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Jubiläum: 30 Jahre aseptica

Anniversary: 30 years of aseptica

週年紀念：無菌雜誌的 30 年

30 years of aseptica: a look back and forward無菌雜誌的 30 年：回顧與展望

Dear readers親愛的讀者,

It fills us with pride and joy to celebrate the 30th anniversary of our scientific journal. For three decades, we have accompanied you on a journey through the world of medical device reprocessing, validation and infection control-related topics. Sometimes this world has changed rapidly, sometimes it has provided a stable basis. With the current edition of aseptica, we would like to look back with you and venture a look into the future.慶祝我們的科學期刊創刊 30 週年，我們感到無比自豪和喜悅。三十年來，我們陪伴您走過醫療器材再處理、驗證和感染控制相關主題的世界。這個世界有時變化很快，有時卻提供了穩定的基礎。透過目前版本的無菌，我們希望與您一起回顧過去並展望未來。

Our beginnings我們的濫觴

When the first reading sample of aseptica was published at Medica 1994, topics such as the validation of reprocessing processes and the training of medical device reprocessing staff were still in their very beginnings. What already existed, however, was a strong drive towards professional cooperation between relevant players in the field of instrument reprocessing. The vision of the founding partners was to address current topics, to provide a consistent mix of science and practice and to represent the attributes of credibility, consistency and diversity.當第一個無菌閱讀樣本在 1994 年 Medica 上發表時，再處理過程的驗證和醫療器材再處理人員的訓練等主題仍處於相當初始的階段。然而，儀器後處理領域的相關參與者之間的專業合作已經存在著強大的動力。創始合作夥伴的願景是解決當前的主題，提供科學與實踐的一致結合，並體現可信性、一致性和多樣性的屬性。

Milestones里程碑

Over the years, we have focused on topics with direct practical relevance and opin-ion-forming positions. From the validation of the cleaning process to the reprocessing of special instruments and surface disinfection – we have never shied away from tackling complex topics and presenting the relevant background of the time in an under-standable and practical way.多年來，我們一直專注於具有直接實際相關性和形成輿論立場的主題。從清潔過程的驗證到特殊器械的再處理和表面消毒——我們從不迴避處理複雜的話題，並以易於理解和實用的方式呈現當時的相關背景。

Change and adaptation改變與適應

The way we consume information has changed dramatically over the last 30 years. We have adapted to this change by introducing the digital PDF format alongside our printed editions. Our aim was and is to provide you with practical specialist articles at least three times a year in a pragmatic and uncomplicated way. From this issue onwards, you will receive aseptica regularly in a joint mailing with *Zentralsterilization* and also at trade fair appearances of the member companies Ecolab, Miele Group, Sirona and Ebro. With moderate layout changes, we have always shown something new, not radically all at once, but gradually.過去 30 年來，我們消費資訊的方式發生了巨大變化。我們適應了這一變化，在印刷版的同時引入了數位 PDF 格式。我們的目標是每年至少三次以務實且簡單的方式為您提供實用的專業文章。從本期開始，您將定期透過與 *Zentralsterilization*(集中滅菌) 聯合郵寄的方式以及在會員公司 Ecolab、Miele 集團、Sirona 和 Ebro 的展會上收到無菌期刊。透過適度的佈局變化，我們總是展示一些新的東西，不是一下子徹底地，而是逐漸地。

Looking to the future展望未來

Let's focus firmly on the future. The coming years promise to be just as dynamic and focused. Topics such as new infectious agents, new technologies, networked devices and new reprocessing methods will continue to change our world. And demand that we always involve, include and inform users in all technological developments. This applies regardless of whether reprocessing is carried out in a large university CSSD or a small dental practice, regardless of whether it is in northern Germany or South America – hygiene, infection prevention and value preservation affect us all.讓我們堅定地著眼於未來。未來幾年預計將同樣充滿活力和專注。新傳染源、新技術、連網設備和新後處理方法等主題將繼續改變我們的世界。並要求我們始終讓用戶參與所有技術發展並為其提供資訊。無論再處理是在大型大學 CSSD(中央無菌供應部) 還是小型牙科診所進行，無論是在德國北部還是南美洲，這一點都適用—衛生、感染預防和價值保存影響著我們所有人。

Our promise我們的承諾

We are committed to remaining at the forefront of practice-oriented scientific media. In doing so, we will我們致力於保持在以實踐為導向的科學媒體之最前沿。在此過程中，我們將:

1. Focus even more strongly on the regular availability of aseptica更重視無菌雜誌的定期供應
2. Expand our digital presence without sacrificing the advantages and offline availa-bility of the printed versions在不會犧牲印刷版本的優勢和離線可用性的情況下擴大我們的數位業務
3. Enter into a stronger dialog with you as our readers與作為我們的讀者的您進行更強有力的對話
4. Expand international distribution擴大國際佈局

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Thanks to our readers, scienti ic advisory board and sponsors感謝我們的讀者、科學顧問委員會和贊助商

Finally, we would like to thank you, our loyal readers, current and former sponsors (Ecolab, Ebro, Sirona, Miele Group, Olympus, Hawo, Kögel, Innovations Medical, Veolia), from the bottom of our hearts. Your curiosity, critical thinking and enthusiasm for technical hygiene have characterized aseptica all these years. A big thank you also goes to the experts on the Scientific Advisory Board, who actively support the editorial team with advice, knowledge and practical experience through their professional activities. Let's shape the next 30 years together, continue to explore the world of hygiene, medical device reprocessing, validation and shape it sustainably together.最後，我們衷心感謝您、我們的忠實讀者、現任和前任贊助商（Ecolab、Ebro、Sirona、Miele Group、Olympus、Hawo、Kögel、Innovations Medical、Veolia）。這些年來，您的好奇心、批判性思維和對科技衛生的熱情一直是無菌的表徵。也要非常感謝科學顧問委員會的專家，他們透過專業活動積極支持編輯團隊，提供建議、知識和實務經驗。讓我們共同塑造未來 30 年，繼續探索衛生、醫療器材再處理、驗證領域，並共同塑造永續發展的世界。

Looking forward to the coming years期待未來年華,

Your editorial team您的編輯團隊

Aaron Papadopoulos, Iven Kruse, Stella Nehr-Werner, Ulrike Weber

Anniversary edition with selected articles from the past 30 years 收錄了過去 30 年精選文章之週年紀念版

To mark the 30th anniversary of aseptica, we have made a very special selection of articles for you. You will find a carefully curated selection of remarkable articles from the past years. Sometimes with a wink, sometimes with astonishment and sometimes with obvious consistency. We have searched our archives and decided on the following articles為了紀念無菌技術問世 30 週年，我們為您精選了一些非常特別的文章。您會發現精心挑選的過去幾年的精彩文章。有時眨眼，有時驚訝，有時明顯一致。我們搜尋了我們的檔案並決定發表以下文章:

- Infection risks on the dance floor and prevention strategies – an ironic comment for public health. (Year 2008): Far too often we forget the hygienic relevance and the possibility of evaluating pleasure outside the CSSD walls with a reasonable awareness of hygiene.舞池中的感染風險和預防策略—對公共衛生的諷刺評論。（2008 年）：我們常常忘記衛生相關性以及以合理的衛生意識評估 CSSD(中央消毒供應部門)牆壁外樂趣的可能性。
- Hygiene in endoscopy – developments, changes, standards (year 2004): The historical background to the reprocessing of endoscopes is wonderfully explained in relevant studies in this article. Technical articles with such a focus and clarity make a strong contribution to the further development of hygienically safe reprocessing procedures and invite interested parties to actively participate內視鏡衛生－發展、變化、標準（2004 年）：本文的相關研究很好地解釋了內視鏡再處理的歷史背景。具有如此重點和清晰度的技術文章為衛生安全再處理程序的進一步發展做出了巨大貢獻，並邀請感興趣的各方積極參與.
- Validation in the CSSD (1998): This article looks at the beginnings of validation and poses the critical question "why start with steam sterilization as the last step in the reprocessing process?". The content of this article is certainly not transferable to 2024 in many statements, but we find the very clear and visionary questioning of the approach at that time impressive. CSSD(中央消毒供應部門)中的驗證（1998）：本文著重於驗證的開始，並提出了關鍵問題「為什麼以蒸汽滅菌開始作為再處理過程的最後一步？」。本文的內容在許多陳述中當然不能轉移到 2024 年，但我們發現對當時方法的非常清晰和富有遠見的質疑令人印象深刻。
- Enzymes – mode of action of biocatalysts. (Year 2000): This article is a perfect and written example of "I've read this somewhere before". Enzymes in the context of automated cleaning and the necessity for the respective tem-perature optimum are well known. This article also uses practical examples and studies to describe the influence of enzymes in a circulating or station-ary wash liquor in the washer-disinfector 酵素－生物催化劑的作用方式。（2000 年）：這篇文章是「我以前在某處讀過這篇文章」的完美書寫範例。自動清潔中的酵素以及各自最佳溫度的必要性是眾所周知的。本文也使用實際例子和研究來描述酵素對清洗消毒器中循環或固定清洗液的影響.
- The story of the "ebro Thermologger" – from nobody to market leader (2012). 25 years of thermologgers in the CSSD and at validation compa-nies, how time flies. This exciting story by visionary Wolfgang Klün tells of the use of his ebro thermologger in the CSSD. Today, unlike 25 years ago, thermologgers became a standard for the routine control and process validation of washer-disinfectors and sterilization processes and have become indispensable. 「ebro 熱記錄器」的故事 - 從無名小卒到市場領導者（2012 年）。熱記錄器在 CSSD(中央消毒供應部門)和驗證公司工作了 25 年，時間過得真快。這個令人興奮的故事由富有遠見的 Wolfgang Klün 講述了他的 ebro 熱記錄器在 CSSD 中的使用情況。如今，與 25 年前不同，熱記錄器已成為清洗消毒器和滅菌過程的常規控制和製程驗證的標準，並且已變得不可或缺

This anniversary edition shows you the development and progress in our field. From very popular questions in 1998 (Why does validation start with steam sterilization and thus with the last step of reprocessing?) to the latest measuring equipment. What all the articles have in common is that we have kept their content in the respective period. So please don't be surprised if prEN standards are still quoted here and there or if similar features from the past 30 years can be found. Whether you are a long-standing expert in the field or a newcomer looking to gain an overview, you will find valuable insights for your own work and new ideas in this special edition本週年紀念版向您展示了我們領域的發展和進步。從 1998 年非常流行的問題（為什麼驗證從蒸汽滅菌開始，然後再處理的最後一步開始？）到最新的測量設備。所有文章的共同點是我們保留了各自時期的內容。因此，如果 prEN (公眾查詢歐洲標準草案)標準仍然到處被引用，或者是否可以找到過去 30 年的相似特徵，請不要感到驚訝。

無論您是該領域的長期專家，還是希望獲得概述的新人，您都會在本特別版本中找到對您自己的工作有價值的見解和新想法.

Validation in the CSSD
CSSD (中央消毒供應部門)中的驗證

Antje Hartwig and Helmut Pahlke (†)

It is currently almost impossible to have a conversation in the CSSD without the word validation being mentioned. What does validation mean目前，在 CSSD (中央消毒供應部門) 中進行對話幾乎不可能不提及驗證一詞。驗證是什麼意思?

