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GRANDEVER BIOTECHNOLOGY CO., LTD.

xylem
Let's Solve Water

21.12.2022

How to perform a proper Thermal Mapping--Guidelines, Processes and Devices如何正確執行熱測繪--準則、流程和設備

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Your Host/Speakers Today您今天的主持人/演講者

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Milliya Tsai

Sebastian Schwarz

Allan Javier

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Agenda議程

1. What is thermal mapping什麼是熱測繪?
2. Regulatory Requirements and Expectations監管要求和期望
3. How to conduct a good thermal mapping work如何做好熱測繪工作?
4. Industry Case Examples in Europe and in Asia Pacific歐洲和亞太地區的工業案例
5. Thermal mapping service from ebro來自 ebro 的熱測繪服務
6. Discussion and Questions討論與提問

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- ebro -

- Founded in 1968 in Freiburg 1968 年成立於弗萊堡
- Main focus on the pharmaceutical, medical and food sectors 主要關注製藥、醫療和食品行業
- Direct sales in Germany 德國直銷
- Part of Xylem Analytics since July 2016 自 2016 年 7 月起成為 Xylem Analytics 的一部分
- Worldwide sales with a total of over 100 distributors 全球銷售總數超過 100 家經銷商

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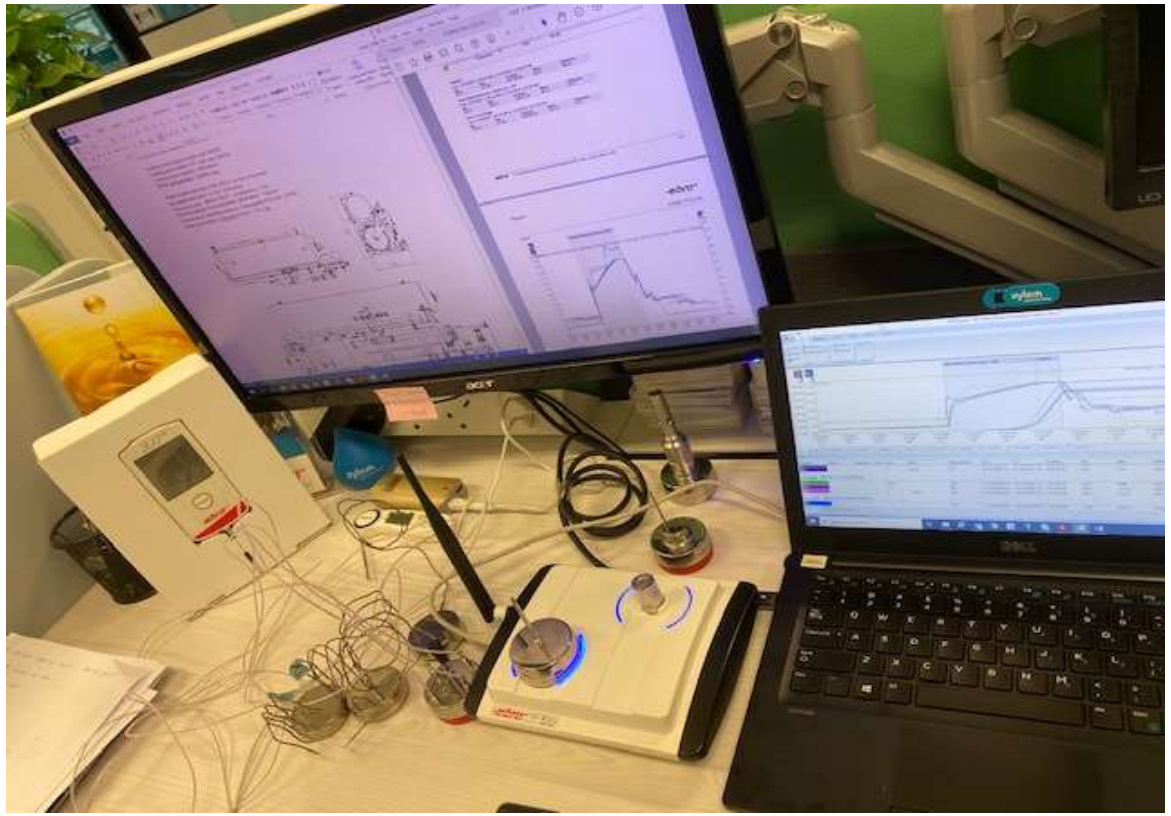
- ebro - Markets, applications and devices 市場、應用和設備

Cold chain 低溫運輸系統

- Transport 運輸
- Cold storage 冷庫
- Refrigerators and freezers冰箱和冰櫃
- Incoming inspection 即將到來的查檢
- Temperature mapping 溫度測繪

Validation 驗證

- Sterilization 消毒
- Washer disinfector 清洗機消毒器
- Refrigerators and freezers 冰箱和冰櫃
- Transport 運輸
- Temperature mapping 溫度測繪



The Pharma / Healthcare Validation Requirements 製藥/醫療保健驗證要求

What Xylem – Ebro could provide the Industry
Xylem – Ebro 可以為工業提供什麼

Pharmaceutical Processes that Typically Require Validation 通常需要驗證的製藥過程

Most Popular 最受青睞:

Autoclaves高壓滅菌器 / Sterilizers 消毒器

Clean Rooms 無塵室

Warehouses 倉庫

Others 其他:

Refrigerators 冰箱

Incubators 培養箱

Climate /Environmental Chambers

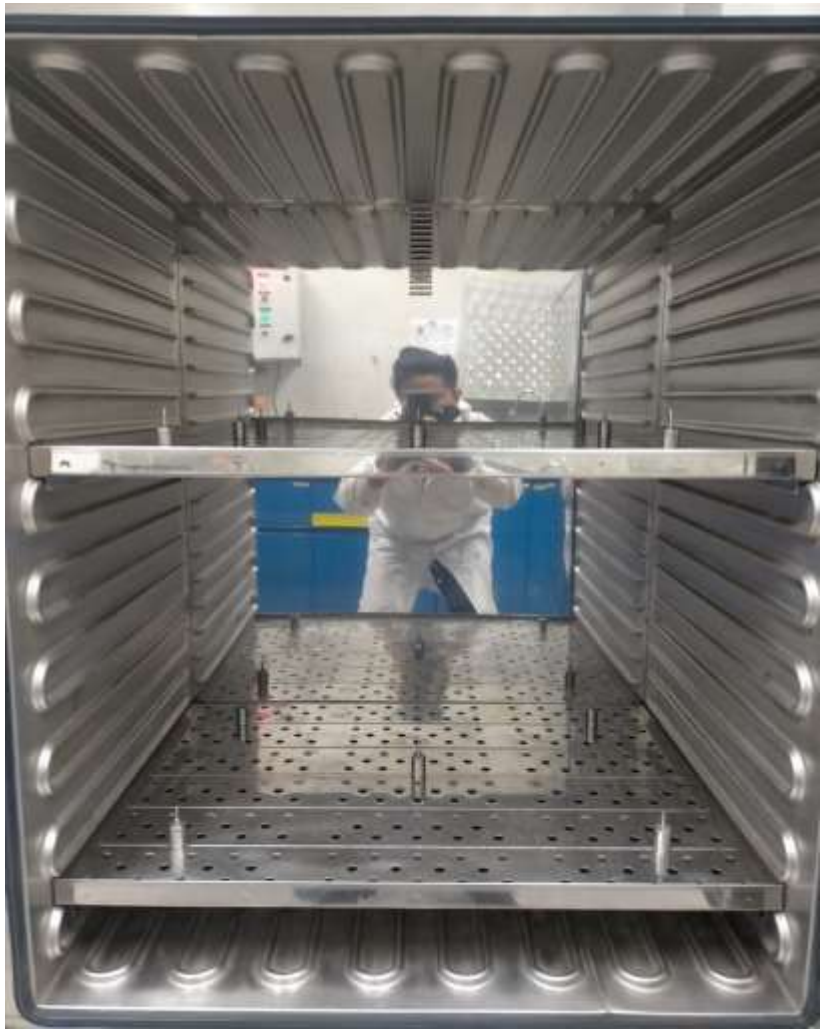
Freezers 氣候/環境室/冷凍機

- ebro – Validation Excerpt 驗證摘錄

Pharmaceutical Processes that Typically Require Validation 通常需要驗證的製藥過程

1. Moist Heat Sterilization 濕熱滅菌
2. Dry Heat Sterilization 乾熱滅菌
3. Ovens / Vacuum Ovens 烤箱/真空烤箱
4. EtO Sterilization 環氧乙烷滅菌
5. H_2O_2 Sterilization 過氧化氫滅菌
6. Depyrogenation 除熱原
7. Freeze Drying 冷凍乾燥
8. Stability Cabinets / Rooms 穩定櫃/室

9. **Warehouse and Storage Area Monitoring and Control** 倉庫和存儲區域監控



Our Main Topic For Today's Meeting 我們今天會議的主題

Who needs thermal mapping 誰需要熱測繪?

Every company must deal with the topic of cold chain monitoring and thus with the topic of temperature mapping, that 每家公司都必須處理冷鏈監控主題，從而處理溫度測繪主題，即

Manufactures and stores pharmaceuticals 製造和儲存藥品

EBI 300/310

EBI 25

EBI 20

Distributes and stores pharmaceuticals 分配和儲存藥品

Distributes and stores basic and intermediate products 分配和儲存基礎和中間產品

Norms & Regulations 規範與法規

Why do we need cold chain validation and temperature mapping為什麼我們需要冷鏈驗證和溫度測繪?

GMP regulations are increasingly focused on storage and distribution.
GMP 法規越來越重視於存儲和分配。

-> Away from "quality by regulation"遠離“ 質量靠監管”

-> towards "quality by design" with a view to risk minimization and patient safety. 以“ 質量源於設計” 為目標，以最大限度地降低風險和確保患者安全。

Other causes are其他原因是

- the increased need for storage space due to globalisation由於全球化對存儲空間的需求增加
- the increasing number of temperature-sensitive products越來越多對溫度敏感的產品
- technological developments技術的發展

Norms & Regulations 規範與法規

Regulatory bodies are organizations 監管機構是組織

mandated by government to supervise, direct and control various industries in the interest of consumer protection - specifically, the protection, promotion and maintenance of the health and safety of the public. 受政府授權監督、指導和控制各行各業以保護消費者利益– 特別是保護、促進和維護公眾的健康和安全。

All regulators seek to promote best practice, globally through standardization.
所有監管機構都尋求通過標準化在全球範圍內推廣最佳實踐。

Widely known regulatory authorities廣為人知的監管機構

EMA (Europe 歐洲)

FDA / USDA (USA 美國)

DHSC (UK 英國)

TGA (Australia 澳洲)

歐洲藥品管理局
科學藥物健康

美國食品藥物管理局

英國國防與安全加速器

澳洲衛生部 治療產品管理局

*There are other organizations and associations in the industry that have great influence on the pharmaceutical industry! (e.g. the PDA, ISPE, ABPI, etc.) 產業內還有其他對醫藥產業有較大影響的組織和協會！（例如 PDA、ISPE、ABPI 等）

Norms & Regulations 規範與法規

FDA PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALSFDA 第 211 部分 - 成品藥物的現行良好生產規範

---

§ 211.142 Warehousing procedures入庫手續.
Written procedures describing the warehousing of drug products shall be established and followed. They shall include應建立並遵循描述藥品倉儲的書面程序。它們應包括:
[…]
(b) **Storage of drug products under appropriate conditions of temperature, humidity在適當的溫度、濕度條件下儲存藥品**, and light so that the identity, strength, quality, and purity of the drug products are not affected.和光，以便不影響藥品的特性、強度、質量和純度。

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§ 211.208 Drug product salvaging藥品回收.
Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, […] shall not be salvaged and returned to the marketplace. […]已經過不當儲存條件（包括極端溫度、濕度、[……]）的藥品不得回收和退回市場

Norms & Regulations 規範與法規

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WHO - GOOD DISTRIBUTION PRACTICES (GDP) FOR PHARMACEUTICAL PRODUCTS醫藥產品良好分配規範 (GDP)

8.10 Where **special storage conditions存放條件特殊的地方** (e.g. temperature and relative humidity例如溫度和相對濕度) are required during transit these should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year, or as required by national legislation **在運輸過程中需要，應提供、檢查、監控和記錄。所有監測記錄的保存期限應至少為所銷售產品的保質期加一年，或按照國家立法的要求. Temperature mapping of vehicles車輛溫度測繪** (where applicable適用時) should support uniformity of the temperature across the vehicle. Recorded temperature monitoring data should be available for review.應支持整個車輛的溫度均勻性。記錄的溫度監測數據應可供審查。

8.11 Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated at predetermined intervals.應支持整個車輛的溫度均勻性。記錄的溫度監測數據應可供審查。

10.8 Methods of transportation, including vehicles to be used, should be selected with care, taking into consideration local conditions including the climate of the region and any seasonal variations experienced. Delivery of products **requiring controlled temperatures** should be carried out by the fastest practical means. 應謹慎選擇交通工具，包括要使用的車輛，同時考慮當地條件，包括該地區的氣候和所經歷的任何季節變化。**需要控制溫度**的產品的交付應以最快的實用方式進行。

11.3 Where special storage conditions are required (e.g. temperature, humidity) these should be **provided, monitored and recorded**.在需要特殊儲存條件（例如溫度、濕度）的情況下，**應提供、監控和記錄**這些條件。

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Norms & Regulations 規範與法規

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EMA - Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use 2013 年 11 月 5 日關於人用醫藥產品良好分配規範的指南

3.2.1. *Temperature and environment control 溫度和環境控制*

Suitable equipment and procedures should be in place to check the environment where medicinal products are stored. Environmental factors to be considered include **temperature**, light, **humidity** and cleanliness of the premises. An **initial temperature mapping** exercise should be carried out on the storage area before use, under representative conditions.應有適當的設備和程序來檢查藥品儲存的環境。需要考慮的環境因素包括處所的**溫度**、光線、**濕度**和清潔度。使用前應在具有代表性的條件下對存儲區域進行**初始溫度測繪**。 Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated according to the results of a risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling equipment. 溫度監測設備的位置應根據測繪練習的結果，確保監測設備位於經歷極端波動的區域。應根據風險評估活動的結果或每當對設施或溫度控制設備進行重大修改時重複測繪活動。For small premises of a few square meters which are at room temperature, an assessment of potential risks (e.g. heaters) should be conducted and temperature monitors placed accordingly.對於常溫下幾平方米的小處所，應評估潛在風險（例如加熱器）並相應放置溫度監測器。

3.3. Equipment設備

All equipment impacting on storage and distribution of medicinal products should be designed, located and maintained to a standard which suits its intended purpose. […]所有影響藥品儲存和分配的設備都應按照適合其預期用途的標准進行設計、定位和維護。 []..

