CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Device Description, Principles of Operation

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01	March 27, 2008	Initial issue
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1. DEVICE DEFINITION

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.

The chest-worn unit includes 4 electrodes on a harness. It houses a 3.6V lithium-thionyl chloride AA battery and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal and a buzzer.

The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds that starts recording on detecting specific rhythms and arrhythmias or when manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by the CG Monitoring Center.

The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.

2. GLOSSARY

AF	Atrial Fibrillation - a type of heart arrhythmia in which the upper chamber of the heart (atria) quivers instead of pumping in an organized way. In this condition, the atrias do not completely empty when the heart beats, which can cause blood clots to form.
Application	A Card Guard proprietary handheld device program for receiving, storing, displaying and transmitting data gathered from the CG-6108 System
Bradycardia	HR slowness, usually fewer than 60 beats per minute in an adult human.
Center	Card Guard proprietary internet-enabled program for patient records storing and retrieval. For use by physicians and medical professionals
Bluetooth (BT)	Wireless communication protocol.
Handheld device	Small mobile hand-held computing device
Heart Rate, HR	Number of beats per minute, measured as bpm
Tachycardia	A rapid heart rate, especially one above 100 beats per minute in an adult

3. CHEST UNIT

Figure 1. Chest-worn ECG Sensor – External appearance

The device functional block diagram is shown in Figure 2.

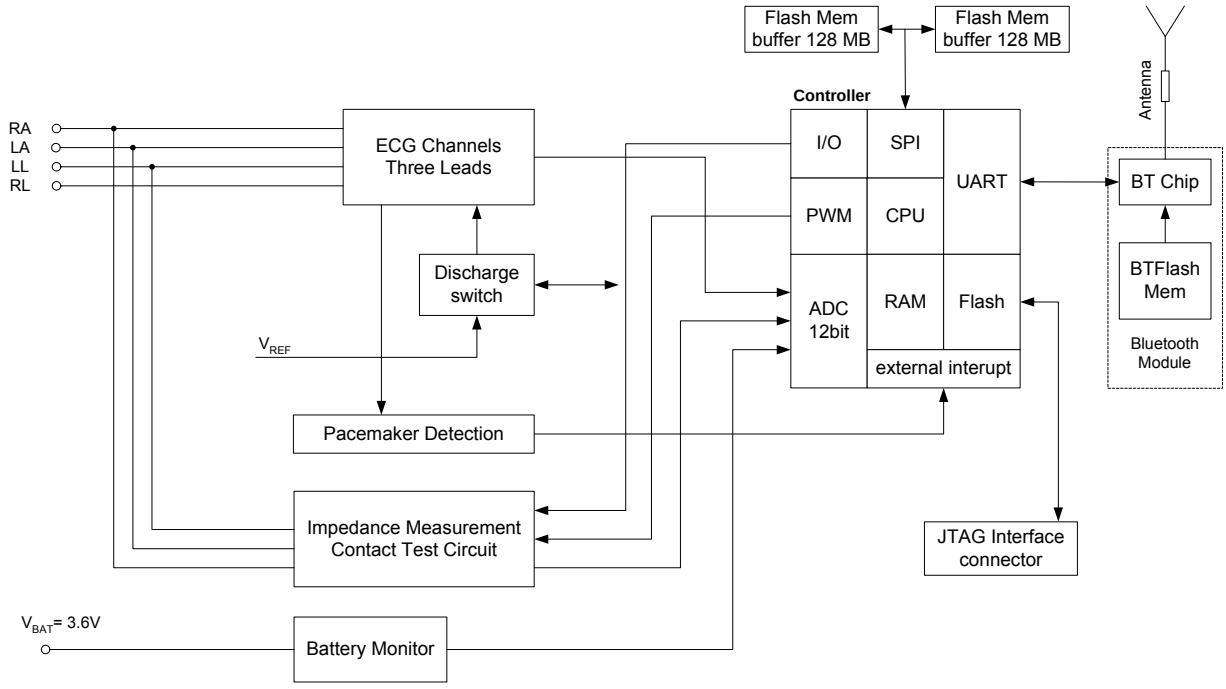

Figure 2. Chest-worn ECG Sensor - Functional Block Diagram

The 3-L chest-worn sensor has 4 disposable electrodes attachable to a harness. The sensor receives analog ECG data from the electrodes attached to the patient body and it continuously transmits this signal to the wireless handheld device via BT protocol - for processing.

