Are all environmental parameters under control to release my products?

Our monitoring solution lets you monitor your GxP environmental parameters and cut your validation costs.

Answers for infrastructure.

SIEMENS

Reduce validation efforts with CMT

No other industry is subject to more regulations than the life science industry. Legal regulations specify that environmental parameters which may negatively affect product quality and thus patient or consumer health must be continuously monitored by validated systems.

We offer a standardized solution – Compact Monitoring Technology (CMT) – to comply with these exacting demands. Since CMT is pre-engineered, pre-installed and pre-tested, it cuts your installation expenses, costs and risks on your way to validated monitoring. Moreover, CMT's scalability means that it can grow with your needs.

Comply with regulatory requirements with CMT

■ International health protection regulations

European and American authorities define measures* that must be carried out to protect public health and safety. One of these measures involves providing documentary evidence that environmental conditions which have a direct impact on product quality – such as temperature, humidity, air pressure and particle measurements – are recorded and saved in a tamper-proof form. CMT makes it possible to conduct all relevant measures efficiently and in compliance with regulations.

■ Extensive expertise for your efficient validation

We have developed a solution consisting of standardized technology and analysis, validation and service components based on the experience we have gained in over 1,500 life science projects throughout the world. The solution makes it easy to comply with legal specifications and reduces your validation efforts considerably. Thanks to our comprehensive services, your CMT solution can be implemented optimally in your environment.
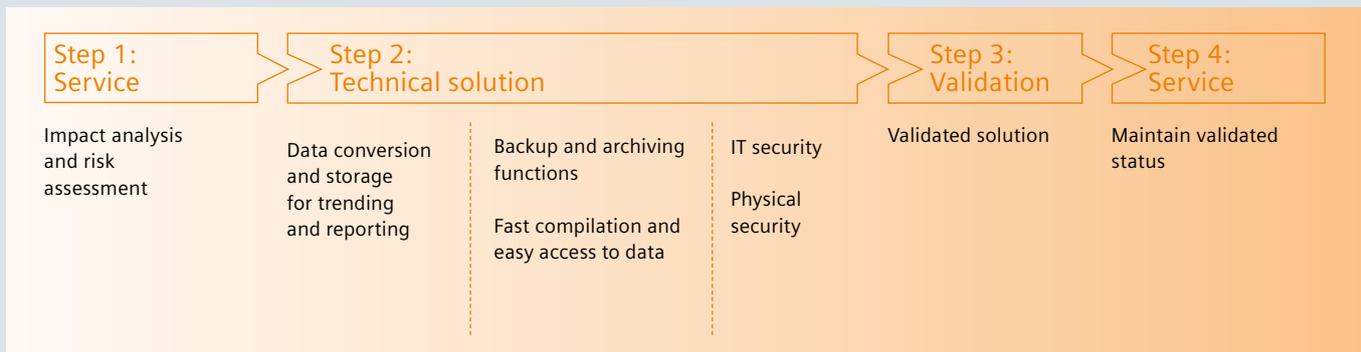
■ Four steps to a validated solution

– The first step of the CMT solution provides a pre-qualification service. Our experts use system analyses to define environmental parameters critical to GxP. CMT only needs to monitor these parameters, which considerably cuts your monitoring and validation costs.
– In step two, we deliver the technology – an independent standardized monitoring system for critical parameters. The advantage of this technology is that it is already pre-engineered, pre-installed and pre-tested under the most stringent conditions.
– In the third and fourth steps, we provide validation services and prepare measures to ensure you maintain your validated status even into the future.

Highlights

■ International regulations are met consistently thanks to CMT

■ Our industry-specific expertise reduces your validation expenses considerably

■ CMT delivers a validated solution in four steps, cutting your costs

Step 1: Service	Step 2: Technical solution			Step 3: Validation	Step 4: Service
Impact analysis and risk assessment	Data conversion and storage for trending and reporting	Backup and archiving functions Fast compilation and easy access to data	IT security Physical security	Validated solution	Maintain validated status

CMT – four steps to a solution

Service – identifying your quality-relevant environmental parameters

Based on our expertise, we offer competent impact analysis and risk assessment support to identify your critical environmental parameters.

