

W

BT-205

# Designing Medical Devices With the BG27

Nicola Wrachien | August 2023



# Agenda

- 01 Introduction: Portable Medical Devices
- 02 BG27 CGM Ref Design: Features
- 03 Hardware
- 04 Firmware
- 05 Mobile App
- 06 Conclusions

A large, bold, blue lowercase letter 'w' is positioned on the left side of the slide. It is partially overlaid by a thick, blue diagonal line that runs from the top left towards the bottom right. The background features several parallel, semi-transparent blue diagonal lines that create a sense of depth and movement.

# Portable Medical Devices

Market opportunities, advantages

# Introduction – Portable Medical Devices



## Non-disposable

- ECG, EEG
- Thermometers
- Wearable devices



## Disposable

- Fluid test
- CGM

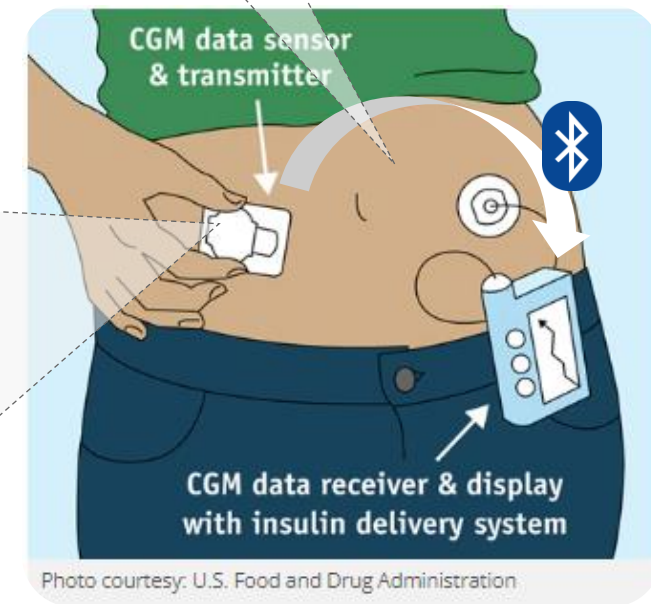
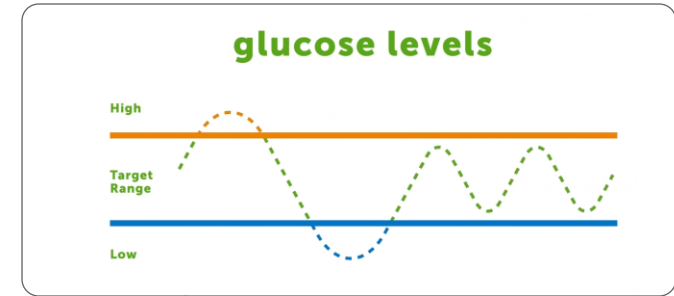
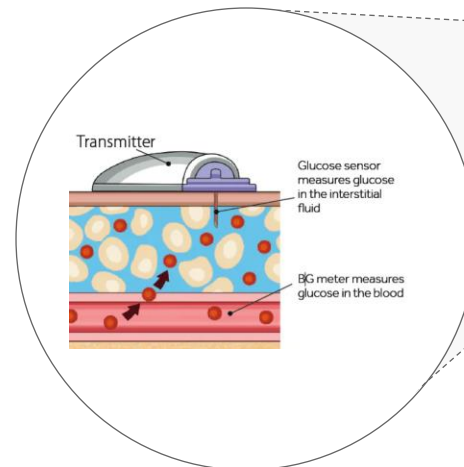
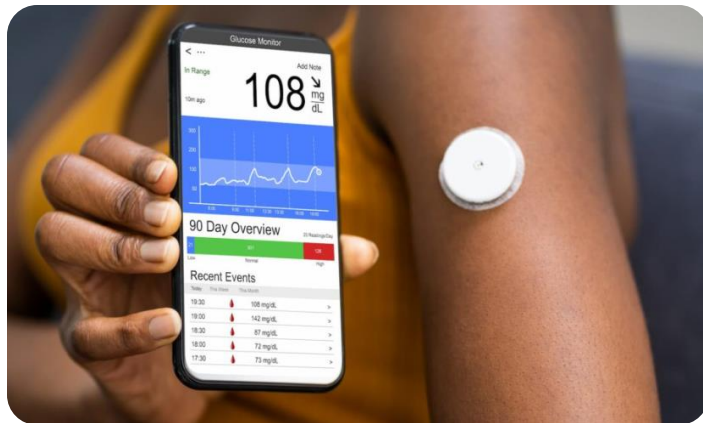
PRECEDENCE  
RESEARCH

PORTABLE MEDICAL DEVICES MARKET SIZE, 2020 TO 2027 (USD BILLION)



# Continuous Glucose Monitoring

- Small form factor wearable medical device
- Button cell battery
- BLE based
  - Low power devices.
  - Allow using smartphones.
  - Good security and privacy
- Disposable



# Advantages and Challenges

## ADVANTAGES



### Better Comfort

No wires  
Less finger sticks  
No hospitalization



### Better Disease Control

Continuous monitoring  
Early feedback  
Proactive rather than reactive management



### Less prone to human error

Automatic feedback  
Less anxiety  
AI/ML

## CHALLENGES



### Cost Effectiveness

BOM Cost  
Lifetime



### Low Power

Shelf lifetime  
Active mode



### Security & Privacy

End user  
IP protection

A large, bold, blue lowercase letter 'w' is positioned on the left side of the slide. It is partially overlaid by a thick blue diagonal line that runs from the top left towards the bottom right. The background features several parallel, semi-transparent blue diagonal lines that create a sense of depth and movement.

