

12-LEAD ELECTRO-CARDIOGRAMS

EXCELLENCE AND EXPERTISE IN ACTION

> Since 1999, **cardiabase** has specialized in the collection, processing, analysis and reporting of ECG data.

> Since 2002, **cardiabase** has been submitting data to the FDA ECG warehouse using the XML-FDA format.

> Our multidisciplinary team of experienced and qualified professionals has always been committed to offering innovative, compliant, site-friendly and cost-effective solutions. Ongoing research and development efforts aim at improving the accuracy of the measurements, reducing turnaround times and exploring new technology.

> The combination of medical, scientific, regulatory and technical expertise has made **cardiabase** one of the global leaders, contributing to more than 500 studies in over 50 countries and 7500 clinical sites.

EQUIPMENT OPTIONS - COMMON ECG DATA FORMAT

> **cardiabase** provides comprehensive equipment rental services including 24/7 support to the clinical sites.

> **cardiabase** has developed a common ECG format and is able to process most digital ECG data formats (Mortara, GE Marquette, Cardionics, Schiller, Phillips...).

> Digital ECG data can also be obtained by extracting discrete ECG' from 12-lead Holter recordings.

> **cardiabase** can process paper-copies of ECG tracings (e.g. for retrospective analyses), using a uniform and consistent methodology.

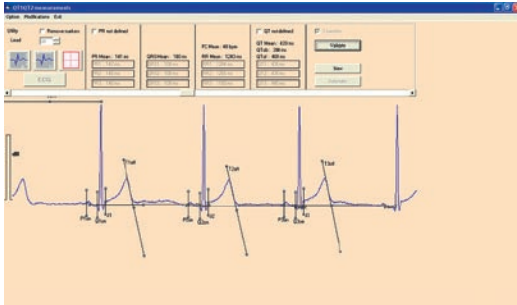


DATA SYSTEMS AND PROCESSES / INPUT AND OUTPUT

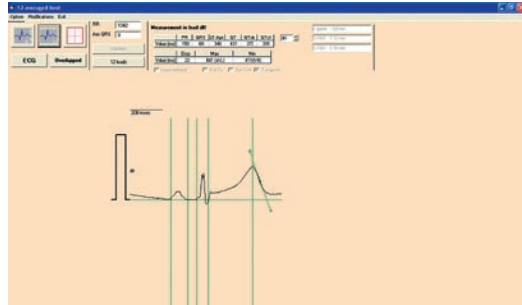
> Cardiologists make serial evaluations of all the ECGs of a patient set by flagging drug-induced abnormalities and identifying qualitative global changes.

> Cardiologist's measurements are systematically checked for intra- and inter- reader variability.

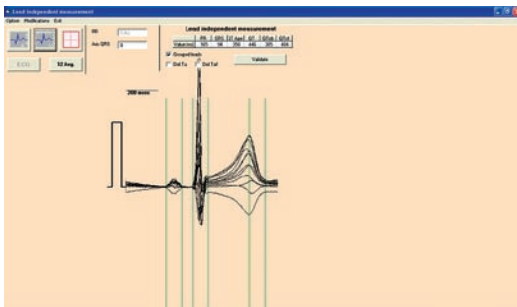
THE ECG SOFTWARE DEVELOPED BY CARDIABASE PROVIDES FOR DIFFERENT MEASUREMENT TECHNIQUES



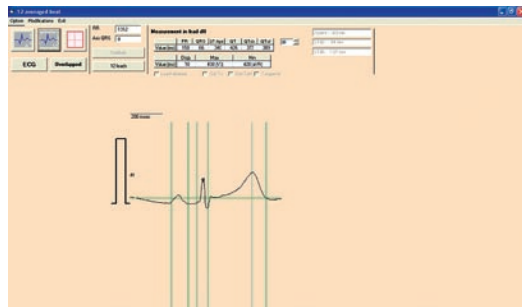
Tangent / Raw beats (3 to 9 consecutive beats)



Tangent / 10-second median complex-single lead



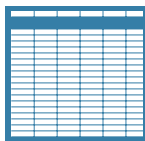
Threshold / Superimposed beats



Threshold / 10-second median complex-single lead

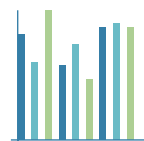
> **cardibase** offers a wide range of data export options, including the FDA-XML format. CardiaBase is certified to submit data to the FDA ECG Warehouse.

REPORTING



INTERIM DATA

As study progresses interim ECG data are provided as electronic files displaying and summarizing results cohort by cohort



GRAPHS

Quality graphs are generated, providing a visual display of the interim results



WEB ACCESS

Secure web access to study results can be set up on request



CARDIOLOGIST CONSULTATION

Senior Management and the Cardiologists assigned to the study are available for medical input, as the need arises and throughout the study