Annex 1 Practical Part- Webinar
附件 1 驗證實踐部分-網路研討會

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Agenda

1. Zoom 說明
2. Brief Introduction 簡介
3. Norms & Regulatory requirements規範和監管要求
4. Validation of sterilization processes滅菌過程的驗證
5. Evaluation of a steam sterilization process with the Winlog.validation 使用 Winlog.validation 評估蒸汽滅菌過程
6. Discussion and wishes討論和願望

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1 Zoom Explanation簡介

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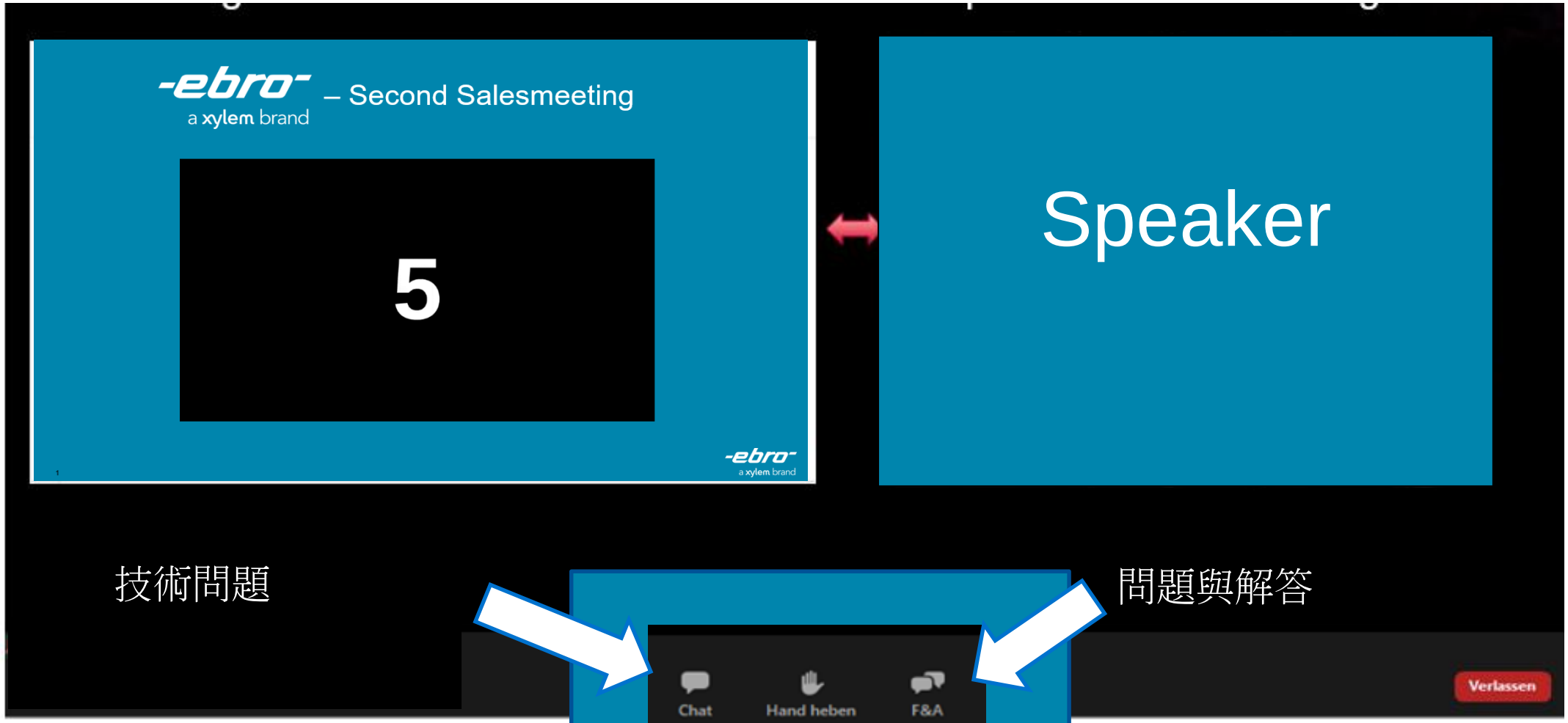
Information – LIVE Webinar via Zoom
信息 – 通過 Zoom 進行的實時網絡研討會

1. Screen / Presentation 屏幕/演示

2. Screen / Speaker 屏幕/揚聲器



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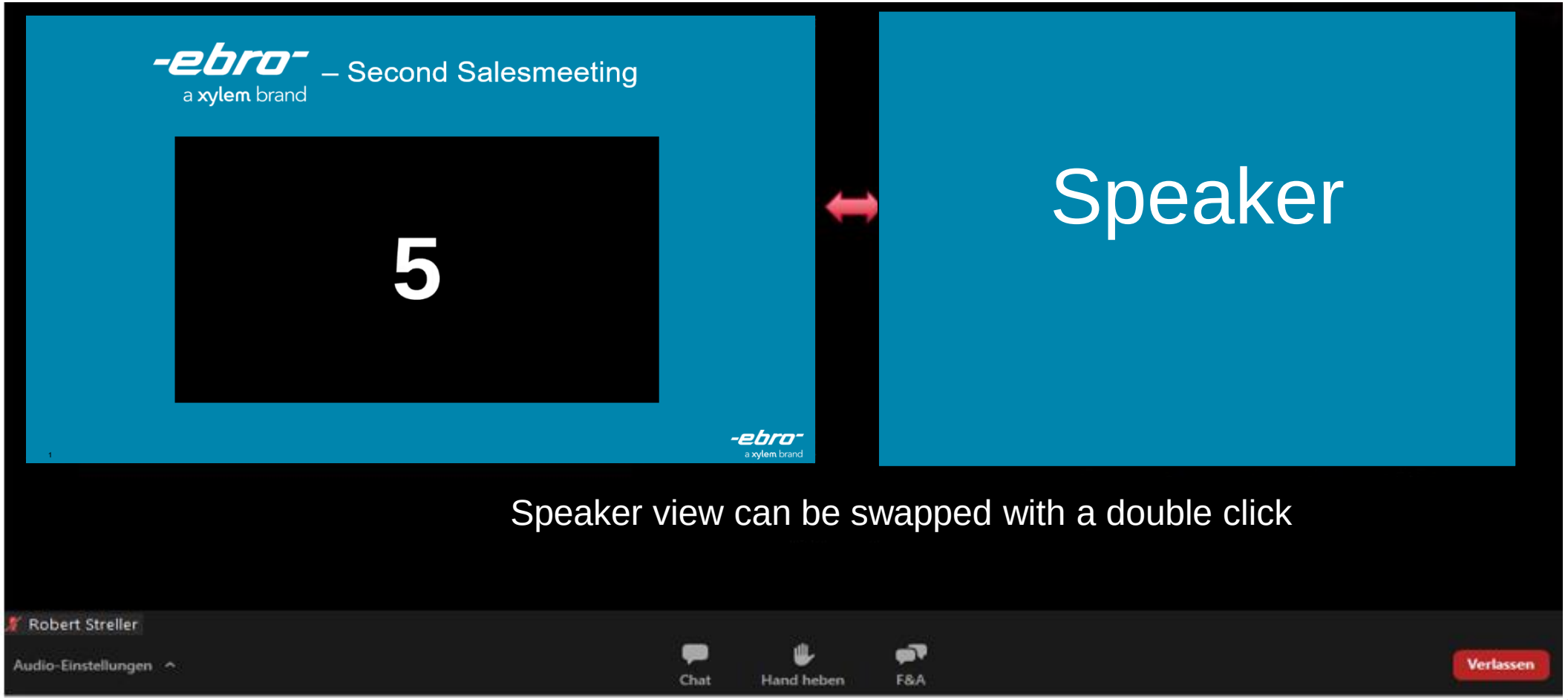