Comments such as “my Sterilizer is validated” very quickly make it clear that there is still a need for information and that not all uncertainties have been resolved. Validation has certainly been misunderstood because the last step of reprocessing was the first to be professionally validated. This gave the impression that the sterilizer as an appliance was validated. The fact is, however, that only a process sequence can be validated. It is not the sterilizer that is validated, but the sterilization process 諸如“我的滅菌器已通過驗證”之類的評論很快就表明仍然需要信息，並且並非所有不確定性都已解決。驗證肯定被誤解了，因為再處理的最後一步是第一個經過專業驗證的步驟。這給人的印像是滅菌器作為一種器具已經過驗證。然而事實是，只能驗證過程順序。驗證的不是滅菌器，而是滅菌過程.

Validation means making the process sequence reproducible (verifiable, repeatable) and documenting it. This process sequence must then always be carried out in the same way (work instructions, program sequences). For sterilization, this means consistent loading of the sterilizer. Loading or batch lists must be created for this purpose (sample batches). In daily operation, all batches are then loaded approximately in the same way as the sample batches created. It is not sufficient for a sterile basket (1 STU) of the same size to be sterilized in the same place, but the filling of the sterilization basket is particularly important. A basket filled with instruments (max. 30 kg) has a different behavior than a basket with swabs驗證意味著使流程序列可重現（可驗證、可重複）並記錄下來。這個過程順序必須始終以相同的方式執行（工作指令、程序順序）。對於滅菌來說，這意味著滅菌器的負載一致。為此必須建立裝載清單或批次清單（樣本批次）。在日常操作中，所有批次的載入方式與建立樣品批次的方式大致相同。相同尺寸的無菌籃（1個STU）在同一個地方進行滅菌是不夠的，但滅菌籃的填充尤為重要。裝滿器械（最多 30 公斤）的籃子與裝有擦拭物的籃子有不同的行為。.

The extent to which sterilization batches can be validated in hospitals will not be discussed here這裡不討論醫院對滅菌批次進行驗證的程度。.

However, it is interesting to note why the last step of the reprocessing of item being sterilized is validated first. This means that the last step of the reprocessing process already provides us with the possibilities for verification that are still missing in the first steps.然而，值得注意的是為什麼要先驗證被滅菌物品的再處理的最後一步驟。這意味著後處理過程的最後一步驟已經為我們提供了第一步驟中仍然缺少的驗證可能性。

Aren’t sufficient cleaning and disinfection of the items being sterilized a requirement for successful sterilization? If so, can the sterilization process be considered completely separate對被滅菌物品進行充分的清潔和消毒不是成功滅菌的必要條件嗎？如果是這樣，滅菌過程是否可以被認為是完全獨立的?

We do not share this opinion. It should start with the cleaning and disinfection of the items being sterilized. Even if cleaning is not carried out according to the state of the art, i.e. manually, this cleaning process can be validated. 我們不同意這個觀點。應從被滅菌物品的清潔和消毒開始。即使沒有按照現有技術（即手動）進行清潔，也可以驗證該清潔過程。

The steps must be specified, documented and then adhered to. What matters here is not the pressure with which the individual employees guide a brush over the instrument, but how the cleaning process is organized.必須指定、記錄並遵守這些步驟。這裡重要的不是個別員工用刷子刷儀器的壓力，而是清潔過程如何組織安排的。

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Even in machine cleaning, the pressure and temperature sequence are not always 100 % the same, but the cleaning program remains the same. The frequently heard opinion that only “factory pro-grams” may be used is not comprehensible to us. Even programmed cleaning sequences can be validated in the same way and must be validated. The extent to which manufacturer liability is affected by this would be worth clarifying即使在機器清潔中，壓力和溫度順序也不總是 100% 相同，但清潔程序保持不變。常聽到的認為只能使用「工廠程序」的觀點對我們來說是無法理解的。即使是已編程的清潔序列也可以以相同的方式進行驗證並且必須進行驗證。製造商責任受此影響的程度值得澄清。.

We are not currently aware of any supplier who assumes that their appliance will achieve optimum cleaning re-sults when using the factory program without on-site adjustments. In this respect, the factory defaults are flexible.目前，據我們所知，沒有任何供應商認為他們的設備在使用工廠程序時無需現場調整即可達到最佳清潔效果。在這方面，工廠預設設定是有彈性的。

We know that time, temperature, chemistry and mechanics must be seen as a unit in cleaning. But what happens if one parameter is not within the “norm”? Then the cleaning process is no longer in balance. If, for example, it has become clear that a spray arm is not moving, which can be seen in some appliances with a glass panel in the door, the program must be aborted and restarted after the fault has been rectified. The same applies to pots or kidney dishes that have been knocked over, as the process sequence assumes that the machines are loaded correctly我們知道，在清潔過程中，時間、溫度、化學和機械必須被視為一個單位。但如果一個參數不在「標準」範圍內會發生什麼事？那麼清潔過程就不再平衡。例如，如果很明顯噴灑臂沒有移動（在某些門上帶有玻璃面板的電器中可以看到這種情況），則必須中止程序並在故障糾正後重新啟動。這同樣適用於被打翻的鍋子或腎皿，因為處理順序假設機器已正確裝載。.

What about checking the vending machines? Are microbiological tests reproducible, or are physical parame-ters more suitable? In the future, microbiological testing will certainly lose its significance, especially as it only shows one result, that of germ reduction. The cleaning result must be verified separately, which is currently still not possible due to a lack of suitable test specimens and test soiling檢查自動販賣機怎麼樣？微生物測試是否可重複，或物理參數是否更合適？未來，微生物檢測肯定會失去意義，尤其是它只顯示一個結果，那就是減少細菌。清潔結果必須單獨驗證，但由於缺乏合適的測試樣本和測試污染，目前尚無法實現。.

The next problem we see are the cleaning agents. They are part of the validated cleaning process How can we validate cleaning agents that are highly dependent on water quality? There is no definition of water quality outside of drinking water quality. Only the dispensing of the cleaning agent cannot be part of the validation of the cleaner, because the amount of water is also a decisive component in order to achieve the cleaning effect我們看到的下一個問題是清潔劑。它們是經過驗證的清潔過程的一部分我們如何驗證高度依賴水質的清潔劑？除飲用水品質外，沒有其他水質定義。僅清潔劑的分配並不能成為清潔劑驗證的一部分，因為水量也是達到清潔效果的決定性因素。.

Correct cleaning is the prerequisite for successful sterilization正確的清潔是成功滅菌的前提。.

This means that we have used the last step of reprocessing as an opportunity for verification, which is still lacking in the first steps. However, this also means that we have an error rate in the hospital, as not only the items to be reprocessed and sterilized are very different, but also the conditions for safe sterilization, as shown in the area of cleaning and disinfection. As already mentioned, the success of sterilization depends on all sub-steps of reprocessing.這意味著我們利用最後一步的再處理作為驗證的機會，而這在第一步中仍然缺乏。然而，這也意味著我們醫院存在錯誤率，不僅是要進行再處理和消毒的物品有很大差異，而且安全消毒的條件也有很大差異，如清潔和消毒領域所示。如前所述，滅菌的成功取決於再處理的所有子步驟。

The points mentioned here alone illustrate the problems of validation during reprocessing. In addition, there is often the question of whether the old appliances can still be used in the CSSD at all.光是這裡提到的幾點就說明了再處理過程中的驗證問題。此外，經常存在這樣的問題：舊設備是否仍然可以在 CSSD （中央無菌供應部）中使用。

There is currently no legally prescribed validation obligation. According to the Federal Ministry of Health, §12 MDD, the placing on the market of medical devices, does not apply to hospitals; the Federal Ministry of Health's statement that DIN EN 554 does not apply to reprocessing in hospitals is therefore meaningful enough. The goal of the greatest possible safety in reprocessing, including sterilization, can be achieved by other means, as before.目前沒有法律規定的驗證義務。根據聯邦衛生部的規定，§12 MDD（醫療器材投放市場）不適用於醫院；因此，聯邦衛生部關於 DIN EN 554 不適用於醫院再處理的聲明是很有意義的。與以前一樣，可以透過其他方式實現再處理（包括滅菌）中最大可能安全性的目標。

This means that appliances for which validation of the process sequence is not technically feasible may continue to be operated. The previously valid control measures should continue to be applied and technical changes should be made to improve parameter control. For example, it is essential to retrofit a recorder for temperature and pressure if this is not yet available. Items being sterilized may only be released if all available parameters (time, temperature, pressure, batch control) indicate that the sterilization process is running correctly. What can we do now to achieve the highest possible quality standard? We need to standardize. Carry out an inventory in the house: What is all reprocessed, what really needs to be reprocessed, where can something be changed? Does each ward need its own special set? Are the surgical trays optimized or "overloaded"? Is reprocessing standardized and are the manufacturer's repro-cessing instructions available? Which sterilization procedures may be used? 這意味著製程順序驗證在技術上不可行的設備可以繼續運作。應繼續採用先前有效的控制措施，並進行技術改造以改善參數控制。例如，如果還沒有溫度和壓力記錄儀，則必須對其進行改造。只有當所有可用參數（時間、溫度、壓力、批次控制）顯示滅菌過程正常運作時，才能放行正在滅菌的物品。我們現在可以做什麼來達到盡可能高的品質標準？我們需要標準化。對家裡進行盤點：什麼是全部重新處理的，什麼是真正需要重新處理的，哪些地方可以改變？每個病房都需要自己的特殊套裝嗎？手術托盤是否經過優化或 "超載" ？再處理是否標準化？可以使用哪些滅菌程序？

This is just a small selection of the points that are requirements. But even if the existing safety controls are maintained, standards increase safety in reprocessing. It goes without saying that all reprocessing steps must be adequately documented. Validated reprocessing without documentation cannot be verified and therefore has no legal fuse rating.這只是要求要點中的一小部分。但即使維持現有的安全控制措施，標準也會提高後處理的安全性。不言而喻，所有再處理步驟都必須充分記錄。沒有文件的再處理驗證無法得到證實，因此沒有合法的保險絲額定值。

In summary, we would like to make it clear that validated reprocessing of item being sterilized is essential for patient safety. However, this has been required for over 15 years. Whether a validated sterilization process in hospitals provides the necessary safety should be questioned, as it is the last step of reprocessing and a variety of batch patterns do not allow for a standard. The exist-ing control measures should continue to be used to ensure function, safety, and sterilization.

