

Washington Hospital

Biomedical Engineering Department

**Who we are
and what we do.**

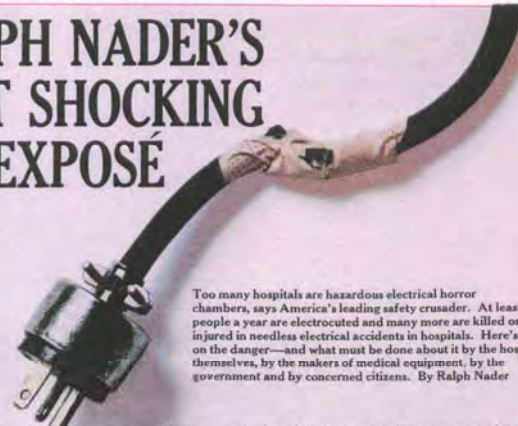
The Beginning of our field – March 1971



WHHS Biomedical Engineering

The Beginning of our field – March 1971

RALPH NADER'S MOST SHOCKING EXPOSE



Too many hospitals are hazardous electrical horror chambers, says America's leading safety crusader. At least 1,200 people a year are electrocuted and many more are killed or injured in needless electrical accidents in hospitals. Here's a report on the danger—and what must be done about it by the hospitals themselves, by the makers of medical equipment, by the government and by concerned citizens. By Ralph Nader

Not long ago, a patient connected to an external heart pacemaker—an electronic device to help the heart function normally—was found dead, part of his body touching the metal frame of his electrically operated hospital bed.

In another hospital, a resident physician was discovered slumped lifeless beside a stainless steel table. He had been

medical machine lead us to believe that most of these risks are unavoidable. The tragedy is that most are not.

Most electrical accidents in hospitals occur because safety measures that can reduce risks are grossly neglected or even unknown among hospital staffs; because complex and highly dangerous equipment is installed in hospitals that have primitive safety systems and the equipment is operated by un-

Too many hospitals are hazardous electrical horror chambers, says America's leading safety crusader. At least 1,200 people a year are electrocuted and many more are killed or injured in needless electrical accidents in hospitals. Here's a report on the danger—and what must be done about it by the hospitals themselves, by the makers of medical equipment, by the government and by concerned citizens. By Ralph Nader

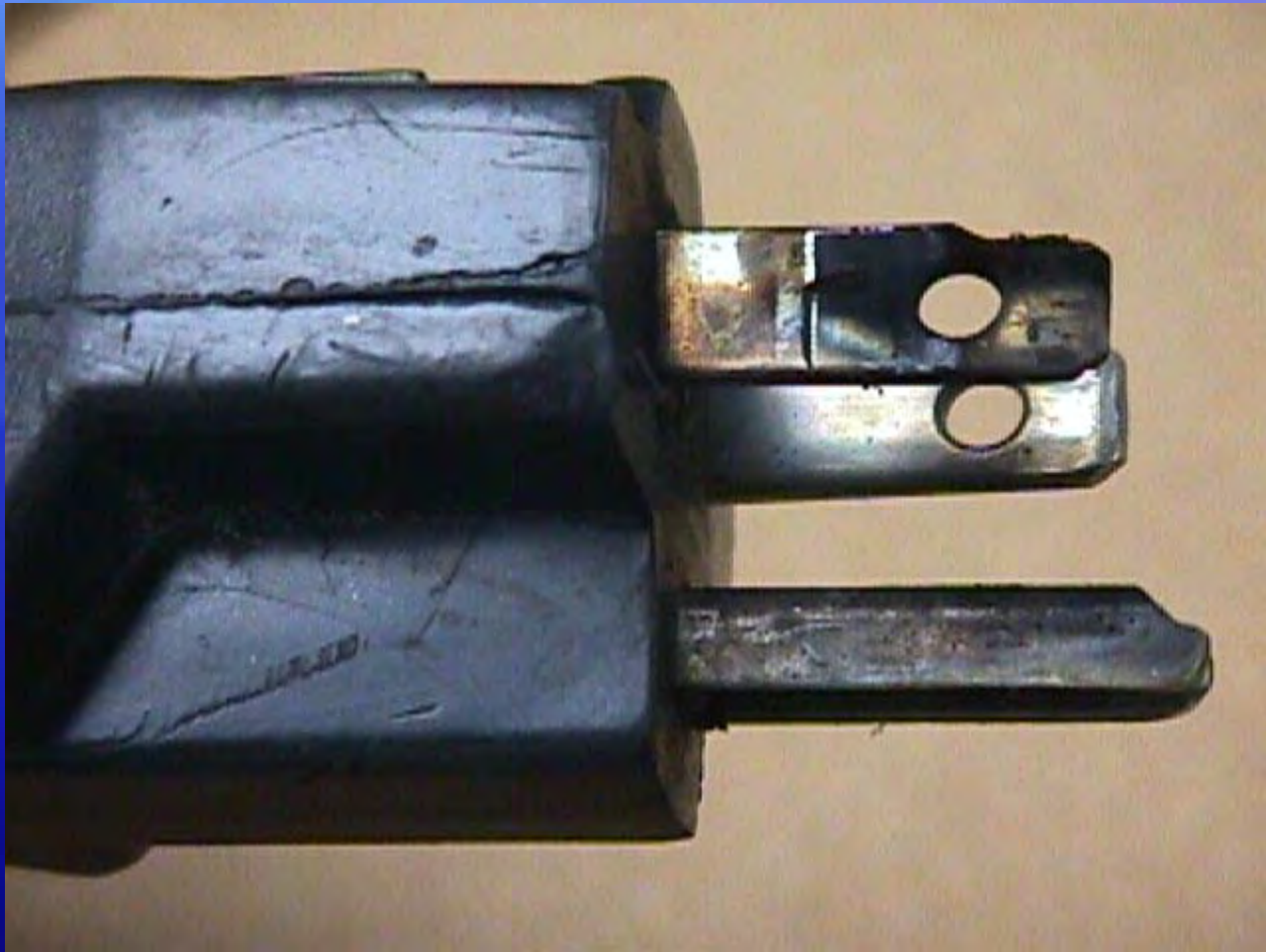
Other patients die as a result of electrical burns, explosions or loss of instrument control. Since the advent of the heart pacemaker and cardiac catheterization—the insertion of a catheter, or tube, into the heart—the hospital environment has become so dangerous that today it is the site of more electrical accidents than any industry except mining.

Spectacular advances in medical technology have unquestionably opened new horizons for people suffering from heart and lung disorders and other diseases. Those who may benefit—for example, the 20,000 patients who receive implanted heart pacemakers each year—may understandably be willing to hazard risks in hope of staying alive. But the myths of the

asked in hospitals, where at the very least 1,200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures.