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Sebastian Schwarz / Dezember 2021

Annex 1 – Practical Part
附件 1 驗證實踐部分

SEBASTIAN SCHWARZ

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2 Brief Introduction簡介

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Brief Introduction

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Webinar Speaker:

Sebastian Schwarz - Market Manager Pharma 市場經理製藥

德國 Erlangen 化學和生物工程師學位

- 8 years experience as a consultant in a GMP controlled environment 8 年在 GMP 受控環境中擔任顧問的經驗
- Projects in the areas of calibration, qualification and validation for pharmaceutical manufacturers throughout Europe 為整個歐洲的製藥商提供校準、鑑定和驗證領域的項目

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sebastian.schwarz@xylem.com

- ebro - 一個 Xylem 品牌

- ebro -

- 1968 年在Freiburg成立
  - 專注於製藥、醫療、實驗室/工業和食品市場
  - 德國直銷
  - 自 2016 年 7 月以來屬於Xylem Analytics
  - 全球覆蓋超過 100 家分銷商

- ebro - Markets, Applications And Devices市場、應用和設備

Cold Chain

- 運輸
- 冷藏
- 冷藏/深度冷凍
- 進貨
- 溫度測繪

Validation

- 消毒
- 洗衣機消毒器
- 冷藏/深度冷凍
- 運輸
- 溫度測繪

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Norms & Regulatory requirements
規範和監管要求

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Regulatory 監管

Regulatory bodies are organisations set up by 監管機構是由以下機構設立的組織

Government with responsibility to monitor, guide and control various industry sectors in the interests of protecting consumers – *Protect, Promote and Maintain the health and safety of the public*.

All Regulatory Authorities strive to encourage best practices, globally by standardization.政府有責任監測、指導和控制各個行業部門以保護消費者的利益— 保護、促進和維護公眾的健康和安全。所有監管機構都努力通過標準化在全球範圍內鼓勵最佳實踐。

Widely Known Regulatory Authorities廣為人知的監管機構

1. EMA (Europe歐洲)
2. FDA / USDA (USA美國)
3. DHSC (UK英國)
4. TGA (Australia澳洲)

***There are other Organizations and Associations in the Industry that influence the Pharmaceutical Industry very highly! (ex. The PDA, ISPE, ABPI, etc.)**工業內還有其他組織和協會對製藥工業影響很大！（例如 **PDA**、**ISPE**、**ABPI** 等）*

EudraLex – 附件 1 <-> FDA美國食品和藥物管理局

基本上，有類似的要求：

- All sterilization processes should be validated! 應驗證所有滅菌過程！
- Where possible, (moist and dry) heat sterilization is the method of choice! 在可能的情況下，（濕和乾）熱滅菌是首選方法！
- Validated loading patterns and mapping studies should be established for all sterilization processes.應為所有滅菌過程建立經過驗證的裝載模式和測繪研究。

However, there is a different approach: 但是，有一種不同的方法：

- Annex 1 附件 1 :

  Biological indicators should be considered as an **additional method** for monitoring the sterilization.應考慮將生物指示劑作為監測滅菌的附加方法。

- FDA美國食品和藥物管理局:

  In general, the **biological indicator should be placed** adjacent to the temperature sensor to assess the correlation between microbial lethality and predicted lethality based on thermal input.一般來說，生物指示劑應放置在溫度傳感器附近，以評估微生物致死率和基於熱輸入預測的致死率之間的相關性。

Important norms regarding sterilization processes
關於滅菌過程的重要規範

- **EN 285** - Sterilization - Validation & routine control of dry-saturated steam sterilization (large size units) 滅菌 - 乾飽和蒸汽滅菌的驗證和常規控制（大型裝置）

- **EN 13060** – Sterilization – Validation & routine control of small (< 60 L) size autoclaves 滅菌— 小型（< 60 L）高壓滅菌器的驗證和常規控制

- **EN 554** - Sterilization of medical devices - Validation & routine control of sterilization by moist heat
  → replaced by **EN ISO 17665-1: 2006** - Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices 醫療器械的滅菌 - 濕熱滅菌的驗證和常規控制

  → 被 EN ISO 17665-1: 2006 - 保健產品滅菌 - 濕熱 - 第 1 部分：醫療器械滅菌過程的開發、驗證和常規控制要求取代

- **EN ISO 11135-1 -** Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
  EN ISO 11135-1 - 保健產品的滅菌 - 環氧乙烷 - 第 1 部分：醫療器械滅菌過程的開發、驗證和常規控制要求

Survey意見調查

What kind of sterilization processes have you used before?您以前使用過什麼樣的滅菌流程？

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4
Validation of sterilization processes
滅菌過程的驗證

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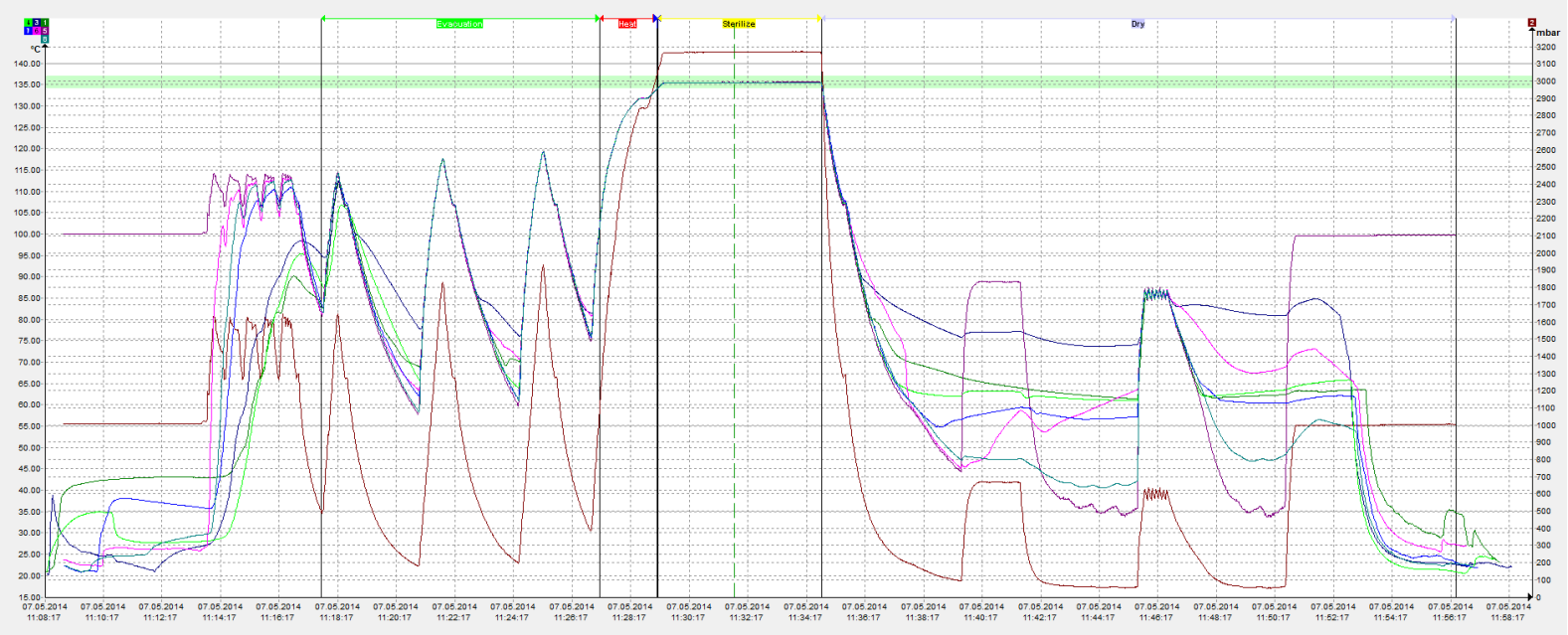
Sterilization processes 滅菌過程