Nature must not stop progress, but a proven measure should be replaced by a better measure. A cost-benefit analysis should be carried out for the same quality.總之，我們想明確的是，經過驗證的滅菌物品再處理對於病人安全至關重要。然而，這項要求已經持續了 15 年多。醫院經過驗證的滅菌過程是否能提供必要的安全性值得質疑，因為它是再處理的最後一步，各種批次模式不允許建立標準。應繼續使用現有的控制措施，以確保功能、安全和滅菌。

大自然不能停止進步，但已被證實的措施應該被更好的措施所取代。對於相同品質應進行成本效益分析。

Enzymes - how biocatalysts work
酵素 - 生物催化劑如何發揮作用

W. Michels and M. Pieper

Enzymes are ingredients of some, particularly neutral, liquid cleaning formulations. Proteases, protein hydrolyzing enzymes, are used here in particular. The importance of their contribution to cleaning performance in the reprocessing of surgical and endoscopic instruments is assessed dif-ferently. Irrespective of this, there are some rather strange ideas about their mode of action, which is brie ly explained here. 酵素是一些液體清潔配方（尤其是中性液體清潔配方）的成分。這裡特別使用蛋白酶、蛋白質水解酶。它們對手術和內視鏡器械再處理中清潔性能的貢獻的重要性有不同的評估。儘管如此，關於它們的作用方式還是有一些相當奇怪的想法，這裡簡要地解釋一下。

Enzymes are proteins (macromolecules) with a complex structure. Their activity is linked to a specific conformation. The active center of the enzyme reacts with the substrate according to the lock-and-key principle, i.e. with high specificity, to form an enzyme-substrate complex (equilibrium reaction). The reaction of the complex into the end products and reformation of the enzyme, which emerges unchanged from the reaction, is the reaction-kinetic rate-determining step. 酶是具有複雜結構的蛋白質（大分子）結構。它們的活性與特定的構造有關。酵素的活性中心與根據鎖和鑰匙原理的受質反應，即具有高特異性，形成酵素受質複合物（平衡反應）。複合物反應成最終產物以及酵素的重組（反應中酵素的重組保持不變）是反應動力學速率決定步驟。

Enzyme + Substrate -> Enzyme-Substrate Complex ->
Enzyme + Product(s)酵素 + 受質 -> 酵素-受質複合物 ->
酵素+產品

The speed at which an enzymatic reaction takes place depends on various factors.酶促反應發生的速度取決於多種因素。

Substrate concentration基質濃度: As the substrate concentration increases, the initial reaction rate increases up to a maximum value. At saturation, the speed of the enzymatic reaction is directly proportional to the enzyme concentration.隨著基質濃度的增加，初始反應速率增加至最大值。在飽和狀態下，酵素反應的速率與酵素濃度成正比。

Temperature溫度: Everyday experience teaches us that an increase in temperature accelerates the course of chemical reactions. On the other hand, thermal denaturation occurs from approx. 40° C, depending on the enzyme.日常經驗告訴我們，溫度升高會加速化學反應的進展。另一方面，熱變性發生在大約 40° C，取決於酵素。

The optimum temperature for each enzyme is therefore determined by determining the enzyme activity at different temperatures.因此，透過測定不同溫度下酵素的活性來確定每種酵素的最適溫度。

pH optimum酸鹼值最佳化: The hydrogen ion concentration, the pH value of the solution, is decisive for the charge distribution of an enzyme. The charge state influences the enzyme activity. For each enzyme there is therefore a pH range in which enzyme activity is particularly high.氫離子濃度（即溶液的酸鹼值）對於酵素的電荷分佈具有決定性作用。電荷狀態會影響酵素活性。因此，對於每種酶，都有一個酶活性特別高的酸鹼範圍。

As a rule, the substrate, the substances to be converted such as proteins, is present in large excess. If this is not the case, the substance conversion is diffusion-controlled. The frequency of collisions between the enzyme and the substrate is decisive. This must be high in order to achieve the optimum material conversion or the maximum enzymatic reaction rate, corresponding to the possible conversion rate of the enzyme. 一般來說，基質，即待轉化的物質，例如蛋白質，大量過量存在。如果不是這種情況，則物質轉化是擴散控制的。酵素和基質之間的碰撞頻率是決定性的。為了實現最佳的物質轉化率或最大的酶反應速率（對應於酶的可能轉化率），該值必須很高。

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The conversion rate indicates the number of substrate molecules that can be converted per second. It is usually in the range of 10^3 to 10^4 per second. A moving solution can only promote the frequency of collisions between enzyme and substrate. The idea discussed of periodically interrupting the movement of the rinsing liquor during automated cleaning so that the enzymes work better is incorrect based on knowledge of reaction kinetics. To prove this fact, 25 µl of reactivated heparinized sheep blood was pipetted onto 4 cm^2 pieces of filter paper and dried at 40° C for one hour. These were stirred continuously for 5 minutes in 20 ml of a solution with enzymatic cleaner at 600 rpm, then stirred for 6 seconds per minute at 600 rpm for 5 minutes, followed by a rest period of 54 seconds. The filter papers from the latter preparation were visually more contaminated. Extraction with 2 ml 1 % SDS and measurement of the residual protein content using the modified OPA method also resulted in 22 % compared to 43 % with constant stirring, and consequently poor cleaning in the procedure with pause.轉化率表示每秒可以轉化的基質分子的數量。通常在每秒 10^3 到 10^4 次的範圍內。移動的溶液只能提高酵素和基質之間碰撞的頻率。基於反應動力學知識，所討論的在自動清洗過程中定期中斷漂洗液的運動以使酶更好地工作的想法是不正確的。為了證明這一事實，吸取了 25 µl 重新活化的肝素化綿羊血液置於4cm^2濾紙上並在40°C下乾燥1小時。將它們在20ml含酶清潔劑的溶液中以600rpm連續攪拌5分鐘，然後以每分鐘6秒於600rpm下攪拌5分鐘，隨後休息54秒的時間。眼下製備的濾紙在視覺上污染更嚴重。以 2 ml 1% SDS 萃取並使用修改的 OPA 方法測量殘留蛋白質含量，結果仍為 22%相較於持續攪拌的 43%，因此過程中有暫停的清潔效果較差。

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Hygiene in Endoscopy – Developments, Changes, Standards內視鏡衛生－發展、變化、標準

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In many areas of medicine, endoscopic examinations and interventions are now an integral part of diagnostics and therapy. Modern gastroenterological endoscopy received decisive impulses with the development of fiberglass technology by Hirschowitz in 1958 and the invention of Bowden cables by Ottenjann in 1966. 在許多醫學領域，內視鏡檢查和干預措施現已成為診斷和治療不可或缺的一部分。隨著 **1958** 年 **Hirschowitz** 開發的玻璃纖維技術和 **1966** 年 **Ottenjann** 發明的鮑登纜線，現代胃腸內視鏡受到了決定性的推動。

Initially, flexible endoscopes could not be fully inserted; only the insertion tube and instrumentation channel were cleaned with water, at most with soap solution. Initially, the reprocessing processes for endoscopes were not subject to consistent disinfection. In the 1970s, the cleaning process consisted of an external wipe disinfection of the insertion tube, suctioning through the instrumentation channel and hanging the insertion tube in disinfection tubes. Remaining sections of the endoscope were wiped with alcohol. 最初，柔性內視鏡無法完全插入；僅用水清洗插入管和儀器通道，最多用肥皂溶液清洗。最初，內視鏡的再處理過程並未經過一致的消毒。在 1970年代，清潔過程包括對插入管進行外部擦拭消毒、通過儀器通道抽吸並將插入管懸掛在消毒管中。用酒精擦拭內視鏡的剩餘部分。

Since the beginning of the 1970s, infectious complications after endoscopic surgery have been reported. Bacterial and viral infections as a direct result of endoscopic examinations are rarely documented and then only casuistically or in small epidemics.自 1970 年代初以來，已有內視鏡手術後感染併發症的報告。內視鏡檢查直接導致的細菌和病毒感染很少有記錄，而且僅是偶然的或小規模的流行病。

In the 1980s, national and international guidelines were increasingly established by professional associations and official bodies. Publications of complications repeatedly led to a sharpening of awareness and continuously improved previously customary processing measures. For example, post-ERCP bacteremias are well documented, which were due to contaminated rinse water (*Pseudomonas* species) and inadequate drying before storage. This resulted in improved drying, increased rinsing water controls and a change in the positioning of the endoscopes (hanging positioning).1980年代，專業協會和官方機構越來越多地制定了國家和國際指南。併發症的反覆發表使人們的認識更加敏銳，並不斷改善先前的慣用處理措施。例如，ERCP (內視鏡逆行性膽胰管造影術)術後菌血症是有據可查的，這是由於沖洗水（假單胞菌屬）污染和儲存前乾燥不充分造成的。這改善了乾燥，增加了沖洗水控制，並改變了內視鏡的位置（懸掛位置）。

The development of fully insertable endoscopes from 1983 onwards eliminated the problem of incomplete disinfection. This development facilitated preparation and improved process safety. In the case of fully insertable endoscopes, the entire outer surfaces and all channel systems now had to be cleaned and disinfected using appropriate irrigation adapters. 1983年起，全插入式內視鏡的開發消除了消毒不徹底的問題。這一發展促進了製備並提高了製程安全性。對於完全插入式內視鏡，現在必須使用適當的沖洗轉接器對整個外部表面和所有通道系統進行清潔和消毒。

Manual brush cleaning of the instrument and suction channel is considered the key point for proper processing. Thorough brush cleaning can achieve up to a 4-log reduction of germs. In addition to coarse dirt particles, parasites are also removed. Nevertheless, the designs of the endoscopes do not accommodate a complete cleaning.手動刷子清潔儀器和抽吸通道被認為是正確處理的關鍵點。徹底的刷子清潔可以使細菌減少多達 4 個對數。除了粗大的污垢顆粒外，寄生蟲也被去除。然而，內視鏡的設計不適合完全清潔。 To date, however, the air-water channel, additional flushing channels and the Albaran Bowden channel are not accessible for brush cleaning in most models of duodenoscopes. Only ONE manufacturer allows manual brush cleaning of all sewer systems. In some cases, fiber instruments that cannot be fully immersed are still in use, which runs counter to current guidelines. Only the consistent inspection of hygiene in the context of preventive and curative colonoscopy, the older models have been eliminated. KV Bayern (Germany) has provided important pacemaker services here. Further developments in the endoscope design also have an immediate positive impact on hygiene. For example, removable thistle caps help to clean the Albaran lever on duodenoscopes.然而，迄今，在大多數型號的十二指腸鏡中，空氣-水通道、附加沖洗通道和阿爾巴蘭鮑登通道無法進行刷子清潔。只有一家製造商允許對所有滲溝系統進行手動刷子清潔。在某些情況下，無法完全浸入水中的纖維儀器仍在使用，這與現行準則背道而馳。只有在預防性和治療性大腸鏡檢查的背景下進行一致的衛生檢查，舊型號才被淘汰。 KV Bayern（德國）在這裡提供了重要的人工節律器服務。內視鏡設計的進一步發展也對衛生產生直接的正面影響。例如，可拆卸的薊帽有助於清潔十二指腸鏡上的阿爾巴蘭桿。

In the mid-1980s, “endoscope washing machines” were developed, today referred to as “Washer Disinfectors for Endoscopes (WD-E)”. The cold-chemical or chemo-thermal processing in the machine initially raised high expectations. In fact, such a “washing machine” makes work much easier and, for the first time, guarantees validated, standardized processing. Many reprocessing steps have been taken over by the WD-E, but it has not replaced manual brush cleaning yet. Today, there is a consensus that manual pre-cleaning must precede by mechanical processing, as the thorough cleaning of the thin channels is not carried out by the machine to the same extent.

