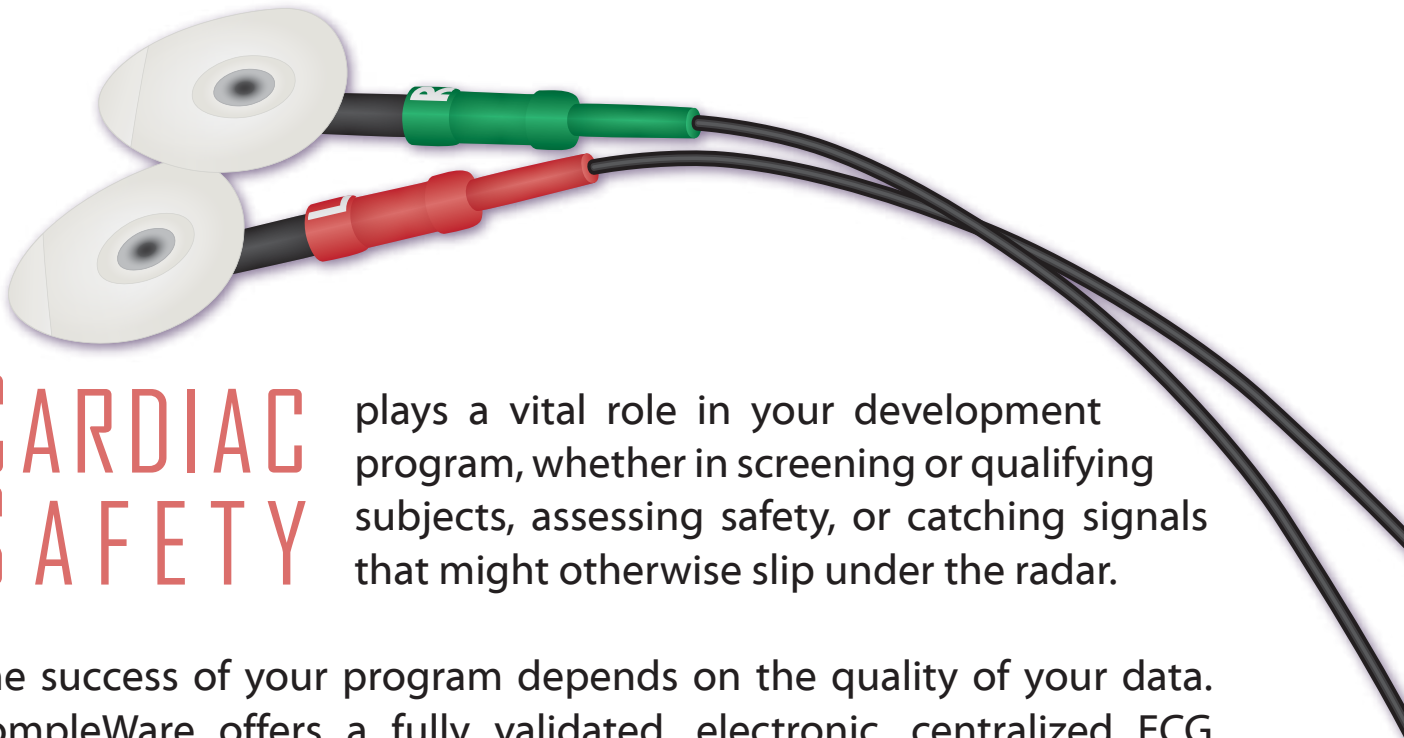




DON'T MISS A BEAT

JUMP START YOUR CARDIAC SAFETY PROGRAM WITH COMPLEWARE®



CARDIAC SAFETY

plays a vital role in your development program, whether in screening or qualifying subjects, assessing safety, or catching signals that might otherwise slip under the radar.

The success of your program depends on the quality of your data. CompleWare offers a fully validated, electronic, centralized ECG system integrated directly in our eCRF software. With CompleWare, the right cardiac safety solution for your program is a heartbeat away.

