

A person wearing a blue cleanroom suit, including a hood and a face mask, is working inside a biosafety cabinet. The person is wearing gloves and is handling a large, clear plastic container. The biosafety cabinet has a glass front and a control panel on the right side. The background is a clean, white laboratory environment.

SIEMENS

Compact Monitoring Technology – your environmental monitoring solution

Monitor your GxP environmental parameters and cut your validation costs.

Solutions for Life Science and Hospitals

www.siemens.com/cmt



Reliable validation for the life science and hospital industries

Ideal environmental conditions are of greatest importance in both the life science and the hospital industries. While no other industry is subject to more and stricter regulations than the life science industry, validating non-regulated areas like operating rooms in a hospital is becoming a growing trend. In both cases, environmental parameters which may negatively affect the quality of products or the health of patients have to be monitored by audited systems.

With our Compact Monitoring Technology (CMT), we provide a standardized solution that complies with the strict legal regulations specified for the life science industry. What's more, CMT is pre-engineered, preinstalled, and pretested. That means for you: fast and easy installation, high cost efficiency, and fewer risks on your way to validated monitoring. And thanks to its scalability, CMT can grow with your needs.

Complying with regulatory requirements

An audited solution for regulated requirements

Processes, requirements, and regulations may differ in the life science and hospital industries. However, there is one thing both have in common: their environment must be safe. With our CMT, we offer a compact solution that is audited for the strict requirements of the life science industry. Using a risk-based approach, it ensures that your GxP-critical environmental parameters are always under control – whether in your pharmaceutical production facility or operating room.

Meeting international health protection regulations

To validate your environment and processes, you need to provide documentary evidence that surrounding conditions that have a direct impact on product quality or the health of patients – such as temperature, humidity, air pressure or air particles – are optimal at all times. CMT monitors, records, and stores these parameters in a tamper-proof manner. The system also provides secure backup and archiving functions as well as easy, safe access to your data. In short: CMT helps you validate your products, processes, and environmental conditions in compliance with all relevant regulations of the life science industry.*

Extensive expertise for efficient validation

We developed CMT on a risk-based approach, utilizing standardized technologies. The validation documentation as well as the dedicated services are based on GAMP 5. CMT helps you comply with legal specifications and considerably reduces your validation efforts. And thanks to our comprehensive service offering, CMT can be optimally implemented in your environment – whether you are in the life science or hospital industry.

Highlights

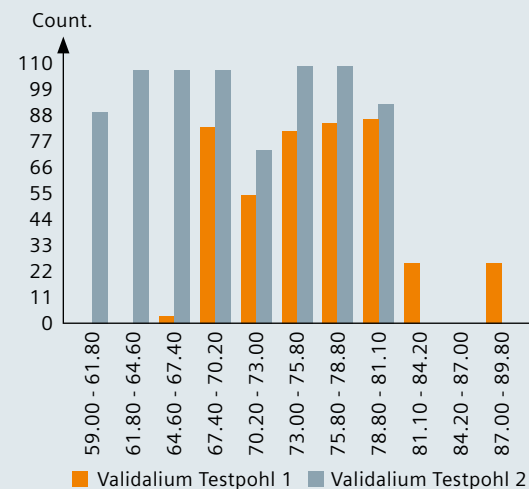
- CMT is audited according to the strict international regulations of the life science industry
- The compact solution is also the ideal choice for non-regulated environments such as operating rooms
- Reliable monitoring, storage, and archiving of GxP-critical environmental parameters
- Low validation costs thanks to standardized technology
- CMT is based on many years of industry-specific expertise from Siemens

* EU Directive 2003/94/EC on good manufacturing practice, Annexes 1, 11, 14, and 15; Section 21 of the US Food and Drug Administration Code of Federal Regulations, Parts 11, 210, 211, 606, and 820, Annex 20





The histogram report



Monitoring and storing critical parameters

Everything under control

In pharmaceutical production, you have to reliably protect your products from contamination – from the raw material to the finished product. In a hospital, you have to ensure sterile environmental conditions, for example in your operating rooms.

CMT continuously monitors up to 100 critical, GxP-relevant parameters such as temperature, humidity, air particles, and air pressure as well as controls access to quarantine areas or to sensitive equipment such as a thrombocyte separator.

Reliable sensors for reliable monitoring

Precise, certified sensors continuously measure all process-critical and quality-relevant environmental parameters. In addition, CMT has a built-in sensor recalibration warning: the system lets you know when the sensors have to be recalibrated. The recalibration cycle can be set up for each sensor – preventing complex calibration schedules.

Alarming in case of deviations

CMT alerts you when monitored systems approach prespecified maximum and minimum values. Should a monitored value fall short of or exceed the predefined value, an alarm is immediately triggered. All reactions to alarms are stored in an alarm database in compliance with 21 CFR Part 11 and Annex 11.

Data recording and archiving

To comply with monitoring and control regulations, CMT records all relevant parameters on an hourly, daily, and weekly basis. The data is archived in an SQL database for the entire life cycle of a product or for a defined time period when monitoring an operating room, for example.