Equipment used to control or to monitor the environment where the medicinal products are stored should **be calibrated at defined intervals** based on a risk and reliability assessment.用於控製或監測藥品儲存環境的設備應根據風險和可靠性評估按**規定的時間間隔**進行校正。

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Norms & Regulations 規範與法規

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Government of Canada - Guidelines for environmental control of drugs during storage and transportation 加拿大政府 - 藥物在儲存和運輸過程中的環境控制指南(GUI-0069)

4.1 The role of environmental controls 環境控制的任務

Environmental controls are essential to maintaining drug safety, quality and efficacy. Drugs must be **stored and transported according to labelled storage conditions or specific transport conditions** supported by data.
Temperature is one of the most important parameters to control. You must transport, handle and store drugs in a way that reduces the risk of exposure to temperatures outside the labelled storage conditions—also known as "temperature excursions".環境控制對於維持藥物安全、質量和功效至關重要。藥品必須**按標示的貯存條件或有數據支持的具體運輸條件貯運**。溫度是最重要的控制參數之一。您必須以能夠降低暴露於標示儲存條件之外的溫度（也稱為"溫度偏移"）的風險的方式運輸、處理和儲存藥物。
Temperature excursions may be acceptable for brief periods if stability data and scientific or technical justification show that product quality is not affected.如果穩定性數據和科學或技術論證表明產品質量不受影響，則短時間的溫度偏移是可以接受的。

5.1 Warehousing and storage

1.Store all drugs according to the conditions described on the label of the product. Ensure any controls for conditions that are specified on the label (e.g. temperature, humidity, light, etc.) are in place根據產品標籤上描述的條件儲存所有藥物。確保對標籤上指定的條件（例如溫度、濕度、光照等）進行任何控制. […]
2.Design or adapt storage areas to ensure good conditions. Make sure they are clean and dry, with enough air circulation. Ensure they are kept within all acceptable temperature limits and ensure they are qualified 設計或調整存儲區域以確保良好的條件。確保它們清潔乾燥，空氣流通充足。確保它們保持在所有可接受的溫度範圍內並確保它們合格[…]
3.Monitor the area to demonstrate storage conditions indicated on the label are being met and keep a record of your findings […]Use **calibrated monitoring devices** to control and monitor temperatures.監控該區域以證明標籤上指示的存儲條件得到滿足，並記錄您的發現[].. 使用**校正的監控設備**來控制和監控溫度。

Norms & Regulations 規範與法規

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United States Pharmacopia美國藥典:

- USP Chapter 1079 Good Storage and Distribution Practices for Drug Products 美國藥典第 1079 章藥品良好儲存和分配規範
- USP Chapter 1118 Monitoring Devices – Time, Temperature, and Humidity 美國藥典第 1118 章監測設備 – 時間、溫度和濕度

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme國際醫藥品稽查協約組織:

- PIC/S GMP Guide Part I: Guide to GMP for Medicinal Products Section 3.19 PIC/S GMP 指南第 I 部分：藥品 GMP 指南第 3.19 節
- PIC/S GMP Guide Part II: Guide to GMP for Medicinal Products Sections 7.42 and 10.1 PIC/S GMP 指南第 II 部分：藥品 GMP 指南第 7.42 和 10.1 節

International Conference of Harmonization國際醫藥法規協和會:

- ICH Q7 – GMP Guidance for Active Pharmaceutical Ingredients ICH Q7 – 活性藥物成分的 GMP 指南
- ICH Q9 – Quality Risk Management ICH Q9 – 質量風險管理
- ICH Q10 – Pharmaceutical Quality System ICH Q10 – 藥品質量系統

International Society for Pharmaceutical Engineering國際製藥工程協會:

- ISPE Good Practice Guide – Controlled Temperature Chamber Mapping and Monitoring ISPE 良好實踐指南 - 受控溫度室測繪和監控

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Norms & Regulations 規範與法規

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Summary of regulatory requirements監管要求摘要:

1) The requirement to monitor environmental conditions during transport or storage is found in virtually all regulations.幾乎所有法規都要求在運輸或儲存期間監測環境條件。

2) The equipment used for monitoring should be calibrated.用於監測的設備應經過校正。

3) Before use, an initial temperature mapping should be carried out in the storage area under representative conditions.使用前，應在具有代表性的條件下在儲存區域進行初始溫度測繪。

4) Computerized systems used for monitoring or recording data should be validated.用於監測或記錄數據的電腦運算系統應經過驗證。

Norms & Regulations 規範與法規

Important Requirements Especially for Tropical Areas or Countries with Extreme Temperatures 重要要求，尤其適用於熱帶地區或極端溫度的國家:

1) Door-Opening Tests 開門測試

2) Power-Failure Tests 斷電測試

3) Traffic and Human Activity Factors 交通和人類活動因素

4) Climate Factors 氣候因素

From the drawing to the study從繪圖到考察

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The requirement for an established or predetermined survey of the Storage Facility or Warehouses
對儲存設施或倉庫進行既定或預定調查的要求

Qualification of a Healthcare Warehouse starts immediately from the completion of the Facility 醫療保健倉庫的資格核定從設施完工後立即開始

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Qualification of a Healthcare Warehouse starts immediately from the completion of the Facility 醫療保健倉庫的資格核定從設施完工後立即開始

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From the drawing to the study從繪圖到考察

The following eight points are elementary in the planning and implementation of mapping以下八點是測繪規劃和實施的基礎**:**

Define the measurement points
定義測量點

Identify the risk areas
識別風險區域

Create a protocol
創建協議

Choose the correct technology選擇正確的技術

Install the equipment
安裝設備

Conduct the study
進行研究

Evaluate the results
評估結果

Apply modifications
應用修改

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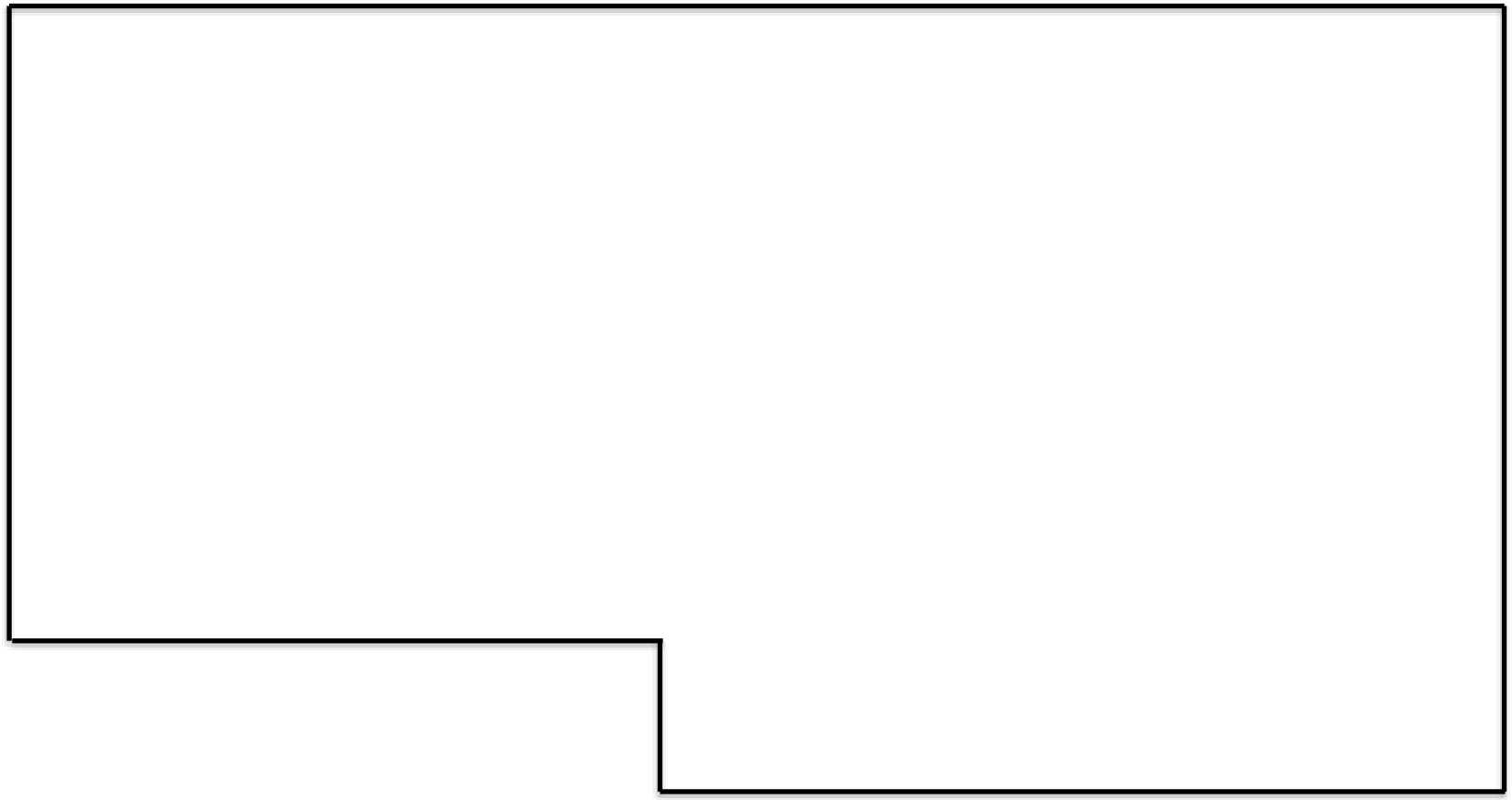
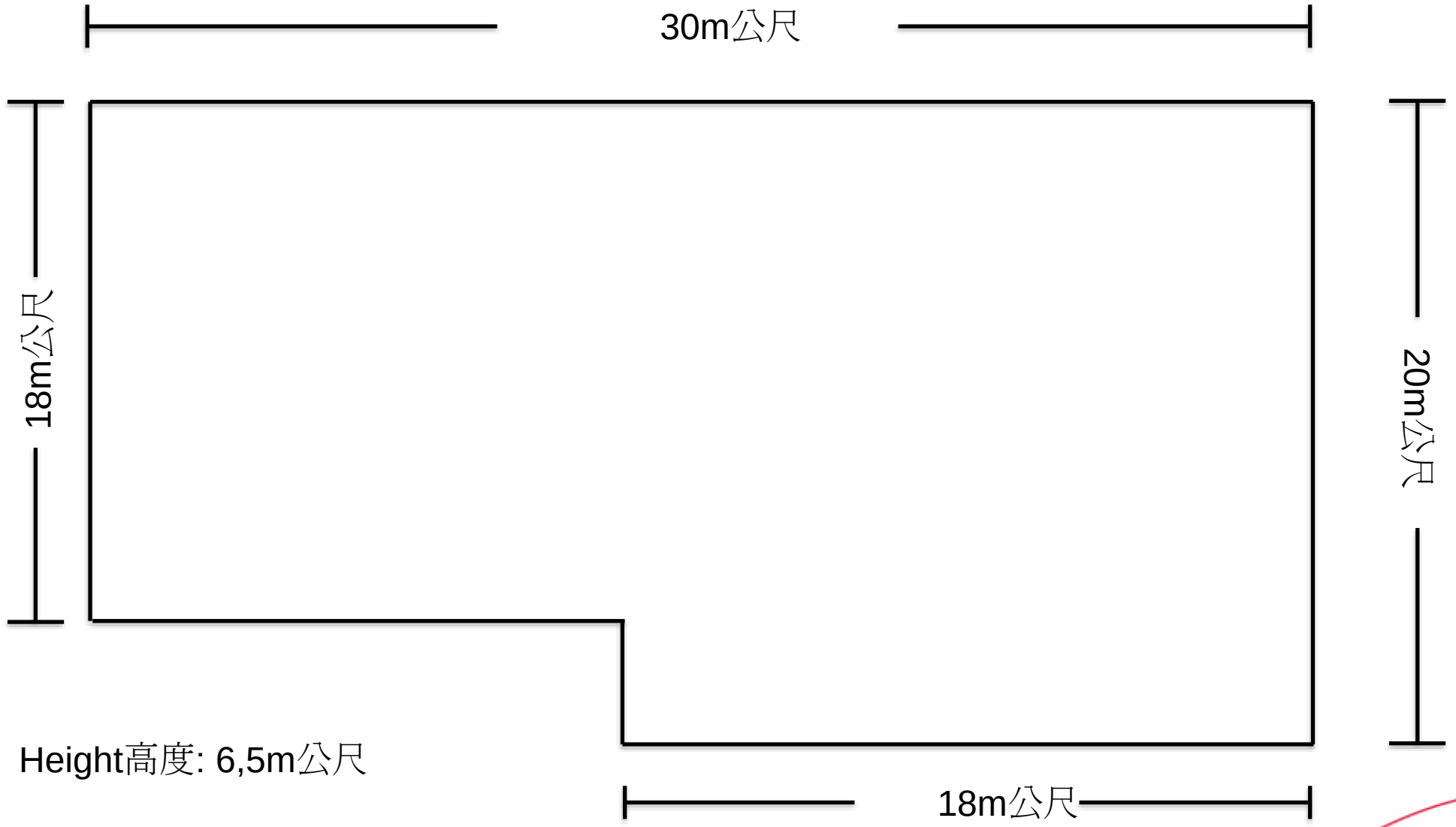
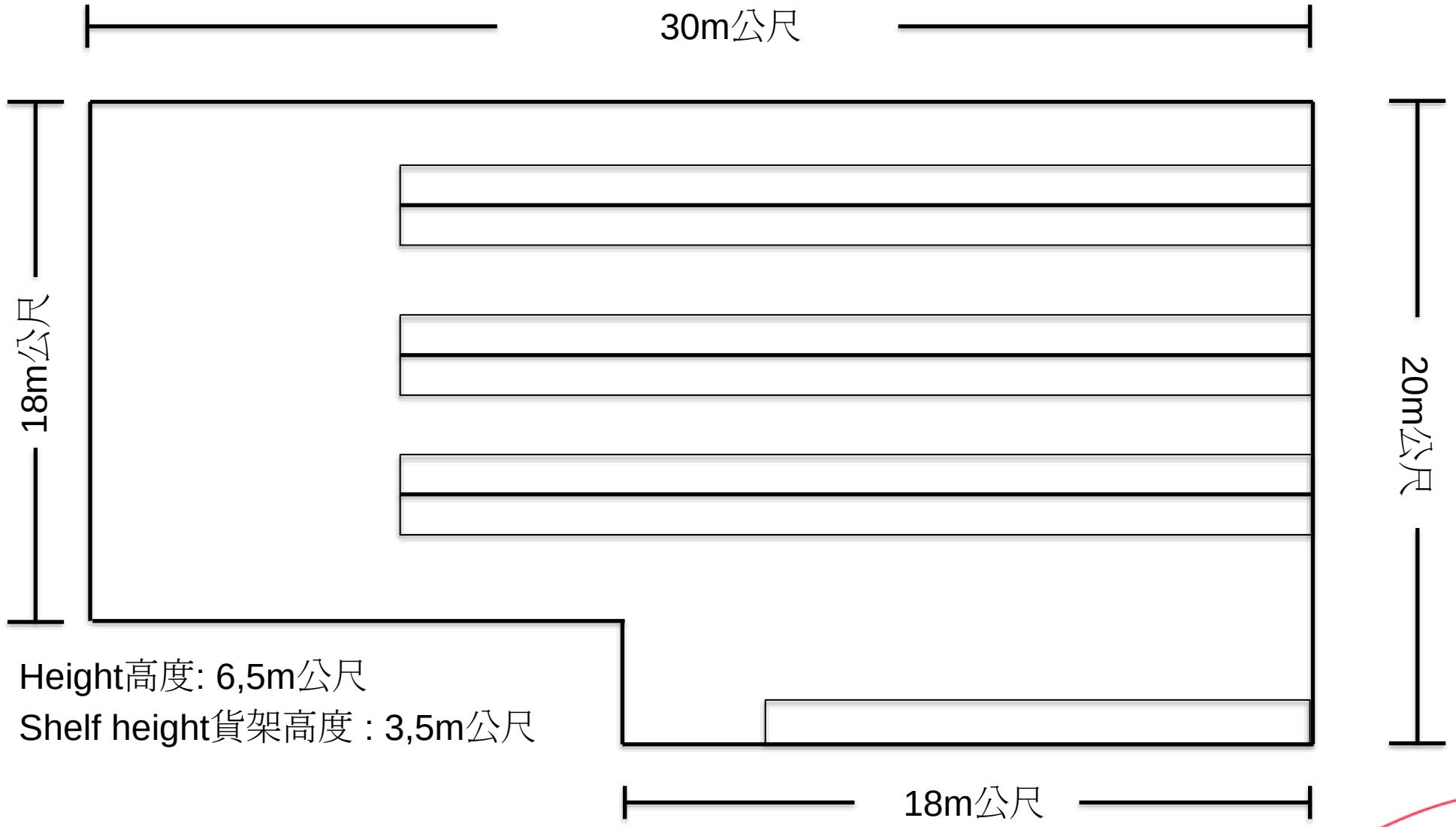
We need to map the following warehouse! What information is important我們需要測繪如下倉庫！哪些信息很重要?



What dimensions什麼尺寸?

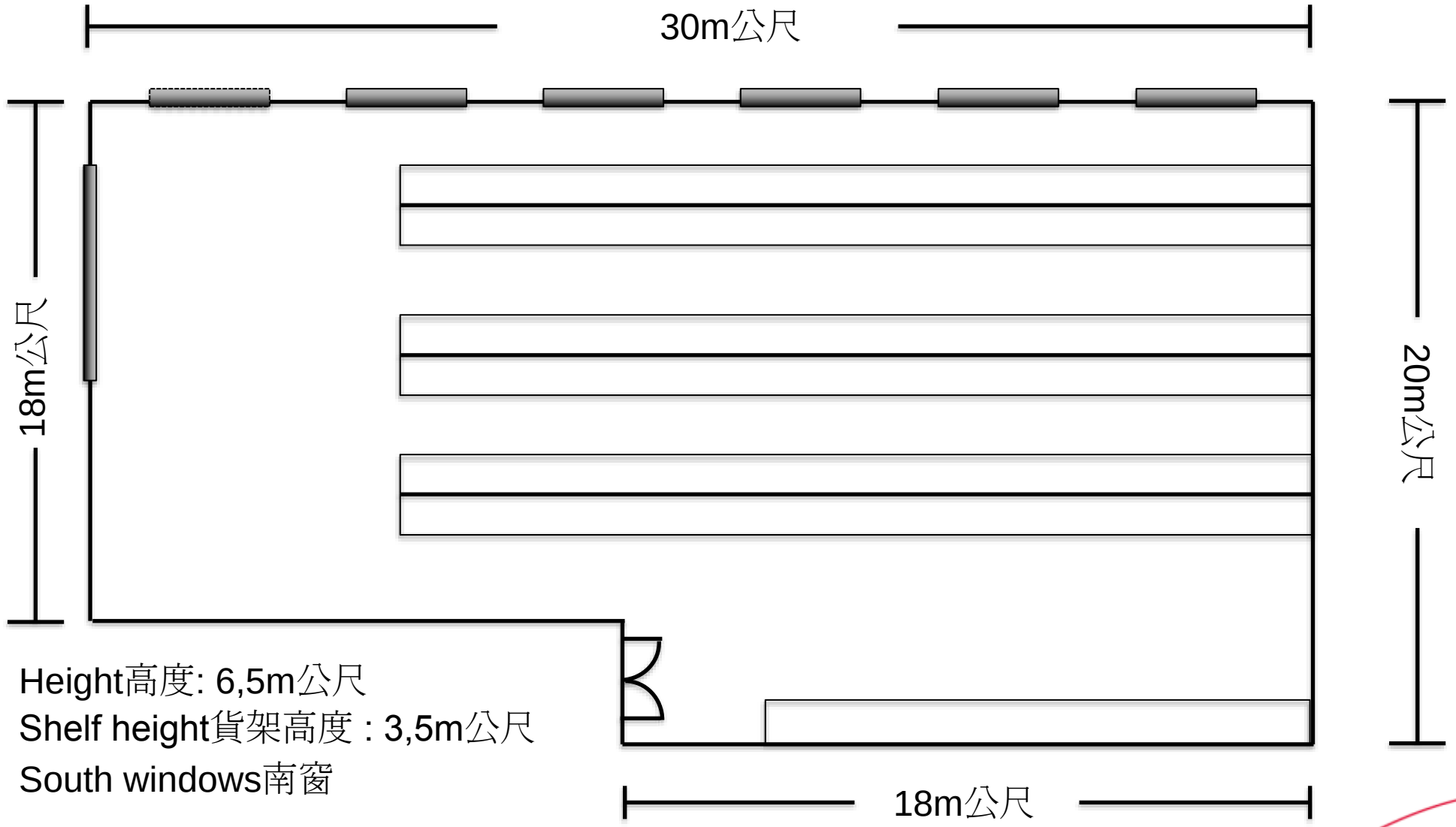


What installations are there有哪些裝置?