# The BG27 Reference design

Features

# The BG27 CGM Reference Design

- Complete design from schematics and layout, up to the mobile application
  - Hardware:
    - Analog front-end included
    - Ultra low current shelf mode support
    - Optimized BOM count
    - Contact-less, ultra low power, non NFC based wake up (patent pending)
    - Tamper detection
    - Runs from a single cell ZnO or Alkaline battery
  - Firmware:
    - Full BLE CGM Profile implementation
    - Support for low power modes
    - Can safely store data for the whole battery duration
    - Tamper detection will flash LED, delete bonding and erase data encryption keys. Additional functionalities can be added.
    - Security
    - Privacy mode
  - Mobile Application
    - Support up to latest Android release (iOS under development)
    - Shows collected data chart, retrieves history on disconnection, set alerts
    - Uses QR code to connect to the device.



# The BG27 CGM Reference Design

Based on EFRBG27 device

- Cortex M33 @ 76.8 MHz
- 768 kB flash (application, OTA downloaded image, data)
- 64 kB RAM
- ADC, with internal temperature sensor
- Mid Level security option
  - Hardware crypto accelerator
  - TRNG
  - DPA countermeasures
  - Anti Tamper
  - Secure key management
  - Secure Boot with RTSL
- Very low current
- Integrated DC/DC boost converter, allows down to 0.8V battery operation