WD-E can also pose a risk of infection perse. The main reason for this risk is a lack of maintenance, when structural deficiencies develop into germ reserves and pass contaminated water on to cleaned instruments. In recent years, extensive safety developments have been made. They range from filter systems to treatment of the last rinse water to various monitoring systems. Finally, models are offered that include single-channel flushing because of the future ISO standard prEN 15883.1980 年代中期，開發了“內視鏡清洗機”，今天稱為“內視鏡清洗消毒機 (WD-E)”。機器中的冷化學或化學熱處理最初引起了很高的期望。事實上，這樣的「洗衣機」使工作變得更加容易，並且第一次保證了經過驗證的標準化處理。許多再處理步驟已被 WD-E 取代，但它尚未取代手動刷子清潔。如今，人們一致認為，手動預洗必須先於機械處理，因為機器無法對細通道進行徹底清洗。

WD-E 本身也可能帶來感染風險。造成這種風險的主要原因是缺乏維護，當結構缺陷發展成為細菌儲備並將受污染的水傳遞到已清潔的儀器時。近年來，安全方面取得了廣泛的進展。它們的範圍從過濾系統到最後沖洗水的處理到各種監控系統。最後，由於未來的 ISO 標準 prEN 15883，提供了包含單通道沖洗的型號。

In 1997, the spectacular case of hepatitis C transmission (same genome sequence in the case of carriers and patients) during colonoscopy triggered new discussions. However, the review of this case revealed gross errors in the reprocessing of endoscopes and instrumental accessories. Is there really a high risk of virus transmission through gastrointestinal endoscopy? Retrospective studies in France of blood donors have shown that as possible risk factor, a previous endoscopic examination is determined.1997年，大腸鏡檢查期間C型肝炎傳播的驚人案例（攜帶者和患者的基因組序列相同）引發了新的討論。然而，對此案的審查發現，內視鏡和器械配件的再處理存在嚴重錯誤。透過胃腸鏡檢查傳播病毒的風險真的很高嗎？法國對捐血者的回顧性研究表明，先前的內視鏡檢查被確定為可能的危險因子。

Although prospective data did not confirm an increased risk of transmission, restrictive restrictions on blood donors were imposed in France and Germany. For example, an endoscopic examination in the previous 6 months excludes a voluntary donation.儘管前瞻性數據並未證實傳播風險增加，但法國和德國對捐血者實施了限制性限制。例如，過去 6 個月內進行的內視鏡檢查排除了自願捐血。The BSE (mad cow disease) crisis triggered additional discussions, as prions are completely insensitive to conventional endoscope processing methods and are not eliminated by the previous chemical actives. Aldehydes are the reference product for endoscope re-processing. The decisive disadvantages, however, are protein fixation and promotion of biofilm formation in endoscope channels. In the 2002 revision of the RKI guidelines, aldehydes were therefore banned from the purification step. For several years now, quaternary ammonium compounds and peracetic acid have established themselves as alternatives in Germany. Aldehydes have a high allergy potential. Extensive data are available from the UK on health damage (skin and mucous membrane reactions, asthmatic diseases) among endoscopic staff. Appropriate protective measures (protective clothing, working methods and room technology systems) were then established as standards. BSE（牛腦海綿狀病變; 瘋牛症）危機引發了更多討論，因為普利昂蛋白疾病（庫賈氏病;傳染性海綿狀腦病）對傳統內視鏡處理方法完全不敏感，並且不會被以前的化學活性物質消除。醛類是內視鏡再處理的參考產品。然而，決定性的缺點是蛋白質固定和促進內視鏡通道中生物膜的形成。因此，在 2002 年修訂的 RKI 指引中，純化步驟中禁止使用醛類。幾年來，四級銨化合物和過乙酸在德國已成為替代品。醛類具有很高的過敏潛力。英國提供了大量有關內視鏡工作人員健康損害（皮膚和黏膜反應、氣喘疾病）的數據。隨後制定了適當的防護措施（防護服、工作方法和房間技術系統）作為標準。

In manual and automated processing, different products have to be worked with due to process differences. Above all, it is important that a treatment concept excludes undesirable interactions between the different chemicals.在手動和自動化加工中，由於製程差異，必須處理不同的產品。最重要的是，處理概念要排除不同化學物質之間不良的相互作用，這一點很重要。

In recent years, large prospective studies have been carried out in Germany on the reprocessing of endoscopes and endoscopic instrumental accessories. The HYGEA and QSHE studies in Bavaria examined the reprocess-ing status in clinics and practices. 近年來，德國針對內視鏡及內視鏡器材配件的再處理進行了大量前瞻性研究。巴伐利亞的 HYGEA 和 QSHE 研究檢視了診所和實踐中的再處理狀況。

Over 50 % of endoscopes were rejected. It was clear that automated processing showed the best results, as well as institutions with a high number of examinations and institutions with well-trained staff.超過 50% 的內視鏡被駁回。很明顯，自動化處理顯示出最好的結果，以及考試數量較多的機構和擁有訓練有素的工作人員的機構。

Manual and automated processing through the ages多年來的手動和自動處理。.

The latest results from the Frankfurt area once again confirm these observations. As a direct consequence of these results, a quality management system for endoscopic institutions has been established, which requires every 6-month hygiene inspections, certificates and training. Poor quality leads to the loss of participation in the screening colonoscopy program.法蘭克福地區的最新結果再次證實了這些觀察結果。這些結果的直接結果是，建立了內視鏡機構的品質管理體系，要求每 6 個月進行一次衛生檢查、證書和培訓。品質不佳導致無法參與篩檢大腸鏡檢查計劃。

Endoscopic instrumental accessories must be sterile, as they penetrate the mucous membrane. While single-use products are increasingly being used in Anglo-Saxon countries, multiuse products are still in the majority on the European market. A German multi-center study showed that biopsy forceps from the colon can be reliably prepared even after repeated use if a strict processing process is followed. The new RKI guidelines (2002) provide detailed recommendations for processable instrumental accessories. With costs still high and budgets tight, the consistent switch to single-use items is a fundamental cost issue for many practices and clinics.內視鏡器械配件必須無菌，因為它們會穿透黏膜。雖然一次性使用的產品在盎格魯撒克遜國家的使用越來越多，但多用途產品在歐洲市場上仍佔多數。德國的一項多中心研究表明，如果遵循嚴格的處理流程，即使重複使用，也可以可靠地準備結腸切片鑷子。新的 RKI (羅伯特・科赫研究所)指南 (2002) 提供了可處理儀器附件的詳細建議。由於成本仍然很高且預算緊張，持續轉向一次性物品是許多診所和診所的基本成本問題。

In recent years, more hygienic relevant laws, ordinances and directives have been revised and reformulated nationally and internationally. Findings from cur-rent studies, such as the HYGEA and the forceps study, were translated into detailed processing instructions. Over the last 30 years, technical developments have improved the hygiene status in endoscopy. 近年來，國內外修訂和重新制定了更多衛生相關法律、條例和指令。 例如HYGEA (胃腸病學衛生 - 內視鏡再處理)和鑷子研究等目前研究的結果已轉化為詳細的處理說明。過去 30 年來，科技的發展改善了內視鏡檢查的衛生狀況。

Scientific studies questioned and investigated infections and technical problems, however with a noticeable delay. It should be emphasized that the documented infections are usually due to non-compliance with the processing guidelines, procedural errors in endoscope reprocessing or inadequately processes instrumental accessories. Key points in processing have not changed over the years: Thorough cleaning (including brush cleaning) is a prerequisite for safe disinfection. Endoscopes are complex instruments with a difficult structure and cannot be sterilized due to their material properties. Rigorous disinfection must therefore be promoted. 科學研究質疑並調查了感染和技術問題，但明顯延遲了。應該強調的是，記錄的感染通常是由於不遵守處理指南、內視鏡再處理過程中的程序錯誤或儀器配件處理不當造成的。多年來處理要點沒有改變：徹底清潔（包括刷子清潔）是安全消毒的前提。內視鏡是複雜的儀器，結構複雜，並且由於其材料特性而無法滅菌。因此必須提倡嚴格消毒。

Automated processing makes work easier. However, it is not really “fully automatic” due to the necessary manual pre-cleaning step. The maintenance of the machines is another key point for continuous processing quality.自動化處理讓工作更加輕鬆。然而，由於必要的手動預清潔步驟，它並不是真正的「全自動」。機器的維護是連續處理品質的另一個關鍵點。

Hygiene is still today a primary priority topic of nursing and assistant staff. Only a few dedicated endoscopists, hygienists and microbiologists deal intensively with this topic. The quality of the entire reprocessing and hygiene process depends crucially on the level of training, the commitment and care of the nursing and assistant staffand quality-oriented doctors. 如今，衛生仍然是護理人員和助理人員的首要任務。只有少數專門的內視鏡醫師、衛生學家和微生物學家深入研究這個主題。整個後處理和衛生過程的品質在很大程度上取決於培訓水平、助理人員和以及品質為本醫生的護理承諾和照顧。

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Infection risks on the dance floor and prevention strategies

An ironic comment for public health舞池裡的感染風險與預防策略-對公共衛生的諷刺評論

A. Kramer

Everywhere, staff in hospital wards, CSSDs, doctors' surgeries and care facilities moan about the "flood" of laws, regulations and guidelines on infection prevention. While on the one hand it is clear to everyone that a scrupulous approach to hygiene is essential for the protection of patients and staff, on the other hand a level of regulation has apparently been reached that many employees can only fully comprehend and implement with great effort - and not without reluctance.無論在哪裡，醫院病房、CSSDs(中央消毒供應部門)、醫生診所和護理機構的工作人員都在抱怨關於感染預防的法律、法規和指南的「氾濫」。一方面，每個人都清楚，嚴格的衛生方法對於保護患者和工作人員至關重要，但另一方面，顯然已經達到了許多員工只能完全理解並付出巨大努力才能實施的監管水平。但並非沒有不情願。

However, despite all understanding for such lawsuits, one must be careful not to deviate from the path taken and thus encourage a dangerous trend: the relativization of the importance of infection prevention efforts! Nowadays, judgments in liability claims in this area are occasionally based on a "residual risk" concept. For example, the Higher Regional Court of Hamm argued in a judgment (Ref.: 3U 93/04 OLG Hamm) that a sufficiently safe prevention of an infection could not be achieved even if all hygiene regulations were observed. Transmissions of pathogens that occur for reasons that cannot be controlled are therefore part of the patient's uncompensated risk. Such a view is, of course, grist to the mill of those who believe that not everything can be controlled or kept germ-free and that life – to paraphrase Erich Kästner – is always to some extent life-threatening. The author of these lines finds such a view highly questionable: does this mean that we should relax our efforts? Is it perhaps honest and ethically justifiable to simply resign ourselves to a "general life risk"? Wouldn't it be our duty and obligation as hygiene experts to make everyday life as a whole safer? 然而，儘管大家對此類訴訟表示理解，但我們必須小心，不要偏離所採取的道路，從而助長一種危險的趨勢：感染預防工作的重要性相對化！如今，該領域的責任索賠判斷有時會基於「殘留風險」的概念。例如，哈姆高等地區法院在一項判決中辯稱（參考號：3U93/04 OLG Hamm），即使遵守所有衛生規定，也無法實現足夠安全的感染預防。因此，由於無法控制的原因而發生的病原體傳播是患者無補償風險的一部分。當然，這樣的觀點對那些相信並非一切都可以控制或保持無菌的人來說是有道理的，並且相信生命（引用埃里希·卡斯特納的闡釋）在某種程度上總是危及生命。這篇文章的作者認為這種觀點非常值得懷疑：這是否意味著我們應該放鬆努力？簡單地接受「一般生命風險」也許是誠實且道德合理的嗎？讓日常生活變得更安全不是我們身為衛生專家的責任和義務嗎？

Too many regulations? On the contrary! Anyone who actually thinks that there are TOO MANY rules and regulations in the field of hygiene is urgently recommended to think about their "nosocomial outside the box thinking": How many people, for example, would benefit if the everyday handling of infectious cash were finally properly regulated in terms of hygiene? 規定太多？恰恰相反！強烈建議任何真正認為衛生領域存在太多規則和規定的人思考他們的「醫院外思維」：例如，如果日常處理傳染性現金最終得到解決，有多少人會受益衛生方面是否得到適當監管？

Almost everyone!