Height高度: 6,5m公尺
Shelf height貨架高度 : 3,5m公尺

What installations are there有哪些裝置?



Define the measurement points定義測量點

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- The sensor distribution must be suitable to represent the temperature distribution in the entire warehouse傳感器分佈必須適合代表整個倉庫的溫度分佈.

- GMP here means that enough sensors are used to successfully minimise risks這裡的 GMP 意味著使用足夠的傳感器來成功地將風險降到最低.

- The sensors must be placed evenly in all three dimensions傳感器必須在所有三個維度上均勻放置.

- Additional sensors are important where specific risks are feared在擔心特定風險的情況下，額外的傳感器很重要.

Define the measurement points定義測量點

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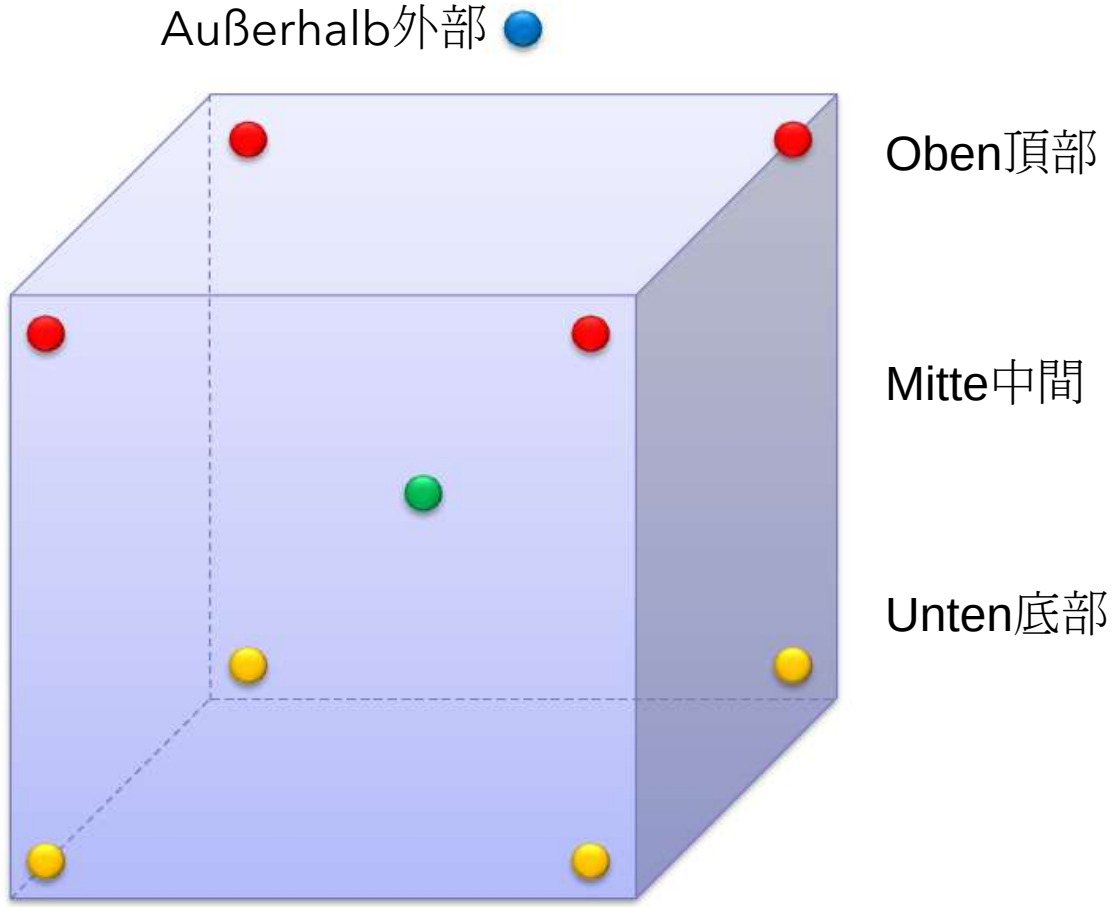
Chamber 房間≤ 2m³
- ISPE regulations法規
- According to 根據AS2853 and和 WHO

•Represents the minimum of loggers代表最少的記錄器

•9 + 1 rule規則



Define the measurement points 定義測量點

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Chamber 房間≤ 2m³ -> For example, refrigerators例如，冰箱

Do not forget不要忘記:

- Door opening tests開門測試
- Power failure simulations電源故障模擬

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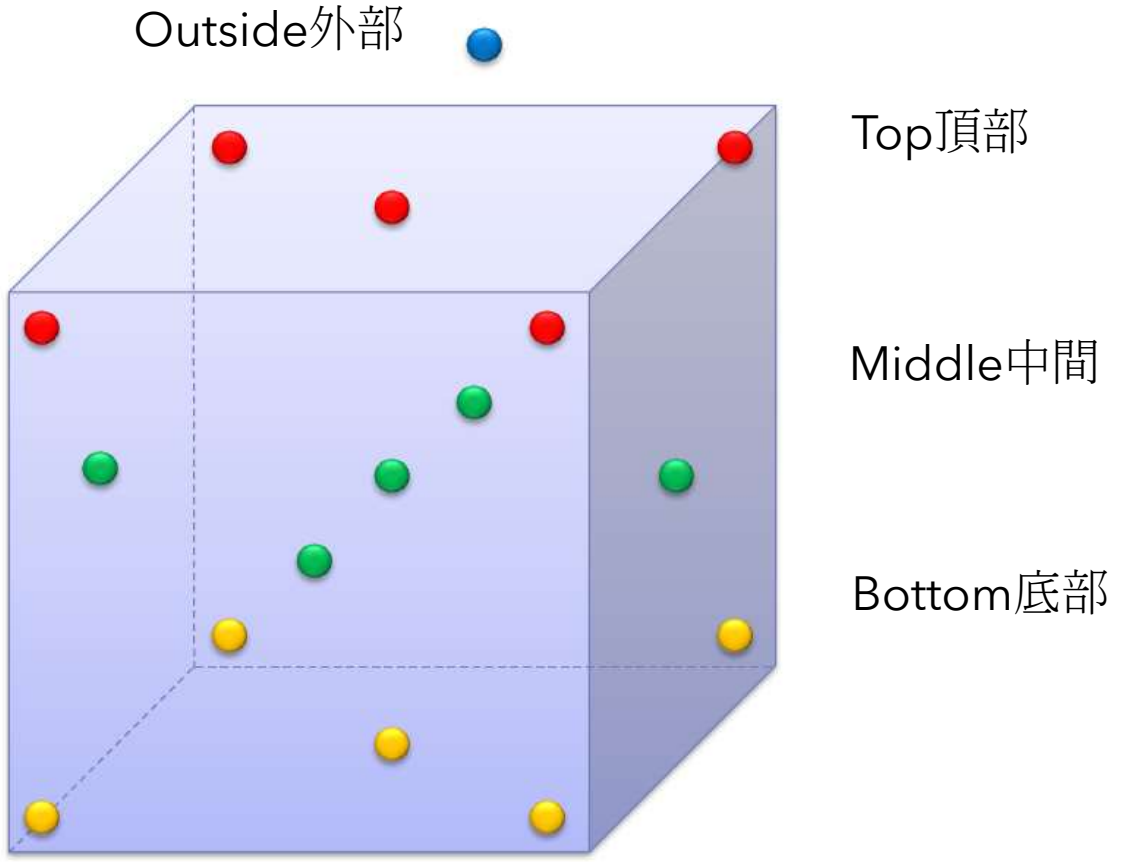
Define the measurement points定義測量點

Chamber 房間>2m³ and和 ≤ 20m³
- ISPE regulations法規
- According to 根據AS2853 and 和 WHO

- Represents the minimum of loggers代表最少的記錄器

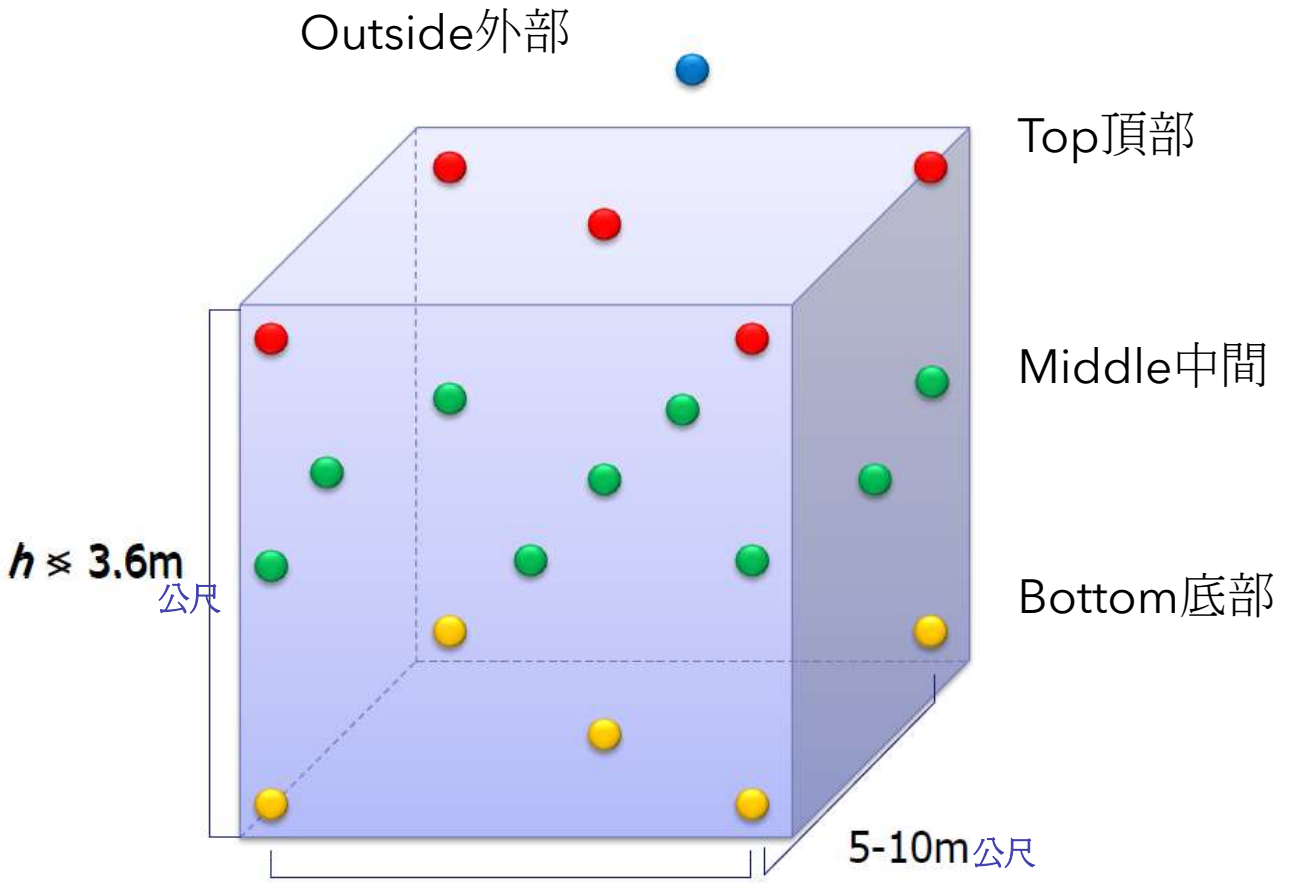
- 15 + 1 rule規則



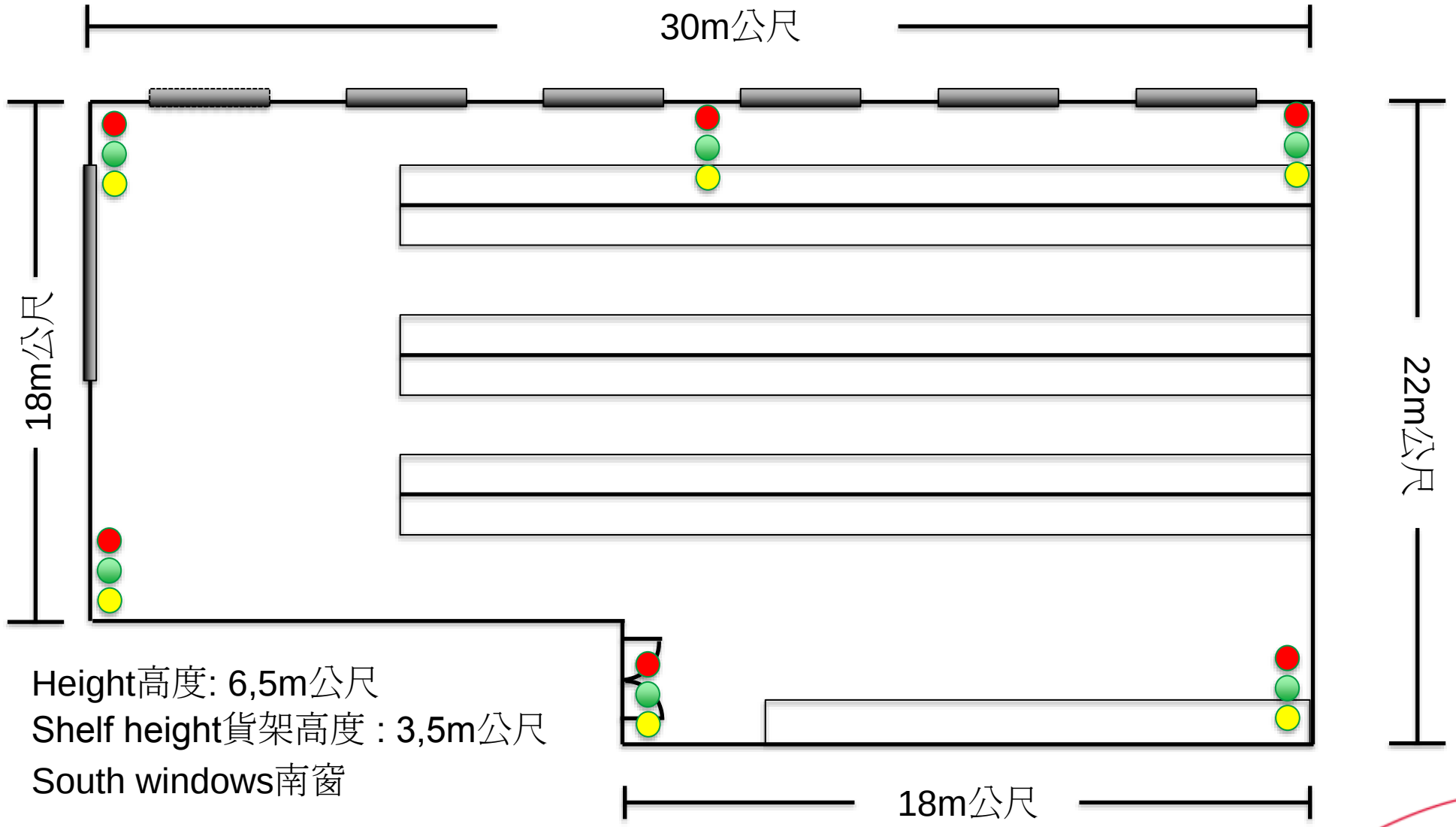
Define the measurement points定義測量點

Chamber房間 >20m³
- ISPE regulation法規
- According to 根據AS2853 and 和 WHO

•19 + 1 rule規則



Define the measurement points定義測量點



Define the measurement points定義測量點

Sensor distribution (Technical supplement to WHO Technical Report Series, No. 961, 2011)
傳感器分佈(世衛組織技術報告系列的技術補充，第 961 號，2011 年)

If the ceiling height is 3.6 m or less, position the loggers directly above one another at high, medium and low level 如果天花板高度為 3.6 公尺 或更小，將記錄器放置在彼此正上方的高、中和低水平
-> floor level, one at 1.2 m and one EDLM at 3.0 m
地板高度，一個在 1.2 公尺處，一個在 3.0 公尺處的 EDLM

If the ceiling height is greater than 3.6m, loggers can be arranged at the bottom, middle (multiple) and top of the space. For instance, for a storage area 6 m in height 如果天花板高度大於3.6公尺，記錄器可以佈置在空間的底部、中間（多個）和頂部。例如，對於 6 公尺高的存儲區域
-> 0.3m公尺, 1.8m公尺, 3.6m公尺 and 5.4m公尺.