The chest-worn sensor is powered by a 3.6V lithium-thionyl chloride AA battery. The sensor's ECG channels constitutes a differential amplifier with 20 MOhm impedance; Band frequency 0.05 – 120 Hz. The baseline is stabilized by a HiPass filter capacitor discharge mechanism, which is controlled by µC.

The electrode-to-skin contact is monitored with the impedance measuring circuit and a special SW application used to evaluate the electrode-to-skin impedance at f=10 Hz. The impedance is checked for each electrode separately vs. the reference electrode. The sine signal synthesized by the µC is applied via the voltage divider between the tested and the reference electrodes. When the impedance is high, the voltage across the divider is higher. The ADC is sensing three samples of this signal with an interval $\tau = 25m\sec$.

The divider output voltage is a function of impedance. The µC SW uses three samples for evaluation of the divider signal amplitude. This sampling method enables the skin-to-electrode impedance calculation in the range of 0 to 793 KOhm, with the resolution 12 KOhm.

The pacemaker artifact detection circuit enables detection of pulse amplitude 2 ÷ 250 mV in the range of 0.2 ÷ 2 msec by width. The circuit has a differential filter and a threshold level comparator. The µC SW implements the final time-based PM pulse discrimination.

The ECG data is digitized and saved to two 128 Mb flash memory buffers in turn. As long as the data is recorded to one buffer, it is deleted from the second. The buffers can store three hours' record of the ECG data at the sample rate 250.

The BT module has a power save (sniff) mode which reduces the current at the communication rate 1500 byte/sec - to 13.5 mA. When the flash buffer is nearly full and the wireless communication is restored, the BT transmits data with a greater rate while the sniff mode is off.

When the communication is lost the chest-worn ECG sensor seeks to restore it through a mechanism of synchronization with the wireless handheld device. In the process it runs the inquiry procedure at a preset time interval. The wireless handheld device is listening in sync with the inquiry signals.

4. HANDHELD DEVICE

The handheld device with a proprietary Medical Application is used to process and transmit the ECG recordings. The ECG signals are transmitted via BT to the handheld device. The Medical Application incorporates an algorithm for detection of arrhythmia events, e.g. AF. A detected event triggers transmission of the signal to the CG Monitoring Center for analysis.

The device uses the same algorithm for arrhythmia detection as its predicate device: CG-6108 *Continuous ECG Monitor and Arrhythmia Detector*. For the algorithm description refer to k071995.

5. 3-LEAD CONFIGURATION

The modification is limited to collection and processing of three ECG leads via three ECG channels instead of one lead and one channel in the predicate embodiment. During the concurrent analysis of the three synchronously running signals the processing mechanism uses a majority criterion for the event true/false decision. Such concurrent signal analysis contributes to minimizing data loss due to noise and other interference. In the process, the algorithm actually detects the noise "contaminated" segments and cuts them out from the record. This method is the same as in the predicate device.

The interference includes Myoelectric (EMG) signals, movement-induced disturbances, and interference from the mains.

1. Myoelectric (EMG) signal - reflects the nervous activation of a muscle (group of muscles), and presents a peak in the region of 40÷100 Hz.

2. Movement Induced Disturbance - movement of the electrodes causes variations in the electrode contact resistance and electrode contact capacitance, which modulate the voltage across the metal-tissue junction to cause a corresponding disturbance. This disturbance, often referred to as "varying baseline", has high-amplitude low-frequency spectral components since it is caused by a slow mechanical movement.
3. Background Noise has an unspecific character and originates from EM sources. It is a random component with spectrum in the whole frequency bandwidth.
4. Interference from the Mains has a well-defined signal shape with a fixed frequency. Unknown parameters are the phase and the amplitude.

