



AMPS-QT is a quarterly journal dedicated to all the people and organizations involved in the world of cardiac safety. Published by AMPS LLC, it covers all aspects of methodology and software technology related to clinical trials and Thorough QT studies.

Editorial

It would appear that the financial crisis that impacted directly most industries during 2008 and 2009, and supposedly abated during 2010, eventually caught up noticeably with the Cardiac Safety industry during 2011. Most, if not all, of the key-player companies reported, directly or indirectly, a shrinking of the business, seeing a reduced number of studies, due in some case to delays or outright cancellations. As it could be expected, and we anticipated, some of the new players suffered most, while others managed to stay afloat with some strategic changes in course. From our small, but somewhat privileged, point of view, and thanks to the renewed confidence of our partners, we are glad to report a consolidated, slight increased business, which seem to indicate that in spite of the crisis the Cardiac Safety industry is still a healthy one.

A good opportunity to assess the situation, and what lays ahead for the future of the technology at the core of the industry, is to attend the 2012 International Society of Electrophysiology (ISCE) meeting next April. Our own Dr. Badilini is the chairman of this edition and he has been working restlessly to provide the most interesting panel of experts, both from the industry and the regulatory agency, which will make attending this event a must, if you wish your company to be in the leading edge for the future. In this issue he is providing a glimpse of the program which, we are sure, will elicit a lot of interest in our readers.

With this 12th issue of AMPS-QT we reach the completion of the third year of publication. Since we started this magazine, in 2009, its distribution and subscription rate has grown steadily, as have the number of positive comments we receive from our readers. We wish to thank all the contributors, as well as all our readers, for your support and confidence: we will strive to continue provide you with

articles and essays worthwhile your reading. From the AMPS Team please accept our best wishes for a successful 2012!

AMPS Views on:

INTERNATIONAL SOCIETY FOR COMPUTERIZED ELECTROCARDIOLOGY ANNUAL MEETING IN BIRMINGHAM

**Please join the International Society for Computerized
Electrocardiology (ISCE) for its 37th Annual
Conference.**

Friday, April 20 to Tuesday, April 24, 2012.

**Renaissance Birmingham Ross Bridge Golf Resort &
Spa Alabama, USA.**

By Fabio Badilini, AMPS llc.

It is my great honour to inform our readers that I will be the chairman of the 2012 International Society of Electrophysiology (ISCE). The meeting will take place in Birmingham, Alabama from April 20 to April 24 2012 and it will be co-chaired by Doctor Kjell Nikus, from Tampere University Hospital, Finland.

I have been attending the ISCE annual meetings for a very long time and I can confidently state that this relatively small conference is the best opportunity for both engineers and cardiologist to meet for a few days in a very informal and extremely constructive environment. It is definitely the ideal combination to learn about different facets of the computerized electrocardiogram world.

The format of the meeting, with plenary sessions in the mornings and evenings, and with poster sessions in the afternoon allows plenty of free time to develop interaction among the attendees.

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The conference will begin the afternoon of Friday April 20th with a tutorial, run by Dr. Kjell Nikus, which will provide a panoramic overview of a very sensitive topic such as the fragmentation of the QRS interval.

The main conference, which will take place from Saturday April 21st through Monday April 23rd, will include sessions focusing on technical aspects of the electrocardiogram, such as the diagnosis of specific cardiac pathologies as well as more clinically-oriented problematic issues.

A specific session will be dedicated to provide a comprehensive review of the high-resolution ECG from implantable cardiac devices and will include discussion on how the selection of high-risk patients for device intervention may change in the near and long-term future.

Another session will provide a detailed update on existing databases that include digital electrocardiograms: we will hear updates from the Framingham Heart Study, from a similar epidemiological database started in 2005 in the central Italy region of Molise, from the telemetric Holter warehouse (THEW), and finally from the FDA ECG warehouse repository managed by the Cardiac Safety Research Consortium (CSRC).

The conference also include a plenary address which I am delighted to announce will be given by Professor Peter Macfarlane from the Glasgow University. Like many other biomedical engineers, I have learned a lot from Peter's papers and books and my current education and understanding of quantitative electrocardiology would have not be the same without his huge contribution to the field; it is thus a great honour for me to have him as the keynote speaker of "my" meeting.

Other interesting sessions will talk about the changing role of the ECG signal with respect diagnostic aspects of left ventricular hypertrophy and the management of patient monitoring alarm fatigue. Last, but not least, we are also going to talk about the pharmaceutical aspects of the electrocardiogram in a dedicated session that will focus on drug induced changes of cardiac repolarization. This session will include speakers from the FDA who will provide an overview of statistical issue related to the Thorough QT Study, aspects related PK/PD modelling of QTc drug influences and finally a perspective over present and so far unresolved challenges. Because of this specific session, but more in general for the content of the whole scientific program, I honestly believe that ISCE2012 will be a great opportunity for those of you involved with the electrocardiographic signal to learn a lot and, more specifically in the 2012 edition, to have the opportunity to

interact directly with experts of the field, both from key players of the industry as well as from academic opinion leaders.

Also on behalf of the ISCE president, Dr Rory Childers from Chicago, I thus invite you to attend ISCE 2012. I hope to see many of you in Birmingham!!!

For more information you can consult the ISCE website www.isce.org or contact me directly at badilini@amps-llc.com.

Products News

Latest Releases

- TrialPerfect v. 2.7.0, with enhanced ECG workflow;
- WinAtrec2 v. 1.3.0.

Looking forward

In Q1 of 2012 AMPS is planning to release:

- FDAEcg Suite v.2: enhanced graphical interface, with advanced scoring display, new scoring metrics and optimized ECG management.
- an update version of FAT-QT with new scoring metrics, synchronized with FDAEcg Suite v.2.
- a new version of TrialPerfect, with enhanced graphical interface and optimized ECG workflow.

And last but not least...

After many years of research, experience accumulated by partnering with the most successful Clinical Research Organizations worldwide, and by using more than 300.000 annotated ECGs from different studies and different CROs, AMPS was able to distill a state-of-the-art algorithm, named Bravo, for the automated analysis and measurement of 12-lead ECGs.

The major features of Bravo include:

- optimization of PR interval onset
- optimization of QRS interval offset
- optimization/tuning of QT interval measurements
- new design of Median beats generation
- QTpeak and TpeakTend intervals
- additional amplitudes (e.g. P, Q, R and S wave amplitudes)
- new re-polarization morphology parameters based on Gaussian Mesa function data fit

Later in 2012 AMPS is planning to release enhanced versions of CalECG, Fat-QT and FDAEcg Suite, based on the new Bravo algorithm.

AMPS Notebook

As reported in the Editorial and in the *AMPS Views on* contribution, Fabio Badilini has been appointed chairman for next year 37th **ISCE conference** that will be held in Birmingham, AL from April 20 to April 24, 2012.

AMPS People

We continue our round of staff introductions with Umberto Spagnoli.

Umberto obtained his Master degree in Engineering in 1995, defending a thesis entitled “An application for interactive analysis of numeric signals in time and frequency domain”, a software about spectral analysis. Umberto has been working for AMPS since 2001 and during his stay has become the lead manager of the HeartScope tool and, starting in 2009, the newer and totally redesigned HeartScopeII.

He is also an expert in software-hardware communication and Database design and maintenance.

His e-mail address is: spagnoli@amps-llc.com



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CalECG

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TrialPerfect

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FDAEcg Suite

View, validate, and score ECGs before the FDA submission

Antares

Extract meaningful ECG strips from holter traces

FAT-QT

Measure automatically thousands of ECG in minutes.