METTLER TOLEDO

Smart sensor support you to define quality

MTTW-IND
Weighing Solution
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Typical Production Challenges

如何確保製造過程的品質？

如何確保批次生產的可追溯性和資料完整性？

如何提高廠內佈局的營運效率與整合度？

如何優化或減少為了遵守cGMP法規多出的成本和時間？

Weighing Sensors in Bioprocessing

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Weight serves a critical process parameter or quality attribute in many Up- and Downstream unit operations

In Media/Buffer Preparation

- Precise Pre-weighing of ingredients
- Mixing and blending in tanks

Container filling

- Consistent fill weight of vials, syringes, IV bags
- Complete documentation

Up-stream Processing - Fermentation

- Control and measurement of feeds like media, buffer, antifoaming agents
- Measure reactor content

Downstream Processing

- Automated dosing of reagents
- Accurate Formulations

3 Levers for Quality, Efficiency and Compliance

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我們可以幫助您提高安全和危險區域生物製藥營運的產能

Designed for Accuracy

隨著準確性和可重複性的提高，OOS 批次數量顯著下降。

Automation Transactions for Error Free Production

工作流程和文件自動化程度的提高可減少操作員錯誤 - 同時考慮資料完整性。

Continuous High Performance

校正和例行測試確保設備在預期的製程允收範圍內運作； 狀態監測可以告知代價高昂的錯誤

Compliance and requirement

USP

⟨41⟩ ▪BALANCES

Change to read:

▪This chapter states the requirements for balances used for materials that must be accurately weighed (see *General Notices, 8.20*). Unless otherwise specified, when substances must be "accurately weighed", the weighing shall be performed using a balance that is calibrated over the operating range and meets the requirements defined for repeatability and accuracy. For balances used for other applications, the balance repeatability and accuracy should be commensurate with the requirements for its use.

For discussion of the theoretical basis of these requirements, see general information chapter *Weighing on an Analytical Balance* ⟨1251⟩, which may be a helpful—but not mandatory—resource.

REPEATABILITY

Repeatability is assessed by weighing one test weight NLT 10 times. [NOTE—The test weight must be within the balance's operating range, but the weight need not be cali-

中華藥典

（10005）天平

本法適用於須精確稱重材料之天平。除非另有定義，
物質須被精確稱重，應使用於該稱重範圍內校正且符
可重複性及準確度要求之天平。於其他應用時，天平
可重複性及準確度須符合該應用需要。

一、可重複性

可重複性試驗乃為針對同一試驗砝碼進行不少於10次之稱重。（注意—所用試驗砝碼之重量須在該天平之操作範圍，但無須校正。因為在天平稱量能力內，標準偏差實際上不受檢品質量影響，若不易操作，可無需使用最小砝碼進行試驗。）

若2乘以稱量值之標準偏差再除以最小稱樣重（即使用於該天平之最小淨重）不超過0.10%，則此可重複性試驗合格。例如標準偏差為0.41 d（d為最小刻度），2 x 0.41 d/ 最小稱樣重所得值若不超過0.10%，則可重複性應為合格。

二、準確度

取一適當試驗砝碼，以天平稱其重量，若所稱得重

EP

CALIBRATION

Calibration is part of balance qualification and is performed by the user or by a suitable competent body. Its aim is to establish traceability of measurement results to SI units (metrological traceability). The calibration results include measurement uncertainty and are documented in a calibration certificate. To ensure traceability, it is recommended to perform calibration before any maintenance operation is carried out on the balance that significantly alters its measurement performance. 'Significant' operations include repairs, transfer of the balance to another location or mechanical adjustment of one or more weighing parameters. The balance must be re-calibrated after significant operations. Re-calibration is not necessary after less significant operations, which include levelling the balance or adjustments using built-in weights.

PERFORMANCE CHECKS

Performance checks are carried out to evaluate the random and systematic error of a balance; they consist of measuring precision and accuracy respectively and comparing the results obtained to pre-defined acceptance criteria. Balances are considered suitable if none of these errors exceeds 0.10 per cent.

In practice, performance checks focus on the two weighing parameters that most significantly affect the performance of the instrument, i.e. repeatability, for precision, and sensitivity as the main component of the accuracy of the balance.

