



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*

We are honored to host in this 39<sup>th</sup> issue of AMPS-QT the contributions of one of the pillars of modern electrocardiography, *Dr. David Mortara*. Much can be written about David's achievements, numerous inventions, and innovations in ECG interpretation, digital ECG, and ECG signal processing. What may not be known to everyone is that in 2011, David was inducted as an honorary fellow of the *American College of Cardiology* in recognition of his lifetime contributions to the science of electrocardiography. The same honorary fellowship was awarded to our own Fabio Badilini in 2009. Notably both David and Fabio are two of the very few recipients who are not Doctors of Medicine. Given their contributions, it is no coincidence they have been known and appreciated each other's work for more than 30 years.

This relationship, in various capacities, and the friendship that has developed from it, has brought them to work together at UCSF on an ambitious project, so we expect David's contribution will be of the utmost interest for our readers.

## *A Noteworthy Contribution:* **New Frontiers on Alarm Fatigue**

By David Mortara, PhD, FACC, founder of Mortara Instrument, Inc; Associate Adjunct Professor, University of California San Francisco, San Francisco, CA, USA.

During my career of entrepreneur working in the field of biomedical waveform-based signals processing, I have been faced and coped with many different facets

of unresolved clinical issues. Nurse alarm fatigue from the intensive bedside monitoring is certainly one of the most fascinating problems I have ever encountered, and where I believe research and innovation are highly needed.

Alarm fatigue occurs when clinicians become desensitized to the constant noise of alarms and either ignore them or simply turn them off. Among the numerous detrimental results are anxiety in hospital staff and patients, sleep deprivation among hospitalized patients, and missed life-threatening heart rhythm events. With the increased sensitivity of ECG equipment, they have become the most common culprit for false alarms.

Alarm fatigue has many causes, including bedside monitoring manufacturers making algorithms more sensitive to every medical event and clinicians or hospital administrators selecting instruments primarily for their sensitivity and purpose, rather than prioritizing on the alarm.

The issue has become so significant that The Joint Commission, a national organization that accredits hospitals, named it a National Patient Safety Goal. This goal required hospitals to establish alarm safety as a priority, identify the most important alarms and establish policies to manage alarms by early 2016.

There's a lot of information to glean from electrocardiograms that we're not tapping into. They also need to be more accurate and clinically relevant.

My motivation to help to contribute to solve (or at least to significantly reduce) the problem of alarm fatigue led to a constantly growing collaboration with the School of Nursing at the University of California at San Francisco (UCSF) which dates back to 2013. The School is a national leader in nursing science, and

has been working on the topic of alarm fatigue for a number of years, with a few important publications, led by the internationally recognized cardiac monitoring expert Barbara Drew, PhD, RN (currently a Distinguished Professor in Physiological Nursing).

In a remarkable study conducted in 2013 at UCSF, Drew and her colleagues found that the five adult ICUs at UCSF Medical Center, which together have 77 beds, logged more than 2.5 million patient-monitoring alarms in just one month [1], namely more than 1.1 million arrhythmic events and more than 380,000 audible alarms, for an audible alarm burden of 187/bed/day.

Using a well-defined alarm annotation protocol, nurse scientists with 95% inter-rater reliability annotated 12,671 arrhythmia alarms. Unfortunately, 88.8% of these 12,671 annotated arrhythmia alarms were false positives. Conditions causing excessive alarms included inappropriate alarm settings, persistent atrial fibrillation, and non-actionable events such as PVCs and brief spikes in ST segments. Low amplitude QRS complexes in some, but not all available ECG leads caused undercounting and false arrhythmia alarms. Wide QRS complexes due to bundle branch block or ventricular pacemaker rhythm caused false alarms. 93% of the 168 true ventricular tachycardia alarms were not sustained long enough to warrant treatment. This publication was the first study to comprehensively define the detailed causes and potential solutions for the widespread issue of alarm fatigue in hospitals, a top recommendation was better computer algorithms.

After a few years, and after a few successful fellowship programs, my collaboration with UCSF recently reached a further and important milestone with the establishment in 2017 of a dedicated Center that will specifically focus on the problem of alarm fatigue, enabling nursing researchers to work directly with UCSF and manufacturing industry to address the high error rate in ECG equipment that leads to millions of unnecessary alarms generated each month in hospital units.

The new UCSF Center for Physiologic Research (CPR) will support research and the establishment of a large annotated ECG database based on expert-validated episodes of lethal arrhythmias (asystole, ventricular tachycardia and ventricular fibrillation)

acquired from different UCSF hospital units over a long period of time (several months). The primary objective will be to collaborate with the Food and Drug Administration through their Medical Device Development Tool program (MDDT) to establish a method to validate new algorithms for the detection of cardiac lethal alarm detection. Ultimately, the goal is to identify specific predictors of adverse patient outcomes, reduce false alarm rates and improve ECG monitoring systems. The Center will also provide opportunities to bring in scholars, recruit new faculty and students, and foster interdisciplinary research with UCSF Health, which comprises UCSF Medical Center, UCSF Benioff Children's Hospitals and other affiliations.