Step 1: Service	Step 2: Technical solution	Step 3: Validation	Step 4: Service

■ **Reduced costs thanks to extensive impact analysis**

Our experts help you create a comprehensive impact analysis of your building infrastructure. The analysis categorizes building infrastructure systems according to their impact on product quality. This differentiation clearly identifies which systems require validation and monitoring using CMT. As a result, only your CMT needs to be validated, which reduces your validation costs considerably.

You also receive documented evidence of the analysis, which is easy to adapt for submittal to the regulatory authorities.

■ **Improved product quality thanks to a comprehensive risk assessment**

Our experts, a system representative and your quality assurance department work together to assess the various risks that may arise throughout the system's life cycle. CMT monitors and identifies critical parameters to minimize risks to your system and keep your validation expenses as low as possible over the long term.

Highlights

■ Identify critical components within your production environment through comprehensive analyses

■ Reduce costs and validation expenses by minimizing parameters that require monitoring

■ Identify efficient measures to minimize risks

■ Create documents for submission to regulatory authorities

Technical solution – compliance with all regulations through CMT

We enable accurate measurements for precise monitoring of relevant environmental conditions.

Step 1: Service	Step 2: Technical solution	Step 3: Validation	Step 4: Service

■ **Creating trends and reports for product release**

All quality-relevant parameters are monitored and backed up on an ongoing basis. Just one click of the mouse creates a full report of the data containing all information for your product release.

■ **Accurate measurements for precise monitoring**

You need accurate measurements for temperature, humidity, pressure and particle counts for CMT to work with correct values. We offer certified sensors with a calibration certificate to measure these parameters accurately. I/O modules let you add a variety of signal types. CMT is pre-configured as standard to enable you to integrate instruments such as a PMS Airnet 510 particle counter via OPC and a 4-20 mA interface.

■ **Sensor calibration without elaborate schedules**

CMT lets you know when sensors need to be re-calibrated. The re-calibration cycle can be set up for each sensor, which keeps you from having to create complex calibration schedules.

■ **Comprehensive trending and reporting**

CMT lets you track room conditions online, letting you identify quickly and easily whether conditions in your room continue to comply with specifications. Another important task of CMT is to take complex data and create meaningful reports specifically for different target groups.

Technical solution – highest degree of security protects your sensitive data

Thanks to integrated IT security functions, CMT ensures that you do not lose any data and that you comply with 21 CFR Part 11.

Step 1: Service	Step 2: Technical solution	Step 3: Validation	Step 4: Service

■ **Regular data backups and archiving**
The system backs up your data hourly, daily, and weekly and stores it in archives over the long term. All CMT data is backed up to an external hard drive on a regular basis. All system activities and user inputs are stored in an audit trail.

■ **Data security in the event of a power failure**
Data is stored temporarily in the event of a power failure thanks to the backup battery integrated into the automation station.

■ **Controlled access**
Restrict system access to authorized users who can access the required data quickly and without time-consuming and expensive training. CMT lets you set up as many as seven user groups with the necessary security levels.

