# AoT-News

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STIX-DEM: Art of Technology lands 3rd Space project in 10 months!

Art of Technology has received a contract (together with Almatech Sarl) from the European Space Agency (ESA) for the design, development and production of the Detector Electronics Module for the Spectrometer / Telescope for Imaging of X-rays (STIX), which is a Swiss experiment under the leadership of the University of Applied Sciences Northwestern (FHNW) and one of 10 Instruments on the Solar Orbiter, an ESA mission planned for launch in 2017.

ARAB HEALTH

27 - 30 January 2014
SAE-58 Swiss Pavillon, Sheik Saeed Hall
Dubai International Exhibition Centre

embedded world Exhibition&Conference ... it's a smarter world

25 - 27 February 2014
Stand No. 2-328, Hall 2
Messezentrum, 90471 Nürnberg

MedTechWorld MEDTEC Europe

5 - 7 June 2014
Swiss Pavillon, Hall 2
Messepiazza, 70629 Stuttgart

# Crowd-Funding Projects

CARUNDA24: Continuous Blood Pressure measurements (without a Cuff) around the clock!

The continuous cuff-less measurement overcomes a 100-year limitation of traditional methods of measuring blood pressure. Wear your future CARUNDA24 just like a wrist-watch and measure your blood pressure, quite literally, around the clock. Help STBL Medical Research AG to develop their successful prototype into a first class medical system. To see how you can help visit CARUNDA24

PANONO
Panoramic Ball Camera

Simply throw the Panono up into the air and it will automatically capture a panorama at the highest point. Your image is wirelessly sent to your smartphone for a quick preview and to the free cloud stitching service.

Help Panono GmbH to develop this impressive prototype into a world beating product. To see how you can be one of the first to get one of these fantastic cameras, visit PANONO

# Under the Microscope

## Support with Certification of Medical Devices

The New Approach Directives of the European Commission (also referred to as the CE Marking directives) stipulate that all medical devices sold in the EU, irrespective of where they are manufactured, must have CE Marking affixed.

Although not a quality mark, the CE mark is a key indicator of a product's compliance with EU legislation and enables the free movement of products within the European market made up by the EEA and EFTA countries.

However, CE marking does not mean that a product was made in the EU, it merely states that the product has been assessed and that it satisfies the legislative requirements.

By affixing the CE marking to a product, a manufacturer is declaring conformity with all of the legal requirements to achieve CE marking. It is a legally binding statement by the manufacturer that its product has met, where applicable, all of the requirements of the New Approach Directives, namely:

| New Approach Directives of the European Commission (EC) |
|---|
| Medical Devices Directive (93/42/EEC) |
| In-Vitro Diagnostic Device Directive (98/79/EC) |
| Active Implantable Medical Device Directive (90/385/EEC) |
| including amendments contained in Directive 2007/47/EC |

**[1]Documentation for CE marking**

Before the CE mark may be affixed to a medical device and legally sold within the European Union, the manufacturer or importer must:

- maintain technical documentation to show the product's compliance with applicable device directive
- receive a device-specific CE-Certificate[2] from a Notified Body
- register the device with the appropriate authorities

While individual country / regional requirements for submission and approvals may differ, the core documentation requirements are essentially similar. This should include as a minimum:

- a description of the product (and any variants)
- technical information and an explanation thereof
- results of risk analysis, design calculations, tests, validation, pre-clinical and clinical evaluation

The information, which will vary depending on the specific directives relevant to your product, should be kept in the form of a Technical File and has to be supplied upon request by an enforcement authority.

**Enforcement and documentation**

There are a number of bodies that enforce CE marking legislation to prevent misuse of the CE marking and to ensure that product safety is maintained to a high standard. It should be noted that is the manufacturer's responsibility to:

- carry out the conformity assessment
- set up the technical file
- issue the EC Declaration of Conformity (DoC)
- affix CE marking on a product

If an enforcement body finds a product that does not meet CE marking requirements, they will often provide the manufacturer with an opportunity to ensure it is correctly CE marked. If you fail to comply with this, you will be obliged to remove your product from the market. You may also be liable to a fine and even imprisonment.

[1] The new revision of the MDD requires that records for implantable devices be kept for a minimum of 15 years. Declaration of conformity, technical documentation, reports, and certificates from Notified Bodies etc. must be kept for at least five years after the product has been taken out of production.

[2] Some Class I and all Class IIa, IIb and Class III devices require Notified Body approval

**Art of Technology** can help you to navigate the CE certification process for medical device development and regulatory submissions. We provide support with the required Quality System elements, review of the submission processes for the Medical Device Directives and if required, the classification and submission requirements of other countries.

Wherever you are in your development cycle, we can provide support to help you meet your compliance needs. From product design to prototype evaluation and pre-compliance to full-compliance testing, we can help you evaluate your medical device, whether it be a Class I[3], IIa[4] / IIb[4] or III[5] device in accordance with the relevant Directives.

