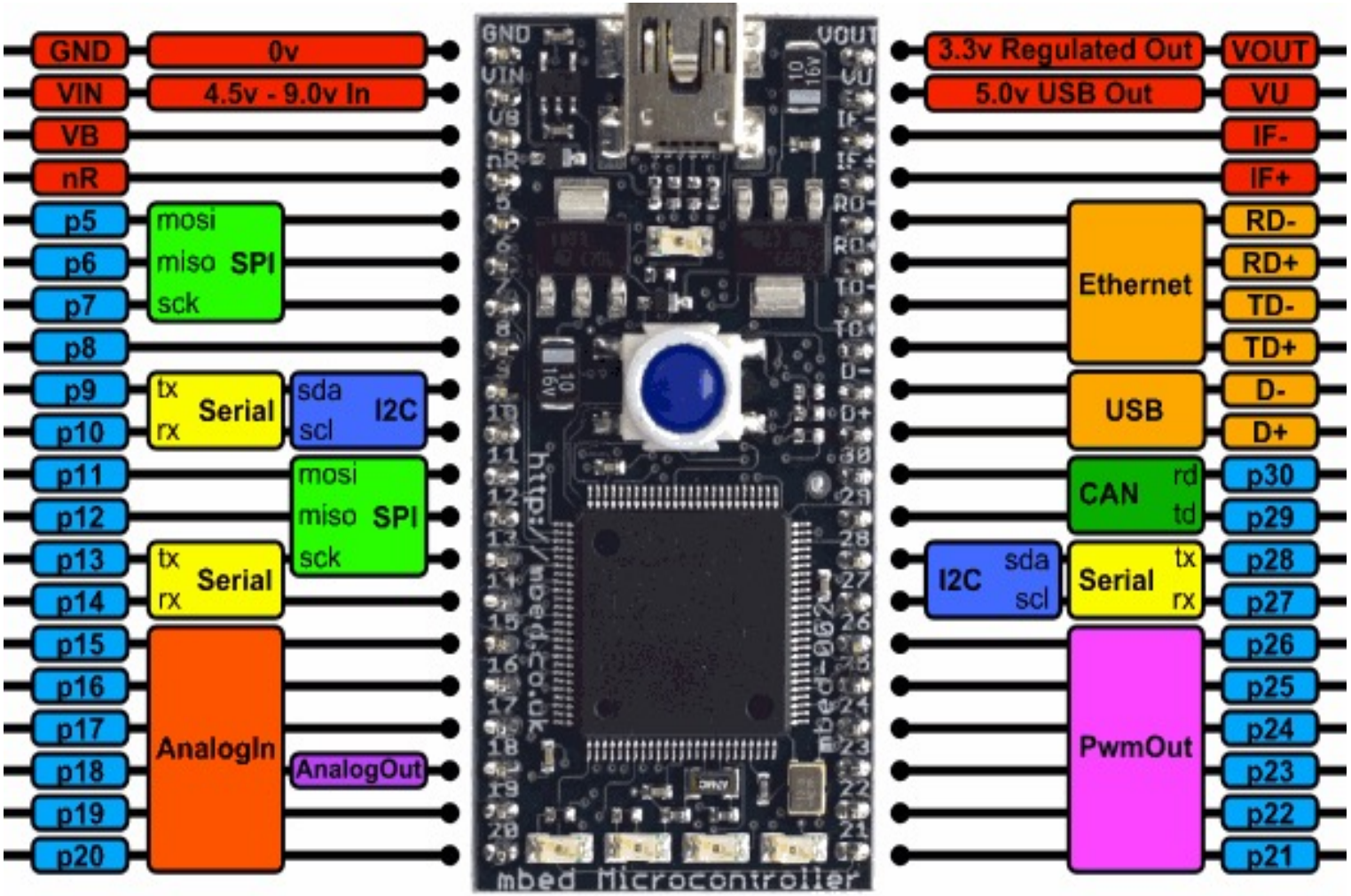
mbed LPC1768



mbed 1768 features

- LPC1768 MCU
  - High performance ARM® Cortex™-M3 Core
  - 96MHz, 32KB RAM, 512KB FLASH
  - Ethernet, USB Host/Device, 2xSPI, 2xI2C, 3xUART, CAN, 6xPWM, 6xADC, GPIO
- Other features
  - 40-pin, 54x26mm
  - 5V USB or 4.5-9V supply
  - Built-in USB drag 'n' drop FLASH programmer

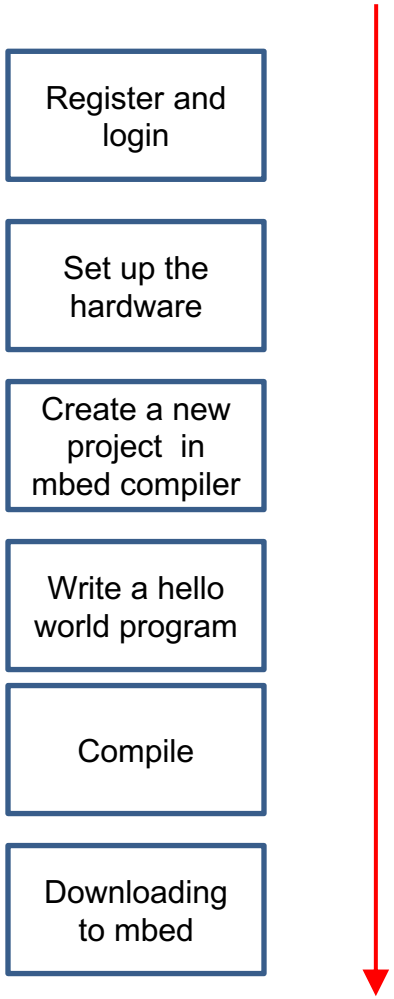
mbed 1768 features



Programming on mbed

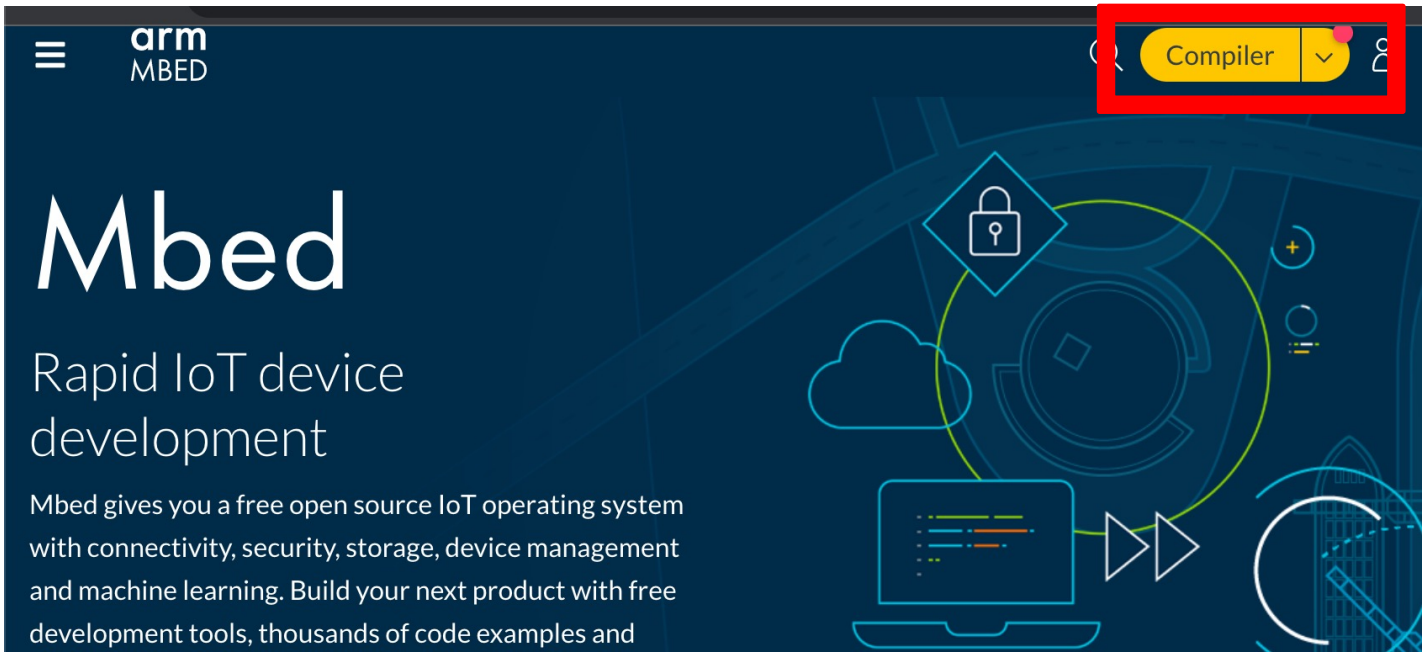
- Website: http://mbed.org/
  - Platform, components, handbook, cookbook, code, questions, Forum, Compile
- Mbed 1768: http://mbed.org/platforms/mbed-LPC1768/
- Mbed OS 5: https://os.mbed.com/docs/mbed-os/v5.13
- TextLCD: http://mbed.org/cookbook/Text-LCD-Enhanced
- Tutorial: https://os.mbed.com/docs/mbed-os/v5.13/tutorials/serial-communication.html
- I/O tutorial, general tutorial
- Books: http://mbed.org/cookbook/Books

Programming on MBED



Register and Login

- Register and login
- Set up the hardware
- Create a new project in mbed compiler
- Write a hello world program
- Compile
- Downloading to mbed



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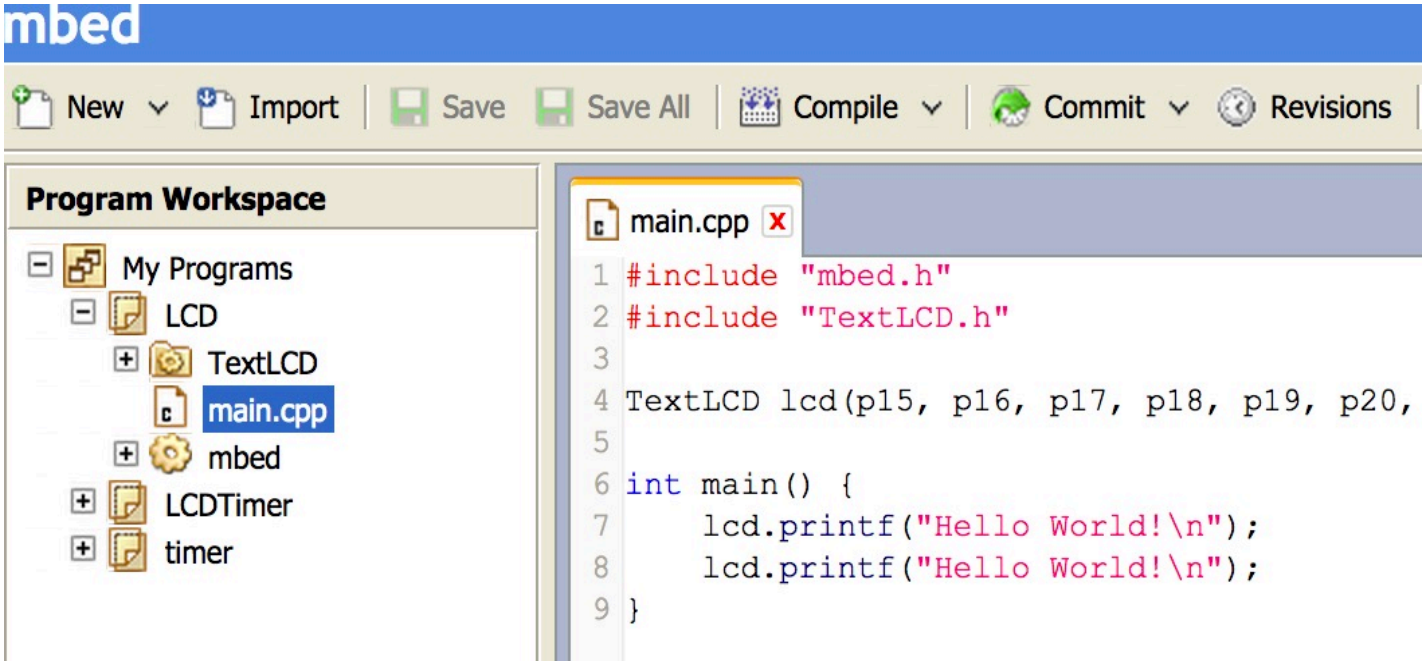

Setup the Hardware

- Register and login
- **Set up the hardware**
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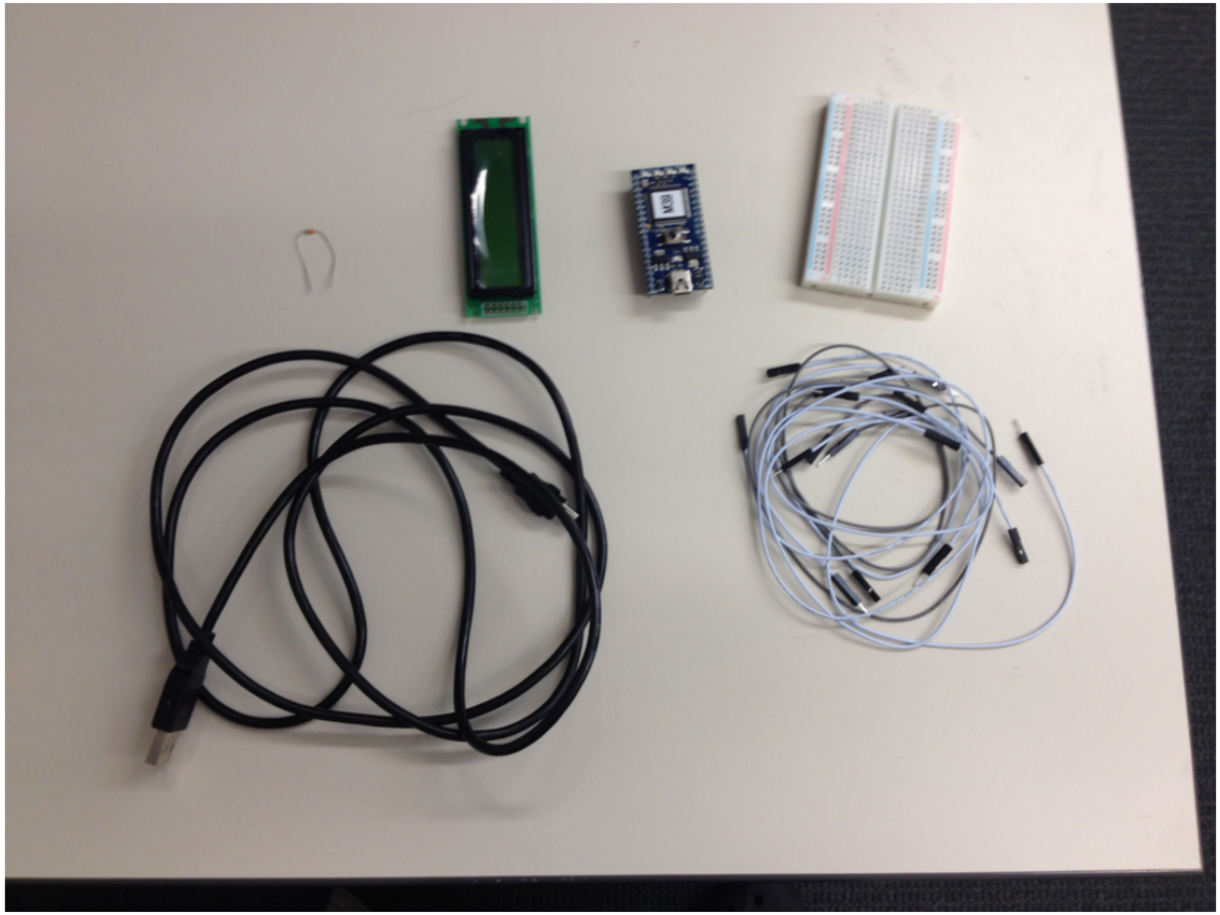

Setup the Hardware - LCD

- Register and login
- **Set up the hardware**
- Create a new project in mbed compiler
- Write a hello world program
- Compile
- Downloading to mbed

LCD pins	mbed pins
p1 GND	p1 0V
p2 VCC	p39 5V VU
p3 VO via 2.2kΩ resistor	p1 0V
p4 RS	p15
p5 RW	p1 0V
p6 E	p16
p11 D4	p17
p12 D5	p18
p13 D6	p19
p14 D7	p20

