



National Workshop on  
The New Clockwork for Time-  
Critical Systems  
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# Medical Perspective on Time Requirements

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# Coordination or Synchronization of Medical Signals: Categorize by:

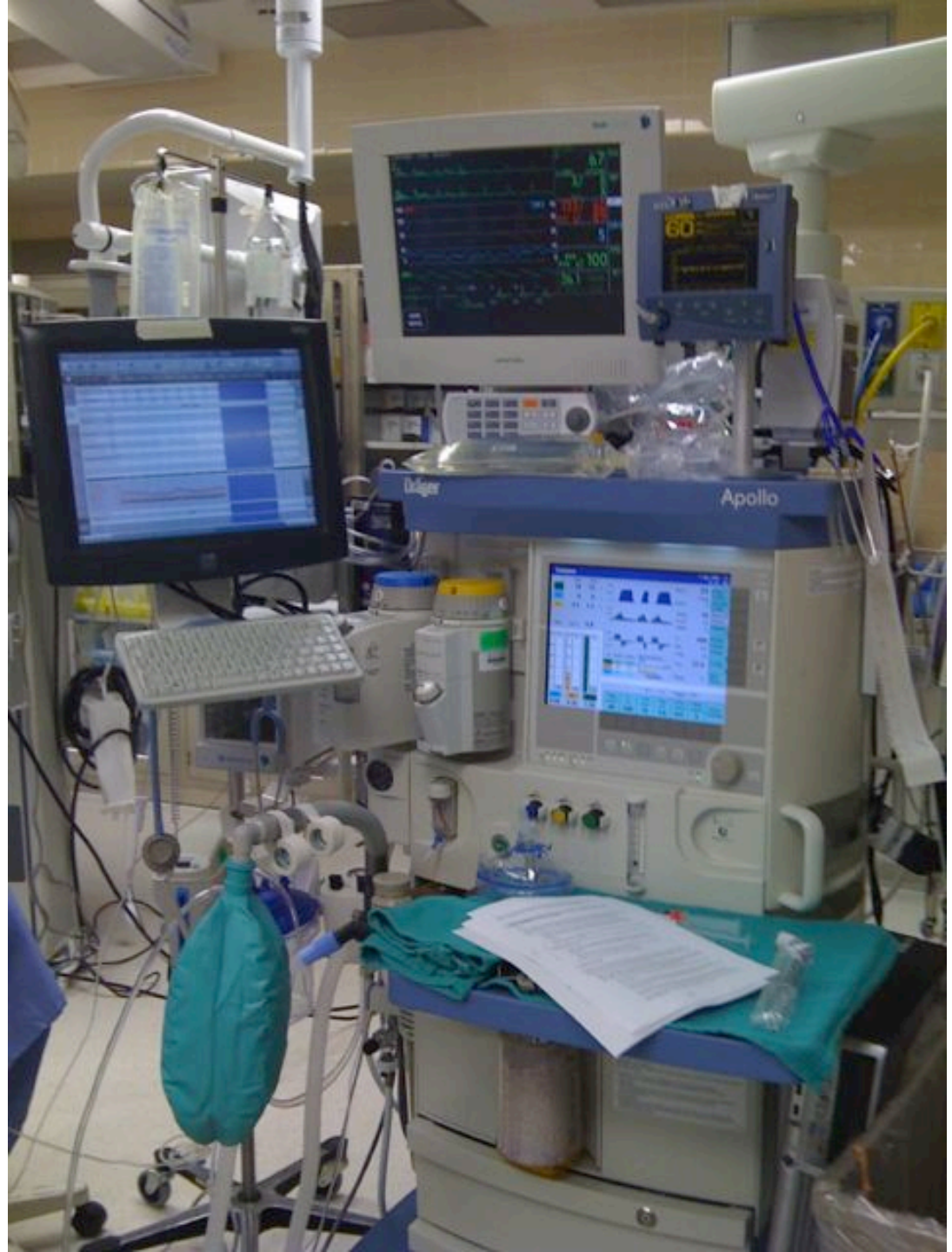
- signals/sensors for diagnosis/monitoring
  - Electrophysiological: ECG, EEG,
  - Non EP: e.g. invasive BP monitoring, blood glucose
- signals/actuators
  - Fast - deliver cardio-version shock
    - Coordinate sensing and delivery in closed-loop
    - Measure results
  - Slower – closed-loop control of BP with IV meds
- Fast / real time – typically electrophysiological
  - Future – other closed-loop energy delivery (photons)