幾乎所有人！

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Unfortunately, there is no authority, no institute, no association that feels responsible for developing such an urgently needed guideline.

The same applies to the proper reconditioning of restaurant cutlery. At this point, I would like to call for infection prevention to be taken out of its "ivory tower" of the medical facilities and food production and to bring them into the full, germ-ridden life in the world "out there". Moreover, I will lead by example by presenting an initial risk analysis for an area of public life that I have identified as being at high risk of infection: dancing. As will be shown, even an initial – admittedly still very superficial – examination of the usual hygienic conditions at such events leads to a whole series of recommendations that can dramatically reduce the risk of dangerous infections, and ultimately perhaps even save lives! So there is an urgent need for research here!

不幸的是，沒有任何權威機構、機構或協會認為有責任制定如此迫切需要的指南。這同樣適用於餐廳餐具的正確翻新。在此，我想呼籲將感染預防工作從醫療設施和食品生產的「象牙塔」中剔除出來，帶入「外面」的世界，充分享受充滿細菌的生活。此外，我將以身作則，對我確定的感染高風險的公共生活領域進行初步風險分析：跳舞。正如將要展示的那樣，即使是對此類活動中通常的衛生條件進行初步檢查（誠然仍然非常膚淺），也會產生一系列建議，可以大大降低危險感染的風險，最終甚至可能挽救生命！所以這裡迫切需要進行研究！

About the method關於方法

Hygiene concepts are necessary to get a grip on the risk of infection in everyday public life. In principle, the structure of such concepts is the same everywhere: the operation and operating processes are described, the risk of possible sources of danger and their potential for infection are estimated (risk assessment) and preventive measures are proposed.

為了控制日常公共生活中的感染風險，衛生觀念是必要的。原則上，這些概念的結構在任何地方都是相同的：描述操作和操作流程，估計可能的危險源的風險及其感染的可能性（風險評估）並提出預防措施。

In detail, the following areas had to be considered and examined具體而言，必須考慮和審查以下方面:

1. Health significance and risks of dance跳舞的健康意義與風險
2. Sources of infection傳染源
3. Transmission paths傳輸路徑
4. Preventive measures預防措施
5. Outbreak management疫情管理

The processing of these sub-questions subsequently allowed a risk assessment and substantiated the evidence for the prevention strategy.這些子問題的處理隨後允許進行風險評估並證實預防策略的證據。

Data was initially collected using the Internet (detailed studies are in preparation). Using the search functions of Medline, Web of Science, the Clinical trails register of the U.S. National Library of Medicine (www.Clinicaltrails. gov) and Google Scholar, relevant key terms from the sphere of dance enjoyment were linked with each other: "dance floor", "dance", "dance movement", "body contact", "sneeze", "kiss", "cleavage" – each in conjunction with the term "infection risk". The keyword search was carried out in two languages (German and English). This was preceded by a search for the phrases "infection risk on the dance floor" or "infection risk at the dance", which – significantly – yielded no results (once again: need for research!!!).數據最初是透過網路收集的（詳細研究正在準備中）。使用 Medline、Web of Science、美國國家醫學圖書館的臨床試驗登記冊 (www.Clinicaltrails.gov) 和 Google 學術搜尋的搜尋功能，將舞蹈享受領域的相關關鍵字相互連結：「舞池」、「跳蹈」、「舞蹈動作」、「身體接觸」、「打噴嚏」、「親吻」、「乳溝」——每個都與「感染風險」一詞結合在一起。關鍵字搜尋以兩種語言（德語和英語）進行。在此之前，我們對短語"舞池感染風險"或"舞會感染風險"進行了搜索，但顯然沒有得到任何結果（再次強調：需要研究！！！）。

Results and recommendations結果和建議

Let's get straight to the point: After evaluating a number of international studies, attending dance events can only be recommended with restrictions from an infection prevention perspective! First of all, it is important to weigh up the risks and benefits carefully and, if you decide to do so, to take a few precautions.

The greatest dangers are not so much from dancing itself. In fact, it can even be considered certain that dancing, laughing and kissing are more beneficial to health as they stimulate the immune system and therefore have an overall infection-preventing effect.言歸正傳：在評估了多項國際研究後，從預防感染的角度來看，只能在有限制的情況下推薦參加舞蹈活動！首先，仔細權衡風險和利益非常重要，如果您決定這樣做，請採取一些預防措施。

最大的危險並不是舞蹈本身。事實上，甚至可以肯定的是，跳舞、大笑和親吻對健康更有利，因為它們可以刺激免疫系統，從而具有整體預防感染的作用。

It has been proven that dancing can counteract senile dementia, which in turn is positively correlated with an increased risk of infection. Conversely, anyone who starts dancing at a young age and continues to do so until old age is actively preventing infection.事實證明，跳舞可以對抗老年癡呆症，而老年癡呆症又與感染風險增加呈正相關。相反，任何從年輕時開始跳舞並堅持到老年的人都在積極預防感染。

Laughter can almost be described as physical exercise, with the added bonus of amusement and calorie consumption: Ordinary everyday laughter – defined as around 100 laughs a day – stimulates cardiac activity in a similar way to rowing for ten minutes. During intense laughter, the lungs are ventilated in such a way that the remaining air is quickly and completely exchanged (incidentally, respiratory therapy attempts to achieve the same therapeutic effect!) Kissing, which is also frequently observed around dance events, also strengthens the immune system in most cases. By exchanging viruses and bacteria, an in-timate kiss acts like an oral vaccination. Other factors contribute to the fact that amorous kisses in particular act as a kind of preventative medicine: 笑幾乎可以被描述為體育鍛煉，還有娛樂和卡路里消耗的額外好處：普通的日常笑——定義為每天笑 100 次左右——刺激心臟活動，就像划船 10 分鐘一樣。在劇烈的笑聲中，肺部進行通氣，從而使剩餘的空氣快速而完全地交換（順便說一句，呼吸療法試圖達到相同的治療效果！）

接吻在舞蹈活動中也很常見，在大多數情況下也能增強免疫系統。透過交換病毒和細菌，親密的親吻就像口服疫苗一樣。其他因素也導致了多情之吻尤其可以作為一種預防藥物：

1. In the short term, blood pressure rises to 180 and the pulse doubles短期內血壓升至180，脈搏加倍;
2. Circulation and metabolism get going循環和新陳代謝開始進行
3. Pain-inhibiting adrenaline and dopamine are released釋放抑制疼痛的腎上腺素和多巴胺;
4. Cortisol, which causes harmful stress effects, is contained含有皮質醇，會造成有害的壓力影響,
5. The pancreas produces more insulin胰臟產生更多胰島素.

According to some studies, regular kissing can increase life expectancy by up to five years!根據一些研究，經常接吻可以延長壽命長達五年！

Nevertheless, caution is advised when kissing, as it is a primary transmission route, for example for infectious mononucleosis (kissing disease). The viral infection occurs through saliva and droplets. One indication of suspected infection is foul breath.儘管如此，接吻時還是要小心，因為它是傳染性單核細胞增多症（接吻病）等疾病的主要傳播途徑。病毒感染是經由唾液和飛沫發生。疑似感染的跡象之一是口臭。

Recommendation建議1: No deep French kissing if you have foul breath! In this case, kissing is allowed anywhere without risk of infection – just not on the mouth!如果你有口臭，就不要深法式接吻！在這種情況下，在任何地方都可以接吻，沒有感染的風險—只是不能在嘴上！

Another less common form of kissing these days is the hand kiss. If the hand to be kissed has come into contact with diarrhea pathogens during the last use of the toilet and no virucidal hand disinfection has taken place afterwards – simple hand washing is not enough! – there is a risk of a norovirus outbreak.如今另一種不太常見的接吻形式是手吻。如果要親吻的手在上次上廁所時接觸過腹瀉病原體，並且之後沒有進行手部消毒，那麼簡單的洗手是不夠的！ – 存在諾羅病毒爆發的風險。

Recommendation 建議 2: Only kiss previously disinfected hands.只親吻之前消毒過的手。

Further risks exist in connection with activities that usually occur around dance events: Drug use, extra-marital sex, excesses. A Chinese study shows that the risk of infection with sexually transmitted diseases (e.g. HIV) is higher where commercial sex services are enjoyed during the dance break or after the dance.舞蹈活動周圍通常發生的活動還有其他風險：吸毒、婚外性行為、過度行為。中國的一項研究表明，在舞會間隙或舞後享受商業性服務的人感染性傳染病（例如愛滋病毒）的風險更高。

Recommendation建議3: Ideally, non-commercial sex should be combined with dancing while observing the relevant preventive measures. 理想情況下，非商業性行為應與舞蹈結合，同時遵守相關預防措施。

In this context, it should be noted that although skin warts are contagious, there is no risk of infection from nipples. Therefore, from an infectiological point of view, even low necklines only represent a harmless challenge. Colfax et al. point out that drug abuse during dancing can also lead to an overall laxer behavior.在這種情況下，應該注意的是，雖然皮膚疣具有傳染性，但不存在乳頭感染的風險。因此，從感染學的角度來看，即使是低領口也只是無害的挑戰。科爾法克斯等指出跳舞時濫用藥物也會導致整體行為放鬆。

Recommendation建議4: If possible, dancing should not be enjoyed under the influence of drugs. Attention: Alcohol also dis-inhibits!如果可能的話，不要在藥物的影響下跳舞。注意：酒精也會解除抑制！

Only in extreme cases do contraceptive measures go completely wrong, as described in an Indian article: A young woman was plagued by coughing, phlegm production and fever for months until doctors removed a condom from her lung that she had apparently accidentally inhaled – possibly at or after a dance event! Finally, a note for professional dancers and amateurs with a penchant for excess: According to a Turkish study, a lot of dancing with low or irregular food intake provokes the occurrence of cachexia, which in turn is associated with an increased risk of all kinds of infections.只有在極端情況下，避孕措施才會完全出錯，正如一篇印度文章中所描述的那樣：一名年輕女子幾個月來一直受到咳嗽、咳痰和發燒的困擾，直到醫生從她的肺部取出了一個顯然是她不小心吸入的避孕套—可能是在舞蹈活動中或之後！最後，給有過度嗜好的專業舞者和業餘愛好者的注意事項：根據土耳其的一項研究，大量跳舞時食物攝入量低或不規律會引發惡病質的發生，而惡病質又會增加各種疾病的風險。

Recommendation 建議5: Don't forget to eat while dancing (and vice versa)! 跳舞時別忘了吃飯（反之亦然）！

Outlook展望

In my opinion, an important first step has been taken with the development of these recommendations. Nevertheless, many questions remain unanswered. Studies for in-depth risk analysis must be initiated. Hand disinfection before dancing is a so far neglected preventive measure whose preventive effect must be confirmed by surveillance. Last but not least, the contribution of the infection-preventing properties of the dancing in hospital could contribute to reducing the rate of nosocomial infections and what protective measures would be necessary in the event of isolation.我認為，這些建議的制定已經邁出了重要的第一步。儘管如此，許多問題仍然沒有答案。必須啟動深入的風險分析研究。跳舞前的手部消毒是一項迄今為止被忽視的預防措施，其預防效果必須透過監測來證實。最後但並非最不重要的一點是，醫院舞蹈的預防感染特性可能有助於降低醫院感染率以及隔離時需要採取哪些保護措施。

The risks of infection in everyday life outside the hos-pital are as numerous as the areas in which people live. In all modesty, I hope that my example will encourage other researchers to take on other potentially highly infectious environments (e.g. public transportation, cinemas, government waiting areas, the "kiosk around the corner", etc.).

