

aseptic

無菌

Besuchen Sie www.aseptica.com und nutzen Sie das umfangreiche Archiv!

28. Jahrgang 2022 | Heft 1



Hygienische Besonderheiten in einer Akutgeriatrie

Special hygiene considerations in an acute geriatric clinic

急性老年病診所的特殊衛生注意事項

Editorial 社論

Dear readers, 親愛的讀者

the aseptica, your specialist magazine for hospital and practice hygiene, is not a political magazine, but the current situation in the Ukraine cannot leave us untouched. The suffering of the Ukrainian population as a result of the Russian war of aggression is extreme great and demands our solidarity. The willingness to help in taking in refugees from the war zones and the willingness to donate urgently needed relief supplies are unbroken even after several weeks and are met by a grateful Ukrainian people - I would like to thank you for that. aseptica(無菌雜誌), 您的醫院和實踐衛生專業雜誌, 不是政治雜誌, 但烏克蘭目前的局勢不能讓我們不受影響。俄羅斯的侵略戰爭造成烏克蘭外移的苦難是極為龐大的而且需要我們的團結。幫助接收來自戰區的難民的意願和捐贈急需的救援物資的意願即使在幾週後仍然沒有中斷, 並得到了感激的烏克蘭人民的滿足 - 我要為此感謝您們。

In the first issue of 2022 in the "Latest News" section, Dr. Kluge Senior Vice President Unit Professional of the Miele Group in an interview about 4 years of Miele & Steelco with the question "what was the most important milestones and moments of this time". 在 2022 年第一期的"最新消息"部分, 德國美諾 Miele 集團單位專業高級副總裁 Kluge 博士接受了德國美諾 Miele & Steelco 其在位4年的採訪, 並提問"這其中最重要的里程碑和該次時刻為何"。

In the "Clinic & Hygiene" focus, Ms. Kenschake considered with the manual preparation of beds in hospitals and Dr. Holz, Dr. van den Abeelen, Mr. Kiesel and Ms. Kemnitz-Frahm with the hygienic features in acute geriatrics. 在"診所與衛生"重點中, Kenschake 女士考慮了醫院床位的手動準備, Holz 博士、van den Abeelen 博士、Kiesel 先生和 Kemnitz-Frahm 女士考慮了急性老年病的衛生特徵。

For validators and AEMP management, the article by Mr. Koster, Mr. Wenzel and Dr. van Doornmalen the use of the new NKG sensor for the parametric release of the steam sterilization by measuring the parameters temperature, steam composition and time. 對於驗證器和 AEMP 管理, Koster 先生、Wenzel 先生和 van Doornmalen 博士的文章使用新的 NKG 傳感器通過測量參數溫度、蒸汽成分和時間來釋放蒸汽滅菌的參數。

What is meant by the term calibration and why is the calibration of data loggers so important for use in validation? Mr. Streller, Mr. Glaser and Mr. Kruse address with the topic of calibration. 校準一詞是什麼意思? 為什麼數據記錄器的校準對於驗證使用如此重要? Streller 先生、Glaser 先生和 Kruse 先生以校準為主題發表演講。

I am particularly pleased to be able to introduce you the company Veolia Water Technologie, a new aseptica partner. The Veolia Group is a leading company in the field of environmental technologies with sustainable solutions in resource management. 我特別高興能夠向您介紹新的無菌合作夥伴威立雅水技術公司。威立雅集團是環境技術領域的領先公司, 在資源管理方面提供可持續的解決方案。

The 16th Congress for Hospital Hygiene of the DGKH (www.krankenhausthygiene.de) will take place from May 1st to 5th as a face-to-face event in the Hotel Berlin Central District (formerly the Maritim Hotel) in Berlin. DGKH 第 16 屆醫院衛生大會 (www.krankenhausthygiene.de) 將於 5 月 1 日至 5 日在柏林的柏林中心區酒店 (原瑪麗蒂姆酒店) 舉行面對面的活動。

I wish you an exciting aseptica. 祝您享有一個令人興奮的無菌雜誌。
Stay healthy, your 保持健康, 您的 Iven Kruse



Contents 內容

Latest News 最新消息

Miele Group wrap-up – 4 years of Miele & Steelco 德國美諾 Miele 集團總結——德國美諾 Miele & Steelco 的 4 年 Interview with Dr. Christian Kluge 採訪 Christian Kluge 博士 29

Hospitals & Hygiene 醫院與衛生

The manual processing of patient beds in the hospital – A smiley face as a motivational tool 醫院病床的流程處理——作為激勵工具的笑臉 32

Special hygiene considerations in an acute geriatric clinic 急性老年病診所的特殊衛生注意事項 35

Info from Industry 來自行業的信息

New preparation system for the nitrous oxide sedation 一氧化二氮鎮靜劑的新製備系統 我們訓練能力! 41



Report 報導

More suicide attempts among adolescents in Germany during second COVID lockdown 在第二次 COVID 封鎖期間, 德國青少年的自殺企圖增加

There was a nearly 3-fold increase in suicide attempts among adolescents aged 12 to 17 years in Germany during the second COVID-19-related lockdown compared with 2017 to 2019, researchers at Essen University Hospital concluded, using data from one-fifth of German pediatric intensive care units. 埃森大學醫院的研究人員使用於兒科重症監護病房五分之一德國人的數據得出結論, 與 2017 年至 2019 年相比, 在第二次與 COVID-19 相關的封鎖期間, 德國 12 至 17 歲青少年的自殺企圖增加了近3倍。The suicide attempts had mostly involved drug intoxications. Compared with the corresponding periods in 2017 to 2019, the rate of suicide attempts among adolescents in the 1st lockdown was reduced by 32%. 自殺企圖主要涉及藥物中毒。與2017年至2019年同期相比, 第一次封鎖期間青少年自殺未遂率減少了32%。The retrospective cohort study of suicide attempts in the 1st lockdown included data from 1,444 admissions to 37 German pediatric intensive care units, representing 21.5% of German pediatric ICU capacity. According to the researchers, pediatric intensive care units are particularly affected by changes in this area because they are often involved in stabilizing patients' vital signs and monitoring them after self-harm and suicide attempts. 第一次封鎖期間自殺未遂的回顧性隊列研究包括來自 37 個德國兒科重症監護病房的 1,444 名住院患者的數據, 佔德國兒科 ICU 容量的 21.5%。據研究人員稱, 兒科重症監護病房尤其受到該領域變化的影響, 因為它們經常參與穩定患者的生命跡象並在自殘和自殺未遂後對其進行監測。

Source 資訊來源: aertzeblatt.de

www.aseptica.com
Download a digital copy of the latest edition now and browse through the extensive archive.

Technology & Hygiene 技術與衛生

Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time 測量蒸汽滅菌參數的參數發布: 溫度、蒸汽成分和時間 42

What is meant by calibration 校正是什麼意思... 48

Miscellaneous & Legal Notice 雜項和法律聲明

New aseptica partner Veolia Water Technologies 新的無菌合作夥伴威立雅水技術 51

Miele Group wrap-up – 4 years of Miele & Steelco

德國美諾 Miele 集團總結 – 德國美諾 Miele & Steelco 的 4 年

An interview with Dr. Christian Kluge, Senior Vice President Business Unit Professional 採訪商務部 Professional 資深副總裁 Christian Kluge 博士

Miele and Steelco announced in 2017 that they were going to join forces. Steelco has been a wholly owned part of the Miele Group since 2021. How satisfied are you with developments? 德國美諾 Miele 和 Steelco 在 2017 年宣布他們將聯手。自 2021 年以來，Steelco 一直是德國美諾 Miele 集團的全資子公司。您對發展的滿意程度如何？

Let me start with our motives: By joining forces, we can offer our clients in hospitals, surgeries, the pharmaceutical industry and other branches better and more comprehensive services at very competitive prices. The customer segments and the product ranges of both firms complement each other to a great degree. And there was huge potential to further strengthen each other. Four years down the line, these expectations have been fully vindicated. 先從我們的動機說起：

通過聯手，我們可以以極具競爭力的價格為醫院、外科、製藥業和其他分支機構的客戶提供更好、更全面的服務。兩家公司的客戶群和產品範圍在很大程度上互補。並且有巨大的潛力進一步加強彼此。四年過去了，這些期望得到了充分證明。

It is quite reasonable to expect a character clash between Eastern Westphalia and Northern Italy. How could integration be successful?

可以合理地預期東威斯特伐利亞和義大利北部之間的性格衝突。整合如何才能成功？

Common values are a sound foundation. There were demands relating to long-term customer relationships, the reliability and longevity of our products on both sides – a common understanding under the umbrella of our 'Immer Besser' motto. And, indeed, cultures have to grow together – and we deliberately set aside enough time for this, in an atmosphere of great mutual respect. Today, we are pleased at the level of trust and confidence on both sides and the blend of talents. 共同價值觀是堅實的基礎。雙方對長期客戶關係、我們產品的可靠性和使用壽命都有要求，這是我們“Immer Besser”座右銘下的共同理解。事實上，不同文化必須共同成長——在相互尊重的氛圍中，我們刻意為此留出足夠的時間。今天，我們對雙方的信任和信心以及人才的融合感到高興。

What were the key milestones and moments during this period? 在此期間，有哪些重要的里程碑和時刻？

Early on in the process, the main milestones were drawing up a joint market strategy and, in 2017, the first joint trade shows, including Medica in Düsseldorf. Worth mentioning, too, are the first products which we each built for the other partner respectively, for example our large-chamber decontamination unit with its patented Pulse Power Cleaning. We have now reached the point where we are working on many aspects of the value creation chain in close union. 在這個過程的早期，主要的里程碑是制定聯合市場戰略，並在 2017 年，包括杜塞爾多夫的 Medica 在內的第一個聯合貿易展。同樣值得一提的是，我們每人都分別為另一個合作夥伴製造了第一批產品，用於檢查我們的大腔室去污裝置及其專利的脈衝功率清潔。我們現在已經達到了這點，即我們正以緊密結合來多方面運作價值創造鏈。



Fig圖. 1: Dr. Christian Kluge, Senior Vice President Business Unit Professional, Miele & Cie. KG. 德國美諾 Miele & Cie. KG 商務部 Professional 資深副總裁 Christian Kluge 博士。

Through all these efforts we have taken sales to new important heights – Steelco turnover has more than doubled since 2017 while Miele Professional has also grown well during the same period. 通過所有這些努力，我們將銷售額提升到了新的重要高度 – Steelco 的營業額自 2017 年以來增加了一倍多，而德國美諾 Miele Professional 在同一時期也取得了良好的增長。

I would like to highlight one very recent milestone, reached at the end of 2021: The successful realignment of our Miele production plant in Bürmoos, Austria. Key products from this plant were rendered obsolete by the acquisition. The team there has succeeded in giving the plant a new and important role, thereby creating a sustainable economic basis. Miele Bürmoos now focuses on baskets, components and load carriers – for both Miele and Steelco. This is a crucial success factor in our line of business, as indicated by more than 750 model versions alone. 我想強調一個最近在 2021 年底達到的里程碑：我們位於奧地利 Bürmoos 的德國美諾 Miele 生產工廠成功的重組。該工廠的主要產品因收購而過時。那裡的團隊成功地賦予了工廠一個新的重要角色，從而創造了可持續的經濟基礎。Miele Bürmoos 現在專注於為 Miele 和 Steelco 提供籃筐、元件和載運裝置。這是我們業務線中一個關鍵的成功因素，僅 750 多個型號版本就表明這一點。





Fig圖. 2: Miele 德國美諾

Would you briefly outline what has changed in Sales and Service over this period? 您能簡要概述一下這段時間在銷售和服務方面發生了什麼變化嗎？

There has been an increasing focus on the deployment of the two brands and sales activities. This involved bringing together the planning and equipping of central sterile supply departments (CSSD) at Steelco (project business) whilst Miele was given responsibility for the medical product business in surgeries and dental practices (transactional business). Sales in the project and the transactional business fields differ considerably, in particular in terms of order complexity, order values and the number of transactions. Hence, it makes sense to specialise. 人們越來越關注這兩個品牌的部署和銷售活動。這涉及將 Steelco 的中央無菌供應部門 (CSSD) 的規劃和設備整合在一起 (項目商業), 同時 Miele 負責手術和牙科實踐中的醫療產品業務 (交易商業)。項目和交易業務領域的銷售差異很大, 特別是在訂單複雜性、訂單價值和交易數量方面。因此, 專業化是有意義的。

In addition to this, we have merged after-sales service for both brands in many countries so that a service in-frastructure guarantees the good and fast availability of spare parts to Steelco customer as well. 除此之外, 我們還合併了兩個品牌在許多國家的售後服務, 因此服務基礎設施也保證了 Steelco 客戶能夠良好和快速地獲得備件。

On the Miele side, we also introduced specialisation to the sales team in 2020, differentiating between Medical/Laboratory/Dental on the one side and HoReCa/Care/Self Service on the other. This alignment with sales channels helps us to serve our clients better. 在德國美諾 Miele 方面, 我們還在 2020 年向銷售團隊引入了專業化, 一方面區分醫療/實驗室/牙科, 另一方面區分HoReCa/照護/自助服務。這種與銷售渠道的一致性有助於我們更好地為客戶服務。



What is special in your mind about the transactional business? 您認為交易商業有什麼特別之處？

Our customers, for instance from medical and dental practices, expect advice, delivery and service on site without extended waits. Proximity to customers is very important to us in this respect. For this reason, we maintain high-performance sales and service structures offering blanket geographical coverage. This is the case both in direct sales through our Miele subsidiaries and via our trading partners. Order volumes commonly reach four- or five-digit figures in euros. Clients are given individual and comprehensive advice which also includes service concepts, matching process chemicals, the routine use of process challenge devices and process documentation solutions. 我們的客戶, 例如來自醫療和牙科診所的客戶, 期望在現場獲得建議、交付和服務, 而無需長時間等待。在這方面, 貼近客戶對我們來說非常重要。出於這個原因, 我們保持高性能的銷售和服務結構, 提供全面的地理覆蓋。通過我們的德國美諾 Miele 子公司和通過我們的貿易夥伴進行的直接銷售都是這種情況。以歐元計算的訂單量通常達到四位數或五位數。向客戶提供個別化和全面的建議, 其中還包括服務概念、匹配流程化學品、流程挑戰設備的常規使用和流程文件解決方案。

In what ways does the project business differ? 項目商業在哪些方面有所不同？

These tend to be larger and in part highly customised orders clinched via a tendering process - typically equipping CSSDs. This business is conducted via Steelco in around 15 countries through our own sales subsidiaries and in more than 100 further countries through dealers. This does not require a blanket sales organisation. This approach to sales generally involves serving an entire country from one single location. As no two projects are ever the same, Steelco provides support with planning, installation and capacity calculations. In the projects sector, order volumes often reach six-, seven- or even eight-digit figures in euros. 這些趨向更大, 部分是通過招標過程獲得的高度客製化的訂單 - 通常配備 CSSD。這項業務通過 Steelco 通過我們自己的銷售子公司在大約 15 個國家開展, 並通過經銷商在另外 100 多個國家開展。這不需要一覆蓋的銷售組織。這種銷售方法通常涉及從一個地點為整個國家/地區提供服務。由於沒有兩個項目完全相同, Steelco 為規劃、安裝和容量計算提供支持。在項目領域, 以歐元計算的訂單量通常達到六位數、七位數甚至八位數。

Professional has been around in its current form since 2020 - what has changed? 自 2020 年以來, Professional 一直以目前的形式出現 - 發生了什麼變化？

The establishment of the Business Unit Professional was part of bigger organisational changes at Miele with the aim of bolstering our focus on individual business fields. Professional is the only business unit to be run consistently as a 'firm within a firm': From development right through to Sales and Service, all core functions are under the same leadership. This enables a greater degree of focus on these complex business deals, greater speed and a more client-centric approach. And we have changed a lot within the business unit, from specialisation in sales through to boosting the customer perspective in product management. 商業部門 Professional 的成立是德國美諾 Miele 更大組織變革的一部分, 目的是加強我們對各個業務領域的關注。Professional 是唯一作為「公司中的公司」始終如一地運行的商業部門: 從開發一直到銷售和服務, 所有核心職能都在同一領導之下。這可以讓您更專注於這些複雜的商業交易、更快的速度和更以客戶為中心的方法。我們在業務部門內發生了很大變化, 從銷售專業化到提升產品管理中的客戶視角。

Professional 包括哪些公司單位？

Alongside solutions for cleaning, disinfection and sterilisation, we also offer various solutions in the fields of laundry and dishwashing technology as well as air purifiers. The products originate from seven production plants, of which five belong to the Professional business unit – two in Germany, one in Austria and two Steelco plants in Italy. The global Professional sales and service network covering Miele and Steelco also counts as part of our business unit. Furthermore, our remit includes companies and startups offering specific customer-specific solutions. I would like to draw particular attention to Bloomest, a company planning and installing turn-key laundrettes, and AppWash providing digital solutions for shared washing machines. 除了清潔、消毒和滅菌解決方案外，我們還提供洗衣和洗碗技術以及空氣淨化器領域的各種解決方案。產品來自七家生產工廠，其中五家屬於Professional 商務部門——兩家在德國，一家在奧地利，兩家在意大利的Steelco 工廠。覆蓋德國美諾 Miele 和 Steelco 的全球 Professional 銷售和服務網絡也是我們業務部門的一部分。此外，我們的職權範圍包括提供特定客戶特定解決方案的公司和初創公司。我想特別關注 Bloomest，一家規劃和安裝交鑰匙洗衣店的公司，以及為共享洗衣機提供數字解決方案的 AppWash。