We do not even have a clear idea of the number of hospital fatalities caused by electric shock. Medical engineers such as Professor Hans von der Mosel, co-chairman of the Subcommittee on Electrical Safety of the Association for the Advancement of Medical Instrumentation and safety consultant to New York City's Health Services Administration, believe that the number might be 10 times as high as the conservative estimate of 1,200. Yet most of these deaths could have been prevented by adequate safety measures. (continued on page 176)

Photograph by Don Swenson



WHHS Biomedical Engineering

In the Beginning

Washington Hospital had joined a group that provided shared Biomedical Services.

This program evolved over time, and eventually was purchased by a large Independent Service Provider – Contractor.

In April 1998 Washington Hospital decided to bring the department in-house.

Sometimes the perception is that equipment service (and servicing) is easy. If Biomed does our job properly it really should be as easy as:

It's not really that easy



WHHS Biomedical Engineering

Who we are

Biomedical Engineering is a team of engineering professionals working in a clinical environment to resolve technology issues related to patient care, improvement in outcomes and cost effectiveness. The Biomedical Engineering Department functions and **provides engineering services to a clinical environment supporting technology, clinicians and the patient technology interface to reduce risks, improve patient outcomes and enhance patient care in a cost effective manner.** This is accomplished via cost effective maintenance, repair and acquisition of all clinical technology, and proper management of clinical technology resources. It is the goal of the Biomedical Engineering Department to be **THE** technical liaison, reference and resource for all clinical equipment. The mission of the Biomedical Engineering Department is to provide knowledgeable, timely and cost effective quality service to clinicians in a professional and responsible manner to improve and enhance patient care by supporting all aspects of patient care related technology .

Biomedical knowledge base

- Anatomy and Physiology
- Medical Terminology
- Safety In The Health Care Facility – Codes and Standards
- Fundamentals of Electricity, Electronics, and Solid-State Devices
- Medical Equipment Function and Operation
- Medical Equipment Problem Solving
- Information Systems
- Customer Service

Certification as Biomedical Equipment Technician (CBET)

EXAMINATION REQUIREMENTS

I. Anatomy and Physiology

A. Systems

- | | |
|--------------------|---------------------|
| 1. Respiratory | 2. Gastrointestinal |
| 3. Nervous | 4. Circulatory |
| 5. Musculoskeletal | 6. Endocrine |

B. Organs

- | | |
|-------------|----------------|
| 1. Heart | 2. Lungs |
| 3. Liver | 4. Kidneys |
| 5. Brain | 6. Gallbladder |
| 7. Pancreas | 8. Other |

C. Blood

1. Components
2. Metabolism

D. Terminology

Certification as Biomedical Equipment Technician (CBET)

II. Public (employee, patient, visitor) Safety In The Health Care Facility

A. Electrical

- | | |
|---|----------|
| 1. Microshock/Electrical Safety Testing | 2. Other |
|---|----------|

B. Chemical

- | | |
|-------------------------------|----------|
| 1. Material Safety Data Sheet | 2. Other |
|-------------------------------|----------|

C. Radiation Hazards

- | | |
|-------------------|------------------|
| 1. Light Spectrum | 2. Types of Rays |
|-------------------|------------------|

D. Biological

- | | |
|--------------------------|----------|
| 1. Universal Precautions | 2. Other |
|--------------------------|----------|

E. Fire

- | | |
|----------|-----------------------|
| 1. Class | 2. Fire Extinguishers |
|----------|-----------------------|

F. Codes and Standards

- | | |
|---|----------|
| 1. JCAHO Comprehensive Accreditation Manual | |
| 2. AABB | |
| 3. NFPA 99 | |
| a. Gas and Vacuum Systems | |
| b. Electrical Systems | |
| 4. FDA | 5. SMDA |
| 6. OSHA | 7. Other |

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III. Fundamentals of Electricity, Electronics, and Solid-State Devices

- A. Transducers
- B. Calculations and Conversions
 - 1. Hex/Decimal/Binary
 - 2. Other
- C. Devices
 - 1. Passive
 - 2. Active
 - 3. Digital
- D. Circuits
 - 1. Operational Amplifier
 - 2. Power Supplies
 - 3. Common Base/Emitter/ Collector Transistor Circuits
 - 4. AC Power
 - a. Transformer
 - b. Distribution
- E. Test Equipment
- F. Batteries
- G. Terminology

Certification as Biomedical Equipment Technician (CBET)

IV. Medical Equipment Function and Operation

- A. Monitoring Systems (*i.e. ECG, EEG, Blood Pressure, Pulse Oximetry, Fetal Monitor*)
- B. Portable Equipment (*i.e. Infusion Devices Syringe Pumps, PCA Pumps; Hypo Hyperthermia*)
- C. Life Support Equipment (*i.e. Defibrillators, Hemodialysis, Anesthesia Machines, Critical Care Ventilators, Balloon Pumps*)
- D. Therapeutic Equipment (*i.e. Infant Warmers, Ultrasound Therapy*)
- E. Laboratory Equipment (*i.e. Centrifuges, Water Baths, Analyzers*)
- F. Diagnostic Imaging (*i.e. Ultrasound, Radiographic/Fluoroscopy*)
- G. Operating Room (*i.e. Electro Surgical Generators, Video Carts, Lasers, Tourniquets, Sterilizers, Warmers*)
- H. Information Systems (*i.e. Computers, Networks, Topology*)
- I. Test Equipment (*i.e. Electrical Safety, Defibrillator, Electro Surgical, Physiologic Simulators, Oscilloscopes, Meters*)
- J. Terminology

Certification as Biomedical Equipment Technician (CBET)

V. Medical Equipment Problem Solving

- A. Electronic Component Level, Block Level
- B. Monitoring Systems (*i.e. ECG, EEG, Blood Pressure, Pulse Oximetry, Fetal Monitor*)
- C. Portable Equipment (*i.e. Infusion Devices Syringe Pumps, PCA Pumps, Hypo Hyperthermia*)
- D. Life Support Equipment (*i.e. Defibrillators, Hemodialysis, Anesthesia Machines, Critical Care Ventilators, Balloon Pumps*)
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- G. Diagnostic Imaging (*i.e. Ultrasound, Radiographic/Fluoroscopy*)
- H. Operating Room (*i.e. Electro Surgical Generators, Video Carts, Lasers, Tourniquets, Sterilizers, Warmers*)
- I. Information Systems (*i.e. Computers, Networks, Topology*)
- J. Situational (*i.e. User error, user training, applications*)

Regulatory Bodies

Advancement of Medical Instrumentation (AAMI)
California Administrative Code (CAC) Title 22
Code of Federal Regulations (CFR)
Environmental Protection Agency (EPA)
FDA - Center for Devices and Radiological Health (CDRH)
Federal Communications Commission (FCC)
Food and Drug Administration (FDA)
International Electrotechnical Commission (IEC)
International Organization for Standardization (ISO)
Joint Commission
National Fire Protection Association (NFPA)
Occupational Safety and Health Administration (OSHA)
Office of Statewide Health Planning and Development (OSHPD)
The American National Standards Institute (ANSI)
Underwriters Laboratories, Inc.