Source: patient    Signal pathway: analog, 1 integrated instrument. Clock Time – At Output



Signal Sources:  
One patient  
Multiple systems  
Electrical and mechanical events  
Different devices; multiple  
manufacturers  
Data synchronization is difficult

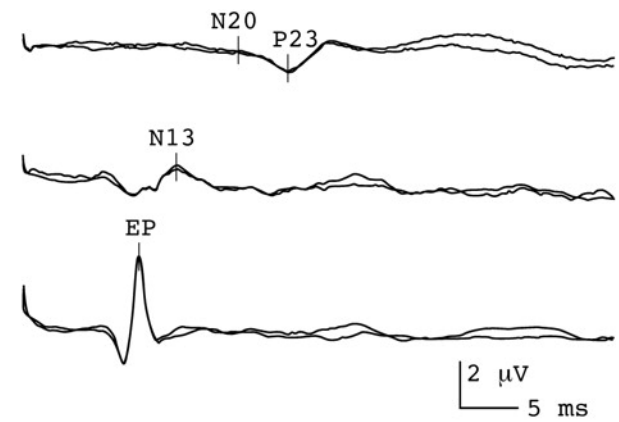
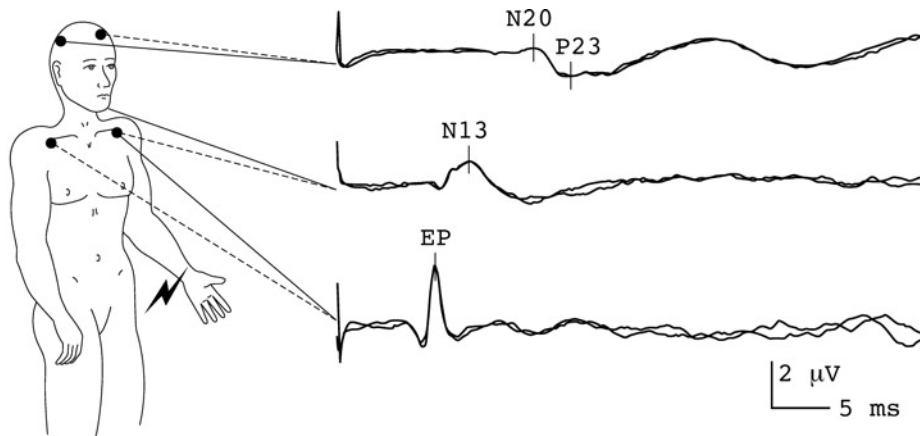




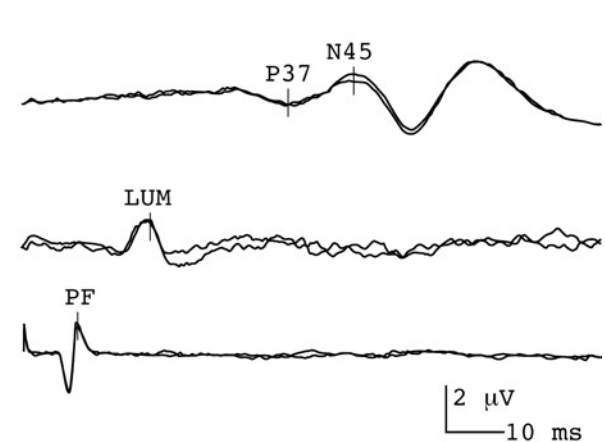
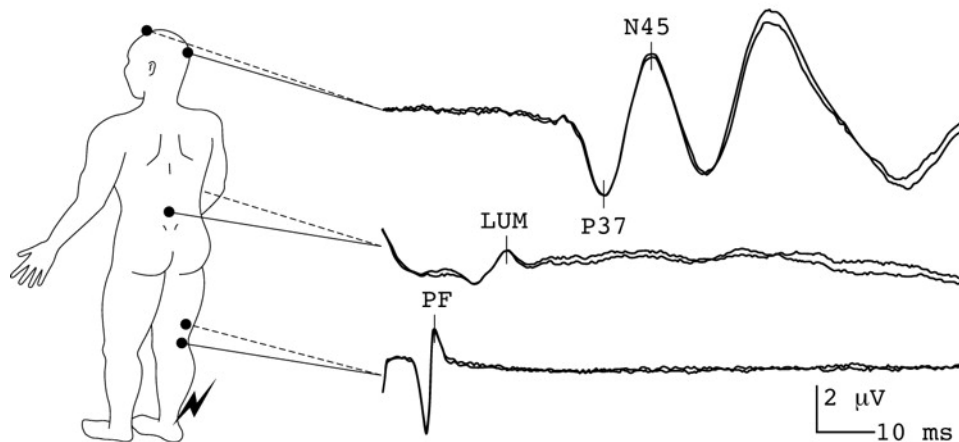
Multiple infusion pumps  
No reliable common time  
reference