Healthcare / Pharmaceutical 醫療保健/製藥

1. Moist Heat Sterilization 濕熱滅菌
2. Dry Heat Sterilization / Depyrogenation
   乾熱滅菌/除熱原
3. Ovens / Vacuum Ovens
   烘箱/真空烘箱
4. H_2O_2 Sterilization
   過氧化氫滅菌
5. EtO Sterilization
   環氧乙烷滅菌



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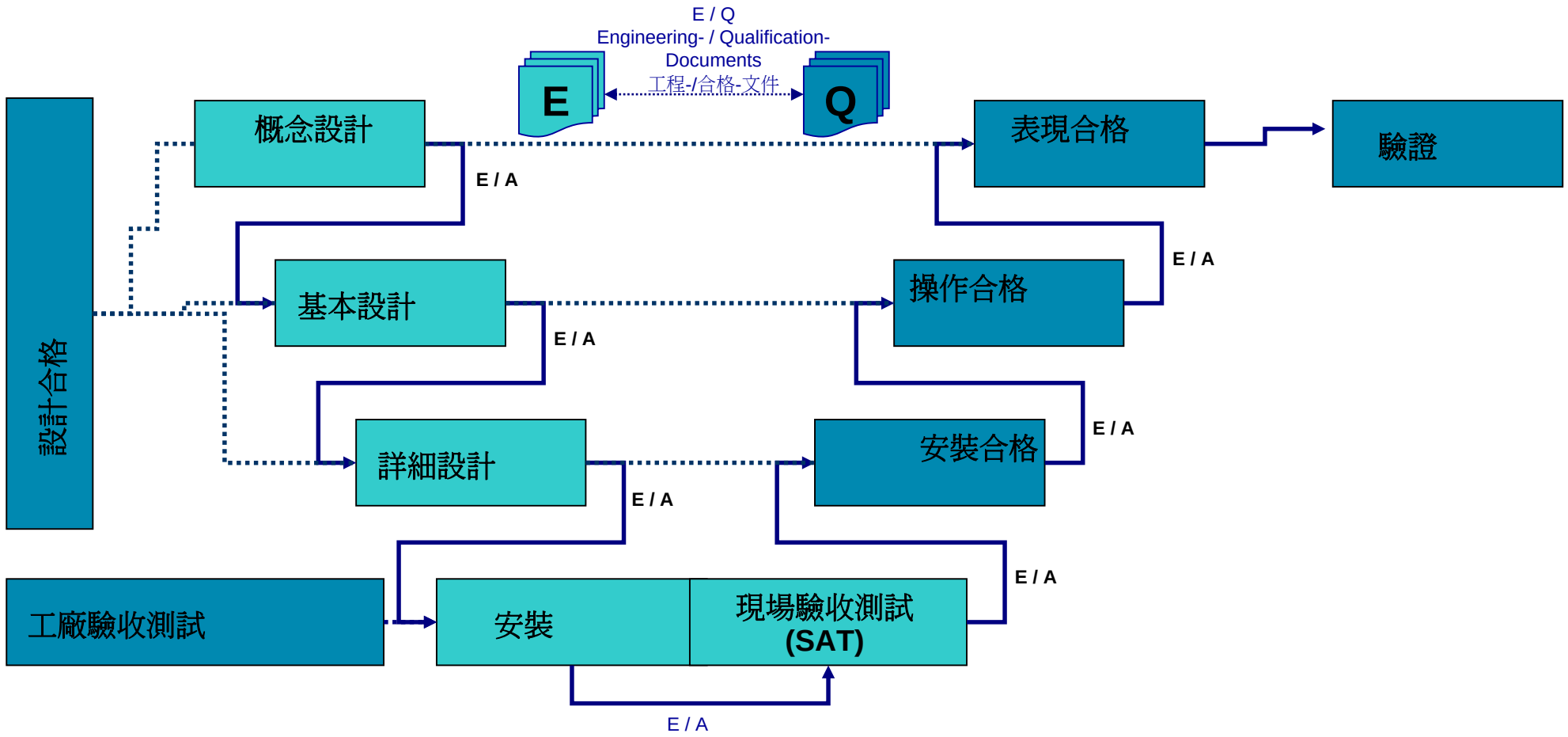
The V-Model of qualification according to EU GMP Annex 15
符合歐盟 GMP 附件 15 的 V-模型



概念設計 - 風險評估

注意可能的風險 -> 創建一個結論性的風險評估

根據您要驗證的過程，記錄器的風險可能會有所不同

流程	失效模式	失效效應	失效原因	…	建議的操作
驗證	滅菌無法成功驗證	順應性影響	使用的記錄儀沒有正確的測量範圍	…	DQ（規格檢查）； IOQ（功能檢查）
驗證	滅菌無法成功驗證	順應性影響	使用的記錄儀無法承受滅菌媒介	…	DQ（規格檢查）； IQ（材料檢查）
驗證	滅菌無法成功驗證	順應性影響	使用的記錄器測量間隔錯誤	…	IOQ（功能檢查） 用戶培訓
驗證	無法檢測到滅菌過程中的冷點	流程影響	滅菌過程中使用的記錄器數量不足	…	用戶培訓
驗證	無法檢測到滅菌過程中的冷點	流程影響	滅菌過程中使用的記錄器的分佈是錯誤的	…	用戶培訓

Conceptual Design – User Requirement Specification
概念設計—用戶需求規範

Knowing your risks, minimate them during conceptual design!

Write the URS with enough depth to avoid discussion later on 了解您的風險，在概念設計期間將其最小化！
以足夠的深度編寫 URS，稍後討論以避免:

Req. Nr.	cGMP	Explanation of the requirement 需求說明
Materials General Requirements 材料一般要求		
45	Yes	All non-product contact surface finishes shall be in accordance with a minimum of mill finish with all welds complete and ground smooth and color free.所有非產品接觸表面的光潔度應符合最低限度的軋製光潔度，所有焊縫完整且打磨光滑且無顏色。
46	Yes	All non-product contact metallic surfaces MOC shall be 304 stainless steel or better ans shall withstand media used for sterilization 所有非產品接觸金屬表面 MOC 應為 304 不銹鋼或更好，並且應承受用於滅菌的介質。
47	Yes	Pharmaceutical equipment shall be capable of being validated as reaching and holding above 121 ºC at a maximum of 127 ºC for 45 minutes minimum during SIP to provide sterility assurance minimum of six log reduction of geobacillus stearothermophilus, >1x10^6 cells at the boundaries required. 製藥設備應能夠被驗證在 SIP 期間達到並在最高 127 ºC 下保持高於 121 ºC 至少 45 分鐘，以提供對嗜熱脂肪地芽孢桿菌至少 6 個對數降減的無菌保證，在邊界所需的> 1x10^6 個細胞。
Analytics		
48	Yes	Temperature range 0 … 140°C; Accuracy +/- 0,1K　溫度範圍 0 … 140° C；精度 +/- 0,1K
49	Yes	Pressure range 1mbar … 4000 mbar; Accuracy +/- 15mbar　壓力範圍 1mbar … 4000 mbar；精度 +/- 15mbar

Qualification Phase - IQ　資格階段 - IQ

IQ – 檢查正確性

- P&I-Diagram　管道和儀表圖
- Installation control: environmental conditions, operating material, equipment, maintenance　安裝控制：環境條件、操作材料、設備、維護
- Calibration of the different sensors　校準不同的傳感器