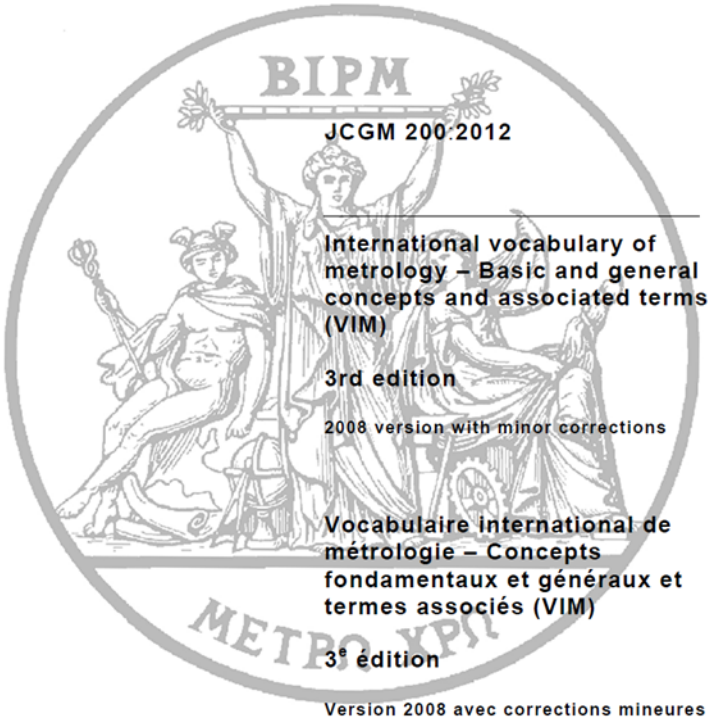
Accuracy is also impacted by two other parameters: eccentricity and linearity. A quadratic addition of the errors of these individual parameters, rather than a more conservative linear addition, provides a more realistic approach to the assessment of the accuracy of the balance because the three individual parameters are known to be largely independent of each other, and it is considered unlikely that they will occur simultaneously and have the same algebraic sign. Therefore, the acceptance criterion for each individual parameter can be set at 0.05 per cent, i.e. half the overall accuracy tolerance of 0.10 per cent. While accuracy is impacted by all three parameters, the impact of eccentricity and linearity is typically less than that of sensitivity. Hence,

Calibration of Instruments

"Operation that, under specified conditions, in a first step, establishes a relation between the quantity values **with measurement uncertainties** provided by measurement standards and corresponding indications with **associated measurement uncertainties** and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication."

International Vocabulary Of Basic And General Terms In Metrology (VIM)
JCGM 200:2012, item 2.39

In simple words: During calibration, the measurement uncertainty of the instrument is determined.



顯示器精度=磅秤精度？準？

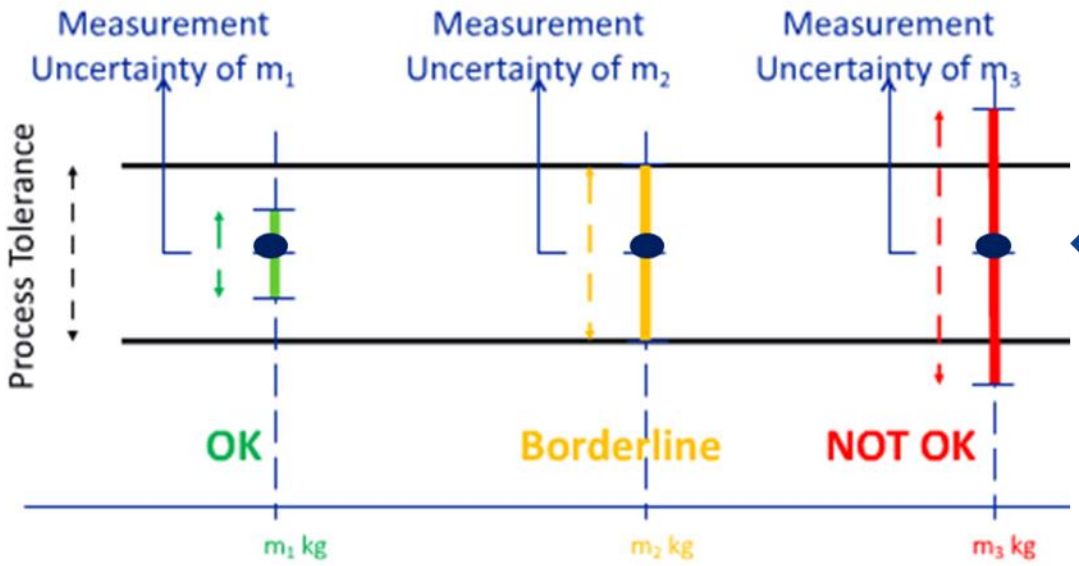
顯示器:你以為的精度=0.01 kg

荷重元:真正的精度來源=? kg

✓ 顯示精度	配合顯示器解析度，最高約1/2,000,000
✓ 有效精度 d	確定供應商的原廠型錄中的可讀數值
✓ 認證精度 e	OIML認證後的能力，基本為3000e