Creating trends and reports

CMT helps you easily create trends and reports that contain all relevant data and information. You can even tailor these reports for different target groups and add graphics or statistics for a better overview and easier evaluation. In addition, you can track room conditions online, enabling you to identify quickly and easily whether they presently comply with specifications.

Highlights

- Monitoring of up to 100 critical environmental conditions
- Precise, certified sensors continuously monitor process-critical, quality-relevant parameters
- Built-in sensor recalibration warning
- Immediate alarming when threshold values are reached
- CMT automatically records and archives all relevant parameters
- Easy creation of clearly arranged trends and reports
- Multi-user operation for up to 10 remote Web clients



Safeguarding data availability and access

Data backup for increased safety

CMT automatically creates a regular backup of all critical data on an external hard drive or optional network drive. Your plus: you have historical data at your fingertips to confirm that environmental conditions always comply with regulations and guidelines.

Controlled system access

CMT allows you to restrict system access to authorized users only. You can even define up to seven user groups with different security levels. Furthermore, new inputs or changes made by users are stored in an audit trail. This also means increased transparency: if parameters have been changed, the system shows the old and the new value and who made the change.

Security against unauthorized access

A physical and logical access control prevents unauthorized access to the monitoring panel. If someone tries to access data or a restricted area without authorization, an alarm is immediately triggered.

Data security in the event of a power failure

CMT comes with an optional backup battery, ensuring uninterrupted power supply and reliable operation even in case of a power outage.

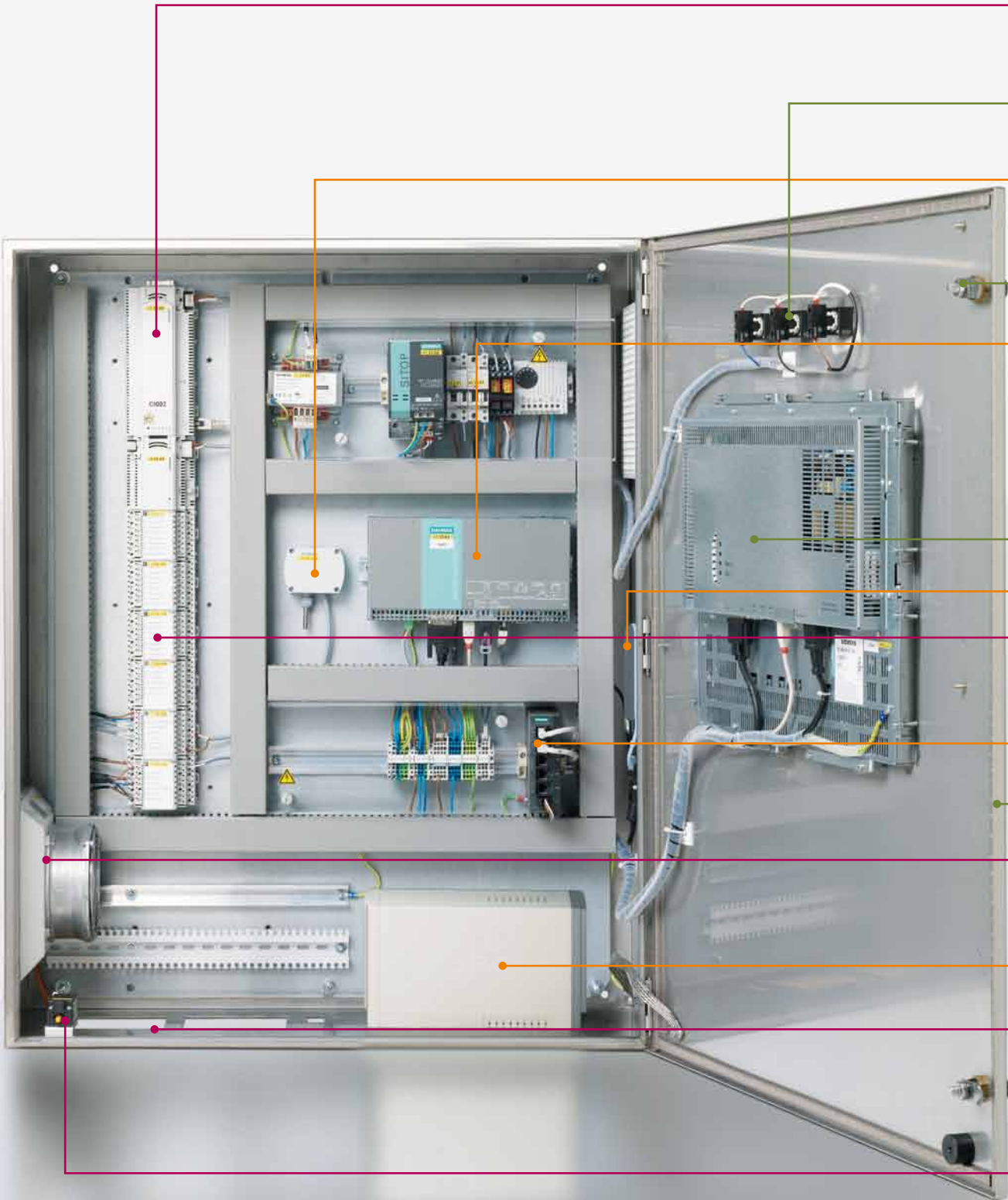
Meeting regulations for data security

All data security functions fully comply with the requirements according to 21 CFR Part 11 as well as Annex 11 of the EU GMP guidelines.