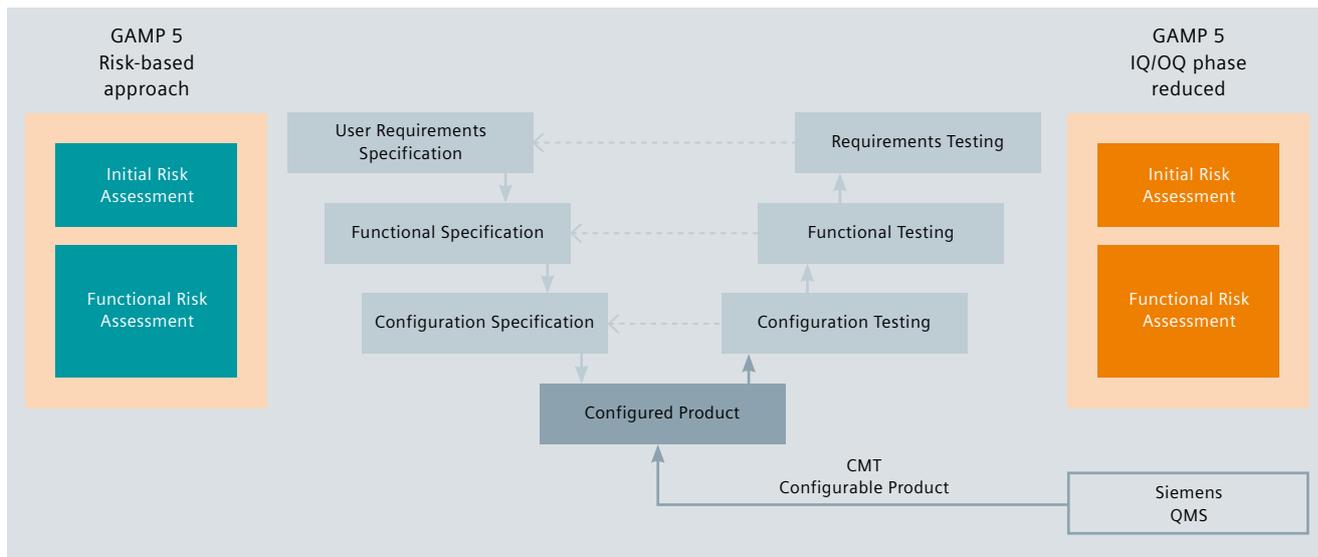■ **Security against unauthorized access**
Door locks are connected to an alarm function. If a door is opened, an alarm light comes on. An alarm is recorded and forwarded in the event of unauthorized access to critical data.

■ **Immediate alarm when systems approach limit values**
CMT alerts you when systems approach specified maximum and minimum values. If you ignore the warning, an alarm is triggered when the particular limit value is reached. All reactions to alarms are stored in an alarm database in compliance with 21 CFR Part 11.

Highlights

■ Precise and seamless monitoring of all important environmental conditions

■ Create clearly arranged trends and reports for making decisions on product releases

■ No data loss thanks to regular backups to external hard drives

■ Immediate reaction to potential problems

■ Automatic notifications of re-calibration

GAMP 5
Risk-based
approach

GAMP 5
IQ/OQ phase
reduced

Initial Risk Assessment

Functional Risk Assessment

User Requirements Specification

Requirements Testing

Functional Specification

Functional Testing

Configuration Specification

Configuration Testing

Configured Product

CMT
Configurable Product

Siemens
QMS

Initial Risk Assessment

Functional Risk Assessment

V-model according to GAMP 5

Validation – faster validation, better quality

The pre-tested CMT solution, which is pre-documented according to the GAMP 5 V-model, considerably streamlines your validation work.

Step 1:
Service

Step 2:
Technical solution

Step 3:
Validation

Step 4:
Service

■ **Cut your validation costs thanks to CMT**

CMT has been pre-configured according to the GAMP 5 V-model, which reduces your validation expenses. As a GMP monitoring system, CMT is validated specifically for each project according to GMP guidelines.

■ **Pre-defined CMT validation documentation for faster project implementation**

CMT has been pre-configured and tested based on the following documents:
– User Requirements Specification (URS)
– Functional Specification (FS)
– Software Design Specification (SDS)
– Factory Acceptance Test Specification (FATS)
– Traceability Matrix

As experts in the field, we install CMT on site according to the following standard documents:
– Site Acceptance Test Specification (SATS)
– Configuration Management Plan (CMP)
– Traceability Matrix
– Verification (IQ, OQ)
– Standard Operation Procedure (SOP)

We can customize the documents to your specific needs as required.