Define the measurement points定義測量點

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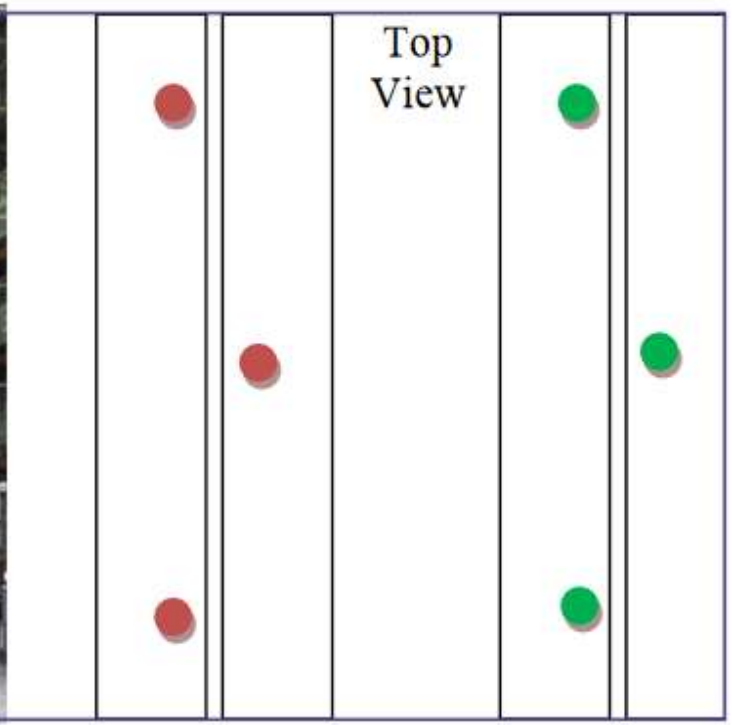
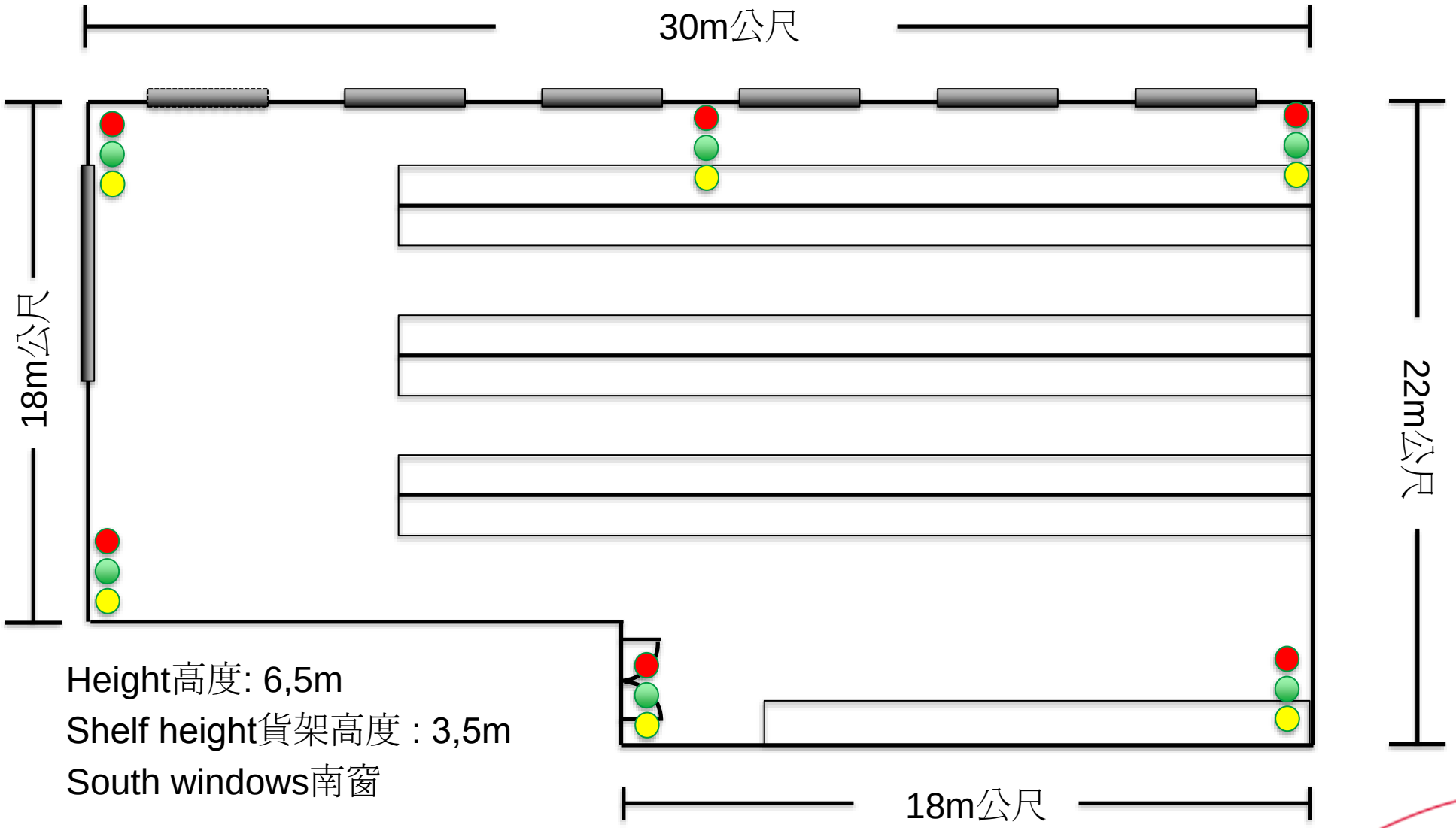
Sensor distribution (Technical supplement to WHO Technical Report Series, No. 961, 2011)
傳感器分佈(世衛組織技術報告系列的技術補充，第 961 號，2011 年)

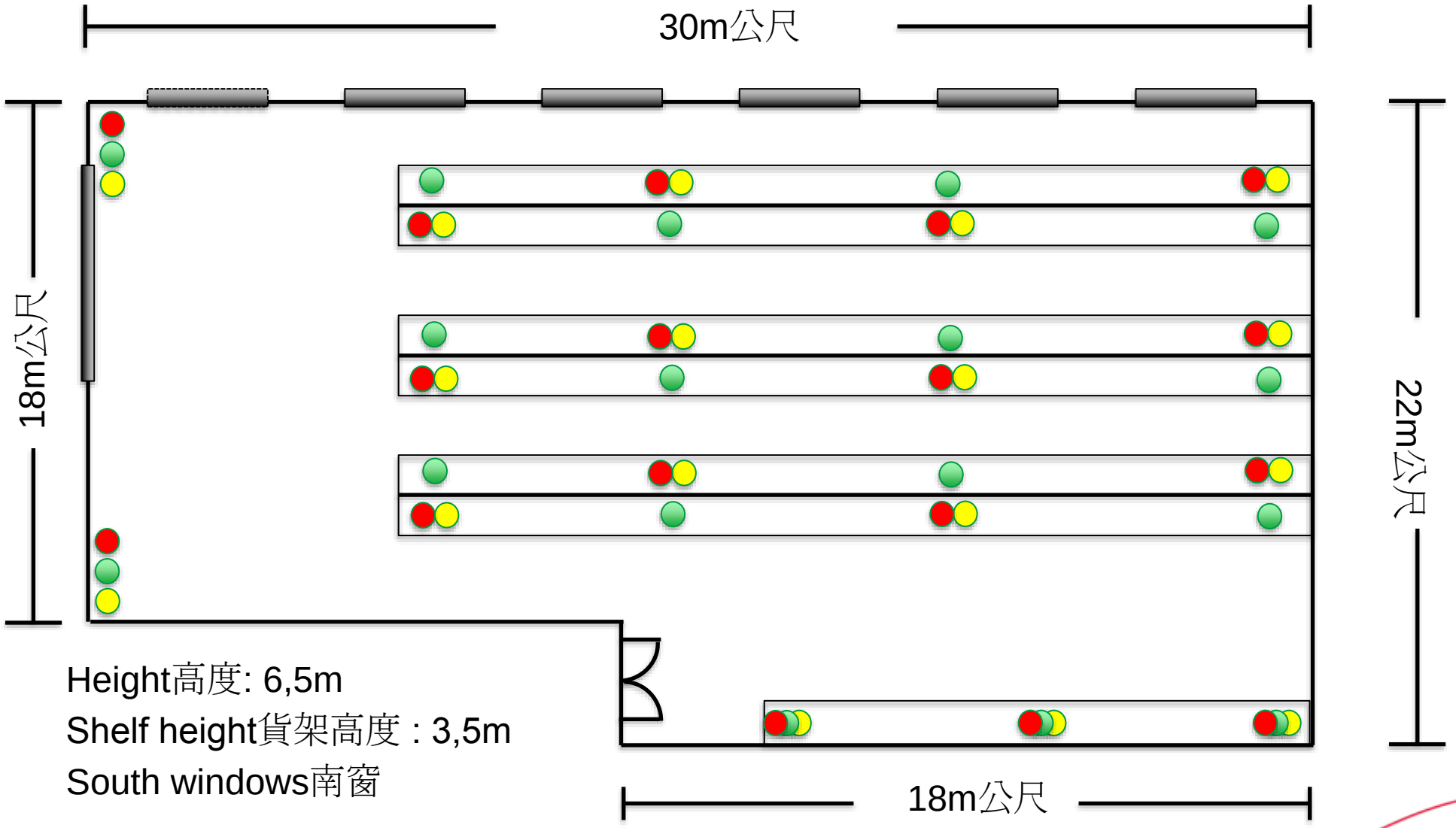
Loggers should be arranged in a grid fashion along the width and length of the area, with loggers located every 5–10 m. 記錄器應沿區域的寬度和長度以網格方式排列，每 5-10 m 放置一個記錄器。
In very large facilities, this can be up to 20 or 30 m.在非常大的設施中，這可以達到 20 或 30 公尺



Minimum number of loggers記錄器的最小數量



Minimum number of loggers including shelves 包括架子在內的最少記錄器數量



Identify the risk areas 識別風險區域

Volume of space.
空間體積

The capacity of diffusers or fans to adequately circulate air.
擴散器或風扇使空氣充分流通的能力。

Temperature gradients between the cooler floor and warmer air near the ceiling.
較冷的地板和天花板附近較暖的空氣之間的溫度梯度。

Independent energy sources, such as space heaters, air conditioners, and fans, which create warm or cold pockets.
獨立能源，例如空間加熱器、空調和風扇，它們會產生暖氣或冷氣。

Layout of racks, shelves, and pallets, which obstruct airflow.
阻礙氣流的層架、貨架和托盤的佈局。

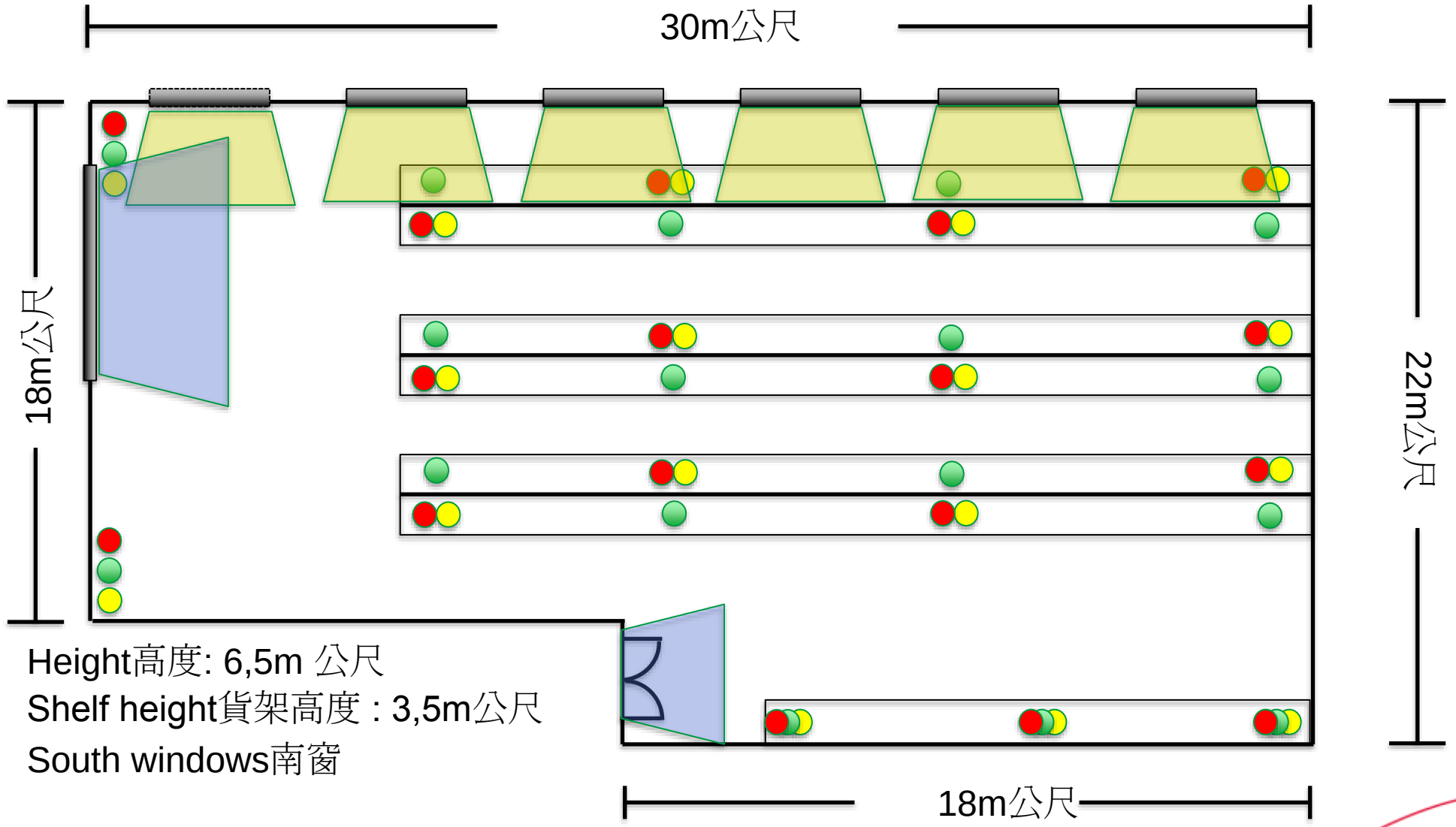
Location of HVAC control sensors.HVAC 控制傳感器的位置。

