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# Bluetooth portable medical application with high accuracy ADC

APAC RA



# Agenda

## ■ Overview

- Why Use Bluetooth in Portable Medical Devices?
- What Are Portable Medical Devices

## ■ Technical introduction

- How to Optimize Power Efficiency
- Increasing Accuracy of Portable Medical Devices
- IoT Security in Portable Medical Devices
- Typical Block Diagram
- CGM(continuous glucose monitors)

## ■ Demo

- Create from an SoC empty example
- Setup
- App Test
- How to do CGM service/profile qualification

# Overview



The enabling wireless devices and applications must feature

- robust IoT device security,
  - small form-factor, and
  - high energy-efficiency
- to enable accurate and safe operation with long life and low cost.

Bluetooth Low Energy (BLE) checks all the boxes, providing manufacturers and device makers with an optimal wireless solution.

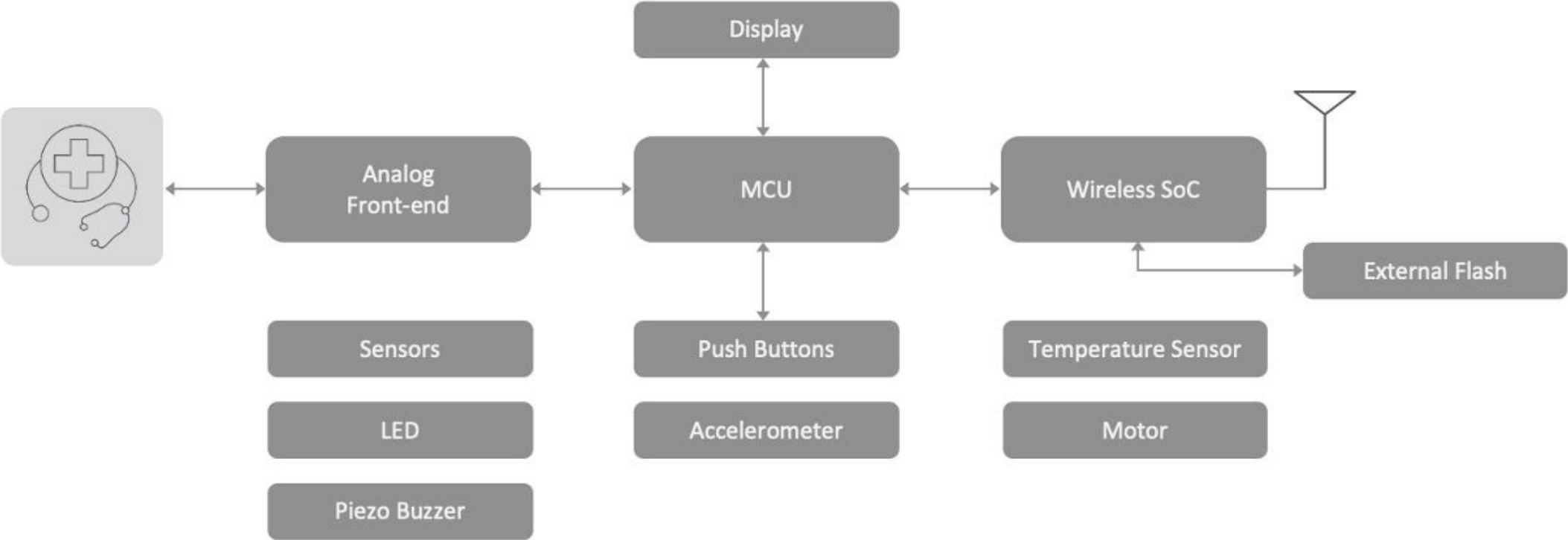
# Portable Medical Devices

- Portable medical devices monitor and track a patient's physiological conditions continuously.
- The collected health data can be viewed **remotely** on a smartphone app via a Bluetooth connection by a healthcare professional.
- The wireless connected portable and wearable medical devices are crucial in enabling outpatient ambulatory care services.
- Bluetooth Low Energy is the most deployed wireless connectivity technology for portable medical devices such as:
  - **BGM**(blood glucose meters),
  - **CGM**(continuous glucose monitors),
  - blood pressure monitors, pulse oximeters, insulin pumps, cardiac monitoring systems, and more.