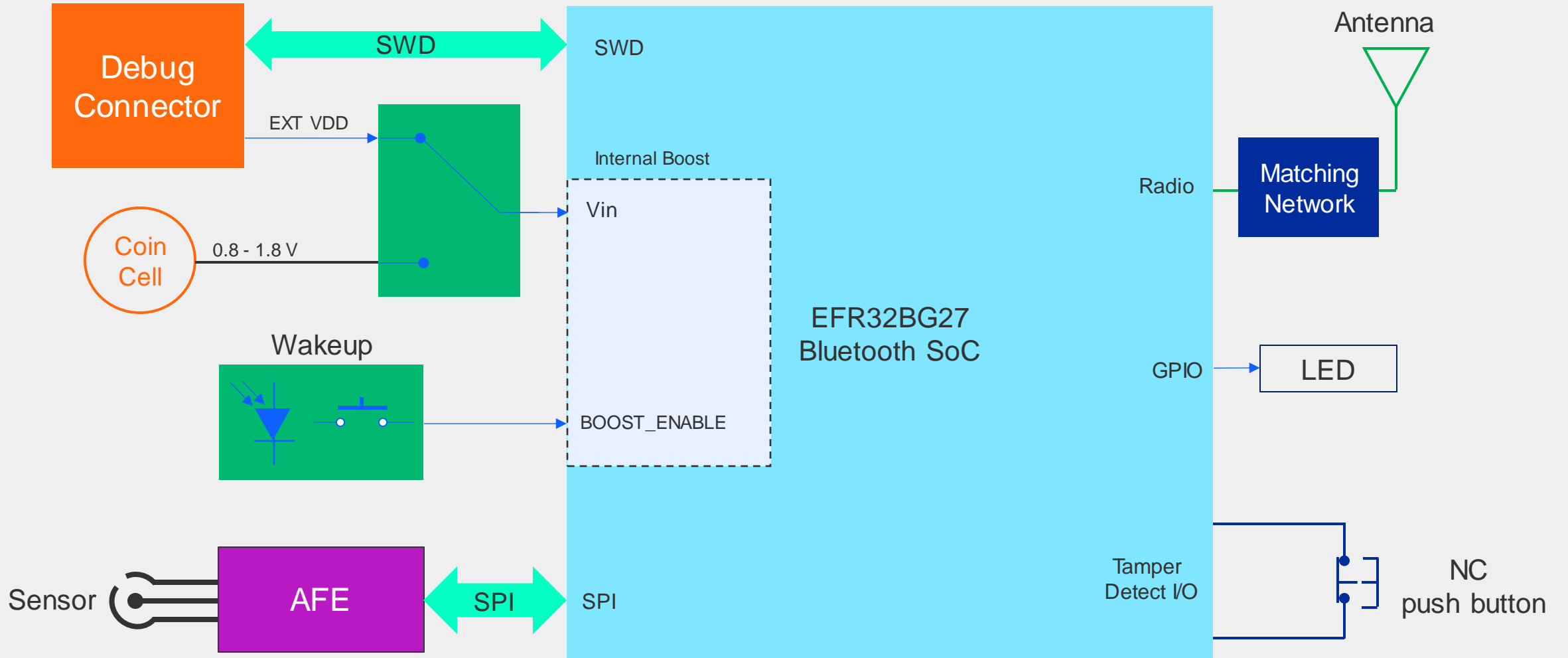


w

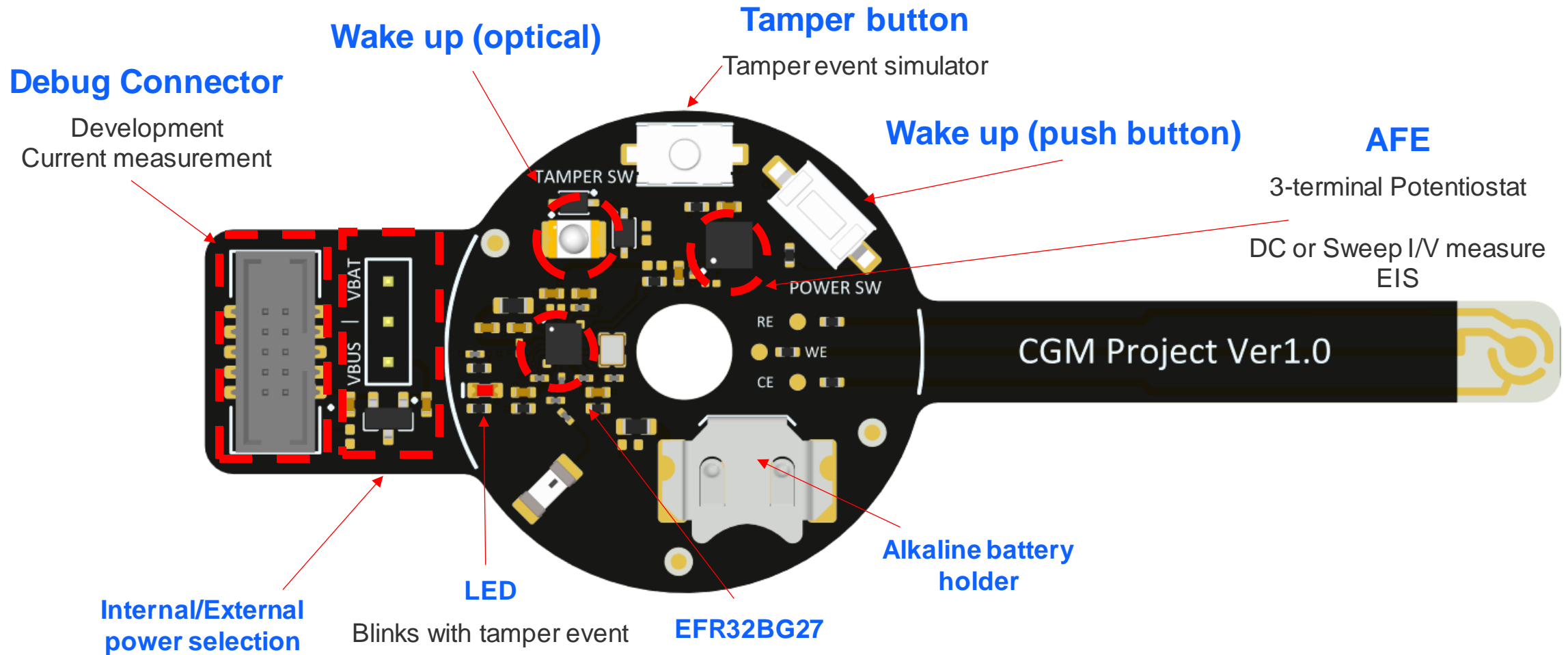
# The BG27 Reference design

Hardware

# Block Diagram

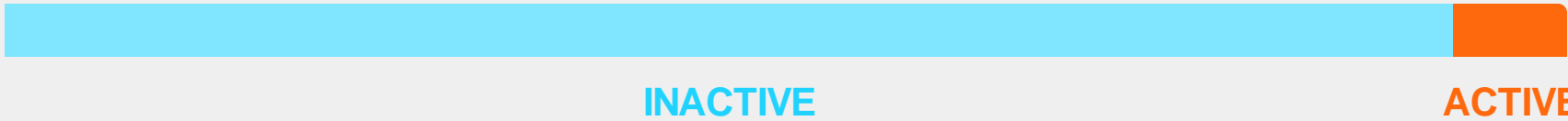


# Layout and Functionality

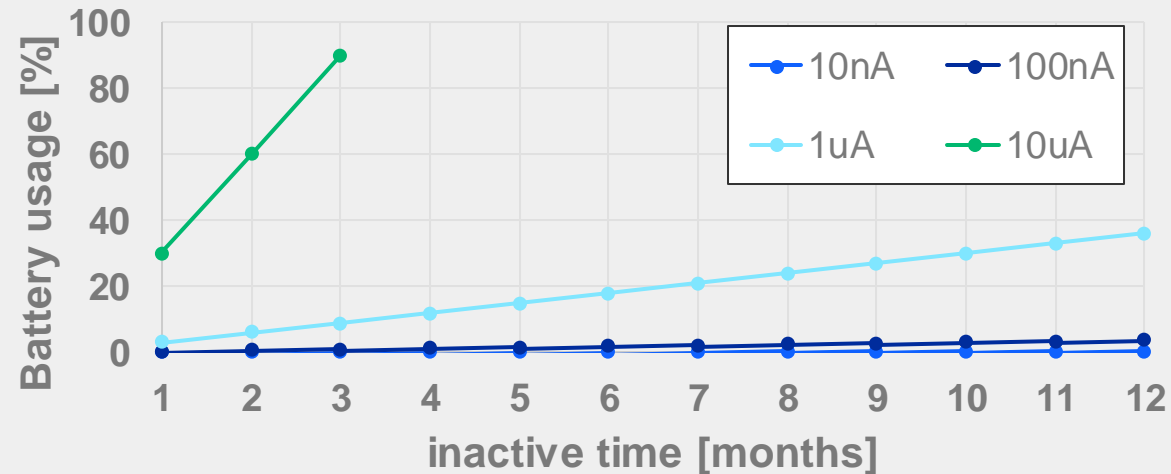


# Shelf Mode Support

Devices are typically sold and used many months after manufacturing



SR66 6.8 x 2.6 mm  
24 mAh



# Shelf mode Support

## Software based shelf mode

- Increasing Advertising Interval
- Going to deepest power down mode between intervals



Suboptimal power saving  
Bad user experience (long time to find the CGM)

## Hardware assisted shelf mode

- External pin to enable the internal BOOST mode
- Can be activated using either a mechanical push button or an external source
  - NFC
  - Magnetic switch