Locations near sources of heat or cold靠近熱源或冷源的位置

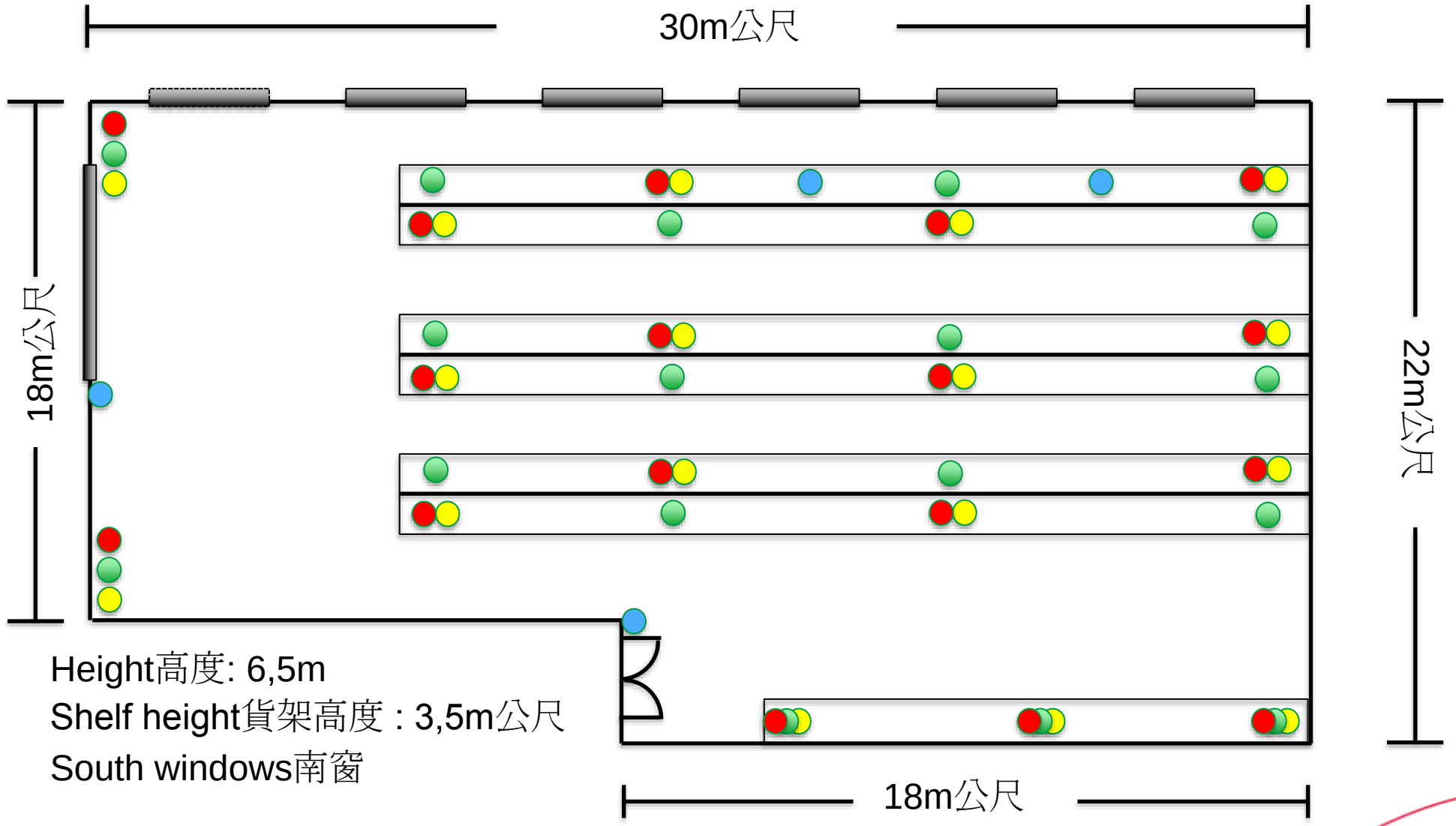
High-traffic areas where product or equipment is moved.產品或設備移動的高通量區域。

Seasonal temperature changes or unusual weather events.季節性溫度變化或異常天氣事件。

Risk areas風險區域



Risk areas風險區域



Thermal Mapping Procedure 熱測繪程序

Develop protocol information
制定協議資料

TYPES OF DATA TO BE GENERATED
生成的數據類型

NUMBER OF SENSORS TO BE USED使用的傳感器數量

MAP OF SENSOR LOCATIONS.
傳感器位置圖

DURATION OF STUDY.
學習期間

CALIBRATION REQUIREMENTS OF THE DATA LOGGERS數據記錄器的校正要求

ACCEPTABLE RANGE OF VARIATION OVER TIME AND ACROSS THE SPACE, WHICH WILL DEPEND ON THE PRODUCT STORED.
隨時間和空間變化的可接受範圍，這將取決於存儲的產品。

ACCEPTABLE LIMITS FOR TEMPERATURE OR RELATIVE HUMIDITY EXCURSIONS.溫度或相對濕度偏移的可接受限制。

REPORTING REQUIREMENTS.
報告要求

Healthcare products that must be stored under defined conditions require appropriate storage instructions 保健產品必須在規定條件並需要適當的儲存說明下儲存

Storage requirements are written in labelling instructions存儲要求寫在標籤說明中:

Conditions on the Label 標籤上的條件	Meaning平均值
Do Not Store Over 不要儲存於超過30.0°C	From從+2.0°C to到 +30.0°C
Do Not Store Over 不要儲存於超過25.0°C	From從 +2.0°C to到+25.0°C
Do Not Store Over 不要儲存於超過15.0°C	From從 +2.0°C to到 +15.0°C
Do Not Store Over 不要儲存於超過8.0°C	From從 +2.0°C to到 +8.0°C
Do Not Store Over 不要儲存於低於8.0°C	From從 +8.0°C to到 +25.0°C
Protect From Moisture防潮	<60.0% **RH** in Normal Storage Condition在正常儲存條件下<60.0% 相對濕度

Raw Materials原料

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Storage Conditions for Pharmaceutical Raw Materials醫藥原料貯存條件

Storage Condition 貯存條件	Pharm. Eur. 歐洲藥典	USP 美國藥典
Cold 寒冷	8°C – 15°C	<8°C
Cool 涼爽	8°C – 15°C	8°C – 15°C
Room temperature 室溫	15°C – 25°C	temperature prevailing in a work area 工作區域中普遍存在的溫度
Controlled room temperature 控制的室溫	–	20°C – 25°C excursions between 15°C and 30°C are allowed 允許 15 到 30 。C, 20-25 。C之間的漂移

Storage Conditions According to Different Pharmacopoeias
不同藥典的貯存條件

Storage Condition 貯存條件	Pharm. Eur. 歐洲藥典	WHO世界衛生組織	USP美國藥典	JP日本藥典
Deep Freeze 深度冷凍	> -15°C	> -20°C	-	-
Refrigerator 冰箱	2.0°C to 8.0°C	-	-	-
Cold寒冷	8°C to 15°C	2.0°C to 8.0°C	< 8.0°C	1°C to 15°C
Cool涼爽	8°C to 15°C	8°C to 15°C	8°C to 15°C	-
Room室溫	15°C to 25°C	15°C to 25°C	Temp. prevailing 溫度廣布	1°C to 30°C
Controlled Room控制的室溫	-	-	20°C – 25°C excursions between 15°C and 30°C are allowed 允許在 15°C 和 30°C，20°C — 25°C 之間偏移	-

Install the equipment安裝設備

Select suitable technology選擇合適的技術

MINIMUM SOURCES OF ERROR
最少的錯誤來源

SENSITIVITY TO SMALL TEMPERATUR E CHANGES
對小溫度變化的敏感性

LONG-TERM STABILITY,.
長期穩定性

HIGH ACCURACY IN THE RANGE OF USE.
使用範圍內的高精度。

TRACEABLE CALIBRATION PERFORMED WITHIN THE MEASUREMENT RANGE
在測量範圍內執行可追溯的校準

CLEAR, COMPREHENS IVE, AND ACCESSIBLE CALIBRATION RECORDS.
清晰、全面且易於接觸的校準記錄。

EBI 20

EBI 25

EBI 300/310

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Thermal Mapping Procedure熱測繪程序

Set Up Mapping Equipment設置測繪設備

Check list 檢查清單

- Equipment has been calibrated
  設備已校準
- Equipment has been validated.
  設備已經過驗證
- Program access has been secured and authenticated.
  程序接觸已得到保護和驗證。
- Software reads and records hardware and firmware model, version, and serial number
  軟體讀取並記錄硬體和找韌體型號、版本和序列號
- The warehouse area under test has been precisely described.
  被測試的倉庫區域已經被精確描述。
- Data logger locations are precisely described 精確描述數據記錄器位置
- Regular sample intervals have been determined.已確定定期採樣間隔。
- Test duration has been determined
  測試持續時間已確定
- Data loggers have been positioned in defined locations.
  數據記錄器已放置在指定位置。

Thermal Mapping Procedures熱測繪程序

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Set up mapping equipment設置測繪設備

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Conduct test and review data進行測試和審查數據

You'll need to establish the reporting information you'll use to evaluate the test. 您需要建立用於評估測試的報告信息。

When the test is complete, software will read the secure files from the data loggers, show recorded data, perform calculations, and graph the results selected for the mapping report 測試完成後，軟體將從數據記錄器中讀取安全檔，顯示記錄的數據，執行計算，並繪製為測繪報告選擇的結果

Evaluate the results評估結果

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The following information must be visible on the document文件上必須顯示以下信息：

- Raw data including time and date原始數據，包括時間和日期
- Calculated values such as maximum, average and minimum values of temperature and relative humidity 計算值，例如溫度和相對濕度的最大值、平均值和最小值
- Graphical representation of all curves所有曲線的圖形表示
- Calibration data校正數據
- Instrument settings儀器設置
- Time and date of the study研究時間和日期

Evaluate the results評估結果

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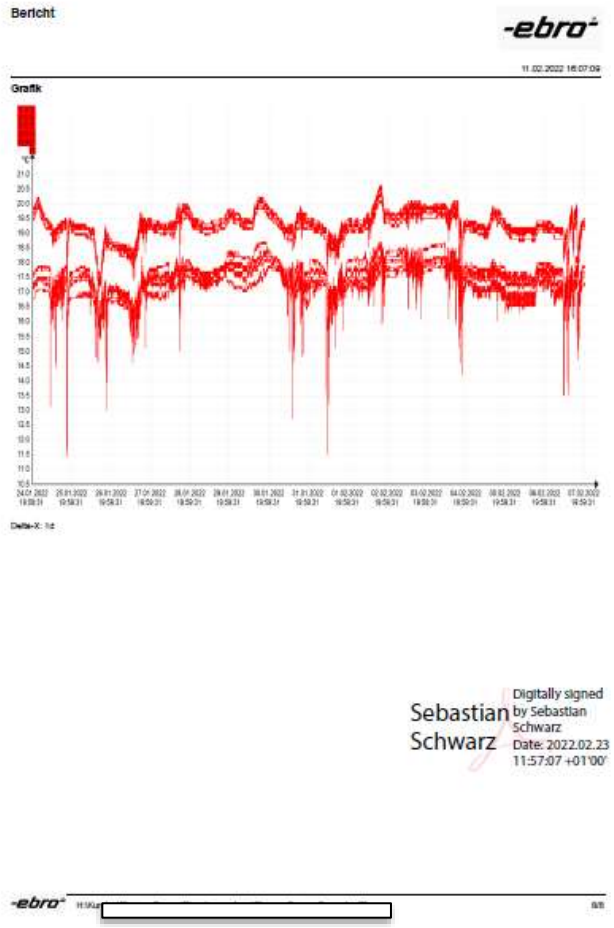
Example information visible on the document文檔中可見的示例信息:


Bericht

-ebro-

Grafik

Sebastian Schwarz

Digitally signed by Sebastian Schwarz
Date: 2022.02.23 11:57:07 +01'00'

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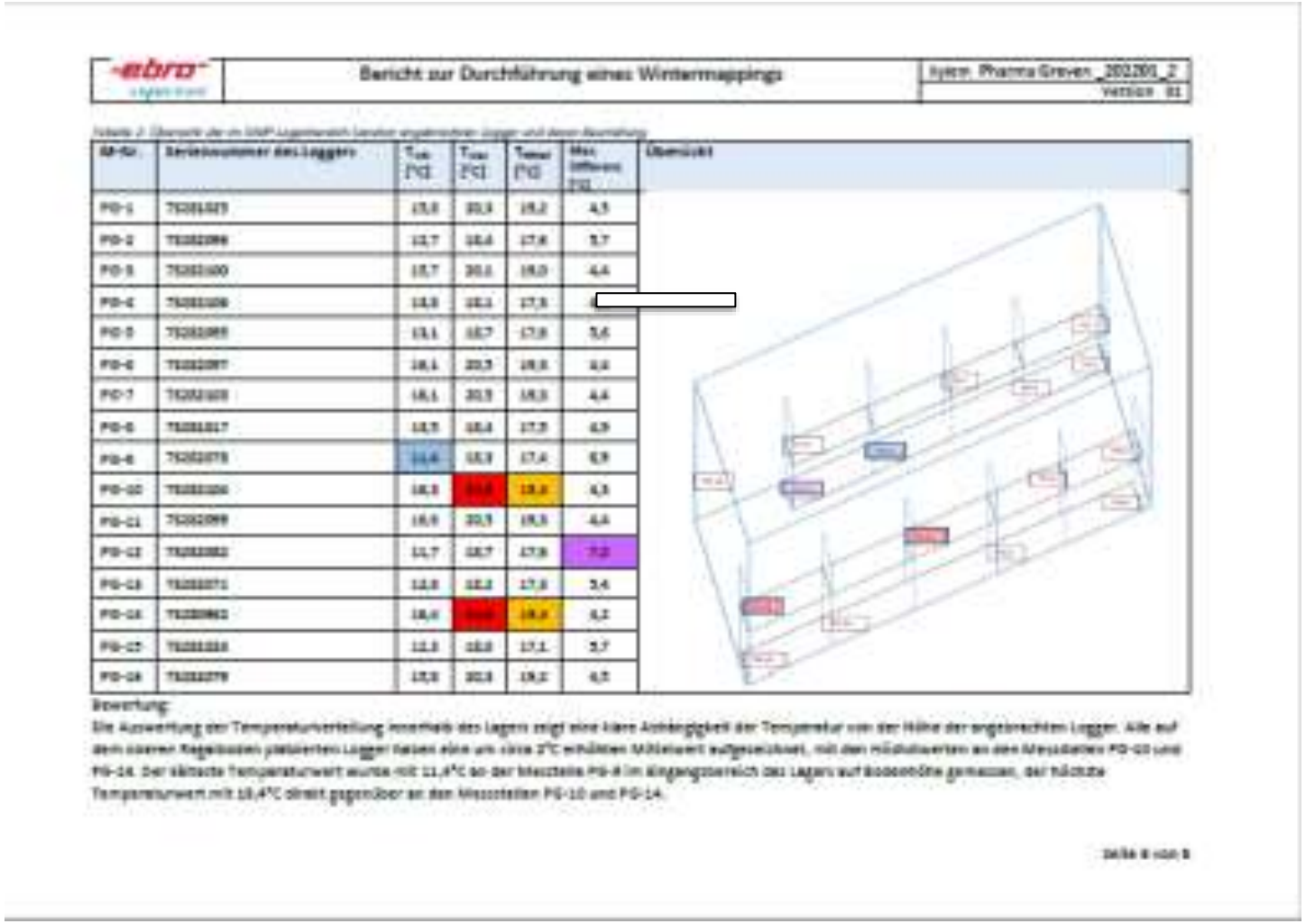

-ebro-

Bericht zur Durchführung eines Wintermappings

PG-1						
PG-2						
PG-3						
PG-4						
PG-5						
PG-6						
PG-7						
PG-8						
PG-9						
PG-10						
PG-11						
PG-12						
PG-13						
PG-14						
PG-15						
PG-16						

Bewertung:

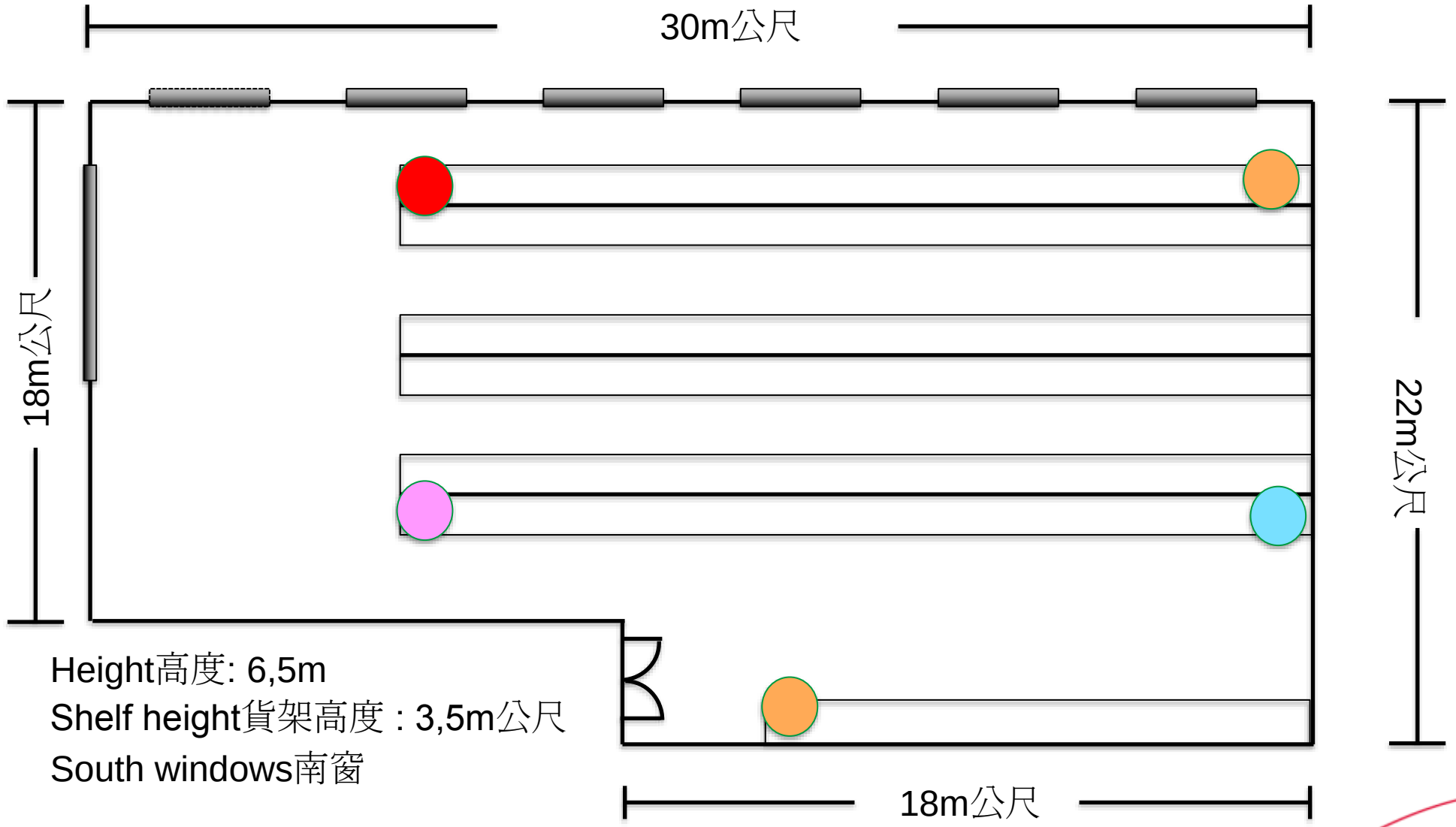
-ebro-
a xylem brand

Apply modifications採用修改

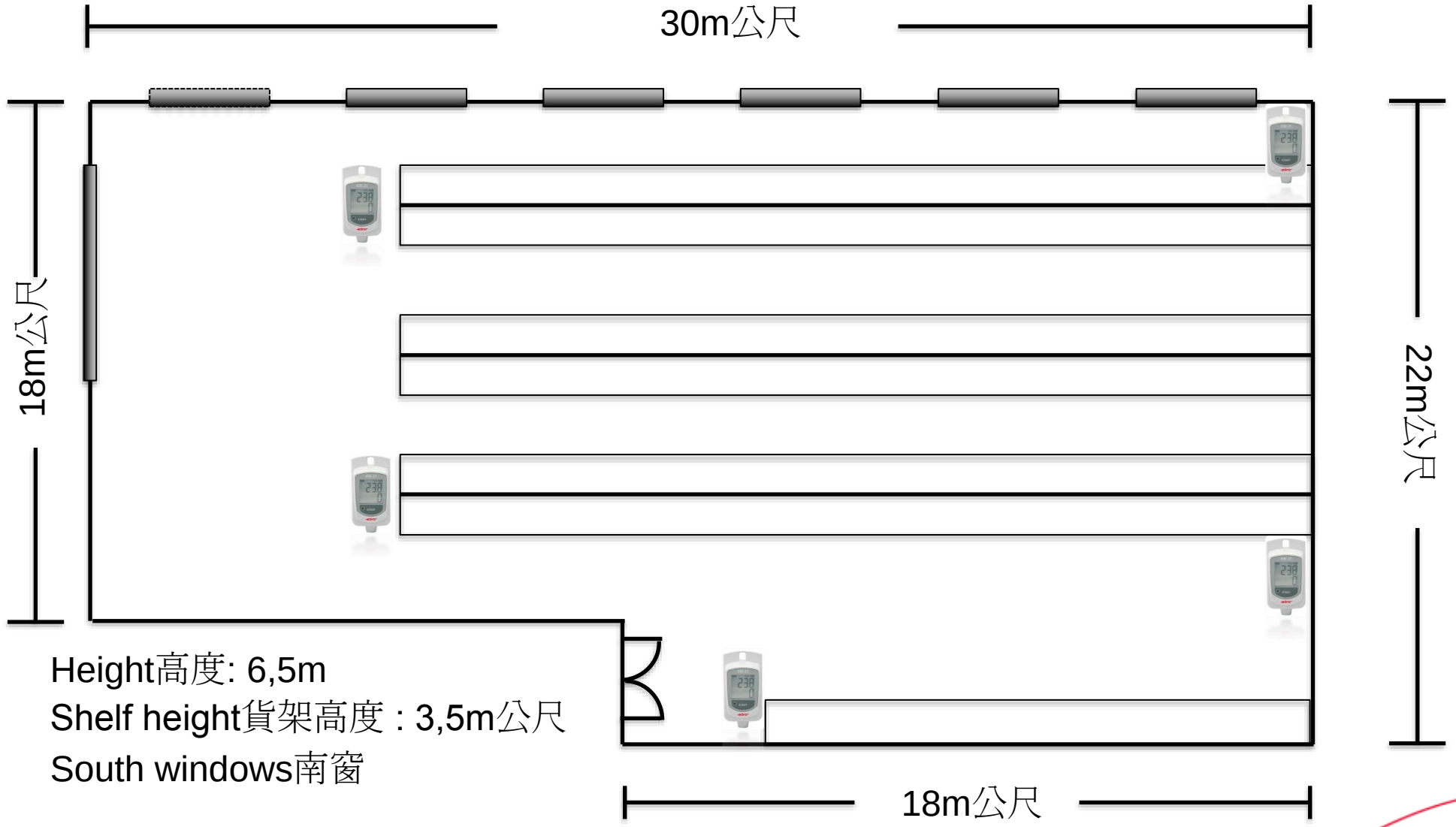
Rethink the general layout of your warehouse and the placement of your sensors. 重新考慮倉庫的總體佈局和傳感器的放置。

Blocking areas for certain products where the required specifications cannot be met無法滿足所需規格之某些產品的阻塞區域

Result of a summer study暑期研究的結果



Result of a summer study暑期研究的結果



Height高度: 6,5m
Shelf height貨架高度 : 3,5m公尺
South windows南窗

Examples of Thermal Mapping Protocols熱測繪協議示例

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THERMAL MAPPING PROTOCOL

For

xxx PHARMA WAREHOUSES

製藥倉儲之熱測繪協議

Written by:	Allan L. Javier	Product Manager / Technical Services Manager		
	Name	Title	Signature	Date
Reviewed by:	xxx	Engineering & Technical Services Manager (xx)		
	Name	Title	Signature	Date
	xxx	Quality and Compliance Manager (xx)		
	Name	Title	Signature	Date
Approved by:	xxx	Operations Director (xx)		
	Name	Title	Signature	Date

Table of contents

THERMAL MAPPING PROTOCOL

GUIDE TO PERFORMING TEMPERATURE MAPPING FOR ZUELLIG PHARMA CORP. STORAGE AREAS / WAREHOUSES AS FOLLOWS:

- Pickface Area
- Regulated Room
- Gold Room
- CLRU
- RA Area
- Secondary Repackaging Area
- VNA Zone 1
- VNA Zone 2

1 INTRODUCTION

This document is intended to give guidance on the performance of temperature mapping activities in the identified storage areas mentioned above that are owned and operated by XX Pharma Corporation located at XXX

This is an essential document to have in place before starting actual data acquisition and mapping procedures and serves as a road map to ensure that all critical factors and issues have been considered. This serves as a temperature mapping protocol for ZPC Storage Facilities.

The following will also be presented: *Validation Template, Graphical overview of logger positions, Statistics Reports and Mean Kinetic Temperature (MKT).*

The FDA regards MKT as a calculation that will show if a product has exceeded storage conditions. It can also be used to determine if storage, handling, shipment or distribution has affected the shelf life of the product.

2 OBJECTIVES

Objectives of the Thermal Mapping

- *To check the performance of the temperature-controlled Storage Areas*
- *Establish the adequacy of AHUs and Chillers in relation to its effect in storage conditions and the warehouse behavior per corresponding period of time*
- *To identify and improve temperature equilibration within the Storage Area*
- *To determine the highest temperature fluctuations within the Storage Areas that will be a basis for further improvements.*
- *To determine the cold and warm regions of the entire warehouse*
- *To revalidate the location of the existing sensors of the current facility monitoring system*
- *To qualify the performance of the storage areas based on the pre-determined acceptance criteria: Temperatures not more than 25.0°C and Temperatures not more than 30.0°C.*
- *To evaluate MKT according to predefined acceptance criteria (Only for Temperatures)*
- *To determine additional 25°C locations in the VNA warehouse.*

3 AREAS FOR THERMAL MAPPING

- Pickface Area

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Example of Thermal Mapping Report熱測繪協議示例

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DAY 5:

Location; Layer Code and Time of Occurrences (LC- Logger in Core)	Minimum Registered Temperature (°C)
EBI20 04; EB-16-02-02 Bottom; 6:00AM	21.70
EBI20 13; EE-42-02-02 Top; 6:00AM	21.79
EBI20 08; ED-33-02-01 Middle; 6:00AM	21.89

Start Time: 11:00am of May 29-30, 2021

DAY 6:

Location; Layer Code and Time of Occurrences (LC- Logger in Core)	Minimum Registered Temperature (°C)
EBI20 04; EB-16-02-02 Bottom ; 6:00AM	21.71
EBI20 13; EE-42-02-02 Top; 6:00AM	21.79
EBI20 08; ED-33-02-01 Middle; 6:00AM	21.89

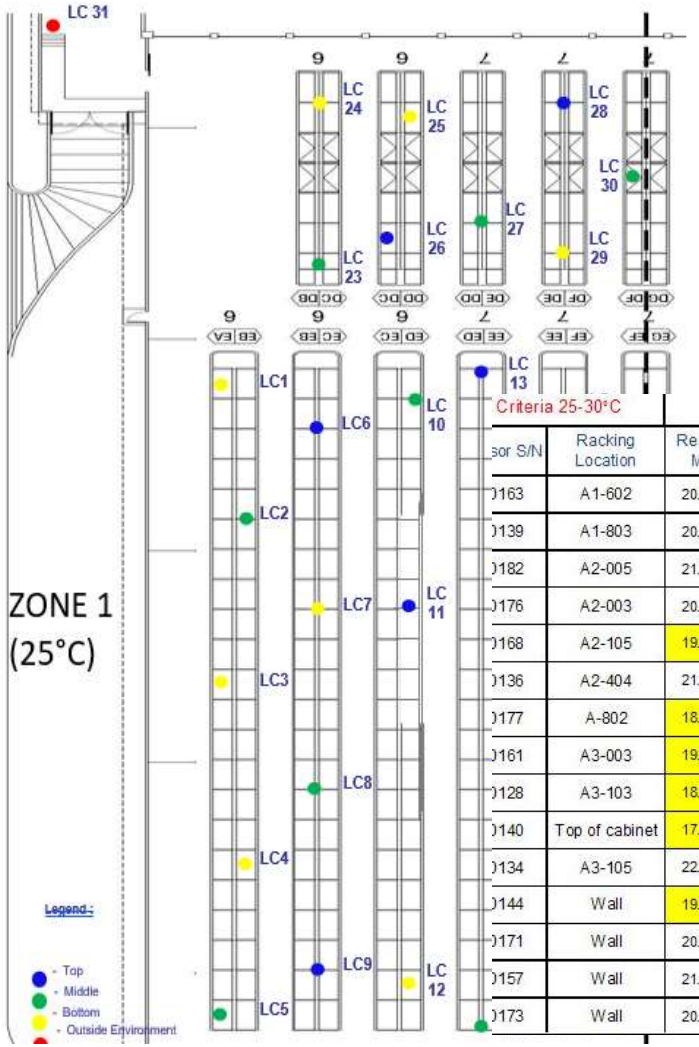
Start Time: 11:00am of May 30-31, 2021

DAY 7:

Location; Layer Code and Time of Occurrences (LC- Logger in Core)	Minimum Registered Temperature (°C)
EBI20 04; EB-16-02-02 Bottom ; 6:00AM	21.71
EBI20 13; EE-42-02-02 Top; 6:00AM	21.79
EBI20 08; ED-33-02-01 Middle; 6:00AM	21.88

Start Time: 11:00am of May 31 to June 1, 2021

2 Illustration- Location of Measuring Points



3 Summary of Results and Recommendations

XXX WAREHOUSE

The *XXX Warehouse was* mapped with fully operation with AHU 180 Tons cooling system running simultaneously.
To fully evaluate the room/storage condition and performance, all captured maximum and minimum temperatures were identified and tabulated on a day-to-day basis as presented on pages 4 to 5.

Maximum registered temperatures were consistent to be in the same locations as summarized below:

Identified Warmest Spot (Global Max.)	EBI20 10; EC-18-05-02 Top; **24.89°C** (3:30PM May 28, 2021)
Warmest Period	12:00pm to 4:30
Coldest Spot (Global Min.)	EBI20 04; EB-16-02-02 Bottom; **21.39°C** (5:30AM May 28, 2021)
Coldest Period	3:00am to 8:00am
Evaluation / Remarks	Passed
MKT: Not more than 298.15°K	Passed

Criteria 25-30°C

		DAY 1				DAY 2				DAY 3			
sor S/N	Racking Location	Reading Min.	Time	Reading Max.	Time	Reading Min.	Time	Reading Max.	Time	Reading Min.	Time	Reading Max.	Time
0163	A1-602	20.68 °C	6:15 AM	21.84 °C	1:15: PM	20.71 °C	3:15 AM	21.01 °C	1:15: PM	20.87 °C	6:15 AM	21.79 °C	1:45: PM
0139	A1-803	20.82 °C	6:15 AM	21.73 °C	1:15: PM	20.71 °C	3:15 AM	21.00 °C	1:15: PM	20.79 °C	6:15 AM	21.81 °C	1:45: PM
0182	A2-005	21.71 °C	6:15 AM	22.09 °C	1:15: PM	21.79 °C	3:15 AM	22.45 °C	1:15: PM	21.95 °C	6:15 AM	22.45 °C	1:45: PM
0176	A2-003	20.29 °C	6:15 AM	21.43 °C	1:15: PM	20.34 °C	3:15 AM	20.54 °C	1:15: PM	20.56 °C	6:15 AM	21.79 °C	1:45: PM
0168	A2-105	19.89 °C	6:15 AM	21.19 °C	1:15: PM	19.94 °C	3:15 AM	20.07 °C	1:15: PM	20.21°C	6:15 AM	21.18 °C	1:45: PM
0136	A2-404	21.12 °C	6:15 AM	21.45 °C	1:15: PM	21.28 °C	3:15 AM	21.76 °C	1:15: PM	21.48 °C	6:15 AM	22.20 °C	1:45: PM
0177	A-802	18.75 °C	6:15 AM	19.11 °C	1:15: PM	19.07 °C	3:15 AM	19.84 °C	1:15: PM	19.34 °C	6:15 AM	21.00 °C	1:45: PM
0161	A3-003	19.41 °C	6:15 AM	19.58 °C	1:15: PM	19.53 °C	3:15 AM	19.84 °C	1:15: PM	19.82 °C	6:15 AM	20.01 °C	1:45: PM
0128	A3-103	18.67 °C	6:15 AM	19.54 °C	1:15: PM	19.08 °C	3:15 AM	20.11 °C	1:15: PM	19.54 °C	6:15 AM	20.18 °C	1:45: PM
0140	Top of cabinet	17.82 °C	6:15 AM	19.45 °C	1:15: PM	19.36 °C	3:15 AM	19.86 °C	1:15: PM	19.69 °C	6:15 AM	20.05 °C	1:45: PM
0134	A3-105	22.83 °C	6:15 AM	23.40 °C	1:15: PM	23.04 °C	3:15 AM	24.21 °C	1:15: PM	23.09 °C	6:15 AM	24.21 °C	1:45: PM
0144	Wall	19.37 °C	6:15 AM	19.74 °C	1:15: PM	19.59 °C	3:15 AM	19.86 °C	1:15: PM	19.99 °C	6:15 AM	20.11 °C	1:45: PM
0171	Wall	20.98 °C	6:15 AM	21.08 °C	1:15: PM	21.04 °C	3:15 AM	21.88 °C	1:15: PM	21.13 °C	6:15 AM	21.50 °C	1:45: PM
0157	Wall	21.36 °C	6:15 AM	21.57 °C	1:15: PM	21.43 °C	3:15 AM	21.70 °C	1:15: PM	21.48 °C	6:15 AM	21.70 °C	1:45: PM
0173	Wall	20.40 °C	6:15 AM	21.00 °C	1:15: PM	20.38 °C	3:15 AM	20.65 °C	1:15: PM	20.66 °C	6:15 AM	21.05 °C	1:45: PM

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GRANDEVER BIOTECHNOLOGY CO., LTD.

