Wireless Telecommunication Symposium (WTS-2014)

April 9-11, 2014

A Wireless *Communicator* for an Innovative Cardiac Rhythm Management (*i*CRM) System

Gabriel Arrobo, Ph.D.
Calvin Perumalla
Stanley Hanke
Thomas Ketterl, Ph.D.
Peter Fabri, M.D. Ph.D.
Richard Gitlin, Sc.D.

Research supported by: Jabil, Inc, NSF Grant IIP-1217306, and the Florida High Tech Corridor Council (FHTCC).

Agenda

- Research Objective
- State of the Art
  - Current Cardiac Rhythm Disease Management (CRDM) Technologies and Systems
- Innovative Wireless Cardiac Rhythm Management (*i*CRM) System
  - Increased Dimensionality
  - *i*CRM Architecture
  - *i*CRM Prototype
  - Expected Benefits of the *i*CRM System
- Preliminary Results
  - Physiobank Database
  - Results with Surface ECG
  - Prototype System Design
  - Demonstrated Benefits of *i*CRM system
- Conclusion and Future Direction

Objective

- The overall objective of this research project is to invent, design and prototype an Innovative Cardiac Rhythm Management (*i*CRM) system that has the potential to improve patient outcomes.

- **Cardiac Rhythm Disease Management (CRDM)** is the field of cardiovascular disease therapy that relates to the detection and treatment of abnormally fast and abnormally slow heart rhythms, and otherwise problematic rhythm disturbances.

State of the Art in Cardiac Rhythm Disease Management

CRDM devices fall into two product classes:

1.Cardiac Rhythm Monitors

- Sense (monitor) only
  - Non ambulatory devices
    - 12-lead electrocardiogram (ECG or EKG)
    - Vector cardiogram (VCG) - external
  - Ambulatory devices
    - Holter monitor
    - Wireless ECG patch

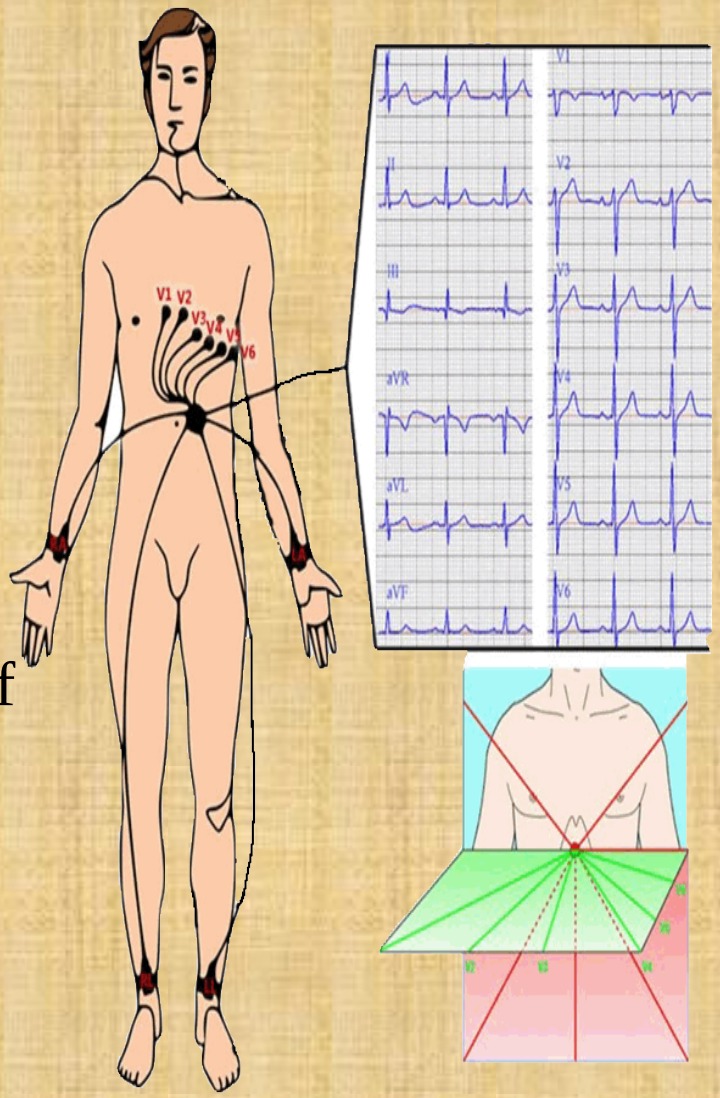
2. Cardiac Rhythm Management Systems

- Sense (monitor) and actuate
  - Pacemakers
  - Implantable Cardiac Defibrillators (ICDs)
  - Cardiac Resynchronization Therapy (CRT) devices
- Actuate only
  - Automatic External Defibrillators (AEDs)

Current [ECG] Monitoring Systems --- The Gold Standard

12-Lead Electrocardiogram (ECG)

- 10 electrodes are placed at strategic points, read the heart's electric activity and produce 12 signals.
- **Dimensionality**: This device presents information about the heart from three different view points (axes or dimensions). Hence, it is known as a 3-dimensional view.



