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Monitoring Mission-Critical 24/7 IT Data Centers in a Pharmaceutical Facility

This article discusses what procedures, documentation, and practices are needed to establish an Integrated Power and Environment Monitoring System in a pharmaceutical facility.

by Nissan Cohen

The IT environment is a non-production area of a pharmaceutical facility. The IT data center and all constituent components are included in FDA scrutiny. The IT environment includes the traditional IT equipment and non-traditional IT equipment. The latter describes power and environmental equipment installed to specifically support the IT environment. The power and environmental equipment are installed to maintain a 24/7/365 (24 hours a day/7 days a week/ 365 days a year) IT and communications network. The installation of a real-time Integrated Power and Environment Monitoring System (IPEMS) has been instituted at pharmaceutical companies to monitor, manage, alarm, and notify IT management on the health and sustenance of the local and remote IT environment.

What procedures, documentation, and practices are needed to establish this equipment in a pharmaceutical facility? How is the facility maintained? How can a monitoring system be installed in a 24/7 mission critical operation without unnecessary disruption? How can the prevention of downtime enhance performance goals? These questions are answered in the following article.

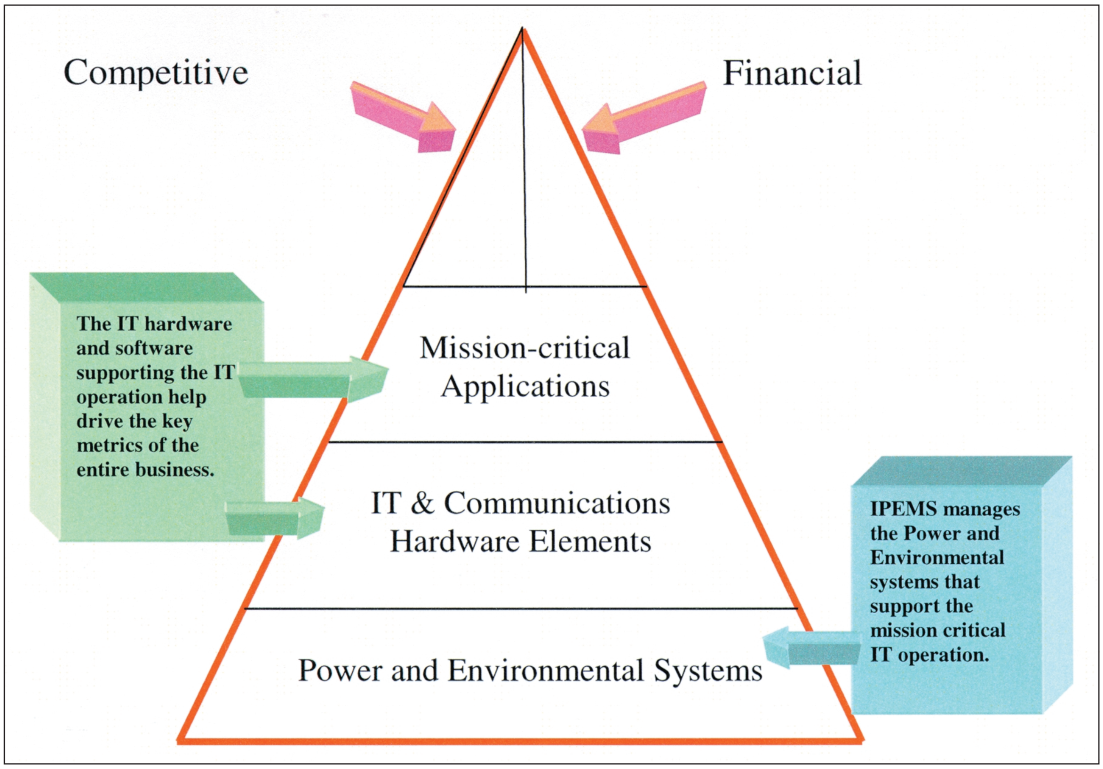
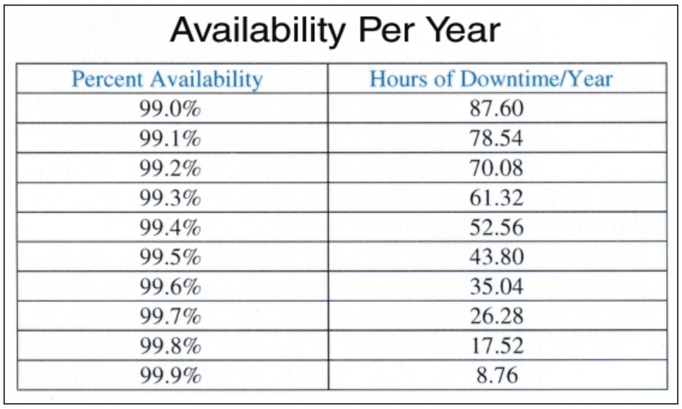

Competitive
Financial
Mission-critical Applications
IT & Communications Hardware Elements
Power and Environmental Systems
The IT hardware and software supporting the IT operation help drive the key metrics of the entire business.
IPEMS manages the Power and Environmental systems that support the mission critical IT operation.