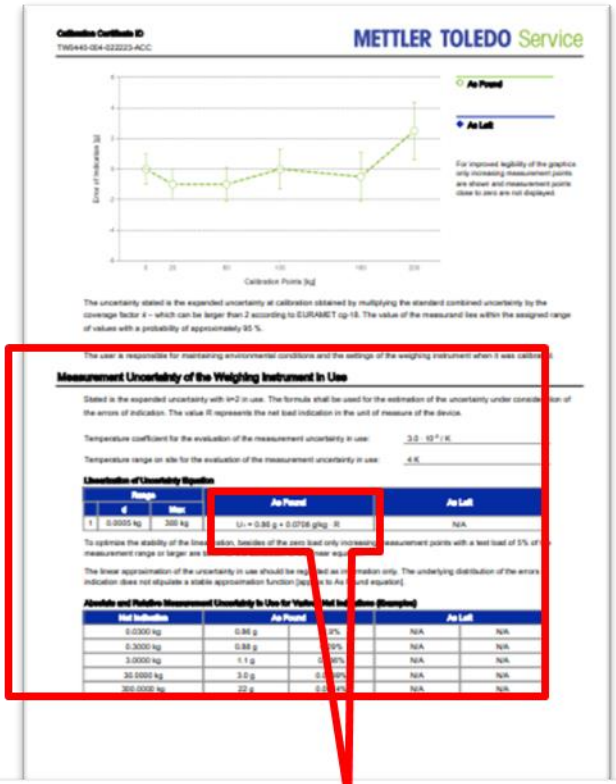
量測不確定度:除了誤差error之外的風險

當顯示器與荷重元完成匹配，
此時量測不確定度的表現方式為 (123.56 ± ?) kg



配合製程允收誤差，
才能判斷合理結果

校正報告(Calibration Certificate)中的量測不確定度



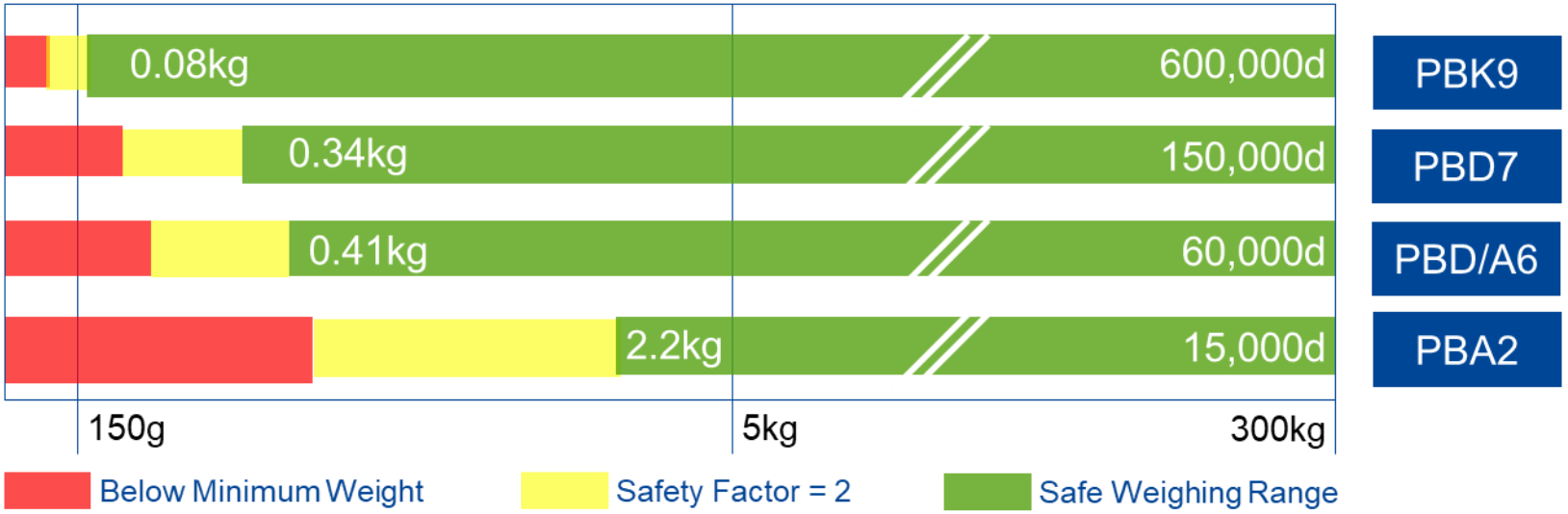
Measurement Uncertainty of the Weighing Instrument in Use

As Found	200 kg ± 15g

$$U_1 = 0.86\ g + 0.0708\ g/kg \cdot R$$

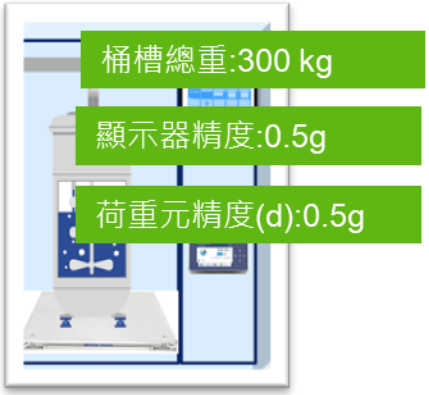
若1%要求下，不同精度磅秤選用時的安全係數

當秤重的相對誤差需控制在1%時，磅秤最小秤重量與安全係數的關係如下:

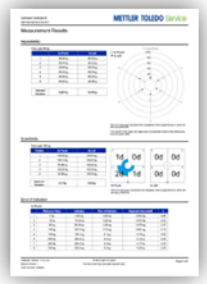


✓ 使用PBK9 (具600,000d有效精度)秤量時，最小秤重量>80g，才能有<1%準確度的結果

準確選型



GWP Verification
最小稱重量(1%)報告
定義與日常檢查建議



原廠校正報告ACC
含不確定度的追溯報告

METTLER TOLEDO Solutions

1 Selection

GWP® Recommendation

2 Installation

3Q Pacs

3 Calibration & Testing

ACC (Uncertainty)