■ **Training for system users**

We offer a comprehensive training program as well as the necessary standard operating procedures (SOPs) that ensure simple and safe operation of your CMT.

Highlights

■ Lower validation costs since the solution is pre-configured according to the V-model

■ Fast project implementation and short time to market thanks to pre-defined validation documentation

■ Compliance with all regulations with significantly less validation effort

■ Readily accepted in the life science industry

Advantage Service Program for the pharmaceutical industry

Service – maintaining your validated status over the long term

Initial validation is the first challenge, but maintaining your validated status during system operation is just as important and challenging.

| Step 1: Service | Step 2: Technical solution | Step 3: Validation | Step 4: Service |

■ **Maintaining your validated status**
We offer a unique service program in-cluding re-calibration of sensors, tests according to 21 CFR Part 11 and integrity tests that help you maintain your vali-dated status over the long term.
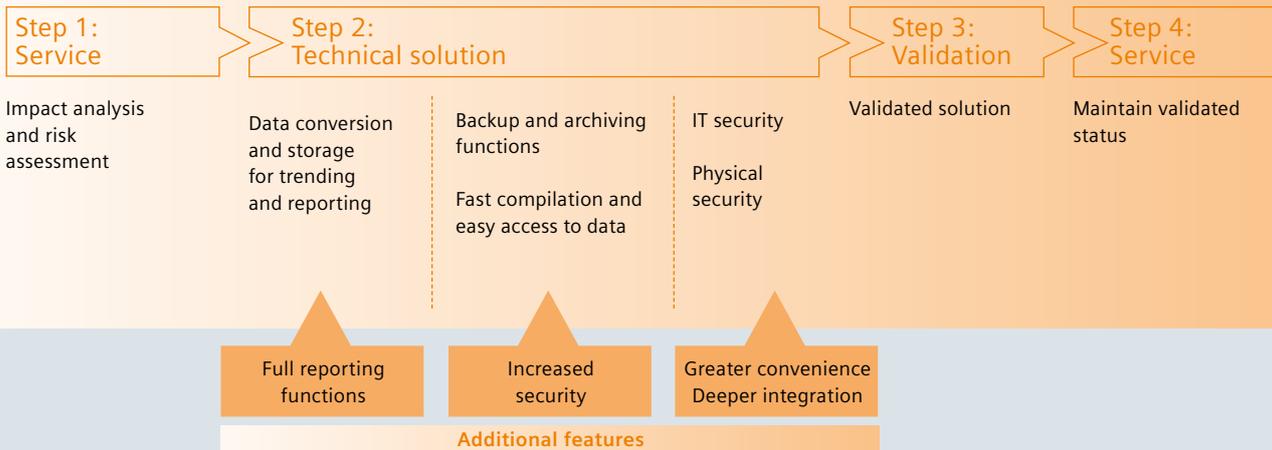
■ **Business process continuity**
Regulatory authorities require evidence that upper limits are not exceeded in the event of failures or breakdowns which would jeopardize product safety and critical data. With our business continuity services we make sure that your data is protected and that you can offer a continuous supply of your products to the market.

■ **Services in detail**
– Backup integrity
  We check that backups are readable.
– Archive tests
  We check the integrity of all archived data and check your data retrieval procedures.
– System integrity
  Your system's performance, integrity and availability are essential for your success. We provide CMT maintenance so you can meet these requirements.
– Calibration
  All regulated facilities are required to re-calibrate all critical process equip-ment routinely. Our calibration service ensures that the sensors used for critical measurements are always within the required tolerances.

Highlights

■ Validated status is ensured over the long term thanks to a compre-hensive service program

■ Proof of backup ensures a continuous supply of products on the market

Step 1: Service	Step 2: Technical solution		Step 3: Validation	Step 4: Service
Impact analysis and risk assessment	Data conversion and storage for trending and reporting	Backup and archiving functions Fast compilation and easy access to data	IT security Physical security	Validated solution	Maintain validated status
	Full reporting functions	Increased security	Greater convenience Deeper integration		
	Additional features				

CMT – four steps to a solution

CMT grows with your requirements

CMT offers a comprehensive standard solution for monitoring your environmental parameters. If you need more functions, more security, faster access or need to comply with additional regulations, CMT offers a tested solution for these needs as well.