Setup the Hardware

- Register and login
- **Set up the hardware**
- Create a new project in mbed compiler
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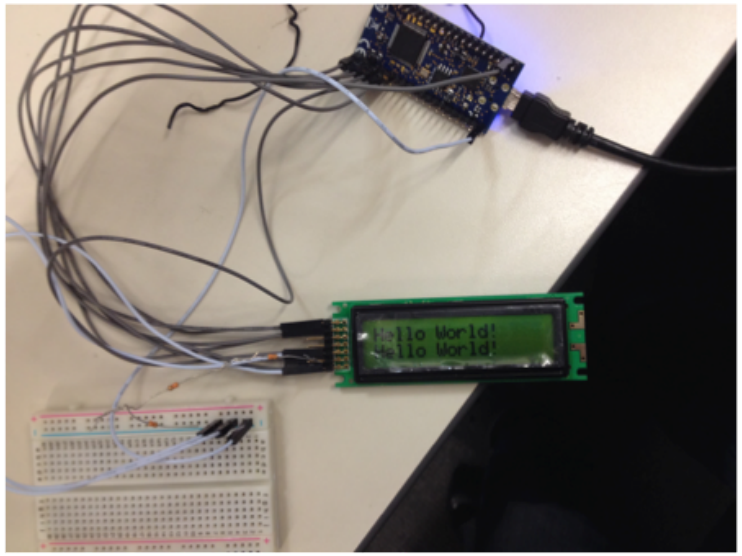
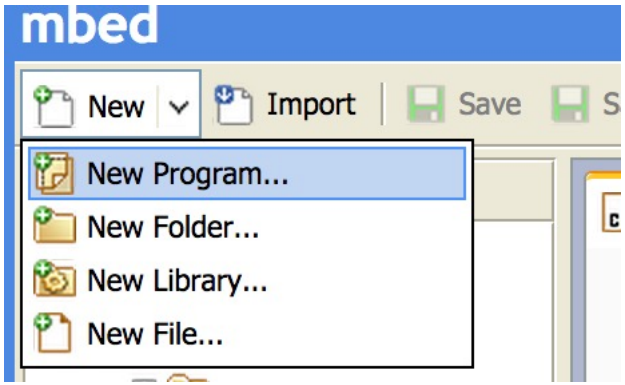
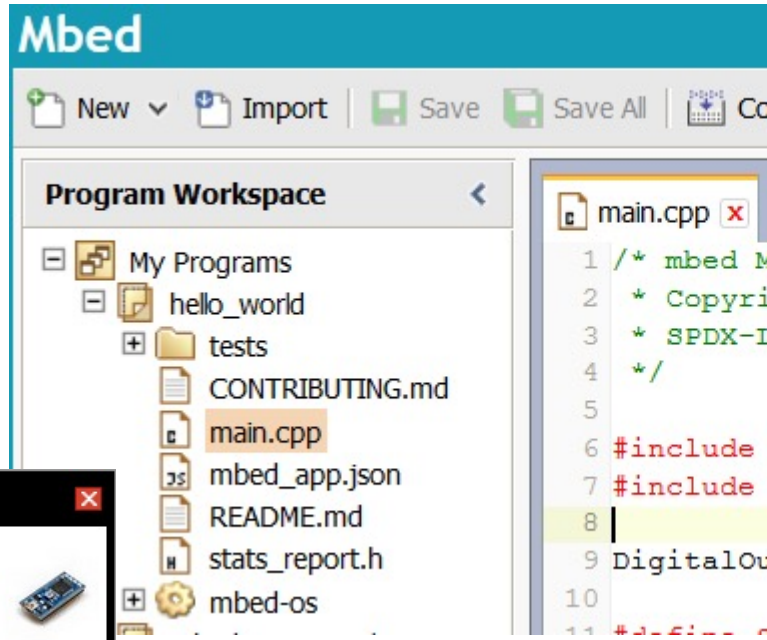
- Compile
- Downloading to mbed

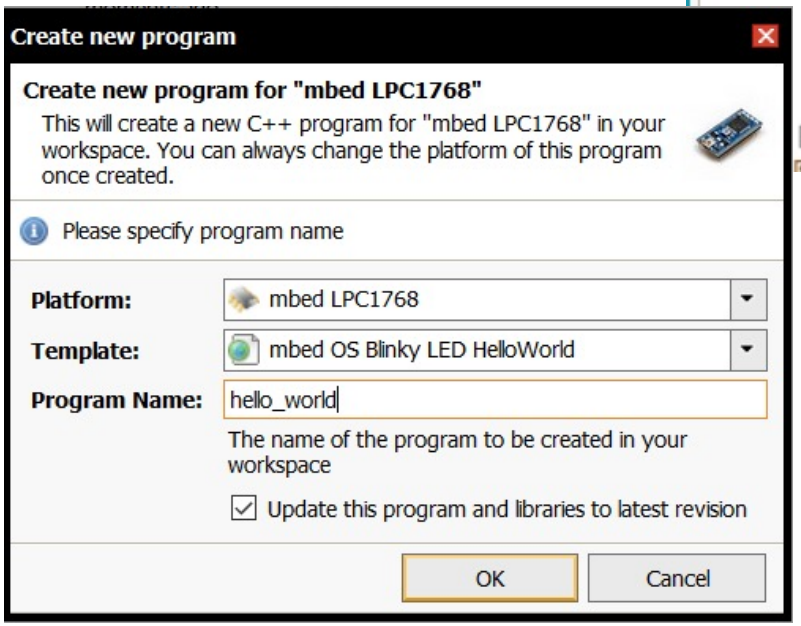


Create a New Project

- Register and login
- Set up the hardware
- **Create a new project in mbed compiler**
- Write a hello world program
- Compile
- Downloading to mbed





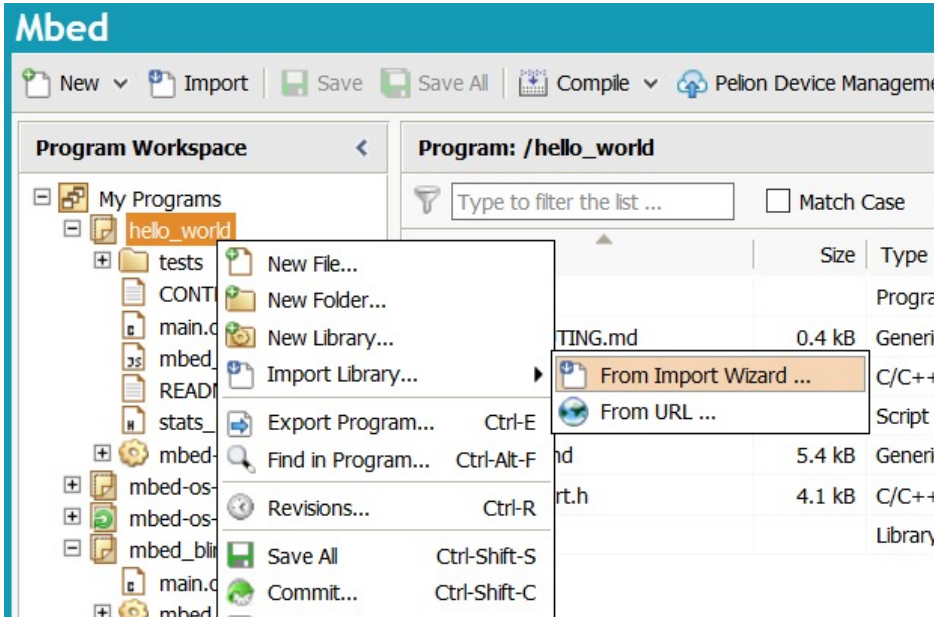


Penn Engineering

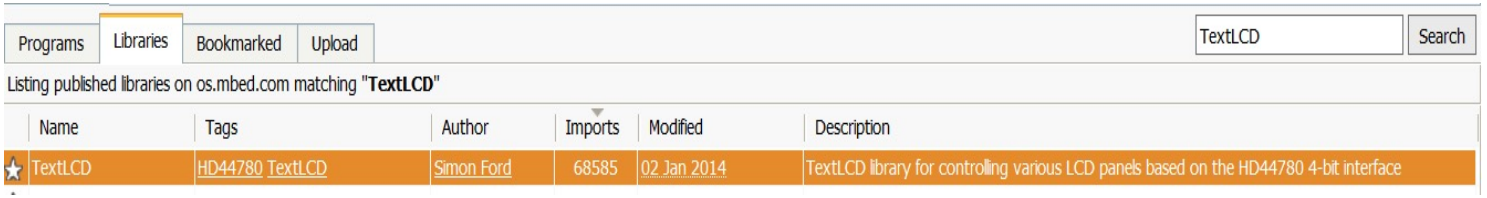
PRECISE

Import Required Libraries

- Register and login
- Set up the hardware
- Create a new project in mbed compiler
- Write a hello world program
- Compile
- Downloading to mbed



Search “TextLCD”



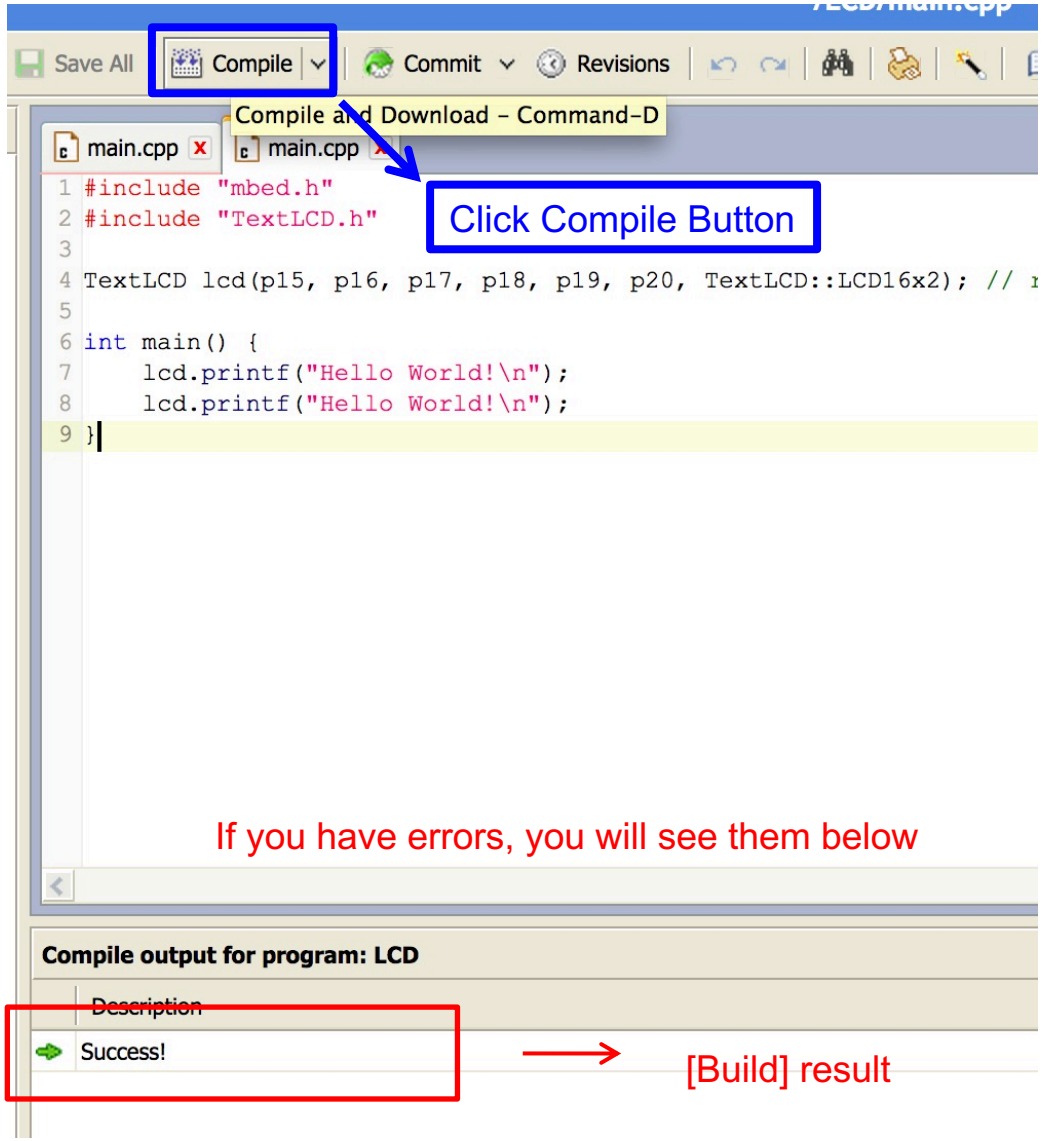
Hello World!

- Register and login
- Set up the hardware
- Create a new project in mbed compiler
- **Write a hello world program**
- Compile
- Downloading to mbed

```
1 #include "mbed.h"
2 #include "TextLCD.h"
3
4 TextLCD lcd(p15, p16, p17, p18, p19, p20, TextLCD::LCD16x2); // rs, e, d4-d7
5
6 int main() {
7     lcd.printf("Hello World!\n");
8     lcd.printf("Hello World!\n");
9 }
```

Compile

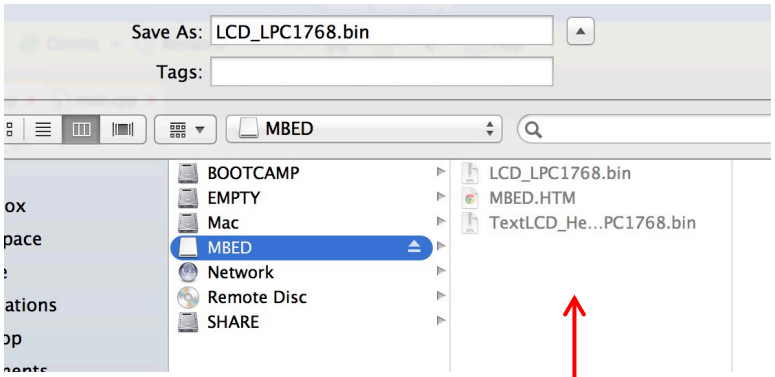
- Register and login
- Set up the hardware
- Create a new project in mbed compiler
- Write a hello world program
- **Compile**
- Downloading to mbed



Download to MBED

- Register and login
- Set up the hardware
- Create a new project in mbed compiler
- Write a hello world program
- Compile
- **Downloading to mbed**

*Make sure the mbed is connected to your computer through USB



Drop compiled file here

hit the reset button on the top of your embed to run

*If you don't have an MBED.HTML file, https://os.mbed.com/platforms/mbed-LPC1768/)

Viewing Output in Terminal

Register and login

Set up the hardware

Create a new project in mbed compiler

Write a hello world program

Compile

Downloading to mbed

- MBED CLI1 to view output in terminal
  - Install python 3 (pip install python3)
  - Install mbed-cli (pip install mbed-cli)
  - (Additional instructions in https://os.mbed.com/docs/mbed-os/v6.15/build-tools/install-and-set-up.html)
  - To verify Mbed CLI installed correctly, run `mbed -help`
  - To open a serial terminal (only work for a single board) for message printing, run `mbed sterm -b <BAUDRATE>` (default `9600`)

Code Reuse

- Programming microcontrollers for a simple task is mostly about setting up the right registers in the right way; however, neither is straightforward.
- Don’t need to start from scratch for everything.
- It’s OK to learn how to initialize, set up timer/interrupts, and write LCD from code that is already available.
- Be sure to cite/ack the sources.