Introduction f the 3-lead configuration enhances the rate of exclusion of false positive events thus dramatically improving Specificity, and Positive Predictivity.
Additionally the new arrangement enables MP at the Medical Center to visualize three correlated signals and refer to an alternative signal when it shows more details than in the current one.

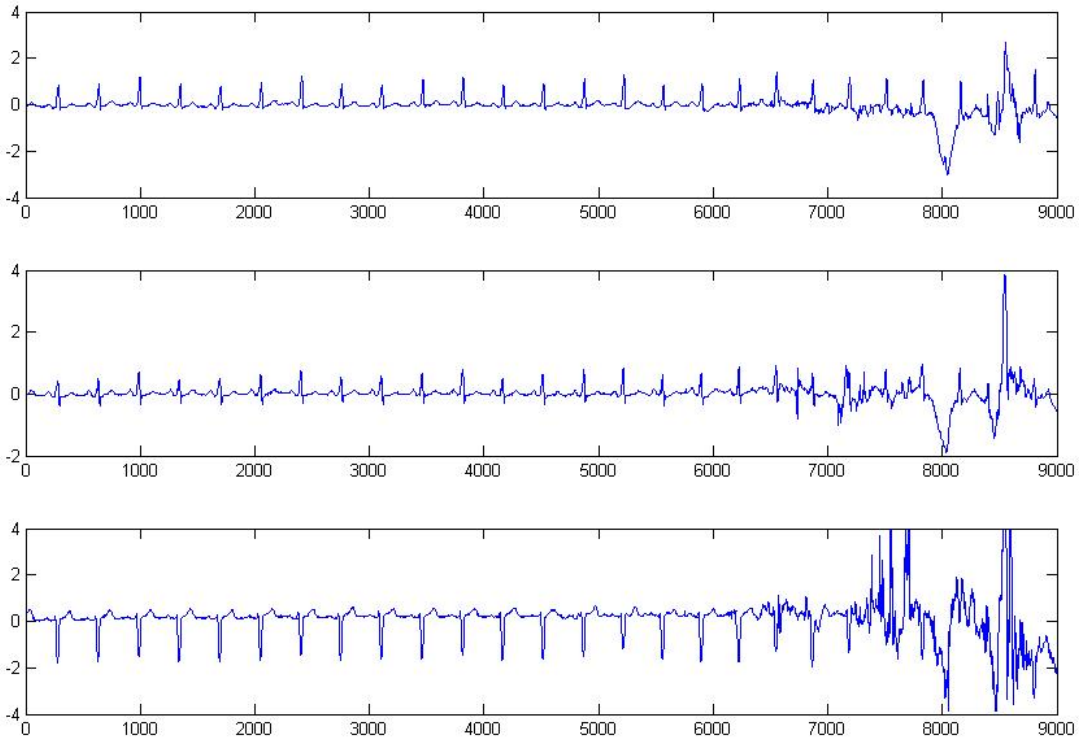

Figure 3. Example of 3-lead View

6. TECHNICAL SPECIFICATIONS

Input Impedance	20 MOhm
Input dynamic range	±5 mV_{p-p}
Current consumption (Tx mode)	Bluetooth Sniff mode average 13.5 mA
BT mode (max)	75 mA
CMRR	75 dB
ADC sample Rate	250 samples/sec
DC offset correction	150 mV
Frequency response	0.05 ÷ 100 Hz
Recording	Up to 30 days (on cell phone monitor)
Contact check	Impedance measurement
ECG data buffer	32 Mbit
Manual ECG event triggering	Yes
PM detection	Yes
BT Transmission range - open space	10 meters
Transmission mode (BT protocol)	SPP profile, Sniff mode, Auto-connection mode
BT sniff mode	6
Battery type	3.6V lithium-thionyl chloride AA
Battery life	2 to 3 days (dependant on the Bluetooth connectivity)
MTBF (hours)	10000
Operating temperature	10 to +40°C (50 to 104°F)
Transport & storage temperature	-20 to +65°C (-4 to 149°F)
Relative humidity non-condensing	30 to 85%
Dimensions (max.)	74 x 57 x 23 mm
Net Weight	54 gr.