Monitoring solution監控解決方案 ► EBI 25 radio logger system
EBI 25無線電記錄系統

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Monitoring solution監控解決方案 ► EBI 25 radio logger system
EBI 25無線電記錄系統




	EBI 25-T	EBI 25-TH	EBI 25-TE	EBI 25-TX
Measure range偵測範圍	-30ºC …+60ºC	-30ºC …+60ºC 0%rh…100%rH	-40ºC …+85ºC	-200ºC …+200ºC
Accuracy精準度	±0,5ºC (-20ºC …+40ºC) ±0,8ºC (remaining range其餘範圍)	±0,5ºC (-20ºC …+40ºC) ±0,8ºC (remaining range 其餘範圍)±3%rH	±0,5ºC (-20ºC …+40ºC) ±0,8ºC (-30ºC …+20ºC /+40ºC …+60ºC) ±1,5ºC (remaining range其餘範圍)	±0,2ºC (-20ºC …+60ºC) ±2ºC (-200ºC …-100ºC) ±0,5ºC (remaining range 其餘範圍)

Monitoring solution監控解決方案 ► EBI 25 radio logger system
EBI 25無線電記錄系統

What do you need您需要什麼?

Wireless Data Points無線數據點

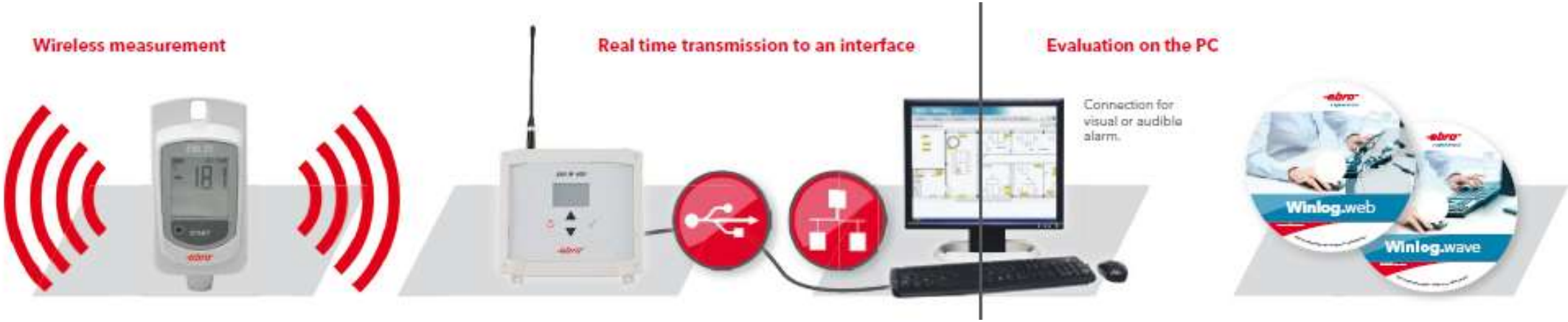
- EBI 25 Temperature sensors溫度傳感器
- EBI 25 Humidity Sensors濕度傳感器

Data Sources數據源

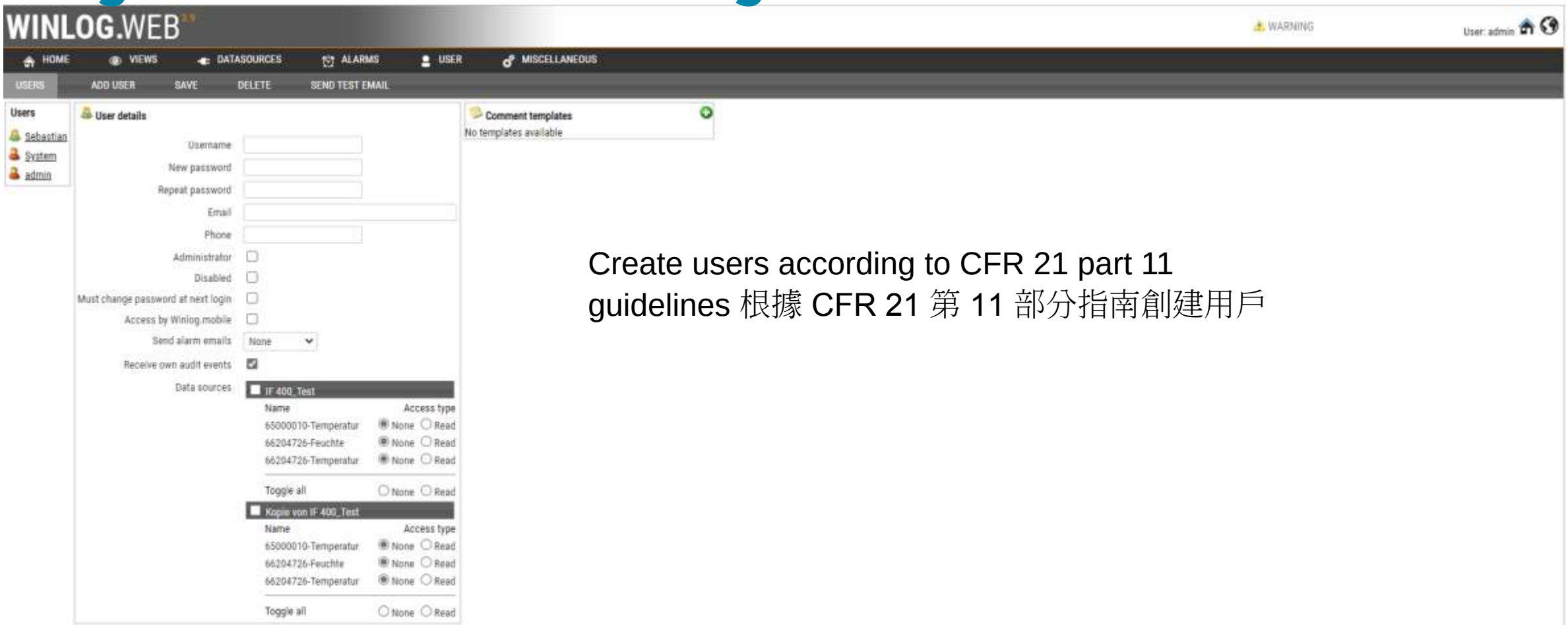
- EBI 25 interface界面(TCP/IP輸控制協議和網際協議 or USB通用串行總線)
- Other sensors integrated via modbus
  其他通過串行通信協議集成的傳感器

Data Display and Storage數據顯示與存儲

- Winlog.Web - network based software網路版軟體
- Winlog.Wave – Single PC based software單機版軟體

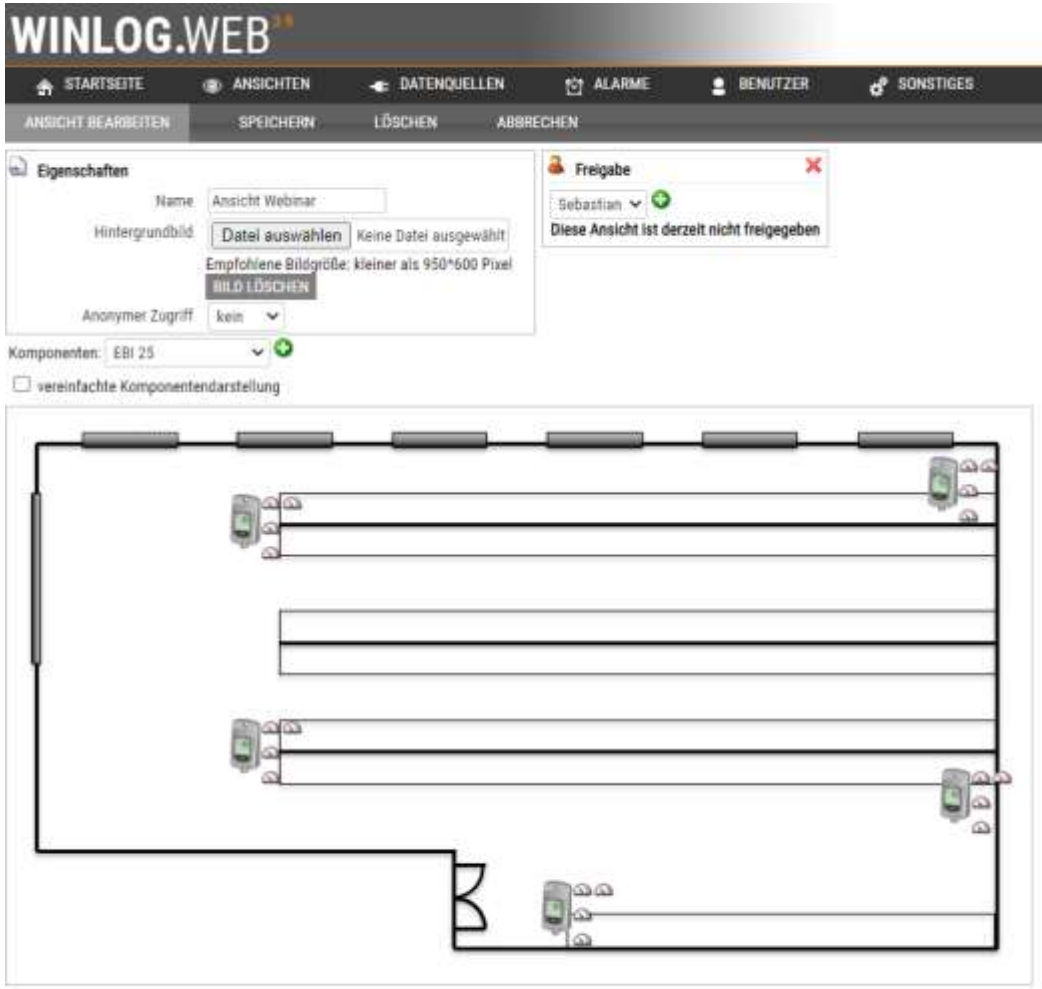


Integrate into 整合到 the Winlog.web



Create users according to CFR 21 part 11 guidelines 根據 CFR 21 第 11 部分指南創建用戶

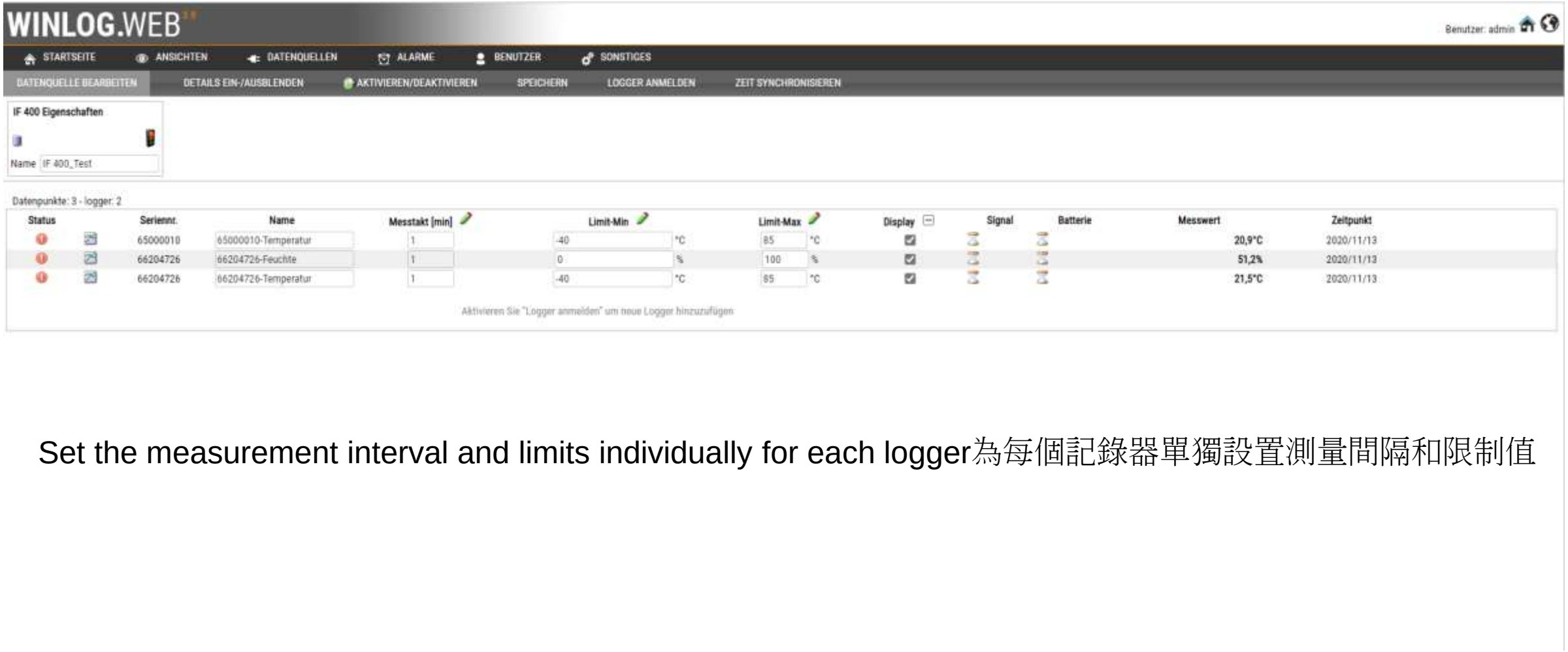
Integrate into 整合到 the Winlog.web



Graphical representations adapted to your circumstances 適合您情況的圖形表示

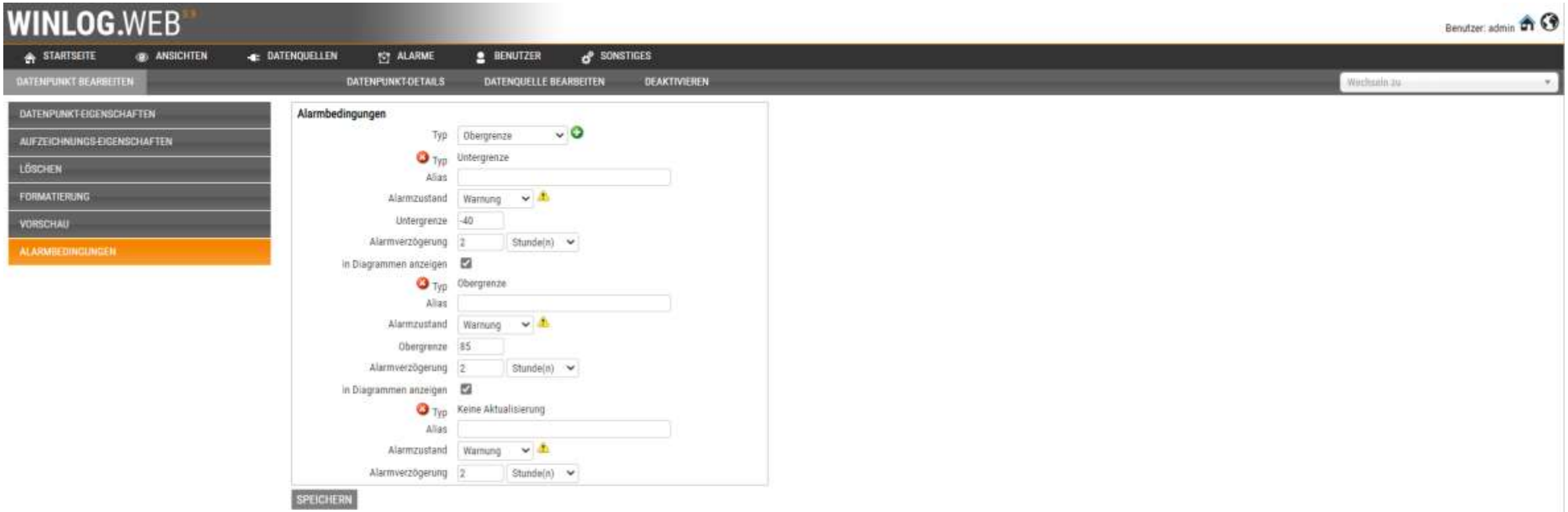
Each logger can be set and viewed individually
每個記錄器都可以單獨設置和查看