Figure 1. Corporate pyramid based on Mission-Critical 24/7 Operations.



Availability Per Year

Percent Availability	Hours of Downtime/Year
99.0%	87.60
99.1%	78.54
99.2%	70.08
99.3%	61.32
99.4%	52.56
99.5%	43.80
99.6%	35.04
99.7%	26.28
99.8%	17.52
99.9%	8.76

Figure 2. Uptime availability per year and the calculation of annual downtime in hours.

Information Technology and Non-Traditional Information Technology Definitions

The operation and sustenance of a data center relies on different tiers of structure and support: the Information Technology (IT) enterprise, the non-traditional IT infrastructure, operational and financial personnel, and engineering staff are needed to maintain coherent and efficient operations.

IT is a heterogeneous environment encompassing multi-vendored products. The single crosslink to all components, regardless of vendor, is a Network Management System (NMS). IBM, HP, Compaq, Convergent, and Tandem products etc. are integrated into a concise enterprise using NMS software. The integration of divergent vendors has been accomplished due to open architecture software. Traditional computer hardware is only a small component of the IT environment. Telephone switching systems, PBXs, network routers, Internet connections, Intranet networks; WANs, and LANs are all 24/7 subgroups of the IT environment.

Global, regional, remote, and local monitoring schemes are integrated into an enterprise monitoring system. This scheme permits the usage of a centralized Network Operations Center (NOC) to monitor the entire enterprise. The centralized NOC can serve as a clearinghouse for alarms and troubleshooting of unmanned and remote sites without the cost of physical on-site intervention. The mission-critical denotation is no longer applied only to the computers and mainframes of data center environment, but to all of the support and foundation equipment of the enterprise.[1]

Non-traditional IT equipment supports the mission-critical IT sector. Equipment, commonly denoted as foundation or support, is being emphasized as an integral element of the IT strategy. Power elements devoted to maintaining the uptime of IT equipment; Uninterruptible Power Supplies (UPS); Diesel and Gas generators; Automatic Transfer Switches (ATS), and Power Distribution Units (PDU) are being continually monitored as critical components in the IT strategy. Environmental elements of the Data Center are being scrutinized with the same veracity. Solitary air conditioning units, temperature, and humidity sensors are strategically placed in Data Centers to ensure maximum cooling and temperature stability. Electrostatic Discharge (ESD) monitoring is recommended to prevent static electricity build-up and discharge to the IT equipment. Hazard and safety components are regularly devised into the monitoring scheme to ensure IT safety from fire, flood, and external atmospheric influences. In total, all elements encompassing the IT environment (traditional or non-traditional), mission-critical applications, and a 24/7 enterprise are in jeopardy if any failure occurs.

A graphic pyramid of this interdependence on all aspects of the corporate structure can be illustrated in Figure 1. The base of the pyramid constitutes the non-traditional IT elements. The second tier denotes the traditional IT and communications equipment. The third tier controls all mission-critical aspects of the enterprise. Upper tier is divided into two sectors “Competitive Advantage” and “Financial Performance.” Any element under the mission-critical banner affects the competitive advantage and the financial performance.

Downtime Calculation

Every facility has a downtime calculation. In the event of an IT outage, the pharmaceutical company can realize revenue loss, documentation loss, actual experimentation or batch loss, and loss productivity of employees. These losses can total a run rate of tens of thousands of dollars an hour to more than a million dollars an hour. A survey conducted in 1997 of the Fortune 1000 companies showed the average IT downtime lasted for four hours at an expense of $330,000 and an annual cost of almost $3 million dollars.[2] This included all companies of the Fortune 1000 in many different industries. Some industries are more susceptible to downtime than others.

Figure 2 shows the amount of downtime per year when the uptime is 99.0% - 99.9%. The downtime calculation of a 99.9% uptime operation is almost nine hours per year. If an hour of downtime can equal $1,200,000 when all totals are tallied, then the following scenario can be calculated:

- 99.9% uptime = 8.76 hours of downtime a year
- $1,200,000 x 8.76 hours = $10,512,000 per year of loss or unrecoverable revenue

At 99.0% uptime, the loss of revenue per year is staggering:

- $1,200,000 x 87.60 hours = $105,120,000 of lost and unrecoverable revenue

Obviously, hourly calculations of revenue loss are the easiest to calculate. Each pharmaceutical company has calculations for downtime and risk factors. Minimizing both factors is imperative. Uptime is costly, but downtime is more expensive!

