

The AMPS Insider

An AMPS LLC Magazine

The AMPS Insider is a quarterly magazine dedicated to all AMPS' partners and customers. Published by AMPS, it provides news and information about AMPS' products and initiatives.

#2 - 2Q2021

Executive Overview

Decentralized Clinical Trials: the new frontier for drug assessment? Product News.

Editorial

Covid-19 changed everything. In the context of clinical trials, the pandemic boosted the implementation of decentralized trials which, despite groundbreaking advances in basic and clinical science and technology, was still staggering.

In many type of trials (e.g. cancer studies), decentralization makes a lot of sense, and there is really no reason to ever go back. Central labs and new industry entities (such as providers of home-based sensor technology) are already making giant steps forward to provide the infrastructure of a complete decentralized clinical platform.

The pharma industry at large is also on the move and a [Decentralized Trials and Research Alliance](#) (DTRA) has been recently established. This global cross-industry coalition includes more than 50 organizations from the pharmaceutical arena and aims to increase access to clinical trials and research for all patient populations.

Together with its customers and technology partners, AMPS is fully engaged and prepared to face this new challenge. While our software solutions are already routinely deployed within telemedicine contexts and are fully compatible with a decentralized clinical trial model, we also advanced in our device-agnostic philosophy, reaching agreements with manufacturers of patch devices, which are a fundamental part of this revolution, to insure the full compatibility with the AMPS software tools.

On the specific of the cardiovascular signals, and depending on the type of study, in the near future it will be important

to seamlessly provide (within the same platform), both real-time data (e.g. from Holter device and/or patches) with the inclusion of non-ECG signals (e.g. blood pressure or respiratory rate), and the traditional diagnostic 12-lead ECG. AMPS has a tradition of providing solutions to analyze such data (see our [Heartscope](#) product) and is therefore perfectly positioned to respond to the needs of the industry.

As usual we encourage our customers to stay in touch with AMPS and suggest ideas for articles or comment on published articles. It is very important to our team to listen to our current and future customers, so please send your ideas and comments to marketing@amps-llc.com

Products News

As we announced in the last issue AMPS obtained the certification of the Continuous ECG Recordings Suite ([CER-S](#)) for the use in the healthcare market both for the US (510K) and European markets (CE).

Recently a major release of CER-S (v 4.2), also received CE and FDA clearance. This version greatly improves the prior certified version with an enhanced graphic interface which provides a smooth and faster editing of automatically detected arrhythmic events.

Looking forward

We are at work on:

- A new release of CER-S (v4.3) with several enhancements including optimized multi-day reporting, increased limit for standard analysis on long recordings, superimposition display.
- A new version of ViewEcg Web allowing for display of ECG traces in real-time.
- The integration of CineECG (<https://www.ecg-excellence.com/2960/0/products/general/0/cineecg>) in CalECG for enhanced ECG reporting.

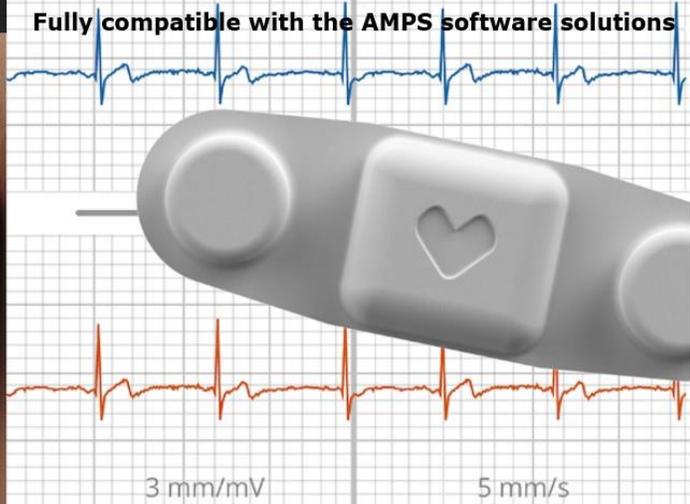
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MULTI-VITAL ECG PATCH
72-hour reusable and rechargeable multi-function patch
Fully compatible with the AMPS software solutions



3 mm/mV 5 mm/s

Troubles with your ecg data?? AMPS can help you!

- ❖ Conversion of ecg paper traces (or scanned images) into digital HL7 FDA xml ecg files
- ❖ Conversion of proprietary digital ecg files formats into the HL7 FDA xml ecg format
- ❖ Validation of HL7 FDA xml ecg and continuous recording ecg files prior to submission to the FDA ECG Warehouse
- ❖ Submission of HL7 FDA xml ecg files to the FDA ECG Warehouse
- ❖ Secondary analysis of studies via state-of-the-art analysis such as: HRV, Holter Bin, B2B.

For further information or questions please contact: AMPS.Services@amps-llc.com

DMS SERVICE

The Brand New Revolutionary myPatch®sl Holter Recorder is Here.

Finally, a patch Holter monitor for the Active Lifestyle.

Now your patients can enjoy a wireless, light-weight, water proof Holter recorder that makes every day life a breeze. Prominent features include 3 channels of continuous ECG, multiple electrode size options, tap-tap event markers, internal clock, rechargeable battery and compatibility with most major Holter analysis systems.

Fully compatible with the AMPS software solutions

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