In the past two years, the world has been in the thrall of the Covid pandemic. How has this influenced the Miele Group? 在過去的兩年中，世界一直處於Covid大流行的束縛中。這對德國美諾 Miele 集團有何影響？

In the early days of Corona, our biggest priority was to continue serving our customers, in particular providing service to critical infrastructures, whilst at the same time ensuring safe working conditions for our employees. Luckily, we were successful in both respects. More specifically, our branch was also faced with issues regarding infection control. The aim was to issue clear recommendations based on scientific insights – for example on the A0 value required to deactivate the Corona virus or efficacy criteria for air purification. 在 Corona 的早期，我們的首要任務是繼續為我們的客戶服務，特別是為關鍵基礎設施提供服務，同時確保我們員工的安全工作條件。幸運的是，我們在這兩個方面都取得了成功。更具體地說，我們的分支機構還面臨感染控制方面的問題。其目的是根據科學見解發布明確的建議——例如滅活冠狀病毒所需的 A0 值或空氣淨化的功效標準。

As everywhere else, the pandemic was also a catalyst at Miele in driving digitalisation. Online meetings have now become the norm. The Miele Group and, indeed, we in Professional have succeeded in mastering the enormous volatility in demand (and in the supply chain) and in growing year-on-year. 與其他任何地方一樣，疫情也是德國美諾 Miele 推動數位化的催化劑。在線會議現在已成為常態。德國美諾 Miele 集團，事實上，我們的專業人士已經成功地控制了需求（和供應鏈）的巨大波動，並實現了逐年增長。

Would you hazard commenting on future prospects? 您會冒險評論未來的前景嗎？

For Professional, we are only just seeing the power and dynamics we are able to unleash with our new organisation and strategy. Lots more will happen, for example in the field of digitalisation. Individual building blocks will increasingly join up and grow into integrated solutions and eco systems. Miele is also making very positive progress in the domestic appliance sector and is moving into new business fields, for example outdoor cooking. The domestic and Professional business fields have common roots, in particular with respect to their focus on quality and our keen pioneering spirit. Both find expression in our – joint – Purpose Statement: 'Miele – Creators of Quality'. 對於Professional，我們只是看到了我們能夠通過我們的新組織和戰略釋放的力量和動力。還會發生更多事情，例如在數位化領域。單個構建塊將越來越多地加入並成長為集成解決方案和生態系統。德國美諾 Miele 在家用電器領域也取得了非常積極的進展，並正在進入新的業務領域，例如戶外烹飪。國內和Professional 商務領域有著共同的根源，尤其是在他們對質量的關注和我們敏銳的開拓精神方面。兩者都可以在我們的聯合宗旨聲明中找到表達：“德國美諾 Miele – 質量的創造者”。



Figure 3: Steelco



The manual processing of patient beds in the hospital – A smiley face as a motivational tool 醫院病床的人工處理—作為激勵工具的笑臉

Author 作者 |

Ines Konschake
Hygienemanagement 衛生管理
Johanniter GmbH
Johanniter Krankenhaus Genthin-Stendal
Wendstraße 31, 39576 Stendal
ines.konschake@sdl.johanniter-kliniken.de

Ines Konschake

For patients, the hospital bed is an important component during their hospital stay and in the process of their recovery. In this bed, wound dressings, small rinses, food intake, excretion of excrement, contact with the outside world and much more takes

place until recovery. 對於患者來說，病床是他們住院期間和康復過程中的重要組成部分。在這張床上，傷口敷料、小沖洗、食物攝入、排泄物、與外界的接觸等等都會發生，直到康復。每個患者都可能要求並期待一張乾淨衛生的床，這樣他/她在入院當天就不會受到病原微生物的負擔。Every patient may demand and expect a clean and hygienically proper bed, so that he/she is not already burdened with pathogenic microbes on the day of admission. 每位患者都可能要求並期待一張乾淨衛生的床，這樣他/她在入院當天就不會被病原微生物所累。

Used patient beds are microbially contaminated depending on the patient clientele and can therefore be a source of nosocomial infections. 使用過的病床會受到微生物污染，具體取決於患者客戶，因此可能是醫院感染的來源。

Consequently, hygienically correct processing of the bed is an important aspect in the infection prevention regime. Patient beds can be processed either automated in a washer disinfectant for beds with a chemo-thermal process or manual by wipe cleaning and disinfection. 因此，衛生正確的床處理是感染預防制度中的一個重要方面。病床可以在清洗消毒器中自動處理，用於具有化學熱過程的病床，也可以通過擦拭清潔和消毒進行手動處理。

The topic of hygienically reasonable bed processing is still particularly important to the cost-benefit discussion, as in terms of the hospital administration there are still considerable streamlining reserves to be mobilized. The subject of manual processing of patient beds in the wiping process is particularly relevant and poses major challenges for hospital staff. 衛生合理的床位處理主題對於成本效益討論仍然特別重要，因為在醫院管理方面仍有相當多的精簡儲備有待調動。在擦拭過程中對病床進行人工處理這一主題尤為重要，對醫院工作人員構成了重大挑戰。



Fig圖.1: Contaminated frame of a hospital bed with blood. 醫院病床的框架被血液污染。

Hospital beds are not easily accessible everywhere in their construction and design, which makes cleaning difficult and very time-consuming (Fig.1). When purchasing beds for patient care, the professional groups of nursing, cleaning and hygiene specialists should be involved in order to evaluate the handling and disinfection resistance of surfaces. 醫院病床的建造和設計並非隨處可見，這使得清潔變得困難且非常耗時（圖1）。在為病人護理購買病床時，應讓護理、清潔和衛生專家組成的專業小組參與，以評估表面的處理和消毒抗性。

The success of a manual processing of patient beds is strongly dependent on the conscientiousness of all employees involved in the processing process. 手動處理病床的成功很大程度上取決於參與處理過程的所有員工的責任心。

A routine success check should be carried out and documented by the hygiene specialist or the hygiene officer at regular intervals. To check the quality of the results, a system for the determination of residues of fluorochemical agents can be used. 衛生專家或衛生官員應定期進行常規成功檢查並記錄在案。為了檢查結果的品質，可以使用測定除氟劑殘留量的系統。

This is an optical implementation control (quality control) of cleaning measures by means of UV light (Fig.2). 這是通過紫外光進行清潔措施的光學實施控制（品質控制）（圖2）。

To determine successful cleaning and disinfection measures, a risk analysis is carried out and a standardized process is required.

Based on three patient groups, the risk of infection is distinguished:

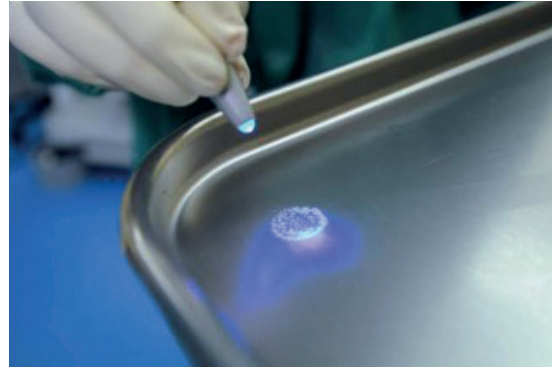
為了確定成功的清潔和消毒措施，需要進行風險分析並需要標準化流程。根據三個患者組，區分感染風險：

1. Patients without colonization or infection, patients without colonization burden with multidrug-resistant pathogens (MRE) (e.g. outpatient procedures, rehabilitation facilities) 沒有定植或感染的患者，沒有多重耐藥病原體（MRE）定植負擔的患者（例如門診手術、康復設施）
2. Patients at risk of infection or MRE-Last (e.g. acute care hospitals, early rehabilitation facilities) 有感染風險或 MRE-Last 的患者（例如急症護理醫院、早期康復機構）
3. Patients with a high risk of colonization or infection (e.g. neonatology, intensive care units, hematology and oncology) 具有高定植或感染風險的患者（例如新生兒科、重症監護室、血液科和腫瘤科）

Daily bed disinfection without changing patients 每日床位消毒不更換病人

The patient bed and the bedside cabinet are disinfected daily by the cleaning staff. In addition, visible contamination is removed by the nursing staff during the care of the patients by a wipe procedure. The product used for disinfection must be adapted to the pathogen, but must meet the minimum requirement bactericidal, yeasticidal and limited virucidal. 清潔人員每天對病床和床頭櫃進行消毒。此外，護理人員在護理患者期間通過擦拭程序去除可見的污染。用於消毒的產品必須適應病原體，但必須滿足殺菌、殺菌和有限殺病毒的最低要求。





Fig圖.2: Control after cleaning measures have been carried out by UV light. 通過紫外線燈進行清潔後的控制。

The proof of efficacy is carried out according to EN standards or VAH / DVV methods and the products are in VAH list or DVV of the IHO database and mapped in the hygiene plan. The hygiene plan is binding both for the staff of the medical institution and for the staff of external companies. The staff observes basic hygiene during disinfection: hygienic hand disinfection, wear disposable gloves and a protective apron.根據 EN 標準或 VAH / DVV 方法進行功效證明，產品在 IHO 數據庫的 VAH 列表或 DVV 中並映射到衛生計劃中。衛生計劃對醫療機構的員工和外部公司的員工都有約束力。工作人員在消毒過程中遵守基本衛生：手部衛生消毒，戴一次性手套和防護圍裙。

For patients without multidrug-resistant pathogens or infections, there is no routine change of bed linen, only in case of visible contamination.對於沒有多重耐藥病原體或感染的患者，床單沒有常規更換，只有在可見污染的情況下。

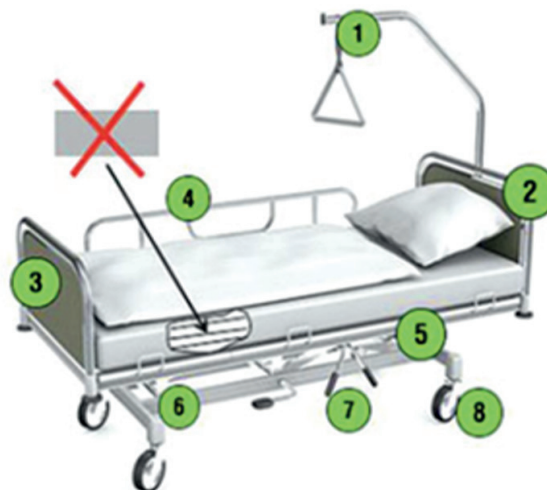
Bed disinfection after discharge, relocation or final disinfection Practical Experience: time spent on bed disinfection 出院、搬遷或最終消毒後的床位消毒實踐經驗：床位消毒所花費的時間

An important part of the work process of proper processing of patient beds are employee consultations. Cleaning staff without training had prepared the patient's bed with-in ten minutes, but insufficiently.正確處理病床的工作過程的一個重要部分即是員工諮詢。未經培訓的清潔人員在十分鐘內就已經準備好病人的床鋪，但還不夠。

It takes 25 minutes for the staff to thoroughly process a patient bed. Only trained personnel should be used in the processing team. The commissioned personnel wears personal protective equipment (PPE). The disinfection must be adapted to the pathogen and the exposure time must be observed, in the case of concentrates, the correct dosage must also be observed. Products with broad efficacy and short exposure times are helpful for praxis to ensure rapid availability of disinfected beds.工作人員需要 25 分鐘才能徹底處理一張病床。在處理團隊中只能使用經過培訓的人員。委託人員穿戴個人防護裝備 (PPE)。消毒必須適應病原體，並且必須遵守暴露時間，對於濃縮物，還必須遵守正確的劑量。具有廣泛功效和短暴露時間的產品有助於實踐，以確保消毒床的快速可用性。

The entire bed (including mattress topper, bed mechanism, bed frame, chassis) is wiped from top to bottom (Fig.3).整個床（包括床墊罩，床機構，床架，底盤）從上到下擦拭（圖 3）。The bed linen is disposed of in the usual sorting system. Pillows and blankets are given to the laundry. 床單在通常的分類系統中處理。枕頭和毯子被送到洗衣店。

The laundry bags must only be filled in such a way that they are still easy to close (two-thirds filling). It must be ensured that no foreign objects (secretion bags, drains, etc.) get into the laundry bag. In case of moisture penetration, the cloth bag is additionally placed in a plastic bag according to the specifications of the laundry. Infectiously contaminated laundry must be disposed of in a laundry bag intended for infection laundry. The laundry is processed in external companies according to a certified procedure. Defective mattress covers must be replaced, if this is not possible, the mattress must be disposed. After finishing the cleaning activity, the PPE is removed, hygienic hand disinfection and the patient bed is upgraded with fresh linen (Fig.4).洗衣袋只能以易於關閉的方式裝滿（裝三分之二滿）。必須確保沒有異物（分泌袋、排水管等）進入洗衣袋。如遇潮氣滲入，根據衣物規格將布袋額外放入塑料袋中。受感染的衣物必須放入用於感染衣物的洗衣袋中處理。衣物在外部公司按照經過認證的程序進行處理。必須更換有缺陷的床墊套，如果無法更換，則必須丟棄床墊。完成清潔活動後，脫下 PPE，進行衛生手消毒，並用新鮮的床單升級病床（圖 4）。



Fig圖. 3: Sequence of the work steps in bed preparation. 床鋪準備工作步驟的順序。





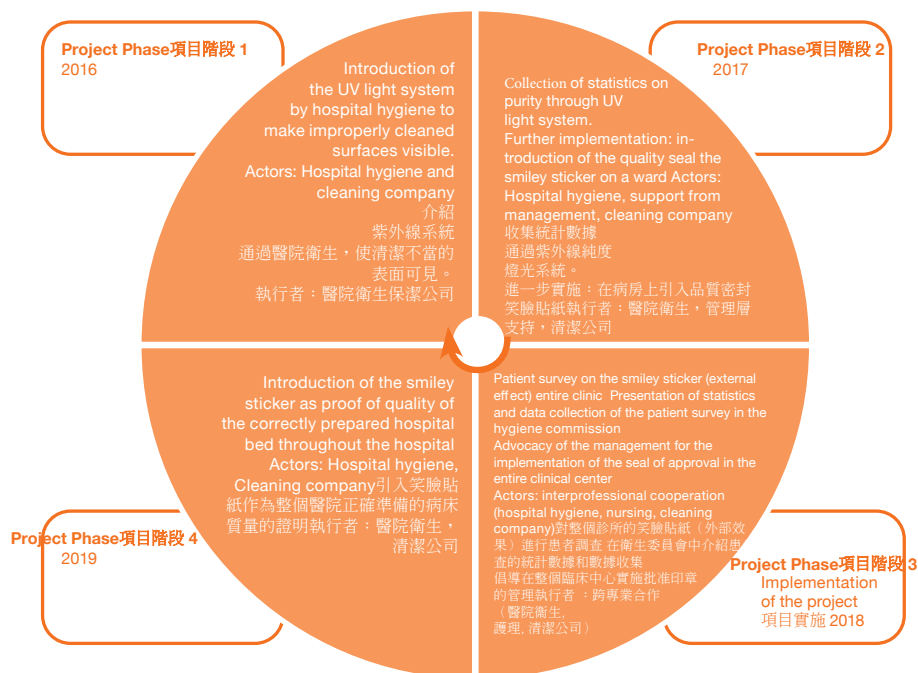
Fig圖.4: Prepared hospital bed and bedside cabinet. 準備好的病床和床頭櫃。

Maintenance / inspection of patient beds 病床的維護/檢查

Patient beds are medical devices and must comply with legal requirements for safety. 病床是醫療設備，必須符合安全的法規要求。

From practice to practice 從實踐到實踐

The smiley project (Fig.5, Fig.6) for the decentralized patient bed processing of the Johanniter GmbH branch in Stendal (Germany). The background to the project was insufficient results for cleaning and final disinfection of patient beds by the cleaning staff. 用於 Johanniter GmbH 分公司 Stendal (德國) 的分散式病床處理的笑臉項目 (圖 5、圖 6)。該項目的背景是清潔人員對病床進行清潔和最終消毒的結果不足。



Objectives of the project 項目目標:

- Increased attention to correctly disinfected surfaces at the patient's bedside. 增加了對患者床邊正確消毒表面的關注。
- Recognition and motivation for the cleaning staff, increased performance 對清潔人員的認可和激勵，提高績效
- Processed bed place immediately recognizable, can be occupied immediately, inquiries of maintenance is omitted, identification by signature of the executor of processing 處理床位可立即識別，可立即佔用，維修查詢省略，處理執行人簽名識別
- Correct disinfection for more patient safety, image enhancement, less indirect or direct transmission of MRE and other pathogens 正確消毒以提高患者安全、圖像增強、減少 MRE 和其他病原體的間接或直接傳播

Conclusion 結論:

The hygienically flawless bed processing in the medical sector serves both cleanliness and infection prevention and is an important key in patient and personnel protection. 醫療領域的衛生完美無瑕的病床處理服務既可清潔又可預防感染，是患者和人員保護的重要關鍵。

The decentralized treatment (in the patient room) can thus easily replace a cost-intensive bed centre and offers the necessary security in everyday hospital life in the interprofessional team. 因此，分散式治療 (在病房內) 可以輕鬆取代成本密集型的病床中心，並為跨專業團隊的日常醫院生活提供必要的安全保障。

Literature references 文獻參考

1. L.C. Weber, Cleaning services and hygiene in hospitals and care facilities DOI 10.1007/978-3-662-52723-8_7. © Springer-Verlag Berlin, Heidelberg 2017
2. Hyg. Med 2003; 28 [1/2]:44-6. Heudorf U. et al. Bed preparation in the Hospital results of infection hygiene monitoring in Frankfurt/Main 2009. Hyg. Med 2011; 36 [9]: 344-50
3. Hygiene & Medicine, Volume 46, 9/2021
4. Working Group Hospital and Practice Hygiene of the AWMF, 2010-2016: Hygienic Preparation of patient beds. AWMF – Register No 029/023