Who we are – Mission Statement

To ensure electrically safe and functional equipment for patients, visitors, and hospital employees through a program of continuing inspection, testing, and repairs of patient care equipment, regardless of ownership, and assistance with inservice training.

To act as a resource in selecting new patient care equipment and fulfilling manufacturers' recalls as needed.

Our main customers are the direct caregivers of Washington Hospital.

Other customers include:

- Support departments
- Patients
- Some of the DEVCO sites
- Administration
- Regulatory authorities such as Joint Commission, and California Department of Health Services (DHS).

Who we are - Services offered

We see ourselves as MEDICAL TECHNOLOGY EXPERTS

- ✓ Pre-purchase Evaluations/ Consulting
MDBuylines - ECRI HPCS - Peers
- ✓ Equipment Recommendations
- ✓ Purchasing assistance
Service Options - Manuals, other Service Media, Training Classes, Specialized Equipment
- ✓ Incoming Inspections
- ✓ Service Equipment
1,000s of Parts in inventory, Specialized Test Equipment
- ✓ Provide (some) Loaners
- ✓ Contract Management (Service)
negotiations and administration
- ✓ User (Inservice) Training
- ✓ Regular Preventive Maintenance / Safety / Performance Testing / Calibrations
- ✓ Corrective Work orders (Repairs)
- ✓ Safety Fair presentations

Who we are - Services offered

- ✓ Equipment Installations
- ✓ Recalls and Alerts FDA/ECRI
- ✓ Obsolescence Notifications
- ✓ Replacement Recommendations
- ✓ International Biomedical Networking
- ✓ User Error Tracking
- ✓ Equipment History on every device - "Regardless of Ownership"
- ✓ Consultation of Equipment Incidents
- ✓ Members of many Committees
 - Safety Committee – Medical Equipment – Environment of Care –
 - Clinical Products Evaluation – Patient Safety - Point of Care – Dialysis
 - Radiation Safety - HIPAA
- ✓ Construction projects – Medical equipment aspects
- ✓ "Community" related activities
- ✓ GOAL - Bring as much "in-house" as possible
- ✓ FREE TECH SUPPORT

Equipment “Asset” tag

Every device has a unique identification number, assigned by us that is used to:



- Track equipment history – from “cradle to grave” (incoming inspection to disposal)
- Assign and track Preventive (Predictive) Maintenance work orders
- Assign and track Corrective work orders (repairs)
- Search for recalled devices
- Analyze trends for replacement or other issues.

Who we are – What we want to prevent



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Who we are - Staff

1 – Manager

1 – Lead Biomedical Technician

3 – Biomedical Technicians

1 – Per-Diem Biomedical Technician

1 – Executive Assistant (half time)

Biomedical Staff



Carol Garibaldi, CBET
Lead Biomedical Technician
April 13, 1998



Christopher Ney, CBET
Biomedical Technician
July 12, 2001



Tiberiu "Tibi" Pop
Biomedical Technician
November 29, 2004

Biomedical Staff



Jim Rominger
Biomedical Technician
May 2, 2005



Fe Mendoza
Executive Assistant
May 30, 2006



James Bocade
Per-Diem Biomedical Technician
February 27, 2007

Who we are – Staff Sergeant Chris Ney



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Medical Equipment Management Plan



CRITERIA FOR SYSTEMS AND COMPONENTS INCLUDED IN PLAN

All powered (electrical, air, nitrogen, etc.) technology that is directly involved or supports patient care is included in the medical equipment management program.

The department oversees all medical equipment repairs, maintenance and service independent of ownership or service methodology.

Medical Equipment Management Plan



PRIORTIZATION

Repair and maintenance work is prioritized by:

- **Life support/life saving**
(ventilators, anesthesia machines, defibrillators)
- **Diagnostic**
(laboratory, radiographic, imaging)
- **“Routine” technologies**
(otoscopes, exam lights)

Medical Equipment Management Plan



HOURS OF SUPPORT

In-house coverage is provided eleven hours per day (7a.m. – 6p.m.), five days a week, excluding holidays.

Biomedical Engineering is available on a call back basis 24 hours a day seven days a week.

All staff have long-range pagers.

Medical Equipment Management Plan



NON-HOSPITAL EQUIPMENT

All medical equipment, REGARDLESS OF OWNERSHIP must be held to the same standards. Loaner, Demo, and Rental devices must have proof of current Preventive Maintenance, and a safety test before use.

Biomedical Engineering keeps this documentation on file.

Departments should notify Biomed when devices leave the Hospital.

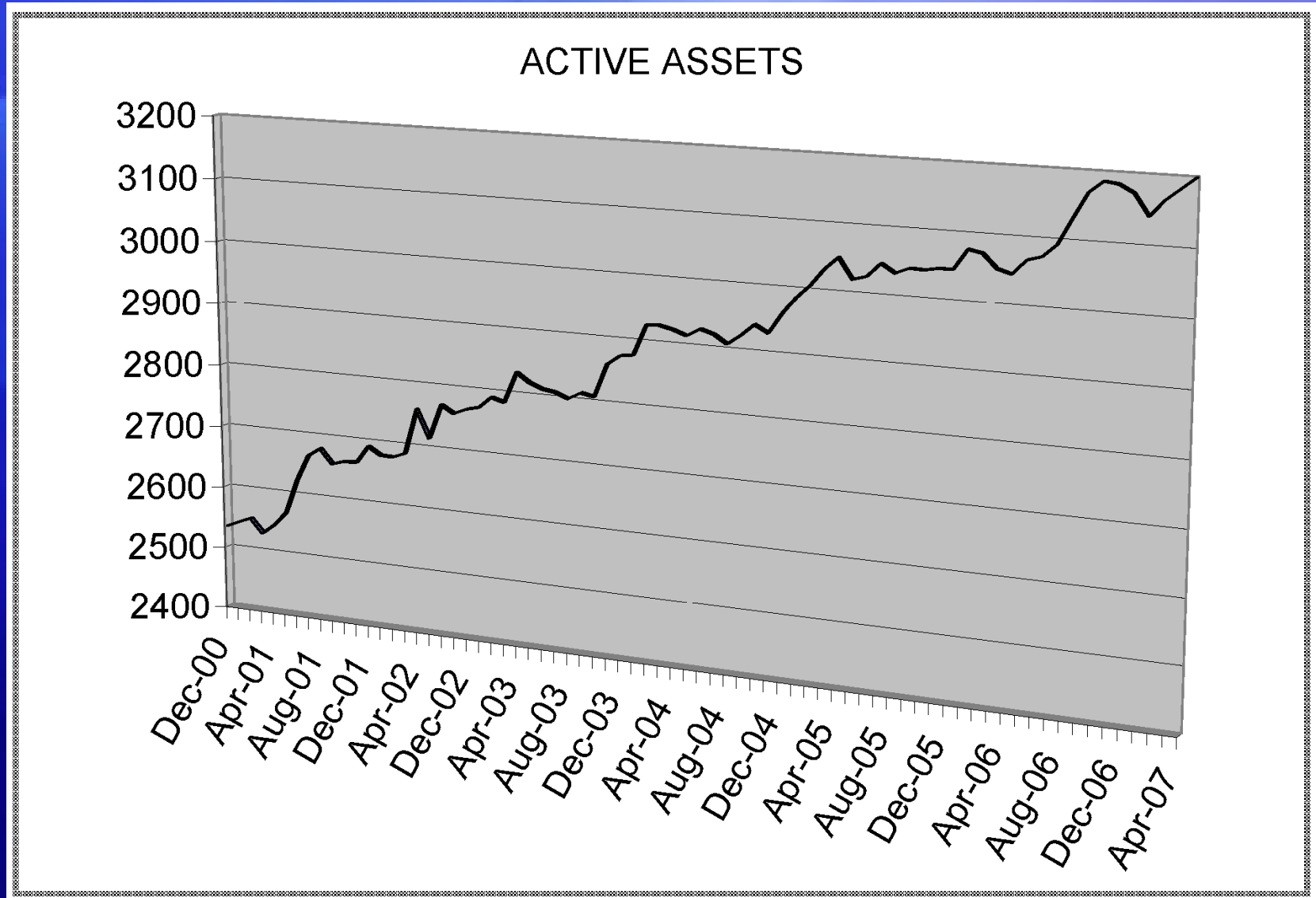
Items returning must be re-tested.