  - Light



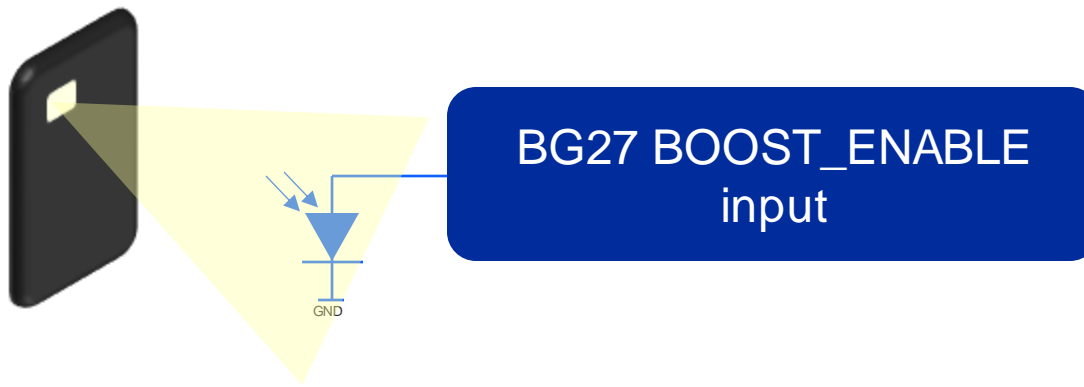
Best shelf life  
Immediate bring-up

# Shelf Mode: Silabs Solution

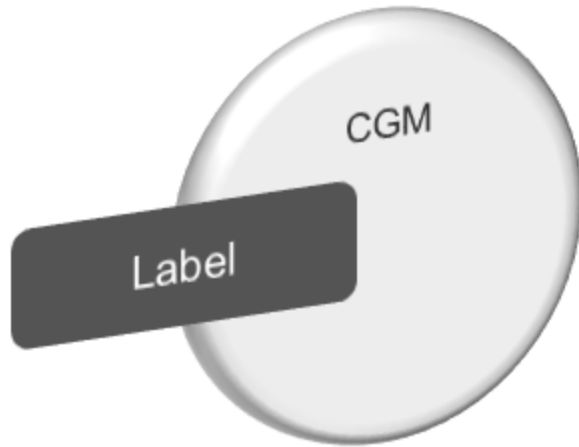
- NFC is still not supported by all new phone models
  - Limits number of customers
  - Requires external NFC support
- Mechanical switch adds complexity to case
  - The case must be bendable, but robust enough to protect circuitry
- Light is available on all the phones (flashlight)



Strong light  
will produce a voltage  
on photovoltaic device  
(high logic level  
on BOOST enable)

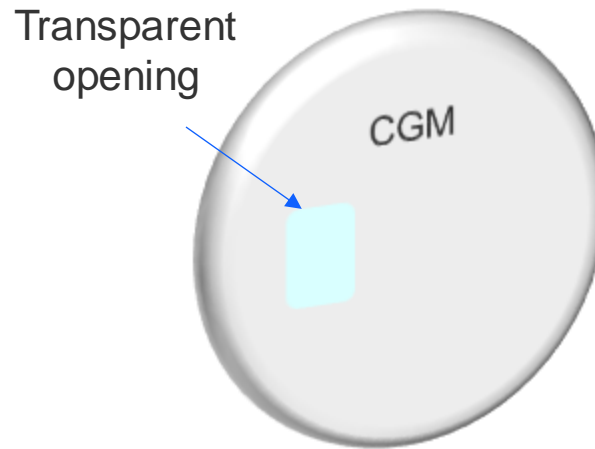


# Shelf Mode: Silabs Solution



## SHELF MODE

An opaque label covers a transparent opening, which is on top of the photovoltaic device to prevent accidental activation.