Special hygiene considerations in an acute geriatric clinic 急性老年病診所的特殊衛生注意事項

Hubert Holz, Lothar van den Abeelen, Markus Kiesel, Hanna Kemnitz-Frahm

Marienhäus Klinikum Mainz (MKM) is categorised as a Level II hospital under the German system and has 602 beds and around 1500 employees. It treats 50,000 inpatients and outpatients a year at its 19 clinics and 10 centres. Marienhäus Klinikum Mainz (MKM) 被歸類為德國系統下的二級醫院，擁有 602 張病床和約 1500 名員工。它每年在其 19 個診所和 10 個中心治療 50,000 名住院病人和門診病人。Although the acute geriatric clinic was set up at MKM 15 years ago, since 2021 our department has been located in a completely new ward on the fourth floor of the Marienhäus Klinikum. We have 59 standard beds and 11 beds for optional services. Our goal is to help our patients retain, regain or improve their level of independence in carrying out daily tasks as much as we can; to minimise or, where possible, avoid the need for care altogether; and to maintain the very best possible quality of life for each patient. Treating our patients as individuals is at the forefront of everything we do.儘管 15 年前在 MKM 設立了急性老年病診所，但自 2021 年以來，我們的科室一直位於 Marienhäus Klinikum 四樓的全新病房。我們有 59 張標準床位和 11 張可選服務床位。我們的目標是幫助我們的患者保持、恢復或提高他們在執行日常任務時的獨立程度；盡量減少或在可能的情況下完全避免護理需求；並為每位患者保持最佳的生活質量。將患者視為個體是我們所做一切的首要任務。

The ward is divided into units and each unit has a ward round trolley, some of which are equipped with a PC workstation, a unit trolley, which acts like a mobile nurse's station, and a care trolley. The geriatric department is home to a small optional services area with 11 beds. This area includes a communal lounge, a balcony and a cosy coffee corner.病房分為多個單元，每個單元都有一個病房巡迴推車，其中一些配備了PC工作站，一個單元推車，就像一個移動護士站，還有一個護理推車。老年科是一個有 11 張病床的小型可選服務區所在地。該區域包括一個公共休息室、一個陽台和一個舒適的咖啡角落。

The multi-professional team working in the acute geriatric clinic is made up of all the various occupational groups involved in patient care, from medics and nurses to physiotherapists, occupational therapists, psycho-therapists and even social services professionals. The hallmark of this team is its interdisciplinary and collaborative approach to its work. Having this type of organisation calls for lots of frank discussions and clear agreements with each other in the interest of finding the best way of working together – and these processes need to be jointly re-evaluated on a regular basis. Besides the everyday communication that goes on between employees and the handovers they conduct, the clinic also holds well-structured team meetings. These meetings not only ensure the team is focussed on delivering multi-disciplinary and multi-professional patient care, they also underline the importance of making sure the department structure is allowed to evolve in the context of continuous improvement.在急性老年病診所工作的多專業團隊由參與患者護理的所有不同職業群體組成，從醫生和護士到物理治療師、職業治療師、心理治療師甚至社會服務專業人員。該團隊的標誌是其跨學科和協作的工作方式。擁有這種類型的組織需要彼此進行大量坦誠的討論和明確的協議，以便找到最佳的合作方式——並且需要定期對這些流程進行聯合重新評估。除了員工之間的日常溝通和他們進行的交接外，診所還舉行了結構良好的團隊會議。這些會議不僅確保團隊專注於提供多學科和多專業的老年護理，還強調了確保部門結構能夠在持續改進的背景下發展的重要性。

Hygiene in a geriatric trauma centre – Special considerations in an acute geriatric clinic 老年創傷中心的衛生——急性老年診所的特殊考慮

Before it opened, many MKM staff were worried that the new geriatric department would act as a gateway for multi-resistant germs and that the number of problem germs would increase considerably. Partly in the interests of quelling this fear, there was close cooperation between the future therapeutic team and the hospital's hygiene team right from the planning and preparation phase for the new acute geriatric clinic.在它開業之前，許多 MKM 工作人員擔心新的老年病科會成為多重耐藥菌的門戶，並且問題細菌的數量會大大增加。部分為了平息這種恐懼，未來的治療團隊和醫院的衛生團隊從新的急性老年病診所的規劃和準備階段就開始密切合作。

Multi-resistant pathogens in geriatric care 老年護理中的多重耐藥病原體

If we look at the data on multi-resistant pathogens contained in the Pathogen-KISS module of the Krankenhaus-Infektions-Surveillance-System (KISS, the hospital infection surveillance system) of the German National Reference Center for Surveillance of Nosocomial Infections (NRZ), 如果我們看一下德國國家院內感染監測參考中心 (NRZ) 克蘭肯豪斯食品監測系統 (KISS, 醫院感染監測系統) 的病原體-KISS模組中包含的多重耐藥病原體的數據，



Fig圖. 1: Coffee corner in the MKM acute geriatric clinic. (Photo credit圖片來源: Hanna Kemnitz-Frahm) MKM急性老年的咖啡角落。

Authors 作者們

Dr Hubert Holz
Chief Hospital Hygienist at Marienhäus Klinikum GmbH
Medical specialist for hygiene and environmental medicine
Marienhäus Klinikum Mainz
An der Goldgrube 11, 55131 Mainz
Hubert.Holz1@marienhäus.de
www.marienhäus-klinikum-mainz.de

Dr Lothar van den Abeelen
Head Physician at the Acute Geriatric Clinic
Specialist in internal medicine with a focus on pulmonology and geriatrics
Marienhäus Klinikum Mainz
An der Goldgrube 11, 55131 Mainz
Lothar.Abeelen@marienhäus.de
www.marienhäus-klinikum-mainz.de

Markus Kiesel, M.Sc.
Hygiene Manager (HygiMa®) and Senior Hygiene Specialist (HFK®)
Marienhäus Klinikum Mainz
An der Goldgrube 11, 55131 Mainz
Markus.Kiesel@marienhäus.de
www.marienhäus-klinikum-mainz.de

Hanna Kemnitz-Frahm
Head Nurse on the Acute Geriatric Ward
Deputy Manager of the Centre for Internal Medicine at Marienhäus Klinikum Mainz
An der Goldgrube 11, 55131 Mainz
Hanna.Kemnitz-Frahm@marienhäus.de
www.marienhäus-klinikum-mainz.de





Fig圖. 2: Communal area for patients in the MKM acute geriatric clinic. MKM 急性老年診所的公共區域。(Photo credit 圖片來源: Hanna Kemnitz-Frahm)

we can see that there is indeed a higher than average prevalence of the most common multi-resistant pathogens found on geriatric wards¹: 我們可以看到確實有一個高於老年病房中發現的最常見多重耐藥病原體的平均流行率¹

· Methicillin-resistant *Staphylococcus aureus* (MRSA) have a significantly higher prevalence on admission, although nosocomial incidence densities are the same as elsewhere.耐甲氧西林金黃色葡萄球菌 (MRSA) 在入院時的患病率明顯較高，儘管醫院發病密度與其他地方相同。

· It's a different picture for vancomycin-resistant enterococci (VRE) and multi-resistant Gram-negative bacteria that are resistant to three of the four classes of antibiotics (3MRGN). For these pathogens, not only the prevalence, but also the nosocomial incidence densities are higher on geriatric wards than the average of all wards. 對於耐萬古黴素腸球菌 (VRE) 和對四類抗生素中的三類 (3MRGN) 具有耐藥性的多重耐藥革蘭氏陰性菌來說，情況就不同了。對於這些病原體，不僅患病率，而且醫院內的發病密度在老年病房都高於所有病房的平均值。

· In contrast, we can see that with multi-resistant Gram-negative bacteria that are resistant to all four of the four classes of antibiotics (4MRGN), and which are therefore the most serious of the multi-resistant problem germs, there is not only a comparable level of prevalence, but there is also a trend towards a slightly lower incidence density of nosocomial cases. 相比之下，我們可以看到，多重耐藥革蘭氏陰性菌對四類抗生素 (4MRGN) 中的所有四種都有耐藥性，因此是多重耐藥問題細菌中最嚴重的，不僅患病率水平相當，但也有院內病例發病率略低的趨勢。

So, there is actually no basis for the claim that a geriatric department will automatically be some sort of "bacterial incubator". On the contrary, we interpret this data to mean that our patients, who frequently have multi-morbidity and a history of contact with a variety of healthcare settings, are more likely to bring a multi-resistant pathogen into the hospital with them, but that our specialist departments are able to deal with these bacteria well or even better than other departments. This applies in particular to the classic problem germs of MRSA and 4MRGN. In our view, the higher incidence densities of nosocomial cases of VRE and 3MRGN can be explained by the much longer hospital stays experienced by our patients (13.6 days on geriatric wards compared to 5.1 days on all wards) as well as their increased susceptibility to infection⁶ by colonisation pathogens. 因此，老年科會自動成為某種“細菌培養箱”的說法實際上是沒有根據的。相反，我們將這些數據解釋為，我們的患者經常患有各種疾病並有與各種醫療機構接觸的歷史，更有可能將多重耐藥病原體帶入醫院，但我們的專業部門能夠很好地處理這些細菌，甚至比其他部門更好。這尤其適用於 MRSA 和 4MRGN 的經典問題細菌。我們認為，醫院內 VRE 和 3MRGN 病例的高發病率可以解釋為我們的患者住院時間更長 (老年病房 13.6 天，而所有病房 5.1 天) 以及他們被定植病原體感染的易感性增加⁶。

To keep a close eye on how these pathogens are developing in the MKM acute geriatric clinic, the ward is also taking part in the Pathogen-KISS module of the NRZ. And now the general picture described earlier comes into even sharper focus. In the MKM acute geriatric clinic there were no nosocomial MRSA cases whatsoever, nosocomial VRE cases are very much the exception and 4MRGN are rarely seen pathogens brought into the hospital from the outside. How is this possible? 為了密切關注這些病原體在 MKM 急性老年病診所中的發展情況，該病房還參加了 NRZ 的 Pathogen-KISS 模組。現在，前面描述的總體情況變得更加清晰。在 MKM 急性老年門診，沒有任何院內 MRSA 病例，院內 VRE 病例非常例外，4MRGN 是很少見的從外部帶入醫院的病原體。這怎麼可能？ From the very start, patients have been universally screened for MRSA on admission to the MKM acute geriatric clinic, so the MRSA status of every single patient, regardless of any risk factors they may have, is always known. In the past, MRSA screening was conducted not only when patients were first admitted to the clinic from outside the hospital, but also whenever in-patients were moved there from a different area of the hospital. However, once the MRSA full screening programme had been introduced in all MKM departments by the end of 2017, this approach was no longer followed. The acute geriatric clinic was a pioneer in this regard and a driving force behind the campaign to totally eradicate nosocomial MRSA cases throughout MKM² 從一開始，患者在進入 MKM 急性老年病診所時就已普遍接受 MRSA 篩查，因此每個患者的 MRSA 狀態，無論他們可能有任何風險因素，始終是已知的。過去，MRSA 篩查不僅在患者首次從醫院外入院時進行，而且在住院患者從醫院的不同區域轉移到那裡時進行。然而，一旦在 2017 年底之前在所有 MKM 部門引入了 MRSA 全面篩查計劃，就不再遵循這種方法。急性老年病診所是這方面的先驅，也是在整個 MKM² 徹底根除醫院內 MRSA 病例的運動背後的推動力。 There is also an intensive admission screening programme in response to the presence of VRE and MRGN, but no universal full screening programme for these pathogens. That said, if easily defined risk criteria are present (patient transferred from another hospital / facility; patient being weaned from / dependent on a ventilator; dialysis or oncology patient; interventions in or treatment of the patient's gastrointestinal tract), specific tests are run to identify these pathogens in the MKM acute geriatric clinic. The rate of positive tests is very high for patients transferred from other clinics and those on ventilation and dialysis in particular.^{3,4} 還有針對 VRE 和 MRGN 存在的強化入院篩查計劃，但沒有針對這些病原體的普遍全面篩查計劃。也就是說，如果存在易於定義的風險標準 (從另一家醫院/設施轉移的患者; 正在斷奶/依賴呼吸機的患者; 透析或腫瘤患者; 對患者胃腸道的干預或治療)，將運行特定測試以在 MKM 急性老年病診所識別這些病原體。從其他診所轉來的患者，尤其是接受通氣和透析的患者^{3,4}，陽性檢測率非常高，so what happens with patients in the acute geriatric clinic if a multi-resistant pathogen of this type is found? Well, that is a complex issue. 那麼，如果發現這種類型的多重耐藥病原體，那麼急性老年病診所的患者會發生什麼情況呢？嗯，這是一個複雜的問題。

The main treatment process in specialist geriatric departments is known as "complex geriatric treatment". It is aimed specifically at older patients suffering from multiple illnesses who have a functional impairment but who cannot (yet) participate in normal follow-up treatment. The decision as to whether complex treatment can be provided will be taken by a specialist geriatric doctor together with the geriatric team during the first few days after the patient is admitted. 老年專科科室的主要治療過程被稱為“複雜老年治療”。它專門針對患有各種疾病的老年患者，這些患者有功能障礙，但 (還) 不能參加正常的後續治療。是否可以提供複雜治療的決定將在患者入院後的最初幾天內，由老年醫學專科醫生與老年醫學團隊共同決定。



Standardised geriatric assessments will be performed at the start, and sometimes the end, of the patient's stay and will cover aspects such as: 標準化的老年病評估將在患者住院開始時進行，有時甚至在結束時進行，並將涵蓋以下方面：

- Mobility, risk of falling 移動性，跌倒風險
- Cognition 辨識
- Emotion 情感
- Capacity to help oneself 自助的能力
- Care situation 護理情況
- Nutrition, pain, difficulties with swallowing 營養、疼痛、吞嚥困難

In order to plan our patients' treatment, we hold week-ly team meetings attended by all the occupational groups involved in patient care. This is where we plan courses of treatment, discuss any action that needs to be taken at the moment and talk about new treatment goals for the upcoming period. During a patient's stay, their treatment will be based on their existing medical issues as well as the results of their geriatric assessments. They will be offered targeted treatments, in line with their particular limitations and treatment goals, by physiotherapists, occupational therapists, speech therapists and, if necessary, psychologists. The nursing procedures are performed according to a special concept called "activating therapeutic care". Therefore, keeping patients in strict isolation may be diametrically opposed to the treatment goals that acute geriatric medicine is striving to meet. 為了計劃患者的治療，我們每週舉行一次團隊會議，所有參與患者護理的職業團體都參加了會議。這是我們計劃治療過程的地方，討論目前需要採取的任何行動，並討論下一個時期的新治療目標。在患者住院期間，他們的治療將基於他們現有的醫療問題以及他們的老年評估結果。物理治療師、職業治療師、言語治療師以及（如有必要）心理學家將根據他們的特殊局限性和治療目標，為他們提供有針對性的治療。護理程序是根據稱為“激活治療護理”的特殊概念進行的。因此，將患者嚴格隔離可能與急性老年醫學努力實現的治療目標截然相反。So whenever a case of a multi-resistant pathogen is identified, especially in the acute geriatric clinic, the hospital's hygiene team discusses the case with the treatment team in a "hygiene consultation".⁵ 因此，每當發現具有多重耐藥性的病原體病例時，尤其是在急性老年病門診，醫院的衛生團隊都會在“衛生諮詢”中與治療團隊討論該病例。⁵

In this meeting, hygiene specialists and the treatment team can decide between them whether the individual patients with a VRE or 3MRGN infection really need to be isolated or whether they can be accommodated normally (good compliance, no acute infections with multi-resistant pathogens).^{3,4} 在這次會議上，衛生專家和治療團隊可以在他們之間決定是否真的需要隔離 VRE 或 3MRGN 感染的個體患者，或者是否可以正常安置（良好的遵守性，沒有多重耐藥病原體的急性感染）。^{3,4} If MRSA is detected, patient isolation and eradication attempts will always be initiated in MKM, but we will also highlight any ways in which those affected can still play an active part in their treatments. It is only where there is evidence of 4MRGN that therapeutic options are limited, although even in these cases we will offer as many options as possible, depending on the pathogen and where it has been located. 如果檢測到 MRSA，將始終在 MKM 中啟動患者隔離和根除嘗試，但我們還將強調受影響者仍可在其治療中發揮積極作用的任何方式。只有在有 4MRGN 證據的情況下，治療選擇是有限的，儘管即使在這些情況下，我們也會根據病原體及其所在位置提供盡可能多的選擇。

The acute geriatric clinic as a high-risk area 急性老年門診是高危地區

Generally speaking, the MKM acute geriatric clinic is classed as a high-risk hygiene area. This classification is due to patients having multi-morbidity as well as the phenomenon of immunosenescence, in which the immune system ages and the body's natural defences become less effective.⁶ 一般來說，MKM 急性老年病門診被列為高風險衛生區。這種分類是由於患者患有多种疾病以及免疫衰老現象，其中免疫系統老化並且身體的自然防禦變得不那麼有效。⁶