Downtime Prevention

Prevention of downtime and guaranteeing uptime is paramount in all mission-critical 24/7 operations. The non-traditional IT infrastructure equipment is designed to enhance the uptime. Back-up systems for power, auxiliary power generation, and corresponding power distribution systems are designed to enhance and alleviate the “dirty” and intermittent power supply from the utility. Uninterruptible Power Supply (UPS) equipment conditions the power to supply constant and even voltage to the needed IT equipment within small tolerances of approximately 0.1%. Fluctuations from the power grid can easily deviate to 10% of the prescribed voltage.

Ensuring the traditional IT infrastructure with conditioned and back-up power is only one way to enhance downtime prevention. The ultimate assessment of uptime may rely on the power back-up scheme and its monitoring.

All equipment can malfunction. Small deviations from operational norms can cause catastrophic outages. One data center, susceptible to chronic network bank failure, had difficulty in pinpointing the cause. Use of a real-time monitoring and management system help diagnose the problem. The installed network cards were susceptible to Electrostatic Discharge (ESD). When the humidity in the data center room dropped to 28%, static build-up and subsequent discharge was sufficient to render the network cards inoperable. The implementation and use of an Integrated Power and Environmental Monitoring System (IPEMS) allowed the data center manager to proactively assess and provide corrective actions inhibiting any further downtime due to ESD. The solution was simple: when the humidity fell to 30%, additional air conditioning and a stand-alone air conditioning unit provided humidity. The IPEMS can watchdog many different and dynamic situations on a second-to-second basis and help in the management of the infrastructure.

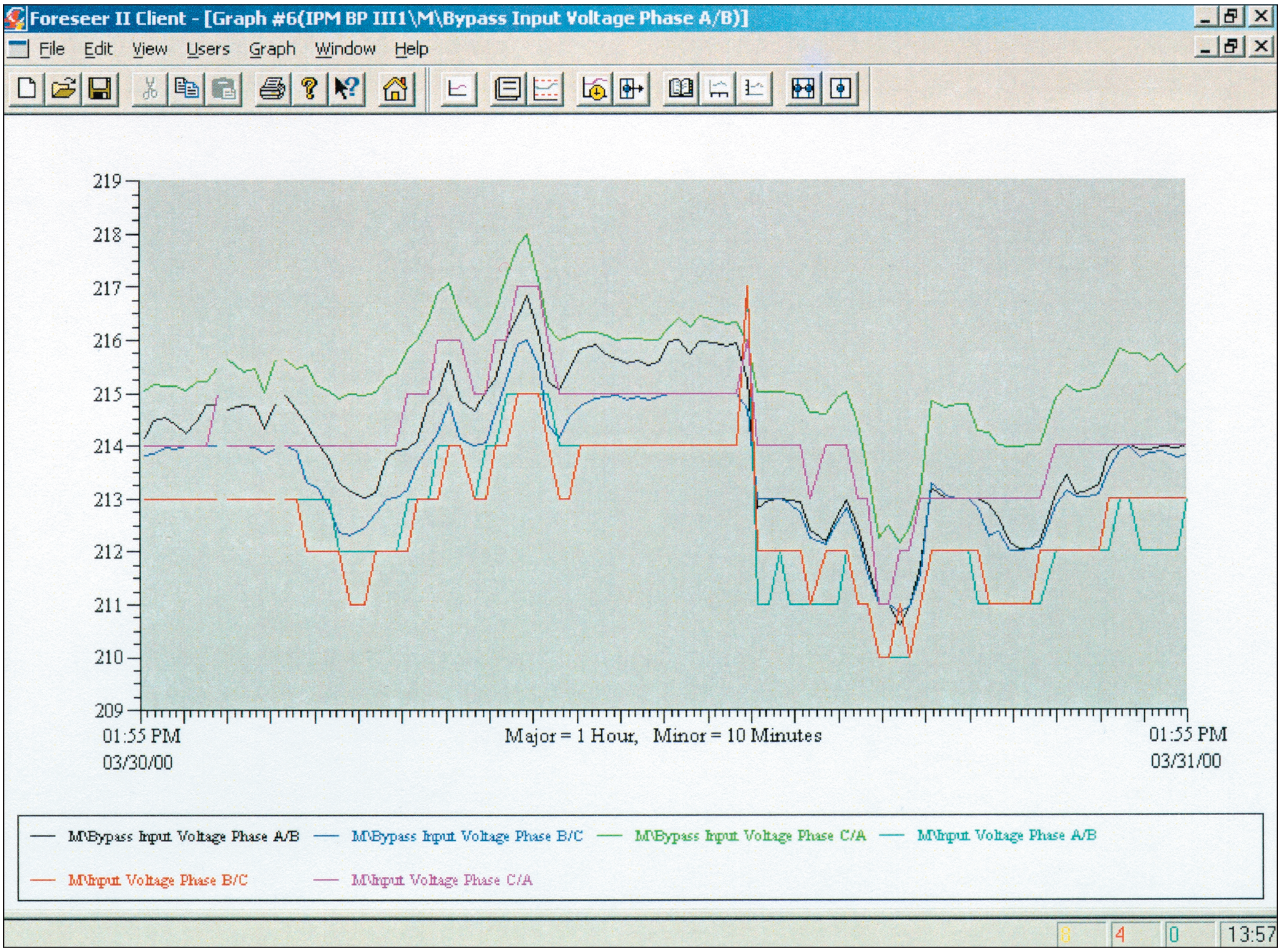
Although no system is infallible, use of IPEMS can improve uptime and reliability of the non-traditional infrastructure. A user of IPEMS in Denver had 100% uptime for more than six and a half years. This data center processes more than $50 million in transactions per day. One hour of downtime equates to more than $2 million in lost revenue. The cause of downtime after six and a half years of uptime was attributed to the engagement of an Emergency Power Off (EPO) switch, inadvertently. The ensuring of uptime more than a six and a half year period translated into an estimated $100 - 200 million in additional revenue to the company.