# Design considerations

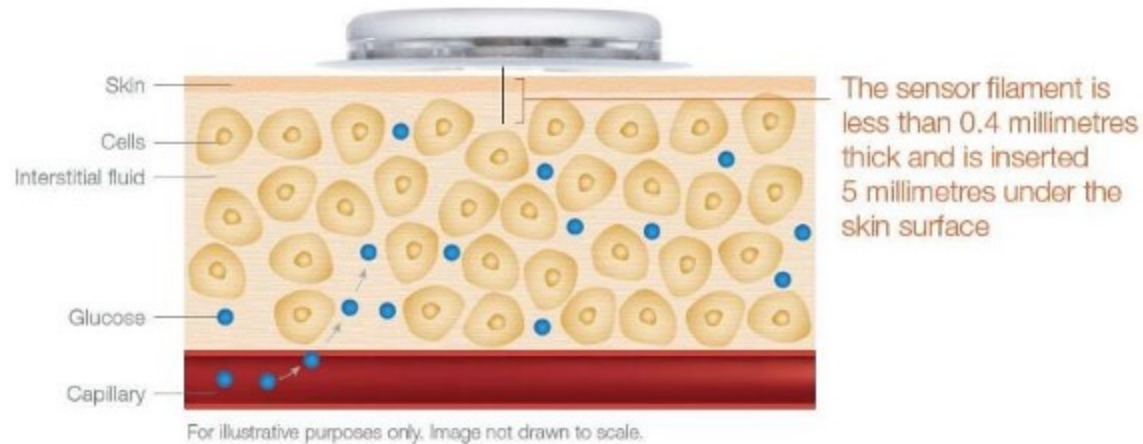
- How to Optimize Power Efficiency
- Increasing Accuracy of Portable Medical Devices
- IoT Security in Portable Medical Devices