GWP® Verification

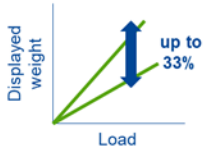
Annex Agenda

除了準確選型，傳統稱重系統中隱藏的風險:

磅秤/天平應用

桶槽應用

溫度的累積變化，
如位置受到輻射熱影響或溫控不佳導致

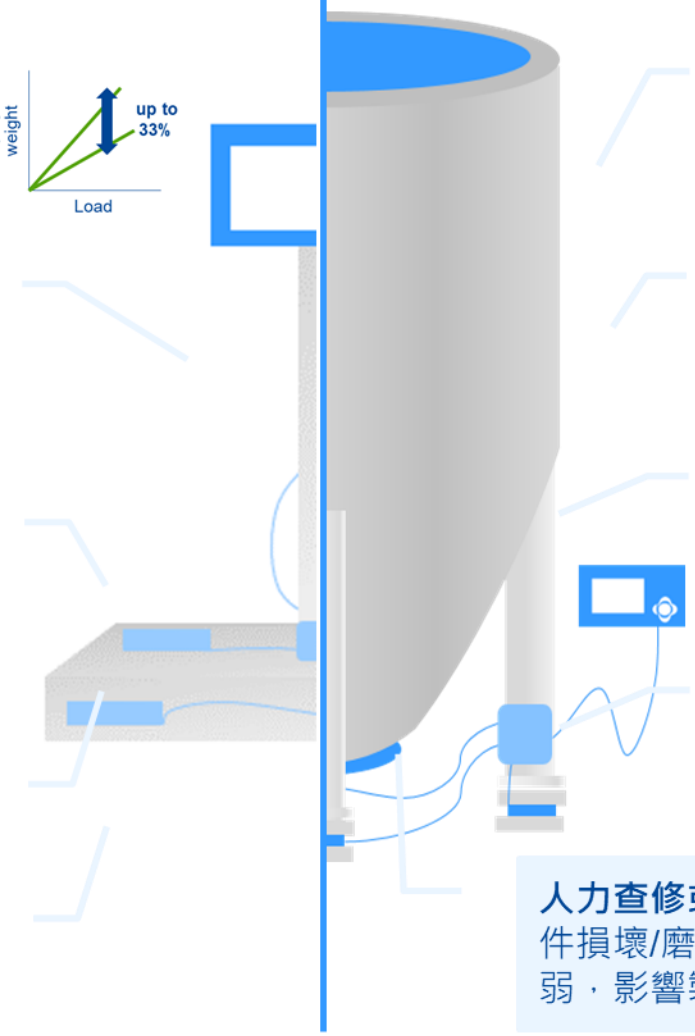


傳統「類比」的荷重元與磅秤，因接線盒，或低估了或無法及時偵測到故障

磅秤的**靈敏度**容易受到周圍環境的制動器、馬達、和幫浦的磁力影響，導致秤重結果的衰退

物料的轉移誤差與交叉汙染問題

充填系統的準確度與環境匹配的取捨



安裝不正確，或系統使用非工業專用組件，造成安全顧慮

機構干涉或變形，導致結果無法即時回饋或錯誤

沒有校正或不適當的校正，低估潛在製程風險與增加未來查核壓力

危險區秤重，不犧牲功能與準確的情況下，如何合規秤重

人力查修或維護不足–長期使用造成的組件損壞/磨損、電纜損壞、進水、基礎薄弱，影響製程結果的準確

Smart sensor & Precise and Self-management

PBK/PFK特點:

- ✓符合3 kg/5 mg到 3 t/5 g秤重需求
- ✓有效精度最高可達1/750,000，業界之最
- ✓全機不銹鋼，防爆一區/二區，TS
- ✓不停機，內砝碼自動校準，異常警報
- ✓無需顯示器與PLC連線，可程序化與監控過程
- ✓多重濾波，高度適應製程環境

IP67 IP68 OIML cULus IEC IECEx Ex FM APPROVED GMP

PBK9

The Monobloc load cell at the core of the PBK9 weighing platform guarantees the highest precision and reliability. The robust load-cell housing features integrated overload protection and durable mechanical interfaces for many years of intensive use.