Outbreak prevention and management 疫情預防和管理

This predisposition to acquire pathogens and shed them over a prolonged period also necessitates targeted concepts for managing other, non-multi-resistant infectious agents, especially in relation to preventing nosocomial infections and outbreaks. In the preventive and proactive phase⁷, detecting infectious diseases early is paramount, with treatment and containment measures being introduced where there is even a suspicion of infection. This might include a new episode of diarrhoea or emesis, a new fever or an unexplained respiratory infection. If illness is confirmed, the case is critically assessed to determine whether it makes sense to isolate the patient. In our experience, where norovirus infections and influenza are detected, neighbouring patients will almost always develop the illness too, 這種獲取病原體並在很長一段時間內釋放病原體的傾向也需要有針對性的概念來管理其他非多重耐藥性感染因子，特別是在預防醫院感染和暴發方面。在預防和主動階段⁷，及早發現傳染病至關重要，甚至在懷疑感染的情況下都會採取治療和遏制措施。這可能包括新的腹瀉或嘔吐發作、新的發燒或不明原因的呼吸道感染。如果確診疾病，將對病例進行嚴格評估，以確定隔離患者是否有意義。根據我們的經驗，在檢測到諾如病毒感染和流感的地方，鄰近的患者幾乎總是會患上這種疾病，



Fig圖. 3: Therapy area for patients in the MKM acute geriatric clinic. (Photo credit: Markus Kiesel) MKM 急性老年門診患者的治療區。（圖片來源：Markus Kiesel）



Black rooms黑色房間	Symptomatic patients with (a suspected) infection 有（疑似感染的）有症狀患者
Grey rooms灰色房間	Asymptomatic contacts during the incubation time and previously sick patients who have recovered (NB: no mixing of the two groups)潛伏期內的無症狀接觸者和已康復的既往病患（註：兩組未混合）
White rooms白色房間	Can be used freely. Black rooms become white rooms again once the previously sick patients have been discharged or moved and the rooms have undergone final disinfection可以自由使用。以前的病人出院或搬移，房間經過最後的消毒後，黑房又變成白房

Tab表. 1 Isolation according to the “Dresden model”. (Source: According to Prof. Lutz Jatzwauk⁸根據 德累斯頓模式⁸進行隔離。（資料來源：根據 Lutz Jatzwauk 教授的說法⁸）

even if isolation measures are put in place immediately. This is presumably because the patient will have been shedding infectious virus particles during the preclinical phase of their illness. Neighbouring patients will therefore also need to be isolated initially until the end of the incubation time. The patient should also remain in their current treatment unit so they cannot spread pathogens around several treatment areas. Once there are two or more cases, then we enter the reactive phase⁷. 即使立即採取了隔離措施。這可能是因為患者在疾病的臨床前階段會散發傳染性病顆粒。因此，在潛伏期結束之前，也需要最初隔離鄰近的患者。患者還應該留在他們目前的治療單元中，這樣他們就不會在幾個治療區域周圍傳播病原體。一旦有兩種或兩種以上的情况，我們就進入反應階段⁷。At MKM this means we immediately convene an Outbreak Management Team (OMT) made up of members of the hospital's hygiene team and senior staff from the various occupational groups. The OMT meets on site every working day, reviews the barrier measures, trains staff and evaluates how things are progressing. Even once the patients are through the acute phase of their illness, there is still a need for further measures because the patients may continue shedding infectious pathogens for a prolonged period of time (safeguarding phase⁷). This applies to noroviruses, rotaviruses and respiratory syncytial virus, for example. In one case, on a weekend a patient was moved into the same room as another long-term in-patient whose clinical phase of a norovirus infection had ended three weeks earlier. This contact then triggered a norovirus outbreak. So at MKM we follow Prof. Jatzwauk's “Dresden model”⁸ for problem pathogens (which are usually viral) such as these. If patients have recovered from this type of illness, they nevertheless remain in a single room (or grouped with other patients who have also recovered) for the rest of their stay. This is known as a “grey room”. Only after the patient has been discharged and a final disinfection has been carried out can the room be used freely again as a “white room”. MKM has seen very good results from applying this concept and has significantly reduced the number of outbreaks experienced in its acute geriatric clinic.在 MKM，這意味著我們會立即召集一個由醫院衛生團隊成員和來自不同職業群體的高級員工組成的疫情管理團隊 (OMT)。OMT 每個工作日都會在現場開會，審查屏障措施，培訓員工並評估事情的進展情況。即使患者經歷了疾病的急性期，仍然需要採取進一步措施，因為患者可能會在較長時間內繼續排出傳染性病原體（防護階段⁷）。例如，這適用於諾如病毒、輪狀病毒和呼吸道合胞病毒。在一個案例中，在一個週末，一名患者與另一名諾如病毒感染臨床階段在三週前結束的長期住院患者被轉移到同一個房間。這種接觸隨後引發了諾如病毒爆發。因此，在 MKM，我們遵循 Jatzwauk 教授的“德累斯頓模型”⁸ 來處理諸如此類的問題病原體（通常是病毒性的）。如果患者已經從這種疾病中康復，他們仍然會在剩餘的逗留期間留在一個房間（或與其他也康復的患者分組）。這被稱為“灰色房間”。只有在患者出院並進行最後一次消毒後，房間才能再次作為“白房”自由使用。MKM 從應用這一概念中看到了非常好的結果，並顯著減少了其急性老年病診所的暴發數量。

Recording infections 記錄感染

Since, as we mentioned earlier, geriatric patients are more susceptible to infection, a hospital's infection surveillance concept should take any acute geriatric department into account. 正如我們前面提到的，由於老年患者更容易受到感染，因此醫院的感染監測概念應考慮到任何急性老年科。

At MKM, all geriatric areas are monitored from the start by recording nosocomial urinary tract infections whether they are associated with transurethral indwelling catheters or not. In previous years, there was a slight increase in the infection rate for patients in the acute geriatric clinic who had transurethral indwelling catheters fitted. And this was because MKM had introduced its “delirium-sensitive hospital” concept. 在MKM，無論是否與經尿道留置導管有關，從一開始就都通過記錄院內尿道感染來監測所有老年病區。前幾年，在急性老年病門診中安裝了經尿道留置導管的患者的感染率略有增加。這是因為 MKM 引入了“譫妄敏感醫院”的概念。

Delirium can have very serious consequences for a patient: it can cause lasting cognitive impairment, lead to a dependency on care or exacerbate existing needs, and it also increases mortality.⁹ It is therefore important to take steps to identify patients who are at risk of delirium and then act to prevent it. 譫妄會對患者產生非常嚴重的後果：它可能導致持久的認知障礙，導致對護理的依賴或現有需求的惡化，而且還會增加死亡率⁹。因此，重要的是要採取措施識別有譫妄風險的患者，然後採取行動加以預防。

One of the methods for preventing delirium at MKM involves removing the transurethral indwelling catheter (which, after all, is a foreign object) as quickly as possible during the early post-operative phase, in a bid to stop post-operative delirium developing. But with our patients it is a real balancing act to find exactly the right moment to do this. In the beginning, new transurethral indwelling catheters occasionally had to be reinserted because of urinary retention. Inserting catheters multiple times like this increased the risk of infection, which we were able to show in the infection surveillance records. The more experience we gained, the better we were able to solve this problem and bring the infection rates back down too. However, sometimes it is still necessary to reinsert a catheter, although this is now rare. Even so, we deem this to be an acceptable risk, as the consequences of post-operative delirium are much more serious and more difficult to control than a potential urinary tract infection. The latter can be largely prevented by following proper hygiene measures and practising careful catheter care or can be cured with specific treatments.在 MKM 預防譫妄的方法之一是在術後早期盡快移除經尿道留置導管（畢竟是異物），以阻止術後譫妄的發展。但對於我們的患者來說，找到正確的時機來做這件事是一種真正的平衡行為。剛開始時，偶爾會使用新的經尿道留置導管，有時不得不重新插入新的經尿道留置導管。像這樣多次插入導管會增加感染的風險，我們能夠在感染監測記錄中顯示這一點。我們獲得的經驗越多，我們就越能更好地解決這個問題並降低感染率。然而，有時仍然需要重新插入導管，儘管現在這種情況很少見。即便如此，我們認為這是可以接受的風險，因為術後譫妄的後果比潛在的尿路感染更嚴重且更難以控制。後者可以通過遵循適當的衛生措施和進行仔細的導管護理在很大程度上得到預防，或者可以通過特定的治療來治癒。



Clostridioides difficile infections (CDI) in the acute geriatric clinic
艱難梭菌感染 (CDI) 在急性老年病門診

Over the last 20 years, the issue of CDI has evolved from an exception to one of the most urgent problems in hospital hygiene¹⁰. If we take a look at the KISS data again, we can see that the incidence density of nosocomial cases is over twice as high on geriatric wards as it is on average on all wards. That said, it is rare to see a serious CDI¹. 在過去的 20 年中，CDI 問題已從一個例外發展為醫院衛生中最緊迫的問題之一¹⁰。如果我們再看一下 KISS 數據，我們可以看到，老年病房的醫院病例發病率是所有病房平均發病率的兩倍多。也就是說，很難看到嚴重的 CDI¹。

The picture at MKM is a similar one: CDI occurs frequently in the acute geriatric clinic, due to the fact that antibiotic treatments are often vital, medically appropriate and indicated. However, CDI is always detected very early on thanks to our incredibly vigilant staff and it is usually treated with antibiotics even before microbiological confirmation of CDI is received. Unlike in other clinical departments at MKM, in the acute geriatric clinic we do not treat a CDI with metronidazole to begin with; instead, we start with oral vancomycin right away. Administering this potent treatment at an early stage speeds up recovery and very often avoids serious infection. The surveillance results from the Pathogen-KISS module relating to acute geriatrics are further confirmation of this. MKM 的情況與此相似：CDI 經常發生在急性老年病門診，因為抗生素治療通常是至關重要的、醫學上合適的和有指徵的。然而，由於我們非常機警的工作人員，CDI 總是很早就被檢測到，而且通常甚至在收到 CDI 的微生物確認之前就用抗生素治療。與 MKM 的其他臨床科室不同，在急性老年科門診，我們一開始不使用甲硝唑治療 CDI；相反，我們立即開始口服萬古黴素。在早期階段進行這種有效的治療可以加快康復速度，並且通常可以避免嚴重的感染。病原體-KISS 模組與急性老年病相關的監測結果進一步證實了這一點。

The challenge of disinfection 消毒的挑戰

One final aspect we want to highlight is disinfection measures. Once again, there are special considerations that must be taken into account in our acute geriatric clinic. Where hand hygiene is concerned, the acute geriatric clinic has more patients who are unable to disinfect their hands themselves, or who are capable, but only when they are given extra guidance and reminded of what to do. It is important to have team members who are patient and have been made aware of this particular issue, so they can guide those they are treating in the direction of good hand hygiene time and time again. 我們要強調的最後一個方面是消毒措施。再一次，在我們的急性老年病門診中必須考慮到一些特殊的考慮。在手衛生方面，急診科有更多的患者不能自己消毒雙手，或者有能力，但只有在給予額外指導和提醒的情況下。重要的是要有耐心並已意識到這一特殊問題的團隊成員，這樣他們就可以一次又一次地指導他們正在接受治療的人保持良好的手部衛生。

The literature often describes **device disinfection and reprocessing** as a problem area. At MKM too, we have long wrestled with the issue of which devices it is appropriate to use from a hygiene point of view on patients who are often confined to their beds for a prolonged period of time (e.g. razors and shavers or nail care tools). But there are also pitfalls when it comes to reprocessing pressure-reducing aids, toilet seats, booster seats, walking aids and mobilisation devices: inaccessible corners, a lack of material compatibility, rapid wear and uneven or damaged surfaces can all impair reprocessing. 文獻經常將**器械消毒和再處理**描述為一個問題領域。在MKM，我們長期以來一直在努力解決從衛生的角度來看，哪些設備適合長期臥床的患者（例如刮鬍刀和剃刀或指甲護理工具）的問題。但在減壓輔助裝置、馬桶座圈、加高座椅、助行器和移動設備的後處理方面也存在缺陷：難以接近的角落、缺乏材料兼容性、快速磨損以及不平整或損壞的表面都會影響後處理。

That is why we regularly conduct unannounced inspections on all these devices and others besides. And even though everyone involved always holds their breath when these tests are carried out (hygiene specialists included!), the results are always flawless – not always a given, as we can see from other departments and the literature. 這就是為什麼我們會定期對所有這些設備和其他設備進行突擊檢查。即使在進行這些測試時，所有相關人員都屏住呼吸（包括衛生專家！），但結果總是完美無缺的——並不總是給定的，正如我們從其他部門和文獻中看到的那樣。

Surface disinfection as one aspect of barrier measures is of course an established standard in all clinical areas. But in the acute geriatric clinic this is also extended to “public” areas such as social rooms, visiting rooms and group treatment rooms (as well as any exercise equipment, like mats and balls, that are shared amongst the group, after patients have hygienically disinfected their hands). Plus there are some other very special areas in our clinic that require surface disinfection. The MKM acute geriatric clinic is on the fourth floor of the hospital and has its very own “bus stop” on site.¹¹ This stop was donated by the Mainzer Stadtwerke public utility company and effectively prevents patients who have a strong urge to move from getting away from the clinic. The bus stop also offers patients a place of refuge, since it is a familiar sight in the unfamiliar hospital setting. And because patients often sit here to calm themselves down, it too is subject to regular surface disinfection as part of routine cleaning work. 表面消毒作為屏障措施的一個方面當然是所有臨床領域的既定標準。但在急性老年病門診，這也擴展到“公共”區域，例如社交室、探視室和團體治療室（以及在患者衛生後在團體之間共享的任何運動器材，如墊子和球）消毒雙手）。此外，我們診所還有一些其他非常特殊的區域需要進行表面消毒。MKM 急性老年病門診位於醫院四樓，現場有自己的“公交站”。¹¹ 該站由 Mainzer Stadtwerke 公共事業公司捐贈，有效防止有強烈搬家衝動的患者遠離診所。公共汽車站還為患者提供了一個避難所，因為這是在陌生的醫院環境中熟悉的景象。而且由於患者經常坐在這裡讓自己平靜下來，因此作為日常清潔工作的一部分，它也需要定期進行表面消毒。



Figure 4: Bus stop 4C for patients in the MKM acute geriatric clinic. (Photo credit: Markus Kiesel)





Fig. 5: A sample from the exhibition “Den Faden verlieren – Kunst trifft Demenz” [“Losing your thread – Where art meets dementia”]. (Photo credit: Marie-Luise Anten-Dittmar¹²展覽“Den Faden verlieren – Kunst trifft Demenz” [失去你的線索 – 藝術與癡呆症相遇的地方]的樣本。(圖片來源: Marie-Luise Anten-Dittmar¹²)

Pictures brighten up the corridors in all the wards at MKM. These might be high-quality photographs of Mainz and the surrounding area or perhaps art prints. But what is really special about the acute geriatric clinic is that it has a permanent art exhibition on the subject of dementia displayed on its walls. These are works made of fabric, thread and wood, which were created by artist Marie-Luise Anten-Dittmar together with patients who have dementia. 圖片照亮了 MKM 所有病房的走廊。這些可能是Mainz和周邊地區的高質量照片，也可能是藝術版畫。但是，這家急性老年病診所的真正特別之處在於，它的牆上有一個關於癡呆症的永久性藝術展覽。這些是由藝術家Marie-Luise Anten-Dittmar 與患有癡呆症的患者共同創作的由織物、線和木頭製成的作品。

The works are displayed along with quotes about their illness from those involved in the project¹². 這些作品與參與該項目的人有關他們疾病的引述一起展出¹²。

When decisions were being made around this project, there were concerns about whether it would be possible to hang these works of art in the corridors of an acute hospital. Of course, the hospital's hygiene team supported the ward when it came to these issues: from our perspective, there was no risk of infection from a work of art hanging on a wall. And so the very moving exhibition “Den Faden verlieren – Kunst trifft Demenz” [“Losing your thread – Where art meets dementia”] can now be viewed in the MKM acute geriatric clinic on a permanent basis. 當圍繞這個項目做出決定時，人們擔心是否有可能將這些藝術品掛在急症醫院的走廊裡。當然，在這些問題上，醫院的衛生團隊支持病房：在我們看來，掛在牆上的藝術品沒有感染風險。因此，非常感人的展覽“Den Faden verlieren – Kunst trifft Demenz” [“Losing your thread – 藝術與癡呆症相遇的地方”] 現在可以在 MKM 急性老年病診所永久觀看。

Conclusion 結論

Generally speaking, the hygiene requirements and regulations that apply in an acute geriatric unit are no different to those in other clinical areas. That said, in this area more than any other, the requirements must be adapted to the specific situation on site, to the individual needs of patients, and to the conditions necessary for effective complex geriatric treatment – and all that without compromising hygienic safety. 一般來說，適用於急性老年病房的衛生要求和規定與其他臨床領域的衛生要求和規定沒有什麼不同。也就是說，在這一領域中，要求必須適應現場的具體情況、患者的個人需求以及有效的複雜老年病治療所需的條件——所有這些都不能影響衛生安全。

This called for the acute geriatrics therapeutic team and the hospital's hygiene team to work closely together in a spirit of trust. In the 15 years since the acute geriatric clinic has been up and running at MKM, this collaborative approach has really proved its worth and is appreciated by both sides. This successful partnership has also led to a number of projects and insights (such as the MRSA full screening programme and the Dresden model) finding their way into the clinical routine throughout MKM. 這需要急性老年病治療團隊和醫院的衛生團隊本著信任的精神密切合作。自 MKM 的急性老年病診所成立並運行 15 年來，這種合作方式確實證明了它的價值，並得到雙方的讚賞。這種成功的合作夥伴關係還促成了許多項目和見解（例如 MRSA 全面篩查計劃和 Dresden 模型）在整個 MKM 中找到了進入臨床常規的途徑。

So in this way, the acute geriatric clinic is not only creating medical added value for the ageing population of its Rhine-Main catchment area, it is also improving the quality of treatments and increasing patient safety in all departments throughout MKM. 因此，通過這種方式，急性老年病診所不僅為其Rhine-Main河集水區的老齡化人口創造了醫療附加價值，而且還提高了整個 MKM 各科室的治療質量和患者安全。