The IPEMS system should not be seen as a monitoring system only, but as a non-traditional infrastructure management tool.

Traditional Alarms Schemes versus IPEMS

Instantaneous data, on-line measurement, and immediate notification are inherent qualities of an IPEMS structure. Proactive situational diagnostics of an excursion can impede or stifle an impending critical breakdown within the data center.

Traditional alarm schemes for status monitoring are of a Boolean nature. Status is monitored by a simple stop light scheme. Red denotes alarm conditions and green denotes normal operations. The traditional systems retain little or no data archive, no graphical interpretation, nor definitive proactive actions. When an alarm is annunciated, many alarms may simultaneously illuminate a panel or indicator board. Confusion may ensue due to the cacophony of buzzers and bells producing sensory overload. Since the indicators, panels, and boards do not archive historical data, "cause and effect" or "post-mortem" analysis will be severely hampered. A panel board with many illuminated red lights does not allow for


Foreseer II Client - [Graph #6(IPM BP III1\M\Bypass Input Voltage Phase A/B)]

File
Edit
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Help
219
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01:55 PM
03/31/00
M\Bypass Input Voltage Phase A/B
M\Bypass Input Voltage Phase B/C
M\Bypass Input Voltage Phase C/A
M\Input Voltage Phase A/B
M\Input Voltage Phase B/C
M\Input Voltage Phase C/A
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4
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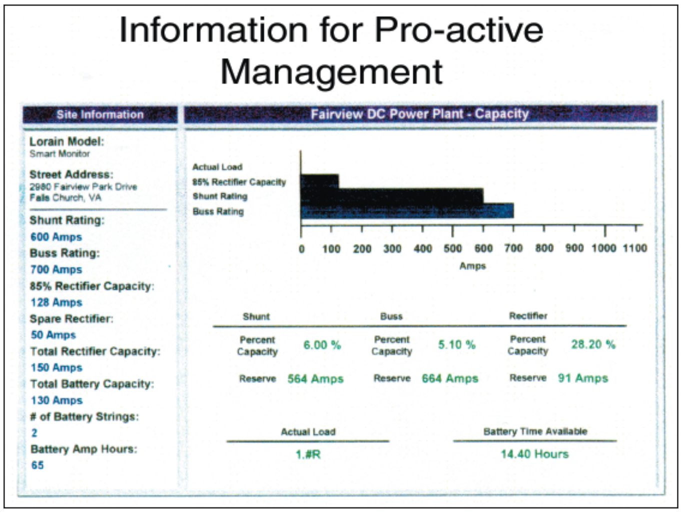
13:57

Figure 3. Multi-channel graphing describes input voltages and changes over a 24-hour time span.