If you would like support with the CE certification of your medical devices contact Paul Sphikas

| As the actual process to be followed depends on the Directives that apply to your product, we can help you to: |
|---|
| identify the directive(s) and harmonised standards applicable to your product(s) |
| classify your product Class I[3], IIa[4] / IIb[4] and III[5] according to the classification rules in Annex IX of the MDD |
| determine the appropriate certification process based on the device class of your product |
| verify the product-specific requirements |
| identify whether an independent conformity assessment is required from a Notified Body |
| test the product and check its conformity |
| ensure that your device fulfils the essential requirements in Annex I of the Medical Device Directive) |
| compile, review, correct the Technical File or Design Dossier |
| select appropriate test-authority and support with technical issues |
| prepare the CE Declaration of Conformity |
| register with the appropriate authorities in Europe |
| implement & maintain an ISO-13485 quality system(s) |
| perform risk analysis and management (ISO 14971): establish processes to identify hazards associated with medical devices, estimate, evaluate and control associated risks and monitor the effectiveness of the controls. |
| establish a monitoring system: as a manufacturer, you are required to monitor your products once they are on the market, in case accidents involving your products occur |

[3] Class I: devices with low risk such as external patient support products

[4] Class IIa and IIb: devices with medium risk such as electro-medical devices

[5] Class III: devices with high risk such as cardiovascular catheters

# Tech-Corner

## Alternative application for Digital Signal Processors (DSP's) normally used in Hearing Aids

Thomas Schwinghammer

Digital Signal Processors (DSP's) with over 40 million instructions per second (MIPS) are widely used in today's hearing aids, which is approximately equivalent to a 486-CPU with an audio CODEC and an output driver that can be worn inside the ear.

These DSP's can be used to enable other sophisticated applications outside of the normal hearing aid applications; applications such as the Lenz.

### The Lenz

is an anti-snoring device, worn just like a hearing aid. The device works on an acoustic basis analysing the sound of the wearer, generating a tone if and when snoring is detected.

The tone generated is registered sub-consciously causing the wearer to move and change his (or her) sleeping position and the snoring stops. Persistent snorers may, however, be awakened on occasion.


The device is available in 2 options, a standard version (shown above) and a customised version, moulded to fit the individual's ear.

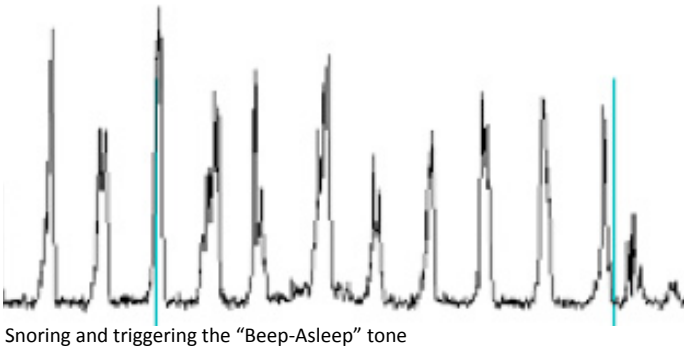
Individual configuration of the device is not necessary, and software adjustments, although not provided as standard, are possible via the I2C interface on the device at any time.

### Beep - Asleep

Sleep is divided into different phases reflecting different levels of responsiveness to external stimulation.

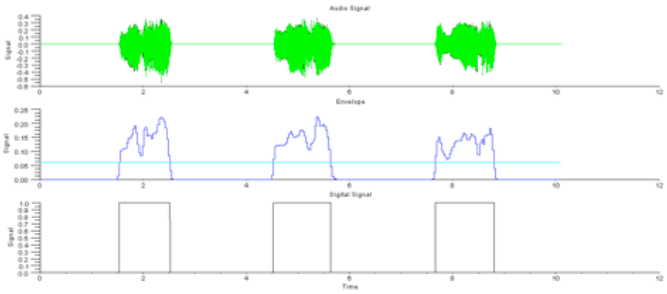
| Stages of Sleep | | | | |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |
| 4 - 5 % | 45 - 55% | 4- 6 % | 12 - 15% | 20 - 25% |
| Light Sleep<br><br>reduced Muscle activity<br><br>Occasional Muscle twitches | Slow breathing pattern and heart rate<br><br>slight decrease in Body temperature | Deep sleep begins<br><br>Brain begins to produce delta waves | Very deep sleep (Delta Sleep)<br><br>Rhythmic breathing<br><br>Limited muscle activity<br><br>Brain produces Delta waves | Rapid eye movement (REM)<br><br>Delta waves accelerate and dreaming occurs<br><br>Muscles relax and heart rate increases<br><br>Rapid and shallow breathing |

In order to respond to these phases a principle was developed to influence the user subconsciously, without waking him or her, using various signals.



Snoring and triggering the "Beep-Asleep" tone
Source: Art of Technology

If snoring stops after a tone is generated the device remains silent. However, if snoring continues the device generates a different sound and checks again, repeating this process until snoring has stopped.