醫院外日常生活中的感染風險與人們居住的區域一樣多。謙虛地說，我希望我的例子能鼓勵其他研究人員研究其他潛在的高度傳染性環境（例如公共交通、電影院、政府等候區、「轉角處的資訊亭」等）。

My thanks go to the DGKH (German Society of Hospital Hygiene), which was convinced of the necessity of my research and generously supported me in a project that does not actually fall within its remit (and which thus filled an institutional vacuum in an unbureaucratic manner). I will report on further results of my study report at this point. 我要感謝DGKH（德國醫院衛生學會），它相信我的研究的必要性，並慷慨地支持我的一個項目，該項目實際上並不屬於其職權範圍（因此以非官僚的方式填補了機構真空））。我將在此時報告我研究報告的進一步結果。

The history of the “ebro Thermologger” - from nobody to market leader「ebro 熱記錄器」的歷史- 從無名小卒到市場領導者

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Company公司

Ebro Electronic GmbH is part of Xylem Inc. Xylem is a leading global technology provider specializing in pumps, water treatment and instrumental analysis. Xylem is represented in more than 150 countries through a range of market-leading product brands. Launched in 2011 from the spin-off of ITT Corporation, the company became Xylem and is now headquartered in Washington DC, USA. With 23,000 employees worldwide, the company generated sales of USD 6.29 billion in 2023.Ebro Electronic GmbH 隸屬於Xylem公司 (Xylem Inc.)。Xylem透過一系列市場領先的產品品牌在 150 多個國家 地區開展業務。該公司於 2011 年從 ITT 公司分拆出來，更名為Xylem，目前總部位於美國華盛頓特區。該公司在全球擁有 23,000 名員工，2023 年銷售額達 62.9 億美元。

* *The author details correspond to those at the time of first publication. 作者詳細資料與首次出版時的資訊一致。*

W. Klün (†)

The first data logger I knew of came from Gould Instruments in the USA and was a 16-channel temperature recording system with a PDP-8 computer, a Telex machine and a temperature amplifier. The data was recorded using a Philips ECMA-34 digital cassette, and it took two hours just to load the operating software via punched tape. All the equipment just fitted into the trunk of my Ford Taunus Turnier, which I drove all over Europe in 1974 to present this data logger to the industry and car manufacturers. Inciden-tally, the price for this data logger was an incredible DM 200,000 at the time. Nearly € 102,300.我所知道的第一台數據記錄器來自美國的 **Gould Instruments**，這是一個 **16** 通道溫度記錄系統，配備 **PDP-8** 電腦、電傳機和溫度放大器。數據是使用飛利浦 **ECMA-34** 數位盒式磁帶記錄的，僅透過穿孔磁帶加載操作軟體就花了兩個小時。所有設備都安裝在我的福特 **Taunus Turnier** 的後備箱中，**1974** 年我開著這輛車走遍了歐洲，向業界和汽車製造商展示了這款數據記錄器。順便說一句，這款數據記錄器的價格當時高達 **20** 萬德國馬克，令人難以置信。近 **102,300** 歐元。

The first handy data logger came from England around 30 years ago and was called “Squirrel”. The device recorded temperatures and worked with an 8-bit com-puter. The customers were mostly well-known pharmaceutical manufacturers who monitored the storage and transportation temperatures of medicines. At this time, data acquisition via electronic storage was revolutionary, because until then only dot printers and multi-channel recorders had been used to record temperature values.第一個便攜式資料記錄器大約 30 年前來自英國，被稱為「松鼠」。本設備記錄溫度並與 8 位元電腦配合使用。客戶大多是對藥品儲存和運輸溫度進行監控的知名製藥公司。此時，透過電子儲存進行資料擷取是革命性的，因為在此之前只有點式印表機和多通道記錄器被用來記錄溫度值。

In the 1980s, ebro Electronic mainly produced plug-in power supply units and handheld measuring devices for temperature, pH and relative humidity. In 1989, ebro and its long-standing business partner Willem Geul developed the first battery-operated ebro temperature logger called Temptimem. The decisive factor for the development was the increased demand from food manufacturers for battery-operated data loggers for temperature monitoring during the transportation and storage of frozen goods. A major customer at the time was McDonald’s with its deep-freeze warehouses throughout Europe.1980年代，ebro Electronic主要生產插入式電源裝置和手持溫度、pH和相對濕度測量設備。 1989 年，ebro 及其長期業務合作夥伴 Willem Geul 開發了第一台電池供電的 ebro 溫度記錄儀，名為 Temptimem。發展的決定性因素是食品製造商對電池供電數據記錄器的需求不斷增加，該數據記錄器用於冷凍食品運輸和儲存過程中的溫度監測。當時的一個主要客戶是麥當勞，其冷凍倉庫遍布歐洲。

Almost at the same time, in 1990, the food industry was looking for a cable-independent temperature measurement system for process monitoring during pasteurization and sterilization. The state of the art at that time was to measure the process temperature using wired thermocouples. Placing the thermocouples in the food to be pasteurized was very laborious, time-consuming and expensive and could therefore only be used to a limited extent for routine process monitoring. This was the birth, so to speak, of the first ebro thermologger called EBI 85. Within a year, this logger was developed together with the engineering office Franz Knopf in Offenburg, a member of the Stuttgart Transfer Center. The EBI 85 could record temperatures in the range from -40 to +85 °C and worked with a specially developed computer of the “Andropan” type, because the PC with the DOS operating system, which was already well known at the time, was not classified as tamper-proof and could therefore not be used as an evaluation system. In December 1992, the logger was finally certified by the Physikalisch-Technische Bundesanstalt (PTB) Berlin.幾乎在同一時間，即 1990 年，食品業正在尋找一種獨立於電纜的溫度測量系統，用於巴氏殺菌和滅菌過程中的製程監控。當時最先進的技術是使用有線熱電偶測量製程溫度。將熱電偶放置在待巴氏殺菌的食品中非常費力、耗時且昂貴，因此只能在有限的範圍內用於常規製程監控。可以說，這就是第一台 ebro 熱記錄器 EBI 85 的誕生。 EBI 85 可以記錄 -40 至 +85 °C 範圍內的溫度，並與專門開發的“Andropan”型電腦配合使用，因為帶有當時已廣為人知的 DOS 作業系統的 PC未歸類為防篡改，因此不能用作評估系統。 1992 年 12 月，記錄器最終獲得了柏林聯邦物理技術中心 (PTB) 的認證。

The temperature range of the EBI 85 data logger was ideal for monitoring pasteurization processes up to +85 °C. However, the data logger was not yet suitable for monitoring sterilization processes. A new, more power-ful data logger with a higher measuring and working range therefore had to be developed. A very close col-laboration with Texas Instruments, the manufacturer of electronic components, made it possible to develop new electronics suitable for use in the sterilization process within a short space of time. Texas Instruments devel-oped the TSS 400 processors for ebro for a new data logger with a measuring range of up to +125 °C. EBI 85 資料記錄器的溫度範圍非常適合監控高達 +85 °C 的巴氏殺菌製程。然而，數據記錄器尚不適合監控滅菌過程。因此，必須開發一種新的、更強大、具有更高測量和工作範圍的數據記錄器。與電子元件製造商德州儀器 (Texas Instruments) 的密切合作，使得在短時間內開發出適用於滅菌過程的新型電子產品成為可能。德州儀器 (TI) 為 ebro 開發了 TSS 400 處理器，用於測量範圍高達 +125 °C 的新型數據記錄器.

With the newly developed EBI 125 data logger, it was now possible to measure and monitor all sterilization processes in the food industry. The data logger was used for the validation and routine monitoring of various pasteurization and sterilization processes for canned meat, vegetables and fruit. 藉著新開發的 EBI 125 數據記錄器，現在可以測量和監控食品行業的所有滅菌過程。此數據記錄器用於罐裝肉類、蔬菜和水果的各種巴氏殺菌和滅菌過程的驗證和常規監控。

With the help of data loggers, validation and daily routine monitoring of food production processes could now be carried out for the first time without having to rely on a validation system with cable-bound thermocouples在數據記錄器的幫助下，現在可以首次對食品生產過程進行驗證和日常監控，而無需依賴電纜熱電偶的驗證系統.

The success of the EBI-125 data logger quickly became known outside the food industry. Thanks to the universal measuring and operating range of -40 to +125 °C, the data logger was also able to be used in the medical industry worldwide. The sterilization temperatures, but also the process temperatures during deep-freeze transport and storage could be documented. This new data logger, with its ideal ranges for many applications in the food and pharmaceutical markets, was therefore far ahead of its timeEBI-125 資料記錄器的成功很快就在食品業之外廣為人知。由於通用測量和工作範圍為 -40 至 +125 °C，此數據記錄器也能夠在全球醫療產業中使用。可以記錄滅菌溫度以及深度冷凍運輸和儲存過程中的製程溫度。這款新型數據記錄器具有適用於食品和製藥市場許多應用的理想範圍，因此遠遠領先於時代。.

Another milestone in the history of ebro data loggers was the ebro Winlog 2000 software developed in 1998, the first software in Europe to fully comply with the Food and Drug Administration Pharma Standard, FDA CFR 21 Part 11. TÜV Süd certified and validated a logger system according to this standard for the first time in 1998. ebro 資料記錄器歷史上的另一個里程碑是1998 年開發的ebro Winlog 2000 軟體，這是歐洲第一個完全符合食品和藥物管理局製藥標準FDA CFR 21 第11 部分的軟體。TUV Süd(南德產品驗證顧問)認證並於1998年首次採用該標準對記錄器系統進行了驗證.