Literature references 文獻參考:

1. Pathogen surveillance in the STATIONS-KISS module – reference data; German National Reference Center for Surveillance of Nosocomial Infections (NRZ); 16 June 2021; https://www.nrz-hygie-ne.de/fileadmin/nrz/module/station/erreger/201601_202012_STATION_ALL_MRECDADRef.pdf.
2. Evaluation eines MRSA-Vollscreenings in einer deutschen Schwerpunkt-klinik [Evaluation of an MRSA full screening programme at a German Level II hospital]; Kiesel, Markus; Holz, Hubert; aseptica 2019; 25 (4): [6–11].
3. Maßnahmen bei MRGN auf Station in Abhängigkeit von individuellen Faktoren [Measures for dealing with MRGN on the ward based on individual factors]; Kiesel, Markus; Holz, Hubert; aseptica 2018; 24 (3): [15–19].
4. Hygienemanagement bei multi-resistenten Enterokokken [Hygiene management with multi-resistant enterococci]; Holz, Hubert; Kiesel, Markus; Kiesel, Heike; aseptica 2020; 26 (3): [14–17].
5. Das Konzept Hygiene-Konsile am kkm [The hygiene consultation concept at kkm]; Holz, Hubert; Kiesel, Markus; Kiesel, Heike; aseptica 2020; 26 (1): [9–13].
6. Das alternde Immunsystem [The ageing immune system]; Djukic, Marija; Nau, Roland; Sieber, Cornelia; Dtsch Med Wochenschr 2014; 139: 1987–1990.
7. Ausbruchmanagement und strukturiertes Vorgehen bei gehäuftem Auftreten nosokomialer Infektionen [Outbreak management and a structured approach to the frequent occurrence of nosocomial infections]; Commission for Hospital Hygiene and Infection Prevention (KRINKO); German Federal Health Bulletin 2002; 45 (2): [180–186].
8. Die Vorteile des “Dresdner Modells zur Isolation” [The benefits of the “Dresden isolation model”]; Kiesel, Markus; Holz, Hubert; aseptica 2018; 24 (1): [9–13].
9. Delir im Krankenhaus [Delirium in hospitals]; Zorremba, Norbert; Coburn, Mark; Dtsch Arztebl 2019; 116 (7): [101–106]; DOI: 10.3238/arztebl.2019.0101.
10. 15 Jahre CDI-Surveillance im Marienhaus Klinikum Mainz [15 years of CDI surveillance in the Marienhaus Klinikum Mainz]; Holz, Hubert; Kiesel, Heike; Kiesel, Markus; aseptica 2021; 27 (2): [13–15].
11. Nächster Halt, Station 4CD. Ein Halt für Menschen mit Demenz [Next stop: Ward 4CD. Bus stop for dementia patients]; Marienhaus Klinikum Mainz; 19.09.2021; https://www.marienhaus-klinikum-mainz.de/startseite/einzelmeldungen-1?tx_ttnews%5Btt_news%5D=9875&cHash=c9bc59e13b6565ba63d754ab665db470.
12. Den Faden verlieren [Losing your thread]; Marie-Luise Anten-Dittmar; 17.01.2018; <https://alzheimer.ch/de/gesellschaft/deutschland/magazin-detail/301/den-faden-verlieren/>.



New preparation system for the nitrous oxide sedation

Miele

From early 2022 onwards, Miele will be offering a space-saving solution for the reprocessing of the hoses and accessories used in nitrous oxide sedation:

A new system which accommodates up to five hoses. The hoses are connected using adapters to the injector nozzles in the slightly inclined holder and routed past the other inserts. This ensures reliable cleaning and drying of all internal and external surfaces, leaving sufficient space for lumened items, e.g. transmission instruments, and further instruments in the same cycle.

Hence, this approach does not interfere with general re-processing.

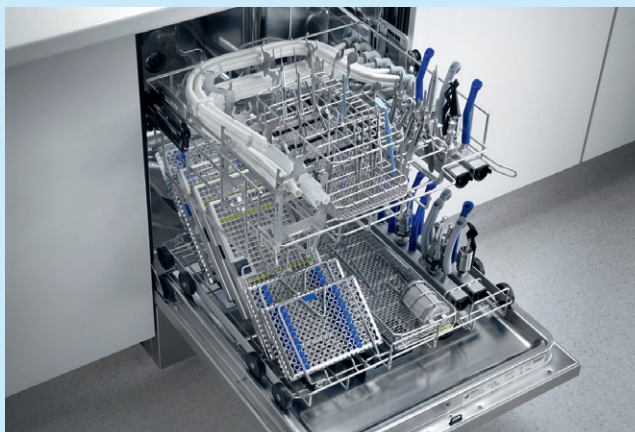


Fig. 1: A 105/1 upper basket with new reprocessing system for APWD 325 nitrous oxide sedation components.

We train competence!

我們培養能力！

-ebro-
a xylem brand



LIVE Webinars
現場網絡研討會



Seminars in the
KompetenzCenter,
Ingolstadt

在Ingolstadt能力中心研討會

More knowledge means more success. 更多的知識意味著更多的成功。 We cordially invite you to our seminars and webinars, where we answer all questions relevant to you as an expert in the field of medical technology. Always stay up to date with the latest knowledge and benefit from the expertise of our speakers in the individual specialist areas. 我們誠摯地邀請您參加我們的研討會和網絡研討會，作為醫療技術領域的專家，我們將回答與您相關的所有問題。始終了解最新知識，並從我們的演講者在各個專業領域的專業知識中受益。

Are you interested in the continuing education pro-gram? Then use the two QR codes and you will certainly find the seminar or webinar for you. 您對繼續教育計劃感興趣嗎？然後使用這兩個二維碼，您一定會找到適合您的研討會或網絡研討會。

NEW新消息: Validation seminars in cooperation with 驗證研討會將與合作: FHT Fachschule für Hygienetechnik/ Desinfek-toren-schule Mainz together with the bbw Bildung-swerk der Wirtschaft in Berlin und Brandenburg e.V., Potsdam.
FHT 衛生技術技術學校/美因茨消毒學校與柏林的 bbw Bildungswerk der Wirtschaft 和波茨坦的勃蘭登堡 e.V. 一起。

Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time

蒸汽滅菌測量的參數發布 參數：溫度、蒸汽組成和時間

Authors 作者們

René Koster

Onze Lieve Vrouwe Gasthuis

location west

Jan Tooropstraat 164, 1061 AE Amsterdam,

The Netherlands

Ralph A.C. van Wezel

Catharina Hospital

Michielangelolaan 2, 5623 EJ Eindhoven,

The Netherlands

Josephus P.C.M. van Doornmalen

Technische Universiteit Eindhoven

Department of Applied Physics,

PO Box 513

5600 MB Eindhoven the Netherlands

René Koster, Ralph A.C. van Wezel, Josephus P.C.M. van Doornmalen

Summary 概要

Background 背景: With the current methods specified in standards, not all the steam sterilisation conditions as specified in standards can be guaranteed in every steam sterilisation process. 使用標準中規定的現行方法，並非在每次蒸汽滅菌過程中都可以保證標準中規定的所有蒸汽滅菌條件。

Aim 目標: Find an easy way to implement a method to monitor steam sterilisation in every steam sterilisation process, as specified in the standards. 根據標準中的規定，找到一種簡單的方法來實施一種方法來監控每個蒸汽滅菌過程中的蒸汽滅菌。

Method 方法: Identify a method that can be used in every steam sterilisation process to determine the steam sterilisation conditions in the sterilizer chamber. 確定可用於每個蒸汽滅菌過程的方法，以確定滅菌室中的蒸汽滅菌條件。

Apply this method in the practice of a Central Sterile Supply Department. 在中央無菌供應部門的實踐中應用這種方法。

Conclusion: With the identified method the steam sterilisation conditions can be determined in every steam sterilisation process. The method is evidence based and easy to implement in the workflow of a Central Sterile Supply Department (CSSD). 結論：通過確定的方法，可以確定每個蒸汽滅菌過程中的蒸汽滅菌條件。該方法以證據為基礎，易於在中央無菌供應部門 (CSSD) 的工作流程中實施。

Introduction 介紹

Before use in surgery invasive medical instruments have to be sterilized. The most applied method of sterilization in health care facilities is steam sterilisation. Steam sterilisation conditions are detailed in the literature^{1, 2, 3} and include the temperature, steam composition and time. Unfortunately the steam composition is not quantitatively specified in the literature. This is resolved in standards^{4, 5} by detailing the amount of Non Condensing Gases (NCG) in the steam with 3.5 ml NCGs in 100 ml condensate⁴ which equals 3.5 % VNCGs/V100 ml condensate.

在手術中使用侵入性醫療器械之前，必須對它們進行消毒。在醫療保健設施中應用最多的滅菌方法是蒸汽滅菌。蒸汽滅菌條件詳見文獻^{1, 2, 3}，包括溫度、蒸汽成分和時間。不幸的是，文獻中沒有對蒸汽成分進行定量說明。這在標準^{4, 5}中通過詳細說明蒸汽中非冷凝氣體 (NCG) 的量得到解決，其中 3.5 毫升 NCG 在 100 毫升冷凝水中⁴等於 3.5 % VNCG/V100 毫升冷凝水。The origin from this amount of NCGs comes from the early period of standard development in the 1960s. At that time no methods were available to measure the steam composition or NCGs in the steam sterilizer chamber. Therefore a method was developed to measure the 'steam quality' in the steam supply line near to the sterilizer chamber. 如此數量的 NCG 來源於 1960 年代標準制定的早期階段。當時沒有可用的方法來測量蒸汽滅菌室中的蒸汽成分或 NCG。因此，開發了一種方法來測量靠近滅菌室的蒸汽供應管線中的“蒸汽質量”。

This method is described in the standard⁴ but has several disadvantages. One of the disadvantages is presented in a note of the 13.3.1 in the standard EN285:2015+A1:2021⁴: “This method does not necessarily express the true content of NCG in steam. The limiting value was defined experimentally in the 1960s in relation to the sensitivity of air detectors commonly used in the UK at that time. Repeated measurements give an idea of the true picture of NCGs in the steam supply”. 該方法在標準中有所描述⁴，但有幾個缺點。缺點之一在標準 EN285:2015+A1:2021⁴ 中的 13.3.1 的註釋中提出：“這種方法不一定表示蒸汽中 NCG 的真實含量。極限值是在 1960 年代根據當時英國常用的空氣探測器的靈敏度通過實驗確定的。重複測量可以了解蒸汽供應中 NCG 的真實情況”。A second disadvantage is that the thermodynamic conditions in the steam supply line differ from the thermodynamic conditions inside a sterilizer chamber. For example, in the steam supply the pressure is higher than in the chamber and relative to the steam in the steam supply line, the steam is not moving in the sterilizer chamber. Especially not in the holding phase, the actual steam sterilisation period of a process. A third disadvantage is that these steam measurements are taken at an arbitrary moment in time while it is known that the steam composition in steam supply (line), and therefore in the chamber, vary over the day. The variation in NCGs in steam makes that every steam sterilization process is a unique event.^{6, 7, 8} This makes it also necessary to monitor or more precise, to determine the steam composition of the NCG amount in every process in the sterilizer chamber. 第二個缺點是蒸汽供應管線中的熱力學條件與滅菌室內的熱力學條件不同。例如，蒸汽供應中的壓力高於腔室中的壓力，並且相對於蒸汽供應管線中的蒸汽，蒸汽在滅菌器腔室中不移動。特別是在保持階段，一個過程的實際蒸汽滅菌期。第三個缺點是這些蒸汽測量是在任意時刻進行的，而已知蒸汽供應 (管線) 中的蒸汽成分，因此室內的蒸汽成分在一天中發生變化。蒸汽中 NCG 的變化使得每個蒸汽滅菌過程都是一個獨特的事件。^{6, 7, 8} 這使得還需要監控或更精確地確定滅菌室中每個過程中 NCG 量的蒸汽成分。

In some countries it is suggested to use the measured temperature and a theoretical temperature calculated out of the pressure to determine the steam composition. This is not a valid method.^{9, 10, 11} With use of physical laws this can be and is written out and available on the internet. For example on the website of the Dutch sterilisation association SVN.¹² 在一些國家，建議使用測量溫度和根據壓力計算得出的理論溫度來確定蒸汽成分。這不是一個有效的方法。^{9, 10, 11} 通過使用物理定律，這可以並且被寫出來並在網際網路上提供。例如在荷蘭滅菌協會 SVN.¹² 的網站上。

In the here reported study a method has been identified with which the NCGs in every process are quantitatively measured in the chamber of a steam sterilizer and in each process. With the identified method the steam composition can be determined. Together with the temperature and the time of the holding phase the steam sterilisation conditions as specified in the literature³ and standard⁴ can be determined in every steam sterilisation process. This increases the safety of sterilisation for patients and staff drastically. 在這里報道的研究中，已經確定了一種方法，該方法在蒸汽滅菌器的腔室和每個過程中定量測量每個過程中的 NCG。使用確定的方法，可以確定蒸汽成分。連同保溫階段的溫度和時間，可以在每個蒸汽滅菌過程中確定文獻³和標準⁴中規定的蒸汽滅菌條件。這大大提高了患者和工作人員的滅菌安全性。



Several methods to determine composition of the steam in the steam sterilisation chamber were identified. Methods with chemical and biological indicators were found not suitable, for example because they depend on subjective human interpretation of colour changes or were not accurate enough.¹³ Also transferring the results to a subjective quantitative result appeared challenging. 確定了幾種確定蒸汽滅菌室中蒸汽成分的方法。使用化學和生物指示劑的方法被發現不合適，例如因為它們依賴於人類對顏色變化的主觀解釋或不夠準確。¹³ 將結果轉換為主觀定量結果似乎也具有挑戰性。

Three methods were identified that make use of the physical properties of present gases. E.g., water in vapor state can condense in the pressure and temperature range of steam sterilization, while the so called non condensing gases cannot condense in these ranges. The two further studied methods were the 3M ETS (3M™, Neuss, Germany)¹⁴ and the SolidToo NCG-sensor (SolidToo B.V., Veldhoven, the Netherlands).¹⁵ 確定了三種利用現有氣體物理特性的方法。例如，蒸汽態的水在蒸汽滅菌的壓力和溫度範圍內可以冷凝，而所謂的非冷凝氣體則不能在這些範圍內冷凝。進一步研究的兩種方法是3M ETS (3MTM, Neuss, 德國)¹⁴ 和 SolidToo NCG 傳感器 (SolidToo B.V., Veldhoven, 荷蘭)¹⁵。

The SolidToo NCG sensor was chosen because of the easiness of use. E.g., the NCG sensors are calibrated, provide quantitative results for the actual steam sterilisation conditions temperature, steam composition (or NCG amount) and time, do not need human interpretation or handling, and, in each process the steam sterilisation conditions (temperature, NCGs and time of the holding phase) are measured in the sterilizer chamber and reported in an Every Load Monitoring (ELM) protocol. On the web-site of the NCG sensor the working principle is further described¹⁵ and the calibration method of the NCG-sensor is specified in the literature.¹⁶ An additional advantage is that this method is retrofittable on all steam sterilizers with a port to introduce probes into the steam sterilizer chamber⁴, in daily practice often referred to as validation port. 選擇 SolidToo NCG 傳感器是因為它易於使用。例如，校準 NCG 傳感器，提供實際蒸汽滅菌條件溫度、蒸汽成分（或 NCG 量）和時間的定量結果，不需要人工解釋或處理，並且在每個過程中蒸汽滅菌條件（溫度、NCG和保持階段的時間）在滅菌室中測量，並在每個負載監測 (ELM) 協議中報告。在 NCG 傳感器的網站上，進一步描述了工作原理¹⁵，文獻中詳細說明了 NCG 傳感器的校準方法。¹⁶ 另一個優點是該方法可在所有帶有端口的蒸汽滅菌器上進行改裝，以引入探針進入蒸汽滅菌器室⁴，在日常實踐中通常稱為驗證端口。

On the four new steam sterilizer of the Onze Lieve Vrouwe Gasthuis (OLVG) location west (Amsterdam, the Netherlands) NCG-sensors were installed. The sterilizers have passed a Performance Qualification according EN285:2015+A1:2021⁴ and ISO17665:2006¹⁰ with a good result before going into production. 在 Onze Lieve Vrouwe Gasthuis (OLVG) 西區（荷蘭阿姆斯特丹）的四台新蒸汽滅菌器上安裝了 NCG 傳感器。滅菌器在投入生產前通過了符合 EN285:2015+A1:2021⁴ 和 ISO17665:2006¹⁰ 的性能鑑定，效果良好。

After identifying the criteria to meet had to be worked out. The steam sterilisation parameters temperature, steam composition and time are the sterilization parameter.³ According to the literature the pressure is not a steam sterilisation parameter. When using the EN285:2015+A1:2021⁴ the criteria for the steam sterilisation become: 在確定了要滿足的標準之後，必須制定出來。蒸汽滅菌參數溫度、蒸汽成分和時間是滅菌參數。³ 根據文獻，壓力不是蒸汽滅菌參數。使用 EN285:2015+A1:2021⁴ 時，蒸汽滅菌的標準變為：

- The steam penetration capacity of a process has to be sufficient for the loads that are processed. 過程的蒸汽滲透能力必須足以處理所處理的負載。
- In every process the steam sterilisation parameters for the holding phase have to be defined, e.g. a 134 °C steam sterilisation process: 在每個過程中，必須定義保持階段的蒸汽滅菌參數，例如：134 °C 蒸汽滅菌過程：

$$\left\{ \begin{array}{l} 134^{\circ}\text{C} \leq T \leq 137^{\circ}\text{C} \\ \square \quad \square \quad \text{NCG} \leq 3.5\% \frac{V_{\text{NCGs}}}{V_{100\text{ ml condensate}}} \\ \square \quad \square \quad t \geq 180\text{ s} \end{array} \right. \quad (1)$$