# Typical Block Diagram



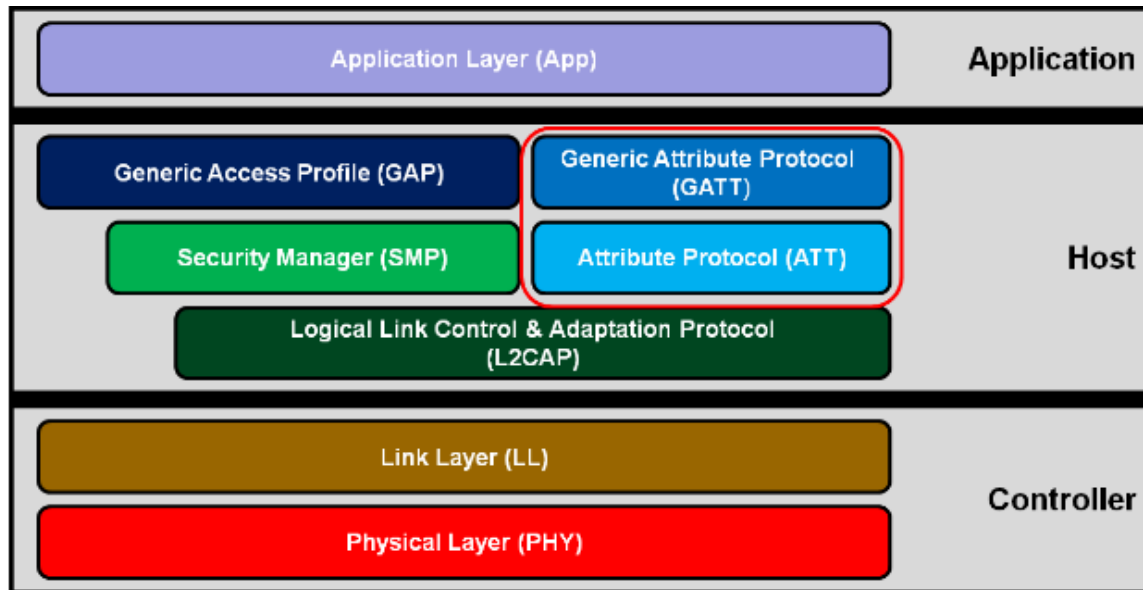


# CGM( continuous glucose monitors)

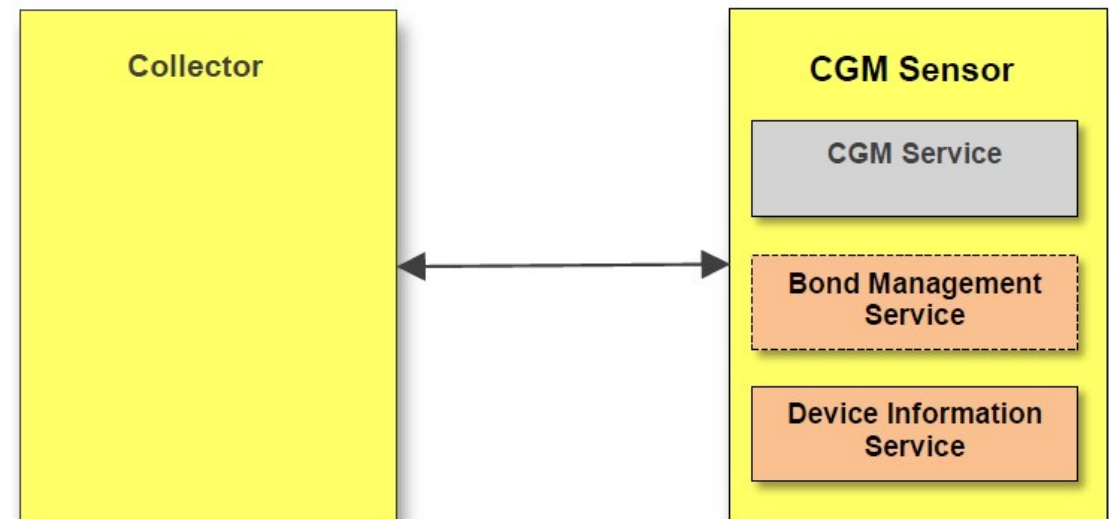


- A continuous glucose monitor (CGM) is a device used for monitoring blood glucose on a continual basis by insulin-requiring people with diabetes, e.g. people with type I, type II diabetes or other types of diabetes (e.g. gestational diabetes).
- Continuous Glucose Monitoring (CGM) systems continually check glucose levels throughout the day and night and can alert you through Bluetooth, if your glucose levels go too high or too low, the system will alert you.

# Bluetooth SIG CGM service/profile



- The CGM Sensor shall be a GATT Server.
- The CGM Collector shall be a GATT Client.





# How SIG CGM service work

- ▼ **[S]** Continuous Glucose Monitoring
  - ▶ **[C]** CGM Measurement
  - [C]** CGM Feature
  - [C]** CGM Status
  - [C]** CGM Session Start Time
  - [C]** CGM Session Run Time
  - ▶ **[C]** Record Access Control Point
  - ▶ **[C]** CGM Specific Ops Control Point

- CGM collector connect to the CGM sensor
- Collector set Notify of CGM Measurement characteristic
- Collector set indicate of CGM Specific Ops Control Point characteristic
- Collector start the session
- Sensor will continuously send notifications to collector
- Collector may stop the session

# Demo



## ■ Hardware

- xG24 explorer kit
- USB wire

## ■ Software

- Simplicity studio
- Serial Debug Tool
- Bootloader.s37
- CGM.s37

# Bluetooth Qualification

- **ALL Bluetooth® Products Must Be Qualified**
- **Completing the Bluetooth Qualification Process**
  - Qualification Process with [No Required Testing](#)
  - Qualification Process with [Required Testing](#)

# Bluetooth Qualification

- RF-PHY
- Link layer
- Host layer
- Profile









# Bluetooth Qualification

- **Silicon Labs has pre-qualified listings for all components**
  - Software-based BLE components (Link Layer and Host) QDIDs can be found in QSG169.

| Bluetooth SDK version | Component                  | QDID  |
|-----------------------|----------------------------|---|
| v2.13.x up to v3.1.x  | Link Layer (Bluetooth 5.2) | Launch Studio Listing Details: <a href="#">147971</a> |
| “                     | Host stack (Bluetooth 5.2) | Launch Studio Listing Details: <a href="#">146950</a> |
| V3.2.x and above      | Link Layer (Bluetooth 5.3) | Launch Studio Listing Details: <a href="#">178212</a> |
| “                     | Host stack (Bluetooth 5.3) | Launch Studio Listing Details: <a href="#">175341</a> |

# Profile Qualification

## Steps

-  Basic Project Information
-  List Project Features (Layers)
-  Select Implementation Conformance Statements (ICS)
-  Generate Test Plan
-  Upload Test Documentation
-  List Products
-  Pay Declaration Fee
-  Declare & Submit

- Use the Bluetooth Qualification tool [Launch Studio](#) to complete the Bluetooth Qualification Process.
- Follow the instruction and complete the Bluetooth Qualification