Acknowledgements

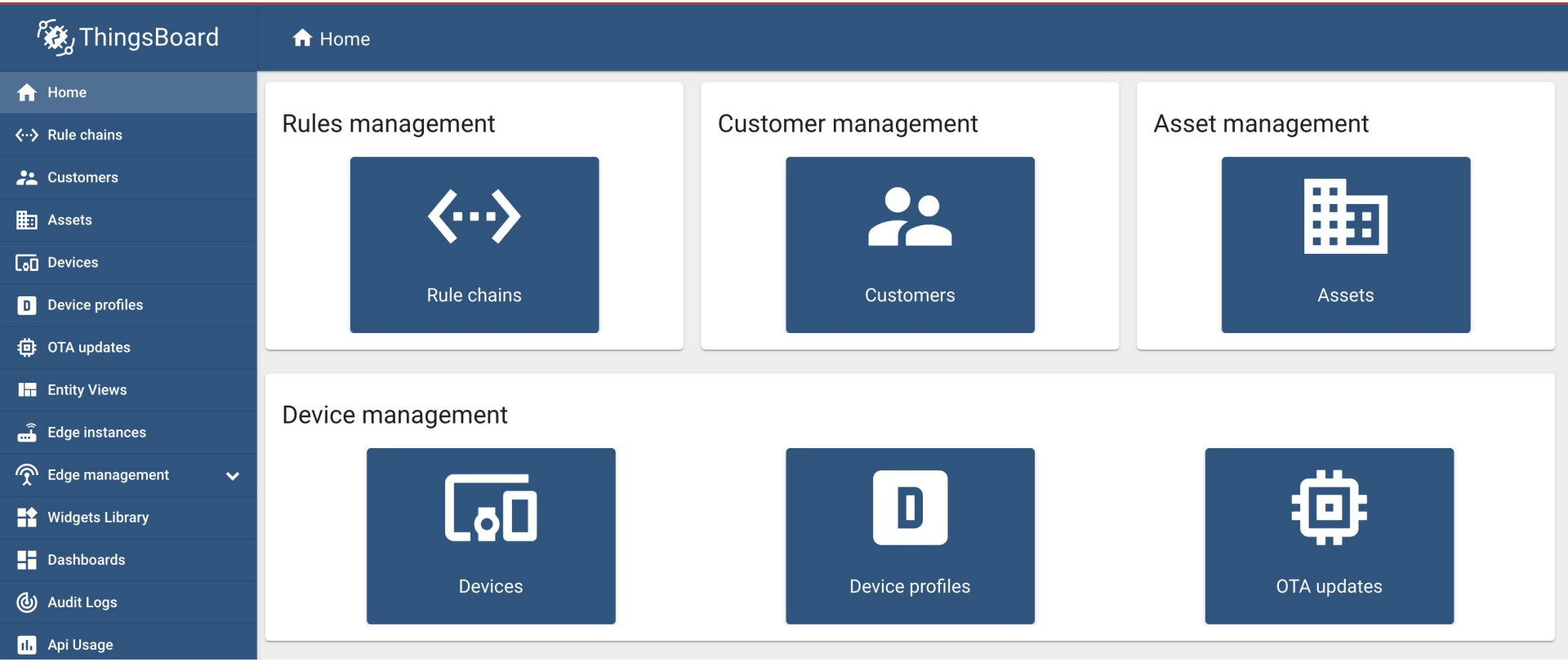
- Slides Created By:
  - Dagaen Golomb
  - Yahan Yang
  - Amanda Watson

Introduction to Thingsboard

ThingsBoard is at https://tb-exp.precise.seas.upenn.edu/

Once you have a team, please contact Amanda Watson (aawatson@seas.upenn.edu) to create an account with you team name and emails for you and your teammates. She will give you access to your group's Thingsboard.

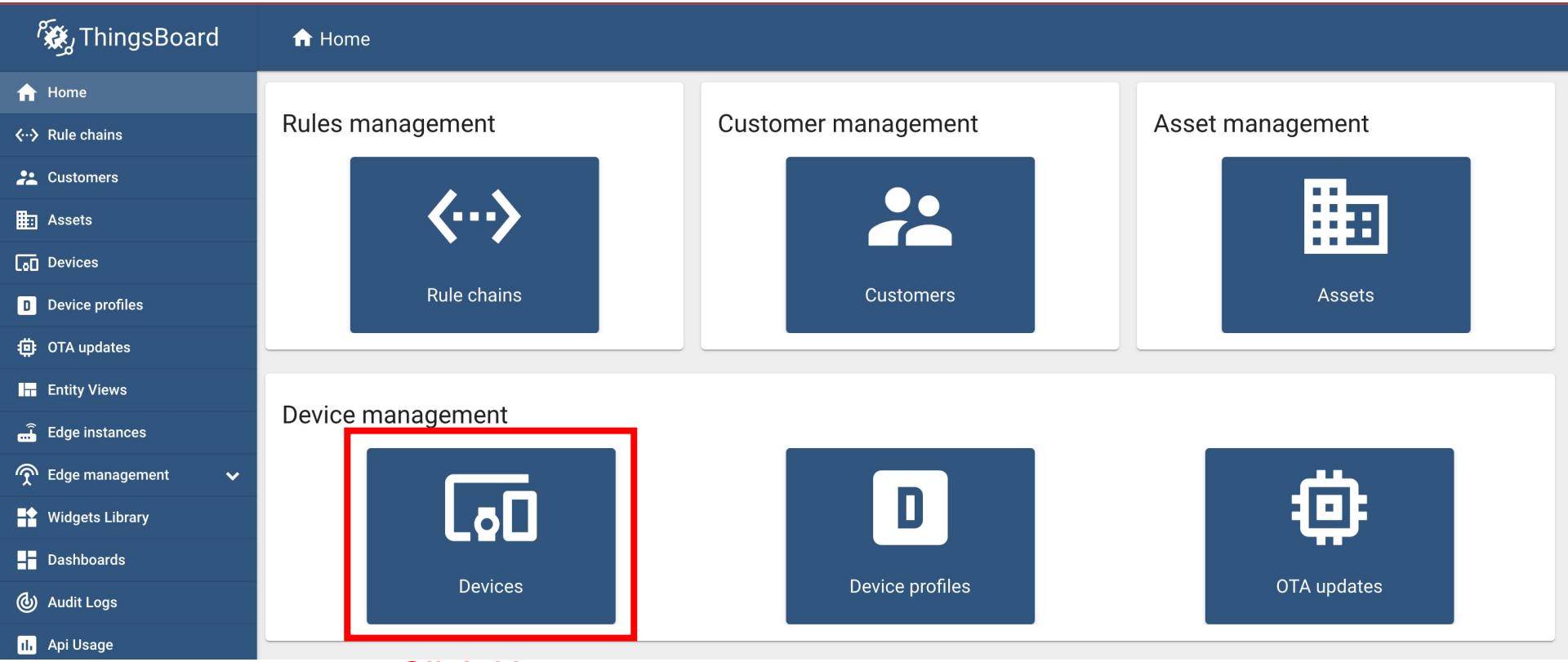
Home Page



Once you have a Thingsboard account, your homepage should look like this.

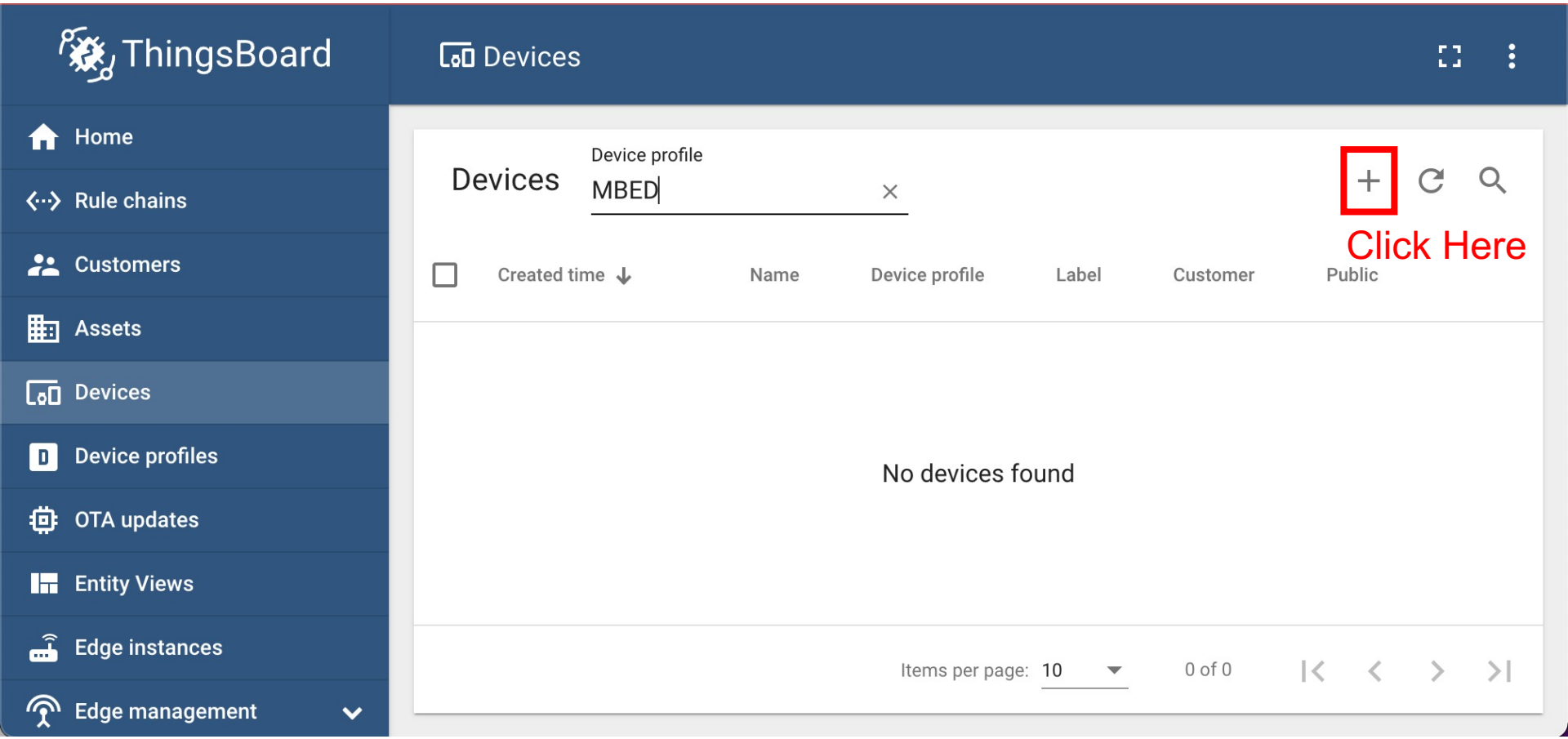
Device Creation

Device Creation

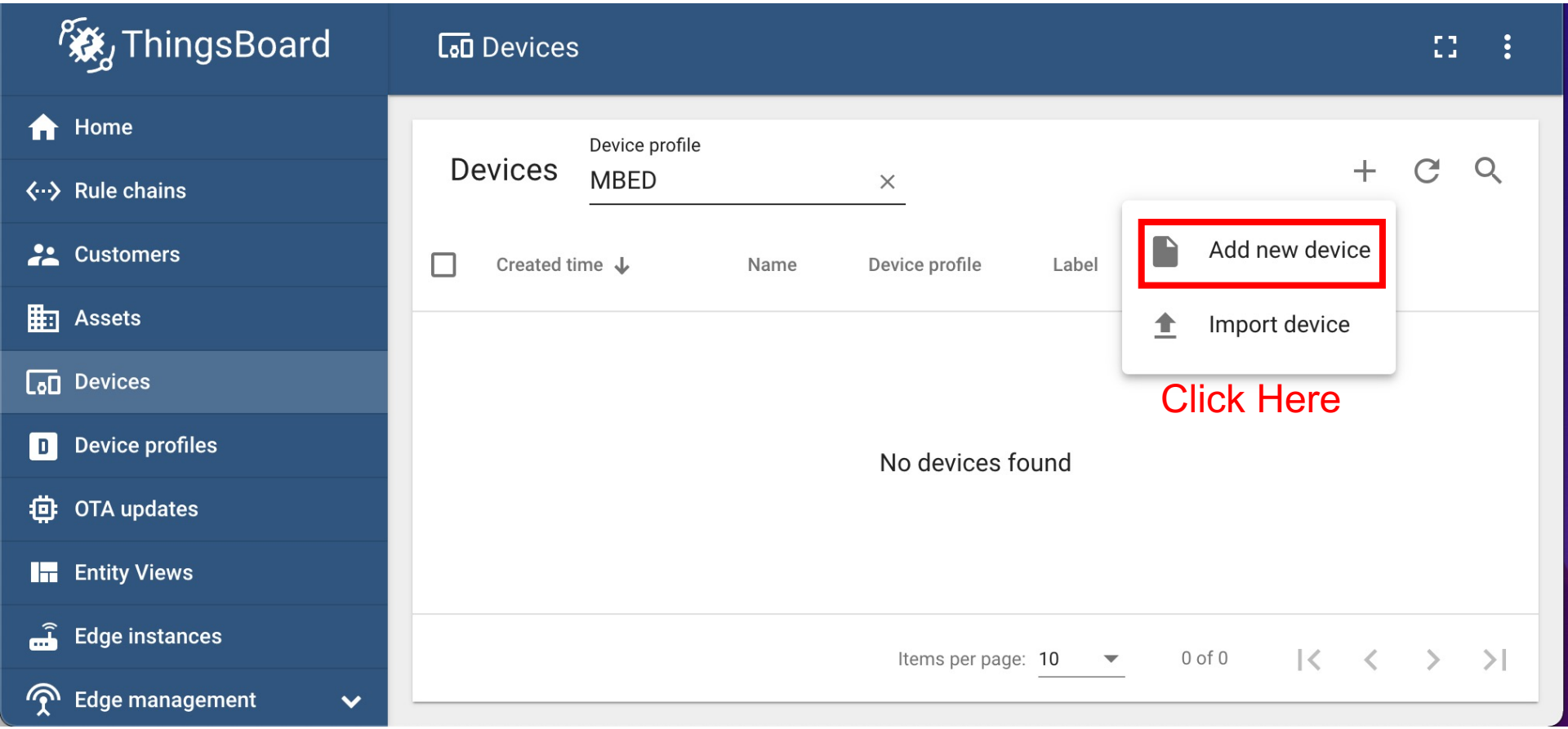


Click Here

Device Creation



Device Creation



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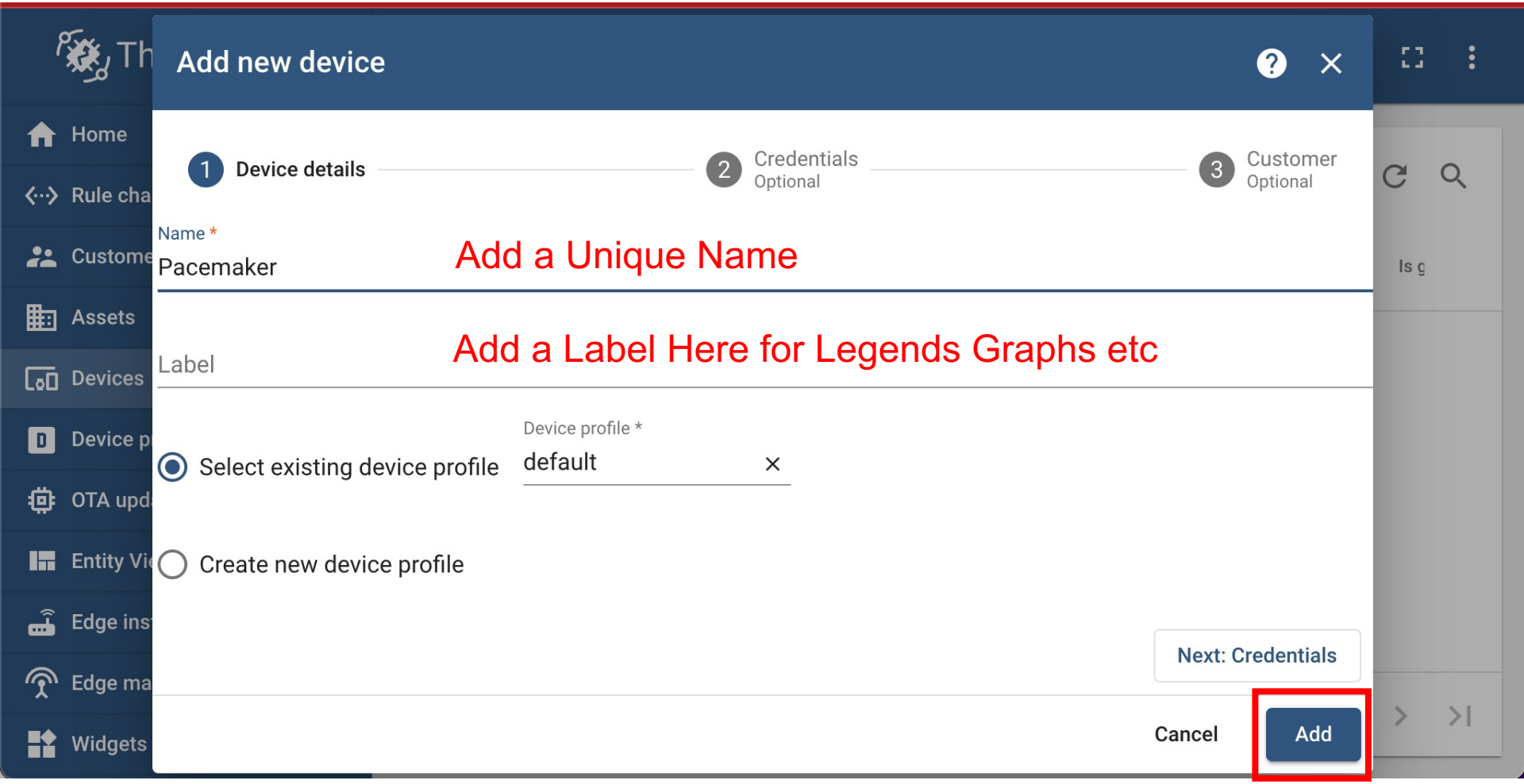