Signal sources: 2 – patient and stimulating current. Current sensed at source and patient

Left side: normal short latency somatosensory evoked potentials (SSEPs) after stimulation of the median nerve (top picture) and posterior tibial nerve (bottom picture).

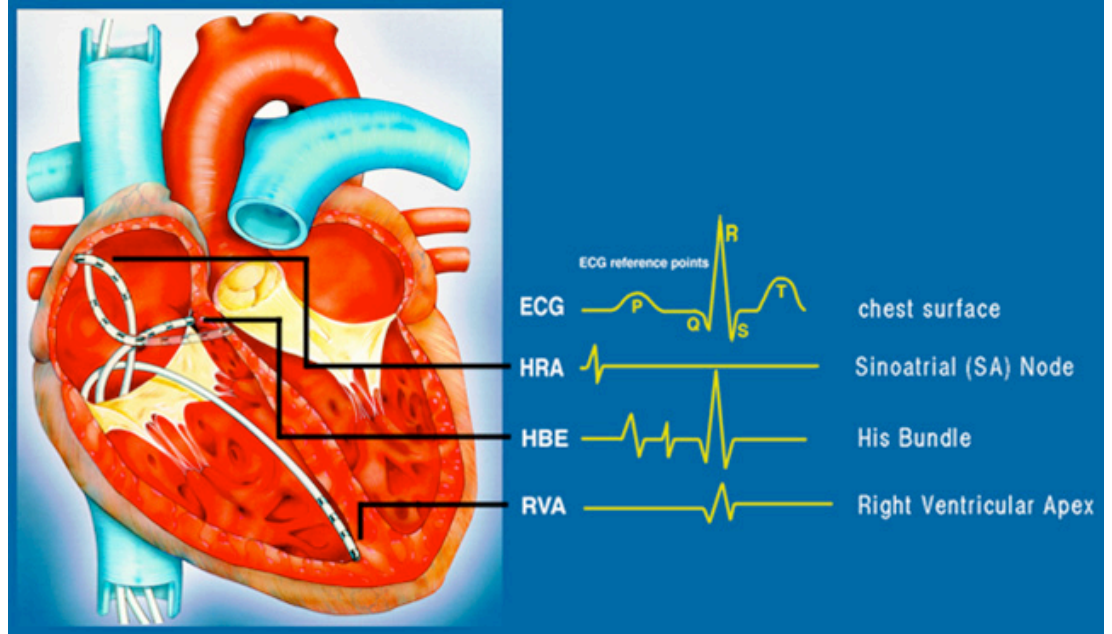
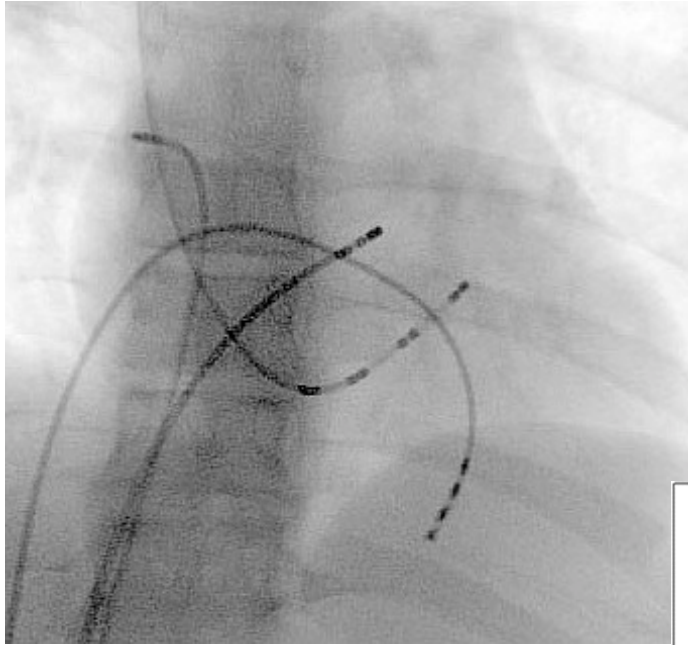