Integrate into 整合到 the Winlog.web



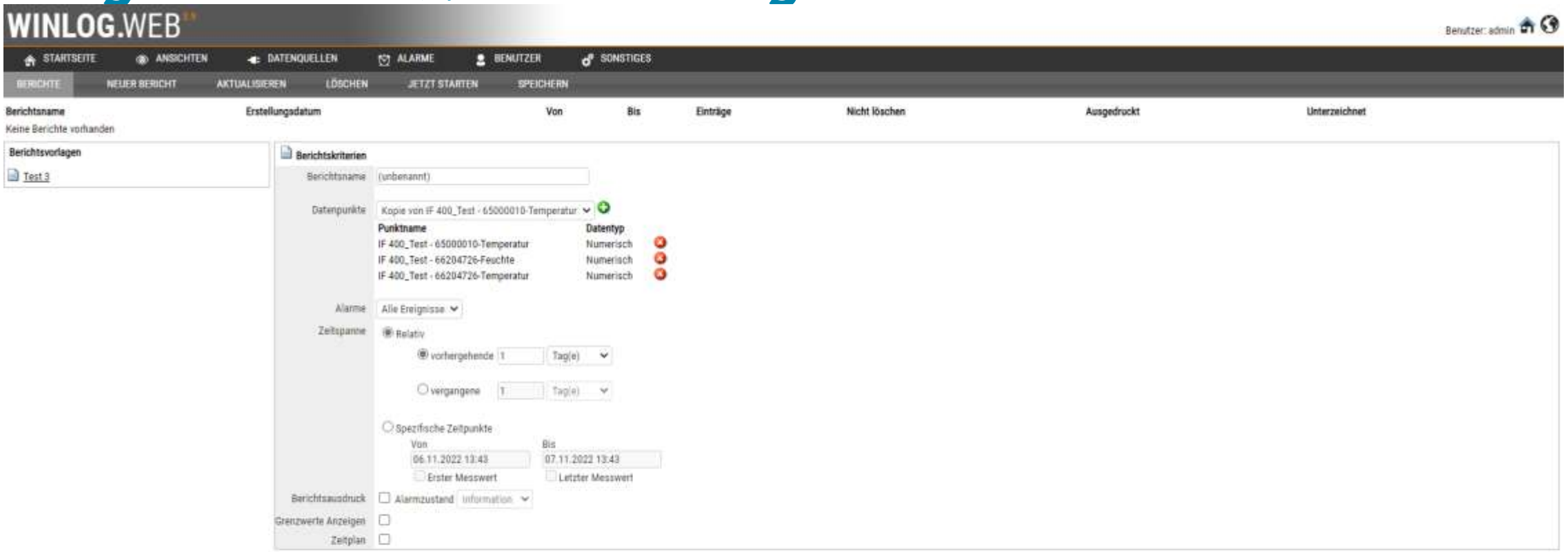
Set the measurement interval and limits individually for each logger為每個記錄器單獨設置測量間隔和限制值

Integrate into 整合到 the Winlog.web



Depending on the criticality of the measuring point, the limit can be displayed as information, warning or alarm 根據測量點的重要性，限制值可以顯示為信息、警告或警報

Integrate into 整合到 the Winlog.web

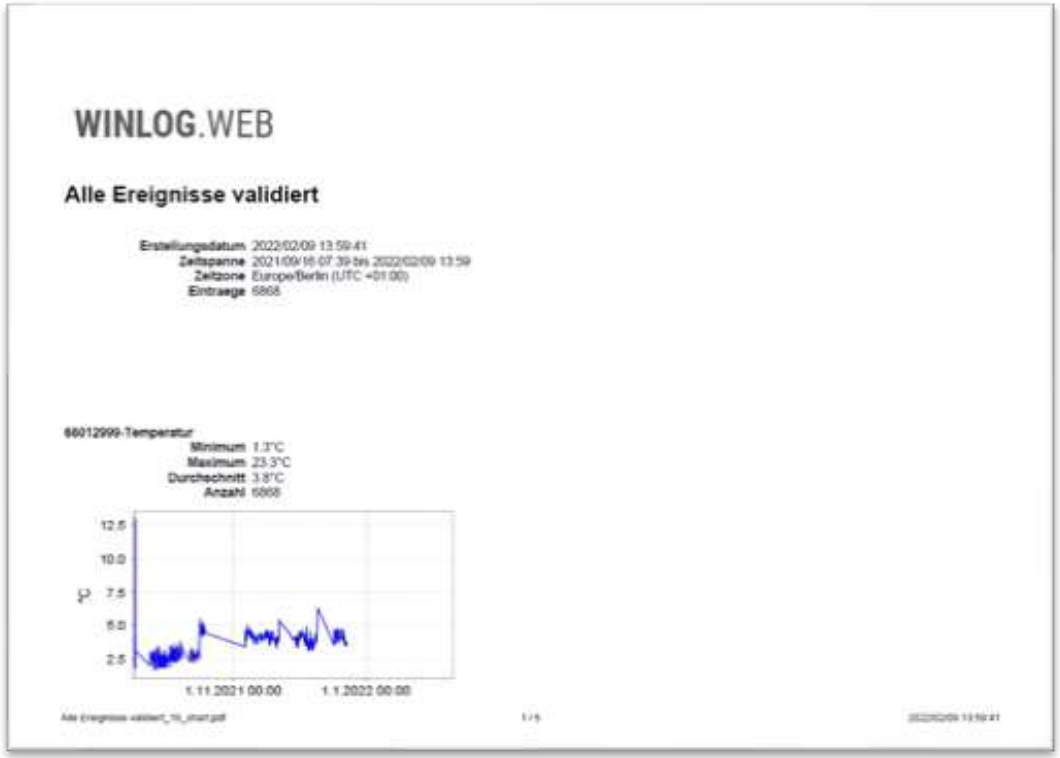


Reports can be created for each measuring point individually or as an overall report
可以為每個測量點單獨或作為整體報告創建報告

Integrate into 整合到 the Winlog.web

Or as a recurring report at a specific point in time
或作為特定時間點的定期報告

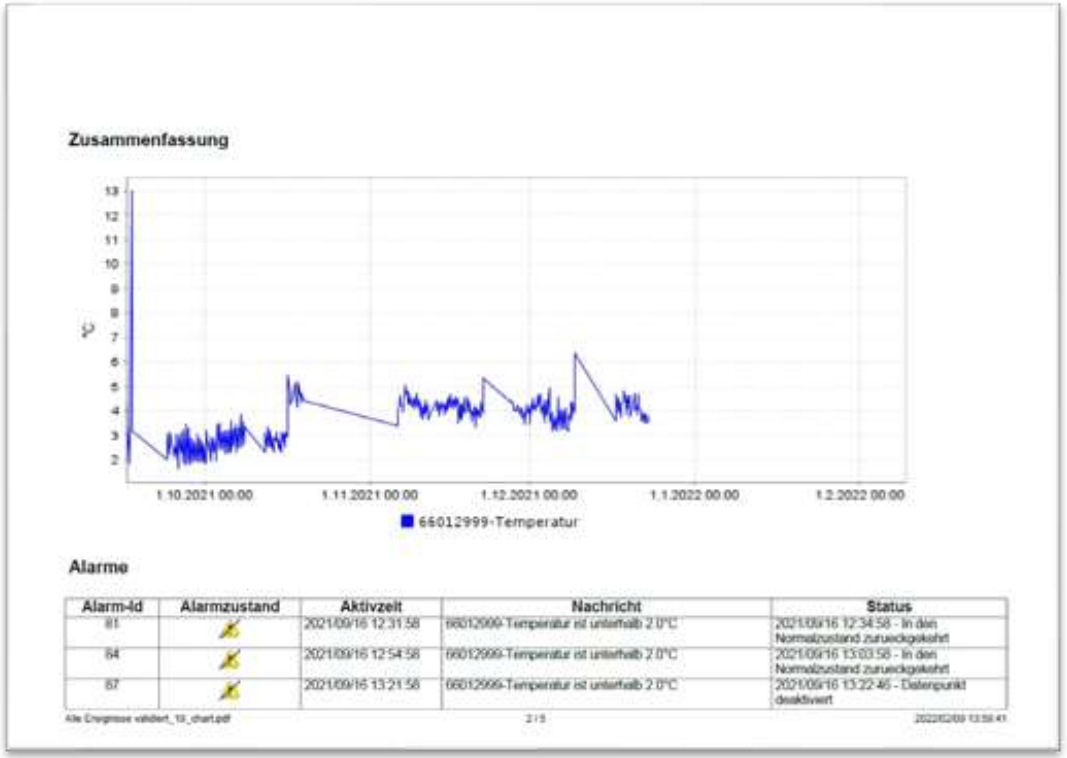
Integrate into 整合到 the Winlog.web


WINLOG.WEB

Alle Ereignisse validiert

Erstellungsdatum 2022/02/09 13:59:41
Zeitspanne 2021/09/16 07:39 bis 2022/02/09 13:59
Zeitzone Europe/Berlin (UTC +01:00)
Eintraege 6868

66012999-Temperatur
Minimum 1.3°C
Maximum 23.3°C
Durchschnitt 3.8°C
Anzahl 6868


Zusammenfassung

66012999-Temperatur

Alarme

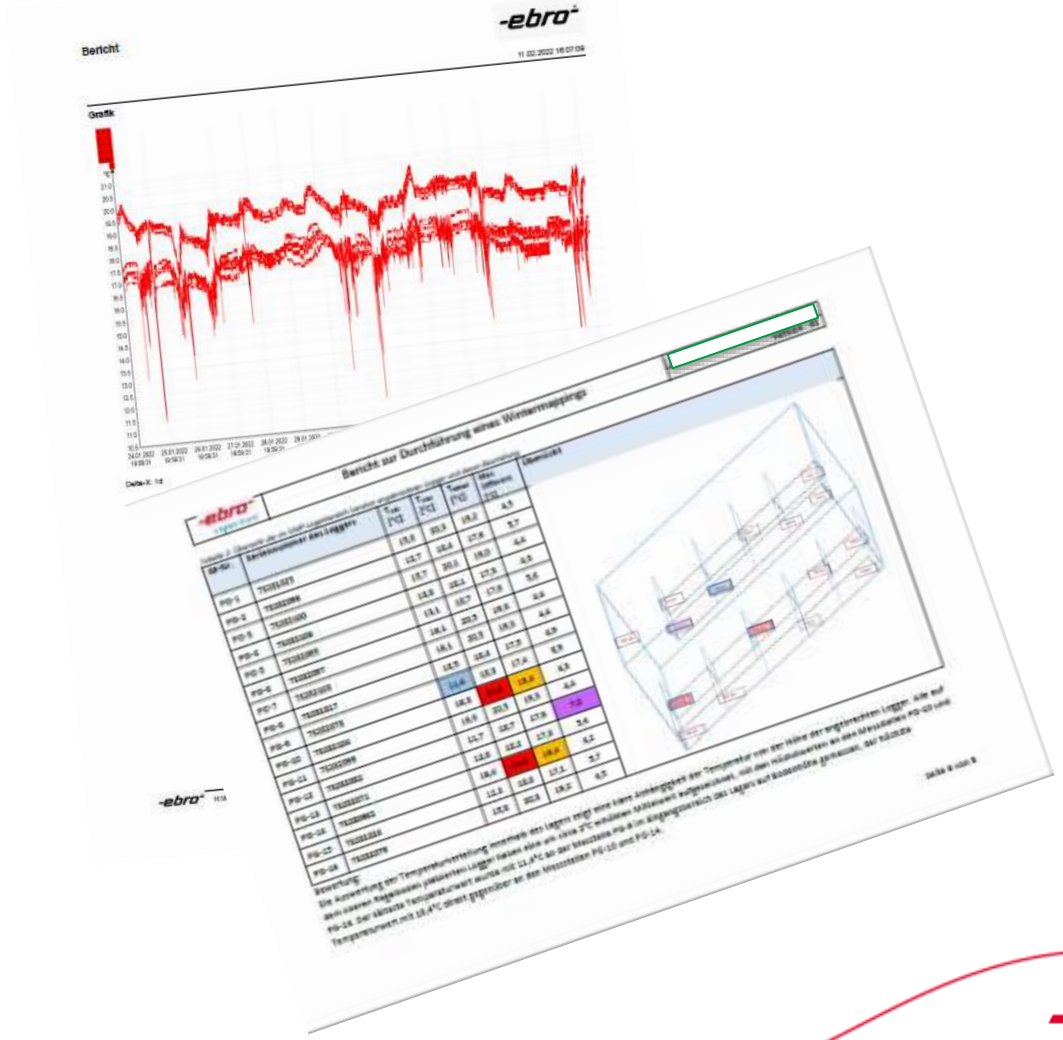
Alarm-Id	Alarmzustand	Aktivzeit	Nachricht	Status
81		2021/09/16 12:31:58	66012999-Temperatur ist unterhalb 2.0°C	2021/09/16 12:34:58 - In den Normalzustand zurueckgekehrt
84		2021/09/16 12:54:58	66012999-Temperatur ist unterhalb 2.0°C	2021/09/16 13:03:58 - In den Normalzustand zurueckgekehrt
87		2021/09/16 13:21:58	66012999-Temperatur ist unterhalb 2.0°C	2021/09/16 13:22:46 - Datenpunkt deaktiviert

So you can easily and conveniently file reports and are automatically informed about alarms and warnings by email　因此，您可以輕鬆方便地提交報告，並通過電子郵件自動收到有關警報和警告的通知

And thus fulfill the requirements according to GMP　從而達到GMP要求!

Industry Case Examples in Europe and in Asia Pacific歐洲和亞太地區的產業案例

GxP-compliant mapping - The ebro service for qualified temperature and humidity mapping符合 GxP 標準的測繪 - 用於合格溫度和濕度測繪的 ebro 服務



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Thermal Process Validation熱過程驗證 | Xylem Singapore新加坡

Contact an Ebro Specialist

Thermal Mapping Service

Our Analytics-LAB Business Unit provides a norm-based, guideline-referenced and GxP-compliant implementation of thermal mapping for Pharmaceutical or Healthcare warehouses and other storage facilities.

Thermal Mapping

Thermal Process Validation

Xylem Singapore's Validation Team is recognized by the U.S. FDA and British Retail Consortium (BRC) as a TPA (Thermal Process Authority). We have the expertise and experience as Process Authenticator, to file and successfully obtain FDA certification for our client.

Thermal Process Validation

Datalogger Calibration and Repair Service

Xylem provides expert calibration and repair services for Medical, Food and Environmental applications. We have a purpose built and certified calibration bath to ensure accurate measurement through the range.

Calibration and Repair

xylem
Let's Solve Water

Xylem Vue | Solutions | Products & Services | Our Brands | Support | Sustainability | About Xylem

< View all Equipment Analysis & Upgrades

Thermal Process Validation

Xylem Singapore's Validation Team is recognized by the U.S. FDA and British Retail Consortium (BRC) as a TPA (Thermal Process Authority). We have the expertise and experience as Process Authenticator, to file and successfully obtain FDA certification for our client.

What is FCE SID Certification?

The FCE (Food Canning Establishment) and SID (Submission Identifier) are the two basic types of process filing and submissions required under the provision of FDA 21 CFR 108.35I(2).

Why do you need FCE SID Certification?

Commercial Processors who manufacture, process, or pack thermally processed low-acid foods (historically referred to by the FDA as "LACF") packaged in hermetically sealed containers such as cans, bottles, jars

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Questions問題?

Answering your question from registration formAnswering your question from registration form…從註冊表中回答您的問題

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- **Do all data loggers for thermal mapping need to be annually calibrated according to the guidelines in the WHO technical report 是否需要根據 WHO 技術報告中的指南對所有用於熱測繪的數據記錄器進行年度校準?**
  YES, annually or smaller interval 是的，每年或更短的時間間隔.
- **Is pre and post needed 是否需要前校後校?**
  If it is a pharma purpose, it is needed 如果是製藥目的，則需要.
- **Person that perform the thermal mapping need have any qualification執行熱測繪的人需要有任何資格?**
  There is no required qualification. But the person should have experience in pharma or quality control, and should be trained according to data integrity or GDP沒有必要的資格。但此人應具有製藥或質量控制方面的經驗，並應根據數據完整性或依循GDP進行培訓.
- **Thermal Mapping has EU norm熱測繪具有歐盟標準?**
  EU is working on the norm. The unpublished guideline is also according to WHO guideline歐盟正在製定規範。未發表的指南也是根據 WHO 指南.
- **Can your loggers work at ultra-low temperatures without failure你的記錄器能在超低溫下無障礙工作嗎?**
  Depends on the temperature and exposure time. ebro suggests/recommends that only the external sensor is introduced to the ultra low chamber. The logger itself is kept outside取決於溫度和暴露時間。 ebro 建議/建議僅將外部傳感器引入超低溫室。記錄器本身保留在外面.
- **Do this device have IQ, OQ這個設備有IQ(安裝驗證)，OQ(操作驗證)嗎?**
  Yes是的
- **Which models will be good for thermal mapping 哪些型號適合熱測繪?**
  We suggest EBI 25 series and EBI 20 series.我們推薦 EBI 25 系列和 EBI 20 系列

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Thank you 謝謝您

Email us if any questions:如有任何問題，請給我們發電子郵件：

Sebastian Schwarz

Sebastian.Schwarz@xylem.com

Allan Javier

allan.javier@xylem.com

Milliya Tsai

Milliya.tsai@xylem.com

GRANDEVER BIOTECHNOLOGY CO., LTD.
大久生物科技股份有限公司
Valuable contribution to the power and science community.
貢獻於電機和科學共同體

11471 台北市內湖區新明路273巷6號1樓
1F., No.6, Ln. 273, Xinming Rd., Neihu Dist., Taipei City 11471, Taiwan (R.O.C.)
服務專線Tel ：(02)8792-3722
服務傳真Fax：(02)8792-3761
電子信箱Email：info@grandever-biotech.com.tw
公司網址Website: www.grandever-biotech.com.tw