## UNBOXING

The user removes the label to expose the transparent opening



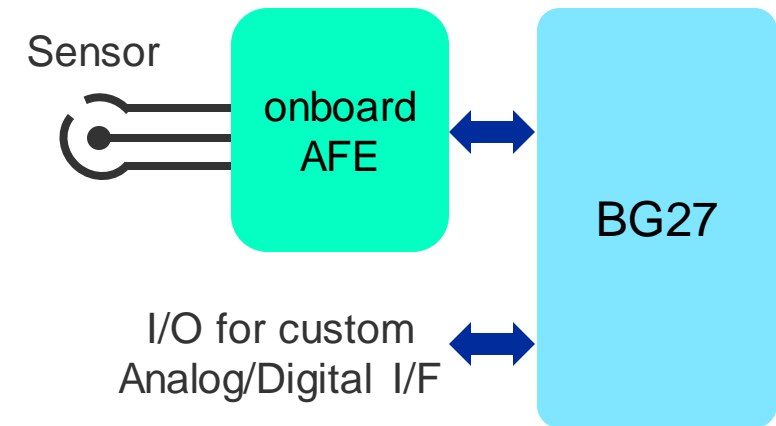
## ACTIVATION

Phone flashlight will bring the device to active mode  
The device starts advertising.  
Go back in shelf mode after timeout.



# AFE and connectivity

- Off-the shelf AFE (MAX30131)
  - From simple DC potentiostat measurement...
  - ... up to advanced Electrochemical Impedance Spectroscopy analysis
- I/O routed to test points, customer can connect its own AFE solution
  - Other brands AFEs
  - Discrete based
  - ASIC
- Internal BG27 temperature sensor
- Battery voltage monitor (internal to BG27)
- Debug connector also allows to measure current consumption using a Wireless STK



# Reduced BOM

- BOM will impact on the device cost...
- ... and performance
  
- We have optimized the BOM for the best tradeoff in terms of:
  - Power consumption
  - Sensitivity
  - Harmonic emission
  
- The reference design has many optional placeholder where additional components (e.g. bypass capacitors) can be put.
  
- Less than 10 components are required! \*

\* Not including AFE and battery.

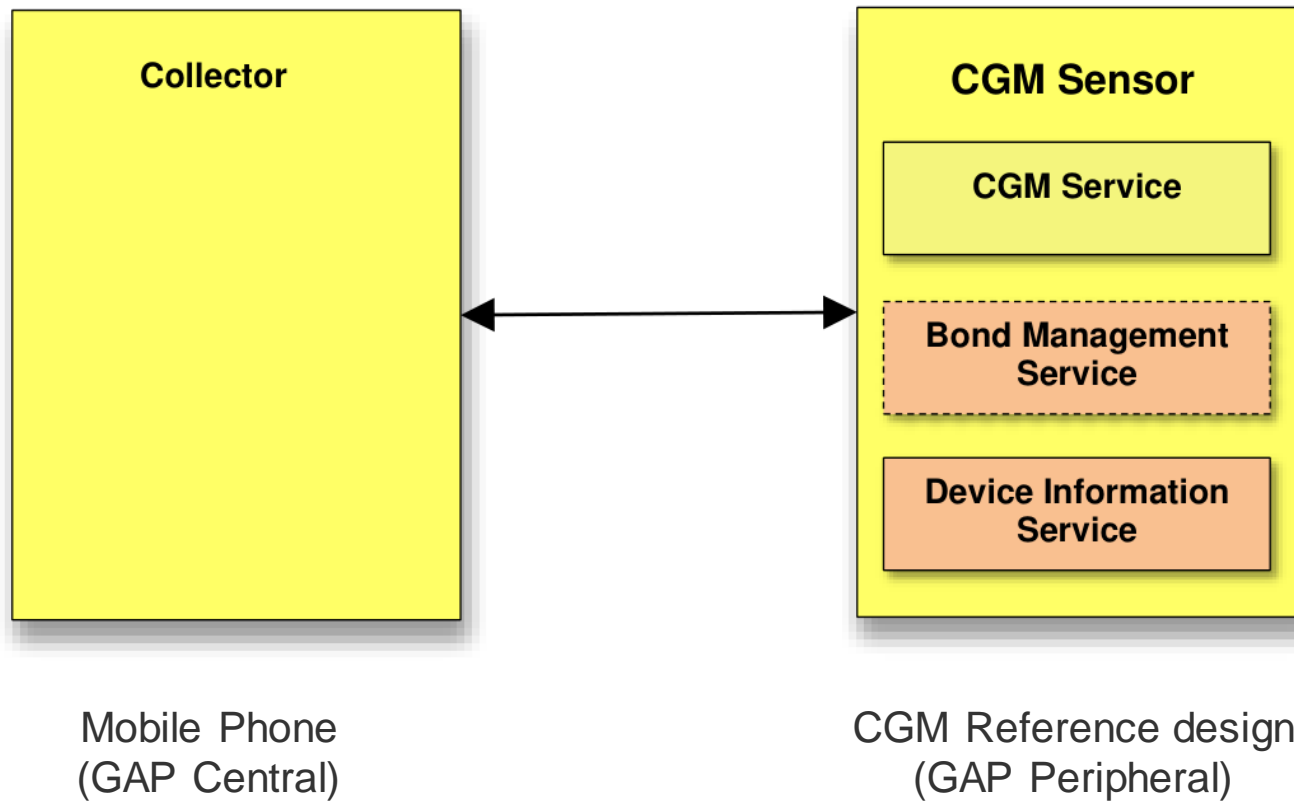
A large, bold, blue lowercase letter 'w' is positioned on the left side of the slide. It is partially overlaid by a thick, blue diagonal line that runs from the top left towards the bottom right. The background features several parallel, semi-transparent blue diagonal lines that create a sense of depth and movement.