In 1999, I realized that not only food and pharmaceutical manufacturers use autoclaves, but that they are also used in the CSSD, the Reprocessing Unit for Medical Devices, in hospitals. That's why this year I asked our sales manager Iven Kruse to come to Medica in Düssel-dorf - the largest trade fair for the medical device indus-try. After a busy day at the trade fair, he told me that no-body needed our Thermologger. The reason for this was that at that time, only chemical or biological indicators were used for the routine control of processes in steam sterilizers or washer-disinfectors (WDs). The need for validation of steam sterilization processes was largely unknown in most hospitals in 1999, despite the validation standard EN 554, and was only implemented very slowly and hesitantly. Validation of washer-disinfector processes was unthinkable of at the time. The relevant legal requirements and the technical awareness to scrutinize the processes were lacking. The CSSD trusted the machines and their processes.1999 年，我意識到不僅食品藥物製造商使用高壓滅菌器，醫院的 CSSD（中央無菌供應部）也使用高壓滅菌器。這就是為什麼當年我邀請我們的銷售經理 Iven Kruse 參加杜塞爾多夫的 Medica——醫療器材行業最大的貿易展。在展會上忙碌了一天后，他告訴我沒有人需要我們的熱記錄器。原因是當時僅使用化學或生物指示劑對蒸汽滅菌器或清洗消毒器 (WD) 的過程進行常規控制。 1999 年，儘管有 EN 554 驗證標準，但大多數醫院對蒸汽滅菌過程驗證的必要性知之甚少，而且實施過程非常緩慢且猶豫不決。清洗消毒器流程的驗證在當時是不可想像的。缺乏相關的法律要求和審查流程的技術意識。 CSSD （中央無菌供應部）信任這些機器及其流程。

This made me feel insecure at first, but also challenged me. I didn't want to accept this statement and wanted to find out for myself whether there was a way to present our thermologgers in the CSSD. So, I planned to present our products at Medica. In cooperation with the company H+P Sterilizers from Munich and with the approval of Dr. Herz, I exhibited Thermologger for the first time at Medica in 2000 on a very small stand of just 2 m² at the H+P stand in Hall 12. 起初這讓我感到不安，但同時挑戰著我。我不想接受這種說法，想親自了解是否有辦法在 CSSD（中央無菌供應部） 中展示我們的熱記錄器。因此，我計劃在 Medica 上展示我們的產品。在與慕尼黑 H+P Sterilizers 公司合作並獲得 Herz 博士的批准後，我於 2000 年在 Medica 12 號展廳的 H+P 展位上首次展出了熱記錄儀，展位面積僅為 2 平方米。

Hall 12 was the right hall and was well attended by CSSD staff, but nobody wanted to hear about our Thermologgers. I had to literally "drag" the CSSD staff to my small stand and show them the new technology. But there was no interest. I realized that although the processes in the pharmaceutical and food industries were not particularly different from the processes in the CSSD, the users behaved differently. Without laws, standards and guidelines, it was virtually impossible to establish thermologgers in the CSSD. 12 號大廳是合宜的大廳，CSSD （中央無菌供應部）工作人員出席的人數很多，但沒有人想了解我們的熱記錄器。我必須把 CSSD 的工作人員「揪」到我的小展位上，向他們展示新技術。但沒有興趣。我意識到，儘管製藥和食品行業的流程與 CSSD 的流程沒有特別不同，但用戶的行為卻有所不同。如果沒有法律、標準和指導方針，實際上不可能在 CSSD 中建立熱記錄器。

At the same time, my old friend Albert Bosch, who was still working for Getinge at the time, realized that we had something special for CSSD applications with the data logger. He carried out various routine control measurements in the steam sterilizer at the University of Aachen and was able to convince a service employee of a steam sterilizer manufacturer for the first time that data loggers were an excellent way of documenting processes.同時，我的老朋友 Albert Bosch（當時仍在 Getinge 工作）意識到我們對帶有資料記錄器的 CSSD（中央無菌供應部） 應用程式有一些特殊之處。他在亞琛大學的蒸汽滅菌器中進行了各種常規控制測量，並首次讓蒸汽滅菌器製造商的服務人員相信數據記錄器是記錄過程的絕佳方式。

> In 1999, the need for validation of steam sterilization processes was largely unknown in most hospitals [...]. Validation of washer-disinfector processes was unthinkable at that time.
> 1999 年，大多數醫院對蒸氣滅菌過程驗證的必要性知之甚少[...]。清洗消毒器流程的驗證在當時是不可想像的。

The two were observed in the background by the head of the CSSD at the time and Albert Bosch explained to him exactly how the data logger can record the temperature and pressure in the steam sterilizer every second interval – the individual phases of the sterilization process – from the evacuation phase through the equilibration time and the holding phase to the cooling phase. He demonstrated the evaluation of the data with his PC and impressed the head of the CSSD, who then commissioned ebro with the first major data logger delivery.當時 CSSD （中央無菌供應部）的負責人在後台觀察了兩人，阿爾伯特.博世向他詳細解釋了數據記錄器如何每秒記錄蒸汽滅菌器中的溫度和壓力 - 滅菌過程的各個階段– 從抽空階段到平衡時間、保溫階段再到冷卻階段。他用自己的電腦展示了數據評估，給 CSSD 負責人留下了深刻的印象，隨後 CSSD（中央無菌供應部） 委託 ebro 交貨了第一個主要數據記錄器。

That was the beginning in the CSSD with our thermologger. Iven Kruse was appointed Product Manager for the medical and CSSD market and in the same year became a member of the DIN committee NAMed NA063 (now renamed NAGesuTech NA176) and a member of the DGSV. A year later, he became a member of the EFHSS, later WFHSS, and another year later Iven Kruse joined the editorial team of *aseptica*.這是 CSSD （中央無菌供應部）與我們的熱記錄器的開始。 Iven Kruse 被任命為醫療和 CSSD（中央無菌供應部） 市場的產品經理，並於同年成為 DIN 委員會 NAMed NA063（現已更名為 NAGesuTech NA176）的成員和 DGSV(德國無菌供應協會) 的成員。一年後，他成為 EFHSS (世界醫院無菌供應論壇)的成員，後來又成為 WFHSS(世界醫院滅菌科學聯邦) 的成員，又一年後，Iven Kruse 加入了 *aseptica期刊* 的編輯團隊。

This was followed up by a series of fruitful collaborations with various consultants and manufacturers of steam sterilizers and washer-disinfectors. At this point, the very good and long-standing cooperation with Dr Thomas Fengler and his colleague Helmut Pahlke († 2010) and Toni Zanette from the University of Tübingen should be mentioned. They recognized early on that validation and routine control is easier to implement with thermologgers.隨後與蒸汽滅菌器和清洗消毒器的各種顧問和製造商進行了一系列富有成效的合作。在這一點上，值得一提的是與 Thomas Fengler 博士及其同事 Helmut Pahlke († 2010) 以及來自蒂賓根大學的 Toni Zanette 的良好且長期的合作。他們很早就認識到，使用熱記錄器更容易實現驗證和日常控制。

EBI 85
Food logger 食物記錄器

EBI 125
Medical technology logger
醫療技術記錄器

EBI 10
Flexible sensors –
pressure and temperature
彈性的傳感器 - 壓力和溫度

EBI 15
Bowie Dick Test Logger
(抽真空測試用)測試記錄器

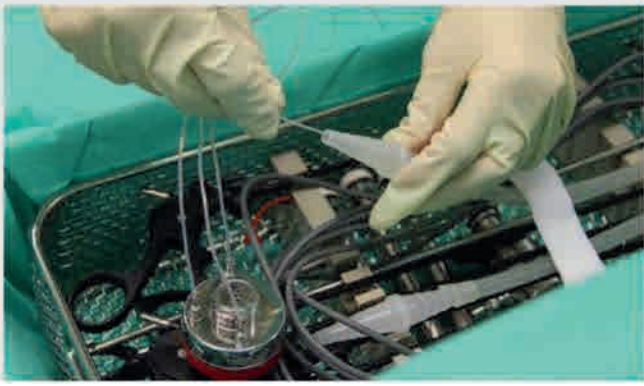
EBI 11
Pressure and temperature壓力和溫度

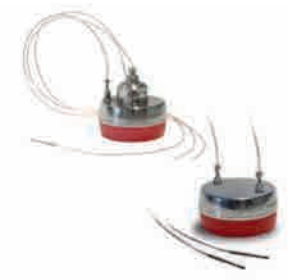
1992 1993 2006 2008 2010

The 1.2 mm thin cable sensors are used to determine the disinfection or sterilization temperature in endoscopes or capillaries with 0.1 °C accuracy.

1.2 mm 細電纜感測器用於確定內視鏡或毛細管中的消毒或滅菌溫度，精度為 0.1 °C。

The rinsing pressure in the washer-disinfector is detected with 10 mbar accuracy using pressure sensors with Luer-Lock connectors.使用帶有魯爾鎖連接器的壓力感測器以 10 mbar 的精度檢測清洗消毒器中的沖洗壓力。





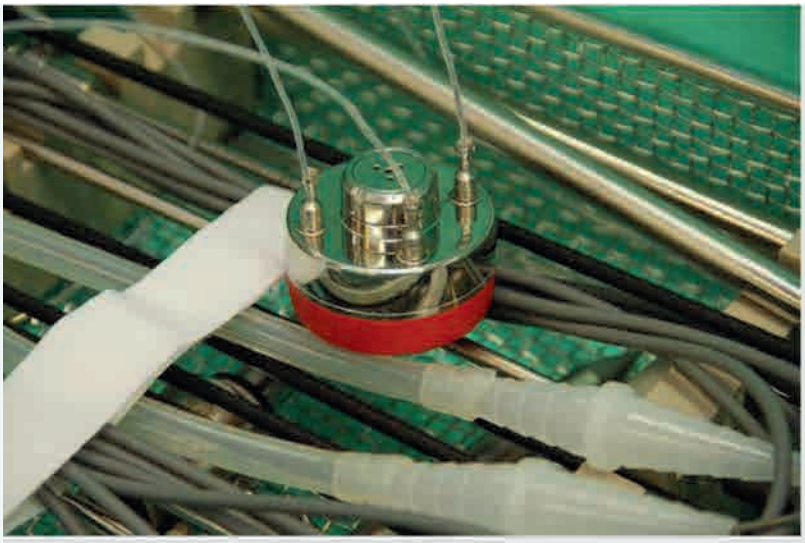
EBI 10
Flexible cable sensor and pressure柔彈性電纜感測器和壓力

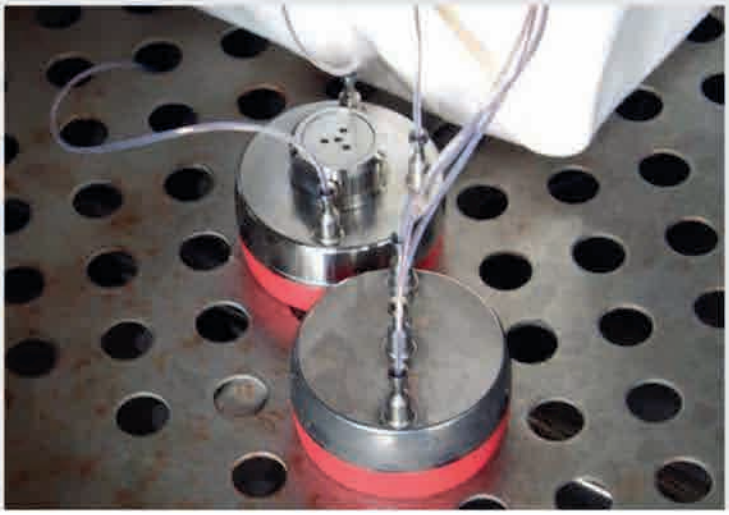
EBI 16
Bowie Dick Test Logger, optimized design(抽真空測試用)測試記錄器，最佳化設計

EBI 11
Pressure and temperature logger, special application DENTAL壓力和溫度記錄儀，特殊應用**牙科**

EBI 12 Complete overview, with various sensor options完整的概觀，具有各種感測器選項

2011 2012 2018 2019 2023





Above上圖:
Validation of the steam sterilization process with EBI 10 cable logger.使用 EBI 10 電纜記錄器驗證蒸氣滅菌過程。

Left左圖:
The electronic Bowie Dick test (抽真空測試用) 電子式測試記錄器EBI 15.