■ More extensive trending and reporting functions
CMT provides pre-defined reports for your parameters. If you need more information about rooms (such as floor plans), you can customize additional charts and reports. CMT uses pre-defined parameter labels that could be exchanged for project-specific labels if required. Values from air particle counters and flow meters can be added to reports.

■ Greater archive and IT system security
We configure a managed Ethernet switch to restrict CMT access to a single MAC address. This reduces the risk of unauthorized persons accessing your data. An additional uninterrupted power supply (UPS) prevents data loss in the event of a power failure. Alarms can be sent to employees using different methods (SMS, e-mail, pager) to ensure a reliable alarm system.

■ Easier to use
You can operate CMT conveniently on site using a touch panel or integrate it into your IT network. Multiple users can access CMT or print reports simultaneously.

■ Deeper system integration
You can run CMT as a stand-alone system or network it with other systems within your technical infrastructure. Siemens building solutions let you integrate all systems in your building infrastructure such as heating, ventilation and air conditioning. Other technological systems can be integrated, such as: elevators, escalators, water treatment systems, laboratories, medical technology systems, and monitoring of information and communication systems. Networking your different systems cuts costs since your building is as convenient, secure and energy efficient as possible.

Highlights

■ Creating project-specific charts and reports

■ Increased security and ease of use

■ CMT integrated into the building automation system

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A single solution for different needs

Seamless monitoring of refrigerators and freezers at the Klinikum Pforzheim hospital.

■ Case study: Klinikum Pforzheim/ Germany

The Institute for Transfusion and Laboratory Medicine provides medical laboratory and transfusion services for patients of the Klinikum Pforzheim hospital. The institute has a blood bank, which provides erythrocyte concentrates, FFP and thrombocyte concentrates to several hospitals in the region. The institute has 45 refrigerators and freezers for storing blood products and reagents. The temperature inside the equipment is monitored, and an alarm is triggered if the temperature falls outside of a required range.

■ Analysis phase

The hospital conducted a risk assessment itself and determined that 16 refrigerators and freezers were GxP-relevant and had to be categorized as risk class A. According to DIN 58371 and DIN 58375 these refrigerators and freezers must maintain a temperature of +4 °C; ±2 K or -34 °C; ±4 K.

Calibrated sensors, which are integrated into reference bodies that have the same temperature profiles as the stored products, are responsible for monitoring the temperature in the 16 risk class A refrigerators and freezers. Klinikum Pforzheim decided to install a monitoring system for all 45 refrigerators and freezers to enable continuous recording of the risk class B reagent refrigerators also.

■ The solution

A CMT monitoring system with three additional TX I/O modules in continuous operation was set up for the 45 refrigerators and freezers. A monitor, keyboard and printer were also installed to enable convenient operation on site. An additional signaling column with a buzzer in the hall in the building section alerts staff. Data is also backed up automatically on the hospital's IT network to minimize data loss.

In choosing CMT, Klinikum Pforzheim has a monitoring system that can grow to accommodate future requirements and that complies with all established GMP guidelines. Moreover, the pre-configured system solution has kept validation costs and effort to a minimum. Our industry-specific expertise and future-proof partnership were key factors that led Klinikum Pforzheim to choose the CMT solution.

