CADT vital signs monitoring

D. Teuchert, September 2008

This is an updated description of the technology currently available on our OEM modules. You can find other information here:

http://www.cadt.de/spo/Start_Englisch.html

Hardware

The hardware of our OEM modules is outsourced and comes from an automated production line. The supplier is certified to ISO 9001. Only brand semiconductors of Maxim, ST, Texas Instruments and Zetex are used. The four layer board is lead-free and includes proper ferrites on all sensor interfaces and about 50 µF of buffer caps (multilayer, no tantal).

Somewhat special in our modules are the easy to use 1/10” gold plated pins that fit into standard contact strips and the full plastic coating.

Basic power consumption of the hardware when operating a standard finger clip is about 2.5 to 3.5 mA at 3 V or 3.3 V. This rating includes sampling the ECG input, but does not include the ECG preamplifier nor the UART to RS232 converter. The current rating depends on the bandwidth of the UART connection and the quantity of data being sent. The minimum sleep mode power consumption of the board is some µA, while during measurement the LED drivers draw short pulses of up to 25 mA.

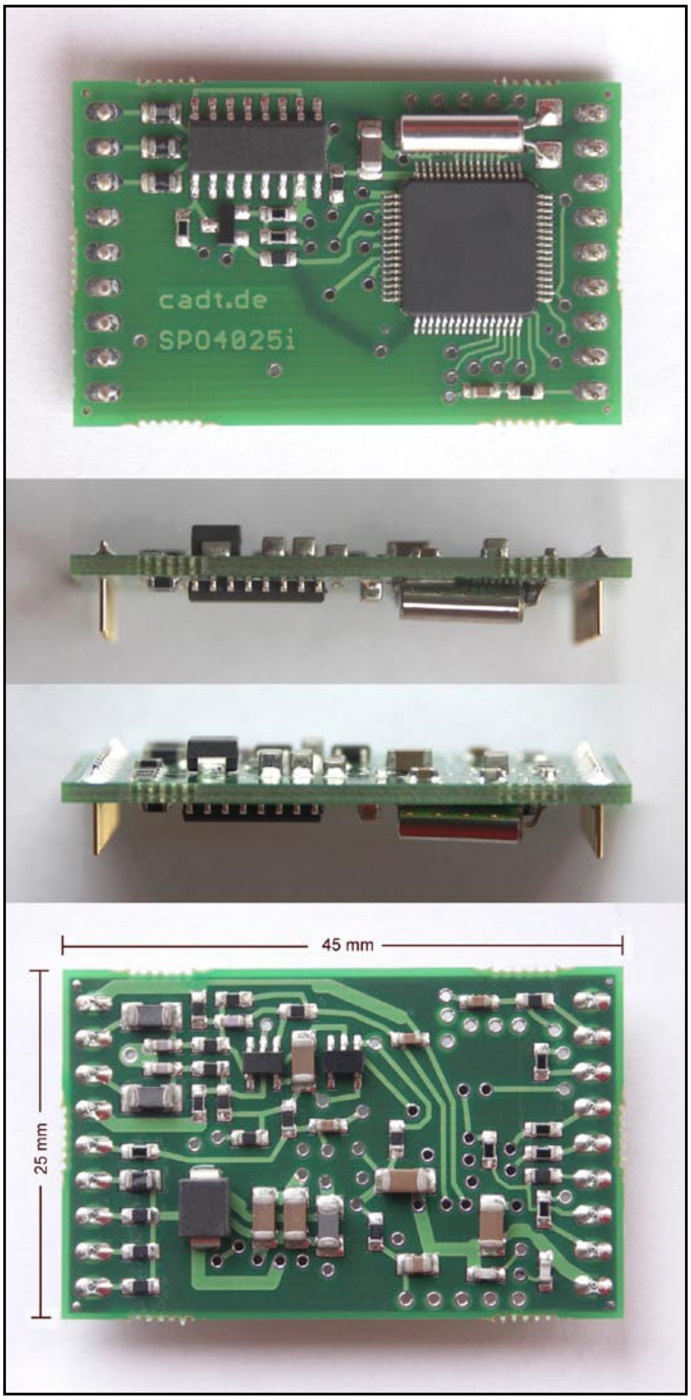
The board has five spare pins that can be linked to ADC, DAC or logic under firmware control. The standard LED driver and timing scheme supports using a third LED for improved/redundant spectrophotometry. The board can also be used to drive microoptical reflective sensors with common anode LEDs.