PB/FK

Smart sensor & Uptime and Condition Monitoring

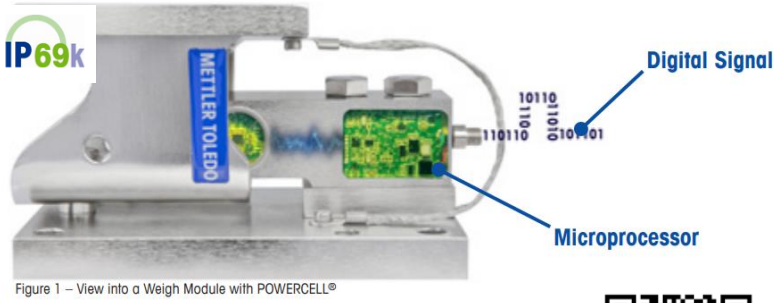
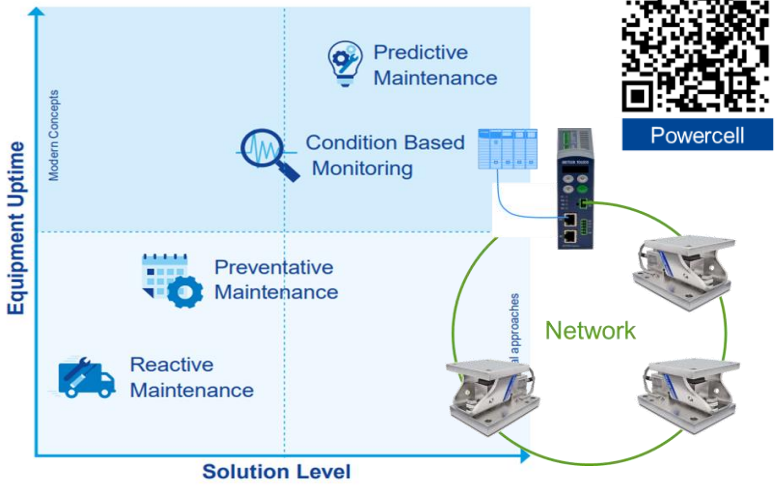


Figure 1 – View into a Weigh Module with POWERCELL®



Powercell 特點:

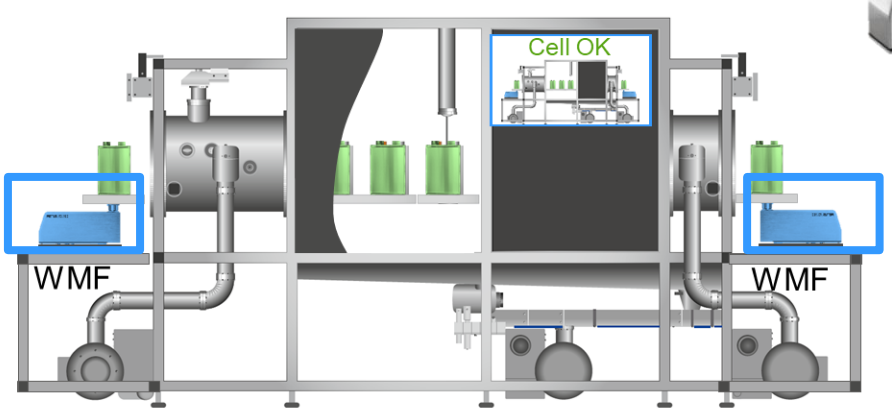
- ✓內建數位晶片，最高C10，免集線盒
- ✓不易受EMC與溫度干擾
- ✓焊封保護等級高達 IP68/IP69K
- ✓異常警報，顯示器提示查修位置，
- ✓異常發生時，發送EMAIL通知遠端
- ✓異常可直接啟動 "Run flat"繼續運轉
- ✓換修後，免重新校正，持續維運

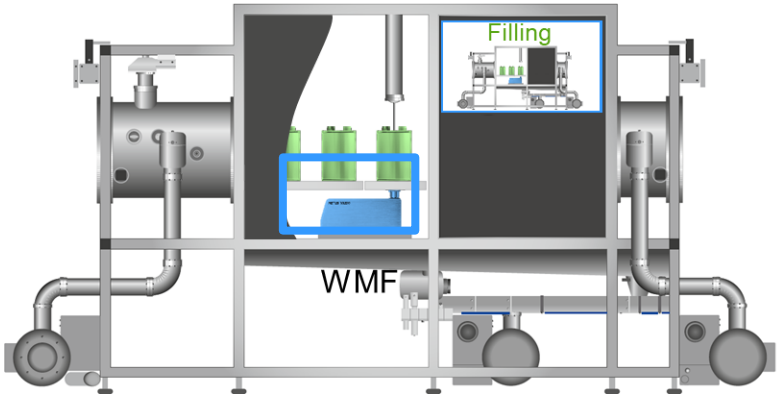
Smart sensor & Flexibility

Small Volume Filling and Dispensing

1. Accurate sensor confirms correct filling

- Feedback to filling device
- Flexibility in cell designs
- No contact with electrolyte
- Consistent cell quality





2. Weight-based filling

- Highest precision with best measurement technology
- Constant adjustment of filler
- Self-calibration and adjustment
- Consistent cell quality

WMF-High precision

- ✓ 小空間並排秤重
- ✓ 支持手套箱消毒
- ✓ 內法碼校準
- ✓ 200g/0.1mg
- ✓ 25 mm width
- ✓ 支持PLC/PC連線
- ✓ 容易安裝
- ✓ 在地技術支持
- ✓ 支持過載保護
- ✓ POE

Smart sensor in Zone1 & Zone2

防爆秤重全方案

IND256X

Terminal

PFD7

- ✓適用於 一區/二區防爆(TS)的稱重方案
- ✓IND256x用於Zone1
  - -支持移動秤重/WIFI數據交換/電池供電
- ✓PFD用於Zone2
  - -60,000有效精度
  - -具有中心加載功能
  - -過載和震動時立即發出警報和警告
  - -平日監控並報告秤的健康狀況
- ✓PFK/PBK用於Zone1/Zone2
  - -最高750,000有效精度
  - -3kg-3000kg使用，可彈性搭配顯示器
- ✓各種顯示器用於Zone1/Zone2
  - -支持I/O 或各種介面的 PLC
  - -與我們的軟件解決方案兼容