This CPR is housed in the school's Department of Physiological Nursing on the UCSF Parnassus campus and it is directed by Fabio Badilini, PhD, FACC, Chief Scientist and founder of AMPS llc, one of the leader companies in quantitative ECG analysis. I personally believe that with his long-lasting experience with the ECG analysis industry and with FDA, Fabio is the right person at the right time to fulfill the ambitious targets of the Center.

I've seen for too long that there is a vendor world of research and a separate medical world of research, and they don't cross very well. The long-term vision of this center is to be a bridge, an innovative center that has resources and people eager to work together to resolve alarm fatigue. Our success will not be just in what we're able to do as a center, but also in what we can get vendors to do.



*David Mortara and Barbara Drew, pioneers in alarm fatigue research.*

## References

[1] Drew BJ, Harris P, et al. Insights into the problem of alarm fatigue with physiologic monitor devices: a comprehensive observational study of consecutive intensive care unit patients. PLoS One. 2014 Oct 22;9(10).

## News from AMPS Italian Subsidiary

### CardioCalm: the new AMPS-LLC company to provide telecardiology services in the Italian and European healthcare markets

By Paolo Verzeletti, MS, CEO of CardioCalm, Montichiari, BS, Italy.

**CardioCalm** is an Italian company, created by AMPS and based in Montichiari (Brescia Italy). The mission of **CardioCalm** seeks to provide the Italian and European healthcare markets with the expertise AMPS has achieved in pharmaceutical research in the US marketplace. AMPS has achieved a notable knowledge base and now seeks to share this knowledge with the traditional European healthcare field and those operating in the areas of innovation and research. To meet this goal, **CardioCalm** developed two products, both using up-to-date AMPS technology.

The first is **Telecardiology System**, which allows the acquisition, transmission, and review of a resting, diagnostic, 12-lead ECG, and in full compliance with the guidelines of the International regulatory bodies. From an architecture perspective, the **CardioCalm** Telecardiology System delivers three key elements:

- a SITE, where the ECGs are collected (e.g. a pharmacy)
- a SERVER, where the ECGs are received and stored
- a READER, where the ECGs are reviewed (either at the site, or remotely read)

At the core of the **Telecardiology System** is AMPS's **WebCor**, a web-based ECG reading software that allows the cardiologist a comprehensive reading of the ECG data, anytime and anywhere. **WebCor** applications gives the cardiologist greater flexibility and it is a **CE** approved medical device.

The second product is **CloudCor**, a web APIs platform. This product provides ECG analysis services via the Internet. **CloudCor** uses proprietary methods to support many applications, including it can generate ECG images to the analysis of continuous ECG for the detection and classification of all the beats, the beats measure and the analysis of arrhythmias.

Recently, **CardioCalm** was chosen by some of the major Italian Cardiologist departments and Telemedicine Centers as their technological partner for the telecardiology services. The use of **CardioCalm** has enjoyed a very fast growth rate regarding both in the number of ECGs analyzed, and with the number of customers enrolled in AMPS telecardiology services.

**CardioCalm** was recently presented to some partners and corporate friends in a meeting to discuss the technological solutions in the field of healthcare for chronic patients. This presentation was made at the new AMPS offices located in Montichiari (Brescia – Italy).



*CardioCalm's partners visiting the photo exhibition "The Age of Elegance" and the Museo Lechi in Montichiari (Brescia - Italy).*





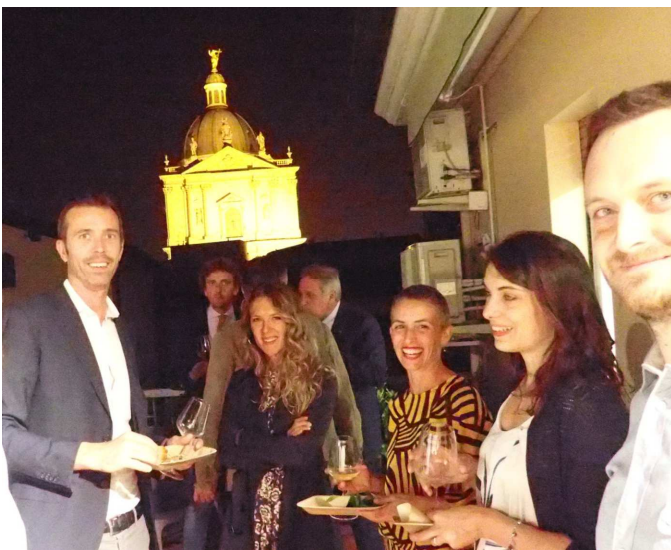
*Fabio Badilini talks about the technological solutions for taking care of the chronic patients with Claudio Cuccia, head of the Fondazione Poliambulanza Cardiovascular Department, one of the major Italian hospitals that have partnered with CardioCalm for their telecardiology service.*

## ***Products News***

### **Looking forward**

In Q4 we are planning to release a new version of CER-S (v.3.2.0), including the following revised platforms:

- Continuous ECG beat detection and classification, including the fully renewed ABILE algorithm, with new long analysis capability, up to 30 days.
- ECG beat editor
- Arrhythmia detection and Arrhythmia editor
- ECG Beat Measure, for measuring averaged time-templates ECG complexes, including ST-displacement assessment.
- Report generation.



*Welcoming meeting with CardioCalm partners in the new offices located in Montichiari.*