Highlights

- All critical data are available at any time thanks to regular backups to external hard drives
- High level of data security, as only authorized users have access to system and critical data
- New inputs or changes are stored in an audit trail for increased transparency
- Backup battery ensures uninterrupted power supply
- Full compliance with international data security regulations and guidelines

Functional scope of CMT at a glance



Controller (PX modular)

Intelligent data collection and data storage even if the connection to the data center (server) is interrupted

Integrated temperature sensor

Measures the temperature inside the control cabinet

3-level alarm

Integrated display with three different system alarms:

- Green – everything is ok
- Yellow – warning
- Red – alarm

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 ...

Optional touch panel (Simatic)

Direct and secure on-site CMT operation

I/O modules (TX)

32 secure datapoint connections for your temperature, humidity, and differential pressure sensors

External hard drive

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

5 port Ethernet switch

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.

CMT is a compact monitoring solution that helps you gain and maintain a validated status. It complies with the strict regulations of the life science industry and can be quickly and easily installed.



Streamlining the validation process

Cost-effective validation

In the life science industry, you have to assure a high product quality to prevent jeopardizing the lives of consumers. CMT is a standardized system that is pretested to FAT before it is delivered to your site. In addition, validation documentation is predefined according to the GAMP 5 V-model – reducing your validation expenses and your time to market.

Extensive impact analysis

As part of our service offering, we consider your industry-specific regulations and examine possible impacts of the building structure on product quality. Then we use the risk assessment to analyze with you which processes and building areas have to be validated – and thus require monitoring using CMT. This makes CMT a cost-effective monitoring solution. Of course, you will receive documented evidence of the analysis, which is easy to adapt for submittal to the regulatory authorities.

Maintaining a validated status

We support you with our unique service program that includes recalibration of sensors, tests according to 21 CFR Part 11, and EU GMP guidelines, Annex 11.

Highlights

- Lower validation costs and shorter time to market, as CMT is preconfigured according to GAMP 5 V-model
- Monitoring is limited to critical processes and building areas that have to be validated
- Our comprehensive service offering supports you in gaining and maintaining a validated status



Orbis Medical Park,
The Netherlands

GMP-relevant information on environmental conditions in the hospital pharmacy are monitored using CMT: 15 temperature, 8 humidity, and 9 pressure values are displayed and archived.



Protecting patients' health reliably in hospitals

Keeping your hospital sterile

Challenging environments in a hospital include the operating room, intensive care ward, in-house pharmacy, blood bank, laboratory, and warehouse. Here, everything has to be kept sterile. During an operation, for example, air quality can be a decisive factor: it can affect the environmental quality and even provide favorable conditions for the formation and growth of bacteria. And this can have negative impacts on the health of patients.

A safe decision

CMT is a proven monitoring system that complies with the strict regulations of the life science industry. That makes it the ideal choice for you to protect your institution and staff against possible legal suits from patients. Because you can provide documented proof that you kept optimal and compliant environmental conditions at all times. Furthermore, CMT is an independent, standardized system that is already preconfigured – making it also a cost-effective solution.

Service that completes our offering

Our service offering includes everything from risk assessment of the areas to be validated to services that help you maintain your validated status – such as tests for data security and system integrity as well as recalibration of sensors.

Highlights

- Monitoring of challenging environments such as operating rooms or intensive care ward
- CMT complies with the strict regulations of the life science industry
- Documented proof of optimal environmental conditions provides protection against legal suits

Klinikum Pforzheim,
Germany

CMT monitors all 45 refrigerators of the blood bank at the hospital. Calibrated sensors were additionally integrated into the 16 GxP-relevant refrigerators.



Siemens Switzerland Ltd
Infrastructure & Cities Sector
Building Technologies Division
International Headquarters
Gubelstrasse 22
6301 Zug
Switzerland
Tel +41 41 724 24 24

The information in this document contains general descriptions of technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.

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Answers for infrastructure.

Our world is undergoing changes that force us to think in new ways: demographic change, urbanization, global warming, and resource shortages. Maximum efficiency has top priority – and not only where energy is concerned. In addition, we need to increase comfort for the well-being of users. Also, our need for safety and security is constantly

growing. For our customers, success is defined by how well they manage these challenges. Siemens has the answers.

“We are the preferred partner for energy-efficient, safe, and secure buildings and infrastructure.”