The fundamental frequencies of the "Beep Asleep" tones are in the range 80 - 640 Hz and the volume between 55 - 95 dBA with a long-time-equivalent sound level ≤85dBA (calculated over 30s; conforms to EN 60065 "Audio, Video - and similar electronic apparatus. Safety requirements")

## Detection Principle

The typical snoring frequencies are extracted by filtering using the overlap-add (OLA) which is an efficient signal processing method to evaluate the discrete convolution of a very long signal with a finite impulse response (FIR). An envelope is formed on the pre-filtered signal and compared with a threshold value and a digital signal is produced.

Using this digital signal, different criteria can be measured at various time intervals. If all criteria are met, the device identifies this as snoring.

Careful selection of parameters prevents other noise events, including speech, being identified as snoring. Scilab was used for the development of the algorithm and parameters. The findings of the analysis and simulation were implemented and tested in the device.

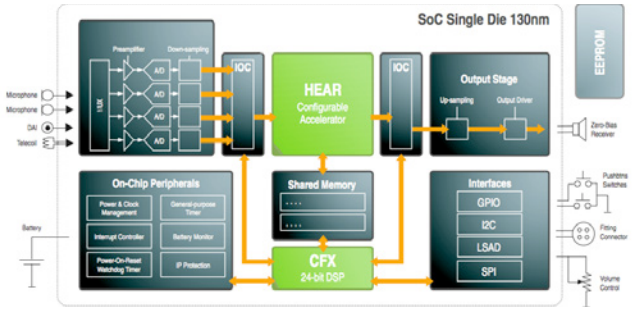
## How does it work?

Sounds are recorded using a microphone and played back via a speaker, both of which are directed via an acoustic coupler into the ear.

The device is very simple to operate;  just open and close the battery compartment, there are no buttons or potentiometers.

The heart of the anti-snoring device is a fully programmable dual-core chip Hearing Ezairo 9500th. This consists of a DSP and a programmable co-processor, both of which have Harvard architecture.

The DSP is programmed in the assembler, the co-processor with a so-called microcode. This special two-core architecture provides an optimal balance between performance and power consumption.




Architecture Diagram
Source: ON Semiconductor Ezairo ™ 5900 Series: High Precision Sound for Next-Generation Digital Hearing Aids

The chip is highly optimised for the processing of audio signals and runs at full performance with a battery output voltage of 1.05V and with a slightly reduced audio quality at 0.95V. The Lenz uses a zinc-air battery, type 312.

The typical signal width of the data is 24-bit. For simultaneous control of a plurality of computing units, a parallel set of commands can be used. In particular, the arithmetic logic unit (ALU) and the data-bus can be used in parallel.

The device is classified as consumer electronics (consumer electronics) and complies with the EMC standards.

## Product Information

| | |
|---|---|
| Contact | info@earsonic.de |
| Product website | www.meinlenz.de/en |
| Manufacturers website | www.easronic.de/en |

## DSP-Applications

| | |
|---|---|
| Art of Technology AG | Thomas Schwinghammer |

# Speed-Dating à la AoT

with Simon Fivat

## What motivates you?

Learning new things and developing myself motivates me - personally, professionally, and in private life. I want to deliver professional work; it's very motivating when customers are happy.

| | |
|---|---|
| Age | 28 |
| Profession | HW/SW Engineer |
| with AoT | since 2012 |
| Star Sign | Pisces |

## How do you spend your free time?

I go regularly salsa dancing and to the gym in winter. I'm involved in tandem language learning.

## What is Tandem Language learning?

It's a method of learning languages via mutual language exchange, where two people come together in a 1:1 situation, in order to teach and help each other. I speak French and German, and I'm learning Spanish and Italian.

## Which hobby would you never do voluntarily?

Martial Arts...it looks painful.

## What would you spend a lot of money on?

Big trips...I like to go far away. Two years ago I was in Zambia and India and last year in Ghana and Togo. I went to China for three weeks in Spring of this year.

## What would you never spend money on?

A Lamborghini... then again, if I had a lot of money? Products which have been manufactured via immoral means or methods.

## What things do you want to do in Life?

I'm still too young for such thoughts about life.

## Which profession would you not want to follow?

Stockbroker or other jobs which juggle with ridiculously large amounts of money. Jobs with very creative requirements such as Writer. Politics is also not for me - it's too stressful.

## Describe yourself in a few words?

I'm open and straightforward, problems are handled straight away and are finished. I don't need a lot to be satisfied and I usually plan not more than one week in advance.

## What upsets you?

Dawdling around, especially when time is of the essence.

## What is your best quality?

I remain calm in difficult situations and am very responsible.

## What are you strengths a work?

Commitment and readiness to help others.

## Which Super-strength would you like to have?

As I generally leave home at the last moment and am always in a hurry, the ability to beam from one place to another would be perfect for me.

## What sound or noise do you love?

Birds chirping early in the morning.

## If you were an animal, which animal would you be?

A fast flying bird - like a Peregrine Falcon (242 mph)

## You're invited to a Costume Party; how would you disguise yourself?

Jar Jar Binks from Star Wars, he's a big klutz, but with a good heart and he's quite amusing in his own way.