The board measures the typical sensor encoding resistor with 0.1% precision. The same pin may also be used to control 1-wire periphery.

The board includes circuitry to continuously monitor ambient light level, supply voltage and temperature.

NOTE:

Depending on contract size, this hardware can be made into different shapes to best match a customer’s needs. Of course, other connector systems are possible, and the SpO_2 sensor socket may be included on board.



VXI Based Initiation

Initiation of our OEM modules happens in-house. We built an automated testbed with a built-in patient simulator from VXI components. Its performance allows doing all series tests on each and every single OEM board.

After a visual inspection the emission spectra are recorded as well as characteristic waveforms. Processor clock frequency is measured with high precision as an “electronic fingerprint”. Each module receives its serial number and a firmware protection fuse gets burnt.

Then the modules receive their protective coating. Electronic documentation of the tests is sent to our customers to be integrated into their certification and documentation scheme.

Our business model includes a full guarantee for each OEM module without time limit. This is an important aspect of a certified product: Complete analysis of each single failure. This includes support for firmware version updates. Currently we are delivering Version i. We can also deliver Version h, which has a different hardware with much higher ambient light operating margin, but consumes about twice as much power.

Until now we delivered about 2700 SPO4025 modules, mainly for application in sleep diagnostics. Ambient light margins are uncritical in sleep screening and diagnostics.

System Firmware

Our proprietary system firmware implements a complete flash operating system that supports upload of software applications or application updates via the UART host connection. Both system and application firmware are protected by ECC methods performed during power up reset.

Each OEM module comes with its own serial number, both printed on a readable label and contained in one of three boot messages.

Application Firmware

Vital sign monitoring in our definition includes pulse oximetry as defined in the lecture books plus

A) digital oversampling with noise reduction filters to detect levels of perfusion amplitude down to 0.05 %.

B) wavelet data compression in order to minimize the required amount of processing for data analysis and patient model.

C) Kalman tracking for patient model in order to get well defined dynamic behaviour.

Our technology supports using the SPO4025 as the basis for a clinical pulse oximeter. The patient model with its 10 s limited time horizon exhibits fast reaction under rapid change and after probe application. With regular conditions the first patient model is derived after the 3rd or 4th heart beat, including perfusion amplitude, saturation, heart rate and other parameters. Our methods have been developed and verified in the area of sleep diagnostics, where long runs must perform without supervision by clinical personal and where a well defined dynamic behaviour is required in order to detect transient apnea.

Currently our standard application software uses one of the spare pins to sample an amplified and filtered ECG signal, if present, with 600 samples/s in order to determine absolute PTT (pulse transition time) with a resolution of about 1 ms, once per heartbeat. For each human individual the PTT is strongly correlated with blood pressure and serves well for the detection of arousals, as well as regular respiration.

This approach also resolves the oximetry motion artefact problem in a more efficient way than the overly complicated software and adaptive filter algorithms of our competitors which contradict the low power requirements of a portable device. Under difficult conditions with strong rhythmical artefacts you can still use the SPO4025, as long as it receives the ECG signal of the patient. The R wave detection algorithm also accepts the time marker signal delivered by a wireless chest belt and its corresponding receiver, like the one used for running and biking.

On start up and when connecting a probe, the application tests the sensor for light on the two principal LEDs and for voltage drop along the LEDs and the constant current LED driving circuit gets calibrated.

The plethysmogram is recorded in a continuous way, even when adjustments of LED current settings are necessary. Artefacts from those adjustments are automatically determined and corrected using a proprietary method.

Data Protocols

As mentioned before, supply current draw depends somewhat on the quantity of data sent to the host. Currently we use three versions:

a) Generic protocol

This implements a full transfer to the host, including sensor raw data, patient model data and internal monitoring information. Sensor raw data and internal monitoring data are sent at a rate of 50 packets/s, while patient model data are updated about once or twice per heartbeat.

This protocol is used during initiation for a full functional test of the device. It requires a 57600 Baud host connection.

b) Reduced protocol

While keeping the full patient model data, this protocol eliminates most of the data stream. Only a preprocessed plethysmogram is transmitted with 50 Bytes/s. Preprocessing means we can provide the plethysmogram free of motion artefacts.

Protocols a) and b) are packet based and include ECC bits in each packet to facilitate error recovery without loss of bandwidth.

c) Minimal protocol

Only the minimal patient model and operation status information is sent in 8 to 10 bytes about once per heartbeat. This protocol can be used with low baud rates like 9600 or 4800.