⚡ Electrical stimulation



Walsh P et al. J Neurol Neurosurg Psychiatry 2005;76:ii16-ii22

# Cardiac Electrophysiology Study



Sensors data acquisition and processing is integrated by one device

What are requirements for wireless sensor array?

RF Catheter Ablation – sync w/ ventilation

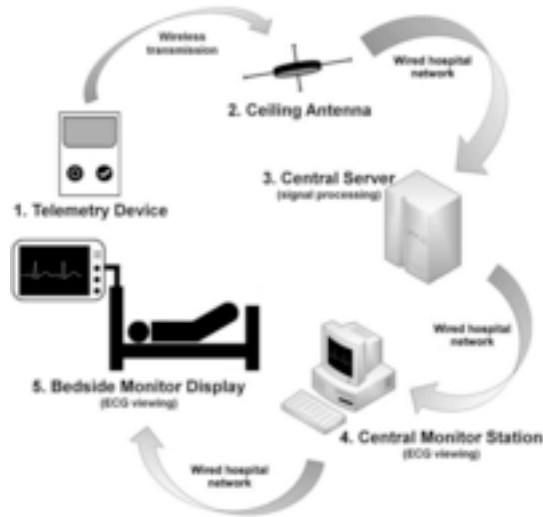




# Consideration for Clinical Signal Time Coordination Requirements

- Analog multi-channel data acquisition systems may be affected by transmission-line effects – usually minimal. Clock required?
- Signal transmission from device-device, device-alarm system, must meet clinical requirements and standards. Time marker is necessary to assess:
  - Bedside alarm AAMI EC13 10s standard for lethal arrhythmias. Same for central station.
    - Must assess central station connectivity state

# “Latency of ECG Displays of Hospital Telemetry Systems A Science Advisory From the American Heart Association”



“Recent observations by healthcare providers indicate that some hospital telemetry systems used for monitoring of patients' heart rhythm, hemodynamic parameters, and oxygen saturation may exhibit clinically significant latency, or delay between the real-time status of the patient and the information displayed on the patient monitor.<sup>10–12</sup> The problem has been reported with wireless networked systems. Unlike older hard-wired systems, wireless networked systems do not transmit directly from the patient's ECG leads to the viewing screen in the patient's room. These digital systems wirelessly transmit data from the patient telemetry transmitter to a central monitor station or network server. The data are then processed on the server and sent back to the monitor or display at the patient's bedside via a wired network”

# “Real Time”

- Electrophysiology – requires 1 msec resolution
- DC Cardioversion – must deliver shock within 60msec of R-wave peak. Problem is >100ms
  - Systems senses ECG R wave and delivers energy. Analog, dedicated connection. Could it be based on distributed components with reliable clocks?