  -> Three points for temperature/ pressure　溫度/壓力　三點

  -> One point for timer or paper speed of the recorder　計時器或記錄器紙速 一點
- Availability of relevant SOPs (at least as draft version): operation, maintenance, …相關 SOP 的可用性（至少作為草案版本）：操作、維護
- Check of the supplier documentation (Completeness, Formal correctness, Correctness of content…)檢查供應商文件（完整性、形式正確性、內容正確性……）

Qualification Phase - OQ　資格階段 - OQ

OQ - Function testing of all procedures & sequences:　OQ - 所有程序和序列的功能測試：

- Tightness and stability of piping after performing a sterilization cycle (Visual checks!)執行滅菌循環後管道的密封性和穩定性（目視檢查！）
- Loading and unloading tests – define the loading patterns　裝載和卸載測試 - 定義裝載模式
- Interlocks of doors (if pass-through autoclave)　門聯鎖（如果通過高壓滅菌器）
- Correct re-start after power failure　停電後正確重啟

Check of programs (with empty chamber):　檢查程序（空腔）：

- Fractionated pre-vacuum　分段預真空
- Heating phase　加熱階段
- Equilibration time　平衡時間
- Sterilization time 滅菌時間
- Drying and Cooling 乾燥和冷却

Qualification Phase - PQ 資格階段 - PQ

PQ – Performance qualification of all procedures & sequences: 所有程序和序列的性能鑑定：

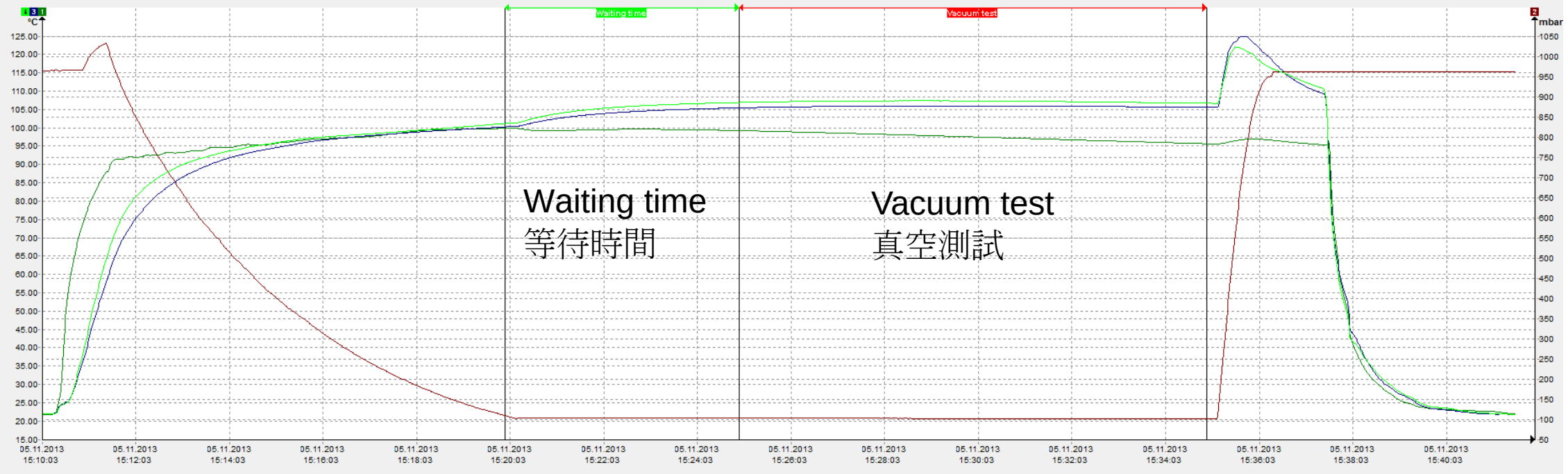
Checks 檢查:

Conductivity of the feed water 給水的電導度

CT 830 Set Conductivity Meter 電導度套組

Qualification Phase 資格階段 - PQ

Vacuum test 真空測試



Ebro Solutions 解決方案

- EBI 12 / EBI 11
- Temperature – Pressure data logger 溫度壓力記錄器

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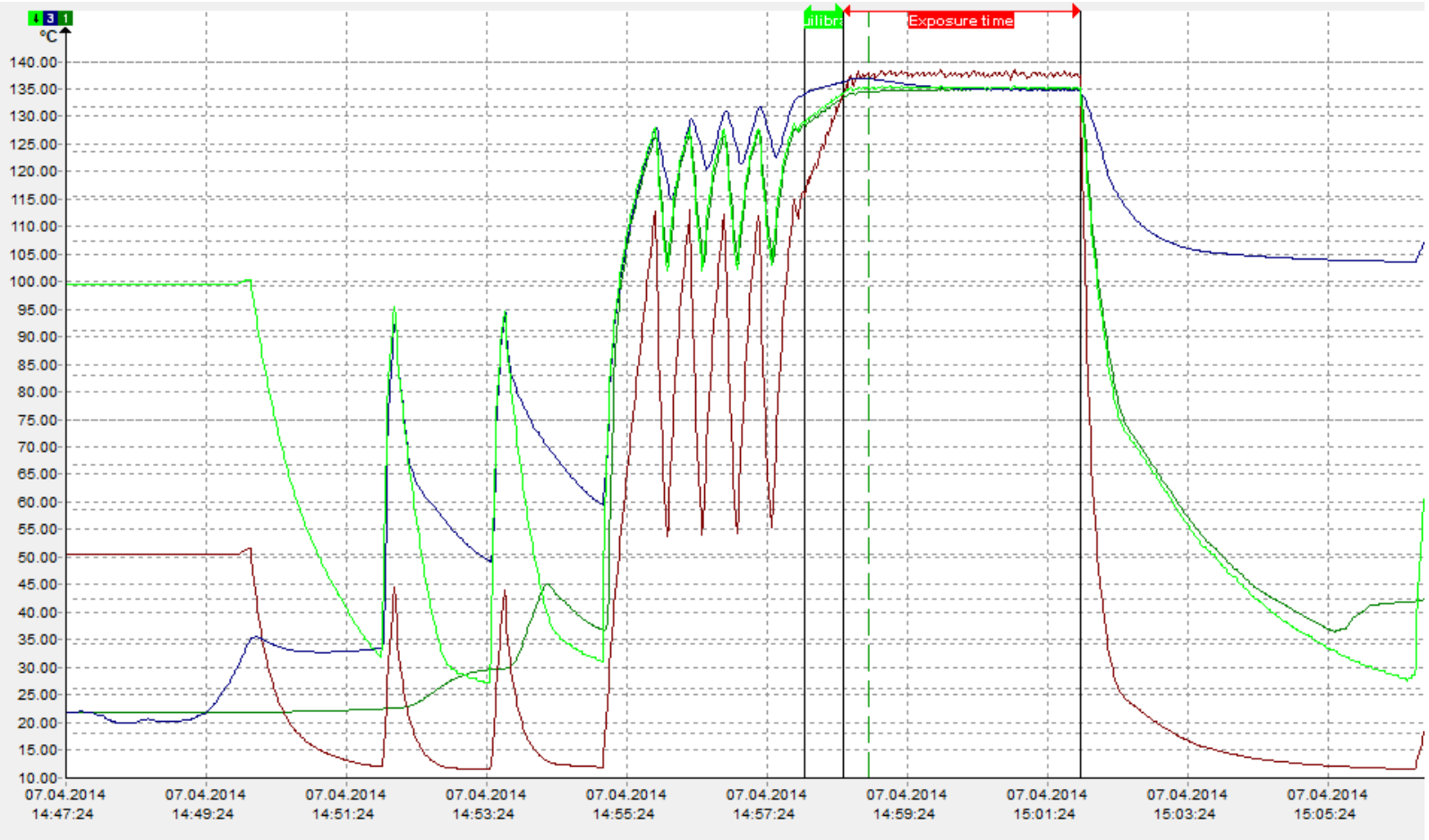
Qualification Phase 資格階段 - PQ