- **The 12-lead ECG** reports the condition of the heart very accurately and is a fundamental tool, the 'gold standard,' for cardiologists.

- Limited to in-office visits and does not capture "big data" over long periods time.

Representative Cardiac Rhythm Monitoring System

Wireless On-body/ambulatory ECG

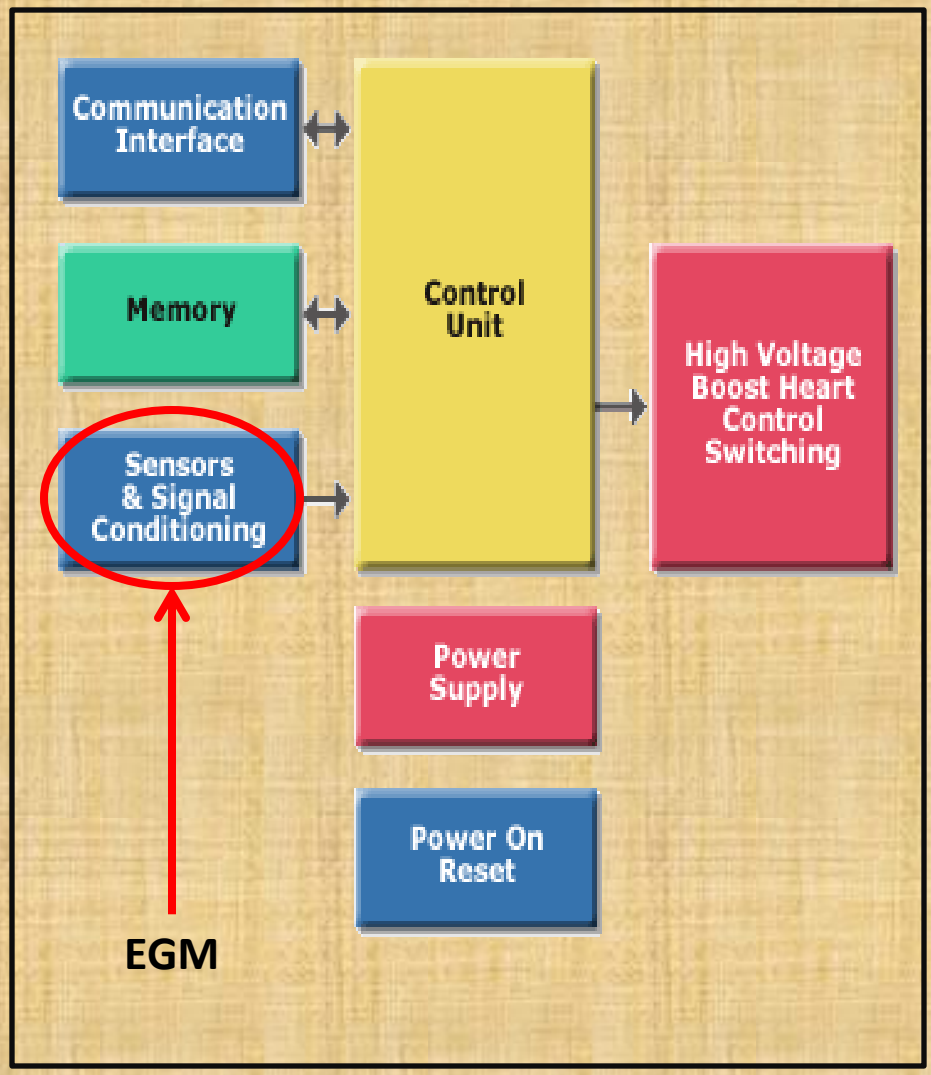
- Is typically a two or three lead ECG.
- Has an adjunct handheld device.
- Reads the ECG information in real time.
- Provides much less information than the 12-lead ECG.

A low-power ECG patch made by *imec*

Example CRM Architecture

Intracardiac Electrogram (EGM):

- Is embedded in the ICD/CRT device.
- Uses 2-3 catheters to sense the electrical activity of the heart.
- Uses this information to make actuation decisions.
- Provides less information than the 12-lead ECG.