- After the process has ended the load has to be dry. 在該過程結束後，負載必須乾燥。

The pressure is not a sterilization parameter. It is a parameter to control the process. However it is mentioned in the standard and therefore it was monitored and judged in the NCG-software. Out of the pressure the theoretical temperature was calculated and judged to the temperature bands specified in the standard.⁴ 壓力不是滅菌參數。它是控制過程的參數。然而，標準中提到了它，因此在 NCG 軟件中對其進行了監控和判斷。根據壓力計算理論溫度並根據標準規定的溫度範圍進行判斷。⁴

Because these criteria cannot be measured on all locations in every steam sterilisation process that is ran, the conditions should be measured as good as possible during Performance Qualification (PQ).^{4, 10} As a consequence it is necessary that during the PQ the combinations of the sterilizer, process, load, loading pattern (including position^{17, 18}) and sterile barrier that would be used in the daily production, are measured and confirmed that the sterilization criteria are met. Once this is established, it is necessary to ensure that similar conditions are present in each process with the qualified combinations. In the standard⁴ accuracies for measurements are specified, e.g., the accuracy for temperature an accuracy of 0.5 K (or °C) is specified. To ensure to comply with this standard⁴ that would mean that the indicated value of the temperature has to be within: the specifications in the standard⁴ are met within the accuracies of the standard⁴. 因為這些標準不能在每個運行的蒸汽滅菌過程中的所有位置都測量，所以在性能確效 (PQ) 期間應盡可能好地測量條件。^{4, 10} 因此，在 PQ 期間有必要將以下各項的組合測量將在日常生產中使用的滅菌器、過程、負載、裝載模式（包括位置¹⁷⁻¹⁸）和無菌屏障，並確認符合滅菌標準。一旦確定了這一點，就必須確保在每個具有合格組合的過程中都存在類似的條件。在標準中規定了測量精度，例如，溫度精度規定為 0.5 K（或 °C）。為確保符合該標準⁴，這意味著溫度的指示值必須在以下範圍內：標準⁴ 中的規格在標準⁴ 的精度範圍內得到滿足。

$$\left\{ \begin{array}{l} 134 + 0.5^{\circ}\text{C} \leq T \leq 137 - 0.5^{\circ}\text{C} \\ \square \quad \square \quad \Leftrightarrow \quad \square \quad \square \\ 134.5^{\circ}\text{C} \leq T \leq 136.5^{\circ}\text{C} \end{array} \right. \quad (2)$$

This means also that when the temperature indication indicate: 這也意味著當溫度指示器指示:

$$\left\{ \begin{array}{l} 133.5^{\circ}\text{C} \leq T < 134.5^{\circ}\text{C} \\ \square \quad \square \quad \text{and} \quad \square \quad \square \\ 136.5^{\circ}\text{C} < T \leq 137.5^{\circ}\text{C} \end{array} \right. \quad (3)$$



When the temperature is in the range 當溫度在範圍內時:

$$\begin{cases} T < 133.5\text{ }^{\circ}\text{C} \\ \square \text{ or } \square \\ T > 137.5\text{ }^{\circ}\text{C} \end{cases}, \quad (4)$$

the temperature does certainly not meet the standards. In Figure 1 the equations the temperature criteria are graphically presented.

The steam composition is a steam sterilisation parameter according to the literature and the standards.^{3, 4, 5, 10} Steam exists out of water in the gas state (also reported as the Water Vapour Fraction (WVF)⁷) and the NCGs, hence: 溫度肯定不符合標準。在圖 1 中，溫度標準的方程以圖形方式呈現。

根據文獻和標準，蒸汽成分是蒸汽滅菌參數。3, 4, 5, 10 蒸汽以氣態存在於水中（也報告為水蒸氣分率 (WVF)⁷）和 NCG，因此：

$$100\% \text{ GAS (steam)} = X\% \text{ WVF} + Y\% \text{ NCGs.} \quad (5)$$

氣體 (蒸汽) 水蒸氣分率 (WVF) 非冷凝氣體 (NCG)

Therefore it is also possible to measure and determine the NCGs in the steam to qualify the steam composition. 因此，也可以測量和確定蒸汽中的 NCG 來確定蒸汽成分。

In the EN285:2015+A1:2021⁴ a method to measure the NCGs is specified. When the accuracies of the methods are used, the criteria for the NCGs (expressed in $V_{NCGs}/V_{100 \text{ ml condensate}}$) can be calculated. This is written out in reference¹⁶ and demonstrates that the 3.5 % are certainly not met when: 在 EN285:2015+A1:2021⁴ 中指定了一種測量 NCG 的方法。當使用這些方法的準確性時，可以計算 NCG 的標準（以 $V_{NCG}/V_{100 \text{ ml 冷凝水}}$ 表示）。這寫在參考文獻 16 中，表明在以下情況下肯定不滿足 3.5%：

$$NCGs \geq 4.3\% \quad (6)$$

When the NCG value is 當 NCG 值為:

$$2.8\% \leq NCGs \leq 4.3\% \quad (7)$$

the standard is met but the value is within the allowed accuracies of the standard 符合標準，但數值在標準允許的精度範圍內。⁴

When the value 當數值:

$$NCGs < 2.8\%.$$

The criteria for NCGs is certainly met. NCG 的標準肯定符合。

In Figure 1 the equations the NCG criteria are graphically presented. 在圖 1 中，以圖形方式顯示了 NCG 標準的方程。

Results 結果

In this study the results of the NCG-sensor-configuration on the four steam sterilizers (OLVG1 to OLVG4) located in the CSSD of the OLVG hospital (Amsterdam, the Netherlands) in the period from 11 October 2021 to 09 December 2021 are reported. In Table 1 a summary of the processes ran in this period on these sterilizers is presented. The table shows that the number of fail processes vary from 0 (OLVG4) to 20 % (OLVG3). This was not expected because the steam sterilizers are from the same brand and the same type, they were new, have passed the Performance Qualification according to EN285:2015+A1:2021⁴ and ISO17665:2006¹⁰. The brand and type of the steam sterilizers are not detailed because it does not add information for the reader of this study. 在本研究中，報告了 2021 年 10 月 11 日至 2021 年 12 月 9 日期間位於 OLVG 醫院（荷蘭阿姆斯特丹）的 CSSD 的四個蒸汽消毒器（OLVG1 至 OLVG4）的 NCG 傳感器配置結果。在表 1 中，列出了在此期間在這些滅菌器上運行的過程的摘要。該表顯示失敗過程的數量從 0 (OLVG4) 到 20 % (OLVG3) 不等。這是出乎意料的，因為蒸汽滅菌器來自同一品牌和同一類型，它們是新的，已通過 EN285:2015+A1:2021⁴ 和 ISO17665:2006¹⁰ 的性能認證。蒸汽消毒器的品牌和類型沒有詳細說明，因為它沒有為本研究的讀者添加信息。

Results per sterilizer and per process type are presented in Table 2. The results in this table indicate that the result of a steam penetration test (Bowie and Dick test) has no relation with the results of the production processes, 134 °C standard process 每個滅菌器和每個過程類型的結果列於表 2。該表中的結果表明蒸汽滲透測試（Bowie 和 Dick 測試）的結果與生產過程的結果無關，134 °C 標準過程

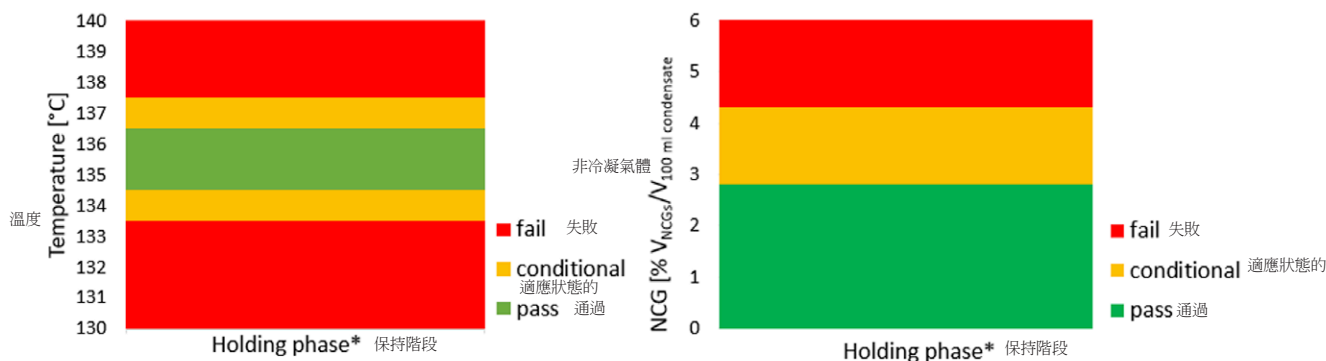
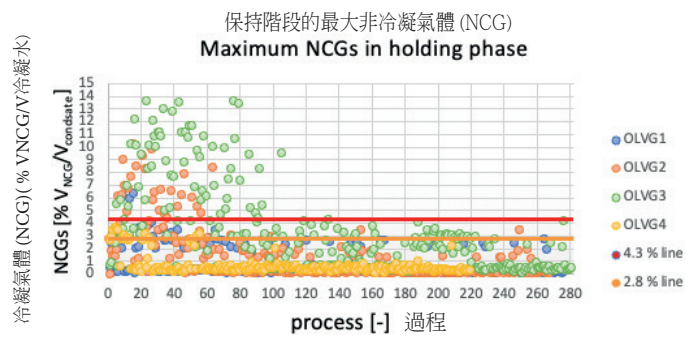
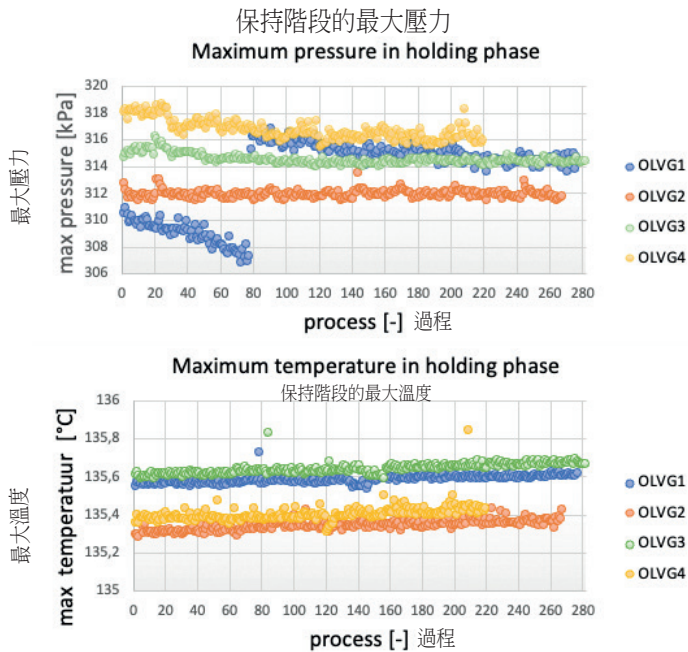


Fig 圖 1: Graphical presentation of criteria for 134 °C steam sterilization process with accuracies for temperature and NCGs. in the holding phase in the chamber according to the standard.⁴ To guarantee steam sterilisation conditions according to the standard⁴ the trace of the temperature and of NCGs have to lay in the green area. When one or both go through the orange area the process is still a pass but is in the accuracies of the standard.⁴ When one or both traces go through the red areas the process does not comply with the criteria in the standard⁴ and is qualified as a fail process. 圖形表示 134 °C 蒸汽滅菌過程的標準，具有溫度和 NCG 的準確性。根據標準，在腔室中的保持階段。⁴ 為保證蒸汽滅菌條件符合標準⁴，溫度和 NCG 的跡線必須放在綠色區域。當一條或兩條跡線通過橙色區域時，該過程仍然是通過，但符合標準的精度。⁴ 當一條或兩條跡線通過紅色區域時，該過程不符合標準中的標準⁴ 並被認定為一個失敗的過程。





Fig圖. 2: Maximum values of pressure, temperature and None Condensing Gases (NCGs) in the holding phase of the 134 °C process of the 4 steam sterilizers of the OLVG in the period from 11 October 2021 to 09 December 2021. In the NCG-graph NCG values below the orange horizontal line fulfil the criteria for steam sterilisation in the standard⁴. When the value of the NCGs is between the red and orange horizontal line the values are within the accuracy in the standard⁴. When the value is above the specification in the standard⁴ are not met. 2021年10月11日至2021年12月9日期間，OLVG的4台蒸汽滅菌器在134度C過程的保持階段的壓力、溫度和無冷凝氣體 (NCG) 的最大值。在 NCG 中- 橙色水平線下方的 NCG 值符合標準中的蒸汽滅菌標準⁴。當 NCG 的值介於紅色和橙色水平線之間時，該值在標準的精度範圍內⁴。當值高於標準⁴中的規範時，不符合。

In Figure 2 the maximum pressure, temperature, NCGs in the holding phase from the 4 steam sterilizers are presented. As mentioned above, the pressure is not a sterilization parameter but is mentioned in the standard⁴. In the pressure values of OLVG1 a 'step' or shift in pressure is made at process number 80. When it was investigated what happened it appeared that the pressure control sensor was recalibrated. However, this step does not occur in the temperatures of this sterilizer. This is another indication that with measuring steam pressure the composition of steam cannot be determined. 圖 2 顯示了 4 個蒸汽滅菌器在保持階段的最大壓力、溫度和 NCG。如上所述，壓力不是滅菌參數，而是在標準中提及⁴。在 OLVG1 的壓力值中，在過程編號 80 處進行了“步進”或壓力變化。當調查發生的情況時，似乎重新校準了壓力控制傳感器。但是，此步驟不會在此滅菌器的溫度下發生。這是另一個跡象，表明通過測量蒸汽壓力無法確定蒸汽的成分。

The most interesting graph in this Figure 2 is the graph with the results of the NCGs in each process. An important result is that in each process the amount of NCGs is different. Further it is interesting that in the first approximately 80 to 90 production processes the variation of the NCGs is larger than after this period. Especially for the sterilizer OLVG3. The results indicate that until the 80-90th process the steam supply for the sterilizers was not the same as after these 80-90 processes. 圖 2 中最有趣的圖表是每個過程中 NCG 結果的圖表。一個重要的結果是，在每個過程中，NCG 的數量是不同的。此外，有趣的是，在最初的大約 80 到 90 個生產過程中，NCG 的變化比這個時期之後的要大。特別是對於滅菌器 OLVG3。結果表明，在第 80-90 道過程之前，滅菌器的蒸汽供應與在這 80-90 道過程之後不同。

A closer look to the pressure and temperature values may indicate a small drift in these measurements. The observed drifts are well within the specifications of the standard⁴. 仔細觀察壓力和溫度值可能表明這些測量值存在小的漂移。觀察到的漂移完全符合標準的規範⁴。

Approximately at the same time that the step in the pressure of the OLVG3 steam sterilizer occurred, the quality of the steam became better. NCGs values went down. From that moment onwards almost no fail processes have been observed. 大約在 OLVG3 蒸汽滅菌器的壓力階躍發生的同時，蒸汽的質量變得更好。NCG 值下降。從那一刻起，幾乎沒有觀察到失敗過程。

蒸汽滅菌器	OLVG1		OLVG2		OLVG3		OLVG4	
Processes過程	[-]	[%]	[-]	[%]	[-]	[%]	[-]	[%]
Total	338	100	326	100	345	100	283	100
Pass	249	74	273	84	197	57	265	94
Conditional	85	25	25	8	77	22	16	6
Fail	3	1	27	8	69	20	0	0
Unidentified	0	0	0	0	1	0	0	0
Fragmented	0	0	0	0	0	0	0	0
Aborted	1	0	1	0	1	0	2	1

Tab表. 1: Summary of the processes and their results in the period from 11-10-2021 to 09-12-2021 of the sterilizer OLVG1 to OLVG4. The processes include the air leakage test (vacuum leakage test), steam penetration test and 134 °C standard process. The differences in the number of fails between steam sterilizers demonstrate that every steam sterilizer is a unique device. 滅菌器 OLVG1 至 OLVG4 在 2021 年 11 月 10 日至 2021 年 9 月 12 日期間的過程及其結果摘要。過程包括漏氣測試（真空洩漏測試）、蒸汽滲透測試和 134 °C 標準過程。蒸汽滅菌器之間故障次數的差異表明，每台蒸汽滅菌器都是獨一無二的設備。



Discussion 討論

Although the sterilizers OLVG1 to OLVG4 are similar sterilizers the results of process differ drastically. This demonstrates that every steam sterilizer is a unique device. Furthermore this stresses the necessity to measure and judge the steam sterilisation parameters, temperature, steam composition (or NCGs) during holding time in each process. 儘管滅菌器 OLVG1 到 OLVG4 是相似的滅菌器，但過程結果卻大不相同。這表明每台蒸汽滅菌器都是獨一無二的設備。此外，這強調了在每個過程的保持時間內測量和判斷蒸汽滅菌參數、溫度、蒸汽成分（或 NCG）的必要性。

The fact that no relation has been found between the results of steam penetration tests and the actual production processes makes it doubtful if a steam penetration test provides additional information. 蒸汽滲透測試的結果與實際生產過程之間沒有發現相關性的事實使得蒸汽滲透測試是否提供額外信息令人懷疑。