TS in Taiwan-TD0404DE

危險區域稱重

符合TS認證防爆安全標示

您對安全的要求，我們已為您做好準備

TD0404DE

依據中華民國職業安全衛生法，爆炸危險性作業場所之電氣設備應符合國家標準，並於產品上張貼合格的安全標示。

請立即下載我們的專業白皮書，教您認識CNS防爆標準與國際防爆法規，以及電氣設備相關型式認證制度。

下載白皮書
www.mt.com/ts_whitepaper

IND780
防爆終端顯示器

IND560X
防爆終端顯示器

ICS466X
防爆磅秤

IND226X
防爆終端顯示器

IND570XX
防爆終端顯示器

IND131/331XX
防爆終端顯示器

AJB641SX
防爆接線盒

ACM200/500
防爆中繼器

SWB505
(0745A/MTB)
防爆秤重模組

SWC415PinM
(SLC611/0782)
防爆秤重模組

SWC515PinM
(SLC611/0782)
防爆秤重模組

SWC615PM
(SLC611D/SLC820)
防爆秤重模組

External
NiMH Ex Battery
防爆電池

APS768X
/APS500
防爆電源供應器

BBA256X
防爆磅秤

MPXI/MPGI
防爆磅秤

Smart Terminal & Local Audit trail

NEW and BETTER

Enclosure & Power
- ✓ Washdown design
- ✓ Stainless Steel (ICS4_9)
- ✓ Power: VAC

Multi Tool Applications
- ✓ Simple Weighing
- ✓ Counting
- ✓ Manual Filling
- ✓ Totalization
- ✓ Over/Under Checkweighing
- ✓ Animal Weighing

Weighing
- ✓ Analog Scale
- ✓ Precision Scale

Protocols
- ✓ Remote Access
- ✓ SICS server
- ✓ SICS Continuous
- ✓ Input template
- ✓ Toledo Continuous - W
- ✓ Toledo Continuous - C
- ✓ Second Display AD-RS-M7
- ✓ Modbus TCP/Modbus RTU
- ✓ DigiTol
- ✓ Demand mode/Demand mode auto
- ✓ Remote Display
- ✓ Reference Balance (XPR, XSR)
- ✓ Transfer command
- ✓ Parameter server

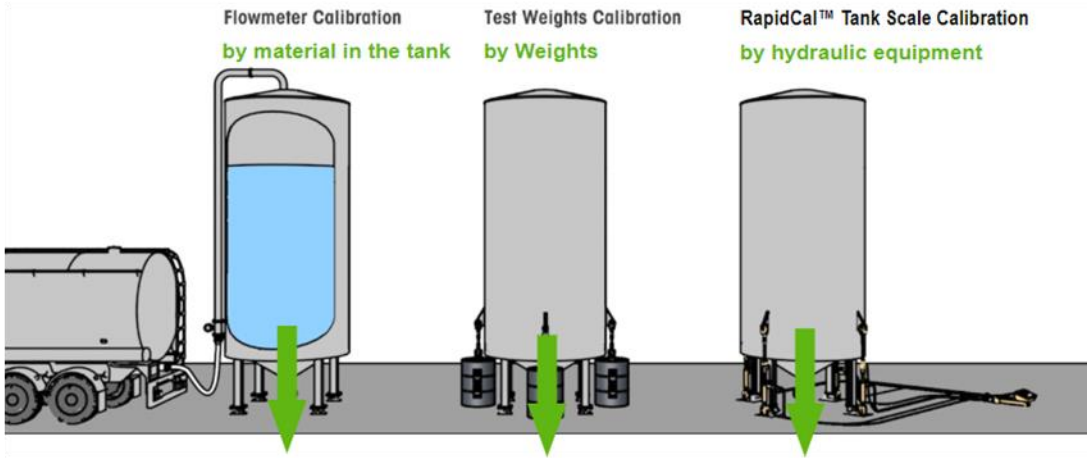
COM
- ✓ WiFi
- ✓ Ethernet
- ✓ RS232
- ✓ RS485
- ✓ USB OTG (Host & Device)
- ✓ DIO

Usability
- ✓ 5" Rough Environment Touchscreen
- ✓ Intuitive user interface
- ✓ Basic tactile keys

Pharma/Food Specials
- ✓ Data integrity
- ✓ PSCP for Pharma

New solution in tank calibration

RapidCal



- Low Accuracy, 0.3% - 1%
- Requires material
- Risk of contamination
- Slow and Costly

- Accurate, 0.03%
- Not practical at high capacities
- Health & Safety concerns
- Slow and Costly