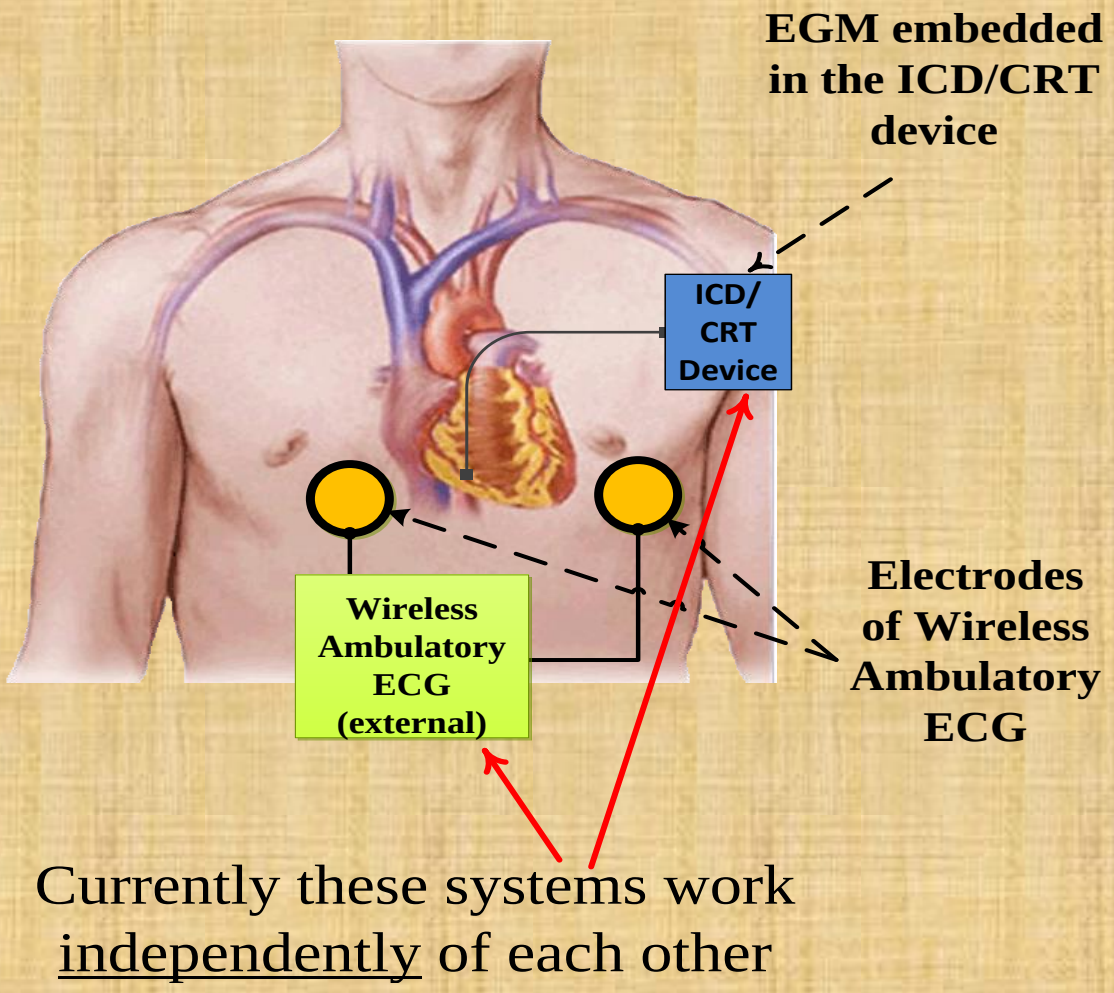


ICD Block Diagram

ICD = Implantable Cardiac Defibrillator
CRT=Cardiac Resynchronization Therapy

Advanced Cardiac Rhythm Disease Management

- As shown in the figure, patients may have more than one CRDM device to collect ECG information:
  - Wireless ambulatory ECG
  - ICD/CRT device (EGM)