STANDARDIZED, DURABLE, PORTABLE DEVICES

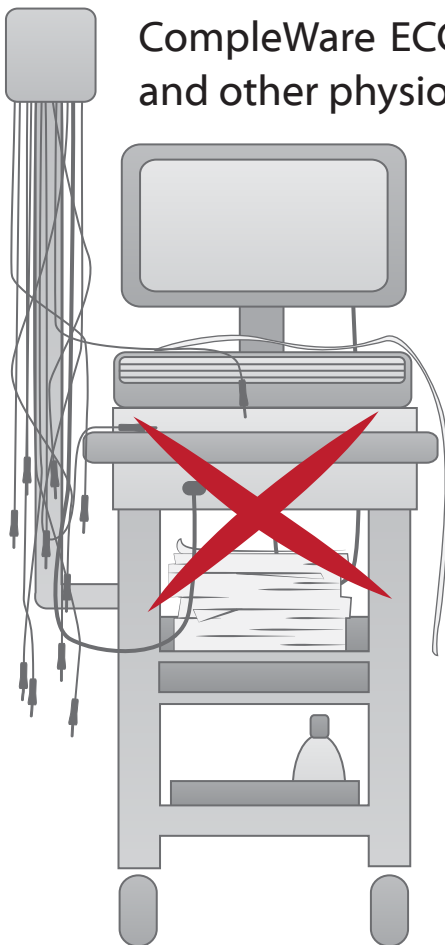
CONNECT TO ANY WINDOWS COMPUTER

With multiple studies going on at once, space for each sponsor's laptop, ECG, and other equipment became a real issue for our site, especially because we needed the ECG equipment to be located near the exam table so the leads could reach to the subject.

~Site Coordinator

WHEN IT COMES TO

data acquisition equipment, less is more. Our ECG units are small, lightweight, portable, 12-channel devices that connect to any Windows computer via USB.

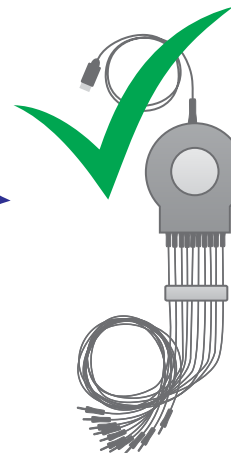


CompleWare ECG units connect to the same laptop used for eCRF and other physiological data collection. All equipment is FDA 510(k) approved, CE marked, and thoroughly tested before shipment to sites. CompleWare works with many trusted vendors to ensure the correct, standardized equipment and supplies are always available for your program.

THEIRS



OURS



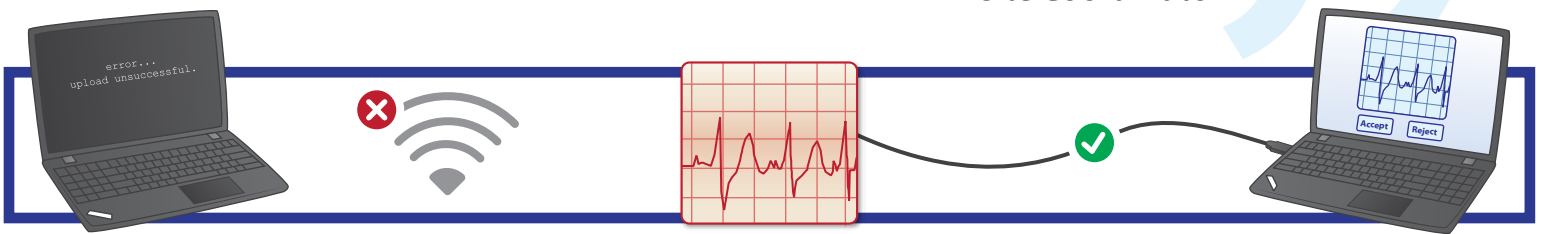
- + Small
- + Lightweight
- + Portable
- + USB connection
- + FDA 510(k) approved
- + CE marked
- + Thoroughly tested



FAST AND EASY CAPTURE INTEGRATED IN eCRF

One Sponsor's ECG equipment had a small wireless transmitter that the leads plugged into, and this device transmitted the ECG data collected via a wireless signal to the laptop the Sponsor provided. The disadvantage was that the unit was very sensitive to other electronic devices in the exam room so we always had to collect subject and staff cell phones and remove them from the room.