Information for Pro-active Management

Site Information

Lorain Model:
Smart Monitor

Street Address:
2980 Fairview Park Drive
Falls Church, VA

Shunt Rating:
600 Amps
Buss Rating:
700 Amps
85% Rectifier Capacity:
128 Amps
Spare Rectifier:
50 Amps
Total Rectifier Capacity:
150 Amps
Total Battery Capacity:
130 Amps
# of Battery Strings:
2
Battery Amp Hours:
65

Fairview DC Power Plant - Capacity

Shunt		Buss		Rectifier	
Percent Capacity	6.00 %	Percent Capacity	5.10 %	Percent Capacity	28.20 %
Reserve	564 Amps	Reserve	664 Amps	Reserve	91 Amps

Actual Load	Battery Time Available
1.#R	14.40 Hours

Figure 4. Real-time information for pro-active management.

diagnosis, rather it will indicate a change in status only, a basic change from “good” to “bad.”

It is difficult to diagnose cause and effect where no historical data exists. Historical data is needed to compare normal operating conditions versus abnormal or alarm conditions.

Historical data, graphing, relationship graphing, “cause and effect” scenarios, and near-term tactical and far-term strategic planning can be elements of an IPEMS. IPEMS is comprised of various data inputs: analog, digital, serial, and derived signals. Live inputs of analog, serial, and digital signals allow for a comprehensive monitoring scheme, but lack finesse to define the total picture – *Figure 3*. Figure 3 depicts the variations of voltages. A single voltage trace may indicate a condition or trend. The availability of multiple trace plotting and historical data display depicts the total conditions over a specific time period. Long-term, short-term, and projected trend analysis provides proactive management of the power train.

A simple example:

Temperature over a specified limit will cause an alarm.

Questions:

- How long was the temperature rising before reaching the limit?
- Was there a sudden deviation from the normal and mean temperatures? If yes, over what period of time?
- Are there other channels of related equipment currently being monitored which show a similar trend?
- If the trend continues, what are the liabilities or risks?
- Has a risk assessment been proffered of this condition previously?
- Are corrective measures, Standard Operating Procedures (SOPs) or procedure steps documented and applicable to this condition?
- Can a decision be implemented before criticality causes malfunction?

Although the questions above may seem trite, these questions are valid and need historical data for verification, validation, and corrective action development to ensure that a similar excursion in the future will be timely managed without disruption to the IT environment.

Commissioning and Documentation

Although no control is administered in the above scenario, verification and validation of the installation and operation of the system is imperative in a regulatory environment. Commissioning documentation is used during the installation and startup of the system. Verification of point-to-point data channels is administered. Verification of values and alarm limits is performed. Verification of communications schemes is documented.

Adherence to compatible instrumentation Installation Qualification (IQ), Operations Qualification (OQ), and Performance Qualification (PQ) documentation established in the pharmaceutical facility is paramount. The installation and use of sensors in the IT data center should correspond to the same documentation and maintenance rigors established for similar sensors in the production areas. The best example is the installation of temperature and humidity sensors in the IT data center. A pharmaceutical facility in the northeast installed similar temperature/humidity sensors as in the production area. These IT temperature/humidity sensors were validated using the same IQ, OQ, PQ, and maintenance documentation.

Pharmaceutical Facility Local and Remote Monitoring

Many large pharmaceutical companies have a campus environment. One pharmaceutical company in the Midwest uses a DataTrax Foreseer IPEMS for monitoring distributed data centers in a campus environment. All power and environmental factors are monitored in real-time. Equipment monitored includes Uninterruptible Power Supplies (UPSs), generators, power distribution units (PDUs), air conditioning units, automatic transfer switches (ATS), power meters, fuel management systems for the generators, and battery monitoring. Not all equipment is installed in each building.

The IT Operations Center in the main data center maintains the NT server. This NT server is the depository for all real-time and historical data, alarms, alarm acknowledgements, reports, and notification schemes for all equipment connected to the IPEMS server. Communication to the equipment installed in buildings outside the data center is via Transmission Communications Protocol/Internet Protocol (TCP/IP). TCP/IP is the common communications protocol used in Internet and Intranet communications. The NT server queries a communications device in the remote building. The remote communications device transmits the data from the remote equipment across the network to the NT server. Local personnel are responsible for the remote devices and buildings during business hours only. The IT Operations Center monitors all devices on the entire campus 24 hours a day. During non-business hours the IT Operations Center focuses on all operating parameters of the entire enterprise. If an excursion or alarm should occur, the IT Operations Center determines the severity or criticality, and notifies the proper personnel.

Each piece of equipment is polled once a second for all corresponding data. The DataTrax Foreseer IPEMS uses serial communication protocols to “talk” to a device. Serial communications allow for many different data values to be transmitted simultaneously. Serial communication schemes allow all of the data and channel values to be transmitted - not just a singular value as in a digital form “c” contact. Some equipment use digital contacts for summary alarms. Although the summary alarm provides adequate notification of an alarm on a given piece of equipment, it does not provide any data of why the equipment malfunctioned or what predicated the malfunction.