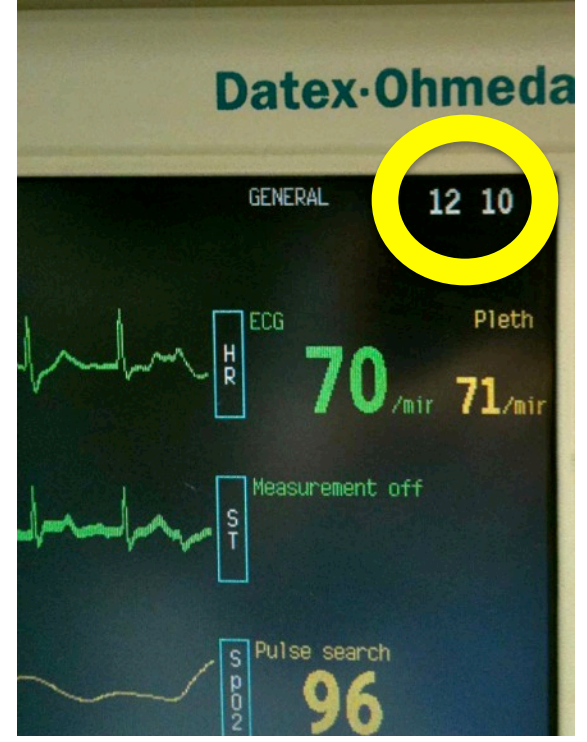
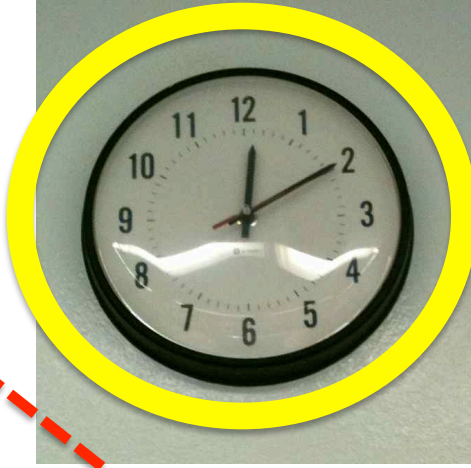
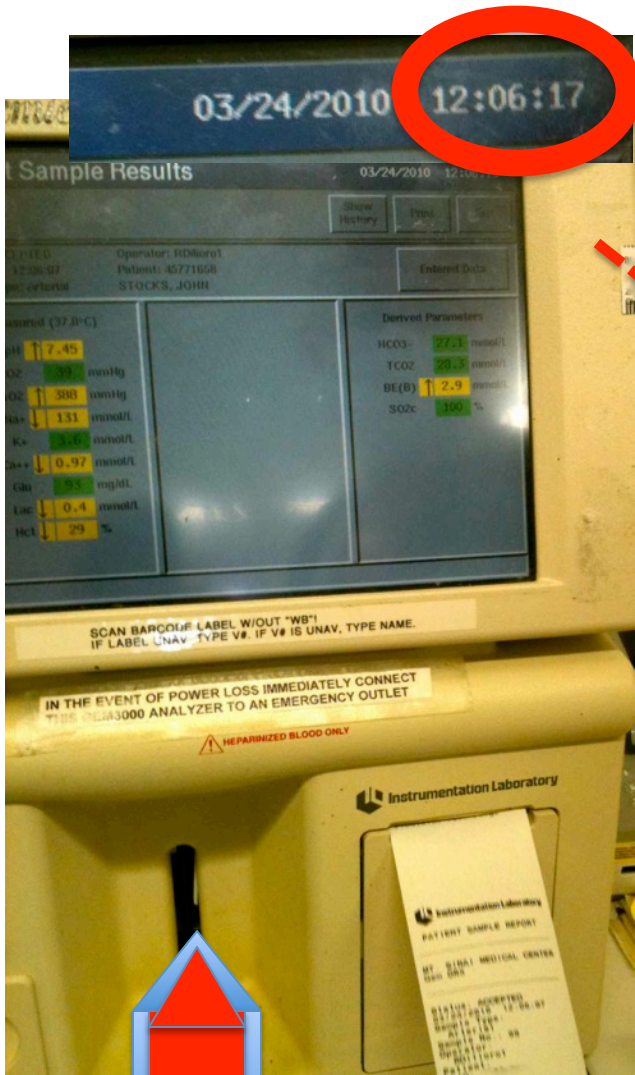


