33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

Hardware for Seizure Prediction: Towards Wearable Devices to Support Epileptic People

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***Abstract*— This paper presents the hardware developed for the EPILEPSIAE project (www.epilepsiae.eu), focused on epileptic seizure prediction. A portable low power acquisition system for EEG signals, called LTM-EU (Long Term Monitoring), with 64 channels and 2048Hz sampling rate each and a safe (high isolation) PC interface on a PCIe bus specifically designed for this task, is described. The acquisition system, designed for a rapid commercialization, though used for research purposes, got the CE certification.**

The signal from the patient, on each channel, is amplified, converted in digital form and stored into a local flash memory (SD-MMC, 4GB). Data are then formatted into a serial stream at 4Mb/s and sent through a half-duplex RS485 link to the host where a specifically designed PCIe (BQPCIe) interface receive them and release the information to the OS (Windows or Linux). The amplifier runs with a couple of AA battery for more than 15 hours (300mW). If a wireless link is established (Bluetooth), a bandwidth limited stream of data (or a subset of channels) is sent for monitoring purposes.

The mission is to support the researchers of the consortium with a suitable hardware to have a real time seizure prediction system for algorithms tests. In the experimental phase all algorithms run on a portable PC, wire or wireless connected to the acquisition system.

I. Introduction

When the first Document Of Work of EPILEPSIAE [1] project was written, in the second part of 2007, a two steps job was planned:

1. a first step which aimed to develop a high performances acquisition system, to enable the researchers to identify the seizure prediction problem and its complexity
2. a second step, operative aimed, tailored for the specific use, commercial graded, for daily use.

The target of EPILEPSIAE project was to reach the deployment of the research acquisition system and to evaluate the feasibility of the latter [4].

A system for EEG [2][3], and specifically for seizure acquisition, must fit a lot of constraints.

Safety issues are of primary importance.

As seizures happen without notice, long term recording (many days) need to be done on patients to collect the events and characterize them. Hence, the recording device needs to be as less invasive as possible (light and truly portable).

EEG signals are very weak. Normal activity, recorded on the scalp, ranges between tens to hundreds of microvolts. During seizures this signal may increase up to some millivolts, depending on age and recording technique.

The research acquisition system should have been designed to have the following initial requirements:

- 64 channels
- uniform 2048Hz sampling rate per channel
- 400Hz analog bandwidth
- low noise (<1µVrms @ max bandwidth)
- 6.4mV dynamic range
- 16bits resolution
- battery powered (low power)
- light to be wearable (<500g)
- wireless capabilities
- compliant with existent acquisition software to allow the integration of acquired data in the EPILEPSIAE database

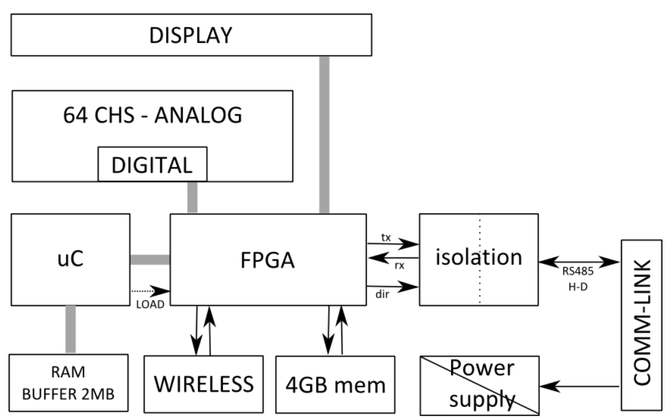

Fig.1. Block schematic of the amplifier

An overview of requirements, constraints and solutions will be presented in the following sections.

II. Constraints and challenges

The major concern, from the design point of view, was that the acquisition systems must be usable also for clinical routine.

It must be considered that to collect sufficient data for seizure prediction algorithms tuning, long recording sessions

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need to be done. Patient must stay in clinic for days and the recording activity for EPILEPSIAE project should not interfere with usual clinical activities [5][6].

The experimental hardware had to be designed respecting all the requirements of a high-level fully-commercial rated device, with extra features.

