

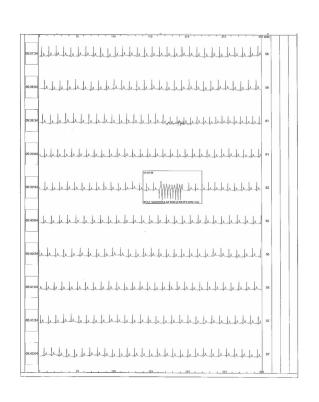
Full-Disclosure, High Resolution ECG and Multi-Modality Devices

By Joseph Yanes

WHY DOES FULL DISCLOSURE MATTER?

Every Beat Monitored

Full Disclosure is the reproduction of every single beat, of every single minute of the day. This method gives the specialists the ability to have access to every single beat. The ability to analyze the data in its purist form is an invaluable tool when making a diagnosis. Any arrhythmia can be quickly and easily verified for accurate diagnosis. ACSD provides a quick and easy approach in the review process—quick and easy review of full disclosure.



"Human waveform is more detailed than the human fingerprint. That is why it's so important to have a cardiologist review ALL the data to make the correct diagnosis."

- Joseph Yanes, Vice President of ACS Diagnostics

True Full Disclosure

Many Holter companies claim to offer full disclosure, but the structural foundation of their methodology is very cumbersome. An experienced doctor knows that true full disclosure is one hour per page. A full disclosure page should be presented as a full report, with every hour presented. There should be min and max heart rates on every page, and every single beat should be able to be viewed in context. Most companies simply do not provide that information—which in most cases exposes their errors in the automation process or A.I. counters.

TEMPLATING

The majority of companies use a method called templating. This method was developed by an engineer to get through what he thought was standard redundant ECG waveform. The ECG is run through filters, to identify certain arrhythmias and tabulate the arrhythmias into individual "buckets". At the end of the analysis process the software would count how many unique beats or arrhythmias are in each bucket. The software would then report what the rhythm was and provide certain samples or representative strips. There's no medical professional that would blindly trust a self-interpreting ECG machines report without reviewing it, so why would vou?















To a cardiologist, ECG waveform tells a whole different story. The ability to store and recreate reviewable and verifiable full disclosure from the recorded data is crucial when making a diagnosis.

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The ability to analyze every single beat in context is invaluable. Yet, most ambulatory Holter device manufactures rely on the artificial intelligence (AI) within the device to make decisions when it comes to providing the specialists the ECG waveform.

Algorithms & Al

Depending too much on algorithms can be risky. We all know the story of self-interpreting ECG machines, where you have a patient lying still on the exam table wearing ten electrodes for an average of 5 minutes and the automatic interpretation is wrong. Every single cardiologist is going to correct and edit that data prior to reporting the results. They will never take that self-interpretive report verbatim and sign their name to it. Holter software is terribly similar. The only difference is that the patient is mobile for twenty-four hours; all while utilizing only three electrodes: white, black and red.

DOC-IN-THE BOX TECHNOLOGY

An auto-analysis, or "Doc-in-the-Box" takes ECG in pieces, separating it into sections as it records it. When an arrhythmia occurs, the ECG is pieced back together, in an attempt to give you a glimpse of what the algorithm caught. Effectively, the software is trying to replace the cardiologist, and create an "easy, sellable" process for Holter, Event or MCT.



It is essential to have the ability to see every raw, unfiltered beat in context.

The catch that these manufacturers don't want the doctor to know-they receive the lion's share of the profit. Because the data is filtered through the algorithm first, and not the physician's office, each test is more profitable for the manufactures-not the specialist.

You can imagine the errors that occur if you are depending on an Al/templating software. Auto analysis, done by an algorithm, and not by the cardiologist, is **incomparable** to original raw, unfiltered ECG. ECG is an essential factor in a diagnosis. You can't make life and death decisions with "doc-in-the-box" technology or the more chic— "Al". It is essential for the physician to have the ability to see every raw, unfiltered beat in context.



In conclusion, full disclosure is essential, beneficial and enables a more accurate diagnosis. Long term holter patch companies and big tech are trying to stomp on the specialty of cardiology. But there is a fact that has remained true for the 30 years I've been in the industry: You cannot remove the cardiologist from the ECG diagnosis.