Community Involvement

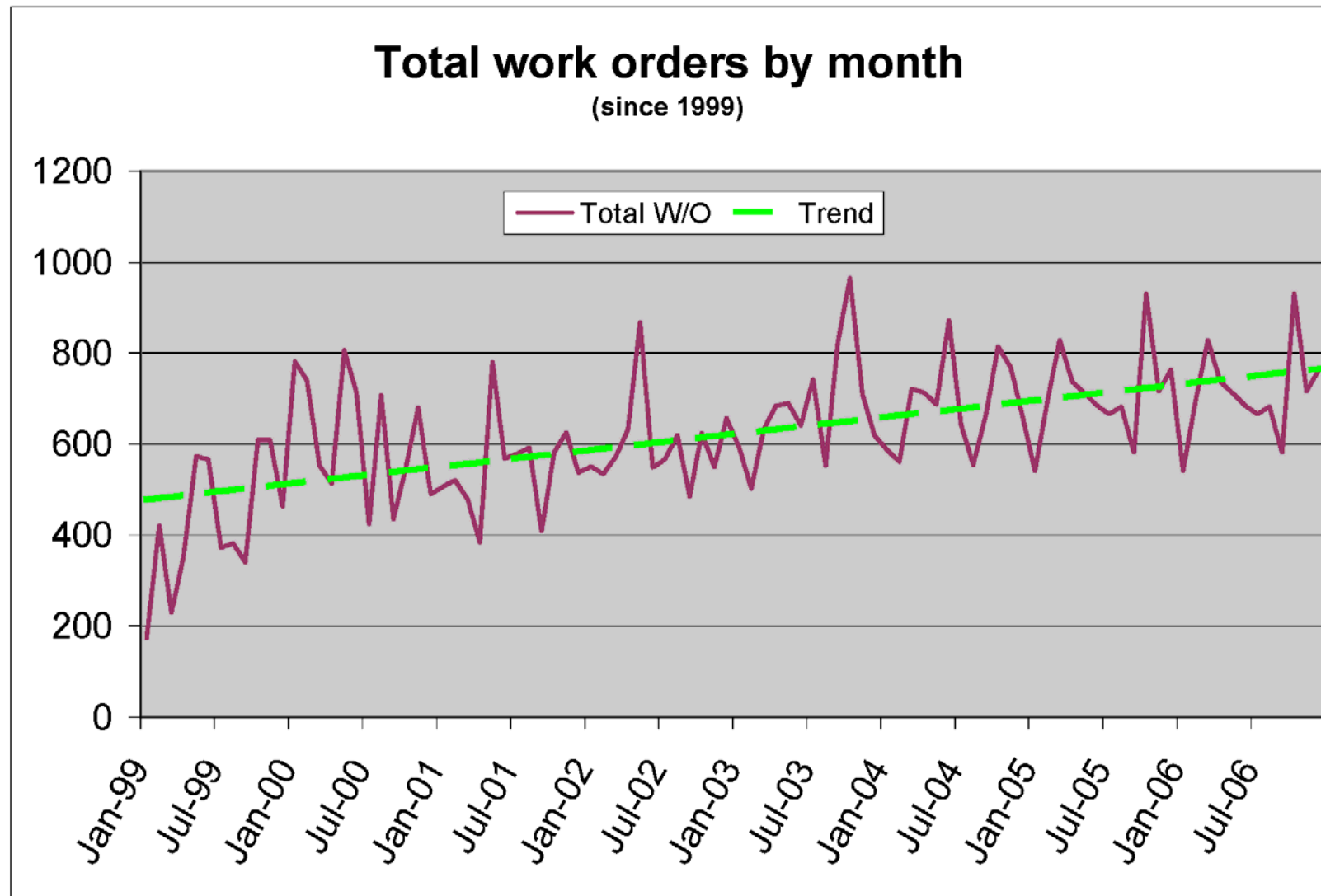


- Partnered with Underwriters Laboratories to orient new Engineers about actual usage of equipment in hospitals

Devices Supported by Biomed



Work orders Closed by Month



Statistics

Current Inventory of devices supported: 3,200

2006

Corrective work orders (Service calls): **4,202**

Preventive Maintenance work orders (PMs) Completed: **4,328**

Total work orders: **8,530**

Biomedical Resources - ECRI



The screenshot shows the ECRI Alerts Tracker web application. At the top, there is a navigation bar with the ECRI logo and links for Home, FAQ, and Help. Below this, a sidebar on the left contains various navigation options such as Search, Alert Tracking, Current Issue, and Action Items. The main content area displays a specific alert for 'GE—ApexPro/ApexPro CH Telemetry Systems: "System Warning" Audible Alarm May Not Occur [U.K.]'. The alert includes details like the Accession Number (A8495), Critical Priority status, and a link to the source document (MDA2007025.pdf). It also lists the device, identifier, manufacturer, and a detailed problem description.