Bowie Dick-test 鮑伊迪克測試

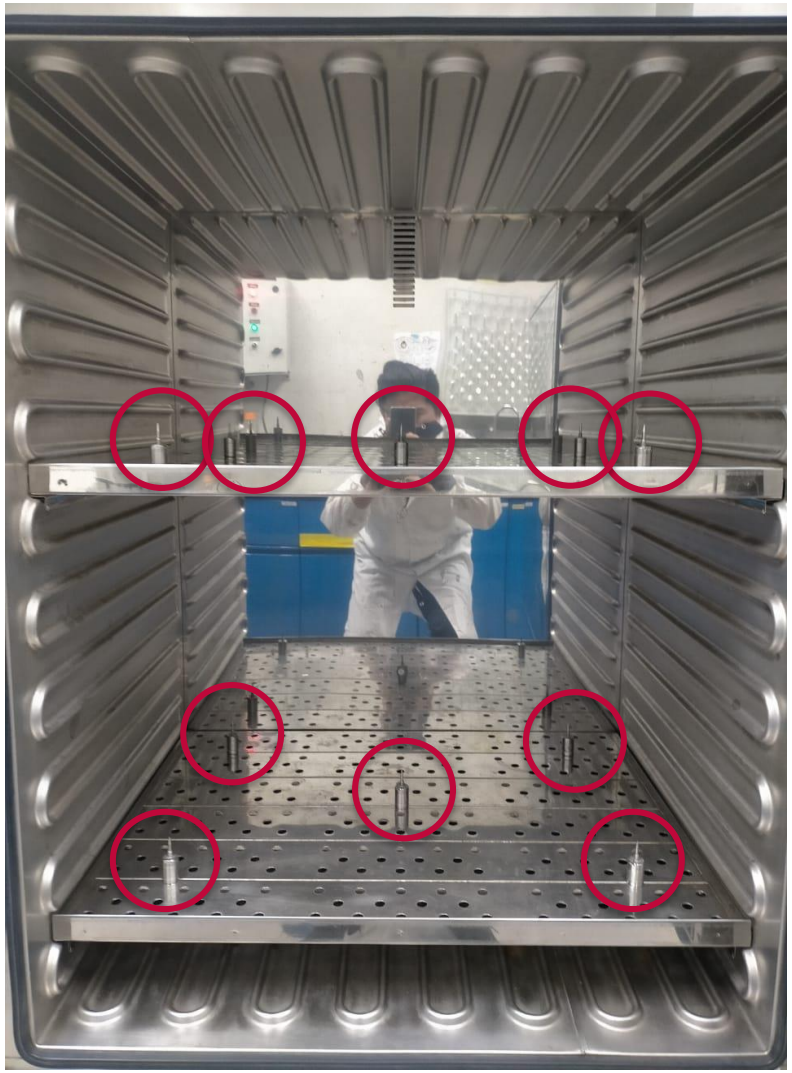


EBI 16 Bowie Dick Test Data Logger 鮑伊迪克測試記錄器

Electronic Bowie Dick Test according to DIN EN ISO 11140-4 符合 DIN EN ISO 11140-4 的電子鮑伊迪克測試

Qualification Phase 資格階段- PQ

Empty chamber profile 空腔輪廓



Goal is to map the autoclave to find possible cold spots
目標是測繪高壓釜以找到可能的冷點

Ebro Solutions 解決方案

- EBI 12 / EBI 11
- Temperature –data logger 溫度記錄器

Moist Heat Sterilization Validation 濕熱滅菌驗證

3 successful validation runs Thermometric check with full loading 3 次成功的運行滿載的溫度檢查驗證

- One probe attached to the Primary Reference 一個探頭連接到主要參考
- One probe attached or near the RTD - Controller 一個探頭連接或靠近標準件 - 控制器
- Two probes in containers filled with the testing medium 兩個探針置於裝有測試介質的容器中的
- A minimum of 3 probes each located in separate areas of each crate or tray 至少 3 個探頭，每個探頭位於每個板條箱或託盤的不同區域
- Initial Temperature and Data Collection Points初始溫度和數據採集點
- A schematic drawing to show the placement of all probes 顯示所有探頭位置的示意圖
- Defined loading patterns 定義的裝載模式

Ebro Solutions 解決方案

- EBI 12 / EBI 11
- Temperature – Pressure data logger 溫度-壓力記錄器

Reaching the sterilization conditions 達到滅菌條件

Recommended minimum number of temperature test locations (sensors)
Base: about 12 Measuring points/1000 l usable volume.
建議的最小溫度測試位置（傳感器）數量 基礎：大約 12 個測量點/1000 公升可用體積。

Capacity in liters 容量（公升）	Number of temperature Test locations (sensors) 溫度測試位置（傳感器）的數量
至 240	7
至 540	9
至1100	11

For sterilizers that do not comply with DIN EN 285 or for special Sterilization processes or configurations a higher number of sensors may be required. 對於不符合 DIN EN 285 的滅菌器或特殊滅菌過程或配置，可能需要更多數量的傳感器。

Reaching the sterilization conditions 達到滅菌條件

The existence of saturated steam in the usable area and within the loading can be considered as reached, **if all temperatures measured** in the usable area and within the loading during the hold time:如果在保持時間內在可用區域和裝載內測量到的所有溫度，則可以認為在可用區域和裝載內存在飽和蒸汽：

- are not below the sterilization temperature 不低於滅菌溫度
- are not more than 3K (large sterilizer and small since 2016)不超過 3K（自 2016 年以來大型滅菌器和小型）
- do not diverge by more than 2K 偏差不要超過 2K
- equilibration time 15 s to 800 liter, 30 s for larger sterilizers平衡時間 15 秒至 800 公升，大型滅菌器為 30 秒
- minimum hold times 121 °C for 15 min; 126 °C for 10 min; 134 °C for 3 min 最短保持時間 121 °C 保持 15 分鐘； 126°C 10 分鐘； 134°C 3 分鐘
- F_0-Value minimum 15 min F0 值至少 15 分鐘

The saturated steam temperature that is calculated with the measured pressure is to be considered as measured temperature. 以測量壓力計算的飽和蒸汽溫度作為測量溫度。

Measuring values outside the tolerances 測量值超出公差

What measures need to be taken in case the results to not correspond to the specifications?如果結果不符合規範，需要採取哪些措施？

1. Check if the loading is correct? 檢查裝載是否正確？
2. Positioning of the measuring sensors 測量傳感器的定位
3. Repeated calibration of the measuring system測量系統的重複校準
4. Adjust process parameters by manufacturer or service company (e.g. confining / chamber pressure, pressure period)由製造商或服務公司調整流程參數（如圍壓/腔壓、壓力週期）
5. Alternative medical products? (materials, construction)替代醫療產品？（材料、結構）

Depyrogenation去熱原

Batch Hot Air Ovens 批次熱風烘箱

- The glass containers are loaded into batch ovens and then sterilized generally 2-6 hours depending on the temperature.將玻璃容器裝入批次烘箱，然後根據溫度進行消毒，一般需要 2-6 小時。
- Batch ovens typically require 12 to 24 measuring points depending on size.批次烘箱通常需要 12 到 24 個測量點，具體取決於尺寸。
- Use of the EBI TIB Thermal Insulation Box is necessary when using either the EBI 12-T22X or the EBI 12-T421.使用 EBI 12-T22X 或 EBI 12-T421 時，必須使用 EBI TIB 隔熱箱。
- The EBI 40 is a practical alternative for the Batch Ovens EBI 40 是批次烘箱的實用替代品

