SPMHBGW1

Body Gateway Electronic patch

Features

- Single Lead AFE for ECG with self calibration circuitry
- Bio-impedance
- STM32F M3 Cortex ARM cortex
- BT radio class 2: STLC 2584
- Digital 3 axis Accelerometer: LIS 331 DLH
- External parallel NAND FLASH 2Gbit
- Battery Level sensing
- Rechargeable battery LiPo 380 mAh
- 3 LEDs
- Mechanical ON/OFF button

Functions

- Heart rate detection
- One lead ECG recording and transmission
- Physical activity estimation
- Breathing rate measurement
- Body position detection

Applications

- Elderly people home monitoring
- Chronic cardiac disease monitoring
- Event monitoring
- Single lead holter

Contents

RoHS compliance

ST modules are RoHS compliant and comply with ECOPACK® norms.

1   Body Gateway device description

The Body Gateway (BGW) Devices is a wearable electronic, battery operated device that is worn on the chest for the acquisition, recording and transmission of physiological parameters to external devices which can analyze or forward the data to additional storage elements or system.

The BGW device is also capable to record symptomatic and asymptomatic events and is indicated for ambulatory monitoring of non lethal cardiac arrhythmias.

Additionally, resident in the Body Gateway device is a heart rate, respiration rate and activity level calculation algorithm, which allows the system to manage information messages from/to the Server according to specific settings defined by the physicians/operators.

The device is a part of a Multi-parameter Analysis System, Body Gateway System (BGW system) and communicates via a BT radio link with the external device. Specification of BGW System is beyond the scope of this document.

At its heart is a 32-bit ARM Cortex microcontroller with 768 kByte Flash, chosen for its flexible architecture and low power processing capability. Bluetooth radio was selected for connectivity because its availability in most commercial mobile phones ensures proper coverage and patient access.

2 Body Gateway device architecture

2.1 Hardware:

The hardware architecture for the BGW device is shown here below.
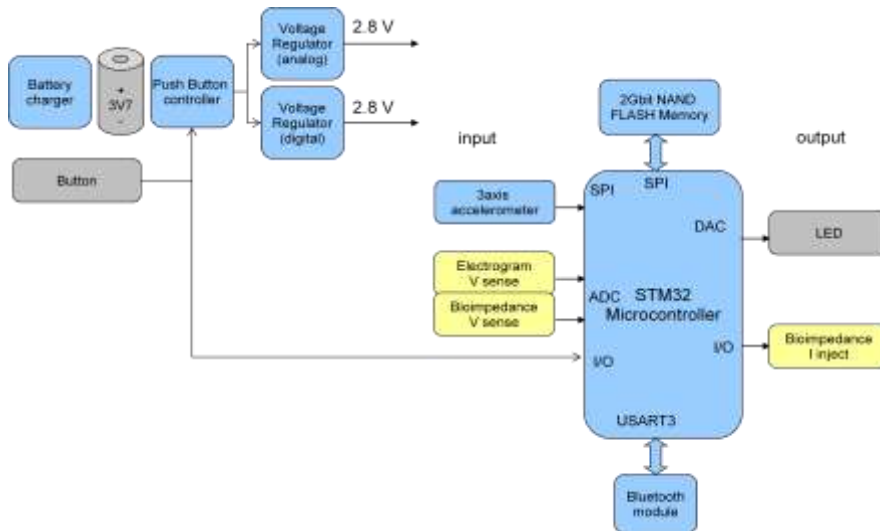
2.2 Embedded SW Framework:

The embedded SW Frameworks includes a RT OS, board support package, proprietary data aggregation algorithms, embedded memory management system, a BT stack and proprietary data exchange protocol.
This SW is modular and provides an application interface to allow integration in customer specific environment including the possibility to plug in proprietary algorithms for physiological data elaboration.
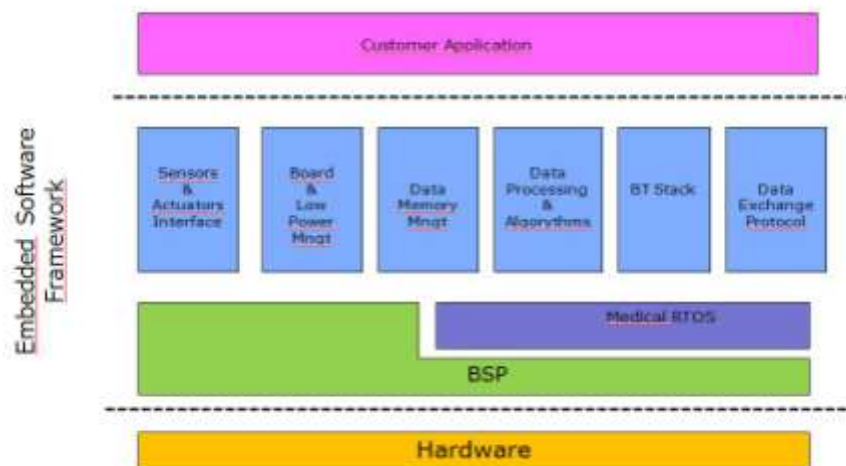
3   Embedded SW Framework

3.1 Connectivity:

- Bluetooth Radio class 2
- BT supported profiles: SPP
- Point to point link to a PC or to any BT enabled device, supporting SPP service, both as a client and as a server
- Proprietary data exchange protocol on top of SPP designed to optimize power consumption minimizing packets overhead.