The reason why the NCGs are measured in the supply line is because in the 1960s no methods were available to measure NCGs in the sterilizer chamber. The NCGs or steam composition in the steam sterilizer is essential, as reported in the literature^{7, 8} and again demonstrated in this study applied method with the NCG-sensor the pressure was reported, even though it is not steam sterilisation parameter. 在供應線中測量 NCG 的原因是因為在 1960 年代沒有可用的方法來測量滅菌室中的 NCG。蒸汽滅菌器中的 NCG 或蒸汽成分是必不可少的，正如文獻 7、8 中所報導的那樣，並且在本研究中再次證明了使用 NCG 傳感器的方法報告了壓力，即使它不是蒸汽滅菌參數。

The pressure is used to control the sterilizer process. The advantage to report the pressure is that it makes it easy to recognise the sterilisation process and its phases. However, it is advised to not use the pressure in the judgement of a steam sterilisation process. 壓力用於控制滅菌過程。報告壓力的優點是可以輕鬆識別滅菌過程及其階段。但是，建議不要在蒸汽滅菌過程的判斷中使用壓力。

In the Figure 2, a step can be observed in the pressure of the steam sterilizer OLVG 1 It is not yet clear where the drift comes from, from the sensors of the steriliser or from the independent pressure and temperature measurements of the NCG-sensor system. It has to be remarked that this kind of trend information on sensors in steam sterilizers is not found in the literature by the authors. However, these result demonstrate again that Every Load Monitoring of the steam sterilisation parameters is essential to guarantee steam sterilization conditions. 在圖 2 中，可以觀察到蒸汽滅菌器 OLVG 1 的壓力的一個階躍。目前尚不清楚漂移來自何處，來自滅菌器的傳感器或來自 NCG 傳感器系統的獨立壓力和溫度測量值。需要說明的是，作者在文獻中沒有發現這種蒸汽滅菌器中傳感器的趨勢信息。然而，這些結果再次表明，蒸汽滅菌參數的每次負載監測對於保證蒸汽滅菌條件至關重要。

Tab表. 2: Summary of the processes. In which 'Proc' stands for the number of processes and 'Cond' for conditional. Conditional means that the process is a pass according to the standards, but is in the accuracy band of a parameter. The parameters are judged in the holding phase. The 't' represents the time, of the holding phase, 'p' the pressure, 'T' the temperature, 'dT' the temperature band per scan and calculated out of the measured temperature and the theoretical temperature calculated out of the pressure and the NCG, the None Condensing Gases. 過程總結。其中 Proc 代表進程，Cond 代表條件。有條件的意味著該過程根據標準是通過的，但在參數的精度範圍內。參數判斷在持有階段。“t”表示保持階段的時間，“p”表示壓力，“T”表示溫度，“dT”表示每次掃描的溫度帶，根據測量溫度計算得出，理論溫度根據壓力和計算得出NCG，無冷凝氣體。

Program程序	Result結果	OLVG1						OLVG2						
		proc	t	p	T	dT	NCG	proc	t	p	T	dT	NCG	
Vacuum leak test真空洩漏測試	Pass	7						6						
	Cond	0						0						
	Fail	0						0						
Steam penetration蒸汽滲透	Pass	43						45						
	Cond	11	0	0	0	11	2	7	0	0	0	3	4	
	Fail	0	0	0	0	0	0	0	0	0	0	0	0	
134 °C standard標準	Pass	199						222						
	Cond	74	0	1	0	76	16	18	0	0	0	0	18	
	Fail	3	0	0	0	0	3	27	0	0	0	0	27	
Program程序	Result結果	OLVG3						OLVG4						
		proc	t	p	T	dT	NCG	proc	t	p	T	dT	NCG	
Vacuum leak test真空洩漏測試	Pass	8						9						
	Cond	0						1						
	Fail	0						0						
Steam penetration蒸汽滲透	Pass	27						52						
	Cond	21	0	0	15	1	8	0	0	0	0	0	0	
	Fail	6	0	0	0	0	6	0	0	0	0	0	0	
134 °C standard標準	Pass	162						204						
	Cond	56	0	0	0	0	56	15	0	0	0	0	15	
	Fail	63	0	0	0	0	63	0	0	0	0	0	0	



Possibly at the same time that the pressure step occurred the steam quality became better (Figure 2). Possibly during work on the steam sterilizers the steam supply was improved as well. No records of this improvement has been found but the results of the NCG sensors indicate the improvement. That this can happen is also reported in the literature²³ and should be monitored with every load monitoring of the steam sterilisation parameter in each process. 可能在壓力階躍發生的同時，蒸汽質量變得更好（圖 2）。可能在蒸汽滅菌器的工作期間，蒸汽供應也得到了改善。沒有發現這種改進的記錄，但 NCG 傳感器的結果表明改進。文獻中也報導了這種情況²³，並且應該在每個過程中對蒸汽滅菌參數進行每次負載監測時進行監測。

Conclusion 結論

To ensure steam sterilisation condition it is essential that the steam sterilisation parameters are monitored in every steam sterilisation process. A robust method to do that has been identified in the NCG-sensor. This method is retrofittable on every steam sterilizer and easy to implement in the workflow of a CSSD. 為確保蒸汽滅菌條件，必須在每個蒸汽滅菌過程中監測蒸汽滅菌參數。在 NCG 傳感器中已經確定了一種強大的方法來做到這一點。該方法可在每台蒸汽滅菌器上進行改造，並且易於在 CSSD 的工作流程中實施。

Literature references 文獻參考

- Perkins JJ, "Principles and Methods of Sterilization," Charles C Thomas, Springfield, 1956.
- Precht JCH, "Temperatur und Leben," Springer Verlag, Berlin, 1955.
- Working Party on Pressure Steam Sterilizers of the, "Sterilisation by steam under increased pressure," *The Lancet*, vol. 273, p. 425-435, 1959.
- European Norm Committee, "EN285:2015+A1:2021 -Sterilization- Steam Sterilizers - large Steam sterilizers," 2021.
- AAMI\ANSI, ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, 2017 tot en met 2020.
- N. Lapanaitis, L. Frizzell, A. Downing and van Doornmalen JPCM, "Correlation between the duration of a steam sterilisation process and the weight of," *Central Service*, vol. 4, no. 26, pp. 225-230, 2018.
- J. van Doornmalen, R. van Wezel and K. Kopinga, "The relation between the load, duration and steam penetration capacity of a surface steam sterilization process," *PDA Journal of Pharmaceutical Science and Technology*, no. DOI:10.5731/pdajpst.2017.008490, 2018.
- van Doornmalen JPCM and Riethoff WJC, "monitoring indicates the necessity of Every Load Monitoring of steam sterilization," A case study of steam penetration monitoring indicates the necessity of Every Load Monitoring of steam sterilization processes, vol. 5, pp. 320-325, 2016.
- IAWPS, "http://www.iapws.org/," [Online]. [Accessed 2021 11 07].
- International Standardization Organisation, "ISO17665:2006 Sterilisation of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices," 2006.
- National Institute of Standards and Technology, [Online]. Available: <https://webbook.nist.gov/cgi/fluid.cgi?ID=C7732185&Action=Page>. [Accessed 07 11 2021].
- White paper on the website SVN, "https://sterilisatievereniging.nl/wetenschappelijk-onderzoek," [Online]. Available: <https://sterilisatievereniging.nl/wp-content/uploads/2021/11/211123-Theoretical-temperature-introduces-false-sense-of-safety.pdf>. [Accessed 15 12 2021].
- van Doornmalen JPCM, Hermsen RJ and Kopinga K, "Six commercially available class 6 chemical indicators tested against their stated values," *Central Service*, vol. 6, p. 400-404, 2012.
- van Doornmalen JPCM and Kopinga K, "Measuring non-condensable gases in steam.," *Review of Scientific Instruments*, vol. 84:115106, 2013.
- "www.solidtoo.com," [Online]. Available: <https://www.solidtoo.com/en/ncg-sensor-system/>. [Accessed 15 12 2021].
- "www.solidToo," [Online]. Available: <https://www.solidtoo.com/wp-content/uploads/2021/11/211022-NCG-calibration-EN.pdf>. [Accessed 15 12 2021].
- van Wezel RAC, van Doornmalen HWJM, de Geus J, Rutten S and van Doornmalen JPCM, "Second case study on the orientation of phaco hand pieces during steam sterilization," *Journal of Hospital Infection*, vol. 2016, p. 193-208; DOI:<https://dx.doi.org/10.1016/j.jhin.2016.06.017>, 2016.
- van Doornmalen JPCM, van Wezel RAC and van Doornmalen HWJM, "Case study on the orientation of phaco hand pieces during steam sterilization processes," *Journal*, vol. 90, p. 52-58, 2015.
- Medical Device Coordination Group, MDCG 2021-5 Guidance on standardisation for medical devices, 2021.
- Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical device, 1993).
- EUROPEAN PARLIAMENT AND OF THE COUNCIL, REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93, 2017.
- Irvine (Jr) TF, *Steam and gas tables with computer equations*, Boca Raton (FL): Academic press, Inc., 1984.
- van Wezel RAC, van Gastel A, de Ranitz A and van Doornmalen JPCM, "Following trends in steam sterilizer performance by quantitative monitoring of non-condensable gases," *Journal of Hospital Infection*.



What is meant by calibration 校正是什麼意思 ...

And why is the calibration of the data logger so important? 為什麼數據記錄器的校正如此重要?

Authors 作者們

Robert Streller

R&D / Lab 研發/實驗室 Kompetenz Centrum ebro

Klaus Glaser

Product Manager Data logger 產品經理數據記錄器

Iven Kruse

aseptica Editorial Team 無菌期刊編輯團隊

Xylem Analytics Germany Sales

GmbH & Co.KG

Peringerstr. 10, 85055 Ingolstadt

ebro@xylem.com

Robert Streller, Klaus Glaser, Iven Kruse

For many years, the processes in the Reprocessing Unit for MEDICAL DEVICES (RUMED) have been subject to metrological controls, for example during routine controls and during validation. The requirements for the construction, conversion and operation of a RUMED include the failure concept to bridge planned and unexpected operational disruptions. 多年來，醫療器械再處理單位 (RUMED) 中的流程一直受到計量控制，例如在常規控制和驗證期間。RUMED 的建造、轉換和運行的要求包括連接計劃和意外運行中斷的故障概念。

In the event of a failure of the server, PC or software for documenting the process data, suitable independent data loggers are used for process documentation. For the validation of the processes in the washer-disinfector or steam sterilizer, independent data loggers have long been established among validators. The question arises, how valid is the recorded data? Does the data logger or the measuring device itself have to be checked, checked and calibrated periodically? The use of calibrated measuring devices / data loggers is regulated in the following standards: Standards DIN EN ISO 17665-1², DIN EN ISO 15883-1³, DIN EN 13060⁴, DIN EN 285⁵ and the German standards⁶, guidelines⁷ and guidelines⁸. The calibration status must be proven in accordance with the requirements of the quality management system. 如果用於記錄過程數據的伺服器、PC 或軟件出現故障，將使用合適的獨立數據記錄器進行過程記錄。為了驗證清洗消毒器或蒸汽滅菌器中的過程，獨立的數據記錄器早已在驗證器中建立。問題來了，記錄的數據有多有效？數據記錄器或測量設備本身是否必須定期檢查和校正？校正測量設備/數據記錄器的使用受以下標準的規定：標準 DIN EN ISO 17665-12、DIN EN ISO 15883-13、DIN EN 130604、DIN EN 2855 和德國標準 6、指南 7 和指南 8 校準狀態必須證明符合質量管理體系的要求。

What does the term calibration mean? 校正一詞是什麼意思？

The International Dictionary of Metrology describes calibration as "an activity which, under specified conditions, in a first step establishes a relationship between the quantity values provided by standards with their measurement uncertainties and the corresponding indications with their associated measurement uncertainties, and in a second step uses this information to establish a relationship by means of which a measurement result is obtained from an indication".

《國際計量學詞典》將校正描述為“在特定條件下，首先在標準提供的數量值與其測量不確定度和相應指示與其相關測量不確定度之間建立關係的活動，並在第二步使用該信息建立關係，通過該關係從指示中獲得測量結果”。

Fig. 1: ebro data logger 溫度壓力記錄器 EBI 12 TP 237



This means that measurement deviations are documented during calibration. 這意味著在校正過程中會記錄測量偏差。

The measurement deviation [e] is the deviation of the measured value [X] in the process from the true value [Xw] of the measurand. If the measurement deviation [e] is subtracted from the measured value [X], an exact result [Xw] is obtained.

測量偏差[e]是過程中測量值[X]與真實值[Xw]的偏差被測量。如果從測量值[X]中減去測量偏差[e]，則獲得準確的結果[Xw]。

$$e = X - X_w$$

A brief explanation of the terms in aseptica is therefore useful: 因此，在無菌術語的簡要解釋很有用：

Calibration is a measuring process to determine and document the deviation of a measuring device compared to another, mostly more accurate, higher-quality measuring device (normal). 校正是測量過程，用於確定和記錄測量設備與另一個更準確、更高質量的測量設備（正常）相比的偏差。Calibration includes taking into account the deviation determined when using the measuring device. **Adjustment or adjustment** is the setting of a measuring device or its display as precisely as possible through professional intervention.

Verification, usually the calibration, is the confirmation that specified requirements have been met (e.g. comparative measurement) 校正包括考慮使用測量設備時確定的偏差。**調整或調整**是通過專業干預盡可能精確地設置測量設備或其顯示。**驗證**，通常是校準，是對已滿足規定要求的確認（例如比較測量）

A comparison standard is, for example, an accurate measuring device that is used for a measurement or is used to calibrate other measuring devices. 例如，比較標準是用於測量或用於校正其他測量設備的精確測量設備。National or international standards are at the top of the calibration hierarchy. Measurement uncertainty or standard deviation limits a range of values within which the true value of the measured variable lies (tolerances, temperature distribution). 國家或國際標準位於校準層次結構的頂部。測量不確定度或標準偏差限制了測量變量的真實值所在的值範圍（公差，溫度分佈）。

Tolerance is the specified, permitted measurement deviation of the measuring device. 公差是測量設備規定的、允許的測量偏差。

Some of the definitions of these terms are also contained in EN ISO 11139:2018. 這些術語的一些定義也包含在 EN ISO 11139:2018 中。

What are the different types of calibrations? 有哪些不同類型的校正？

Accredited calibration, e.g. 經認可的校正，例如 DAkkS

The accredited calibration procedures and documents are the benchmark for all industrial calibration tasks. The appearance and content of the certificates are determined by the state accreditation body and are stored in the quality assurance manual of the laboratory. DAkkS certificates are approved as binding evidence in court cases in Germany, for example. 經認可的校準程序和文件是所有工業校正任務的基準。證書的外觀和內容由國家認可機構確定，並存放在實驗室的質量保證手冊中。例如，DAkkS 證書在德國的法庭案件中被批准為具有約束力的證據。

ISO calibration 校正:

ISO calibrations are used in all areas in which test equipment monitoring and calibration are required, but no DAkkS calibrations are required. ISO 校正用於所有需要測試設備監控和校正的領域，但不需要 DAkkS 校正。

Normative requirements for calibration 校正的規範要求:

The standards DIN EN ISO 17665-1², DIN EN ISO 15883-1³, DIN EN 13060⁴, DIN EN 285⁵ and the German standards⁶, guidelines⁷ and guidelines⁸ describe the calibration. All measuring chains of the machine, for the control as well as for the recording and the independent test devices and data loggers are considered in these documents and must be calibrated. 標準 DIN EN ISO 17665-1²、DIN EN ISO 15883-1³、DIN EN 13060⁴、DIN EN 285⁵ 和德國標準 6、指南 7 和指南 8 描述了校準。這些文件中考慮了機器的所有測量鏈，用於控制以及記錄以及獨立的測試設備和數據記錄器，並且必須進行校正。





”And in section 23.3.2.4 for the test equipment: ”The calibration of every test measuring system must be carried out using a working standard or reference standard that can be traced back to a national standard or primary stan-

dard.” 在測試設備的第 23.3.2.4 節中：“每個測試測量系統的校正必須使用可以追溯到國家標準或主要標準的工作標準或參考標準進行。”

How often does a data logger have to be calibrated? 數據記錄器多久需要校正一次？

The intervals for the calibration depend on the manufacturer and the device. 校正間隔取決於製造商和設備。

Fig圖. 2: DAKKS accreditation certificate 認可證書 Fig圖. 3: Types of calibration. 校正類型

Xylem Analytics Germany GmbH Xylem分析德國有限公司。

The maximum permissible measurement deviation of the measuring chains is identical for both the sterilizers and the WD machines. An accuracy of 0.5 K (± 0.25 K) is required for temperature measurement. 對於滅菌器和 WD(清洗消毒器) 機器，測量鏈的最大允許測量偏差相同。溫度測量需要 0.5 K (± 0.25 K) 的精度。 This also applies to the independent measurement chain / data logger that is used, for example, for process validation tasks. This means that data loggers that are used for validation or routine control must show a maximum deviation of ± 0.25 K. 這也適用於例如用於流程驗證任務的獨立測量鏈/數據記錄器。這意味著用於驗證或常規控制的數據記錄器必須顯示出 ± 0.25 K 的最大偏差。 If the independent data logger or the measuring device is used to test and calibrate the machine measurement chains, a significantly higher accuracy of 0.2 K (± 0.1 K) according to the cited standards must be maintained. 如果使用獨立的數據記錄器或測量設備來測試和校正機器測量鏈，則必須根據引用的標準保持顯著更高的 0.2 K (± 0.1 K) 精度。 The DIN EN ISO 15883-1³ washer-disinfectors - Part 1: General requirements, section 6.2.3 describes calibration as follows: "6.2.3.1 The calibration must be carried out in accordance with the instructions of the measuring device manufacturer using a validated procedure; a working or reference standard is to be used that can be traced back to a national standard." DIN EN ISO 15883-1³ 清洗消毒器 - 第 1 部分：一般要求，第 6.2.3 節描述校正如下：“6.2.3.1 校正必須按照測量設備製造商的說明使用經過驗證的程序；將使用可追溯到國家標準的工作或參考標準。”