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THE IMPORTANCE OF HIGH RESOLUTION EKG

Quick, Easy & Accurate ECG

To a cardiologist, the reproduction of EKG is more detailed than a human finger-print. When you have general practitioners interpreting waveform, they don't pick up certain idiosyncrasies the way a cardiologist would. Cardiologists need and appreciate a higher resolution reproduction of that waveform. When they can identify the exact location—they can identify exactly what is occurring. Simple things, like P—wave wanders, notching of an R—wave, and right and left bundles are very telling when diagnosing a patient.

A lot of lower resolution devices and technology (including some popular ones today, like the patch technology), are not producing that high quality resolution. The diagnosis is not as accurate as a higher resolution product.

High resolution provides a quick and easy diagnosis. Doctors today don't want to spend a lot of time in a report format. They want to quickly and easily look at a report format in its truest form, the highest waveform resolution, and diagnose what is happening. A quick, easy, and accurate report is powerful.



High quality waveform is important and should be a necessity when diagnosing any type of patient ECG. EKG machines sample at 1000 samples per second for a 5 minute test. ACS Diagnostics is unique in our high resolution. We are reproducing the waveform at over 3000 samples per second. Being able to pick up the true pacemaker spikes is crucial. Being able to pick up high frequency response is crucial for diagnosing A-Fib, wandering P waves, notching of R waves, bundle branch block, left and right bundle; these are easily identified with high resolution waveform.

"High resolution gives the doctor the ability to get a report and make a quick and easy diagnosis."

- Joseph Yanes, Vice President of ACS Diagnostics

Waveform resolution is best described with an analogy of a pacemaker. A pacemaker fires at .5 milliseconds. If the physician is sampling anything at less than .5 they wont see the pacemaker spike. It will appear an augmented signal, a strange R-wave or waveform. Cases like this require devices and software that reproduce that waveform at higher samples per second. ACS Diagnostics are able to produce that waveform in its truest form, reproducing .27 samples per second. ECG machines sampling at over 1000 samples per second, are able to give you a very clean, clear story of what is happening.

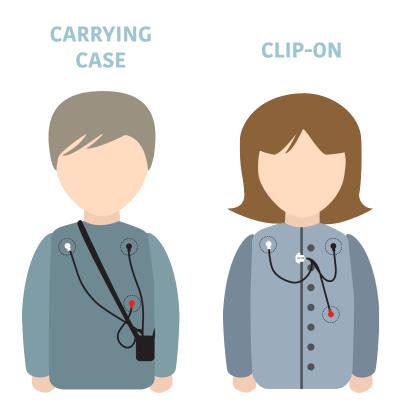
HOLTER MONITORING

Re-usable vs. Disposable

Carrying cases, straps and lanyards are things of old. These are outdated, and patients don't want to wear them anymore. Simple, lightweight products that make the patient comfortable are the new normal. A product that hangs off the electrodes is a thing of the past. Patients want products that can be worn very discreetly or attached under a shirt.

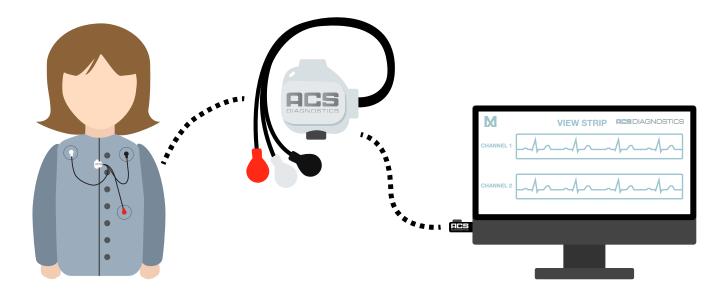
There are a lot of disposable devices out there, but that is coupled with a waste of money and products. Re-useable devices are environment friendly-and fast becoming a necessity. These not only offer up front cost savings but allow the doctor a lot of control.

The device is put on the patient and the patient returns with the same device. The results can be grabbed quickly on download. The patient doesn't need to charge or change the configuration. The electrodes can be modified based on the anatomy of the patient. These factors are all tremendous benefits to the majority of doctor's offices.