Local and Remote Monitoring

Monitoring schemes in the pharmaceutical industry include global, regional, citywide, campus, and individual system's environments. As described above, a campus environment is most often employed in the pharmaceutical industry. Many buildings in the campus are connected via a communications network using TCP/IP. Many sites on the campus can be monitored in real-time using the network backbone provided by the IT department. Most multi-site pharmaceutical companies have Wide Area Networks (WANs). This communications backbone allows for Intranet and e-mail traffic at high-speeds. IPEMS are instituted to monitor the entire regional enterprise, which may encompass many sites in a regional area of the United States. The aforementioned northeast pharmaceutical company monitors their main IT data center, local campus, and a remote site in the Boston area on a single IPEMs system across the WAN. Still, other companies utilize IPEMS for monitoring of far-flung international operations in real-time across many time zones.

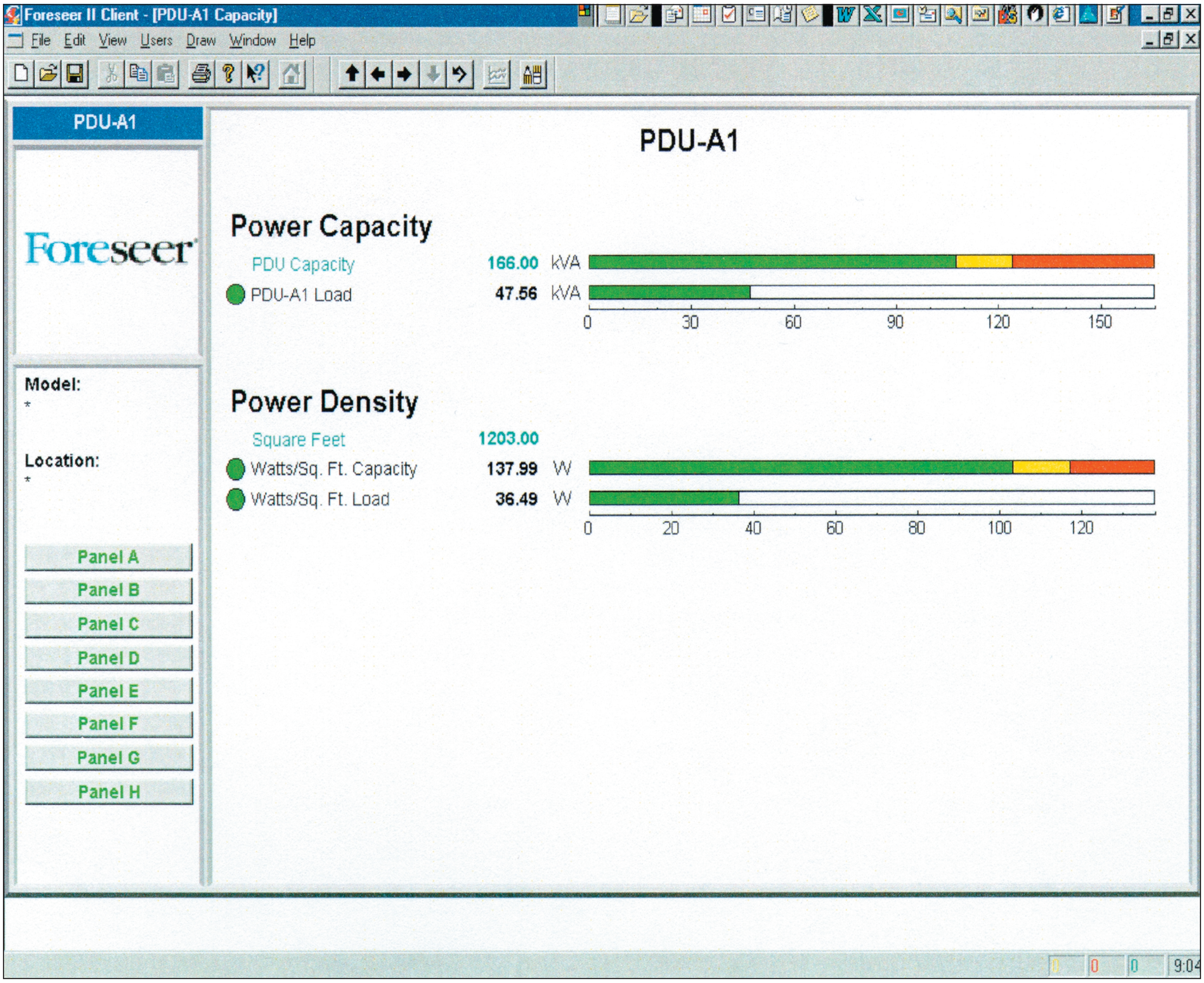
The crux of these operations is the imperative of providing data and IT services 24/7/365. Multi-national, national, and 24-hour pharmaceutical production facilities need access to data and IT operations at all times.