Highlights

- ■ Monitoring of 45 refrigerators and freezers for storing blood products, plasma and reagents

- ■ CMT upgraded to include three additional I/O modules

- ■ Convenient local CMT operation on site

Functional scope of the technical solution
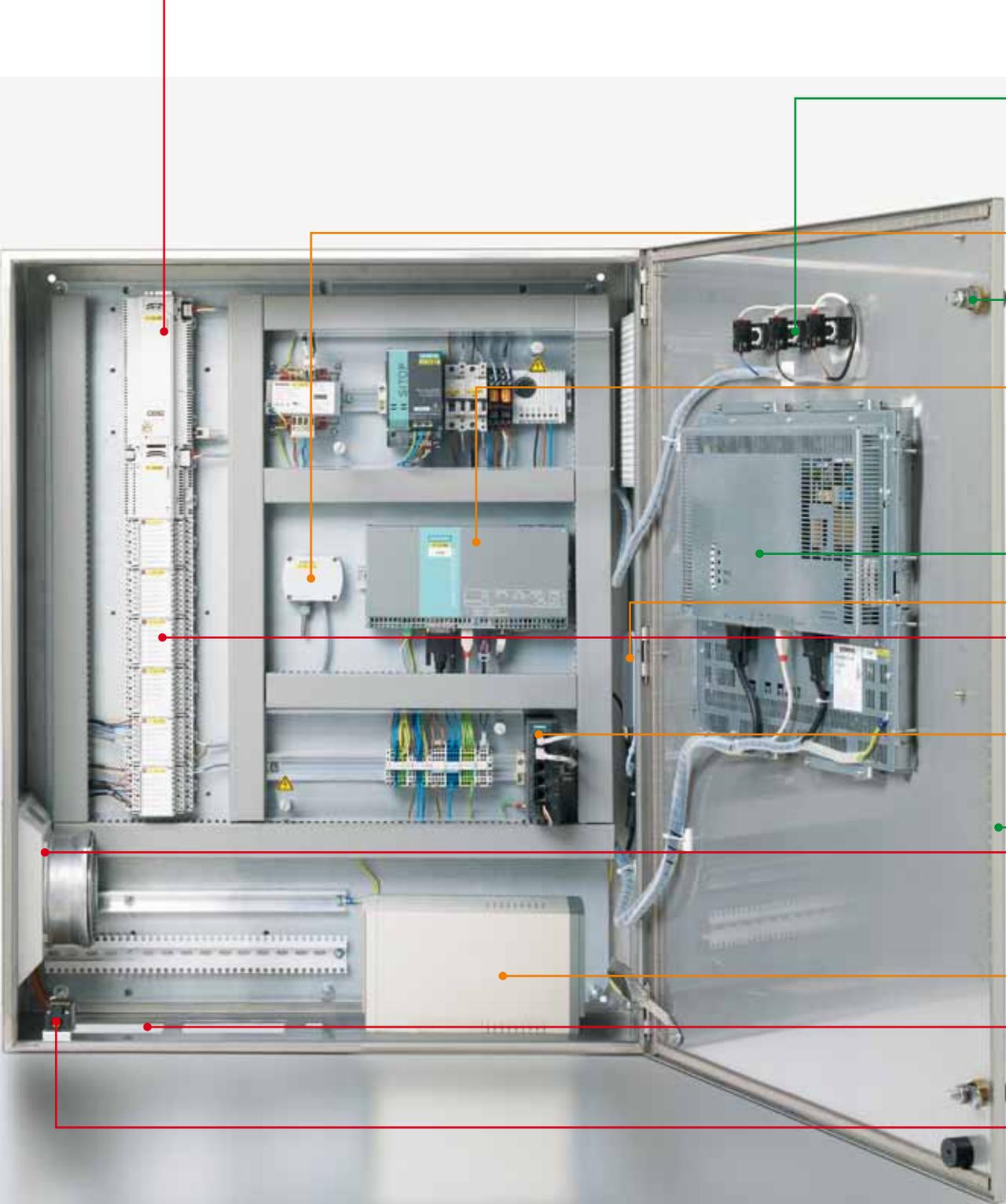
Controller (PX modular)
Intelligent data collection and data storage
even if the connection to the data center
(server) is interrupted

3-level alarm
Integrated display with three different
system alarms:
• Green – everything is ok
• Yellow – warning
• Red – alarm

Integrated temperature sensor
Measures the temperature inside
the control cabinet

Safety lock
Ensures physical security; restricts access
to authorized staff only

**Intelligent system
(Reporting and Archiving)**
The system's data processing center
converts your data into meaningful
information, creates reports and charts,
sends alarms, saves data to databases
and more besides ...