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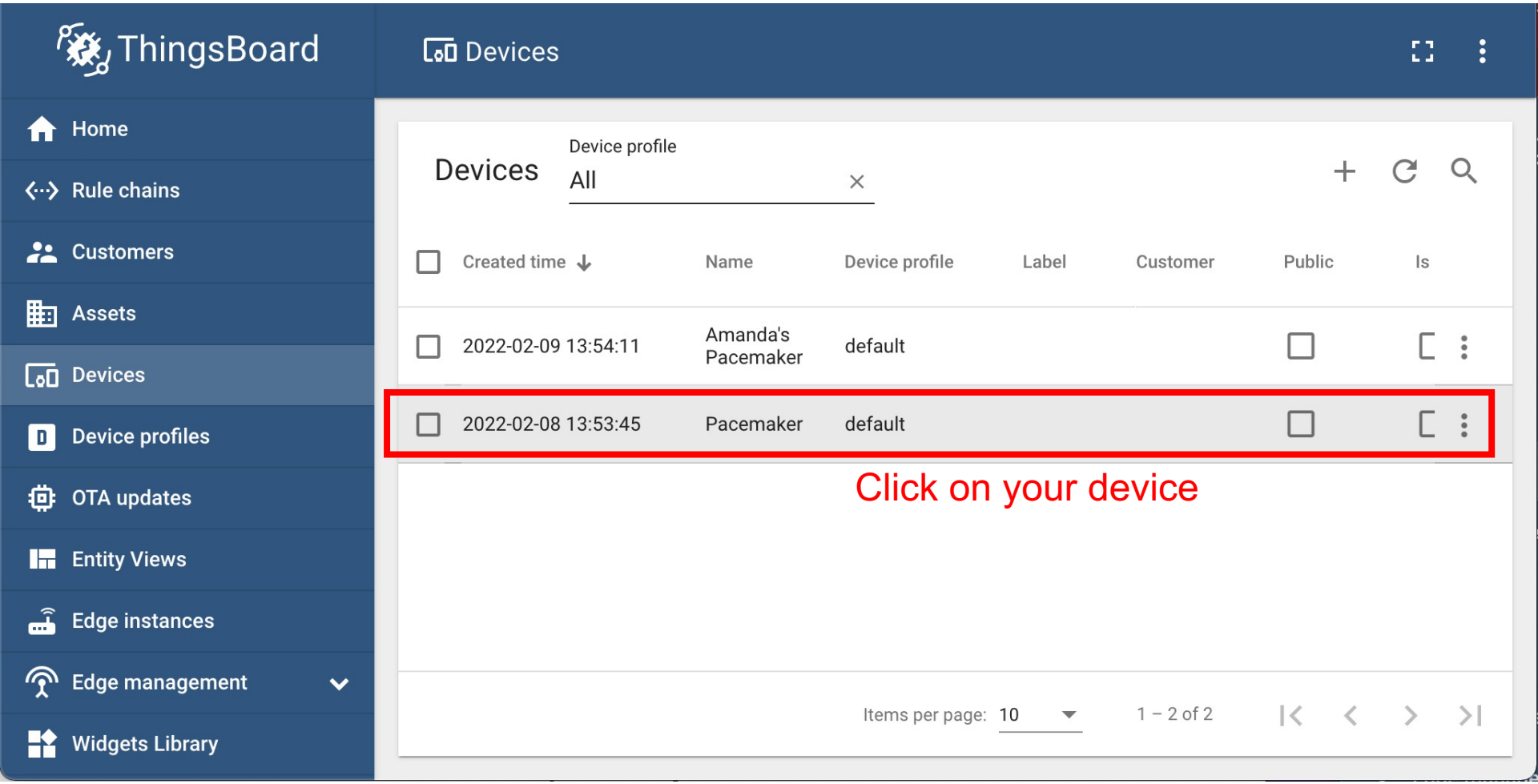
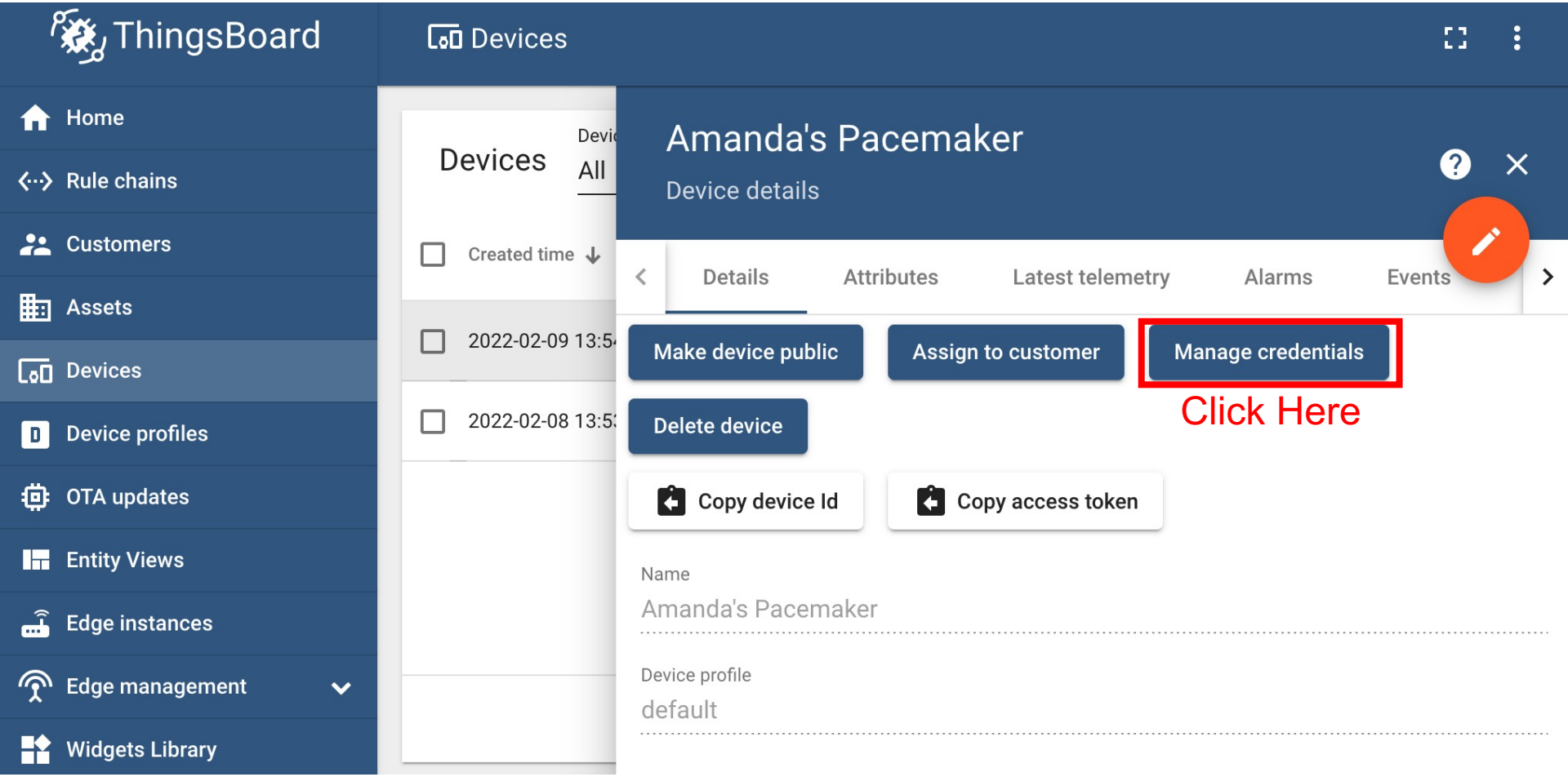
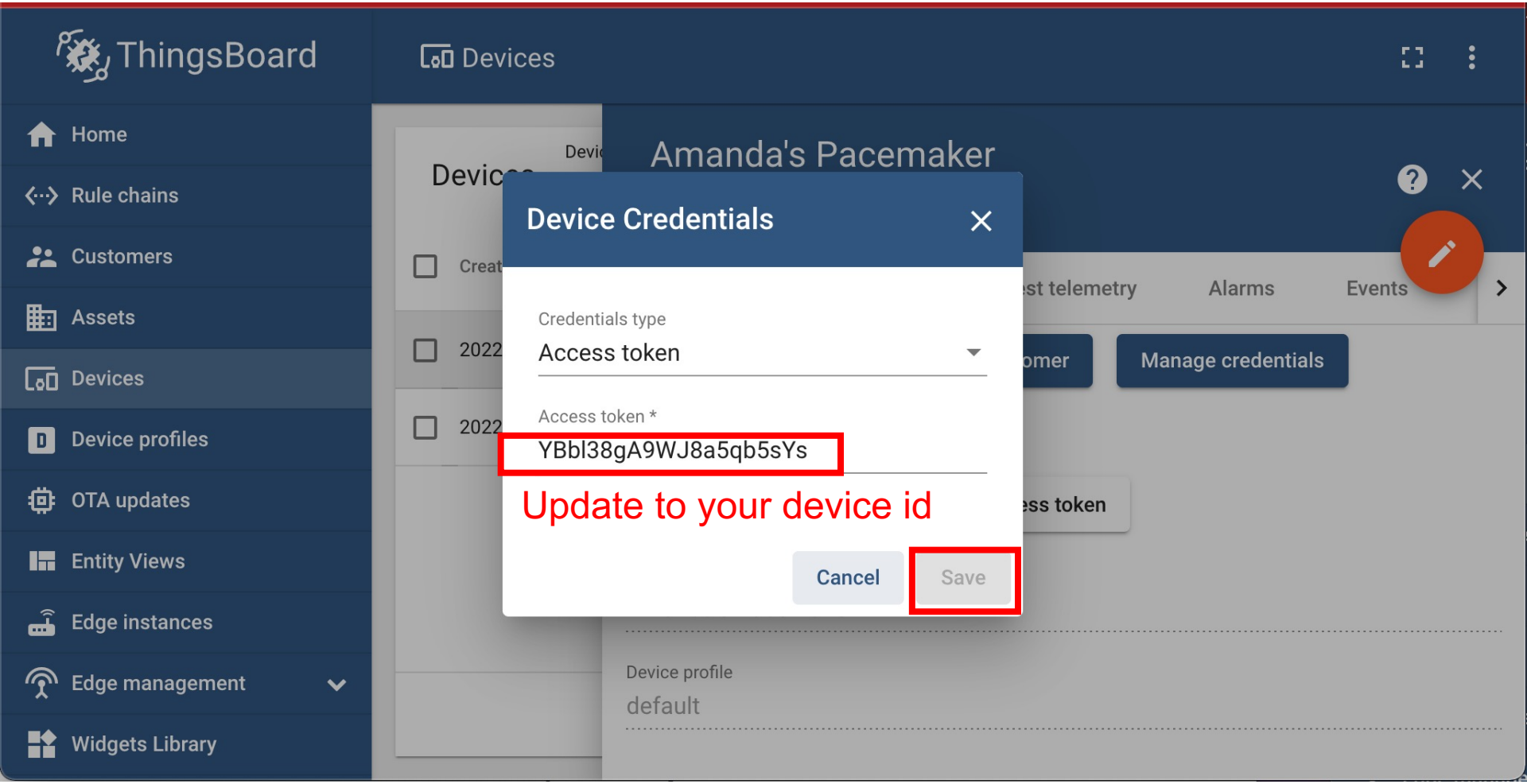