Capacity Planning Using IPEMS

IPEMS can manage the infrastructure, predict needed capacity, and forewarn impending barriers or bottlenecks. IPEMS can accurately manage the non-traditional IT equipment with no adverse affect.[3]

As a data center is being populated with racks of equipment, each additional piece of equipment installed strains the environment, power, and sub-systems. If an UPS and a PDU have certain capacities, the more equipment placed against those capacities will diminish the efficacy of the power supplied. What is the threshold of the "point of no return" when additional equipment will overtax the supply? How many racks and banks of computers will it take to reach that point? When racks of computers are added, how much additional heat is generated? How much additional cooling is needed to offset the heat generation? Are the smoke, fire, and leak detection systems operational for the newly populated area?

Figure 4 depicts the load capacities of a DC rectifier plant commonly used in telecommunication structures. The calculation for load capacities is in real-time and congruent with the peak and off-peak usage. Actual load calculations fluctuate on a second to second basis. As new equipment is populated the capacity, load,



PDU-A1

Model: *

Location: *

PDU-A1

Power Capacity

PDU Capacity 166.00 kVA

PDU-A1 Load 47.56 kVA

Power Density

Square Feet 1203.00

Watts/Sq. Ft. Capacity 137.99 W

Watts/Sq. Ft. Load 36.49 W

Figure 5. Power capacity vs. real-time load measurements per Power Distribution Unit. Calculation of watts per square foot for power density.

and reserve characteristics change commensurate with the equipment power draw, as depicted in Figures 5 and 6. These actual power calculations, for new equipment, can be pre-programmed as a derived channel and added to the existing software before actual installation, thus, creating a "what-if" scenario with positive assessment before the installation.

IPEMS can help with the resources to systematically allocate the proper hardware for each population addition in the data center. As the new racks of computer hardware are installed, an equally important non-traditional IT component is installed and functional. This exercise can beneficially help financial planning, scheduling of installations, ordering of equipment, project management, commissioning, and human resources planning for the build, installation, initial, and continuous operation of a data center. All of these tasks are a lengthy description of capacity planning.

Summary

Mission critical 24/7 operations have unique and specialized functions and criteria. The investment by the data center operator in the computers, servers, networking equipment, routers, networks, communications, and connectivity devices is in the millions of dollars.

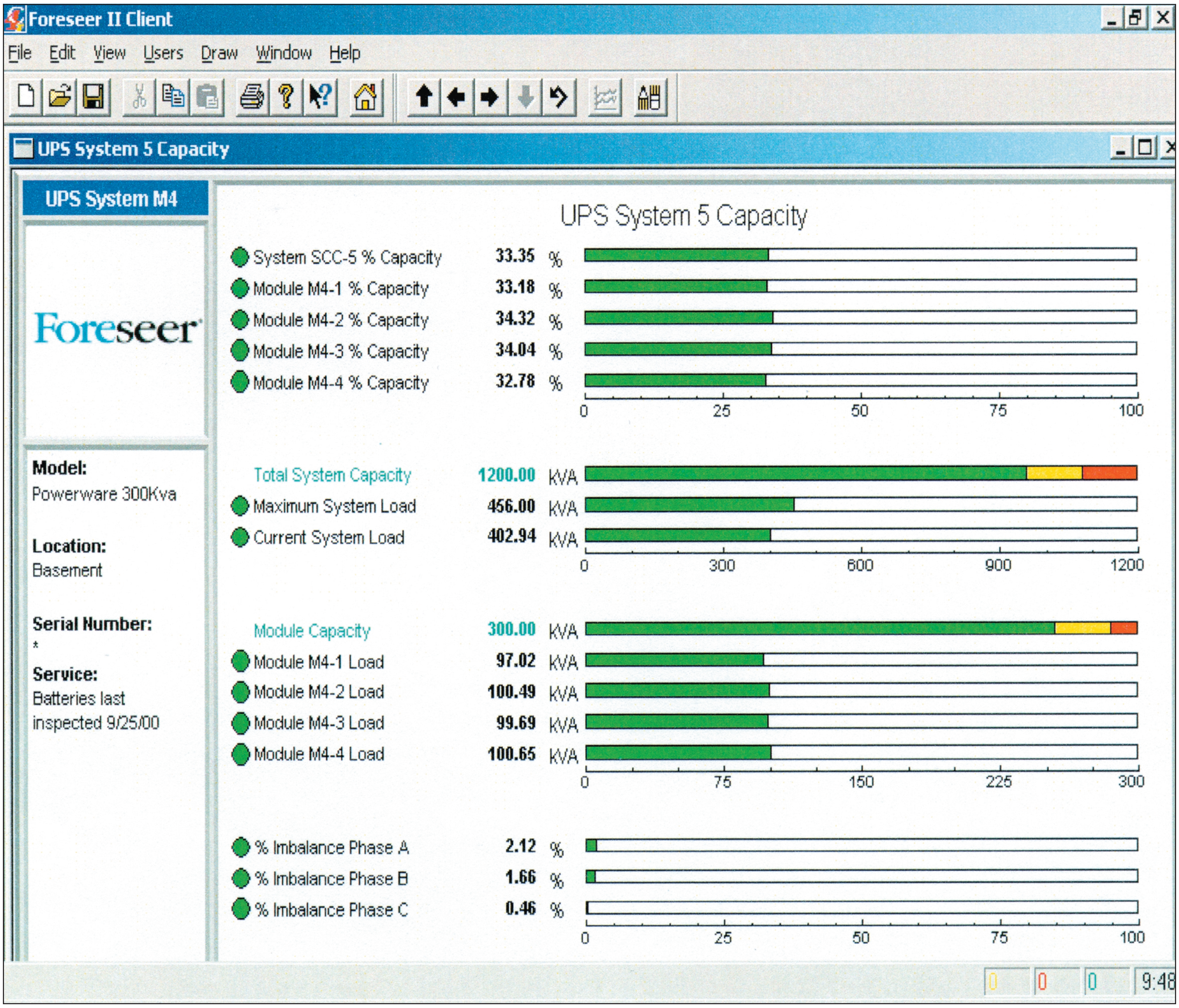
The non-traditional IT equipment installed to support the data center and communications gear is integral to the operation and IT availability strategy.