# The BG27 Reference design

Firmware

# BLE CGM Profile

- The device fully supports the Continuous Glucose Monitoring Profile V1.0.2, in Low Energy mode.



# BLE CGM Profile - Connection

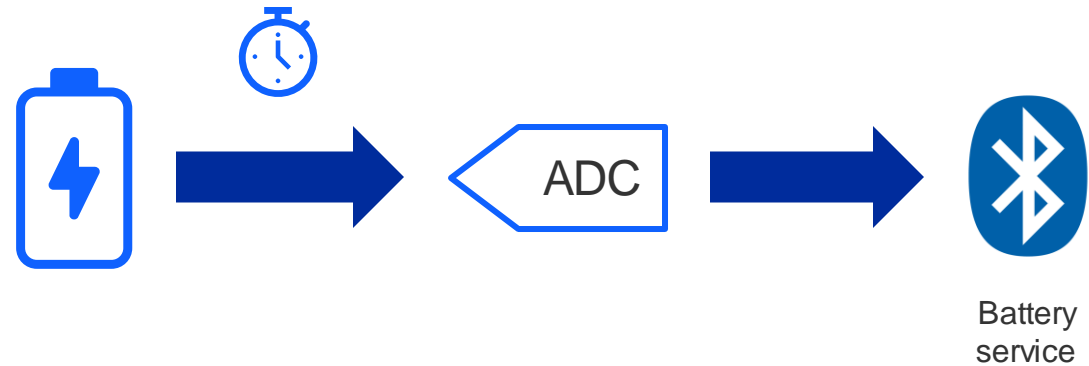
- Advertising when not bonded:
  - Connectable, scannable, undirected
    - Fast (first 30 seconds): 300 ms (30 ms to 300 ms recommended)
    - Slow (after 30 seconds, before going back to shelf mode): 1 s (1 s to 10.24 s recommended)
  
- Advertising when bonded (connection lost):
  - Connectable, scannable, undirected
  - Fast: (first 30 seconds): 0.3 s
  - Slow (after 30 seconds): 3 s
  
- Connection interval:
  - 1 s, peripheral latency 1
  - Good tradeoff between user experience and battery consumption in active mode
  - Can be easily modified in the firmware source code

# BLE CGM Profile - Data recording

- The device records and forwards data every minute, through notification.
- Data read out follows the BLE CGM Profile.
- Interval can be increased on user input from the application.
- Data is also stored in a RAM buffer, so it can be retrieved in case of connection lost, by the application using Record Access Control Point (RACP) characteristics, through indication.
- Optionally, when RAM buffer is full, older data can be stored in flash
  - For privacy mode data is stored encrypted
  - Encryption key is in RAM. It's erased in case of battery removal / exhausted, if the device is disposed, or in case of tamper event

# BLE Battery Service

- BG27 monitors battery voltage through the ADC.
- No need of external hardware/connections.
- Measurement is done periodically e.g. once per hour.
- Exposes it as percentage, using BLE battery service
- This allows to notify the application when the CGM is about to stop working.



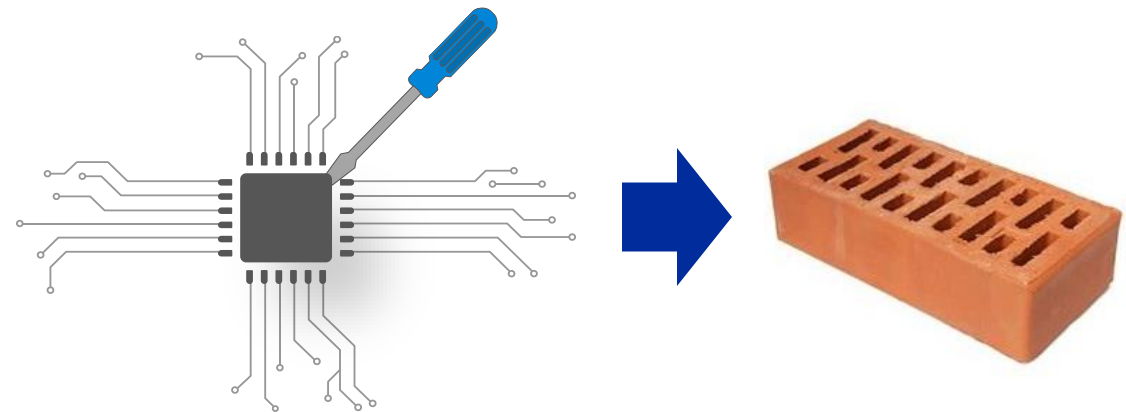
# BLE Over The Air Update

- Excellent firmware brings added value to the product
  - Bad firmware affects the user experience and negatively impact on company reputation.
  - Updates might still be required to fix issues or improve user experience when the device is on the field
  - → OTA images can be easily achieved
- Firmware development is a huge investment
  - Need protection to protect investment
- Firmware authenticity and integrity check is desired
  - And might become mandatory in some countries in the future.
- Silabs BG27 CGM reference design supports:
  - OTA update
  - Encrypted images
  - Signature check before update and before each boot (using Secure Boot with RTSL)