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Depyrogenation去熱原

Continuous Hot Air Tunnels 連續熱風隧道

- The glass containers are run via conveyors through the tunnel, typically at 300˚C or higher, from 15 to 30 minutes.玻璃容器通過傳送帶通過隧道，通常在 300°C 或更高溫度下運行 15 到 30 分鐘。
- Tunnels usually require 3 rows of 5 monitoring points about 3 feet apart, totally 15 measuring points 隧道通常需要3排5個相距約3英尺的監測點，共15個測量點
- EBI 12-T421 is recommended with the EBI TIB Thermal Insulation Box. 建議將 EBI 12-T421 與 EBI TIB 隔熱箱一起使用。

Pharma / Healthcare Applications製藥/醫療保健應用

Ovens / Vacuum Ovens 烘箱/真空烘箱

- Vacuum Ovens are used for drying heat sensitive materials such as powder to extract moisture真空烘箱用於乾燥熱敏材料例如粉末以粹取水分
- The vacuum oven enables drying treatment at a lower temperature for specimens that cannot be treated by conventional high-temperature drying.• 真空烘箱可以在較低溫度下對常規高溫乾燥無法處理的樣品進行乾燥處理。
- Validation is necessary to avoid too fast, too slow or unevenly drying of the goods必須進行驗證以避免貨物太快、太慢或乾燥不均勻
- Typically, temperature testing, evaporation, drying 通常，溫度測試、蒸發、乾燥

EtO Sterilization 環氧乙烷滅菌

Preconditioning預處理 – expose product to “tropical” environment for at least 12 hours - 55°C/70% RH. 將產品暴露在“熱帶”環境中至少 12 小時 - 55°C/70% RH。

Exposure暴露 – pull vacuum and expose to gas usually for 4 to 8 hours (varies per product and must be validated).抽真空並暴露在氣體中通常 4 到 8 小時（因產品而異，必須經過驗證）。

Post conditioning 後調節– air out all the EtO gas. 8-12 hours 將所有 EtO 氣體排出。8-12小時

! Annex 1: Sterilization with ethylene oxide 附件 1：環氧乙烷滅菌

This method should only be used when **no other method is practicable**. 只有在沒有其他方法可行時才應使用此方法。

Ebro Solutions解決方案

EBI 12 loggers 記錄器

- Temperature + RH data loggers 溫度+相對濕度數據記錄儀
- Temperature溫度 – Pressure壓力 – RH% 相對濕度(Atex certificated 防爆證明)

Survey

Which information and reports are useful for your process evaluations?哪些信息和報告對您的過程評估有用？

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2. Brief Introduction 簡介
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6. Discussion and wishes 討論和願望

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Evaluation of a steam sterilization process with the Winlog.validation
使用 Winlog.validation 評估蒸汽滅菌過程

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Requirements for the measuring technology as per EN 285 / ISO 17665根據 EN 285 / ISO 17665 對測量技術的要求

Sensors for temperature measurement 溫度測量傳感器

➢ Sensor diameter 傳感器直徑	< Ø 2 mm (3,1mm²)
➢ Sensor length 傳感器長度	given by application
➢ Range 範圍	0 … 140°C
➢ Accuracy 精準度	± 0,25K

Sensors for pressure measurement 壓力測量傳感器

➢ Range 範圍	< 50 … 4000mbar (< 5kPa …400kPa)
➢ Accuracy 精準度	± 20 mbar at 25°C
➢ Connector 連接器	(± 2 kPa at 25° C) no connector required (chamber pressure)無需連接器（腔室壓力）

Validation of the thermal process in sterilizers 驗證滅菌器中的熱過程

Suitable temperature logger 合適的溫度記錄器

EBI 12 temperature logger with 1.2 to 1.5 mm flex probes radial and axial
EBI 12 溫度記錄器，帶有 1.2 至 1.5 mm 徑向和軸向柔性探頭

EBI 11 temperature logger with 2 mm rigid probes (diameter 1.95 mm)
EBI 11 溫度記錄器，帶 2 mm 剛性探頭（直徑 1.95 毫米）

Suitable pressure logger 合適的壓力記錄器

EBI 12 pressure logger with 1.5 mm flex probe with luerlock
EBI 12 壓力記錄儀，帶 1.5 mm 柔性探頭，帶魯爾鎖

EBI 11 pressure logger with and without luerlock
EBI 11 壓力記錄器，帶和不帶魯爾鎖

Requirements for the validation software 驗證軟體的要求

CERTIFICATE

No. Z2 16 08 96885 001

Holder of Certificate: Xylem Analytics Germany GmbH
Peringerstr. 10
85055 Ingolstadt
GERMANY

Production Facility(ies): 96885

Certification Mark:

Product: Application Software

Model(s): Data logger systems: Winlog.validation, Winlog.med

Parameters: Data logger system to read and process data for routine control and validation applications in the field of medicine, pharmacy and food

Tested according to: TÜV SÜD Product Service testing principles based on
- ISO/IEC 25051:2014 (Functionality)
- DIN EN ISO 9241-110:2008 (Usability)
- FDA 21 CFR Part 11

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.: 028-713084780-000

Valid until: 2017-08-31

Date, 2016-08-11 (Siegfried Muckenschnabl)

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Evaluation software 評估軟件 Winlog. Validation

Software for validating and steam sterilizer processes as per DIN EN 15883, EN ISO 17665 and per DIN 58929
根據 DIN EN 15883、EN ISO 17665 和 DIN 58929 驗證和蒸汽滅菌器過程的軟件