This set two important milestones in the project design flow:

1. the integration of the hardware in a clinical reliable software acquisition-analysis suite to send data in a standard database for analysis,
2. the certification of the acquisition hardware (CE), medical rated, to facilitate the use inside the clinics not only for research purposes but also for routine.

Without these characteristics, it would be impossible even thinking to have some feedback from the clinical partners in 36 months.

Unexpectedly but quite reasonably, during the project kick-off meeting the commission asked us to anticipate the hardware to 20 months to allow the partners to use it before the project end date. This further challenged the hardware design.

A market driven design strategy was chosen since the very beginning of the project.
A solid foundation was available, especially from the firmware side: we started from a 64 channels acquisition system that sampled data at 512Hz, already developed and on the market. But a four time data-rate required a deep revision of the whole framework, from the power efficiency, to the computational power, to the communication layer.
The hardware of the LTM-EU acquisition system deals with two different aspects:

1. the patient applied part
2. the data interface.

III. Patient applied part

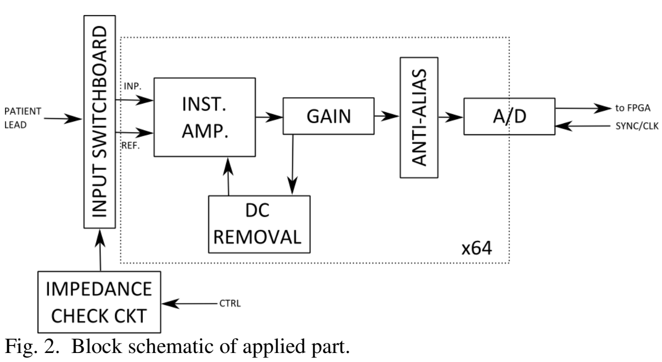

Fig. 2. Block schematic of applied part.

The applied part is the most critical. It must deal with signals as low as few microvolts and with artifacts of tens of millivolts.
Generally a 16bits dynamic is sufficient if some precautions are taken in front-end design (low noise amplifier and low bias current). Digital noise reduction (resolution enhancement) is also possible in some cases.

Safe data transfer must be accomplished over long distances (100m), at medium speed rate (15Mb/s) with low power budget.
To keep the power consumption low, for the best efficiency, it was decided to use assembler for the firmware coding and many functions were demanded to an FPGA (Field Programmable Gate Array).
To comply with the 2048Hz sampling rate constraint, it was necessary to redesign the A/D block and the analog front-end of the old slow system. Also the data management system was been completely reviewed. In fact, it is necessary to manage 64ch*2*2048=262244byte/s with a microcontroller (clocked at 16MHz). These data need to be stored and retrieved to and from a local flash memory. Then they need to be sent, in a reliable way, through the communication link, in real time.

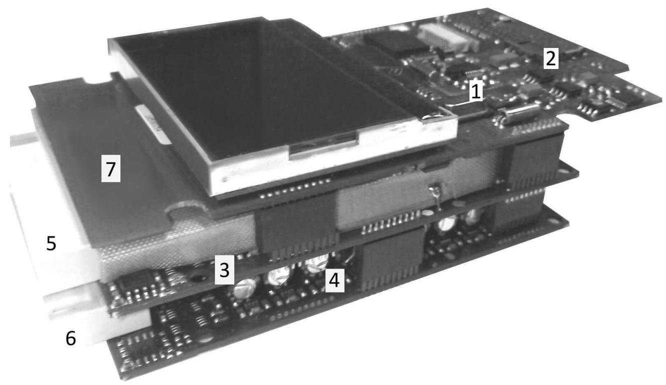

Fig. 3. The unboxed amplifier: 1) Bluetooth amplifier, 2) SD-MMC slot, 3) Analog board, first 32 channels, 4) Analog board, second 32 channels, 5) 6) Input connectors, 7) Digital board .