"6.2.3.2 The device must have a valid test certificate and the calibration data must include a temperature within the disinfection temperature range." The WD guideline describes: "So that the calibration values do not always have to be added manually for each release according to physical parameters (temperature / pressure), an adjustment is always recommended, especially if the deviations are significant. Calibration and adjustment are instruments of quality management and quality assurance. Therefore they are not automatically part of the maintenance. The user is therefore not responsible for calibrating the measuring equipment and machines." 6.2.3.2 設備必須有有效的測試證書，校正數據必須包括消毒溫度範圍內的溫度。” WD(清洗消毒器) 指南描述：“因此不必總是根據物理參數(溫度/壓力)為每次釋出手動添加校正值，因此始終建議進行調整，尤其是在偏差很大的情況下。校正和調整是質量管理和質量保證的工具。因此，它們不會自動成為維護的一部分。因此，用戶不負責校正測量設備和機器。 The monitoring is regulated by the QM manual. "The section 14.2 in the DIN EN 285 Sterilization - Steam Sterilizers - Large Sterilizers, describes the calibration for the machine: "All measuring chains of the sterilizer must be calibrated. Before carrying out any test, the calibration status of all test measuring devices must be verified." 監控由 QM(質量管理) 手冊規定。“DIN EN 285 滅菌 - 蒸汽滅菌器 - 大型滅菌器中的第 14.2 節描述了機器的校正：“必須校準滅菌器的所有測量鏈。在進行任何測試之前，必須驗證所有測試測量設備的校正狀態。

The calibration interval for data loggers is usually annually, please ask the manufacturer of the data logger for this. The creation of a risk assessment can deviate from the manufacturer's information, but the use of calibrated measuring devices must meet the requirements of the quality management system and is the responsibility of the operator or validator. Calibration intervals can be extended or shortened by evaluating external influences. Ideally, the operator or validator maintains a test equipment monitoring database which, in addition to the data logger / measuring device and the calibration cycle, also contains the respective calibration provider and any existing works contracts. Since test equipment monitoring is not available with every validator or in the RUMED, the ebro[®] data loggers of the EBI 10, EBI 11, EBI 12 series use the calibration date, which is displayed in the evaluation software in the routine or validation report. 數據記錄器的校正間隔通常為每年一次，請諮詢數據記錄器的製造商。風險評估的創建可能會偏離製造商的信息，但使用經過校正的測量設備必須滿足質量管理體系的要求，並且是操作員或驗證者的責任。通過評估外部影響，可以延長或縮短校正間隔。理想情況下，操作者或驗證者維護一個測試設備監控數據庫，除了數據記錄器/測量設備和校準週期外，還包含相應的校準提供商和任何現有的工程合同。由於並非每個驗證器或 RUMED 都提供測試設備監控，因此 EBI 10、EBI 11、EBI 12 系列的 ebro[®] 數據記錄器使用校準日期，該日期顯示在評估軟件的常規或驗證報告中。

Why is a calibrated data logger so important? 為什麼經過校正的數據記錄器如此重要？

A temperature sensor drift of the data logger or the built-in WD machine sensor of only 1 °C results in a result change of 25% when calculating the A0 value in the WD. 數據記錄器或內置 WD 機器傳感器的溫度傳感器漂移僅為 1°C，導致計算 WD 中的 A0 值時結果變化為 25%。 That means, if the measuring system of the WD or the data logger measures 1 °C too low, instead of the expected result of e.g. A0 value of 3500 only a result of A0 value 2780 is recorded or displayed. In this case, the disinfection effect A0 value is less than 3000 and is not permissible, which means the machine would have to be repaired and the validation of the processes must be repeated. In the event of an incorrect measurement in the sterilizer, a deviation in the measuring system has a particularly negative effect on the equilibration time, the sterilization temperature and also on the holding time. Deviations of more than 0.5K are not acceptable for the validation of sterilization processes. 這意味著，如果 WD 或數據記錄器的測量系統測量 1°C 過低，而不是預期的結果，例如 A0 值 3500 僅記錄或顯示 A0 值 2780 的結果。在這種情況下，消毒效果 A0 值小於 3000 並且是不允許的，這意味著必須修理機器並且必須重複流程驗證。如果滅菌器中的測量不正確，測量系統的偏差會對平衡時間、滅菌溫度以及保持時間產生特別不利的影響。對於滅菌過程的驗證，超過 0.5K 的偏差是不可接受的。

These errors can be identified through the routine checks of the physical process parameters and the associated verification of the measurement results on the basis of the validation results. 這些錯誤可以通過物理流程參數的例行檢查和基於驗證結果的測量結果的相關驗證來識別。



Use of the calibrated data logger: 校正數據記錄器的使用

A validator uses calibrated data loggers with the accuracy required by the standards. To ensure that the data loggers maintain the required accuracy, the validator regularly compares and verifies the calibration of the data logger, e.g. by comparing all sensors of the data logger in a known process in the washer-disinfector or sterilizer. The maximum deviation of all temperature sensors must not exceed ± 0.25 K. The calibration of the WD or sterilizer sensors is also part of the validation. For this reason, the validator uses data loggers with increased accuracy during validation. 驗證器使用經過校正的數據記錄器，其準確性符合標準要求。為確保數據記錄器保持所需的精度，驗證器會定期比較和驗證數據記錄器的校準，例如通過比較清洗消毒器或消毒器中已知過程中數據記錄器的所有傳感器。所有溫度傳感器的最大偏差不得超過 ± 0.25 K。WD 或滅菌器傳感器的校準也是驗證的一部分。出於這個原因，驗證器在驗證期間使用具有更高準確性的數據記錄器。The validator compares his measurement results with the measurement results of the machines and thus carries out a calibration. If deviations occur, these are documented in the validation report. If the deviations are outside the specification, the validation cannot be assessed as a "pass". The operator must inform the service department in the event of deviations and commission repairs or adjustments and calibration. 驗證者將他的測量結果與機器的測量結果進行比較，從而進行校正。如果出現偏差，則將其記錄在驗證報告中。如果偏差超出規範，則驗證不能被評估為“通過”。如果出現偏差和委託維修或調整和校準，操作員必須通知服務部門。

Conclusion 結論

Routine checks with calibrated data loggers can detect errors in the RUMED at an early stage and counteract misinterpretations, malfunctions or machine failures. In addition, data loggers are an indispensable tool in the event of an accident or malfunction, they serve for process reliability and ultimately also for patient safety. 使用校正的數據記錄器進行例行檢查可以及早發現 RUMED 中的錯誤，並消除誤解、故障或機器故障。此外，數據記錄器是發生事故或故障時不可或缺的工具，它們為過程可靠性提供服務，最終也為患者安全提供服務。

can be carried out for temperature, relative humidity and pressure values. ebro® offers you highly precise calibration services through our trained service technicians and through DAkkS accreditation. 可以進行溫度、相對濕度和壓力值。 ebro® 通過我們訓練有素的服務技術人員和 DAkkS 認證為您提供高度精確的校正服務。We recommend that you have your data loggers calibrated annually to ensure the accuracy of your measurements. On request, we will be happy to include you in the calibration reminder service, which is free of charge for you. So you don't miss the right time to calibrate your data loggers. The registration form for the ebro® calibration reminder service can be found at 我們建議您每年校準一次數據記錄器，以確保測量的準確性。根據要求，我們很樂意為您提供校正提醒服務，該服務對您免費。因此，您不會錯過校正數據記錄器的正確時間。 ebro® 校正提醒服務的註冊表可在以下網址找到：https://www.ebro.com/fileadmin/pics/PDFS/Service/Service-Form Validation and Process Loggers EN 2022_v3.pdf Since October 18th 2021, the ebro® data loggers will be calibrated in the new service center in Weilheim. 自 2021 年 10 月 18 日起，ebro® 數據記錄器將在 Weilheim 的新服務中心進行校正。

https://www.ebro.com/fileadmin/pics/PDFS/Service/Service-Form Validation and Process Loggers EN 2022_v3.pdf



Figure 4: ebro® ISO calibration certificate 校正證書

In order to be able to guarantee a correct validation of the complex processes in the WD or sterilizer according to the standard, only normative and calibrated equipment should be used. **Contents of an ISO calibration certificate:** 為了能夠保證按照標準正確驗證 WD 或滅菌器中的複雜過程，只能使用規範和校準的設備。ISO 校正證書的內容：

- Clear identification of the measuring equipment 清楚地識別測量設備
- Description and identification of measuring equipment 測量設備的描述和識別
- Calibration date 校正日期
- Calibration results obtained after adjustment or repair 調整或維修後得到的校準結果
- Identification of the calibration procedure 校正流程的識別

Literature references 文獻參考

1. DIN EN ISO 11139:2018 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018); German and English version EN ISO 11139:2018
2. DIN 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 (ISO 17665-1:2006); German version EN ISO 17665-1:2006
3. DIN EN ISO 15883-1:2014-10 Washer disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006 + Amd 1:2014); German version EN ISO 15883-1:2009 + A1:2014
4. DIN EN 13060:2019 Small steam sterilizers; German version EN 13060:2014+A1:2018
5. DIN EN 285:2021 Sterilization - Steam sterilizers - Large sterilizers; German version EN 285:2015+A1:2021
6. DIN 58946-7:2014-01 Sterilization - Steam sterilizers - Part 7: Edificial preconditions, requirements for the services and the operation of steam sterilizers used in health care facilities
7. DIN SPEC 58929:2012-08 Operation of small steam sterilizers in the health-care system - Guidance for validation and routine control of sterilization processes. DIN ISO/TS 17665-2:2009-07 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1 (ISO/TS 17665-2:2009); German version CEN ISO/TS 17665-2:2009
8. Guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices. 5th edition 2017 Guideline for the validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes.

- Normal that was used to ensure traceability 用於確保可追溯性的正常值
- Environmental conditions 環境條件
- Specification of the uncertainties when calibrating the measuring equipment 校正測量設備時的不確定度規範
- Identification of the person(s) who carried out the confirmation 確認執行人的身份

In the calibration laboratory of Xylem Brand -ebro®, DAkkS calibrations in the accredited area as well as ISO calibrations 在 Xylem Brand -ebro® 的校正實驗室，DAkkS 校正在認可區域以及 ISO 校正

Note: 此新聞稿中文翻譯的部分若有進一步疑問，請參考原文或洽詢大久生物科技。



11471 台北市內湖區新明路273巷6號1樓
1F, No. 6, Ln. 273, Xinning 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



New aseptica partner Veolia Water Technologies

The Veolia Group is the leading company in environmental technologies and the global benchmark for sustainable solutions in resource management. With Veolia Water Technologies, the group has expertise in water and wastewater treatment that can look back on more than 130 years of history in Germany. With strong brands such as Berkefeld, ELGA Labwater or EVALED, Veolia Water Technologies has been a reliable partner for planning, delivery and service of water treatment solutions in hospitals, therapeutic facilities, laboratories and industry for many years.

We are the specialists for water

Whether for the technical building equipment in hospitals, the ultra-pure water requirements in clinical and analytical laboratories or for the sensitive requirements in the manufacture of medical pharmaceutical products, Veolia Water Technologies offers comprehensive turnkey solutions for municipalities and industry.

The core competencies include:

- Central sterile supply department (CSSD) / reprocessing unit for medical devices (AEMP)
- Ventilation for sensitive environments and clean rooms
- Pure and ultra-pure water for laboratories
- Cooling water treatment
- Heating water treatment incl. local/district heating
- Swimming pool water incl. therapy and exercise pools
- Complex drinking and waste water solutions

In addition to the 350 employees at the company headquarters in Celle, Lower Saxony, more than 30 sales engineers and 50 technicians are working around the clock in Germany, providing critical infrastructure throughout the country with know-how and comprehensive services.



Water for central sterile supply

Safe and standard-compliant water treatment is a prerequisite for the hygienic operation of CSSDs or AEMPs. In addition to the appropriate system technology, Veolia Water Technologies also provides a comprehensive range of training, services and additional service solutions, such as the digital service from Hubgrade, which allows the essential parameters of the water treatment to be permanently monitored, documented and analyzed online - across all our locations and on any terminal device.

Sustainable solutions for water treatment

For a real ecological transformation, innovative and efficient technologies are needed, as well as simple investment opportunities and reliable support for the plants. Veolia Water Technologies offers the full range of expertise and is the strong partner for water treatment from planning support, flexible financing models such as pay-per-use and rental systems, up to plant and system services. Switching to sustainable solutions for water treatment has never been so easy to realise.

Legal notice

Scientific advisory council:

H. Biering, Düsseldorf
F. Brill, Hamburg
J. Gebel, Bonn
A. Hartwig, Berlin
H. L. Holz, Mainz
T. Miorini, Graz
U. Junghannß, Köthen
S. Kauertz, Dortmund
S. Kaufmann, Saarbrücken
I. Korschake, Stendal
M. Pietsch, Mainz
B. Wilbrandt, Berlin

Publisher:

Office, das Büro der aseptica
Bernd Vieregge
Frieda-Nadig-Straße 53
33332 Gütersloh, Germany
E-mail: info@aseptica.com

Responsible for content:

Dr Ulrike Weber
Professional business unit

Miele & Cie. KG
Carl-Miele-Straße 29
33332 Gütersloh, Germany
Tel.: +49 5241 89-1494
Fax: +49 5241 891950

Overall production:

COLLET Concepts Communication
Ziethenstraße 10
33330 Gütersloh, Germany
Tel.: +49 5241 50 56 664
E-mail: info@aseptica.com
Website: www.aseptica.com
Stefan Collet, Sandra Acicportali

In co-operation with:
Ecolab Deutschland GmbH
Ecolab-Allee 1 | 40789 Monheim am Rhein,
Germany;
Miele & Cie. KG
P.O. box | 33325 Gütersloh, Germany;
Dentsply Sirona Deutschland GmbH
Fabrikstraße 31 | 64625 Bensheim, Germany;
Xylem Analytics Germany Sales GmbH & Co. KG
Ebro
Peringerstraße 10 | 85055 Ingolstadt, Germany;
Innovations Medical Vertriebs GmbH
Badstraße 11 | 78532 Tuttlingen, Germany

Veolia Water Technologies Deutschland GmbH
Lückenweg 5 | 29227 Celle

Editorial team:

Aaron Papadopoulos, Ecolab
Ulrike Weber, Miele
Kathrin Sichler, Dentsply Sirona
Iven Kruse, ebro
Tobias Junke, Veolia

Title image: adobe stock
Circulation: 6500
Publication schedule: three times a year
Printed on chlorine-free bleached paper

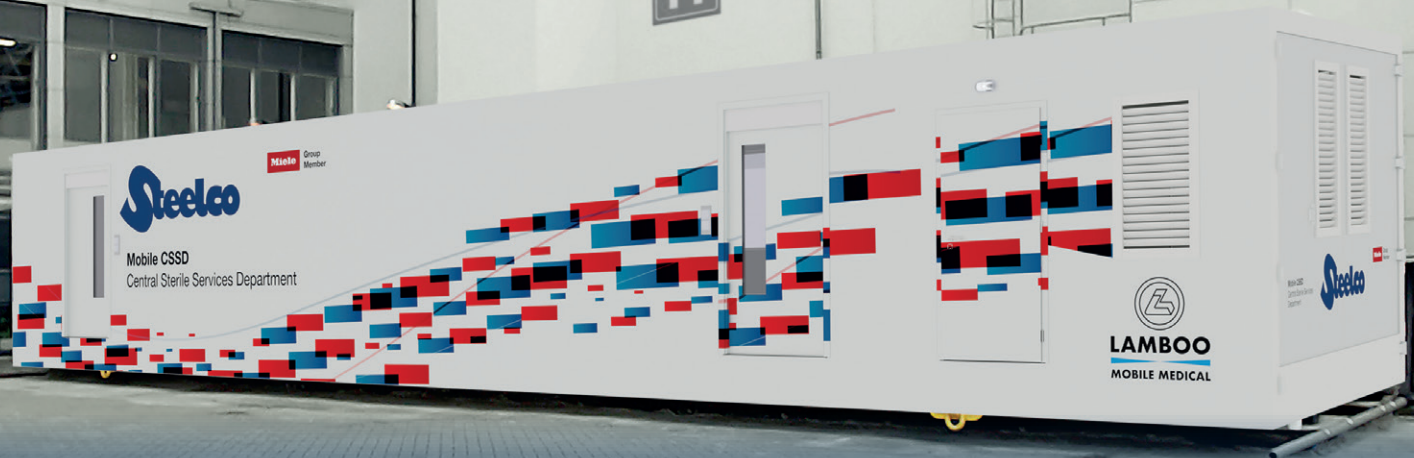
Only to be reprinted with the permission of the editorial team. Articles by named authors do not necessarily reflect the opinion of the editorial team. No liability is assumed for unsolicited manuscripts and photographs. The editorial team reserves the right to shorten letters from readers.

ISSN 1439-9016



Miele

Group Member



Mobile CSSD Solutions

Uncompromised continuity
in surgical instrument
reprocessing



watch the video

Steelco's answer to your temporary needs,
a single module, pre-fab, turn key CSSD

Solutions for processing up to
70.000 or 140.000 STU/year.

Set up within a single working day!



www.steelcogroup.com
info@steelcogroup.com