## Automate protocol and profile interoperability testing.

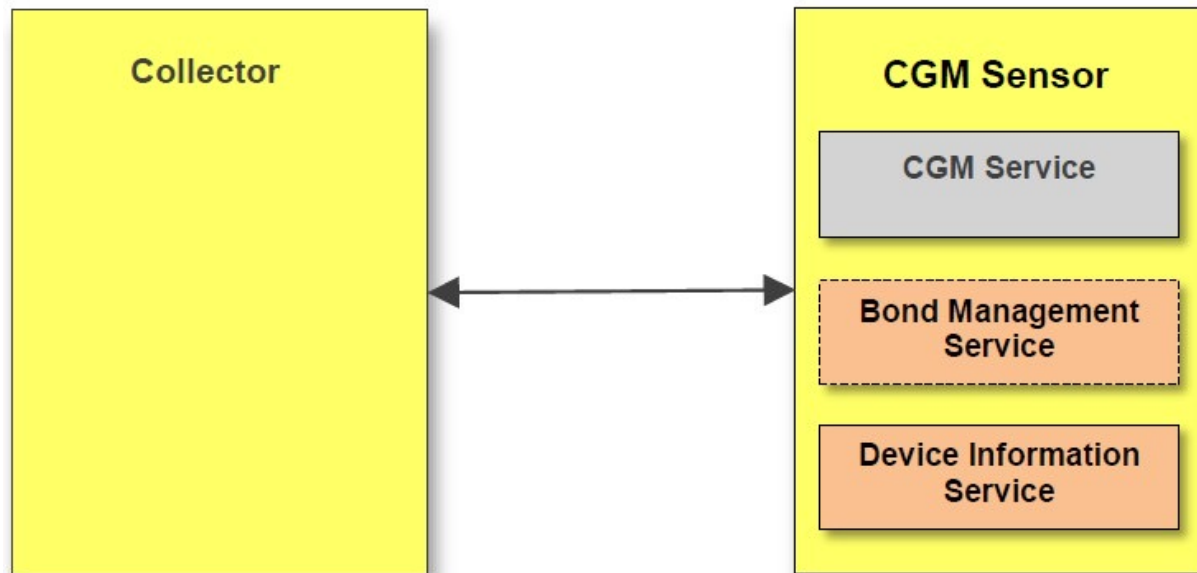
The *Bluetooth*® Profile Tuning Suite (PTS) is testing software that automates compliance testing to the specified functional requirements of Bluetooth Host Parts and specifications that reside above the Host Controller Interface (HCI). The vision of the product is to provide complete and validated test coverage, of all specified functional requirements in scope, to the Bluetooth development and testing community.

- **Software: PTS**
- **Hardware: [PTS dongle](#)( [Dongle Firmware Upgrade Software](#))**





- The test diagram block and environment is as below



## ■ The whole picture of PTS is as below

The screenshot displays the Profile Tuning Suite (PTS) software interface. The main workspace shows the Bluetooth logo and the title 'Profile Tuning Suite (PTS)'. It includes a 'Release Statement PTS v8.1.0' section with a notice about updates to PTS 8.0.0 and 8.0.1. The 'New Features & Support' section lists updates to TCRL 2021-1, bug fixes, and a completed overhaul of the GAP test cases. The 'Areas of Maintenance & Bug Fixes' section lists supported protocols and modules. The 'Upcoming Release(s)' section mentions planned updates for 2021. The right-hand side features a table of test cases with columns for Name, Description, and True/False status. The bottom of the interface shows the 'Test Case History Tool Window - CGMS' with a table of test cases, including their dates, verdicts, and debug status.

**Release Statement PTS v8.1.0**

**Notice:**

Starting with PTS 8.0.0, the manual step of selecting and connecting to one of the available radio modules will be required before executing PTS test cases (See PTS Help, Section "Connecting a Dongle").

In addition, updates to PTS Automation API clients will be necessary (See corresponding PTS Sample Code and Documentation).

To enable utilization of Extended Advertising feature, PTS 8.0.0 introduced support for a new Bluetooth Low Energy radio module (Laird Connectivity, part number 451-00004). Starting with PTS 8.0.1, the protocol viewer will no longer be included in the PTS installation package. The protocol viewer can be downloaded separately from the PTS installer (See PTS/PV Download Page)

**New Features & Support:**

1. TCRL 2021-1 Support
2. Bug fixes
3. Completed overhaul of the GAP test cases to improve flow control and maintainability. Please see release notes for details.