Optional touch panel (Simatic)
Direct and secure on-site CMT operation

External hard drive
160 GB hard drive for backing up and
archiving your critical measurements
and parameters

I/O modules (TX)
32 secure datapoint connections
for your temperature, humidity and
differential pressure sensors

5 Ethernet switches
Interfaces to your local IT network

Stainless steel housing
Made from approved and accepted
material for the specific industry

Integrated fan
Keeps the temperature inside the CMT
constant to prevent system outages

Optional UPS
Uninterruptible power supply prevents
system outages due to power failure

Cabling space
Connect easily and directly to sensor
cables

Door contact
Linked directly to the alarm. An alarm
warns you if the CMT system is open and
thus not safe.

Case study: hospital pharmacy

Extensive monitoring of the production of application-ready cytostatic solutions at the Orbis/Sittard Medical Park.

■ **Case study: Orbis Medical Park/ the Netherlands**

Orbis Medical Park (OMP) in Sittard-Geleen, the Netherlands, is the best example of the future of health care. Together with Siemens, Orbis has created a twenty-first century hospital, which allows Orbis to offer better and more health care at a lower cost. The new Orbis Medical Park building in the town of Sittard replaced the former Maasland hospital in the southern Netherlands.

The general hospital serves around 200,000 inhabitants. It includes 410 patient rooms, a psychiatric and rehabilitation clinic, and an outpatient clinic. Businesses in the shopping area offer health care-related products. The new building cost around EUR 360 million. All processes at Orbis Medical Park are defined, organized and largely standardized with patients in mind.

■ **Preparation of application-ready cytostatic solutions**

Despite industrial development, hospitals have a considerable need for individually formulated special preparations. For this reason, pharmaceutical technology plays an important role. Cytostatic solutions are prepared at a special sterile workbench in separate rooms in the hospital pharmacy with optimum safety precautions. The cytostatic solutions are custom filled for each patient based on the physician's prescription and are ready to use.

■ **The solution**

Orbis Medical Park chose to monitor GMP-relevant information on environmental conditions in the hospital pharmacy using CMT. In all, 15 temperature, eight relative humidity and nine differential pressure values are displayed and archived online. The areas for aseptic formulation, preparation of cytostatics, packaging/storage and air locks are monitored.

CMT is equipped with an uninterruptible power supply and connected to the management station of the building automation system over the IT network.

As an intelligent solution with a risk-based approach, the CMT concept fits perfectly into the highly organized environment of Orbis Medical Park. With CMT – the 2009 Siemens Innovation Award winner – the innovative Orbis Medical Park has chosen a likewise innovative solution.

Highlights

- Monitoring of the production of application-ready cytostatic solutions

- CMT integrated into the building automation system

- CMT upgraded to include an uninterruptible power supply

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Answers for infrastructure.

■ **Megatrends driving the future**
The megatrends – demographic change, urbanization, climate change, and globalization – are shaping the world today. These have an unprecedented impact on our lives and on vital sectors of our economy.

■ **Innovative technologies to answer the associated toughest questions**
Throughout a 160-year history of proven research and engineering talent, with more than 50,000 active patents, Siemens has continuously provided its customers with innovations in the areas of healthcare, energy, industry, and infrastructure – globally and locally.

■ **Increase productivity and efficiency through complete building life cycle management**
Building Technologies offers intelligent integrated solutions for industry, commercial and residential buildings, and public infrastructure. Over the entire facility's life cycle, our comprehensive and environmentally conscious portfolio of products, systems, solutions, and services for low-voltage power distribution and electrical installation technology, building automation, fire safety and security ensures the:
– optimum comfort and highest energy efficiency in buildings,
– safety and security for people, processes, and assets,
– increased business productivity.

www.siemens.com/cmt