The monitoring of the power, environmental, and independent systems installed to support the IT and communications environment is imperative to countermand downtime.

Historical trending, data, reports, records, real-time data, alarms, notification schemes, capacity planning, and trending prognostication are elements shared by all financial, operations, and engineering personnel.

The implementation of commissioning documentation, IQ, OQ, PQ and maintenance documentation where appropriate to non-pharmaceutical production equipment, sensors, and areas can meet and/or exceed FDA guidelines.

Uptime equals revenue. Action by the appropriate personnel before an alarm or situation reaches criticality prevents downtime, maintenance issues, and inoperative equipment.



UPS System 5 Capacity

Model:
Powerware 300Kva

Location:
Basement

Serial Number:
*

Service:
Batteries last inspected 9/25/00

System SCC-5 % Capacity	33.35	%
Module M4-1 % Capacity	33.18	%
Module M4-2 % Capacity	34.32	%
Module M4-3 % Capacity	34.04	%
Module M4-4 % Capacity	32.78	%
Total System Capacity	1200.00	KVA
Maximum System Load	456.00	KVA
Current System Load	402.94	KVA
Module Capacity	300.00	KVA
Module M4-1 Load	97.02	KVA
Module M4-2 Load	100.49	KVA
Module M4-3 Load	99.69	KVA
Module M4-4 Load	100.65	KVA
% Imbalance Phase A	2.12	%
% Imbalance Phase B	1.66	%
% Imbalance Phase C	0.46	%

Figure 6. UPS power load vs. capacity, KVA usage, and phase imbalance in real-time measurements.

References

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2. FIND/SVP, "System Downtime," Information Advisor 2000, KM4:3.

3. DataTrax® Systems, "Power Management with the Foreseer Software," copyright 2001.

Additional Reference Source

AFCOM – The Leading Association for Data Center Professionals, Web site www.afcom.com.

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Nissan Cohen has more than 25 years of experience in Mission-Critical Monitoring with emphasis in Semiconductor Manufacturing, Pharmaceutical Process and Production, Ultrapure Water and Chemical Systems, Nuclear Power, Foreign and Domestic Commercial and Governmental Data Centers, Fiber Optic Networks, and Internet Service Providers. Cohen has written more than 25 technical and peer reviewed articles for various publications including **Pharmaceutical Engineering**, **Pharmaceutical Technology**, **Ultrapure Water**, **Semiconductor International**, **Contamination** and **The Journal of the Institute for Environmental Sciences**. Cohen is the International Sales Manager for DataTrax Systems. Cohen received a BS from the University of Wisconsin and a MS from Hebrew University, Israel. Cohen can be reached at: 1-303/665-5577 or nissan.cohen@datatrax.invensys.com.

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