Currently these systems work <u>independently</u> of each other

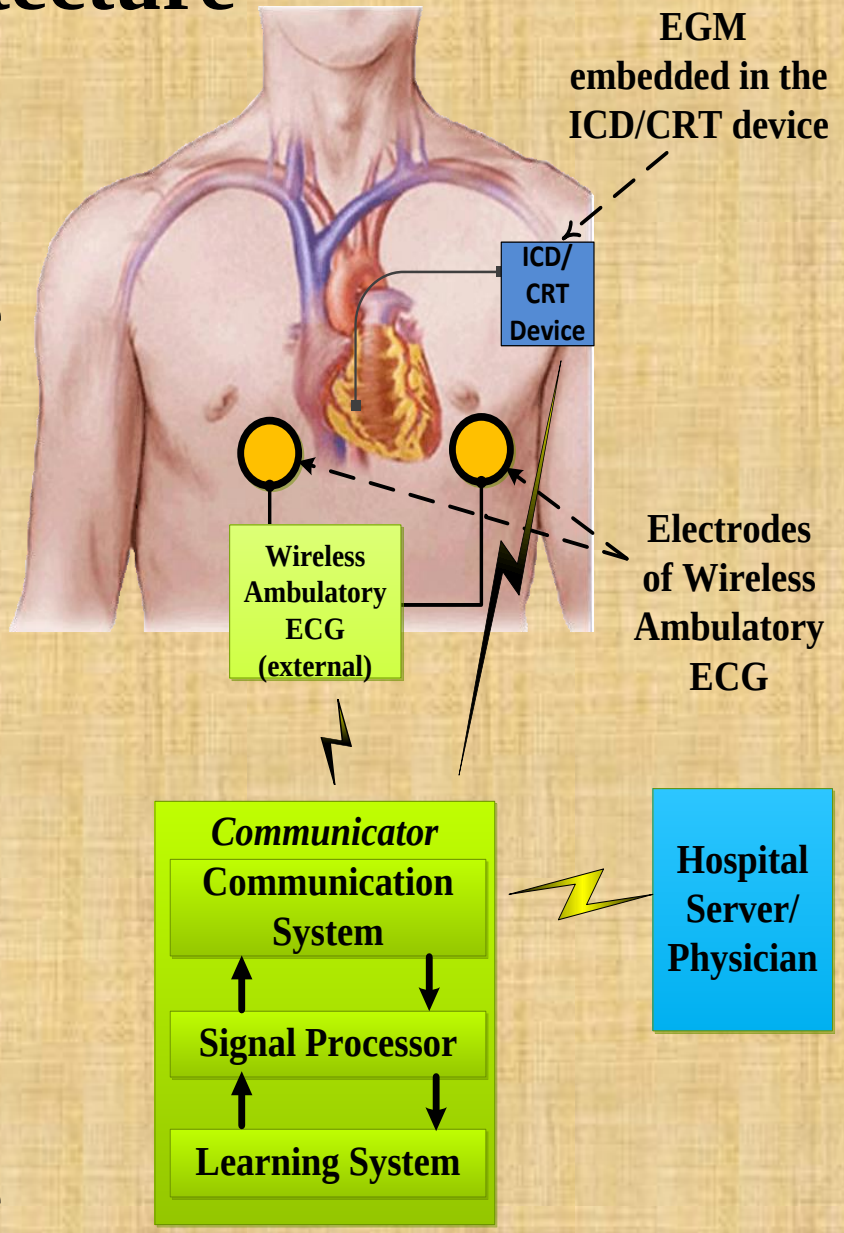
Innovative CRM (*i*CRM) System

Approach: Increase Signal Dimensionality

- Dimension: A dimension represents a unique spatial perspective (view) of the heart's time varying electrical activity.
- In both the EGM and the Wireless Ambulatory ECG, the polarization cycle of the heart is observed in no more than two dimensions.
- This information cannot be used to effectively diagnose as large a range of diseases as can be diagnosed by the information from the 12-lead ECG.

*i*CRM Architecture

- The *i*CRM system consists of a wireless *Communicator*, the Wireless Ambulatory ECG, and the EGM. We can also add additional wireless sensors (e.g., on the back) which communicate with the central communicator.
- The *Communicator* communicates with
  i. ECG and EGM sources
  ii. Other implanted devices*
  iii. Hospital/Physician