~Site Coordinator



CONNECTING DIRECTLY to the laptop via USB avoids potential problems with wireless transmission or interference with other electronic equipment. With a direct connection for capture and uploading, there is no need to remove a flash card or to take the device to another computer for data upload.

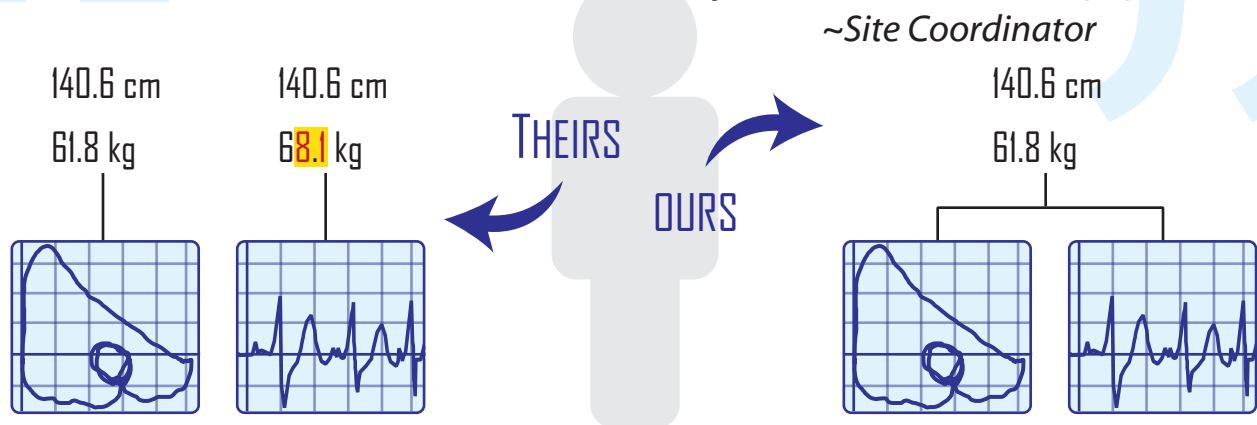
Capturing an ECG in our software, CompleClinical®, is as close to foolproof as you can get. It allows only the pre-configured number of ECGs to be acquired and will alert the user of problems during acquisition. ECGs are captured directly within CompleClinical so there is no need to document results in a separate eCRF. ECGs are transmitted as soon as the site saves the tracing. Instantaneous transmission allows for quick identification and response to any errors via query from within the software or direct communication to the site.



CONSISTENCY THROUGH SIMPLICITY

ONE FOR ALL, AND ALL FOR ONE

Some Sponsors providing ECG capabilities require inputting the demographics in their equipment separate from the demographics entered for the spirometry equipment. This can lead to an increase in user data entry error and less standardization for that subject across all sets of equipment.



USE OF DIFFERENT

ECG machines across clinical sites means more “noise” in your data. Use of dissimilar measurement algorithms can lead to disproportionate screen fails and incorrect randomizations.

Standardizing your equipment and utilizing a team of highly qualified technicians and physicians will ensure high-quality capture and interpretation of your centralized ECG data. With CompleClinical, all ECGs are assessed using the same report form configured exactly to study inclusion/exclusion criteria.

ECG evaluation criteria and processes are clearly defined prior to study start and central reviewers such as cardiologists evaluate tracings for quality as well as study-specific parameters. Additionally, inter- and intra-reader variability assessments are completed throughout the study to ensure data integrity.