Support also came from Dr Jatzwauk from the Univer-sity of Dresden, who used our thermologger for the first time in 1998 during routine checks of washer-disinfector processes with the then completely unknown determination of the A0 value. This was followed by a publication in the central sterilization publication: Thermal disinfection effect of washer-disinfectors. 德勒斯登Dresden大學的 Jatzwauk 博士也提供了支持，他於 1998 年在對清洗消毒器過程進行例行檢查時首次使用了我們的熱記錄儀，當時 A0 值的測定完全未知。隨後，中央滅菌出版物發表了一篇文章：清洗消毒器的熱滅菌效果。

> Without laws, standards and guidelines, it was virtually impossible to establish thermo- loggers in the CSSD.如果沒有法律、標準和指導方針，實際上不可能在 CSSD （中央無菌供應部）中建立熱記錄器。

Central Service 2001; 9: 14–16. Dr Yushi Uetera from the University of Tokyo, now a member of the *Central Service* editorial board, also recognized the benefits of the ebro thermologger in faraway Japan. Many manufacturers also joined in, and here I would like to emphasize one in particular, the Miele Professional company with Dr Winfried Michels, who always supported ebro in word and deed, with advice.中央服務2001； 9：14-16。東京大學的 Yushi Uetera 博士（現為 Central Service 編輯委員會成員）也認識到 ebro 熱記錄儀在遙遠的日本所帶來的好處。許多製造商也加入其中，在這裡我想特別強調一家 Miele Professional 公司的 Winfried Michels 博士，他始終在言行上支持 ebro，並提供建議。

In 2002, the legal basis for the reprocessing of medical devices in Germany was created with the Medical Devices Act (MPG), the Medical Device Operator Or-dinance (MPBetreibV) and the RKI recommendation "Hygiene requirements for the reprocessing of medical devices". These required suitable validated procedures to ensure that reprocessed medical devices do not pose a health risk to patients, users and third parties. The validation of automated cleaning and disinfection processes for thermostable medical devices was defined by the then unpublished standard prEN DIN ISO 15883-1/2/3 and the guideline of the DGSV, DGKH and AKI. The standards DIN EN 285/554 and DIN 589466, later ISO 17665, defined routine control and validation for the operation of large sterilizers in the healthcare sector. The new guidelines and laws in particular, as well as inspections by the health authorities, presented CSSD personnel with new challenges. 2002 年，德國醫療器材再處理的法律依據是《醫療器材法》(MPG)、《醫療器材經營者條例》(MPBetreibV) 和 RKI 建議「醫療器材再處理的衛生要求」。這些需要經過適當的驗證程序，以確保再加工的醫療器材不會對病人、使用者和第三方構成健康風險。耐熱醫療器材自動清潔和消毒過程的驗證由當時未發布的準則 prEN DIN ISO 15883-1/2/3 以及 DGSV、DGKH 和 AKI 指南定義。準則 DIN EN 285/554 和 DIN 589466（後來的 ISO 17665）定義了醫療保健領域大型滅菌器運作的常規控制和驗證。特別是新的指導方針和法律，以及衛生部門的檢查，給CSSD（中央無菌供應部）人員帶來了新的挑戰。This was the opportunity for the ebro team led by Iven Kruse. They contacted CSSD employees and all manufacturers of steam sterilizers and washer-disinfectors. Temperature tests in washer-disinfectors were carried out during routine monitoring and validation with temperature data loggers to prove that the temperature in the chamber and in the load was reached during the process. If the washer-disinfectors used did not have recording devices with no permanently installed temperature sensor, the temperatures of the load had to be recorded by additional data loggers. 這對伊文克魯斯（Iven Kruse）領導的ebro團隊來說是一個機會。他們聯繫了CSSD（中央無菌供應部）員工以及所有蒸氣滅菌器和清洗消毒機的製造商。在使用溫度資料記錄器進行日常監測和驗證期間，對清洗消毒機進行了溫度測試，以證明在此過程中達到了腔室和負載中的溫度。如果所使用的清洗消毒機沒有記錄裝置且沒有永久安裝的溫度感測器，則必須由額外的資料記錄器記錄負載的溫度。

The evaluations of the data loggers showed the temperature curves in the overall process and made it possible to calculate the A_0 value. The A_0 value concept was successfully introduced by ISO 15883 and completely replaced biological indicators in the validation and routine control of washer-disinfector processes.數據記錄器的評估顯示了整個過程的溫度曲線，並使得計算A0值成為可能。 ISO 15883 成功引入了 A0 值概念，並在清洗消毒過程的驗證和常規控制中完全取代了生物指標。

For medical devices contaminated with heat-resistant viruses, e.g. hepatitis B viruses, an A_0 value of at least 3000 was set. The use of biological indicators instead of thermologgers was no longer justifiable (DIN EN 15883-1, point 6.8.1.). In steam sterilizers, the pressure and temperature values of each batch were documented using the integrated recording system. At that time, however, many sterilizers did not yet have a recording system, so the ebro-Thermologger was also used here for pressure and temperature monitoring. The Winlog.med software solution was developed specifically for users in the CSSD in order to create the possibility of simple routine monitoring. Within five years, ebro Electronic GmbH has become the European market leader for thermologgers in the CSSD sector. Many CSSD employees spoke of "the ebro" and meant a thermologger.對於被耐熱病毒污染的醫療器械，例如乙型肝炎病毒，A0值設定為至少3000。使用生物指示器代替熱記錄器不再合理（DIN EN 15883-1，第 6.8.1 點）。在蒸氣滅菌器中，使用整合記錄系統記錄每批的壓力和溫度值。然而，當時許多滅菌器還沒有記錄系統，因此這裡也使用了 ebro-熱記錄器來進行壓力和溫度監測。Winlog.med 軟體解決方案是專門為 CSSD （中央無菌供應部）用戶開發的，旨在創造簡單的日常監測的可能性。五年內，ebro Electronic GmbH 已成為歐洲 CSSD 領域熱記錄器市場的領導者。許多 CSSD 員工談到「ebro」時，指的是溫度記錄器。

Despite our success, we were not yet able to convince all validators and major manufacturers of our data loggers. What was missing were more flexible temperature sensors and, of course, the possibility of real-time measurement as in a validation system with thermocouples. However, if you consider the great effort involved in calibrating the thermocouple sensors and placing them in the WD or steam sterilizer, which is only possible from the outside via the connection piece, you quickly real-ize that a new wireless logger offers great potential for savings.儘管我們取得了成功，但我們尚未能夠說服所有驗證者和主要製造商使用我們的數據記錄器。缺少的是更靈活的溫度感測器，當然，也缺少使用熱電偶的驗證系統進行即時測量的可能性。然而，如果您考慮到校準熱電偶感測器並將其放入WD (清洗消毒機)或蒸汽滅菌器中需要付出巨大的努力，而這只能透過連接件從外部進行，您很快就會意識到新型無線記錄器提供了巨大的潛能的省力。

The new innovative EBI 10 wireless thermologger family from ebro Electronic makes it possible, the EBI 10 wireless technology enables routine checks and validation of WD and steam sterilization processes to be carried out wirelessly in real time. The EBI 10 transmits its measurement data from the closed WD or steam sterilizer, allowing the person responsible to follow the process live on the monitor and immediately stop any faulty process. This saves a lot of work and time. The completely waterproof and steam-tight EBI 10 (IP 68) has a temperature measuring range of –80 to +400 °C and a pressure measuring range of 1 to 4000 mbar. The memory capacity is 100,000 measured values, allowing processes to be recorded for up to ten hours with a measuring cycle of 250 milliseconds. ebro 電子的新型創新 EBI 10 無線熱記錄器系列使之成為可能，EBI 10 無線技術能夠即時無線地執行 WD (清洗消毒機)和蒸氣滅菌過程的例行檢查和驗證。 EBI 10 從封閉的 WD (清洗消毒機)或蒸氣滅菌器傳輸測量數據，使負責人能夠在監視器上即時追蹤流程並立即停止任何有缺陷的流程。這節省了大量的工作和時間。完全防水和蒸氣密封的 EBI 10 (IP 68) 的溫度測量範圍為 –80 至 +400 °C，壓力測量範圍為 1 至 4000 mbar。記憶體容量為 100,000 個測量值，可記錄過程長達 10 小時，測量週期為 250 毫秒。

The temperature and pressure accuracy is very high at ±0.1 °C and ±10 mbar respectively and is documented in the corresponding ISO certificate.溫度和壓力精度非常高，分別為 ±0.1 °C 和 ±10 mbar，並記錄在相應的 ISO 證書中。

The data loggers are operated with the special EBI 10 interface with integrated antenna. It operates on the globally approved 2.4 GHz frequency and complies with the IEEE 802.15.4 radio standard, which means that the logger can be used without any problems. At the same time, fast, flexible and vapor-tight Pt-1000 temperature sensors were developed, which have the same response time (t90) as thermocouples.數據記錄器透過具有整合天線的特殊 EBI 10 (連結)介面進行操作。它以全球認可的 2.4 GHz 頻率運行，符合 IEEE 802.15.4 無線電標準，這意味著記錄器可以毫無問題地使用。同時，開發了快速、靈活且氣密的 Pt-1000(鉑電阻1000) 溫度感測器，其反應時間 (t90, 達到其濃度90%所需要的時間)與熱電偶相同。

Our EBI-10 system was rounded off with the new validation software Winlog.validiation, which meets the requirements of ISO 15883 and ISO 17665. Our validation system was also successfully certified by TÜV Süd in 2008. In the last 5 years, further development has led to the establishment of the EBI 12 series, where we offer dataloggers for alternative sterilization devices like VH2O2, due to the optimized housing design, now also able for use with ATEX procedures like ETO sterilization, as well as including other sensors, like EBI 12-TC 230 for conductivity of final rinse water in WD. 我們的 EBI-10 系統透過新的驗證軟體 Winlog.validiation 得以完善，該軟體滿足 ISO 15883 和 ISO 17665 的要求。我們的驗證系統也於 2008 年成功獲得了 TUV Süd (南德產品驗證顧問)的認證。在過去 5 年中，進一步的發展催生了 EBI 12 系列，我們為 VH2O2(汽化式過氧化氫) 等替代滅菌設備提供數據記錄儀，由於經過優化的外殼設計，現在還能夠與 ETO (環氧乙烷)滅菌等 ATEX (防爆)程序一起使用，還包括其他感測器，例如用於測量 WD 最終沖洗水電導率的EBI 12-TC 230。

At the same time, ebro developed a cost-effective electronic Bowie-Dick test (EBI 15) for the CSSD in accordance with ISO 11140-4. Using modern electronic data acquisition, the EBI 15 provides a clear result ("pass"/"fail"). The functionality of the EBI 15 logger has also been tested by TÜV Süd and SMP in accordance with EN ISO 11140-4. The successor model is called EBI 16, and has doubled in capacity, like 1,000 cycles to monitor the process.

It has been a long road from nobody to market leader for thermal loggers in the CSSD, but it has spurred us on to this very day and continues to drive us to find solutions that make processes in the CSSD safer. 同時，ebro 根據 ISO 11140-4 為 CSSD （中央無菌供應部）開發了一種經濟高效的電子式 Bowie-Dick (抽真空測試用)測試 (EBI 15)。使用現代電子資料收集，EBI 15 提供明確的結果（「通過」/「失敗」）。 EBI 15 記錄器的功能也經過 TÜV Süd (南德產品驗證顧問)和 SMP 根據 EN ISO 11140-4 進行測試。後續型號稱為 EBI 16，容量增加了一倍，例如可監控過程 1,000 個週期。

在CSSD （中央無菌供應部）熱記錄器從無名小卒到市場領導者經歷了漫長的道路，但它一直激勵著我們直到今天，並持續驅策我們找尋能為 CSSD （中央無菌供應部）營造出流程更安全的解決方案。

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。

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