3.2 Embedded Data Aggregator

3.2.1 ECG: extraction of

· Heart rate
· RR peak variability
· Heart Rate variability
· Electrode detachment alert

3.2.2 Bio-impedance: extraction of

· Breathing rate

3.2.3 Accelerometer: extraction of

· Activity level index
· Body posture

Baselines and thresholds are programmable for 3.2.1., 3.2.2., 3.2.3. with hysteresis to avoid false alerts.

4 Operating modes:

Platform can operate in 4 modes:

a) **Power down mode** : BGW device is completely switched off

b) **Idle mode:** the BGW device is visible and connectable to the remote unit through the BT link

c) **Streaming Mode:** is when the Body Gateway is powered ON and sampling the data as specified in the Configuration Settings, sending them directly to the External Device with periodicity specified by the last configuration commands received from the External Device.

d) **Monitoring mode**: is when the Body Gateway is powered ON, gathering and storing in the internal memory data at the frequency specified in the Configuration Settings, and sending the data as requested by the Associated Device.

5 Physiological parameters & personalization features

5.1 Parameters:

- Heart rate
- Heart rate reliability
- RR interval variability
- Breathing rate
- Activity level
- Body position

Other available data:

- ECG raw
- Z0 bio impedance
- Electrode reliability
- Battery level

5.2 Personalization:

Available data and parameters depends on the selected operative mode

Streaming mode

- Raw Data:
    - ECG (128 or 256 Hz)
    - 3-axis accelerometer (32Hz or 64Hz or 50 Hz)
    - dZ bioimpedance (32 Hz)
    - Z0 bioimpedance (32Hz)
- Derived values:
    - Heart rate values,
    - Heart rate reliability,
    - Breathing rate values,
    - Activity level,
    - RR interval variability,
    - Body position values,
    - Battery level

Monitoring mode

- Raw Data
    - ECG (128 or 256 Hz)
- Derived values
    - Activity level
    - Body position values
    - Breathing rate values
    - Heart rate values
    - Heart rate reliability
    - RR interval variability
    - Battery level

Signals and Parameters	Streaming Mode	Monitoring mode
ECG raw	128/256 Hz	128/256 Hz
Heart Rate	1 each 10-15-30-60 secs	1 each 10-15-30-60 secs
Heart Rate Reliability	1 each 10 secs	1 each 10 secs
R-R Variability	1 each 10 secs	1 each 10 secs

XYZ raw	50.0 Hz	-
Activity level	1 each 5-10-15-30-60 secs	1 each 5-10-15-30-60 secs

BIOIMP-Z0 raw	32 Hz	-
BIOIMP-DZ raw	32 Hz	-
Breathing Rate	1 each 15-30-60 secs	1 each 15-30-60 secs

Battery Level	1 each 10-15-30-60 secs	1 each 10-15-30-60 secs

6 Body Gateway mechanical dimension

6.1 Body Gateway device

BGW device is water resistant IPx4

Mechanical dimension:

- Weight: 35g
- Size: 59 x 50 x 16.4mm

7 Power consumption

7.1 Usage model example 1: streaming mode

Continuous data acquisition, processing and real time transmission (ECG raw signal, Bio-impedance signal, accelerometer data raw signal, HR, BR, Activity level, RR variability, HR reliability and battery level)

Using a 3.7V 380 mAh rechargeable battery, battery will last in 16Hours

7.2 Usage model example 2: monitoring mode

Continuous data acquisition, processing and storage (ECG raw signal, Bio-impedance signal, HR, BR, Activity level, RR variability, HR reliability and battery level), wireless uploading of all physiological parameters plus 5 minutes ECG and bio-impedance raw data per hour