**Areas of Maintenance & Bug Fixes:**

- **BR:** A2DP, AVCTP, AVDTP, BIP, FTP, HDP, HFP, HID11, IOPT, MAP, MPS, OPP, PBAP, SAP, SYNC
- **LE:** CCP, CGMP, CGMS, CPP, CPS, CSIS, CTS, GLP, HOGP, HPS, MCP, PLXS, PXP, TDS, UDS
- **Mesh:** MESH, MMDL
- **Core:** GAP, GATT, GAVDP, L2CAP
- **Protocol:** SM

**Upcoming Release(s):**

The following are planned for the upcoming release(s) in 2021:

| Name           | Description                                  | True/False                          |
|----------------|--|-------------------------------------|
| TSPC_CGMS_5_7  | Within range of (inclusive) Operator - Time  | <input type="checkbox"/>            |
| TSPC_CGMS_5_8  | First record Operator (O)                    | <input type="checkbox"/>            |
| TSPC_CGMS_5_9  | Last record Operator (O)                     | <input type="checkbox"/>            |
| TSPC_CGMS_6_1  | Null Operator (M)                            | <input checked="" type="checkbox"/> |
| TSPC_CGMS_7_1  | All Records Operator (M)                     | <input checked="" type="checkbox"/> |
| TSPC_CGMS_7_2  | Less than or equal to Operator (O)           | <input type="checkbox"/>            |
| TSPC_CGMS_7_3  | Less than or equal to Operator - Time Offset | <input type="checkbox"/>            |
| TSPC_CGMS_7_4  | Greater than or equal to Operator (M)        | <input checked="" type="checkbox"/> |
| TSPC_CGMS_7_5  | Greater than or equal to Operator - Time C   | <input checked="" type="checkbox"/> |
| TSPC_CGMS_7_6  | Within range of (inclusive) Operator (O)     | <input type="checkbox"/>            |
| TSPC_CGMS_7_7  | Within range of (inclusive) Operator - Time  | <input type="checkbox"/>            |
| TSPC_CGMS_7_8  | First record Operator (O)                    | <input type="checkbox"/>            |
| TSPC_CGMS_7_9  | Last record Operator (O)                     | <input type="checkbox"/>            |
| TSPC_CGMS_8_1  | Null Operator (M)                            | <input checked="" type="checkbox"/> |
| TSPC_CGMS_9_1  | Null Operator (M)                            | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_1 | Generic Attribute Profile Server (GATT) (M)  | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_2 | Attribute Protocol Supported over BR/EDR     | <input type="checkbox"/>            |
| TSPC_CGMS_10_3 | Attribute Protocol Supported over LE (C1)    | <input type="checkbox"/>            |
| TSPC_CGMS_10_4 | Read Characteristic Value (M)                | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_5 | Write Characteristic Values (M)              | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_6 | Notifications (M)                            | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_7 | Indications (M)                              | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_8 | Read Characteristic Descriptors (M)          | <input checked="" type="checkbox"/> |
| TSPC_CGMS_10_9 | Write Characteristic Descriptors (M)         | <input checked="" type="checkbox"/> |
| TSPC_CGMS_11_1 | Support for Server Role (M)                  | <input checked="" type="checkbox"/> |
| TSPC_CGMS_11_2 | Protocol Descriptor List (M)                 | <input checked="" type="checkbox"/> |
| TSPC_CGMS_11_3 | Browse Group List (M)                        | <input checked="" type="checkbox"/> |
| TSPC_ALL       | Turns on all the test cases                  | <input checked="" type="checkbox"/> |

| Testcase             | Imported Testcase | Date                  | Verdict | Debug |
|----------------------|-------------------|-----------------------|---------|-------|
| CGMS/SEN/RAR/BV-01-C |                   | 10/13/2021 4:30:02 PM | PASS    | False |
| CGMS/SEN/RAR/BV-01-C |                   | 10/13/2021 4:19:24 PM | FAIL    | False |


# Launch Studio-Test Documentation

## Test Documentation

- After finishing the PTS test, back to the Launch Studio project

|                 |                |                 |        |                        |            |
|-----------------|----------------|-----------------|--------|------------------------|------------|
| Getting Started | Draft Projects | Manage Listings | Search | Manage Declaration IDs | References |
|-----------------|----------------|-----------------|--------|------------------------|------------|

## Draft Projects

 Import From File

[File a Test Specification Errata \(TSE\)](#) | [Browse Test Case Waivers \(TCW\)](#)

| Project Name               | Declaration ID | Project Type                        | Alerts | Date Created |                                   |
|----------------------------|----------------|-------------------------------------|--------|--------------|-----------------------------------|
| <a href="#">silabs-CGM</a> |                | Qualification with Required Testing |        | 2021-11-09   | <a href="#">Project Actions</a> ▼ |

as well as any test evidence/reports as required by the PRD.

## Test Evidence

| Report Name                            |
|--|
| TP_20211109-0406493484 (1) (2) (3) (4) |
| TestReport_CGMS_2021_11_16_14_20_23    |
| Report_CGMS_2021_11_16_14_20_23        |
| Report_CGMP_2021_11_16_14_20_39        |

[+ Add Test Evidence](#) [Download All Evidence](#)

Thank you!

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