# Tamper Detection

- Simulated by a normally closed push button connecting two GPIOs
  - A random sequence is sent from the input to the output, to prevent easy workaround.
- A call back function is called:
  - Flash the on-board LED to notify the developer.
  - Erases BLE bonding information.
  - Generates a new encryption key for data in flash. Old data is unusable to protect privacy.
- Additional features offered by tamper detection
  - Ignore
  - Reset
  - Increment Counter
  - Brick device



# Security and Privacy

## ■ Security

- Firmware always checked with a one-time programmable sign key
  - Accidental or intentional corruption prevented
- Updates are encrypted (code confidentiality) and signed.
- BLE connection with Security Mode 1 level 3
- Certificate Based Authentication and Pairing can be added for increased security

## ■ Privacy

- Device uses private resolvable random address to prevent traceability
  
- Collected data destroyed on:
  - Tamper
  - Loss of power
  - Device deactivation

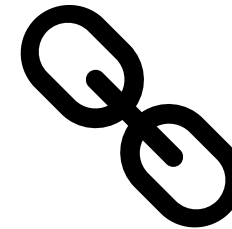
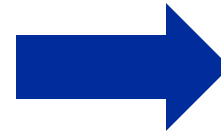
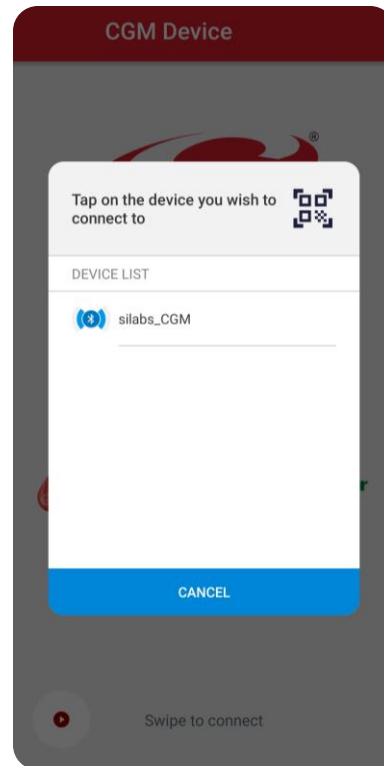
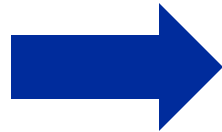
A large, bold, blue lowercase letter 'w' is positioned on the left side of the slide. It is partially overlaid by a thick blue diagonal line that runs from the top left towards the bottom right. The background features several parallel, semi-transparent blue diagonal lines that create a sense of depth and movement.

# The BG27 Reference design

Mobile Application

# Pairing through QR Code

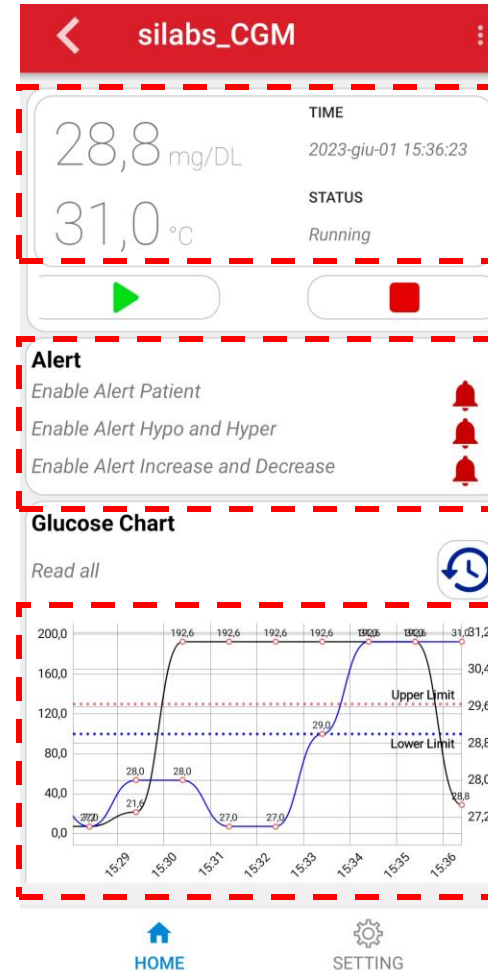
- The application assumes that a device-unique QR code is available
- Other mechanisms can be used with cloud support, e.g. CBAP, to improve security.