FDA 21 CFR Part 11 compliant software 符合 FDA 21 CFR Part 11 的軟體

Validated by independent company like TÜV
經 TÜV 等獨立公司驗證

Calibration certificates 校準證書

IQ, OQ documentation 確效文件

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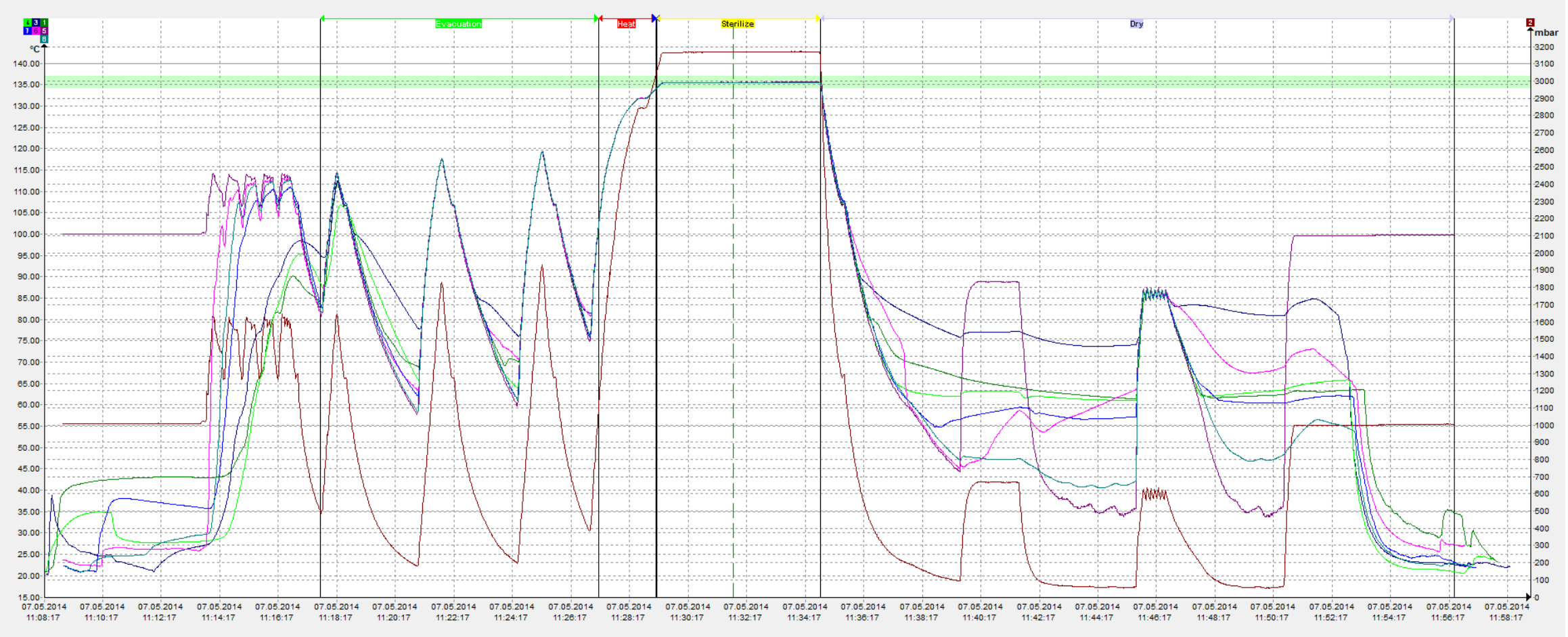
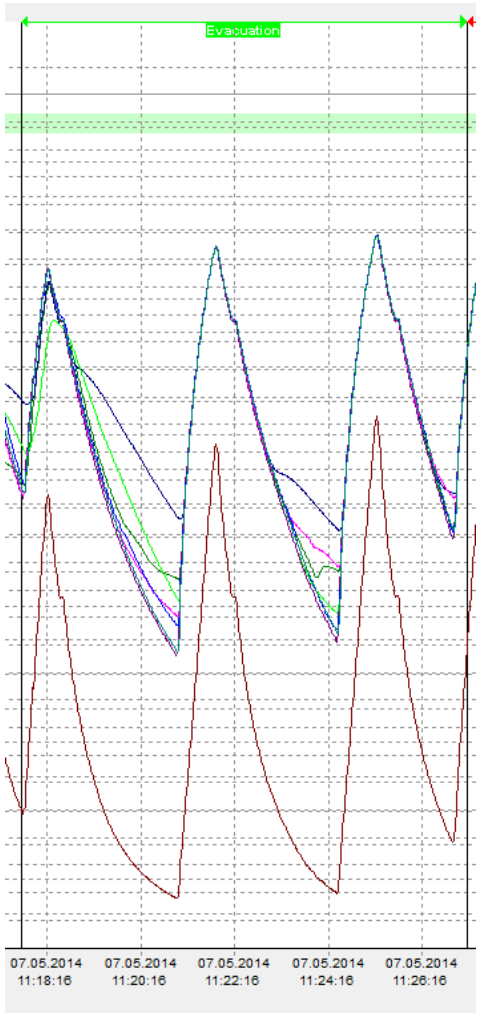
Validation evaluation 驗證評估

What would a typical steam sterilization report look like? 典型的蒸汽滅菌報告是什麼樣的？

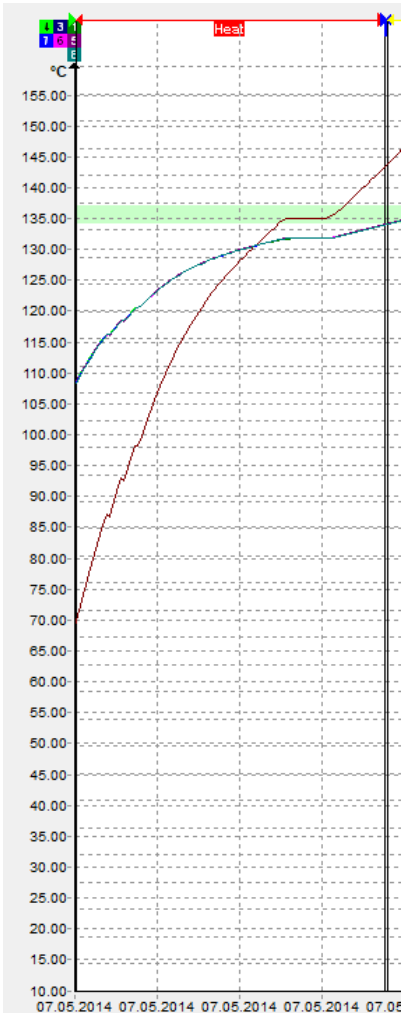


Validation evaluation 驗證評估

疏空 階段



加熱階段



F_0-value F0值

飽和蒸汽滅菌過程的 F0 值是在 121ºC 的溫度下，該過程以等效時間（以分鐘為單位）表示的致死率，該過程以 Z 值為 10 的微生物為基準，將其傳遞到其最終容器中的產品。

$$F0 = \Delta t \sum 10^{\frac{T-121.1}{z}}$$

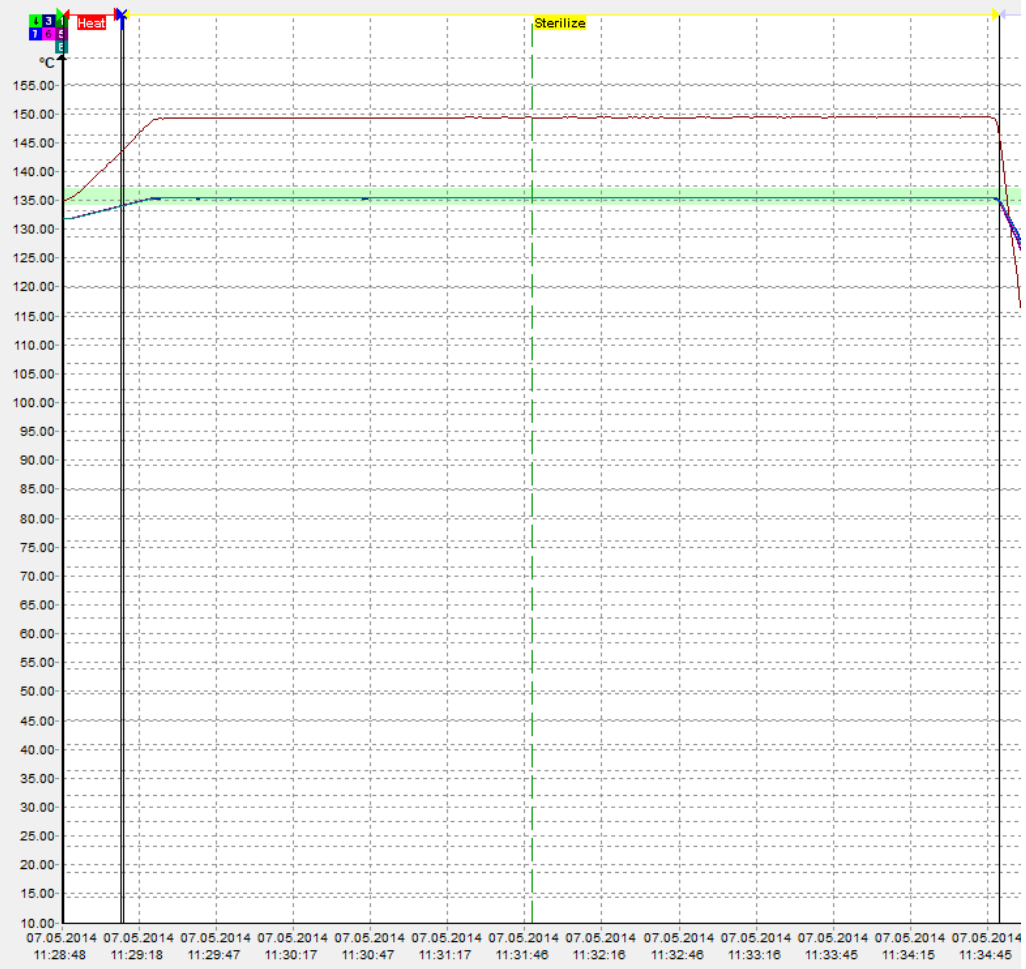
Δt – the time interval between two temperature readings 兩次溫度讀數之間的時間間隔