ECRI Alerts Tracker

Paul Kelley

Friday, April 06, 2007

Tracking **Coordination**

Health Devices Alerts

1 of 24 [Next](#)

User Status: **Not Applicable** [Track this alert](#) [N/A](#) Set as Not Applicable to me

[PRINT](#) [EMAIL](#) [Assignments](#) [Current Status of this Alert for all users](#)

Accession Number : A8495 Critical Priority Updated : Friday, April 6, 2007

GE—ApexPro/ApexPro CH Telemetry Systems: "System Warning" Audible Alarm May Not Occur [U.K.]

Source Document(s): [MDA2007025.pdf](#)

In This Issue: GE ApexPro/ApexPro CH Telemetry Systems [U.K.]

UMDNS Device Term(s): Monitors, Telemetric [20-180]

Device: Telemetry Systems: (1) ApexPro, (2) ApexPro CH [Capital Equipment]

Identifier: Software Version v3.8 and earlier; units distributed in the U.K.

Manufacturer: GE Healthcare UK [401906], 71 Great North Road, Hatfield Hertfordshire AL9 5EN, England

Problem: The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a Medical Device Alert warning healthcare workers that the above telemetry systems may not issue visual or audible system-failure alarms under certain conditions. Specifically, when a patient is monitored by the above systems, when ST-segment monitoring is disabled, and when a preexisting condition triggering a continuous "Message" or "Advisory" level alarm precedes a "System Warning" level alarm, the "System

HEALTH DEVICES

March 2007, Volume 36, Number 3

Guidance Article

The Hazards of Alarm Overload

Keeping Excessive Physiologic Monitoring Alarms from Impeding Care



- The Problem: Excessive Alarms Degrade the Quality of Care
- The Sources of Excessive Alarms
- Developing a Systematic Plan

Also in This Issue

- Evaluation Updates
- Portable/Transport Ventilators
- For Home-Care/Long-Term-Care Settings
- For In-Hospital Transport

Problem Report

Hazard: Siemens X-ray Tube Switch Failure

Talk to the Specialist

Choosing and Applying Pulse Oximetry Sensors

2007 Health Devices Achievement Award

- The Deadline for Submitting an Application is Approaching



Device Alert notice

Health Devices Alerts Action Item

Accession Number : A7547

Friday, July 28, 2006

Blood Pressure Monitors and Sphygmomanometers: MHRA Offers Advice on Obtaining Accurate Blood Pressure Measurements [U.K.]

Priority : Normal Priority

In This Issue: Blood Pressure Monitors and Sphygmomanometers [U.K.]

Monitors, Bedside, Blood Pressure [16-764];

Physiologic Monitor Modules, Invasive Blood Pressure [20-772];

Physiologic Monitor Modules, Noninvasive Blood Pressure [20-773];

Sphygmomanometers [13-106]

Device: (1) Blood Pressure Monitors; (2) Sphygmomanometers [*Capital Equipment*]

Problem: The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a Medical Device Alert because it has received reports of user problems related to obtaining accurate blood pressure measurements.

Action Needed: On a poster titled "Measuring Blood Pressure—Top Ten Tips," MHRA offers the following guidance on obtaining accurate blood pressure measurements:

(1) Ensure that only clinically validated equipment is purchased for use and that all sphygmomanometers are checked regularly—mercury devices should be checked at least once annually, and aneroid devices should be checked at least twice annually.

(2) To reduce the likelihood of inappropriate cuff use, ensure that both large and regular cuffs are available in each consulting room.

Biomedical Resources - MDBuyline

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[FDA Device Recalls - Beta](#) 

[Rate Your Vendor](#) 

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Anesthesia Depth Monitoring

Anesthesia Information Management System

Anesthesia Machine

Audiometer

Autologous Blood Recovery System

Automated Dispensing System

Bed

Bed Management System

Biopsy Systems

Blood and Fluid Warmer

Blood Bank Automation

Blood Gas Analyzer

Bone Densitometer

Cardiac Cath and Special Procedures Angiography

Cardiac Stress Test System

Cardiac Ultrasound (ECHO)

Cardiology Echo PACS

Cardiology Management System

Cardiology PACS

Cardio-pulmonary Bypass Pump

Lithotripter

Localization System

Long Term Epilepsy Monitoring

Magnetic Resonance Imager (MRI)

Mammography Information System

Mammography System

Materials Management

Medical Records Administration

Metabolic Measurement System

Microbiology System

Microtome

Mini C-Arm

Mobile C-Arm

Molecular Diagnostics

Neonatal Ventilator

Non Invasive Cardiac Output

Non-Invasive Vascular Diagnostic System

Nurse Call

Oncology Information Management System

Open Shift Management

Ophthalmic Laser

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AAMI Standards



The image is a screenshot of the AAMI Standards on CD website. The header features the AAMI logo on the left and the title "Standards on CD" in a large, stylized blue font. Below the title is a navigation bar with six tabs: "BIOT", "Dialysis", "Devices", "QM", "Safety", and "Sterilization". The main content area is divided into two columns. The left column, under the heading "Main Menu", lists various links: "About AAMI Documents", "Glossary of Equivalent Standards", "Copyright Information", "About AAMI", "www.aami.org", "Membership: Join Now!", "Calendar of Events", "AAMI Conference & Expo", "Courses and Seminars", and "Download New Documents". The right column, under the heading "MAIN MENU", lists six categories with right-pointing triangle bullets: "Biological Evaluation of Medical Devices", "Dialysis", "Medical Devices", "Quality Management", "Safety and Design", and "Sterilization". The footer contains the address "1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795", contact information "703-525-4890 | fax 703-276-0793", a copyright notice "Copyright © 2006 Association for the Advancement of Medical Instrumentation", and a "CONTACT US" link.

AAMI *Standards on CD*

BIOT | Dialysis | Devices | QM | Safety | Sterilization

Main Menu

About AAMI Documents

Glossary of Equivalent Standards

Copyright Information

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MAIN MENU

- ▶ Biological Evaluation of Medical Devices
- ▶ Dialysis
- ▶ Medical Devices
- ▶ Quality Management
- ▶ Safety and Design
- ▶ Sterilization

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CONTACT US

Stand Designed by Biomedical Engineering



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Cabling diagram for equipment on cart



Video Tower
12989
EUS

Sony
Monitor
Line A In from
processor
RGB-A
In from
processor
Line B
In from
processor



Processor
CV-140
Photo to output
on printer
Monitor to
monitor connection
on ultrasound
center
Keyboard out to
EUS on ultrasound