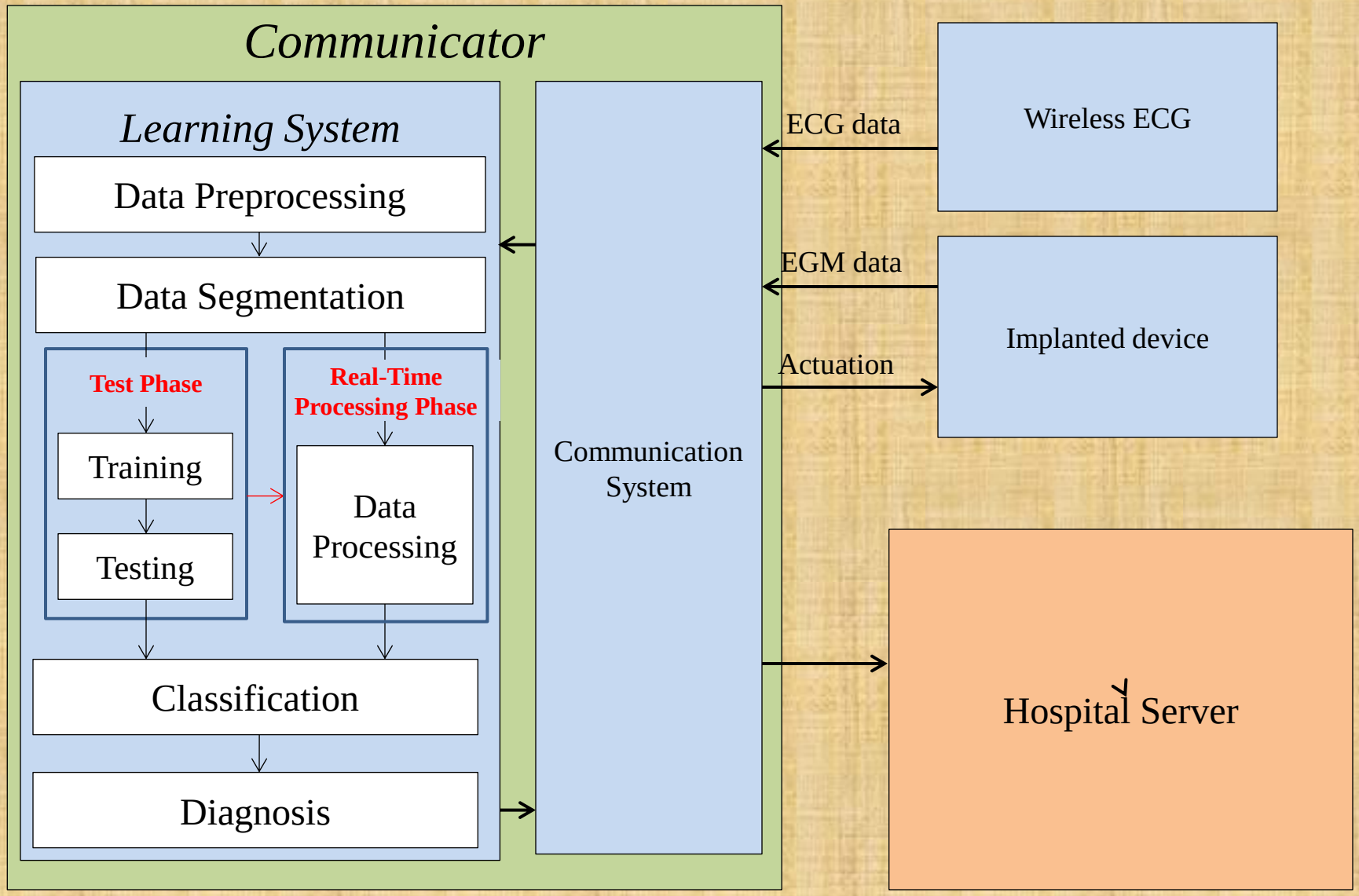
iCRM Architecture

*For example, insulin administration devices, blood pressure monitor, and other implanted device that require information regarding the heart rate and condition.

*i*CRM Architecture (Contd.,)

- The *Communicator* has three subsystems that work together to increase the dimensionality:
  i. Communication System
  ii. Signal Processor
  iii. Learning System
- The *Communicator* jointly processes the EGM and Wireless Ambulatory ECGs information to create an enhanced ECG signal that provides more information.
- The Learning System uses this enhanced information to improve diagnostic and actuating decisions.