A wide flash memory was integrated (4GB SD-MMC) allowing the recorder to run autonomously, without any connection to the host system, for more than 4 hours at the maximum performances. The system was designed in such a way that, if the communication link is broken, as soon as the link to the host is back, all unsent data are recovered while still recording (no missing data).
A Bluetooth wireless interface was provided to test the possibility to get data (with limited bandwidth) without any connection to the host computer. The Bluetooh technology was chosen as the best trade-off between power consumption and bandwidth.
As Bluetooth cannot grant the necessary bandwidth to the full data throughput, only a limited number of channels can be sent wireless, for monitoring purposes or the sampling frequency must be reduced. Anyway, the whole set of channels is always stored into local flash memory as it is the highest priority location for data.
Special care was taken in the design of the front-end amplifier, trying to minimize the input bias current.
This current generates artifacts during the acquisition as the electrode impedance may change, e.g. due to movements, and a signal superimposes over the EEG. In epileptic patients and in long term acquisitions, when the patient is free to move, this effect is very common. A bias current as

low as 200pA was achieved. During the research phase of the EPILEPSIAE project, patients are in hospital and their EEG is continuously acquired for days, waiting for seizures to happen. In this period the patient is free to do many things and to move in different environments and, hence, it is necessary that the acquisition system is robust enough to record also in presence of strong EMI (Electro-Magnetic Interferences). For example, it is quite frequent that mobile phones are in the neighborhood of the patient. For this reason, special care was taken in input amplifier selection, choosing those with best RF (Radio Frequency) rejection.

Traditionally, the signal chain doesn't include any filtering except for the antialias before conversion and DC removal (no notch-filters). Signals are sampled as raw as possible.

A four time oversampling (8192Hz internal sampling rate) was adopted to relax the antialising filtering and to improve the noise performances.

A decimation under-sampling filtering was then applied to provide different output sampling rates.

SAR AD (Successive Approximation Register, Analog to Digital) converter have been chosen for energy efficiency and low conversion noise.

On the safety side, isolation techniques have been adopted: power supply and communication link are isolated from the applied parts.

High isolation level reduces the capacity between patient side and the host. This reduces the common mode current from the mains with good effects on signal artifacts.

A three axis accelerometer is also embedded to provide information on patient dynamic (while on the bed or during seizures).

IV. THE DATA INTERFACE

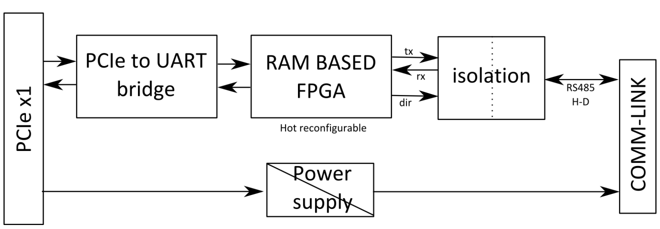

Fig. 4. Block schematic of PCIe interface

When data are sampled at 2048Hz from 64 channels, the bit-rate is greater than 2.62Mb/s (10 bits per byte plus services). This information is sent through a safe, isolated on both sides, half-duplex, serial RS485 link, over a distance up to 100m.

The PC interface was developed over a PCI-Express hardware but due to short design time availability, an off-the-shelf solution was chosen. In particular, a PCIe-to-UART bridge chip was found and a RAM-based FPGA was integrated to hold the application-specific code.

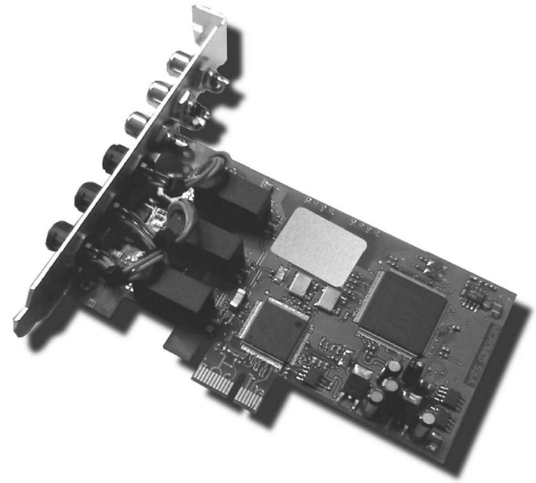
Fig. 5. The PCIe data acquisition interface

The circuit was design to allow dynamic reconfiguration of the FPGA in run-time (see block schematic) allowing great flexibility and easy firmware debug.