Coordinating  
device data is  
challenging

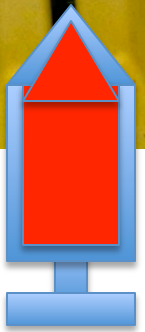


# Time Coordination of Medical Device Data Logs

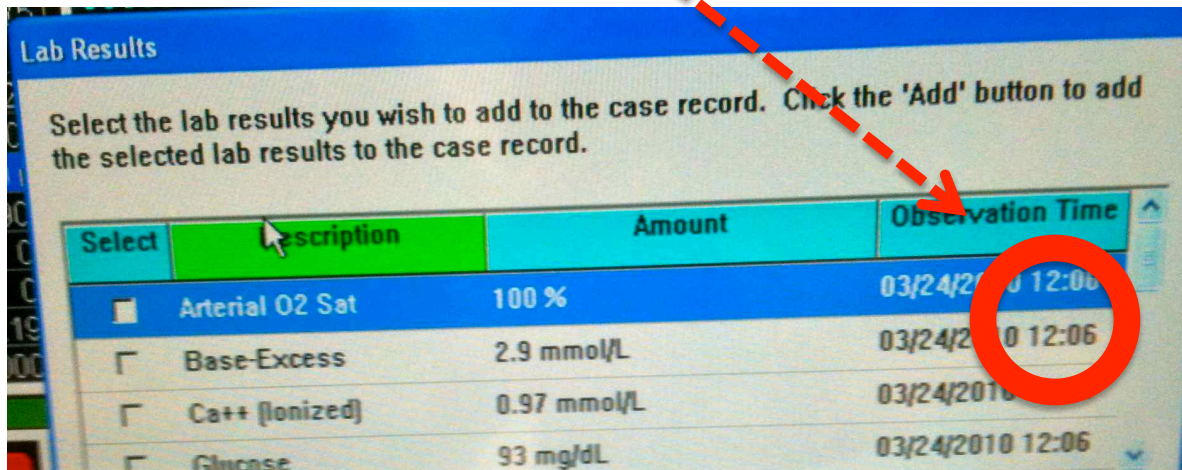
- Medical device data logs are essential , but
  - Typically have incorrect time reference
  - Difficult to align with data from other devices and clinical interventions
- Is logging of one device that is independent of the “system” sufficient?
  - A device may function correctly, but can still have adverse event; analysis requires system data to address “device is OK, but patient is not” Need “marker” – presumably an accurate time stamp
  - E.g. How can one assess the clinical impact of a ventilator problem without complete data from
    - Ventilator – airway pressure, flow, etc.
    - Oxygenation monitor / pulse oximeter
    - Hemodynamic data (blood pressure etc.)



EMR time stamp error:  
Is 4 min clinically significant?



Blood gas analyzer in OR



## Medical Device Clock Time Errors Consolidated 4 Hospital Summary (Draft)

Device Type	Count	StdDev Offset	Average Offset	Maximum Offset
Medical Devices (Excl. Workstations & Wall Clocks)	1324	1:32:34	0:33:26	16:42:10
All devices	1732	1:22:12	<b>0:25:58</b>	16:42:10
Networked Devices that Auto-Sync	291	0:02:16	0:00:53	0:31:16
Stand-alone Devices	950	1:46:38	0:46:06	16:42:10
Hospital A	52	0:31:11	0:30:25	1:52:00
Hospital B	495	1:41:23	0:32:55	16:42:10
Hospital C	468	0:47:12	0:17:10	13:39:28
Hospital D	717	1:27:24	0:26:35	13:18:47