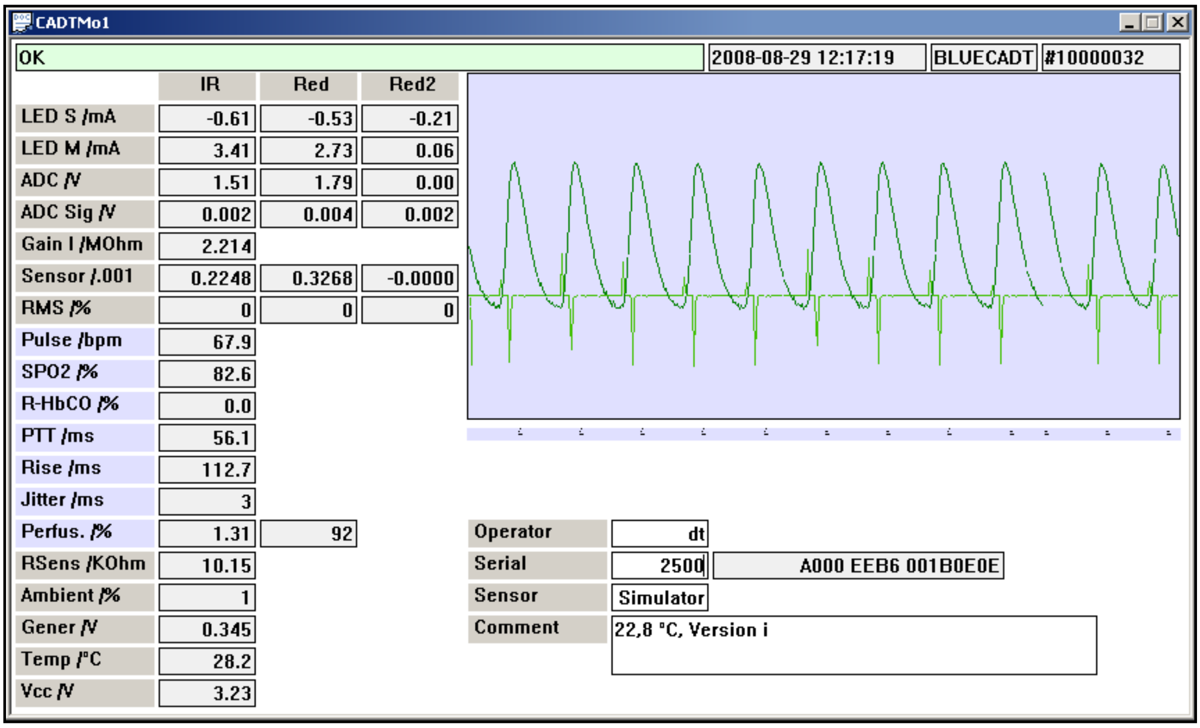
The protocol to be used can be selected at runtime, either by command or by tying certain pins to Gnd or V_{CC}.

TCP/IP and httpd included in monitoring application.

e) Using a SPO4025 as a portable, battery driven standalone monitor, connected to LCD display with four button menu system, acoustic alarms and recording to SD card, implementing FAT.

f) Using the SPO4025 with a differential pressure sensor and a pneumotachograph for an academic research on the dynamics of breath and oxigenization.

Due to its low power consumption a SPO4025 runs on a RS-232 connection without further power supply. For ECG applications, though, when an additional insulation barrier is required for safety reasons, we recommend using a USB adapter, which supports an insulating DC-DC-Converter.



Test Kits

We have test kits demonstrating:

a) Using a SPO4025 with a Bluetooth connection. We have Java software that can be used with a Java enabled cell phone to monitor vital signs.

b) Using a SPO4025 with a PDA. A C application has been written for monitoring with a simple B&W PDA with acoustical alarms.

c) Using a SPO4025 with a 5 kHz wireless chest belt, e.g. "Polar", with support for the PTT measurement and for motion artefact reduction during sports.

d) Using a SPO4025 as a POE ethernet device with

We developed a Win32 application software that can be used with a test kit and a Windows XP computer to visualize and record data sent by the SPO4025.

Future Developments

We are currently studying new methods to reduce power consumption even further. As it turns out, under regular measurement conditions with good perfusion we may run the device with very low LED currents and with less oversampling, reducing total power consumption by another factor of two or three.