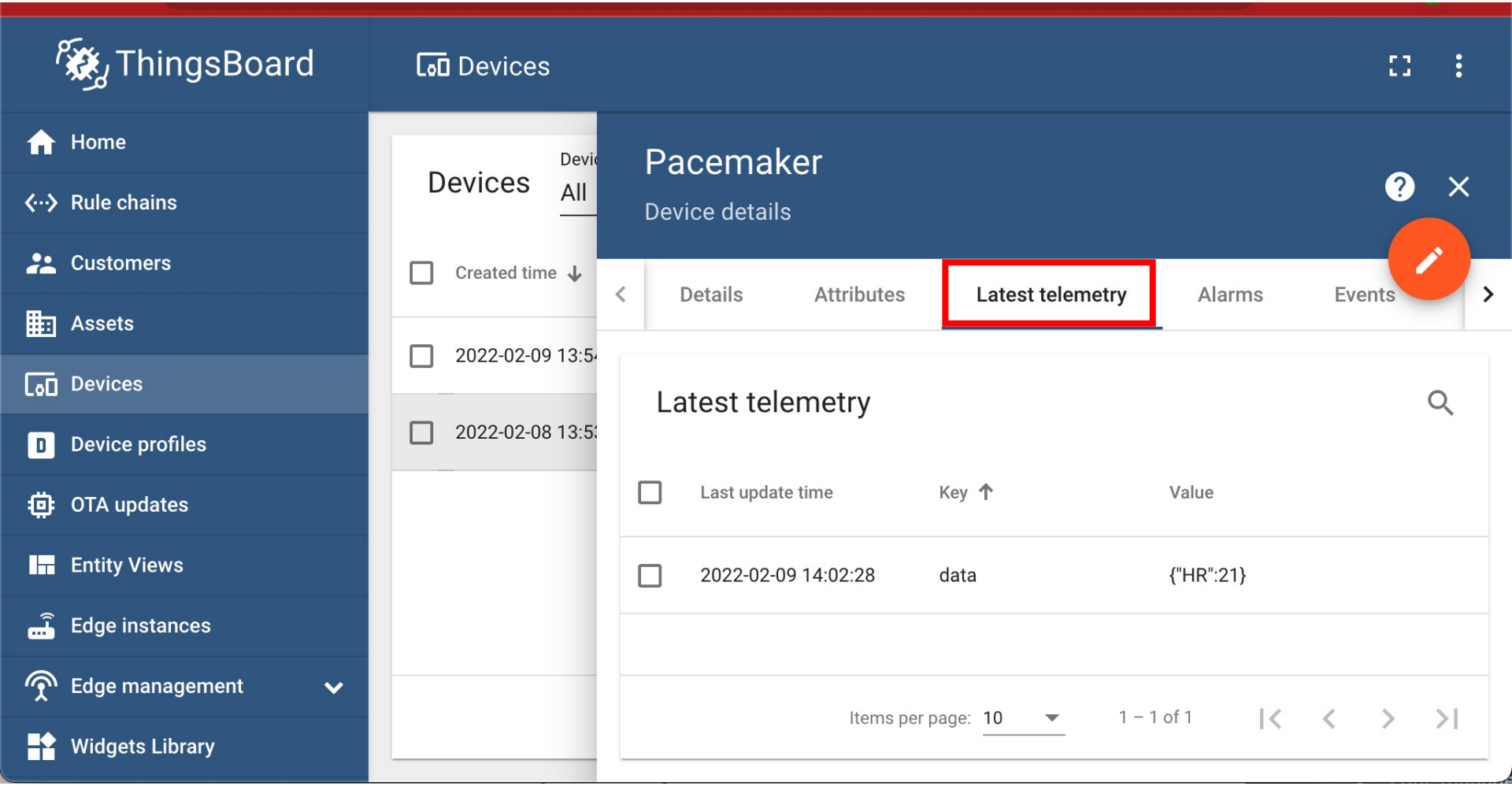
Device Creation



Device Creation



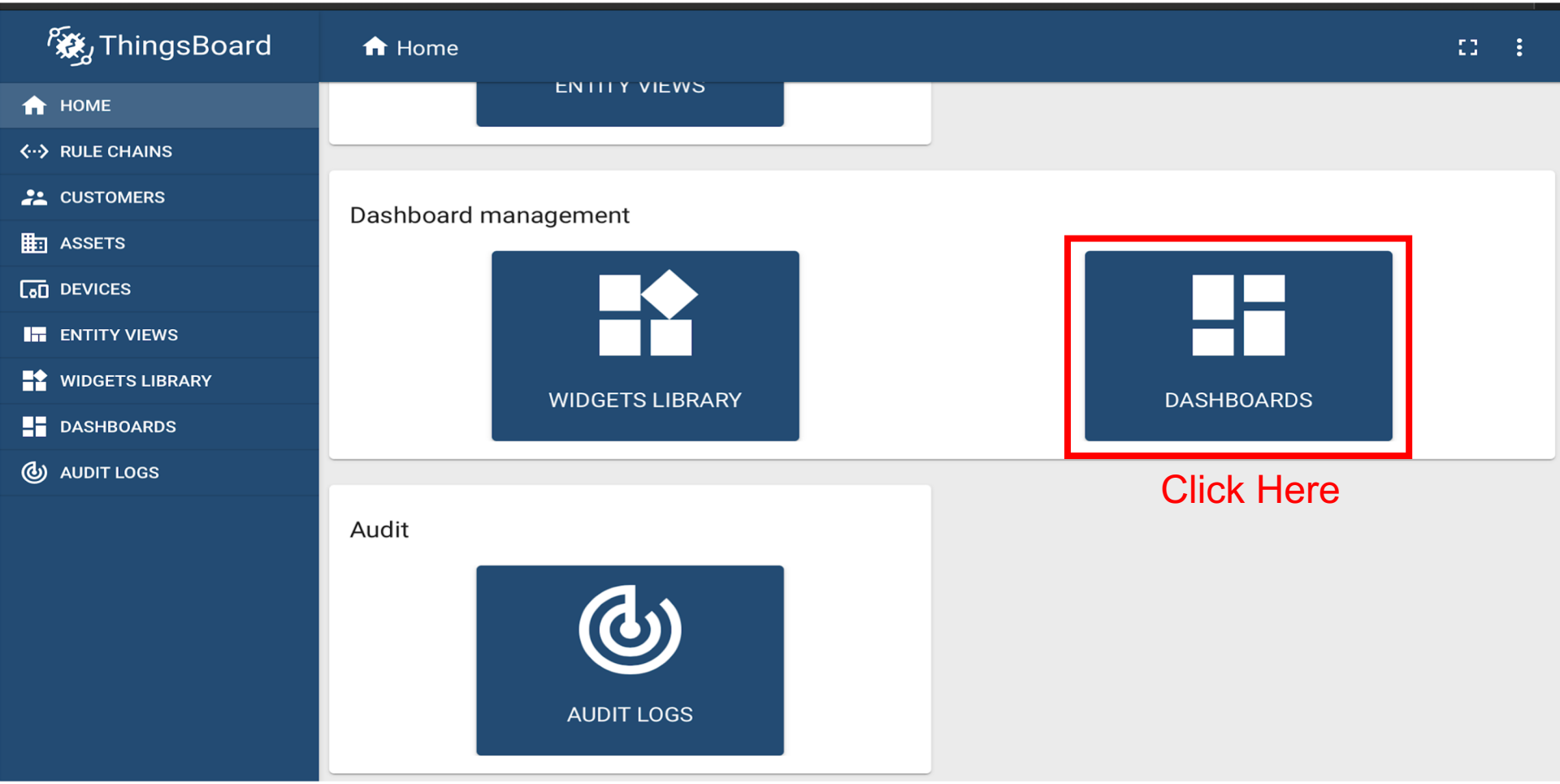
Device Creation



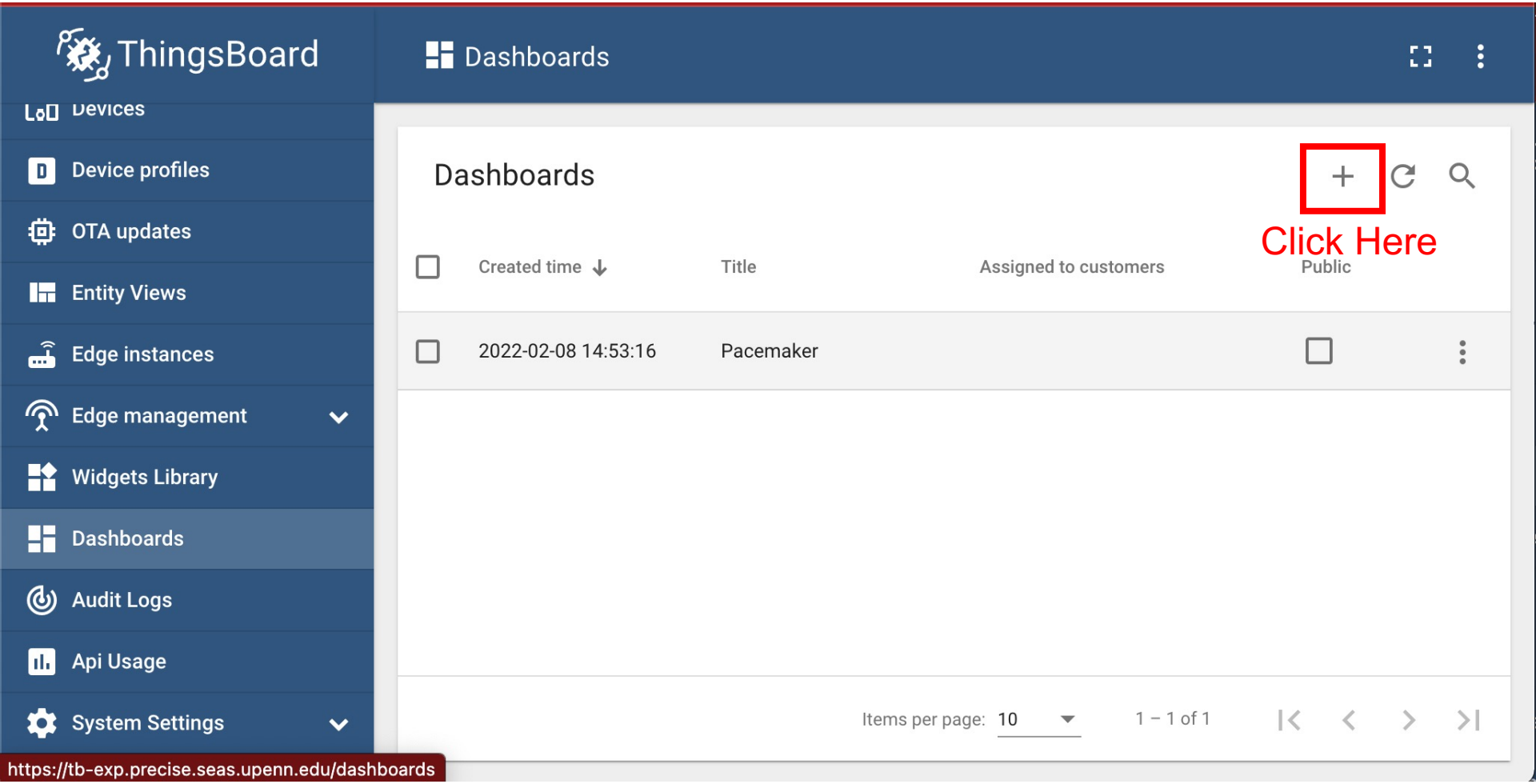
If set up correctly, and data is streaming, you will see your device data here

Dashboard Creation

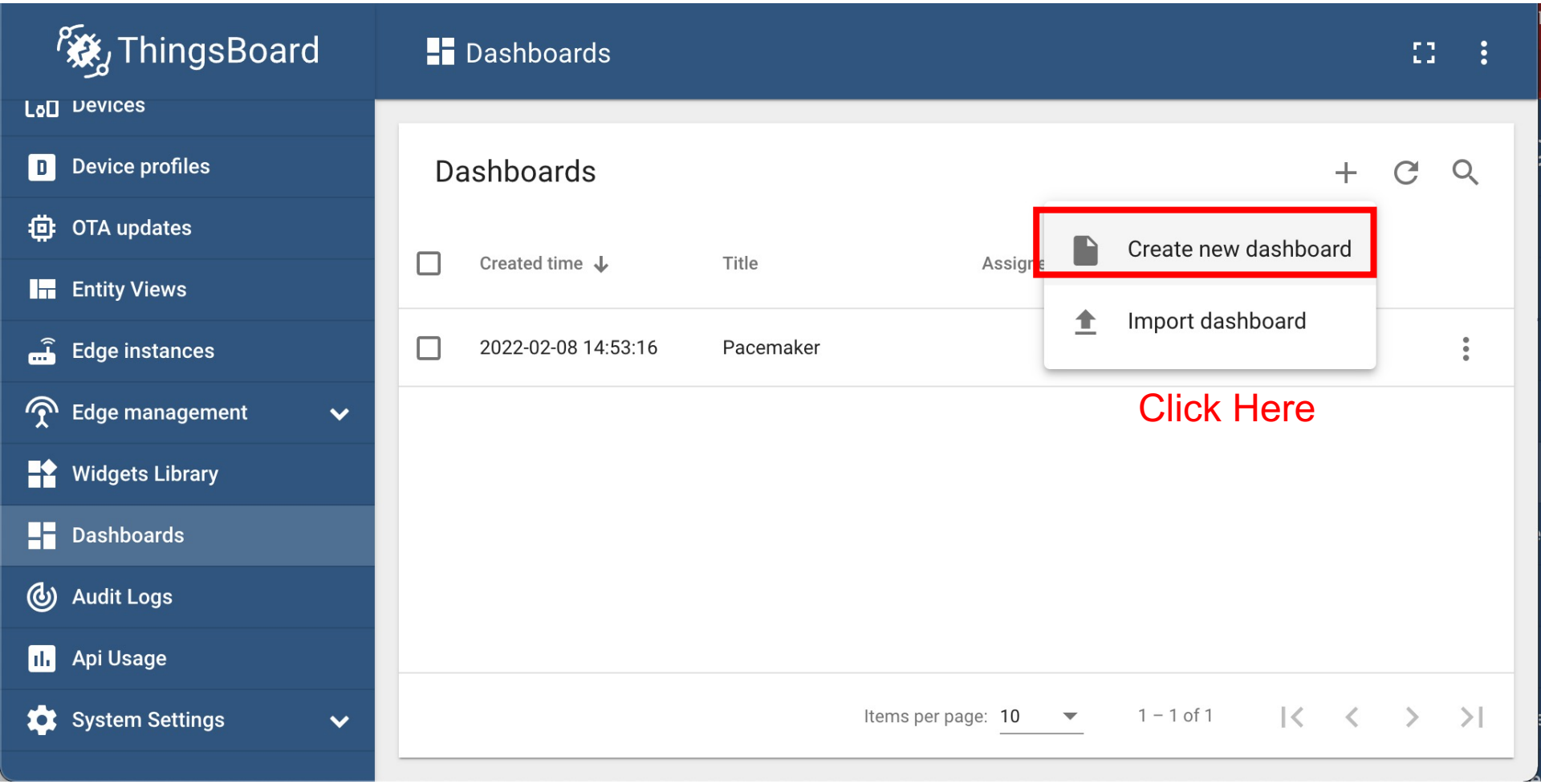
Dashboard Creation



Dashboard Creation



Dashboard Creation



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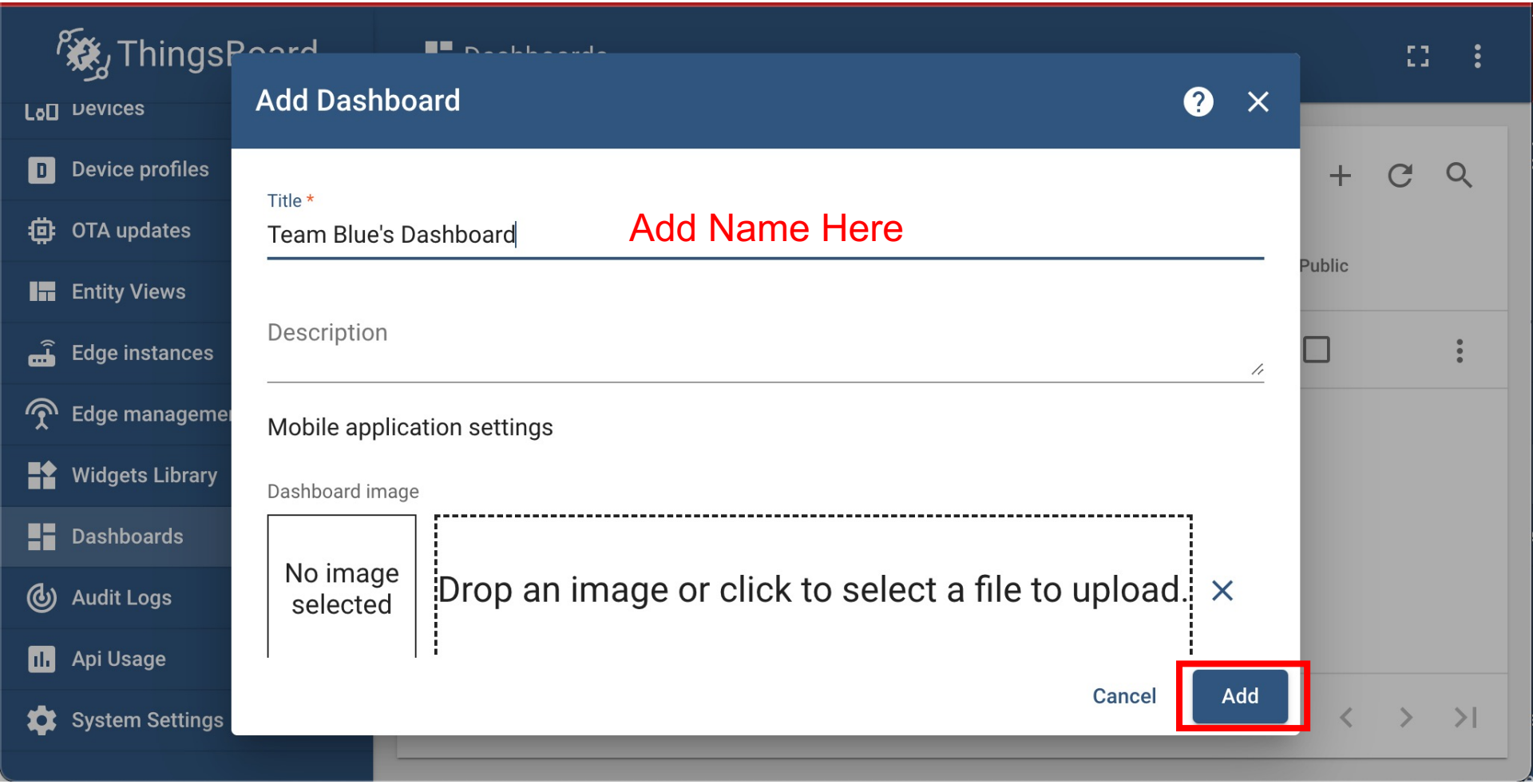

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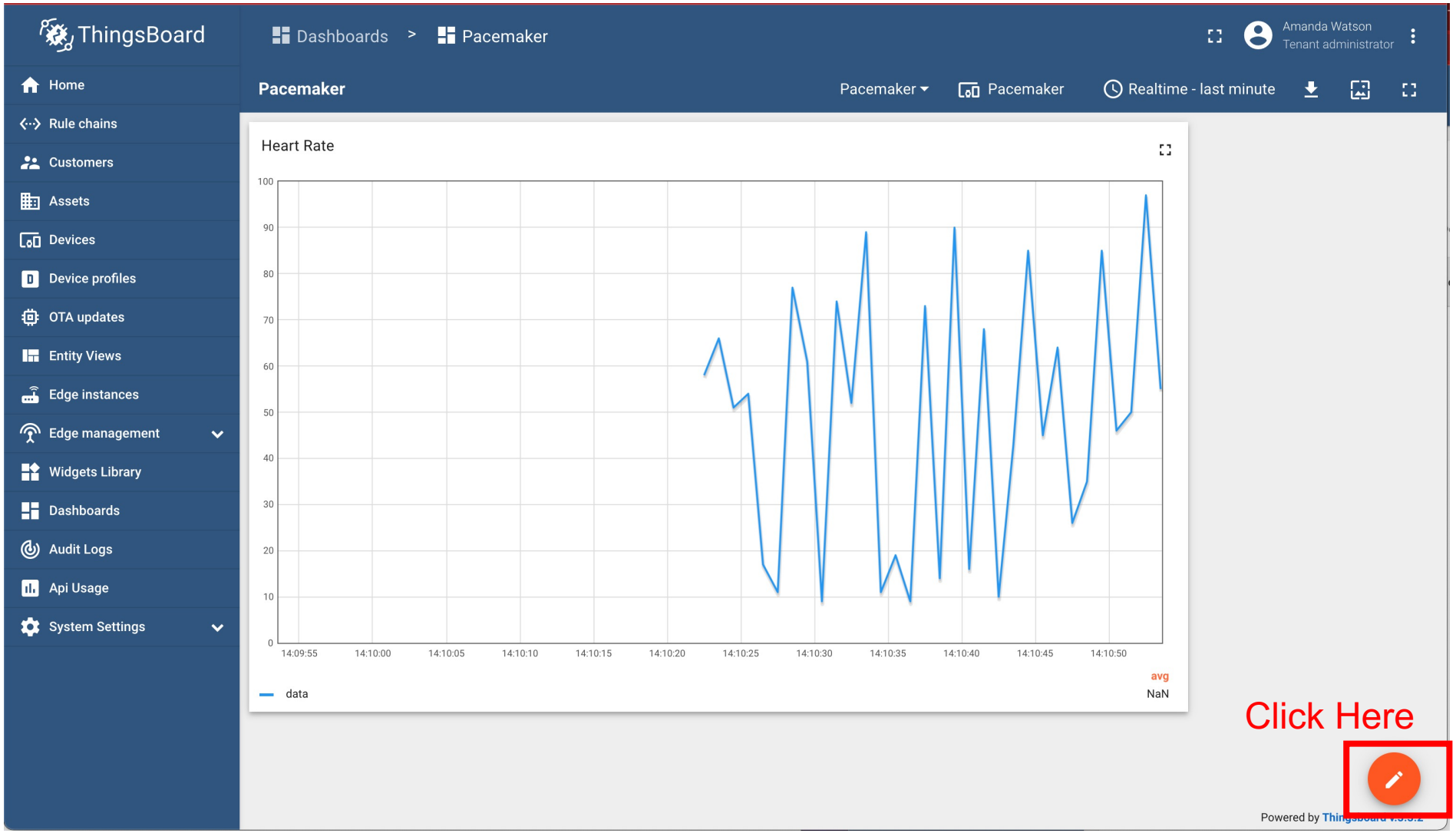