Functional View of the *Communicator* LS Algorithm

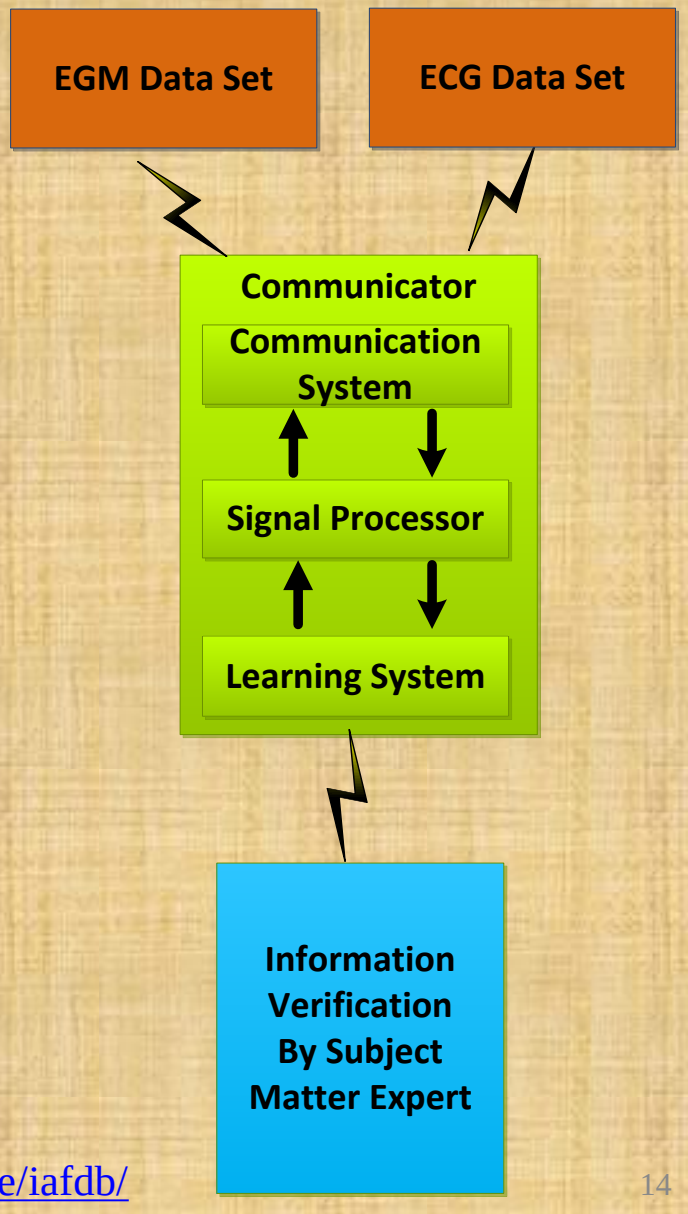


Expected Benefits of the *i*CRM

- Provides innovative information compared to the individual EGM or Wireless ECG signals.
- Increases ICD or CRT performance by making improved decisions via the Learning System or by the (remote) physician.
- Enhanced real-time and remote monitoring of the heart.
- Episode recording and additional reliable diagnosis with recent log of actuator (ICD/CRT) activity (“big data” of the heart).

Prototype Multi-Dimensional *i*CRM System

- Since we do not have access to real-time data from patients, our approach is to emulate these signals from an available database[1].
- The one database that we were able to find with multiple devices consists of ECG information from 8 patients undergoing atrial fibrillation as read by an EGM and a three lead on-body ECG.
- An algorithm will be designed to extract the enhanced, multi-dimensional information input to the Learning System to make enhanced decisions.

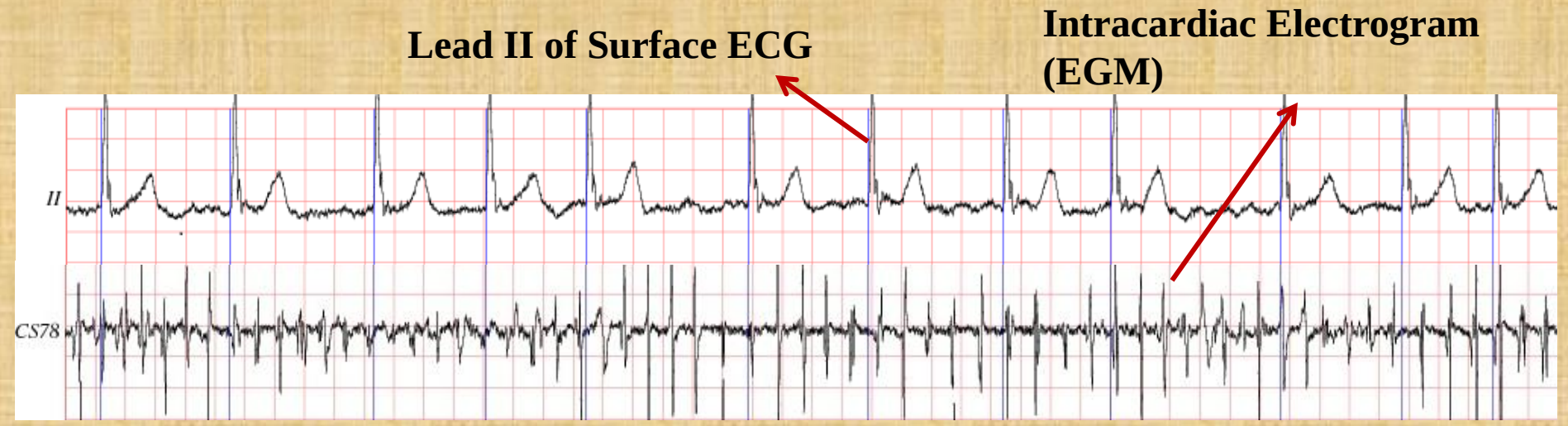


[1] http://www.physionet.org/physiobank/database/iafdb/

Preliminary Results

Physiobank Database

- The database consists of 32 recordings of 1-3 minutes each of 8 patients undergoing cardiac abnormality, either ‘Atrial Fibrillation’ or ‘Atrial Flutter’, at the time of recording. We also have a database for ‘Normal Sinus Rhythm’.
- The ECG signals are recorded from 8 channels: 3 recordings are external (Surface ECG), and 5 recordings are internal (Intracardiac Electrogram (EGM)).