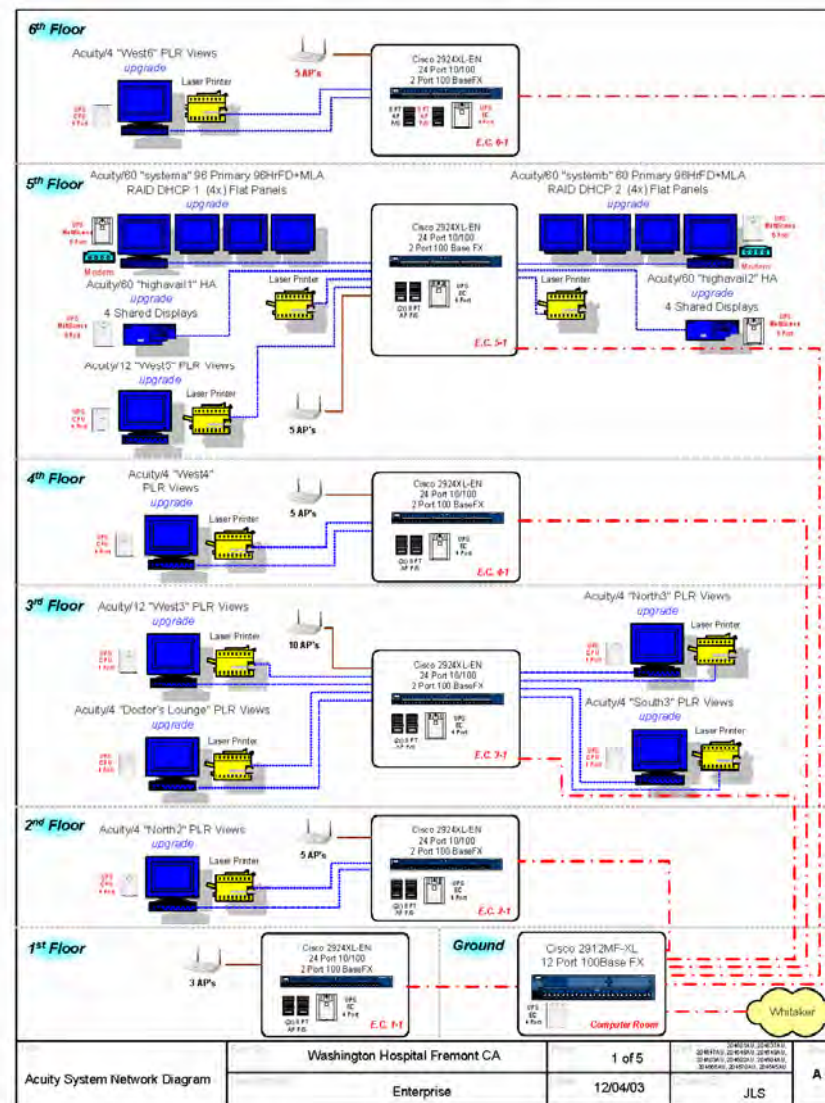
Printer
UP-5600
Input to
photo connection
on processor