Using a 3.7V 380 mAh rechargeable battery, battery will last in 40 hours

8 ECG EC38 signal snapshot

Electrocardiogram ECG
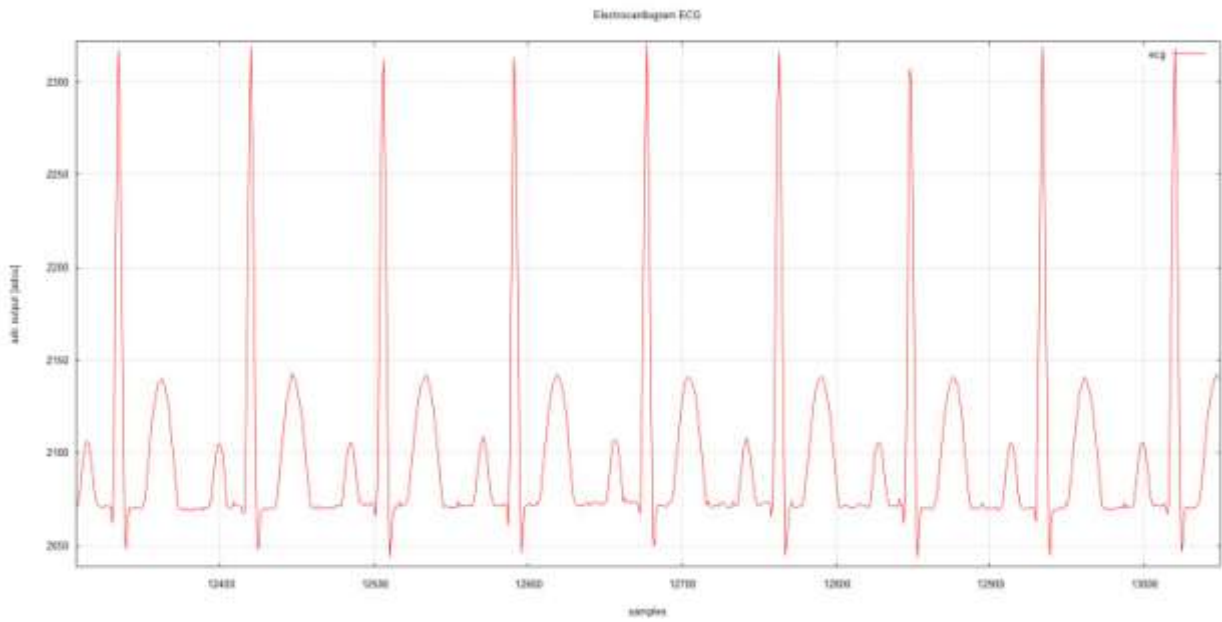
9 Regulatory Compliance

FCC

FCC ID: S9NMHBGW1

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CE

Safety and EMI Approval,
Compliance with
IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60601-1-6
IEC 60601-2-47
IEC 60601-2-49
IEC 60529
EC38
EC57
UL 60601-1
CAN/CSA C22.2

10 Revision history

Date	Revision	Description of changes
10/07/2011	1.0	First issue.

Please Read Carefully:

Information in this document is provided solely in connection with ST products. STMicroelectronics NV and its subsidiaries ("ST") reserve the right to make changes, corrections, modifications or improvements, to this document, and the products and services described herein at any time, without notice.

All ST products are sold pursuant to ST's terms and conditions of sale.

Purchasers are solely responsible for choice, selection and use of the ST products and services described herein, and ST assumes no liability whatsoever relating to the choice, selection or use of the ST products and services described herein.

No license, express or implied, by estoppels or otherwise, to any intellectual property rights is granted under this document. If any part of this document refers to any third party products or services it shall not be deemed a license grant by ST for the use of such a third party products or services, or any intellectual property contained therein or considered as a warranty covering the use in any manner whatsoever of such third party products or services or any intellectual property contained therein.

UNLESS OTHERWISE SET FORTH IN ST'S TERMS AND CONDITIONS OF SALE ST DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY WITH RESPECT TO THE USE AND/OR SALE OF ST PRODUCTS INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE (AND THEIR EQUIVALENTS UNDER THE LAWS OF ANY JURISDICTION), OR INFRINGEMENT OF ANY PATENT, COPYRIGHT OR OTHER INTELLECTUAL PROPERTY RIGHT.

UNLESS EXPRESSLY APPROVED IN WRITING BY AN AUTHORIZED ST REPRESENTATIVE, ST PRODUCTS ARE NOT RECOMMENDED, AUTHORIZED OR WARRANTED FOR USE IN MILITARY, AIR CRAFT, SPACE, LIFE SAVING, OR LIFE SUSTAINING APPLICATIONS, NOR IN PRODUCTS OR SYSTEMS WHERE FAILURE OR MALFUNCTION MAY RESULT IN PERSONAL INJURY, DEATH, OR SEVERE PROPERTY OR ENVIRONMENTAL DAMAGE. ST PRODUCTS WHICH ARE NOT SPECIFIED AS "AUTOMOTIVE GRADE" MAY ONLY BE USED IN AUTOMOTIVE APPLICATIONS AT USER'S OWN RISK.

Resale of ST products with provisions different from the statements and/or technical features set forth in this document shall immediately void any warranty granted by ST for the ST product or service described herein and shall not create or extend in any manner whatsoever, any liability of ST.

STMicroelectronics group of companies

Australia – Belgium - Brazil – Canada - China – Czech Republic - Finland - France - Germany - Hong Kong - India – Israel - Italy - Japan - Malaysia - Malta – Morocco - Singapore - Spain - Sweden - Switzerland - United Kingdom – United States of America

http://www.st.com