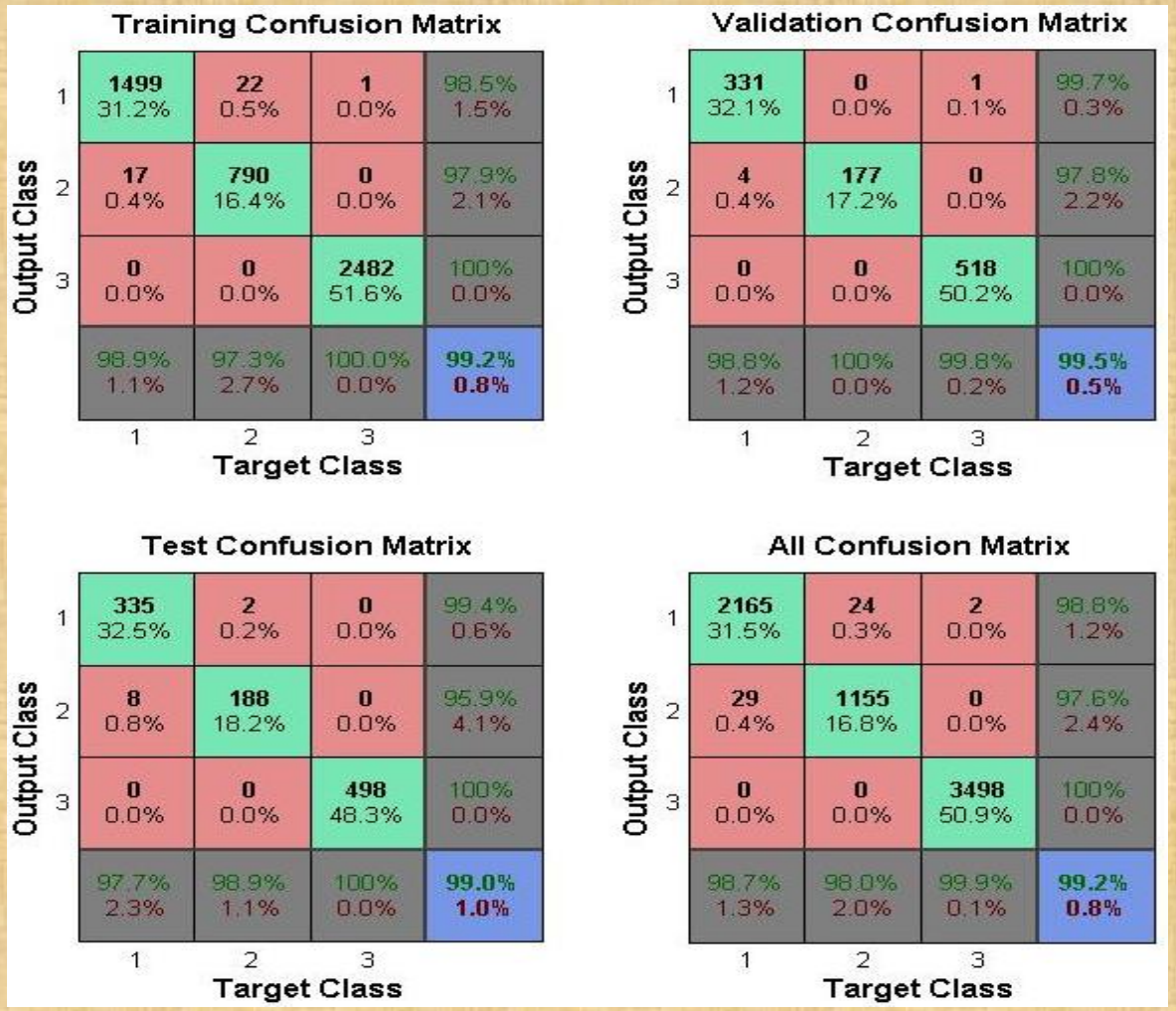
A 10 second recording of the database consisting of ECG and EGM

Physiobank Database (Contd.,)

- We have extracted the data in the form of time samples.
- The ECG of a single heartbeat consists of a wave called the PQRST wave, where the P-wave, QRS complex and T-wave mark electrical activity of different parts of the heart.
- To record the EGM a catheter is placed in specific parts of the heart.
- Depending on the position of the catheter, the EGM gives a detailed view of a portion of the heart.