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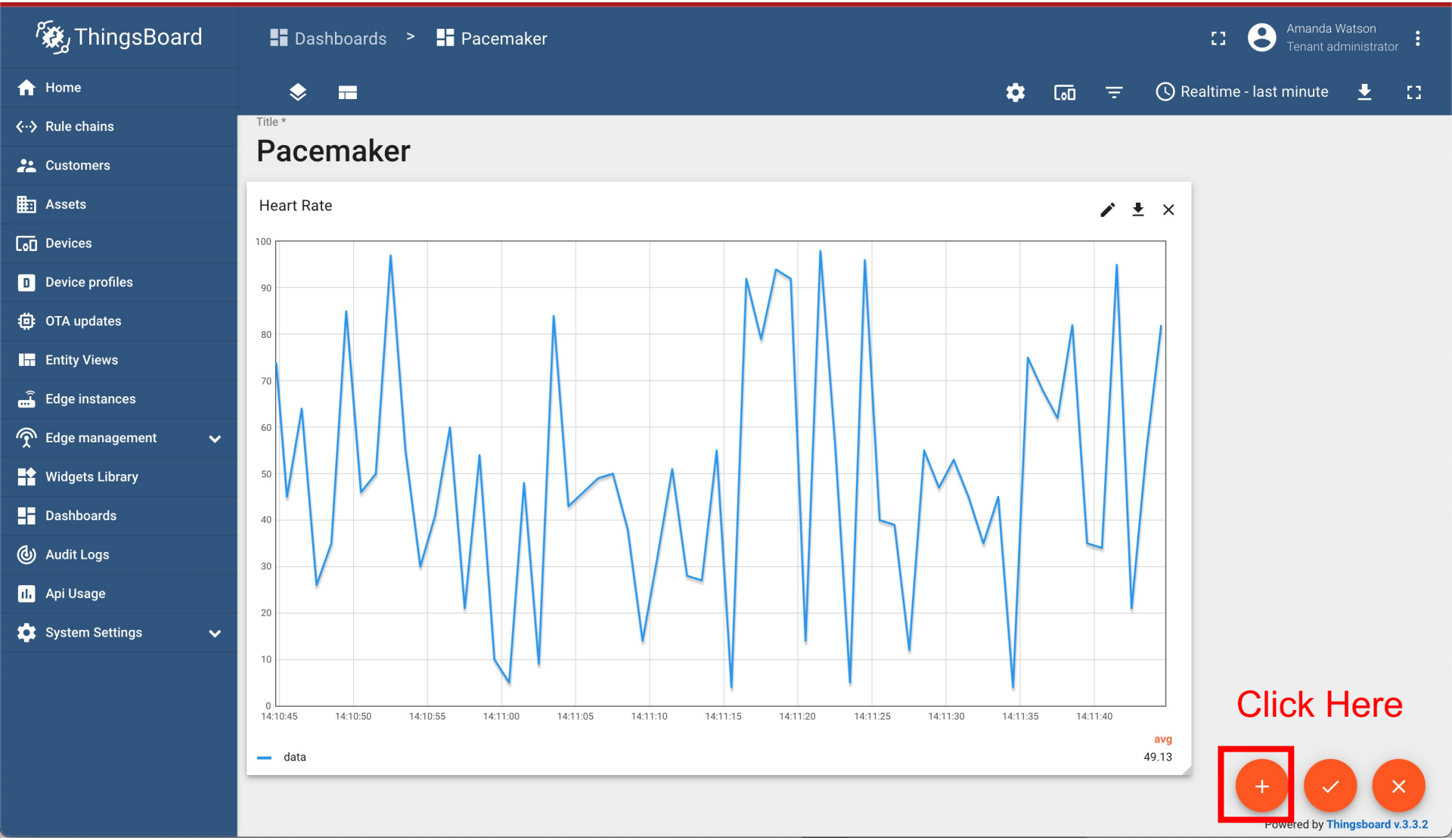
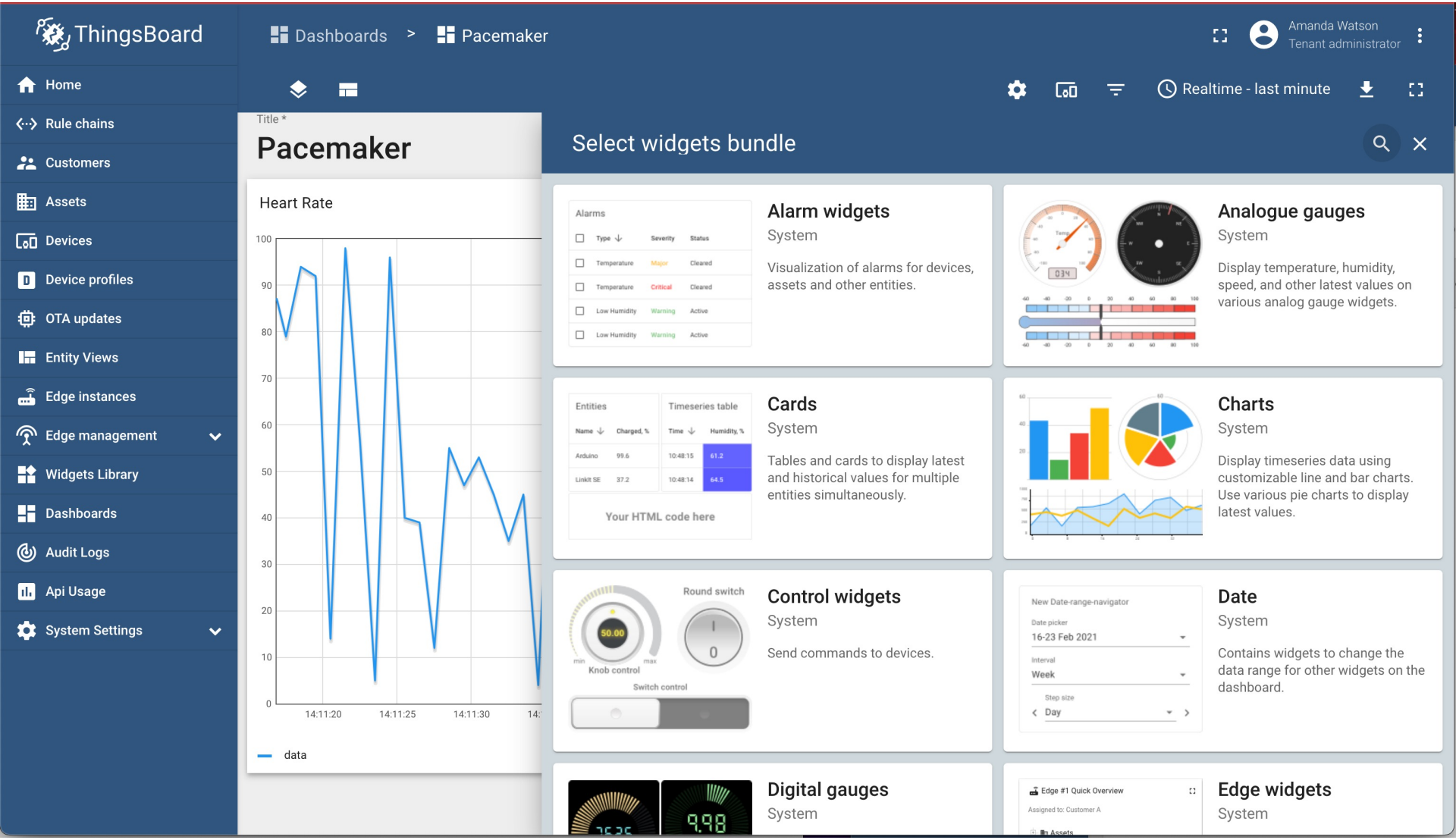