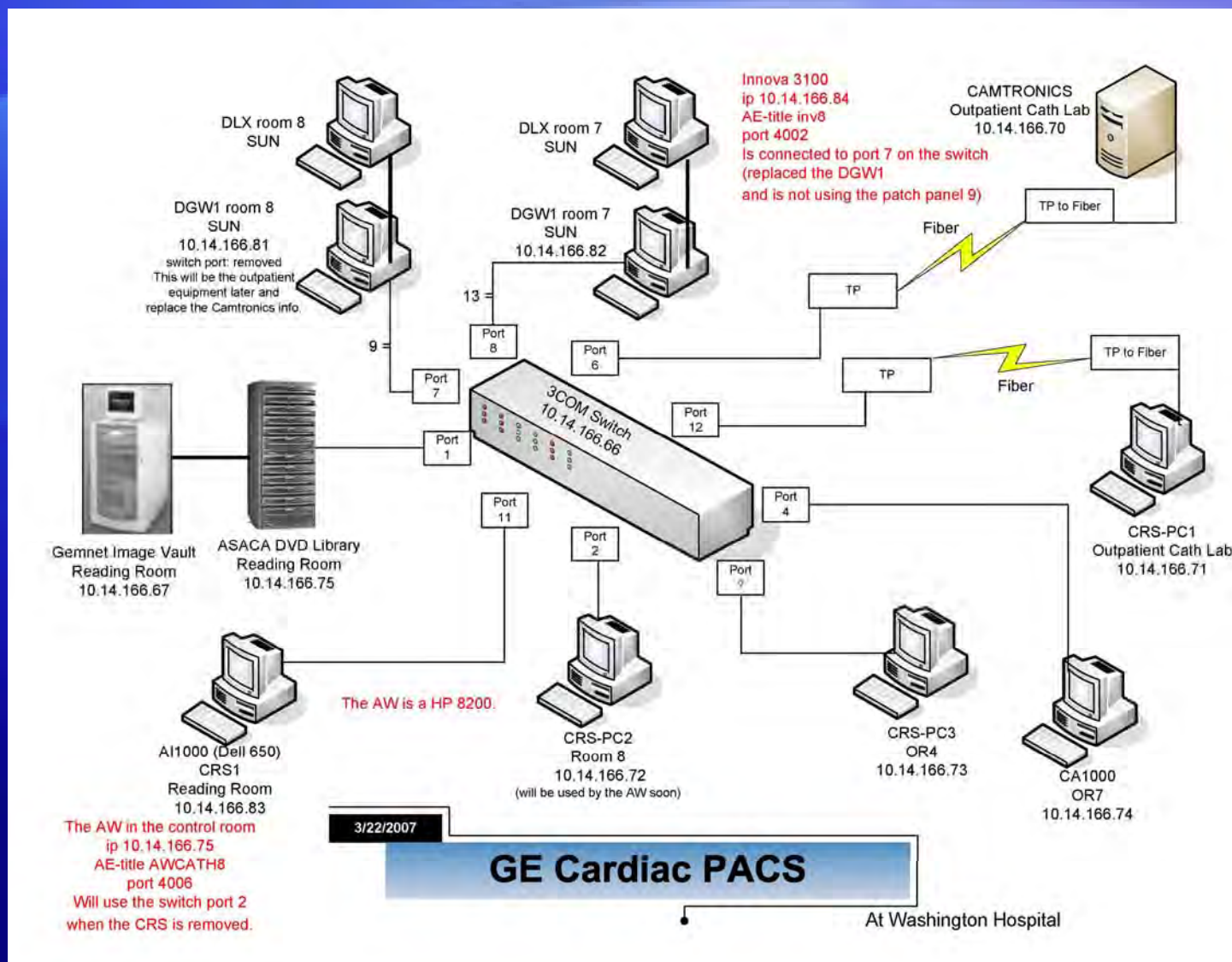
Endoscopic
ultrasound
center
EU-M30

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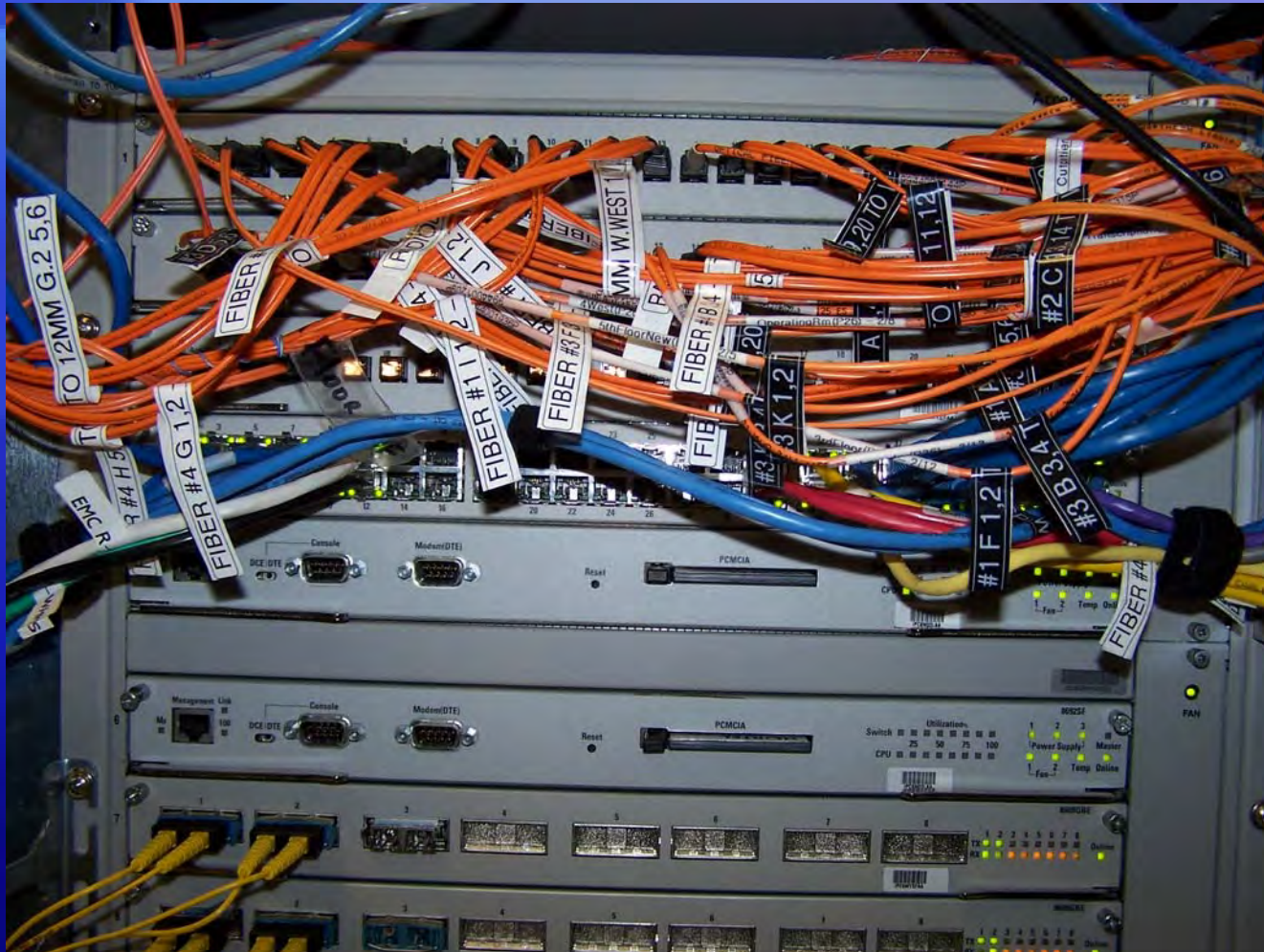
Welch Allyn “Acuity” Network



Cardiac PACS in the Cath Lab



Medical Network



WHHS Biomedical Engineering

Supported Devices - Defibrillators



Supported Devices – Ventilator and CRRT



Supported Devices – Patient Monitors



Supported Devices

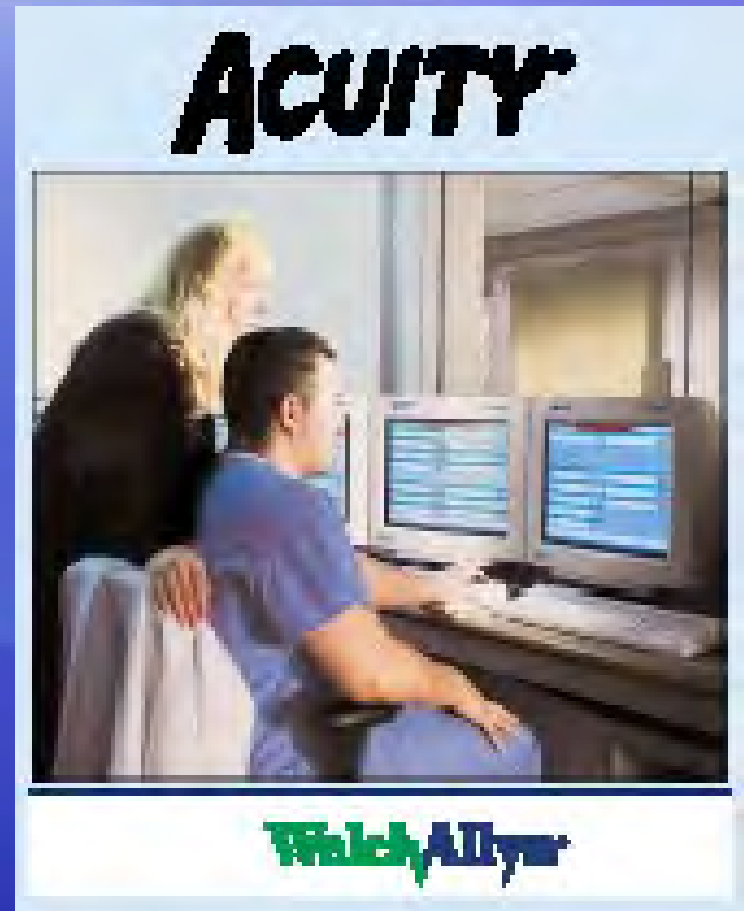
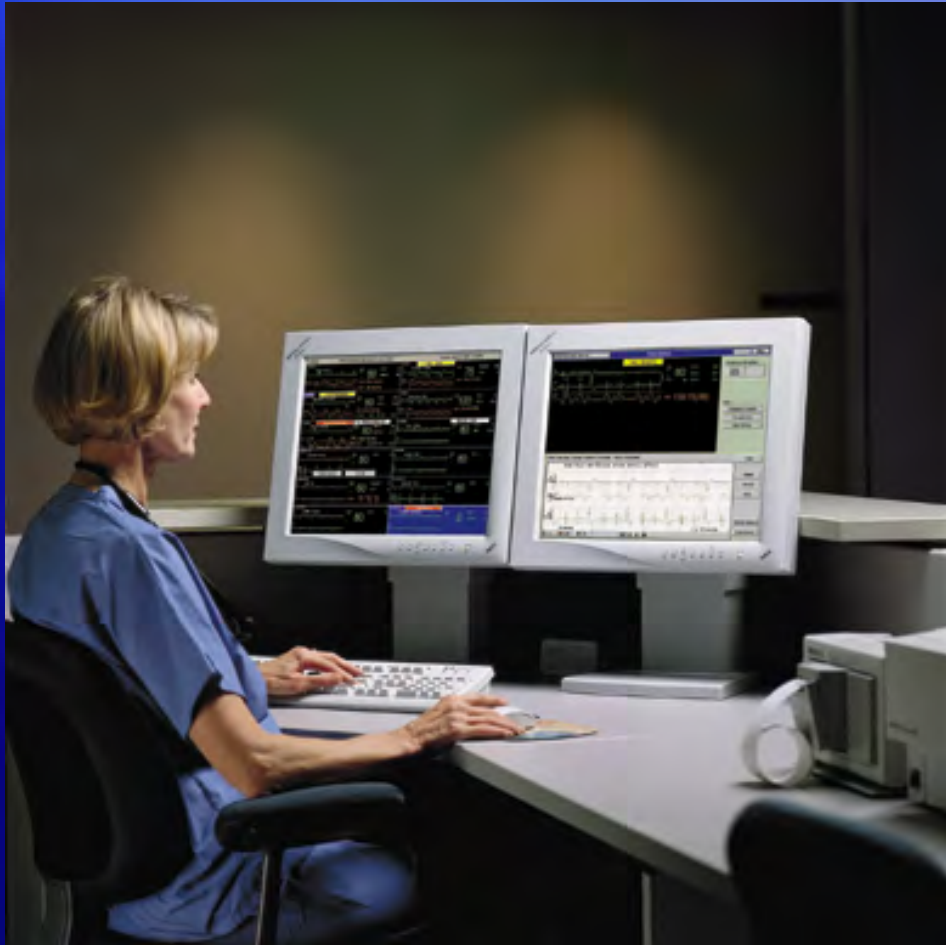