BENEFIT TO THE DOCTOR

The benefit of a reusable device is tenfold. The return on investment is increased, as well a quicker turn-around of patients. No more waiting for almost a month to get results. Download results, quickly recharge, and send the product out on a new patient within the hour. Multiple leads allow for adaption of the device based on the body type. The doctor can deliver a diagnosis and treat a patient within a day of the patient's initial problem and visit. Not only is the return on investment greater, but the patients receive a higher quality of care.



ACSD'S CLIP HOLTER MONITOR

ACS Diagnostics' Clip Holter Monitor is small, reusable, and flexible for all patient body types. The battery recharges in around 10 minutes. The flashcard is removable and can be changed out with a new one for an easy turn-around. Everything is easily available and can be simply wiped down and put on the next patient. ACS Diagnostics can send the device direct to patient's homes with online tutorials that describe how to wear the device, what to do when showering, and what to do when applying and removing the device. The Clip is an easy-to-use product, that patients and doctors both love.

BENEFIT TO THE PATIENT

Feedback from physicians has shown that patients dislike the disposable monitors both because of the long duration and the skin irritation. Once applied, the patient cannot adjust the disposable without disrupting the test. The device is sticking to the patient's skin up to 14 days in duration.

A Holter has multiple leads than can be adjusted without disrupting the test. The device can be removed if the patient has to shower or anything else, only recording artifact, and not pausing the test. The electrodes are more comfortable for the patient, bearing only the small weight of the lead, and not the entire device which pulls against the skin.

In addition to being uncomfortable, the disposable device takes a considerable length of time to return results. A standard disposable device is returned to the doctor's office by the patient, then shipped overseas to a company that scans the results. Once the company receives the results, the arrhythmias are put into reports and shipped back to the physician. This process often takes almost a month.

In contrast, re-usable holter monitors offer rapid results, when the data can be downloaded and reviewed in the physician's office. Holters ensure that any arrhythmias can be caught quickly and efficiently.

With high turnaround, coupled with full disclosure, the patient is able to receive quick and efficient care.

THE POWER OF A MUTLI-MODALITY DEVICE

Continuity of Care

Rather than making a decision on what device to put on a patient based on the insurance, having a device that offers all modalities is the answer. Regardless of insurance the patient can get the highest quality testing device available.

With the same device, start with a 12 Lead ECG, run into a holter and then an MCT, depending on the symptom or the events felt. The physician has complete control-using only one device.

If you decide to use a holter monitor from one company, an event monitor from another company and a MCT monitor from another company; you forfeit continuity of care. Your patient has to come in for multiple types of test, and often times results take longer to acquire. With a multi-modality device, there is efficiency and continuity of care.

FESDIAGNOSTICS

Continuity of care allows the patient and physician to work together to get the an-

swers they are looking for.

"Why am I feeling the way I am?"

"How many tests do I have to take?"

"How many times do I have to come into the office?"

If a patient can remain at home and have several different tests on one device, that

will save the patient time and doctor time, and allow the physician to get to the

diagnosis quicker.

This is continuity of care. The patient doesn't have to keep returning to the doctor's

office. They don't have to come back to sit in the lobby to wait for another EKG, or

put on another device. Continuity of care streamlines the patient encounter, enrich-

ing both the doctor and physician experience.

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About ACS Diagnostics

ACSD has proved our necessity in this market. We have competed with the big boys and succeeded. Whenever the decision is given to a doctor or cardiologist, we win every time. We may not be the cheapest product, but we can confidently say we are the most accurate product. There are a lot of bells and whistles on a lot of other devices, but we are better at giving our customers an entire package of quality, continuity and excellence in cardiac monitoring devices.

"Quality Products for those Who Care"; the tagline for ACS Diagnostics, came out in 1994. The significance of this phrase began back when companies were using cassette tapes to record ECG. These ECG recording tapes had a certain amount of data you could record on them. We were the only company that held firm to a certain resolution of about 3000 samples per second. When you had pacemaker activity or high frequency responses like pediatric waveform, it was very crucial to record at over 500 samples per second just to capture the waveform.

None of our competitors were doing it; the closest competitor at the time was sampling at 186 samples per second. It wasn't even close when it came to waveform reproduction. Over the years, ACS Diagnostics has perfected the ability to provide high quality ECG. With human waveform being detailed than the human fingerprint, it is so important to have a cardiologist review ALL the data to make the correct diagnosis.

ACS Diagnostics is a company committed to designing, developing and manufacturing high quality cardiac monitoring devices.