Results with Surface ECG

- Our initial simulations included using only the external lead II and classes AFB, AFL and NSR for arrhythmia classification.
- The database has been formatted into PQRST wave segments and used to train the ANN algorithm that had ten hidden nodes.
- The input data set contained over 6000 examples and 3 classes of heart condition: Atrial Fibrillation (AFB), Atrial Flutter (AFL) and Normal Sinus Rhythm (NSR).
- 85% of the samples were used for training/validation.



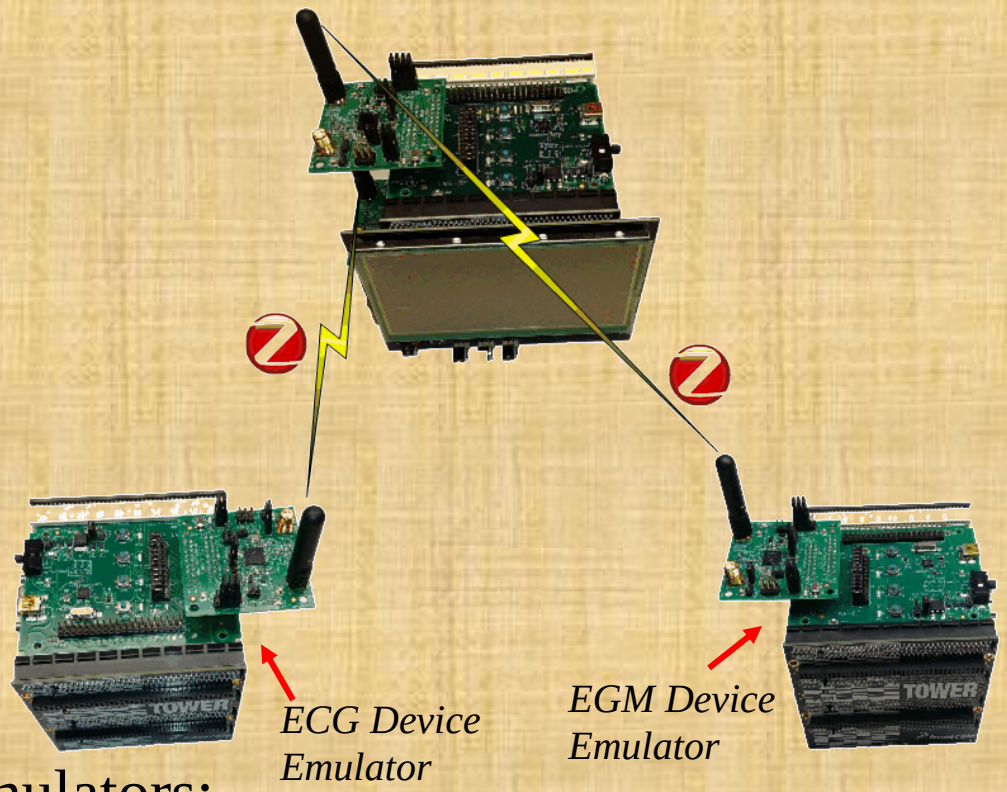
1=Atrial Fibrillation (AFB); 2=Atrial Flutter (AFL); 3=Normal Sinus Rhythm (NSR)

Results with Surface ECG (Contd.,)

- Initial results displayed in the “Confusion Matrix” show how many samples were correctly classified for each class [AFB, AFL and NSR].
  - For the 3320 abnormal cases, there were 53 misclassifications giving an accuracy of 99.2 %.
- The next step of the project is in progress to use both the EGM and ECG data. This involves pre-processing of EGM data so as to remove noise and other artifacts.

Prototype System Design

- Based on the *Freescale* Tower system with 32-bit CPU.
- The *Communicator* receives wireless data from device emulators.
- The embedded *Learning System* performs data analysis using an ANN algorithm.



ECG Device Emulators:

- Use 32-bit microcontrollers to transmit ECG database record stored in memory.

Demonstrated Advantages of *i*CRM System

- We have demonstrated accuracies of more than 99%. This is a high level of accuracy compared to similar results in other research papers.
- We have been advised by several physicians that our algorithms are believed to be better at diagnosing the three heart condition- Atrial Fibrillation, Atrial Flutter and Normal Sinus Rhythm than physicians.
- ANN algorithms can learn patterns and apply to real-time data very well compared to other machine learning techniques.
- Implanted devices are designed to be low-power and have a life time of eight to nine years. The *i*CRM device allows more complexity in signal processing algorithms as power is not of serious concern.

Conclusion and Future Work

- A high degree of accuracy was achieved in predicting atrial arrhythmia in 8 patients using only an external ECG when we used an ANN neural network with 10 hidden neurons with a back propagation algorithm.
- Future work involves extracting information from the EGM that compliments the information of the surface ECG and implementing these algorithms on hardware.