WORK FLOW THAT TRULY FLOWS

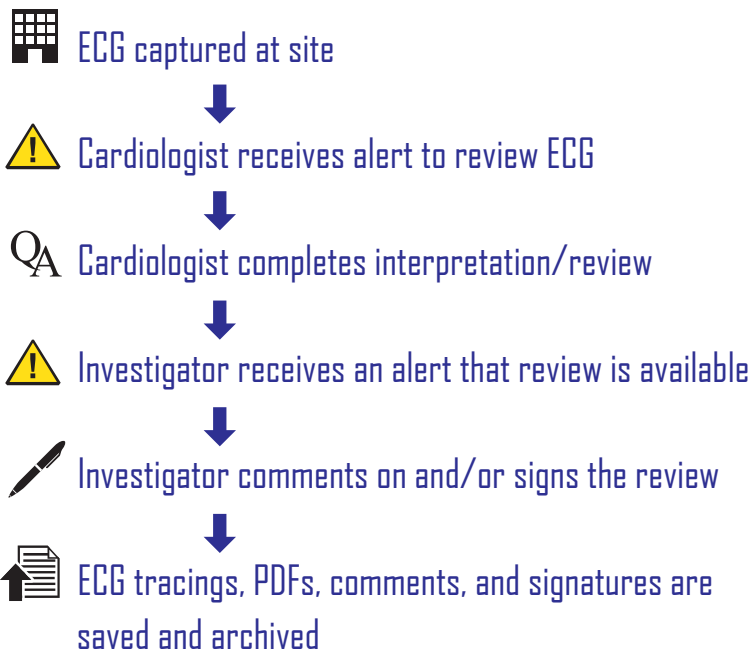
ALERTS TO CARDIOLOGISTS AND INVESTIGATORS

Keeping track of all steps in the ECG data acquisition process manually could become burdensome quickly, especially with a large number of subjects. Getting automated alerts when an ECG is ready to be signed, or when a query has been issued, helps keep the process moving efficiently and smoothly.

~Site Coordinator

COMPLECLINICAL ECG data to be accessed anywhere in the world on the Web, fostering prompt and efficient review. Online availability of data provides timely access for central reviewers of ECG data, as well as access for CRAs performing remote monitoring.

ALLOWS ALL



ECG QA Report

ECG Machine Read

H Rate 58	RR 1222	P 104
PR 178	QRS 87	QT 430
QTcB 388	QTcF 405	P Axis 3
QRS Axis 72	T Axis 31	

Interpretation

Abnormal But Not Clinically Significant

Comments

ECG QA Report

Investigator Signature

Accepted
Investigator: David R. Jones
Signature Time: 02/16/2018 11:13:46
Investigator Interpretation: Agreed



No Lost ECGs

FULLY TRACEABLE, 21 CFR 11 COMPLIANT SYSTEM

Some ECG systems have few built-in safeguards and allow you to capture as many ECGs as you want, which could lead to subjects being enrolled or randomized in error. Other systems require you to upload the data from a separate flash card that can be lost or overwritten.

~Site Coordinator

ONCE AN ECG IS

captured in CompleClinical, it is immediately recorded in the audit trail. CompleClinical's meticulous audit trail captures all accesses or attempts to access the system, all data entries, and any actions to change or delete data.

Users cannot delete ECGs within the software, they can only accept or reject a tracing. The data for a rejected tracing remains accessible. CompleClinical is fully compliant with 21 CFR Part 11 regulations for electronic signatures, the predicate rules, and with the published guidance from the FDA. Capture ECGs with CompleClinical and never lose another ECG!

Audit Trail

Accepted Log

User Name: David Jones

UTC Time: 02/14/2018 15:02:17

Comment: Acceptable tracings

Rejected Log

User Name: David Jones

UTC Time: 02/14/2018 14:51:41

Comment: Lead off

Close

ECG	ECG Date	Status	Review ECG	Review QA Report
1	2/14/2018 8:41:25 AM	Rejected	<input type="button" value="Review"/>	<input type="button" value="New Report"/>
2	2/14/2018 8:58:48 AM	Accepted	<input type="button" value="Review"/>	<input type="button" value="Signed Report"/>