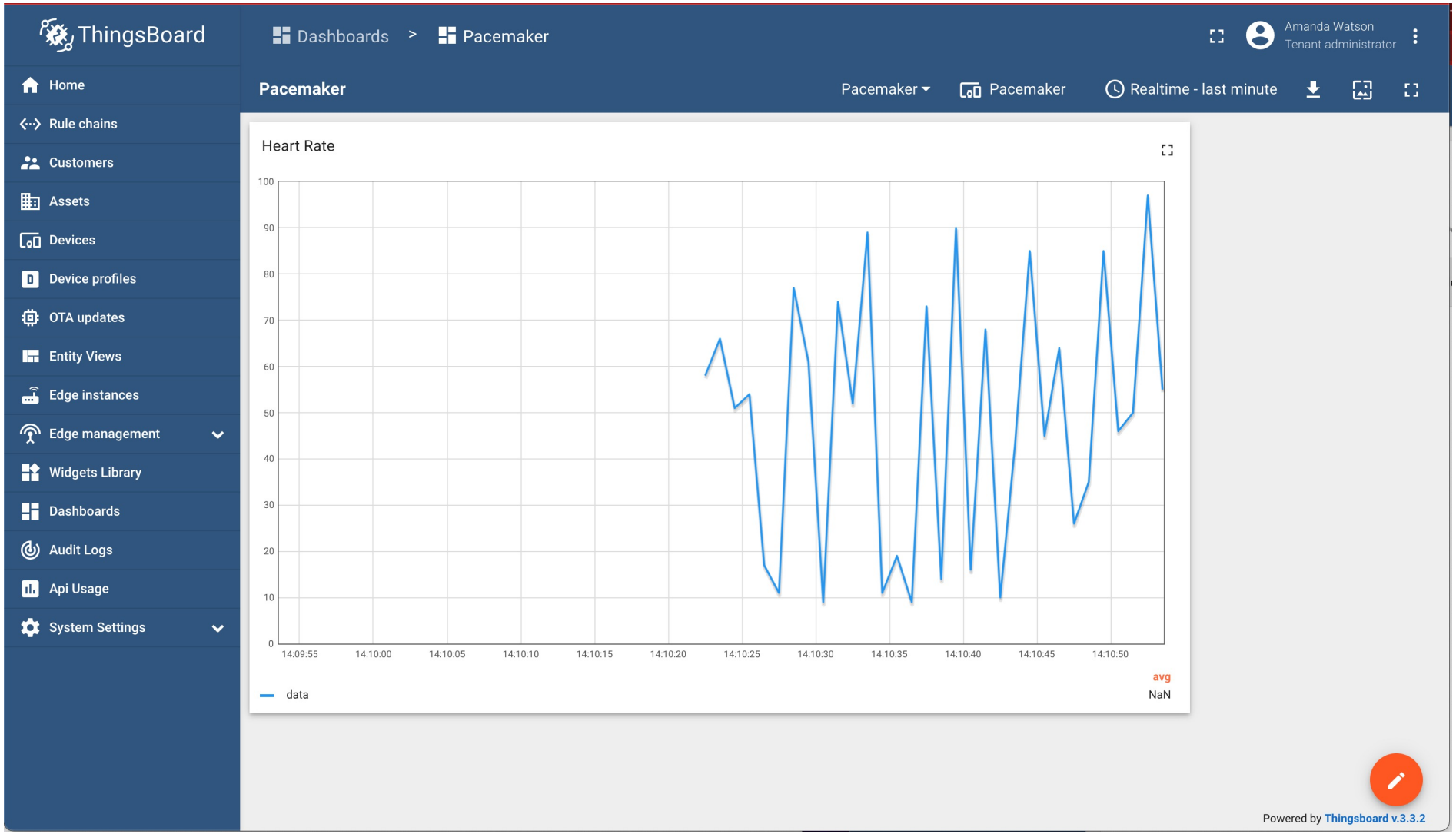
Penn Engineering

PRECISE

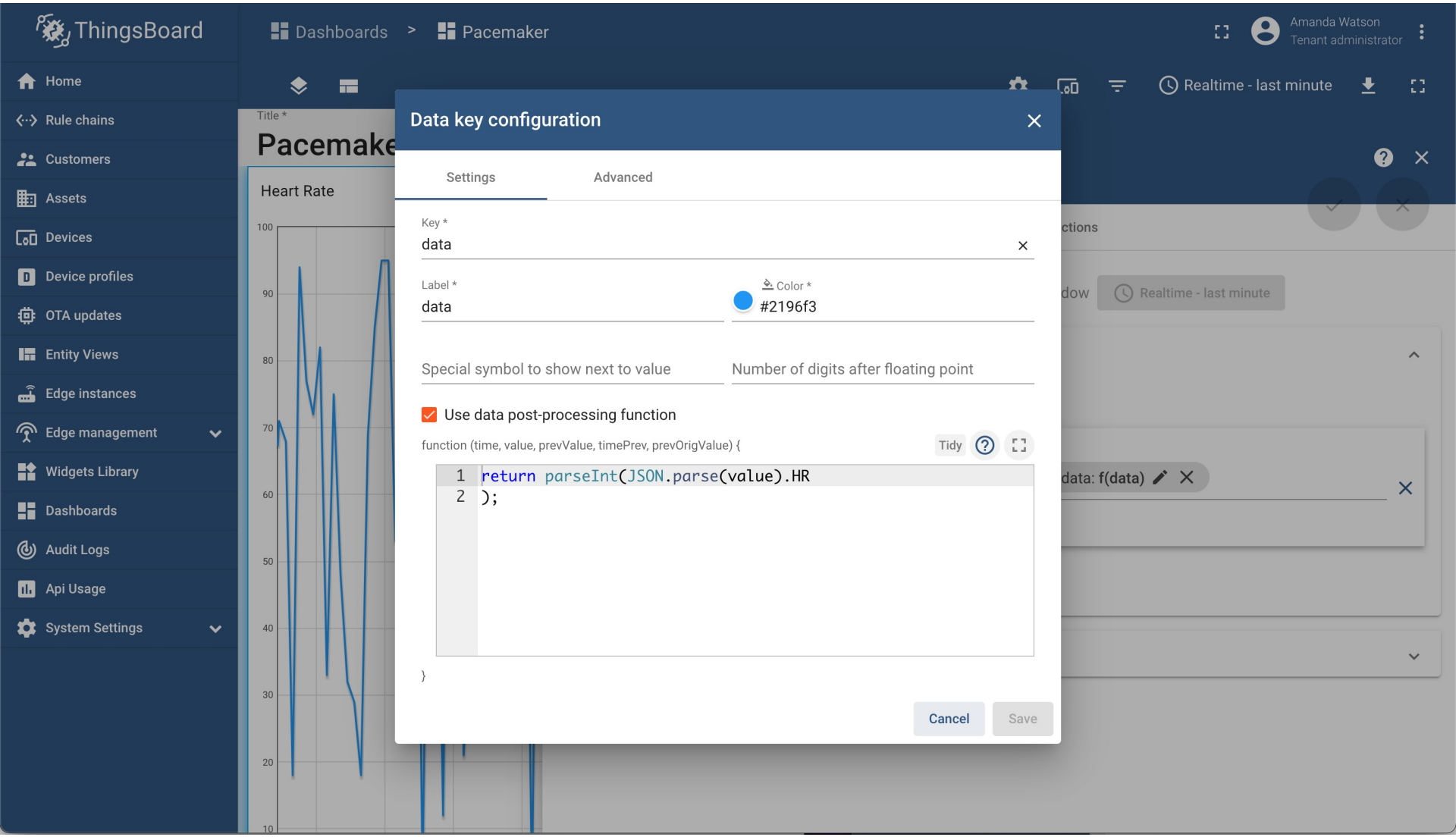
Dashboard Creation



Dashboard Creation



Dashboard Creation



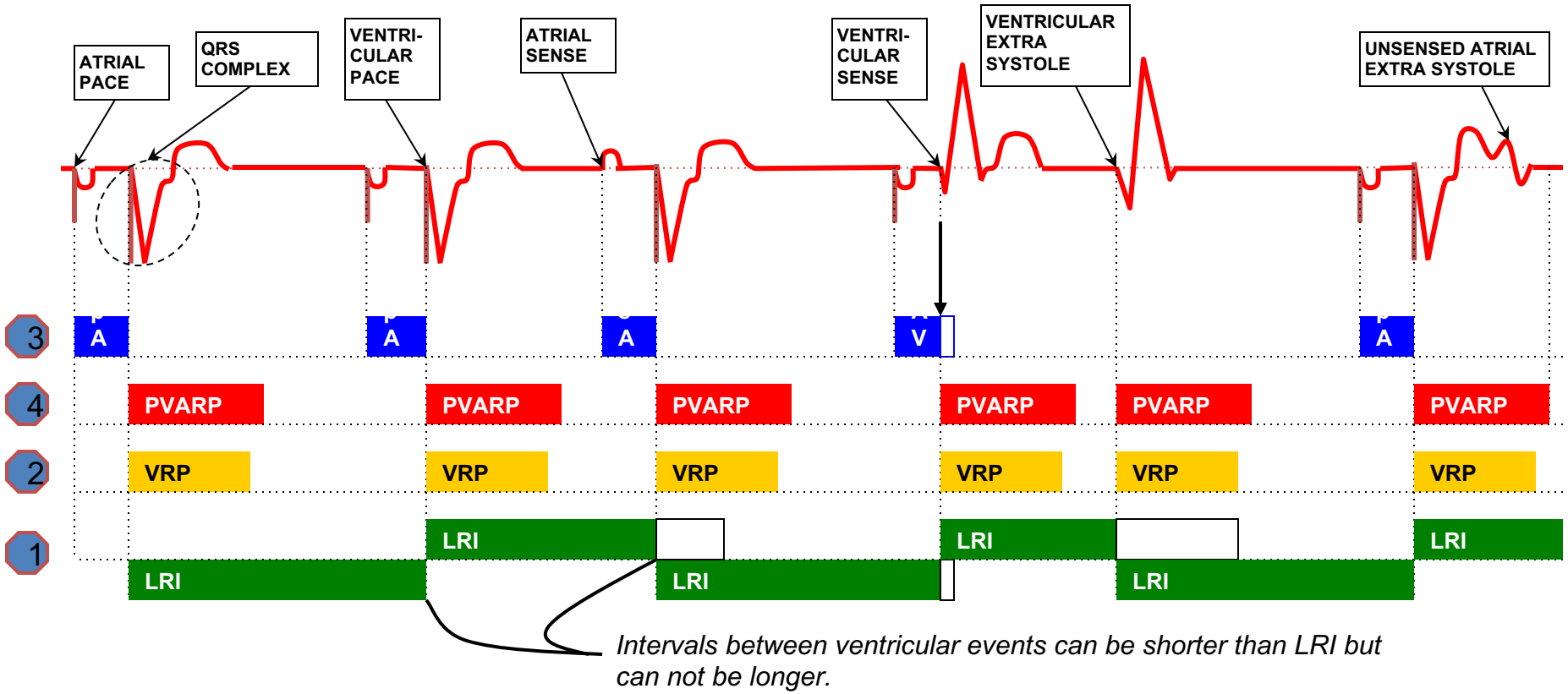
Penn Engineering

PRECISE

Pacemaker Appendix:

More on realistic pacemaker timing constraints

Four Fundamental Timing Cycles

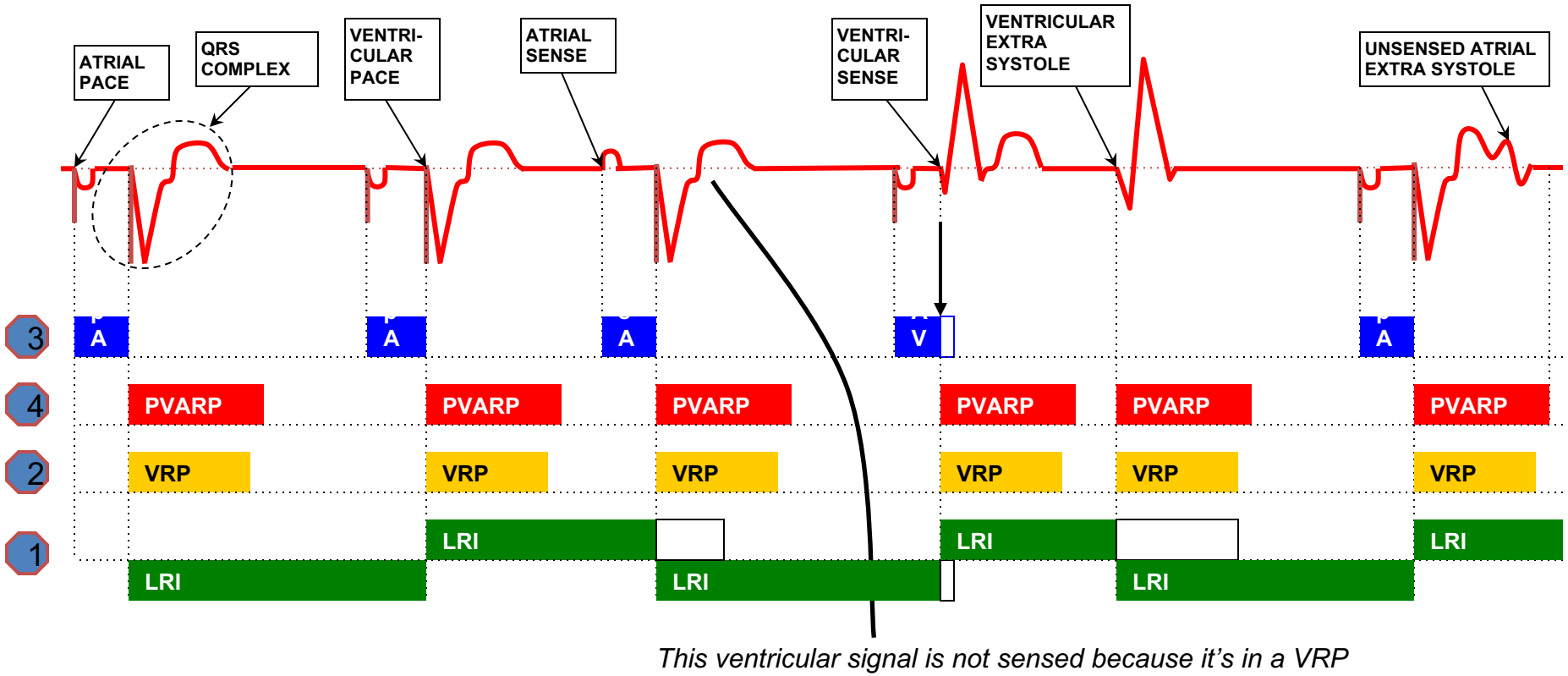


1 LRI = Lower Rate Interval

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

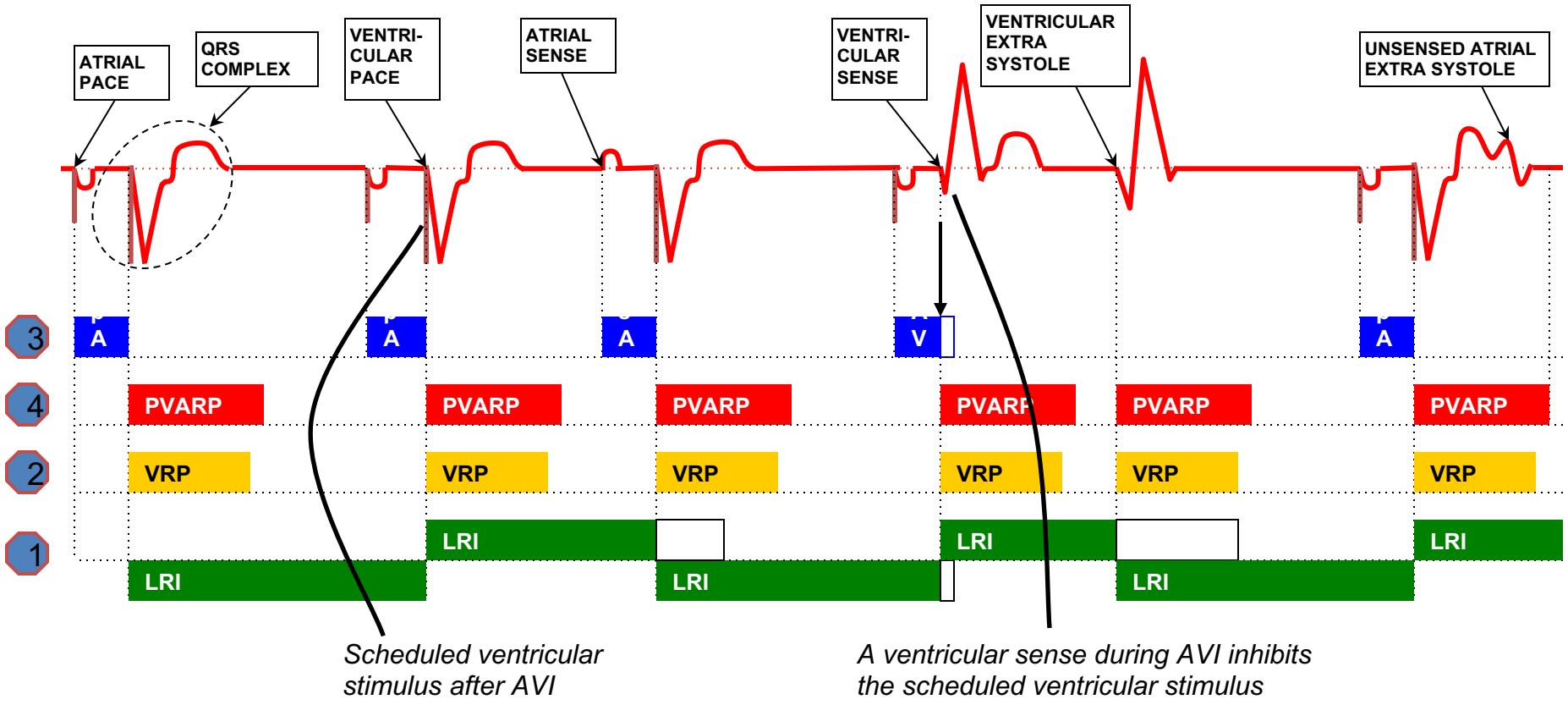


2 VRP = Ventricular Refractory Period

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, after potential,…) 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

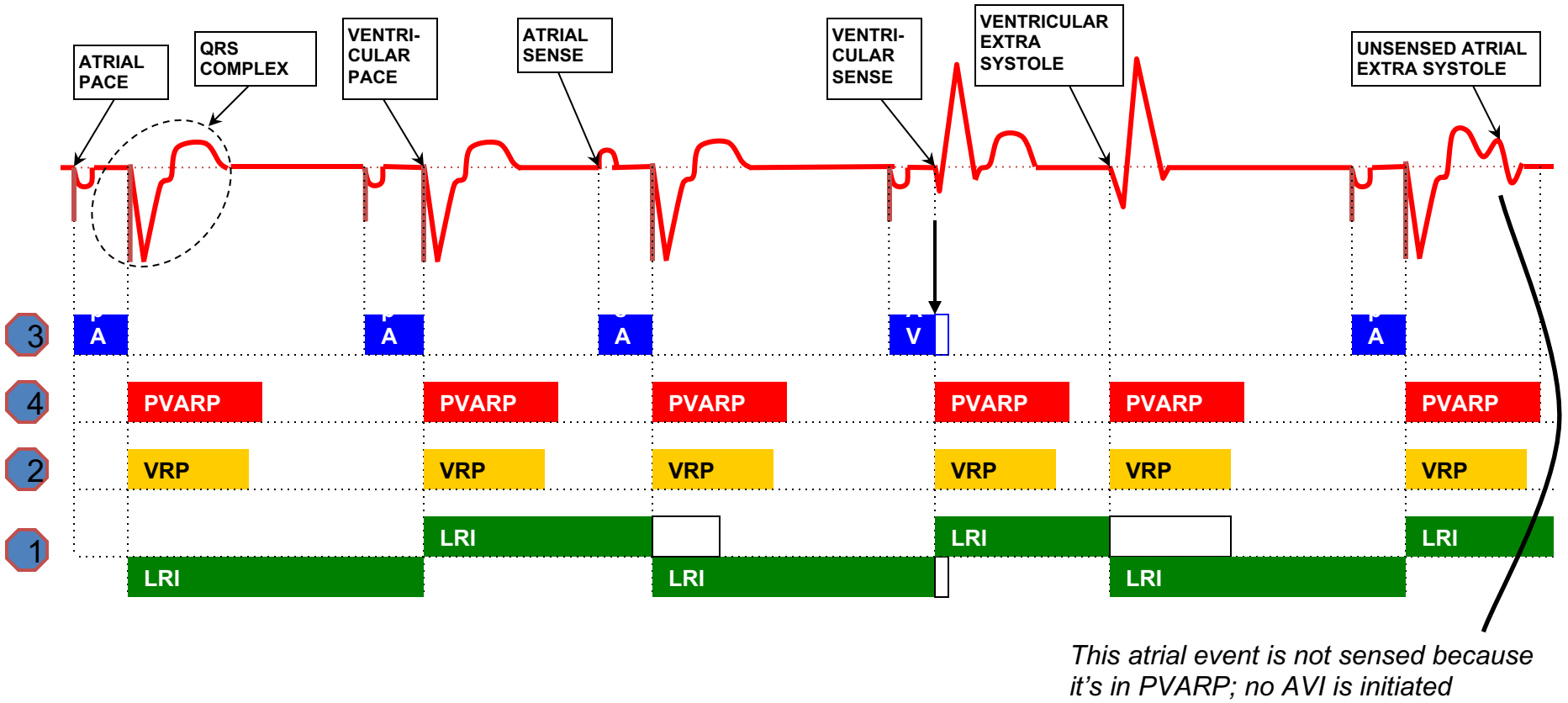
Interval between an atrial event and the scheduled delivery of a ventricular stimulus.