Connected

# GUI – Main screen

Current value and status



Session start/stop

active notifications

Get history data

## Chart

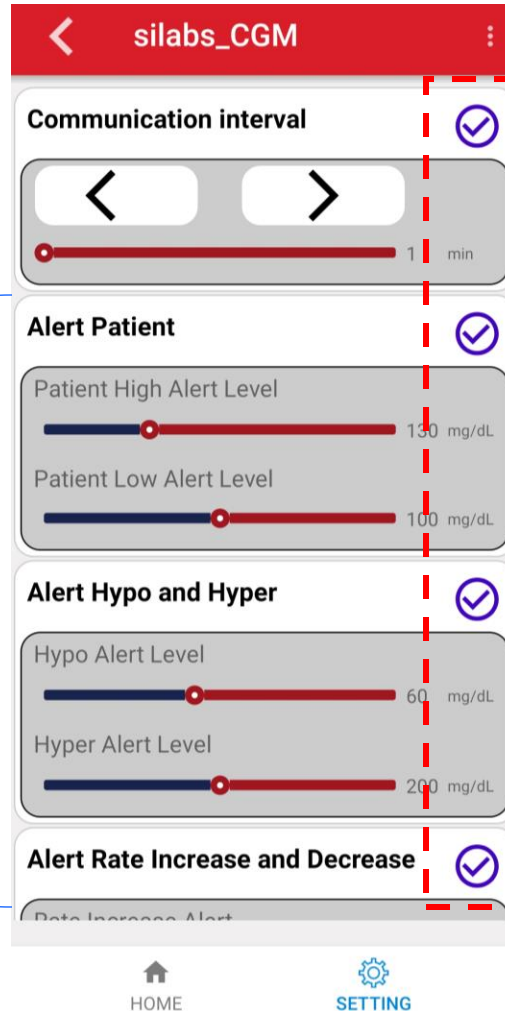
- The chart is automatically updated when new data arrives.
- The user can zoom in/out and see the history
- Warning levels are indicated on the chart

# Settings

Connection interval 1 – 30 mins

Min-Max Alerts levels

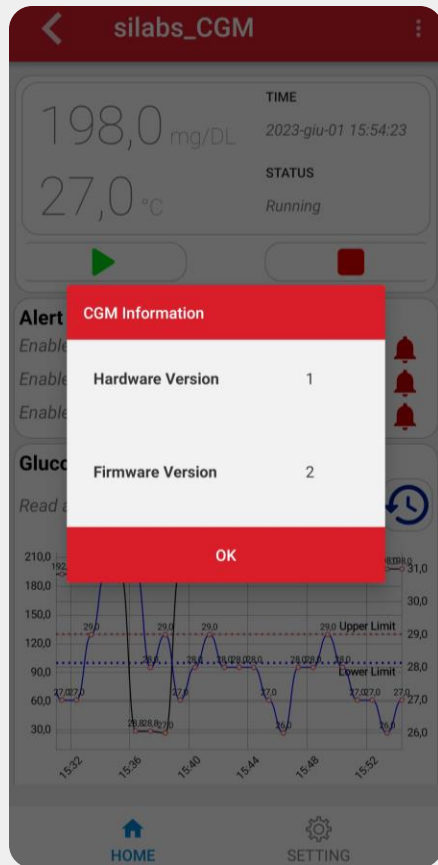
- Instantaneous value
- Rate of variation



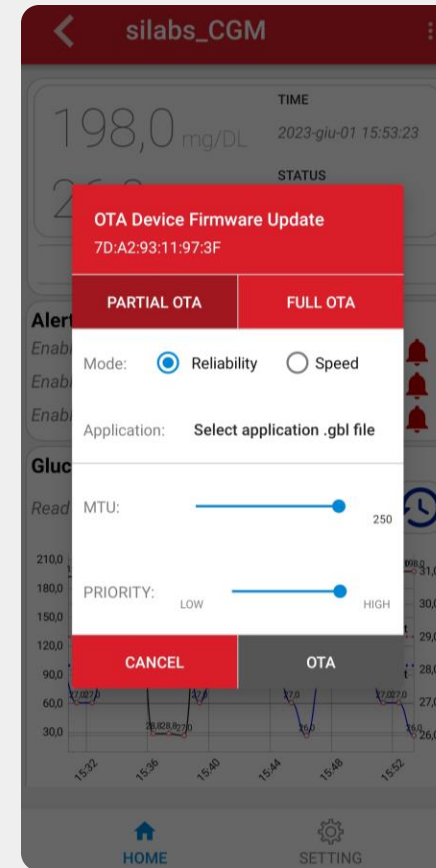
Enable/disable

# OTA Update

- Device firmware/hardware versions are reported to the application.



- Firmware update can be done via app.



A large, bold, blue lowercase letter 'w' is positioned on the left side of the slide. It is partially overlaid by a thick blue diagonal line that runs from the top left towards the bottom right. The background of the slide features several parallel diagonal lines in various shades of blue, creating a sense of depth and movement.

# Conclusions



# Conclusions

- The Continuous Glucose Monitor Reference Design is a complete solution.
  - From Schematics, up to the mobile app
  - From Analog Front End up to the Wireless communication SoC
- Focus on
  - Low power
    - Shelf mode with pushbutton or optical activation.
    - Many years of shelf mode, many weeks in active mode.
  - Privacy and Security
  - Cost, customization, evaluation and development
    - Reduced number of external components
    - Placeholder for additional components available
    - Testpoints
    - Debug port
    - Easy current measurement using WSTK board
  - Tamper detection and IP protection
    - Secure Boot