- Accuracy: 0.1%
- No contamination
- Requires anchors
- Much Faster

New Method of Tank calibration : RapidCal

- ✓ 快速、準確、省水、避免交叉污染
- ✓ 1t-32t的最新校正方案，具備可追溯性的文件

More Smart Solution

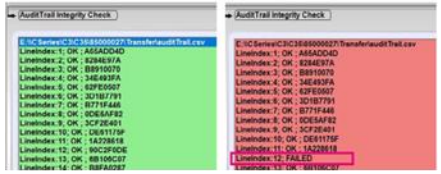
重量檢測機和金屬檢測機如何符合Audit trail

符合21CFR & Audit trail 報表產出

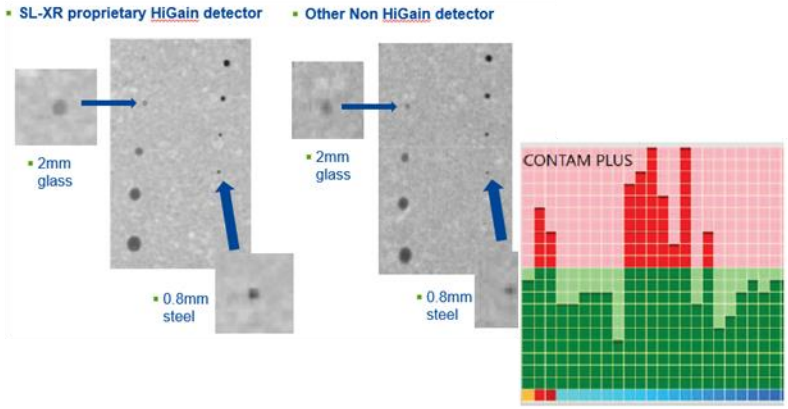
- **製藥報表內容**
  - 區間計數器讀數
  - 平均值和標準差
  - 特殊異常計數器讀數
  - 單個計數器讀數佔整個批次的百分比
  - 產品名
  - 訂單號
  - 批號
  - 分批號
  - 生產時間/日期和批次最終評估
  - 參數修改(舊值/新值，由誰修改)
- **通過 USB 導出**
- **通過共享文件夾（乙太網路）**
- **通過 OPC UA 協議（乙太網路）**
- **FreeWeigh.Net MT軟體(全設備兼容)**

Booster by MD

CW In pharma



X-Ray如何更安全並且資料可追朔



更安全並且資料可追朔

- **本機符合21CFR Part11 Audit trail**
- **設備配合軟體設計,產能數據精確?(OEE)**
  - 每日PVR測試報告
  - 剔除日誌(異常,汙染圖片留存)
  - 權限登入記錄
  - 警報和警告(電子郵件提醒)
  - 參數修改(舊值/新值，由誰修改)
- **設備配合軟體設計,提供可靠數據**
  - 汙染物確實剔除機制
  - 操作動作紀錄,避免數據失真
- **支援通訊平台,不限PLC或MES,ERP(OPC UA 協議)**
- **自動化及完整數據留存軟體**
  - 可通過 USB 導出
  - ProdX報表軟體(含SQL)
  - FreeWeigh.Net MT軟體(全設備兼容) -21CFR Part11 Audit trail

Why Xray

ProdX

線上純水量測稽核追朔方案

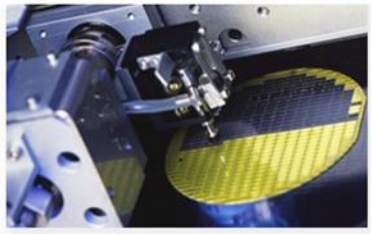
可歸屬性	• 誰產生資料？ • 誰（若有）修改了資料？ • 哪些系統/儀器產生了資料？
清晰性	• 資料必須為可讀/易讀 • 電子資料必須讓人類覺得「可讀」
同期性	• 必須在建立時記錄 • 不能稍後轉錄 • 無便利貼，不需要備註
原始性	• 所有資訊必須採用其建立時的原版格式，以保持準確性、完整性、內容及意義 • 紙本列印成品在技術上不具有「原始性」
準確性	• 記錄的資料必須準確，且需要由第二名人士驗證（在適當情況下） • 處於多個位置的資料必須彼此確認

多參數ALCOA+資料完整性

- 即時性數據量測，提供隨時可稽核的系統
  - 配備RecordLOC的M800 Water 2-CH 21CFR傳送器通過實施加密稽核存底，滿足ALCOA+對真實且未被修改資料的要求。
- 數據/時間戳審計追踪
  - 透過快速存取審核追蹤中的時間和資料資訊（ALCOA+、一致、同期、原始），使審核過程更加輕鬆
- 多參數資料完整性解決方案
  - 稽核存底會紀錄與TOC、電導率和/或臭氧有關的所有使用者介入與偏移情形，讓您對水系統更有信心