Also the data link was isolated from the PC for safety reasons. The cable link was then isolated on both sides.

Half-duplex communication allows a better use of the channel and the use of a lighter cable with mechanical advantages, especially considering the fact that the patient is connected to the system for a long time.

Four acquisition units may be connected to the system at the same time (bus sharing) allowing up to 256 channels to be acquired at full performances (only commercial version).


Fig. 6. The LTM-EU

V. SOFTWARE

The acquired data from the PCIe interface need to be read and analyzed (by clinicians) and stored in the database.

These functions are performed by an acquisition/presentation software framework suite already available but with specific new acquisition module. Windows and Linux drivers have been developed to accommodate the requirements of PCIe management and allow the researchers to operate at their discretion.

To allow the researchers to analyze data in real time, a special TCP-IP module, that sends data though the network, have been developed. In this way, while patient is monitored for clinical purposes, the same data may be sent to a remote host for study (real time seizure prediction).

TABLE I
SUMMARY OF RESULTS

Quantity	Performance	Comment
Sampling rate	2048Hz per channel over 64 channels	256KB/s, >2.5Mb/s Internal oversampling=8192Hz
Floor noise	<1μVrms	2048Hz s.r., on a 3.8KΩ input resistor
Memory capacity	4GB	SD-MMC flash, >4h recording time @ max performances without connection to the host
Size	85x170x45 mm	Weight: 300g, easy to transport
Comm. PHY	RS485	(Physical layer) Cheap medium speed link
PC interface	PCIe bus	Wide bandwidth, appropriate also for future use
Power Supply	2xAA batteries	Batteries may be changed without system stop: 20hrs continuous acquisition on a single set
Extra channels	X Y Z accelerometer	Patient movements recording (same EEG record)
	8x Polygraphic channels	For eyes movements, ECG (Electrocardiogram), muscle activity, etc.
Modularity	Up to 4 units on the same link	256 channels @2048Hz sampling rate (commercial feature)

VI. WIRELESS

A Bluetooth module have been integrated in the hardware to test the chance to send data wireless.

To avoid any problem due to link loss, all the information is always stored into the flash memory and sent through the wireless channel as soon as the channel is available.

Due to limitation on power budget, the wireless coverage is limited to 10/15 meters. To extend this range, without power increasing, a different transmission management technique was tested.

A roaming strategy was set to track the acquisition system while the patient is free to move in hospital environment.

A certain number of Bluetooth nodes (3 for the test) were installed in strategic positions inside clinics and wire connected through Ethernet network to the host PC. The mobile acquisition device is registered though all the nodes.

When it enters in the range of a node, the connection is established and data start flowing from that node to the host, eventually recovering the packets lost during the network unavailability. All these link switches are transparent to the host and to the acquisition unit.

VII. CONCLUSIONS

At the moment the results from the seizure prediction algorithms don't allow to evaluate the real computational effort necessary for an embedded application and, hence, the hardware for a stand alone predictor is not yet defined.

Nevertheless, thanks to the experience of EPILEPSIAE project, a family of acquisition systems have been developed and released for commercial use. Also PCIe interface for acquisition is now available to the market.

The high potentials of this system make it suitable for other different applications both for research and clinical (e.g. BCI and EEG holter).

For the future the idea is to develop a small stand alone device, with a DSP (Digital Signal Processing), GPS and GSM, with a limited number of channels (5 to 10) and with the right prediction algorithms embedded, tailored for the specific patient. If the condition of an incoming seizure is met, a message is sent through the GSM network and, eventually, a local alarm is issued.

This second phase development will take a large amount of time, also because of the necessary deep validation.

VIII. ACKNOWLEGMENTS

This project has been financed by the European Community under the seventh framework program “FP7”, grant agreement 211713. The EPILEPSIAE consortium is made by seven partners: the FCTUC University and HUC Hospital of Coimbra, Portugal, the UKLFR clinic and ALUFR university of Freiburg, Germany, the CNRS (“La Pitié Salpêtrière” Hospital and the CRICM Institute) of Paris, France and the industrial company Micromed S.p.A. from Treviso-Italy.

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