# Clock Study Collaborators

## Hospital of University of Pennsylvania (HUP)

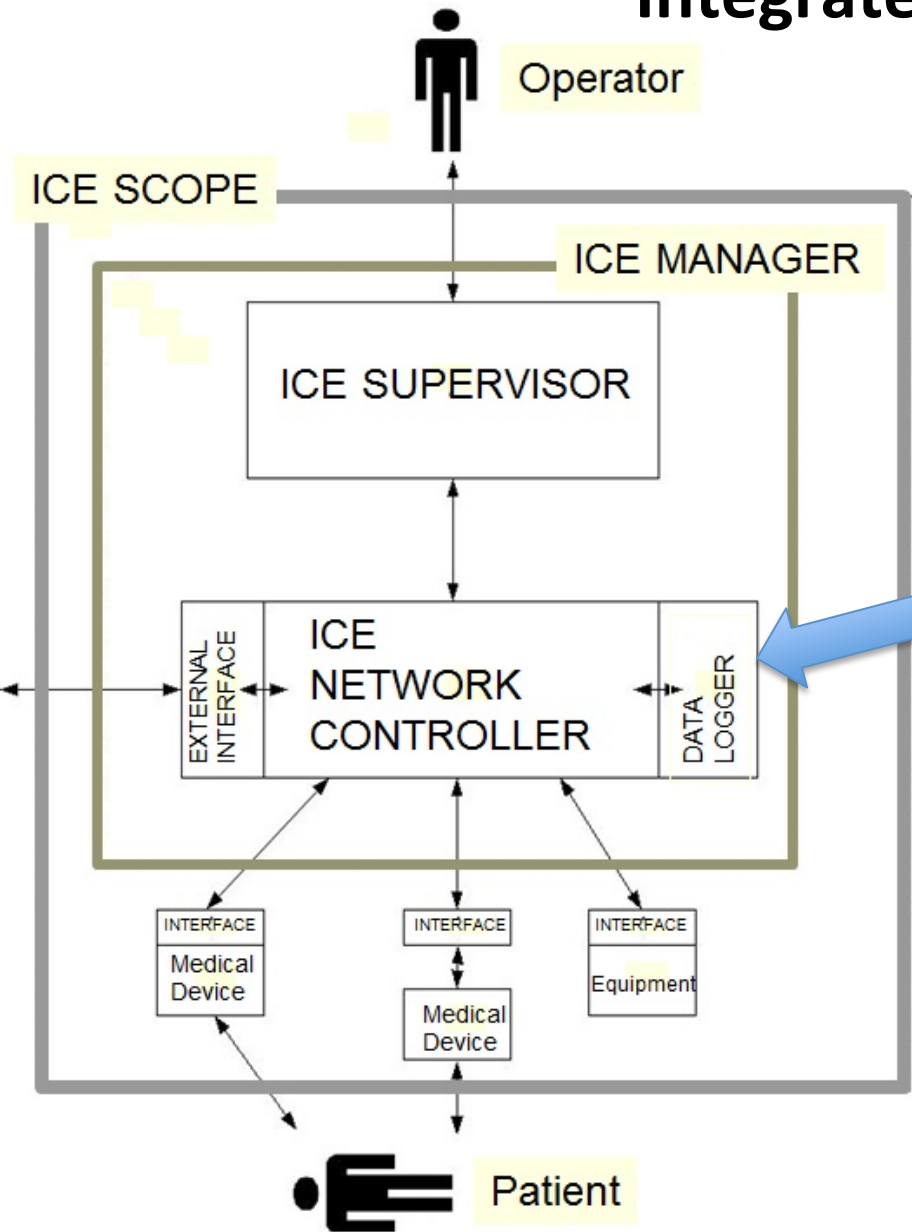
- Dr. Insup Lee - Cecilia Fidler Moore Professor, Department of Computer and Information Science, Upenn.
- Dr. Oleg Sokolsky - Research Associate Professor, Department of Computer and Information Science, Upenn.
- Soojin park, MD - Director of Neurocritical Care Monitoring and Informatics
- Margie Fortino, MSN, RN - Operations Director, Penn e-lert eICU

## Johns Hopkins Hospital (JHH)

- James C. Fackler, MD – Anesthesiology & Pediatrics
- Maria Cvach MS, RN, CCRN - Assistant Director of Nursing, Clinical Standards
- Dina A. Krenzischek, PhD, MAS, RN, CPAN – PACU Nurse Manager
- Jeff Frank – Clinical Engineering Manager
- Judy Ascenzi, MSN – Clinical Nurse Specialist, Pediatrics



# ASTM F2761-09 standard for Integrated Clinical Environment



ICE "Data Logger"