Record LOC

高精度的超純水量測方案

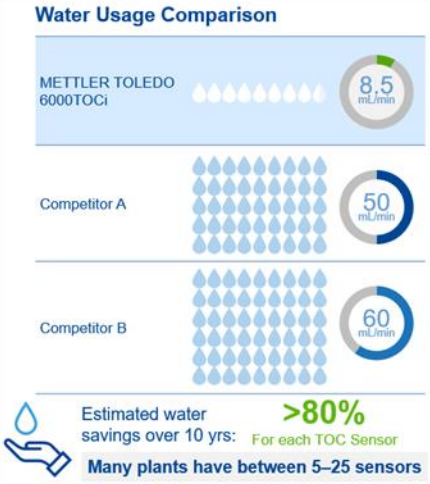


最大化半導體製造良率

METTLER TOLEDO純水導電度電極常數在全球範圍內受到半成品廠的信賴，可幫助維護其超高壓水系統，防止水系統問題對生產產量產生負面影響。

先進的測量電路提高了精度

UniCond系列在線水質導電率感測器採用先進的內建測量電路，提供卓越的精度並降低干擾風險。



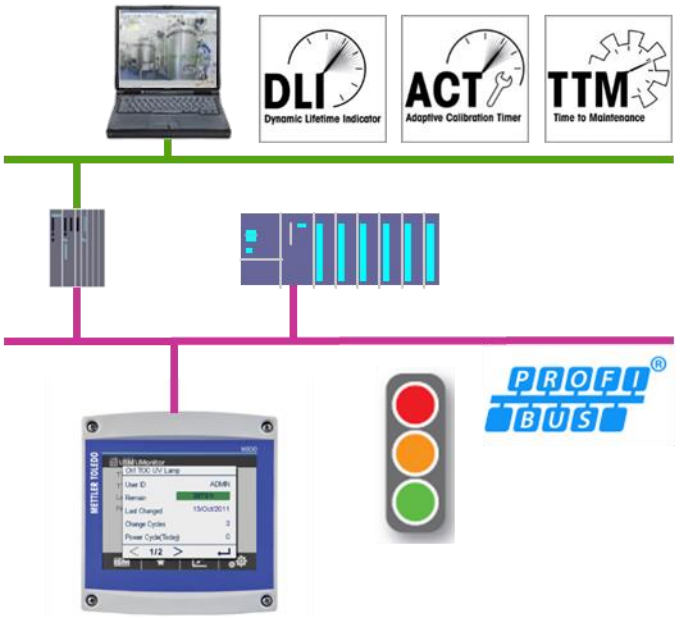
TOC

UPW Unicond

即插即測，高精度純水量測方案

- TOC，智能監控UV燈，業界最省水
  - 梅特勒TOC每秒更新數值，非批次性偵測
  - 符合ESG，節省80%用水，8.5ml /min
  - 預告功能隨時偵測UV的異常情況，而不僅是壽命倒數計時。確保UV燈的精確狀態，最大化合規產品生產量，並將停機時間降至最低
  - 時監控，以偵測總有機碳含量的變化
  - DLI可以監測紫外線燈的剩餘壽命，使您能夠在問題
- 超純水電阻率測量效能的新境界
  - 採用先進的內建測量電路，提供卓越精度降低干擾風險
  - 使用整合測量電路進行最高準確度的電阻率測量
  - WideRange技術藉由一台設備覆蓋整個補充、淨化處 理系統和使用點

整合感測器資訊的ISM技術介紹



ISM

智能傳感器管理

- 提高了測量結果的可靠性並減少了生產停機時間
- 整套方案包括智慧感測器、可量測多重參數、即插即用、可視化的傳輸器，符合智能型生產趨勢

藥廠的合規性要求

Performance
Maintenance & Optimization

Optimal performance to yield top product quality:

- Professional installation
- Well documented traceable configuration and settings
- Proactive maintenance
- Protection or restoration of your equipment's reliability

Compliance
Assurance & Certification

In full compliance with standards & regulations:

- Calibration and performance verification
- Audit-proof documentation of equipment qualification testing
- Recommendations for routine testing and maintenance schedules

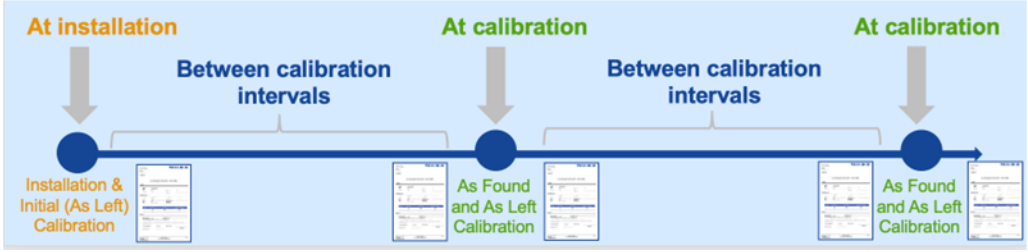
ASTM INTERNATIONAL
EURAMET
USP U.S. Pharmacopeial Convention
OIML

✓ 製藥業的客戶對於設備服務的期望

- 全球通用與一致性的文件與操作手法
- 完整的性能查核、日常驗證與合規性文件
- 定期的調整與性能確校

✓ METTLER TOLEDO可以提供

- IPAQ/EQPAQ 文件符合客戶的裝機驗證要求
- 全電子化的校正報告確保年度性能無虞
- 機台保養與性能調整
- 完整的教育訓練與日常查核規劃建議



問題與討論

METTLER TOLEDO

很高興成為您的合作夥伴!

無論您的目標是什麼，我們都將竭力幫助您實現