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

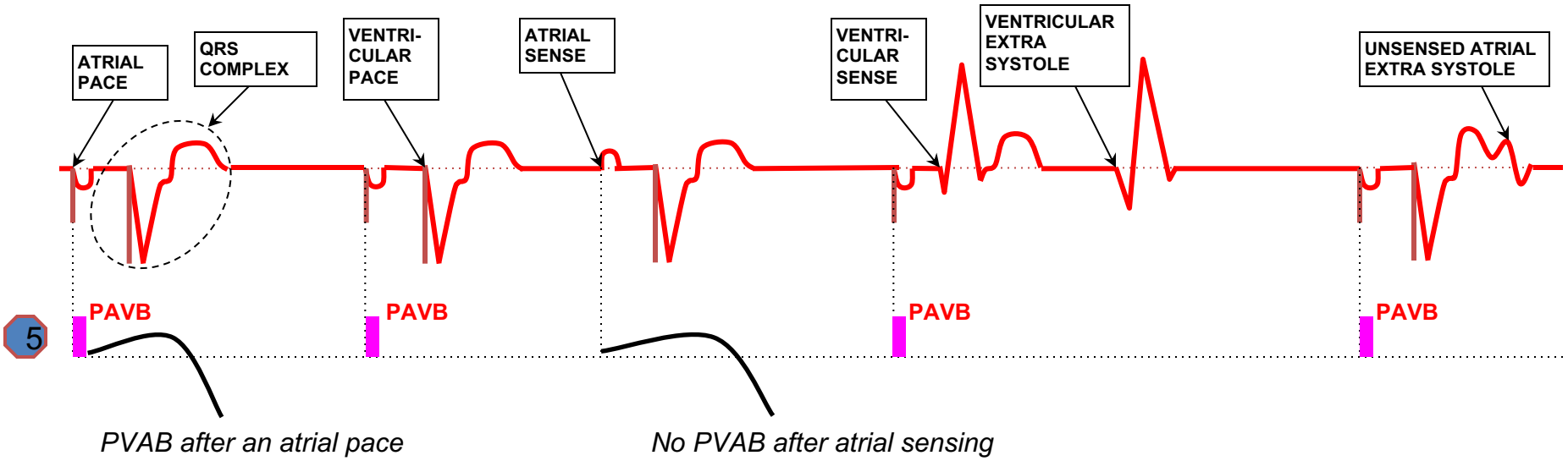


4 PVARP = PostVentricular-Atrial Refractory Period

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

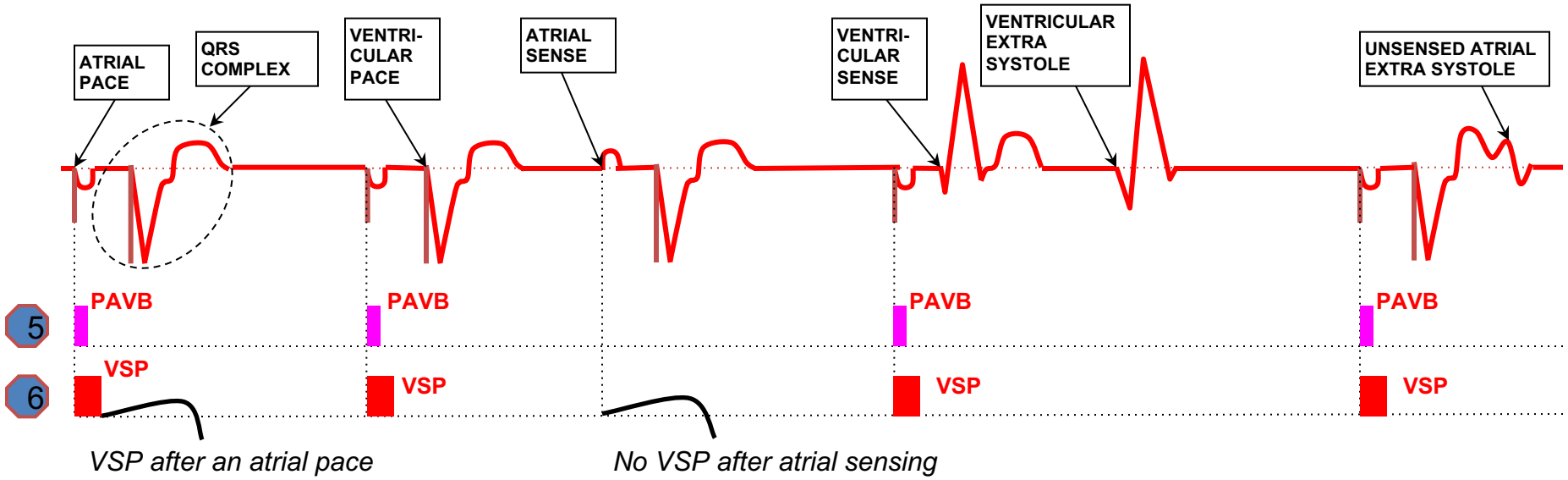
The disturbance caused by an atrial stimulus which, if sensed by the ventricular channel, may cause ventricular inhibition.

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.

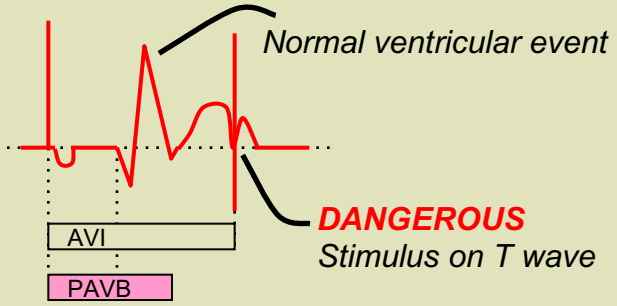
There is no PVAB after an atrial sense since it does not cause disturbance.

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).

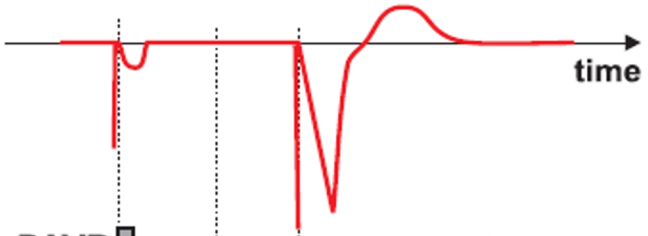
If PAVB is too short: crosstalk may still happen.



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.

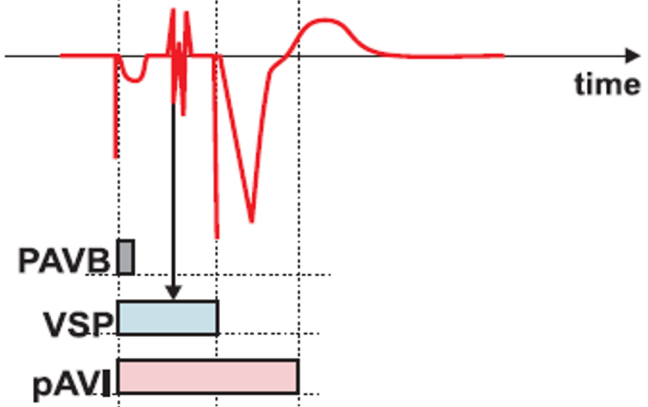


PAVB postatrial ventricular blanking

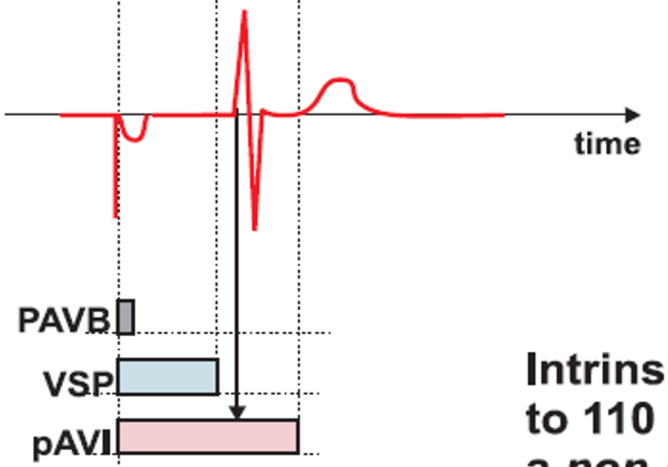
VSP ventricular safety pacing window

pAVI programmed AV interval

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



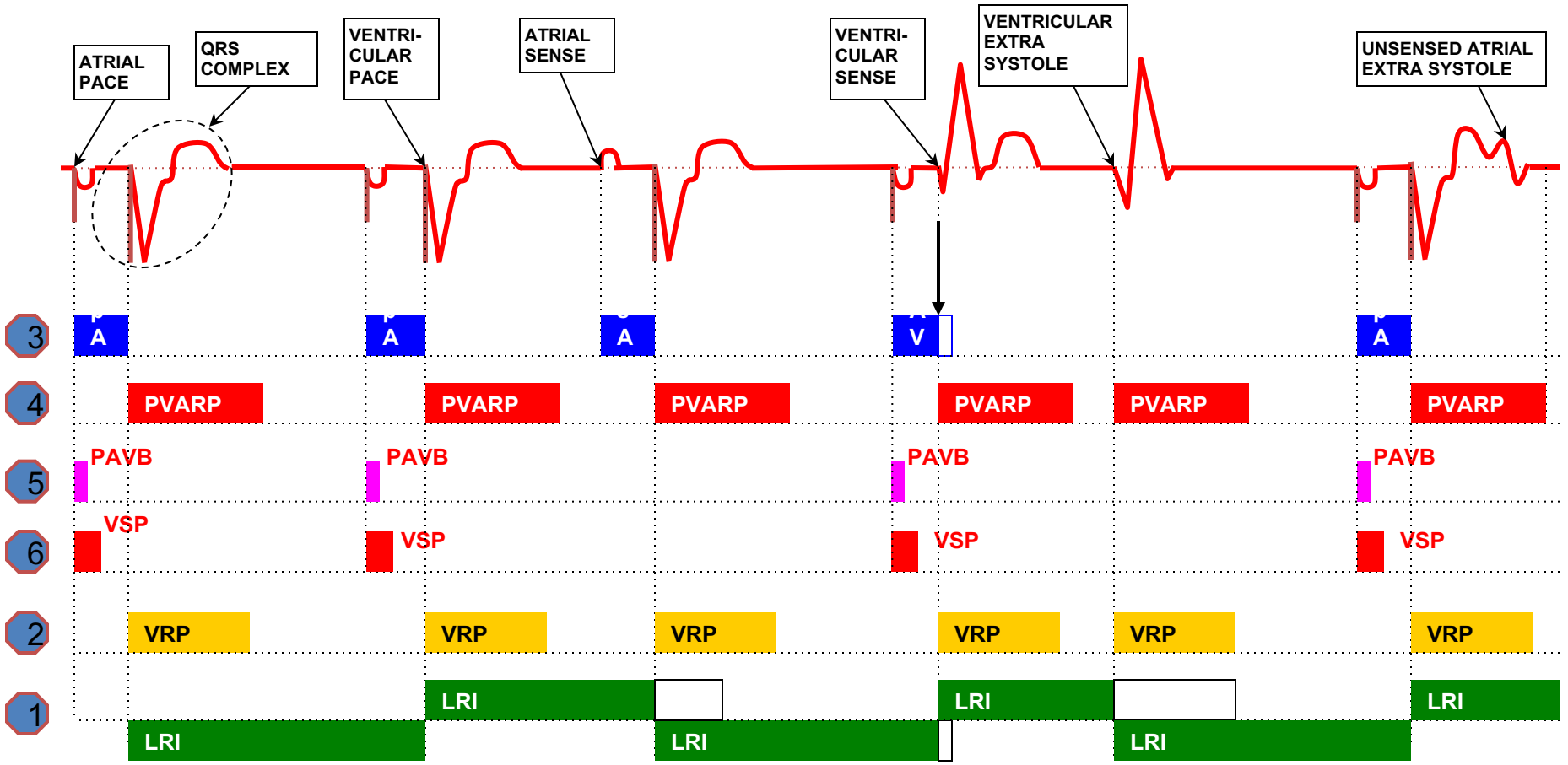
Interference (or early QRS) during the VSP window (beyond the PAVB) results in a committed ventricular stimulus at the end of that window and a characteristic shortening of the AV interval



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*

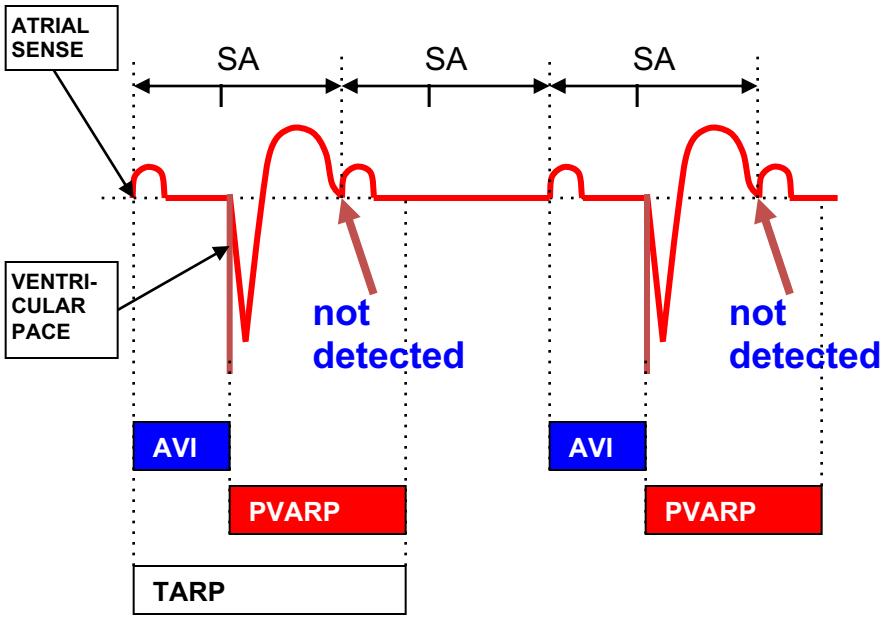
The TARP Timing Cycle

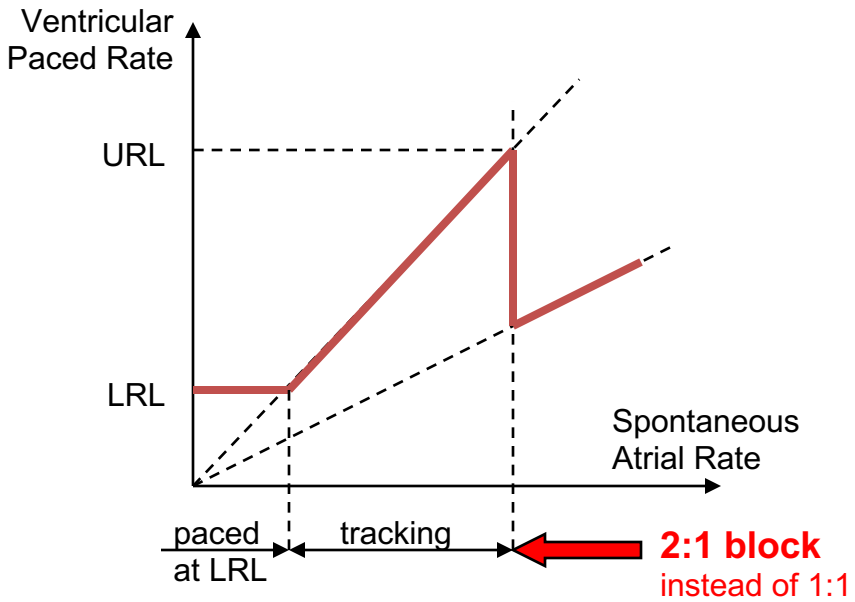


TARP = AVI + PVARP = Total Atrial Refractory Period

Tracking Mode

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



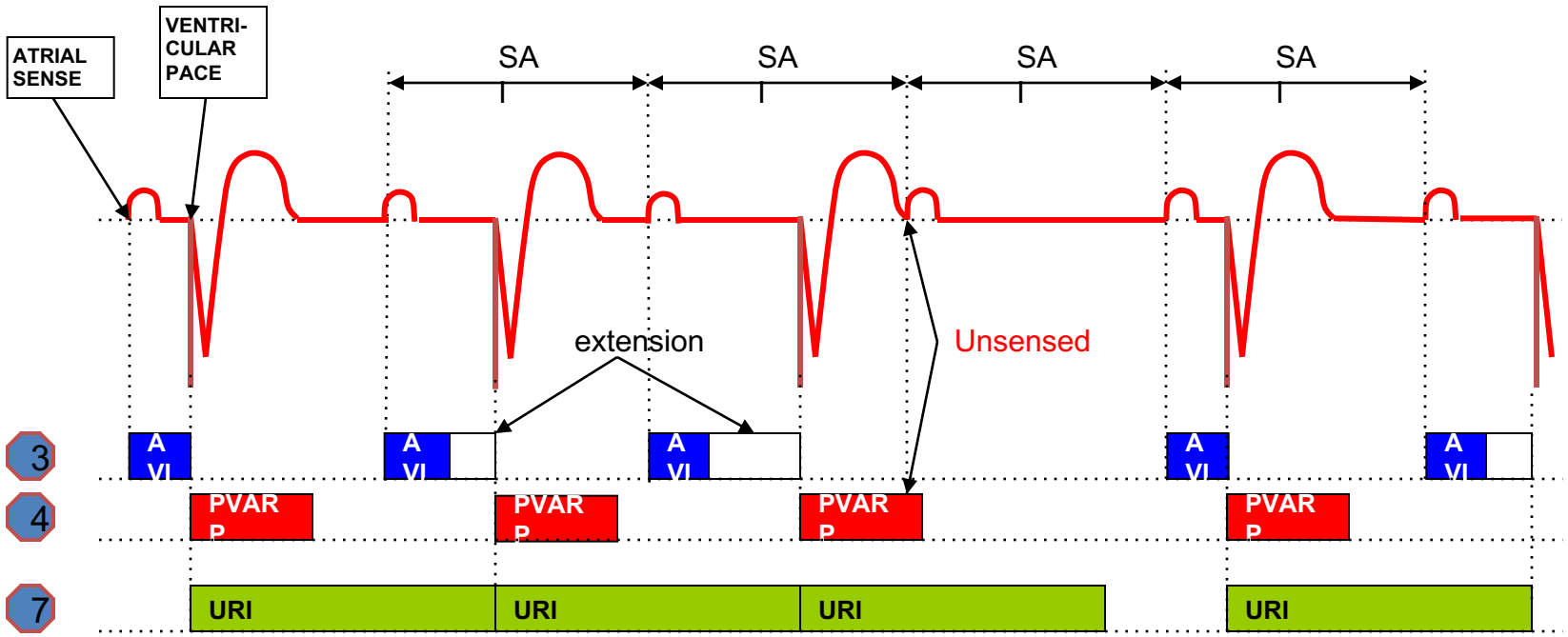


SAI = Spontaneous Atrial Interval

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.