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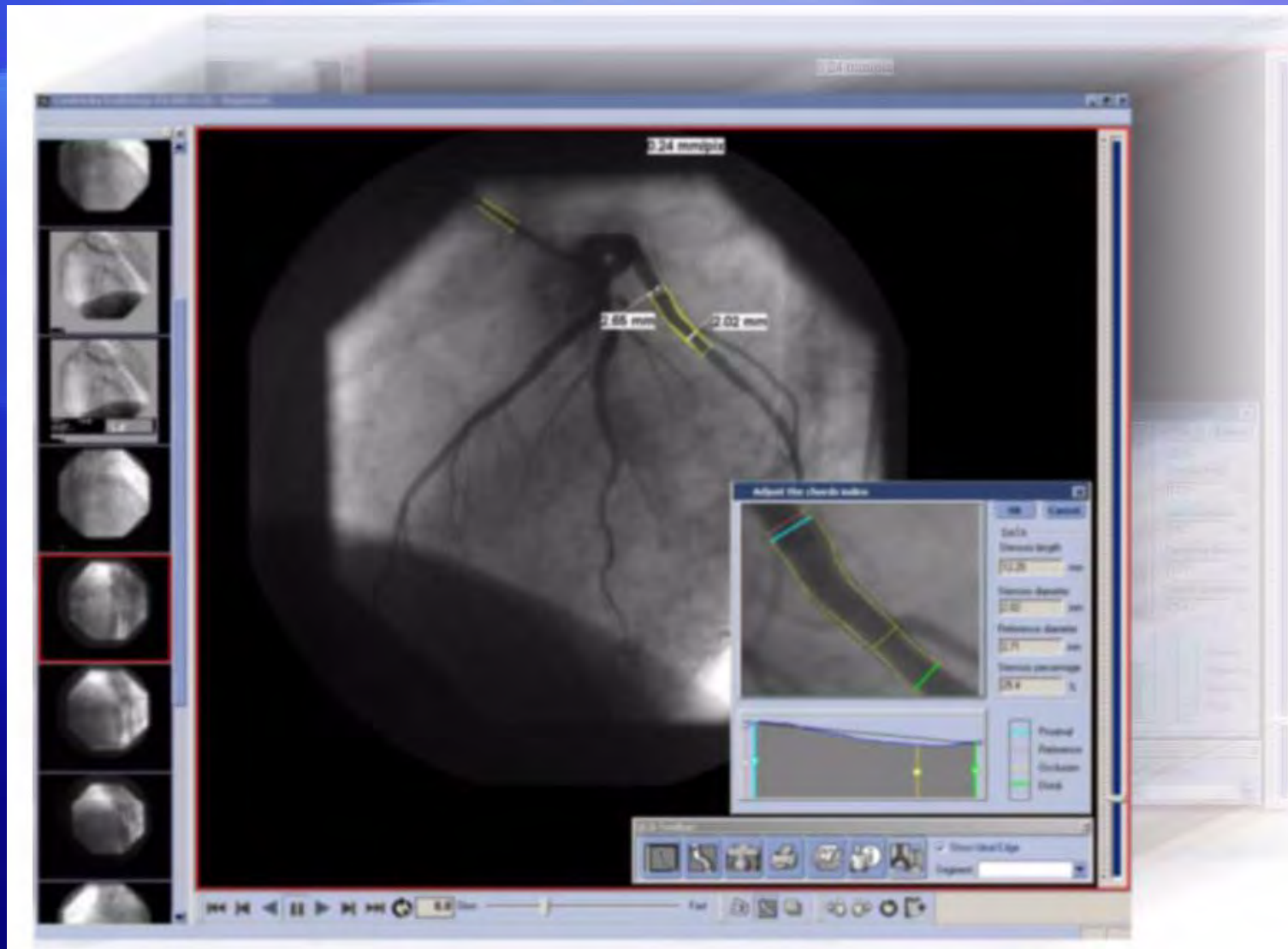
Supported Devices - Pumps



Supported Devices – Central Stations



Supported Devices – Cardiac PACS



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New Vital Sign Monitors



WHHS Biomedical Engineering

BioWeb

“BioWeb” is the Biomedical Engineering presence on the intranet.

To access it, go to the WHHS intranet homepage

Click on “**Department Postings**”

and then “**Biomedical**”

BioWeb



WHHS Biomedical Engineering



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Thank You



Be safe