T – the temperature at time t of the product under sterilization 滅菌產品在時間 t 的溫度

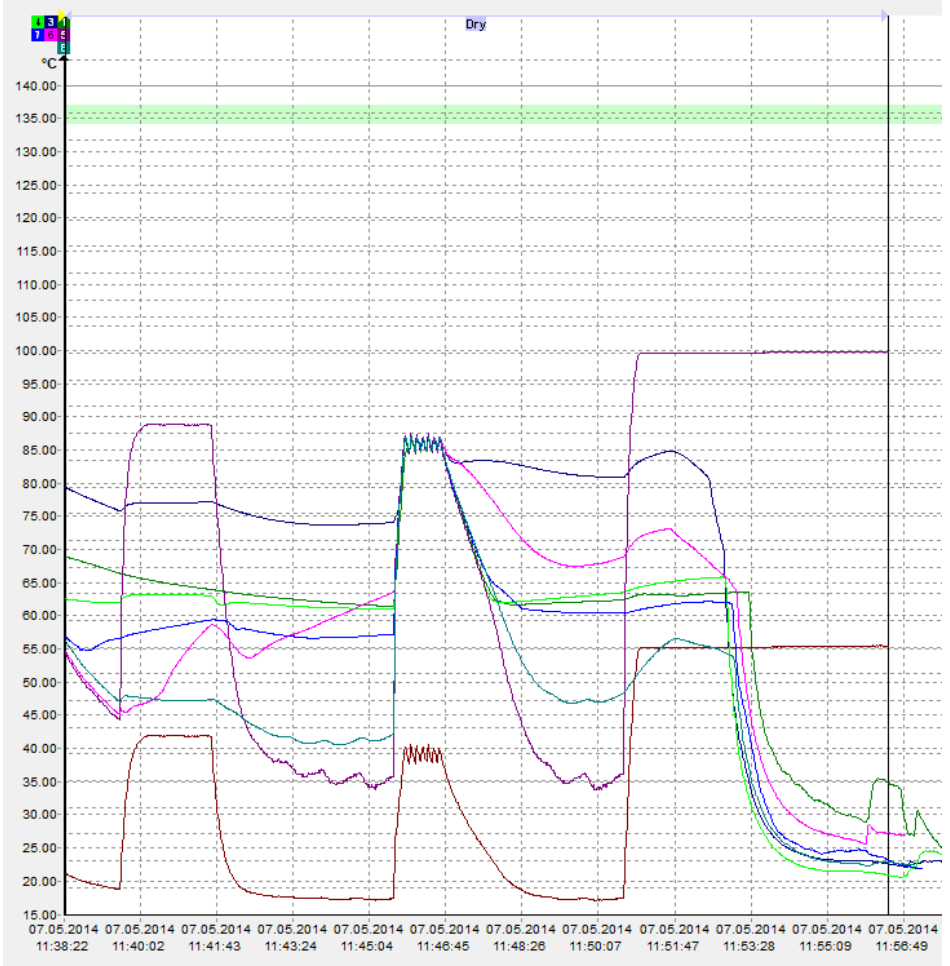
z – temperature coefficient (assumed as 10° C) 溫度係數（假設為 10°C）

Validation evaluation 驗證評估

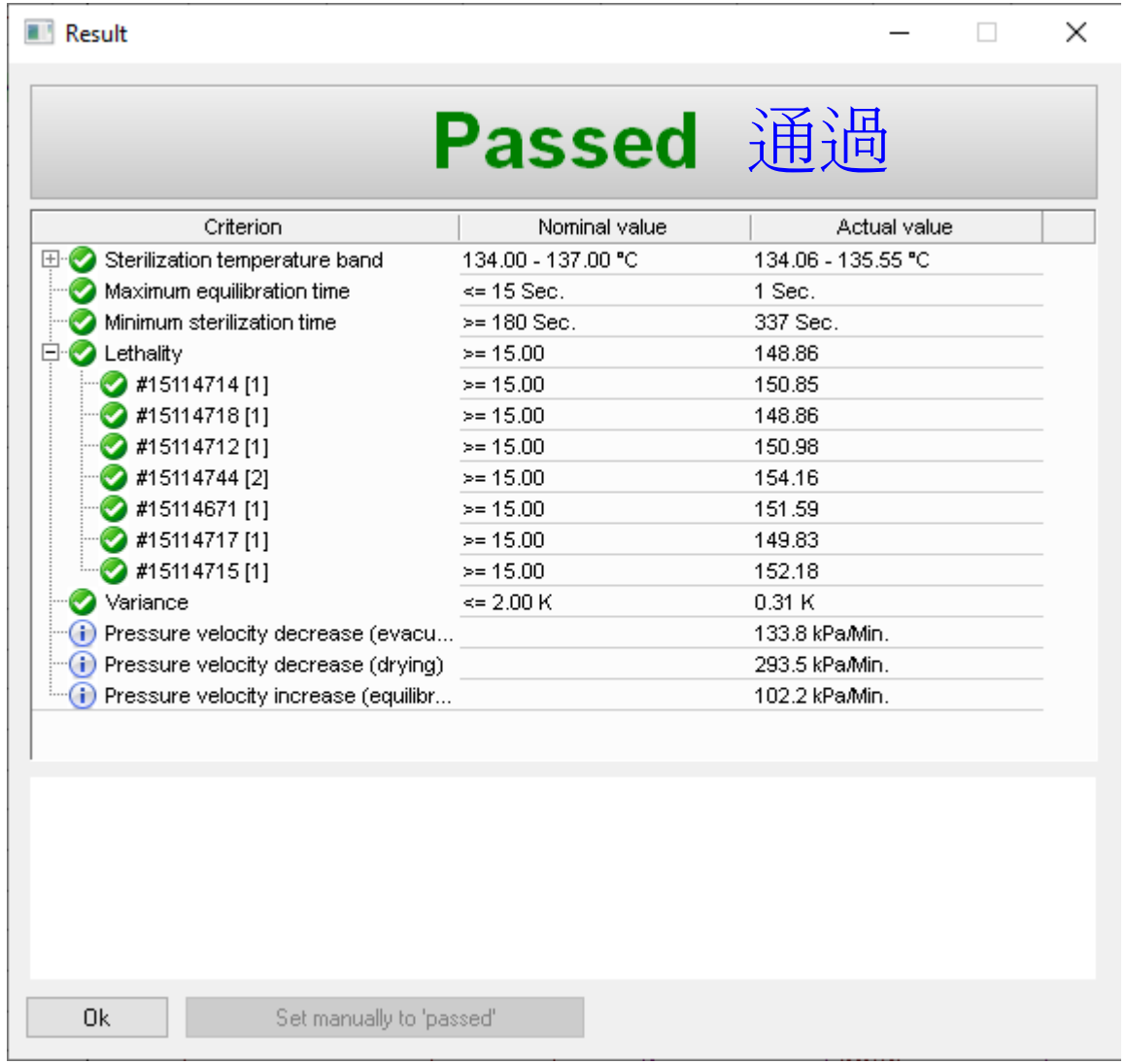
滅菌階段



乾燥階段



Validation evaluation 驗證評估



Further questions? Don’t hesitate to contact me under: 進一步的問題？請隨時通過以下方式與我聯繫：

0049-8419547837

sebastian.schwarz@xylem.com

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7 Discussion & Wishes

討論和願望

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Next Webinar下一個網絡研討會:

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